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

Content Standards Workgroup

Comments to the Interoperability Roadmap

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Content Standards Workgroup

First Name	Last name	Organization	Type
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Interoperability Roadmap – Questions

Workgroup	Content Standards
General Questions (as they apply to the assigned Roadmap section)	• 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 (LHS) 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 Section	• J. Consistent Data Formats and Semantics

Interoperability Roadmap – Draft Feedback
The workgroup embraced key concepts:

- Need for consistency in data formats and semantics
- Use of Standards Development Organizations (SDOs) to develop, curate and maintain standards and create implementation specifications / profiles; and need for ongoing collaboration among SDOs
- Improve consistency in the implementation of Consolidated CDA through further guidance or constraints
- Extension of standards to promote exchange across the care continuum, including new sources of patient generated health data, device/sensor, environmental and other big data
- Agreement on a core standardized common clinical data set that is extensible and consistently shared during care transitions
- Need for agreement on use cases that each vocabulary supports
- Need to exchange information in a more granular form, such as FHIR
- Many of the initiatives listed including FHIR, CIMI, DAF (should limit to these three)

Interoperability Roadmap – Draft Feedback Specificity in Defining Goal and Actions

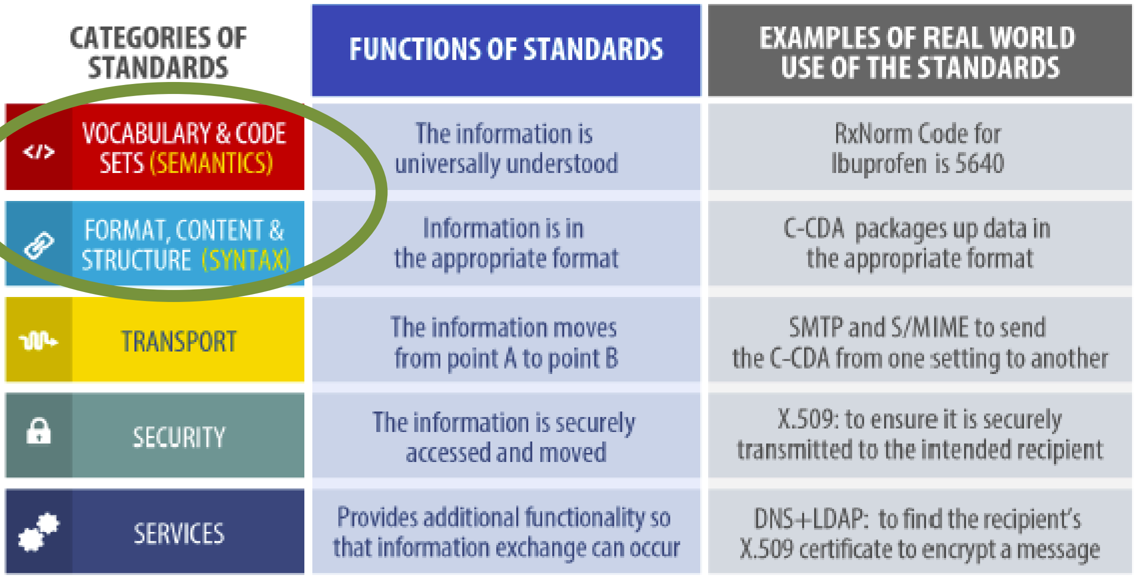
- Laser focus: achieving national scale with selected standards should be top priority
  - Consolidated CDA release 2 and Direct Project are key first steps
  - Multi-year cycle time for standards to be absorbed nationally
  - Broad group of stakeholders that need time to respond to changes
  - Use all available levers to pursue nationally, encourage aligned adoption of specific named standards
  - Focus on specifying universal codes and getting data from the source to the provider and others in need of the data
  - Assure that all federal payers are aligned with common core of standards and incentivize commercial payers to follow
- Avoid one hand clapping: greater specificity in standards
  - Be specific on how the standards support prioritized use cases for each wave of interoperability
  - Refine those standards over time, but limit structural change
  - Recommendations include concepts related to improving interoperability between research and clinical domains, stakeholders should consider these and provide input on the use cases in that space that would create the greatest value and subsequent actions
    - Suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by the US and international agencies and SDOs (e.g., CDISC)

Interoperability Roadmap – Draft Feedback
Specificity in Defining Goal and Actions

- Know where we are going: greater specificity in Learning Health System definition
  - Need to consider the constraints of policy, privacy and security
  - APIs by themselves will not open up clinical systems for learning
  - Great references (e.g., IOM, Learning Community, ESTEL, ONC Query Health)
  - Use Cases
    - Select a few use cases that will deliver high return on investment for interoperability instead of the large number included now (56)
    - The clinical, research, public health and other programs may find that the use cases that they deem most valuable cannot be addressed in the first wave of interoperability
    - The highest return targets for interoperability may come from other communities, while use cases for other communities are intended to follow as we gain traction and skill in the review process and requirements-gathering to which these use cases must be subjected
  - The important gaps are not in standards, but in policy maker attention to the need to deliver clinical data from the source to the users. Seems not to be on the radar screen
- Need to ensure that the Roadmap features short-term tactical wins that will promote progress towards the longer-term vision (e.g., improving implementation guidance for CCDA in the short term, while simultaneously working to improve CCDA's next release)

Interoperability Roadmap – Draft Feedback
Categories of Standards

Figure 8: Standards Categories



CATEGORIES OF STANDARDS	FUNCTIONS OF STANDARDS	EXAMPLES OF REAL WORLD USE OF THE STANDARDS
VOCABULARY & CODE SETS (SEMANTICS)	The information is universally understood	RxNorm Code for Ibuprofen is 5640
FORMAT, CONTENT & STRUCTURE (SYNTAX)	Information is in the appropriate format	C-CDA packages up data in the appropriate format
TRANSPORT	The information moves from point A to point B	SMTP and S/MIME to send the C-CDA from one setting to another
SECURITY	The information is securely accessed and moved	X.509: to ensure it is securely transmitted to the intended recipient
SERVICES	Provides additional functionality so that information exchange can occur	DNS+LDAP: to find the recipient's X.509 certificate to encrypt a message

- Conflation of concepts which should be logically separated
- From the highest level down this should be re- organized as follows (below) with Functions of standards defined for each category

Semantics, Context & Content

Vocabularies, Dict. & Code Sets

Format and Structure

Detailed Comments on the Interoperability Roadmap

Interoperability Roadmap Section J1
Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions 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?

Category	2015-2017 Send, receive, find and use a common clinical data set	2018-2020 Expand interoperable health IT and users	2021-2024 Achieve nationwide LHS
J1. Common, list of interoperability standards	1. ONC will annually publish a list of the best available standards and implementation specifications 2. Implementers and decision-makers should use ONC’s list of the best available standards to enable specific use cases 3. Implementers will update their systems to align with the list of the best available standards • C-CDA 2.0 • Associated vocabulary standards • Associated code sets supporting common clinical data set	4. ONC will annually publish an updated list of the best available standards and implementation specifications.	5. ONC will annually publish an updated list of the best available standards and implementation specifications.

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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. ONC will annually publish a list of the best available standards and implementation specifications	• There are opportunities with HL7 v2 (with some universal coding) – the advantages: it's familiar, it's implemented everywhere, and would send well across institutions • ONC should further clarify the narrower set of national priorities from this list (e.g., best practices v. mandated / regulatory) • Annual refresh of the list of best available has the potential to do both good and harm. ○ Industry needs time to adapt, updates if too frequent could result in a mix of standards and could come at the expense of usability ○ When assessing the pace of change, it may be useful to determine the type of change proposed; evolutionary or revolutionary and set the pace accordingly • Should include notation of what's in use and/or mature ○ Quality Measures and Reporting are not mature • Updates should include progress on harmonization • Standards should be linked to use cases to avoid creating too much leeway in implementers' interpretations which causes higher-than-desired integration costs. • The migration pathway and lack of backwards compatibility makes the one line roadmap line item about C-CDA 2.0 too simplistic. ○ ONC should also be careful to finish the job it started with consolidated CDA, which will ensure these document standards work nationally, reliably, and at low cost in the market
2. Implementers and decision-makers should use ONC's list of the best available	• Recommended standards should be published with the pros and cons of each approach/recommendation to enable more informed decisions • Use cases should guide development of standards lists and implementation guidance • ONC should be clear about how compliance with this be assessed, incentivized

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2015-2017 Send, receive, find and use a common clinical data set	Comments
3. Implementers will update their systems to align with the list of the best available standards • C-CDA 2.0 • Associated vocabulary standards • Associated code sets supporting common clinical data set	• Workgroup agrees with "completing the job" as it relates to Consolidated CDA (v2.0) and establishment of associated standards for vocabulary and code sets supporting common clinical data set • It is assumed that the list of best available represents a reference to the 2015 Interoperability Standards Advisory – Best Available Standards and Implementation Specifications • Proposed time frame creates risk because of the time required to execute changes to conform / comply. ○ Burden on the whole industry here, and the time lags for both vendors and then implementers are important ○ Anything that can be done to expedite this should be specified in the roadmap, for example focus the first step on interchange (interoperability) and ensuring that source systems can deliver a message (or document) that can be filed automatically into the destination system • ONC needs to be very specific about requirements that should be in place to support 2015-2017 interoperability • As vendors move toward FHIR there could be a "double standard" or multiple standards that vendors will need to meet • As standards transition a clear transition paths should be defined as some vendors / implementers will be at various levels of alignment with new and existing standards (Continued on Next Slide)

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2015-2017 Send, receive, find and use a common clinical data set	Comments
3. Implementers will update their systems to align with the list of the best available standards • **C-CDA 2.0** • **Associated vocabulary standards** • **Associated code sets supporting common clinical data set**	**(Continued from Previous Slide)** • **Accepted vocabulary standards are not necessarily updated at the frequency required for clinical practice thus implementers will need guidance on approaches to use required vocabulary standards while addressing the greater need to manage the issues presenting in clinical practice. Most of them are hardly used yet. The Roadmap should focus on getting more universal adoption before such 1% issues related to updating especially considering that institutions do not want frequent updates in many contexts.** • **While C-CDA 2.0 is helpful, the need to share information for other than direct clinical care (e.g., with public health registries) remains tied to HL7 V2 messages** ○ **Requirements to align with multiple standards for the same information is duplicative. If EHR vendors are expected to transition and implement new standards, all users of the same data (including public health) should be expected to align with the same standards** ○ **Suggested vocabularies and code sets do not align well with widely used research and clinical standards, including those defined by FDA and other US and international agencies and SDOs such as CDISC (e.g., MedDRA)** ○ **If universal codes were added to messages for all of the other kinds of diagnostic studies sent in HL7 messages with local codes substantial progress would be made**

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2018-2020 Expand interoperable health IT and users	Comments
4. ONC will annually publish an updated list of the best available standards and implementation specifications.	• What will drive the expansion of interoperable health IT and users? ○ New specifications and standards, or will there be programs in place to promote, fund and champion the expansion? • Advance notice of standards publication would help industry respond more effectively • Too many standards in parallel maybe challenging for industry to adapt • Should consider the following: ○ Continue to make CCDA work for interop ○ Ensure that standards are well enough formed before they become foundation for interoperability and asking industry to adopt / migrate ○ Define "best available“ • At what point emerging standards will be considered “best available”; when current “best available” standards will sunset? • Expand scope of “best available,” to include inter domain specific data, examples : workflows and overall architectures as discussed previously including enterprise imaging, clinical research and device data

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2021-2024 Achieve nationwide LHS	Comments
5. ONC will annually publish an updated list of the best available standards and implementation specifications.	• We should explicitly ask for research funding to enable more formal testing of concepts behind standards development as they are being defined and created. Funding should also support more formal testing and evaluation of standards once they have been implemented. This would be an improvement over the current method of simply collecting comments and feedback from those who have experience with the standards or gaps in standards • Only mature standards and implementation specifications should be listed • There should be regional experiments to test / assess the proper technologies, procedures, policies and governance precepts to ensure all concerns are appropriately managed • Ensure updated list include updates and updated guidance to pre-existing standards that are in place and that the list is not just about new standards (e.g., HL7 messaging standard used for many state exchanges - the previous version does not fall out of use just go away because something new gets introduced)

Interoperability Roadmap Section J2 Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions 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?

Category	2015-2017 Send, receive, find and use a common clinical data set	2018-2020 Expand interoperable health IT and users	2021-2024 Achieve nationwide LHS
J2. Architecture in support of standards activities	Through coordinated governance, public and private stakeholders will: 1. Establish and maintain a prioritized set of use cases and functional requirements for delivery system reform and LHS (see Appendix H) 2. Develop a nationwide technical architecture for an interoperable LHS 3. Define a set standards activities to support: • Prioritized use cases • Functional requirements • Agreed upon architecture	4. Stakeholder input requested	5. Stakeholder input requested

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2015-2017 Send, receive, find and use a common clinical data set	Comments
Through coordinated governance, public and private stakeholders will: 1. Establish and maintain a prioritized set of use cases and functional requirements for delivery system reform and LHS (see Appendix H)	• ONC should promote use of Universal codes in messages where local codes are now used (e.g., LOINC for Observations, SNOMED for coded results, UCUM for units of measure, RxNorm for drugs) • Use cases need to be rooted in business needs ○ The list of use cases cited, represents a nice set of ideas, however healthcare is a business, and nice ideas need to be grounded in the reality profit / loss and cost / benefits. Are those receiving the benefits, paying for them? If not, who does? Does the patient benefit in any direct way? If not, why are they paying for this service? ○ Input from communities that have actual lessons learned and feedback based on the use of standards and registered terminologies should be weighted with more value than input from hypothetical cases • Process ○ A more open, crowd-sourced approach to establishing and prioritizing use cases is important ○ Development of simple use cases without consideration for other related use cases for the same information can cause a limited approach that is not scalable. ○ Participants can be easily overwhelmed with too many efforts such that wide vetting of “agreements” is challenging ○ The efforts need to be carefully coordinated to avoid burn out by significant stakeholders. ○ Ensure that SDOs and professional societies and domains (e.g. public health, clinical research, surgery) are included in the process • Consumer Needs ○ Use case list development and prioritization should have increased emphasis on consumer needs for generating and exchanging data and shared decision making

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2015-2017 Send, receive, find and use a common clinical data set	Comments
2. Develop a nationwide technical architecture for an interoperable LHS	• ONC should encourage research on the question of whether we can always link patients accurately enough for patient care? • This action may not be appropriate or possible unless the nation is willing to establish consistently applied, durable and unambiguous standards to establish patient identity across settings of care (e.g., a national patient identifier) • Technical architecture needs to accommodate innovation and new developments in technology. Care must be taken to avoid limiting innovation by restrictive architecture requirements. • Build on current efforts • A nationwide technical architecture would have to take into account state-specific considerations ○ The risk of a single nationwide approach is the likelihood that all users would be forced to adhere to the constraints set by the most restrictive state • Since this is a precondition for an LHS, this is more urgent. Timing is critical—by year end 2016 would not be too soon

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2015-2017 Send, receive, find and use a common clinical data set	Comments

Through coordinated governance, public and private stakeholders will:
3. Define a set of standards activities to support:
• Prioritized use cases
• Functional requirements
• Agreed upon architecture
	Process - Each new use case will likely generate changes in implementation guidance, as use cases define requirements, inclusive of data requirements. The process should be:
	• Define use case
	• Prioritize use cases (proceed with a small set between 1 - 3)
	    • Independently assess the benefits and cost
	    • Consider opportunities for quick wins (e.g., delivery of test results to a provider’s EMR without costly mapping or interface efforts per source with HL7 v2 if ONC promote standard test and units and answer codes
	• Determine functional / data requirements
	• Update the standards / implementation guides as needed
	• Assess current pilot implementations, if none then establish pilot implementations
	• Where appropriate promote to national implementation status
	
	Stakeholders - Similar to development of use cases, standard setting needs to address:
	• A more open, crowd-sourced approach to establishing and prioritizing standards is important
	• The more coordination that is involved the slower the process, there may be benefits to breaking it down into smaller dynamic parts
	• Participants can be easily overwhelmed with too many efforts such that wide vetting of “agreements” is challenging. The efforts need to be carefully coordinated to avoid burn out by significant stakeholders
	• Ensure involving the correct stakeholders example SDOs in standards, need to promote communication and collaboration among stakeholders Consider new roles for NLM
	
	Content
	• Functional requirements must be published, public, and clear. Transparency is critical to avoid the appearance that requirements are not well grounded in use cases and actual lessons learned
	• Use cases are less important than the architecture and requirements
	• Concern expressed that the roadmap does not specify a data model

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2018-2020 Expand interoperable health IT and users	Comments
4. Stakeholder input requested	• Technical architecture supports a digital health platform and data model that is person centric and institutional centric and supportive of move to value-based care • Continue the open feedback process from 2015 – 2017. Set specific goals after gaining some 2015 – 2017 experience and implementation feedback
2021-2024 Achieve nationwide LHS	**Comments**
5. Stakeholder input requested	• Technical architecture further extended to support consumer mediated exchange across person/family/caregivers--with providers, community health groups, payers, research, disease advocacy groups, clinical trials (see figure 5 listing of stakeholders for LHS); and across personal, community and institutional health records

Interoperability Roadmap Section J3 Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions 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?		
Category	**2015-2017** **Send, receive, find and use a common clinical data set**	**2018-2020** **Expand interoperable health IT and users**	**2021-2024** **Achieve nationwide LHS**
J3. Develop and pilot new standards for priorities	1. SDOs will advance and accelerate semantic standards for lab orders, other orders and other LHS priorities 2. Research and clinical trial communities will pilot the use of the common clinical data set 3. SDOs will advance consumer-friendly terminologies 4. HIT developers and SDOs support human-centered design including abilities to provide information: • To those with varying levels of health literacy • In [the individuals'] primary language 5. Stakeholders will pilot data format and vocabulary standards in to provide feedback to the SDOs for further refinement 6. States and other stakeholders to further explore and determine the role that NIEM can serve with regards to supporting health care and human services interoperability 7. SDOs and industry will agree on best practices and provide guidance on unstructured data exchange (e.g., physician note)	8. Stakeholder input requested	9. Stakeholder input requested

Interoperability Roadmap Section J3 Consistent Data Formats and Semantics

Category	Comments
J3. Develop and pilot new standards for priorities	**Instead, this should be worded as:** **J3 “Develop new standards and priorities”** **SDOs will advance and accelerate semantic standards for lab orders, other orders and other LHS priorities** • **Focus on updated semantic standards, focusing first on** ○ **Lab orders and results** ○ **Goals and interventions** ○ **Care planning** • **Pilot the common clinical data set with** ○ **Clinical content management systems (EHRs, PHRs, HIEs)** ○ **Research systems** ○ **Clinical trial communities** ○ **Public health and other clinical content analytical systems** • **Advance human-centered design in information systems** • **Promote health literacy**

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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. SDOs will advance and accelerate semantic standards for lab orders, other orders and other LHS priorities	<u>Recommendation</u> • Align key concepts between research and clinical domains, methodologies and data sets to promote interoperability between clinical and research data sets • Researchers, clinicians and patients would all benefit from increased interoperability between clinical and research domains especially given that the clinical community does not have a lot of experience with standards and terminologies featured in the Roadmap • As a first step, identify / validate clinician needs, explore how to align standards and terminologies across research and clinical groups (Continued on Next Slide)

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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. SDOs will advance and accelerate semantic standards for lab orders, other orders and other LHS priorities	**(Continued from Previous Slide)** **<u>Sample Issues and Opportunities</u>** • **Issue: Current interim targets are not clearly defined that will achieve a learning health system, where person and provider data are used for research and population health** ○ **Opportunity: Identify key use cases will illustration of purposes of these opportunities would serve to demonstrate time, cost and other values to help prioritization** ○ **Looking at outcomes and related upstream data, such as social determinants, may help identify good use cases that cut across both domains and lend themselves to such mapping exercises** ○ **Opportunity: Create or borrow SNOMED-CT concept definitions from other terminologies** • **Issue: CDASH & CCDS are similar at the domain level but not the element level** ○ **Opportunity: Consider mapping data elements - review data elements in each domain (approximately 7 - 10 elements) which is a core set of data being used around the world and create a mapping among CCDS, CCDA (FHIR) and SNOMED, also consider the relationship to LOINC** ○ **Opportunity: Consider mapping SNOMED to MedDRA and to CCDS, could start with approximately 790 adverse events codes and then progress through other CDASH and CCDS domains, there is an opportunity to build on some work that has already been accomplished on this level** ○ **Recommend formalizing a set of connections between SNOMED and MedDRA to represent adverse events** • **Issue: Common data elements (CDEs), used at NIH, may have 3 or 4 standards for each** ○ **Opportunity: Agree on the core pieces then agree on vocabularies and other components to promote interoperability**

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2015-2017 Send, receive, find and use a common clinical data set	Comments
3. SDOs will advance consumer-friendly terminologies	• When language exists that may characterize a condition in "layman's" vocabulary its use should be encouraged and when it is not then ONC should encourage linkage to resources that help a consumer understand the technical and medical terminology. However, this is not an SDO function – rather a commercial patient education function • The term "consumer-friendly" should be more clearly defined with respect to the expectations. (Many medical terms lack a clear "layman's" term equivalent so this would not be possible for all terms) • Workgroup members cited research that indicates those with chronic diseases know the medical terms associated with their conditions and that many patients desire to have the specific medical terms in their records in order to be able to convey detailed information when needed

2015-2017 Send, receive, find and use a common clinical data set	Comments
4. HIT developers and SDOs support human-centered design including abilities to provide information: • To those with varying levels of health literacy • In [the individuals'] primary language	• The term human-centered needs to be more clearly defined • Interoperability involves transmitting information to people with varying levels of health literacy from professionals to patients / consumers • The Roadmap seems to want to reach some sort of mean and ways for those who want more information to get it and for those who lack understanding to obtain clarity • Not an SDO function

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2015-2017 Send, receive, find and use a common clinical data set	Comments
5. Stakeholders will pilot data format and vocabulary standards to provide feedback to the SDOs for further refinement	• The term pilot should be changed to implementations to emphasize that constant feedback should be obtained from actual use of standards and the associated best practices and lessons learned to create a process of continuous quality improvement • An open and public process to generate and provide feedback on a continuous basis is essential • Consider ways to encourage the development of real time feedback loops to encourage adoption and ability for SDO's to increase cycle time of development

2015-2017 Send, receive, find and use a common clinical data set	Comments
6. Stakeholders will pilot data format and vocabulary standards in to provide feedback to the SDOs for further refinement	• Same comments apply from J.3.4. • The term pilot should be changed to implementations to emphasize that feedback should be obtained from actual use of standards and the associated best practices and lessons learned • An open and public process to generate and provide feedback on a continuous basis is essential • Consider ways to encourage the development of real time feedback loops to encourage adoption and ability for SDO's to increase cycle time of development

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2015-2017 Send, receive, find and use a common clinical data set	Comments
6. States and other stakeholders to further explore and determine the role that NIEM can serve with regards to supporting health care and human services interoperability	• Building out NIEM for healthcare • We recommend that if there is a need to interoperate with non-healthcare stakeholders and it is a national priority then it makes sense to assess NIEM as a potential solution to support the non-healthcare human services interoperability. ○ For example, there could be a priority use case around domestic violence and/or child abuse data that would be valuable for analyzing social determinants of health.

2015-2017 Send, receive, find and use a common clinical data set	Comments
7. SDOs and industry will agree on best practices and provide guidance on unstructured data exchange (e.g., physician note)	• There should be a focus on ensuring that the patient's story is reflected in the medical record and that the associated context or narrative is not lost in the structured data

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2018-2020 Expand interoperable health IT and users	Comments
8. Stakeholder input requested	• Continuous crowd-sourced input on standards and their use is essential for a learning health system • Encourage ways to capture the output of health related devices to populate medical records and reduce reliance on human entry • Build upon initial work from 2015-2017
2021-2024 Achieve nationwide LHS	**Comments**
9. Stakeholder input requested	• Expand decision support capabilities by better putting to use the data captured in EHRs • Consider the roles of various individuals in the workflow (e.g., doctor, nurse, therapist, patient, caregiver) and what information they need at different points in time • A taxonomy for capabilities is needed to allow clinical decision support, messaging and clinical workflow to be managed in a consistent manner. Lack of such a taxonomy to help guide care workflow is a gap in the existing process • Build upon initial work from 2015-2017 and 2012-2014

Interoperability Roadmap Section J4 Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions 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?		
Category	**2015-2017 Send, receive, find and use a common clinical data set**	**2018-2020 Expand interoperable health IT and users**	**2021-2024 Achieve nationwide LHS**
J4. Vocabulary approach	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 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)	3. Stakeholder input requested	4. Stakeholder input requested

Interoperability Roadmap Section J4 Consistent Data Formats and Semantics

Category	Comments
J4. Vocabulary approach	• The Roadmap appears to be directing us towards a situation where the SDO could be an international level and the NLM Value Set Authority Center (VSAC) could be setting standards at the national level. Below that there might be some layers for specialty societies and individual organizations where they define what they require at these various level • There should be a mechanism whereby standards at these various levels can be escalated and recommendations proposed and adopted as vocabulary standards

1. Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?
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2015-2017 Send, receive, find and use a common clinical data set	Comments
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	• General agreement with a federated approach, however, it should also incorporate the accomplishments of specialty societies (e.g., ANA, ANI and success of community based health care, using OMAHA system focused on patient outcomes/value should be considered). Ensure that ANA is identified as a key stakeholder to leverage the soon to be published Position Statement on recognized nursing terminologies and their alignment with the “best available” standards. • Currently, there is insufficient governance to require clear metadata detailing the intended use, inclusion and exclusion criteria for each value set used in standards, quality measures and clinical decision support efforts. • Strong governance is also required to require harmonization so that the same value sets are used for the same meaning across clinical care delivery, quality measurement, decision support and research. • The current variation is problematic and creates re-work for users and implementers, and limits the meaning of the results. SDOs and all organizations involved in data reuse need to be covered by this governance process. Example: for RxNorm – it is being implemented in different ways – and is not being used for the higher functionalities needed for a LHS (like CDS, quality reported, etc.) ○ Examples for clarification would be helpful • Should significantly reduce the risk of non-standard and non-current code sets. Example of NLM and SNOMED licensing is a good one. ○ Examples for clarification would be helpful

1. Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?
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2015-2017 **Send, receive, find and use a common clinical data set**	**Comments**
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)	• **Need to further define how translation and adapter services will connect to data generated by mHealth devices, sensors, etc. Need to further define accurate translation and adapter services – and the stakeholders that will benefit, including consumer/family caregivers and community workers, who will be more active in exchanging health and care data.** • **Where translations are needed, these should be authoritative, maintained with adequate funding and openly available. The infrastructure developed in 2015-2017 should provide ongoing continuous mechanisms to maintain the input, harmonization and updates.** • **Use cases that articulate "Learning Cycles", between and among individuals and other stakeholder in the LHS will generate new insights into standards needed. Standards will need to support shareable, comparable data among a variety of learning cycles for the individual and LHS stakeholders.** • **On-going, measure and focus on use of standards-based interoperable IT in actual clinical and consumer practice starting with a baseline. Set specific goals after gaining some 2015 – 2017 experience and implementation feedback.** • **See related Content Standards Workgroup comments on priority use cases. In general, need a smaller more focused set, phased in over time.** • **With regards to vocabulary terms, if the translations are not defined within the vocabulary system, where it can be reviewed and corrected as needed, it is likely that they are not accurate. Therefore, translations of terms need to be defined by the Vocabulary SDOs, not by the Health IT developers.**
2018-2020 **Expand interoperable health IT and users**	
3. Stakeholder input requested	
2021-2024 **Achieve nationwide LHS**	
4. Stakeholder input requested	

Interoperability Roadmap Section J5 Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions the right actions to improve interoperability nationwide in the near term while working toward a LHS 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?

Category	2015-2017 Send, receive, find and use a common clinical data set	2018-2020 Expand interoperable health IT and users	2021-2024 Achieve nationwide LHS
J5. Maintain and improve standards	1. SDOs will maintain and improve existing standards based on implementation feedback	2. SDOs will maintain and improve standards.	3.SDOs will maintain and improve standards.
	Comments • VSAC and the process of value set stewardship should be incorporated in a process that is sensitive to end user requirements and the timing required for implementation • ONC should convene SDOs to learn from one another's best practices		

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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. SDOs will maintain and improve existing standards based on implementation feedback	• SDOs need to provide mechanisms to evaluate real use of draft and normative standards and to receive feedback. Currently feedback mechanisms are based on organizations with sufficient resources to support participation in cumbersome standards setting process. A mechanism to generate and respond to user feedback and to determine the frequency standards are used (draft and normative) in actual clinical and consumer practice starting with a baseline will significantly benefit the value of the standards and help groups like HITSC decide on readiness for the LHS. Mechanisms need to allow for alignment with international standards and SDOs as needed. • Need to define "true, disciplined implementation feedback" and appropriate handling and response • SDOs need to be part of developing the standards, processes and expectations regarding "implementation feedback" and its management in an iterative process. • Consider impact on SDO process, bandwidth and funding • Involve SDOs in the process; should not be top down mandate • Emphasize that constant feedback should be obtained from actual use of standards and the associated best practices and lessons learned to create a process of continuous quality improvement • An open and public process to generate and provide feedback on a continuous basis is essential • Consider ways to encourage the development of real time feedback loops to encourage adoption and ability for SDO's to increase cycle time of development
2018-2020 Expand interoperable health IT and users	
2. SDOs will maintain and improve standards.	
2021-2024 Achieve nationwide LHS	
3. SDOs will maintain and improve standards.	

Interoperability Roadmap Section J6 Consistent Data Formats and Semantics

Questions for Workgroup Discussion	• Are the actions the right actions to improve interoperability nationwide in the near term while working toward a LHS 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?		
Category	**2015-2017 Send, receive, find and use a common clinical data set**	**2018-2020 Expand interoperable health IT and users**	**2021-2024 Achieve nationwide LHS**
J6. New standards that support new and evolving requirements and priorities	1. Through coordinated governance, public and private stakeholders will advance items to support LHS use cases (see Appendix H): • Development and maintenance of data format standards • Vocabulary standards • Implementation guidance necessary to support priority	2. Stakeholder input requested	3. Stakeholder input requested

1. Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?
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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. Through coordinated governance, public and private stakeholders will advance items to support LHS use cases (see Appendix H): • Development and maintenance of data format standards • Vocabulary standards • Implementation guidance necessary to support priority	• This just basically seems to be a restatement of J1 and is unnecessary duplication. • Requirements derived from community identified use cases should be forwarded to SDOs, the SDOs should then be charged with the development of standard formats, vocabularies and implementation guidance. If this process does not work, it should be fixed • In general need a clear roadmap with corresponding and comprehensive use cases. Need incentives for innovation to adapt to emerging practices and technologies such as genetic sequencing, personalized medicine, etc. We need to establish a definition for population health measurement. Generally, the notions of a learning health system and population health are not mature in this document. They do not consider the needs of organizations to control what data is shared and for what purpose. Sending questions to the data rather than data to the questions is a critical concept for workable and robust population health measures • This could be enhanced by J2 and maintaining sophisticated use cases the push the HealthIT boundaries • The addition of rich contextual data about patients and generated by patients (including environmental, geographical, social, behavioral, imaging data, genomic, wearable device and sensors and more) will lead to breakthroughs for individuals, families, communities and populations. Incentives will be needed for innovation to adapt these emerging practice and domains, and impact health for individuals, families, communities and populations

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4. Are the right actors/stakeholders associated with critical actions?

2015-2017 Send, receive, find and use a common clinical data set	Comments
1. Through coordinated governance, public and private stakeholders will advance items to support LHS use cases (see Appendix H): • Development and maintenance of data format standards • Vocabulary standards • Implementation guidance necessary to support priority	• The addition of rich contextual data about patients and generated by patients (including environmental, geographical, social, behavioral, imaging data, genomic, wearable device and sensors and more) will lead to breakthroughs for individuals, families, communities and populations. Incentives will be needed for innovation to adapt these emerging practice and domains, and impact health for individuals, families, communities and populations • In general need a clear roadmap with corresponding and comprehensive use cases. Need incentives for innovation to adapt to emerging practices and technologies such as genetic sequencing, personalized medicine, etc.

1. Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?
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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. Through coordinated governance, public and private stakeholders will advance items to support LHS use cases (see Appendix H): • Development and maintenance of data format standards • Vocabulary standards • Implementation guidance necessary to support priority	We need to establish a definition for population health measurement. Generally, the notions of a learning health system and population health are not mature in this document. They do not consider the needs of organizations to control what data is shared and for what purpose. Sending questions to the data rather than data to the questions is a critical concept for workable and robust population health measures. This needs to be revisited. Specific feedback on the additional points associated with specific use cases: 9. ONC needs to think more broadly about other participants in the health ecosystem – home health, skilled nursing, treatment outside of the network. The suggestions here are too narrowly applied. 17. This could be expanded beyond patients and providers in terms of who has access. For example, ONC needs to include the patient's caregivers, the broader care team, etc. 20. Providers haven't expressed an interest in this consistently. They want alerts when things are outside the norm and every so often want to see the data, but frequently they indicate that they are not interested in incorporating that data into their EHR 29. This use case is not very clear 32. How does this vary from #16? Clarification is needed if there is a difference intended 33. What is the expected standard for querying across different networks? 36. How does this vary from #7? Clarification is needed if there is a difference intended 41. We appreciate the intent to facilitate more rapid distribution of information with patients, but there are situations where lab results should not be sent directly because they require physician interpretation or explanation 46. ONC should clarify "appropriate use"

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2015-2017 Send, receive, find and use a common clinical data set	Comments
1. Through coordinated governance, public and private stakeholders will advance items to support LHS use cases (see Appendix H): • Development and maintenance of data format standards • Vocabulary standards • Implementation guidance	• Quality measures continue to add significant rework for providers to document information that is best managed through cognitive decisions and narrative text. Forcing documentation about decisions may have benefit but doing so in a structured form does not necessarily provide reliable and valid data. The measure development process needs to change to address true documented evidence of outcomes and not processes. Alerts and reminders (CDS) has similar issues but adds role-based workflow challenges. The ability to identify functional-based roles is a clear gap. Patient engagement is not limited to providing patient access to information but includes participation in decision making. Further feedback about what works and collection of best practices is needed • SDO's will benefit from the progress the LHS community is making on defined "learning cycles" to assure that the standards are facilitating easy movement of health data to support the learning cycles • New learning cycles + use cases will emerge, as we mature the addition and adoption of rich contextual data about patients and generated by patients (including environmental, geographical, social, behavioral, imaging data, genomic, wearable device and sensors and more) will lead to breakthroughs for individuals, families, communities and populations • ONC and HHS will be stymied in their progress towards a learning health system by policy and privacy constraints. ONC and HHS need to consider methods used by the learning health system community (e.g., PCORnet's sending questions to the data, FDA Sentinel's de-identification of organizations, etc.) and policy changes to overcome these limitations
2018-2020 Expand interoperable health IT and users	
2. Stakeholder input requested	
2021-2024 Achieve nationwide LHS	

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2015-2017 Send, receive, find and use a common clinical data set	General Comments
Page 80	• *Add <u>italicized, underlined</u> text to paragraph 3* ○ In some cases the implementation guides provide sufficient clarity, specific implementation instructions and reduce the potential for implementation variability to a minimum. In other cases, further work is necessary among SDOs to further refine implementation guidance as well as to develop best practices to improve implementation consistency among health IT developers, *<u>including those developing mHealth, telehealth, wearables and sensors.</u>* • The suggested variability in implementations does not allow a receiving system to process the information and properly integrate it into the patient record and may even prohibit the end user from viewing the information in a human readable format • A system should never fail to show the human readable text, even if some discrete content could not be understood or found. Our first priority should be to always show the human readable text, and to discretely process if and only if the receiving provider/system indicates a desire to attempt to incorporate discrete content into their maintained version of a medical record
Page 81	• We should push to have reports stay in their discrete state when they get shipped to a practice. There is also the case exemplified by the provider who dictates his note. He will never succeed in converting that to discrete coded content. And we should not push him/her to do so