

ONC INTEROPERABILITY ROADMAP PLANNING MEETING

Subject Matter Expert Meeting Summary Report and Synthesis

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National Coordinator for Health IT by:

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Executive Summary

The Office of the National Coordinator for Health IT (ONC) has set out to establish an ambitious but pragmatic plan for achieving real-world interoperability among health technology solutions. This interoperability plan is intended to be relevant not only to systems supporting the care delivery system, but also more broadly to systems relevant to population health research, wellness, and other social services delivery programs. It is this broader applicability that extends beyond the traditional boundaries of health IT interoperability objectives, yet it is rooted in the ability to execute on those more familiar and near-term opportunities related to the delivery system.

In order to improve the health and wellness of the nation, the Department of Health and Human Services (HHS) has established the goal of developing a learning health system.¹ The vision of the learning health system is a patient-centric model which can incorporate broader aspects of a patient's life that affect their health. The learning health system also includes population health analytics and clinical research-based evidence that is relevant to a patient's care to be produced and delivered to the point of care in real-time. The learning health system will necessarily be enabled by health information technology (health IT), and a nationwide infrastructure that supports interoperability amongst all organizations. While widespread adoption of electronic health records (EHRs) is a necessary first step towards interoperability, much work remains for systems to be fully interoperable, meaning "the ability of a system or product to work with other systems/products, *without special effort* [emphasis added] on the part of the customer."²

In the interest of continuing to drive the nation towards an interoperable ecosystem, HHS, including Centers for Medicare and Medicaid Services (CMS) and ONC developed a strategy for enabling health information exchange (HIE). One component of the strategy was to develop a collaborative interoperability roadmap that would serve as a guide for the nation to move towards the learning health system. ONC further defined the 10 year vision for the nation (with intervals at three, six, and 10 years) and framed the road-mapping process by identifying five building blocks that require incremental progress over the next decade in order to support our near and mid-term data exchange goals while building towards the learning health system. The five building blocks include:

1. Core technical standards and functions;
2. Certification to support adoption and optimization of health IT products and services;
3. Privacy and security protections for health information;
4. Supportive business, clinical, cultural, and regulatory environments; and
5. Rules of engagement and governance.

These five building blocks are the foundation for the interoperability roadmap that ONC will work with the healthcare community to develop. Once the roadmap is developed, ONC will revisit it periodically to measure progress towards the goals and milestones and evaluate

¹ Best Care at Lower Cost: The Path to Continuously Learning Health Care in America. Institute of Medicine. September 2012. <http://www.iom.edu/Reports/2012/Best-Care-at-Lower-Cost-The-Path-to-Continuously-Learning-Health-Care-in-America.aspx>

² http://www.ieee.org/education_careers/education/standards/standards_glossary.html



necessary modification to the roadmap as new information becomes available over time. ONC is utilizing a number of channels to work collaboratively with the industry to develop the roadmap and to accept feedback. One such channel was via subject matter experts (SMEs) from within the healthcare industry and from other industries that have achieved interoperability, and across a broad range of stakeholder types. ONC contracted with Audacious Inquiry (Ai) to facilitate the SME workgroup. Ai hosted three meetings in Washington, DC to obtain feedback and input on goals and milestones that must be achieved in each building block at three, six, and 10 year intervals.

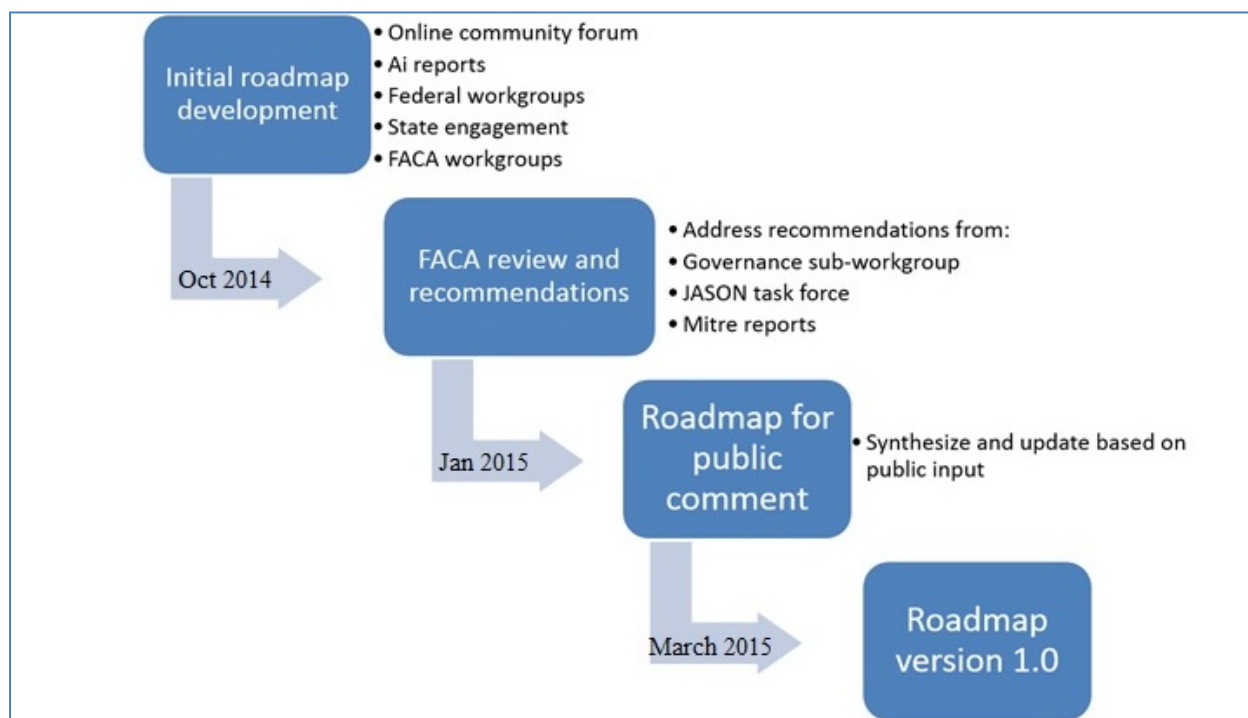
The SME group provided valuable feedback into the roadmap. While there were naturally areas of disagreement among the group, there were many areas of convergence on what aspects of a roadmap should be included in the three and 10 year intervals. While the group originally intended to identify milestones and goals for the six year mark, the conversation and discussion led to identify only three and 10 year goals and milestones. The group strived to ensure the three year goals and milestones would provide a stepping stone to the 10 year vision of the learning health system, while recognizing that the 10 year goals and milestones can describe functionality, but not necessarily technology standards. The following report provides a synthesis of the discussion from the SME meetings, and the goals and milestones for each period that the group identified for each building block.

Introduction/Background

In August 2013, HHS, including CMS and ONC, released a report titled *Principles and Strategy for Accelerating Health Information Exchange (HIE)*.³ The report articulates objectives and high-level strategies to move the nation toward interoperability. The strategy identified the need for an interoperability and standards roadmap that would be used to guide the country towards ubiquitous HIE over the coming years. To advance forward from the HHS report, ONC developed a vision of interoperability over the next 10 years, and in June 2014, released its high level vision in *Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure*.⁴ ONC developed a set of guiding principles, as well as five building blocks that should show definitive progress at three, six, and ten year intervals. ONC also provided high level use cases for each time period to offer a more specific set of data exchange capabilities to support the vision. In addition, ONC committed to developing in collaboration and coordination with a range of industry stakeholders, a national interoperability roadmap that would set goals and milestones for each time period to ensure the country is effectively moving towards interoperability to support the learning health system, a vision described further below.

Process for Developing the Roadmap

In order to develop a shared roadmap that is informed by a broad set of stakeholders with diverse perspectives, ONC has created a process to receive direct input and feedback through multiple channels as the roadmap is developed. ONC developed the diagram below to illustrate the roadmap drafting process.



³ See http://healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf for full report.

⁴ See <http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf> for full report.

As of the release of this report, ONC is in the initial roadmap development phase, soliciting input through a number of channels. ONC recently launched an online community forum, which allows the general public to provide feedback on each of the five building blocks included in the ONC 10-Year Vision Report, as well as the general use cases for each time period (three, six, and 10 years). ONC is also working with states, including State HIT Coordinators and State Designated Entities for HIE to solicit input and for those leaders to provide feedback during the development of the roadmap. Federal workgroups, such as the Federal Health Architecture (FHA) workgroup and a number of FACA workgroups are also providing feedback to the interoperability roadmap. Finally, ONC contracted with Ai to convene a series of meetings to engage SMEs from both healthcare and other IT-related fields. Ai facilitated three in-person meetings of the SME group in Washington, DC held on July 17, 2014, August 25, 2014, and August 26, 2014.

The interoperability roadmap will necessarily be a living document that is repeatedly reviewed and modified based on evolving realities and innovations in technology. The timeline for reviewing the roadmap may be annual, but based on developments in the industry could be more frequent. ONC has committed to working with the industry on an ongoing basis to review and update the roadmap to move towards the learning health system. The SME group panel indicated that ONC should define a more detailed process for updating the plan, including how feedback will be enlisted across the broadest group of stakeholders – both public and private.



Report Objective

This report is intended to convey the distilled perspective communicated by the SME panel from each of the sessions. The report will offer a summary of the discussion surrounding each building block and summarize the SME group’s perspectives, where possible. Naturally, a range of perspectives were presented during the SME sessions and debated vigorously. The facilitators did not attempt to gain consensus from the group. This report seeks to represent the discussion and outcomes as accurately as possible and to offer a synthesis for each of the building block discussion areas, to inform the broader roadmap development process outlined above.

Attendees

The SME sessions were facilitated by Ai staff members Scott Afzal and Genevieve Morris. In addition, a number of ONC staff members attended portions of the meetings, including Karen DeSalvo, M.D., MPH, M.Sc, National Coordinator; Erica Galvez, Interoperability and Exchange Portfolio Manager; Chris Muir, Director, State Health Information Exchange Cooperative Agreement Program; Julie Crouse; and Hunt Blair, Principal Advisor, State HIT-enabled Care Transformation. The individuals below attended the July and/or the August meetings in Washington, DC and represent the subject matter expert group.

Name	Organization
Bill Howard	Caradigm
Christopher Ross	Mayo Clinic
David Kendrick, M.D.	My Health Access Network
David Whitlinger	New York eHealth Collaborative
Deven McGraw	Manatt
Eric Dean	Arthur J. Gallagher & Co
John Loonsk, M.D.	CGI
Landen Bain	CDISC
Lisa Gallagher	HIMSS
Lori Evans Bernstein	GSI Health
Marc Overhage, M.D.	Siemens
Mariann Yeager	Healthway, Inc.
Mark Frisse, M.D.	Vanderbilt University
Micky Tripathi	MAeHC
Noam Arzt	HLN Consulting, LLC
Paul Tuten	RxAnte
Peter Devault	Epic
Rim Cothren	A Cunning Plan
Rob Wilmot	Cerner
Yvan Charpentier	Mirth/NextGen

Learning Health System Vision

The Learning Health System will evolve over a 10 year timeframe with the nation's interoperable health IT infrastructure facilitating health improvement through active individual health management, improved information sharing with public health, and the ability for new information, including research generated evidence, that was not previous available to be delivered to the point of care.⁵ In order to reach this 10 year vision, the three and six year milestones and goals in the interoperability roadmap will need to build towards the 10 year infrastructure and system interoperability requirements.

To ensure that the SME attendees were working towards the same vision, the group discussed a more detailed description of what the learning health system will be, based on the diagram below (developed by a sub-group of SMEs), which identifies the current state and the future state in 10 years. The diagram below was not intended to be a definite and comprehensive end-state of the learning health system, but rather, a tangible basis from which the SME group could begin to debate details and offer new thinking. In addition, to support the discussion, an additional definition of interoperability for the learning health system was included (based on the updated IEEE definition): “the ability of a system or product to work with other systems/products, *without special effort* [emphasis added] on the part of the customer. Interoperability is made possible by the implementation of standards.” The diagram was developed by David Kendrick, MD, MPH, Chair, Department of Medical Informatics at the University of Oklahoma School of Community Medicine, Associate Professor of Internal Medicine, Pediatrics, and Medical Informatics, Kaiser Chair in Community Medicine, CEO of MyHealth Access Network, and Senior Counsel for Interoperability to the National Coordinator for Health IT. It was updated based on feedback from the SMEs provided during the meeting.

⁵ Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure. ONC, June 2014. <http://healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf>

Current American Health System		Learning Health System
Clinical records are source-centric and limited	→	Patient-centric clinical records comprehensive of all patient healthcare experience
Data exchanged non-standardized, non-computable format	→	Data exchanged in standardized computable formats
Data sources are incented NOT to exchange data	→	Data sources are incented to exchange data
Providers must review all data on each patient to make recommendations confidently	→	Providers review only the relevant data in optimal form to make accurate recommendations
Recommendations are based on consensus guidelines and incomplete data	→	Recommendations are tailored to the individual based on continuous analysis of big data
Patient consent is managed at the source level and "all or none"	→	Patients manage their preferences for the use of their data at a granular level
Patients have little to no insight into who is using their healthcare data and for what purposes	→	Patients have clear visibility into the use of their healthcare data
Systems are designed to measure safety issues but the rate of errors and timing of corrections is inadequate	→	Rapid detection of potential patient safety issues and implementation of preventive/corrective measures
Patients perceive and experience significant inconvenience when interacting with the healthcare system	→	Patients perceive that the experience of seeking care is as convenient as any other consumer activity they engage in
A significant portion of each dollar spent on healthcare is waste, error, or ineffective	→	Expenditures for waste, errors, and ineffective care are minimized and tracked
New knowledge in healthcare is generated in separate, costly, time-limited studies which are rarely validated	→	New knowledge is generated and validated continuously based on real-time analyses yielding significant conclusions
Data to support health and healthcare is derived almost exclusively from healthcare professional-gathered information stored in health IT systems	→	Data to support the LHS comes from a wide variety of sources including the patient, their own devices such as a cell phone, and other useful information systems
Members of each patient's healthcare team are often located in multiple organizations and struggle to coordinate their work and care effectively	→	Members of each patient's healthcare team may remain independent but have the information and tools to work together as a virtually integrated team
Individuals and most stakeholder organizations have little influence over the policies and procedures for health information exchange and data use.	→	Individuals and all relevant organizations have a clear role to play in the governance of health information exchange and data use.

SME attendees discussed whether a specific architecture model needed to be described in the Roadmap to ensure the country moves towards the end state described above. While a few attendees felt that a specific architecture model should be adopted and would benefit the path towards the 10-year vision, the majority felt that the three, six, and 10 year milestones would themselves be the basis of the roadmap. Generally, attendees felt that the architecture would begin to emerge as the ten year vision becomes operationalized, and that rather than a pre-defined architecture model, characteristics of an architecture would be more productive and more likely to be adopted by the range of technology solution providers. The discussion surfaced concern about whether unintentional architecture assumptions could be introduced within the vision of the learning health system that should be avoided as the roadmap is developed. As the learning health system was discussed, the need to develop methods for making data interpretable, not just interoperable, emerged. If the learning health system is meant to provide real-time,

point-of-care access to comparative effectiveness data, for example, there will be a need to interpret the data that is being used by clinicians to make decisions.

A specific but fundamental concern was raised about the prospect of delivering research-based evidence to the point of care. That concern was rooted in the perspective that data is likely to be biased due to small sample sizes, and that the Internet provides a forum for more rapid publication of results that may not be repeatable and have not undergone peer review. Additionally, providers select which patients receive a medication based on a number of factors, so self-selection bias is necessarily introduced into the sample, limiting the statistical significance of the evidence. However, there was general agreement that this may be outside the scope of the SMEs, who should focus on the ingredients necessary to ensure the secure but ubiquitous availability of the data to appropriate participants in the learning health system. The SMEs agreed that the new definition of interoperability and the functions of the learning health system should be constraints to the conversation, and that the group should identify the pieces of interoperability needed so that the lack of data exchange is not an inhibitor to the learning health system, but rather the underpinning infrastructure that enables it.

Roadmap Guidelines

ONC's 10 year vision document lays out nine guiding principles for developing the interoperability roadmap. These guidelines were presented to the SME group to be used as foundational concepts that could serve to test a given approach to meeting a building block objective.

- Build upon existing health IT infrastructure
- One size does not fit all
- Empower individuals
- Leverage the market
- Simplify
- Maintain modularity
- Consider the current environment and support multiple levels of advancement
- Focus on value
- Protect privacy and security in all aspects of interoperability

In discussing the principles, the SME group indicated that while it is important that any approach not exclude the individual and their ability to exercise their rights regarding the use of their data, the interoperable nationwide health IT infrastructure of the future, should be cautious about depending on individuals to mediate the exchange of information. Further, the group found the barriers to exchanging sensitive health information may need addressed in the near-term and that the industry should consider including more than behavioral health information in the exchange equation, i.e. social determinants like unemployment, substance abuse, and other social or demographic factors. There was general agreement from attendees that the guiding principles were helpful to facilitating the development of milestones and priorities for each building block. The group discussed each of the five building blocks and the potential milestones and goals for each time period (three, six, and 10 years) associated with each block.

Building Block 1: Core Technical Standards and Functions – Discussion Overview and Synopsis

Building block one is the core technical standards and functions necessary to meet the objectives assigned to each time period. There are potentially three layers to the milestones for building block one, the features needed for the learning health system, the functions that support the features, and the standards that support the functions. However, looking at the 10 year timeframe, the milestones should be established at a high level with more focus on the functions, rather than the standards, to recognize and affirm that the roadmap should avoid predicting or constraining technical innovation. In that vein, identifying particular standards for the technical contours of a ten year timeframe could be counterproductive in moving the country towards the learning health system.

In discussing standards, there was a strong feeling that security standards are an imperative and needed to be prioritized in order to support the 10 year vision. There was recognition that healthcare lags behind other industries, with respect to security protections and the processes associated with them, particularly infrastructure that is considered critical infrastructure for the country, and that a lack of security standards that are widely deployed or deployed consistently, could be an inhibitor to the learning health system. There was general agreement that the three year timeframe could be used to identify the best practices and security standards needed; the six year timeframe could be used to deploy the standards; and the 10 year timeframe could be a ubiquitous use of mature security standards.

In reviewing the standards landscape, the SME group discussed the need for further development and enhancement of standards that exist today (IHE for query, C-CDA, HL7, etc.), rather than developing net new standards, which is a sentiment aligned with the guiding principles. There was debate and some disagreement among the SMEs as to how current standards can be further refined and relied upon for the basis of the vision, while still developing or allowing for the development of the next generation of standards. However, many SMEs felt that relying on newer standards, such as FHIR, for near to mid-term planning (particularly the three year timeframe) would be impractical. That is not to say that new standards will not be relevant to the future state, but rather to underscore the general sentiment that the longer-term vision should not be rooted in specific standards. Some SMEs felt that the current set of standards would be insufficient to support the learning health system, even if they are evolved, refined, and further developed and that new standards (FHIR was referenced frequently) will likely be necessary. However, others were concerned that the industry not simply abandon existing standards that are increasingly being deployed and working in pockets of the country, in favor of new standards that are not yet proven. Others felt strongly that the current standards with additional constraints (particularly the C-CDA for document structure) and transport standards, such as Direct, could be relied on to make important advancement towards the learning health system. The group agreed that what was most necessary is a well-defined and adhered to process for developing, piloting, promulgating, and testing standards and their use in the field. The lack of the vendor community implementing advancements in interoperability in the past (or the limited progress of past efforts) is tied to the naturally competitive vendor landscape, a lack of incentives for hospitals and practices to work together to share information, and Meaningful Use requirements taking precedence over other product development activity. However, the group noted the rapid changes to the incentive structures, largely surrounding value-based payment models, providing

financial motivation for hospitals and practices to work together. However, there was robust discussion about how effective the current range of value-based payment models are to truly modify providers' demand for inter-organization data exchange, and in turn, if that demand existed, how it would trickle down to the vendor community. The general sentiment was that EHR vendors attempt to be responsive to their customers' needs, and with customers being motivated to exchange data, vendors' competitive nature should be reduced, leading to agreement on standards implementation. However, a counterpoint was that so long as Meaningful Use requirements continue to drive the development roadmap for vendors, there is a limited ability to focus on non-Meaningful Use related development. Consequently, a more tailored focus on data exchange and interoperability requirements in Stage 3 could help align the development activities within the vendor community with the demand of their customers to exchange data.

A number of SMEs felt that the guiding principle for standards development and implementation should be to consolidate and perfect the standards the industry has now (including transport, content, and vocabularies), while facilitating ongoing development and implementation of standards for innovative use cases. This will enable the industry to leverage what has been developed, but not limit inclusion of other standards and approaches to avoid stagnating innovation. It was suggested that stimulation of the implementation of standards, requires an organization to act in a capacity of selecting standards from existing standards development organization (SDOs), constrain them as necessary, certify their use by vendors, and ensure they are being used, as certified, in the field. There are currently a number of organizations that work in different but related aspects of standards development with respect to interoperability and data exchange, adoption, constraint, implementation, and testing of standards: IHE (including publish/subscribe, query/response, patient matching, etc.), HL7 for content (C-CDA, QRDA, ADT, public health, etc.), EHR|HIE Interoperability Workgroup (plug-and-play interoperability, HPD+, etc.), Healthway (eHealth Exchange, including query/response, patient matching, etc.), and others. The SME group discussed the role of ONC in releasing a request for proposal (RFP) to designate an organization to act as the entity that is responsible for establishing the use of standards to support interoperability. However, the SMEs felt that the industry should be given the chance to identify and coalesce around an organization, prior to ONC pursuing an RFP process to designate such an organization. There were some that felt this would not occur without ONC using the RFP process, but most felt that this should be used only if the industry fails to coalesce around an organization.

Application programming interfaces (APIs), generally speaking, are widely relied on to support system integration for modules within a single platform and between separate systems. Many health IT vendors utilize APIs within their systems in order to share data across platforms. However, APIs may be proprietary and closed, meaning they are less effective (or not effective at all) in supporting the exchange of data, without special effort of the user or customer. There was discussion amongst the SMEs on whether "open / published"-APIs are needed in order to advance interoperability. The industry has not yet developed a consistent definition of an open and/or published API or the expectations associated with offering such an API. Typically, a published API is documented and available for consumption by someone other than the vendor that developed the underlying solution. There was general agreement that open and published APIs are needed, but that new APIs may be unnecessary, and that refinement of existing APIs (such as IHE profiles for system-to-system query interaction) is what is needed to support

interoperability. However, some SMEs felt that the existing IHE profiles, even if further constrained, could not support the new definition of interoperability (i.e. “no special effort”) agreed to by the group.

Finally, the SMEs agreed that in the 10 year timeframe, the standards and functions must be able to support an end user accessing a complete representation of a patient’s current status, with the ability to filter the data to find what is needed for the particular care or service being provided. This may require de-duplication of data, but must allow for a curated list of the patient’s data (such as problems, medications, allergies, and the care plan), though it was not discussed who would curate the list. The table below provides a list of potential milestones and goals developed by the SMEs for each timeframe. In the near term, the milestones are categorized into semantics, transport, and security. SMEs focused primarily on the three and 10 year timeframes. The milestones listed were not necessarily unanimously supported by the SMEs, but did have a relatively strong level of support from the group.



Building Block 1: Core Technical Standards and Functions

Current State:

- Exchange of some Structured data
- Varying implementations of the same standards
- Directed Exchange
- Publish and Subscribe within networks
- Query and Response within networks
- Standardized vocabularies and code sets for specific domains of data

Desired State:

	Vision: Send, receive, find, and use health information to improve health care quality	Vision: The learning health system
Category	3 Year Milestones	10 Year Milestones
Semantic	<ul style="list-style-type: none"> • A well-constrained summary record (C-CDA format) is implemented and ubiquitous. • An entity is identified to own/manage the iterative process of developing, maintaining, testing, certifying, and propagating standards, implementation guides, and test cases for semantic interoperability. 	<ul style="list-style-type: none"> • Systems should have the ability to analyze risks and benefits of a particular treatment for a particular set of patients and provide the data to a provider at the point of care. • Patient records can be matched across systems to an industry set specificity or accuracy. • Ubiquitous and mature security controls are in use. • There is uniform consistency in semantics and coding to ensure that the correct meaning of data persists as it is moved between systems. • A mechanism for adding new data elements to exchange is automated. • Consent management is available for the data type, organizational type, and purpose/use of the data. • Exchange of clinical data is ubiquitous. • Identity management of organizations, providers, patients, and resources is ubiquitous. • All relevant data sources and consumers of data are connected both directly and indirectly.
Transport	<ul style="list-style-type: none"> • An entity is identified to own/manage the iterative process of developing, maintaining, testing, certifying, and propagating standards and implementation guides for transport interoperability, including query, publish-subscribe, Direct messaging, and others. • Development and implementation of open/published APIs. 	
Security	<ul style="list-style-type: none"> • An entity is identified to own/manage the iterative process of developing and maintaining standards and implementation guides for security to support interoperability. 	

Building Block 2: Certification – Discussion Overview and Synopsis

Building Block 2 is focused on the certification of health IT products for interoperability and conformance to standards. Under the authority granted by the Public Health Service Act 3001(c)(5), ONC manages the Health IT Certification Program, including the development of certification criteria and oversight of the accredited testing laboratories and accredited certification bodies. In recent months, ONC has held a number of hearings to discuss stakeholder concerns with the certification process, aimed at identifying opportunities to improve the process and tailor it towards interoperability. The majority of SMEs indicated that the current certification requirements and process focus too heavily on functionality of an EHR and exclude criteria related to the interoperability of systems (particularly those that may not be a traditional EHR). The certification program should be used to set the minimum floor for interoperability, but in its current state does not include criteria or processes that will accomplish that objective. There was recognition that certification is valuable for ensuring a broader set of use cases can be met than the market may have enabled on its own, as standards and technology change and move towards interoperability. In particular, functions like public health reporting that are a public good, but not necessarily financially incentivized by the market, are likely to be excluded from interoperability priorities, and the Government has an important role in ensuring that services that are in the public interest, and which the market may not prioritize its own, are supported. There is a parallel to this within the telecommunications space, with both 911 call centers and emergency service alerts. The federal government required telecom carriers to provide 911 call center access, and more recently emergency service alerts to cell phones. Both are public goods that the carriers may not have done without being required by the government, since there is not necessarily a financial incentive to do so. The government may need to play the same role with the health IT industry and use certification to ensure services that are a public good are available, including public health reporting, consumer access to data, and others.

Based on the SMEs concerns about the current certification program and its limited application and relevance to interoperability, a number of SMEs felt that there should be a separate certification program for interoperability that is run outside of the current ONC program. This program would run in parallel with the current certification program, and there may be some overlap between the two programs, but the focus would be on interoperability, and ultimately “plug-and-play” interoperability. Some SMEs felt that the certification program should be led by the same organization that develops and curates interoperability standards, and that the organization could provide some type of stamp of approval to signal to the industry that a product or system meets interoperability standards. There was general agreement that test harnesses that are aligned with the certification criteria are needed, particularly for use after implementations to ensure continued adherence to the standards. A process for making test harnesses available to the general public to allow for phenotypic testing would need to be developed and managed, potentially by the same organization. There was also agreement that the organization would be responsible for performing after-market surveillance and adjudicating complaints, including the use of punitive measures for non-compliance, such as decertification.

The table below provides a list of potential milestones and goals developed by the SMEs for each timeframe. SMEs focused primarily on the three and 10 year timeframes. The milestones listed



were not necessarily unanimously supported by the SMEs, but did have a fairly strong level of support from the group.



Building Block 2: Certification to support adoption and optimization of health IT products and services

Desired State:

Category	Vision: Send, receive, find, and use health information to improve health care quality 3 Year Milestones	Vision: The learning health system 10 Year Milestones
Certification	<ul style="list-style-type: none"> • Interoperability testing is implemented that focuses on a specific, and initially limited, set of exchange transaction use cases. • The certification process has shifted focus to interoperability testing rather than functionality testing. • Closed-loop system testing should be considered for incorporation into any certification process. • Develop some type of post-market surveillance and reporting. • Develop use-case based testing. 	<ul style="list-style-type: none"> • The exchange ecosystem can evolve with system enhancements without disruption to services. • Government may play a role in defining minimum public services or other features/functions for certification, such as public health requirements. • Coordinated vendor test environments for interoperability (pre-production). • Production interoperability test tools are widely available for use by participants. • Forward and backward compatibility to avoid disruption occurs as the ecosystem evolves.

Building Block 3: Privacy and Security – Discussion Overview and Synopsis

The third building block covers privacy and security, including policies, practices, technology, and standards. The Health Insurance Portability and Accountability Act (HIPAA) provides the privacy and security rules governing the sharing of protected health information. HIPAA covers a large number of data exchange scenarios under the broad grouping of treatment, payment, and healthcare operations; however, there is a general lack of understanding within the industry on the specific requirements and protections of HIPAA and other Federal laws. Many providers interpret the rules strictly and conservatively, and anecdotally, sometimes create significant hurdles for patients' access to their own health information. Additionally, risk averse providers and organizations are reticent to share data electronically with other organizations, for fear of a data breach and sharing information without legally required authorizations and subsequent penalties and public relations challenges. This risk averse nature of organizations is a significant barrier to sharing data that is otherwise permissible by law, particularly without one-off data sharing agreements, which can be onerous, especially for small practices. The SME group agreed that there is a need for education within the industry on the factual requirements of HIPAA and other relevant Federal laws, as well as safe harbors that will allow risk averse organizations to properly interpret and enable data sharing within the confines of the law. However, there is also a more complicated need to modify regulations to enable the sharing of sensitive and behavioral health information as appropriate. The learning health system requires a holistic view of the patient (even beyond the care delivery system), which includes data that is not currently permitted to be shared due to well-intended but significantly restrictive regulations, specifically 42 CFR Part 2. It was noted by some SME attendees that based on current law, the organizations that hold the data are responsible for complying with applicable laws and policies. Once data is legally disclosed from one organization to another, the sending organization is not responsible for how the receiving organization handles the data or the purposes for which they use the data. The group felt that much of the industry does not operate under this understanding, which leads to a lack of sharing among organizations that are in different states with different state-level laws and regulation or that may not have the same permitted use of data.

The SME group generally agreed that the healthcare industry lags behind other industries in leveraging the most advanced security standards. The US healthcare infrastructure has been identified by the Department of Homeland Security as critical infrastructure for the country; however, the industry as a whole, may not meet the minimum security standards of critical infrastructure. There is a need for the industry as a whole to consistently implement identification, authentication, and encryption standards to protect electronic health information both at rest and in transit. Partly due to the lack of adherence to security standards, organizations often do not trust each other for data sharing, without implementing complex legal agreements. It was suggested that one way to lessen the need for these agreements is to develop and implement trust marks in coordination with the National Strategy for Trusted Identities in Cyberspace (NSTIC) work currently taking place.⁶ The industry has the ability to define a set number of characteristics that would make up the healthcare trust mark. While trust marks may assist with exchanging information about an organization's information security controls and

⁶ A trust mark contains important privacy and security information about a particular organization and can be exchanged along with data to provide a level of trust to the receiving organization that the sending organization abides by specific criteria. For information on NSTIC's trust mark pilots, visit <https://trustmark.gtri.gatech.edu/>.

compliance with applicable security standards, the industry would need to agree to the minimum necessary security requirements in order to exchange data.

Finally, the learning health system will require improved ways to provide information about patient consent and preferences when exchanging data related to that specific patient. Patient consent needs to persist with the data and must include context information (i.e. what was the setting or use within which the patient provided consent) and temporal information (when was consent provided was it permanent or for a single exchange, etc.). A number of SMEs did not feel that maintaining patient consent data at the data element level or the individual data element level was necessary to support the learning health system. While data-element level consent granularity could be powerful, accomplishing this vision, which is related to the atomic level data concepts and data provenance concepts articulated in prior reports, may not be pragmatic given the current trajectory and market drivers for development. The SME group did agree that patients should be provided with a consistent and understandable way to express their preferences related to how information pertaining to them is exchanged, and that those preferences must be shared across all data sources. However, patient preference is not always the highest authority and some data uses will transpire independent of a patient's expressed consent preferences, i.e. state-level public health reporting requirements.

The table below provides a list of potential milestones and goals developed by the SMEs for each timeframe. SMEs focused primarily on the three and 10 year timeframes. The milestones listed were not necessarily unanimously supported by the SMEs, but did have a fairly strong level of support from the group.



Building Block 3: Privacy and security protections for health information

Desired State:

Category	Vision: Send, receive, find, and use health information to improve health care quality 3 Year Milestones	Vision: The learning health system 10 Year Milestones
Privacy and Security	<ul style="list-style-type: none"> • The trust level for exchange is defined. • Organizations use industry best practices to secure their environment, including: <ul style="list-style-type: none"> ○ Secure transport, use of PKI for encryption or signing transactions. ○ Communications encrypted at two levels, transport and content. ○ Data receivers are able to decrypt content. • NSTIC solutions for authentication and authorization are published and widely implemented. • Legal and policy framework for big data and precision medicine are developed. • Create a deeming authority ⁷ to manage privacy and security. • Create safe harbors for physicians to lessen liability concerns and impacts. • Develop nationwide rules of the road to set minimum security and privacy policy standards. • Develop and implement education programs for the legal community, providers, hospitals, and patients. • Identify the attributes of consent that should be sent electronically and develop standards to make the data attributes consumable and ensure they are contextual and temporal. • OCR has clarified HIPAA requirements and instituted educational activities to address invalid perceptions and concerns about HIPAA requirements. 	<ul style="list-style-type: none"> • Patient preferences can be consistently captured and communicated across all data sources. • Systems have the ability to characterize data in a way that allows for the matching of patient consent preferences with the data itself and its application to nationwide use. • Legal and policy framework for big data and precision medicine is widely understood and implemented. • Systems meet and sustain the security requirements of critical infrastructure as defined by the Department of Homeland Security. • There is collective and continuous identification of cyber security threats. • Patients have the ability to express consent across all networks and uses (though their consent does not negate all uses of data). • Patients have transparency as to where their data resides and have the ability to check for errors, annotate records, and request corrections.

⁷ A deeming authority is an approved accrediting organization granted the authority by a Federal agency to deem organizations and/or systems as compliant with privacy and security standards.

Building Block 4: Business, Clinical, Cultural, and Regulatory Environment – Discussion Overview and Synopsis

Building block four centers on having an environment that fosters and incentivizes interoperability, including business drivers and barriers, clinical practice realities, cultural norms and shifts in attitudes, and regulations that are all favorable to exchanging health information. HHS has been reviewing policy levers beyond Meaningful Use, to encourage and in some cases incentivize interoperability. HHS plans to utilize the incentive/penalty framework to encourage provider organizations to share data across systems. The Medicare Share Savings programs, Center for Medicare and Medicaid Innovation (CMMI) grants are both incentivizing the exchange of data. In addition, HHS is working to use payment reform and tools like OASIS to encourage long-term care facilities and home health agencies to adopt health IT and exchange data. The SME group agreed that the policy levers HHS is pursuing will be valuable for motivating organizations, particularly those that are risk-averse and concerned about liability, to share data. As HHS shifts the payment models for Medicare and works with states to add interoperability requirements to Medicaid reimbursement models, the SMEs felt that commercial plans would follow, and begin to shift the financial incentives for all providers and organizations. The SMEs did feel that clarification and further guidance from the Office for Civil Rights (OCR) to address invalid perceptions and concerns about HIPAA would be necessary to truly move the dial on information exchange.

One of the components for facilitating interoperability is moving the cultural norm towards one where patients expect their data to be available to their providers no matter where they seek care. Organizations, such as the Robert Wood Johnson Foundation among others, are actively pursuing specific objectives related to shifting towards a culture of wellness and the associated system changes that support that future culture. Additionally, patients should expect to have access to their own data and expect to be able to share it with whomever they desire. This is a cultural shift from today's world, where patients do not understand their rights to access their data. Many of the SMEs noted that one of the main issues with patient access to electronic data is the lack of a consolidated view of their data. Each hospital and practice sets up its own patient portal, and the current standards for view, download, and transmit, do not really allow patients to maintain a single record of their data in one place. Their data is segmented across their providers, and they have very little ability to consolidate or share their data. In addition to changing the cultural norm for patients, the standard of care, which is the cultural norm for providers, needs to be modified. The current standard of care does not include routinely querying for patient information or electronically sharing information with the next provider of care. In order for providers to fully participate in information exchange, the standard of care must include reviewing external data sources for information about the patient.

The table below provides a list of potential milestones and goals developed by the SMEs for each timeframe. SMEs focused primarily on the three and 10 year timeframes. The milestones listed were not necessarily unanimously supported by the SMEs, but did have a fairly strong level of support from the group.



Building Block 4: Supportive business, clinical, cultural, and regulatory environments

Current State:

- Individuals have limited access to health information electronically
- Providers do not understand where legal responsibilities begin/end for data sharing
- Fee for service payment structure does not incent interoperability and data sharing

Desired State:

Category	Vision: Send, receive, find, and use health information to improve health care quality 3 Year Milestones	Vision: Use information to improve health care quality and lower cost 6 Year Milestones	Vision: The learning health system 10 Year Milestones
General	<ul style="list-style-type: none"> • Individuals have consolidated electronic access to the Meaningful Use core set of data from all healthcare providers they have seen. • Providers have access to consolidated health information (Meaningful Use core set of data) from across the patient care setting. • Public health has access to consolidated health information (Meaningful Use core set of data) from across the patient care setting. 	<ul style="list-style-type: none"> • Individuals have seamless electronic access to the Meaningful Use core set of data across all healthcare providers they have seen, either by allowing consumers to manage the aggregation of their data or allowing consumer access to HIOs. 	<ul style="list-style-type: none"> • Robust analytical methods for large scale healthcare data that account for bias and other data limitations (such as statistical significance) exist. • The standard of care supports the use of data by physicians to treat patients. • The payment structure evolves to deliver efficient, high quality care. • Analytics is not just academic in nature but also includes quality, efficiency, and wellness research to improve care and prompt an intervention or prevention technique.

Building Block 5: Rules of Engagement and Governance – Discussion Overview and Synopsis

The final building block, and one of the most vigorously discussed, includes the rules of engagement between organizations and governance of data exchange. Governance includes oversight, enforcement, and policies that enable interoperability between organizations. The healthcare delivery system, while only part of the learning health system, has evolved as a network of networks model, relying on both HITECH funded efforts and private exchanges, many rooted in health systems exchange needs. The most basic network participant is a single EHR with one pool of users that aggregates data. The second network level is an organization or system that pulls data from multiple sources. The organization at the top can be an HIO, an EHR vendor, or an accountable care organization (ACO). The most complex network level is the network of networks that connects together the second level of organizations or systems. The governance required at each network level is different. As milestones and goals are developed for the roadmap, the SMEs agreed that they should be the minimum necessary to enable exchange across the network of networks, without being too onerous at the lower network levels. Point-to-point agreements used at the lower network levels cannot necessarily be extrapolated across the network of networks. However, the SMEs felt that the industry needs to agree on the basic governance and principles for trust that are needed for larger scale exchange, while allowing organizations in the lower level networks to set their own guidelines and policies.

The SMEs categorized governance into three categories:

- standards development organizations, which includes setting and testing standards as well as enforcing them;
- data use agreements and sharing of data; and
- operational oversight, which is mainly monitoring that participants are following the rules.

The SMEs agreed that the industry will need to agree to a set of common guidelines for each governance category, and that ONC could use its influence to encourage the use of the guidelines. A number of the SMEs felt that ONC did not need to identify a particular organization to set, maintain, or enforce governance, but rather could endorse the guidelines developed by the industry through white papers and FAQs. The SMEs believed that ONC's endorsement of the guidelines would be sufficient to encourage adoption across the industry.

The table below provides a list of potential milestones and goals developed by the SMEs for each timeframe. SMEs focused primarily on the three and 10 year timeframes. The milestones listed were not necessarily unanimously supported by the SMEs, but did have a fairly strong level of support from the group.



Building Block 5: Rules of engagement and governance

Current State:

- Multiple governing entities with varying requirements
- No single over-arching governance structure
- FACAs make recommendations for federal direction for policy and standards

Desired State:

Category	Vision: Send, receive, find, and use health information to improve health care quality 3 Year Milestones	Vision: The learning health system 10 Year Milestones
General	<ul style="list-style-type: none"> • Stakeholders develop a set of guiding principles/policies through a process convened by ONC. • Federal regulators provide additional guidance on the guiding principles that signals the validity of the principles and encourages implementation. 	<ul style="list-style-type: none"> • The common rules of the road that must be the same across all networks are defined and governed. • Governance organizations have evolved as a function of incentives and motivation to participate in a given network. • Governance will be nimble, flexible, enabling, and able to change and adapt to meet market needs.

Key Themes and Synthesis

A number of key themes and focus areas that spanned the building blocks were repeatedly raised and discussed over the course of the three SME meetings. The building block concepts are deeply intertwined as they relate to pursuing a 10 year learning health system vision. Achieving the 10 year vision will necessarily require coordination among entities beyond both the delivery system, ONC, and HHS more broadly.

While the SME group arrived at a range of recommended milestones, there were areas of disagreement on which milestones would push towards the 10 year vision of interoperability. There is a tension within the industry between improving and refining the current stack of standards, and pushing more aggressively to develop and implement new standards. One of the guiding principles is to build on existing infrastructure; however, the existing standards may not be extensible and easily implementable in the form of open/published APIs, to support the complex use cases of the future, including seamless access to a single view of a comprehensive patient record. However, the two concepts need not be mutually exclusive. The milestones may be able to be constructed to allow for refinement of the current standards, with an eye towards emerging technologies, like FHIR, that have the potential to meet the 10 year learning health system needs. The risk is that any approach that is incorporated into Meaningful Use will receive priority; therefore potentially demoting viable alternatives. However, ONC could focus on a core set of standards to from a Meaningful Use perspective and not be overly prescriptive, thereby creating a baseline of capability but allowing the market to innovate.

The SME group spent a fair amount of time discussing the historical and current motivations for interoperability. Many in the group felt that the financial incentives to share data are significantly shifting, and this shift will help to push forward with interoperability. Many of the milestones for building block one (standards and functions) and building block five (rules of engagement and governance) are a push to maintain the status quo, and allow the industry to push forward with interoperability without significant involvement of ONC. Issues with the C-CDA standard and concerns about heavy-handed, mandated governance, similar to ONC's governance request for information (RFI), may be an underlying concern for the industry and be part of the motivation for an industry-based approach. In addition, the shifting incentives to exchange data may push the industry forward without intervention by the government. However, new payment models are not widespread and some have not demonstrated the success that was expected. There are areas of the country where value-based payment models are working well and are gaining participants, but independent practices and organizations in rural areas, are unlikely to be involved in these new payment models in the near future, and run the risk of being left behind in regards to interoperability. It is unclear whether the shifting incentives will naturally push hospitals and vendors to support the type of interoperability envisioned for the learning health system, without government involvement. In regards to the milestones included in the interoperability roadmap, ONC will need to carefully consider its partnership with the industry, and identify areas where oversight and regulation are necessary, and where guiding principles and FAQs can be used to guide the industry towards interoperability.

A number of milestones that the SME group arrived upon are in some manner being worked on today. There is a near-term need to further constrain the C-CDA. While many organizations are sending HL7 messages, like ADTs and labs, C-CDA is becoming the main document for exchange, primarily due to Meaningful Use requirements. As organizations have begun sharing

C-CDA documents, weaknesses within the standard, primarily due to a lack of constraint have become apparent. The HIT Standards Committee Implementation Workgroup has taken on the charge to constrain the C-CDA and is currently evaluating the standard. In regards to certification, the need for test harnesses was discussed multiple times. A number of initiatives that start to move towards this milestone exist, including NIST's Meaningful Use test tools (Transport Test Tool, Immunization Information System, Syndromic Surveillance, ePrescribing, etc.), ONC's Standards Implementation & Testing Environment,⁸ ONC's Cypress tool for CQMs,⁹ ONC's open test method development pilot,¹⁰ Healthway's eHealth Exchange onboarding process,¹¹ and the EHR|HIE Interoperability Workgroup's (IWG's) HIE Certified program.¹² These tools may be leveraged to provide test harnesses that could be used for phenotypic testing by end-users. Finally, projects like NSTIC are building trust marks that can be leveraged to exchange information about organization's security policies, procedures, and operations.¹³

The vision of the learning health system will be pivotal to moving the U.S. towards a culture of wellness, and it will be underpinned by health IT and the fluid exchange of health information. Technology, policy, business, culture, and regulation must all coalesce together to ensure that data can be exchanged between all organizations in a secure manner that does not require extra effort by the end user or customer. The SME group recognized the importance of the task at hand, and their part in guaranteeing the learning health system becomes a reality, and provided invaluable feedback during the meetings. Ai and ONC are appreciative of their contribution to the interoperability roadmap.

⁸ <http://sitenv.org/>

⁹ <http://projectcypress.org/>

¹⁰ <http://healthit.gov/open-test-method>

¹¹ <http://healthwayinc.org/index.php/exchange/participant-testing>

¹² <http://www.interopwg.org/certification.html>

¹³ <http://www.nist.gov/nstic/>