

Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap – Final Version 1.0

HIT Joint Advisory Committee Presentation

October 6, 2015



A health system that provides better care, spends dollars more wisely, and has healthier people Health IT.gov

Focus Areas

Description

INCENTIVES

- Promote value-based payment systems
 - Test new alternative payment models
 - Increase linkage of Medicaid, Medicare FFS, and other payments to value
- Bring proven payment models to scale
- Align quality measures

CARE DELIVERY

- Encourage the integration and coordination of clinical care services
- Improve individual and population health
- Support innovation including for access

INFORMATION

- Bring electronic health information to the point of care for meaningful use
- Create transparency on cost and quality information
- Support consumer and clinician decision making

Commitments



- Commitment 1: Help consumers easily and securely access their electronic health information, direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.
- Commitment 2: Help providers share individual's health information for care with other providers and their patients as much as permitted by law and refrain from blocking electronic health information (defined as knowingly and unreasonably interfering with information sharing).
- Commitment 3: Implement federally recognized national interoperability standards, policies, guidance, and practices for electronic health information and adopt best practices including those related to privacy and security.

Interoperability Defined

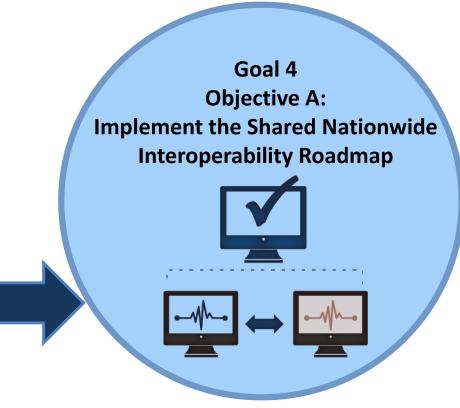


- The ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user.
- All individuals, their families and health care providers should be able to send, receive, find and use electronic health information in a manner that is appropriate, secure, timely and reliable to support the health and wellness of individuals through informed, shared decisionmaking.

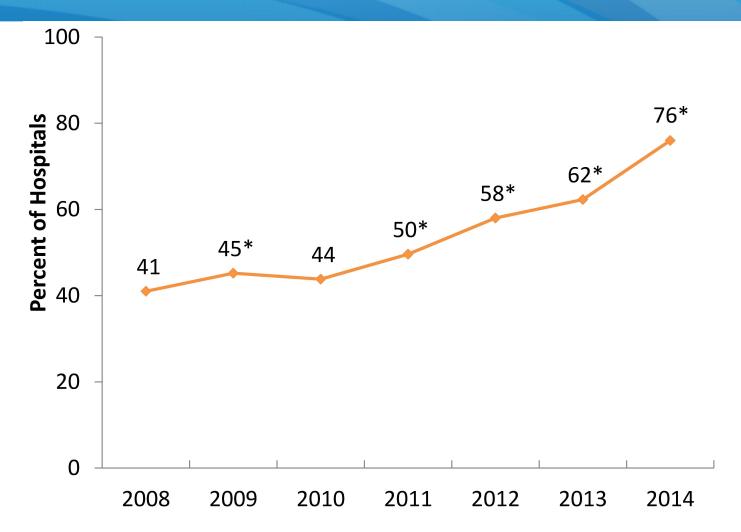
Big Picture: The Federal Health IT Strategic Plan & the Interoperability Vision for the Future Health IT.gov

Federal Health IT Strategic Plan Goals





Exchange with outside ambulatory care providers and outside hospitals is increasing. Health IT.gov

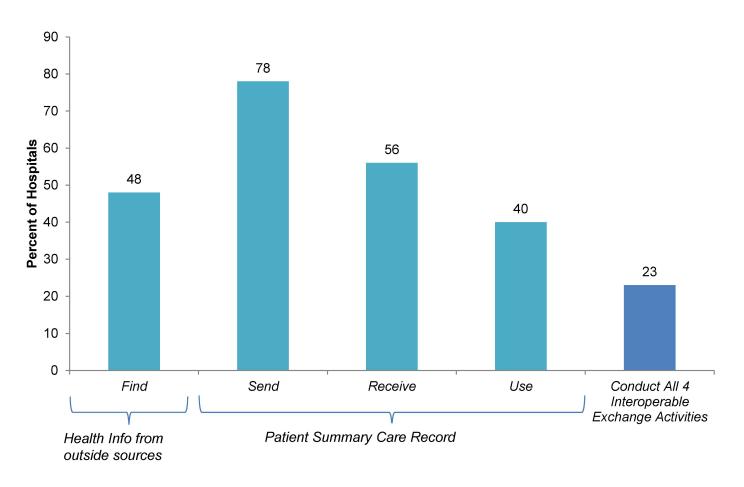


SOURCE: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement.

NOTES: Percent of non-federal acute care hospitals that electronically exchanged laboratory results, radiology reports, clinical care summaries, or medication lists with ambulatory care providers or hospitals outside their organization: 2008-2014

*Significantly different from previous year (p < 0.05).

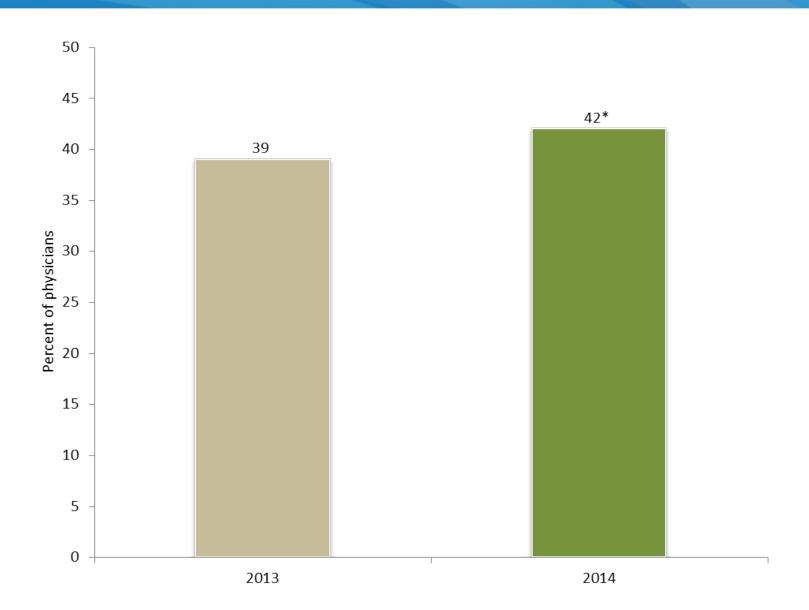
One-quarter of hospitals nationwide are finding, sending, receiving AND using data electronically. Health IT.gov



SOURCE: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement

NOTES: "Find" is only interoperable exchange activity not specific to summary of care records. Find refers to query. "Send" and "Receive" include routine
exchange using secure messaging using an EHR, using a provider portal, OR via health information exchange organization or other third party. "Use"
requires that the records are integrated into the hospital's EHR system without the need for manual entry.

Proportion of physicians who reported electronically sharing health information Health IT.gov



Varied Landscape





NATIONAL ASSOCIATION FOR TRUSTED EXCHANGE











Shared Roadmap - Version 1.0 Overview of the Process and Timeline



Initial roadmap development

- · Online community forum
- Listening sessions
- Experts convened
- Federal workgroups
- State engagement
- FACA workgroups and joint meeting

Oct 2014

FACA review and recommendations

- HITPC interoperability and HIE workgroup recommendations including governance subgroup, and JASON task force
- Governance and business environment reports
- Additional community input

Jan 2015

Roadmap released for public comment

- Update based on public input
- FACA review

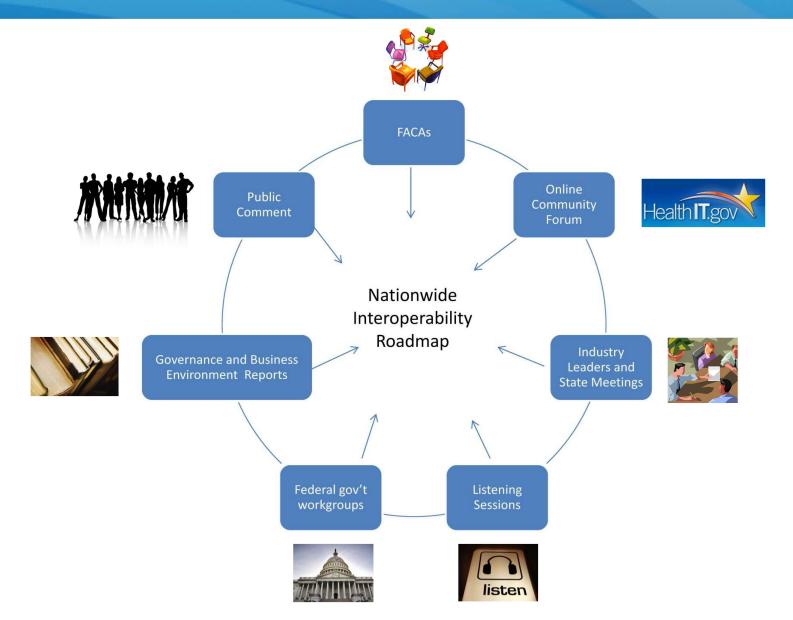
Q3/Q4 2015

Nationwide Interoperability Roadmap Version 1.0

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Shared Roadmap - Version 1.0 Vehicles for Stakeholder Feedback





Overview of Feedback from Draft Roadmap



- General agreement on interoperability requirements set forth in the draft, even if some disagreement about details
 - Mixed feedback on governance approach
 - Desire for more clarity/detail on standards direction
 - Call for unique health identifier
 - Confusion about some privacy and security concepts,
 particularly related to permission/choice
 - Recommendations to restructure the document

Principle-based Interoperability





BUILD UPON EXISTING HEALTH IT INFRASTRUCTURE



MAINTAIN MODULARITY



ONE SIZE DOES NOT FIT ALL



CONSIDER THE CURRENT ENVIRONMENT AND SUPPORT MULTIPLE LEVELS OF ADVANCEMENT



EMPOWER INDIVIDUALS



SIMPLIFY



PROTECT PRIVACY AND SECURITY IN ALL ASPECTS OF INTEROPERABILITY



LEVERAGE THE MARKET



FOCUS ON VALUE



Structure of the Final Roadmap v 1.0

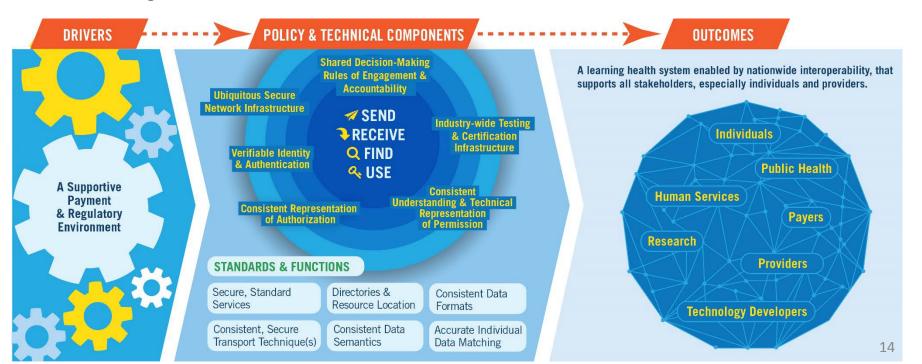


Goals:

2015-2017: Send, receive, find and use priority data domains to improve health care quality and outcomes.

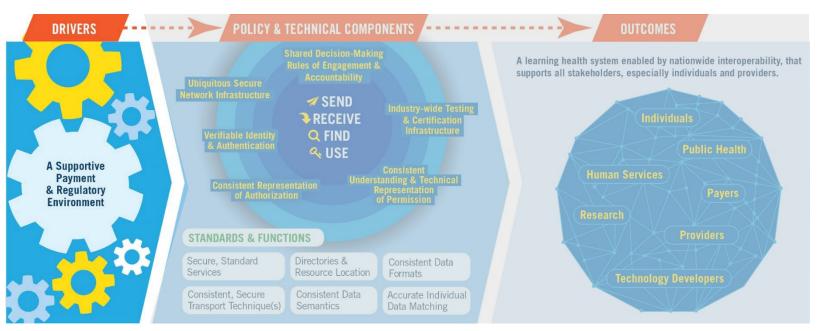
2018-2020: Expand data sources and users in the interoperable health IT ecosystem to improve health and lower cost.

2021-2024: Achieve nationwide interoperability to enable a learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.





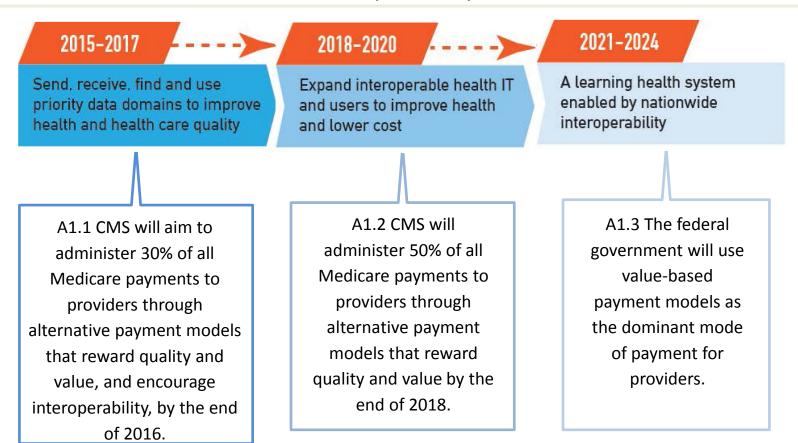
Drivers



Supportive Payment and Regulatory Environment A1. Milestones



Rapidly shift and align federal, state, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability.



Supportive Payment & Regulatory Environment A2. Examples of Calls to Action



2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- States with managed care contracts should routinely require provider networks to report performance on measures of standards-based exchange of information in required quality strategies, performance measurement reporting, etc.
- A growing number of private payers should implement provisions supporting interoperability within valuebased payment arrangements covering commercial populations.
- Purchasers should consider health plans' commitment to the use of interoperable health IT and health information exchange among network and nonnetwork providers in their purchasing decisions.

Supportive Payment & Regulatory Environment A1. Commitments



2015-2017



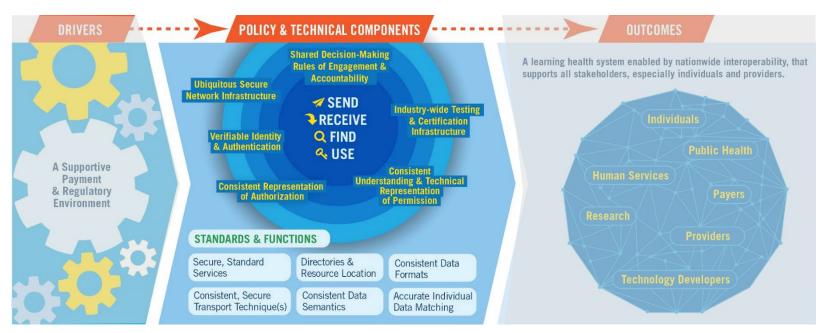
Send, receive, find and use priority data domains to improve health and health care quality

- CMS will take advantage of opportunities, when possible, to build interoperability requirements into relevant payment rules and programs where appropriate.
- CMS will encourage states with Medicaid managed care programs to include references to health IT or health information exchange in any relevant sections of their state quality strategies. ¹

¹¹ For more information, see Sec 101(e) of the 2015 Medicare and CHIP Reauthorization Act



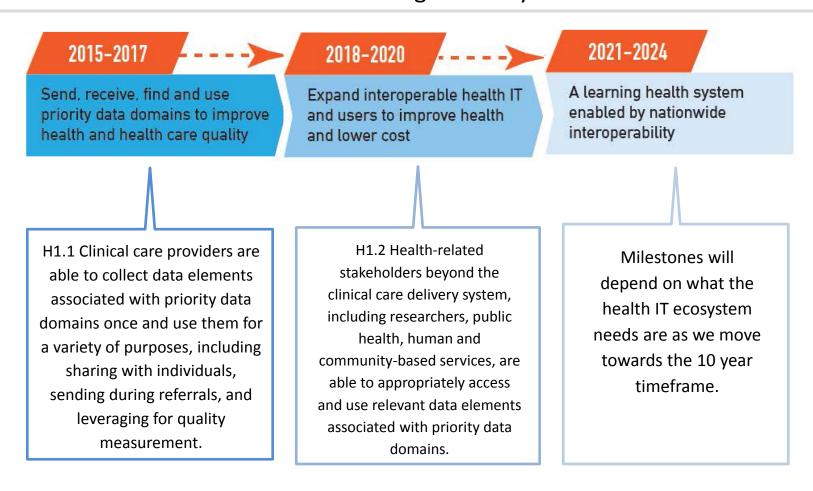
Policy and Technical Components



Consistent Data Semantics H1. Milestones



As electronic health information is shared and used among different stakeholders, its meaning must be consistently maintained in order to maximize its usage and value in a learning health system.



Consistent Data Semantics H2. Examples of Calls to Action



2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- Technology developers should provide accurate translation and adapter services where needed in order to support priority delivery system reform and learning health system needs.
- Health IT users should provide feedback to SDOs and other stakeholders, including government, regarding additional data elements and/or data domains that should be prioritized for semantic alignment.
- NLM, FDA, CDC, CMS and other stakeholders should collaborate regarding approaches to promoting laboratory information exchange (especially through the use of LOINC, SNOMED-CT, UCUM and UDIs) between in vitro diagnostic devices and database systems, including laboratory information systems and EHRs.

Consistent Data Semantics H3. Commitments



2015-2017



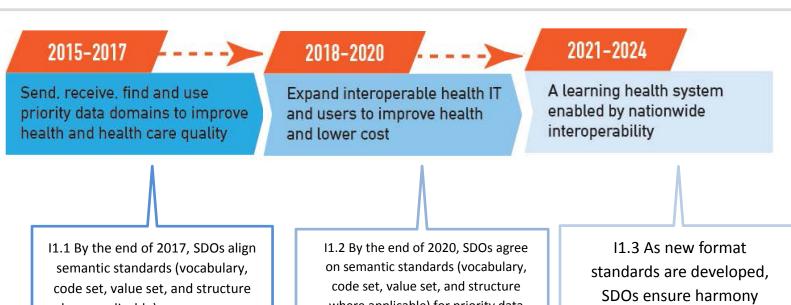
Send, receive, find and use priority data domains to improve health and health care quality

- ONC will promote and participate in collaborative processes to align SDOs and technology developers on the implementation and use of vocabularies, code sets, value sets and structure necessary to consistently represent and maintain the meaning of data elements associated with priority data domains across systems.
- During 2016 and 2017, ONC will promote and participate in collaborative processes to align SDOs and technology developers on the implementation and use of vocabularies, code sets, value sets and structure necessary to consistently represent and maintain the meaning of priority data elements associated with priority data domains across systems.

Consistent Data Formats I1. Milestones



Consistently representing electronic health information across different stakeholders and systems is the bedrock of successful interoperability. In a learning health system, while user interfaces can and should be different depending on the user, the format in which electronic health information is shared between health IT systems must be consistent and machine readable, so that the meaning and integrity of information is retained as a variety of users interact with it.



semantic standards (vocabulary, code set, value set, and structure where applicable) across common electronic health information format standards with semantic standards adopted in ONC's 2015 Edition for priority data domains and associated data elements.

I1.2 By the end of 2020, SDOs agree on semantic standards (vocabulary, code set, value set, and structure where applicable) for priority data domains and associated data elements not defined in ONC's 2015 Edition final rule and align to those standards across common electronic health information format standards.

I1.3 As new format standards are developed, SDOs ensure harmony across all format standards, particularly for the priority data domains and associated data elements.

Consistent Data Formats 12. Examples of Calls to Action



2015-2017 --

Send, receive, find and use priority data domains to improve health and health care quality

- SDOs, in coordination with ONC, should work together to align semantic standards (vocabulary, code set, value set, and structure where applicable) across health information format standards (starting with HL7 v2, C-CDA, QRDA, FHIR, and NCPDP SCRIPT) with semantic standards adopted in ONC's 2015 Edition for priority data domains and associated data elements.
- Provider and patient-facing technology developers should update their products and services to use format standards identified in ONC's most recent finalized Interoperability Standards Advisory, starting with the most recent version of C-CDA.
- SDOs and stakeholders should document best practices and guidance on methods for exchanging unstructured health information, such as physician notes, in an interoperable manner.

Consistent Data Formats 13. Commitments



2015–2017 ----Send, receive, find and use priority data domains to improve health and health care quality

 ONC will promote and participate in collaborative processes to align semantic standards across format standards to consistently represent and maintain the meaning of data elements associated with priority data domains across systems.

Consistent, Secure Transport Techniques K1. Milestones



Interoperability requires transport techniques that are non-proprietary, easy to configure and widely and consistently used. The fewest number of protocols necessary to fulfill the needs of learning health system participants is most desirable.

2015-2017

2018-2020

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2021-2024

Send, receive, find and use priority data domains to improve health and health care quality

Expand interoperable health IT and users to improve health and lower cost

A learning health system enabled by nationwide interoperability

K1.1 The majority of hospitals, ambulatory providers, and individuals are able to send and receive data elements associated with priority data domains with their trading partners of choice, using at least the Direct transport protocol.

K1.2 Long term care providers and behavioral health providers are able to send and receive data elements associated with priority data domains with their trading partner of choice, using at least the Direct transport protocol.

Milestones will depend on what the health IT ecosystem needs are as we move towards the 10 year timeframe.

Consistent, Secure Transport Techniques K2. Calls to Action



2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- Providers (including hospitals, ambulatory providers, long-term care centers and behavioral health providers) should adopt and use Direct to enable broad scale ability to send and receive data elements associated with priority data domains commensurate with the organization's required LoA.
- Technology developers and Direct service providers (i.e., HISPs) should join a single common trust community and trust bundle to enable all their users to send and receive priority data elements with each other or develop a simple method for reciprocity between trust communities.
- Public health agencies should converge on the use of standardized web services to support data submission as well as data query from registries and other systems.
- Technology developers, providers and research communities should use standards for query functionality identified in ONC's most recent finalized Interoperability Standards Advisory.

Secure, Standard Services J1. Milestones



Services should be modular, secure and standards-based wherever possible.

2015-2017

Send, receive, find and use priority data domains to improve health and health care quality

2018-2020

Expand interoperable health IT and users to improve health and lower cost

2021-2024

A learning health system enabled by nationwide interoperability

J1.1 Certification approaches that encourage the adoption of specific APIs or consistently functioning APIs in a manner that does not prevent the adoption of innovative new APIs are developed and implemented by ONC and other industry stakeholders.

J1.2 More than 50% of technology developers provide access to electronic health information through standard, public APIs.

J1.3 More than 75% of technology developers provide access to electronic health information through standard, public APIs.

Secure, Standard Services J2. Calls to Action



2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- SDOs, through efforts such as the Data Access Framework (DAF), Argonaut Project and HEART initiative should provide technology developers with profiles, reference implementations, and implementation guides (IGs) to standardize APIs for querying and retrieving priority data elements such as a C-CDA document and as discrete data elements.
- Technology developers should implement standard APIs from the DAF, HEART and Argonaut projects and make them publicly available.
- Technology developers should work with SDOs to develop standard APIs for interoperable medical devices.
- ONC, NIST, CMS, CDC and FDA should collaborate to advance laboratory data interoperability, including the establishment of requirements for common application programming interfaces (APIs) that meet CLIA requirements for laboratory test ordering and reporting.

Secure, Standard Services J3. Commitments

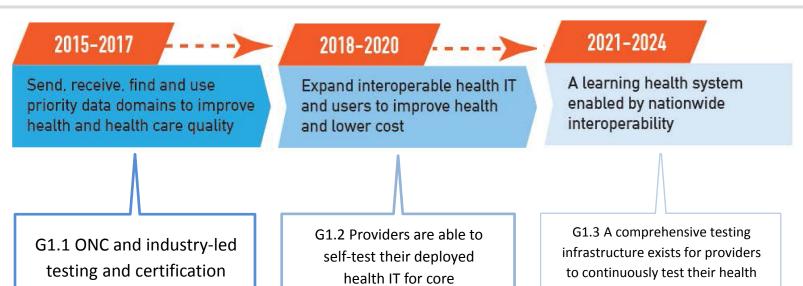


Send, receive, find and use priority data domains to improve health and health care quality

 ONC will support implementation of new API requirements in certification by working with industry stakeholders to develop and disseminate best practices and technologies to ensure that existing and emerging APIs facilitate interoperability in a secure way.

Industry-wide Testing & Certification Infrastructure Health IT.gov

A variety of health IT testing tools and resources must be broadly available to stakeholders to support technology from development through deployment. Testing and certification programs must provide health IT users with reasonable assurance that health IT is interoperable.



G1.1 ONC and industry-led testing and certification programs develop a standard set of best practices and policies that ensure consistency across testing and certification bodies.

self-test their deployed health IT for core interoperability functions to ensure their systems operate as expected after implementation and to hold technology developers and network service providers accountable.

G1.3 A comprehensive testing infrastructure exists for providers to continuously test their health IT as new components are added and old components are phased out to ensure their systems operate as expected after implementation and to hold technology developers and network service providers accountable.

Industry-wide Testing & Certification Infrastructure G2. Calls to Action Health IT.gov

2015-2017 ----

Send, receive, find and use priority data domains to improve health and health care quality

- Technology developers, SDOs, government and other stakeholders should accelerate the
 development and availability of a suite of testing tools that can be used by technology users,
 not just developers, post-implementation to test and ensure interoperability while health IT
 is in use.
- SDOs should release comprehensive schema and associated testing tools for each standard and implementation guide they release in order to support more stringent testing of standards by technology developers.
- Existing industry certification programs should address interoperability functions that ONC's
 program does not address, in a manner that is complementary to and not duplicative of
 ONC's certification program, to ensure that different aspects of health IT support a range of
 interoperability needs.
- Care providers and professional and trade associations involved in alternative payment
 models should collect and share ongoing feedback with ONC regarding health IT certification
 needs for EHRs and other health IT in support of new models of care delivery.

Industry-wide Testing & Certification Infrastructure G3. Commitments Health IT.gov

2015-2017 ----

Send, receive, find and use priority data domains to improve health and health care quality

- ONC will work with NIST and the industry to develop more rigorous testing processes for critical interoperability standards, such as C-CDA.
- ONC will consider approving non-governmental test tools within its certification program.
- ONC will make an extensive set of computable data about certified health IT products publicly available on the Certified Health IT Product List (CHPL).

FACA Discussion



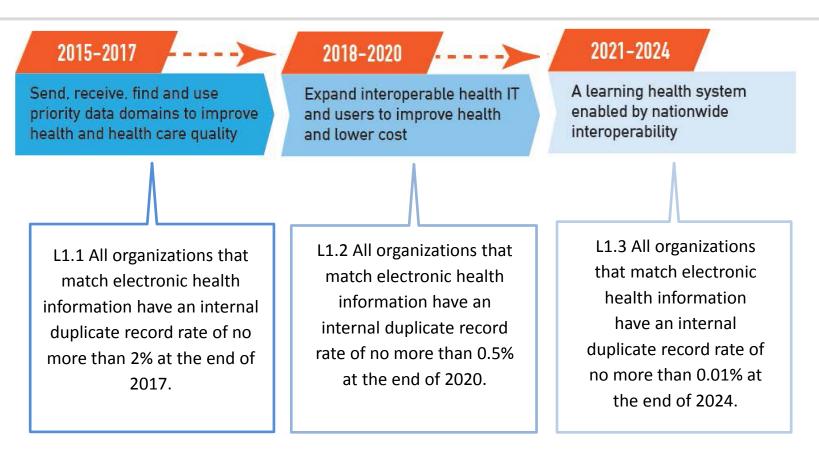
BREAK 15 Minutes



Accurate Individual Data Matching L1. Milestones



Whether aggregated in a repository or linked "just in time," electronic health information from disparate sources must be accurately matched to prevent information fragmentation and the incorrect merging of records. As technology evolves, provider identities, system identities, device identities and others that support public health and clinical research will need to be accurately matched.



Accurate Individual Data Matching L2. Calls to Action



2015-2017



- Public and private stakeholders should work with SDOs to ensure that data elements for individual data matching are standardized, and can be consistently captured and shared in all health information queries and record linking transactions.
- The industry should work together to document evidence-based best practices for individual data matching processes, data quality and matching technology.
- Technology developers and health care organizations, in collaboration with ONC, should advance the use of industry-recognized data definition and data normalization standards.
- Technology developers should include the capability to report duplication and matching rates in their products.

Accurate Individual Data Matching L3. Commitments



2015–2017 – – – – Send, receive, find and use priority data domains to improve health and health care quality

 ONC will work with public and private stakeholders to identify and test a core set of metrics that can be used across the health IT ecosystem to consistently assess matching algorithm performance across different data sets and settings.

Health Care Directories and Resource Location M1. Milestones



The ability to rapidly locate resources, including providers, individuals, APIs, networks, etc. by their current or historical names and descriptions will be necessary for finding, accessing and/or sharing electronic health information.

2021-2024 2015-2017 2018-2020 A learning health system Send, receive, find and use Expand interoperable health IT enabled by nationwide priority data domains to improve and users to improve health interoperability health and health care quality and lower cost M1.2 Rules of the road for M1.3 A well-functioning M1.1 A glide path for moving participating in distributed dynamic and distributed from current provider management of resource location, directories to future resource architecture for learning if appropriate for the architecture

M1.1 A glide path for moving from current provider directories to future resource location techniques is developed via a public, transparent process, and widely disseminated.

M1.2 Rules of the road for participating in distributed management of resource location, if appropriate for the architecture and actors are established via a transparent process. This includes establishing policies and procedures for operation of resource location services, including curation of directory information to maintain data quality.

M1.3 A well-functioning dynamic and distributed architecture for learning health system resource location is in place supported by common national technical standards, and best practices for data quality maintenance and updates.

Health Care Directories and Resource Location M2. Calls to Action



2015-2017

- Provider directory operators should align existing directories to the extent possible
 with best available standards for provider directories as identified in ONC's most
 recent finalized Interoperability Standards Advisory or with emerging RESTful
 approaches if implementation timelines are not near-term.
- ONC's Federal Advisory Committees should assess the critical health care directory
 questions identified in the roadmap and how current standards and/or legacy
 services already incorporated into products, can be used or extended to support
 stakeholder needs.
- Through public, transparent processes, stakeholders should prioritize the
 participants and services that are to be discoverable using resource location and
 identify a near-term goal for the first small set of resources to be included in initial
 implementations, such as Direct addresses, electronic service information, web
 addresses, and multiple practice locations.
- CMS should, via various policies, require that Direct addresses and electronic service information are entered into and maintained in NPPES.

Health Care Directories and Resource Location M3. Commitments



2015-2017 ----

- As an interim step, ONC will work with health IT stakeholders to encourage uptake of current provider directory activities.
- CMS will continue to support efforts to ensure that health plan provider directories are made electronic and published according to best available national standards to support learning health system resource location.
- ONC and other certification bodies will determine how to support provider directories through certification processes.

FACA Discussion



Ubiquitous, Secure Network Infrastructure C1. Milestones



Enabling an interoperable, learning health system requires a stable, trusted, secure, widely available network capability that supports technology developer-neutral protocols and a wide variety of core services.

2015-2017 ---- 2018-2020

Send, receive, find and use priority data domains to improve health and health care quality

Expand interoperable health IT and users to improve health and lower cost

2021-2024

A learning health system enabled by nationwide interoperability

C1.1 100% of Technology developers should follow best practice guidance for "building security in" their health IT products and services. Security considerations should be incorporated at all phases of the software development lifecycle, including penetration testing. Health IT products and services should be deployed with secure defaults enabled, such as encryption, and easily patched when security issues are identified.

C1.2 The joint public-private
Cybersecurity Workgroup within
Health and Public Health (HPH)
continues to develop and release
general cybersecurity best
practices and guidance, such as
tailored NIST Cybersecurity
Framework, encryption, risk
management, monitoring and
security testing implementation
guides for varying levels of
audiences.

C1.3 As a result of the efforts from the joint public-private Cybersecurity Workgroup, 80% of large organizations in the HPH sector adopt the NIST Cybersecurity Framework or equivalent risk management framework that addresses common security risks and controls such as encryption, monitoring, and security testing.

Ubiquitous, Secure Network Infrastructure C2. Examples of Calls to Action Health IT.gov

2015-2017



- Organizations deploying health IT should ensure that it is deployed and maintained in a secure manner, including regular penetration testing and security risk assessments.
- Health care organizations should implement the NIST Cybersecurity
 Framework as part of their Risk Management and Incident Management programs
- Health care organizations should participate in an information sharing environment such as an Information Sharing and Analysis Organizations (ISAO) or Information Sharing and Analysis Center (ISAC) to share and retrieve threat information in an ongoing basis.

Ubiquitous, Secure Network Infrastructure C3. Examples of Commitments Health IT.gov

2015-2017



- ONC will identify best practices for implementing encryption policies for existing at rest and in transit encryption standards (e.g., NIST).
- HHS will continue to support, promote, and enhance the capability of a
 health and public health sector Information Sharing and Analysis Center
 (ISAO) for bi-directional information sharing about cyber threats and
 vulnerabilities between private health care industry and the federal
 government.
- ONC will work with NIST and OCR to finalize and publish the NIST Critical Infrastructure Cybersecurity Framework and HIPAA Security Rule Crosswalk.

Verifiable Identity & Authentication of All

Participants

D1. Milestones



Legal requirements and cultural norms dictate that users of systems—whether people or machines—be known so that access to data and services is appropriate.

This is a requirement for all participants in nationwide interoperability that supports a learning health system regardless of their role (e.g., individual, patient, provider and administrator).

2015-2017

Send, receive, find and use priority data domains to improve health and health care quality

2018-2020

Expand interoperable health IT and users to improve health and lower cost

2021-2024

A learning health system enabled by nationwide interoperability

D1.1 65% of health care organizations permit patient access to patient portals via username and password plus knowledge-based attributes or emerging technologies in lieu of passwords to reduce vulnerabilities in identity theft.

D1.2 At least 50% of health care organizations have implemented identity proofing and authentication best practices developed in D3.1.

D1.3 90% of health care registration systems support the creation of accounts for caregivers, proxies and personal representatives.

Verifiable Identity & Authentication of All Participants D2. Examples of Calls to Action Health IT.gov

2015-2017

- Technology developers should develop or adopt innovative solutions, such as mobile technologies and RESTful approaches, to provide efficient, effective paths for individual and provider identity authentication.
- Health care industry stakeholders should begin leveraging the Federal Identity, Credential, and Access Management (FICAM) Roadmap and Implementation Guide for identity management standards and best practices.
- NIST, OCR, CMS, CDC, FDA and other stakeholders should collaborate regarding approaches for identity management, including HIPAA guidance for remote identity, authentication and access management.

Verifiable Identity & Authentication of All Participants Health IT.gov

2015-2017

Send, receive, find and use priority data domains to improve health and health care quality

 ONC, in consultation with stakeholders, will establish and adopt best practices for provider and individual/consumer identity proofing and authentication, including specific levels of assurance and will consult with OCR to ensure they are consistent with the HIPAA Security Rule and best practices already adopted for other comparable industries.

Consistent Representation of Authorization to Access Electronic Health Information E1. Milestones



When coupled with identity verification, this allows consistent decisions to be made by systems about access to information.

2015-2017 ---- 2018-2020 ---- 2021-2024 Send, receive, find and use priority data domains to improve health and health care quality Expand interoperable health IT and users to improve health and lower cost A learning health system enabled by nationwide interoperability

E1.1 30% of health care organizations convey information on user attributes and authentication using agreed upon assertion technology, such as SAML, Organization for the Advancement of Structured Information Standards (OASIS), or other nationally recognized standards, when requesting electronic health information across organizational boundaries.

E1.2 90% or more of health care organizations convey information on user attributes and authentication using standard assertion technology.

E1.3 Large scale
adoption of
authentication and
authorization
technology by 100% of
healthcare
organizations to
increase and facilitate
access to data.

Consistent Representation of Authorization to Access

Electronic Health Information

E2. Examples of Calls to Action

2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- Health care organizations and other organizations with access to electronic IIHI
 should ensure that their access control rules and organizational policies are
 aligned to leverage permitted uses and disclosure under HIPAA to advance
 interoperable exchange of information and the learning health system.
- Health care organizations and other organizations with access to IIHI should ensure
 that their access controls enable individuals or third parties designated by
 individuals to electronically access and transport electronic health information
 about that individual where the individual directs, consistent with HIPAA's patient
 access rules.
- SDOs should work with technology developers to conduct pilots of standardsbased approaches, including RESTful approaches, for expressing and communicating authorization for electronic health information access/use.

Health IT.gov

Consistent Representation of Authorization to Access

Electronic Health Information

E3. Commitments

2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- ONC, in collaboration with stakeholders, will work to identify the technical standards and means by which a user's authority can be clearly represented among exchange partners.
- OCR will consider where additional guidance may be needed to help stakeholders understand how HIPAA Privacy and Security Rules apply in an environment where ACOs and other multi-stakeholder entities permeate the landscape in support of value-based purchasing.
- ONC will convene workshops or listening sessions on the types of electronic health information sharing that may be required, by role, to support value-based purchasing. A major goal of the workshops will be to evaluate how close the nation can come to achieving its interoperability goals through existing privacy rules.

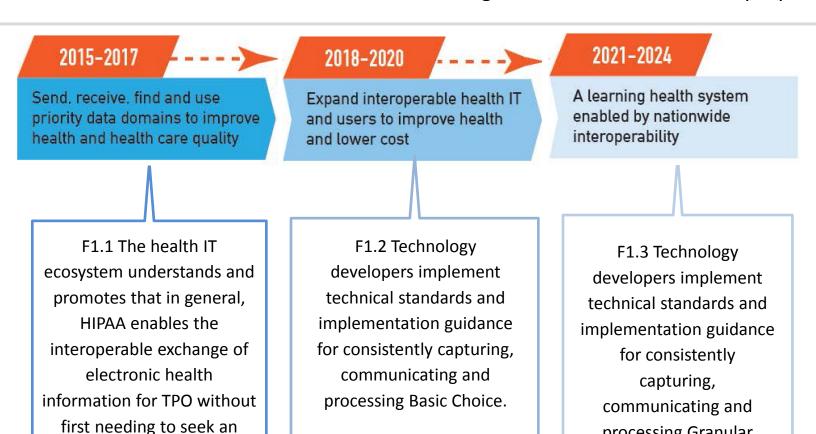
Health IT.go

Consistent Understanding and Technical Representation of Permission to Collect, Share and Use Identifiable Electronic Health Information F1. Milestones

individual's permission.



Though requirements differ across states, nationwide interoperability requires a consistent way to represent legal permission to collect, share and use individually identifiable electronic health information, including with whom and for what purposes.



processing Granular

Choice.

Consistent Understanding and Technical Representation of Permission to Collect,

Share and Use Identifiable Electronic Health Information

F2. Examples of Calls to Action

2015-2017

- A majority of states should conduct an assessment of their health privacy laws to determine alignment with permitted uses of electronic health information regulated by HIPAA.
- Professional Associations of health lawyers should educate their members about how the current HIPAA rules support interoperable exchange and patient access as important supports for national policy to improve health and build a learning health system.
- ONC, standards development organizations, technology developers and appropriate stakeholders should harmonize technical standards and implementation guidance for consistently capturing, communicating and processing Basic Choice across the ecosystem.

Consistent Understanding and Technical Representation of Permission to Collect,

Share and Use Identifiable Electronic Health Information

F3. Examples of Commitments

2015-2017

- ONC, in collaboration with states, national and local associations, and other federal agencies will launch a project to better understand the complexity of the rules environment, especially the diversity among more privacy restrictive state laws and their impact on computable privacy.
- ONC will identify a definition of "Basic Choice" and provide policy guidance regarding if/when Basic Choice should be offered, even when not required by law based on recommendations from the HITPC by the end of CY 2016.
- ONC will convene a group of industry stakeholders to determine if it is
 possible to create an open source mapping of the codes that capture
 clinical care to sensitive health conditions such as mental health. These
 mappings can serve as the foundation for common rules to be used by
 rules engines for determining what data may be shared based on
 individual permission.

Shared Decision-Making, Rules of Engagement and Accountability B1. Milestones



Nationwide interoperability across the diverse health IT ecosystem will require stakeholders to agree to and follow a common set of standards, services, policies and practices that facilitate the appropriate exchange and use of health information nationwide and do not limit competition.

Maintaining interoperability once established will also require ongoing coordination and collaborative decision-making about future change.

2015-2017

Send, receive, find and use priority data domains to improve

health and health care quality

2018-2020

Expand interoperable health IT and users to improve health and lower cost

2021-2024

A learning health system enabled by nationwide interoperability

B1.1 At least 50% of electronic health information sharing arrangements (as defined above), including health information service providers (HISPs), adhere to recommended policies and business practices such that electronic health information can be exchanged by participants across organizational boundaries.

B1.2 100% of electronic health information sharing arrangements (as defined above), including HISPs, adhere to recommended policies and business practices such that electronic health information can be exchanged by participants across organizational boundaries.

B1.3 Non-healthcare stakeholders, such as human services, community-based services, and researchers are included in electronic health information sharing arrangements in support of a learning health system.

Shared Decision-Making, Rules of Engagement and Accountability B2. Examples of Calls to Action



2015-2017

Send, receive, find and use priority data domains to improve health and health care quality

- Public and private sector health IT stakeholders should establish shared-decision making process to address operational issues related to standards, services, policies and practices that enable interoperability, including agreement on a nationwide learning health system technical architecture, and establishing clear, consistent feedback between SDOs and implementers about implementation successes and limitations, as well as supporting non-certification related testing of technical standards.
- Existing and future data sharing arrangements between organizations should align with ONC's policy guidance.
- The shared decision-making process should select standards for specific use cases/functions from ONC's most recent finalized Interoperability Standards Advisory (ISA) when the ISA contains relevant standards.

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Shared Decision-Making, Rules of Engagement and Accountability B3. Commitments



2015-2017



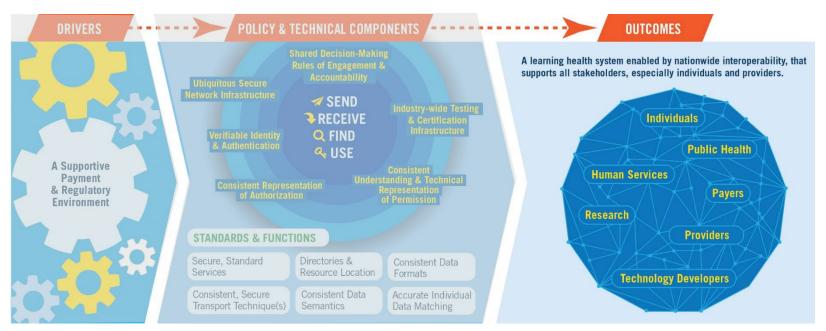
- ONC will publish an advisory that addresses policies and business practices that advance trust and interoperability.
- ONC will annually publish and update a list of the best available standards and implementation specifications for health IT interoperability purposes and to support priority learning health system functions (ONC's Interoperability Standards Advisory (ISA)). ONC will create this ISA list through an open and transparent process that facilitates competition between standards for selection.

FACA Discussion





Outcomes



Individuals N1. Milestones



Individuals have access to longitudinal electronic health information, can contribute to that information, and can direct it to any electronic location.

2015-2017 ---- 2018-2020 --

Send, receive, find and use priority data domains to improve health and health care quality

Expand interoperable health IT and users to improve health and lower cost

2021-2024

A learning health system enabled by nationwide interoperability

N1.1 A majority of individuals are able to securely access their electronic health information and direct it to the destination of their choice.

N1.2 Individuals regularly access and contribute to their longitudinal electronic health information via health IT, send and receive that information through a variety of emerging technologies, and use that information to manage their health and participate in shared-decision making with their care, support and service

teams

N1.3 Individuals are able to seamlessly integrate and compile longitudinal electronic health information across online tools, mobile platforms and devices to participate in shared decision-making with their care, support and service teams.

Individuals N2. Calls to Action



2015-2017



- Health IT purchasers and developers should include individuals and caregivers in the co-creation of digital, accessible health information tools that can securely exchange health information.
- Health care organizations and consumer groups alike should engage with patients to promote trust that individuals' health information (such as that generated/collected via home monitoring devices or other emerging technologies) is protected and secure when it is electronically shared.
- Consumer groups in collaboration with government agencies, associations and payers should develop and disseminate resources, such as the Blue Button campaign materials, to assist individuals with accessing and using their electronic health information.
- Individuals and providers should work together to define a reconciliation process for electronic health information from multiple data sources to ensure accuracy, completeness and a more comprehensive picture of a person.

Individuals N3. Commitments



2015-2017



- ONC will work with the health IT community to support the Blue Button Initiative to spur consumer demand for their health information and encourage testing and implementation of a portfolio of existing and emerging standards that support consistent methods for sharing health information with individuals.
- ONC will continue to work with the health IT community to remove barriers and support consumers' ability to access and electronically share their health information with whomever they trust.
- ONC will promote consistent, easy, and efficient methods for sharing health information with individuals by supporting existing and emerging standards for exchange, including APIs, and continuous iteration and development of those standards in partnership with the health IT community.

Providers O1. Milestones



Provider workflows and practices include consistent sharing and use of patient information from all available and relevant sources.

2021-2024 2015-2017 2018-2020 A learning health system Send, receive, find and use Expand interoperable health IT enabled by nationwide priority data domains to improve and users to improve health interoperability health and health care quality and lower cost **O1.3** Providers O1.1 Providers evolve care O1.2 Providers routinely routinely use relevant processes and information and proactively seek info from a variety of reconciliation to ensure outside information about sources, including essential health information individuals and can use it environmental, is sent, found and/or to coordinate care. occupational, genetic, received to support safe human service, and transitions in care. cutting edge research evidence to tailor care

to the individual.

Providers O2. Calls to Action



2015-2017



- Technology developers should develop technology platforms that allow providers and other users to perform certain key interoperability functions, such as standardized exchange, within their system with minimal effort and ease, using clear instructions provided by the technology developers and made publicly available.
- Providers and their staff should proactively offer individuals timely electronic access to their own health information and encourage them to access it.
- Providers should use the "Blue Button" and the Blue Button® and Download My Data® marks to indicate where consumers can go online to access their health information.
- Public and private stakeholders should incorporate interoperability into the training of new providers and continuing professional education.

Providers O3. Commitments



2015-2017

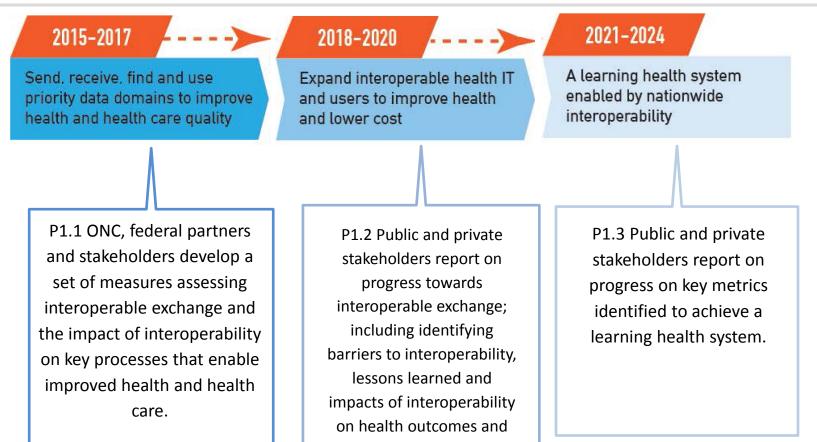


- ONC, federal agencies and the industry will identify additional best practices for the incorporation of patient-generated health data in health care delivery and research.
- ONC will develop a Health IT Playbook consisting of tools and resources designed to assist providers working towards the adoption and optimization of health IT, including key interoperability workflow considerations, and engaging consumers to access and use their electronic health information.

Tracking Progress and Measuring Success P1. Milestones



Measuring nationwide interoperability directly informs our national progress toward achieving better care, smarter spending and healthier people and ultimately a learning health system.



costs.

Tracking Progress and Measuring Success P2. Calls to Action



2015-2017



Send, receive, find and use priority data domains to improve health and health care quality

- Industry and health care organizations that enable exchange (e.g. HISPS, HIOs) should provide
 input on how to address measurement needs including identifying ways to address
 measurement gaps using data generated by systems and infrastructure that enables
 interoperable exchange.
- The behavioral health community should work with ONC and federal partners such as SAMHSA to determine the community's health IT needs and ways to measure interoperable exchange among their providers.
- The LTPAC community should work with ONC and federal partners such as CMS to determine the community's health IT needs and ways to measure interoperable exchange among their providers.
- Stakeholders, federal partners, and ONC should work together to identify measures related to individuals and determine ways to address measurement gaps (i.e., consumer engagement in measurement, use of patient-generated health data).
- Stakeholders across the broader ecosystem (i.e., non-health settings) should work with ONC and federal partners to identify measures and potential data sources across their respective communities.

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Tracking Progress and Measuring Success P3. Commitments



2015-2017



- ONC will analyze and report on nationwide progress, including a report to Congress on proposed measures mandated under MACRA.
- ONC will work with federal partners and stakeholders to address measurement gaps, and identify future measures resulting in the development of a long-term measurement framework. This includes consulting with external stakeholders to develop proposed measures as mandated under MACRA.

FACA Discussion



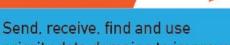


Appendix

Supportive Payment & Regulatory Environment A2. Additional Calls to Action



2015-2017



priority data domains to improve health and health care quality

- All states should consider having operational plans for supporting interoperability in their health-related strategic plans.
- States should propose and/or implement strategies to leverage Medicaid financial support for interoperability.
- Roughly half of states should use their state-level authorities to advance interoperability beyond their current efforts.
- ONC should work with CMS to evaluate the use of health IT by providers participating in advanced payment models.

Shared Decision-Making, Rules of Engagement and Accountability B2. Additional Calls to Action



2015-2017



- Participants in the shared decision making process should agree on a nationwide technical architecture for an interoperable learning health system.
- Federal agencies that provide or pay for health services should align their policies for interoperability with ONC's policy guidance.
- ONC, in collaboration with stakeholders, should define a policy framework for exchange of patient-generated health data and pilot it.
- Participants in the shared decision making process should prioritize use cases based on a balance of national priorities and local needs.
- Participants in the shared decision-making process should work with ONC to establish metrics for monitoring and assessing nationwide interoperability and methods for data collection.
- Health IT developers, certification programs and governing bodies should look first to ONC's most recent finalized Interoperability Standards Advisory when making decisions about the standards they will use to enable specific interoperability functions and use cases.

Ubiquitous, Secure Network Infrastructure C2. Additional Calls to Action Health IT.gov

2015-2017



- Technology developers should follow Department of Homeland Security (DHS) and NIST guidance for "building security in" their health IT products and services.
 Security considerations should be incorporated at all phases of the software development lifecycle, including penetration testing.
- Health care providers, business associates, technology developers, and other
 industry stakeholders should begin adopting existing encryption standards to
 ensure that all electronic IIHI is encrypted "at rest" and "in transit," taking
 advantage of the most robust commercially available algorithms such as AES-256
 as identified by NIST. Encryption solutions should be able to be upgraded to
 address emerging standards without requiring a complete replacement of existing
 hardware.

Ubiquitous, Secure Network Infrastructure C3. Additional Commitments Health IT.gov

2015-2017



- ONC will work with payers to explore the availability of private sector financial incentives to increase the rate of encrypting, starting with discussions with casualty insurance carriers who offer cybersecurity insurance.
- ONC will coordinate with the Office of the Assistant Secretary for Preparedness and Response (ASPR) on priority issues related to cybersecurity for critical public health infrastructure.

Verifiable Identity & Authentication of All Participants D2. Additional Calls to Action Health IT.gov

2015-2017



- Health care organizations should work with identity SDOs (e.g., Safebiopharma, Kantara, OpenID foundation, OAuth2) to ensure health care use cases are addressed in identity management frameworks.
- The Federal Health Architecture (FHA) and participating federal agencies should adopt ONC recommended best practices on authentication.



2015-2017



- Federal and state governments, in coordination with organizational health information privacy policymakers, should conduct outreach and disseminate educational materials about Permitted Uses and Disclosure, and Individual Access to health information.
- Technology developers should begin implementing harmonized standards that document and communicate an individual's Basic Choice.

Consistent Understanding and Technical Representation of Permission to Collect,

Share and Use Identifiable Electronic Health Information

F3. Additional Commitments

2015-2017



- ONC will analyze and provide guidance on the consequences of offering Basic Choice on an Opt in vs. Opt out basis.
- ONC will monitor other consent management work such as: the Social Security Administration's (SSA) written permission to share data across states for disability determinations, and FTC's implementation of simple consumer preferences (akin to "basic choice") through the FTC's "Do Not Call" Registry to determine lessons applicable to Basic Choice for electronic health information sharing.
- Federal government (e.g., Office for Civil Rights (OCR) and Substance Abuse and Mental Health Services Administration (SAMHSA)), will consider where additional guidance in the form of education and outreach may be needed to help stakeholders understand a) the applicability of federal regulations regarding the confidentiality of substance use information, and b) how the HIPAA Privacy Rule permits health information to be exchanged (use and disclosure) for TPO without permission.
- OCR, in collaboration with ONC, will work to address barriers that prevent patients from accessing their health data. OCR will develop additional guidance materials to educate the public and health care providers about a patient's right to access his or her electronic health information under HIPAA.
- Federal and state governments, in coordination with organizational health information privacy policymakers, will conduct outreach and disseminate educational materials about Permitted Uses and Disclosure, and of Individual Access to health information.

Consistent Data Semantics H2. Additional Calls to Action



2015-2017 /---

- Public and private stakeholders should work with SDOs to define a standard approach to federated distribution of centrally maintained code sets, including ongoing support for publicly available, API-enabled repositories like the Value Set Authority Center (VSAC).
- SDOs should advance and accelerate semantic standards for laboratory orders, other orders and other priorities for a learning health system that require updated or new semantic standards
- SDOs should advance consumer-friendly terminologies and mappings of accepted synonyms to coded terms.
- Research and clinical trial communities should pilot the use of priority data elements associated with priority data domains for clinical research and precision medicine.
- CDC should encourage development of training aids to help laboratories use LOINC for laboratory test ordering and reporting in a structured format that includes data elements necessary to meet CLIA requirements.

Consistent Data Formats 12. Additional Calls to Action



2015-2017



- States and other stakeholders across the ecosystem should further explore and determine the role that NIEM can serve in supporting health information interoperability across domains such as human services and justice.
- Technology developers and providers should use best practices and standardized methods for exchanging unstructured health information, such as physician notes, in an interoperable manner.
- SDOs and ONC should identify necessary updates to format standards (HL7 v2, C-CDA, QRDA, FHIR and NCPDP) to ensure priority data domains are not only required in those standards, but are also represented consistently across format standards.
- ONC, NIST, CMS, CDC and FDA should collaborate to advance laboratory data interoperability, including specifications to ensure compliance with CLIA, state and local quality laboratory regulations.

king Progress and Measuring Success Additional Calls to Action



2015-2017

- The behavioral health community should work with ONC and federal partners such as SAMHSA to determine the community's health IT needs and ways to measure interoperable exchange among their providers.
- The LTPAC community should work with ONC and federal partners such as CMS to determine the community's health IT needs and ways to measure interoperable exchange among their providers.
- Stakeholders, federal partners, and ONC should work together to identify measures related to individuals and determine ways to address measurement gaps (i.e., consumer engagement in measurement, use of patient-generated health data).

Statements of Support



Federal Partners



- "As the Interoperability roadmap makes clear, a patient's information must follow them wherever they choose to get care and any efforts to block that from happening are unacceptable. CMS believes that data and information are as important an ingredient as paying for value in keeping people healthy."
- "ONC's interoperability Roadmap will help guide our progress toward seamless integration of electronic health record data," said Mr. Christopher Miller, program executive officer for Defense Healthcare Management Systems within the Department of Defense. "We are proud to be working closely with ONC and other public and private partners to ensure that our health care providers have a complete picture of health information from all sources. The availability of this information increases the medical readiness of our operational forces and enables delivery of the highest quality care that our service members, veterans and their families deserve. We look forward to our continued partnership with ONC as we expand the safe and secure exchange of standardized healthcare data to improve the overall health of our nation."

Federal Partners, continued



- "The Roadmap is a critical tool for improving the health care delivery system through the safe and secure use of health information technology," said Jim Macrae, Acting Administrator for the Health Resources and Services Administration. "The opportunities for coordination and collaboration provided by the Roadmap will help our programs deliver better quality care for the populations they serve."
- "As part of the Precision Medicine Initiative, the National Institutes of Health plans to build a national research cohort of 1 million or more Americans to expand our knowledge and practice of precision medicine," said NIH Director Francis S. Collins, M.D., Ph.D. "Accurate data will both enable and define the scientific possibilities for the Precision Medicine Initiative. ONC's interoperability Roadmap will be essential for standardizing data acquisition, technologies and policies to ensure data arising from healthcare delivery can support both discovery science and healthcare improvement."

Federal Partners, continued



- "Health plans contracted with OPM's Federal Employees Health Benefits (FEHB) program cover health services for more than 8.2 million Federal employees, retirees and their family members in every county in the country and overseas. The exchange of health data through safe and secure channels using common standards and protocols will lead to better care for our enrollees and a more efficient health system overall. OPM appreciates the leadership of the HHS Office of the National Coordinator on this issue and commits to working with our 97 contracted health insurance carriers to incorporate these standards and data sharing protocol in their information systems."
- "Veterans live and work in every health care delivery market in this country. Approximately six out of 10 Veterans receive some portion of their health care from private sector providers. As such, Veterans represent one of the nation's strongest business cases for interoperability. The Office of the National Coordinator for Health Information Technology (ONC) Interoperability Roadmap represents a multi-stakeholder effort to converge on foundational goals and strategies to achieve interoperability. VA is fully supportive of this national approach to address policies, foster technological advancement and expand health information exchange. The roadmap framework supports VA's goal to achieve Veterancentric care by making information available, coordinating patient goals and care plans across the continuum and using holistic data to drive care management, decision support and analytics. VA looks forward to continuing to working closely with ONC, as well as our federal and private sector partners to further health information exchange in our nation."

Private Sector



- AHIMA
- athenahealth
- Cerner
- CHIME
- Commonwell Health Alliance
- Electronic Health Record Association (EHRA)

- eHealth Initiative
- Federation of American Hospitals
- Health IT Now Coalition
- HIMSS
- McKesson
- National Partnership for Women & Families