

Interoperability FAQs August 2016

1. **What is interoperability?**

A person-centered, interoperable health IT ecosystem makes the right electronic health information available to the right people, at the right time, across software systems and organizations, in a way that can be relied upon and meaningfully used by recipients – i.e., clinicians taking care of patients.

The Office of the National Coordinator for Health IT (ONC) bases its definition of interoperability on the IEEE definition: *“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.”*¹

- The [ONC Interoperability Roadmap](#) also adds, *“All individuals, their families and their health care providers have appropriate access to electronic health information that facilitates informed decision-making, supports coordinated health management, allows individuals and caregivers to be active partners and participants in their health and care and improves the overall health of the nation’s population.”*

2. **Who are the key stakeholders engaged in achieving and who will benefit from widespread interoperability?**

Examples include:

- Providers
- Patients and their families and caregivers
- Device manufacturers
- Standards developers
- EHR/health IT developers
- Health information exchange (HIE) organizations
- Congress
- ONC, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA)
- State governments
- Payers

3. **What are key use cases for interoperability?**

The primary objective of interoperability is to provide access to providers and patients (and those they authorize) to all the relevant data at the right time, to the right user, in order to minimize duplicate data collection, reduce unnecessary tests, and ensure consistent information to improve the quality and efficiency of patient care. We should always ask, “Interoperability for what purpose?” Examples include:

- Enhancing clinical decision making
- Coordinating care across providers, particularly important for chronically ill patients
- Ordering diagnostic services and share prior laboratory and imaging results
- Enabling a learning healthcare system
- Improving public health reporting
- Enhancing clinical trial reporting and other clinical research
- Improving quality reporting required for a variety of state and federal programs

¹ <http://www.healthit.gov/policy-researchers-implementers/interoperability>

- Streamlining reimbursement and support new payment models (e.g., accountable care organizations (ACOs) and alternative payment models (APMs))
- Providing patient access to or input of data

4. *Where has interoperability been successful and what are the metrics?*

Generally, there are several areas where the progress toward broad interoperability has been very successful, including ePrescribing; the exchange of lab orders and results; nationwide access to patient summaries via various regional and national standards-based exchange initiatives; and, the increase in utilization of [Direct protocols](#) to send standardized clinical summaries and other [information](#). These are examples of successful interoperability initiatives where challenges related to financial sustainability, governance, privacy and security, standards, and the integration of different technologies have been largely resolved. Overall progress is significant as illustrated by [data from ONC](#). For further illustration on the contributions of interoperability the EHRA developed an [Interoperability in Healthcare Fact Sheet](#).

5. *Are there key statistics on the status of interoperability?*

The [eHealth Exchange](#), a rapidly growing network of exchange partners who securely share clinical information over the Internet across the US, using a standardized approach, reports connectivity spanning all 50 states, including:

- Four federal agencies (DoD, VA, CMS, SSA)
- Nearly 50% of all US hospitals
- 26,000 medical groups
- More than 3,400 dialysis centers
- Serving more than 100 million patients

Based on [data from ONC](#), the percentage of non-federal acute care hospitals that are exchanging clinical information outside their organizations increased from less than 50% in 2009 to 75% in 2014. While this does not specifically assess the ambulatory environment, one can assume that many of those participating in data exchange are included in this analysis. Other national cross-provider, cross-vendor initiatives such as [Direct Connect](#), [Carequality](#), and [Commonwell](#), are gaining traction as well.

6. *What are the important core characteristics of interoperability available now?*

Interoperability can be categorized in a number of different ways based on use cases, as well as by categories of data exchange, including:

- Push vs. pull – The party or system initiating data exchange either sends data to a targeted recipient (push) or asks another party to supply certain data (pull or query).
- Synchronous vs. asynchronous – Data exchange requires either tight coupling between systems to enable immediate response (synchronous), or the communication can be performed with delayed responses (asynchronous), depending on the time sensitivity of the use case.
- Message vs. document vs. service vs. context – This categorization represents a mix of how the data is organized and managed as part of the data exchange. It is important to note that there is sometimes overlap in the use cases, so data may be available and used for different purposes.

It is also important to distinguish between intra-organizational interoperability and inter-organizational interoperability, regardless of whether systems are provided by the same health IT developer or several health IT developers. Technical and governance issues are more easily resolved within a single organization (even with multiple facilities and types of care delivery) than they are when unaffiliated organizations are participating in Health Information Exchange (HIE).

7. What is the role of standards in achieving widespread interoperability?

Standards and standards development organizations (SDOs) such as [HL7](#), [ASTM](#), and others (including standards profiling organizations, such as [IHE](#)) are key to achieving our shared interoperability goals. There are a number of standards in place:

- Terminology standards include [SNOMED](#), [LOINC](#), and [RxNorm](#) for diagnoses, diagnostic tests, medications, etc.
- The dominant imaging standard is [DICOM](#) to exchange images.
- Content standards include [HL7 V2](#), [HL7 CDA®](#) and [C-CDA®](#), [HL7 FHIR®](#), [ASC X12](#), and [QRDA](#) to communicate lab orders/results, exchange documents, deploy emerging APIs, submit claims, and report on quality measures.
- Standards for data transport include [Direct](#), [IHE XDR/XDS/XCA](#), and [RESTful Services](#) to establish the basic “plumbing” to exchange data securely with providers directly, through an HIE organization, or in emerging service-oriented architectures.

The ONC [Interoperability Roadmap](#) and [2016 Interoperability Standards Advisory](#) provide a useful discussion and recommendations for the development and deployment of such standards as they move from initial pilot implementations to widespread adoption.

Standards are a necessary foundation, but their successful deployment and adoption requires a supportive ecosystem with timely implementation guides, testing tools, and piloting in clinical practice.

8. How do we measure interoperability maturity?

Key components of measuring interoperability maturity relate to:

- Availability of standards and implementation guides that allow for near “cookie cutter,” consistent, repeatable implementation of interoperability across stakeholders (e.g., connecting a provider to multiple laboratories, exchanging documents across providers).
- The number of connections and exchange volumes.
- The actual use of the data by the recipient/requester.

Insight into this information can help focus decision-making on whether further maturation of standards and guidance is appropriate or whether the standards and guidance is ready for widespread adoption through a variety of incentives.

9. How widely does the standard need to be deployed before it can be considered mature?

It is important that the standard has been widely used for its intended purpose with minimal variations in interpretation and implementation. While there is debate about when a standard is mature enough to drive wide adoption through regulation, experience to date has shown that adoption of new and rapidly evolving (i.e., immature) standards creates unnecessary effort and add

cost for stakeholders. On the other hand, waiting for “perfect” standards would delay realizing the value and benefits enabled by interoperability.

10. What are the roles of different types of interoperability testing?

There are a number of different types of testing that apply to interoperability:

- Pre-release testing to ensure that individual components operate as intended, including regression testing as specifications are upgraded, and formative usability testing.
- End-to-end interoperability testing to ensure that all relevant components of interoperability are available and work as intended, involving not only technologies, but also processes.
- Pilot testing through actual deployment to ensure that all use cases work in the operational environment, including user acceptance testing.
- Performance testing to ensure that the solutions can support the expected volumes in operational use.

11. Is certification needed to advance interoperability?

It is doubtful whether additional certification requirements beyond rigorous testing would increase electronic health record (EHR) interoperability. However, more robust and complete testing tools would streamline consistent standards adoption across the industry. Alternatives to the current certification process should allow vendors to provide test reports from robust testing tools as attestation. Over time, the goal should be greater dependence on the availability of internal testing and validation documentation by the EHR vendor rather than reliance on attestation or certification testing.

12. What is the importance of patient consent models for interoperability?

Patient consent to make protected health information (PHI) available to other healthcare providers and organizations is a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and every healthcare organization is responsible for obtaining such consent. There are currently a number of initiatives that seek to reinforce and extend HIPAA requirements. EHRA recommends that the sponsors of these initiatives review the original HIPAA tenets relative to emerging interoperability objectives to ensure that any expansion of these requirements is warranted.

13. Do we need a national framework to guide interoperability?

A national framework to provide guidance on common issues like governance and the use of standards could support more rapid progress toward our shared interoperability goals. However, any government oversight in this area should focus on areas where the private sector cannot be effective (e.g., the endorsement of core nationwide standards for immunization reporting) and should not hinder innovation. To be clear, we are not referencing a technical framework or architecture; but, rather, we suggest that federal policy and regulations help establish and maintain a minimum agreed set of interoperability capabilities that all can support, without limiting the industry to only use these capabilities to achieve the more important objectives of improving care coordination while maintaining a secure environment that protects patients’ data and privacy.

14. What are the key drivers that would help providers and their health IT vendors achieve interoperability?

The primary drivers for inter-organizational interoperability are new care delivery models and payment reforms that focus on improved outcomes (e.g., ACOs and APMs). Until these programs are more broadly in place, provider organizations will be challenged to focus their resources on broader interoperability as they work to meet increasing government regulatory program requirements.

15. How has the EHR Incentive Program (meaningful use) impacted interoperability?

Stages 1 and 2 established the foundation for widespread interoperability, incenting high levels of EHR adoption (~80%), and defining standards for content, vocabulary, transport, and requirements for data exchange.

Stage 3 expands on aspects of interoperability with significant advancements in the 2015 Certification Edition starting to be deployed in 2017:

- Introduction of API support to provide dynamic patient engagement.
- Expansion of ePrescribing transactions.
- Updates to various standards and implementation guides (e.g., C-CDA 2.1, various vocabularies).
- Expansion of the Common Clinical Data Set (CCDS).

We anticipate that the emerging [Merit-Based Incentive Payment System \(MIPS\)](#) and [Advanced Alternative Payment Model \(APM\) programs under the Medicare Access and CHIP Reauthorization Act of 2015 \(MACRA\)](#) and other payment reform initiatives will further establish incentives that will drive the need for expanded interoperability.

16. Who will pay for the needed infrastructure for interoperability?

Cross-organizational interoperability will only be achieved when there are clear business drivers – i.e., financial incentives and operational value. Currently, the burden to fund interoperability is primarily on providers with little or no return on investment or a strong business case to support investment. With a business case to support interoperability, providers will have a more likely return on investment for purchasing and implementing tools and services that support interoperability. Where the primary benefit is to public health, steps must be taken to standardize nationally so that costs can be minimized and consideration should be given to state or federal support.

17. How can interoperability further patient engagement?

Enabling EHRs with open, standard APIs that can connect with a variety of patient-focused apps, as well as patient portals and Personal health records (PHRs), which are provided by both healthcare providers and payers, and offer the opportunity to engage patients in managing their health by presenting information from EHRs in an understandable and actionable format through applications of their choice. With the proliferation of personal health monitoring devices, there is much discussion of if and how to incorporate data from these devices into EHRs and other health IT. Care must be taken, however, to not overwhelm physicians with data that does not contribute to their care of the patient.

18. What information does a physician need via a transition of care summary (e.g., the Consolidated Clinical Document Architecture, C-CDA) when a patient is transferred?

The following data is most frequently of interest as part of a transition of care (TOC), with an opportunity to query for more information as needed:

- Problems (past and current)
- Medications (past and current)
- Allergies
- Immunizations
- Past procedures
- Transition notes
- Plan of care

Enabling initiating providers to include in a document what they believe is relevant for the next provider, no more and no less, is important to ease the creation and transmission of TOC documentation, while at the same time, the receiving provider is not overwhelmed with the documentation (currently a “given,” considering the data that is required to be included by regulation).