

Interoperability FAQs July 2015

The EHR Association (EHRA) has long been committed to health IT interoperability in support of thousands of provider organizations using our technologies to exchange information and participate in a wide variety of delivery system reform initiatives. These working partnerships with our clients and the tremendous work conducted to certify our products for the EHR Incentive Program has furthered our expertise in developing interoperable products and services.

Given the ongoing conversation about the role of health IT in successfully moving healthcare to an outcomes-driven model, the following frequently asked questions (FAQs) and responses regarding interoperability have been developed by the EHRA to contribute to ongoing discussions of this critical topic and to establish an understanding of healthcare interoperability. These FAQs reflect the commitment of the Association and its members to effective interoperability, drawing on lessons learned from our support of the majority of hospitals and ambulatory provider organizations that are exchanging information and participating in data exchange initiatives, as well as our leadership and experience in many interoperability and standards initiatives.

1. What is interoperability?

Consistent with ONC's perspective, we believe a health IT ecosystem must be person-centered to ensure the right electronic health information is 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 clinicians taking care of patients and patients seeking access to their own information.

Interoperability across such an ecosystem is essential to achieve these goals. In its *Connecting Health and Care for the Nation: A 10 Year Vision to Achieve An Interoperable Health IT Infrastructure*, the Office of the National Coordinator for Health IT (ONC) based its definition on the following 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

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

- Providers
- Patients managing their health and wellness, as well as their caregivers
- Payers
- EHR/health IT developers
- Device manufacturers with devices that connect to health IT
- Standards developers
- The Department of Health and Human Services, including ONC and the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA)
- State governments
- Congress

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

The shared sense of urgency about the need to increase the volume and types of data being exchanged is growing, especially with the critical efforts underway to reform the healthcare delivery and payment systems in this country.

3. What are key use cases for interoperability?

A “use case” is a term that describes an actual scenario that contains a list of steps to achieve a goal, including interactions between “actors” (people and systems) that require interoperability support. There are a number of priority use cases for interoperability; each will have both similarities and differences from the others in applicable standards, technologies, and policies.

Interoperability enables access to all the relevant data at the right time to the right user when data is captured in different systems and organizations. Such access helps minimize duplicate data collection, reduce unnecessary tests, and ensure consistent information to improve the quality and efficiency of patient care. However, it is important to drill down to the use case in designing interoperability solutions and policies. We should always ask, “Interoperability for what purpose?”

Examples of priority use cases include:

- Clinical decision support using externally defined guidelines.
- Longitudinal patient-centric record across providers and care coordination across providers, particularly important for chronically ill patients.
- Enabling a learning healthcare system through sharing healthcare system performance data.
- Improving public health reporting.
- Enhancing clinical trial reporting and research.
- Improving quality reporting, required for a variety of state and federal programs.
- Streamlining reimbursement and supporting new payment models (e.g., accountable care organizations (ACOs)).
- Documenting patient generated data using a patient’s personal health records.

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

Interoperability can be achieved using a variety of techniques. From a user perspective, the most notable characteristics can be summarized as follows:

- The user can receive the data without having asked for it (*push*) or can ask/query for specific information (*pull*).
- The information can be exchanged immediately to support urgent/immediate data requirements (synchronous, such as insurance eligibility requests), or may take more time for later use (asynchronous, such as communication for a referral a few weeks from now).
- The data is either in a human readable, summary format (document), or it is sent as a collection of raw data sufficient for the IT systems to manage workflow and processes (messaging or services).

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. An example of intra-organizational interoperability is the placing of lab orders within a hospital to the hospital’s laboratory, while inter-organizational interoperability would be the request for a referral between two independent providers. Both are

very important, with intra-organizational interoperability widely deployed and inter-organizational interoperability growing in use. 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).

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

Standards and standards development organizations (SDOs) such as HL7, ASTM, and others (including standards profilers such as IHE) are key to achieving our shared interoperability goals. Most SDOs are designated and operate under the rules of ANSI (American National Standards Institute) and/or (given the importance of global standards) ISO (International Organization for Standardization). There are a number of healthcare IT standards in place:

- Terminology standards allow concepts to be expressed in a common language. For example, assigning codes to particular medications so that they can be consistently referenced and understood across systems. Terminology standards in common use include SNOMED (conditions), LOINC (results), DICOM (imaging), and RxNorm (medications).
- Content standards package information for consistent consumption so that the information is machine readable. Common standards include HL7 V2, CCD, QRDA, FHIR, X12 5010, and NCPDP Script.
- Standards for data transport include Direct, IHE XDR/XDS/XCA, and RESTful services.

The ONC Interoperability Roadmap and Standards Advisory, as referenced above, provides a useful discussion on the current state of and recommendations for the development and deployment of such standards. However, before mandating these and other standards through national certification programs, it is important that each standard has been used in practical settings, has clear and unambiguous implementation guidance that yields consistent implementations, and has robust testing tools. Standards that have only been published by SDOs are not suitable candidates for national endorsement for these reasons.

6. *How do we assess interoperability maturity?*

Assessing the maturity of an interoperability standard should consider the extent to which such data exchange is used (i.e., the number of implementations), the availability of a version of the standard that allows for consistent implementations, and the availability of robust testing tools (a common measurement for adherence to the standard). Although there is debate on what is sufficient for each of these measures to mandate adoption of interoperability requirements and supporting standards, experience to date has shown that mandated adoption of very new or rapidly evolving (i.e., immature) standards creates unnecessary effort and adds cost for stakeholders. It is important that a standard has been widely used for its intended purpose with minimal variations in interpretation and implementation. That said, waiting for “perfect” standards would delay realizing the value and benefits enabled by interoperability, so the right balance of speed and maturity is important, with maturity most important when regulation is the driver for use.

7. *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” (i.e., while a feature is being developed and refined) usability testing.

- End-to-end interoperability testing to ensure that all relevant components of interoperability are available and work as intended, involving not only technology, 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.

8. *Is certification needed to advance interoperability?*

It is unclear whether more or improved certification requirements would increase EHR interoperability. However, it is clear that more consistent and robust testing tools would streamline standards adoption across the industry.

9. *What are the alternatives to the current ONC certification approach?*

If certification is more limited in scope through a more focused definition of certified EHR technology (CEHRT) and targeted to assure interoperability, an alternative to the current certification process should allow developers to provide test reports from robust testing tools as part of attestation. In any event, over time, the goal should become greater dependence on the availability of internal testing and validation documentation by the EHR developer rather than reliance on external attestation or certification testing.

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

Generally, there are several areas where the progress toward broad interoperability has been widely successful, including ePrescribing, exchange of lab orders and results, the increase in utilization of Direct protocols (i.e., *push*) to exchange information between providers of all sizes (see below), and long-standing and growing use of standards-based query models using IHE profiles like XCA and XDS, especially between exchange networks and large healthcare organizations. 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.

There are a number of metrics and proof statements that provide encouraging news regarding progress toward broad interoperability:

- 58% of hospitals exchanged data with providers outside their organization in 2012, a 41% increase since 2008 (HL7's "The State of Health Information Exchange", <http://www.hl7standards.com/blog/2014/02/25/the-state-of-health-information-exchange/>)
- The percentage of primary care physicians able to submit electronic immunization data to local public health agencies increased from 52% in 2011 to 68% in 2013 (Health IT Dashboard, <http://dashboard.healthit.gov/quickstats/pages/FIG-Percent-Medicare-Eligible-Primary-Care-Physicians-Selecting-Immunization-Measure.php>)
- The percentage of nongovernment hospitals that electronically exchanged lab test results, radiology reports, care summaries, or medication lists with other hospitals or other providers outside their organizations rose from 41% in 2008 to 62% in 2013 (HITPC presentation, August 2014, www.healthit.gov/FACAS/sites/faca/files/HITPC_InteroperabilityUpdate_2014-08-06.pdf)
- 73% of office-based physicians used ePrescribing in 2013, up from 58% in 2011. (<http://surescripts.com/news-center/national-progress-report-2013#use>)

11. What is the impact of patient consent on 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 for obtaining patient consent to enable interoperability among providers. Further, differences in consent requirements across state lines can be a very real barrier to exchange that can cause delays at a minimum or abandonment of data exchange efforts in the worst case.

12. 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 would 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 accomplish key national goals on its own (e.g., the selection of nationwide standards for immunization reporting), and such oversight must be designed and implemented in ways that do not hinder innovation. To be clear, we are not referencing a technical framework or architecture, but rather policy at the federal level that will support private sector response to market demand. Technical architectures will evolve to support the requirements and should not be hampered by prescriptive regulations that do not anticipate future capabilities.

13. What are the key drivers and potential barriers for interoperability beyond EHR and health IT vendors?

The primary drivers for interoperability across healthcare organizations are new care delivery models and payment reforms that focus on improved outcomes (e.g., ACOs), and the primary barrier is the absence of such drivers and related aligned incentives. 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.

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

Stages 1 and 2 established the foundation for widespread interoperability, helping to drive the US rapidly to very high levels of EHR adoption (~80%), successfully defining or “recognizing” standards for content, vocabulary, transport, and also specifying requirements for data exchange in many instances. Further, these stages triggered an increased interest in data exchange – between providers, with public health entities, and to patients – which we continue to see developing today. Stage 3 could be a positive step forward if it focus on interoperability, building on and expanding from Stage 2, especially for query (or *pull*) models, while encouraging emerging standards (e.g., HL7 FHIR).

15. What is the appropriate intersection between private and public sector efforts post-MU2 to proliferate interoperability?

Successful interoperability requires the participation of many stakeholders. The first critical component is to use a core set of standards that support common use cases to which everybody adheres, while leaving opportunities for new ways to interoperate and the exploration of new technologies. Additionally, the public sector can play a critical role in encouraging information exchange by continuing to expand the payment and delivery models that reward the desired behavior.

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. We believe that it will ultimately be found that public infrastructure for information exchange must be supported by public entities, similar to other (e.g., electrical, highway) infrastructures in this country.

17. Some argue that industry participants should not compete on access to individually identifiable patient data. What is the role of EHR developers in this argument?

EHR developers design features to support secure access to patient data for authorized users and to provide tools to allow providers to configure access and grant authority in keeping with their organizational policies and legal/regulatory requirements.

18. How can interoperability further patient engagement?

Broadly, patient access to their health data, whatever the source of that data, can enhance patient engagement. Specifically, EHRs are increasingly able to be accessed by patients and their families, using standards and technologies (e.g., patient portals, application programming interface (API) access to applications, etc.) that are part of certified EHRs and that also go beyond these requirements, who in turn can also contribute information to the EHR. With the proliferation of personal health monitoring devices, there is much discussion of how best to incorporate data from these devices into EHRs and other health IT. Overall, there are many tools already made available to the market to help address this goal, but we expect that more attention will need to be paid to patient participation, while also continuing standards development for the increased points of data that will be coming from patients and their caregivers.

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

We have heard repeatedly from our clients that they do not want to be overwhelmed with more information than they need. The following data is most frequently of interest as part of a transition of care (TOC), with an opportunity to query for more additional information as needed.

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

20. What did the 2014 Edition of ONC certification bring in terms of advancing interoperability?

A significant advancement of the 2014 Edition was the adoption of new standards-based electronic exchange as a part of clinician workflow, as well as greater patient engagement through new capabilities.