

A black and white photograph of a road surface, viewed from a high angle. The road is dark asphalt with white painted lane markings. In the foreground, there are two large white arrows pointing forward, one on the left and one on the right, separated by a vertical dashed line. Above the arrows, there are solid white lines marking the edges of the lanes. The text "Interoperability Testing" is overlaid in green on the upper left portion of the image.

Interoperability Testing

Where the Rubber Hits the Road

INTRODUCTION | This white paper is published by the Certification Commission for Health Information Technology (CCHIT®) in collaboration with the EHR/HIE Interoperability Workgroup, a New York eHealth Collaborative (NYeC)-led consortium of states and vendors; and Healthway, the public-private partnership that operates the eHealth Exchange (formerly referred to as the Nationwide Health Information Network Exchange), a network of public and private organizations representing hundreds of hospitals, thousands of providers and millions of patients across the country.

In October 2012, the Interoperability Workgroup and Healthway announced a program to test and certify electronic health records, other health IT and health information exchange participants to enable reliable transfer of data within and across organizational and state boundaries. The coalition selected CCHIT to carry out the testing and certification program.

As the coalition readies the program for launch, we offer this analysis of the current efforts to promote interoperability at the federal, state and local levels.

We invite you to direct any comments, requests or questions to HIE Everywhere™ at hiecertified.cchit.org



EXECUTIVE SUMMARY

Despite the government's sustained efforts to increase interoperability among health IT systems, critical information is still not being routinely shared in transitions of care, officials of the Office of the National Coordinator for Health IT (ONC) acknowledged in a 2012 Health Affairs article.¹ For example, only 19% of hospitals reported in 2010 that they exchanged clinical record information electronically with providers outside their system.

A major reason for the low level of interoperability, the ONC officials said, is the expense of interconnecting disparate electronic health record (EHR) systems.

“The lack of widely adopted standards, failure to use existing standards, and flexibility in the way that standards are implemented have all contributed to the high cost of exchange...One clear opportunity is to increase the standardization of health information exchange, which would reduce the cost and complexity for providers, vendors, and health information exchange organizations.”

Farzad Mostashari, national coordinator of health IT, noted at a recent Congressional hearing that the government could not impose this kind of standardization by fiat. Although ONC is using all of the policy levers at its disposal to promote interoperability, including the federal EHR incentive program, he said, “We want to really work with industry to get consensus and to accelerate this.”²

Such a consensus was reached recently by a powerful private-public coalition, including 42 technology vendors, states that include more than half of the U.S. population, and the organization that operates the successor to the Nationwide Health Information Network (NwHIN) Exchange. As a result, the industry is on the verge of a breakthrough in two important areas of interoperability: the ability of health-

care providers to send and receive summaries of care within their clinical workflow, and their ability to look up patient records seamlessly across disparate EHRs used by other health-care organizations.

This “plug and play” capability will enable clinicians to view and download patient information that originates outside their organizations without having to interrupt their work and go to a website. It will also lower the costs of connecting to health information exchanges (HIEs) by eliminating the need to write separate interfaces for each EHR. And healthcare organizations will be able to use this form of interoperability to aggregate data from multiple sources so they can improve care coordination and manage population health.

Leading the effort to create plug and play interoperability is a partnership of two public-private groups: the EHR/HIE Interoperability Work Group (IWG), an alliance of 19 states, 20 EHR vendors, and 22 HIE suppliers spearheaded by the New York eHealth Collaborative (NYeC); and Healthway, the nonprofit firm that manages the eHealth Exchange (EHE), which is the successor to the NwHIN Exchange. In a competitive bidding process, the partnership chose the nonprofit Certification Commission for Health

Information Technology (CCHIT) to test and certify EHR and HIE products and participants in the eHealth Exchange for their compliance with IWG/Healthway standards.³

Two other national interoperability networks have emerged recently: Surescripts and the CommonWell Health Alliance. Surescripts, which provides the connectivity between physician offices and pharmacies for electronic prescribing, has broadened its offering to include secure clinical messaging.⁴ CommonWell, an alliance of several leading EHR vendors, plans to provide patient record lookup services within a proprietary network.⁵ Major health IT companies are supporting both of these initiatives. But neither of them is considered a competitor of EHE or of the IWG/Healthway effort; in fact, CommonWell intends to connect with EHE.

Meanwhile, the leading EHR and HIE vendors—including those involved in CommonWell and Surescripts—have joined IWG and have committed themselves to use its specifications for health information exchange.⁶ Some of the statewide HIEs that belong to IWG plan to contract preferentially with vendors that meet these standards. So it is likely that the partnership’s interoperability approach will be the one adopted across the country, at least in the short term.

CONSORTIUM FOR INTEROPERABILITY

To understand the rapidly evolving movement toward interoperability, one needs to know something about the key players and the environment in which they operate. What follows are descriptions of the organizations involved, where they are coming from, and what their goals are. In addition, efforts to promote interoperability at the federal, state and local levels are briefly summarized.

eHealth Exchange (EHE)

ONC defines the Nationwide Health Information Network (NwHIN) as “the set of standards, specifications and policies that enable the secure exchange of health information over the Internet.” The NwHIN Exchange, EHE’s predecessor, is defined as a community that has implemented these standards, specifications and policies. All public and private participants in the NwHIN Exchange/EHE are required to sign the Data Use and Reciprocal Support Agreement (DURSA), which specifies their roles and responsibilities.⁷

As of March 2012, the NwHIN Exchange consisted of 34 organizations, including more than 500 hospitals and 4,000 providers, many of them involved in the Virtual Lifetime Electronic Record pilot of the Departments of Defense (DoD) and Veterans Affairs (VA).⁸ Kaiser Permanente, the Marshfield Clinic, and a few private HIEs such as MedVirginia

and HealthBridge participated in the NwHIN Exchange. So did several federal agencies, including the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), DoD, VA, and the Social Security Administration (SSA).⁹

In October 2012, ONC completed its transfer of operational responsibilities for the newly renamed eHealth Exchange to Healthway, a nonprofit firm. In the new structure, the policy-making body to which Healthway reports is the eHealth Exchange Coordinating Committee (ECC). Established by the DURSA pact, ECC represents all EHE participants. Healthway is governed by a board of directors elected by its membership, which includes EHE members and other stakeholders.¹⁰

EHE has grown considerably since ONC turned over the reins to Healthway,

and it's continuing to grow rapidly. Last fall, it included 40 organizations that were actively exchanging information, and by February, another 40 were waiting to be connected to EHE. In March, the number of entities in the queue leaped to 80. And some organizations in production, such as the VA system, are still in early stages of rolling out EHE connectivity; only 14 of the 178 VA medical centers are online so far.

Care Connectivity Consortium

An important ally of Healthway is the Care Connectivity Consortium, which includes Geisinger Health System, Kaiser Permanente, Mayo Clinic, Intermountain Healthcare, and Group Health Cooperative. Since 2011, these five not-for-profit healthcare systems have been developing interoperability between each other's EHRs, using the NwHIN standards.¹¹ In 2012, they agreed to provide R&D services to Healthway.¹² Kaiser Permanente is already an EHE participant, and the other CCC members are all in the process of being on-boarded to the national exchange.

EHR/HIE Interoperability Work Group

Shortly after it was started up, Healthway formed a partnership with the EHR/HIE Interoperability Work Group (IWG).¹³ The force behind this group is the New York eHealth Collaborative (NYeC),

which operates the Statewide Health Information Network of New York (SHIN-NY) in conjunction with the state department of health. In 2011, NYeC realized that one state alone did not have enough leverage with the vendor community to reduce variability in the implementation of the national interoperability standards. So NYeC decided to partner with other states and with the vendor community to drive interoperability. The initial effort started with seven states, eight EHR vendors, and three HIE vendors. Today, IWG includes 19 states, 20 EHR vendors, and 22 HIE suppliers.¹⁴

From the outset, IWG was determined to make patient record lookup and secure messaging plug and play by eliminating optionality and variability in the use of national standards in those processes. For example, the Integrating the Healthcare Enterprise (IHE) web services profiles had been around for years, but they hadn't created true interoperability because too many options in their use were allowed.

So IWG's vendor members put their software engineers to work on eradicating the variability in how the standards for query-based and directed exchange could be implemented. All of the vendors agreed on the technical specifications and committed themselves to incorporating them into their

applications within a certain period of time. After IWG partnered with Healthway, the organizations selected the Certification Commission for Health Information Technology (CCHIT) to test products and certify that they met the Healthway/IWG specs.

ONC recently entered into a cooperative agreement with IWG under its new Exemplar HIE Governance Program. While the government gave IWG only a small grant to carry out its work, this agreement conferred official recognition on IWG's efforts to promote interoperability. For its part, IWG committed to addressing issues such as patient matching and querying provider directories, while aligning itself with other ongoing ONC initiatives.¹⁵

Certification Commission for Health Information Technology

Founded in 2004, CCHIT has been certifying EHRs since 2006 and is the most experienced health IT certification body in the U.S. The original goal of the nonprofit organization was to show potential purchasers of EHRs whether particular systems met basic criteria for functionality and security. The certification criteria were developed through a voluntary, consensus-based process that involved diverse stakeholders, and the federal government officially recognized CCHIT as an EHR

certification entity. By 2009, CCHIT-certified EHR products represented more than 75% of the market.

After the launch of the EHR incentive program in 2009, CCHIT was one of several organizations authorized by ONC to certify the compliance of complete EHRs and EHR modules with government criteria. Meanwhile, CCHIT has certified homegrown systems that meet the ONC requirements; it is creating a health IT framework for accountable care organizations; and it continues to certify products in areas not covered by ONC's EHR certification program, including EHRs used in long-term and post-acute care and behavioral health.

MEANINGFUL USE

One reason for EHR vendors' interest in the IWG/Healthway project is the government's requirements for showing "meaningful use" of EHRs. While stage 1 of Meaningful Use barely scratched the surface of interoperability, Meaningful Use stage 2 has fairly stiff criteria in this area. Under these rules, which take effect next year, an eligible professional (EP) must provide a summary of care record in at least 50% of transitions of care or referrals to other providers. In at least 10% of these transitions and referrals, the clinical summary must be electronically transmitted either directly between certified

EHRs or indirectly through an HIE. And eligible professionals must conduct at least one successful exchange of information with a provider that is using an EHR from a different company than the one that supplied their EHR.¹⁶ Hospitals have similar requirements.¹⁷

To help EPs and hospitals transmit these summaries of care electronically to other providers, ONC requires that certified EHRs incorporate the Direct Project secure messaging protocol.¹⁸ Developed by a private-public consortium in 2010 and compatible with EHE standards, the Direct protocol is essentially a form of e-mail that requires the use of health information service providers (HISPs), provider directories, and digital certificates.¹⁹⁻²⁰ As of July 2012, only 14 EHR vendors had imbedded Direct in their products, but many more were expected to before 2014.²¹

The Meaningful Use stage 2 criteria have had a major unintended effect on the eHealth Exchange. Although Healthway expected only federal agencies, state and regional HIEs, and large healthcare organizations to join EHE, an increasing number of smaller healthcare systems and operators of private HIEs have asked to be connected directly to the national exchange. Healthway attributes much of this activity to EHR vendors telling providers to join EHE in states where public HIEs are unavailable

or not ready to provide the connectivity required for Meaningful Use.

OTHER ONC INITIATIVES

The ONC and CMS work plans for 2013 emphasize interoperability. The Department of Health and Human Services (HHS), which includes both agencies, recently issued a public request for information that “will strengthen the business case for electronic exchange across providers,” according to a press release.²²

Meanwhile, CMS and the HHS Office of Inspector General recently proposed extending from 2013 to 2016 the exception to the federal physician self-referral law and the safe harbor in the anti-kickback statute that allow hospitals and some other entities to subsidize EHRs for private practices. This exception might be expanded to remove barriers to health information exchange. Also, CMS could create quality measures that encourage sharing of data among providers.²³

ONC’s biggest move to encourage interoperability—aside from the Meaningful Use stage 2 criteria—has been to dispense \$548 million to states to support the development of HIEs.²⁴ The states are using this money in a variety of ways. Some are building statewide exchanges that connect regional HIEs; others are

focusing their efforts on connecting providers in areas that lack local exchanges; and still others are providing technical support to local exchange initiatives.²⁵

LACK OF A BUSINESS CASE

The key challenge for public exchanges—whether regional or statewide—has been their lack of a business case that would encourage providers to participate in them.²⁶ That is starting to change with the emergence of accountable care organizations and bundled payment contracts that necessitate information exchange across business boundaries. But the costs of connecting EHRs to HIEs and of building the infrastructure for query-based exchange remain daunting. In addition,

physicians are reluctant to leave their EHR-based workflow and go to a website to look up outside information on their patients.²⁷ The IWG/Healthway initiative is designed to address both of these issues.

Meanwhile, healthcare organizations are continuing to develop private HIEs at a much faster pace than public HIEs are being built.²⁸ These private HIEs connect hospitals to physician practices and other parts of the healthcare enterprise. In some cases, organizations are linking not only with their employed physicians, but also with community practices that use disparate EHRs. So these private HIEs may become conduits for providers to connect with statewide HIEs and/or EHE.

TESTING AND CERTIFICATION PROGRAM

In March 2013, CCHIT announced the beginning of the pilot phase of its IWG/Healthway compliance testing and certification program.²⁹

When the program is complete, it will include the following certifications:



HIE Certified Direct™

for EHR and HISP systems, which certifies the compliance of products with the Direct protocol so that providers can send secure health information directly to trusted recipients, including patients, over the Internet.



HIE Certified Community™

for EHR and HIE systems, enables clinicians to share patient information within and across care delivery communities.



HIE Certified Network™

for HIT systems that enable HIE-to-HIE connectivity and for connection to the eHealth Exchange.

Certification will be specific to each technology and each version of a product, and will include testing of commercially available products, healthcare provider participants, and health information exchanges. As with EHR certification by an ONC-authorized certification body (ACB), applicants will have to meet all testing requirements in order to be certified.

CCHIT has created an automated, web-based testing program that utilizes an open source version of a tool devel-

oped by AEGIS.net. This tool relies on the set of specifications created by the IWG/Healthway partnership.

Certification for compliance with IWG/Healthway standards requires much more rigorous adherence to standards than does ONC's 2014 EHR certification process. Nevertheless, government regulations specify that providers can use only ONC HIT certified EHR technology to show or attest to Meaningful Use. So, even if an EHR has received IWG/Healthway certification for interoper-

ability, it must also be tested by an ONC-approved Accredited Testing Laboratory (ATL) and certified by an ONC-ACB in the separate ONC 2014 Edition program.

Specified Content

Meaningful Use stage 2 requires the exchange of a particular kind of clinical summary document known as the consolidated CDA (C-CDA). However, most vendors and providers involved in EHE and IWG are using an advanced form of the Continuity of Care Document (CCD) called the C-32.³⁰ Because of the variability allowed in the C-32 format, not all systems could exchange these summaries. So the joint task force of the partnership hammered out a constrained version of the C-32 that all systems can understand.

The new C-32 format includes the extra elements that are in the C-CDA. As a result, vendors that incorporate it will be able to meet ONC's C-CDA requirement. The next version of the IWG/Healthway specs is expected to use the C-CDA.

HIE Certified Direct



As noted earlier, to be ONC 2014 Edition certified, EHRs must incorporate Direct messaging capability so that providers can

push summaries of care to each other during referrals and other transitions of care. Assuming that the sender has access to a HISP and that the receiver is in the provider directory of that HISP or another HISP with which the first one can communicate, compliance with the Direct protocol should theoretically enable summaries to be exchanged between disparate EHRs.

But ONC's specifications for Direct messaging functionality are far less rigorous than those of the IWG/Healthway partnership. CCHIT will test EHR vendors for compliance with these more constrained standards so that providers can send and receive Direct messages without subsequent testing.

IWG/Healthway certification will also require vendors to comply with the specifications for Healthcare Provider Directory (HPD) Plus, an enhanced version of an IHE profile that supports management of healthcare provider directories.

Apart from CCHIT's product testing and certification, the work of DirectTrust, another nonprofit organization, is expected to make it easier for providers to use the Direct protocol to send messages to trusted parties. DirectTrust, which recently entered a cooperative agreement with ONC under the Exemplar HIE Governance Program, is developing a national accreditation program for HISPs,

certificate authorities, and registration authorities. Accredited HISPs will be able to exchange Direct messages without having to contract with one another separately.

HIE Certified Community



Under the IWG/Healthway standards, the basis for query-based exchange is the web services profiles

developed by IHE, an industry group that has long worked to advance interoperability.³¹ These profiles, which use XML tagging of data elements, have been demonstrated at numerous IHE Connectathons and annual conferences of the Healthcare Information Management and Systems Society (HIMSS). But for any given profile, an IHE Connectathon presents only a dozen or so test cases, none of which are particularly challenging. So, even though two systems are both claimed to be IHE-compliant, they may not be able to communicate with each other.

To remedy this situation, the IWG/Healthway joint task force sorted through the IHE profiles, picked out the relevant ones, and collaboratively worked with the EHR and HIE vendors to determine exactly how they were to be used. Each vendor will be required to show that users

can locate and request specific patient information across disparate systems in hundreds of test cases.

The test cases are based on the NwHIN specifications for all possible uses of query-based transactions. For example, there are many different ways to query for information on a patient. The initiator of the request doesn't have to support all those ways of asking, but the responder has to support all ways of being asked. There are also many different ways to ask about an initiator's identity and ask what documents are available for a patient.

HIE Certified Network



CCHIT has begun piloting HIE Certified Network and expects certification to begin within a few months.

To receive this designation, which HIEs need to connect with the eHealth Exchange, they will have to use a certified HIE product. They must also go through additional testing to verify that their version and configuration of certified HIE software permits the exchange of data with other EHE participants. But this testing is expected to be relatively minor, requiring only a small fraction of the effort that HIE vendors will have to put into getting certified.

Providers that use IWG/Healthway-certified EHRs must also undergo participant testing before connecting to EHE. Again, this should not require extensive work; CCHIT will simply check to make sure that providers have not changed their certified products in ways that don't conform to the IWG/Healthway specifications.

In the long run, participant testing is expected to diminish and likely disappear as specifications, tests, products and implementations mature. In pursuit of that goal, production issues will be fed back into the testing process to improve it and make it more rigorous.

Vendor compliance

The EHR and HIE vendors that belong to IWG have not only ratified the IWG/Healthway specifications, but have also signed a memorandum of understanding committing them to include those standards in their products. The suppliers agreed in November 2011 to incorporate the specs within one or two release cycles, and many of them will be

ready for testing by the summer or fall of 2013.

Despite these assurances, there will inevitably be laggards. So the states participating in IWG are encouraging vendors to honor their commitments through preferred-vendor contracts and other policies. The New York eHealth Collaborative, for example, has contracts requiring that EHR vendors comply with the IWG/Healthway specs for Direct messaging within six months of the certification program's launch to be considered preferred suppliers.³²

EHE participants are also driving their vendors to get their products certified, because this is now a condition of participating in EHE.

With the help of the statewide HIEs, the partnership also plans to educate healthcare providers about the value of the IWG/Healthway labels attached to certified products. If physicians and hospitals begin to demand that their EHRs be certified, the vendors will have to comply.

FUTURE DIRECTIONS

The pace of evolution in health information exchange continues to be very rapid. Many challenges must still be overcome, and the IWG/Healthway partnership recognizes that it must remain open to new ideas even as it consolidates the gains made to date and transforms them into practical, real-world approaches.

In this regard, the alliance between Healthway and the Care Connectivity Consortium (CCC) is expected to be particularly significant. To recap, CCC consists of five of the most technologically advanced healthcare organizations in the U.S.: Geisinger Health System, Kaiser Permanente, Mayo Clinic, Intermountain Healthcare, and Group Health Cooperative. These organizations are already exchanging data with each other based on NwHIN/EHE standards, and they will all be using HIE Certified systems as EHE participants.

CCC members have overcome a number of implementation obstacles in achieving interoperability, and other provider organizations can learn from their experience. Under CCC's agreement with Healthway, CCC will also do development and innovation work in areas such as provider directories, patient identity management, consent management and, eventually, population health management.³³ CCC is also creating extensions to the C-32 and C-CDA clinical summaries in areas such as vital signs, lab results, radiology reports, and discharge summaries.

As CCC develops new functionalities for data exchange, it will pilot them among its member groups. Then the consortium will bring them to the IWG/Healthway joint working group, which will decide whether to require them in products and add them to the HIE Certified testing and certification program.

Discrete data exchange

CCHIT will certify the ability of EHRs and other HIT systems to exchange clinical summary documents in compliance with the IWG/Healthway standards. Vendors are expected to give users the ability to view these summaries within their EHR or HIT system workflow or download them into their systems as documents. But no vendors currently program their applications to extract the data elements from a summary generated by a disparate system and insert them into the fields of the receiving EHR.

While it is theoretically possible to do this, there are numerous technical and medico-legal obstacles. For true plug and play import capability, a user needs to have assurance of

non-repudiation of origin, date of provenance, and digital signatures within the document, not at the overall document level. In addition, there are issues with patient consent and state privacy laws, especially for sensitive data.

CCC has put the automated importation of discrete data on its roadmap, but much more testing of the requisite elements needs to be done. This kind of automated importation is also in the 2014 work plan of the Health IT Standards Committee, which advises ONC on standards development.

CommonWell's plans

The recent announcement of the CommonWell Health Alliance has given rise to several theories about the motivations of its founding companies. Whatever those are, Healthway and ONC regard CommonWell as a positive development if the organization

increases interoperability among its members' products in accordance with national standards.

CommonWell's leaders have assured Healthway that they support EHE and plan to connect their network to EHE. But within its network, CommonWell is looking at using newer content and transport standards that could provide a foundation for population health management activities. Among these is an HL7 alternative to the consolidated CDA known as Fast Healthcare Interoperability Resources (FHIR).³⁴ CommonWell is also considering a web services transport standard called RESTful that does not use XML and that allows looser coupling of services than the SOAP transport mechanism does.³⁵

Healthway and IWG will continue to monitor these developments, and as they evolve, will evaluate their potential contribution to interoperability.

CONCLUSION

The consensus reached among public and private stakeholders through the IWG/Healthway partnership has opened the way for the first true plug and play interoperability among disparate EHR and HIE products. The ability to exchange clinical summaries and look up patient records across these systems without writing customized interfaces for each instance of each application represents a breakthrough that will have a major impact on healthcare.

One expected consequence of this kind of interoperability will be to increase the viability and accelerate the spread of HIEs. Providers will be able to connect with HIEs at a fraction of the cost they must now pay for this connectivity. And clinicians will be far more likely to seek information from other providers if they

can view or download it within their EHRs rather than go to websites outside their workflow.

The eHealth Exchange will both benefit from and help to create this plug and play interoperability. By using certified products and submitting to participant testing, HIEs and providers will be able to join EHE and easily exchange information with other EHE participants across the country.

Finally, CCHIT is the entity that provides the technical expertise and the depth of experience required to make this all happen. CCHIT's selection by IWG/Healthway is a tribute to its solid reputation in the industry and the confidence that stakeholders have in its ability to make interoperability real.

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