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December 15, 2011

ONC Health IT Standards Committee

(<http://healthit.hhs.gov/blog/faca/index.php/2011/11/09/hitsc-seeks-comments-on-exchange-specifications-by-december-15-2011/>)

EHR Association Response to the Health IT Standards Committee Questions

1. Please identify yourself, your organization, and your position within the organization.

The EHR Association is a trade association of electronic health record (EHR) software developers that work together to lead the health information technology (HIT) industry in accelerating safe and meaningful adoption of EHRs in hospital and ambulatory care settings in the United States.

Representing a substantial portion of the installed EHR systems in the US, the Association provides a forum for industry experts to participate in standards development, the EHR certification process, interoperability, performance and quality measures, and other pressing HIT issues. Membership is open to HIMSS corporate members that are legally formed companies designing, developing, and marketing their own commercially-available EHRs with installations in the US. The Association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himsssehra.org>

Our response to this survey is based on our members' experiences and our Association's unique collective view of the industry landscape.

2. When did your organization implement the Exchange specifications?

About twenty (20) of our members have implemented Exchange or closely related specifications (e.g. IHE XDS, XCA, PDQ, XCPD) going back as early as 2006.

3. Why did your organization implement the Exchange specifications? Are the functional capabilities that Exchange provides adequate for your current and expected information-exchange purposes?

Two key points should be made:

- The Exchange specifications address two critical use cases for nationwide health information network (NwHIN) participants and other providers who desire to engage in health information exchange: a query and retrieve of records, and a send/receive of documents directed to a source of information.
- The Exchange specifications are largely based on IHE profiles (XCA, XCPD, XDR) that are implemented in health information exchange (HIE) projects in the US and internationally. Our support of the Exchange specifications thus opens a market for our products and our customers to interoperate more broadly.
- Given the prior point, it is important for ONC to also support and advance the intra-community complements to the Exchange protocols.

We have found that our customers often require more than just the Exchange specifications to support the use case of intra-community sharing with a centralized HIE. Many of these provider organizations and HIEs, including several state health information exchanges (HIEs) funded by the Office of the National Coordinator for Health IT (ONC), use IHE XDS (included in HITSP TP13).

Our experiences show that the vast majority of care transitions occur within a community, not across multiple communities. In overlooking this “private, local, regional” segment of HIE, we were concerned that the NwHIN Power Team’s Draft Recommendations of September 2011 took an overly pessimistic view of the maturity and adoption of widely-supported IHE standards like XDS, which have been tested, implemented, and iteratively refined over several years. NwHIN cross-community access and patient discovery are certainly important but, limiting the scope of the recommendations of HITSC and the questions in this survey to NwHIN Exchange specifically, overlooks the implementation synergy of Exchange specifications with the body of specifications that support other common and prevalent scenarios.

4. What business functions does Exchange currently support in your organization?

The larger family of IHE standards, on which the NwHIN Exchange is based, provides the members of the EHR Association with a common baseline for supporting straightforward exchange among our common clinical customers. These customers may connect to each other, to statewide data repositories, or to federal NwHIN partners, but the standards remain essentially the same, allowing HIT suppliers to focus development plans on the clinician-facing workflows that differentiate and distinguish one software solution from another.

5. What is the current monthly volume of documents that are transferred among different organizational entities as part of your implementation?

As a trade association, our vendor members support their clinical customer organizations toward specific HIE objectives. This information is not available through the EHR Association. However, we encourage HITSC to review a sampling of current system approaches, which are included in response to Question 14.

6. What methods and protocols do you use today for clinical exchange? When considering the exchange activities anticipated for the next few years, what proportion do you expect will use Exchange? What other methods and protocols do you plan to use over the next few years?

Today our member companies support:

- Exchange, and
- HITSP TP13 (IHE XDS) and HITSP TP23 and T22 (PIX/PDQ profiles) for community-based HIE – that is, “private, local, regional” HIE within a community. These specifications are very closely related to NwHIN Exchange standards.

In our collective experiences, smaller communities of exchange are much more common in clinical practice, and thus our clinical customers are prioritizing these latter standards. Perhaps this can be attributed to the vast majority of care transitions that occur within a community, not across multiple communities. However, intra-community standards and Exchange standards are very similar; leading many of us to adopt both to give HIT suppliers and the healthcare delivery organizations we serve as much flexibility as possible.

Our members also intend to support Direct Project information transfer, which is very similar to the NHIN Document Submission specification. Collective experiences have not uncovered further needs for other transport standards, as explained in our EHR Association Transport Framework White Paper (<http://www.himssehra.org/ASP/whitepapers.asp>)

We would also like to express our concerns with the HITSC’s proposal for a RESTful alternative to the Exchange specifications. Given the NwHIN’s role as a national backbone, federating across many different organizational boundaries with multiple layers of security and privacy policies, relying on a SOAP-based rather than a RESTful approach is a better fit, not simply a matter of preference.

7. Have the organizations with whom you want to exchange data implemented Exchange? If not, do they plan to do so? If they are not implementing Exchange, what alternatives are you considering using for these exchanges?

In our experience, healthcare delivery organizations who use software developed by our members want to connect to each other, to local exchanges, and ultimately, to the NwHIN Exchange. While other software vendors and local exchanges are often in the process of implementing Exchange-related standards, we must fill the gap with HL7 V2-based interfaces that are mapped to Exchange or closely related specifications.

8. What was your personal role in the implementation of the Exchange specifications?

The EHR Association provides a structure and framework for its technical, engineering, services, and marketing executives to support standards development as well as implement those standards in their solutions. EHR Association members and member companies participate in many Exchange-, IHE-, and ONC-led standards development initiatives.

9. Which of the following Exchange specifications did you implement?

The following Exchange specifications have been implemented by our member organizations

- NHIN Messaging Platform Specification
- NHIN Web Services Registry Specification
- NHIN Authorization Framework Specification
- NHIN Patient Discovery Specification
- NHIN Query for Documents Specification
- NHIN Retrieve Documents Specification
- NHIN Access Consent Policies Specification
- NHIN Document Submission Specification
- NHIN Administrative Distribution Specification

10. Did you implement these specifications as prescribed, or did you make some adjustments for your environment? If the latter, what adjustments did you make at the time of initial implementation or have you made since? Were these adjustments made through bilateral agreements or did they apply to all participants in your exchange?

Most of our members, in addition to their support of the Exchange standards, have reported that they have or would consider implementing the HITSP TP13 (XDS) standards mentioned above. Technically, the standards are so similar that providing support for both allows us to offer software that not only connects to organizations on the NwHIN, but also local communities of exchange, state-based registries, and other implementations that support these stable and widely-accepted IHE profiles.

We generally recognize that singular environmental adjustments are costly and unsustainable. Where possible, our member organizations attempt to prioritize unambiguous standards and implementations so we can focus our development resources on delivering the best value to our healthcare delivery organizations and users.

11. How easy or difficult were the Exchange specifications to understand, interpret, and implement? Compared to other service-oriented implementations you've been involved with, was Exchange easier, harder, or about the same level of complexity?

Generally, our members found the specifications similar in complexity to other service-oriented implementations. Some of our members took advantage of open source toolkits such as CONNECT, OHT IHE profiles, OHT MOSS, etc., and the testing support provided by IHE, its Connectathon events, and test tools.

Industry adoption and vendor readiness to support the NwHIN Patient Discovery, Query for Documents, and Retrieve (IHE XCPD and XCA) standards is more advanced than reflected in the NwHIN Power Team's Recommendations of September 2011. The IHE XCPD and XCA specifications, on which the NwHIN Exchange specifications are based, have been tested by over 100 vendors, as can be seen in the IHE Connectathon results for the past several years. (Go to <http://connectathon-results.ihe.net/> for more information.) Given this ubiquitous level of technological availability, we believe that policy and workflow issues impede larger health industry adoption of the NwHIN Exchange specifications, not the complexity of the standards themselves.

For example, HITSC's NwHIN Power Team found the NHIN Patient Discovery Specification to be "highly complex" and problematic. We argue that the specification itself is not complex. It describes a query with patient attributes that expects a response with a matching local patient identifier. The complexity and problems come from the operational management associated with patient discovery in large-scale environments where there are no shared identifiers (e.g., different matching policies, updates, caching of identifiers, etc.). Since the complexity does not lie in the specification, we urge the HITSC to recognize that any other specification in the same environment will result in the same complexity.

12. What operational and administrative coordination and technical infrastructure have you needed to put in place in order to deploy and operate Exchange?

The needed operational or administrative coordination and technical infrastructure have been addressed successfully by many HIE projects, at the project level itself. Such examples include the multi-state, multi-vendor EHR/HIE Interoperability Workgroup (www.interopWG.org), the Care Continuity Consortium (Kaiser, Mayo Clinic, Intermountain Healthcare, Geisinger, Group Health), and other exchanges such as KeyHIE, Tennessee State HIE, Connecticut, etc. All of these leverage the Exchange specifications or closely related specifications.

13. How many hours of technical time did the project entail before reaching full interoperability?

Our member developers have reported varying implementation efforts, depending largely on whether they used an open source toolkit. Regardless, over 100 vendors, from small to large, have implemented and tested the Exchange and HITSP TP13 standards at IHE Connectathon for the past several years (<http://connectathon-results.ihe.ent>)

Our member developers report that an up to one week of configuration work will allow a system that has successfully tested XCA and XCPD to also support Exchange standards. This time is largely spent on the set-up of the Exchange security and privacy environment. It is likely that this time will be reduced once NwHIN Exchange support personnel and our service staff have been better trained and the support processes streamlined. Our members have reported that state or community HIEs with a central document registry have managed to reduce this set-up time to a couple days.

In order to bring overall efficiency, we recommend to better structure of the overall testing process in the onboarding of Exchange partners, with clearer hand-offs from one layer of compliance to the next. Our experience on a wide range of projects in the US and abroad leads us to propose a structure for the overall testing strategy using a top-down model with a policy layer and a technical layer further divided into three sub-layers:

1. **Policy compliance:** assessing that Exchange Partner operates its Exchange Gateway System in an environment which complies with the Exchange Policies (technical compliance being only one of the elements to be complied with for an Exchange Partner to be/remain on-boarded). Exchange Partner Approval: Exchange Coordination Committee authorizes applying partner to operate as Exchange Partner by validating that:
 1. System used passed Exchange-Ready System Testing (See 2.2 below)
 2. Partner passed Exchange-Ready Pilot Partner Testing (See 2.3 below)
 3. Partner signed DURSA and satisfies any other audits, if desired.

2. ***Technical compliance:*** testing the Exchange Gateway Systems installed by the Exchange Partners for conformance and interoperability in terms of their technical/clinical compliance:
 - 2.1. ***Optional Connectathon:*** Vendor becomes familiar and tests conformance and interoperability for the IHE profiles used by exchange (*modular Profile level testing*).
 - 2.2. ***Exchange-Ready System Testing:*** Test product/implementation (including Open Source) for conformance (self-testing with tools). When successful, test for interoperability at an Exchange Projectathon – held several times a year (*moves to “holistic” Exchange specifications and end-to end Exchange test cases*).
 - 2.3. ***Exchange-Ready Pilot Partner Testing:*** Exchange Partner installs Exchange-Ready System (performs integration with community HIE or health system EHR) and tests for interoperability with three other Exchange Partners that offer a “stand-by Exchange Gateway System”.

14. What other questions do you wish we had asked about your experience deploying, operating, and maintaining your Exchange implementation?

We encourage the HITSC to solicit input from implementers not only of the Exchange specifications *but also of closely related specifications*. The Exchange Specifications are based on the IHE XCA and XCPD profiles, which are nearly identical to the IHE XDS/PDQ profiles used to connect EHRs to HIEs and to other EHRs today. To address this gap, we include nine statements from EHR Association members. These were provided to ONC and HITSC as part of **EHR Association Comments on the HIT Standards Committee NwHIN Power Team Evaluation and Draft Recommendations** in September 2011 and have been updated since publication.

(http://www.himss.org/docs/20111012_EHRAInputNWHINPowerTeamEvaluationFINAL.pdf),

In the **EHR Association Transport Framework White Paper**, a survey of its members identified that more than 40 commercial EHRs (including vendors outside of the Association) are connected and operational in exchanging clinical information using three closely related specifications: NwHIN Exchange (IHE XCA/XCPD), Direct (IHE XDR/XDM), and IHE XDS/PIX/PDQ. We know that there are also several implementations supported by EHR suppliers that are neither Association members nor survey participants. More specifically, here is a sampling of real world implementations:

- **Vendor A:** Vendor A’s interoperability platform, which uses SOAP-based transactions and supports the NwHIN specifications discussed here, is live at 88 customer sites that cover an estimated 45 million patients. Some of these customers are live on the NwHIN today, exchanging data with the SSA, the DoD, and the VA.
- **Vendor B:** 40 customers actively involved in state or private HIEs, 30 using one or more IHE profiles in those exchanges; the majority are utilizing HL7 push technology; 100 implementations in progress surrounding HITSP C32 CCD Exchange; one utilizing full complement of IHE profiles for CCD Exchange; no NHIN Direct Customers to date; of Vendor B’s 2000 customers only three have asked for it and the vendor is designing a solution available 2012. The short response is that until NHIN Direct becomes a meaningful use requirement, the vendor believes there is little traction.
- **Vendor C:** Has deployed live HIE configurations in eight communities and has another dozen in active implementation. These HIEs are based on the IHE XDS specifications (the same standard as NwHIN Exchange), connecting live to 39 different vendors’ EHRs systems, most of which offer this

interoperability native off-the shelf. These HIEs cover more than 6 Million patients.

- **Vendor D:** Has deployed 15 test HIE connectivity solutions in 12 HIEs that are expected to go live in 2011, using NwHIN Direct (XDR option) and IHE XDS. This covers approximately 2000 providers. In addition, there are approximately 10 additional sites that will be installed in 2011 with NwHIN Direct XDR and/or IHE XDS as a result of requirements from approximately seven other HIEs.
- **Vendor E:** Has “connected” several regional health information organization (RHIOs) and is working with multiple state HIE vendors, connecting hospitals and millions of patients to both HIE and immunization registries. Vendor E is using the IHE XDS Profile and CCDs to share problems, procedures, meds, med allergies, vital signs, and lab results, and is “VERY excited to enable better patient outcomes through a 360 “view” of care across the patients’ care continuum, during transitions in care, across systems, solutions, providers and facilities!”
- **Vendor F:** This vendor currently has five sites in production utilizing CCD-based documents for exchange of clinical data (over non-XDS transports), covering approximately 34,000 unique patients. Approximately 100,000 CCDs have been transported over these interfaces thus far. Vendor F participated in the CHIEP pilot in 2010 which utilized NHIN (NwHIN) XDR-based transport standards and C32/C83 documents for clinical data. The NHIN CONNECT open source implementation was used to handle the XDR-based transport requirements. Vendor F will have two sites in production by year end 2011, connected to two separate HIEs in New York State. IHE XDS and associated standards as well as CCD/C32 standards are being utilized in both of these HIEs. The number of unique patients in the systems total to approximately 70,000. The number of unique patients in both HIEs totals to approximately 2 million (these facts are a bit dated so numbers could be higher today). This vendor expects to accelerate adoption quickly in other sites after the first two implementations are complete, and is on the cusp of going live with an XDS-based CCD exchange for immunization content to an immunization registry in California. Approximately 25,000 unique patients are managed at this site and there is potential to expand the same XDS-based interoperability quickly to additional sites in the area. Additionally, Vendor F has approximately 10 XDS-capable HIEs on the near-term implementation roadmap. This includes a variety of disparate infrastructure vendors as they achieve this type of scalable interoperability.
- **Vendor G:** XDS/XDR interoperability solution (using IHE profiles upon which NwHIN Exchange specifications are based) was released to the market recently and already has one live XDS implementation connecting to an HIE sharing among ambulatory and acute EHRs. Vendor G has over 30 enterprises who have contracted for the solution, most of which will connect to different local, regional, and state HIEs around the country.
- **Vendor H:** This vendor currently does not have any customers who utilize any of the IHE profiles, and unfortunately they do not track to that level the interfaces we have installed. Currently, Vendor H’s customers who do participate with some type of HIE feed just HL7 events/messages, typically for ADT transactions and lab results.
- **Vendor I:** We are implementing the following IHE profiles on the state level:
 - PIX HL7v3. (ITI x 1), PIX Query, PIX Add/Update
 - XDS.b Provide and Register Document set (ITI 15 b) for MTOM and Inline documents

- XDS.b Registry Stored Query (ITI 18)
- XDS.b Retrieve Document Set

We have implemented the following SOAP/HL7 2.x based web service-based interoperability scenarios:

- Request CCD 32 via HL7 2.x QRY^T12 over SOAP/TLS
- Provide CCD 32 via HL7 2.x MDM message over SOAP/TLS
- Provide Immunization data via HL7 VXU^V04 over SOAP/TLS

Sincerely,

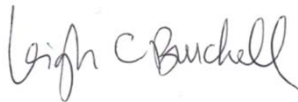


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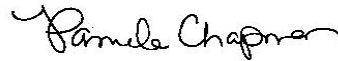


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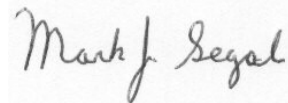
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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himsshehra.org>.

