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September 26, 2011

Director, Office of Interoperability and Standards Office of the National Coordinator for HIT
Health IT Standards Committee Members

EHR Association Comments on the HIT Standards Committee NwHIN Power Team Evaluation and Draft Recommendations from September 9, 2011

Summary

The EHR Association is pleased with the confirmation presented by the NwHIN Power Team that both the Direct and the Exchange specification are mature and serving their intended purposes. Although neither of these two specifications is in widespread deployment, the EHR Association believes that the evaluation of the current maturity and adoption of core Exchange specifications could have been more accurately represented in the Power Team conclusions. Our specific comments focus on:

1. Industry adoption and vendor readiness to support the NwHIN Patient Discovery, Query for Documents, and Retrieve (IHE XCPD & XCA) standards is more advanced than reflected.
2. There is a gap resulting from the decision to not consider the use case for sharing in HIE communities of health Information, despite what we interpret to have been the Power Team's charge to do so. This use case has a very mature specification with IHE XDS, PIX/PDQ (with the most significant EHR and HIE vendor readiness), and implementation experience.
3. The evaluation statement expressing concerns with the complexity of the Patient Discovery specification needs to be corrected. It does not reflect the reality that the complexity comes not from the specifications, but from policy decisions not to develop shared patient identification principles and related operational deployment challenges.
4. The rationale for proposing to develop a RESTful approach as an alternative to the NwHIN specification reflects a faulty premise. Given the NwHIN use case to serve as a national backbone supporting loosely connected data exchange, relying on a SOAP-based approach is a better solution based on the requirements (not a matter of preference). A RESTful approach may be a "trend", but the rationale for its development needs to be validated. We recommend positioning the RESTful approach in the context of last-mile connectivity of mobile applications.

5. "NHIN Document Submission" should be rated the same under its Exchange name as it is in the context of Direct (XDR). It simply defines a PUSH transaction over SOAP, based on IHE XDR.
6. From their August and September meetings transcripts, we believe that the Power Team misunderstood how the NwHIN query/retrieve operates. There was mention about "return from a query several gigabytes of content when only the most recent image was desired". To the contrary, any XCA query implemented according to the standards does not return large sets of data, only pointers to those sets.
7. The Power Team discussion about why a specification gets a low or medium rating was constructive, but was not documented in these conclusions.

Detailed Comments and Recommendations

Methodology Notes – Industry Adoption

The Power Team measurement of industry adoption does not represent current support of deployed interoperability initiatives, nor do we believe it fully accounts for the actual barriers to adoption. These points were raised in August by the NwHIN Specification Factory, which includes NwHIN Exchange implementers such as DoD, VHA, SSA, and a significant numbers of HIEs. In particular, the NwHIN Messaging platform, the NHIN Patient Discovery specification, the NHIN Query for Documents, and the NHIN Retrieve Documents specifications have scores of "Low" for the industry adoption criteria. However, that ranking does not accurately reflect the availability of the underlying technology based on several objective criteria:

1. The IHE XCA and XCPD 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.)
2. Given this ubiquitous level of technological availability, we believe that policy and workflow issues impede larger health industry adoption of the NwHIN Exchange specifications. The Power Team should consider **vendor readiness**, in addition to industry adoption. (See Appendix on Vendor Readiness).
3. NwHIN Exchange specifications are being implemented by the Care Connectivity Consortium (Mayo Clinic, Geisinger, Kaiser Permanente, Intermountain Healthcare, and Group Health).

Therefore, in regards to the “HIT Standards Committee NwHIN Power Team, Updated Scores, Grids and DRAFT Recommendations-September 9, 2011” slides:

- **Point 2 of the Conclusions (slide 11) is incorrect, given the elements stated above and the live implementations listed in the Appendix. It should be reworded as “The Exchange specifications have been adopted beyond their pilots. They have been proven on a significant scale in production environments, across a broad range of healthcare organizations.”**

Power Team Charge and Meaningful Transport Building Blocks

There are different use cases (e.g., push, pull, subscribe) and different environments where there are no community-based HIEs, or NwHIN-connected HIEs. One key Stage 2 goal is to get **actual information exchanges flowing, using the standards for content and transport** (not just

"perform one test" as in Stage 1). So, we commend the Power Team for evaluating of candidate standards, and for the scope of its "charge" (copied below from the August 17 presentation by the Power Team). The key phrase is highlighted.

“Using the NwHIN Exchange and Direct Project specifications as primary inputs, recommend a building blocks approach that can be selectively combined and integrated to enable the ***trusted exchange of content in support of the meaningful use of electronic health record (EHR) technology.***”

We are concerned that the Team’s recommendations do not fully fulfill this charge. We acknowledge that, in some email exchanges, Power Team members explained that the charge from ONC was really just to review the Exchange and Direct Specifications. If that was the boundary, we are not faulting the Power Team for doing what was asked. However, we believe that the charge – as stated above – should have covered a broader spectrum of health information exchange. This could still have been done using NwHIN Exchange and Direct Project specifications as “primary inputs”, not the *only* inputs, recognizing other specifications used in community HIEs that are *very closely related* to NwHIN Exchange and which have much higher adoption than pure NwHIN Exchange specifications.

There seems to be a gap, for which we have the following suggestions:

1. Since the Power Team charge is to recommend transport/security/content building blocks for meaningful use of EHRs, **the scope should consider the very common use case of *community sharing HIE*** (aka "private, local, regional"), in addition to Direct and NwHIN Exchange. Community-based HIEs are equally legitimate as the means to exchange health information. Many of these HIEs use IHE XDS (included in HITSP TP13, which was mentioned, but did not seem to receive attention in the analysis). Several statewide HIEs also use XDS.
2. The Power Team’s report focuses heavily on Direct and NwHIN Exchange (different ends of the interoperability spectrum), but not the "middle ground" of community HIEs. As a result, it takes an overly pessimistic view of the maturity and adoption of widely-supported IHE standards like XDS which has been tested, implemented, and iteratively refined over several years (See Appendix on Industry Readiness). Additionally, this creates the perception that Direct is as least as mature, or even more mature and adopted, than the IHE profiles like XDS. However, Direct specifications were only finalized in the first quarter of 2011 and have not yet been recognized by any standards organization. Existence of SMTP technology in non-health IT systems like e-mail does not mean that it is widely adopted in healthcare.

We suggest the Power Team should meet its charge and cover the use cases that give the most “bang for the buck”, **using *healthcare industry adoption and vendor readiness as its yardstick.*** We therefore recommend the following use cases and technology (in order of the current level of adoption):

1. **Community-based HIE Query/Retrieve -- based on IHE XDS** (also in HITSP TP13), and supporting profiles for patient identifications management like PIX/PDQ

2. **Direct Project Push** -- as already included in the Power Team recommendation, including the SMTP core protocol, as well as the XDR/XDM for Direct Messaging specification
3. **NwHIN Exchange Query/Discovery/Retrieve** -- as already included in the Power Team recommendation

For query/retrieve use cases, our experience shows that the vast majority of the care transitions occur within a community, not across multiple communities. NwHIN cross-community access and patient discovery are certainly important, but limiting the scope of the recommendations to *only* Direct and NwHIN standards overlooks the most common and prevalent scenarios. We refer the Power Team to the EHR Association Transport Framework whitepaper which describes, compares, and positions the various protocols (Direct, XDM, XDR, XDS, XCA) relative to each other. Community Sharing is Use Case #4 in the whitepaper. (Go to www.himssehra.org/ASP/whitepapers.asp)

RESTful Alternatives and Adoption

Point 6 of the Conclusions (slide 14) is based on two faulty premises. The first one is that a given architectural style of designing **systems** is applicable to designing a **network**. The second one is that the creation of "new specification for RESTful exchange of clinical information" is simple and will improve adoption.

- It is important to understand that one of the main drivers of technology adoption within a particular software product is the support for that technology on the software development platform used for that product. The NwHIN Exchange specifications are based on technology with almost universal support among software platforms (from .NET and Java to PHP libraries).
- Unlike the SOAP-based specifications, which are supported in a very consistent way, as the Power Team points out, "not all "RESTful" implementations are implemented in the same way". A call for a new RESTful implementation must consider not only the user-facing EHR software, but also the foundational support within the development platform that supports it, as well as critical and careful consideration of timelines and resources required for successful adoption.

We believe that RESTful has a role to play, but not as an alternative to the NwHIN specification. Given the NwHIN Exchange use case to serve as a national backbone, federating across many different organizational boundaries with multiple layers of security and privacy policy, relying on a SOAP-based approach is a better fit, not simply a matter of preference. A RESTful approach may be a "trend" but the rationale for its development could be easily substantiated in the Power Team output. IHE is considering such a proposal for a new profile.

We recommend improving the clarity in the recommendation by proposing RESTful in the context of last-mile connectivity of mobile applications.

NwHIN Query/Retrieve Effectiveness

From the Power Team August and September meetings transcripts, we believe that the Power Team misunderstood how the NwHIN query/retrieve operates. There was mention about "return from a query several gigabytes of content when only the most recent image was desired". To the contrary, any XCA query implemented according to the standards does not return large sets of

data, only pointers to those sets. We are unsure how the testimony arrived at this conclusion and would welcome the opportunity to explain the standards in more technical detail. The use case of image access was never specified nor implemented by NwHIN, although it is supported by IHE content profiles (XCA-I and XDS-I), building upon the XCA/XDS in a very effective and selective way. This did not seem to be known by the Power Team, nor by those presenting the testimony from NwHIN exchange participation (DOD and VA), who stated that this was a current problem.

Therefore, with regard to the “HIT Standards Committee NwHIN Power Team, Updated Scores, Grids and DRAFT Recommendations-September 9, 2011” slides:

- **Point 1 of the Conclusions (slide 15) should be revised. The current NwHIN approach effectively supports the access to large sets of data, including images. This has been deployed by an NIH NIBIB project and is under evaluation.**

NwHIN Document Submission

On slide 8, "NHIN Document Submission" is placed in the “maturing” category, but should be in the “mature” category. This rating seems to be a misunderstanding of what the NwHIN Exchange document specifies. It simply defines a push transaction over SOAP, based on IHE XDR.

As it is specified as mature in the context of Direct, this specification should be rated the same under its Exchange name.

NHIN Patient Discovery

The 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 (an HL7V3 query similar to the Markle RLS). The complexity and problems come from the operational management associated with patient discovery in large-scale environments where there are no shared identifiers (i.e., different matching policies, updates, caching of IDs, etc.). Since the complexity does not lie in the specification, we urge the Power Team to recognize that any other specification in the same environment will result in the same complexity.

The Power Team should be aware that the NwHIN Patient Discovery is based on IHE-XCPD, which enables many models for patient matching, including several defined by leading experts in the field. Further, this model supports algorithms that can be adjusted over time based on changing policies, supporting the dynamic nature of patient identity policy, such as being worked out by a workgroup of the HIT Standards Committee. All of these algorithm changes are hidden from the requesting system through the service interface abstraction, thus making the interface independent of the algorithm. For example, with adequate policies, a much simpler mode of operation than the one used by NwHIN is supported when “shared patient ID”, (e.g., voluntary IDs) is used.

Contrary to the Power Team’s findings, the Patient Discovery Specification is not always implemented together with Query for Documents and Retrieve Documents. The point was made

several times by the Power Team members that Document Query and retrieve had to be considered together, which has no bearing on complexity. Unlike the close relationship between the Document Query and Retrieve, Patient Discovery operates quite independently of the others in live deployments today.

Therefore, with regard to the “HIT Standards Committee NwHIN Power Team, Updated Scores, Grids and DRAFT Recommendations-September 9, 2011” slides:

- **Fourth row, slide 4 - remove “Spec has problems”. As described above, the problems do not lie in the specification.**
- **Slide 13 - replace “The Exchange specifications are highly complex and present opportunities for simplification” with “The Exchange Specifications contain elements that could be simplified.”**
- **Slide 13 - remove fourth bullet which is not related to specification complexity: “NHIN Patient Discovery Specification – highly complex”**
- **Slide 13 - remove the last sub-bullet, “Because the Query for Documents, Patient Discovery, and Retrieve Documents specifications are usually implemented together, any alternatives should be considered within this context.”**

Documentation of the Rationale Supporting the Ratings

The Power Team discussion about why a specification gets a low or medium rating was constructive, but was not documented in these conclusions. Other groups cannot easily build upon this work, making the conclusions quite difficult to evaluate because the assumptions upon which they are based are not documented.

We recommend adding the rationale for each rating.

Additional Notes

On slide 4, "TLS over REST" is listed as an alternative to the NwHIN Authorization Framework. Given that TLS is required as part of the NwHIN Messaging Platform, it is not clear how "TLS over REST" can provide the additional functionality of the NwHIN Authorization Framework without re-inventing the SAML standard used there. TLS only provides system identity. The Authorization framework includes far more advanced security around the user context (e.g., federated identity, roles, locations, authentication method used, etc.), patient context (e.g., consent, authorization), and the purpose of the request. The effort to replicate this functionality within a RESTful specification is likely to be significant, and the implementations will be more prone to errors given the 'bleeding edge' state of the technology.

Appendix: Vendor Readiness

In [the EHR Association Transport Framework whitepaper](#), a survey of its members identified that more than 40 commercial EHRs are connected and operational in exchanging clinical information using NwHIN Exchange (IHE XCA), Direct (IHE XDR/XDM), and IHE XDS. We know that there are also several implementations supported by EHR suppliers that are not Association members. 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 71 customer sites that cover an estimated 35 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 Health Information Exchanges (HIE's) 30 using 1 or more IHE profiles in those exchanges; majority are utilizing HL7 push technology; 100 Implementations in progress surrounding HITSP C32 CCD Exchange; 1 utilizing full complement of IHE profiles for CCD Exchange; No NHIN Direct Customers to date; of our 2000 customers only 3 have asked for it; we are designing a solution - available 2012; The short comment is, that until NHIN Direct becomes a MU requirement, we are seeing little traction.

Vendor C: Has deployed live HIE configurations in eight communities and has another dozen in active implementation. These HIE's are based on the IHE XDS specifications (the same standard as NwHIN Exchange) connecting live 39 different vendor EHRs systems most of which offer this interoperability native off-the shelf. These HIE's cover more than 6 Million patients.

Vendor D: Has deployed 15 test HIE connectivity solutions in 12 HIE's 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 7 other HIE's.

Vendor E: Has "Connected" several RHIO's and is working with multiple State HIE Vendors, connecting hospitals and millions of patients to both HIE and Immunization Registries. Using the IHE XDS Profile, CCD's: Problems, Procedures, Meds, Med Allergies, Vitals, And Lab Results – 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: Currently has five sites in production utilizing CCD based documents for exchange of clinical data (over non-XDS transports) covering approximately 34K unique patients. Approximately 100K CCDs have been transported over these interfaces thus far. 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 implemented to handle the XDR based transport requirements. 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 70K. The number of unique patients in both HIEs totals to approximately 2M (these facts are a bit dated so numbers could be higher today). Is expecting to accelerate adoption quickly in other sites after the first two site implementations are complete. Is on the cusp of going live with an XDS based CCD exchange for immunization content to an Immunization Registry in California. Approximately 25K 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 has approximately 10 XDS capable HIEs on the near term implementation roadmap. This includes a variety of disparate infrastructure vendors as we achieve this type of scalable interoperability.

Vendor G: XDS/XDR interoperability solution (using IHE profiles upon which NwHIN Exchange specs 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 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: We currently do not have any customers who utilize any of the IHE profiles, and unfortunately we don't track to that level the interfaces we have installed. Currently, our customers who do participate with some type of Health Exchange feed just HL7 events /messages; typically ADTs and Lab results (ORU).

Vendor I: We are implementing the following IHE profiles on the state level.

PIF 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

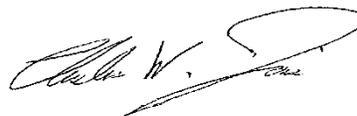
Provide CCD 32 via HL7 2.x MDM message over SOAP/TLS

Provide Immunization data via HL7 VXU^V04 over SOAP/TLS

Sincerely,

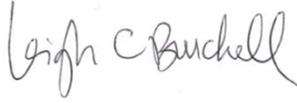


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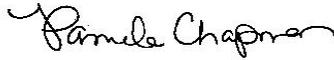
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About HIMSS EHR Association

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.himsschera.org>.