HIMSS Electronic Health Record Association

Supporting a Robust Health Information Exchange Strategy with a Pragmatic Transport Framework

An Electronic Health Record (EHR) Association White Paper

June 2011

Executive Summary

The EHR Association presents this white paper to promote a practical approach to health information data exchange. The Association supports the most recent interoperability standards regulations and associated policy work that have focused primarily on health data content, but is concerned that, without specific standards on how to transport this content, the health data exchange that is needed for the meaningful use of EHR systems will not be achieved. Our objective is to engage health IT stakeholders in an open dialog about how best to achieve real interoperability for the transport of health information. The white paper represents the collective view of EHR Association member companies who support the majority of installed, operational EHRs in the US. The focused recommendations in the white paper, aimed at key health IT stakeholders, are based on the use of proven standards, and build on the work that has been done by Integrating the Healthcare Enterprise (IHE), the Direct Project, and the Nationwide Health Information Network (NwHIN).

We present five primary transport use cases, the first three below in the category of point-to-point exchange, and the fourth and fifth in the category of health information sharing:

1. The **Blind "Push" to a Known Partner** use case involves sending documents to destination partners specifically identified by the sender. In this use case, the recipient systems need human intervention to understand the content and purpose of the communication, as there is no computer processable metadata, beyond the addressee and what may be provided informally "on the cover page". This use case is similar to fax communication in use today within healthcare.
2. The **Labeled Documents Pushed to Known Partners** use case improves workflow, as it goes beyond replacing basic fax capabilities. This data package includes sufficient labeling by the sender to allow the receiving system to derive the purpose of the communication without opening the sent documents.
3. The **Labeled Documents Delivered to Known Partner with Linked Patient** use case builds on the second use case by further strengthening the workflow surrounding the point-to-point exchange by including metadata that matches patient IDs across systems, and by notifying the sender if there is a failure in delivery.
4. By introducing "pull" via the **Community Sharing Health Information Exchange** use case, health information sharing is managed within a "community". The shared records are tagged with

metadata to be queried and retrieved. No geographic restrictions are placed on the boundary of such communities.

5. The **Nationwide Health Information Network Exchange** use case represents the ability to pull information across communities (such as those covered by use case 4 above).

All of these use cases take into consideration the utility of metadata, interaction with other systems (e.g., record locator systems, enterprise master person indices (EMPIs), and "edge systems"), and the protection of clinical context and patient privacy. The progression across the point-to-point and health information sharing use cases is not intended to be interpreted as a sequential deployment roadmap. Rather, it demonstrates a range of capabilities that helps with analyses of HIE requirements.

A number of industry and governmental initiatives have created standards and implementation specifications (guides or profiles) for the transport mechanisms that support the use cases identified above. They are:

- The Direct Project – focusing on the directed push use case, to enable simpler exchange variants
- Integrating the Healthcare Enterprise (IHE) – using and augmenting HL7 and other standards to create a number of implementation profiles that can support more advanced, including bi-directional and cross-community exchange
- The Nationwide Health Information Network Exchange (NwHIN) project – focusing on standards (many of which draw on the work of IHE) to enable a nationwide exchange network.

We believe that the collective accomplishments of these initiatives provide a strong foundation on which to build, considering lessons learned and innovations as the industry collaborates to meet our shared goals for effective, secure health information exchange that does not compromise patient privacy or clinician workflow. Continued national endorsement and deployment of these widely agreed upon capabilities extends from simple, directed push communication between two providers, all the way to dynamic share and "pull" communication across many provider organizations involved in a patient's care and secondary data analyses – first within a local community and then beyond that community.

The Transport Framework described in this document, as developed to date through the Direct Project, IHE, and the NwHIN Exchange, is shown to provide a substantial and practical foundation that supports key recommendations of the PCAST report.

Based on this Transport Framework, this white paper recommends an interoperability roadmap for health information exchanges (HIEs), personal health records (PHRs), and EHRs. A three-pronged approach is proposed:

- Deployment of Point-to-Point Transport Services for HIE (covering Use Cases 1, 2, and 3)
- Deployment of Community Health Information Sharing Transport Services (covering Use Case 4)
- Deployment of Nationwide Health Information Network Transport Services (covering Use Case 5)

This approach allows an "HIE project" at the national (or even state level) to start with any one of the above three approaches and evolves as driven by its use cases to ultimately support all three approaches to transport. These approaches, with their deployment model, may be combined to meet specific needs. This flexibility is based on the fact that each approach has been designed as part of the overall, standards-based Transport Framework described in the white paper. This strategy ensures that models used in production can be easily integrated when deployed independently, and become a consistent and robust national infrastructure that can be deployed bottom-up or top-down.

It is important to recognize that meaningful use Stage 1 is silent on transport methods. Eligible professionals (EPs) and eligible hospitals (EHs) may, therefore, conform with any of the approaches presented as part of this framework As the next stages of meaningful use provide an opportunity to become more explicit on data transport, the EHR Association urges that the HIT Policy Committee, the HIT Standards Committee, CMS, and ONC take advantage of the Cross-Systems Transport Framework presented in this paper to offer a cohesive interoperability roadmap for meaningful use Stage 2 (assumed start in 2013) and Stage 3 (assumed start in 2015). ***It is very important that clear Stage 3 roadmap requirements are announced no later than the Final Rules for Stage 2.***

A number of business use cases where the need for such a range of transport approaches is also discussed in this white paper. These businesses use cases cover public health and immunization reporting and inquiries, syndromic surveillance and notifiable/reportable lab results reporting, quality measurement and reporting, patient engagement, EHR/ PHR interaction, and care delivery.

The proposed framework is based on the critical elements defined by the ONC Standards and Interoperability Framework for standards readiness. A thorough examination is performed on the maturity of the specifications, availability of reference implementations, availability of test tools, maintenance of standards and implementation specifications, and finally, the availability of commercial products.

The Transport Framework proposed in this white paper delivers a low-cost entry point for both smaller provider and small vendor organizations, enabling a more rapid deployment than does the current state of uncertainty resulting from today's fragmented approach to transport in HIE projects. The proposed Cross-Systems **Transport Framework also offers an approach to interoperability that is neutral across all business models for health information interchange**, whether community HIE-centric, PHR-centric, or state/regional HIE-driven. New payment and delivery models, such as Accountable Care Organizations (ACOs) and patient-centered medical homes will require robust bi-directional exchange that can be tightly integrated into provider workflow. All these models can coexist while remaining interoperable for the ultimate benefit of the patient and consumer.

As often stated by ONC leadership, no single transport solution can address the expected range of mainstream information exchange use cases. **Failing to deploy the right transport service for a given use case** (as needed by clinical, personal, research, and public health IT use cases) **will add unnecessary complexity to the communicating systems and negatively impede provider and patient workflows**. **A short-term approach to health information exchange transport that is overly reliant on point-to-point solutions will fail to meet the nation's challenges** and miss the opportunity to take advantage of a

broader range of standards, existing capabilities, and infrastructure in which the industry is already invested.

In presenting a practical approach for the transport and exchange of health information and a comprehensive framework that supports the five key transport use cases, it is the EHR Association's[1] goal to provide clarity to policymakers, providers, and other stakeholders as we work toward broad consensus.

Introduction

The EHR Association presents this white paper to promote a practical approach to health information data exchange. The most recent interoperability standards regulations and associated policy work have focused primarily on health data content. This is important but, without specific standards on how to transport this content, the health data exchange that is needed for the meaningful use of EHR systems will not be achieved. This white paper represents the collective view of EHR Association member companies who support the majority of installed, operational EHRs in the US.

The purpose of this white paper is to inform health IT stakeholders about interoperability options provided by coordinated use of Integrating the Healthcare Enterprise (IHE), the Direct Project, and the Nationwide Health Information Network (NwHIN). It further describes the relationship of those options to the proposals in the President's Council of Advisors on Science and Technology (PCAST) report of December 2010. Such stakeholders include:

- The Office of the National Coordinator (ONC),
- Health Information Technology Policy Committee (HIT-PC),
- Health Information Technology Standards Committee (HIT-SC)
- Entities responsible for the management and creation of health information exchanges (HIE)
- Health professionals and their associations
- Electronic health record system developers, including those from the EHR Association membership

[1] At the time of publication, the members of the EHR Association (www.himssehra.org) include the following companies: AllMeds, Inc., Allscripts Healthcare Solutions, Amazing Charts, Aprima Medical Software, Inc., BlueWare, Inc., Cerner Corporation, CPSI, CureMD, digiChart, Inc., digitalMD Systems, eClinicalWorks, e-MDs, Epic, GE Healthcare IT, GEMMS, Inc., gloStream, Inc., Greenway Medical Technologies, Healthcare Management Systems, Inc., Healthland, HealthPort, Lake Superior Software (LSS) Data Systems, MacPractice, Inc., McKesson Corporation, MED3OOO, Inc., MedcomSoft, MEDHOST, Inc., MediServe Information Systems, Inc., MEDITECH, Inc., NexTech Systems Inc., NextGen Healthcare, Noteworthy Medical Systems, Pulse Systems Inc., QuadraMed, Sage, Sevocity- Division of Conceptual Mindworks, Inc., Siemens, Spring Medical Systems, Inc., SRS Software, LLC, STI Computer Services, Suncoast Solutions, UNI/CARE Systems, Inc., VersaSuite, Workflow.com, LLC, Xpress Technologies.

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A. Information Exchange Transport Use Cases

Throughout the healthcare industry, a number of business use cases have emerged that identify varying approaches to health information exchange (HIE) between providers (physicians and hospitals), as well as between providers and their patients. Although the number of business use cases is large, only a few transport use cases have been identified as necessary to support those business use cases. We have attempted to segment these five different health information transport use cases under two deployment models. To varying degrees, each of these uses cases relies on metadata associated with the content being exchanged.[2]

- ***Point-to-Point Exchange:*** Three transport use cases
- ***Health Information Sharing:*** Two transport use cases

Point-to-Point Exchange

Point-to-point exchanges deal with use cases where information is directed between known parties: for example, send information from Party A to Party B. In these cases, parties exchanging data are expected to be trusted by each other based on agreement to a number of policy, legal, and data handling guidelines (including patient identification matching algorithms). These communications may be patient

[2] Metadata is defined as data providing information about one or more aspects of the data, such as means of creation of the data, purpose of the data, time and date of creation, creator or author of data, placement on a computer network where the data was created, and standards used. Metadata describes business objects in various enterprise systems and applications and may be persisted to facilitate information search.

to provider, provider to provider, provider to patient, or from a patient's tethered to un-tethered personal health record (PHR). [3]

Three use cases can be distinguished:

1. **Blind "Push" to a Known Partner**
   This transport use case involves directed push of a document from one system to an identified receiving partner, where the recipient systems need human intervention to understand the content and purpose of the communication. This use case is similar to fax communications in use today within the healthcare, where metadata beyond the addressee is provided informally "on the cover page". This transport can be specifically characterized as follows:
   - The communication is pushed to a specific destination address and contains typically a single document.
   - The document's purpose and content is unknown to the receiving computer system (no metadata) until successfully opened on the receiver side.
   - If there are content processing errors, the sender may never realize that the communication failed.
   - Patient identification (ID) association must be performed once the document content has been successfully opened by the receiver and depends on the document format. Such identification often requires manual processes.
   - Managing the consent to release the information is the sender's responsibility, and has to be assumed by the receiver through prearranged policy agreements between the parties.
   - Accounting of disclosure is not integral to the exchange model.

2. **Labeled Documents Pushed to Known Partners**
   The second transport use case improves workflow, as it goes beyond replacing basic fax capabilities. This data package sent includes sufficient labeling to derive the purpose of the communication without opening sent documents.
   - Document content is pushed and the format/clinical purpose can be known before content is successfully opened on the receiver side.
   - Several documents may be conveyed in a single exchange and each is "labeled" with metadata.
   - The purpose of transaction may be known at a high-level, providing the opportunity for the receiver to reject or appropriately route the communication. The full detail is known once the document is opened.
   - In case of content processing errors, the sender may never realize that there was a failed communication.
   - Patient ID association may be performed from the metadata before the document content is opened on the receiver side, using either automatic or manual processes.

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[3] See John Halamka, MD blog on PCAST Use Cases: http://geekdoctor.blogspot.com/2011/03/pcast-use-cases.html

- Consent to release the information is the sender's responsibility, and may be included in the document set with metadata identification so that it can be accessed before the document is actually opened.
- Accounting of disclosure is not integral to the exchange model.

3. Labeled Documents Delivered to Known Partner with Linked Patient

This third transport use case builds on the second use case by further strengthening the workflow surrounding the point-to-point exchange in two major ways:

- The documents are labeled and identification contained in metadata is matched to a patient ID (or patient identification process) that is linked to the same patient in both systems.
- An end-to-end service with online acknowledgement ensures that, in case of content processing errors (e.g., receiver rejects document for whatever reason), the sender will know of rejection by the receiver.
- Accounting of disclosure is, again, not integral to the exchange model.

Health Information Sharing

With health information sharing, the focus expands to include transport use cases that enable dynamic sharing of information where the source makes documents available (via publishing) and any number of receivers may pull (via queries for and access to) documents when they have a legitimate need for and interest in access. Scenarios included range from a provider searching for the patient's records for a patient presenting at an emergency department to queries for de-identified aggregate data mining. These scenarios, like the first three, were considered by the HIT Policy Committee PCAST Work Group and described by John D. Halamka, MD on his blog[4]. This type of health information exchange involves known systems in a geographical, organizational, or virtual community (e.g., regional, provider health system, patient controlled health record system, etc.). Information sharing may begin in a single community of exchange and subsequently propagate outwards to span several communities across the nation. In these scenarios, relationships are one-to-many and data is shared so that discrete data contributed may be retrieved in a discrete form (i.e., bi-directional HIE[5]).

4. Community Sharing Health Information Exchange

In this fourth transport use case, health information sharing is managed within a "community". No geographic restrictions, however, are placed on the boundary of such communities.

- The communities may include a geographic area, any form of integrated care delivery system, users and contributors to a patient controlled health record, and many others.

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[4] http://geekdoctor.blogspot.com/2011/03/pcast-use-cases.html

[5] "Bi-directional HIE" is a loosely defined concept that generally refers to architectures where data is sent to the HIE infrastructure and can be retrieved in structured form by multiple other users/edge systems, thus enabling import and clinical decision support in EHRs. This approach contrasts with many exchange architectures, including those that support only push/e-mail or approaches wherein shared information may only be accessed by viewing through a web browser (central database and web application server) and the accessed data cannot be consumed into an EHR system.

- There are usually many partners in communication, including primary care providers, hospitals, specialists and patients, sharing data based upon an agreed patient identification management scheme.
- Health records shared are labeled with metadata that allows for clinical context of the document to be processed in receiving systems' workflows.
- Information sources (e.g., point of care systems) share standardized content in a secured way.
- Critical to this ability to share are lightweight centralized services, such as record locator services and patient identification linkage services (e.g., EMPI).
- Communities may include centralized data repositories among the shared services or retain data in existing information sources (distributed data).
- In many cases, the community exchange model is designed so that, as needed initially or at a later time, data can be shared across communities using standards-based exchange models that are complimentary to the intra-community exchange (See Transport Use Case 5).
- The security approach ensures system-to-system encryption between trusted systems, and privacy under patient control by expression and exchange of consent to release and/or access health information that provides simple to manage segmentation that patients will understand and control (e.g., by shared document, or output from an encounter).

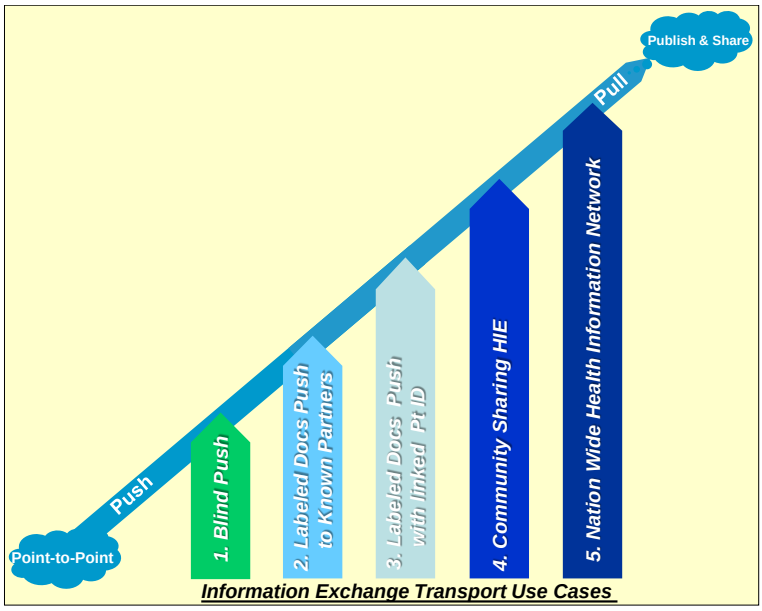
5. Nationwide Health Information Network Exchange

This transport use case represents the exchange of information across communities (such as those covered by Use Case 4 above).

- This use case requires a level of trust to connect community HIEs by bridging the distance from community (irrespective of its nature)-level exchange to the regional or national level, and fully realizing a network of networks.
- The communities HIEs that exchange information in this use case may include a variety of types of HIEs, including any form of integrated care delivery system, patient controlled health record, and many others.
- Health records are labeled with metadata that allows for clinical context of the documents to be queried and relevant documents retrieved.
- This access may be performed in a targeted way by query/retrieve to a specific source or by broadcast of queries to any community HIEs without the need for any centralized services, such as record locator access and patient identification linkage services (e.g., EMPI).
- Security measures ensure network-to-network encryption among trusted systems, and privacy under patient control by expression and exchange of consent to release and/or access health information that may span multiple communities/networks.

This progression across the point-to-point and health information sharing use cases is not intended to be interpreted as a sequential deployment roadmap. Rather it demonstrates a range of capabilities that helps with analyses of HIE transport requirements.

Figure 1: Five Transport Use Cases



Each one of these transport use cases is in operational use today. This white paper proposes a coherent approach to addressing these individual use cases by first reviewing the solutions selected by the most visible industry and governmental initiatives in this area and then proposing to assemble the chosen standards and implementation specifications in a consistent Cross-Systems Transport Framework.

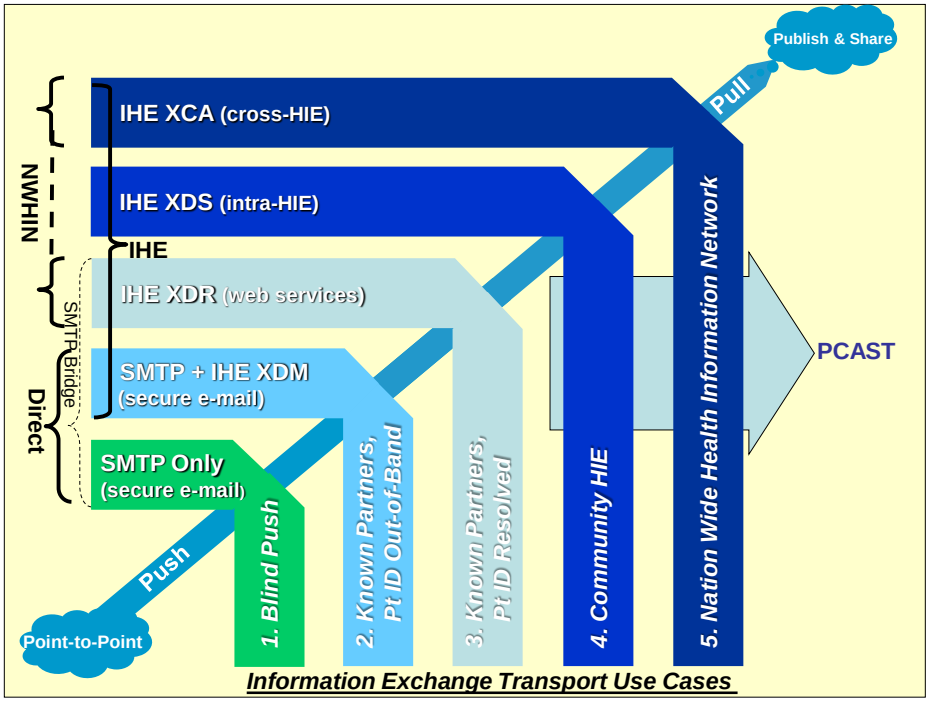
B. Cross-Systems Transport Framework

A number of industry and governmental initiatives have created standards and implementation specifications (guides or profiles) for the transport mechanisms to support the use cases identified above. They are:

- The Direct Project – focusing on the directed push use case, to enable simpler exchange variants
- Integrating the Healthcare Enterprise (IHE) – using and augmenting HL7 and other standards to create a number of implementation profiles that can support more advanced bi-directional and cross-community exchange
- The Nationwide Health Information Network Exchange project – focusing on standards to enable a nationwide exchange network, many of which draw on the work of IHE

The following sections describe these contributions in more detail and place them in perspective. Used in concert, these exchange approaches can form a cohesive and robust transport framework as depicted in the figure below. The contributions analyzed in this section provide a set of transport service solutions addressing each one of the five transport use case introduced in Section A.

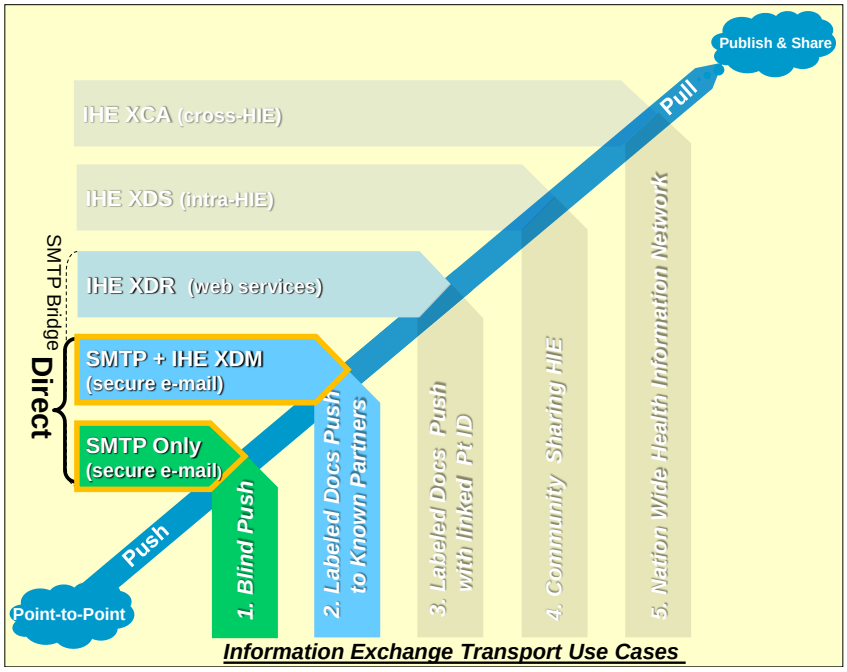
Figure 2: Mapping Transport Use Case and Supporting Transport Framework



The Direct Project

The Direct Project is an ONC-sponsored project (http://directproject.org) to create the set of standards and services that enable simple, directed, routed, scalable, and secure transport over the Internet to be used for exchange between known participants in support of meaningful use (MU) of EHRs. The Direct Project can be placed in the cross-system transport framework and is in the lower left quadrant of the following diagram:

Figure 3: Direct Project and Mapping to Transport Use Cases



The Direct Project introduced an SMTP[6]-only exchange mechanism to support Use Case 1, *Blind Push*, and recommended SMTP + IHE XDM as the *preferred* exchange mechanism for these purposes. It also established guidance on an SMTP bridge to enable IHE XDR-based exchanges to connect.

The Direct Project's intent is to work in concert with other exchange methodologies already in place and to offer a simple methodology to connect where none already exists. Its key features are that it is:

- Basic: It connects health stakeholders through universal addressing using simple push of information.
- Secure: Users can easily verify messages are complete and not tampered with in transit.
- Scalable: Deployment is facilitated with the addition of Health Information Service Providers (HISP).
- Standards-based: Built on common Internet standards for secure e-mail communication.

[6] SMTP is the standard used for almost all internet e-mail.

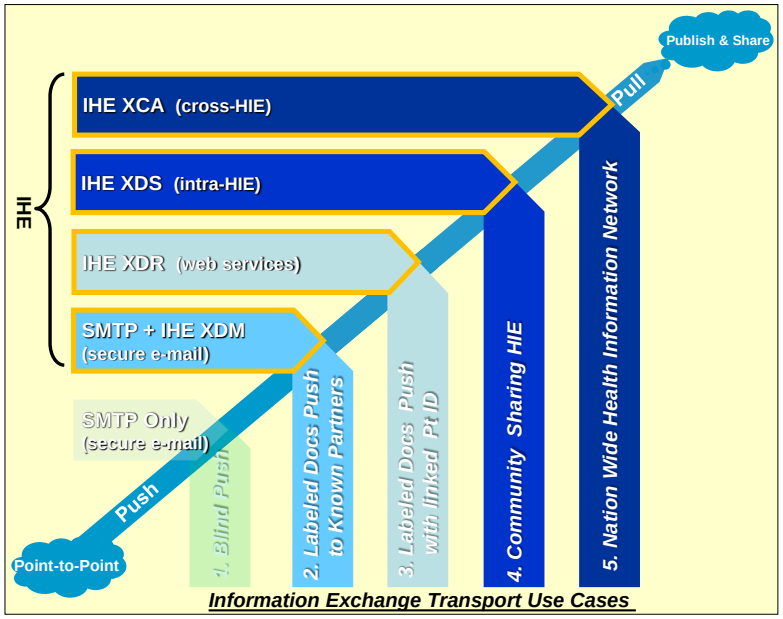
The Direct structure involves obtaining an e-mail-like Direct Address and a security certificate. The sender transmits the content (usually one document) securely using most e-mail clients or via contract with a HISP that performs authentication, encryption, and trust verification on the sender's behalf. Many HIEs are starting to offer this Direct HISP service.

As a result, the Direct Project provides a very useful and scalable entry point to begin exchange across providers without substantial upfront infrastructure investments or complex privacy consent structures. The latter are needed to support the more advanced exchange use cases. Direct supports two of the five transport uses cases of the cross-system framework (e-mail only and recommended XDM + e-mail). Direct (e-mail only), however, has several limitations, including the need for manual handling, especially by the receivers (See Section A, Use Case 1: *Blind Push to Known Partners*) and lack of automated integration into provider workflow. This limitation follows from the fact that, there are no guaranteed metadata to establish the purpose of the payload or to match the patient associated with the payload to those patients known to the receiver, without the receiver examining that payload.

The IHE Contribution

IHE (www.ihe.net) has created a set of transport profiles (implementation specifications) that support a number of use cases depicted in the following diagram:

Figure 4: Mapping Transport Use Cases to IHE Profiles



These profiles and specifications have been adopted by several national and regional HIT projects around the world. They include:

- Cross-Enterprise Document Media Exchange (XDM-e-mail), which supports Use Case 2, *Labeled Documents Pushed to Known Partners*, where the partners are known, the document is metadata-tagged, and the patient is identified according to the sender.
- Cross-Enterprise Reliable Exchange (XDR) with Patient Identification Reconciliation (PIX/PDQ), which supports Use Case 3, *Labeled Documents Pushed to Known Partners with Patient*

Identification Resolved, building on XDM by providing the ability to reconcile the patient identifiers across partners and offer exchange as a web service.

- Cross-Enterprise Document Sharing (XDS) supports Use Case 4, *Community Sharing Health Information Exchange*, moving from a directed push paradigm into the dynamic share and pull paradigm. Metadata-tagged documents are registered and thus searchable for participating partners, typically within an HIE or Integrated Delivery Network (IDN). The PIX and PDQ profiles are used here as well to reconcile patient identifiers across partners.
- Cross-Community Exchange (XCA) supports Use Case 5, *Nationwide Health Information Network Exchange*, taking the next step and enabling exchange across multiple communities such as multiple HIEs or IDNs that can take the exchange nation-wide. The Cross-Community Patient Discovery (XCPD) profile is now used as a lightweight record locator service to determine which HIE has the patient's documents of interest.

Various combinations of these capabilities are supported today by over 200 US and international infrastructure and clinical IT products (see http://www.ihe.net/connectathon_results), including open source solutions (e.g., Open Health Tools, CONNECT, NIST, Open HIE, Microsoft). See Section D - Implementation Maturity.

The Nationwide Health Information Network Exchange Contribution

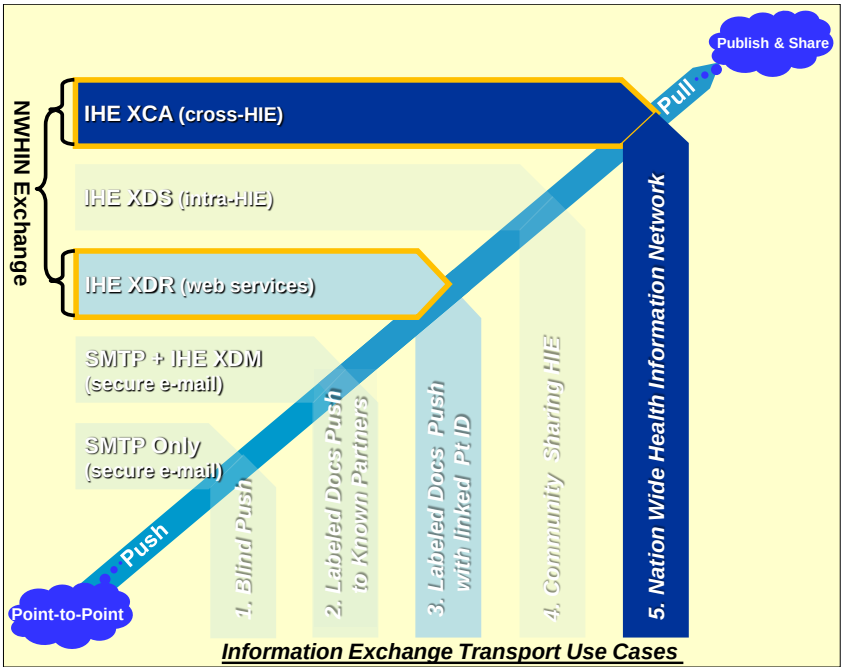
The Nationwide Health Information Network Exchange (formerly "NHIN" and now NwHIN)) is an ONC-sponsored project that ties together health information exchanges, integrated delivery networks, pharmacies, government, labs, providers, etc.

The NwHIN is a set of standards, services, and policies that enable secure health information exchange over the Internet. A group of federal agencies, local, regional, and state-level HIE organizations and IDNs has been helping to develop the network standards, services, and policies. These organizations are demonstrating live health information exchange through the NwHIN today. For more information, see http://www.hhs.gov/healthit/healthnetwork/background/.

The standards and profiles selected by the NwHIN extend the IHE XCA and XCPD profiles for document query and retrieval, while using IHE XDR for point-to-point exchange.

ONC has indicated that participation in the NwHIN Exchange model could be greatly expanded with participation rules and process changes to be in place by the end of 2011.

Figure 5: NwHIN Mapping to Use Cases and IHE Profiles



Entities participating in NwHIN Exchange today include:

- Social Security Administration (SSA) contracts – awarded to 15 organizations
- Kaiser Permanente interconnection to the Veterans Administration
- Beacon Communities
- ONC - State HIE Cooperative Agreements
- Centers for Disease Control and Prevention contracts to receive bio-surveillance data
- CMS' Care Health Information Exchange Project (C-HIEP) contracts to receive de-identified data for quality assessment purposes
- Other federal contracts, grants, or cooperative agreements that include participation in the NwHIN Exchange as part of their scope of activities

CONNECT is a set of free, open source software solutions, associated with the NwHIN project, that supports health information exchange – both within a community and across communities at the national level. CONNECT uses NwHIN exchange standards, services, and policies to make sure that HIEs are compatible with other exchanges being set up throughout the country. CONNECT is broader than NwHIN and also includes, for example, open source support for community HIE with implementation of the document registry/repository for the IHE-XDS profile. CONNECT is the result of a unique collaboration among federal agencies that is coordinated through the Federal Health Architecture program under ONC. For more information on CONNECT, see http://www.connectopensource.org/ and http://www.connectopensource.org/adopters.

The Need for an Overall Cross-System Transport Framework

This white paper proposes a **cross-systems transport framework with significant reuse** of specification modules across all use cases:

- Two transport interaction approaches are supported: e-mail for Direct (e-mail only and e-mail +XDM) and Web Services for XDR, XDS and XCA.
- The query and retrieve models for community sharing (XDS) and nationwide pull (XCA) are identical.
- The publication transactions for point-to-point (XDR) and community sharing (XDS) are identical.
- The metadata definition used in XDM, XDR, XDS, and XCA is also the same.

As stated above, the document content standards set by meaningful use Stage 1, and expected for Stages 2 and 3, can be used across all transport use cases. Although the PCAST[7] report on health IT has been interpreted by some as rejecting packaging of discrete data elements into documents, its authors have provided a more nuanced view at a HIT Policy Committee hearing[8] on this report.

The transport framework proposed in this white paper delivers a low-cost entry point for both the smaller provider and small vendor organizations, enabling a more rapid deployment than does the current state of uncertainty resulting from today's fragmented approach to transport in HIE projects. The proposed cross-systems transport framework also offers an approach to interoperability that is neutral across all business models for health information interchange, whether community HIE-centric, PHR-centric, or state/regional HIE-driven. All these models can coexist while remaining interoperable for the ultimate benefit of the patient and consumer.

As often stated by ONC leadership, no single transport solution can address the expected range of mainstream information exchange use cases. Failing to deploy the right transport service for a given use case (as needed by clinical, personal, research, and public health IT use cases) will add unnecessary complexity to the communicating systems and negatively impede provider and patient workflows. A short-term approach to health information exchange transport that is overly reliant on point-to-point solutions will fail to take advantage of a broader range of standards, existing capabilities, and infrastructure in which the industry is already invested.

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[7] Go to http://www.whitehouse.gov/administration/eop/ostp/pcast/docsreports for the full report.

[8] The HITPC presentation on the PCAST report can be found at http://healthit.hhs.gov/portal/. Moreover, Wes Rishel of Gartner and a member of the HITSC has also stated that document packaging was useful: http://blogs.gartner.com/wes_rishel/2011/02/13/pcast-documents-vs-atomic-data-elements/.

C. The PCAST Report and the Proposed Cross-System Transport Framework

The vision described in the PCAST report on health IT addresses the need to dynamically "pull" data for one or more patients from multiple EHRs. These requests would be based on metadata tagging to support queries. Metadata tagging enables the requestor to utilize the results for both care delivery and secondary uses of data. Since the report's publication, much debate has taken place about the intended and appropriate level of granularity of the metadata tagging, the opportunities presented compared with existing capabilities, and the many challenges involving patient safety, patient identification, and privacy/security.

The EHR Association supports the PCAST report's main vision, but has expressed concerns in a number of areas:

- The proposed seemingly very fine (i.e., atomic) level of data granularity has a high risk of losing critical clinical and patient context.
- Privacy/security may be compromised when sensitive patient data is included in data that can be accessed and stored in Internet-based search engines.
- Embedding privacy and security access controls inside clinical data. See this related blog post for further commentary: http://healthcaresecprivacy.blogspot.com/2011/03/access-controls-around-pcast-use-cases.html).

Many of the public comments received by ONC on the PCAST report were consistent with the EHR Association's feedback, expressing concerns with the proposed implementation approach. For a more detailed analysis, see the EHR Association's response[9] to the HIT Policy Committee and other comments from various EHR Association members, as well as from providers such as Kaiser Permanente[10]. The EHR Association has shared with ONC an approach that meets the PCAST objectives with a different solution design that could be done more quickly and delivers more advantages[11]. This approach is based on the Transport Framework presented in this white paper.

The EHR Association suggests that the Transport Framework described in this document, as developed to date through the Direct Project, IHE, and the NwHIN Exchange, provides a substantial and practical foundation that supports key recommendations of the PCAST report.

- Cross-Enterprise Document Sharing (XDS) provides a mechanism to share documents across provider organizations, typically focused within a local community such as an IDN or region,

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[9] EHR Association Response to Public Comments request from ONC: http://www.himssehra.org/docs/20110124_EHR_AssociationResponsePCAST_Report.pdf

[10] Kaiser Permanente Response to Public Comments request from ONC: http://www.regulations.gov/#!documentDetail;D=HHS-OS-2010-0030-0095

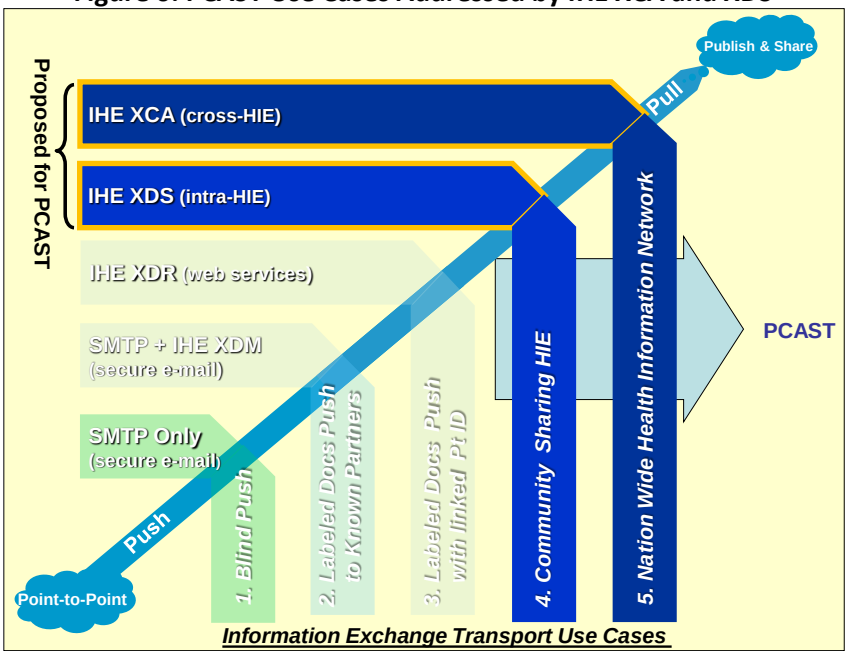
[11] EHR Association: Achieving PCAST Objectives with Existing Solutions: http://www.himssehra.org/docs/201104_EHRA_PCAST_Objectives.pdf

using metadata tagging to facilitate locating appropriate documents meeting the provider's search.

- Cross-Community Exchange (XCA) extends this capability by enabling sharing across communities and provides queries to other communities that may have data on the patient. The NwHIN Exchange specifications are based on this mechanism.

Consequently, the EHR Association suggests that the most critical aspects of the PCAST report's vision can be achieved by adopting and building upon the XDS and XCA profiles specifications and underlying standards. This approach is presented in the following diagram:

Figure 6: PCAST Use Cases Addressed by IHE XCA and XDS



Benefits of building on the existing, proven framework are:

- XDS and XCA define proven metadata tagging for document discovery and enables robust interoperability among HIEs and between HIEs and EHRs. This approach uses a generic level of metadata-tagging that is document content independent.
- Document content specific multi-level tagging, as supported by CDA documents already specified by Stage 1 (HITSP C32 and CDD).
- Metadata-tagged document sharing has been evaluated and is deployed by several HIEs as well as national and regional programs around the world.
- There is extensive open source software (Open Health Tools, NIST, Microsoft, MOSS, etc.), supporting many HIE infrastructure products, and EHRs from small and large vendors, with robust NIST test tools used by international programs.
- New payment and delivery models, such as Accountable Care Organizations (ACOs) and patient-centered medical homes will require robust bi-directional exchange that can be tightly integrated into provider workflow.

Continued national endorsement and deployment of these widely agreed upon capabilities extends the logical progression from simple, directed push communication between two providers, all the way to dynamic share and "pull" communication across many provider organizations involved in a patient's care -- first within a local community and then beyond that community. The benefits of this logical progression include:

- The opportunity to start simple, and incrementally expand existing communication paradigms while re-using components deployed in prior steps.
- Propagation of a common data model for content whether the content is part of simple, directed communication or part of queries across providers.

We recommend accelerating existing efforts that focus on sharing metadata-tagged data packaged in documents (e.g., the CCD). These documents, and the expected outcome of the CDA template consolidation project by the ONC-led Standards and Interoperability Framework Initiative (S&I) provide additional metadata tagging capabilities. This strategy will result in greater structured access to individual data elements where the requesting IT system can filter and aggregate these data elements as needed. This approach maintains patient context while providing "molecular" and "atomic" levels of granularity as needed. It has several advantages:

- Reduced risks to patient safety.
- Consistency with provider workflow and cognitive processes.
- Consistency with the current NwHIN Exchange design.
- No need for "rip and replace" or use of complex gateways for existing health IT systems.
- Fully leveraging the Stage 1 meaningful use investment in CCD/C32.
- A ready "on ramp" for providers as well as health IT developers and vendors.
- The IHE profiles have been implemented by close to 200 health IT products around the world, including a number of open source solutions, many already in production in the US.
- Test tools have already been developed by NIST and are widely used in IHE Connectathons (i.e., interoperability testing events).
- Most HIE and EHR vendors in the US are familiar with these profiles, so this strategy can be rolled out rapidly.
- This approach is consistent with several other international and regional health IT projects around the world including EU-Level epSOS, Austria, France, Japan, China, Switzerland, Luxemburg, NHS Wales, etc.

As the industry deploys and enhances this framework, the EHR Association recognizes that other data sets beyond documents may be identified that have potential value for dynamic exchange, while preserving appropriate context. *The Association believes that, in cooperation with ONC, IHE, and the underlying standards organizations, the framework described in this document is expandable to accommodate those new data sets, rather than building such capabilities "from scratch", creating a new and different data model, new and different vocabularies, or new and different standards.*

D. Recommended Interoperability Roadmap for HIEs, PHRs and EHRs

When health information exchange needs to be organized within a community, state, nationwide, or any other constituency (e.g., IDN, consumers, etc.), several factors must be considered:

1. Minimizing the need for healthcare-specific communication technology (e.g., leveraging the Internet and industry-agnostic standards as much as possible)
2. Providing cost effective approaches for health IT infrastructures that enable robust health information exchange
3. Supporting a flexible range of health information transport mechanisms
4. Use of proven health information transport interoperability standards and profile specifications that are flexible and neutral in terms of the business models and deployment of the transport infrastructure (geographical multi-stakeholder HIEs, state HIEs, PHR-driven HIEs, IDN-type HIEs, etc.)
5. Ensuring support for bi-directional exchange[12] within existing health IT applications and provider workflows to support access to health information for clinical decision-making, quality and public health reporting, and research
6. Simplifying the interfaces between EHR systems and other health IT systems with HIE infrastructure through standards and profiles
7. Providing robust security and privacy controls that are understandable by patients.
8. Ensuring that real-world clinical workflows are automated by the use of payload metadata (clinical context, document class, provider info, etc.).

To support a health information organization that is responsible for deploying such a robust, bi-directional HIE infrastructure, we propose a roadmap that is based on the standards and profiles recommended in this white paper and that meets the eight principles listed above. This roadmap supports the five use cases presented in Section A, and leverages the standards and profiles identified in Section B. To ensure consistency among various HIE projects across the nation where any of the transport use cases may be deployed over time, three deployment models are considered:

1. Point-to-point exchanges (support of Use Cases 1-3)
2. HIE community sharing (support of Use Case 4)
3. NwHIN Exchange (support of Use Case 5)

[12] "Bi-directional HIE" is a loosely defined concept that generally refers to architectures where data is sent to the HIE infrastructure and can be retrieved in structured form by multiple other users/edge systems, thus enabling import and clinical decision support in EHRs. This approach contrasts with many exchange architectures, including those that support only push/e-mail or approaches wherein shared information may only be accessed by viewing through a web browser (central database and web application server) and the accessed data cannot be consumed into an her system.

Each model described below is specific about the standards and profiles specifications used, and suggests how to achieve maximum flexibility in the deployment of each project, both for the HIE infrastructure and the systems connected to the HIE infrastructure (edge systems).

Deployment of Point-to-Point Transport Services for HIE

The figure and table below focus on deployment of two transport services for health information transport for the three point-to-point transport use cases (see Use Cases 1-3 in Section A of this white paper). The table lists the standards and profiles for the infrastructure systems offering the transport services in the first column, and the second column identifies the standards and profiles to be supported by the edge systems. The figure below presents a subset of the point-to-point information flows that may be used.

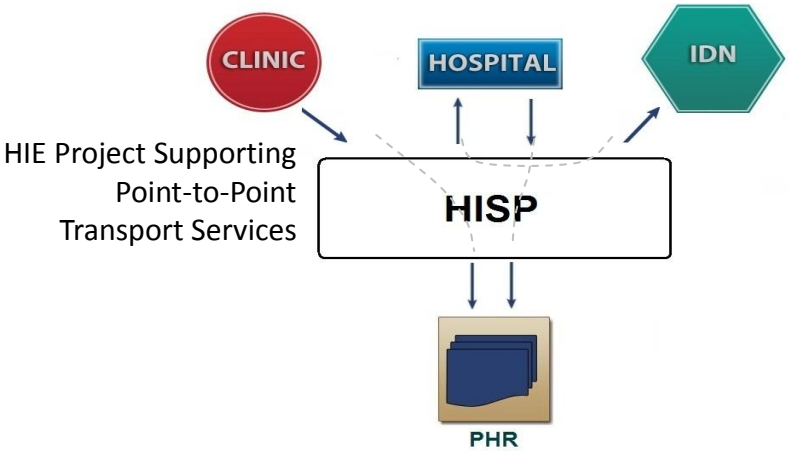


Figure 7: Point-to-Point Transport

Standards and Profiles Supported by the Transport Services	Standards and Profiles Supported by the Edge Systems
HIE infrastructure shall support both[13]: 1. Push/Direct e-mail (SMTP only and SMTP with XDM) 2. Point-to-point (XDR)	EHRs and PHRs should implement either: 1. Direct/XDM push and create metadata[14] automatically to simplify recipient workflow 2. XDR point-to-point to/from HIE

[13] The Framework proposes that HIEs support or plan to support not only Direct, but also XDR so that edge systems may interface with either, and are offered more flexibility. This approach is used by several Direct pilot sites such as the MedAllies HIE implementation experience.

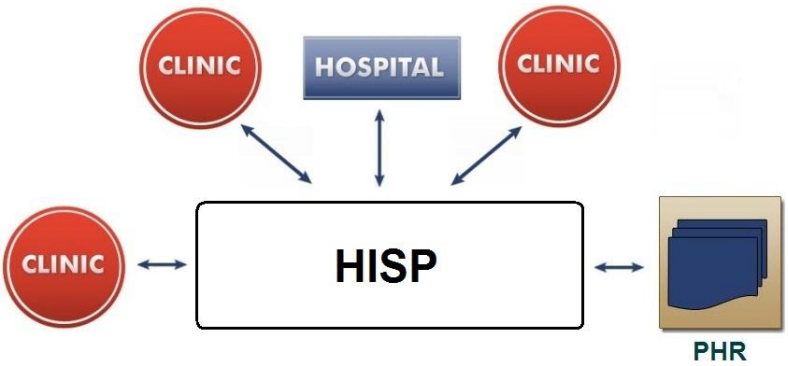
[14] Such metadata would include source provider name and type of health facility, class and precise type of document, service date and time, source care setting, format of document, and would be created by the sending system either by configuration or extraction from the document.

The strategy proposed above allows an "HIE project" to support all three point-to-point use cases by offering an infrastructure with a HISP capable of both Direct SMTP-only and point-to-point XDR transport service (including the Direct bridge between them). As a result, EHRs and PHRs may implement either one. Patients with access to Internet-connected computers could use either Direct with their existing e-mail clients but could more likely take advantage of patient portals or cloud-based patient health records that directly or indirectly support secure, HIPAA-compliant messaging, including Direct and XDR.

Deployment of Community Health Information Sharing Transport Services

The figure and table below focus on the deployment of the service for health information transport for the community health information sharing use case (see Use Case 4 in Section A of this white paper). The table lists the standards and profiles for the infrastructure systems offering the transport service in the first column, and the second column identifies the standards and profiles to be supported by the edge systems.

Figure 8: Community HIE Sharing Transport



Standards and Profiles Supported by the Transport Services	Standards and Profiles Supported by the Edge Systems
PHR/state/regional community sharing shall support XDS, PIX, and the associated IHE security and privacy profiles.	EHRs[15] and PHRs shall support XDS, PIX[16], and the associated IHE security and privacy profiles

[15] The case of interoperability to or from an Integrated Delivery Network may be approached in two ways. Either the entire IDN is considered a single EHR (although multi-site) and appears as an edge system in a community HIE as discussed in this section. Alternatively, the IDN may choose to form a community by itself and appears as a community HIE using the transport services to interconnect community HIEs as addressed by the NwHIN transport services deployment model discussed in the next paragraph.

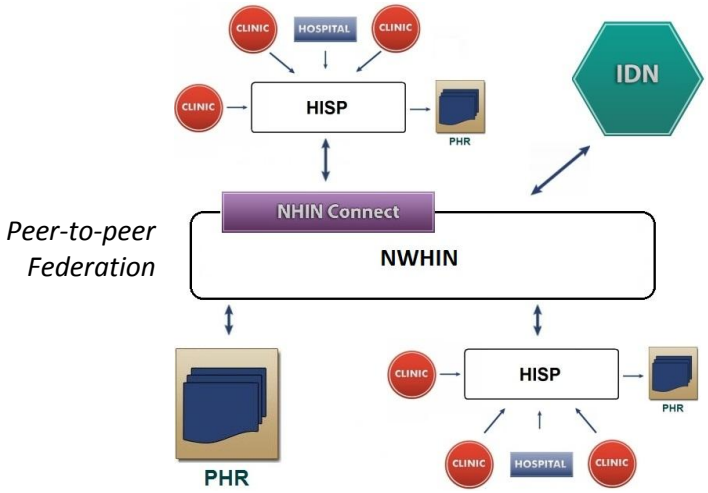
[16] IHE offers PIX (based on HL7 V2) and PIXV3 based on HL7 V3. A choice between these would have to be made, allowing the widest product adoption to facilitate deployment.

The strategy proposed above allows an "HIE project" to support the community sharing use cases by offering a lightweight infrastructure (XDS registry and PIX manager). The EHRs and PHRs implementing these standard transactions (provide-and-register metadata, query/retrieve) benefit from the reuse of standards in the Transport Framework where the provide-and-register transaction is identical to the XDR transaction. Likewise, the query/retrieve transaction is identical to the XCA query/retrieve of XCA (used by NwHIN Exchange).

Deployment of Nationwide Health Information Network Transport Services

The table below focuses on deployment of the services for health information transport for the nationwide health information sharing use case (see Use Case 5 in Section A of this white paper). The table lists the standards and profiles for the infrastructure systems offering the transport service in the first column, and the second column identifies the standards and profiles to be supported by the edge systems.

Figure 9: Nationwide Health information Network Transport



Standards and Profiles Supported by the Transport Services	Standards and Profiles Supported by the Edge Systems
Cross-community/PHR[17] Exchange (XCA, XCPD, and the associated IHE security and privacy profiles)	HIEs, IDNs (large multi-site EHRs), PHRs[16] to support XCA and XCPD and the associated IHE security and privacy profiles.

The strategy proposed above allows an "HIE project" at the national (or even state-wide levels) to support interoperability between peer HIEs, national systems (e.g., SSA) or IDNs (e.g., VHA, Kaiser). The edge systems are much larger systems, than in the previous community sharing HIEs, which will directly interact, peer-to-peer in a query/retrieve mode. Such large edge systems would include HIE community

[17] PHR may play two roles: a health information exchange platform as well as an HIT application serving consumers.

projects (including an IDN-based HIE) as well as those specifically focused on the previous deployment model. The peer-to-peer query/retrieve mode of operation of XCA and XCPD are critical to support such a fully distributed national backbone that operates without any central national-level infrastructure systems. However, It is important to note that implementers of the XCA/XCPD transactions would benefit from the reuse of the XDS/PIX/PDQ transactions supporting the previous HIE community deployment.

Roadmap for Deployment of Health Information Exchange and Meaningful Use Criteria

The above three exemplar deployment models may be combined to meet specific needs. This flexibility is based on the fact that they have been designed as part of the overall, standards-based Transport Framework described in this white paper. This approach ensures that models used in production can be easily integrated when deployed independently and become a consistent, robust national infrastructure.

Different organizations, given their business priorities, may start with any one of the deployment models. For example, the VA and Kaiser naturally chose the NwHIN transport services to start; whereas Pennsylvania's KeyHIE, Virginia's CareSpark, and New York eHealth Collaborative chose the community health information sharing deployment; and the MedAllies HIE chose the point-to-point transport services (with Direct/XDR). Of note, HIE community sharing projects can be connected easily (due to the Transport Framework consistency) into the NwHIN Exchange.

It is important to recognize that meaningful use Stage 1 is silent on transport methods. Eligible professionals (EPs) and eligible hospitals (EHs) may, therefore, conform with any of the approaches presented as part of this framework As the next stages of meaningful use provide an opportunity to become more explicit on data transport, the EHR Association urges that the HIT Policy Committee, the HIT Standards Committee, CMS, and ONC take advantage of the Cross-Systems Transport Framework presented in this paper to enhance the interoperability roadmap for meaningful use Stage 2 (assumed start in 2013) and Stage 3 (assumed start in 2015). It is very important that clear Stage 3 roadmap requirements are announced no later than the Final Rules for Stage 2. The table below suggests such a roadmap.

Proposed Meaningful Use Stages 2 and 3 Interoperability Requirements

The table below proposes an approach that responds to the following objectives:

1. The adoption and deployment of a consistent Transport Framework is achieved by Stage 3, while providing a glide path for Stage 2 that does not exclude any party.
2. Ensure a balance between simplicity of software development to support the "blind push" use case with Direct (SMTP Only) and the provider expectations for ease of use of meaningful use offered by the metadata-labeled point-to-point transport services (SMTP+XDM or XDR), given that Direct pilots have clearly demonstrated that HISPs may simply bridge their coexistence, Direct (SMTP only) remaining the minimal default.
3. The MU Stage 2 objectives drive the demand for the underlying transport services, while taking into account for the Stage 3 transport services the bigger picture of overall health system

reform. The recognition that the deployment of ACOs will require anticipating support of some of the transport services that would become required only for MU Stage 3.

4. Requirements placed on hospitals and physicians take into account their dependencies on available HIE infrastructures (state HIEs, community HIEs, PHRs, etc.) to attest to Stage 2 and Stage 3 meaningful use
5. Access to the NwHIN Exchange transport services by EHRs is primarily of concern to large IDNs in the context of meaningful use. They should be able to attest to meaningful use like medium or small EHRs used in hospitals and physician practices, without placing the burden on EHR vendors to support NwHIN access, when community sharing is much simpler and more appropriate.

<table>
<tr><th rowspan="2">Transport Use Case</th><th rowspan="2">Transport Framework</th><th colspan="2">Meaningful Use EHR Certification</th><th colspan="2">Meaningful Use EHR Provider Requirement</th></tr>
<tr><th>Stage 2</th><th>Stage 3</th><th>Stage 2</th><th>Stage 3</th></tr>
<tr><td>1. Blind Push</td><td>Direct SMTP only</td><td rowspan="3">EHRs shall support at least one (if needed by Stage 2 “push” Workflows)</td><td rowspan="3">EHRs shall support all three</td><td colspan="2" rowspan="3">Provider shall use at least one (if needed by Stage 2 “push” Workflow)</td></tr>
<tr><td>2. Labeled Document Pushed</td><td>Direct SMTP+XDM</td></tr>
<tr><td>3. Labeled Document with Linked Patient Id</td><td>Direct XDR</td></tr>
<tr><td>4. Community Sharing HIE</td><td>XDS/PIX</td><td>EHRs shall support (if needed by Stage 2 “pull” workflows)</td><td>EHRs shall support this one</td><td rowspan="2">Provider shall use at least one (if needed by Stage 2 Pull Workflows)</td><td rowspan="2">Provider shall use at least one</td></tr>
<tr><td>5. Nationwide Health Info Network Exchange</td><td>XCA/XCPD</td><td>Optional* (requirement to be driven by IDNs need)</td><td>Optional* (requirement to be driven by IDNs need)</td></tr>
</table>

* See rationale for making these optional below

This roadmap sets the direction for both vendors and providers for Stage 2 and Stage 3. It allows the necessary investment to be made for infrastructures such as HIEs and PHRs, with increased likelihood of a sufficient base of EHR systems supporting the standards and profiles, given the inclusion of requirements based on MU Stage 2 objectives and the maturity of product availability. The development of the NwHIN (especially use of XCA cross-community exchange) would be driven by policy, funding, and business levers – beyond the EHR incentives – to meet the needs of IDNs, PHRs, and HIEs to be interconnected at the national level. **This is why it has been made optional.*

The current implementation experiences for each one of the three point-to-point approaches is of the same depth (e.g., a majority of the EHR vendors in the Direct pilots implemented XDR), and the large number of Community Sharing HIEs that are now being deployed leads the Association to recommend requiring some elements of all five approaches required for Stage 2 but primarily required for Stage 3.

E. Business Use Cases That Benefit From Health Information Exchange

Each section below focuses on three categories of business use cases that depend on health information exchange. They cover public health, quality reporting, and patient engagement. For each, the subsection provides a table outlining appropriate transport deployment models supporting each use case within the category. Benefits or limitations of each transport deployment model are explained following the table.

Public Health

The table below is focused on three typical public health applications. For each one, we consider the use of the above transport deployment models, and identify the ones best suited and the limitations of others. The need to use all three deployment models is demonstrated.

Public Health Applications and Transport Deployment Models
Point-to-Point Transport Deployment Model for: - Immunization reporting to an immunization registry (IIS) (meaningful use Stage 1) - Immunization query limited to single registry (Immunization Information System, IIS)[18]. - Syndromic surveillance (meaningful use Stage 1) - Reportable and notifiable lab result reporting (meaningful use Stage 1)
Community Sharing Transport Deployment Model for: - Immunization reporting and query without specific interfaces. Ready for nationwide access to immunization (CareSpark HIE)[19] - Community-level syndromic surveillance - Reportable and notifiable lab result reporting
Nationwide Pull Among Community HIEs, PHRs or IDNs Deployment Model for: - Immunization query with nationwide access to immunization[8] - National and state-wide syndromic surveillance

- Immunization Reporting and Queries

  Immunization reporting can be supported by point-to-point deployment or community deployment models. In the point-to-point models, the Direct protocol, if used, should use

[18] Point-to-point push is effective for reporting immunizations to a state public health registry. The CDC EHR-IIS Interoperability Expert Panel Project is finishing its recommendations on a single recommended transport method with an accompanying implementation guide for Immunization interoperability. This work is expected to be completed in the June – Sept 2011 timeframe. It will use Web Services as use of Direct/e-mail for queries is not practical.

[19] Leveraging a community sharing HIE as an immunization registry sharing immunization data has been demonstrated to be viable, as immunization data are not substantially different from other elements of a shared patient record.

XDM (metadata) to automate patient identity resolution. IHE XDR may also be used to communicate immunization data directly to an IIS. However, point-to-point models using the Direct protocol are not well-suited for query/response interfaces. We recommend a strategic analysis of the transport method that is best suited to meet all immunization use cases. In particular, community or nationwide sharing models may be best suited as they support reporting and querying immunization data stored in either an IIS or an HIE, and scale to nationwide access.

- Syndromic Surveillance and Notifiable/Reportable Lab Result Reporting
  Syndromic surveillance and notifiable/reportable lab result reporting use cases are very similar. Both involve reporting information to public health agencies, and may also involve query/response interfaces at the community or nationwide levels to gather information used to generate aggregated statistical results.

Both point-to-point and community sharing models are well-suited for reporting data, but have different attributes with respect to the level of aggregation that needs to be considered. In surveillance and reporting efforts, local policies often prohibit use of patient identifiable data. This prohibition requires anonymization or pseudonymization of reported data. These processes can be performed at the encounter[20] or provider[21] level. This will result in higher double-counting for events where a patient is seen at two (or more) providers for the same condition. Data can only be aggregated to the same level at which the anonymization or pseudonymization is performed. When community deployment models are used, double-counting is reduced, because patient identities are anonymized or pseudonymized within the community rather than at the encounter or provider level.

Access to reported events is supported in a pull model using the community or nationwide deployment models. Access can be anonymized/pseudonymized.

Quality Measurement

The table below is focused on the quality measurement reporting application. It considers the use of the above deployment models and identifies the ones best suited and limitations of others. In particular, the need to use two out of the three models is demonstrated.

[20] All results for the same encounter would use the same pseudonymous identifier for the same patient.

[21] All results for the same provider or provider organization would use the same pseudonymous identifier for the same patient.

Quality Reporting Applications and Transport Deployment Models
Point-to-Point Transport Deployment Model for: - Sending a quality measure report computed by a provider - Sending patient-specific data to a quality measure reporting system for aggregation and reporting - Sending aggregated data to quality reporting registries
Community Sharing Transport Deployment Model for: - Sending patient specific data to a quality measure reporting system for aggregation and reporting - Computing cross provider quality measures
Nationwide Pull Among Community HIEs, PHRs, or IDNs Deployment Model for: - Querying for patient data used to compute quality measures

- Quality Data Reporting
  Data used to compute quality measures can be shared using the point-to-point or community sharing transport models. Data used to compute measures could also be queried for using the nationwide "pull" deployment model. Measure data communicated that may be used to compute measures applicable across more than one encounter should use at least the Direct+XDM approach to ensure that patient data can be appropriately attributed for measure computation.
- Quality Measure Computation
  The Community Sharing deployment model supports computation of measures within a community of care. Information that is shared may be accessed in the HIE to compute measures within an organization or across organizations within the community of care.
- Quality Measure Reporting
  Reporting of aggregate results can be supported using the point-to-point model. Aggregated results are not specific to a single patient, and so are not typically applicable in patient-centric community or nationwide "pull" deployment models.

Patient Engagement

The table below is focused on three typical applications supporting patient engagement. For each one, it considers use of the above deployment models, and identifies the ones best suited and the limitations of others. The need to use all three models is demonstrated.

Patient Engagement Applications and Transport Deployment Models
Point-to-Point Transport Deployment Model for: - Provider feeds a document to PHR or patient e-mail address (HIPAA compliant) upon patient request - Patient sends a document to provider of choice
Community Sharing Transport Deployment Model for: - Patient-authorized "pull" into PHR, documents shared by provider - Provider is allowed by patient to "pull" documents from PHR
Nationwide Pull Among Community HIEs, PHRs, or IDNs Deployment Model for: - Patient "pull" into PHR, documents shared by provider - Provider is allowed by patient to "pull" documents from PHR - Patient transfers documents from one PHR to another

- Importing data into a PHR
  Import of provider-generated data into a PHR (other than the tethered PHR from the provider) may be performed through a point-to-point "push", through retrieval from community HIEs, or nationwide sharing. For the point-to-point "push", a Direct-based push initiated by a provider is sufficient, as the destination is the patient-specific account on a PHR application. When patient information is shared via a community HIE or nationwide, it is no longer necessary to have each provider perform this "blind push" to each one of its patients' PHRs. The patient, through a PHR application, may manually or automatically access shared information that is stored in a community or national HIE model through an XDS or XCA query/retrieve (authenticated by the same digital certificate that is used with the Direct e-mail only) and manage it as needed through the PHR application.
- Authorizing access to PHR stored data
  The patient's PHR application may store received or retrieved documents so that they be made available to be queried/retrieved by authorized providers in cases where the PHR is hosted as part of a community HIE infrastructure or a tethered PHR that is connected to a community HIE infrastructure. Such authorization requires that providers, both as persons and organizations, be tracked in a health provider directory, uniquely identified, and authenticated. Although not discussed in this white paper, interoperability with such provider directories, associated provider authentication, and patient authentication have sufficient standards and profiling available. However, these capabilities remain a significant policy and deployment challenge. It is also important to note that PHRs should store documents as received from providers and make them available as received when accessed by other providers. Such maintenance of critical elements in the trust and preservation of clinical content is essential. Patients may also summarize health information and share their own aggregate data in documents that they create and share using the same community HIE and national health information networks.

Care Delivery

Beyond the sample applications areas above, health information exchange, in general, needs to serve care coordination and information exchange between EHR systems. There are several key considerations in the coordinated delivery of care and associated information exchange where the use of the correct transport deployment model is very important:

- Point-to-point modes of communication work best with a limited number of known destinations. If stretched to large constituencies and more complex workflows, they become error prone. The sender must maintain an up-to-date address book of known destinations for the many workflows applicable to their patients. The selection of an incorrect destination is difficult to correct and may breach privacy.

- Some providers have suggested that, for the same set of documents, they would like to both direct their exchange to a targeted partner and share the same information to ensure easy recovery and changes in care plans.

- When the sender is a patient with no specialized application except an e-mail client, there is no need for added metadata. The patient's message will as a result, however, require manual handling at the receiving provider.

- As soon as the data source is a provider with even a simple EHR, skipping the first use case ("blind push", e-mail without metadata) and moving to the second (e-mail with metadata) becomes practical for the sender and beneficial for the receiver. For the sender, the metadata can be automatically created by the source EHR. For the receiver, the presence of metadata may have a significant positive impact when receivers are embedded in institutions with complex internal routing and challenges for senders to identify the right known destination.

From the review of these use cases (public health, quality measurement, patient engagement, care delivery), it is clear that the use of the best suited approach to transport for a given use case is important to avoid introducing needless complexity. It is, therefore, important to offer a range of cross-system transport services where all five transport use cases are supported so that, where available, the best mode of transport can be used to simplify deployment and accelerate adoption.

F. Implementation Maturity

When considering this Cross-Systems Transport Framework, covering the five transport use cases presented in Section A, ease of implementation is critical for a rapid deployment. The ONC Standards and Interoperability Framework identifies several critical elements for standards readiness. For each of these elements, we offer the following assessment of the framework described above:

- **Maturity of the specifications**
  XDS and XCA reference essentially a single standard (OASIS ebRS). The associated Web Services operate over the internet and are supported by the common operating systems used by EHRs and other health IT solutions. Hundreds of implementers – from very small to very large companies, from many countries – have successfully implemented these standards. They are continuously improved by NwHIN Exchange and IHE IT Infrastructure under NIST guidance. XDM reuses the same metadata definition and tooling along with common e-mail applications.
- **Availability of reference implementations**
  As mentioned earlier, at least five open source implementations[22] (e.g., XDR, XDS, PIX, XCA, and XCPD) are available and, except for CONNECT (planned but not performed yet), others have passed the IHE Connectathon repeatedly for three to five years (e.g., NIST, Open Health Tools, Microsoft, and MOSS). They are already used by commercially and clinically installed EHRs.
- **Availability of test tools**
  The responsibility for these test tools has been primarily held by NIST, which has developed and maintains these test tools. These test tools are being used outside the USA by several regional and national programs that have already deployed XDS and XCA operationally.
- **Maintenance of standards and implementation specifications**
  The implementation specification leveraged in the propose Transport Framework are under active maintenance. They are maintained by IHE International, IT Infrastructure Technical Committee. With more than 450 organizations members (see www.ihe.net/governance), this committee of IHE International has significant common membership with the Exchange Specifications Factory (organized under ONC contract).
- **Availability of commercial products**
  This capability can be measured at the level of IHE Connectathon testing, where the testing is performed independently from any vendor. It is administered only by users who monitor testing and publish the list of more than 100 implementers[23] who passed IHE Connectathon for the profiles

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[22] Open Health Tools: IHE profiles: https://www.projects.openhealthtools.org/sf/projects/iheprofiles;jsessionid=0D167F7CB5088927F6D8E2045B881D67
Open Health Tools: OpenExchange: https://www.projects.openhealthtools.org/sf/projects/openexchange;jsessionid=0D167F7CB5088927F6D8E2045B881D67
NIST: http://sourceforge.net/projects/iheos/
Microsoft: http://ihe.codeplex.com/
MOSS: http://sourceforge.net/projects/braid/

[23] To access IHE Connectathon results, go to http://connectathon-results.ihe-europe.net/ in the box "*select an IHE integration profile*", select for example in the pull down menu: "*Cross-Enterprise Clinical Documents Share (XDS.*b)"

used by this Framework. A survey conducted of EHR Association members identified that more than 40 commercial EHRs are connected and clinically operational exchanging information using XDS or XCA today. Several of those are not Association members.

G. Conclusion

In presenting a practical approach for the transport and exchange of health information and a comprehensive framework that supports the five key transport use cases, it is the EHR Association's goal to provide clarity to policymakers, providers, and other stakeholders as we work toward broad consensus on a consistent set of standards and implementation specifications for the transport of health information exchange. These are the result of the multi-stakeholder and federal investments made over the past several years through multiple initiatives, including the Direct Project, IHE International, IHE USA, HITSP, HL7, the Nationwide Health Information Network Exchange, and CONNECT. This consensus also responds directly to and is consistent with the PCAST objectives, building on the strengths of current capabilities and extending into a new world in the cloud.

There is no question that a cohesive framework for health information transport is needed. The initial experience with Stage 1 of meaningful use has highlighted the importance of transport for several objectives, including exchange of clinical summaries and submission to public health organizations. Although no single transport approach will cover all business use cases, this set of five use cases is organized with three deployment models, so that any health information exchange project may start with the right choice or set of choices of standards-based transport service and expand as driven by its business use cases. This flexibility, with a consistent set of standards and profiles set for the nation, will ensure that the various business models that are already deployed as well as those that are being explored can proceed independently but in a cohesive way to reduce risks and any further delays in the secure transport of health information. Our proposed approach will allow us to focus on growing the semantically-rich clinical content that the S&I Framework is set to deliver shortly with the CDA harmonization project and the decisions to be made for meaningful use Stages 2 and 3.

The Transport Framework proposed in this white paper delivers a low-cost entry point for both the smaller provider and small vendor organizations, enabling a more rapid deployment than does the current state of uncertainty resulting from today's fragmented approach to transport in HIE projects. **The proposed Cross-Systems Transport Framework also offers an approach to interoperability that is neutral across all business models for health information interchange**, whether community HIE-centric, PHR-centric, or state/regional HIE-driven. All these models can coexist while remaining interoperable for the ultimate benefit of the patient and consumer.

As often stated by ONC leadership, no single transport solution can address the expected range of mainstream information exchange use cases. **Failing to deploy the right transport service for a given use case** (as needed by clinical, personal, research, and public health IT use cases) **will add unnecessary complexity to the communicating systems and negatively impede provider and patient workflows.** New payment and delivery models, such as Accountable Care Organizations (ACOs) and patient-centered medical homes will require robust bi-directional exchange that can be tightly integrated into provider workflow. **A short-term approach to health information exchange transport that is overly**

reliant on point-to-point solutions will fail to meet the nation's challenges and miss the opportunity to take advantage of a broader range of standards, existing capabilities, and infrastructure in which the industry is already invested.

As the next stages of meaningful use will likely become progressively more explicit on transport, the EHR Association urges policymakers to consider data transport requirements in the context of this overall Framework, with clear Stage 3 choices released as part of Stage 2 regulations. It is important that the Stage 2 recommendations positions the health IT and EHR supplier community to support providers in achieving meaningful use Stage 3 for the breadth of transport services needed by the nation by encouraging adoption of all three point-to-point services, HIE community sharing, and NwHIN Exchange transport services.

Sources:

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http://www.himssehra.org/docs/20110124_EHR_AssociationResponsePCAST_Report.pdf

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IHE IT Infrastructure Technical framework:

- XDS (in Chapter 10):
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