EHR-IIS Interoperability Enhancement Project

Transport Layer Protocol Recommendation

Transport Layer Expert Panel

EHR-IIS Interoperability Enhancement Project

Immunization Information Systems Support Branch (IISSB)

National Center for Immunization and Respiratory Disease (NCIRD)

Centers for Disease Control and Prevention (CDC)

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Table of Contents

Acknowledgements 4
Executive Summary 6
1. Project Background 8
1.1. Meaningful Use and the Need for Enhanced Interoperability 8
2. Purpose 9
3. Transport Layer Expert Panel 9
3.1. Intended Audience 10
3.2. Intended Usage 10
3.3. Approach 10
3.4. Mission/Goal 14
3.5. Objectives 15
3.6. Scope 15
4. Summary of Alternative Transport Protocols Evaluated 16
4.1. ebXML 16
4.2. SMTP+S/MIME 17
4.3. HTTPS POST/REST 18
4.4. SOAP 19
5. Recommendation of SOAP Transport Layer Protocol 20
5.1. Process of Selection 20
5.2. Justification of SOAP Selection 21
6. Acknowledgement of Other Transport Protocols 22
7. Impacts 25
7.1. IIS Program Impacts 25
7.2. EHR Vendor Impacts 26
7.3. Provider Impacts 27
8. Conclusions 27

Appendices 29
Appendix A: Subject Matter Experts 30
Appendix B: Protocol Research Workgroups 35
Appendix C: Business Requirements 36
Appendix D: Use Cases 39
Appendix E: Comparison by Defined Business Requirements 41
Appendix F: Known Global Issues 69
Appendix G: Technology Recommendation Development Workgroups 71
Appendix H: Definitions 73
Appendix I: Related Background Reading Materials 74

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Executive Summary

The American Reinvestment & Recovery Act (ARRA) includes many measures to modernize infrastructure. The Health Information Technology for Economic and Clinical Health (HITECH) Act is a measure which supports the concept of Electronic Health Records - Meaningful Use [EHR-MU]. HITECH proposes the meaningful use of interoperable electronic health records throughout the U.S. healthcare delivery system as a critical national goal and awards funds to time-limited projects which demonstrate innovative approaches that enhance this interoperability, including an effort to promote EHR and Immunization Information Systems (EHR-IIS) interoperability. Immunization Information Systems (IIS) are confidential, population-based, computerized information systems that attempt to collect vaccination data within a geographic area. IIS are an important tool to increase and sustain high vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices, and providing official vaccination forms and vaccination coverage assessments.

To facilitate the development and implementation of EHR-IIS integration enhancement, the Centers for Disease Control & Prevention (CDC) Immunization Information System Support Branch (IISSB) focused on the recommendation of a transport layer protocol and supporting documentation to address the issue of utilization of multiple transport layer protocols across grantee programs and vendors and the limitations in real-time message transmission.

The CDC established a panel of subject matter experts and external reviewers, consisting of industry experts, to evaluate and analyze currently utilized industry transport protocols and recommend the most suitable option for EHR-IIS interoperability. It was the vision of this panel to recommend technologies to further promote health system interoperability. Based on research with funded project grantees, the protocols identified for consideration included the following:

- ebXML (PHINMS)
- SMTP+S/MIME (Direct Project)
- SFTP
- HTTPS POST/REST
- SOAP

An initial meeting and subsequent sessions over eight weeks involved the discussion and formulation of the mission, scope, approach, definitions, business requirements, and use cases for the project as well as detailed research on each transport layer protocol. During a three-day, in-person session, the panel SMEs were provided with a project overview and detailed feedback on each transport layer protocol option. Panel members identified SOAP as the best choice to meet the current and future needs of IIS data exchange, with the best chance for broad adoption across disparate healthcare

systems. In addition, SOAP was recommended for a variety of reasons including, but not limited to:

- SOAP supports synchronous real-time vaccination update and query/response.
- SOAP has a natural look and feel for developers on both the sender and receiver side.
- SOAP has a machine-readable contract that allows for a clear interface across all healthcare systems.

With the panel's recommendation of SOAP came the acknowledgment of the role and value of other transport layer options as well as the expectation that IIS would continue to use other transport layer technologies currently in place. IISSB supports the effort to recommend a standard transport option that our grantee cities and states as well as other healthcare systems would support for immunization interoperability.

1. Project Background

Immunization Information Systems (IIS) are confidential, population-based, computerized information systems that attempt to collect vaccination data concerning all covered populations within a geographic area. IIS are an important tool to increase and sustain high vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices, and providing official vaccination forms and vaccination coverage assessments.

1.1. Meaningful Use and the Need for Enhanced Interoperability

The American Reinvestment & Recovery Act (ARRA) includes many measures to modernize our nation's infrastructure. In particular, the "Health Information Technology for Economic and Clinical Health (HITECH) Act" is one such measure which supports the concept of Electronic Health Records - "Meaningful Use" [EHR-MU], an effort led by Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) for Health IT. HITECH proposes the "meaningful use" of interoperable electronic health records throughout the U.S. healthcare delivery system as a critical national goal. There are federal financial incentives designed to spur healthcare organizations toward meeting meaningful use standards for electronic health records.

Funds have been awarded to the following seventeen states and three city immunization program grantees through a competitive process for a two-year CDC cooperative agreement for conducting time-limited projects. This demonstrates how innovative approaches can successfully and measurably enhance the interoperability of electronic immunization data exchange between EHR systems and IIS.

- Arizona
- Colorado
- District of Columbia
- Idaho
- Michigan
- Minnesota
- Mississippi
- Montana
- New Mexico
- New York City
- North Dakota
- Oregon
- Philadelphia
- Rhode Island
- South Dakota
- Texas
- Utah
- Washington
- Wisconsin
- Wyoming

2. Purpose

The purpose of this EHR-IIS Interoperability Enhancement Project is to provide support for the enhanced interoperability of EHRs with IIS, specifically focusing on the exchange of vaccination records and reduction of the burden of duplicate data entry for providers. The project will also obtain technical and operational information and provide guidance to HITECH Act grantees for the Immunization Information Services Support Branch (IISSB). This project will produce documents on new guidance, refine/modify existing guidance, and develop necessary materials for enhancing EHR-IIS interoperability.

A recommended transport protocol allows the vendor focus to be on clinical functionality, as opposed to resources spent on supporting multiple transports. A transport protocol recommendation should allow for cost savings to the stakeholder practices as a result of an interoperable solution that works across all participating registries.

The project focuses on three separate and independent technological components related to enhancing interoperability: Transport Layer/Technical Interoperability; HL7 2.5.1 Messaging/Semantic Interoperability; and Client De-Duplication. Each component is assigned to a dedicated expert panel as a distinct segment to address in greater detail.

3. Transport Layer Expert Panel

The Transport Layer panel addressed the problem of technical complexity caused by the utilization of multiple transport layer protocols across grantee programs and vendors and the limitations in real-time message transmission. The goal of the panel was to recommend a transport layer protocol and supporting documentation for the immunization industry to move toward as well as technical support and guidance documentation to facilitate the eventual utilization of the recommended transport layer by the immunization community. The Transport Layer provides electronic transmission and receipt of health data from one system to another and is independent of the message itself. In addition to its use by all grantees, the recommended protocol can be utilized by all IIS, EHRs, HIEs, and other healthcare system community members.

3.1. Intended Audience

Artifacts produced by the Transport Layer Panel were designed to be read by programmatic, technical, and operational experts who are involved in creating or maintaining an IIS, HIE, EHR or other health system. The intent of the document was to bridge the gap between technical and program staff to facilitate a mutual understanding of the importance of a standard transport layer protocol and target actions to address these recommendations.

3.2. Intended Usage

The Transport Layer Panel's recommendation document is a collection of expert best practice recommendations. It provides technical and operational consultation and guidance for entities choosing to implement these recommendations. It is a means of advocacy and feedback for the community.

The Transport Layer Panel's recommendation document encourages IIS to employ any or all of the project implementation specifications once they are finalized. Guidance and consultation will be provided to those grantees that choose to implement these recommendations.

The document does not establish technological mandates or requirements. It will not provide hands-on execution of data clean-up or other technical activities. Grantees are not dependent on the recommendations found in the panel document and are encouraged to continue moving forward with their current implementation plans, if necessary. However, the protocol mentioned herein may help build for flexibility.

3.3. Approach

Initial preparatory off-line work, including assembly of pertinent materials, production of preparatory notes, analysis of current transport layer protocols, and development of preliminary approach documentation, was performed by the project team (Appendix I). IIS Fact Sheets were obtained from the 20 project grantees to evaluate and determine transport protocols for evaluation and next steps. There were 5 overlapping transport methods: ebXML (PHINMS), SMTP+S/MIME (Direct Project), SFTP, HTTPS and SOAP.

The CDC IISSB extended invitations and formed a panel consisting of subject matter experts (SMEs) and external reviewers representing industry experts from the following groups/organizations.

- 16 of the 20 funded project grantees
- ONC (Office of the National Coordinator for Health Information Technology)
- CDC Public Health Informatics and Technology Program Office (PHITPO)
- AIRA (American Immunization Registry Association)
    - Comprised of 50 members representing state, regional, and local IIS Programs; IIS Vendors; IIS consultants; and reciprocal partners.
- EHRA (Electronic Health Record Association)
    - Comprised of 45 EHR vendors from across the nation.
    - Includes 90% of the installed electronic health records and health information systems in the nation.
- IHS (Indian Health Service)
    - Uses RPMS (Resource and Patient Management System) to track immunizations in 34 states.
    - Supports interoperability with a number of IIS.
- IIS vendors (Immunization Information System) and platform providers
    - Involved 4 IIS vendors supporting 31 IIS.
- EHR vendors

There was a panel kick-off meeting to discuss a detailed understanding of the mission, scope and approach for the project and the specific roles of SMEs and external reviewers. The panel was also given an electronic "packet" of background reading materials following the session.

The SMEs met in two facilitated sessions to agree upon panel mission, objectives, scope, definitions (Appendix H) and 20 business requirements.

The SMEs were divided into workgroups, each focusing their efforts on the evaluation of a different protocol (Appendix B). In creating the workgroup assignments, the project team sought to strike a balance on each workgroup of those with a deep expertise and knowledge of the particular transport protocol as well as those new to the protocol. This was done to foster discussion and explore all possible scenarios.

The SME workgroups evaluated and compared transport options against the 20 business requirements (Appendix C). Each workgroup created a summary of its assigned transport layer option and an analysis of each option against those business requirements (Appendix E). The following table is a summary of their findings.

Subject Area	***SOAP***	***HTTPS POST/REST***	***The Direct Project /SMTP+S/MIME***	***PHINMS/ebXML***
General Solution Requirements				
Payload Size	No Limitations		Often limited by gateways	No limitations
Synchronous Response	No Limitations		Does not support	With client install, true end-to-end (EHR -> IIS) synchronous transactions difficult
Asynchronous Response	No limitations or differences			
Technology Neutral	No limitations or differences			
Technology Credibility	IIS usage; very active in EHRs; WSDL providing machine readable contract	HTTPS POST VXU/VXQ use cases implemented in numerous states since 2002	Growth in healthcare; minimal EHR/IIS use; not best for Meaningful Use Stage 3 and immediate query/response use cases	Few IIS implementations; no known new installations; native EHR interface difficult
Secure Transmission	Secure transmission provided by TLS		Secure transmission through S/MIME; SMTP header not encrypted	Secure transmission by TLS
Reliable Transmission	WS-Reliable Messaging protocol	No differences or advantages		
Authentication	Authentication and trust models of relatively equal effort			
IIS or Receiver Requirements				
Ease of Implementation	Slightly more complex than HTTPS	Shortest implementation timeframe	Significant IIS learning curve	Lengthy initial implementations
Ease of Maintenance	No differences or advantages			
Scalable	No limitations or differences			
Ease of Use	No differences or advantages			

Performance	No differences or advantages
Cost Effective	No differences or advantages
Sender Requirements	
Ease of Implementation	No differences or advantages
Ease of Maintenance	No differences or advantages
Scalable	No limitations or differences
Ease of Use	No differences or advantages
Performance	No differences or advantages
Cost Effective	No differences or advantages

The workgroups also evaluated their assigned transport protocol against the HL7 2.5.1 Use Cases (Appendix D):

1) Send Immunization History
2) Receive Immunization History
3) Request Immunization History
4) Return Immunization History
   4a) Find Candidate Clients
5) Accept Requested History
6) Send Demographic Data
7) Accept Demographic Data
8) Acknowledge Receipt
9) Report Error

In this comparison, the panel acknowledged that all use cases could be met. The lone exception was a constraint by the CDC HL7 Implementation Guide on "Request Immunization History" and "Return Immunization History" use cases commonly referred to as "Query/Response". The constraint dictates that the "Query/Response" loop be "immediate" or synchronous. Both the Direct Project and PHINMS (in certain settings) do not provide the possibility for the exchange to be synchronous.

Several known global issues were identified by the workgroup (Appendix F). During these workgroup sessions, it was apparent that the global issues identified were present in all protocols, and thus were not useful in comparison. Additional global issues continued to be identified throughout the analysis process.

A three-day, in-person session with the Transport Layer Expert Panel for the EHR-IIS Interoperability Project was held March 8-10, 2011 in Atlanta, Georgia. The SMEs were divided into subgroups related to their protocol to generate the contents of this document, as well as appendices (Appendix G).

Relatively rigorous conditions for inclusion of a recommendation in the best practice guidelines were used and received approval by every expert. Room for inevitable disagreements in minor details and preferences among experts was provided by implementing the following definition of consensus: "I can live with that and support it." The first part of this definition ("I can live with that") allowed the group to focus on achieving a consensus in principle, avoiding prolonged discussions on minor features (e.g., "at least no one disagrees strongly enough to veto the agreement"). The second part ("I support it") provided a due diligence check to ensure that there were no serious disagreements left among the experts and assurance that they agreed enough with the recommendation to stand behind it and support it.

The external reviewers held a preliminary meeting to review findings and held additional individual meetings to clarify feedback as required. External reviews provided iterative review and input into the creation of a Transport Layer Technology Recommendation Document. This group will also provide ongoing implementation guidance that will support project grantees choosing to implement the recommended transport protocol.

3.4. Mission/Goal

The Transport Layer Expert Panel is comprised of key stakeholders focused on recommending a unified technical interoperability framework for immunization-related transport that allows for both broad adoption and long-term viability as an industry standard.

The recommendation will identify and support the transport protocols necessary for electronically sharing immunization information among the stakeholders. It is the vision of this panel to recommend technologies to further promote health system interoperability.

It is the goal of the Transport Layer Expert Panel to enhance interoperability of electronic immunization data exchange between healthcare systems and Immunization Information Systems (IIS) through the recommendation of a standardized transport layer protocol.

3.5. Objectives

The Transport Layer Expert Panel will recommend a transport methodology for health care system-to-health care system HL7 immunization messaging interoperability for long-term and broadest adoption with a focus on providers and future potential meaningful use phases. The panel will create a recommendation document detailing the results of their analysis, identifying the recommended transport methodology and acknowledging the usage of alternative transport methods. The panel will also create an implementation Wiki based upon the recommended transport methodology that will provide technical guidance to grantees.

It should be noted that while the transport layer is message agnostic, the panel focused on HL7 V2 messages presently used in the IIS setting.

3.6. Scope

In recommending a transport methodology, the expert panel took into consideration and addressed the following topics:

- Payload size
- Synchronous and asynchronous messaging
- Secure transmission of the message
- Authentication between the sender and the receiver
- Sustainability of the transport methodology
- Performance
- Reliable message transmission
- Ease of implementation
- Use cases which include both Unsolicited Vaccination Updates (VXU) and queries (VXQ, QBP) from one health system to another health system

Out of Scope issues included the following:

- Other public healthcare systems such as vital records, Medicaid, and chronic disease reporting
- Authorization following authentication. Authorization can occur in numerous different ways and is foundationally specific to the IIS itself and not transport
- Hands-on execution of data clean-up or other program technical activities
- Interface or data quality certification

4. Summary of Alternative Transport Protocols Evaluated

The SFTP transport protocol was eliminated from consideration early in the process because it failed to fully meet many identified business requirements.

As a result, the four technologies under consideration by the expert panel were:

- ebXML
- SMTP+S/MIME
- HTTPS POST/REST
- SOAP

4.1. ebXML

Wikipedia defines ebXML as follows:

> *Electronic Business using eXtensible Markup Language, commonly known as e-business XML, or ebXML as it is typically referred to, is a family of XML based standards sponsored by OASIS (Organization for the Advancement of Structured Information Standards) and UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business). Their mission is to provide an open, XML-based infrastructure that enables the global use of electronic business information in an interoperable, secure, and consistent manner by all trading partners.*[1]

Developed by the CDC, the Public Health Information Network Messaging System (PHINMS) uses the ebXML infrastructure to securely transmit public health information over the Internet. PHINMS is a generic, standards-based, interoperable and extensible message transport system that is platform-independent and loosely coupled with systems that produce outgoing messages or consume incoming messages.

It was the intent of the panel to evaluate the ebXML protocol standard and not the PHINMS product (an implementation of ebXML). The panel acknowledged to date, EHR–IIS transport over ebXML is exclusively through PHINMS. Further, the panel's experience with ebXML was directly related to PHINMS' implementation of ebXML, PHINMS usage, and the historical knowledge of PHINMS. Thus, ebXML was evaluated in the context of PHINMS.

[1] ebXML – Wikipedia http://en.wikipedia.org/wiki/EbXML (Nov. 15, 2010)

4.2. SMTP+S/MIME

Wikipedia provides the following definitions for SMTP + S/MIME.

> *Simple Mail Transfer Protocol (SMTP) is an Internet standard for electronic mail (e-mail) transmission across Internet Protocol (IP) networks. SMTP was first defined by RFC 821 (1982, eventually declared STD 10), and last updated by RFC 5321 (2008) which includes the extended SMTP (ESMTP) additions, and is the protocol widely used today. SMTP is specified for outgoing mail transport and uses TCP port 25. The protocol for new submissions is effectively the same as SMTP, but it uses port 587 instead.*
>
> *While electronic mail servers and other mail transfer agents use SMTP to send and receive mail messages, user-level client mail applications typically only use SMTP for sending messages to a mail server for relaying. For receiving messages, client applications usually use either the POST Office Protocol (POP) or the Internet Message Access Protocol (IMAP) or a proprietary system (such as Microsoft Exchange or Lotus Notes/Domino) to access their mailbox accounts on a mail server.*[2]
>
> *S/MIME (Secure/Multipurpose Internet Mail Extensions) is a standard for public key encryption and signing of MIME data. S/MIME is on an IETF standards track and defined in a number of documents, most importantly RFCs. S/MIME was originally developed by RSA Data Security Inc. The original specification used the recently developed IETF MIME specification with the de facto industry standard PKCS#7 secure message format. Change control to S/MIME has since been vested in the IETF, and the specification is now layered on Cryptographic Message Syntax, an IETF specification that is identical in most respects with PKCS #7. S/MIME functionality is built into the majority of modern e-mail software and interoperates between them.*[3]
>
> The only implementation of SMTP+S/MIME in the IIS community is via the National Health Information Network (NHIN) Direct Project-specified transport protocol.

[2] Simple Mail Transfer Protocol – Wikipedia http://en.wikipedia.org/wiki/Simple_Mail_Transfer_Protocol (Feb. 8, 2011)

[3] S/MIME – Wikipedia http://en.wikipedia.org/wiki/S/MIME (Feb. 8, 2011)

4.3. HTTPS POST/REST

In a review of data exchange technologies, the American Immunization Registry Association defined the HTTPS POST protocol as follows:

> *The POST method is commonly used to submit form data from web browsers. The IIS implementation of HTTP/POST uses the same approach for transporting data that is used to transport data from a web page form, but uses specific data fields that are defined for authentication information and the HL7 payload. The IIS responds with a single character string comprised of the HL7 message, for example – an ACK response that acknowledges receipt of the message.*[4]

Wikipedia provides the following conceptualization of the REST architecture:

> *REST (Representational State Transfer)-style architectures consist of clients and servers. Clients initiate requests to servers; servers process requests and return appropriate responses. Requests and responses are built around the transfer of representations of resources. A resource can be essentially any coherent and meaningful concept that may be addressed. A representation of a resource is typically a document that captures the current or intended state of a resource.*
>
> *At any particular time, a client can either be in transition between application states or "at rest". A client in a rest state is able to interact with its user, but creates no load and consumes no per-client storage on the set of servers or on the network.*
>
> *The client begins sending requests when it is ready to make the transition to a new state. While one or more requests are outstanding, the client is considered to be in transition. The representation of each application state contains links that may be used the next time the client chooses to initiate a new state transition.*
>
> *RESTful architectures of HTTPS can be based on other Application Layer protocols if they already provide a rich and uniform vocabulary for applications based on the transfer of meaningful representational state. RESTful applications maximize the use of the pre-existing, well-defined interface and other built-in capabilities provided by the*

[4] AIRA, *Evaluating Data Exchange Technologies for Communicating with IIS* http://www.immregistries.org/pdf/AIRA_IIS_TransportLayer_Review.pdf (Nov. 3, 2010)

chosen network protocol, and minimize the addition of new application-specific features on top of it.[5]

4.4. SOAP

Wikipedia's definition of the SOAP protocol is as follows:

> *SOAP, originally defined as Simple Object Access Protocol, is a protocol specification for exchanging structured information in the implementation of web services in computer networks. It relies on Extensible Markup Language (XML) for its message format, and usually relies on other application layer protocols, most notably Remote Procedure Call (RPC) and Hypertext Transfer Protocol (HTTP), for message negotiation and transmission. SOAP can form the foundation layer of a web services protocol stack, providing a basic messaging framework upon which web services can be built.*
>
> *This XML-based protocol consists of three parts: an envelope, which defines what is in the message and how to process it; a set of encoding rules for expressing instances of application-defined data types; and a convention for representing procedure calls and responses.*
>
> *A simple example of how SOAP procedures can be used is as follows:*
>
>> *A SOAP message could be sent to a web-service-enabled website (for example, a real estate price database) with the parameters needed for a search. The site would then return an XML-formatted document with the resulting data (e.g., prices, location, features). Because the data is returned in a standardized, machine-parseable format, it could then be integrated directly into a third-party website or application.*[6]

[5] Representational State Transfer – Wikipedia http://en.wikipedia.org/wiki/REST (Nov. 3, 2010)

[6] SOAP – Wikipedia http://en.wikipedia.org/wiki/SOAP (Nov. 3, 2010)

5. Recommendation of SOAP Transport Layer Protocol

5.1. Process of Selection

During the three-day session, a presentation by and for panel SMEs provided a project overview and detailed feedback on each transport layer protocol option and the additional known global issues.

A selected panelist from each transport workgroup led a discussion summarizing the findings of the workgroup for each option.

After the four protocol discussions were complete, the panel was assessed to determine if an early consensus could be attained. Although there was no early consensus, the panel was able to eliminate SMTP+S/MIME and ebXML from further consideration as a protocol recommendation, further narrowing the transport layer options down to two: SOAP and HTTPS.

SMTP+S/MIME did not meet the EHR-IIS current use cases or long-term goals as well as the other protocols. Particularly, it did not allow for synchronous communication and did not support the following three HL7 use cases:

- Request Immunization History From Another System
- Find Candidate Clients From Another System and Select One to Be Used When Requesting An Immunization History
- Accept Requested Immunization History In Response to a Query for an Immunization History From Another System

The NHIN Direct-specified protocol will still be supported as a valid strategy for certain scenarios, but the other transports have a better chance of broad adoption with synchronous data updates and query/response, both required in the EHR and IIS community and consistent with the panel's mission for a long-term solution (Please see Section 6 for more details).

ebXML was identified as highly complex and as having too much product reliance upon PHINMS. Concerns regarding the future and long-term viability of this protocol were also discussed. Also, PHINMS, as it is configured, does not allow for synchronous communication. Similar to SMTP, ebXML does work as a transport layer, and the panel acknowledged that those currently utilizing these technologies should not discontinue doing so (Please see Section 6 for more details).

The two remaining transport options, HTTPS and SOAP, were revisited. This included the evaluation of both sets of business requirements and discussion of only the differences between HTTPS and SOAP. The following business requirements comparisons were made:

- Protocol Credibility
  - HTTPS for VXQ and VXU has been implemented in numerous states since 2002.
  - SOAP has only a few known live implementations, but numerous states working towards an implementation.
  - SOAP provides a machine-readable contract at the interface level (WSDL).
- Ease of Implementation (Sender and Receiver)
  - It is slightly quicker to implement HTTPS.
- Reliable Transmission
  - While not used in current implementations, SOAP has the WS-Reliable Messaging specification, which could be implemented if necessary.

During these discussions, very minor differences were identified between the two protocols, and it was noted that success could be found through either option.

The vote on the remaining two protocols determined the SOAP Web Service to be the recommended transport protocol for electronically sharing immunization information. This was the result of the overall expectation of the panel members that SOAP would allow for the broadest EHR adoption. Forty known EHRs and nine known IIS currently support SOAP-based transport. The protocol also is officially supported by the organizations, Integrating the Healthcare Enterprise (IHE) and the Electronic Health Records Association (EHRA).

The results of the vote included 13 panel members recommending SOAP, 3 members recommending HTTPS, and 2 members abstaining. All 5 panel members who did not vote for SOAP indicated that they could live with and support SOAP as the panel's recommendation. The panel used the previously implemented definition of a consensus ("I can live with that and support it") among subject matter experts (SMEs) regarding the recommendation.

The determining factors leading to the selection of SOAP as the preferred standard protocol by the expert panel are detailed in the following section.

5.2. Justification of SOAP Selection

The SOAP protocol performed well when analyzed for the use cases and business requirements identified by the panel.

Members concluded that SOAP would meet not only the current needs of IIS data exchange, but also stand strong in the future. In summary, SOAP was selected for a variety of reasons.

- SOAP had the best chance for broad adoption across disparate healthcare systems. While nearly impossible to measure, the best chance at broad adoption is a key factor in the success of any technology decision and even more important when considering an interoperability project. The panel addressed this by looking at key stakeholders, prior implementations, and industry trends. With numerous EHRs supporting SOAP efforts today, the inclusion of SOAP transports in the IHE XDS.b profile, and several IIS supporting or moving to SOAP, the panel determined there was the broad community adoption necessary to support the choice of SOAP.
- It is widely used by the EHR community. The 2011 Integrating the Healthcare Enterprise (IHE) Connectathon included 40 EHRs which support the SOAP-based IHE XDS.b profile.
- SOAP has a natural language specific syntax for developers on both the sender and receiver side. From a development standpoint, multiple SOAP development and support toolkits exist ranging from open source to privately licensed software along with a large community of practice, web resources, tutorials and example code which freely exist to make ease of use very attractive.
- SOAP has a machine-readable contract between sender and receiver to describe its conventions (such as how and where to specify authentication credentials) that allows for a clear interface across all healthcare systems.
- Several IIS are either live with a SOAP service or working towards a SOAP service. For example, New York City, one of the 20 grantees represented on this panel, has a live SOAP Web Service.
- Expert panel creation of a common Web Service Definition Language (WSDL) will allow for easier EHR adoption.
- As HL7 immunization messaging moves towards HL7 version 3, with XML-based HL7 messages, SOAP has the ability to transport streams of text as well as object models.

6. Acknowledgement of Other Transport Protocols

While the panel recommended SOAP, it acknowledged the role and value of other transport layer options. It is not the expectation of the panel that registries discontinue the usage of other transport layer technologies currently in place or not implement technologies necessary to meet specific scenarios requiring something other than SOAP.

ebXML

PHINMS is already used in several states for immunization-related messaging, supporting millions of transactions annually. It has a proven, successful, and flexible health system-to-health system history of implementation supported by standards. The panel's recommendation of SOAP should not be interpreted as a statement of lack of support for ebXML by CDC or this expert panel. ebXML will continue to be supported by CDC for immunization registries and other public health organizations.

SMTP+S/MIME

As specified by the Direct Project, SMTP+S/MIME provides interoperable universal addressing and transport for directed information exchange between known recipients. Because the desired scope for transport focused on query/retrieve as well as directed exchange, the Direct Project specifications were not appropriate for the entire needs within the panel's scope. However, the transport workgroup encouraged IIS utilization of Direct when appropriate. Such uses could include submission of VXU HL7 messages as an interim strategy, copies of submitted immunization data from EHRs to consumers, pushed notifications to EHRs of missing immunizations, and other scenarios where a pushed message is appropriate.

HTTPS

HTTPS POST has been widely used by the IIS community over the past several years and was comparable to SOAP in many of the evaluation categories considered by the panel, since SOAP transactions typically use HTTPS POST as the underlying protocol. In 2002, the HL7 Immunization Registry Task Force subgroup on HTTP message transport published "Transport of Immunization HL7 transactions over the Internet Using Secure HTTP[7]," and many registries adopted the conventions in that document, adding a degree of standardization to the use of HTTPS POST for IIS HL7 interfaces. Because the implementation guides for HL7 immunization messaging call for the HL7 messages to be sent intact as streams of text, the simplicity of HTTPS POST has been a good match for its relatively simple payload.

The use of raw HTTPS POST – while conceptually simple compared to higher-level protocols – is dissimilar from the SOAP-based services common to the EHR

[7] Transport of Immunization HL7 transactions over the Internet Using Secure HTTP http://www.immunizeusa.org/attachments/wysiwyg/1/HL7_Secure_Transport_Ver1-0Sept02.pdf (Sept. 17, 2002)

industry, as well as the emerging REST-based services common to many other web-based vendors. Unlike SOAP, HTTPS POST lacks a machine-readable contract between sender and receiver to describe its conventions (such as how and where to specify authentication credentials).

The panel's subgroup on HTTPS POST also evaluated REST. However the lack of any current immunization messaging implementation in REST was seen as a disadvantage. Finally, as HL7 immunization messaging moves towards HL7 version 3, with XML-based HL7 messages, SOAP – with its ability to transport not just a stream of text but an object model – may be more appropriate for IIS messaging of the future.

It is the expectation of the expert panel that registries and their trading partners that use HTTPS POST for HL7 v2.x will continue to do so even as they add support for SOAP.

SFTP

SFTP is widely available for a number of platforms and provides acceptable functionality for many users. While the panel did not move forward with an evaluation of SFTP, that should not imply a lack of its use and value in the appropriate setting. SFTP continues to see heavy use in the IIS community including but not limited to vital records feeds, Medicaid feeds, Women Infants and Children (WIC) extracts, and data migration projects. Many registries in other health systems such as infectious disease and cancer reporting rely on SFTP for transmittal of electronic data in other public health arenas.

The panel did not determine that SFTP is not acceptable; however other options identified were better suited for this project. Some of the reasons that were cited by panel members include the following:

- The SFTP protocol was not proven to be scalable for real-time transactions/responses.
- The SFTP protocol was not synchronous; it is appropriate for old interfaces but not a good choice for a national standard.
- SFTP could have a significant overhead for establishing authentication for all providers.
- SFTP will not support real-time reporting. The protocol is not forward-looking; it is difficult to use to meet real-time requirements.
- SFTP is not robust enough to fulfill all of the requirements.
- SFTP is hard to integrate into EHRs and workflow.

7. Impacts

The recommendation of SOAP Web Services has a number of effects on the Immunization Information System (IIS) and Electronic Health Record (EHR) communities. The Transport Layer Workgroup will create an implementation Wiki that defines the standard Web Service interface. Following this, there are a number of activities that immunization registries will need to work on, in order to gain benefits from these services.

7.1. IIS Program Impacts

The Immunization Information Services Support Branch (IISSB) supports the effort to recommend a standard transport option that grantee cities and states as well as other health care systems would support for immunization interoperability.

Today, IIS in many settings have successful models for interoperability between numerous external systems including EHRs, vital records, Medicaid systems, WIC programs, and HMOs. Those interoperability models use a variety of transport layer protocols including SFTP, HTTPS, SOAP, REST, PHINMS, SMTP + S/MIME, and potentially others. There are also efforts to engage with an HIE in many locales. The expert panel acknowledges the large amount of interoperability effort already in place, or soon to be in place, and has no intentions or expectations to remove or interfere with those capabilities.

Moving forward, the expert panel is recommending a transport layer protocol that will benefit the broadest area of health care systems to promote interoperability today and into the future. By working closely with AIRA, EHRA, IHS, ONC, and PHITPO on a standard interface, the IIS community can be confident their investment in SOAP will lead to a transport layer protocol external senders can use to quickly connect to their IIS.

Moving into a SOAP web service will involve a commitment similar to any other enhancement to an IIS. While each IIS is in its own unique situation, for an IIS with a stable HL7 engine, adding the SOAP web service to transport the HL7 message and its response should be a straight-forward development process.

IIS that have implemented a SOAP service have been able to build their capabilities over time. This means it is entirely possible to build a simple SOAP service which only processes vaccination updates at first. Once stable, the IIS

can then focus on expanding their SOAP service to handle query/response use cases.

The final important positive impact to an IIS is the ability to add a SOAP service without disrupting existing transport layer protocols already in place. Existing providers using existing transport layer protocols can continue business as usual. New providers can be encouraged to use their EHR-supported SOAP interface and existing providers can be encouraged to adopt the SOAP service in due time.

7.2. EHR Vendor Impacts

EHR vendors and their clients at healthcare facilities will need to work with IIS to connect the software deployed at hospitals, clinics, and private doctor's offices to the IIS. The Electronic Health Record Association (EHRA) supports the effort to recommend a single transport option that member companies would utilize for immunization interoperability. When technology companies need to assign resources for the same clinical functionality (exporting/importing immunization information to/from registries), but with different technical implementations, it increases the cost to the entire stakeholder base. By identifying SOAP as a recommended transport, EHR vendors will be able to focus on one transport protocol as a baseline for interoperability with immunization registries, while having a protocol that is scalable enough for the emerging requirements for query functionality.

The level of interoperability achieved for short term benefits is a baseline standard across all participating immunization registries for a faster and less expensive deployment solution. A single recommended transport allows the vendor focus to be on clinical functionality, as opposed to resources spent on supporting multiple transports. A single transport recommendation should allow for cost savings to the stakeholder practices as a result of an interoperable solution that works across all participating registries. Consideration should be given to current development efforts of the EHR vendors as this transition to the recommended protocol is implemented.

Two points of resistance to immunization reporting are development costs and the need for clinical staff to leave their EHR to obtain immunization information through a separate IIS web application. After the Transport Layer Workgroup implementation guide is complete and the nationally recommended SOAP interface is defined and implemented, the primary benefit to IIS will be that EHR vendors will be able to seamlessly exchange immunization information with immunization registries in both directions, with minimal effort. Ideally, the healthcare facility's electronic system will only need to use the SOAP-enabled

version of the EHR software, after technical staff has pointed it to the state, local, or regional immunization registry. In reality, some initial testing will be required before the integration between the EHR and IIS is used in production.

7.3. Provider Impacts

After the EHR systems are deployed in production, the lag between the date that a vaccine is administered and reported can be reduced to less than one day through real-time reporting. Use of real-time querying through an HL7 VXQ/QBP service will enable viewing of full immunization histories for patients that have been previously seen at other healthcare facilities and provide comprehensive display of vaccinations to date as IIS hold information from multiple sources of immunizations and hence help inform the healthcare provider. Decision support recommendations based on the ACIP immunization schedule will also be returned to the EHR by these services, which will help inform the clinician of valid/invalid vaccines in the patient's record, along with the dates that the vaccines are due next, so that they can set their next appointment with the patient.

Added future benefits to IIS include enabling the same seamless sharing of immunization information between different immunization registries and the potential for more services to be developed to provide more health information to the EHRs (e.g. lead screening, newborn screening, body mass index/height /weight, etc).

If the provider has an existing stable exchange with the IIS and the IIS plans to continue support, there should be no immediate work for the provider. However, those providers looking to start an exchange with an IIS and those ready to move to real-time bidirectional exchange should evaluate their options with their IIS. Providers looking to create a SOAP exchange with their IIS will have coding samples and supporting documentation on the IIS Transport Layer Wiki to be used by their technical team or vendors.

8. Conclusions

The expert panel recommends SOAP as a best practice transport layer with the goal of universal adoption by all IIS. However, this does not preclude other transport mechanisms from being utilized. The panel supports all transport methods discussed in this document and members look forward to promoting health system interoperability and assisting other IIS with data exchange efforts.

Implementation guidance will be made available by a Wiki. It will continue to be developed by the expert panel and include regular updates as they become available. The plans include but are not limited to:

- Scope and audience for the Wiki
- Lessons learned from IIS and EHR SOAP implementers
- Case studies
- SOAP tooling information and support
- Community-wide standardized WSDL approach
- Community-wide standardized authentication approach
- Effort considerations for the IIS and EHR
- Developers' guide section for both senders and receivers including code samples
- Contact information
- SOAP specification document

Appendices

Appendix A: Subject Matter Experts

Angel Aponte, New York Citywide Immunization Registry (CIR)
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Angel Aponte is a Computer Software Specialist at the Citywide Immunization Registry in New York City's Department of Health and Mental Hygiene, with 10 years of experience in the technical aspects of Immunization Information Systems, including software development in Java and .net, server systems, network troubleshooting, web application support and maintenance, relational database support and maintenance, data analysis, oversight of technology vendors and other technical partners, and writing/managing contract deliverables. Angel is a past co-chair of the American Immunization Registry Association (AIRA) Transport Layer Workgroup.

Bob Barker, Electronic Health Record Association (EHRA)
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Robert Barker is the Manager of Interoperability and Standards for NextGen Healthcare, with experience in development of technology solutions across disparate platform vendors. He is currently the co-chair of the Electronic Health Record Association (EHRA) and has 10 years of experience in the Heath HIT community.

Michael Berry, HLN Consulting, LLC / Rhode Island KIDSNET
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Michael Berry is a project manager for HLN Consulting, LLC. He has worked on immunization information systems since 2003, with specific experience developing web-based and web services solutions for registries in Rhode Island and New York City. Since 2006 he has also been engaged in standards-based connectivity of Public Health to HIE, focusing on messaging architecture and privacy and security.

Nathan Bunker, Dandelion Software & Research, LLC / ImmTrac (TX)
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Nathan Bunker is an independent software developer, immunization registry consultant, and HL7 interface specialist with seven years experience working with various state and local immunization registries in the US.

Marcelo Caldas, CDC Public Health Informatics and Technology Program Office (PHITPO)
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Marcelo Caldas is a Software Engineer with 14 years of experience in Web and SOA development. He's been with Northrop Grumman working for the Centers for Disease Control and Prevention since 2004, engaged in several projects and currently supporting and enhancing the PHINMS product, a transport solution used by several public health partners nationwide for Heath Exchange Information.

Concetto "Frank" Caniglia, American Immunization Registry Association (AIRA)
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Frank Caniglia is the IIS manager of the Pennsylvania Statewide Immunization Information System and has 15 years of experience in all aspects of IIS, including project management, technical support, interoperability, provider recruitment, training, policies and contracts. He is also a current Board Member of the American Immunization Registry Association (AIRA), member of the Modeling of Immunization Registry Operations Work Group (MIROW) Steering Committee, and AIRA Board representative to the Joint Public Health Informatics Taskforce (jPHIT).

George Cole, Allscripts / Electronic Health Record Association (EHRA)
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George Cole is Principal Scientist, Integrated Solutions at Allscripts. He has been involved with EHR application interoperability for more than 7 years. George is a member of the EHRA Standards and Interoperability Workgroup, the IHE IT Infrastructure Technical Committee, the CDA Academy Faculty Board, as well as ASTM, IEEE, and ACM. He is co-editor of the IHE Retrieve Form for Data Capture (RFD) Profile and contributed code to the Direct Project reference implementation.

Emily Emerson, Minnesota Immunization Information Connection (MIIC)
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Emily Emerson is the IIS manager of the Minnesota Immunization Information Connection and has 10 years of experience in all aspects of IIS, including project management, technical support, provider recruitment and training, and policies and contracts. She is also the current president of the American Immunization Registry Association (AIRA) and co-chair of the AIRA Standards and Interoperability Steering Committee.

Josh Friedman, Hewlett Packard (HP)
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Joshua Friedman is a SOA architect for Hewlett Packard Enterprise Services, having designed systems for immunization registries for 5.5 years. He has experience designing Statewide IIS web services solutions for the states of Wisconsin and Oregon, in addition to custom soap based web services tooling and monitoring software.

Paul Groll, Michigan Care Improvement Registry (MCIR)
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Paul Groll, CISSP, is an Enterprise Architect with the State of Michigan, specializing mainly in solution and security design. He has worked on a number of large-scale integration projects for the state since 1994, with a focus on health systems since 2009. Paul is currently engaged in all design aspects of Michigan's internal Health Information Exchange, and provides technical representation for the state in the broader aspects of Michigan's state-wide HIN efforts.

Gautam Kesarinath, CDC Public Health Informatics and Technology Program Office (PHITPO)
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Gautam Kesarinath is the Portfolio Manager and Enterprise Architect for CDC Public Health Informatics Technology Program Office (PHITPO). He was the program manager for PH interoperable systems including PHIN MS, PHIN VADS and Data Message Brokering at CDC between 2007 and 2010. He has 10 years public health experience at CDC and 18 years overall in technology management and systems architecture.

Thomas Maerz, Wisconsin Immunization Registry (WIR)
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Thomas Maerz is the Designer & Manager of the Wisconsin Immunization Registry which is used by numerous grantees nationwide. Having extensive applications development knowledge as well as being an experienced Network Engineer, he has 16 years of experience in all aspects of IIS, including project management, functional design, technical support, provider recruitment, training and the writing of technical support documents, policies, procedures and contracts. His additional experience includes working within Wisconsin's Vital Records system for 5 years and 11 years working as a Customer Support manager for an Electronic Medical Record vendor.

Arien Malec, NHIN Direct
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Arien Malec is Coordinator, S&I Framework and Direct Project, for the Office of the National Coordinator (ONC). He has nearly 20 years experience in healthcare and life sciences software and informatics. He has held senior leadership positions in product management and services, most recently as Vice President, Product Management for RelayHealth, where he managed business strategy and requirements for Software as a Service platform providing HIE, EHR, and PHR capabilities.

Ben Martinez, New Mexico Statewide Immunization Information System (NMSIIS)
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Ben Martinez is the Business/System Analyst assigned to the NM Immunization Information Registry with over 25 years in the IIS field, and has supported various state government agencies and applications, including health, finance, payroll, inmate information, and probation and parole.

Deborah Rochat, Oregon ALERT IIS
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Deborah Rochat is an Operations Analyst for the Oregon Immunization ALERT IIS. She has over 12 years of data management and analysis experience in both public and private sectors, including four years of experience as the Immunization ALERT Data Quality Coordinator. Most recently she is working with ALERT on data conversion and migration efforts, as well as with interoperability grants.

David Rose, Scientific Technologies Corporation (STC)/ Washington CHILD Profile Immunization Registry
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David Rose is the Solution Architect for Scientific Technologies Corporation, focusing on the interfaces between public health applications, including immunization registries and disease surveillance systems, and external systems, including EMR and EHR systems, laboratory LIMS, and HIE gateways.

Purvesh Shah, NextGen Healthcare
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Purvesh Shah is leading the development of Ordering system for NextGen Healthcare and has over 15 years of experience (7 years in healthcare) in all aspects of a software development life cycle, including requirements gathering & analysis, software architecture & development and mentoring other developers. He holds a Masters degree in Computer Science from St. Joseph's University.

Shane Speciale, Avanza Systems Inc. / South Dakota Immunization Information System
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Shane Speciale is the President of Avanza Systems, an immunization registry product manufacturer. Shane has been personally involved in the planning, design, development, implementation, and/or support of more than 20 immunization registries at the local, state, and federal (DOD) levels over the past 18 years and has intimate knowledge of and experience with HL7 data exchange and related transport.

Cecile Town, Indian Health Service (IHS)
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Cecile Town is a CDC Research Officer assigned to the Indian Health Service Immunization Program in Albuquerque, New Mexico. Since 2006, she has worked with IHS, IIS and vendor partners to establish standards-based interfaces between IIS and the IHS Resource and Patient Management System (RPMS). She is also a federal liaison to the American Immunization Registry Association (AIRA) Board of Directors.

Appendix B: Protocol Research Workgroups

SOAP Web Service Workgroup

- **Angel Aponte**, New York Citywide Immunization Registry (CIR)
- **Nathan Bunker**, Dandelion Software & Research, LLC
- **George Cole**, Allscripts
- **Josh Friedman**, Hewlett Packard (HP)
- **Deborah Rochat**, Oregon ALERT IIS

SMTP+S/MIME Workgroup

- **Bob Barker**, Electronic Health Record Association (EHRA)
- **Concetto "Frank" Caniglia**, American Immunization Registry Association (AIRA)
- **Paul Groll**, Michigan Care Improvement Registry (MCIR)
- **Gautam Kesarinath**, CDC Public Health Informatics and Technology Program Office (PHITPO)
- **Arien Malec**, Direct Project

REST / HTTPS POST Workgroup

- **Michael Berry**, HLN Consulting, LLC
- **Ben Martinez**, New Mexico Statewide Immunization Information System (NMSIIS)
- **David Rose**, Scientific Technologies Corporation (STC)
- **Cecile Town**, Indian Health Service (IHS)

ebXML and ebMS Workgroup

- **Marcelo Caldas**, CDC Public Health Informatics and Technology Program Office (PHITPO)
- **Emily Emerson**, Minnesota Immunization Information Connection (MIIC)
- **Tom Maerz**, Wisconsin Immunization Registry (WIR)
- **Shane Speciale**, Avanza Systems
- **Purvesh Shah**, NextGen Healthcare

Appendix C: Business Requirements

Business Requirement #	Subject Area	Comment
General Solution Requirements		
1	Payload Size	The transport layer should support data transmissions of a significant size. This will allow for transmissions of large batches of data.
2	Synchronous Response	The transport layer should allow for the receiving system to return response(s) immediately.
3	Asynchronous Response	The transport layer should allow for the receiving system to acknowledge receipt of the payload and process the payload on its own schedule. The sender may check back at a later time for a response payload, or the receiver may initiate a response (reply) to the sender with the response payload. It is expected that the sender and receiver will support either a "check back" or an "unsolicited push or reply" response model, but not necessarily both models.
4	Technology Neutral	The transport layer must be language, platform, payload, message, and product agnostic.
5	Technology Credibility	The transport layer must be based on existing technologies with a proven successful health system to health system history supported by standards.
6	Secure Transmission	The transport layer must provide support for a secure point-to-point transmission of PHI and PII related data.

7	Reliable Transmission	The transport layer must provide support for a reliable point-to-point transmission of PHI and PII related data. Reliable transmission includes ensuring the message has successfully made it from source to destination and providing a framework to deal with unsuccessful transmissions, Errors during transmission, and the ability to resubmit an unsuccessful transmission.
8	Authentication	The transport layer must provide an easily implemented and maintained system-to-system authentication framework/protocol. This score should also consider operational management as the number of external systems increases.
IIS or Receiver Requirements		
9	Ease of Implementation	The transport layer must be easy to implement for an IIS.
10	Ease of Maintenance	The transport layer must be easy to maintain for an IIS.
11	Scalable	The transport layer must be able to efficiently handle increases in serial and parallel requests to the IIS as the number of external systems that communicate with the IIS simultaneously increases.
12	Ease of Use	The transport layer must provide effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.
13	Performance	The transport layer must provide framework to achieve service quality to the user from the start to the finish of a given task. However, it must not degrade other system services to accomplish its task.
14	Cost Effective	The transport layer must be as cost effective as possible for the IIS.
External System or Sender Requirements		
15	Ease of Implementation	To achieve an optimal score the transport layer must be easy to implement for an EHR.

16	Ease of Maintenance	To achieve an optimal score the transport layer must be easy to maintain for an EHR.
17	Scalable	The transport layer must be able to efficiently handle increases in the number of users, patients, and vaccines in the EHR system.
18	Ease of Use	The transport layer must provide effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.
19	Performance	The transport layer must provide framework to achieve service quality to the user from the start to the finish of a given task. However, it must not degrade other system services to accomplish its task.
20	Cost Effective	The transport layer must be as cost effective as possible for the EHR.

Appendix D: Use Cases

HL7 2.5.1 Use Cases

Use Case	Title	Goal
1	Send Immunization History	To send an immunization history for an individual client from one system to another. In addition to EHR-S and IIS, other systems such as vital records systems or billing systems could use this message to send immunization histories.
2	Receive Immunization History	To receive an unsolicited immunization history. It may be an update or a new record. This use case does not have responsibility for the processing of the message. The receiving system may review and accept the immunization history if it chooses, but this outside the scope of this use case.
3	Request Immunization History	To request an immunization history from another system.
4	Return Immunization History	To return an immunization history. It does not include the processes used to find candidate clients
4A	Find Candidate Clients	To find one or more candidate clients from another system and select one to be used when requesting an immunization history.
5	Accept Requested History	To accept an immunization history in response to a query for an immunization history from another system.
6	Send Demographic Data	To send demographic data about a person. It may be an update or a new record. This use case does not have responsibility for the processing of the message. The message will include an indication of the expected/requested acknowledgement.

7	Accept Demographic Data	To accept demographic data about a person. It may be an update or a new record. This use case does not have responsibility for the processing of the message. The message will include an indication of the expected/requested acknowledgement.
8	Acknowledge Receipt	To acknowledge receipt of a message. This can be an immunization history, request for immunization history, demographic update, observation report or request for personal id. It may indicate success or failure. It may include error messages. One example occurs when a query is well-formed, but finds no candidates. In this case the acknowledgement reports this fact.
9	Report Error	To send error messages related to messages.

Appendix E: Comparison by Defined Business Requirements

Payload Size: The transport layer should support data transmissions of a significant size. This will allow for transmissions of large batches of data.

ebXML:

- ebXML has no limitation
- Older versions of PHINMS had limitations. Newer versions of PHINMS can chunk the file to allow for larger payloads and is now more limited by the runtime environment rather than the transport. Newer versions have tested transporting up to a 5GB payload.

SMTP+S/MIME:

- There is no limitation on payload size with SMTP+S/MIME.
- However, most email gateways are configured to block messages over a certain size based on policy decisions by the receiving entity.

HTTPS POST/REST:

- No limitations to payload. Large files are very normal in many IIS using HTTPS POST.
- 150 MB in WIR-based applications, but constrained to 150 MB by the application not the transport.
- HTTP supports compression to aid in transport performance as the payload size increases.
- RESTful architectures follow the Atom Publishing Protocol for attachments, using the POST (or PUT) verb to submit a resource (file).

SOAP:

- There is no size limitation from a transport perspective.
- The panel noted two approaches for large payloads via SOAP.
    - Message Transmission Optimization Mechanism (MTOM)
    - SOAP with Attachments (SwA)
        - It is acknowledged that MTOM is more efficient for large payloads than SOAP with Attachments is. “Large” would need to be defined, but MTOM offers performance improvements.
        - MTOM has been adopted by IHE XDS.b profile.

Synchronous Response: The transport layer should allow for the receiving system to return response(s) immediately.

ebXML:

- ebXML could be built to be entirely synchronous from the EHR into the IIS and back.
- PHINMS as it is implemented today falls short of a true synchronous response due to the required EHR file poling in the PHINMS directories for a response.
- It is important to note that “round trip” performance times are still achievable as proven by both Minnesota and Wisconsin.

SMTP+S/MIME:

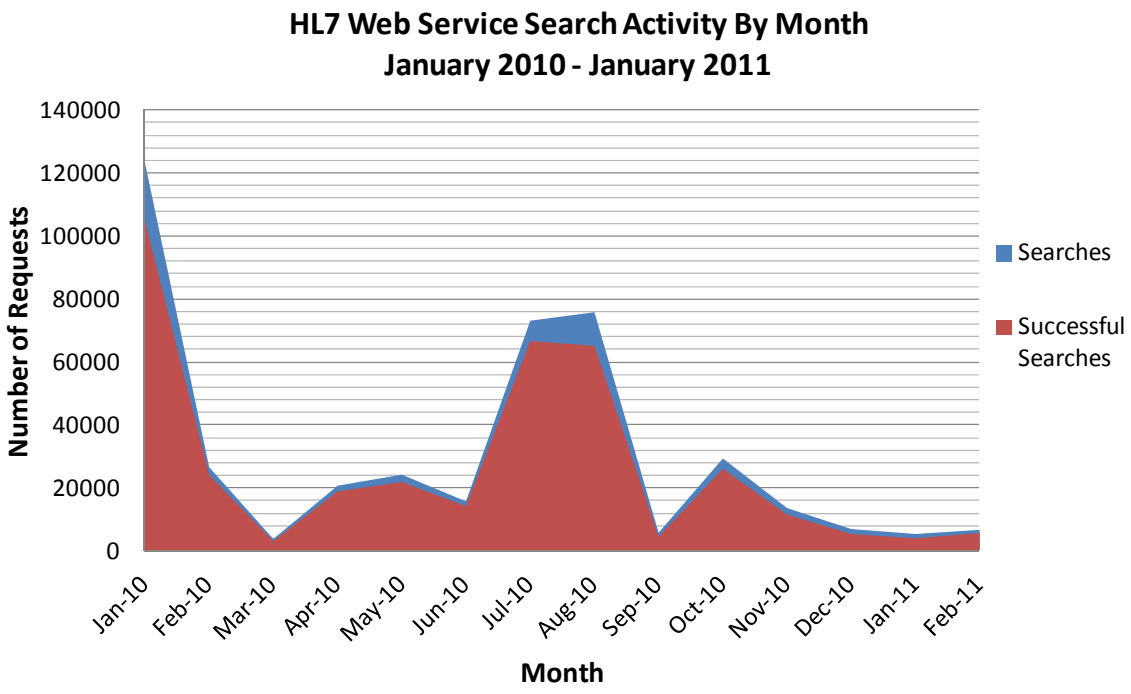
- SMTP+S/MIME do not support a synchronous response.

HTTPS POST/REST:

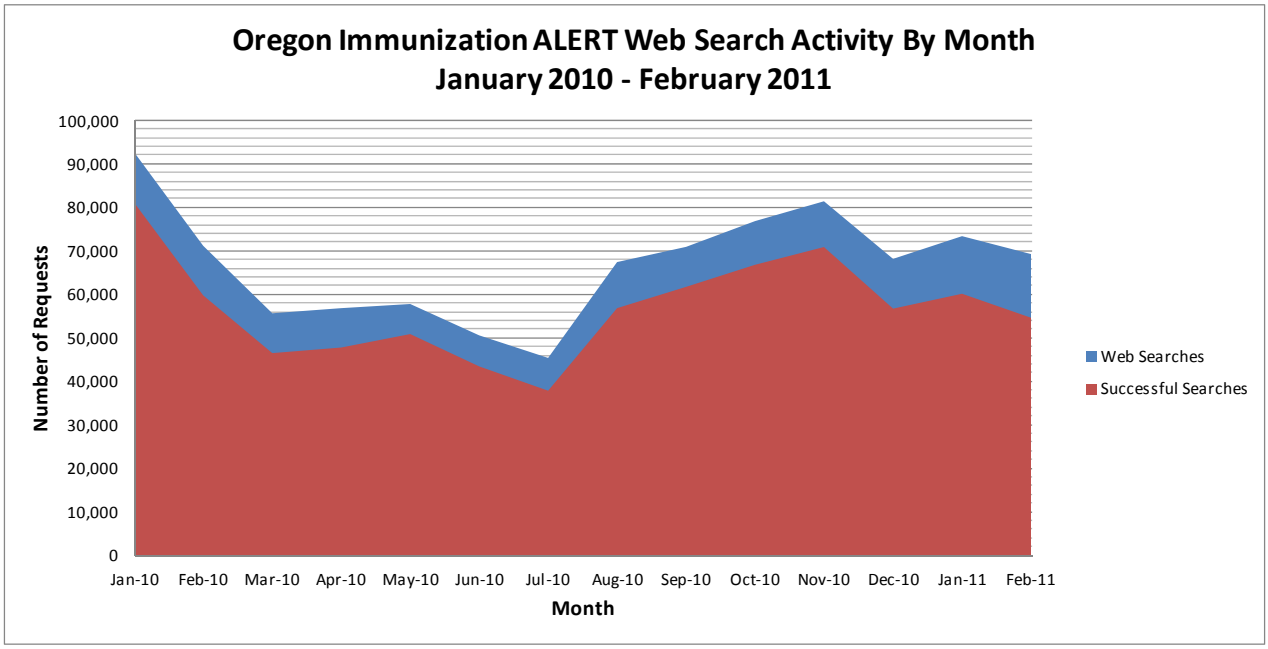
- By definition, HTTPS request/response model is synchronous.
- Since a RESTful architecture is implemented using HTTPS as its underlying transport, it supports synchronous response.

SOAP:

- When implemented as SOAP over HTTPS, then by definition of HTTPS, it is synchronous.
- A graphical view of New York City’s synchronous queries over time is shown below.



- In addition to synchronous query/response processing, New York City has also started processing unsolicited vaccination updates (VXU) synchronously using their SOAP web service.
- While Oregon had not implemented their SOAP service in 2010, they have a similar graph of potential Web Service queries (to understand potential volume) based on their IIS usage.



Asynchronous Response: The transport layer should allow for the receiving system to acknowledge receipt of the payload and process the payload on its own schedule. The sender may check back at a later time for a response payload, or the receiver may initiate a response (reply) to the sender with the response payload. It is expected that the sender and receiver will support either a "check back" or an "unsolicited push or reply" response model, but not necessarily both models.

ebXML:

- Both "check back" and "unsolicited push or reply" models could be implemented.
- It is noted that the "check back" model would be easier to implement and maintain for the sender.

SMTP+S/MIME:

- SMTP+S/MIME supports an "unsolicited push or reply" asynchronous response model.

HTTPS POST/REST:

- HTTPS POST could easily be implemented to support an asynchronous response. It could support both a "check back" model by the sender as well as an "unsolicited push or reply" model.

- While it would be possible to support either model, it is much easier implemented (and maintained) as a "check back" model where the sender is responsible for retrieving the response.
    - IHS (sender) has an asynchronous model in Arizona and Utah.
    - IHS (sender) is responsible for picking up the response.
    - IHS (sender) payload size is roughly 4 -5 MB per day during the week and 2 MB on the weekends.
- HTTPs GET would be used to retrieve the response. In a RESTful architecture, the sender would be responsible for retrieving the resource (response payload).

SOAP:

- SOAP could easily be implemented to support an asynchronous response over HTTP. It could support both a "check back" model by the sender as well as an "unsolicited push or reply" model.
- While it would be possible to support either model, it is much easier implemented (and maintained) as a "check back" model where the sender is responsible for retrieving the response.
- Wisconsin is working on an asynchronous model for providers who submit large batches of data.

Technology Neutral: The transport layer must be language, platform, payload, message, and product agnostic.

ebXML:

- The ebXML standard has no limitations or restrictions to a language, platform, payload, or product.

SMTP+S/MIME:

- Both SMTP and S/MIME specifications have no limitations or restrictions to a language, platform, payload, or product.

HTTPS POST/REST:

- The HTTP(s) protocol has no limitations or restrictions to a language, platform, payload, or product.
- The RESTful architecture uses HTTP(s) as its transport for transmission from source to destination. As such, there is no language, platform, payload, or product specific technology that is required to implement.

SOAP:

- The SOAP protocol specification has no limitations or restrictions to a language, platform, payload, or product.

Technology Credibility: The transport layer must be based on existing technologies with a proven successful health system to health system history supported by standards.

ebXML:

- ebXML is a family of XML-based standards sponsored by OASIS and UN/CEFACT whose mission is to provide an open, XML-based infrastructure that enables the global use of electronic business information in an interoperable, secure, and consistent manner by all trading partners.[8]
- In the Minnesota Immunization Information Connection (MIIC):
    - The healthcare systems are using Allscripts/Touchworks and the second the shot is added in the EHR, it is sent off to MIIC.
    - Below is a snapshot from Tuesday 2/8/2011.
        - HIE using VXQ COMPLETE (5)
        - Health System A sending VXU: COMPLETE (543)
        - Health System B sending VXU: COMPLETE (148)
- In the Wisconsin Immunization Registry (WIR)
    - ebXML transport is being used to submit/query HL7 payloads by EPIC, Cerner, and RPMS.
    - WIR processed 1 million VXU messages via ebXML in 2009.
- The state of Georgia IIS also uses ebXML for transport of messages.

SMTP+S/MIME:

- Simple Mail Transfer Protocol (SMTP) is an Internet standard for electronic mail (e-mail) transmission across Internet Protocol (IP) networks. SMTP has been defined through several RFCs and is in widespread use today.
- Secure/Multipurpose Internet Mail Extensions (S/MIME) is a standard for public key encryption and signing of MIME data. S/MIME is on an IETF standards track and defined in a number of documents.
- IIS Usage:
    - ABILITY Network, Inc., a Healthcare Internet Service Provider (HISP), is currently receiving SMTP+S/MIME immunization messages from a provider in Minnesota and then passing those messages to the Minnesota

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8 ebXML – Wikipedia http://en.wikipedia.org/wiki/EbXML_ (Feb. 14, 2011)

IIS via Public Health Information Network Messaging System (PHIN-MS), an ebXML-based transport protocol.
    - ABILITY Network, Inc. is working on a similar SMTP+S/MIME to PHIN-MS message transmission in Oklahoma.
- Other healthcare related information exchanges using SMTP+S/MIME are as follows:
    - Rhode Island's implementation of a provider-to-provider directed exchange uses the SMTP+S/MIME protocol.
    - Various EHR directed pushes to PHRs use SMTP+S/MIME.
    - Veterans Affairs Medical Center mammography referrals to a private sector clinic occur via SMTP+S/MIME.
- The Applicability Statement 1 (AS1) specification for Electronic Data Interchange (EDI) is very similar to SMTP+S/MIME (as defined by the Direct Project) and has been in broad use in the EDI industry for some time.
- SMTP+S/MIME introduces a transport protocol that isn't widely used today by existing operational EHR's or IIS's.
- Looking ahead at Meaningful Use Stage 3 requirements for immediate immunization query and response by the EHRs into the IIS is not a strong suit for SMTP+S/MIME.

HTTPS POST/REST

- HTTP standards development has been coordinated by the Internet Engineering Task Force (IETF) and the World Wide Web Consortium (W3C). Their work created RFC 2616 which defines HTTP/1.1 standard.
    - While HTTP is a standard, the implementation of HTTPS POST as a standard transport protocol isn't. It isn't known to be a common, or standard, approach to messaging outside of the IIS community.
- HTTPS POST was the recommended by the "HL7 Immunization Registry Task Force sub group on HTTP message transport" in 2002.
- HTTPS POST is currently being supported by at least 20 IIS which include but are not limited to the following IIS:

Alaska	Arizona	Idaho	Indiana	Louisiana
Maine	Maryland	Minnesota	Mississippi	Missouri
Montana (in progress)	New Jersey	Oregon	Rhode Island	South Dakota
Utah	Washington	West Virginia	Wisconsin	Wyoming

- Indian Health Services (IHS) submits data with the following IIS using HTTPS POST:

Alaska	Arizona	Idaho	Louisiana	Maine	Mississippi
Montana (in progress)	San Diego	South Dakota	Washington	Wyoming	

- IHS sends out HL7 messages to the following IIS using an HTTPS POST upload feature of the IIS:

Minnesota	Utah	Wisconsin

- There is no official standard for RESTful web services. This is because REST is an architecture and not a protocol. Even though REST is not a standard, a RESTful implementation can use standards like HTTP, URL, XML, PNG, etc.
- RESTful implementations have broad adoption across many different industries including e-prescribing.
- There are no known live or planned RESTful IIS implementations to date.

SOAP:

- The SOAP 1.2 standard is maintained by the XML Protocol Working Group of the World Wide Web Consortium (W3C).
- Of the 20 grantees represented on this panel, New York City has a live SOAP Web Service with Colorado, Oregon, Utah, and Wisconsin planning or actively working on a SOAP Implementation.
    - New York City Usage
        - In 2010, New York City processed over 417,136 HL7 2.3.1 VXQ query/response messages from one large hospital network.
        - Between 01/27/2011 and 02/23/2011, 10,137 VXU messages were received from one EMR system spanning 5 healthcare facilities.
    - New York City's Planned Growth
        - By August 31, 2011, New York City plans to be exchanging with 150 healthcare facilities.
        - By August 31, 2012, New York City plans to be exchanging with an additional 200 healthcare facilities.
    - In 2011, New York City is actively working to bring on 8 of their larger EHR systems.
    - Wisconsin has a SOAP Implementation live in production and is working to bring on providers in the near future.
    - Colorado and Oregon are working to implement their SOAP service.

        - Oregon intends to implement HL7 messaging with 30 partners (133 physical sites) over an 18 month period. The sites are being strongly encouraged to use their SOAP web service.
        - 9 partners (83 physical sites) are working in conjunction with Oregon's go-live plan and looking to exchange HL7 messages starting in spring 2011.
        - In total, Oregon is planning to work with 15 EHR vendors as part of this project.
    - Colorado, Oregon, and Wisconsin have all agreed to a common Web Service Definition Language (WSDL) which will allow for easier EHR adoption.
    - The 2011 IHE Connectathon included 40 EHR's which support the SOAP-based IHE XDS.b profile.

Secure Transmission: The transport layer must provide support for a secure point-to-point transmission of PHI and PII related data.

ebXML:

- The Message Service Specification (ebMS) describes a communication-neutral mechanism Message Service Handlers (MSH) must implement in order to exchange business documents.
- Based on the ebMS specification, the underlying transport protocol (HTTP, SMTP, etc…) is open for design time decisions.
    - Wisconsin, Minnesota and Georgia use HTTPS as their underlying transport to support ebXML specifications based on a few factors including:
        - It is easier to implement than SMTP for the IIS and the EHR.
        - The IIS's were currently live with an HTTPS port already listening to the outside world.
        - The use of ebXML didn't require an additional interface with an email server or directory polling for the incoming payload.
        - It allowed for synchronous processing of real-time messages supporting immunization updates and query/response processing.
- Transport Layer Security (TLS) cryptographic protocol provides communication security over the internet.

SMTP+S/MIME:

- S/MIME is used to encrypt the message and payload. However, it does not encrypt the "from", "to", "subject", nor any other e-mail header field. These are transported as clear text.

- S/MIME supports 128 and 256-bit encryption.

HTTPS POST/REST:

- Transport Layer Security (TLS) cryptographic protocol provides communication security over the internet.

SOAP:

- SOAP supports different transport layers with HTTP and SMTP being the most common implementations.
    - New York City, Oregon, Wisconsin, and Colorado have chosen HTTPS as their transport layer for few reasons including:
        - HTTPS is easier to implement than SMTP for the IIS and EHR.
        - The IIS's were currently live with an HTTPS port already listening to the outside world.
        - It didn't require an interface with an email server or directory polling for the incoming payload.
        - HTTPS allowed for synchronous processing of real-time messages.
        - It is easier for data exchange providers from a "sending" standpoint based on their IT environment.
- Transport Layer Security (TLS) cryptographic protocol provides communication security over the internet.

Reliable Transmission: The transport layer must provide support for a reliable point-to-point transmission of PHI and PII related data. Reliable transmission includes ensuring the message has successfully made it from source to destination and providing a framework to deal with unsuccessful transmissions, Errors during transmission, and the ability to resubmit an unsuccessful transmission.

ebXML:

- ebXML supports reliable message delivery based on the WS-Reliability and WS-ReliableMesaging specifications.

SMTP+S/MIME*:*

- Message Disposition Notification for success or failure and reason for failure. Message Disposition Notification is an IETF standard.
- The "Message-ID" in the message header of SMTP can be used to check for duplicate messages during IIS processing to quickly determine if a message is a duplicate and doesn't need to be processed.

  - Further, the Message-ID can be used for correlated workflows where the reply to an initial payload could be correlated through the Message-ID.
- Given the use of X.509v3 standards for public key infrastructure (PKI) to create trust policies between the sender and the receiver, it is recommended to turn off Spam detection software to avoid trusted messages from being blocked or not delivered to the inbox. Further, configuration settings should prevent non-trusted emails from entering the inbox. It is also recommended to separate work-related "Direct" emails from personal emails through separate email accounts.

HTTPS POST/REST*:*

- HTTPS uses the HTTP response status codes for the sender to ensure reliable transmission of the message.

SOAP*:*

- New York City addressed reliable transmission with their senders by having them resubmit any message they felt didn't yield an expected response. The expected response can be a few different things depending upon the use case, but is usually an ACK, ERR, or query response. Since the Citywide Immunization Registry (CIR), and all other IIS, must properly apply business rules (de-duplicate immunizations, update addresses, etc.), potentially receiving and processing a message twice is not harmful to the IIS or its data.
- Wisconsin looked into WS-ReliableMessaging, but found it to not be beneficial for their use and appeared to add some overhead without value. Similar to New York City, the Wisconsin Immunization Registry (WIR) also has the responsibility to apply appropriate business rules of incoming data, so seeing a duplicate message is not harmful to the IIS or its data.
- SOAP Faults can be used to properly address the failed SOAP transmission and determine what actions to take based on the failed transmission.

Authentication: To achieve an optimal score, the transport layer must provide an easily implemented and maintained system-to-system authentication framework/protocol. This score should also consider operational management as the number of external systems increases.

ebXML:

- Collaborative Partner Profile Agreements are XML-based documents specifying a trading agreement between trading partners. Each trading partner will have their own Collaboration Protocol Profile (CPP) document that describes their abilities in an XML format. For instance, this can include the messaging protocols they support, or the security capabilities they support. A CPA document is the intersection of two CPP documents, and describes the formal relationship between two parties. The following information will typically be contained in a CPA document:
    - Identification information: the unique identifiers for each party and their roles within the trading relationship
    - Security information: for instance, are digital signatures required, and what algorithms do they use.
    - Communication information: the protocols that will be used when exchanging documents.
    - Endpoint locations: the URL to which service and action messages should be sent.
    - Rules to follow when acknowledgments are not received for messages, including how long to wait before resending, and how many times to resend.
    - A decision on whether duplicate messages should be ignored
    - A decision on whether acknowledgments are required for all messages[9]

- It is important to note that for each sender there must be a CPP Agreement between the sender and the receiver, meaning the receiver must maintain a CPA document for each sender. As the list of senders grows, the list of CPA's the receiver is responsible for also grows. From a maintenance standpoint, tracking all of the CPA's could become a substantial effort.
    - Wisconsin has worked to operationalize and mitigate this concern over the years since its initial implementation in 2003.

SMTP+S/MIME:

- SMTP+S/MIME authentication, or trust model, within the Direct Project is to use the ITU-T X.509v3 standards for public key infrastructure (PKI) based on IETF Internet certificate profiles (PKIX) will enable Direct Project users to create trust policies that enable network encryption by the use of digital certificates, public and private keys and certificate authorities. The content encapsulated in the messaging protocol is secured using the Secure/Multipurpose Internet Mail Extensions (S/MIME) protocols.

[9] ebXML – Wikipedia http://en.wikipedia.org/wiki/EbXML (Feb. 15, 2011)

HTTPS POST/REST

- Today, most IIS implementations perform authentication by passing name value pairs in the body of the POST which include a username, password and in some cases a facility ID. This approach mimics a web-form and follows the Transport of Immunization HL7 Transactions over the Internet Using Secure HTTP version 1.0 by the HL7 Immunization Registry Task Force subgroup on HTTP Message Transport.
- Authentication occurs during each transaction (trip).
- It could be possible to extend this model for session-based "conversations" where once the sender is authenticated, multiple transactions (trips) could be made without being required to authenticate with each trip. A logout or timeout would require the sender to authenticate again.
- It would be entirely feasible to consider other authentication methods such as Basic Access Authentication or Digest Access Authentication for continued sender simplicity.
- While no REST IIS implementations exist, it is agreed the HTTPS POST approaches can be applied to a RESTful architecture.
- Other authentication approaches to explore include Public Key with client certificates, SAML Tokens and Secure Remote Password protocol.

SOAP:

- New York City uses HTTP Basic Authentication which includes a facility ID, password, and a CIR created Identity Key for each provider. The identity key is a long string unique to each sender.
  - New York City considered using a facility ID, password, and client certificate, but opted against it at this time for simplicity and maintenance ease. Their design doesn't prevent them from considering a client certificate in the future.
- WIR-based IIS will be using a custom CA Certificate for authentication. Each sender will have an individual certificate. WIR is building a "sender bundled package" which can be easily installed by the sender and provide a simple API to the EHR for calling off to the registry. The bundled package will contain the individual certificate.
  - WIR is also planning to use SAML tokens with Epic and possibly other large providers
  - Small providers will use the WS-Security Username Token Authentication
- Authentication in both scenarios happens with each transaction. Neither New York City nor Wisconsin has seen a performance issue with that approach.
- In comparing the two methods of authentication, the subgroup agreed that maintenance in Wisconsin is likely larger than New York City but more secure. Maintenance is larger because certificates expire and must be reissued, the sender could change IP addresses rendering the certificate invalid. Wisconsin is

more secure because client certificates ensure the message is truly coming from the sender it purports to be.
- VPN could be considered, but it is known to have scalability issues from an operational standpoint to be viable.

IIS or Receiver Requirements

Ease of Implementation: The transport layer must be easy to implement for an IIS.

ebXML:

- Wisconsin implemented in 2003. At that time, WIR implementation took several months and was very complex to install, configure and test. Wisconsin's ebXML implementation uses the PHINMS product and required very little custom coding. It took several months from the start of the project to Go-Live.
    - Support issues from the CDC related to installation and usage for an IIS setting were difficult to work through at the time of installation.
- Minnesota's implementation (2008) followed a similar story to Wisconsin's effort, and they also opted to install PHINMS. The two install models are slightly different based on state data center policies and overall architecture vision from a central IT perspective, but the install and configuration process was very time consuming. It took Minnesota several months from the start of the project to Go-Live.
- The silver lining between Wisconsin and Minnesota is the flexibility in ebXML to support the different architectures. Both approaches proved to be successful with minor configuration and coding changes between the two states.
- ebXML as a whole is complex and overall knowledge is limited which often leads to large learning curves and implementations which take longer than first anticipated.

SMTP+S/MIME:

- From an IIS setting, it is not entirely clear how long it will take to fully implement an SMTP+S/MIME solution or exactly how complex it will be.
    - SMTP+S/MIME are familiar and heavily used in IT which will allow for easier acceptance through governance procedures.
- John Halamka, CIO at Beth Israel Deaconess Medical Center (BIDMC), wrote on his blog "BIDMC engineers installed the open source Direct Gateway inside the BIDMC firewall. They worked with Healthvault engineers to exchange certificates so that the digital signing and encryption aspects of Direct's S/MIME implementation would guarantee data security and integrity. BIDMC engineers

then sent my Continuity of Care Record and Continuity of Care Document via the Direct gateway to my secure Health email address."

- This implementation was performed in 1 day. This implementation and its supported use case is different than some of the EHR to IIS use cases but does show some of the flexibility and ease with which SMTP+S/MIME can be implemented.

- Pennsylvania and Michigan estimate the project to be a few months for an SMTP+S/MIME implementation.
  - It is anticipated to take a few months due to the following reasons (there may be other reasons):
    - State Data Center interaction/timeline.
    - Potential additional interface required to complete the delivery of email to the IIS server for processing.
    - Creation of a sweeping program to monitor incoming directory for the payload for processing.
    - Creating a reply (once processing is finished) message involves sending an SMTP+S/MIME message back. Again, another interface with an email server may be required. Some IIS can send outbound email directly from the IIS server. Others are restricted from sending email due to policy.
    - Lack of development knowledge on IIS development team or with IIS vendor to properly and quickly implement SMTP+S/MIME.
      - Reference Implementations aid in mitigating the learning curve.
    - How does an IIS map the PKI trust model into a facility in the IIS for processing? Most IIS operate on a purely web-based authentication model of username and password for identity.
      - Could look at mapping incoming email address into the IIS user or facility for processing.
    - Capacity planning.
    - Governance Issues.

HTTPS POST/REST:

- HTTPS POST can be implemented easily through common tools already used by an IIS development team.
- There is a very small learning curve for HTTPS POST due to the use of existing tools and the HTTP model most IIS staff are already familiar with.
- HTTPS POST implementation timeframe can be measured in weeks versus months based on Transport of Immunization HL7 Transactions over the Internet Using Secure HTTP version 1.0. With existing web-based IIS, most of the framework and architecture are already in place.

- REST is not drastically different than HTTPS POST. There is a bit of a learning curve that may not exist in HTTPS POST for those unfamiliar with a RESTful architecture, but it would add an architecture over raw HTTPS POST.
  - Making the step from HTTPS POST up to a full RESTful architecture would be very manageable.
- There are no known REST IIS implementations to refer to, but it is believed the timeframe would be slightly longer than an HTTPS POST implementation due to the learning curve.

Ease of Implementation

SOAP:

- New York City:
  - It took about 6 months to implement.
  - Implementation was completed in 2009.
  - If NYC had to do it again, they could probably do it more efficiently with generation tools such as Java2WSDL to reduce the implementation timeframe.
  - Overall, it was a straightforward implementation in Java in Linux using Apache AXIS.
- Wisconsin:
  - Java implementation on Linux was deployed using Glassfish.
  - WI took roughly 6 months to implement.
- Oregon:
  - Oregon is leveraging WIR's SOAP implementation. Configuration issues were based on mildly different architectures (Proxy server and Solaris), but they have resolved those configuration issues.
  - Implementation time will also be measured in months.

Ease of Maintenance: The transport layer must be easy to maintain for an IIS.

ebXML:

- The Wisconsin maintenance story is much different than the install story. Once the install was complete, the ebXML transport piece is usually an afterthought on a daily basis. Once live with a provider, one or two support calls per year would be a lot.

    - Subsequent installs (due to new servers) has become easier. Initial learning curve is more problematic than subsequent installs.
- Minnesota echoes Wisconsin in maintenance. Once the implementation hurdles have been cleared, maintenance has been very minimal.

SMTP+S/MIME:

- There are no operational IIS to reference at this point.
- Email services can go down and may go down for a day. Operationally, this wouldn't be acceptable for an IIS and its Service Level Agreements.

HTTPS POST/REST:

- Known situations which have caused issues have been SSL certificate changes and also using a lesser-known certificate. There have been issues with lesser-known certificates and trust by client-side applications.
- From a pure transport perspective, daily maintenance is very minimal, and there are very few support calls directly related to the transport.
- With no known REST implementations, it can only be assumed that maintenance would be very similar to HTTPS POST.
- It is possible with a RESTful architecture, there will be a bit more complexity due to the use of more HTTP verbs (GET, PUT, and DELETE).

SOAP:

- NYC:
    - From a transport perspective, there is minimal daily effort or issues.
    - New Provider Rollout
        - It included a confidentiality agreement for the EHR vendor and healthcare facility.
        - A test environment account was created.
            - Some providers run with it and are successful; others ask questions and require a bit more support to get up and running.
            - Once the provider is ready for formal test, the provider sends a month worth of data through single transactions.
        - With increased staff, CIR staff can now work in greater detail with providers to ensure a more successful and repeatable process to provider roll-out.

    - No major issues or special consideration would be required for new server install.
- WIR:
    - Recently went live (January 2011), so very early in the maintenance process. Working to bring up the first provider.
    - Support from Glassfish has been very good.
- Oregon:
    - As of mid-February 2011, Oregon is actively testing their SOAP interface and working towards a Spring 2011 Go-Live.

Scalable: The transport layer must be able to efficiently handle increases in serial and parallel requests to the IIS as the number of external systems that communicate with the IIS simultaneously increases.

ebXML:

- There are no known limitations in a real-time setting where the payload is small.
- When the payload becomes larger, ebXML doesn't offer a framework for chunking the payload to support transmission of large payloads. Newer versions of PHINMS can chunk data to support larger payloads. If creating an ebXML transport (not PHINMS or any other product), the chunking component would have to be addressed.

SMTP+S/MIME:

- From a transport perspective, there are no anticipated scalability issues.

HTTPS POST/REST:

- There are no known scalability issues with HTTPS or the implementation approach to HTTPS POST.
- While there are no known REST implementations by an IIS, there are numerous implementations of REST both in healthcare and web-world as a whole. The underlying transport to REST is HTTP which has proven very scalable.
- It is acknowledged that there is a potentially longer timeframe from the start of the project to Go-Live for REST.

SOAP:

- No known scalability issues

- New York City sees multi-threaded submission and processing from sending providers which is handled easily through New York City's SOAP service allowing for simultaneous messages from a single provider.

Subject Area: Ease of Use: The transport layer must provide effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.

ebXML:

- A large payload size can cause an operational issue.
    - In an older PHINMS implementation this can lead to the PHINMS component "freezing" until it is restarted.
- There are numerous toolkits in support of ebXML development and maintenance ranging from open source to privately licensed software.

SMTP+S/MIME:

- From a development standpoint, numerous SMTP+S/MIME development and support toolkits exist ranging from open source to privately licensed software.
- The Direct project has two reference implementations in different programming languages.

HTTPS POST/REST:

- Development and monitoring tools exist in nearly all major programming languages for HTTP and HTTPS.
- Existing tools used by IIS development staff could be used without the need for new tools or learning curve.

SOAP:

- From a development standpoint, multiple SOAP development and support toolkits exist ranging from open source to privately licensed software.
- A large community of practice, web resources, tutorials and example code all freely exist to make ease of use very attractive.

Performance: The transport layer must provide framework to achieve service quality to the user from the start to the finish of a given task. However, it must not degrade other system services to accomplish its task.

ebXML:

- Payload size may be bloated based on the SOAP with Attachments specification ebXML implements for attaching payloads.
- It is expected, but not proven, that ebXML may perform slightly slower than other frameworks due to the flexibility and complexity within the ebXML specification not found in other frameworks.
- In Wisconsin, an HL7 message query and response "round trip" usually takes around 3 to 4 seconds.

SMTP+S/MIME:

- Currently there are not enough SMTP+S/MIME implementations to prove performance, but at this time there are also no known concerns with this approach related to performance from a transport perspective.
- When looking at the HL7 use cases which must be supported, it is acknowledged that SMTP+S/MIME has limitations in a query/response model where response time must be within seconds in order to repaint an EHR screen.

HTTPS POST/REST:

- There are no known limitations in the HTTPS transport protocol which would cause performance degradation or a disruption to existing IIS services and/or end users.
- In use, HTTPS POST has proven to be a very solid solution with great round trip response times.

SOAP:

- SOAP with Attachments can create bloat with large payloads.
    - This is mitigated by using **Message Transmission Optimization Mechanism** (MTOM) rather than SOAP with Attachments.

- There are no known limitations when working with small quick individual transactions.

Subject Area: Cost Effective: The transport layer must be as cost effective as possible for the IIS.

ebXML:

- With a canned product (such as PHINMS), there is considerable installation, configuration and testing time, but far less than creating an ebXML framework from the ground up.
- Creating an ebXML framework would be a substantial undertaking involving several people and measured in months of effort, not weeks. Possibly some open source ebXML frameworks could be used to aid in development time.

SMTP+S/MIME:

- Certificate costs will be an initial and on-going cost ranging from $100 - $900 per certificate per year.
- Verizon Business runs a large number of trust services and they are currently offering zero dollar certificates for the provider.
- Most Direct Project implementations have been able to use existing email servers to avoid the purchase of specific hardware for the project.
- There is potentially a nominal fee from State Data Center for email support/services.

HTTPS POST/REST:

- Based on both Ease of Implementation and Ease of Maintenance, the cost effectiveness of this approach is very attractive. IIS development staff will have a very small learning curve which does not require additional third-party tools on top of their existing toolset.
- From development into production, there is no requirement for additional hardware, software, or external IT staff (network, data center, etc…) to operationalize this approach. The web-based IIS already provides the necessary environment and network to move this forward into production.

SOAP:

- No license, hardware, software, third party support costs known.

EHR or Sender Requirements

Ease of Implementation: The transport layer must be easy to implement for an EHR.

ebXML:

- Keys to success:
  - IIS must accept a support role for helping providers install/configure.
  - The install process must be as easy as possible with minimal manual steps.
  - Level of technical knowledge at the provider level is a key factor to success.
- Pros:
  - In Wisconsin and Minnesota, the process of installing PHINMS with the provider has become very repeatable and manageable over time. Newer versions of PHINMS have also helped as the install process is easier.
  - Once actively engaged in the project, providers can usually be ready to submit data (queries) within a week.
  - ebXML provides a very extensive set of rules to allow for better interoperability.
- Cons:
  - ebXML is a bit more obscure than web services and providers may struggle to work with it.
  - Very few EHR's are interested in bundling a third-party tool into their EHR.
- Other notes
  - Still being rolled out to providers.
  - Providers that at one time declined to install PHINMS are now moving to implement PHINMS.

SMTP+S/MIME:

- Polaris Medical Management EHR Implementation of SMTP+S/MIME fit very nicely into their development cycle. No issues were encountered and it was described as simple and easy.
- From an EHR perspective, if the EHR is hosted at the practice:

  - Email servers aren't typically tied to EHR platform which creates an interface problem between the EHR and the email server.
    - EHR vendors are starting to build exchange capabilities into the EHR to mitigate this. Usually based on the IHE XDR profile or a proprietary exchange.
  - Often from an EHR perspective, it is easier to stay within your own platform and product for sending than potentially interfacing with an unknown server such as email or a HISP.
- Integrating into an EHR may take a similar amount of effort as an HTTPS model.

HTTPS POST/REST:

- IIS perspective:
  - From the IIS perspective, success largely depends upon the technical expertise at the provider setting. Most IIS provide some level of an Implementation Guide, Guidelines, sample code, and varying level of support in implementing.
  - This is usually performed with minimal questions due to the straightforward approach of HTTPS POST and the familiarity with HTTP at the provider level.
- IHS Perspective:
  - Considered a "medium" for easiness compared to other technical tasks given to local technical staff. The technology is easy for those familiar with it, but the local IT staff isn't always familiar with HTTPS POST at this level of detail.
  - Usually successful within a couple weeks.
- The other key driver to ease of implementation is how the EHR is supported.
  - If the provider has an "EHR-Hosted" solution it is very simple and straightforward, as the EHR vendor is responsible for the implementation
  - If the provider has the EHR installed locally, it often takes a bit longer as the IIS is working directly with the provider with a limited IT skill set.
- REST may add some complexity over simple HTTPS POST.
- Making the step from HTTPS POST up to a full RESTful architecture would be very manageable.

SOAP:

- Pros:
  - The tooling across the variety of languages makes SOAP easy to work with.
  - Exposing the WSDL at the endpoint makes for an easier implementation.

    - SOAP provides the ability for IIS to easily provide sample code in various languages aids in EHR adoption and development time.
    - Wisconsin is working on a small bundled client which can be installed with minimal effort to eliminate provider technical resources from having to learn web services.
- Cons:
    - Private Key installation into a key store can sometimes be difficult due to OS access issues. Local technical resources are not always familiar with these issues.
- Other notes:
    - Timeline for the EHR in NYC is currently 3-6 months, but that timeframe is being condensed as the process is refined.
    - Oregon, Wisconsin, and NYC all provide some level of documentation to the provider to specify how to interface with their IIS.
    - Dependency on the EHR to become actively engaged often drives the timeline.
- Once an EHR has it implemented, rolling it out to multiple providers become easier.

Ease of Maintenance: The transport layer must be easy to maintain for an EHR.

ebXML:

- Pros:
    - When PHINMS is running, it is very solid. Providers rarely have to call in for support issues.
- Cons:
    - Older versions of PHINMS have an issue with limited package size.
    - Sending and Receiving directories have caused confusion at the provider level.
    - In Wisconsin, if they have to perform maintenance and shutdown PHINMS, they must inform their “senders” to restart their instances for future successful communication.
    - Sometimes providers are unaware their PHINMS install has stopped sending data. The IIS help desk must reach out to the provider for a restart.
    - Providers sometimes run into PHINMS counter issues requiring technical support by the IIS to aid in properly setting their counter.
    - Providers and EHR’s can struggle interfacing with PHINMS.

- Native ebXML could eliminate many of the cons listed above, but would require much deeper ebXML knowledge on the provider side which is known to be limited.

SMTP+S/MIME:

- Most will likely be implemented with a HISP who will be managing support for the provider.
    - While this is not necessarily a problem, it does add an extra layer of support the providers have to consider when dealing with maintenance issues and where the support comes from (EHR, HISP, or IIS).

HTTPS POST/REST:

- IHS Perspective:
    - Once implemented, it is very solid and issues rarely occur.
    - If an issue does occur it is not immediately clear where the problem is from the provider perspective, but this is likely an issue with all transports.
        - A better defined flow or process would help this.
        - Once the problem is properly identified, fixing the problem is very easy.
- The IIS rarely sees problem with the transport itself. More times than not the issue with the content (data).

SOAP:

- From the sender perspective, the largest hurdle is certificate management and occasional TLS issues related to the certificate or OS access issues.
- From a transport perspective, very minimal issues occur once the transport is implemented and operational.

Scalable: The transport layer must be able to efficiently handle increases in the number of users, patients, and vaccines in the EHR system.

ebXML:

- It has proven to be scalable in Wisconsin, but EHR's have significant work in interfacing with PHINMS.
- Native ebXML has no known scalability issues.

SMTP+S/MIME:

- There are no known scalability issues from a transport perspective.

HTTPS POST/REST:

- There are no known limitations.
- It transports 4-5 Mb of HL7 data per day from Large IHS provider in Arizona.

SOAP:

- No scalability issues from the senders point of view. SOAP scales nicely in the EHR setting.
- In New York City, one of the large providers has found a way to parallelize their submissions to the IIS.

Ease of Use: The transport layer must provide effectiveness, efficiency, and satisfaction with which the intended users can achieve their tasks in the intended context of product use.

ebXML:

- Development ease of use may be difficult for the EHR or provider side to tie request and response together.
- Once installed, maintenance activities are easy for the provider.

SMTP+S/MIME:

- Plenty of toolkits are available to support the use of SMTP+S/MIME.
- Direct Project has reference implementations available for developers.
- SMTP+S/MIME plays well in system-to-system sending and receiving for asynchronous processing.
- SMTP+S/MIME do not play well in synchronous query/response or synchronous unsolicited data submissions.

HTTPS POST/REST:

- Both live interactions with a human invoking a call to the IIS (seamless to the user) and system-to-system interactions are a natural fit for the EHR and support all of the HL7 use cases.
- Similar to the IIS, the same tools can be used by the EHR to develop and support HTTPs POST.

SOAP:

- Rich Toolsets exist for most any language which makes development easy to work with.
- The nature of this protocol can be implemented in a workflow agnostic manner and made very seamless to the end user.
- SOAP has a very repeatable implementation process for the EHR.

Performance: The transport layer must provide a framework to achieve service quality to the user from the start to the finish of a given task. However, it must not degrade other system services to accomplish its task.

ebXML:

- ebXML has no known performance issues. ebXML's underlying transport is HTTPS.
- Using PHINMS it is known to be slower for the full trip due to the EHR's requirement to interface with PHINMS over native ebXML.

SMTP+S/MIME*:*

- There are no known performance issues.

HTTPS POST/REST:

- There are no known limitations.

SOAP:

- SOAP is a very thin client. No additional installation is required outside of what the EHR already provides.

- SOAP has a natural fit with EHRs.
- There are no known performance issues.

Cost Effective: The transport layer must be as cost effective as possible for the EHR.

ebXML:

- The only cost in Wisconsin and Minnesota for the provider is the human time to install the sender.

SMTP+S/MIME:

- Costs would be developer resources for implementation. Minimal on-going costs would be similar to other transport models.

HTTPS POST/REST:

- There are no known barriers. There are both open source and privately licensed products. This could be entirely implemented with open source tools.

SOAP*:*

- The only cost is development cost.
- Some IIS may supply a certificate.

Appendix F: Known Global Issues

In considering the selection of a top choice for a transport protocol, the team listed and discussed a number of factors that are common to all transport layer protocols. Some were locally variable issues (e.g., laws), some were addressed through implementation and configuration decisions (e.g., Certificates), and some will need to be addressed by each site in the design of their systems and environment. Because these issues applied to all protocols, the panel considered them out of scope for conducting their evaluation and comparison of the protocols. In no particular order, these issues include:

- IIS support for provider implementations
- EHR support for multiple transport options
- Distributed Denial of Service attacks (DDoS)
- Certificate Management
- Community Policies and Laws
- Integration Engineering
- Demographic Matching and Forecasting

IIS support for provider implementations

For any IIS, the broader community of provider participants will likely present a challenge in terms of the numbers and types of transport that will require support. We recognize that the path to recommending a single transport standard will not suddenly make all the others go away - expertise and support for existing and currently implemented transport mechanisms will be needed for many months ahead (and possibly longer in some jurisdictions). New development should take advantage of the emerging standard, so we should see an asymptotic curtailing of legacy support in the long term.

EHR support for multiple transport options

The same challenge will face the EHR vendor community, with regard to IIS partners. In a sense, it may be an even broader problem for the EHR vendors, as they will need to meet the transport needs of diverse IIS systems across states, HIEs, etc.

Certificate Management

Any of the candidate technologies that rely on X.509 certificates (or similar) must address a number of challenges common to this method:

The simple numbers problem - As the number of sites grows, the sheer number of certificates under management grows as well - along with all the concomitant problems.

For sites lacking an automated workflow tool for this purpose, this can become a significant amount of work.

The CRL problem - As the number of certificates under management grows, the task of checking the Certificate Revocation Lists for revoked certificates becomes more arduous, and must become more frequent. This is exacerbated by the likelihood that the overall community will come to use certificates from a growing number of Certificate Authorities as the practice matures, so multiple CRLs must be checked.

The total cost of operation - Most certificates are non-free, so the overall cost to the participating population continues to increase as the number of certificates in use increases.

Error rate - Common certificate errors include expiration and failure to update when switching to a new IP address, which invalidates the certificate. Even at a fixed error rate, as the number of players increases, the amount of time spent in troubleshooting and resolving these and other problems will continue to grow.

Community Policies and Laws

Based on experiences across the team, it is very clear those local rules, whether city or state policies or laws, will introduce a set of potential challenges for which each site must adapt. This is most evident in the areas of privacy and security, but also in records retention, audit requirements, separation of duties, and many other factors. These are not really addressed by the recommendation of a single transport solution.

Integration Engineering

For any transport method, most sites will have a local version of the 'last mile engineering' problem - some amount of custom development, configuration, or tooling will likely be needed to fully integrate the messaging transport with the IIS proper.

Demographic Matching and Forecasting

This is nominally a special case of the 'local rules' problem - each site will need to address the issue of validating patient and provider identities for records matching, especially in jurisdictions lacking a single or central master patient index.

Appendix G: Technology Recommendation Development Workgroups

Project Background

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Known Global Issues

Developer:

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Appendix H: Definitions

Asynchronous Response: As it relates to this panel, the transport layer should allow for the receiving system to acknowledge receipt of the payload and process the payload on its own schedule. The sender may check back at a later time for a response payload, or the receiver may initiate a response (reply) to the sender with the response payload.

Authentication: As it relates to this panel, this is defined to be server-to-server authentication. This recommendation should be successful regardless of the payload being sent. Today our goal is HL7, but it is very probable something other than HL7 will be transported in the future.

Health System: As it relates to this panel, a health system is the structured and interrelated set of all actors and institutions contributing to health improvement.

Payload Size: As it relates to this panel, payload size refers to the message size in support of large batches of data.

Receiver: As it relates to this panel, the receiver is any health system accepting receipt of immunization related messages for processing and possible response back to the sender.

Reliable Transmission: As it relates to this panel, reliable transmission will be defined as the concept of communicating messages across an unreliable infrastructure whilst being able to make certain guarantees about the successful transmission of the message and appropriate handling of faulty and/or unsuccessful transmissions.

Secure Transmission: As it relates to this panel, secure transmission will be defined as the secure method by which payload will be transported from system to system.

Sender: As it relates to this panel, the sender can be any health system initiating a transmission of immunization related messages.

Synchronous Response: As it relates to this panel, the transport layer should allow for the receiving system to return response(s) immediately.

Transport Methodology: As it relates to this panel, Transport Methodology refers to the transport protocol and the application of that transport protocol. It does not refer to a software package or product that implements such technology.

Appendix I: Related Background Reading Materials

General

- HLN Guide to Immunization-related Electronic Data Exchange
- Common Framework for Private and Secure Information Exchange
- Wikipedia: Health information exchange
- eHealth Initiative
- Wikipedia: OSI model
- Wikipedia: Internet Protocol Suite
- IHS Interface Guide (pdf)
- AIRA IIS Transport Layer Review (pdf)
- Wikipedia: Authentication
- Wikipedia: Authorization
- Wikipedia: XDS.b Implementation (IDS)
- IHE ITI Technical Framework Supplement XDS-2 (pdf)
- HIMSS News - Standards Corner: Update: The Direct Project
- Wikipedia: Web Service
- RFC 216: Hypertext Transfer Protocol -- HTTP/1.1: (Draft Standard)
- AIRA: Immunization Information Systems: Keeping Pace With Evolving Public Health Initiatives

Web Service

- Wikipedia: Web Services Description Language
- W3C: SOAP Message Transmission Optimization Mechanism
- Wikipedia: SOAP
- W3C: Latest SOAP versions
- W3C: Simple Object Access Protocol (SOAP) 1.1
- W3C: SOAP Version 1.2 Part 1: Messaging Framework (Second Edition)
- AIRA: Evaluation of Web Service for Communicating with IIS (pdf)

HTTPS POST/REST

- Working Together on Data Exchange: A Guide to Indian Health Service (IHS) and State Immunization Information System (SIIS) Interfaces
- AIRA: Evaluation of HTTPS POST/REST for Communicating with IIS
- Wikipedia: POST (HTTP)
- Wikipedia: HTTP
- Wikipedia: Representational State Transfer
- What protocol for NHIN Direct? (Blog, Fred Trotter)

ebXML

- PHIN Messaging System
- Rhapsody/PHINMS Interoperability (pdf)
- AIRA: Evaluation of ebXML for Communicating with IIS
- ebXML
- Wikipedia: ebXML

SMTP+S/MIME

- Wikipedia: Simple Mail Transfer Protocol
- Wikipedia: S/MIME
- The Direct Project
- NHIN Direct - Overview For Consensus
- The Direct Project: Deployment Models
- RFC 821: Simple Mail Transfer Protocol
- RFC 5321: Simple Mail Transfer Protocol (Draft Standard)
- Wikipedia: MIME
- HIT Standards Committee Meeting: November 20, 2010

SFTP and SCP

- Wikipedia: File Transfer Protocol
- Wikipedia: SSH File Transfer Protocol
- Wikipedia: Secure Copy
- RFC 959: File Transfer Protocol (FTP) (Standard)
- RFC 2228: FTP Security Extensions (Proposed Standard)
- RFC 2428: FTP Extensions for IPv6 and NATs (Proposed Standard)