Improving Immunization Information Sharing through Unified Adoption of a Transport Standard

November 4, 2020

Reflects Comments from IIP Team and Executive Committee

A Report from the Immunization Integration Program (IIP) Collaborative

Introduction

The sharing of information between the electronic health records (EHRs) used by health care providers and immunization information systems (IISs) plays a critical role in assuring that both clinicians and public health agencies have access to the immunization information they need to support both clinical decision-making and improvements in public health, contributing to increased vaccination coverage and reductions in vaccine-preventable disease.

Immunization is one of the most effective and successful tools for preventing disease, improving public health, and saving lives.[1] The United States has benefited from high vaccination coverage rates for children and increasing coverage rates among adolescents and adults.[2,3,4] Fully realizing the goals of immunization requires a strong immunization information infrastructure.

IISs and EHRs are key elements of the nation's immunization infrastructure. IISs are statewide or jurisdictional tools used to consolidate immunization records, support response to outbreaks, support vaccine ordering and management of inventory, conduct vaccine coverage assessment, provide vaccine forecasting (or clinical decision support), and remind patients when vaccines are due.[5] EHRs assist health care providers in the ability to identify patients who have missed recommended vaccinations and provide alerts and reminders to clinicians--as well as patients--to close gaps in coverage. They also provide access to an individual patient's immunization history and clinical guidelines to provide clinical decision support. Finally, they enable patients (and their caregivers) to have easy access to their immunization information to not only demonstrate coverage for schools or employers, but also to help them manage their health.[6,7,8] The sharing of information between IISs and EHRs is essential to enabling both health care providers and public health agencies to have access to the information they need to improve vaccination coverage and reduce vaccine-preventable disease.

Having a strong immunization information structure in place is important now, more than ever. The COVID-19 pandemic has resulted in a decline in routine vaccination coverage among both children and adults, given the limitation of movement outside the home to essential activities due to concerns about exposure to the disease.[9,10,11] As the 2020 flu season begins, public health agencies and health care providers alike are concerned about lower than normal influenza vaccine coverage, given the additional burden that will be placed on an already taxed health care system due to COVID-19.[12] Finally, a strong immunization infrastructure must be in place to support the administrative, management, and reporting capabilities associated with new COVID-19 vaccines that are expected to emerge in the coming months.[13]

The Immunization Integration Program (IIP) brings clinicians, EHR developers, health information exchanges (HIEs), and IISs together to gain agreement on and advance the adoption of capabilities and interoperability and information sharing solutions that will

help assure that both clinicians and IISs have timely access to complete and accurate immunization data to support clinical and public health decision-making. Ultimately, the IIP intends to move the needle on increasing vaccination coverage and reducing vaccine-preventable disease.

This program, which began in 2013, is supported and convened by the Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases (NCIRD) Immunization Information Systems Support Branch (IISSB), Chickasaw Nation Industries (CNI) organizations, the Healthcare and Information Management and Systems Society (HIMSS), the American Immunization Registry Association (AIRA), and the Drummond Group.

The IIP accomplishes its goals through two primary programs. The IIP Collaborative, brings stakeholders together to develop and drive the adoption of solutions to improve interoperability, data sharing, and access to immunization information by clinicians and public health. IIP Testing and Recognition facilitates adoption of consensus immunization-related capabilities within EHRs to improve clinical decision-making and information sharing with IISs.

To help support interoperability and information sharing associated with immunizations, on May 20, 2020, the IIP Collaborative—with leadership by its Executive Committee–launched an effort focused on improving immunization data sharing through unified adoption of a transport standard among EHRs and IISs, as well as intermediaries, including HIEs. This report summarizes the results of the IIP Collaborative's work in this area, including recommendations designed to improve information sharing among health care providers—through their EHRs—and IISs, to improve immunization management and ultimately, public health.

This report contains five primary sections, outlined below:

1. Standards for EHR-IIS Interoperability and Information Exchange;
2. Current Levels of Standards Adoption;
3. Barriers to Standards Adoption;
4. IIP Collaborative Recommendations; and
5. Measuring Adoption and Impact.

Standards for EHR-IIS Interoperability and Information Exchange

Congress defined interoperability within Section 4003 of the *21st Century Cures Act* as health IT that enables the secure exchange of electronic health information with, and the use of electronic health information from, other health IT without "special effort" on the part of the user, among other things.[14] The Office of the National Coordinator for Health IT (ONC) published its final rule, *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* on March 9, 2020,

which implements the *21st Century Cures Act*, emphasizing that it "supports seamless and secure access, exchange, and use of electronic health information."[15] To implement the provisions of the Act, the final rule requires health IT developers to publish application programming interfaces (APIs)—using the HL7 FHIR® standard—to allow information to be accessed, exchanged, and used "without special effort."[16] Several federal agencies—including those within the Department of Health and Human Services, as well as the Department of Defense and the Veterans Administration—have embraced HL7 FHIR®, in particular for enabling patient access to health information. The CDC is currently exploring the use of HL7 FHIR® for various use cases and has implemented the standard not only to improve mortality reporting, but also to accelerate electronic case reporting for COVID-19.

The adoption of common standards across disparate health IT systems—regardless of where they reside—facilitates interoperability. Public health agencies at the state and local levels require the reporting of clinical and other data through various public health programs including electronic laboratory reporting, syndromic surveillance, electronic case reporting, public health registry reporting, and immunization reporting to IISs. Adoption of common standards for interoperability is particularly important for public health reporting given the multitude of health IT products (more than 900 of which are listed on the ONC Certified Health IT Product List) which must connect with state and local public health agencies—including IISs across 64 jurisdictions—within the United States and its territories.[17,18]

Through its IIS Functional Standards, v4.1, the CDC sets the expectation that IISs will exchange data with health information systems in accordance with current interoperability standards.[19] ONC also has requirements for EHR products that transmit data to IISs through §170.315(f)(1) *Transmission to Immunization Registries*, of the ONC Health IT Certification Program.[20]

The Centers for Medicare and Medicaid Services (CMS)—through the Promoting Interoperability Program for hospitals and critical access hospitals, and the Merit-Based Incentive Payment Systems (MIPS) Program for clinicians—requires health care providers to attest that they are in active engagement to submit data for at least two of six public health-related purposes, one of which represents immunization reporting to IISs.[21,22] Health care providers must use ONC-certified EHR technology for such reporting.

The effective and efficient exchange of data between EHRs and IISs—a primary focus of the IIP—requires adoption of standards for message content, format, and transport.

The federal government has established standards for both message content and format for the exchange of immunization information for both EHRs and IISs. Both within the ONC Health IT Certification Program and the CDC's IIS Functional Standards, v4.1, EHRs and IISs, respectively, are required to conform with the HL7 2.5.1

Implementation Guide for Immunization Messaging, Release 1.5, October 2014 and HL7 Version 2.5.1 Implementation Guide for Immunization Messaging (Release 1.5)—Addendum, July 2015.[23,24,25,26]

In addition to these message and content standards, for any two systems to connect and exchange data, they must also use an agreed-upon **transport layer**—which is the focus of this report.

As outlined in Section 8.1 of its IIS Functional Standards, v4.1, CDC sets the expectation that IISs will support the Simple Object Access Protocol (SOAP) standard interface and the Web Services Definition Language (commonly referred to as the CDC WSDL), standards that emerged from an expert panel convened by CDC in 2011.[27]

Currently, within §170.315(f)(1) *Transmission to Immunization Registries* of the ONC Health IT Certification Program, ONC does not require EHRs to comply with any transport standard. While the ONC Certification Companion Guide does note that the expert panel convened by CDC recommended the SOAP-based standard for transport of immunization data, it has stated that "developers who pursue ONC Health IT Certification have the discretion to decide which transport standard to implement."[28] Several EHRs have already adopted the CDC WSDL.

Variability in the transport protocols used by both EHRs and IISs to send and receive immunization data results in considerable burden, including both time and cost for EHR developers and IISs related to exchanging data, as well as delays in onboarding of health care providers and their EHRs to the IIS, which—in turn—has a negative impact on the completeness of data for both public health and clinical decision-making. Failure to adopt a common transport can also result in additional costs for health care providers who must support the development of customized interfaces.

Current Levels of Standards Adoption

Through its Measurement and Improvement (M&I) Initiative, AIRA provides IISs with information and tools to more fully align with CDC's IIS Functional Standards. The AIRA M&I effort connects AIRA testing processes with IIS pre-production (or test) systems, and/or analyzes de-identified data, and shares results through the Aggregate Analysis Reporting Tool (AART). More than 80 percent of IISs participate in the AIRA M&I Initiative.[29]

Transport is one of the six content areas introduced to date in which AIRA measures IIS functionality and capability. AIRA assesses message transport using three measures, as summarized below:

- **Measure 1**: The IIS supports the **Connectivity Test Operation** as defined in the SOAP Standard Interface 1.2 specification, WSDL, as endorsed by CDC.

  The Connectivity Test Operation is a "ping-like" feature that allows electronic health records (EHRs) and other sending systems to perform a simple test with

an IIS to verify the two systems can at least "see" each other without having to worry about the semantics of Health Level Seven (HL7) and/or authentication.

- **Measure 2**: The IIS supports the **Submit Single Message Operation** as defined in the SOAP Standard Interface 1.2 specification, WSDL, as endorsed by CDC.

  The Submit Single Message Operation is the primary function of the CDC WSDL designed to carry an HL7 V2.x message, along with the authentication (username, password, facility ID) parameters to make data exchange possible.

- **Measure 3**: The IIS supports the **Security Fault** as defined in the SOAP Standard Interface 1.2 specification, WSDL, as endorsed by CDC.

  The Security Fault shall be thrown by the IIS if the initiating system fails to authenticate (e.g., when a bad username password combination occurs).[30]

AIRA publishes the aggregate results of its conformance testing of the IIS community's CDC WSDL implementation. Such conformance testing utilizes the National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool, which provides consistent, conformance-based results for all measured IISs.

IISs have made significant progress in conforming to the CDC WSDL since the initial baseline measurement in Quarter 3 of 2016. According to AIRA's Quarter 3, 2020 Transport Assessment, Aggregate Report, 44 (or 76 percent) of the 58 IISs that were encouraged to be measured in the IIS Transport Assessment had a CDC WSDL endpoint available for testing. This is an increase of 23 IISs since the baseline measurement in the third quarter of 2016.[31]

Of the 44 IIS with a CDC WSDL end point available for testing:

- 35 of the 44 IISs (or 80 percent) met all three measures;
- 8 IIS met two out of three measures, with all cases missing Measure 3, the Security Fault measure; and
- 1 IIS met one out of three measures.

Progress made within the IIS community with regard to conformance with the CDC WSDL protocol related to transport is illustrated in Figure 1 below.

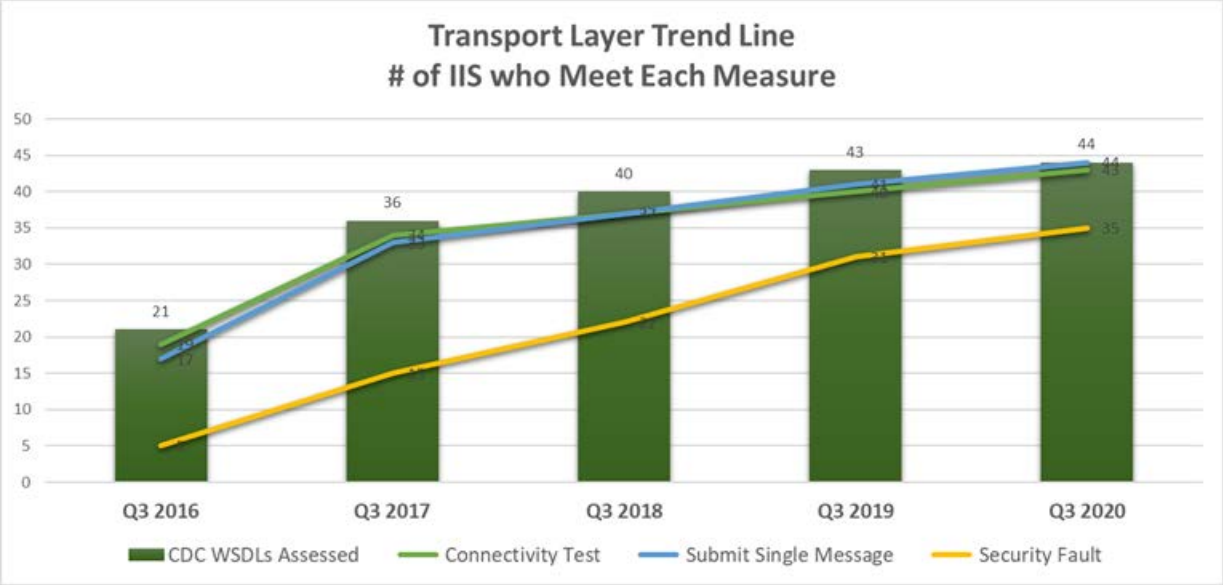

Figure 1: IIS Progress Toward AIRA M&I Measures Related to Transport[32]

Given that 76 percent of IISs are offering the CDC WSDL as one common method of transport, and 80 percent of those tested have met the three measures contained in the AIRA IIS Assessment for transport, the opportunity for movement toward a unified transport protocol is significant. The next logical steps are to:

- Encourage EHRs—many of which have already adopted the CDC WSDL in order to successfully transmit immunization data to the majority of IISs—to more broadly adopt the CDC WSDL as a standard transport protocol; and
- Encourage the remaining 24 percent of IISs not offering the CDC WSDL as one transport method, to begin doing so.

Barriers to Standards Adoption

The IIP Collaborative explored barriers to adoption of the CDC WSDL among both EHR developers and IISs. Key insights shared are summarized below:

- Some EHR developers have been unsure whether adoption of the standard would solve the problem of variability across IISs; many were unaware of the level of adoption (greater than 75 percent) of the CDC WSDL among IISs.
- IISs who have not yet adopted the CDC WSDL cite jurisdictional barriers, such as state IT policies that prohibit the use of the protocol, or interplay with HIEs.
- Both EHR developers and IISs observe that in some cases, HIEs serve as an intermediary for messages, and do not always follow the standard; any movement toward a unified protocol would need to include HIEs.
- EHR developers and IISs also recognize that even with adoption of the CDC WSDL by all parties, there are still some “last mile” variabilities that would need

to be addressed. Participating EHR developers and IISs expressed willingness to work through top priority issues to facilitate effective and efficient exchange of immunization information.

Finally, IIP Collaborative members recognize that Representational State Transfer (REST) and RESTful interfaces have increasingly become more common among organizations implementing exchange both inside and outside of health care and are the predominant mode of transport for HL7 FHIR® APIs. Collaborative members generally agree that—at the current time—unifying around the SOAP Web Services and CDC WSDL as the preferred transport protocol for v2 based messaging represents the most practical and feasible option in light of the already considerable level of adoption among both IISs and EHRs.

IIP Collaborative Recommendations

The IIP Collaborative makes the following recommendations to improve immunization information sharing, with the ultimate goal of enabling clinicians and IISs to have timely access to complete and accurate information, to not only improve immunization management and clinical decision-making, but also to increase vaccination coverage and reduce vaccine-preventable disease.

1. All EHRs Should Adopt the CDC WSDL to Support the Unified Adoption of a Standard Transport Protocol and Improve EHR-IIS Interoperability and Immunization Information Sharing

The IIS Community has embraced the CDC WSDL as a standard transport protocol for the sharing of immunization information with health care providers through their EHRs. This standard—which is one of CDC's IIS "Essential Infrastructure" Functional Standards, has already been adopted by 76 percent of IISs.[33,34] The vast majority of EHRs are also using this standard to facilitate information sharing with IISs. Those EHR developers that have not already adopted the CDC WSDL should do so in the near-term to reduce burden and improve immunization sharing.

ONC should explore how to support EHR adoption of the CDC WSDL for transmission of immunization data to IISs and—as noted in the CDC IIS Functional Standards—consider other transport solutions endorsed by the CDC in the future.[35]

To support EHR adoption of the CDC WSDL, the IIP will take the following actions:

- With guidance and support from its Technical Advisory Panel (TAP), the IIP Testing and Recognition Program is adding new capabilities and tests associated with conformance with the CDC WSDL transport protocol in its 2020 update to the IIP Testing and Recognition Program. These updates will enable EHR developers to voluntarily test the ability of their products to submit immunization data to IISs using the CDC WSDL.

- The IIP will develop and conduct—in collaboration with others—an education and outreach campaign targeting all developers of EHR products, encouraging them to adopt the CDC WSDL transport protocol, and describing the value and rationale for doing so.
- The IIP will support—both directly and in collaboration with others—EHR adoption of standard transport protocols, by facilitating the sharing of lessons learned, best practices, and other guidance.

2. IISs Should Universally Adopt the CDC WSDL to Support the Unified Adoption of a Standard Transport Protocol and Improve EHR-IIS Interoperability and Immunization Information Sharing

As noted above, the vast majority of IISs have already adopted the CDC WSDL as their transport protocol for the sharing of immunization information with health care providers through their EHRs, consistent with CDC's IIS Functional Standards. AIRA has developed a robust Measurement and Improvement Initiative to provide IISs both information and tools to support conformance with the standard. Adoption of a common transport protocol across IISs—as well as EHRs—plays a key role in improving interoperability and immunization information sharing to support public health goals. Despite such progress, fourteen IISs have either not adopted or have not had the transport protocol assessed, which is primarily due to jurisdictional policies and barriers, and in some cases, practices of local HIEs.

States and other local jurisdictions whose IISs have not yet adopted the CDC WSDL should remove jurisdictional barriers and both enable and encourage their IISs to comply with the standard transport protocol. CDC should also prioritize this issue in their communications to and requirements for awardees.

To support IIS adoption of the CDC WSDL, the IIP will also take the following actions:

- The IIP will collaborate with national, state, and local influencers—including large employers, health plans, health systems, and others—to educate policymakers within state and local jurisdictions whose IISs have not yet adopted the CDC WSDL, about the value and importance of adopting the standard and the negative implications associated with failing to adopt the standard, among health care providers and public health.

3. HIEs Should Adopt the CDC WSDL When Supporting Immunization Information Sharing to Promote Unified Adoption of a Standard Transport Protocol

In many cases, HIEs serve as intermediaries between EHRs and IISs. As a result, regardless of the transport protocol and individual EHR or IIS uses, the protocol used to send a message to the ultimate recipient may be different. Therefore, it is

crucial to engage HIEs in the unified adoption of a standard transport protocol for immunization data. The IIP Collaborative participated in a dialogue with several HIEs organized by the Strategic Health Information Exchange Collaborative, which revealed that the level of adoption of the CDC WSDL varies by HIE.

To support adoption of the CDC WSDL among HIEs, the IIP will take the following actions:

- The IIP—in collaboration with others—will conduct an education and outreach campaign targeting all HIEs, encouraging them to adopt the CDC WSDL transport protocol within their own operations and support the adoption of the protocol among their participating organizations, describing the value and rationale for doing so.

4. EHR Developers, IISs, and HIEs Should Work Together to Identify "Last Mile" Issues Associated with Transport and Both Develop and Adopt Common Solutions to Improve Interoperability and Immunization Data Sharing

EHR developers and IISs involved in the IIP Collaborative noted that there are some "last mile" issues that would still need to be addressed, even if a transport protocol was universally adopted. For example, some EHR developers would benefit from greater clarification and additional guidance regarding how the "facilityID" SOAP parameter should be populated for HL7 transmissions to IISs. Both EHR developers and IISs expressed interest in collaborating on the identification, prioritization, and development of solutions to such issues.

To support the resolution of high-priority, last-mile issues that stand in the way of effective and efficient transport, the IIP will take the following actions:

- The IIP will engage key stakeholders—including EHR developers, IISs, HIEs, health care providers, and others, as appropriate—in identifying and prioritizing last mile issues associated with transport, and both developing and driving the adoption of common solutions to address high-priority issues.

Measuring Adoption and Impact

The IIP Collaborative has developed a set of measures to assess both adoption and impact of its recommendations. Ideally, baseline measures should be calculated upon release of this report, and subsequently—on a periodic basis—to assess progress made. Such measures are summarized below.

Adoption Measures

The following measures have been developed by the IIP Collaborative to assess adoption of the recommendations contained in this report:

1. The number of EHRs that have adopted the CDC WSDL and offer it as one transport method;
2. The number (and percentage) of IISs that have adopted the CDC WSDL and offer it as one transport method;
3. The number (and percentage) of IISs that have met all three measures contained in the AIRA IIS Transport Assessment;
4. The number (and percentage?) of HIEs that facilitate exchange of information between health care providers/EHRs and IISs, that have adopted the CDC WSDL and offer it as one transport method;
5. The number of high-priority "last mile" issues identified, addressed, and where possible, resolved, through collaboration among EHRs, IISs and—to the extent applicable—HIEs.

Impact Measures

The following measures have been developed by the IIP Collaborative to reasonably assess impact of the adoption of the recommendations contained in this report. Ideally, baseline measures should be calculated upon release of this report, and subsequently—on a periodic basis—to assess progress made. These measures are designed to align with measures expected to be collected as part of the formal evaluation of the IIP. The IIP Collaborative recognizes that impact improvements cannot be isolated and attributed solely to the adoption of transport protocols.

1. Increase in the percentage of health care provider submissions of immunization messages to IISs through their EHRs (e.g., provider participation);
2. Improvements in the timeliness of health care provider submissions of immunization messages to IISs through their EHRs;
3. Reductions in the amount of time spent onboarding health care provider EHR implementations; and
4. Reductions in perceived burden of onboarding among both EHRs and IISs.

Conclusion

Interoperability and information sharing play a key role in enabling both clinicians and public health leaders to have access to the immunization information they need to support both clinical decision-making and improvements in public health. The adoption of a transport standard among EHRs, IISs, and HIEs is expected not only to improve interoperability and information sharing, but also to reduce burden and cost. Adoption of the IIP Collaborative's transport recommendations can help pave the way toward an interoperable infrastructure that supports the important role of immunization in preventing disease, improving public health, and ultimately saving lives.

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End Notes

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