Preparing for Immunization Interoperability with Public Health:

Keys to Connectivity for Post-Acute and Long-Term Care Electronic Health Record Vendors

Contents

Introduction

Despite the widespread adoption of certified health information technology (IT) among health care providers and long-standing public health support for standards-based immunization data exchange, there is a lack of interoperability between post-acute and long-term care (PAPALTC) electronic health record (EHR) systems and public health immunization information systems (IIS). The lack of connectivity between these systems is due to several historical and current challenges, as reviewed in a companion white paper, *Improving Immunization Interoperability Between Post-Acute and Long-Term Care and Public Health.*

This resource aims to help advance connectivity between PALTC EHRs and IIS by serving as a guide for EHR vendors to ensure technical readiness for exchange with IIS.

Background

Public health IIS are confidential, population-based, computerized databases that aim to record all immunization doses administered by participating providers within a geopolitical area. IIS support clinical practice and population health by providing consolidated immunization histories, clinical decision support for immunization, and data and tools to support tracking and improvement in immunization rates across a population.[1]

There are 61 IIS in operation across the United States and US territories.[2] While each system operates independently under its respective jurisdictional laws and policies, IIS strive to operate as a cohesive nationwide network of systems. Nearly half of jurisdictions engage in inter-jurisdictional data exchange, to support access to complete and accurate immunization records for individuals who move or receive care across jurisdictional borders.[3]

In terms of data exchange with provider systems, connectivity with IIS may be direct, with interface(s) with each jurisdictional system (or potentially health information exchange system where applicable) or may be facilitated by the Centers for Disease Control and Prevention (CDC) IZ Gateway, as directed by CDC. The IZ Gateway serves as a secure, centralized connection with routing to jurisdictional IIS.[4]

Regardless of data flow (direct with a jurisdiction/IIS or mediated by the CDC IZ Gateway), interoperability with IIS requires support for standards and data elements used in immunization data exchange.

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[1]About IIS, CDC

[2]There are 61 IIS operating in each of the 50 states as well as American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, the Federated States of Micronesia, Guam, New York City, Philadelphia, Puerto Rico, the Republic of the Marshall Islands, the Republic of Palau, and the Virgin Islands.

[3]Public Health Impact of Interjurisdictional Immunization Data Exchange, CDC, 2023

[4]Immunization (IZ) Gateway

Purpose

This resource outlines five keys to connectivity to support long-term care EHR vendor technical readiness for immunization data exchange:

1. Support SOAP-based web service exchange.

2. Support HL7 v2.5.1 messaging.

3. Support interface configurability, to align with jurisdictional laws and policies.

4. Ensure workflows to capture and manage data elements.

5. Prepare for processes associated with connectivity: onboarding and ongoing monitoring and maintenance.

Together, these keys to connectivity help ensure technical readiness to support exchange standards and operational capacity to successfully interoperate with jurisdictional IIS. In addition to this resource, a companion *Supporting Immunization Interoperability Workbook* supports self-assessment of the standards and data elements needed to support immunization interoperability, as described in Appendix A.

Interoperability between long-term care and public health supports improved immunization assurance and infection prevention and control, ultimately decreasing morbidity and mortality from preventable disease in an especially vulnerable population.

Suggested uses of this resource

- **PALTC EHR/health IT vendors:** Use this information to guide planning and development efforts in support of advancing immunization data exchange with IIS.

- **PALTC organizations:** Use this information to ensure contracted technical vendors are prepared to support immunization interoperability.

- **Public health immunization programs and IIS:** Review this information in preparation for working with long-term care organizations and their technical vendors to establish connectivity.

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Keys to Connectivity

Support SOAP-based web service exchange

SOAP web service is the preferred transport protocol for the secure transmission of immunization information between systems. Web Service Description Language (WSDL) specifications detail use of SOAP operations to support immunization data exchange.

A CDC WSDL outlines specifications for use of SOAP for direct connectivity with an IIS. If connectivity is mediated via the IZ Gateway (as directed by CDC), an IZ Gateway WSDL is used, along with a digital certificate to support authentication.[5] Both the CDC WSDL and IZ Gateway WSDLs support two operations: Connectivity Test and Submit Single Message. The Connectivity Test operation supports initial connectivity testing, to ensure availability of the SOAP web service. The Submit Single Message operation is used with authorizing credentials to support the secure transport of HL7 immunization messages between systems.

According to the American Immunization Registry Association (AIRA), a member association representing jurisdictional IIS, 96% of IIS achieved basic validation for transport capabilities supporting the CDC WSDL, i.e., these jurisdictions have implemented the CDC WSDL in line with national specifications.[6]

The National Institute of Standards and Technology (NIST) Immunization Test Suite offers self-service SOAP envelope testing and SOAP connectivity testing to assess conformance of CDC WSDL implementation with national specifications.

Quick Links

- *Supporting Immunization Interoperability Self-Assessment Workbook: Transport (Appendix A)*
- SOAP Web Services Specification, CDC WSDL, CDC
- Immunization Test Suite, NIST

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[5] If connectivity is mediated via the IZ Gateway, as directed by CDC, the IZ Gateway team will provide specifications for the IZ Gateway WSDL and further information on obtaining, installing, and maintaining a digital certificate for client-side authentication.

[6] American Immunization Registry Association. Transport Validation: Basic Level, 2023. Among 57 IIS measured.

Support HL7 v2.5.1 immunization messaging

While SOAP-based web services support the secure movement of immunization information between systems, HL7 messaging supports the encoding of this information for transmission between systems. The HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, and Addendum (National IG) provides specifications for the construction of HL7 messages used in immunization exchange. The usage rules within the National IG govern the requirements and expectations related to population of a given element in an HL7 message (see Box 1). The National IG also specifies how certain data elements within a message must be encoded, using indicated code and value sets.

HL7 messaging supports querying an immunization information system to request a patient immunization history and forecast (QBP/RSP messaging) as well as submission of patient immunization information (VXU/ACK messaging). According to AIRA, 88% of IIS achieved basic validation for submission and acknowledgment messaging, i.e., these jurisdictions have implemented HL7 messaging in line with national specifications.[7]

The NIST Immunization Test Suite offers self-service testing to assess conformance of HL7 v2.5.1 messages with the national specifications. Health IT developers supporting HL7 v2.5.1 messaging can have their product(s) certified under the ONC Health IT Certification Program for certification criteria 170.315(f)(1), transmission to immunization registries, which also uses the NIST tool to support testing.

Quick Links

- *Supporting Immunization Interoperability Self-Assessment Workbook:* Format, Vocabulary and Code Sets, Sample HL7 Messages (*Appendix A*)
- HL7 v2.5.1 Implementation Guide for Immunization Messaging, Release 1.5, and Addendum, AIRA and CDC
- Guidance on HL7 Immunization Messages, AIRA and CDC
- Immunization Test Suite, NIST
- Health IT Certification Program, ONC
- Health IT Certification, Transmission to Immunization Registries, ONC

Box 1

Understanding Usage Designations in the National IG

R – Required. This element shall be present.

RE – Required but may be empty. This element shall be present if the data is available within the EHR/health IT system. Note: Many IIS expect certain data elements indicated as RE to be regularly populated, to support matching and deduplication and other business processes.

X. This element shall not be present.

O – Optional. Usage is not defined and may be defined locally, by individual IIS.

C(a/b) - Conditional. Usage is dependent on the specified condition. For example, an element may be R for an administered immunization and RE for a historically reported immunization.

[7]AIRA. Submission/Acknowledgement Validation: Basic Level, 2023. Among 57 IIS measured.

Support interface configurability, to align with jurisdictional laws and policies

Given IIS operate under their respective jurisdictional laws and policies, EHR vendors and long-term care organizations should prepare to support interface configurability. Requirements and expectations for data exchange vary based on jurisdictional laws that govern patient consent, provider reporting, and data sharing. For example, some public health jurisdictions have specific requirements regarding patient consent for participation in the IIS, which may be implemented in HL7 messaging in different ways.

Furthermore, while the National IG provides a framework to support standards-based immunization data exchange, IIS may further constrain the National Implementation Guide (National IG) specifications to support local laws and policies. For example, a jurisdiction may opt to require an element that is required but may be empty in the National IG. This is an allowable constraint within HL7. Local Implementation Guides (Local IGs) published by public health immunization programs provide further detail on these local requirements and specifications. The *Supporting Immunization Interoperability Self-Assessment Workbook* provides an indication of notable local requirements for data elements used in exchange.

Despite jurisdictional differences, the IIS community is actively working to harmonize practices and support inter-jurisdictional exchange of immunization data to operate as a nationwide network of systems. A community-driven Measurement and Improvement initiative provides IIS with information and guidance to promote alignment and consistency in implementation of national data exchange standards. The initiative has demonstrated increasing IIS standardization since measurement began in 2015.

Quick Links

- *Supporting Immunization Interoperability Self-Assessment Workbook:* Data Elements (*Appendix A*)
- Why a National IIS Doesn't Exist, AIRA
- IIS-EHR Interoperability Common Areas of Variability Based on Jurisdictional Law/Policy, AIRA

Ensure workflows to capture and manage data elements

In addition to SOAP web services and HL7 messaging, another key to connectivity is ensuring the capture and management of data elements to support interoperability. Complete and accurate transmissions to IIS ensure submitted immunization information is available in the patient's consolidated immunization history and help ensure patient matches when querying the IIS.

IIS rely on several data elements to support organization and facility identification and patient- and vaccine-level matching/de-duplication. In addition, public health programs rely on high-quality data to support programmatic efforts, such as ensuring vaccine accountability, immunization coverage assessments, identification of pockets of need, reminder/recall, and more. These "high value" data elements are listed in Table 1.

Table 1. High value data elements used by IIS and public health

Provider Org/Site Information	Patient Information	Vaccination Information
Responsible organization (i.e., health system/corporate entity) Facility (i.e., individual, physical site)	• Medical record number • Name (first, middle, last) • Date of birth • Address (street, city, state, and ZIP) • Race • Ethnicity • Gender • Phone number • Responsible person name (first, last) • Mother's maiden name • Multiple birth indicator and birth order, if applicable • Consent indicator, as needed based on jurisdictional law/policy (aka patient protection indicator)	• Encounter date • Vaccine administered product type (CVX/NDC) • Administered/ historical indicator • Lot number* • Lot expiration date* • Dosage administered amount* • Manufacturer* • Eligibility code* • Funding source* *For report of an administered vaccine*

Ensure workflows to capture and manage data elements *(continued)*

While many of these high-value data elements are designated as "Required but may be empty" per the National IG usage specifications, IIS will expect these elements to be regularly populated in submitted messages to ensure high-quality IIS data for all users. Public health jurisdictions will assess this information for accuracy and completeness and alignment with jurisdictional requirements before allowing an interface to "go-live" (see Prepare for Processes Associated with Connectivity below). Given the need for interface configurability to align with jurisdictional laws and policies, vendors should err on the side of preparing to capture and maintain this information, to support their inclusion in HL7 messages as needed. Note, there are some data elements that would benefit from further collaborative discussion to clarify IIS and EHR community expectations regarding their inclusion in messages; these are noted in Appendix B.

Ensuring workflows and processes are in place to support the capture and management of data elements will support successful interoperability. The Immunization Integration Program (IIP), a collaborative between the CDC, AIRA, HIMSS, and Drummond Group, offers several resources to support health care providers and EHR vendors in supporting immunization workflows and exchange capabilities. EHR vendors may also work with IIP to certify for (f)(1) capabilities in the ONC Health IT certification program and become an IIP-recognized vendor.

Quick Links

- *Supporting Immunization Interoperability Self-Assessment Workbook: Data Elements (Appendix A)*
- Immunization Integration Program, (IIP)
- Training Resources for Vaccine Data Entry Users, Immunization Integration Program
- Immunization Capabilities and Guidance, Immunization Integration Program
- Vaccine 2D Barcode Scanning Implementation Toolkit, CDC

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Prepare for processes associated with connectivity: onboarding and ongoing monitoring and maintenance

A final key is to prepare for processes associated with connectivity. Onboarding is the process of working with IIS to establish initial connectivity and complete testing prior to go-live. Once an interface is live, ongoing monitoring and maintenance is required for the life of the interface.

If connectivity is direct with a jurisdiction/IIS, long-term care organizations and their EHR/health IT vendors must work with the jurisdiction to complete their onboarding process. Jurisdictional onboarding processes are typically described as a sequence of four steps, as outlined in Box 3. This process is based on consensus-based recommendations developed by EHRs and IIS to guide connectivity.[9]

If connectivity is mediated by the IZ Gateway, as directed by CDC, the IZ Gateway team provides centralized coordination and management of onboarding with applicable jurisdictional IIS. Regardless of the data flow, the onboarding process ensures interface compliance with national standards and jurisdictional laws and policies where applicable. The process also ensures appropriate authorization agreement(s) are signed prior to connectivity testing and helps ensure data submitted to IIS are high-quality.

Once an interface is live, ongoing monitoring and maintenance is required. Monitoring ensures actionable IIS responses to queries and ensures immunization information submitted to a system is complete and accurate, to support processing and availability for all immunization information system users. A key part of monitoring is follow-up on errors identified in acknowledgement messages returned by IIS. These 'ACK' messages indicate IIS processing results and provide information on errors. Errors with severity level of 'E' (as indicated within an ACK message) should be addressed in the sending system and re-submitted. Finally, maintenance is required to ensure inclusion of new codes in an interface, e.g., when new vaccines are introduced. These codes should generally be made available to clinical staff within the EHR, without the need for additional manual processes.

[9] Onboarding Consensus-Based Recommendations, AIRA

Prepare for processes associated with connectivity: onboarding and ongoing monitoring and maintenance *(continued)*

Box 2

Typical Jurisdictional IIS Onboarding Process

1 **Discovery and Planning**: Preparatory activities completed by the health care provider and EHR/health IT vendor team to demonstrate readiness for exchange and a commitment to the onboarding process. Includes health care provider/facility enrollment in the IIS to ensure authorization to access and use IIS data, completion of onboarding/data exchange form(s), and a kickoff meeting.

2 **Development and Testing**: Sharing of credentials to establish connectivity with an IIS testing/onboarding environment and review of submitted HL7 messages and data. Testing ensures conformance with standards, IIS requirements, and data expectations. Successful testing culminates in the IIS approval to proceed with go-live.

3 **Production Approval and Go-Live**: Transition to the IIS production environment with immediate post-go-live monitoring to ensure continued success. Also includes clinical confirmation of query/response messaging, submission of legacy immunization information, and close-out of the onboarding project.

4 **Ongoing Monitoring**: Includes activities associated with ongoing maintenance and monitoring of the interface, to ensure inclusion of new immunization codes and follow-up to address messaging errors as indicated in IIS ACK messages.

Quick Links

- *Supporting Immunization Interoperability Self-Assessment Workbook:* Jurisdictional IIS (*Appendix A*)
- Jurisdictional Immunization Websites, CDC (Note: search for "Data Exchange" and/or "Onboarding" within these websites)
- Aggregate Immunization Acknowledgment Message Reports Guidance White Paper, Immunization Integration Program
- Immunization Data Code Sets, CDC

Conclusion

Pursuing immunization data exchange with IIS requires an investment in technology, consideration of workflows and processes to support data capture and management, and navigation of laws, policies, and processes associated with immunization data exchange. However, this investment reaps considerable rewards for long-term care organizations in facilitating seamless access to residents' consolidated immunization histories and immunization forecasts. Ensuring residents are up to date with recommended immunizations is imperative to minimizing risk and poor outcomes associated with vaccine-preventable disease in a high-risk, vulnerable population.

Acknowledgments

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Appendix A

Supporting Immunization Interoperability:
Self-Assessment Workbook

PALTC EHR and health IT vendors are encouraged to use the *Supporting Immunization Interoperability Self-Assessment Workbook* to assess capabilities and data elements needed to support successful interoperability with IIS.

This workbook lists transport, format, vocabulary and code sets, and data elements to support querying an IIS for a patient's immunization history and forecast and support submission of immunization information to an IIS. The workbook also provides a list of jurisdictional IIS to aid in planning for connectivity.

>>To access the workbook please click here.

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Funding provided by CDC Cooperative
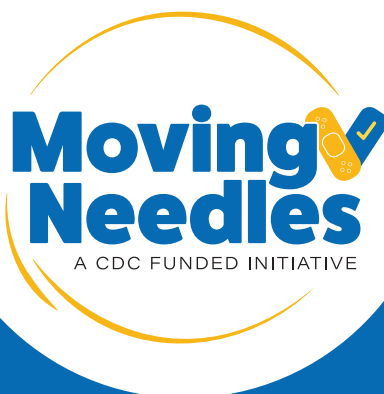Agreement NH23IP922655

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Appendix B

Data Elements for Further Clarification

The following data elements would benefit from further discussion among public health and PALTC EHR vendors, to clarify public health expectations for inclusion in query and/or submission messages from PALTC organizations. Addressing these questions will support more successful onboarding and PALTC-IIS interoperability. If left unaddressed, there will likely be variability in jurisdictional expectations for these elements in submitted messages and longer onboarding processes.

As indicated in the table, there may be questions about what the data element should represent and/or how it should be messaged. In other cases, these may be data elements that PALTC EHR vendors are not planning to support or may be optional for users to record.

Data Element	Query (QBP)	Submission (VXU)	Outstanding Questions
Patient address	X	X	What are IIS expectations for what address(es) should be indicated in a QBP and/or VXU for a resident in a PALTC setting? How should this information be messaged? E.g., PALTC facility address, patient home address, indication of address type(s), sequencing if multiple address types are submitted.
Mother's maiden name	X	X	What are IIS expectations for PALTCs to include this information in a QBP and/or VXU?
Patient birth order and multiple birth indicator	X	X	What are IIS expectations for PALTCs to include this information in a query and/or VXU?
Patient responsible person/ Next of kin		X	What are IIS expectations for PALTCs to include this information in a VXU? Who should be indicated?
Vaccine funding program eligibility		X	What are IIS expectations for PALTCs to include this information in a VXU for an administered immunization?
Vaccine funding source		X	What are IIS expectations for PALTCs to include this information in a VXU for an administered immunization?

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