



# ONBOARDING CONSENSUS-BASED RECOMMENDATIONS

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**AIRA**  
AMERICAN IMMUNIZATION  
REGISTRY ASSOCIATION

# Executive Summary

Onboarding is a term used to describe the process and activities related to establishing an electronic interface between an immunization provider's electronic health record (EHR) system and a jurisdiction's immunization information system (IIS). The onboarding process begins at the point when a provider expresses or registers intent to establish an interface and ends after an interface has been successfully transitioned to the IIS production environment.

Community surveys and stakeholder feedback indicate wide variability among jurisdictional onboarding approaches resulting in significant nationwide backlog for establishing EHR-IIS interfaces. The variability in onboarding approaches and lengthy wait times contribute to frustration among all major stakeholders in the onboarding process and adversely impact the timeliness of vaccination reporting to IIS.

To date, there have been limited guidelines to assist IIS programs in the development of their Health Level Seven (HL7) onboarding processes. The American Immunization Registry Association (AIRA) initiated a project using a community-driven approach to develop guidance for improving and standardizing onboarding with a specific focus on:

- Standardizing the onboarding process across jurisdictions
- Improving onboarding process efficiencies by streamlining activities and introducing appropriate support tools and technologies
- Decreasing the overall number of providers waiting in queue and the amount of time providers spend in process from start to finish
- Facilitating the transition of existing interfaces to align with current and future messaging and transport standards
- Maximizing limited resources—time, money, and staff—for all onboarding partners
- Improving stakeholder relations

This document is intended for both technical and programmatic staff that make up IIS onboarding teams and program administrators responsible for the allocation of onboarding resources. EHR vendors, providers, and health information exchange (HIE) partners may also find this document informative. Material is divided into two primary sections: (1) **Process – Improvements and Recommendations** and (2) **Implementation – Considerations and Recommendations**. Content was developed and validated with input from all major onboarding partners.

This project identified two primary bottlenecks that impede the onboarding process: (1) the period immediately following registration and (2) the programmatic data-quality phase of testing. The following overarching strategies were identified to address these challenges and improve the entire onboarding experience for all stakeholders:

- Minimize variation across jurisdictions. Strive to align with HL7 implementation guidance and standard code sets except where otherwise required by state law or mandate.
- Manage expectations through well crafted onboarding documentation and proactive written and verbal communication between stakeholders.
- Identify opportunities to reduce reliance on IIS staff participation by automating manual processes and strategically leveraging IIS reports and supporting tools/technologies.
- Create opportunities for onboarding providers and EHR vendors to conduct preliminary testing and issue resolution independently.
- Leverage general momentum and provider enthusiasm by focusing IIS resources on providers with the most interest and readiness to proceed.

The guidance in this document is intended to stimulate conversation and challenge IIS programs to reevaluate their current onboarding protocols and identify opportunities for improving and streamlining all elements of the onboarding process. A list of actionable improvements and recommendations appears at the end of each topic discussion. This project also uncovered a number of gaps and challenges that could not be addressed within the scope and time frame allotted for the current effort. These gaps and challenges should be prioritized for future stakeholder discussions.

# TABLE OF CONTENTS

<b>EXECUTIVE SUMMARY</b>	<b>i</b>		
<b>1 INTRODUCTION</b>	<b>1</b>	<b>3 IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS</b>	<b>38</b>
Background	2	Onboarding partners	40
Audience, methodology, and document organization	4	Partner considerations	45
Reader guidance	6	Importance of standards	48
		Managing backlog	52
		Onboarding prerequisites	54
		Data quality	56
		Provider interface training	58
		Communication	60
		Documentation	62
		Onboarding tools and attributes	66
<b>2 PROCESS – IMPROVEMENTS AND RECOMMENDATIONS</b>	<b>7</b>		
Step 1: Discovery and Planning	11	<b>4 CONCLUSION</b>	<b>70</b>
Registration	11		
Preparatory	14		
Step 2: Development and Testing	18		
Stages of testing	18		
Importance of ACK messaging	22		
Test environment and test data	23		
Abbreviated testing protocols	26		
Step 3: Production Approval	29		
Step 4: Interface Monitoring	31		
New or updated production interface	31		
Existing production interface	32		
Re-onboarding	32		
Onboarding: Bidirectional HL7 query/response	33		
Matching algorithms	36		

# APPENDICES

## **APPENDIX A** **ABBREVIATIONS/ACRONYMS 74**

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## **APPENDIX B** **SYNOPSIS OF KEY RESOURCE MATERIALS 75**

B-1. Materials developed/published by CDC	75
B-2. Materials developed/published by AIRA	78
B-3. Materials developed/published by NIST	85
B-4. IIS sample onboarding materials	87

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## **APPENDIX C** **ONBOARDING REFERENCE LIST 91**

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## **APPENDIX D** **CONSOLIDATED ONBOARDING RECOMMENDATIONS 93**

---

## **APPENDIX E** **BARRIERS/CHALLENGES 99**

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## **APPENDIX F** **GAPS 100**

---

## **APPENDIX G** **ACKNOWLEDGMENTS 102**

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# 1

## INTRODUCTION



# 1 INTRODUCTION

## BACKGROUND

Onboarding is a term used to describe the process and activities related to establishing an electronic interface between an immunization provider's electronic health record (EHR) system and a jurisdiction's immunization information system (IIS).

Some interfaces represent direct point-to-point connections between a provider organization and the IIS, while others utilize a centralized reporting hub, like a health information exchange (HIE) or a vendor-supported solution. IIS serve as a centralized resource for consolidated patient immunization records that are leveraged by a variety of authorized stakeholders. EHR-IIS interfaces facilitate clinical decision support (CDS) and improved patient care through the mutual exchange of patient-level vaccination information.

For the purposes of this document, a provider begins the onboarding process at the point when it expresses or registers intent to establish an interface and ends after the interface has been successfully transitioned to the IIS production environment. Results from the latest IIS Meaningful Use Survey<sup>1</sup> indicate significant variability among jurisdictions with respect to the number of provider sites that are currently in queue to begin onboarding or in progress at various stages of the onboarding process. Survey results also indicate large numbers of providers submit data to the IIS using the legacy Health Level Seven (HL7) 2.3.1 standard versus the current v2.5.1 standard. Interfaces leveraging older standards and technologies are expensive to maintain and contribute to additional onboarding backlog as those interfaces are transitioned to align with current standards.

### Meaningful Use Survey Results:

- **Number of awardees responding to survey: 59**
- **Number of providers in queue to begin onboarding: 27, 263 (range 0 to 9,200)**
- **Number of providers in progress: 9,953 (range 0 to 2,623)**
- **Number of sites submitting production data using HL7 2.3.1: 8,741 (range 0 to 2,385)**

<sup>1</sup> CDC IIS Meaningful Use Survey Results Summary: Q4 2017

In many jurisdictions, providers report spending weeks or even months waiting to begin onboarding or delayed at various stages in the process. While waiting to establish an interface between their EHR and the IIS, providers may be burdened by duplicate data entry or may inconsistently report administered doses to the IIS. When vaccinations are not reported to the IIS, patient and vaccination data in the IIS remains incomplete and can adversely impact other stakeholders who rely on the completeness of this data. Like IIS programs, provider organizations must prioritize and balance limited resources. Onboarding is not a core clinical activity, and lengthy onboarding activities divert focus away from patient care.

IIS and EHR system configurations coupled with jurisdictional business rules and practices, such as state or local policies around HIEs, business practices regarding prioritization of providers, and the level of testing/data quality required prior to and during onboarding, all contribute to the variability of the onboarding process. This wide variability in IIS onboarding approaches and long-standing queues/backlogs indicate a need for standardization of the onboarding process.

To date, there have been limited guidelines to assist IIS programs in the development of their HL7 onboarding processes. The American Immunization Registry Association (AIRA) initiated a project using a community-driven approach to develop guidance for improving and standardizing the onboarding experience. A specific focus was placed on decreasing the overall time and effort it takes to onboard immunization partners. Standardizing and improving the onboarding process are important elements in assuring the long-term sustainability of IIS.

### **Project Objectives:**

- **Standardize the onboarding process across jurisdictions.**
- **Improve onboarding process efficiencies by streamlining activities and introducing appropriate support tools and technologies.**
- **Decrease the number of providers waiting in queue and the amount of time providers spend in process from start to finish.**
- **Facilitate the transition of existing interfaces to align with current and future messaging and transport standards.**
- **Maximize limited resources—time, money, and staff—for all onboarding partners**
- **Improve stakeholder relations.**

# AUDIENCE, METHODOLOGY, AND DOCUMENT ORGANIZATION

This document is intended for both technical and programmatic staff that make up IIS onboarding teams and program administrators responsible for the allocation of onboarding resources.<sup>2</sup> EHR vendors, providers, and HIE partners may also find this document informative. Material is divided into two primary sections: (1) *Process – Improvements and Recommendations* and (2) *Implementation – Considerations and Recommendations*. Both sections provide guidance collected and validated through community resource review, a series of web-based surveys, subject matter expert interviews (conducted via teleconference in November 2017), and an in-person facilitated discussion (March 20–22, 2018, in Phoenix, Arizona).

Subject matter experts informing this document included representation from a variety of IIS programs, larger EHR partner organizations, IIS vendors, and the American Academy of Pediatrics (AAP). Individual participants are listed in *Appendix G. Acknowledgements*.

This project leveraged the collective efforts of previous AIRA workgroups documented in the following resources:

- *Data Validation Guide for the IIS Onboarding Process*<sup>3</sup>
- *IIS Data Quality Practices: Monitoring and Evaluating Data Submissions*<sup>4</sup>
- *Data Quality Assurance in Immunization Information Systems: Incoming Data (MIROW)*<sup>5</sup>
- *Data Quality Assurance: Selected Aspects (MIROW)*<sup>6</sup>
- *IIS Functional Guide: Query and Response*<sup>7</sup>

A summary of each resource is presented in *Appendix B. Synopses of Key Resource Materials*.

**Figure 1** provides a visual map of this document along with the general content covered in each chapter.

<sup>2</sup> In some cases, onboarding may be handled outside of the IIS purview (e.g., larger HIEs, centralized IT, unified meaningful use approach). Awardees are encouraged to share key messages from this document with whomever oversees the IIS onboarding process.

<sup>3</sup> [http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)

<sup>4</sup> [http://repository.immregistries.org/files/resources/59cabe6404421/data\\_quality\\_phase\\_ii.pdf](http://repository.immregistries.org/files/resources/59cabe6404421/data_quality_phase_ii.pdf)

<sup>5</sup> [http://immregistries.org/files/resources/5835adc2dbbe4/data\\_quality\\_assurance\\_in\\_immunization\\_information\\_systems\\_incoming\\_data.pdf](http://immregistries.org/files/resources/5835adc2dbbe4/data_quality_assurance_in_immunization_information_systems_incoming_data.pdf)

<sup>6</sup> [http://immregistries.org/files/resources/5835adc2dd10f/data\\_quality\\_assurance\\_in\\_immunization\\_information\\_systems\\_selected\\_aspects.pdf](http://immregistries.org/files/resources/5835adc2dd10f/data_quality_assurance_in_immunization_information_systems_selected_aspects.pdf)

<sup>7</sup> [http://repository.immregistries.org/files/resources/5a83216a1d369/iis\\_functional\\_guide\\_february\\_2018.pdf](http://repository.immregistries.org/files/resources/5a83216a1d369/iis_functional_guide_february_2018.pdf)

**Figure 1** | Process overview diagram

## READER GUIDANCE

The guidance in this document is intended to stimulate conversation and challenge IIS programs to reevaluate their onboarding protocols and identify opportunities for improving and streamlining all elements of the onboarding process. A list of actionable improvements and recommendations appears at the end of each topic section. These individual lists have been consolidated into a single resource in [Appendix D. Consolidated Onboarding Recommendations](#). Each reader should approach this document with the assumption that their current process can be improved to maximize limited resources and enhance the onboarding experience for all participating stakeholders.

While this guidance document suggests numerous opportunities to standardize and improve the onboarding process, this project also uncovered a number of gaps and challenges that could not be readily or immediately addressed within the scope and time frame allotted for the current effort. These gaps and challenges are documented in [Appendix E. Barriers/Challenges](#) and [Appendix F. Gaps](#), respectively, for consideration in future stakeholder discussions.





**PROCESS –  
IMPROVEMENTS AND  
RECOMMENDATIONS**

**2**



## 2 PROCESS – IMPROVEMENTS AND RECOMMENDATIONS

The AIRA *Data Validation Guide for the Onboarding Process*<sup>8</sup> defines five steps for establishing HL7 electronic data exchange: Discovery, Planning, Development and Testing, Data Validation, and Go Live.

The current project leveraged these previously defined process steps to guide discussions and categorize material; however, in some cases, these steps were condensed or expanded to better describe and illustrate various elements of the onboarding process, including separate consideration for query/response interfaces. The modified steps of the onboarding process are presented in Figure 2 below.

**Figure 2** | Condensed schematic of process overview diagram



For the purposes of this document, onboarding begins when the provider expresses intent to initiate an interface with the IIS. Onboarding activities end after the interface has transitioned to the IIS production environment with successful transmissions during the initial two-week monitoring period that follows. Each step of the onboarding process will be discussed in detail following this section.

Core documents used to support each step in the onboarding process are presented in [Table 1](#). A description of each document listed and additional discussion on implementation improvements and recommendations regarding documentation are presented in the section titled [Documentation](#).

<sup>8</sup> [http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)

**Table 1** | Core documents used during each step of the onboarding process<sup>9</sup>

DOCUMENTS	DISCOVERY AND PLANNING	DEVELOPMENT AND TESTING	PRODUCTION APPROVAL	INTERFACE MONITORING	QUERY/ RESPONSE
IIS Enrollment Forms	X				X
Security and Confidentiality Agreement(s)	X				X
Site/User Agreements	X				X
Provider Site Mapping	X	X	X	X	X
Onboarding Plan	X	X	X	X	X
Data Exchange Enrollment Forms	X				X
Data Exchange Questionnaire	X	X			X
Data Exchange Readiness Checklist	X				X
Roles and Responsibilities Document/Form	X	X	X		X
CDC HL7 Implementation Guide <sup>10</sup> and Addendum <sup>11</sup>	X	X		X	X
CDC IIS Code Sets	X	X		X	X
CDC Transport Layer Protocol Recommendation Formal Specification <sup>12</sup>	X	X		X	X
State-Specific Implementation Guide (delta version)	X	X		X	X
State-Specific Required Fields Guide/Checklist	X	X		X	X
Test Cases/Scenarios	X	X			X
End User Communication/ Training Plan			X		X
Roles and Responsibilities Document/Form (post production)			X	X	X
Go-Live Readiness Checklist			X		X

<sup>9</sup> Links to IIS sample onboarding materials and referenced documents are included in Appendix B-4. IIS sample onboarding materials and Appendix C. Onboarding Reference List.

<sup>10</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>11</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

<sup>12</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html>

In addition to core documents, jurisdictions use a variety of tools to support their onboarding activities. Appropriately leveraged tools help maximize staff resources for troubleshooting interfaces and eliminating manual or paper-based processes. The following table illustrates commonly used tools and where each tool is typically used to support the onboarding process. A description of each tool and additional discussion on implementation improvements and recommendations regarding onboarding tools are presented in the section titled [Onboarding tools and attributes](#).

**Table 2** | *Tools used during each of the onboarding steps*

TOOLS	DISCOVERY AND PLANNING	DEVELOPMENT AND TESTING	PRODUCTION APPROVAL	INTERFACE MONITORING	QUERY/ RESPONSE
Registration Tool	X				X
Project Tracking Tool	X	X	X	X	X
HL7 Message Format/ Structure Pretest	X	X			
HL7 Message Content Validation		X			
HL7 Data Quality Analysis Testing		X	X	X	
HL7 Feed Monitoring		X	X	X	X

The sections that follow describe consensus-based recommendations and considerations for improving each step in the onboarding process.

## STEP 1: DISCOVERY AND PLANNING

Discovery and Planning encompasses onboarding registration (and IIS enrollment if the provider is not already enrolled), preparatory work, and all onboarding-related activities that precede Development and Testing.



### Discovery and Planning includes:

- Onboarding registration
- IIS enrollment (if not a previously enrolled facility)
- Completion of all required forms/paperwork
- Demonstrated readiness to proceed with onboarding
- Project communication with all relevant stakeholders
- Managing expectations

### REGISTRATION

Each onboarding project begins when a provider expresses an interest in establishing an electronic interface with the IIS. Some IIS programs have a formal registration process, while others will initiate an onboarding project based on a phone call or email. As a prerequisite to onboarding, the provider site must be enrolled in the IIS. In some cases, the site may already be enrolled in the IIS and is now ready to initiate electronic data exchange between the EHR and IIS. In other cases, the site may be new to the IIS and will need to enroll in the IIS and register for onboarding simultaneously.

Once a provider has expressed an interest in onboarding, a number of forms and questionnaires are used to convey and collect important information that can be referenced throughout the onboarding process (see also [Documentation](#)). Forms commonly used during registration and enrollment include:

- IIS Enrollment Forms
- Security and Confidentiality Agreement(s)
- Site/User Agreements
- Provider Site Mapping
- Data Exchange Enrollment Forms
- Data Exchange Questionnaires

IIS programs can implement an electronic registration tool for capturing basic project information (see also [Onboarding tools and attributes](#)).<sup>13</sup> **Online registration tools can streamline the onboarding registration/enrollment process and introduce efficiencies by leveraging electronically captured registration data to facilitate various elements of the onboarding process.** This includes capturing registration and enrollment data using online forms; storing data captured in online forms in a way that is easily accessible, searchable, and sortable; automatically populating organization/facility-level details in the IIS; and utilizing registration/enrollment tools to automatically trigger subsequent steps in the onboarding process.

Hover fields or glossaries embedded within electronic forms can be used to provide definitions, explanations, and examples to clarify appropriate/expected responses to registration and enrollment questions. These features can reduce or eliminate confusion for users when completing online forms. Digital signatures can also be implemented to eliminate the need for transmitting and storing paper copies. Data collected using online forms can be stored electronically for future access and reference by IIS onboarding staff.

Electronically captured data provides a centralized, long-term historical record and serves as a general onboarding resource. This data can be used to identify providers using similar EHR products, categorize providers by type or by participation in the vaccines for children program (VFC), or assess form submission dates to establish common timelines for progressing through the various onboarding stages. Electronic registration tools could also be used for updating or adding to registration and enrollment data throughout the onboarding process, including project contacts following “go-live.”

Finally, onboarding registration can be used to facilitate subsequent steps in the onboarding process. Some IIS programs use registration submission to automatically initiate an onboarding welcome email that includes relevant documentation and readiness checklists. Some IIS programs also use onboarding registration data to automatically create a new project in their online project tracking tool to facilitate project assignment, communication with stakeholders, and onboarding activity monitoring.

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<sup>13</sup> In some jurisdictions, onboarding registration is part of a broader agency-wide approach related to meaningful use (MU) initiatives. IIS programs should investigate whether the MU registration tool and/or the data captured during registration can be leveraged to support IIS onboarding activities.

**A tracking tool or process should be used for logging each provider that registers for onboarding and documenting their progress throughout the onboarding process.**

These tools facilitate a more efficient and organized onboarding experience while reducing the burden on IIS onboarding staff. Project tracking tools can also support increased transparency for participating stakeholders about where the provider organization is in the process, the next action to be taken, and who is responsible for performing that action. Commercial tracking tools are full-featured and designed to support all aspects of managing an onboarding project; however, commercial products may be cost-prohibitive to some IIS programs. Many jurisdictions use ticket tracking tools to support their help desk operations. These tools may include features that could be adapted to support tracking activities for onboarding projects.

While a number of jurisdictions rely on Excel-type spreadsheets for documenting registration and basic onboarding activities, these simple spreadsheets are generally not sophisticated enough to perform all registration and project tracking functions. Programs should assess the costs and benefits associated with implementing a registration or project tracking tool and look for joint development or shared platform opportunities. See also [Onboarding tools and attributes](#) and [Managing backlog](#).

**Process – Improvements and Recommendations: Registration**

- Provide a web-based interface to allow providers to complete required IIS enrollment and onboarding/data exchange enrollment forms online. See also [Onboarding tools and attributes](#).
- Store data captured in online forms in a way that is easily accessible, searchable, and sortable by onboarding staff (e.g., database or document repository).
- Utilize registration/enrollment tools to automatically trigger subsequent steps in the onboarding process (e.g., initiation of a welcome email, creation of a new project in an online project tracking tool).
- Maintain a tracking tool or process for documenting the status and progress of each onboarding project. See also [Onboarding tools and attributes](#).

## PREPARATORY

Once a provider completes the necessary registration and enrollment forms, there are a number of activities that can help prepare the provider/EHR vendor for onboarding and expedite the onboarding process. These activities serve two primary purposes: managing provider/EHR expectations and establishing provider/EHR readiness.

Providing access to current onboarding documentation and facilitating active communication are key strategies for managing stakeholder expectations. A welcome email should be initiated immediately following registration/enrollment. The welcome email should provide links to all relevant onboarding documentation or include these documents as attachments. The most important documents for preparing to onboard include:

- Onboarding Plan
- Data Exchange Readiness Checklist
- *CDC HL7 Implementation Guide*<sup>14</sup> and *Addendum*<sup>15</sup>
- CDC IIS Code Sets
- *CDC Transport Layer Protocol Recommendation Formal Specification*<sup>16</sup>
- State-Specific Implementation Guide (delta guide)<sup>17</sup>
- State-Specific Required Fields Guide/Checklist<sup>18</sup>
- Roles and Responsibilities Document/Form

All onboarding documentation should also be posted to the IIS website where it can be easily located. Forms and documents should be reviewed and updated as needed. Updated documents should replace older versions on the IIS website to ensure that the website always displays the most current version(s). See also [Documentation](#).

**Expectations and thresholds/requirements for success should be clearly documented and communicated at the various steps of the onboarding process.** The onboarding plan should detail each step in the onboarding process, specific activities and requirements at each step, and measurements/thresholds to successfully advance to subsequent steps in the process. The onboarding plan can also help drive the agenda for the initial project kickoff call. Sample onboarding plans are listed in [Appendix B-4. IIS sample onboarding materials](#).

<sup>14</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>15</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

<sup>16</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html>

<sup>17</sup> A primary objective of this project is to minimize variation in the onboarding process, including interface requirements, by encouraging IIS programs to align with standard HL7 implementation guidance and code sets unless otherwise required by state law or mandate. Tools available through the National Institute of Standards and Technology (NIST) and the Public Health Informatics Institute (PHII) IIS Training Hub (<https://www.phii.org/iishub>) may be useful references as IIS programs develop/revise state-specific delta guidance. See also Importance of standards and Documentation.

<sup>18</sup> Ibid.

**A data exchange readiness checklist ensures that a provider is prepared to begin actively onboarding with the IIS.** Provider readiness can be determined by establishing a set of preliminary onboarding criteria detailed in a readiness checklist. These checklists should be introduced and completed before the project kickoff call. The primary purpose of a readiness checklist is to ensure that a provider is prepared to onboard before actively engaging IIS staffing resources. Sample readiness checklists are included in [Appendix B-4. IIS sample onboarding materials](#).

Requiring an HL7 message format/structure pretest is an important step in determining an EHR vendor's/provider's readiness to proceed through the onboarding process. This activity can be performed using the Immunization Test Suite<sup>19</sup> developed by the National Institute of Standards and Technology (NIST). The NIST Immunization Test Suite is a web-based application that supports end-to-end conformance testing and validation of HL7 v2.5.1 messages using simulated operational environments. Some jurisdictions use the NIST tools exclusively, while others have adapted or customized these tools to more closely simulate the jurisdiction's IIS.

Each unique interface should be tested even if the EHR vendor had previous success with other provider interfaces or product versions. The specific settings and configurations of an individual product installation or nuances of the operating environment/platform introduces the potential for different testing results.



**NOTE:** The onus for understanding HL7 and producing a viable HL7 v2.5.1 message should be placed on the EHR vendor or technical provider staff. It is not the IIS staff's responsibility to provide education on HL7. The EHR vendor/provider should require education or clarification from the IIS on only the elements where the jurisdiction deviates from the HL7 standard (see also [Importance of standards](#)). All certified EHR products must be able to produce an HL7 message in order to pass certification. Providers or EHR vendors needing more information or assistance regarding HL7 should be pointed to appropriate resources such as the *CDC HL7 Implementation Guide*<sup>20</sup> and *Addendum*<sup>21</sup> and supporting NIST tools.

<sup>19</sup> <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>

<sup>20</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>21</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

Once a provider has met the readiness requirements established by the IIS, an official project kickoff call can be conducted with all relevant technical and programmatic experts for the IIS, provider, EHR vendor, and HIE (where applicable). The kickoff call should include a review of completed forms, the onboarding process, important onboarding documentation, requirements for a successful interface, and stakeholder roles and responsibilities (see also [Onboarding partners](#)).<sup>22</sup> Following the kickoff call, the IIS should issue appropriate credentials and provide links to the testing platform(s) using a secure or protected communication.

<sup>22</sup> The process for how this information is exchanged, confirmed, or distributed is not prescriptive. If a call with all relevant stakeholders is not feasible, IIS programs should identify alternative strategies for communicating kickoff information and addressing any questions/concerns posed by the other participating stakeholders.

### Process – Improvements and Recommendations: Preparatory

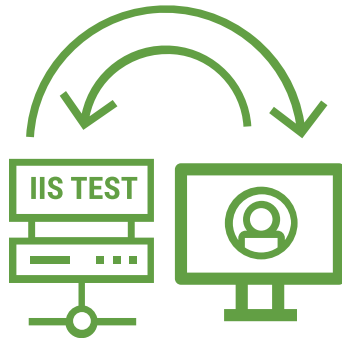
- Develop a written onboarding plan to guide the entire onboarding process.
- Develop onboarding checklists for providers/vendors listing the various thresholds/requirements at each step of the onboarding process.
- Provide access to current versions of all onboarding documentation in a readily accessible area of the IIS website.
- Send a welcome email to new onboarding prospects immediately following registration/enrollment with links to all relevant documentation or as attached documents.
- Require each new onboarding provider/EHR vendor to produce a valid, correctly formatted HL7 v2.5.1 message using an appropriate self-service testing tool prior to engaging IIS onboarding staff. See also Onboarding tools and attributes.
- Host a project kickoff call at the beginning of each new onboarding project to review the onboarding process, expectations, completed forms, and stakeholder roles/responsibilities.

Discovery and Planning is a primary roadblock in the onboarding process for a number of IIS programs. In these programs, limited IIS staff availability has necessitated the use of an onboarding queue, where providers are prioritized and then invited to onboard as IIS resources become available. In some cases, providers report spending weeks or months waiting to begin onboarding. This challenge can be mitigated by creating opportunities for providers and their EHR vendors to independently prove onboarding readiness through a set of meaningful preparatory tasks. Readiness activities offer the provider an opportunity to engage immediately following registration, leverage provider enthusiasm, and encourage project momentum by streamlining the Discovery and Planning phase. This also ensures that IIS staff resources are focused on those providers who are the most ready and able to proceed through the onboarding process.



## STEP 2: DEVELOPMENT AND TESTING

Development and Testing encompasses all activities required for configuring and validating an EHR-IIS interface. While this onboarding step focuses primarily on testing and validating interfaces, technical development may be needed to resolve issues identified through testing or to improve interface architecture.

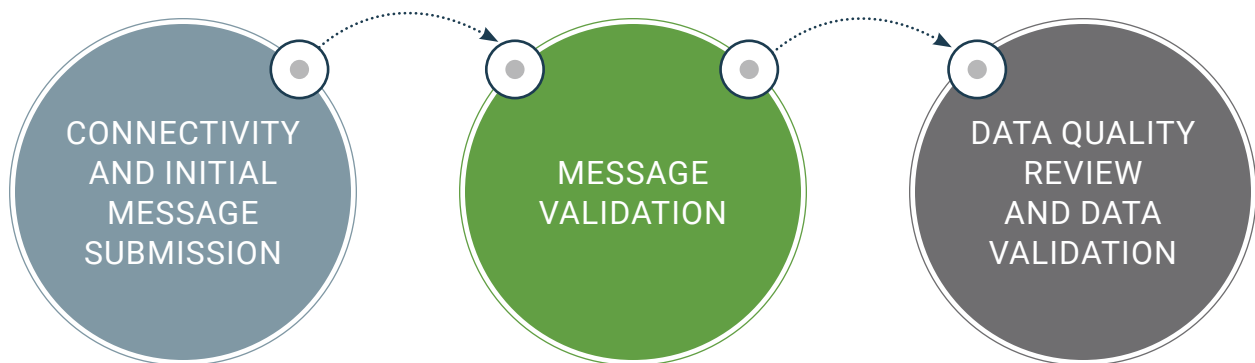


### Development and Testing includes:

- Connectivity and transport
- Testing environments and platforms
- Use of test data or production data
- Volume of records needed to perform testing and validation
- Technical testing versus programmatic testing
- Importance of ACK messages
- Opportunities for provider/EHR vendor self-service testing

### STAGES OF TESTING

This document defines three primary testing stages:



The following narrative describes the activities that take place during each stage of testing, the expertise needed to perform these activities, and the typical measure(s) for success.

## CONNECTIVITY AND TRANSPORT

The primary purpose of the Connectivity and Transport stage of testing is to confirm that the provider's EHR can successfully connect with the IIS to (1) submit a properly structured HL7 2.5.1 message and (2) successfully receive an acknowledgement (ACK) message returned by the IIS. The standard for message transport endorsed by the Centers for Disease Control and Prevention (CDC) is SOAP Web Services utilizing the CDC Web Services Definition Language (WSDL).<sup>23,34</sup> This protocol is supported by all major EHR partners. **IIS programs should support and promote the CDC-endorsed SOAP/WSDL standard as the preferred method for connection and transport.**

This phase of testing is technical (e.g., transport, web services, security) and requires the involvement of technical experts representing the EHR vendor/provider and the IIS and/or partner HIE. The NIST Immunization Test Suite can be used by EHR vendors/providers for preliminary "proof of concept" testing of connectivity and transport, but a final test should be performed in the IIS test environment.

Success is defined by the establishment of a confirmed connection.

## MESSAGE VALIDATION

The primary purpose of the Message Validation stage of testing is to further confirm connectivity using routine, volume submissions from the provider's EHR and receipt of appropriate ACK messages by the submitter. This level of testing is used to verify population of required fields in the IIS and use of appropriate codes/code mappings as defined in the HL7 implementation guidance.

Message validation is typically accomplished by reviewing ACK messages to identify and resolve critical errors and assess/address warnings. This process can be automated to some extent through the use of an HL7 message content validation tool (see also [Onboarding tools and attributes](#)). As issues are identified, adjustments may need to be made to the EHR or IIS software code, code sets, configurations, settings, or even user workflows. After necessary changes have been made, messages should be retested to ensure that issues have been satisfactorily resolved.

This phase of testing is mostly technical (software development, interface specialists) and requires the involvement of a variety of technical experts from both the EHR vendor/provider and IIS onboarding teams. On occasion, the involvement of programmatic experts from the provider and/or IIS may be needed to help identify issues resulting from clinical workflows or data entry. The NIST Immunization Test Suite and sandbox-type access to the IIS test environment can be offered to EHR vendors/providers to promote independent testing and validation of HL7 messages. Final testing should be performed in the IIS test environment.

<sup>23</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/downloads/transport-specification.pdf>

<sup>24</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html>

The IIS program performs the final review and approval. Success is defined as routine message submission with no critical errors or failures.



**NOTE:** When messages repeatedly error or fail based on field-level validations, the IIS should work with the provider/vendor to determine (1) if and how the element is being captured, (2) if the EHR is capable of sending it, and (3) if the EHR is actually transmitting it. On occasion, some IIS have found direct on-site testing or interactive web meetings with project technical leads to be successful for expediting issue identification and resolution.

### DATA QUALITY REVIEW

The primary purpose of the Data Quality Review stage of testing (also known as Data Validation) is to build upon the previous testing activities and further examine submissions for data issues around VFC program support and decrementing of inventory, completeness and accuracy of patient records, IIS deduplication/matching algorithms, and verifying that submissions align with expected “provider type” profiles.

Data validation testing typically relies heavily on review of data quality and inventory reports in the IIS interface, use of prescriptive testing scenarios, and manual comparison of selected patient records between the EHR and IIS. Some portions of the data quality review process could potentially be automated through the use of an HL7 data quality analysis tool (see also [Onboarding tools and attributes](#)). This phase of testing is helpful for identifying issues that cannot be identified or resolved through ACK message review. As issues are identified, adjustments to the provider dataset (patients/vaccinations), EHR or HL7 interface software code/configurations, or clinical workflows/data flows may be needed. After necessary changes have been made, messages should be retested to ensure that issues have been satisfactorily resolved.

This phase of testing is mostly programmatic (record review, workflows) and requires involvement of programmatic staff from the provider and IIS. If issues are identified that require software-related changes or adjustments, technical experts from one or more of the onboarding partners may need to be involved. IIS programs may consider offering EHR vendors/providers access to data quality and inventory reports through an HL7 data quality analysis tool or sandbox-type access to the IIS test environment to promote independent testing and review of data quality elements (to the extent possible).

The IIS program performs the final review and approval using data in the IIS test environment. Success is defined by criteria and thresholds determined by the individual IIS/immunization programs. For additional guidance on these criteria, readers should refer to the following AIRA documents:

- *Data Validation Guide for the IIS Onboarding Process* (2017)<sup>25</sup>
- *IIS Data Quality Practices: Monitoring and Evaluating Data Submissions* (2017)<sup>26</sup>
- *IIS Data Quality Practices: To Monitor and Evaluate Data at Rest* (2018)<sup>27</sup>
- MIROW Data Quality Assurance Chapters
  - *Incoming Data* (2008)<sup>28</sup>
  - *Data Quality Assurance: Selected Aspects* (2013)<sup>29</sup>

Programmatic data quality testing and validation contributes to considerable delays in the onboarding process because it is the most staff and resource intensive for all stakeholders as well as the least defined (see also [Importance of standards](#)). In lieu of standardized implementation guidance, many jurisdictions have created their own programmatic testing requirements. While data quality testing during onboarding may be the best opportunity to correct errors in workflow and data capture when the provider and EHR are actively engaged in establishing the interface, extensive data quality testing during onboarding can cause considerable delays in the onboarding process.

There is a general concern about balancing the time and effort required to establish a new interface with the implications of introducing low-quality data into the IIS production environment. However, the amount of data-quality testing that should be performed in conjunction with onboarding requires further consideration by a panel of experts comprised of representatives from all major stakeholders (see also [Data quality](#)). These discussions should also assess the potential to automate portions of the data quality validation process and promote opportunities for EHR vendors/providers to perform independent data quality testing. **Ultimately, population of required fields with proper codes from the Message Validation phase should be the minimum requirement for approving a production interface** (see also [Message Validation](#)).

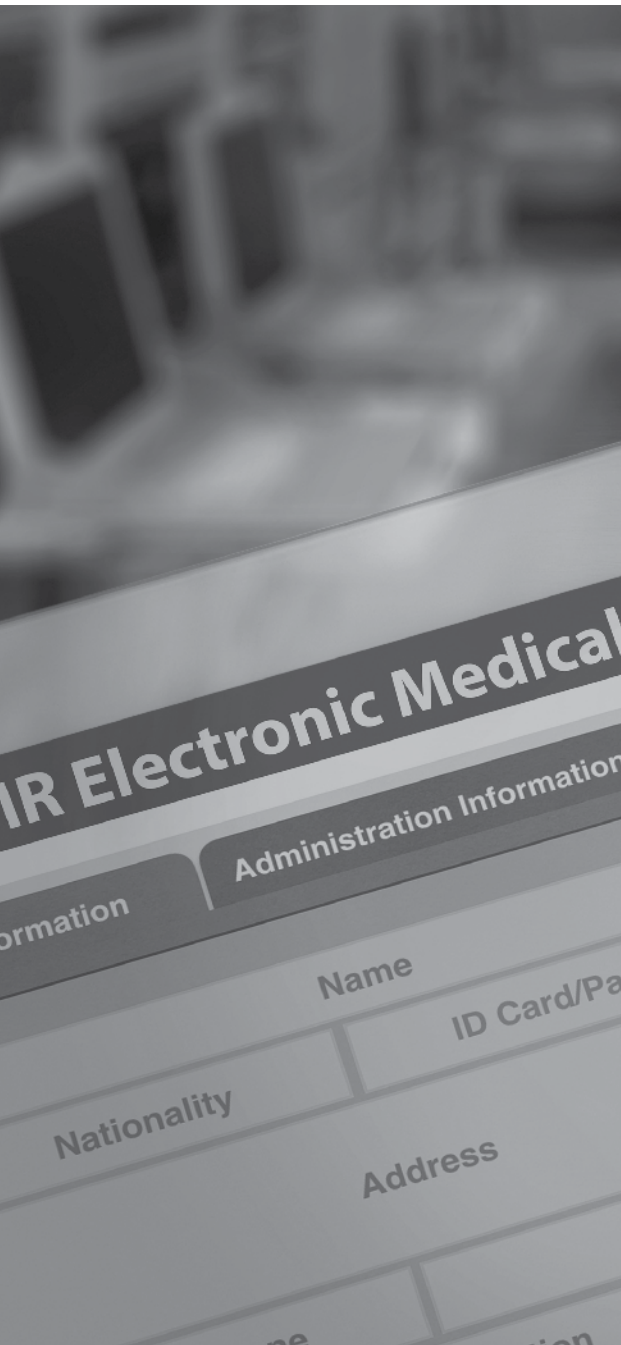
<sup>25</sup> [http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)

<sup>26</sup> [http://repository.immregistries.org/files/resources/59cabe6404421/data\\_quality\\_phase\\_ii.pdf](http://repository.immregistries.org/files/resources/59cabe6404421/data_quality_phase_ii.pdf)

<sup>27</sup> <http://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/>

<sup>28</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-incoming-data-1/>

<sup>29</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>



## IMPORTANCE OF ACK MESSAGING

Acknowledgement (ACK) responses to an HL7 message submission provide valuable feedback to the submitter about how the message was processed by the IIS. The development and testing phase relies heavily on proper and consistent ACK messaging to troubleshoot new interfaces. ACK messaging is also a critical component of long-term interface monitoring in the IIS production environment.

**ACK messaging produced by the IIS should be meaningful, readable, and actionable.** There are three primary ACK responses: Accept (AA), Error (AE), or Reject (AR). Error responses are further broken down in the error segment (ERR) through error codes that detail the nature and severity (e.g., informational, warning, fatal error) of each error. These error responses are intended to guide users on how to address or resolve these issues.

Person(s) involved with testing and monitoring the EHR-IIS interface should be knowledgeable about where to review ACK messages and how to interpret the content. See also [Provider interface training](#). With the ability to review and interpret ACKs, stakeholders can test independently or serve as more active onboarding participants. This also relieves IIS onboarding staff of the need to duplicate ACK messages and provide translations.

IIS programs should consult the following resources for consistent implementation of ACK guidance across jurisdictions:

- *CDC HL7 Implementation Guide*<sup>30</sup> and *Addendum*<sup>31</sup>
- *Guidance for HL7 ACK Messages to Support Interoperability*<sup>32</sup>
- National Set of Error Codes

<sup>30</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>31</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

<sup>32</sup> This document provides unified guidance to both IIS and EHR partners on the actions that should be taken for informational, warning, and error notices in the ERR segments. [http://repository.immregistries.org/files/resources/5835adc2add61/guidance\\_for\\_hl7\\_acknowledgement\\_messages\\_to\\_support\\_interoperability\\_.pdf](http://repository.immregistries.org/files/resources/5835adc2add61/guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf)

## TEST ENVIRONMENT AND TEST DATA

The IIS testing platform should be an exact replica of the production environment by mirroring all settings, configurations, and authentication/authorization settings. The patient and vaccination data in the testing environment does not have to be fully synchronized with the production IIS, but it should be sufficiently up to date to support all of the appropriate validation testing required by the IIS for approving a new interface.

Some IIS have implemented test environments where testing occurs in a partitioned area of the production environment, while other IIS programs maintain a separate, replicated instance of the IIS. The primary considerations for which model to use include the cost involved with maintaining multiple instances of the IIS and the process/resources needed to periodically refresh the database leveraged by the test environment. IIS training and user acceptance testing (UAT)<sup>33</sup> environments should not be used for onboarding validations, because they might not align closely enough with the production environment and might not be stable enough to support proper testing of production-quality interfaces.

A number of tools are being utilized across the IIS community to help facilitate and expedite the different stages of testing. Initial message submission testing can be expedited with an HL7 v2.5.1 message format pretest using NIST or similar jurisdictionally developed tools during the Discovery and Planning phase (see also [Preparatory](#)). A technical message validation tool can streamline the review of all technical elements and identify critical trouble points (see also [Message Validation](#)). Finally, a data quality analysis tool or report suite can facilitate the review and validation of programmatic onboarding requirements (see also [Data Quality Review](#)). Some IIS programs use or have developed tools that combine the features of several tools to support multiple phases of testing. A number of IIS programs also use tracking tools, mentioned previously, to document the progress of each provider throughout the testing process and create tickets to aid with communication, issue assignment, and problem resolution. Refer to the section titled [Onboarding tools and attributes](#) for more information on typical attributes of these common testing support tools.

**Typically, two weeks or 10 business days' worth of production-level provider data submissions with no critical errors or failures is a good benchmark for message validation success. Time-based submission is a better indicator of quality than a specified record count.** Testing should be performed with production EHR data. If the EHR is still in the process of being implemented, then data used for testing should be considered production-quality. The two-week rule should be suitable for the majority of practice sizes and provider types.

<sup>33</sup> In this statement, a training environment is defined as an instance of the IIS where patient, vaccination, inventory, and facility data may be loosely populated or populated with fictitious data. A UAT environment is defined as an instance of the IIS where the installed version is a preproduction release that contains features that may or may not have been thoroughly tested and may or may not be present in the IIS production environment.

Very small providers may require a longer period of additional monitoring following the move to production but should not be held to a different standard than their larger counterparts (see also [Production Approval](#) and [Interface Monitoring](#)). Organizations with more than one facility should be required to submit messages from each provider site that will be reporting through the interface.

Use of engineered testing scenarios or training-type data is not sufficient for onboarding validation. This type of testing does not provide a true representation of the data a provider will ultimately be submitting to the production IIS. Some IIS choose to offer a handful of prescribed test scenarios to assess specific data elements or workflows, but these should be used in addition to the larger validation data set, not in lieu of it. Testing scenarios can help validate the most critical elements and workflows, but they can also be difficult to create and maintain. A list of selected [Test cases/scenarios](#) are included in [Appendix B-4. IIS sample onboarding materials](#).

**Testing platforms and all data used for onboarding validations should adhere to the same security and confidentiality protections, policies, and protocols applied to the production IIS since production data often contains personally identifiable information.** IIS programs may also choose to include a review of their privacy and security policies as part of the initial onboarding paperwork/disclosures.

### THE “SANDBOX”

Jurisdictions should provide sandbox-type access to the test environment so EHR vendors/providers can perform autonomous, self-service message testing. The main testing platform can serve as a sandbox, or the IIS program may choose to support a separate production-replica environment leveraging the same set of issued credentials.

Access to the sandbox offers two key benefits:

1. Ability for the vendor or provider to independently conduct its own testing for more efficient issue identification and resolution without relying on the assistance of IIS staff
2. Ability to test new software updates to verify the integrity of existing interfaces

IIS programs may even consider requiring self-service testing as part of the onboarding process to ease the burden on limited IIS staff resources. This encourages EHR vendors/providers to perform testing and validation in accordance with the requirements and thresholds documented in the onboarding plan/implementation guide(s) and troubleshoot their own interfaces. This also encourages project momentum and maximizes available onboarding partner resources. The IIS can then focus efforts on performing the final assessment and approval of the pretested interface.

Providers/EHR vendors using the sandbox may still need to contact the IIS periodically if there are questions, inconsistencies from the HL7 specification, or other unexpected errors and problems. If the IIS program does not have the capacity to answer questions and troubleshoot with the provider/EHR while it is using the sandbox, the IIS should communicate these limitations prior to providing access to the provider/EHR vendor. Further, if sandbox support becomes burdensome, the IIS may choose to allow sandbox access to only the larger or more sophisticated EHR vendors and technically savvy providers. Access for others requiring more assistance would then be restricted to periods of active onboarding only.

### **Process – Improvements and Recommendations: Test Environment and Test Data**

- Design the IIS testing platform(s) to mirror all elements of the production environment, including version(s), settings, configurations, and authentication/authorization settings.
- Refresh patient and vaccination data in the test environment as often as needed to ensure the data is sufficient to support all of the appropriate validation testing required for approving a new interface.
- Implement appropriate testing tools to facilitate and expedite the various phases of testing. See also [Onboarding tools and attributes](#).
- Leverage production EHR data for testing interfaces or utilize production-quality data if the EHR is still in the process of being implemented.
- Establish a benchmark for two weeks or 10 business days' worth of provider data with no critical errors or failures as the threshold for message validation success.
- Require larger health systems to submit messages from each provider site that will be reporting through the interface.
- Identify opportunities for providers and EHR vendors to conduct preliminary testing and issue resolution independently (e.g., NIST tools, sandbox-style access to test environments).



## ABBREVIATED TESTING PROTOCOLS

There are specific situations where an abbreviated testing protocol may be appropriate: mergers and acquisitions, changes to the transport or messaging standard, and interfaces utilizing a centralized reporting hub. Abbreviated testing protocols are typically reserved for updates or modifications to successfully established production interfaces.

## MERGERS AND ACQUISITIONS

When a facility or organization is acquired by or merges with another organization, the provider will typically migrate to the new parent organization's EHR product and reporting structure. When the new parent organization has an existing interface with the IIS, the merger/acquisition typically requires a simple remapping of the facility under the umbrella of the new parent organization in the IIS (provider site map). With mergers and acquisitions, it is not necessary to perform a full re-onboarding process. If the provider is still using its original EHR system and is not yet reporting through the new organization's interface, the facility should be maintained separately until it has fully transitioned to the new parent organization's EHR.

Some IIS programs may choose to verify that the provider is able to successfully submit records after the remapping is complete. Some programs may additionally choose to reverify various VFC elements after the transition has been completed to ensure that inventory decrementing and accounting are handled appropriately within the new organizational structure. These activities are considered optional, as resources permit, and should not create any unnecessary delays in provider reporting to the IIS.

### CHANGES TO STANDARDS

Periodically there are changes to messaging and transport standards that may impact IIS, EHR, and even HIE partners. A good example of a change in standard was the HL7 transition from v2.3.1 to v2.5.1. When new standards are released, the IIS should establish an expedited, “mini-onboarding” testing protocol to revalidate all existing interfaces against the new standard. New standards are not always backward-compatible, so IIS should plan accordingly to address these impacts in their testing methodology. Revalidation of interfaces may also be needed if the IIS or a major EHR partner makes a significant platform or module change that has potential to adversely affect production interfaces.

**When new messaging and transport standards are released, there should be an appropriate period of time for the affected stakeholder(s) to transition and conform to the new standard.** For EHR vendors these time frames are typically driven by the Office of the National Coordinator for Health Information Technology (ONC) and provider demand for adopting new standards. The IIS may need to support both standards simultaneously for a period of time. IIS may consider building a second instance of the IIS test environment so new and existing interfaces can be validated using both the current and new standard simultaneously.



### REPORTING HUBS

Reporting hubs represent a centralized solution for facilitating the exchange of medical record data between health care providers and other entities, such as IIS and other public health systems. Reporting hubs generally include HIEs and EHR vendor hosted/facilitated reporting solutions. Providers submit their data to a central platform that transports the messages to the intended destination(s). Some hubs may simply direct message traffic and transport messages without alteration; other hubs provide message formatting services (HL7 2.5.1), alter various segments of the HL7 message, or store data elements before sending them on.

For IIS, an IIS-hub connection represents a single interface that can be used to receive data from numerous providers through a single data feed. Reporting hubs eliminate the need for direct point-to-point connections between the IIS and each individual provider organization/facility. The process for establishing the initial interface connection between the hub and the IIS would follow the same process/protocols used for any other onboarding project.

Reporting hubs expedite the onboarding process for providers because connectivity and basic HL7 requirements have already been validated through the initial establishment of the IIS-hub interface. IIS programs must still review data from each facility reporting through the hub to confirm the facility ID and to address any basic data quality concerns. While the hub is able to confirm connectivity and basic message construct, the hub does not and cannot guarantee the quality of the data being submitted by the provider.

All providers that will be reporting to the IIS through a hub must first be enrolled in the IIS and should register for onboarding through the standard process. The hub should notify the IIS whenever a new facility begins reporting through the hub. The hub and/or IIS should have a mechanism for preventing submission of data for a provider that has not yet been approved by the IIS.

**Reporting hubs should provide ACK messages back to the sending facility so the users can correct and resend messages that error or fail. Likewise, IIS should be required to send standardized ACK messages that clearly indicate the error.** These capabilities are also required to support providers interested in implementing query and response through a reporting hub.

### **Process – Improvements and Recommendations: Abbreviated Testing Protocols**

- Leverage abbreviated testing protocols for changes or updates to existing production interfaces to bypass steps in the testing process that have been previously validated.

## STEP 3: PRODUCTION APPROVAL

Production Approval encompasses all activities related to approving an interface and transitioning an interface to the production environment.



### Production Approval includes:

- Production approval
- Preproduction forms completion
- Interface training (optional)
- Moving provider credentials to the production environment

After an interface meets all of the requirements laid out in the Onboarding Plan and the provider has submitted two weeks' worth of provider data with no critical errors or failures, the interface is ready to transition to the IIS production environment.

**The transition to production should be accompanied by a project closeout/"go live" call.** Like the kickoff call, the closeout call should be attended by the IIS, provider, EHR vendor, and HIE (where applicable) representatives. The agenda for the call should include a review of final forms, process for transitioning to production, production credentials, and expectations for ongoing monitoring and error resolution.<sup>34</sup> See also [Provider interface training](#).

### Closeout Call

- **Confirm readiness to go live.**
- **Review and update relevant documents and forms.**
- **Confirm project contacts and go-forward expectations.**
- **Issue production credentials and confirm the provider interface is pointed to the production IIS.**

<sup>34</sup> The process for how this information is exchanged, confirmed, or distributed is not prescriptive. If a call with all relevant stakeholders is not feasible, IIS programs should identify alternative strategies for communicating closeout information and addressing any questions/concerns posed by the other participating stakeholders.

Forms and documents commonly used during Production Approval include:

- Onboarding Plan
- Provider Site Mapping
- Roles and Responsibilities Document/Form
- Go-Live Readiness Checklist
- End User Communication and Training Plan

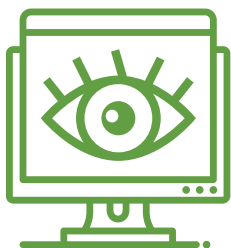
It is important that the transition from the testing environment to production is confirmed as a final step in the onboarding process. This will help avoid situations where the interface is still transmitting data to the test environment while the provider believes the interface is reporting to the IIS production environment.

### **Process – Improvements and Recommendations: Production Approval**

- Host a project closeout call at the end of each onboarding project to review final forms, activities, and timelines; issue production credentials; and confirm expectations for ongoing monitoring and error resolution.
- Use appropriate forms to identify/confirm go-forward points of contact and communicate long-term expectations.
- Confirm that the provider interface is properly transitioned to the production environment as a final step in the onboarding process.

## STEP 4: INTERFACE MONITORING

Interface Monitoring begins after an interface is transitioned to the IIS production environment.



### Interface Monitoring includes:

- Short-term production monitoring
- Long-term production monitoring
- Re-onboarding triggers

The level of monitoring needed for an interface depends on whether the interface is new or newly updated versus an existing production interface. The monitoring protocols for existing production interfaces are beyond the scope of this document. Readers are encouraged to refer to the resources summarized in [Appendix B-2. Materials developed/published by AIRA](#) for additional guidance on long-term monitoring efforts.

### NEW OR UPDATED PRODUCTION INTERFACE

**New or updated production interfaces should be closely monitored for the first two weeks after the “go live” date.** IIS programs should establish a two-week probationary period during which production submissions are closely monitored to ensure provider submissions are successful and have no significant issues. The IIS should confirm that data is coming in from all sites that are part of the interface for a multi-facility organization. The IIS, EHR, and provider onboarding partners should continue to monitor all of the elements reviewed during the various testing stages in the production environment during this critical probationary stage.



**NOTE:** For many EHR vendors, dedicated interface/implementation teams will transition the interface to their longer-term support teams after “go live.” If the IIS and/or provider still want additional support during the initial probationary period, they should not officially sign off on the interface until everything has proven satisfactory in production.

After successfully passing the initial two-week monitoring period, the interface should transition out of “onboarding” to the routine, ongoing data quality and quality improvement program activities facilitated by the IIS and immunization programs (e.g., VFC and IQIP<sup>35</sup> program activities).

<sup>35</sup> Immunization Quality Improvement for Providers

## EXISTING PRODUCTION INTERFACE

The IIS should have administrative-level tools/reports for monitoring and alerting IIS staff when facilities start producing an increased number (or percentage) of fatal errors and/or a significant decrease or increase in the number (or percentage) of record submissions. Some IIS have implemented dashboard views or provider report cards detailing the number of records submitted and number of warnings/errors issued during a specified time period as a way to increase provider involvement and ownership of their data submissions.

Ideally, EHR products should offer their own set of performance reports, as well as the ability to compile, review, and resubmit messages with fatal errors. This may also include some mechanism to proactively notify the provider or end user when messages are erroring or failing to trigger. This functionality may not be a standard feature in most EHR systems.

## RE-ONBOARDING

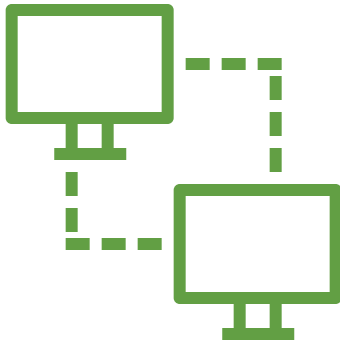
Once an issue has been identified, the IIS should work directly with the provider/EHR vendor to troubleshoot and resolve any issues. While IIS have the ability to turn off an existing interface, this tactic is very rarely used. The preferred strategy is to work with the provider to troubleshoot interface issues and then resubmit messages as needed. **Re-onboarding of an existing provider should be necessary only when the organization/facility transitions to a new EHR product.**

### Process – Improvements and Recommendations: Interface Monitoring

- Closely monitor new interfaces for the first two weeks following the transition to the IIS production environment.
- Confirm that the IIS is receiving data from all sites reporting through a new production interface.
- Transition interfaces to routine monitoring if no issues are detected during the initial two-week monitoring period.
- Implement a tool or process for monitoring production HL7 feeds to identify issues such as increased warnings/failures, deviations in data quality, or changes in volume of submissions. See also [Onboarding tools and attributes](#).

# ONBOARDING: BIDIRECTIONAL HL7 QUERY/RESPONSE

The process for establishing a bidirectional interface follows the same general steps used for a standard (VXU-only) reporting interface described in the preceding sections: Discovery and Planning, Development and Testing, Production Approval, and Interface Monitoring.



## Query/Response includes:

- Differences in processes and procedures compared to standard interfaces (VXU only)
- Discovery and Planning
- Development and Testing
- Production Approval and Monitoring
- Additional steps

An interface for query/response (Q/R) can be established in conjunction with vaccine update (VXU) reporting, independently of VXU, or as a Q/R-only interface. Both processes utilize similar documentation and require completion of similar forms/paperwork at both the initiation and closeout of the project. Query/response security and transport requirements are the same as those applied to VXUs. The primary differences in the onboarding procedure occur during development and testing.

**Unlike a standard VXU interface, testing and validation for Q/R can be performed almost entirely by the provider and its EHR vendor.** Initial testing for Q/R should be performed in an IIS test environment using test scenarios prescribed by the IIS program or a set of test patients generated from the EHR.<sup>36</sup> If this initial round of testing produces expected results, the next level of testing should be performed in the IIS production environment using production patients from the EHR to confirm that the interface is successful. For production-level testing, a physician or other clinical user should be directly involved in order to confirm that the query retrieved appropriate matches and that the returned patient/vaccination/evaluation/forecast data is consumed and displayed correctly by the EHR.

<sup>36</sup> Some providers/EHR vendors may be concerned about introducing test patients into their production environments during this initial round of testing. Providers and their vendors should discuss how the use of IIS test systems/scenarios may impact the provider's production data.

Prescribed test cases or testing scenarios prepared by the IIS have proven to be very beneficial for confirming match strategies and expected returns when performing the initial rounds of testing. Well defined test cases are valuable for Q/R testing but do introduce maintenance challenges resulting from provider modification of patients/records in the test set. Use of test cases requires that the IIS program periodically review test patients and perform necessary cleanup to restore the integrity of the test. The alternative is having providers issue VXUs and then query for their own patients, but this typically does not provide an adequate test of all match scenarios or proper consumption of patient records that contain updated information by the EHR. Sample Q/R test sets are suggested in [Appendix B-4. IIS sample onboarding materials](#).

All query/response testing should be preceded by a readiness checklist and kickoff call that includes representation from the IIS, EHR vendor, and provider (and HIE, if appropriate). **The kickoff call is a critical opportunity to share information and gain clarification on a variety of issues around the establishment of a Q/R interface.** The kickoff call should be used to address questions about how queries are triggered, matching algorithms used by the IIS, deduplication in the IIS, reconciliation of selected records in the EHR, etc. IIS programs may consider developing a script to guide these kickoff call discussions.<sup>37</sup>

### Q/R Kickoff Call

- Review onboarding forms, documents, testing process, and IIS matching algorithm.
- Discuss EHR query triggers and ability of the EHR to consume/display and reconcile vaccination data.
- Discuss common issues: echo/ deathloop, use of the IIS ID, challenges created during IIS deduplication and the merging/unmerging of patients, etc.

<sup>37</sup> Suggested script topics include EHR triggers for initiating a query; EHR capabilities for consuming/reconciling data returned by the IIS (including both historical and administered vaccinations); preventing “echo” or “deathloop” caused when the EHR issues a follow-up query after a response has already been received and consumed; IIS matching algorithm used for determining matches; EHR capabilities for handling of multi-match returns and match selection; the role of the IIS patient ID, how it is used by the EHR, and how the IIS unique patient identifier (IIS ID) may be impacted by IIS deduplication protocols.

IIS programs should leverage momentum with the provider and EHR vendor by implementing Q/R in conjunction with VXUs whenever possible to take advantage of dedicated/available resources and general enthusiasm. While testing of bidirectional interfaces will be predominately guided by the provider and/or EHR vendor, the IIS onboarding team should be available for general consultation/support throughout this process.



**NOTE:** There is specific concern around HIEs that (1) do not use the CDC WSDL, and/or (2) support only one-way interfaces. Bidirectional interfaces require a secure method of transport in line with current CDC- and ONC-endorsed standards. Bidirectional interfaces also require that a response message is returned to the provider that initiated the query.

### Process – Improvements and Recommendations: Query/Response

- Host a Q/R project kickoff call to address questions about how queries are triggered, matching algorithms used by the IIS, deduplication in the IIS, reconciliation of selected records in the EHR, etc.
- Perform initial Q/R testing in an IIS test environment using test scenarios prescribed by the IIS program or a set of test patients generated from the EHR.
- Perform secondary Q/R testing in the IIS production environment using production patients from the EHR.
- Engage a physician or other clinical user in production-level Q/R testing to confirm that the query retrieved appropriate matches and that the returned patient/vaccination data is consumed and displayed correctly by the EHR.
- Implement Q/R in conjunction with VXUs whenever possible.



## MATCHING ALGORITHMS

Current guidance around the Q/R matching algorithm is not adequate to support standardized development and implementation across the IIS community. In lieu of standard guidance, some IIS have leveraged elements of their deduplication algorithm, and others have relied on legacy HL7 implementation guidance for high versus low confidence match criteria.

Updated match guidance should address the following notable deficiencies:

- Detailed criteria used to determine high versus low confidence matches and establishment of a confidence level for each candidate in the possible match return.
- Weighting criteria applied to various demographic fields.
- Documented baseline security protections for multiple-match returns: guidance should address confidentiality and security measures including standard privacy/confidentiality and site/user agreements required by all users accessing data from the IIS; address concerns of some stakeholders that multiple matches could possibly violate HIPAA.<sup>38</sup>
- Workflows for match selection: when multiple matches are returned for a query, the EHR and IIS must have some mechanism to note that the selection is intentional/specific (e.g., re-query for only the selected IIS ID) so the secondary response includes only the single, selected match candidate.
- Challenges around IIS ID storage in EHRs: the IIS ID can create issues with merging/un-merging when it results in the creation of new patients with a new IIS ID. EHRs should store the IIS ID, but further discussion is needed on whether this should be stored long-term or short-term (e.g., as a session ID).
- Core guidance for implementation by all IIS programs noting areas where jurisdictionally specific nuances may be allowed/accommodated.

<sup>38</sup> Health Insurance Portability and Accountability Act of 1996

Additional guidance may also be needed to establish a minimum and maximum number of match returns (as determined by the RCP-2 value) and business rules to support related processing decisions. IIS programs may also want to examine how other IIS search processes address this issue (e.g., web application search, data submission matching process). Some sample considerations may include:

- All IIS should accept a minimum RCP-2 value of “1.” If there are multiple high-confidence matches, the IIS should consider returning no matches.
- The maximum number of match returns may ultimately need to be hardcoded by the IIS to a default RCP-2 value. This may be set as a specific number or based on a defined threshold for match confidence to ensure the return of only the highest-probability match candidates.
- It may be better to return no matches than a bad match or too many match candidates.
- For batch or automatic queries (if supported), when a single, exact match for a patient is not able to be located, return none.

**High-quality match strategies contribute to improved provider perception of IIS data and increased confidence in IIS-EHR interfaces.** Matching algorithms should be shared and reviewed with EHR vendors/providers during project kickoff calls. Sharing and discussing the IIS matching algorithm during the kickoff can help provide additional clarification on when the IIS will return a single match, multiple match, or no match response. Communicating match criteria and thresholds manages expectations for match returns and mitigates perceptions that the IIS does not have good data or can't return a proper match.

### **Process – Improvements and Recommendations: Matching Algorithms**

- Improve community-wide guidance for standardizing and implementing Q/R match strategies.
- Share matching algorithms and review with EHR vendors/providers during project kickoff calls.
- Promote synchronous processes and minimize asynchronous interfaces.



# **IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS**

# 3



### 3 IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS

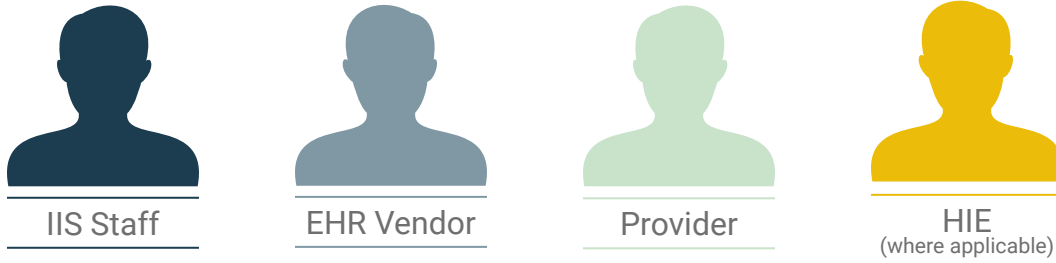
In addition to the basic onboarding process steps, there are a number of overarching implementation considerations and recommendations that can be applied to improve and standardize the onboarding process. These important onboarding considerations are presented in [Figure 3](#) below.

**Figure 3** | *Overarching considerations and recommendations for implementation*



## ONBOARDING PARTNERS

There are four primary stakeholders in the onboarding process:



**Stakeholder roles and responsibilities should be clearly stated and agreed to at the beginning of the onboarding project.** The following tables lay out the roles and responsibilities of each of the primary onboarding partners both during and after onboarding. Additional examples for defining roles and responsibilities are included in [Appendix B-4. IIS sample onboarding materials](#).

The label “IIS Staff” is an inclusive term intended to represent any person or entity performing onboarding duties on behalf of the IIS. This may include Department of Health employees (e.g., IIS and other immunization program staff), IIS product vendors or other third parties performing contracted onboarding services, and/or centralized state IT operation centers. On occasion, some providers or EHR vendors will engage the services of an integrated delivery network that operates as a reporting hub/intermediary between the provider and the IIS. Roles and responsibilities for these service providers may include elements from “EHR Vendor,” “Provider,” and “HIE” depending on the extent of the services being provided. In addition, some provider organizations might not have any EHR vendor support. In these cases, the roles of the provider would be expanded to include the activities listed under “EHR Vendor.”



IIS Staff

### During

- Provide general coordination/project management, communication, and customer service.
- Provide specific contacts with technical and programmatic expertise.
- Provide an appropriate testing/validation platform.
- Communicate details about the onboarding process and thresholds for success.
- Make onboarding documentation easily accessible/readily available and ensure that it is up to date at all times.
- Provide timely feedback on message conformance/performance and data quality.
- Assist with issue identification and troubleshooting.
- Manage expectations about process, milestones, and timelines.
- Inform stakeholders of any system updates/changes.

### After

- Provide appropriate training for providers and communicate ongoing expectations for a production interface.
- Provide continued communication and coordination.
- Monitor data feeds for errors.
- Notify providers of any changes or outages that may impact existing interfaces. *Note: this should be done as early as possible so other partners can properly prepare and execute any changes required on their end.*
- Continue to post updated documentation as requirements and standards evolve.



EHR Vendor

**During**

- Provide project management and technical expertise (testing and development) on behalf of the EHR team.
- Be an active participant in all elements of the onboarding process and attend all meetings/conference calls.
- Ensure the EHR system aligns with HL7 transport and messaging standards.
- Work with IIS to identify, troubleshoot, and quickly resolve any issues with the interface or submitted messages.
- Help IIS manage expectations about process, milestones, and timelines with the provider.
- Assist providers with proper configuration of their EHR.

**After**

- Assist providers with proper configuration of their EHR.
- Train providers on how to monitor their interface (performance and ACKs) and resolve issues or seek assistance as needed.
- Facilitate transition from the onboarding/implementation team to the long-term support team.
- Assist with maintaining the connection and monitoring the interface for performance and errors.
- Provide technical support to the provider and resolve any technical issues.
- Maintain conformance with HL7 transport and messaging standards.
- Notify providers (and possibly IIS) of any changes or outages that may impact existing interfaces.



Provider

**During**

- Complete all necessary enrollment forms/paperwork and engage the EHR vendor to get onboarding resources assigned.
- Identify a primary sponsor to be an active participant in all elements of the onboarding process and attend meetings/conference calls as appropriate.
- Provide production or production-quality data for testing and validation.
- Coordinate appropriate staff for end user testing and troubleshooting.
- Identify and resolve issues caused by improper workflows or poor data entry that adversely impact data quality.
- Work with EHR vendor or provider technical staff to resolve issues with the interface or submitted messages.

**After**

- Verify initial setup is correct and data from the EHR is successfully populating the production IIS.
- Monitor ACK interface and appropriate EHR/IIS reports to identify changes in volume or quality of messages or anything else that raises red flags about the interface.
- Immediately report issues to the IIS and EHR contacts for assistance in troubleshooting.
- Correct data entry errors and establish appropriate policies/procedures to address issues with workflow and data quality; train staff as needed.
- Communicate with IIS about any system changes/updates or outages that may impact existing interfaces.
- Provide updated contact information for staff changes at either the provider or EHR vendor.
- Notify the IIS of any mergers, acquisitions, or closures.
- Keep vaccinating!



HIE

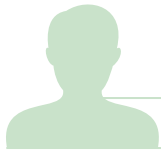
**During**

- Provide support for connectivity testing and troubleshooting (staffing and infrastructure).
- Provide project management and technical expertise on behalf of the HIE team.
- Be an active participant in the onboarding process and attend meetings/conference calls when appropriate.
- Ensure that the HIE aligns with HL7 transport and messaging standards.
- Ensure all IIS ACKs are returned to provider/EHR.
- Work with the IIS and/or EHR vendor/provider to identify, troubleshoot, and quickly resolve any issues with the interface or submitted messages.
- Help IIS manage expectations about process, milestones, and timelines with the provider.
- Assist EHR vendor/provider with proper configuration of the EHR.

**After**

- Assist providers with proper configuration of their connection.
- Provide continued support for monitoring and maintaining connectivity.
- Provide technical support to resolve any connectivity issues.
- Ensure all IIS ACKs are returned to sender/provider.
- Communicate with IIS about any system changes/updates or outages that may impact existing interfaces.
- Provide the IIS with updated contact information for staff changes.

## PARTNER CONSIDERATIONS



Provider

**The provider is the primary stakeholder in the onboarding process.** The provider's ultimate goal is to administer vaccinations and provide quality patient care. Sometimes peripheral activities like onboarding can get in the way or divert resources from focusing on this goal. IIS and EHR representatives should be sensitive to these priorities by making the onboarding process as easy and streamlined as possible.

The designated provider representative must be high enough in the organizational structure to make decisions independently and enforce changes to workflows or policies. A physician or nurse manager is optimal. Staff members without independent decision-making authority are typically not effective representatives and can create additional delays throughout the process. The provider representative does not have to participate in every call but does need to actively participate during the testing phase (especially any data quality testing) and at other critical decision points and action steps (e.g., paperwork, kickoff, and closeout calls).



EHR Vendor

Each EHR vendor operates with a unique staffing structure and business model for its supported products. EHR customers range from large multi-state health systems to independent, single-provider practices. Some vendors establish direct point-to-point connections between the provider organization's EHR and the IIS, whereas other vendors offer a centralized reporting hub solution. Staffing models may include a dedicated corporate onboarding team, regional teams, product-specific onboarding teams, or even third-party contractors. As a result of these staffing variations, it is not uncommon for IIS staff to encounter different onboarding contacts between provider sites using the same EHR product.

### IIS staff are likely to encounter:

- **Different onboarding contacts between provider sites using the same EHR product**
- **Providers using the same vendor and product line but operating on different release versions**
- **Providers using the same product and same version with different implementations due to custom configurations and settings**

Some EHR vendors support a single product line, while others may support numerous product lines and product versions. Provider uptake of newly released versions is not required or imposed. As a result, IIS are likely to encounter providers using the same vendor and product line but operating on different versions. In addition, even providers using the same product and same version may have different implementations that impact the nature of the EHR-IIS interface. This illustrates why there can be significant variation between providers even when they are using the same EHR vendor, product, and version. This also supports the importance of testing every reporting interface independently.

EHR products may connect with and report to numerous external systems. As a result, developing and maintaining standardized interface functionality that can be leveraged across multiple jurisdictions is critically important to the establishment of sustainable interfaces. **State-by-state variation in IIS interfacing requirements and guidance interpretation is very difficult for EHR vendors to execute and maintain.**

EHR vendors must comply with ONC requirements in order to become certified and maintain certification for the Meaningful Use program. It is difficult for EHR vendors to make custom changes to accommodate the requirements of a single IIS, and it is difficult to maintain one-off changes. IIS should be mindful of the challenges faced by EHR vendors and the volume of products and providers they support. All IIS should strive to align with HL7 implementation guidance and standard code sets. Areas where IIS commonly deviate from the standard (e.g., consent requirements, VFC requirements, OBX and ACK values) should be further defined and included in the universal implementation guidance to ensure proper and consistent implementation across all EHR partners. See also [Importance of standards](#).



Most HIEs serve as a simple connection for passing messages between the EHR and the IIS. It is important that HIEs conform to proper security protocols and CDC standards for message transport. Some HIEs transfigure reported messages or store select data elements. When the HIE serves as more than a pass-through, the IIS should handle HIE testing and validation in the same manner that it handles new and existing EHR interfaces. It is especially important in these scenarios that the HIE conforms to the HL7 standards for messaging and transport. Regardless of whether the HIE is used strictly for transport or is used for transforming data or data storage, it is important that the HIE facilitate end-to-end communication between the IIS and the provider EHR.

## Implementation – Considerations and Recommendations: Onboarding Partners

- Clearly document and communicate stakeholder roles and responsibilities at the beginning of every onboarding project.
- Ensure that the designated provider representative is high enough in the organizational structure to make decisions independently and enforce changes to workflows or policies.
- Test and validate every new interface connection even if the EHR vendor, product, and product version have been previously tested and approved.
- Encourage HIE partners to conform to proper security protocols and CDC-endorsed standards for HL7 messaging and transport when interfacing with the IIS.
- Emphasize the importance of end-to-end communication between the IIS and the provider EHR.



# IMPORTANCE OF STANDARDS

Standards provide a framework for system design and core feature development. Standards are intended to ensure that core system feature functionality is applied consistently to minimize and/or eliminate variation between implementations. As noted previously, ONC is the governing authority responsible for defining the guidelines used to certify EHR products for meaningful use. **EHR vendors are required to comply with standards for capturing, transmitting, and protecting data in order to become certified and maintain certification.**

The current standards endorsed by CDC and ONC for IIS-EHR interfaces are documented in the following resources:

- *CDC HL7 Implementation Guide*<sup>39</sup> and *Addendum*<sup>40</sup>
- CDC IIS Code Sets
- *CDC Transport Layer Protocol Recommendation Formal Specification*<sup>41</sup>

However, state-specific implementation guides and the best practice guidance commonly leveraged and highly supported by the IIS community (e.g., MIROW and AIRA resources) are not considered to be part of these core implementation standards. **Ideally, all best practice guidance that represents a universally accepted requirement for interfacing with an IIS should be clearly defined and incorporated into the core implementation standards documents.** The following discussion will address the challenges of individual IIS deviation from standards as well as some of the more common limitations of the current HL7 Implementation Guide.

EHR products typically connect with and report to numerous external systems (labs, imaging services, billing systems, vital records, IIS, etc.). **Developing and maintaining standardized interface functionality that can be leveraged across numerous jurisdictions is critically important to the establishment of sustainable interfaces.** State-by-state variation in IIS onboarding implementation requirements and/or non-standard guidance interpretation is very difficult for EHR vendors to execute and maintain from both a cost and human resource perspective. IIS programs should be mindful of the challenges faced by EHR vendors and the volume of products and providers they support across multiple IIS jurisdictions when establishing local requirements that deviate from the national standards.

<sup>39</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>40</sup> The HL7 Implementation Guide and Addendum must always be distributed and discussed together as a single resource. The Addendum provides clarified and expanded guidance, but not all IIS or EHR partners have fully implemented the Addendum guidance. <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

<sup>41</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html>

The areas where IIS most often deviate from the standard include consent management, VFC program requirements, general handling of OBX segments, and implementation of ACK messaging. These deviations typically occur when there is no guidance or when existing guidance has not been explicit enough to avoid individual interpretation. One area that is particularly problematic for all stakeholders is the interpretation and handling of programmatically essential data elements required for the VFC Program, specifically funding source and eligibility. This issue has resulted in considerable variability in how individual IIS have chosen to implement and enforce these features. Common areas of deviation should be further explored, clearly defined, and then included in future releases of the standard HL7 implementation guidance to ensure proper and consistent implementation across all IIS and EHR partners. Representatives from all affected stakeholders should be invited to participate in these discussions and the development of new standards.

Handling of vaccine administered (CVX) codes presents another common problem. While CVX codes are a standardized data element, some IIS have chosen to support only a subset of these codes by excluding disease-based and other non-immunization codes (e.g., immunoglobulin and antitoxins) or by accepting only a selection of vaccine codes (childhood only). When unwanted codes are submitted, the IIS issues a fatal error in response to a code that is technically correct, requiring the EHR product to create custom workarounds to meet the requirements of the individual IIS. Alternatively, this issue would be better handled with an appropriate ACK warning or informational message stating that the IIS does not accept the submitted code. EHRs must be capable of sending all active CVX codes and other required data elements, but the onus should be on the individual IIS to accept the codes/fields that the IIS will store and simply ignore unwanted codes/data elements.



**Deviations from core implementation standards should be limited to items specifically required under state laws/regulations (e.g., consent) or to allow for a period of transition after a new standard has been introduced.** It may also be appropriate for IIS to build in some flexibility or alternative onboarding criteria to accommodate certain provider types such as pharmacies or influenza-only providers that do not fall within the traditional EHR interface model. Beyond these examples, IIS programs should carefully assess where they are off-standard and strive to align with HL7 implementation guidance and standard code sets as closely as possible.

The AIRA IIS Measurement and Improvement Initiative<sup>42</sup> is an ongoing effort focused on applying, refining, and adopting national standards. IIS staff interested in assessing how closely their IIS aligns with these standards are encouraged to perform an initial assessment using AIRA's Aggregate Analysis Reporting Tool.<sup>43</sup> The Measurement and Improvement Initiative offers support and assistance to IIS programs working toward improving their conformance with national standards.

For IIS programs that must deviate from the standard or need to provide additional clarification, full-size state-specific implementation guides are strongly discouraged. These documents create extra work for external onboarding partners and lead to unnecessary confusion. Short delta guides are preferred, noting only those items where the jurisdiction deviates from the HL7 Implementation Guide (cross walk) and guidance on how specialized message segments should be handled for the respective IIS. Delta guides should be limited to a few pages, easy to read, and easy to navigate. The delta companion document should accompany the HL7 Implementation Guide and Addendum wherever they are used or discussed.

### IGAMT

- **The NIST IGAMT tool was designed for IIS to be able to input their local HL7 requirements to develop a delta implementation guide.**
- **See [Appendix B-3. Materials developed/published by NIST](#) for more details on this tool and others developed by NIST.**

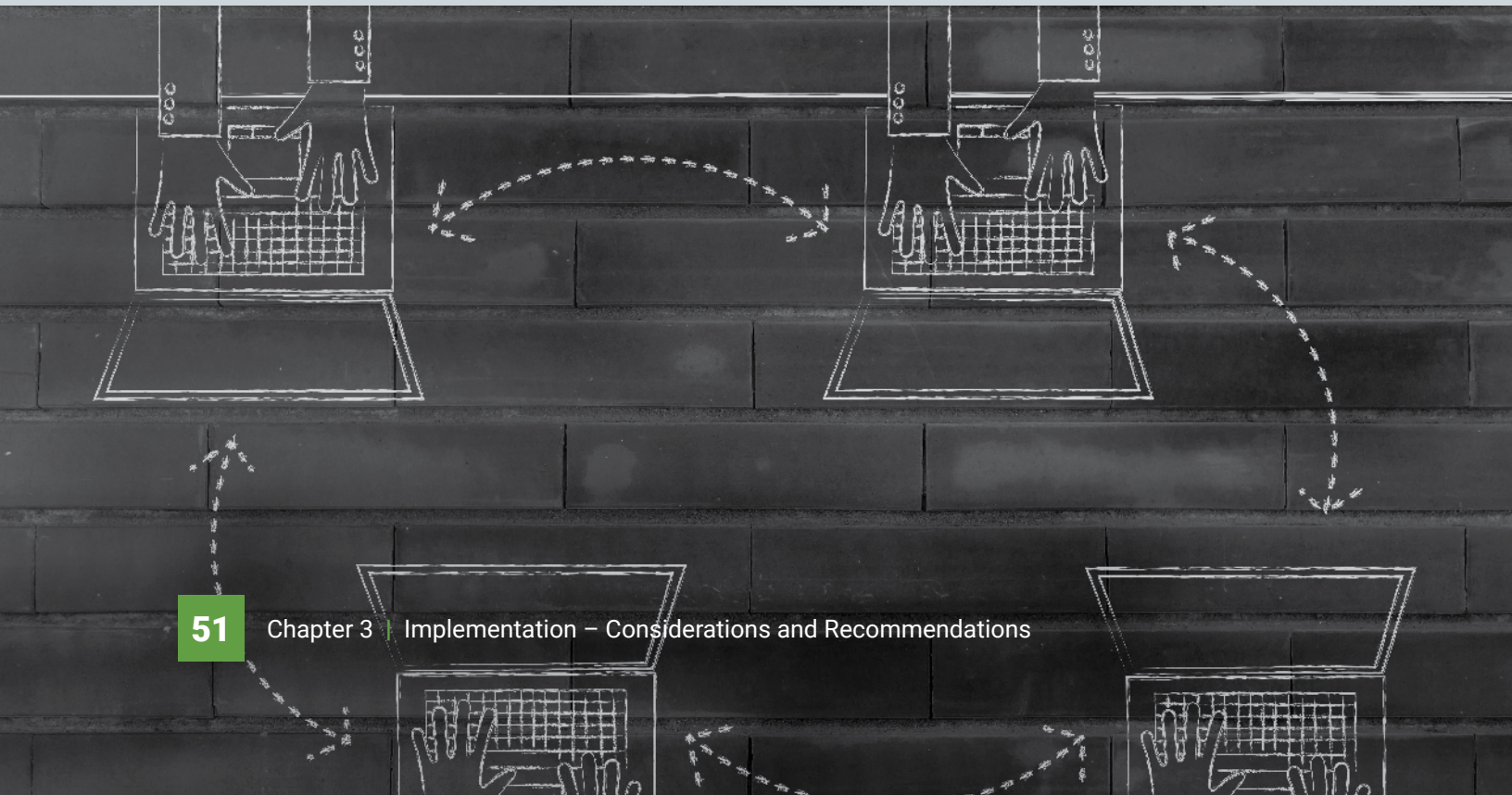
It should also be noted that for connectivity and transport, all major EHR partners support the use of SOAP Web Services and the CDC WSDL as the currently endorsed CDC standard. IIS programs should continue to support and promote the CDC-endorsed standard as the preferred transport method; this includes current standards as well as future standards that align with evolving technologies and protocols. HIEs and other hubs should also be encouraged to align with transport and security standards. See also [Changes to standards](#).

<sup>42</sup> <https://www.immregistries.org/measurement-improvement>

<sup>43</sup> <https://www.immregistries.org/aggregate-analysis-reporting-tool>

## Implementation – Considerations and Recommendations: Importance of Standards

- Support and promote the current CDC- and ONC-endorsed standards for HL7 messaging and transport for IIS interfaces.
- Minimize variation across jurisdictions. Strive to align with HL7 implementation guidance and standard code sets except where otherwise required by state law.
- Improve community interpretation of implementation guidance for VFC program requirements, use of OBX segments, implementation of ACK responses, and handling of CVX codes.
- Accept codes and data elements that the IIS will store and ignore any unwanted codes/data elements with an appropriate ACK warning. Do not error the message.
- Consider flexible requirements and testing protocols to accommodate non-traditional provider types that do not operate within the constructs of typical vaccine providers—e.g., pharmacies and influenza-only providers.
- Develop short delta guides for noting where the jurisdiction deviates from the HL7 Implementation Guide. Eliminate the use of full-size custom implementation guides.



## MANAGING BACKLOG

The term “backlog” encompasses all providers that are actively onboarding or waiting to begin the onboarding process. Staffing resources and availability are a challenge for every onboarding stakeholder, and it becomes increasingly difficult when trying to align all resources simultaneously. Ultimately having an efficient onboarding process, managing expectations through good documentation and communication, and leveraging general momentum and enthusiasm can maximize resources for all stakeholders. **IIS programs should focus their efforts on the providers that are the most eager and ready to proceed as determined through the use of readiness checklists and resource availability on behalf of the provider and its EHR vendor.**

### Keys to Managing Backlog:

- **Implement an efficient onboarding process.**
- **Manage expectations through good documentation and active communication.**
- **Leverage provider enthusiasm and general momentum.**
- **Provide checklists and self-testing platforms.**

With limited onboarding staff and support resources, some IIS programs have implemented strategies to prioritize providers for onboarding by maintaining an ongoing provider queue. While the general practice of maintaining a master list of all providers that are onboarding or waiting to onboard is an overarching best practice,<sup>44</sup> IIS programs that currently rely on a prioritized onboarding queue should carefully assess their current onboarding procedures and implement strategies to allow more providers to onboard simultaneously. **Ideally, IIS programs should never be the barrier that prevents a provider from beginning the onboarding process.** Many of the strategies identified in this document consider staffing challenges and suggest efficiencies to better maximize limited resources.

If the IIS is not able to immediately dedicate staffing resources to providers that are ready to proceed with onboarding, the IIS should provide checklists and self-testing platforms (e.g., sandbox access to the test environment) to allow providers/EHR vendors to make forward progress even when IIS staff availability is limited. IIS staff may still need to be available to answer questions and issue testing credentials; however, allowing providers/EHR vendors to test independently takes advantage of project momentum and allows providers/EHR vendors to identify issues and queue up necessary changes in their development cycles without directly tying up IIS onboarding staff.

Each interface is unique and may advance through the various onboarding phases at different rates. Strict timelines are not recommended as long as an interface is consistently progressing. This can be

<sup>44</sup> Logging and tracking onboarding providers can be accomplished by using a full-featured tracking tool (see also Onboarding tools and attributes) or Excel spreadsheet. While an Excel-type spreadsheet can be used to provide minimal project tracking support, simple spreadsheets are generally not sophisticated enough to perform all registration and project tracking functions.

monitored and determined through the use of a tracking tool or process. If a provider starts to lag or fails to progress after entering the onboarding process, the IIS program should conduct periodic check-ins with the provider to get status updates and provide assistance as needed.

For IIS programs with limited onboarding staff, it may be necessary to temporarily put a provider on hold until the provider is ready and able to resume active onboarding. In these situations, the provider and its EHR vendor should receive a communication that this action is being taken and instructions for how it can resume the onboarding process. This strategy allows the IIS program to actively focus resources on providers with the most interest and momentum. **A provider should be removed from the onboarding list only if it specifically requests to be removed.**

To the extent possible, all IIS programs should reassess their onboarding protocols to better leverage provider enthusiasm, availability of provider/EHR vendor resources, economies of scale, and general project momentum. If IIS programs find that prioritization of interested providers is still a necessity, emphasis should be placed on large multi-facility organizations, EHR vendors with a strong presence in the jurisdiction, demonstrated readiness of the provider/EHR vendor to connect (determined by a readiness checklist), VFC providers, and new EHR implementations (especially for providers with existing interfaces that are changing EHR products). Data collected during registration can be used to identify providers with these attributes. IIS programs should provide adequate transparency about who gets prioritized, how many providers are in the queue, and where each provider is positioned on that list.

### Implementation – Considerations and Recommendations: Managing Backlog

- Maintain a master accounting of all providers that are onboarding or waiting to onboard by using a tracking tool or process. See also Onboarding tools and attributes.
- Focus IIS resources on providers with the most interest and readiness to proceed.
- Conduct periodic check-ins with a provider that is engaged in onboarding to get status updates and maintain project momentum.
- Place a hold on providers that are not able to dedicate appropriate resources to the onboarding process. Resume onboarding when the provider is ready and has available resources.
- Identify opportunities to automate processes and reduce reliance on IIS staff participation and manual processes.

## ONBOARDING PREREQUISITES

**All prerequisites for onboarding should be laid out in the onboarding readiness checklist.** Use of a readiness checklist will ensure that the provider/EHR vendor is ready to proceed with onboarding before directly engaging the IIS onboarding team. Readiness to onboard should focus on the ability to produce a properly formatted HL7 message, supporting required fields and code sets, and completing necessary paperwork. Some IIS have imposed prerequisites for onboarding that have not been proven to result in improved interfaces and may actually hinder the onboarding process. This section describes some of these unnecessary onboarding requirements.

### Onboarding Prerequisites:

- **Ability to produce a properly formatted HL7 message**
- **Supporting required fields and code sets**
- **Completion of necessary paperwork**

Some IIS programs require that a provider use a certified EHR product in order to connect with the IIS. Requiring an EHR to be certified does not correlate to the success of an interface. Certification supports standards but does not guarantee that the EHR will be able to exchange data with the IIS. **The most important aspect of onboarding success is the quality of the messages produced by the EHR and not the certification itself.** IIS can recommend use of a certified product to providers but should not establish certification as a requirement for onboarding.

Some IIS programs require testing directly with each EHR vendor as a preliminary “proof of concept” for message production. This practice adds additional resource requirements for all stakeholders, significantly increases timelines, and might not result in efficiencies in the onboarding process. Further, each EHR vendor may be supporting multiple products and product versions simultaneously. Each EHR-IIS interface is somewhat unique, and all point-to-point connections should be tested and approved independently. Additionally, HL7 standards and EHR products are always evolving, so a point-in-time test with a vendor is not a good indicator of future success.

Imposing a waiting period to interface with a new provider EHR implementation is a missed opportunity for IIS to take advantage of the expedited development cycles and augmented staffing on behalf of both the EHR vendor and the provider. **New EHR implementations typically have additional vendor resources assigned during pre-deployment and the two weeks immediately following implementation.** These resources include technical team members

who can troubleshoot interfaces and make immediate code changes. Following deployment, providers enter a more traditional service support model with their EHR vendor. Tasks/jobs must then be prioritized, and resources might not be as readily available. Working with providers during EHR implementation also ensures that all workflows and data flows align with IIS expectations from the beginning versus trying to troubleshoot and retrain clinic staff after the behaviors have already become ingrained.

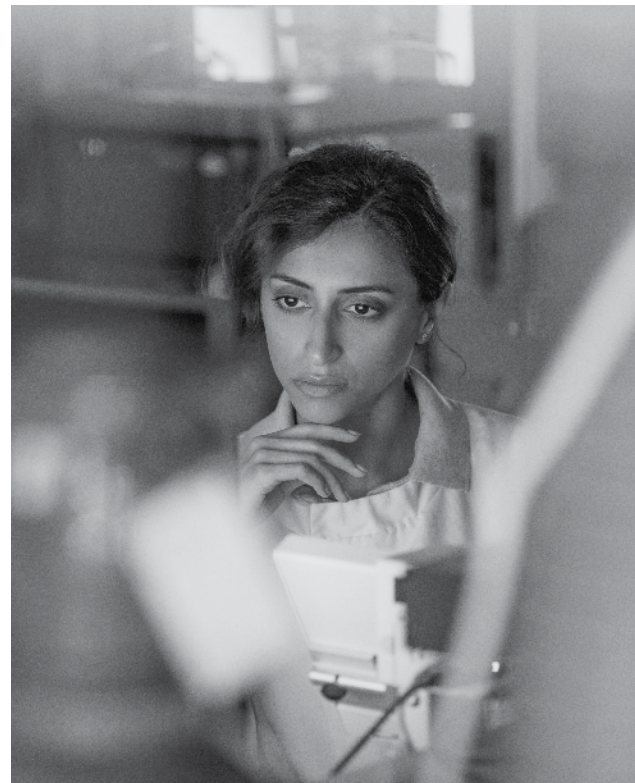
In general, if the provider is otherwise ready and willing to begin the onboarding process and has met the readiness requirements established by the IIS, the IIS should make every attempt to leverage momentum on the provider and EHR vendor side whenever these partners have enthusiasm for the project and dedicated/available resources for testing and development.

### **Implementation – Considerations and Recommendations: Onboarding Prerequisites**

- Develop readiness checklists for VXU and Q/R detailing the requisite criteria to proceed with onboarding.
- Consider eliminating waiting periods and proof-of-concept testing.
- Leverage augmented staffing and expedited development cycles associated with new EHR implementations to troubleshoot interfaces and ensure proper workflows and data flows for IIS interfaces.

## DATA QUALITY

IIS data quality is an ongoing challenge for all IIS programs and consumes a significant amount of program staffing resources. Programmatic-level data quality testing and validation is extremely important but also contributes to considerable delays in the onboarding process because it is the most time consuming and resource intensive for all stakeholders. This phase of testing is also the least standardized element of the testing protocol. This is due in part to a reliance on manual validation processes and a wide variation in the testing requirements and approaches applied from jurisdiction to jurisdiction. Population of required fields with proper codes from the Message Validation phase of testing should be the minimum requirement for approving a production interface (see also [Stages of testing](#)), but onboarding also presents an opportunity for more in-depth data review and validation. **The onboarding process should strike a balance between the time and effort required to establish a new interface and the implications of introducing poor-quality data into the production IIS environment.**



A notable problem facing the IIS community is the decline in data quality observed after an interface goes live. While much effort is placed on identifying and improving data quality issues in order to advance providers through the onboarding data validation process, interfaces may demonstrate a decline in data quality over time in the production IIS. This trend suggests the importance of longer-term data quality identification and resolution strategies.

Data quality testing during onboarding is designed to ensure that data transmitted to the IIS meets an acceptable threshold for quality and that a newly established interface does not inadvertently introduce low-quality data into the IIS production environment. However, data quality issues often result from system/software upgrades or configuration changes, staffing changes, poor data capture and workflow practices, and other factors that occur outside of the onboarding process. This poses the question of how much data quality can be controlled for during the onboarding process versus what should be controlled for when a new interface is being established.

The level of data quality testing that should be performed in conjunction with onboarding requires further consideration by a panel of experts comprised of representatives from all of the primary onboarding stakeholders (IIS/immunization program, EHR vendors, providers, and HIE partners). The IIS community has developed several guidance documents about onboarding and data

quality monitoring in electronic interfaces; however, participants informing these documents were comprised of primarily IIS representatives. These documents should be consulted during the broader stakeholder discussions to further refine guidance regarding which data quality/validation components can and should be included during onboarding versus longer-term data-monitoring strategies. Ongoing discussions should also identify opportunities for eliminating/minimizing manual data quality review activities that are particularly resource intensive for all stakeholders. IIS programs should then be encouraged to adopt the resulting recommendations in order to facilitate a standardized onboarding approach across all jurisdictions.

**Ultimately, data quality monitoring is an ongoing activity that should take place before, during and after onboarding.** IIS programs should have long-term strategies and routines for identifying and resolving general data quality issues. One approach is to ensure that all inbound data submissions to the production IIS are validated using the same expectations and thresholds used for testing during the onboarding process. An additional strategy includes increased monitoring and targeted training for providers with known data quality challenges. Data quality discussions should also be incorporated into other routine immunization program interactions with the provider (e.g. VFC and IQIP program activities) to maintain focus on the importance of identifying and resolving data quality challenges.

### **Implementation – Considerations and Recommendations: Data Quality**

- Determine the level of data quality testing that is appropriate for the onboarding process by assessing which elements of data quality can be controlled for during onboarding versus what should be controlled for when a new interface is being established.
- Eliminate/minimize manual data quality review activities to the extent possible.
- Establish long-term data monitoring strategies to identify and resolve data quality issues outside of the onboarding process.

## PROVIDER INTERFACE TRAINING

There are two primary training considerations for interfacing with the IIS: (1) reviewing and interpreting ACK messages and (2) correcting messages with fatal errors.<sup>45</sup> The responsibility for training may be shared between the IIS and EHR depending on which interface the provider will be using to identify and resolve errors.

**The person(s) responsible for monitoring the EHR-IIS interface should be trained on where to review ACK messages and how to interpret the content** (see also [Importance of ACK messaging](#)). This training may occur during the development and testing phase as well as during the production approval phase. Review of ACK messages may occur in the IIS interface, EHR interface, or both. IIS should also work with HIEs to ensure that ACK messages are being transmitted back to the submitter so that these messages can be appropriately assessed and resolved.

Ideally, EHR vendors should provide an interface where the provider representative can view ACK messages. In this case, provider training would be conducted by the EHR vendor on how to monitor ACKs in the EHR interface. If the EHR does not provide an interface for monitoring submissions and managing ACKs, the IIS should provide training to the provider on the tools available through the IIS interface.

ACK messaging produced by the IIS should be meaningful, readable, and actionable. The document titled *Guidance for HL7 ACK Messages to Support Interoperability*<sup>46</sup> provides unified instruction for responding to informational, warning, and error responses in the ERR segment of the HL7 ACK response. IIS staff may need to provide training on how to interpret these messages. This training may need to be offered to the provider, EHR vendor, or both depending on who has access to the ACK log and who is responsible for monitoring the interface.



**NOTE:** ACK monitoring should be addressed in the roles/responsibilities document reviewed at the beginning and end of the onboarding process.

<sup>45</sup> Sample training resources for monitoring interfaces or interpreting/resolving errors were not collected in conjunction with this project. Programs should take advantage of community resource sharing opportunities to solicit resources or share proven training materials/protocols on these topics.

<sup>46</sup> [http://repository.immregistries.org/files/resources/5835adc2add61/guidance\\_for\\_hl7\\_acknowledgement\\_messages\\_to\\_support\\_interoperability\\_.pdf](http://repository.immregistries.org/files/resources/5835adc2add61/guidance_for_hl7_acknowledgement_messages_to_support_interoperability_.pdf)

**At least one high-level user from the provider organization should know how to log in and interact with the IIS user interface (e.g., basic IIS features, manual patient and vaccination entry, and relevant reports).** Providers are expected to correct data quality issues identified through ACKs and other IIS reports/assessments. In most EHRs, the provider can make these corrections in the EHR and trigger the corrected message(s) to be resubmitted to the IIS; however, on occasion, providers may need to log in directly to the IIS to resolve issues that can't be addressed appropriately through the EHR. Manual data entry into the IIS may also be needed if the provider's system or EHR-IIS interface fails and records are no longer being reported through the electronic interface.



**NOTE:** IIS user interface training is traditionally an element of IIS enrollment. Onboarding requires that a provider is already enrolled in the IIS, so if training is performed at IIS enrollment, it is not necessary to require basic IIS training as an activity in the onboarding process.

### Implementation – Considerations and Recommendations: Training

- Implement appropriate tools or reports for monitoring interface performance and reviewing/troubleshooting ACK messages. See also Onboarding tools and attributes.
- Communicate expectations for the active monitoring of submissions and resolution of warnings/failures.
- Provide training on reviewing and interpreting ACK messages generated by the IIS.
- Ensure that at least one high-level user from the provider organization has been trained on how to log in and interact with the IIS interface (e.g., basic IIS features, manual patient and vaccination entry, generating relevant reports).

## COMMUNICATION

Lack of communication contributes to stakeholder frustration, delays in the onboarding process, and challenges with interface maintenance. Well crafted onboarding documentation and proactive written and verbal communication between stakeholders are essential strategies for managing stakeholder expectations and facilitating an efficient onboarding experience.

Some of the primary strategies that can be employed by the IIS include:

- Providing access to all current onboarding documentation and forms on the IIS website where they can be easily located
- Facilitating proactive communications: welcome emails, kickoff calls, closeout calls, tracking tool updates
- Clearly outlining expectations, requirements, and thresholds in the onboarding plan and supporting checklists
- Defining stakeholder roles and responsibilities for the onboarding process and beyond—see also [Onboarding partners](#).

As the primary stakeholders in the onboarding process, **provider representatives should always be kept in the loop on activities and project status even when their immediate presence is not necessary or required.** Providers should be invited to participate in all phone calls and testing activities, but they should be informed about when their participation is critical versus optional/informational. EHR vendors know the software, but the provider knows the clinic workflows and culture.

Roadblocks are inevitable during the onboarding process and can occur for a variety of reasons at any stage in the process. The goal is to overcome these roadblocks as quickly and efficiently as possible. Targeted communication (having the right people talking to each other) is the best strategy for overcoming these challenges and can directly affect how quickly or slowly an interface progresses. Having too many intermediaries adversely impacts progress. Technical issues require direct tech-to-tech contact; programmatic issues require direct programmatic-to-programmatic contact. On occasion, some IIS programs have found in-person, on-site testing or interactive web meetings with project technical or programmatic leads to be successful for expediting issue identification and resolution. IIS programs should be prepared to facilitate the direct communications necessary to quickly resolve issues.

### **Implementation – Considerations and Recommendations: Communication**

- Improve onboarding communication strategies through well crafted onboarding documentation and proactive written and verbal communication between stakeholders.
- Informationally include provider representatives in all onboarding project communications but inform them when their input or participation is required.
- Facilitate direct communication between technical or programmatic contacts to quickly troubleshoot and resolve onboarding roadblocks.



# DOCUMENTATION

The documents used to support the various phases of the onboarding process were presented previously in [Table 1](#).

Documentation is critical for communicating requirements and for setting and managing expectations throughout the onboarding process. The volume of documentation and paperwork required for onboarding can be overwhelming. IIS programs should assess their current onboarding documentation and consider whether there are documents that can be simplified, combined, condensed, or eliminated entirely. Documents used for onboarding should be reviewed periodically and updated as needed.

**Documentation and tools/resources used to support the onboarding process should be readily accessible to participating stakeholders.** Documents to be used or completed by external partners should be posted to the IIS or immunization program website on a single web page dedicated to onboarding. This web page should be easy to locate, be well organized, and include all necessary onboarding documentation. Documentation posted to the web page should always represent the latest version of each document.

Documents to be used or referenced by internal program staff should be maintained in a centralized repository, shared document, or shared tool/resource accessible by all internal onboarding team members. Candidate documents or resources include scanned copies of completed paper forms, tracking tools or spreadsheets, current and historical reference documents, etc.

In addition to simplifying, combining, and/or condensing current onboarding documentation, IIS should make efforts to reduce or eliminate the use of paper-based forms and hardcopy documents. Most forms and questionnaires used for onboarding can be captured electronically using online forms. This creates opportunities for the development of searchable databases that allow programs to sort and evaluate data while facilitating additional onboarding efficiencies. Required agreements can also be collected electronically through the use of electronic signatures. Agreements could then be stored electronically in a repository accessible by IIS and immunization program staff.

The following table provides a description of the most common onboarding documents along with additional consideration of how and where these documents may be used to facilitate improvements in the onboarding process. Links to IIS sample onboarding materials and referenced documents are included in [Appendix B-4. IIS sample onboarding materials](#) and [Appendix C. Onboarding Reference List](#).

**Table 3** | Core onboarding document descriptions and considerations

DOCUMENTS	DESCRIPTION	ADDITIONAL CONSIDERATIONS
IIS Enrollment Form(s)	Collects facility details, contact information, users, and user types	Needed only if provider was not previously enrolled with the IIS.
Security and Confidentiality Agreement(s)	Describes the security and confidentiality policies of the IIS and other applicable federal, state, local, and territorial laws	IIS may also consider including their Security Guide and/or Web Services Guide in the initial set of documents shared during Discovery and Planning and/or Development and Testing.
Site/User Agreement(s)	Describes the terms of use in order for a site/user to gain access to the IIS and the data contained therein	These agreements cover access to protected health information (PHI) and should encompass all onboarding activities in the IIS test and production environments.
Provider site mapping	Lists all facilities/facility IDs that will be submitting through the interface	Should be updated periodically after “go live” to account for any additions/removals.
Onboarding Plan	Defines steps of the onboarding process, details specific requirements at each step, and gives measurements/thresholds for success in order to advance to subsequent steps	Onboarding Plan is also important for managing expectations and should drive the agenda for the initial kickoff call.
Data Exchange Enrollment Form(s)	Collects details about the EHR product and vendor, initial contact information for relevant stakeholders, practice type, and profile statistics	These forms can be completed online or, at minimum, should be readily accessible for download online to be completed at any time.
Data Exchange Questionnaire	Collects information on the nature of interface, basic workflows, system triggers, capabilities, etc.	May include a gap analysis of where the EHR and IIS differ on codes and fields. May be combined with the Data Exchange Enrollment Form(s).
Data Exchange Readiness Checklist	Lists the various prerequisites and requirements for advancing to the onboarding process	May be combined with the Data Exchange Questionnaire.
Roles and Responsibilities Document/Form	Defines the responsibilities of all players before, during, and after the onboarding process	Very important to have a version for post-production as well that defines go-forward expectations and contact information.
CDC HL7 Implementation Guide <sup>47</sup> and Addendum <sup>48</sup>	Provides guidance on implementing electronic data exchange using the HL7 standard  Defines syntax and vocabulary for constructing and transmitting an HL7 2.5.1 message	The HL7 Implementation Guide and Addendum must always be distributed and discussed together as a single resource. Current version is Release 1.5. Onboarding activities should focus on the most recently published version.

<sup>47</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf><sup>48</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

**Table 3** | Core onboarding document descriptions and considerations (continued from previous page)

DOCUMENTS	DESCRIPTION	ADDITIONAL CONSIDERATIONS
CDC IIS Code Sets	Includes: <ul style="list-style-type: none"> <li>• CVX Codes</li> <li>• MVX Codes</li> <li>• Core Data Elements</li> </ul>	Code set updates do not necessarily align with HL7 Implementation Guide updates. Onboarding activities should include the most recent code set versions.
<i>CDC Transport Layer Protocol Recommendation Formal Specification</i> <sup>49</sup>	Defines transport, security, and SOAP operations, parameters, and faults for SOAP-based HL7 submissions and queries to an IIS using the CDC WSDL	Some IIS use additional protocols; however, SOAP/CDC WSDL is the current CDC-endorsed standard for connectivity and transport for IIS interfaces.
State-Specific Implementation Guide (delta version)	Abbreviated version noting only those areas where the jurisdiction differs from the <i>CDC HL7 Implementation Guide</i> <sup>50</sup> or where additional clarification is needed based on the jurisdiction's interpretation of the HL7 implementation guidance	Full-size custom guides are strongly discouraged. Delta guides should be only a few pages long and note only those items where the jurisdiction deviates from the HL7 Implementation Guide and how specialized message segments should be handled for the respective IIS.
State-Specific Required Fields Guide/Checklist	Notes any fields required/not required where the jurisdiction differs from the nationally supported code sets	State codes may be included in the state-specific delta guide as a single document.
Test Cases/Scenarios	Provides detailed patients and workflows designed to produce a specific testing result	Should include expected results.
End User Communication/ Training Plan	Includes general expectations for ongoing communication, IIS user interface training requirements, EHR-IIS interface training, etc.	See also <a href="#">Communication</a> and <a href="#">Provider interface training</a> .
Roles and Responsibilities Document/Form (post production)	Establishes expectations and contact information for technical and data quality contacts for the period following "go live"	Contacts often differ between "during" and "after" as the implementation team transitions to the day-to-day support team.  This may be a simple update to the Roles and Responsibilities Document/Form used during onboarding and does not necessarily have to be a separate document.
Go-Live Readiness Checklist	Addresses issues such as completing the provider site mapping, issuing production credentials, post-production roles/responsibilities and contacts, and IIS training requirements	There should be a go-live production readiness checklist on both the IIS side and the EHR side.  Should be used to guide the agenda for closeout/"go live" calls.

<sup>49</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html><sup>50</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

### **Implementation – Considerations and Recommendations: Documentation**

- Review existing onboarding documentation and look for opportunities to update, simplify, or eliminate.
- Reduce or eliminate the use of paper forms and paper processes to the extent possible.
- Improve accessibility to onboarding resources for both internal staff and external partners.



## ONBOARDING TOOLS AND ATTRIBUTES

A number of tools are being used across the IIS community to facilitate various elements of the onboarding process. The primary tools used during each onboarding step were presented previously in [Table 2](#). Appropriately leveraged tools help maximize staff resources, troubleshoot interfaces, and eliminate paper-based processes. For example:

- A registration tool<sup>51</sup> allows IIS programs to collect and store details related to the facility, EHR, and interface capabilities in a searchable and sortable manner. The registration tool can also be used to initiate other steps in the onboarding process or populate other databases/programs used by the immunization program.
- Project tracking tools<sup>52</sup> facilitate improved organization and communication for both internal and external onboarding partners. These tools support the management of project tasks and trouble tickets and provide a historical record of project-related activities and communications.
- An HL7 message pretesting tool, like the NIST Immunization Test Suite, supports a critical first step in ensuring that the provider's EHR is able to produce an appropriately formatted HL7 message before engaging IIS staff resources.
- HL7 content validation and data quality testing tools and reports help IIS programs quickly identify and communicate problem areas. When access to these features is also provided to external partners, especially larger EHR vendors, a considerable amount of testing and resolution can be performed independently and reduces the reliance on IIS staff resources.
- HL7 feed-monitoring tools and reports allow both IIS and provider staff to monitor interface performance after “go-live” to ensure that data is being routinely transmitted as expected.

Some onboarding tools are offered under commercial licenses, while others may be available to IIS programs as open-source applications. Some tools may require custom, in-house development or modification of existing tools to best meet IIS program needs. Programs should assess the costs and benefits associated with implementing onboarding support tools and look for opportunities for joint development or shared platforms. The following table details the common capabilities and attributes associated with each of the primary onboarding tools.

<sup>51</sup> Excel-type spreadsheets are generally not sophisticated enough to perform all necessary registration and project tracking functions.

<sup>52</sup> Ibid.

**Table 4** | *Attributes of common tools used to support onboarding*

TOOLS	ATTRIBUTES
Registration Tool	<ul style="list-style-type: none"> <li>• Should provide an interface that is accessible externally to providers/vendors</li> <li>• Captures facility details (facility name, address, etc.)</li> <li>• Captures facility/org contacts (names, phone number, email, etc.)</li> <li>• Captures EHR details (vendor, product/version, vendor contact info, etc.)</li> <li>• Includes electronic signing of required forms if applicable or as allowed by jurisdictional law/policies</li> <li>• Includes questionnaire-type questions (system capabilities, type of interface requested, connection method, type of practice, number of doses administered, facility client profile, ability to capture required fields, etc.)</li> <li>• Should be stored in a searchable format</li> <li>• Should have the capability for electronically transferring the information into other IIS/onboarding tools (tracking tool, provider profile, etc.)</li> <li>• Could utilize appropriate triggers in the registration workflow to improve efficiencies and automate other onboarding actions (e.g., welcome email, creating a ticket in the tracking tool, etc.)</li> <li>• Tool should be integrated into each IIS's individual onboarding workflows</li> </ul>
Project Tracking Tool	<ul style="list-style-type: none"> <li>• Typically used as an internal resource for the IIS program</li> <li>• Provides a master dashboard for the status of each active onboarding "project" that can be viewed by all internal team members</li> <li>• Ability to create a unique tracking project for each active onboarding entity</li> <li>• Ability to move the project through each of the various onboarding phases</li> <li>• Ability to define jurisdiction-specific onboarding phases (e.g., forms completion, connectivity testing, validation testing, preproduction)</li> <li>• Ability to assign projects to internal team members when action is needed</li> <li>• Ability to document actions, communications, and milestones for each project/provider</li> <li>• Includes ability to securely post project-related documents and screenshots</li> <li>• Includes ability to generate automated emails</li> <li>• Provides a historical record of all production interfaces</li> </ul>

**Table 4** | *Attributes of common tools used to support onboarding (continued from previous page)*

TOOLS	ATTRIBUTES
HL7 Message Format/Structure Pretest (see also NIST Immunization Test Suite)	<ul style="list-style-type: none"> <li>• Offered as a self-service tool to providers/vendors</li> <li>• Provides guidance on constructing an appropriate HL7 message</li> <li>• Provides ability to submit and assess a sample HL7 message for proper segments (parsing)</li> <li>• Provides ACK feedback on the submitted message</li> <li>• Customized to meet any jurisdiction-specific requirements</li> <li>• Provides minimum/core test scenarios and expected results</li> </ul>
HL7 Message Content Validation	<ul style="list-style-type: none"> <li>• Historically used as an internal resource for the IIS program</li> <li>• Should be available to providers/vendors through an outward-facing user interface</li> <li>• Meets <i>CDC HL7 Implementation Guide</i><sup>53</sup> and <i>Addendum</i><sup>54</sup> standards</li> <li>• Customizable to meet jurisdiction-specific HL7 implementation guidance requirements</li> <li>• Provides support for volume assessment of in-bound VXUs from an EHR test or production environment</li> <li>• Provides user interface to review ACKs for submitted messages</li> <li>• Ability to drill down into message (parsing) for troubleshooting selected messages</li> <li>• Ability to drill down into ACK detail for troubleshooting</li> <li>• Ability to filter on specific segments or values within segments</li> <li>• Ability to assess population of required technical elements—expected percentage and actual percentage</li> <li>• Includes support for other data validations</li> <li>• Provides minimum/core test scenarios and expected results</li> </ul>
HL7 Data Quality Analysis Testing	<ul style="list-style-type: none"> <li>• Typically used as an internal resource for the IIS/immunization program</li> <li>• Assesses whether required fields are populated with valid info (correct codes)</li> <li>• Ability to assess population of required programmatic elements—expected percentage and actual percentage</li> <li>• Includes inventory management/decrementing verification</li> <li>• Provides end user data quality report(s) for providers and other onboarding partners</li> <li>• Ability to automate report generation based on predetermined criteria</li> <li>• Includes support for other data validations</li> <li>• Could possibly be combined with HL7 Message Content Validation</li> </ul>

<sup>53</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>54</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

**Table 4** | *Attributes of common tools used to support onboarding (continued from previous page)*

TOOLS	ATTRIBUTES
HL7 Feed Monitoring	<ul style="list-style-type: none"> <li>• Can be used as an internal resource for the IIS program or external resource for EHR vendors and/or providers</li> <li>• HL7 stats monitoring—volume of messages coming in, number and type of ACKs</li> <li>• Should track Query/Response in addition to VXUs</li> <li>• Ability to drill down to org-level, facility-level, etc. performance</li> <li>• Ability to automate report generation or alerting mechanism based on predetermined criteria</li> </ul>

### Implementation – Considerations and Recommendations: Onboarding Tools

- Strategically implement tools to better facilitate various elements of the onboarding process.
- Create opportunities for provider/EHR vendors to leverage tools for testing message construct and content independently and reduce the need for IIS staff participation.

## CONCLUSION



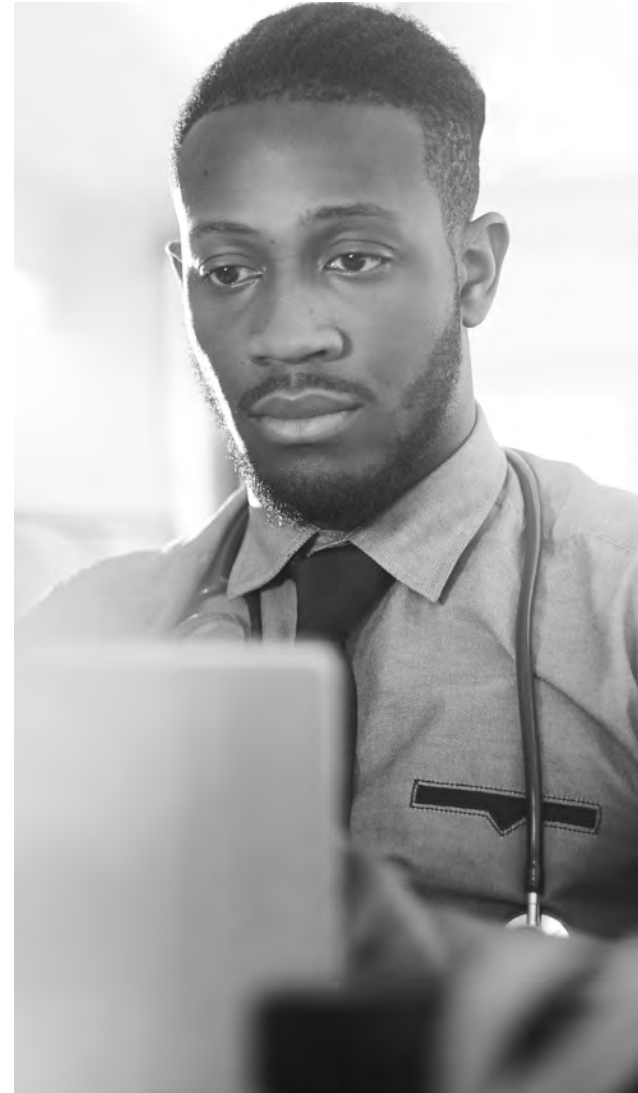
## 4 CONCLUSION

Medical providers and public health programs have a common mission to prevent disease in the community and ensure that patients receive timely vaccinations.

Electronic interfaces support this mission by facilitating the reporting of vaccination data to the IIS which further benefits numerous other stakeholders who rely on the availability and completeness of this data. Improving the onboarding process to establish more EHR-IIS interfaces is a means to achieving this common mission.

This project used a community-driven approach to develop guidance for improving and standardizing the onboarding experience. The preceding document identifies numerous onboarding process improvements and implementation considerations compiled with the input of all major onboarding partners to:

- Standardize the onboarding process across jurisdictions
- Improve onboarding process efficiencies by streamlining activities and introducing appropriate support tools and technologies
- Decrease the overall number of providers waiting in queue and the amount of time providers spend in process from start to finish
- Facilitate the transition of existing interfaces to align with current and future messaging and transport standards
- Maximize limited resources—time, money, and staff—for all onboarding partners
- Improve stakeholder relations



Two primary bottlenecks in the onboarding process were identified through this project: (1) the period immediately following registration and (2) the programmatic data quality review phase of testing. IIS programs should pay particular attention to strategies that can be applied to help eliminate obstacles and improve the process activities associated with these onboarding steps.

In addition to resolving these primary challenges, there are a number of strategies that can be applied universally to enhance the onboarding experience for all stakeholders:

- Minimize variation across jurisdictions. Strive to align with HL7 implementation guidance and standard code sets except where otherwise required by state law or mandate.
- Manage expectations through well crafted onboarding documentation and proactive written and verbal communication between stakeholders.
- Identify opportunities to reduce reliance on IIS staff participation by automating manual processes and strategically leveraging IIS reports and supporting tools/technologies.
- Create opportunities for onboarding providers and EHR vendors to conduct preliminary testing and issue resolution independently.
- Leverage general momentum and provider enthusiasm by focusing IIS resources on providers with the most interest and readiness to proceed.

The guidance in this document is meant to stimulate conversation and challenge IIS programs to reevaluate their current onboarding protocols. The actionable suggestions that appear at the end of each topic discussion are intended to improve and streamline various elements of the onboarding process. The gaps and challenges listed in [Appendix E. Barriers/Challenges](#) and [Appendix F. Gaps](#) require additional stakeholder discussion and should be prioritized for future conversations.



# APPENDICES

## APPENDIX A ABBREVIATIONS/ACRONYMS 74

## APPENDIX B SYNOPSSES OF KEY RESOURCE MATERIALS 75

B-1. Materials developed/published by CDC	75
B-2. Materials developed/published by AIRA	78
B-3. Materials developed/published by NIST	85
B-4. IIS sample onboarding materials	87

## APPENDIX C ONBOARDING REFERENCE LIST 91

## APPENDIX D CONSOLIDATED ONBOARDING RECOMMENDATIONS 93

## APPENDIX E BARRIERS/CHALLENGES 99

## APPENDIX F GAPS 100

## APPENDIX G ACKNOWLEDGMENTS 102



# APPENDIX A ABBREVIATIONS/ ACRONYMS

ABBREVIATIONS/ACRONYMS	
AAP	American Academy of Pediatrics
ACK	HL7 Acknowledgment Message
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CDSi	CDC Clinical Decision Support Logic for immunizations
CVX	CDC Code for Vaccine Administered
DQA	Data Quality Assurance
EHR	Electronic Health Record
ERR	An HL7 messaging segment
HIE	Health Information Exchange
HIPAA	Health Insurance Portability and Accountability Act of 1996
HL7	Health Level Seven International
IIS	Immunization Information System
IIS ID	Immunization Information System unique patient identifier
IQIP	Immunization Quality Improvement for Providers
MIROW	Modeling of Immunization Registry Operations Workgroup
MSH	An HL7 messaging segment
MXV	CDC Code for Manufacturers of Vaccines
NCIRD	CDC National Center for Immunization and Respiratory Diseases
NIST	National Institute of Standards and Technology
OBX	An HL7 messaging segment
ONC	Office of the National Coordinator for Health Information Technology
PV1	An HL7 messaging segment
Q/R	HL7 Query/Response
RCP	An HL7 messaging segment
RXA	An HL7 messaging segment
SOAP	Simple Object Access Protocol
UAT	User Acceptance Training
VFC	Vaccines for Children Program
VXU	HL7 Unsolicited Vaccination Record Update Message
WSDL	Web Services Definition Language

## APPENDIX B SYNOPSES OF KEY RESOURCE MATERIALS

This appendix provides publication information with a high-level overview from key resource materials used to develop this guide.

### APPENDIX B-1 MATERIALS DEVELOPED/ PUBLISHED BY CDC

#### CURRENT HL7 STANDARD CODE SET CVX – VACCINES ADMINISTERED<sup>55</sup>

The CDC National Center for Immunization and Respiratory Diseases (NCIRD) developed and maintains the CVX (vaccine administered) code set. It includes both active and inactive vaccines available in the United States. These CVX codes are used for immunization messages using either HL7 Version 2.3.1 or HL7 Version 2.5.1. CVX codes for inactive vaccines allow transmission of historical immunization records.

##### Publication Information:

- **Date:** January 18, 2018
- **Audience:** IIS managers, IIS staff, IIS vendors, and EHR vendors
- **Page Count:** PDF = 7; other formats available

#### STANDARD CODE SET MVX – MANUFACTURERS OF VACCINES<sup>56</sup>

The CDC NCIRD developed and maintains HL7 Table 0227, Manufacturers of Vaccines (MVX). It includes both active and inactive manufacturers of vaccines in the United States. Inactive MVX codes allow transmission of historical immunization records.

##### Publication Information:

- **Date:** January 18, 2018
- **Audience:** IIS managers, IIS staff, IIS vendors, and EHR vendors
- **Page Count:** PDF = 7; other formats available

<sup>55</sup> <https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>

<sup>56</sup> <https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx>

## IIS RECOMMENDED CORE DATA ELEMENTS<sup>57</sup>

The CDC core data elements represent the data elements that are needed by an IIS to record vaccination events to meet the IIS Functional Standards.<sup>58</sup> An IIS should store the core data elements if the elements are sent from an external information system and meet the IIS's data quality criteria. The list does not include all data elements external information systems—such as EHRs, vital records, practice management, or billing systems—are expected to send to an IIS. The list might not include all data elements an IIS produces, stores, or sends.

### Publication Information:

- **Date:** December 7, 2012
- **Audience:** IIS managers, IIS staff, immunization program managers, IIS partners, IIS vendors, and EHR vendors
- **Page Count:** 1

## IIS TRANSPORT (SOAP) (INCLUDES SPECIFICATIONS FOR A CDC WEB SERVICES DEFINITION LANGUAGE (WSDL))<sup>59</sup>

The CDC NCIRD developed and maintains resources related to data transport. Transmission and receipt of health data from one system to another is achieved through an agreed-upon transport layer. In 2011, a panel of industry experts concluded that SOAP Web Services was the best fit for meeting the needs of transmitting immunization data via HL7 messaging. The experts also defined a WSDL for all trading partners to implement, with the goal that all trading partners implement at least the nationally specified WSDL. This doesn't preclude IIS and others from supporting additional transport layers.

### Publication Information:

- **Date:** December 13, 2016
- **Audience:** IIS managers, IIS staff, IIS vendors, and EHR vendors
- **Page Count:** WSDL = 3; multiple documents referenced

## IMPLEMENTATION RESOURCES:

- **Formal specification (v1.2)<sup>60</sup>** – Defines transport, security, and SOAP operations, parameters, and defaults for SOAP-based HL7 submissions and queries to an IIS. Pages seven to nine of this specification contains the SOAP Web Services Definition Language (WSDL), which should be implemented without modification.
- **Implementation Testing Support<sup>61</sup>** – NIST provides testing tools to ensure consistent and conformant implementation of the CDC WSDL. The tools can test both the sender and the receiver sides of the CDC WSDL.

<sup>57</sup> <https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>

<sup>58</sup> <https://www.cdc.gov/vaccines/programs/iis/func-stds.html>

<sup>59</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/services.html>

<sup>60</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/downloads/transport-specification.pdf>

<sup>61</sup> <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/soapConn>

**EDUCATIONAL MATERIAL:**

- AIRA has developed the following educational resources related to SOAP and the CDC WSDL:<sup>62</sup>
  - Transport 101
  - SOAP WSDL 101
  - SOAP Transition Strategies
  - NIST Immunization Test Suite

### HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE FOR IMMUNIZATION MESSAGING, RELEASE 1.5<sup>63</sup> AND ADDENDUM<sup>64</sup>

The *CDC HL7 Implementation Guide* is intended to facilitate the exchange of immunization records between different systems by using a nationally recognized standard for electronic data exchange between systems housing health care data: HL7. The HL7 standard defines a syntax or grammar for formulating the messages and describes a standard vocabulary that is used in these messages. It is platform independent. The HL7 Implementation Guide specifies usage requirements for immunization-related data elements that are not included in the standard HL7 usage designations. The implementation guide is based on HL7 Version 2.5.1 and pre-adopts a number of features of HL7 Version 2.7.1.

**Publication Information:**

- **Date: October 1, 2014 (Implementation Guide) and July 2015 (Addendum)**
- **Audience: IIS, IIS vendors, and EHR vendor system managers and technical staff**
- **Page Count = 408 total; 278 in the body of the document**
- **Page Count: Addendum = 28 pages**

The implementation guide addresses:

- Sending and receiving immunization histories for individuals
- Requesting immunization histories for individuals
- Requesting an evaluated history and forecast for individuals
- Responding to requests for immunization histories by returning immunization histories
- Responding to requests for evaluated history and forecast
- Acknowledging receipt of immunization histories and requests for immunization histories
- Reporting errors in the messaging process
- Sending observations about an immunization event (this may include patient eligibility for a funding program, reactions, forecasts, and evaluations)

Local implementation guides outline business rules and other processes that are not intended to be addressed in the national implementation guide.

<sup>62</sup> <https://www.immregistries.org/training-videos>

<sup>63</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>64</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

## APPENDIX B-2 MATERIALS DEVELOPED/ PUBLISHED BY AIRA

### DATA VALIDATION GUIDE FOR THE IIS ONBOARDING PROCESS<sup>65</sup>

The guide focuses on the data validation aspect of onboarding. The guide covers activities that occur after a data source receives a test account, establishes connectivity to the IIS test environment, and receives approval to begin testing.

The guide builds on prior IIS community resources. Primary source materials are listed on page three of the guide and include references to MIROW guides (*Data Quality Assurance in Immunization Information Systems: Incoming Data* 2008,<sup>66</sup> *Data Quality Assurance in Immunization Information Systems: Selected Aspects* 2013,<sup>67</sup> and *Decrementing Inventory via Electronic Data Exchange* 2015<sup>68</sup>), the CDC HL7 *Implementation Guide*,<sup>69</sup> and *Addendum*,<sup>70</sup> and onboarding materials furnished by IIS.

During data validation, the IIS ensures that the quality of data meets IIS standards using real patient data and preestablished criteria. After data validation requirements are satisfied and provider organization data flows to the IIS production environment, data quality processes continue. An IIS interface requires ongoing, often daily, monitoring by the IIS and the provider organization.

The guide provides direction on various aspects of data validation:

- Source of data: While “fake” or “test” data may have been used in the development and testing phase of onboarding (e.g., in the HL7 message validation process), data quality uses preproduction, real patient data from each provider site.
- Sample data set for testing: The sample size varies based on type and size of the immunization practice. For larger practices, the sample size may be a set number of patients and HL7 messages. For smaller practices, the sample size may include all immunizations over a set time period. The sample should include the full range of ages in the vaccination practice and both historical and administered immunizations.

#### Publication Information:

- **Date:** 2017
- **Audience:** IIS managers, IIS staff, immunization program managers, IIS and AIRA partners, IIS vendors, and EHR vendors
- **Page Count:** Total = 49 total; 23 in the body of the document

<sup>65</sup> [http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)

<sup>66</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-incoming-data-1/>

<sup>67</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>

<sup>68</sup> [http://repository.immregistries.org/files/resources/5835adc2a034b/aira\\_mirow\\_di-v-edc\\_guide\\_final\\_010417.pdf](http://repository.immregistries.org/files/resources/5835adc2a034b/aira_mirow_di-v-edc_guide_final_010417.pdf)

<sup>69</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>70</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

- Data quality: Data quality includes accuracy, completeness, and timeliness. Accuracy and completeness are examined during onboarding, with timeliness examined later as a part of ongoing monitoring.
- Accuracy: Table 1 of the guide contains a prioritized list of the MIROW 2013 *Data Quality Assurance in Immunization Information Systems: Selected Aspects*<sup>71</sup> guide business rules that ensure data accuracy. Table D-1 contains a list of selected data checks from the MIROW 2008 *Data Quality Assurance in Immunization Information Systems: Incoming Data*<sup>72</sup> guide.
- Completeness: Completeness demonstrates the percent of submitted records that contain data in various data fields/elements. In determining completeness levels, each IIS program should examine the importance of each data element to its own system and immunization program. Table 2 of the guide contains a list of data elements with recommended completeness thresholds.
  - Thresholds
    - Required data elements—Each IIS will have established critical data elements that result in rejecting a message, taking into consideration the CDC core data elements and the HL7 Implementation Guide.
    - Non-required data elements—A rule of thumb is that, if an electronic health record captures a data element that has a corresponding field in the IIS, the IIS should encourage the provider organization to submit it, regardless of its priority.
- Methodology: The guide offers examples of methodology that can be used by IIS to examine data quality.
- Aggregate data analysis: Appendix F of the guide includes examples of data quality reports using aggregate data analysis. Some IIS choose to compare IIS data to the originating medical record to complete the data validation process. Although quite time consuming, manual review of patient records can be valuable in revealing problems that are not obvious in an aggregate review.
- Provider profiles: Appendix D of the guide contains information on development and use of provider profiles (an expected distribution of immunizations based on type of practice).
- Data quality reports: Data validation continues after the data source begins submitting data to IIS production. The IIS can produce regular data quality reports to share with the data source for a period of time after the go-live date. Appendix F of the guide gives examples of data quality reports.

The guide was developed in expectation that each IIS program will adjust implementation to its own specific needs and unique concerns. The list of recommendations is not exhaustive. Individual IIS may choose to implement additional rules and processes based on their requirements. The recommendations and examples represent an attempt to balance ideal practices with pragmatic considerations of what is possible within the IIS.

<sup>71</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>

<sup>72</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-incoming-data-1/>

## IIS DATA QUALITY PRACTICES: MONITORING AND EVALUATING DATA SUBMISSIONS<sup>73</sup>

This document offers IIS practical guidance on real-world data monitoring and evaluation practices of incoming data. The guide is intended to assist IIS in identifying and addressing data quality issues in data submissions to help ensure that IIS data can be used for its intended purposes. This guide focuses on the process that begins immediately after a provider has passed the onboarding phase and has been approved to submit data to the production environment. Refer to the *AIRA Data Validation Guide for the IIS Onboarding Process* (2017)<sup>74</sup> for practical guidance on data quality measures implemented in an IIS to support the onboarding process. This guide also offers recommendations on how to conduct outreach and education to data submitters regarding data quality issues.

### Publication Information:

- **Date:** September 2017
- **Audience:** IIS managers and IIS staff with responsibility for ensuring and overseeing IIS data quality. Staff involved in the onboarding process and staff involved in the technical maintenance and development of IIS functionality may also benefit.
- **Page Count:** Total = 94; 37 in the body of the document

Topics covered in the document include:

- A review of data quality indicators
- Methodologies for data quality review
- Sample data quality monitoring and evaluation protocol
- Strategies for outreach and education regarding data quality
- Implementation considerations
- Sample data monitoring and evaluation reports from IIS
- Review of open source tools for monitoring and evaluating data submissions

Appendix A of the guide contains a list of data elements cross-referenced by use to assist IIS in prioritizing data elements for data quality evaluation and monitoring. Appendix C of the guide contains sample data evaluation and monitoring reports from a variety of IIS.

<sup>73</sup> [http://repository.immregistries.org/files/resources/59cabe6404421/data\\_quality\\_phase\\_ii.pdf](http://repository.immregistries.org/files/resources/59cabe6404421/data_quality_phase_ii.pdf)

<sup>74</sup> [http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)

### DATA QUALITY ASSURANCE IN IMMUNIZATION INFORMATION SYSTEMS: INCOMING DATA, RECOMMENDATIONS OF THE AIRA MODELING OF IMMUNIZATION REGISTRY OPERATIONS WORKGROUP (MIROW)<sup>75</sup>

The main focus of the guide is incoming data quality assurance (DQA) in IIS. The types of data quality validations for incoming data to IIS are precertification, preload, and existing data validations.

#### Publication Information:

- **Date:** February 11, 2008
- **Audience:** Programmatic, technical, and operational personnel involved in creating or maintaining an IIS
- **Page Count:** Total = 100; 67 in the body of the document

Precertification is the process of evaluating the incoming data quality of new submitters before allowing them to regularly add data to the IIS to ensure that the data sent are correctly formatted and complete. The guide makes recommendations about how to construct and use provider profiles to help to identify systematic problems and patterns.

Preload validation consists of inspecting the data reported by certified submitters prior to loading that data to the IIS. Many of the business rules included in the guide were updated in the MIROW 2013 *Data Quality Assurance in Immunization Information Systems: Selected Aspects*.<sup>76</sup>

Validation of existing data can reveal additional data quality issues after data have been loaded and allow them to be addressed. This guide considered data within the first 30 days after it is loaded into the database.

Appendix E of this guide gives examples of utilization of provider profiles for data quality analysis. Appendix F of this guide describes a possible statistical approach to an automated methodology for utilization of provider profiles for data quality analysis.

### DATA QUALITY ASSURANCE IN IMMUNIZATION INFORMATION SYSTEMS: SELECTED ASPECTS, RECOMMENDATIONS OF THE AIRA MODELING OF IMMUNIZATION REGISTRY OPERATIONS WORK GROUP (MIROW)<sup>77</sup>

The guide gives recommendations on facility identification management (i.e., how to properly identify a provider organization associated with reported data in cases of complex organizational hierarchy). The guide makes recommendations that impact onboarding from the time an entity contacts an IIS, through changes in provider organizational structure that could impact onboarding, and finally an IIS de-authorizing a provider. The impact on data quality is considered throughout the process.

#### Publication Information:

- **Date:** May 17, 2013
- **Audience:** Programmatic, technical, and operational personnel involved in creating or maintaining an IIS
- **Page Count:** Total = 113; 91 in the body of the document

<sup>75</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-incoming-data-1/>

<sup>76</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>

<sup>77</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>

The guide includes business models and illustrations documenting three roles (vaccinator, submitter, and recorder) that organizations play in the submittal chain of vaccination and demographic information to IIS and presents eight operational scenarios that illustrate the three roles.

The guide also revised and updated business rules for validations of incoming IIS data initially presented in the MIROW 2008 *Data Quality Assurance in Immunization Information Systems: Selected Aspects*<sup>78</sup> guidelines.

The guide also defines expected/minimum sets of data items for vaccination event submissions based on the key data element administered/historical Indicator and exceptions when a reduced set of data items may be accepted.

### IIS FUNCTIONAL GUIDE: QUERY AND RESPONSE VOLUME<sup>79</sup>

The guide leverages existing resources (e.g., the HL7 Implementation Guide, IIS local requirements, functional test plans, MIROW guidelines, Clinical Decision Support for immunizations (CDSi), CDC core data elements, and the IIS Functional Standards), to ensure a consistent picture across resources and reduce gaps between resources.

#### Publication Information:

- **Date:** August 17, 2017
- **Audience:** IIS managers, IIS staff, IIS vendors, EHR vendors, pharmacy systems, school-based systems
- **Page Count:** Total = 68; 47 in the body of the document

The guide does not dictate that a system must provide certain functionality, but rather, it defines the requirements if a system chooses to supply certain functionality. The scope of the guide is devoted to functionality for a querying system and a responding system. The guide defines the system and functional requirements for the querying system to (1) submit an initial query and (2) submit a second query to distinctly identify the patient from the list of possible patients.

The guide further defines the system and functional requirements for the responding system to respond to a query:

- If a single patient is found, including an evaluation and forecast
- If no patient is found
- If multiple potential patients are found
- If too many patients are found
- If patient does not consent to release of data

<sup>78</sup> <http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>

<sup>79</sup> [http://repository.immregistries.org/files/resources/5a83216a1d369/iis\\_functional\\_guide\\_february\\_2018.pdf](http://repository.immregistries.org/files/resources/5a83216a1d369/iis_functional_guide_february_2018.pdf)

The guide recommends that the responding system return as much data as the responding system is allowed to return per local policy and to always include the clinical decision support (i.e., evaluation and forecast). Appendix A of the guide contains a discussion of how this recommendation differs from the HL7 Implementation Guide.

The guide contains a list of terms that have a finite list of possible values and recommends that responding systems not create one-off local values but work to expand national lists as needed for all responding systems to use consistently.

## GUIDANCE FOR HL7 ACK MESSAGES TO SUPPORT INTEROPERABILITY<sup>80</sup>

Release 1.5 of the National HL7 Implementation Guide (IG) allows for a few ways to provide an ACK that conforms to the IG. This results in varied understanding and implementation of ACK messages. This guidance document seeks to clarify those issues in an effort to drive all IIS toward common, standardized ACK messaging. Further conformance clarifications will be needed in a future release of the IG.

### Publication Information:

- **Date:** October 2015
- **Audience:** IIS staff, IIS vendors, EHR vendors
- **Page Count:** 6

As documented in the IG, the ACK message requires the use of one and only one Message Acknowledgement (MSA) segment. The second segment is the Error (ERR) segment that can be repeated. The ERR segment is defined as a Required, But May Be Empty (RE) segment. Both the MSA and ERR have one critical field to help determine initial understanding of successful processing, MSA-1 (Acknowledgement Code) and ERR-4 (Severity) respectively. This document provides guidance on consistent usage of MSA-1 and ERR-4 in response to a submitted VXU message.

ERR-4 (Severity) and the value set (I, W, E) of this field documents how serious the error is and what the IIS expects of the sending system in regard to this error. The decision of the severity of a detected condition is left to the determination of each IIS. However, the distinction between a Severity of Error (E), Warning (W), and Information (I) along with the expectation of the sender must be consistent across IIS. A message must be examined in its entirety to determine that, because multiple ERR segments can occur. The document gives guidance on when an organization sending a message must correct and/or resubmit a message based on the Severity code.

Similar to ERR-4, the values in MSA-1 should have consistent meaning and usage. The document gives guidance on the actions a sender should take based on each code in MSA-1. This guidance defines a consistent way to highlight errors in response to a submitted message, but the ACK is not well suited to indicate what data was consumed. As such, it is expected that a sender first investigate any error (E) conditions, correct any issues in the sending system, and then resubmit the corrected version of the data. It is important to note that correcting errors may include conversation with an IIS, as the error may be on the IIS side.

<sup>80</sup> [http://repository.immregistries.org/files/resources/5835adc2add61/guidance\\_for\\_hl7\\_acknowledgement\\_messages\\_to\\_support\\_interoperability.pdf](http://repository.immregistries.org/files/resources/5835adc2add61/guidance_for_hl7_acknowledgement_messages_to_support_interoperability.pdf)

## NATIONAL SET OF ERROR CODES<sup>81</sup>

Release 1.5 of the IG shows how to return errors generated while receiving and processing VXU or QBP messages. The ERR segment is used to exchange error-related data. The IG defines six application error codes belonging to HL7 Table 0533 for use in ERR-5. However, community implementation and enhancement of acknowledgement and response

messages has revealed the need for additional application error codes. Several jurisdictions have begun to expand the error value set. However, in the absence of national-level coordination, the same error code has been defined multiple ways in different jurisdictions.

This document defines and recommends implementation of an expanded set of nationally defined application error codes for use in HL7 ERR-5 and has the potential to automate error response handling and resolution in clinical systems. A companion spreadsheet catalogues application error codes and actions expected of the sending system. All IIS and EHRs are highly encouraged to adopt the expanded set of error codes and curtail the use of locally defined codes.

### Publication Information:

- **Date: October 2017**
- **Audience: IIS staff, IIS vendors, EHR vendors**
- **Page Count: 3**

<sup>81</sup> [http://repository.immregistries.org/files/resources/59ee748913785/national\\_error\\_code\\_set\\_guidance\\_20171115\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/59ee748913785/national_error_code_set_guidance_20171115_new_logo.pdf)



## APPENDIX B-3 MATERIALS DEVELOPED/ PUBLISHED BY NIST

### IMMUNIZATION TEST SUITES – WEB APPLICATION (IMMUNIZATION VALIDATION TOOL)<sup>82</sup>

The NIST immunization test suite is a web-based application that supports end-to-end conformance testing. The test suite is independent—a user can enter it at any time. It provides phase-by-phase testing with multiple levels in each phase. The user can start simple and progress to detailed test cases and data and scenarios.

The test suite includes:

- CDC SOAP envelope and SOAP connectivity based on the CDC WSDL
- Tests against *CDC HL7 Implementation Guide*<sup>83</sup> and *Addendum*.<sup>84</sup>
  - Context-free testing validates message structure and message vocabulary, with support for all eight profiles (VXU (Z22), ACK (Z23), QBP (Z34 and Z44) and RSP (Z31, Z32, Z33, and Z42))
  - Context-based testing validates messages against test cases—ONC 2015 Edition Certification
  - Data quality assurance
- EHR-S and IIS functional requirements—Simulated operational environments provide an interactive round trip using scenarios

#### Publication Information:

- **Date:** March 10, 2018
- **Audience:** IIS managers, IIS vendors, and EHR vendors
- **Page Count:** Various

### IMPLEMENTATION GUIDE AUTHORIZING AND MANAGEMENT TOOL (IGAMT)<sup>85</sup>

Implementation Guide Authoring and Management Tool (IGAMT) is a tool used to create local HL7 v2.x implementation guides that contain one or more conformance profiles. The tool provides capabilities to create both narrative text (akin to a word processing program) and messaging requirements in a structured environment. IGAMT contains a model of all the message events for every version of the HL7 v2 standard. Users begin by selecting the version of the HL7 v2 standard and the message events they want to include and refine (constrain) in their implementation guide.

#### Publication Information:

- **Date:** None stated on website, accessed on March 12, 2018
- **Audience:** IIS managers, IIS vendors, and EHR vendors
- **Page Count:** Various

<sup>82</sup> <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>

<sup>83</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

<sup>84</sup> <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

<sup>85</sup> <https://hl7v2.igamt.nist.gov/igamt/#/home>

IGAMT produces artifacts for:

- Input to validation tools (NIST or others)
- Message generation
- Profile viewing
- Code generation

## NIST HL7 V2 RESOURCE PORTAL<sup>86</sup>

NIST provides a number of tools and utilities in support of the HL7 v2.x messaging standard. Conformance testing tools include web applications and web services for validating HL7 v2.x message instances based on message profiles. The foundation of the toolkit is a set of Java application programming interfaces (APIs) that support testing activities such as automated message generation and message validation. The APIs are organized as a testing framework, which can be used to build tools such as web services and web applications. NIST provides the testing tools via this portal, or the utilities can be incorporated into third-party applications and testing environments.

### Publication Information:

- **Date:** September 6, 2017, Application Version 1.0
- **Audience:** IIS managers, IIS vendors, and EHR vendors
- **Page Count:** Various

Tools relevant to the IIS community include:

- Testing Tools:
  - NIST Immunization Test Suite<sup>87</sup>
- Productivity Tools:
  - Test Case Authoring and Management Tool (TCAMT)<sup>88</sup>
  - Implementation Guide Authoring and Management Tool (IGAMT)<sup>89</sup>
- Testing Artifacts
  - Profiles
  - Profile schemas
  - Value set schemas
- Informational Resources
  - Papers
  - Presentations
- Source Code

<sup>86</sup> <https://hl7v2tools.nist.gov/portal/#/>

<sup>87</sup> <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>

<sup>88</sup> <https://tcamt.nist.gov/tcamt/#/home>

<sup>89</sup> <https://hl7v2.igamt.nist.gov/igamt/#/home>

## APPENDIX B-4 IIS SAMPLE ONBOARDING MATERIALS

The following appendix offers examples of a variety of onboarding resources referenced in this document. Sample resources were solicited from the IIS community at various stages of this project. Some resources are available on the respective jurisdiction's website, but others may require a direct request to the IIS program contact.

### ONBOARDING PLANS

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
Alaska	<a href="mailto:vactrak@alaska.gov">vactrak@alaska.gov</a>	<ul style="list-style-type: none"> <li>VacTrAK Electronic Data Exchange – Interface Project Stages</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_Interface_Project_Stages.pdf">http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_Interface_Project_Stages.pdf</a></li> </ul>
California	Eric Dansby ( <a href="mailto:eric.dansby@cdph.ca.gov">eric.dansby@cdph.ca.gov</a> )	<ul style="list-style-type: none"> <li>CAIR Gateway/CAIR2 – 5 Steps to Data Exchange</li> <li>CAIR Test Plan for HL7 VXU Submission to CAIR2</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://cairweb.org/imp2/">http://cairweb.org/imp2/</a></li> <li><a href="http://cairweb.org/docs/CAIR2_TestPlanv1.3.pdf">http://cairweb.org/docs/CAIR2_TestPlanv1.3.pdf</a></li> </ul>
Colorado	Kim Gulliver ( <a href="mailto:kim.gulliver@state.co.us">kim.gulliver@state.co.us</a> )	<ul style="list-style-type: none"> <li>CIIS Immunization Interface Process</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://drive.google.com/file/d/1FcipT9eahh1ezrWWidrdpEwnwuloerT0/view">https://drive.google.com/file/d/1FcipT9eahh1ezrWWidrdpEwnwuloerT0/view</a></li> </ul>
Kansas	<a href="mailto:KDHE.IMMOnboarding@ks.gov">KDHE.IMMOnboarding@ks.gov</a>	<ul style="list-style-type: none"> <li>KSWebIZ Direct HL7 Interface Onboarding</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.kdheks.gov/immunize/ehr_toolkit/14b_kswebiz_hl7_information_ehr_toolkit.pdf">http://www.kdheks.gov/immunize/ehr_toolkit/14b_kswebiz_hl7_information_ehr_toolkit.pdf</a></li> </ul>
Massachusetts	Tricia Charles ( <a href="mailto:tricia.charles@state.ma.us">tricia.charles@state.ma.us</a> )	<ul style="list-style-type: none"> <li>MIIS Onboarding Process: Electronic Data Exchange</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.contactmiis.info/FileSystem/Draft/MIIS_Onboarding_Document_Final.pdf">https://www.contactmiis.info/FileSystem/Draft/MIIS_Onboarding_Document_Final.pdf</a></li> </ul>
Michigan	Sallie Sims ( <a href="mailto:simss7@michigan.gov">simss7@michigan.gov</a> )	<ul style="list-style-type: none"> <li>MCIR Data Quality Assurance (DQA) Process</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.mcir.org/hl7-landing-page/hl7-3/">https://www.mcir.org/hl7-landing-page/hl7-3/</a></li> </ul>
Minnesota	Angie Felt ( <a href="mailto:angela.felt@state.mn.us">angela.felt@state.mn.us</a> )	<ul style="list-style-type: none"> <li>Process for Working on Data Exchange with MIIC</li> <li>MIIC Immunization Onboarding Process</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/dataprocess.html">http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/dataprocess.html</a></li> <li><a href="http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/onboardproc.pdf">http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/onboardproc.pdf</a></li> </ul>
Nevada	Jane Lammers ( <a href="mailto:jlammers@health.nv.gov">jlammers@health.nv.gov</a> )	<ul style="list-style-type: none"> <li>NV WebIZ HL7 Onboarding Procedure</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://dpbh.nv.gov/Programs/HL7/HL7_-_Home/">http://dpbh.nv.gov/Programs/HL7/HL7_-_Home/</a></li> </ul>
New York City	Jessica Rao ( <a href="mailto:cir_interop@health.nyc.gov">cir_interop@health.nyc.gov</a> )	<ul style="list-style-type: none"> <li>Onboarding Guide</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page">http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page</a></li> </ul>

**ONBOARDING PLANS** *(continued from previous page)*

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
South Carolina		<ul style="list-style-type: none"> <li>HL7 Data Exchange Onboarding Quick Reference Guide</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://apps.dhec.sc.gov/Health/SCIAPPS/content/documents/HL7_On_Boarding_Quick_Reference_Guide.pdf">https://apps.dhec.sc.gov/Health/SCIAPPS/content/documents/HL7_On_Boarding_Quick_Reference_Guide.pdf</a></li> </ul>
Wyoming	John Anderson ( <a href="mailto:john.anderson@wyo.gov">john.anderson@wyo.gov</a> )	<ul style="list-style-type: none"> <li>WylR Interface Project Stages</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://health.wyo.gov/wp-content/uploads/2018/05/WylR-Interoperability-Project-Stages.05.18.pdf">https://health.wyo.gov/wp-content/uploads/2018/05/WylR-Interoperability-Project-Stages.05.18.pdf</a></li> </ul>

**ONBOARDING PLANS (Q/R)**

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
Alaska	<a href="mailto:vactrak@alaska.gov">vactrak@alaska.gov</a>	<ul style="list-style-type: none"> <li>VacTrAK Query Project Stages</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/Query_Project_Stages.pdf">http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/Query_Project_Stages.pdf</a></li> </ul>
Michigan	Sallie Sims ( <a href="mailto:simss7@michigan.gov">simss7@michigan.gov</a> )	<ul style="list-style-type: none"> <li>QBP in MCIR: Query by Parameter Onboarding Process</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.mcir.org/hl7-landing-page/hl7-qbp/">https://www.mcir.org/hl7-landing-page/hl7-qbp/</a></li> </ul>
New York City	Jessica Rao ( <a href="mailto:cir_interop@health.nyc.gov">cir_interop@health.nyc.gov</a> )	<ul style="list-style-type: none"> <li>EHR Vendor Query Interface (QBP) Onboarding Process for HL7 CIR Connections (HL7 version 2.5.1)</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page">http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page</a></li> </ul>
Wyoming	John Anderson ( <a href="mailto:john.anderson@wyo.gov">john.anderson@wyo.gov</a> )	<ul style="list-style-type: none"> <li>QBP Testing and Implementation Guide</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://health.wyo.gov/wp-content/uploads/2017/10/WylR-QBP-Testing-and-Implementation-Guide.pdf">https://health.wyo.gov/wp-content/uploads/2017/10/WylR-QBP-Testing-and-Implementation-Guide.pdf</a></li> </ul>

**DATA EXCHANGE READINESS CHECKLIST**

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
Alaska	<a href="mailto:vactrak@alaska.gov">vactrak@alaska.gov</a>	<ul style="list-style-type: none"> <li>VacTrAK Provider Electronic Data Exchange Readiness Checklist</li> <li>Query Readiness Checklist</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_Provider_Electronic_Data_Exchange_Checklist.pdf">http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_Provider_Electronic_Data_Exchange_Checklist.pdf</a></li> <li><a href="http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/Query_Readiness_Checklist.pdf">http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/Query_Readiness_Checklist.pdf</a></li> </ul>
California	Eric Dansby ( <a href="mailto:eric.dansby@cdph.ca.gov">eric.dansby@cdph.ca.gov</a> )	<ul style="list-style-type: none"> <li>CAIR2 Bi-directional DX Readiness Check List</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://cairweb.org/docs/BiDX%20Readiness%20Checklist.pdf">http://cairweb.org/docs/BiDX%20Readiness%20Checklist.pdf</a></li> </ul>

**DATA EXCHANGE READINESS CHECKLIST** *(continued from previous page)*

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
Connecticut		<ul style="list-style-type: none"> <li>CT DPH Provider Readiness Questionnaire for EHR Reporting</li> </ul>	<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>
Michigan	Sallie Sims ( <a href="mailto:simss7@michigan.gov">simss7@michigan.gov</a> )	<ul style="list-style-type: none"> <li>MCIR Provider Checklist for Achieving Meaningful Use</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.mcir.org/mu/">https://www.mcir.org/mu/</a></li> </ul>
Wyoming	John Anderson ( <a href="mailto:john.anderson@wyo.gov">john.anderson@wyo.gov</a> )	<ul style="list-style-type: none"> <li>WylR Provider Onboarding Readiness Checklist</li> </ul>	<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>

**TEST CASES/SCENARIOS**

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
California	Eric Dansby ( <a href="mailto:eric.dansby@cdph.ca.gov">eric.dansby@cdph.ca.gov</a> )	<ul style="list-style-type: none"> <li>CAIR Test Plan for HL7 VXU Submission to CAIR2</li> <li>CAIR2 Bi-directional Data Exchange (BiDX) Test Plan</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://cairweb.org/docs/CAIR2_TestPlanv1.3.pdf">http://cairweb.org/docs/CAIR2_TestPlanv1.3.pdf</a></li> <li><a href="http://cairweb.org/docs/CAIR2BiDXTestPlan.pdf">http://cairweb.org/docs/CAIR2BiDXTestPlan.pdf</a></li> </ul>
Minnesota	Angie Felt ( <a href="mailto:angela.felt@state.mn.us">angela.felt@state.mn.us</a> )	<ul style="list-style-type: none"> <li>Test Message Preparation and Validation for NIST tooling</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/nist.pdf">http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/nist.pdf</a></li> </ul>
South Carolina		<ul style="list-style-type: none"> <li>SC-DHEC HL7 Test Plan</li> </ul>	<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>
Wisconsin			<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>

**HELPFUL MATERIALS FROM IIS (PRESENTATIONS, FORMS, MISC.)**

JURISDICTION	CONTACT	RESOURCE TITLE/ DESCRIPTION	RESOURCE LINK
Alaska	<a href="mailto:vactrak@alaska.gov">vactrak@alaska.gov</a>	<ul style="list-style-type: none"> <li>VacTrAK Roles and Responsibilities</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_User_Roles_and_Responsibilities.pdf">http://dhss.alaska.gov/dph/Epi/iz/Documents/vactrak/docs/VacTrAK_User_Roles_and_Responsibilities.pdf</a></li> </ul>
Kansas	<a href="mailto:KDHE.IMMOnboarding@ks.gov">KDHE.IMMOnboarding@ks.gov</a>	<ul style="list-style-type: none"> <li>KSWebIZ HL7 Data Quality Requirements</li> </ul>	<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>
Michigan	Sallie Sims ( <a href="mailto:simss7@michigan.gov">simss7@michigan.gov</a> )	<ul style="list-style-type: none"> <li>MCIR HL7 Provider Site Roles and Responsibilities Information Form</li> </ul>	<ul style="list-style-type: none"> <li><a href="https://www.mcir.org/hl7-landing-page/hl7-3/">https://www.mcir.org/hl7-landing-page/hl7-3/</a></li> </ul>
Minnesota	Angie Felt ( <a href="mailto:angela.felt@state.mn.us">angela.felt@state.mn.us</a> )	<ul style="list-style-type: none"> <li>MIIC Data Exchange Worksheet</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/dataexchange.pdf">http://www.health.state.mn.us/divs/idepc/immunize/registry/hp/dataexchange.pdf</a></li> </ul>

**HELPFUL MATERIALS FROM IIS (PRESENTATIONS, FORMS, MISC.)** *(continued from previous page)*

JURISDICTION	CONTACT	RESOURCE TITLE/DESCRIPTION	RESOURCE LINK
New York City	Jessica Rao ( <a href="mailto:cir_interop@health.nyc.gov">cir_interop@health.nyc.gov</a> )	<ul style="list-style-type: none"> <li>Onboarding Kickoff Call Agenda</li> <li>Data Quality Assurance Checklist</li> </ul>	<ul style="list-style-type: none"> <li><a href="http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page">http://www1.nyc.gov/site/doh/providers/reporting-and-services/citywide-immunization-registry-cir.page</a></li> </ul>
North Dakota	Mary Woinarowicz ( <a href="mailto:mary.woinarowicz@nd.gov">mary.woinarowicz@nd.gov</a> )	<ul style="list-style-type: none"> <li>NDIIS Interoperability Initial Onboarding Questionnaire</li> </ul>	<ul style="list-style-type: none"> <li>Contact jurisdiction directly for a copy of this resource.</li> </ul>



# APPENDIX C ONBOARDING REFERENCE LIST

- AIRA.** Data Quality Assurance: Selected Aspects. Modeling of Immunization Registry Operations Workgroup (MIROW). May 2013.  
<http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-selected-aspects/>
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<http://repository.immregistries.org/resource/data-quality-assurance-in-immunization-information-systems-incoming-data-1/>
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[http://repository.immregistries.org/files/resources/58a601d626d7a/aira\\_data\\_validation\\_guide\\_-\\_final\\_new\\_logo.pdf](http://repository.immregistries.org/files/resources/58a601d626d7a/aira_data_validation_guide_-_final_new_logo.pdf)
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[http://repository.immregistries.org/files/resources/5835adc2a034b/aira\\_mirow\\_di-v-edc\\_guide\\_final\\_010417.pdf](http://repository.immregistries.org/files/resources/5835adc2a034b/aira_mirow_di-v-edc_guide_final_010417.pdf)
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<http://repository.immregistries.org/resource/iis-data-quality-practices-to-monitor-and-evaluate-data-at-rest/>
- AIRA.** IIS Data Quality Practices: Monitoring and Evaluating Data Submissions. September 2017.  
[http://repository.immregistries.org/files/resources/59cabe6404421/data\\_quality\\_phase\\_ii.pdf](http://repository.immregistries.org/files/resources/59cabe6404421/data_quality_phase_ii.pdf)
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[http://repository.immregistries.org/files/resources/5a83216a1d369/iis\\_functional\\_guide\\_february\\_2018.pdf](http://repository.immregistries.org/files/resources/5a83216a1d369/iis_functional_guide_february_2018.pdf)
- AIRA.** Transport 101, SOAP 101, SOAP Transition Strategies, NIST Immunization Test Suite Training Videos, Accessed September 23, 2018.  
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<https://www.cdc.gov/vaccines/programs/iis/technical-guidance/soap/downloads/transport-specification.pdf>
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<https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx>
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- NIST.** Immunization Test Suites – Web Application (Immunization Validation Tool).  
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- NIST.** Implementation Guide Authoring and Management Tool (IGAMT),  
<https://hl7v2.igamt.nist.gov/igamt/#/home>
- NIST.** Implementation Testing Support.  
<https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/soapConn>
- NIST.** HL7 V2 Resource Portal.  
<https://hl7v2tools.nist.gov/portal/#/>
- NIST.** Test Case Authoring and Management Tool (TCAMT),  
<https://tcamt.nist.gov/tcamt/#/home>

# APPENDIX D CONSOLIDATED ONBOARDING RECOMMENDATIONS

## PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: REGISTRATION

- Provide a web-based interface to allow providers to complete required IIS enrollment and onboarding/data exchange enrollment forms online. See also [Onboarding tools and attributes](#)
- Store data captured in online forms in a way that is easily accessible, searchable, and sortable by onboarding staff (e.g., database or document repository).
- Utilize registration/enrollment tools to automatically trigger subsequent steps in the onboarding process (e.g., initiation of a welcome email, creation of a new project in an online project tracking tool).
- Maintain a tracking tool or process for documenting the status and progress of each onboarding project. See also [Onboarding tools and attributes](#)

## PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: PREPARATORY

- Develop a written onboarding plan to guide the entire onboarding process.
- Develop onboarding checklists for providers/vendors listing the various thresholds/requirements at each step of the onboarding process.
- Provide access to current versions of all onboarding documentation in a readily accessible area of the IIS website.
- Send a welcome email to new onboarding prospects immediately following registration/enrollment with links to all relevant documentation or as attached documents.
- Require each new onboarding provider/EHR vendor to produce a valid, correctly formatted HL7 v2.5.1 message using an appropriate self-service testing tool prior to engaging IIS onboarding staff. See also [Onboarding tools and attributes](#).
- Host a project kickoff call at the beginning of each new onboarding project to review the onboarding process, expectations, completed forms, and stakeholder roles/responsibilities.

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS:****TEST ENVIRONMENT AND TEST DATA**

- Design the IIS testing platform(s) to mirror all elements of the production environment including version(s), settings, configurations, and authentication/authorization settings.
- Refresh patient and vaccination data in the test environment as often as needed to ensure the data is sufficient to support all of the appropriate validation testing required for approving a new interface.
- Implement appropriate testing tools to facilitate and expedite the various phases of testing. See also [Onboarding tools and attributes](#).
- Leverage production EHR data for testing interfaces or utilize production-quality data if the EHR is still in the process of being implemented.
- Establish a benchmark for two weeks or 10 business days' worth of provider data with no critical errors or failures as the threshold for message validation success.
- Require larger health systems to submit messages from each provider site that will be reporting through the interface.
- Identify opportunities for providers and EHR vendors to conduct preliminary testing and issue resolution independently (e.g., NIST tools, sandbox-style access to test environments).

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS:****ABBREVIATED TESTING PROTOCOLS**

- Leverage abbreviated testing protocols for changes or updates to existing production interfaces to bypass steps in the testing process that have been previously validated.

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: PRODUCTION APPROVAL**

- Host a project closeout call at the end of each onboarding project to review final forms, activities, and timelines; issue production credentials; and confirm expectations for ongoing monitoring and error resolution.
- Use appropriate forms to identify/confirm go-forward points of contact and communicate long-term expectations.
- Confirm that the provider interface is properly transitioned to the production environment as a final step in the onboarding process.

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: INTERFACE MONITORING**

- Closely monitor new interfaces for the first two weeks following the transition to the IIS production environment.
- Confirm that the IIS is receiving data from all sites reporting through a new production interface.
- Transition interfaces to routine monitoring if no issues are detected during the initial two-week monitoring period.
- Implement a tool or process for monitoring production HL7 feeds to identify issues such as increased warnings/failures, deviations in data quality, or changes in volume of submissions. See also [Onboarding tools and attributes](#).

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: QUERY/RESPONSE**

- Host a Q/R project kickoff call to address questions about how queries are triggered, matching algorithms used by the IIS, deduplication in the IIS, reconciliation of selected records in the EHR, etc.
- Perform initial Q/R testing in an IIS test environment using test scenarios prescribed by the IIS program or a set of test patients generated from the EHR.
- Perform secondary Q/R testing in the IIS production environment using production patients from the EHR.
- Engage a physician or other clinical user in production-level Q/R testing to confirm that the query retrieved appropriate matches and that the returned patient/vaccination data is consumed and displayed correctly by the EHR.
- Implement Q/R in conjunction with VXUs whenever possible.

**PROCESS – IMPROVEMENTS AND RECOMMENDATIONS: MATCHING ALGORITHMS**

- Improve community-wide guidance for standardizing and implementing Q/R match strategies.
- Share matching algorithms and review with EHR vendors/providers during project kickoff calls.
- Promote synchronous processes and minimize asynchronous interfaces.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS:****ONBOARDING PARTNERS**

- Clearly document and communicate stakeholder roles and responsibilities at the beginning of every onboarding project.
- Ensure that the designated provider representative is high enough in the organizational structure to make decisions independently and enforce changes to workflows or policies.
- Test and validate every new interface connection even if the EHR vendor, product, and product version have been previously tested and approved.
- Encourage HIE partners to conform to proper security protocols and CDC-endorsed standards for HL7 messaging and transport when interfacing with the IIS.
- Emphasize the importance of end-to-end communication between the IIS and the provider EHR.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS:****IMPORTANCE OF STANDARDS**

- Support and promote the current CDC- and ONC-endorsed standards for HL7 messaging and transport for IIS interfaces.
- Minimize variation across jurisdictions. Strive to align with HL7 implementation guidance and standard code sets except where otherwise required by state law.
- Improve community interpretation of implementation guidance for VFC program requirements, use of OBX segments, implementation of ACK responses, and handling of CVX codes.
- Accept codes and data elements that the IIS will store and ignore any unwanted codes/data elements with an appropriate ACK warning. Do not error the message.
- Consider flexible requirements and testing protocols to accommodate non-traditional provider types that do not operate within the constructs of typical vaccine providers—e.g., pharmacies and influenza-only providers.
- Develop short delta guides for noting where the jurisdiction deviates from the HL7 Implementation Guide. Eliminate the use of full-size custom implementation guides.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS:****MANAGING BACKLOG**

- Maintain a master accounting of all providers that are onboarding or waiting to onboard by using a tracking tool or process. See also [Onboarding tools and attributes](#).
- Focus IIS resources on providers with the most interest and readiness to proceed.
- Conduct periodic check-ins with a provider that is engaged in onboarding to get status updates and maintain project momentum.
- Place a hold on providers that are not able to dedicate appropriate resources to the onboarding process. Resume onboarding when the provider is ready and has available resources.
- Identify opportunities to automate processes and reduce reliance on IIS staff participation and manual processes.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS:****ONBOARDING PREREQUISITES**

- Develop readiness checklists for VXU and Q/R detailing the requisite criteria to proceed with onboarding.
- Consider eliminating waiting periods and proof-of-concept testing.
- Leverage augmented staffing and expedited development cycles associated with new EHR implementations to troubleshoot interfaces and ensure proper workflows and data flows for IIS interfaces.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS: DATA QUALITY**

- Determine the level of data quality testing that is appropriate for the onboarding process by assessing which elements of data quality can be controlled for during onboarding versus what should be controlled for when a new interface is being established.
- Eliminate/minimize manual data quality review activities to the extent possible.
- Establish long-term data monitoring strategies to identify and resolve data quality issues outside of the onboarding process.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS: TRAINING**

- Implement appropriate tools or reports for monitoring interface performance and reviewing/troubleshooting ACK messages. See also [Onboarding tools and attributes](#).
- Communicate expectations for the active monitoring of submissions and resolution of warnings/failures.
- Provide training on reviewing and interpreting ACK messages generated by the IIS.
- Ensure that at least one high-level user from the provider organization has been trained on how to log in and interact with the IIS interface (e.g., basic IIS features, manual patient and vaccination entry, generating relevant reports).

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS: COMMUNICATION**

- Improve onboarding communication strategies through well crafted onboarding documentation and proactive written and verbal communication between stakeholders.
- Informationally include provider representatives in all onboarding project communications but inform them when their input or participation is required.
- Facilitate direct communication between technical or programmatic contacts to quickly troubleshoot and resolve onboarding roadblocks.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS: DOCUMENTATION**

- Review existing onboarding documentation and look for opportunities to update, simplify, or eliminate.
- Reduce or eliminate the use of paper forms and paper processes to the extent possible.
- Improve accessibility to onboarding resources for both internal staff and external partners.

**IMPLEMENTATION – CONSIDERATIONS AND RECOMMENDATIONS:  
ONBOARDING TOOLS**

- Strategically implement tools to better facilitate various elements of the onboarding process.
- Create opportunities for provider/EHR vendors to leverage tools for testing message construct and content independently and reduce the need for IIS staff participation.

## APPENDIX E BARRIERS/CHALLENGES

The following is a list of barriers/challenges encountered by subject matter experts through various onboarding experiences:

- Some HIEs have been resistant to offering SOAP Web Services and/or the CDC WSDL. This has been problematic for both IIS and EHRs. In addition, some HIEs are not following standard security measures, presenting a larger, general concern. HIEs and other hubs need to align with transport and security standards.
- Current CDC WSDL documentation leaves room for a fair amount of subjective interpretation by IIS and EHRs around a number of topics: facility ID and assignment strategy (especially for large health systems), MSH-4, passing of credentials for hub versus individual credentials, etc.
- Some HIEs are not communicating ACKs back to the provider. This has been a major barrier in some jurisdictions. It also prohibits the ability to implement Q/R interfaces.
- There are some elements of the HL7 implementation guidance that seem to be particularly problematic (e.g., MSH-4, RXA-11, PV1, OBX, patient consent, facility hierarchy/relationships, VFC funding source, and eligibility). The primary issue is how certain segments are being handled/interpreted by the various IIS.
- Many IIS are confusing “required” with “nice to have” and are erroring/failing messages that are technically coded to standard.
- There is a general concern about balancing the value of getting an interface established in a timely manner and the implications of introducing poor quality data into the production IIS environment. Data quality is not part of the HL7 standard. IIS are trying to implement community-based best practice guidance that is not backed by HL7 implementation standards. The prevailing challenge is with declining data quality over time after the interfaces goes live.
- Resource challenges: Cost-benefit of implementing new tools or automating existing manual processes. General challenges around inadequate staffing to onboard or even improve the process or onboarding documentation. Staff turnover for all stakeholders is a common problem and slows project momentum.
- Ongoing challenge with how to best communicate updated software releases that may impact existing interfaces—both from the provider side to IIS and the IIS side to EHR via the provider.
- Updated standards releases are not always backward-compatible. Many IIS are trying to maintain support across multiple standards instead of sunseting older standards to focus maintenance and support on current standards.

## APPENDIX F GAPS

The following is a loosely categorized list of the gaps identified during the group discussion where additional standardization, guidance, documentation or tools are needed to better support the onboarding process.

### HL7 Codes and Standards:

- The HL7 Implementation Guide and Addendum should be combined into a single resource.
- The IIS community may need to clarify and better standardize how to handle and communicate known challenges/deficiencies in the HL7 implementation guidance and addendum.
- The IIS community needs to establish a standard for ACK errors and error messaging for use across all IIS.<sup>90</sup>
- Guidance and clarification for OBX types are needed on a variety of elements.
- Programmatic needs around VFC field requirements need to be better defined and incorporated into the standard. The HL7 Implementation Guide needs to provide stronger/clarified guidance on use of OBX, specifically for dose-level eligibility (required) and funding source (optional). The Functional Guide should consider defining requirements around VFC versus non-VFC providers, as well as the handling of children (especially VFC) versus adults.
- Need standard use cases for how to handle patient active/inactive status in HL7 interfaces. Standard guidance should include what to send, how to send it, and when to trigger the update (e.g., demographic-only update).
- Additional discussion/guidance is needed on disease-based CVX codes and whether these are appropriate for collection/storage in an IIS and then update the standard accordingly.
- The IIS community needs to establish a standard protocol for ignoring data that they don't want/need with a warning versus a fatal error.<sup>91</sup>
- The IIS community needs to establish guidance on appropriate timelines and reasonable expectations for cutting over new and existing interfaces whenever new standards are released.
- HL7 Feed Monitoring Tool: need for guidance on a general performance report that could be standardized across all IIS.

<sup>90</sup> ACK messaging guidance is provided in the CDC HL7 Implementation Guide and Addendum, the Guidance for HL7 ACK Messages to Support Interoperability, and the National Set of Error Codes. These documents should be assessed to determine whether current guidance is adequate and/or whether jurisdictions are failing to adopt these recommendations resulting in inconsistent ACK implementation.

<sup>91</sup> The document titled Guidance for HL7 ACK Messages to Support Interoperability may be helpful in guiding these discussions.

**Security and Transport:**

- Issues with the current CDC WSDL documentation need to be addressed and clarified by an appropriate panel of experts composed of both IIS and EHR security/technical experts.
- The IIS community needs to establish security standards around expiration and revocation of certificates and credentials.

**Data Quality:**

- The IIS community needs ongoing discussion to provide additional guidance on the appropriate role/level of data quality (programmable) testing and validation in the onboarding process.
- There is a gap/need for guidance on how to maintain interfaces and data quality after an interface goes live. Additional discussion is needed on how to use the IIS interface, post onboarding, to monitor and identify data quality issues and what the triggers are for requiring additional provider training.

**Query/Response:**

- The IIS community needs a standardized matching algorithm and match selection protocol for Q/R.
- IIS programs could benefit from a script to guide kickoff calls for Q/R and document responses to critical questions.
- The role of IIS ID in Q/R needs to be better defined.

**Miscellaneous:**

- IIS should develop protocols to identify when a corrected message has been resubmitted by the provider.
- Need to investigate a proper tool/platform for notifying IIS and EHRs when the other partner has upcoming changes that may impact new or existing interfaces and what those changes will be.
- May need to develop a standardized template for a “Provider Site Mapping” form as a general community resource.
- Automation of the registration process and how this data can be used to support other elements of the onboarding process needs to be further assessed from a cost-benefit standpoint.
- May be a need for further discussion to specify use cases for when asynchronous is appropriate.
- The role of EHRs in pandemic preparedness planning requires further discussion.

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