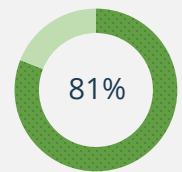
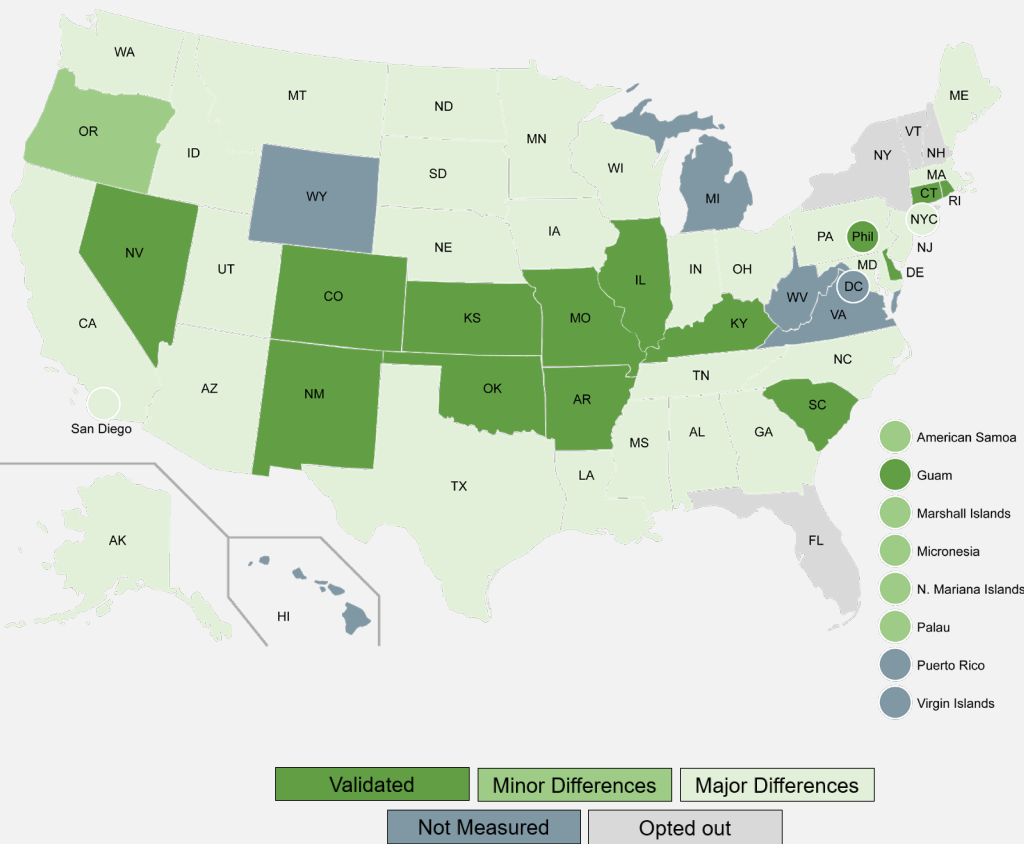
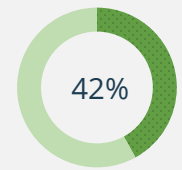


SUBMISSION/ ACKNOWLEDGMENT VALIDATION Complete Level

2021



50 of 62 (81%) IIS were connected with the testing process and measured.



21 of 50 (42%) connected IIS were Validated or Validated with Minor Differences at the complete level for Submission/Acknowledgment (passed all 16 measures).

The American Immunization Registry Association (AIRA) launched its community-driven immunization information system (IIS) Measurement and Improvement Initiative in mid-2015, with the dual goals of providing IIS with information to more fully align with IIS Functional Standards, while also developing a summary of where IIS are as an overall network in meeting standards and best practices. This report shares the results of IIS that have been measured in Validation as the third stage of the voluntary, phased Measurement and Improvement Process.

Introduction

Measurement and Improvement

The American Immunization Registry Association (AIRA) launched its community-driven immunization information system (IIS) Measurement and Improvement Initiative in mid-2015, with the dual goals of providing IIS with information to more fully align with IIS Functional Standards, while also developing a summary of where IIS are as an overall network in meeting standards and best practices. The initiative connects AIRA testing processes with IIS pre-production (or test) systems and shares actionable results with IIS. AIRA is continuing to connect and test with a growing number of IIS interfaces, with more than 3 quarters of the IIS community's pre-production systems currently connected. The data available are helping to guide individual IIS enhancements to align with standards, and the AIRA Measurement for Assessment and Certification Advisory Workgroup (MACAW) is seeing significant improvements in interoperability between IIS and electronic health record (EHR) systems across the community.

The first 2 stages of Testing and Discovery and IIS Assessment are well under way. This report shares the results of IIS that have been measured in Validation as the third stage of the voluntary, phased Measurement and Improvement process for IIS measurement. This stage recognizes those IIS aligning with standards while also acknowledging IIS progressing toward meeting standards. Submission/Acknowledgment is the second content area to move into Validation.

The following table presents the phased schedule for Measurement and Improvement, with emphasis on this current report on Submission/Acknowledgment Validation.

		Stages		
		Testing and Discovery Stage	Assessment Stage	Validation Stage
Content Area	Transport	→		
	Submission/ACK	→		
	Query/Response	→		
	CDS	→		
	Data Quality (6)	→		
	Functions			
	Policy			
	Security			

Submission/Acknowledgment

The IIS Assessment process utilizes the National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool.¹ This tool provides consistent conformance-

¹ <https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home>

based results for all measured IIS. In addition, the technical requirements for data Submission and Acknowledgment are documented in the *HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5*² and addendum.³ This is referred to as the “National IG” in the remainder of this document.

This report provides results for the **complete** level of Submission/Acknowledgment Validation; results for the **basic** level can be found [here](#).

Summary information is presented for all measured IIS; individual results are available to authorized users in the [Aggregate Analysis Reporting Tool \(AART\)](#). An [overview document](#) is available that details the entire Measurement and Improvement Initiative.

Methods

AIRA technical staff are responsible for implementing and conducting all testing efforts within the Measurement and Improvement Initiative. Current test methodology involves connecting with IIS pre-production systems through a web services interface, submitting test messages, and receiving back and analyzing test results.

All measures and tests are developed by [MACAW](#) and approved by the AIRA board of directors. Submission/Acknowledgment measures were approved by the AIRA board in December 2016 for Assessment and in March 2018 for Validation. Measures and tests are based on the CDC’s [IIS Functional Standards](#). For Submission/Acknowledgment, the Functional Standards and Operational Guidance Statements referenced include:

FS 1.0: The IIS contains complete and timely demographic and immunization data for children, adolescents and adults residing or immunized within its jurisdiction.

OGS 1.5: The IIS ensures that submitted vaccination and demographic data are processed and viewable in a timely manner.

OGS 1.6: The IIS assures the receipt, processing and storage of demographic and vaccination data elements as endorsed by the CDC.

FS 8.0: The IIS exchanges data with health information systems in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.

OGS 8.2: The IIS receives submissions and returns acknowledgments consistent with the current CDC endorsed HL7 Implementation Guide.

The Validation stage uses the same (or a subset of) measures and tests that have been developed, vetted, and approved by the IIS community and AIRA board for IIS Assessment. Measures for each content area of Validation will be drawn from published IIS Assessment measures and tests. No new measures or tests will be introduced in the Validation stage that are not already measured and visible in the Assessment stage.

² <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf>

³ <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf>

Validation reports are run quarterly, and an IIS can achieve Validation status during any quarter of the year. Once achieved, Validation is considered “active” for the calendar year. Validation will be retested and renewed in the first quarter of each subsequent calendar year.

Measures

Validation is measured at 2 levels: basic and complete. The **complete** level of Submission/Acknowledgment Validation contains 16 measures⁴:

1. The IIS processes an administered vaccine for a patient.
2. The IIS processes a historical vaccine for a patient.
3. The IIS processes the submission of a full immunization record for a patient.
4. The IIS processes an update to a previously submitted vaccination event.
5. The IIS processes a delete to a previously submitted vaccination event.
6. The IIS processes a submission where the patient does not give consent (i.e., patient data is protected) to share data.
7. The IIS processes a refusal of a vaccination.
8. The IIS processes an adverse event.
9. The IIS processes an observation about a patient that specifies a contraindication or immunity to a vaccine-preventable disease.
10. The IIS processes messages in accordance with the National IG.
11. The IIS processes both complete and incomplete/partially administered doses.
12. The IIS responds to a correctly formatted message with no errors.
13. The IIS responds to a submission that has an error.
14. The IIS responds to a submission with an ACK within 5 seconds or less for 95% of the records submitted.
15. The IIS processes an administered vaccine using the preferred NDC format.
16. The IIS processes an administered vaccine using alternative NDC formats.

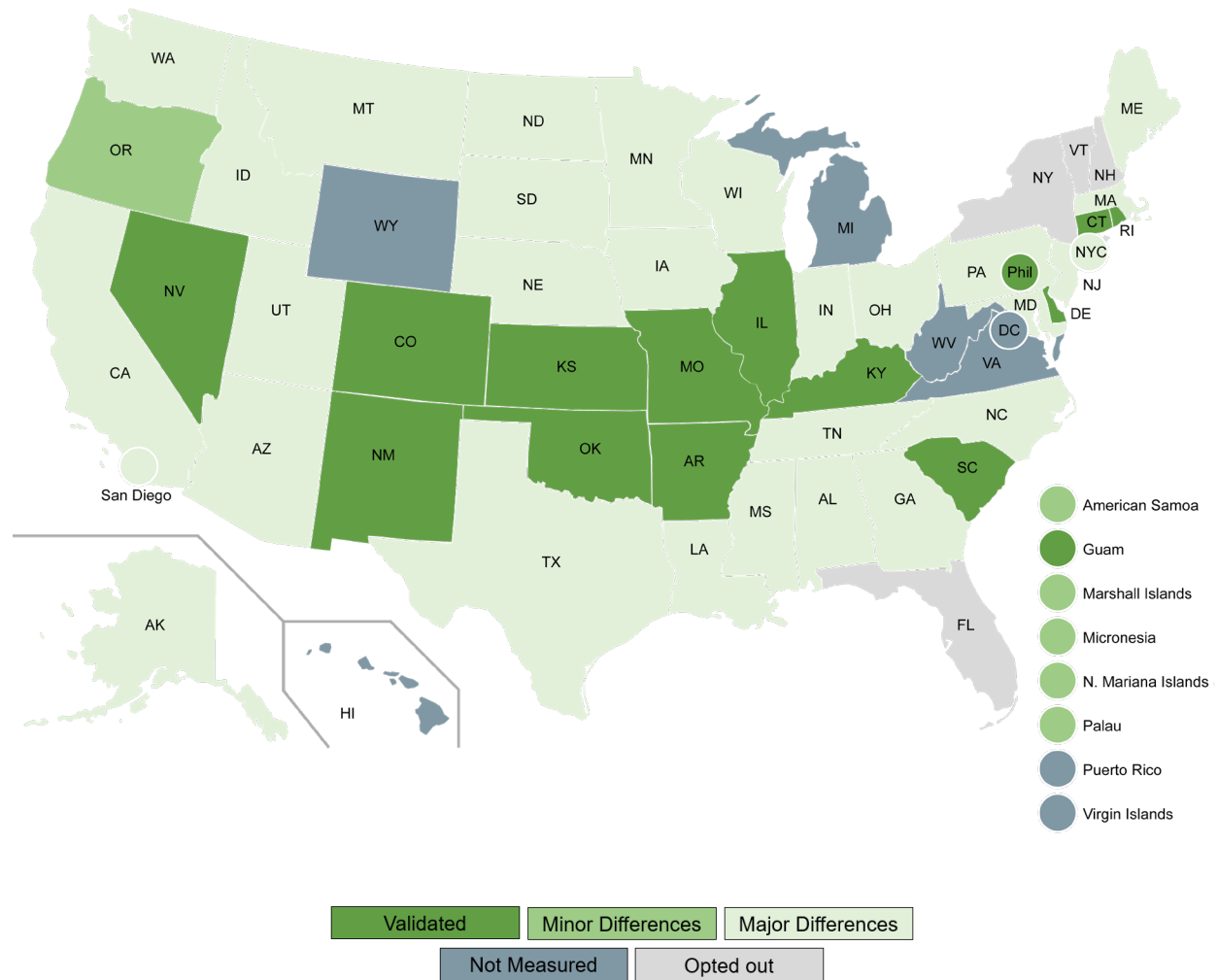
The **basic** level report is also available by request. Visit the [AIRA repository](#) for more detailed information about Submission/Acknowledgment measures and tests.

Results

Below are results for Submission/Acknowledgment Validation for 2021. Unless an IIS declares otherwise, the functionality tested in pre-production is presumed to be available to end users in production.

⁴ Measure 15 and 16 moved into Complete Validation in Q1 2021.

Map: Submission/Acknowledgment Validation, Complete Level 2021



Sixty-two IIS (comprising all 50 states, plus American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, the Federated States of Micronesia, Guam, New York City, Philadelphia, Puerto Rico, the Republic of the Marshall Islands, the Republic of Palau, San Diego, and the Virgin Islands⁵) were encouraged to voluntarily be measured for Submission/Acknowledgment Validation. Of the 62⁶ IIS, 50 were connected with the testing process and measured. Of those measured, only 21 (42%) were Validated or Validated with Minor Differences at the complete level for Submission/Acknowledgment,

⁵ Note that four of the Pacific Islands were not initially targeted for measurement due to limited transport technology. As capabilities and ability to be measured expand, additional Pacific Islands are being included in this report.

⁶ Note that the denominator for M&I participation increased from 58 to 62 in Q1 2021.

meaning they met all 16 measures. Another 29 IIS were measured but displayed Major Differences with the standard.

Eight additional IIS were not able to be measured at this time, while 4 opted not to be measured in Submission/Acknowledgment Validation. Validation reports are run quarterly, and an IIS can achieve Validation status during any quarter of the year. Once achieved, Validation is considered “active” for the calendar year. Validation will be retested and renewed in the first quarter of each subsequent calendar year.

Below are results for Submission/Acknowledgment Validation for 2021 in tabular form.

Table: Submission/Acknowledgment Validation, Complete Level 2021

Validation Status and Definition	IIS
Validated: The IIS must meet Measures 1-16.	Arkansas, Colorado, Connecticut, Delaware, Guam, Illinois, Kansas, Kentucky, Missouri, Nevada, New Mexico, Oklahoma, Philadelphia, Rhode Island, South Carolina
Validated with Minor Differences: The IIS deviates in 1 or more measures.	American Samoa, Marshall Islands, Micronesia, N. Mariana Islands (CNMI), Oregon, Palau
Major Differences: The IIS does not meet 1 or more measures.	Alabama, Alaska, Arizona, California, Georgia, Idaho, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Montana, Nebraska, New Jersey, New York City, North Carolina, North Dakota, Ohio, Pennsylvania, San Diego, South Dakota, Tennessee, Texas, Utah, Washington, Wisconsin
Not Measured: The IIS is not able to be tested at this time.	District of Columbia, Hawaii, Michigan, Puerto Rico, Virginia, Virgin Islands, West Virginia, Wyoming
Opted Out: The IIS has chosen not to be measured.	Florida, New Hampshire, New York State, Vermont

Conclusion

Many IIS are continuing to implement functionality to fully conform with the IIS Functional Standards, particularly as it relates to full implementation of HL7 2.5.1, release 1.5. For the complete level of Validation for Submission/Acknowledgment, the bar is set high, with IIS needing to meet all 16 measures to be Validated. We look forward to seeing continued progress in this area of testing for Submission/Acknowledgment. Published Validation reports offer transparency into the progress IIS are making to come into full alignment with

our community-driven standards. AIRA staff are also available to provide technical assistance to IIS programs and vendors as requested.

For more background or information on the Measurement and Improvement Initiative, please visit [AIRA's web page](#). Contact Kristi Siahaya with questions at ksiahaya@immregistries.org.

Appendix A: Glossary of Terms and Acronyms

AART: The Aggregate Analysis Reporting Tool, an application used to display and share results from the Measurement and Improvement process.

Assessment Stage: A more formal testing step to measure IIS systems using IIS community-selected measures and tests, to share those results for quality improvement, and to provide technical assistance to accelerate improvement. This is the second of 3 stages.

Basic Level: A level of Validation measurement that includes only essential measures to functionally meet this content area.

Complete Level: A level of Validation measurement that includes conformance to all measures approved for Validation.

Content Area: A category for measuring IIS functionality and capability within a specific functional area, made up of distinct measures and tests. Measures and tests will become more formalized as they progress into different stages.

MACAW: Measurement for Assessment and Certification Advisory Workgroup.

Major Differences Status: The IIS cannot support the measures because of additional requirements that conflict with the national standard; the IIS must make significant changes in 1 or more measures to align with standards.

Measure: A metric developed to measure how well an IIS aligns with IIS Functional Standards/Operational Guidance Statements or other recognized standard.

Stage: A distinct period of testing in the Measurement and Improvement process.

Testing and Discovery Stage: A step in testing IIS systems to gather preliminary and general information on community alignment with standards. Testing and Discovery precedes all stages.

Validated Status: The IIS has achieved full alignment with community-selected measures.

Validated with Minor Differences Status: The IIS has achieved full alignment with community-selected measures except for differences that (1) are allowed by the standard (e.g., constraints) or (2) are meeting requirements of local policy/law that do not conflict with standard requirements.

Validation Stage: A summary step to acknowledge IIS that are progressing toward or achieving alignment with community-selected measures and tests. A Validation designation is automatically achieved when an IIS meets the designated measures and tests in a specific content area (e.g., Transport, Submission/Acknowledgment, Query/Response, etc.).

Appendix B: Planned Stages and Content Areas of Measurement

The stages and content areas of measurement were developed by MACAW. A stage is defined as a distinct level of testing in the Measurement and Improvement process. The stages of measurement are defined as follows:

Stage	Definition
Testing and Discovery Stage	An initial step in testing IIS systems to gather preliminary and general information on community alignment with standards. Testing and Discovery precedes all stages.
Assessment Stage	A more formal testing step to measure IIS systems using IIS community-selected measures and tests, to share those results for quality improvement, and to provide technical assistance to accelerate improvement. This is the second of 3 stages.
Validation Stage	A summary testing step to acknowledge IIS that are progressing toward or achieving alignment with community-selected measures and tests. A Validation designation is automatically achieved when an IIS meets the designated measures and tests in a specific content area (e.g., Transport, Submission/Acknowledgment, Query/Response, etc.), but interim steps toward Validation are also recognized. Validation statuses include Validated, Validated with Minor Differences, Major Differences, Not Measured, and Opted Out. This is the third and final stage of measurement for each content area at this time.

Content areas for measuring IIS functionality and capability within a specific functional area are made up of distinct measures and tests. Measures and tests will become more formalized as they progress into different stages. The table below includes planned content areas for Assessment. The order may be subject to change.

Planned Content Area	Definition
Transport Messaging	Assessing alignment with standard protocols of SOAP/Web Services and specifications for the CDC WSDL for communications over a computer network.

Planned Content Area	Definition
Submission/ Acknowledgment Messaging	Assessing alignment with the Health Level Seven (HL7) 2.5.1 release 1.5 Implementation Guide and addendum for Immunization Messaging for Submission and Acknowledgment.
Query/ Response Messaging	Assessing alignment with the HL7 2.5.1 release 1.5 Implementation Guide and addendum for Immunization Messaging for Query and Response.
Clinical Decision Support	Assessing alignment with specifications for Clinical Decision Support for Immunizations, based on the Advisory Committee for Immunization Practices.
Data Quality – tentatively planned to include 6 topic areas	Assessing alignment with guidance and best practices from MIROW (Modeling of Immunization Registry Operations Workgroup) and AIRA Data Validation guides for testing new incoming ongoing data, and existing (data at rest) patient and immunization data via HL7 and User Interface entry for completeness, accuracy, and timeliness. Assessing completeness for enrollment and submission of provider organizations within a jurisdiction. Assessing completeness for demographic records for a patient population within a jurisdiction. Assessing the ability to detect unique and redundant patient and vaccination records and resolve appropriately in accordance with standards and best practices.
Functions	Assessing the availability of specific functionality or capacity within the program or the system, and its adherence to published standards or guidance (e.g., quality improvement initiatives).
Policy	Assessing the existence of policies and procedures that the program, or an individual in the program, is responsible for (e.g., a written disaster recovery plan).
Security	Assessing the existence of business rules or automated procedures that have been implemented to maintain the security of the system (e.g., ensuring data is backed up on a periodic basis).