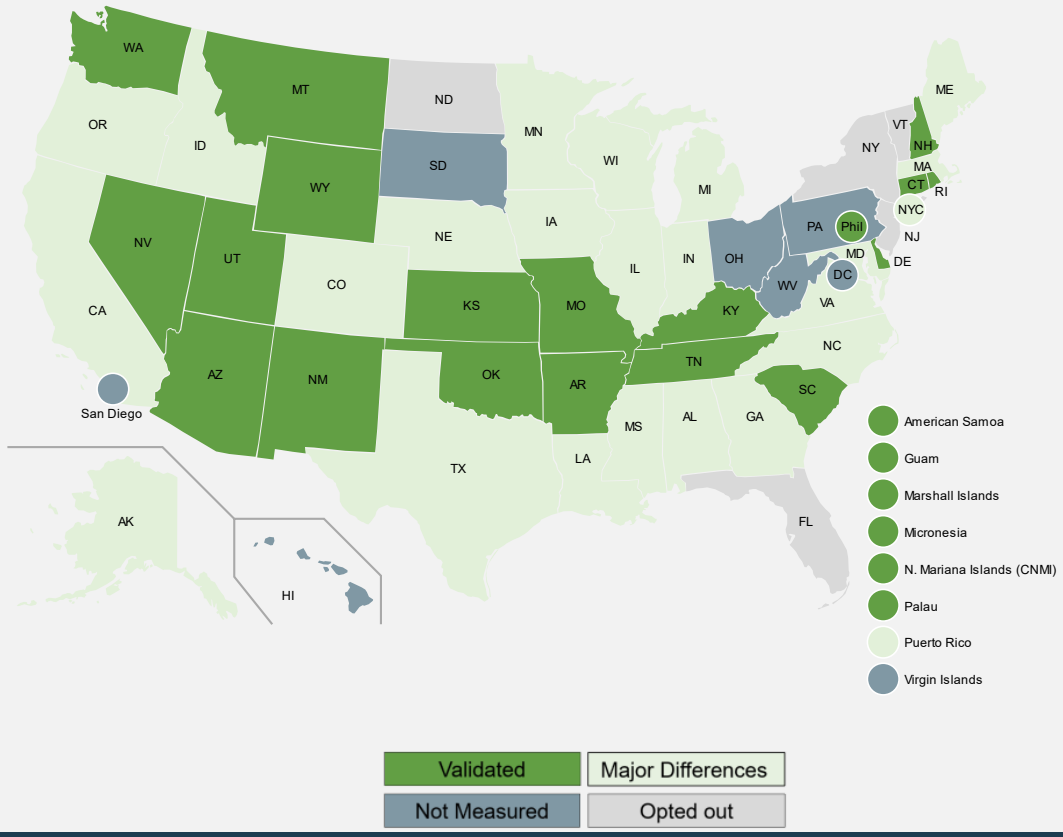
CLINICAL DECISION SUPPORT VALIDATION

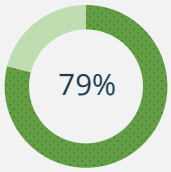
Basic Level

2021

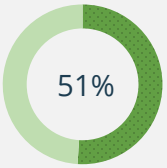
AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

M&I
MEASUREMENT & IMPROVEMENT





49 of 62 (79%) IIS were connected with the testing process and measured.



25 of 49 (51%) connected IIS were Validated or Validated with Minor Differences at the basic level for Clinical Decision Support.

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.

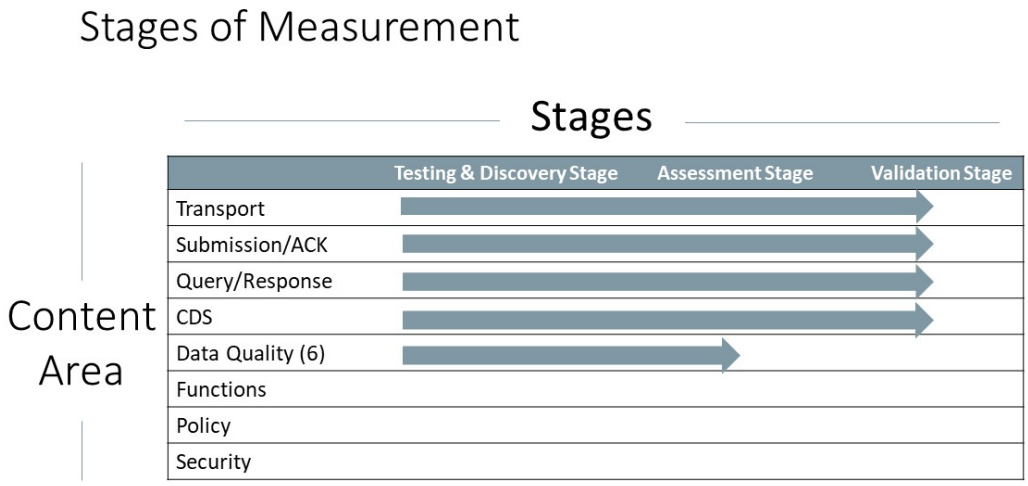
Introduction

Measurement and Improvement

The American Immunization Registry Association (AIRA) launched its community-driven immunization information system (IIS) Measurement and Improvement (M&I) 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 & 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. This stage recognizes those IIS aligning with standards while also acknowledging IIS progressing toward meeting standards. Clinical Decision Support (CDS) is the fourth content area to move into Validation.

The following table presents the phased schedule for Measurement and Improvement, with emphasis on this current report on Clinical Decision Support Validation.



Clinical Decision Support

The CDS Assessment process utilizes the National Institute of Standards and Technology (NIST) Forecasting for Immunization Test Suite (FITS).[1] This tool provides consistent results for all measured IIS. In addition, the requirements for accurate immunization based CDS are documented as part of the Centers for Disease Control and Prevention (CDC) Clinical Decision Support for Immunization (CDSi) project[2].

It is important to keep in mind that immunization recommendations are updated and changed regularly throughout the year by the Advisory Committee for Immunization Practices (ACIP)[3]. This report not only constitutes an early initial baseline but also, in conjunction with each jurisdiction's individual report, can provide valuable information to guide ongoing and upcoming enhancements.

This report provides results for the **basic** level of Clinical Decision Support Validation; results for the **complete** 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 informed by the IIS community and AIRA board of directors. Measures and tests are based on the CDC's IIS Functional Standards. For Clinical Decision Support, the Functional Standards and Operational Guidance Statements referenced include:

Functional Standard 10.0: The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with the Advisory Committee on Immunization Practices (ACIP) recommendations.

> **10.1:** The IIS uses Clinical Decision Support (CDS) functionality that can be updated to reflect new or revised ACIP recommendations.
>
> **10.2:** The IIS displays and sends an evaluated immunization history that adheres to ACIP recommendations for each vaccination event.
>
> **10.3:** The IIS displays and sends a forecast that adheres to ACIP recommendations, with status indicators for each vaccine and vaccine family.

[1] https://fits.nist.gov/fits/#/home
[2] https://www.cdc.gov/vaccines/programs/iis/cdsi.html
[3] https://www.cdc.gov/vaccines/acip/index.html

10.4: The IIS CDS functionality is updated for the IIS in a timely fashion after new ACIP recommendations are incorporated into the CDC Clinical Decision Support for immunization (CDSi) resources published on the CDC website.

The Validation stage uses the same (or a subset of) measures and tests that have been developed, vetted, and informed 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.

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 measures focus on three CDS concepts that can be returned in a Health Level 7 (HL7) message as defined in the CDSi resources and the Functional Guide Volume on Query and Response. The concepts—defined below—are the Evaluation Status, Earliest Date, and Recommended Date. Each IIS is assessed on capability to return a concept and on accuracy if the concept is returned. This results in a total of four measures for each CDS concept:

- One capability measure to measure if the concept is returned
- Three accuracy measures to measure the content returned, one each for pediatric, adolescent, and adult

The **basic** level of Clinical Decision Support Validation contains 8 measures (measures 5-12 Assessment measures).

Earliest Date

Definition: The date at which point the patient could receive the next dose if the patient was likely not to return or has other reasons to accelerate the schedule more quickly than the recommended date.

5. The IIS HL7 interface returns an Earliest Date for each forecasted dose.
6. The Earliest Date returned by the IIS matches the CDC CDSi expected value for routine age-based pediatric recommendations.
7. The Earliest Date returned by the IIS matches the CDC CDSi expected value for routine age-based adolescent recommendations.
8. The Earliest Date returned by the IIS matches the CDC CDSi expected value for routine age-based adult recommendations.

Recommended Date

Definition: The date at which point the patient should receive the next dose.

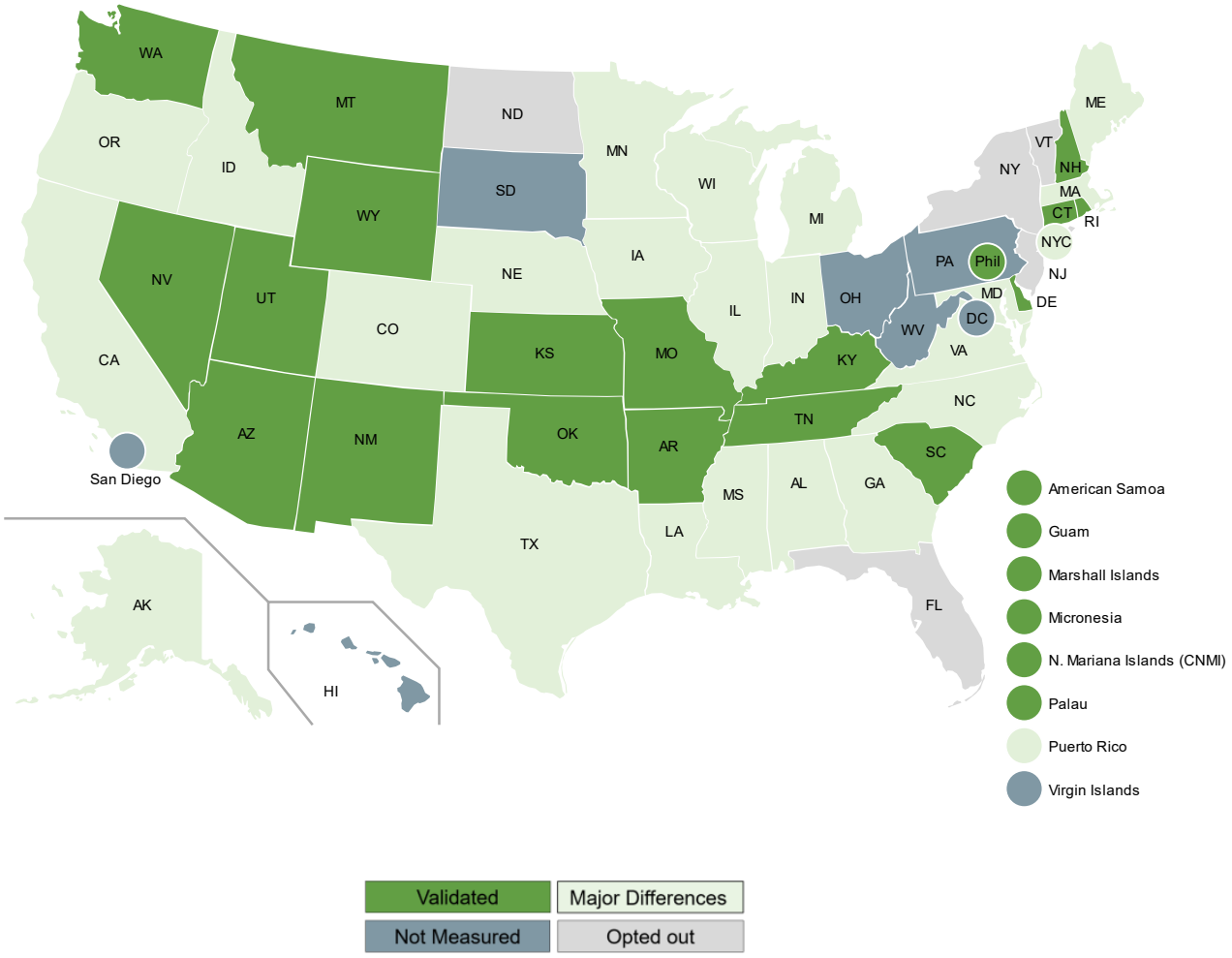
9. The IIS HL7 interface returns a Recommended Date for each forecasted dose.
10. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based pediatric recommendations.
11. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based adolescent recommendations.
12. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based adult recommendations.

Visit the AIRA repository for more detailed information about Clinical Decision Support measures and tests.

Results

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

Map: Clinical Decision Support Validation, Basic 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 Islands[4]) were encouraged to voluntarily be measured in Clinical Decision Support Validation. Of the 62[5] IIS, 49 were connected with the testing process and measured. Of those measured, 25 (51%) were Validated at the basic level for Clinical Decision Support. Another 24 IIS were measured but displayed Major Differences.

Eight additional IIS were not able to be measured at this time, while 5 opted not to be measured in Clinical Decision Support 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 Clinical Decision Support Validation for 2021 in tabular form.

Table: Clinical Decision Support Validation, Basic Level 2021

Validation Status and Definition	IIS
Validated: The IIS must meet Measures 5-12.	American Samoa, Arkansas, Arizona, Connecticut, Delaware, Guam, Kansas, Kentucky, Marshall Islands, Micronesia, Missouri, Montana, Nevada, New Hampshire, New Mexico, N. Mariana Islands (CNMI), Oklahoma, Palau, Philadelphia, Rhode Island, South Carolina, Tennessee, Utah, Washington, Wyoming
Major Differences: The IIS does not meet 1 or more measures specified above.	Alabama, Alaska, California, Colorado, Georgia, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, North Carolina, New York City, Oregon, Puerto Rico, Texas, Virginia, Wisconsin

[4] 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.

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

Not Measured: The IIS is not able to be tested at this time.	District of Columbia, Hawaii, Ohio, Pennsylvania, San Diego, South Dakota, Virgin Islands, West Virginia
Opted Out: The IIS has chosen not to be measured.	Florida, New Jersey, New York State, North Dakota, Vermont

Conclusion

Many IIS are continuing to implement functionality to fully conform with the IIS Functional Standards, particularly as it relates to aligning with ACIP recommendations. These results suggest that IIS have improvements to make, particularly around full conformance with CDSi test cases. There are likely to be dips in testing results due to the nature of continually new ACIP recommendations as well as increased IIS being measured. However, long term we expect to see increases in IIS meeting all CDS measures, indicating positive progress across the community.

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, Clinical Decision Support, 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, Clinical Decision Support, 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).