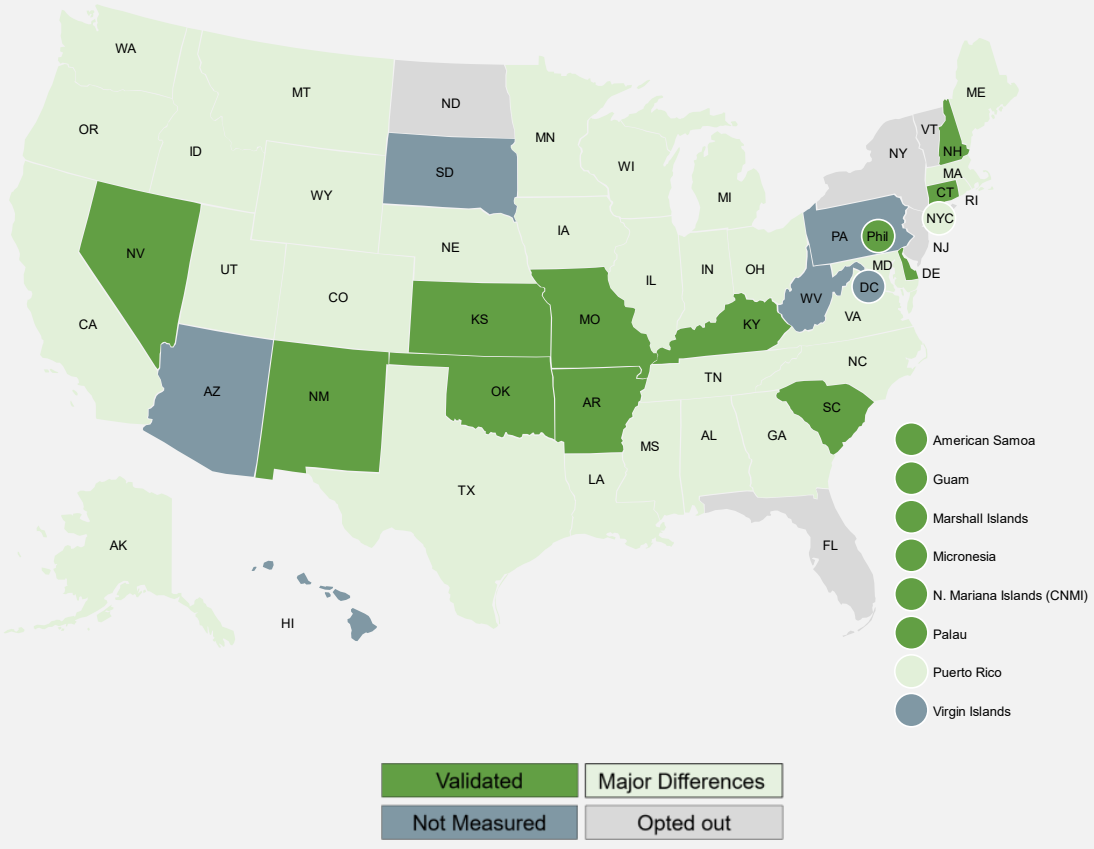
CLINICAL DECISION SUPPORT VALIDATION

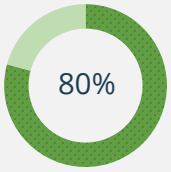
Complete Level

2022

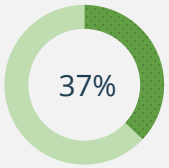
AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

M&I
MEASUREMENT & IMPROVEMENT





49 of 61 (80%) IIS were connected to the testing process and measured.



18 of 49 (37%) connected IIS were Validated at the complete level for Clinical Decision Support.

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 align with IIS Functional Standards while also developing a summary of IIS community alignment progress with best practices and standards. This report contains the results of IIS that have been measured within Validation, the final stage of the M&I process.

Introduction

The American Immunization Registry Association (AIRA) launched its community-driven immunization information system (IIS) Measurement and Improvement (M&I) Initiative in mid-2015, The M&I Initiative provides IIS with information and guidance to align with the IIS Functional Standards. These standards are a set of specifications that describe the operations, data quality, and technology needed by IIS to support immunization programs, vaccination providers, and other immunization stakeholders.

M&I connects AIRA testing processes with IIS pre-production (or test) systems, and/or analyzes deidentified data, and shares results through the Aggregate Analysis Reporting Tool (AART). AIRA continues to test with a growing number of IIS interfaces, with over 90% of IIS programs currently participating. The initiative is demonstrating significant improvements in interoperability between IIS and electronic health record (EHR) systems across the community, as well as improvements in standards-based functionality.

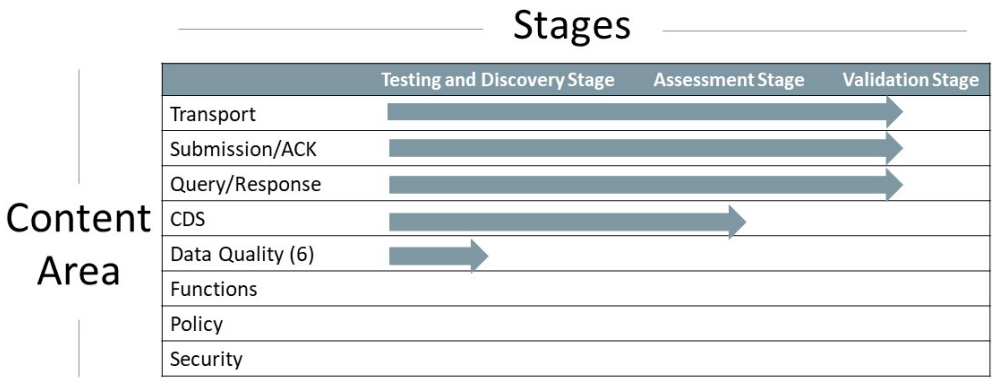
M&I is a three-stage process for IIS to measure their alignment with current standards:

- Testing & Discovery gathers preliminary information on community alignment with standards.
- IIS Assessment involves more formal testing to measure individual IIS systems using IIS community-selected measures and tests.
- Validation is a summary stage to acknowledge and share results for IIS that are progressing toward or achieving alignment with community-selected measures and tests.

Each content area for measuring IIS functionality and capability progresses through each stage. M&I stages and content areas are developed by the Measurement for Assessment and Certification Advisory Workgroup (MACAW), a panel of IIS subject matter experts.

M&I's third and final stage, Validation, uses the same, or a subset of, the measures and tests that have been developed, vetted, and approved by the IIS community for IIS Assessment, the second stage of M&I. Validation is measured at two levels: basic and complete. No new measures or tests are introduced in the Validation stage that are not already measured and visible in the Assessment stage. An overview is available that details the M&I Initiative, its content areas, and associated stages of measurement.

The following table presents an overview of M&I content areas and their respective progress across M&I stages.



Clinical Decision Support

Immunization information systems (IIS) supply health care providers with immunization clinical decision support (CDS) tools designed to automatically determine the recommended immunizations needed when a patient presents for vaccination. These recommendations are developed by the Advisory Committee on Immunization Practices (ACIP). [1] It is important to note that ACIP reviews and updates or issues new vaccine recommendations and immunization schedules throughout the calendar year. In an effort to harmonize the outcomes of existing CDS tools, the Immunization Information Systems Support Branch (IISSB) at the CDC funded the Clinical Decision Support for Immunization (CDSi) Project to develop new CDS resources for each vaccine-preventable disease in accordance with ACIP recommendations.

Methods

All measures and tests are developed by MACAW and informed by the IIS community. Measures and tests are based on the CDC's IIS Functional Standards. Visit the AIRA repository for more detailed information about CDS measures and tests.

For CDS, 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 ACIP recommendations.

[1] https://www.cdc.gov/vaccines/acip/index.html

10.1: The IIS uses 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.

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

AIRA technical staff are responsible for implementing and conducting all M&I testing efforts. The CDS Assessment and Validation process utilizes the National Institute of Standards and Technology (NIST) Forecasting for Immunization Test Suite (FITS).[2] This tool provides consistent results for all measured IIS. 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.

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.

This report provides results for the **complete** level of CDS 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).

Measures

CDS measures focus on three 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

[2] https://fits.nist.gov/fits/#/home

The **complete** level of Clinical Decision Support Validation contains all 12 measures (measures 1-12 Assessment measures):

Evaluation Status

Definition: The determination if the vaccine event "counted" (e.g., valid, not valid).

1. The IIS HL7 interface returns an Evaluation Status (e.g., dose validity) for each vaccination event.
2. The Evaluation Status returned by the IIS matches the CDC CDSi expected value for routine age-based pediatric recommendations.
3. The Evaluation Status returned by the IIS matches the CDC CDSi expected value for routine age-based adolescent recommendations.
4. The Evaluation Status returned by the IIS matches the CDC CDSi expected value for routine age-based adult recommendations.

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

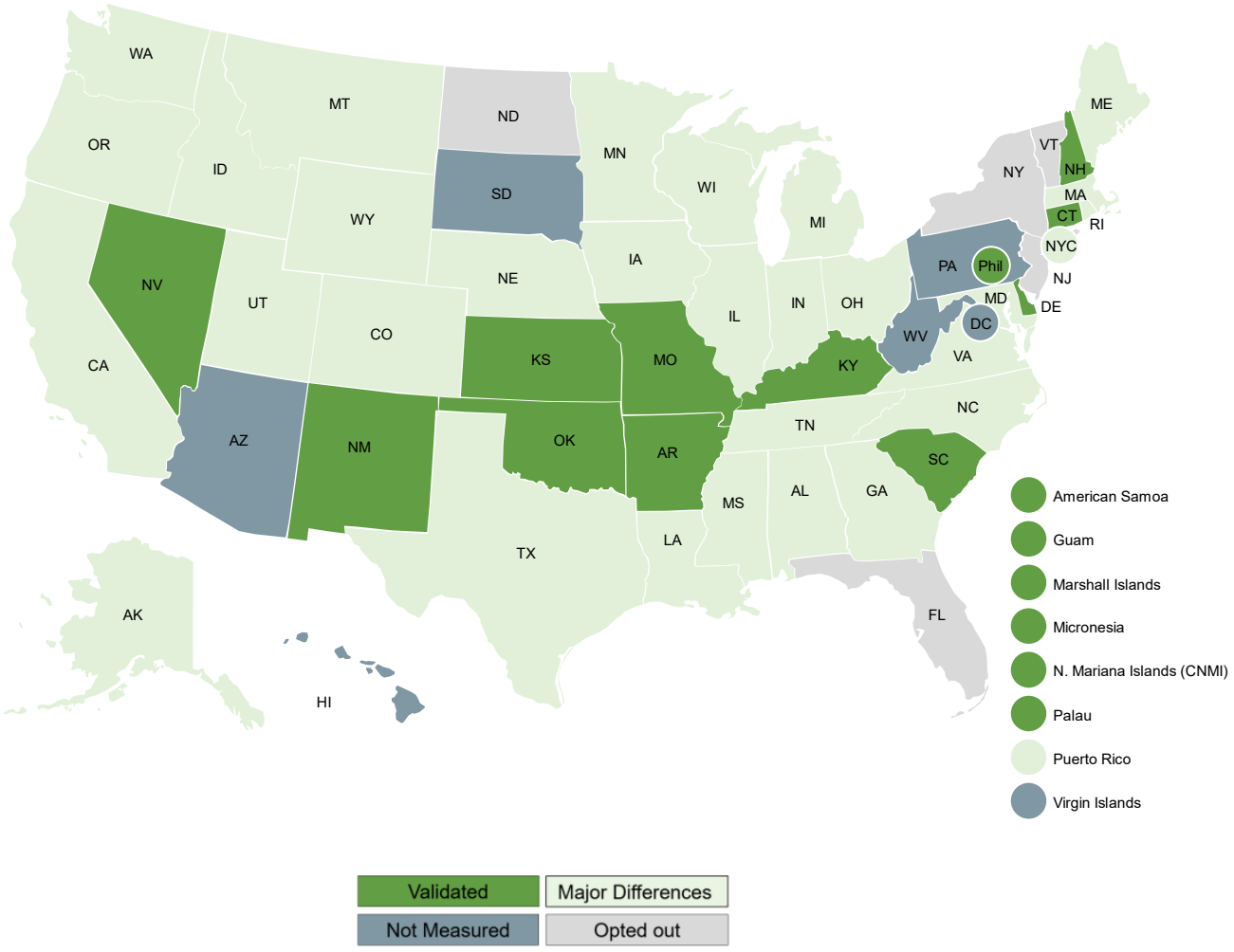
Definition: The date at which point the patient should receive the next dose.

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.

Results

Below are results for Clinical Decision Support Validation for 2022. 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, Complete Level 2022



The 61[3] IIS participating[4] in AIRA's M&I Initiative were encouraged to be formally measured in CDS Validation. Of the 61 IIS, **49 (80%) were connected** to the testing process and

[3] Note that the denominator for M&I participation decreased from 62 to 61 in Q2 2022, due to San Diego IIS merge with CA's state IIS.

[4] Includes all 50 states, American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, the Federated States of Micronesia, Guam, New York City, Philadelphia, Puerto Rico, the Republic of the Marshall Islands, the Republic of Palau, and the Virgin Islands.

measured. Of those measured, **18 (37%)** were **Validated** at the complete level for CDS. Another 31 IIS were measured but displayed Major Differences. Seven IIS were not able to be measured at this time, while five opted not to be measured in CDS Validation.

Below are results for CDS Validation for 2022 in tabular form.

Table: Clinical Decision Support Validation, Complete Level 2022

Validation Status and Definition	IIS
Validated: The IIS meets Measures 1-12.	American Samoa, Arkansas, Connecticut, Delaware, Guam, Kansas, Kentucky, Marshall Islands, Micronesia, Missouri, Nevada, New Hampshire, New Mexico, N. Mariana Islands (CNMI), Oklahoma, Palau, Philadelphia, South Carolina
Major Differences: The IIS does not meet one or more measures specified above.	Alabama, Alaska, California, Colorado, Georgia, Idaho, Illinois, Indiana, Iowa, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, North Carolina, New York City, Ohio, Oregon, Puerto Rico, Rhode Island, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, Wyoming
Not Measured: The IIS is not able to be tested at this time.	Arizona, District of Columbia, Hawaii, Pennsylvania, 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 fluctuations in testing results due to evolving ACIP recommendations as well as in the number of IIS measured in each period. However, in the

long term, we expect to see increases in the number of IIS meeting all CDS measures, indicating positive progress across the community.

Published Validation reports offer insight into the progress IIS are making with community-driven standards alignment. AIRA staff are also available to provide technical assistance to IIS programs and vendors as requested.

Please visit AIRA's website for more background or other information on the M&I Initiative. Please direct questions and/or comments via AIRA's online Technical Assistance form.

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 one 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.).