

Background

In 2015, AIRA launched a testing and discovery project to determine the level of alignment between current immunization information systems (IIS) and community-vetted standards and recommendations. The testing and discovery project, still currently in place, connects with IIS pre-production systems directly and submits sample messages to these IIS development platforms.

The testing project is the first step in an overall IIS Measurement and Improvement process. The next stage is IIS Assessment. The results from the testing and discovery project are used to inform the IIS assessment process, which is also heavily guided by IIS Functional Standards¹ and Operational Guidance Statements. A third stage following IIS Assessment is Validation.

In early 2016, the Measurement for Assessment and Certification Advisory Workgroup (MACAW) was convened to systematically research and formulate key IIS assessment components, develop measures, and implement the IIS assessment and validation process. MACAW utilizes the testing and discovery project results to identify and develop assessment measures for particular IIS components. Those measures are then vetted and informed by the IIS community. Clinical Decision Support (CDS) Assessment is the fourth official measurement content area for IIS Assessment, and this report contains the aggregate results of the assessment completed in Quarter 1 of 2021. This process will be repeated in Quarter 2 of 2021 and every quarter thereafter to determine if progress is being made toward broader standards adoption throughout the community.

In addition to this aggregate report, a detailed individual report is provided to each jurisdiction for use within their own projects for improvements. AIRA will not redistribute any individual IIS results outside of their respective jurisdiction and self-selected sharing settings within the Aggregate Analysis Reporting Tool (AART).²

The CDS Assessment process utilizes the National Institute of Standards and Technology (NIST) Forecasting for Immunization Test Suite (FITS).³ 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) project⁴.

¹ http://www.cdc.gov/vaccines/programs/iis/func-stds.html

² https://app.immregistries.org/aart/home

³ https://fits.nist.gov/fits/#/home

⁴ https://www.cdc.gov/vaccines/programs/iis/cdsi.html

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)⁵. 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.

CDS Measures

The CDS Assessment⁶ spans 12 measures in all; these measures are guided by the following Functional Standards.

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.
- **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 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 <u>if</u> the concept is returned
- Three accuracy measures to measure the <u>content</u> returned, one each for pediatric, adolescent, and adult

⁵ https://www.cdc.gov/vaccines/acip/index.html

⁶ https://repository.immregistries.org/resource/test/

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.

- 1. The IIS HL7 interface returns an Earliest Date for each forecasted dose.
- 2. The Earliest Date returned by the IIS matches the CDC CDSi expected value for routine age-based pediatric recommendations.
- 3. The Earliest Date returned by the IIS matches the CDC CDSi expected value for routine age-based adolescent recommendations.
- 4. 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.

- 1. The IIS HL7 interface returns a Recommended Date for each forecasted dose.
- 2. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based pediatric recommendations.
- 3. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based adolescent recommendations.
- 4. The Recommended Date returned by the IIS matches the CDC CDSi expected value for routine age-based adult recommendations.

Test Cases

The MACAW members developed high-level strategies for establishing detailed test cases for each measure. Test cases were developed with the following guiding principles in mind:

- **Isolate the test case to the measure:** Each test case should be isolated to the measure to ensure consistent measurement across all IIS.
- Expectations for a test case should be few, not many: Multiple expectations—either in number or variation—lead to inconsistencies in assessment across all IIS. For example, IIS "A" could fail for one reason while IIS "B" could fail for a different reason. When results are aggregated across all IIS, it becomes difficult to tease apart the variation and develop actionable improvement strategies.
- Leverage current CDC CDSi test cases: Test cases created and vetted by the community should be reused if at all possible. CDS Assessment will use the CDSi published test cases as soon as they are available. With each published version of CDSi test cases, the CDS Assessment will test, but not score, new or changed CDSi test cases during their first quarterly assessment. They will be included in scoring during subsequent quarters. This approach will allow IIS to see the new or changed test cases and address them prior to the next quarterly assessment.
- Also measure the middle: CDSi test cases focus on the edge—or boundary—between valid and invalid doses. This is an interesting area and much needed, but many vaccines are administered at the recommended time and forecasting should be tested in these cases as well. Additional test cases have been added by AIRA to test typical administration patterns.

Test Outcomes

Each test case has a defined Test Case Expectation. The test cases and test case expectations are used during testing to determine how well a CDS engine aligns with the CDC CDSi expectations. Each test is marked as either "Meets" or "Does Not Meet" based on the CDC CDSi expectations.

Measure Outcomes

Each measure is given a "degree of alignment" score by dividing the number of test cases passed by the number of total tests within a measure.

The degree of alignment score is used to determine a Measure Outcome defined as follows⁷:

 $^{^7}$ Note that thresholds for Deviates and Does Not Meet changed in Q1 2021. In 2019 & 2020, the threshold for Deviates was 65-89%. In 2019 & 2020, the threshold for Does Not Meet was Less than 65%.

- **Meets:** The IIS has a degree of alignment score of at least 90% or more.
- **Deviates:** The IIS has a degree of alignment score of at least 89% but less than 80%.
- **Does Not Meet:** The IIS has a degree of alignment score of less than 80%.
- **Vaccine Family Threshold:** The IIS will be downgraded one measure outcome level (e.g., from Meets to Deviates) if any individual vaccine family has a degree of alignment below 65%, provided at least 10 test cases exist within the vaccine family.

Testing Method

Each test case will be first submitted to the IIS via an HL7 VXU submission. A query (QBP) will then be issued for the patient, and the response (RSP) will be analyzed. The query (QBP) will be either the Z34 (Complete History) or the Z44 (Evaluated History and Forecast), based on IIS preference. Both of those query responses can contain clinical decision support.

Results

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 Islands⁸) were encouraged to be measured in the IIS Assessment. Of the 62⁹, 42 (68%) could be measured and are included in this report. IIS were unable to be measured for the following reasons:

- 12 IIS: AIRA is not connected to the IIS, or the IIS is currently unavailable for measurement.
- **3 IIS:** The IIS does not include CDS in its response to a query.
- **4 IIS:** The IIS is unable to process the submission and respond to a query for the patient in a timely manner.

⁸ 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.

⁹ Note that the denominator for M&I participation increased from 58 to 62 in Q1 2021.

• 1 IIS: The IIS does not have query capability.

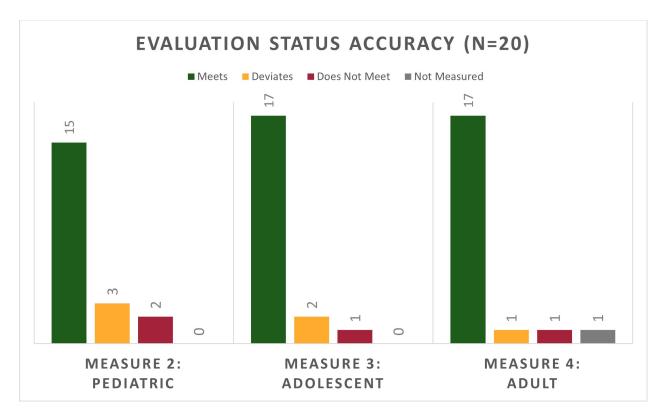
CDS Concepts Supported

Measures 1, 5, and 9 assess which CDS concepts are supported as part of an IIS HL7 interface. Of the 42 IIS that were assessed, the following table shows how many IIS support the CDS concepts.

CDS Concept	Supports (N=42)
Measure 1: Evaluation Status	20
Did the dose count?	20
Measure 5: Earliest Date	39
When could the next dose be given?	33
Measure 9: Recommended	
Date	42
When should the next dose be given?	

Evaluation Status Accuracy Results

Measures 2 (Pediatric), 3 (Adolescent), and 4 (Adult) measure the accuracy of the Evaluation Status when it is returned by the IIS. Twenty IIS (see Measure 1 above) supported Evaluation Status and were measured for their alignment with the CDSi expectations.



Of the 20 IIS assessed for Evaluation Status, the following high-level notes should be understood when reading the graph above:

• Pediatric Measure:

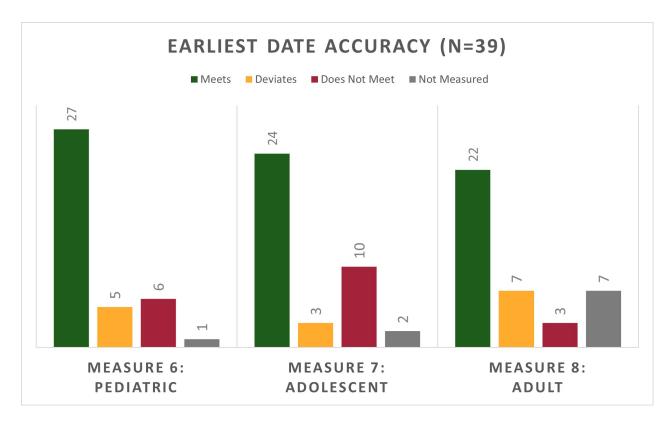
 Vaccine Family Threshold: One IIS was downgraded from Meets to Deviates because at least one vaccine family was below the vaccine family threshold.

Adult Measure:

 Not Measured: One IIS showed support for Evaluation Status but did not return it consistently across all vaccine families. As such, the IIS was not able to be measured for its accuracy.

Earliest Date Accuracy Results

Measures 6 (Pediatric), 7 (Adolescent), and 8 (Adult) measure the accuracy of the Earliest Date when it is returned by the IIS. Thirty-nine IIS (see Measure 5 above) supported Earliest Date and were measured for their alignment with the CDSi expectations.



Of the 39 IIS assessed for Earliest Date, the following high-level notes should be understood when reading the graph above:

• Pediatric Measure:

- Vaccine Family Threshold: One IIS was downgraded from Meets to Deviates because at least one vaccine family was below the vaccine family threshold.
- Vaccine Family Threshold: Two IIS were downgraded from Deviates to Does Not Meet because at least one vaccine family was below the vaccine family threshold.
- Not Measured: One IIS showed support for Earliest Date but did not return
 it consistently across all vaccine families. As such, these IIS were not able to
 be measured for their accuracy.

Adolescent Measure:

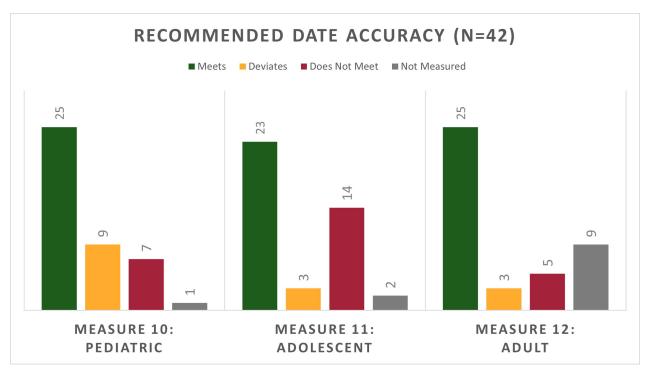
 Not Measured: Two IIS showed support for Earliest Date but did not return it consistently across all vaccine families. As such, these IIS were not able to be measured for their accuracy.

Adult Measure:

 Not Measured: Seven IIS showed support for Earliest Date but did not return it consistently across all vaccine families. As such, these IIS were not able to be measured for their accuracy.

Recommended Date Accuracy Results

Measures 10 (Pediatric), 11 (Adolescent), and 12 (Adult) measure the accuracy of the Recommended Date when it is returned by the IIS. Forty-two IIS (see Measure 9 above) supported Recommended Date and were measured for their alignment with the CDSi expectations.



Of the 42 IIS assessed for Recommended Date, the following high-level notes should be understood when reading the graph above:

• Pediatric Measure:

- Vaccine Family Threshold: Two IIS was downgraded from Meets to Deviates because at least one vaccine family was below the vaccine family threshold.
- Not Measured: One IIS showed support for Recommended Date but did not return it consistently across all vaccine families. As such, the IIS were not able to be measured for their accuracy.

Adolescent Measure:

- Vaccine Family Threshold: Four IIS were downgraded from Deviates to Does Not Meet because at least one vaccine family was below the vaccine family threshold.
- Not Measured: Two IIS showed support for Recommended Date but did not return it consistently across all vaccine families. As such, the IIS were not able to be measured for their accuracy.

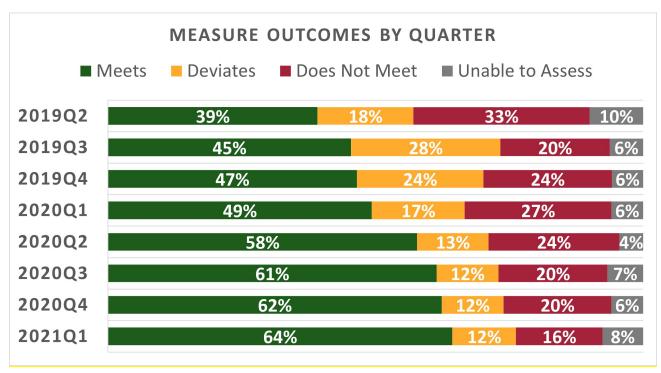
Adult Measure:

 Not Measured: Nine IIS showed support for Recommended Date but did not return it consistently across all vaccine families. As such, these IIS were not able to be measured for their accuracy.

Summary of Progress

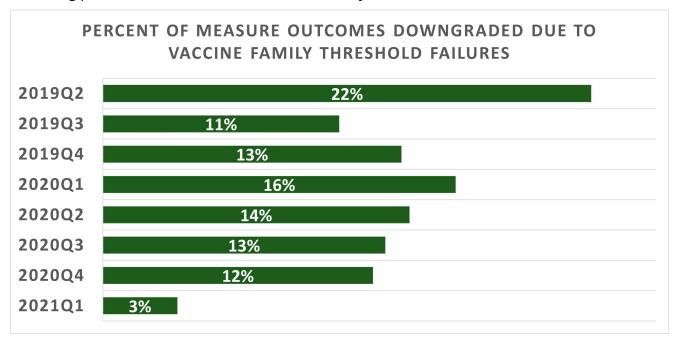
IIS are continuing to implement functionality to align with ACIP recommendations. Community progress will be monitored using two key indicators: 1) aggregate outcome for all measures and 2) reduction in vaccine family threshold failures.

The following graph shows quarterly outcomes for all CDS measures. In the baseline measurement (Q2 2019), 39% of all measures had an outcome of Meets. In Quarter 1 2021, 64% of all measures had an outcome of Meets. Quarter-to-quarter comparisons will likely result in dips 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.



The following graph shows quarterly results related to vaccine family failures that resulted in a measure outcome downgrade. In the baseline measurement (Q2 2019), 22% of measure outcomes were downgraded because the IIS performed poorly on at least one vaccine family. In Q1 2021, 3% of measure outcomes were downgraded because the IIS performed poorly on at least one vaccine family. This significant change is the result of

raising the bar for Deviates from 65% to 80% in Q1 2021. The majority of IIS who had issues with vaccine family thresholds now fall into Does Not Meet. There for they do not have to be downgraded. We expect to continue to see decreases in these percentages over time, indicating positive movement across the community.



Remeasurement

The next remeasurement for CDS Assessment will take place in Quarter 2 of 2021, and we hope to show increases in both the number of IIS being measured and in the number of IIS that meet measures for this content area of measurement.

Limitations

- Comparison across time: Unlike Transport, Submission, and Query Assessment, CDS Assessment is a bit more difficult to compare across time as ACIP recommendations continually evolve. Each quarter, test cases evolve to match the evolving ACIP recommendations. At a high-level, trends can be seen, but it is also highly possible that changes from quarter-to-quarter (in either positive or negative directions) could be due to recommendation changes and not necessarily CDS engine changes. However, looking over several quarters should provide a much better view of the progress IIS are making to align with ACIP recommendations.
- **Requirements to be measured:** For an IIS to be able to be measured, the IIS must be able to do the following three things. Some IIS were able to meet some but not all of these requirements, so they were unable to be measured.

- 1. The IIS must be able to accept a basic HL7 VXU message with historical vaccination events. This loads the test case scenario into the IIS.
- 2. The IIS must fully process the VXU and make the patient available for querying within 60 seconds.
- 3. The IIS must respond to the guery and include well-formed CDS in the RSP.
- Vaccine matching: The only standards-based way to measure CDS engines at this time is through HL7 version 2. This is a great way to test, but it doesn't entirely isolate the CDS engine. The HL7 version 2 processing rules sometimes get in the way of testing CDS. Vaccine matching business rules may merge two vaccination events that the CDS test cases intend to be unique. When this is discovered, the test case must be left unmeasured. This isn't to suggest the vaccine matching within an IIS isn't accurate. This is to note that some things simply can't be tested until a direct interface to the CDS engine exists void of external business processing.
- CDS engine scope: Not all jurisdictions or IIS CDS engines provide evaluation or forecasts for all ages. In these cases, the IIS will not be assessed on measures outside of their scope of CDS.
- Test case focus: This testing focuses on age groups and specific vaccine families within those age groups. It does not focus on entire patient forecasts across all age groups. The Functional Guide Volume on Query and Response¹⁰ does address this issue and should be reviewed by all implementers outside of this CDS Assessment effort.

General Recommendations

- 1. Continued education and direction are needed on CDS recommendations. ACIP recommendations change regularly, and it is imperative that IIS remain in alignment with those recommendations.
- Evaluation Status is not returned nearly as often as the Forecasted Dates. Returning
 the Evaluation Status and Evaluation Reason (not assessed) can help explain to
 clinical staff why a dose may need to be repeated. From an assessment standpoint,
 the Evaluation Status can also help pinpoint where misalignment exists and where
 corrective action is needed.
- 3. Many IIS had one or two vaccine families that were problematic and dropped their measures lower than expected. In many cases, the IIS could focus on those vaccine families to quickly move closer to alignment with ACIP recommendations.

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¹⁰ https://repository.immregistries.org/resource/iis-functional-guide/

Questions and/or Comments

Please direct questions and/or comments on this aggregate report to the <u>AIRA Technical Assistance Team</u>.