

Background

In 2015, AIRA launched a testing and discovery project to determine the level of alignment between current immunization information systems (IIS) and the community's alignment with community vetted standards and recommendations. The testing 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 discovery project are used to inform the IIS Assessment process, which is heavily informed 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 initiated to systematically research and formulate key IIS assessment components, develop measures, and implement the IIS assessment and validation process. MACAW utilizes the testing discovery project results to identify and develop assessment measures for particular IIS components. Those measures are then vetted and informed by the IIS community. Query and Response Assessment is the third official measurement content area for IIS Assessment, and this report contains the aggregate results of the remeasurement completed in Quarter 1 of 2021 This process will be repeated in Quarter 2 of 2021 to determine if progress is being made in 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 IIS Assessment process utilizes the National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool.³ This tool provides consistent conformance-based results for all measured IIS. In addition, the technical requirements for query and response are documented in the *HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5*⁴ and addendum.⁵ This is referred to as the "National IG" in the remainder of this document.

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

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

³ https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home

⁴ https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf

⁵ https://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-addendum-7-2015.pdf

It is important to keep in mind that, at the time of measurement, many IIS were currently in the midst of implementing release 1.5 of the National IG. 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.

Query and Response Measures

The Query and Response Assessment⁶ spans eight measures in all; these measures are guided by the following Functional Standards.

Functional Standard 1.1: The IIS provides individual immunization records accessible to authorized users at the point and time where immunization services are being delivered.

Functional Standard 1.4: When the IIS receives queries from other health information systems, it can generate an automatic response in accordance with interoperability standards endorsed by CDC (Centers for Disease Control and Prevention) for message content/format and transport.

Functional Standard 3.4: The IIS can store all CDC endorsed data elements.

The following are the community-approved Query and Response Assessment measures that are reported in this document. Note that Measures 1 and 2 focus on query, Measures 3–6 focus on response, Measure 7 focuses on CDC endorsed data element storage, and Measure 8 focuses on timeliness.

- 1. The IIS processes a query requesting a patient's immunization record.
- 2. The IIS processes a query requesting a patient's evaluated immunization record and forecast.
- 3. The IIS responds to a query for a known patient (one-to-one match).
- 4. The IIS responds to a query for a patient who is not in the IIS.
- 5. The IIS responds to a query that results in multiple possible patients.
- 6. The IIS responds to a query that has a significant error that cannot be accepted.
- 7. The IIS responds to a query for a known patient and returns known CDC endorsed data elements.
- 8. The IIS responds to a query with a response (RSP) within 5 seconds or less for 95% of the queries submitted.

⁶ http://www.immregistries.org/resources/aira-initiatives/assessment/IIS_Assessment_Measures_and_Tests_-
Query_and_Response - final.pdf

The terms below were carefully chosen and defined to mean the following within each measure:

Processes: This means the IIS reads the incoming message and makes appropriate decisions (e.g., deduplicates, stores, queries, rejects, etc.) based on the information in the incoming message and previously known information already in the IIS.

Responds: This means the IIS returns a final resolution, or outcome, of processing the message with a conformant HL7 [Health Level Seven] message.

Test Cases

Each measure is assessed through the use of test cases that were reviewed and agreed upon by the community. Each measure has at least one test case but may have more as needed. In all, 11 test cases were developed, reviewed, and approved across the 8 measures. 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: Having multiple expectations—in either number or variation—leads to inconsistencies in Assessment across all IIS. For example, IIS "A" could fail for one reason while IIS "B" fails for a different reason. When results are aggregated across all IIS, it becomes difficult to tease apart the variation and develop actionable improvement strategies.

Test for good behavior: Assessment should focus on the proper behavior based on standards. There is little value in testing with negative or edge cases at this stage, and a focus on desired behavior will help maintain a manageable number of test cases. Testing and Discovery (aka the AART pentagon report) uses a significant number of negative and edge test cases, so key concepts of interest can be tested in that stage.

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 an IIS aligns with the National IG. Once each test case is executed against an IIS, the IIS is deemed to be in one of the following three categories:

Meets: The IIS meets the test case expectation without modification to the test case or test case expectation(s).

Deviates from National Standard: The IIS can meet the test case expectation with modification to the test case or test case expectation(s) that supports local business need, policy, or law.

Does Not Meet: The IIS cannot meet the test case expectation due to non-standard requirements, capability limitations, or otherwise arbitrary requirements that do not support local business need, policy, or law.

Measure Outcomes

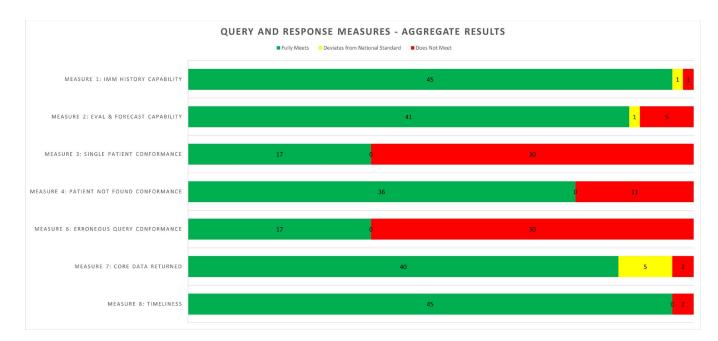
Once test cases have been executed and their outcomes assessed, each individual measure is assessed to determine a measure outcome. Similar to test outcomes, measure outcomes can be categorized as: Meets, Deviates from National Standard, or Does Not Meet. These categories are derived by rolling up the test outcomes for the measure and assigning the lowest test outcome as the measure outcome. For example, Measure 5 consists of three tests. If an IIS "Meets" one test, "Deviates" on one test, and "Does Not Meet" one test, the measure outcome is categorized as "Does Not Meet" since that is the lowest test outcome. To "Meet" a measure, all test outcomes must be categorized as "Meets."

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 Islands⁷) were encouraged to be measured in the IIS Assessment. Of the 62⁸, 47 (76%) could be measured and are included in this report.

⁷ Note that the six Pacific Islands were not initially targeted for measurement due to limited transport technology. As capabilities and ability to be measured expand, Pacific Islands are being included in this report.

⁸ Note that the denominator for M&I participation increased from 58 to 62 in Q1 2021.



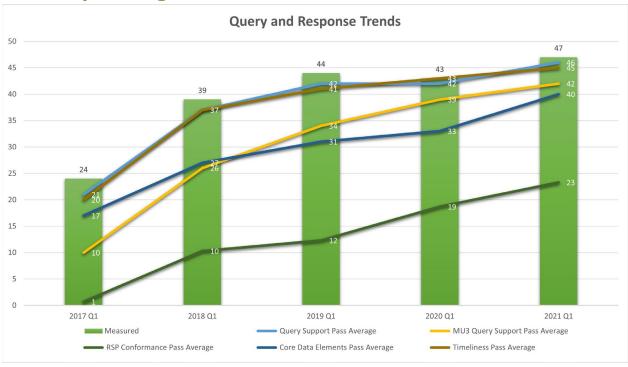
Of the 47 IIS assessed, the following high-level notes should be understood when reading the graph above:

- Measures 1 and 2: Measures 1 and 2 assess if an IIS has the capability to accept a query and return a response. Measure 1 is a query that has been around longer than Measure 2. Measure 2 is a new query as part of release 1.5 of the National IG and is included in the Promoting Interoperability⁹ program.
- **Measures 3, 4, and 6:** These measure the RSP from the IIS for the proper answer (e.g., did the IIS accept and process a query with the proper HL7 RSP profile) as well as RSP conformance. In most cases, the IIS response used the proper HL7 profile, but the RSP failed technical conformance. Conformance with a defined standard is an all-or-nothing measurement. Some IIS were extremely close to passing while others were quite far away, yet both are classified as Does Not Meet.
- **Measure 5:** Measure 5 attempted to submit twins to the IIS to measure conditions where more than 1 patient is found from a query. In most cases, the IIS did not detect these patients as twins. As such, the measure was unable to measure the condition it was intending to measure. This measure will need to be reconsidered to determine if there is value in continuing this measure. For this reason, Measure 5 is not shown on the graph above.
- **Patient Never Found:** 1 IIS was unable to return the patient under any circumstances, which resulted in measures failing for patient matching problems rather than HL7 query and response requirements.

⁹ https://www.cms.gov/EhrIncentivePrograms/

Finer details on the testing results where IIS deviated or did not meet the standard can be seen in Appendix A.

Summary of Progress



This remeasurement showed progress in the following areas:

- **Single Patient Found Conformance:** 17 IIS have successfully passed the measure testing conformance when a single patient is found (Measure 3). No IIS passed this measure during the initial baseline. This measure is arguably the most technically complex measure, as it requires the IIS to create two different RSP profiles and both must meet all of the conformance rules within an HL7 message.
- **Patient Not Found Conformance:** 36 IIS have successfully passed the measure testing conformance when no patients are found in the IIS (Measure 4). This is an increase of 34 IIS since the initial baseline.
- **Promoting Interoperability Query Support (Measure 2):** 42 (89%) of IIS measured support the Z44 query profile. The profile is required for the Promoting Interoperability program. Only 10 (42%) of IIS measured supported this query at the initial baseline.

Remeasurement

The next remeasurement for Query and Response 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 and tests for this content area of measurement.

Limitations of Report

- Acknowledgment (ACK) inconsistencies: Acknowledgments (ACK) are improving, but non-standard acknowledgment messages are still present. This inconsistency makes understanding the difference between an accepted message and a rejected message difficult to discern across the entire landscape of IIS interfaces.
 - Impact on Assessment: All of the measures—except Measures 4 and 6—begin by submitting a vaccine update (VXU) message so the IIS contains a known patient who is then able to be queried. If that patient is not found during a query—when it is expected to be—the IIS fails the measure. It is possible the IIS never accepted the initial VXU, so the patient is not in the IIS. If the patient was accepted, the IIS may have returned the patient. The misunderstood ACK may result in more failures than if the initial VXU had been accepted.
- Auto-Accept IIS: Two IIS return a positive ACK (MSA-1 = AA) all of the time regardless of the message quality.
 - o **Impact on Assessment:** IIS that auto-accept the data may actually reject the data submitted without informing the testing process of the problem. This means that when a subsequent query fails it is assumed that the IIS is unable to respond to the query when in fact the real problem may be that it is unable to properly process the initial update.

General Recommendations

- 1. Continued education and direction are needed on ACK messaging to ensure IIS are implementing standards consistently across all systems. The ACK is becoming the face of the IIS and is the only way to determine in an automated (and real-time) fashion if the submitted data was accepted by the IIS. Positive movement is being seen by select IIS, but more work is needed while moving closer to Promoting Interoperability, where certified electronic health records (EHRs) are required to consume ACK messages per the National IG.
- 2. In general, IIS are using the correct HL7 profile when returning their RSP, but most of them contain technical conformance errors that make understanding the RSP more difficult. IIS should utilize the conformance tool provided by NIST when developing and/or improving implementation of the HL7 standards. The tool can aid

- the software development process. The tool is located at https://hl7v2-iz-r1.5-testing.nist.gov/iztool/#/home and is free to use without installation or registration.
- 3. Measure 5 should be reviewed, and either be improved so it can better measure a condition where multiple patients are found or be removed until such time as it can be better measured. In its current form, Measure 5 is rarely measuring HL7 RSP as it is intended to measure, because the proper pre-conditions cannot be created in the IIS.
- 4. Overall, success in matching the patient was achieved, but some IIS are quite strict in finding a match, and minor demographic differences or submitting too much data and/or slightly too little data seemed to have different impacts and outcomes across different IIS. The primary purpose of this assessment was not patient matching, but it was secondarily discovered as an area that varied across IIS and likely needs a strategy for improvement and/or consistency.
- 5. Operationally, IIS should coordinate with their interface partners in jointly aligning with standards while, whenever possible, not disabling existing interfaces. It is important to communicate to partners that modifications may demand short-term work but yield long-term gains in faster and easier interoperability and interface development.

Questions and/or Comments

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

Appendix A

The following appendix provides the specific details on the reasons why IIS either deviated from or did not meet the Query and Response Assessment measures.

Query Measures

Measures 1 and 2 focus on submitting a specific query to an IIS and then measure the response based on whether or not they returned the correct profile.

Measure 1: Immunization History (Z34)

Measure 1 is a query for a patient's immunization record, but it does not necessarily contain the clinical decision support (e.g., evaluation and forecast). To meet this measure, an IIS must return a Z32 RSP. Technical HL7 conformance of the Z32 RSP is not required to pass this measure.

Deviates from Standard	Does Not Meet
Requires Security Field: The IIS will reject	Low confidence match: The IIS returned a
the message without the security field	low confidence match and thus failed the
(MSH-8) populated. This is an optional field	measure.
in the National IG.	

Measure 2: Evaluated History and Forecast (Z44)

Measure 2 is a query for the patient's evaluated immunization history and forecast. In this case, the evaluation and forecast must be included. To meet this measure, an IIS must return a Z42 RSP. Technical HL7 conformance of the Z42 RSP is not required to pass this measure.

Deviates from Standard	Does Not Meet
Requires Security Field: The IIS will reject the message without the security field (MSH-8) populated. This is an optional field in the National IG.	Return Z32: The IIS returned a Z32 response rather than the expected Z42 response. This is a strong indication of a pre-release 1.5 implementation.
	Low confidence match: The IIS returned a low confidence match and thus failed the measure.

Response Measures

Measures 3 through 6 measure the different types of responses that must be returned depending upon the condition (e.g., patient found, patient not found, etc.).

Measure 3: Single Patient Found Response

Measure 3 is the flip side of Measures 1 and 2. In Measure 3, the IIS must respond with the proper Z32 or Z42 RSP profile, and the RSP must be technically conformant. Conformance with a defined standard is an all-or-nothing measurement. Some IIS were extremely close to passing while others were quite far away, yet both are classified as Does Not Meet. This measure included two tests, so some IIS may overlap more than one category.

Deviates from Standard	Does Not Meet
	Correct profile but failed HL7 conformance: The IIS had some level of conformance error in either the Z32 profile, the Z42 profile, or both profiles.
	Returned wrong profile: The IIS returned a Z32 response rather than the expected Z42 response. This is a strong indication of a pre-1.5 implementation.
	Low confidence match: The IIS returned a low confidence match and thus failed the measure.

Measure 4: Patient Not Found

Measure 4 submitted a randomly generated patient not already in the IIS. The IIS was expected to return a Z33 RSP profile, and the RSP must be technically conformant. Conformance with a defined standard is an all-or-nothing measurement. Some IIS were extremely close to passing while others were quite far away, yet both are classified as Does Not Meet.

Deviates from Standard	Does Not Meet
	Supplied correct answer but failed HL7
	conformance: The IIS had some level of
	conformance error when returning the
	expected Z33 response profile.
	expected topological

Incorrect RSP profile: IIS did not return a
Z33 profile as expected. Invalid profiles included Z34, and an empty profile ID.
included 254, and an empty prome 15.

Measure 5: Multiple Patients Found

Measure 5 attempted to submit twins to the IIS to measure conditions where more than 1 patient is found from a query. In most cases, the IIS did not detect these patients as twins. As such, the measure was unable to assess the condition it was intending to measure. This measure will need to be reconsidered to determine if there is value in continuing this measure.

Measure 6: Erroneous Query

Measure 6 intentionally submitted a query with missing data elements to measure the IIS response. The IIS was expected to return a Z33 profile, and the RSP must be technically conformant. Conformance with a defined standard is an all-or-nothing measurement. Some IIS were extremely close to passing while others were quite far away, yet both are classified as Does Not Meet.

Deviates from Standard	Does Not Meet
	Supplied correct RSP profile but failed HL7 conformance: The IIS had some level of conformance error when returning the expected Z33 response profile.
	Incorrect RSP profile: The IIS did not return a Z33 profile. Invalid profiles included Z23, Z34, and an empty profile ID.
	Non-HL7 Response: The IIS did not return an HL7 response.

CDC Endorsed Data Element Measure

Measure 7 focused on detecting storage of CDC endorsed data elements through a query to the IIS for a known patient. A subset of the CDC endorsed data elements was chosen. Those elements are critical for informing vaccination decisions the clinician must make and support patient identification. To pass this measure, the IIS were required to return the following CDC endorsed data elements:

- Patient ID (Submitted medical record number (MRN) from VXU)
- Patient Name (first, middle, last)
- Patient DOB
- Patient Gender
- Vaccine Product Type Administered (CVX)
- Vaccination Administration Date

Deviates from Standard	Does Not Meet
Does not return MRN: The IIS does not return the MRN which was submitted to the IIS prior to query.	Low confidence match: The IIS returned a low confidence match and thus failed the measure.
Middle Initial: The IIS does not return the full middle name, only the middle initial.	Does not return vaccination data: The IIS did not return both vaccination records which were submitted to the IIS prior to query.

Timeliness Measure

Measure 8 focused on the round-trip response time from the time the message was submitted until the response from the IIS was received. To meet this measure, the IIS needed to respond within 5 seconds for 95% of the query by parameter (QBP) messages. The total number of QBPs submitted as part of the Assessment process was 19. This means the IIS was permitted to respond more slowly than 5 seconds on only one of those queries, which is quite tight. Future assessments may want to reconsider how to measure timeliness over a larger sample size. A second consideration is the use of pre-production environments for Assessment, which might not put as much emphasis on performance as production environments do or, conversely, may perform faster as a result of housing less data.

Deviates from Standard	Does Not Meet
	Did not respond within 5 seconds 95% of
	the time: The percentages below are the
	percentage of times these respective IIS
	returned a response within 5 seconds and
	thus fell short of the 95% threshold.
	• 0% - 2 IIS