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Background

In 2015, AIRA launched an initiative to determine the level of alignment among current immunization information systems (IIS) with community-vetted standards and recommendations. This Measurement and Improvement (M&I) Initiative is an ongoing project that connects with IIS preproduction systems directly and submits sample messages to these IIS development platforms.

<u>Testing and Discovery</u> (T&D) is the first stage of the overall IIS M&I process. The next stage is <u>IIS Assessment</u>. The results from T&D are used to design the final measures and tests for the IIS Assessment process, which also relies on <u>IIS Functional Standards</u> and operational guidance statements. The final stage following IIS Assessment is <u>Validation</u>.

In early 2016, the <u>Measurement for Assessment and Certification Advisory Workgroup</u> (MACAW) was initiated to systematically research and formulate key IIS assessment components, develop measures, and implement the IIS Assessment and Validation process. MACAW uses T&D results to identify and develop assessment measures for specific IIS components. Those measures are then vetted and approved by the IIS community. **Query and Response (QBP/RSP)** is the third content area of the M&I Initiative, and this report contains the aggregate results of the IIS Assessment remeasurement completed in **Quarter 4 of 2023**. This process will be repeated in Quarter 1 of 2024 to measure progress within the community.

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

The IIS Assessment process uses the <u>National Institute of Standards and Technology (NIST)</u> <u>Immunization Test Suite Validation Tool</u>. This tool provides consistent conformance-based results for all measured IIS. In addition, the technical requirements for query and response are documented in the <u>HL7 Version 2.5.1: Implementation Guide for Immunization</u> <u>Messaging, Release 1.5</u> and associated <u>addendum</u>. This is referred to as the "National IG" in the remainder of this document.

This report represents a quarterly snapshot of standards alignment and, 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 Assessment spans eight measures in all; these measures are guided by the following Functional Standards. The detailed measures and tests document is located on the <u>AIRA repository</u>.

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

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

Functional Standard 8.3: The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC-endorsed HL7 Implementation Guide.

The following are the community-approved QPB/RSP Assessment measures for which results 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 five seconds or less for 95% of the queries submitted.

The terms below were thoughtfully 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 Health Level Seven (HL7) message.

Test Cases

Each measure is assessed through the use of test cases that were reviewed and agreed upon by the IIS 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 eight 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 discern variations 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 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 will fall into 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.

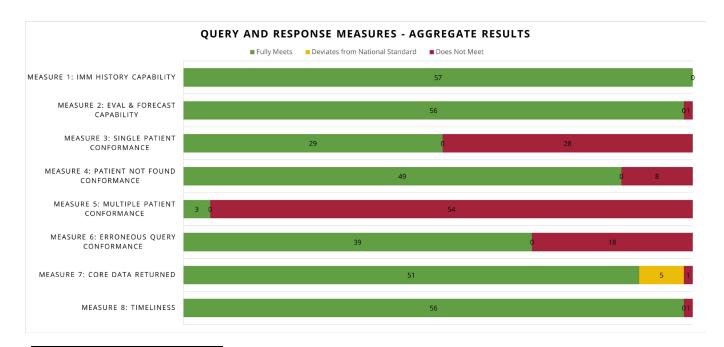
Does not meet: The IIS cannot meet the test case expectation due to non-standard requirements, capability limitations, or otherwise arbitrary requirements that do not support local business need, policy, or law.

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-one¹ IIS were encouraged to be measured in the QBP/RSP Assessment. Of the 61 participating IIS,² **57** (93%) could be measured and are included in this report.



¹ The denominator for M&I participation decreased from 62 to 61 in Q2 2022, due to San Diego IIS's merge with California's state IIS.

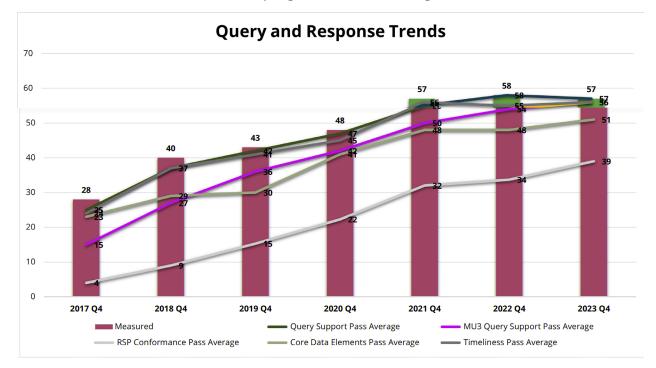
² Includes all 50 states, American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, the Federated States of Micronesia, Guam, New York City, Philadelphia, Puerto Rico, the Republic of the Marshall Islands, the Republic of Palau, and the Virgin Islands.

Of the 57 IIS assessed, the following high-level observations provide additional context for reading and interpreting the aggregate results graph:

- **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 Centers for Medicare and Medicaid Services (CMS) Promoting Interoperability <u>program</u>.
- 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. Although some IIS were extremely close to passing
 while others were on the opposite end of the spectrum, both are classified as "does
 not meet."
- **Measure 5:** Measure 5 attempted to submit twins to the IIS to validate it can respond with a conformant RSP message when multiple possible patients are found. In most cases, the IIS did not detect these patients as twins. As such, the test was unable to measure the condition it was intending to evaluate because the preconditions are not present in the IIS. This measure will need to be reconsidered to determine if there is value in continuing this measure.
- Please refer to <u>Appendix A</u> for additional details that contribute to IIS measure deviations and/or nonalignment.

Summary of Progress

This remeasurement demonstrated progress in the following areas:



- **Single patient found conformance:** Twenty-nine 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 the conformance rules within an HL7 message.
- **Patient not found conformance:** Forty-nine IIS have successfully passed the measure testing conformance when no patients are found in the IIS (Measure 4). This is an increase of 47 IIS since the initial baseline.
- **Promoting interoperability query support (Measure 2):** Fifty-six (98%) of IIS measured support the Z44 query profile. The profile is required for CMS's Promoting Interoperability program. Only 10 (42%) of 24 IIS measured supported this query at the initial baseline.

Remeasurement

The next remeasurement for Query and Response Assessment will take place in Quarter 1 of 2024. The goal of each remeasurement is to demonstrate increases in both the number of IIS that are measured and the number that meet measures and tests for this content area.

Limitations of Report

- **Auto-accept IIS:** One IIS always return a positive ACK (MSA-1 = AA), regardless of the message quality.
 - o **Impact on assessment:** IIS that auto-accept the data may ultimately 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
 - a. Both are needed for 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 timely fashion if the submitted data were 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. Use the NIST conformance tool
 - a. 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 use 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 and is free to use without installation or registration.

3. Evaluate Measure 5

a. In its current form, Measure 5 is rarely measuring HL7 RSP as it is intended to measure, because the proper preconditions cannot be created in the IIS. The community will need to determine if the measure should be (1) retained and improved so it can better measure a condition where multiple patients are found, (2) suspended until further notice, or (3) returned to the T&D stage for additional investigation.

4. Patient matching

a. 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 that likely needs a strategy for improvement and/or consistency.

- 5. Standard alignment among partners
 - a. Operationally, IIS should coordinate with their interface partners to jointly align 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 via AIRA's online technical assistance form.

Appendix A

The following appendix provides the specific details as to 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 it 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

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
	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.

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.

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 had to 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.

Measure 5: Multiple Patients Found

Measure 5 attempted to submit twins to the IIS to measure conditions where more than one 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's response. The IIS was expected to return a Z33 profile, and the RSP had to 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 and an empty profile ID.

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	Does not return vaccination data: The IIS
return the MRN which was submitted to	did not return both vaccination records
the IIS prior to query.	which were submitted to the IIS prior to
	query.

Timeliness Measure

Measure 8 focused on the round-trip response time from message submission to receipt. To meet this measure, the IIS needed to respond within five seconds for 95% of the query by parameter (QBP) messages. The total number of QBPs submitted as part of the Assessment process was 25. This means the IIS was permitted to respond more slowly than five 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 preproduction 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 storing less data.

Deviates from Standard	Does Not Meet
	Did not respond within five seconds 95%
	of the time: The percentages below are
	the percentage of times these respective
	IIS returned a response within five seconds
	and thus fell short of the 95% threshold.
	• 0% - 1 IIS