



Background

In 2015, AIRA launched an Interoperability Testing and Discovery Project to determine the level of alignment between current Immunization Information Systems (IIS) and the community's interoperability standards. 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 step is IIS Assessment. The results from the testing and discovery project are used to develop the IIS Assessment process which is heavily informed by IIS Functional Standards¹ and Operational Guidance Statements. A third step following IIS Assessment being explored is IIS Certification.

In early 2016, the [Measurement for Assessment and Certification Advisory Workgroup](#) (MACAW) was initiated to systematically research and formulate key IIS assessment components, develop metrics, and implement the IIS assessment and certification process. MACAW utilizes the testing and discovery project results to identify and develop assessment metrics for particular IIS components. Those measures are then vetted and approved by the IIS community. Query and Response Assessment is the third official measurement area for IIS Assessment and this report contains the aggregate results of the initial baseline measurement completed in January 2017. This process will be repeated in April 2017 to determine if progress is being made in the community.

In addition to this aggregate report, a detailed individual report is provided to each participating 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, or AART.²

The IIS Assessment process utilizes the National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool.³ This tooling provides consistent conformance based results for all participants. 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.

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 in conjunction with each jurisdiction's individual report, can provide valuable information to guide ongoing and upcoming enhancements.

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

² <http://ois-pt.org/dgacm/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>

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 for message content/format and transport.

Functional Standard 3.4: The IIS can store all Core Data Elements.

The following are the community approved Query and Response Assessment measures which are reported in this document. Note that Measures 1-2 focus on query, Measures 3-6 focus on response, Measure 7 focuses on core 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 that 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 Core Data Elements.
- 8) The IIS responds to a query with an RSP within 5 seconds or less for 95% of the queries submitted.

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., de-duplicates, 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 message.

Test Cases

Each measure is assessed through the use of test cases which 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 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:** Multiple expectations – either in number or variation – leads to inconsistencies in assessment across all IIS. For example, IIS “A” could fail

⁶ http://www.immregistries.org/resources/aira-initiatives/assessment/IIS_Assessment_Measures_and_Tests_-_Query_and_Response_-_final.pdf

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:

Fully 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) which supports the local business need, policy, or law.

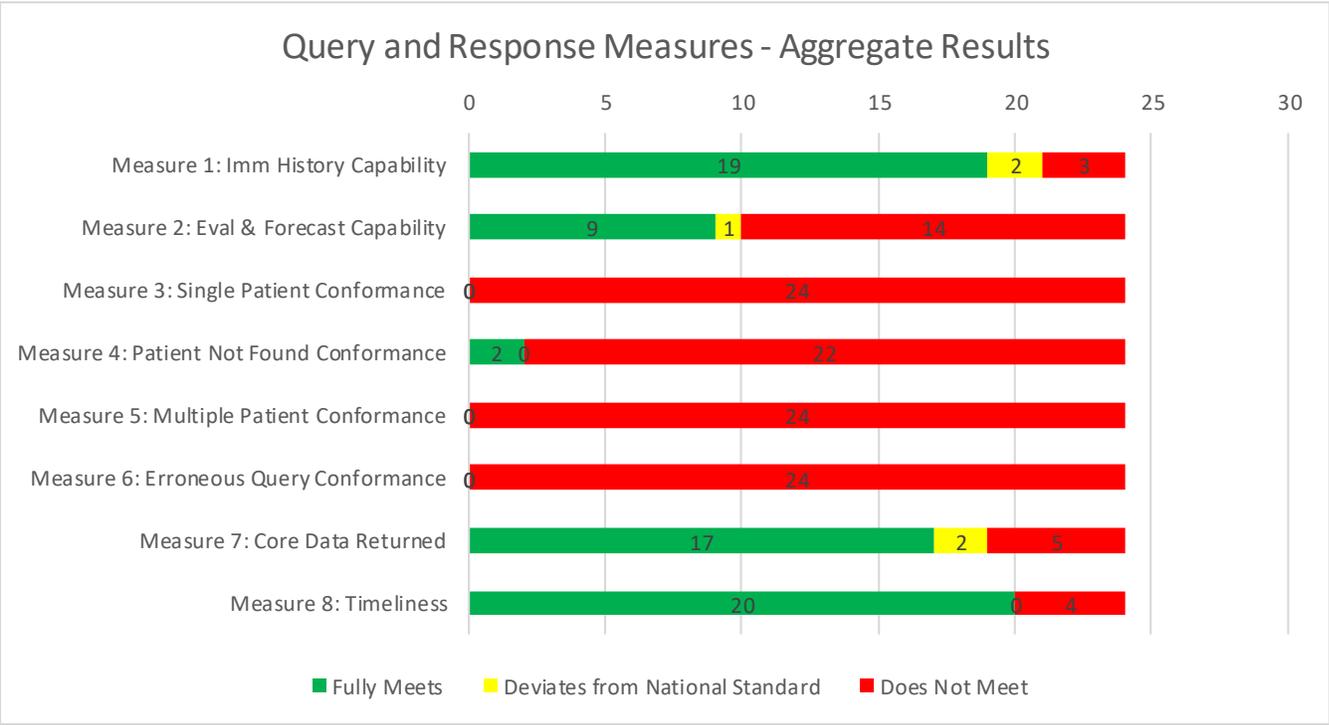
Does Not Meet: The IIS cannot meet the test case expectation either due to non-standard requirements, capability limitations, or otherwise arbitrary requirements which do not support local business need, policy, or law.

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: Fully Meets, Deviates from National Standard, or Does Not Meet. These categories are derived by rolling up the test outcomes for the measure assigning the lowest test outcome as the measure outcome. For example, Measure 5 consists of three tests. If an IIS “Fully Meets” one test, “Deviates” on one test, but “Does Not Meet” one test, the measure outcome is categorized as “Does Not Meet” since that is the lowest test outcome. To “Fully Meet” a measure, all test outcomes must be categorized as “Fully Meets”.

Results

57 IIS (which includes all 50 states, plus D.C., New York City, Philadelphia, Puerto Rico, San Diego, San Antonio, and the Virgin Islands) were encouraged to voluntarily participate in the IIS Assessment. Of the 57, 27 IIS opted to participate in the IIS Query and Response Assessment for the baseline measure in February, 2017.



Of the 24 IIS assessed, the following high-level notes should be understood when reading the graph above:

- Measures 1-2:** Measures 1 and 2 assess if an IIS has the capability to accept a query and return a response. Measure 1 is a query which 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 Meaningful Use Stage 3.
- Measures 3, 4, 6:** These measure the Response (RSP) from the IIS for proper answer (e.g., did the IIS accept a reply 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 in an effort 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.
- Patient Never Found:** Two IIS were unable to return the patient under any circumstances and results in measures failing for patient matching problems rather than HL7 query and response requirements.

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

Re-measurement

The first re-measurement for Query and Response Assessment will take place in May 2017, and we hope to show increases in both participation and in IIS who fully meet measures and tests for this phase of measurement. Participation settings can be updated in [AART](#) at any time.

Limitations of Report

- **Acknowledgement (ACK) inconsistencies:** Acknowledgements (ACK) continue to be quite variable and non-standard. 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 Measure 4 and 6 – begin by submitting a VXU message so the IIS contains a known patient which 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 isn't in the IIS. Had the patient been accepted, the IIS may have returned the patient. The misunderstood ACK may result in more failures than is reality had the initial VXU been accepted.
- **Auto-Accept IIS:** Some IIS return a positive Acknowledgment (MSA-1 = AA) all of the time regardless of the message quality.
 - **Impact on Assessment:** IIS who 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.
- **Release 1.5 Focus:** It is important to keep in mind that this phase of measurement looks at IIS alignment with the HL7 2.5.1 release 1.5 Implementation Guide, and many IIS are in the midst of the planning or implementation process of enhancing their systems to align with this guide.
 - **Impact on Assessment:** This makes the testing process especially useful to inform and test enhancements, but may artificially suppress results while IIS are testing and rolling out their updates.

General Recommendations

1. Continued education and direction is 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 Meaningful Use Stage 3 where certified EHRs are required to consume ACK messages per the National IG.
2. In general, IIS are using the correct HL7 profile when returning their response (RSP), but most of them contain technical conformance errors which make understanding the RSP more difficult. IIS should utilize conformance tooling provided by NIST when developing and/or improving implementation of the HL7 standards. The tooling 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 improved so it can better measure a condition where multiple patients are found or removed until such time it can be better measured. In its current form, Measure 5 is rarely measuring HL7 RSP as it is intended to measure as the proper pre-conditions are unable to 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, 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 wasn't 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 [AIRA Technical Assistance Team](#).

Appendix A

The following appendix provides the specific details on the reasons why assessment participants either “Deviates From” or “Does Not Meet” the Query and Response Assessment measures.

Query Measures

Measure 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 fully 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
(1 IIS) Requires the Security field: MSH-8 is an optional field in the National IG, but required by the IIS or all messages will be rejected.	(2 IIS) Patient Not Found: Two IIS were unable to find the patient and thus failed the measure.
(1 IIS) Requires old Code System: One IIS requires the use of an older coding system, and does not allow the usage of a newer coding system in the Release 1.5 addendum of the National IG.	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing interfaces already configured to meet the non-standard usage of MSH-4.

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 fully 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
(1 IIS) Requires the Security field: MSH-8 is an optional field in the National IG, but required by the IIS or all messages will be rejected.	(9 IIS) Return Z32: Nine IIS returned a Z32 response rather than the expected Z42 response. This is strong indication of a pre-Release 1.5 implementation.
	(4 IIS) Not Supported: Four IIS returned a response indicating they do not support a Z44 query.

	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing interfaces already configured to meet the non-standard usage of MSH-4.
	(1 IIS) Patient Not Found: One IIS was unable to find the patient and thus failed the measure.

Response Measures

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

Measure 3: Single Patient Found Response

Measures 3 is the flip side of Measure 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
	(21 IIS) Correct profile, but failed HL7 conformance: 21 IIS had some level of conformance error in either the Z32 profile, the Z42 profile, or both profiles.
	(9 IIS) Returned wrong profile: Nine IIS returned a Z32 response rather than the expected Z42 response. This is strong indication of a pre-Release 1.5 implementation.
	(4 IIS) Not Supported: Four IIS returned a response indicating they do not support a Z44 query.
	(2 IIS) Patient Not Found: Two IIS were unable to find the patient and thus failed the measure.
	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing

	interfaces already configured to meet the non-standard usage of MSH-4.
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Measure 4: Patient Not Found

Measures 4 submits 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
	(14 IIS) Supplied correct answer, but failed HL7 conformance: 13 IIS had some level of conformance error in when returning the expected Z33 response profile.
	(8 IIS) Incorrect RSP profile: Seven IIS did not return a Z33 profile. Five IIS returned a Z34 Profile, two IIS did not return a profile identifier, and one IIS returned a Z32 profile, but indicated no patient was found.
	(1 IIS) Patient Not Found: Two IIS were unable to find the patient and thus failed the measure.
	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing interfaces already configured to meet the non-standard usage of MSH-4.

Measure 5: Multiple Patients Found

Measure 5 attempted to submit twins to the IIS in an effort 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 5 consists of 3 tests for a grand total of 72 test case outcomes across the 24 IIS included in this baseline measurement. The correct answer was returned in 11 of 72 (15%) test case outcomes with all eleven having conformance errors.

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
	(14 IIS) Incorrect RSP profile: Ten IIS did not return a Z33 profile. Seven IIS did not return a profile identifier, four IIS returned a Z23 profile and three returned a Z34 profile.
	(8 IIS) Supplied correct answer, but failed HL7 conformance: Eight IIS had some level of conformance error in when returning the expected Z33 response profile.
	(1 IIS) Non-HL7 Response: One IIS returned a non-HL7 set of characters.
	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing interfaces already configured to meet the non-standard usage of MSH-4.

Core Data Element Measure

Measure 7 focused on detecting storage of Core Data Elements through a query to the IIS for a known patient. A subset of Core Data Elements was chosen which 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 core data elements:

- Patient ID (Submitted 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
(1 IIS) Requires the Security field: MSH-8 is an optional field in the National IG, but required by the IIS or all messages will be rejected.	(4 IIS) Patient Not Found: Four IIS were unable to find the patient and thus failed the measure.
(1 IIS) Requires old Code System: One IIS requires the use of an older coding system, and does not	(1 IIS) Invalid use of MSH-4: One IIS requires non-standard usage of MSH-4. This limitation results in a rejection of all measures, so the IIS is

allow the usage of a newer coding system in the Release 1.5 addendum of the National IG.	effectively unable to be measured until this issue is resolved. It should be noted that fixing this to align with standards will need careful consideration as it is rolled out with existing interfaces already configured to meet the non-standard usage of MSH-4.
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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 fully meet this measure the IIS needed to respond within 5 seconds for 95% of the QBP messages. The total number of QBPs submitted as part of the assessment process was 20. This means the IIS is only able to respond slower than 5 seconds on 1 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 may 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
	<p>(4 IIS) Did not respond within 5 seconds 95% of the time: The four failing IIS met the 5 second requirement as follows:</p> <ul style="list-style-type: none"> • IIS1: 13 out of 20 (65%) • IIS2: 16 out of 20 (80%) • IIS3: 18 out of 20 (90%) • IIS4: 18 out of 20 (90%)