AIRA

AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

Submission and Acknowledgment Assessment

Aggregate Report

2020 – Quarter 3

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 Standards[1] 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. Submission and Acknowledgment Assessment is the second official measurement content area for IIS Assessment, and this report contains the aggregate results of the remeasurement completed in Quarter 3 of 2020. This process will be repeated in Quarter 4 of 2020 to monitor progress 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 IIS who are able to be measured. In addition, the technical requirements for data submission and acknowledgement 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.

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[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 the National IG. This report not only constitutes a quarterly snapshot of standards alignment but also, in conjunction with each jurisdiction's individual report, can provide valuable information to guide ongoing and upcoming enhancements.

Submission and Acknowledgment Measures

The Submission and Acknowledgment Assessment[6] spans 16 measures in all and is guided by the following Functional Standards.

> **Functional Standard 1.5:** The IIS can receive submissions 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.
>
> **Functional Standard 3.6:** The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.

The following are the community-approved Submission and Acknowledgment Assessment measures that are reported in this document. Note that Measures 1–11 focus on Submission, 12–13 focus on Acknowledgment (ACK), 14 focuses on timeliness, and 15-16 focus on NDC acceptance

1. The IIS processes an administered vaccine for a patient.
2. The IIS processes a historical vaccine for a patient.
3. The IIS processes the submission of a full immunization record for a patient.
4. The IIS processes an update to a previously submitted vaccination event.
5. The IIS processes a delete to a previously submitted vaccination event.
6. The IIS processes a submission where the patient does not give consent (i.e., patient data is protected) to share data.
7. The IIS processes a refusal of a vaccination.
8. The IIS processes an adverse event.
9. The IIS processes an observation about a patient that specifies a contraindication or immunity to a vaccine-preventable disease.
10. The IIS processes messages in accordance with the National IG.
11. The IIS processes both complete and incomplete/partially administered doses.
12. The IIS responds to a correctly formatted message with no errors.
13. The IIS responds to a submission that has an error.

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

14. The IIS responds to a submission with an ACK within 5 seconds or less for 95% of the records submitted.
15. The IIS processes an administered vaccine using the preferred NDC format.
16. The IIS processes an administered vaccine using alternative NDC formats.

The following words 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, 31 test cases were developed, reviewed, and approved across the 16 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.
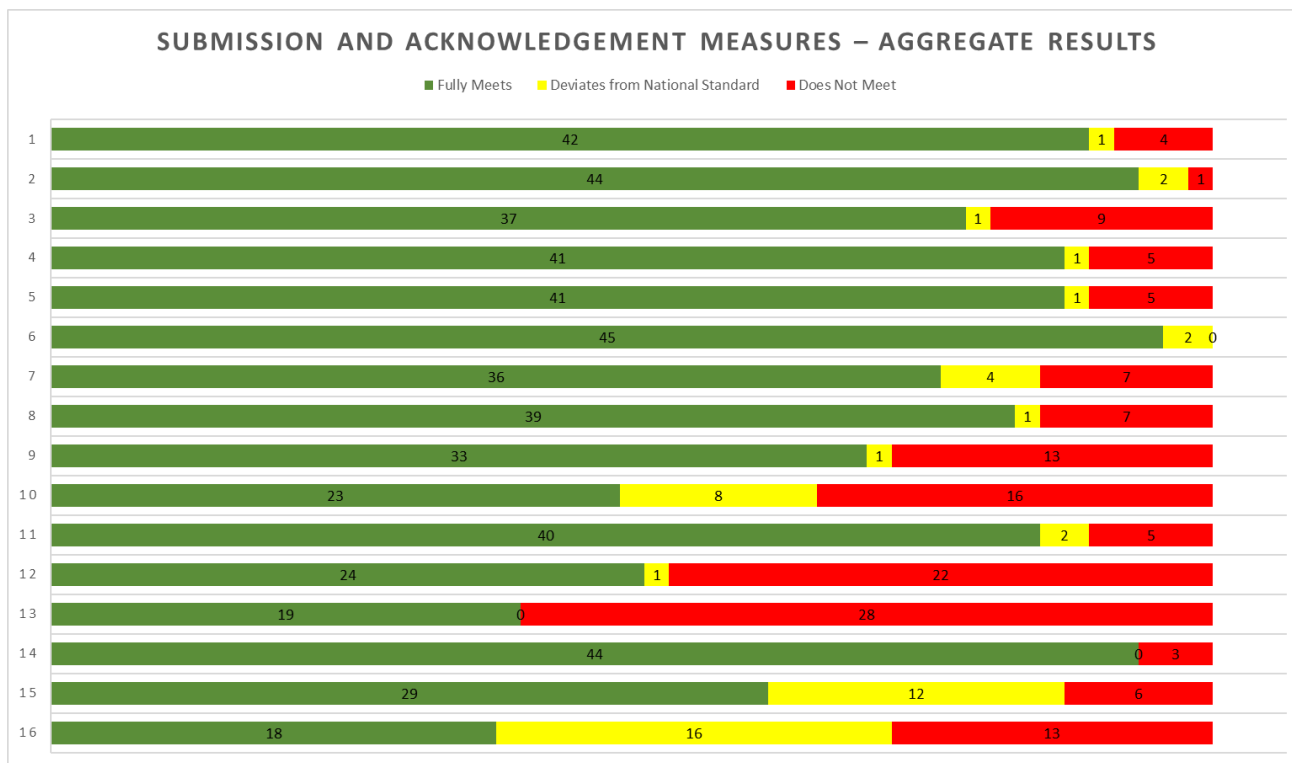
Measure Outcomes

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 10 consists of five tests. If an IIS "Meets" two tests, "Deviates" on two tests, 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

Fifty-eight IIS (comprising all 50 states, plus the Commonwealth of the Northern Mariana Islands, the District of Columbia, Guam, New York City, Philadelphia, Puerto Rico, San Diego, and the Virgin Islands[7]) were encouraged to be measured in the IIS Assessment. Of the 58, 47 (81%) were able to be measured and are included in this report.

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

SUBMISSION AND ACKNOWLEDGEMENT MEASURES – AGGREGATE RESULTS

Legend: ■ Fully Meets ■ Deviates from National Standard ■ Does Not Meet

| Measure	Fully Meets	Deviates from National Standard	Does Not Meet
1	42	1	4
2	44	2	1
3	37	1	9
4	41	1	5
5	41	1	5
6	45	2	0
7	36	4	7
8	39	1	7
9	33	1	13
10	23	8	16
11	40	2	5
12	24	1	22
13	19	0	28
14	44	0	3
15	29	12	6
16	18	16	13

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

- **Barcode VIS:** All measures processing an administered dose (Measures 1, 3, 4, 5, 10, 11, 15, 16) included at least one barcoded VIS (Vaccine Information Statement). 4 IIS were unable to process messages that contained a barcoded VIS. This accounted for 27 (30%) of the 91 "Does Not Meet" outcomes across Measures 1–11 and 15-16 (the submission measures).
- **Measure 10:** Measure 10 repeats Measures 1, 2, 7, 8, and 9 but supplies only the minimal amount of data required by the National IG. IIS that were unable to process a message when fully supplied in earlier measures also were not able to process the messages when minimally supplied. In Measure 10, success is limited most significantly by Measure 9, which has the most IIS not meeting the measure.
- **Measure 12 and 13:** These measure the ACK from the IIS for proper answer (e.g., did the IIS accept a clean message, did the IIS point out a data quality problem) as well as ACK conformance. The IIS almost always came to the proper answer, but the ACK failed technical conformance. Some IIS were extremely close to passing while others were quite far away.
- **Measure 15 and 16:** These were introduced in Quarter 4 of 2019 and expect the IIS to accept NDC messages either in the preferred format (Measure 15) or alternative formats (Measure 16). IIS able to accept the NDC alone met this measure. IIS able to

accept the NDC when the corresponding CVX code was also submitted had an outcome of Deviates.

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

Summary of Progress
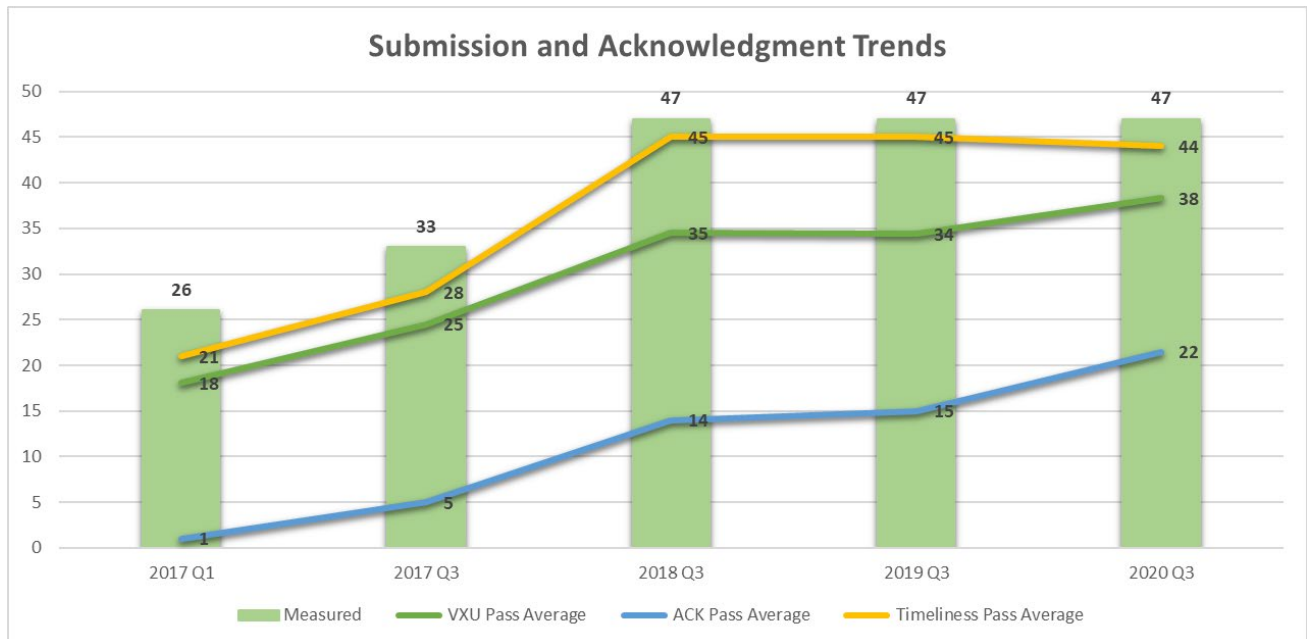
This remeasurement showed progress in the following areas:

- **Reduction in "Does Not Meet" outcomes:** The percent of measures with a Does Not Meet outcome across all IIS and all measures is currently at 19%. This is down from 35% Does Not Meet outcome rate during the initial baseline. Over the same period, we have seen an increase in IIS being measured and number of measures.
- **Accepts minimally required messages:** 23 IIS can now accept messages that contain only the required fields as specified by the National IG (Measure 10). This is an increase of 10 IIS since the initial baseline. Another 8 IIS have local law or policies which require additional data be submitted, yet in line with HL7 V2 constrainable standards.

This remeasurement showed challenges in the following area:

- **Barcode VIS:** Barcode VIS continues to be the largest single barrier—30% of all failures—to some IIS passing Submission Measures 1, 3, 4, 5, 10, 11, 15, and 16.

Remeasurement

The next remeasurement for Submission and Acknowledgment Assessment will take place in Quarter 4 of 2020, and we hope to show increases in both the number of IIS who are measured and in IIS that meet measures and tests for this content area of measurement.

The limitations section below notes that one of the primary limitations in the accuracy of this report is the inconsistency in the IIS ACK despite the National IG. At some point in the future, remeasurements will assess and raise the bar on ACK consistency in Measures 1–11 and 15-16 to ensure consistent application of the measures and outcomes across all measured IIS.

Limitations of Report

- **Focus on HL7, not functional outcomes:** This content area of Assessment focuses (as much as possible) on HL7 alignment, not necessarily on functional outcomes. For example, Measure 5 focuses on deleting a vaccination event which was previously submitted. The acknowledgment message from the IIS is used to assess the submitted vaccine update (VXU) message containing the deletion. An ACK indicating the IIS accepted the VXU results in a passing measure. Further work is needed to determine if the vaccination event was actually deleted.
  - **Impact on Assessment:** IIS might pass HL7 conformance but not actually be performing the underlying function.
- **Acknowledgment inconsistencies:** Acknowledgments are improving, but non-standard acknowledgment messages are still present. This inconsistency makes understanding the difference between a warning and a rejection difficult to discern across the entire landscape of IIS interfaces.
  - **Impact on Assessment:** This problem can be both a false positive and a false negative. IIS might actually accept the message, but the assessment process determines the message was rejected. Conversely, some IIS might actually reject a message, but the assessment process determines the IIS accepted the message.
- **Auto-Accept IIS:** Two IIS return a positive ACK (MSA-1 = AA) all of the time regardless of the message quality.
  - **Impact on Assessment:** Measures 1–11 and 15–16 (the Submission measures) use the ACK message to determine acceptance or rejection of the message. IIS that auto-accept the data may actually reject the data later on in processing, but this goes unnoticed. The IIS is noted as meeting the National IG when, in fact, it does not accept some of the data the way its ACK implies.
- **Release 1.5 Focus:** It is important to keep in mind that this content area of measurement looks at IIS alignment with the National IG and many IIS are in the

midst of the planning or implementation process of enhancing their systems to align with this guide.

- o **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 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 to successfully communicate with certified electronic health records (EHRs) in a standardized way.
2. Accepting VIS data is problematic for a significant number of IIS. There is also a growing discussion nationally on the value and need for this data in an IIS. VIS data alone negatively impacted 8 of the 13 Submission measures. National direction is needed on commitment to VIS data or removal of VIS data as a key data element for IIS to capture, maintain, and use.
3. Refusals, adverse events, contraindications, and immunities proved to be challenging to construct and submit to IIS in part due to the looser-than-normal requirements in the National IG. As such, this resulted in varied implementations of the standard for IIS that accept this type of data. Improving future National IGs will help stabilize these messages and implementation thereof. In the meantime, guidance should be provided to implementers who are planning for the future or looking to improve on this area of their IIS.
4. IIS should closely review identified cases where the IIS "Deviates from the National Standard" to see if they can align with the National IG while still meeting their business needs. This measurement process has now discovered 14 distinct local requirements among 8 IIS. Two questions should be asked when reviewing deviations:
   a. Can I live without this data and still accept the message?
   b. Is the data I'm getting today in this field accurate and of good quality, or is it sometimes default or filler data (e.g., 100 Main St., abnormal percentage of intramuscular shots, etc.) to meet my additional local requirements?
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.

6. 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.

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 IIS either deviated from or did not meet the Submission and Acknowledgment Assessment measures.

Submission Measures

Measures 1–11 and 15-16 focus on the submission of data to the IIS via the VXU message. The following reasons were uncovered during Assessment for why an IIS "Deviates" or "Does Not Meet" the National Standard.

Deviates from Standard	Does Not Meet
Requires address: The IIS will reject the message without patient address information.	**Rejects valid HL7:** It is possible that an IIS doesn't collect certain data, but it is important that an IIS react to this data appropriately when a conformant message is submitted. In several cases, IIS respond with an error indicating the VXU submission had an error when, in fact, the limitation is on the IIS in receiving valid HL7. There is nothing within the HL7 standard the VXU submitter can do to correct the message and have the IIS accept the message. Rather the IIS should return an informational message the data is not currently collected. These responses were isolated to messages containing deletes (Measure 5), refusal (Measures 7, 10), adverse event (Measures 8, 10), contraindication/immunity (Measures 9, 10), or partial administration (Measure 11).
Requires at least 1 vaccination or the patient exist in IIS: The IIS requires that at least one vaccination event be included in a message or the patient be already in the IIS. Refusal (Measures 7, 10), adverse event (Measures 8, 10), and contraindication/immunity (Measures 9, 10) all submit the message without a	**No ACK, unclear ACK:** Depending upon the message submitted, the IIS responded to the VXU in such a way that it wasn't clear what the IIS did with the data. In all of these cases, the IIS either didn't respond or responded with plain text (e.g., not HL7) or an ACK that said there was a problem but nothing more (e.g., it couldn't be determined what the problem was). These

vaccination event but are rejected unless a vaccination event is also included.	responses were isolated to messages related to refusal (Measures 7, 10), adverse event (Measures 8, 10), or contraindication/immunity (Measures 9, 10).
Requires route: The IIS will reject administered vaccination events without route of administration being supplied.	**Rejects barcode VIS:** Release 1.4 (8/1/2012) of the National IG introduced a way to message the VIS presentation as a barcode. Starting with release 1.5 (10/1/2014) of the National IG, the barcode method is the preferred approach over legacy methods for submitting the VIS data to the IIS. EHRs preparing for Promoting Interoperability through certification are being required to submit VIS using the barcodes. The inability to accept VIS affected Measures 1, 3, 4, 5, 10, and 11, which all had at least one test containing a barcoded VIS as part of the message.
Requires consent: The IIS will reject the message without proper consent in the message. This is Required but may be Empty (RE) in the National IG.	**Rejects valid CVX and MVX codes:** IIS rejected valid CVX & MVX codes which are regularly used (e.g., MMR, Hep A, and various unspecified vaccines).
Requires race: The IIS will reject the message without patient race being supplied.	**Rejects messages with valid NDC:** The IIS is unable to process a message with NDC regardless if CVX is submitted or not.
Requires VFC eligibility on historical doses: The IIS will reject historical vaccination events unless VFC eligibility is supplied.	
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.	

Requires body site: The IIS will reject administered vaccination events without body site being supplied.	
Requires a zip code: The IIS will reject the message without a zip code for the patient. This field is Required but may be Empty (RE) in the National IG.	
Requires CVX with NDC: The IIS requires CVX codes when NDCs are being submitted or the IIS will reject the message.	

Acknowledgment Measures

All measures use the ACK from the IIS to determine the outcome of processing, but only two measures (Measures 12 and 13) focus explicitly on the technical conformance of the ACK.

Measure 12

The purpose of this measure is to validate the conformance of the ACK message when a conformant VXU message is submitted.

Deviates from Standard	Does Not Meet
Populates X Usage Field: The IIS populates a field in the ACK with a defined usage of X (Not Supported) in the National IG. This is usually for backwards compatibility. IIS should be aware that EHRs will likely not read this field given its defined usage of X in the National IG.	**Supplied correct answer but failed HL7 conformance:** IIS accepted the basic message containing one historical vaccination event, but the ACK response stating acceptance did not meet the technical conformance per the National IG.

Measure 13

The purpose of this measure is to validate the conformance of the ACK message when a problematic message is submitted to the IIS. The measure contains two tests, so some IIS show up in more than one row below.

Deviates from Standard	Does Not Meet

	Supplied correct answer but failed HL7 conformance: IIS identified the problem with the message and returned an ACK indicating the data problem, but the ACK(s) did not meet the technical conformance per the National IG.
	Appeared to accept message: IIS did not return an ACK indicating a problem with the poor data in the message. The IIS appears to have accepted the data.

Timeliness Measure

Measure 14 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 VXU messages. The total number of VXUs submitted as part of the assessment process was 55. This means the IIS was permitted to respond more slowly than five seconds on only three of those submissions, 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.

Deviates from Standard	Does Not Meet
	Did not respond within 5 seconds 95% of the time: The percentages below are the percentage of times the respective IIS returned a response within 5 seconds and thus fell short of the 95% threshold. • 0% • 87% - 2 IIS