AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Submission and Acknowledgment Assessment

Aggregate Report

2023 – Quarter 1

M&I
MEASUREMENT & IMPROVEMENT

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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.

Testing and Discovery (T&D) is the first stage of the overall IIS M&I process. The next stage is IIS Assessment. The results from T&D are used to design the final measures and tests for the IIS Assessment process, which also relies on IIS Functional Standards and operational guidance statements. The final 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 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. **Submission and Acknowledgment** is the second content area of the M&I Initiative, and this report contains the aggregate results of the IIS Assessment remeasurement completed in **Quarter 1 of 2023**. This process will be repeated in Quarter 2 of 2023 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 National Institute of Standards and Technology (NIST) Immunization Test Suite Validation Tool. This tool provides consistent conformance-based results for all IIS that are measured. In addition, the technical requirements for data Submission and Acknowledgment are documented in the HL7 Version 2.5.1: Implementation Guide for Immunization Messaging, Release 1.5 and associated addendum. 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.

Submission and Acknowledgment Measures

Submission and Acknowledgment (Sub/Ack) Assessment spans 16 measures and is guided by the following Functional Standards. Visit the AIRA repository to review the detailed measures and tests for Sub/Ack.

> **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 1.6:** The IIS assures the receipt, processing, and storage of demographic and vaccination data elements as endorsed by CDC.
>
> **Functional Standard 3.6:** 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 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 National Drug Code (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 to share data (i.e., patient data are protected).
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.
14. The IIS responds to a submission with an ACK within five 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 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 using 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 total, 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 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.
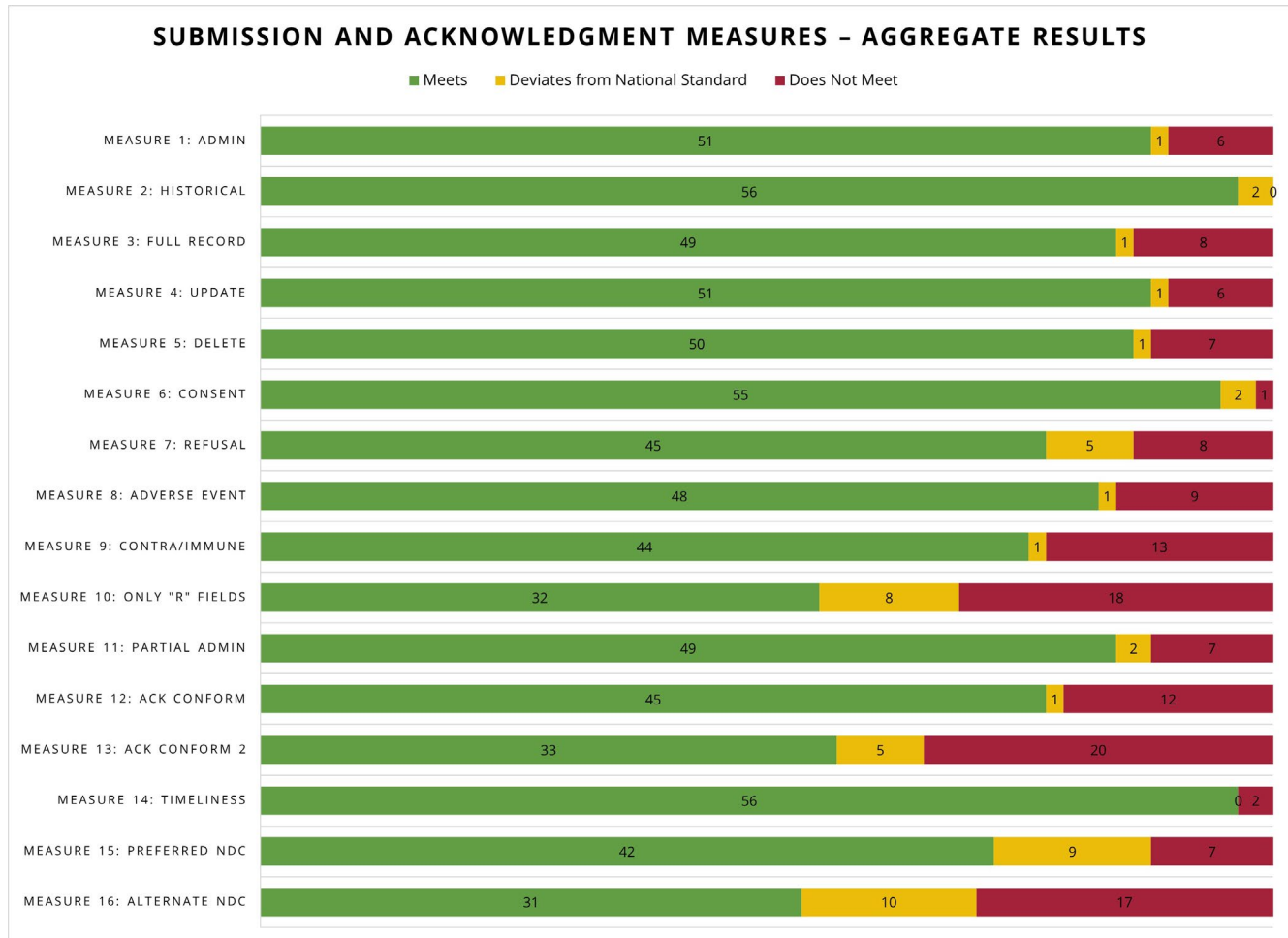
Measure Outcomes

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 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" because that is the lowest test outcome. To meet a measure, all test outcomes must be categorized as "meets."

Results

Sixty-one[1] IIS were encouraged to be measured in the Sub/Ack Assessment. Of the 61 participating IIS,[2] **58 (95%)** could be measured and are included in this report.

SUBMISSION AND ACKNOWLEDGMENT MEASURES – AGGREGATE RESULTS

■ Meets ■ Deviates from National Standard ■ Does Not Meet

Measure	Meets	Deviates	Does Not Meet
MEASURE 1: ADMIN	51	1	6
MEASURE 2: HISTORICAL	56	2	0
MEASURE 3: FULL RECORD	49	1	8
MEASURE 4: UPDATE	51	1	6
MEASURE 5: DELETE	50	1	7
MEASURE 6: CONSENT	55	2	1
MEASURE 7: REFUSAL	45	5	8
MEASURE 8: ADVERSE EVENT	48	1	9
MEASURE 9: CONTRA/IMMUNE	44	1	13
MEASURE 10: ONLY "R" FIELDS	32	8	18
MEASURE 11: PARTIAL ADMIN	49	2	7
MEASURE 12: ACK CONFORM	45	1	12
MEASURE 13: ACK CONFORM 2	33	5	20
MEASURE 14: TIMELINESS	56	0	2
MEASURE 15: PREFERRED NDC	42	9	7
MEASURE 16: ALTERNATE NDC	31	10	17

The following high-level observations provide additional context for reading and interpreting the aggregate results graph:

- **Barcode VIS:** All measures processing an administered dose[3] included at least one barcoded VIS (Vaccine Information Statement).

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[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.

[3] Includes Measures 1, 3, 4, 5, 10, 11, 15, 16

Submission/Acknowledgment Assessment Report, Q1 2023
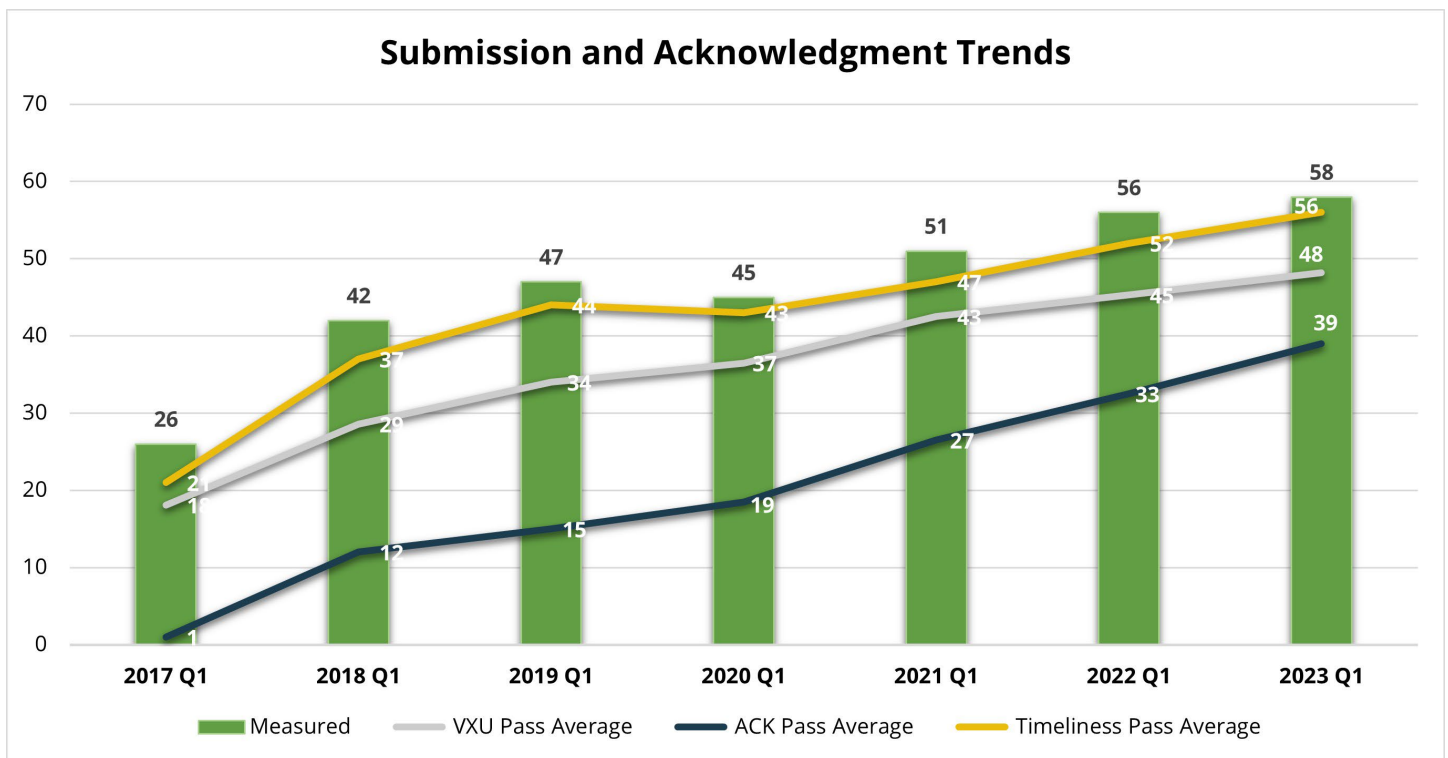Remeasurement 24

- Five IIS were unable to process messages that contained a barcoded VIS. This accounted for 30 (28%) of the 107 "does not meet" outcomes across Submission-related Measures 1–11 and 15-16.

- **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 had 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. Passing success varied widely among IIS.

- **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."

Please refer to Appendix A for additional details that contribute to IIS measure deviations and/or nonalignment.

Summary of Progress

This remeasurement demonstrated progress in the following areas:

Submission and Acknowledgment Trends

- **Reduction in "does not meet" outcomes:** The percent of measures with a "does not meet" outcome across all IIS and all measures is currently 15%.
  - This is a decrease from the initial baseline rate of 35%.
  - Over the same period, we have seen an increase in IIS participation and an increase in the number of measures against which IIS are measured.
- **Accepts minimally required messages:** Thirty-two IIS can now accept messages that contain only the required fields as specified by the National IG (Measure 10).
  - This is an increase of 20 IIS since the initial baseline.
  - Another eight IIS have local laws or policies that require additional data be submitted, although they remain within HL7 V2 constrainable standards.

This remeasurement revealed challenges in the following area:

- **Barcode VIS:** Barcode VIS accounts for 28% of all failures and continues to be the largest single barrier for some IIS to pass Submission-related Measures 1, 3, 4, 5, 10, 11, 15, and 16.

Remeasurement

The next remeasurement for Submission and Acknowledgment Assessment will take place in Quarter 2 of 2023. 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.

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 focuses primarily on HL7 alignment and not necessarily on functional outcomes. For example, Measure 5 focuses on deleting a vaccination event that 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 is a passing measure. Further work is needed to determine if the vaccination event was deleted from the record.
  - **Impact on assessment:** IIS may pass HL7 conformance but not actually be performing the underlying function.
- **Auto-accept IIS:** Two IIS always return a positive ACK (MSA-1 = AA), regardless of the message quality.
  - **Impact on assessment:** Submission-related Measures 1–11 and 15–16 use the ACK message to determine acceptance or rejection of the message. IIS that auto-accept the data may reject the data later during processing, but this will not change the result of the initial test. 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.

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 to successfully communicate with certified electronic health records (EHRs) in a standardized way.

2. VIS data value and impact
   a. Accepting VIS data is problematic for a significant number of IIS. There is also a growing national discussion on the value and need for these data in an IIS. VIS data alone negatively impacted 8 of the 13 Submission measures. National direction is needed on commitment to or removal of VIS data as a key data element for IIS to capture, maintain, and use.

3. Refusals, adverse events, contraindications, and immunities
   a. These data proved to be challenging to construct and submit to IIS in part due to the more flexible requirements in the National IG. As such, this resulted in varied implementations of the standard for IIS that accept these types 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 or looking to improve on this area of their IIS.

4. Review deviations to assess opportunities
   a. 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. Two questions should be asked when reviewing deviations:
      i. Can I live without these data and still accept the message?
      ii. Are the data I'm getting today in this field accurate and of good quality, or are they sometimes default or filler data to meet my additional local requirements (e.g., 100 Main St., abnormal percentage of intramuscular shots, etc.)?

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.

6. Leverage the NIST conformance tool
   a. 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/iztool/#/cf and is free to use without installation or registration.

Questions? Comments?

Submit your questions and 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 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 deviated or did 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 does not collect certain data, but it is important that an IIS react to those 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 that the data are 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 one vaccination or that the patient exist in IIS: The IIS requires that at least one vaccination event be included in a message or that the	**No ACK, unclear ACK:** Depending on the type of message submitted, the IIS generated response messages that were unclear about how the data was processed.

patient record currently exist in the IIS. Refusals (Measures 7, 10) submit the message without a vaccination event but are rejected unless a vaccination event is also included.	In some cases, the IIS did not respond at all, while in others, it provided plain text responses that were not in HL7 format, or an ACK message indicating a problem without further details. These issues were mainly isolated to messages related to full record (Measure 3), consent (Measure 6), refusal (Measures 7, 10), adverse event (Measures 8, 10), or contraindication/immunity (Measures 9, 10).
Requires ethnicity: The IIS will reject the message without Ethnicity (PID-22). This field is required but may be Empty (RE) in the National IG.	**Rejects barcode VIS:** Release 1.4 (August 1, 2012) of the National IG introduced a way to message the VIS presentation as a barcode. Starting with release 1.5 (October 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, 11, 15, and 16, all of which had at least one test containing a barcoded VIS as part of the message.
Requires VFC eligibility on historical doses: The IIS will reject historical vaccination events unless VFC eligibility is supplied.	**Rejects valid CVX and MVX codes:** IIS rejected valid, routinely used CVX and MVX codes (e.g., MMR, HepA, and various unspecified vaccines).
Requires CVX with NDC: The IIS requires CVX codes when NDCs are being submitted, or the IIS will reject the message.	**Rejects messages with valid NDC:** The IIS is unable to process a message with NDC, regardless of if CVX is submitted.

Requires lot number: The IIS requires lot number for all vaccination events, or the IIS will reject the message.	**Overuse of "error" severity:** The IIS returns informative ACK messages with proper levels of detail but uses the severity of "E" in ERR-4 for all errors, which implies the IIS is rejecting the message when in fact it is not always rejecting the message.
Requires ordering provider: The IIS will reject the message without ordering provider information.	

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
User Message is too long: The IIS populates ERR-8 (User Message) with a length that exceeds the HL7 standard of	**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 technical conformance per the National IG.
250 characters. This could lead to truncation by the receiving EHR system.	
	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 focuses 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 VXU messages. The total number of VXUs submitted as part of the assessment process was 67. 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 preproduction 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 five seconds 95% of the time: The percentages below are the percentage of times the respective IIS returned a response within five seconds and thus fell short of the 95% threshold. • 0% - 2 IIS