AIRA

AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Submission and Acknowledgement Assessment

Aggregate Report

2018 – Quarter 2

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 inform the IIS Assessment process which is heavily informed by IIS Functional Standards[1] and Operational Guidance Statements. A third step 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 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. Submission and Acknowledgement Assessment is the second official measurement area for IIS Assessment and this report contains the aggregate results of the re-measurement completed in quarter 2, 2018. This process will be repeated in quarter 3, 2018 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 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] http://ois-pt.org/dqacm/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 in conjunction with each jurisdiction's individual report, can provide valuable information to guide ongoing and upcoming enhancements.

Submission and Acknowledgement Measures

The Submission and Acknowledgement Assessment[6] spans 14 measures in all and are guided by the following Functional Standards.

> **Functional Standard 1.5:** The IIS can receive submissions 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.
>
> **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 Acknowledgement Assessment measures which are reported in this document. Note that Measures 1-11 focus on submission, 12-13 focus on acknowledgement, and 14 focuses on timeliness.

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 which results in a contraindication or immunity to a vaccine preventable disease.
10. The IIS processes messages in accordance with the HL7 2.5.1, release 1.5 guide.
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.

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., 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, 25 test cases were developed, reviewed, and approved across the 14 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 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.
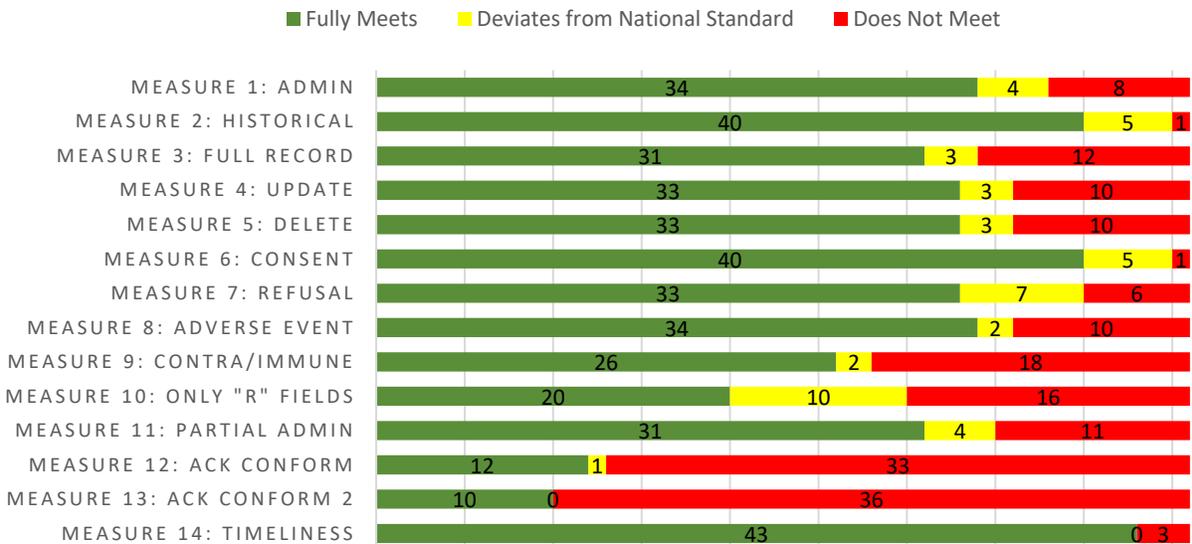
Measure Outcomes

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

58 IIS (which includes all 50 states, plus CNMI, D.C., Guam, New York City, Philadelphia, Puerto Rico, San Diego, and the Virgin Islands) were encouraged to voluntarily participate in the IIS Assessment. Of the 58, 56 (97%) IIS opted to participate in the IIS Submission and Acknowledgement Assessment for the re-measure in quarter 2, 2018.

Of the 56 IIS participating in the Submission and Acknowledgement Assessment baseline, 46 were able to be measured. AIRA was unable to connect to 10 IIS at the time of this report and they are not included in the results below.

## SUBMISSION AND ACKNOWLEDGEMENT - AGGREGATE RESULTS

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

Measure	Fully Meets	Deviates from National Standard	Does Not Meet
MEASURE 1: ADMIN	34	4	8
MEASURE 2: HISTORICAL	40	5	1
MEASURE 3: FULL RECORD	31	3	12
MEASURE 4: UPDATE	33	3	10
MEASURE 5: DELETE	33	3	10
MEASURE 6: CONSENT	40	5	1
MEASURE 7: REFUSAL	33	7	6
MEASURE 8: ADVERSE EVENT	34	2	10
MEASURE 9: CONTRA/IMMUNE	26	2	18
MEASURE 10: ONLY "R" FIELDS	20	10	16
MEASURE 11: PARTIAL ADMIN	31	4	11
MEASURE 12: ACK CONFORM	12	1	33
MEASURE 13: ACK CONFORM 2	10	0	36
MEASURE 14: TIMELINESS	43	0	3

Of the 46 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) included at least one barcoded VIS. Eight (8) IIS were unable to process messages that contained a barcoded VIS. This accounted for 48 (47%) of the 103 "Does Not Meet" outcomes across Measures 1 – 11 (the submission measures).
- **Measure 10:** Measure 10 repeats Measures 1, 2, 7, 8, and 9, but only supplies the minimal amount of data required by the National IG. IIS who were unable to process a message when fully supplied in earlier measures, also were not able to process the messages when minimally supplied in all but one IIS. 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.

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

Summary of Progress

Submission and Acknowledgement Trends
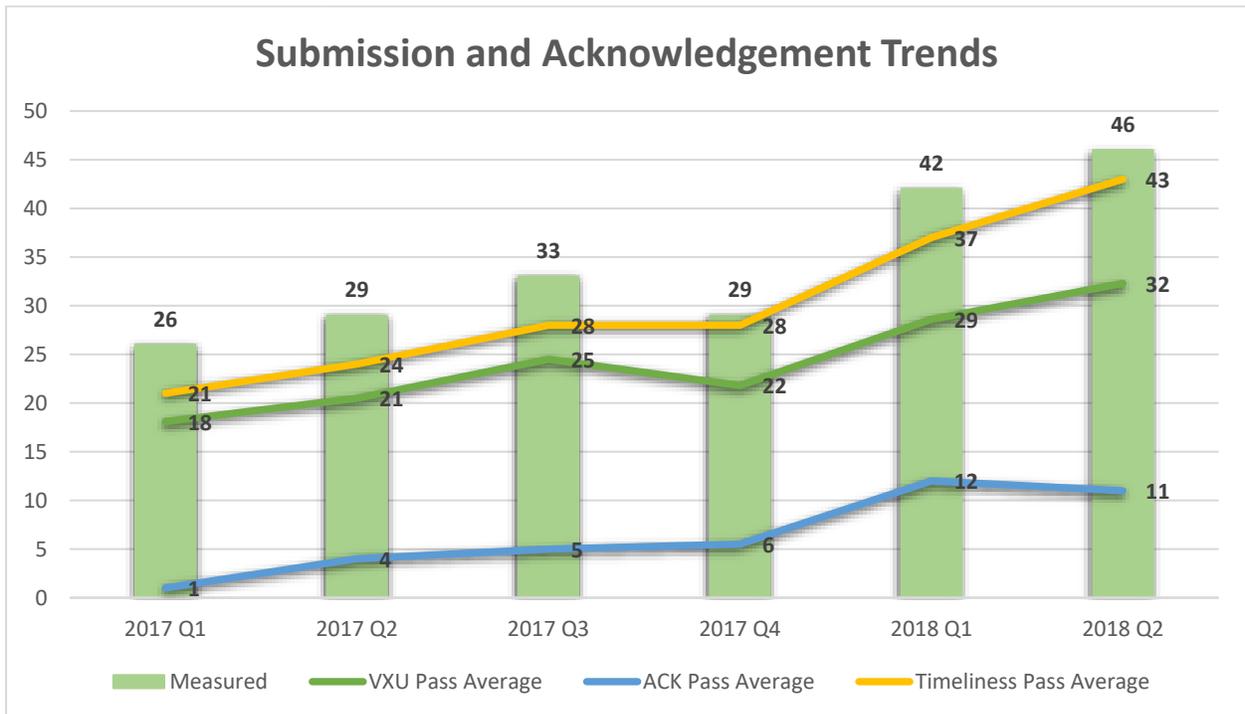
This re-measurement showed progress in the following areas:

- **Increase in Participation:** 56 IIS agreed to participate in this measurement. This is an increase of 28 IIS since the initial baseline. The large jump in 2018 Q1 was due to a change in the Measurement and Improvement program to auto-enroll IIS for participation. IIS are still able to opt-out of participating should they wish.
- **Reduction in "Does Not Meet" outcomes:** The percent of measures with a Does Not Meet outcome across all participants and all measures is currently at 27.2%. This is down from 35.4% Does Not Meet outcome rate during the initial baseline.
- **Passed all measures:** 7 IIS have successfully passed all measures and tests. No IIS passed all measures during the initial baseline measure.
- **Accepts Minimally Required Messages:** 20 IIS can now accept messages which only contain the required fields as specified by the National IG (Measure 10). This is an increase of 9 IIS since the initial baseline.

This re-measurement showed challenges in the following areas:

- **Barcode VIS:** Barcode VIS continues to be the largest single barrier – 47% of all failures – to some IIS passing Submission Measures 1, 3, 4, 5, 10, and 11.

Re-measurement

The next re-measurement for Submission and Acknowledgement Assessment will take place in quarter 3, 2018, 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.

The limitations section below notes 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, re-measurements will assess and raise the bar on ACK consistency in Measures 1-11 to ensure consistent application of the measures and outcomes across all participants.

Limitations of Report

- **Focus on HL7, not functional outcomes:** This phase 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 acknowledgement (ACK) message from the IIS is used to assess the submitted (VXU) message containing the delete. 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 performing the underlying function.
- **Acknowledgement (ACK) inconsistencies:** Acknowledgements (ACK) continue to be quite variable and non-standard. 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:** Some IIS return a positive Acknowledgment (MSA-1 = AA) all of the time regardless of the message quality.
  - **Impact on Assessment:** Measures 1-11 (the submission measures) use the Acknowledgement message to determine acceptance or rejection of the message. IIS who auto-accept the data, may actually reject the data later on in processing but this goes unnoticed. The IIS is noted as fully meeting the national IG when, in fact, they do not accept some of the data the way their ACK implies.

- **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.
- **Meaningful Use Stage 3 Readiness:** One item above and beyond release 1.5 is the use of NDC codes – rather than CVX codes – for administered vaccines. This first baseline used CVX codes for administered vaccines given the pulse of the community and testing and discovery work performed to date. At some point in the future, the tests will be changed to submit NDC codes for administered vaccines.
    - **Impact on Assessment:** Measures 1, 3, 4, 5, 10, and 11 all submit administered vaccines, but do not submit an NDC at this time. This limits the understanding of true technical readiness for Meaningful Use.

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 as we move closer to Meaningful Use Stage 3 where certified EHRs are required to consume ACK messages per the National IG.
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 six of the 11 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 who 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 amongst eight 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 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.

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 "Did Not Meet" the Submission and Acknowledgement Assessment measures.

Submission Measures

Measures 1-11 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 From" or "Does Not Meet" the National Standard.

Deviates From Standard	Does Not Meet
(9 IIS) Requires Address: The IIS will reject the message without Patient Address information.	**(13 IIS) Rejects valid HL7:** It is possible that an IIS may not 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 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), refusals (Measures 7, 10), adverse events (Measures 8, 10), contraindications/immunities (Measures 9, 10), or Partial Administrations (Measure 11).
(5 IIS) 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. Refusals (Measures 7, 10), adverse event (Measures 8, 10), and contraindication/immunity (Measures 9, 10) all submit the message without a	**(10 IIS) 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, responded with plain text (e.g., not HL7), or an ACK which dictated a problem, but nothing more (e.g., it couldn't

vaccination event but are rejected unless a vaccination event is also included.	be determined what the problem was). These responses were isolated to messages related to consent (Measure 6), refusals (Measures 7, 10), adverse events (Measures 8, 10), or contraindications/immunities (Measures 9, 10).
(3 IIS) Requires Route: The IIS will reject administered vaccination events without route of administration being supplied.	**(8 IIS) Reject 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 preferred approach over legacy methods for submitting the VIS data to the IIS. EHR's preparing for Meaningful Use Stage 3 through certification are being required to submit VIS using the barcodes. The inability to accept VIS affected Measures 1, 3, 4, 5, 10, 11 which all had at least one test containing a barcoded VIS as part of the message.
(2 IIS) 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.	**(4 IIS) Reject valid CVX codes:** IIS rejected CVX codes which were valid and regularly used (MMR, Hep A, and various unspecified vaccines).
(1 IIS) Requires Body Site: The IIS will reject administered vaccination events without body site being supplied.	**(1 IIS) Rejected duplicate immunization in incoming record:** The IIS rejected a possible duplicate immunization record in the HL7 message. This was in Measure 3 (full record) which contains numerous vaccination events. It wasn't clear which two immunizations were considered duplicates based on the ACK message. A manual review of the submitted message couldn't identify the duplicate either.

(1 IIS) Requires Race: The IIS will reject the message without patient race being supplied.	
(1 IIS) Requires VFC eligibility on historical doses: The IIS will reject historical vaccination events unless VFC eligibility is supplied.	
(1 IIS) Requires Patient Primary Facility: The IIS will reject the message without the patient primary facility (PD1-3) which is an optional field in the National IG.	
(1 IIS) Requires Administration End Date: The IIS will reject the message without the administration End Date (RXA-4) which is an optional field in the National IG.	
(1 IIS) Requires specific code for MRN: The IIS will reject the message without MRN codes being defined as "PI" in PID-3.5. Most examples in the community use "MR". Most IIS accept either code to represent the EHR identifier.	
(1 IIS) Requires Batch segments: The IIS will reject the message without proper Batch Header and Trailer Segments (BHS/BTS). These referenced in the IG and optional to include per the base HL7 standard, but not specifically part of the VXU profile in the Immunization IG.	
(1 IIS) 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.	
(1 IIS) Requires Administering Provider: The IIS will reject the message without Administering Provider (RXA-10) populated	

on administered doses (RXA-9 = 00). This is Required but may be Empty (RE) in the National IG.	
(1 IIS) Requires Completion Status for contraindications: The IIS will reject the contraindication if Completion Status (RXA-20) is not set to "NA" for "Not Administered". This is Required but may be Empty (RE) in the National IG.	
(1 IIS) Requires Responsible Person for minors who are VFC eligible: The IIS will reject the message without a responsible person (NK1 segment) for minors who are VFC eligible. The NK1 segment is Required but may be Empty (RE) in the National IG.	
(1 IIS) 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.	
(1 IIS) Requires Birth Order: The IIS will reject the message without Birth Order (PID-25) being populated. This is Required but may be Empty (RE) when PID-24 is valued "Y" or Optional (O) when PID-24 is not valued "Y" in the National IG.	
(1 IIS) Requires Ethnicity: The IIS will reject the message without Ethniticy (PID-22). This is Required but may be Empty (RE) in the National IG.	

Acknowledgement Measures

All measures use the Acknowledgement (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
(1 IIS) 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 it's defined Usage of X in the National IG.	**(33 IIS) 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
	(33 IIS) Supplied correct answer, but failed HL7 conformance: IIS identified the problem with the message and returned an acknowledgement (ACK) indicating the data problem, but the ACK(s) did not meet the technical conformance per the National IG.
	(6 IIS) Appeared to accept message: IIS did not return an acknowledgement (ACK) indicating a problem with the poor data in the message. The IIS appears to have accepted the data.
	(2 IIS) No HL7 ACK response: IIS did not return an ACK, but rather plain text indicating there was a generic error.

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 fully meet this measure the IIS needed to respond within 5 seconds for 95% of the VXU messages. The total number of VXU's submitted as part of the assessment process was 55. This means the IIS is only able to respond slower than 5 seconds on 3 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 may not put as much emphasis on performance as production environments do.

Deviates From Standard	Does Not Meet
	(3 IIS) Did not respond within 5 seconds 95% of the time: The percentages below are the percentage of time the IIS returned a response within 5 seconds and thus fell short of the 95% threshold. • 76% • 62% • 56%