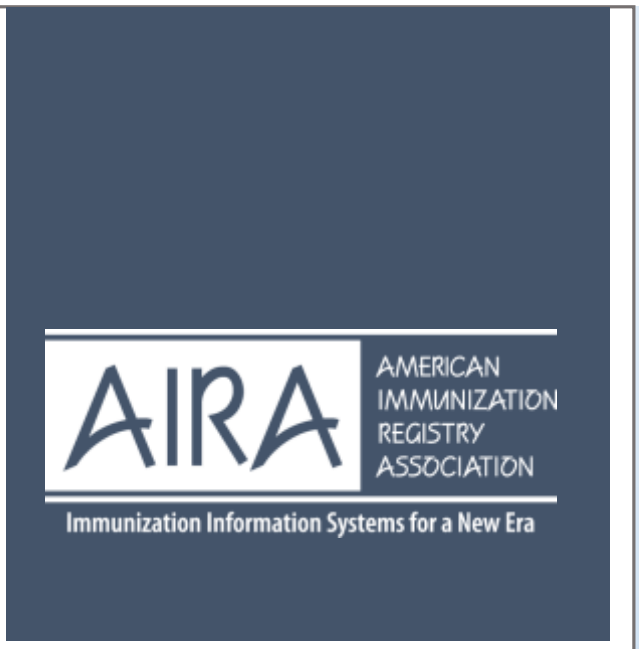

Measures and Tests for Assessment

Message Submission and Acknowledgement

Measurement for Assessment and Certification Advisory Workgroup (MACAW)

November 18, 2016

Background and Context

The consolidation of immunization records from multiple sources is a primary function of Immunization Information Systems (IIS)[1]. To ensure complete, accurate and timely consolidated records, IIS must receive data from a high proportion of immunizers within their catchment area through standardized reporting channels. Messaging standards have been present across the IIS community for more than twenty years, and have increasingly gained importance as Electronic Health Record (EHR)-IIS interoperability has grown in necessity across health care. The primary standard for IIS messaging is the HL7 Version 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5[2].

In 2016, AIRA convened the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to develop and propose measures for IIS Assessment. Submission measures and tests will be the second phase to be developed. These measures and tests will be shared with the AIRA Board of Directors and the full AIRA community to ensure broad community input and agreement.

Functional Standards

The use of standardized messaging is referenced throughout the 2013-2017 IIS Functional Standards[3] and Operational Guidance Statements. The revised IIS Functional Standards were developed by the Immunization Information Systems Support Branch, CDC/NCIRD, through a consensus-based process involving input from a variety of IIS managers and technical experts from across the U.S. They are intended to lay a framework for the development of IIS through 2017, and represent the standards all IIS should meet by the end of 2017. The Operational Guidance Statements were released in 2016 to provide further guidance to the IIS community about how to achieve the functional standards and to inform the development of measures for achievement. The following Functional Standards and Operational Guidance Statements are included – at some level – in the MACAW measures and tests defined in this document.

Programmatic Goal 1: Support the delivery of clinical immunization services at the point of immunization administration, regardless of setting.

> **Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport
>
> > **OGS** 1.5.1: IIS returns an ACK for every received VXU message consistent with the CDC-endorsed HL7 IG. (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)
> >
> > **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)

Programmatic Goal 3: Maintain data quality (accurate, complete, timely data) on all immunization and demographic information in the IIS.

> **Functional Standard 3.4:** The IIS can store all Core Data Elements.
>
> > **OGS 3.4.1:** The IIS can receive and store all core data elements as endorsed by CDC, from the IIS User Interface and from electronic data transfer.
>
> **Functional Standard 3.6:** The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner.

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[1] http://www.cdc.gov/vaccines/programs/iis/about.html
[2] http://www.cdc.gov/vaccines/programs/iis/technical-guidance/downloads/hl7guide-1-5-2014-11.pdf
[3] http://www.cdc.gov/vaccines/programs/iis/func-stds.html

OGS 3.6.1: Demographic only information (for non-birth records) and historical vaccination records received by IIS are processed and posted to production within 72 hours of submission.

OGS 3.6.4: The IIS has the ability to capture complete and incomplete/partial administered doses.

Measures and Tests

MACAW convened an in-person meeting the week of July 25th to define measures and high-level scenarios for submission of immunization related data to an IIS and querying for immunization related data within an IIS. This document focuses on the measures and tests for submission of immunization related data to an IIS. A companion document focuses on measures and tests for querying for immunization related data within an IIS.

Measures

The following submission measures were consented and are further defined in the remainder of this document.

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.
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.

Tests

The in-person meeting also developed a few high-level scenarios and expectations for each measure. A scenario laid out a common situation an IIS should be able to process (e.g., 12-month old received an MMRV). An expectation defined how an IIS should respond based on the scenario. These scenarios and expectations were used to create detailed test cases for each measure. 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" 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 negative or edge cases at this stage and will help maintain a manageable number of test cases. Testing and Discovery (aka: The AART pentagon report) has a significant number of edge and negative test cases.

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 published national standards. Once each test case is executed against an IIS, the IIS is slotted into 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.

Submission measures (1 through 11) use the ACK to validate if the IIS processed the message. This does not imply storage. MACAW discussed querying the IIS to determine storage during Submission tests, but opted against this for two major reasons.

1) This methodology would require IIS to have Query (QBP/RSP) capabilities in order to participate in submission assessment which seemed an unnecessary burden to participation
2) There is no guarantee that because an IIS stored a piece of data, that it would be returned.

Additionally, there are future phases of assessment which are looking into storage data.

Measure and Test Layout

Each measure – and associated test cases – are defined in the following structured layout.

MEASURE <*n*>:

The IIS …<*measure statement*>

Purpose	**Supports**
The purpose section defines why this measure is important to the IIS community and why IIS need to support it.	*This will be a list of which Functional Standard(s) (FS) and Operational Guidance Statement(s) (OGS) this measure supports. In some cases, the measure can only address part of an FS and/or OGS and this should be noted.*

Test Case	Test Case Expectations
This defines each test case in significant enough detail to describe the intent of the test case, what the test case is looking for, and what it isn't looking for. Further, a test case may involve more than one step (e.g., a VXU followed by a QBP). These need to be defined here.	*Test Case Expectations define what the IIS should do based on the Test Case. For example, the expectation could be that the IIS accept the submitted data and respond with a conformant ACK message.*
Subsequent test case and test case expectations will each be on their own row.	

Each test case will be detailed, but the goal is to define the test case and test case expectation as succinctly as possible. The final technical details of each test case will be in the HL7 message(s) corresponding to each test case.

MEASURE 1:

The IIS processes an administered vaccine for a patient.

Purpose	Supports
The processing of a vaccination event is the core of EHR to IIS electronic data exchange. The purpose is to measure that an IIS can process administered vaccination events in accordance with the National IG across common scenarios. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
1a) A patient receives an MMRV at age 12 months. The submission is fully populated with all nationally "required" (R) and "required, but may be empty" (RE) usage segments and fields including VIS and VFC information.	The IIS responds with an ACK indicating it has accepted the message.

MEASURE 2:

The IIS processes a historical vaccine for a patient.

Purpose	Supports
The processing of a vaccination event is the core of EHR to IIS electronic data exchange. The purpose is to measure that an IIS can process historical vaccination events in accordance with the National IG across common scenarios. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging). **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
2a) A patient brings an immunization record during a routine visit, and communicates that s/he received an MMR vaccine from a previous provider. The submission contains the following: **Patient Related Information:** All R, RE usage segments and fields are included. **Vaccination Event Related Information:** All R usage segments and fields are included.	The IIS responds with an ACK indicating it has accepted the message.

MEASURE 3:

The IIS processes the submission of a full immunization record for a patient.

Purpose	Supports
The processing of a full immunization record for a patient is necessary to support new provider onboarding where full patient histories are submitted to the IIS and in situations where a patient has paper records which are transcribed into an EHR and submitted to the IIS. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging). **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
3a) A one-year-old has received shots within a primary clinic and a separate clinic. A record including administered and historical vaccines is messaged to the IIS from an EHR. The EHR sends multiple vaccination events in one HL7 message. **Patient Related Information:** All R, RE usage segments and fields are included. **Vaccination Event Related Information:** Historical Vaccines will have only R usage segments and fields included. Historical vaccines will be prior to the one-year-old visit and will be all recommended vaccines at the appropriate time. Administered vaccines will be the one-year-old recommended vaccines. Administered vaccines will have all R and RE usage segments and fields included.	The IIS responds with an ACK indicating it has accepted the message.

MEASURE 4:

The IIS processes an update to a previously submitted vaccination event.

Purpose	Supports
The processing of an updated record is necessary to support error corrections of previously submitted vaccination events. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
4a) Two messages will be submitted. Both will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The second message is a correction to the vaccination date by 2 days submitted in the first message. The order filler number (ORC-3) is the same in both messages. The Action Code (RXA-21) is "A – Add" in the first message and "U – Update" in the second message.	The IIS responds with an ACK for each message indicating it has accepted each message. The ACK for the second message should not indicate the correction was ignored or otherwise not successful in updating vaccination event.
4b) Two messages will be submitted. Both will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The second message is a correction to the vaccination type (e.g., from Hep A to Hep B) submitted in the first message. The order filler number (ORC-3) is the same in both messages. The Action Code (RXA-21) is "A – Add" in the first message and "U – Update" in the second message.	The IIS responds with an ACK for each message indicating it has accepted each message. The ACK for the second message should not indicate the correction was ignored or otherwise not successful in updating vaccination event.
4c) Two messages will be submitted. Both will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The second message is a correction to the vaccination date by 2 days submitted in the first message. The order filler number (ORC-3) is different in the two messages. The Action Code (RXA-21) is "A – Add" in the first message and "U – Update" in the second message.	The IIS responds with an ACK for each message indicating it has accepted each message. However, the second ACK may indicate a warning or informational severity error that the order filler number (ORC-3) did not match previously submitted order filler numbers.

MEASURE 5:

The IIS processes a delete to a previously submitted vaccination event.

Purpose	Supports
The processing of a deleted record is necessary to support removal of previously submitted vaccination events which may have been submitted erroneously. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)

Test Case	Test Case Expectation
5a) Two messages will be submitted. Both will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The first message will contain two vaccination events. The second message will delete the first of the two vaccination events submitted in the first message. The order filler number (ORC-3) for the first shot is the same in both messages. The Action Code (RXA-21) is "A – Add" in the first message and "D – Delete" in the second message.	The IIS responds with an ACK for each message indicating it has processed each message per local business rules and policy. That is, not all IIS process deletes through HL7 or have policies in place where deletes are allowed in certain conditions, but not others. The ACK should be clear about the outcome of processing.

MEASURE 6:

The IIS processes a submission where the patient does not give consent (i.e., patient data is protected) to share data.

Purpose	Supports
The consent (e.g., opt-in, opt-out, consent, protection, etc.) laws vary from jurisdiction-to-jurisdiction. HL7 supports this through the use of a "Protection Indicator" and should be supported by IIS. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
6a) The patient does not consent to share their record. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including one vaccination event. The Protection Indicator (PD1-12) will be set to "Y – Protect the data (Do not share)".	The IIS responds with an ACK per local jurisdictional policy. For example, this could be any of the following: • A simple acceptance with or without an informational error message. • An error with severity (ERR-4) warning indicating the IIS does not accept patients who do not consent to share. • An error with severity (ERR-4) error indicating the jurisdictional policy is mandated and PD1-12 must be "N" or empty.
6b) The patient consents to share their record. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including one vaccination event. The Protection Indicator (PD1-12) will be set to "N – Do not protect (Sharing is OK)".	The IIS responds with an ACK indicating it has accepted the message.

MEASURE 7:

The IIS processes a refusal of a vaccination.

Purpose	Supports
The processing of a parent refusal of a vaccination event is a core data element for IIS to collect. This information can be used for AFIX visits and patient education indicators. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging). **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
7a) A parent refuses a vaccination for their child. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including one refusal. The Completion Status (RXA-20) will be "RE – Refusal". The Refusal Reason (RXA-18) will be one of the values from table NIP002	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the refusal was ignored or otherwise not successfully accepted by the IIS.

MEASURE 8:

The IIS processes an adverse event.

Purpose	Supports
The processing of an adverse event related to a vaccination event is a core data element for IIS to collect. This information can be used to contraindicate future vaccinations and inform physicians through query/response. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
8a) Two messages will be submitted. The first will be a vaccination event. The second will be an adverse event close in time (i.e., same day, next day) to the vaccination event. Both messages will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The adverse event will be a value from PHVS_VaccinationReaction_IIS (OID: 2.16.840.1.114222.4.11.3289).	The IIS responds with an ACK for each message indicating it has accepted each message. The ACK for the second message should not indicate the adverse event was ignored or otherwise not successfully accepted by the IIS.

MEASURE 9:

The IIS processes an observation about a patient which results in a contraindication or immunity to a vaccine preventable disease.

Purpose	Supports
The processing of an observation about a patient which may result in a contraindication or immunity is a core data element for IIS to collect. This information can be used to contraindicate or prevent unnecessary future vaccinations. The information can also be useful information for physicians through query/response. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response.

Test Case	Test Case Expectation
9a) A message will be submitted containing an observation about a patient. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The observation will be a value from PHVS_VaccinationContraindication_IIS (OID: 2.16.840.1.114222.4.11.3288) using LOINC 30945-0. The observation will have an effective date using LOINC 30946-8.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the observation was ignored or otherwise not successfully accepted by the IIS.
9b) A message will be submitted containing an observation about a patient. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The observation will be a value PHVS_EvidenceOfImmunity_IIS (OID: 2.16.840.1.114222.4.11.3293) using LOINC 59784-9	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the observation was ignored or otherwise not successfully accepted by the IIS.
9c) A message will be submitted containing an observation about a patient. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields. The observation will be a value from PHVS_SerologicalEvidenceOfImmunity_IIS (OID: 2.16.840.1.114222.4.11.7245) using LOINC 75505-8	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the observation was ignored or otherwise not successfully accepted by the IIS.

MEASURE 10:

The IIS processes messages in accordance with the HL7 2.5.1, release 1.5 guide.

Purpose	Supports
Release 1.5 of the HL7 2.5.1 implementation guide specifies the core requirements of an HL7 message across various vaccine-related information that can be submitted. The purpose of this measure is to measure IIS ability to accept messages when only the minimally required information is supplied. The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)

Test Case	Test Case Expectation
10a) Administered Immunization. The message will contain all R usage segments and fields. RE and O usage segments and fields will not be populated. The message will contain 1 administered dose.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the immunization was ignored or otherwise not successfully accepted by the IIS.
10b) Historical Immunization. The message will contain all R usage segments and fields. RE and O usage segments and fields will not be populated. The message will contain 1 historical dose.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the immunization was ignored or otherwise not successfully accepted by the IIS.
10c) Refusal. The message will contain all R usage segments and fields. RE and O usage segments and fields will not be populated. The message will contain 1 refusal.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the refusal was ignored or otherwise not successfully accepted by the IIS.
10d) Adverse Event. The message will contain all R usage segments and fields. RE and O usage segments and fields will not be populated. The message will contain 1 Adverse Event.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the adverse event was ignored or otherwise not successfully accepted by the IIS.
10e) Patient Observation (e.g., Non-vaccine, contraindication, immunity, indication). The message will contain all R usage segments and fields. RE and O usage segments and fields will not be populated. The message will contain 1 Patient Observation.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the patient observation was ignored or otherwise not successfully accepted by the IIS.

MEASURE 11:

The IIS processes incomplete/partially administered doses.

Purpose	Supports
The purpose of this measure is to support situations where a dose is only partially administered (e.g., the child jumped). The ACK from the IIS will be reviewed for acceptance of the submitted message, but conformance to the ACK standard is not part of this measurement. Other measures address ACK conformance.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport **OGS 1.5.4:** IIS accepts VXU consistent with the current CDC-endorsed HL7 IG from authorized users and systems (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.4:** The IIS can store all IIS Core Data Elements. **OGS 3.4.1:** The IIS can receive and store all core data elements, as endorsed by CDC, from the IIS User Interface and from electronic data transfer. **Note:** This only measures the "receipt" portion of this OGS. The "store" portion is measured leveraging query and response. **Functional Standard 3.6:** The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner. **OGS 3.6.4:** The IIS has the ability to capture complete and incomplete/partial administered doses.

Test Case	Test Case Expectation
11a) A patient jumps when receiving a dose of MMR, and only receives part of a dose. The provider enters a partial dose into their EHR, and it is sent to the IIS as a partial administered dose. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the immunization was ignored or otherwise not successfully accepted by the IIS.
11b) A patient shares that they received a partial dose at a previous provider. The provider enters a partial dose into their EHR as a historical dose, and it is sent to the IIS as a partial administered dose. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields.	The IIS responds with an ACK indicating it has accepted the message. The ACK should not indicate the immunization was ignored or otherwise not successfully accepted by the IIS.

MEASURE 12:

The IIS responds to a correctly formatted message with no errors.

Purpose	Supports
The purpose of this measure is to validate the conformance of the ACK message when a conformant VXU message is submitted.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport. **OGS 1.5.1:** IIS returns an ACK for every received VXU message consistent with the CDC-endorsed HL7 IG. (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)

Test Case	Test Case Expectation
12a) A message with 1 historical vaccination will be submitted. The message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields.	The IIS responds with a conformant ACK message indicating it has accepted the message. The format and content of the ACK must meet the conformance rules defined in the implementation guide. Depending upon local business rules and data quality checks, it is entirely possible an IIS may return Error Severity (ERR-4) of an I or a W.

MEASURE 13:

The IIS responds to a submission that has an error.

Purpose	Supports
The purpose of this measure is to validate the conformance of the ACK message when a problematic message is submitted to the IIS.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport. **OGS 1.5.1:** IIS returns an ACK for every received VXU message consistent with the CDC-endorsed HL7 IG. (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging)

Test Case	Test Case Expectation
13a) The submitted message contains an intentional data quality/completeness error (e.g., before birth immunization, missing lot number, etc.). The remainder of the message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields.	The IIS responds with a conformant ACK indicating a problem with the message. The format and content of the ACK must meet the conformance rules defined in the implementation guide. Depending upon local business rules, this may have an Error Severity (ERR-4) of W – Warning or E – Error.
13b) The submitted message contains an intentional missing data element that is deemed critical (i.e., patient name, dob, vaccination date, vaccine type). The remainder of the message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields.	The IIS responds with a conformant ACK indicating a problem with the message. The format and content of the ACK must meet the conformance rules defined in the implementation guide. Given the nature of the error, the ACK must have indicate an Error Severity (ERR-4) of E – Error indicating the submitter should correct and resubmit the message. Resubmission will not be tested.

MEASURE 14:

The IIS responds to a submission with an ACK within 5 seconds or less for 95% of the records submitted.

Purpose	Supports
The purpose of this measure is to support timely interfaces which will not disrupt – but rather support – clinical workflow. The same timeliness metrics (5 seconds or less for 95% of messages) found here are also found in the Query and Response measures.	**Functional Standard 1.5:** The IIS can receive submissions in accordance with interoperability standards endorsed by CDC for message content/format and transport. **OGS 1.5.1:** IIS returns an ACK for every received VXU message consistent with the CDC-endorsed HL7 IG. (See HL7 Version 2.5.1 Implementation Guide for Immunization Messaging) **Functional Standard 3.6:** The IIS records and makes available all submitted vaccination and/or demographic information in a timely manner. **OGS 3.6.1:** Demographic only information (for non-birth records) and historical vaccination records received by IIS are processed and posted to production within 72 hours of submission. NOTE: This only measures the timeliness aspect of these functional standards.

Test Case	Test Case Expectation
No test cases are developed for this measure. Rather all other submission and acknowledgement tests will be measured during the testing process to vet this measure.	The IIS will pass this “test” and measure by responding to 95% of submitted messages within 5 seconds.