

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 1.5².

In 2016, AIRA convened the Measurement for Assessment and Certification Advisory Workgroup (MACAW) to develop and propose measures for IIS Assessment. Query and Response measures and tests will be the third content area 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 IIS Functional Standards, v4.0³. 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 reflect the functionality an IIS should strive to attain to fully support program and stakeholder immunization-related goals. The following Functional Standards are included – at some level – in the MACAW measures and tests defined in this document.

Functional Standard 1.5: The IIS ensures that submitted vaccination and demographic data are processed and viewable in a timely manner.

Functional Standard 1.6: The IIS assures the receipt, processing, and storage of demographic and vaccination data elements as endorsed by CDC.

Functional Standard 8.3: The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

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 https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.htmll

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 querying for immunization related data from an IIS. A companion document focuses on measures and tests for submission of immunization related data to an IIS.

Measures

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

- 1) The IIS processes a query requesting a patient's immunization record.
- 2) The IIS processes a query requesting a patient's evaluated immunization record and forecast.
- 3) The IIS responds to a query for a known patient (one-to-one match).
- 4) The IIS responds to a query for a patient that is not in the IIS.
- 5) The IIS responds to a query that results in multiple possible patients.
- 6) The IIS responds to a guery that has a significant error that cannot be accepted.
- 7) The IIS responds to a query for a known patient and returns known Core Data Elements.
- 8) The IIS responds to a query with an RSP within 5 seconds or less for 95% of the queries submitted.

The 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 (i.e., ACK, RSP)

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.

Finally, it should be noted that all of the tests below will be submitted on behalf of the same provider organization.

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:

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.

These measures and tests address both the timeliness and the necessary automated steps of message handling. Although some IIS may have processing delays or manual QA steps that occur prior to data being processed, the measures are designed to test the IIS ability to support a provider's need to query and receive a response at the point of care most (~95%) of the time. As such, the results may highlight an area of needed enhancement around how an IIS processes messages.

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) this measure supports. In some cases, the measure can only address part of a Functional Standard 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.

MFASURF 1:

The IIS processes a query requesting a patient's immunization record.

Purpose	Supports
The purpose of this measure is to validate an IIS is able to process a query requesting a patient's complete immunization record. The RSP from the IIS will be reviewed for acceptance of the message, but conformance to the RSP standard is not part of this measurement. Other measures address RSP conformance.	Functional Standard 8.3 : The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case Test Case Expectation 1a) Two messages will be submitted to the **VXU Message:** The IIS responds with an IIS. The first will be a submission (VXU) ACK indicating it has accepted the message followed by a query (QBP) for the message. patient submitted in the VXU. The submission (VXU) message will be populated to meet conformance of the **QBP Message:** The IIS responds with a National IG with population of all R and RE complete immunization record response usage segments and fields including two profile (RSP Z32 profile) for the patient identified by the submission message. historical vaccination events. The query (QBP) will be submitted with the same name, date of birth, gender, and MRN used in the submission message. The query will be the Complete Immunization Record profile (Z34).

MFASURF 2:

The IIS processes a query requesting a patient's evaluated immunization record and forecast.

Purpose	Supports
The purpose of this measure is to validate an IIS is able to process a query requesting a patient's evaluated immunization record and forecast. The RSP from the IIS will be reviewed for acceptance of the query message, but conformance to the RSP standard is not part of this measurement. Other measures address RSP conformance. The quality or validity of the evaluation and forecast is also not part of this measurement.	Functional Standard 8.3: The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case Expectation Test Case 2a) Two messages will be submitted to the **VXU Message:** The IIS responds with an IIS. The first will be a submission (VXU) ACK indicating it has accepted the message followed by a query (QBP) for the message. patient submitted in the VXU. The submission (VXU) message will be populated to meet conformance of the **QBP Message:** The IIS responds with a National IG with population of all R and RE complete immunization record response usage segments and fields including two profile (RSP Z42 profile) for the patient historical vaccination events. The query identified by the submission message. (QBP) will be submitted with the same name, date of birth, gender, and MRN used in the submission message. The query will be the Evaluated Immunization Record and Forecast profile (Z44).

MEASURE 3:

The IIS responds to a query for a known patient (one-to-one match).

Purpose	Supports
The purpose of this measure is to validate an IIS is able to respond with a conformant response (RSP) message when exactly one patient is found.	Functional Standard 8.3 : The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case

3a) Two messages will be submitted to the IIS. The first will be a submission (VXU) message followed by a query (QBP) for the patient submitted in the VXU. The submission (VXU) message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including two historical vaccination events. The query (QBP) will be submitted with identical demographics and MRN. The query will be the Complete Immunization Record profile (Z34).

3b) Two messages will be submitted to the IIS. The first will be a submission (VXU) message followed by a query (QBP) for the patient submitted in the VXU. The submission (VXU) message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including two historical vaccination events. The query

Test Case Expectation

VXU Message: The IIS responds with an ACK indicating it has accepted the message.

QBP Message: The IIS responds with a conformant complete immunization record response profile (RSP Z32 profile). The data itself (e.g., Name, DOB, gender, etc.) will not be validated. Only that the response returned conforms to the expectations of the National IG.

VXU Message: The IIS responds with an ACK indicating it has accepted the message.

QBP Message: The IIS responds with a conformant evaluated immunization record and forecast response profile (RSP Z42 profile). The data itself (e.g., Name,

(QBP) will be submitted with identical demographics and MRN. The query will be the Evaluated Immunization Record and Forecast profile (Z44).

DOB, gender, etc.) will not be validated. Only that the response returned conforms to the expectations of the National IG.

MEASURE 4:

The IIS responds to a query for a patient this is not in the IIS.

Purpose	Supports
The purpose of this measure is to validate an IIS is able to respond with a conformant response (RSP) message when no patients are found.	Functional Standard 8.3 : The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case Expectation 4a) A query (QBP) will be submitted with randomly created demographic information and MRN. The query will be the Complete Immunization Record profile (Z34). The IIS responds with a conformant response profile (RSP Z33 profile) indicating no patients were found (QAK-2 = "NF"). The data itself (e.g., Name, DOB, gender, etc.) will not be validated. Only that the response returned conforms to the expectations of the National IG.

MFASURF 5:

The IIS responds to a query that results in multiple possible patients.

Purpose	Supports
The purpose of this measure is to validate an IIS is able to respond with a conformant response (RSP) message when multiple possible patients are found.	Functional Standard 8.3 : The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case Test Case Expectation 5a) Three messages will be submitted, two **VXU Messages:** The IIS responds with an submission (VXU) messages followed by a ACK for each VXU message indicating it Query (QBP). has accepted the message. Both submission (VXU) messages will be populated to meet conformance of the **QBP Message:** The IIS responds with one National IG with population of all R and RE of the following RSP messages per usage segments and fields including two jurisdictional policy: historical vaccination events. The patients are twins and will have similar names with • A conformant response profile (Z31) containing a list of patients. properly set Multiple Birth Indicator and • A conformant response profile (Z33) Patient Birth Order. indicating no patients were found (QAK-The guery (QBP) will be submitted with 2 = "NF"). vague demographics which could match A conformant response profile (Z33) either twin. The guery will be the Complete indicating too many patients were found (QAK-2 = "TM"). Immunization Record profile (Z34). 5b) The QBP from 5a will be resubmitted, **VXU Messages:** The IIS responds with an but this time the query will be the Evaluated ACK for each VXU message indicating it Immunization History and Forecast profile has accepted the message. (Z44).

QBP Message: The IIS responds with one of the following RSP messages per jurisdictional policy:

- A conformant response profile (Z33) indicating no patients were found (QAK-2 = "NF").
- A conformant response profile (Z33) indicating too many patients were found (QAK-2 = "TM").

5c) The QBP from 5a will be resubmitted, but this time the query will request no more than 1 patient by setting RCP-2 (Quantity Limited Request) to a value of 1. The Complete Immunization Record Profile (Z34) will be used.

The IIS responds with one of the following RSP messages per jurisdictional policy:

- A conformant response profile (Z33) indicating no patients were found (QAK-2 = "NF").
- A conformant response profile (Z33) indicating too many patients were found (QAK-2 = "TM").

MEASURE 6:

The IIS responds to a query that has a significant error that cannot be accepted.

Purpose	Supports
The purpose of this measure is to validate an IIS is able to respond with a conformant response (RSP) message when the query is erroneous or otherwise incomplete.	Functional Standard 8.3 : The IIS receives queries from, and sends responses to, health information systems consistent with the current CDC endorsed HL7 Implementation Guide.

Test Case	Test Case Expectation
6a) Submit a query without a name and date of birth.	The IIS responds with a conformant response profile (RSP Z33 profile) indicating an error in the query. (QAK-2 = "AE").

MFASURF 7:

The IIS responds to a query for a known patient and returns known Core Data Elements.

Purpose

The purpose of this measure to detect storage of Core Data Elements through a query to the IIS for a known patient. A subset of Core Data Elements was chosen which are critical for informing vaccination decisions the clinician must make and support patient identification. Test cases will explicitly submit a subset of core data elements to the IIS. A query will then be made to the IIS with the expectation that the IIS return the Core Data Elements which were submitted.

Supports

Functional Standard 1.6: The IIS assures the receipt, processing, and storage of demographic and vaccination data elements as endorsed by CDC.

NOTE: This measures a subset of core data elements at this point (patient submitted MRN, patient name, DOB, gender, vaccine type - CVX, and vaccination date).

Test Case

7a) This test will focus on an administered vaccine. This will cover a select number of core data elements. The submission (VXU) message will be populated to meet conformance of the National IG with population of all R and RE usage segments and fields including two vaccination events. The query (QBP) will be submitted with identical demographics. The query will be the Complete Immunization Record profile (Z34).

Test Case Expectation

VXU Message: The IIS responds with an ACK indicating it has accepted the message.

QBP Message: The response will validate the following Core Data Elements are returned to prove they were stored.

- Patient ID (Submitted MRN from VXU)
- Patient Name (first, middle, last)
- Patient DOB
- Patient Gender
- Vaccine Product Type Administered (CVX)
- Vaccination Administration Date

MEASURE 8:

The IIS responds to a query with an RSP within 5 seconds or less for 95% of the queries 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	Functional Standard 1.5: The IIS ensures that submitted vaccination and demographic data are processed and viewable in a timely manner.	
95% of messages) found here are also found in the Submission and Acknowledgment measures.		

Test Case No test cases are developed for this measure. Rather all other Query and Response 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 all query messages within 5 seconds. Most test cases include a submission of data to pre-populate the IIS prior to the query. These will not be included in this measure. Submission and Acknowledgment has a distinct timing measure of its own.

Change History

Version	Date	Description of Change
1.0	November 18, 2016	Initial Version
1.1	January 15, 2019	Updated to 2018-2022 Functional Standards
1.2	June 6, 2019	Updated "phases" to "content areas" and "Fully Meets" to "Meets"