Test Plan Summary

HIMSS Immunization Integration Program CDC Modular Test Plan v11

Test Case Group: High Level Description of Capabilities and Functions Included in Essentials Module

Description

The current IIP test plan includes eight capabilities. Each of these capabilities describes workflow-related concepts that group together common testable actions. The change from prior versions of the IIP test plan provides greater clarity regarding the intent and purpose of each grouping. Current capabilities include:

- Test Preparation – Data Load and PH Configuration
  - Facilities
  - People
  - Vaccine Inventory
  - Public Health Configuration

- Care Provision and Documentation
  - Select Patients
  - Enter patient provided immunization related information
  - Display patient's updated immunization local system (non-IIS) forecast
  - Enter vaccination order
  - Record vaccines with 2D barcode scanner and manually (no barcode scanner)
  - Produce printable version of patient's immunization record
  - Display a patient's local immunization forecast after adding vaccine administration events to the immunization history
  - Vaccine dose expiration is visually apparent to administering practitioner
  - Identify and record publicly provided-vaccine program eligibility
  - Record adverse events
  - Inform users of risks due to previous adverse events within the ordering or administering workflows for potential causative agents
  - Record vaccine administration refusal
  - Produce cohort reports

- Query, Response and Reconciliation
  - Display local forecast
  - Transmit query to the IIS and receive response
  - Compare IIS-provided information
  - Display SUT vaccination history including the user-reconciled IIS-provided history
  - Re-evaluate patient's immunization forecast
  - Not an exact match response (RSP)

- Transmission and Acknowledgment
  - Transmit newly recorded immunization records to IIs
  - Receive and process acknowledgement messages
  - Update vaccine record previously submitted to IIS
  - Transmit newly recorded historical immunization record
  - Transmit and delete record and for immunization
  - Transmit refusal for immunization
  - Transmit patient consent (protection status)

- Patient Access
  - Provide patient or a designated individual electronic access to the patient's immunization record.

- Clinical Configuration
  - Add new vaccine codes
  - Update immunization schedule to reflect changes in ACIP recommendations

- Transport

- Send and receive immunization messages using the CDC WSDL

- Data Quality
  - Prevention of critical date data entry errors.

Test Case Group: Crosswalk for patient by patient workflow

Description

Please use the crosswalk located here: under user documents>HIMSS IIP Test Plan v11.0 Crosswalk

Test Case Group: 2.0.0 Test preparation - data load

Description

This provides the data that should exist in the system under test before testing scenarios are performed.

Test Objectives

Mother's maiden name is expected to be populated for all minor patient.

Middle names are expected to be populated for all patients.

Middle names for next of kin are expected to be populated for all patients.

Phone number and email (if provided with patient data load) is expected to be populated for all patients.

The SUT SHALL link standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization.

Test Case	2.1.0 Facilities
Test Steps	

Test Case	2.2.0 People
Test Steps	

Patient Pre-load: Lance Gaige Duncan (LGD)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Functions associated with this patient: 3.1.0, 3.2.0, 3.3.0, 3.4.0, 3.5.0, 3.6.0, 3.7.0, 3.8.0, 3.9.0, 5.1.0, 5.2.0, 5.3.0, 5.4.0 Name abbreviated in Function and Test Step title as: LGD **Test Objectives** Patient Pre-load
Patient Pre-load: Alexandria Jacqueline Montoya (AJM)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Functions associated with this patient: 3.10.0, 3.11.0, 5.7.0 Name abbreviated in Function and Test Step title as: AJM **Test Objectives** Patient Pre-load
Patient Pre-load: Selma Nadia McKay (SNM)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Functions associated with this patient: 3.12.0, 3.13.0, 4.1.0, 4.2.0, 4.3.0, 4.4.0, 4.5.0 Name abbreviated in Function and Test Step title as: SNM **Test Objectives** Patient Pre-load

Patient Pre-load: Deborah Charlotte McKay (DCM)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Functions associated with this patient: 3.14.0, 5.5.0, 5.6.0 Name abbreviated in Function and Test Step title as: DCM **Test Objectives** Patient Pre-load
Patient Pre-load: Franklin Mayhew Nesbitt (FMN)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Steps associated with this patient: 4.6.4, 4.6.5, 4.6.6 Name abbreviated in Function and Test Step title as: FMN **Test Objectives** Patient Pre-load
Patient Pre-load: James John Smith (JJS)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Steps associated with this patient: 4.6.1, 4.6.2, 4.6.3 Name abbreviated in Function and Test Step title as: JJS **Test Objectives** Patient Pre-load

Patient Pre-load: Finley Ira Nash (FIN)	**Description** This step provides the details for the patient that should exist in the system under test before testing scenarios are performed. Functions associated with this patient: 7.0.0 Name abbreviated in Function and Test Step title as: FIN **Test Objectives** Patient Pre-load
Practitioner Pre-load: Daniela Jennifer Wyatt	**Description** This step provides the details for the practitioner that should exist in the system under test before testing scenarios are performed. **Test Objectives** Practitioner Pre-load
Practitioner Pre-load: Ramon Michael Bradshaw	**Description** This step provides the details for the practitioner that should exist in the system under test before testing scenarios are performed. **Test Objectives** Practitioner Pre-load

Test Case	**2.3.0 Vaccine Inventory**
Test Steps	

Test Case	**2.4.0 - Configure system to meet local IIS reporting requirements**
Description See test step for details.	
Test Steps	

2.4.1 Add new vaccine program eligibility codes (e.g., VFC/317 vaccine programs). Supports test steps under function 7.0.0	**Description** The SUT shall be required to capture the respective vaccine program applicable to the vaccine administered. Various jurisdictions are establishing new programs to provide vaccines and their administration to defined patient populations for some or all vaccines. Many are jurisdiction-specific programs. For context, the Immunization standard 2.5.1 uses OBX-5 to specify the client's eligibility for a funding program and the dose administered level. Table 0064 lists available codes as V01 Not VFC eligible, V02 VFC eligible-Medicaid/Medicaid Managed Care, V03 VFC eligible Uninsured, V04 VFC eligible American Indian/Alaskan Native, VFC eligible-Federally Qualified Health Center (underinsured), V07 Local-specific eligibility. The extension of the Financial Class code set supports local vaccine program eligibility - IIP024- Emergent Tick Borne Illness Vaccine Program **Test Objectives** To test the ability that the SUT can manage new program eligibility codes as they become available Add Jurisdiction-Specific Vaccine Eligibility Code: The SUT demonstrates the ability to manage/add new program eligibility codes as they become available and to configure dose-level vaccine eligibility codes per jurisdictional requirements.

Test Case Group: 3.0.0 - Capability: Care Provision and Documentation

Description

This "test group" includes basic functionality that allows SUT users to prepare, administer, and record care provision. Advanced functionality is excluded from this capability.

Test Case	LGD 3.1.0 - Select patient
Description See test step for details.	
Test Steps	

3.1.1 Not-evaluated: Select patient	**Description** Requirement: The SUT allows a practitioner to query and then select a patient's local medical record to perform subsequent actions such as view or update information or initiate a query for information to an IIS. The user selects Lance Gaige Duncan, Jr as the patient. See HIMSS IIP v11.0 Job Aid for patient DOB, Today (day of test) the patient is 0 years, 1 months, and 17 days old. **Test Objectives** That the SUT can select a patient from a list of active patients.

Test Case	LGD 3.2.0 - Enter patient-provided immunization-related information
Description See test step for details.	
Test Steps	
3.2.1 - Enter patient-provided immunization-related information	**Description** Lance Gaige Duncan Jr.'s mother, Ingrid Stacy Duncan, brings a paper copy of the patient's birth hospital vaccine record to Oregon Family Medicine. This includes a birth dose of hepatitis B. The hospital record does not indicate which hepatitis B vaccine product, therefore, the practitioner entering the vaccine in the patient's record uses CVX code 45 hepatitis B vaccine, unspecified formulation. This CVX code allows reporting of a vaccination when formulation is unknown (for example, when recording a HepB vaccination when noted on a vaccination card). **Test Objectives** The SUT must enable entry of an immunization provided elsewhere, i.e., not administered by the practice running the software. The software must be able to allow a practitioner to directly enter information about an immunization reported by a patient with minimum data requirements including: (1) name of immunization product (2) date of immunization (may be at specificity of year; month; and day) (3) source of information (e.g. from IIS, from another practitioner) Additionally, the software must store the source data captured and assure it is displayed in the immunization history indicating provenance (the data elements required). The proctor may accept display with an indicator which provides a mouse-over or a hyperlink for users to view all of the provenance details.

Test Case	LGD 3.3.0 - Display patient's updated immunization history

Description

See test step for details.

Test Steps

3.3.1 - Display patient's updated immunization history	**Description** Lance Gaige Duncan Jr.'s SUT medical record now includes a hepatitis B vaccine dose record provided by a parent with minimum data. **Test Objectives** To test the capability that the SUT is able to display updated immunization history.

Test Case	LGD 3.4.0 - Display patient's immunization local system (non-IIS) forecast

Description

See test step for details.

Test Steps

3.4.1 - Display patient's immunization forecast	**Description** The SUT is able to Display a single patient's immunization forecast report which may be (1) from the IIS - forecast with history of vaccinations this patient has received or (2) display immunization forecast created after reconciliation of IIS data with local data, or (3) in the absence of a new forecast, display the forecast obtained from the IIS (i.e., must display a forecast which SHALL be post-reconciliation if any changes have been made, or the original IIS forecast received if no reconciliation has occurred. **Test Objectives** To test the capability that the SUT is able to display forecast after immunization record updated.

Test Case	LGD 3.5.0 - Enter vaccination order

Description

The SUT supports the ability to enter vaccine orders.

Test Steps

3.5.1 - Enter vaccination order	**Description** Allow practitioners to order the administration of immunizations to a patient using filters for type of vaccine, including combination vaccines. Dr. Ramon Michael Bradshaw, orders the four vaccines to be administered to Lance Gaige Duncan Jr.: PEDIARIX, CVX 110 ActHIB, CVX 48 Rotarix, CVX 119 Prevnar 20, CVX 216 **Test Objectives** To test the capability that the SUT allows the order of immunizations for a patient using filters for vaccine types, including combination vaccines.

Test Case	**LGD 3.6.0 - Scan 2D barcodes found on vaccine vials and syringes to input the vaccine information**

Description

The SUT supports the ability to perform immunization data entry by scanning 2D barcodes found on vaccine vials and syringes: vaccine type and manufacturer (found within the NDC which is encoded in the GTIN), expiration date, and lot number.

Test Objectives

See test case for details

Test Steps

3.6.1 - Scan 2D barcodes found on vaccine vials and syringes to input the vaccine information	**Description** The SUT supports the ability to perform immunization data entry by scanning 2D barcodes found on vaccine vials and syringes: vaccine type and manufacturer (found within the NDC which is encoded in the GTIN), expiration date, and lot number. Based upon the orders of Dr. Ramon Michael Bradshaw, Nurse Daniela Jennifer Wyatt prepares to administer and record vaccines for Lance Gaige Duncan Jr. The following vaccines will be administered AND have 2D barcodes printed upon their vials/syringes: PEDIARIX, Rotarix, and ActHIB. These 2D barcodes are to be scanned to record vaccine type, lot number, and expiration date. **Test Objectives** To test the capability that the SUT is able to scan 2D barcodes for vaccine administrations.

Test Case	**LGD 3.7.0 - Record vaccine administration via manual entry (not scanned)**

Description

The SUT supports the ability to perform immunization data entry by hand keying in vaccine details found vials and syringes: vaccine type and manufacturer (found within the NDC which is encoded in the GTIN), expiration date, and lot number.

Test Objectives

See test case for details

Test Steps

3.7.1 - Record vaccine administration via manual entry (not scanned)	**Description** The SUT supports the ability to perform immunization data entry by hand keying in vaccine details found vials and syringes: vaccine type and manufacturer (found within the NDC which is encoded in the GTIN), expiration date, and lot number. Based upon the orders of Dr. Ramon Michael Bradshaw, Nurse Daniela Jennifer Wyatt prepares to administer and record a dose of Prevnar 20 00005-2000-01, lot number LLBUAYMO6 for Lance Gaige Duncan Jr. However, the 2D barcode printed upon its vial/syringe is smudged and will not scan. Vaccine type, lot number, and expiration date are to be entered without a barcode scanner. **Test Objectives** To test the ability that the SUT allows for manual entry of data from vaccine UoU.

Test Case	**LGD 3.8.0 - Print immunization record**

Description

The SUT produces a printable version a patient's immunization record that can be provided to a patient or caregiver.

Test Steps

3.8.1 - Print immunization record	**Description** Produces a printable version a patient's immunization record that can be provided to a patient or caregiver. At the end of the visit for Lance Gaige Duncan Jr. mother, Ingrid Stacy Duncan requests a printed immunization record she can provide to her childcare provider as proof of Lance Gaige Duncan Jr. in-progress vaccine status. **Test Objectives** To test the capability that The SUT produces a printable version a patient's immunization record that can be provided to a patient or caregiver.

Test Case	**LGD 3.9.0 - Display local immunization forecast (post administration)**

Test Steps

3.9.1 - Display local immunization forecast (post administration)	**Description** Display a patient's local immunization forecast, updated after administration of vaccination doses. **Test Objectives** To test the capability that the SUT is able to display a patient's local immunization forecast, updated after administration of vaccination doses.

Test Case	**AJM 3.10.0 - Vaccine dose expiration is visually apparent to administering practitioner**
Description SUT Informs the practitioner administering a vaccine if the dose chosen for administration is expired.	
Test Steps	
3.10.1 - Not evaluated: Select Patient	**Description** Supports 3.10.3 - Informs administering practitioner that vaccine is expired The user selects Alexandria Jacqueline Montoya (DOB 03/27/2012) as the active patient and opens her record in the SUT. **Test Objectives** The SUT is able to select a patient for the purpose of entering an order.

3.10.2 - Not evaluated: Order vaccine	**Description** Supports 3.10.3 - Informs administering practitioner that vaccine is expired Dr. Ramon Michael Bradshaw, orders a dose of GARDASIL 9 (HPV9) for Alexandria Jacqueline Montoya (DOB: 03/27/2012). He is unaware of the current vaccine inventory, vaccine funding or patient vaccination program eligibility status. **Test Objectives** To test the ability of the SUT to order a vaccine from a selection of non-expired inventory.
3.10.3 - Make vaccine dose expiration date prominently available to user	**Description** Administering Practitioner Daniela Jennifer Wyatt begins the process of fulfilling Dr. Ramon Michael Bradshaw vaccine order for Alexandria Montoya (DOB: 03/27/2012). Daniela Jennifer reviews the GARDASIL 9 - HPV9 inventory in the SUT. Daniela Jennifer Wyatt notes two vaccine items are in the clinic's vaccine storage unit, both for GARDASIL 9 - HPV9, one is expired (Lot Number IIPVAXN09) and the other (Lot Number IIPVAXN08) is unexpired (i.e., still potent). **Test Objectives** To test the capability that the SUT allows the administering practitioner to distinguish between expired and unexpired vaccine doses or prohibits the administering practitioner from selecting an expired vaccine dose.

Test Case	**AJM 3.11.0 - Patient vaccine program eligibility does not match vaccine funding**
Test Steps	

3.11.1 - Inform administering user that the patient's vaccine program eligibility does not match vaccine funding source	**Description** Administering Practitioner Daniela Jennifer Wyatt continues the process of fulfilling Dr. Ramon Michael Bradshaw's vaccine order for Alexandria Montoya (DOB: 03/27/2012). Daniela Jennifer Wyatt recalls there was only one potent (i.e., not expired) GARDASIL 9 - HPV9 product in the vaccine storage unit (Lot Number IIPVAXN08). Daniela Jennifer Wyatt notes that lot number IIPVAXN08 for GARDASIL 9 - HPV9 was paid for using Private funds which conflicts with the vaccine program eligibility for Alexandria Montoya (DOB: 03/27/2012), VFC eligible - Medicaid/Medicaid Managed Care After determining infrequent replenishment is allowed by the State VFC Program and to ensure the patient begins the HPV9 series, Daniela Jennifer Wyatt decides to use lot number IIPVAXN08 for today's visit and replace the privately funded vaccine after the next VFC vaccine order is received. **Test Objectives** To test the capability that the SUT allows the administering practitioner be aware of a mismatch of the vaccine product's funding source and the patient's vaccine program eligibility.

Test Case	**SNM 3.12.0 - Record adverse events**

Description

Nurse Daniela Wyatt receives a secure message that indicates one of the clinic's patients was recently seen by an associated hospital emergency department due to an adverse reaction associated with a vaccine dose administered outside the patient's medical home.

On 12/22/2023 Selma Nadia McKay (DOB 02/05/2023) is vaccinated against Hepatitis A outside of her medical home (Oregon Family Medicine).

After receiving the vaccine, Selma experiences an anaphylactic reaction and paramedics transfer her to a hospital emergency department. She recovers and is discharged home.

Selma’s mother follows up with Selma’s primary care provider, providing the outside clinic vaccination record and the Emergency Department (ED) discharge documentation. The SUT user records this historical vaccination in the SUT (during preload).

Test Objectives

See test step for additional details.

Test Steps

3.12.1 Not evaluated: Select Patient	**Description** Nurse Daniela Wyatt receives a secure message that indicates one of the clinic's patients was recently seen by an associated hospital emergency department due to an adverse reaction associated with a vaccine dose administered outside the patient's medical home. On 12/22/2023 Selma Nadia McKay (DOB 02/05/2023) is vaccinated against Hepatitis A outside of her medical home (Oregon Family Medicine). After receiving the vaccine, Selma experiences an anaphylactic reaction and paramedics transfer her to a hospital emergency department. She recovers and is discharged home. Selma's mother follows up with Selma's primary care provider, providing the outside clinic vaccination record and the Emergency Department (ED) discharge documentation. The SUT user records this historical vaccination in the SUT (during preload). Supports 3.12.2 Enables local capture of structured data regarding adverse events. The user selects Selma Nadia McKay (DOB 02/05/2023) as the patient and opens the patient's record in the SUT. **Test Objectives** The SUT is able to select a patient for the purpose of recording adverse event details in the patient's medical record.
3.12.2 - Enable local capture of structured data regarding adverse events	**Description** Nurse Daniela Wyatt receives a secure message that indicates one of the clinic's patients was recently seen by an associated hospital emergency department due to an adverse reaction associated with a vaccine dose administered outside the patient's medical home. **Test Objectives** To test the capability that the SUT allows a user to record an adverse event with an established Vaccination Reaction and Adverse Event (IIS) code as structured data (not free text). See Note #1. Due to the lack of maturity of standards and acceptance of adverse events, transmission to IIS is excluded from the IIP test plan.

Test Case	SNM 3.13.0 - Inform ordering user of previous adverse event

Description

See test step for details.

Test Steps

3.13.1 - Inform users ordering vaccine (procedures) to previous adverse events for a specific patient	**Description** A practitioner at Oregon Family Medicine views the vaccine schedule for Selma Nadia McKay (DOB 02/05/2023) and orders the vaccine to be administered to the patient. **Test Objectives** To test the capability that the SUT informs the user of the previous vaccine-related adverse reaction although the user overrides the information and enters the order (or the order generates an alert).
3.13.2 - Inform users administering vaccine to previous adverse events for a specific patient	**Description** A vaccine administering practitioner at Oregon Family Medicine attempts to administer Hepatitis A vaccine to Selma Nadia McKay (DOB 02/05/2023) based on the order previously entered. **Test Objectives** To test the capability that the SUT informs the individual administering a vaccine that the patient had an adverse reaction this vaccine in the past. The method and timing of notification can be specified to meet local clinical workflow. This requirement is a "failsafe" mechanism in case the practitioner orders a vaccine dose that may be unsafe for the patient.

Test Case	DCM 3.14.0 - Record vaccine administration refusal by patient or caregiver

Description

See test step for details.

Test Steps

3.14.1 Not evaluated: Select Patient for refused vaccine	**Description** Supports Test Step 3.15.3-During a well child exam, Dr. Ramon Bradshaw recommends that Deborah Charlotte McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay, disagrees with Dr. Ramon Bradshaw's recommendation due to Deborah's twin Selma having a previous adverse reaction to the vaccine and wants to make her refusal clear that Deborah Charlotte McKay is not to receive the vaccine today or in the future. The user selects Deborah Charlotte McKay (DOB 02/05/2023) as the patient and opens the patient's record in the SUT. **Test Objectives** The SUT selects a patient record to perform subsequent actions.
3.14.2 Not evaluated : Practitioner enters order for Hep A vaccine that will later be refused	**Description** Supports Test Step 3.15.3-During a well child exam, Dr. Ramon Bradshaw recommends that Deborah McKay receive a hepatitis A vaccine. Prior to the exam, Dr. Bradshaw reviews the patient's medical record and preps the record by entering the recommended vaccine orders in the encounter. **Test Objectives** The SUT allows the order of a vaccine.
3.14.3 - Not evaluated: Record vaccine administration that was refusal by patient or caregiver	**Description** During a well child exam, Dr. Ramon Bradshaw recommends that Deborah Charlotte McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay, disagrees with Dr. Ramon Bradshaw's recommendation and wants to make her refusal clear that Deborah Charlotte McKay is not to recieve the vaccine today or in the future. Practitioner pre records the vaccine administration prior to giving the vaccine and patient's mother refusing. The vaccine is transmitted but later deleted (step 5.5.3) and refusal sent (step 5.5.5). **Test Objectives** This test step sets up future flow for transmission to the IIS supporting the ability to delete a record. It is not evaluated

3.14.4 - Record vaccine refusal by patient or caregiver	**Description** During a well child exam, Dr. Ramon Bradshaw recommends that Deborah Charlotte McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay, disagrees with Dr. Ramon Bradshaw's recommendation and wants to make her refusal clear that Deborah Charlotte McKay is not to receive the vaccine today or in the future. **Test Objectives** To test the capability that the SUT allows users to record vaccine administration refusal by a patient or caregiver.

Test Case	**3.15.0 - Produce cohort reports**
Description See test step for details.	
Test Steps	
3.15.1 - Attestation: Cohort Report Requirements	**Description** The SUT provides customers with the ability to list a cohort of patients who are (a) due for vaccines, (b) overdue for vaccines, and (c) recipients of specific vaccine lot numbers. **Test Objectives** The ability to create cohort reports based upon specific filtering parameters

Test Case Group: 4.0.0 - Capability: Query, Response, and Reconciliation

Description

The SUT allows for the query of a patient's evaluated immunization history and vaccine forecast. SUT receives various responses to a query of a patient's evaluated immunization history and vaccine forecast from IIS. SUT allows for the reconciliation of immunization data received from IIS.

Test Case	**SNM 4.1.0 - Display Local Forecast**

Description

SUT Proctor takes a screenshot of the SUT's local forecast before performing query for evaluated history and forecast. This is to support Step 4.5.1 - re-evaluate patient's immunization forecast after reconciling IIS-provided vaccine history.

The user selects Deborah Charlotte McKay (DOB 02/05/2023) as the patient and opens the patient's record in the SUT.

Test Objectives

See test step

Test Steps

4.1.1 Pre-test step, display local forecast	## Description The SUT forecast for Selma Nadia McKay (DOB 02/05/2023) is being displayed. A patient's immunization history in the SUT is incomplete. A query for an immunization history and forecast to the IIS and processing a response have not yet been performed. The incomplete nature of the patient's immunization history also impacts the SUT's forecast. The SUT is likely recommending vaccine doses that have been administered yet are not known to the SUT. Since the SUT has not yet queried the IIS for the patients vaccination history, the local vaccination history is incomplete and the forecast is based upon the same incomplete information. ## Test Objectives The ability of the SUT to display an updated forecast post-reconciliation of the immunization history.

Test Case	SNM 4.2.0 - Query sent to the IIS

Description

SUT Requests (query) a patient's evaluated immunization history and vaccine forecast from an IIS using an HL7 v2.5.1 Z44 profile message.

Test Steps

4.2.1 - Requests (query) a patient's evaluated immunization history and vaccine forecast from an IIS	**Description** SUT shall Requests (query) a patient's evaluated immunization history and vaccine forecast from an IIS using an HL7 v2.5.1 Z44 profile message. Nurse, Daniela Wyatt, uses SUT to lookup (query) Selma Nadia McKay evaluated immunization history and forecast. **Test Objectives** To test the capability that the SUT is able to query patient immunization history and forecast from IIS.
4.2.2 - Receive and process a patient's evaluated immunization history and vaccine forecast from an IIS	**Description** After receiving a query for the patient's evaluated history and forecast, the IIS generates and sends a return evaluated history response (RSP -- Z42 profile) message to the SUT. **Test Objectives** Confirms valid receipt and display of response message using the Juror Document. To test the capability that the SUT is able to consume immunization history returned from IIS.

Test Case	**SNM 4.3.0 - Compare IIS-provided information**
Description See test steps for details	
Test Steps	

4.3.1 - Reconcile and import IIS history and forecast response	**Description** The IIS returns an evaluated immunization history and forecast (Z42 profile message) to the SUT in response to the query for patient (Selma Nadia McKay) The SUT shall allow user to compare IIS supplied immunization history with existing local system medical record. **Test Objectives** To test the ability that the SUT shall allow user to compare IIS supplied immunization history with existing local system medical record.

Test Case	SNM 4.4.0 - Display SUT vaccination history, includes user-reconciled IIS-provided information

Description

Display SUT vaccination history which includes user-reconciled IIS-provided information.

Test Steps

4.4.1 - Display SUT vaccination history, includes user-reconciled IIS-provided information	**Description** The SUT shall display SUT vaccination history which includes user-reconciled IIS-provided information. The SUT displays all of the patient's vaccination history including the 2 vaccines known only to the SUT and the 17 vaccines known to the IIS. **Test Objectives** To test the ability that the SUT shall display all of the patient's vaccination history including the 2 vaccines known only to the SUT and the 17 vaccines known to the IIS.

Test Case	SNM 4.5.0 - Re-evaluate patient's immunization forecast

Description

After reconciling IIS provided vaccine records with those in the SUT, the forecast provided by the SUT is updated.

Test Steps

4.5.1 - Re-evaluate patient's immunization forecast after reconciling IIS-provided vaccine history	**Description** Practitioner shall Re-evaluate patient's immunization forecast after 1) IIS-provided information is reconciled by a user, or 2) patient-provided information is reconciled by a user. After reconciling IIS provided vaccine records with those in the SUT, the forecast provided by the SUT is updated. **Test Objectives** The SUT displays the immunization forecast performed on the reconciled immunization history containing all vaccine data from the SUT and from the IIS in response to the Step 4.2.1 query. The proctor compares this new forecast to the pre-query forecast shown in step 4.1.1 and confirms the changes for each vaccine listed; two of the vaccines (Hep B and Pneumococcal) are no longer listed in the new forecast as the series for each is now complete.

Test Case	**4.6.0 - Non Match RSP**
Test Steps	
JJS 4.6.1 Not Evaluated-Select Patient: Receive and process outcomes from IIS noting too many matches	**Description** Nurse Daniela Wyatt uses SUT to access the medical records of James John Smith, specifically the area of the record that permits a query to the IIS for evaluated history and forecast. **Test Objectives** The SUT is able to select patients for the purpose of performing subsequent actions.
JJS 4.6.2 Not evaluated: Requests (query) a patient's evaluated immunization history and vaccine forecast from an IIS	**Description** Nurse, Daniela Wyatt, uses SUT to query James John Smith DOB 4/05/1974, for an evaluated immunization history and forecast. **Test Objectives** The SUT is able to query the IIS for patient's of interest.

JJS 4.6.3 - Receive and process outcomes from IIS noting too many clients match the criteria sent query-response	**Description** After receiving a query for the patient's evaluated history and forecast, the IIS generates and sends an acknowledgment (ACK -- Z33 Profile) message from an IIS that indicates too many matches. **Test Objectives** Tests the ability of the SUT to process a response message that returns too many matches (i.e., no patients are returned for that reason) and to provide an indication to the end user.
FMN 4.6.4 Not Evaluated-Select Patient: Receive and process outcomes from IIS noting non match outcomes	**Description** Nurse Daniela Wyatt uses SUT to access the medical records of Franklin Mayhew Nesbitt, DOB 04/05/1984, specifically the area of the record that permits a query to the IIS for evaluated history and forecast. **Test Objectives** The SUT is able to select a patient for the purpose of performing subsequent actions.
FMN 4.6.5 Not evaluated: Requests (query) a patient's evaluated immunization history and vaccine forecast from an IIS	**Description** Nurse, Daniela Wyatt, uses SUT to query Franklin Mayhew Nesbitt evaluated immunization history and forecast. **Test Objectives** The SUT is able to query the IIS for a patient's immunization and forecast.

FMN 4.6.6 - Receive and process outcomes from IIS noting no clients match the criteria sent within the query from the SUT	**Description** The IIS performs a search for Franklin Mayhew Nesbitt and does not find a high-confidence match. The IIS returns a response message indicating no person found in the querying system. **Test Objectives** Test the ability of the SUT to process a response message that returns no persons found and to provide an indication to the end user.

Test Case Group: 5.0.0 - Capability: Transmission & Acknowledgment

Description

The SUT supports the ability to send newly documented patient immunization records to the IIS.

Test Case	LGD 5.1.0 - Transmit newly recorded immunization records to IIS
Description The SUT supports the ability to send newly documented patient immunization records to the IIS.	
Test Steps	

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.1 - Receive and process acknowledgment messages from IIS	**Description** SUT is able to Receive and process acknowledgment messages from an IIS that indicate there were no errors found during the course of processing the patient immunization record. **Test Objectives** To test the ability that the SUT is able to Receive and process acknowledgment messages from an IIS that indicate there were no errors found during the course of processing the patient immunization record.

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.2 - Receive and process acknowledgment messages from IIS returned with an error (E)	**Description** SUT is able to receive and process acknowledgment messages from an IIS that indicate an error was found during the course of processing the patient immunization record. The IIS has a mapping error in their NDC table and is unable to recognize the NDC code sent in RXA-5 even though it is valid. The IIS is unable to identify the appropriate vaccine and will not load the vaccine data. **Test Objectives** To test the ability of the SUT for Error Handling Support for a fatal error returned by the IIS, and the ability of the SUT to display and inform the end user. See: https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.3 - Receive and process acknowledgment messages from IIS returned with an warning (W)	**Description** SUT is able to Receive and process acknowledgment messages from an IIS that indicate a warning was found during the course of processing the patient immunization record. A mapping error in the IIS software results in the IIS being unable to recognize the administration sites sent in RXR-2 even though it is valid. The acknowledgement message returned contains a warning for an invalid value, the message was accepted but the value will not be saved. **Test Objectives** To test the ability of the SUT for Error Handling Support for a warning returned by the IIS, and the ability of the SUT to display and inform the end user. See: https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.4 - Receive and process acknowledgment messages from IIS returned with an informational warning (I)	**Description** SUT is able to receive and process acknowledgment messages from an IIS that indicate an informational warning was found during the course of processing the patient immunization record. A mapping error in the IIS software results in the IIS being unable to recognize the patient's county. The message was accepted but the value will not be saved. **Test Objectives** To test the ability of the SUT for Error Handling Support for an informational warning returned by the IIS, and the ability of the SUT to display and inform the end user. See: https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.5 - Receive and process acknowledgment messages from IIS returned with multiple warnings (W)	**Description** SUT is able to receive and process acknowledgment messages from an IIS that indicate multiple warnings were found during the course of processing the patient immunization record. A mapping error in the IIS software results in the IIS being unable to recognize the administration route and site sent in the associated RXR-1 and RXR 2 segments even though they are valid. The acknowledgment message returned contains warnings for an invalid value. The message was accepted but the value will not be saved. **Test Objectives** To test the ability of the SUT for Error Handling Support for multiple warnings returned by the IIS, and the ability of the SUT to display and inform the end user. See: https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

5.1.1 - Transmit newly recorded administered vaccine documented within the SUT to the IIS	**Description** The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. This includes four doses of newly administered vaccines. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for mother's maiden name, patient full middle name, next of kin, next of kin full middle name. Support for both phone number and email of patient and first next of kin. Support for patient consent Support for VIS, funding source and VFC data Support for Telecommunication Equipment Type
5.2.6 - Receive and process acknowledgment messages from IIS returned with an error (E)	**Description** SUT is able to receive and process acknowledgment messages from IIS, indicating a fatal system error due to the inability to process the entire message. The message was rejected, no data was saved. **Test Objectives** To test the ability of the SUT for Error Handling Support for a fatal error returned by the IIS, and the ability of the SUT to display and inform the end user. See: https://repository.immregistries.org/resource/guidance-for-hl7-acknowledgement-messages-to-support-interoperability/

Test Case	LGD 5.3.0 - Update Vaccine Record

Description

The SUT supports the ability to send updated patient immunization records to the IIS.

Test Steps	
5.3.1 - Document update to vaccine record with correct lot number manually keyed within the SUT	**Description** In Step 3.7.1 the administering practitioner manually keys in the wrong lot number. The practitioner realizes this after the vaccine record has been completed in the SUT and transmitted to IIS. The practitioner reopens the record and correctly enters the lot number of LLBUAYM06 to update the record. **Test Objectives** To test the ability of the SUT that updates to vaccine record details are allowed in the SUT and are visible to the user.
5.3.2 - Transmit update VXU to newly administered vaccine (previously sent) with correct lot number manually keyed, documented within the SUT to the IIS	**Description** In Step 3.7.1 the administering practitioner manually keys in the wrong lot number. The practitioner realizes this after the vaccine record has been completed in the SUT and transmitted to IIS. The practitioner reopens the record and correctly enters the lot number to update the record. The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical.

5.3.3 - Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case	LGD 5.4.0 - Transmit newly recorded historical immunization records to IIS

Description

The SUT supports the ability to transmit newly documented historical immunization records to the IIS.

Test Steps

5.4.1 - Transmit newly recorded historical vaccine documented within the SUT to the IIS	**Description** Supports test step 3.2.1 This includes a dose of newly recorded historical vaccine. The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and **CVX is required for historical.**

5.4.2 - Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive and process acknowledgment messages from an IIS that indicate there were no errors found during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case	**DCM 5.5.0 - Transmit Hep A and Hep A Delete**
Description The SUT supports the ability to transmit newly documented refused immunizations to the IIS.	
Test Steps	
5.5.1 - Transmit VXU for newly documented as administered, Hep A vaccination that was actually refused	**Description** In Step 3.14.2, Dr. Ramon Bradshaw recommends that Deborah McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay declines the recommendation and refuses the vaccine for Deborah. The Administering practitioner incorrectly documents the administration of the Hep A vaccine in the SUT instead of a refusal in Step 3.14.3. The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. **Test Objectives** To test the ability that the SUT is able to send newly administration vaccine doses to the IIS that will later be deleted. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for multiple birth indicator and birth order.

5.5.2 Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.
5.5.3 - Transmit delete VXU for newly documented as administered, Hep A vaccination that was actually refused	**Description** In Step 3.14.2, Dr. Ramon Bradshaw recommends that Deborah McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay declines the recommendation and refuses the vaccine for Deborah. The Administering practitioner incorrectly documents the administration of the Hep A vaccine in the SUT instead of a refusal. The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to supplied test data in the 'Test Data Specification' section of this test step. **Test Objectives** To test the ability that the SUT allows users to submit vaccine administration deletes. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical.
5.5.4 Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case	DCM 5.6.0 - Transmit Hep A Refusal

Description

The SUT supports the ability to transmit newly documented refused immunizations to the IIS.

Test Steps

5.6.1 Transmit refusal for Hep A vaccination documented within the SUT to the IIS. Supports step 3.14.4 (Record Refusal)	**Description** In Step 3.14.2, Dr. Ramon Bradshaw recommends that Deborah McKay receive a hepatitis A vaccine. Deborah's mother, Angeline McKay declines the recommendation and refuses the vaccine for Deborah. The Administering practitioner incorrectly documents the administration of the Hep A vaccine in the SUT instead of a refusal. The SUT generates an unsolicited vaccine update (VXU - Z22 profile message) correctly and without omission according to the supplied test data in the 'Test Data Specification' section of this test step. **Test Objectives** To test the ability that the SUT allows users to submit vaccine administration refusals. The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical.
5.6.2 Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case	AJM 5.7.0 - Transmit patient protection status

Description

Transmit patient's protection indicator for a patient without consent (no sharing of patient data) to IIS

Test Steps

5.7.1 Transmit patient's protection indicator for a patient without consent (no sharing of patient data) to IIS	**Description** In Step 3.11.1, administering provider, Daniela Jennifer Wyatt, records a dose of GARDASIL 9 (Lot Number IIPVAXN08) in the SUT for Alexandria Jacqueline Montoya (DOB 02/18/2012), triggering the transmission of the record to the IIS. **Test Objectives** To test the ability that the SUT is able to transmit an unsolicited vaccine update (VXU) message which indicates the patient's protection indicator (PD1-12) is "Y" (protected, do not share) along with an effective date (PD1-13). The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. Both NDC and CVX are required for new immunizations and CVX is required for historical. Support for no consent given. Support for long first and middle name.
5.7.2 Not evaluated: Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to Receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case Group: 6.0.0 - Capability: Patient access

Description

This "test group" includes basic functionality that allows patients or their caregivers access to immunization records.

Test Case	6.1.0 - Provide patient or a user on the patient's behalf electronic access to patient's immunization record
Description Includes basic functionality that allows patients or their caregivers access to immunization records.	
Test Steps	
6.1.1 - Attests that patients or their caregivers can electronically access a patient's immunization record	**Description** The SUT supports the ability for patients or a user on the patient's behalf access to the patient's immunization record. This ability is managed via attestation as many SUTs provide such access through patient portals which may be separate products managed by different vendors. The ability requires that the SUT makes all immunizations administered available to the patient. **Test Objectives** To test the ability that the SUT can allow patients or their caregivers to electronically access the patient's Immunization record.

Test Case Group: 7.0.0 - Capability: Clinical Configuration

Description

This "test group" includes basic functionality that allows the SUT to be configured and updated to meet new vaccination reporting requirements.

Test Case	FIN 7.1.0 - Add New Vaccine Codes
Description Demonstrate the ability to add new vaccine codes for a novel virus vaccine prior to its availability in standard medication knowledge bases. The purpose of adding the new code is to allow entry of the vaccine in inventory and administering it to a patient.	
Test Steps	

7.1.1 - Accommodate updates to vaccine code sets (vaccine codes (CVX), National Drug Codes (NDC), and Vaccine Information Statement codes (VIS)) when released from CDC	**Description** CDC identified a new variant of tick-borne Heartland disease causing rapid and significant development of leucopenia, thrombocytopenia, high propensity for intracerebral hemorrhage, and renal failure. The incidence rose sharply beginning March 2024 due to climate change with proliferation of lone star ticks (Amblyomma americanum) and their rapid spread to northern and western states. Due to the increase in disease incidence and severity, the White House established a Heartland Disease Commission and funded rapid development of Heartland-24 vaccine. The first such vaccine, Heartland-24_mRNA just became available but it has not yet been added to commercial drug knowledge bases. The vaccine is available to physician practices and pharmacies but the coding must be added to existing content available in commerical drug knowledge bases. Heartland-24_mRNA vaccine is a single-dose vaccine, given IM, and recommended for all adults over the age of 50 residing in or frequenting non-urban environments. **Test Objectives** To test the ability that the SUT can support the entry of newly developed vaccine code sets.
7.1.2 Not evaluated- Supports 7.1.1 Add New Vaccine Codes. Enter vaccine inventory for newly developed vaccine	**Description** After receiving the inventory for this newly developed vaccine, details are entered into the SUT with the applicable codes and data. **Test Objectives** That the SUT is able to add newly developed vaccines with all applicable codes to the inventory to be ordered by practitioners.
7.1.3 Not evaluated- Supports 7.1.1 Add New Vaccine Codes. Order new vaccine for patient administration	**Description** After being approved by FDA and CDC, Finley Ira Nash (DOB 04/05/1966) is looking to be vaccinated against Heartland virus (a rare tick-borne virus). Dr. Ramon Bradshaw orders the vaccine. The patient also states he needs a hepatitis B vaccine for new employment. The patient has no vaccine history and the practitioner also orders Hep B vaccine to start the series. **Test Objectives** That the SUT is able to order newly developed vaccines which have been recently updated/added to the SUT ordering module.

7.1.4 Record vaccine administration for new vaccine product with new vaccine program eligibility code	**Description** After being approved by FDA and CDC Finley Ira Nash (DOB 04/05/1966) is vaccinated with a new vaccine for Heartland virus (a rare tick-borne virus), along with a Hep B vaccine that the patient states is required for new employment. The patient has no record of hep B vaccine and the practitioner starts the series. **Test Objectives** To test the ability that the SUT allows for manual entry of data from newly entered vaccine product in the SUT inventory.
7.1.5 - Transmit new vaccine code administered with new vaccine program eligibility code documented within the SUT to the IIS	**Description** After being approved by FDA and CDC Finley Ira Nash (DOB 04/05/1966) is vaccinated with a new vaccine for Heartland virus (a rare tick-borne virus), along with a Hep B vaccine that the patient states is required for new employment. The patient has no record of hep B vaccine and the practitioner starts the series. Vaccine Name: Heartland-24_mRNA Vaccine Manufacturer (if required by the SUT): Moderna CVX Code: 234 National Drug Code (NDC): 8077-0743-15 Vaccine Information Sheet: Heartland-24 Vaccine 03-28-2024 VIS Vaccine MVX: MOD Vaccine Name: Hep B, Adult (ENGERIX-B) Vaccine Manufacturer (if required by the SUT):GlaxoSmithKline CVX Code:43 National Drug Code (NDC): 58160-0820-43 Vaccine Information Sheet: Hepatitis B Vaccine VIS Vaccine MVX: SKB **Test Objectives** • To test the ability that the SUT can support transmission of newly developed vaccine data recorded in the SUT • The SUT links standard codes (i.e., LOINC for tests or evaluation tools, NDC codes for current immunizations, CVX for historical immunizations, MVX manufacturer codes, VIS codes, and appropriate codes for administration site, route, method, etc.) to discrete data elements associated with an immunization. • Both NDC and CVX are required for new immunizations and CVX is required for historical. • Support for Sending Responsible Organization (MSH-22) and Receiving Responsible Organization (MSH-23) to include: 1. Identifier, 2. Identifier Type Code, 3. Assigning Authority for the Identifier • Support for OIDs • Support for Adult Not VFC Eligible

7.1.6 - Receive acknowledgment messages from an IIS during the course of processing the patient immunization record	**Description** SUT is able to receive acknowledgment messages from an IIS during the course of processing the patient immunization record. **Test Objectives** The SUT is able to receive an acknowledgment in response to VXU transmissions.

Test Case	**7.2.0 - Clinical Configuration, Updates immunization schedule**
Description All SUT used to provide and record immunization to patient requires the most up-to-date immunization schedule as recommended by the CDC Advisory Committee on Immunization Practices (ACIP). This test evaluates the process for updating the schedule as ACIP recommendations change.	
Test Steps	
7.2.1 - Attests that the immunization schedule is updated regularly to reflect changes in ACIP immunization recommendations	**Description** Each SUT uses an immunization forecasting engine to establish the immunization recommendations to provide to each patient and such forecasting must be updated regularly to reflect new recommendations as they are published by the ACIP. The SUT may use its own forecasting engine or it may access a third-party engine (e.g., but not limited to STC, ICE). The SUT must attest to the fact that it incorporates updates to its active immunization schedule, and provide the following discovery data: (1) Forecasting engine used; (2) Frequency of update to forecasting engine; (3) Indication of whether a clinical site may use the SUT with a forecasting engine other than the one incorporated with the SUT product "out of the box" **Test Objectives** To test the ability that the SUT has a process for updating vaccine schedules based on changes to ACIP recommendations.

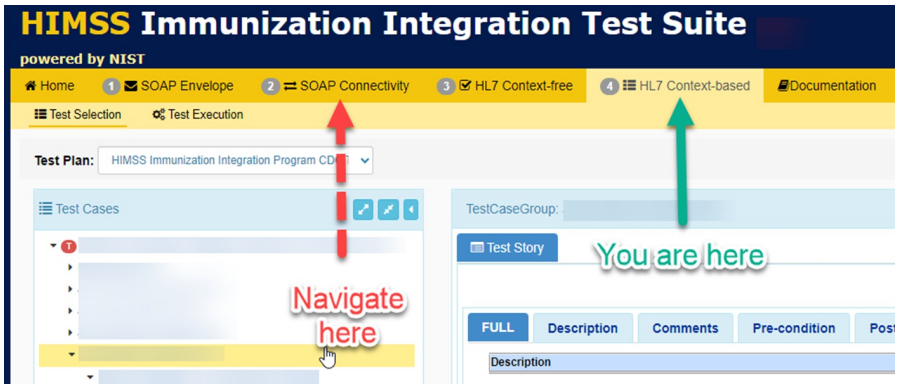
Test Case Group: 8.0.0 - Capability: SOAP Testing

Description

This "test group" includes a single SOAP test:

Connect to an immunization information system (IIS) and to generate and transmit a message conforming to the SOAP 1.2 standard and CDC WSDL 1.0 that may be used for transporting an HL7 message to an immunization information system (IIS).

See test case within the SOAP Connectivity yellow navigation tabs at the top of this tool. All testing for this capability is done outside of the HL7 Context-based menus.



Test Objectives

Configure SOAP-based CDC WSDL for Transport: The EHR or other clinical software system configures connectivity using the SOAP-based CDC WSDL and demonstrates compliance with this standard transport.

Test Case Group: 9.0.0 - Capability: Basic data quality checks

Description

See test case for details.

Test Case	Yuiko Kami Nakano 9.1.0 - Basic data quality checks

Description

See test case steps for details.

Test Objectives

Alerts a user to the following data entry issues:
1. patient born in the future (DOB (PID-7) after TODAY)
2. patient DOB too old (Today-DOB>150 years)
3. patient vaccinated before birth (IZ Administered (RXA-3/4) before DOB (PID-7))

Test Steps	
9.1.1 Attestation: Alert a user when data entered indicates the patient is born in the future (DOB (PID-7) after TODAY)	**Description** Attests that if SUT user enters a typo indicating the patient Yuiko Kami Nakano's date of birth is in the future, the SUT then alerts the user of the issue. **Test Objectives** The SUT is able to prevent a user from entering a patient's DOB in the future.
9.1.2 Attestation: Alert a user when a date of birth (PID-30) is entered which indicates a patient is more than 150 years of age (TODAY-DOB > 150 Years)	**Description** Attests that if SUT user enters a typo indicating the patient Yuiko Kami Nakano is more than 150 years of age, the SUT then alerts the user of the issue. **Test Objectives** The SUT prevents a user from entering a patient's DOB too far in the past.
9.1.3 - Alert a user when data entered indicates the patient received a vaccine before birth (DOD (PID-30) before DOB (PID-7))	**Description** A SUT user selects the wrong patient (Yuiko Kami Nakano); inadvertently recording a vaccine which occurs before the patient's date of birth. The SUT then actively alerts the user of the issue.