Test Plan Summary

IZ COVID-19 Test Plan

Description

This test plan is intended to be used for testing electronic immunization messages generated by HIT Modules for COVID-19 vaccinations. The test plan includes common use cases for reporting COVID-19 administrations (VXU Z22 Profile). A summary of the test plan is given below:

1. Two-dose Vaccine Series with History of 1st Dose (e.g. Moderna vaccine)"
2. Two-dose Vaccine Series with no History of 1st Dose (e.g. Pfizer vaccine)
3. Vaccine Refusal
4. Single-dose Vaccine Series (e.g. Janssen (Johnson & Johnson) vaccine)

Along with the test cases, the test plan includes example messages for each test case.

The test plan provides scenario-based test cases and test steps to test messages for conformance to the Z22 profile (Send Immunization Record) as described in the HL7 2.5.1 Immunization Implementation Guide Release 1.5 and associated Addendum as named in the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries. The requirements for this test plan differ slightly from the ONC requirements in that codes from either the CVX code set or the NDC Directory are required for vaccines in new vaccine administered records. The ONC certification requirement mandates an NDC code or both an NDC code and a CVX code. **Although an NDC code or a CVX code can be sent for COVID-19 vaccine reporting, best practice is to send both.**

Acknowledgment messages returned by the IIS are out of scope for this Test Plan.

Test Case Group: Administration Group

Description

A vaccine reporting application uses the HL7 v2.5.1 Z22 Immunization Profile (VXU Message) with specific test data to create immunization records for patients offered COVID-19 vaccines. The patient vaccine administration records are then transmitted to the IIS. Acknowledgment messages returned by the IIS are out of scope for this Test Group. The administration group of test cases include:

Test Case 1: Two-dose Vaccine Series with History of 1st Dose (e.g. Moderna vaccine)

Test Case 2: Two-dose Vaccine Series with no History of 1st Dose (e.g. Pfizer vaccine)

Test Case 3: Vaccine Refusal

Test Case 4: Single-dose Vaccine Series (e.g. Janssen (Johnson & Johnson) vaccine)

The Administration Group is designed to test the creation of immunization messages to support vaccine administrations, refusals, vaccination history and various observations related to the administration of COVID-19 vaccines. ACK messages are outside the scope of Test Cases and VIS is being replaced with Vaccine EUA Recipient-Caregiver Fact Sheets, which are specific for each COVID-19 vaccine. Test Data are used to create immunization messages specific for the HL7 v2.5.1 Immunization Profile, which is based on the Immunization Standard Z22 Profile-VXU Message.

Test Case	IZ-COVID-19_1_Adult_Admin_Moderna

Description

A sending application creates a vaccination record to be transmitted to the IIS for a healthy adult who received the 1st dose of the Moderna COVID-19 vaccine on 12/28/20 and the 2nd dose of the Moderna COVID-19 vaccine on 1/25/21.

Test Objectives

This test case assesses the ability of a sending application to

- Create vaccine administration messages based on the Z22 profile as defined in the HL7 2.5.1 Immunization Implementation Guide Release 1.5 and associated Addendum HL7 v2.5.1 Z22
- 1st message for an adult patient who received the 1st dose of a multi-dose COVID-19 vaccine
- 2nd message for an adult patient who received the 2nd dose of a multi-dose COVID-19 vaccine
- 2nd message to include historical information about the 1st dose of the COVID-19 vaccine received
- Create administration messages containing a new administration using an NDC, a CVX code, or both for the COVID-19 vaccine.

Test Steps

IZ-1.1_AA_Send_COVID-19_Dose-1_Moderna	## Description A healthy 32-year-old female, Elise Wong, visits a pharmacy in Alabama to be vaccinated on 12/28/2020 for COVID-19. A staff member collects basic patient demographic information including name, date of birth, and sex. A pharmacist, Wilma Thomas (ID 654), reviews the patient's medical history with the patient and orders the Moderna vaccine for her. The patient is given the EUA patient factsheet for the vaccine, which replaces the Vaccine Information Sheet (VIS), to review. After reading it, the patient agrees to receive the recommended COVID-19 vaccine. She also agrees that the data should be shared once it is incorporated into the local IIS and that reminders and recalls may be sent by any method. An appropriate dose of COVID-19 Moderna vaccine is selected from the clinic's stock of vaccines. A clinician, Lily Jackson (ID 7824), prepares and administers the dose to the patient and then enters the data into the sending application and transmits it to the IIS. The patient is told to return for the 2nd dose of the Moderna vaccine in 4 weeks. She is given a CDC COVID-19 Vaccination Record Card and instructed to bring it when receiving the 2nd dose of the vaccine. ## Test Objectives This test case assesses the ability of the sending application: - To create a vaccine administration message for an adult who received the 1st dose of the Moderna COVID-19 vaccine. - To include a patient factsheet instead of a VIS in the message. - To support vaccination series status as incomplete (Dose 1 of 2) - To support more than one race. - To support email address. - To support mother's maiden name.

IZ-1.2_AA_Send_COVID-19_Dose-2_Moderna	**Description** Elise Wong, a 32-year-old female, returns to the pharmacy in Alabama where she was vaccinated on 12/28/2020 with the 1st dose of the Moderna COVID-19. She presents her CDC COVID-19 Vaccination Record Card to a staff member and states she wants to receive the 2nd dose of the vaccine. The staff member confirms basic patient demographic information including name, date of birth, and sex. A pharmacist, Wilma Thomas (ID 654), reviews the patient's medical history with the patient and orders the 2nd dose of the Moderna vaccine for her. The patient is given the EUA patient factsheet for the vaccine to review again. After scanning it, she agrees to receive the recommended COVID-19 vaccine. She also agrees that the data should be shared once it is incorporated into the local IIS and that reminders and recalls may be sent by any method. An appropriate dose of COVID-19 Moderna vaccine is selected from the clinic's stock of vaccines. A clinician, Robert Shaw (ID 1919), prepares and administers the 2nd dose of the vaccine to the patient and then enters the data into the sending application. Both the information about the 1st dose of the Moderna vaccine that was given on 12/28/2020 and the 2nd dose administered are then transmitted to the IIS. **Test Objectives** This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who received the 2nd dose of the Moderna COVID-19 vaccine. • To include historical information about the 1st dose of the Moderna COVID-19 vaccine received. • To include a patient factsheet instead of a VIS in the message. • To support vaccination series status as complete (Dose 2 of 2). • To support more than one race. • To support email address. • To support mother's maiden name.

Test Case	**IZ-COVID-19_2_Adult_Admin_Pfizer**

Description

A sending application creates vaccination records to be transmitted to the IIS for a healthy adult female who received the 1st dose of the Pfizer COVID-19 vaccine on 1/7/2021 and the 2nd dose of the Pfizer COVID-19 vaccine on 1/28/2021. The patient indicated that her information should not be shared (no consent) by the IIS.

Test Objectives

This test case assesses the ability of a sending application to:

- Create vaccine administration messages based on the Z22 profile as defined in the HL7 2.5.1 Immunization Implementation Guide Release 1.5 and associated Addendum HL7 v2.5.1 Z22
- 1st message for an adult patient who received the 1st dose of a multi-dose COVID-19 vaccine
- 2nd message for an adult patient who received the 2nd dose of a multi-dose COVID-19 vaccine
- Sending system has insufficient knowledge of the first administration so a historical record is not included in the 2nd message
- Create administration messages containing a new administration using an NDC, a CVX code, or both for the COVID-19 vaccine.

Test Steps

IZ-2.1_AA_Send_COVID-19_Dose-1_Pfizer	**Description** A 71-year-old female, Nancy Peters, visits a small rural vaccination clinic in Western Pennsylvania to be given a COVID-19 vaccine on 1/7/2021. A clinic staff member collects basic patient demographic information including name, date of birth, and sex. A clinic provider, Lisa Bonn (physician ID 546), reviews the patient's medical history and orders the Pfizer vaccine for her. The patient is given the EUA patient factsheet for the vaccine, which replaces the Vaccine Information Sheet (VIS), to review. After reading it, the patient agrees to receive the recommended vaccine, but does not want the data to be shared once it is incorporated into the local IIS and does not want reminders and recalls. An appropriate dose of the COVID-19 Pfizer vaccine is selected from the clinic's stock of vaccines. A clinician, Macy Jane Rogers (ID 8247), prepares and administers the dose to the patient and then enters the data into the sending application and transmits it to the IIS. The patient is told to return for the 2nd dose of the Pfizer vaccine in 3 weeks. She is given a CDC COVID-19 Vaccination Record Card and instructed to bring it when receiving the 2nd dose of the vaccine. **Test Objectives** This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who received the 1st dose of the Pfizer COVID-19 vaccine. • To include a patient factsheet instead of a VIS in the message. • To support no consent for sharing data. • To support no for reminders and recalls. • To support vaccination series status as incomplete (Dose 1 of 2) • To support sending middle names.

IZ-2.2_AA_Send_COVID-19_Dose-2_Pfizer	**Description** A 71-year-old female, Nancy Peters, visits a different rural clinic in a neighboring town in Western Pennsylvania on 1/28/21 to receive her second COVID-19 vaccination. She indicates to a staff member that she lost her CDC COVID-19 Vaccination Record Card, had received a first dose of the Pfizer vaccine about three weeks ago, and states she wants to receive the 2nd dose of the vaccine. A clinic staff member collects basic patient demographic information including name, date of birth, and sex. A clinic provider, Connor Langlois (physician ID 1799), reviews the patient's medical history and orders the Pfizer vaccine for her. The patient is given the EUA patient factsheet for the vaccine, which replaces the Vaccine Information Sheet (VIS), to review. After reading it, the patient agrees to receive the recommended vaccine, but does not want the data to be shared once it is incorporated into the local IIS and does not want reminders and recalls. An appropriate dose of the COVID-19 Pfizer vaccine is selected from the clinic's stock of vaccines. A clinician, Cindy Lou Stien (ID 2217), prepares and administers the 2nd dose of the vaccine to the patient and then enters the data into the sending application and transmits it to the IIS. Based on what the patient said, this small rural clinic does know that the patient received the first dose of the Pfizer vaccine. However, not enough detail is known about that vaccination, so only the newly administered vaccine information is sent in the message. **Test Objectives** This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who received the 2nd dose of the Pfizer COVID-19 vaccine at a clinic other than the clinic where she received the 1st dose. • To include a patient factsheet instead of a VIS in the message. • To support no consent for sharing data. • To support no for reminders and recalls. • To support vaccination series status as complete (Dose 2 of 2) • To support sending middle names.

Test Case	**IZ-COVID-19_3_Refusal**

Description

A sending application creates a vaccination record to be transmitted to the IIS for a patient who attended a local medical center and is eligible to receive the 1st dose of the EUA Pfizer COVID-19 vaccine. However, after reading the EUA Recipient/Caregiver Fact Sheet for COVID-19 vaccine, the patient refused to be vaccinated.

Test Objectives

This test case assesses the ability of a sending application to create an administration message for a patient who refused a COVID-19 vaccine.

Test Steps

IZ-3.1_RE_Send_COVID-19	**Description** An 18-year-old, Wray Charles Paige, visits a medical center in Pennsylvania on 1/23/2021 for a COVID-19 vaccine. A medical center staff member collects basic patient demographic information including name, date of birth, and sex. A medical center provider, Harry Porter (physician ID 954), reviews the patient's vaccination history with the patient. The patient identifies as Native American, and after reading the EUA patient factsheet for the Pfizer vaccine, which replaces the Vaccine Information Sheet (VIS), he decides not to receive the COVID-19 vaccine. A clinician, Janet Prince (ID 7282), enters the data into the sending application and transmits it to the IIS. **Test Objectives** This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who refused a COVID-19 vaccine. • To support multiple birth indicator.

Test Case	**IZ-COVID-19_4_Adult_Admin_JJ**

Description

A sending application creates a vaccination record to be transmitted to the IIS for a healthy adult who received the single dose Janssen COVID-19 vaccine on 3/24/21.

Test Objectives

This test case assesses the ability of a sending application to

- Create a vaccine administration message based on the Z22 profile as defined in the HL7 2.5.1 Immunization Implementation Guide Release 1.5 and associated Addendum HL7 v2.5.1 Z22 for an adult patient who received a dose of a single-dose COVID-19 vaccine
- Create an administration message containing a new administration using an NDC, a CVX code, or both for the COVID-19 vaccine.

Test Steps

IZ-4.1_AA_Send_COVID-19_Single_Dose_JJ	## Description A 25-year-old male, Mario Valquez visits an urgent care clinic in Chicago on 03/24/2021 and gets vaccinated for COVID-19. A clinic staff member collects basic patient demographic information including name, date of birth, and sex. A clinic provider, David Cato (physician ID 465), reviews the patient's medical history with the patient and notes the patient is due for a dose of the EUA COVID-19 Janssen (J&J) vaccine. The patient is given the EUA patient factsheet for the vaccine, which replaces the Vaccine Information Sheet (VIS), to review. After reading it, he agrees to receive the recommended vaccine. He also agrees that the data should be shared once it is incorporated into the local IIS and that reminders and recalls may be sent by any method. An appropriate dose of COVID-19 Janssen vaccine is selected from the clinic's stock of vaccines. A clinician, Jack Debonair (ID 2782), prepares and administers the dose to the patient and then enters the data into the sending application and transmits it to the IIS application. ## Test Objectives This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who received a COVID-19 vaccine. • To create a Z22 VXU message containing a new administration using an NDC, a CVX, or both for the Janssen vaccine in RXA-5. • To include a patient factsheet instead of a VIS in the message. • To support vaccination status “complete”. • To support mother's maiden name.