

IZ COVID-19 Test Plan

Immunization

Version 1.0.1

9th June 2021

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IZ COVID-19 Test Plan

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 Story

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.

1. Administration Group

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 Story

| Description |
|--|
| <p>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:</p> <p>Test Case 1: Two-dose Vaccine Series with History of 1st Dose (e.g. Moderna vaccine)</p> <p>Test Case 2: Two-dose Vaccine Series with no History of 1st Dose (e.g. Pfizer vaccine)</p> <p>Test Case 3: Vaccine Refusal</p> <p>Test Case 4: Single-dose Vaccine Series (e.g. Janssen (Johnson & Johnson) vaccine)</p> |

1.1. IZ-COVID-19_1_Adult_Admin_Moderna

A vaccine reporting application uses the HL7 v2.5.1 Immunization Profile to send COVID-19 vaccination administration record to the IIS for an adult.

Test Story

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.

1.1.1. IZ-1.1_AA_Send_COVID-19_Dose-1_Moderna

Test Step Type: SUT_INITIATOR

Tests the ability of an HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS for an adult who received a COVID-19 vaccine.

Test Story

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.

Comments

The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates.

Pre-condition

Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message.

Post-Condition

System/Provider has knowledge of the 1st dose of the COVID-19 vaccine administration for the patient.

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.

Evaluation Criteria

Message Validation Report

Notes

The use of CVX 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” is prohibited for the current administration of a COVID-19 vaccine.

COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.

Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.

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Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|----------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Presence-Configuration |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20201228084727.655-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-1-AA_Send_COVID-1M | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Presence-Configuration |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Presence-Configuration |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|-------------|--|------------------------|------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 89778 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Wong | Presence-Content Indifferent |
| PID-5.2 | Given Name | Elise | Presence-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | | Indifferent |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | Xhang | Indifferent |
| PID-6.7 | Name Type Code | M | Value-Profile Fixed |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 19880417 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | F | Value-Test Case Fixed |
| PID-10[1] | Race | | |
| PID-10[1].1 | Identifier | 2028-9 | Value-Test Case Fixed |
| PID-10[1].2 | Text | Asian | Presence-Test Case Proper |
| PID-10[1].3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-10[2] | Race | | |
| PID-10[2].1 | Identifier | 2131-1 | Value-Test Case Fixed |
| PID-10[2].2 | Text | Other Race | Presence-Test Case Proper |
| PID-10[2].3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 89 West 21st Ave | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Birmingham | Presence-Content Indifferent |
| PID-11.4 | State or Province | AL | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 35203 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13[1] | Phone Number - Home | | |
| PID-13[1].2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13[1].3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13[1].4 | Email Address | | |
| PID-13[1].6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13[1].7 | Local Number | 5554019 | Presence-Content Indifferent |
| PID-13[2] | Phone Number - Home | | |
| PID-13[2].2 | Telecommunication Use Code | NET | Value-Test Case Fixed |
| PID-13[2].3 | Telecommunication Equipment Type | | Indifferent |
| PID-13[2].4 | Email Address | Elise.Wong@jsp.com | Presence-Content Indifferent |
| PID-13[2].6 | Area/City Code | | NonPresence |
| PID-13[2].7 | Local Number | | NonPresence |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | Not Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | N | Value-Test Case Fixed |
| PID-25 | Birth Order | 1 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Value-Test Case Fixed |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|------------------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 02 | Value-Test Case Fixed |
| PD1-11.2 | Text | Reminder/recall - any method | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | N | Value-Test Case Fixed |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Presence-Content Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20031221 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 5237 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 31309 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 7824 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Jackson | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Lily | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Suzanne | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 654 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Thomas | Presence-Content Indifferent |
| ORC-12.3 | Given Name | Wilma | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | Elizabeth | Presence-Content Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | RPH | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|--------------------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20201228 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 80777-0273-99 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Moderna COVID-19 Vaccine | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.5 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 00 | Value-Test Case Fixed |
| RXA-9.2 | Text | New Record | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 7824 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Jackson | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Lily | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | Suzanne | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | 025L20A | Presence-Content Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210205 | Presence-Content Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | MOD | Value-Test Case Fixed |
| RXA-17.2 | Text | Moderna US, Inc. | Presence-Test Case Proper |
| RXA-17.3 | Name of Coding System | MXV | Value-Profile Fixed |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXR : Pharmacy/Treatment Route

| Location | Data Element | Data | Categorization |
|----------|-----------------------|---------------|---------------------------|
| RXR-1 | Route | | |
| RXR-1.1 | Identifier | C28161 | Value-Test Case Fixed |
| RXR-1.2 | Text | Intramuscular | Presence-Test Case Proper |
| RXR-1.3 | Name of Coding System | NCIT | Value-Profile Fixed |
| RXR-2 | Administration Site | | |
| RXR-2.1 | Identifier | RD | Value-Test Case Fixed |
| RXR-2.2 | Text | Right Deltoid | Presence-Test Case Proper |
| RXR-2.3 | Name of Coding System | HL70163 | Value-Profile Fixed |

OBX[*]

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 1 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30963-3 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Source | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 1 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | VXC50 | Value-Test Case Fixed |
| OBX-5.2 | Text | Public | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201228 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 2 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 64994-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Program Eligibility | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 2 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | V01 | Value-Test Case Fixed |
| OBX-5.2 | Text | Not VFC Eligible | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70064 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201228 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | VXC40 | Value-Test Case Fixed |
| OBX-17.2 | Text | Eligibility captured at the immunization level | Presence-Test Case Proper |
| OBX-17.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|---|------------------------------|
| OBX-1 | Set ID - OBX | 3 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 69764-9 | Value-Test Case Fixed |
| OBX-3.2 | Text | Document Type | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | 253088698300034911210401 | Value-Test Case Fixed |
| OBX-5.2 | Text | COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | cdcs1 vis | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201201 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 4 | Value-Profile Fixed |
| OBX-2 | Value Type | DT | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 29769-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Date Vaccine Information Statement Presented | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 20201228 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201228 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-----------------------|------------------------------|
| OBX-1 | Set ID - OBX | 5 | Value-Profile Fixed |
| OBX-2 | Value Type | ST | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30973-2 | Value-Test Case Fixed |
| OBX-3.2 | Text | dose number in series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 1 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201228 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-------------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 6 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 59783-1 | Value-Test Case Fixed |
| OBX-3.2 | Text | Status in immunization series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | N | Value-Test Case Fixed |
| OBX-5.2 | Text | No | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70136 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201228 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|--|
| Patient Name | Elise Wong |
| Mother's Maiden Name | Xhang |
| ID Number | 89778 |
| Date/Time of Birth | 04/17/1988 |
| Administrative Sex | Female |
| Patient Address | 89 West 21st Ave Birmingham AL 35203 USA |
| Local Number | (406)555-4019 |
| Email | Elise.Wong@isp.com |
| Race1 | Asian |
| Race2 | Other Race |
| Ethnic Group | Not Hispanic or Latino |
| Multiple Birth Indicator | No |
| Birth Order | 1 |

Immunization Registry Information

| Element | Data |
|---|------------------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 12/21/2003 |
| Publicity Code | Reminder/recall - any method |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | No |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information

| Element | Data |
|------------------------------------|--------------------------|
| Administered Vaccine | Moderna COVID-19 Vaccine |
| Date/Time Start of Administration | 12/28/2020 |
| Administered Amount | 0.5 |
| Administered Units | mL |
| Administration Notes | New Record |
| Administering Provider | Lily Jackson |
| Substance Lot Number | 025L20A |
| Substance Expiration Date | 02/05/2021 |
| Substance Manufacturer Name | Moderna US, Inc. |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | Intramuscular |
| Administration Site | Right Deltoid |
| Entering Organization | NISTEHRFacility |
| Entered By | Lily Jackson |
| Ordered By | Wilma Thomas |

| Element | Data |
|--|---|
| Vaccine Funding Source | Public |
| Vaccine Funding Program Eligibility | Not VFC Eligible |
| Document Type | COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet |
| Date Vaccine Information Statement Presented | 12/28/2020 |
| dose number in series | 1 |
| Status in immunization series | No |

1.1.2. IZ-1.2_AA_Send_COVID-19_Dose-2_Moderna

Test Step Type: SUT_INITIATOR

Tests the ability of an HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS for an adult who received a COVID-19 vaccine.

Test Story

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.

Comments

The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates.

Pre-condition

Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message.

Knowledge of the first dose vaccine is known by the clinic system administering the second dose.

Post-Condition

No Post Condition

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.

Evaluation Criteria

Message Validation Report

Notes

The use of CVX 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” is prohibited for the current administration of a COVID-19 vaccine.

COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.

Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.

| |
|--|
| |
|--|

Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|------------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Presence-Configuration |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20200125101737.232-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-1.1-AA_Send_COVID-2M | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Presence-Configuration |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Presence-Configuration |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|-------------|--|------------------------|------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 89778 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Wong | Presence-Content Indifferent |
| PID-5.2 | Given Name | Elise | Presence-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | | Indifferent |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | Xhang | Indifferent |
| PID-6.7 | Name Type Code | M | Value-Profile Fixed |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 19880417 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | F | Value-Test Case Fixed |
| PID-10[1] | Race | | |
| PID-10[1].1 | Identifier | 2028-9 | Value-Test Case Fixed |
| PID-10[1].2 | Text | Asian | Presence-Test Case Proper |
| PID-10[1].3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-10[2] | Race | | |
| PID-10[2].1 | Identifier | 2131-1 | Value-Test Case Fixed |
| PID-10[2].2 | Text | Other Race | Presence-Test Case Proper |
| PID-10[2].3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 89 West 21st Ave | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Birmingham | Presence-Content Indifferent |
| PID-11.4 | State or Province | AL | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 35203 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13[1] | Phone Number - Home | | |
| PID-13[1].2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13[1].3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13[1].4 | Email Address | | |
| PID-13[1].6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13[1].7 | Local Number | 5554019 | Presence-Content Indifferent |
| PID-13[2] | Phone Number - Home | | |
| PID-13[2].2 | Telecommunication Use Code | NET | Value-Test Case Fixed |
| PID-13[2].3 | Telecommunication Equipment Type | | Indifferent |
| PID-13[2].4 | Email Address | Elise.Wong@jsp.com | Presence-Content Indifferent |
| PID-13[2].6 | Area/City Code | | NonPresence |
| PID-13[2].7 | Local Number | | NonPresence |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | Not Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | N | Value-Test Case Fixed |
| PID-25 | Birth Order | 1 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Value-Test Case Fixed |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|------------------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 02 | Value-Test Case Fixed |
| PD1-11.2 | Text | Reminder/recall - any method | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | N | Value-Test Case Fixed |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Presence-Content Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20031221 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC[*]

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 9345 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 34555 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 1919 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Shaw | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Robert | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | William | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 654 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Thomas | Presence-Content Indifferent |
| ORC-12.3 | Given Name | Wilma | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | Elizabeth | Presence-Content Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | RPH | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 5237 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 31309 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-1 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 7824 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Jackson | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Lily | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Suzanne | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | | Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | | Indifferent |
| ORC-12.3 | Given Name | | Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | | Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | | Indifferent |
| ORC-12.13 | Identifier Type Code | | Indifferent |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|--------------------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20210125 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 80777-0273-99 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Moderna COVID-19 Vaccine | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.5 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 00 | Value-Test Case Fixed |
| RXA-9.2 | Text | New Record | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 1919 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Shaw | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Robert | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | William | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | 025L32B | Presence-Content Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210301 | Presence-Content Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | MOD | Value-Test Case Fixed |
| RXA-17.2 | Text | Moderna US, Inc. | Presence-Test Case Proper |
| RXA-17.3 | Name of Coding System | MXV | Value-Profile Fixed |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|---------------------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20201228 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 80777-0273-99 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Moderna | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.5 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 01 | Value-Test Case Fixed |
| RXA-9.2 | Text | Historical Administration | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 7824 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Jackson | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Lily | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | Suzanne | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | 025L20A | Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210205 | Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | MOD | Indifferent |
| RXA-17.2 | Text | Moderna US, Inc. | Indifferent |
| RXA-17.3 | Name of Coding System | MXV | Indifferent |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXR : Pharmacy/Treatment Route

| Location | Data Element | Data | Categorization |
|----------|-----------------------|---------------|---------------------------|
| RXR-1 | Route | | |
| RXR-1.1 | Identifier | C28161 | Value-Test Case Fixed |
| RXR-1.2 | Text | Intramuscular | Presence-Test Case Proper |
| RXR-1.3 | Name of Coding System | NCIT | Value-Profile Fixed |
| RXR-2 | Administration Site | | |
| RXR-2.1 | Identifier | RD | Value-Test Case Fixed |
| RXR-2.2 | Text | Right Deltoid | Presence-Test Case Proper |
| RXR-2.3 | Name of Coding System | HL70163 | Value-Profile Fixed |

OBX[*]

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 1 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30963-3 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Source | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 1 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | VXC50 | Value-Test Case Fixed |
| OBX-5.2 | Text | Public | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210125 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 2 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 64994-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Program Eligibility | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 2 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | V01 | Value-Test Case Fixed |
| OBX-5.2 | Text | Not VFC Eligible | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70064 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210125 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | VXC40 | Value-Test Case Fixed |
| OBX-17.2 | Text | Eligibility captured at the immunization level | Presence-Test Case Proper |
| OBX-17.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|---|------------------------------|
| OBX-1 | Set ID - OBX | 3 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 69764-9 | Value-Test Case Fixed |
| OBX-3.2 | Text | Document Type | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | 253088698300034911210401 | Value-Test Case Fixed |
| OBX-5.2 | Text | COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | cdcgslvis | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201201 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 4 | Value-Profile Fixed |
| OBX-2 | Value Type | DT | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 29769-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Date Vaccine Information Statement Presented | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 20210125 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210125 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-----------------------|------------------------------|
| OBX-1 | Set ID - OBX | 5 | Value-Profile Fixed |
| OBX-2 | Value Type | ST | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30973-2 | Value-Test Case Fixed |
| OBX-3.2 | Text | dose number in series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 2 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210125 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-------------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 6 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 59783-1 | Value-Test Case Fixed |
| OBX-3.2 | Text | Status in immunization series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | Y | Value-Test Case Fixed |
| OBX-5.2 | Text | Yes | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70136 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210125 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|--|
| Patient Name | Elise Wong |
| Mother's Maiden Name | Xhang |
| ID Number | 89778 |
| Date/Time of Birth | 04/17/1988 |
| Administrative Sex | Female |
| Patient Address | 89 West 21st Ave Birmingham AL 35203 USA |
| Local Number | (406)555-4019 |
| Email | Elise.Wong@isp.com |
| Race1 | Asian |
| Race2 | Other Race |
| Ethnic Group | Not Hispanic or Latino |
| Multiple Birth Indicator | No |
| Birth Order | 1 |

Immunization Registry Information

| Element | Data |
|---|------------------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 12/21/2003 |
| Publicity Code | Reminder/recall - any method |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | No |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information[*]

Vaccine Administration Information

| Element | Data |
|------------------------------------|--------------------------|
| Administered Vaccine | Moderna COVID-19 Vaccine |
| Date/Time Start of Administration | 01/25/2021 |
| Administered Amount | 0.5 |
| Administered Units | mL |
| Administration Notes | New Record |
| Administering Provider | Robert Shaw |
| Substance Lot Number | 025L32B |
| Substance Expiration Date | 03/01/2021 |
| Substance Manufacturer Name | Moderna US, Inc. |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | Intramuscular |
| Administration Site | Right Deltoid |
| Entering Organization | NISTEHRFacility |
| Entered By | Robert Shaw |
| Ordered By | Wilma Thomas |

| Element | Data |
|--|---|
| Vaccine Funding Source | Public |
| Vaccine Funding Program Eligibility | Not VFC Eligible |
| Document Type | COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet |
| Date Vaccine Information Statement Presented | 01/25/2021 |
| dose number in series | 2 |
| Status in immunization series | Yes |

Vaccine Administration Information

| Element | Data |
|------------------------------------|---------------------------|
| Administered Vaccine | Moderna |
| Date/Time Start of Administration | 12/28/2020 |
| Administered Amount | 0.5 |
| Administered Units | mL |
| Administration Notes | Historical Administration |
| Administering Provider | Lily Jackson |
| Substance Lot Number | 025L20A |
| Substance Expiration Date | 02/05/2021 |
| Substance Manufacturer Name | Moderna US, Inc. |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | |
| Administration Site | |
| Entering Organization | NISTEHR Facility |
| Entered By | Lily Jackson |
| Ordered By | |

1.2. IZ-COVID-19_2_Adult_Admin_Pfizer

A vaccine reporting application uses the HL7 v2.5.1 Immunization Profile to collect COVID-19 vaccination data for a patient who withholds consent to share data.

Test Story

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.

1.2.1. IZ-2.1_AA_Send_COVID-19_Dose-1_Pfizer

Test Step Type: SUT_INITIATOR

Tests the ability of a HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS when no consent is given to share patient data.

Test Story

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.

Comments

The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates.

Pre-condition

Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message.

Post-Condition

No Post Condition

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.

Evaluation Criteria

Message Validation Report

Notes

The use of CVX 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” is prohibited for the current administration of a COVID-19 vaccine.

COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.

Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.

Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|------------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Presence-Configuration |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20210107084727.655-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-2.1-AA_Send_COVID-1P | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Presence-Configuration |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Presence-Configuration |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|------------|--|------------------------|-------------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 89778 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Peters | Presence-Content Indifferent |
| PID-5.2 | Given Name | Nancy | Presence Length-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | Katherine | Presence Length-Content Indifferent |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | Jones | Presence-Content Indifferent |
| PID-6.7 | Name Type Code | M | Value-Profile Fixed |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 19491221 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | F | Value-Test Case Fixed |
| PID-10 | Race | | |
| PID-10.1 | Identifier | 2106-3 | Value-Test Case Fixed |
| PID-10.2 | Text | White | Presence-Test Case Proper |
| PID-10.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 105 Laurel Run Road | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Kersey | Presence-Content Indifferent |
| PID-11.4 | State or Province | PA | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 15846 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13 | Phone Number - Home | | |
| PID-13.2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13.3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13.4 | Email Address | | NonPresence |
| PID-13.6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13.7 | Local Number | 5554019 | Presence-Content Indifferent |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | Not Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | N | Value-Test Case Fixed |
| PID-25 | Birth Order | 1 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Value-Test Case Fixed |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|--------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 01 | Value-Test Case Fixed |
| PD1-11.2 | Text | No reminder/recall | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | Y | Value-Test Case Fixed |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Presence-Content Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20031221 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 9217 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-2 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 44333 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-2 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 8247 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Rodgers | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Macy | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Jane | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 546 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Bonn | Presence-Content Indifferent |
| ORC-12.3 | Given Name | Lisa | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | R | Presence-Content Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | MD | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|----------------------------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20210107 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 59267-1000-02 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Pfizer-BioNTech Covid-19 Vaccine | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.3 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 00 | Value-Test Case Fixed |
| RXA-9.2 | Text | New Record | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 8247 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Rodgers | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Macy | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | Jane | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | EL8982 | Presence-Content Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210531 | Presence-Content Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | PFR | Value-Test Case Fixed |
| RXA-17.2 | Text | Pfizer, Inc. | Presence-Test Case Proper |
| RXA-17.3 | Name of Coding System | MXV | Value-Profile Fixed |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXR : Pharmacy/Treatment Route

| Location | Data Element | Data | Categorization |
|----------|-----------------------|---------------|---------------------------|
| RXR-1 | Route | | |
| RXR-1.1 | Identifier | C28161 | Value-Test Case Fixed |
| RXR-1.2 | Text | Intramuscular | Presence-Test Case Proper |
| RXR-1.3 | Name of Coding System | NCIT | Value-Profile Fixed |
| RXR-2 | Administration Site | | |
| RXR-2.1 | Identifier | LD | Value-Test Case Fixed |
| RXR-2.2 | Text | Left Deltoid | Presence-Test Case Proper |
| RXR-2.3 | Name of Coding System | HL70163 | Value-Profile Fixed |

OBX[*]

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 1 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30963-3 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Source | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 1 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | VXC50 | Value-Test Case Fixed |
| OBX-5.2 | Text | Public | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210107 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 2 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 64994-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Program Eligibility | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 2 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | V01 | Value-Test Case Fixed |
| OBX-5.2 | Text | Not VFC Eligible | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70064 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210107 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | VXC40 | Value-Test Case Fixed |
| OBX-17.2 | Text | Eligibility captured at the immunization level | Presence-Test Case Proper |
| OBX-17.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 3 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 69764-9 | Value-Test Case Fixed |
| OBX-3.2 | Text | Document Type | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | 253088698300033211210501 | Value-Test Case Fixed |
| OBX-5.2 | Text | COVID-19 Pfizer BioNTech Vaccine EUA Recipient-Caregiver Fact Sheet | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | cdcs1 vis | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201201 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|---|------------------------------|
| OBX-1 | Set ID - OBX | 4 | Value-Profile Fixed |
| OBX-2 | Value Type | DT | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 29769-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Date Vaccine Information Statement Presented | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 20210107 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210107 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-----------------------|------------------------------|
| OBX-1 | Set ID - OBX | 5 | Value-Profile Fixed |
| OBX-2 | Value Type | ST | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30973-2 | Value-Test Case Fixed |
| OBX-3.2 | Text | dose number in series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Test Case Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 1 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210107 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-------------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 6 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 59783-1 | Value-Test Case Fixed |
| OBX-3.2 | Text | Status in immunization series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Value-Test Case Fixed |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | N | Value-Test Case Fixed |
| OBX-5.2 | Text | No | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70136 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210107 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|---|
| Patient Name | Nancy Katherine Peters |
| Mother's Maiden Name | Jones |
| ID Number | 89778 |
| Date/Time of Birth | 12/21/1949 |
| Administrative Sex | Female |
| Patient Address | 105 Laurel Run Road Kersey PA 15846 USA |
| Local Number | (406)555-4019 |
| Race | White |
| Ethnic Group | Not Hispanic or Latino |
| Multiple Birth Indicator | No |
| Birth Order | 1 |

Immunization Registry Information

| Element | Data |
|---|--------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 12/21/2003 |
| Publicity Code | No reminder/recall |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | Yes |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information

| Element | Data |
|------------------------------------|----------------------------------|
| Administered Vaccine | Pfizer-BioNTech Covid-19 Vaccine |
| Date/Time Start of Administration | 01/07/2021 |
| Administered Amount | 0.3 |
| Administered Units | mL |
| Administration Notes | New Record |
| Administering Provider | Macy Rodgers |
| Substance Lot Number | EL8982 |
| Substance Expiration Date | 05/31/2021 |
| Substance Manufacturer Name | Pfizer, Inc. |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | Intramuscular |
| Administration Site | Left Deltoid |
| Entering Organization | NISTEHRFacility |
| Entered By | Macy Rodgers |
| Ordered By | Lisa Bonn |

| Element | Data |
|--|---|
| Vaccine Funding Source | Public |
| Vaccine Funding Program Eligibility | Not VFC Eligible |
| Document Type | COVID-19 Pfizer BioNTech Vaccine EUA Recipient-Caregiver Fact Sheet |
| Date Vaccine Information Statement Presented | 01/07/2021 |
| dose number in series | 1 |
| Status in immunization series | No |

1.2.2. IZ-2.2_AA_Send_COVID-19_Dose-2_Pfizer

Test Step Type: SUT_INITIATOR

Tests the ability of a HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS when no consent is given to share patient data.

Test Story

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.

Comments

The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates.

Pre-condition

Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message.

Knowledge of the first dose vaccine is known by the clinic system administering the second dose; however there is insufficient detail of the record to send the historical record..

Post-Condition

No Post Condition

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.

Evaluation Criteria

Message Validation Report

Notes

The use of CVX 213 “SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED” is prohibited for the current administration of a COVID-19 vaccine.

COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.

Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.

Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|------------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Presence-Configuration |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20210128121654.511-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-2.2-AA_Send_COVID-2P | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Presence-Configuration |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Presence-Configuration |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|------------|--|------------------------|-------------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 89778 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Peters | Presence-Content Indifferent |
| PID-5.2 | Given Name | Nancy | Presence Length-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | Katherine | Presence Length-Content Indifferent |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | Jones | Presence-Content Indifferent |
| PID-6.7 | Name Type Code | M | Value-Profile Fixed |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 19491221 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | F | Value-Test Case Fixed |
| PID-10 | Race | | |
| PID-10.1 | Identifier | 2106-3 | Value-Test Case Fixed |
| PID-10.2 | Text | White | Presence-Test Case Proper |
| PID-10.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 105 Laurel Run Road | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Kersey | Presence-Content Indifferent |
| PID-11.4 | State or Province | PA | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 15846 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13 | Phone Number - Home | | |
| PID-13.2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13.3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13.4 | Email Address | | NonPresence |
| PID-13.6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13.7 | Local Number | 5554019 | Presence-Content Indifferent |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | Not Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | N | Value-Test Case Fixed |
| PID-25 | Birth Order | 1 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Value-Test Case Fixed |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|--------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 01 | Value-Test Case Fixed |
| PD1-11.2 | Text | No reminder/recall | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | Y | Value-Test Case Fixed |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Presence-Content Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20031221 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-------------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 9388 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-2 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 48973 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-2 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 2217 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Stien | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Cindy | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Lou | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 1799 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Langlois | Presence-Content Indifferent |
| ORC-12.3 | Given Name | Connor | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | W | Presence-Content Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | MD | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC-E | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility-E | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|----------------------------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20210128 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 59267-1000-02 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Pfizer-BioNTech Covid-19 Vaccine | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.3 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 00 | Value-Test Case Fixed |
| RXA-9.2 | Text | New Record | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 2217 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Stien | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Cindy | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | Lou | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | EL9015 | Presence-Content Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210622 | Presence-Content Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | PFR | Value-Test Case Fixed |
| RXA-17.2 | Text | Pfizer, Inc. | Presence-Test Case Proper |
| RXA-17.3 | Name of Coding System | MXV | Value-Profile Fixed |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXR : Pharmacy/Treatment Route

| Location | Data Element | Data | Categorization |
|----------|-----------------------|---------------|---------------------------|
| RXR-1 | Route | | |
| RXR-1.1 | Identifier | C28161 | Value-Test Case Fixed |
| RXR-1.2 | Text | Intramuscular | Presence-Test Case Proper |
| RXR-1.3 | Name of Coding System | NCIT | Value-Profile Fixed |
| RXR-2 | Administration Site | | |
| RXR-2.1 | Identifier | LD | Value-Test Case Fixed |
| RXR-2.2 | Text | Left Deltoid | Presence-Test Case Proper |
| RXR-2.3 | Name of Coding System | HL70163 | Value-Profile Fixed |

OBX[*]

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 1 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30963-3 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Source | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 1 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | VXC50 | Value-Test Case Fixed |
| OBX-5.2 | Text | Public | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210128 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 2 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 64994-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Program Eligibility | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 2 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | V01 | Value-Test Case Fixed |
| OBX-5.2 | Text | Not VFC Eligible | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70064 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210128 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | VXC40 | Value-Test Case Fixed |
| OBX-17.2 | Text | Eligibility captured at the immunization level | Presence-Test Case Proper |
| OBX-17.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 3 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 69764-9 | Value-Test Case Fixed |
| OBX-3.2 | Text | Document Type | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | 253088698300033211210501 | Value-Test Case Fixed |
| OBX-5.2 | Text | COVID-19 Pfizer BioNTech Vaccine EUA Recipient-Caregiver Fact Sheet | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | cdcs1 vis | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20201201 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|---|------------------------------|
| OBX-1 | Set ID - OBX | 4 | Value-Profile Fixed |
| OBX-2 | Value Type | DT | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 29769-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Date Vaccine Information Statement Presented | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 20210128 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210128 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-----------------------|------------------------------|
| OBX-1 | Set ID - OBX | 5 | Value-Profile Fixed |
| OBX-2 | Value Type | ST | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30973-2 | Value-Test Case Fixed |
| OBX-3.2 | Text | dose number in series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Test Case Fixed |
| OBX-4 | Observation Sub-ID | 4 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 2 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210128 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-------------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 6 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 59783-1 | Value-Test Case Fixed |
| OBX-3.2 | Text | Status in immunization series | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 4 | Value-Test Case Fixed |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | Y | Value-Test Case Fixed |
| OBX-5.2 | Text | Yes | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70136 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210128 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|---|
| Patient Name | Nancy Katherine Peters |
| Mother's Maiden Name | Jones |
| ID Number | 89778 |
| Date/Time of Birth | 12/21/1949 |
| Administrative Sex | Female |
| Patient Address | 105 Laurel Run Road Kersey PA 15846 USA |
| Local Number | (406)555-4019 |
| Race | White |
| Ethnic Group | Not Hispanic or Latino |
| Multiple Birth Indicator | No |
| Birth Order | 1 |

Immunization Registry Information

| Element | Data |
|---|--------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 12/21/2003 |
| Publicity Code | No reminder/recall |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | Yes |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information

| Element | Data |
|------------------------------------|----------------------------------|
| Administered Vaccine | Pfizer-BioNTech Covid-19 Vaccine |
| Date/Time Start of Administration | 01/28/2021 |
| Administered Amount | 0.3 |
| Administered Units | mL |
| Administration Notes | New Record |
| Administering Provider | Cindy Stien |
| Substance Lot Number | EL9015 |
| Substance Expiration Date | 06/22/2021 |
| Substance Manufacturer Name | Pfizer, Inc. |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | Intramuscular |
| Administration Site | Left Deltoid |
| Entering Organization | NISTEHRFacility-E |
| Entered By | Cindy Stien |
| Ordered By | Connor Langlois |

| Element | Data |
|--|---|
| Vaccine Funding Source | Public |
| Vaccine Funding Program Eligibility | Not VFC Eligible |
| Document Type | COVID-19 Pfizer BioNTech Vaccine EUA Recipient-Caregiver Fact Sheet |
| Date Vaccine Information Statement Presented | 01/28/2021 |
| dose number in series | 2 |
| Status in immunization series | Yes |

1.3. IZ-COVID-19_3_Refusal

A vaccine reporting application uses the HL7 v2.5.1 Immunization Profile to create a immunization record for a patient who refused a COVID-19 vaccine.

Test Story

| 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. |

1.3.1. IZ-3.1_RE_Send_COVID-19

Test Step Type: SUT_INITIATOR

Tests the ability of an HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS for a patient who refused a COVID-19 vaccine.

Test Story

| 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. |
| Comments |
| The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates. |
| Pre-condition |
| Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message. |
| Post-Condition |
| No PostCondition |
| Test Objectives |
| <p>This test case assesses the ability of the sending application:</p> <ul style="list-style-type: none">• To create a vaccine administration message for an adult who refused a COVID-19 vaccine.• To support multiple birth indicator. |
| Evaluation Criteria |
| Message Validation Report |
| Notes |
| <p>If known, the specific CVX code for the COVID-19 vaccine that is refused should be used, but CVX 213 "SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED" may be used to indicate that a patient refused a COVID-19 vaccine.</p> <p>COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.</p> |

Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|---------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Indifferent |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20210123084727.655-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-3.1-RE_Send_COVID | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Indifferent |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Indifferent |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|------------|--|------------------------|------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 8891 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Paige | Presence-Content Indifferent |
| PID-5.2 | Given Name | Wray | Presence-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | Charles | Presence-Content Indifferent |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | | Indifferent |
| PID-6.7 | Name Type Code | | Indifferent |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 20020602 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | M | Value-Test Case Fixed |
| PID-10 | Race | | |
| PID-10.1 | Identifier | 1002-5 | Value-Test Case Fixed |
| PID-10.2 | Text | Native American | Presence-Test Case Proper |
| PID-10.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 924 Sycamore Lane | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Arroyo | Presence-Content Indifferent |
| PID-11.4 | State or Province | PA | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 00714 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13 | Phone Number - Home | | |
| PID-13.2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13.3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13.4 | Email Address | | NonPresence |
| PID-13.6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13.7 | Local Number | 5555835 | Presence-Content Indifferent |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | Not Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | Y | Indifferent |
| PID-25 | Birth Order | 2 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Indifferent |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|-------------------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 08 | Value-Test Case Fixed |
| PD1-11.2 | Text | Reminder/recall - to provider | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | N | Indifferent |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20040602 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | 5645 | Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-3 | Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | 9999 | Value-Profile Fixed |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-3 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 7282 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Prince | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Janet | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Suzanne | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Indifferent |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 954 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Porter | Presence-Content Indifferent |
| ORC-12.3 | Given Name | Harry | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | James | Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | MD | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Indifferent |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|---|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20210123 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 208 | Value-Test Case Fixed |
| RXA-5.2 | Text | COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | CVX | Value-Profile Fixed |
| RXA-6 | Administered Amount | 999 | Presence-Test Case Proper |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | | NonPresence |
| RXA-7.2 | Text | | NonPresence |
| RXA-7.3 | Name of Coding System | | NonPresence |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | | NonPresence |
| RXA-9.2 | Text | | NonPresence |
| RXA-9.3 | Name of Coding System | | NonPresence |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | | |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | | |
| RXA-10.3 | Given Name | | |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | | |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | | Indifferent |
| RXA-10.13 | Identifier Type Code | | |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | | NonPresence |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | | NonPresence |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | | |
| RXA-17.2 | Text | | |
| RXA-17.3 | Name of Coding System | | |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | 03 | Presence-Content Indifferent |
| RXA-18.2 | Text | Patient decision | Presence-Test Case Proper |
| RXA-18.3 | Name of Coding System | NIP002 | Value-Profile Fixed |
| RXA-20 | Completion Status | RE | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|---------------------------------------|
| Patient Name | Wray Charles Paige |
| Mother's Maiden Name | |
| ID Number | 8891 |
| Date/Time of Birth | 06/02/2002 |
| Administrative Sex | Male |
| Patient Address | 924 Sycamore Lane Arroyo PA 00714 USA |
| Local Number | (406)555-5835 |
| Race | Native American |
| Ethnic Group | Not Hispanic or Latino |
| Multiple Birth Indicator | Yes |
| Birth Order | 2 |

Immunization Registry Information

| Element | Data |
|---|-------------------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 06/02/2004 |
| Publicity Code | Reminder/recall - to provider |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | No |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information

| Element | Data |
|------------------------------------|---|
| Administered Vaccine | COVID-19, mRNA, LNP-S, PF, 30 mcg/0.3 mL dose |
| Date/Time Start of Administration | 01/23/2021 |
| Administered Amount | 999 |
| Administered Units | |
| Administration Notes | |
| Administering Provider | |
| Substance Lot Number | |
| Substance Expiration Date | |
| Substance Manufacturer Name | |
| Substance/Treatment Refusal Reason | Patient decision |
| Completion Status | Refused |
| Action Code | Add |
| Route | |
| Administration Site | |
| Entering Organization | NISTEHRFacility |
| Entered By | Janet Prince |
| Ordered By | Harry Porter |

1.4. IZ-COVID-19_4_Adult_Admin_JJ

A vaccine reporting application uses the HL7 v2.5.1 Immunization Profile to create an immunization record for a patient who received the second dose of a multi-dose COVID-19 vaccine.

Test Story

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.

1.4.1. IZ-4.1_AA_Send_COVID-19_Single_Dose_JJ

Test Step Type: SUT_INITIATOR

Tests the ability of a HIT Module to create a valid COVID-19 vaccination message for transmission to the IIS for a patient who received the second dose of a COVID-19 vaccine.

Test Story

| 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. |
| Comments |
| The dates used in the test story and test messages are examples and can be changed to reflect appropriate current dates. |
| Pre-condition |
| Sending systems should have the capability of sending an HL7 v2.5.1 standard-based Immunization Message Z22 Profile-VXU Message. |
| Post-Condition |
| No Post Condition |
| Test Objectives |
| <p>This test case assesses the ability of the sending application:</p> <ul style="list-style-type: none">• 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. |
| Evaluation Criteria |
| Message Validation Report |
| Notes |
| <p>The use of CVX 213 "SARS-COV-2 (COVID-19) vaccine, UNSPECIFIED" is prohibited for the current administration of a COVID-19 vaccine.</p> <p>COVID-19 vaccines have received Emergency Use Authorization (EUA) by the FDA. Per the CDC, the VIS code set is being used to provide the EUA Recipient/Caregiver Fact Sheet codes for EHRs/EMRs for use in a manner analogous to the electronic system and workflow documentation of VIS. These codes were developed in advance of potential EUA decision by FDA for each vaccine.</p> <p>Per the ONC 2015 Edition HIT Certification Criterion §170.315(f)(1) Transmission to immunization registries, codes from the NDC Directory are required for vaccines in new vaccine administered records in Z22 VXU messages. However, for this test plan either an NDC, a CVX, or both can be messaged. Best practice is to send both.</p> |

Message Contents

MSH : Message Header

| Location | Data Element | Data | Categorization |
|-----------|------------------------------------|------------------------------|------------------------------|
| MSH-1 | Field Separator | | Value-Profile Fixed |
| MSH-2 | Encoding Characters | ^~& | Value-Profile Fixed |
| MSH-3 | Sending Application | | |
| MSH-3.1 | Namespace ID | NISTAPP | Presence-Configuration |
| MSH-3.2 | Universal ID | | Indifferent |
| MSH-3.3 | Universal ID Type | | Indifferent |
| MSH-4 | Sending Facility | | |
| MSH-4.1 | Namespace ID | NISTFAC | Presence-Configuration |
| MSH-4.2 | Universal ID | | Indifferent |
| MSH-4.3 | Universal ID Type | | Indifferent |
| MSH-5 | Receiving Application | | |
| MSH-5.1 | Namespace ID | IISAPP | Presence-Configuration |
| MSH-5.2 | Universal ID | | Indifferent |
| MSH-5.3 | Universal ID Type | | Indifferent |
| MSH-6 | Receiving Facility | | |
| MSH-6.1 | Namespace ID | IISFAC | Presence-Configuration |
| MSH-6.2 | Universal ID | | Indifferent |
| MSH-6.3 | Universal ID Type | | Indifferent |
| MSH-7 | Date/Time Of Message | | |
| MSH-7.1 | Time | 20210324123717.655-0500 | Presence-System Generated |
| MSH-9 | Message Type | | |
| MSH-9.1 | Message Code | VXU | Value-Profile Fixed |
| MSH-9.2 | Trigger Event | V04 | Value-Profile Fixed |
| MSH-9.3 | Message Structure | VXU_V04 | Value-Profile Fixed |
| MSH-10 | Message Control ID | NIST-IZ-4.1-AA_Send_COVID-J1 | Presence-System Generated |
| MSH-11 | Processing ID | | |
| MSH-11.1 | Processing ID | P | Presence-Content Indifferent |
| MSH-12 | Version ID | | |
| MSH-12.1 | Version ID | 2.5.1 | Value-Profile Fixed |
| MSH-15 | Accept Acknowledgment Type | ER | Value-Profile Fixed |
| MSH-16 | Application Acknowledgment Type | AL | Value-Profile Fixed |
| MSH-21 | Message Profile Identifier | | |
| MSH-21.1 | Entity Identifier | Z22 | Value-Profile Fixed |
| MSH-21.2 | Namespace ID | CDCPHINVS | Value-Profile Fixed |
| MSH-21.3 | Universal ID | | Indifferent |
| MSH-21.4 | Universal ID Type | | Indifferent |
| MSH-22 | Sending Responsible Organization | | |
| MSH-22.1 | Organization Name | NISTFAC | Presence-Configuration |
| MSH-22.6 | Assigning Authority | | |
| MSH-22.7 | Identifier Type Code | | Indifferent |
| MSH-22.10 | Organization Identifier | | Indifferent |
| MSH-23 | Receiving Responsible Organization | | |
| MSH-23.1 | Organization Name | IISFAC | Presence-Configuration |
| MSH-23.6 | Assigning Authority | | |
| MSH-23.7 | Identifier Type Code | | Indifferent |
| MSH-23.10 | Organization Identifier | | Indifferent |

PID : Patient Identification

| Location | Data Element | Data | Categorization |
|------------|--|------------------------|------------------------------|
| PID-1 | Set ID - PID | 1 | Value-Profile Fixed |
| PID-3 | Patient Identifier List | | |
| PID-3.1 | ID Number | 89778 | Presence-Content Indifferent |
| PID-3.4 | Assigning Authority | | |
| PID-3.5 | Identifier Type Code | MR | Value-Test Case Fixed |
| PID-5 | Patient Name | | |
| PID-5.1 | Family Name | | |
| PID-5.1.1 | Surname | Valquez | Presence-Content Indifferent |
| PID-5.2 | Given Name | Mario | Presence-Content Indifferent |
| PID-5.3 | Second and Further Given Names or Initials Thereof | | |
| PID-5.7 | Name Type Code | L | Value-Test Case Fixed |
| PID-6 | Mother's Maiden Name | | |
| PID-6.1 | Family Name | | |
| PID-6.1.1 | Surname | Jones | Presence-Content Indifferent |
| PID-6.7 | Name Type Code | M | Value-Profile Fixed |
| PID-7 | Date/Time of Birth | | |
| PID-7.1 | Time | 19950417 | Presence-Content Indifferent |
| PID-8 | Administrative Sex | M | Value-Test Case Fixed |
| PID-10 | Race | | |
| PID-10.1 | Identifier | 2106-3 | Value-Test Case Fixed |
| PID-10.2 | Text | White | Presence-Test Case Proper |
| PID-10.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-11 | Patient Address | | |
| PID-11.1 | Street Address | | |
| PID-11.1.1 | Street or Mailing Address | 89 West 21st Ave | Presence-Content Indifferent |
| PID-11.2 | Other Designation | | Indifferent |
| PID-11.3 | City | Chicago | Presence-Content Indifferent |
| PID-11.4 | State or Province | IL | Presence-Content Indifferent |
| PID-11.5 | Zip or Postal Code | 60630 | Presence-Content Indifferent |
| PID-11.6 | Country | USA | Presence-Content Indifferent |
| PID-11.7 | Address Type | P | Value-Test Case Fixed List |
| PID-13 | Phone Number - Home | | |
| PID-13.2 | Telecommunication Use Code | PRN | Value-Test Case Fixed |
| PID-13.3 | Telecommunication Equipment Type | PH | Value-Test Case Fixed |
| PID-13.4 | Email Address | | NonPresence |
| PID-13.6 | Area/City Code | 406 | Presence-Content Indifferent |
| PID-13.7 | Local Number | 5554019 | Presence-Content Indifferent |
| PID-22 | Ethnic Group | | |
| PID-22.1 | Identifier | 2186-5 | Value-Test Case Fixed |
| PID-22.2 | Text | non Hispanic or Latino | Presence-Test Case Proper |
| PID-22.3 | Name of Coding System | CDCREC | Value-Profile Fixed |
| PID-24 | Multiple Birth Indicator | N | Value-Test Case Fixed |
| PID-25 | Birth Order | 1 | Indifferent |
| PID-29 | Patient Death Date and Time | | |
| PID-29.1 | Time | | NonPresence |
| PID-30 | Patient Death Indicator | N | Value-Test Case Fixed |

PD1 : Patient Additional Demographic

| Location | Data Element | Data | Categorization |
|----------|---|------------------------------|------------------------------|
| PD1-11 | Publicity Code | | |
| PD1-11.1 | Identifier | 02 | Value-Test Case Fixed |
| PD1-11.2 | Text | Reminder/recall - any method | Presence-Test Case Proper |
| PD1-11.3 | Name of Coding System | HL70215 | Value-Profile Fixed |
| PD1-12 | Protection Indicator | N | Value-Test Case Fixed |
| PD1-13 | Protection Indicator Effective Date | 20150624 | Presence-Content Indifferent |
| PD1-16 | Immunization Registry Status | A | Value-Test Case Fixed |
| PD1-17 | Immunization Registry Status Effective Date | 20031221 | Presence-Content Indifferent |
| PD1-18 | Publicity Code Effective Date | 20150624 | Presence-Content Indifferent |

ORC : Common Order

| Location | Data Element | Data | Categorization |
|------------|--|-----------------|------------------------------|
| ORC-1 | Order Control | RE | Value-Profile Fixed |
| ORC-2 | Placer Order Number | | |
| ORC-2.1 | Entity Identifier | MC7722 | Presence-Content Indifferent |
| ORC-2.2 | Namespace ID | NIST-AA-IZ-4 | Presence-Content Indifferent |
| ORC-2.3 | Universal ID | | Indifferent |
| ORC-2.4 | Universal ID Type | | Indifferent |
| ORC-3 | Filler Order Number | | |
| ORC-3.1 | Entity Identifier | MC64411 | Presence-Content Indifferent |
| ORC-3.2 | Namespace ID | NIST-AA-IZ-4 | Presence-Content Indifferent |
| ORC-3.3 | Universal ID | | Indifferent |
| ORC-3.4 | Universal ID Type | | Indifferent |
| ORC-10 | Entered By | | |
| ORC-10.1 | ID Number | 2782 | Presence-Content Indifferent |
| ORC-10.2 | Family Name | | |
| ORC-10.2.1 | Surname | Debonair | Presence-Content Indifferent |
| ORC-10.3 | Given Name | Jack | Presence-Content Indifferent |
| ORC-10.4 | Second and Further Given Names or Initials Thereof | Wayne | Presence-Content Indifferent |
| ORC-10.9 | Assigning Authority | | |
| ORC-10.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| ORC-12 | Ordering Provider | | |
| ORC-12.1 | ID Number | 465 | Presence-Content Indifferent |
| ORC-12.2 | Family Name | | |
| ORC-12.2.1 | Surname | Cato | Presence-Content Indifferent |
| ORC-12.3 | Given Name | David | Presence-Content Indifferent |
| ORC-12.4 | Second and Further Given Names or Initials Thereof | Peter | Presence-Content Indifferent |
| ORC-12.9 | Assigning Authority | | |
| ORC-12.10 | Name Type Code | L | Value-Test Case Fixed |
| ORC-12.13 | Identifier Type Code | MD | Value-Test Case Fixed List |
| ORC-17 | Entering Organization | | |
| ORC-17.1 | Identifier | NISTEHRFAC | Presence-Content Indifferent |
| ORC-17.2 | Text | NISTEHRFacility | Presence-Content Indifferent |
| ORC-17.3 | Name of Coding System | HL70362 | Value-Profile Fixed |

RXA : Pharmacy/Treatment Administration

| Location | Data Element | Data | Categorization |
|------------|--|---------------|------------------------------|
| RXA-1 | Give Sub-ID Counter | 0 | Value-Profile Fixed |
| RXA-2 | Administration Sub-ID Counter | 1 | Value-Profile Fixed |
| RXA-3 | Date/Time Start of Administration | | |
| RXA-3.1 | Time | 20210324 | Presence-Content Indifferent |
| RXA-5 | Administered Code | | |
| RXA-5.1 | Identifier | 59676-0580-05 | Value-Test Case Fixed List |
| RXA-5.2 | Text | Janssen | Presence-Test Case Proper |
| RXA-5.3 | Name of Coding System | NDC | Value-Profile Fixed |
| RXA-6 | Administered Amount | 0.5 | Value-Test Case Fixed |
| RXA-7 | Administered Units | | |
| RXA-7.1 | Identifier | mL | Value-Test Case Fixed |
| RXA-7.2 | Text | mL | Presence-Test Case Proper |
| RXA-7.3 | Name of Coding System | UCUM | Value-Profile Fixed |
| RXA-9 | Administration Notes | | |
| RXA-9.1 | Identifier | 00 | Value-Test Case Fixed |
| RXA-9.2 | Text | New Record | Presence-Test Case Proper |
| RXA-9.3 | Name of Coding System | NIP001 | Value-Profile Fixed |
| RXA-10 | Administering Provider | | |
| RXA-10.1 | ID Number | 2782 | Presence-Content Indifferent |
| RXA-10.2 | Family Name | | |
| RXA-10.2.1 | Surname | Debonair | Presence-Content Indifferent |
| RXA-10.3 | Given Name | Jack | Presence-Content Indifferent |
| RXA-10.4 | Second and Further Given Names or Initials Thereof | Wayne | Presence-Content Indifferent |
| RXA-10.9 | Assigning Authority | | |
| RXA-10.10 | Name Type Code | L | Value-Test Case Fixed |
| RXA-10.13 | Identifier Type Code | PRN | Value-Test Case Fixed List |
| RXA-11 | Administered-at Location | | |
| RXA-11.4 | Facility | | |
| RXA-15 | Substance Lot Number | 041A21A | Presence-Content Indifferent |
| RXA-16 | Substance Expiration Date | | |
| RXA-16.1 | Time | 20210412 | Presence-Content Indifferent |
| RXA-17 | Substance Manufacturer Name | | |
| RXA-17.1 | Identifier | JSN | Value-Test Case Fixed |
| RXA-17.2 | Text | Janssen | Presence-Test Case Proper |
| RXA-17.3 | Name of Coding System | MXV | Value-Profile Fixed |
| RXA-18 | Substance/Treatment Refusal Reason | | |
| RXA-18.1 | Identifier | | NonPresence |
| RXA-18.2 | Text | | NonPresence |
| RXA-18.3 | Name of Coding System | | NonPresence |
| RXA-20 | Completion Status | CP | Value-Test Case Fixed |
| RXA-21 | Action Code - RXA | A | Value-Test Case Fixed |

RXR : Pharmacy/Treatment Route

| Location | Data Element | Data | Categorization |
|----------|-----------------------|---------------|---------------------------|
| RXR-1 | Route | | |
| RXR-1.1 | Identifier | C28161 | Value-Test Case Fixed |
| RXR-1.2 | Text | Intramuscular | Presence-Test Case Proper |
| RXR-1.3 | Name of Coding System | NCIT | Value-Profile Fixed |
| RXR-2 | Administration Site | | |
| RXR-2.1 | Identifier | LD | Value-Test Case Fixed |
| RXR-2.2 | Text | Left Deltoid | Presence-Test Case Proper |
| RXR-2.3 | Name of Coding System | HL70163 | Value-Profile Fixed |

OBX[*]

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|------------------------|------------------------------|
| OBX-1 | Set ID - OBX | 1 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30963-3 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Source | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 1 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | VXC50 | Value-Test Case Fixed |
| OBX-5.2 | Text | Public | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210324 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX: Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 2 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 64994-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Vaccine Funding Program Eligibility | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 2 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | V01 | Value-Test Case Fixed |
| OBX-5.2 | Text | Not VFC Eligible | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | HL70064 | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210324 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | VXC40 | Value-Test Case Fixed |
| OBX-17.2 | Text | Eligibility captured at the immunization level | Presence-Test Case Proper |
| OBX-17.3 | Name of Coding System | CDCPHINVS | Value-Profile Fixed |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|---|------------------------------|
| OBX-1 | Set ID - OBX | 3 | Value-Profile Fixed |
| OBX-2 | Value Type | CE | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 69764-9 | Value-Test Case Fixed |
| OBX-3.2 | Text | Document Type | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | 253088698300036311210201 | Value-Test Case Fixed |
| OBX-5.2 | Text | COVID-19 Janssen Vaccine EUA Recipient-Caregiver Fact Sheet | Presence-Test Case Proper |
| OBX-5.3 | Name of Coding System | cdcs1 vis | Value-Profile Fixed |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210201 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|--|------------------------------|
| OBX-1 | Set ID - OBX | 4 | Value-Profile Fixed |
| OBX-2 | Value Type | DT | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 29769-7 | Value-Test Case Fixed |
| OBX-3.2 | Text | Date Vaccine Information Statement Presented | Presence-Test Case Proper |
| OBX-3.3 | Name of Coding System | LN | Value-Profile Fixed |
| OBX-4 | Observation Sub-ID | 3 | Presence-Test Case Proper |
| OBX-5 | Observation Value | 20210324 | Presence-Content Indifferent |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | NonPresence |
| OBX-6.2 | Text | | NonPresence |
| OBX-6.3 | Name of Coding System | | NonPresence |
| OBX-11 | Observation Result Status | F | Value-Profile Fixed |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210324 | Presence-Content Indifferent |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | Indifferent |
| OBX-17.2 | Text | | Indifferent |
| OBX-17.3 | Name of Coding System | | Indifferent |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-----------------------|-----------------------|
| OBX-1 | Set ID - OBX | 5 | |
| OBX-2 | Value Type | ST | Value-Test Case Fixed |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 30973-2 | |
| OBX-3.2 | Text | dose number in series | |
| OBX-3.3 | Name of Coding System | LN | |
| OBX-4 | Observation Sub-ID | 4 | |
| OBX-5 | Observation Value | 1 | |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210324 | |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

OBX : Observation/Result

| Location | Data Element | Data | Categorization |
|----------|------------------------------|-------------------------------|----------------|
| OBX-1 | Set ID - OBX | 6 | |
| OBX-2 | Value Type | CE | |
| OBX-3 | Observation Identifier | | |
| OBX-3.1 | Identifier | 59783-1 | |
| OBX-3.2 | Text | Status in immunization series | |
| OBX-3.3 | Name of Coding System | LN | |
| OBX-4 | Observation Sub-ID | 4 | |
| OBX-5 | Observation Value | | |
| OBX-5.1 | Identifier | Y | |
| OBX-5.2 | Text | Yes | |
| OBX-5.3 | Name of Coding System | HL70136 | |
| OBX-6 | Units | | |
| OBX-6.1 | Identifier | | |
| OBX-6.2 | Text | | |
| OBX-6.3 | Name of Coding System | | |
| OBX-11 | Observation Result Status | F | |
| OBX-14 | Date/Time of the Observation | | |
| OBX-14.1 | Time | 20210324 | |
| OBX-17 | Observation Method | | |
| OBX-17.1 | Identifier | | |
| OBX-17.2 | Text | | |
| OBX-17.3 | Name of Coding System | | |

Test Data Specification

Patient Information

| Element | Data |
|--------------------------|---------------------------------------|
| Patient Name | Mario Valquez |
| Mother's Maiden Name | Jones |
| ID Number | 89778 |
| Date/Time of Birth | 04/17/1995 |
| Administrative Sex | Male |
| Patient Address | 89 West 21st Ave Chicago IL 60630 USA |
| Local Number | (406)555-4019 |
| Race | White |
| Ethnic Group | non Hispanic or Latino |
| Multiple Birth Indicator | No |
| Birth Order | 1 |

Immunization Registry Information

| Element | Data |
|---|------------------------------|
| Immunization Registry Status | Active |
| Immunization Registry Status Effective Date | 12/21/2003 |
| Publicity Code | Reminder/recall - any method |
| Publicity Code Effective Date | 06/24/2015 |
| Protection Indicator | No |
| Protection Indicator Effective Date | 06/24/2015 |

Vaccine Administration Information

| Element | Data |
|------------------------------------|-----------------|
| Administered Vaccine | Janssen |
| Date/Time Start of Administration | 03/24/2021 |
| Administered Amount | 0.5 |
| Administered Units | mL |
| Administration Notes | New Record |
| Administering Provider | Jack Debonair |
| Substance Lot Number | 041A21A |
| Substance Expiration Date | 04/12/2021 |
| Substance Manufacturer Name | Janssen |
| Substance/Treatment Refusal Reason | |
| Completion Status | Complete |
| Action Code | Add |
| Route | Intramuscular |
| Administration Site | Left Deltoid |
| Entering Organization | NISTEHRFacility |
| Entered By | Jack Debonair |
| Ordered By | David Cato |

| Element | Data |
|--|---|
| Vaccine Funding Source | Public |
| Vaccine Funding Program Eligibility | Not VFC Eligible |
| Document Type | COVID-19 Janssen Vaccine EUA Recipient-Caregiver Fact Sheet |
| Date Vaccine Information Statement Presented | 03/24/2021 |
| dose number in series | 1 |
| Status in immunization series | Yes |