IZ COVID-19 Test Plan

Immunization

Version 1.0.5

17th October 2022

Table of Contents

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
A vaccine reporting application uses the HL7 v2.5.1 Z22 Immunization Profile (VXU Message) with specific test data to create immunization records for patients offered COVID-19 vaccines. The patient vaccine administration records are then transmitted to the IIS. Acknowledgment messages returned by the IIS are out of scope for this Test Group. The administration group of test cases include: **Test Case 1:** Two-dose Vaccine Series with History of 1st Dose (e.g. Moderna vaccine)   **Test Case 2:** Two-dose Vaccine Series with no History of 1st Dose (e.g. Pfizer vaccine)   **Test Case 3:** Vaccine Refusal   **Test Case 4:** Single-dose Vaccine Series (e.g. Janssen (Johnson & Johnson) vaccine)

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 and subsequently q 2nd dose of the Moderna COVID-19 vaccine.

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 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.

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@isp.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	MVX	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	253088698300034911220901	Value-Test Case Fixed
OBX-5.2	Text	COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet – 6 yrs and older	Presence-Test Case Proper
OBX-5.3	Name of Coding System	cdcgs1vis	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		

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 – 6 yrs and older
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 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 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@isp.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[*]

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	MVX	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	MVX	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	253088698300034911220901	Value-Test Case Fixed
OBX-5.2	Text	COVID-19 Moderna Vaccine EUA Recipient-Caregiver Fact Sheet – 6 yrs and older	Presence-Test Case Proper
OBX-5.3	Name of Coding System	cdcgs1vis	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		

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 – 6 yrs and older
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	NISTEHRFacility
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	MVX	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 EUA Recipient-Caregiver Fact Sheet-12 years and older	Presence-Test Case Proper
OBX-5.3	Name of Coding System	cdcgs1vis	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 EUA Recipient-Caregiver Fact Sheet-12 years and older
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

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

Location	Data Element	Data	Categorization

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	MVX	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 EUA Recipient-Caregiver Fact Sheet-12 years and older	Presence-Test Case Proper
OBX-5.3	Name of Coding System	cdcgs1vis	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		

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 EUA Recipient-Caregiver Fact Sheet-12 years and older
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
This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who refused a COVID-19 vaccine. • To support multiple birth indicator.

Evaluation Criteria
Message Validation Report

Notes
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. 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.

Message Contents

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
This test case assesses the ability of the sending application: • To create a vaccine administration message for an adult who received a COVID-19 vaccine.   • To create a Z22 VXU message containing a new administration using an NDC, a CVX, or both for the Janssen vaccine in RXA-5.   • To include a patient factsheet instead of a VIS in the message.   • To support vaccination status "complete".   • To support mother's maiden name.

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	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	MVX	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	cdcgs1vis	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		

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