Description

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

Pre-condition

Selma Nadia McKay (DOB 02/05/2023) is registered in the SUT and one dose of Hep A ped/Adol has been recorded (in preload historical data.). Patient has received 1 of 2 doses.

Daniela Jennifer Wyatt is the practitioner.

Post-Condition

A user has recorded and saved the adverse event for Selma Nadia McKay (DOB 02/05/2023) associated with one dose of Hep A, ped/adol, 2 dose (CVX 83) vaccine as structured data in the SUT. Patient received 1 of 2 doses.

Go to step 3.13.1

Test Objectives

To test the capability that the SUT allows a user to record an adverse event with an established Vaccination Reaction and Adverse Event (IIS) code as structured data (not free text). See Note #1.

Due to the lack of maturity of standards and acceptance of adverse events, transmission to IIS is excluded from the IIP test plan.

Evaluation Criteria

The SUT interface allows the a user to enter the minimum required data elements for recording an adverse event including causative agent, reaction date, adverse event (detail in "minimum required data elements")

Minimum Required Data Elements:		
Presumed causative agent	Hep A, ped/adol, 2 dose (CVX 83)	See Note #2
Reaction noted date	12/22/2023	See Note #3
Structured adverse event	Anaphylaxis (disorder) - 39579001 - SNOMED-CT	See Note #4

The proctor will save screenshots of the user interface showing the required information. If the UI does not includes the structured data (e.g., CVX code and/or SNOMED Code) the proctor will request SUT display and obtain a screenshot of the underlying terminology mapping.

Notes

#1 - The list of coded vaccination reactions may be found here: https://phinvads.cdc.gov/vads/ViewValueSet.action?id=635A4FEA-8232-E211-8ECF-001A4BE7FA90
#2 - Alternatively, the SUT's local equivalent may be used. The SUT's graphic user interface may display text that differs, however this must be bound to an underlying hepatitis A vaccine CVX code listed here: https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvx. Free text is NOT permitted.
#3 - The value for reaction noted date may vary from what is listed in the minimum required elements. It could be: the date reaction occurred, the date identified by a practitioner, or the date recorded in the SUT. Exact dates cannot be assured in data entry so any related date is acceptable.
#4 - Alternatively, the SUT's local equivalent may be used. The SUT's graphic user interface may display text that differs, however this must be bound to an underlying code in the Vaccination Reaction and Adverse Event (IIS) value set. For this specific tested reaction, free text is NOT permitted as anaphylaxis is included in the Vaccination Reaction and Adverse Event (IIS) value set.
#5 In the past IIP tested functionality that included reporting presumed vaccine-related adverse reactions to local public health authorities through data exchange with and IIS as well as reporting of presumed vaccine-related adverse reaction to CDC and FDA, US national public health authorities through a report to Vaccine Adverse Event Reporting System (VAERS). This functionality is considered out of scope and is therefore not tested in the current IIP test plan basic interoperability and data quality module.
#6 In the IIP test case, the SUT is merely being used to record presumed adverse reactions in the local system. This functionality is required to enable subsequent workflow. The SUT should determine the location in the software where entry of the adverse event is appropriate (may vary by SUT - e.g., allergy list, immunization record)