

Description

Administering Practitioner Daniela Jennifer Wyatt begins the process of fulfilling Dr. Ramon Michael Bradshaw vaccine order for Alexandria Montoya (DOB: 03/27/2012). Daniela Jennifer reviews the GARDASIL 9 - HPV9 inventory in the SUT.

Daniela Jennifer Wyatt notes two vaccine items are in the clinic's vaccine storage unit, both for GARDASIL 9 - HPV9, one is expired (Lot Number IIPVAXN09) and the other (Lot Number IIPVAXN08) is unexpired (i.e., still potent).

Pre-condition

- (1) The patient, Alexandria Jacqueline Montoya (DOB 03/27/2012), is registered in the SUT.
- (2) Two vaccine items have been entered into the SUT's inventory both for GARDASIL 9 - HPV9, one is expired (Lot Number IIPVAXN09) and the other (Lot Number IIPVAXN08) is unexpired (i.e., still potent).
- (3) Dr. Bradshaw has ordered GARDASIL 9 - HPV9 for Alexandria Jacqueline Montoya (DOB 03/27/2012).
- (4) Daniela Jennifer Wyatt, the administering practitioner, has opened the SUT's records for Alexandria Jacqueline Montoya (DOB 03/27/2012).

Post-Condition

The SUT makes the expired vaccine dose visually apparent from the unexpired doses to the administering practitioner or does not permit the administering practitioner from selecting an expired vaccine dose.

Go to step 3.11.1

Test Objectives

To test the capability that the SUT allows the administering practitioner to distinguish between expired and unexpired vaccine doses or prohibits the administering practitioner from selecting an expired vaccine dose.

Evaluation Criteria

While selection from a list would allow passive informing of expiration date, bar code scanning only allows active informing. "Active" informing means that the SUT either disallows the entry or allows the entry with information. If disallowed, the user by default must select a different product. If allowed, the user must delete the "incorrect" entry, and proceed to select the different product.

The SUT distinguishes the expired vaccine dose from the unexpired doses and is visually apparent to the administering practitioner. Alternatively, the SUT may prevent expired vaccine doses from being visible or selected by users.

The selection workflow includes clear evidence of a product expiration date in at least one of the following ways (only 1 method is required):

- Passive: The vaccine product with expiration date before today not displayed by the SUT (i.e., cannot be chosen)
- Passive: The display of selectable vaccine products has includes the expiration date and expiration dates before today are displayed with some indication that choosing that product is discouraged (e.g., hover over tooltip, color, bolding, graying out, or other UI indication used by the SUT for similar issues)
- Active: Selection of a specific expired vaccine product to administer generates an informative messages in a method consistent with the SUT for similar issues) - Active informing

Notes

Alternatively, the SUT may meet the requirement by prohibiting the selection of an expired dose. However, careful consideration should be made when implementing such a strategy. A recent real-world example was the extension of emergency use authorization (EUA) vaccine product's expiration date by FDA. In systems where a product's expiration date is not able to be extended, users may need the option to administer vaccine product that the system believes to be expired.