

A Brief on Different Vaccine Lot Numbers on Unit of Sale (package) and Unit of Use (vial/syringe)

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Background

Over the last five years, several vaccine manufacturers have implemented labeling changes related to lot numbers for selected vaccine products. Some of these changes, for approximately ten percent of publically funded vaccine products, resulted in similar but slightly different lot numbers on the unit of sale (UoS) which can be found on the package and the unit of use (UoU) found on the vial/syringe. Those vaccines with different UoU and UoS lot numbers occurred primarily among those vaccines which are reconstituted. This was done to denote a meaning such as the location of the manufacturers' facility or the packing level. FDA regulations allow manufacturers to use different lot numbers on the package UoS versus the container UoU (i.e., individual syringe or vial), but do not require manufacturers to do so.

Challenge

In brief, although some manufacturers use a defined pattern across UoU and UoS lot numbers, it is not always possible to derive the UoS lot number from the UoU lot number. Some Immunization Information Systems (IIS) operations require UoS lot numbers (e.g., for vaccine ordering and inventory management) when reporting public vaccine. However, depending on a provider's clinical workflow and implemented technology solutions (e.g., recording National Drug Codes [NDCs] and lot numbers by scanning 2D barcodes on vaccine vials/syringes), a provider may capture and send to the IIS either the UoS lot number or UoU lot number. The variation in lot numbers poses a challenge to IIS and other health information management systems, e.g. electronic health records (EHR), with inventory modules, to accurately decrement the vaccine inventory from the lot number information captured at the point of vaccine administration. IIS and other systems have difficulty cross-walking between UoU and UoS lot numbers.

Current Tools

Currently, AIRA maintains a published guidance document, [Vaccine Lot Number Patterns: Unit of Sale/Unit of Use Guidance](#). This document is based upon a survey conducted by CDC to identify those public vaccines with different lot numbers and contains a table listing all known vaccines with different lot numbers and the corresponding lot number pattern for a particular vaccine. Those public vaccines not on this list have identical UoS and UoU lot numbers, as reported by the vaccine manufactures. The survey was originally done in 2014 and updated in 2016 to ensure that all applicable vaccines are identified. While providing a general reference on the lot numbers issue, the guidance has limitations – in some cases it is impossible to crosswalk between UoU and UoS lot numbers.

Ongoing Efforts

CDC-IISSB and AIRA are both working to assess the impact on IIS of vaccines with different lot number and to make manufacturers aware of the issue. There are several possible options to address this matter. The first is to persuade manufacturers to return to making UoS and UoU lot numbers identical.

The second is to obtain from vaccine manufactures information on all UoS and UoU lot numbers, and to provide a centralized functionality for lot number mapping that IIS can utilize. This would allow the identification of UoS lot numbers based upon the actual UoU lot numbers, not on lot number patterns. A third solution, to include UoU information in the vaccine ordering system. This would be an expansion of both the IIS and VTrckS systems. In case of the second and third options, appropriate modification of IIS and VTrckS systems to accommodate crosswalk functionality would be necessary. A strong business case will be needed to justify such modifications. CDC and AIRA are partnering to continue to explore these and other potential solutions, and will be working with the IIS community to develop guidance as solutions are found. In the interim, we encourage IIS and immunization program staff to ensure providers are aware that these issues may affect the accuracy of vaccine decrementing, and to be prepared to correct or reconcile inventory as needed.

Updating Information

The survey to the vaccine manufacturers went to those participating in VTrckS: GlaxoSmithKline, MedImmune, Merck, Novartis/GSK, Pfizer/Wyeth, Sanofi Pasteur, and Seqirus. Vaccines from non-VTrckS manufacturers have not been assessed. If you become aware of any vaccine where the lot number differs on the UoS and the UoU (or on the UoS and the UoU lyophilized vaccine powder for the reconstituted vaccines), please share that information with IISinfo@cdc.org ___ and preferably include some images of the respective packages.