

Multi-Dose Vials of Vaccine Should Not Be Discarded after 30 Days

According to the General Recommendations on Immunization of the Advisory Committee on Immunization Practices, published January 28, 2011, page 19, “For multidose vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer.”

Multi-dose vials of vaccine may be used until they reach their expiration date because they contain preservatives. Preservatives are used in vaccines to prevent microbial growth in the event that the vaccine is accidentally contaminated, as might occur with repeated puncture of multi-dose vials. The United States Code of Federal Regulations (the CFR) requires, in general, the addition of a preservative to multi-dose vials of vaccines; indeed, worldwide, preservatives are routinely added to multi-dose vials of vaccine.

The Oklahoma State Department of Health Immunization Service and the Vaccines for Children Program follow the recommendations of the Advisory Committee on Immunization Practices and these recommendations must be followed for all vaccine supplied by the Immunization Service or the Vaccines for Children Program.

References:

Advisory Committee on Immunization Practices *General Recommendations on Immunizations*:

<http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>

U.S. Food and Drug Administration: <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228>

Opened Multi-Dose Vials of Vaccines with Preservatives: Erroneous Myth Persists*

Some errors, once made in publication, seem to take on a life of their own and persist for years, even though the publishing agency later issues a correction. Such an error is the myth that a multi-dose vial of a vaccine which contains preservatives and does not need to be re-constituted with a diluent (e.g., DTP, DTaP, Td, DT, Hepatitis B, Hepatitis A, IPV, influenza, pneumococcal vaccine, and the Hib vaccine “HibTITER” - if they are indeed supplied in multi-dose vials, which is not always the case) should be discarded within 30 days after first opening.

In fact, opened vials of these vaccines can be kept (under appropriate refrigeration) until all doses have been used or until the expiration date on the vial, whichever comes first. CDC and Immunization Branch guidelines on vaccine storage and handling make this clear. Further, the California Department of Health Services Licensing and Certification Program has removed any directive that such vaccine vials be discarded within 30 days after first being opened.

What contributes to the continued confusion is that many pharmaceutical agents without preservatives, if supplied in multi-dose containers (which is now rare), do need to be discarded within shorter time periods. This includes live virus vaccines and vaccines supplied as a lyophilized powder or pellet with diluent for reconstitution by the user.

Various accreditation agency inspectors and other technical advisors continue, from time to time, to make the same error with regard to vaccines with preservatives in multi-dose vials. Health care facilities which encounter such inaccurate statements should let the inspector/advisor (or their supervisor if resistance is encountered) know of their error.

*Taken from the State of California's Immunization Update newsletter, April 10, 1998, page 6