



CDC Policy on Unused Smallpox Vaccine

October 17, 2005

Introduction

CDC has developed this policy on unused smallpox vaccine in response to questions raised by several smallpox vaccination programs and to provide a recommendation on maintaining a readiness to respond to an attack involving the use of smallpox. The sections below describe why CDC recommends that all smallpox vaccination programs should continue to maintain unopened vials of Dryvax[®] vaccine to assure a readiness to respond to a smallpox outbreak or to continue vaccination activities.

Background

The goal of smallpox preparedness is to ensure federal, state, and local health agencies have the optimal capacity to respond to a smallpox outbreak. National smallpox preparedness capacity has been increased by: (1) offering vaccination safely to volunteer public health teams (including vaccinators) in order to conduct investigations and outbreak control for the initial cases of a smallpox event; and (2) offering vaccinations safely to key volunteer healthcare workers who would treat and manage the initial smallpox cases and suspects.

The currently available licensed smallpox vaccine Dryvax[®] was produced more than 20 years ago and has been remarkably stable since that time. Its storage and handling requirements are similar to those of other licensed vaccines, and are detailed in the website listed below in the Unopened Vials of Smallpox Vaccine section. To assure a readiness to respond to a smallpox outbreak, the post-event smallpox vaccine inventory and ancillary supplies will be maintained by the Strategic National Stockpile (SNS) in addition to the more modest supplies of smallpox vaccine deployed for pre-event vaccination efforts conducted by state and local health agencies.

Following the attacks of September 11, 2001, fears about potential terrorist attacks involving smallpox prompted the removal of some Dryvax[®] smallpox vaccine supplies from storage facilities maintained at -20 o C to cold stores maintained at 2 o to 8 o C in order to conduct testing for re-licensure of the product. It is the intent of Wyeth Pharmaceuticals, manufacturer of Dryvax[®] (smallpox vaccine), to continue to monitor and perform routine tests, as required, on the vaccine that has been released under their license. These tests include potency of distributed lots of Dryvax[®] and, if appropriate, provide a notice of dating extension for all lots of vaccine. Notification of dating extension will occur via the State and Local Preparedness Program in the Office of Terrorism Preparedness and Emergency Response (SLPP), SNS, and the National Immunization Program (NIP). Considering the stability of Dryvax[®], CDC believes that this potency testing process is likely to result in dating extensions for the foreseeable future or until the new smallpox vaccine is licensed and available.

Unopened Vials of Smallpox Vaccine

CDC recommends that unopened vials of Dryvax[®] vaccine distributed for pre-event vaccination efforts continue to be maintained by state and local health agencies to assure a readiness to respond to a smallpox outbreak or to continue vaccination activities. In contrast to pediatric vaccines that are routinely

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returned for credit or disposal, once Dryvax® is distributed, it will not be recovered by CDC for redistribution and/or disposal.

As part of their post event smallpox plan, state and urban area BT programs have the flexibility to forward deploy local stores of Dryvax®, e.g., in local clinics or hospitals. Forward deployment must follow the policies and procedures described in the "Guidelines for Smallpox Vaccine Packing and Shipping" developed by SNS in January 2003 (available from <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/packing-shipping.pdf>).

Opened Smallpox Vaccine Vials

CDC recommends that unopened vials of Dryvax® vaccine distributed for pre-event vaccination efforts continue to be maintained by state and local health agencies to assure a readiness to respond to a smallpox outbreak or to continue vaccination activities. In contrast to pediatric vaccines that are routinely returned for credit or disposal, once Dryvax® is distributed, it will not be recovered by CDC for redistribution and/or disposal.

As part of their post event smallpox plan, state and urban area BT programs have the flexibility to forward deploy local stores of Dryvax®, e.g., in local clinics or hospitals. Forward deployment must follow the policies and procedures described in the "Guidelines for Smallpox Vaccine Packing and Shipping" developed by the Strategic National Stockpile (SNS) in January 2003 (available from <http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/packing-shipping.pdf>). This document also describes policies and procedures regarding smallpox vaccine storage and handling (Section 2) and protecting smallpox vaccines and diluent (pages 3-5).

Two major problems in storage and handling can rapidly reduce vaccine potency: 1) freezing vaccines that should not be frozen or 2) letting infectious (live) vaccines warm. Smallpox vaccine must be kept at appropriate temperatures to retain effectiveness.

- Smallpox vaccine should be kept between 2° to 8°C (36° to 46°F).
- Smallpox vaccine, like DTaP, Hep A, Hep B, Hib, PCV and IPV, should **never** be frozen.
- Diluents should **not** be frozen.
- Smallpox vaccine should **always** be protected from heat.

Dryvax® vaccine that has been frozen should be discarded using vaccine disposal procedures noted in the following section.

Dryvax® vaccine that has been exposed to temperatures above 8°C (46°F) should be quarantined at 2° to 8°C (36° to 46°F) and not used for vaccination unless approval is provided by Drug Services, Scientific Resources Program, National Center for Infectious Diseases at CDC. Smallpox vaccination programs must contact Drug Services by calling (404) 639-3670 to receive approval for use of Dryvax® vaccine subjected to temperatures above 8°C (46°F).

Questions regarding the use of Dryvax® vaccine diluent in smallpox vaccine kits exposed to temperatures outside the recommended range of 2° to 8°C (36° to 46°F) should also be directed to CDC Drug Services.

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Smallpox Vaccine Disposal

Unopened vials of smallpox vaccine which have been frozen, subjected to temperatures of $<2^{\circ}\text{C}$, or $>8^{\circ}\text{C}$ and not approved for use by CDC Drug Services, or have passed expiration and/or extension dating, should be discarded using medical waste disposal procedures. Vaccine vials can be dropped into the hospital sharps container and autoclaved, or disposed of following the procedure for all other biohazard materials. These instructions are also true for empty, used smallpox vaccine vials and unused, unopened vials which have exceeded the expiration date.

In places where medical waste is buried, soaking the medical waste in a 1:10 dilution of bleach for at least 10 minutes before disposal is advised.

For more information, visit www.cdc.gov/smallpox,
or call CDC at 800-CDC-INFO (English and Spanish) or 888-232-6348 (TTY).

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