



CDC Policy on Unused Smallpox Vaccine

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 ° C to cold stores maintained at 2 ° to 8 ° C in order to conduct testing for re-licensure of the product. From the fall of 2001 to May 31, 2003, Dryvax[®] has been tested and had dating extension approved 2 times. 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 (~4th Q-2004).

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

Once a vial of Dryvax ® has been reconstituted, the vaccine has a shelf life of 90 days if maintained at 2 ° to 8 ° C (36 ° to 46 ° F). The vial and any vaccine unused after this 90 day time period must be disposed of using proper biological waste disposal techniques.

As stated in the Background section above, it is the intent of Wyeth to continue to retest the potency of the smallpox vaccine and, if appropriate, provide dating extension letters for all lots of vaccine. A vial of Dryvax ® that has been opened for less than 90 days, but which has passed the expiration date, should be held by the program pending notification of an extension of the expiration date. While waiting for an expiration date extension, the vaccine cannot be used to vaccinate individuals. However, once the extension is granted, the vaccine can be used up until the end of the 90-day shelf life of an opened vial of vaccine. Any vaccine remaining after 90 days past opening of the vial must be disposed using proper biological waste disposal techniques regardless of an extension of expiration date.

Reconstituted smallpox vaccine must not be forward deployed (see discussion above on forward deployment of vaccines) to another state smallpox vaccination program.

Smallpox Vaccine Disposal

Opened, unused vials of smallpox vaccine, which have been reconstituted and have passed expiration and/or extension dating, should be discarded using medical waste disposal procedures. It 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.

Accounting for Smallpox Vaccine

State and urban area BT programs are responsible to report to the State and Local Preparedness Program in the Office of Terrorism Preparedness and Emergency Response the number of vials and the estimated number of disposed doses of smallpox vaccine. Reports should be submitted in conjunction with reports (progress, semi-annual and annual) required by the Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism – Budget Year Four. Reports should use the following format:

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Name of Smallpox Vaccine Storage Site	Smallpox Vaccine Lot #	Expiry Date	# <i>Un-opened</i> Vials On Hand As of (Reporting Date)	# <i>Opened</i> Vials On Hand As of (Reporting Date)	Total # Vials On Hand As of (Reporting Date)

For further information, contact the State and Local Preparedness Program in the Office of Terrorism Preparedness and Emergency Response at (404) 498-2200, Thomas MacKay, (404) 639-5991, at the Strategic National Stockpile, or Gary Urquhart.

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)