

Clinical Guidance for Smallpox Vaccine Use IN A POSTEVENT VACCINATION PROGRAM

WB2559

PROGRAM DESCRIPTION:

The goal of this report is to provide recommendations that are intended to outline the clinical use of the three smallpox vaccines stored in the U.S. Strategic National Stockpile for persons who are exposed to smallpox virus or at high risk for smallpox infection during a post-event vaccination program following an intentional or accidental release of the virus.

OBJECTIVES:

Upon completion of this educational activity, the reader should be able to:

- (1) describe the basic natural history of smallpox virus infection,
- (2) describe the characteristics/properties of the three smallpox vaccines,
- (3) describe the basic public health and infection control measures used to control and prevent the transmission of smallpox virus,
- 4) describe the rationale and methods employed by CDC to develop the recommendations,
- 5) describe the populations, for whom smallpox vaccine is recommended,
- 6) describe the populations at high risk of adverse events from smallpox vaccine.

FACULTY/ CREDENTIALS:

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EXPIRATION DATE:	February 20, 2017
URL:	www.cdc.gov/mmwr
HARDWARE/SOFTWARE:	Computer Hardware; Internet connection; Browser
MATERIALS:	Access to internet
TARGET AUDIENCE:	Physicians, Registered Nurses, Public Health Community
PREREQUISITES:	Knowledge of the clinical use of the smallpox vaccines
FORMAT:	Web-based, MMWR Journal
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CDC, our planners, our presenters content experts, and their spouses/partners wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters with the exception of Dr. Sharon Frey and she wishes to disclose that she has worked on several clinical trials for smallpox vaccines in the past that were funded by the current manufacturers of smallpox vaccines (i.e., Sanofi Pasteur and Bavarian Nordic) and by the NIH, received funding from the current smallpox vaccine manufacturers for past travel expenses to present at conferences and a training session, and will organize one study site for a clinical trial investigating Imvamune funded by the NIH and Bavarian Nordic. Following the workshop and during the writing of the guidance, Dr. Frey disclosed that she accepted an offer by Bavarian Nordic before initiation of guidance development to serve as the chair of a committee evaluating the ability of smallpox vaccine to induce a major or equivocal cutaneous reaction in participants of a clinical study.

Content will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Petersen's, Dr. Damon's and Dr. Lynfield's discussion on two investigational smallpox vaccines. The report includes recommendations for two investigational smallpox vaccines that are anticipated to be used under emergency use authorization or investigational new drug protocols in the event of a declared public health emergency involving smallpox.

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