



## **Smallpox Pre-Vaccination Information Packet: Contents and Instructions**

**The following information is for state and hospital personnel implementing smallpox vaccination programs.**

### **Contents**

- 1. Cover Letter** – A letter from Dr. Julie Louise Gerberding, M.D., MPH., Director of the Centers for Disease Control and Prevention (CDC) to potential vaccinees explaining the purpose of the national smallpox preparedness program, encouraging individuals to know their health status and to err on the side of caution in making their vaccination decision and detailing the contents of the Smallpox Pre-Vaccination Information Packet.
- 2. Smallpox Vaccine Information Statement (VIS)** - This document, entitled "Smallpox Vaccine: What You Need to Know," contains information about smallpox disease, the benefits and risks of smallpox vaccine, contraindications, vaccination site care instructions, what to do if a reaction occurs after vaccination, and where to get more information.
- 3. Pre-Event Screening Worksheet for Smallpox Vaccine** – a worksheet with questions to help individuals determine whether or not they should receive smallpox vaccine because of certain medical conditions that would place them at a greater risk for an adverse reaction from the vaccine. Some of these questions are of a personal and sensitive nature. Those implementing smallpox vaccination clinics should be prepared to discuss, but not collect, this sheet.
- 4. Someone You are Close to May Get Smallpox Vaccine: What You Should Know and Do** - a fact sheet that informs close contacts of people considering vaccination about the health conditions that put people at risk if they are in close physical contact with someone who has been vaccinated. This sheet also provides information about the steps close contacts can take to protect themselves.
- 5. Smallpox Vaccine: Decision Point for the Smallpox Vaccine Candidate** – a short video intended as an overview for use at vaccination clinic sites to supplement the written materials listed above.
- 6. Patient Medical History and Consent Form** – a form for clinic personnel to record patient information. The form also confirms the absence of contraindications and contains a consent signature line for the patients. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.
- 7. Temporary Proof of Vaccination and Site Check Reminder Sheet** – This form serves as temporary proof of vaccination, contains follow-up appointment information, and provides vaccine recipients with a phone number to call if they think they are having an adverse reaction to the vaccine.

### **Instruction for Use**

This package of materials is to be used as part of the national smallpox preparedness program to help ensure that potential vaccinees are adequately informed of the benefits and risks of smallpox vaccination, to assist in screening out individuals who should not receive the vaccine, and to obtain signed consent from those individuals who receive smallpox vaccine. In particular circumstances as provided by law, the federal government may assume liability for injury or death attributable to a smallpox vaccination. The materials contained in this packet fulfill federal obligations to inform vaccinees about the risks and benefits of the smallpox vaccine. **Use of the items in this packet as instructed below is mandatory. Do NOT alter the materials or replace them with alternative documents.**

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- **Provide items 1, 2, 3, and 4** to potential vaccinees as early as possible **before they make an appointment for vaccination**. Potential vaccinees should be given adequate time to obtain HIV or pregnancy testing, discuss contraindications with household contacts, talk to their health care providers, and check medical records.
- **Provide items 1-4** again to persons **when they present to the clinic** to receive smallpox vaccination. Give all individuals an opportunity to read the materials and view the "Decision Point" video (**item 5**) **before they consent to be vaccinated**. Offer to read the documents for individuals, especially if you suspect that they have difficulty understanding the material due to reading ability or language barriers. **Questions and concerns should be elicited from potential vaccinees and addressed by a trained health care provider.**
- Use the Patient Medical History and Consent Form (**item 6**) to confirm the absence of contraindications. Obtain signed consent and date on this form from all vaccinees. This document **must be retained by the clinic** for 5 years or the length of time required by state law, whichever is longer.
- Following immunization, provide vaccinees the Temporary Proof of Vaccination and Site Check Reminder Sheet (**item 7**). Clinic sites should insert local or state telephone numbers for adverse event reporting.
- Provide vaccinees a record of immunization following vaccination site examinations. It is the responsibility of each state to determine what type of permanent record of immunization they will use. Adult immunization cards may be obtained from the Immunization Action Coalition at [www.immunize.org](http://www.immunize.org).

Providing the materials in this packet does not preclude clinic personnel from verbally educating potential vaccinees. Provide all individuals considering vaccination the opportunity to discuss the topics covered in these materials with a trained health care provider.

**The materials in this packet may be revised periodically. Each state is responsible for ensuring that all of their participating smallpox vaccination clinics use the most current versions of the materials. All current print materials are available on the CDC's smallpox website at [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox).**

### States May Alter and/or Supplement the Materials Only as Follows

As stated previously, CDC requires use of the materials in this packet, without alteration. States, however, may alter or supplement the materials only as follows:

- Some states may wish to supplement the CDC packet with statements on workers compensation coverage, health insurance coverage and/or wage issues. CDC does **not** need to review such materials.
- Some states may wish to include a cover letter when providing the CDC information packet. In general, we recommend that such letters be short given the amount of other materials to be provided to potential vaccinees. Cover letters and other supplemental materials must not contradict information already in the CDC information packet. CDC does not need to review cover letters that merely address logistical issues related to volunteering for the response teams and arrangements for being immunized.
- In particular circumstances, with CDC's concurrence, states may choose to apply further restrictions in availability of smallpox vaccination within their jurisdictions. States may explain these

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restrictions by using supplemental materials, provided they are **approved by CDC**. Specifically, some states have expressed interest in excluding from smallpox vaccination in the early phases of the program individuals who have children less than one year of age in their household. The ACIP has noted that this is not a contraindication to receipt of smallpox vaccine. However, as noted, states may choose to further restrict availability of the smallpox vaccine to certain populations. Materials should not describe such a state restriction as a "contraindication."

- The CDC Patient Medical History and Consent Form must be used. If a state determines that state law requires an additional consent form, CDC needs to review and approve the additional form. Such requests must be accompanied by an explanation of the specific provisions of state law that require an additional consent form.
- CDC does not object to states reformatting the Patient Medical History and Consent Form to ease data entry as long as the content is identical to the original form.
- The CDC Patient Medical History and Consent Form no longer includes fields to collect employer information or a medical screener signature. Some states may wish to continue to collect employer, employer address, and medical screener signatures and may do so without obtaining approval from CDC.

Each state is responsible for ensuring that all of their participating smallpox vaccination clinics use the entire CDC smallpox vaccine information packet and approved state supplements, without alteration.

Submit all proposed supplemental materials to Raymond Strikas, M.D., [ras8@cdc.gov](mailto:ras8@cdc.gov), 404-639-8813, and Denise Jackson, at [dhj9@cdc.gov](mailto:dhj9@cdc.gov), 404-639-8775. CDC will reply to requests for approval within two working days with approval, disapproval with explanation, or note we need more time to review.

For more information, visit [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox) or  
call the CDC Clinician Information Line at (877) 554-4625 (English)