



**Review of the Centers for Disease Control and  
Prevention's Smallpox Vaccination Program  
Implementation: Letter Report 3**  
Committee on Smallpox Vaccination Program  
Implementation

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# Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation

Letter Report # 3

Committee on Smallpox Vaccination Program Implementation  
Board on Health Promotion and Disease Prevention

INSTITUTE OF MEDICINE  
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Willing is not enough; we must do.”*

—Goethe



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### Consultant

- WILLIAM H. FOEGE, M.D., M.P.H.,** Presidential Distinguished Professor, Department of International Health, Emory University and Health Advisor, Bill and Melinda Gates Foundation

## **Study Staff**

**KATHLEEN STRATTON, Ph.D.**, Study Director

**ALINA BACIU, M.P.H.**, Program Officer

**ANDREA PERNACK, M.P.H.**, Program Officer

**NICOLE AMADO, M.P.H.**, Research Associate

**AMBER CLOSE**, Senior Project Assistant

**ROSE MARIE MARTINEZ, Sc.D.**, Director, Board on Health Promotion and Disease Prevention

## REVIEWERS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

**John Ball, M.D., J.D.**, American Society for Clinical Pathology  
**Ruth Berkelman**, Emory University  
**Bobbie Berkowitz, Ph.D., R.N.**, University of Washington  
**R. Gordon Douglas, Jr., M.D.**, Cornell University Medical College  
**Mary Gilchrist, Ph.D.**, University of Iowa  
**Peter Jensen, M.D.**, University of California, San Francisco  
**Michael Katz, M.D.**, March of Dimes Birth Defects Foundation  
**Fitzhugh Mullan, M.D.**, *Health Affairs*  
**Tener Goodwin Veenema, Ph.D., M.P.H.G., M.S.**, University of Rochester  
**Robert A. Weinstein, M.D.**, John Stroger Hospital of Cook County (IL)

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Ronald Estabrook, Ph.D.**, University of Texas Southwestern. Appointed by the National Research Council and Institute of Medicine, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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## REVIEW OF THE CENTERS FOR DISEASE CONTROL AND PREVENTION'S SMALLPOX VACCINATION PROGRAM IMPLEMENTATION

### Letter Report #3

May 23, 2003

Dr. Julie Gerberding  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE  
Atlanta, GA 30333

Dear Dr. Gerberding:

The Committee on Smallpox Vaccination Program Implementation is pleased to offer you our third letter report in a series of brief reports providing advice to the Centers for Disease Control and Prevention (CDC) on the implementation of the pre-event smallpox vaccination program. In addition to some general comments about program activities, the committee would like to draw your attention to two main issues:

1. Considerations for next steps in the pre-event vaccination program, and
2. The smallpox components of the Continuation Guidance for the Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism—Budget Year Four detailed in Program Announcement 99051 (DHHS, 2003a).<sup>1</sup>

In particular, the committee would like to reaffirm the need for a pause in the program, before the vaccine is offered more widely, and also make some specific suggestions about the recently issued guidance. In a forthcoming report, the committee intends to focus on issues surrounding definitions and measurements of smallpox preparedness, and its integration into broader bioterrorism readiness. The committee will also discuss screening and follow-up issues relevant to the continuation of the vaccination program, and answer specific questions asked by CDC and its partners at the May 1, 2003 committee meeting.

### General Comments

The committee reiterates its high regard for CDC and its partners, and the remarkable amount of work completed in the national smallpox vaccination program, especially in the context of additional strain on all resources caused by the emergence and spread of Severe Acute Respiratory Syndrome (SARS). In fact, the committee heard from program administrators that

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<sup>1</sup> The guidance was issued on May 2, 2003, after the release of the committee's second report on March 27, 2003. State applications are due July 1, 2003.

the effective response to SARS both at the national and local level was at least in part facilitated by smallpox preparedness efforts, in particular the improved communication and collaboration among parties.

The committee has noted that the safety system implemented by CDC worked as intended, bringing the cardiac adverse events to the immediate attention of the ACIP Smallpox Vaccine Safety Working Group and program administrators at CDC who responded promptly by modifying screening procedures and informed consent materials. The program has progressed with deliberation and caution. Thus far, the screening of potential vaccinees may have played a role in preventing several of the historically expected moderate-to-severe adverse events (e.g., eczema vaccinatum, progressive vaccinia) to the vaccine in 36,217 people vaccinated in the civilian program as of May 9, 2003 (CDC, 2003c). Also, it appears that vaccinee education on the risk of vaccinia transmission to contacts and measures taken to prevent it with appropriate bandaging and site care have worked well, and may in part account for the absence of reported cases of vaccinia transmission from civilian vaccinees to either healthcare or personal contacts.

Although safety data to date have not revealed many of the moderate-to-severe adverse events or transmission that historically have been associated with smallpox vaccination, this does not necessarily mean that more robust trends will not be discovered later in the process, as vaccination numbers increase and more occupationally diverse volunteers consider vaccination.

The enactment of the smallpox vaccination compensation legislation (Smallpox Emergency Personnel Protection Act of 2003; P.L. 108-20) is likely to remove one of the barriers to vaccination identified by the committee and others (APHA, ASTHO and NACCHO, 2003).<sup>2</sup> As this is a complex matter, the committee notes the need for additional clarification by CDC to the states on the provisions of the law, and for fact sheets or other explanatory materials for potential vaccinees. These fact sheets should clearly explain the provisions of the legislation and protections enacted, and refer potential vaccinees to additional information sources, such as their own state health department.

### **Considerations for Next Steps in the Vaccination Program**

It is imperative that before continuing to expose individuals to a vaccine that is effective, but not without some risks, the national and state programs determine what level of pre-event vaccination is needed for preparedness. In its first report (IOM, 2003a), the committee recommended that “sufficient time should be allowed between the two phases to ensure adequate assessment and plan revision by CDC and its partners” and in its second report (IOM, 2003b), recommended that the evaluation of “the effectiveness of implementation and the safe use of the vaccine” be carried out as extensively as allowed by “the mandates and realities of the vaccination program.” At the program’s beginning, it appeared that a wide variety of data about the process and the outcomes of the first phase of vaccination would be available, and that comprehensive evaluation could be conducted between phases. Although the initially expected civilian numbers have not been reached, pausing to evaluate remains an important component of

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<sup>2</sup> At the time of the writing of this report, the compensation language in CDC’s Vaccine Information Statement had not yet been updated to reflect the newly enacted legislation.

the overall program of safely building smallpox preparedness. Also, by combining the safety data from both civilian and military vaccinations (totaling over 460,000 vaccinees) a great deal can be learned, shared, and disseminated (CDC, 2003a; DoD, 2003). CDC acknowledges that there is “a natural pause that occurs between stage one and stage two” (Henderson, 2003).

The committee recognizes that pausing also involves potential risks. A pause implies slower vaccination of the number of responders a jurisdiction may require for preparedness, a loss of momentum, and perhaps vulnerability in the event of a potential smallpox event. However, given that the smallpox threat level, as it is publicly described, has not changed, the committee continues to believe that the benefits of the pause likely outweigh the risks. The committee is aware that some jurisdictions have already begun offering the vaccine to a wider population of potential vaccinees, but reaffirms the need for a pause.

The committee recognizes that it is important for states to finish the vaccination of volunteers to complete health care and public health response teams according to state plans. However, in reiteration of its previous recommendations, **the committee recommends CDC facilitate the efforts of states that wish to pause to evaluate the process and outcomes of their vaccination efforts to date, and plan for next steps before deciding whether and when to begin vaccination of new personnel. CDC should provide states with a target date for when CDC expects to have completed its revision of materials, data systems (adding new occupational categories, etc.), and guidelines. States that have identified a need for more vaccinated volunteers to carry out specific smallpox response functions will then be able to set their own timeline for vaccinating these new groups.**

The pause is important for three programmatic reasons.

- 1. Safety.** First, a pause is needed to evaluate the vaccination program’s processes and outcomes to date, and thus ensure that expanded vaccination continues to be as safe as possible for both vaccinees and their contacts. The fact that by April 29, 2003, only 34% of vaccinees<sup>3</sup> were included in the Smallpox Vaccine Adverse Event Active Surveillance System (Mootrey, 2003) is an example of the additional work needed to help provide more data for a national view of the program. Some adverse events might not arouse concern on a state level, but aggregated nationally, new patterns could emerge. The cardiac complications were unexpected adverse events, and there may be others. That is why it is important to ascertain whether or not the vaccine played a role in the cardiac events, and rule out any other reasons for concern before vaccination is expanded to other populations.
- 2. Changing circumstances.** Second, a pause would allow time for CDC and the states to modify vaccination plans, data systems, and materials in response to changing circumstances (i.e., a new population of potential vaccinees). At the committee’s second and third meetings, states commented on the need to revise educational materials before expanding vaccination to new types of volunteers (Bresnitz, 2003; Toomey, 2003; Pezzino, 2003). Furthermore, the Pre-Vaccination Information Packet has not been updated since March 31, 2003 (CDC, 2003b). It would be helpful for many states if these

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<sup>3</sup> Of vaccinees at 28 or more days post-vaccination.

changes and revisions were made before they proceeded with vaccination, in part to avoid the difficulty of implementing changes midcourse (ASTHO, 2003; Pezzino, 2003).

- 3. Overall smallpox preparedness.** Third, vaccination is not a goal in itself, but a component of overall smallpox preparedness. Therefore, a pause is needed to re-evaluate the vaccination program's implications for and integration into overall smallpox preparedness nationally and locally (i.e., to determine what level of pre-event vaccination is needed, and what personnel should be vaccinated to play specified roles in smallpox response).

Some issues to be addressed before deciding whether and how to proceed with vaccination include tasks to be accomplished in the short-term, before moving on to new types of vaccinees:

- The completion of an in-depth analysis and investigation of all known serious adverse events to date and possible risk factors;
- The determination of what numbers and types of vaccinated personnel are needed to achieve preparedness;
- The update of educational and training materials by CDC;
- The revision of program data systems to include new types of vaccinees and to account for differences in data entry anticipated in expanding to a wider range of occupational contexts and personnel; and
- The development of guidelines regarding vaccine "take" readings, vaccination site checks and site care, and other issues related to vaccination follow-up of new types of vaccinees.

There are also tasks to be addressed on an ongoing basis and that are also significant to smallpox preparedness in general:

- The establishment of communication and collaboration with other partners (e.g., first responders, security personnel, health care and hospital systems, community-based health care providers);
- The revision by state and local programs of response plans that lay out clear roles and activities for teams responding to a potential event; and
- The need for strategic planning and reconciliation of the smallpox vaccination program with other bioterrorism programs and other public health priorities.

A break in the course of the vaccination program may help prevent vaccinating potentially large numbers of additional volunteers (e.g., health care workers, traditional first responders, and others) less safely than in the first phase of vaccinations, without adequate time to implement or update safeguards (e.g., screening, training and education) that would be appropriate to new types of vaccinees and their contacts.

## Comments About the Guidance

The continuation guidance issued May 2, 2003 outlines three elements of smallpox preparedness (DHHS, 2003b).<sup>4</sup> In its review, the committee has focused largely on the first element, “preparing key responders before an event occurs,” and noted that jurisdictions may define both “preparing” and “key responders” differently (DHHS, 2003b).

Part of the “preparation of key responders” (DHHS, 2003b: 2) occurred when health care and public health response teams were trained and vaccinated as part of what has previously been called “phase I” of the pre-event vaccination plan. As the committee has learned (ASTHO, 2003; Judson, 2003; Madlock, 2003; Selecky, 2003), state and local jurisdictions differ in their definitions of key responders, and the decisions about what preparation means. As noted, we will address this in a forthcoming report. The committee believes it is important that in addition to facilitating expanded vaccination if states conclude it is needed for preparedness, CDC should also facilitate the other smallpox preparedness activities (e.g., training, planning) of states that decide they have enough personnel vaccinated at this time.

The guidance contains several areas that may require clarification either because they provide insufficient direction for state programs, or may not be consistent with the overall tenor of the guidance documents. Several such items are found in Annex A of the guidance (DHHS, 2003b).

- First, page 2 states that since smallpox could appear in any hospital, “considerations must be made to ensure each facility has an acceptable number of teams vaccinated.” Although many hospitals have formed and vaccinated response teams, this statement seems to imply that all hospitals need vaccinated response teams in order to be prepared, but this differs from the decisions and plans made by some jurisdictions and their partners. This guideline needs clarification or restating to call for planning to ensure each facility has the ability to train, and where applicable, train and vaccinate, identified individuals and teams pre-event, and that all facilities have access to vaccine and plans for vaccination of their employees post-event or if the threat level rises.
- Second, on page 5 the development of a comprehensive smallpox response plan is described as including post-event plans from “participating hospitals.” It is unclear how “participating” is being defined. If it refers to hospitals that have vaccinated personnel, it should also be described how hospitals that choose not to participate in pre-event vaccination will be included in the planning process.
- Third, page 3 provides a list of the types of personnel to be trained and vaccinated “in the following order.” If these categories are indeed to be prioritized in this way, it is unclear why vaccinating security staff pre-event is more important than vaccinating health care providers. Furthermore, it is not clear in this section what type of staff should be trained as vaccinators.

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<sup>4</sup> The three elements of preparedness are: “(1) preparing key responders before an event occurs; (2) rapid detection, identification, investigation and response to suspect or confirmed cases of smallpox; and (3) protection of the public including provision of mass vaccination clinics” (DHHS, 2003b).

- Fourth, on page 4, the guidance states that the public should be assured that public health has the capacity to “fully vaccinate the entire population within a short period of time once smallpox has been identified” and on page 6 of 7, that large-scale vaccination is to be “rapidly” executed. State programs might benefit from more specific guidance about the time frame for which they should aim.

The committee also noticed that the final enhanced capacity described in Focus Area B corresponds to one of the ingredients of smallpox preparedness identified in our phone discussions with local and state programs (“working links between health department staff and key individuals and organizations engaged in healthcare, public health, and law enforcement”) (personal communications to staff, April 21–29, 2003). It is not clear why this important issue has not been identified as a critical capacity; preparedness appears to require working relationships with hospital administrators, fire, emergency and law enforcement officials, and many others.

In closing, the committee expresses its thanks for the opportunity to be of assistance to CDC and its partners. It would like to reiterate its call for a pause to facilitate evaluation and planning before moving on to more widespread voluntary vaccination of other types of personnel. Furthermore, the committee hopes its comments on the recently released guidance are helpful as states prepare their responses, and as CDC evaluates those responses.

Brian L. Strom, *Committee Chair*  
Kristine M. Gebbie, *Committee Vice Chair*  
Robert B. Wallace, *Committee Vice Chair*  
Committee on Smallpox Vaccination Program Implementation

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