

American Nurses Association
Review of the Institute of Medicine Report
Review of the Centers for Disease Control and Prevention's Smallpox Vaccination
Program Implementation
Letter Report #1

1/24/2003

On January 17, 2003, the Institute of Medicine's (IOM) Committee on Smallpox Vaccination Program Implementation issued its first report, *Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation, Letter Report #1*. The Centers for Disease Control and Prevention (CDC) charged the committee with providing guidance on how to best implement the President's policy regarding pre-event smallpox vaccination, addressing the following eight areas:

1. the informed consent process;
2. contraindications screening;
3. the system in place to assess the safety profile of the smallpox vaccine;
4. guidance for the treatment of vaccine complications;
5. professional training programs CDC is developing;
6. the communication efforts;
7. guidance CDC offers to states in developing their implementation plans; and
8. overall progress at achieving the goals of the program.

The committee met on December 19, 2002, to deliberate and gather information. ANA provided testimony before the committee on the concerns of the nursing community.

The following is a review of the recommendations made in the report. To the extent that ANA has spoken to that particular recommendation or the recommendation reflects ANA policy this will be noted in italics.

The committee urges CDC to consider these key messages:

1. Highlight the unique nature of the smallpox vaccination program as a public health component of a national bioterrorism preparedness policy, focusing on the delivery of clear, consistent, science-based information.
2. Proceed cautiously, allowing continuous opportunity for adequate and thoughtful deliberation, analysis, and evaluation. Embark on phase II only after adequate evaluation of phase I has occurred.
3. Use a wide range of methods for proactive communication, training, and education, and customize it to reach diverse audiences, including potential vaccinees, all health care providers, and the general public.
4. Designate one credible, trusted scientist as key national spokesperson for the campaign and sharpen and expand communication plans and strategies to ensure rapid, transparent, and sustained contact with the media throughout implementation.

The committee addressed the issue of national security concerns and its relationship with the known risks of this particular vaccination as understood from previous use, and the assumed benefit of the vaccine reflective of the potential risk for encountering the smallpox virus. The report goes on to say that "based on the administration's statement that the risk of a smallpox attack is indeterminate (not zero but currently assumed to be very low), the benefit of the vaccination program to the public also is not zero but is assumed to be very low. The benefit to any individual might indeed be zero if the individual never encounters the smallpox virus. However, in the event of exposure to smallpox virus, the benefit to individuals may be very high. Given this profile of high

vaccination risk and likely very low to zero benefit, the administration's policy to offer vaccination to public health, medical, and emergency workers must be implemented in a most prudent cautious manner."

The committee recommends that CDC develop and communicate criteria (e.g., types and rates of adverse reactions) that would trigger a reconsideration of the current systems in place to protect vaccinees and their contacts.

In its testimony, ANA called for a more measured and deliberate process that will help to ensure that the program is implemented appropriately and that the screening for those at risk is thorough. Subsequent to ANA testifying before the Committee, ANA called on the Bush Administration to delay implementation of the smallpox vaccination program until the questions raised have been addressed.

To most effectively evaluate the progress and outcomes of the first phase, the committee recommends that CDC utilize the variation in implementation by hospitals and health departments (e.g., differences in granting administrative leave, types of bandages used, different site care instructions, degree of patient contact, adverse reaction investigation) to obtain safety data, and to analyze these data before embarking on subsequent phases of the vaccination program.

Since June 2002, ANA has argued against vaccination of the general public stating that the response to a potential bioterrorist attack must be weighed against a real understanding of the risk. This is particularly true when talking about Smallpox and the initiation of a prevention vaccination program where the vaccine poses a substantial health risk to those who receive and it poses a risk for transmission from one person to another, particularly in a population with a large number of immunocompromised or otherwise at risk individuals.

The committee recommends that CDC and its state and local public health partners immediately work to clarify each state's worker compensation program's position on coverage for smallpox vaccine-related injuries and illnesses for workers covered under their programs.

ANA has clearly called on the Administration to address this question and is working in coalition with other unions, provider groups and public health associations to address this issue within the Administration and legislatively.

The committee recommends that CDC and the Department of Health and Human Services support all efforts, some of which might be administratively or legislatively bold and creative, to bring this issue of compensation for smallpox vaccine adverse reactions – including those reactions that occur despite non-negligent manufacture and administration of the vaccine – to speedy resolution.

ANA would strongly concur and has recommended delay in implementation of the program until this question has been addressed.

The committee recommends that during phase 1, CDC assess the effects of the current situation regarding administrative leave, disseminate the analysis widely, and before phase II begins, decide whether the ACIP recommendation needs to be reassessed. Any evidence of transmission of vaccinia virus to a patient from an immunized health care workers should lead to an active case investigation or to an immediate reassessment of policy.

ANA has expressed concern about the ACIP's recommendation against furloughing vaccinated health care providers. Current ACIP guidance provides for covering the vaccination site with an absorbent and/or an occlusive dressing. It is unclear if this is sufficient to protect patient and family members from transmission of the vaccinia virus.

The committee recommends that CDC work with their public health partners to document as well as possible the true costs of the smallpox program.

ANA is working in coalition with the unions and public health associations to develop a costing methodology that will capture both the costs to the public health system, as well as the costs associated with potential lost work time and treatment of adverse reactions.

INFORMED CONSENT PROCESS:

The committee recommends that all consent documents include a statement that the risks of the smallpox vaccine, while very low, are predictably higher than the risks associated with most other vaccines, but that the benefit is presently unknown – possibly very low (absent exposure to smallpox) or very high (in the event of exposure).

ANA would concur with this recommendation.

The committee further recommends that informed consent forms include explicit notification of the availability, or lack thereof, of compensation for adverse reactions.

ANA would strongly concur with this recommendation.

CONTRAINDICATIONS SCREENING:

Understanding that different populations may interpret the educational and screening materials somewhat differently, the committee recommends that CDC pre-test the educational and screening materials in populations with different educational, socioeconomic, and cultural backgrounds before these materials are used for the first phase of the pre-event smallpox vaccination program, if this is possible given the time frame. If not, then material should be evaluated after phase I, and modified before phase II.

In its testimony, ANA called for the development of literature that provides guidelines and resources for avoiding contact and accidental exposure to the vaccinia virus. ANA stated that these materials must be made available in all public health settings and any place where vaccinated health care workers are employed.

The committee recommends that CDC develop specific educational materials for household contacts of potential vaccinees.

ANA would concur with this recommendation.

The committee recommends that the materials also include instructions about how household members can avoid accidental infection with vaccinia, should the household member choose not to disclose the contraindication to the vaccinee.

ANA would concur with this recommendation.

The committee recommends that CDC collect data on the reasons why potential vaccinees choose not to be vaccinated.

ANA would concur as long as issues of confidentiality and privacy are addressed.

ASSESSMENT OF SAFETY PROFILE:

The committee strongly recommends that active surveillance for adverse reactions be employed, rather than relying exclusively on the passive surveillance systems that already exist.

ANA would concur with this recommendation.

The committee recommends that CDC use the Pre-Event Vaccination System (PVS) as the primary data collection system for adverse reactions.

The committee recommends a follow-up on a subset of individuals in PVS rather than a telephone survey of vaccine recipients. The follow-up survey could be used to gather information on long-term effects from the vaccine, as well as information on cases of accidental vaccinia infection in household members of vaccinees, rather than focusing on obtaining data on common adverse reactions.

The committee strongly recommends analysis of the phase I PVS data as a series of nested case-control studies, with results available before moving on to phase II of the vaccination program.

TREATMENT OF VACCINE COMPLICATIONS/CDC SAFETY SYSTEM GUIDANCE TO STATES:

The committee recommends CDC evaluate each state's capacity for managing adverse reactions before indicating that a state is ready to begin vaccinations.

In its November 7, 2002 letter, ANA stated that sufficient doses of Vaccinia Immune Globulin (VIG) should be readily available.

TRAINING AND EDUCATION:

The committee recommends that CDC expand the scope of their training and education regarding the identification, treatment, and reporting of serious adverse reactions to all clinicians.

ANA would concur with this recommendation.

The committee recommends that the first communication clinicians receive is basic information about the details of the pre-event smallpox vaccination program.

ANA would strongly concur with this recommendation.

COMMUNICATION:

The committee recommends that CDC’s communication efforts about smallpox vaccination clearly separate public health issues from national security matters. The latter are best addressed by representatives of the administration more directly involved in such matters, and not be representatives of scientific agencies. Therefore, the responsibility of CDC is to deliver clear, consistent, and science-based public health communications.

ANA would strongly concur with this recommendation. In its testimony, ANA stated that initiating a smallpox vaccination program is not something to be undertaken lightly and its ultimate success and the success of future bioterrorism protection measures will depend upon the transparency of the plan and the trust that health care workers and citizens have in the government to protect both their national security and their health and safety.

The committee recommends that CDC identify a single “voice” for the national vaccination program, a credible individual with a strong scientific background. Additionally, the agency should develop several back-up sources for the media who can offer the same level of informed comment and thoughtful observation as the program’s primary voice.

ANA would concur with this recommendation.

The committee recommends that more attention be given to developing a variety of materials and channels to inform and educate the public about the immunization program before vaccinations begin.

ANA would concur with this recommendation.

AREAS OF POTENTIAL FUTURE INQUIRY:

- Discussion of the optimal response to an immediate change in the determination of smallpox threat, with a focus on state and local preparedness;
- A review of local readiness for implementation and an assessment of opportunity costs and resource allocation issues;
- Assessment of the adequacy of the screening materials, based on experiences during the first phase;
- Assessment of the adequacy of the informed consent materials (particularly the information provided to vaccinees on the relation of risks to benefits and the range of possibilities for adverse reactions), based on experiences during the first phase;
- Assessment of secondary transmission to contacts, including an assessment of site care guidance and vaccinee’s adherence to that guidance;
- Occupational safety issues, particularly related to bifurcated needles;
- A review of organization and function of the Data and Safety Monitoring Board (DSMB); and
- Prioritization of recommendations recognizing that multiple demands may be necessary and some of the committee’s recommendations require resources.

Committee on Smallpox Vaccination Program Implementation

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