Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program Implementation: Letter Report 2

Committee on Smallpox Vaccination Program Implementation

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Letter Report # 2

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

INSTITUTE OF MEDICINE
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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:

Ruth Berkelman, M.D., Emory University
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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 **Elaine Larson, Ph.D., R.N.,** Columbia University. Appointed by the National Research Council and Institute of Medicine, she 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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Letter Report #2

March 21, 2003

Dr. Julie Gerberding
Director
Centers for Disease Control and Prevention
1600 Clifton Road, NE
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Dear Dr. Gerberding:

The Committee on Smallpox Vaccination Program Implementation is pleased to offer you our second letter report. We appreciate your timely response to our first report issued on January 17, 2003 (Gerberding, 2003). In particular we note that a number of recommendations have been implemented or their implementation is planned, including, but not limited to:

- creating and implementing active surveillance for adverse events;
- developing an information sheet for contacts of vaccinees;
- adding information about the status of compensation issues in the Vaccine Information Statement; and
- enhancing evaluation efforts.

We hope that our second report proves useful to you and your partners. We also realize that the Centers for Disease Control and Prevention's (CDC) planning and implementation activities have been advancing rapidly while the committee has been developing its report, and it is possible that at the time of the report's release, CDC will have already made changes congruent with some of our recommendations.

CURRENT PROGRAM CONTEXT

At the time the committee met on February 13, 2003, the vaccination program was three weeks old. Approximately 1,000 vaccinations had taken place in the civilian population, and the military program reported well over 100,000. Within one week, the number of civilian vaccinations had more than doubled. As of March 14, 2003, the total number of civilians vaccinated by the states was nearly 22,000 (CDC, 2003d). On March 6, 2003, the Secretary of the Department of Health and Human Services (DHHS) announced a proposal for a compensation program for vaccinees who are injured as a result of receiving the smallpox vaccine. On the same day, states were instructed that they could expand voluntary vaccination to all health care workers and first responders (e.g., firefighters, law enforcement, and emergency

workers) as a continuation of the first phase rather than as a distinct second phase of vaccinations (Connolly, 2003c). Also, vaccinations were to be offered to certain federal employees (e.g., Commissioned Corps of the Public Health Service, CDC staff). Despite the plan for expansion, many impediments to participation remain as they were in December 2002. Many health care workers and the officials of health agencies or organizations:

- do not consider themselves (or their institutions) at high risk of a smallpox attack;
- are confident that, in the event of an attack, vaccinations can take place quickly enough to protect them and the public;
- are troubled about the possibility, however small, of transmitting the virus to their patients, particularly those who are immunosuppressed;
- remain concerned about the lack of comprehensive, no-fault adverse event compensation (The committee is pleased that the administration has attempted to remove this barrier by proposing a smallpox vaccination compensation plan to Congress, in the hope that a resolution of this issue will lead to greater willingness to receive the vaccine. However, at the time of this writing, Congress had not yet made a decision regarding compensation.); and
- remain concerned about the implications of possible administrative leave or duty reassignment.

In this report, the committee addresses several important issues: the vaccination program's need for evaluation (including program safety) and clearly defined objectives; a needed emphasis on defining preparedness against smallpox attack; CDC's communications plans; CDC's training and education efforts; the systems for monitoring the safety of the vaccine; the need for a compensation program; and matters of resource allocation.

CDC completed an enormous amount of work between the committee's first and second meetings. The committee extends its congratulations and expresses its admiration to CDC and the thousands of state and local partners in health departments, hospitals, and elsewhere involved in this program. The vaccination program has thus far progressed cautiously and with great deliberation, with states, local jurisdictions, and hospitals taking locally appropriate steps (Henderson, 2003). It is fitting that the beginning, scale, and pace of each local program have been dictated by considerations of the safety of participants and their families and close contacts (who may be vulnerable to spread of vaccinia from an improperly cared for vaccination site), and by local decisions and analyses about what smallpox preparedness requires.

SUMMARY OF KEY MESSAGES

The committee urges CDC to:

1. Carry out all aspects of ongoing discussion, planning, and analysis of the smallpox vaccination program with the intent to advance the goal of smallpox **preparedness**.
2. Conduct comprehensive **evaluation** of the program and its outcomes in order to improve its implementation and to protect the vaccinees and the public.

OVERARCHING ISSUES: PREPAREDNESS AND EVALUATION

Plans for implementation of the vaccination program have evolved in a way that precludes the firm demarcation between what were initially intended as two distinct phases or stages of the program. The committee hopes that this turn of events will not impair efforts to ensure the safest vaccination program possible, but steps must be taken to (1) define and progress toward smallpox preparedness, and (2) evaluate the effectiveness of implementation and the safe use of the vaccine as extensively as the mandates and realities of the vaccination program will allow. Thus, evaluation at the national level might not take place before the program progresses (although some state and local jurisdictions may be able to pause for evaluation before expanding their program activities) but at least should occur simultaneously, to ensure that lessons are learned from phase I even in the face of a rapid expansion.

In its first report (IOM, 2003: 5), the committee observed that generally, "public health interventions are undertaken with recognition of some benefit to some individuals, no effect on others, and the possibility of some risk to a small percentage of the population …, with expectation of overall benefit to the population receiving the intervention." The committee believes it is important to reiterate the risk-benefit context of the smallpox vaccination program.

> "Based on the administration's statement[1] that the risk of a smallpox attack is indeterminate (not zero but currently assumed to be very low) (White House, 2002), 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 and cautious manner."

Understanding this complex reality highlights the importance of both preparedness to ensure optimal benefit to the public (i.e., rapid vaccination in the event of smallpox attack) and evaluation to ensure the lowest risk from the vaccine (i.e., overall program safety, including safe use of the vaccine).

A Focus on Preparedness

The expressed intent of the expansion, as the committee understands it, is to make the vaccine available to greater numbers of relevant personnel. However, it is important to retain a focus on smallpox preparedness as the goal of the program. Increasing the number of vaccinated persons might contribute to meeting that goal, but it does not mean preparedness to respond to a smallpox attack has been achieved. Having more vaccinated individuals is only as effective as

[1] The President's statement was made on December 13, 2002. Although there has been no public statement about an increase in the risk of smallpox attack specifically, at the time of this writing, the Homeland Security Department has elevated the national threat level to Level Orange, or high risk of attack, and the U.S. campaign in Iraq has begun (White House, 2003).

the plans for deploying these individuals in a potential smallpox bioterrorist event and the collaboration and communication among the various agencies responsible for aspects of smallpox preparedness. This means that a jurisdiction needs not only sufficient workers to vaccinate the public, diagnose and treat cases, and conduct other needed activities (e.g., identify and protect immediate contacts), but also well-defined roles for all auxiliary agencies and workers, such as law enforcement, firefighters, and emergency personnel. Communities, in partnership with state and federal public health agencies, will need to define smallpox preparedness, assess how close they are to attaining it, and decide what additional actions are needed to ensure they are prepared.

At its February 2003 meeting, the committee heard from CDC and its partners that the success of program activities should not be judged solely by number of vaccinees reached, but by what has been a principal goal since the beginning—preparedness, in terms of safely building capacity to respond effectively to a potential smallpox bioterrorism event (Anderson, 2003; Henderson, 2003). It is important to note that the President's statement on December 13, 2002, gave no numerical goal, but later statements by the administration and the Department of Health and Human Services offered between 400,000 and 500,000 vaccinees as a possible total (CDC, 2002). Although based on assumptions and very rough calculations,[2] these figures quickly became the symbolic target for phase I of the program, but as was noted in the February 6, 2003 CDC telebriefing, the program "goal is achievement of a preparedness capacity" (CDC, 2003a).

The Committee strongly agrees with the emphasis on preparedness. Although original estimates were useful in planning and initiating the program, the practical experience acquired by states and localities in the first several weeks of the program suggests that other benchmarks are equally, if not more important. CDC will now be able to consider both the realities of operationalizing the vaccination program and a more careful view of how many vaccinated individuals, and in what roles, it would take to achieve preparedness to respond to a smallpox attack.

Defining Preparedness

In general, state and local jurisdictions will be able to determine when they are prepared to respond to a case of smallpox in their region, but due to the movement of populations across state boundaries and to geographic, program, and resource variations among states, there is an undeniable need for leadership and coordination at a national level. Also, agreement on local, state, and national definitions of smallpox preparedness would be helpful in evaluating the program's success. (An outbreak in one state has implications for that state's neighbors and all

[2] The June 2002 Advisory Committee on Immunization Practices (ACIP) recommendation was for the creation of at least one public health response team per state or territory and for health care teams in designated hospitals to serve as referral center for initial smallpox cases. Rough estimates made at that time indicated that approximately 15,000 vaccinees would be required. That recommendation was revised in October 2003 due in part to concerns that no one hospital would volunteer for what could be viewed as the stigma of "the smallpox hospital" in that state. Thus, the recommendation was amended to offer all acute-care hospitals the opportunity to create smallpox health care teams. Rough estimates made at that time indicated that this approach would result in approximately 500,000 vaccinees (AMA-CSA, 2003). In practice, it appears that the reality of the program will result in a number of vaccinees somewhere between these two estimates.

states need the assurance that neighboring jurisdictions are sufficiently prepared and have the capacity to assist in an emergency if needed.) The Public Health Competencies for Bioterrorism and Emergency Preparedness and the state and local Emergency Preparedness and Response Inventories may be useful resources in developing smallpox-specific inventories and checklists of competencies to guide action and enable evaluation (Columbia University, 2002).

CDC and its state and local partners face the need to determine how to best and most rapidly integrate a new set of potential vaccinees into efforts toward smallpox preparedness. CDC's goals for the entire vaccination program (i.e., preparedness/ capacity to respond, protection of those who will investigate and treat suspected cases, and gaining experience with vaccination, [Anderson, 2003]), suggest that states may determine that once each local jurisdiction: (1) has ready access to both a public health and a health care response team;[3] (2) is capable of investigating an outbreak and caring for cases;[4] and (3) is ready to rapidly and safely vaccinate anyone else necessary—from additional health care workers to the general public—it can conclude that it has completed precautionary smallpox vaccination of critical personnel, thus accomplishing one component of overall preparedness. Clearly, the contribution of additional vaccinees to this profile of preparedness can best be assessed by each jurisdiction in partnership with CDC.

As the committee noted in its first letter report (IOM, 2003), state and local officials working to approach smallpox preparedness goals would benefit from taking into account program sustainability, particularly in terms of staff turnover. At the state level, program management and leadership could be affected by turnover in state health commissioners, and at the local level, the ability of a jurisdiction to rapidly vaccinate great numbers of people could be affected by changes in the employment status of members of public health and health care response teams. The prospect of such changes requires planning, recruitment, training, and education for volunteers needed to replenish the smallpox response teams, and training and education of new state public health officials, to help ensure program continuity.

Thus, the committee recommends that CDC work with states to decide what more is needed to achieve smallpox preparedness, if anything. Further, given the routine turnover in personnel, each state should evaluate what it needs to maintain this preparedness.

Concerns About Program Expansion and Implications for Preparedness

The committee has a number of significant concerns triggered by the program's rapid expansion to make the vaccine available to all health care providers, emergency responders, and others (Connolly, 2003c). First, the program's swift expansion may inhibit CDC and state efforts to evaluate the program with a focus on strengthening the systems that promote the safest and most effective vaccination program possible. These systems include analyzing vaccine

[3] Note: this does not require that each jurisdiction should contain a public health or health care smallpox response team.

[4] October 2003 ACIP recommendation states that a health care team should be sufficient to provide "continuity of care" for two days.

adverse event data, the effectiveness of training and education materials, the ability of screening and informed consent measures to protect vaccinees, and the effectiveness of clinical care setting-based processes (e.g., bandages and leave) in preventing spread. In other words, expanding the program before conducting a thorough evaluation may preclude the opportunity to learn from the first phase or stage of the program before proceeding.

The committee's second concern pertains to funding. As discussed later in the report, some public health agencies and hospitals participating in the program have described serious difficulties in making limited resources adequately address general public health prevention needs, overall bioterrorism preparedness, as well as the requirements of the smallpox program (Libbey, 2003; NACCHO, 2003). Expanding the vaccination program may negatively affect other aspects of smallpox preparedness, bioterrorism preparedness in general, and even the delivery of essential public health services. At the time this report is being written, it is not clear when or even if additional funding will be made available to state and local programs for the expansion of smallpox vaccination.

Third, the committee is concerned about the opening of the program to more potential vaccinees before guidance pertaining to this expansion is available, and before many states and localities have had the opportunity to develop new objectives and more detailed plans about the integration of new types of workers into overall smallpox preparedness. Furthermore, many states and localities may not have had the chance to initiate or enhance linkages with the agencies (e.g., local police and fire departments, emergency management, etc.) that will be involved in the expansion. New populations of potential vaccinees imply at a minimum new training and education needs, novel types of occupational and contact issues, and additional communication to the general public.

The committee's concerns are further informed by the clear unease expressed at the committee's February 13, 2003 meeting by the liaison panel to the committee—a group of organizations invited to inform the committee of the real-world implications of the program—about the plan for one continually expanding vaccination effort. They asserted that this did not seem consistent with the way the program was described at its launch, and expressed great concern that such an attempt to seamlessly blend the two phases would pre-empt and prevent attempts to evaluate the first phase before embarking on wider vaccination.

The committee will hold its third meeting on May 1, 2003. At this meeting, leaders of state, local, and hospital-based vaccination programs will discuss the lessons learned and best practices demonstrated in the first three months of the vaccination program, and will also discuss how the communities are defining and measuring smallpox preparedness. The committee expects that sufficient experience will have been gained by that time to help create a significant contribution to the smallpox vaccination program evaluation for CDC and its partners.

A Need for Evaluation

As the administration and CDC likely anticipated, and the committee observed in its first report (IOM, 2003), the program has evolved. Although our understanding of existing threat assessments has not changed, the vaccination program has moved from the tabletop into the field, where things have progressed in ways determined by state and local circumstances and decisions. **The committee recommends that CDC conduct comprehensive evaluation of the program and its outcomes in order to improve its implementation and to protect the vaccinees and the public.** This would ideally occur before program expansion, but present circumstances may require creative ways to evaluate during expansion.

Ongoing evaluation at the national and state levels should include (1) learning about best practices and process issues in implementing the program (including an assessment of program costs), (2) a determination of smallpox preparedness, and (3) an assessment of the program's safety. Evaluating the ways the program has been conducted might include the logistical and administrative issues addressed by states and localities, from clinic management to communication methods and messages. Determining whether preparedness has been reached might include comparing outcomes to objectives identified in planning, such as number of response teams, and measures for wide-scale vaccination, such as the number and distribution of mass vaccination clinics, and security and transportation issues. Evaluating program safety might include, but not be limited to, careful data collection about adverse events following vaccination, accurate clinical descriptions that are integrated with laboratory data, taking advantage of the national experience to determine modern incidence rates for vaccine reactions, and identifying risk factors for these reactions. Since the Department of Defense (DoD) has vaccinated a much larger cohort than the civilian vaccination program to date, it is hoped that data on adverse events in DoD's vaccination program will be incorporated, to the extent possible, in the overall evaluation of vaccine safety.

As the committee has stated previously, evaluation is a matter of data analysis, not specifically of time, and would entail, among other issues, the necessary reasoned analysis of the strengths and weaknesses of the procedures used to ensure patient and contact safety in the first phase. Because vaccination programs in most jurisdictions by early March 2003 are unlikely to be of sufficient size for a full evaluation, an evaluation of national scope is needed to assure that the analysis is powerful enough to provide meaningful information as the program progresses. Although present realities may make it impossible to conduct a national evaluation at a particular point in time, efforts must be made to analyze data on a national scale as soon as sufficient data are available. Based on the findings of such an evaluation, supplemented with state-level evaluations, states may deem that preparedness goals have been reached. If more vaccinees are needed, the evaluation will be important in guiding efforts to make the program better, faster, and safer.

Any effort to assess the level of smallpox preparedness must be linked with an analysis of the threat of a smallpox attack. Accurate communication (discussed in the next section) about the current threat assessment is critical, and the federal government has a responsibility to

communicate any change in that threat assessment, whether an increase or decrease, to the American public. Ensuring both preparedness (capacity to extend the benefits of the vaccine to the public) and the lowest possible vaccine risk to the public's health is only possible if decisions and informed consent are based on the best available information about the level of threat.

PROGRAMMATIC ISSUES

Communication[5]

CDC is to be congratulated for greatly expanding its communication efforts in a short amount of time and demonstrating recognition of the importance of communications in the implementation of the smallpox vaccination program. Below, the committee will address broad issues related to CDC's communication planning, as it has been presented to the committee, and later will address specifics, including answers to questions asked by CDC about its communications.

Overarching Communications Issues

The communication effort could be strengthened if CDC defines the objectives for the program's expansion, and for smallpox preparedness in general, and then determines the communication strategies that will help meet these objectives. As in its first report (IOM, 2003), the committee urges CDC to focus on defining audiences, developing clear messages for each, determining best and multiple channels for communication, and explaining to each audience its present role. Media coverage of the program may leave members of the general public confused about the immediacy of the threat, the need to get vaccinated, and other issues. It is critical that CDC, as the nation's trusted public health authority, inform the public about what steps are being taken to protect them against smallpox and other bioterror threats. Ultimately, despite the novel challenges of our time and this particular program, CDC is still engaged in carrying out what has always been its defined and historic mission of safeguarding the public by promoting health and preventing disease.

In addition to the need to strengthen communication capacity, the committee believes that communication means much more than dissemination. It also involves listening to the public to assess their level of knowledge about smallpox (disease and vaccine), as well as their opinions and attitudes. Efforts to survey the public should be ongoing, to help refine communication materials and diversify channels for communication. The planning, implementation, and evaluation of strategic communication activities for the smallpox vaccination program could begin to form a foundation for broader communication about bioterrorism.

[5] Communication, training, and education have overlapping meanings. For the purpose of clarity and brevity, this report will generally use "communication" to describe activities that target the media and the general public , and "training and education" when the audiences are public health and health care response team members and other vaccinees with functional roles in smallpox preparedness.

Communication Specifics

Communicating with the General Public. Print and broadcast media interest in the program has been a constant since the program began. However, it has also become apparent that smallpox vaccination is a subject of greater complexity than many health issues in the public dialogue, due to its emergence out of national security considerations, its relationship to other bioterrorism preparedness measures, and persisting concerns about liability and compensation. This complexity may make it more difficult to communicate clearly and accurately. The program's expansion to other categories of responders highlights the fact that communication will continue to be an area of critical importance, in relaying information about the evolving program to the public and gauging public understanding and opinion about the issues.

Media reports provide a wide range of on-the-ground perspectives and informal program implementation updates. Some media reports about the vaccination program have reflected the concerns of organizations, agencies, and individuals, others have conveyed reassurance about the public health system's readiness to respond to bioterror threats. Some adverse events following smallpox vaccination have been reported in the media before CDC has formally described these adverse events. There seems to be a range of perceptions, both reflected in and by the media, about the program and the vaccine. Some concerns about and attitudes toward the vaccination program may be in part related to the current lack of clarity about the program's objectives mentioned above. For example, because the parameters for the program are unclear (e.g., timelines, definitions, and evaluation of preparedness), it is possible to conceive of each hospital that declines to participate as a blow to preparedness, or of vaccinee numbers that are far from target as a detriment to the first line of response. Such conclusions may not be warranted, but are somewhat understandable in the existing information environment. Therefore, **the committee recommends CDC revisit and communicate to the public the program's objectives in view of state-level realities, and provide a preliminary perspective on the national and state success in reaching those objectives. The CDC should continue to support, as well as build on the experience of state and local health departments who are developing their communication strategies about state and local program implementation.**

The committee is aware of CDC's forthcoming public service announcements, and looks forward to additional communication activities targeting the general public. A great range of groups are important to consider as audiences and as partners in communication, including schools, religious congregations, local community organizations, and professional associations, among others. Local resources, such as community leaders and other trusted individuals could be mobilized in addition to national spokesperson(s) for the vaccine, and a wide range of communication channels employed to reach the broadest constituencies.

States have begun to develop and disseminate public communications (e.g., newspaper inserts) on the subject of bioterrorism, including information about smallpox disease, vaccine, and the vaccination program. Although national and state efforts to keep communities informed are needed, the committee expressed some concern that the messages given to the public may not be timely, may be too broad, and may provide a great deal of unfocused, undifferentiated information.

The committee recommends that CDC and its state and local partners develop communications strategies that:

1. **Provide adequate quality and quantity of information.** Communication to the public should consist of well-developed, consistent messages that provide scientific and public health information specifically relevant to the current assessment of disease risk (Covello and Sandman, 2002). Although pages of small print and dozens of facts and details, are useful in some cases and with some audiences, public communication would be most effective using clear, concise, and focused language, in an easy-to-read and culturally appropriate format, with instructions for accessing more detailed information (e.g., through a website, toll-free information hotline). Also, it may be helpful to generate core messages for nation-wide use, to which information relevant to local circumstances may be added.
2. **Are timely.** The timing of messages is important to promote a realistic understanding of current risk. For example, vaccinations are not recommended for the general public at this time, and communication efforts should carefully reflect this. However, other messages and information should be finalized and ready for release in the event circumstances require a change in communication content.
3. **Reassure the public that efforts are in progress to protect them in the event of a smallpox attack.** People should be informed that the public health system is increasing its capability to protect them, with response teams ready to vaccinate, and identify and treat cases. However, such communication can occur only if program objectives are defined and supported by adequate resources, and preparedness is demonstrated by subsequent evaluation efforts. Clearly, jurisdictions can only reassure the public about their readiness to respond to a smallpox attack if they indeed are ready; thus, communication is contingent on achieving an adequate degree of preparedness. Information should be made available about post-event readiness as part of the pre-event communication strategies.

As is the case with training and education efforts, discussed later in this report, messages about smallpox (disease, vaccine, and vaccination) call for careful planning, design, and pretesting to ensure comprehension, and require evaluation to determine whether anticipated knowledge and behavior changes have occurred. Several polls and surveys (Blendon et al., 2002; Nowack et al., 2002; NNii, 2003) have demonstrated that many people, including health professionals, have inaccurate or incomplete understanding about matters related to smallpox, and such misinformation can be easily spread, creating unnecessary anxiety. It is also possible that confusion over smallpox vaccination could have an adverse impact on public attitudes and behaviors regarding childhood immunization, unless communication is very carefully planned.

It is not easy to reconcile the program's present focus on public health and health care response teams with the need to communicate with and to the public. Although the public needs information and education on the subject of smallpox, this would ideally be accomplished without creating or confirming a sense of crisis and anxiety, hence the need for sufficient, but focused information. Current vaccination policy, based on a threat assessment that is believed to be low but not zero, and possible but not imminent, states that it is not necessary for the public to

receive smallpox vaccine at this time. Therefore, the public should receive enough information that will reassure them that these actions are appropriate at this time.

Communicating with the Media. Furthermore, while media reports provide the valuable service of informing the public about the vaccination program's progress, they sometimes include inaccurate information (e.g., misrepresenting the severity of adverse reactions). For example, generalized vaccinia is a condition that may result from smallpox vaccination, and it consists of a generalized, benign rash. Although this is not considered a life-threatening adverse reaction to the vaccine, it might sound like one, and without adequate explanation in media reports, the public may perceive it as such. In order to facilitate accuracy in media reports**, the committee recommends CDC develop and offer journalists training materials and opportunities specifically designed for the media, explaining the program's clinical components, providing the best available scientific evidence, and dedicating staff experts to provide technical support to media representatives.**

CDC asked the committee to provide advice on the level of investment that should be committed to communication efforts. It is clear that communication is one of the core aspects of the program, not a marginal, disposable component, and the effectiveness of communication activities in the smallpox program will build a foundation for other bioterrorism activities. Assuring the public has basic accurate knowledge about the disease and the vaccine, and informing about the public health system's efforts to prepare itself to protect the public's health could strengthen the credibility of CDC as a trusted source of health information.

Communicating with Health Care Workers and Others. In addition to communicating with the media and the general public, it is important that CDC and its state and local public health partners maintain regular communication with health care entities, as well as law enforcement, fire, emergency response, and other relevant agencies. Local governments should ensure that public health, health care, and emergency responders are well-informed about post-event vaccination plans and, should the threat level of smallpox attack rise, about the processes by which the state would reconsider and communicate its decision about expanded precautionary vaccinations and widespread vaccination.

Training and Education

The committee applauds CDC's efforts to develop partnerships with professional organizations and clinician networks to provide a forum for education, training, and clinician communication with CDC. The committee noted the stratification of information for clinicians into "Just in case" and "Just in time" — demonstrating readiness both to provide essential information broadly to all clinicians, and to release additional information for immediate clinician access in the event of a suspected case or outbreak. The committee is also pleased to see that CDC has enlarged the circle of clinicians to include others, such as nurses and physician's assistants. However, the evidence base used to develop training and education for clinicians must go beyond how physicians learn to include nurses and physician's assistants. CDC's intention to utilize a broad array of methods is likely to be of assistance in educating and training.

Given the program's expansion, great care should be given to developing training and education materials to be delivered through a wide range of channels to the potential vaccinees who may include other health care workers, as well as emergency, law enforcement, and fire personnel. This may require functional modules addressing the occupation issues of all possible areas of practice. Training and education efforts should also include continuing broad dissemination of information to and dialogue with all health care providers around the country, as well as evaluating the effectiveness of training and education. It is important to note that carrying out this component of the program might require resources.

Broad Issues Relevant to Training and Education

CDC has produced a vast array of training and education tools, and is disseminating them widely. The committee believes it would be of great value, however, to conduct outcome evaluation and not just process evaluation of these activities. Some excellent learning tools have been developed, but an assessment of the effectiveness of educational materials in increasing knowledge is needed. Such an assessment might evaluate the dissemination of materials (i.e., are they easily accessed) and their effectiveness in increasing target group knowledge (e.g., increasing familiarity with CDC smallpox site care in clinicians and vaccinees, clinician and vaccinee knowledge of expected reactions to vaccinia, health care provider familiarity with local smallpox response plans and their personal roles, and clinician awareness of clinical resources, such as the CDC Clinician Information Line).

Specific Issues in Training and Education

It is not apparent from the materials and information available to the committee whether educational products and training activities for other health care providers (e.g., respiratory therapists and radiology technicians) and other members (e.g., security and housekeeping staff) of hospital response teams are available at the time of the writing of this report. Furthermore, the committee's liaison panel expressed a need for educational materials that are relevant to professional practice and the circumstances of vaccination, (for example, health care providers working with recently vaccinated patients, or emergency medical technicians and other first responders who may be exposed to newly vaccinated individuals). Each of these groups, as well as the functional groups within public health response teams, requires customized materials and information, and the committee encourages CDC to assess and respond to their needs for training and education utilizing a range of materials and channels of dissemination most appropriate for each group.

The committee was pleased to find out that CDC has been taking steps to increase the readability of materials developed to provide important information about smallpox vaccine and vaccination, and even to translate many into other languages (Nowak, 2003). **The committee recommends that all print materials addressed to a diverse audience (e.g., the public) should be easily read and understood by all members of that audience. Also, all communication materials in other languages should be culturally appropriate.** Simple translation may not be enough in cases where illustrations, format, and other facts are not

culturally appropriate for the target audience. States will likely request materials in languages that correspond to the profile of their potential vaccinees.

Although CDC has thoughtfully developed its process for informing and educating potential vaccinees and their contacts, more is needed to ensure an adequate level of comprehension is reached. For this reason, **the committee recommends that educational and training materials be tested for ease of comprehension with samples representing a cross-section of the sex, race, ethnicity, and level of education.** This should be done for all current materials, and should routinely be done prior to wide dissemination of all newly developed material, though time constraints might make this more difficult. Special attention is needed to highlight uncertain compensation for adverse reactions, and simplifying legal explanations currently provided on the Informed Consent form.

The dissemination of training and education materials to physicians and other health care providers is a vitally important component of the vaccination program, and CDC should take steps to determine the most effective ways to reach clinicians. For example, mailed materials may not even get past the administrative office, and may not be effective in changing clinician knowledge or behavior. Diverse and interactive means of reaching physicians and other clinicians may be needed (e.g., use opinion leaders, professional associations). Furthermore, tallying the number of materials (brochures, videos, CD-ROMs) sent out to physicians and others is not sufficient to evaluate impact of education and communication efforts; this is only an evaluation of the process, but not of its outcomes. Developing ways to measure change in level of knowledge and translation of knowledge to action is necessary to demonstrate effectiveness and determine where further attention is needed.

The committee was asked to provide recommendations to guide CDC's tracking of state training activities, and evaluating the impact of training initiatives. Given their geographic, cultural, and social diversity, states are likely to use a wide range of strategies to train vaccinators, inform clinicians, and educate vaccinees and their contacts. The ongoing weekly discussions between states and CDC can capture some of this information, but CDC could also develop a format states can use to summarize their training activities and encourage states to complete it on a regular basis online. That may facilitate the sharing of best practices, and the evaluation of phase I discussed above. With some additional planning, the impact of training activities (related to their quality, quantity, dissemination) could be linked to better program outcomes, such as better screening for contraindications, enhanced vaccinee education and reinforcement of good site care and hygiene practices, and improved clinical diagnostic ability.

Data to Assess Vaccine and Program Safety

Pre-Event Vaccination System (PVS)

The committee was pleased to hear that the Pre-Event Vaccination System (PVS) is being revised, and that the system will be fully operational relatively soon. Data gathered through PVS will be extremely useful for evaluating vaccine take rates, vaccine distribution, and vaccine

immunogenicity. The ability to create clinic-specific, state-specific, and national reports from PVS data will enhance overall evaluation of the pre-event smallpox vaccination program.

Through the Smallpox Vaccine Adverse Events Monitoring and Response System (which includes the Hospital Smallpox Vaccination Monitoring System, the Smallpox Vaccine Adverse Event Active Surveillance System [both described in detail below], the Vaccine Adverse Events Reporting System, inquiries received through CDC's Clinician Information Line, and requests for vaccinia immune globulin and cidofovir), data on adverse events will be linked to a vaccinee's record in PVS using the vaccinee's Patient Vaccination Number (PVN). A case investigation of the adverse event will involve a reevaluation of whether the vaccinee had any contraindications that were not disclosed initially or were not recognized at the time. Because contraindications will be part of the case investigation, and it is possible that revisions will be made to the list of contraindications as the vaccination program moves forward, it will be necessary to know which version of the Pre-Vaccination Information Packet the vaccinee received. **The committee recommends that a data field be added to PVS to indicate which version of the Pre-Vaccination Information Packet was provided to the vaccinee, in order to document what information was given to the vaccinee prior to consent.**

Survey to Assess Common Adverse Reactions

CDC has proposed conducting a telephone follow-up survey of 10,000 vaccinees in eight states to study the rate of common adverse reactions in vaccinees and the average amount of time lost from work due to reactions to the vaccine. CDC plans to use a stratified sampling scheme to ensure adequate representation of men and women, and primary vaccinees and re-vaccinees. The planned survey should provide valuable information about the rate of common adverse reactions in vaccinees, and the committee is pleased that CDC has designed a method for gathering these data.

CDC proposes to use an internal comparison/"control" group to control for the rates of common health events that will be observed during the course of this study. Since, in the context of the smallpox vaccination program, the health status of unvaccinated persons may differ significantly from vaccinees (i.e., due to contraindications), CDC proposes to use a comparison group exposed to the vaccine as a "control" group. CDC assumes that common adverse reactions associated with the vaccine will resolve by day 30 post-vaccination. Working under this assumption, the "control" group will be drawn from vaccinees who agreed to participate in the survey but were not selected for the sample. These "controls" will be observed for 21 days (the same length of time that the "treatment" group will be observed) following day 30 post-vaccination. The "controls" will receive the same diary card (for recall purposes) that is used by the "treatment" group (updated to reflect the different observation period), and will be observed for the 21 day period when they are assumed to experience "normal" health events (i.e., not due to the vaccine, since health events due to the vaccine are assumed to resolve by day 30 post-vaccination).

The committee suggests that CDC consider using an unvaccinated control group as well, especially if there are insufficient vaccinees to provide both an exposed (i.e., exposed to the

vaccine) group of 10,000 and a control group that can be studied prospectively from the time the survey is scheduled to begin (currently expected to be late-March). The use of an unvaccinated control group may provide insights into the impact of vaccination on common potential problems such as rates of work loss, febrile and rash illnesses, and temporary decreases in physical and social function. The committee agrees that it may not be appropriate to draw the control group from the complete pool of potential vaccinees that could not be vaccinated due to contraindications, since their health status may significantly differ from the health status of those who were vaccinated. However, this control group could perhaps be drawn from those potential vaccinees that could not be vaccinated because of secondary contraindications (e.g., contraindications in their close personal contacts).

The committee notes that the data gathered through the Hospital Smallpox Vaccination Monitoring System (HSVMS, discussed in more detail below) may supplement the data obtained through the survey. The HSVMS collects data on workdays lost due to illness, workdays with restrictions on work duties (e.g., no patient contact), the presence and severity of symptoms reported by the vaccinee, the type of dressing covering the vaccination site, the condition of the dressing, physical findings at the vaccination site, and vaccine take. Depending upon how many monitoring sites (i.e., hospitals, health departments, clinics) decide to use HSVMS, HSVMS could be considered as a means for gathering real-time monitoring data on common adverse reactions and days lost from work for a large proportion of vaccinees.

Active Surveillance for Serious Adverse Events and Monitoring Common Adverse Events

The committee congratulates CDC on developing so quickly a comprehensive active surveillance system for serious adverse events associated with smallpox vaccination. In its first letter report, the committee recommended that active surveillance for adverse events be employed. CDC has designed the Smallpox Vaccine Adverse Event Active Surveillance System (hereafter called the "Active Surveillance System") to accomplish active surveillance for serious adverse events following smallpox vaccination among all vaccinees during phase I of the vaccination program. The Active Surveillance System (and other coordinated data systems) will build upon the data that were gathered in the Pre-Event Vaccination System (described in detail in the committee's first letter report). The coordinated use of the Active Surveillance System with the Vaccine Adverse Events Reporting System (VAERS), the Hospital Smallpox Vaccination Monitoring System (HSVMS), inquiries received through CDC's Clinician Information Line, and requests for vaccinia immune globulin (VIG) and cidofovir will allow CDC to systematically collect information on vaccinees' experiences following vaccination and will greatly increase the likelihood that all serious adverse events following smallpox vaccination will be detected.

Active Surveillance System. The Smallpox Vaccine Adverse Event Active Surveillance System is designed to collect data on all vaccinees at the "close-out" of the vaccination process (this is usually 21 to 28 days after vaccination, when the scab falls off). The Active Surveillance System is a web-based system that is accessible through CDC's Secure Data Network (SDN). State and local health departments, hospitals, and vaccination clinics can enter data into the Active

Surveillance System as long as they have been given authorization to access the SDN. The Active Surveillance System will collect information on:

1. Whether contraindications to vaccination among the vaccinee, or contacts of the vaccinee, were identified since the time of vaccination;
2. Whether the vaccinee received medical care for an adverse event; and
3. Whether vaccinia transmission to contacts of the vaccinee occurred.

Information from the Active Surveillance System will be supplemented with information from PVS, VAERS, the Clinician Information Line, and requests for VIG and cidofovir to help give a complete picture of the details of each adverse event.

Both PVS and HSVMS (discussed in more detail below) will include a link to the Active Surveillance System. When the Active Surveillance System is accessed through these means, many of the fields in the Active Surveillance System will be pre-populated with data from PVS or HSVMS. By pre-populating as many data fields as possible with data from PVS or HSVMS, the risk of data entry error will be reduced.

By its nature, the Active Surveillance System is designed to obtain a confirmed outcome on every vaccinee. To ensure that the Active Surveillance System is truly "active," CDC instructs vaccination monitors to make at least three attempts at contacting the vaccinee before the vaccinee is designated as "unable to contact vaccinee for follow-up." The percentage of vaccinees that will be lost to follow-up should be relatively low, considering that phase I vaccinees are affiliated with a particular smallpox response team and monitors are instructed to make at least three attempts to contact the vaccinee for follow-up. However, it will be important to specifically identify any vaccinees that are lost to follow-up due to death or hospitalization. CDC is planning to track how many vaccinees are lost to follow-up.

To monitor the effectiveness of contraindications screening, the Active Surveillance System will seek to determine if any contraindications were missed during the initial screening of vaccinees. If the Active Surveillance System identifies a vaccinee or a close personal contact of a vaccinee that has a contraindication to vaccination not identified during pre-vaccination screening, an epidemiologist at CDC will follow-up with the local Adverse Events Coordinator to determine why the contraindication was not identified during the initial screening process.

For serious adverse events that are identified through the Active Surveillance System, CDC requests that a VAERS report be filed (if one was not filed already). The Active Surveillance System includes a field for indicating the VAERS report number.

The Active Surveillance System also specifically asks whether transmission of vaccinia virus to contacts of the vaccinee occurred. If vaccinia virus was transmitted to a contact of the vaccinee, CDC requests that a VAERS report be filed for each contact to whom transmission of vaccinia occurred. The Active Surveillance System includes a field for indicating the VAERS report number for each contact.

The committee notes that the Active Surveillance System is designed to obtain a confirmed outcome on every vaccinee in the short-term. However, it should be recognized that long-term side effects from the vaccine are possible. The committee encourages CDC to begin thinking about ways to monitor for long-term side effects from smallpox vaccination.

Hospital Smallpox Vaccination Monitoring System (HSVMS). Another system that CDC will use for gathering data on vaccinees' experiences following smallpox vaccination is the Hospital Smallpox Vaccination Monitoring System (HSVMS). The HSVMS is a voluntary, web-based system designed to assist hospitals and other vaccination monitoring sites (e.g., vaccination clinics and health departments) in real-time monitoring and tracking of vaccinees following vaccination. The HSVMS will provide a link to the Active Surveillance System.

As was mentioned in a previous section, the HSVMS collects data on workdays lost due to illness, workdays with restrictions on work duties (e.g., no patient contact), the presence and severity of symptoms reported by the vaccinee, the type of dressing covering the vaccination site, the condition of the dressing, whether the healthcare worker is wearing long sleeves, physical findings at the vaccination site, medications that were prescribed, and vaccine take.

To use HSVMS, monitoring sites only need to have Internet access (with 4.0 or higher Internet Explorer or comparable Netscape) and obtain a digital certificate and password from CDC. HSVMS was ready for use beginning February 18, 2003.

Name and social security number will not be collected in HSVMS. This system will, however, collect the Patient Vaccination Number (or state equivalent), gender, year of birth, occupation, and clinical specialty (for physicians). It will also include an optional category for race and ethnicity.

The HSVMS allows monitoring sites to create reports on all vaccinees seen at their site, vaccinees that are due for a take reading, vaccine symptoms seen at their site, physical findings for vaccinees, and the status of site care and dressings at their site, as well as summary reports by day and by each vaccinee seen at their site. Health departments can access HSVMS to view and obtain data from their specific state or jurisdiction. HSVMS data can also be exported into Excel or Access.

The committee supports CDC's plan to use these data to evaluate progress and outcomes of phase I of the pre-event smallpox vaccination program. The HSVMS data will be only one component of the overall evaluation plan, but these data will be essential to the analysis and evaluation of the ongoing vaccination program.

The Active Surveillance System, HSVMS, and VAERS will all provide valuable data on vaccinees' experiences following vaccination. Since these data systems are designed to work together, by offering one more place that serious adverse events can be identified, the likelihood of missing a serious adverse event following vaccination will be reduced even further. **The committee recommends that CDC consider adding a data field to HSVMS to indicate whether a serious adverse event occurred or whether a VAERS report was filed**

(understanding that more complete information about circumstances surrounding the adverse event will be entered into VAERS and the Active Surveillance System).

Implications of Program Expansion for Collection of Data on Adverse Events

The relatively quick expansion of the vaccination program to include all healthcare workers, firefighters, law enforcement, and emergency workers creates a number of implications for the capacity to collect data on serious adverse events, common adverse events, and vaccinees' experiences following smallpox vaccination. Up until now, CDC has designed the data systems for the smallpox vaccination program primarily for the logistical circumstances of the first phase of the program. CDC will have to consider if and how the data systems will need to be adapted for the expansion of the program (formerly "phase II") and beyond.

Conducting active surveillance of vaccinees from the recently expanded vaccination program (vaccination offered to all health care workers, firefighters, law enforcement, and emergency workers) may be more difficult. Since vaccinees in this category may not be members of a particular smallpox response team, and there may not be enough vaccination site care monitors available to contact and follow-up with each of these vaccinees (let alone conduct "take" readings and monitor their vaccination sites on a daily basis), the ability of the Active Surveillance System to determine a confirmed outcome on each of these vaccinees currently is uncertain.

Accordingly, it will also be more difficult to collect data on common adverse reactions and vaccinees' experiences following smallpox vaccination. Because of the much larger number of vaccinees that will be included in the recently expanded vaccination program, there may not be enough vaccination site care monitors available to monitor vaccinees on a daily basis. If monitors are not designated or available to follow all of these vaccinees, and consequently, no data are entered into HSVMS for these vaccinees, valuable data could be lost. This could hinder the ability to evaluate the vaccination program on a national scale, since this expansion of the program would provide the majority of the sample size needed for significant results in an evaluation.

Collection of data on serious adverse events, common adverse events, and vaccinees' experiences following smallpox vaccination is important not only for "phase I" but also for any expansion of the program. Only with larger sample sizes can significant results be obtained from the data. **In order to assure the continued integrity and safety of the expanded vaccination program, the committee recommends that CDC work to ensure that a qualified health professional monitors, conducts a "take" reading, and provides a regular vaccination site inspection for each vaccinee in the program, and enters the relevant data into the appropriate smallpox vaccination program data system.**

ACIP Working Group on Smallpox Vaccine Safety

In its first letter report (IOM, 2003), the committee recommended that CDC assure the independent functioning of the group charged with monitoring data and vaccine safety. (The

smallpox vaccine data and safety monitoring board now is formally called the Advisory Committee on Immunization Practices [ACIP] Working Group on Smallpox Vaccine Safety, which will hereafter be referred to as the "ACIP working group.") The committee is pleased that CDC already has taken some steps to address its concerns.

Adverse events reported following smallpox vaccination may be causally associated with the vaccine, or they may be coincidental illnesses that would have occurred anyway. Adverse events may also be interpreted as more serious than they actually are (e.g., generalized vaccinia).

The ACIP working group was charged with (1) evaluating data on vaccine safety, and the vaccine safety monitoring and treatment system, of the civilian National Smallpox Vaccination Program and the Department of Defense's Smallpox Vaccination program, and (2) monitoring safety data for use of vaccinia immune globulin and cidofovir (both of which are under an investigational new drug protocol).

There are two competing concerns that surround the disclosure of the data that are reviewed by the ACIP working group: (1) the need for confidentiality of vaccinees' medical data and for private deliberations of the working group to analyze those data, and (2) the need for public disclosure of the ACIP working group's findings based on analysis of these adverse event data. Both of these concerns are extremely important, and one must not be jeopardized for the sake of the other.

Private deliberations of the ACIP working group are necessary for ensuring that adverse events that are coincidental illnesses rather than reactions to vaccination do not alarm the public needlessly about the safety of the vaccine or the safe use of the vaccine. These private deliberations are also necessary for ensuring confidentiality of vaccinees' medical data. Even if vaccinees' personally identifiable information is not discussed during the working group meetings, a vaccinee's particular circumstances could lead to identification if disclosed to the public (e.g., living in a state that only vaccinated a small number of response team members, unique characteristics of the adverse event that would be evident to the vaccinee's personal or professional contacts, unique job description).

The committee notes that reports of adverse events often appear in the media very early and may be unverified. Conducting case investigations of adverse events and designating them as suspected or probable are vitally important activities for all reported adverse events, whether or not they appear in the media before being formally described by CDC. The ACIP working group plays a valuable role in this process by conducting the final assessment of the putative adverse events.

Although recognizing that protection of the confidentiality of vaccinees' medical data and private deliberations of the ACIP working group are paramount to ensuring free discussion of data surrounding each reported adverse event, the committee also strongly believes that the working group should be able to freely issue findings or recommendations once they have reached a conclusion. Should the American public come to believe that relevant vaccine and program safety data are not being completely disclosed, the committee fears that lack of public

trust in the implementation of the pre-event smallpox vaccination program could become an impediment to continued successful operation of the program. **The committee recommends that whenever the ACIP working group issues findings/recommendations to the ACIP and through it to the Director of CDC, it carefully consider concurrent release to the public, and do so if it would be in the interest of transparency and maintaining the public's trust in the program.**

Maintaining public trust in the smallpox vaccination program also entails assuring the public that the ACIP working group is functioning independently from its sponsoring agency. To more fully understand the operating procedures of the ACIP working group and the implications of these procedures on the working group's independence, the committee requests that more information be provided about the working group's specific operating procedures and the criteria that the working group will use to decide when to issue findings/recommendations. The committee has much confidence in the ability and integrity of the members of the ACIP working group. However, given that the ACIP working group is participating in a very high profile activity, the committee has concerns that the close organizational tie of the ACIP working group to the government entities responsible for the pre-event smallpox vaccination program (i.e., CDC and DoD) could affect the appearance of independence of the data monitoring group from the vaccination program managers. The issue is one of perceived independence, rather than actual independence. The committee is confident that the ACIP working group will deliberate and issue their findings/recommendations in a scientific and unbiased manner, but the committee encourages CDC to be forthcoming and proactive in sharing information about the working group's operating procedures and publicizing any findings/recommendations issued by the working group. Once the committee gains more information on the ACIP working group's operating procedures, it will consider suggesting other processes that would not impair the working group's work or confidentiality, while assuring the public that its processes are being conducted without interference.

Reporting Adverse Events

Adverse events following smallpox vaccination often have appeared in the media before being formally described by CDC (Melton, 2003; Richardson, 2003). Currently, formal descriptions of adverse events following smallpox vaccination in the civilian population are reported in the Morbidity and Mortality Weekly Report (MMWR) every Thursday. Because the MMWR is released on a weekly basis, there is sometimes a delay between the time that a supposed adverse event is reported in the media and the release of a formal description of the adverse event in the MMWR. This delay can pique the media's and the public's interest, and lead to confusion about why CDC is not reporting the adverse event immediately. **Considering the confusion that can arise from the timing of reports on adverse events and the multiple sources of adverse event data that are available, the committee recommends that CDC be very clear about what types of adverse events will be reported to the public and when.**

The committee understands that the MMWR will be the definitive source for information about adverse events reported following smallpox vaccination. However, the information distributed on adverse events by CDC's Office of Communication (CDC, 2003d: 8) is presented

in a different format than the information presented in the MMWR. **The committee recommends that the vaccination report webpage use categories that correspond to the categories presented in the MMWR adverse event reports.**

The committee is also pleased to see that CDC and the DoD are planning to provide regular updates on adverse events reported following smallpox vaccination. (The reports can be found at http://www.cdc.gov/od/oc/media/smpxrprt.htm and http://www.smallpox.army.mil/media/pages/SPSafetySum.asp, respectively.) The committee encourages CDC and DoD to commit to a regular schedule for reporting adverse events, and to adhere to that schedule. Regular disclosure of adverse events could assure the public that the vaccination program is worthy of their trust. (As of March 19, 2003, CDC has updated its adverse event report web page every Thursday; DoD has not updated its adverse event report web page since February 12, 2003.)

Along with preparedness, safety has always been a paramount goal of the pre-event smallpox vaccination program. Effective and comprehensive screening for contraindications to vaccination is the first way to ensure safety. Breakdowns in the contraindications screening process could be considered "adverse" and could point to places where improvements could be made in the implementation of the pre-event vaccination program. It is important for both program managers and the public to know where improvements could be made in the contraindications screening process. **The committee recommends that CDC report on a regular basis how effective screening practices have been at identifying contraindications (e.g., pregnancy, HIV status, eczema or atopic dermatitis) prior to vaccination.** This should be done in a method that accomplishes the dual goals of protecting patients' confidentiality while also being forthcoming with the public.

Recent press reports (Richardson, 2003) have highlighted an adverse event reporting issue that may need to be resolved. It was reported that a civilian in Los Angeles county acquired an eye infection through close contact with someone vaccinated in the military's smallpox vaccination program. If the case investigation determines that this is indeed transmission of vaccinia to a contact of a vaccinee, then this would be considered an adverse event.

Although both civilian and military vaccination data have been reviewed by the ACIP working group, CDC and DoD have publicly reported civilian and military adverse events separately. For such a situation where a military vaccinee inadvertently inoculates a civilian, or vice versa, it is not clear how this adverse event would be reported—whether by CDC or by DoD. **If protocols governing such a situation have not yet been developed or finalized, then the committee recommends that CDC work with DoD to decide how adverse events that involve both the civilian and military populations will be reported.**

Compensation

In its first letter report (IOM, 2003), the committee noted its concern that the lack of compensation for adverse reactions "could seriously affect achievement of the stated goal of the

program—to increase the nation's bioterrorism preparedness." Recently, there has been a steady increase in evidence that the lack of compensation for adverse reactions to the smallpox vaccine is impeding full implementation of the pre-event smallpox vaccination program as originally envisioned (Connolly, 2003a; Denogean, 2003; Geraghty, 2003; Meckler, 2003). On March 6, 2003, the Secretary of the Department of Health and Human Services proposed a plan to create a smallpox vaccination compensation program to provide benefits to public health and hospital response team members who are injured as a result of receiving the smallpox vaccine (DHHS, 2003). The proposed compensation program, modeled on the Public Safety Officers Benefit program, would include:

- a $262,100 permanent and total disability benefit for disability caused by administration of the smallpox vaccine;
- a $262,100 death benefit for deaths caused by administration of the smallpox vaccine;
- a temporary or partial disability benefit, providing two-thirds of lost wages after the fifth day from work, up to a maximum of $50,000; and
- a health care benefit for reasonable out-of-pocket medical expenses for other than minor injuries.

The proposed program would also provide compensation to third parties who contract vaccinia from public health and hospital response team workers who have been vaccinated. Rep. Henry Waxman (D-CA) has introduced a bill (H.R.865) that proposes an alternative compensation program. At the writing of this report, a smallpox vaccine compensation bill had not yet been passed by Congress (Pear, 2003).

Workers' Compensation

Some of potential vaccinees' concerns about compensation may be addressed by workers' compensation coverage. However, as noted in the committee's first letter report (IOM, 2003), and again in this report since it appears that this issue has not yet been resolved in most states, workers' compensation coverage is heterogeneous across states and not all vaccinated workers in all states will be eligible for compensation through their state's workers' compensation program, should they experience an adverse reaction to the smallpox vaccine.

Workers' compensation coverage is an uncertain solution for a number of reasons. Workers' compensation often only provides coverage for a percentage of the worker's salary, rather than the full salary. Workers often have to use a certain number of days of sick leave before they can receive compensation for days lost from work due to reaction to the vaccine. For vaccinees who experience common adverse reactions, they may only feel sick enough to take sick leave for one or two days (Lane et al., 1969; Lane et al., 1970). Some states' workers' compensation programs may not provide coverage if they deem the vaccination to be a "voluntary" component of work duties. Workers' compensation programs may not provide coverage for contacts of vaccinees that acquire vaccinia through contact transmission.

In some states, a provisional decision about coverage for smallpox vaccine adverse reactions by a state workers' compensation board may not be tested until an initial case is

decided by the courts (ASTHO/NACCHO, 2002; Juffras, 2003). A vaccinee involved in the first case in a state may have to undergo months, or even years, of administrative and/or judicial proceedings before a final decision is made. Without a national compensation program in place, the possibility of months or years of legal action to resolve a workers' compensation claim may be more of a risk than many potential vaccinees are willing to take.

Lack of Compensation Impeding Program Progress

State health departments, hospitals, and individual vaccinees have expressed concern over the past two months about the lack of a national compensation program to cover medical expenses for adverse reactions, time lost from work, and (in the worst possible outcomes) permanent disability or death. (McNeil, 2003) The committee is concerned that lack of compensation will be a continuing barrier to full implementation of the pre-event smallpox vaccination program if a smallpox vaccination compensation program is not created. Consequently, the nation's preparedness to respond to a smallpox attack could be hindered.

The voluntary pre-event smallpox vaccination has started off more slowly than originally anticipated. This is not necessarily a problem, given that the most recent statement of the President on the risk of a smallpox attack stated, "[o]ur government has no information that a smallpox attack is imminent" (White House, 2002). **However, if CDC and the states determine that there are insufficient response teams to ensure preparedness to respond to a smallpox attack, then the committee recommends that CDC gather data on the reasons why potential vaccinees are declining vaccination, and document the extent to which lack of compensation is identified as a barrier, among other possible barriers (e.g., uncertainty surrounding risk of smallpox, fear of transmitting virus to contacts, extent to which local programs are encouraging vaccination).**

Notification About Availability of Compensation or Lack of Compensation

CDC implemented the committee's recommendation from its first letter report (IOM, 2003: 13) that, "informed consent forms include explicit notification of the availability, or lack thereof, of compensation for adverse reactions." The January 16, 2003 version of CDC's revised Vaccine Information Statement (VIS) includes the statement, "Treatment of severe reactions can be very expensive. Workers' compensation or health insurance may not cover these expenses. There is no federal program to reimburse you for time lost from work, either because of illness due to vaccination or concern about spreading the virus to others. Your employer can tell you if they, or workers compensation, will cover these expenses" (CDC, 2003e).

The committee commends CDC for more clearly describing the compensation situation to potential vaccinees. However, the committee believes that the language used for this statement should be in bold type and should be simpler, so it can be more easily understood by a wider cross-section of potential vaccinees, especially considering the recent expansion of the program to a more diverse pool of vaccinees. The committee believes that it is very important that all vaccinees have a clear understanding of what types of coverage and protection they can

or cannot expect from their employer, their state, and the federal government. More readable compensation language could take the form of:

- "Right now, if you get sick or have to take time off from work, you cannot expect compensation." or,
- "Right now, if you get sick or have to take time off from work, the availability of compensation is uncertain." or,
- "Although other federal and state compensation proposals are under discussion, they have not yet been approved and you should not assume that you will be compensated for any injuries or illnesses that result from vaccination."

No matter what specific language CDC decides to use, the committee recommends that the compensation language be easy to read and understandable to a wide range of audiences.

CDC has included the notification about the availability, or lack thereof, of compensation in the VIS. It is expected that potential vaccinees will have read the VIS before signing the informed consent form. The informed consent form asks vaccinees to confirm that they have, "[r]eceived, read and understand the Smallpox Pre-Vaccination Information Package, including 1) the Vaccine Information Statement (VIS), 2) the VIS Supplements (A-E) on reactions after smallpox vaccination, vaccination site appearance and care, skin conditions, weakened immune system, pregnancy and breastfeeding, and 3) the pre-event screening worksheet" (CDC, 2003c). The availability of compensation for adverse reactions due to the smallpox vaccination may be an important factor affecting a potential vaccinee's decision to be vaccinated. **The committee recommends that potential vaccinees be reminded of the current compensation situation before they formally give their consent to be vaccinated.** It is possible that Congress will pass a smallpox vaccination compensation package soon; until then, the committee suggests that CDC include an explicit, bold print statement about the compensation situation directly on the informed consent form.

It also will be important for vaccinees to know that compensation may not be available to any contacts to whom they may accidentally transmit the vaccinia virus. This knowledge will be another important component of informed consent. The committee encourages CDC to expand the notification about compensation to address this issue. Such an addition could take the form of: "Should you accidentally transmit the vaccinia virus to someone else, that person cannot expect compensation."

The committee believes that it would also be helpful to test vaccinees' comprehension of this statement, in addition to other statements contained in the Pre-Vaccination Information Packet. Such a test could involve testing for a vaccinee's comprehension of a short list of key facts (e.g., decision is voluntary, major contraindications, types of adverse events that are possible, current lack of compensation for adverse events, what to do if a suspected adverse event occurs).

Funding

As reflected in media reports about health departments and hospitals around the country, and as anecdotally or formally documented by some organizations themselves, the smallpox vaccination program has produced significant financial worries among states and local health departments, and also in hospitals whose participation in forming health care response teams has been solicited (Connolly, 2003b; email communication, R. Schulman, AHA, February 27, 2003; NACCHO, 2003). At the health department level, such worries appear to have resulted in the shifting of substantial financial and human resources from essential public health services to smallpox related activities (Connolly, 2003b; NACCHO, 2003). Hospitals could also incur costs by having health care response teams immunized, and there is reason for concern that this may overburden hospitals that are under strain already, such as public hospitals (NAPH, 2002; Green Sheet, 2003). Community health centers and public health clinics may also incur cost burdens. Since local health departments report that cost issues constitute a difficulty in program implementation, expanding the program as much as 20-fold may be unfeasible, unless additional resources are provided to states, local health departments, and their hospital partners.

Moreover, the committee remains very concerned about opportunity costs created by the program (including staffing-related costs), as well as redirecting resources from other areas, such as other disease prevention activities, and even broader bioterrorism preparedness. The committee was pleased to find out that CDC intends to conduct an assessment of the smallpox vaccination program's costs. **However, the committee recommends that this inquiry be broad in scope, and include not only cost to local and state health departments, but also the financial impact on the provision of other essential public health services, the costs incurred by participating hospitals, and cost estimates of expanding the vaccination program to additional health care and public health workers, and emergency first responders.**

Additional Data That Should Be Gathered

The committee applauds CDC for preparing a plan for phase I evaluation and research (CDC, 2003b). Many of the data and information needs that the committee raised in its first letter report (IOM, 2003) are addressed in this plan.

The committee understands that CDC has plans for estimating and evaluating the actual costs of the smallpox vaccination program and reasons for regional cost variations, the cost of diverting public health staff, and the opportunity costs of the smallpox program to other public health programs (CDC, 2003b). The committee believes that these studies will be extremely important for determining how the smallpox vaccination program should proceed in the future. The committee is very interested in these studies, in particular, and offers its assistance in designing these studies in any way that CDC deems useful.

To help provide ongoing advice to CDC about implementation of the smallpox vaccination program, the committee requests to see further details of the plans and protocols for the evaluation and research that CDC is proposing, (e.g., the plan for the proposed case-control

study nested within the cohort of vaccinees). The committee applauds CDC for developing the evaluation and research plan so quickly, and looks forward to receiving further communication from CDC about these issues.

CONCLUDING REMARKS

In closing, the committee reiterates its key recommendations.

- Advancing the smallpox vaccination program should occur with a focus on defining and then achieving national and local preparedness against a possible smallpox attack.
- Every effort should be made to evaluate on a national scale the program's implementation, and most importantly, its safety.

The committee wishes to thank you for the continuing opportunity to be of assistance to the Centers for Disease Control and Prevention as it works to protect the nation's health.

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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APPENDIX

Committee on Smallpox Vaccination Program Implementation

SUMMARY OF RECOMMENDATIONS

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

Letter Report #2

OVERARCHING ISSUES: PREPAREDNESS AND EVALUATION

A Focus on Preparedness

The committee recommends that CDC work with states to decide what more is needed to achieve smallpox preparedness, if anything. Further, given the routine turnover in personnel, each state should evaluate what it needs to maintain this preparedness.

A Need for Evaluation

The committee recommends that CDC comprehensively evaluate the program and its outcomes in order to improve its implementation and to protect the vaccinees and the public.

PROGRAMMATIC ISSUES

Communication

The committee recommends CDC revisit and communicate to the public the program's objectives in view of state-level realities, and provide a preliminary perspective on the national and state success in reaching those objectives. The CDC should continue to support, as well as build on the experience of state and local health departments who are developing their communication strategies about state and local program implementation.

The committee recommends that CDC and its state and local partners develop communications strategies that:

1. Provide adequate quality and quantity of information.
2. Are timely.
3. Reassure the public that efforts are in progress to protect them in the event of a smallpox attack.

The committee recommends CDC develop and offer journalists training materials and opportunities specifically designed for the media, explaining the program's clinical components, providing the best available scientific evidence, and dedicating staff experts to provide technical support to media representatives.

Training and Education

The committee recommends that all print materials addressed to a diverse audience (e.g., the public) should be easily read and understood by all members of that audience. Also, all communication materials in other languages should be culturally appropriate.

The committee recommends that educational and training materials be tested for ease of comprehension with samples representing a cross-section of the sex, race, ethnicity, and level of education.

Data to Assess Vaccine and Program Safety

The committee recommends that a data field be added to PVS to indicate which version of the Pre-Vaccination Information Packet was provided to the vaccinee, in order to document what information was given to the vaccinee prior to consent.

The committee recommends that CDC consider adding a data field to HSVMS to indicate whether a serious adverse event occurred or whether a VAERS report was filed (understanding that more complete information about circumstances surrounding the adverse event will be entered into VAERS and the Active Surveillance System).

The committee recommends that CDC work to ensure that a qualified health professional monitors, conducts a "take" reading, and provides a regular vaccination site inspection for each vaccinee in the program, and enters the relevant data into the appropriate smallpox vaccination program data system.

The committee recommends that whenever the ACIP working group issues findings/recommendations to the ACIP and through it to the Director of CDC, it carefully consider concurrent release to the public, and do so if it would be in the interest of transparency and maintaining the public's trust in the program.

The committee recommends that CDC be very clear about what types of adverse events will be reported to the public and when.

The committee recommends that the vaccination report webpage use categories that correspond to the categories presented in the MMWR adverse event reports.

The committee recommends that CDC report on a regular basis how effective screening practices have been at identifying contraindications (e.g., pregnancy, HIV status, eczema or atopic dermatitis) prior to vaccination.

The committee recommends that CDC work with DoD to decide how adverse events that involve both the civilian and military populations will be reported.

Compensation

The committee recommends that CDC gather data on the reasons why potential vaccinees are declining vaccination, and document the extent to which lack of compensation is identified as a barrier, among other possible barriers (e.g., uncertainty surrounding risk of smallpox, fear of transmitting virus to contacts, extent to which local programs are encouraging vaccination).

The committee recommends that the compensation language be easy to read and understandable to a wide range of audiences.

The committee recommends that potential vaccinees be reminded of the current compensation situation before they formally give their consent to be vaccinated.

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The committee recommends that this inquiry be broad in scope, and include not only cost to local and state health departments, but also the financial impact on the provision of other essential public health services, the costs incurred by participating hospitals, and estimates of costs of expanding the vaccination program to additional health care and public health workers, and emergency first responders.