



AARC Smallpox Health Care Team Guidance Document

The purpose of this document is intended to provide guidance to respiratory care managers involved in developing a Smallpox Health Care Team at their facilities.

The Disease

There are two clinical forms of smallpox. Variola major is the severe and most common form of smallpox, with a more extensive rash and higher fever. There are four types of variola major smallpox: ordinary (the most frequent type, accounting for 90% or more of cases); modified (mild and occurring in previously vaccinated persons); flat; and hemorrhagic (both rare and very severe). Historically, variola major has an overall fatality rate of about 30%; however, flat and hemorrhagic smallpox usually are fatal. Variola minor is a less common presentation of smallpox, and a much less severe disease, with death rates historically of 1% or less.

Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing. Rarely, smallpox has been spread by virus carried in the air in enclosed settings such as buildings, buses, and trains. Humans are the only natural hosts of variola. Smallpox is not known to be transmitted by insects or animals.

A person with smallpox is sometimes contagious with onset of fever (prodrome phase), but the person becomes most contagious with the onset of rash. At this stage the infected person is usually very sick and not able to move around in the community. The infected person is contagious until the last smallpox scab falls off. Source: <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp>

Current Knowledge of Smallpox Vaccine's Impact on Safety of Workers and Patients

The following recommendations regarding pre-event vaccination programs were developed after formation of a joint Working Group of the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) in April 2002, joined in September 2002 by the Healthcare Infection Control Practices Advisory Committee (HICPAC), and a series of

public meetings and forums to review available data on smallpox, smallpox vaccine, smallpox control strategies, and other issues related to smallpox vaccination. In October,

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the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) issued additional guidelines regarding a pre-outbreak smallpox vaccination strategy for hospital workers. The recommendations listed below are extracted from the full report that should be reviewed in its entirety at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2d226.htm>

Pre-Release Vaccination of Selected Groups to Enhance Smallpox Response Readiness

Smallpox Health Care Teams

- That in the first stages of the pre-event smallpox vaccination program, each acute care hospital identify a group of healthcare workers who would be vaccinated and trained to provide direct medical care for the first few smallpox patients requiring hospital admission and to evaluate and manage patients who present to the Emergency Department with suspected smallpox.
 - This team would provide care 24 hours a day for the first several days after patients with smallpox have been identified, until additional healthcare personnel can be vaccinated.
 - Non-vaccinated workers would be restricted from entering into the rooms of smallpox patients or (under emergency conditions) would wear personal protective equipment.
- That Smallpox Health Care Teams include respiratory therapists

Preventing contact transmission of vaccinia virus

- That good infection control practices should essentially eliminate the risk of vaccinated healthcare workers transmitting vaccinia to patients, and that placing healthcare workers on administrative leave could create staffing shortages that would be a risk to patients.
- That healthcare personnel providing direct patient care should keep their vaccination sites covered with gauze or a similar absorbent material in combination with a semipermeable dressing to absorb exudates that develop and to provide a barrier for containment of vaccinia virus to minimize the risk of transmission.
 - Dressings used to cover the site should be changed frequently (e.g., every 3-5 days or more frequently if exudates accumulate) in order to prevent buildup of exudates and consequent maceration.
- The most critical measure in preventing contact transmission is consistent hand-hygiene with antimicrobial soap and water or an approved alcohol based hand-rub after any contact with the vaccination site or with materials that have come into contact with the site and before patient contact. In addition, care should be taken to prevent contact with the site or contaminated materials from the site.
- Hospitals should include a site-care component to their smallpox vaccination programs in which designated staff assess dressings for all vaccinated healthcare workers daily (whether involved in direct patient care or in other duties), determine if dressings need changing (i.e., when accumulation of purulent material is visible), and change the dressing if indicated.

Administrative Leave for Vaccinated Health Care Workers

Administrative leave is not required routinely for newly vaccinated healthcare personnel unless they:

1. are physically unable to work due to systemic signs and symptoms of illness;
2. have extensive skin lesions which cannot be adequately covered, or if they
3. are unable to adhere to the recommended infection control precautions.

The very close contact required for transmission of vaccinia to household contacts is unlikely to occur in the healthcare setting.

Contraindications for Use of Smallpox Vaccine in the Pre-event Smallpox Vaccination Program

Smallpox vaccination is contraindicated for persons with a history or presence of eczema or atopic dermatitis; that have other acute, chronic, or exfoliative skin conditions; that have conditions associated with immunosuppression; who are pregnant or breast-feeding; are aged <1 year; or who have a serious allergy to any component of the vaccine. Persons with other active acute, chronic, or exfoliative conditions (e.g.,

burns, impetigo, varicella zoster, herpes, severe acne, severe diaper dermatitis with extensive areas of denuded skin, or psoriasis) are at higher risk for clinically significant inadvertent inoculation and should not be vaccinated until the condition resolves. Additionally, persons with Darier's disease can develop eczema vaccinatum and therefore should not be vaccinated. Pre-event vaccination is also contraindicated among persons with household contacts: that have a history or presence of eczema or atopic dermatitis, irrespective of disease severity or activity; that have other acute, chronic, or exfoliative skin conditions; that have conditions associated with immunosuppression (see above); or who are pregnant. For purposes of screening for contraindications for pre-event vaccination, "household contacts" should be considered to include persons with prolonged intimate contact with the potential vaccinee, including the potential for direct contact with the vaccination site, e.g., sexual contacts. The presence of an adolescent or child (including an infant) in the household is not a contraindication to vaccination of adult members of the household; data suggest that the risk of serious complications from transmission from an adult to a child is extremely small.

Smallpox Vaccine and Heart Problems

Careful monitoring of smallpox vaccinations given over recent months has suggested that the vaccine may cause heart inflammation (myocarditis), inflammation of the membrane covering the heart (pericarditis), and/or a combination of these two problems (myopericarditis). Experts are exploring this more in depth.

Heart pain (angina) and heart attack also have been reported following smallpox vaccination. However, it is not known at this time if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). Experts are investigating this question also.



Reported events are not necessarily caused by the vaccine, and some or all of these events might be coincidental.

As a precautionary step, if you have been diagnosed by a doctor as having a heart condition with or without symptoms you should NOT get the smallpox vaccine at this time while experts continue their investigations. These include conditions such as:

- known coronary disease including:
 - previous myocardial infarction (heart attack)
 - angina (chest pain caused by lack of blood flow to the heart)
- congestive heart failure
- cardiomyopathy (heart muscle becomes inflamed and doesn't work as well as it should)
- stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)
- chest pain or shortness of breath with activity (such as walking up stairs)

- other heart conditions under the care of a doctor

In addition, you should NOT get the smallpox vaccine if you have 3 or more of the following risk factors:

- You have been told by a doctor that you have high blood pressure.
- You have been told by a doctor that you have high blood cholesterol.
- You have been told by a doctor that you have diabetes or high blood sugar.
- You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
- You smoke cigarettes now.

These may be temporary exclusions and may change as more information is gathered. The presence of these conditions in a close contact is not a reason for you to defer vaccination.

If you have received the smallpox vaccine, you should see a health care provider right away if you develop chest pain, shortness of breath, or other symptoms of cardiac disease after vaccination.

If you have been diagnosed by a doctor as having heart disease and you have already received the smallpox vaccine, you should contact your heart disease specialist or your regular health care provider if you have questions.

What has been reported?

- **Past Experience:** Rare cases of heart inflammation following smallpox vaccination were reported in the 1960s and 1970s. Most of these did not occur in the United States and involved a different smallpox vaccine than is being used in the U.S. now.
- **Civilian Vaccinations:** Of the 25,645 civilians who had received the smallpox vaccine as of March 21, 2003, 7 reported heart problems. These included problems like angina (chest pain caused by lack of blood flow to the heart) and heart attacks. Two people who had heart attacks died. It is not known at this time if smallpox vaccination caused these events.
- **Military Vaccinations:** Between December 13, 2002 and March 31, 2003, approximately 325,000 troops received the smallpox vaccine. Eleven cases of heart inflammation have been reported among approximately 225,000 members of the military who received the vaccine for the first time (a rate of about 1 in 20,000). No such cases occurred in people who had been vaccinated before. According to the Department of Defense, one of the cases became severely ill with heart failure on March 27, 2003 and remains hospitalized as of March 31, 2003. The other 10 individuals had mild to moderate disease and have recovered.

Source: <http://www.hhs.gov/smallpox/VaccineHeartProbs.html>

CHILDREN SHOULD NOT BE GIVEN SMALLPOX VACCINE

For Release: January 30, 2003 10 a.m. (ET)

Washington, DC—As the Bush Administration implements the first stage of its smallpox vaccination plan, the American Academy of Pediatrics (AAP) testified today before Congress that given the information currently available, the general public, particularly children, should not receive the vaccine prior to an outbreak.

“Unfortunately, the concept of a pre-event voluntary vaccination program for the public makes the least sense from a scientific and public health standpoint,” said Jon S. Abramson, M.D., chair of the AAP Committee on Infectious Diseases, in testimony before the U.S. Senate Health, Education, Labor and Pensions Committee. “The concept

The AAP testimony also called for Congress to ensure that the smallpox vaccine is tested for use in children, similar to the testing required for other childhood vaccines.

of voluntary vaccination is a misnomer. If the vaccine is made available to the general public, infants and children who don't get the vaccine could be unintentionally inoculated from a vaccinated adult. This could have serious consequences since we know children are particularly vulnerable to suffering complications from the vaccine.”

Last year, the Academy announced support for the “ring vaccination” strategy that is an effective method for containing the disease, if it occurs, while minimizing risks. The Academy does recognize the need for select medical and emergency personnel to be vaccinated now in order to carry out their responsibilities to the public if any smallpox cases occur, but liability and compensation for adverse events from the vaccine still needs to be addressed.

“If I as part of the healthcare team suffer a serious adverse event from getting the vaccine, I am covered by my state workers' compensation program,” said Dr. Abramson. “However, if I indirectly inoculate one of my children at home or a patient I am caring for in the hospital, and they develop a serious side effect, they are not covered.”

The Academy urged Congress to enact a “no-fault” system to compensate those injured directly or indirectly by the smallpox vaccine. It could function in a way similar to the National Vaccine Injury Compensation Program established in the mid-80s.

The AAP testimony also called for Congress to ensure that the smallpox vaccine is tested for use in children, similar to the testing required for other childhood vaccines.

"We don't even know if the vaccine is safe for use in children," Dr. Abramson said. "If a smallpox attack did occur are we really willing to let millions of children be part of an emergency experiment? We need to be prepared to help children at the time of an outbreak with an effective vaccine at the right dose. Congress can see to it that the necessary studies are done now."

Source: http://www.aap.org/advocacy/washing/smallpox_vaccine.htm

Simultaneous Administration of Smallpox Vaccine with other Vaccines

Timing of Tuberculosis Screening and Smallpox Vaccination

Suppression of tuberculin skin test (purified protein derivative [PPD]) reactivity has been demonstrated following administration of smallpox vaccine [51], as has been observed following administration of other parenteral live virus vaccines [33]. Healthcare workers due to receive an annual PPD skin test should not receive the skin test for one month after smallpox vaccination to prevent possible false negative reactions.

Future Directions

The ACIP will review these recommendations periodically, or more urgently if necessary. These reviews will include new information or developments related to smallpox disease, smallpox vaccines (including licensure of additional smallpox vaccines), risk of smallpox attack, smallpox vaccine adverse events, and the experience gained in the implementation of the current recommendations. Revised recommendations will be developed as needed.

Positions taken by other organizations

AACN Position:

AACN supports the efforts of the CDC and encourages all nurses to familiarize themselves with the activities that would need to be undertaken in a smallpox emergency. http://www.aacn.org/__882565100000a416.nsf/0/07402e877ec0ad5f88256b1e006e5bf3?OpenDocument&Highlight=2,smallpox

AMA Position:

AMA ENDORSES GUIDELINES ON SMALLPOX VACCINE

Statement attributable to: Ronald M. Davis, MD, Trustee

"The American Medical Association supports the recommendations announced today by the Advisory Committee on Immunization Practices. The committee said the general public should not be vaccinated against smallpox, due to the low risk of widespread outbreaks occurring as the result of the deliberate release of contaminants. Any potential benefits are significantly outweighed by the risk of complications from the vaccine.

"The AMA believes that there should be increased efforts to educate both physicians and the general public about issues related to smallpox.

"Physicians need to understand how to diagnose and treat smallpox, and the appropriate actions to take should a case be identified." http://www.ama-assn.org/ama1/pub/upload/mm/36/smallpox_release.doc

AHA Position:

We commend the CDC for its comprehensive approach to planning a response to an outbreak of smallpox. CDC has indicated that it will update its plan regularly to reflect changes in public resources for responding to a smallpox emergency. We appreciate this open approach and, in that spirit, we offer suggestions for revisions to Guides C, D and F of the plan that can help the plan better reflect the hospital environment.

CDC has consistently emphasized the use of scientific evidence as a basis for developing infection prevention and control guidelines for health care facility-associated infections. Our organizations have worked with CDC and other federal agencies to improve safety by encouraging health care facilities to develop and sustain infection control and safety strategies that are evidence-based. These efforts include: the prevention of transmission of tuberculosis in health care facilities; the "look-back" for hepatitis C virus infections; the implementation of blood borne pathogen standards; the prevention of sharps injuries in hospitals; and, most recently, the CDC's draft *Guidelines for Environmental Infection Control in Healthcare Facilities*, 2001.

In general, our overriding concern, as expressed in the attached technical comments, is that the draft plan is, in many places, not consistent with existing CDC and other authoritative guidelines (e.g. Guidelines for the Design and Construction of Hospital and Health Care Facilities, a national consensus guideline adopted by over 40 state governments¹) for ventilation and engineering controls, disinfection and sterilization of patient care equipment and laundry, and waste management. Given the broad scope of the CDC Smallpox Plan, it may be that the flaws we discuss below reflect the urgency with which the plan was released, given the events of September 11, 2001. However, if a smallpox outbreak were to occur in the United States, it would be critical that all health professionals working from the same set of infection control principles, based upon the most recent thinking in health care engineering, disinfection, and ventilation. In our assessment, the areas of the draft plan that do not reflect current infection control and/or disinfection practice are located in Guides C (Isolation and Quarantine) and F (Decontamination Guideline).

<http://www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/comment/CL-031202-249.html>

The ACIP recommendations do not address the important issue of liability for adverse events associated with vaccination. The AHA believes that the Administration and Congress need to establish a federal fund to compensate individuals injured by the vaccine, similar to the National Vaccine Injury Compensation Program that addresses adverse events associated with common childhood vaccines. Further, in order for the smallpox vaccination program to move forward, hospitals and health care workers must be insulated from liability for adverse events related to vaccination.

American Physical Therapy Association:

No stated position

Reference Bibliography

The Centers for Disease Control and Prevention (CDC) has released a working draft of a plan that outlines the CDC's strategies for responding to a smallpox emergency. The plan has been sent to all state bioterrorism coordinators, state health officers, state epidemiologists, and state immunization program managers for review and comment. It identifies many of the federal, state, and local public health activities that would need to be undertaken in a smallpox emergency,

The Tools may not apply to all patients with smallpox vaccine adverse reactions and are not intended to substitute for evaluation by a trained clinician.

including response plan implementation, notification procedures for suspected cases, CDC and state and local responsibilities and activities, and CDC vaccine and personnel mobilization. It also provides state and local public health officials with a framework that can be used to guide their smallpox planning and readiness efforts as well as guidelines for many of the general public health activities that would be undertaken during a smallpox emergency. A summary of the plan has been posted on the CDC Web site at <http://www.cdc.gov/nip/diseases/smallpox>

The Centers for Disease Control and Prevention released a Hospital Smallpox Vaccination Monitoring System intended to help hospitals monitor and track workers who receive the smallpox vaccine. The Web-based application is a component of the CDC Smallpox Vaccination Program being offered as a free service to hospitals. It is designed to capture data such as symptoms reported by vaccine recipients, fitness for duty and work days lost, and to produce summary and overview reports of the hospital's experience. More information, including how to enroll in the voluntary program is available at: <http://www.bt.cdc.gov/agent/smallpox/vaccination/hsvms/>

The Centers for Disease Control and Prevention (CDC) and its partners in the Clinical Immunization Safety Assessment (CISA) network have developed Clinical Evaluation Tools to

help health care providers manage patients with potential adverse reactions from smallpox vaccination in the absence of circulating smallpox virus (pre-event setting). These Clinical Evaluation Tools are based on studies conducted before routine childhood US smallpox vaccination was discontinued in 1972 and on expert opinion; they are not entirely evidencebased. The Tools may not apply to all patients with smallpox vaccine adverse reactions and are not intended to substitute for evaluation by a trained clinician. These tools are designed for use during face-to-face patient encounters and are not designed to be telephone triage tools, although they may be useful as a companion to other telephone triage materials. These tools can be used by field clinicians to assess patients with suspected adverse events following smallpox vaccination.

To view these Clinical Evaluation Tools, please visit the CDC website below and please share with your external partners. Currently only the clinical tool for assessment of dermatologic reactions localized to the smallpox vaccination site is posted. <http://www.bt.cdc.gov/agent/smallpox/vaccination/clineval/>

American Society of Health-System Pharmacists provide an excellent document that discusses the smallpox vaccine and related information at : <http://www.ashp.org/emergency/smallpox.pdf>


News Release
FOR IMMEDIATE RELEASE
Thursday, March 20, 2003
Contact: HHS Press Office
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HHS ANNOUNCES BIOTERRORISM AID FOR STATES, INCLUDING SPECIAL OPPORTUNITY FOR ADVANCE FUNDING

HHS Secretary Tommy G. Thompson today announced \$1.4 billion to be provided to states this year to help them enhance preparations against terrorism or other public health emergencies. At the same time, he announced special provisions that would allow states to obtain up to 20 percent of their 2003 funding immediately in order to support current activities, including smallpox vaccination for selected health workers and emergency responders.

Appendix:

<http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp>

| Smallpox Disease | |
|--|---|
| Incubation Period (Duration: 7 to 17 days) <i>Not contagious</i> | Exposure to the virus is followed by an incubation period during which people do not have any symptoms and may feel fine. This incubation period averages about 12 to 14 days but can range from 7 to 17 days. During this time, people are not contagious. |
| Initial Symptoms (Prodrome) (Duration: 2 to 4 days) <i>Sometimes contagious*</i> | The first symptoms of smallpox include fever, malaise, head and body aches, and sometimes vomiting. The fever is usually high, in the range of 101 to 104 degrees Fahrenheit. At this time, people are usually too sick to carry on their normal activities. This is called the prodrome phase and may last for 2 to 4 days. |
| Early Rash (Duration: about 4 days) <i>Most contagious</i> Rash distribution:  | <p>A rash emerges first as small red spots on the tongue and in the mouth.</p> <p>These spots develop into sores that break open and spread large amounts of the virus into the mouth and throat. At this time, the person becomes most contagious.</p> <p>Around the time the sores in the mouth break down, a rash appears on the skin, starting on the face and spreading to the arms and legs and then to the hands and feet. Usually the rash spreads to all parts of the body within 24 hours. As the rash appears, the fever usually falls and the person may start to feel better.</p> <p>By the third day of the rash, the rash becomes raised bumps.</p> <p>By the fourth day, the bumps fill with a thick, opaque fluid and often have a depression in the center that looks like a bellybutton. (This is a major distinguishing characteristic of smallpox.)</p> <p>Fever often will rise again at this time and remain high until scabs form over the bumps.</p> |
| Pustular Rash (Duration: about 5 days) <i>Contagious</i> | The bumps become pustules -sharply raised, usually round and firm to the touch as if there's a small round object under the skin. People often say the bumps feel like BB pellets embedded in the skin. |
| Pustules and Scabs (Duration: about 5 days) <i>Contagious</i> | The pustules begin to form a crust and then scab . By the end of the second week after the rash appears, most of the sores have scabbed over. |
| Resolving Scabs (Duration: about 6 days) <i>Contagious</i> | The scabs begin to fall off, leaving marks on the skin that eventually become pitted scars . Most scabs will have fallen off three weeks after the rash appears. The person is contagious to others until all of the scabs have fallen off. |
| Scabs resolved <i>Not contagious</i> | Scabs have fallen off. Person is no longer contagious. |
| * Smallpox may be contagious during the prodrome phase, but is most infectious during the first 7 to 10 days following rash onset. | |