

New Jersey Department of Health and Senior Services

Guidelines for the Management of a Suspect Case Of Smallpox in Medical Care Settings

Since the events of September 11, 2001, there has been an acceleration of public health preparedness at the local, state, and federal levels, with respect to potential bioterrorist incidents. Although the risk of a bioterrorist incident involving smallpox is not known, it is considered very low. However, given the theoretical concerns that smallpox virus may be used intentionally, the New Jersey Department of Health and Senior Services (NJDHSS) has developed guidelines for hospitals and other medical care settings to use when evaluating a patient with suspected smallpox.

These guidelines focus on the management of a “suspect” case of smallpox occurring in the absence of an already recognized outbreak, which may represent the index case of a bioterrorist event. Once a case is confirmed as smallpox, further guidance on management of the patient as well as all contacts will be provided by the NJDHSS and the Centers for Disease Control and Prevention (CDC).

The guidelines are divided into the following topics:

I. Steps all hospitals should take to prepare

II. Initial evaluation of patients with acute, generalized vesicular or pustular rash

III. Risk Assessment

IV. Consultation with NJDHSS

V. Management of patient

VI. Management of emergency department or clinic area

VII. General recommendations

I. The NJDHSS recommends that all hospitals ensure their preparedness for the evaluation and management of a suspect smallpox case through the following steps:

A. Ensure that an effective emergency response infrastructure is in place.

1. Ensure the presence of an active, functional Emergency Operations Committee with an incident command/management system. Representatives should include staff from:
 - a. hospital, medical and nursing administration;
 - b. internal medicine, pediatrics, infectious disease, emergency medicine, and intensive care departments;
 - c. infection control;
 - d. microbiology;
 - e. pharmacy;
 - f. employee health;
 - g. public affairs;
 - h. operations;
 - i. Management Information Systems;
 - j. legal services;
 - k. mental health;
 - l. central supply;
 - m. engineering;
 - n. laundry;
 - o. food service,
 - p. housekeeping,
 - q. waste management; and
 - r. hospital safety and security.
2. Ensure the presence of pre-designated roles, lines of authority and chains of communication, with at least one appropriate alternate/back-up person for each position. The presence of an incident command system is recommended for most emergency response plans. An incident command system allows coordination of the emergency response along standardized functional responsibilities. Job action sheets should be prepared ahead of time outlining the roles and responsibilities for all emergency response staff. Examples are available at the Hospital Emergency Incident Command System website at <http://www.emsa.cahwnet.gov/Dms2/heics3.htm>. Additionally, staff in the Bioterrorism Preparedness Unit of the Communicable Disease Service at NJDHSS is available for additional guidance and consultation.
3. Notification protocols that ensure all relevant hospital staff and outside agencies are notified rapidly in the event of an emergency should be established ahead of time. This will require 24-hour contact information (home telephone, pagers, cell phones and electronic mail

addresses) for all key staff, and a telephone tree system or emergency notification software to ensure the ability to rapidly contact staff and request that they report to duty. A copy of the NJDHSS notification protocol that includes key local and state agency contact information should be included in the hospital disaster response plan (Attachment A).

4. A 24/7 communications network with back-up communication systems should be considered in the event that the routine network is disabled.
 5. Each hospital should have at least one key staff member subscribing to the state Health Alert Network through the Local Information Network and Communication System (LINCS).
 6. Regular educational training should be provided to all hospital staff regarding the hospital's emergency response plans, and each staff person's expected role and responsibilities.
- B. As part of overall emergency response planning, each hospital should develop a specific emergency management plan for smallpox (or develop an annex to an existing bioterrorism plan). This plan should be developed in conjunction with the NJDHSS hospital guidelines and response plan. Tabletop exercises and drills to evaluate the hospital response to a suspect smallpox case should be conducted at least annually and in conjunction with local, county, state and regional agencies and efforts.
- C. Ensure that emergency departments and all primary care clinics have protocols in place to quickly identify patients presenting with fever and rash illness and to isolate them immediately pending clinical evaluation (see Section II). All ambulance services associated with the hospital should be alert to the need to pre-notify emergency department staff if transporting a patient with fever and rash illness so that the patient can be immediately placed in isolation on arrival.
- D. Ensure that emergency departments have airborne infection isolation rooms as required by OSHA/PEOSH.
1. Airborne infection isolation rooms are defined as negative pressure isolation rooms with a minimum of 6-12 air exchanges per hour and direct exhaust to the outside which is located more than 25 feet from an air intake and from where people may pass (if air cannot be exhausted directly to the outside more than 25 feet from an air intake and from where people may pass, then air should be filtered through a portable HEPA filter system according to manufacturer's directions). These rooms should be tested monthly (and daily, when in use) to verify negative airflow.

2. In clinical areas that do not have airborne infection isolation rooms that meet the above criteria (e.g., primary care clinics), an enclosed room(s) with a portable HEPA filter system (used according to the manufacturer's directions) should be pre-identified that would allow the suspect patient to be isolated from other patients and staff as best as possible pending clinical evaluation (e.g., an examination room at the end of a hallway).
 3. Ideally, the airborne infection isolation room should have a toilet, sink, and bath or shower for the patient. It is also preferable that there be an anteroom for stocking protective clothing and equipment for persons entering the patient's room.
- E. Pre-identify a floor or unit in the hospital that would be used to admit a suspect or confirmed smallpox case(s) that contains airborne infection isolation rooms meeting the criteria defined above in Section I D.
- F. Provide education to clinical staff on at least an annual basis regarding the potential for bioterrorism and the key diagnostic clues to potential bioterrorist agents, including smallpox.
1. All medical staff should receive education on the clinical presentation of smallpox and the differential diagnosis of vesicular and pustular rashes.
 2. Place copies of the CDC's poster on "Evaluating Patients for Smallpox – Acute, Generalized Vesicular and Pustular Rash Illness Protocol," and the NJDHSS one-page decision tree/evaluation (Attachment B) in the medical areas of the emergency department and all primary care clinics. The CDC poster is available at <http://www.cdc.gov/agent/smallpox/index.asp>.
 3. All healthcare providers should know how to report any suspect smallpox case to the NJDHSS immediately (24-hour contact numbers for NJDHSS are listed in Section IV).
- G. Acquire at least one digital camera and train key personnel in its use and in the e-mail transmission of images to facilitate rapid consultation with the NJDHSS and CDC. Ensure that staff trained to take digital photos and transmit images by e-mail is available on all shifts. The camera must be available in the emergency department 24 hours a day, 7 days a week.
- H. Pre-identify teams of healthcare providers who would be mobilized to care for any suspect or confirmed case. These teams might include staff from the departments of medicine, pediatrics, emergency medicine, infectious disease, obstetrics, radiology

and dermatology; respiratory therapy; nursing; laboratories; security, food service and housekeeping.

1. Until the federal government initiates its plans for pre-vaccination of healthcare workers, it is suggested that these pre-identified staff be persons who were vaccinated at least once previously, although these staff would still need to use appropriate personal protective equipment and airborne and contact precautions during all patient care activities. Previous vaccination may not confer complete protection, however, staff with one or more smallpox vaccinations in the past may have some protection against severe illness.
2. These staff should all be educated in airborne and contact precautions and undergo fit testing for respiratory protective equipment/masks (N-95 or higher) as part of a program meeting the OSHA/PEOSH Respiratory Protection Standard.

II. Initial evaluation of patients with acute, generalized vesicular or pustular rash

A. Pre-incident

1. All hospitals and clinics should have policies in place to ensure that any patient presenting for evaluation in an emergency department or other primary care clinical setting with fever and an acute, generalized vesicular or pustular rash be immediately identified and placed in isolation with airborne and contact precautions.
2. The infection control staff should be notified pending further evaluation (the isolation measures are the same as those that should be applied in cases of suspected measles and tuberculosis).

B. During incident

1. All ambulance services associated with the hospital should be alert to the need to pre-notify the emergency department staff if transporting a patient with fever and rash illness so that the patient can be immediately placed in isolation on arrival.
2. Security guards at the entrance to emergency departments or clinics, as well as triage and receptionist staff should be trained to be alert for patients with rash illnesses.
3. At the walk-in entrance to the emergency department or clinic, place signs (bi or multilingual depending on the hospital's patient population) stating that any patient with fever and rash illness immediately inform triage staff.

4. If a patient with fever and rash illness presents to the emergency department, immediately notify the appropriate staff to expedite the patient's placement in an airborne infection isolation room (see Section III for details on isolation precautions).
5. A surgical mask should immediately be placed on patients with fever and rash illness and the patient should be escorted directly to an airborne infection isolation room.
6. If suspect patients are initially seen in clinical areas (e.g., primary care clinics) that do not have airborne infection isolation rooms as defined in Section I D, a surgical mask should be placed on the patient, and he/she should be isolated from other patients and staff as best as possible, pending clinical evaluation (e.g., an enclosed examination room separated from other patients at the end of a hallway).
7. An isolation sign noting the need for airborne and contact precautions should be displayed outside the patient's room. An adequate supply of personal protective equipment should be readily available (in an isolation cart placed outside the door if possible).
8. Only essential staff and members of the immediate family should be allowed to enter the patient's room. All staff and visitors should wear a gown, gloves, and a mask/respirator (N-95 or above) prior to entering the patient's room. This may/will require distribution of appropriate sized respirators and fit testing before use.
9. Doors to these patients' rooms should be kept closed (self-closing doors are preferable).
10. Suspected or confirmed smallpox patients should be kept in their rooms except for medically essential procedures that necessitate transport to other hospital locations. To minimize the potential for contamination when transported outside of their isolation rooms, a surgical mask should be placed on the suspected or confirmed smallpox patient(s), a sheet should be used to cover their skin as much as possible, and efforts should be made to minimize patient movement.
11. Care should be used when handling the patient's linens, to minimize aerosolization.

III. Risk Assessment

Health care providers should perform a clinical assessment to determine if the patient is at low, moderate or high risk for smallpox, according to CDC criteria

(Attachment B). The full protocol with color photographs is available as a poster, “Evaluating Patients for Smallpox – Acute, Generalized Vesicular and Pustular Rash Illness Protocol.” Copies of this poster can be obtained at the CDC website at <http://www.cdc.gov/agent/smallpox/index.asp>.

- A. For **low risk patients** (See Attachment B) when chickenpox or disseminated herpes zoster is the likely diagnosis based on history and physical examination:
1. **It is NOT necessary to report the case to the NJDHSS, unless a consultation is desired/needed.**
 2. The patient should be kept under airborne and contact isolation. Varicella laboratory testing is optional.
 3. Chickenpox (varicella) is the most likely condition to be confused with smallpox. In chickenpox, the following findings on history and physical examination are usually found:
 - a. No or mild prodrome;
 - b. Lesions are superficial vesicles (“dewdrops on a rose petal”);
 - c. Lesions appear in crops; on any one part of the body, there are lesions in different stages (papules, vesicles, pustules, crusted lesions);
 - d. Centripetal distribution: greatest concentration of the lesions on the trunk, fewest lesions on the distal extremities. May involve the face and scalp. Occasionally, the entire body is equally affected;
 - e. First lesions appear on the face or trunk;
 - f. Patients are rarely toxic or moribund;
 - g. Lesions progress through a rapid evolution (< 24 hours) from macules to papules to vesicles to crusted lesions;
 - h. Palms and soles are rarely involved;
 - i. Patient lacks reliable history of either varicella infection or vaccination;
 - j. 50-80% of patients recall a recent exposure to chickenpox or shingles within the 10-21 days before the onset of their rash.
 4. Laboratory testing for varicella zoster virus antigen (performed at NJDHSS using rapid Direct Fluorescent Antibody [DFA] or Polymerase Chain Reaction [PCR] tests) and/or other conditions should be considered as indicated clinically.
- B. For **moderate risk patients** (See Attachment B).
1. **The NJDHSS should be contacted immediately.**

2. An infectious disease or dermatology consult should be arranged, and rapid testing for varicella (DFA or PCR testing for varicella antigen) performed at NJDHSS. **If specialty consultation is not available, or the diagnosis remains uncertain, the NJDHSS will assist in arranging for consultation and rapid diagnostic testing to rule out varicella.**

C. For **high risk patients** (See Attachment B).

1. **The NJDHSS should be contacted immediately.**
2. An infectious disease or dermatology consult should be arranged, and rapid testing for varicella (DFA or PCR testing for varicella antigen) performed at NJDHSS. **If specialty consultation is not available, or the diagnosis remains uncertain, the NJDHSS will assist in arranging for consultation and rapid diagnostic testing to rule out varicella.**
3. After consulting with NJDHSS and receiving from NJDHSS support for the high-risk assessment, the NJDHSS will notify the Local Health Department, CDC and the State Police. They will also send an epidemiology team to the hospital to initiate an epidemiologic investigation.

IV. Consultation with NJDHSS

- A. The NJDHSS should be consulted immediately for any patient deemed to be at **moderate** or **high risk** for smallpox.
- B. **To report a suspect case of smallpox to the NJDHSS:**
 1. **During normal business hours (Monday-Friday, 8am-5pm), call (609) 588-7500 and ask for the Bioterrorism Unit.**
 2. **During nights, weekends and holidays, contact the NJDHSS emergency number at 609-392-2020.**
 3. **The NJDHSS has rapid assessment teams available 24 hours a day, 7 days a week, to assist providers in evaluating suspect smallpox patients. Additionally, NJDHSS has rapid varicella DFA antigen testing available to assist in differentiating chickenpox from smallpox.**
- C. A member of the NJDHSS Bioterrorism Unit will initially discuss the case by telephone with the reporting physician. Additional consultation is available from Medical Emergency Disaster Preparedness and Response Expert Panel (MEDPREP) consultants on an as-needed basis. A rapid assessment will be made to support the risk assessment and determine the need for further evaluation.

- D. If the patient is deemed to be at **moderate** or **high risk** for smallpox, and no other etiology can be quickly determined, the NJDHSS will work closely with the hospital staff to obtain appropriate clinical specimens for laboratory testing. NJDHSS will perform varicella testing. Currently, confirmatory tests for smallpox are only available at the CDC. Therefore, the NJDHSS will arrange urgent transportation to the CDC to expedite testing, when needed. Preliminary results should be available within 8-12 hours of the specimen's arrival in Atlanta to guide further clinical and public health management of the patient.

V. Management of patient

- A. Until the diagnosis of smallpox has been effectively ruled out by clinical examination and/or laboratory testing (PCR and DFA for variola antigen and/or electron microscopy at CDC may take up to 24 hours, including transport time to Atlanta), **moderate** and **high risk** patients (see **Attachment B**) should be **kept in an airborne infection isolation room (see section I D) with airborne and contact precautions**.
- B. The NJDHSS recommends the following additional steps for managing suspect **moderate or high risk patients** and potential contacts of suspect moderate or high risk patients:
1. **Infection control personnel must be notified immediately.**
Infection control staff should track the names, job duty (for staff), home address, and contact numbers (including home and work telephone, cellular phone, and beepers) for all hospital and ambulance/first aid/police staff and visitors who have spent any time with the patient from the moment he/she entered the hospital. The usual mechanism of spread of smallpox is droplet transmission with larger particles falling out of the air quickly. **Please note that spread beyond six feet from the suspect case-patient is unlikely, and unless the patient is coughing (and if oropharyngeal lesions are present), aerosolization is also not likely. Therefore, for purposes of tracking, "potential contacts" are defined as persons who were in close proximity (i.e. within six feet) to the suspect case-patient.** These persons will need to be counseled on:
 - a. the potential exposure and the likelihood of this being smallpox;
 - b. the risk of their being infected with smallpox, given the type and length of exposure that they had to the suspect patient (with consideration of whether the patient has cough symptoms);

- c. the timeframe involved in determining whether the suspect case-patient does indeed have smallpox (i.e., the expected time before laboratory test results will be available) and how they will be notified of the results;
 - d. the consequences of a confirmed diagnosis (i.e., that if smallpox is confirmed, the NJHDSS and/or the hospital would be contacting them within the next 24 hours to ensure that they immediately receive smallpox vaccine) and the fact that they would not be infectious to their household and close contacts immediately after exposure, even if the suspect case did have smallpox (i.e., that these persons could go home while awaiting laboratory test results and do not need to be quarantined).
2. The NJDHSS should be notified of any patient or visitor to the emergency department for whom there is concern that the patient may be difficult to locate after discharge (e.g., homeless or with no known address). These persons should be held in the hospital, pending NJDHSS evaluation to determine if alternate arrangements need to be made to ensure the ability to locate and vaccinate the individual(s) in the event that smallpox is confirmed.
3. While a patient is being transported from the emergency department or clinic to an in-patient room, the patient should wear a surgical mask. A sheet should be used to cover the skin as much as possible and efforts should be made to limit patient movement and manipulations of the linen, to minimize aerosolization.
4. Minimize the number of persons who enter the patient's room, as well as the traffic in and out of the room, as much as possible. All hospital staff (including transport personnel) and visitors (limited to immediate family ONLY) must don contact and airborne personal protection equipment prior to entering a suspected or confirmed smallpox patient's room (i.e., disposable gloves, gowns and a surgical mask or properly fit-tested respirator, N-95 or higher; see section II B 8 for more information).
 - a. Preferably, no staff without at least one prior vaccination for smallpox should be allowed in the patient's room.
 - b. Ensure that all staff and visitors entering the room are instructed in the meaning of contact and airborne precautions.
 - c. Dedicated equipment (e.g., blood pressure cuffs and stethoscopes) should be left in the room when possible. No personal equipment (e.g., stethoscopes) should be used on the

suspect patient and then taken out of the room for use on other patients until decontaminated. A disinfectant labeled “tuberculocidal” is recommended for use on diagnostic equipment used on the patient.

- d. Use disposable items whenever possible. Arrange to have food brought into the room in disposable containers. Disinfect and/or sterilize non-disposable medical devices according to the manufacturer’s specifications. No extraordinary efforts are necessary. Articles contaminated with excessive blood or body fluids (i.e. lesions or respiratory secretions) should be handled as regulated medical waste. All other non-sharps waste can be handled as regular waste.
- e. Ideally all laundry and linens (e.g., bedding, towels) should be handled by the vaccinated staff caring for the patient. Laundry/linen can be put in impervious bags in the patient’s room. Any staff wearing gloves can transport the bagged linen according to the hospital’s standard laundry protocol.

VI. Management of emergency department or clinic area

The following guidelines apply to the emergency department or clinic area where the **moderate to high-risk** patient was initially seen and may have spent time prior to being placed in an airborne infection isolation room, while awaiting results of diagnostic tests.

- A. **All hospital emergency departments and primary care clinics are expected to have effective triage protocols in place to rapidly identify and effectively isolate any patient with a suspected rash illness in order to minimize the number of persons potentially exposed in the waiting area** (see Section I). As mentioned previously in this document, the usual mechanism of spread of smallpox is droplet transmission (with larger particles falling out of the air quickly and spread beyond six feet from the patient much less likely), and unless the patient is coughing (and if oral lesions are present), aerosolization is unlikely. Nosocomial transmission of smallpox was rarely reported in the past, and since then there has been marked improvements in the environmental safeguards in hospital's given the infection control measures taken for tuberculosis and other communicable diseases. Therefore, it would be extremely unlikely for there to be any risk of smallpox transmission to staff, patients or visitors who did not have direct contact with the suspect patient, especially if the suspect case patient is rapidly placed in an appropriate airborne infection isolation room. This being the case, it should not be necessary to consider quarantine of the entire hospital building or termination of all acute care services while waiting for NJDHSS evaluation or laboratory test results.
- B. **It is strongly recommended that the decision to close an emergency department or clinic area ONLY be made in consultation with the NJDHSS.** There are only limited circumstances under which an emergency department should be closed due to the presence of a patient with suspected smallpox with the potential for airborne transmission. These circumstances include:
1. If the patient could not be effectively isolated;
 2. If the patient had a significant cough, was not recognized immediately, and spent time in the waiting room where aerosolization may have occurred; and,
 3. If the emergency department had been disrupted (e.g., by multiple patients, or by panic among patients, families and staff) to such an extent that the emergency department could no longer function to provide patient care.
- C. The names, home addresses, and 24-hour contact information (including home and work telephone, cellular phone, and beeper numbers), should be noted for all emergency department or clinic visitors who were exposed to the suspect patient before he/she was placed in isolation.

- D. All equipment and surfaces in the emergency department that may have been in contact with the suspect patient (including in the waiting room and any other rooms in which the patient was placed prior to moving to the isolation room) should be decontaminated with standard hospital disinfectants (e.g., 5% aqueous solution of a phenolic germicidal detergent such as Lysol or amphy1), especially in any areas where a suspect case-patient has been coughing.

VII. General recommendations

A. Activation of the hospital emergency operations plan

1. The decision whether to activate the hospital's emergency operations plan should be made based on the individual circumstances of the event.
2. For a suspect case-patient thought to be at **moderate to high risk** for smallpox or if media attention or staff/patient/visitor's concerns are high enough so that the hospital is unable to function normally, the emergency operations plan should be activated, including the hospital's emergency operations center.
3. The hospital's Emergency Operations Committee should ensure that the internal notification procedures and contact lists include all essential staff (e.g., infection control, infectious diseases, dermatology) that might be needed in the event of a smallpox emergency as well as emergency contact information for all key local and state agencies.

B. Notifications

1. The NJDHSS should be notified immediately when a patient is determined to be at **moderate to high risk** for smallpox.
2. The NJDHSS will notify the Local Health Department, State Police and CDC prior to coming to the hospital and will maintain communications with them throughout the event.
3. The State Police will notify all other appropriate agencies, as indicated.

C. Communication issues

1. Internal:
 - a. The hospital administration and/or Emergency Operations Committee should ensure that a mechanism and plan is in place for frequent communication with all hospital staff to address the likely concerns that they may have about the risk of

smallpox in the institution and to provide timely updates on the situation, as new information becomes available. Mechanisms may include broadcast fax, e-mail, frequent meetings for each hospital shift, and internal websites.

- b. The NJDHSS will work closely with the hospital staff to develop and distribute educational materials and fact sheets, as well as provide speakers for internal debriefings, as needed.
- c. **NOTE: In the event of a suspect case that is being preliminarily worked up, it is strongly recommended that all clinical care staff be advised to minimize discussion of the suspected smallpox diagnosis in open areas where others may overhear and misinterpret the situation.** This will avoid unnecessary panic or a leak to the media for a case that may quickly be determined NOT to be smallpox.

2. External:

- a. It is essential that a coordinated communication strategy be developed between the hospital public affairs staff and the state response agencies.
- b. The NJDHSS, in coordination with State Police and the Governor's Office, will provide the news media with the medical, epidemiologic, and infection control details relevant to the event. The NJDHSS will work closely with the hospital staff if a public statement or press conference is needed while awaiting laboratory test results. The NJDHSS Communications Office will produce consistent messages about the likelihood of smallpox and the steps being taken by the hospital and government agencies to determine the diagnosis, as well as any contingency plans being put into place, if indicated.

D. Security issues:

- 1. Ensure sufficient security is present to respond to any potential disruptions that may occur due to the concerns about smallpox (e.g., significant media attention). Security plans should include:
 - a. Ability to minimize points of access and egress to the physical plant.
 - b. A rapid identification process for hospital staff and local, state and federal emergency workers.

- c. An external vehicular “flow of traffic” prioritizing emergency vehicle access, supply delivery needs and law enforcement access.
 - d. A method for routing persons other than patients to and from the facility.
 - e. A triage protocol to route additional patients that may have smallpox based on fever and rash symptoms for immediate clinical evaluation to an appropriate, pre-designated site with sufficient airborne infection isolation rooms.
 - f. Assurance that appropriate protective equipment is provided to security staff, when indicated.
2. Local and State Police are available for assistance, as needed.