

State of New Jersey

Smallpox Vaccination Plan

December 9, 2002

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(Note: appendices A2, A-5 and F have been redacted)

D) Introduction

A) Background

In response to the potential use of biological agents against civilians, the federal government has committed to upgrading preparedness, readiness, and national defenses against bioterrorism weapons. The Centers for Disease Control and Prevention (CDC) has been designated as the lead federal agency for upgrading national public health capabilities for responding to biological terrorism. Many biological agents could be used to attack civilians; however, only a few, such as smallpox (variola) virus, have the ability to cause illness or panic to the extent that existing medical and public health systems would be overwhelmed. Although smallpox was globally eradicated by the late 1970s, there remains concern that stores of smallpox virus may exist in laboratories other than the two WHO-designated repositories. Moreover, if an outbreak of smallpox were to occur, several factors could contribute to a more rapid spread of smallpox than was routinely seen before this disease was eradicated. These factors include: 1) virtually nonexistent immunity to smallpox in the absence of naturally occurring disease and the discontinuation of routine vaccination in the United States in the early 1970s, 2) potentially delayed recognition of smallpox by health personnel who are unfamiliar with the disease presentation, and 3) increased mobility and crowding of the population. Because of these factors, a single case-patient of smallpox would be considered an outbreak and would require an immediate and coordinated public health and medical response to contain the outbreak and to prevent further infection of at-risk individuals.

Smallpox vaccine is a highly effective immunizing agent. It is a live-virus vaccine composed of vaccinia virus, an orthopoxvirus that induces antibodies that also protect against smallpox. Its use in focused ring vaccination campaigns that relied on intensive surveillance and contact-tracing during the smallpox eradication program helped bring about the global eradication of smallpox. The last naturally acquired case of smallpox occurred in Somalia in 1977. In May 1980, the World Health Assembly certified that the world was free of smallpox.

Although smallpox vaccine is considered a safe vaccine, post-vaccination adverse events can occur. These adverse events and their rates as determined in a 1968 10-state survey include: 1) inadvertent auto-inoculation (529.2/million primary vaccinations), 2) generalized vaccinia (241.5/million primary vaccinations), 3) eczema vaccinatum (38.5/million vaccinations), 4) progressive vaccinia (1.5/million primary vaccinations), and 5) postvaccinial encephalitis (12.3/million primary vaccinations). Death also occurs in about one per million primary vaccinations and is usually a result of progressive vaccinia, postvaccinial encephalitis, or severe eczema vaccinatum.

Several groups have been identified as having a higher risk for developing post-vaccination complications. These include 1) persons with eczema (including a history of eczema) or other forms of chronic dermatitis, and 2) persons with altered immune states (e.g., HIV, AIDS, leukemia, lymphoma, immunosuppressive drugs, etc.). In addition, because of the small risk for

fetal vaccinia, vaccination is not recommended during pregnancy. Children under 1 year of age or older adolescents or young adults receiving primary vaccination may also have a greater risk of postvaccination complications. Vaccinia Immune Globulin (VIG) is used to treat certain vaccine adverse reactions; however, supplies of the VIG are also limited.

B) Purpose of the Document

The New Jersey Department of Health and Senior Services (NJDHSS, the Department) is the lead state agency that works in partnership with the CDC and other state and local government agencies, law enforcement agencies, private enterprises, and voluntary organizations that operate statewide to provide services that are essential to the health of the public. The Department has developed this Smallpox Vaccination Plan (the Plan), based on CDC Guidelines (<http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>) to define the roles, resources, and materials needed to plan and conduct a smallpox vaccination program for use in New Jersey, if necessary.

The Plan is a work in progress, and an infusion of federal and state funds is supporting extensive capability and capacity-building efforts. The NJDHSS will modify the Plan as appropriate in response to changing threats, vulnerabilities, and response capabilities/capacity.

The Plan describes the logistical considerations for both voluntary public health care system preparedness (Stage I, pre-event) and large-scale response (post-event) smallpox vaccination clinics. Following a confirmed smallpox outbreak within the United States, rapid voluntary vaccination of a large population may be required to: 1) supplement priority surveillance and containment control strategies in areas with smallpox case-patients; 2) reduce the “at-risk” population for additional intentional releases of smallpox virus if the probability of such occurrences is considered significant; or 3) address heightened public or political concerns regarding access to voluntary vaccination. Large-scale voluntary smallpox vaccination would be considered part of an overall national vaccination strategy and would be initiated following the approval of the Secretary of the US Department of Health and Human Services.

In developing this Plan, the following considerations apply:

1. Except for a limited amount of licensed vaccine for Stage I preparedness vaccination (See Section II.C.), current smallpox vaccines are available under a Food and Drug Administration (FDA) Investigational New Drug (IND) protocol only, and informed consent must be obtained.
2. The shortened IND process for obtaining informed consent should be followed.
3. Separate clinic(s) should be considered for vaccination and counseling of identified contacts of smallpox case-patients, but resources to handle contacts must also be available at voluntary clinics because some contacts may show up for vaccination at those facilities.
4. Medical screening for contraindications must be done, and vaccination should generally not be recommended for persons with contraindications who are not otherwise identified as contacts. Medical screening planning should include strategies to facilitate referral to local public health or medical laboratories or clinics for voluntary and confidential HIV

or pregnancy testing if requested by the participant. Consideration should be given to the potential use of rapid HIV tests at laboratories and clinics performing voluntary HIV testing if such a test is available and FDA-approved.

5. Appropriate amounts of VIG should be available within the National Pharmaceutical Stockpile (NPS) to treat anticipated adverse events prior to initiating large-scale, voluntary vaccination as a component of the national response to a smallpox outbreak.
6. Treatment of adverse events will occur in facilities separate from vaccination clinics.
7. Existing immunization program resources should be utilized in the implementation of voluntary vaccination programs, and coordination should occur between state and local immunization program and bioterrorism planning personnel.
8. Pre-designated healthcare sites, such as annexes to hospitals, will be established, as part of the community smallpox response plan, for the evaluation of symptomatic individuals to rule out smallpox. These evaluation sites should be separate from designated vaccination clinics, but should also have the capability to administer vaccination, using the IND information and informed consent process. (Written scripts of the video may be used if video viewing facilities are not available.)
9. The pre-designated sites for evaluating symptomatic individuals for smallpox will be identified in public service announcements and these individuals will be discouraged from presenting to voluntary vaccination clinics.
10. Vaccination clinic and transportation personnel should be vaccinated prior to beginning vaccination clinic activities in order to provide protection against exposure from symptomatic contacts who may inadvertently present to the vaccination clinic. Establishment of voluntary clinics may need to be done in a stepwise fashion over 2 to 3 days to accommodate administration of staff vaccinations prior to opening a clinic. (NOTE: Vaccination clinic personnel do not require a “waiting period” after receiving vaccination before beginning vaccination activities, as long as a triage system to prevent admission of ill/potentially infectious individuals into the clinic is in place at each clinic site. Personnel involved specifically in the triage and/or evaluation of ill individuals who may present to vaccination clinics should use other personal protective measures until a vaccine take is confirmed. Vaccination take rates are expected to be >95%.)

The Plan supplements the following documents:

State of New Jersey, Emergency Operations Plan: Terrorism Incident Annex (the Terrorism Incident Annex);

State of New Jersey, Emergency Operations Plan: Bioterrorism Appendix (the Bioterrorism Appendix) – DRAFT;

State of New Jersey, Emergency Operations Plan: Emergency Support Function #8, Health & Emergency Medical Annex (the ESF#8), including Appendix B, Pharmaceutical Stockpile Access and Distribution;

State of New Jersey, Emergency Operations Plan: Emergency Support Function #13, Public Information Annex (the ESF#13).

C) Description of Primary New Jersey Agencies/Advisory Boards

The Terrorism Incident Annex, the Bioterrorism Appendix-DRAFT, the ESF#8 and ESF #13 provide administrative and operational guidance for the primary and support agencies. The following description of primary agencies/advisory boards is listed only to provide context for the Plan.

1. New Jersey Department of Health and Senior Services (NJDHSS)

The NJDHSS provides strategic and operational leadership and direction, coordination, provision of services, and assessment of activities to ensure state and local readiness, interagency/multidisciplinary collaboration, preparedness for terrorism and other outbreaks of infectious disease, natural disasters, and other public health threats and emergencies.

2. New Jersey State Police – State Office of Emergency Management (NJ SOEM)

The NJ SOEM is the lead State agency in disaster recovery operations and is responsible for coordinating State preparedness plans for major disasters.

3. New Jersey Domestic Security Preparedness Task Force (DSPTF)

The New Jersey DSPTF and its Planning Group are comprised of representatives of State government, local emergency management and law enforcement officials, the Federal Emergency Management Agency (FEMA), the Federal Bureau of Investigation (FBI), and other organizations responsible for developing a coordinated plan of action to prepare for, respond to, and recover from, incidents of terrorism. The DSPTF provides statewide coordination and supervision of all activities related to domestic preparedness and response to a terrorist attack.

- a. DSPTF is charged with managing responses in accordance with the State Emergency Operations Plan.
- b. The disaster remediation, recovery, and response functions performed by the DSPTF shall supplement those disaster relief functions currently performed by the NJ SOEM, which shall continue in its current capacity, subject to the direction and supervision of the Superintendent of State Police.
- c. The DSPTF and NJ SOEM shall coordinate and consult with each other on the performance of their respective remediation, recovery, and relief functions.
- d. The DSPTF Planning Group assists the DSPTF by developing a coordinated statewide plan that serves as the framework for the state to prepare for, respond to, mitigate, and recover from, incidents of terrorism.
- e. The Planning Group includes members of NJDHSS, other departments of state government, health care agencies, and

representatives of various emergency response and public service organizations.

- f. The Planning Group developed the statewide Terrorism Incident Plan (Terrorism Annex) and the Bioterrorism Appendix – DRAFT.

4. MEDPREP/Terrorism Advisory Committee

The members of the Governor’s Medical Emergency and Disaster Prevention and Response Expert Panel (MEDPREP), a multidisciplinary panel of experts in medicine, nursing, pharmacy, public health, emergency medical services, emergency management and pre-hospital/hospital based health care, provide subject matter expertise to the NJDHSS on issues related to bioterrorism and public health emergencies. NJDHSS’ Cooperative Agreements with the CDC and the Health Resources Services Administration (HRSA) require the establishment of an advisory committee to assist the State in bioterrorism planning. The MEDPREP/Terrorism Advisory Committee has been expanded to include other state and federal partners and will continue to provide advice and counsel to the NJDHSS and county and local public health agencies to:

- a. build the critical capabilities and capacities necessary to achieve the desired state of readiness to prepare for, and respond to, acts of terrorism and other public health emergencies;
- b. provide subject matter expertise in assisting the NJDHSS to meet its intended objectives related to terrorism preparedness and response;
- c. serve as liaison to public health, medical, emergency management and academic sector members as a way of promoting prevention and response efforts; and,
- d. foster more effective communication and collaboration.

D) Scope of NJDHSS Activities

The public health care system in New Jersey was heavily engaged in the response and consequence management efforts for both the World Trade Center attack and the anthrax events in the fall of 2001. The following activities related to preparedness and response to a confirmed smallpox case-patient have been and are being further expanded and developed under the primary authority and responsibility of the NJDHSS Commissioner.

Preparedness

The NJDHSS has the primary responsibility to:

- 1) coordinate the development and delivery of specialized training programs for public health care providers statewide;
- 2) develop and maintain a public health surveillance and identification program for infectious diseases;
- 3) direct epidemiological investigations of infectious disease outbreaks and syndromes;
- 4) integrate the CDC National Pharmaceutical Stockpile Program into State protocols to ensure the rapid distribution and dissemination of medications and vaccines;
- 5) participate in Federal and State training exercises related to terrorism response;
- 6) plan and coordinate a regional approach to the delivery of emergency health care services.
- 7) plan and exercise public health and emergency response activities across all state jurisdictions.

Response

In the event of a confirmed case-patient of smallpox, the NJDHSS Commissioner shall have primary authority and responsibility to:

- 8) coordinate the integration of public health roles and responsibilities with the New Jersey National Guard, law enforcement, and fire officials;
- 9) provide laboratory support as required;
- 10) serve as the Primary Agency for Emergency Support Function (ESF#8), Health and Emergency Medical Support, to the State EOP and to coordinate the transition from crisis to consequence management for emergency medical response agencies throughout the State;
- 11) serve as part of the State representation at the Federal Joint Operations Center (JOC), as required.

In addition, the NJDHSS shall have primary responsibility for:

- 12) authorizing quarantine, vaccination, and/or isolation of individuals;

- 13) communication of public health information; and,
- 14) coordination with appropriate federal agencies.

E) Federal Resources Provided for Vaccination Clinics

The Federal Government will provide the following resources to state and local public health authorities for use in voluntary vaccination programs following confirmation of a smallpox outbreak:

1. smallpox vaccine and the following vaccine administration supplies: bifurcated needles and diluent for reconstitution of vaccine;
2. vaccine administration directions (written and video demonstration);
3. IND protocols and supporting materials in major languages (at a minimum English and Spanish), including:
 - a. medical screening and consent forms
 - b. information sheets on:
 - i. smallpox vaccine
 - ii. vaccine adverse events
 - iii. specialized information for persons with contraindications
 - iv. smallpox disease
 - c. contact information
 - d. vaccine take recognition card
 - e. vaccine site care instructions
 - f. vaccination card for use within clinics;
4. VIG and/or Cidofovir for use as IND products for the treatment of serious adverse events that may be expected to respond to these treatments;
5. technical assistance with clinic design, development of clinic databases, and vaccination tracking systems;
6. assistance, including with outbreak investigation, as otherwise outlined in the Federal Response Plan, if activated.

The amount of personnel resources provided by the Federal Government will be dependent upon the scale of the voluntary vaccination program. Additional government personnel resources available to the state and local authorities will be limited for any programs implemented on a large-scale in multiple sites (e.g., implementation of a nationwide voluntary vaccination program).

II. Preparedness Capacities

A) Organization and Management

Upon confirmation of a case-patient of smallpox and declaration of a public health emergency in New Jersey by the Governor, after consultation with federal authorities, the NJDHSS Commissioner will initially:

1. make first contact with the DSPTF and NJ SOEM to open a line of communication;
2. notify all senior staff and activate an incident command system;
3. designate an individual to take the department operational lead in responding to the incident. The designated individual, the NJDHSS Incident Commander, will work with the NJDHSS Commissioner to:
 - a. assess the situation, establish objectives, brief staff and fill necessary functions of the NJDHSS incident response team;
 - b. provide, with the NJDHSS Commissioner and Senior Staff, organizational leadership and communicate policy decisions to NJDHSS staff;
4. assure that the NJDHSS activities are integrated with law enforcement, fire/hazmat services and the National Guard;
5. assign a NJDHSS staff pharmacist to coordinate activities related to vaccine supply and medical supply stockpiles. Currently, a staff pharmacist from another program will be reassigned to duties during an emergency; however, the intent is to hire a permanent full time employee for this duty;
6. activate an Executive Coordinating Committee (ECC) to facilitate resources, inter-agency communications, and make available NJDHSS resources to carry out those tasks necessary to protect the public's health and safety. The ECC will operate from the Commissioner's Office, and have representation from the:
 - Office of the Commissioner,
 - Chief of Staff,
 - State Epidemiologist,
 - Assistant and Deputy Commissioners of the impacted programs,
 - Office of Communications,
 - The MEDPREP/Terrorism Advisory Committee,
 - Public Health Emergency Operations Center.

The ECC shall make recommendations to the Commissioner and Governor on implementation of the Smallpox Vaccination Plan to control the outbreak;

6. activate a Public Health Emergency Operation Center (PHEOC) under the supervision of the NJDHSS Emergency Response Coordinator to support the ECC and the operations at the SEOC. The PHEOC will have departmental representation from the Communicable Disease Service, Health Care Systems Analysis, Public Health Services, Long Term Care Systems, Senior Affairs, Public Health Service, Public Health and Environmental Laboratories, and Local Health and Emergency Services, and will also have representation from the Office of the Commissioner, including but not limited to, the Office of Communications. The PHEOC will house staff from federal, state, and/or law enforcement and other response agencies, if necessary. The activities of the PHEOC are described in Section III.M.

B) Assignment of Staff Roles and Responsibilities

1) NJDHSS Commissioner

The NJDHSS Commissioner shall:

- a) report directly to the Governor and work in conjunction with the DSPTF;
- b) serve as the senior state government official on matters related to public health and public health emergencies and be responsible to maximize and effectuate coordination of public health responses including, but not limited to, decisions to quarantine, vaccinate, or isolate individuals;
- c) shall serve as the primary contact in the communication of policy decisions to the Governor, the DSPTF, and the SOEM;
- d) attend, or send an alternate, to daily briefings by the NJDHSS Incident Commander Director with the ECC. This briefing will bridge communication between the DSPTF, the ECC, and the PHEOC;
- e) serve as the primary contact between the state and the public on matters of public health including, but not limited to, municipal and county elected officials; and,
- f) make available to the SEOC and PHEOC, through a NJDHSS answering service, a list of personnel available to respond to emergencies.

2) NJDHSS Deputy Commissioner, Terrorism Preparedness and Response

The NJDHSS Deputy Commissioner for Terrorism Preparedness and Response will:

- a) coordinate the NJDHSS response to acts of terrorism;
- b) serve as policy advisor in the consequence management;
- c) serve as liaison with local, state, and federal public health, public safety, and emergency management personnel on matters of policy; and,
- d) may serve in the role of the Incident Commander, if designated by the Commissioner.

3) Incident Commander

The NJDHSS Incident Commander will facilitate:

- a) implementation of policy developed by the Governor, the NJDHSS Commissioner, and the DSPTF;
- b) communications with key agencies inside and outside of New Jersey concerning operations;
- c) integration of public health with law enforcement, fire/hazmat services and the National Guard;
- d) identification of and request needed resources including, but not limited to medication and medical supply stockpiles;
- e) coordination of the response to the outbreak by assessing problems to identify necessary staff;
- f) a daily briefing for Senior Staff; and,

- g) communications between the New Jersey's Health Alert Network (Local Information Network and Communication System (LINCS)) Coordinator and NJDHSS Senior Staff.

4) State Epidemiologist

The NJDHSS State Epidemiologist shall:

- a) coordinate public health surveillance procedures to prevent, detect, manage and coordinate response to infectious diseases and other outbreaks within the state;
- b) serve as the primary contact with the CDC in matters related to an epidemiological investigation;
- c) supervise epidemiological investigations;
- d) prepare information on the extent of the outbreak and progress of the investigation and control efforts; and,
- e) coordinate a statewide vaccination program.

5) Director, NJDHSS Office of Emergency Medical Services

The Director, NJDHSS Office of Emergency Medical Services (EMS) will:

- a) through the SEOC, coordinate with the counties to facilitate response activities and the establishment of staging areas for medical and EMS resources, and make available EMS system related information and listings of EMS providers;
- b) establish ground and air transportation for individuals requiring treatment as a result of the outbreak to medical facilities, in coordination with other State agencies, New Jersey State First Aid Council Mobilization Coordinators, county EMS coordinators and New Jersey designated air medical helicopter dispatch centers;
- c) direct and activate the deployment of healthcare and EMS resource needs and provide for prioritization or allocation of available supporting resources in response to requests for State assistance.

6) Director, Office of Government Affairs

The Director, Office of Government Affairs will:

- a) ensure that local, county, state and congressional elected officials receive public health alerts and news releases; and,
- b) arrange for briefings between NJDHSS and local, county, state and congressional elected officials, as appropriate.

7) Director, Office of Communications

The Director, Office of Communications, will:

- a) organize press coverage of major events for various press outlets;
- b) produce news releases to send to media and post on the NJDHSS web site (news releases will provide information to both the public and health care professionals);
- c) manage press briefings;
- d) respond to press calls, arrange for interviews;
- e) brief the Governor's Office; and,
- f) serve as liaison with secondary state and federal support agency press offices.

8) NJDHSS Emergency Response Coordinator

The NJDHSS Emergency Response Coordinator will:

- a) direct the activities of the PHEOC when activated;
- b) serve as the principal liaison to the SEOC, county EOCs, and local law enforcement agencies;
- c) facilitate delivery of specimens to the State Lab, where needed;
- d) organize staffing of the PHEOC to provide telephone response to calls from the public, healthcare professionals or law enforcement agencies; and
- e) provide technical support to the epidemiological investigation team.

C) Preparedness Vaccination of Public Health and Health Care Response Personnel

The NJDHSS will be finalizing its Smallpox Preparedness (Stage I) Vaccination Plan, which is based on the CDC's Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (NSVP), once the President makes a decision on the final elements of the plan.

It is assumed that issues of liability and workers' compensation coverage will be addressed and resolved in advance of the implementation of the New Jersey Smallpox Preparedness Vaccination Program (the Program), removing these issues as barriers to encouraging workers to volunteer to join a response team. Vaccination will be voluntary and will not be required as a condition of employment. However, participation in certain activities (e.g. treatment of a high risk patient for smallpox) will be limited to vaccinated personnel only.

There will be 3 phases of the Program: Pre-implementation: early December 2002 to late-January 2003.
Implementation: late-January to late-February
Post-implementation: late-February to late March

1. Organization and Management

The ECC (see II.A.6.) will provide oversight of the Program, which was developed with input and advice from the MEDPREP/Terrorism Advisory Committee at a meeting on November 26, and a meeting of County Health Officers on December 5th. The State Epidemiologist/Assistant Commissioner will serve as the Coordinator of the Program. Attachment A1 includes the organizational chart of the Program. Attachment A2 lists the contact information for key personnel. Attachment A3 contains the projected timeline for the completion of the Program.

2. Identification of Smallpox Public Health Response Team (PHRT)

New Jersey will have 5 PHRTs, corresponding to the 5 regions described in the Cooperative Agreement Application (See map, Appendix A4). Each of the 21 counties in New Jersey has a lead County Health Agency called the Local Information Network Communication System (LINCS) agency. The Newark and Paterson City Departments of Health are also LINCS agencies. Each team will consist of both NJDHSS and LINCS personnel and will include a:

- physician team leader (NJDHSS)
- epidemiologist (LINCS)
- public health nurse/vaccinator (LINCS)
- laboratory worker (NJDHSS)
- law enforcement agent (State Police)
- state regional planner/coordinator (NJDHSS)
- a LINCS regional planner/coordinator (LINCS)
- industrial hygienist (NJDHSS)

The responsibilities of each of these positions will be as follows:

Physician team leader: Will be a NJDHSS employee responsible for:

- coordinating all activities of the team when it is deployed to a hospital to investigate a high risk case-patient;
- setting priorities in the field investigation;
- communicating with the State Epidemiologist;
- leading the interview of the case-patient;
- coordinating investigation efforts with the law enforcement member of the PHRT.

Epidemiologist: Will be a LINCS agency employee responsible for:

- assisting with the case-patient investigation/interview;
- identifying potential contacts;
- assessing risk category of contacts;
- ensuring completion of all forms;
- coordinating data transmission from the field to the NJDHSS.

Public health nurse/vaccinator: Will be a LINCS agency employee responsible for:

- interfacing with the hospital Infection Control Professional (ICP) to identify potential hospital contacts;
- receiving vaccine, if needed, to vaccinate unvaccinated hospital personnel;
- vaccinating unvaccinated hospital personnel with direct contact to the case-patient if the case is confirmed.

Laboratory worker: Will be a NJDHSS employee responsible for:

- assisting with collecting, packaging and shipping of clinical specimens, according to CDC protocols;
- serving as direct liaison to CDC laboratory personnel.

Law enforcement agent: Will be a State Police/FBI agent responsible for:

- interviewing the case-patient, family members and witnesses;
- securing of evidence and ensuring chain of custody, as needed;
- communicating with his/her respective agency;
- interfacing with hospital security personnel;
- communicating with the NJDHSS Incident Commander;
- assuring delivery of specimens to the CDC.

Regional and LINCS Planners/Coordinators: Will be NJDHSS employees responsible for:

- assuring that the PHRT has all necessary supplies/materials to conduct its investigation;
- interacting with the Incident Commander on logistics issues;
- providing information to the Emergency Response Coordinator if the PHEOC is activated;
- interface with the other Regional and LINCS Planners/Coordinators.

Industrial hygienist: Will be a NJDHSS employee responsible for:

- ensuring that all members of the PHRT are familiar with and adhere to all isolation and bloodborne pathogens precautions;
- interface with the hospital safety supervisor to ensure that isolation rooms have appropriate negative pressure and ventilation;
- review all safety precautions with the hospital safety supervisor.

a. LINCS Agencies

Each of the 22 LINCS agencies will be creating their own component of the response team (epidemiologist, nurse/vaccinator, planner/coordinator) to “plug into” one of the five PHRTs should a response be required in their respective jurisdiction. Potential PHRT members will be identified by December 23rd and will be vaccinated when the Program is implemented.

There will be 5 regional and 1 additional MMRS-focused Smallpox Preparedness Vaccination Clinics.

The LINCS agencies in each region will be responsible for:

- identifying and coordinating regional staff who will implement the vaccination clinics;
- identifying a potential pool of eligible volunteers for vaccination to be members of the PHRTs or a vaccinator ;
- providing a list of potential members of their PHRT to the NJDHSS by December 23rd
- identifying a lead contact person and a backup for the Program at the clinic;
- providing pre-Program education about smallpox and the vaccine to all potential PHRT members;
- providing information of what would be expected of members of the team if a confirmed case of smallpox was identified;

- identifying regional staff who will attend training sessions offered by the CDC and/or NJDHSS;
- administering a medical questionnaire to screen out individuals with contraindications for smallpox vaccine in a pre-outbreak program;
- counseling women of child-bearing age of the potential measures to ensure that a pregnant woman not receive smallpox vaccine;
- ensuring that individuals at risk for HIV infection, but whose status is unknown, receive counseling about HIV testing, including testing sites;
- scheduling employees for the vaccination clinic;
- completing demographic and other information to populate the NJDHSS smallpox vaccination data management system (see Section II.I.) in advance of the scheduled clinics;
- establishing an agreement with a New Jersey general hospital that will establish a smallpox vaccination program for follow-up of their vaccinated employees by healthcare providers trained to assess any adverse events and provide vaccination site management;
- ensuring that vaccinated members of the PHRT return to the clinic one week after vaccination for assessment of vaccination “take”;
- maintaining a roster of all employees, their vaccination status and medical eligibility/exclusion for smallpox vaccination.

b. Local Health Departments (LHDs)

Local Health Departments are a critical component of countywide and regional public health preparedness and response, and an important contributor to the smallpox preparedness vaccination program and PHRT effort. Each LHD is responsible for:

- assisting LINCS agencies in developing a regional plan for the Program;
- identifying and arranging for LHD staff to serve as members of the vaccination team, including vaccinators and/or support personnel, at Program clinics based on needs;
- providing LHD staff/volunteers for conducting other related response activities and who will potentially be vaccinated as additional staff to meet the PHRTs needs and demands;
- ensuring that participating LHD staff attend education and training sessions about smallpox and the smallpox vaccine offered by the CDC, NJDHSS, and/or LINCS agencies;
- ensuring that vaccinated staff are evaluated for adverse reactions and vaccination take;
- establishing the LHD Health Officer as the lead contact person, as well as one (1) back-up contact person, for Program-related activities, and providing pertinent contact information to the NJDHSS and LINCS agency;
- ensuring an appropriate level of LHD participation in planning and response activities by formally entering into agreement with the LINCS agency by January 15th, 2003 using the NJDHSS-developed Interlocal Partnership Agreement for Public Health Preparedness and Response.

3. Identification of Hospital Health Care Response Teams (HHCRT)

Based on guidance from the CDC, the MEDPREP/Terrorism Advisory Committee, the Infectious Disease Society of New Jersey and the Advisory Committee on Immunization Practices (ACIP), the NJDHSS recommends that all 85 acute care hospitals have a core team of healthcare workers pre-identified who would care for a smallpox patient admitted to their facility. Healthcare workers assigned to this team should preferentially be permanent full time staff that have been vaccinated against smallpox at least once previously and be medically eligible for smallpox vaccination. These individuals would be then eligible for Stage 1 smallpox preparedness vaccination. Of importance, preparedness vaccination is voluntary. The suggested composition for a HHCRT is outlined below.

In general, the team should include sufficient inpatient staffing to take care of an adult or pediatric patient requiring intensive care for 7 days. In addition, there is a "vaccinator/occupational health" category. This includes nursing and employee health staff who would be involved in monitoring vaccinees, changing dressings, and potentially assuming a lead role in vaccination should smallpox occur. Also, the team should include a significant number of emergency department staff. During December (see timeline, Appendix A3), hospitals will begin the process for identifying potential healthcare workers within these groups who are eligible for vaccination and would consider participating in a smallpox preparedness vaccination program to become part of their HHCRT. The table shows the suggested composition of the HHCRT for each hospital.

Healthcare Worker Position	Number for Each Hospital*
ED Nurse	All eligible
ED Physician/PA/NP	All eligible
ED Technicians	All eligible
Intensive Care Unit staff	All eligible
Housekeeping/laundry staff	2 per shift
Security staff	2 per shift
Respiratory therapy staff	8
Infection control staff	4
Lab workers	2 per shift
Sub-specialists: Pulmonologist, Dermatologist, Ophthalmologist, ID Specialist, Pediatrician, Adult Intensivist, Nephrologist	2 of each
Engineering/HVAC	1 per shift
Vaccinators/Occupational Health	10
Radiology technicians	2 per shift
Dialysis nurse	2 per shift

* Where the number per shift is recommended, hospitals should determine how many should be vaccinated so that there is around-the-clock coverage.

Each hospital should identify no more than 150 eligible individuals who would be offered smallpox vaccine to allow them to become part of the HHCRT in their hospital.

The NJDHSS is working closely with the New Jersey Hospital Association (NJHA) to enhance hospital preparedness and response capabilities to a bioterrorism event such as a smallpox attack. The NJHA is also a member of the MEDPREP/Terrorism Advisory Committee. A memo was sent to the Chief Executive Officer of each hospital on December 4, outlining the elements of the Program and what was expected of each hospital. The NJHA will host two meetings, one on December 9 (for their Disaster Preparedness Committee) and one on December 18 (for all hospitals), to review the elements of the national and New Jersey Program and to distribute planning materials.

All of New Jersey's 85 acute care general hospitals will be responsible for:

- identifying and providing a list of potential members of their HHCRT to the NJDHSS by December 23rd. Approximately 100-150 personnel at each hospital can be expected to be members of the HHCRT and will be vaccinated at one of the 6 vaccination clinics (see Section II.C.4.);
- developing a specific Emergency Management Plan for smallpox (or develop an annex to an existing Emergency Management Plan), to include a protocol for the management of a "suspected" case-patient of smallpox occurring in the absence of an already recognized outbreak (See Section II.D.);
- identifying a lead contact person and a backup for the Program at their hospital;
- providing pre-Program education about smallpox and the vaccine to all potential HHCRT members as well as all hospital staff;
- providing information of what would be expected of members of the team if a confirmed case of smallpox was identified;
- identifying staff who will attend training sessions offered by the CDC and/or NJDHSS;
- administering a medical questionnaire to screen out individuals with contraindications for smallpox vaccine in a pre-outbreak program;
- counseling women of child-bearing age of the potential measures to ensure that a pregnant woman not receive smallpox vaccine;
- ensuring that individuals at risk for HIV infection, but whose status is unknown, receive counseling about HIV testing, including testing sites;
- scheduling employees for the vaccination clinics;
- completing demographic and other information to populate the NJDHSS smallpox vaccination data management system (see Section II.I.) in advance of the scheduled clinics;
- providing follow-up of their vaccinated employees to assess any adverse event and provide vaccination site management;
- maintaining a roster of all employees, their vaccination status and medical eligibility/exclusion for smallpox vaccination;
- identifying hospital physicians before the implementation phase who will be trained to assess and manage adverse events related to the vaccine among vaccinees and their contacts.

4. Selection of Clinic Sites and Vaccination Teams

The NJDHSS has identified 6 clinic sites for the Program, one in each of the 5 State regions (Appendix A5) and 1 in Newark, an MMRS city. A member of the NJDHSS staff will be assigned to be the Departmental Liaison to the individual identified as the Clinic Manager at each site. The Departmental

Liaison will be the initial contact person for all issues related to the planning and implementation of the vaccination clinics. The LINCS agencies in each of the regions will be responsible for identifying and selecting the members of the vaccination team at each site. Potential vaccination clinic personnel and their responsibilities are outlined in Section III.H.

Each clinic will need approximately 30 staff to conduct a 6-8 hour session that will vaccinate about 540-720 individuals (30 per vaccination station X 3 stations X 6-8 hours). The total number of clinic staff that will be needed is approximately $30 \times 6 = 180$.

The Smallpox Vaccination Program Coordinator and NJDHSS staff met with LINCS agencies health officers and their staff on December 5 to review the elements of the Program and what was expected of LINCS agencies and LHDs in the implementation of the Program. The Commissioner met with the NJ Association of Counties on December 6 to review the Program plans and NJDHSS expectations. LINCS agencies health officers have been asked to provide lists of vaccination clinic staff to the NJDHSS by December 23, at the latest. In addition, all 22 LINCS agencies have been asked to identify up to 5 potential vaccinators/response staff in their jurisdictions as potential vaccinees who could be immediately deployed to staff a broader vaccination effort in the event of a confirmed case of smallpox.

5. Scheduling

Vaccination clinic staff will be trained on all aspects of clinic operations during the first 2 weeks of January (pre-implementation phase). During Week 1 of the implementation phase of the Program, a clinic will be conducted at a NJDHSS site to vaccinate the PHRTs, clinic staff who will be vaccinated from all 6 sites, and the vaccinator/response staff from the LINCS agencies (Total of about 200-300 individuals). Prior to the vaccination session that day, NJDHSS Program staff will review the Program implementation plan, clinic operations, and address and resolve any last minute issues raised by clinic site staff.

Each vaccination clinic will conduct 2-4 clinic sessions to vaccinate HHCRTs during the Implementation Phase. The schedule is as follows:

Week 2: Mon, Tues: NorthEast region and MMRS site
Weds, Thurs: CentralWest and NorthWest regions
Fri: South and CentralEast regions

Repeat this schedule Weeks 3-5, depending on numbers of vaccinees per region.

Approximately 2700-3600 individuals will be vaccinated weekly. Clinic site staff will be responsible for coordinating scheduling with hospitals and other agencies.

6. Vaccine Logistics and Security

The Points of Contact for vaccine logistics and security are listed in Appendix A2.

The NJDHSS is requesting a total of 15,000 doses of vaccine. The vaccine should be shipped to:

(Redacted)

The NJDHSS has designated a primary and alternate facility as the smallpox vaccine storage center. This facility is centrally located along major transportation arteries in New Jersey. At this facility the vaccine will be received, stored, maintained at proper temperature (35° to 45° F) and repacked into specified quantities for distribution to clinic sites. Security personnel will staff these facilities 24 hours 7 days per week. The vaccine will be kept under lock and key in a room with surveillance videos and motion detectors. The refrigeration units will be secured within the designated facility and will only be accessible by NJDHSS distribution team members.

The Medical Director of the NJDHSS Vaccine Preventable Diseases Program is designated as the primary individual responsible for accepting and collaborating with the CDC National Pharmaceutical Stockpile for receipt of smallpox vaccine into New Jersey, and will head the NJDHSS distribution team.

Upon arrival of the smallpox vaccine inventory, the NJDHSS distribution team will oversee logistical requirements. The vials of vaccines will be tracked, inventoried and placed immediately into refrigeration between 35° and 45° F (a seven day recording thermometer will be used to continuously monitor temperature). The temp tale will be removed from the shipping containers and contact will be made with FedEx Priority Overnight (800) 463-3339 to schedule the pick up of the temp tale. Additionally, a refrigerated trailer (diesel fuel powered) will be placed on site to serve as a back up in the event of any electrical power outages. If electrical power is lost, the vials of vaccine will be transferred to the refrigerated trailers along with the recording thermometer. The DHSS Public Health and Environmental Laboratories, Sanitary Bacteriology program will provide and calibrate the recording thermometer through the use of a certified thermometer to ensure accuracy.

Vials of vaccine will not be available for use until the NPS program grants final authorization. (Release authorization once the temp tales from the shipment are received by NPS, downloaded and approved by an NPS staff pharmacist). In the event that any vials of vaccine are damaged, the distribution team will contact NPS immediately.

Each of the 6 clinic sites will have pre-designated individuals and transportation vehicles personnel who will be summoned to the primary distribution center to receive the allotment for their region. Transportation vehicles will be escorted at all times by State law enforcement personnel. Appropriate refrigeration for transportation and security during shipment to their region is the responsibility of clinic transporters. A signed roster for each of the 6 transporters documenting quantity of vaccine, lot numbers and expiration dates will be maintained (electronically if possible). Each clinic transporter in turn will be similarly responsible for maintenance of the documented distribution chain to the local clinics. A daily report to the primary distribution center by each of the clinic managers on vaccine inventory will be required.

Overall, inventory controls will be maintained on a daily basis via telephone, fax or electronic reporting from clinic sites managers to the primary distribution center. Maintenance of the "cold chain" of the vaccine will be a priority from receipt into the State until individual administration is completed.

Licensed pharmacists will be identified to assist in the proper handling and dispensing of the vaccine to minimize waste and possible cross contamination. They will also ensure that the vaccine is properly stored between vaccination sessions. County Offices of Emergency Management, with local law enforcement agencies, will coordinate security during storage.

Daily/Weekly summary reports will be prepared by the Medical Director of Vaccine Preventable Diseases for review by the NJ State Epidemiologist and transmittal to the CDC National Pharmaceutical Stockpile Headquarters to ensure full logistical communication.

7. Clinic Operations and Management

Clinic operations are described in section III.H. The clinics will be scaled to vaccinate the pre-selected and limited number of vaccinees identified in the Program. The NJDHSS and LINCS agencies will pre-screen potential members of the PHRTs, using the medical screening questionnaire that is part of the NJDHSS smallpox vaccination data management system. Hospitals will similarly pre-screen their employees who are potential members. In addition, at the time of the actual scheduled clinic, potential vaccinees will be screened again, using the same questionnaire. A record of all ineligible, pre-screened individuals will be maintained.

All scheduled clinics will be asked to complete the CDC-provided check lists to ensure the preparation and provision of adequate supplies, materials, etc., before the start of clinic operations, based on expected numbers of vaccinees at each clinic.

The timeline for the Program is contained in Appendix A3.

8. Vaccine Safety Monitoring, Reporting, Treatment and Patient Referral

The NJDHSS will follow the protocol for vaccine monitoring, reporting, treatment and referral as outlined in Annex 4 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (NSVP). The contact persons for this element of the Program are listed in Appendix A2.

The NJDHSS, through an MOA with the University of Medicine and Dentistry of New Jersey, will facilitate the training of designated physicians at each hospital to recognize and manage vaccine-related adverse events (AE). These physicians will be provided information on the elements and protocols of the Program, including how to interface with the NJDHSS Vaccine Safety Coordinator and the CDC's Smallpox Immunization Safety System (SISS).

The NJDHSS Vaccine Coordinator will ensure that the treating hospital physician completes a VAERS form for each vaccinee who sustains an adverse event. The form will be submitted to the NJDHSS for transmission to the CDC.

9. Training and Education

The elements of the training and education program that must be conducted as part of the overall Smallpox Vaccination Plan are contained in Section II.H. The specific Pre-implementation training and education activities are outlined in the Timeline in Appendix A3.

10. Data Management

The NJDHSS will be utilizing the NJ Smallpox Vaccination Data Management System described in Section II.I. This system will exchange data with the CDC's Pre-Event Vaccination System (PVS). The NJDHSS will provide unique identifiers, but not names of vaccinated individuals, to the CDC. The NJ Smallpox Vaccination Data Management System meets the minimum functional system requirements identified in Annex 6, and the data exchange requirements outlined in Annex 7 of the CDC's Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program.

The contact individuals are listed in Appendix A2.

Hospital-based physicians, responsible for and trained in treating vaccinees with adverse events, will complete a CDC/FDA Vaccine Adverse Event Reporting System (VAERS) forms, which will be e-mailed or faxed to the NJDHSS for transmission to the CDC.

11. Communications

The contact individuals for Communications issues are listed in Appendix A2.

Critical communication issues that will be addressed as the Program proceeds include the following:

Development of messages/information for 7 distinct audiences:

1. People receiving first wave of vaccines
2. People for whom vaccine is recommended but cannot get it
3. General public/media/
4. Families and co-workers of people receiving vaccine.
5. Elected Officials at all levels
6. Other State agencies
7. Health care workers and all first responders.

Program communications –

- Press release on New Jersey's plan – Held on December 9th
- Identify DHSS smallpox experts
- Develop fact sheets in addition to those from the CDC
- Web site – smallpox page
- Create NJ hotline
- Who will talk to media

During vaccination program

Updates on vaccination efforts

- how many people have been vaccinated
- how many adverse events
- how many people declining vaccination
- any differences in vaccination locations
- any differences among hospitals

Mechanism for updates – daily teleconference calls. Press release/updates.

Work with NJHA and hospital public affairs staff to develop consistent communications messages

Crisis Communications – first adverse event/serious illness in country.

- press conference/teleconference
- press release

Crisis Communications – first adverse event/serious illness in New Jersey.

- Work with hospital where incident occurs to craft message
- Hold press conference
- Develop informational material

12. Reporting

The NJDHSS will submit semi-weekly status reports (Annex 11 form) to the CDC NIP, Data Management Division.

13. Evaluation

The NJDHSS has developed and will implement a Program Evaluation Plan to assess the strengths, weaknesses, successes and gaps in the Plan. The evaluation will assess the planning, implementation and outcomes of the Program.

D) Management of a Suspected Smallpox Case-Patient in Medical Care Settings

This section focuses on the management of a patient of smallpox occurring in the absence of an already recognized outbreak, which may represent the index case-patient of a bioterrorism event. Once a patient is confirmed to have smallpox, further guidance on management of the patient as well as all contacts will be provided by the NJDHSS and the CDC.

The section is divided into the following topics:

1. Steps all hospitals should take to prepare

2. Initial evaluation of patients with acute, generalized vesicular or pustular rash
3. Risk Assessment
4. Consultation with NJDHSS
5. Management of patient with suspected smallpox
6. Management of emergency department or clinic area
7. General recommendations

1. Steps all hospitals should take to prepare

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

- a. Ensure that an effective emergency response infrastructure is in place.
 - i. Ensure the presence of an active, functional Emergency Operations Committee with an incident command/management system. Representatives should include staff from:
 - hospital, medical and nursing administration;
 - internal medicine, pediatrics, infectious disease, emergency medicine, and intensive care departments;
 - infection control;
 - microbiology;
 - pharmacy;
 - employee health;
 - public affairs;
 - operations;
 - Management Information Systems;
 - legal services;
 - mental health;
 - central supply;
 - engineering
 - laundry
 - food service
 - housekeeping
 - waste management
 - safety and security

- ii. Ensure the presence of pre-designated roles, lines of authority and notification chains 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 Office of Terrorism and Public Health Planning and Response in the NJDHSS is available for additional guidance and consultation.
 - iii. 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 B).
 - iv. A 24/7 communications network with back-up communication systems should be considered in the event that the routine network is disabled.
 - v. Each hospital should have at least one key staff member subscribing to the state Health Alert Network through the LINCS.
 - vi. 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 Emergency Management Plan). This plan should be developed in conjunction with the NJDHSS Smallpox Vaccination Plan. Tabletop exercises and drills to evaluate the hospital response to a suspect smallpox case-patient 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.D.2.). 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.
 - i. 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.
 - ii. 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 suspected case-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).
 - iii. 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 suspected or confirmed smallpox case-patient(s) that contains airborne infection isolation rooms meeting the criteria defined above in Section II.D.1.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.
 - i. All medical staff should receive education on the clinical presentation of smallpox and the differential diagnosis of vesicular and pustular rashes.
 - ii. 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 C) 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>.

- iii. All healthcare providers should know how to report any suspected smallpox case-patient to the NJDHSS immediately (24-hour contact numbers for NJDHSS are listed in Section II.D.4.).
- 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-patient. These teams will include staff listed in Section II.C.3. All personnel designated for smallpox-related healthcare activities must be vaccinated prior to providing care.
 - i. Until the federal government initiates its plans for Stage I preparedness 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.
 - ii. 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.

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

- a. No confirmed case
 - i. 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.
 - ii. 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.

- iii.* 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.
- iv.* 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.

b. During outbreak

- i.* If a patient with fever and rash illness presents to the emergency department, the appropriate staff should be immediately notified to expedite the patient's placement in an airborne infection isolation room (see Section II.D.1.d. for details on isolation precautions).
- ii.* A N-95 or N-100 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.
- iii.* 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 II.D.1.d., a N-95 or N-100 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).
- iv.* 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).
- v.* 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.
- vi.* Doors to these patients' rooms should be kept closed (self-closing doors are preferable).
- vii.* Suspected smallpox case-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 N-95 or N-100 mask should be placed

on the suspected 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.

- viii. Care should be used when handling the patient's linens, to minimize aerosolization.
- ix. All pre-existing hospital infectious disease transmission prevention protocols should be strictly adhered to at all times.

3. 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.

Classification of evaluated patients

a. High Risk (epi-linked):

- i. Patients epidemiologically linked to a confirmed case of smallpox who have a history of a febrile prodrome and on examination had a maculopapular rash with predominantly face/distal extremity distribution OR involvement of the palms and/or soles.
- ii. Patients epidemiologically linked to a confirmed case of smallpox who have a viral syndrome with fever $>101^{\circ}\text{F}$ and systemic symptoms (prostration, headache, backache, chills, vomiting, or abdominal pain) for <4 days but who do not have a generalized rash on examination.

b. High Risk (not epi-linked):

Patients not epidemiologically-linked with a severe prodromal illness consisting of temperature $>101^{\circ}\text{F}$, 1 to 4 days before rash onset and at least one of the following: prostration, headache, backache, chills, vomiting, or abdominal pain AND

- i. Generalized rash of acute onset that is either: comprised of deep, round, dermal lesions characteristic of smallpox; maculo-papular rash involving the palms and/or soles, OR distributed more densely on the face and distal extremities than the trunk, AND no other lab-confirmed diagnosis that would adequately explain the illness;
- ii. Prostration or shock, AND either maculo-papular rash, hemorrhagic rash, or rash with flat, velvety lesions that may be

confluent, AND no other lab-confirmed diagnosis that would adequately explain the illness.

c. Moderate Risk (not epi-linked):

Patients with no known contact, brief or uncertain contact to a smallpox case-patient with a prodromal illness consisting of temperature $>101^{\circ}\text{F}$ and at least one of the following: prostration, headache, backache, chills, vomiting, or abdominal pain, AND a generalized rash of acute onset that is atypical for smallpox (e.g., lesions on oral mucosa only, maculo-papular rash with localized distribution to face, or face and forearms, hemorrhagic/petechial rash), AND no other laboratory-confirmed diagnosis that would adequately explain the illness.

d. Low Risk (not epi-linked): Patients who are not epidemiologically linked to a smallpox case AND

- i. Lack a history of a febrile prodrome,
- ii. Do not have classic smallpox lesions, OR
- iii. Have a laboratory confirmed non-smallpox diagnosis compatible with their illness.

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.bt.cdc.gov/agent/smallpox/diagnosis/pdf/spox-poster-full.pdf>.

- a. For low risk patients (when chickenpox (varicella) or disseminated herpes zoster is the likely diagnosis based on history and physical examination):
 - i. It is NOT necessary to report the case-patient to the NJDHSS, unless a consultation is desired/needed from the MEDPREP/Terrorism Advisory Committee.
 - ii. The patient should be kept under airborne and contact isolation. Varicella laboratory testing will be conducted by a Laboratory Response Network laboratory to rule in varicella on low and moderate risk specimens through use of a Direct Fluorescent Antibody (DFA) assay.
 - iii. Chickenpox is the most likely condition to be confused with smallpox. In chickenpox, the following findings on history and physical examination are usually found:
 - No or mild prodrome;
 - Lesions are superficial vesicles (“dewdrops on a rose petal”);
 - Lesions appear in crops; on any one part of the body, there are lesions in different stages (papules, vesicles, pustules, crusted lesions);

- 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;
 - First lesions appear on the face or trunk;
 - Patients are rarely toxic or moribund;
 - Lesions progress through a rapid evolution (< 24 hours) from macules to papules to vesicles to crusted lesions;
 - Palms and soles are rarely involved;
 - Patient lacks reliable history of either varicella infection or vaccination;
 - 50-80% of patients recall a recent exposure to chickenpox or shingles within the 10-21 days before the onset of their rash.
- iv. Laboratory testing for varicella zoster virus antigen (performed at NJDHSS using rapid DFA or Polymerase Chain Reaction [PCR] tests) and/or other conditions should be considered as indicated clinically (Attachment E).
- b. For moderate risk patients
- i. The NJDHSS should be contacted immediately.
 - ii. An infectious disease or dermatology consult should be arranged immediately, through a combination of rapid methods including DFA for varicella antigen and PCR testing for varicella DNA as well as tissue culture growth utilizing a Chemicon method. If specialty consultation is not available immediately, 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
- i. The NJDHSS should be contacted immediately.
 - ii. An infectious disease or dermatology consult should be arranged immediately. If specialty consultation is not available immediately, or the diagnosis remains uncertain, the NJDHSS PHRT will assist in arranging for consultation from the MEDPREP/Terrorism Advisory Committee and rapid diagnostic testing to rule out varicella.
 - iii. 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 a Public Health Response Team (PHRT) to the hospital to initiate an epidemiologic investigation. All PHRT members must be vaccinated prior to initiating contact with high risk patients.

4. Consultation with NJDHSS

- a. The NJHDSS should be consulted immediately for any patient deemed to be at moderate or high risk for smallpox.
- b. To report a suspected case-patient of smallpox to the NJDHSS:
 - i. During normal business hours (Monday-Friday, 8am-5pm), call (609) 588-7500 and ask for the Bioterrorism Unit.
 - ii. During nights, weekends and holidays, contact the NJDHSS emergency number at 609-392-2020.
 - iii. The NJDHSS has rapid assessment teams available 24 hours a day, 7 days a week (MEDPREP/Terrorism Advisory Committee and PHRTs), to assist providers in evaluating suspect smallpox case-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-patient by telephone with the reporting physician. Additional consultation is available from MEDPREP/Terrorism Advisory Committee 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, a PHRT will work closely with the hospital staff to obtain appropriate clinical specimens for laboratory testing. NJDHSS will perform varicella testing only on samples from moderate risk smallpox case-patients. Currently, confirmatory tests for smallpox are only available at the CDC. Therefore, the NJDHSS and law enforcement agencies will assist with urgent transportation of specimens 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.

5. Management of suspected case-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 should be quarantined in an airborne infection isolation room (see section II.D.1.d.) with airborne and contact precautions.

- b. The NJDHSS recommends the following additional steps for managing suspected moderate or high risk case-patients and potential contacts of suspected moderate or high risk case-patients:

i. 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:

- the potential exposure and the likelihood of this being smallpox;
- 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);
- 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;
- 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-patient did have smallpox (i.e., that these persons could go home while awaiting laboratory test results and do not need to be quarantined).

ii. 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 or a designated quarantine facility, 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.

- iii. While a suspected smallpox case-patient is being transported from the emergency department or clinic to an in-patient room, the patient should wear a N-95 or N-100 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.
- iv. 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 properly fit-tested N-95 or N-100 mask; see section II.D.1.h. for more information).
 - Preferably, no staff without at least one prior vaccination for smallpox should be allowed in the patient's room.
 - Ensure that all staff and visitors entering the room are instructed in the meaning of contact and airborne precautions.
 - 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 case-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.
 - 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.
 - 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.

6. 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 II.D.1). 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 have been marked improvements in the environmental safeguards in hospitals, 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 suspected case-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. The NJDHSS requires 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:
 - i. if the patient could not be effectively isolated;
 - ii. if the patient had a significant cough, was not recognized immediately, and spent time in the waiting room where aerosolization may have occurred; and,
 - iii. 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 suspected case-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 suspected case-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 amphy), especially in any areas where a suspected case-patient has been coughing.

7. General recommendations

a. Activation of the hospital emergency management plan

- i. The decision whether to activate the hospital's emergency management plan should be made based on the individual circumstances of the event.
- ii. For a suspected 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 Management Plan should be activated, including the hospital's Emergency Operations Center.
- iii. 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

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

c. Communication issues

i. Internal:

- 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.

- 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.
- NOTE: In the event of a suspected case-patient who is being evaluated, it is strongly recommended that all clinical care staff be advised to avoid discussion of the suspected smallpox case-patient 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-patient who may quickly be determined NOT to have smallpox.

ii. External:

- It is essential that a coordinated communication strategy be developed between the hospital public affairs staff and the state response agencies.
- The NJDHSS, in coordination with State Police, the Governor's Office and the CDC 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. The LINCS/Health Alert Network will be used to distribute information broadly.

d. Security issues

- i. 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:
 - ability to minimize points of access and egress to the physical plant;

- a rapid identification process for hospital staff and local, state and federal emergency workers;
- an external vehicular “flow of traffic” prioritizing emergency vehicle access, supply delivery needs and law enforcement access;
- a method for routing persons other than patients to and from the facility;
- 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;
- assurance that appropriate protective equipment is provided to security staff, when indicated.

ii. Local and State Police are available for assistance, as needed.

E) Laboratory Testing

When a patient with moderate to high risk of smallpox, and no other etiology determined, has been identified, the NJDHSS will send a PHRT to the healthcare facility to evaluate the patient. The team will include personnel from the State Public Health and Environmental Laboratories (State Lab) who will provide direct on-site technical guidance to the clinical (hospital) or medical personnel handling the patient’s clinical specimens. Section II D outlines the protocol that hospitals should follow if they are evaluating a suspected smallpox case-patient.

After review by members of the PHRT, if smallpox is still suspected the NJDHSS will immediately report the patient to the LHD and LINCS agency, and one of the following:

- Poxvirus Section, Division of Viral and Rickettsial Diseases, NCID, CDC, Atlanta, GA 30333 (8am to 5pm, weekdays)
- Bioterrorism Preparedness and Response Program, NCID, CDC (8am to 5pm, weekdays)
- Emergency Preparedness and Response Branch, NCEH, CDC (24/7)

Approval must be obtained from the NJDHSS and the CDC prior to the shipment of smallpox case-patient clinical samples to the CDC. State Lab technical staff, which may include the Laboratory’s Quality Assurance Coordinator and Bioterrorism Coordinator, will direct the process of appropriate specimen collection, packaging and transport of the suspected smallpox specimen to the CDC for confirmation. These individuals are trained in the IATA Packaging and

Transporting Biological Specimens Guidelines, and will have, if necessary, the appropriate specimen packaging materials. They will also have CDC's "Guide D – Specimen Collection and Transport Guidelines" (<http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>) which must be adhered to as the full detailed protocol for handling a suspected smallpox specimen.

The State Lab's technical advisors will remain with the PHRT until the suspected smallpox specimens are collected, packaged and secured for transport to the CDC by the NJ State Police, the FBI or the appropriate designated law enforcement official.

CDC is in the process of developing national guidelines for handling surge capacity for smallpox specimens.

Note: The New Jersey State Lab does not have a testing protocol for smallpox since it is not a BSL 4 agent. The State Lab has the capability and testing protocols in place to identify similar viruses such as Varicella-Zoster (VZV).

F) Identification of Clinic Sites

To date, 400 sites have been identified for potential use throughout the state (Appendix F). Initially, 1-2 sites in each county will serve as the major vaccination sites in Stage II (if approved by the President) of New Jersey's Smallpox Vaccination Program. (see section III.F.) The NJDHSS provided the following guidelines to LINCS agencies for selecting mass prophylaxis/vaccination clinics:

- Size of structure should be large enough to house 8 work stations (about 72 people per shift). These work stations, in brief, would include: 1) health screening area; 2) educational/information area; 3) triage; 4) consent, vaccination, and photo; 5) post-counseling and aftercare instructions; 6) medical consultation as needed; 7) mental health counseling as needed. The floor space needed for this operation is approximately the size of a medium to large gymnasium, or alternate flow friendly floor arrangement (examples: community centers, hospital setting, sport/entertainment centers, colleges, conference centers, hotels, fire houses with reception areas, malls, etc.).
- Secure area within the building to store medication;
- Parking – easy access from main roads; traffic flow considerations; should include the potential of offsite parking with shuttle transportation to and from the facility;
- Bathrooms for staff and the public; the use of portable toilet facilities should be considered, if necessary;
- Work station setting to include tables, chairs, lighting, electrical, heat, AC, etc.; arrangements should be made to have these items brought in, as necessary;
- Inner city and rural community considerations to include how person without transportation can get to the site, via use of mass transit, etc;

- Considerations for the impaired/disabled and seniors may include: ramps, elevators, resources for the hearing impaired, etc. or other means to accommodate individuals with special needs;
- Building flow – preferable persons entering in the building from one area and exiting from another to allow for proper flow;
- Police security to maintain crowd control;
- Basic needs for staff including: break areas, food;
- Operating hours – consideration for 24/7 operation;
- Familiar sites – sites should be easy to find;
- Refrigeration (standard household size refrigerators or alternate means of refrigeration) to maintain vaccine at 35° to 45° F;
- Separate areas – for video/physical orientation, separated/partitioned room that can hold up to 50-75 people;
- Additional space is needed for the actual vaccination area;
- Site selection for smallpox should be larger facilities, at minimum, the size of a large gymnasium.

G) Collaboration with LHDs and MMRS cities

LINCS agencies, with Local Health Departments (LHDs) and Metropolitan Medical Response System cities in their counties, are key partners in New Jersey's Smallpox Vaccination Plan. LINCS agencies Health Officers have been tasked with preparing a smallpox vaccination clinic operations plan to include the following responsibilities (also see Section II.C.):

1. developing county-based smallpox vaccination plans;
2. identifying potential vaccination, isolation and quarantine sites;
3. managing and operating vaccination clinics;
4. receiving, handling and storing smallpox vaccine for county use;
5. identifying personnel needed to staff the vaccination clinics;
6. distributing public health messages through the LINCS;
7. assisting with case-patient tracing, contact investigation and monitoring;
8. assisting with active and enhanced surveillance activities;
9. training and education of all vaccination clinic personnel.

H) Training, Education and Communications

Training of public health care workers in advance of implementing a mass smallpox vaccination plan is important to ensure a coordinated and efficient vaccination effort. Public health care workers include all those expected to participate in the NJ smallpox response plan. These include workers in ambulatory and institutional healthcare facilities, the NJDHSS, LHDs, and professional organizations. Public health care workers will need to have general information on smallpox, smallpox vaccine and the smallpox response plan, in addition to information on their roles and the roles of others in responding to a smallpox outbreak. Public health care workers will be a high priority group to be vaccinated within 1-3 days of a confirmed case of smallpox anywhere in the country, to allow them to participate in the NJ smallpox response plan.

A health educator in the Communicable Disease Service, is responsible for overseeing all smallpox health education efforts in the NJDHSS. She will work closely with the 22 LINCS health educators funded through the CDC Cooperative Agreement, as well as Infection Control Professionals (ICPs) in healthcare facilities throughout the state. The health educators and ICPs will serve as the principal individuals to train others in their institutions and jurisdictions about the specifics of the smallpox response plan.

The health educator will also work closely with the NJDHSS distance learning coordinator and the Acting Director of the Division of Local Health and Emergency Response to coordinate distance learning programs conducted by the CDC and other organizations. The University of Medicine and Dentistry of New Jersey and Rutgers University, as well as professional organizations are the State's partners in educating healthcare professionals on smallpox-related issues. The health educator will be responsible, in conjunction with the Communicable Disease Service staff and the State Epidemiologist, for reviewing and distributing all educational smallpox-related training materials prepared by the CDC. Many of these materials can easily be distributed through LINCS, New Jersey's Health Alert Network.

The provision of accurate, timely and informative information to the public will be facilitated by the creation of Standard Operating Procedures (these SOPs) for communicating through the media. The NJDHSS Press Secretary, will be the key contact person in the NJDHSS in the event of a smallpox outbreak. The Press Secretary will coordinate all interactions/press releases/conferences with the press office at the CDC, Governor's Office, LINCS agencies, Local Health Departments, and local, state and federal elected representative.

Purpose:

To rapidly and effectively inform and educate the public, media, health care professionals, public health officials, and partner organizations about smallpox, smallpox vaccination, and outbreak management issues.

1. NJDHSS Personnel

a. Establishing Education/Communication Team

- Identify appropriate personnel to act as the NJDHSS Communications Team (Director of Communications, Risk Communication Specialist, Administrative Assistant, web specialist, health educator).
- Identify team leader.
- Director of Communications will act as liaison with the Governor's press office and NJDHSS Commissioner. Risk Communication Specialist is liaison with CDC, and local health departments.
- Determine the areas of focus for each team member (i.e., media contact, liaison to NJDHSS Office of Communications, public education, professional training, etc.)
- Determine division of labor among team members.

b. Risk Communication Training

- Identify key public health authorities (Commissioner, selected senior staff, Chief of Staff, etc.) to receive risk communication training in order to effectively deliver messages to the media and public
- Prepare list of appropriate responses to smallpox questions for various audiences according to risk communication principles
- Prepare templates for daily media briefings (i.e., number of new cases, fatalities, location of vaccine clinics, etc.)
- Design, conduct, and analyze training needs surveys, including a risk communication component. (Rutgers MOA)

c. Public Health Emergency Operations Center (PHEOC)

- Upon completion of the physical facility for the PHEOC, conduct an orientation for key team members regarding equipment, facility lay-out, capabilities, and anticipated operational procedures

d. Logistical Considerations

- Arrange with NJDHSS print shop priority duplication services for NJDHSS and/or CDC educational materials upon announcement of smallpox emergency to ensure rapid production
- Establish communications center within the new Public Health Emergency Operations Center (PHEOC)
- Identify pre-determined locations to serve as educational information "depots" throughout the state. Coordinate this activity with to ensure continuity with any existing emergency management plans.

e. Health Educator Training

- Train health educators to present community-based programs (Taking the Terror Out of Bioterrorism) on BT, including smallpox, to build a foundation of understanding of BT-related agents and diseases.

f. Vaccine Training and Education

- Identify individuals to be trained in the administration of the smallpox vaccine to pre-designated smallpox response teams statewide (pre-event). Identify additional individuals to be trained in the administration of smallpox vaccine to the general public (post-event).
- Identify trainings being offered by the CDC to prepare these individuals to administer vaccine.
- Develop training modules for smallpox vaccine administration and follow-up care. Include information on vaccination technique, prevention of secondary inoculation, wound care, adverse reactions, tracking procedures, etc.

g. General Considerations

- Maintain a comprehensive display binder of materials currently available and store in a readily accessible area of the PHEOC. Include any fact sheets, FAQs, clinical guidelines, diagnostic/treatment tools for clinicians, press releases, vaccine management information, etc.
- In conjunction with Rutgers University (recipient of an MOA to conduct bioterrorism training needs assessment) determine critical gaps in current trainings. Identify appropriate channels for delivery of the needed training.
- Establish an “emergency” area of the NJDHSS website for easier linkage to the smallpox information. This will include a highly visible button on the NJDHSS home page that will take individuals directly to the smallpox website.
- Identify the contact person in OITS who would be responsible for activating the “emergency” smallpox website upon direction to do so and for monitoring/reporting that updates are made accordingly.
- Survey local health departments to determine their access to the Internet during emergencies.
- Promote the availability of the smallpox website to NJDHSS personnel.
- Ensure that PHEOC has capacity to communicate with hearing impaired individuals.
- Identify methods to reach disabled populations with important smallpox information.
- Design, create, and manage web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)
- Improve and enhance New Jersey’s existing distance learning network by upgrading the capacity of the network to promote and deliver bioterrorism distance learning programming. (Rutgers MOA)

2. Public

a. General Considerations

- Establish procedures and personnel for review and approval of smallpox education materials

- Enhance NJDHSS website organization and educational materials for public audiences to ensure that smallpox information is prominently featured.
- Promote the availability of the smallpox website to the public.
- Establish statewide emergency distribution network for health education materials

b. Educational Presentations

- Health educators participating in the above training will present community-based programs on bioterrorism
- Develop, market, and conduct town meetings to educate and inform residents, businesses, and community organizations in hard to reach urban communities. At least three meetings will be coordinated in Newark, Camden, and Trenton. (UMDNJ MOA)
- Establish and manage an expert speaker's bureau to provide factual and timely information on bioterrorism to a wide range of audiences including community groups. (UMDNJ MOA)

c. Educational Material Development

- Create educational fact sheets and FAQs utilizing current CDC materials as a guideline
- Provide public information via website, media, written materials, on isolation and quarantine measures to increase understanding and compliance with any enforced actions.
- Develop materials for people and/or families caring for smallpox patients at home. Emphasize self-protection measures, handling and disposal of infectious materials, supportive care, etc.

3. Local Health Departments

a. Health Educator Training

- Conduct training needs assessment among 22 new county-level BT health educators
- Provide necessary training in risk communication/health education for the 22 new county-level BT health educators
- Train health educators to present community-based programs (Taking the Terror Out of Bioterrorism) on BT, including smallpox, to build a foundation of understanding of BT-related agents and diseases

b. Vaccine Training and Education

- Identify individuals to be trained in the administration of the smallpox vaccine to pre-designated smallpox response teams statewide (pre-event). Identify additional individuals to be trained in the administration of smallpox vaccine to the general public (post-event).
- Identify trainings being offered by the CDC to prepare these individuals to administer vaccine.
- Develop training modules for smallpox vaccine administration and follow-up care. Include information on vaccination technique, prevention of secondary inoculation, wound care, adverse reactions, tracking procedures, etc.

c. General Considerations

- Enhance NJDHSS website organization, education, and resource materials for public health authority audiences.
- Promote accessibility to LINCS to municipal level health departments.
- Establish a smallpox information and resource “depot” on NJDHSS website including information on diagnostics, patient management, infection control, protocols/policies/procedures, links to other relevant sites, etc.
- Promote the availability of the smallpox website to local health departments via LINCS.
- Make available up to five peer-reviewed articles (to be published in New Jersey Medicine) focusing on bioterrorism. Articles will be posted on NJDHSS website and distributed via the statewide Health Alert Network. (UMDNJ MOA)
- Participate in training needs surveys, including a risk communication component. (Rutgers MOA)
- Promote web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)
- Promote availability of a 40-hour bioterrorism training certificate program. (Rutgers MOA)
- Administer two Infectious Disease Summits for public health care professionals. These summits will provide the latest information on bioterrorism and related topics. (Rutgers MOA)

4. Health Care Professionals – Health Care Facilities (hospitals, LTC facilities, FQHCs, pre-hospital)

a. General Considerations

- Promote accessibility to LINCS
- Enhance NJDHSS website organization, education, and resource materials for health care audiences
- Establish a smallpox information and resource “depot” on NJDHSS website including information on diagnostics, patient management, infection control, protocols/policies/procedures, links to other relevant sites, etc.
- Promote the availability of the smallpox website to health care providers via NJHA, NJ Primary Care Association, and other agencies.
- Make available up to five peer-reviewed articles (to be published in New Jersey Medicine) focusing on bioterrorism. Articles will be posted on NJDHSS website and distributed via the statewide Health Alert Network. (UMDNJ MOA)
- Participate in training needs surveys, including a risk communication component. (Rutgers MOA)
- Promote web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)

- Administer two Infectious Disease Summits for public health care professionals. These summits will provide the latest information on bioterrorism and related topics. (Rutgers MOA)
- Through the NJHA, encourage and promote additional training on universal precautions as a means to control transmission of bioterrorism-related diseases.

b. Health Educator Training

- Train health educators to present community-based programs (Taking the Terror Out of Bioterrorism) on BT, including smallpox, to build a foundation of understanding of BT-related agents and diseases

c. Vaccine Training and Education

- Identify individuals to be trained in the administration of the smallpox vaccine to pre-designated smallpox response teams statewide (pre-event). Identify additional individuals to be trained in the administration of smallpox vaccine to the general public (post-event).
- Identify trainings being offered by the CDC to prepare these individuals to administer vaccine.
- Develop training modules for smallpox vaccine administration and follow-up care. Include information on vaccination technique, prevention of secondary inoculation, wound care, adverse reactions, tracking procedures, etc.

d. Diagnosis/Treatment

- Distribute laminated posters (Evaluating Patients for Smallpox – CDC) to all hospital EDs
- Expand OEM WMD training for hospital emergency staff to enhance smallpox diagnostic skills and outbreak management. Expansion will provide up to 30 additional one-day courses, reaching up to 1,000 participants.
- Develop a 4-hour certification, and 2-hour re-certification, EMS training program focusing on mass casualty management, emergency medical operations, epidemiology, disease transmission, surveillance and control. (UMDNJ MOA)
- Develop a train-the-trainer program to orient existing NJ EMT training network providers on course content and delivery. (UMDNJ MOA)
- Develop content for and conduct a Roving Symposia Series targeting physicians and infectious disease specialists. (UMDNJ MOA)

d. Isolation/Quarantine

- Develop self-administered training modules for distribution to all hospitals, LTC facilities, and FQHCs regarding protocol for outbreak control, isolation and/or quarantine procedures and implementation.
- Provide public information via website, media, written materials, on isolation and quarantine measures to increase understanding and compliance with any enforced actions.
- Promote availability of the smallpox website to health care providers via NJHA, the NJ Primary Care Association, and other agencies.

- Participate in training needs surveys, including a risk communication component. (Rutgers MOA)
- Promote web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)
- Through the NJHA, encourage and promote additional training on universal precautions as a means to control transmission of bioterrorism-related diseases.

5. Health Care Professionals – Private Office

a. General Considerations

- Promote accessibility to LINCS via professional medical organizations.
- Provide public information via website, media, written materials, on isolation and quarantine measures to increase understanding and compliance with any enforced actions.
- Develop content for and conduct a Roving Symposia Series targeting physicians and infectious disease specialists. (UMDNJ MOA)
- Make available up to five peer-reviewed articles (to be published in New Jersey Medicine) focusing on bioterrorism. Articles will be posted on NJDHSS website and distributed via the statewide Health Alert Network. (UMDNJ MOA)
- Participate in training needs surveys, including a risk communication component. (Rutgers MOA)
- Promote web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)
- Administer two Infectious Disease Summits for public health care professionals. These summits will provide the latest information on bioterrorism and related topics. (Rutgers MOA)
- Encourage and promote additional training on universal precautions as a means to control transmission of bioterrorism-related diseases.

b. Vaccine Training and Education

- Identify individuals to be trained in the administration of the smallpox vaccine to pre-designated smallpox response teams statewide (pre-event). Identify additional individuals to be trained in the administration of smallpox vaccine to the general public (post-event).
- Identify trainings being offered by the CDC to prepare these individuals to administer vaccine.
- Develop training modules for smallpox vaccine administration and follow-up care. Include information on vaccination technique, prevention of secondary inoculation, wound care, adverse reactions, tracking procedures, etc.

6. Ancillary Staff – Private Office

a. General Considerations

- Provide public information via website, media, written materials, on isolation and quarantine measures to increase understanding and compliance with any enforced actions.

- Participate in training needs surveys, including a risk communication component. (Rutgers MOA)
- Promote web-based searchable clearinghouse of emergency preparedness and bioterrorism programs. (Rutgers MOA)
- Encourage and promote additional training on universal precautions as a means to control transmission of bioterrorism-related diseases.

7. Mental Health Professionals

- Provide self-study training modules to mental health workers who have been identified to participate in smallpox vaccination clinics.

8. Funeral Directors

- Through the NJ Association of Funeral Directors, encourage and promote additional training on handling bodies as a means to control transmission of bioterrorism-related diseases.

I) Data Management

The NJDHSS Smallpox Vaccination Data Management System has two components: the New Jersey Immunization Information System (NJIIS, Immunization Registry) and the Becton, Dickinson and Company (BD) Bio-Terrorism Preparedness (BTP) Network. This system will be used for New Jersey's smallpox preparedness and response vaccination programs. Both preparedness and response vaccination programs require the collection and storage of information on vaccinees that must be kept confidential and secure. The Immunization Registry and the information in the registry are protected pursuant to the NJDHSS' role in public health oversight activities, disease investigation and surveillance. This is consistent with Federal HIPAA regulations. In addition, New Jersey's Domestic Security Preparedness Task Force will declare the Registry and data within the Registry confidential for security purposes.

1. NJIIS

The NJDHSS has developed and placed in production the NJIIS, a web-enabled immunization registry that includes a complete electronic immunization history for each patient, generates a recommended immunization schedule and provides reminder/recall notices and other reports for physicians, clinics and other approved medical providers. Most infants are initially enrolled in NJIIS through the electronic birth certificate (EBC) process. The NJDHSS Vital Statistics and Registration Program electronically forwards EBC data records to NJIIS. Immunization data entry by physicians and their staff is done via a user web-interactive interface and, in the future, it will be done through an electronic data load from Managed Care Organizations (MCO's), Medicaid and other external systems. The NJDHSS is in the process of developing a "smallpox module" that can be utilized for tracking smallpox vaccination of individuals.

2. BD BTP Network

The NJDHSS has entered into an agreement with the Becton, Dickinson and Company (BD) to pilot test and eventually utilize a Bio-Terrorism Preparedness (BTP) platform that provides a paperless tracking and management system that can assist federal, state and local agencies in collecting data that are required to implement a large scale smallpox vaccination program. The BTP Network utilizes scalable and flexible state-of-the-art client server wireless computer technology, which can be rapidly deployed to various immunization sites during an emergency situation. The system can be readily deployed in both permanent and temporary sites. The BTP architecture structure is composed of two elements: the clinic systems and a central data center. The Clinic System consists of a group of laptop PCs (including specialized Tablet PCs) that are linked via a wireless network to a local clinic server.

The Data Center is the centralized repository of all collected vaccination information from all clinics. It is also the core network infrastructure that supports all local mobile servers and tablets used in the clinics. It redundantly replicates all clinic information stored in the clinic local server and allows the data to be available remotely. In the event that the data center is "down", the clinic computer operations will continue independently. Once the data center is brought back "up", the local clinic information that was stored will be forwarded to the data center.

In the Clinic System, data is captured via a series of Tablet PCs linked to digital cameras and printers, which are networked wirelessly to a local clinic server. The computer workstations are highly configured tablet PCs on which clinicians directly enter patient demographics, medical history, vaccination history, vaccine lot numbers, and vaccination consent. The tablet PC allows for touch-screen as well as keyboard data entry. The laptop PC's are thin clients and the data storage is with the local server. Images of people vaccinated are transferred directly from the digital camera are directly transferred to the Tablet PC's through wireless connection. The clinics will be served with printers to support local print needs.

The digital camera is used to capture digital images of the patient's face for personal identification, the vaccine site for vaccine "take" confirmation, and any lesions or any cutaneous adverse effects. The camera image is transferred to a PC via USB and to the local server through wireless connection. Specialists may retrieve the images remotely and provide their opinions and recommendations to the remote sites.

The clinic client server technology infrastructure provides the key services to the clinic. The data center will be a secured operation with encryption-based protocols to help lesson the threat of hacking. Together they form a tight information technology operation that will benefit the public in case of an outbreak.

3. NJ Smallpox Vaccination System

The NJIIS will receive BTP immunization data daily from the BTP data center. The data will be loaded into the NJIIS platform which will allow for exporting of data to whatever database system the CDC develops to track the administration and side effects of the vaccine. The NJDHSS NJIIS application will be the vehicle to connect to the CDC-based systems. Although not part of the initial setup, the NJIIS application and NJ computer operations can be the disaster site backup for direct data entry in case the BTP data center is down for an extended time, even though this event is a remote possibility.

The NJDHSS smallpox data management system (the BD BTP platform and the NJIIS) meets the functional needs and data exchange requirements described in Version 1.0 of the CDC data management guidelines.

The NJDHSS Chief Information Officer will oversee, coordinate, and collaborate with state, local, CDC and BD data management information experts to facilitate full knowledge, understanding, acceptance and support of the data system, its implementation, and its evaluation.

III Outbreak Response Capacities

Sections A-F summarize surveillance, epidemiological investigation and contact tracing activities in the event of an outbreak of smallpox. These guidelines include recommendations outlined in CDC's "Guide A—Surveillance, Contact Tracing and Epidemiological Investigation Guidelines" available at <http://www.bt.cdc.gov/agent/smallpox/surveillance/index.asp>. Figure 1 is a flowchart of surveillance, epidemiological/clinical field investigation, laboratory tracking, contact tracing, data management and operations management components.

A) Surveillance

1. Objectives

- a. To improve case-patient finding
- b. To describe the spectrum of clinical signs and symptoms of possible smallpox illness
- c. To characterize the population at risk
- d. To determine the magnitude of the outbreak

2. Team members

- a. Team leader—epidemiologist who coordinates surveillance activities; acts as liaison to LINCS Surveillance and Epidemiology Coordinators, NJDHSS Communications Office, and CDC
- b. Local Health Officers and LINCS Surveillance and Epidemiology Coordinators (SECs)—facilitate surveillance activities in local region, assist in educating community health care providers and hospitals on surveillance activities
- c. Clinical triage personnel—clinicians (RN, MD) who review and triage reports of suspect smallpox illnesses
- d. Health educator(s)—assist in developing surveillance information

3. Required resources

- a. A centralized place for initial reporting of a potential case-patient should be established at the NJDHSS and communicated to potential reporting sources.
- b. NJDHSS has established potential redundant mechanisms for communicating to reporting sources. These may include:

- i. Broadcast fax
 - ii. Listserv
 - iii. Epi-X
 - iv. Health Alert Network (LINCS)
 - v. Telephone notification.
- c. Mechanisms for receiving reports from reporting sources include:
- i. Secured fax
 - ii. Secured web-based reporting
 - iii. Database transmission via modem to secure server
 - iv. Direct telephone reporting
 - v. Secured e-mail transmission.

4. Responsibilities

- a. Establish reporting sources—see Appendix D, “Active hospital-based and enhanced passive surveillance” for guidelines on establishing surveillance systems among hospitals and health care providers.
- b. Provide training to reporting sources—general guidelines
 - i. Train health care community and local health departments in case-patient ascertainment, reporting, treatment and management;
 - ii. Distribution of clinical case-patient definitions and case-patient classifications for suspected, probable and confirmed case-patients of smallpox to public health personnel involved in surveillance, and hospitals, clinics, and individual practitioners involved in patient care;
 - iii. Distribution of reporting forms (CDC-prepared, Form 1);
 - iv. Distribution of above materials to the NJDHSS Public Health Emergency Operations Center (PHEOC), since PHEOC might receive phone inquiries regarding reporting;
 - v. Prepare and distribute health alerts to keep medical community up-to-date on evolving situation during outbreak emergency;
 - vi. Prepare disease-specific content information specific to the public as well as to the medical community.
- c. Receive reports of suspect illnesses—mechanisms of reporting listed above in sections III.A.3.b. and III.A.3.c.
- d. Triage suspect case-patients—review and refer reports of probable and suspected case-patients to the epidemiological/clinical field investigation team team for follow-up. N.B. Reporting sources will not be required to report low risk patients, but in the event that low-risk patients are referred to the NJDHSS, the surveillance team will filter out these reports from being referred to the epidemiological/clinical field investigation team. See

<http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-a.doc> and Appendix E for the CDC case classification.

- e. Communicate with reporting sources
 - i. Surveillance staff should actively contact major reporting sources (hospitals, large clinics, or other designated smallpox facilities) at least once a day to encourage timely reporting.
 - ii. Surveillance staff should provide periodic summary reports of surveillance data to reporting sources.
- f. Communicate with neighboring states and CDC—surveillance staff should share surveillance data regularly with neighboring states and CDC

B) Epidemiological/Clinical Field Investigations

1. Objectives

- a. To establish the diagnosis and case-patient classification of suspect case-patients.
- b. To perform initial identification of contacts of case-patients for tracing, vaccination and surveillance activities.
- c. To impose isolation of confirmed, probable and suspected case-patients.
- d. To identify the most likely source of initial exposure for the case-patient
- e. To monitor the clinical course and outcome of case-patients.
- f. To monitor the epidemiology of the outbreak for analysis and communications purposes.

2. Team members: All personnel designated for smallpox case-patient interviews or clinical investigation activities must be vaccinated prior to initiating their first face-to-face interview with a suspect, probable, or confirmed smallpox case-patient.

- a. Team leader—clinician or epidemiologist who coordinates epidemiological/clinical field investigations and facilitates information transfer to surveillance and contact tracing teams
- b. Investigators—clinicians who collect data on suspected case-patients, perform initial identification of contacts of case-patients, conduct follow-up on suspected and confirmed case-patient, establish case-patient classification (confirmed, probable, suspected, or not a case-patient) and recommend public health control measures.

3. Responsibilities

- a. Collect initial and follow-up data on suspected case-patients—please refer to the CDC Smallpox web site, “CDC Forms” section for specified forms (<http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>).

Finalized forms will be available at a later time; however, anticipate data collection to include the following:

- i. “Core data” for initial case-patient reporting at the time of first notification of the case-patient-- minimal information, to be reported immediately following diagnosis for each suspected/probable/confirmed smallpox case-patient, including:
 - First and last name
 - Social Security number
 - Date of birth
 - Sex
 - Race and ethnicity
 - Occupation
 - Home address
 - Home telephone number
 - Pre-existing medical conditions that are risk factors for severe disease and outcome (HIV status, pregnancy, other)
 - Date of fever onset and symptoms of prodrome
 - Date of rash onset and initial case-patient presentation
 - Vaccination status: past and approximate age; current: date
 - Date of medical evaluation
 - Place of medical evaluation
 - Date, time and place of case-patient isolation
 - Known exposure to suspected/probable/confirmed case-patient
 - Initial case-patient classification (confirmed, probable, or suspected)
 - Case-patient status (alive, dead) on date of reporting.

- ii. Case- patient’s clinical data, to follow outbreak course temporally, geographically and by person characteristics in sufficient detail to assess vaccine failure, unusual disease presentations, disease morbidity and mortality and risk for adverse outcome to assist in targeting/refining vaccination efforts, including:
 - Updated clinical description of smallpox at the height of the illness
 - Duration of rash and fever
 - Complications and sequelae
 - Outcome: survival or death
 - Date of death, autopsy results
 - Results of laboratory testing for smallpox
 - Final disposition (discharged to home, deceased, lost to follow-up, etc.)
 - Final case-patient classification, including “not smallpox” (see Appendix II, “Case-patient classification of suspect smallpox case-patients”)

- b. Establish final case-patient classification on suspect illnesses, based on clinical and laboratory case-patient definitions and case-patient classification criteria.
- c. Perform initial identification of contacts
 - i. Identification of persons who have had close contact with the smallpox case-patient since date of onset of fever. Since smallpox is a contagious disease, once a case-patient is confirmed, the highest priorities for public health officials are to reduce risk of ongoing transmission by immediately identifying and vaccinating close contacts of case-patients and isolating the case-patients.
 - ii. Identified contacts should be referred to the contact tracing team (see section III.D.)
- d. Identify the most likely source of initial exposure (hopefully within 24 hours of the first confirmation of smallpox). This may require extensive trace-back capabilities if the initial recognition and confirmation of smallpox occurred later than the first generation of disease in the outbreak.
- e. Identify and estimate the population-at-risk
 - i. To the extent possible, the population-at-risk should be identified. Exposure could be due to an infected person's presence at a specified location; use of a specified mode of transportation; or presence at a location of suspected smallpox virus release.
 - ii. These persons should be placed under surveillance; public health action to consider would include offering smallpox vaccine to the exposed population and to their household contacts.
 - iii. These persons at risk should be referred to the contact tracing team for additional follow-up (see section III.D.).
- f. Identify any unexpected epidemiological features of the outbreak (e.g., unusual presentation, morbidity, mortality, incubation period, transmission, affected population).
- g. Evaluate the characteristics and extent of the outbreak to develop the most effective containment strategies.

C) Laboratory Test Results Tracking

1. Objectives
 - a. To coordinate tracking of laboratory specimens.
 - b. To facilitate specimen packaging and transportation to CDC laboratories.
 - c. To follow-up on test results.

2. Team members: (all personnel designated for interacting with a suspected case-patient must be vaccinated prior to initiating contact).
 - a. SECs and/or public health representatives— assist the clinical/epidemiological field investigation team in appropriately obtaining clinical specimens.
 - b. State Lab staff representative—act as liaison with laboratory tracking team.
3. Responsibilities
 - a. Become familiarized with CDC’s “Guide D: Specimen Collection and Transport Guidelines” available at <http://www.bt.cdc.gov/agent/smallpox/lab-testing/index.asp>.
 - b. Develop protocol in conjunction with the NJ State Lab and CDC regarding packaging/transportation of specimens (including requisition forms to accompany specimens) and safety issues .
 - c. Coordinate and follow up on transportation of specimens to CDC laboratories.
 - d. Track status of specimens sent for testing, including anticipated delivery date/time and date/time of specimen arrival to laboratories.
 - e. Follow-up on status of testing results with CDC.
 - f. Update test results in NJDHSS database.

D) Tracing, Vaccination and Monitoring of Contacts

1. Objectives
 - a. To coordinate activities related to contacts of smallpox case-patients.
 - b. To facilitate vaccination or contacts.
 - c. To monitor health status of contacts.
2. Team members: (all personnel designated for smallpox contact-tracing activities must be vaccinated prior to initiating contact tracing activities).
 - a. Team leader—epidemiologist who coordinates contact tracing activities between NJDHSS, local health departments and SECs.
 - b. Contact tracing personnel—epidemiologists who identify and triage contacts; identify and locate contacts, monitor and follow-up on contacts, for counties that do not have SECs.
 - c. SECs—identify and locate contacts, monitor and follow-up on contacts; report back to contact tracing team leader and data management team at NJDHSS headquarters.
 - d. Contact vaccination coordinator—epidemiologist or public health representative who facilitates vaccination activities for contacts.

3. Responsibilities

- a. Utilize CDC contact identification module—please refer to “Forms” section for specified forms. N.B. All activities will utilize CDC-developed forms. Forms noted in this plan reflect draft versions (Version 3.0, see (<http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>)
 - i. The contact identification module (Forms 3, 3A, 3B, 3C and 3D) must be used with Form 5A. This separate module has been developed to enumerate and identify the risk status of all persons (names and contact numbers) who had face-to-face contact with the case-patient and locations that case-patient visited (where names of persons may not be known, e.g., a doctor’s office) since date of onset of fever. Although smallpox is considered most infectious during the first 7-10 days of the exanthem (rash), some patients may not notice the first exanthemous lesions. In addition, an enanthem also occurs causing ulcerated lesions in oropharynx; the patient may be highly infectious during this time period, which may immediately precede or coincide with onset of the exanthem (rash).
 - ii. Contact identification is the most urgent task when investigating smallpox case-patients since vaccination of close contacts as soon as possible following exposure but preferably within 3-4 days may prevent or modify disease. This was the successful strategy used for the global eradication of smallpox.
- b. Trace contacts—see <http://www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-a.doc> , Figure 3 (Appendix E) for the CDC’s contact tracing algorithm.
 - i. Find locating or contact information for each contact of a smallpox case-patient. Use work and school contact numbers, telephone directories, voting lists, neighborhood interviews, site visits, “hangouts” etc., to trace contacts when contact information is unknown or incomplete.
 - ii. If contacts cannot be found through these mechanisms, other sources for notification of potential contacts, such as media announcements, may have to be considered.
 - iii. Interview each contact to confirm contact with the suspected, probable, or confirmed smallpox case-patient, the presence or absence of symptoms in the contact (fever and/or rash) and to identify additional contacts that may not have been listed by the case-patient. Record this information on Form 2D.

- iv. Make arrangements for immediate vaccination of the contact and his/her household contacts, and if this is not conducted at the household by the contact tracer, provide a form that documents names and identifying information of all persons in the household who are referred for vaccination on Form 2D.
 - v. If the contact is symptomatic with fever or rash, the contact should be immediately transported to a designated evaluation site for medical evaluation to rule out smallpox. The patient should be referred to the clinical/epidemiological field investigation team (see section III.B., Epidemiological/Clinical Field Investigations). The patient should be interviewed as a suspected case-patient using the Smallpox Case-Patient Investigation Form and his/her contacts should be identified, interviewed, and vaccinated while the evaluation for smallpox is being undertaken.
 - vi. If the contacts do not have fever or rash, place the contact under surveillance, so that if they develop fever or rash they are immediately isolated and evaluated and do not expose other persons (see below).
 - vii. Identify household contacts (including regular household visitors and persons who work in the home) of the contact of the smallpox case-patient. Record their names, ages, relationship to the case-patient, and other information on Form 2D (secondary contact person worksheet).
 - viii. If household members cannot be vaccinated due to contraindications, they should avoid contact with the contact until the end of the contact's quarantine period, or until all vaccinated persons in the household are noninfectious for vaccinia virus (after the scab at the vaccine site has separated, 14 to 21 days after vaccination).
 - ix. Notify the surveillance team member responsible for reporting out-of-state contacts to the CDC and/or state health departments if it is learned that a contact has left New Jersey.
 - x. For coordination of contact tracing with vaccination, personnel should make a list of names, date of birth and Social Security numbers (or drivers license numbers) of contact and household members who will be referred for vaccination and provide this list to the fixed vaccination clinic site where the contacts/household members will be sent.
- c. Perform surveillance and monitoring of health status and vaccine "take" of contacts
- i. Contacts who do not have fever or rash at the time of interview must remain under active surveillance for 18 days after their last contact with the smallpox case-patient, or 14 days following successful vaccination.

The contact tracer will establish methods for daily reporting with the contact including methods for daily tracking if the contact does not have access to a home telephone.

1. Contacts must monitor and record their temperature in the morning and early evening each day. (Forms 2E and 2F)
 2. Each day before 8 p.m. they must call or be called by contact tracing team members to report their daily temperatures, health status and any severe adverse vaccine reaction in themselves or household members following vaccination.
 3. During the surveillance period they may continue their usual daily activities, (e.g. going to work or attending school), as long as no temperatures $\geq 101^{\circ}\text{F}$ (38°C) are measured. They should not, however, travel away from their city of residence.
 4. If they have a temperature $\geq 101^{\circ}\text{F}$ (38°C), they must remain in their own home. If they have two successive temperature readings of $\geq 101^{\circ}\text{F}$, they must contact health department personnel immediately, and remain at home, having contact only with vaccinated household members, until further evaluated by health department personnel.
 5. On day 7 following vaccination, depending on local arrangements and staff availability, contacts must visit or report to the health department the status of their vaccine site (does the area of their arm where they were vaccinated look like the picture they were given when they were vaccinated?) and the vaccine sites of their household members.
- ii. Contact tracing staff assigned to monitor the health status of contacts will answer questions of contacts who are under surveillance, record daily temperature readings and health status, record information on vaccine “take” and severe adverse vaccine reactions among contacts and their household members, and refer for in-home follow-up any contacts who fail to report in and cannot be contacted by telephone. N.B.: If resources permit, contact tracing staff will visit the household on day 7 following vaccination to record vaccine “take”.
 - iii. These personnel will maintain Form 11 for each contact. Record information on the date and type of follow up (in person or by telephone), recorded temperature, other symptoms of illness, and on day 7 after vaccination, vaccine site reaction.
 - iv. These personnel will obtain information on the vaccine “take” of other persons in the household and record it on the same form.

- v. In addition, a daily tracking form should be used to record on a master sheet summary information from all contacts monitored. (Forms 2E and 2F).
- vi. If personnel are limited, NJDHSS and federal health authorities may institute a passive system of monitoring the health status of contacts. This change should only be implemented by the State Epidemiologist after consultation with the Commissioner of Health and Senior Services, the ECC, and Federal health authorities and only if limited personnel resources and the size of the outbreak do not permit effective institution of the standard procedure. In this approach, contacts under monitoring are only required to call health department personnel if:
 - They have 2 consecutive temperatures $\geq 101^{\circ}$ F (38° C) or develop a rash;
 - They have no reaction at the vaccine site on day 7;
 - They have a severe adverse vaccine reaction; or
 - They have completed the period of monitoring (18 days from last contact with the case-patient or 14 days following successful vaccination) and are reporting in to be officially released from monitoring.

E) Management of Surveillance/Epidemiology Data

1. Objectives

- a. To manage data collected from all surveillance, epidemiological/clinical investigation, and contact tracing activities.
- b. To maintain all elements of the database.

2. Team members

- a. Data analysts—maintain and manage data collected from surveillance, epidemiological/clinical field investigation, contact tracing, and laboratory tracking teams.
- b. Data entry clerks—enter collected data from surveillance, epidemiological/clinical field investigation, contact tracing, and laboratory tracking teams.

3. Required resources

- a. A computer system for data entry and analysis of all the collected case-patient investigation and surveillance information will be provided by federal health authorities and must be managed and maintained for all confirmed, probable, and suspected case-patients.
- b. The database should possess relational capabilities to link data from surveillance, epidemiological/clinical field investigation, laboratory tracking and contact tracing activities.

- c. The database should have secure access for authorized staff members from the surveillance, epidemiological/clinical field investigation, laboratory tracking and contact tracing teams.
- d. Hardware should include laptops to facilitate data collection in the field, personal computers at NJDHSS headquarters, and printers.

4. Responsibilities

- a. Maintain database, as developed by CDC.
- b. Create relationships within database to link data collected from surveillance, epidemiological/clinical field investigation, contact tracing, and laboratory tracking teams.
- c. Develop and generate summary reports
 - i. Surveillance team
 - 1. Summary data on suspect case-patient reports by hospital and county
 - 2. Summary data on overall case-patient reports statewide
 - ii. Epidemiological/clinical field investigation team
 - 1. Linelist of suspect case-patients by status, to facilitate follow-up and tracking
 - 2. Epidemic curves
 - iii. Laboratory: linelist of status of case-patient-patients' laboratory results to facilitate follow-up and tracking
 - iv. Contact tracing team
 - 1. Provide a daily master report to the contact tracing team which includes:
 - a. Contacts found
 - i. Symptoms of contacts
 - ii. Disposition of found contacts
 - 1. Interviewed and vaccinated/referred for vaccination
 - 2. Interviewed and referred for illness evaluation
 - 3. Isolated if fever or rash develops
 - iii. Number of contacts' household members
 - iv. Number of contacts' household members vaccinated/referred for vaccination
 - b. Contacts not found
 - i. Whereabouts known but unable to contact for interview
 - ii. Whereabouts unknown.
- d. Clean and maintain data

- i. Identify and reconcile duplicate records in database, in concert with surveillance, epidemiological/clinical field investigation, laboratory tracking and contact tracing teams.
 - ii. Maintain database links between suspect case-patient and contact linelists (i.e., if a contact becomes a case-patient, facilitate data links between the epidemiological/clinical field investigation and contact tracing teams).
 - iii. Organize and maintain hard copies of all data collected by surveillance, epidemiological/clinical field investigation, laboratory tracking and contact tracing teams.
- e. Plan redundant backup systems for database.

F) Operations Management

1. Objective: To provide ancillary supportive services to surveillance, epidemiological/clinical field investigation, laboratory tracking, data management, and contact tracing teams.
2. Team members

Operations administrator(s)—clerical staff who ensure that surveillance, epidemiological/clinical field investigation, contact tracing, data management and laboratory tracking teams have the equipment and supplies needed to conduct their activities; provide ancillary clerical support.
3. Responsibilities
 - a. Provide ancillary clerical support, including:
 - i. Identify and provide office supplies needed for all surveillance, epidemiological/clinical field investigation, laboratory tracking, and contact tracing activities
 - ii. Record/note keeping for all meetings.
 - b. Collate and disseminate written daily action plans and data summaries from surveillance, epidemiological/clinical field investigation, laboratory tracking, and contact tracing teams.
 - c. Assemble lists of staff in surveillance, epidemiological/clinical field investigation, contact tracing, laboratory tracking and data management teams; lists should include names, roles, and contact information.
 - d. Assemble contact lists (include fax, beeper, cellular, work and home phone numbers; e-mail and land addresses) of key partners in public health investigations, including, but not limited to:
 - i. CDC New Jersey Investigation Team

- ii. Local health officers
- iii. SECs
- iv. NJHA
- v. Neighboring state/city health departments (e.g., DE, PA, NYS, NYC, Philadelphia).

G) Isolation and Quarantine Protocol

The CDC is preparing Guidelines for Quarantine and Isolation. New Jersey will submit its quarantine and isolation plan once the CDC guidelines have been published, and the New Jersey Attorney General completes an assessment of the statutory authority for isolation and quarantine powers.

H) Vaccination Clinic Operations and Management

Adapted from Annex 3, CDC Smallpox Response Plan and Guidelines
<http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.doc>

1. Model Staffing Estimates

The following section describes a model of a vaccination program that addresses the different activities needed for the administration of smallpox vaccine as well as an example of personnel estimates for clinic staffing. The output goal of this example clinic model would be the administration of vaccine to 1 million persons over 10 days. The model could be expanded or contracted, as needed, to address changes in vaccination administration goals for different population areas and different overall vaccination policies. The example staffing estimates were arrived at by: 1) review of previous large-scale-clinic models and publications, 2) considerations of requirements for administering a vaccine, and 3) computer modeling for clinic flow and output estimates with different example staff numbers. Parameters of low and high completion times for specific activities within the clinic were estimated within the model. The time requirement for these activities may differ depending upon the overall demands placed on the vaccine clinic delivery system and could require adjustment of staffing estimates. The computer modeling of the example clinic to determine staffing needs utilized the following parameters:

- 97% of people presenting to clinic will be processed through the normal clinic flow
 - 1% will have some illness that will require evaluation before processing through clinic;
 - 2% will be identified as a contact or possible contact to smallpox and will be processed through the separate “Contact Evaluation” unit .
- 20% of people coming through the clinic will require medical counseling in addition to the orientation video
 - Medical counseling/questions will require 5 to 15 minutes (some individuals will require >15 minutes and others will require <5 minutes);
 - Physician would be available to handle more difficult medical screening to keep clinic flowing;

- 50% of persons getting additional medical counseling (i.e., the 20% above) will be vaccinated, and 50% will defer vaccination because of contraindications or other reasons;
- Distributing informational packets and providing initial instructions would take between 30 seconds and 2 minutes;
- Video orientations will be done approximately every 30 minutes in 4 orientation rooms that hold 75 people per room;
- It will take 2 to 3 minutes for individuals to provide the medical history;
- Vaccination and completing vaccination cards would require between 0.5 and 2 minutes.

The numbers shown in the table below are examples of the human resources needed with the above clinic assumptions and configuration. Alterations in the assumptions regarding clinic activity time estimates and staffing requirements can be explored to determine ways to further maximize clinic output and human resource utilization. Although staff numbers may vary depending upon the assumptions and clinic output requirements, the general tasks that must be addressed within the clinic (patient education, medical history screening, medical counseling, vaccination, etc.) would not change.

CDC plans to make available to state and local public health officials a software program ("Maxi-Vac") that will allow officials to further refine human resources allocation needs (e.g., physicians, nurses, and other staff) in such a manner that will maximize patient flow-through for target vaccination goals. Conversely, this software program may also be used to determine maximum vaccination output that may be achieved with different human resource estimates.

The example model as outlined assumes that clinics can be operating at near full efficiency to meet vaccination goals once the decision to offer voluntary vaccination is made.

Overall Vaccination Administration Goal = 1 million persons over 10 days
(Approximately 100,000 per day)

	DESCRIPTION	COMMENTS
Vaccination Clinics (VC)	22 clinic sites One clinic per LINCS site	More sites could be added to accommodate larger population bases
Vaccination Stations (VS)	<ul style="list-style-type: none"> ▪ 8 VS per shift ▪ 1 vaccinator per station ▪ 1 vaccine assistant per station ▪ 16 vaccinators/vaccine assistants per shift 	Vaccinators will require frequent breaks to minimize arm/hand fatigue
Hours of Operation	At a minimum 16 hours/day	Consider expanding hours for higher daily output or to address overflow
Vaccination Delivery	<ul style="list-style-type: none"> ▪ 45 vaccinations per VS/ hour ▪ 360 vaccinated/hr/VC ▪ 5760 per day/VC ▪ 126,720 per day total with 22 VC ▪ 1,267,200 vaccinated in 10 days 	30 to 60 vaccinations per VS/hour allows for variations caused by vaccinator rotation, re-supply requirements, completing vaccination card, and other considerations

Breakdown of Clinic Personnel per Vaccination Clinic

Position	Number per 8-h Shift	Number per 16-h Day	Experience
Health Screeners	2	4	Registered Nurses, Nurse Practitioners, PA's
Registrars	6	12	Clerical
Run Education Video	4	8	Registered Nurses, Nurse Practitioners, PA's
Triage	6	12	Registered Nurses, Nurse Practitioners, PA's
Medical Counselors	2	4	Physicians to evaluate ill or more difficult medical history screening
Vaccinators/Vaccine Assistants	8 vaccinators, 8 vaccine assistants	32	Vaccinators must be Registered Nurses, Nurse Practitioners, or PA's. Vaccine Assistants are non-medical.
7 Day Follow-Up	2 licensed, 2 non-medical	8	Registered Nurses, Nurse Practitioners, PA's; non-medical for photo
Mental Health Counselor	1	2	MSW, MHA, PhD
Clinic Manager	2	4	Existing Vaccine Programs Personnel
Security	20	40	Non-public health resource
Special Needs Translator	At least one per major language and hearing –impaired per shift	Unknown	Bilingual Health Educator Will work with NJ Dept of Human Services available through NJ FamilyCare
Clinic Flow Monitor	4	8	Non-medical volunteers
Post-counseling/aftercare	2	4	RN, NP, PA
EMT; EMT-P (Paramedic)	2 EMT; 1 EMT-P	6	Certified EMT and EMT-P
IT Support	2	4	Non-medical technician
Total Personnel	72	144	

- HEALTH SCREENERS [RN, NP, PA]- 2 x 2 shifts = 4 total- Screeners will evaluate individuals entering the clinic to screen for sick individuals who require transport to a healthcare facility.
- REGISTRARS [clerical]- 6 x 2 shifts = 12 total- Registrars to enter demographic information to register each individual who enters the clinic area.
- TRIAGE [RN, NP, PA] – 6 x 2 shifts = 12 total – Triage personnel to direct ill patients to other evaluation facilities and direct identified contacts, persons with contact with a case-patient of rash illness in last 3 weeks, and their household family members to high-priority evaluation location within clinic (1 minute/person). Triage should also utilize signs explaining where people should go if they are ill or are identified contacts. [Note: Ill persons should be triaged out and evaluated at designated offsite parking sites before boarding bus for transportation to clinic if offsite parking with busing is used for clinics.]
- EDUCATIONAL VIDEO [RN, NP, PA] – 4 people x 2 shifts = 8 total – Personnel to run video orientation regarding clinic procedures, paperwork, consent information, reasons for vaccination, contraindications to vaccination; 4 rooms running concurrently that hold 75 people/session with 1 staff/room (~20 minutes per session, allowing for 5 to 10 minutes for moving people into and out of orientation room) or a total of approximately 2 sessions/hour (~600 people oriented).
- MEDICAL COUNSELORS FOR QUESTIONABLE CONTRAINDICATIONS [LICENSED PHYSICIAN] — 2 per shift x 2 shifts = 4 total – Medical counselors to review patient history for those with contraindications and answer questions for informed consent, evaluate/examine triaged sick persons and provide backup counseling if needed, evaluate any immediate problems following vaccination (e.g., fainting or anaphylaxis). estimate 5 to 10 minutes/person; numbers may need to be increased if too many people require further screening and lines start to back up at this part of clinic.
- MENTAL HEALTH COUNSELOR – 1 x 2 shifts = 2 total – Provide reassurance/limited counseling to “worried well”, fearful contacts, etc.
- VACCINATORS [RN, NP, PA]/ASSISTANTS – 16 x 2 shifts = 32 total – Eight vaccination stations with 1 vaccinator and 1 vaccination assistant per vaccination station/shift (to alternate with other stations), reconstitute and administer vaccine, fill out vaccination card, and witness/collect signed vaccination consent (each of the eight vaccinating stations doing 45 people/h for total of 360 people vaccinated/hr). Vaccinators should consist of those allowed to administer vaccine under state law.
- POST-COUNSELING/AFTERCARE PERSONNEL – [RN, NP, PA] 2 x 2 shifts = 4 total – Personnel to answer any final questions about site care, adverse event symptoms or non-take reporting procedures/follow-up, and other issues following vaccination.
- CLINIC MANAGERS – 2 x 2 = 4 total – Oversees all clinic functions/problem solving.
- SUPPLY MANAGERS – 2 x 2 = 4 total – Oversees all supply needs; tracks vaccine supply/lot numbers, distribution, and wastage; re-supplies vaccination stations.

- CLINIC FLOW MONITORS [volunteers] – $4 \times 2 = 8$ total – Help maintain clinic flow, rotate through waiting areas, and talk with people to assure them, as needed.
- SECURITY PERSONNEL – $20 \times 2 = 40$ total – Maintain crowd control outside and security within clinic; assist with clinic and traffic control, and other security matters. Non-public health resource; however, arrangements must be made with appropriate agencies or organizations to provide security as part of coordinated planning.
- SPECIAL NEEDS TRANSLATORS – One for each major language spoken in community per shift; more may be needed depending upon major language of clinic population. Translators proficient in sign language should also be identified to assist with hearing-impaired individuals. Local and state authorities should identify language translations needed based on makeup of the community. Consider identifying specific clinics for referral of populations who need translators, as well as those with impairments or disabilities.
- EMT and EMT-P – $2+1 \times 2 = 6$ total – To assist with medical emergencies, fainting, etc., transport to hospital facility
- IT PERSONNEL – 2 per shift $\times 2 = 4$ total – To support computer, programming, electronic equipment maintenance needs, and other information technology requirements.

OTHER VOLUNTEERS AS NEEDED FOR FLOAT STAFF AND RELATED CLINIC ACTIVITIES

VC Staff needed per single VC to cover two 8-h shifts – approximately 144 (72/shift) + translators [NOTE: 40 people are security people from non-public health resources.]

Non-medical volunteers can be used for: forms distribution, data entry, supply staff, clinic flow assistance, security, traffic flow, translators, float staff, and IT support.

Total Staff needed for 22 Vaccination Clinics – $144/VC \times 22 VC = 3168^{**}$
For 22 VCs operation of two 8h shifts/day + translators

**Should consider increasing staffing by approximately 20% with cross-trained personnel to allow for no-shows, breaks, surge needs, and other contingencies.

Each LINCS Health Officer is responsible for developing and implementing county-based smallpox vaccination clinic plans. Responsibilities are listed in Section II.C.2.

2. Clinic Stations

a. Health Screening Stations

- i. Health Screeners will be at the door to greet each client.
- ii. Will identify those persons that are obviously ill.

- iii. Will request that the Clinic Flow Monitor escort those that are determined to be ill to Medical Counselor. The Medical Counselor will register these people using the first screen of the computer tablet.
- iv. The Clinic Flow Monitor escorts those that are determined not to be ill, to the Registration Station.
- v. Health Screeners will identify those clients with special needs and request that the Clinic Flow Monitor escort those with special needs to the Special Needs Station.

b. Special Needs Station.

- i. Those clients with mobility, sight or communication problems are seen by a Special Needs Staff to determine how best to move them through the Clinic.
- ii. Those clients with language barriers are teamed up with an Educator who speaks their language. That Educator continues through the Clinic with the client.

c. Registration Station

- i. Registrar checks client into clinic and enters demographic information into the computer tablet.
- ii. Registrar sends client to Education Station.

d. Education Station

- i. Clinic Flow Monitor takes clients to room/area for education about exposure and vaccine contraindications.
- ii. Educator provides information on the exposure, why we are vaccinating, what to expect at the clinic, how vaccination is done, and that more information will be coming on how to follow-up.
- iii. Shows CDC video on smallpox vaccine.
- iv. Allows 5 to 10 minutes for questions and answers.
- v. Sends clients to Triage Station.
- vi. Staggered start times for education sessions (repeated every 30 minutes as needed).
 - Separate sessions for contacts and for specific languages as needed.
 - Clients with additional questions are sent to the Medical Counselor.

e. Triage Station

- i. Triage Staff enters medical history information for each client into the computer tablet.
- ii. If client says “yes” to any absolute contraindications, Triage Staff enters this information into the computer tablet and sends client home.

- iii. If client says “yes” to any answers regarding questionable contraindications to vaccination, Triage Staff sends client to Medical Counseling Station for review of contraindications, common reactions, and adverse events for vaccinia vaccine.
 - iv. If client is determined to have contraindications for vaccination, Medical Counselor sends client home.
 - v. Medical Counselor enters this information into the computer tablet.
 - vi. If client is determined not to have contraindications for vaccination, Medical Counselor sends client to Vaccination Station.
 - vii. All clients not sent to Medical Counselor will be sent directly to the Vaccination Station.
- f. Vaccination Station
- i. Clinic Flow Monitor directs vaccinee to Vaccination Station.
 - ii. Each Vaccination Station will have one table, one vial of vaccine, one Vaccinator and one Vaccine Assistant.
 - iii. Vaccine Assistant shows client the consent form on the computer and allows time for the client to read it.
 - iv. After client reads and understands the consent form, he/she signs on the tablet.
 - v. The Vaccine Assistant and the Vaccinator also sign on the tablet.
 - vi. Vaccine Assistant helps client expose their upper arm (or other anatomic site where vaccination will be given).
 - vii. Vaccinator administers vaccine.
 - viii. Vaccine Assistant takes photo of vaccine site that is automatically entered into the computer tablet.
 - ix. Vaccine Assistant applies appropriate covering to the vaccination site and directs the client to the Post Counseling/Aftercare Station.
- g. Post Counseling/Aftercare Station
- i. Educator instructs vaccinee on:
 - Care of vaccination site.
 - What to watch for (“take”) and how to report adverse reactions and where to go if they occur.
 - Where to go for revaccination if no “take”.
 - ii. Educator prints out the vaccinee’s vaccination record and gives a fact sheet on home care of vaccination site.
 - iii. Educator instructs vaccinee to return in seven days so that vaccination site can be inspected for “take” and /or photographed.
- h. Seven Day Follow-Up Station
- i. After seven days have passed, vaccinee returns to the clinic so that the vaccination site can be inspected for “take”.
 - ii. If vaccine has “taken”, a second photo will be taken and entered into the computer tablet.

- iii. If the vaccine did not “take”, the client is referred to the Vaccination Station for revaccination, and the entire process is repeated.
- iv. Seven-day follow up clinics will be located and staffed by appropriate trained personnel.

3. Staff Organization and Responsibilities

The official responsible for overall direction of the vaccination operation must assign a clinic manager who is responsible for overall clinic operation, is the primary decision maker for the site, and supervises all non-medical personnel. All staffing assignments should be documented on a clinic assignment sheet.

- a. Clinic Flow Monitors
 - i. Should have a good working knowledge of the clinic flow.
 - ii. Should maintain the smooth flow of clinic operations.
 - iii. Reports to the Triage Leader.
- b. Health Screeners
 - i. Should have basic medical assessment skills and have a good concept of the overall purpose and function of the vaccination effort.
 - ii. Will identify persons who are sick using specific screening questions, perform a visual check and quick review of each exposed person to assess for symptoms suggestive of smallpox.
 - iii. Identifies those with special needs and requests that Clinic Flow Monitor escorts them to the Special Needs Station.
 - iv. Directs all others to the Registration Station.
 - v. Reports to the Triage Leader.
- c. Registrars
 - i. Registrars are clerical staff that are skilled at data entry.
 - ii. Reports to the Incident Commander.
- d. Educators
 - i. Educators at Education and Post Counseling/Aftercare Station are well versed in exposure and vaccine contraindications.
 - ii. Will be bi-lingual in the language(s) of the population attending the clinic
 - iii. Must be registered nurses, nurse practitioners or PA's
 - iv. Report to the Medical Counselor.
- e. Triage Staff
 - i. The Triage Leader will orient the Triage Staff to their specific roles.
 - ii. Triage Leader supervises all Triage Staff.
 - iii. Triage Leader provides technical assistance to Health Screeners.

- iv. Triage Leader refers members of the media to the Incident Commander.
 - v. Triage Leader maintains smooth flow of operations.
 - vi. Triage Leader and Triage Staff must be registered nurses, nurse practitioners or PA's.
 - vii. Triage Leader reports to the Medical Counselor.
- f. Medical Counselor
- i. The Medical Counselor will be a physician.
 - ii. The Medical Counselor will assess illness symptoms of clients and provide a medical assessment.
 - iii. If symptoms are compatible with the disease and are associated with an exposure, arranges transport of patient by ambulance to a hospital for care.
 - iv. Responds, with EMTs on site, to anaphylactic reactions.
 - v. Supervises the vaccinators.
 - vi. Reports to the Incident Commander.
- g. Vaccine Assistants
- i. Helps clients prepare to receive vaccine.
 - ii. Applies covering to the vaccination site.
 - iii. Take photo of vaccine site.
 - iv. Reports to the Vaccinator Leader.
- i. Vaccinators
- i. Vaccinators should be registered nurses, nurse practitioners or PA's.
 - ii. Must be licensed by the state to administer vaccine.
 - iii. Reconstitute vaccine as needed.
 - iv. Report to the Medical Counselor.
- j. Special Needs Staff
- i. Identifies clients with special needs (those with mobility, sight or communication problems).
 - ii. Supervises interpreters.
 - iii. Facilitates smooth traffic flow by providing separate attention to those
 - iv. with special needs.
 - v. Reports to the Triage Leader.
- k. Mental Health Staff
- i. Provides emotional support for vaccinees and clinic staff.
 - ii. Reports to Incident Commander.
- l. Security Staff
- i. Are non-public health staff.
 - ii. Maintains crowd control and order inside and outside the clinic.

- iii. Will have some law enforcement background.
- iv. Reports to the Incident Commander.

4. Staff Training

The staff operating a clinic site should receive a group orientation to the overall purpose, function, and flow of the vaccination clinic as well as specific verbal and written directions for their individual roles.

During the orientation a diagram with annotations should be provided to show traffic flow, the functions of all clinics stations, and a list of staff assigned to each role and each station, if possible. The general responsibilities of each area of the vaccination clinic are reviewed with the entire staff. All staff need to know where they will work, where their supplies and resources are located, and who their consultants are as well as how to summon them.

In small clinics there are roles within the clinic that should be flexible to accommodate to the needs of the clinic and decrease congestion and waiting time (“bottlenecks” and “lags”) and to permit breaks for staff. In larger clinics, this can be accomplished by cross-training. Therefore, orienting staff in small, interchangeable teams is suggested.

For training vaccine administrators and assistants, a demonstration video is available from CDC. Ideally, vaccinators should practice on each other and other staff before administering vaccine to the public. Copies of package inserts, MMWR, VIS, and any other significant administration materials should be available during training and actual vaccine clinics.

If time permits, a mock vaccination clinic or role-playing session should be conducted to train and evaluate the potential performance of staff. Vaccinating clinic staff as well as first responders and other health care providers is suggested as a way to provide critical training and experience for all staff, especially the vaccine administrators.

Emergency personnel should also attend the group orientation and be given information about smallpox and managing potential exposure to smallpox. They should be familiar with the layout of the clinic site and know where ill patients will be maintained prior to transport.

Daily post-clinic debriefings should be held to assess staff performance and ascertain if additional training or clinic reconfiguration is needed.

I) Vaccine Receipt, Distribution, Storage and Handling

The Medical Director of Vaccine Preventable Diseases Program of NJDHSS, is the primary individual responsible for accepting and collaborating with the CDC National Pharmaceutical Stockpile for receipt of smallpox vaccine into New Jersey.

The NJDHSS has designated a primary and alternate facility as the smallpox vaccine storage center. This facility is centrally located along major transportation arteries in New Jersey. At this facility the vaccine will be received, stored, maintained at proper temperature (35° to 45° F) and repacked into specified quantities for distribution to clinic sites. Security personnel will staff these facilities 24 hours 7 days per week. The vaccine will be kept under lock and key in a room with surveillance videos and motion detectors. The refrigeration units will be secured within the designated facility and will only be accessible by NJDHSS distribution team members.

The NJDHSS will:

- determine which method of delivery and what quantity of vaccines are to be delivered to New Jersey;
- prioritize deliveries of vaccines as dictated by the medical situation within the state;
- ensure, with NJOEM, that arrival destinations within the state are notified and prepared to accept the vaccines shipments;
- notify, with NJOEM, special teams scheduled to assist with the offloading, inventorying, warehousing, breakdown and delivery of vaccines packages;
- coordinate the participation of the state's healthcare infrastructure in the distribution process for vaccines;
- coordinate, with NJOEM, the participation of county and local emergency management and law enforcement agencies;
- ensure, with NJOEM, that the Joint Information Center has updated situation reports to facilitate preparation of critical news releases and information bulletins.

Upon arrival of smallpox vaccine inventory, a distribution team will be activated by the SEOC to oversee logistical requirements. Formal distribution will necessarily be event driven and population focused under the direction of the NJ State Epidemiologist. It is anticipated that impacted areas and immediate environs will receive priority attention in the distribution process. (For analytical purposes, the 2000 U.S. Census Report will be used calculating population bases).

Each of New Jersey's 22 LINCS agencies will pre-designate individuals and transportation personnel and vehicles that will be summoned to the primary distribution center to receive the allotment for their region. Appropriate refrigeration for transportation and security during shipment to their region is the responsibility of LINCS agency transporters. A signed roster for each of the 22 LINCS transporters documenting quantity of vaccine, lot numbers and expiration dates will be maintained (electronically if possible). Each LINCS transporter in turn will be similarly responsible for maintenance of the documented distribution chain to the vaccination clinic(s). A daily report to the primary state distribution center by each of the 22 LINCS coordinators on vaccine inventory will be required.

Overall, inventory controls will be maintained on a daily basis via telephone, fax or electronic reporting from local clinic sites to LINCS coordinators and then to the primary distribution center. Maintenance of the "cold chain" of the vaccine will be a priority from receipt into the state until individual administration.

Licensed pharmacists will be identified to assist in the proper handling and dispensing of the vaccine to minimize wastage and cross contamination. They will also ensure that vaccine is properly stored and secured between vaccination sessions. The county Office of Emergency Management, together with local law enforcement agencies, will coordinate security of the stored vaccine.

Daily/weekly summary reports will be prepared by the Medical Director of Vaccine Preventable Diseases for review by the NJ State Epidemiologist and transmittal to the CDC NPS Headquarters to ensure full logistical control of all inventory.

Once federal authorities have authorized the release of vaccine, the initial vaccine shipment to a state or local area may be provided in a self-contained shipping and storage unit called a Vaxicool. One Vaxicool unit contains approximately 300 vials of vaccine and can also be used for continued storage of up to 300 vials of vaccine with an appropriate outlet power source. The number of vaccine vials contained within a Vaxicool unit may depend upon the specific vaccine dispensed (e.g., Wyeth, Aventis, Acambis, or Baxter vaccine) and the potential need for refrigeration of the specific diluent during shipping.

Diluent for vaccine reconstitution and needles for single-use vaccine administration will also be included in all vaccine shipments but may be in containers separate from vaccine. Shipments will contain vial holders to secure the vial and prevent accidental tipping during needle preparation for vaccination.

Subsequent vaccine shipments will be in Styrofoam shipping containers. These Styrofoam shippers can support 100 to 1500 vials of vaccine, depending upon the shipment size required. Vaccine shipped in Styrofoam containers will require arrangements for refrigerated storage at 35° to 45° F upon arrival. The need for storage of subsequent vaccine shipments of vaccine should be incorporated into all general smallpox vaccine storage site plans at the state level and all vaccination clinics plans at the state and local level.

Current plans for rapid, large-scale shipment of vaccine through NPS system allows for shipment of up to 500 Vaxicool systems on day 1 (75 million total vaccine doses), with up to 615 additional vaccine shipments/day in Styrofoam shipping containers on days 2 through 6. This plan provides for distribution of 280 million doses of smallpox vaccine from the NPS storage sites to states' field sites within 5 to 7 days. Vaccine shipments can also be dose adjusted and sent to cities with populations of 10,000 or greater.

Potential Types of Vaccine Formulations

Vaccine	Doses per Vial	Storage	Reconstitution/Storage
ACAM1000 (Acambis)	100	35° to 45° F	0.25 ml of diluent. Store at 35° to 45° F once reconstituted
ACAM2000 (Baxter)	100	35° to 45° F	0.25 ml of diluent. Store at 35° to 45° F once reconstituted
Aventis Pasteur	100	32 °F or below	32 °F or below
Dryvax (Wyeth)	500	35° to 45° F	1.25 ml of diluent. Store at 35° to 45° F once reconstituted

NOTE: Since the brand of vaccine to be used will not be known beforehand, storage and handling instructions for the specific vaccine being used should be reviewed with all staff before they begin their shift.

J) Vaccination Guidelines

The NJDHSS will adhere to the guidelines for the preparation and administration of the vaccine outlined in Guide B of the CDC Smallpox Response Plan and Guidelines.

See: <http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>

K) Post-Vaccination Care and Protocol

The NJDHSS will follow the protocol for vaccine monitoring, reporting, treatment and referral as outlined in Annex 4 of the Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program (NSVP).

The NJDHSS, through an MOA with the University of Medicine and Dentistry of New Jersey, will facilitate the training of designated physicians at each general hospital to recognize and manage vaccine-related adverse events (AE). These physicians will be provided information on the elements and protocols of the Program, including how to interface with the NJDHSS Vaccine Safety Coordinator and the CDC’s Smallpox Immunization Safety System (SISS). The Vaccine Safety Coordinator will be responsible for requesting Vaccinia Immune Globulin from the CDC, after conferring with the CDC’s SIIS .

The NJDHSS Vaccine Coordinator will ensure that the treating hospital physician completes a VAERS form for each vaccinee who sustains an adverse event. The form will be submitted to the NJDHSS for transmission to the CDC.

L) Training, Education and Communications

1. A public health emergency or terrorism event requires a coordinated and integrated communications plan. NJDHSS' Office of Communications coordinates all communications activities for the Department.

The NJDHSS Press Secretary oversees the Office of Communications, which is responsible for:

- developing an outline of how and through which media the public will be provided information and broadcast this information;
- discussing and agreeing on the roles of the NJDHSS Office of Communications, the Governor's Press Office, and the Joint Information Center (JIC);
- working with the Governor's press office to have the Governor address media at press conferences with any medical questions being answered by the NJDHSS Commissioner, or the Commissioner's designate. The goal is to speak with one clear, understandable, informed, authoritative voice;
- providing public health information to the Governor's Office for daily press release;
- monitoring print and broadcast news for public health information;
- helping develop public messages for Office of the Governor including creation of talking points to be used by public information officers at JIC;
- developing daily public health messages for the health care community to be disseminated electronically through the LINCS;
- updating NJDHSS website on 24/7 basis with press releases, FAQs, technical and medical protocols for health care providers, and other updates on the situation; and,
- coordinating activities with those of LINCS communications personnel.

2. Critical Training and Communication Elements: First 48 Hours Post Confirmed Case

a. NJDHSS Personnel

i. Communication/Education Team Issues

- All NJDHSS communication team members will establish contact with their CDC counterparts to review all communications plans and materials, and determine how they will cooperate in the implementation of the NJDHSS Smallpox Response Education plan.
- NJDHSS communication team members will learn what resources their CDC counterparts bring to the effort and determine how to best incorporate these resources into the NJDHSS plan.
- NJDHSS Communications Team members will meet twice daily, morning and late afternoon, to receive the latest updates, provide each other with pertinent information, identify problems, and brainstorm solutions to identified problems.

ii. Website Issues

- Activate the “emergency” smallpox website.
- Add new materials and updates at least once daily.
- Add links to other government websites that are providing updates on the event (ex; CDC).

iii. PHEOC Staff Issues and Training

- Upon confirmed outbreak, the PHEOC will be deployed. Provide all PHEOC assigned staff members with information and materials as needed (caller intake/documentation forms, resource materials to answer caller questions, press releases, guidelines/protocols, etc.)
- Provide detailed training to all personnel deployed to the PHEOC on call intake, documentation procedures, resources, etc.
- Shift supervisors shall review call documentation and categorize types of questions being received. Summary shall be provided to the health educator for review. Health educator will determine any revisions to be made to currently existing educational materials based on this feedback.
- Ensure that the PHEOC has knowledge of TTY capability for the hearing impaired and direct calls appropriately.

iv. Vaccine Training and Education

- Provide any additional training to vaccinators not previously reached in the preparedness phase of planning.
- Identify, designate, and train physician sub-investigators to carry out the requirements of the IND protocols for smallpox vaccine and Vaccinia Immune Globulin.

v. Contact Tracing Team Issues and Training

- Provide in-house training of staff identified as part of contact tracing teams. Include training of all forms and materials to be used, documentation procedures, and guidelines for case identification, interviewing methods and skills, initiating isolation and/or transport of suspected cases and vaccination for contacts.

b. Local Health Departments/LINCS agencies

i. General Considerations

- Disseminate initial information release via LINCS. Include resource information, important contact phone numbers, NJDHSS website address and synopsis of what can be found on the website. Include any instructions that are pertinent to the LINCS recipients at this time.
- Send updates via LINCS at least twice daily or as needed.
- Provide instruction via LINCS and the NJDHSS smallpox website on conducting active surveillance

- Provide in-house training of staff identified as part of contact tracing teams. Include training of all forms and materials to be used, documentation procedures, and guidelines for case identification, interviewing methods and skills, initiating isolation and/or transport of suspected cases and vaccination for contacts.

ii. Vaccine Education and Training

- Provide any additional training to vaccinators not previously reached in the preparedness phase of planning.
- Identify, designate, and train physician sub-investigators to carry out the requirements of the IND protocols for smallpox vaccine and Vaccinia Immune Globulin (VIG).

c. Media

i. General Considerations

- Create and disseminate a media advisory that provides information regarding the situation, major actions being taken, information about smallpox, public guidance, and resources.
- Post all media materials to the NJDHSS website.
- Issue information updates to the media once or twice daily to prevent, or correct, errors and misperceptions.
- Determine format for media updates (i.e.; teleconferences, in person press events, written updates, etc.)
- Monitor messages that are appearing in the media for consistency, content, accuracy, etc. Determine any corrective action necessary.

d. Public

i. General Considerations

- Promote the National Immunization Hotline and the State Hotline which will provide information to the public regarding vaccine clinic locations, quarantine guidelines, etc.
- Identify public information needs conducting primary research with affected populations
- Revise any currently existing educational materials in order to accurately reflect the nature of the situation at hand. Tailor general messages to meet the needs of subgroups or special target populations. Conduct message tests with groups representative of the affected population as often as possible. Obtain translator services as often as possible.
- Coordinate town-meetings for affected communities. Ensure accessibility for disabled or special needs individuals.
- Ensure that the PHEOC has TTY capability for the hearing impaired.
- Identify methods to reach disabled populations with important smallpox information.

3. Critical Training and Communication Elements: Ongoing Outbreak Management

a. NJDHSS Personnel

- Continue to provide training to PHEOC personnel on an ongoing basis as needed.
- Continue to update the comprehensive display binder housed in the PHEOC.
- Continue to update NJDHSS smallpox website.

b. Public

- Continue to provide educational materials as needed via the health education emergency distribution network or as per request.
- Continue to coordinate town meetings on an as-needed basis.
- Continue to provide expert speakers via the speaker's bureau on an as-needed basis.
- Continue to identify public education needs through analysis of calls received by PHEOC and through primary research with affected populations.

c. Local Health Departments

- Continue to provide information and alerts via LINCS.
- Continue to update NJDHSS smallpox website as needed

d. Health Care Professionals – Health Care Facilities (hospitals, LTCs, FQHCs, pre-hospital)

- Continue to provide support and information services via PHEOC, LINCS, and the NJDHSS smallpox website information “depot”.

e. Ancillary Staff – Health Care Facilities (hospitals, LTCs, FQHCs)

- Continue to promote training opportunities via NJ Distance Learning Network.
- Continue to provide information and support via PHEOC and NJDHSS smallpox website.

f. Health Care Professionals – Private Office

- Continue to promote training opportunities via NJ Distance Learning Network.
- Continue to provide information and support via PHEOC, LINCS, and NJDHSS smallpox website.

g. Ancillary Staff – Private Office

- Continue to promote training opportunities via NJ Distance Learning Network.
- Continue to provide information and support via PHEOC and NJDHSS smallpox website.

M) Public Health Emergency Operations Center (PHEOC)

To set up a NJDHSS emergency operations center to answer questions from the public, healthcare providers or law enforcement regarding smallpox vaccination during an outbreak, pre-selected, trained clerical, professional and medical staff will be identified. A general supervisor will also be identified. Pre-trained staff from the Communicable Disease Service, Health Care Systems Analysis, Senior Affairs, Long Term Care Systems, Public Health Services and Local Health and Emergency Services, along with the county planners will be notified to report to the PHEOC. The LINCS Communications Coordinator will also join the PHEOC operations to facilitate rapid dissemination of information through LINCS.

The PHEOC will operate two shifts: 8AM to 4PM and 3PM to 11PM. This will allow for overlap from 3PM to 4PM for information sharing and briefing between the shifts. If the PHEOC will be operational 24 hours per day, there will be three shifts, each shift consisting of 8 hours. A site supervisor will be identified for each shift whether there are two or three shifts. The PHEOC will be activated and a phone bank consisting of 25 phones and lap top computers will be set up. Five clerical staff per shift will triage calls to either professional or medical staff depending on the public's question. All staff will be reassigned to the PHEOC for the duration of the smallpox emergency.

The PHEOC will also accommodate federal staff, including staff from CDC, other state, and/or law enforcement and other response agencies, if necessary.

Daily morning briefings will be held between the general supervisor and the ECC staff. Information from that briefing will be given in writing to the PHEOC staff answering the phones so that they will have the most up-to-date information to give to the public. Communication between the ECC staff and PHEOC general supervisor will take place several times per day (i.e. 8AM, 12 Noon, 2PM, 5PM) to assure that the PHEOC staff has the most up-to-date information.

A computer with internet access will be placed in the PHEOC so that Public Health Bulletins can be retrieved immediately by the site or general supervisor. These Public Health Bulletins will then be copied for each of the staff on the phone bank. An Information Technology staff person will be designated for each shift to handle any computer related issues. A fax machine will also be placed in the PHEOC to receive messages from the ECC or the CDC.

IV. Summary

New Jersey has developed a Smallpox Vaccination Plan, combining both preparedness (Stage I, pre-event) and response (post-event) activities into one comprehensive and integrated blueprint for State action. This plan puts into place policies, procedures and protocols to prepare our public health care workforce to respond to a potential smallpox attack. The plan was developed with input from senior staff in the NJDHSS, Local Health Departments, the New Jersey Hospital Association, the MEDPREP/Terrorism Advisory Committee, the Infectious Disease Society of New Jersey and others organizations.

The preparedness plan targets three groups of public health care workers for vaccination: 5 Public Health Response Teams (PHRT), 85 Hospital Health Care Response Teams (HHCRT), and 22 Lead County Health Departments. Each PHRT would have 8 members, led by a NJDHSS physician. Each HHCRT would be composed of up to 150 hospital personnel including ED, ICU, medical specialists, technical and support staff. Vaccinations would occur over 4 weeks in 5 regional clinics, and 1 MMRS-based clinic in Newark. Approximately 2700-3600 people would be vaccinated weekly, up to 15,000 statewide. NJDHSS has partnered with Becton, Dickinson and Company to develop and utilize a wireless, PC Tablet-based data management system that will be integrated with the NJ Immunization Registry from which vaccination data will be exported to the CDC's PVS. Follow-up for assessment of vaccine "take" would occur at the vaccination clinics. Hospital-based and trained physicians and clinical staff would assess and manage the vaccination site for adverse events and consult first with the NJDHSS Vaccine

Safety Coordinator for use of VIG, if necessary. An extensive communication plan that will be implemented throughout Stage I has been developed.

The response plan follows the CDC guidelines for surveillance, epidemiologic investigations, contact tracing and vaccination of contacts. The CDC model was used to estimate the number and types of personnel that would be required to staff 22 statewide clinics to vaccinate 1,267,000 people in 10 days. The plan allows for expansion if the entire population of eligible individuals would require vaccination, based on national policy. A similar plan for vaccine receipt, distribution, storage and handling is described for both the preparedness and response components of the Smallpox Vaccination Plan. Extensive training and education activities outline, in detail, how the State will rapidly and effectively inform and educate the public, media, health care professionals, public health officials, and partner organizations about smallpox, smallpox vaccination, and outbreak management issues. An Executive Coordinating Committee will oversee program activities and make recommendations to the Commissioner and Governor on implementation of the Smallpox Vaccination Plan to control an outbreak.

V. Appendices