Annex 3

Guidelines for Large Scale Smallpox Vaccination Clinics

Logistical Considerations and Guidance for State and Local Planning for Emergency, Large-Scale, Voluntary Administration of Smallpox Vaccine in Response to a Smallpox Outbreak

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Introduction

This document describes the logistical considerations for voluntary, large-scale, postevent smallpox vaccination clinics. This example model may be used to supplement other state and local vaccination planning considerations for responding to a smallpox outbreak within their community.

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 cases, 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 Health and Human Services.

The following considerations apply:

1. Current smallpox vaccines are available under an Investigational New Drug (IND) protocol only, and informed consent must be obtained. (See attached draft combination medical screening/consent form.)
2. The shortened IND process for obtaining informed consent should be followed. (See attached description of shortened IND informed consent process and draft supporting documents.)
3. Separate clinic(s) should be considered for vaccination and counseling of identified contacts of smallpox cases, but resources 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 vaccinia immune globulin (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. Predesignated sites or clinics 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 predesignated 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. Vaccine 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" 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%.)

11. The recommended guidelines for the logistics, design, and implementation of a voluntary vaccination clinic are interim and are meant to support existing emergency vaccination clinic plans that state or local public health authorities have developed.

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 established following confirmation of a smallpox outbreak:

1. Smallpox vaccine and the following vaccine administration supplies: diluent for reconstitution of vaccine and bifurcated needles.
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 form
    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 duplication and 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 as otherwise outlined in the Federal Response Plan, if activated. [See Annex 2.]

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).

Vaccine Delivery and Packaging Logistics

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 2 to 8 °C 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 planning logistics at the state and local level.

Current plans for rapid, large-scale shipment of vaccine through the National Pharmaceutical Stockpile (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	2 to 8 ºC	0.25 ml of diluent. Store at 2 to 8 ºC once reconstituted
ACAM2000 (Baxter)	100	2 to 8 ºC	0.25 ml of diluent. Store at 2 to 8 ºC once reconstituted
Aventis Pasteur	100	0 ºC or below	0 ºC or below
Dryvax (Wyeth)	500	2 to 8 ºC	1.25 ml of diluent. Store at 2 to 8 ºC 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.

Security Considerations

Specific security needs should be formally assessed and incorporated into planning efforts to support large-scale vaccination programs. Provision of appropriate security should be made for the following:

1. Vaccine storage sites (clinic and non-clinic) to include security personnel and locked, limited access areas for vaccine storage.
2. Backup power sources (generators) should be identified for all sites where vaccine is stored (vaccination clinics and storage sites).
3. Vaccination clinic sites: security personnel for crowd control, traffic movement, clinic personnel safety, and related security issues.
4. Vaccine transportation to storage sites and dispensing clinics.

Large-Scale Vaccination Clinic Organization and Personnel Estimates

The following section describes a model of a vaccination program that addresses the different activities needed for the administration of IND 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. The example staffing estimates were arrived at by: 1) review of previous large-scale-clinic models and publications, 2) considerations of requirements for administering an IND 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. State and local planners should evaluate these activity time estimates and consider what staffing or flow adaptations may be needed to accommodate increases or decreases in activity time requirements. 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 IND packets and providing initial instructions would take between 30 seconds and 2 minutes
- Video orientations will be done approximately every 30 minutes in 5 orientation rooms that hold 75 people per room
- It will take 2 to 3 minutes for individuals to fill out the medical history screening forms
- 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)

Clinic Estimates

Vaccination Clinics (VC)	20 clinic sites	More sites could be added to accommodate larger population bases
Vaccination Stations (VS)	▪ 8 VS per shift ▪ 1 vaccinator per station ▪ 0.5 to 1 witness/helper per station (who can also alternate vaccinating) ▪ 16 vaccinators/witnesses per shift	
Hours of Operation	At a minimum 16 hours/day	Consider expanding hours for higher daily output or to address overflow
Vaccination Delivery	▪ ~ 30 to 60 vaccinations per VS/ hour ▪ ~ 370 vaccinated/hr/VC ▪ ~ 5900 per day/VC ▪ ~ 118,000 per day total with 20 VC ▪ 1 million vaccinated in ~ 9 days	30 to 60 vaccinations per VS/hour allows for variations caused by vaccinator rotation, resupply requirements, completing vaccination card, and other considerations

Breakdown of Clinic Personnel per VC

Position	Number per 8-h Shift	Number per 16-h Day	Experience
Forms Distribution+	9	18	Nonmedical volunteers
Triage for Ill or Contact	2	4	Nurse or EMT
Run Orientation Video	8	16	Nonmedical (five running rooms and three floating between rooms to assist)
Referral Personnel	16	32	Nonmedical volunteers
Medical Screeners	7	14	Medical training required nurse or MD
Physician Evaluators	2	4	Physicians to evaluate ill or more difficult medical history screening
Vaccinators/Witness	16 (vaccinator, witness, surge personnel)	32	Cross-trained to alternate vaccination, fill out vaccine card, and sign as witness
Vaccine Preparation/Supply to VS	2	4	Pharmacist, pharmacy tech, or nurse experienced with vaccine or medication reconstitution
Exit Review	2	4	Medical or public health personnel for final questions/instructions
Medical Records/Data Entry	10	20	Nonmedical, data entry for information collected on vaccinees
Clinic Manager	2	4	Existing Vaccine Programs Personnel
Supply Manager	2	4	Nonmedical
Clinic Flow/QA Reviewer/Forms Helpers	8	16	Nonmedical volunteers to assist with forms completion, collection, and clinic flow
Security	20	40	Non-public health resource
Traffic Flow	2	4	Nonmedical, assist with loading and unloading buses at site if offsite parking utilized
Translator (not counted in total clinic staffing estimates)	At least one per major language per shift	Unknown	Language fluency with training
Float Staff	3	6	Nonmedical volunteers
Contact Evaluation	4	8	Public health
EMT	1	1	Medical
IT Support	1	2	Nonmedical
Total Personnel	**117**	**234**	

- **FORMS/INFO PACKET DISTRIBUTION** – 9 x 2 shifts = **18 total** – Personnel to put together patient forms/information packets and hand out packets with information sheets/registration forms/informed consent/other IND forms (1 minute/person), clipboards, and pencils. People will begin filling in demographic information on forms while in line awaiting initial clinic entry for video briefing.
- **TRIAGE** [nurse or EMT] – 2 x 2 shifts = **4 total** – Triage personnel to direct ill patients to other evaluation facilities and direct identified contacts, persons with contact with a case 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.]
- **VIDEO ORIENTATION** – 8 people x 2 shifts = **16 total** – Personnel to run video orientation regarding clinic procedures, paperwork, IND consent information, reasons for vaccination, contraindications to vaccination; **5 rooms running concurrently that hold 75 people/session with 2 staff/room** (~20minutes 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** (~750 people oriented/hr).
- **REFERRAL PERSONNEL**– 16 people x 2 shifts = **32 total** – Can be trained volunteers with no medical background; to look at medical screening/vaccination consent forms and send persons without "yes" checked boxes who have signed form on to vaccination station and redirect people with contact checked boxes or other "yes" or "maybe" checked boxes on to contact or medical screeners. Float staff personnel can relieve as needed to allow all stations to continue running during staffing breaks.
- **MEDICAL SCREENERS FOR CONTRAINDICATIONS, EVALUATION/INFORMED CONSENT QUESTIONS COUNSELING** (should be medically trained personnel, such as physicians, nurses, physician assistants, or nurse practitioners) — 7 per shift x 2 shifts **= 14 total** – Medical screeners to review patient history for those with contraindications and answer questions for informed consent (est. 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.
- **PHYSICIAN EVALUATORS** – 2 x 2 shifts = **4 total** – Physicians to evaluate/examine triaged ill persons and provide backup counseling if needed to contacts and noncontacts identified with possible contraindications by medical screeners (~ 10 minutes/person), and evaluate any immediate problems following vaccination (e.g., fainting or anaphylaxis).
- **VACCINATORS/ASSISTANTS** – 16 x 2 shifts = **32 total –** Eight vaccination stations with 1.5 **to** 2 vaccinators per vaccination station/shift to trade off vaccination, fill out vaccination card, and witness/collect signed vaccination consent/med screening form (each of the eight vaccinating stations doing 35 to 45 people/h for total of 360 people vaccinated/hr). Vaccinators should consist of those allowed to administer vaccine under state law.
- **VACCINE PREPARATION FOR VS** – 2 x 2 shifts = **4 total –** For preparation of vaccine vials to supply VS as needed. Should be pharmacist, pharmacy technician, or other personnel trained in preparation of medications or reconstitution of vaccines and as allowed by state law.
- **EXIT REVIEW PERSONNEL** – (should be medical or public health personnel) 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.
- **MEDICAL RECORDS/DATA ENTRY PERSONNEL** – 10 x 2 shifts = **20 total –** Collect retained records and enter registration/vaccination information (e.g., name, SS#, passport number/country, and contact information) into database (estimated 1 minute/record entry if database already set up) – important to have onsite, if possible, to maintain "real-time" record of number of vaccinations and database for later use for adverse events or non-takes requiring revaccination; Web-based entry with centralized database of all clinics preferable.
- **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/QA/FORMS HELPER PERSONNEL** [volunteers] – 8 x 2 = **16 total** – Help maintain clinic flow, assist with forms, quality assurance, retrieve clipboards and forms from VS and

takes forms to medical record entry personnel and clipboards back to form distribution, rotate through waiting areas to answer questions, and talk with people to assure them, as needed.

- **SECURITY PERSONNEL** – 20 x 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.
- **TRAFFIC FLOW PERSONNEL** – 2 x 2 = **4 total** – Maintain traffic flow and order in parking area if parking onsite; if busing from offsite parking is used, these personnel may not be needed.
- **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 deaf 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.
- **FLOAT STAFF PERSONNEL [volunteers]** – 3 x 2= **6 total** – Float staff personnel to answer telephones, assist clinic personnel as needed, collect forms, assist with handicapped and elderly, etc.
- **CONTACT EVALUATION UNIT PERSONNEL** – 4 x 2 = **8 total** – For separate medical screening, education, and registering of identified contacts and their household contacts. Contacts will also be registered for surveillance for smallpox symptoms and given instructions on any travel restrictions and reporting requirements. Must be educated on contact surveillance process, smallpox signs/symptoms, and contact evaluation issues.
- **EMT** – 1 x 2 = **2 total** – To assist with medical emergencies, fainting, etc.
- **IT PERSONNEL** – 1 per shift x 2 = **2 total** – To support computer, programming, electronic equipment maintenance needs, and other information technology requirements.

Although not formally included in the above staffing estimates, the addition of mental health staff at each clinic site should be considered.

OTHER VOLUNTEERS AS NEEDED FOR FLOAT STAFF, FORMS ASSISTANCE, REFERRAL PERSONNEL, AND RELATED CLINIC ACTIVITIES

VC Staff needed per single VC to cover two 8-h shifts – approximately 234 (117/shift) + translators
[NOTE: 40 people are security people from non-public health resources.]

Nonmedical volunteers can be used for: forms distribution, orientation video, referral personnel, data entry, supply manager, clinic flow/QA/forms assistance, security, traffic flow, translators, float staff, and IT support.

Total Staff needed for 20 Vaccination Clinics – 234/VC x 20VC = 4680**
For 20 VCs operation of two 8h shifts/day + translators
[NOTE: ~17%, or 800, of these personnel are non-public health resources required for security.]

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

Considerations for Vaccine Non-Takes and Adverse Events

Telephone hotlines should be established for the following:

1. **Reporting and Handling of Vaccination Non-Takes**
   Noncontacts: Vaccinated individuals who are not otherwise identified as contacts to a smallpox case will be given vaccination cards and vaccine take recognition cards at the time of their vaccination (in the IND packet) and instructed to call a designated number (a hotline set up by local health officials) if their vaccination site does not resemble the picture on the card at day 7.

They will be counseled through the hotline to return to a VC with their vaccination card for revaccination if they are suspected of having a vaccine non-take. Individuals presenting back to VC for revaccination would not require repeat medical screening as long as they present their vaccination card from the previous VC visit, but may be required to review the informed consent material (video) and sign an additional consent form. Following this signing, they can be triaged directly to the vaccination area for revaccination.

Contacts: Vaccinated contacts under surveillance and their household members will also receive vaccine take recognition cards and vaccination cards. If possible, they will be followed up with visual confirmation of vaccine take as a part of the contact surveillance process. If visual confirmation is not possible because of a large number of contacts requiring surveillance by limited personnel, contacts and their household members will be instructed to report possible vaccine non-takes to a designated contact symptom surveillance telephone number at the local or state health department. Revaccination will be done for contacts and their household members who do not have a vaccine take at day 7. This revaccination may be done through referral back to the contact evaluation unit of a VC, referral to another specified location, or through direct administration of vaccine by health department personnel at the time of visual evaluation (dependent upon what is allowed through the IND process).

2. **Reporting, Evaluation, and Treatment of Suspected Adverse Events**
   Evaluation and treatment for vaccine adverse events should occur at a designated site or sites separate from VCs. A local telephone number for reporting of suspected adverse events should be established and staffed and included in the Smallpox Vaccine Information Statement (VIS) that is handed out to vaccine recipients. Staff should be instructed on where to refer callers for further medical evaluation. As a part of smallpox bioterrorism (BT) planning, local and state health authorities should designate the facilities where suspected vaccine adverse events will be referred, evaluated, and treated. In addition, state public health authorities should establish a state-based reporting and consultation mechanism for healthcare providers to report potential VIG-requiring adverse events [see Annex 2].

Additional Considerations

Mobile Facilities

Consider mobile facilities (for nontransportable populations) if needed for fixed population vaccination:

- Retirement communities, nursing homes, hospitals, prisons, or other residential facilities
- Defined high-density areas/facilities, such as apartment and housing complexes

People with Disabilities

- Must have accessibility for persons with disabilities for clinics and transportation vehicles to clinics
- Consider wheelchairs to assist the elderly who cannot ambulate from station to station

Referral Testing

- Strategies for the referral of persons who request HIV or pregnancy testing to local laboratories or medical clinics that perform confidential testing should be considered and communicated as a part of the overall clinic planning. Planners should maintain a list of local clinics that offer this testing. In addition, consideration should be given to the potential use of rapid HIV tests within these clinics if an FDA-approved test is available.

Waste Disposal

- Two to three disposal-trucks and staff, scheduled to collect medical and other waste from 20 VCs at least daily.

Rest Area

- An area for staff to rest/sleep if working more than 8 hours or if there is inclement weather and staff are unable to return to their homes after their shift.

Transportation for Staff

- Depending on the location, arrangements may be needed to transport staff to the VC.

Public Announcements

- Use national, local and educational TV and radio networks to present uniform messages. Planners should consider how these messages could be quickly developed, locally, to accommodate sudden changes in sites and/or recommendations.
- Establish list of non-English speaking media outlets that can be utilized to deliver messages to immigrants/refugees and other non-English speaking communities
- Messages (videos, tapes, press conferences, experts)
    - **Pre-Event BT Messages** – Advising population on various BT-related diseases and prevention and treatment messages; preparatory steps being taken by the health department (1 million in 10-day vaccination plan); methods to be used to inform public in case of impending event; outline of health department plan if an event occurs; adequacy of vaccine supply.
    - **Event Messages**
        - State plan that is being put into operation, including:
            - urgency and patience, but not panic
            - plan regarding the number of VCs
            - timing to prevent smallpox
            - vaccine supply
            - trained personnel
            - listing of collection areas where people will be picked up by buses
            - any materials that might be required to prove eligibility for admittance into clinic
            - listing of normal activities being suspended
            - hotline numbers
            - review of vaccine recommendations.
        - Frequently updated "wait-times" for vaccination clinics via multiple communication outlets (e.g., local television station designated for public service announcements and updates, Web sites, or telephone number with automated updates) to assist with determining clinic utilization.

Metro-Central Headquarters

- Management
    - Devise and continuously update central plan for providing vaccinations of the above scale
    - Convene and maintain a core group of health, administrative, media, public services, education, communication, and nongovernment collaborative organizations
    - Identify person(s) responsible for "operationalizing" each of the plan components
    - Solicit personnel to staff each of the above functions in the event
    - Plan and work through a mock event and revise plan, as needed
- Designate the 20 VCs and staff for each if an event occurs, identify safety/security, stock or identify source of supplies; establish distribution chain for vaccine, medical supplies, forms, waste pickup; plan/provide communication network for VCs
- Ensure that command and communications center plan is available, adequate and realistic and shared with all partners (e.g., emergency response, administrators, and clinic sites)

- Solidify communications and responsibilities among city/state officials, press, safety, health, federal/state emergency agencies, and other public agencies
- Colocate Vaccine Clinic Metro-Central Headquarters (MCH) near established Emergency Operations Centers to provide for better coordination and communications
- Use MCH to track overall clinic activities and utilization and provide hourly updates regarding vaccine clinic activities to public, press, and other emergency coordinators etc.
- Utilize MCH to provide continuous communications regarding clinic "wait times"
- Designate a group of people to function within MCH solely to anticipate "future" issues and problems and address these in a proactive manner

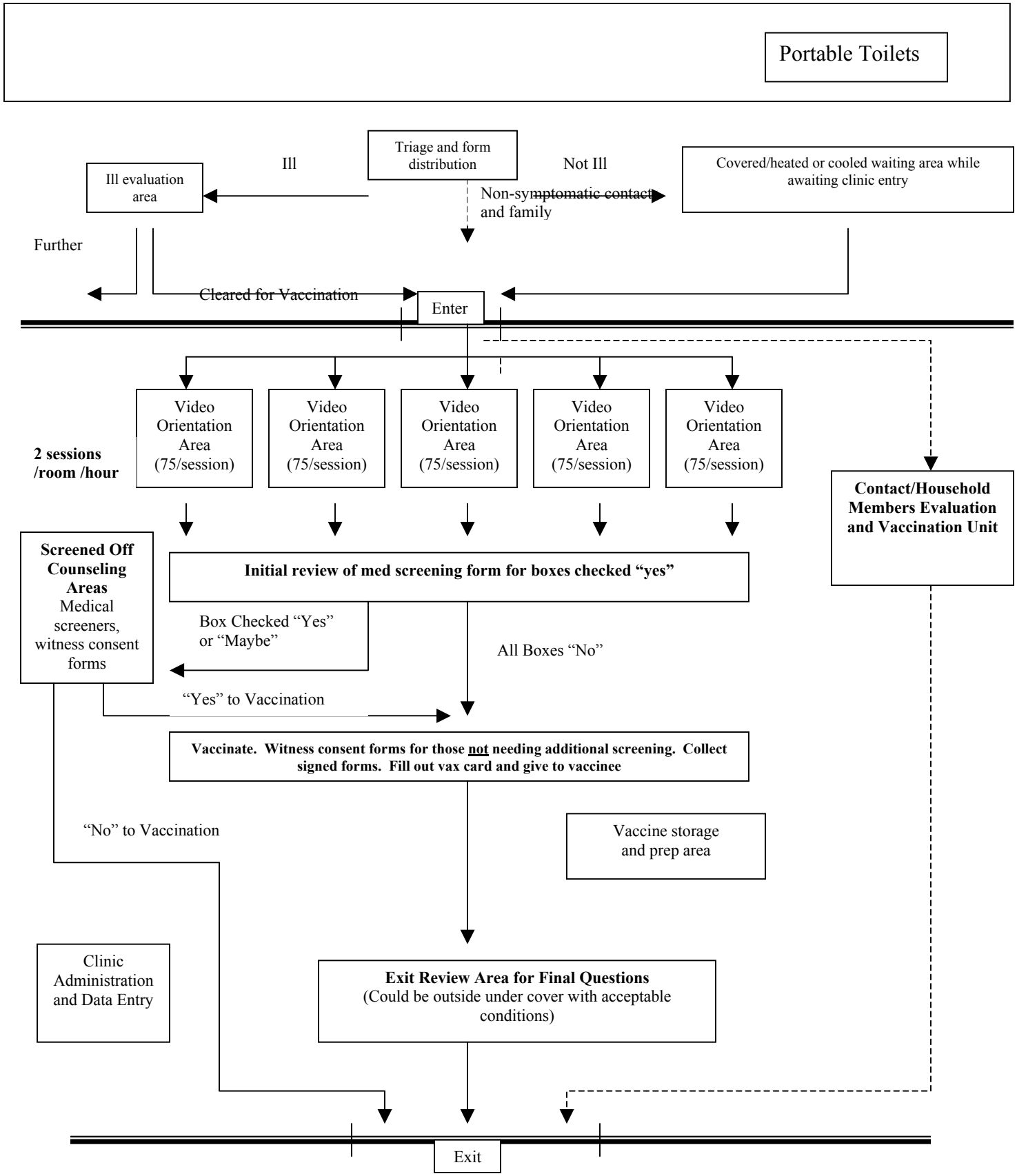
Vaccination Facilities

- Consider geographic and population density placement.
- If possible, establish Memorandums of Understanding (MOUs) with facilities to serve as vaccination clinics during pre-event planning activities.
- Facility Considerations
    - Large floor space facility
    - Handicap accessible
    - Possible use of schools – Larger schools, such as high schools [parking lots] and middle schools, first; primary schools as needed to assure adequate population distribution in areas of greater population [choose larger schools and those with larger gyms/auditorium/other space]. Schools are pre-designated
    - Other public health vaccination clinics if can support daily numbers as VC
    - Supplement with auditoriums, college halls, arenas, conference halls, large churches/temples, theaters, perhaps some malls; any large, preferably open-area buildings with parking to help assure widespread population access
    - Adequate sanitary facilities at all VCs
- Publicize VC locations and their suggested catchment areas.

Vaccinee Logistics and Access to VCs

- Self-access VCs
    - Regular public bus and metro-type routes – free transport
    - Adequate private vehicle parking at VCs – free parking
- Offsite parking with collection area (CA) access
    - Designated bus and metro route stop CA with busing to and from VCs – 20 CAs
    - Designated peripheral CAs (e.g., malls, movie complexes, parks, landmarks, and open areas) with adequate parking for private vehicles, with busing to and from VCs – 20 CAs
    - Public and school buses commandeered for delivery to and return from VCs for each CA
    - Designation of buses and drivers, along with routes, collection points and VCs to be serviced (two shifts); enough buses/drivers to deliver approximately 6000 people to each VC/day, average of 400 h to each VC
    - CA and VC area transport organizers (4 persons x 100 VC/CA x 2 shifts = 800)
    - Adequate sanitary facilities at all major collection areas
    - Publicize CA areas, their suggested catchments area, and the VC each area serves (e.g., TV, radio, newspapers, printed lists, and public transport advertisements)
- Consider ways to organize the population to attend VC on a day-by-day schedule, such as the use of the last 3 digits of the household head's Social Security number (e.g., Day 1: 000-099; Day 2: 100-199 … Day 9: 800-899) or use of other neighborhood designations, worksite designations, zip codes, school districts
- Advise population to bring identification (e.g., Social Security card, driver's license, passport, or other ID)

Fig. 1 Schemata of Model Vaccination Clinic



Smallpox Clinic Supplies and Equipment

General Supplies and Equipment	Vaccine Administration Supplies	Emergency Supplies
Tables Chairs Water and cups Paper Pens, pencils Envelopes Rubber bands Tape Stapler/staples Scissors Post-it Notes Clipboards File boxes Telephones FAX machine Photocopy machine Paper towels Kleenex tissues Table pads and clean paper to cover table for work site Garbage containers and trash bags ID badges for staff List of emergency phone numbers 5 or more large screen video setups with VCRs or DVD players to show Orientation video 7 Orientation videos (allows for extra if video damaged) Cleaning supplies (mop, bucket, etc.)	Smallpox vaccine Cooler/ refrigerator for vaccine Vaccine diluent Sterilized bifurcated needles "Sharps" containers Latex gloves Latex-free gloves Antibacterial handwashing solutions Acetone Rectangle Band-aids Gauze Adhesive tape Spray bottle of bleach Solution Paper Gowns (for patients wearing clothes that do not give ready access to arm) Screens (for changing, counseling, or administration, as needed)	Standing orders for emergencies "Code" kit with defibrillator Ampules of epinephrine 1:1000 SQ or EPI pen Ampules of diphenhydramine 50mg IM 3cc syringes with 1", 25-gauge needles 1.5" needles Tuberculin syringes with 5/8" needles (for epinephrine) Alcohol wipes Blood Pressure Cuffs (various sizes) Oxygen tank with tubing IV Solution and tubing Tongue depressors Adult and Pediatric pocket masks with one-way valve Adult and Pediatric airways Tourniquet Gurney Stethoscope Flashlight Cots Blankets Pillows ER Report Form Asthma Inhaler Thermometer Emesis basin Aspirin, Tylenol, insulin, D50
	Crowd Management and Triage Supplies Signs for clinic stations and between stations, and at Triage area Queue partitions (to keep people in lines)	**Computer Equipment and Supplies** Computers Printers Paper Internet access for forms or database entry

Additional Supply Considerations

Additional Clinic Supplies and Personnel Support for Each VC (Total of 20 VCs)

- Duplication – 1 or more rapid copy machines for duplicating IND paperwork as needed; crate of duplicating paper at each VC; extra machine toner cartridges.

- Computers – 12 desktops and/or laptops for data entry (all need internet connection if Web-based database used) with appropriate software (need to standardize software, if possible).
- Centralized supplies warehouse(s) – Estimate quantity of clinic supplies needed for 1 week of operation (paper, pens, staplers, etc.) and package accordingly for single unit delivery to each VC, weekly deliveries for continued.
- Shipping – Dedicated trucks/vehicles, staff, and drivers and preplanned routes to support vaccine and supplies delivery to 20 VCs.

Communications Equipment

- Telephones – 5 telephones/separate lines for each VC + 1 FAX at each VC.
- Cell phones should be considered for nondata/fax needs and/or if easy access to phone lines might be difficult within the vaccination area (e.g., gymnasiums or auditoriums).
- Hand-held radio system to communicate on site without having to send a runner.

Emergency Management

- Each VC should have clear, written procedures established to deal with emergencies caused by both vaccine adverse reactions and other reactions that could be triggered by the stress of the event (e.g., heart attacks, anaphylactic shock, or asthma).

Provision of Food and Beverages for Clinic Personnel

- Consider using resources, such as Red Cross.
- Local businesses may be willing to donate food and beverages.

Information Materials

- Obtain 2-day supply of forms (e.g., VIS, IND forms, contraindications, vaccine take, adverse event diary, and vaccination cards) directly from national stockpile (120,000 sets to support 20 VCs for first day) or pre-print forms locally as part of planning.
- Arrange to duplicate adequate numbers of all forms for day 2, day 3, etc. (120,000/day).
- Arrange for dedicated trucks (above), staff, and drivers and preplanned route to support delivery to 20 VCs.
- Provide information on local clinics and laboratories that can provide HIV testing to individuals who elect to have testing done before getting vaccinated. Payment for HIV testing would be the responsibility of the individual.

Logistics for IND Administration of Smallpox Vaccine

This section outlines the use of smallpox vaccine during the response to a smallpox emergency. This IND protocol would be implemented as outlined below if there was a confirmed case of smallpox.

Please refer to Flow Diagram (Figure 2)

- Public Service Announcements (PSAs) are the first item for the logistics of the vaccination clinic. These PSAs should be crafted to include important information on the disease, vaccination, contact numbers/vaccination clinics, clinic procedures, what to bring or wear to the clinic (identification, loose clothing to allow easier vaccination), how to get there, etc. PSAs should be in multiple languages and should use media outlets that will reach both English and non-English speaking individuals in the community.

- Triage for Illness: The first triage point for the vaccination clinic is triage for illness and/or contacts of confirmed cases of smallpox. This checkpoint is to screen out those individuals that may be ill or contacts from the rest of the individuals at the clinic so as not to expose the clinic population.
    - Ill (e.g., fever or rash): These individuals will be taken out of the mainstream flow prior to entering the clinic and will be attended to as required by their symptoms/illness (e.g., monitoring, referral, or supportive care).
    - Contacts: These individuals will be taken out of the mainstream flow to be counseled on follow-up procedures and registered for monitoring for symptoms of smallpox. They will also be vaccinated.
    - Not Ill (mainstream progression through the clinic): Those individuals that will progress to the next station within the clinic who have not presented as ill or a contact.
- Distribution of Information Packet: All individuals (contacts and mainstream) will receive the "mainstream" information packet that will include all of the following information:
    - Video script
    - Screening form
    - Expanded Vaccine Information Statement (VIS)
    - Vaccination Site Care Card
    - Proof of Vaccination Card

After receiving this information, "mainstream" individuals will proceed to the video screening area, while "contacts" will proceed to the contact evaluation area.

- Video Screening Areas: Individuals will view the video that contains the essential elements of informed consent as promulgated in 21 CFR 50.25. This video viewing will be witnessed to comply with FDA regulations for the oral presentation of consent information. The script of the video is included in the "mainstream" packet and will include, at a minimum, English presentations and Spanish language translations. Additional language translations may be needed at the local level to address special populations.

After the video, the individuals will be instructed to complete the screening form that will move them through the remainder of the vaccination clinic.

- Postvideo Triage: Individuals will proceed to this triage point with their completed screening forms. The screening forms are for self-identified contraindications for the individual or family members with contraindications (e.g., contact history, altered immune status, autoimmune diseases, concomitant medications that alter immune status, skin conditions, pregnancy, reactions to previous smallpox vaccinations, allergies to vaccine components, and children less than 1 year old) and/or questions relating to the decision to be vaccinated.
    - If individuals check "yes" or "maybe" to any of the boxes on the Screening form, they will proceed to the Counseling Stations where they will receive additional information based on the contraindication that they checked.
    - If individuals have no self-identified contraindications or questions, they will proceed to the vaccination area.
    - If individuals decide to decline vaccination and are not a contact, they will be escorted to the exit.

- Vaccination Area:
    - At the vaccination station individuals who did not require additional counseling will sign the consent form located on the back of their Medical History Screening Form that states that they have viewed the video and had all questions answered. They will also have the chance here to ask any remaining questions; if they do have remaining questions, they may be referred back to the counseling area. Once signed by the vaccinee, these forms will be signed by the vaccinating assistant as a "witness to consent" and then collected.

- Individuals who were referred to the vaccination stations after receiving additional counseling will have had their consent forms witnessed by the medical counselor and will proceed with vaccination.
- Following vaccination, the "Proof of Vaccination" form will be stamped by the vaccinating assistant and returned to the vaccinee.
- Any noncontact who refuses vaccination will be allowed to exit the clinic. (Contacts who refuse vaccination will be instructed on appropriate quarantine measures, the symptoms to monitor for, and appropriate contact information within the "Contact Evaluation Unit" area.)

- Postvaccination Information and Review: This is the final station in the clinic for any remaining questions. This station should also ensure that individuals exit with *all* their information sheets and instructions. (A supply of extra information sheets should be kept here to distribute, as needed.)

Attachment 1

Examples of Supporting IND Forms for Smallpox Vaccine Clinics*

* IND forms are subject to change. The contained example forms should be utilized for planning and educational/training purposes only. The most current IND forms will be distributed with vaccine shipments or available through the state-based co-investigator and should be utilized for all actual IND program administration within vaccination clinics.

Investigational Smallpox Vaccine

Screening and Consent Signature Form

Date:_____

Patient Identifying Number: _____

(Please check only one: ☐ SSN ☐ Passport # ☐ Driver's license # and Issuing State:____ Other ☐ , List:_____ None available☐)

Participant Information:

Print Name:_____ Date of Birth:_____ Sex: M☐ F☐

Current Address:_____

City *State* *Zip code* *Telephone Number*

Contact History:

Have you been told that you may have been a contact to someone with smallpox? Yes ☐ No☐

Have you been in contact with someone who had a bad rash in the past 3 weeks? Yes ☐ No ☐

Screening:

Do the following apply to you or your child?

Yes	No	Maybe	
☐	☐	☐	Immune system problems such as HIV/AIDS, cancer, leukemia, lymphoma, organ transplant, agammmaglobulinemia
☐	☐	☐	Autoimmune system problem like lupus that weakens your immune system
☐	☐	☐	Currently taking medicines like oral steroids (such as prednisone), chemotherapy agents/radiation, or organ transplant medications.
☐	☐	☐	Eczema, atopic dermatitis, or a history of eczema or atopic dermatitis
☐	☐	☐	Other skin conditions such as burns, impetigo, contact dermatitis, or zoster.
☐	☐	☐	Currently pregnant
☐	☐	☐	Allergy to antibiotics polymixin B, streptomycin, chlortetracycline, neomycin
☐	☐		Age less than 1 year old
☐	☐		Have additional questions about any health conditions you might have and whether you should be vaccinated
☐	☐		Are you less than 18 years of age and your parent or guardian is not with you?
☐	☐		Do you have any questions you would like to have answered before you decide on vaccination?
☐	☐		This adult is incapacitated and this screening/consent signature form is being completed by the parent or guardian [checked box for this question alone does not require additional screening counseling]

Participant Informed Consent Signature for Vaccination:

I HAVE:

- Viewed the vaccine informational video or read the video script in the packet, or talked with a translator.
- Received the information packet (which includes information on why this vaccine is being offered, why it is investigational, voluntary participation, benefits, risks, side effects, risks to contacts, precautions for vaccination and adverse events, Vaccinia Immune Globulin, cidofovir, care of my vaccination site, confidentiality, costs, what to do in case of injury, my right to refuse, alternative treatments, and contact information for problems or questions.)
- Completed the medical screening form
- Received counseling and additional information if I was identified as a contact or fell into any of the groups listed on the front of this form
- Had the opportunity to have my questions answered

I have been informed of why smallpox vaccine is being made available, the risks and benefits associated with vaccination and based on the information provided to me, I have decided to receive or have my child receive smallpox vaccination today.

Participant Signature/ Parent or Guardian:_____

FOR VACCINATOR USE ONLY

Vaccine clinic ID:_____Vaccinator ID (name or ID number): _____

Vaccine Name: ☐ Dryvax ☐ Aventis ☐ ACAM1000 ☐ ACAM2000 Lot #: _____

Smallpox Vaccine Investigation of New Drug (IND)

Record of Immunization

Bring this card with you if you present for revaccination or for evaluation of a vaccine related illness

Name: _____

Patient Identifying Number (use same ID# as Medical Screening Form): _____

Please identify that this number is:

- ☐ SSN
- ☐ Passport # and Issuing Country_____
- ☐ Drivers license # and Issuing State:_____
- ☐ Other: List_____
- ☐ None available

Address: _____

(City) (State) (Zip code)

Telephone: (_____)_____

BELOW TO BE FILLED OUT BY VACCINE ADMINISTRATORS

Date (mm/dd/yy)	Vaccine Type (check box)	Vaccine LOT #	Vaccination Site (check box)	Clinic Name	Person administering vaccine
	Dryvax ☐ Aventis ☐ ACAM1000 ☐ ACAM2000 ☐		Right arm ☐ Left arm ☐ Other ☐		
	Dryvax ☐ Aventis ☐ ACAM1000 ☐ ACAM2000 ☐		Right arm ☐ Left arm ☐ Other ☐		
	Dryvax ☐ Aventis ☐ ACAM1000 ☐ ACAM2000 ☐		Right arm ☐ Left arm ☐ Other ☐		
	Dryvax ☐ Aventis ☐ ACAM1000 ☐ ACAM2000 ☐		Right arm ☐ Left arm ☐ Other ☐		

SMALLPOX VACCINE

WHAT YOU NEED TO KNOW IF YOU HAVE SKIN CONDITIONS SUCH AS ECZEMA, ATOPIC DERMATITIS, IMPETIGO, UNHEALED BURNS, CONTACT DERMATITIS, OR CHICKEN POX

Please refer to your Smallpox Vaccine General Information Sheet for additional information about smallpox, smallpox vaccine, vaccine reactions, and vaccine site care instructions.

1 What is smallpox?

Smallpox is a serious disease. It is caused by a virus called ***variola,*** which is spread from person to person through close contact.
Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected)

The last case of smallpox was in 1978.

2 Why am I being offered smallpox vaccine today?

Smallpox vaccine is being offered to you today because one of the following has happened:

- you have been exposed to smallpox virus,
- you have been in close contact with someone who has smallpox,
- you have not been exposed to the virus, but you live with someone who has been exposed and could develop smallpox,
- you have not been exposed to the virus yet, but there has been a smallpox outbreak and you may be exposed in the future.

3 What do I need to know about smallpox disease with a skin condition?

If you have a skin condition and are exposed to smallpox virus, if you develop the disease, you are at no known additional risk of death from smallpox than people who do not have a skin condition. Approximately one person of every three who gets smallpox dies from the disease.

4 Should I get the smallpox vaccine?

- In an outbreak emergency, everyone who has been in contact with a person with smallpox or was exposed to the virus is recommended to receive the one-dose vaccine, regardless of his or her age, allergies, pregnancy, or medical conditions.
- If you have one of the skin conditions listed above, and ***you have been exposed*** to smallpox, you are advised to accept the vaccine because your risk of catching the disease is greater than any additional risks from the vaccine.
- If you have one of the skin conditions listed above, and ***you have not been exposed*** to smallpox, you are advised to avoid the vaccine because your risk of catching the disease is less than any special risks from the vaccine.

5 If I have a skin condition, when should I not be vaccinated, or wait to be vaccinated?

- Anyone who has eczema or has a past history of eczema should not get smallpox vaccine unless they have been told that they have been exposed to smallpox virus.
- Anyone with certain skin conditions, such as allergic rash, severe burns, impetigo, chickenpox, should wait until the condition clears up before getting smallpox vaccine, unless they have been told that they have been exposed to smallpox virus.
- If someone in your household requires vaccination, and you have a high-risk skin condition, you should not have contact with that person, or live with them, until their vaccination mark has completely healed and the scab has fallen off.

6 What are the additional risks from smallpox vaccine to people with skin conditions?

All people receiving smallpox vaccine are at risk for the complications discussed on your general vaccine information sheet.

In addition, people with skin conditions like eczema and atopic dermatitis have a high risk of developing a severe rash called "Eczema Vaccinatum" if they receive smallpox vaccine or touch another person's vaccination mark, before it is completely healed and the scab has fallen off. While most people recover from this rash, it can be quite severe, sometimes leading to death.

Even people who do not have eczema at the time of vaccination, but have a past history of eczema, have an increased chance of developing Eczema Vaccinatum.

7 What special signs should I look for?

Fever or a severe rash over the entire body, a reaction that spreads from the vaccination site and does not get better, or blisters on other parts of the body.

8 What should I do if I think I am vaccinated and think that I am having a bad reaction to the vaccine?

Call a doctor right away. Tell your doctor what is happening, the date and time it started, and when the vaccination was given. Your doctor will tell you what to do next.

9 What are the treatments for Eczema Vaccinatum caused by smallpox vaccine?

There are two treatments that may help if you develop eczema vaccinatum. They are called Vaccinia Immune Globulin (VIG) and Cidofovir**.** Both of these medications are given by a needle into the vein (intravenous, IV) and require you to be in the hospital. They are investigational and may cause a number of serious side effects themselves.

CDC (Centers for Disease Control and Prevention) will pay for the costs of these medicines. The other costs of hospital and medical care will not be covered by CDC and will need to be paid by you, your insurer, Medicare, or Medicaid.

10 What if I decide not to get the smallpox vaccine?

- It is your choice whether or not to get the vaccine.
- If you ***have*** been in contact with a person who has smallpox and you decide ***not*** to get the vaccine, you may be placed in isolation for 18 days. This means that you would not be able to be in contact with other people who have not been vaccinated. You would not be able to stay at home or go to work. You will be watched to be sure that you do not develop smallpox and to be sure that you do not give smallpox to others.
- If you ***have not*** been in contact with anyone with smallpox and you decide ***not*** to get the vaccine, you should stay away from anyone you suspect may have smallpox. You may go to work and school, but would probably be safest if you stay close to home.

11 How can I learn more?

- If you have questions about your or your child's vaccination site, please call the 24-hour hotline at 1-800-…….
- If you have questions about smallpox or the vaccine, call your local or state health department at telephone number……. Or the Centers for Disease Control and Prevention at telephone number……
- If you have questions about your rights as a vaccine recipient please call 1-800-584-8814. You will be connected to the Deputy Associate Director for Science at CDC. Please leave a message with your name and phone number, including your area code. Someone will call you back as soon as possible.

SMALLPOX VACCINE

WHAT YOU NEED TO KNOW IF YOUR CHILD IS LESS THAN 1 YEAR OLD

Please refer to your Smallpox Vaccine General Information Sheet for additional information about smallpox, smallpox vaccine, vaccine reactions, and vaccine site care instructions.

1 What is smallpox?

Smallpox is a serious disease. It is caused by a virus called ***variola***, which is spread from person to person through close contact.
Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected)

The last case of smallpox was in1978.

2 Why is my child being offered smallpox vaccine?

Your child is being offered smallpox vaccine because one of the following has happened:

- your child has been exposed to smallpox virus
- your child has been in close contact with someone who has smallpox
- your child has not been exposed to the virus but live with someone who was exposed and could develop smallpox
- your child hasnot been exposed to the virus yet but there has been a smallpox outbreak and he/she may be exposed in the future.

3 What do I need to know about smallpox disease in young children?

Smallpox in very young children can be very severe. Children less than 4 years old may have a greater risk of dying from smallpox than older children. Children older than 4 years usually handle smallpox better than younger children and have less risk of dying from the disease.

4 What additional risks does my child have from the vaccine if he/she is younger than 1 year old?

All people who receive smallpox vaccine can have some risks from the vaccine. These risks are discussed in your general vaccine information sheet.

Infants less than 1 year old who are vaccinated may have a greater risk of developing complications from the vaccine, such as brain swelling or a total body rash. Brain swelling is a rare complication but can occur in about 42 out of every 1 million infants who are vaccinated. Brain swelling can lead to permanent brain damage or even death.

The total body rash than can develop after vaccination is usually mild and resolves on its own without treatment but can rarely be severe and require medical treatment.

Young children may also be more likely to touch the vaccination site with their hands and transfer vaccine virus to another part of the body (such as the eyelid, face, mouth, genital area), causing a similar sore to develop there. This may be avoided by covering the site and making sure the child doesn't touch the site and washes his/her hands well if they do.

5 Should my child get the smallpox vaccine?

In an outbreak emergency, everyone who has been in contact with a person with smallpox or was exposed to the virus is recommended to receive the one dose vaccine, regardless of his or her age, allergies, pregnancy, or medical conditions.

If your child was exposed to smallpox virus, the vaccine would be recommended for you in order to try and prevent or lessen the severity of smallpox.

6 If my child is less than 1 year old, when should they *not* be vaccinated, or wait to be vaccinated?
You should consider waiting to have your child vaccinated until he/she is older than 1 year, if he/she has ***not*** been in contact with smallpox virus or a person with smallpox.

7 What should I do if my child is vaccinated and I think that my child is having a bad reaction to the vaccine?
Call a doctor right away. Tell your doctor what is happening, the date and time that it started, and when the vaccination was given. Your doctor will advise you on what to do next.

8 What are the treatments for reactions to smallpox vaccine?
There are two treatments that may help if your child has a serious reaction to the smallpox vaccine. They are called Vaccinia Immune Globulin (VIG) and Cidofovir. Both of these medications are given by a needle into the vein (intravenous, IV) and require you to be in the hospital. They are investigational and may cause a number of serious side effects themselves. These treatments would not be effective for brain swelling from vaccination, but other medical treatments would be used.

CDC (Centers for Disease Control and Prevention) will pay for the costs of these medicines. The other costs of hospital and medical care will ***not*** be covered by CDC and will need to be paid by you, your insurer, Medicare, or Medicaid.

9 What if I decide not to get the smallpox vaccine for my child?

- It is your choice whether or not to get the vaccine for your child.
- If your child ***has*** been in contact with a person who has smallpox and you decide ***not*** to get the vaccine for your child, your child may be placed in isolation for 18 days. This means that your child would not be able to be in contact with other people who have not been vaccinated. Your child may not be able to stay at home. Your child will be watched to be sure that he/she does not develop smallpox and to be sure that they do not give smallpox to others if they do develop the disease.
- If your child ***has not*** been in contact with anyone with smallpox and you decide ***not*** to get the vaccine for your child, your child should stay away from anyone you suspect may have smallpox.
- If your child is not vaccinated and lives in the same house with a person who has been vaccinated because they were exposed to smallpox virus, you should consider having your child live elsewhere for a while and avoid contact with that person until they are no longer at risk of developing smallpox. Public health officials will tell you when your household member is no longer at risk for developing smallpox. Usually this period is for 18 days after their contact with smallpox virus or 14 days after their vaccination.

10 How can I learn more?

- If you are vaccinated and have questions about your vaccination site, please call the 24-hour hotline at 1-800-…….
- If you have questions about this vaccine or smallpox, call your local or state health department at telephone number……. Or the Centers for Disease Control and Prevention at telephone number……
- If you have questions about your rights as a vaccine recipient, please call 1-800-584-8814. You will be connected to the Deputy Associate Director for Science at CDC. Please leave a message with your name and phone number, including your area code. Someone will call you back as soon as possible.

SMALLPOX VACCINE

WHAT YOU NEED TO KNOW IF YOU ARE PREGNANT

Please refer to your Smallpox Vaccine General Information Sheet for additional information about smallpox, smallpox vaccine, vaccine reactions, and vaccine site care instructions.

1 What is smallpox?

Smallpox is a serious disease. It is caused by a virus called ***variola***, which is spread from person to person through close contact.
Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected)

The last case of smallpox was in 1978.

2 Why am I being offered smallpox vaccine?

You are being offered smallpox vaccine because one of the following has happened:

- you have been exposed to smallpox virus
- you have been in close contact with someone who has smallpox
- you have not been exposed to the virus but live with someone who was exposed and could develop smallpox
- you have not been exposed to the virus yet but there has been a smallpox outbreak and you may be exposed in the future.

3 What do I need to know about smallpox disease during pregnancy?

If you are pregnant and are exposed to smallpox virus, if you develop the disease, you may have a more serious illness and a higher risk of dying than a woman who is not pregnant. The infection could also cause the following to occur:

- miscarriage
- stillbirth
- premature birth
- baby born with no problems or infection

Before smallpox was eradicated in 1980, smallpox infections caused pregnancies to end early in 75% of pregnant women who developed the disease early in their pregnancy and in 60% of the women who developed the disease later in their pregnancy.

4 What additional risks do I have from the vaccine if I am pregnant?

All people who receive smallpox vaccine can have some risks from the vaccine. These risks are discussed in your general vaccine information sheet.

Smallpox vaccine is a live-virus vaccine made from a virus called ***Vaccinia***. In general, vaccination with vaccines that have live viruses are not recommended during pregnancy. On rare occasions, smallpox vaccine can cause an infection in the unborn child of a pregnant woman who was vaccinated during her pregnancy that can lead to premature delivery, stillbirth, or death in the child soon after delivery. Even though millions of people have been vaccinated against smallpox, less than 50 cases of this have been reported.

5 Should I get the smallpox vaccine?

In an outbreak emergency, everyone who has been in contact with a person with smallpox or was exposed to the virus is recommended to receive the one-dose vaccine, regardless of his or her age, allergies, pregnancy, or medical conditions

If you are pregnant and were exposed to smallpox virus, the vaccine would be recommended for you in order to try and prevent or lessen the severity of smallpox.

6 If I am pregnant, when should I *not* be vaccinated, or wait to be vaccinated?

You should consider waiting to be vaccinated until after you have delivered your baby if you have ***not*** been in contact with smallpox virus or a person with smallpox.

7 What should I do if I am vaccinated and think that I am having a bad reaction to the vaccine?

Call a doctor right away. Tell your doctor what is happening, the date and time that it started, and when the vaccination was given. Your doctor will advise you on what to do next.

8 What are the treatments for reactions to smallpox vaccine?

There are two treatments that may help if you have a serious reaction to the smallpox vaccine. They are called Vaccinia Immune Globulin (VIG) and Cidofovir. Both of these medications are given by a needle into the vein (intravenous, IV) and require you to be in the hospital. They are investigational and may cause a number of serious side effects themselves.

CDC (Centers for Disease Control and Prevention) will pay for the costs of these medicines. The other costs of hospital and medical care will ***not*** be covered by CDC and will need to be paid by you, your insurer, Medicare, or Medicaid.

9 What if I decide not to get the smallpox vaccine?

- It is your choice whether or not to get the vaccine.
- If you ***have*** been in contact with a person who has smallpox and you decide ***not*** to get the vaccine, you may be placed in isolation for 18 days. This means that you would not be able to be in contact with other people who have not been vaccinated. You would not be able to stay at home or go to work. You will be watched to be sure that you do not develop smallpox and to be sure that you do not give smallpox to others.
- If you ***have not*** been in contact with anyone with smallpox and you decide ***not*** to get the vaccine, you should stay away from any one you suspect may have smallpox.
- If chose not to be vaccinated and you live in the same house with a person who has been vaccinated because they were exposed to smallpox virus, you should consider living apart from and avoiding contact with that person until they are no longer at risk of developing smallpox. Public health officials will tell you when your household member is no longer at risk for developing smallpox. Usually this period is for 18 days after their contact with smallpox virus or 14 days after their vaccination.

10 How can I learn more?

- If you are vaccinated and have questions about your vaccination site, please call the 24-hour hotline at 1-800-…….
- If you have questions about this vaccine or smallpox, call your local or state health department at telephone number……. Or the Centers for Disease Control and Prevention at telephone number……
- If you have questions about your rights as a vaccine recipient, please call 1-800-584-8814. You will be connected to the Deputy Associate Director for Science at CDC. Please leave a message with your name and phone number, including your area code. Someone will call you back as soon as possible.

INVESTIGATIONAL SMALLPOX VACCINE

WHAT YOU NEED TO KNOW IF YOU HAVE IMMUNE SYSTEM PROBLEMS (HIV, AIDS, ORGAN TRANSPLANTS, CANCER CHEMOTHERAPY, HIGH-DOSE STEROID THERAPY, RADIATION THERAPY, CELLULAR OR HUMORAL IMMUNITY PROBLEMS, AND OTHER IMMUNE SYSTEM PROBLEMS)

Please refer to your Smallpox Vaccine General Information Sheet for other facts about smallpox, smallpox vaccine, vaccine reactions, and vaccine site care instructions.

1 What is smallpox?
Smallpox is a serious disease. It is caused by a virus called ***variola,*** which is spread from person to person through close contact.
Smallpox can cause:

- a severe rash, which can leave scars when healed
- high fever
- tiredness
- severe headaches and backache
- blindness
- death (in up to 30% of those infected)

The last case of smallpox disease was 1978.

2 Why am I being offered smallpox vaccine?
You are being offered smallpox vaccine because one of the following has happened:

- you have been exposed to smallpox virus
- you have been in close contact with someone who has smallpox
- you have not been exposed to the virus but live with someone who was exposed and could develop smallpox
- you have not been exposed to the virus yet, but there has been a smallpox outbreak and you may be exposed in the future.

3 What do I need to know about smallpox disease in people with immune system problems?
The last cases of smallpox disease occurred over thirty years ago. At that time, little was known about immune system problems. While we know a lot about the immune system now, we do not have experience with people with immune system problems having smallpox. From what we know about serious infections in people with immune system problems, we believe that smallpox infections in these people may be more serious than smallpox infections occurring in people with healthy immune systems.

4 What other risks from vaccine do I have if I have immune system problems?
All people who receive smallpox vaccine can have some risks from the vaccine. These risks are talked about in your general vaccine information sheet.

The smallpox vaccine is made from a live vaccinia virus (not smallpox virus). People with immune system problems are often advised to avoid vaccines made from live viruses because their immune systems cannot stop the growth of the virus in their bodies. In general, the risk for severe reactions from smallpox vaccine in people with immune system problems is not known. There have been a few cases of a serious vaccine infection in people with HIV who have received the smallpox vaccine. This infection spreads through the body and can occur in two forms: generalized vaccinia and progressive vaccinia. You can see pictures of these rashes on your general vaccine information sheet. In rare cases, these rashes can lead to illnesses that cause death.

There is no proof that receiving smallpox vaccination will cause immune system problems to happen faster.

There are no facts about the level of immunosupression (T-cell count) that would put a

person with immune system problems at risk for bad reactions from the vaccine.

5 Should I get the smallpox vaccine?
In an outbreak emergency, everyone who has been in contact with a person with smallpox or was exposed to the virus is advised to receive the one-dose vaccine, regardless of his or her age, allergies, pregnancy, or medical conditions.

If you have been exposed to smallpox virus, the vaccine would be advised for you in order to try and prevent or lessen the seriousness of smallpox.

6 When should I *not* be vaccinated or wait to be vaccinated?
If you have ***not*** been in contact with smallpox virus or a person with smallpox, you should think about not being vaccinated or waiting to be vaccinated until you have completed any treatments that affect your immune system function. Often, the waiting period can be as long as 3 months after finishing treatment. Your personal doctor should advise you on when it will be safer to receive the vaccination.

7 What do I do if I am vaccinated and think that I am having a bad reaction to the vaccine?
Call a doctor right away. Tell your doctor what is happening, the date and time that it started, and when the vaccination was given. Your doctor will advise you on what to do next.

8 What are the treatments for reactions to smallpox vaccine?
There are two treatments that may help if you have a serious reaction to the smallpox vaccine. They are called Vaccinia Immune Globulin (VIG) and Cidofovir (VISTIDE®). Both of these medicines are given by a needle into the vein (intravenous, IV) and require you to be in the hospital. They are investigational and may cause a number of serious side effects. These medicines would be given if supplies are available and both your doctor and experts at the Centers for Disease Control and Prevention (CDC) think they are necessary. These treatments are not effective for brain swelling from vaccination, but other medical treatments would be used.

CDC will pay for the costs of these medicines. The other costs of hospital and medical care will ***not*** be covered by CDC and will need to be paid by your insurer, Medicare, Medicaid or you.

9 What if I decide not to get the smallpox vaccine?

- It is your choice whether or not to get the vaccine.
- If you ***have*** been in contact with a person who has smallpox and you decide ***not*** to get the vaccine, you may be kept apart from other people for 18 days. This means that you would not be able to be in contact with other people who have not been vaccinated. You will not be able to stay at home or go to work. You will be watched to be sure that you do not develop smallpox and/or give smallpox to others.
- If you ***have not*** been in contact with anyone with smallpox and you decide ***not*** to get the vaccine, you should stay away from anyone you suspect may have smallpox. Public health experts can give you more facts on special things you can do to protect yourself and how long you will need to do these things***.***
- If you are not vaccinated and live in the same house with a person who has been vaccinated because he/she was exposed to smallpox virus, you should consider living apart from and avoid contact with that person until he/she is no longer at risk of getting smallpox. Public health experts will tell you when your household member is no longer at risk for getting smallpox. Usually this period is for 18 days after the contact with smallpox virus or 14 days after the vaccination.

10 How can I learn more?

- If you are vaccinated and have questions about your vaccination site, please call the 24-hour hotline at 1-800-…….
- If you have questions about this vaccine or smallpox, call your local or state health department at telephone number……. or the CDC at telephone number……
- If you think you have been injured or have questions about your rights as a participant in this program please call 1-800-584-8814. You will be connected to the Deputy Associate Director for Science at CDC. Please leave a message with your name and phone number, including your area code. ***Say that you are calling about CDC protocol # 3585.*** Someone will call you back as soon as possible.

INFORMATION FOR PEOPLE WHO HAVE BEEN IN CLOSE CONTACT TO A PERSON WITH SMALLPOX

You are receiving this information because you have been in close contact with someone who has smallpox. People who have been in close contact with a person who has smallpox are sometimes called "contacts."

What is close contact?
Close contact means that you:

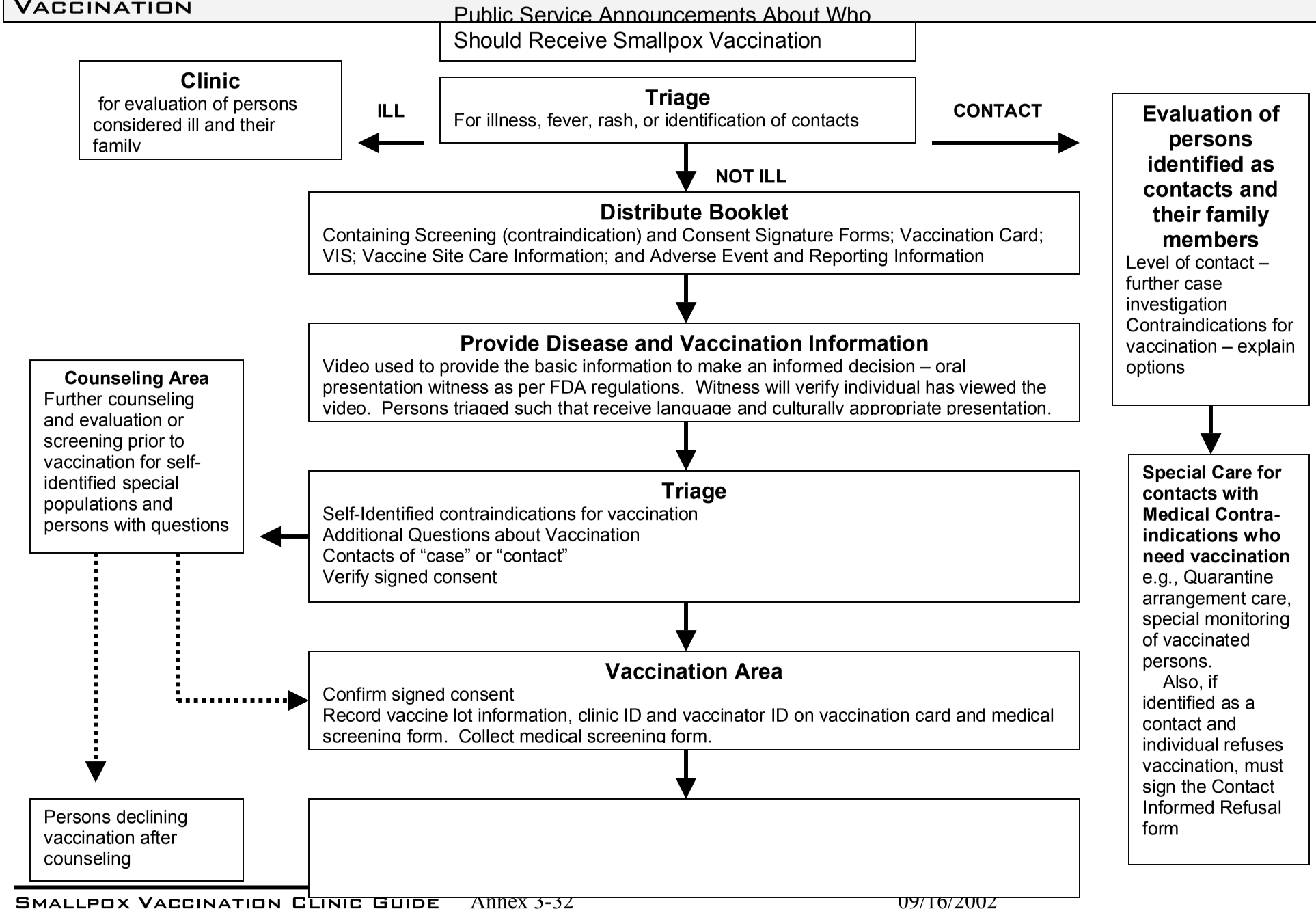
- Live in the same home (house, apartment, shelter) as someone who has smallpox
- Have spent at least 3 hours in the same room with someone who has smallpox

What happens to "contacts?"

- Contacts are at risk of developing smallpox because the smallpox virus may have been spread to them from the person with smallpox. The virus is spread through the air on tiny drops of saliva when the infected person talks, laughs, coughs, or sneezes.
- Contacts are offered smallpox vaccination. The vaccine can protect some contacts from getting sick with or dying from smallpox if it is given within a few days of spending time with the sick person. It is considered advisable for contacts to get the vaccine regardless of their medical conditions, allergies or age. This is because ***for contacts*** the risk of serious illness or death from getting smallpox is greater than the risk of getting sick from the vaccine.
- Contacts are watched carefully for signs and symptoms that they are getting sick with smallpox disease. You will be watched for signs and symptoms of smallpox even if you take the vaccine.
- The signs and symptoms include:
  - Temperature over 101° F or 38° C orally
  - A red skin rash
  - Tiredness
  - Backache
  - Headache
  - Muscle aches
- Someone from the Department of Health will visit or call you twice every day to check you for these signs of getting smallpox, or you may be asked to call the Health Department twice a day to let them know how you are feeling.
- You will be watched for these signs and symptoms for 18 days, which is the length of time it can take someone to develop smallpox.
- People you live with and work with ***may*** also be offered vaccination to protect them in case you develop smallpox.
- If someone you live with cannot take the vaccine because of a medical condition, or decides not to take the vaccine, they will have to make arrangements to live somewhere else for the 18-day period.
- During the 18-day period, you may leave your house, but you should not travel more than 1 hour from your home. This allows you to be able to return home quickly if you begin feeling ill.

Please call 1-800-xxx-xxxx, if you have other questions.

Fig 2. Informed Consent Process Flow for Use During Emergency Smallpox Vaccination



ATTACHMENT 2

Mass Patient Care Smallpox Response Planning Template for State and Local Jurisdictions

SMALLPOX RESPONSE PLANNING TEMPLATE FOR STATE AND LOCAL JURISDICTIONS

Planning parameters for managing the consequences of the release of smallpox, as a weapon of mass destruction will include a variety of factors at the local and state levels. All planning efforts must work in conjunction with established federal support planning. This template, along with the guidelines set forth by the CDC, will allow local jurisdictions and state agencies to effectively respond to a smallpox incident.

PLANNING CONSIDERATIONS FOR MASS PATIENT CARE

The primary consideration needs to be for the rapid expansion of capacity. This can be accomplished in a number of ways.

- **Expand existing personnel capacity by augmenting staff**

  Expansion of physical capacity can be accomplished by opening closed beds, wards, and floors. Converting large, interior spaces into patient care areas can develop further capacity.

  Looking first to some or all of the following local sources can augment staff: Medical Schools, Osteopathic Schools, Nursing Schools, Physician Assistant Programs, Dental Schools, Veterinary Medicine Schools, Vocational Nursing Programs, Physical Therapy Programs, Lab Technology Programs, EMT Training Programs, Dental Assistant/Hygienist Programs, Medical Records Programs, Nursing Assistant Programs, local chapters of the American Red Cross, Salvation Army, Fire Academies, and Police Academies. Consider adjacent/nearby military training reservations/academies.

  NOTE A: Each of these potential sources for augmenting staff may require the establishment of a Memorandum of Understanding. This must be done ahead of time. In addition to these local sources, the Department of Health and Human Services is initiating planning for the development of local Volunteer Medical Reserve Corps. (Information on building a local Volunteer Medical Reserve Corps will be provided by the Department of Health and Human Services.) Guidance for the development of a local Medical Reserve Corps will be made available in the near future.

  NOTE B: Each of these cohorts adds an additional vaccination requirement.

  An available source(s) of staff augmentation outside of local sources are Traveling Nurse companies. These companies advertise in the national nursing journals. Beyond that, it may be necessary to turn to assets that are available statewide and ultimately to the Federal Government for additional assets.

> It is important to remember that augmentation needs for Mass Patient Care are *in addition to* those required for a Mass Vaccination Program. (It has been estimated that the personnel required to vaccinate a population of 1,000,000 persons over 7 days could be as many as 4,600 persons.)

- **Use of auxiliary facilities (e.g. hotels/schools)**
  An important consideration in planning for the use of auxiliary facilities is that those facilities may not ever be able to be used again as originally intended. The use of auxiliary facilities

may require that some "standards of care" be relaxed. If so, it is important to address these legislative issues/concerns during the planning stage.

- **Move patients out (non-smallpox)**
- **Move Resources In (personnel, portable facilities)**
  Department of Defense mobile/portable facilities can be accessed through Emergency Support Number 8 of the Federal Response Plan.

  Home care may be suitable for the X and R patient cohorts described below. Plan for the three facility types recommended by the CDC in the referred to document. (C=Smallpox Patients; X=Vaccinated Febrile Patients without Rash; R=Asymptomatic Contacts)
  http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/GuideC/guide-C-pages1-18only.pdf

COMMAND AND CONTROL

All elements of your command and control must be exercised regularly.

- Utilize the incident command system.
- Utilize the unified command system.
- Identify relevant contact information and update regularly.
- Notify necessary local, state, and federal agencies.
- Centralize Communications Control Center.
- Centralize Control of Medical Logistics and Equipment
- Centralize Control of Transportation.
- Consider use of non-traditional (alternate) means of emergency transportation, such as using public transportation for patient movement.
- Establish procedures for patient movement to appropriate facilities and mobility of healthcare providers to/from treatment facilities.
- Develop a family support center in coordination with the American Red Cross for the dissemination of information to family members of victims.

PERSONNEL REQUIREMENTS

Consider a vaccination plan for both personnel and their families.

Preparing for the consequences of a smallpox outbreak will require significant numbers of personnel associated with each component of the response. Resources provided by Federal and State agencies will not be sufficient to offset the medical human resource needs associated with a large-scale smallpox outbreak. Appropriate staffing of health and medical requirements will be critical for the success of this operation.

- Develop a plan for coordination with other local, state and federal agencies to avoid "double counting" potential augmentation resources.
- Address credentialing issues to allow non-local physicians and other care providers to legally practice within jurisdiction. Ensure that during a smallpox response, unlicensed personnel can be utilized under the supervision of licensed personnel.
- Manage the dissemination of information via Public Affairs.
- In-hospital providers and first responders who would respond to a smallpox case should be identified.
- Maintain adequate support staff (laundry, housekeeping, central supply) to provide mass care.
- Identify adequate hospital-based infectious disease specialists for disease consultation.

- Establish separate staffing to maintain normal medical functions, such as labor and delivery, non-related injuries.
- Provide for the segregation of providers treating smallpox victims from other providers.
- Establish control procedures to prevent medical personnel from fleeing from or flooding into medical treatment facilities.
- Consider the potential loss of healthcare providers due to smallpox exposure or fear of smallpox exposure.
- Consider auxiliary personnel to assist with mass care (e.g., medical/nursing/veterinary students).
- Establish vaccination plan for healthcare providers, public health officials, and their families.
- Identify personnel mobilization points.
- Provide for the welfare and safety of emergency workers. It is important to remember that auxiliary response personnel may number in excess of 5,000 persons.
- Provide appropriate personal protective equipment and infection control measures for personnel.
- Include numbers of personnel required by category (physician, nurse, EMT).
- Consider the use of non-traditional personnel as described on Page 1.
- Use auxiliary personnel (who may be trained on the spot but will require close professional supervision).
- Train support personnel (e.g., clergy, mental health workers) in the use of personal protective equipment and infection control procedures.
- Develop family support plan for medical providers and response personnel.
- Develop plan for the housing, feeding, and clothing needs of emergency responders.

TREATMENT

- Train medical staff to recognize and manage smallpox patients, special considerations include immune compromised patients and patients with adverse vaccination reactions.
- Provider appropriate personal protection equipment.
- Provide treatment protocols to all providers that include plans for immunocompromised patients.
- Prepare to maintain appropriate documentation.
- Develop triaging procedures for smallpox victims.
- Establish a hotline number for information on vaccination takes.
- Develop information for those whose vaccinations do not take, including information about revaccination.
- Must be prepared to treat persons with adverse reactions to vaccination. These patients must not return to the mass vaccination site.
- Utilize telemedicine for consultation.

PROVISION OF MENTAL HEALTH SERVICES

- Plan for mental health services for victims and their families.
- Plan for mental health services for emergency workers and their families.
- Plan for the management of the worried well and provision for psychological counseling of the same.

PATIENT TRACKING

- Match patients with appropriate medical facilities and other pre-selected treatment locations.
- Track patients at all facilities.

FACILITIES

- Plan for the three facility types recommended by the CDC in the referred to document. (C=Smallpox Patients; X=Vaccinated Febrile Patients without Rash; R=Asymptomatic Contacts)
  http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/GuideC/guide-C-pages1-18only.pdf
- Home care may be suitable for the cohorts X and R noted above.
- Plan for admission procedures for smallpox patients into hospitals or established treatment facility.
- Establish a standardized community reporting method to report bed availability.
- Establish plans for the expedient expansion of the existing healthcare system capacity.
- Utilize isolation beds within existing facilities.
- Maximize utilization of existing healthcare facilities, including augmentation of staff.
- Consider secondary treatment centers for temporary augmentation of healthcare capabilities.
- Consider the use of long-term care facilities.
- Consider the use of warehouses/schools, keeping in mind that such use may render the facilities permanently contaminated and/or may require extensive decontamination.
- Consider the use of neighborhood-based treatment centers versus centralized treatment centers.
- Consider the integration of Federal assets, such as Veteran Administration (VA) and Department of Defense (DoD) medical treatment facilities and NDMS/DoD field hospitals into existing local plans.
- Establish procedures to staff, equip and transport personnel and victims to/from secondary treatment facility.
- Establish procedures for the movement of patients not infected with smallpox to other locales (e.g., NDMS).
- Ensure adequate monitoring of the food, air and water within medical treatment facilities.
- Enforce strict infection control procedures.
- Review and utilize CDC's Decontamination Guidelines. (Guide F: Pages 1-6)
  http://www.bt.cdc.gov/Age***n***t/Smallpox/Smallpox.asp

ISOLATION OF PATIENTS

- Identify personnel responsible for local/state coordination of activities.
- Identify appropriate facilities to be utilized for isolation and care.
- Identify appropriate law enforcement entities to enforce isolation and to control access to facilities.
- Review and coordinate plan with CDC Isolation Guidelines.
- CDC Isolation and Quarantine Guidelines (Guide C: Pages 1-23)
  http://www.bt.cdc.gov/Agent/Smallpox/Smallpox.asp

SECURITY

- Provide security for medical treatment facilities and medical personnel (e.g., crowd control, preventing a rush of individuals wanting treatment and vaccinations).
- Provide security for medical supplies.

NOTE C: This may create a new cohort requiring vaccination.

TRAINING AND EXERCISES

- Train personnel regarding the clinical aspects of a smallpox response.
- Train healthcare and civilian personnel regarding the principles of homecare.
- Train personnel on proper isolation techniques.
- Exercise mechanisms to adapt and expand existing facilities.
- Exercise all components of the local response system.

PLANNING CONSIDERATIONS FOR MASS FATALITY MANAGEMENT

- Plan for vaccinating mortuary personnel and their families.
- Maximize use of existing facilities.
- Establish plans for the use of non-traditional facilities to augment existing facilities (e.g., cold storage, reefers).
- Establish plans requesting deployment of NDMS/DoD assets (portable morgue facilities and personnel to augment local capability).
- Establish plans to identify the deceased.
- Establish plans to augment with NDMS/DoD assets, as necessary.
- Establish decontamination/isolation procedures available to terminal care providers.
- Establish containment procedures for the deceased, following established protocols for double-body bagging/double taping.
- Exclude embalming procedures.
- Consider use of vaults for burial purposes, if they are available and can handle more than one body. Above ground mausoleums will not be used.
- Establish plans for engaging the religious community.
- Prepare for appropriate documentation.

ATTACHMENT 3

Clinic Preparation Checklists

Overall Planning and Management

- ❑ Metro-Central Headquarters Identified
  - ❑ Location
  - ❑ Staffing for General Operations
  - ❑ Staffing for Problem-Solving
  - ❑ Memoranda of Understanding (as required)
  - ❑ Communications Protocol
- ❑ Central Vaccine Storage Site Identification
  - ❑ Central facility with security and backup generator
  - ❑ Central Supplies Warehouse
  - ❑ Shipping Company Selection
  - ❑ Printing Company Selection (for mass form production)
- ❑ All Supply Resources Identified (See Supply and Equipment Checklist)
- ❑ Vaccination Clinic Site Identification (x20)
- ❑ Procedure for Designating Vaccination Site/Time (i.e., zip code? SSN?)
- ❑ Procedure for Identification
- ❑ Computer Networking Identified for Exchange of Data
- ❑ Standing Orders for Emergencies
- ❑ Agreement(s) with local media for public service announcement coverage/production

CLINIC SITE CHECKLIST

Clinic Site: **Number of**

- ☐ Facility Resources
  - ☐ Large, open space to accommodate clinic flow
  - ☐ Weather Protection for those in line
  - ☐ Ability to be made secure
  - ☐ Backup generator
  - ☐ Accessible for People with Disabilities
  - ☐ Ease of Access for Community
  - ☐ Communication Resources Available
  - ☐ Equipment Resources Available (See Supply and Equipment Checklist)
  - ☐ Tables Available
  - ☐ Screening Rooms Available
  - ☐ Waste Disposal
  - ☐ Rest Area for Staff
  - ☐ Transportation/Parking for Staff?
- ☐ Transportation Procedures
  - ☐ Parking Identified
  - ☐ Bus Service Company Selection
  - ☐ Routes for Bus Service
- ☐ Vaccination Clinic Personnel Identified (See Personnel Checklist)
  - ☐ Vaccinators
  - ☐ Physician Evaluators
  - ☐ Support Functions
- ☐ HIV Testing Referral Plan
- ☐ Equipment Resources Identified (See Supply and Equipment Checklist)

SUPPLY AND EQUIPMENT CHECKLIST

Clinic Site: **Number of**

Equipment Needs

- ☐ Copier
- ☐ FAX Machine
- ☐ 12 Computers or Laptops
- ☐ 5 DVD or VCR Players
- ☐ 5 Large-Screen Televisions
- ☐ Cell Phones
- ☐ Handheld Radios

General Supplies

- ☐ Tables
- ☐ Chairs
- ☐ Water and Cups
- ☐ Paper
- ☐ Pens, Pencils
- ☐ Envelopes
- ☐ Rubber Band
- ☐ Tape
- ☐ Stapler/Staples
- ☐ Paper Clips
- ☐ Scissors
- ☐ Post-It Notes
- ☐ File Boxes
- ☐ Telephone
- ☐ Paper Towel
- ☐ Tissues
- ☐ Table pads and clean paper
- ☐ Garbage containers
- ☐ Trash Bags
- ☐ ID Badges for Staff
- ☐ 7 Copies of Video
- ☐ Food and Drink for Staff
- ☐ List of Emergency Phone #s
- ☐ Cleaning supplies

Crowd Management and Triage Supplies

- ☐ Queue Partitions
- ☐ Signs for Site Designation
- ☐ Signs for Clinic Flow

Vaccine Administration Supplies

- ☐ Smallpox Vaxicools/Refrigerator
- ☐ Vaccine Diluent
- ☐ Sterilized Bifurcated Needles
- ☐ Sharps Containers
- ☐ Latex Gloves
- ☐ Latex-Free Gloves
- ☐ Anti-Bacterial hand washing solutions
- ☐ Acetone
- ☐ Rectangle Band-Aids
- ☐ Gauze
- ☐ Adhesive Tape
- ☐ Spray Bottle of Bleach Solution
- ☐ Paper Gowns
- ☐ Vaccination Screens

Emergency Supplies

- ☐ Standing Orders for Emergencies
- ☐ "Code" kit with defibrillator
- ☐ Ampules of Epinephrine 1:1000 SQ, or
- ☐ EPI Pen Adult/EPI Pen Child
- ☐ Ampules of diphenhydramine (50mg IM)
- ☐ 3cc syringes with 1", 25-guage needles
- ☐ 1.5" needles
- ☐ Tuberculinsyringes with 5/8" needles
- ☐ Alcohol Wipes
- ☐ Blood Pressure Cuffs (Various Sizes)
- ☐ Oxygen Tank
- ☐ Oxygen Tank Tubing
- ☐ IV Solution
- ☐ IV Solution Tubing
- ☐ Thermometer
- ☐ Aspirin, Tylenol, Regular insulin, D50
- ☐ Asthma Inhaler
- ☐ Tongue Depressors
- ☐ Emesis basis
- ☐ Adult pocket masks with one-way valve
- ☐ Pediatric pocket masks with one-way valve
- ☐ Adult and pediatric airways
- ☐ Tourniquet
- ☐ Gurney
- ☐ Stethoscope
- ☐ Flashlight
- ☐ Cots, Blankets, and Pillows
- ☐ ER Report Form

PERSONNEL CHECKLIST

Clinic Site: **Number of**

☐ Forms Distribution

AM Shift

1. 6.
2. 7.
3. 8.
4. 9.
5.

PM Shift

1. 6.
2. 7.
3. 8.
4. 9.
5.

☐ Triage for Ill or Contacts

AM Shift

1. 2.

PM Shift

1. 2.

☐ Run Orientation Video

AM Shift

1. 5.
2. 6.
3. 7.
4. 8.

PM Shift

1. 5.
2. 6.
3. 7.
4. 8.

☐ Referral Personnel

AM Shift

1.
2.
3.
4.
5.
6.
7.
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10.
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16.

PM Shift

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16.

☐ Medical Screeners

AM Shift

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3.
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7.

PM Shift

1.
2.
3.
4.
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6.
7.

☐ Physician Evaluators

AM Shift

1.
2.

PM Shift

1.
2.

☐ Vaccinators

AM Shift

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16.

PM Shift

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16.

☐ Vaccine Preparation/Supply

AM Shift

1.
2.

PM Shift

1.
2.

☐ Exit Review

AM Shift

1.
2.

PM Shift

1.
2.

☐ Medical Records/Data Entry

AM Shift

1.
2.
3.
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8.
9.
10.

PM Shift

1.
2.
3.
4.
5.
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☐ Clinic Manager

AM Shift

1.
2.

PM Shift

1.
2.

☐ Supply Manager

AM Shift

1.
2.

PM Shift

1.
2.

☐ Clinic Flow/QA Reviewer/Forms Helpers

AM Shift

1.
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8.

PM Shift

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8.

☐ Security

AM Shift

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PM Shift

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20.
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☐ Traffic Flow

AM Shift

1.
2.

PM Shift

1.
2.

☐ Translators

AM Shift

1. Language:
2. Language:

PM Shift

1. Language:
2. Language:

☐ Float Staff

AM Shift

1.
2.
3.

PM Shift

1.
2.
3.

☐ Contact Evaluation

AM Shift

1.
2.
3.
4.

PM Shift

1.
2.
3.
4.

☐ IT Support

AM Shift

1.

PM Shift

1.