Pandemic Influenza Plan – Vaccine Storage and Distribution

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INTRODUCTION

Vaccination against the circulating pandemic virus is a major focus of pandemic response efforts. Vaccination is crucial in reducing morbidity and mortality, and in minimizing social disruption by maintaining essential services.

In response to the 2009 H1N1 influenza pandemic, public health authorities conducted a vaccination campaign to protect tens of millions of Americans from the virus. This was one of the biggest public health initiatives in the United States history. The goal was to ensure that everyone who wanted to be vaccinated was able to be vaccinated. Providing one dose of vaccine to everyone in groups considered to be at high risk for serious complications would have required 159 million doses, a much greater task compared to 85 million people who are vaccinated annually for seasonal influenza. Funded by the federal government, vaccine was allocated to states in proportion to the size of their total population, regardless of the disease burden in each state and the number of state residents in the Advisory Committee on Immunization Practices (ACIP) target groups. Each state then developed its own plan to distribute and administer vaccine. Vaccine was shipped directly to public and private provider vaccination sites from the central distributor, based on orders placed by the states. States developed many kinds of distribution plans. Some states, such as Missouri, relied mostly on local health departments, which then distributed to other stakeholders. Other states distributed vaccine to a combination of state and local public health authorities, private healthcare providers, and pharmacies. A smaller number of states received all the states' vaccine supply and handled the physical redistribution to vaccine administrators themselves, a so-called centralized distribution model. The diversity in distribution methods across the country meant that neighboring jurisdictions often had different distribution systems. This caused confusion and communications challenges, some participants noted, especially in states in which each local health department developed its own distribution plan. Despite challenges caused by delays in supply, the identification of priority groups to receive the initial supply of vaccine, and associated public health messaging complexities, 61 million Americans were vaccinated in the first 3 months of the campaign.

OBJECTIVES

- Ensure timely and equitable distribution of pandemic vaccine.
- Track pandemic vaccine use across the state.
- Monitor pandemic vaccine safety.
- Ensure that the public and the health care providers have access to accurate and timely information on vaccine use and availability.

PLANNING ASSUMPTIONS

Since during the initial stages of a pandemic supply of vaccine will be limited, the CDC and ACIP are likely to provide epidemiologic information and guidelines for the prioritization of pandemic vaccine distribution and use. During the H1N1 pandemic, the high risk groups previously defined as a priority for the seasonal influenza vaccination needed to be redefined for

pandemic vaccination due to the different epidemiology of the pH1N1 virus. The Missouri Department of Health and Senior Services (DHSS) will use the CDC recommendations for guidance on how to specifically address vaccinating those prioritized for vaccine. Groups usually considered for vaccine prioritization include:

- Maintain essential services (e.g., homeland and national security, critical infrastructure).
- At high risk for contracting influenza during a pandemic (e.g., first responders, health care providers).
- At high risk for complications or death from the pandemic virus (e.g., young children, elderly, etc.).
- In the beginning of the pandemic, it will not be known how quickly the pandemic vaccine will become available.
- Vaccine supply is likely to be limited during the early stages of the pandemic.
- Two doses of vaccine will be likely required to achieve a protective response from the vaccine.
- The effectiveness of the pandemic vaccine may be limited depending on the emergent strain.
- The amount of vaccine allocated and delivered to Missouri might not be adequate to vaccinate all persons in the high priority groups.

DHSS ACTIVITIES BY THE PANDEMIC INTERVAL

Pre-pandemic interval

- Provide information and tools for mass vaccination.
- Assess vaccine storage capacity within state and counties.
- Review vaccine storage and handling procedures. (Vaccines for Children [VFC] guidelines)
- Estimate number of people in each pandemic virus vaccination priority group.
- Develop a plan on how persons in priority groups would be identified at vaccination clinics and how vaccine would be most efficiently provided to those groups.
- Develop a plan to vaccinate the remainder of the population after priority groups have been vaccinated.
- Discuss security provisions for vaccine supply.
- Review adverse event reporting procedure.
- Clarify responsibilities of community partners in vaccination.
- Identify potential funding sources to support vaccine related activities during pandemic.
- Monitor new pandemic developments, and modify existing vaccination plans as needed to reflect new recommendations.
- Identify sources of additional vaccinators if needed for surge.
- Assist local health departments to assess vaccine quantities needed based on priority levels.
- Develop a communications plan with local public health agencies (LPHAs) and a communications plan to the public.

Pandemic Interval

<u>Prior to Pandemic Vaccine Availability</u>

- Mobilize healthcare partners and prepare to activate plan for distributing and administering vaccines.

- Work with LPHAs and health care partners to distribute, deliver, administer, and track pre-pandemic or stockpiled vaccines to designated priority groups, if available.
- Work with Centers for Disease Control and Prevention (CDC) and other federal partners, vaccine manufacturers and public health organizations to establish plan for acquisition and distribution of initial vaccine supplies.
- Communicate new pandemic developments, and modify existing internal plans as needed to reflect new recommendations to LPHAs and the public, as necessary.
- Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccines and the expected timeline for vaccine distribution.
- Review and update modifications, if any, to recommendations on vaccinating priority groups.
- Make any revisions of priority groups needed and communicate the changes to LPHAs and health care partners.
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

<u>After Pandemic Vaccine Available for Distribution</u>

- Work with LPHAs and health care partners to distribute, deliver, administer, and track pandemic vaccine to priority groups.
- Consider redistribution of vaccine as needed to provide an equitable geographic distribution of supplies.
- Continue to review and revise priority groups, and communicate changes to LPHAs and health care partners.
- Introduce vaccination of the rest of the population after priority groups have been vaccinated or demand from priority groups has waned.
- Maintain existing Vaccine Adverse Event Reporting System (VAERS) reporting procedures during pandemic.
- Work with Public Information Officers (PIOs) to provide timely and accurate public messages regarding vaccine availability and location of vaccine administration sites.

Pandemic Vaccine Distribution

This vaccine will be distributed to local jurisdictions based on population. However, DHSS may allocate significant portions of the vaccine based on the epidemiology of the disease, with additional amounts being provided to those areas being more severely impacted early in the pandemic in terms of illnesses, deaths, or loss of critical infrastructure. DHSS has identified the ship-to site that will receive the bulk delivery of the pre-pandemic and pandemic vaccine into the state. Planning guidance from the United States Department of Health and Human Services (HHS) indicates that the 240,000-dose allocation will be received as one shipment. DHSS, in collaboration with the Missouri Department of Public Safety (DPS), will ensure the regional and local distribution of these vaccines to pre-determined sites. Local emergency management, public health and public safety authorities, in conjunction with the state authorities, will play key roles in ensuring the safe and proper storage and handling of the vaccine. DHSS will develop a memorandum of understanding with DPS to establish roles and responsibilities.

The pre-pandemic vaccine

The pre-pandemic vaccine will be administered per the tiered priority structure through those methods deemed most appropriate by local authorities, in accordance with minimal levels of handling as established and verified by the state. The local public health authority will be the lead in ensuring proper vaccine distribution and administration. These methods may include clinics at the site of the prioritized recipients, through mass clinics, and through other distribution and administration structures as best fits the needs and resources of each local community. Minimal levels of handling to be followed are those established through Missouri's VFC program. (See Attachments A, B and C.)

Pandemic Vaccine

When vaccine will be made available, the DHSS will order from weekly allocations of the vaccine to be shipped by the centralized distributor to the designated ship-to site(s). The designated ship-to sites could include LPHAs, hospitals, and any other designated medical centers that could then further distribute the vaccine to other private providers or administer the vaccine to local residents. In some local jurisdictions, the LPHA may choose to also have private providers designated as ship-to sites to expedite the distribution process. DHSS will allocate vaccine to local jurisdictions according to the number of persons in priority groups, general population, and the disease burden.

Vaccine Logistics and Security

Logistics and security at the state level will be the dual responsibility of DHSS and DPS, and at the local level by local public health and law enforcement with state support.

- Vaccine will be shipped from the manufacturer or distributor to the state ship-to site.
- DHSS will maintain, on a real-time basis, a database inventory of each dose of vaccine that is shipped from the manufacturer or distributor and received at each ship-to site. Ship-to sites will maintain, on a real-time basis, an inventory of vaccine in stock, the manufacturer, lot numbers, expiration dates for each lot, and a record of each dose of vaccine transferred to any clinics designated to conduct the vaccination clinics. All such data will be transmitted to DHSS electronically, and DHSS will transmit it to CDC.

Local Clinic Sites and Administration

- Based on experience during the H1N1 event, the LPHAs would work within their jurisdiction to conduct mass vaccination clinics that would be effective in reaching the priority populations. Many LPHAs would collaborate with private providers in organizing and conducting the clinics.
- In the event that the Strategic National Stockpile (SNS) for Missouri is activated, a State Security Officer will be identified in the memoranda of agreement. Security for additional transport for vaccine administration to on-site priority groups or for administration at clinics outside the sites will be the responsibility of local law enforcement, with state support. Local authorities will ensure that they have a workable security plan in place to continue dispensing operations. DHSS and DPS will review security plans during the monitoring process and provide technical planning assistance. State public health and public safety staff will work with local authorities to assist them in establishing relationships to assure the security of the vaccine and the orderly operation of vaccine clinics. Protocols will be established with

guidance from DPS and DHSS. DPS will provide assistance with site vulnerability assessments.

- Local authorities will need to implement a system of staff security and identification and in addition implement a system of pre-identifying those in the priority groups. This system must be able to function effectively while stressed. Staffing plans will be the responsibility of each allocation site. The system employed can be designed to best suit local needs and resources but must pass review by the state. Incidents will be managed at local sites and reported to the state as needed.
- All handling of the vaccine and management of clinics, including transportation and storage environment, must be done according to the stipulations from the Centers for Disease Control and Prevention. The LPHA has primary responsibility to ensure this compliance. This may include providing a vaccine site manager for each site (see Attachments A, B, C, and D). The practices will be monitored by the DHSS, Bureau of Immunizations (BI) staff through regular site visits and the routine communication via e-mail, fax, regular mail, and phone.
- In the event that the SNS for Missouri is activated, a DHSS site manager will be assigned to the state storage and distribution site to ensure compliance with vaccine transportation and storage requirements.
- Refrigeration devices at sites will be maintained according to manufacturer and DHSS recommendations. Refrigeration units must be validated by LPHA staff or staff from the VFC Program before shipment of vaccines may be received. Refrigerators must have calibrated data logger thermometers that will be monitored and recorded twice daily. If temperatures are outside acceptable ranges, the LPHA will contact the manufacturer for appropriate instructions.
- Vaccine inventories will be tracked in a DHSS-provided database.
- Vaccine balances will be tracked daily.

Vaccine Administration and Tracking

Ideally, the Immunization Registry (ShowMeVax) would be used to track pandemic influenza vaccines administered. However, based on experience gained during H1N1 and depending on the clinic logistics, response and time constraints, this might not be feasible. If it was not possible for all the individual records to be entered into ShowMeVax, aggregate reporting of vaccines administered would be required of the LPHAs and private providers. Providers (LPHAs and private providers) will use ShowMeVax to record pandemic influenza immunizations. Data transmissions will be made into the Countermeasures Response Administration (CRA) system.

- LPHAs have extensive guidance procedures for screening patients and administering vaccines, as well as for storing, handling, and accounting for vaccines. LPHAs will ensure staff that provides vaccines be trained and demonstrate competency in the assessment and administration of vaccine. Job descriptions will include vaccine administration and related duties associated with the activities of safe handling and storage of vaccine. BI provides written guidance as well as technical support (see Attachments A, B and C). Those documents refer providers to other resources for more specific information, such as the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases,* guidance on the website of the National Center for Immunization and Respiratory Diseases, Emergency Use Authorization (EUA) Fact Sheets, and Vaccine Information Statements.
- Based on experience gained during H1N1, it is evident that, depending on the clinic logistics, response and time constraints, it might not be feasible for all the individual records to be

entered into ShowMeVax upon administration. In that situation, administered doses would be required to be uploaded or manually entered into ShowMeVax within 60 days.
- Any adverse event reported will be entered into VAERS.
- In the event that a second dose of vaccine is required, recipients will be recalled for the second dose based on the information in the database.

Clinic Operations and Management

Trained DHSS staff will be available to conduct site visits at the request of the LPHA to provide technical assistance for proper vaccine handling, documentation, dating, storage, and overall maintenance of the vaccine.

Vaccine Safety Monitoring, Reporting, Treatment, and Patient Referral

VAERS reports should go directly to the VAERS site. The DHSS will provide technical assistance and communicate with CDC on all aspects of vaccine adverse event reporting. Vaccine safety education will be done by BI to providers statewide.

- The Division of Community and Public Health (DCPH) has established a legal basis for reporting adverse events using criteria developed for the federal VAERS. The VAERS safety coordinator position is housed in BI.
- DHSS and the LPHAs will utilize CDC's clinic guidelines, screening forms, and fact sheets to educate individuals concerning possible adverse events.
- A DHSS workgroup will identify information that must be captured to provide appropriate follow-up of primary vaccines, including adverse reactions. The workgroup will utilize federal disease reporting forms to capture this information. DHSS will educate medical care providers and LPHAs regarding adverse reactions and reporting requirements. LPHAs will educate patients about reporting adverse events. Adverse events that occur at the vaccinating clinics will be treated and reported at the time of vaccination.
- Medical care providers will report to VAERS vaccine adverse reactions. LPHAs will provide follow up in consultation with DHSS and with logistical support from DHSS as needed.
- DHSS will report adverse reactions and investigation findings to CDC.
- Best practices regarding off-site clinics and vaccine management are described in this resource: https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/.

Resources

Institute of Medicine. 2010. “The 2009 H1N1 influenza vaccination campaign: Summary of a workshop series”. Washington DC: *The National Academies Press.*

Missouri Vaccines for Children, LPHA Program Manual, 2018:
Available upon request

Vaccine Adverse Events Reporting System:
www.vaers.hhs.gov/

Department of Health and Human Services, *Pandemic Planning Update IV*. A Report from Secretary Michael O. Leavitt, July 18, 2007.

The CDC’s detailed guidance on how vaccine will be prioritized by tier and according to the severity of pandemic is available on the pandemic flu website: https://www.cdc.gov/pandemic-flu/index.html

Tools to Assist Satellite, Temporary, and Off-Site Vaccination Clinics
https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/

Attachment A

VACCINE COLD CHAIN PROTOCOL

MISSOURI VACCINES FOR CHILDREN (VFC) PROGRAM

POST IN A CONSPICUOUS PLACE

Required Temperatures:
Refrigerator:
36-46 Degrees Fahrenheit
2-8 Degrees Celsius
Freezer:
-58 to 5 Degrees *Fahrenheit* **or below**
-50 to -15 Degrees Celsius

"Maintaining the cold chain" means keeping vaccines at the recommended temperature. The cold chain begins at the manufacturer, extends to the distributor and continues at the provider until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability. The importance of maintaining the cold chain cannot be overstated. When the cold chain is not maintained, the vaccine may cease to be effective and will not provide protection from disease. **Any vaccine suspected of cold chain violation should be segregated from viable vaccine and NOT USED until the manufacturer determines viability.**

The **Vaccine Cold Chain Protocol** provides vaccine handling guidelines and action steps for health care providers in the event of a vaccine cold chain failure.

Cold chain failure occurs when there is a break in any link of this chain. Cold chain failure may occur due to a power outage, equipment failure, staff error, etc. To prevent vaccine cold chain failure, it is essential to have properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols for handling vaccines.

Immunization Providers Utilizing Vaccine Supplied by the VFC Program shall:

- Develop and maintain a current written Vaccine Emergency Plan, providing guidelines to ensure vaccine cold chain maintenance to include:
  - Identification of an alternative storage facility (i.e., hospital, packing plant, local public health agency, nursing home, fire department, etc.) with back-up power (generator) where the vaccine can be stored and monitored during a power failure.

- Identification of staff responsible to pack and move vaccine during an emergency.
- Maintenance of a supply of appropriate packing materials (insulated containers; the type vaccines are shipped in not soft side or high peaked, gel/ice packs).
- Identification of transportation to move vaccine to a secure storage facility during an emergency.
- Establishment of procedures to monitor vaccine temperature during transport to confirm its viability with the manufacturer upon its return.

Policies/procedures will be available for review by program representatives as requested. A template is attached for use in preparing a Vaccine Emergency Plan (attached).

Protocol for *Suspected* Vaccine Cold Chain Failure, the Provider shall:

- **Within 24 hours:**
  - Inventory all vaccines determined to have been stored at inappropriate temperatures. They should be labeled **"DO NOT USE."** Store potentially compromised vaccines at proper refrigerator/freezer temperatures while assessing viability.
  - Contact the VFC-SMV Help Desk at (866) 256-31664. Be prepared to provide:
    - **Ambient room temperature**
    - **Vaccine storage unit temperature**
    - **Estimated duration of event**
    - **Vaccine name**
    - **Lot number**
    - **Expiration date**
    - **Number of doses at risk**
    - **Provide the electronic log of temperatures from the required temperature data logger**

- **The VFC program representative will investigate and determine what to do with the vaccine, and the provider will be given instructions on returning the vaccine for credit.**

Protocol for *Confirmed* Vaccine Cold Chain Failure, the Provider shall:

- **No later than 24 hours of the confirmed cold chain failure:**
  - Notify the VFC-SMV Help Desk at (866) 256-3166.
  - Contact the vaccine manufacturer for guidance and provide the following information:
    - **Ambient room temperature**
    - **Vaccine storage unit temperature**
    - **Estimated duration of event**
    - **Vaccine name**
    - **Lot number**
    - **Expiration date**
    - **Number of doses lost**

- Return non-viable vaccines (full, unopened vials only) to the VFC vaccine distributor, McKesson Specialty Distribution, using vaccine return packing slip within 15 days.
- Review patient records to identify persons receiving vaccines during the identified cold chain failure periods as deemed necessary by the VFC Program and/or the manufacturer.
- Compile and submit a Corrective Action Plan to the VFC Program outlining the steps to identify, recall and revaccinate persons within one week.
- Contact identified persons and/or appropriate parent/guardian by telephone or written correspondence with the following information within 30 days of approval of the Corrective Action Plan.
    - **Purpose of recall**
    - **Need for revaccination**
    - **Information about available clinics and times for revaccination**
- Schedule clinics and appointments to revaccinate persons vaccinated during the cold chain failure event as identified in the Corrective Action Plan.
- Document appropriate vaccination information on the person's immunization record or provide an immunization record with the appropriate vaccination information at the time of revaccination.
- Instruct the appropriate parent/guardian of a revaccinated child to provide revaccination information immediately to the child's school and/or childcare facility.
- Keep an ongoing log with the following:
    - Number of persons revaccinated; and
    - Number of doses and date of each vaccine administered.

Submit status report **each Monday for the preceding week** to the VFC Program. The report must include:

- ❖ Names of patients revaccinated
- ❖ Vaccines administered
- ❖ Documentation of parental refusal to revaccinate

Provide proper vaccine storage and handling guidelines and vaccine administration protocols to each new employee, continually review and document this information with the staff to assure optimal cold chain practices.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
VACCINES FOR CHILDREN PROGRAM

EMERGENCY RESPONSE PLAN

Your Emergency Response Plan must include actions to be taken in the event of refrigerator or freezer malfunction, out-of-range temperatures, power failure, natural disaster or other emergencies that might compromise appropriate vaccine storage conditions. You must complete and remit a copy of this plan.

All staff should review, sign and date the emergency response plan on an annual basis or when there is a change in staff that has responsibilities outlined in the emergency response plan.

FACILITY INFORMATION

FACILITY NAME	VFC PIN

PRIMARY PERSON RESPONSIBLE	
PHONE	CELL

SECONDARY PERSON RESPONSIBLE	
PHONE	CELL

PERSON WITH 24-HOUR ACCESS TO BUILDING	
PHONE	CELL

POWER OUTAGE ***REPORT TO THE VFC PROGRAM IMMEDIATELY AT 866.256.3166***

How will you be notified of a power outage at your facility (alarm, phone call, paging service)? Insert description of how the responsible person will be notified. Who will be notified first, second, etc.?

1. NAME	PHONE	CELL

2. NAME	PHONE	CELL

3. ALARM COMPANY (IF APPLICABLE)	
PHONE	CELL

4. ELECTRIC COMPANY	PHONE

If your facility does not have a generator: Identify at least one location with a generator (hospital, pharmacy, nursing home or fire station) that may be used for a back-up location for vaccine storage.

ALTERNATE STORAGE FACILITY (IF APPLICABLE)	
PHONE	CELL

If your facility has a generator: Who will turn on the generator and maintain it (supplying fuel if needed) during the power outage?

NAME	PHONE	CELL

When entering the vaccine storage facility, please do the following:

Utilize the (insert which entrance) _____ of the building.

Flashlights will be located on the _____.

Circuit breakers may be checked and the box is located: _____.

THEN use the Emergency Response Worksheet to document vaccine that has been subjected to unsafe temperatures.
LABEL vaccine "DO NOT USE" until the efficacy of the vaccine has been determined.
SEND a copy of **ALL** documentation must be sent to the VFC program upon completion.

TRANSPORT per the Transport Vaccine Procedures.

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EMERGENCY RESPONSE PLAN

MECHANICAL FAILURE OF EQUIPMENT *****REPORT TO THE VFC PROGRAM IMMEDIATELY AT 866.256.3166*****

MECHANICAL FAILURE OF EQUIPMENT INCLUDES situations where the refrigerator or freezer door was left open, the temperature of the refrigerator or freezer was too warm or too cold, the storage unit was unplugged or any other situation which would cause improper storage conditions.

TAKE ACTION! Correct the mechanical failure if you can (shut the door, plug in the unit, or move the thermostat to the correct position). If the mechanical failure cannot be immediately rectified refer to the Transport Vaccine Procedures.

THEN use the Emergency Response Worksheet to document vaccine that has been subjected to unsafe temperatures.
LABEL vaccine "DO NOT USE" until the efficacy of the vaccine has been determined.
SEND a copy of **ALL** documentation to the VFC program upon completion.

Who needs to be contacted to repair or replace the unit?

1. NAME	PHONE	CELL
2. NAME	PHONE	CELL
3. NAME	PHONE	CELL

TRANSPORT VACCINE PROCEDURES

Who will transport the vaccine (personal vehicles may be used)? CDC discourages transporting vaccine in the trunk of a car or in the bed of a truck during weather extremes.

NAME	PHONE	CELL

Call: Before transporting vaccine, call the back-up location site to ensure that their generator is working and they are aware you will be transporting vaccine to them. Once you arrive at the back-up location, assure that they are aware of how to properly store and maintain the vaccine while it is in their possession.

Contact Person at Back-up Location:

NAME	PHONE	CELL

Where are ice/gel packs to be used for transport located? _____

Insulated containers (styrofoam or vaccine shipping boxes) to use are located: _____

Bubble wrap and/or other barrier are located: _____

Count and document the lot numbers and expiration dates of all vaccines to be transported.

Label vaccine containers with your facility name and contact information.

Packing Refrigerator Vaccine: To pack for transport, place ice/gel packs in the bottom of a container, lay a barrier (bubble wrap, crumpled paper, etc.) on top of the ice/gel packs followed by the vaccine and the data logger, cover with another layer of bubble wrap or crumpled paper followed by an additional layer of ice/gel packs. Close lid. Log time and temperature on documents before transport and immediately upon arrival at destination.

Packing Freezer Vaccine: MMR (not diluents), MMRV, and Varicella (VAR) must be transported in a separate container with extra ice/gel packs to maintain freezer temperatures. No barrier is needed. Mark the container "Freezer Vaccines" place the vaccine in the container along with a data logger and pack container with enough ice/gel packs to maintain temperature. If temperature exceeds 5°F (-15°C) contact the vaccine manufacturer for assistance. Log time and temperature on documents before transport and immediately upon arrival at destination.

Take the most direct route to the back-up location. Directions:

Upon Arrival: Open the containers, record the temperatures, inventory the stock (with the receiving person) and ensure that the receiving person places vaccines in the proper storage units which are maintained at the proper temperature ranges.

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EMERGENCY RESPONSE PLAN

REVIEW EMERGENCY PLAN

The emergency plan must be reviewed and/or updated annually or when changes in staff occur.

The primary and secondary vaccine coordinators are responsible for training other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation, following the facility's vaccine storage and handling plan.

All staff should review, sign and date the emergency plan annually.

PRIMARY VACCINE COORDINATOR (PRINT NAME)	
SIGNATURE	DATE
BACK-UP VACCINE COORDINATOR (PRINT NAME)	
SIGNATURE	DATE
ADDITIONAL STAFF (PRINT NAME)	
SIGNATURE	DATE
ADDITIONAL STAFF (PRINT NAME)	
SIGNATURE	DATE

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VACCINE MANAGEMENT PLAN
STORAGE AND HANDLING

- Ensure vaccines are kept away from the sides and back of the refrigerator.
- Remove produce drawers and place bottles of water in that space.
- Ensure vaccines are not stored in the refrigerator door and place bottles of water in that space.
- Line the freezer sides and floor with ice packs.
- Regularly check all storage units to ensure adequate air circulation is occurring around vaccines and that vaccines have not been placed in closed bins (such as the plastic closed containers supplied by drug manufacturer representatives).
- Take appropriate steps to ensure refrigerators and freezers are not unplugged accidentally, the "Do Not Unplug" sticker is visible, and the use of plug guards or other means to secure plugs are in place.
- Ensure that units are plugged directly into wall outlets, not power strips or extension cords.
- Identify and label the circuit breakers for the vaccine refrigerators and freezers using the "Do Not Turn Off" stickers or similar labeling.
- Will only open one box of vaccine at a time.
- Will not "dump" vaccines into other containers (even if they are the same vaccine).
- Ensure that all staff are proficient in their ability to properly pack vaccines for transfer or emergency shipping.
- Ensure that all staff are proficient in their ability to read data loggers, know correct temperature ranges, and can properly record temperatures. Ensure that temperatures are recorded twice per day, once in the AM and once in the PM. The minimum and maximum temperatures must also be recorded during the AM recording and then cleared from the thermometer. These temperatures must be logged on an approved temperature log and submitted in ShowMeVax.
- VFC and/or VFA contact or designee will record temperatures daily. A temperature log containing an out-of-range temperature marked "Yes" indicating temperature was within range is considered negligence.

VACCINE ORDERING

- Ensure that all required VFC and/or VFA monthly reports are submitted to Missouri's Immunization Program on time in ShowMeVax.
- Order the number of boxes that are needed, not doses, and verify the doses per package being ordered.
- Ensure that if more than one vaccine manufacturer is available, order one brand as much as possible to lessen administration and accounting errors.
- Ensure that the vaccine ordered is only to maintain approximately a 30-45 day supply of vaccine.
- Ensure that the vaccine orders, reconciliations, and temperature logs are submitted electronically through ShowMeVax. Reconciliations and orders must be submitted anytime from the first through the fourteenth of each month.

- Temperature logs are to be documented from the first day of the month through the close of business on the last day of the month. Temperatures must be submitted in ShowMeVax by the first business day of the month.
- If at any time there is a break in the cold chain Missouri's Immunization Program is to be immediately notified and provided with the completed Emergency Response Worksheet.

VACCINE SHIPMENTS

- Immediately open the shipping box to:
  - examine for damage.
  - count vaccines received to compare the numbers against the shipping invoice and order form.
  - check the temperature indicator to ensure the vaccine cold chain has been maintained.
  - immediately store vaccines in the appropriate storage units, checking expiration dates and placing the order received in the proper stock rotation to ensure vaccines with the shortest expiration date are used first.
  - contact Missouri's Immunization Program within two hours of delivery if abnormalities are noted.
  - maintain vaccine packing slip from manufacturers for three years.
- Receive the shipment in ShowMeVax into inventory upon receipt.
- Document the date and time your order was received on the packing slip.
- Tape boxes of vaccine shut that are not already secured by the manufacturer to avoid opening more than one box of vaccine at a time and to help facilitate your monthly vaccine inventory count.

INVENTORY CONTROL (INCLUDES STOCK ROTATION & VACCINE TRANSFER)

- Check and use vaccine within time frames specified by the manufacturer's labeling and recommendations prior to vaccine administration.
- Check expiration dates monthly.
- Put the expiration date on the box so it is easily visible yet not obscuring vital vaccine information on the box.
- Rotate vaccines as needed to ensure that the shortest expiration-dated vaccine is used first.
- Ensure that vaccines do not expire.
- If the expiration date is within 90 days, efforts should be made to ensure the vaccine will be utilized or transferred according to the Vaccine Replacement Policy.
- Before a transfer is made, contact your VFC Consultant or the VFC-SMV Operations Team at 866.256.3166 or vfc-smvsupport@health.mo.gov for transfer approval.

Responsibilities for Vaccine Transfers Include:

- Ensure that all staff are proficient in their ability to properly pack vaccines for transfer or emergency shipping.
- Initiate and complete the vaccine transfer in ShowMeVax.
- Transport vaccine per Chapter 6.3 of the VFC Provider Manual.

- The receiving provider must accept the vaccine in their inventory in ShowMeVax upon receipt.

VACCINE WASTAGE

- Wastage must be reported in ShowMeVax prior to completing monthly reconciliation.
- Ensure all wasted vaccine doses are deducted from ShowMeVax inventory.
- Vaccines that are unaccounted for will be considered waste and are subject to replacement.
- Providers will be held responsible for replacing vaccine doses due to negligence.

Guidelines for Large Scale Pandemic Influenza Vaccination Clinics

Introduction

This document provides information specific to influenza vaccination clinics during a pandemic, and is based on the general guidance for planning and conducting large-scale immunization clinics. Specific planning at the state, local and clinic levels should be flexible and build around varied scenarios.

This document covers important topics such as clinic settings, clinic flow, staffing functions, administration and storage of vaccine, clinic supplies and equipment, security, documentation, post-vaccination observation, handling and disposal of needles

1. Determine Resource Needs

Based on the vaccination strategy (i.e., priority groups, disease severity and prevalence, seasonal flu patterns, etc.) the number and duration of clinics, and number of staff required should be calculated. The precise number of personnel needed for any one clinic will vary, however, depending on the size and layout of clinic facilities, location of clinic, geographic area being served by the clinic, estimated number of vaccine recipients at each clinic. The over-all staffing needs should be estimated based on the model described under Section 1: Clinic Operations.

2. Identify Potential Clinic Sites

Potential clinic sites should be selected based on the estimated number of people expected to be served and the size and layout of the facility. The size and type of facilities needed for novel influenza immunization clinics will vary depending on the number of persons to be served. Small clinics, such as those to immunize health care workers, can be conducted in almost any available space, most likely a local health department, hospital occupational clinic, or similar facility. Larger clinic sites could be housed in schools, churches, industrial locations, office buildings, or apartment complexes. Schools may be the preferred location for any clinic required to be larger than a local health department. Schools have parking lots, long corridors, large classrooms, gymnasiums, cafeterias, private offices, and other immediately available resources, such as tables and chairs, and offer an ideal physical structure that can meet most clinic needs. Elementary schools are preferable because they are numerous and serve fairly well-defined neighborhoods convenient to the public. The use of middle or high schools may also be considered.

In selecting clinic sites, handicap access must be assured. Also, consideration should be given to ensuring a smooth flow of clients, accessibility of the facility to major streets, restroom facilities, parking, refrigeration, heating/air conditioning, protection from the elements, personal and client safety and security. Before final selection, a visit should be made to the location to ensure that the facility meets the needs of the vaccination operation.

3. Obtain Authorization / Standing Orders

Before a clinic can be implemented, standing orders must be obtained from the public health authority, usually the state and/or local health officer to provide authorization for administration of the influenza vaccine. Standing orders are also needed for responding to medical emergencies that occur during vaccination clinics, ranging from minor injuries and illnesses to anaphylactic shock. In addition to providing standing orders, the health officer or his/her designee must approve the content of informational materials and serve as medical consultants for nursing and other staff.

4. Plan Training

All public and private health care workers and the many volunteer workers who may become involved in influenza vaccination efforts should receive both job specific and, where possible, cross job training in advance and/or on the job. Large numbers of clinic staff can be trained using a train-the trainer approach.

5. Publicize the Clinic

After immunization clinic locations are determined and recipient populations identified, public announcements with information about these clinics should be released as soon as possible.

When developing communications materials, all relevant information should be included. As decisions are made, the information disseminated must clearly describe the groups for whom the clinic is intended or not intended. For example, certain locations might serve priority groups exclusively. Non-English speaking groups may be asked to come at specific dates and times when translator resources are available. Information identifying clinic locations and directions, dates and times of operations, length of time the vaccination process may take, tips on type of clothing to wear, and what to expect once at a clinic should be provided through various media outlets (TV, newspapers, etc.) in as many languages as needed.

The CDC's education and communication materials will be made available electronically and in printed formats. When available they should be translated into the appropriate languages for the geographical area, reproduced in appropriate quantities and ready for rapid distribution. Patient education materials may need to be modified in consultation and coordination with immunization partners and representatives of the community to ensure that the information provided is adequate and culturally appropriate for local audiences. Printed materials should be at reading levels suitable for their intended audiences.

Using professional public relations assistance when available, announcements should be updated from the CDC materials and released for television, radio, and newspaper media. If specific groups require additional information, (e.g., to counteract misconceptions about vaccination) clinic organizers may need to distribute flyers to targeted populations in apartment buildings, neighborhoods, workplaces, schools, and/or religious centers.

If special transportation can be provided for persons with physical or age-related disabilities, the telephone number for requesting special transportation should be included in all clinic publicity.

To ensure accurate reporting by the media, a list of subject experts and media spokespersons from state and local public health agencies and community partners should be developed and made easily accessible to the media through an approved format. If necessary, individuals who can be called upon to serve as interpreters should be identified to help inform non-English speakers. This list should note the foreign languages spoken by these individuals. To improve understanding of the subject matter, photographs and graphics should be provided in various media.

In addition to information about the specific clinic being publicized, a concerted effort should be made to provide information to the public that emphasizes:

- The rationale of the immunization strategy.
- Disease containment measures are effective.
- All possible measures are being taken to prevent the further spread of the disease.

Section 1: Clinic Operations

1. The Vaccination Clinic Process

Step One: Orientation
As vaccine recipients arrive, they are routed to the clinic entrance by security personnel who are handling outside traffic flow and parking. Staff will screen patients for signs and symptoms of an influenza-like illness (ILI). Clients who present with symptoms of an ILI will be directed to an alternative section of the clinic. Well-clients enter the clinic building and are directed to a location where the greeter-educator briefs groups about what is going to take place during the clinic process and hands out paperwork for the client to fill out. Clients will begin to read and fill in required personal information (name, address, etc.) Multiple educator-greeters locations may be necessary to accommodate the rate at which people arrive.

Step Two: Form Completion and Assessment for Contraindications
Clinic flow coordinators direct vaccination clients to tables where staff is available to answer questions and aid clients in completing required forms. Vaccine clients who check ‘yes’ for allergy to eggs and/or previous problems following a previous influenza vaccinations are directed to a separate station where a medical professional will complete a more in-depth evaluation.

Step Three: Vaccination
Vaccine clients with no medical contraindications are directed to the vaccination area. This area is a screening area that affords privacy to persons who find it necessary to remove clothing in order to expose the vaccination site. A vaccination assistant helps vaccine recipients expose their vaccination site (upper arm, thigh) and cleans the vaccination site if necessary. The vaccine administrator then administers the vaccine and the assistant applies a bandage to the vaccination site. The patient’s clinic documents and a patient-held vaccination card are completed.

Step Four: Post Vaccination Observation, Clinic Forms Collection and Exit
The vaccine recipients are routed to an area set aside to be observed for 10-15 minutes for potential post-vaccination problems. During this time the clinic forms collector ensures that forms are complete, answers any remaining questions and informs vaccine recipients that they will need a second vaccination or are finished with the process, as appropriate. This individual also ensures that the vaccinee has been provided a completed vaccination card.

2. Staffing and Training

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

Management and Coordination Functions
To assist the manager with large clinic operations, coordinators should be identified for the various clinic functions as outlined below:

Nurse Coordinator: Oversees nursing staff assigned to the clinic; assists clinic manager in making clinic assignments for nursing staff; assists on-duty nurses as needed.

Supply Officer/ Vaccine Manager: Ensures that all necessary clinic supplies are on site and are available in sufficient quantities during clinic operations; ensures vaccine supply and orders vaccine; tracks vaccine supply at the beginning and end of each day, maintains an inventory of supplies; oversees distribution of supplies to appropriate locations in the clinic; ensures that the vaccine is maintained properly (refrigeration, vaccine monitoring) and in a secure manner at the clinic site; accounts for unused vaccine; very importantly, maintains adequate vaccine and other supplies at the vaccine station; and ensures that 'sharps' containers and other waste are disposed of appropriately.

Security Coordinator: Oversees personnel assigned to security activities at the clinic site; assists the clinic manager in making duty assignments of security personnel; determines appropriate number of security staff necessary according to clinic size and location; maintains a list of authorized clinic staff and their phone numbers; assigns and coordinates use of cell phones and pagers; establishes staff check-in and check-out procedures; ensures that all staff wear ID badges; maintains communication with local law enforcement officials.

Volunteer Coordinator: Oversees volunteer activity at the clinic site. Assists the clinic manager in making duty assignments of volunteer staff; maintains roster of persons available for volunteer duty; and maintains a schedule of times that volunteers will be available to work.

Staff Functions
Following is a summary of suggested responsibilities of the staffing roles as outlined in the operational concept above:

Clinic Screeners: Screeners intercept clinic clients outside the clinic area and separate clients presenting with signs and symptoms of influenza-like illness from well clients. They direct well clients into the clinic area and ILI patients to an alternate area.

Greeter-Educators: Greet and conduct initial orientation of potential vaccine recipients upon their arrival; provide basic information about the vaccine and the vaccination process; distribute informational material and clinic documents and answer questions.

Greeter-Educators must be able to explain the purpose of receiving the vaccine, outline the vaccination clinic process, and distribute and explain the clinic documents to vaccine recipients.

Forms Completion Assistants/ Contraindication Assessment Staff: Assist and review each vaccine client's documents for completeness, accuracy, and address those that answered, "yes" to any questions that concerns contraindications to influenza vaccine.

These staff must be familiar with the content of each form. They must be prepared to respond to exceptional situations such as non-English speaking patients or patients who are anxious, hostile, disoriented or physically disabled. The documentation staff will aid clients in completing all forms accurately. They should be prepared to read the forms to illiterate or semiliterate persons needing their assistance. If a "yes" is indicated by the client in a question concerning a contraindication to an influenza vaccine, the staff directs the client to the medical station.

Medical Evaluator: Medical personnel further evaluate clients who indicate they might have a contraindication, provides medical aid to vaccinees experiencing medical problems following vaccination, and participates in further evaluation of clients who presented with ILIs.

This role should be filled by a physician, nurse or paraprofessional who is well-versed in contraindications to vaccination and the risks of influenza disease. The medical evaluator will review in greater detail the specified contraindication with the client and will assist in making a final decision about whether or not to vaccinate.

Medical personnel must be able to respond to emergencies, including reactions ranging from the minor to anaphylactic shock and serious medical emergencies that are incidental and unrelated to vaccination but can be expected to occur whenever large groups of people congregate. For large operations, a physician, physician's assistant, nurse practitioner or emergency medical technician should be on-site at all times during clinic operations.

Vaccination Assistants: Assist the vaccine administrator with all aspects of pre-and post-vaccine administration activities; ensure that vaccination station maintains adequate

supplies; at site of vaccination, assist vaccine recipients in preparing the vaccination site (roll up sleeves, remove arm from shirt/blouse, expose thigh, etc.); ensure that "sharps" containers and other waste materials are correctly handled and disposed of, and help complete clinic forms.

Vaccination assistants must have a thorough understanding of the vaccination process and the necessary supplies, proper care and handling of vaccine in the clinic, how to disinfect contaminated surfaces and dispose of soiled materials, and where to access additional supplies. Vaccination assistants are also responsible for entering the vaccine lot numbers and other required information onto the patients' clinic record and personal vaccination card. Finally, the assistant directs the patient to the post-vaccination observation area.

Vaccine Administrators: Oversee the immunization process; determine appropriate type (inactivated, injectable or live, attenuated, nasal spray) and dose volume (child or adult) of vaccine: administer the vaccine; appropriately dispose of "sharps" containers, sign the clinic record (if required) and observe vaccine recipients in the post-vaccination observation area for reactions or complications.

Vaccine administrators can be RNs, physicians, LPN, MAs or designated paraprofessionals (according to individual state rules/regulations) who have received technical training in administration of each type of influenza vaccine (inactivated, injectable and live-attenuated, nasal spray). Vaccinators must have training to be able to quickly select the appropriate type of vaccine to administer based on clients' age. They must have in-depth people skills, and understanding of proper vaccination techniques, methods to prevent contamination of the vaccine, preparation of the vaccination site and normal and abnormal post vaccination responses. Vaccinators must also be prepared to recognize, respond to and alert emergency medical personnel of possible post-vaccination reactions and other medical emergencies that occur within the vaccination area.

Forms Collectors: Answer client questions, verify that forms are correctly completed; collect all necessary forms from recipients before departure.

The forms collector is responsible for checking that the vaccination team has signed the clinic record (if required) and entered the lot numbers on the appropriate documents. As the last staff to have contact with the vaccine recipients, the forms collector must have the ability to ensure a response by the appropriate staff to any remaining concerns those clients may have.

Clinic Flow Controllers: Direct vaccine clients through the clinic process and monitor clinic flow.

Clinic flow coordinators are responsible for continuously monitoring and directing client activity throughout the facility. They must be able to calmly manage and assist people who may be anxious and unable to follow directions. When congestion (backlog) is noted, flow controllers determine if staff at other locations are less busy and request

assistance in the congested area. They are also responsible for feeding back information about the number and rate of upstream clients to the vaccination assistants to enable them to maximize use of all vaccine doses in opened vaccine vials. Flow controllers may be in a position to provide early alert of situations that may require additional security personnel.

Security Staff: Ensure an orderly flow of traffic and parking at the clinic site; assist in maintaining orderly movement of vaccine recipients through the clinic process; provide necessary control if persons become unruly; assist supply officer in maintaining security of vaccines and other clinic supplies.

Security Staff can be off-duty law enforcement officers, professional security personnel and/or volunteers who are experienced and trained in crowd control. Potential responsibilities of security staff are described in detail below (under Security).

Staff Training

The staff operating a clinic site should receive a group orientation about the overall purpose, function, and flow of the vaccination clinic, as well as specific verbal and written directions for their individual roles. During the orientation a diagram with annotations should be provided to show traffic flow, the functions of all clinic stations and a list of staff assigned to each role and each station, if possible. The responsibilities of each area of the vaccination clinic are reviewed with the entire staff. All staff need to know where they will work, where supplies and resources are located, and who their consults are as well as how to summon them. Daily post-clinic debriefings should be held to assess staff performance and ascertain if additional training or clinic reconfiguration is needed.

In small clinics, staff roles can be flexible to accommodate changes in clinic flow and patient numbers, and to permit rest breaks for other staff. In large clinics this, and accommodating unexpected staff absences, can be accomplished by cross-training of staff. Therefore, orienting staff in small, interchangeable teams is suggested.

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

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

3. Clinic Layout and Flow

Clinics should have clearly marked entrance and exit points with adequate “waiting” space for queues of people seeking vaccination. Security staff should be posted at both locations to maintain order. The traffic flow within the clinic should be controlled and should follow a logical path from entry into the clinic to exit from the clinic. A linear path of traffic flow from entry to

exit on opposite sides of the facility is optimal. If time permits, easy-to-read signage should be provided to guide people through the clinic process. (See – Example of Large Scale Influenza Vaccination Clinic below.)

One or more persons (screeners) should ask about and monitor clients for signs and symptoms of influenza-like illness (ILI) while outside the entrance to the clinic. All persons presenting without such ILI signs and symptoms should proceed into the clinic. Those found to have symptoms of ILI should be directed to a set-aside alternative area for a more detailed medical evaluation.

Within the clinic, greeter-educators provide information to clients on clinic procedures and hand out clinic forms for completion of Vaccine Information Statements (VISs) and other materials. A separate area should be provided in which clients can be seated to complete forms and have staff member are available to answer questions and assist in the completion of client forms. Medical providers are available to interview clients with histories of contraindications to influenza vaccine. All this should be performed in an area separate from the vaccine administration stations.

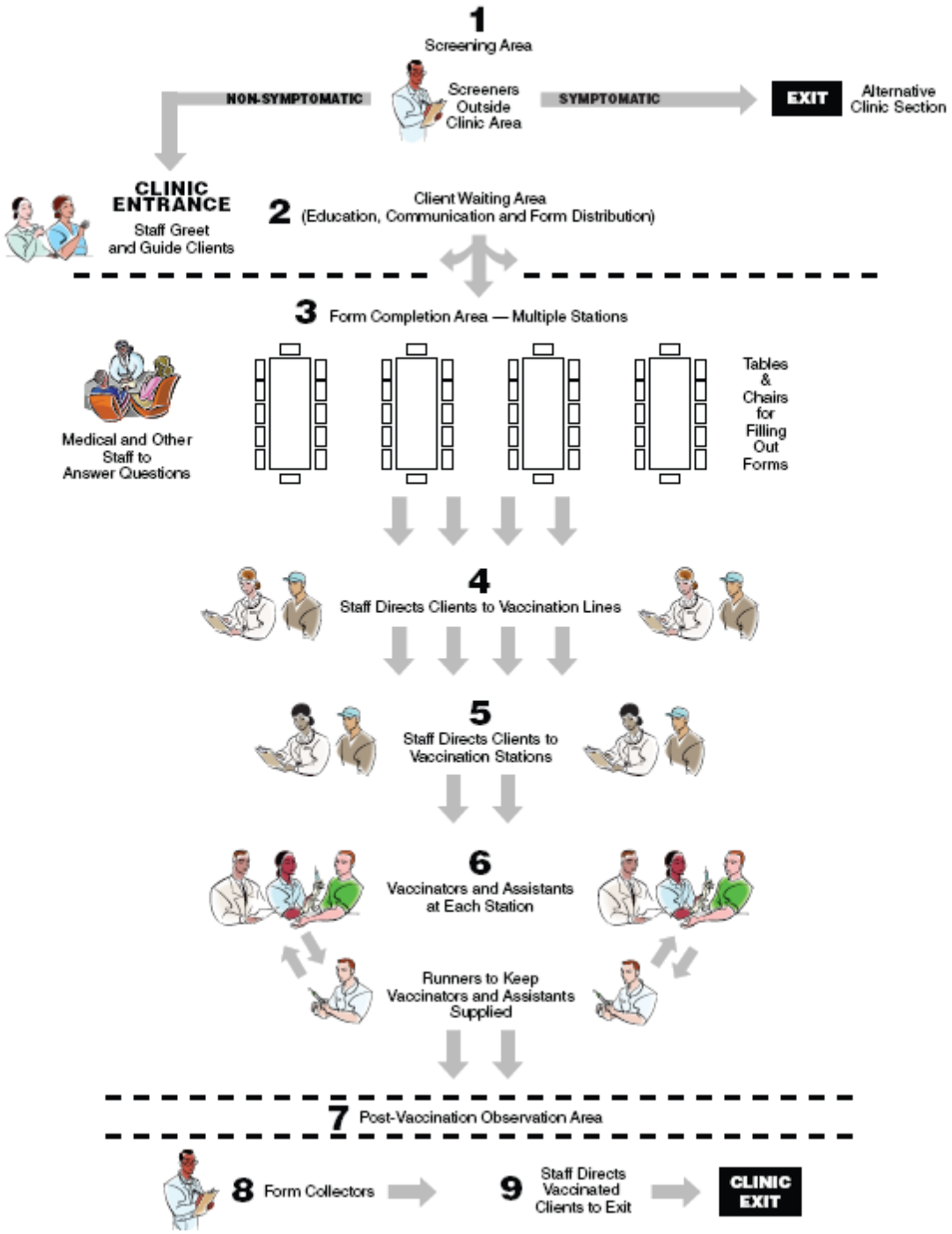
It is likely that form completion will become the most time-consuming clinic activity. Sufficient staff should be assigned to move persons through these areas with some dispatch in order to maintain a steady flow of clients to the vaccination areas and maximize the efficiency of the vaccinators. Client overflow should be held in a location in the clinic designated for this contingency.

Traffic in the area where vaccine is being administered should be kept to a minimum. Ideally, each vaccination station should be physically organized so that clients must present one at a time at the vaccine administration table. The three steps of the actual vaccination process (site preparation, vaccination, and dressing application) shared by the vaccination team will take place in a relatively small space (one or two tables) in the same area. Since some vaccine recipients may need to remove shirts or blouses in order to be vaccinated, a separate, screened privacy area should be available out of view of other persons waiting to be vaccinated. If possible, a separate vaccination station should be opened for the families with young children and elderly and persons with disabilities who may need additional time, a and station for single adults and adolescents.

The clinic vaccination record for each vaccine recipient should be completed and verified. The recipient should also be provided with a personal vaccination card.

The post-vaccination observation area and medical emergency area should be located as close to the vaccine administration area as possible.

Example of the Steps in a Large Scale Influenza Vaccination



4. Documentation and Paperwork

Vaccinee-specific documents that may be required by a novel H1N1 influenza immunization clinic must be collected (Table 1.). The clinic vaccination record of each recipient must be retained by the clinic in paper or electronic format. If computer resources are available, required recipient clinic data should be entered in "real time" throughout the vaccination process. However, paper-based documents may be the only available collection format. Where possible, these can then be entered into a computer for storage and to provide a summary.

Certain administrative documents and worksheets, such as staffing assignments, attendance, doses available, administered and wasted, will be required to assist in clinic management and keeping track of the vaccine (Table 2).

5. Security

Early in the vaccination program, especially if influenza cases are many, severe and rapidly increasing in number and vaccine availability is not well defined, the level of risk perceived by the public may be extreme. In these circumstances, state and local public health officials should be prepared for a high level of demand for vaccine by the public. Likewise state, local and contract law and security agencies should be prepared for traffic and crowd control near vaccination clinics.

Management Responsibilities

The clinic manager must ensure that the following activities are handled at each site:

- Notify state/local police and EMS of the time location of the clinic
- Assign a security coordinator
- Ensure presence of police or other security personnel
- Require that all staff wear identification cards
- Determine need for trained security guards, crowd control and traffic control personnel
- Designate entrances/exits for staff use
- Provide list of authorized staff for each clinic site
- Establish staff check-in/check-out procedures
- Establish methods and locations to safeguard vaccine and other clinic supplies
- Maintain a system to vaccinate clients in their order of arrival

TABLE 1

POSSIBLE VACCINATION DOCUMENTS

Document	Information Collected Or Provided	How Used
Screening Protocols: a) ILI symptoms b) Contraindications c) Prioritization	Symptoms of ILI or not Contraindications to Flu Vaccine or Components Priority Group	> Screen ILI suspects from entering clinic > Identify/send to medical person for expert opinion > Ensure vaccination of high priority groups first
Vaccine Information Statement and/or EUA Fact Sheet (if required)	Verbal: Yes/No: Have you read? Do you understand? VAERS instructions.	Provide disease and vaccine information at clinic; Taken home by vaccinee to inform/advise how to report adverse events to VAERS
Clinic Vaccination Record	Name, Address, Date age/DOB,M/F, lot number, manufacturer, type of administration (injection/ nasal), other state, local, and clinic- required data	Official clinic medical record retained and available for VAERS review and/or FDA/CDC review under EUA
Patient Vaccination Card	Name, Clinic Name and phone, Date age/DOB,M/F, lot number, manufacturer, type 1st dose, 2nd dose, date to return for 2nd dose	Proof of vaccine receipt; Information presentable to health provider in the advent of an Adverse Event; Reminder/recall for 2nd dose and date for 2nd dose verify receipt of vaccine

TABLE 2

POSSIBLE ADMINSTRATIVE WORKSHEETS

Document	Information Collected Or Provided	How Used
Daily Vaccine Tracking Record By: • Inactivated types • Life, attenuated type	• Beginning Inventory • Dose received • Doses Administered • Ending Inventory • Doses Wasted • Signature of clinic official	Documents where, when and how much vaccine was used; daily vaccine supply monitoring, accountability
Staffing/Volunteer Assignment Sheet	• Date of Clinic • Clinic Roles • Individuals Assigned • Attendance	Record staffing/volunteer assignments

Security Staff Responsibilities

Security staff functions include: (1) maintaining orderly clinic operations; (2) protecting patients; (3) protecting employees; (4) protecting facility property, including medical supplies and vaccine; and (5) enforcing the direction of ILI symptomatic clients to an alternative section of the clinic. To fulfill these functions, security staff must have the capacity to:

- Manage the facilities' security resources.
- Monitor the physical facility.
- Recognize potential for mob behavior.
- Control access to the facility and areas within it.
- Provide a means to identify authorized employees.
- Update an authorized personnel list on an ongoing basis.
- Coordinate with other security agencies.
- Direct person in need of care to alternative facilities.
- Remove individuals who pose a risk to the facility and its operation.
- Follow the emergency response plan of the state, local and/or facility.
- Communicate with clinic staff, the command center, and external security personnel.
- Perform a secure lock down of the facility quickly.
- Obtain additional security resources in a predefined "emergency" situation.
- Respond with appropriate force if required.
- Provide information to persons massed outside the facility.

Security Strategy

To manage a large number of people arriving at clinic sites, the main strategy should be to (1) secure a limited access perimeter at a designated distance from the physical facility; (2) secure the clinic itself (interior perimeter; e.g., the facility's main and secondary entrances, front drive, and parking area); and (3) maintain order within the facility. To carry out these strategies, security personnel must be prepared to:

- Intercept and detain individuals attempting unauthorized entry to the facility.
- Continuously provide situation information to state/local disaster command and control.
- Disseminate public information, including leaflet distribution.
- Control and disperse crowds.
- Operate available security equipment such as closed circuit television, metal detectors, security alarm systems and radio communications system.

Emergency Protocol

In a medical or public safety emergency, security staff should immediately undertake the following activities:

- Set up an outer perimeter
- Arrange to meet emergency vehicles at the outer perimeter and guide them to the appropriate entrance.

- Meet mass transit and supply vehicles at the outer perimeter and direct them to the appropriate entrance.
- Meet individuals coming to the facility at the outer perimeter and identify them as either authorized staff or eligible for care.
- Deny ineligible or unauthorized persons admission using standard scripts.
- Direct authorized persons to the admission station at the interior perimeter. Offer disabled persons, the elderly, and parents with small children an escort, when appropriate.
- Monitor length on lines at the clinic entrance and relay information to the outer perimeter to limit admission, when necessary.
- Refer over-flow to other clinics, if necessary.
- Lock down the facility in the event the security objectives were compromised.

6. Clinic Supplies and Equipment

A secure area should be identified for maintaining clinic supplies including vaccine. A list of clinic supplies should be kept on hand at the clinic site to be used for staff training, clinic set-up, and restocking. A list of suggested supplies is provided in Table 3.

7. Transportation

Depending on circumstances (security concerns, parking facilities, clinic size and location, etc.) the following groups may require transportation assistance:

- Clinic staff,
- High-risk, elderly and disabled individuals, or specific priority group
- The general public (i.e., persons with lower or unknown risk of exposed).

In addition, transportation will be needed to keep adequate amounts of vaccine and various clinic supplies in stock. Pick-up locations for staff and supplies should be arranged and clearly communicated to drivers and staff.

Although transportation of clinic staff can be handled with agency motor pool or rented vans, special security arrangements may be required. Until vaccine supplies are no longer critical, vaccine can be transported in law enforcement or similar secure vehicles. If transportation of large numbers of vaccine clients is required, public and/or private buses may be needed. In these cases, a hotline or other mechanism must be established to enable individuals to obtain information about bus departure locations and schedules. Special consideration should be given if transportation of special populations becomes necessary (e.g., children, the elderly, homeless persons, remote populations, and disabled [including homebound] persons). The ability to communicate with drivers via radio or cell phones is critical.

TABLE 3

PANDEMIC INFLUENZA CLINIC SUPPLIES AND EQUIPMENT

General Supplies and Equipment

- Tables
- Chairs
- Water and cups
- Paper
- Pen, pencils
- Envelopes
- Rubber bands
- Tape
- Stapler/staples
- Scissors
- Post-it Notes
- Clipboards
- File boxes
- Telephone/Cell phones
- Paper towel
- Kleenex tissue
- Table pads/clean paper
- Trash containers/bags
- ID badges for staff
- List of emergency phone numbers

Vaccine Administration Supplies

- Cooler/refrigerator for vaccine
- Needles
- Syringes
- "Sharps" containers
- Latex gloves
- Latex-free gloves
- Antibacterial hand-washing solutions
- Alcohol wipes
- Rectangle band-aids
- Gauze
- Adhesive tape
- Spray bottle of bleach solution
- Thermometers for vaccine and people
- Curtain for privacy

Emergency Supplies

- Standing orders for emergencies
- Epinephrine 1:1000 SQ
- Diphenhydramine 50 mg IM
- 3cc syringes with 1", 25-guage needles
- 1.5' needles
- Tuberculin syringes with 5/8" needles (for epinephrine)
- Alcohol wipes/Sterile dry pads
- Bandages
- Tongue depressors
- Adult and pediatric pocket masks with one way valve
- Adult and pediatric airways tubes
- Tourniquet
- Gurney
- Stethoscope
- Flashlight/batteries
- Blood Pressure Monitor
- Instant Cold Packs
- Cots
- Blankets
- Pillows

Crowd Management Supplies

Signs for clinic stations and between stations
Queue partitions (to keep people in lines), roping

Computer Equipment and Supplies

Computers
Printers/Ink Cartridges
Paper
Internet access

8. Vaccine Storage and Handling

Guidelines for handling and storage of inactivated and live-attenuated influenza vaccines are appended. The package inserts should be consulted for optimal cold storage criteria. For both types of vaccine, the cold storage temperature recommendations for vaccine refrigerators, shipping containers and day storage at administration sites is 2-8° C. Vaccine shipping boxes and equivalent containers and cold gel packs are adequate for day use. If the clinic lasts for more than one day, arrangements must be used to store the vaccine in a secure, temperature-monitored refrigerator. Vaccine usage should be monitored closely, and arrangements made to obtain additional vaccine, as needed.

9. Disposal of Needles and Medical Supplies

All vaccination operations should observe universal precautions for preventing blood exposures and blood borne pathogen transmission (i.e., hepatitis B and C viruses [HBV, HCV], and human immunodeficiency virus [HIV]). Specific guidelines for the proper disposal of instruments and other potentially contaminated material during a novel H1N1 influenza vaccination operation are summarized below:

1. Appropriate disposal of pre-sterilized needles after use:
    - Medical waste sharps containers should be available in the area where the sharp is used.
    - Arrangement should be in place for transport and destruction of filled sharps containers.

Other medical waste, including gauze or cotton used during administration of vaccine, other potentially contaminated material, and empty vaccine vials and nasal spray containers should be bagged in appropriately marked biohazard bags and incinerated or autoclaved on-site if possible

10. Vaccine Security and Tracking

Since the demand for influenza vaccine for novel H1N1 may be very high, care must be taken to protect the vaccine supply from theft and fraud. In addition, great care and pre-planning must occur to minimize vaccine wastage that may result from improper handling and storage, and discarding prefilled syringes and partially used vials. Because of these factors, each and every dose and vial should be accounted for before and after each clinic session.

11. Communication Systems

Each clinic must have a working phone and computer facilities for e-mail traffic. If available, walkie-talkies and cell phones should be distributed to the clinic staff. Ideally, replacement batteries and/or battery chargers for each device also should be made available. A list of important land and cell phone numbers should also be distributed to all clinic staff.

12. Post Clinic Activities

Post-clinic activities are necessary to ensure that the event is documented for the public record, to determine the cost of the operation and to enhance efficiency for future efforts. In this context, evaluation of novel influenza clinics should include review of expenditures and in-kind cost incurred in the operation, identification of gaps and problems, recommended changes in emergency response plans, and a description of implications for public health infrastructure.

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