

Section 6: Vaccine Procurement, Distribution, and Use

- I. Overview**
- II. Objectives**
- III. Prioritization**
- IV. Administration of Vaccine**
- V. Vaccine Procurement, Allocation, and Distribution**
- VI. Information Technology in Support of Vaccine Distribution**
- VII. Vaccine Monitoring**
- VIII. Communication**
- IX. Staffing**
- X. Training**
- XI. Activities by WHO Pandemic Period and CDC Pandemic Interval**

Appendices:

- 6-A: Vaccine Priority Groups
- 6-B: Mass Clinic Planning
- 6-C: Vaccine Procurement and Distribution
- 6-D: Site Certification Checklist

I. Overview

Once available, a vaccine against the circulating pandemic virus strain will be a major focus of pandemic response efforts. Ensuring rapid, efficient, and equitable distribution of vaccine is central to pandemic planning. Vaccine will be key to reducing the morbidity and mortality resulting from the pandemic, and to minimizing social disruption by maintaining essential services. It is not known how quickly the pandemic vaccine will become available, and supply is likely to be limited during the early stages of the pandemic. Furthermore, it is likely that two doses of vaccine will be required to achieve a protective response from the vaccine. Therefore, when vaccine becomes available it is essential that it be distributed in an equitable and consistent manner across New York State.

A limited amount of avian influenza A (H5N1) vaccine is being stockpiled and will be considered for early use in the event of an H5N1 pandemic. Development of vaccines against other strains with pandemic potential is also being considered. A monovalent vaccine directed against a novel circulating pandemic virus strain of influenza should begin to be available within 4-6 months after identification of the new pandemic virus strain. The number of persons who may be protected by vaccination depends on manufacturing capacity, the amount of antigen needed per dose for a protective immune response, and the number of doses required. Preliminary results from a recent trial of an H5N1 vaccine in healthy adults suggested that two doses and more than the amount of antigen usually contained in the annual seasonal influenza vaccine were required. Additional clinical trials are ongoing to evaluate possible ways to improve the immune response and to lower the amounts of vaccine antigen needed for protection.

The Department of Health and Human Services (DHHS) and the National Vaccine Advisory Committee (NVAC), in cooperation with the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP), have been working to provide guidance on prioritization during a pandemic. The categories that have been specified are included in this plan in Appendix 6-A. More recently, draft guidance has been developed that will change the order and content of the pre-pandemic priority groups. A summary of the proposed changes in priority groups is also included in Appendix 6-A. Any priority groups established during the pre-pandemic period will have to be reassessed, and possibly altered, as soon as epidemiologic data on the specific pandemic virus becomes available.

There are two ongoing activities conducted by the New York State Department of Health (NYSDOH), local health departments (LHDs) and health care partners that are essential for pandemic preparedness: 1) annual influenza vaccination campaigns, and 2) emergency preparedness planning. The strength of the annual influenza vaccination program should improve the success of the pandemic influenza vaccination program. Higher annual vaccination rates will foster increased familiarity with and confidence in influenza vaccines, increased immunization manufacturing capacity, and strengthened distribution channels. In addition, the work already done on developing plans for emergency mass distribution of medical supplies provides the basis for developing local pandemic vaccination plans. The promotion of the appropriate use of pneumococcal vaccine is also important so that vulnerable populations will be protected from pneumococcal pneumonia, a serious sequela to influenza infection.

This section provides recommendations on planning for the necessary elements of a pandemic vaccination program. Objectives specific to vaccine use are outlined and guidelines for prioritization are included. Also included are plans for vaccine procurement and distribution, vaccine safety monitoring, data collection, communication, staffing and training. Finally, recommended activities for vaccine planning are described according to pandemic period and interval. Guidelines for mass clinic planning can be found in Appendix 6-B.

II. Objectives

- Ensure efficient and equitable distribution of pandemic vaccine;
- Plan for the acquisition, allocation, distribution, and administration of vaccine;
- Monitor vaccine use and safety during a pandemic to assure that the benefits outweigh the risks;
- Collect appropriate data on vaccine procurement, allocation, distribution, administration, safety, effectiveness, and resistance; and
- Describe and plan for risk communication activities and methods to enable the public and providers to access information on vaccine use and availability.

III. Prioritization

During the initial stages of a pandemic, the supply of vaccine will most likely be limited, and the CDC will likely be providing epidemiologic information and guidelines for the prioritization of vaccine distribution and use. During the interpandemic period, the NYSDOH needs to plan for determining and vaccinating priority groups.

A. Priority Groups

A list of and rationale for priority groups for receiving vaccination that was developed by NVAC and ACIP in 2005 is provided in Appendix 6-A. Since then, a federal interagency workgroup has been established and a great deal of work has been done to clarify and reorganize priority groups for vaccination. The new priority schema has been discussed with many partners, including two public forums. It is still in draft form and can also be found in Appendix 6-A. The NYSDOH will look to the final document for guidance on how to specifically address vaccinating those prioritized for vaccine. Planning for how to reach priority groups for vaccination can proceed with the order of vaccination being adjusted according to the final decisions of the workgroup. Flexibility is an important component of planning for vaccination during a pandemic since priority groups will most likely be modified again according to the epidemiology of the pandemic.

Groups who have been considered for vaccine prioritization include:

1. Those who maintain essential services (e.g., public safety and health care).
2. Those at high risk for contracting influenza during a pandemic (including those who would work in response to an outbreak of avian influenza).
3. Those at high risk for complications or death from the pandemic strain.

In the more recent draft federal guidance, the categories of persons recommended for vaccination have been modified to include:

1. Those who protect homeland and national security.
2. Those who provide health care and community support services.
3. Those who maintain critical infrastructure.
4. Those in the general population.

The new guidance allows for vaccination of subsections of each of these categories at the same time, acknowledging that each category contains those who are at a high priority for vaccination. As the pandemic progresses, the prioritization moves down within each category allowing for continued vaccination across groups. In addition, the new prioritization schema allows for differences in the severity of the pandemic and adjusts those prioritized accordingly. For details, please see Appendix 6-A.

B. Pre-pandemic Vaccination

A stockpile of H5N1 vaccine is being established for possible use before a pandemic occurs or for use if the strain that causes a pandemic is contained in the vaccine. The federal government plans to have enough vaccine to immunize 20 million people with 2 doses of vaccine. Discussion continues to define which groups would be eligible and what the timing to the use of this vaccine will be. Priority groups for pre-pandemic vaccine will be determined at the national level. All pre-pandemic vaccine will be purchased by the federal government and New York State will follow national guidelines for the use of this vaccine if any is made available. Administration of vaccine will proceed according to mass distribution plans that have been established.

IV. Administration of Vaccine

Administration of vaccine is the process whereby vaccine is given to those individuals who are prioritized to receive immunization during a pandemic. Vaccine is likely to be in short supply during the initial phases of a pandemic and will first be given to those who are prioritized to receive it. Therefore, when vaccine is in short supply vaccine will only be available through the public health system. As the supply of vaccine increases, it may be possible to revert to the usual methods and sites of influenza vaccine distribution. A great deal of work has been done in regard to planning for large-scale distribution of medications and vaccines in the context of planning for a bioterrorist event using the Point of Dispensing (POD) model. Pandemic administration plans will use what has been planned and learned from the POD model, but it may be necessary to operate small-scale vaccination clinics when supply is scarce. While vaccine is in short supply, the administration of antivirals may take place throughout the duration of the first pandemic wave to treat those who are ill with influenza and, if supply allows, to prophylax those who are unable to be vaccinated.

Vaccination will most likely occur in the following phases:

Phase 1: Vaccination with stockpiled pre-pandemic vaccine, conducted by public health potentially in collaboration with agencies and institutions.

Phase 2: Vaccination with pandemic vaccine, conducted by public health.

Phase 3: Vaccination with pandemic vaccine, conducted by the private sector.

Planning Assumptions and Considerations

- Vaccine will be purchased by the Federal government and distributed to the state by the manufacturers.
- Vaccines will be delivered to pre-determined sites within counties. When supply is scarce, LHDs will be the vaccination sites. As supply increases, vaccine may be made available to medical facilities, pharmacies, and others.
- Vaccines will require:
 - 30 ug of antigen per dose;
 - 2 doses will be needed at least 28 days apart; and
 - Manufacturing capacity will allow each state to vaccinate 1.5% of its population with 2 doses per month.
- Vaccine will be shipped weekly.
- The amounts that will be delivered to the LHDs will be determined by population size and critical infrastructure located within a county, hospital and long-term care facility bed numbers, healthcare facility staff size and roles, and established priority groups.
- When directed, CDC/SNS will most likely deliver vaccine to the State without waiting for a request. The amount delivered will be a pre-determined allocation based on population size and supply.
- Vaccine will be delivered from the State stockpiles once a novel strain of influenza has been detected in New York State or when instructed to do so by the CDC.
- Priority groups for vaccine use will be determined at the national level. For planning purposes, the groups outlined in Appendix 6-A will be the priority groups that are used.
- The rank order of priority groups is subject to change based upon further work by the Federal workgroup, the severity and epidemiology of the pandemic and vaccine supplies.
- Vaccine use guidelines will be made available by the State. All prioritization and use recommendations will be designated by the NYSDOH as the Standard of Care in New York State. As such, it is expected that all physicians, nurses, and licensed health care facilities will adhere to these recommendations.
- Vaccine will be administered to priority groups sequentially. If supply is not adequate for an entire priority group, sub-prioritization may be necessary.
- The location of vaccine administration will be based on county of residence, occupational group, and location of health care facilities.

A. Sites for Vaccine Administration

Initially, when vaccine supply is limited, LHDs will be the primary site for the administration of vaccine. Vaccination will be limited to priority groups and it may be necessary to conduct small secure vaccination clinics at which priority group status is

verified. As supply is expanded, several additional sites may be used to administer vaccine. The appropriate combination within a county will depend on several factors, including the size of the population, the number of health care facilities that are within a county, the presence of critical infrastructure, the availability of 24-hour access, and the geographic features and barriers present. Sites that can be considered for planning purposes are described below. For sites used, agreements will need to be put into place that guarantee that vaccine will be used according to state guidelines, stored appropriately, kept securely, and that usage will be tracked and recorded. An appropriate individual will be designated at each site to receive and monitor use of vaccine supply.

Local Health Departments (LHDs)

The NYSDOH and other New York State agencies have been working with LHDs to develop the capability for mass distribution of medications and vaccines. In New York State LHDs are the primary sources of public health services. LHDs have established relationships with partners and sites within their communities to conduct dispensing activities. The LHDs have established memorandums of agreement (MOAs) and points of contact within their counties and have addressed staffing requirements and the ability to administer medications or vaccines within set amounts of time. All of the 57 LHDs in the State outside New York City have conducted exercises to test their capabilities and to identify gaps and strengths. Many have used the lessons learned to address real emergencies that have required mass distribution of vaccine or medication.

Health Care Facilities

Hospitals and long-term care facilities would be logical sites for the administration of vaccine. Health care facilities (HCFs) have the staff with appropriate vaccination skills and are also sites where those prioritized for vaccination, such as health care workers and critical infrastructure work or visit.

Alternate Care Sites

During a pandemic, alternate care sites will serve as overflow facilities to care for ill persons who cannot be accommodated in a full-service hospital. These sites will be able to administer vaccine to staff and patients.

Private Provider Offices and Clinics

Patients who are prioritized for vaccination may be able to receive immunizations at their own medical provider site. This will be feasible when vaccine is in adequate supply so that the usual channels of vaccine distribution are able to be used.

Emergency Rooms

It is important that emergency rooms be reserved for the most severely ill patients and for after-hours use. Therefore, emergency rooms may not be the most appropriate site for the administration of vaccine. Public health messages informing communities about how best to access vaccine will help keep emergency rooms from being overwhelmed.

Pharmacies

Currently, pharmacists are not permitted to immunize in New York State. If that changes, then pharmacies can be used to administer vaccine when supply allows.

B. Security

Security for the vaccine supply and administration sites will be extremely important if supply is limited. Each county, health care facility, and pharmacy will need to develop a security plan in conjunction with those already established by the SNS program. Law enforcement must be a partner in planning at the local and State levels.

C. Administering Vaccine to Priority Groups

Priority groups can be divided into occupationally-defined groups and risk-based groups. Occupationally-defined groups are those priority groups defined on the basis of worksite and work role, and would include individuals designated as providers of critical infrastructure services and public safety. Risk-based groups are defined on the basis of being at risk for serious outcome (e.g., 65 and older, underlying conditions) or being a household contact of high-risk persons. Initially, all occupational and other prioritized groups will obtain vaccination from small LHD-based clinics. As supply increases it will be possible for occupational groups to obtain vaccine from their work site. The 4 major categories described to obtain vaccine are:

1. Those who protect homeland and national security
2. Those who provide health care and community support services
3. Those who maintain critical infrastructure
4. Those in the general population.

Those Who Protect Homeland Security and National Security

The administration of vaccine to firefighters, police, emergency medical technicians (EMTs) and other persons with responsibility for public safety will take place at LHDs or at occupational sites.

Those Who Provide Health Care and Community Support Services

Initially vaccine will be given at LHD clinics. As soon as supply allows, vaccine will be delivered to hospitals and long-term care facilities for administration to health care workers who are prioritized to receive them. Each facility needs to implement a process for verifying priority group status and medical assessment of workers.

Those Who Maintain Critical Infrastructure

This group is yet to be defined by the DHHS. This group will be able to receive vaccine from LHDs on site or later, when supply increases, at an occupation-based clinic. A method must be in place to verify occupation, priority group status and identity (see D. Verification of Priority Group Membership).

**Those in the General Population
Ambulatory Outpatients and the General Public**

Persons who are prioritized for vaccine will initially be vaccinated at a LHD clinic. Once supply is sufficient, it may be possible for individuals to receive vaccine in several ways:

- From their own provider;
- At a dispensing site run by a LHD or a participating pharmacy; and
- At an alternate care site.

There are a large number of outpatients in priority group categories and it may be necessary to sub-prioritize administration. National recommendations for sub-prioritization of antiviral administration within these large groups will be forthcoming. States may be given flexibility in defining subgroups within these larger groups.

D. Verification of Priority Group Membership**Occupation-Based Priority Groups**

Companies designated as critical infrastructure will need to prioritize their employees, and provide local public health authorities with a list of individuals considered essential to continuity of critical infrastructure or public safety in the order in which they are prioritized. Federal and State guidelines will assist employers in making these designations. LHDs need to work with these entities within their counties to facilitate the exchange of lists and to inform the companies and agencies about the procedure to obtain vaccine. Individuals in occupations prioritized to receive vaccine need to be able to provide proof of their identity and occupation or workplace. A work identification card (ID) and picture ID, such as a driver's license, would be sufficient proof.

Within hospitals and long-term care facilities, a designated person will be responsible for coordinating the decision-making process to determine which staff members are eligible for vaccine administration by site and work role. Federal and State guidelines will assist facilities in prioritizing their staff. The facility will need to establish procedures for ensuring that only those who are prioritized receive vaccine.

Risk-Based Priority Groups

Priority group status based on risk can be verified in the following ways:

- A note or prescription from a provider verifying risk status;
- Certain prescription bottles or copies of prescription labels with the person's name on it;
- Identification cards or driver's licenses can be used to verify age and should be used to verify identity;
- Individuals who are at high risk or have a chronic medical condition should be encouraged to obtain documentation of risk status from their providers in advance of a pandemic.

The NYSDOH will work to provide guidelines for which medications and conditions make individuals eligible for antivirals.

Special Populations

In a state as large and diverse as New York State, there exist numerous groups that may present challenges to providing access to appropriate medical care and vaccine during a pandemic. LHDs must make an effort to identify those groups within their communities and to work with the NYSDOH to create plans to reach these populations. Examples of special population groups may include:

- Tribal communities;
- Religious groups;
- Individuals that primarily speak a language other than English;
- Individuals in home care and hospice;
- Homebound individuals;
- Disabled individuals; and
- Homeless individuals.

In regard to these groups it is important to:

- Plan in advance with groups that represent these individuals.
- Insure that materials are available in appropriate languages.
- Make sure that clinics can be accessed by public transportation.
- Ensure that the needs of the physically disabled are met at planned sites.
- Work on ways to communicate with special needs populations.

E. Administering a Second Dose of Vaccine

Annually administered influenza vaccine requires that a second dose of vaccine be administered to those individuals under the age of 9 years who have never received a vaccine before. Since the population will be immunologically naïve to a pandemic influenza viral strain, it is likely that 2 doses will be needed for individuals of all ages to mount an adequate immune response. Clinical trials completed on pre-pandemic vaccine targeted to an H5N1 influenza strain have documented the need for a 2 dose series.

Federal planning assumptions have outlined the need for 2 doses given 4 weeks apart and have stated that the projected allocation to states for planning purposes is that each state would be able to vaccinate 1.5% of its population per month with 2 doses. After the first 4 weeks of the initiation of pandemic vaccination, a portion of each shipment will need to be reserved for second doses.

Persons receiving their first does will need to receive information about returning for the second dose and information systems will need to be able to track the doses given and document when an individual has received the 2 doses. As the vaccination program progresses, information on return rates will be available and it will be possible to plan for the amount of doses that need to be reserved for those returning for administration of a second dose (see VI. Information Technology in Support of Vaccine Distribution).

V. Vaccine Procurement, Allocation and Distribution

The administration of vaccine will be central to a response to an influenza pandemic, although there still may be significant morbidity and mortality in the period during which an effective vaccine is being developed and produced in sufficient quantities. The federal government continues to work closely with vaccine manufacturers in the creation of vaccines that may be beneficial in combating likely pandemic strains of influenza and will signal to manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at full capacity. However, because of the uncertainties associated with predicting which influenza strain will be the cause of a pandemic, and the time needed to produce vaccine in amounts great enough to have an impact, it is anticipated that there will be a period of several months before pandemic vaccine is available for administration.

Pandemic vaccine will be supplied by the federal government to the states. This may be different from pre-pandemic vaccine, which is currently being developed and produced for the CDC under the DHHS. After exhaustion of pre-pandemic vaccine, vaccine will be supplied through the DHHS as available from vaccine manufacturers. In New York State, the NYSDOH will take the lead in determining the distribution of vaccine to LHDs for administration to the public.

For a detailed description of the logistics involved with the procurement, storage and distribution of vaccines, refer to Appendix 6-C: Vaccine Procurement and Distribution. The requirements and activities described in Appendix 6-C apply to public health crises involving pandemic influenza where local and State medical treatment capabilities are exceeded, necessitating the use of SNS assets or State and locally procured supplies.

VI. Information Technology in Support of Vaccine Distribution

The capability to gather essential information regarding the acquisition, allocation, distribution, and use of pandemic vaccine will be a critical aspect of the response to a pandemic. The goal is to track inventory, record the number of doses given and to whom they were given, monitor adverse events, and fulfill federal reporting requirements. An integrated system utilizing pre-existing electronic applications that have already been developed would meet the data needs of a pandemic response.

To ensure optimal use of a new pandemic influenza vaccine, data will need to be collected on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety. The NYSDOH will utilize the NYS Vaccine Ordering and Distribution System and the NYS Clinic Data Management System (CDMS) to collect, store, recall and process immunization and demographic data for patients and public health responders and can be utilized in both routine and emergency situations. CDMS has the capacity to track the status of immunizations for patients and public health responders via paper, web or LAN-based data submissions. The system is being adapted to incorporate data collection templates and forms that are event-specific and appropriate for mass vaccination clinics.

The NYSDOH informatics workgroup is currently assessing various aspects of the CDMS, including compliance with the Public Health Information Network (PHIN) and the integration of the NYSDOH Pre-Event Smallpox Vaccination System (PVS) and the Vaccine Ordering and Distribution System with the Countermeasure and Response Administration (CRA) system. During 2005 and 2006, the NYSDOH promoted, trained and tested Version 1.0 of the CDMS with 57 LHDs and two Tribal Nations during Points of Dispensing (POD) exercises. Time-study information was collected and recommendations were made resulting in further improvements to the form and system; Version 2.0 will be released in June 2007. The CDMS continued to be used successfully during mass vaccination exercises in the Fall of 2008.

The NYSDOH will develop a strategy for monitoring vaccine distribution by public health. Data elements that may be collected include:

- The distribution of state and federal supplies of vaccine, including
 - Where vaccines have been shipped;
 - Who has received them, including demographic information on the recipients;
 - Type of administration: pre-pandemic or pandemic;
 - Priority groups reached;
 - Number of doses administered by person and in the aggregate; and
 - Relevant medical history.
- Adverse events following administration of vaccine; and
- Rates of severe influenza illness and death among those vaccinated.

Data collected will be reported to the CDC on a weekly basis. The minimum data elements that CDC requires are:

- Date of administration;
- Age group;
- Priority group;
- 1st or 2nd dose; and
- County or zip code.

Data will be collected by administration sites and transmitted to the state. Once vaccination is on-going in the private sector, only vaccinators that will collect and submit appropriate data will be permitted to receive and administer pandemic vaccine.

VII. Vaccine Monitoring

Vaccine safety monitoring during a pandemic is critical to assess the occurrence of adverse events and provide data regarding any risks of vaccination. Influenza vaccine, like all vaccines, occasionally causes local reactions at the site of injection and may cause mild systemic symptoms such as headache or fever. More severe systemic reactions generally are extremely rare. The safety profile of a pandemic vaccine may be different than that usually seen with the annual influenza vaccine.

A. Vaccine Efficacy

The benefit of vaccination is measured by determining vaccine efficacy. During a pandemic the determination of vaccine efficacy would most likely be the role of CDC. However, the NYSDOH may be asked or required to participate in efficacy studies. The NYSDOH may wish to conduct efficacy studies in the early stages of the pandemic when fewer individuals are being vaccinated and active surveillance is more practical. It is possible that accurate and complete efficacy data may not be available until the later stages of the pandemic, depending on how much notice CDC and manufacturers have to develop a novel vaccine.

B. Contraindications

There are currently very few contraindications to vaccination against influenza. Vaccine should not be administered to persons with known anaphylactic hypersensitivity to eggs or other vaccine components as described in the package inserts.

In the setting of a pandemic, desensitization may be an option for those with a history of anaphylaxis to egg products and with high risk for influenza or its complications. An alternative for prevention would be prophylaxis with an antiviral medication.

If the technology and methods used to manufacture the pandemic influenza vaccine are the same as those currently used, the same contraindications would exist. Providers are comfortable and familiar with these restrictions on the use of influenza vaccine. However, if a lethal strain of influenza is circulating, persons may be asked to take risks in regard to receiving vaccine that they might not take during a typical influenza season. Efforts must be made to educate all health care providers, vaccine administrators, and vaccine recipients on the potential risks of the particular pandemic vaccine when they become known. Clinical guidelines will need to be developed in regard to vaccination risk assessment and evaluation. Those at particular risk may need to be actively followed or monitored in a health care facility post vaccination.

C. Vaccine Adverse Event Monitoring and Reporting

In the U.S., national surveillance for adverse events following immunization is routinely conducted through the Vaccine Adverse Event Reporting System (VAERS), which is managed jointly by the CDC and Food and Drug Administration (FDA). Events that may be associated with vaccination can be reported on paper forms, by telephone, or electronically by health care providers, patients, health departments, or vaccine manufacturers. Reports of serious adverse events are followed up to collect additional information for analysis to determine whether such events are reported more frequently than expected.

During a pandemic, VAERS would remain the major reporting mechanism, much as it was during the smallpox vaccination campaign. Adverse events related to pandemic influenza vaccination would likely be made reportable in New York State. The

NYSDOH would require that all such adverse events be reported to the local health department of the county where the affected person resides utilizing the same reporting mechanism available for the reporting of other communicable diseases in the state. The requirement would include that adverse events be reported in a timely fashion, within a designated time frame. The NYSDOH has identified a vaccine safety coordinator as well as a back-up vaccine safety coordinator to oversee reporting policies, methodologies and procedures as well as to ensure that adverse events are reported to VAERS and followed up appropriately.

During a pandemic, vaccine recipients with concerns about a potential adverse event will be referred to their own health care provider or the local emergency department for medical evaluation. If a provider requires medical advice or support, he or she may call the medical director of their local health department or their designated medical regional resource center. There are 8 regional resource centers throughout the upstate area. These are medical centers with a complete selection of medical specialists that can care for and address adverse events. Physicians at the NYSDOH will be available for consultation on vaccine related adverse events, and can consult experts at the CDC if required.

It is likely that VAERS will be supplemented by additional surveillance and studies to rapidly evaluate the safety of the vaccination program. Active surveillance for adverse events in a sample of vaccine recipients could be conducted by the use of self-report diary cards or by telephone interviews at specific intervals after vaccination. Existing databases can be analyzed to compare rates of medical visits and hospitalizations for person who are vaccinated with those who are not. Databases also can be analyzed to compare rates of illness and medical care shortly after vaccination with other time periods. Large scale safety studies are best conducted by national organizations, and once a campaign to vaccinate large numbers of individuals is underway, active surveillance will be impractical.

The NYSDOH is developing a vaccine safety monitoring system that will coordinate with VAERS. To accomplish this, the NYSDOH will continue to expand its Clinic Data Management System (CDMS) to collect adverse event information. This system provides a standardized format for the NYSDOH and LHDs to collect, store, recall and process treatment and demographic data for patients and public health responders and can be utilized in both routine and emergency situations. CDMS has the capacity to track the status of medication administration for patients as well as vaccinated or prophylaxed public health responders via paper, web or LAN-based data submissions. The system is being adapted to incorporate data collection templates and forms that are event-specific and appropriate for mass prophylaxis and/or vaccination clinics.

Additionally, the NYSDOH is participating in a project directed by the DHHS and CDC to collect, aggregate, and transmit data on vaccine doses administered to the CDC Countermeasure and Response Application (CRA) weekly, as part of their National Pandemic Plan. The NYSDOH will develop and test an application that captures the minimum data elements (patient's date of birth, POD ID, and date of clinic) on the

CDMS using patient information gathered during the seasonal flu PODS exercises slated for November 2007.

D. Contingency Planning for Investigational New Drug Use and Experiment Use Authorization

It may be necessary to distribute unlicensed vaccine during a pandemic. Unlicensed vaccine may be needed, for example, if pandemic spread is rapid and there is insufficient time to conduct standard vaccine efficacy studies. There are two mechanisms for use of unapproved medical products or unapproved uses of approved products. The first is under the FDA's Investigational New Drug (IND) provisions. IND provisions require completion of a signed consent form from each person who receives the medication, and mandatory reporting of specified types of adverse events. IND provisions also require strict inventory control and record-keeping, and approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other venues. The FDA regulations permit use of a national or "central" IRB. The NYSDOH has staffing capabilities and printing facilities to coordinate the receipt, mass production and distribution of the IND protocols and consent forms. However, it is anticipated that IND requirements will be too difficult to meet during a widespread emergency such as a pandemic.

As an alternative to IND use, DHHS may utilize the drug product under Emergency Use Authorization (EUA) procedures. If a national emergency is declared by the Secretary of the DHHS, the FDA Commissioner may authorize the use of an unapproved medical product or an unapproved use of a licensed medical product. Once issued, an EUA is active for one year but may be terminated earlier if the DHHS Secretary determines that it is no longer needed. EUA procedures are described in the FDA draft guidance "Emergency Use Authorization of Medical Products" available on the FDA website at www.fda.gov/cber/gdlns/emeruse.pdf.

EUA requirements include record keeping, distribution of information sheets to providers and patients, and adverse event reporting. CDC plans to issue an operational plan for EUAs.

Adverse events related to the use of IND vaccines may need to be reported through other mechanisms in addition to or in place of VAERS, in accordance with specific regulatory or policy requirements. Adverse events will also be monitored through the Vaccine Safety Datalink (www.cdc.gov/nip/vacsafe/default.htm#VSD), a network of seven geographically diverse health maintenance organizations through which active surveillance vaccine safety studies are conducted. The NYSDOH will utilize the reporting mechanism determined by the CDC.

VIII. Communication

Timely, clear, consistent and effective messaging is essential to ensure that members of the public understand limitations on vaccine availability and efficacy and are willing to engage in other critical risk reduction measures (pharmaceutical or non-pharmaceutical interventions) in the event that sufficient supplies of vaccine are not available for all ill persons. It is also

important that messages relating to vaccine availability, efficacy and prioritization are crafted to help address the problem of worried individuals over- burdening healthcare resources. To accomplish this goal the NYSDOH will:

- Provide pre-event education to various sectors using mass media, public engagement and targeted communications;
- Prepare and disseminate information for health care providers;
- Prepare public information materials pre-event and provide them to public website staff for posting on the Department's "test" website;
- Provide script templates and pre-recorded messages to the Department's contract call center operators, and also disseminate these materials to key communications partners;
- Provide information for internal audiences (e.g., DOH/Health Research, Inc employees); and
- Utilize materials provided by the Federal government and adapt for use in New York State.

Materials and messages will need to be developed that reach a broad spectrum of the public. This may mean dissemination in a variety of languages and reading levels, and the utilization of methods to reach those not ordinarily accessible by mainstream methods.

IX. Staffing

Staffing is an important component of running any type of long-term dispensing system and can be estimated once the number of sites required is identified and the hours during which they will operate are set.

Hospitals, Medical Reserve Corps (MRCs) and LHDs should be working together to identify and recruit medical and non-medical volunteers who can assist in healthcare settings or PODs. These volunteers should be included in local emergency efforts when exercising hospital-PODs and LHD PODs. In the aftermath of September 11th, the NYSDOH developed a statewide Public Health Preparedness Volunteer Practitioner Database of licensed professionals who would be willing to volunteer their services in the event of a public health emergency. The purpose of this Volunteer Practitioner Database is to assure that NYS, NYC and the 57 remaining counties of the state have adequate resources to prepare for and respond to any public health emergency when their local volunteer resources are depleted. The database is designed not to deter or compete with volunteer recruitment efforts on the local level, but rather to supplement and serve as a logical extension of those efforts. Volunteers who agree to participate in this state-sponsored volunteer program are provided the personal liability protection of Public Officers Law § 17 if they are activated and deployed by New York State. Staffing of security personnel will be critical during a pandemic as the demand for vaccine will likely be greater than the supply.

X. Training

The NYSDOH has been conducting training in roles associated with mass smallpox vaccination clinics since 2003. In 2004, training was expanded to include roles associated with both mass

vaccination clinics and mass prophylaxis clinics, with emphasis on transferability of skills across clinic type. In 2006, training was modified again to include pediatric clinics, as well as roles associated with push methodologies for vaccination or prophylaxis. Job action sheets have been created for all clinic roles, and a just-in-time training guide has been integrated into the NYSDOH POD Standard Operating Guide. Training has also been provided to state and local public health providers in the “Clinic Planning Model Generator,” to assist in identification of numbers of staff needed for clinics based on type of clinic, population, and other factors associated with mass clinics.

Training will continue via diverse methodologies (didactic, webinar, videoconference, online training) not only for roles associated with mass clinics, but also for roles associated with the Strategic National Stockpile (Job action sheets have been developed for each of these roles).

Additionally, volunteers have been integrated into mass clinic exercises via agreements with local Medical Reserve Corps. Just-in-time training has been provided in clinic roles at both state operated mass influenza vaccination clinics, as well as such clinics at the local level. Mass clinic exercises with associated training will continue on a yearly basis. These activities are ongoing for both short-term and long-term operationalization of the pandemic influenza plan.

XI. Activities by WHO Pandemic Period and CDC Pandemic Interval

A. Vaccine Prioritization

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department

- Continue to enhance use of annual influenza vaccine;
- Continue to promote the use of pneumococcal vaccine;
- Identify a process for reviewing national recommendations for pandemic influenza vaccination and developing state specific modifications or refinements in priority groups, depending on local circumstances;
- Continue to meet to address prioritization issues;
- Continue the development of specific definitions for priority groups identifying occupational categories and sub-categories;
- Estimate the size of relevant priority groups;
- 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;
- Educate professional organizations and other stakeholders about the need for priority groups and the rationale for the groups currently recommended;
- Stockpile pre-pandemic vaccine if available;
- Establish a pre-pandemic vaccination plan;

- Continue to plan for the use and training of non-licensed persons to administer vaccine; and
- Continue public health preparedness activities especially in regard to mass distribution of vaccines.

Local Health Departments

- Continue to enhance the use of annual influenza vaccine;
- Continue to promote the use of pneumococcal vaccine;
- Continue to identify and quantify priority groups within the county;
- Identify hard to reach groups within the county that would require immunization;
- Develop a plan on how individuals in priority groups would be reached and vaccinated;
- Develop a plan on how to identify priority groups at vaccination clinics;
- Educate providers and other stakeholders about local health department plans for vaccination;
- Continue public health preparedness activities especially in regard to mass distribution of vaccines; and
- Continue to plan for the use and training of non-licensed persons to administer vaccine.

Healthcare Partners

- Enhance use of annual influenza vaccine;
- Enhance the use of pneumococcal vaccine;
- Identify those in priority groups within a practice or facility;
- Work with local health department staff in mass distribution planning; and
- Continue public health preparedness activities especially in regard to mass distribution of vaccines.

Pandemic Period- After the first reports of pandemic influenza are confirmed and before a pandemic vaccine becomes available (Initiation, Acceleration, Peak, Deceleration Intervals)

State Health Department

- Work with local health departments and health care partners to distribute, deliver, administer, and track pre-pandemic or stockpiled vaccines to designated priority groups, if available;
- Mobilize healthcare partners and prepare to activate plan for distributing and administering vaccines;
- Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccines;
- Review and update modifications if any to recommendations on vaccinating priority groups;
- Make any revisions of priority groups needed and communicate the changes and their rationale to LHDs and health care partners; and

- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications and disseminate risk messages.

Local Health Departments

- Work with the NYSDOH to distribute, deliver, administer, and track pre-pandemic vaccine to designated priority groups;
- Keep providers and other health care partners informed about projected timelines for availability of vaccines;
- Communicate any changes in priority group designations to health care partners;
- Actively identify and locate priority groups in preparation for the availability of a vaccine; and
- Accelerate training in vaccine monitoring for public health staff and partners responsible for vaccinating priority groups.

Healthcare Partners

- Work with LHDs to identify priority groups members;
- Communicate priority group designations and changes to patients and staff; and
- Actively identify and locate priority groups in preparation for the availability of a vaccine.

Pandemic Period - After a vaccine becomes available (*Initiation, Acceleration, Peak, Deceleration Intervals*)

State Health Department

- Work with LHDs and health care partners to distribute, deliver, administer, and track pandemic vaccine to priority groups;
- Continue to review and revise priority groups, and communicate changes and their rationale to LHDs and health care partners;
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated; and
- Provide updated information to the public via the news media.

Local Health Departments

- Work with NYSDOH and health care partners to distribute, deliver, administer, and track pandemic vaccine to priority groups; and
- Phase-in vaccination of the rest of the population after priority groups have been vaccinated.

Healthcare Partners

- Work with LHDs to distribute, deliver, administer, and track pandemic vaccine to priority groups; and
- Vaccinate the rest of the population after priority groups have been vaccinated.

B. Vaccine Procurement and Distribution

- See Appendix 6-C.

C. Vaccine Safety Monitoring

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department

- Establish an adverse event monitoring system;
- Designate an adverse event coordinator;
- Monitor adverse events if pre-pandemic vaccine is used;
- Consider how vaccine efficacy studies would be conducted and coordinate within DOH, especially with researchers and Wadsworth laboratories;
- Disseminate information to LHDs and health care partners on the adverse event monitoring system;
- Identify those health care providers that would provide medical consultation on adverse events on the state level;
- Consider how the implementation of active surveillance would be done; and
- Plan for the use of an IND or Emergency Use Authorization protocol is needed.

Local Health Departments

- Establish an adverse event monitoring system based on the requirements of the statewide system;
- Identify which staff would be responsible for adverse event monitoring;
- Identify which staff would provide medical consultation for adverse events on the local level;
- Disseminate information on the adverse event monitoring system to local health care partners; and
- Work with the NYSDOH to plan for IND or Emergency Use Authorization protocols.

Healthcare Partners

- Establish an adverse event monitoring system within health care facilities and practices;
- Identify staff that would be responsible for adverse event monitoring;
- Identify staff that would be responsible for medical consultation for adverse events;
- Disseminate information on adverse event monitoring to staff; and
- Work with NYSDOH and LHDs to plan for IND or Emergency Use Authorization protocols.

Pandemic Phase-Before and After a Vaccine is Available (*Initiation, Acceleration, Peak, Deceleration Intervals*)

State Health Department

- Implement the adverse event monitoring system;
- Institute emergency regulations making pandemic vaccine adverse events reportable;
- Collect vaccine adverse event data from LHDs and providers;
- Conduct any vaccine efficacy or adverse events studies required by CDC or agreed upon within NYSDOH;
- Provide medical consultation for adverse events;
- Consult with CDC on adverse events as needed;
- Report all adverse events to VAERS;
- Update LHDs and providers on any new adverse events identified or any updates on the vaccine adverse event profile;
- Conduct active surveillance for adverse events as needed;
- Provide guidance to LHDs for case investigation of adverse events; and
- Implementation of IND or Emergency Use Authorization protocols if needed.

Local Health Departments

- Implement the adverse event monitoring system;
- Collect reports on adverse events from providers and patients, and provide the information to the NYSDOH;
- Conduct adverse event case investigations;
- Participate in vaccine efficacy or adverse event studies as needed;
- Provide medical consultation for local adverse events;
- Update health care partners on new adverse events or updates on the vaccine adverse event profile;
- Participate in active surveillance as needed; and
- Implement IND or Emergency Use Authorization protocols if needed.

Healthcare Partners

- Implement the adverse event monitoring system in health care facilities;
- Report all adverse events to LHD;
- Participate in adverse event case investigations;
- Provide medical consultation for vaccine adverse events in patients or health care facilities;
- Participate in active surveillance as needed; and
- Implement IND or Emergency Use Authorization protocols as needed.

D. Data Collection

Interpandemic and Pandemic Alert Periods (*Investigation, Recognition Intervals*)

State Health Department

- Through the Data Management Workgroup develop a data collection system that can collect all required vaccine data elements;
- Ensure that the system can be used to supply required elements to CDC and calculate vaccine coverage and efficacy rates;
- Participate in the Pandemic Influenza Doses Administered Pilot Reporting Event project; and
- Provide information on vaccine data collection to LHDs and health care partners.

Local Health Departments

- Participate in the development of the vaccine data management system; and
- Provide information on data collection to staff and health care partners.

Healthcare Partners

- Participate in the development of the vaccine data management system; and
- Provide information on vaccine data collection to facility and practice staff.

Pandemic Phase (*Initiation, Acceleration, Peak, Deceleration Intervals*)

State Health Department

- Activate the data collection system;
- Add any new data elements identified in the course of the pandemic;
- Use the data collection system to aid in calculating vaccine efficacy or coverage rates;
- Provide technical assistance to LHDs and providers using the system;
- Collect data from LHDs and providers on vaccine efficacy and coverage and transmit to CDC at regular intervals as required; and
- Calculate efficacy in and coverage of priority groups.

Local Health Departments

- Activate and use the data collection system;
- Provide feedback if experiencing any difficulty using the system; and
- Ensure that all vaccine data elements are complete.

Healthcare Partners

- Activate and use the data collection system;
- Provide feedback if experiencing any difficulty using the system; and
- Ensure that all vaccine data elements are complete.

Table 1: Vaccine Allocation by Priority Group
New York State (Outside of New York City), Source Federal Pandemic Influenza Plan

Tier	Sub tier	Population Group	NYS Population (Outside of NYC)	Week Group is Completely Vaccinated*	Rationale
1	A	• Vaccine and antiviral manufacturers ¹	1,501	1	Groups are critical for an effective public health response to a pandemic.
		• Medical Workers and Public Health Workforce with Direct Patient Contact ²	381,498	10	Individuals involved with direct patient care will be at risk of repeated exposures and surge capacity for this sector is low.
	B	• 65 and over with one complicating condition ¹	686,140	26	Groups are at high risk of hospitalization and death.
		• 6 months to 64 years of age with 2 or more complicating conditions ¹	109,330	29	Groups are at high risk of hospitalization and death.
		• 6 months or older with history of hospitalization for pneumonia or influenza in the past year ³	27,898	29	Groups are at high risk of hospitalization and death.
	C	• Pregnant Women ⁴	97,763	32	Groups are at high risk of hospitalization and death.
		• Household Contacts of the severely immunocompromised (transplants, AIDS, incident cancer) ⁵	101,790	34	These groups have a lower likelihood of responding to influenza vaccination. Thus, strategies to prevent severe influenza illness in this group should include vaccination of household contacts.
	D	• Public Health Emergency Response Workers ⁶	5,500	39	Group has been critical in past influenza pandemics and influenza vaccine shortages and little surge capacity may be available during an influenza pandemic.
		• Key Government Leaders ⁷	2,000	39	Group is critical for an effective public health

					response to a pandemic.
2	A	• Healthy 65 years and older ⁸	839,492	59	Groups are at high risk of hospitalization and death.
		• 6 months to 64 years with 1 high-risk condition ¹	1,349,660	91	Groups are at high risk of hospitalization and death.
		• 6 to 23 months, healthy ¹	207,200	96	Groups are at high risk of hospitalization and death.
	B	• Other Public Health Responders ¹	11,310	97	Groups are critical for an effective public health response to a pandemic.
		• Public Safety Workers (police, fire, corrections) ⁹	179,123	101	Groups are critical for an effective public health response to a pandemic.
		• Utility Workers essential for maintenance of power, water, sewage system functioning ¹	13,723	101	Groups are critical for an effective public health response to a pandemic.
		• Transportation workers transporting fuel, water, food, and medical supplies as well as public ground transportation ¹	143,260	104	Groups are critical for an effective public health response to a pandemic.
			• Telecommunications/IT for essential network operation ¹	40,716	105
3	A	• Other Government Health Decision Makers ⁷	1,000	105	Groups are critical for an effective public health response to a pandemic.
		• Funeral Directors/embalmers ¹	2,262	105	Groups are critical for an effective public health response to a pandemic.
4	A	• Healthy Person aged 2-64 years not included above ¹⁰	6,648,681	264	Includes others who do not fall within above groups who would benefit from immunization.

*According to CDC's, "Pandemic Influenza Vaccination: A Guide for State, Local, Territorial, and Tribal Planners" it is assumed that once a pandemic strain is identified and begins production, manufacturers can produce enough vaccine for 1.5% of the population per month. Under this assumption, New York State, outside of New York City would receive approximately 41,880 doses of vaccine per week.

1. Extrapolated using HHS pandemic influenza plan (Table D-12). The population of New York State outside of New York City is 3.77% of the United States population.
2. Healthcare workers are estimated using census 2000 calculations- Summary File 3 for social, economic and housing characteristics available at www.census.gov. Assumes 2/3 of healthcare workers have direct patient contact.
3. Extrapolated using HHS pandemic influenza plan (Table D-12). The population of New York State outside of New York City is 3.77% of the United States population. This will be updated following the analysis of SPARCS data for New York State outside of New York City.
4. Number of Pregnant Women- Number of Live Births in New York State outside of New York City in 2004 multiplied by 75% (Estimates the average number of pregnant women at any particular time during the year).
5. Extrapolated using HHS pandemic influenza plan (Table D-12). Immunocompromised persons estimated at 1.95 million in United States. The population of New York State outside of New York City is 3.77% of the United States population. HHS estimates 1.4 contacts per IC person.
6. Includes state and local health department staff as reported to public health responder survey March 2006, HHS assumes 1/3 of total PH workforce
7. Allows for vaccination for roughly 30 government leaders for each county and roughly 300 government leaders at the state level.
8. Population estimates using from www.census.gov for 2005. Comprised of those over the age of 65 excluding those who have previously been vaccinated as part of a population group in Tier 1B.
9. Police data from New York State Statistical Yearbook of 2004 (Rockefeller Institute). Firefighters from the New York Department of State Fire Service Resource Inventory (June 2005). Corrections include New York State Department of Corrections staff.
10. Total NYS population outside of New York City minus those covered by a previous priority group.

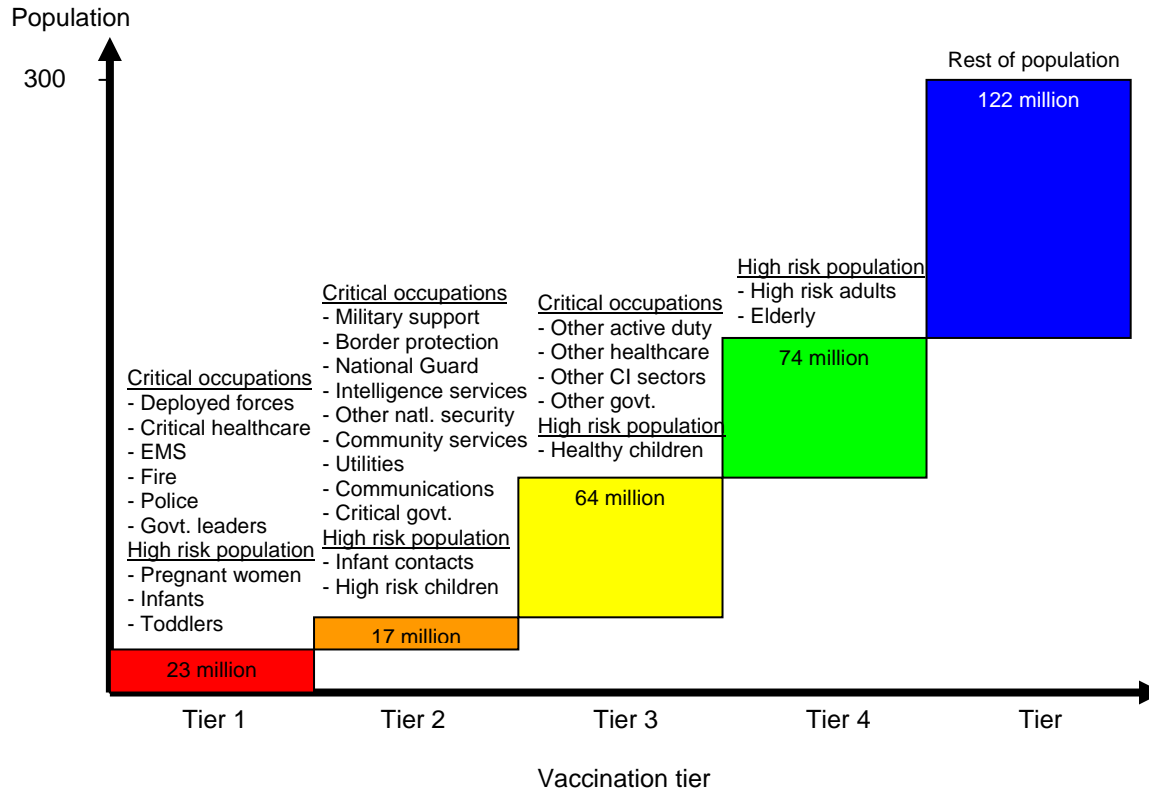
Table 2: Vaccination target groups, estimated populations, and tiers for severe, moderate and less severe pandemics as defined by the Pandemic Severity Index (PSI)

Source: *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*, October 17, 2007

Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Not targeted
CATEGORY	TARGET GROUP	ESTIMATED NUMBER	SEVERE	MODERATE	LESS SEVERE
Homeland and national security	Deployed and mission critical pers.	700,000			
	Essential support & sustainment pers.	650,000			
	Intelligence services	150,000			
	Border protection personnel	100,000			
	National Guard personnel	500,000			
	Other domestic national security pers.	50,000			
	Other active duty & essential suppt.	1,500,000			
Health care and community support services	Public health personnel	300,000			
	Inpatient health care providers	3,200,000			
	Outpatient and home health providers	2,000,000			
	Health care providers in LTCFs	800,000			
	Community suppt. & emergency mgt.	600,000			
	Other important health care personnel	500,000			
Critical infrastructure	Emergency Medical Service personnel	2,000,000			
	Law enforcement personnel				
	Fire services personnel				
	Mfrs of pandemic vaccine & antivirals	50,000			
	Key government leaders	50,000			
	Electricity sector personnel	1,900,000			
	Natural gas personnel	to 4,400,000			
	Communications personnel				
	Water sector personnel				
	Critical government personnel				
	Transportation sector personnel	1,400,000			
	Food and agriculture sector personnel	to 3,500,000			
	Banking and finance personnel				
	Pharmaceutical sector personnel				
Chemical sector personnel					
Oil sector personnel					
Postal and shipping personnel					
Other important government personnel					
General population	Pregnant women	3,100,000			
	Infants & toddlers 6–35 mo old	10,300,000			
	Household contacts of infants < 6 mo	4,300,000			
	Children 3–18 yrs with high risk cond.	6,500,000			
	Children 3–18 yrs without high risk	58,500,000			
	Persons 19–64 with high risk cond.	36,000,000			
	Persons ≥65 yrs old	38,000,000			
Healthy adults 19–64 yrs old	121,800,000				

Table 3. Vaccination tiers and target groups for a severe pandemic. This figure illustrates how vaccination is administered by tiers until the entire U.S. population has had the opportunity to be vaccinated, and how tiers integrate target groups across the four categories balancing vaccine allocation to occupationally defined groups and the general population.

Source: *Draft Guidance on Allocating and Targeting Pandemic Influenza Vaccine*, October 17, 2007



Mass Clinic Planning

Overview

Vaccination is the primary intervention to decrease morbidity and mortality from influenza during a pandemic. Antiviral chemoprophylaxis also may have an important role in preventing infection and antiviral therapy may reduce complications and improve outcomes. Dispensing of antiviral medications and/or vaccines is a cornerstone of any mass prophylaxis campaign against outbreaks of preventable disease. Without the ability to safely dispense large volumes of medications or vaccines to community-based and hospitalized individuals, efforts to curtail the pandemic will not translate into an effective public health response. The ability to vaccinate, treat, or prophylax those initially prioritized to receive vaccine or antiviral medication, and to expand operations as possible is a central activity that requires planning.

The New York State Department of Health (NYSDOH) has undergone an extensive mass clinic planning and training initiative centered around the Point of Dispensing (POD) concept. All local health departments (LHDs) and hospitals have been introduced to POD planning and have developed materials, defined roles, and undertaken exercises in regard to mass clinic planning. The NYSDOH has developed and distributed a POD Standard Operations Guide (POD SOG) that provides both generic guidelines and templates, along with disease specific materials. Planning for pandemic influenza mass vaccination clinics is adequately covered in POD training and planning activities, and the POD SOG is an important adjunct to the pandemic influenza plan. The POD SOG includes most of the essential influenza materials and will be updated yearly, or as frequently as needed during a pandemic. The POD SOG, therefore, will form the basis for all pandemic influenza guidelines. The POD SOG is available on the Health Provider Network at <https://commerce.health.state.ny.us/hpn/hanweb/sns/podguide.html>

I. Planning Considerations for Large-Scale Prevention Clinics

A. The POD SOG provides guidance on all major elements needed for mass clinic planning. The following areas are covered:

1. Command and control;
2. Staffing roles required, and job descriptions;
3. Clinic supplies;
4. Procedures for requesting vaccine or medication;
5. Vaccination clinic location;
6. Clinic lay-out and specifications;
7. Crowd management outside of the clinic;
8. Crowd management inside of the clinic;
9. Clinic security;
10. Clinic advertising;
11. Risk communications/health education;
12. Adverse event tracking;
13. Data management; and
14. Information on special needs populations.

B. The POD SOG includes the following influenza specific materials:

1. Target groups for vaccination;
2. Composition of the current vaccine;
3. Standing orders for administering influenza vaccine and antiviral medication;
4. Information on live attenuated influenza vaccine (LAIV);
5. General influenza vaccine information;
6. Information on how to administer influenza vaccine;
7. Sample forms to screen for contraindications;
8. Facts sheets from the Centers for Disease Control and Prevention (CDC) in English and Spanish;
9. Vaccine information sheets (VISs) on influenza vaccine in English, Spanish, and Russian;
10. Information on respiratory hygiene in healthcare settings;
11. Information on the administration of antiviral medication, including dosing information;
12. Patient education materials; and
13. Information on avian influenza in English and Spanish.

II. References and Resources for Mass Vaccination or Antiviral Dispensing

- Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP)
<http://www.cdc.gov/mmwr/PDF/rr/rr5408.pdf>
- General Guidelines for Smallpox Vaccination Clinics:
www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-2.pdf
- Guidelines for Large Scale Vaccination Clinics:
www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf
- Pandemic Influenza Response and Preparedness Plan
www.pandemicflu.gov
- Vaccination Ventures: Explanation and Outcomes of Mass Smallpox Vaccination exercises. San Francisco Department of Public Health
www.dph.sf.ca.us/Reports/June17Drill/FnlJune17Rpt.pdf
- Guidelines for Large-Scale Influenza Vaccination Clinic Planning
<http://www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf>
- Information on Investigational New Drug (IND) Use
http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr312_99.html
- Information on Emergency Use Authorization
<http://www.fda.gov/cber/gdlns/emerase.pdf>

Vaccine Procurement and Distribution

The receiving, handling and distribution of vaccine require extra precautions and activities during an influenza pandemic. Appendix 6-C is intended to serve as an operational guide to the request, receipt, storage, shipment and distribution of pandemic influenza vaccine. It should be recognized that supplies of vaccine may be limited during a pandemic. Access to these products will be through New York State and will be controlled at the local level by county health departments. In all cases, the disposition of vaccine must be carefully tracked to ensure appropriate use and efficacy.

I. Levels of Supply

A public health crisis involving pandemic influenza necessitating the need for distributing vaccine may be similar to events that require activation of the New York State Strategic National Stockpile (SNS) plan. Vaccine availability will change during the course of a pandemic and pandemic response strategies will vary dependent upon supply. Four vaccine supply levels can be defined.

A. No Vaccine Supply

At the beginning of a pandemic, it is possible that no vaccine will be available.

B. Limited Vaccine Supply

When first available, the vaccine supply will most likely be less than that required. Priority groups for vaccine have been identified. During a time of limited vaccine supply it will be important to inform priority groups about the availability of vaccine and where to receive it. State and local public affairs professionals will be responsible for educating the public regarding vaccine priorities and their rationale. Vaccine effectiveness and safety need to be monitored. Depending on the amount of vaccine available, a State SNS Mobilization Site may be activated and repackaging may be required.

C. Adequate Vaccine Supply

Vaccine supply will match the need and ability to distribute vaccine. This will allow a shift from priority groups to the wider population. Strategies are being developed to assure equitable distribution to special needs populations. The State SNS Plan may still need to be activated to facilitate distribution of the vaccine.

D. Excess Vaccine Supply

Vaccine supplies exceed what is needed to protect the New York State population. The State SNS Plan may still need to be activated to facilitate distribution of the vaccine. With less demand and abundant supply, vaccine distribution may return to normal pre-pandemic supply strategies that include the use of private distribution and/or private providers.

II. Operational Assumptions

- Pre-pandemic and pandemic vaccines will be purchased by the Federal Government and distributed to New York State. Pre-pandemic vaccine need is estimated to be 20 million courses for the entire nation.
- A planning assumption of 50.4 million manufactured vaccine courses per year or 4.2 million courses per month will be available nationwide once production begins. One course equals 2 doses of vaccine.
- Based upon the planning assumption, New York State will receive sufficient vaccine to immunize 1.5% of its population per month.
- If vaccines with applicable influenza strains are not immediately present during initial stages of the pandemic, it will take 4 to 8 months between the pandemic alert and vaccine availability.
- All federal SNS vaccine material will be procured by the Centers for Disease Control and Prevention (CDC) and arrive at either the NYSDOH Vaccine Depot or one of the State SNS Mobilization Sites that can ensure cold-chain management. This State Mobilization Site has been identified and the information provided to the CDC and the DHHS.
- There may be multiple local requests for vaccine assets as well as competing requests from neighboring states.
- The State will determine allocation of vaccine within its jurisdiction.
- New York State will activate its SNS Plan to facilitate the widespread distribution of vaccines.
- Influenza vaccine will be distributed rapidly to the public sector through partnership arrangements with local health departments (LHDs) and health care facilities.
- Requests for vaccine may not be accepted, depending on supply. If requests are permitted, multiple shipments of vaccine may be requested and deployed.
- State agency resources and personnel will likely be needed to support local distribution and dispensing efforts.
- The affected locality will be responsible for vaccine delivered to it and will have identified suitable locations for storage and distribution.
- The State will adhere to all requirements regarding the use and return of undistributed supplies to the federal authorities.

III. Vaccine Deployment

The goal of deployment is to quickly deliver in an orderly fashion needed supplies to local agencies to allow them to immunize their communities. Distribution will be via the State's SNS plan. The distribution of vaccine will involve numerous local, State, Federal, volunteer, and private agencies. There are five critical centers that must coordinate actions and ensure a smooth flow of information:

1. State Emergency Operations Centers (State EOC);
2. County Emergency Operations Centers (County EOC);
3. State Mobilization Site/Vaccine Storage Depot ;
4. County Staging Sites; and
5. Points of Dispensing.

The deployment of vaccine to New York State will be broken down into four distinct phases.

A. Request or Allocation Phase

The request phase includes the local and state analysis of the situation potentially requiring the deployment of vaccine, the request itself and the decision to deploy vaccine with or without requests. The New York State Department of Health (NYSDOH) will assume the lead role in requesting vaccine with support from the State Emergency Management Office (SEMO). Depending on supply, local jurisdictions may be able to request vaccine through their County Emergency Operations Center to SEMO after coordination among appropriate local agencies. Local jurisdictions may be required to accept pre-determined amounts based on population and county-based occupational groups. SEMO will coordinate all local requests and allocations with the NYSDOH.

B. Mobilization and Staging Phase

The mobilization phase of distributing vaccine involves all activities associated with the receipt, off-loading, staging, processing, repackaging, and transportation of material. A large state like New York requires rapid distribution to multiple locations throughout a large and diverse geography. State agencies, regional agencies, and some counties will be responsible for all activities associated with the mobilization effort. Local resources may also be utilized, where available, to assist with mobilization efforts. Local resources, when utilized, will be integrated into state activities. Counties have planned for the establishment of a local staging site within the county limits that will receive shipments from the State Mobilization Site. This staging site must have the ability to manage and maintain the cold chain for vaccines. Certain health care facilities may also be designated to receive vaccine directly from the state. These facilities will have the same requirements for management and storage of these assets.

C. Immunization Phase

The immunization phase includes activities associated with the set-up and operation of PODs as well as medical facilities that provide services, such as immunizations, to members of the public. The NYSDOH will provide guidance to counties detailing groups prioritized for vaccine since supply will be limited during the initial phases. LHDs may need to operate small secure immunization clinics during the initial stages of this phase.

Collection, storage and transmission of information on individuals who are vaccinated will be undertaken by local public health agencies using the HERDS framework under the supporting architecture of the NYS Commerce System. Information concerning administration of vaccine and tracking of vaccine supplies will be achieved through the use of a countermeasures response system that is integrated with the Clinic Data Management System (CDMS) and HERDS. A description of this system and the detailed requirements for data collection are included in Section 13 of the New York State Pandemic Influenza Plan, “Public Health Preparedness Informatics.”

The NYSDOH will provide specific guidance on the disposition of vaccine to local public health authorities to ensure that circumstances surrounding their use and

administration are consistent with established priorities; all recipients of state supplied vaccine will be required to follow the guidance provided.

D. Recovery Phase

The recovery phase includes those activities associated with the return of unused assets to state control. Local public health agencies will be advised by the NYSDOH on how excess supplies will be collected and redistributed (if necessary).

IV. Logistics

A. Transport:

The Federal Government will ship vaccine to up to 100 ship-to-sites in each project area weekly. In NYS, each county has identified one primary and one secondary vaccine receipt location. These sites are designated by the respective county health department and are capable of maintaining cold-storage. It is the responsibility of each county to coordinate with local resources to further distribute vaccine.

B. Handling & Storage (Cold Chain):

It is important to keep vaccines at the specified temperature at all times starting from the manufacturer until the vaccine is used to maintain the “cold chain.” It is important to keep vaccines from freezing and/or getting warmer than the temperatures specified for proper storage.

Problems that may occur with the “cold chain” of vaccine include storage unit malfunctions, power outages, or staff errors. During an influenza pandemic, it will be necessary to exert vigilance in maintaining the cold chain as vaccine supply will be scarce and will not be able to be replaced. Therefore, it will be essential to have the appropriate equipment, train staff, and develop standard operating procedures outlining protocols to protect the vaccine “cold chain.” For more information on Site Certification, refer to Appendix 6-D.

1. Handling Vaccine

- a. Maintain a daily temperature log; check unit temperature two times per day.
- b. Open and store vaccine shipments immediately upon arrival.
- c. Monitor inventory daily in the initial phases of vaccination, less frequently when supply increases.
- d. Rotate vaccine according to expiration dates; those with shortest expiration dates should be used first.
- e. Securely close refrigerator and freezer doors.
- f. Lock refrigerator and freezer doors at the end of each day.
- g. Provide personnel in charge of vaccine with 24-hour access to building and storage location; develop standard procedures on how to notify individual if there is a power outage or problem in the vaccine storage location.

- h. Identify a maintenance repair company in the event that the unit breaks down.
- i. Provide security to assure the safety of scarce vaccine supplies through existing security plans as identified in the respective SNS Plan.

2. Storing Vaccine

- a. Vaccine should be stored in a refrigerator/freezer unit. *It should not be a refrigerator unit that utilizes a freezer tray, such as a dormitory style, because they are not able to maintain temperature.*
- b. The unit should be capable of maintaining a temperature between 35-46 deg F (2-8 deg C) in the refrigerator section and 5 deg F (-15 deg C) in the freezer.
- c. Place a warning at the plug and the associated circuit breaker to ensure neither has power removed without first informing appropriate personnel.
- d. A thermometer should be located in both the refrigerator and the freezer section.
- e. An alarm system should be integral to monitor for both temperature and possible tampering.
- f. The doors or storage location should be secured with a locking mechanism.
- g. The unit should have a back-up generator power in case of an outage.
- h. Vaccine should be stored in the center of the unit, never in the doors.
- i. Food or beverages should never be kept in the same unit as vaccine.
- j. Avoid opening and closing the unit as much as possible in order to maintain a constant temperature.
- k. Storing bottled water and gel packs in the doors may help in regulating the space temperature and maintaining the temperature during a short power outage.
- l. Train employees on correct storage of vaccine, acceptable temperature ranges and emergency procedures.
- m. A specific written plan should be available in the case of a power outage.
- n. There should be a plan for an alternate storage location in the event that the vaccine needs to be moved in an emergency (Hospital, Fire Department, etc.).

3. Transporting Vaccine

In order to transport vaccine appropriately, it is imperative that the following shipping materials have been purchased: insulated styrofoam containers, ice packs, temperature monitors, and sheets of bubble or foam wrap. Procedures for proper transport include the need to:

- a. Place ice packs on the bottom of the styrofoam container.
- b. Place bubble wrap or foam wrap on top of ice packs. (Vaccine should not come in direct contact with ice packs).
- c. Place vaccine in the container.
- d. Insert temperature monitors near the center of the vaccine.
- e. Place more bubble wrap or foam wrap on top of vaccine.

- f. Place more ice packs on top of bubble wrap.
- g. Ensure vaccine is secure in the container and close and seal the lid.
- h. Clearly label the container **“Vaccine- Refrigerate Immediately”** and deliver vaccine to destination without delay.
- i. Ship using **Priority Overnight Mail** on Monday, Tuesday or Wednesday to ensure the product arrives before the weekend.
- j. Some shippers require the styrofoam container to be inside an additional cardboard box for shipping.

4. Equipment Malfunction

If equipment breaks down or the storage location becomes inadequate due to an emergency:

- a. Move the vaccine to an alternate refrigerator.
- b. Move the vaccine to an alternate storage location.
- c. If vaccine reaches temperatures outside of the recommended range, immediately store it in a location at the appropriate temperature and clearly mark and separate it from other vaccines so that it may be checked later. Don't assume that it is spoiled; depending on the recommendations of the manufacturer the vaccine may still be viable.
- d. Contact the manufacturer for guidance regarding the status of the vaccine.
- e. Do not discard spoiled or expired vaccine. Contact the NYSDOH and return vaccine accordingly.

5. Security

New York State Police will provide security and escort material, as needed, to Mobilization Sites and County Staging Sites.

6. Release Procedures

A designated NYSDOH physician or representative will meet and sign for assets.

7. Request Procedures

Vaccine requests, if permitted, should be made as all other SNS assets are through the applicable County EOC to the State EOC.

8. Primary vaccine reception point

The primary reception point for vaccine delivery will be identified by the NYSDOH – Immunization Program and may include the NYSDOH Vaccine Depot located in Wadsworth Center, Albany, New York and/or other depots as defined when vaccine becomes available.

9. Tracking & Accountability

Although vaccines are not considered “controlled substances” they must be tracked and accounted for, therefore a tracking record should be utilized for monitoring product location and usage.

V. Activities by WHO Pandemic Period and CDC Interval

Interpandemic Period (*Investigation, Recognition Intervals*)

State Health Department:

- Continue to develop and refine pandemic plan.
- Identify/determine ship-to-sites, up to 100 allowed per state, to receive shipments on a weekly basis.
- Determine how vaccine will be transported from ship-to-sites to vaccination sites.
- Ensure the availability of sufficient storage at all locations to maintain the cold chain.
- Develop chain of custody procedures.
- Develop/implement a certification process to insure chain of custody procedures and vaccine storage and handling, distribution, security and accountability requirements are met.
- Certify vaccine ship-to-sites and administration sites.
- Develop/implement a security plan to protect vaccine assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.
- Ensure that proper storage requirements exist for the contents of the SNS during storage at the mobilization site and during transport.
- Examine systems requirements for the Vaccine Ordering System to ensure applicable tracking and distribution of influenza vaccine.
- Develop, implement and maintain a tracking system for vaccine receipts, inventory, point of distribution, and doses administered that captures at a minimum:
 1. Product;
 2. Manufacturer;
 3. Lot number;
 4. Expiration date;
 5. NDC number; and
 6. Depending on product availability some vaccine types, devices, manufacturers, may be targeted to specific populations when warranted.
- Identify overflow storage facilities and make necessary arrangements for use. This may include contracts or memorandums of understanding.
- Identify applicable transportation facilities to distribute vaccine. Examples may include UPS and FedEx normal and custom critical.
- Identify applicable supplies needed for standard shipping and monitor availability.
- Identify applicable staff for backup to assist with receiving and distribution of vaccine.
- Develop/assemble applicable materials and train/educate staff to meet certification requirements for chain of custody, including storage, handling and distribution.
- Identify backup or alternative distribution facilities to be used if required.
- Identify sources of pneumococcal vaccine.
- Determine proportion of pre-pandemic and pandemic vaccine for each ship-to-site that will/may be allocated to further points of distribution, if applicable.
- Identify any vaccine specific roles that are required and develop training materials and a training plan.

- Estimate weekly allocation of vaccine based on CDC-specified criteria and population size.

Local Health Departments:

- Determine county requirements based upon the guidance received from the NYSDOH.
- Select/identify primary and secondary county staging site(s) where assets may be delivered including vaccine distribution end points (administration and ship-to-sites) as a component of the LHD's disaster preparedness plan and according to NYSDOH guidance.
- Assist NYSDOH with certification of all sites expected/anticipated to serve as primary staging sites, ship-to-sites and administration sites.
- Once supplied with project allocation amounts of vaccine, make specific plans for location and use of these assets.

Pandemic Alert Period (*Recognition, Investigation Intervals*)**State Health Department:**

- Continue training staff identified to assist with receiving and distributing vaccine.
- Continue the certification of all ship-to-sites to ensure proper storage and handling requirements for vaccine.
- Distribute pre-pandemic flu vaccine if applicable (CDC estimates that it will have a stockpile 20 million courses of H5N1 vaccine for early vaccination to persons providing critical infrastructure. The trigger is yet to be determined).
- Provide staff support, equipment, patient information forms, protocols for receipt, storage and distribution, and adverse event monitoring.
- Ensure the proper storage requirements the vaccine at the central mobilization site and during transport.
- Identify and assign technical specialists to support command, operations and planning associated with SNS receipt, repackaging and distribution efforts. Technical specialists may include physicians, pharmacists, logisticians, GIS personnel, etc.
- Assist the locality by providing protocols for distribution, adverse event monitoring, and other support as coordinated or requested.
- Monitor supplies and ensure availability in all areas.
- Monitor backup facility availability and readiness.
- Monitor transportation availability from private contractors.
- Revise allocation numbers and plans for distribution as updated information on the epidemiology of the possible pandemic strain, supply information, and changes in priority group designations are received.

Local Health Departments:

- Assess their local vaccine resources.
- Ensure the proper storage of any items received.
- Ensure the security of any items received both at the county staging site and at all POD sites in accordance with the State Education Department Board of Pharmacy standards.
- Ensure adequate staffing at county-designated PODs to ensure patient safety, including adequate staffing to screen patients for contraindications, ensure medical consultation on-

site, ensure patient education, and immunize in accordance with NYSDOH and State Education Department requirements.

- Develop a distribution plan to support local sites such as hospitals, diagnostic and treatment centers, and other healthcare providers.
- Once supplied with updated project allocation amounts of vaccine, make any needed modifications to specific plans for location and use of these assets.
- Continue to identify/establish vaccine distribution end points (administration and ship-to-sites) and report these sites to the NYSDOH.

Pandemic Period (*Investigation, Acceleration, Deceleration Intervals*)

State Health Department:

- Obtain guidance from health officials on the level of severity of the pandemic and its impact relative to NYS population.
- Receive and inventory pre-pandemic vaccine at Albany Depot.
 - Determine proportion of pre-pandemic vaccine that are to be allocated to each ship-to-site
 - Calculate the amount of pre-pandemic vaccine for each certified NYSDOH ship-to-site.
 - Determine how pre-pandemic vaccine will be transported to vaccinating sites.
 - Distribute pre-pandemic vaccine to each certified NYSDOH ship-to-site.
 - Implement security plan to protect pre-pandemic vaccine assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.
- Revise allocation numbers and plans for distribution as updated information on the epidemiology of the pandemic strain, supply information, and changes in priority group designations are received.
- Work with Disaster Preparedness Unit to assist in delivery of vaccine, as needed.
- Work with local health officials to determine the need for extended or long-term dispensing efforts. Plans will be developed utilizing pharmacies, postal service, health care facilities and PODs to accomplish these objectives.
- If severity is sufficient and vaccine supply exists within the SNS program, Managed Inventory (MI) or other CDC-designated location, order vaccine to inoculate part/all of affected population.
 - Determine how pandemic vaccine will be transported to vaccinating sites.
 - Estimate/calculate weekly allocation of pandemic vaccine based on vaccine availability and population size.
 - Continue to certify ship-to-sites as needed.
 - Arrange for the shipment of weekly pandemic vaccine to the NYSDOH Vaccine Depot located in Wadsworth Center, Albany, New York
 - Receive and inventory pandemic vaccine at the Albany Depot.
- Implement security plan to protect vaccine assets that addresses all receiving sites, ship-to-sites and administration sites. Law enforcement will be an active partner in planning at both the state and local levels with clear delineation of roles and expectations. Distribute pandemic vaccine to NYSDOH certified ship-to-sites.

- Communicate plans for distribution and obtain backup resources as needed.

Local Health Department:

- Track dispensing of vaccine by lot number and amount.
- Retain responsibility for any undistributed assets until they are returned to the State.
- Assist NYSDOH by maintaining chain of custody, storage, handling, distribution, accountability and security of vaccine assets.

Site Certification Checklist for the Receipt of Pandemic Influenza Vaccine

The Reason for Certification

This document is intended to serve as an appendix to the RSS Facility Checklist for sites which will serve as emergency vaccine redistribution sites. The state will evaluate these sites on the basis of comprehensive county plans in order to ensure optimal coordination for all aspects of activities between state, county and local responsibilities. The state will require certification of these sites for vaccine receipt, storage, repackaging and redistribution to PODs. The ultimate purpose behind certifying facilities is to address integration and logistical concerns pre-event and establish a framework for action in response to an actual influenza pandemic to utilize scarce vaccine resources effectively and avoid spoilage. There is no intent for these plans to be final or unalterable. Each county is required to identify a primary and secondary site for vaccine receipt, storage, repackaging, and redistribution.

Vaccine source

Pandemic vaccine will be supplied by the federal government to the states. This may be different from Pre-Pandemic vaccine, which is currently being developed and produced for the Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services (DHHS). After exhaustion of this supply, vaccine will be supplied through the DHHS as available from vaccine manufacturers.

Vaccine supply

Existing vaccine administration schedules for new pandemic strains call for two doses separated by a minimum of two weeks. Optimal protection is reached approximately two weeks after the second dose is administered. The state will likely supply vaccine via a “push” mechanism when the supply does not meet demands, as is expected in the beginning of a pandemic. This situation is likely to reverse as vaccine production progresses. It is expected that during the beginning of any pandemic, the demand for vaccine will far outweigh the supply.

Priority groups

Priority group recommendations are intended to focus vaccine distribution to those who are necessary for vital services including medical personnel, those responsible for public safety (fire, police, EMS) and those who maintain critical infrastructure (telephone, electricity). Priority groups also include those at greatest risk for complications of infection. While the elderly are generally at elevated risk for complications due to influenza, other groups including infants and children are also at elevated risk.

Vaccine Facility Assessment Form (Primary Location)

The following is a checklist of components critical to the successful management of emergency vaccine supplies. This is an appendix to the main RSS Facility Checklist for sites which will serve as vaccine staging sites. This should be a tool both for counties and the State in evaluating sites.

Date:

Project Area:

Facility Name:

Street Address:

City:

Site's Physical Characteristics:

(Should include information on the owner of the building, physical description, government or private building)

Contact Person(s) for Vaccine Distribution Program:

Primary:

Alternate:

Name:	Name:
Work Phone:	Work Phone:
Cell:	Cell:
Pager:	Pager:
Email:	Email:

Security Contact Person(s):

Primary:

Alternate:

Name:	Name:
Work Phone:	Work Phone:
Cell:	Cell:
Pager:	Pager:
Email:	Email:

Location

Who is the facility owner?		
Has an MOU been established between the county and facility owners?	Y	N
Will the MOU/MOA require renewal?	Y	N
What is the primary function of the site?		
Describe the location of the site including directions from major highways (Include map)		
Name any potential threats to the facility:		
Is the facility located in a high crime area?		
Location of nearest police station:		
Route:		
Distance:		
Location of nearest fire station:		
Route:		
Distance:		
Location of nearest hospital:		
Route:		
Distance:		

Accessibility

Is parking available?	Y	N
Is there controlled access to the grounds?	Y	N
Are there any points vulnerable to unauthorized entry?	Y	N
Is there sufficient outdoor lighting?	Y	N
Is workspace lighting sufficient for safe work?	Y	N
Is there a loading dock?	Y	N
Are passageways adequate for moving supplies: 72" aisles, 45" doorways?	Y	N
Are hallways or ramps sloped? (Pallet weight > 500lb)?	Y	N
Are there working freight elevators to move containers?	Y	N
Have alternate container movement routes been identified?	Y	N
Is sufficient fuel or batteries available for moving equipment?	Y	N
What is the distance in feet from the loading to the storage area?		
What is the minimum doorway width?		
What is the minimum aisle width?		
Number of forklifts available?		
Number of pallet jacks available?		
Number of empty pallets on-site?		
How much working space is available?		
How much space is designated for storage of non-refrigerated materials?		

Total available space:**Environmental Conditions (Room)**

Is there a system to maintain temperature between 59 and 86 F?	Y	N
Is there a system for maintaining humidity levels below 60%?	Y	N
Is the facility equipped with a thermostat?	Y	N
Is there a lock on the thermostat?	Y	N
Are work and storage areas free of solvents, petroleum products and flammable material?	Y	N
Is the location clear of trash?	Y	N
Is there adequate pest control?	Y	N

Phone Lines

Are there phone lines dedicated to both environmental and refrigeration monitoring?	Y	N
Are there phone lines dedicated to security and monitoring services?	Y	N
How many phone lines are available for dedication to operation of the vaccine receiving site?		
What communication systems are available on-site?		
What communication systems are available in the work areas?		
Are these sufficient for emergency monitoring, security and operations?	Y	N

Electric Power

Is the electrical supply suitable and sufficient for all utilities?	Y	N
Are the electrical outlets suitably located for their uses?	Y	N
Is back-up emergency power available?	Y	N
Do the work spaces have emergency lighting?	Y	N
Will security, environmental, and refrigeration monitoring systems function in case of electrical failure?	Y	N
What must be done to activate emergency power?		
Itemize electricity needs by device type:		

Refrigeration

How many and what type of refrigeration units will be available?		
What is the available volume of storage space available for vaccine storage space?		
What type of thermometer will be used in the refrigeration units?		
What kind of emergency notification system is in place in case of refrigerator temperature deviation?		
Will refrigeration units receive back-up power?	Y	N
Are thermometers properly located within the refrigerators?	Y	N
Have the thermometers been calibrated and certified?	Y	N
Are water and storage containers available for use in stabilizing refrigerator	Y	N

temperature?		
Do the refrigerators have locks?	Y	N
How will refrigerator key access be controlled?		
What are the refrigerators customarily used for?		
Have relocation plans been made for these items?	Y	N

Security and Alarm Response

Do the storage and work space rooms have controlled access?	Y	N
Has a list of staff with access privileges been established?	Y	N
Is there a key custodian?	Y	N
Is the surveillance system continuously monitored?	Y	N
Are the environmental sensors in the storage area and refrigeration units continuously monitored?	Y	N
Are the sensors regularly tested according to manufacturer specification?	Y	N
What type of surveillance system is used: motion sensor/video surveillance?		
How is the area monitored?		
Who will be notified in an emergency?		
What notification system is in place for notifying staff of environmental or refrigeration problems?		

System Integration

Will the site be used for vaccine distribution only?	Y	N
Will antiviral medications be handled by the site?	Y	N
Will ancillary supplies be handled by the site?	Y	N
Do the receiving site and PODs serve the entire county?	Y	N
Will PODs be located in the same facility as the receiving site?	Y	N

Amenities

Are there sufficient bathrooms available?	Y	N
Are showers available?	Y	N
Are spaces for resting or eating and taking breaks available?	Y	N
Does staff have access to vending machines?	Y	N
Does staff have access to drinking fountains?	Y	N
Is there equipment for food storage/ prep: coffee machine, microwave, refrig.?	Y	N

Staffing

Detail staff, contact information, their availability and their primary employers:		
Is staff available on short notice?	Y	N

Training

What training has been conducted or planned?
