

# **Pandemic Influenza Vaccination: A Guide for State, Local, Territorial, and Tribal Planners**

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## **Introduction**

The purpose of this document is to assist state, local, territorial, and tribal officials in developing pandemic influenza vaccination plans. It addresses specific planning challenges that are associated with influenza vaccination in a pandemic scenario—notably those caused by the current limited capacity to manufacture vaccine—and provides detailed guidance on working with those challenges to conduct large-scale vaccination efforts.

State and local preparedness for mass dispensing of vaccines has advanced substantially because of smallpox vaccination planning and subsequent public health efforts that occurred in 2003. Nevertheless, planning for pandemic influenza immunization will include the need to conduct targeted vaccination of predetermined priority groups, and the possibility of a vaccination program of long duration. A campaign of this magnitude and duration necessarily involves collaboration across many entities, and clear delineation of roles and responsibilities is crucial. Flexibility in planning also is essential because some key variables will remain unknown until the time of the event. Ability to scale plans will be important in implementing an effective vaccination program.

This document is divided in two parts. The first provides updates on key issues, such as vaccine availability, that affect vaccination planning and lists planning assumptions, i.e., what planners can assume given the current situation, pertaining to these issues. The second section covers the key components of a pandemic influenza vaccination program, listing the actions that should be taken, things that can be assumed, and additional things that should be considered for each component. Planning actions are consolidated into a checklist at the end of this document. This document will be updated and re-issued periodically as more information becomes available.

## **Definitions**

**Project areas:** 62 areas that receive funding through CDC's Preparedness Cooperative Agreement

**Pandemic vaccine:** Influenza vaccine to be developed to protect against the specific strain/s causing an influenza pandemic.

**Pre-pandemic vaccine:** Vaccine against the H5N1 virus—to be stockpiled and used if a pandemic caused by an H5N1 virus begins (other subtypes with pandemic potential may be stockpiled in the future).

## **I. Updates on key issues**

### **A. Availability of pandemic vaccine**

Vaccine production will require 4–6 months from the time the pandemic vaccine strain is selected. Whether pandemic vaccine becomes available during or after the first wave of

illness will depend on where the pandemic begins, how soon it is detected, the efficiency of spread, and the impact of containment measures. Once production is begun, the vaccine will likely be manufactured at a steady rate. The number of vaccine doses that will be manufactured each month will be a function of both manufacturing capacity, and of the amount of antigen required per dose of vaccine.

*Manufacturing capacity:* For planning purposes, it is assumed that only U.S.-manufactured pandemic influenza vaccines will be available for U.S. purchase during a pandemic. During 2008, U.S. manufacturing capacity for influenza vaccines is expected to increase by at least 4-fold. By 2011, it is expected to increase further.

*Antigen per dose:* The amount of antigen that will be included in each dose has not been determined. A NIH trial of a Sanofi-Pasteur H5N1 vaccine found that high amounts of antigen (up to two 90- $\mu$ g doses) were required to generate an immune response inferred to be protective in most healthy adults (Treanor et al. NEJM 2006, 354:1343-51). This amount represents a 12-fold increase over the 15  $\mu$ g required for each strain in the routine seasonal vaccine. The inclusion of an adjuvant could reduce the amount of antigen needed. Two recently published trials of H5N1 vaccine with adjuvant have shown immunogenicity with two 10- $\mu$ g and two 30- $\mu$ g doses (Lin et al. Lancet 2006, 368:991-7 and Bresson et al. Lancet 2006, 367:1657-64). In addition GlaxcoSmithKlein (GSK) has issued a press release announcing findings from a trial of an H5N1 vaccine that required only two 3.8- $\mu$ g doses.

Table 1 shows estimated availability of pandemic vaccine at present and in 2008 for vaccine containing 90  $\mu$ g/dose and for vaccine with adjuvant containing 10 $\mu$ g and 30  $\mu$ g/dose (2006 estimates are based on US-based capacity for seasonal trivalent 15  $\mu$ g vaccine, and the 2008 estimates assume a four-fold increase in capacity). The possibility that even lower amounts of antigen per dose may be effective is demonstrated by the low dose reported for the GSK vaccine. CDC will keep project areas informed of changes in pandemic vaccine manufacturing capacity.

Table 1: Estimates of availability of pandemic vaccine, by year and formulation

Year and formulation	2-dose courses per month manufactured	% population vaccinated per month (2 dose course)	2-dose courses manufactured per year
2006*			
90 $\mu$ g/dose	1.4M	0.5%	16.8M
30 $\mu$ g/dose	4.2M	1.5%	50.4M
10 $\mu$ g/dose	12.6M	4.5%	151.2M
2008			
90 $\mu$ g/dose	5.6M	2.0%	67.2M
30 $\mu$ g/dose	16.8M	6.0%	201.6M
10 $\mu$ g/dose	50.4M	18%	604.8M

### **Planning assumption**

- Manufacturing capacity of 50.4 million courses per year, or 4.2 million courses per month. This is based on use of vaccine with adjuvant that reduces antigen requirement to 30 µg per dose, and corresponds to each project area being able to vaccinate 1.5% of its population with 2 doses per month.

### **B. Pre-pandemic vaccine**

A stockpile of H5N1 vaccine is being established in response to concerns about the avian influenza H5N1 virus currently circulating in Asia. Its purpose is early vaccination of persons critical to maintaining infrastructure. In the absence of a virus specifically matched to the pandemic virus, it is hoped that pre-pandemic H5N1 vaccine will have sufficient cross-reactivity to afford some protection to these groups.

The goal is to have sufficient vaccine for 20 million persons (at 2 doses per person). The trigger for using pre-pandemic vaccine has yet to be determined but would likely be evidence that an H5N1 virus had acquired the ability to spread efficiently from person to person. However, because the stockpiled vaccine will eventually lose potency, discussion has also occurred regarding possible administration to selected groups before the onset of a pandemic.

Discussions are underway to define the groups eligible for vaccination with pre-pandemic vaccine (see section I C).

### **Planning assumptions**

- Pre-pandemic vaccine will be shipped for immediate administration once sustained person-to-person transmission has been documented anywhere in the world.

### **C. Priority groups**

Priority groups for pre-pandemic and pandemic vaccination will be determined at the national level. Draft priority groups are listed in the HHS Pandemic Plan (<http://www.hhs.gov/pandemicflu/plan/appendixd.html>). The order of these groups is subject to change based on review by a wide array of government agencies and other stakeholders. In addition, priority groups may change based on epidemiologic information once the pandemic begins.

Pre-pandemic vaccine (see Section I B) will be targeted to persons whose work helps maintain critical infrastructure. The Department of Homeland Security is leading an effort to define the most critical infrastructure among the seventeen critical infrastructure sectors defined by the White House and to identify the most critical tasks and groups within those sectors. Healthcare workers (including vaccine and antiviral drug manufacturers, public health workers, and those who would be involved in implementing pandemic vaccination or other response components), emergency service workers (i.e., emergency medical services, fire, and law enforcement), and public health emergency workers are among the groups that have been identified as providing critical services to

society and being at increased occupational risk in a pandemic, and therefore as eligible for pre-pandemic vaccine. Additional groups currently under discussion includes those responsible for critical services, e.g., utilities, transportation, and communications.

#### **Planning assumptions**

- Groups listed in the DHHS plan (Table D-1, HHS plan Appendix D) will be priority groups for pre-pandemic and pandemic vaccine.
- The rank order of priority groups is subject to change.
- Priority groups will be vaccinated sequentially.
- Although project areas will be required to vaccinate according to the ranking set nationally, they will have some flexibility in defining priority groups and subprioritizing within them.
- Further guidance on defining Tier 2B in Table D-1, HHS Plan Appendix D (critical infrastructure) is forthcoming.

#### **D. Vaccine purchase and allocation**

All pre-pandemic vaccine will be purchased by the federal government. Pandemic vaccine may be purchased by the federal government or jointly by the federal government and the project areas, but initially will be purchased solely by the federal government.

#### **Planning assumptions**

- The federal government will purchase all pandemic vaccine through the first year.
- Most pre-pandemic vaccine will be allocated in proportion to population. Exceptions will be made for critical infrastructure personnel who are not evenly spread across the nation.
- Pandemic vaccine will be allocated to project areas in proportion to their total population.

## **II. Planning for Key Components of Pandemic Influenza Vaccination Program**

### **A. General planning issues**

Vaccination in the context of an influenza pandemic will take place over many months and involve vaccinating an unprecedented number of persons. Special planning challenges include the need for close collaboration among immunization programs and preparedness programs at the state and local levels, identifying sufficient staffing, and building flexibility into the planning to allow the campaign to adjust to changes in vaccine availability and to ensure the sustainability effort.

## **Planning actions**

- Establish and sustain collaboration between offices responsible for emergency preparedness and immunization in regard to pandemic vaccination planning, with clear delineation of respective roles and responsibilities.
- Define responsibilities of state and local planners with respect to each aspect of planning discussed here.
- Use vaccine availability assumptions provided in Section I A as a basis for planning and consider how increases or decreases in vaccine would affect vaccine administration.
- Define criteria for transitioning from a tightly controlled vaccination program administered by state and local health departments to inclusion of broader array of vaccination partners from the private sector.

## **Planning considerations**

### a) Roles and responsibilities

In many states and localities, mass dispensing of vaccines falls under the auspices of emergency preparedness programs. It is critical that preparedness programs work closely with immunization programs in developing plans for mass vaccination because lessons learned by immunization programs during the influenza vaccine shortages of recent years are relevant to pandemic influenza vaccination, as well as familiarity of immunization program staff with vaccine handling issues. Roles and responsibilities of emergency responders and immunization programs must be delineated in advance. Because much of the planning for vaccination occurs at the local level, clear delineation of state-level and local-level responsibilities is also critical.

### b) Planning for a phased program

Vaccination in the context of pandemic influenza will take place over many months and may therefore unfold in several phases:

- Phase 1: Vaccination with stockpiled pre-pandemic vaccine (assuming vaccine of the same subtype as the pandemic strain is available), conducted by public health potentially in collaboration with agencies and institutions (see Section II C)
- Phase 2: Vaccination with pandemic vaccine, conducted by public health.
- Phase 3: Vaccination with pandemic vaccine, conducted by the private sector

During phases 1 and 2, demand is expected to exceed supply, and it will be critical to ensure that vaccine dispensation is carefully controlled (e.g., via limited distribution points) and targeted to priority groups. Over time, project areas may elect to shift control from public health departments to the private sector. The timing of this transition will vary between project areas and will be affected by such factors as availability and demand for vaccine and ability of the public health infrastructure to sustain the vaccination campaign.

### c) Flexibility

Flexibility will be an important attribute of the vaccination program. Although planning assumptions regarding vaccine availability (Section I A) should be the foundation of planning, planners must keep in mind that actual vaccine availability could be greater or less and must consider how such changes would affect their plans.

### d) Sustainability

Because a pandemic vaccination program is expected to be of long duration, and because public health resources will be stressed, identifying sufficient staffing for vaccination will be a key challenge. Engaging partners to assist in conducting vaccination clinics will be necessary, and delegation of vaccination to other institutions or agencies (see Section II C) will help free up public health staff for other activities.

## **B. Vaccine distribution and allocation**

Pre-pandemic and pandemic vaccines will be purchased by the federal government and distributed to project areas, who will determine allocation of vaccine within their jurisdictions. Distribution of vaccine will involve shipment to pre-arranged ship-to sites in each project area. Project areas will be responsible for ensuring the security of vaccine once it has been delivered to ship-to sites.

### **Planning actions**

- Estimate project area's weekly allocation of vaccine based on vaccine availability assumptions (Section I a) and project area population size.
- Determine designated recipients (ship-to sites) for pre-pandemic and pandemic vaccine, up to 100 per project area.
- Determine what proportion of vaccine will be allocated to each ship-to site.
- At ship-to sites, determine what proportion of pre-pandemic and pandemic vaccine will be allocated to further points of distribution, if applicable.
- Ensure the availability of sufficient storage at all relevant locations to maintain the cold chain.
- Determine how vaccine will be transported to vaccinating sites.
- Develop chain of custody procedures
- Develop a vaccine security plan.

### **Planning assumptions**

- Pre-pandemic vaccine will be shipped by the manufacturer(s) and distributors to project area-designated recipients (ship-to sites) throughout the country.
- Distribution of pandemic vaccine will be similar to that of pre-pandemic vaccine, except that it will take place over time as vaccine stocks becomes available (see Section I A).

- Up to 100 ship-to sites can be designated per project area. These sites may be local and tribal health departments, but may also be healthcare facilities such as hospitals or nursing homes.
- Vaccine will be shipped weekly.
- A secure Internet site that will record and display ship-to sites, relative allocations, and number of doses shipped weekly will be accessible by project areas, CDC, and manufacturers/distributors.

## **Planning considerations**

### a) Distribution

The number of ship-to sites in each project area will depend on the amount of vaccine available, storage and security requirements, and local resources for repackaging and transporting vaccine securely from ship-to sites to sites of administration. The major advantage of having limited numbers of ship-to sites is greater control over vaccine stocks such as greater ease in tracking the receipt and distribution of vaccine stocks. The major disadvantage is the increased need for resources for repackaging, local transport, and security. There would also be greater potential for interruptions in the cold chain. In any given area the ideal approach will depend on these factors.

Project areas may consider a phased approach, whereby Phases 1 and 2 are characterized by tight state-level control of vaccine and fewer distribution sites (see Section II A). Eventually, in Phase 3, more widespread distribution would take place. As stated above (II. A), project areas may vary with respect to the timing of the transition to wider distribution. Project areas should plan to provide their initial list of ship-to sites to CDC by spring 2007. A separate communication with more information is forthcoming.

### b) Allocation

Because vaccination of occupationally defined groups (Section II C) will be associated with the place of work rather than the place of residence, allocation of vaccine within project areas will need to be based on number of persons in targeted occupational groups and on their location of employment. When allocating vaccine to institutions or agencies, for example, project areas should allocate in proportion to size, as measured by number of beds or number of staff.

For risk-based groups, i.e., those at high risk of serious outcomes and their contacts (see Section II D), it is reasonable to consider allocating vaccine within project areas according to total population size. Planners may also consider taking into account proportion of the population 65 and older, if this varies markedly within a project area. In cases where a local jurisdiction lacks resources or infrastructure to hold vaccination clinics, responsibility for vaccination of that jurisdiction's population should be assigned to a neighboring jurisdiction.

### c) Security

Ensuring the security of vaccine once it has been delivered to ship-to sites is of utmost importance. Given that demand for vaccine may be extremely high once it becomes available, vaccine security at all levels, from ship-to sites to administration sites, must be addressed. Law enforcement must be an active partner in planning at both the state and local levels with clear delineation of roles and expectations.

### **C. Vaccination of priority groups**

Approaches to vaccinating the different priority groups may vary. In particular, approaches to vaccinating occupationally-defined and risk-based groups are likely to be different. For example delegation of vaccination to institutions or agencies may be possible for some occupationally-defined groups. Given the scarcity of vaccine, verification of priority group status must be part of vaccination protocols.

#### **Planning actions**

- For each target group, determine whether it will be vaccinated by public health, or by institutions or agencies to whom responsibility has been delegated, or a combination..
- Develop memoranda of agreement with institutions and agencies to whom vaccination will be delegated, where applicable.
- Develop protocols for verification of priority group membership.

#### **Planning assumptions**

- Groups listed in the DHHS plan (Table D-1, HHS plan Appendix D) will be priority groups for pre-pandemic and pandemic vaccine.
- The rank order of priority groups is subject to change.
- Priority groups will be vaccinated sequentially.
- Although project areas will be required to vaccinate according to the ranking set nationally, they will have some flexibility in defining priority groups and subprioritizing within them.
- Further guidance on defining Tier 2B in Table D-1, HHS Plan Appendix D (critical infrastructure) is forthcoming.

#### **Planning considerations**

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 occupation, for example health care workers or public safety workers. Many, but not necessarily all, of these groups will be among those eligible for stockpiled pre-pandemic vaccine (see Section I B). Risk-based groups are defined on the basis of being at risk for serious outcome (65 and older, underlying conditions) or being a household contact of such persons. Planners should define how each group will be vaccinated, and approaches for different groups may vary. Considerations for specific groups are detailed below.



a) Inpatient healthcare workers and those who support them

Mechanisms for vaccination of this group include:

- Vaccination delegated to institutions (e.g., hospitals and nursing homes). Public health departments should pre-identify a point-of-contact at each institution who will be responsible for ensuring that all eligible staff are vaccinated. Agreements between institutions and health agencies must be in place to ensure that dose tracking requirements are met (see Section II I).
- Vaccination conducted by public health departments. Each healthcare institution should provide its local health department with a list of eligible staff members. During a pandemic, these staff members should present themselves (with proper identification) to the public health clinic at assigned dates.

b) Vaccination of outpatient healthcare workers and those who support them

Due to the large number of outpatient offices in most localities, it may be impractical for public health agencies to deliver vaccine to individual offices. Therefore, planners should designate distribution sites where medical office staff may pick up vaccine stocks. Public health may elect to vaccinate staff from small practices at the distribution site to help limit wastage that could occur with vaccinating staff in small practices since vaccine will be provided in multi-dose vials. If vaccine stocks are insufficient to vaccinate all staff within a medical practice, each recipient will need to determine how best to use its allocation to maintain services.

c) Persons responsible for public safety.

As with vaccination of hospital workers, vaccination of firefighters, police, and other persons with responsibility for public safety may be provided by health departments or delegated to healthcare institutions. In practice, however, only large fire and police departments are likely to have the internal resources to vaccinate their own employees. In some jurisdictions, vaccination might be provided by EMS groups associated with municipal fire departments.

d) Persons responsible for critical infrastructure

Additional information will be provided by HHS and DHS after this priority group is more fully defined (see Section I C).

e) Persons at risk of serious outcomes and their contacts.

This group encompasses several groups that total approximately 90 million persons (Tiers 1B, 1C and 2A), as described in Table D-1, Appendix D of the HHS Plan. Because the number of persons in the risk-based groups is large, it will be necessary to sequence vaccination according to some criteria. National recommendations for sequencing of

vaccination within these large groups are pending. As discussed in Section II A, vaccination programs will be phased, with fewer points of administration early on compared with later. Plans must be flexible given the uncertainty around the number of vaccine doses available each week. Considerations for clinic planning are discussed in Section II D.

#### f) Verification of priority group membership

The identity of persons in occupationally defined groups should be verified before they can be vaccinated. When vaccination has been delegated to other institutions or agencies, verification of identity is the institution's responsibility. When vaccination is taking place at public health clinics, employers should provide public health staff with lists of eligible employees, and these persons should present identification at the vaccination clinic. Staff from outpatient clinical settings presenting to pick up vaccine at a distribution site should be asked to provide a validated list of employees to be vaccinated (e.g., payroll records) to ensure that vaccine is not used for persons outside of the priority group, such as family members.

For risk-based groups possible ways of verifying high risk status include requiring a doctor's note verifying a chronic medical condition or requiring the vaccinee to provide prescription bottles or copies of prescription labels (issued in the past year). Requirements for verification of health status should be flexible, to ensure that eligible persons who experience difficulty obtaining documentation (e.g., persons with chronic conditions who are not under the care of a physician) are not turned away.

During a wave of pandemic influenza, physicians may not be able to devote time to providing documentation of patients' risk status. Public health departments should consider launching education campaigns that encourage persons with chronic conditions to seek documentation before a pandemic begins (i.e., as part of personal preparedness planning). These campaigns should target both physicians and the general public.

### **D. Logistical issues associated with vaccination planning**

This section addresses selected practical considerations associated with planning vaccination clinics.

#### **Planning actions**

- Determine number and location of clinics.
- Estimate number of doses to be administered per shift, based on assumed vaccine availability and relative allocation within project areas.
- Determine staffing requirements for each clinic.
- Identify sources of staffing and develop memoranda of agreement.
- Develop training plan.
- Develop security plan.
- Develop incident response plan for potential riots or other incidents.
- Develop plan for instruction about second dose.

- Develop infection control plan.
- Conduct vaccination clinic exercises

### **Planning assumptions**

- Two doses of vaccine will be needed, with second dose 4 or more weeks after the first does
- Vaccine will be distributed mostly in multi-dose vials
- Ancillary vaccination supplies will not be provided by SNS

### **Planning considerations**

#### a) Large scale vaccination planning

Procedures for large-scale vaccination—including site selection, clinic set up, and staffing—may be found at [www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf](http://www.bt.cdc.gov/agent/smallpox/response-plan/files/annex-3.pdf) and [www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf](http://www.cdc.gov/flu/professionals/vaccination/pdf/vaxclinicplanning0405.pdf). A “Clinic Planning Model Generator” is available at [www.isr.umd.edu/Labs/CIM/projects/clinic/](http://www.isr.umd.edu/Labs/CIM/projects/clinic/) and is designed to assist in planning efficient clinics.

In determining the number of clinic sites, planners must balance accessibility to clinics and available staffing. While greater numbers of clinics will enhance access, they will also increase staffing needs, including needs for security. Economies of scale are less for smaller clinics because of minimum staffing requirements.

Once number of clinics has been determined, vaccination planners should estimate their projected staffing needs, based on their expected total weekly allocation of vaccine (see Section I A for planning assumptions) and the proportion of vaccine stocks that will be provided to each clinic in their jurisdiction. The greatest challenge will be to support this level of staffing over a long period of time. The identification of professional partners and volunteers who can help run these clinics is a critical aspect of pandemic planning. Potential partners include: Community Health Centers, the Visiting Nurse Association, and other community vaccinators, nursing and medical students, and pharmacists, dentists and veterinarians.

During a pandemic, additional security staff may be needed for crowd control purposes, as well as to ensure vaccine security. Hotlines that allow persons to call in advance to inquire about their priority group status and about whether vaccine is available may be useful to prevent over-crowding. Other ways to reduce over-crowding are suggested below. (See below, Infection control).

Vaccination clinic exercises are important in ensuring the ability to conduct large scale vaccination in an orderly and efficient way. Seasonal vaccination clinics are one means of testing clinic procedures.

## b) Infection control

The benefits of vaccination outweigh the risks posed by potential transmission in vaccination clinic settings. Nevertheless, it is prudent to incorporate infection control measures into plans for mass vaccination. These may include:

- Separating potential influenza cases from non-ill persons
- Selecting large facilities to help lessen crowding
- Minimizing wait times by issuing tickets that specify when the holder should present him or herself for vaccination
- Holding open air clinics where feasible
- Offering hand hygiene materials, tissues, and waste receptacles on site

Clinic personnel who must have direct contact with ill individuals should adhere to the published guidance for healthcare personnel (<http://pandemicflu.gov/plan/maskguidancehc.html>); in addition, if vaccinees must congregate, it may be beneficial for each vaccinee to wear a surgical-type mask while in proximity to one another in order to facilitate respiratory hygiene and cough etiquette. Screening of vaccinees to identify individuals with fever, respiratory illness, or those who have ill household members can facilitate separation of potential influenza cases from other vaccinees.

## c) Two dose schedule

A two-dose vaccination schedule will pose unique challenges because not all vaccinees will return on time for the second dose, which will most likely be given a minimum of 4 weeks after the first dose. First and second dose vaccination will take place concurrently after the first 4 weeks of the vaccination campaign. A portion of each shipment will be used for 2<sup>nd</sup> dose vaccination. As the vaccination program unfolds, information on rates of second-dose vaccination will become available to adjust vaccination plans as that will determine how much vaccine is available for first dose vaccination of the next group.

Persons receiving their first dose will need to receive information about the need to return for their second dose. The media should also be used to reinforce messages about the importance of returning for the second dose.

## d) Ancillary supplies

The potential shortage of ancillary vaccination supplies such as syringes, needles, alcohol pads, and sharps containers is an important concern. Although the federal government plans to purchase some syringes and ancillary supplies for the Strategic National Stockpile, decisions have not yet been made on the quantities to be stockpiled. Project areas are encouraged to work with distributors to develop plans for emergency purchase of needles and syringes once a pandemic has begun (“just in time” purchasing). Project areas may also consider stockpiling these materials. Additional information will be forthcoming.

#### e) Security

During periods where vaccine is in highest demand (e.g., initially, during disease waves) the number of personnel needed to provide security and crowd control at vaccination sites should not be underestimated.

### **E. Vaccination of Tribal populations**

State and local planners must ensure that tribal populations are included in planning for vaccination. Because tribes often cross state lines, coordination across project areas must occur.

#### **Planning actions**

- Ensure that tribal populations are included in vaccine allocation plans.
- Include IHS and tribal planners in planning activities.
- Ensure cross-border coordination of vaccination plans for tribal communities that cross project area boundaries.

#### **Planning assumptions**

- There will be no separate vaccine allocation for IHS-served populations and other tribal communities. Vaccine for these populations will be part of the project area's allocation.

#### **Planning considerations**

Tribal governments and federal partners such as the Indian Health Service (IHS) are an important component of the overall public health infrastructure within the state and will be key partners in ensuring that members of priority groups in tribal communities are vaccinated. The IHS Pandemic Influenza Workbook ([http://www.ihs.gov/Medical/Programs/epi/pi/documents/Pandemic\\_Influenza\\_Planning\\_Workbook.pdf](http://www.ihs.gov/Medical/Programs/epi/pi/documents/Pandemic_Influenza_Planning_Workbook.pdf)) calls for tribal sites and IHS to identify and quantify priority groups (as outlined in the *HHS Pandemic Influenza Plan*) and develop mass vaccination plans to vaccinate community members. It is important that vaccination sites for tribal communities be included in state allocation plans and that tribal authorities receive appropriate resources and training. IHS and tribal communities may have health care personnel that can staff vaccination sites for tribal communities, reducing some of the burden on the state/local public health infrastructure.

### **F. Special needs populations**

Special needs populations would face unique challenges during an influenza pandemic which must be taken into account by planners.

#### **Planning actions**

- Ensure that information is available in locally spoken languages

- Ensure that vaccination clinics are in locations that can be reached by persons who rely on public transportation (and consider that public transportation may be disrupted).
- Ensure that the needs of the physically disabled are met (e.g., availability of special needs sections of clinics with wheelchairs and extra chairs, specialized transportation).
- Ensure that plans have been made for vaccinating homebound persons.
- Ensure that proper communications channels are used to reach populations with special needs.

### **Planning considerations**

One of the most important aspects of planning for vaccination of populations with special needs is to ensure that groups who represent and serve these populations are intimately involved in the planning from the beginning. The first working draft of the CDC “*Public Health Workbook to Define, Locate and Reach Special, Vulnerable and At-Risk Populations in an Emergency*” is a useful resource (<http://www.bt.cdc.gov/workbook/>).

### **G. Communications**

Communications play an essential role during any crisis, and many communications planning activities are generic and are not listed here (Reynolds B. Crisis and Emergency Risk Communication: By Leaders for Leaders. Atlanta, GA: Centers for Disease Control and Prevention; 2004). Dissemination of information related to vaccination will play an important role in ensuring that the vaccination campaign unfolds in an orderly manner. Clear, consistent, and timely messages to the public will assist in establishing transparency and trust regarding the vaccination strategy.

### **Planning actions**

- Develop a communications plan that prepares local communications materials in appropriate languages.
- Develop a plan to ensure dissemination of vaccination-related information via different means and languages to reach all segments of the population.
- Ensure messages are delivered to those less likely to seek vaccination.

### **Planning assumptions**

- Materials that may be tailored to local needs will be provided by the federal government

### **Planning considerations**

Consistent and accurate communications about vaccination will be critical to ensure that the vaccination campaign unfolds in an orderly manner and instills trust and confidence by providing transparency in decisions being made. Public health agencies will need to explain the need and rationale for prioritization and provide instructions on when and where priority group members will be vaccinated and what documentation they will need to establish eligibility as a priority group member. Assuming that two doses of vaccine

are needed, it will be important to use the media to reinforce messages about the importance of the second dose of vaccine. Hotlines with vaccination information may also be considered.

## **H. Vaccine tracking**

Tracking the total number of vaccine doses administered will be important, particularly early on in the vaccination program, both to provide a means of monitoring the use of scarce vaccine, and to provide a denominator for calculating adverse event rates. Project areas will be expected to track doses administered and to collect minimum data elements (specified below) to monitor their program and to fulfill federal reporting requirements.

### **Planning actions**

- Determine how minimum data elements (specified below) and other project area-required data will be collected at the administration sites.
- Determine how these data will be transmitted from administration sites to local and state health departments.
- Determine how minimum data elements will be transmitted to CDC.
- Determine what additional data (if any) will be collected for local and state use, and develop specifications.
- Determine personnel needs.
- Develop a training plan.
- Determine equipment needs, including hardware and software needed for data entry and aggregation

### **Planning assumptions**

- The number of vaccine doses administered will need to be reported to CDC on a weekly basis, along with minimum data elements, in aggregate form.
- Collection of state-level coverage data will be coordinated by CDC e.g., using the Behavioral Risk Factor Surveillance System (BRFSS) or the National Immunization Survey (NIS).
- CDC's Countermeasure and Response Administration (CRA) can be used to report required information to CDC.

### **Planning considerations**

a) Tracking administration of vaccine doses

Project areas may collect vaccine tracking information via:

- Existing state or local immunization information systems (IIS) such as vaccine registries
- A modified version of the CDC Countermeasure and Response Administration (CRA) system that is currently under development (information forthcoming).
- Alternative tracking systems that allow collection and transmission of minimum data elements required by CDC

Minimum data elements that must be transmitted to CDC are:

- Date of administration
- Age group
- Priority group
- 1<sup>st</sup> or 2<sup>nd</sup> dose
- County or zip code

Specifications are not final at this time. Additional information and training materials will be forthcoming.

For project areas planning to use IIS or alternative systems, specifications for the minimum data elements required by CDC are being developed and will be provided. Project areas may decide to collect additional data elements for local use, keeping in mind that collection of additional information during a pandemic may be difficult.

Within each project area, procedures to guide the transmission of data from vaccinating sites, through a local health department (if applicable) and to the state (if applicable) must be developed. Project areas will need to determine what information vaccinating sites must transmit, and also meet minimum requirements for reporting aggregate data back to CDC. Planners must provide specifications for required data elements (beyond those required by CDC), determine personnel and equipment needs, including hardware and software for data entry and aggregation, and plan a schedule that will ensure reporting timeliness. Staff at vaccination clinics should be identified and trained to enter data into the IIS or the state-based CRA, or to keep tallies of vaccinated persons to meet minimum project area and CDC data requirements. Training on standardized data collection, transmission and timeliness will need to be provided. Routinely collected vaccination information for each recipient (demographics, contact information, vaccine lot numbers, etc) must be maintained at the vaccination clinic. Where vaccination is delegated to other institutions or agencies, a plan to ensure collection of required data elements from these sites must be developed.

#### b) Vaccine coverage ascertainment

Ascertainment of vaccination coverage levels by state—a complementary activity to vaccine-dose tracking—will be implemented through the CDC Behavioral Risk Factor Surveillance System (BRFSS) or through the National Immunization Survey (NIS). The survey used will be modified to support near real-time monitoring of vaccine coverage. While survey data may not provide accurate coverage estimates during the earliest stages of a vaccination campaign, these numbers will become increasingly reliable and useful as the numbers vaccinated increases.

#### **I. Vaccine safety monitoring**

In a situation like a pandemic influenza vaccination campaign, reports of adverse events following immunization (AEFI) can be expected based on the number of vaccinated persons alone. Determining in a timely manner whether such reports are causally linked to vaccination will be critical.



### **Planning actions**

- Designate a vaccine safety coordinator.
- Review policies for reporting adverse events.
- Develop a plan to ensure timely reporting of adverse events when the number of reports is large.
- Familiarize program staff with reporting procedures.

### **Planning considerations**

State and local health departments should develop or enhance systems for reporting and investigating AEFI with pre-pandemic and pandemic influenza vaccine, building on the infrastructure and experience developed during the 2003 smallpox vaccination program.

Adverse events should be reported to the national Vaccine Adverse Event and Reporting System (VAERS; [www.vaers.hhs.gov](http://www.vaers.hhs.gov)), which typically involves direct reporting by individual healthcare providers and/or coordinated reporting through state and local health departments, with periodic feedback to the states. During a pandemic, state health departments that coordinate VAERS reporting may continue to review individual AEFI reports and decide which cases need investigation. State-level coordination can also help minimize duplicate reporting to VAERS.

Project areas should identify staff who will plan for and implement adverse-events reporting, provide outreach to healthcare providers (e.g., by adapting and distributing federally developed letters and materials for vaccine recipients and for providers). These staff members will serve as state-level contacts with federal government staff that oversee VAERS and related safety monitoring activities. Because of the possibility of large numbers of AEFI reports resulting from the scope of the vaccination program, these staff should review existing policies for AEFI reporting and follow-up to ensure timeliness of reporting and rapid feedback from VAERS on AEFI of potential significance. Program staff must be familiar with the objectives, strengths, and limitations of VAERS and have a working knowledge of the types of AEFI events that should be reported. They should also be familiar with reporting options, including secure electronic submission via [www.vaers.hhs.gov](http://www.vaers.hhs.gov).

### **J. Administering vaccine under Emergency Use Authorization (EUA) or Investigational New Drug (IND) protocol**

Vaccination with unlicensed vaccine poses special challenges. Planning must take into account additional requirements.

#### **Planning activities**

- Review CDC-developed EUA operational plan when available

#### **Planning assumptions**

- Vaccine will be administered under EUA (not IND)

## **Planning considerations**

If a national emergency is declared by the Secretary of Health and Human Services, the FDA Commissioner may authorize the use of an unapproved medical product or an unapproved use of an approved medical product. The most likely mechanism for administration of a pandemic influenza vaccine is an Emergency Use Authorization (EUA). Once issued, an EUA is active for one year but may be terminated earlier if the HHS Secretary decides it is no longer needed. EUA requirements include:

- Record keeping (e.g., vaccinee's name and contact information)
- Distribution of information sheets to healthcare providers and patients.
- Adverse events reporting via VAERS

An EUA does not require Institutional Review Board (IRB) approval and informed consent. CDC is developing an EUA operations plan to help to train state and local health authorities on the EUA process.

A pandemic vaccine is less likely to be administered under an IND protocol, which would include requirements that might be difficult to fulfill during a pandemic. IND requirements include

- Record keeping (as described for an EUA)
- Signed consent or parental permission
- Designation of a Principal Investigator (PI) in each state for each site in which the vaccine is being administered
- IRB approval for each site
- FDA approval for each site

The PI would be responsible for ensuring that pandemic vaccine is administered according to an IRB-approved protocol developed by CDC. The protocol would cover parameters of vaccination (e.g., dosage), collection of data elements, provision of medical information and consent forms to vaccinees, and procedures for evaluating vaccine safety. Any proposed revisions to the protocol once the vaccination campaign has begun, no matter how minor, would require review and approval either by the state's IRB or by the CDC IRB.

## **K. Use of polysaccharide and conjugate pneumococcal vaccines**

### **Planning actions**

- Increase vaccination in populations for whom it is routinely recommended

### **Planning assumptions**

- Pneumococcal vaccine will not be stockpiled

**Planning considerations**

Because influenza increases susceptibility to *Streptococcus pneumoniae* infection, which is a known complication of influenza, the role of pneumococcal vaccines has been under discussion. At this time there is no plan to stockpile these vaccines for use once a pandemic begins. Current activities should focus on increasing vaccination levels in the populations for whom they are recommended. Discussions are underway regarding stockpiling of antibiotics.

## Appendix A: Planning checklist

### 1. Overarching issues

- Establish and sustain collaboration between offices responsible for emergency preparedness and immunization in regard to pandemic vaccination planning, with clear delineation of respective roles and responsibilities.
- Define responsibilities of state and local planners.
- Use vaccine availability assumptions provided in Section I A as a basis for planning and consider how increases or decreases in vaccine would affect vaccine administration.
- Define criteria for transitioning from a tightly controlled vaccination program administered by state and local health departments to inclusion of broader array of vaccination partners from the private sector.

### 2. Vaccine distribution and allocation

- Estimate project area's weekly allocation of vaccine based on vaccine availability assumptions (Section I a) and project area population size.
- Determine designated recipients (ship-to sites) for pre-pandemic and pandemic vaccine, up to 100 per project area.
- Determine what proportion of vaccine will be allocated to each ship-to site.
- At ship-to sites, determine what proportion of pre-pandemic and pandemic vaccine will be allocated to further points of distribution, if applicable.
- Ensure the availability of sufficient storage at all relevant locations to maintain the cold chain.
- Determine how vaccine will be transported to vaccinating sites.
- Develop chain of custody procedures
- Develop a vaccine security plan.

### 3. Vaccination of priority groups

- For each target group, determine whether it will be vaccinated by public health, or by institutions or agencies to whom responsibility has been delegated, or a combination..
- Develop memoranda of agreement with institutions and agencies to whom vaccination will be delegated, where applicable.
- Develop protocols for verification of priority group membership.

### 4. Selected logistical issues associated with vaccination planning

- Determine number and location of clinics.
- Estimate number of doses to be administered per shift, based on assumed vaccine availability and relative allocation within project areas.
- Determine staffing requirements for each clinic.

- Identify sources of staffing and develop memoranda of agreement.
- Develop training plan.
- Develop security plan.
- Develop incident response plan for potential riots or other incidents.
- Develop plan for instruction about second dose.
- Develop infection control plan.
- Conduct vaccination clinic exercises

#### 5. Vaccination of Tribal populations

- Ensure that tribal populations are included in vaccine allocation plans.
- Include IHS and tribal planners in planning activities.
- Ensure cross-border coordination of vaccination plans for tribal communities that cross project area boundaries.

#### 6. Special needs populations

- Ensure that information is available in locally spoken languages
- Ensure that vaccination clinics are in locations that can be reached by persons who rely on public transportation (and consider that public transportation may be disrupted).
- Ensure that the needs of the physically disabled are met (e.g., availability of special needs sections of clinics with wheelchairs and extra chairs, specialized transportation).
- Ensure that plans have been made for vaccinating homebound persons.
- Ensure that proper communications channels are used to reach populations with special needs.

#### 7. Communications

- Develop a communications plan to prepare local communications materials in appropriate languages.
- Develop a plan to ensure dissemination of vaccination-related information via different means and languages to reach all segments of the population.
- Ensure messages are delivered to those less likely to seek vaccination.

#### 8. Vaccine tracking

- Determine how data will be collected at the administration sites.
- Determine how data will be transmitted from administration sites to local and state health departments.
- Determine how minimum data elements (specified below) will be transmitted to CDC.

- Determine what additional data (if any) will be collected for local and state use, and develop specifications.
- Determine personnel needs.
- Develop a training plan.
- Determine equipment needs, including hardware and software needed for data entry and aggregation

#### 9. Vaccine safety monitoring

- Designate a vaccine safety coordinator.
- Review policies for reporting adverse events.
- Develop a plan to ensure timely reporting of adverse events when the number of reports is large.
- Familiarize program staff with procedures.

#### **10. Administering vaccine under Emergency Use Authorization or Investigational New Drug protocol**

- Review CDC-developed EUA operational plan when available