

Arizona Influenza Pandemic Response Plan

Supplement 6: Vaccine Distribution and Use

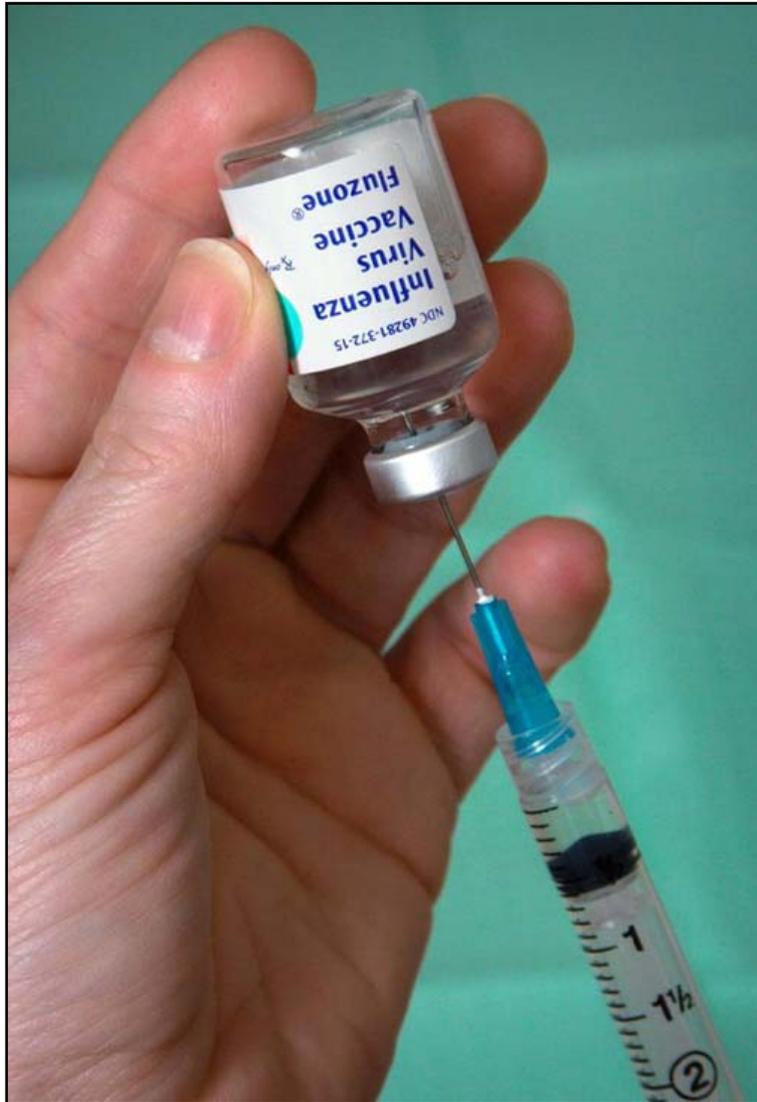


Photo by James Gatheny

Supplement 6: Table of Contents

| | | |
|-------------|---|--------------|
| | SUMMARY OF PUBLIC HEALTH ROLES AND RESPONSIBILITIES FOR VACCINE DISTRIBUTION AND USE | S6-2 |
| I. | RATIONALE | S6-4 |
| II. | OVERVIEW | S6-4 |
| III. | ACTIONS FOR THE INTERPANDEMIC AND PANDEMIC ALERT PERIODS | S6-5 |
| | A. Vaccination against seasonal influenza virus strains | S6-5 |
| | B. Preparedness for vaccination against a pandemic influenza virus | S6-6 |
| | 1. Vaccination of priority groups | S6-7 |
| | 2. Vaccine production, procurement and distribution | S6-11 |
| | 3. Vaccine monitoring and data collection | S6-12 |
| | 4. Public health communications | S6-14 |
| | 5. Coordination with bordering jurisdictions | S6-14 |
| | 6. Legal preparedness | S6-14 |
| | 7. Training | S6-14 |
| IV. | ACTIONS FOR PANDEMIC PERIOD | S6-15 |
| | A. Before a vaccine is available | S6-15 |
| | B. When a vaccine becomes available | S6-15 |
| V. | APPENDICES | |
| | Appendix 1. Time table of immunizations to various priority groups | S6-17 |

Summary of Public Health Roles and Responsibilities for Vaccine Distribution and Use

(The following actions for HHS, ADHS, and county and tribal health departments are described in further detail, later in this Supplement. The roles and responsibilities of health care partners in vaccine distribution and use are described in Supplement 3.)

Interpandemic and pandemic alert periods

ADHS

- Work with local health departments, health care providers and other stakeholders to develop state-based plans for monitoring vaccine effectiveness and safety, and coordinating vaccine distribution and use.

County and tribal health departments

- Develop and implement plans, systems and capacities to receive, distribute, and administer vaccine to population of jurisdiction

HHS agencies:

- Work with manufacturers to expedite public-sector vaccine purchasing contracts during a pandemic and establish mechanisms for vaccine procurement and distribution.
- Develop guidance on priority groups for vaccination.
- Develop and stockpile vaccine for influenza strains with pandemic potential.
- Expedite the rapid development, licensure, and production of new influenza vaccines, as well as evaluate dose optimization strategies to maximize use of limited vaccine stocks.
- Estimate rates of reports of mild and severe adverse events following immunization (AEFIs)
- Identify mechanisms and define protocols for conducting vaccine-effectiveness studies.
- Develop reporting specifications for tracking data on vaccine administration
- Develop and distribute communication and education materials for use by states and other stakeholders.

Pandemic period

After the first reports of pandemic influenza are confirmed and before a vaccine becomes available:

ADHS

- If stockpiled vaccine of the pandemic subtype is available, ensure delivery to county and tribal health departments and health care partners, as determined by priority status.
- Keep the health care and public health workforce up-to-date on projected timelines for availability of vaccines against pandemic influenza.
- Provide updated information to public on vaccine status and prioritization (see Supplement 10).

County and tribal health departments

- Mobilize response partners, and prepare to activate plans for receiving, distributing, and administering vaccines.
- Activate plans and systems to receive, distribute, and administer pre-pandemic stockpiled vaccines to designated groups, upon delivery by ADHS
- Review modifications, if any, to recommendations on vaccinating priority groups.
- Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups.
- Be prepared to administer unlicensed vaccines (if needed) under FDA's Investigational New Drug (IND) provisions
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

HHS agencies:

- Facilitate vaccine procurement, distribution, and tracking, working with private partners.
- Revise recommendations on vaccination of priority groups, guided by epidemiologic information about the pandemic virus
- Provide guidance on reporting specifications for tracking administration of vaccine
- Provide guidance on Investigational New Drug (IND) and Emergency Use Authorization (EUA)
- Provide guidance on which adverse event reports are highest priority for investigation.
- Provide regulatory guidance to vaccine manufacturers

After a vaccine becomes available:

ADHS

- Submit requests to HHS for appropriate number of vaccine doses
- Work with emergency management to ensure the safe delivery of pandemic vaccines to county and tribal health departments and to health care agencies, for prioritized vaccinations
- Monitor vaccine supplies, distribution, and use.
- Monitor and investigate adverse events.
- Provide updated information to the public via the news media.
- Ensure that vaccine requests to HHS and distribution to clinics and other facilities accounts for the need for second doses
- Work with HHS to evaluate vaccine-related response activities when the pandemic is over.

County and tribal health departments

- Activate plans and systems to receive, distribute and administer vaccines to designated groups, upon delivery from ADHS.
- Phase in vaccination of the rest of the population after priority groups have been vaccinated.

HHS agencies:

- Provide forecasts of pandemic vaccine availability from the manufacturers
- Continue to provide input into appropriate strain selection for seasonal influenza vaccine.
- Distribute public stocks of vaccines to state and large city health departments and to federal agencies with direct patient care responsibility, as needed.
- Implement protocols for assessing vaccine effectiveness.
- Monitor vaccine coverage rates.



Photo by James Gatheny

I. Rationale

The initial response to an influenza pandemic will include medical care, community containment and personal protective measures, and targeted use of antiviral drugs. Before a vaccine containing the circulating pandemic virus strain becomes available, pre-pandemic vaccine from stockpiles (if available for the pandemic subtype or partially cross-protective to the circulating virus) may be considered for persons in designated priority groups. Once a vaccine against the circulating pandemic virus strain becomes available, its distribution and delivery will be a major focus of pandemic response efforts. Public health goals for vaccination during an influenza pandemic include:

- Developing pre-pandemic strategies for vaccine manufacturing and stockpiling that will maximize manufacturing capability
- Stockpiling influenza vaccine for strains and subtypes with pandemic potential
- Expediting development of a pandemic virus reference strain and distribution of the strain to vaccine manufacturers
- Accelerating production of a pandemic vaccine
- Maximizing the immune response to the vaccine
- Ensuring efficient and equitable distribution of pandemic vaccine, according to priority lists
- Rapidly determining vaccine effectiveness
- Providing ongoing and timely monitoring of vaccine coverage
- Providing ongoing and timely monitoring of vaccine safety

ADHS goals for vaccination, once vaccine becomes available, are:

- Securing sufficient quantities of vaccine for priority groups
- Ensuring equitable distribution of vaccine to providers serving priority groups
- Distributing and delivery of vaccine to pre-identified public providers
- Facilitating special immunizations clinics for easy access by the priority groups, the vulnerable, and hard to read population
- Monitoring vaccine usage and effectiveness according to set protocols
- Communicating the benefits of vaccine for priority groups
- Collecting data and reporting any adverse events following vaccination

II. Overview

Supplement 6 provides recommendations to state and local partners and other stakeholders on planning for the different elements of a pandemic vaccination program. The recommendations for the Interpandemic and Pandemic Alert Periods focus on planning for vaccine distribution, vaccination of priority groups, monitoring of adverse events, tracking of vaccine supply and administration, vaccine coverage and effectiveness studies, communications, legal preparedness, and training. The recommendations for the Pandemic Period focus on working with health care partners to implement plans for vaccination against pandemic influenza and initiate monitoring activities.

The activities described below are primarily the responsibility of government health authorities at the state, federal, local, and tribal levels. Additional issues that might be of interest to health partners that administer vaccine are addressed in Supplement 3.



III. Actions for the Interpandemic and Pandemic Alert Periods

ADHS

- Work with local health departments, health care providers and other stakeholders to develop state-based plans for monitoring vaccine effectiveness and safety, and coordinating vaccine distribution and use.

County and tribal health departments

- Develop and implement plans, systems and capacities to receive, distribute, and administer vaccine to population of jurisdiction

A. Vaccination against seasonal influenza virus strains

During the Interpandemic Period, the Arizona Department of Health Services (ADHS) and county health departments will continue to work with tribes, IHS, community partners, mass immunizers, health care partners, targeted populations, and immunization coalitions to promote and enhance levels of:

- 1) Seasonal influenza vaccination in groups at risk for severe influenza
 - a. persons aged ≥ 65 years with co-morbid conditions
 - b. residents of long-term care facilities
 - c. persons aged 2-64 years with co-morbid conditions
 - d. persons aged ≥ 65 years without co-morbid conditions
 - e. children aged 6-23 months
 - f. pregnant women
 - g. health care personnel
 - h. household contacts and out-of-home caregivers of children aged < 6 months
 - i. household contacts of children and adults at increased risk for influenza-related complications
- 2) Pneumococcal polysaccharide vaccination among those for whom it is recommended:
 - a. persons aged ≥ 65 years
 - b. persons aged 2-64 years with co-morbid conditions or who are living in special environments or social settings
 - c. persons aged 50-64 years
 - d. immunocompromised persons

The success of the pandemic influenza vaccination program will be determined in large part by the strength of the ADHS and local vaccination programs during the Interpandemic Period. ADHS, county health departments, and mass immunizers work collaboratively each year, to increase public confidence and to provide flu vaccine to high-risk populations and to the general public. ADHS participates in the Adult Immunization coalition with representatives from health plans, vaccine manufacturers, mass immunizers to address annual flu vaccine concerns/issues and to get information to the public regarding these issues. The ADHS Immunization Program Office supports the Community Information and Referral (CIR) hotline and website, the statewide “flu and pneumococcal immunization clinic locator” each year by publicizing the hotline number and web address in print materials and media messages. During an influenza pandemic, the CIR Hotline will play a critical role providing information to the general public.

Higher annual vaccination rates will foster increased familiarity with and public confidence in influenza vaccines, increased manufacturing capacity for influenza vaccines, and strengthened distribution channels. HHS is working with industry partners to ensure influenza vaccine can be produced on an emergency basis at any time throughout the year (see Box 1). In past years, approximately 80%-90% of flu vaccine administered in Arizona has been administered by the private sector. Although geographical, provider, and demographic information on this segment has not been readily available, ADHS and county health departments have improved communications the past 2 years prompted by the flu vaccine shortage in 2004-2005, and delayed shipments in 2005-2006.

Increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Because large-scale pneumococcal vaccination might not be feasible once a pandemic occurs, the Interpandemic Period and Pandemic Alert is the ideal time to deliver this preventive measure. Pneumococcal vaccine is indicated for most persons for whom influenza vaccine is recommended. Specific guidelines on the prevention of pneumococcal disease can be found at <http://www.cdc.gov/mmwr/pdf/rr/rr4608.pdf>, Recommendations of the Advisory Committee on Immunization Practices (ACIP).

With funding from the Governor's Health Crisis Fund, ADHS began a campaign promoting pneumococcal immunization on December 26, 2005. The campaign will be conducted through March and again from October – December, 2006. Media messages will be broadcast in English and Spanish on cable and radio channels, and educational materials will be developed, printed and distributed to provider offices serving targeted populations.

The state has recognized the increased need to vaccinate the high risk population with pneumococcal vaccine. Each year, pneumococcal vaccination will be promoted in advance of an influenza pandemic. These efforts have begun in December 2005 to vaccinate those individuals 65 and older as well as other individuals with a high-risk medical conditions for which this vaccine is recommended.

B. Preparedness for vaccination against a pandemic influenza virus

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 the circulating pandemic virus strain of influenza should begin to be available within 4-6 months after identification of the new pandemic virus strain (Box 1). The number of persons who may be protected by vaccination depends on the manufacturing capacity, the amount of antigen per dose needed for a protective immune response, and the number of doses required. Although annual influenza vaccine is immunogenic in older children and adults with a single 15 microgram (μg) dose, a higher antigen concentration and/or two doses may be needed for pandemic vaccine where persons have no previous exposure to the influenza subtype and lack any immunity. Preliminary results from a recent clinical trial of an H5N1 vaccine in healthy adults suggested that two doses of 90 μg were required. Additional clinical trials are ongoing to evaluate possible ways to improve the immune response to lower the amounts of vaccine antigen needed for protection.

Initial pandemic vaccine stocks will be used to vaccinate designated priority groups (Part 1, Appendix D). After vaccination of these priority groups, vaccination of all those who desire it will be phased in depending on available supplies. In working with health care partners to develop state-based plans for distributing vaccines, ADHS and county health departments might use existing state-based plans for emergency mass distribution of medical supplies as the basis for developing local pandemic vaccination plans (e.g., smallpox and bioterrorism response plans).



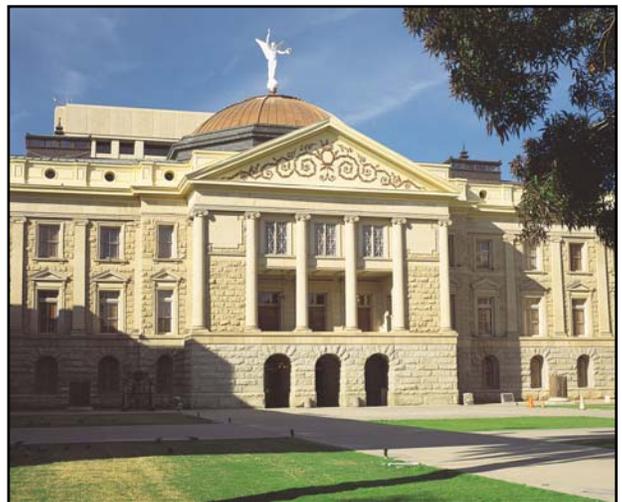
| Preparation Steps by ADHS to protect Arizona's population |
|--|
| <input type="checkbox"/> Review CDC's priority groups and recommendations; accept or modify groups for Arizona |
| <input type="checkbox"/> Update "Arizona's Influenza Vaccine Estimate Worksheet" with the numbers of individuals in targeted priority groups established by CDC |
| <input type="checkbox"/> Prompt CHD's to compile list of potential clinic sites for vaccine administration |
| <input type="checkbox"/> Compile list of qualified ADHS staff who can assist or administer vaccine in the clinics and/or provide support functions (e.g., set-up, crowd control, data entry) |
| <input type="checkbox"/> Compile list of volunteers from other agencies/organizations, who can assist. |
| <input type="checkbox"/> Prompt CHD's to compile list of physicians in community who are/ would likely be giving vaccine. |
| <input type="checkbox"/> Conduct inventory of vaccine distribution related supplies (e.g. styrofoam coolers, ice packs) and establish written procedures/ names of vendors to order additional supplies. |
| <input type="checkbox"/> Identify additional storage facilities (refrigerators) for vaccine. |
| <input type="checkbox"/> Review written SOPs for mass vaccination clinics and update if needed. |
| <input type="checkbox"/> Educate and train clinic staff on importance of proper storage and handling protocols |
| <input type="checkbox"/> Establish financial/logistical mechanisms for obtaining and distributing necessary vaccine and distribution supplies |
| <input type="checkbox"/> Recommend appropriate security measures during vaccine storage and transportation |
| <input type="checkbox"/> Review SNS protocol in the event state supplies become exhausted |
| <input type="checkbox"/> Anticipate adverse reactions to vaccine, possible vaccine failures, and potential liability issues |
| <input type="checkbox"/> Establish a continuity of operations plan in the event of increased workload, staff absenteeism, or staff losses |

1. Vaccination of priority groups

A list of priority groups for receiving vaccination and the rationale for prioritization is provided in Part 1, Appendix D, as interim recommendations. In addition, during a pandemic, changes may be made based on the characteristics of the causative virus (e.g., transmissibility, virulence, initial geographic distribution, age-specific attack rates, complication rates) and on vaccine effectiveness.

In the pandemic alert periods, ADHS will establish a Vaccine and Antiviral Prioritization Policy Committee (VAPPC) composed of

- Representative(s) from the Governor's office
- State Epidemiologist
- State physician(s)
- ADHS influenza epidemiologist
- Office of Infectious Disease Services office chief
- ADHS administrator(s)
- Arizona Immunization Program Office (AIPO) representative
- Arizona Local Health Officers Association representative
- Arizona Medical Association representative
- Hospital Association representative
- Arizona Emergency Medical Service representative
- Arizona Pharmacy Alliance representative
- Long-term care representative



The VAPPC will define how these priority groups will apply on a local level, and will define who should be included in the groups of public safety workers, essential service providers, and key governmental decision makers.

During an influenza pandemic, the VAPPC will modify these priority groups as needed based on the availability of antiviral medicines and vaccine, the characteristics of the causative virus (e.g., drug susceptibilities, initial geographic distribution, fatality rate, age-specific morbidity and mortality rates) and the effectiveness of implemented strategies.

The VAPPC will provide the rationale for establishing the priority groups so that the reasons for prioritization can be communicated to the community.

A listing of the priority groups identified by the federal pandemic plan has been inserted into the Arizona's Influenza Vaccine Estimate Worksheet (Table 1). The worksheet also acts as a tool for a County Health Department to estimate the County's population in each group. The definition of each prioritization group and the rationales for each groups are found in the HHS Pandemic Influenza Plan, Appendix D, Part 1. Some priority groups require further discussion (ie: key government leaders, telecommunications, utility service workers, etc) for better estimation of numbers.



Table 1. Arizona's Influenza Vaccine Estimate Worksheet

Resource: 2005 National Strategy for Pandemic Influenza Appendix D: Table D-1

Assumptions: 2004 Census data and AZ/US ratio ~2%

Estimates include Federal health care providers to Indian Nations and Tribes

| Tiers | Pandemic Priority Groups | Estimated Population | | | County | # of doses (2 doses per person) |
|-------|--|----------------------|-----------------------|--|--------|------------------------------------|
| | | U.S. | Arizona Pop. | Arizona Winter Pop and migrant seasonal workers | | |
| ALL | Total Population | 312,000,000 | 5,832,150 | 600,000 | | 11,664,300 |
| 1A | Vaccine & antiviral manufacturers | ~ 40,000 | ~ 800 | | | |
| 1A | Medical workers and public health workers w/direct patient care | ~ 8 – 9 million | ~160,000 – 180,000 | | | |
| 1B | Persons ≥ 65 years w/ 1 or more high-risk conditions | ~ 18.2 million | ~364,000 | 250,000 | | |
| 1B | Persons 6 months to 64 w/ 2 or more high-risk conditions | ~ 6.9 million | ~138,000 | | | |
| 1B | Persons 6 months or older w/ history of hospitalization for pneumonia or influenza in past year | ~ 740,000 | ~14,800 | | | |
| 1C | Pregnant women | ~ 30 million | ~ 600,000 | | | |
| 1C | Household contacts of severely immunocompromised persons who could not receive vaccine | ~ 2.7 million | ~ 54,000 | | | |
| 1C | Household contact of children < 6 months olds | ~ 5.0 million | ~100,000 | | | |
| 1D | Public health emergency response workers critical to pandemic response | ~ 150,000 | ~ 3,000 | | | |
| 1D | Key government leaders | TBD | TBD | | | |

| | | | | | | |
|----|--|----------------|------------|---------|--|--|
| 2A | Healthy persons 65 years and older | ~ 17.7 million | ~ 354,000 | 300,000 | | |
| 2A | Persons 6 months to 64 years of age w/1 high-risk condition | ~ 35.8 million | ~716,000 | 50,000 | | |
| 2A | Healthy children 6 – 23 months olds | ~ 5.6 million | ~112,000 | | | |
| 2B | Other public health emergency responders | ~ 300,000 | ~6,000 | | | |
| 2B | Public safety workers including police, fire, 911 dispatchers, and correctional facility staff | 2.99 million | 59,800 | | | |
| 2B | Utility workers essential for maintenance of power, water, and sewage | 364,000 | 7,280 | | | |
| 2B | Transportation workers transporting fuel, water, food, and medical supplies | 3.8 million | 72,000 | | | |
| 2B | Telecommunications/IT for essential network operations and maintenance | 1.08 million | 21,600 | | | |
| 3 | Other key government health decision-makers | TBD | TBD | | | |
| 3 | Funeral directors/embalmers | 62,000 | 1,240 | | | |
| 4 | Healthy persons 2-64 years not included in other categories | ~179.3 million | ~3,026,630 | | | |

Table 2 below represents the total populations by tier/groups needed for Arizona:

| Tiers/Groups | Arizona population | Migratory/ Seasonal |
|------------------|--------------------|---------------------|
| 1 | 1,455,600 | 250,000 |
| 2 | 1,348,680 | 350,000 |
| 3 | 1,240 | 0 |
| 4 | ~ 3,026,630 | ? |
| Total Population | 5,832,150 | 600,000 |

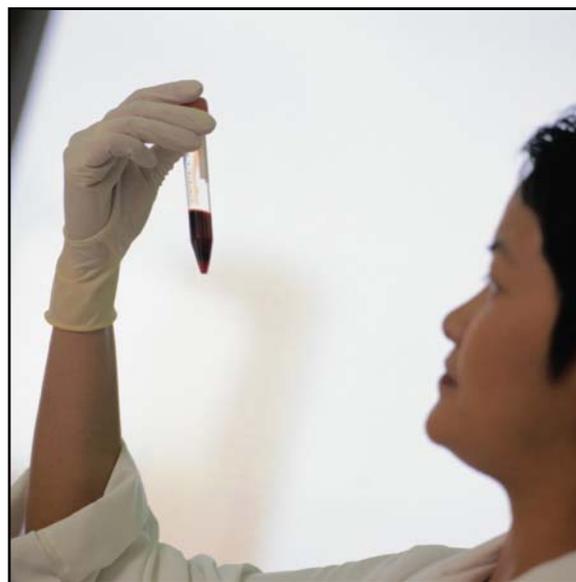
2. Vaccine production, procurement and distribution

HHS is working to expand pandemic influenza vaccine production capacity and will signal to manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at full capacity.

At the onset of an influenza pandemic, HHS, in concert with the Congress in collaboration with the states, will work with the pharmaceutical industry to acquire vaccine directed against the pandemic strain. Distribution of pandemic vaccine to ADHS and providers will occur via private-sector vaccine distributors or directly via manufacturer. (Only stockpiled pre-pandemic vaccine would be distributed by the federal government, if used.)

ADHS will receive available vaccine in proportion to the size of its population in defined priority groups. The following concepts are used to formulate the event-specific vaccination response plan, specific to the amount of vaccine that available to the state:

- Use of the Vaccine and Antiviral Prioritization Policy Committee (VAPPC) to determine and estimate the size of the priority groups that will be vaccinated
- Identify organizations that will provide vaccination to persons in priority groups
- Identify locations for vaccination clinics to achieve vaccination of those populations
- Determine whether vaccine will be shipped from the manufacturer to ADHS further distribution or directly to immunization providers
- Ensure event-specific plan includes strategies for vaccinating medically underserved, hard to reach populations, seasonal visitors, and migrant populations to improve equity in access within priority groups and, later, the general population.
- If vaccinations are provided by private-sector organizations or providers at offices, clinics, or other sites, ADHS and county health departments will:
 - Allocate vaccine based on projected need.
 - Collect unused vaccine (if any) from health care providers who have met their priority vaccination goals and distribute the vaccine to those who have not.
 - Monitor that vaccine administration follows existing plans on priority groups.



ADHS, in conjunction with the county health departments, will the authorized vaccine providers pre-authorized to receive influenza vaccine. ADHS will procure the influenza vaccine through CDC and/or the vaccine manufacturers. It is anticipated the CDC will determine the number of doses each state is allotted on monthly basis.

Arizona Influenza Vaccine Distribution:

- Submit the quantity of desired or monthly allotment of influenza vaccine to CDC and/or vaccine manufacturer
- Request direct shipments of vaccine from the manufacturer to the vaccine providers. It is highly unlikely the vaccine manufacturers could accommodate nationwide direct shipments. Arizona has 500-1000 potential influenza vaccine providers.
- Utilize a two-prong approach to vaccine distribution, dependent upon doses in inventory and scheduled shipments allotted from manufacturer. Current vaccine storage capacity at ADHS is 100,000 doses at any time. ADHS will utilize the existing 3rd party distributor, to handle the storage and distribution of this vaccine if ADHS storage capacity is exceeded.
- Transport vaccine from ADHS to predetermined locations on a weekly basis to control distribution and adjustments to geographical areas, minimize storage problems at the vaccine providers.
- Review the adequacy of the current security measures at ADHS and CHD offices and enhance security, if needed. ADHS may request assistance from law enforcement agencies. The AIPO would remain responsible for management of vaccine, including coordination of distribution. Enhanced security for vaccine at the local distribution sites will be the responsibility of the local authorities.

a) Second-dose vaccination

A vaccine against pandemic influenza will likely require two doses, administered at least a month apart, to provide a level of immunity comparable to that obtained with seasonal influenza vaccines. Recommendations on the number of required doses and the timing of the second dose will be issued once immunogenicity trials have been completed. If two doses are required to achieve immunity, it will be necessary to ensure that vaccinated persons return for the second dose.

b) Contingency planning for Investigational New Drug use

ADHS and county and tribal health departments need to be prepared to distribute unlicensed vaccines (if needed) under FDA's Investigational New Drug (IND) provisions. Unlicensed vaccines might be needed, for example, if pandemic spread is rapid and standard vaccine efficacy and safety tests are not completed in time to play a role in the response.

IND provisions require strict inventory control and record-keeping, completion of a signed consent form from each vaccinee, and mandatory reporting of specified types of adverse events.

IND provisions also require approval from Institutional Review Boards (IRBs) in hospitals, health departments, and other vaccine-distribution venues. The FDA regulations permit the use of a national or "central" IRB. A treatment IND is one IND mechanism that FDA has available for use and is especially suited for large scale use of investigational products (http://www.access.gpo.gov/nara/cfr/waisidx_99/21cfr_99.html).

As an alternative to IND use of an unapproved antiviral drug, HHS may utilize the drug product under Emergency Use Authorization procedures as described in the FDA draft Guidance "Emergency Use Authorization of Medical Products" (<http://www.fda.gov/cber/gdlns/emerguse.pdf>).

3. Vaccine monitoring and data collection

i. Vaccine effectiveness

To ensure optimal use of a new pandemic influenza vaccine, state and county and tribal health departments and participating immunization providers should be prepared to collect data on vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety.

ADHS has the capability and capacity to collect data and store vaccine/immunization data in the Arizona State Immunization Information System (ASIIS), the state immunization registry. Vaccine supply can be tracked and data collected on coverage. Vaccine effectiveness and safety will be monitored through ASIIS, VAERS reports, and disease surveillance. ASIIS is continually upgraded and enhanced to collect additional information and expand data collection on all ages (currently, Arizona providers are only required to report immunizations administered to individuals birth through 18 years of age only). ASIIS is a web-based system which will allow any health care professional licensed under title 32 to provide immunizations, to enroll and submit immunization data on any age person to ASIIS

ii. Vaccine supply and distribution

Vaccine effectiveness will be assessed by comparing rates of influenza-related illness, hospitalization, and/or death among vaccinated and unvaccinated persons. These studies will be implemented by CDC in collaboration with health care and university partners and with state and local health departments that participate in influenza surveillance systems (see Supplement 1)

- Vaccine tracking and coverage information may be used by federal, state, and local decision-makers to estimate adverse event rates based on the number of doses administered and to determine if vaccine is being administered according to established priority groups for pandemic vaccine (especially in the early phases of vaccination). Data will be collected from individual providers, collated at the local and state levels, and reported to federal authorities on a scheduled routine basis.
- ADHS will be able to utilize the state immunization registry, ASIIS, to track coverage with pandemic influenza vaccine. Health professionals administering vaccines to individuals birth through 18 years of age have been required (ARS §36-135) to report those immunizations to ASIIS since 1998. ASIIS is a web-based system and can be expanded to allow any health professional administering pandemic flu vaccine to any age person to report those doses and other needed information. Data currently collected includes name, address, social security number if known, gender, and date of birth. Fields can be added to collect, at a minimum, tracking data such as:
 - Number of doses administered, by date and age, priority group, and state or county (or zip code)
 - ASIIS includes a reminder/recall program that could be utilized to recall patients for a second dose, if necessary.
 - ADHS and county and tribal health departments may consider additional data requirements for their own needs.

iii. Vaccine coverage

CDC will work with ADHS to develop a system for monitoring vaccination rates at regular intervals, using a pre-existing population-based survey tool (e.g., Behavioral Risk Factor Surveillance System) that provides national and state-level estimates and complements the vaccine tracking systems described above.

iv. Vaccine safety

ADHS and county health departments will use VAERS to report and investigate adverse events following immunization (AEFI) with a pandemic influenza vaccine.

- Currently, the Immunization Services Manager in the ADHS Immunization Program Office, serves as the point of contact for adverse events occurring in and reported by facilities using publicly purchased vaccine. Currently, AEFI occurring in private provider offices are reported directly to VAERS by the provider site.
- ADHS will review existing policies for AEFI reporting and follow-up to ensure timeliness of reporting and will work with private provider organizations and mass immunizers to report all AEFI to the state coordinator to minimize duplicate reporting of AEFI to VAERS.
- ADHS will develop a plan to ensure timely reporting of and communication about large numbers of AEFI reports.
- ADHS will review procedures for and familiarize program staff with the strengths, imitations, and objectives of VAERS. VAERS typically involves direct reporting by individual health care providers, with periodic feedback to the states. AEFI reporting in Arizona will build on the infrastructure and experience developed during the 2003 smallpox vaccination program. Adverse events related to use of IND vaccines may 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. Another potential resource for vaccine safety research is CDC's Clinical Immunization Safety Assessment (CISA) **network** (www.vaccinesafety.org/CISA/index.htm).



4. Public health communications

The provision of vaccine information will be an important component of ongoing public health communication during a pandemic (see Supplement 10).

- ADHS and county and tribal health departments need to work with federal partners to disseminate accurate, useful, and consistent public health messages and should tailor information to local needs as indicated.
- ADHS and county health departments need to provide information to health care providers, state and local government officials, and the news media on:
 - Rationale for prioritization and list of priority groups
 - Phasing of vaccination, if any, after priority groups have been vaccinated
 - When and where vaccination is available
 - Importance of vaccination given likelihood of subsequent pandemic waves, particularly if public interest in vaccination has decreased
- ADHS will disseminate information on vaccine use to health care providers who purchase private stocks of pandemic influenza vaccine. In addition, all vaccine providers will need vaccine information sheets that describe the risks and benefits of, and contraindications to, vaccination.

5. Coordination with bordering jurisdictions

ADHS and county and tribal health departments will coordinate vaccine distribution plans with health authorities in bordering jurisdictions, including neighboring states, Sonora, Mexico, and other unique populations.

6. Legal preparedness

ADHS and county and tribal departments need to ensure that appropriate legal authorities are in place to facilitate implementation of plans for distributing pandemic influenza vaccines.

- ARS 36-787 provides authority to ADHS to coordinate a mass immunization campaign during a public health emergency
- Arizona Revised Statutes delineate who is allowed to provide immunizations in the state of Arizona (see below).
- ARS also allows for licensed volunteers or health care workers from other jurisdictions to administer influenza vaccines.
- During a declared public health emergency under ARS 36-787, licensing requirements can be suspended to allow others to perform these tasks
- ARS 36-788 provides for mandatory vaccination during a public health emergency, with an exception for those who refuse on religious grounds, who in turn can be quarantined during the period of risk for exposure. It is not felt that this would be an appropriate action for a pandemic response in Arizona.

7. Training

ADHS and county health departments will assist health care partners in conducting training exercises to facilitate rapid and effective delivery and use of vaccines (see Supplement 3). Exercises and drills are essential to ensure that emergency procedures are in place and roles and responsibilities are well understood. By 2006, most Arizona CHDs have exercised their own county-wide mass vaccination clinic plans, or have participated in such exercises with ADHS. Such exercises have included practice in receiving large quantities of vaccine; storing and handling vaccine from distributor and from the Strategic National Stockpile; setting up and staffing clinics; administering vaccine; testing information management systems; educating the public, media, and medical providers; targeting specific priority groups). Ongoing exercising of rapid response activities will be undertaken.



Administration of vaccine to the general population will most likely take place at large vaccination “clinics”. CHDs will continually evaluate existing emergency response plans and supplement them as needed to ensure that lists of appropriate sites, properly licensed professionals who can be called on to staff clinics, and partner organizations (e.g., voluntary organizations, health care facilities) are up-to date.

Presently in Arizona, physicians, registered nurses and registered nurse practitioners have authority to administer vaccines in accordance with their respective “scopes of practice.” Additionally, physician’s assistants may do so under protocols established with a supervisory physician. Medical assistants and personal care assistants may administer vaccinations under appropriate physician supervision. Certain military personnel may have training as well to administer vaccinations. The potential emergency need for additional non-professional personnel to administer vaccinations will be assessed and necessary mechanisms (e.g., emergency orders from the Governor), appropriate training, supervisory guidelines, etc. of such staff will be developed.

IV. Actions for the Pandemic Period

A. Before a vaccine is available

ADHS

- If stockpiled vaccine of the pandemic subtype is available, ensure delivery to county and tribal health departments and health care partners, as determined by priority status.
- Keep the health care and public health workforce up-to-date on projected timelines for availability of vaccines against pandemic influenza.
- Provide updated information to public on vaccine status and prioritization (see Supplement 10).

County and tribal health departments

- Mobilize response partners, and prepare to activate plans for receiving, distributing, and administering vaccines.
- Activate plans and systems to receive, distribute, and administer pre-pandemic stockpiled vaccines to designated groups, upon delivery by ADHS
- Review modifications, if any, to recommendations on vaccinating priority groups.
- Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating priority groups.
- Be prepared to administer unlicensed vaccines (if needed) under FDA's Investigational New Drug (IND) provisions
- Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.

B. When a vaccine becomes available

- Submit requests to HHS for appropriate number of vaccine doses
- Work with emergency management to ensure the safe delivery of pandemic vaccines to county and tribal health departments and to health care agencies, for prioritized vaccinations
- Monitor vaccine supplies, distribution, and use.
- Monitor and investigate adverse events.
- Provide updated information to the public via the news media.
- Ensure that vaccine requests to HHS and distribution to clinics and other facilities accounts for the need for second doses
- Work with HHS to evaluate vaccine-related response activities when the pandemic is over.

County and tribal health departments

- Activate plans and systems to receive, distribute and administer vaccines to designated groups, upon delivery from ADHS.
- Phase in vaccination of the rest of the population after priority groups have been vaccinated, based on age or other criteria that will ensure fair, equitable, and orderly distribution
- After the pandemic has ended, ADHS and county health departments will evaluate all response activities, including vaccine tracking and delivery, adverse event monitoring, and communications. Written reports of all such activities will be available to HHS and CDC.

Box 1. Development of vaccines against pandemic strains of influenza

HHS is working with industry partners to ensure that influenza vaccine can be produced on an emergency basis at any time throughout the year (<http://www.HHS.gov/nvpo/pandemicplan/>) and to facilitate the development of cell- and recombinant-based interpandemic and pandemic influenza vaccines towards FDA licensure in U.S.-based manufacturing facilities. Activities in support of these goals include:

- Stimulating expanded manufacturing capacity by increasing annual demand for influenza vaccines by the CMS and CDC
- Securing a year-round egg supply for production of inactivated egg-based influenza vaccines
- Promoting the development of new technologies that:
- Shorten the time required to develop a vaccine against a new strain of influenza.
- Facilitate rapid expansion of vaccine production during a pandemic.
- Optimize the use of limited vaccine supplies (e.g., antigen-sparing strategies).

HHS is also spearheading the development of human vaccines against avian influenza A (H5N1) and against other influenza A viruses with pandemic potential. HHS is providing funding to develop and manufacture pilot investigational lots of these vaccines at licensed influenza vaccine manufacturers and to evaluate their safety and immunogenicity in NIH-sponsored clinical trials in healthy adult, elderly, and pediatric populations.

HHS is acquiring commercial scale lots of influenza A (H5N1) vaccine to provide vaccine manufacturers with experience initially and then to establish and maintain stockpiles of pre-pandemic H5N1 vaccine.

Appendix 1
Time Table of Immunizations to Various Priority Groups

| Time table of immunizations to various priority groups | | | |
|--|-----------------------|------------------------------|-----------|
| | Dose 1 | Dose 2 (if needed) | |
| Vaccine Priority Groups | Total doses per group | Estimated doses in Weeks 1-4 | Weeks 5-8 |
| 1A | 180,800 | 135,600 | |
| 1B | 514,800 | 463,320 | |
| 1C | 754,000 | 377,000 | |
| 1D | 3,100 | 2,790 | |
| Subtotal | 1,452,700 | 978,710 | |
| 1A = 180,800 doses Assumption: 75% coverage rate = 135,600 1B = 514,800 doses Assumption: 90% coverage rate = 463,320 1C = 754,000 doses Assumption: 50% coverage rate = 377,000 1D = 3,100 doses Assumption: 90% coverage rate = 2,790 | | | |