

# **Utah Pandemic Influenza Response Plan**

## **Vaccine Distribution and Administration Plan**

Revised May 2008



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## **Goal**

To increase and enhance Utah's pandemic preparedness capacity to decrease health impacts including severe morbidity and death and minimize societal and economic impacts.

## **Objectives**

1. Develop and implement the Utah Pandemic Influenza Vaccination Program for vaccine distribution and administration.
2. Provide guidance to local health departments as they prepare to respond to the different elements of a pandemic event, and as they collaborate with hospital, medical, emergency and public safety responders, and tribes in communities/jurisdictions throughout Utah related to vaccination.
3. Provide guidance to health care organizations as they prepare to respond to a pandemic event and as they work externally collaboratively with public health and community agencies.
4. Offer vaccination safely, efficiently, and with equitable distribution to priority groups and later the general populations.
5. Develop a plan following federal guidelines for providing ongoing and timely monitoring and accountability of vaccine coverage and safety.

## **Purpose**

While influenza vaccine is the most effective tool for preventing complications of influenza, the distribution and use of pandemic influenza vaccine will differ from that of the annual vaccine in several ways. Pandemic influenza vaccine would not be available due to production lags for at least 4-6 months after the pandemic virus had been identified and the supply of vaccine from manufacturers would be insufficient for some time after that.

This plan contains recommendations on planning for the different elements of a pandemic vaccination program. It explains the processes involved with the acquisition, storage, distribution, accountability, and administration of pandemic influenza vaccine for Utah to assure optimal use of available vaccine.

This is a working document. Pandemic vaccine plans may be adapted to fit the scope of an actual event. The Utah Department of Health (UDOH) may use this plan as directed.

Other related plans developed for emergency management and response at the State and/or the local and or tribal level will be consulted in an actual emergency.

## **Situation Description**

Influenza vaccination is the cornerstone for prevention and control of seasonal influenza and its complications. Planning for administration of a pandemic vaccine is an important component of pandemic preparation. An influenza pandemic would be a worldwide outbreak caused by a novel influenza virus to which humans have limited or no immunity.

Based on historical experience, the severity of illness caused by a pandemic could vary widely. Some pandemics have caused widespread, serious morbidity and mortality. The initial response to an influenza pandemic will include medical care, community containment and personal protective measures, and targeted use of antiviral drugs.

The best lifesaving protection against a pandemic influenza virus would be an effective vaccine. However, a pandemic vaccine can only be made after the pandemic virus has been identified and cannot be stockpiled in advance of an outbreak. The vaccine used for seasonal influenza would not be effective against a pandemic influenza virus.

Pre-pandemic vaccine from government stockpiles (if available for the pandemic subtype or partially cross-protective to the circulating virus) may be considered for persons in designated priority groups.

Consequently, a vaccine would probably not be available during the early stages of a pandemic and would be in limited supply thereafter under the control of the Centers for Disease Control and Prevention (CDC). Once a pandemic influenza vaccine specific to circulating pandemic virus strain is available, two doses administered at visits separated by a month or more will probably be needed to stimulate effective immunity. The distribution and administration of this vaccine would be an important and demanding component of pandemic response efforts.

## **Planning Assumptions**

1. Under most scenarios, a vaccine would not be available during the early stages of a pandemic and would be in limited supply thereafter. Vaccine for a pandemic influenza strain would not be available until at least World Health Organization (WHO) pandemic Phase 6; widespread availability may not occur until many months after the onset of a pandemic. It would require two doses, separated over a period of time.
2. A pandemic influenza vaccine would be purchased and distributed by CDC to states primarily according to population size. The number of doses that are available once production begins will depend on manufacturing capacity and characteristics of the vaccine. Current information suggests that once

production begins, 12,500-112,500 doses per month might be available for Utah based on 2006 production capacity. Those estimates could increase to 50,000-450,000 doses per month based on planned 2008 production capacity. A recent estimate by CDC of Utah's distribution from pre-pandemic stockpiles (non novel influenza subtypes) was estimated to be 50,000 initially. This would initially be delivered in incremental weekly distribution. State and local plans will need to consider and assure distribution of vaccine to Native American Tribes.

UDOH maintains a secure on-site central vaccine depot to store and distribute vaccine with capacity to store approximately 90,000 doses. During an emergency, UDOH would receive and distribute all vaccine initially available to Utah from CDC. As supplies stabilize from CDC or manufacturers, UDOH Immunization Program would redirect shipping to certified vaccine depots/sites through VACMAN/VODS (CDC vaccine distribution system). Shipments can be redirected as supplies stabilize to up to 100 optional certified sites (in the current system).

3. In a pandemic, priority recommendations would be established nationally by the Advisory Committee on Immunization Practice (ACIP)/National Vaccine Advisory Committee (NVAC)/CDC. The priorities for administration of available pandemic influenza vaccine would be different from those used for seasonal influenza vaccination. In particular, health care providers and other essential community responders would receive a higher priority and probably would be the first group to receive vaccine before members of the general public.
4. Priorities for vaccine use established in advance at a national or state level would need review for possible alterations due to specific circumstances of the vaccine, vaccine supply, or the health impact of the vaccine on different populations.

Eventually, sufficient vaccine should be available for mass vaccination of the population. Given the magnitude of the vaccination effort, detailed planning needs to occur at the local as well as at the state and national level. A central aspect of planning will be determining how public and private sectors will work together to manage this effort and accomplish the goal.

5. Statewide utilization of procedures and information systems to track vaccine inventory, administration, coverage of priority groups, adverse events, and effectiveness of distribution will be required by federal agencies and essential to an effective response. UDOH has established links to the CDC systems to which states must link which are VACMAN/VODS for vaccine distribution and accountability and the Countermeasure and Response Administration System (CRA) for vaccine administration tracking. The Emergency Immunization Management System (EIMS) will be evaluated to ensure compliance with the

Public Health Information Network (PHIN) and Countermeasure Response Administration (CRA).

6. In the absence of vaccine during the early phases of a pandemic, other health protection measures should be utilized. Pneumococcal polysaccharide vaccination should be utilized as a first line of defense for all people at risk, following general recommendations. Infection control practices can provide some protection against complications of influenza.
7. Space for vaccine storage, transportation/security and supplies for administration of vaccine could be in short supply.

## **Vaccine Distribution and Administration Plan Format and Content**

The Utah Department of Health Immunization Program (UIP) will provide support to meet the goal of this plan through overall statewide leadership, coordination and feedback, regarding the implementation and achievement of all plan objectives and activities.

UIP will develop policies and procedures in consultation with partners to ensure that activities support community level planning and implementation based on agency and community needs and resources. UIP will work closely with local public health departments and partners to ensure optimal utilization of available resources.

## **Concept of Operations**

The pandemic influenza vaccine allotted to Utah will be distributed and used according to this plan. This plan will delineate information distribution for all pandemic vaccine – pre-pandemic federal stockpile and novel strain pandemic vaccine as developed. It 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 healthcare partners to implement plans for vaccination against pandemic influenza and initiative monitoring activities.

This plan would be activated by the approval of UDOH Executive Director's Office upon determination that there is a novel strain of influenza that threatens



the public's health in Utah. The implementation of this plan will be under the direction of the UDOH Executive Director or his designee(s).

## **Pandemic Vaccine Distribution Planning Process**

The distribution of pandemic vaccine planning and administration process involves incorporation of planning guidance as directed by the CDC. This plan is reviewed and developed using a committee process. This portion will be reviewed as part of the Pandemic Influenza Workgroup conducted by the UDOH. Primary oversight of the Pandemic Influenza Workgroup is given to the State Epidemiologist. The Pandemic Influenza Workgroup is comprised of a broad cross-section of State and local public health, State Division of Homeland Security, healthcare organizations, and other related stakeholders.

Local pandemic vaccine distribution and administration plans will be incorporated into this plan by providing local health departments specific format pertaining to: planning for vaccine storage and redistribution/administration, 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 Utah Scientific Vaccine Advisory Committee will evaluate vaccine and vaccine policy issues on an ongoing basis and make recommendations for distribution and administration of vaccine as needed.

The Utah Adult Immunization Coalition (UAIC) will collaborate with and assist the State Immunization Program in the development and implementation of influenza contingency plans. Since the UAIC encompasses a broad spectrum of community services and organizations (public and private), it will allow grass-roots input and establish comprehensive support for plans developed.

Plans will be modified as exercise and real events indicate that changes are needed. Regular reviews of this plan will be included as part of the Pandemic Influenza Workgroup, or as needed by UDOH program staff.

## **Pandemic Vaccine Distribution**

### **Utah Allocation Process for Pandemic Vaccine**

The US Department of Health and Human Services (DHHS) is working to expand pandemic influenza vaccine production capacity and will signal manufacturers when to shift from annual to pandemic vaccine production and assure that pandemic vaccine is produced at the fullest capacity. There are currently 3

manufacturers of pre-pandemic influenza (H5N1) vaccine: sanofi Pasteur, Novartis, and GlaxoSmithKline (GSK).

At the onset of an influenza pandemic, DHHS, in concert with the Congress and in collaboration with the States, will work with the pharmaceutical industry to acquire vaccine directed against the pandemic strain. UDOH will work with federal agencies to receive available vaccine in proportion to the state population, starting with priority groups. Regardless of the production technology used, there will a production lag of 4-5 months from the time the pandemic virus is isolated until the time formulated and filled vaccine will be available from manufacturers for distribution.

In the future antigen sparing potential of adjuvants could substantially increase the number of doses of pre-pandemic and pandemic influenza vaccine, when it becomes available. Adjuvant and antigen would then be mixed and administered at the point of dispensing (POD) and require less rigorous storage and handling requirements. This will require planning for points of receiving, storing, allocating, repackaging, and redistributing adjuvant.

## **UDOH Policies and Administration**

The UDOH under the direction of the Executive Director or designee will convene a policy group with identified leadership. The determination to use pandemic influenza (pre-pandemic federal stockpile and/or novel strain pandemic vaccine) vaccine as available will be made by UDOH Executive Director in consultation with the Governor's Office, the State Epidemiologist, and Utah Immunization Program.

The Utah Scientific Vaccine Advisory Committee (USVAC) will evaluate vaccine and vaccine policy issues and Operating Procedures (SOPs) on an ongoing basis and make recommendations for distribution and administration of vaccine as needed to UDOH.

Utah may also receive additional vaccine allotments through other distribution streams example Homeland Security for predetermined priority groups. Use of this vaccine should be coordinated for regional distribution and storage and handling, security, safety monitoring and accountability.

## **Notification and Information for Response**

UDOH will notify response agencies including all local health departments prior to receipt and distribution of pandemic influenza vaccine. Agencies or individuals needing information will receive automated messages through land line phones, cell phones, email, fax machines, and pagers. People notified are instructed to

log in to the Utah Notification and Information System (UNIS) website for additional information. The UNIS web address is <http://health.utah.gov/unis>

Documentation, plans, and related information may be posted in UNIS as a secure web-based area for response partners.

## **Request Process for Pandemic Vaccine**

The request process for pandemic vaccine (pre-pandemic and novel pandemic) will be initiated by UDOH to CDC as novel influenza becomes pandemic following notification and protocols from DHHS and CDC. The federal request process will be established by CDC.

The vaccine will be requested and distributed by CDC to states including Utah through UIP utilizing the federal VACMAN/VODS system. The request process and distribution process could also be for federally stockpiled pre-pandemic vaccine. State allotments from CDC to Utah will be determined by the following: the amount of vaccine available nationally; determination of need for second doses; by priority population data; and by state disease surveillance data. UDOH will develop estimated allotments to determine the proportion of vaccine that will be allocated from UDOH to local health department jurisdictions determined by the amount of vaccine available to Utah; need for second doses reserves; by priority population data; and by state disease surveillance data. Allotments will be reviewed as vaccine availability becomes more stable.

Local health officers have authority to request from UDOH on behalf of their jurisdiction a quantity of initial and/or monthly allotments of pandemic influenza vaccine. Requests must be based on local pandemic plan data from predetermination estimates and identification of priority groups, population in their service area/jurisdiction including tribal governments, consideration of need for second doses, and current disease surveillance data.

Redistribution of state allotments from CDC to UDOH will be under the discretion/approval of the Executive Director or designee. The vaccine will be distributed by the UIP under the management of the UIP Vaccine Manager to local health departments and/or other pre-certified vaccine depot sites designated in local health department plans through VACMAN/VODS system. Backup for distribution will be provided by UIP staff who have been trained following job action sheets. Second dose allotments for each jurisdiction will be held in the central depot that the jurisdiction can draw against based on need and documentation in Emergency Immunization Management System (EIMS) and the Counter Measure Response Administration (CRA) report. As supplies increase and priority populations are covered, UDOH, in collaboration with local health departments, will determine release of second dose allotments.

The use of vaccine may initially be limited to pre-designated priority groups. Use and allocation of local health jurisdiction allotments will be determined by the local health officers, partners, and tribal leadership for their respective jurisdictions per priority protocol. Dispensing to the general public will only be performed as sufficient vaccine is available and authorized.

UDOH, UIP, will monitor unused vaccine from local health departments who have met their priority vaccination goals based on data collected for CRA weekly reports and VACMAN/VODS data. UDOH will have authority to collect and/or direct redistribution to local health department service areas who may have unmet needs or more prevalent disease from surveillance data.

## **Storage and Security of Pandemic Influenza Vaccine**

### **Receipt of Pandemic Influenza Vaccine**

Initial state allotments of pandemic influenza vaccine (pre-pandemic and novel pandemic) will be received by UIP Vaccine Management Coordinator and staff. It will be stored and distributed from the central UDOH vaccine depot. Storage will be coordinated by the UIP and overall inventories will be maintained by the UDOH. The UIP vaccine depot includes security, communication access, emergency power, accountability, supplies and staffing for distribution. Standard Operating Procedures (SOPs) are in place for the current vaccine program and will be modified to include pandemic needs. UIP staff members are very familiar with the VACMAN/VODS system as it is used for routine vaccine delivery for the Vaccine for Children program (VFC) and have standardized inventory accountability procedures.

As supplies and vaccine shipments stabilize from CDC or manufacturers, UDOH can redirect shipping sites to local health departments and other sub-recipient providers through VACMAN/VODS. CDC pandemic plans currently allow for redirection to up to 100 sub-recipient sites over time. Decisions for redirection would be done in consultation with local health departments.

Local facilities for event driven vaccine allotments will include local health departments who have submitted plans and whose vaccine depots have been pre-certified for vaccine storage and handling and security. Local health departments might decide to utilize allocations for some redistributed based on need and local plan by the local health district under the direction of a local distribution manager to local area hospitals, clinics, or administration sites. All sub-recipient sites would have to be pre-certified by UDOH for storage and handling and security.

Initial distribution of vaccine from UDOH to local facilities will be on a weekly basis to control distribution and adjustments to geographical areas, and minimize and address any storage problems identified at the vaccine provider depots.

Appendix A: Covers guidelines/resource for local estimates and enumeration of priority groups.

## **Security Resources and Storage Capacity and Chain of Custody**

Security resources for vaccine in the UDOH central vaccine depot are maintained and tested including drills/tests to determine and address vulnerability areas including potential for riot control . Additional security is provided by secure card reader access allowing only access by designated UDOH staff holding certified UDOH identification badges and is supported by constant camera monitoring by security guards. The list for access to the vaccine depot is reviewed quarterly.

The UDOH depot has constant temperature monitoring of all mechanical refrigeration units by an offsite third party and the refrigeration units are connected to a backup generator which is tested weekly by the Division of Construction and Facilities Management (DFCM). A maintenance contract is in place for UDOH refrigeration units on an ongoing basis. .

UDOH has capacity to store approximately 90,000 doses (estimated multidose vials) at any given time and has stockpile supplies for shipping. In addition, a dual temperature vaxi-cool is maintained for additional storage and transportation with a capacity of approximately 1,000 doses.

Chain of custody procedures must be followed at each level. DHS is the federal agency responsible for coordinating security when vaccine is under federal control. Once vaccine is distributed to state programs or local officials at ship to sites, local entities will assume responsibility for security and accountability. Local health department pandemic plans must document provision for security for pandemic influenza vaccine that be provided by staff and security resources. Delivery of vaccine if needed may be under the direct supervision of the Utah Highway Patrol and supporting facility and local law enforcement agencies. UDOH will develop state level agreements or Memorandum of Understanding (MOUs). Local security resources will be developed and coordinated by local authorities upon delivering vaccines to a local health department and security plans should be in place for vaccine administration sites also especially if that is at an offsite location. Local security resources could include county sheriffs, municipal police departments, and other local resources as identified and designated in local plans and local agreements/MOUs. The local plans will include incident response plans for potential riots or other security incidents.

Once on site at a local health department or redistribution site, the pandemic vaccine must be stored in a physically secure area at all times and only accessed by designated local health department staff that have local health department badges. It will be required to be stored with vaccine alarm and monitoring systems. All staff with vaccine related responsibility must complete storage and handling certification tests. A written emergency plan for vaccine storage and handling at all sites including back up generator must be in place to protect the integrity of the vaccine if a power or mechanical failure occurs. Drills of the local emergency plan must be held on a regular basis and documented to determine and address vulnerability areas. The central local health department receiving facility should have capacity to store approximately 10,000 doses (estimated multidose vials). To redistribute to sub-recipients, local health departments must maintain shipping supplies (shipping containers, jell packs, freeze indicators, warm marks, foam, packing tape, shipper warning labels)

Appendix B: Covers requirements for certification as vaccine storage/handling and security.

## **Cold Chain Documentation for Pandemic Vaccine**

Appropriate cold chain must be maintained throughout the storage and distribution process. Cold chain requirements for pre-pandemic and pandemic vaccine are the same as for seasonal influenza vaccine.

UDOH will only distribute pandemic influenza vaccine to agencies (local health departments or sub-recipient sites) certified to store and handle pandemic influenza vaccine as previously outlined. This will be documented prior to an event and addressed in local plans. A standard form will be maintained within UIP for certification and updated annually.

UIP will provide all local health departments with appropriate cold chain documentation in shipping documentation for all vaccine received from the central depot. All shipments will have vaccine temperature shipping monitors. As distribution stabilizes and direct shipments are reestablished, CDC's third party distributor or the manufacturers will be responsible for cold chain information and shipment monitoring.

Local health departments must utilize and provide documentation on cold chain to any sub-recipient site(s).

# **Administration of Pandemic Influenza Vaccine**

## **Priority Groups and Public Administration**

UDOH has adopted the National Vaccine Advisory Committee's (NVAC) guidelines for priority groups to receive pre-pandemic and pandemic influenza medications. Information may be found at <http://www.hhs.gov/pandemicflu/plan/appendixd.html> These guidelines are being updated in light of vaccine technology advances and domestic capacity building. Draft recommendations are posted for public comment at: <http://www.pandemicflu.gov/vaccine/prioritization.html>

The Department of Homeland Security may have further occupationally defined priority groups that may need to be considered.

Priority groups may have changes based on the characteristics of the causative virus and on vaccine effectiveness and availability.

The administration of pandemic influenza to the public will be performed under the authority of the local health departments after state authority to go beyond the priority group vaccination is approved. This would be under the authority of the Executive Director of UDOH or designee.

Local health departments will focus initial distribution to pre-designated sites for priority distribution. Local health departments may or may not be required to open emergency vaccination centers as needs and circumstances change.

## **Administration Sites**

Local health departments in collaboration with local stakeholder agencies and Tribes will develop local/regional plans for administration of pandemic vaccine including identification of the number and location of administration sites to reach target groups based on planning assumptions. This will be accomplished as needed with development of memoranda of agreements as applicable. Information on planned sites and locations will be included in local health department plans accepted and on file with UDOH.

## **Administration of 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, local health department plans must have strategies to ensure that vaccinated persons return for the second dose and include plan to release dose if person doesn't return or can't receive a second dose.

In such a case, UDOH and local health departments will:

- Arrange for information about the need for a second dose to be disseminated through public service announcements and other methods, according to established communication plans, and at the time of first vaccination.
- Ensure that vaccine procurement and distribution to vaccination sites accounts for the need to use portions of future shipments for second doses, thus reducing the number of available first doses. In this case communication will include strong encouragement of methods for preventing the spread of the virus.
- Utilize the reminder/recall functionality of the Utah Statewide Immunization Information System (USIIS) and/or EIMS or local EMR systems for recall and reminder.

## **Administration Supplies**

At present, the Federal government plans to provide state immunization projects with needles and syringes for administration of pre-pandemic influenza vaccine. At present the allocation amounts are undetermined as are availability of supplies for pandemic vaccine.

## **Contingency Planning for Investigational New Drug Use**

If a pandemic spread is rapid and standard vaccine efficacy and safety tests have not been completed by the time of response, unlicensed vaccines might be needed. In such a case, UDOH and local health departments would distribute unlicensed vaccines under the Food and Drug Administration (FDA) Investigational New Drug provisions.

All parties administering vaccine need to have plans in place to distribute unlicensed vaccines (if needed) under FDA's Investigational New Drug (IND) provisions or an alternative to IND Emergency Use Authorization (EUA) may be utilized.

***IND Definition:*** IND means an investigational new drug application. "IND" is synonymous with "Notice of Claimed Investigational Exemption for a New Drug." *Investigational new drug means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in*



*vitro for diagnostic purposes.* The terms "investigational drug" and "investigational new drug" are deemed to be synonymous.

Unlicensed vaccines might be needed, for example, if pandemic spread is rapid and standard vaccine efficacy and safety tests are not completed in time. IND provisions require strict inventory control and record keeping, completion of a signed consent form from each vaccine, and mandatory reporting of specified types of adverse events.

Documentation for IND would be determined by the manufacturer and CDC at the time of the event based on the pandemic vaccine produced. IND provisions require strict inventory control and record keeping, completion of a signed consent form from each vaccine recipient, 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. FDA regulations permit the use of a national or "central" IRB.

## **Accountability and Tracking Procedures**

The National Pandemic Influenza Plan calls for monitoring of the appropriate use of pre-pandemic and a scarce new pandemic influenza vaccine. To accomplish this, CDC will require states and UIP to track vaccine doses administered and collect and aggregate minimum data elements and transmit weekly to CDC through CRA.

UDOH, local health departments and participating immunization providers must be prepared to collect data based on national established data standards to include vaccine effectiveness, vaccine supply and distribution, vaccine coverage, and vaccine safety monitoring and reporting. Mechanisms for tracking vaccine supply and distribution will depend on how the vaccine is produced and distributed.

UDOH will establish data standards based on CRA requirements. CRA requirements are evolving but currently include maintaining patient information for each pandemic vaccine dose administered including IND information if required. At minimum the information required will include: patient name, contact information, type of medication, lot number, and pertinent patient medical history and other information as required by CRA. Other specific information may be required for a specific pandemic event by CDC.

UDOH is responsible for data management systems needed to implement federal reporting requirements. Statewide utilization of procedures and information systems to track vaccine inventory, administration, coverage of priority groups, adverse events, and effectiveness of distribution will be required

by federal agencies and is essential to an effective response. UDOH electronic information systems link to required CDC systems which are VACMAN/VODS and CRA. The linkage is through the EIMS which is a part of USIIS and is prepared to provide all reports to CDC as required using XML and manual file update through the CRA application. This was successfully tested in December 2007. This will evolve in the future to HL7, using the PHIN MS (Public Health Information Network Messaging Service). UDOH will maintain PHIN compliant information systems for tracking vaccine distribution and administration

The local health department will be required to certify that their electronic medical record system (EMR) will link to USIIS/EIMS or enter information directly into USIIS/EIMS to transfer information to document number and priority of vaccine recipients per data standards/policy. Federal requirements require that this reporting standard applies to all sub-recipient distribution sites that may be defined by the local health departments in their local plans and that a means of tracking the status of vaccinations by those sub-recipient sites.

## **Vaccine Coverage Data**

DOH is responsible for state reports from VACMAN/VODS and EIMS to CRA to provide coverage and accountability data.

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

CDC may also implement studies to assess vaccine effectiveness by comparing rates of influenza related illness, hospitalization, and/or death among vaccinated and unvaccinated persons. The studies would be done in collaboration with healthcare and university partners and with state and local health departments that participate in influenza surveillance systems.

## **Vaccine Safety**

Monitoring for vaccine adverse events will be necessary following immunization with a pandemic influenza vaccine. UDOH is responsible for state reporting through CRA and to plan for vaccine safety and the timely and complete reporting of pandemic influenza vaccine adverse events following immunization. (AEFI) Follow-up information on vaccine safety through the Vaccine Adverse Event Reporting System (VAERS) will need to be collected and reported to the UDOH state reporting system in UIP. Additionally, providers will also report through the VAERS system as they do with any vaccine. State level coordination can also help minimize duplicate reporting of AEFI.

VAERS is an established system with which local health departments and providers are familiar. The Immunization Program Manager and/or the Vaccine Safety Coordinator (state VAERS contact in UIP) will serve as the point of contact for vaccine safety (reporting/surveillance) in planning for the use and monitoring of vaccines and follow-up and case management reports. The point of contact will serve as the primary educator for vaccine safety, building a network of vaccine safety contacts, and serve as a resource for vaccine safety related issues. Local health departments will appoint a local Vaccine Safety Coordinator to coordinate with healthcare organizations that may serve as points of vaccine distribution will be responsible for follow-up and case management at the local level.

## **Communication Plan for Vaccine Distribution and Administration**

### **Public Information**

UDOH has adopted the National Vaccine Advisory Committee (NVAC) guidelines for priority groups to receive pandemic influenza vaccine. That means the pandemic vaccines as with antivirals will initially only be available to certain groups of people. In order to minimize concern on the part of the public, information must be made available prior to the incident outlining the pertinent aspects of the guidelines and how and to whom the vaccines will be administered.

In order to counteract any undue alarm that may accompany this type of announcement, we need to provide information during the pandemic influenza outbreak that focuses on general measures to prevent illness and what the public can do to improve their situation rather than antiviral medication use. We must also stress that at the time of an outbreak, work will begin on a vaccine, but it won't be ready for approximately six months.

As per emergency communication plans, information will be coordinated at a Joint Information Center. Local partners will be included to ensure consistent and accurate messages and to ensure that citizens are informed and know in advance where they will be vaccinated when vaccine to the public is available. UIP will coordinate with the Communication Committee to develop ideas for key points to consider in communication messages.

All pandemic level plans should include messages for routine seasonal immunization for flu and pneumococcal vaccine. Higher vaccination rates will foster increased familiarity with and public confidence in influenza vaccines and increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic.

Key messages for dissemination will include:

- Rationale for prioritization and listing of priority groups to receive vaccine
- Established phasing and anticipated timeline of vaccination according to and after priority groups have been vaccinated
- Times and locations where vaccinations will be available
- Emphasis of the importance of vaccination in order to prevent future pandemic waves
- Information on risks, benefits, and contraindications.

## **Vulnerable and Hard to Reach Populations**

UDOH has developed baseline information for most of the unique populations within the State. Local plans need to ensure event-specific 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.

Information for pandemic vaccine distribution will follow recommendations as part of the public information outreach during a pandemic outbreak. Issues addressed include language barriers, trust, mentally and physically impaired, etc. Liaisons and resources for communication to the vulnerable and hard to reach populations will be utilized to the extent that they are available. Pre-event messaging for pandemic influenza is being developed and implemented as part of the comprehensive planning for preparedness.

## **Tribal Populations**

At this time, Utah tribe's contract with local hospitals and providers for services where hospitalization is required. Native American tribes can purchase annual influenza vaccine through the Veterans Administration Prime Vendor contract and through the private sector distribution markets as well.

Most of Utah's tribes cross state boundaries and local health department jurisdictions. At this time pending a national decision they would receive access to pandemic influenza vaccine through their local health department service area following priority group designations.

All tribal issues will be coordinated with the UDOH Indian Health Liaison. Planning and real event policies must follow UDOH Tribal Consultation Policy and meet the approval of the Utah Indian Health Advisory Board.

Tribes will be provided access to UDOH pre-scripted messages, public messages, educational tools and support to assist in reaching their populations

related to pandemic influenza vaccine messages. State Tribal leaders may assist with or be responsible for translation of materials in their native language.

## **Training and Exercise for Pandemic Vaccine Distribution and Administration**

This plan and related response plans will be used as a tool in training and exercise development by UDOH. Current training for pandemic influenza response is coordinated by UDOH Training and Education Center. Training curricula includes development emergency response teams for all UDOH staff, volunteer training, and outreach efforts to all stakeholders. Exercise development for influenza vaccine distribution has been done by local health departments and includes clinic planning, administration, and documentation. Local health departments have done mass clinic exercises since 2005 and after action plan reports are available. Past training and after action exercise reports are archived in UDOH shared drives for review.

Local health departments, most of Utah's tribes, and local stakeholders have developed or are coordinating training and exercise plans for related pandemic influenza response. All training and exercise reports are encouraged to be submitted to UDOH for review purposes. U-Train is also being highly promoted as a means to provide training to isolated areas such as some of Utah's tribes.

## References

1. HHS Pandemic Influenza Plan, U.S. Department of Health and Human Services, November 2005.
2. Pandemic Influenza Vaccination: A Guide for State, Local, Territorial, and Tribal Planners. December 11, 2006.
3. Nichol KL, Treanor JJ. Vaccines for seasonal and pandemic influenza. *JID* 2006;194 (Suppl 2):S111-S118).
4. USDHHS. HHS Pandemic Influenza Plan. Appendix D: NVAC/ACIP Recommendations for Prioritization of Pandemic Influenza Vaccine and NVAC Recommendations on Pandemic Antiviral Drug Use. Accessed on December 19, 2006 at: <http://www.hhs.gov/pandemicflu/plan/appendixd.html>

## **Appendices**

## Appendix A: Influenza Vaccine Estimate Worksheet

### Instructions for Influenza Vaccine Estimations Worksheet

#### **Purpose:**

The ultimate goal of pandemic influenza vaccination will be to **vaccinate the entire population of the United States**. However, it will be necessary in the early part of an influenza pandemic to administer vaccine to individuals using a strategy that minimizes morbidity, mortality and social disruption. The purpose of the *Influenza Vaccine Estimations Worksheet* is to document the number of persons within specific tier groups in each county who will need to be prioritized to receive pandemic influenza vaccine.

#### **Tier Groups**

- ACIP and NVAC have drafted vaccine priority group recommendations which are outlined in the US DHHS Pandemic Influenza Plan, November 2005. The priority groups are arranged into tiers with persons in Tier 1 being targeted to receive vaccine sooner than persons in Tier 2. Persons in subtier 1A would be targeted to receive vaccine before persons in subtier 1 B.
- It may not be a feasible strategy to vaccinate all individuals in one tier before offering vaccine to individuals in another tier. It may be necessary to offer pandemic vaccine to a *proportion* of individuals in several tier or subtier groups simultaneously.
- These tier groups are only recommendations and may be updated as the pandemic unfolds. Members of the ACIP and NVAC realize that state and local circumstances may result in some modifications to the tier and subtier groupings.
- Rationales for each tier and subtier as well as more detailed descriptions of members of each group are discussed in the US DHHS Pandemic Influenza Plan, Part 1, Appendix D.

#### **Public Health and Healthcare Personnel**

- Persons directly involved with influenza vaccine and antiviral manufacturing and distribution
- Can include those involved with distribution, essential support services and suppliers (e.g., *growers of pathogen-free eggs* for growth of vaccine virus).
- Healthcare workers with direct patient contact and a proportion of persons working in essential healthcare support services needed to maintain healthcare services.
- Consider all healthcare facilities within the county: local health department, hospitals, long-term care facilities, home care, and physician offices. EMS personnel should be included in this category / tier group as well.
- Infection control practitioners and occupational health personnel at hospitals can serve as a resource for determining the number of healthcare personnel at their facility. Office managers can serve as a resource for estimating the number of personnel in physician offices.



- Public health workers with direct patient contact
- Should include vaccinators, individuals who would distribute antivirals, and public health workers who provide patient care
- Public health emergency response workers critical to pandemic response (should comprise approximately 1/3 of public health workforce in county)
- Include persons who do not have direct patient contact but who are essential for:
  - surveillance of influenza and its impact
  - allocation of public health resources
  - development and implementation of public health policy
- Other public health workers emergency response workers (should comprise the remaining 2/3 of your public health workforce)
- Use additional sheets as necessary for other healthcare and public health personnel not listed.
- Public safety personnel include firefighters, police, dispatchers, and correctional facility staff.
- Key government leaders are those individuals needed to make policy on pandemic influenza prevention and control efforts.
- Utility workers (water, power and sewage management)
- Transportation workers
  - who maintain a critical supply of food, water, fuel and medical equipment
  - who provide public transportation essential for provision of medical care, transportation of healthcare workers to work and transportation of ill persons seeking care
- Telecommunication and information technology service workers who are critical for maintenance and repairs of these systems
- Use additional sheets as necessary for other public safety and essential community personnel not listed. Local circumstances will likely vary.

### ***Groups at High Risk of Influenza Complications***

- Persons 65 years and older
- If possible, estimate which persons are at the *highest risk* of complications
- Persons with at least one medical condition for which influenza vaccine is recommended besides their age
- Persons 6 months - 64 years with a medical condition for which influenza vaccine is recommended
- If possible, estimate a proportion of persons at *highest risk* of complications
- Persons with at least two medical conditions for which influenza vaccine is recommended
- Persons hospitalized within the last year for influenza, pneumonia or other influenza high-risk condition
- Pregnant women
- Household contacts of severely immunocompromised persons (AIDS, transplant recipients, incident cancer cases)

- Household contacts of children < 6 months
- Healthy children 6-23 months

ACIP and NVAC are not currently recommending that nursing home residents and severely immunocompromised persons be prioritized to receive pandemic influenza vaccine; however, they do recommend these groups be prioritized for antiviral treatment and prophylaxis as well as a recommendation to vaccinate healthcare workers and household contacts of these individuals to reduce transmission of influenza to these high-risk groups. Further definitions and discussion of this decision can be found in the US DHHS Pandemic Influenza Plan, Part 1, Appendix D, pages D-17 and D-18.

**Worksheet Submission:** Mail to the Immunization Program, PO Box 142001, Salt Lake City, Utah 84114.

Include contact information; local health department submitting worksheet, date of completion, person completing and phone number. Local health departments would submit a separate worksheet for each county in their jurisdiction.

**Retention:** Maintain a completed copy, updated annually, in the local health department emergency preparedness plan.

LHD \_\_\_\_\_

County \_\_\_\_\_

Date \_\_\_\_\_

Person Completing \_\_\_\_\_

Phone/Email \_\_\_\_\_

Essential Personnel for Pandemic Response	Tier <sup>1</sup>	County population <sub>2</sub>	Vaccine Estimations <sup>3</sup>	
			Single-Dose Packages	Multi-Dose (10 Dose Packages)
Public Health and Healthcare Personnel				
Vaccine/antiviral manufacturers and essential support	1A			
Healthcare workers with direct patient contact AND essential support workers to maintain healthcare services	1A			
Public health workers with direct patient contact (including vaccinators)	1A			
Public health emergency response workers critical to pandemic response	ID			
Other public health emergency responders	2B			
(list other Public Health/Healthcare Personnel on additional sheet— if needed)				
Public Safety Personnel				
Police	2B			
Firefighters	2B			
911 dispatchers	2B			
Correctional facility staff	2B			
(list other Public Safety Personnel on additional sheet — if needed)				
Essential Community Service Personnel				
Key government leaders	ID			
Essential utility workers (power, water, sewage)	2B			
Transportation workers	2B			
Essential telecommunications/IT	2B			
Other key government health decision-makers	3			
Funeral directors/embalmers	3			
(list other Essential Community Personnel on additional sheet— if needed)				
TOTALS				

<sup>1</sup> Tier groups are listed in order and further described in the *US DHHS Pandemic Influenza Plan*, November 2005 (Part 1, Appendix D, pages D-13 through D-18).

<sup>2</sup> Estimate the total number of persons in each category for your county. Collaborate with appropriate healthcare facilities and public service personnel to obtain realistic numbers.

<sup>3</sup> Document packaging preferences for Vaccine Estimations based on administration sites and storage facilities.

LHD \_\_\_\_\_ County \_\_\_\_\_

Date \_\_\_\_\_

Person Completing \_\_\_\_\_

Phone \_\_\_\_\_

Groups at High Risk of Influenza Complications	Tier <sup>1</sup>	County population <sup>2</sup>	Vaccine Estimations <sup>3</sup>	
			Single-Dose Packages	Multi-Dose (10 Dose Packages)
Persons 65 years and older <sup>4</sup>				
1 or more high-risk medical conditions	IB			
Healthy (no high-risk medical conditions)	2A			
Persons 6 months to 64 years <sup>5</sup>				
2 or more high-risk medical conditions	IB			
History of hospitalization for influenza, pneumonia or other influenza high-risk condition in the past year	IB			
Pregnant women	1C			
Household contacts of severely immunocompromised persons	1C			
Household contacts of children <6 month olds	1C			
Healthy children 6-23 months	2A			
1 high-risk medical condition	2A			
<b>TOTALS</b>				

<sup>1</sup> Tier groups are listed in order and further described in the US *DHHS Pandemic Influenza Plan*, November 2005 (Part 1, Appendix D, pages D-13 through D-18).

<sup>2</sup> Estimate the total number of persons in each category for your county.

<sup>3</sup> Document packaging preferences for Vaccine Estimations based on administration sites and storage facilities.

<sup>4</sup> Excludes the elderly in nursing homes.

<sup>5</sup> Excludes individuals who are immunocompromised.



**Table 1: Vaccine Priority Group Recommendations\***

Tier	Subtier	Population	Rationale
1	A	<ul style="list-style-type: none"> <li>• Vaccine and antiviral manufacturers and others essential to manufacturing and critical support (~40,000)</li> <li>• Medical workers and public health workers who are involved in direct patient contact, other support services essential for direct patient care, and vaccinators (8-9 million)</li> </ul>	<ul style="list-style-type: none"> <li>• Need to assure maximum production of vaccine and antiviral drugs</li> <li>• Healthcare workers are required for quality medical care (studies show outcome is associated with staff-to-patient ratios). There is little surge capacity among healthcare sector personnel to meet increased demand</li> </ul>
	B	<ul style="list-style-type: none"> <li>• Persons &gt; 65 years with 1 or more influenza high-risk conditions, not including essential hypertension (approximately 18.2 million)</li> <li>• Persons 6 months to 64 years with 2 or more influenza high-risk conditions, not including essential hypertension (approximately 6.9 million)</li> <li>• Persons 6 months or older with history of hospitalization for pneumonia or influenza or other influenza high-risk condition in the past year (740,000)</li> </ul>	<ul style="list-style-type: none"> <li>• These groups are at high risk of hospitalization and death. Excludes elderly in nursing homes and those who are immunocompromised and would not likely be protected by vaccination</li> </ul>
	C	<ul style="list-style-type: none"> <li>• Pregnant women (approximately 3.0 million)</li> <li>• Household contacts of severely immunocompromised persons who would not be vaccinated due to likely poor response to vaccine (1.95 million with transplants, AIDS, and incident cancer x 1.4 household contacts per person = 2.7 million persons)</li> <li>• Household contacts of children &lt;6 month olds (5.0 million)</li> </ul>	<ul style="list-style-type: none"> <li>• In past pandemics and for annual influenza, pregnant women have been at high risk; vaccination will also protect the infant who cannot receive vaccine.</li> <li>• Vaccination of household contacts of immunocompromised and young infants will decrease risk of exposure and infection among those who cannot be directly protected by vaccination</li> </ul>
	D	<ul style="list-style-type: none"> <li>• Public health emergency response workers critical to pandemic response (assumed one-third of estimated public health workforce = 150,000)</li> <li>• Key government leaders</li> </ul>	<ul style="list-style-type: none"> <li>• Critical to implement pandemic response such as providing vaccinations and managing/monitoring response activities</li> <li>• Preserving decision-making capacity also critical for managing and implementing a response</li> </ul>

<b>Tier</b>	<b>Subtier</b>	<b>Population</b>	<b>Rationale</b>
2	A	<ul style="list-style-type: none"> <li>• Healthy 65 years and older (17.7 million) 6 months to 64 years with 1 high-risk condition (35.8 million)</li> <li>• 6-23 months old, healthy (5.6 million)</li> </ul>	<ul style="list-style-type: none"> <li>• Groups that are also at increased risk but not as high risk as population in Tier IB</li> </ul>
	B	<ul style="list-style-type: none"> <li>• Other public health emergency responders (300,000 = remaining two-thirds of public health work force)</li> <li>• Public safety workers including police, fire, 911 dispatchers, and correctional facility staff (2.99 million)</li> <li>• Utility workers essential for maintenance of power, water, and sewage system functioning (364,000)</li> <li>• Transportation workers transporting fuel, water, food, and medical supplies as well as public ground public transportation (3.8 million)</li> <li>• Telecommunications/IT for essential network operations and maintenance (1.08 million)</li> </ul>	<ul style="list-style-type: none"> <li>• Includes critical infrastructure groups that have impact on maintaining health (e.g., public safety or transportation of medical supplies and food); implementing a pandemic response; and on maintaining societal functions</li> </ul>
3		<ul style="list-style-type: none"> <li>• Other key government health decision-makers (estimated number not yet determined)</li> <li>• Funeral directors/embalmers (62,000)</li> </ul>	<ul style="list-style-type: none"> <li>• Other important societal groups for a pandemic response but of lower priority</li> </ul>
4		<ul style="list-style-type: none"> <li>• Healthy persons 2-64 years not included in above categories (179.3 million)</li> </ul>	<ul style="list-style-type: none"> <li>• All persons not included in other groups based on objective to vaccinate all those who want protection</li> </ul>

\*The committee focused its deliberations on the U.S. civilian population. ACIP and NVAC recognize that the US Department of Defense needs should be highly prioritized. Department of Defense Health Affairs indicates that 1.5 million service members would require immunization to continue current combat operations and preserve critical components of the military medical system. Should the military be called upon to support civil authorities domestically, immunization of a greater proportion of the total force will become necessary. These factors should be considered in the designation of a proportion of the initial vaccine supply for the military.

Other groups also were not explicitly considered in these deliberations on prioritization. These included American citizens living overseas, non-citizens in the US, and other groups providing national security services such as the border patrol and customs service.

## **Appendix B: Vaccine Storage/Handling and Security Certification**

### **Requirements**

Documentation of local security resources that could include county sheriffs, municipal police departments, and other local resources as identified and designated in local plans and local agreements/MOUs.

Documentation by site visit and documentation on file:

- Documentation of ability to store vaccine in a physically secure area at all times only accessed by designated local health department staff holding local identification badges. Area must have capacity to securely store at minimum 10,000 doses (estimated to be in multi-dose vials)
- Documentation of vaccine alarm and monitoring systems including back up generator must be in place to protect the integrity of the vaccine if a power or mechanical failure occurs.
- Documentation that all staff with vaccine related responsibility including backup staff have completed storage and handling certification tests.
- Documentation of a written emergency plan for vaccine storage and handling for all sites
- Documentation of drills of the emergency plan held on a regular basis.

Sub-recipients of vaccine must meet the same certification standards.



## **Appendix C: Vaccine Distribution and Administration: State and Local Roles by Alert Period**

### **State Roles by Pandemic Phase**

The success of the pandemic influenza vaccination program will be determined in large part by the strength of the vaccination programs conducted and the plans developed during the Interpandemic Period. For example, higher vaccination rates will foster increased familiarity with and public confidence in influenza vaccines and increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Personnel in UIP will provide technical assistance, as needed, on acquisition and distribution of vaccine in the event of a pandemic.

### **Interpandemic Phases 1 and 2 (State Level A, B)**

1. Provide technical assistance, as needed, to local health departments for vaccine-related program planning and policy development including:
  - Assess vaccine storage capacity within county
  - Review vaccine storage and handling procedures
  - Estimate number people in each priority group
  - Discuss security provisions for vaccine supply
  - Provide information and tools for mass vaccination
  - Review adverse event reporting procedure
  - Clarify responsibilities of community partners in vaccination (e.g. hospitals, nursing homes)
  - Use of EIMS to record all doses of flu vaccine given regardless of source (public or private) and for reminder/recall for second doses of vaccine.
  - Provide information and/or vaccination to high-risk or vulnerable populations
2. Monitor pandemic influenza vaccine information provided by CDC.
3. Communicate CDC pandemic vaccine updates to local health departments.
4. Encourage seasonal influenza vaccination, particularly of health care workers and high-risk populations.
5. Encourage pneumococcal vaccination of high-risk populations.
6. Work to identify potential funding sources to support vaccine related activities during pandemic.

### **Pandemic Alert Phases 3-5 (State Level C, D)**

1. Continue activities of Interpandemic Phases 1 & 2
2. Provide technical assistance, as needed, to local health departments and other agencies for continued program planning and policy development as well as exercising pandemic response plans, with particular emphasis on mass vaccination clinics.
3. Work with other stakeholders to develop pandemic-related educational programs for local health departments, such as the on-line pandemic influenza course available through U-Train.

4. Continue to research and communicate new pandemic developments. Modify existing plans as needed to reflect new recommendations.
5. Assist local health departments in identifying possible sources of additional vaccinators if needed for surge (e.g. retired nurses and doctors, EMS personnel, nursing students, etc).
6. Continue to assist local health departments with Pandemic Influenza Vaccine Estimations for Priority Groups (Appendice A) to assess vaccine quantities needed based on priority levels. Assist LHDs with estimating number of individuals who may need to receive pre-pandemic vaccine based on national guidance.

### **Pandemic Phase 6 (State Level C, D) Prior to Vaccine Availability**

1. Continue to research and communicate new pandemic developments. Modify existing internal plans as needed to reflect new recommendations.
2. Work with CDC and other federal partners, vaccine manufacturers and public health organizations (e.g. AIM, NACCHO, ASTHO) to establish plan for acquisition and distribution of initial vaccine supplies. It is likely that strategies utilized for acquisition and distribution will change as vaccine supplies increase in availability during the pandemic period. Per the CDC document "Pandemic Influenza Vaccination: A Guide for State, Local, Territorial and Tribal Planners (December 11, 2006) the following planning assumptions can be made regarding vaccine acquisition and distribution of vaccine in a pandemic situation:
  - If pre-pandemic vaccine is available it will be purchased by the federal government.
  - Pandemic vaccine will be purchased by the federal government through the first year.
  - Most pre-pandemic vaccine will be allocated in proportion to population, though exceptions will be made for critical infrastructure personnel who are not evenly distributed across the nation.
  - Pandemic vaccine will be allocated to project areas in proportion to their total population.
3. Determine expected timeline for vaccine distribution.
4. Keep healthcare providers and other stakeholders apprised of timeline for vaccine distribution through use of conference calls, established listserves (e.g. Public Health Leaders and Local Health Directors), blast faxing, NCIR announcement page, websites of state government and professional healthcare organizations (e.g. Utah Pediatric Society, Utah Academy of Family Physicians) and the Utah Medicaid Bulletin.
5. Work with Public Affairs Office to keep citizens informed about vaccine development and begin to craft messages about where, when and who will be vaccinated
6. Provide technical assistance for training of additional vaccinators, as needed, utilizing existing CDC resources.
7. Increase data storage capacity and number of support staff for USIIS/EIMS.

8. If private providers are utilized for vaccine administration, those not registered on USIIS/EIMS will report vaccine doses administered/wasted by submitting monthly Vaccine Administration Logs (VALs) to the Immunization Program. They will utilize copies of these forms for reminder/recall. See Appendice A for template forms and instructions.
9. Update Public Affairs Office frequently on vaccine availability status and dosing schedule (probable need for two doses of vaccine administered one month apart).

### **Vaccine Available for Distribution**

1. Assist in vaccine distribution according to established federal plan.
2. Assist in the redistribution of vaccine as needed to provide an equitable geographic distribution of supplies.
3. Maintain existing VAERS reporting procedures during pandemic. UIP will provide technical assistance on follow-up on adverse events.
4. Work with Public Affairs Office to continue providing accurate public messages regarding vaccine availability and location of vaccine administration sites

### **Post Pandemic Period (State Level E)**

1. Determine total amounts of vaccine distributed, administered and wasted from data contained in VACMAN, USIIS/EIMS and VALs.
2. Evaluate internal agency plan
3. Solicit feedback from local partners and stakeholders regarding evaluation of plan.
4. Revise plan based on evaluation findings.

### **Local Health Department Roles by Pandemic Phase Interpandemic Phases 1 and 2 (State Level A, B)**

- Consider participation in the Sentinel Provider Network (SPN) to conduct disease-based surveillance for influenza-like illness (ILI)
- Consider recruiting healthcare providers in your county to participate in the SPN
- Investigate and report cases of pediatric mortality associated with influenza
- Investigate clusters of ILI
- Outside of the regular influenza season
- In nursing homes and healthcare facilities
- Develop strategies to increase uptake of seasonal influenza vaccine among all of your county's residents as well as specific groups:
  - High-risk individuals as described in the annual ACIP recommendations
  - Contacts of high-risk individuals
  - Healthcare workers (HCWs)
  - Particular emphasis should be placed on improving rates among HCWs because of their potential role in transmitting influenza virus to patients. Less than 40% of HCWs receive seasonal influenza vaccine each year.

- Selected resources addressing strategies to improve HCW influenza vaccination rates
- the National Foundation for Infectious Diseases (NFID) publication on improving influenza vaccination rates among HCWs, available at <http://www.nfid.org/pdf/publications/calltoaction.pdf>
- the Association of Practitioners in Infection Control (APIC) toolkit for improving influenza vaccination rates among HCWs, available at <http://66.11.193.197/Content.html#Anchor-APIC-23240>
- Develop strategies to increase pneumococcal vaccination rates among the elderly and high-risk residents
- Consider performing a mass vaccination exercise using seasonal influenza vaccine

### **Pandemic Alert Phase 3 (State Level A, B, C)**

- Educate health department staff about avian and pandemic influenza
- Educate healthcare providers about avian and pandemic influenza
- Consider performing a mass vaccination exercise using influenza vaccine
- Estimate number of people in priority groups for pandemic influenza vaccine and antiviral administration (see Appendice A)
- Review and modify guidelines for mass vaccination clinic
- Coordinate with local EMS personnel to identify sites for mass vaccination clinics

### **Pandemic Alert Phase 4 (State Level C, D)**

- Update health department staff about avian and pandemic influenza
- Update healthcare providers about avian and pandemic influenza
- Submit forms to the Immunization branch of UDOH with estimates for priority groups to receive pandemic influenza vaccine (Appendix A)
- Continue to identify sites to be used for alternate care facilities, mass vaccination clinics and temporary morgues with EM personnel

### **Pandemic Alert Phase 5 (State Level C, D)**

- Establish communication plan with Immunization program regarding vaccine acquisition
- Communicate with PHP&R regarding possible role of the SNS for distribution of antivirals and / or pandemic influenza vaccine
- Review guidelines for mass vaccination clinics with health department staff
- Identify additional vaccinators that could be called upon if needed
- Confirm locations of sites to be used for alternate care facilities, mass vaccination clinics and temporary morgues with EM personnel

### **Pandemic Phase 6 (State Level D)**

- Before vaccine is available, discuss with Immunization branch approximate timeline for vaccine availability
- Prepare for mass vaccination clinics

- Set times and locations
- Determine which individuals will be vaccinated and how to contact them
- Administer pandemic influenza vaccine as it becomes available
- Track doses of pandemic influenza vaccine administered in EIMS (Appendices A)
- Assist state health department with obtaining data to determine age-specific attack rates, morbidity and mortality
- Work with state health department to determine vaccine efficacy
- Note that between the end of the first wave and the onset of the second wave, preparedness plans and surveillance activities need to remain at a heightened level

### **Post Pandemic Period (State Level E)**

- Conduct an after-action review of mass vaccination efforts
- Determine the amount of vaccine administered
- Determine the population covered by vaccine
- One dose of vaccine
- Two doses of vaccine
- Assess the communication channels established during the pandemic
- Local and state health department communication
- Local health department and healthcare provider communication
- Local health department and the public
- Local health department and emergency management

## Appendix D: Mass Vaccination Clinic Recommendations

### Mass Vaccination Plan

#### I. Introduction

Preparation for a mass vaccination clinic requires the cooperation of all health providers in Utah to follow uniform guidelines to assure that available vaccine reaches the highest risk priority populations first. Routine advance preparation for mass vaccination clinics should be employed on an annual basis and will lay the groundwork for addressing adverse conditions created by any influenza outbreak.

Local health departments need to develop and submit a mass clinic vaccination plan, specific to the needs of their community. Following is a guideline as to the components needed in the plan. An appendix is also included which provides more detailed information and resources that may be needed when developing a mass vaccination plan. Additional information can also be found at the following website resources:

- <http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>
- <http://www.slu.edu/colleges/sph/csbei/bioterrorism/products.htm>

(Although addressing smallpox, many of the basic principles of mass vaccination would be the same no matter the agent).

#### II. Guidelines

Each local health department's mass vaccination plan should include a description of:

- A. When and who will implement the mass vaccination clinic (under what conditions, determined by whom, etc). (This may be done by an overseeing committee that was addressed earlier in the overall plan). (REFER TO APPENDIX A)
- B. How to mobilize the plan into action (steps to be taken when and by whom). (REFER TO APPENDIX B)
- C. Clinic sites (such as schools, community centers, etc), including plans to accommodate increased number of traffic (parking space available, or transported via bus, etc). MOUs/MOAs to use these facilities should also be included. (REFER TO APPENDIX C)
- D. Vaccine Management issues including coordination plans with UIP personnel regarding vaccine shipments; the storage of mass quantities of vaccine in a secure location; transportation of vaccine; identification of hospitals and other facilities that can securely store vaccine and implement vaccination programs. (REFER TO APPENDIX D)

- E. Roles and responsibilities of vaccination team members (specific persons and his/her employer should be identified for the various roles, when appropriate) and others personnel needed to help run the clinic. When developing this keep in mind:
- i. All areas in which DOH can be of assistance or how other local health agencies, the state or federal workers could easily step in to assist.
  - ii. The number of sites and personnel needed depend upon the demand and type of vaccination. (REFER TO APPENDIX E)
  - iii. A system for identifying mass clinic personnel (ID badges, vests, etc)
- F. A rapid vaccination plan for additional public health and hospital staff needing immediate vaccination. These plans should include detail such as to whom and where will vaccination occur.
- G. The number and types of supplies and forms needed, including plans to ensure that clinics will have adequate supplies, equipment/computers, forms/VIS, and education and screening materials. (REFER TO APPENDIX G)
- H. The process for ensuring adequate screening and education of potential voluntary vaccinees (this process may also be done by the referring local healthcare facility/hospital). This would include the requirements for who should be vaccinated and when. (REFER TO APPENDIX H)
- I. An integrated clinic strategy and flow that will maximize the efficiency of the clinic to include but not be limited to: (REFER TO APPENDIX I)
- How appointments and walk-in services will be integrated
  - Patient flow, obtaining consent, process for documenting take
  - Record keeping and data management.
  - Accommodations for disabled, non-English speaking persons, etc
  - Description of security plans.
  - Description of emergency plans and available equipment, including the number of staff that are current on CPR certification.
  - Guidelines as to how to handle “worried well,” those who refuse to be vaccinated, and people from other communities (or states)
- J. Other clinic support including, food, water, mental health workers, volunteers, etc. and how these will be addressed.
- K. Clear means of communication with public regarding clinical operation,

among clinics, and between clinics and other related elements of pandemic response teams (signs for the public in pictures and words, two-way radio system, phone lines, media messages, and outreach regarding clinic locations, times, etc. (This section may be addressed in the overall communication plan)

L. Plans for debriefing after the event

M. An evaluation method for clinic efficiency and feasibility

N. Specific activities for certain types of clinics, such as smallpox or pandemic flu. For example:

*Smallpox specific:*

- Description of follow up procedures to read takes and conduct 21-day active surveillance.
- Tighter control over vaccine
- Staff needed may be different due to more in depth screening of the patient and possible contraindications and adverse events.

*Pandemic Flu specific:*

- Distribution of vaccine plan to agencies including health care providers and other agencies that works with the populations most at risk.
- Estimated number of doses to be administered per shift based on estimated vaccine availability.
- Priority of those to be vaccinated (high risk groups) first may differ than for other agents.

#### INFORMATION REQUIRED:

##### **Due: November or earlier based on schedule for mass clinic exercise**

- Mass Vaccination Clinic Plan, with all components as listed above.
- Recognition that LHD has reviewed the plan and identified other agencies that will be involved (police, fire, EMS, security, volunteers, etc); and ensured each agency clearly understands and accepts its roles and responsibilities. Secure MOAs/MOUs as needed.
- Identification of training needs, as identified by the plan
- Plan (timetable) for when clinic trainings/exercises will occur

##### **Legal Review:**

A legal review of the mass vaccination plan should be conducted by local legal consultants to identify issues of concern regarding public health authority and to ensure that laws and statutes concur with the stipulations of the plans.



INFORMATION REQUIRED:

**Due: Following review of Local health department mass clinic plans**

Written verification stating proper legal review of the plans was conducted, and identification of any concerns, conflicts or problems.

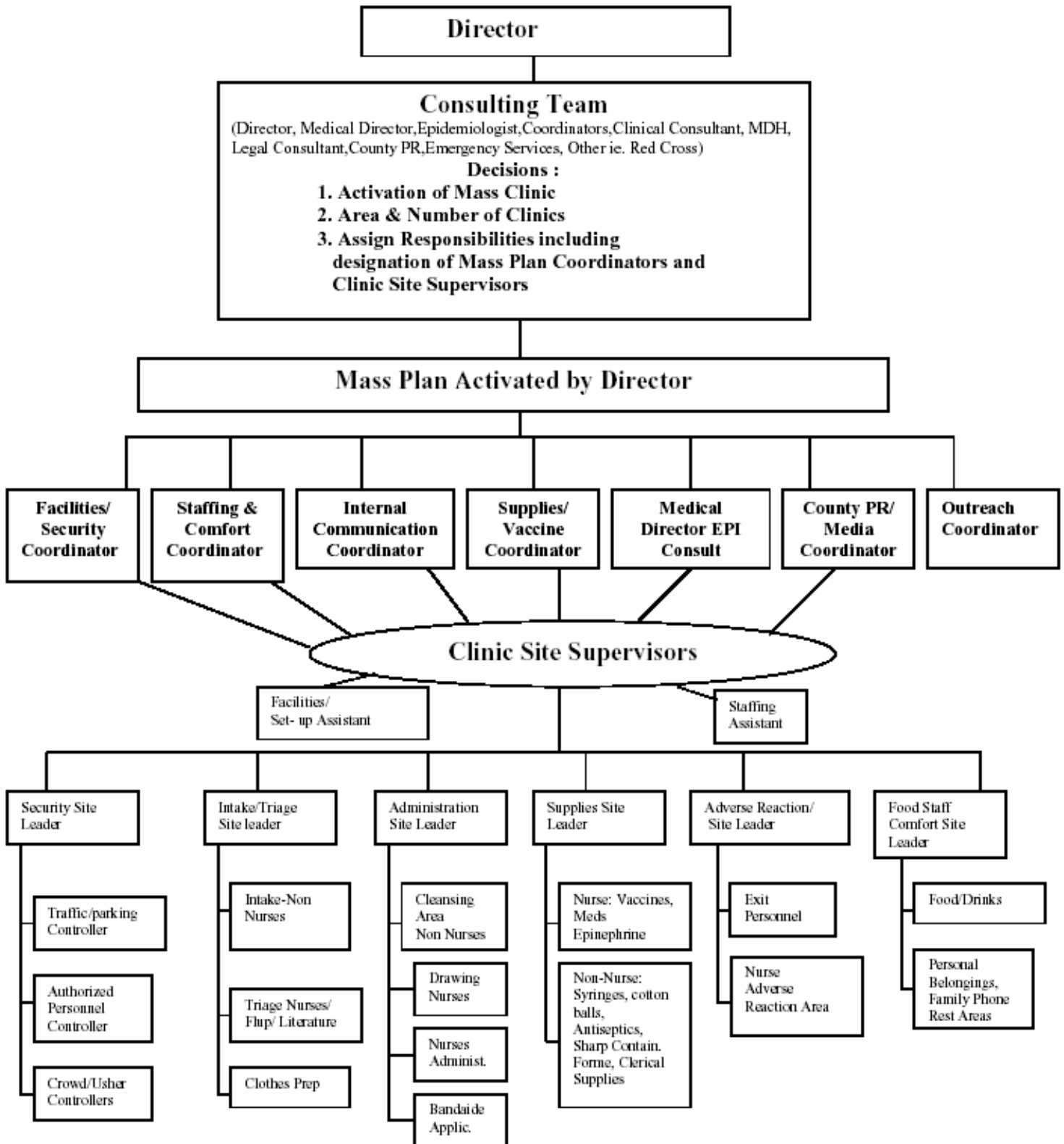
## Appendix E: Clinic Planning, Roles/Responsibilities and Accountability

### E.1. Suggested Clinic Overseeing Leadership:

- *The Local Health Officer:* Activates the mass clinic plan, in consultation with the CDC and State Health Department Officials. Keeps other agencies such as Board of Health, County Commissioners, UDOH up-to-date. Keeps in close contact with emergency services. Provides information to the media. Coordinates debriefing meeting after mass clinics are completed.
- *Consulting Team:* Attends and participates in the mass immunization emergency consultant team meeting. Helps decide when to activate a mass clinic plan, clinic locations, number of clinics needed, who will be responsible for each component.
- *Facilities/Security Coordinator:* Determines security needs, including entrances and exits (separate for employees), crowd control, adequate parking or coordination for alternative transportation. Maintains close contact with the nursing supervisor and health officer.
- *Staffing Coordinator/Nursing Supervisor:* Mobilizes staff and makes clinic assignments. Responsible for personnel issues and works closely with comfort coordinators to ensure staff and client needs are met. Determines supply needs during a clinic. Ensures all clinic personnel are appropriately identified with photo ID and “uniform.” Works closely with medical director, health officer, and UDOH.
- *Immunization Coordinators:* Set up facility equipment, tables, waste receptacles, chairs, signs, dividers, etc. Obtains and distributes vaccines, antibiotics, syringes, alcohol wipes, sharp containers, band-aids, etc. to clinic sites. Obtains and distributes anaphylactic emergency kits. Develops, prints and distributes needed forms for each clinic site, including follow-up forms. Ensures forms are in appropriate languages. Maintains close communication with Nursing Supervisor.
- *Medical Director:* Provides medical consultation to Nursing Supervisor and Nursing staff. Provides standing orders for clinics. Communicates with UDOH, Local Health Officer and Nursing Staff.
- *Client Comfort Coordinators:* Ensures adequate seating for clients. Keeps lines formed and moving smoothly. Determines and provides appropriate accommodations for disable clients, and translators for non-English speaking clients. Maintains close contact Staff Comfort Coordinator, Nursing Supervisor, and facilities coordinator.
- *Staff Comfort Coordinator:* Ensures adequate food and drinks for staff. Facilitates connections with staff families. Works closely to ensure adequate supplies are at clinic. Works closely with client comfort coordinator.
- *Volunteer Coordinator:* Ensures volunteers are in appropriate roles and responsibilities and thoroughly trained. Works closely with Nursing Supervisor to determine the best placements of volunteers.

Suggested organizational structure

**Organizational Chart**



## **E.2. Suggested Staff Activation/Mobilization Plan**

Upon suspicion of smallpox (or other outbreak) requiring mass vaccination the following steps will be used to activate and mobilize the plan:

1. The Health Officer, in conjunction with CDC and UDOH, calls an emergency meeting with the Consulting Team that a Mass Clinic Plan may need to be activated. At the meeting decisions are made whether to activate the Mass Clinic Plan, which areas to locate clinics and number of clinics to hold.
2. The Health Officer, through the Nursing Supervisor or Staffing Coordinator, notifies Staff to become on alert (staff mobilization).
3. Each Mass Plan Coordinator will be responsible to the Health Officer and will be in close communication with the other coordinators.
4. A debriefing meeting will be held after completion of the mass clinic operations.

The Staff Mobilization Plan includes steps and/or components, which will guide the staffing and position assignments for the Mass Clinic.

1. Staffing Coordinators will be the Nursing Supervisor or someone identified by the Health Officer and Consulting Team.
2. The Staffing Coordinator activates the staff mobilization plan.
3. The Staffing Coordinator determines the number of staff and mass clinic positions that are needed based on the decisions that were made at the Consulting Team Meeting
4. Once the preplanned clinic locations and number of clinics are determined, the staffing Coordinator and Facility Coordinator will work closely and a determination will be made which staff will go to which location.
5. Each staff will be notified by telephone of activation of the mass clinic plan and staff mobilization plan. Each staff will receive from their Supervisor a copy of their clinic assignment and position.

## **E.3. Clinic Site Selection**

Local health departments are working with their communities to determine locations for mass vaccination clinics. Suggestions include schools, churches, senior citizen centers, and community gymnasium. Once sites have been selected local health departments will secure memorandums of agreement, as necessary. The following criteria will be used when selecting a site:

- Protected from weather; adequate climate control (heat, air)
- Multiple rooms that ensure adequate space for large crowds, intake, briefing, screening, vaccine or prophylaxis administration, and medical emergencies. Adequate space to contain long lines inside. The site

- should be large enough to handle the target population with “room to spare.” Additional rooms for screening, staff, data, communications, etc.
- Adequate power sources for equipment and hygiene for workers and public; access to water and electricity (and back up generator)
  - Familiar and accessible to the public
  - Adequate parking and/or easy access for public transportation
  - Storage for large amounts of supplies and waste
  - Adequate restrooms/space for portable restrooms, if necessary
  - Accommodation available for special needs (wheelchairs)
  - Communication including telephone and FAX
  - Secure or can be made secure with adequate law enforcement personnel
  - Equipment resources available on site (i.e. AV equipment, room dividers, cots, power strips, etc.)
  - Tables and chairs on site
  - Waste disposal
  - Storage space

#### **E.4. Vaccine Management**

Information regarding the Strategic Pharmaceutical Stockpile (SPS) can be found at: <http://www.bt.cdc.gov/stockpile/index.asp>

In many cases the SNS has identified distribution sites in each local health department area. These sites are often public schools or other buildings with adequate space and parking. MOAs may already be in place with these schools. These schools could also be the clinic site, if deemed appropriate.

#### **E.5. Roles and Responsibilities**

Roles and responsibilities including coordinator (1/team), triage (1/team), medical screener (2/team), vaccinator (2/team), exit interviewer (1/team), data entry (1/team). Local health departments will determine how many teams they will need to vaccinate their community at different speeds required for the scenarios developed in the statewide template. Considerations will include lengths of shifts, numbers vaccinated per shift, hours of clinic operation, etc.

Roles and responsibilities of other personnel needed in a mass clinic, including law enforcement/security (30/ building), physician evaluator (1-2/ building), parking/transportation (2-5/building), primary media contact (1/building), supply manager (1-2/building), volunteers (20-30/building), translators (1-2 per language/building), etc. (As appropriate, memorandums of agreement should be included so that each agency clearly understands each other’s role and responsibility).

When developing the plan, identify specific persons who will be assigned to the roles/responsibility. This is extremely important as many LHD employees wear many hats. During an emergency outbreak the person can not be conducting surveillance and administering vaccinations at the same time. Also determine which roles other LHD or UDOH employees could do in the event more personnel are needed.

### ***Suggested Staffing Positions per Clinic (for 8 stations)***

All clinic staff should follow the same procedures regarding:

- Designated employee doors to exit and enter
- Identification such as an official picture ID badge (or other appropriate picture ID), as well as other clothing/vests which have been identified previously.
- Check in process with the staffing assistant prior to going to a workstation, and prior to leaving the site.

#### ***Nursing Clinic Supervisor: 1/shift***

Oversees individual clinic operations. Maintains close contact with coordinators. Carries a pager, cell phone (or 2 way radio). Deals with personnel issues. Checks in all clinic personnel.

#### ***\*Forms distribution: 9/shift***

Distributes packets with information sheets/registration forms/informed consent/other IND forms (1 minute/person), clipboards, pencils, to allow people to begin filling in demographic information forms while in line waiting initial clinic entry.

#### ***Triage: 2/shift***

Triage personnel to direct ill patients to other evaluation facilities and direct identified contacts, persons with contact to a rash in last 3 weeks, and their household family members to high priority evaluation location within the clinic (1 minute/ person). Also utilizes signs explaining where people should go if they are ill, contacts, or neither if done at the clinic. Also helps facilitate translators for non-English speaking persons.

#### ***\*Orientation Video Operator: 8/shift***

Operates the video orientation regarding clinic procedures, paperwork, IND consent information, reasons for vaccination, contraindications to vaccinate.

#### ***\*Referral Personnel: 8/shift***

Reviews consent forms and sends persons with “yes” checked boxes who have signed form on to vaccination station and redirects people with

contact checked boxes or other “yes” or “maybe” checked boxes on to contact or medical screeners.

***Medical Screeners:*** 8/shift

Medical screeners to review patient history for those with contraindications and answer questions for informed consent (est. 5-10 minutes person), numbers may need to be increased if too many people need further screening and start to get backed up at this point of the clinic.

***Physician Evaluators:*** 2/shift

Physicians to evaluate/examine triaged ill persons and provide backup counseling if needed to contacts and non-contacts identified with possible contraindications by medical screeners, and evaluate any immediate problems following vaccination (fainting, anaphylaxis, etc.)

***Vaccinators/witness:*** 16/shift

Educates client regarding site care, adverse event symptoms or non-taking reporting procedures/follow-up, etc. following vaccination. Alternate to vaccinate and witness vaccination of person.

***Exit Review:*** 2/shift (should be medical or public health personnel).

Answers any final questions and instructs client regarding follow up take appointment.

***Medical Records/Data Entry:*** 10/shift

Collects and retains records and enters registration/vaccination information into database. In order to maintain “real-time” record of number vaccinations it is important to have this person on-site.

***Primary Media Contact:*** 1/shift

All media questions are referred to this person. This person may be the site administrator or may have other assigned responsibilities.

***Security Leader:*** 30/shift

Maintains crowd control outside and security within clinic; assist with clinic and traffic control, etc. Non-public health resource, however arrangement must be made with appropriate agencies or organizations to provide security as part of coordinated planning.

***Contact Evaluation Unit Personnel:*** 4/shift

For separate medical screening, education, and registering of identified contacts and their household contacts. Contacts will also be registered for surveillance for smallpox symptoms and given instructions on any travel restrictions and reporting requirements. Must be educated on contact surveillance process, smallpox signs/symptoms, etc.

**Supply Manager:** 1/shift

Oversees all supply needs, tracks vaccine supply/lot numbers, distribution, and wastage re-supplies vaccination stations.

**\*Clinic flow:** 8/shift

Helps maintain clinic flow, assist with forms, quality assurance, retrieve clipboards and forms from VS and takes forms to Medical records entry personnel and clipboards back to form distribution, rotate through waiting areas to answer questions and talk with people to assure them as needed.

**Translators:** at least 1 for each major language spoken in community

Provide translation for non-English speaking clinics in each clinic area.

**\*Traffic Flow/parking Lot:** 2/shift

Maintains traffic flow and order in parking area if parking onsite, if busing in from off site parking helps direct flow of traffic from bus to clinic.

**\*Float Staff/Volunteers:** approximately 3/shift

Answer telephones, assist clinic personnel as needed.

**Vaccine Preparation for VS:** 2/shift

For preparation of vaccine vials to supply VS as needed. Should be trained personnel.

**IT Personnel:** 1/shift

Provide support for computer programming, electronic equipment maintenance needs, etc.

\*indicates non-medical personnel position, possible volunteer position

### E.6. Determining the Number of “Teams” Needed

The number of teams needed for a clinic depends upon the number of persons needing to be vaccinated. Each local health department will determine the number of teams needed to vaccinate: Entire population, ½ LHD population, and ¼ LHD population, etc.

Type of administration	Number given by individual nurse/hour
Arm administration	20/hour
Hip administration	15/hour
Oral administration	50/hour



A tool has also been developed to help local health departments determine the numbers needed for their community. This tool specifically addresses smallpox and can be found at <http://www.bt.cdc.gov/agent/smallpox/vaccination/maximum-vac/index.asp>

Another downloadable program computerized staffing model can be found at: [www.ahrq.gov/research/biomodel.htm](http://www.ahrq.gov/research/biomodel.htm)

## **E.7. Recommended Supplies and Equipment**

This section includes a list of supplies needed for a mass clinic. The actual quantities per item needed is not listed here, but should be determined by each local health department after careful evaluation of Phase I clinics.

### **Registration:**

- Pens and pencils
- Forms (including consent forms)
- Fact sheets/handouts/instructions (in other languages as appropriate to the area)
- Clip boards
- File boxes
- Rubber bands
- Tape
- Post-it notes
- Pads of paper
- Paper clips
- TV with video capabilities

### **Pharmaceuticals:**

- Vaccines/diluents
- Antibiotics/other
- Refrigeration containers
- Pill bottles/baggies
- Labels/instructions

### **Administration:**

- Syringes
- Bifurcated needles
- Gauze/ rectangle bandages
- Wipes/alcohol/cotton balls
- Sharps containers
- Band-Aids
- Disposable Table cloths
- Disposable gloves

- Masks (if indicated)
- Hand-washing solutions
- Paper towels
- Waste containers
- Disposable liners
- Water
- Sanitation supplies - cleaning
- Tape
- Latex and non-latex gloves
- Red bags
- Spray bottle with bleach
- Acetone
- Paper cups
- Tissues
- Pens

**Reaction/Sick Area:**

- Cots
- Disposable coverings
- Disposable emesis containers
- Water
- Paper cups
- Disposable wipes
- Handwashing solutions
- Anaphylaxis Kits (Children and Adults)

**Security Area:**

- Badges/name tags colored shirts for security
- Parking-flashlights at night
- Parking cones
- Rope/barricades

**Facilities:**

- Signs (including picture signs, other languages if appropriate)
- Tables
- Chairs
- Dividers/partitions

**Employee Comfort:**

- Cots
- Handwashing solutions
- Food and Beverages
- Potable water
- Personal effects storage (coats, bags, etc.)

- Bathroom Facilities
- Table/Chairs
- Private Phone area

**Exit:**

- Paperwork forms (in many languages)
- Referrals
- Follow-up returns
- Handouts/patient education/instructions (in many languages)
- File boxes
- Pens
- Immunization cards
- Date stamp
- Cleaning supplies- mop, bucket, and broom

**Clinic Staff Communication Supplies:**

- Walkie Talkies
- Cell Phones
- Pagers
- Computers
- Portable generators
- Wireless modems

**Misc.:**

- Masks (if indicated)
- Transport vehicles for staff
- Portable toilets
- Signs/pictorial instructions
- Diapers
- Disposable ice packs
- Aprons/vests (clinic worker identifier)
- Disinfectant agents
- Wheelchair

**Emergency Supplies:**

- BP cuff
- Stethoscope
- O2 with tubing

**Reminder:** All clinic personnel should have name badges, and preferably colored vests, coats for easy ID purposes.

## **E.8. People Who Should Receive Vaccine (from CDC)**

Two Priority guidelines:

### **I. One time exposure (i.e. anthrax, botulism, tularemia)**

Persons exposed to a certain agent at a particular location and time range that are symptomatic. (no person to person transfer)

### **II. One time event resulting in person to person transmission. (i.e. pneumonic plague, smallpox, eboli, cholera) or continual exposure (i.e. pandemic influenza).**

- A. Ring vaccination of those persons immediately exposed to communicable disease (including family members of patient, hospital personnel caring for patient)
- B. Persons necessary to maintain basic community infrastructure:
- Currently licensed health care workers (physicians, physician's assistants, licensed nurses)
  - Public health officials
  - Hospital Staff
  - Local public safety personnel
  - Laboratory workers,
  - EMS and emergency
  - National guard
  - Utility field workers
  - Communications personnel
  - Fuel suppliers, food suppliers
- C. Persons providing essential community services:
- Public transportation drivers
  - Air travel personnel
  - Morticians
  - Pharmacists,
  - Red Cross field workers
  - Correctional staff
  - Long-term care facility staff
  - US Postal service workers
- D. Immediate family members to those in groups A & B
- E. Persons determined to be at highest risk of developing complications
- F. Rest of population

**\*\*\*SMALLPOX VACCINATION FOR AN ACTUAL SMALLPOX CASE SHOULD BEGIN, UNDER THE DIRECTION OF CDC AND STATE PUBLIC HEALTH OFFICIAL, UPON CONFIRMATION OF THE SMALLPOX DISEASE.\*\*\***

1. Face-to-face close contacts ( $\leq 6.5$  feet or household contacts to smallpox patients after the onset of the smallpox patient's fever)
2. Persons exposed to the initial release of the virus (if the release was discovered during the first generation of cases and vaccination may still provide benefit)
3. Household members (without contraindications to vaccination) of contacts to smallpox patients † (to protect household contacts should smallpox case contacts develop disease while under fever surveillance at home)
4. Persons involved in the direct medical care, public health investigation and response\*, or transportation of confirmed or suspected smallpox patients (including designated initial smallpox response teams)
5. Laboratory personnel involved in the collection and/or processing of clinical specimens from suspected or confirmed smallpox patients
6. Other persons who have a high likelihood of exposure to infectious materials (e.g. personnel responsible for hospital waste disposal and disinfection)
7. Personnel involved in contact tracing and vaccination, or quarantine/isolation or enforcement, or law-enforcement interviews of suspected smallpox patients \*
8. Persons permitted to enter any facilities designated for the evaluation, treatment, or isolation of confirmed or suspected smallpox patients ‡ (only essential personnel should be allowed to enter such facilities)
9. Persons present in a facility or conveyance with a smallpox case if fine-particle aerosol transmission was likely during the time the case was present (e.g. hemorrhagic smallpox case and/or case with active coughing)

§ Although individuals with smallpox are not infectious until the onset of rash, vaccinating persons who had contact with the patient from the time of the onset of fever helps provide a buffer and assures that contacts who may have been exposed at the early onset of rash, when the rash may have been faint and unrecognized, have been vaccinated.

\* Includes personnel whose public health activities involve direct patient contact such as case interviewing

† Household members of contacts who have contraindications to vaccination should be housed separately from the other vaccinated household members until the vaccination site scab has separated (~ 2 weeks) to prevent inadvertent transmission of vaccinia virus. They should be also housed separately from the contact until the incubation period for smallpox has passed and the contact is released from surveillance.

‡ Only personnel without contraindications to vaccination should be chosen for activities that would require vaccination for their protection. Personnel with contraindications should not perform duties that would place them at risk for smallpox exposure and should otherwise only be vaccinated if an exposure has already occurred.

§ Evaluation of the potential risk for aerosol transmission and initiation of vaccination for non-direct contacts will be done by CDC, state, and local public health personnel. The decision to offer vaccination to non-direct contacts of smallpox cases will be made jointly by Federal and the State health officials.

## E.9. Suggested Clinic Organization

Figure 1 - Smallpox Clinic Setup

