



Texas Department of State Health Services
Vaccine Allocation, Distribution, and Storage Plan
Guidelines

Appendix L of the
Pandemic Influenza Plan Operational Guidelines

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OVERVIEW

Introduction

During an influenza pandemic, most of the world's population will be highly susceptible to infection, and it is conceivable that the virus will spread rapidly. The Department of State Health Services' (DSHS) strategies to mitigate the impact of an influenza pandemic involve both non-pharmaceutical and pharmaceutical interventions. The pharmaceutical approach includes influenza vaccines and antivirals for treatment and prophylaxis. Immunization against influenza is considered an essential public-health intervention in controlling both seasonal epidemics and influenza pandemics. However, the availability of a vaccine based on the pandemic influenza strain may be delayed by several months because of the time requirements for vaccine formulation and production. Furthermore, it is probable that insufficient production capacity will restrict access to the vaccine, at least during the first wave of the pandemic.

Early in a pandemic, the scarcity of vaccine for avian influenza and delayed production of pandemic influenza vaccine will likely mean that the vaccine supply will be administered to target populations rather than the general public. Pre-Pandemic vaccine refers to influenza vaccine that is produced to combat an avian virus strain that is believed to have pandemic potential. Currently, all available doses of pre-pandemic vaccine are held by the United States Department of Health and Human Services (HHS). Depending on which influenza strain may emerge as the pandemic strain, stockpiled pre-pandemic vaccine may provide some protection, but it requires a second dose. A vaccine directed against the circulating pandemic virus strain of influenza should become available within 4 to 5 months after identification of the new pandemic virus strain. Since the vaccine will be available in small quantities at first, targeted distribution and delivery of vaccine will be a major focus of pandemic response efforts.

The DSHS pandemic vaccine strategy provides recommendations for the Interpandemic and Pandemic Alert Periods (WHO, 2005) focusing on planning for vaccine distribution, vaccination of target 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 widespread vaccination against pandemic influenza and initiate monitoring activities.

How These Guidelines Apply to Different Entities in Texas

DSHS is committed to using the VADS Guidelines to carefully make the best decisions related to state-level and regional issues and challenges associated with pandemic influenza vaccine management and distribution. Local health departments (LHDs) are encouraged to consider these guidelines as they construct, update, and implement their local-level VADS plans.

Healthcare entities, including hospitals, hospital systems, and primary care providers, are encouraged to familiarize themselves with these guidelines, build organizational plans that address vaccine prioritization and delivery, and work collaboratively with their local public health agencies to contribute to local-level planning for pandemic influenza vaccine allocation, distribution, and storage.

FOUNDATION FOR THE TEXAS AADS PLAN GUIDELINES

Scientific Support

While a vaccine—specific for the pandemic strain—is generally considered the best countermeasure for a pandemic, one will not likely be available for the first wave of disease. Because it is not possible to predict which subtype of avian influenza virus will cause the next human pandemic, the ideal vaccine would elicit an immune response that protects the host from infection from a broad range of influenza viruses from the same or different subtypes. The potential benefits of a universal influenza vaccine are great, but these vaccines are still in pre-clinical development.

The Use of Vaccines

Vaccination is one of the most effective ways to reduce illness and death from influenza. However, the initial response to an influenza pandemic will be limited to symptomatic care, community containment, personal protective measures, and targeted use of antiviral drugs until a vaccine targeting the circulating pandemic virus strain becomes available. Pre-Pandemic vaccine from stockpiles may be considered for persons in designated target groups. Once a vaccine against the circulating pandemic virus strain becomes available, its distribution and delivery will be a major focus of pandemic response efforts.

The success of the pandemic influenza vaccination program will be determined in large part by the strength of DSHS and local vaccination programs during the Interpandemic Period. Higher annual vaccination rates for seasonal flu will foster increased familiarity with and public confidence in influenza vaccines, increased manufacturing capacity for influenza vaccines, and strengthened distribution channels. During the Interpandemic Period, DSHS and local health departments will work with health-care partners to enhance levels of 1) seasonal influenza vaccination in groups at risk for severe influenza and in health-care workers, and 2) pneumococcal polysaccharide vaccination among those for whom it is recommended.

Increased use of pneumococcal polysaccharide vaccine may decrease rates of secondary bacterial infections during a pandemic. Because large-scale pneumococcal vaccination might not be feasible once a pandemic occurs, the Interpandemic Period and Pandemic Alert is the ideal time to deliver this preventive measure. Pneumococcal vaccine is indicated for most persons for whom seasonal influenza vaccine is recommended.

While vaccine is in short supply, control will be maintained in the public sector. The Centers for Disease Control and Prevention (CDC) and the Immunization Services Division of the National Center for Immunization and Respiratory Diseases (NCIRD/ISD) will coordinate the distribution of both pre-pandemic and pandemic vaccines. States will be notified of quantities and delivery details at the time of the event (personal communication, Virginia Baresch, October 15, 2007) or as new information is obtained from CDC. CDC's current focus is on vaccine planning. When DSHS receives new information, it will be shared with HSRs and LHDs.

Guiding Principle

Vaccination, one of the most effective ways to minimize morbidity and mortality associated with pandemic influenza, may be notably affected by the current limited capacity to manufacture vaccine. Therefore, planning for pandemic influenza immunization will have to address the need to vaccinate predetermined target groups and the possibility of a vaccination program of long duration. A campaign of this magnitude and duration involves collaboration with many groups, and clear delineation of roles and responsibilities is crucial. Flexibility in planning will also be essential because some key variables will remain unknown until the time of the event. The ability to scale plans will be important in implementing an effective vaccination program.

Ethical Principles

- Respect: All life is precious and deemed important.
- Equity: Reduce significant differences in influenza-related mortality.
- Protect the public from harm: Minimize long-term social disruption and economic impact.
- Reciprocity: Protect those with disproportionate burden in protecting the public good.
- Stewardship: Those entrusted with governance roles must demonstrate ethical behavior and good decision making.

Goals

Texas has adopted the goals for pandemic influenza planning developed by the United States Department of Health and Human Services (HHS). These are:

- Vaccinate all persons in the United States who choose to be vaccinated
- Prevent morbidity and mortality
- Minimize social disruption
- Minimize economic effects.

In addition, Texas goals include:

- Prevent or delay spread geographically
- Prevent significant compromise of basic healthcare, public health and public emergency infrastructures
- Ensure the integrity of the healthcare and public health infrastructures to allow for an adequate response
- Allocate scarce vaccine resources efficiently and effectively
- Consider vaccine priorities and use in the context of all prevention and control activities.

Assumptions

- Plans must be flexible to respond to changing situations.
- Demand for significant resources will be regional, and treatment and prevention strategies will be tailored to unique state, regional, and local circumstances.
- Current societal expectations about access to health care may have to change during a public health crisis of major proportions.
- Employers, healthcare partners, and local/state government will identify in advance those serving in essential response functions.

- Response roles will determine target group placement rather than job category.
- Seasonal influenza vaccination may or may not offer some level of protection against a novel pandemic influenza strain.
- Surveillance for pandemic influenza will provide information critical to the implementation of control measures, such as restricting travel, closing schools, canceling public gatherings, and initiating antiviral and vaccine usage in target groups.
- It is highly unlikely that a well-matched pandemic strain vaccine will be available when a pandemic begins. Pandemic vaccine production may require 4 to 5 months from the time the pandemic influenza strain is identified.¹
- Only U.S. manufactured pandemic influenza vaccines will be available for U.S. purchase during a pandemic.²
- Pre-pandemic and pandemic vaccine will be allocated to states based on population.³
- Pre-pandemic and pandemic vaccine will be allocated to DSHS Health Service Regions (HSR) in proportion to their total population.
- If pre-pandemic and/or pandemic vaccine is limited, HSRs will allocate vaccine in proportion to target group population. Exceptions will be made for critical infrastructure personnel who are not evenly spread across the state.
- Groups listed in the DSHS Plan Guideline will be target groups for pre-pandemic and pandemic vaccine.
- The rank order of target groups is subject to change depending upon disease epidemiology, pandemic severity, and vaccine supply.
- Categories of target groups will be vaccinated sequentially. Tiers within categories will be vaccinated simultaneously unless the shortage is severe, in which case, sub prioritization will be necessary.³ (See [Appendix C.](#))
- A small portion of Texas' vaccine allocation will be maintained at DSHS for distribution based on the specific needs at the state level.³
- Pre-pandemic vaccine will be made available by CDC either shortly before or early in the pandemic for all critical infrastructure workers who want to take it. ([See Table 1.](#))
- The Federal Government will own all pre-pandemic and pandemic vaccine for at least the first year of production or until supply exceeds demand.²
- Distribution of pre-pandemic/pandemic vaccine may differ according to availability of vaccine.
- Two doses of vaccine are needed for immune response. The second dose should be administered 4 or more weeks after the first dose.
- Vaccine will be distributed mostly in multi-dose vials.
- Ancillary vaccination supplies will not be provided by the Strategic National Stockpile (SNS).
- Vaccinations will be tracked.
- Vaccine may be administered under Emergency Use Authorization (EUA).
- Pneumococcal vaccine will not be stockpiled.

¹ CDC (November 26, 2007). Update: status of pandemic influenza vaccine manufacturing capacity, pre-pandemic stockpile, and planning for vaccine distribution: p.1.

² CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at

http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf

³ CDC (October 17, 2007). Draft guidance on allocating and targeting pandemic influenza vaccine, Available at <http://www.pandemicflu.gov/vaccine/prioritization.html>.

Case Definition

- The Centers for Disease Control and Prevention (CDC) case definitions in place at the start of pandemic response will be used. DSHS may revise case definitions based on the epidemiology of the disease and character of the virus as the pandemic unfolds.

PLANNING ¹

Pre-pandemic Vaccine

Allocation

The Federal Government currently has 14.8 million doses of pre-pandemic vaccine produced by Sanofi Pasteur at 90 µg per dose, and expects to have 20 million 2-dose courses sometime in 2008. Two additional manufacturers, Novartis and GlaxoSmithKline are also producing pre-pandemic vaccine. The amount of vaccine available depends upon increased production and success of augmentation with adjuvants.

Pre-pandemic vaccine will be targeted to persons whose work helps maintain critical infrastructure. It will be shipped for **immediate administration** when sustained person-to-person transmission occurs anywhere in the world. The planning scenarios are:

Table 1. CDC Pre-Pandemic Vaccine Planning Scenarios

<u>Scenario 1</u> <u>90 µg</u> 20M 2-dose courses²	<u>Scenario 2</u> <u>15 µg</u> 120M 2-dose courses	<u>Scenario 3</u> <u>7.5 µg</u> 280M 2-dose courses
Tier 1 target populations: Critical Infrastructure ³	Tier 2 target populations: Higher Risk General Populations	Lower Risk General Populations

Pre-pandemic vaccine will be allocated to states based on the number of critical service providers in the state, **not on per capita population**. States will be expected to provide numbers and locations of Tier 1 and Tier 2 critical infrastructure providers and plans to verify priority group membership to HHS/CDC after a workgroup develops descriptions of qualifying workers (Personal Communication, Toscha Stanley, March 18, 2008). Pre-pandemic vaccine will be shipped to drop sites based on state-submitted Tier 1 (and Tier 2 priorities under Scenario 2 in Table 2) lists of priority group membership based on numbers of priority group members in the jurisdictions, **not per capita according to population**.

¹ Unless noted by a footnote, requirements are excerpted from: [CDC \(November, 26, 2007\)](http://www.dshs.state.tx.us/comprep/pandemic/CDC%20vaccine%20planning%20update%20November%2026%202007.pdf). Update: Status of pandemic influenza vaccine manufacturing capacity, pre-pandemic stockpile, and planning for vaccine distribution. Available at <http://www.dshs.state.tx.us/comprep/pandemic/CDC%20vaccine%20planning%20update%20November%2026%202007.pdf>

² A yet to be determined amount of pre-pandemic vaccine will be allocated to the Federal Government for federal critical infrastructure per CDC.

³ If doses remain, use will expand past critical infrastructure.

Distribution

- a. Pre-pandemic vaccine will be shipped for **immediate administration** once sustained person-person transmission has been documented anywhere in the world.¹ Long term storage of vaccine is not expected.
 - b. Initially, each manufacturer will ship their vaccine (or collaborate with a chosen distributor to ship their vaccine) to Texas ship-to sites, taking into account state allocation, number of ship-to sites, and allocation among ship-to sites. Each ship-to site will, therefore, receive shipments from each of the 3 manufacturers as they come on-line.
 - c. Centralized distribution will be considered once Vaccine Management Business Improvement Project (VMBIP), currently being deployed for distribution of childhood vaccines, is fully functioning throughout the country.
 - d. Amount of vaccine to be distributed to both ship-to sites and points of delivery is based on numbers of critical service providers working in each jurisdiction whose names and place of employment have been submitted to the State.
 - e. Distribution from ship-to-sites to the points of delivery (PODS) is the responsibility of the Distribution Coordinator.
2. **Number of shipments**
- a. Vaccine will be shipped in 3–4 shipments and may include:
 - Stockpiled vaccine already filled in multi-dose vials
 - Stockpiled bulk vaccine to be filled (takes approximately 3 weeks to fill vaccine—this will be the largest shipment)
 - Additional pre-pandemic vaccine produced, if any, before start of production of pandemic vaccine.
3. **Packaging of vaccine** (see [Appendix E](#) for additional packaging information):
- a. Vaccine will be shipped primarily in increments of 100 vial master cartons.
 - b. The dimensions and weight of the shipping containers for the master cartons are 12.0 inches x 6.5 inches x 6.0 inches and 5.5 lbs; and a pallet consists of 147 master cartons, with dimensions and weight of 48.0 inches x 40.0 inches x 45.5 inches and 850–900 lbs.

Pandemic Vaccine

Allocation

At present, Sanofi Pasteur is the only manufacturer able to produce vaccine using cell-based technology. They will be the only manufacturer for pandemic vaccine in the U.S. until 2010 when additional manufacturers will have cell-based production capabilities. For this reason, production of vaccine through egg based technology will be the primary method of production if the pandemic occurs before 2010. Prior to 2010, pandemic vaccine will become available six to eight months after virus identification. After 2010, vaccine may be available as soon as four to six months.

¹ CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf

Pandemic vaccine will be allocated to states according to population. However, the Federal Government may require allocation within the states stratified by priority groups. Within Texas, allocation will be per capita according to county percent of total Texas population with doses given to people according to priority group membership.

Table 2. Pandemic Vaccine Planning Scenarios for Texas

Concentration # Per shipment	Scenario 1 90 µg per dose / 5 dose vial	Scenario 2 15 µg per dose / 10 dose vial	Scenario 3 7.5 µg per dose / 20 dose vial
Doses			
• Initial	517,910	6,802,400	20,098,000
• Subsequent	51,791	680,240	2,009,800
Vials			
• Initial	103,580	680,240	1,004,900
• Subsequent	10,358	68,024	100,490
100 vial master packs			
• Initial	1,036	6,803	10,049
• Subsequent	104	681	1,005

Distribution

- a. As long as Sanofi Pasteur is the only manufacturer, pandemic vaccine will be shipped to designated ship-to sites via commercial carrier. Commercial carriers can support shipments to 3500 sites nationally.
 - b. Once additional manufacturers are producing vaccine, vaccine will be shipped using a centralized distribution system, such as the VMBIP, with distribution to pre-determined regional and local ship-to sites.
 - c. Pandemic vaccine will be administered as soon as possible after receipt.
 - d. Amount of vaccine to be distributed to both ship-to sites and points of delivery is based on the percent of population living in each jurisdiction. However, administration will be according to priority groups.
 - e. Distribution from ship-to-sites to the points of delivery (PODS) is the responsibility of the Distribution Coordinator.
1. Shipments
 - a. Frequency
 - The first shipment of pandemic vaccine will represent approximately 10 weeks-worth of production and will therefore be about 10 times greater than subsequent shipments.
 - Subsequent shipments will occur weekly; each ship-to-site will receive a percentage of the weekly allocation based upon the Texas population served by the ship-to-site.
 - b. Changes to number and location of ship-to sites:
 - Changes in number of sites will require approximately a 2 week notice
 - Changes in location of sites will require less advance notice.
 2. Packaging information can be found in [Appendix E](#).
 - a. Scenario 1 (Table 2):

- Vaccine may be shipped in smaller cartons than 100 vials master cartons. This greater flexibility in terms of packaging is possible because the amounts of vaccine to be shipped are so much smaller.
 - b. Scenarios 2 and 3 (Tabl2 3)
 - The majority of vaccine will be shipped in 100 vial master cartons.
 - c. The dimensions and weight of the shipping containers for the master cartons are 12.0 inches x 6.5 inches x 6.0 inches and 5.5 lbs; and a pallet consists of 147 master cartons, with dimensions and weight of 48.0 inches x 40.0 inches x 45.5 inches and 850–900 lbs.
3. The ***Determination of Refrigerated Vaccine Storage Space worksheet*** located in [Appendix F](#) may be used to determine adequacy of refrigerated space or to determine amount of storage required.

Storage of Vaccine

1. Cold chain
 - a. Must be maintained throughout distribution and storage
 - b. Requirements are the same as seasonal influenza vaccine protocols (according to package insert).
2. Storage sites
 - a. Ship-to and storage site evaluation is the responsibility of local jurisdictions.
 - b. Ship-to sites must be able to:
 - Receive weekly shipments;
 - Have adequate space for storage; and
 - Maintain vaccine at 36–46F (2–8C) (temperature monitoring systems are in place).
 - c. Site consideration must include location's ability to rapidly respond.

Security of Vaccine

1. The DHS is responsible for coordination of safety while vaccine is under federal control.
2. Once control is turned over to officials at ship-to sites, the state or local government assumes responsibility.
3. Monitoring vaccine inventory will be accomplished through the Pharmacy Inventory Control System (PICS) currently used to track vaccine receipt and distribution for all state programs including smallpox.
4. The Texas Inventory Management System (TIMS), which tracks pharmaceuticals and supplies during a disaster, will serve as the back-up inventory control system.

Monitoring Vaccine Doses Administered

1. States will assign Vaccine Tracking Coordinators to manage data collection and transmission.
2. States will implement a plan to collect, aggregate, and submit aggregate data for both pre-pandemic and pandemic vaccine.
3. ImmTrac is designated by Texas law as the tracking method for antivirals and vaccine given during a pandemic.
4. Aggregate data must be submitted through the federal Countermeasure and Response Administration (CRA) system.

5. Determine a means to provide verification of vaccination of critical service providers for employers.

VACCINE TARGET GROUP GUIDELINES

Texas Vaccine Allocation Model

Appendix A contains *The Texas Pre-Pandemic Vaccine Allocation Model* and the *Texas Pandemic Vaccine Allocation Models* which reflect the conceptual underpinning for the DSHS Vaccine Allocation, Distribution, and Storage (VADS) Plan. Decisions are based on the latest science and input from participants in an Expert Panel convened in 2006 by DSHS to discuss priority groups for antivirals and vaccine. Participants included representatives from Health Service Regions (HSRs) and Local Health Departments (LHDs), academicians, attorneys, community advocates, epidemiologists, ethicists, faith community representatives, hospital representatives, influenza experts, pharmacists, nurses, and practicing physicians. Subsequently, the Department of Health and Human Services (HHS) published its vaccine priority recommendations that are nearly identical to those developed by DSHS.¹

Initial pandemic vaccine stocks from the HHS will be used to vaccinate designated target groups (Appendix B). After vaccination of target groups, vaccination of other persons will be phased in depending on available supplies. NCIRD/ISD is in the process of developing and clearing their vaccine distribution plan. Details of the plan may necessitate changes in the DSHS VADS Plan Operating Guidelines.

To distribute vaccines, LHDs may choose to use existing plans for emergency mass distribution of medical supplies as the basis for developing local pandemic vaccination plans (e.g., smallpox and SNS plans). LHDs must include identification of target populations, numbers in target populations, and processes for vaccinating target populations, and methods for verifying membership in target populations in their plans.

Vaccine Target Group Guidelines

A list of target groups for receiving vaccination and the rationale for prioritization is provided in Appendix B. It should be noted that, during a pandemic, changes may be made based on the epidemiology of the pandemic virus and vaccine effectiveness.

To prepare for vaccination of target groups at the local level, LHDs should:

- Identify a process for reviewing national and state recommendations for pandemic influenza vaccination and developing area-specific modifications or refinements in target groups, depending on local circumstances.
- Estimate the size of relevant target groups.
- Develop a plan on how persons in target groups would be identified at vaccination clinics and how vaccine would most efficiently be provided to those groups.
- Educate professional organizations and other stakeholders about the need for target groups and about the rationale for the groups currently recommended.

¹ CDC (October 17, 2007). Draft guidance on allocating and targeting pandemic influenza vaccine. Available at <http://www.pandemicflu.gov/vaccine/prioritization.html>.

DEVELOPMENT AND MAINTENANCE OF VADS PLAN GUIDELINES

Development

These guidelines are based on certain assumptions, and the existence of specific resources and capabilities may be subject to change. Flexibility is built into the implementation of these guidelines. Some deviation in the implementation of the operational concepts identified in these guidelines may be necessary to protect the health and safety of the public. Additionally, Texas developed these VADS Guidelines prior to the release of federal guidance. They will be updated as new information is received from our federal partners.

Maintenance

DSHS will review and update the guidelines as needed. Revisions will reflect CDC updates, changes in implementation procedures, improved capabilities, changes in rules and regulations, and correction of deficiencies identified in exercises, after action reports, stakeholder reviews and actual incidents.

SUMMARY OF DSHS AND LHD ROLES AND RESPONSIBILITIES

INTERPANDEMIC/PANDEMIC ALERT PERIODS: WHO Phases 1–5; Federal Response Stages 0–2

Planning Considerations

Texas is a local-control state, and many decisions about pandemic influenza response will be made at the local government level. These guidelines were developed with local input to provide a simple, flexible process adaptable for state, regional, and local jurisdiction use. The World Health Organization (WHO) and the federal government have developed response stages for pandemic influenza. The following roles and responsibilities are outlined to match these phases and stages.

Vaccination in the context of pandemic influenza will take place over many months and may unfold into three distinct steps:¹

- Step 1. Pre-pandemic Vaccination: Vaccination with stockpiled pre-pandemic vaccine, just prior to the declaration of a pandemic and during the early pandemic, until matched pandemic vaccine is available. Vaccine will be owned and disbursed through government entities.
- Step 2. Early Pandemic Vaccination: Vaccination with pandemic vaccine when it first becomes available and is in short supply and offered to priority groups through government entities.
- Step 3. Later Pandemic Vaccination: Vaccination with pandemic vaccine offered to all priority groups when vaccine is more plentiful. Government control will transition to the private sector.

¹ CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf

During Federal Government Response Stages 3 and 4, demand is expected to exceed supply, and it will be critical to ensure that vaccine dispensing is carefully controlled (e.g., via limited distribution points) and aimed at target groups. Under this scenario, the government will maintain control with none available in the private sector. Once pandemic vaccine is readily available, CDC may release control of vaccine. At that time HSRs and LHDs may elect to shift control from public health departments to the private sector. The timing of this transition will vary and will be affected by such factors as availability and demand for vaccine and ability of the public health infrastructure to sustain the vaccination campaign.

Tables 2 and 3 above reflect Texas' share of pre-pandemic and pandemic vaccine doses. Plans developed will need to be flexible to handle any of these scenarios assuming that at least Texas' critical infrastructure (Tier 1) workers have received one dose of pre-pandemic vaccine.

During the Interpandemic Period, state and local health departments should work with healthcare partners to enhance levels of 1) seasonal influenza vaccination in groups at risk for severe influenza and in healthcare workers, and 2) pneumococcal polysaccharide vaccination among those for whom it is recommended.

Department of State Health Services Responsibilities

Planning

1. Collaborate with federal, state and local partners to develop statewide plans for the purchase, storage, dissemination and use of influenza vaccine including medical supplies in the SNS.
2. Work with HSRs and LHDs in conjunction with public sector and private sector stakeholders to identify persons (including critical service providers) to be included on both pre-pandemic and pandemic vaccination target population lists within jurisdictions.
3. Work with DSHS and HSR leadership to ensure that business continuity and COOP planning is ongoing.
4. Assist regional and local public health and healthcare facilities in conducting exercises and drills to test healthcare response issues and build partnerships among healthcare and public health officials, community leaders, and emergency response workers.
5. Ensure LHDs have exercised mass vaccination clinics per SNS plans as well as smaller points of distribution in preparation for any of the pre-pandemic and pandemic vaccine scenarios.
6. Develop a communications infrastructure to facilitate and ensure the timely dissemination and transfer of information between the healthcare and public health sectors.
7. Work with regional, local, and healthcare partners to enhance levels of:
 - a. Seasonal influenza vaccination in groups at risk for severe influenza and in healthcare workers; and
 - b. Pneumococcal polysaccharide vaccination among those for whom it is recommended.
8. Address legal issues that can affect staffing and patient care.

Vaccine Allocation and Distribution

1. Estimate weekly allocation of vaccine for Texas local and regional health departments based on vaccine availability (Scenarios 1-3) and target group populations.
2. In consultation with local and regional health departments:

- a. Determine designated ship-to sites for pre-pandemic and pandemic vaccine.
- b. Determine what proportion of vaccine will be allocated to each ship-to site.
 - Pre-pandemic vaccine will likely be allocated according to numbers of people in target populations. This number will vary depending upon availability of vaccine. Amount available depends upon approval of adjuvants that can decrease amounts of antigen required from 90 μ to potentially as low as 7.5 μ (see pp. 9-10)
 - Pandemic vaccine will be allocated per capita. However, it should be distributed to priority groups Tier 1 priority groups as presented in Appendix B Table 3.
3. At ship-to sites, determine what proportion of pre-pandemic and pandemic vaccine will be allocated to further points of distribution, if applicable.

Vaccination of Target Groups

1. Estimate the size of relevant target groups for the state.
2. Develop protocols for verification of target group membership.
3. Because target group membership is associated with place of work rather than residence, allocation within the LHD or HSRs will need to be based on number of persons in targeted occupational groups and location of employment.¹
4. Educate professional organizations and other stakeholders about the need for target groups and the rationale for the groups currently recommended.

Vaccination of Tribal and Special Needs Populations

1. Ensure that tribal populations are included in vaccine allocation plans.
 - a. Include Indian Health Service (IHS) and tribal planners in planning activities.
 - b. Ensure cross-border coordination of vaccination plans for tribal communities that cross project area boundaries such as state lines.
 - c. Provide technical assistance as required
1. Provide guidance to LHDs on identifying and accessing special needs.

Quarantine Stations (To be developed)

1. Coordinate with quarantine station staff to . . .

Communications

1. Develop professional and public communication strategies.
2. Plan for coordinated release of information across federal, state, regional and local lines.
3. Plan assessments of when to activate provider and public communication.
4. Keep up-to-date plans to ensure dissemination of vaccination-related information via different means and languages to reach all segments of the population.
5. Ensure messages are delivered to those less likely to seek vaccination.
6. Plan for continuity of operations during a pandemic.

¹ CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf

Vaccine tracking

During the Texas legislative session in 2007, the state's childhood immunization tracking program, ImmTrac, was expanded to include adults and requires tracking of medications and vaccines used for treatment and prevention during public health emergencies. A number of actions must occur to prepare ImmTrac to track adults and emergency medications and vaccinations. These actions include:

1. Programming the ImmTrac software to include tracking of adults and children receiving vaccines, vaccine effectiveness, and adverse reactions¹.
2. Determine how minimum data elements² and other project area-required data will be collected at the administration sites. Note: The Texas VIS Addendum Consent Form may be modified to include the minimum data elements and serve as the paper back-up.
3. Determine how the data will be transmitted from administration sites to local and state health departments.
4. Determine how minimum data elements will be transmitted to CDC.
5. Determine what additional data (if any) will be collected for local and state use, and develop specifications.
6. Determine central office personnel needed to support a tracking system.
7. Develop a training plan.
8. Determine equipment needs, including hardware and software needed for data entry and aggregation.
9. Develop informational brochures for emergency responders.
10. Activate ImmTrac for first dose of pre-pandemic vaccine if CDC releases it before the pandemic.
11. Provide information about receipt of second dose of pre-pandemic vaccine.
12. Report minimum data set aggregate numbers to CDC weekly.

Vaccine Safety Monitoring

1. A Vaccine Safety Coordinator (and a back-up) who is the main point of contact for vaccine safety surveillance and reporting has been designated located in the Strategic Preparedness Branch of the Community Preparedness Section.
 - a. Serves as point of contact for health care providers for safety-related issues.
 - b. Facilitates reporting during events from other with other health care system vaccine safety coordinators.
 - c. Serves as primary educator for vaccine safety reporting at the state and local levels.
 - d. Ensures timely reporting of adverse reactions.
2. **Adverse Vaccine Reactions will be documented in ImmTrac**
3. The DSHS Drug and Medical Devices Group (DMDG) within the Division for Regulatory Services, Environmental and Consumer Safety Section monitors adverse reactions through the VAERS reporting system.
 - a. DMDG tracks reports filed with the State Health Department either by patients or providers who report directly to VAERS or to the state health department.
 - b. DMDG investigates each report.
4. Review policies for reporting adverse events.

¹ This work will begin as soon as funding is encumbered.

² Minimum data set includes: Date of administration, age group, priority group membership, and 1st or 2nd dose.

System-related

1. Laws/rules/policies/procedures
 - a. Pursue the possibility of establishing a pre-scripted and pre-approved disaster declaration waiver of rules that limit pandemic response.
 - b. Develop “blanket order for dispensing” template.
 - c. Ensure that plans for distribution of vaccines are reviewed by appropriate legal authorities.
 - d. Determine whether state and local laws allow non-licensed volunteers or healthcare workers from other jurisdictions to administer influenza vaccines.
 - e. Work with professional organizations and unions to consider options for emergency performance of tasks outside of standard job descriptions.
 - f. Determine whether state and local laws allow mandatory vaccination to protect public health, if needed.
2. Coordinate assessment and planning which is essential for pandemic prevention and containment with bordering U.S. states & Mexico Border States.
3. Outline decision making process for handling requests from local health department for shipment of additional vaccine.
4. Review SNS policy and procedures for use of non-approved vaccines released by the Food and Drug Administration under an Emergency Use Authorization (EUA) for vaccines labeled as Investigational New Drugs released by the government before final approval by the Food and Drug Administration (FDA)¹.

Local and Regional Responsibilities

Planning

1. Develop local and regional plans for the storage, dissemination and use of influenza vaccine and accompanying medical supplies according to guidelines in the Texas SNS Program Manual (SNSPM).
2. Assist healthcare facilities in conducting exercises and drills to test healthcare response issues and build partnerships among healthcare and public health officials, community leaders, and emergency response workers.
3. Develop a communications infrastructure to facilitate and ensure the timely dissemination and transfer of information between the healthcare and public health sectors.
4. Work with health department management to ensure that continuity of operations (COOP) planning is completed.

¹ Vaccine will be distributed under CDC-developed EUA operational plan currently in development. See CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at: http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf. Once the Secretary of HHS declares an emergency, the FDA will authorize use of the vaccine under the EUA. Unlike the authorization requirements for an Investigational New Drug, the EUA does not require Institutional Review Board approval, informed consent, or naming of a principle investigator.

Vaccine Allocation and Distribution

1. Determine a plan to ensure that vaccine will be transported safely from original drop site to vaccinating sites while maintaining safety and security.
2. Determine a plan to ensure cold chain is maintained during transport.
3. From initial drop sites, determine what proportion of pre-pandemic and pandemic vaccine will be allocated to further points of distribution, if applicable.
4. Ensure the availability of sufficient and appropriate storage at all relevant locations to maintain the cold chain.

Vaccine Safety and Storage

1. Develop chain of custody procedures according to the guidance in the SNSPM.
2. Coordinate with law enforcement to develop a vaccine security plan per SNSPM. Local health departments bear the responsibility for vaccine security once it is in their possession.
3. Ensure that the point of distribution (POD) has sufficient security according to the SNSPM.
4. Ensure that the ship-to-sites and points of distribution have adequate storage that include refrigeration and temperature monitoring systems.

Vaccination of Target Groups

CDC requires vaccination according to federal target groups. As allowed, a few modifications in target group definition or sub-prioritization have been done.¹

1. Identify target group members:
 - a. Obtain names and target group membership from agencies and businesses who will be receiving vaccination from the LHD.
 - b. Obtain numbers for target populations from healthcare settings and others which are providing vaccination as designated PODs.
2. Educate stakeholders about the need for target groups and the rationale for the groups currently recommended.

Logistical Issues Associated with Vaccination Planning

1. Determine for each target group how vaccine would most efficiently be provided, e.g. whether members will be vaccinated by public health or by institutions, agencies, or workplaces in which they are employed, or a combination.
 - a. Develop a plan on how persons in target groups will be identified and documented at vaccination sites.
 - b. Develop memoranda of agreement with institutions and agencies to which vaccination will be delegated, where applicable.
 - c. Determine if vaccine will be delivered to sites or picked up from a central distribution site.
 - d. Ensure points of distribution are registered as ImmTrac users and the point of contact has been trained to use it.
2. Determine what proportion of pre-pandemic and pandemic vaccine will be allocated to further points of distribution, such as mass clinic PODs, if applicable.

¹ CDC (December 11, 2006). Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners. Available at:
http://michigan.gov/documents/mdch/PandemicVaccinationPlanningGuide121106_180928_7.pdf

3. According to the guidance outlined in the Texas SNS Program Manual:
 - a. Determine number and location of clinics.
 - b. Estimate (as closely as possible) the number of doses that might be administered per shift, based on assumed vaccine availability and relative allocation and any unique jurisdictional limitations.
 - c. Determine staffing requirements for each clinic.
 - d. Identify sources of staffing and develop memoranda of agreement.
 - a. Develop training plan related to vaccine administration requirements (verification of target group membership; minimum data set; VIS sheets; paperwork for opting into ImmTrac for non-emergency vaccinations; returning for second dose).
 - b. Coordinate with law enforcement to develop security plan.
 - c. Conduct mass vaccination clinic exercises according to SNS requirements
4. The second dose of vaccine is due a minimum of 4 weeks after the first. **A portion of each delivery must be earmarked for the second dose.** It is important to keep this in mind as you plan which target groups will be contacted for vaccination. ImmTrac is an option for determining how many second doses will be required during any given week.
5. Determine how to obtain syringes and ancillary supplies.
 - a. Currently, the Federal Government has planned to purchase syringes and needles for up to 20M 2-dose courses of vaccine which will cover the first deliveries of pre-pandemic vaccine.
 - b. The Federal Government is in discussion with suppliers regarding the purpose of additional supplies.

Special Needs Populations

Identify special needs populations within the jurisdiction and develop plans to reach these populations to provide vaccine consistent with each person's target group membership.

Vaccination of Tribal Populations

Identify and collaborate with American Indian tribes within the jurisdiction to ensure that:

1. Include tribes in local vaccine planning activities.
2. Ensure tribes within the jurisdiction are included in LHD allocation decisions for obtaining vaccine according to target group membership.
3. Have access to vaccination sites within tribal communities.

Quarantine Stations (To be developed)

1. Coordinate with quarantine station staff to . . .

Communications

1. Develop a communications plan that prepares local communications materials in appropriate languages.
2. Plan assessments of when to activate provider and public communication.
3. Plan for coordinated release of information across federal, state, regional and local lines.
4. Develop a plan to ensure dissemination of vaccination-related information via different means and languages to reach all segments of the population.
5. Ensure messages are delivered to those less likely to seek vaccination.
6. Plan for continuity of operations during a pandemic.

Vaccine Tracking

1. Determine how data about vaccinated persons will be collected (i.e., collected using paper forms and then transmitted to ImmTrac or real-time data entry, etc.) and transmitted from administration sites to local and state health departments.
2. Determine personnel needed for vaccine tracking.
3. Develop a local training plan. ImmTrac training is available on the internet. Instructions for access and use will be developed by ImmTrac and included as an appendix.
4. Determine local equipment needs, including hardware and software needed for data entry and aggregation.

Vaccine Safety Monitoring—Vaccine Adverse Events Reporting

1. Review Immunization Program manuals for vaccine safety instructions.
2. Review product insert for possible side effects and adverse reactions.
3. Report adverse reactions per Immunization Program requirements. Notify the DSHS Vaccine Safety Coordinator of the reaction.

System-related Issues

1. Ensure that plans for distribution of vaccines are reviewed by appropriate legal authorities.
2. Review local compensation laws covering workers being given vaccinations.
3. Review local requirements related to EUA use of experimental drugs
 - a. Vaccine will most likely be distributed under CDC-developed EUA operational plan¹
 - b. The Secretary of HHS declares an emergency, the FDA will authorize use.
 - c. EUA does not require Institutional Review Board approval or informed consent.

Administering vaccine under Emergency Use Authorization (EUA) protocol

1. Review CDC-developed EUA operational plan when available
2. Review the DSHS IND/EUA policy in the Texas SNSPM.

Polysaccharide and conjugate pneumococcal vaccines

1. Increase vaccination in populations for whom it is routinely recommended.

Healthcare Facility Responsibilities

Planning

1. Develop written plans that address: disease surveillance, hospital communications, education and training, triage and clinical evaluation, facility access, occupational health, use and administration of vaccines and antiviral drugs, surge capacity, supply chain and access to critical inventory needs, and mortuary issues.

Vaccine distribution and allocation (if serving as a point of distribution for public caches)

1. Ensure the availability of sufficient refrigerator or freezer storage to maintain the cold chain.

¹ In development: See CDC (December 11, 2006), Pandemic influenza vaccination: A guide for state, local, territorial, and tribal planners, p. 17.

2. Develop internal chain of custody procedures according to the guidance in the [Texas SNS Program Manual](#).
3. Develop a vaccine security plan.

Vaccination of target groups

1. Develop memoranda of agreement with local health departments from whom vaccination for target populations will be delegated, where applicable.
2. Develop protocols for verification of target group membership. Notify LHD of number in priority groups and supply names if required by CDC.

Logistical issues associated with vaccination planning

1. Estimate number of doses to be administered per shift, based on assumed vaccine availability and target population size.
2. Determine staffing requirements for each clinic.
3. Identify sources of staffing.
4. Develop training plan.
5. Develop security plan.
6. Develop security plan for potential riots or other incidents.
7. Develop plan for instruction about second dose (if needed).
8. Develop infection control plan.
9. Conduct vaccination clinic exercises.

Special needs populations

1. Ensure that information is available in locally spoken languages.
2. Ensure communication with cultural communities is maintained.
3. Ensure that persons who are physically challenged have no barriers limiting access to vaccine when available to their appropriate target groups.

Vaccine tracking

1. Determine how data about vaccinated persons will be collected (i.e., collected using paper forms and then transmitted to ImmTrac or real-time data entry, etc.) and transmitted from administration sites to local and state health departments.
2. Determine personnel needed for data entry into ImmTrac.
3. Determine equipment needs, including hardware and software needs for data entry into ImmTrac.
4. Obtain appropriate Vaccine Information Sheets (VIS) with the Texas Addendum from the LHD or HSR.

Vaccine safety monitoring

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

Administering vaccine under Emergency Use Authorization (EUA)

1. Review CDC-developed EUA operational plan when available.
2. Review DSHS IND/EUA policy in the Texas SNS PM.
3. Ensure healthcare facility plans conform to both CDC and DSHS EUA guidelines.

Use of polysaccharide and conjugate pneumococcal vaccines

1. Increase vaccination administration to populations for whom it is routinely recommended

**PANDEMIC PERIOD: WHO Phase 6; Federal Response Stages 3–6
Federal Government Response Stage 3**

Widespread human outbreaks in multiple locations overseas

Recommendations for vaccine use may be updated throughout the course of an influenza pandemic to reflect epidemiology, laboratory data, and the amount and type of vaccine available.

Department of State Health Services, Local and Regional Responsibilities

1. Review the state vaccine distribution plan with local partners and stakeholders.
 - a. Modify the distribution plan to reflect updated recommendations on target groups and updated information on projected vaccine supply.
 - b. Notify medical community about the plan's status and vaccine availability.
2. Work with CDC to provide local physicians and hospital administrators with updated information and guidance as the situation unfolds.
3. Activate ImmTrac for first dose of pre-pandemic vaccine if not activated earlier for pre-pandemic release of vaccine.

Healthcare Facility Responsibilities

1. Heighten institutional surveillance for influenza
2. Prepare to activate institutional pandemic influenza vaccination plans, as necessary.

Federal Government Response Stages 4 and 5

If an influenza epidemic begins in or enters the United States

Department of State Health Services and Health Service Region Responsibilities

Mobilize health-care partners, and activate state-based plans for distributing and administering vaccines per SNS Manual.

1. Keep the healthcare and public health workforce up-to-date on projected timelines for availability of vaccine.
2. Make recommendations—based on the epidemiology, severity, and availability of vaccine—for change (if needed) on vaccinating target groups.

3. Accelerate training in vaccination and vaccine monitoring for public health staff and for partners responsible for vaccinating target groups.
4. If stockpiled pre-pandemic vaccine is available and has not been distributed and administered pre-pandemically, work with healthcare partners and other stakeholders to distribute, deliver, and administer vaccines to designated target groups.
5. Provide for LHDs to give to those vaccinated at the time of vaccination information about obtaining the second dose of vaccine.
 - a. If pre-pandemic vaccine is given early in the pandemic, and vaccine manufacturing technology allows for quick production of pandemic vaccine, the second dose may be pandemic vaccine.
 - b. If pre-pandemic vaccine is given before the pandemic and/or vaccine technology will not produce vaccine for four to five months after pandemic begins, plan second doses of pre-pandemic vaccine.
6. If first dose was distributed and given pre-pandemically to target group members, begin second dose reminders through ImmTrac.
7. Work with other governmental agencies and non-governmental organizations to ensure effective public health communications.
8. Implement the ImmTrac immunization registry for second doses as appropriate.

After a pandemic vaccine becomes available

1. Work with health-care partners and other stakeholders to distribute, deliver, and administer pandemic vaccines to target groups per SNS Manual.
2. Monitor vaccine supplies, distribution, and use during the event through the Texas Inventory Management System (TIMS)¹ which is available to all HSRs and LHDs with vaccination programs per SNS Manual.
3. Monitor and report adverse events through [VAERS](#).
4. Provide updated information to the public via the news media.

Local Health Responsibilities

1. Activate plans to:
 - a. Provide health-care facilities with information about the state and local situation through the PHIN and existing communication strategies including Trauma Service Areas, Regional Advisory Councils, Texas Medical Association, Texas Osteopathic Medical Association, Texas Hospital Association, and Texas Nurses Association, etc.
 - b. Vaccinate persons in target groups, in accordance with existing recommendations.
 - c. Provide a second dose, as required by CDC.
 - d. Monitor vaccine supplies, distribution, and use using TIMS and ImmTrac.
 - e. Monitor, investigate, and report adverse events.
 - f. Continue coordinated communication with partners and the public.
 - g. Phase in vaccination of the rest of the population, according to general population target group priority placement after critical health, service, and emergency target groups have been vaccinated.
 - h. Instruct vaccinees on how to report vaccine adverse reactions through [VAERS](#).

¹ TIMS will most likely remain the inventory system used as long as the pandemic continues.

Healthcare Facility Responsibilities

1. Activate institutional pandemic influenza plans, in accordance with the “Hospital Pandemic Influenza Triggers” Available at <http://www.hhs.gov/pandemicflu/plan/sup3.html#table>.
 - a. Provide a second dose of vaccine, if required, for immunity.
 - b. Ensure vaccine safety and security during vaccination efforts.
 - c. Monitor vaccine supplies, distribution, and use.
 - d. Monitor and investigate adverse events. Report adverse events to local health department and through VAERS.
 - e. Continue coordinated communication with partners and the public.
 - f. Phase in vaccination of the rest of the population after target groups have been vaccinated and vaccine has been released to the private sector.

Federal Government Response Stages 6

Recovery and preparation for subsequent waves

While a pandemic may affect the United States for several months to more than a year, any community can expect to be affected by a particular pandemic wave for at least 6 to 8 weeks. Because several waves of illness have occurred in previous pandemics, communities will need to revitalize as soon as possible to lessen the impact of the continuing outbreak.

Department of State Health Services Response

1. Evaluate usefulness of the VADS guidelines in reaching Target Groups and distributing vaccine to stakeholders for administration to target groups. Adjust as needed.
2. Evaluate Texas SNS Plan successes and lessons learned. Adjust as needed.
3. Inventory remaining supplies and restock if possible.
4. Evaluate disease epidemiology to determine age groups with the highest morbidity and mortality. Adjust vaccine Target Groups to reflect current information.
5. Continue first and second doses of vaccine as they become available.
6. Provide community updates about vaccine status and any changes in distribution.
7. Continue to monitor data entry into ImmTrac, evaluate ImmTrac’s usefulness and identify problems. Work with the ImmTrac branch to adjust as needed.
8. Provide CDC with requested aggregate data of vaccine distribution.

Local and Regional Health Department Responsibilities

1. Evaluate usefulness of local VADS guidelines and adjust preparations for next wave related to:
 - Reaching Target Groups
 - Determining administration sites
 - Administration sites vaccinating Target Groups.
2. Inventory supplies and restock if possible.
3. Complete entering data to ImmTrac.
4. Evaluate use of ImmTrac and recommend improvement to DSHS.

Healthcare Facility Responsibilities

1. Evaluate usefulness of institutional pandemic influenza plans and “Hospital Pandemic Influenza Triggers” and make adjustments as necessary.
2. Inventory supplies and restock if possible.
3. Continue vaccinating Tier 1 personnel if the facility was identified as a vaccination station.
4. Communicate with LHD regarding status.

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5.

APPENDICES

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Appendix A

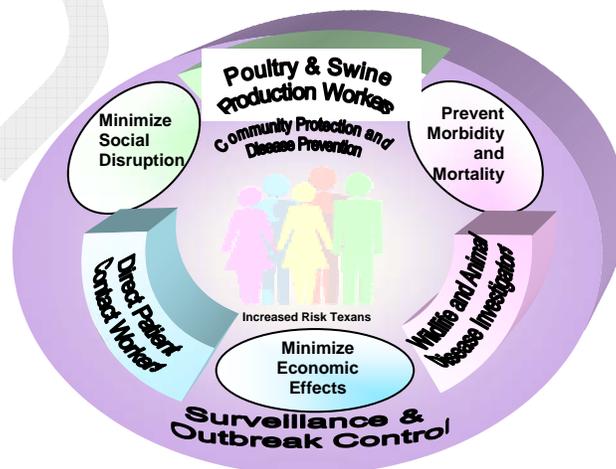
The Texas Vaccine Allocation Models

The Texas Pre-Pandemic Avian Vaccine Allocation Model and the Texas Pandemic Vaccine Allocation Models reflect the conceptual underpinnings for the Texas Department of State Health Services' (DSHS) **Vaccine Allocation, Distribution, and Storage Planning Guidelines** (VADS). Decisions are based on the latest science with input from participants in an Expert Panel convened by DSHS. Participants included academicians, attorneys, community advocates, epidemiologists, ethicists, faith community representatives, hospital representatives, influenza experts, pharmacists, nurses, practicing physicians, and local and regional health departments.

Both vaccine allocation models are similar to the Antiviral Allocation Model, but reflect the variable of time on the choice of target populations for vaccine distribution to minimize risk and potential transmission. The Texas Pre-Pandemic Avian Vaccine Allocation model reflects priorities for early release of vaccine developed from avian strains that is currently being stockpiled by the Federal Government. The pre-pandemic vaccine is not specific for the pandemic-strain virus since this virus most likely does not exist at this time. It is assumed that the avian strain vaccine would be most beneficial in protecting those who are at risk for contracting avian influenza who, if infected, could potentially further the evolution of the pandemic-causing human virus. It is also assumed that once the pandemic vaccine has emerged, those at risk for contracting avian influenza are at no higher risk than critical infrastructure providers are at risk for contracting pandemic influenza. The Texas Pandemic Influenza Vaccine Model can be applied to both continued distribution of pre-pandemic avian vaccine prior to or during the pandemic and distribution of the human pandemic vaccine developed from the specific influenza strain causing the pandemic.

Currently two doses of vaccine will be required if the first dose is avian vaccine. This first dose will be considered a primer dose. It is assumed that anyone receiving the primer dose will receive a reminder recall notice to return for a second dose of either the pre-pandemic vaccine if pandemic vaccine is not available or a second dose of pandemic vaccine when the pandemic strain vaccine is developed and available.

Figure 1. Texas Pre-Pandemic Avian Vaccine Allocation Model



Prevent morbidity and mortality

Surveillance. The Pre-Pandemic Avian Vaccine Allocation Model relies on careful observation and analysis of wild birds, especially waterfowl on known migratory routes. Vigilance in monitoring atypical morbidity and mortality patterns in domestic chicken and turkey flocks, as well as routine testing, will promote early identification and intervention to limit outbreaks. In an effort to prevent or delay widespread infection in domestic fowl, outbreak control in production facilities is of highest priority. Disease must be identified rapidly and flocks managed appropriately which includes workers using personal protective equipment and being vaccinated with pre-pandemic avian vaccine.

Poultry and swine production workers and animal disease investigators. To minimize the potential for avian influenza virus mutation that will make it easily transmissible between humans through exchanging DNA with seasonal influenza viruses, persons at high risk for exposure to avian influenza must be encouraged to receive seasonal flu vaccine. If the avian influenza vaccine is released by CDC prior to the emergence of the pandemic-causing human strain, persons most at risk for exposure to this novel virus should be vaccinated. Poultry and swine production workers are at highest risk for exposure to avian influenza by the nature of their jobs. To prevent disease or maximize the potential for timely outbreak management, those who investigate wild fowl and domestic flock diseases, and commercial and backyard swine diseases should also receive avian vaccine.

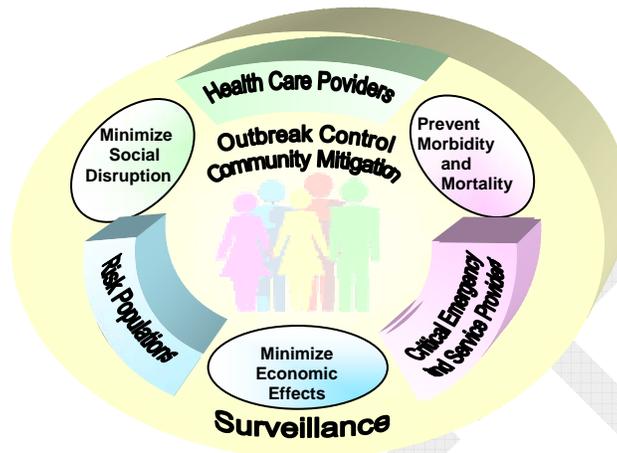
Health care workers. In the few sporadic instances where there has been secondary human-to-human transmission of avian flu, it has occurred in household contacts that provided patient care prior to hospitalization or death. Therefore, healthcare workers pre-identified to provide direct patient care to persons diagnosed with avian influenza and pre-identified public health outbreak investigators who may be in direct contact with ill patients should be vaccinated before they have contact with an infected patient. In addition, these workers should also receive post exposure antiviral therapy to prevent disease since efficacy of the vaccine in vivo after exposure to the avian virus is still unknown. To minimize the potential for avian influenza virus to shift to become easily transmissible between humans through exchanging DNA with seasonal influenza viruses, persons at high risk for exposure to avian influenza must be encouraged to receive seasonal flu vaccine.

Minimize economic effects

Targeting the aforementioned groups would limit morbidity and mortality while limiting hospitalizations to minimize the costs of care. Extremely important is protecting poultry flocks from infection thus minimizing poultry industry losses as much as possible. Early identification in wild birds may prevent introduction into poultry production facilities and backyard flocks. Introduction into poultry economically impacts the producer, the industry, and the communities dependent on the industry.

Minimize social disruption

Social panic will increase with each occurrence in poultry. Panic may lead to food shortages, self-isolation, missed work days, etc. before there is pandemic influenza in humans. Demonstrating the ability to prevent primary infection in poultry and wildlife workers as well as secondary infections of caregivers with avian influenza may minimize social disruption.

Figure 2. The Texas Pandemic Vaccine Allocation Model

Outbreak Control and Community Mitigation. In an effort to prevent or delay widespread infection, outbreak control is of highest priority. Research indicates that the use of a strain-specific vaccine is the best prevention for an influenza pandemic. However, specific vaccine will not be available for 4 to 5 months depending on advances in the science and numbers of production facilities. Until a vaccine specific for the circulating strain is available, avian vaccine either released at the beginning of the pandemic or remaining from the early release program described previously should be used as outbreak control for close household contacts and in target populations as a primer dose. Since the avian vaccine has not been tested in vivo with exposure to the actual pandemic virus, its efficacy against the pandemic-specific virus cannot be known. Research has demonstrated some cross over immunity in vitro to newer strains. However, a post-exposure course of antivirals should still be used for those receiving avian vaccine for an outbreak. Other contacts should receive post-exposure prophylaxis with antivirals.

Since vaccine will be in limited supply and distributed according to target populations as it becomes available, community mitigation strategies must continue to be used along with targeted antiviral prophylaxis. Mathematical modeling indicates the use of antivirals in targeted prophylaxis to family and social (school or work) contacts for 60% of diagnosed cases will have the greatest impact on reducing attack rates surpassed only by adding school closures and social distancing to the mix (Germann, Kadau, Longini, & Macken, 2006). Antivirals must be started within 48 hours of initial symptoms. Patients sick enough for hospitalization may be beyond the window of opportunity.

Health Care Providers. The federal Health and Human Services (HHS) Pandemic Influenza Implementation Plan assumptions include a 30% attack rate during a pandemic. Of these, HHS assumes that half will be cared for in hospitals. Under normal circumstances, health care staffing in hospitals is insufficient and nurses and other direct care staff are required to work overtime. Hospitals in Texas report that seasonal influenza hospitalizations challenge facilities and staffing. Texas cannot afford to lose 30% of staff. Given the high likelihood of pandemic influenza introduction into Texas and challenges of providing care to those living in rural underserved areas that comprise 224 of Texas' 254 counties (Nelson, Banning, Kroll, & Bailey, 2006), it is imperative that the health care providers are high priority for treatment and post-prophylaxis.

Fifteen percent of persons who are ill and not hospitalized will be seen in community settings, cared for by home caregivers, and possibly visited by home health nurses. This will be the backbone of care since only the very sickest will receive hospital care.

Minimize social disruption

Maslow's hierarchy of human needs lists physical survival needs (food, water, warmth, health) and need for safety and security (physical safety, economic security) as the foundation upon which human development builds. These are needs that are rarely thought about if met, yet cause the most anxiety if not met and are the greatest motivators for action to alleviate the need. Supporting community structures that maintain physical and social environments is imperative. It will be difficult to care for the sick without maintenance of infrastructure.

Critical emergency responders. Critical emergency responders will have more demands on their time. In addition to regular duties for protection of the public in emergency situations, there will be the added duties related to responsibilities in emergency management and more demands for services in the community from locating patients and transport to increased crime as shops and homes are left empty. If anarchy occurs, it will not be possible to limit morbidity and mortality in the general population.

Essential infrastructure service providers. If essential services such as power, natural gas, food, transportation, communication, and safe drinking water are not available, other illnesses will occur and treatment of those with influenza will be compromised. In rural Texas communities there is little, if any, excess staff to manage these services. Despite cross training, the loss of one worker could compromise systems.

Minimize economic effects

Minimizing negative economic effects is a result of appropriate decision making regarding health and emergency management. Targeting the aforementioned groups and interventions would limit morbidity and mortality while limiting hospitalizations thereby minimizing the costs related to health care and the economy in general.

Appendix B Pandemic Vaccine Target Group Guidance

Table 3. Beginning of Pandemic

TIERS & CATEGORIES		TARGET GROUP*	RATIONALE	
OUTBREAK CONTROL*		<ul style="list-style-type: none"> • Continue outbreak response with antivirals—treatment of ill; post exposure prophylaxis with antivirals of contacts. • Vaccinate outbreak responders with avian strain vaccine and supplement with antivirals. • Once Pandemic Human Vaccine is available, recall outbreak responders previously vaccinated with avian strain vaccine for second immunization according to target group membership. 	<ul style="list-style-type: none"> • Early control efforts are critical to slowing the spread of influenza and buying time to institute mitigation strategies. • About 2 weeks are required for vaccines to produce an adequate antibody response, therefore post-exposure treatment with antivirals should continue for at least 2 weeks post vaccination. • Avian Vaccine is not specific for the flu strain that will cause a pandemic since that strain does not exist yet. It will provide some cross-protection and therefore can serve as a primer dose. 	
INFRASTRUCTURE	1A (Fed Tier 1)	HEALTH	<ul style="list-style-type: none"> • Workers with direct patient contact, care responsibilities, or response responsibilities: <ul style="list-style-type: none"> ○ Healthcare workers inpatient and outpatient ○ Emergency medical service providers (EMS) ○ Public health personnel ○ Long term care facilities ○ Home health 	<ul style="list-style-type: none"> • Healthcare workers are required for quality medical care. There is little surge capacity among healthcare sector personnel to meet increased demand. • If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.
	1B (Fed. Tier 2)	EMERGENCY	<ul style="list-style-type: none"> • Critical community emergency responders such as <ul style="list-style-type: none"> ○ Law enforcement, firefighters, Texas Military Forces (National Guard), Other essential support and sustainment personnel ○ Mortuary services workers. ○ Zoonosis control, parks and wildlife, Texas Animal Health Commission who may have direct contact with infected wildlife. ○ Key government officials and essential personnel responsible for the continuity of emergency operations for the State of Texas. ○ Communications services (9-1-1; 3-1-1; 2-1-1 operators) ○ Emergency public community / public broadcasters 	<ul style="list-style-type: none"> • Public safety personnel are critical to maintaining public safety and health. Security of vaccine and antivirals along with crowd control must be maintained. • Licensed funeral directors, morticians, and their staffs are critical to dispose of remains and prevent disease. • Public Health workers are necessary for disease investigation and outbreak control to limit morbidity and mortality. • Animal workers have the greatest chance for exposure pre-pandemic and would be most likely to be dually infected with seasonal flu and the potential for shift. • Government officials are needed for decision making related to population, community, and state well-being/
	1C (Fed. Tier 3)	SERVICE	<ul style="list-style-type: none"> • Essential infrastructure service workers such as <ul style="list-style-type: none"> ○ Public utility workers responsible for maintenance of critical functions, such as clean water, energy, and sewage system functioning. ○ Transportation workers transporting water, fuel, and food. ○ Telecommunications / IT for essential network operations and maintenance. 	<ul style="list-style-type: none"> • These groups are critical to maintaining community services necessary for function and safety. • If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.

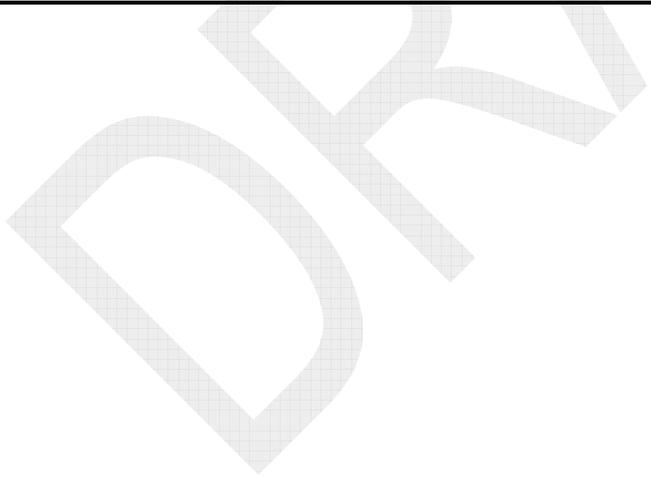
TIERS* & CATEGORIES		TARGET GROUP*	RATIONALE	
GENERAL POPULAION	2A (FT 1)	HIGHER RISK	<ul style="list-style-type: none"> Persons at higher risk for morbidity and mortality: <ul style="list-style-type: none"> Pregnant women and their household contacts Children 6-36 months 	<ul style="list-style-type: none"> In past pandemics and for annual influenza, pregnant women have been at high risk; vaccine are not approved for infants <6 months; antivirals are not approved for children <12 months;
	2B (FT 2)		<ul style="list-style-type: none"> Household contacts of infants less than six months old Household contacts of immunosuppressed. Children 3-18 with high risk 	<ul style="list-style-type: none"> 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.
	2C (FT 3)		<ul style="list-style-type: none"> Children 3-18 years 	<ul style="list-style-type: none"> Immunization of these subpopulations has been shown to reduce flu morbidity and mortality in the population at large. School children are frequent contacts to each other and many other groups.
	2C (FT 4)	LOWER RISK	<ul style="list-style-type: none"> 19-64 with lung or heart disease or other chronic illness and their contacts. Persons 65 or > Persons hospitalized in prior year with pneumonia or influenza or other high risk condition. 	<ul style="list-style-type: none"> 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.
	3 (FT 3)		<ul style="list-style-type: none"> Remaining service providers: <ul style="list-style-type: none"> Government officials and public health workers not involved in direct care or pandemic response. Other utility workers. Other transportation workers. Other telecommunications / IT for essential network operations and maintenance. 	<ul style="list-style-type: none"> If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group. 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. Other important societal groups for a pandemic response but of lower priority.
	4 (FT 5)		<ul style="list-style-type: none"> Other healthy adults 19-64 years 	<ul style="list-style-type: none"> All persons not included in other groups based on objective to vaccinate all those who want protection.

* Epidemiology and community needs and characteristics will ultimately shape decisions.

**See Table 5 for alternate highest priority

Table 4. Alternate Highest Priority for Early Distribution of Pre-Pandemic Vaccine*

INFRASTRUCTURE	1A	MOST AT RISK FOR EXPOSURE*	<p>Poultry production workers such as Texas Animal Health Commission Farm animal veterinarians Parks and Wildlife</p>	<p>If vaccine is released prior to the existence of the pandemic virus, the most at risk for exposure to avian flu are those who work with poultry. If poultry handlers have seasonal influenza, the viruses may mix and form the pandemic virus.</p>
	1A	HEALTH*	<p>Those with direct patient contact with or care responsibilities for poultry workers infected with avian influenza, such as: Healthcare, Emergency Medical Service (EMS) professionals pre-identified to care for infected poultry or other animal workers. Public Health workers pre-identified for on-site outbreak management. Healthcare and Emergency Medical Service (EMS) professionals in areas with identified avian influenza in poultry.</p>	<p>Those healthcare workers caring for people with avian influenza are at higher risk for acquiring it. The only documented case of human to human transmission has occurred in household contacts who were caregivers of ill patients. If the epidemiology follows other pandemics, the case fatality rate will be disproportionately higher for persons in the working age group.</p>



Appendix C

Sub-prioritization of vaccination among tiered target groups

If vaccine supplies are severely limited, prioritization may need to occur within and among tier groups. Maintaining the effectiveness of those persons in occupations critical to maintaining the health system to care for the ill and those who maintain the infrastructure that keeps supplies of electricity, gas, water and other services as well as food on the shelves is crucial for the survival of the community. In addition, in some target groups, disease burdens are likely to be markedly increased and risk of occupational exposure and infection may be high.

Targeting vaccine to critical infrastructure providers that serve important societal needs is balanced by including in this sub-tier pregnant women and infants (6–11 months old) who are at high risk of dying during a pandemic. No influenza antiviral agents are currently approved for use in infants younger than 12 months of age (American Academy of Pediatrics, 2007). Limited information is available on the safety of antiviral drugs in women who are pregnant (FDA pregnancy Category C). In addition, household contacts of those who are immunocompromised and do not respond well to vaccination are included. Protecting them will help in protecting the immunocompromised.

Table 5. Proposed sub-prioritization of vaccination if vaccine is in short supply

Priority	Group	Rationale
1 (1A)	Front-line inpatient and hospital-based health care workers (essential for maintaining function in emergency departments, intensive care units, and other front-line medical and nursing staff).	Critical role in providing care for the sickest persons; highest risk of exposure and infection.
2 (1A)	Front-line Emergency Medical Service (EMS) personnel (those providing patient assessment, triage, and transport), and communications dispatch and public referral and information services (i.e., 9-1-1; 3-1-1; 2-1-1 operators)	Provide critical medical care including procedures such as intubation that increase the risk of aerosol exposure and occupational infection.
3 (1A)	Front-line outpatient health care providers (physicians, nurses respiratory therapy; includes public health personnel who provide outpatient care for underserved groups).	Effective outpatient care is critical to decrease the burden on hospitals; high risk of exposure and occupational infection.
4 (1B)	Front-line fire and law enforcement personnel; Texas Military Forces	Essential to public order and safety; less substantial/more predictable exposure risk
5 (2A)	Pregnant women and infants 6–11 months old (if vaccine approved for this age group).	High-risk documented in prior pandemics and annually; reflects public values to protect children; vaccination of pregnant women will also protect the infant; infants 6–11 months old are at high-risk and antiviral drugs are not FDA approved for children <1 year old.
6 (1C)	Others in Tier 1 (includes health care workers not vaccinated previously, home health, long term care facilities, and public health; emergency service providers; manufacturers of vaccine and antiviral drugs and other key pandemic response materials).	Includes persons in critical settings who have less exposure.
7 (2A)	Children 12–35 months old.	Includes toddlers with less risk of severe disease or death than younger infants, yet are able to receive antiviral treatment based on FDA approval of antiviral drugs.

Appendix D

Sources of Target Group Data *

Licensed Professional Providers**

Table 6. Licensed Professional Providers

Profession	Number	Possibly Non-duplicated	Source	Priority	Priority Possibly Non-duplicated
Physicians—MD	39,388	39,388	TMB	1	39,388
Physicians—DO	2,634	2,634	TMB	1	2,634
Medical Students MD/DO	5,326	5,326	TMA	1	5,326
Residents MD/DO***	6,548		TMA	1	
Physician Assistants***	2,937		TMB	1	
Advanced Practice Nurses***	10,404		BNE	1	
Registered Nurses***	172,627		BNE	1	
Licensed Practical Nurses***	74,847		BNE	1	
Nursing Assistants***	113,540		DADS	1	
Medication Aids***	9,105		DADS	1	
Medical Radiological Technologists***	20,972		DSHS-PLCU		
Dentists	8,213	8,213	TSDBE	1	8,213
Dental Hygienists	8,548	8,548	TSDBE	1	8,548
Respiratory Care Practitioners***	11,768		DSHS-PLCU	1	
Emergency Medical Services Personnel	50,291	50,291	BEM	1	50,291
Occupational Therapists & Assistants***	7,225		ECPTOTE		
Physical Therapists & Assistants***	12,328		ECPTOTE		
Pharmacists***	16,944		TSBP	1	
Optometrists	2,577	2,577	TOB		
Podiatrist	814	814	TSBPME		
Chiropractor	4,091	4,091	TBCE		
Acupuncturists	657	657	TSBAE		
TOTAL	581,784	122,539		524,015	114,400

* Replace if/when better data is available from State Demographer

** May or may not be practicing

*** Probably counted as employees under Healthcare in "Texas Employment Totals" (see Table 5, Appendix D) in part or totally.

Table 7. Texas Employment Totals and Links to Sector Definitions

Infrastructure Service	Private Sector*	Public Sector**	Select Services (most critical)
Utilities			
Electric power generation, transmission, & distribution	38,583	8,050	
Natural gas distribution	8,705	1,379	
Water, sewage, & other systems including solid waste	4,684	29,665	
TOTAL		91,066	
Transportation			
Water transportation	4,730	955	
General freight trucking	67,756		
Hazardous materials trucking (except waste), local	2,410		
Hazardous materials trucking (except waste), long-distance	2,415		
Agricultural products trucking without storage, local	1,657		
Agricultural products trucking, long-distance	1,950		
Urban transit systems	4,022	10,762	
Interurban & rural bus transportation	2,581		
School & employee bus transportation	3,400		
Pipeline transportation	10,777		
Scheduled air transportation	982	4,968	
Nonscheduled chartered freight air transportation	503		
TOTAL		119,868	
Support activities for transportation			
Support activities for air transportation	14,544		
Support activities for water transportation	7,736		
Freight transportation arrangement	21,057		
Other support activities for transportation	6,379		
TOTAL		49,716	
Warehousing and storage			
Refrigerated warehousing & storage	2,343		
Farm product warehousing & storage	1,525		
TOTAL		3,868	
Healthcare Professionals not "employed" ***	114,400		
Healthcare		34,349	
Hospitals		78,434	
General medical & surgical hospitals	297,112		
Psychiatric & substance abuse hospitals	11,122		
Specialty (except psychiatric & substance abuse) hospitals	27,318		
Nursing and residential care facilities			
Nursing care facilities	85,104		
Residential mental retardation/health & substance abuse facility	19,659		
Community care facilities for the elderly	23,252		

Other residential care facilities	6,374		
Ambulatory care facilities			
Offices of physicians	136,255		
Offices of mental health practitioners (except physicians)	3,691		
Outpatient care centers	31,093		
Home health	124,962		
Medical & diagnostic laboratories	15,467		
Ambulance services	7,409		
TOTAL		1,016,001	
Selected social services			
Services for the elderly & persons with disabilities	25,364		
Community food & housing/emergency & other relief services	7,100		
TOTAL		32,464	
Government leaders			
Judicial and legal		24,269	
Financial administration		23,745	
Other government administration		16,077	
TOTAL		64,091	32,050
Death care services			
Death care services	10,954		
TOTAL		10,954	10,954
Manufacturing			
Food mfg	85,157		
Petroleum refineries	16,926		
Pharmaceutical & medicine mfg	5,029		
TOTAL		107,112	
Retail stores			
Grocery stores	169,025		
Pharmacies & drug stores	44,983		
TOTAL		214,008	
Public Safety			
Police Officers		45,765	45,765
Police Others		15,769	7,896
Firefighters		22,204	22,204
Fire Other		1,720	860
Corrections		68,371	
TOTAL		153,829	
Emergency response workers—other			
TXDOT		14,400	10,000
Texas Army National Guard—7.7% x 333,177		25,655	25,655
TOTAL		40,055	
TOTAL		1,903,032	

* 2002 Economic Census, Texas. U.S. Census Bureau

** 2005 Public Employment Data, State and Local Governments, Texas. U.S. Census Bureau

*** See "Licensed Professional Providers" A24(some numbers that may overlap deleted since accounted for by employer, e.g., RNs are employed by hospitals, etc; physicians tend to be independent)

Appendix E

Additional Packaging Information

Table 8. Size of Polystyrene Containers

Single Unit (5-ml vials) - Packed into Polystyrene Containers			
BOX	5-ml Vials	Dimensions (In)	Weight (lbs)
Box 1	1 – 12	12.2 x 9.7 x 10.2	6
Box 2	13 – 48	15.3 x 12.3 x 11.7	12
Box 3	49 – 132	20.3 x 15.3 x 13.6	23
Box 4	133 – 199	21.2 x 20.7 x 14.0	40

Table 9. Size of Master Cartons Packed into Polyurethane Containers

Master Cartons - Packed into Polyurethane Containers			
BOX	Master Cartons (1=100 x 5ml Vials)	Dimensions (In)	Weight (lbs)
E186	2 – 4	23.2 x 19.2 x 19.2	51 – 62
E568	4 – 13	27.0 x 25.7 x 28.2	117 – 166
EF1500	13 – 24	39.5 x 31.8 x 45.7	253 – 314
EF2700	24 – 36	47.0 x 40.2 x 50.0	394 – 460

Table 10. Contents of One Truckload

Full (Refrigerated) Truckload			
	Contents	Dimension (In)	Weight (lbs)
1 Master Carton	= 100 x 5ml vials	12.0 x 6.5 x 6.0	5.5
1 Pallet	= 147 Master Cartons = 14,700 x 5ml vials	48.0 x 40.0 x 45.5	850 – 900
1 Refrigerated Truck	= 24 Pallets = 3,528 Master Cartons = 352,800 x 5ml vials	---	---

Appendix F

Determination of Refrigerated Vaccine Storage Space Worksheet [{HYPERLINK}](#)

1	Subject	Programmed Distribution & Storage of Vaccine	Populations of service areas*			
2			City/County	882,457	County	
3	State	Texas	County		County	*If the county has a city LHD in it, deduct city population
4	LHD or	Anycity LHD	County		County	
5	HSR		County		County	

See Instruction Tab 3.0 Instruction to complete this section. Data will appear at the top of each subsequent page.

Vaccine Storgae Requirements
Excel 2008 Version 1.3

This appendix consists of an Excel workbook embedded in this Word document. To use this workbook, double click on the table above and navigate among the worksheets and cells as you would in Excel. Enter the requested information and the workbook will automatically calculate the required results. When you have finished, click outside the worksheet to return to this Word document.

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