






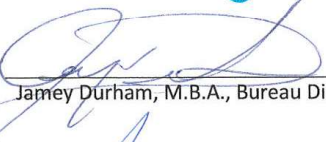

ADPH Pandemic Influenza Operational Plan

May 2018



2018 ADPH Pandemic Influenza Operational Plan

Routing Sheet

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This plan has been reviewed Cindy Lesinger, Kelly Stevens, and Dr. Burnestine Taylor. Their changes have been incorporated into this draft.

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Background

This emergency preparedness planning document addresses how the Alabama Department of Public Health (ADPH) responds to pandemic influenza through its Emergency Operations Plan (EOP). This document will be periodically reviewed and updated to ensure that information contained within the document is consistent with current knowledge and changing infrastructure.

Before, during, and after a pandemic influenza outbreak, ADPH has a responsibility to ensure the continuation and delivery of essential public health services while providing for the emergency needs of the population. The appendices of this document contain specific guidance and handouts for pandemic preparedness.

Pandemic Influenza Phases

The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have defined phases of pandemic influenza in order to assist with planning and response activities in states. Identification and declaration of the stages outlined in Table 1 will be done at the national level. Refer to Appendices A and B for a listing of activities that will be conducted during each phase of pandemic influenza at the state level.

Table 1. Pandemic Influenza Phases

TABLE 1. Preparedness and response framework for novel influenza A virus pandemics: World Health Organization phases and CDC intervals, with federal and state/local indicators			
WHO phases	CDC intervals	Federal indicators for CDC intervals	State/Local indicators for CDC intervals
<p>Interpandemic phase: Period between influenza pandemics</p> <p>Alert phase: Influenza caused by a new subtype has been identified in humans</p>	<p>Investigation: Investigation of novel influenza A infection in humans or animals</p>	<p>Identification of novel influenza A infection in humans or animals anywhere in the world with potential implications for human health</p>	<p>Identification of novel influenza A infection in humans or animals in the United States with potential implications for human health</p>
	<p>Recognition: Recognition of increased potential for ongoing transmission of</p>	<p>Increasing number of human cases or clusters of novel influenza A infection anywhere in the world with virus</p>	<p>Increasing number of human cases or clusters of novel influenza A infection in the United States with virus</p>

	a novel influenza A virus	characteristics, indicating increased potential for ongoing human-to-human transmission	characteristics indicating increased potential for ongoing human-to-human transmission
Pandemic phase: Global spread of human influenza caused by a new subtype	Initiation: Initiation of a pandemic wave	Confirmation of human cases of a pandemic influenza virus anywhere in the world with demonstrated efficient and sustained human-to-human transmission	Confirmation of human cases of a pandemic influenza virus in the United States with demonstrated efficient and sustained human-to-human transmission
	Acceleration: Acceleration of a pandemic wave	Consistently increasing rate of pandemic influenza cases identified in the United States, indicating established transmission	Consistently increasing rate of pandemic influenza cases identified in the state, indicating established transmission
	Deceleration: Deceleration of a pandemic wave	Consistently decreasing rate of pandemic influenza cases in the United States	Consistently decreasing rate of pandemic influenza cases in the state
Transition phase: Reduction in global risk, reduction in response activities, or progression toward recovery actions	Preparation: Preparation for future pandemic waves	Low pandemic influenza activity but continued outbreaks possible in some jurisdictions	Low pandemic influenza activity but continued outbreaks possible in the state

Assumptions

Because the precise impact of a future pandemic is unpredictable, national, state, and local planners need multiple scenarios for pandemic planning to implement rapid response efforts. Pandemic planning in Alabama is based on the following assumptions about viral epidemiology and human susceptibility:

- Delays in availability of vaccines and shortages of antiviral drugs are likely, particularly early in the pandemic.
- The seasonality of a pandemic cannot be predicted with certainty. With seasonal influenza, peak disease usually occurs during December through March in the United States.

- The novel virus will have the ability to spread rapidly worldwide.
- If the pandemic is characterized by severe disease, it will have the potential to disrupt national and community infrastructures (including health care, transportation, commerce, utilities, and public safety) due to widespread illness, absenteeism, and death among workers and their families, as well as concern about ongoing exposure to the virus.
- Alabama and its neighboring jurisdictions may be affected simultaneously, thereby limiting the ability to support and assist other jurisdictions.
- ADPH will take the lead in distributing influenza vaccine. Health departments will work in partnership with health care providers to facilitate distribution. A vaccine may also be administered under an Investigational New Drug (IND) protocol.
- During a pandemic, infection in a localized area can last about six to eight weeks. At least two pandemic disease waves will be projected. If the situation does not fully develop to that level, the response can be adjusted. Following the pandemic, the newly circulating virus is likely to become a regularly occurring seasonal influenza.
- Immunity to the novel pandemic influenza subtype will vary based on the strain of the virus, but most people will likely be susceptible, depending on whether a similar strain has circulated in previous seasons.
- The clinical disease attack rate could range from 20% to 30% of the overall population. Illness rates will likely vary by age group (and other epidemiologic characteristics) and could create selective pressures on segments of the community, such as nursing homes or schools.
- The typical incubation period (the time between acquiring the infection and becoming ill) for influenza averages two days (range is one to four days).
- Of those who become ill with influenza, up to 50% will seek outpatient medical care.
- The number of hospitalizations and deaths will depend on the severity of the disease and the success of steps to mitigate its transmission. Nonetheless, estimates could differ by as much as a factor of 10 between more and less severe scenarios.
- Risk groups for severe and fatal infections cannot be predicted with certainty. During annual fall and winter influenza seasons, infants and the elderly, people with certain chronic illnesses, people with morbid obesity, and pregnant women are usually at higher risk of complications from influenza infections than other groups. In contrast, in the 1918 pandemic, deaths were notably evident among young, previously healthy adults; in 2009, elderly people were disproportionately spared severe illness and death.

- People who become infected will shed virus and transmit infection for up to one day before the onset of illness.
- Viral shedding and the risk for transmission will be greatest during the first two days of illness and may persist for five to seven days.
- Children will shed the greatest amount of virus and, therefore, are likely to pose the greatest risk for transmission.
- The most severely ill people with influenza will shed the most virus for the longest period of time.
- One or two secondary infections will occur as a result of transmission from someone who is ill. In contrast, some estimates from past pandemics have been higher, with up to three secondary infections per primary case.
- There may be critical shortages of health care resources in Alabama, such as, staffed hospital beds, mechanical ventilators, morgue capacity, and other resources.
- Advance planning for Alabama's emergency response could save lives and prevent substantial economic loss.
- Federal and State declarations of emergency will change legal and regulatory aspects of providing public health services during a pandemic.

See: <https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf>

Federal Role

An influenza pandemic will represent a national health emergency requiring coordination of response activities. As outlined in Homeland Security Presidential Directive 8, the Department of Homeland Security has primary responsibility for coordinating domestic incident management and will coordinate all non-medical support and response actions across all federal departments and agencies. Health and Human Services (HHS) will coordinate the overall public health and medical emergency response efforts across all federal departments and agencies. Authorities exist under the Public Health Service Act for the HHS Secretary to declare a public health emergency and to coordinate response functions. In addition, the President can declare an emergency activating the Federal Response Plan, in accordance with the Stafford Act, under which HHS has lead authority for Emergency Support Function #8 (ESF8).

State Role

States are individually responsible for coordination of the pandemic influenza response within and between their jurisdictions. Specific ADPH responsibilities include:

- Identify public and private sector partners needed for effective planning and response.
- Develop and enhance key components of pandemic influenza preparedness plan: surveillance, distribution of vaccine and antivirals, documentation and communications.
- Integrate pandemic influenza planning with other planning activities conducted under CDC and Health Resources and Services' Administration (HRSA) Emergency Preparedness Cooperative Agreements.
- Coordinate with public health districts to ensure development of local plans and to provide resources such as templates to assist in the planning process.
- Coordinate with the Alabama Department of Agriculture and Industry (ADAI) for zoonotic health issues related to pandemic influenza.
- Develop data management systems needed to implement components of the plan.

Local Role

Public health districts and county health departments (CHDs) are responsible for coordination of pandemic influenza response with other organizations in their region. Specific areas of preparedness responsibilities include the following:

- Identify public and private partners to assist with preparedness activities (planning, training, and exercises) as well as local or regional response to an outbreak.
- Identify local resources to deliver vaccine and antiviral medications to all residents in their local communities. This will include identification of facilities, transportation, and storage resources and vendors capable of delivering key items immediately prior to or during a response, and identification of community leaders to assist in disseminating emergency messages to specific populations.
- Identify, train, and equip staff to activate a pandemic flu response upon notification.
- Establish relationships with partner agencies to provide response assistance, e.g., security and crowd control.

Legal Considerations

During an influenza pandemic, declarations of emergency, disaster, or public health emergency at federal, state, or local levels alter the existing legal environment to allow government public health and safety officials and others sufficient flexibility and powers to respond. Though essential to emergency responses, such flexibility may also allow decisions or actions in real-time that may not be consistent with prior planning for the distribution of antivirals.

In essence, government officials may be empowered during declared states of emergency to deviate from pre-emergency plans for the distribution of antivirals. Public health or emergency management authorities may seek shifts in existing prioritization plans for many

reasons, but ideally decisions should be grounded in what are viewed as the most effective strategies to protect the public's health. Household prophylaxis, for example, may be viewed as critical to garner the efforts of essential health care personnel or others to treat patients with influenza, or others suffering from other life-threatening conditions.

Regardless of the justification, deviations from existing distribution strategies are predictable during emergencies as the extent of the impact of pandemic influenza is measured within populations and available supplies are assessed. As a result, although it may not be possible to specify legal responses to emergency circumstances arising from pandemic influenza, advance planning and real-time assessments of public health needs should heavily influence communal actions.

Incident Management System

During an influenza pandemic, the State Health Officer will determine when and if activation of the Incident Management Structure (IMS) of ADPH is necessary. Many of the activities outlined in this document will be carried out through the appropriate IMS units as assigned by the Incident Manager and Scientific Response Manager.

This plan for responding to pandemic influenza will serve as an annex to the ADPH EOP, which addresses issues such as: command and control procedures; legal authority; intra and interagency coordination; hospital and emergency medical services coordination; infection control; security, communications; and education and training. While this document serves as a guide for specific influenza intervention activities, during a pandemic, the judgment of public health leadership, based on knowledge of the specific virus, may alter the strategies that have been outlined.

During a pandemic, CDC, under the direction of the HHS, will provide guidance to states on vaccine availability and distribution. CDC will provide guidance on influenza vaccine IND protocols in the event that the Food and Drug Administration (FDA) has not approved the vaccine. If the vaccine is in short supply, CDC, in conjunction with advisory committees and immunization practices, will provide guidance for a priority order listing of priority groups for vaccination. The priority order could be based on: the need to maintain elements of community infrastructure that are essential to carrying out the pandemic response plan; limiting mortality among high-risk groups; reducing morbidity in the general population; and minimizing social disruption and economic losses.

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological and nuclear (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

In January 2017, FDA finalized the guidance: **Emergency Use Authorization of Medical Products and Related Authorities**. For more information, please see the January 13, 2017, **Federal Register notice** .

Communications: Joint Information System

A Joint Information System (JIS) provides the mechanism to organize, integrate, and coordinate information to ensure timely, accurate, accessible, and consistent messaging across multiple jurisdictions and/or disciplines with nongovernmental organizations and the private sector. It includes the plans, protocols, procedures, and structures used to provide public information. Federal, State, tribal, territorial, regional, or local Public Information Officers (PIO) and established Joint Information Centers (JICs) are critical supporting elements of the JIS.

The primary communications goal of ADPH during a pandemic will be to ensure a timely, accurate, and consistent flow of information. *See Appendix C: Risk Communication Sample Messages.* Information will primarily be provided to public health district (PHD) staff, CHD staff, health professionals and the general public. ADPH staff will be available as needed to provide information and technical assistance directly to health professionals on: vaccine management; antiviral use for treatment and chemoprophylaxis; influenza surveillance; infection control; and treatment and care of patients.

Communication from CDC will include:

- Basic communication materials (such as question and answer sheets and fact sheets) on influenza, influenza vaccine, antiviral agents, and other relevant topics in various languages.
- General preventive measures such as “dos and don'ts” for the general public.
- Information and guidelines for health care providers.
- Training modules (Web-based, printed, and video).
- Presentations, slide sets, videos, and documentaries.
- Updated guidelines on surveillance, treatment, and prophylaxis.

Communication by ADPH will include:

- Monitoring bulletins from the CDC and WHO regarding virologic, epidemiologic, and clinical findings associated with new variants isolated within or outside of the country.
- Distribution of timely and appropriate influenza bulletins and alerts through the Health Alert Network (HAN).
- Live, interactive videoconferences on influenza, which can be initiated for CHD, PHD and ADPH central office personnel as well as private providers as necessary.
- Planning guidance to CHD, schools, hospitals, clinics, pharmacies, and others on preparing for and responding to pandemic influenza. Planning guidance for health departments can be found in Appendices A, B, C and H. Guidance documents for other partners will be developed throughout the pre-pandemic phase.
- Weekly reporting on influenza activity levels across the state.

- Education of the general public on best practices to help reduce risk of infection.
- Education of the general public on how to care for the ill at home.
- ADPH PIO will coordinate translation of major public information documents for non-English speaking persons and will also coordinate and arrange for news conferences, as they are needed. Throughout the pre-pandemic period, communications staff will develop risk communications messages for different vaccination scenarios.
- Because of anticipated shortages of both vaccine and antiviral medication, it will be critical to develop messages informing the population about availability of medications and addressing the rationale for priority groups and measures to be taken until supplies are available. Other important topics include:
 - (1) Basic information about influenza (including symptoms and transmission).
 - (2) Information about the course of the pandemic (contagiousness, geographic spread, case counts, etc.).
 - (3) Information about which symptoms should prompt seeking medical assistance and which symptoms should be managed at home.
 - (4) Information about school and business closures, suspended public meetings, and travel restrictions and quarantine laws.

Communication by Immunization Division (IMM) will include:

- Train all providers involved on the IND vaccine protocols.
- Disseminate links on Vaccine Adverse Events Reporting System (VAERS) through the HAN.
- Disseminate information about vaccine availability and distribution plans to all providers involved.
- Disseminate the influenza Vaccine Information Sheets (VISs) link to all providers involved.
- Communicate information about groups at high-risk for complications from influenza to all providers involved.
- Coordinate the vaccine distribution.

Communication by PHD and CHD will include:

- Maintain two identified spokespersons for each PHD who will, along with CHD PIO, be responsible for addressing pandemic influenza related media concerns.
- Distribution of timely and appropriate influenza bulletins to health care providers and community partners.
- Dissemination of information about vaccine availability and distribution plans to community partners.
- Dissemination of the influenza vaccine information sheet to clinic patients and area health care providers.
- Communication of information about groups at high-risk for complications from influenza to health care providers and community partners.

Surveillance

Alabama's influenza surveillance system is designed to detect geographic spread of disease and identify the strains involved in order to facilitate early public health intervention. The system has five main components: Virologic Surveillance, Outpatient Illness Surveillance, Mortality Surveillance, Hospitalization Surveillance, and Summary of the Geographic Spread of Influenza.

Virologic Surveillance

ADPH's virologic surveillance depends on hospitals and healthcare providers to voluntarily submit specimens to the BCL from all hospitalized patients with influenza-like illness (ILI), all pregnant females with ILI, all patients with recent international travel and ILI, and any persons with recent exposure to swine or live poultry and ILI. Hospitals and healthcare providers are encouraged to submit specimens year-round for influenza detection and further subtyping. Influenza specimen submissions from hospitals and healthcare providers help determine if influenza activity is increasing or decreasing; what influenza viruses should be included in the seasonal influenza vaccine; and detect a rare event like novel influenza or antiviral resistance.

Outpatient Illness Surveillance

U.S. Outpatient ILI Surveillance Network (ILINet)

As part of the CDC's ILINet, ADPH has recruited 28 outpatient healthcare providers to report the number of patients seen with ILI by age group, as well as the total number of patients seen for the week. These providers are located in every PHD.

ILI is defined as fever [temperature $\geq 100^{\circ}\text{F}$ (37.8°C)] with cough and/or a sore throat without another known cause. Reports of positive results from rapid diagnostic tests are not reliable for influenza surveillance.

The percentage of patients presenting to outpatient healthcare providers is compared to a pre-determined baseline. When the percentage exceeds the threshold (determined by 1.645 standard deviations above baseline), activity is considered to be "significant". During the 2016-2017 influenza season, the national baseline was 2.2% and the regional baseline (Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee) was 1.7%.

Syndromic Surveillance Data

Alabama's syndromic surveillance system seeks to use existing health data in near real-time to assist with the early detection of outbreaks and monitor trends of various syndromes or symptom groups, prior to a diagnosis being made, in order to mobilize a rapid response and reduce morbidity and mortality in the community.

As such, emergency departments have been asked to report various syndromes, including ILI, to ADPH via the Early Notification of Community-based Epidemics (ESSENCE) system. Data elements include patient age, sex, chief complaint, date/time of visit, race/ethnicity, discharge disposition, discharge diagnosis, patient zip code of residence, unique encounter identifier, and hospital name. Individuals are classified as presenting with ILI if their chief complaint included any of the following: influenza; or fever with cough or sore throat without another fever-causing illness (i.e., Rocky Mountain Spotted Fever, Yellow Fever, Q Fever, Dengue, or Malaria).

These data are then monitored by staff at the State to determine when activity exceeds the expected threshold.

Mortality Surveillance

There are two systems that help ADPH track influenza-associated deaths among Alabama residents: the National Center for Health Statistics (NCHS) Mortality Surveillance System and the Influenza-Associated Pediatric Mortality Surveillance System.

NCHS Mortality Surveillance System

The Alabama Center for Health Statistics (ACHS) reports all death certificate data to NCHS, including those deaths associated with pneumonia and influenza (P&I, based on select ICD-10 multiple cause of death code). Surveillance data are then aggregated at the national level by week of death occurrence. The weekly percentage of all deaths due to P&I is then compared to a moving five-year seasonal baseline. When the percentage exceeds the epidemic threshold (determined by 1.645 standard deviations above seasonal baseline), P&I mortality is considered to be “significant”.

Influenza-Associated Pediatric Mortality Surveillance System

In 2011, Alabama made Influenza-Associated Pediatric Mortality a reportable condition. As such, any laboratory-confirmed influenza-associated death in persons under the age of 18 years is required to be reported to ADPH within five days of diagnosis. Additionally, ACHS notifies ID&O of any influenza-associated pediatric deaths as soon as the death certificate is filed. Once notified, District Disease Investigators (DDI) contact the family to obtain additional information surrounding the child’s death.

Hospitalization Surveillance

There are two ways that ADPH is able to monitor influenza-like illness hospitalizations among Alabama residents. First, ADPH requests that emergency departments (ED) submit the number of patients admitted to their facility with ILI to the Alabama Incident Management System (AIMS) once every 24 hours. Second, hospitals and healthcare providers are required to indicate on the laboratory requisition form as to whether or not an influenza specimen is for a patient who was hospitalized.

Summary of the Geographic Spread of Influenza

The influenza season in Alabama typically runs from October of one year through March of the following year. Data collected through ILINet are tabulated weekly. This information, along with laboratory information collected through virologic surveillance, is used to monitor the geographic spread during the influenza season. Geographic spread of influenza activity is reported as no activity, sporadic, local, district, or widespread according to the definitions outlined in Table 2.

Table 2. Activity levels used to describe the geographic spread of influenza in Alabama.

Level	Description
No Activity	No laboratory-confirmed cases of influenza and no reported increase in the number of cases of ILI.
Sporadic	Small numbers of laboratory-confirmed influenza cases or a single laboratory-confirmed influenza outbreak has been reported, but there is no increase in cases of ILI.
Local	Outbreaks of influenza or increases in ILI cases and recent laboratory-confirmed influenza in a single district of the state.
District	Outbreaks of influenza or increases in ILI and recent laboratory confirmed influenza in at least two but less than half the districts of the state with recent laboratory evidence of influenza in those districts.
Widespread	Outbreaks of influenza or increases in ILI cases and recent laboratory-confirmed influenza in at least half the districts of the state with recent laboratory evidence of influenza in the state.

Enhanced Influenza Surveillance Activities

During a pandemic, in addition to routine surveillance, other activities will be undertaken in order to assess and control the scope of the disease across the state. Checklists of activities for all phases of pandemic influenza have been included in the appendices. Activities that will be the responsibility of ADPH and PHDs are in *Appendices A and B*.

Additional surveillance activities, which will begin during the Pandemic Alert phase and continue through the end of the Second Wave of the pandemic, will include:

1. Pharmacy: Collection and analysis of antiviral adverse events data. ADPH will rely on the federal system, which may include a telephone and web-based reporting network for adverse events from antiviral medications. Data will be collected, analyzed, and reported by CDC. Recommendations for use of antiviral medications may be adjusted based on information learned from adverse event data analysis.

2. Public Health Veterinarian: Coordination to monitor populations affected by outbreaks of influenza in swine, poultry and/or water fowl. If an outbreak of avian influenza is identified in Alabama, the ADPH Veterinarian will work with the ADAI to communicate with poultry producers and processors to monitor human populations who are at risk of becoming infected.

Enhanced surveillance measures, as outlined above, will be used to detect pandemic influenza activity levels across the state and to facilitate public health investigation and control interventions. When necessary, ADPH may implement additional surveillance measures in order to identify and control the spread of influenza. *See Appendix E: Influenza Infection Control Measures.*

Bureau of Clinical Laboratories (BCL)

ADPH state and county offices will work with the BCL to ensure the proper collection, transport, and testing of influenza specimens throughout all stages of an influenza pandemic. Virus collection kits for nasopharyngeal specimens are provided by ADPH for monitoring and outbreak investigations. Nasopharyngeal specimens (swab or wash) are collected for laboratory testing to detect and identify influenza virus. ADPH leadership will consult with the BCL about laboratory testing and interpretation of results. Guidance for Laboratory Testing guidelines can be found in *Appendix F*.

The preferred specimen for detection of influenza virus is a nasopharyngeal swab or wash. ADPH BCL currently performs real time polymerase chain reaction (PCR) testing to detect influenza virus in nasopharyngeal specimens: ILI-NET physicians routinely submit specimens for year-round surveillance testing. The BCL utilizes the “CDC Flu rRT-PCR Dx Panel” to subtype influenza A and B viruses. Selected positive specimens are submitted to the CDC for further characterization as part of the WHO surveillance to determine antiviral resistance and optimal vaccine development. The BCL’s testing capacity includes the ability to presumptively identify novel influenza strains. In the event a novel strain is suspected, the specimen will be forwarded to the CDC for confirmation.

During the Pandemic Alert stage, ADPH Infectious Diseases & Outbreaks (ID&O) Division will establish a sampling protocol for influenza laboratory testing across all public health districts. Once pandemic influenza has been established in a health region, laboratory testing for that region may be scaled down, depending on the public health need for additional testing. Sampling protocols may be changed once progression to the next pandemic influenza phase has been declared.

Case Confirmation Investigation

Once a positive pandemic or novel influenza strain is discovered to be circulating in Alabama, District and Central Office Disease Investigators would be called to investigate the case to determine if there are other people infected or exposed. The case investigation would also entail contacting and collecting those exposed to be tested for the novel virus.

Vaccine and Antiviral Priority Groups

When the United States confirms the first case of pandemic influenza disease, a decision must be made regarding who will receive the available antivirals or vaccine available. The decision will impact the mortality, morbidity, loss of quality of life, and damage the economy of Alabama. Current high-risk group recommendations are expected to change, because past pandemic influenza outbreaks have also affected the young and healthy people. *See Appendix G: Antiviral Recommendations.* For vaccine, the priority groups will be determined by HHS, *Guidance on Allocating and Targeting Pandemic Influenza Vaccine*, <https://www.cdc.gov/flu/pandemic-resources/pdf/allocatingtargetingpandemicvaccine.pdf>.

Satellite, Temporary, or Off-Site Vaccination Clinics

To facilitate the most efficient and safe delivery of available vaccine via large community clinics, these recommendations and guidelines have been developed to assist with planning local large-scale influenza vaccination clinics. This document provides guidance to help ensure smooth operations at satellite, temporary, or off-site vaccination clinics for ADPH. *See Appendix H: Satellite, Temporary, or Off-Site Vaccination Clinics.*

Checklist of Best Practices for Vaccination Clinics

The CDC and IMM strongly recommend all staff at vaccination clinics read and complete CDC's Checklist of Best Practices for Vaccination Clinics prior to administering any vaccine doses. This will ensure the clinics follow the best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. *See Appendix I: Checklist of Best Practices for Vaccination Clinics.*

Vaccine Storage

This policy provides an overview of best practice guidance for storage and handling. Most of the information that follows is taken directly from the CDC Epidemiology and Prevention of Vaccine Preventable Diseases and the CDC's Vaccine Storage and Handling Toolkit. *See Appendix J: Vaccine Storage and Handling/Cold Chain Policy.*

Appendix A: ADPH Planning Influenza Activities

Inter-Pandemic Phase/Investigation

No unusual influenza activity patterns or strains have been reported to ADPH authorities.

- ❑ Health Promotions in conjunction with Subject Matter Experts will develop printed and electronic communications capabilities to assist in distribution of information to PHDs, CHDs, Private Providers and the general public.
- ❑ Educate the general public and stake holders regarding pandemic influenza issues.
- ❑ IMM will remind all providers involved to check their plan for storage and handling of vaccines.
- ❑ Assess ways to improve immunization rates for influenza and pneumococcal vaccines.
- ❑ Health Promotions will develop risk communications messages targeted for pandemic influenza.
- ❑ ID&O will update pandemic influenza surveillance, investigation, and control measure recommendations.
- ❑ ID&O will coordinate sentinel provider surveillance during the regular influenza season (October-April), ensuring participation of at least one provider site per 250,000 population. Implement year-round surveillance.
- ❑ BCL will test specimens submitted to provide year-round surveillance. Investigate and respond to unusual influenza outbreaks. Enhance laboratory testing of outbreak strains.
- ❑ Public Health Veterinarian will maintain ongoing communication with the ADAI regarding epizootic and zoonotic influenza disease.
- ❑ ADPH Pharmacy division will promote the establishment of private pharmacy antiviral stockpiles.

Alert Phase/Recognition

A novel influenza virus has been detected in one or more humans. The general population would have little or no immunity. During this phase, a pandemic is potential but not inevitable.

- ❑ State Epidemiologist and State Health Officer will notify CHD and other stakeholders of a novel virus alert.
- ❑ Center for Emergency Preparedness (CEP) will notify the Alabama Department of Emergency Management and private partners of novel virus alert.
- ❑ ID&O will monitor bulletins from the CDC and WHO regarding clinical, epidemiological, and virologic characteristics of novel variant and disseminate to CHD, stakeholders and partners.
- ❑ BCL will conduct enhanced lab surveillance to detect the appearance of new influenza variants in Alabama.
- ❑ ID&O will activate routine surveillance systems for influenza (if pandemic alert occurs during non-influenza season).
- ❑ If a novel virus is identified in an Alabama resident or visitor, ID&O will work with the CHD and PHD staff to conduct an epidemiologic investigation and determine possible exposure source(s), risk factors, and symptoms. Identify contacts, place under surveillance for illness, and work with the BCL to determine whether testing of contacts is appropriate.

Pandemic Initiation

A novel virus has demonstrated sustained person-to-person transmission and causes multiple influenza cases in the same geographic area.

- ❑ Notify state agencies and other partners of the potential for an influenza pandemic.
- ❑ Activate ICS.
- ❑ Bureau of Communicable Disease (BCD) will collaborate with the CDC to determine which groups are at high risk for morbidity and mortality.
- ❑ IMM and Pharmacy will collaborate with all providers involved to ensure that identified high-risk groups and others receive vaccine and antiviral medications.
- ❑ Activate Strategic National Stockpile (SNS) Plan
- ❑ ID&O will collaborate with providers and BCL to increase testing for influenza viruses in specimens from travelers to pandemic areas.
- ❑ BCL will send representative and unusual virus isolates to the CDC for appropriate testing (to include antiviral resistance studies).
- ❑ ID&O will continue to monitor bulletins from the CDC and WHO regarding clinical, epidemiological, and virologic characteristics of novel variant, and update CHD, stakeholders, and partners.
- ❑ Health Promotions in conjunction with Bureau of Communicable Disease will review and revise drafts of public information documents (fact sheets and guidelines).
- ❑ IMM will review vaccine distribution plans with stakeholders and partners, and modify as needed.
- ❑ CEP/SNS will monitor availability and coordinate distribution and delivery of public-sector vaccines.
- ❑ Health Promotions will prepare translated versions of major public information documents for non-English speaking persons.

Pandemic Acceleration

A novel virus has caused unusually high rates of morbidity and mortality in multiple, widespread geographic areas.

- ❑ ID&O will continue to monitor bulletins from the CDC or WHO regarding clinical, epidemiological, and virologic characteristics of novel variant. Update CHD, stakeholders, and partners.
- ❑ Pharmacy will implement surveillance and data collection for adverse events following use of antivirals and drug-resistant strains of influenza.
- ❑ ID&O will coordinate surveillance activities and findings with other states and federal agencies.
- ❑ IMM will maintain current listings of all providers involved in ImmPRINT and monitor availability and coordinate distribution and delivery of public-sector vaccines.
- ❑ BCL will request Medical Examiner to provide lab with selected autopsy specimens for influenza testing.
- ❑ ADPH will continue to recommend control measures in accordance with the CDC and other federal recommendations including social distancing & policies or orders related to quarantine.

- ❑ CEP will ensure that the Emergency Operations Center (EOC) and key health officials are kept informed of all health and medical developments and decisions during pandemic.
- ❑ ID&O will continue to monitor bulletins from the CDC and WHO regarding clinical, epidemiological, and virologic characteristics of novel variant. Update PHD, CHD, stakeholders, and partners.
- ❑ PIOs will coordinate release of health information.
- ❑ Pharmacy will monitor antiviral adverse events weekly and transmit information to the CDC so that unexpected adverse events can be detected early and antiviral recommendations altered according to federal recommendations.
- ❑ BCL will send selected influenza specimens to the CDC for antiviral resistance testing so resistance prevalence can be estimated and to make antiviral recommendations.
- ❑ ID&O will describe unusual clinical syndromes, describe unusual pathologic features associated with fatal cases, and assess the effectiveness of control measures.

Pandemic Deceleration

Successive pandemic “waves” have subsided and is accompanied by the return of a more typical seasonal trend.

- ❑ BCD will summarize findings and report to the CDC on the epidemiological characteristics of the pandemic in Alabama and on the lessons learned.
- ❑ CEP will assess state capacity to resume normal public health function and health care delivery.

Transition / Preparation

Low pandemic influenza activity but continued outbreaks possible in the state. A recurrence of epidemic activity within several months following the initial wave of infection occurs.

- ❑ Continue all activities listed under Pandemic phase.
- ❑ Review, evaluate and modify as needed, the ADPH pandemic response.
- ❑ Continue to coordinate vaccine.
- ❑ Monitor resources and staffing needs.

Appendix B. Public Health Districts Planning Checklist

Inter-Pandemic Phase/Investigation

No unusual influenza activity patterns or strains have been reported to health authorities.

District Staff:

- ❑ EP will review all-hazards plans for inclusion of mass vaccination campaigns and security with local EMA law enforcement authorities.
- ❑ EP will conduct a county-wide space and site resource inventory. Determine the availability of shelters, firehouses, schools, gymnasiums, nursing homes, day care centers, and other potential sites for aggregate care. Work with hospitals in your jurisdiction to identify appropriate sites to serve as triage centers, treatment centers, and mass vaccination sites or as holding areas for acutely ill patients not able to be admitted to an acute care hospital. Make arrangements with owners of each facility to use the site, if necessary, to care for ill persons during a pandemic.
- ❑ EP will identify facilities/resources with sufficient refrigerated storage to serve as temporary morgues, if necessary. Develop a plan for management of bodies when morgue capacity has been exceeded.
- ❑ IMM in coordination with ADPH will devise a plan for local distribution and administration of public-sector vaccine.
- ❑ EP will work with local private and volunteer organizations to develop and synchronize local response to a pandemic influenza outbreak.
- ❑ EP will coordinate with other public health disaster planning at the local level.

Alert Phase/Recognition

- ❑ A novel influenza virus has been detected in one or more humans. The general population would have little or no immunity. District PIO will notify hospitals and local private and public partners of novel virus using prepared public health information documents from Health Promotions.
- ❑ EP will notify local emergency management director of novel virus alert.
- ❑ PIO will disseminate bulletins received from the CDC or ADPH regarding clinical, epidemiological, and virologic characteristics of variant strain.
- ❑ ID&O District Investigator will encourage ILINet Providers to collect specimens for submission to the BCL in order to detect the presence of variant strains in Alabama.
- ❑ If a novel virus is identified in a resident, ID&O District Investigator will conduct an epidemiologic investigation and determine possible exposure source(s), risk factors, and symptoms. Identify contacts, place under surveillance, and determine with the laboratory whether testing of contacts is appropriate.

Pandemic Initiation

A novel virus has demonstrated sustained person-to-person transmission and causes multiple influenza cases in the same geographic area.

- ❑ EP in coordination with ADPH will update pandemic influenza response plans.
- ❑ EP in coordination with ADPH, update hospitals, EMA, emergency medical services (EMS), local law enforcement, and local, private and public partners.

- ❑ IMM will ensure that high-risk groups and essential personnel receive vaccine and antiviral medications.

Pandemic Acceleration

A novel virus has caused unusually high rates of morbidity and mortality in multiple, widespread geographic areas.

- ❑ IMM will review plan for distribution of vaccine.
- ❑ IMM will provide ADPH with vaccination sites for all providers involved from ImmPRINT.
- ❑ ID&O District Investigator will enhance collection of clinical specimens and transport to BCL.
- ❑ IMM will contact private partners to review their plans for distribution and administration of private-sector vaccine, if applicable.
- ❑ ID&O District Investigator will finalize surveillance plans with area hospitals outlining mechanisms to obtain data.
- ❑ EP will coordinate use of local resources during pandemic, including private, public, and volunteer resources.
- ❑ ID&O District Investigator will report pandemic-related information, including influenza data obtained from hospitals, regularly to the ADPH ID&O Division.
- ❑ EP will assess effectiveness of local response and available local capacity.
- ❑ IMM will implement mass vaccination clinics to administer vaccine once it becomes available.
- ❑ ID&O District Investigator will notify hospitals to monitor emergency departments for influenza activity, including a review of emergency department visits, hospital admissions, and hospital deaths.

Pandemic Deceleration

Successive pandemic “waves” has subsided and it accompanied by the return of a more typical seasonal trend.

- ❑ EP will assess local capacity to resume normal public health functions.
- ❑ EP will assess local capacity to resume normal health care delivery.
- ❑ EP will assess fiscal impact of pandemic response.
- ❑ EP will report results of assessment to ADPH.
- ❑ EP will modify the local EOP and Pandemic Influenza Response Plan (PIRR) based on lessons learned.

Transition/Preparation

Low pandemic influenza activity but continued outbreaks possible in the state. A recurrence of epidemic activity within several months following the initial wave of infection occurs.

District Emergency Preparedness Staff in conjunction with district IMM and ID&O staff:

- ❑ Continue all activities listed under Pandemic phase.
- ❑ Review, evaluate, and modify the local pandemic response.
- ❑ Report pandemic-related information regularly to ADPH.
- ❑ Continue to vaccinate.
- ❑ Monitor resources and staffing needs.

Appendix C: Risk Communications Sample Messages

Key messages: 7–9 second sound bites (21 – 27 words)

- Because we are faced with a limited supply of vaccine, we will look at ways to do the most good for the most people.
- To make sure healthcare providers are available to care for those who develop influenza, it is imperative that we vaccinate healthcare workers immediately.
- To ensure that our community is safe and has water, electricity and other services we all rely on, we must prioritize vaccinating essential services workers.
- (Fill in age group)-olds are more seriously affected by this strain of influenza. They are high risk and, therefore, must be vaccinated early.
- Although this influenza vaccine has not been approved by the FDA, it will be given as an investigational new drug. Its benefits far outweigh the risks.

Gather Supporting Facts:

- A. Track case numbers and mortality by age group and by locality
- B. Identify groups of essential services workers
- C. Develop clear explanations of risks associated with the disease and vaccination
- D. Develop credible community sources that will validate the key message
- E. Establish relationships and agreements with infectious disease specialists

Appendix D: County Health Departments Planning Guidance

A. Background Information

- Frequent mutations of surface glycoprotein genes result in new influenza virus variants.
 - Antigenic shift → emergence of completely new subtypes (type A only; leads to pandemics)
 - Antigenic drift → minor changes (all types; leads to frequent outbreaks & epidemics)
- Antigenic drift necessitates annual reformulation of flu vaccine to incorporate >1 new strains.
- The emergence of a new influenza subtype due to antigenic shift could result in high attack rates among the entire population and the need for reformulation of the vaccine for adequate coverage.
- Through the sentinel physician and laboratory surveillance programs, ADPH obtains information as to which influenza strains are circulating in the community. If a new subtype emerges, the ADPH central office will notify CHDs immediately so that they can begin preparations for an emergency vaccination program.
- In the event of a pandemic, a joint team comprised of CDC, ADPH central office and CHD members will coordinate mass vaccination and chemoprophylaxis programs.

B. Priority Vaccination in Pandemics

- Persons involved in medical/public health evaluation, care or transportation of cases.

- Laboratory personnel involved in collecting or processing clinical specimens.
 - Emergency Responders.
 - Selected law enforcement personnel.
 - Military personnel.
 - Other specified groups that provide essential community services.
 - Persons at high risk for morbidity and mortality from influenza.
- C. Persons at High Risk for Complications from Influenza during Interpandemic Years
It is possible that persons at increased risk for complications from influenza during the typical influenza season may also be considered high-risk during a pandemic. They include:
- Persons age 6-23 months and greater than 65 years old.
 - Residents of nursing homes and other chronic-care facilities.
 - Persons with chronic cardiac, pulmonary, metabolic and renal conditions, and hemoglobinopathies.
 - Immuno-compromised.
 - Children and teenagers (ages 6 months-18 years) who are receiving long-term aspirin therapy.
 - Women who are pregnant.
- D. Vaccine Contraindications
- If you have any severe, life threatening allergies. If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
 - If you ever had Guillain-Barré. Syndrome (also called GBS). Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
 - If you are not feeling well. It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

Appendix E: Influenza Infection Control Measures

Influenza viruses are spread from person-to-person, primarily through inhalation of small particle aerosols and large droplet transmission. Transmission may also occur through direct and indirect contact with infectious respiratory secretions. Persons can be infectious starting the day before symptoms begin through approximately five days after illness onset. Children can be infectious for a longer period. The main option for controlling influenza is immunoprophylaxis with the inactivated vaccine. Use of antiviral drugs for treatment is an important adjunct to vaccination. The general public will have to consider “isolation in place” to reduce the risk of spreading the pandemic influenza to others.

Special guidelines for infection control should be in place during pandemic influenza, taking into account the likelihood a high proportion of the population will be affected and secondary infections are a major source of morbidity and mortality. In physician offices, airborne precautions should be followed.

See: http://www.cdc.gov/ncidod/hip/ISOLAT/airborne_prec_excerpt.htm).

Healthcare facilities, in addition to airborne precautions, may want to consider the following:

- **Staff education:** Staff should be educated annually about the prevention and control of influenza, focusing on transmission of infection. Staff should be reminded that they can transmit the virus via their hands or fomites (e.g. towels, medication cart items, etc.).
- **Hand washing:** Hands should be washed after touching blood, body fluids, secretions, excretions, and contaminated items, whether or not gloves are worn. Hands should be washed with plain soap or detergent for at least 10-15 seconds under running water.
- **Gloves:** Clean, disposable gloves should be worn when touching blood, body fluids, secretions, excretions, and contaminated items. Gloves should be removed after use, before touching any non-contaminated items, or before touching another patient. Hands should be washed immediately with soap and water or an alcohol-based hand-rub.
- **N-95 Masks:** Only healthcare workers that have been screened, trained, and Fit tested may wear an N-95 Mask when working with a patient. Should the patient have visitors, all visitors as well as the patient should wear surgical masks to provide some level of protection. Should patient transport become necessary, the patient should wear a surgical mask.
- **Bed Management:** Consideration should be given to cohorting ill patients, since private rooms are not likely to be available for influenza patients during a pandemic. Movement and transport of patients should also be limited as much as possible.

Long-term care facilities (LTCF) may take the following measures to control influenza:

- LTCF should call the CHD if an increase in cases of respiratory illness is observed, especially if it is associated with an increase in hospitalizations or deaths. Maintain a heightened surveillance for febrile and respiratory illness among residents and staff.
- LTCF staff should be assigned to work with either sick or well patients, but not circulated between both groups. Staff should not work while ill.
- Visitation should be restricted.
- If admissions are restricted due to an outbreak, when admissions resume, any new admissions should be vaccinated and segregated from the general population for two weeks.
- Vaccinate all residents or staff.
- Separate residents taking antiviral medications for treatment from other residents.

In some circumstances, such as a novel virus alert, public health officials may advise that certain patients should be managed under standard plus droplet and contact precautions. This may happen if a novel virus is isolated in humans and the possibility of person-to-person transmission cannot be ruled out. In such circumstances, healthcare facilities should initiate the following additional precautions for patients hospitalized with, or under evaluation for, infection with a novel virus:

- Gloves and gowns: Clean, disposable gloves and gowns should be worn for all patient contact.
- Eye protection: Routinely wear eye protection when within 3 feet of patient. If splash or spray of respiratory secretions or other body fluids is likely, protect the eyes with goggles or a face shield. The face shield should fully cover the front and wrap around the side of the face. Corrective eyeglasses or contact lenses alone are not considered eye protection.
- Isolation: Place the patient in an airborne isolation room (e.g., monitored negative air pressure in relation to the surrounding areas with 6 to 12 air changes per hour).
- N-95 Masks: Only healthcare workers that have been screened, trained, and Fit tested may wear an N-95 Mask when working with a patient.
- Patient transport: Limit patient movement and transport outside the airborne isolation room to medically necessary purposes. If patient movement or transport is necessary, ensure the patient wears a surgical mask, puts on a clean patient gown, and performs hand hygiene before leaving the room. If a surgical mask cannot be tolerated, apply the most practical measures to contain respiratory secretions.

Appendix F: Guidance for Laboratory Testing for Influenza Viruses

What specimens should be submitted?

Specimens should be collected from:

- All hospitalized patients with ILI***
- All pregnant females with ILI***
- All patients with recent international travel and ILI***
- All patients reporting exposure to pigs**
- All patients reporting exposure to backyard flock**
- Any healthcare provider can submit influenza specimens year round**
 - Sampling as directed from outpatient visits with ILI*
 - Do not collect more than **one** specimen per family, household, or close contact.
 - Guidance and specimen threshold may change during the season, depending on influenza activity.
 - Check www.alabamapublichealth.gov/Influenza

*ILI symptoms include: fever greater than or equal to 100°F AND cough and/or sore throat without a known cause other than influenza.

How do I order a flu test kit?

- Email flutestkit@adph.state.al.us
- Enter in Subject line “flu test kit”
- Explain in the body of email what you need, for example the entire flu test kit or individual items, like cooler, ice packs, Dacron swabs, viral/universal transport media, etc.

What specimen should I collect?

- Nasopharyngeal swabs, nasopharyngeal aspirates/washes, throat swabs, and nasal swabs
- Swab specimens should be collected **only on swabs with synthetic tips** (polyester, Dacron, etc.) with aluminum or plastic shafts.
- Cotton swabs, wooden shafted swabs, and calcium alginate swabs are not acceptable. Calcium alginate can inhibit laboratory-testing procedures.
- Specimens should be **collected within 72 hours of onset** of symptoms and **shipped immediately** to the BCL.

*If specimen cannot be shipped immediately, it must be stored in the refrigerator, but **must be received at the BCL within seven days of collection**.

***DO NOT FREEZE** the specimens as this reduces viral recovery.

How do I collect the specimen?

Nasopharyngeal swab or aspirate/wash

Specimen should be collected by trained personnel per the instructions used at the collecting facility.

Throat swab

1. Ask patient to cough; swab the posterior pharynx and tonsil areas (avoid tongue).
2. Place swab into tube of viral/universal transport medium.
3. **Break shaft of swab** so that it does not protrude above the rim of the tube.
4. Screw cap on tube securely to avoid leakage.
5. Label the transport tube with the patient's name, specimen source, collection date.
6. Refrigerate specimen(s) until ready to ship to the laboratory as described above.
Note that refrigerated specimens must arrive at the laboratory within seven days of collection.

Nasal Swab

1. Insert a sterile Dacron swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level on the turbinates (less than one inch into the nostril).
3. Rotate the swab a few times against the nasal wall.
4. Place swab into tube of viral/universal transport medium.
5. **Break shaft of swab** so that it does not protrude above the rim of the tube and cap.
6. Label the transport tube with the patient's name and specimen source.
7. Refrigerate specimen(s) until ready to ship to the laboratory as described above.
Note that refrigerated specimens must arrive at the laboratory within seven days of collection.

How do I package the specimen?

1. Place swab or aspirate into viral/universal transport media.

2. **Break the swab shaft** off low enough for the cap to screw on tightly.
3. Place the media tube into a sealable plastic bag with absorbent material and place in Styrofoam box. More than one media tube may be placed in the plastic bag. A canister may also be used.
4. Place a **frozen** cold pack on top of the specimen(s).
5. Place the Styrofoam lid on the box.
6. Place the printed form from the Web Portal (or completed Requisition Form, <http://www.alabamapublichealth.gov/bcl>) in a separate sealable plastic bag and place on the cooler in the box. (Make sure your facility name is included.)
7. Close and seal the cardboard box.
8. Place the appropriate shipping labels on the box: address label and UN 3373 (biological substance) label if not already on the outer box.

How do I submit the specimen?

- Log in to the facility's State Lab's Web Portal account and print out a bar code for shipping. You will receive the patients' results electronically. If you have not signed up for the Web Portal yet, contact the BCL at 334-260-3409 to be set up.
- Alternatively, you may complete the ADPH BCL Requisition Form, but your results will be mailed.

How do I ship the box?

1. You may ship the package on Monday through Thursday (specimen must be received within seven days of collection) to:

**Bureau of Clinical Laboratories
8140 AUM Drive
Montgomery, AL 36117**

2. You may take the box to your local county health department to be placed into the courier system (to be received within seven days of collection) Monday through Friday. The specimen **MUST** be properly packaged before taking to the county health department. Coordinate delivery prior to arrival to meet daily shipping cut-off times.

Unsatisfactory Specimens

- Specimens received warm or hot because of missing or melted ice packs
- Specimens in media other than viral/universal transport media
- Dry swabs (not in transport media)
- Expired transport media
- Specimens that were collected and stored longer than seven days
- Specimens without patient identification

- Specimens where required Clinical Laboratory Improvement Amendments (CLIA) demographics cannot be attained
- Incomplete lab slips

How Do I Get the Results?

- All influenza tests submitted using the secure Web Portal and associated printed forms will receive PCR results electronically immediately, upon completion.
- PCR results for influenza tests submitted using the ADPH BCL Requisition Form will be mailed.

Influenza Testing & Surveillance Contact information

- For more information about specimen collection, please go to www.alabamapublichealth.gov/bcl, Influenza specimens or call 334-260-3429.
- For more information about influenza surveillance, please go to www.alabamapublichealth.gov/Influenza or call 1-800-338-8374.

ADPH Influenza Specimen

Submitting Collection Supply Order Form

Please order a month’s supply of material.

- You may order complete kits or items individually.
- Please allow 1 week for shipments to be delivered.

Number Ordering	Item
	Complete Specimen Collection Kits

Number Ordering	Individual Items Not in a Complete Kit
	Styrofoam Cooler and Cardboard Shipping Boxes
	Dacron Swabs
	Ice Packs
	Plastic Zip Lock Bags
	UN 3373 Biological Substance Labels
	Flu PCR Lab Slips
	Viral Transport Media Vials

Ship To

Practice Name	
Contact Person	
Physical Address	Street Address
	Suite # or Building #
	City and Zip
Contact Person's Phone Number	

- Fax the completed form to 334-274-9805 or email your request to: FluTestKit@ADPH.state.AL.US.
- For more information about specimen collection, please go to www.alabamapublichealth.gov/bcl/, Seasonal Influenza, or call 334-260-3429.
- For more information about influenza surveillance, please go to www.alabamapublichealth.gov/Influenza or call 1-800-338-8374.

As of January 1, 2014, all specimens (except newborn screening) require the patient's demographic and insurance information. Complete a separate form for each test requested.

Patient Information			Healthcare Provider Information				
Patient ID Number/MRN		Specimen Collection Date / /		Facility Name			
Patient Name (Last and First)		Date of Birth (mm/dd/yyyy) / /		Physician/Requestor Name (Last and First)		NPI#	
Specimen Source	Race (mark all that apply) <input type="checkbox"/> American Indian/ <input type="checkbox"/> Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Black/African-American <input type="checkbox"/> Hawaiian/Pacific <input type="checkbox"/> Islander <input type="checkbox"/> White/Caucasian <input type="checkbox"/> Unknown	Ethnicity <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Non-Hispanic or Latino <input type="checkbox"/> Unknown		Street Address			
Date of Onset / /		Sex Male Female		City	State	Zip	
Hospitalized Yes No		Pregnant <input type="checkbox"/> Yes <input type="checkbox"/> No		Phone Number		Fax Number	
Patient Street Address			Laboratory Use Only				
City		State					Zip
Patient SSN		Patient Phone Number					
Insurance Information (Please include copy of insurance card)							
Bill To	Patient's Insurance	Patient	Ordering Facility	ADPH Program _____			
Insurance Carrier	Policy Holder's Name (Last, First, MI)		ID Number	Group Number			

BC/BS United Healthcare Medicaid Medicare No Insurance Other (Specify)	Policy Holder's DOB (mm/dd/yyyy)		Policy Holder's Mailing Address		Patient's Relationship to Policy Holder (Self, Child, Spouse, Unknown)
	Diagnosis Code(s)	Code 1	Code 2	Code 3	

Test Requested	
Frequently Ordered	AFB/Mycology/Microbiology
Recent Travel? Yes/No When and where? _____ Recent Vaccine? Yes/No When and whattype? _____ CT/GC/TV Syphilis History of treatment? Yes /No HIV EIA HIV EIA Form # _____ Blood Lead Capillary Venous Follow-up? Yes/No HIV Viral Load HIV Genotyping Lymphocyte Subset (CD4) Hepatitis B Surface Antibody Hepatitis B Surface Antigen Post Vaccine Employee? Yes/No Needle Stick? Yes/No CBC without differential Chemistry Panel (Only one form required per Chemistry Request) Comprehensive Metabolic Lipid Basic Metabolic Thyroid Renal Function TB Hepatic Function Electrolytes Chemistry Analyte (s) _____ Urine Culture Symptomatic / Post Treatment / Other: _____ Arboviral Testing Agent suspected: _____ Other Test _____	AFB Mycology Microbiology – Reference/Gram Stain _____ Microbiology – <i>Salmonella/Shigella</i> Microbiology – PCR Test _____ Other _____ Agent suspected: _____ Special Instructions: _____ _____ _____ _____ _____ _____

Appendix G. Antiviral Recommendations

Chemoprophylaxis is not a substitute for vaccination. However, in the event of an influenza pandemic, vaccine may not be available, or may only be available in limited quantities.

Due to the limited supply of antivirals and the quantity needed to administer them prophylactically it is anticipated that the State Health Officer and Board of Health will recommend antivirals be used for treatment rather than prophylaxis except in unique situations.

- ❑ Benefits of using antiviral agents in the treatment of influenza are limited.
- ❑ When administered within two days of illness onset, antivirals may reduce duration of uncomplicated influenza illness by approximately 1 day.
- ❑ None of the four antiviral agents have been demonstrated to be effective in preventing serious influenza-related complications such as bacterial or viral pneumonia.

- ❑ Death from influenza is much more likely to occur in the event of a serious influenza-related complication, especially among high-risk individuals. Preventing influenza rather than attempting to shorten the duration of illness can achieve maximum benefit. Therefore, in the event of an influenza pandemic, use of antivirals (excluding zanamivir) should be prioritized for treatment rather than prophylactically treatment purposes.

Recommendations for chemoprophylaxis are provided primarily to help healthcare providers make decisions regarding persons who are at greatest risk of severe illness and complications from influenza. Prophylactic use of antivirals should be considered for the following groups:

1. Individuals targeted to receive vaccine who cannot be vaccinated due to severe, life threatening allergies, a history of Guillain-Barre' syndrome, or are not feeling well on vaccination day.
2. Unvaccinated persons aged ≥ 65 years of age.
3. Unvaccinated residents of nursing homes and other chronic-care facilities that house individuals of any age with chronic medical conditions.
4. Unvaccinated adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including children with asthma.
5. Unvaccinated adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immune-suppression caused by medications or by human immunodeficiency virus.
6. Unvaccinated children and adolescents (aged 6 months-18 years) who are receiving long-term aspirin therapy and therefore, may be at risk of developing Reye syndrome after influenza infection.
7. Unvaccinated employees of nursing homes, chronic-care facilities, and assisted living residences who have contact with patients or residents.
8. Unvaccinated individuals who provide home care to persons at high-risk.
9. Unvaccinated household members (including children) of persons at high-risk.

Pregnant Women

According to the CDC, the following information should be considered current for the 2016-2017 influenza seasons for clinical practice regarding the use of influenza antiviral medications, but does not include recommendations specific to the use of peramivir in pregnant and postpartum women.

These recommendations are consistent with current recommendations for antiviral treatment from the Advisory Committee on Immunization Practices. In addition, CDC convened a meeting of experts on August 12-13, 2010, to review the evidence and provide input on treatment and prevention of influenza during pregnancy. Experts in the fields of influenza, obstetrics, pediatrics, pharmacy, teratology, maternal-fetal medicine, preventive medicine, public health, emergency response, and others participated in the meeting (Rasmussen, 2011). Data from the 2009-2010 influenza season showed that women who were treated early with antiviral medications were less likely to be admitted to an intensive care unit and less likely to die (Siston

et al., 2010; Louie et al., 2010). In addition, available data suggest that neuraminidase inhibitors (oseltamivir and zanamivir) are not teratogenic (Rasmussen et al., 2009; Tanaka et al., 2009; Greer et al., 2010). These treatment recommendations will be updated as needed.

Drug Resistance

To limit the potential transmission of drug-resistant virus during institutional outbreaks, measures should be taken to reduce contact as much as possible between persons taking antiviral drugs for treatment and other persons, including those taking the same drugs for chemoprophylaxis.

Combination of Antiviral Medications

No published data are available concerning the safety or efficacy of using combinations of any of these three influenza antiviral drugs. For more detailed information concerning potential drug interactions for any of these influenza antiviral drugs, the package insert should be consulted. It is important to be aware of persons already taking one of these medications for another purpose so that they will not be prescribed an additional amount, and thus receive too large a dose of the drug.

Antiviral Agents for Prophylaxis and Treatment of Influenza

	Trade Name	Flu Type	Use	Age Restrictions
Zanamivir	Relenza®	A and B	Treatment only	≥ 7 years
Oseltamivir	Tamiflu®	A and B	Prophylaxis/Treatment	≥ 1 year for treatment ≥ 13 years for prophylaxis
Peramivir	Rapivab	A and B	Intravenous use only	≥ 18 years and avoid pregnant and post-partum women

Appendix H: Satellite, Temporary, or Off-Site Location Pandemic Vaccination Clinics Guide

Federal Considerations or Assumptions

- Persons of all ages may be equally susceptible to infection from a new pandemic virus and all ages may be at risk of severe disease associated with that infection.
- Persons of all ages recommended for vaccination may need two pandemic vaccine doses, separated by 21 days, for optimal protection against a new pandemic virus.
- Each dose of pandemic vaccine antigen may need to include an adjuvant in order to obtain high enough antibody levels after vaccination and/or in order to increase the number of

vaccine doses available in a shorter time (the amount of vaccine antigen needed per dose is much smaller if an adjuvant is used).

- Antigen/ adjuvant combinations may need to be the same (i.e. matched) for each dose
- The adjuvant and vaccine antigen may be shipped in separate vials and need to be mixed by vaccine providers at the point of administration.
- The pandemic vaccine and adjuvant may only be available under an Emergency Use Authorization, which may require that patients receive additional documentation provided to programs by United States Government (USG).
- The Federal government would purchase and distribute pandemic vaccine and adjuvant, if recommended, through the contracted vaccine distributor used for existing publicly funded routine vaccines managed by CDC.
- Pandemic vaccine products would be allocated to states and territories by the Federal government on a weekly pro-rata or census population based system.
- Alabama would need to manage provider vaccine orders, allocations, and accountability in their state and submit these allocation requests to CDC for distribution to these providers.
- If disease is severe, public demand for vaccination may be much higher than during 2009 H1N1 pandemic or any prior influenza season.
- More doses of vaccine may be available per week in the U.S. compared to during the 2009 H1N1 pandemic. More vaccine doses may be available for distribution to providers for the following reasons:
 - Improvements in U.S.-based influenza vaccine manufacturing capacity since 2009 H1N1 pandemic.
 - Use of dose sparing strategies, such as the use of adjuvant would allow for less antigen to be used in each vaccine dose and result in an increase in the total number of doses.
 - Also, because disease may peak earlier (e.g. <20 weeks after detection of the first U.S. case) in a severe pandemic, compared to the 2009 H1N1 pandemic, which peaked more than 6 months after the first detected U.S. case, programs must be prepared to rapidly vaccinate at least 5 times as many persons per week as were vaccinated during the 2009 H1N1 pandemic.
 - This would mean that programs must be prepared to register a large number of immunizers and vaccination sites, including many non-VFC providers in order to increase access to vaccines for adults.
 - Since the Vaccines For Children (VFC) program includes mostly providers who serve children, and the 2009 H1N1 response focused heavily on children, adult providers may have played a less prominent role in the 2009 H1N1 vaccination campaign.
 - Establishing formalized relationships and agreements for pandemic vaccine administration, accountability, planning, and response in ImmPRINT for immunizers of adults, especially pharmacies, will be extremely important in expanding vaccine access to adults, meeting overall demand for vaccination, and a major responsibility of public health programs.

- Because disease may peak early and stockpiled pandemic vaccine products would be used early in the response, programs would need to be ready to vaccinate within 60 days of the USG's decision to initiate a national pandemic vaccine campaign.
- Alabama will utilize ImmPRINT to help providers track pandemic vaccine administration to ensure appropriate doses, intervals, and antigen/adjuvant matching.
- In addition, it is likely that many patients will receive their 2 doses from different providers. ImmPRINT will be required all providers to maintain a centralized state-based database of vaccine administration.
- In an effort to deliver vaccine rapidly, in large quantities, and to prioritized groups, states and/or their local jurisdictions may need to deliver much of their vaccine through mass vaccination clinic settings.
- Overall, programs should plan to manage a much larger vaccine response than during the 2009 H1N1 pandemic and aim to vaccinate at least 80% of their jurisdiction's population with at least two doses of pandemic vaccine 21 days apart within 16 weeks.

Satellite, Temporary or Off-Site Locations should be planned based on ADPH, CEP's SNS Point of Dispensing (POD) Plan, because vaccine is the countermeasure, like antivirals or antibiotics. SNS Plans areas specific to pandemic influenza include, but are not limited to, local clinic leaders, staff, locations, clinic layouts, crowd management, security, and advertising. Planning areas for pandemic influenza should consider the following:

ADPH ICS Leadership will provide:

- Directions and decisions for public health staff statewide during the pandemic.
- Respond to requests from Alabama Emergency Management Agency or Governor.
- Decide who, when, and where the vaccine will be available.

Area Administrators will provide:

- Leadership for all counties clinics in their district.
- Local CHD for clinics.
- District staff for clinics at CHD and other mass clinics.

Center for Emergency Preparedness will provide:

- Countermeasure SNS POD Plan details.
- Subject Matter Experts (SMEs) for consultation on staffing, logistics, and supplies.

IMM will provide:

- Pandemic influenza vaccine.
- ImmPRINT, immunization registry, to order and account for all vaccine distributed.
- SMEs for consultation on the vaccine storage and handling, and ImmPRINT.

Clinic Managers

Clinic Managers should be experience nurses like a CHD Nurse Managers or others designated by ADPH ICS Leadership or District Administrators, and are responsible for overall vaccination campaign operations and should follow CEP's SNS POD Plan, which may include but not limited to:

- Designate and supervise clinic staff.
- Collaborate with local agencies and state public health departments, and CEP volunteer network for surge capacity staffing, particularly at clinic opening time, where pre-scheduling will not be done or large numbers of unscheduled clients are anticipated.
- Communicate with local community.
- Supplies, logistics, medical personnel, support functions and their respective
- Infection control at the clinic, which includes ensuring that healthcare personnel who are preparing and administering the vaccinations are appropriately trained on safe injection practices.
- Ensure language needs of the community using multi-lingual staff or use the language line.
- Ensure clinic staff are trained and have demonstrated knowledge in the proper vaccine storage, handling and administration of vaccines using "Just in Time" training and the following resources:
 - [Vaccine Storage & Handling Toolkit](#)
 - [Vaccine Administration Recommendations and Guidelines](#)
- Clinic support agreements are the responsibility of the local health department. Testing and exercises are also a local responsibility.
- Ensure staff well-being by scheduling times for rests and snacks in a designated area. See SNS plan or local plan for details.

Clinic Staff

Clinic Staff could be district staff, and central office when needed, and should follow CEP's SNS POD Plan, which may include but not limited to:

- Greeters to greet and guide clients.
- Registration personnel to assist clients complete registration and form completion area at multiple stations of tables and chairs for filling out forms.
- Educators at the clinic entrance.
- Medical screeners to determine high-risk patients to enter the clinic or not high-risk to exit and to answer questions.
- Priority client screeners.
- Form, payment collectors.
- Clinic flow controllers to direct clients to vaccination lines, tables, and exit.
- Vaccination coordinator to ensure vaccine is available, stored and handled properly, and inventoried, and accounted.
- Vaccinators and assistants are at each station.
- ImmPRINT data entry staff.
- Security and emergency medical personnel.

Vaccination Clinic Location Criteria

The clinic locations should follow CEP's SNS POD Plan, which may include but is not limited to:

- Ensure proximity of clinics to population centers with considerations for mass transit, ample parking, and the following other considerations:
 - Separate entry
 - Exit doors
 - Adequate lighting and heating
 - Functional and accessible restrooms
- Adequate space for all clinic functions such as screening, registration, vaccine storage, vaccination, and staff breaks.
- On-site space in refrigerator units that can be used to store vaccines, preferably that the vaccine can be shipped directly. If vaccine must be transported to the clinic, ensure cold chain is maintained during transport and confirmed upon arrival.
- Select school gyms, churches, auditoriums, theaters or other large covered public spaces accessible to the elderly and persons with disabilities. An agreement would need to be in place for use of such properties, but that is a local responsibility.

Mass Vaccine Clinic Lay Out and Specifications

Clinic lay out should follow CEP's individual facility POD plans, which may include but not limited to:

- Set up for unidirectional client flow from an external gathering area → eligibility screening area (multiple stations) → clinic entrance → facility waiting area(s) → registration/question and answer/form completion area (multiple stations) → medical screening/treatment area (as needed) → Medicare and other payment area (multiple stations) → vaccination area (multiple stations) → exit at a location distant from the entrance.
- Clinics should also have a designated area for vaccine preparation. Vaccines should not be prepared (including drawing up) at the individual vaccination stations. Use rope, stands, and signs in multiple languages, as needed, in outside waiting area(s) and inside clinic to delineate routes for clients to follow from station to station.
- Provide adequate number of copies of Vaccine Information Statements (VISs) in the Question and Answer area. Staff should be trained to answer common questions.
- Provide seating for clients and the person administering the vaccine at each vaccination station and have one or more vaccination stations with surrounding screens where over-clothed clients can bare their arms for vaccination. Each station must also have adequate administration supplies.
- Section off private area(s) where clients who experience acute adverse events after vaccination or who have medical problems can be evaluated and treated.
- Adequate number of computers/tablets and internet access to determine immunization history and enter administered doses into ImmPRINT.
- Ensure the presence of an onsite emergency medical kit and a designated trained physician, emergency medical technician (EMT), pharmacist, or nurse certified in basic cardiopulmonary resuscitation who can administer treatment for allergic reactions and address urgent medical problems.

Crowd Management Outside of the Clinic

Outside crowd control should follow CEP's individual facility POD plans, which may include but not limited to:

- Schedule staff to arrive 1 to 2 hours before clinic opening time to welcome and screen clients for vaccine eligibility, indications and contraindications and for insurance, if insurance will be billed for the vaccination, even if pre-scheduling is being used.
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) for expedited access into the clinic.
- Direct arriving clients into several lines and use numerous signs and announcements to clarify who falls into high-risk groups.
- Communicate the number of vaccine doses available at the clinic to the clients.
- Instruct clients to assess their eligibility to receive vaccination by reviewing the CDC, ADPH, or similar, self-screening form and ensure staff administering vaccine reviews the forms with the clients prior to vaccination. An example of an influenza vaccination screening forms can be found at www.immunize.org.
- Provide all clients with an up-to-date VIS, if available.
- Provide language translation services where necessary.
- Update clients on their estimated waiting times to be screened.
- Schedule at least 2 screeners per line to reduce crowd size and waiting times by rapidly identifying and retaining prioritized clients and letting others know about vaccination priorities of the clinic.
- Consider distributing sequentially numbered tickets, VIS, or other forms in appropriate languages that permit entry into the clinic to persons in prioritized patient groups only.
- Provide clients who cannot be served for lack of vaccine an up-to-date listing of alternative clinics providing vaccinations.

Crowd Management Inside of the Clinic

Inside crowd control should follow CEP's individual facility POD plans, which may include but not limited to:

- Vaccinate clients in the order of their arrival.
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) to receive expedited vaccination – consider a dedicated vaccination line.
- Communicate clinic updates and wait times for vaccination so that clients are free to leave and return to be vaccinated.
- Provide entertainment materials, TV and/or refreshments if wait times are anticipated to be long.
- Assist clients in completing required forms (e.g., consent forms and/or vaccination cards) by having sufficient registration staff available.
- Maintain a steady flow of clients through the clinic so that vaccinators are never without a client at their stations; redirect clients who create bottlenecks.
- Provide adequate facilities (e.g., waiting areas, restrooms, water) to meet the needs of the clients.

Clinic Security

Security should follow CEP's individual facility POD plans, which may include but not limited to:

- Require all staff to wear identification cards color coded for their job functions.
- Consider using uniformed presence to act as security and assist in managing crowds.
- Employ security personnel to monitor the mood of waiting crowds and communicate deteriorating situations to the clinic manager.
- Secure the vaccine and protect clinic staff and their valuables.
- Recruit local volunteers familiar to clinic customers since they may be especially effective in diffusing crowd-related tension.

Clinic Advertising/Press Releases

ADPH or district PIO should follow CEP's SNS POD Plan, which may include but not limited to:

- Use multi-lingual and multimedia channels to widely post clinic purpose, dates, locations, times, and which populations will be served.
- Provide instructions on how to set up appointments via telephone, in person, or other systems if pre-scheduling will be used.
- Know how much vaccine is available for a scheduled clinic and how to reallocate vaccine through centralized or individual clinic efforts to meet the acute needs of other providers.
- Recognize that scheduling may be overwhelmed and therefore not be maintainable or able to meet clients' needs during a time of severe vaccine shortage; direct clients to other facilities as required.

Appendix I: Checklist of Best Practices for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations




This checklist was created by the Influenza Work Group of the National Adult and Influenza Immunization Summit, version 2 (Updated February 2, 2017),

https://www.izsummitpartners.org/content/uploads/2017/02/NAIIS-Vaccination-Clinic-Checklist_v2.pdf

OVERVIEW OF THIS DOCUMENT

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow CDC guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. This checklist outlines CDC guidelines and best practices that are essential for patient safety and vaccine effectiveness. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held.** To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. (This individual will be responsible for completing the steps below and will be referred to as “you” in these instructions.)
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: . If you check “NO” in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic. Follow your organization’s protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, concerns about whether patients’ personal information was protected appropriately, or concerns about other responses that you have marked as “NO” on rows that do not have the .
5. This checklist should be used in conjunction with CDC’s Vaccine Storage and Handling Toolkit: <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>. For information about specific vaccines, consult the vaccine manufacturer’s package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures.**
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). (*If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.*)
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts), and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor: _____


Name of facility where clinic was held: _____









Address where clinic was held (street, city, state): _____

Time and date of vaccination clinic shift (the portion you oversaw): _____
Time (AM/PM) Date
(MM/DD/YYYY)




Time and date when form was completed: _____
Time (AM/PM) Date (MM/DD/YYYY)

Signature of clinic coordinator/supervisor: _____

If you check “NO” in ONE OR MORE answer boxes that contain a , **DO NOT move forward with the clinic**. Follow organization’s protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic. Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.





BEFORE THE CLINIC (Please complete each item before the clinic starts.)			
VACCINE SHIPMENT			
YES	NO	N.A.	
			Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (<i>Direct shipment is preferred for cold chain integrity.</i>)
VACCINE TRANSPORT (if it was not possible to ship vaccines directly to the			
YES	NO	N.A.	
			Vaccines were transported using a portable vaccine refrigerator or qualified container and pack-out designed to transport vaccines within the temperature range recommended by the manufacturers (i.e., between 2-8° Celsius or 36-46° Fahrenheit for ALL refrigerated vaccines). <u>Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE.</u> See CDC's <i>Vaccine Storage and Handling Toolkit for information on qualified containers and pack-outs:</i> http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf .
			The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (<i>Your qualified container and pack-out should include packing instructions. If not, contact the company for instructions on proper packing procedures.</i>)
			The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).
			A digital data logger with a buffered probe and a current and valid Certificate of Calibration Testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.
			The amount of vaccine transported was limited to the amount needed for the workday.
VACCINE STORAGE AND HANDLING (upon arrival at facility/clinic)			
YES	NO	N.A.	
			If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.
			If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). <i>Note: CCMs are for one-time use and should be thrown away after being checked.</i>
			Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain the manufacturer-recommended temperature range). <i>Follow the guidance for unpacking and storing vaccines specified in CDC's Vaccine Storage and Handling Toolkit:</i> http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf .
			Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (<i>i.e., between 2-8° Celsius or 36-46° Fahrenheit for ALL refrigerated vaccines.</i>)
			Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.
			Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.










CLINIC PREPARATION AND SUPPLIES











YES	NO	N.A.	
			A contingency plan is in place case vaccines need to be replaced.
			An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.
			All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in the event of an emergency, and know the location of epinephrine and are trained in its indications and use.
			There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).
			Adequate infection control supplies, including hand hygiene supplies, adhesive bandage strips, individually packaged sterile alcohol wipes, a sufficient number of sterile needles and syringes, and biohazard sharps container(s) are provided.
			Needles in a variety of lengths are available to optimize injection based on the prescribed route/technique and patient size.
			Reasonable accommodations (e.g., privacy screens) are available for patient privacy during vaccination.
			Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.
			If using a standing order protocol, the protocol is current and available at the clinic/facility site.
			A sufficient number of screening forms are available at the clinic/facility site.
			A sufficient number of Vaccine Information Statements (VISs) are available at the clinic/facility site.
			A designated clean area for vaccine preparation has been identified and set up prior to the clinic.
			A qualified individual has been designated to oversee infection control at the clinic.

DURING THE CLINIC (Please complete each item while the clinic is occurring and review at the end of your shift.)

VACCINE STORAGE AND HANDLING (at facility/clinic)

YES	NO	N.A.	
			Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (<i>i.e., a portable vaccine refrigerator or qualified container and pack-out specifically designed and tested to maintain correct temperatures when opened and closed during the clinic</i>).
			Vaccine temperature is being monitored during the clinic using a digital temperature data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. <i>Follow the temperature monitoring guidance specified in CDC's Vaccine Storage and Handling Toolkit: http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling</i>
			If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (<i>i.e., between 2-8 degrees or 36-46 degrees Fahrenheit for ALL refrigerated vaccines</i>). <i>If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.</i>
			If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified pack-out with a temperature monitoring device (with a probe in a thermal buffer) placed as closely as possible to the vaccines, and temperatures are being read and recorded <u>at least once an hour</u> . The container is being kept closed as much as possible.

			Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.
VACCINE PREPARATION			
YES	NO	N.A.	
			Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered.
			Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items.
			If using reconstituted vaccines, they are being prepared according to the manufacturer's guidelines.
			Vaccines are being prepared at the time of administration.
			If vaccines are predrawn from a multidose vial, only the contents of 1 multidose vial (a maximum of 10 doses per vial), are being drawn up at one time by each staff member administering vaccines.
			If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine and dose.
			Once drawn up, vaccines are being kept in the recommended temperature range. (<i>Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.</i>)
VACCINE ADMINISTRATION			
YES	NO	N.A.	
			Vaccine Information Statements (VISs) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
			All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).
			Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled.
			If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between each patient.
			Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer's package insert, if applicable) before drawing up and administering vaccine.
			Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
			If injectable vaccine is being administered, a new needle and new syringe are being used for each injection. Needles and syringes should never be used to administer vaccine to more than one person.
			Each staff member is administering only the vaccines they have prepared.
			If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
			Single-dose vials or manufacturer-filled syringes are being used for only one patient.
			Vaccines are being administered using aseptic technique and following safe injection practices.
			Seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.


			Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥ 3 years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged 1-2 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤ 12 months. For subcutaneous route: thigh for infants aged < 12 months; upper outer triceps of arm for children aged ≥ 1 year and adults [can be used for infants if necessary].)
			Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
			Staff is administering vaccines to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient's name and date of birth are verified prior to vaccination).
			Staff is administering vaccines using the correct route per manufacturer instructions.
			Staff is administering the correct dosage (volume) of vaccine.
			Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
			For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval, if applicable. <i>Follow the recommended guidelines in Table 1 of the General Recommendations on Immunization:</i> http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6002a1.htm .
			If vaccine administration errors are observed, corrective action is being taken immediately.
			Multidose vials are being used only for the number of doses approved by the manufacturer.
			Vaccines are never being transferred from one syringe to another.
			Used needles and syringes are being immediately placed in a sharps container following administration. (Needles are NOT being recapped.)
			Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
			Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events.



VACCINE DOCUMENTATION

YES	NO	N.A.	
			Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine type, lot number, manufacturer; patient receipt of Vaccine Information Statement (VIS), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.
			Patients are receiving documentation for their personal records and to share with their medical providers.

AFTER THE CLINIC (Please complete each item after the clinic was conducted.)

POST-CLINIC ACTIONS

YES	NO	N.A.	
			Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer- recommended temperature (<i>i.e., between 2-8° Celsius or 36-46° Fahrenheit for ALL refrigerated vaccines</i>), follow your organization's protocols and/or contact your state or local health department for guidance.

		Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. <i>An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines, or returned to the supplier for credit.</i>
		Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer- recommended temperature range at the end of the clinic day, and was not stored in a dormitory-style or bar- style combined refrigerator/freezer unit under any circumstances. (This includes vaccine transported for a multi- day clinic to a remote location where adequate storage at the site is not available.)
		Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization).
		Any vaccine administration errors were reported to all appropriate entities.
		All biohazardous material was disposed of properly.
POST-CLINIC DOCUMENTATION		
YES	NO	N.A.
		Vaccinations were recorded in the jurisdiction’s immunization information system (IIS) or vaccine registry, where available.
		If not submitted to an IIS or vaccine registry, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.
		Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): https://vaers.hhs.gov/index
		All patient medical information was placed in secured storage locations for privacy protection.
		The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).

N.A. means Not Applicable.

This checklist was adapted from materials created by the California Department of Public Health, the Centers for Disease Control and Prevention, and the Immunization Action Coalition.

ADDITIONAL INFORMATION AND RESOURCES

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

CDC’s guidelines for vaccine storage, handling, administration, and safety were updated in 2016:

- Vaccine storage and handling: <http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
- Vaccine administration: www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
- Injection safety: www.cdc.gov/injectionsafety/providers.html
- Vaccine Information Statements: www.cdc.gov/vaccines/hcp/vis/

- The Immunization Action Coalition has a skills checklist for staff administering vaccines: <http://www.immunize.org/catg.d/p7010.pdf>.
- The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available: Screening tools: <http://www.immunize.org/handouts/screening-vaccines.asp>
- Vaccination after-care:
 - Children: <http://www.immunize.org/catg.d/p4015.pdf>
 - Adults: <http://www.aimtoolkit.org/docs/vax.pdf>
- The Immunization Action Coalition has information on the medical management of vaccine reactions:
 - Children: <http://www.immunize.org/catg.d/p3082a.pdf>
 - Adults: <http://www.immunize.org/catg.d/p3082.pdf>
- Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccine: http://www.immunize.org/packageinserts/pi_influenza.asp.
- Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.

Documenting Vaccines Administered and Use of IMM Integrated Patient Resources with Technology (ImmPRINT) Information Systems

All vaccines administered should be fully documented by federal law and entered into ImmPRINT within 72 hours and the data required include but not limited to:

- Date of administration.
- Vaccine manufacturer.
- Vaccine lot number.
- Name and title of the person who administered the vaccine and the address of the facility where the permanent record will reside.
- Vaccine information statement (VIS) date printed on the VIS and the date VIS given to patient or parent/guardian.
- Vaccine type.
- Expiration date.

The Patient/Parent Card will be printed after vaccine is administered and given to patient and/or parent. All providers who receive vaccine are responsible in ensuring data entered for vaccine administered is complete within 72 hours.

Appendix J: Vaccine Storage and Handling/Cold Chain Policy

CDC's Vaccine Storage and Handling Toolkit, <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>, contains comprehensive information on best practices and recommendations. Manufacturers' product information and package inserts include the most current information about the storage and

handling of specific vaccines. Refer to CDC's Storage and Handling webpage for links to these and other resources, <http://www.cdc.gov/vaccines/recs/storage/default.htm>.

There are few immunization issues more important than the appropriate storage and handling of vaccines. Exposure of vaccines to temperatures outside the recommended ranges can decrease their potency and reduce the effectiveness and protection they provide. Vaccine management, including proper storage and handling procedures, is the basis on which good immunization practices are built. Vaccines must be stored properly from the time they are manufactured until they are administered. Assuring vaccine quality and maintaining the cold chain is a shared responsibility among manufacturers, distributors, public health staff, and health-care providers.

A proper cold chain is a temperature-controlled supply chain that includes all equipment and procedures used in the transport and storage and handling of vaccines from the time of manufacture to administration of the vaccine.

Storage and Handling Plans

Every facility must have detailed written protocols for routine and emergency vaccine storage and handling and should be updated annually. These policies and procedures should be available in writing as a reference for all staff members and easily accessible.

A routine storage and handling plan provides guidelines for daily activities, such as:

- Ordering and accepting vaccine deliveries.
- Storing and handling vaccines.
- Managing inventory.
- Managing potentially compromised vaccines.

Every facility should also have an emergency vaccine retrieval and storage plan. The plan should identify a back-up location where the vaccines can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability, and a back-up generator that can maintain power to the vaccine storage units. Potential back-up locations might include a local hospital, pharmacy, or long-term care facility.

There should be an adequate supply of packing materials and portable refrigerators or qualified containers and pack-outs on hand to accommodate the facility's largest annual vaccine inventory (e.g., flu season). A refrigerated truck may be needed to move large inventories of vaccine.

Power outages or natural disasters are not the only events that can compromise vaccine. Forgotten vials of vaccine left out on the counter or doses of vaccine stored at improper temperatures due to a storage unit failure are other examples of how vaccines can be potentially compromised. Contact the local Immunization Compliance Manager (ICM) or team members or IMM, vaccine manufacturer(s), or both for appropriate actions or guidelines that should be

followed for all potentially compromised vaccines. Do not discard vaccines unless directed to by IMM.

Staff Training and Education

A primary vaccine coordinator should be designated who is responsible for ensuring that vaccines are stored and handled correctly at each facility. Designate at least one alternate (back-up) vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator. These responsibilities include, but are not limited to, the following tasks:

- Ordering vaccines.
- Overseeing proper receipt and storage of vaccine deliveries.
- Organizing vaccines within the storage unit(s).
- Temperature monitoring of the storage unit(s) with a calibrated continuous digital data logger.
- Recording temperature readings on a log.
- Daily physical inspection of the storage unit(s).
- Rotating stock so that vaccines closest to their expiration dates will be used first.
- Monitoring expiration dates and ensuring that expired vaccines and diluents are removed from the storage unit(s) and not administered to patients.
- Responding to potential temperature excursions.
- Overseeing proper vaccine transport.
- Maintaining all appropriate vaccine storage and handling documentation, including temperature excursion responses.
- Maintaining storage equipment and maintenance records.
- Maintaining proper documentation in participating facilities.
- Ensuring that designated staff is adequately trained.

A physician partner or member of management should be directly involved with the clinical staff that is responsible for vaccine storage and handling. Management staff should have a clear understanding of the vaccine replacement costs and clinical implications of mismanaged vaccines.

All personnel who handle or administer vaccines should be familiar with the storage and handling policies and procedures for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine.

CDC has a free web-based storage and handling module as part of the online training tool, “You Call the Shots,” at [http:// www.cdc.gov/vaccines/ed/youcalltheshots.htm](http://www.cdc.gov/vaccines/ed/youcalltheshots.htm). Continuing education credit for a variety of healthcare professionals and a certificate of completion are available.

Receiving and Unpacking Vaccine Deliveries

Proper vaccine storage and handling is important from the moment the vaccine arrives at the facility. All office staff should be trained to notify the vaccine coordinator or the alternate (back-up) coordinator when a vaccine delivery has arrived. This is extremely important for receptionists or other front desk staff since they may be the first to know that vaccines have been delivered. Avoid having other people accept deliveries who may not understand the importance of storage at appropriate temperatures. The vaccine coordinator should request delivery during office hours and update vaccine orders to reflect any period of time the office will be closed, such as holidays or scheduled vacation time.

Examine deliveries right away and store vaccines at the proper temperatures immediately upon arrival. Examine the shipping container and its contents for any evidence of damage during shipment. Cross check the contents with the packing slip to be sure they match. Check heat and cold temperature monitors/indicators if either are included in the shipping container following instructions on the monitors for reading and reporting. If a monitor indicates a possible temperature excursion during shipping, the monitor reading should be documented for future reference. Report the reading to the distributor immediately. Vaccines sent directly by the manufacturer are in specially designed boxes and may not contain heat or cold temperature monitors.

Allowable shipping time varies among distributors and manufacturers and is dependent on the type of container and pack-out. Determine if shipping time was within allowable limits noted on shipping insert or container. If the shipping time was more than the allowable limit or there are any discrepancies with the packing slip or concerns about the contents, immediately notify the primary vaccine coordinator (or the alternate [back-up] coordinator). If neither is available, notify a supervisor immediately. Label the vaccines "DO NOT USE" and store the vaccines under appropriate conditions separate from other vaccines. Contact your ICM and team, the distributor, and/or vaccine manufacturer(s) for guidance.

Record the contents of each container on an inventory log (stock record). This log should include the name of each vaccine, the number of doses for each vaccine received, the date it was received, the condition of the vaccines upon arrival, the names of the vaccine manufacturers, the lot numbers, the expiration dates for each vaccine, and any action taken regarding questionable vaccines.

Vaccine Storage and Temperature Monitoring Equipment

These items should be selected carefully, used properly, maintained regularly (including professionally serviced when needed), and monitored consistently to ensure the recommended temperatures are maintained. This chapter provides only general guidelines for equipment. Providers should consult their ICM and team for any specific storage equipment requirements.

Each refrigerator must have a calibrated continuous digital data logger to record and maintain temperatures with the required range of 36-46F. In addition, keep a logbook for each piece of vaccine storage equipment. The serial number of each piece of equipment, the date each

piece of equipment was installed, the dates of any routine maintenance tasks (such as cleaning), the dates of any repairs or service, and the contact information of the service provider should be recorded. A logbook is also an ideal place to keep the instructions that came with the equipment.

Refrigerators

Using proper vaccine storage units can help prevent costly vaccine losses and the inadvertent administration of compromised vaccines. CDC recommends stand-alone units, meaning self-contained units are suitable for vaccine storage. These units can vary in size, from compact, counter-top or under-the-counter style to large, pharmaceutical grade units. Studies demonstrated that stand-alone units maintain the required temperatures better than combination units.

If existing equipment is a household, combination refrigerator/freezer, CDC recommends using only the refrigerator compartment for refrigerated vaccines. This applies to both temporary and long-term storage.

Any refrigerator used for vaccine storage must be able to maintain the required temperature range throughout the day, week, month, and year. The unit should be dedicated to the storage of biologics and must be large enough to hold inventory a provider might have at the busiest point in the year without crowding (including flu vaccine). There should also be enough room to store water bottles in the refrigerator to stabilize the temperatures and help maintain temperature longer in a power outage.

Good air circulation around a vaccine storage unit is essential for proper cooling functions. A storage unit should be in a well-ventilated room with space around the sides and top and at least 4 inches between the unit and a wall. Nothing should block the cover of the motor compartment and the unit should be level and stand firmly with at least 1 to 2 inches between the bottom of the unit and the floor.

CDC does not recommend storage of any vaccine in a dormitory-style or bar-style, combined refrigerator/ freezer unit under any circumstances, even temporarily. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment within the refrigerator. These units have exhibited severe temperature control and stability issues throughout the entire storage area. Dormitory-or bar-style units pose a significant risk of freezing vaccines, even when used for temporary storage. The use of this type of unit is prohibited for storage of VFC vaccines or other vaccines purchased with public funds.

Temperature Monitoring Devices

Temperature Monitoring is a critical part of good storage and handling practice. CDC recommends using only a calibrated digital data logger with a current and valid certificate of calibration testing (also known as a Report of Calibration). This certificate informs the user of a temperature monitoring device's level of accuracy compared to a recognized standard. Calibrated

temperature monitoring devices are required for providers who receive VFC vaccines or other vaccines purchased with public funds.

All temperature monitoring devices, through normal use, drift over time, which affects their accuracy. Because of this, temperature monitoring devices should undergo periodic calibration testing. Testing should be performed every 1 to 2 years from the last testing date or according to the manufacturer's suggested timeline. CDC recommends that testing meets standards defined in the Vaccine Storage and Handling Toolkit. If calibration testing indicates that your temperature monitoring device is no longer accurate, it should be replaced.

Several types of temperature monitoring devices are available. CDC recommends digital data loggers with the following characteristics: a digital display easily readable from outside the unit; a detachable probe in a buffered material, which more closely reflects vaccine temperatures rather than air temperature in the unit; an alarm for out-of-range temperatures; current and minimum and maximum temperature accuracy within $\pm 1^{\circ}\text{F}$ ($\pm .5^{\circ}\text{C}$); a low battery indicator; memory that stores at least 4000 readings; and user programmable logging interval. CDC recommends a back-up digital data logger for each vaccine storage unit. Staff should be trained and understand how to set up, read and analyze temperature data provided by the data logger.

Temperature monitoring device placement within the unit is just as important as device selection. Place the buffered probe with the vaccines. This should be in the middle, center of the storage unit away from walls, ceiling, cooling vents, door, floor, and back of the unit. Prior to storing vaccines in a unit, allow the unit temperature to stabilize for a week before placing vaccines in the unit. CDC recommends using a digital data logger to monitor the temperature in the storage unit prior to storage of vaccines.

Temperature Monitoring

Regular temperature monitoring is key to proper cold chain management. Store all other routinely recommended vaccines in a refrigerator between 36°F and 46°F (2°C and 8°C). The desired average refrigerator vaccine storage temperature is 40°F (5°C). Exposure to temperatures outside these ranges may result in reduced vaccine potency and increased risk of vaccine-preventable diseases.

CDC recommends reviewing and recording temperatures in the refrigerator units at least two times each workday, in the morning and before leaving at the end of the workday. This best practice recommendation applies to all vaccine storage units, regardless of whether or not there is a temperature alarm, or a digital data logger that continuously records temperatures in the unit. These readings will provide a better indication of any problems with the storage unit's function.

Reviewing and recording temperatures also provides an opportunity to visually inspect the storage unit, reorganize the vaccines when necessary (e.g., moving vaccine away from walls or cold air vents), identify vaccines and diluents with short expiration dates, remove any expired vaccines and diluents, and provide a timely response to temperature excursions. Post a temperature log on each storage unit door or nearby in a readily accessible and visible location. In addition, if using a device that enables download of temperature data, review and

store data at least once every week and reset the device before returning to storage unit monitoring.

CDC recommends maintaining an ongoing file of temperature data, including hard copies and downloaded data for at least 3 years or according to individual state record retention requirements. As the storage unit ages, recurring temperature variances or problems can be tracked and documented. This data can be important when evaluating the need for a new storage unit or if there is a potential need to recall and revaccinate patients because of improperly stored vaccine.

Twice daily temperature monitoring may not be accomplished when a provider's office is closed. A digital data logger that stores data and/or can be accessed remotely can provide information on storage temperatures while the office is closed and help assure that timely corrective action can be taken if temperatures go out of range. Providers should determine how they are to be notified in the event of an emergency (e.g., a power outage) during hours when the facility is not open.

Equally important to temperature monitoring is taking timely corrective action when there is a temperature excursion. If it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but separated from other vaccine supplies and marked "DO NOT USE" until guidance can be obtained. Contact your ICM and team, and vaccine manufacturer(s) for guidance.

Vaccine, Diluent Placement and Labeling

Vaccines should be stored in the center of the unit as this is the area where appropriate temperatures are typically most stable. A storage unit should be big enough so that vaccines can be placed in the part of the unit best able to maintain the constant, required temperature away from the walls, coils, cooling vents, ceiling, door, and floor and back of the unit. Vaccines and diluents should be kept in their original packaging with the lids on until ready for administration and stacked in rows with vaccine and diluent of the same type. Trays or uncovered containers/bins that allow for air circulation can be used to organize the vaccines and diluents within the storage unit. Do not store vaccines in unit doors or in deli, vegetable, or fruit crisper drawers. Avoid storing vaccines on the refrigerator top shelf. If the top shelf must be used, place water bottles close to the vent and only store vaccines not sensitive to coldest temperatures (e.g., MMR).

Some diluents must be refrigerated and others may be stored in the refrigerator or at room temperature. Always follow the manufacturer's guidance in the product information/package inserts. If possible, store diluent next to the corresponding vaccine. Some of these diluents may contain vaccine antigen.

There should be space between the vaccine and diluent stacks or containers. This will help to avoid confusion between products, provide for air circulation around and through stacks for even cooling, and protect vaccines from unnecessary light exposure. Not only live attenuated

vaccines, but also some inactivated vaccines must be protected from light. Information on light sensitivity can be found in the manufacturer's product information/package insert.

Each vaccine and diluent vial or container should be clearly labeled. This can be accomplished by attaching labels directly to the shelves on which vaccines and diluents are stored or by placing labels on the containers. Store all pediatric and adult vaccines on different shelves. Use color coded labels that include the vaccine type, as well as age and gender indications, if applicable. Having each vaccine and diluent vial or container labeled helps decrease the chance that someone will inadvertently administer the wrong vaccine or use the wrong diluent to reconstitute a vaccine. Vaccines that sound or look alike should not be stored next to each other, e.g., DTaP and Tdap. VFC vaccines and other vaccines purchased with public funds should be identified and stored separately from vaccines purchased with private funds.

Vaccine Storage Troubleshooting

To maintain the proper temperature ranges, the refrigerator units must be in good working condition and they must have power at all times. There are several things that can be done to prevent problems.

Plug storage units directly into wall outlets. Do not use power outlets with built-in circuit switches (they have little red reset buttons), outlets that can be activated by a wall switch, or multi-outlet power strips. These can be tripped or switched off, resulting in loss of electricity to the storage unit. Plug only one storage unit into an outlet. This will help to prevent a safety switch from being triggered to turn off power and reduce the risk of overloading the outlet which could be a fire hazard.

Use plug guards or safety-lock plugs to prevent someone from inadvertently unplugging the unit. A temperature alarm system that will alert staff to after-hour temperature excursions, particularly if large vaccine inventories are maintained, may be helpful in assuring a timely response to storage problems. Label circuit breakers to alert custodians and electricians not to unplug vaccine storage units or turn off the power. This can be done by posting a warning sign near the electrical outlet, on storage units, and at the circuit breaker box. Warning signs should include emergency contact information.

Place containers of water, labeled "DO NOT DRINK," in the refrigerator to help stabilize the temperature in the unit. Place water bottles where vaccines are not stored, such as the door, top shelf, and on the floor of the storage unit. Be careful that the water bottles do not weigh down doors so much that the seals are compromised and the doors do not close properly. These measures will help keep the temperature stable with frequent opening and closing of the storage unit.

In addition to temperature monitoring, a physical inspection of storage units should be performed daily. An inspection should include the following:

- Are the vaccines placed properly in the unit?
- Are the vaccines in their original packaging?

- Are vaccines being stored away from the walls, coils, cooling vents, ceiling, and floor and not in the doors?

During a workday it is easy for vaccines to be shifted into an area of the storage unit where the temperature may not be appropriate or stable, such as against a wall, under a cold air vent, or in the door. CDC recommends that vaccines be kept in storage units dedicated only to vaccines. If other biologic specimens, such as blood or urine, must be stored in the same unit as vaccines, specimens should be stored on a lower shelf. This is to ensure that if a specimen leaks, the vaccines will not be contaminated. Food and beverages should not be stored in a vaccine storage unit because frequent opening of the unit can lead to temperature instability.

While it is important to take measures to prevent problems, equally important is taking immediate corrective action when a problem does exist, for example, when the storage unit temperature falls outside the recommended range. Staff should know who to contact in case of a malfunction or disaster.

If you experience a power outage, immediately begin to implement your emergency plan. Depending on room temperature, storage temperatures may be maintained for only a very short period of time. If there is an extended period of time before the situation can be corrected and there are no other storage units available on site, move the vaccines to the back-up storage facility using the guidelines in the emergency plan.

Vaccine and Diluent Inventory Control

Conduct a vaccine inventory monthly to ensure adequate supplies to meet demand. Include vaccine diluents in the inventory. Determining factors for the amount of vaccine and diluent ordered include: projected demand, storage capacity, and current vaccine supply. Avoid overstocking vaccine supplies, which could lead to vaccine wastage or having outdated vaccine on hand.

Check vaccine and diluent expiration dates a minimum of weekly. Rotate stock so that vaccines and diluents with the soonest expiration dates are used first to avoid waste from expiration. If the date on the label has a specific month, day, and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the last day of that month. A multi-dose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

Some vaccines should be used within a certain time frame after the first time a needle is inserted (e.g., multi-dose vials), after the vaccine is reconstituted (e.g., vaccines requiring reconstitution), or if the manufacturer deems it is necessary to shorten the expiration date. This time frame is called the "beyond use date" or BUD. The BUD is the date or time after which the vaccine should not be used. It may not be the same as the expiration date printed on the vial by the manufacturer. The BUD varies among vaccines and can be found in the package insert.

Check the package insert to determine if the vaccine has a BUD, and for the correct time frame (e.g., days, hours) the vaccine can be stored once the vial has been entered or has been reconstituted. Calculate the BUD using the time interval found in the vaccine's package insert. Label the vaccine with the correct beyond use date/time and your initials. Refer to the CDC's Vaccine Inventory Management for specific vaccine product information, including the beyond use dates at <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handlingtoolkit.pdf>. Note on a vial any change from the original expiration date/time printed on it, along with your initials. Never use expired vaccine or diluent and immediately remove them from the storage unit.

Emergency or Off-Site/ Satellite Facility Transport

General guidance regarding transport is provided here and in CDC's Vaccine Storage and Handling Toolkit.

Vaccine manufacturers do not generally recommend or provide guidance for transport of vaccines and CDC discourages regular transport. If possible, have vaccines delivered directly to the off-site/satellite facility. Each transport increases the risk that vaccines will be exposed to inappropriate storage conditions.

Plan for emergencies by ensuring you have the proper equipment to maintain the cold chain procedures during transport. CDC recommends that if emergency transport of vaccines is necessary, it should be done using a qualified container and pack-out or portable refrigerator. Vaccine manufacturers do not recommend re-use of shipping containers and packing material for routine transport.

If vaccines must be transported to an off-site/satellite facility, the amount of vaccines transported should be limited to the amount needed for that workday, including transport and work time (maximum 8 hours). CDC recommends using a digital data logger with a current and valid certificate of calibration testing. CDC does not recommend cold chain monitors (CCMs) since they do not provide adequate data on excursions that may occur during transport.

The facility's standard operating procedure (SOP) should specify that:

- Vaccines are attended at all times during transport to maintain the cold chain.
- Vaccines are not placed in the vehicle trunk.
- Vaccines are delivered directly to the facility.
- Vaccines are promptly unpacked and placed in appropriate storage units on arrival.

A digital data logger with a current and valid certificate of calibration testing is placed with the vaccines during transport.

Diluents should be transported with their corresponding vaccines to ensure that there are always equal numbers of vaccine and diluent for reconstitution. Follow manufacturer guidance for specific temperature requirements. Diluents that contain antigen (e.g., DTaP-IPV diluent used with Hib lyophilized vaccine) should be transported with their corresponding vaccines at refrigerator temperature. NEVER transport any diluents at freezer temperature. Refer to CDC's Vaccine Storage and Handling Toolkit for guidance on vaccine and diluent transport.

Monitoring Temperatures at Off-Site/ Satellite Facility

Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the alternate facility. CDC recommends placing a digital data logger in the storage unit(s) with the vaccines. Read and document temperatures 2 times during the workday. CDC does not recommend keeping vaccines in a transport container unless it is a portable refrigerator unit. If vaccines must be kept in transport containers during an off-site clinic:

- Container(s) should remain closed as much as possible.
- Calibrated temperature monitoring device(s) (preferably with a buffered probe) should be placed as close as possible to vaccines.
- The temperature(s) inside the containers(s) should be read and documented at least hourly.
- Only the amount of vaccine needed at one time (no more than 1 multi-dose vial or 10 doses) should be removed for preparation and administration by each vaccinator.