

Policy for School-located Influenza Vaccination Clinics

Definition: Influenza is an acute infectious disease characterized by fever, chills, myalgia, headache, respiratory and/or gastrointestinal symptoms. Influenza A (including H1N1) and B are the two types of influenza viruses that cause human disease. Influenza viruses are spread from person to person primarily through the coughing and sneezing of infected persons. The typical incubation period for influenza is 1-4 days with an average of 2 days.

Purpose: To provide guidance for vaccine providers planning and conducting influenza vaccination clinics targeting school-aged children enrolled in elementary, middle, and high schools in Alabama.

Glossary:

ADPH – Alabama Department of Public Health
CDC – Centers for Disease Control and Prevention
LAIV – live, attenuated influenza vaccine
SLIC – School Located Influenza Clinics
IIV – inactivated influenza vaccine
ILAC – International Laboratory Accreditation Cooperation
MRA – Mutual Recognition Arrangement
TIV – trivalent influenza vaccine
QIV – quadrivalent influenza vaccine
VFC – Vaccines for Children program
VIS – Vaccine Information Statements

Procedure:

1. VFC providers who meet the requirements outlined herein shall be authorized by the Alabama Department of Public Health to administer the influenza vaccine at school-based clinics.
2. An emergency plan must be in place in the event of anaphylaxis or symptoms of immediate hypersensitivity following administration of the vaccine. Prior to the clinic, all school vaccine providers attending the clinic shall be familiar with the emergency procedures for anaphylaxis and the administration of epinephrine and diphenhydramine (Benadryl).
3. VFC providers must follow the VFC program requirements as outlined in the VFC provider profile that is signed each year.
4. To maximize protection from influenza vaccine during the peak months of influenza disease (flu disease in AL is typically at its peak in January/February), clinics need to be

completed by February 28. For those patients who require a second dose of influenza vaccine, these doses should be administered by the end of February. Exceptions may be made solely at the discretion of the ADPH based on special circumstances such as morbidity trends or vaccine shortages.

5. No greater than 30 days prior to the administration of the vaccine, the parent/guardian shall be given both of the current vaccine year's Vaccine Information Statements (VIS) for the vaccine that is to be administered (LAIV and TIV/QIV). The **National Childhood Vaccine Injury Act** (NCVIA) requires that patients (or their parent or legal representative) be given, or shown, a copy of the appropriate Vaccine Information Statement prior to receipt of any vaccine listed on the routine childhood immunization schedule – this is Federal law. The year of the VIS must match the year of the vaccine.
6. No greater than 30 days prior to the administration of the vaccine, the parent/guardian shall be sent a consent form for their child to receive flu vaccine. By use of the consent form, the school vaccine provider shall obtain a health history for the purpose of determining possible contraindications to receiving the vaccine and to determine the number of vaccines appropriate for each child this season (i.e., if the child is under the age of 9 and has never received influenza vaccine before, that child needs two doses).
7. No greater than 30 days prior to the administration of any second doses of vaccine, the parent/guardian shall be sent a second consent form and VIS for their child to receive flu vaccine. By use of the consent form, the school vaccine provider shall obtain the most current health information for the purpose of determining possible contraindications for receiving the second dose of vaccine.
8. VFC providers must follow all ACIP recommendations.

CONTRAINDICATIONS:

9. The following persons are not to receive the injectable influenza vaccine (TIV/QIV):
 - a) Children less than 6 months of age
 - b) Persons who are known to have anaphylactic hypersensitivity or severe allergy to eggs or to other components of the influenza vaccine
 - c) Persons that have had a severe reaction after receiving a previous dose of influenza vaccine
 - d) Persons with a history of Guillian-Barre Syndrome
 - e) Persons who are moderately or severely ill (i.e., fever of $>100^{\circ}\text{F}$).
10. The following persons are not to receive the intranasal vaccine (LAIV):
 - a) Children less than 2 years of age
 - b) Children younger than 5 years of age with asthma or one or more episodes of wheezing within the past year
 - c) People who have long-term health problems with heart disease, lung disease, asthma, kidney or liver disease, metabolic disease such as diabetes, and anemia or other blood disorders

- d) Anyone with certain muscle or nerve disorders such as seizure disorders or cerebral palsy that can lead to breathing or swallowing problems
- e) Anyone with a weakened immune system
- f) Children or adolescents on long-term aspirin treatment
- g) Pregnant adolescents or women
- h) Persons in close contact with anyone who has a severely weakened immune system requiring care in a protected environment, such as a bone marrow transplant unit
- i) Anyone with a nasal condition serious enough to make breathing difficult
- j) Persons who are known to have anaphylactic hypersensitivity or severe allergy to eggs or to other components of the influenza vaccine
- k) Persons that have had a severe reaction after receiving a previous dose of influenza vaccine
- l) Persons with a history of Guillian-Barre Syndrome
- m) Persons who are moderately or severely ill (i.e., fever of $>100^{\circ}\text{F}$)
- n) Persons who have received live attenuated or an injectable live-virus vaccine (e.g., MMR, varicella, yellow fever) in the past 4 weeks should wait 28 days before receiving another live virus vaccine.

ABSOLUTE CONTRAINDICATIONS:

11. Absolute contraindications for administration **in school-based settings** include:

- a) Persons who have experienced a severe allergic reaction to a prior dose of influenza (TIV or LAIV), or who are known to have a severe allergy to a vaccine component. These persons should not be vaccinated but referred back to their primary care provider. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to receipt of the vaccine.
- b) Persons with severe egg allergy defined as a person who develops hives or anaphylaxis after ingesting eggs. Note: CDC recommends (1) they receive TIV (not LAIV), (2) the vaccine be administered by a healthcare provider familiar with the potential manifestations of egg allergy, and (3) the vaccine recipient be observed for at least 30 minutes after receipt of the vaccine for signs of a reaction. Refer persons with a history of hives or severe egg allergy back to their primary care provider.
- c) Persons with moderate to severe acute illness. Vaccination should be deferred for a person with moderate or severe acute illness until his/her condition improves. Please refer these children back to their primary care physicians with the reasons for referral noted.

- d) Precautions should be used with persons with hemophilia. A patient with hemophilia can be vaccinated if they provide a note indicating such from their physician.
 - e) Refer all children with absolute contraindications back to their primary care provider.
12. Vaccine should be provided that meets the needs of all VFC children served during the flu clinic. Please refer to numbers 8 and 9 above. If a child has a contraindication to one formulation but not the other, that child should be given the appropriate formulation. For example, a child has asthma which is a contraindication to nasal mist but no contraindications to injectable, that child should receive the injectable. Both formulations of influenza vaccine should be available, and choice for an individual student should be based on medical issues and parental/student preference.
13. The school vaccine provider shall have the parent/guardian sign the appropriate consent form (sent home no greater than 30 days prior to the administration of the vaccine) which shall include the following:
- a) The vaccine recipient's name, address, telephone number, date of birth, and name of their primary healthcare provider.
 - b) The signature of the parent/guardian indicating their consent for the vaccine administration and allowing parent to choose between LAIV and TIV/QIV to be administered to their child.
 - c) VFC eligibility status – no VFC-eligible child may be turned away due to their eligibility status or the parent/guardian's inability to pay.
 - d) Insurance category – including space for their insurance carrier and policy number.
 - e) The name of the vaccine, dosage, manufacturer, lot number, site of injection (list "nasal" for LAIV), and expiration date.
 - f) The signature of the provider administering the vaccine.
 - g) The date of the administration of the vaccine.
14. A copy of each individual consent form shall be retained by the provider for a minimum of 10 years.

Storage and Handling of Influenza Vaccines:

All non-direct ship vaccine doses purchased through CDC's federal vaccine purchase contracts will be distributed via CDC's centralized distributor. Under centralized distribution, provider orders that include federally-funded vaccine shall only be sent to immunization providers (VFC providers) who administer vaccine, not to depots for further distribution.

- a. A provider is defined as an individual or entity that administers the vaccine it receives to patients, either at the site the vaccine is received or at an alternative site where federally-

funded vaccine is not routinely stored during non-clinic hours and to which the recipient of the order takes the vaccine on the date of service and then administers it to patients.

b. Any provider who stores federally-funded vaccine during non-clinic hours should place orders independently, using a unique PIN number. Any such provider site must be an active VFC provider's office and must have an individual who is responsible for proper vaccine storage and handling on site.¹

Vaccine should be limited in the number of times that it is moved and handled. A location in closest proximity (i.e., same county) to the mass clinic locations will reduce the risk of compromising the cold chain. If stored at an off-site facility, vaccine must be stored at an enrolled and active VFC provider office within the same county where the mass/SLIC clinics are being held. The VFC provider would be responsible for maintaining the vaccine and performing all VFC requirements including proper storage and handling procedures.

If vaccines must be transported to an off-site facility, the amount of vaccines transported should be limited to the amount needed for that workday to avoid potential loss of vaccines. Vaccines should be (a) attended at all times during transport; (b) not placed in the trunk of the vehicle; (c) delivered directly to the facility; (d) promptly unpacked and placed into appropriate storage units upon arrival unless transported in CDC recommended portable refrigerator units; and (e) at the end of the clinic day, the vaccine must be returned to the VFC provider's office for storage.

Packing Vaccines for Transport

CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain the recommended temperature range (between 35° and 46°F [2° and 8°C]). The packing of vaccines for transport consists of 6 layers (coolant, barrier, thermometer/vaccine, barrier, coolant, and barrier).

- * Place a layer (at least 2 inches) of "conditioned" coolant packs in the transport container first. Coolant packs that are frozen must be "conditioned" by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and the packs look like they've been "sweating." Frozen coolant packs that are not "conditioned" can freeze vaccine.
- * Place an insulating barrier on top of the coolant packs (e.g., bubble wrap or Styrofoam pellets).
- * Place a calibrated thermometer (digital data logger with a biosafe glycol-encased thermometer probe) on top of the barrier next to the vaccines.

¹ Immunization Program Operations Manual, Unit A, Program Stewardship and Accountability, page 7.

- * Stack the vaccines on top of the barrier and thermometer, ensuring that the vaccines do not touch the coolant packs.
- * Place another insulating barrier layer on top of the vaccines.
- * Place another layer of “conditioned” coolant packs on top of the insulating barrier layer, ensuring there is no direct contact between the coolant packs and the vaccines.
- * Place a final insulating barrier layer (at least 2 inches) on top of the coolant packs along with an inventory list of the vaccines in the container.²

If transport is necessary on a regular basis, the provider should use a portable refrigerator or freezer for transport, especially if over 8 hours and if the vaccine is stored in these units during the off-site clinic. These units can be purchased for \$500-\$1500 depending on the size needed or leased.

No matter what container is used, the vaccine must be monitored at all times by a calibrated temperature monitoring device, digital data logger with a probe in buffered material, that provides continuous monitoring information and can be downloaded for review.

Monitoring Temperatures at Off-Site Facilities

Vaccines should be placed in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the school clinic. CDC does not recommend keeping vaccines in the transport container(s) unless it is a portable refrigerator unit. Place a calibrated digital data logger in the storage unit(s) with the vaccines. If vaccines must be kept in a transport container(s) during an off-site clinic:

- (a) The container(s) should remain closed as much as possible.
- (b) Only the amount of vaccine needed at one time should be removed for preparation and administration.
- (c) The calibrated thermometer(s) (digital data logger with biosafe glycol-encased probe) should be placed as close as possible to the vaccines.
- (d) The temperature(s) inside the container(s) should be read and documented hourly.³ Vaccines exposed to temperature excursions must be labeled "do not use" until further information can be gathered from the manufacturer(s) and awardee on the usability of the vaccine. At the end of each clinic day, the mass vaccinator must assess temperature data temperatures prior to placing vaccine back into storage units to prevent inadvertent administration of vaccine that may have been compromised.
- (e) Use of a digital data logger with a biosafe glycol-encased probe that will measure liquid temperature is required. Studies by the National Institutes of Standards and Technology (NIST) conducted in 2009 showed that compared to temperature monitors that measure ambient air temperature, the digital data logger with glycol-encased probe more accurately reflects the temperature of the vaccine vial and does not register extraneous air temperature fluctuations which do not impact vaccine temperature. Because the main factor affecting

² CDC's Vaccine Storage and Handling Toolkit, pages 91, 93-94.

³ CDC's Vaccine Storage and Handling Toolkit, pages 95-96.

potency of refrigerated vaccines is exposure to freezing temperatures, it is important that glycol-encased probes be placed in the same area where the vaccine is stored, and at least for refrigerated vaccines, in the part of the refrigerator unit where appropriate temperatures are best maintained.

The use of a digital data logger with a biosafe glycol-encased probe should be able to provide continuous data monitoring information in an active display and be placed on the outside of the unit door to allow for reading temperatures without opening the unit door. The data stored in the thermometer should be easily downloadable for review. This means that the digital data logger should have a detachable probe (that is kept in the glycol-filled bottle). A detachable probe facilitates downloading temperature data without removing the probe from the storage unit, and should simplify daily use and minimize operator cause of temperature variability. The digital data logger should also include the following:

- * Alarm for out-of-range temperatures;
- * Current temperature, as well as minimum and maximum temperatures;
- * Reset button;
- * Low battery indicator;
- * Accuracy of $\pm 1^{\circ}\text{F}$ (0.5°C);
- * Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full;
- * User programmable logging interval (or reading rate).

Providers enrolled in the VFC Program are required to have calibrated data loggers in all refrigerator and freezer compartments used for VFC vaccine storage in order to monitor temperatures. Each device is to be covered by a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Thermometer calibration must be tested annually or according to manufacturer recommendations by a laboratory with accreditation from an ILAC MRA signatory body. Laboratories that have attained this accreditation meet the requirements for traceability. Providers are responsible for maintaining Certificates of Traceability and Calibration Testing (also known as Report of Calibration).⁴

For additional information, please refer to the Alabama VFC Enrollment packet, Alabama VFC Provider Manual, CDC's Vaccine Storage and Handling Toolkit, and CDC's Immunization Program Operations Manual.

⁴ VFC Operations Guide, M-6 Vaccine Management, pgs. 4-6