Policy & Procedure Summary

The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times.

The Indiana Immunization Division supports the implementation of off-site clinics for the vaccination of children and adults in non-traditional clinic settings. All off-site clinics should be approved by the Immunization Division and should be in conjunction with the respective Local Health Department (LHD.) Please provide both agencies with advance notification of the clinics. The Immunization Division requests a minimum of 30 days notification, understanding that outbreak response may be an exception. Each off-site clinic will be required to complete a check-list to ensure they are following proper procedures for holding a clinic off-site.

Policy Statement

This policy supersedes all policies previously issued by the Indiana Immunization Division addressing the transport of publicly funded vaccine. It replaces the following policy:

Title of Policy: School Clinics
Policy Number: II-05
Removed from Policy and Procedures Manual March 2011

Title of Policy: Non-Traditional Sites for Immunization Services
Policy Number: II-07
Removed from Policy and Procedures Manual March 2011

Providers MUST receive prior approval from the Indiana Immunization Division before transporting vaccines to another enrolled provider office or to an off-site clinic. This notification is to ensure all vaccine transport practices and procedures are practiced and that proper screening for eligibility will be taking place. Notification of any scheduled off-site clinics must be made at least 30 days prior to the scheduled event with the off-site checklist completed at that time. The Immunization Division can be reached at (800)701-0704.

Most often, vaccine transport is conducted by a field representative from the Indiana Immunization Division. All vaccinations administered during an off-site clinic must be entered into CHIRP within seven (7) days.

Providers hosting an off-site clinic are responsible for the return transport and permanent storage of any additional doses of vaccine not administered during the clinic.

Providers are not allowed to transfer vaccines to another provider/facility regardless of their enrollment status in one of Indiana’s Publicly Funded Vaccine Programs without prior approval from the Indiana Immunization Division.

Having a patient pick up a dose of vaccine at a pharmacy and transporting it in a bag to a clinic for administration is not an acceptable transport method for varicella-containing or any other vaccine.
Vaccine Transport and Temperature Monitoring for Off-Site Clinics

Changes have been made to the requirements for transport of vaccines to any off-site clinic beginning on or after January 1, 2018. Providers will no longer follow the procedures for emergency transport of vaccines and they can no longer transport vaccines to/from off-site clinics in hard-side coolers or coolers available at general merchandise stores.

All off site clinics must follow the following requirements:

1. All clinic must use portable vaccine refrigerators/freezers or qualified pack-out units. These types of units are defined in the Centers for Disease Control and Prevention Storage and Handling Toolkit as a type of container and supplies specifically designed for use when packing vaccines for transport. They are qualified through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time.

2. Digital data loggers with a buffered probe and a current and valid Certificate of Calibration Testing must be placed directly with the vaccines and used to monitor vaccine temperature during transport.

3. If vaccines are transferred to a permanent storage unit at the location of the off-site clinic, the storage unit must meet the minimum storage requirements for storage of VFC vaccines and the unit must have been monitored prior to the clinic day with a digital data logger. If vaccines cannot be stored in a permanent storage unit at the clinic location, they can be kept in the portable unit or qualified pack-out.

4. Vaccines must be monitored during the clinic using a digital data logger at least once an hour and documented on the Refrigerator Temperature Log. The Indiana Immunization Division has developed an hourly temperature monitoring form located in the References and Resources section of this policy to assist with this process.

5. Within the 24 hours following completion of the off-site clinic and return of all vaccines to the permanent storage unit, the data logger must be downloaded and the report must be reviewed and sent to the respective field representative.

Use of Multi-dose vials and Diluent at Off-Site Clinics

When a multi-dose vial is used, Food and Drug Administration (FDA) regulations require that it be used only by the provider’s office where it was first opened. A partially used vial may be transported to or from off-site clinics operated by the same provider as long as the cold chain is properly maintained. However, such a vial may not be transferred to another provider or transported across state lines. While there is no defined limit to the number of times vaccine may be transported to different clinic sites, each transport increases the risk that vaccine will be exposed to inappropriate storage conditions.

Diluent should travel with its corresponding vaccine to ensure that there are always equal numbers of vaccine vials and diluent vials for reconstitution. Diluent should be transported at room temperature or inside the same insulated cooled container as the corresponding vaccine, according to manufacturer guidelines for each diluent. If transported inside cooled containers, diluent must not be in direct contact with conditioned water bottles because of the potential for freezing. If any diluents that have been stored at room temperature are going to be carried in the insulated transport container, refrigerate the diluents in advance so they do not raise the temperature of the refrigerated vaccines. Do NOT transport any diluent, including the diluent for varicella-containing vaccines, on dry ice.

Transporting Varicella-Containing Vaccines to Off-Site Clinics
CDC strongly discourages transport of varicella-containing vaccines to off-site clinics, because Varicella-containing vaccines (VAR, Varivax; MMRV, ProQuad; ZOS, Zostavax) are sensitive to temperature excursions. Portable freezers may be available for rent in some places. Providers who choose to transport these vaccines to an off-site clinic, must follow the appropriate procedures:

- Transporting with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C) is best practice. Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines for an off-site clinic.

- The use of dry ice is not allowed, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

- Discard reconstituted vaccine if it is not used within 30 minutes.

- Varicella-containing vaccines may be transported and stored at refrigerator temperatures, between 36°F and 46°F (2°C to 8°C), for up to 72 continuous hours prior to reconstitution. Varicella-containing vaccine stored at refrigerator temperatures must be discarded if it is not used within 72 hours. If the vaccines must be transported at refrigerated temperatures, follow these steps (Please note: this is considered to be a temperature excursion):

  1. Place a calibrated, glycol-encased, digital data logger probe in the container used for transport as close as possible to the vaccines

  2. Place the vaccines in the freezer between -58°F and +5°F (-50°C and -15°C) and label "DO NOT USE" immediately upon arrival at the alternate storage facility. Contact the vaccine manufacturer prior to using varicella vaccine that has experienced the temperature excursion

  3. Document:

     a. The time the vaccines are removed from the container and placed in the alternate storage unit and the time the vaccines are removed from the storage unit and placed in the container

     b. The temperature at the beginning, during and end of transport

This policy prohibits providers from refreezing varicella-containing vaccines that are stored at refrigerated temperatures, so please plan accordingly with your vaccine doses.

Do not discard any unused vaccine without first contacting the manufacturer, and the Indiana Immunization Division at (800) 701-0704

Procedure Details

Step 1) Providers should contact the Immunization Division to discuss plans for an off-site clinic and complete off-site checklist.
Step 2) Providers should keep an adequate supply of packing materials (i.e. coolers/insulated shipping containers, bubble wrap/packing materials and frozen water bottles) to accommodate the facility’s clinic supply.

Step 3) Providers should conduct routine temperature readings and record on a temperature log throughout the clinic day.

References & Resources


Additional Resources can be found at the National Adult and Influenza Immunization Summit website at: https://www.izsummitpartners.org/naiis-workgroups/influenza-workgroup/off-site-clinic-resources/

Off-Site Clinic Refrigerator & Freezer Temperature Log

Inventory Control Log - Vaccine Going into Cooler

Vaccine Wastage Log

Immunization Clinic Consent Form(s)

Revision History
07/17/2012, Created
11/19/2014, Revised
02/15/2016, Revised
04/01/2017, Revised
01/01/2018, Revised