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<p><b>Title:</b> Storage and Handling - Transporting to Off-Site Clinics 2024</p>	<p><b>Policy #:</b> IDOH Immunization Division Policy 12</p>
<p><b>Effective dates:</b> 01-Jan-24 to 31-Dec-24</p>	<p><b>Approvals:</b></p> <p><i>Dave McCormick</i></p> <hr/> <p>Dave McCormick, Immunization Director</p> <p>July 7, 2024</p> <hr/> <p>Date</p>

## Policy Statement

This policy is for the transport of vaccines to an off-site clinic in non-emergency situations; for information regarding emergency transport of vaccines please see Policy 10. 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.

## Procedures

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 standards of the respective Local Health Department (LHD.) Please provide both agencies with a minimum of 30 days notification, understanding that outbreak response may be an exception. Each off-site clinic will be required to complete a checklist to ensure they are following proper procedures for holding a clinic off-site.
- All vaccinations administered at an off-site clinic must be entered into the Children and Hoosier Immunization Registry Program (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
- 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 any vaccine



## Vaccine Transport and Temperature Monitoring for Off-Site Clinics

### All off-site clinics must follow the requirements below:

All providers 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.

- Providers can no longer transport vaccines to or from off-site clinics in hard-side coolers or coolers available at general merchandise stores
- Soft-sided containers specifically engineered for vaccine transport are acceptable. Do not use commercially available soft-sided food or beverage coolers.
- 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

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 for Children) 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 for up to six (6) hours. If a unit that can be plugged into a vehicle and household outlet is used (an active cooling unit), the vaccines can be kept for up to 10 hours.

- Vaccines must be monitored during the off-site clinic using a digital data logger at least once an hour and documented in 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.
- 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 regional quality assurance specialist
- The total time for transport alone or transport plus clinic workday should be a maximum of eight (8) hours (e.g., if transport to an off-site clinic is one [1] hour each way, the clinic may run for up to six [6] hours), or 10 hours if an active cooling unit is used.

## 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 any diluents that have been stored at room temperature are going to be carried in the 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):
  - Step 1: Place a calibrated, glycol-encased, digital data logger probe in the container used for transport as close as possible to the vaccines.
  - Step 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.
- Step 3: Document:
  - 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
  - The temperature at the start, during and end of transportation

Per the manufacturer's package insert, any Varivax stored at refrigerator temperatures should be discarded if not used within 72 hours of removal from frozen storage. 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.

## References

Centers for Disease Control and Prevention. Vaccine Storage and Handling Toolkit, Revised January 2023. <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

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/>

## Forms

Off-Site Clinic Checklist

<https://www.in.gov/health/immunization/files/Off-site-clinic-checklist.pdf>

Off-Site Clinic Refrigerator & Freezer Temperature Log

<https://www.in.gov/health/immunization/files/ISDH-Refrigerator-Freezer-Temperature-Logs-Clinic-Day.pdf>

Immunization Clinic Consent Form(s)

<https://www.in.gov/health/immunization/files/School-Immunization-Clinic-Parent-Consent-Form-All-Ages.pdf>