



DIVISION OF IMMUNIZATIONS PROVIDER BULLETIN

SUBJECT: Vaccine Cold Chain Protocol for Immunization Providers

Revised 8/8/2018

By Direction Of: Thomas McCleaf, Director
Division of Immunizations, Bureau of Communicable Diseases

Policy Statement: Keeping vaccines at the recommended temperature is called **maintaining the cold chain**. The cold chain begins at the manufacturer, extends to the distributor and continues in the provider site until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability.

Vaccine cold chain failure occurs when there is a break in any link of the chain. Cold chain failure may occur due to a power failure, staff error, equipment failure, etc. Preventing vaccine cold chain failure requires: properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols.

Procedures: Vaccine cold chain protocols provide vaccine-handling procedures to maintain the cold chain and action steps to be taken in the event of a cold chain failure by provider sites receiving vaccine from the Department of Health (DOH).

I. Utilizing DOH Supplied Vaccine - Providers Shall:

- A. Follow the vaccine management guidelines as outlined in the DOH provided Vaccines for Children (VFC) Provider Handbook.
- B. Freezers and refrigerators:
DOH-approved equipment for vaccine storage and temperature monitoring
 - Any new vaccine storage equipment must be approved by the VFC program, through a site visit by the immunization nurse, prior to storing vaccine in the unit.

DOH supplied vaccine must be stored in one of the following:

- Stand-alone storage units (medical/pharmaceutical grade, highly recommended);
- Household combination unit (refrigerator portion only, must have separate stand-alone freezer); or
- Medical/pharmaceutical grade combination units.

ALL NEW providers enrolling in the VFC program are required to use stand-alone refrigerators and stand-alone freezers for vaccine storage.

- C. Absolutely NO DORMITORY style units will be accepted; this results in an immediate suspension of vaccine ordering privileges.
- All vaccines stored in a dormitory style unit are considered non-viable and must be returned to McKesson Specialty Distribution. Complete and submit a Vaccine Return Form found in the VFC Provider Handbook, section 6.
- D. DOH-approved household combination units are no longer permitted for new/replacement unit purchases.
- If a DOH-approved household combination unit is not accompanied by a stand-alone freezer, providers will be immediately suspended from ordering all VFC vaccines.
 - Providers will remain suspended until a stand-alone freezer is acquired and approved by VFC.
 - After one year of suspension, the provider will be disenrolled from the VFC program.
- E. Certified digital data logger calibration
- CDC recommends the use of continuous digital data loggers/ continuous temperature monitoring systems with detachable probes encased in a biosafe buffered material (glycol-encased probe recommended) for temperature monitoring.
 - Providers must use calibrated digital data loggers with a current certificate of traceability and calibration.
 - The best calibration is annual; however, the Department of Health will accept manufacturer suggestion but not to exceed two years.
 - Refer to the VFC Provider Handbook for a listing of digital data logger manufacturers with certificates of traceability and calibration of products from National Institute of Standards and Technology (NIST).

Effective 2018, CDC requires all VFC providers to purchase a digital data logger/continuous temperature monitoring system with an active temperature display, continuous monitoring and recording capabilities, and a detachable probe encased in a biosafe buffered material (glycol-encased probe

recommended) in all VFC storage units. VFC providers are also required to have at least one backup digital data logger/continuous temperature monitoring system with a valid and current certificate of calibration, readily available at the site, to ensure that temperature assessment and recordings can be performed twice a day.

- F. Provide training on proper vaccine storage and handling guidelines and vaccine administration protocols to each new employee at the time of employment orientation, including any additional staff that handles vaccines, and review this information annually with all staff. Maintain documentation of this training for three years.
- G. Participate in annual training /education provided by the Department of Health/CDC on proper storage and handling requirements and VFC program requirements. Maintain documentation of attendees.
- H. Develop and maintain a current written Vaccine Disaster Recovery Plan, providing guidelines to ensure the vaccine cold chain is maintained. The plan should include:
 - Identification of an alternative storage facility, such as a hospital, packing plant or local pharmacy, with back-up (generator) where the vaccine can be stored and monitored during an emergency;
 - Identification and training of staff responsible to pack and move vaccine during an emergency;
 - Maintenance of a supply of appropriate packing materials (insulated containers, ice packs, frozen water bottles, etc.);
 - Identification of transportation to move vaccine to a secure storage facility during an emergency; and
 - If frozen vaccine must be transported, it is recommended that Merck be contacted with the details.Document all transports on Vaccine Transport Monitoring Form.

II. Suspected Vaccine Cold Chain Failure - Providers Must:

- A. Refer to the Vaccine Disaster Recovery Plan and the VFC Provider Handbook for vaccine management guidance.
- B. Contact the appropriate vaccine manufacturers within one workday of a suspected vaccine cold chain failure, to determine viability of the vaccine.
- C. Request all viability research information be sent from the vaccine manufacturers to the provider, and include with incident report to DOI.
- D. Complete and submit the Vaccine Incident Report and Worksheet form and fax to the VFC Program at 717-214-7223 within five days of a suspected cold chain failure, and

- E. Be prepared to provide:
- Vaccine name;
 - Lot number;
 - Expiration date;
 - Number of doses at risk;
 - Documented refrigerator and freezer temperatures; and
 - Duration of exposure to out of range temperatures.

III. Confirmed Vaccine Cold Chain Failure - Providers Must:

- A. Notify Division of Immunizations (DOI) by completing the Vaccine Incident Report and Worksheet Form within five days of confirmation of the vaccine cold chain failure. The Quality Assurance staff will assist you if needed at 1-888-646-6864.
- B. Review refrigerator/freezer temperature logs to verify whether other "out of range" temperatures occurred that could indicate other periods of cold chain failure and submit copies with the incident report to DOI.
- C. Complete a Vaccine Return Form found in the VFC Provider Handbook, section 6.
- D. Unopened vials of all expired/wasted vaccines, including influenza vaccine, must be returned, preferably within six months, to McKesson Specialty Distribution in a prepaid McKesson shipping container. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to 717-214-7223 at the Division of Immunizations and a vaccine return label from McKesson Specialty Distribution will be emailed/mailed to the provider site. When the label arrives, enclose a copy of the Vaccine Return Form with the expired/wasted vaccines in a box and set out for UPS to pick up.
- E. Any new refrigerator/freezer equipment purchased must be approved by the VFC program through a site visit by the immunization nurse, prior to storing vaccine in the unit.
- F. Within 14 workdays of confirmation of vaccine cold chain failure, review office databases, registries, patient charts to identify those individuals receiving vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.
- G. Within 21 workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to the Division of Immunization staff outlining the steps to identify, recall and revaccinate patients who received potentially compromised vaccine.

- H. Within six weeks of confirmation of cold chain failure, contact identified patients and/or guardians of children by telephone or written correspondence and inform them of the following information:
- Purpose of recall;
 - Need for revaccination;
 - Information about available clinics and times for revaccination; and
 - Set appointments to revaccinate individuals who were vaccinated during the cold chain failure timeframe.
- I. Provide DOI with copy of patient revaccination notification letter template, without patient personal information. If notifying by telephone, please provide copy of script provider staff will use for notification of revaccination.
- J. Document appropriate vaccination information on the patient's medical record and/or immunization record.
- K. Instruct parent/guardian of a revaccinated child to provide revaccination information to the child's school and/or childcare facility.
- L. Keep an ongoing log of the number of persons revaccinated and the number of doses of each vaccine administered.
- M. Submit interim status report and/or final report as directed by Division of Immunizations to:

Pennsylvania Department of Health
Division of Immunizations
Room 1026 Health and Welfare Building
625 Forster St.
Harrisburg, PA 17120
Fax: 717-214-7223