



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section

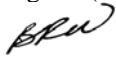
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June 18, 2012

MEMORANDUM

TO: North Carolina Immunization Program (NCIP) Participants
FROM: Beth Rowe-West, R.N., B.S.N., 
Head, Immunization Branch
SUBJECT: *URGENT:* Federal Study Focused on Vaccine Storage and Handling Issues

The purpose of this memo is to alert providers of a recent report issued by the DHHS Office of Inspector General (OIG) entitled *Vaccines for Children Program: Vulnerabilities in Vaccine Management* and to remind providers of their VFC obligations. The OIG studied a sample of VFC provider practices in five states. North Carolina was not included in the study. The OIG report identifies two types of findings: problems with storage and handling of vaccine, and program management issues. Storage and handling issues include improper temperature and unapproved storage units as well as expired vaccine stored alongside non-expired vaccine. Program management issues include a lack of required documentation, program oversight, and vaccine management at provider sites.

The findings do not raise concerns about the safety of vaccines administered to children. The primary focus of the Inspector General’s report was on documentation/oversight issues and proper temperature storage for vaccines. The concern with improper storage temperatures is that they can make vaccines less potent rather than less safe. For the complete OIG report, go to: <http://oig.hhs.gov/oei/reports/oei-04-10-00430.asp>

The North Carolina Immunization Branch takes its stewardship of the VFC program very seriously. **It is important to note challenges in assuring proper storage and handling practices are not unique to the VFC provider sites included in this study.** Ensuring appropriate storage and handling includes the maintenance of proper temperatures and use of approved storage units, as well as preventing expired vaccine from being stored alongside non-expired vaccine. Proper VFC program management includes documentation of patient eligibility, program compliance, and appropriate vaccine management at all provider sites. These issues are a priority for NCIP, CDC, and our partners.

The NCIP requires VFC providers to adhere to CDC vaccine management practice requirements. Providers are required to follow programmatic guidance as outlined in the CDC’s *VFC Operations Guide* at: <http://www.cdc.gov/vaccines/programs/vfc/operations-guide.htm>, and in the storage and handling section of the web site at: <http://www.cdc.gov/vaccines/recs/storage/default.htm>. Additionally, vaccine storage and handling guidance may be found at the NCIP web site at: <http://www.immunize.nc.gov/providers/storageandhandling.htm> Attached you will find the recently updated *Minimum Storage and Handling* guidance prepared and distributed to our providers annually.

NCIP will continue working with providers to resolve any challenges and barriers providers face in meeting VFC requirements and identify strategies to improve compliance. If you have questions about the proper storing and handling of vaccines, contact us via our NCIP email account: imminfo@dhhs.nc.gov.

Thank you for all you do to ensure the integrity of the vaccine program.

Attachment
cc: RICS SMT CO Staff Vaccine Manufacturers Steve Shore
RINs Joy Reed Greg Griggs Jessica Gerdes

Vaccine Personnel

- ❖ Providers are required to designate one staff member to be the primary vaccine coordinator, and at least one back-up vaccine coordinator, to be responsible for oversight for all vaccine management.
- ❖ Train other staff members who handle or administer vaccines about the site's policies and procedures for vaccine storage and handling.

Storage and Handling Plans

- ❖ Providers are required to have routine vaccine storage and handling plans in writing as a reference for all staff members. Plans should include guidance on routine vaccine management areas such as: a) ordering vaccines b) controlling inventory c) storing vaccines and monitoring storage conditions d) minimizing vaccine wastage and e) vaccine shipping, including receiving, packing and transporting.
- ❖ A completed Disaster Recovery Plan is required to be posted on or near the vaccine storage equipment. Ensure that all staff (current and new) read the plan and understand it. Also ensure that janitorial and security staff are aware of the plan and know the procedures to follow for notifying designated personnel about any problems with the vaccine storage equipment. Review and update the contact lists in the plan quarterly; review and update the entire plan annually. The plan must include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies. The emergency plan should include: a) name of person(s) responsible for preparing and transporting vaccine, including contact information, b) how this person will be notified that vaccine needs to be moved and the location that will receive vaccine c) how receiving location will be notified of transport d) how to pack vaccine for transport and e) a way to document the steps taken when vaccine is involved in a power or equipment failure.

Vaccine Storage Equipment

- ❖ Providers are required to have appropriate equipment that can store vaccine and maintain proper conditions. Two types of storage units are acceptable: 1) a refrigerator that has a separate freezer compartment with a separate exterior door, or 2) stand-alone refrigerators and freezers.
- ❖ Refrigerators or freezers used for vaccine storage must be able to maintain required vaccine storage temperatures year-round and must be large enough to hold the year's largest inventory. It is strongly recommended that providers who receive more than 2,000 vaccine doses per year have a stand-alone refrigerator and stand-alone freezer.
- ❖ It is recommended that freezer units have separate controls from the refrigerator to prevent exposing refrigerated vaccines to inappropriate temperatures.
- ❖ The refrigerator and freezer compartments are required to each have one working certified calibrated thermometer and the thermometer is to be used for recording temperatures. The thermometer must be certified in accordance with National Institute of Standards and Technology (NIST) standards. Place in a central area inside each storage compartment. It is best practice to keep working thermometers on every other shelf that contains vaccine and that temperatures are properly maintained.
- ❖ Certified calibrated thermometers require periodic recertification and recalibration against reference thermometers in order to remain accurate. Contact the manufacturer of your thermometer for instructions regarding recalibration procedures.
- ❖ A continuous-monitoring temperature alarm/notification system should be considered, especially for practices with large inventories. Facilities storing large vaccine inventories may consider installing backup generators that automatically provide power to the storage units to maintain the recommended storage temperatures in the event of power outages.
- ❖ The unit is required to be dedicated to the storage of vaccines. Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.
- ❖ All dorm-style refrigerators for **permanent storage** are to be phased-out of provider offices by December 31, 2009. A dorm-style refrigerator is a considered a combination refrigerator/freezer unit that is outfitted with one external door.
- ❖ As of December 31, 2009, dormitory-style refrigerators may only be used to store a clinic's single-day supply of **refrigerated** vaccines. Vaccines must be returned to the main refrigerator storage unit at the end of each clinic day. Temperatures must be monitored with a dedicated certified thermometer and documented twice a day on temperature logs specifically for that unit.
- ❖ Allow 1 week of twice-daily refrigerator and freezer temperature recordings in range before using a newly installed or newly repaired refrigeration unit to store vaccines.
- ❖ A provider whose storage equipment does not meet requirements will not be able to order vaccine until proper equipment is in place.

Vaccine Storage Practices

- ❖ Providers are required to rotate vaccine stock monthly by placing vaccines with shorter expiration dates in front of those with longer expiration dates. Check for short-dated vaccine. Notify the Immunization Branch at least four months before the expiration date if you have vaccine that you will not use before it expires. The branch may be able to assist you in relocating vaccine before it expires.
- ❖ Store vaccines in the middle of the compartment away from the coils, walls, floor, and cold air vent. Vaccine should be placed with space between the vaccine and the compartment wall, and with space between each large box, block, or tray of vaccine to allow for cold air circulation around the vaccine. Do not store vaccines in the door of the storage unit, vegetable bins, or other containers that would prevent adequate air circulation.
- ❖ Water bottles and frozen packs help regulate temperatures as well as maintain temperatures in the event of a power outage or mechanical failure. Store water bottles against the inside walls and in the door racks of the refrigerator. Keep frozen packs in the freezer along the walls, back, and bottom of the freezer compartment and inside the racks of the freezer door. Gel packs should only be used in the freezer and not in the refrigerator. Gel packs are not able to maintain temperatures properly in a refrigerator and therefore should only be used in the freezer.
- ❖ Store MMR in the freezer. It is best practice not to store other medications and biologic products inside the vaccine storage unit. If there is no other choice, these products must be stored below the vaccines on a different shelf to reduce the likelihood of medication errors and prevent contamination of the vaccines should the products spill. Never leave vaccine out of the refrigerator or freezer when it is not in use.

Temperature Monitoring

- ❖ Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. Train all staff using vaccine how to monitor temperatures and how to respond to and document actions taken when temperatures are outside the appropriate range.
- ❖ Providers are required to post a temperature log on or nearby the vaccine storage unit and record refrigerator and freezer temperatures twice each day, once at the beginning and again at the end of the day. Refrigerator temperature must be maintained between 2°C and 8°C (36° and 46° F) with an optimum of 5°C (40°F). Freezer temperature must be maintained at -15°C or lower (5°F or lower) with an optimum of -20° C (-4°F). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. Temperature logs must be maintained for 3 years.
- ❖ Providers are required to take immediate action when temperatures are out-of-range. Isolate the affected vaccine vials or packages, mark them "DO NOT USE," and store the vaccines under appropriate conditions in a properly functioning vaccine storage unit. Do not allow the vaccine to remain in a nonfunctioning unit. Call the Immunization Branch at 1-877-873-6247 for assistance. Document on the temperature log any actions taken regarding the out of range temperatures.

Vaccine Shipments and Transfers

- ❖ Never refuse delivery of a vaccine shipment. Immediately check vaccine cold chain monitors and take proper action if cold chain monitor was activated. The Varicella shipping container must contain residual dry ice at the time of arrival. Do not place unopened shipments of vaccine in the refrigerator/freezer before examining the contents.
- ❖ Check your vaccine order against the invoice and the actual vaccines received. It is important to check quantity, lot number, and expiration dates of the vaccines and report any discrepancies immediately. North Carolina Immunization Registry (NCIR) users need to verify the quantity, lot number, and expiration dates to the inbound transfer in the NCIR before acceptance.
- ❖ Use coolers, ice packs, thermometers, and polyfoam to ensure the cold chain is not broken when transporting vaccine. Refrigerated vaccines must have an insulating barrier such as bubble wrap between the refrigerated/frozen packs and the vaccines to prevent accidental freezing. Varicella should be transported on dry ice.
- ❖ If you transfer or borrow vaccine from another North Carolina Immunization Program provider, please notify the Immunization Branch immediately. Complete a Transfer and/or use "New Transfer in NCIR." Open multi-dose vials may not be transferred between providers.

Vaccine Wastage

- ❖ Notify the Immunization Branch at 1-877-873-6247 of vaccine cold chain failure/wastage incidents involving vaccines promptly after discovery of the incident. Never waste vaccine without first consulting with the Immunization Branch.
- ❖ Remove wasted/expired vaccine from storage containers with viable vaccine to prevent inadvertent administration. Return all spoiled and/or expired unopened vials and manufacturer pre-filled syringes to the Immunization Branch with a completed Wasted/Expired Vaccine Report. Do not return drawn but not administered vaccine or open multidose vials; dispose of them at your facility and complete a Wasted/Expired Vaccine Report indicating the vaccine was wasted.

Vaccine Preparation

- ❖ It is not an acceptable clinical practice to pre-draw vaccines into syringes. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

Vaccine Ordering and Inventory Management

- ❖ Order all vaccines (when available) once every other month. Stock enough vaccines to maintain a three-month supply, if you have the storage capabilities. Orders are reviewed and adjusted to prevent providers from receiving more than a three-month supply. Please update the Immunization Branch if you have special needs with the order. Alert office staff you placed an order.
- ❖ Providers are required to be able to distinguish between their public and private vaccine stock but do not have to have separate storage units. Maintain complete, accurate, and separate stock records for both public and private vaccines.
- ❖ It is best practice to store each vaccine in its own specifically labeled section of the refrigerator or freezer. This helps decrease the chance that someone will mistakenly administer the wrong type of vaccine.
- ❖ It is best practice to store all opened and unopened vials of vaccine in their original containers to help protect the vaccine from damage due to storage errors. This also decreases the possibility of administration errors from inadvertently confusing similarly packaged vaccines.
- ❖ Use only the specific diluent provided by the manufacturer for each type of vaccine to ensure adequate potency and safety of the resulting mixture.
- ❖ Multi-dose products may be used until the expiration date stamped on the vial unless otherwise indicated in the manufacturer's package insert. Vaccine with expiration dates on the vial with only the month and year may be used through the last day of that month. As doses are used, mark multi-dose vials to keep an accurate inventory.

Vaccine Security and Equipment Maintenance

- ❖ Safeguard vaccines by taking security measures, such as adding temperature alarms to storage equipment, and restricting access to vaccine storage and handling areas. Use a safety-lock plug or an outlet cover to reduce the chance of the unit becoming inadvertently unplugged.
- ❖ Avoid using power outlets with built-in circuit switches and outlets that can be activated by a wall switch.
- ❖ Providers are required to post a warning sign at the plug and on the refrigerator or freezer alerting staff, janitors, and electricians not to unplug the unit. Label the fuses and circuit breakers to alert people not to turn off the power to the vaccine storage unit.

If ever in doubt about anything, call the Immunization Branch at 1-877-873-6247. Refer to the National Center for Immunization and Respiratory Diseases Vaccine Storage and Handling Toolkit, available at <http://www.immunizenc.com>, for more detailed information.