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Division of Public Health

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June 10, 2014

MEMORANDUM

TO: North Carolina Immunization Program (NCIP) Participants

FROM: Wendy Holmes, R.N., Head *WH*
Immunization Branch

SUBJECT: 2014 Hurricane Season Preparedness

The purpose of this memo is to ensure you are prepared for the 2014 hurricane season. During the months of June through November, hurricanes or tropical storms could pose a threat to North Carolina. In preparation, we would like you to take precautions to protect your vaccine supply now.

To ensure your facility is ready, please take a moment to review your storage and handling preparedness:

- Review and update the Disaster Recovery Plan (now known as the Emergency Vaccine Management Plan). All providers are required to have a current plan (updated yearly) posted on or near the vaccine storage equipment.
- All staff (current, new, and temporary) should read the plan and understand what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies. Janitorial and security staff should be aware of the plan and know the procedures to follow to notify designated personnel about any problems with the vaccine storage equipment or power outages.
- The primary and primary and back-up vaccine coordinator are responsible for monitoring storage equipment, tracking weather conditions, severe weather patterns, and safe transportation of vaccine if needed (even after hours)
- Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that might cause a power outage. A continuous-monitoring temperature alarm/notification system should be considered, especially for facilities with large inventories.
- Whenever possible, suspend vaccination activities BEFORE the onset of emergency conditions to allow sufficient time to pack and transport vaccine.
- Review and update as necessary, written protocols for: a) vaccine packing, b) transportation, and c) proper storage of vaccine at the alternate storage facility. Verify you have the appropriate packing materials to safely transport or temporarily store your vaccine. A certified calibrated thermometer with a current certificate of calibration is required to transport vaccine.
- If backup generators are used, test monthly during hurricane season. (Check manufacturer specifications for test procedures and maintenance schedules).
- During a short power outage (less than two hours), the storage temperature can probably be maintained with the proper amount of water containers in the refrigerator, with frozen coolant packs in the freezer, and by keeping the storage unit door(s) closed.

Key points to remember if a power failure occurs:

- Determine the cause of the power failure and estimate the time it will take to restore power. If a timeframe for the restoration of power cannot be determined, **do not leave vaccine in a non-working unit**. If the outage is expected to be long term (greater than 2 hours), transport the vaccine to the back-up facility.
- If temperatures reach 8° C or warmer in the refrigerator, or -15° C or warmer in the freezer, begin your emergency vaccine procedures. Immediate action is required when temperatures fall outside the recommended range.
- Do not discard vaccine or administer vaccines exposed to out of range temperatures without consulting with the Immunization Branch. Mark vaccine with "DO NOT USE" sign, and move the vaccine to an approved working storage unit and contact the Immunization Branch at 1-877-873-6247 for further instruction about the viability of the vaccine.

Please take time to review the attached 2014 version of the *NCIP Minimum Required Vaccine Ordering, Handling, and Storage Procedures* and the *NCIP Transportation Guidance for Vaccines*. These documents may be found on the NCIP web site at: www.immunize.nc.gov/providers/storageandhandling.htm.

If you have questions, call the Help Desk Staff at 1-877-873-6247.

Attachments

cc:	SMT	CO Staff Joy Reed	Vaccine Manufacturers Desiree Elekwa-Izuakor	Steve Shore Terri Pennington	RINs Jason Swartz	RICs Ann Nichols	Gregg Griggs Frank Skwara
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NORTH CAROLINA IMMUNIZATION PROGRAM (NCIP)

MINIMUM REQUIRED VACCINE ORDERING, HANDLING, AND STORAGE PROCEDURES

Vaccine Personnel

- ❖ Designate one staff member as the primary vaccine coordinator and at least one back-up vaccine coordinator. Staff must participate in yearly, documented training/education on proper storage and handling practices and VFC program requirements
- ❖ All changes to key staff must be communicated to the NCIP

Storage and Handling Plans

- ❖ Maintain and update annually or as needed written Routine Vaccine Management Plan as a reference for staff. Plan must include guidance on: a) proper vaccine storage and handling practices, b) vaccine shipping and receiving, c) vaccine ordering, d) inventory control, e) vaccine expiration, spoilage, and waste prevention
- ❖ Post a current Emergency Vaccine Management Plan on or near the vaccine storage equipment and update annually. Ensure that all staff read and understand what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies. The plan must include: a) name, contact information, and how to notify staff responsible for preparing and transporting vaccine, b) alternative vaccine storage facility information, c) how to pack vaccine for transport, and d) how to document steps taken

Vaccine Storage Equipment

- ❖ DO NOT store vaccine in a dormitory or dorm-style refrigerator/freezer at any time
- ❖ Dedicate refrigerators and freezers to the storage of vaccines only. Units must be able to maintain required vaccine storage temperatures year-round and be large enough to hold the year's largest inventory, along with sufficient room to store water bottles in the refrigerator and frozen coolant packs in the freezer
- ❖ Place the storage unit in a well vented room with space around the sides and at least 4 inches between the back of the unit and the wall
- ❖ Do not plug storage units in power strips, ground fault interrupters outlets, or outlets that are activated by a wall switch. These can be tripped or switched off, resulting in loss of electricity to the storage unit
- ❖ Post a "DO NOT UNPLUG" sign on the refrigerator, freezer, and circuit breakers
- ❖ Do not store food and beverages in the vaccine storage unit
- ❖ Replace storage units that do not meet the minimum requirements or that have malfunctioned
- ❖ Maintain one back up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer)

Vaccine Storage Practices

- ❖ Rotate vaccine stock weekly and use vaccines with shorter expiration dates before those with longer expiration dates. Remove expired immediately and contact the NCIP for wastage instructions. Notify NCIP at least four months before the expiration date to avoid restitution for improper inventory management. Keep vaccines in their original packages and store similar looking vaccines on different shelves to avoid confusion and medication errors
- ❖ Place vaccine in the central area of the storage unit to allow for proper air circulation around the vaccine. Do not store vaccines in the door, vegetable bins, on the floor of the unit or near the cooling vents at the top of the unit
- ❖ Store water bottles against the inside walls, on the top shelves, and in the doors of the refrigerator
- ❖ Keep frozen coolant packs in the freezer along the walls and floor and inside the freezer door
- ❖ Store MMR in the freezer
- ❖ Store other medications and biologic products in a separate storage unit

Temperature Monitoring

- ❖ Read and manually record temperatures twice each day, once when the clinic opens and once when the clinic closes (including half days), from an internal thermometer. Recorded temperatures must include time of reading, name and/or initials of the person assessing temperature. Thermometers should be placed centrally, near vaccine and have a current certificate of calibration issued by an ILAC-accredited laboratory
- ❖ Post the temperature log on the vaccine storage unit and maintain copies of all temperature logs for 3 years
- ❖ Refrigerator temperature must be maintained between 2°C and 8°C (35° and 46° F) with an optimum of 5°C (40°F)
- ❖ Freezer temperature must be maintained between -50°C and -15°C (-58°F and +5°F) with an optimum of -20° C (-4°F)
- ❖ Take immediate action when temperatures are out-of-range. Call the NCIP at 877-873-6247 for assistance and document on the temperature log any actions taken regarding the out of range temperatures. Isolate the affected vaccine vials or packages, mark "DO NOT USE," and store the vaccines under appropriate conditions in a properly functioning vaccine storage unit

Vaccine Shipments and Transfers

- ❖ Immediately unpack vaccine deliveries, examine quantity, lot number, and expiration dates of the vaccine order against the invoice, and store appropriately. Call NCIP if cold chain monitor was activated
- ❖ Arrange for deliveries only when the vaccine coordinator or back-up will be available. Consider holidays, vacations, staff schedules, and changes in hours of operation when designating vaccine delivery date and time
- ❖ Never refuse delivery of a vaccine shipment

Vaccine Ordering and Inventory Management

- ❖ Order and administer all ACIP-recommended vaccines based on actual population served
- ❖ Draw up vaccine only at the time of administration
- ❖ Physically distinguish between public and private vaccine stock and maintain complete, accurate, and separate stock records
- ❖ Store vaccine in their original containers. Use only the specific diluent provided by the manufacturer
- ❖ 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
- ❖ Do not transfer or borrow vaccine without prior approval from the NCIP

North Carolina Immunization Program Transportation Guidance for Vaccines

Transportation of vaccines should be a rare occurrence and expected length of transport should be less than 30 minutes. The CDC Storage and Handling Toolkit offers *transport* guidance based on current available data. If *transport* must occur, provider must use a thermometer with a current and valid certificate of calibration. It is strongly recommended that a digital data logger be used to transport vaccine.

Short-dated vaccine may be transferred to another NCIP provider with the approval of the NCIP and if the cold chain can be maintained. Providers must notify the NCIP of any vaccine doses that will expire before they can be administered at least four months before the expiration date to avoid restitution for improper inventory management. Providers must coordinate with the NCIP to transfer and document the transfer of vaccine between providers. Vaccine transfers between providers can occur only after receiving approval from the NCIP.

Transporting Refrigerated Vaccine

Guidelines for vaccine transport

Assemble packing supplies

1. **Cooler.** Use hard plastic Igloo-type coolers. Attach a "Vaccines: Do Not Freeze" label to the cooler.
2. **"Conditioned" cold packs.** Condition frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they've been "sweating." Cold packs that are not conditioned can freeze vaccine. **Do not use dry ice.**
3. **Thermometer.** Prepare the thermometer by placing it in the refrigerator at least 2 hours before you pack the vaccine.
4. **Packing material.** Use two 2-inch layers of bubble wrap. Not using enough bubble wrap can cause the vaccine to freeze.



Pack vaccine

1. Cold packs

Spread conditioned cold packs to cover only half of the bottom of the cooler.



2. Bubble wrap

Completely cover the cold packs with a 2-inch layer of bubble wrap. Then, place the thermometer/probe on top of the bubble wrap directly above a cold pack.



3. Vaccine

Stack layers of vaccine boxes on the bubble wrap. Do not let the boxes of vaccine touch the cold packs.



4. Bubble wrap

Completely cover the vaccine with another 2-inch layer of bubble wrap.



5. Cold packs

Spread "conditioned" cold packs to cover only half of the bubble wrap. Make sure that the cold packs do not touch the boxes of vaccine.



6. Form & display

Fill the cooler to the top with bubble wrap. Place the thermometer's digital display on top. It's ok if temperatures go above 46°F while packing.



As soon as you reach the destination site, check the vaccine temperature. If the vaccine is:

- Between 35°F and 46°F, put it in the refrigerator.
- Below 35°F or above 46°F, contact your VFC Rep or the VFC program immediately. Then label the vaccine "Do Not Use" and put it in the refrigerator.

Transporting Frozen Vaccines

Guidelines for vaccine transport in emergency situations

- Routine transport of varicella-containing vaccines (MMRV and varicella vaccine) is not allowed. These vaccines should only be moved and transported when absolutely necessary.
- Make sure you have a vaccine emergency plan that includes the name and address of the destination site where you can take your frozen vaccine in an emergency.
- If vaccines must be transported, contact your VFC Program Representative or the VFC Program.
- Varicella-containing vaccines should preferably be transported under frozen conditions (below 5F or -15C).
Do not freeze diluent for varicella-containing vaccines
- Vaccines must be placed in a freezer maintaining temperatures below 5F (-15C) immediately upon arrival at the backup storage facility.

Assemble packing supplies and documents

Most emergencies happen suddenly. Be sure you are prepared for emergency transport of frozen vaccine by always having the following supplies ready.

- 1. Cooler.** Use hard plastic Igloo-type coolers.
- 2. Frozen cold packs.** Keep enough frozen cold packs in your vaccine freezer to make two layers in the transport cooler. You will need 6-8 frozen packs per cooler. **NEVER USE DRY ICE.**
- 3. Thermometer.** Keep a portable MIN/MAX thermometer in your vaccine freezer even if you normally use a continuous read thermometer for monitoring vaccine freezer temperatures.
- 4. Packing materials.** Use any material like bubble wrap to place on top of the frozen cold packs to prevent contents from shifting. Make sure you **DO NOT** place bubble wrap between the vaccine and frozen packs.

Pack vaccines and prepare for transport

Prepare for transport

- Verify that the destination site has enough room for your vaccine and that someone will be there when the vaccine arrives.
- Verify that you have all the packing supplies on the above list.

Pack vaccines



Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice.

1



Spread another layer of frozen ice packs to cover the vaccine.

4



Stack layers of vaccine boxes directly on top of the frozen ice packs.

2



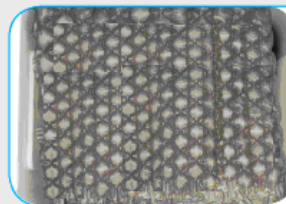
Fill the cooler to the top with insulation material (bubble wrap).

5



Place the thermometer probe with the top layer of vaccine.

3



Place the thermometer's display on top of the insulation/packing material. Then close the cooler and transport the vaccine.

6