UPMC
PHYSICIAN SERVICES (PS)
POLICY AND PROCEDURE MANUAL

POLICY: CO-023
INDEX TITLE: Clinical Operations

SUBJECT: Vaccine Recovery Policy
DATE: February 15, 2015

I. POLICY

Emergency procedures should address the protection of vaccines to ensure proper storage and handling. Exposure of vaccines to temperatures outside the recommended ranges can adversely affect their potency and reduce the protection that they provide.

II. SCOPE

This policy applies to the clinical sites of UPMC Physician Services (PS) as applicable. VFC supplied vaccines must be maintained and/or transported according to specific VFC Guidelines.

III. PURPOSE

To protect the vaccine inventory and minimize the potential monetary loss from natural disasters or other emergencies.

IV. PROCEDURE

Vaccines must be stored at the proper temperature from the time they are manufactured until they are administered to the patient.

1) In advance of an emergency situation, all providers should:
   a) Identify an alternative storage facility with back-up power (such as a generator) where the vaccine can be properly stored and monitored during the event of equipment failure, power outage, or natural disaster.
   b) Insure the availability of staff to pack and move the vaccine.
   c) Maintain appropriate packing materials including refrigerants (check with individual manufacturers for specific vaccine requirements).
   d) Ensure a means of transport for the vaccine to the alternative storage facility.

2) Maintain a list of Emergency phone numbers and points of contact (see Attachment A) for:
   a) Electrical Power Company
   b) Refrigeration Repair Company
   c) Backup Storage
   d) Transportation to backup storage

e) National Weather Service
f) Vaccine Manufacturers:
   i) Merck: 800-637-2590
   ii) Sanofi-Pasteur (Aventis): 800-VACCINE (800-822-2463)
   iii) GlaxoSmithKline: 888-825-5249
   iv) Wyeth: 800-999-9384
   v) MedImmune: 877-359-6478

3) Vaccine Storage and Handling Guidelines:
   a) All office personnel who handle and/or administer vaccines need to be aware of proper storage and handling. This includes not only those employees who administer vaccines, but also those who accept shipments or who have access to the units where the vaccines are stored.
   b) Refrigerators are to be commercial-style or household-style with separate freezer compartments. (Not dormitory-type refrigerators). CDC recommendation is that refrigerator and freezer should be stand-alone units with no dormitory-type refrigerators.
   c) Post sign "DO NOT UNPLUG; VACCINES INSIDE" next to the refrigerator's electrical outlet or purchase a plug guard to prevent people from unplugging the refrigerator/freezer.
   d) Do not store vaccines in the door of the refrigerator or freezer.
   e) Refrigerators and freezers are to be equipped with digital, calibrated, certified thermometers. (Note: VFC requires thermometers with current annual NIST certification.)
      Thermometer sensors should be located in the center of the storage compartment.
      i) Place refrigerator thermometer away from the fan and not too close to freezer.
      ii) Maximum/Minimum thermometers must be used to monitor temperatures as well as to determine the range of temperatures to which vaccines have been exposed.
      iii) Digital Maximum/Minimum thermometers should be reset /cleared at the end of each shift to ensure temperature ranges to which vaccines are exposed during office closure are accurate. This information is necessary to provide to vaccine manufacturers in the event of a power interruption or refrigerator failure.
   f) Refrigerator temperature is to be maintained between 35º to 46º F (2º to 8º C).
   g) Freezer temperature is to be maintained at -58º F to 5º F (-50º to -15º C).
   h) Check Min/Max temperatures at the beginning of each day; determine that temperatures have stayed within acceptable ranges and document this.
   i) Check temperatures of both refrigerator and freezer **twice a day**: first thing in the morning and again before the office closes and record on the temperature log.
   j) Reset/clear thermometer memory after the second temperature is recorded.
   k) To help maintain temperatures, keep extra containers of water (labeled "Do not drink") in refrigerator and ice packs in the freezer as needed.

l) In the event of an accidental storage problem (i.e., power failure, vaccine stored incorrectly, etc.) the Vaccine Manufacturer (Merck, Sanofi, GSK, Wyeth, etc.) must be contacted regarding the handling of the affected vaccine to determine if it can be used. Label all affected vaccines as "Do Not Use" until manufacturer can verify the efficacy of the vaccine.

4) Power Outage Guidelines:
   a) Maintain vaccines in required refrigeration. Keep doors of refrigerator and freezer closed to maintain temperatures.
   b) Determine the last temperature prior to the power failure:
      i) What was the maximum/minimum temperature recorded by the thermometer?
      ii) Review temperature log to determine last recorded temperature.
   c) Continue to monitor temperatures.
   d) If the power outage is ongoing (more than 2 hours), and an alternate storage with a reliable power source is available, transfer vaccine products to the back-up facility.
      i) If transporting vaccine, follow vaccine packing instructions of the manufacturer of the respective vaccine.
      ii) Open refrigerated units only when absolutely necessary and after you have made all preparations for packing and moving the vaccine to alternative storage.
      iii) Measure the temperature of the refrigerator and freezer when the vaccines are removed.
      iv) Use properly insulated containers for transport with a thermometer in each container. CDC recommends portable freezers and refrigerators.
      v) Record vaccine type, quantity, date, time, and originating facility on the container.
      vi) Transport the vaccine following proper manufacturer's procedures for storage and handling, or if not possible, try to record the temperature the vaccine is exposed to during transport.
      vii) Document the storage container temperature at the time the vaccine is removed for storage at the alternate site.
      viii) When power has been restored:
         (1) Check memory of digital thermometer and record the minimum and maximum temperatures during the outage as well as the duration of the outage. This will provide data on the maximum temperature and maximum duration of exposure to elevated temperatures.
         (2) Label all affected vaccines as "Do Not Use" until manufacturer can verify the efficacy of the vaccine. Keep exposed vaccine separated from any new product and continue to store at the proper temperature if possible.
      ix) Do not discard and do not administer affected vaccines until you have verified their stability and contacted the entities listed below:

(1) If you receive vaccine from VFC (Vaccines for Children) or your state or local health department, they can provide guidance.

(2) Contact the manufacturer for further instructions to determine if the vaccine can still be used.

(3) If it is determined that vaccines are not usable, contact the office's general liability insurance carrier to determine if a claim can be filed. Please note: some insurers may require that the product be sent to them when processing a claim.

SIGNED:

Steven D. Shapiro, MD
Executive Vice President, UPMC
Chief Medical and Scientific Officer
President, Health Services Division

ORIGINAL: November 6, 2007
REVIEW MONTH: February
PRECEDE: September 15, 2013
SPONSOR: Director, Clinical Support Services & Safety Officer

ATTACHMENT A

CONTACT INFORMATION FOR VACCINE RECOVERY

(Please print out this page and provide phone numbers. Post in an area that is easily accessible to all staff, in the event of emergency or power outage).

Agency/Company	Name of Agency/Company	Phone number
Electrical Power Company		
Refrigeration Repair Company		
Backup Storage facility		
Transportation to backup storage		
National Weather Service		