

Vaccine Storage



Protect your vaccine ~ Protect your patients October, 2011



DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION



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Information contained in this document is based on the recommendations of the Advisory Committee on Immunization Practices (ACIP) and the manufacturer's product information.

A combination vaccine is defined as a prod¬uct containing components that can be divided equally into independently available routine vaccines. A dash (-) between vaccine products indicates that products are supplied in their final form by the manufacturer and do not require mixing or reconstitution by the user. A slash (/) indicates that the products must be mixed or reconstituted by the user.

Vaccine Storage and Handling Best Practices

Vaccines must be stored properly from the time they are manufactured until they are administered. Immunization providers are responsible for proper storage and handling from the time vaccine arrives at the facility until the vaccine is given. Below is an outline of vaccine storage and handling best practices. CDC's Storage and Handling Toolkit contains detailed information on vaccine management. Immunization providers and staff are strongly encouraged to review the Storage and Handling Toolkit annually. Educate all staff, including temporary staff, as part of new staff orientation. In addition, Vaccines for Children (VFC) providers should follow VFC policy and work with their immunization program.

- Vaccine Management includes, but is not limited to, these three components.
 - 1. The **equipment** used for vaccine storage and temperature monitoring is **reliable and appropriate.**
 - 2. **Staff is knowledgeable** regarding proper vaccine storage and handling. At least 2 staff members should be responsible for vaccine management.
 - 3. Written storage and handling plans are updated at least annually for:
 - routine storage and handling of vaccines; and
 - emergency vaccine retrieval and storage.

Routine Vaccine Storage and Handling Plan should include the following four elements.

1. Ordering and Accepting Vaccine Deliveries

- Store vaccines at the recommended temperatures IMMEDIATELY upon arrival.
 - Store refrigerated vaccines between 35°F and 46°F (2°C and 8°C).
 - Store frozen vaccines between -58°F and +5°F (-50°C and -15°C).
- Ensure vaccines are delivered when the facility is open. Vaccine shipments should be delivered when staff is available to unpack and store the vaccine properly. Inform manufacturer/distributor when vaccine shipments can be delivered. VFC providers should also notify the immunization program. Consider holidays, vacations, changes in hours of operation, and staff schedules when ordering vaccines.
- Educate all facility staff about vaccine storage. Vaccine shipments are often accepted by nonmedical staff. They should be aware that vaccine needs to be stored according to the manufacturer's guidelines immediately upon delivery.

- Order vaccines to maintain an adequate amount to meet the needs of the facility's patients. The amount of vaccine needed can vary throughout the year. Anticipate peak periods such as back-to-school appointments or influenza season and order accordingly.
- Order the vaccines and presentations that are appropriate for the ages and types of patients the facility serves. Influenza vaccine, for example, is available from many manufacturers with differing indications.
- Maintain a vaccine inventory log including:
 - 1. vaccine name and number of doses received;
 - 2. date vaccine received;
 - 3. condition of vaccine on arrival;
 - 4. vaccine manufacturer and lot number; and
 - 5. vaccine expiration date.

2. Storing and Handling Vaccines

- Store vaccines in refrigerator and freezer units which can maintain the appropriate temperature range and are large enough to maintain the year's largest inventory without crowding. Stand alone units are preferred but household combination units with separate exterior doors and thermostats can be used. Dormitory-style refrigerators should not be used. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door with an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.
- Store vaccine in storage units designated specifically for biologics. If biologic specimens must be stored in the same unit, these should be stored on a lower shelf to prevent contamination. Food and drinks should never be stored in the same unit with vaccines.
- Keep a calibrated thermometer with a Certificate of Traceability and Calibration* in the refrigerator and freezer. These thermometers should be recalibrated as recommended by the manufacturer.
- Post "Do Not Unplug" signs next electrical outlets and "Do Not Stop Power" signs near circuit breakers to maintain a consistent power source.
- Read and document refrigerator and freezer temperatures at least twice each workday- in the morning and before the end of the workday. Keep temperature logs for at least 3 years.

*Certificate of Traceability and Calibration thermometer with calibration measurements traceable to a testing laboratory accredited by the International organization of Standardization, to the standards of the National Institute of Standards and Technology, or to another internationally recognized standards agency

- Store vaccine according to the manufacturer's instructions. Aim to maintain storage unit temperatures within the middle of the acceptable temperature range. This allows for the small temperature fluctuations that can occur in refrigerators and freezers without exposing vaccines to unacceptable temperatures.
- Ensure good air circulation around the vaccine in the storage unit. Proper air circulation is essential to maintaining the correct storage temperatures. Bins, baskets, or some other type of uncovered containers with slotted sides or openings should be used to store the vaccines. There should be space between the containers to promote air flow.
- Store vaccines on the shelves away from the walls, and vents in the part of the unit best able to maintain the required temperature. Vaccines should never be stored in the door of the freezer or refrigerator. The temperature here is not stable.
- Place frozen packs in the door of the freezer and water bottles in the door of the refrigerator to help the storage unit maintain a constant temperature. Frozen packs or water bottle should be placed securely so they do not dislodge and prevent the door from closing. In addition, caution must be taken to avoid weighing down the door so much that the seal is compromised when the door is closed.
- Store unopened and opened vaccines in their original box with the lid in place until administration. Several vaccines must be protected from light. This practice also helps to ensure different vaccines are not stored together in the same bins or containers which can lead to vaccine administration errors. And in the event of a power failure, studies have shown storing vaccines in the box helps to maintain the vaccine at the appropriate temperature.
- Prepare vaccines at the time the vaccine is administered. This includes reconstituting or "mixing" vaccine, if indicated. Use only the diluent supplied by the vaccine manufacturer. Store diluent according to the manufacturer's instructions.

3. Managing Inventory

- Rotate stock so vaccine and diluent with the shortest expiration date is used first. Place vaccine with the longest expiration date behind the vaccine that will expire the soonest. Remove expired vaccine and diluent from usable stock.
- Keep vaccine stock well organized. VFC providers should separate and identify VFC and other vaccines purchased with public funds within the storage unit. In addition, clearly label the space where the vaccine is placed to help staff choose the appropriate vaccine.

- Inspect the storage unit daily. A physical inspection helps to ensure vaccines and thermometers are placed appropriately within the unit. During a busy work day, vaccines and thermometers can be easily moved or displaced to an area inappropriate for vaccine storage.
- Dispose of all vaccine materials using medical waste disposal procedures. Contact the immunization program for details and state specific guidance.
- 4. Managing Potentially Compromised Vaccines
 - Identify and isolate all potentially compromised vaccines and diluents. Label these "DO NOT USE". Store separately from uncompromised vaccines and diluents in the recommended temperature range. A clearly labeled paper bag can be used for this purpose. Do not automatically discard the vaccine or diluent.
 - Contact vaccine manufacturers and/or state immunization program for appropriate actions that should be followed for all potentially compromised vaccines and diluents.
 - Educate staff administering vaccines on correct handling and preparation procedures to decrease the likelihood of vaccine or diluent inadvertently being compromised. For example, each vaccine should be prepared just prior to administration.

Emergency Vaccine Retrieval and Storage Plan should include the following components.

- Designate an alternate site where vaccines and diluents can be safely stored. Considerations when choosing a site include types of storage unit(s) available, temperature monitoring capabilities, and back-up generator. Potential back-up locations include local hospitals, another provider's facility, retail or clinic pharmacies, long-term care facilities, or the Red Cross. Identify procedures that allow 24-hour access to alternate facilities.
- 2. Obtain and store an adequate number/amount of appropriate packing containers and materials (e.g., frozen and refrigerated gel packs, bubble wrap) in the facility that will be needed to pack vaccines for safe transport. Acceptable packing containers are described in the *Storage and Handling Toolkit*. Consider the year's largest inventory when stocking supplies. Store these supplies with a copy of the emergency vaccine retrieval and storage plan. Communicate to staff where everything is kept.
- 3. Include written directions for packing vaccines and diluents for transport. A calibrated thermometer should be placed in each packing container near the vaccine or refrigerated diluent.

- 4. Develop a plan in which vaccine coordinators will be notified of power outages at the facility. Include instructions for gaining 24-hour access to where the vaccines are stored.
- 5. Incorporate written procedures for managing potentially compromised vaccines.
- 6. Include contact information for vaccine manufacturers and/or the immunization program.

For more detailed information on proper vaccine storage and handling please refer to CDC's *Vaccine Storage and Handling Toolkit*.

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Diphtheria Toxoid-, Tetanus Toxoid- and acellular Pertussis-Containing Vaccines DTaP: DAPTACEL, Infanrix, Tripedia DTaP-HepB-IPV: Pediarix DTaP-IPV: KINRIX DTaP-IPV/Hib: Pentacel

Condition upon Arrival

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines (DTaP, DTaP-HepB-IPV, DTaP-IPV, DTaP-IPV/Hib) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

• **DTaP-IPV/Hib (Pentacel) has 2 components.** The lyophilized Hib vaccine (ActHIB) and DTaP-IPV diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

 DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX): Refrigerate between 35°F* and 46°F (2°C and 8°C). DTaP-IPV/Hib (Pentacel): Refrigerate the lyophilized Hib vaccine (ActHIB) and the vaccine diluent (DTaP-IPV) together between 35°F* and 46°F (2°C and 8°C). Do not store them separately.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX), DTaP-IPV/Hib (Pentacel) vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **DTaP, DTaP-HepB-IPV (Pediarix), DTaP-IPV (KINRIX):** Just before use, shake vial or manufacturer-filled syringe well. After shaking, the vaccine should be a cloudy, white colored liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- **DTaP-IPV/Hib (Pentacel):** This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute DTaP-IPV/Hib (Pentacel) prior to administering it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them".
 - 1. Just before use, shake the vial of DTaP/IPV diluent.
 - 2. Withdraw the entire contents of the diluent vial (blue capped vial) and inject it into the vial containing the lyophilized vaccine component (green capped vial).
 - 3. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.

4. The reconstituted vaccine is a cloudy, uniform, white to off-white (yellow tinged) liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

DTaP-IPV/Hib (Pentacel): All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted DTaP-IPV/Hib may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Do not freeze or expose reconstituted vaccine to freezing temperatures. Agitate stored, reconstituted vaccine prior to administration.

• Do not administer reconstituted DTaP-IPV/Hib (Pentacel) vaccine if it is not used within 30 minutes. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturerfilled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid-, tetanus toxoid- and acellular pertussis-containing vaccines are easily confused increasing the risk for error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Haemophilus influenzae type b-Containing Vaccines Hib: ActHIB, Hiberix, PedvaxHIB Hib-HepB: Comvax Note: Information pertaining to DTaP/IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Haemophilus influenzae type b-containing vaccines (Hib, Hib-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

• ActHIB and Hiberix vaccines each have 2 components. The lyophilized Hib vaccine and diluent vials should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer's guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures.

 PedvaxHIB and Comvax vaccines: Refrigerate vaccine between 35°F* and 46°F (2°C and 8°C).

- ActHIB vaccine: Refrigerate lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C). Do not store them separately.
- **Hiberix vaccine:** If space allows, store the lyophilized vaccine and diluent together in the refrigerator.

Vaccine: Refrigerate the lyophilized vaccine between 35°F* and 46°F (2°C and 8°C). Protect vaccine from light at all times by storing in the original box.

Diluent: Store in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C).

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at end of this document for information on vaccine administration.

- PedvaxHIB and Comvax vaccines: Just before use, shake the vial. The vaccine should be a slightly opaque, white liquid. Do not use vaccine if it cannot be resuspended with thorough agitation.
- ActHIB and Hiberix vaccines: These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute these vaccines. ActHIB and Hiberix diluents are not the same and they are NOT interchangeable. ActHIB is reconstituted with 0.4% sodium chloride diluent. Hiberix is reconstituted with 0.9% sodium chloride diluent. Hiberix is reconstituted by the vaccine manufacturer to reconstitute the vaccine. Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them".
 - 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized Hib vaccine.

- 2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- 3. The reconstituted vaccine should be a clear and colorless liquid.

Beyond Use Date*: Shelf Life after Opening

PedvaxHIB and Comvax vaccines: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **ActHIB and Hiberix vaccines:** All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted ActHIB or Hiberix may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 24 hours. Do not freeze or expose reconstituted vaccines to freezing temperatures. Protect reconstituted Hiberix from light. Agitate stored, reconstituted vaccine prior to administration.

• Do not administer reconstituted ActHIB or Hiberix vaccine if it is not used within 24 hours. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturerfilled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Hepatitis-Containing Vaccines

HepA: Havrix, VAQTA

HepB: Engerix-B, Recombivax HB

HepA-HepB: Twinrix

Note: Information pertaining to DTaP-IPV-HepB (Pediarix) can be found on page 11 Information pertaining to Hib-HepB (Comvax) can be found on page 15

Condition upon Arrival

Hepatitis-containing vaccines (HepA, HepB, HepA-HepB) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended with thorough agitation. After shaking, the vaccine should be white, slightly cloudy in color. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Manufacturer-Filled Syringes:** Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, single antigen HepA and HepB vaccines have different formulations based on age. Storing multiple products and presentations can be confusing to staff and increases the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

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Human Papillomavirus Vaccines HPV2: Cervarix HPV4: Gardasil

Condition upon Arrival

Human papillomavirus vaccine (HPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

• **HPV4 (Gardasil):** Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. After shaking, HPV vaccine is a white, cloudy liquid. Through agitation immediately before administration is needed to maintain suspension. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

• HPV2 (Cervarix): May separate to a fine, white deposit on the bottom of the vial with a clear, colorless liquid above during storage. This does not indicate deterioration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.

4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. There are two HPV products available from different manufacturers with different indications. HPV4 can be administered to males and females. HPV2 is approved for use in females only. Consider indications and the facility's patient population when ordering HPV vaccine.

Vaccines that sound alike are often confused. For example, HPV, HepB and Hib vaccines are often confused, increasing the risk for an error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Label the space where HPV is stored with name, gender and age indications to help decrease the likelihood of a vaccine administration error. Refer to the Resources section at the end of this document for examples of labels.

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Influenza Vaccines LAIV: FluMist

Condition upon Arrival

Live, attenuated influenza vaccine (LAIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the nasal sprayer. Do not use after the expiration date shown on the label.

Preparation

This vaccine should not be combined or mixed with any other vaccines. Each nasal sprayer contains a single dose of LAIV. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Sprayer: The nasal sprayer should be removed from the refrigerator at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Often providers have different influenza presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Influenza Vaccines

TIV: Afluria, Fluarix, FluLaval, Fluvirin, Fluzone, Fluzone High-Dose, Fluzone Intradermal

Condition upon Arrival

Trivalent influenza vaccine (TIV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

• Afluria, Fluarix, FluLaval, and Fluvirin: Protect vaccine from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Influenza vaccine is formulated for use during the current influenza season. Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial or manufacturer-filled syringe well before use. Shake multidose vials each time before withdrawing a dose. Do not use vaccine if it cannot be resuspended with thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered. **Intradermal Microinjection Syringe:** Manufacturer-filled microinjection syringe should be activated (i.e., needle cap removed) at the time the vaccine is administered.

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single age-appropriate dose of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C). A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

• Once entered, a multidose vial of Afluria or FluLaval should be discarded after 28 days.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Vaccines, including TIV, should be drawn from the vial into the syringe at the time of administration. CDC strongly discourages providers from prefilling syringes in advance. If more than one dose of vaccine must be predrawn, only draw up a few syringes (no more than 10 doses or the contents of one multidose vial).

Provider prefilled syringes should be administered by the person who filled them. Any syringes prefilled by the provider must be stored within the recommended temperature range and used or discarded by the end of the workday.

CDC recommends manufacturer-filled syringes for large immunization events, such as community influenza vaccination clinics. Once a manufacturer-filled syringe is activated (e.g., syringe cap removed or needle attached) it must be stored within the recommended temperature range and used or discarded by the end of the workday.

Often providers have different TIV presentations in the same storage unit. Influenza products and presentations have different approved indications (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, dosage and route of administration can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

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Measles-, Mumps- and Rubella-Containing Vaccine MMR: M-M-RII

Note: Information pertaining to MMRV (ProQuad) can be found on page 69

Condition upon Arrival

Measles, Mumps, Rubella vaccine (MMR) has 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store lyophilized vaccine and diluent according to the manufacturer's guidelines immediately upon arrival.

Lyophilized vaccine: Store MMR lyophilized vaccine in the refrigerator or freezer between -58°F and +46°F (-50° and +8°C). Protect vaccine from light at all times by storing in the original box.

Diluent: Store diluent in the refrigerator between 35°F* and 46°F (2°C and 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the label.

Preparation

MMR is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

- 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
- Shake the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- 3. The reconstituted vaccine should be a yellow, clear liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MMR may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect reconstituted vaccine from light at all times. Agitate stored, reconstituted vaccine prior to administration.

• Do not administer reconstituted MMR vaccine if it is not used within 8 hours. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between -58°F and +46°F (-50°C and +8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

MMR vaccine can be stored in the refrigerator or freezer. Consider storing MMR in the freezer between -58° F and $+5^{\circ}$ F (-50° C and -15° C).

- Storing MMR in the freezer can free up storage space in the refrigerator. More vaccines must be stored in the refrigerator than in the freezer. Storing MMR in the freezer increases the space available for vaccines that should be stored in the refrigerator.
- In addition, storing MMR in the freezer can decrease confusion when stocking both MMR and MMRV (ProQuad). MMRV must be stored in the freezer. MMRV has been inadvertently moved to the refrigerator storage because staff confused it with MMR. Storing MMR and MMRV in the freezer decreases the likelihood of this happening.

MMR may be stored and/or transported in an insulated container between 35°F and 46°F (2°C and 8°C). Place a calibrated thermometer in the container with the vaccine. Monitor and record the temperature. **Use of dry ice is not recommended**, even for temporary storage. Dry ice may subject MMR vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the same vaccine in the storage unit, for example, MMR and MMRV (ProQuad) vaccines. Vaccine

products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.
Meningococcal Vaccines MCV4: Menactra, Menveo

Condition upon Arrival

Meningococcal conjugate vaccine (MCV4) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

• Menveo has 2 components. The lyophilized Men A vaccine and the diluent (Men C, Y, W-135) vials should arrive packaged together in the same shipping container.

Storage Requirements

Refrigerate vaccine and diluent, if applicable, immediately upon arrival. Do not freeze or expose to freezing temperatures.

- Menactra: Refrigerate between 35°F and 46°F (2°C and 8°C).
- Menveo: Refrigerate the lyophilized Men A vaccine and vaccine diluent (Men C, Y, W-135) together between 35°F* and 46°F (2°C and 8°C). Do not store them separately. Protect Menveo from light at all times by storing in the original box.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe of the vaccine AND diluent, if applicable. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- Menactra: This vaccine is a clear to slightly cloudy liquid.
- Menveo: This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine. Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them".
 - 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
 - 2. Shake the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation
 - 3. The reconstituted vaccine should be a clear, colorless liquid.

Beyond Use Date*: Shelf Life after Opening

Menactra: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Menveo: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted Menveo may be stored at or below 77°F (25°C) for up to 8 hours. Do not freeze or expose reconstituted vaccine to freezing temperatures. Protect from light. Agitate any stored, reconstituted vaccine prior to administration.

• **Do not administer reconstituted Menveo vaccine if it is not used within 8 hours.** Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications, and/or route of administration can help prevent vaccine administration errors. Refer to the Resources sections at the end of this document for examples of labels.

Meningococcal Vaccines MPSV4: Menomune

Condition upon Arrival

Meningococcal polysaccharide vaccine (MPSV4) has 2 components: lyophilized vaccine and diluent. MPSV4 should arrive packed in an insulated container. Both components should arrive packaged together in the same shipping container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine and diluent in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from other uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate the lyophilized vaccine and diluent immediately upon arrival. **Store the lyophilized vaccine and diluent between 35°F and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use vaccine or diluent after the expiration date shown on the label.

Preparation

MPSV4 is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for an example of a label and the educational handout "Vaccines with Diluents: How to Use Them". This vaccine should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

- 1. Just before use, withdraw the entire contents of the diluent vial and inject it into the vial containing the lyophilized vaccine component.
- Swirl the vial containing the lyophilized vaccine and diluent well to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- 3. The reconstituted vaccine should be a clear, colorless liquid. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted MPSV4 vaccine may be stored in the refrigerator between 35°F and 46°F (2°C and 8°C) for up to 30 minutes. Agitate any stored, reconstituted vaccine prior to administration.

• Do not administer reconstituted MPSV4 vaccine if it is not used within 30 minutes. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

Multidose Vials: Shake well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).

• Once entered, the multidose vial of MPSV4 should be discarded after 35 days.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). For example, meningococcal vaccines (MCV4 and MPSV4) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Pneumococcal Vaccines PCV13: Prevnar 13 PPSV23: Pneumovax 23

Condition upon Arrival

Pneumococcal vaccines (PCV13, PPSV23) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect the vaccine visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- **PCV13:** During storage, the aluminum phosphate particles may settle, and this can result in a clear liquid solution above the aluminum phosphate particles. Just before use, shake VIGOROUSLY. After shaking, PCV13 is a white liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- **PPSV23:** Just before use, shake vial well. After shaking, PPSV23 should be a clear, colorless liquid. Do not use the vaccine if it cannot be resuspended with thorough agitation.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time of administration.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

PPSV23 Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). For example, pneumococcal vaccines (PCV13 and PPSV23) can be confused when stored in the same storage unit. Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors. Refer to the Resources section of this document for examples of labels.

Poliovirus-Containing Vaccine

IPV: IPOL

Note: Information pertaining to DTaP-IPV (KINRIX) can be found on page 11 Information pertaining to DTaP-IPV/HepB (Pediarix) can be found on page 11 Information pertaining to DTaP-IPV-Hib (Pentacel) can be found on page 11

Condition upon Arrival

Inactivated polio vaccine (IPV) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. This vaccine should not be

combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed or needle attached) at the time the vaccine is administered. **Multidose Vials:** Withdraw a single dose (0.5 mL) of vaccine into sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C)**. A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date (time) the manufacturerfilled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers can have different products or presentations containing the same vaccine in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications and uses (e.g. ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Rotavirus Vaccines RV1: ROTARIX RV5: RotaTeq

Condition upon Arrival

Rotavirus vaccines (RV1, RV5) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

• **RV1 (ROTARIX) has 2 components.** The lyophilized vaccine and diluent should arrive packaged together in the same shipping container.

Storage Requirements

Store the vaccine and diluent, if applicable, according to the manufacturer's guidelines immediately upon arrival. Do not freeze or expose to freezing temperatures. Protect vaccine from light at all times by storing in the original box.

- RV1 (ROTARIX): Refrigerate lyophilized vaccine between 35°F and 46°F (2°C and 8°C). Store diluent separately at room temperature between 68°F and 77° F (20°C and 25°C).
- RV5 (RotaTeq): Refrigerate between 35°F* and 46°F (2°C and 8°C).

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of vaccine AND diluent. Do not use vaccine or diluent, if applicable, after the expiration date shown on the label.

Preparation

RV1 and RV5 should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

- RV1 (ROTARIX): This vaccine is supplied in 2 vials that must be mixed together before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine. Reconstituted vaccine is a cloudy, white liquid. Refer to the Resources section at the end of this document for an educational handout "Vaccines with Diluents: How to Use Them".
- **RV5 (RotaTeq):** This vaccine is supplied in a single dose squeezable plastic, latexfree dosing tube with a twist off cap. The dosing tube is contained in a pouch

Beyond Use Date*: Shelf Life after Opening

RV1 (ROTARIX): After reconstitution, **administer immediately**. Store unused, reconstituted RV1 in the oral applicator between 35°F and 46°F (2°C and 8°C) or at room temperature up to 77°F (25°C) for up to 24 hours. Agitate any stored, reconstituted vaccine prior to administration. Do not freeze reconstituted vaccine.

• Do not administer reconstituted RV1 vaccine if it is not used within 24 hours. Follow the immunization program guidance before discarding VFC or other publicly purchased vaccines. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

RV5 (RotaTeq): This vaccine should be removed from the refrigerator and the screw cap removed at the time the vaccine is administered. Once the screw cap has been removed, the dosing tube should not be returned to the refrigerator. **Administer immediately.**

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Providers may have different products or presentations containing the same vaccine in the storage unit. Vaccine products and presentations often have different approved indications and uses (e.g., ages). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications and route of administration can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Tetanus Toxoid Vaccine TT: Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid vaccine (TT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/ manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container or vial. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial well. Do not use vaccine if it cannot be resuspended with thorough agitation. This vaccine should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Multidose Vials: Shake vial well prior to withdrawing each dose. Withdraw a single dose (0.5 mL) of vaccine into a sterile syringe using a sterile needle at the time the vaccine is administered. A separate, sterile syringe and needle should be used for each immunization. **Unused portions of multidose vials should be refrigerated between 35°F and 46°F (2°C and 8°C).** A multidose vial that is normal in appearance, stored and handled properly can be used through the expiration date printed on the vial unless otherwise stated in the manufacturer's product information.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

TT vaccine should only be used for tetanus immunization if the person has a severe, life-threatening allergy to the diphtheria component in other tetanuscontaining vaccines. For persons 11 years of age and older who need a tetanus toxoid-containing vaccine, the Advisory Committee on Immunization Practices recommends the following:

• Tdap vaccine, if available, is preferred to TT or Td for those not previously vaccinated with Tdap.

- Td vaccine, if available, is preferred to TT for those previously vaccinated with Tdap.
- Tdap or Td vaccines, if neither available, TT should be administered.

Tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Tetanus Toxoid- and diphtheria toxoid-Containing Vaccines Td: DECAVAC DT: Diphtheria and Tetanus Toxoid

Condition upon Arrival

Tetanus toxoid- and diphtheria toxoid-containing vaccines (Td; DT) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F and 46°F (2°C and 8°C)**. Do not freeze or expose to freezing temperatures.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or

manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

• After shaking, Td vaccine is a cloudy, whitish-gray colored liquid.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered.

Manufacturer-Filled Syringes: Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines

in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for examples of labels.

Tetanus Toxoid-, diphtheria toxoid-, and acellular pertussis- Containing Vaccines Tdap: Adacel, Boostrix

Condition upon Arrival

Tetanus toxoid-, diphtheria toxoid- and acellular pertussis-containing vaccine (Tdap) should arrive packed in an insulated container. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the distributor/manufacturer and arrival of the vaccine at the facility has been more than 48 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- Immediately place the vaccine in the refrigerator between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the distributor and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Refrigerate immediately upon arrival. **Store between 35°F* and 46°F (2°C and 8°C).** Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container, vial or manufacturer-filled syringe. Do not use after the expiration date shown on the label.

Preparation

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Just before use, shake vial or manufacturer-filled syringe well. Do not use vaccine if it cannot be resuspended after thorough agitation. After shaking, Tdap should be a cloudy, white colored liquid. These vaccines should not be combined or mixed with any other vaccines. Refer to the Resources section at the end of this document for information on vaccine administration.

Beyond Use Date*: Shelf Life after Opening

Single-Dose Vials: All of the vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Manufacturer-Filled Syringes:** Manufacturer-filled syringes should be activated (i.e., syringe tip removed and/or needle attached) at the time the vaccine is administered.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Vaccine exposed to temperatures outside the recommended range- either too warm or too cold- **requires immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- 1. Place the vaccine in the recommended storage between 35°F and 46°F (2°C and 8°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

Diphtheria toxoid- and tetanus toxoid-containing vaccines are easily confused increasing the risk for a vaccine administration error. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name, age indications or other information unique to the vaccine can help prevent vaccine administration errors. Refer to the Resources section at the end of this document for an example of a label.

Varicella-Containing Vaccines VAR: Varivax (chickenpox) ZOS: Zostavax (herpes zoster/shingles) MMRV: ProQuad

Condition upon Arrival

Varicella-containing vaccines (VAR, MMRV and ZOS) have 2 components: lyophilized vaccine and diluent. Both components should arrive together in the same shipping container. The vaccine and diluent should be in separate compartments. Examine the shipping container and contents for damage during transport. Some vaccines are shipped with a temperature monitor. If a temperature monitor is present, check and follow the instructions. The vaccine should not have been frozen or exposed to freezing temperatures. If the interval between shipment from the manufacturer and arrival of the vaccine at the facility has been more than 72 hours or you have questions about the condition of the vaccine at the time of delivery, you should take three steps.

- 1. Immediately place the vaccine in the freezer between -58°F and +5°F (-50°C and -15°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the distributor, manufacturer and/or the immunization program for guidance.

NOTE: Contact the manufacturer and immunization program regarding shipments of Vaccines for Children (VFC) or other vaccines purchased with public funds that may not have been transported properly.

Storage Requirements

Store the lyophilized vaccine and diluent according to the manufacturer's guidelines immediately upon arrival. Do not store lyophilized vaccine and diluent together.

Lyophilized vaccine: Store lyophilized vaccine in the freezer between -58°F and +5°F (-50°C and -15°C). Protect vaccine from light at all times by storing in the original box. Vaccine should only be stored in freezers or refrigerator/freezer units with separate compartments and exterior doors.

Diluent: Store separately from lyophilized vaccine in the refrigerator between 35°F* and 46°F (2°C to 8°C) or at room temperature between 68°F and 77°F (20°C and 25°C). Do not freeze or expose to freezing temperatures.

*Storage temperatures between 36°F and 46°F (2°C and 8°C) are specified in the label and the license for these products. However, 2°C is exactly converted to 35.6°F so the manufacturer's guidance for Fahrenheit is rounded by the manufacturer.

Shelf Life

Check expiration date on the container or vial of the vaccine AND diluent. Do not use after the expiration date shown on the labels.

Preparation

These vaccines must be reconstituted before administration. Consider posting reminders or labeling the vaccine to remind staff to reconstitute it. **Only use the diluent supplied by the vaccine manufacturer to reconstitute the vaccine.** Refer to the Resources section at the end of this document for examples of labels and the educational handout "Vaccines with Diluents: How to Use Them". These vaccines should not be combined or mixed with any other vaccines. The Resources section at the end of this document also includes vaccine administration information.

- 1. Just before use, withdraw the entire contents of the diluent vial and inject it slowly into the vial containing the lyophilized vaccine vial.
- 2. Gently shake or agitate the vial now containing the lyophilized vaccine and diluent to mix thoroughly. Do not use the vaccine if it cannot be resuspended with thorough agitation.
- 3. Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Reconstituted vaccine should have the following appearance:
 - VAR: Clear, colorless to pale yellow liquid.
 - ZOS: Semi-hazy to translucent, off white to pale, yellow liquid.
 - MMRV: Pale yellow to light pink, clear liquid.

Beyond Use Date*: Shelf Life after Opening

All of the reconstituted vaccine should be drawn into a sterile syringe using a sterile needle at the time the vaccine is administered. **Administer immediately.** Unused, reconstituted varicella and MMRV vaccines may be stored at room temperature between 68°F and 77°F (20°C and 25°C) for up to 30 minutes. Protect from light. Do

not freeze or exposed reconstituted vaccine to freezing temperatures. Agitate any stored, reconstituted vaccine prior to administration.

• Do not administer reconstituted varicella-containing vaccine (VAR, ZOS, MMRV) if it is not used within 30 minutes. Follow the immunization program guidance before discarding VFC or other vaccines purchased with public funds.

*The date or time after which the vaccine should not be used; determined from the date or time the manufacturer-filled syringe is activated, vial is entered or vaccine is reconstituted; may be different from the expiration date.

Vaccines Exposed to Inappropriate Temperatures (Temperature Excursions)

Varicella-containing vaccines exposed to temperatures outside the recommended range **require immediate corrective action!** Vaccine providers should have a current emergency vaccine retrieval and storage plan that includes, but is not limited to, these four actions.

- Vaccine exposed to temperature above +5°F should be stored in the refrigerator between 35°F and 46°F (2°C and 8°C).
 Vaccine exposed to temperatures below -58F should be stored in a freezer between -58°F and +5°F (-50°C and -15°C).
- 2. Mark vaccine "Do Not Use" and separate from uncompromised vaccines. A clearly labeled paper bag can be used for this purpose.
- 3. Follow your immunization program policy and contact the manufacturer and/ or the immunization program for further guidance.
- 4. Do not discard vaccine unless directed to by the immunization program and/ or the manufacturer.

NOTE: Contact the immunization program whenever VFC or other vaccines purchased with public funds are exposed to temperatures outside the recommended range.

Special Instructions

In order to maintain temperatures between -58°F and +5°F (-50°C and -15°C), it will be necessary in most combination refrigerator/freezer models to turn the temperature dial down to the coldest setting. This may result in the refrigerator compartment temperature being lowered as well. Careful monitoring of the refrigerator temperature will be necessary to avoid freezing vaccines stored in the refrigerator.

"Dormitory-style" refrigerator/freezer is not appropriate for the storage of varicellacontaining vaccines. A dormitory-style refrigerator is defined as a small combination freezer/refrigerator unit that is outfitted with one exterior door and an evaporator plate (cooling coil), which is usually located inside an icemaker compartment (freezer) within the refrigerator.

CDC and the vaccine manufacturer do not recommend transporting varicellacontaining vaccines. If varicella-containing vaccines must be transported, CDC recommends transport with a portable freezer unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places. According to the manufacturer's product information varicellacontaining vaccines may be stored between 35°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution. If varicella-containing vaccines must be transported between 35°F and 46°F (2°C and 8°C) complete the following actions:

- 1. Place a calibrated thermometer in the container as close as possible to the vaccine.
- 2. Record:
 - a. the time refrigerator storage began
 - b. the time refrigerator storage ended
 - c. storage temperature during transport
- 3. Contact the manufacturer (1-800-9-VARIVAX) immediately upon arrival at the alternate storage facility for further guidance.
- 4. Do not discard vaccine without contacting the manufacturer and/or the immunization program for guidance.

Use of dry ice is not recommended, even for temporary storage. Dry ice may subject varicella-containing vaccine to temperatures colder than -58°F (-50°C).

Providers can have different products or presentations containing the varicellacontaining vaccines in the storage unit. For example, single antigen and combination vaccines. Vaccine products and presentations often have different approved indications and uses (e.g., ages, route). Storing multiple products and presentations can be confusing to staff and increase the risk for vaccine administration errors. Consider organizing vaccines in the storage unit by age group and/or color coding labels to distinguish vaccines from each other. Do not store sound-alike or look-alike vaccines next to each other. Labeling the space where the vaccine is stored with name and age indications can help prevent vaccine administration errors.

CDC Resources

Advisory Committee on Immunization Practices U.S. VACCINE ABBREVIATIONS

http://www.cdc.gov/vaccines/recs/acip/downloads/vac-abbrev.pdf

Epidemiology and Prevention of Vaccine-Preventable Diseases 12th Edition Storage and Handling Chapter 5

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf

Storage and Handling Resources Appendix C

<u>http://www.cdc.gov/vaccines/pubs/pinkbook/pink-appendx.htm#appc</u> Vaccine Administration Appendix D

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-d.pdf

Epidemiology and Prevention of Vaccine-Preventable Disease Course Session 2 includes vaccine storage and handling information

http://www.cdc.gov/vaccines/ed/epivac/default.htm

General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)

http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf

Storage and Handling web page

http://www.cdc.gov/vaccines/recs/storage/default.htm

Storage and Handling ToolKit

http://www2a.cdc.gov/vaccines/ed/shtoolkit/

Vaccine Label Examples

http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf

Vaccine Administration web page

http://www.cdc.gov/vaccines/recs/vac-admin/default.htm

Other Resources

Alliance for Immunization in Michigan (AIM) Provider ToolKit www.aimtoolkit.org

Storage and Handling Materials

http://www.aimtoolkit.org/vaccine.php Vaccine Administration Materials Children http://www.aimtoolkit.org/children.php Adolescents http://www.aimtoolkit.org/adolescents.php Adults http://www.aimtoolkit.org/adults.php

EZIZ- California Vaccines for Children (VFC) Program

Storage and Handling Educational Video http://eziz.org/eziz-training/ Storage and Handling Job Aides http://eziz.org/resources/materials_storageandhand.html Vaccine Administration Educational Video http://eziz.org/eziz-training/ Vaccine Administration Job Aides http://eziz.org/resources/vaccine-admin-job-aids/

Immunization Action Coalition (IAC)

www.immunize.org

Handling and Storage Resources

http://www.immunize.org/handouts/vaccine-storage-handling.asp Handling and Storage FAQ's http://www.immunize.org/askexperts/experts_general.asp Checklist for Safe Vaccine Storage and Handling http://www.immunize.org/catg.d/p3035.pdf Don't be Guilty of These Errors in Vaccine Storage and Handling http://www.immunize.org/catg.d/p3036.pdf Emergency Response Worksheet http://www.immunize.org/catg.d/p3051.pdf

Skills Checklist for Immunization
http://www.immunize.org/catg.d/p7010.pdf
Temperature Logs for Refrigerator and Freezer:
Celsius http://www.immunize.org/catg.d/p3039a.pdf
Fahrenheit http://www.immunize.org/catg.d/p3039.pdf
Vaccines with Diluents: How to Use Them
http://www.immunize.org/catg.d/p3040.pdf
Vaccine Handling Tips
http://www.immunize.org/catg.d/p3048.pdf
Vaccine Administration Resources
http://www.immunize.org/clinic/administering-vaccines.asp
Vaccine Administration FAQ's
http://www.immunize.org/askexperts/experts_general.asp#admin
Administering Vaccines: Dose, Route, Site, and Needle Size
http://www.immunize.org/catg.d/p3085.pdf
How to Administer IM and SC Injections
http://www.immunize.org/catg.d/p2020.pdf
Manufacturer's Product Information
http://www.immunize.org/packageinserts/

Thermal Analysis of Refrigeration Systems Used for Vaccine Storage http://www.nist.gov/customcf/get_pdf.cfm?pub_id=904574

State Immunization Program Information

State Immunization Program Websites

http://www.cdc.gov/vaccines/spec-grps/prog-mgrs/grantee-imz-websites.htm

Manufacturer / Distributor Websites	Telephone Number/E-mail	Products
Centers for Disease Control and Prevention www.cdc.gov/ncidod/srp/drugs/ drug-service.html http://www.cdc.gov/laboratory/ drugservice/index.html	404-639-3670/ drugservice@cdc.gov	Distributor for diphtheria antitoxin, VIG, smallpox vaccine
GlaxoSmithKline (GSK) http://www.gskvaccines.com/	866-475-8222	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, HPV2, RV1, Tdap, TIV
Massachusetts Biological Labs http://www.umassmed.edu/ massbiolabs/index.aspx	617-474-3000	IGIM, Td, TT
MedImmune http://www.medimmune.com/	877-633-4411 medinfo@medimmune.com	LAIV
Merck & Co., Inc https://www.merckvaccines.com/	800-637-2590	HepA, HepB, Hib, Hib- HepB, HPV4, MMR, MMRV, PPSV23, Td, TIV, VAR, ZOS
Biotest Pharmaceuticals http://www.biotestpharma.com/ products/nabiHB.html	800 458-4244 ma@biotestpharma.com	HBIG
Novartis http://www.novartisvaccines.com/ us/index.shtml	877 683-4732 Vaccineinfo.us@novartis.com	TIV
Pfizer/Wyeth http://pfizerpro.com/	800-438-1985	PCV13
Sanofi Pasteur https://www.vaccineshoppe.com/	800-822-2463	DT, DTaP, DTaP-IPV/ Hib, Hib, IPV, MCV4, MPSV4, Rabies, RIG, Td, Tdap, TIV, TT
Talecris Biotherapeutics http://www.talecris.com/talecris- biotherapeutics-us-home.htm	800-520-2807 talecris@medcomsol.com	HBIG, IGIM, RIG, TIG