

North Dakota Immunization Program Vaccine Management Plan



NORTH DAKOTA
DEPARTMENT *of* HEALTH

Division of Disease Control
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Immunization Program Staff

Molly Sander, Immunization Program Manager msander@nd.gov	701.328.4556
Abbi Pierce, Immunization Surveillance Coordinator apierce@nd.gov	701.328.3324
Darcey Tysver, Vaccines for Children Coordinator dtysver@nd.gov	701.328.2035
Keith LoMurray, NDIIS Sentinel Site Coordinator klomurray@nd.gov	701.328.2404
Kim Weis, AFIX Coordinator kweis@nd.gov	701.328.2385

Vaccine Distribution/Inventory Assistance

Teri Arso, Vaccine Distribution tarso@nd.gov	701.328.3386
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NORTH DAKOTA
DEPARTMENT *of* HEALTH

Division of Disease Control
600 E. Boulevard Ave.
Bismarck, ND 58505-0200

701.328.3386 or 800.472.2180
(FAX) 701.328.2499

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Introduction

Vaccines for Children Program Background

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who are VFC eligible. The VFC Program was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan. The VFC Program offers free vaccine only to individuals 18 and younger who are Medicaid eligible, American Indian or Alaskan Native, without health insurance, or underinsured (a child whose health insurance benefit plan does not cover a particular vaccine). The program was officially implemented in October 1994 as part of President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Federal Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount and distributes them to grantees — i.e., state health departments and certain local and territorial public health agencies — which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices through passage of VFC resolutions.

Importance of Storage and Handling

Vaccine storage and handling are important in order to ensure the efficacy of vaccines in preventing vaccine-preventable diseases. Failure to store vaccines properly can lead to an inadequate immune response from the vaccines in children.

Storage and handling are also important in order to prevent the wastage of increasingly expensive vaccines. In 2008, North Dakota providers reported wasting 5,014 doses of vaccine, which is approximately \$78,309.64 worth of vaccine. This is only the reported wastage. There is no way to know how much vaccine was wasted and not reported.

Proper vaccine storage and handling are necessary in order to prevent having to repeat vaccinations in children who received improperly stored vaccine. Repeat vaccinations can lead to an increase in adverse reactions and wasted money spent on vaccinations that weren't needed.

It is important for providers to thoroughly read the North Dakota Department of Health Vaccines for Children Manual in order to understand the requirements of the VFC program and to prevent vaccine wastage in North Dakota.

VFC Program Requirements

- Providers must enroll annually with the Prevention Partnership Program to receive VFC or state-supplied vaccine. This enrollment must be signed by the medical director or equivalent and list all the providers within the practice (hospitals do not need to list all providers).
- A Provider Profile must be completed annually by each provider using data from the previous year. This information can be obtained by running a “Doses Administered” report for 2008, available under the “Reports” section of the North Dakota Immunization Information System (NDIIS). Under the “Reports” tab, select the “Doses Administered” report along with the desired criteria, such as dates and client type.
- All patients must be screened for eligibility at all immunization encounters.
- VFC vaccine must be administered only to children age 18 or younger who meet one or more of the following categories:
 - American Indian or Alaska Native.
 - Enrolled in Medicaid.
 - No health insurance.
 - Underinsured (a child whose health insurance benefit plan does not cover any or specified vaccines). Must be vaccinated at Federally Qualified Health Centers (FQHC) or rural health clinics or at providers who have a Letter of Agreement with a FQHC.
- State-supplied vaccine must be administered only to those eligible according to the most recent Vaccine Coverage Table.
- Screening information must be documented on the Vaccine Administration Record (VAR) or on the Patient Eligibility Screening Form **and** in the NDIIS.
- The immunization schedule, dosage and contraindications that are established by the ACIP and included in the VFC program must be followed unless:
 - In the provider’s medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate. This determination must be made on a case-by-case basis.
 - The particular requirements contradict state law, including those pertaining to religious and other exemptions.

- Distribute the most current Vaccine Information Statements (VIS) every time a vaccine is administered, and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
 - VIS forms can be ordered from the North Dakota Department of Health (NDDoH) and are also available at www.cdc.gov/vaccines/pubs/vis/default.htm and www.immunize.org/vis/.
 - If the NDDoH VAR is not used, the following information about VISs must be kept in the patient’s permanent medical record.
 - Which VIS was given?
 - Date of publication of the VIS.
 - Date the VIS was given.
 - VAERS forms should be faxed to the NDDoH at 701.328.0355. **(See Appendix 1 for a VAERS form)**
- Maintain all records (including patient screening forms, temperature logs, etc.) related to the VFC program for a minimum of three years and make these records available to public health officials including the North Dakota Department of Health or U.S. Department of Health and Human Services upon request.
- The maximum vaccine administration fee that may be charged for VFC or state-supplied vaccine is \$13.90.
- The reimbursement for immunization administration set by the state Medicaid agency for vaccine administered to children enrolled in Medicaid must be accepted.
- Immunize eligible children with VFC or state-supplied vaccine at no charge to the patient for the vaccine.
 - Patients or Medicaid cannot be billed for the cost of VFC or state-supplied vaccine.
 - Do not administer VFC vaccine to patients not eligible for the VFC program.
 - Borrowing VFC vaccine to administer to a non-VFC eligible patient can occur only in rare, unplanned situations (i.e., outbreaks, shortages, etc.).
 - Replace the vaccine as soon as possible with privately purchased vaccine.

- Record all borrows/returns in the NDIIS.
- Do not deny administration of a VFC or state-supplied vaccine to a patient because the child's parent or guardian or the patient is unable to pay the administration fee.
 - Other visit or office fees may be charged.
- Operate within the VFC program in a manner intended to avoid fraud and abuse.
- Comply with the NDDoH requirements for ordering, vaccine accountability and vaccine management according to the Vaccine Loss Policy, Vaccine Fraud and Abuse Policy and the Vaccine Management Plan.

Vaccine Personnel

- Providers should designate a primary vaccine coordinator and at least one backup. These people must be responsible for the following:
 - Monitoring and recording twice daily the temperatures on the temperature logs for each storage unit containing state-supplied vaccine.
 - Adjusting the temperature of a vaccine storage unit.
 - The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
 - Checking expiration dates of vaccine and ensuring the earliest outdates are placed in the front of the freezer/refrigerator.
 - Receiving all VFC vaccine shipments or ensuring that others who may receive the order are aware of the procedure for receiving vaccine.
- Training of other staff who are responsible for administering vaccine should be the responsibility of the vaccine coordinator.
- The coordinator can be the same person who orders vaccine.

Vaccine Storage, Handling and Disposal Guidelines

Providers must follow recommendations and general guidelines for handling, storage and disposal of vaccines from *Vaccine Management: Recommendations for Handling and Storage of Selected*

Biologicals, a publication from the U.S. Department of Health and Human Services. (See Appendix 2) This guide is also available online at www.cdc.gov/vaccines/pubs/vac-mgt-book.htm. Information in addition to these recommendations is listed below. These recommendations are NOT a substitute for the package insert included with each biological.

Vaccine Storage

Storage Requirements

All VFC providers are required to have appropriate equipment that can store and assist with the maintenance of proper conditions of vaccines. Refrigerators without freezers and stand-alone freezers may be better at maintaining the required temperatures. However, combination refrigerator/freezer units are acceptable for vaccine storage if the refrigerator and freezer components each have a separate external door.

Refrigerators and freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required, stable vaccine storage temperatures year-round.
- Be large enough to hold the year’s largest inventory.
- At minimum, have a working certified thermometer inside each storage compartment.
- Be dedicated to the storage of vaccines. Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.

After December 31, 2009, the CDC will no longer allow VFC vaccine to be stored in dorm-style fridges, and these types of units will not be considered acceptable storage units for VFC vaccine. Dorm-style fridges are not adequate for long-term or permanent storage of vaccine because they do not maintain proper temperatures and pose a high risk of freezing vaccine. As of January 1, 2010, the only acceptable use of dorm-style fridges will be to store a clinic’s single-day supply of refrigerated (never frozen) vaccine, and these vaccines must be returned to the main refrigerator storage unit **at the end of each day**. Temperatures must still be monitored and recorded twice daily for any dorm-style fridges used for storing single-day supplies of vaccine. These logs must be submitted to the NDDoH monthly with the main storage unit’s logs. **Providers currently using dorm-style fridges for permanent VFC or state-supplied vaccine storage will need to have acceptable storage units in use by January 1, 2010, in order to be compliant with the requirements of the VFC program.**

Refrigerated Vaccines

These biologicals **MUST** be stored at the recommended temperatures of 2° to 8 ° C or 35° to 46° F):

DT	Influenza
DTaP	IPV

DTaP/Hib	Live attenuated influenza vaccine
DTaP/HBV/IPV	MCV-4
DTaP/Hib/IPV	MPV-4
DTaP/IPV	PCV-7
HBIG	PPV-23
Hepatitis A	Rotavirus
Hepatitis B	Td
Human Papillomavirus	Tdap
Hib	

The above vaccines must **NOT** be stored in the freezer.

- Vaccine diluents may be stored at room temperature.
- MMR vaccine may be stored in the refrigerator or the freezer. Storing MMR in the freezer prevents vaccine wastage due to power failures because the vaccine will take longer to warm to out-of-range temperatures when frozen.
- MMRV **MUST NOT** be stored at refrigerator temperature at any time.

Frozen Vaccine

Varicella, MMRV and Shingles:

- Varicella, MMRV, and shingles vaccines are required to be stored at a temperature of -15° C or +5° F or below.
- Discard reconstituted varicella, MMRV and shingles vaccine after 30 minutes.
- Do not freeze reconstituted varicella, MMRV or shingles vaccine.
- Protect varicella, MMRV and shingles vaccine from light before and after reconstitution.

Providers must monitor the temperature of their refrigerator/freezer with certified thermometers.

- Thermometers must be certified in accordance with National Institute of Standards and Technology or the American Society for Testing and Materials standards. Minimum/maximum thermometers are available from the NDDoH for storage units containing state-supplied vaccine.
- The optimal system for monitoring refrigerator/freezer temperatures is an automated temperature-sensing device. If a sensing device is not feasible, a min/max thermometer is recommended. Thermometers should be placed in the center of the refrigerator, next to the vaccine.
- Monitor and log temperatures (preferably using a min/max thermometer) at least twice per day (beginning and end). Post a temperature-recording chart on your refrigerator/freezer to record the temperatures. Copies of temperature recording charts must be sent in to the NDDoH at the end of every month for each unit containing state-supplied vaccine. **(For temperature recording charts, see Appendix 3 to 5).**
- Temperature logs must be saved for a minimum of three years.
- **Action must be taken and recorded on every out-of-range temperature.** If refrigerator or freezer temperatures are out-of-range, record the temperature on a temperature log and immediately isolate the affected vaccine. Mark “do not use” until the NDDoH and vaccine manufacturers have been contacted. Do not assume that the vaccine is not viable and do not discard any state-supplied vaccine until the NDDoH has been contacted. Recorded actions should be sent monthly to the NDDoH along with the temperature logs.
- Do not use the freezer of a dormitory-style refrigerator.
- Do not store food or beverages in a refrigerator that contains biologicals.
- Stack vaccine with enough air space between stacks to allow cold air to circulate around the vaccine.
- Do not stack vaccine next to coils in the refrigerator. The coils are extremely cold and could result in the vaccine being frozen.
- Never store vaccine in the refrigerator door. Opening and closing doors in refrigerators causes unnecessary temperature changes and could cause vaccine failure.
- Rotate biologicals in the refrigerator/freezer so that the shortest dated vaccine is used first.

- Once a month, check vaccine inventory for expiring vaccine. **If vaccine is expiring within three months and the clinic will be unable to use the vaccine before expiration, transfer the vaccine to another provider.** It is the provider’s responsibility to find another provider to accept the vaccine and to properly package and ship the vaccine following standard cold-chain procedure. Contact information for other VFC providers can be found in the NDIIS under the “Provider Search” tab. Do not return any vaccine to the NDDoH.
- Place ice packs in the freezer and filled plastic water jugs in the refrigerator to help maintain temperature stability. This helps keep temperatures uniform and provides additional cold mass, both of which are useful, particularly if there is a power failure.
- Unofficial studies have indicated some biologicals will retain their potency when left at room temperature for short periods of time. Please contact the vaccine manufacturer for efficacy of vaccine not stored properly.
- Place a warning sign to prevent unplugging the refrigerator/freezer by the plug/outlet to help ensure that the refrigerator/freezer is not turned off. **(See Appendix 6)** Also place a warning sign on the circuit breaker for the refrigerator/freezer.

Other suggestions

- Install **PLUG GUARDS/PROTECTORS** in outlets. This helps prevent power loss.
- Lock storage facilities and equipment. This prevents unauthorized removal of vaccine and use of storage for other purposes.
- Diluent should be stored outside the refrigerator. It takes up space and does not need to be refrigerated.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily identifiable.
- Stabilize refrigerator and freezer temperature with proper placement and use of water bottles and frozen packs.
- Keep vaccines organized. (Place opened vials of vaccine in a tray so that they are readily identifiable.)
- Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.

- Open only one vial, or box, of a particular vaccine at a time to control vaccine usage and allow easier inventory control.
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.
- Follow manufacturer's recommended schedule for recalibration of the certified thermometers.
- Conduct a monthly inventory to monitor vaccine use, anticipate needs and remove expired vaccines.
- Safeguard public vaccines by providing facility security such as temperature alarms and restricted access to vaccine storage and handling areas.
- In larger clinics, provide a source of backup power (generators) and a security system to alert the appropriate personnel in the event of a power outage.
- If applicable, test backup generators quarterly and maintain backup generators at least annually. (Check manufacturer specifications for test procedures and maintenance schedules)

Vaccine Handling

- **It is recommended that vaccines not be drawn up prior to administration.**
- Biologicals may lose efficacy if stored in syringes for any period of time.
- If vaccines are drawn up prior to administration because of large clinics or limited staff, observe the following guidelines:
 - NO vaccine should be administered if drawn up in syringes for more than eight hours.
 - NEVER return vaccine to a multiple-dose container.
 - MMR may be kept up to eight hours in a dark, cool place after reconstitution.
 - Varicella, MMRV and shingles vaccines must be administered within 30 minutes after reconstitution. Discard reconstituted vaccine if not used within 30 minutes.
 - MMRV MUST NOT be stored at refrigerator temperature at any time.

- Properly stored vaccines are valid until expiration date. If the expiration date is listed as a month and year only, vaccine is valid until the end of that month (e.g., July 98 -- valid until July 31, 1998). **Vaccines should be utilized until the expiration date.**

Emergency Vaccine Storage and Handling

In the event of a freezer/refrigerator failure, power failure, natural disaster or other emergency that may compromise the storage condition of vaccines, each provider must have a written emergency vaccine storage and handling plan. **(For an example, see Appendix 7)** This plan should be reviewed and updated as needed and at least annually. NDDoH staff making site visits will ask to see this plan. This plan must include:

- Person(s) responsible for preparing and transporting including contact information.
- How this person will be notified that vaccine needs to be moved.
- Location that will receive vaccine.
- How receiving location will be notified of transport.
- How to pack vaccine for transport.
- Worksheet to document vaccine involved in power or equipment failure.

Vaccine Return and Wastage

Immediately notify the NDDoH if any vaccine is exposed to temperatures outside of the normal storage condition for that vaccine. Failure to report wasted vaccine to the NDDoH may result in your facility no longer being able to receive state-supplied vaccine.

Return all unopened vials and manufacturer’s pre-filled syringes of non-viable vaccine to McKesson. Vaccine provided by the NDDoH should never be discarded. The one exception would be open vials or syringes, including multi-dose vials from which doses have already been withdrawn. These can no longer be sent back to McKesson. A wastage form must still be filled out and sent to the NDDoH, and the open vials and syringes should then be discarded per your facility’s policy.

Procedure for returning non-viable vaccine to McKesson:

- Complete a Non-viable Vaccine Return and Wastage Form before returning unopened non-viable vaccine. **(See Appendix 8)**

- Make two copies of the form, one for your records and one for McKesson.
- Prior to shipping non-viable vaccine, fax the form to the NDDoH Immunization Program at 701.328.2499.
- Ship non-viable vaccine and a copy of the completed return form to McKesson in a shipping container that you received from previous vaccine shipments.
- Ship via UPS. Return labels will be included in each shipment of vaccine received from McKesson. Contact the NDDoH if you do not have a return label.
- Providers should not directly contact UPS to schedule a pickup, as this may result in the provider being charged for the shipping fees. Providers can either give the package to a UPS driver who is already there for another pickup or delivery, or contact the Immunization Program, who will schedule a pickup through McKesson.
- **DO NOT** ship viable vaccine to McKesson.
- **DO NOT** ship viable or non-viable vaccine to the NDDoH.

Procedure for returning empty coolers to McKesson:

- Remove all ice packs and materials.
- Return labels are included on the underside of the flap of each cooler. Contact the NDDoH if you do not have a return label.
- Ship via UPS. Do not directly contact UPS for a pickup, as this may result in your facility being charged for shipping fees. Providers may either give the coolers to a UPS driver who is already there for another pickup or delivery or contact McKesson directly to schedule a pickup at 877.822.7746. **Please note:** Providers may contact McKesson directly only to schedule the pickup of empty coolers. All other issues related to vaccine orders, shipments, etc., must be directed to the NDDoH.

Vaccine Transfer

- Providers who have state-supplied vaccine that will not be used before expiration should transfer the vaccine to other enrolled providers. This process should be started three to six months before the vaccine expires. It is the provider’s responsibility to find another provider willing to take the vaccine and to pack and ship the vaccine to the provider following standard cold-chain procedures. Contact information for other enrolled providers can be found in the NDIIS under the “Provider Search” tab.

- Providers must either transfer the vaccine in NDIIS or submit a completed Vaccine Transfer Form to the NDDoH when vaccine is transferred from one enrolled vaccine provider to another enrolled vaccine provider. **(See Appendix 9)** This process removes the doses from the inventory of the transferring provider and adds them to the inventory of the receiving provider.
- Cold-chain procedures must be used during the transfer of vaccine, even if the distance between providers is minimal.
- Frozen vaccine can be transferred only on dry ice or in a portable freezer designed for this purpose. Frozen vaccine must stay at +5° F or -15° C or below.

Vaccine Disposal

Dispose of all materials properly:

- Syringes, needles, empty vials and material containing biologicals should be discarded in sharps containers, designated waste containers, etc., and burned, boiled or autoclaved before disposing in landfills.
- Other disposable items such as cotton balls, gauze, etc., should be secured in garbage bags for disposal.

Vaccine Ordering and Distribution

Vaccine Ordering

- Vaccine requests are accepted by the NDDoH by mail, fax or online. Requests are not accepted by telephone. This is to ensure accuracy in filling provider requests. **(See Appendix 10 for the Vaccine/Materials Order Form.)** Providers also may place vaccine and material orders online at www.ndhealth.gov/Immunize/Providers/Order.htm.
- Vaccine order forms should be filled out completely, including provider's doses on hand or an accurate inventory. **The NDDoH will not fill the order if this data is not provided.**
- **Vaccine orders cannot be processed until the NDDoH has received a Monthly Doses Administered Report and temperature logs from the provider. (A Monthly Doses Administered Report can be found in Appendix 11.)** Doses administered reports also may be obtained from the North Dakota Immunization Information System (NDIIS). Doses administered reports should reflect only the number of state-supplied doses given, and not doses given to insured children with private vaccine. Orders may be adjusted by the NDDoH if a

provider has ordered too much vaccine based on provider inventory and doses administered reports.

- Providers may order only enough vaccine to last one month beyond their Tiered Order Frequency (TOF) as follows:
 - High-volume clinics that can order monthly – two-month supply
 - Medium-volume clinics that can order bi-monthly – three-month supply
 - Low-volume clinics that can order quarterly – four-month supply
 - Very low-volume clinics that can order as needed – as needed
- Providers may only order vaccine according to their TOF as listed above. No provider may place more than one order per month except in the case of an emergency. Please call the NDDoH for approval prior to placing a second order.
- Providers should notify clinic staff that vaccine is being shipped to their clinic after they have ordered vaccine. This is to prevent vaccine wastage.
- Providers should allow three weeks for delivery.

Vaccine Distribution

- The NDDoH will act as the central contact for VFC and state-supplied vaccine distribution and ordering.
- McKesson Specialty, Ltd. will act as the distributor for VFC and state-supplied vaccine.
- Vaccine is shipped on Mondays, Tuesdays and Wednesdays only. This ensures the vaccine will arrive at the provider site before the weekend.
- The method of shipping vaccine is a commercial shipping company (usually FedEx).
- Varicella, MMRV and shingles vaccine are shipped on dry ice directly to providers from the vaccine manufacturer.
- Vaccine shipments from the NDDoH via McKesson are recorded in the NDIIS database, which includes the lot number, expiration date, doses sent and the provider to whom the vaccine is sent.
- The NDIIS will record and account for vaccine distributed to providers.

- Providers are responsible for entering privately purchased vaccine lot numbers into NDIIS.

Receiving Vaccine

- It is the responsibility of the provider to arrange for someone to be available in your office to immediately receive and properly store the vaccine. This employee must be trained in proper vaccine storage and handling. A backup employee also should be trained. The National Immunization Program created a Vaccine Storage and Handling Toolkit that is available online at www2a.cdc.gov/nip/isd/sh toolkit/splash.html. The NDDoH recommends that all clinic staff involved in vaccine storage and handling view this toolkit online.
- Providers should have written protocols in place for receiving vaccine.
- Immediately upon arrival of a vaccine shipment, the temperature monitor contained in the shipment should be checked to determine that the vaccine has remained at proper storage temperature. Notify the NDDoH **immediately** if the temperature monitor indicates that proper temperatures were not maintained during shipment of vaccine.
 - If compromised vaccine is received, the NDDoH will contact McKesson to arrange for a pickup of the compromised vaccine and for a replacement shipment to be sent as soon as possible.
 - All contents of the shipment (including the compromised vaccine, packing slip and thermometers) should be returned to the cooler. McKesson will arrange for FedEx to pick up the vaccine.
- Compare the vaccine received with the information on the invoice. Notify the NDDoH **immediately** if there are any discrepancies in the order, including lot numbers or expiration dates.
- All vaccines, except varicella, MMR, MMRV, and shingles, must be refrigerated immediately at 2° to 8° C or 35° to 46° F.
- Varicella, MMRV, and shingles vaccine must be stored in the freezer at a temperature of -15° C or +5° F or colder.
- MMR can be stored in the refrigerator or the freezer.

Vaccine Packaging/Shipping

A variety of materials is available to ensure that vaccines are protected and are kept at the appropriate temperature during shipment. Vaccines other than varicella, MMRV and shingles need

to be kept cool, but not frozen, during the shipping process. Varicella, MMRV and shingles vaccines, on the other hand, need to be kept frozen while being shipped.

- Varicella, MMRV and shingles vaccines must remain frozen during shipping. Use dry ice in block form to ship varicella, MMRV and shingles vaccine. Do not handle the dry ice with your bare hands! Wear gloves while handling dry ice so you do not burn your hands. It is recommended to use no less than 5 lbs. of dry ice per package.
- Do not ship vaccine if the daytime temperature is expected to exceed 90° F.
- Do not ship vaccine if the nighttime temperature is expected to be below 0° F unless it is vaccine that should be frozen.
- Vaccines must stay adjacent to the cold packs in order to maintain the desired internal temperature range when the outside temperature is extremely high.

Consider outside temperatures when traveling with biologicals. Do not leave vaccine in a vehicle for extended periods of time in either very cold or very hot temperatures.

Appendix

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- 2 Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals
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- 4 Temperature Log (Celsius)
- 5 Temperature Log (Fahrenheit and Celsius)
- 6 “Do Not Unplug” Warning Signs
- 7 Emergency Relocation Plan
- 8 Vaccine Return Form
- 9 Vaccine Transfer Form
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- 11 Doses Administered Report

DIRECTIONS FOR COMPLETING FORM

Fax completed form to the North Dakota Department of Health Immunization Program

Fax: 701-328-0355

(Additional pages may be attached if more space is needed)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.

VACCINE MANAGEMENT

Recommendations for Storage and Handling of Selected Biologicals

November 2007



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



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DT: Diphtheria, Tetanus Toxoids—Pediatric Td: Tetanus, Diphtheria Toxoids—Adult

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of

multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

**DTaP: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine—Pediatric**

**DTaP/Hib: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine Combined with *Haemophilus
influenzae* type b Conjugate Vaccine*—Pediatric**

**DTaP/HepB/IPV: Diphtheria Toxoid, Tetanus Toxoid,
Acellular Pertussis Vaccine, Hepatitis B Vaccine,
Inactivated Polio Vaccine—Pediatric**

**Tdap: Tetanus Toxoid, Diphtheria Toxoid,
Acellular Pertussis Vaccine—Adult**

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer’s Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial, or manufacturer-filled syringe.

**Instructions for Reconstitution*
or Use**

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

**Shelf Life after Reconstitution*
or Opening**

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

* DTaP/Hib (TriHIBit®) is ActHIB® (sanofi pasteur) reconstituted with Tripedia® (sanofi pasteur). Once reconstituted, this combination vaccine must be used within 30 minutes or discarded. The only DTaP vaccine that can be used to reconstitute ActHIB® is Tripedia®. No other brand of DTaP is approved for this use.

Hepatitis Vaccines: Hepatitis A, Hepatitis B, Hepatitis A/B, Hepatitis B/*Haemophilus influenzae* type b

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Hib: *Haemophilus influenzae* type b Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution* or Use

Inspect visually for extraneous particulate matter and/or discoloration. If these conditions exist, the vaccine should not be used. Shake vial well before use. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Reconstitution* or Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

* ActHIB® (sanofi pasteur) reconstituted with 0.4% sodium chloride diluent should be used within 24 hours after reconstitution. If sanofi pasteur DTaP-Tripedia® is used to reconstitute ActHIB®, the TriHibit® vaccine must be used within 30 minutes of reconstitution. Only sanofi pasteur DTaP-Tripedia® or the diluent shipped with the product may be used to reconstitute the sanofi pasteur ActHIB® product. No other brand of DTaP is licensed for use in reconstitution of ActHIB®.

HPV: Human Papillomavirus Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.** Protect from light at all times.

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

IPV: Inactivated Polio Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless

otherwise stated in the manufacturer's product information.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

TIV: Trivalent Inactivated Influenza Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.** Protect Fluarix® and FluLaval™ from light at all times by storing in original package.

Shelf Life

Formulated for use during current influenza season. Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after

withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

LAIV: Live Attenuated Influenza Vaccine

Shipping Requirements

Initially shipped to authorized distributors in the frozen state 5°F (-15°C). Shipped from the distributor to healthcare facilities in the refrigerated state at 35° – 46°F (2° – 8°C).

Condition upon Arrival

Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.** (If LAIV is inadvertently frozen, the vaccine should be moved immediately to the refrigerator and may be used until the expiration date printed on the package.)

Shelf Life

Formulated for use during current influenza season. Check expiration date on package.

Instructions for Use

LAIV is a colorless to pale yellow liquid and is clear to slightly cloudy; some particulates may be present but do not affect the use of the product. After removal of the sprayer from the refrigerator, remove the rubber tip protector. Follow manufacturer's instructions to deliver ½ dose into one nostril. Then remove the dose-divider clip and deliver the remainder of the dose into the other nostril.

Shelf Life after Opening

Single-Dose Sprayer: The vaccine should be administered shortly after removal from the refrigerator.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MMR: Measles/Mumps/Rubella Vaccine, MR: Measles/Rubella Vaccine, Measles Virus Vaccine, Mumps Virus Vaccine, Rubella Virus Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with refrigerant. Maintain temperature at 50°F (10°C) or less. If shipped with dry ice, diluent must be shipped separately.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Maintain at 50°F (10° C) or less. **Do not use warm vaccine.** Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). Protect from light at all times, since such exposure may inactivate the vaccine viruses.

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Note: MMR vaccine may be stored in the refrigerator or freezer.

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life after Reconstitution, Thawing or Opening

Single-Dose Vials: After reconstitution, use immediately or store at 35° – 46°F (2° – 8°C) and protect from light. **Discard if not used within 8 hours of reconstitution.**

Multidose vials: Withdraw single dose of reconstituted vaccine into separate sterile needle and syringe for each immunization. The vaccine dose should be administered shortly after withdrawal from vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C), but must be discarded if not used within 8 hours after reconstitution.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MMRV: Measles/Mumps/Rubella/Varicella Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style units" are not appropriate for the storage of MMRV vaccine. **Do not store lyophilized vaccine in the refrigerator. If lyophilized vaccine is inadvertently stored in the refrigerator, it should be used within 72 hours. Lyophilized vaccine stored at 35° – 46°F (2° – 8°C) which is not used within 72 hours should be discarded.**

Protect the vaccine from light at all times since such exposure may inactivate the vaccine viruses.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most refrigerator/freezer models to adjust 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 killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life after Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used **within 30 minutes** of reconstitution. **Do not freeze reconstituted vaccine.**

Special Instructions

Rotate stock so that the earliest dated material is used first.

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-MERCK-90 for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MCV: Meningococcal Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

MPSV: Meningococcal Polysaccharide Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before using according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life after Reconstitution or Opening

Single-Dose Vials: Use within 30 minutes of reconstitution.

Multidose Vials: Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used up to 35 days after reconstitution.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

PCV: Pneumococcal Conjugate Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial or manufacturer-filled syringe.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Manufacturer-Filled Syringes: The vaccine should be administered shortly after the needle is attached to the syringe.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

PPV: Pneumococcal Polysaccharide Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). Do not freeze or expose to freezing temperatures.

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

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

Shelf Life

Check expiration date on vial.

Instructions for Use

Inspect 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. Discard vaccine if it cannot be resuspended with thorough agitation.

Shelf Life after Opening

Single-Dose Vials: The vaccine should be administered shortly after withdrawal from the vial.

Multidose Vials: Withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. The vaccine should be administered shortly after withdrawal from the vial. Unused portions of multidose vials may be refrigerated at 35° – 46°F (2° – 8°C) and used until

expired, if not contaminated or unless otherwise stated in the manufacturer's product information.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Rotavirus Vaccine

Shipping Requirements

Should be shipped in insulated container. Maintain temperature at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.**

Condition upon Arrival

Should not have been frozen or exposed to freezing temperatures. Refrigerate upon arrival.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Refrigerate immediately upon arrival. Store at 35° – 46°F (2° – 8°C). **Do not freeze or expose to freezing temperatures.** Protect from light at all times, since such exposure may inactivate the vaccine viruses.

Shelf Life

Check expiration date on package.

Instructions for Use

Each dose is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration. The dosing tube is contained in a pouch. Remove the dosing tube from the pouch, screw the cap clockwise to puncture the tube, and screw the cap off counter-clockwise so that the liquid can be squeezed from the tube during oral administration of the vaccine.

Shelf Life after Opening

Pouched Single-Dose Tubes: The vaccine should be administered shortly after withdrawal from the refrigerator. The dosing tube should not be returned to the refrigerator once the screw cap has been removed.

Special Instructions

Rotate stock so that the earliest dated material is used first.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Varicella (Chickenpox) Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style units" are not appropriate for the storage of varicella vaccine. **Do not store lyophilized vaccine in the refrigerator. If lyophilized vaccine is inadvertently stored in the refrigerator, it should be used within 72 hours. Lyophilized vaccine stored at 35° – 46°F (2° – 8°C) which is not used within 72 hours, should be discarded.**

Protect the vaccine from light at all times since such exposure may inactivate the vaccine virus.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most 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 killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life after Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used **within 30 minutes** of reconstitution. **Do not freeze reconstituted vaccine.**

Special Instructions

Rotate stock so that the earliest dated material is used first.

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-9-VARIVAX for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Zoster (Shingles) Vaccine

Shipping Requirements

Vaccine: Should be shipped in insulated container. Must be shipped with dry ice only, at 5°F (-15°C) or colder. Should be delivered within 2 days.

Diluent: May be shipped with vaccine, but do not place in container with dry ice.

Condition upon Arrival

Should be frozen. Vaccine should remain at 5°F (-15°C) or colder until arrival at the healthcare facility. Dry ice should still be present in the shipping container when vaccine is delivered.

If you have questions about the condition of the material at the time of delivery, you should 1) immediately place material in recommended storage; and 2) then follow your state health department immunization program policy and contact either the Manufacturer's Quality Control office or the immunization program for guidance.

Storage Requirements

Vaccine: Freeze immediately upon arrival. Maintain vaccine in a continuously frozen state at 5°F (-15°C) or colder. **No freeze/thaw cycles are allowed with this vaccine.** Vaccine should only be stored in freezers or refrigerator/freezers with separate external doors and compartments. Acceptable storage may be achieved in standard household freezers purchased in the last 10 years, and standard household refrigerator/freezers with a separate, sealed freezer compartment. "Dormitory-style units" are not appropriate for the storage of zoster vaccine. **Do not store lyophilized vaccine in the refrigerator.** Protect the vaccine from light at all times since such exposure may inactivate the vaccine virus.

In order to maintain temperatures of 5°F (-15°C) or colder, it will be necessary in most 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 killed or inactivated vaccines.

Diluent: May be refrigerated or stored at room temperature (68° – 77°F [20° – 25°C]). **Do not freeze or expose to freezing temperatures.**

Shelf Life

Check expiration date on vial.

Instructions for Reconstitution and Use

Reconstitute just before use according to the manufacturer's instructions. Use only the diluent supplied to reconstitute the vaccine.

Shelf Life after Reconstitution, Thawing or Opening

Single-Dose Vials: Discard reconstituted vaccine if it is not used **within 30 minutes** of reconstitution. **Do not freeze reconstituted vaccine.**

Special Instructions

Rotate stock so that the earliest dated material is used first.

If this vaccine is stored at a temperature warmer than 5°F (-15°C), it will result in a loss of potency and a reduced shelf life. If a power outage or some other situation occurs that results in the vaccine storage temperature rising above the recommended temperature, the healthcare provider should contact Merck, the vaccine manufacturer, at 1-800-MERCK-90 for an evaluation of the product potency before using the vaccine.

Note: All vaccine materials should be disposed of using medical waste disposal procedures. Contact the state health department for details.

Manufacturer Quality Control Office Telephone Numbers

Manufacturer/Distributor	Telephone Number	Products
sanofi pasteur www.sanofipasteur.us	800-822-2463	DTaP, DTaP-Hib, DT, Td, Tdap, TT, Hib, Influenza (TIV), IPV, MCV4, MPSV4
Talecris Biotherapeutics www.talecrisusa.com/	800-520-2807	HBIG, IGIM, RIG, TIG
Centers for Disease Control and Prevention Drug Service www.cdc.gov/ncidod/srp/drugs/drug-service.html	404-639-3670	Distributor for Diphtheria antitoxin
Novartis www.novartis-vaccines.com/products/index.shtml	800-244-7668	Influenza (TIV)
GlaxoSmithKline www.gsk.com/	866-475-8222 (customer support) 888-825-5249 (customer support)	DTaP, DTaP-HepB-IPV, Tdap, HepA, HepB, HepA-HepB, Influenza (TIV)
Massachusetts Biological Labs	617-474-3000 617-983-6400	Td, IGIM, TT
MedImmune, Inc. www.medimmune.com	877-358-6478	Influenza (LAIV)
Merck www.merckvaccines.com	800-637-2590	Hib, Hib-HepB, HepA, HepB, HPV, Measles, Mumps, Rubella, MMR, MMRV, PPV23, Rotavirus, Varicella, Zoster
Nabi Biopharmaceuticals www.nabi.com	800-635-1766	HBIG
Wyeth www.wyeth.com	800-999-9384	Hib, PCV7



FAHRENHEIT (°F) TEMPERATURE LOG
 NORTH DAKOTA DEPARTMENT OF HEALTH
 SFN 53775 (01-09)

Provider ID:

Month:

REFRIGERATOR 35 - 46° F																					
Day of Month	Time	Staff Initials	Temperature (°F)																		
			≥49	48	47	46	45	44	43	42	41	40	39	38	37	36	35	34	33	≤32	
1			am																		
1			pm																		
2			am																		
2			pm																		
3			am																		
3			pm																		
4			am																		
4			pm																		
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30			pm																		
31			am																		
31			pm																		

FREEZER ≤ 5° F						
Day of Month	Time	Staff Initials	Temperature (°F)			
			≥8	7	6	5
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1						
2						
2						
3						
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Instructions: Plan an "X" in the box that corresponds with the temperature (columns), day of the month, and am or pm (rows) for your temperature check. Then enter your initials and the time you monitored the temperature in the appropriate boxes. **If the temperature is in the gray range:** Store vaccine under proper conditions as quickly as possible, call the vaccine manufacturers to determine whether the potency of vaccine has been affected, and call the North Dakota Immunization Program at 1-800-472-2180. Document action on the back of this form.

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

Emergency Vaccine Relocation Plan TEMPLATE

Provider Name: _____

Date: _____

Person Completing Form: _____

These are guidelines to follow in developing routine and emergency vaccine storage and handling plans. They should be posted near your storage unit or where they can be easily accessed in case of an emergency. **All office staff, including maintenance, cleaning, and security staff, should know the standard procedure to follow, and where/how the individual vaccines are to be stored.**

Routine Vaccine Storage/Handling Plan

- Designate two people responsible for routine vaccine storage and security (update as staff changes):
Primary Person: _____ Title: _____
Secondary Person _____ Title: _____
- Vaccine ordering will be done every _____ or on the _____ day of each month.
Primary Person: _____ Title: _____
Secondary Person: _____ Title: _____

- Maintain proper temperature for storage of vaccine:

Unit	Fahrenheit (F)	Celsius (C)
Refrigerator	35° - 46° F	2° - 8° C
Freezer	5° F or colder	-15° C or colder

- Monitor temperatures and record twice daily.
- Immediately take action if temperatures are out of range. On the temperature log, document what was done to ensure vaccine viability as well as action taken to establish proper temperatures.
- Keep temperature logs on file for at least three years.
- Immediately unpack vaccine shipments, check the temperature monitors and store at proper temperature.
- Label VFC vaccines and store separately from private stock.
- Conduct monthly inventory counts.
- Store and rotate vaccines according to expiration dates, and use vaccines with the shortest expiration dates first.
- If vaccines are within 90 days of expiration and will not be used, arrange for provider-to-provider transfers. Fill out a "Vaccine Transfer Form" and fax to the NDDoH.
- Check the unit doors to ensure they are closed and, if possible, locked.
- Place "DO NOT UNPLUG" stickers next to outlet and circuit breakers.
- Use safety outlet covers where possible.
- Advise maintenance and cleaning personnel not to unplug refrigerator/freezer units.
- If VFC vaccine is expired, wasted or spoiled: complete the "Vaccine Return and Wastage" form, fax one copy to the NDDoH and place one copy with the vaccine and return to McKesson.

Emergency Vaccine Relocation Plan

- Designate two people responsible for emergency vaccine storage and security (update as staff changes):
 Primary Person: _____ Title: _____
 Secondary Person _____ Title: _____
- How will designated personnel be contacted in vaccine storage emergency? (ie: phone, alarm, etc) _____
- These people have 24-hour access to storage units storing vaccines:

NAME	TITLE	CONTACT INFORMATION

- Steps to follow for proper storage and handling of vaccines to protect them from becoming spoiled. (How to pack and move vaccines)
 1. _____
 2. _____
 3. _____

- Designate alternative storage units and facilities (back-up refrigerator, fire dept., hospital, another provider).

ALTERNATE LOCATION	CONTACT PERSON	ADDRESS & TELEPHONE #

- Procedures that the designated personnel should follow to access alternative units and facilities.
 1. _____
 2. _____
 3. _____

- Designate a refrigerator/freezer repair company to contact for equipment problems.
 Company Name: _____
 Phone Number: _____

- Record the following information on each refrigerator/freezer unit.
 Brand: _____
 Model #: _____
 Serial #: _____

NOTE: NDDoH staff will ask for a copy of your clinic's vaccine storage & handling plan, including relocation policy, during on-site visits.



VACCINE TRANSFER FORM
 NORTH DAKOTA DEPARTMENT OF HEALTH
 SFN 53766 (Rev. 11/08)

<u>Transferring Provider</u>		
Provider ID Number:	Provider Name:	Date:
Street Address:	City:	Zip Code:
Contact Person:	Telephone No.:	

Return this form to:
 North Dakota Department of Health
 Division of Disease Control
 600 East Boulevard Ave
 Bismarck, ND 58505-0200
 Fax Number: 701.328.2499

1. Complete this form when transferring vaccine.
2. Maintain proper vaccine temperature during transfer.

Vaccine	Receiving Provider Name	Receiving Provider ID Number	Lot Number	Number of Doses
DT				
DTaP				
DTap/Hib/IPV				
DTaP/HepB/IPV				
DTaP/HIB				
DTap/IPV				
HepA				
HepB				
HIB				
HPV				
IPV				
Influenza				
MCV-4				
MMR				
MMRV				
PCV-7				
PPV				
Rotavirus				
Shingles				
Td				
Tdap				
Varicella				
Reason for Transfer:				
Has this transfer been documented in NDIIS? YES <input type="checkbox"/> NO <input type="checkbox"/>				

Contact the North Dakota Department of Health with any questions or concerns at 701.328.3386 or 800.472.2180



Request for Vaccine

Provider ID Number:	Provider Name:	Date:	
Delivery Address:	City:	State: ND	Zip Code:
Contact Person:	Telephone Number:	<input type="checkbox"/> Check here if this is a new address, telephone number, or contact person.	

Special Delivery Instructions:

All sections must be completed in order for your order to be processed. Allow up to 3 weeks for delivery. Vaccine and materials are shipped on Mondays, Tuesdays, and Wednesdays (weather permitting). Orders will not be filled until the NDDoH has received a doses administered report and temperature charts.

Vaccines	Packaging	Unit size (in doses)	Doses Requested	Doses on Hand
DTaP (For children ≤6 years of age)	Syringes	5		
	Single-dose vials	10		
DTaP/HepB/IPV (Pediatrix®) – <u>IHS only</u>	Syringes	5		
	Single-dose vials	10		
DTaP/Hib/IPV (Pentacel®)	Single-dose vials	5		
DTaP-IPV (Kinrix®)	Single-dose vials	10		
	Syringes	5		
Hepatitis A	Havrix® Syringes	5		
	Havrix® Single-dose vials	10		
	Vaqta® Single-dose vials	10		
Hepatitis B	Syringes	5		
	Single-dose vials	10		
Hib (PedvaxHIB®) – <u>IHS only</u>	Single-dose vials	10		
Hib (ActHIB®)	Single-dose vials	5		
HPV	Single-dose vials	10		
IPV	Multi-dose vials	10		
Meningococcal Conjugate Vaccine (MCV-4)	Single-dose vials	5		
MMR	Single-dose vials	10		
Pneumococcal Conjugate Vaccine (PCV-7)	Syringes	10		
Pneumococcal Polysaccharide Vaccine (PPV-23)	Multi-dose vials	5		
Rotavirus (Rotateq®)	Single-dose tubes	10		
Tdap	Boostrix® Syringes	5		
	Boostrix® Single-dose vials	10		
	Adacel® Single-dose vials	10		
	Adacel® Syringes	5		
Varicella (Shipped directly from manufacturer)	Single-dose vials	10		
HBIG (Available to hospitals for perinatal use only)	Single-dose vials	1		
Td (Available for use in children ≥7 years of age who have not completed the primary series of DTaP)	Syringes	10		
Shingles (Shipped directly from manufacturer): Only available for order by local public health units	Single-dose vials	10		
DT pediatric (Contact ND Immunization Program for pre-approval before ordering)	Single-dose vials	10		
Influenza (Seasonal, use separate Influenza Pre-book order form)				

Request for Materials

Provider			
Provider ID Number:	Provider Name:	Date:	
Delivery Address:	City:	State: ND	Zip Code:
Contact Person:	Telephone No.:	<input type="checkbox"/> Check here if this is a new address, telephone number, or contact person.	

Note: Please allow 2 weeks for delivery of materials

Item	Quantity	Item	Quantity
CDC Vaccine Information Statements		Miscellaneous	
Chickenpox Vaccine		After the Shots... What to do if your child has discomfort	
Diphtheria, Tetanus, and Pertussis (DTaP) Vaccine		Are you 11-19 years old? Then you need to be vaccinated against these serious diseases!	
<i>Haemophilus influenzae</i> type B (Hib) Vaccine		Baby 411 (Ari Brown)	
Hepatitis A Vaccine		Health Record Folder with inserts	
Hepatitis B Vaccine		Health Record Folder without inserts	
Human papillomavirus (HPV) Vaccine		Immunizations for Babies (A Guide for Parents)	
Inactivated Influenza		Recommended Childhood Immunization Schedule (CDC)	
Live Attenuated Influenza		Screen Questionnaire for Child and Teen Immunizations	
Meningococcal Vaccine		Vaccinations for Adults	
MMR Vaccine		When Do Children and Teens Need Vaccinations? (chart)	
Multiple Vaccines			
Pneumococcal Conjugate Vaccine		State Forms	
Pneumococcal Polysaccharide Vaccine		Certificate of Immunization (SFN 16038)	
Polio Vaccine		Lifetime Immunization Record (SFN 13895)	
Rotavirus Vaccine		Request for Vaccine/Materials (SFN 13800)	
Shingles Vaccine		Temperature Log (Fahrenheit) (SFN 53775)	
Tetanus, Diphtheria, and Pertussis Vaccine (Tdap)/ Td		Temperature Log (Celsius) (SFN 58468)	
Camera-ready copy: (please circle) Rabies Typhoid Yellow Fever		Temperature Log (Fahrenheit and Celsius) (SFN 58469)	
Brochures		Vaccine Administration Monthly Report (SFN 53774)	
Help Prevent Cervical Cancer: HPV Vaccination for Your Daughter		Vaccine Administration Record 2-part (SFN 18385)	
The HPV Vaccine: Your Cervical Cancer Defense		Vaccine Administration Record (Series) (SFN 50922)	
What if you don't immunize your child?		Vaccine Transfer Form (SFN 53766)	
Questions parents ask about baby shots		Vaccine Return and Wastage Form (SFN 53767)	
Miscellaneous		North Dakota Advisory Committee Immunization Schedule 2008	
Vaccine Safety Q & A (CHOP)		North Dakota Immunization Schedule for Indian health Services 2008	
Reliable Sources of Immunization Information		Adult Tdap Flyer	
Vaccine Adverse Events Reporting Form (VAERS)		Vaccine Safety Fact Sheet	

Fax Completed Form To: NDDoH, Division of Disease Control
Fax No.: 701.328.2499
Phone No.: 701.328.3386 or 800.472.2180

