

Nebraska Immunization Program Provider Manual

Nebraska Department of Health and Human Services

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Department of Health & Human Services



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1. Acknowledgement of Policies & Signature Page

As an enrolled provider, it is a federal requirement that you have written vaccine management policies adopted into practice for the management of publicly purchased vaccine. Proper vaccine management is important to ensure the sustainability and quality of vaccination programs. This manual serves to fulfill most of the federal requirement of vaccine management policies to ensure screening of eligibility, proper vaccine ordering, and ensuring the cold chain is maintained minimizing vaccine loss and waste and the potential need to revaccinate that could result from administering compromised vaccine.

You can use this manual to fulfill the above federal requirement if:

- The primary vaccine coordinator and their backup(s) read and sign this page, certifying that they have read and understand the manual and take responsibility for adopting policies into clinic processes
- All staff who work with vaccines (i.e.: all those who administer or order vaccines, staff who receive vaccine shipments, billing staff who deal with administration fees, the office manager etc.) are familiar with this manual, and read/sign as appropriate
- An Emergency Vaccine Management Plan is developed and adopted
- This page is updated as staffing changes
- This manual is reviewed annually

By signing below I certify that I have read and understand this Nebraska Immunization Program Provider Manual revised 2016 and take responsibility for adopting policies into clinic processes.

Name	Date
Primary Vaccine Coordinator	
Backup Vaccine Coordinator	
Office Manager	

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2. Overview of Programs

Vaccines for Children (VFC) Program

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children from birth through age 18 who might not otherwise be vaccinated because of an inability to pay. The medical provider has the benefit of being provided publically purchased vaccines at no cost and the children have the benefit of receiving all the recommended vaccines. The VFC program encourages providing healthcare services within the child's established medical home.

Adult Immunization Program (AIP) – Section 317 Funds

Section 317 of the Public Health Service Act authorized the federal purchase of vaccines to fill critical public health needs by providing routine vaccination for those adults who are uninsured or underinsured. These funds are also allocated for responding to outbreaks of vaccine-preventable diseases.

Nebraska (NDHHS) Immunization Program

The goal of the Nebraska Department of Health and Human Services (NDHHS) Immunization Program is to ensure that communities have what they need to fully vaccinate Nebraska citizens. The funding for vaccine for both the VFC and Adult Immunization Programs is distributed by the Centers for Disease Control and Prevention (CDC) to the NDHHS Immunization Program. The NDHHS Immunization Program supplies the vaccine at no charge to enrolled public and private providers. The NDHHS Immunization Program is responsible for ensuring that enrolled providers adhere to program requirements, are good stewards of the resources given, and are ensuring the viability of the vaccine at all times.

Nebraska State Immunization Information System (NESIIS)

The Nebraska State Immunization Information System (NESIIS) is a secure, statewide, web-based system that has been developed to connect and share immunization information among healthcare providers and provides patients access to their records.

Enrolled providers must use NESIIS to order federal/state funded vaccine, manage vaccine inventory, and generate required reports. The NDHHS Immunization Program strongly recommends that clinics utilize NESIIS to document immunizations administered to clients. This is a requirement for public clinics.

- **Exchanging Information with NESIIS**

State statutes 71-539 to 71-544 protect the exchange of Public Health Information (including information in NESIIS). The intent of these laws is to allow the exchange of immunization information between a variety of health professionals, schools, licensed child care facilities, and other entities in order to facilitate age-appropriate immunizations.

- Immunization clinics may access this information for purposes of direct patient care, public health activities, or enrollment in school or child care services
- The unrestricted, confidential immunization information shared may include, but is not limited to, the patient's name and date of birth, the dates and vaccine types administered, and any immunization information obtained from other resources
- Parents or legal guardians may request their child's immunization information in NESIIS at any time
- A patient or, if the patient is a minor, the patient's parent or legal guardian may deny access to this information.
- Every person presenting for immunizations in a public immunization clinic will have their immunization information input into NESIIS unless they "opt-out"
- To opt-out, the NESIIS Opt-out Form must be signed and submitted to NESIIS to keep on file.

- **Reminder / Recall NESIIS Capability**

Recall systems are designed to help meet the goal of getting every child appropriately immunized. Recall systems are a very important part of the immunization process. These systems are designed to alert a parent/guardian that a child is due for his/her next vaccination. NESIIS has capabilities to generate a list of children who should be recalled. The components of a recall system include:

- Conducting recall on a routine basis, such as quarterly, biannually, or for back-to-school time.
- Identifying the children who are overdue for the next dose in their series of immunizations
- Notifying those parents whose children have fallen behind
- Identifying those children who have been lost to recall from moving or going to a different clinic so that their records may be moved to inactive status in NESIIS

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3. Roles & Responsibilities

Vaccine Coordinator Role

Every clinic must have one person designated as the primary vaccine coordinator.

- Clinics must also designate at least one back-up or alternate vaccine coordinator who has been trained and involved. The back-up coordinator must be able to assume oversight responsibilities immediately in the absence of the primary vaccine coordinator without interruption in meeting program requirements.

Responsibilities of the Vaccine Coordinator

- **Ensure Annual Training for the Primary and Back-up Coordinators**
 - Annually read and sign the Nebraska Immunization Program Provider Manual
 - Annually review vaccine storage and handling requirements
 - Reading the manual serves this requirement
 - Beginning in 2016, all new staff acting as primary and back-up vaccine coordinators must view the CDC developed training module, “You Call the Shots: Vaccine Storage and Handling” and print the certificate within three months of beginning duties. This and other modules can be viewed at: <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>
- **Ensure Education and Communication for All Staff**
 - Educate and train staff on vaccine management policies when hired and annually as they relate to their existing job roles
 - Encourage all staff working with vaccines to read and sign the Nebraska Immunization Program Provider Manual
 - Encourage all staff working with vaccines to complete annual storage and handling training
 - Disseminate NDHHS Immunization Program communication such as updates, memos, and faxes to all employees who may have contact with federal or state purchased vaccine
 - Contact the assigned Community Health Nurse immediately to report all contact changes such as the primary vaccine coordinator, back-up vaccine coordinator, clinic address, clinic days or hours, clinic phone number, clinic name, or changes with the sponsoring physician
- **Ensure Compliance with Program Requirements**
 - Eligibility for Vaccines & Screening
 - Administration Fees, Donations, & Medicaid Billing
 - Vaccine Administration & Documentation
 - Ordering & Receiving Vaccines
 - Vaccine Accountability & Required Reports
 - Storage Units & Storing Vaccine within the Storage Unit
 - Thermometer Documentation & Thermometers
 - Temperatures Out of Range (a.k.a. Temperature Excursion)
 - Emergency Vaccine Management Plan & Transporting Vaccine
 - Visits
 - Fraud and Abuse, & Termination

Back-Up Vaccine Coordinator Role & Responsibilities

- In addition to the primary vaccine coordinator, each clinic must also designate at least one back-up or alternate vaccine coordinator who can assume oversight responsibilities in the absence of the primary vaccine coordinator
- The back-up vaccine coordinator should be trained and involved in order to assume responsibilities when needed to ensure no interruption in the clinic meeting program requirements
- The back-up vaccine coordinator must annually review and sign the Nebraska Immunization Program Provider Manual
- Beginning in 2016, all new staff acting as primary and backup vaccine coordinators must view the CDC developed training module, “You Call the Shots: Vaccine Storage and Handling” and print the certificate within three months of beginning duties. This and other modules can be viewed at: <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>. All staff working with vaccines are encouraged to take part in annual storage and handling training.

Clinic Roles & Responsibilities

It is the clinic’s role to ensure that everyone who works with vaccines at the clinic is properly trained to perform their job from actually administering vaccine to billing for the cost of the administration fee. Everyone who works with vaccines should support the efforts of the primary and back-up vaccine coordinators to ensure program requirements are met. Additionally, each year the clinic must re-enroll and submit a new signed Provider Agreement and Provider Profile.

Public Clinics in Nebraska

For the purposes of the NDHHS Immunization Program, a public clinic is a clinic operated by a public or non-profit agency, such as a county or district health department, tribal health facility, or community action agency that meets the needs of the community that are not already met by other providers, so in a large way serves as a “safety net” for those populations. A listing of the public immunization clinics may be found on the NDHHS Immunization Program website or at the below link:

<https://mapsengine.google.com/map/viewer?mid=zUmqOvOqNtwA.k6KVBMFyOBSs>

- Public clinics have some unique circumstances
 - Public clinics often have a sponsoring physician who is located off-site
 - Public clinics serve healthy clients without contraindications
 - Public clinics offer all ACIP recommended vaccines with the exception of those intended for use with high-risk patients
 - Public clinics have the capacity to serve all eligible patients
 - Public clinics accommodate walk-in patients, although they may ask patients to make an appointment
 - A walk-in client means the client has never been seen, is irregularly seen at the clinic, or presented without an appointment
 - **The sponsoring agency is responsible for the following clinic operations:**
 - Providing staff and an appropriate place for the clinic to be held
 - Receiving VFC vaccine

- Providing appropriate vaccine storage facilities that meet VFC requirements
- Securing the sponsoring physician
- Ensuring that staff are properly trained in all clinical functions
- Putting in place appropriate policies and procedures to govern clinic operations, such as:
 - Emergency management plan
 - Plan for responding to medical errors and/or needle sticks
- **The sponsoring physician is responsible for the following items:**
 - Ensuring written standing orders are on site at each clinic for administration of vaccines as well as an emergency protocol signed by the sponsoring physician annually
 - Signing the appropriate Provider Agreement(s) each year
 - Agreeing to be on call during all clinics to provide consultation as needed
 - Providing a back-up physician if s/he is unavailable during a clinic and informing the public clinic of the change
 - Be familiar with immunizations, clinic policies, procedures and guidelines
- **Staff at the public clinics must meet the following requirements:**
 - Be a licensed RN or LPN if administering vaccines
 - LPN must be approved by sponsoring physician and supervised by an RN directly or indirectly according to scope of practice
 - Have working knowledge of the current ACIP recommended immunization schedules
 - Verify emergency protocol and epinephrine expiration date
 - Ensure that vaccines are handled, prepared, and administered according to the manufacturer's instructions and ACIP recommendations and guidelines for immunization practices
 - Be trained and use NESIIS as the medical record of all clients served
 - Be familiar with medical contraindications or circumstances when immunizations are not to be given and document accordingly in NESIIS
 - If immunizations offered at the appropriate time are refused, this refusal is documented in the "Client Comment(s)" tab of the client's record in NESIIS, use the drop down menu to choose the appropriate comment
 - Notify physicians of all immunizations given to their clients
 - Notify the NDHHS Community Health nurse and the sponsoring physician of changes in location, time, days, or staff changes

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4. Resources & Communication

Advisory Committee on Immunization Practices (ACIP) Resources

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States.

- The ACIP consists of 15 experts who are voting members and are responsible for making vaccine recommendations. The Secretary of the U.S. Department of Health and Human Services (DHHS) selects these members after an application, interview, and nomination process. Fourteen of these members have expertise in vaccinology, immunology, pediatrics, internal medicine, nursing, family medicine, virology, public health, infectious diseases, and/or preventive medicine. One member is a consumer representative who provides perspectives on the social and community aspects of vaccination.
- The ACIP works with 30 professional organizations that are highly regarded in the health field. Examples of these professional organizations with which ACIP develops the annual harmonized childhood schedule are the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP). These members comment on ACIP's recommendations and offer the perspectives of groups that will implement the recommendations.
- The current ACIP recommended vaccination schedules for children, teens, and adults along with links to other ACIP resources can be accessed online at: <http://www.cdc.gov/vaccines/schedules/hcp/index.html>
- Refer to the Appendix for ACIP Recommended Immunization Schedules

Centers for Disease Control and Prevention (CDC) Resources

The Centers for Disease Control and Prevention (CDC) has a wealth of vaccination resources. The CDC has a webpage specific for Healthcare Professionals and Providers with links to the immunization schedules, vaccine administration education, vaccine information statements (VIS), storage and handling tools, free continuing education opportunities and more at <http://www.cdc.gov/vaccines/hcp.htm>

- Refer the Appendix for CDC Immunization Resources for You & Your Patients

NDHHS Immunization Program Communication

The NDHHS Immunization Program communicates with providers in several ways. This manual serves as a detailed resource to inform enrolled clinics of program requirements, protocols, and provides useful resources for education. The program also communicates in other ways depending upon the topic, urgency, and financial resources. Each clinic is highly encouraged to check our website at <http://dhhs.ne.gov/immunization> monthly for updates, copies of newsletters, copies of faxes or memos, influenza allocation information, and links to other information and resources. Additionally, please ensure faxes are given to the primary vaccine coordinator. Please check the provided email address regularly. Contact your assigned Community Health Nurse or NDHHS for questions.

- Refer to the Appendix for the Contact List for NDHHS Immunization Program & NESIIS

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5. Eligibility for Vaccines & Screening

Screening for Eligibility

- Inform the patient, parent, or legal representative of the eligibility requirements and determine their eligibility
 - Enrolled providers agree to never deny vaccination or refer their eligible patients elsewhere due to inability to pay an administration fee.
- Document patient eligibility at every immunization encounter either on paper or electronically
- Paper or electronic eligibility screening records must be kept for three years from the date of the patient's visit
- Eligibility records must be retrievable during the annual Compliance Site Visit
- As a resource, please refer to the Appendix for a sample Vaccine for Children (VFC) Program Patient Eligibility Screening Record that outlines eligibility categories and may be used by clinics

Who is eligible for Vaccines for Children (VFC) vaccine?

- Children birth through 18 years of age **AND** one of the following:
 - American Indian or Alaska Native
 - Medicaid enrolled
 - Uninsured (have no health insurance)
 - Underinsured*
 - Children who have commercial (private) health insurance but the coverage does not include vaccines
 - Children whose insurance covers only selected vaccines (VFC eligible for non-covered vaccines only)
 - Children whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached these children are then categorized as underinsured)

Children whose insurance has a very high deductible (catastrophic insurance) are **NOT considered underinsured*

***Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), Rural Health Center (RHC) or a deputized public immunization clinic*

Who is eligible for Adult Immunization Program (AIP) vaccine?

- Age 19 or older **AND** one of the following:
 - Uninsured (have no health insurance)
 - Underinsured* (see above for definition of underinsured)

***Eligible adults who are uninsured and underinsured are only eligible to receive vaccine at an enrolled Adult Immunization Program clinic**

- Most ACIP recommended adult vaccines are available at certain public immunization clinics and Federally Qualified Health Centers who are enrolled AIP providers which is a separate enrollment process
- As a reminder, Adult Immunization Program (AIP) vaccines must be kept separate from VFC vaccines and borrowing between VFC and AIP is not allowed.
- Clinics enrolled in the Adult Immunization Program must follow the same requirements as the VFC program such as storage and handling, inventory management, reports, etc.

Who is eligible for Outbreak Response vaccine from section 317 funds?

- The NDHHS Immunization Program will provide guidance during a confirmed outbreak regarding the use of 317 funds which are shared with the Adult Immunization Program.
- Please consult the NDHHS Immunization Program for any questions. All attempts are to be made to screen for eligibility during an emergency outbreak response and provide vaccine from the appropriate funding sources.

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6. Administration Fees, Donations, & Medicaid Billing

Administration Fees

- Never charge for the cost of the actual vaccine. Vaccines are given to the provider through the entitlement program at no cost, therefore providers can never charge the patient or Medicaid for the cost of federally or state purchased vaccine.
- For non-Medicaid VFC eligible children (American Indian, Alaskan Native, uninsured, and underinsured):
 - Do not charge a vaccine administration fee that exceeds the Nebraska administration fee cap of \$19.82 per vaccine injection
 - This fee cap is set for each individual state by the Centers for Medicare and Medicaid Services (CMS)
- For Medicaid VFC-eligible children, accept the reimbursement for the vaccine administration fee set by the state of Nebraska Medicaid agency or the contracted Medicaid health plans
- Do not deny the administration of federally or state purchased vaccine to an established patient because of inability to pay the administration fee
 - Public clinics must post a sign to be prominently displayed that states:

ATTENTION: Children who are eligible for VFC vaccines may not be denied vaccines due to inability to pay.

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- Providers cannot send the parent/guardian/individual of record to collections if they are unable to pay the administration fee after the service

Donations

- Clinics may request a modest donation not exceeding \$19.82 per injection instead of an administration fee; however, no one may be denied vaccine due to inability to make a donation
- Funds received from donations or administration fees are to be used to support the public immunization clinic functions

Medicaid Billing

- Use the appropriate CPT code for the vaccine with an SL modifier to bill Medicaid for the administration of the VFC vaccine
- If there are questions regarding Medicaid coverage or billing, please contact Leah Spencer at (402) 471-9368 or 1-855-632-7633 or via email at dhhs.mltcphysicalhealth@nebraska.gov

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7. Vaccine Administration & Documentation

Administering & Handling Vaccine

Properly handling vaccine prior to administration is important to ensure maximum vaccine viability and to reduce the likelihood of medication administration errors.

- Always follow the rights of medication administration
 - Right patient
 - Right drug (vaccine)
 - Right dose
 - Right route
 - Right time
- Prepare vaccine after the patient agrees to receive the vaccine and just immediately prior to administering the vaccine
 - Always check the vaccine fully including expiration date
 - Only draw up or reconstitute vaccine immediately prior to administration
 - Only use diluent made specifically for that vaccine
 - Most vaccines need to be protected from light
 - Some vaccines only have a maximum 30 minute shelf life once reconstituted then must be discarded

Offering All ACIP Recommended Vaccines

Participating providers must comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) unless:

- In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for an individual patient or contradicts any other state law or governance

Nebraska State Law

- State laws concerning vaccination school requirements for the State of Nebraska can be accessed online at: http://dhhs.ne.gov/publichealth/Pages/immunization_forms.aspx
- Medical and religious exemption requirements for refusal of vaccination in the State of Nebraska can be found in online at: http://dhhs.ne.gov/publichealth/Pages/immunization_forms.aspx
- The State of Nebraska statutes do not allow a philosophical exemption option for refusal of vaccination for school age children
- As a program requirement, patients are to be offered all the ACIP recommended vaccines to help protect them and others; not just the vaccines required for school entry

National Childhood Vaccine Injury Act (NCVIA) Vaccine Documentation

The National Childhood Vaccine Injury Act (NCVIA) has recordkeeping requirements for all health care providers who administer vaccines. Maintain records in accordance with the NCVIA which also includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

- Under federal law, clinic staff must document certain required information in each patient's medical record for each dose of vaccine given:
 - Vaccine
 - Date vaccine was administered
 - Manufacturer of vaccine
 - Lot number of vaccine
 - Clinic/Facility address
 - Name and title of individual who administered the vaccine
 - VIS publication/edition date
 - Date the VIS was given to the patient, parent, or legal representative
- Best practice documentation guidelines are encouraged which include the actual type or brand of vaccine, route, dosage and site. Providers can maintain these records using their electronic health record system, paper charts, or using NESIIS.

Vaccine Information Statements (VIS)

As required under the National Childhood Vaccine Injury Act (NCVIA), all health care providers in the United States who administer vaccines shall, prior to administration of each dose of the vaccine, provide a copy of the current edition of the applicable Vaccine Information Statement (VIS) to the parent or legal representative of the child or the adult patient. The VIS provides information about the vaccine preventable disease and provides education on the benefits and risk of the vaccine.

- It is a federal requirement to distribute the VIS prior to administration of each vaccine at each immunization encounter
- Let the patient, parent, or legal representative keep a paper copy of the VIS
 - If they do not want keep a paper copy, they must be provided the opportunity to read the VIS and ask any questions prior to administration
- Patients are to be offered any VIS that has been translated in their native or preferred language
 - Translated VIS are available online free of charge through the Immunization Action Coalition at <http://www.immunize.org/vis/>
- Keep VIS statements up to date by checking monthly or signing up for email alerts about changes in VIS at <http://www.cdc.gov/vaccines/hcp/vis/index.html>
- Parent/legal representative does not need to sign anything to show they have received the VIS but per the NCVIA, the clinic must document:
 - VIS publication/edition date
 - Date the VIS was provided to the patient, parent, or legal representative
- If a parent or legal representative cannot be present at the time of vaccination, arrangements must be made to ensure that all appropriate steps for consent are taken in advance including screening for vaccine eligibility. Often public clinics use a proxy form for this purpose. A proxy form can provide:
 - Documentation of having read the VIS provided

- Education of vaccine risks and benefits via the VIS
- An opportunity to ask and receive satisfactory answers to questions
- Screening for vaccine eligibility
- Screening regarding contraindications to immunizations
- Refer to the Appendix for Instructions for the Use of Vaccine Information Statements

Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a surveillance program which collects information about adverse events following administration of a licensed vaccine.

- Providers are required to report any event listed in the “Reportable Events” table that occurs within a specified time period after vaccination
- Providers are required to report events which are listed by the vaccine manufacturer as a contraindication to subsequent doses of that vaccine
- This information is used to monitor side effects and to identify any important safety concerns about the vaccines
- Providers are asked to report any clinically significant adverse event, even if not sure if the vaccine caused the event
- For more information and the forms visit <http://vaers.hhs.gov/index>

Record Retention

Maintain all records related to the Nebraska Immunization Program for a minimum of 3 years, or longer if required by state law. Make these records available to public health officials, including NDHHS, upon request. Check your facility’s policies about keeping records beyond three years.

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8. Ordering & Receiving Vaccine

Ordering Vaccine

- Vaccine orders are placed through NESIIS (Nebraska State Immunization Information System)
- All ACIP recommended vaccines are to be ordered and offered to patients
- Clinics should place orders when they have a four-week supply of vaccine available, to ensure there is enough stock to allow for potential delays. Avoid maintaining a stockpile or building up an excess amount of vaccine. Smaller, more frequent orders are preferred to minimize the amount of loss if an incident occurs during shipment or in the storage unit. In general, clinics order once a month as needed.
 - Influenza vaccine can be ordered as it becomes available to clinics
 - Td vaccine has the option to be ordered by the dose in NESIIS to avoid vaccine loss due to expiration
 - Bexsero® serogroup B meningococcal vaccine has the option to be ordered by the dose in NESIIS to avoid vaccine loss due to expiration
 - PPSV23 can be ordered by the dose by contacting the NDHHS Immunization Program. Clinics can keep a dose on hand to avoid borrowing.
- Prior to placing an order in NESIIS, the clinic inventory in NESIIS must have been accurately modified at least one time in the past month using the monthly transaction summary report process.
- The NDHHS Immunization Program has implemented quality-control steps within the vaccine ordering process. These include looking at the inventory quantity on hand and usage patterns of clinics to ensure an accurate, appropriate vaccine order. In some cases, NDHHS may contact clinic staff with questions about the submitted order, or may deny the order partially or in whole. Typically this is done because the clinic already has a sufficient amount or their usage patterns fail to justify the quantity ordered. NDHHS staff will make every effort to communicate with clinics if an order is modified, however there is always a note within NESIIS. Clinic staff should check NESIIS after submitting orders to find out the status of the order.

*****Vaccine ordering privileges can be suspended for not complying with program requirements*****

Receiving Vaccine

- Vaccine shipments will arrive according to the days and times indicated in your clinic's NESIIS profile
- If clinic shipping hours change, the profile in NESIIS must be updated immediately along with notifying the NDHHS Immunization Program
 - **Clinics will be held liable for non-viable vaccine that sits on a delivery truck or is delivered in the event they are not open to receive vaccine at the stated days and times on record**
- The contract with McKesson distributors allows 5 shipping days before receipt
 - McKesson typically ships on Mondays, Tuesdays, and Wednesdays. However, shipments may be sent out on other days of the week as well.
- The contract with Merck (Varicella & ProQuad only) allows up to 2 weeks before receipt
- If the vaccine has not arrived within a reasonable amount of time contact the NDHHS Immunization Program office so the shipment may be tracked
- **Do not refuse a vaccine shipment**
 - Always accept vaccine shipments, place in the appropriate storage unit and contact the NDHHS Immunization Program immediately (within 2 hours) if it is incorrect
- Do not keep a signature on file with FedEx or UPS because vaccine may be delivered when the clinic is closed
- Check the mailing label to assure that vaccine has been delivered to the correct location
- Check the condition of vaccines and the temperature monitor (cards) inside the box immediately when the shipment arrives
 - Refrigerated vaccines should be cold, not frozen from the CDC distributor McKesson. Store in the refrigerator immediately.
 - Note that MMR vaccine arrives refrigerated as it can be stored refrigerated or frozen. Please note, clinics are encouraged to **store MMR in the freezer** because during a temperature excursion or power outage, the MMR vaccine would be better protected in the freezer.
 - Frozen vaccines (Varicella and ProQuad) will arrive from Merck. The vaccine will come in a box surrounded by frozen gel packs.
 - The vaccine should not be damaged
 - Cold or warm mark activators (card) should not be activated
- Check the vaccine shipment log against the vaccine in the box
- Use the packing slip to determine the length of time in transit
- Check the vaccine expiration date and notify the NDHHS Immunization Program if there is less than 6 months to expiration
 - Diluents and vaccine may not have the same expiration dates
- Confirm that diluent doses equal the number of vaccine doses
 - Contact the NDHHS Immunization Program immediately if they do not, more diluents can only be ordered on the day the shipment is received
- Store the vaccines at the right temperature immediately after receiving them. Put those with the earliest expiration date in front to be used first.

- Keep packing slips or an inventory log for at least 3 years
- In NESIIS within the Inventory tab, click on Manage Transfers and “Accept Transfer” to automatically populate the shipment into the clinic inventory on the day vaccine was received
 - **When a vaccine shipment is incorrect, please follow the below protocol:**
 - Always physically accept the shipment from the shipper & store appropriately
 - **Immediately (within 2 hours) call the NDHHS Immunization Program at 402-471-6423 or 800-798-1696 to report any incorrect orders or discrepancies between the shipping log and the order placed.**
 - If no one answers, call another staff member of the NDHHS Immunization Program until you talk to someone. See the appendix for Contact List for NDHHS Immunization Program & NESIIS.
 - **If there is any question about the condition of the vaccine when it arrives:**
 - Always physically accept the shipment from the shipper
 - Mark the vaccine “Do Not Use” but store appropriately immediately
 - **Immediately (within 2 hours) call the NDHHS Immunization Program at 402-471-6423 or 800-798-1696 to report any vaccine that arrived with the temperature monitors activated, if the temperature monitors are missing from the shipment container, or if there are questions regarding the condition of the vaccine.**
 - If no one answers call another staff member of the NDHHS Immunization Program until you talk to someone. See the appendix for Contact List for NDHHS Immunization Program & NESIIS.
 - In the event that a person with the NDHHS Immunization Program cannot be located, contact McKesson or Merck directly within **TWO HOURS** of receiving the shipment. If the distributor is contacted within two hours of signing the receipt of the vaccine shipment, they are liable for the compromised vaccine delivery.
 - Contact McKesson at 1-877-836-7123
 - Contact the Merck Order Management Center at 1-800-637-2579

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9. Vaccine Accountability & Required Reports

Vaccine Accountability Systems & Required Reports

Each enrolled clinic is given thousands of dollars of federally and state purchased vaccines annually. Proper vaccine management and accountability is important to ensure the sustainability and quality of vaccination programs. The clinic is responsible for ensuring that vaccine is used only for eligible patients and that the vaccine is stored and handled appropriately. Each clinic is responsible for developing a vaccine accountability system that includes the below:

- Eligibility screening process that screens each patient at each vaccine visit
- Documenting patients' eligibility clearly for that visit and allowing for historical review in case of changes
- A clinic process to ensure that all staff administering vaccines know which vaccine stock to use according to proper funding source they are eligible for
- A clinic process to track how many doses were actually administered, wasted, returned, and/or borrowed from each funding stream (VFC, AIP, or outbreak response)
 - The system can be a paper line listing which is similar to a tally system or can be a report from the electronic medical record.
 - Refer to Appendix for Sample Line Listing
 - Refer to section on Transaction Summary Report for more details.
 - Refer to section on Wasted Vaccine & Doses Wasted Report for more details.
 - Refer to section on Returning Vaccine & Doses Returned Report for details.
 - Refer to section on Borrowing Vaccine & Borrowing Report for more details.
- Reports are required to be submitted to the NDHHS Immunization Program by the due dates to avoid suspension of vaccine ordering privileges or termination from the program.
 - Provider Agreement
 - Annually beginning of each calendar year
 - Provider Profile
 - Annually beginning of each calendar year
 - Transaction Summary Report
 - Monthly by the 15th for the previous calendar month
 - Doses Wasted Report
 - Monthly with the Transaction Summary Report (if applicable)
 - Doses Returned Report
 - Quarterly (if applicable)
 - Borrowing Report
 - Once doses replaced within a month (if applicable)

Provider Agreement

The Provider Agreement is signed annually by the medical provider with prescribing authority who agrees to comply with program requirements and take responsibility for the VFC and/or Adult Immunization Program at the clinic.

- The Provider Agreement instructions are distributed at the beginning of each calendar year
- The Provider Agreement is printed from NESIIS, signed, and then returned to NDHHS

Provider Profile

The Provider Profile provides data on the patient population of the clinic. It is submitted annually, and is used to evaluate provider ordering patterns.

- The Provider Profile instructions are distributed at the beginning of each calendar year
- The Provider Profile form is printed from NESIIS once data is entered then returned to the NDHHS Immunization Program.
- If the patient population significantly changes during the calendar year, an updated Provider Profile is needed

Transaction Summary Report

The monthly Transaction Summary Report is completed in NESIIS and is due by the 15th of the month for the previous calendar month. The Transaction Summary Report must be reflective of actual vaccine activity that occurred the previous month (i.e., the Transaction Summary Report for October 1st through October 31st is due on November 15th). This time every month is also a good time to check the NDHHS Immunization Program Website for updated information and also a good time to check the CDC website for updated VISs.

- Providers are required to keep track of all federally or state purchased vaccine inventory and vaccine use in NESIIS
- Below are instructions for completing the monthly Transaction Summary Report:
 - Look at the NESIIS “Manage Transfer” tab and ensure all inbound and outbound vaccine transfers (both from the NDHHS Immunization Program as well as other enrolled clinics) have been accepted
 - Transfers should be accepted the same day as the vaccine shipment is received, as soon as the shipment is verified as correct. This automatically adds the vaccine to the appropriate NESIIS inventory.
 - Manually adding inventory should not occur unless instructed to do so by your Community Health Nurse or the NESIIS Help Desk. Clinic staff should check all vaccine received for accuracy then accept the transfer in NESIIS, which automatically adds it to the appropriate NESIIS inventory. Manually adding inventory can lead to assumptions of missing vaccine and excessive waste. Manually adding inventory can result in data entry errors leading to vaccine being assigned to the wrong stock, wrong NDC number, wrong lot number, and wrong expiration date.
 - Print the Inventory Report under the “Manage Inventory” tab and use it to count the vaccine in the storage units
 - A helpful hint is to count the vaccine on the 1st day of the month before any vaccine has been given (or the last day of the month after all the vaccine has been given). After inventory is modified in NESIIS based upon actual documented vaccine usage, the inventory count in NESIIS should match what was physically counted in the storage unit.
 - Inventory must be modified prior to running the Transaction Summary
 - Each provider office must have a system of accountability such as a paper line listing (tally sheet) and/or a report from their electronic medical record that lists how many doses were actually administered and/or wasted for the specific time period

- To modify vaccine inventory in NESIIS select the vaccine and modify the quantity on hand (QOH) by choosing the appropriate option based upon actual vaccine activity.
 - Doses Administered
 - Doses Wasted (remember to submit the NESIIS Wasted Report)
- Never adjust doses administered to match the storage units! If your count of doses administered does not justify what was counted in the storage units at that time, double check your numbers then call your assigned Community Health Nurse to discuss. The missing dose(s) may need to be entered as “waste” due to loss or unaccounted for vaccine.
- Contact your Community Health Nurse for any vaccine accountability issues that includes missing or extra vaccine.
- Under the “Transaction Summary” tab in NESIIS, generate the Transaction Summary Report
 - Select the appropriate Site
 - Select the appropriate Report Date Range
 - Select the Public Only funding source
 - Select the Transaction Summary report type
- Submit this report to the NDHHS Immunization Program by the 15th of the month via fax at (402) 471-6426 or email to dhhs.immunization@nebraska.gov

Wasted Vaccine & Doses Wasted Report

Vaccine waste is defined by the CDC as vaccine that cannot be returned for federal excise tax credit. Wasted vaccine is not returned to NDHHS Immunization Program but must be documented in NESIIS with a Doses Wasted Report generated and sent in with the applicable monthly Transaction Summary Report. Waste should be rare. Never draw up vaccine until the patient has agreed to receive the vaccine and only immediately before administration and some vaccines are only viable up to 30 minutes after reconstitution then are wasted.

- The below are wasted vaccine:
 - Broken vials or syringes
 - Doses left in an open multi-dose vial after expiration or “beyond the use date”
 - Vials or syringes that were uncapped or drawn up and not administered
 - Provider may be held responsible for replacing vaccine lost due to preventable waste
 - Lost or unaccounted for vaccine
 - Provider may be held responsible for replacing vaccine
- Modify the Quantity on Hand (QOH) then choose the correct reason why the dose was wasted. Do not use the “other” reason unless absolutely necessary.
- Do NOT return wasted vaccine to the NDHHS Immunization Program
- Dispose of all sharps in the appropriate sharps container

Returning Vaccine & Doses Returned Report

Vaccine doses that are unopened and have expired or have been spoiled (non-viable due to exposure to temperatures out of range) must be returned to the NDHHS Immunization Program within 3 months of expiration or spoilage.

- **Expired Vaccine:** Inform the NDHHS Immunization Program **60 -90 days** prior to vaccine expiring
 - Write a note at the bottom of the submitted monthly Transaction Summary Report of any vaccine that the clinic can't use up before expiration
 - Adjust ordering patterns as needed to prevent overstock of vaccine
 - NDHHS will try and work with clinics to transfer vaccine to another clinic before expiration
 - Copies of temperature logs must accompany any vaccine transfer
 - All unopened expired or spoiled vaccine is returned for excise tax credit which is a CDC requirement
 - Do not return open multi-dose vials, those doses left are waste
 - Failure to notify NDHHS may result in the clinic replacing vaccine dose for dose
 - **Once vaccine has expired or spoiled IMMEDIATELY remove it from the refrigerator or freezer and mark it "Do Not Use"**
- **Spoiled Vaccine:** Inform the NDHHS Immunization Program immediately of any spoiled vaccine
 - Vaccine spoilage may occur due to circumstances beyond the provider's control, such as:
 - Prolonged power outages due to severe weather or other unavoidable/unanticipated causes
 - Vaccine transport company error (failure of the provider to notify NDHHS of a change in delivery times, office hours, or address is not considered a transport error)
 - Acts of nature are not considered negligent as they are unavoidable
 - Vaccine spoilage may occur to preventable negligence:
 - Failure to ensure the vaccine is promptly stored when received
 - Leaving the vaccine outside of the storage units
 - Leaving the storage unit door open and unattended
 - Failure to follow appropriate procedures for transporting vaccine
 - Failure to address temperature excursions leaving vaccine unviable

The clinic may be required to replace vaccine dose for dose when vaccine was lost due to preventable waste, failure to notify NDHHS of expiring vaccine, and vaccine lost due to preventable spoilage.
- Reconcile inventory by choosing the vaccine that spoiled and modify the quantity on hand in NESIIS by choosing the appropriate option
 - Enter any doses administered before the vaccine had expired or was spoiled
 - Enter any doses wasted due to the multi-dose vial being opened and now the vaccine has expired or is spoiled.
 - Enter any doses returned for just the unopened spoiled vaccine (not expired)
 - **Do NOT modify the quantity on hand for any unopened expired vaccine. NESIIS automatically moves expired vaccine to the Expired Inventory tab and will automatically list those doses as eligible for return on the Returned Report**

- Under the “Manage Inventory “ tab, click on Transaction Summary then change the Report Type to “Doses Returned” and ensure the date includes the day after the doses expired and the day the spoiled doses were returned. Generate the report and make 2 copies.
 - Keep a copy for your records
 - Place the vaccine in a box with bubble wrap or in a padded envelope with the Doses Returned Report Form (this is the packing slip)
 - Mail the unopened expired and/or unopened spoiled vaccine to:
Nebraska Immunization Program
DHHS/ Public Health/ Immunizations
P.O. Box 95026
Lincoln, NE 68509-5026
- Refer to the Appendix for Returned & Wasted Vaccine Process

Borrowing Vaccine & Borrowing Report

Borrowing vaccine from a different funding source (i.e. using a VFC vaccine for a private-pay patient) should be a rare occurrence that is always documented on the Borrowing Report. The Borrowing Report is to be submitted within 1 month of the borrowing instance once doses are replaced.

- **No borrowing can occur between VFC and Adult Immunization Program vaccine**
- **No borrowing can occur for influenza vaccine as there is no guarantee that the influenza vaccine will be an equal replacement or replaced within the same season**
- **No borrowing can occur with federally or state purchased vaccines on allocation due to delay in supply or shortage of supply.**
- Enrolled providers are expected to maintain an adequate inventory of vaccine for their VFC, Adult Immunization Program (AIP), and insured patients
 - Federally purchased vaccine cannot be used as a replacement system for a provider’s privately purchased vaccine inventory
- The provider must ensure that borrowing federally purchased vaccine will not prevent an eligible patient from receiving a needed vaccination
- Borrowing should occur only when there is lack of appropriate stock vaccine due to unexpected circumstances such as delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time incorrectly
- Infrequent exchanging between federally purchased and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date
- Borrowed vaccine is required to be replenished within one (1) month of the date the borrowing occurred, and must be replaced on a dose for dose basis
- A Borrowing Report must be filled out and signed by a provider with prescribing authority whenever borrowing occurs regardless of which stock is borrowed from
 - The Borrowing Report should be faxed/emailed with the other monthly reports once doses have been replaced and the form is complete and signed
 - Borrowing Reports must be kept on file for 3 years
 - Refer to the Appendix for a Vaccine Borrowing Report to copy and submit

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10. Storage Units & Storing Vaccine within the Storage Unit

Storage Units

- Clinics that are enrolling now are required to have stand-alone freezer units, and the refrigerators must be either stand-alone or only using the refrigerator section of a combination unit. Pharmaceutical units are recommended.
- All clinics when purchasing new storage units will be required to have stand-alone freezer units as noted above, pharmaceutical units are recommended
- Currently enrolled clinics using both sections of a combination unit will be allowed to continue this until January 1, 2018 as long as the unit is able to keep both the refrigerated and frozen sections within appropriate temperature ranges at all times
- CDC recommends the below for storage units due to temperature stability data:
 - 1st choice: Pharmaceutical or “purpose built” units made for vaccines
 - 2nd choice: Household stand-alone freezer or stand-alone refrigerator
 - 3rd choice: Household style combination refrigerator/freezer with separate exterior doors and only use the unit for refrigerated vaccines
 - A separate stand-alone freezer should be used to store frozen vaccines
 - Nebraska allows currently enrolled clinics to store both refrigerated and frozen vaccine in an already purchased household combination refrigerator/freezer unit with separate exterior doors until 1/1/2018
- Other storage unit specifications are listed below:
 - **Dormitory style refrigerators are not allowed at any time for storage**
 - Storage units must be large enough for vaccine volume
 - Must be large enough to hold the year’s largest inventory such as during influenza season and back to school season
 - Must be large enough to allow air circulation in the unit
 - Storage units must be able to maintain required vaccine storage temperatures
 - Refrigerator always: 35° to 46° F (2° to 8° C)
 - Freezer always: -58° F to 5° F (-50° C to -15° C)
 - Storage units must be free of frost, ice, water pooling or coolant leaks
 - Clinics need a maintenance plan for handling vaccines if frost builds up and the freezer must be defrosted
 - Storage units that are dedicated to only storing vaccines are preferred
 - No food or drink is allowed in the refrigerator/freezer with vaccine
 - Water bottles labeled “Do Not Drink” are to be placed in the storage units to help keep temperatures stable
 - Place frozen water bottles or cold packs in the freezer to keep the temperatures stable
 - Clinics may store biological products in the unit below the vaccine
 - Safeguard the electrical supply
 - Plug the storage unit directly into the outlet
 - Extension cords are not acceptable
 - Make sure the unit cannot be unplugged accidentally, use a safety lock plug if possible
 - Use an outlet connected to a generator if possible

- Label the refrigerator, freezer, electrical outlets, fuse boxes, and circuit breakers with “DO NOT UNPLUG” or WARNING stickers
- Storage units must be repaired or replaced immediately if there are mechanical problems
 - Clinics will need to submit 1 week of temperature logs on a repaired or replaced refrigerator/freezer indicating that the temperature has stabilized to the appropriate range before additional vaccine can be ordered
- Storage units must have an approved certified and calibrated thermometer with the temperature probe in glycol in each refrigerator/freezer section used to store vaccine

Storing Vaccine within the Storage Unit

- Federally purchased vaccine must be stored visually separately from state and privately purchased vaccine
 - Clearly mark the boxes or baskets containing federally purchased vaccine
 - Keep federally purchased vaccine separate from state and privately purchased vaccine
 - Keep all federally purchased vaccines separated (i.e.: VFC vaccine separate from Adult Immunization Program vaccine)
- Rotate vaccine stock monthly by placing vaccines with shorter expiration dates in front of those with longer expiration dates and check for short dated vaccine
- Keep track of expiring vaccine through NESIIS
 - Inform the NDHHS Immunization Program **60 -90 days** prior to vaccine expiring
 - Remove expired or wasted vaccine from the storage unit immediately once expired. Use notes on the vaccine or electronic reminders to ensure expired vaccine is removed and never used.
 - Initiate the return process and submit the Return Report
- Store vaccines that require refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vents
- Store vaccines that require freezer storage in the middle of the freezer compartment away from the walls and coils
- Never store vaccines in the doors of the storage units, in vegetable/fruit crispers, or in the space where the drawers were removed
- Store vaccines with enough space to allow for air circulation around the vaccine
 - If using containers to organize vaccines, use open ventilated tray type
- Keep vaccines in their original box with lids intact until administration, since most vaccines must be protected from light
- Store diluents according to the manufacturer’s instructions
 - Diluent is never stored in the freezer

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11. Temperature Documentation & Thermometers

Appropriate Temperatures for Vaccine Storage

Exposure of vaccines to temperatures outside the recommended ranges can decrease their potency and reduce the effectiveness and protection they provide. Storage and handling errors can cost thousands of dollars in wasted vaccine and revaccination. Vaccine must be stored properly from the time they are manufactured until they are administered.

- Refrigerated vaccine appropriate temperature range: 35° to 46°F (2° to 8° C)
- Frozen vaccine appropriate temperature range: -58°F to 5°F (-50°C to -15° C)

Twice Daily Temperature Documentation & Assessment

- Check and record the temperature in each refrigerator/freezer twice a day, first thing in the morning and the last thing before staff leave.
 - Record the actual temperature within the storage unit twice daily
 - Beginning January 1, 2016 clinic staff must also record the minimum and maximum temperature in the refrigerator as well as the current temperature, and reset the thermometer at each temperature reading
 - The recorded temperatures should be assessed to determine whether they are in range, and responded to if not
 - This process will give close to a 12 hour window of recorded minimum and maximum temperatures of refrigerator/freezer units in case of a cold chain failure
 - The temperature log must include the below for each reading twice daily:
 - Date
 - Time
 - Actual temperature of both refrigerator and freezer
 - Minimum temperature of the refrigerator
 - Maximum temperature of the refrigerator
 - Initials of the person documenting and assessing the temperature
 - If there is more than one thermometer in the storage unit, staff must always record temperatures from the same thermometer which meets program standards as described in this manual
 - Even if the clinic uses an electronic monitoring system, staff must manually check the temperature twice daily and document as required
 - The primary vaccine coordinator is to review temperature logs as least weekly to ensure all temperature excursions have already been addressed
 - Keep temperature logs for three years
 - If any vaccine is to be transferred, temperature logs must accompany the vaccine
 - Refer to the Appendix for sample Temperature Logs

Thermometers

Overtime, thermometers can become less accurate. Thermometers that are calibrated according to specifications ensure that proper temperature can be maintained in storage units. Appropriate thermometers must:

- Be certified as calibrated, this means the thermometer comes with a certificate of calibration from the NIST (National Institute of Standards and Technology) stating it has been calibrated according to their standards
- Be recalibrated according to the calibration due date on the certificate, but no later than two years from previous calibration
 - It may be less expensive to replace the thermometer than to recalibrate it
 - Clinic staff will be asked to provide the documentation of certification at the annual compliance site visit
- Have a temperature probe inserted into buffered material to measure the temperature inside the vial, not the temperature of the air in the storage units. Buffered material can be:
 - Liquid such as glycol, ethanol, or glycerin
 - Loose media such as sand or glass beads
 - A solid block of material such as Teflon® or aluminum
- Have probes placed in the central section of the storage unit
 - Effective October 2015 thermometers do not have to be centrally located in pharmaceutical or purpose-built storage units. These thermometers still need to have a valid certificate of calibration.

Many different types of thermometers will have a calibration certificate. The NDHHS Immunization Program recommends that clinics find a thermometer that will conform to best practices. A recommended thermometer will:

- Be accurate within +/- 1° F or +/- 0.5° C
- Have a digital display of the internal storage unit temperature which is placed on the outside of the storage unit door to allow for reading temperatures without opening the unit door
- Be capable of showing current temperature
- Be capable of providing minimum and maximum temperatures
- Include an alarm for out-of-range temperatures
- Be capable of being reset for minimum and maximum temperature recording
- Have a low battery indicator. Batteries should be replaced per manufacturer's recommendations. Changing the battery may require reprogramming the thermometer.

All enrolled providers are required to have a readily available back-up thermometer with a current certificate and valid certificate of calibration.

Effective 1/1/2018 CDC will require the use of continuous temperature monitoring in storage units housing federally-purchased (VFC or AIP) vaccine. Digital data loggers continuously monitor temperatures, which results in more accurate and comprehensive monitoring of temperatures to which vaccines may be exposed.

Data loggers are especially recommended for any clinics closed 2 or more days a week. A recommended data logger will have the following characteristics:

- Detachable probe so that the digital display can be removed to download the temperature data to a computer without removing the probe from the storage unit
- Accuracy of +/- 1 °F (0.5 °C)
- Display current temperature as well as minimum and maximum temperature
- Record temperatures at intervals throughout the day, the frequency of reading set by the user, but ideally no less than every 30 minutes.
- Maintain memory storage of at least 4000 readings, and not rewrite over old data if memory is full
- Alarm for out-of-range temperatures
- Indicate a low battery

***Upcoming Requirement* Beginning January 1, 2018 a data logger will be required for any storage unit holding federally purchased vaccine.**

To assist with this upcoming requirement, NDHHS will transition the types of thermometers that are provided to enrolled clinics from a min/max to a data logging thermometer beginning in 2016. At this time, there is no requirement that clinics use a data logging thermometer, however this is the only type that will be provided from the state.

NDHHS will be transitioning clinics starting in early 2016 and will provide one data logger for a refrigerator storage unit, one data logger for a freezer storage unit, one docking station, and other materials for installation and training. Additional data logging thermometers may be available for clinics with multiple storage units in the future as resources allow. The Community Health Nurse assigned to each clinic will contact clinic staff to discuss the transition. Important items to note include:

- The product offered is the Log Tag TRED 30-7R data logging thermometer for both refrigerator and freezer
- A simple free software program will need to be downloaded for the data logger, so clinic staff may need to work with IT if they don't allow other staff to install the disc.
- Clinics are responsible for ensuring that a certified back-up thermometer with a current certificate of calibration is on hand
- Clinics might be responsible for re-calibrating the data logging thermometer as necessary. Thermometers must be recalibrated according to the calibration due date on the certificate, but no later than two years from previous calibration (an estimated cost of approximately \$50)

As mentioned above, clinics are not required to use the thermometers offered by NDHHS. This Nebraska Immunization Program Provider Manual has details on allowable thermometers if a clinic chooses to purchase different thermometers for monitoring temperatures of publicly-funded vaccine.

Maintaining Calibrated Thermometers & Certificates

Calibration testing and traceability must be performed by a laboratory accredited by an ILAC MRA signatory body **OR as an alternative** by a laboratory or manufacturer that provides documentation that demonstrates that calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability. Between the two options, CDC recommends that testing be performed by ILAC accredited laboratories.

- Re-calibrate the thermometer according to the calibration due date on the certificate, but no later than two years from previous calibration
- In the absence of manufacturer recommended timelines for re-calibration, calibration testing must be performed every two years
- If calibration testing indicates that your thermometer is no longer accurate within, +/- 1 °F (0.5 °C) then your thermometer should be replaced
 - Adjustments to correct the accuracy of the thermometer are not recommended
- Between the two laboratories **CDC recommends that testing be performed by ILAC accredited laboratories.** The below are what are need on the certificate:
 - **ILAC accredited laboratories:**
 - An ILAC MRA accredited laboratory symbol on the certificate is the easiest way to identify that the instrument has been tested correctly according to international standards
 - The following are ILAC accredited laboratories
 - A2LA
 - L-A-B
 - ACLASS
 - IAS
 - PJLA
 - NVLAP
 - The certificate must include the following elements:
 - Model and serial number of thermometer tested
 - Whether instrument passed or failed testing
 - Documented uncertainty within +/- 1 °F (0.5°C)
 - Refer to the Appendix for Checklist for Certificate of Calibration Testing
 - **Non-ILAC accredited laboratories and manufacturers:**
 - These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:
 - Model and serial number of thermometer tested
 - Date of calibration testing or calibration report date
 - Whether instrument passed or failed testing
 - Documented uncertainty within +/- 1 °F (0.5°C)
 - Statement that calibration testing conforms to ISO 17025
 - Refer to the Appendix for Checklist for Certificate of Calibration Testing

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12. Temperatures Out of Range (a.k.a. Temperature Excursion)

Temperature Excursion Definition

A temperature excursion is defined as anytime the temperature (actual temperature or minimum or maximum temperature) in the storage unit goes out of the acceptable range. The thermometer probes are buffered to mimic the temperature of the actual vaccine so even if the temperature is out of range by one degree or for a short period of time, that is a temperature excursion. Ensure refrigerated vaccine stays 35 to 46 ° F (2 to 8 Celsius). Ensure frozen vaccine does not get warmer than 5 F (negative -15 Celsius) and does not get colder than - 58 ° F (- 50 Celsius). The below protocol must be initiated for each temperature excursion.

Temperature Excursion Protocol

1. Mark the vaccine “Do Not Use” and store at the appropriate temperature (move to another refrigerator, freezer, or coolers if necessary)
2. Do not automatically throw out the vaccine
3. Collect the following data
 - Current temperature of the vaccine
 - Amount of time the vaccine was in out-of-range temperatures
 - How quickly temperature rose, if available
 - Vaccine name, lot#, expiration date, number of doses for each vaccine affected
4. Call the Community Health Nurse assigned to your program or call the NDHHS Immunization Program at **1-800-798-1696** or **402-471-6423**. Leave a message if there is no answer and proceed to calling the vaccine manufacturers.
5. Call the vaccine manufacturers to determine vaccine viability immediately. **Clinic staff must ask for manufacturer documentation to be sent to them of the vaccine viability determination and keep this information with the temperature logs.**
 - Refer to the Appendix for Vaccine Manufacturer Contact Information
6. Document the temperature excursion details along with summary of actions taken and results. Send the summary via email or fax to the Community Health Nurse assigned to your clinic and keep this summary for your records.
 - Refer to the Appendix for a sample Vaccine Storage Troubleshooting Record as a helpful resource
 - Refer to <http://www.immunize.org/catg.d/p3041.pdf> for a fillable Vaccine Storage Troubleshooting Record as a helpful resource

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13. Emergency Vaccine Management Plan & Transporting Vaccine

Emergency Vaccine Management Plan

Participating providers must have a written emergency vaccine management plan available to all staff and ensure that the staff have access to the plan with instructions and materials so the plan is implemented in the event of a cold chain failure, such as power failure or equipment malfunction. This plan must include the following information:

- Provider site name
- Provider site address
- Primary Vaccine Coordinator
- Primary Vaccine Coordinator emergency phone number
- Back-up Vaccine Coordinator
- Back-up Vaccine Coordinator emergency phone number
- Alternate location of predetermined vaccine storage units if vaccine is to be moved
- Instructions for transporting vaccine, refer to the section on Transporting Vaccine
 - Have coolers, bubble wrap, cardboard and flashlights on hand
 - Refer to the Temperature Excursion Protocol if vaccines become compromised due to out of range temperatures
- Refer to the Appendix for a sample Emergency Vaccine Management Plan
 - NESIIS can provide an inventory report or a template Emergency Response Worksheet is available at <http://www.immunize.org/catg.d/p3051.pdf>

Transporting Vaccine – Public Clinics

The NDHHS Immunization Program recognizes the unique needs of public clinics operating in rural areas. These include infrequent clinic hours (i.e. one day per month), volunteer staff, and/or serving a population that spreads across a large geographic area. For these reasons, there are circumstances where NDHHS will allow a public clinic to transport vaccine with prior approval.

- **Transporting** vaccine occurs when an enrolled public clinic packs up the vaccine to take to an approved offsite/satellite clinic for short-term operation
 - Only pack enough vaccine for that day's satellite clinic (8 hours or less)
 - See section on Acceptable Vaccine Packing Methods
 - Anytime vaccine must be moved, the NDHHS Immunization Program strongly recommends using a portable electronic refrigerator/freezer that can plug into the vehicle and/or wall outlet
 - If a portable refrigerator/freezer is unavailable, the vaccine should be transported in a hard-sided cooler with a minimum of 2" thick walls using an appropriate packing method
 - Temperatures must be monitored and recorded hourly while in transport
 - A certified/calibrated thermometer must be used
 - Keep daily and transport temperature logs for three years
 - Refer to the Appendix for sample Vaccine Transport Log

- Once the vaccine arrives at the satellite clinic, the vaccine should be stored in the maintained appropriate refrigerated and freezer units with proper certified calibrated thermometers
 - If there is not an appropriate refrigerator or freezer on site the vaccine should remain in the portable electronic refrigerator/and or freezer as long as it can plug into a wall outlet and temperatures are monitored and recorded hourly

Acceptable Vaccine Packing Methods

Anytime vaccine must be moved, the NDHHS Immunization Program strongly recommends using a portable electronic refrigerator/freezer that can plug into the vehicle and/or wall outlet. If a portable refrigerator/freezer is unavailable, the below packing method should be followed, which will keep all vaccines except varicella and MMRV within the recommended temperature range for up to 8 hours during transport and/or storage outside the primary storage unit.

If the vaccine will be stored in refrigerators after transport, be sure those refrigerators have maintained temperatures between 35°F and 46°F for at least 7 days.

REFRIGERATED VACCINE PACKING METHOD: Refer to Appendix for Packing Vaccine for Transport during Emergencies

Assemble packing supplies and documents

Cooler. Use a hard-sided cooler with at least 2-inch thick walls or a Styrofoam™ cooler. Attach a “Vaccines: Do Not Freeze” label to the cooler.

“Conditioned” frozen water bottles (or conditioned cold packs if necessary). Condition frozen water bottles by placing them in lukewarm or cool water until there is a layer of water around the frozen water and the ice block “spins” freely. If necessary, use conditioned frozen gel packs by leaving them at room temperature for 1 to 2 hours until the edges have defrosted and packs look like they’ve been “sweating.” Cold packs that are not conditioned can freeze vaccine! **Do not use dry ice.**

Thermometer. Prepare an approved thermometer by placing it in the refrigerator at least 5 hours before you pack the vaccine. If you normally use a continuous-read monitoring system, you will need a portable thermometer for vaccine transport.

Packing material. Use two 1-inch or more layers of bubble wrap or similar packing material. Not using enough bubble wrap can cause the vaccine to freeze.

Corrugated cardboard: Use two sheets to layer.

Vaccine Transport Log. Complete a Vaccine Transport Log to document the duration and temperature monitoring information.

Pack REFRIGERATED vaccine and prepare for transport: Bottom to Top Packing

1. One layer of **conditioned** frozen water bottles (or **conditioned** cold packs if necessary) on the bottom of the cooler.
 - Ensure the ice block spins freely within the water bottle and wipe dry outside
 - If using cold packs ensure they have been taken from the freezer to sit 1-2 hours at room temperature or they may freeze the vaccine
2. One sheet of corrugated cardboard.
3. One layer of at least 1 inch thick of bubble wrap.
4. Vaccine(s).
5. Diluents: Should be transported with vaccines if necessary, and should follow manufacturer guidance for temperature requirements. As with vaccine, pack diluents within the insulating barrier if they must be refrigerated.
6. Thermometer.
7. One layer of at least 1 inch thick of bubble wrap.
8. One sheet or corrugated cardboard.
9. One layer of **conditioned** frozen water bottles (or **conditioned** cold packs if necessary). Ensure the ice block spins freely.
 - Ensure the ice block spins freely within the water bottle and wipe dry outside
 - If using cold packs ensure they have been taken from the freezer to sit 1-2 hours at room temperature or they may freeze the vaccine
10. One layer of **conditioned** frozen water bottles (or **conditioned** cold packs if necessary). Ensure the ice block spins freely.
11. Close lid and attached the thermometer display with the Vaccine Transport Log to the top of the lid.

FROZEN VACCINE PACKING METHOD: Refer to Appendix for Packing Vaccine for Transport during Emergencies

Assemble packing supplies and documents

Cooler. Use a hard-sided cooler with at least 2-inch thick walls.

Frozen Cold Packs. Keep enough frozen cold packs in your vaccine freezer to make at least two layers in the transport cooler. **NEVER USE DRY ICE.**

Thermometer. Prepare an approved thermometer by placing it in the freezer at least 2 hours before you pack the vaccine. If you normally use a continuous-read monitoring system, you will need a portable thermometer for vaccine transport.

Packing materials. Use any material like bubble wrap to place on top of the frozen cold packs to prevent contents from shifting. Make sure you **DO NOT** place bubble wrap between the vaccine and frozen packs.

Vaccine Transport Log. You must document the total timeframe and temperatures vaccines were exposed to during transport to and from the back-up facility. Put a copy of the log in each cooler that might be used to transport frozen vaccine.

Diluents. Remember to pack the diluents for frozen vaccine separate as they are never frozen.

Pack FROZEN vaccine and prepare for transport: Bottom to Top Packing

1. **Frozen Ice Packs.** Spread a layer of frozen ice packs to cover the bottom of the cooler. Do not use dry ice even for temporary storage or emergencies.
2. **Vaccine.** Stack layers of vaccine boxes directly on top of the frozen ice packs.
3. **Thermometer.** Place the thermometer probe with the top layer of vaccine.
4. **Frozen Ice Packs.** Spread another layer of frozen ice packs to cover the vaccine.
5. **Bubble Wrap.** Fill the cooler to the top with insulation material (bubble wrap).
6. **Close lid and attached the thermometer display with the Vaccine Transport Log to the top of the lid.**
7. **Upon Arrival.** Immediately upon arrival at the alternate storage facility record the temperature in the cooler on the Transport Log before removing the vaccine. If it is:
 - **Below 5°F (-15°C),** unpack the vaccine and put it in the freezer.
 - **Above 5°F (-15°C),** label the vaccine “Do Not Use” and place it in the freezer. Then follow the Temperature Excursion Protocol and call the Community Health Nurse or the NDHHS Immunization Program immediately at 1-800-798-1696.

Transferring Vaccine in NESIIS

A vaccine Transfer occurs when vaccine is moved from one enrolled clinic to another enrolled clinic for use.

- A vaccine transfer might occur when vaccine is short dated and another clinic would be able to use it before it expires; or if a clinic has run out of vaccine and is not able to order more (such as during holiday shipping blackouts); or if there is a power outage and vaccine must be moved to an alternate location.
 - NDHHS Immunization Program staff should review and approve any vaccine transfer
 - The clinic must email or fax the last 3 months of reviewed temperature logs to the Community Health Nurse assigned to clinic prior to efforts being started to relocate the vaccine
 - A “New Transfer” must be initiated in NESIIS
 - The “Packing List” must be printed from NESIIS for the vaccine
 - Select “Ship” when the vaccine is shipped or moved
 - Clinics must include copies of temperature logs for the vaccine being transferred so that the receiving clinic has a record of it being stored appropriately
 - A Packing List printed from NESIIS must accompany the vaccine
 - Vaccine must be packed for transport according to the instructions above in the section titled “Acceptable Vaccine Packing Methods”
 - The receiving clinic must check the Packing List and “Accept Transfer” in NESIIS to complete the transaction automatically adding the inventory into NESIIS
 - Do not manually add inventory unless requested to do so by the Community Health Nurse or a member of the NESIIS team

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14. Visits

Compliance Site Visit

The annual Compliance Site Visit is designed to answer any questions about the program and to evaluate the vaccine management practices, documentation, and adherence to requirements of the federal program, the NDHHS Immunization Program, and the National Childhood Vaccine Injury Act (NCVIA).

- Clinics must be prepared to have primary and back up vaccine coordinators present during the visit. In addition billing staff and the clinic provider may need to be available.
- The compliance site visit includes:
 - Verifying demographic and contact information
 - An assessment of eligibility screening and billing practices
 - An assessment of vaccine documentation practices in accordance with the National Vaccine Childhood Injury Act requirements
 - An assessment of vaccine management policies and practices which includes ordering practices, accepting and receiving vaccine, waste, borrowing, and emergency vaccine management plans
 - An assessment of vaccine storage and handling
 - An assessment of compliance with any other program requirements as outlined in this manual
 - Education as needed as it relates to program requirements, recommendations, and best practices related to immunizations

Site Visit Feedback and Follow-Up

After participating in a Compliance Site Visit, the clinic must follow up on any issues of non-compliance. Additionally, enrolled providers must participate in any educational opportunities related to NDHHS Immunization Program requirements.

- If the NDHHS Community Health Nurse finds that the clinic is not meeting program requirements, a provider follow up plan will be developed to assist the clinic in coming into compliance
- The provider follow up plan will be signed by both the NDHHS Community Health Nurse and the clinic provider, with the primary vaccine coordinator given a copy
- This plan will need to be completed within a specified time frame
- The clinic will receive a follow-up phone call, email, letter or an unannounced storage and handling visit depending on the level of non-compliance
 - NDHHS Immunization Program staff will make every effort to work with clinics to develop a plan to remedy the situation
 - The clinic may also call on the NDHHS Community Health Nurse for in-service training, guidance in developing policies and procedures, and troubleshooting vaccine concerns
 - If clinics fail to take action to meet follow-up or corrective action plan objectives, the NDHHS Immunization Program may suspend or terminate participation in the program

Unannounced Storage and Handling Visits

NDHHS Immunization Program staff must conduct unannounced storage and handling visits on 5% of enrolled providers beginning in January 2016. The unannounced visit will focus on storage and handling, and so will not take as long as a regular compliance visit. Clinics must be prepared to assist NDHHS staff in an unannounced visit at any time during normal clinic operation, and NDHHS will make every attempt to avoid disruption any more than necessary.

Assessment, Feedback, Incentives & eXchange (AFIX) Visits

AFIX is the immunization coverage level assessment of individual clinics used as a tool to indicate how well the ACIP immunization recommendations are being carried out.

- AFIX will provide data on the vaccination rates of different ages for a specific clinic
 - It will identify children who are up-to-date
 - Identify children who received invalid doses
 - Identify children who are delayed in obtaining recommended vaccines
- The AFIX assessment will provide a baseline level of immunization coverage rates that will be used to help clinic staff, with the participation of the provider, to select Quality Improvement (QI) Strategies.
- Quality Improvement (QI) Strategies are interventions which can help to improve coverage rates. They can include such activities such as:
 - Reminder/recall
 - Maximizing immunization opportunities
- A QI Plan will be developed to help clinic staff determine action steps, timelines and roles.
- NDHHS staff will follow-up with the clinic 3-6 months after the initial visit to determine the success of the selected QI Strategies by re-running coverage rates.

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15. Fraud and Abuse, & Termination

Participating providers must operate within the Nebraska Immunization Program in a manner intended to avoid fraud and abuse, consistent with “fraud” and “abuse” as defined in the Medicaid regulations at 42CFR§ 455.2, and as defined below for the purposes of the NDHHS Immunization Program.

Definitions

- **Fraud:** is the intentional deception or misrepresentation that an individual makes, the individual knows to be false, and could result in some unauthorized benefit to him or her or some other person.
 - Example: *A provider administers federally purchased vaccine to all patients regardless of eligibility, or a provider administers federally purchased vaccine to a child who is insured and bills the insurance company for the cost of the vaccine.*
- **Abuse:** is defined as “provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.”
 - Example: *A provider does not accurately account for the federally purchased vaccine and does not know how many doses were used for their eligible patients.*

Investigations

The NDHHS Immunization Program will work with all enrolled providers to resolve identified problems regarding accountability. If such efforts are proven ineffectual, the NDHHS staff will refer for official investigation. Referral will be accepted from other individuals (such as public and clinic staff) and investigated as appropriate.

There is great importance placed on accountability for vaccines purchased with public funds. This protocol is established to provide guidance and methods in identifying, reporting, and investigating suspected fraud and abuse within the Nebraska Immunization Program. The NDHHS Immunization Program reserves the right to suspend vaccine ordering privileges during an investigation. Termination may be the end result for program non-compliance or for determinations of probable fraud and/or abuse.

Referrals

- Allegations of suspected fraud and/or abuse should be reported to the NDHHS Immunization Program
 - Provide the health care provider’s name, clinic name, and address
 - Provide a brief description of the allegations or reason for referral
 - Provide name, address, and telephone number of complainant
- This information will be documented and kept in a confidential manner. The incident will be investigated within 5 working days if warranted.
- The CDC Project Officer for the State of Nebraska will be notified of the allegation and kept updated as to progress and resolution of the situation

- Persons making the referral may notify the NDHHS Immunization Program by phone, fax, letter, or email and may remain anonymous

Further investigation

- The provider will be visited by the regional NDHHS representative to discuss the allegations, inspect record keeping and procedures at the site
- A search of the Medicaid billing records will be conducted
- Vaccine ordering, shipping, and usage reports will be reconciled and verified and compared to Medicaid billing records if appropriate
- Notification of all suspected referrals will be made within two (2) working days to CDC
- Notification will be made within 10 working days of issue identification to CMS, and can include the following:
 - Provider's identifying information, to include clinic name, physician name, license number and Medicaid provider number
 - A brief description of the allegations or reason for referral
 - A summary of any investigation or activity by the NDHHS Immunization Program staff to verify or validate the complaint

Resolution

- If the charges are not substantiated any temporary hold on vaccine ordering is lifted and the provider may continue to participate in the Immunization Program
 - NDHHS staff will work closely with the provider to educate and correct any procedures which contributed to non-compliance issues previously discovered
 - The provider may be required to submit progress updates or reports showing how the problem areas have been addressed
- If fraud allegations are proven, vaccine will be removed from the provider's office and they will be terminated from the Immunization Program
 - Other penalties such as recoupment of funds, referral for criminal prosecution, or civil resolution may be exacted by the Medicaid Fraud Control Unit
- The final outcome of the investigation is communicated to the provider, the person who made the initial allegation, the CDC contact person, and other appropriate parties

Termination or Voluntary Disenrollment

The NDHHS Immunization Program or the provider may terminate this agreement at any time for personal reasons or inability to comply with requirements. If a provider is terminated for any reason or voluntarily disenrolls, they agree to properly return any unused federally or state purchased vaccine, as well as any equipment or unused supplies received from the NDHHS Immunization Program.

If a provider is terminated from the Program, a letter will be sent detailing the instances of non-compliance and giving the provider time to dispute findings and/or submit documentation if desired. If the Program does not hear from the provider within the stated timeframe, the Community Health Nurse will contact clinic staff to arrange a time to pick up any vaccine or equipment.

Leaving the Immunization Program

- The provider is to submit a written letter terminating the program
- Notify the Community Health Nurse or the NDHHS Immunization Program at 402-471-6423 or toll free at 800-798-1696 to arrange for vaccine/equipment/supply pick up
- The provider must provide a final monthly transaction summary report and copies of temperature logs for any returned vaccine
- All federally or state purchased vaccine must be returned to the Nebraska Immunization Program
- Any equipment or unused supplied received from the NDHHS Immunization program must be returned

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Appendix

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- **ACIP Recommended Childhood & Teen Immunization Schedule**
- **ACIP Recommended Adult Immunization Schedule**
- **CDC Immunization Resources for You and Your Patients**
- **Contact List for NDHHS Immunization Program & NESIIS**
- **Vaccines for Children (VFC) Program Patient Eligibility Screening Record**
- **Instructions for the Use of Vaccine Information Statements**
- **Sample Line Listing**
- **Returned & Wasted Vaccine Process**
- **Vaccine Borrowing Report**
- **Temperature Logs**
- **Checklist for Certificate of Calibration Testing**
- **Vaccine Manufacturer Contact Information**
- **Vaccine Storage Troubleshooting Record**
- **Emergency Vaccine Management Plan**
- **Vaccine Transport Log**
- **Packing Vaccines for Transport during Emergencies**

Recommended Immunization Schedules for Persons Aged 0 Through 18 Years

UNITED STATES, 2015

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967).

The Recommended Immunization Schedules for
Persons Aged 0 Through 18 Years are approved by the

Advisory Committee on Immunization Practices
(<http://www.cdc.gov/vaccines/acip>)

American Academy of Pediatrics
(<http://www.aap.org>)

American Academy of Family Physicians
(<http://www.aafp.org>)

American College of Obstetricians and Gynecologists
(<http://www.acog.org>)



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

EFFECTIVE MAR 27, 2015

- 9vHPV, 4vHPV, or 2vHPV for routine vaccination of females 11 or 12 years* of age and females through 26 years of age who have not been vaccinated previously or who have not completed the 3-dose series.
- 9vHPV or 4vHPV for routine vaccination of males 11 or 12 years* of age and males through 21 years of age who have not been vaccinated previously or who have not completed the 3-dose series.
- 9vHPV or 4vHPV vaccination for men who have sex with men and immunocompromised men (including those with HIV infection) through age 26 years if not vaccinated previously.

Syndicated and print schedules do not yet reflect this change. This recommendation will be incorporated in the immunization schedules that will be published in February 2016.

*Can be given starting at 9 years of age.

See [MMWR](#) for complete vaccine recommendations.

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2015.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE [FIGURE 2]).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13–15 yrs	16–18 yrs	
Hepatitis B ¹ (HepB)	1 st dose	←----- 2 nd dose ----->		←----- 3 rd dose ----->													
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2												
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose				←----- 4 th dose ----->			5 th dose					
Tetanus, diphtheria, & acellular pertussis ⁴ (Tdap: ≥7 yrs)														(Tdap)			
<i>Haemophilus influenzae</i> type b ⁵ (Hib)			1 st dose	2 nd dose	See footnote 5		←----- 3 rd or 4 th dose -----> See footnote 5										
Pneumococcal conjugate ⁶ (PCV13)			1 st dose	2 nd dose	3 rd dose				←----- 4 th dose ----->								
Pneumococcal polysaccharide ⁶ (PPSV23)																	
Inactivated poliovirus ⁷ (IPV: <18 yrs)			1 st dose	2 nd dose	←----- 3 rd dose ----->						4 th dose						
Influenza ⁸ (IIV; LAIV) 2 doses for some: See footnote 8						Annual vaccination (IIV only) 1 or 2 doses					Annual vaccination (LAIV or IIV) 1 or 2 doses		Annual vaccination (LAIV or IIV) 1 dose only				
Measles, mumps, rubella ⁹ (MMR)					See footnote 9		←----- 1 st dose ----->					2 nd dose					
Varicella ¹⁰ (VAR)							←----- 1 st dose ----->					2 nd dose					
Hepatitis A ¹¹ (HepA)									←----- 2-dose series, See footnote 11 ----->								
Human papillomavirus ¹² (HPV2: females only; HPV4: males and females)														(3-dose series)			
Meningococcal ¹³ (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥9 mos; MenACWY-CRM ≥ 2 mos)	See footnote 13													1 st dose			Booster

Range of recommended ages for all children

 Range of recommended ages for catch-up immunization

 Range of recommended ages for certain high-risk groups

 Range of recommended ages during which catch-up is encouraged and for certain high-risk groups

 Not routinely recommended

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm>) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/acip>), the American Academy of Pediatrics (<http://www.aap.org>), the American Academy of Family Physicians (<http://www.aafp.org>), and the American College of Obstetricians and Gynecologists (<http://www.acog.org>).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

FIGURE 2. Catch-up immunization schedule for persons aged 4 months through 18 years who start late or who are more than 1 month behind —United States, 2015.

The figure below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. Always use this table in conjunction with Figure 1 and the footnotes that follow.

Children age 4 months through 6 years					
Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Hepatitis B ¹	Birth	4 weeks	8 weeks and at least 16 weeks after first dose. Minimum age for the final dose is 24 weeks.		
Rotavirus ²	6 weeks	4 weeks	4 weeks ²		
Diphtheria, tetanus, and acellular pertussis ³	6 weeks	4 weeks	4 weeks	6 months	6 months ³
<i>Haemophilus influenzae</i> type b ⁵	6 weeks	4 weeks if first dose was administered before the 1 st birthday. 8 weeks (as final dose) if first dose was administered at age 12 through 14 months. No further doses needed if first dose was administered at age 15 months or older.	4 weeks ⁵ if current age is younger than 12 months and first dose was administered at younger than age 7 months, and at least 1 previous dose was PRP-T (ActHib, Pentacel) or unknown. 8 weeks and age 12 through 59 months (as final dose) ⁵ • if current age is younger than 12 months and first dose was administered at age 7 through 11 months; OR • if current age is 12 through 59 months and first dose was administered before the 1 st birthday, and second dose administered at younger than 15 months; OR • if both doses were PRP-OMP (PedvaxHIB; Comvax) and were administered before the 1 st birthday. No further doses needed if previous dose was administered at age 15 months or older.	8 weeks (as final dose) This dose only necessary for children age 12 through 59 months who received 3 doses before the 1 st birthday.	
Pneumococcal ⁶	6 weeks	4 weeks if first dose administered before the 1 st birthday. 8 weeks (as final dose for healthy children) if first dose was administered at the 1 st birthday or after. No further doses needed for healthy children if first dose administered at age 24 months or older.	4 weeks if current age is younger than 12 months and previous dose given at <7months old. 8 weeks (as final dose for healthy children) if previous dose given between 7-11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was given before age 12 months. No further doses needed for healthy children if previous dose administered at age 24 months or older.	8 weeks (as final dose) This dose only necessary for children aged 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus ⁷	6 weeks	4 weeks ⁷	4 weeks ⁷	6 months ⁷ (minimum age 4 years for final dose).	
Meningococcal ¹³	6 weeks	8 weeks ¹³	See footnote 13	See footnote 13	
Measles, mumps, rubella ⁹	12 months	4 weeks			
Varicella ¹⁰	12 months	3 months			
Hepatitis A ¹¹	12 months	6 months			
Children and adolescents age 7 through 18 years					
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis ⁵	7 years ⁴	4 weeks	4 weeks if first dose of DTaP/DT was administered before the 1 st birthday. 6 months (as final dose) if first dose of DTaP/DT was administered at or after the 1 st birthday.	6 months if first dose of DTaP/DT was administered before the 1 st birthday.	
Human papillomavirus ¹²	9 years	Routine dosing intervals are recommended. ¹²			
Hepatitis A ¹¹	Not applicable (N/A)	6 months			
Hepatitis B ¹	N/A	4 weeks	8 weeks and at least 16 weeks after first dose.		
Inactivated poliovirus ⁷	N/A	4 weeks	4 weeks ⁷	6 months ⁷	
Meningococcal ¹³	N/A	8 weeks ¹³			
Measles, mumps, rubella ⁹	N/A	4 weeks			
Varicella ¹⁰	N/A	3 months if younger than age 13 years. 4 weeks if age 13 years or older.			

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Footnotes — Recommended immunization schedule for persons aged 0 through 18 years—United States, 2015

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

For vaccine recommendations for persons 19 years of age and older, see the Adult Immunization Schedule.

Additional information

- For contraindications and precautions to use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the relevant ACIP statement available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.
- For purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Vaccine doses administered 4 days or less before the minimum interval are considered valid. Doses of any vaccine administered ≥ 5 days earlier than the minimum interval or minimum age should not be counted as valid doses and should be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see *MMWR, General Recommendations on Immunization and Reports* / Vol. 60 / No. 2; Table 1. *Recommended and minimum ages and intervals between vaccine doses* available online at <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>.
- Information on travel vaccine requirements and recommendations is available at <http://wwwnc.cdc.gov/travel/destinations/list>.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, "Vaccination of persons with primary and secondary immunodeficiencies," in *General Recommendations on Immunization* (ACIP), available at <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf>; and American Academy of Pediatrics. "Immunization in Special Clinical Circumstances," in Pickering LK, Baker CJ, Kimberlin DW, Long SS eds. *Red Book: 2012 report of the Committee on Infectious Diseases*. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics.

1. Hepatitis B (HepB) vaccine. (Minimum age: birth)

Routine vaccination:

At birth:

- Administer monovalent HepB vaccine to all newborns before hospital discharge.
- For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) 1 to 2 months after completion of the HepB series at age 9 through 18 months (preferably at the next well-child visit).
- If mother's HBsAg status is unknown, within 12 hours of birth administer HepB vaccine regardless of birth weight. For infants weighing less than 2,000 grams, administer HBIG in addition to HepB vaccine within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if mother is HBsAg-positive, also administer HBIG for infants weighing 2,000 grams or more as soon as possible, but no later than age 7 days.

Doses following the birth dose:

- The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
- Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months starting as soon as feasible. See Figure 2.
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks), administer the third dose at least 8 weeks after the second dose AND at least 16 weeks after the **first** dose. The final (third or fourth) dose in the HepB vaccine series should be administered **no earlier than age 24 weeks**.
- Administration of a total of 4 doses of HepB vaccine is permitted when a combination vaccine containing HepB is administered after the birth dose.

Catch-up vaccination:

- Unvaccinated persons should complete a 3-dose series.
- A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
- For other catch-up guidance, see Figure 2.

2. Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV1 [Rotarix] and RV5 [RotaTeq])

Routine vaccination:

Administer a series of RV vaccine to all infants as follows:

1. If Rotarix is used, administer a 2-dose series at 2 and 4 months of age.
2. If RotaTeq is used, administer a 3-dose series at ages 2, 4, and 6 months.
3. If any dose in the series was RotaTeq or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

Catch-up vaccination:

- The maximum age for the first dose in the series is 14 weeks, 6 days; vaccination should not be initiated for infants aged 15 weeks, 0 days or older.
- The maximum age for the final dose in the series is 8 months, 0 days.
- For other catch-up guidance, see Figure 2.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks. Exception: DTaP-IPV [Kinrix]: 4 years)

Routine vaccination:

- Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15 through 18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose. However, the fourth dose of DTaP need not be repeated if it was administered at least 4 months after the third dose of DTaP.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine (cont'd)

Catch-up vaccination:

- The fifth dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
- For other catch-up guidance, see Figure 2.

4. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for both Boostrix and Adacel)

Routine vaccination:

- Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
- Tdap may be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
- Administer 1 dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferred during 27 through 36 weeks' gestation) regardless of time since prior Td or Tdap vaccination.

Catch-up vaccination:

- Persons aged 7 years and older who are not fully immunized with DTaP vaccine should receive Tdap vaccine as 1 dose (preferably the first) in the catch-up series; if additional doses are needed, use Td vaccine. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years should NOT be administered. Td should be administered instead 10 years after the Tdap dose.
- Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoid (Td) booster doses every 10 years thereafter.
- Inadvertent doses of DTaP vaccine:
 - If administered inadvertently to a child aged 7 through 10 years may count as part of the catch-up series. This dose may count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11 through 12 years.
 - If administered inadvertently to an adolescent aged 11 through 18 years, the dose should be counted as the adolescent Tdap booster.
- For other catch-up guidance, see Figure 2.

5. Haemophilus influenzae type b (Hib) conjugate vaccine. (Minimum age: 6 weeks for PRP-T [ACTHIB, DTaP-IPV/Hib (Pentacel) and Hib-MenCY (MenHibrix)], PRP-OMP [PevaxHIB or COMVAX], 12 months for PRP-T [Hiberix])

Routine vaccination:

- Administer a 2- or 3-dose Hib vaccine primary series and a booster dose (dose 3 or 4 depending on vaccine used in primary series) at age 12 through 15 months to complete a full Hib vaccine series.
- The primary series with ActHIB, MenHibrix, or Pentacel consists of 3 doses and should be administered at 2, 4, and 6 months of age. The primary series with PevaxHib or COMVAX consists of 2 doses and should be administered at 2 and 4 months of age; a dose at age 6 months is not indicated.
- One booster dose (dose 3 or 4 depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months. An exception is Hiberix vaccine. Hiberix should only be used for the booster (final) dose in children aged 12 months through 4 years who have received at least 1 prior dose of Hib-containing vaccine.
- For recommendations on the use of MenHibrix in patients at increased risk for meningococcal disease, please refer to the meningococcal vaccine footnotes and also to *MMWR* February 28, 2014 / 63(RR01);1-13, available at <http://www.cdc.gov/mmwr/PDF/rr/rr6301.pdf>.

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

5. *Haemophilus influenzae* type b (Hib) conjugate vaccine (cont'd)

Catch-up vaccination:

- If dose 1 was administered at ages 12 through 14 months, administer a second (final) dose at least 8 weeks after dose 1, regardless of Hib vaccine used in the primary series.
- If both doses were PRP-OMP (PedvaxHIB or COMVAX), and were administered before the first birthday, the third (and final) dose should be administered at age 12 through 59 months and at least 8 weeks after the second dose.
- If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a third (and final) dose at age 12 through 15 months or 8 weeks after second dose, whichever is later.
- If first dose is administered before the first birthday and second dose administered at younger than 15 months, a third (and final) dose should be given 8 weeks later.
- For unvaccinated children aged 15 months or older, administer only 1 dose.
- For other catch-up guidance, see Figure 2. For catch-up guidance related to MenHibrix, please see the meningococcal vaccine footnotes and also *MMWR* February 28, 2014 / 63(RR01);1-13, available at <http://www.cdc.gov/mmwr/PDF/rr/rr6301.pdf>.

Vaccination of persons with high-risk conditions:

- Children aged 12 through 59 months who are at increased risk for Hib disease, including chemotherapy recipients and those with anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, immunoglobulin deficiency, or early component complement deficiency, who have received either no doses or only 1 dose of Hib vaccine before 12 months of age, should receive 2 additional doses of Hib vaccine 8 weeks apart; children who received 2 or more doses of Hib vaccine before 12 months of age should receive 1 additional dose.
- For patients younger than 5 years of age undergoing chemotherapy or radiation treatment who received a Hib vaccine dose(s) within 14 days of starting therapy or during therapy, repeat the dose(s) at least 3 months following therapy completion.
- Recipients of hematopoietic stem cell transplant (HSCT) should be revaccinated with a 3-dose regimen of Hib vaccine starting 6 to 12 months after successful transplant, regardless of vaccination history; doses should be administered at least 4 weeks apart.
- A single dose of any Hib-containing vaccine should be administered to unimmunized* children and adolescents 15 months of age and older undergoing an elective splenectomy; if possible, vaccine should be administered at least 14 days before procedure.
- Hib vaccine is not routinely recommended for patients 5 years or older. However, 1 dose of Hib vaccine should be administered to unimmunized* persons aged 5 years or older who have anatomic or functional asplenia (including sickle cell disease) and unvaccinated persons 5 through 18 years of age with human immunodeficiency virus (HIV) infection.

*Patients who have not received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months of age are considered unimmunized.

6. Pneumococcal vaccines. (Minimum age: 6 weeks for PCV13, 2 years for PPSV23)

Routine vaccination with PCV13:

- Administer a 4-dose series of PCV13 vaccine at ages 2, 4, and 6 months and at age 12 through 15 months.
- For children aged 14 through 59 months who have received an age-appropriate series of 7-valent PCV (PCV7), administer a single supplemental dose of 13-valent PCV (PCV13).

Catch-up vaccination with PCV13:

- Administer 1 dose of PCV13 to all healthy children aged 24 through 59 months who are not completely vaccinated for their age.
- For other catch-up guidance, see Figure 2.

Vaccination of persons with high-risk conditions with PCV13 and PPSV23:

- All recommended PCV13 doses should be administered prior to PPSV23 vaccination if possible.
- For children 2 through 5 years of age with any of the following conditions: chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); diabetes mellitus; cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; solid organ transplantation; or congenital immunodeficiency:
 1. Administer 1 dose of PCV13 if any incomplete schedule of 3 doses of PCV (PCV7 and/or PCV13) were received previously.
 2. Administer 2 doses of PCV13 at least 8 weeks apart if unvaccinated or any incomplete schedule of fewer than 3 doses of PCV (PCV7 and/or PCV13) were received previously.
 3. Administer 1 supplemental dose of PCV13 if 4 doses of PCV7 or other age-appropriate complete PCV7 series was received previously.
 4. The minimum interval between doses of PCV (PCV7 or PCV13) is 8 weeks.
 5. For children with no history of PPSV23 vaccination, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.

6. Pneumococcal vaccines (cont'd)

- For children aged 6 through 18 years who have cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; generalized malignancy; solid organ transplantation; or multiple myeloma:
 1. If neither PCV13 nor PPSV23 has been received previously, administer 1 dose of PCV13 now and 1 dose of PPSV23 at least 8 weeks later.
 2. If PCV13 has been received previously but PPSV23 has not, administer 1 dose of PPSV23 at least 8 weeks after the most recent dose of PCV13.
 3. If PPSV23 has been received but PCV13 has not, administer 1 dose of PCV13 at least 8 weeks after the most recent dose of PPSV23.
- For children aged 6 through 18 years with chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure), chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), diabetes mellitus, alcoholism, or chronic liver disease, who have not received PPSV23, administer 1 dose of PPSV23. If PCV13 has been received previously, then PPSV23 should be administered at least 8 weeks after any prior PCV13 dose.
- A single revaccination with PPSV23 should be administered 5 years after the first dose to children with sickle cell disease or other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; generalized malignancy; solid organ transplantation; or multiple myeloma.

7. Inactivated poliovirus vaccine (IPV). (Minimum age: 6 weeks)

Routine vaccination:

- Administer a 4-dose series of IPV at ages 2, 4, 6 through 18 months, and 4 through 6 years. The final dose in the series should be administered on or after the fourth birthday and at least 6 months after the previous dose.

Catch-up vaccination:

- In the first 6 months of life, minimum age and minimum intervals are only recommended if the person is at risk of imminent exposure to circulating poliovirus (i.e., travel to a polio-endemic region or during an outbreak).
- If 4 or more doses are administered before age 4 years, an additional dose should be administered at age 4 through 6 years and at least 6 months after the previous dose.
- A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age. IPV is not routinely recommended for U.S. residents aged 18 years or older.
- For other catch-up guidance, see Figure 2.

8. Influenza vaccines. (Minimum age: 6 months for inactivated influenza vaccine [IIV], 2 years for live, attenuated influenza vaccine [LAIV])

Routine vaccination:

- Administer influenza vaccine annually to all children beginning at age 6 months. For most healthy, nonpregnant persons aged 2 through 49 years, either LAIV or IIV may be used. However, LAIV should NOT be administered to some persons, including 1) persons who have experienced severe allergic reactions to LAIV, any of its components, or to a previous dose of any other influenza vaccine; 2) children 2 through 17 years receiving aspirin or aspirin-containing products; 3) persons who are allergic to eggs; 4) pregnant women; 5) immunosuppressed persons; 6) children 2 through 4 years of age with asthma or who had wheezing in the past 12 months; or 7) persons who have taken influenza antiviral medications in the previous 48 hours. For all other contraindications and precautions to use of LAIV, see *MMWR* August 15, 2014 / 63(32);691-697 [40 pages] available at <http://www.cdc.gov/mmwr/pdf/wk/mm6332.pdf>.

For children aged 6 months through 8 years:

- For the 2014-15 season, administer 2 doses (separated by at least 4 weeks) to children who are receiving influenza vaccine for the first time. Some children in this age group who have been vaccinated previously will also need 2 doses. For additional guidance, follow dosing guidelines in the 2014-15 ACIP influenza vaccine recommendations, *MMWR* August 15, 2014 / 63(32);691-697 [40 pages] available at <http://www.cdc.gov/mmwr/pdf/wk/mm6332.pdf>.
- For the 2015-16 season, follow dosing guidelines in the 2015 ACIP influenza vaccine recommendations.

For persons aged 9 years and older:

- Administer 1 dose.

For further guidance on the use of the vaccines mentioned below, see: <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

9. Measles, mumps, and rubella (MMR) vaccine. (Minimum age: 12 months for routine vaccination)

Routine vaccination:

- Administer a 2-dose series of MMR vaccine at ages 12 through 15 months and 4 through 6 years. The second dose may be administered before age 4 years, provided at least 4 weeks have elapsed since the first dose.
- Administer 1 dose of MMR vaccine to infants aged 6 through 11 months before departure from the United States for international travel. These children should be revaccinated with 2 doses of MMR vaccine, the first at age 12 through 15 months (12 months if the child remains in an area where disease risk is high), and the second dose at least 4 weeks later.
- Administer 2 doses of MMR vaccine to children aged 12 months and older before departure from the United States for international travel. The first dose should be administered on or after age 12 months and the second dose at least 4 weeks later.

Catch-up vaccination:

- Ensure that all school-aged children and adolescents have had 2 doses of MMR vaccine; the minimum interval between the 2 doses is 4 weeks.

10. Varicella (VAR) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Administer a 2-dose series of VAR vaccine at ages 12 through 15 months and 4 through 6 years. The second dose may be administered before age 4 years, provided at least 3 months have elapsed since the first dose. If the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid.

Catch-up vaccination:

- Ensure that all persons aged 7 through 18 years without evidence of immunity (see *MMWR* 2007 / 56 [No. RR-4], available at <http://www.cdc.gov/mmwr/pdf/rr/rr5604.pdf>) have 2 doses of varicella vaccine. For children aged 7 through 12 years, the recommended minimum interval between doses is 3 months (if the second dose was administered at least 4 weeks after the first dose, it can be accepted as valid); for persons aged 13 years and older, the minimum interval between doses is 4 weeks.

11. Hepatitis A (HepA) vaccine. (Minimum age: 12 months)

Routine vaccination:

- Initiate the 2-dose HepA vaccine series at 12 through 23 months; separate the 2 doses by 6 to 18 months.
- Children who have received 1 dose of HepA vaccine before age 24 months should receive a second dose 6 to 18 months after the first dose.
- For any person aged 2 years and older who has not already received the HepA vaccine series, 2 doses of HepA vaccine separated by 6 to 18 months may be administered if immunity against hepatitis A virus infection is desired.

Catch-up vaccination:

- The minimum interval between the two doses is 6 months.

Special populations:

- Administer 2 doses of HepA vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection. This includes persons traveling to or working in countries that have high or intermediate endemicity of infection; men having sex with men; users of injection and non-injection illicit drugs; persons who work with HAV-infected primates or with HAV in a research laboratory; persons with clotting-factor disorders; persons with chronic liver disease; and persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. The first dose should be administered as soon as the adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.

12. Human papillomavirus (HPV) vaccines. (Minimum age: 9 years for HPV2 [Cervarix] and HPV4 [Gardasil])

Routine vaccination:

- Administer a 3-dose series of HPV vaccine on a schedule of 0, 1-2, and 6 months to all adolescents aged 11 through 12 years. Either HPV4 or HPV2 may be used for females, and only HPV4 may be used for males.
- The vaccine series may be started at age 9 years.
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks); administer the third dose 24 weeks after the first dose and 16 weeks after the second dose (minimum interval of 12 weeks).

Catch-up vaccination:

- Administer the vaccine series to females (either HPV2 or HPV4) and males (HPV4) at age 13 through 18 years if not previously vaccinated.
- Use recommended routine dosing intervals (see Routine vaccination above) for vaccine series catch-up.

13. Meningococcal conjugate vaccines. (Minimum age: 6 weeks for Hib-MenCY [MenHibrix], 9 months for MenACWY-D [Menactra], 2 months for MenACWY-CRM [Menveo])

Routine vaccination:

- Administer a single dose of Menactra or Menveo vaccine at age 11 through 12 years, with a booster dose at age 16 years.
- Adolescents aged 11 through 18 years with human immunodeficiency virus (HIV) infection should receive a 2-dose primary series of Menactra or Menveo with at least 8 weeks between doses.
- For children aged 2 months through 18 years with high-risk conditions, see below.

Catch-up vaccination:

- Administer Menactra or Menveo vaccine at age 13 through 18 years if not previously vaccinated.
- If the first dose is administered at age 13 through 15 years, a booster dose should be administered at age 16 through 18 years with a minimum interval of at least 8 weeks between doses.
- If the first dose is administered at age 16 years or older, a booster dose is not needed.
- For other catch-up guidance, see Figure 2.

Vaccination of persons with high-risk conditions and other persons at increased risk of disease:

- Children with anatomic or functional asplenia (including sickle cell disease):
 1. Menveo
 - o *Children who initiate vaccination at 8 weeks through 6 months:* Administer doses at 2, 4, 6, and 12 months of age.
 - o *Unvaccinated children 7 through 23 months:* Administer 2 doses, with the second dose at least 12 weeks after the first dose AND after the first birthday.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
 2. MenHibrix
 - o *Children 6 weeks through 18 months:* Administer doses at 2, 4, 6, and 12 through 15 months of age.
 - o If the first dose of MenHibrix is given at or after 12 months of age, a total of 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.
 3. Menactra
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart. If Menactra is administered to a child with asplenia (including sickle cell disease), do not administer Menactra until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.
- Children with persistent complement component deficiency:
 1. Menveo
 - o *Children who initiate vaccination at 8 weeks through 6 months:* Administer doses at 2, 4, 6, and 12 months of age.
 - o *Unvaccinated children 7 through 23 months:* Administer 2 doses, with the second dose at least 12 weeks after the first dose AND after the first birthday.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
 2. MenHibrix
 - o *Children 6 weeks through 18 months:* Administer doses at 2, 4, 6, and 12 through 15 months of age.
 - o If the first dose of MenHibrix is given at or after 12 months of age, a total of 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.
 3. Menactra
 - o *Children 9 through 23 months:* Administer 2 primary doses at least 12 weeks apart.
 - o *Children 24 months and older who have not received a complete series:* Administer 2 primary doses at least 8 weeks apart.
- For children who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or the Hajj, administer an age-appropriate formulation and series of Menactra or Menveo for protection against serogroups A and W meningococcal disease. Prior receipt of MenHibrix is not sufficient for children traveling to the meningitis belt or the Hajj because it does not contain serogroups A or W.
- For children at risk during a community outbreak attributable to a vaccine serogroup, administer or complete an age- and formulation-appropriate series of MenHibrix, Menactra, or Menveo.
- For booster doses among persons with high-risk conditions, refer to *MMWR* 2013 / 62(RR02);1-22, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>.

For other catch-up recommendations for these persons, and complete information on use of meningococcal vaccines, including guidance related to vaccination of persons at increased risk of infection, see *MMWR* March 22, 2013 / 62(RR02);1-22, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>.

Recommended Adult Immunization Schedule

United States - 2015

The 2015 Adult Immunization Schedule was approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Nurse-Midwives (ACNM). On February 3, 2015, the adult immunization schedule and a summary of changes from 2014 were published in the *Annals of Internal Medicine*, and a summary of changes was published in the *Morbidity and Mortality Weekly Report (MMWR)* on February 5, 2015.

All clinically significant postvaccination reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Additional details regarding ACIP recommendations for each of the vaccines listed in the schedule can be found at www.cdc.gov/vaccines/hcp/acip-recs/index.html.

American Academy of Family Physicians (AAFP)

www.aafp.org/

American College of Physicians (ACP)

www.acponline.org/

American College of Obstetricians and Gynecologists (ACOG)

www.acog.org/

American College of Nurse-Midwives (ACNM)

www.midwife.org/



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Recommended Adult Immunization Schedule—United States - 2015

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group¹

VACCINE ▼	AGE GROUP ▶	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza ^{*2}		1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) ^{*3}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Varicella ^{*4}		2 doses					
Human papillomavirus (HPV) Female ^{*5}		3 doses					
Human papillomavirus (HPV) Male ^{*5}		3 doses					
Zoster ⁶						1 dose	
Measles, mumps, rubella (MMR) ^{*7}		1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) ^{*8}		1-time dose					
Pneumococcal polysaccharide (PPSV23) ⁸		1 or 2 doses					1 dose
Meningococcal ^{*9}		1 or more doses					
Hepatitis A ^{*10}		2 doses					
Hepatitis B ^{*11}		3 doses					
<i>Haemophilus influenzae</i> type b (Hib) ^{*12}		1 or 3 doses					

*Covered by the Vaccine Injury Compensation Program

- For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster
- Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)
- No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

VACCINE ▼	INDICATION ▶	Pregnancy	Immuno-compromising conditions (excluding human immunodeficiency virus [HIV]) ^{4,6,7,8,13}	HIV infection CD4+ T lymphocyte count ^{4,6,7,8,13}	Men who have sex with men (MSM)	Kidney failure, end-stage renal disease, receipt of hemodialysis	Heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement deficiencies) ^{8,12}	Chronic liver disease	Diabetes	Healthcare personnel
Influenza ^{*2}		1 dose IIV annually			1 dose IIV or LAIV annually	1 dose IIV annually				1 dose IIV or LAIV annually	
Tetanus, diphtheria, pertussis (Td/Tdap) ^{*3}		1 dose Tdap each pregnancy	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs								
Varicella ^{*4}		Contraindicated				2 doses					
Human papillomavirus (HPV) Female ^{*5}		3 doses through age 26 yrs				3 doses through age 26 yrs					
Human papillomavirus (HPV) Male ^{*5}		3 doses through age 26 yrs				3 doses through age 21 yrs					
Zoster ⁶		Contraindicated				1 dose					
Measles, mumps, rubella (MMR) ^{*7}		Contraindicated				1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) ^{*8}						1 dose					
Pneumococcal polysaccharide (PPSV23) ⁸						1 or 2 doses					
Meningococcal ^{*9}						1 or more doses					
Hepatitis A ^{*10}						2 doses					
Hepatitis B ^{*11}						3 doses					
<i>Haemophilus influenzae</i> type b (Hib) ^{*12}						1 or 3 doses					
						post-HSCT recipients only					

*Covered by the Vaccine Injury Compensation Program

- For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

- Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

- No recommendation



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These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly recommended for adults ages 19 years and older, as of February 1, 2015. For all vaccines being recommended on the Adult Immunization Schedule: a vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/hcp/acip-recs/index.html). Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

1. Additional information

- Additional guidance for the use of the vaccines described in this supplement is available at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- Information on vaccination recommendations when vaccination status is unknown and other general immunization information can be found in the General Recommendations on Immunization at www.cdc.gov/mmwr/preview/mmwrhtml/r6002a1.htm.
- Information on travel vaccine requirements and recommendations (e.g., for hepatitis A and B, meningococcal, and other vaccines) is available at wwwnc.cdc.gov/travel/destinations/list.
- Additional information and resources regarding vaccination of pregnant women can be found at www.cdc.gov/vaccines/adults/rec-vac/pregnant.html.

2. Influenza vaccination

- Annual vaccination against influenza is recommended for all persons aged 6 months or older.
- Persons aged 6 months or older, including pregnant women and persons with hives-only allergy to eggs can receive the inactivated influenza vaccine (IIV). An age-appropriate IIV formulation should be used.
- Adults aged 18 years or older can receive the recombinant influenza vaccine (RIV) (FluBlok). RIV does not contain any egg protein and can be given to age-appropriate persons with egg allergy of any severity.
- Healthy, nonpregnant persons aged 2 to 49 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist) or IIV.
- Health care personnel who care for severely immunocompromised persons who require care in a protected environment should receive IIV or RIV; health care personnel who receive LAIV should avoid providing care for severely immunosuppressed persons for 7 days after vaccination.
- The intramuscularly or intradermally administered IIV are options for adults aged 18 through 64 years.
- Adults aged 65 years or older can receive the standard-dose IIV or the high-dose IIV (Fluzone High-Dose).
- A list of currently available influenza vaccines can be found at www.cdc.gov/flu/protect/vaccine/vaccines.htm.

3. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination

- Administer 1 dose of Tdap vaccine to pregnant women during each pregnancy (preferably during 27 to 36 weeks' gestation) regardless of interval since prior Td or Tdap vaccination.
- Persons aged 11 years or older who have not received Tdap vaccine or for whom vaccine status is unknown should receive a dose of Tdap followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid containing vaccine.
- Adults with an unknown or incomplete history of completing a 3-dose primary vaccination series with Td-containing vaccines should begin or complete a primary vaccination series including a Tdap dose.
- For unvaccinated adults, administer the first 2 doses at least 4 weeks apart and the third dose 6 to 12 months after the second.
- For incompletely vaccinated (i.e., less than 3 doses) adults, administer remaining doses.
- Refer to the ACIP statement for recommendations for administering Td/Tdap as prophylaxis in wound management (see footnote 1).

4. Varicella vaccination

- All adults without evidence of immunity to varicella (as defined below) should receive 2 doses of single-antigen varicella vaccine or a second dose if they have received only 1 dose.
- Vaccination should be emphasized for those who have close contact with persons at high risk for severe disease (e.g., health care personnel and family contacts of persons with immunocompromising conditions) or are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).
- Pregnant women should be assessed for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health care facility. The second dose should be administered 4 to 8 weeks after the first dose.
- Evidence of immunity to varicella in adults includes any of the following:
 - documentation of 2 doses of varicella vaccine at least 4 weeks apart;
 - U.S.-born before 1980, except health care personnel and pregnant women;
 - history of varicella based on diagnosis or verification of varicella disease by a health care provider;
 - history of herpes zoster based on diagnosis or verification of herpes zoster disease by a health care provider; or
 - laboratory evidence of immunity or laboratory confirmation of disease.

5. Human papillomavirus (HPV) vaccination

- Two vaccines are licensed for use in females, bivalent HPV vaccine (HPV2) and quadrivalent HPV vaccine (HPV4), and one HPV vaccine for use in males (HPV4).
- For females, either HPV4 or HPV2 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years and for those aged 13 through 26 years, if not previously vaccinated.

- For males, HPV4 is recommended in a 3-dose series for routine vaccination at age 11 or 12 years and for those aged 13 through 21 years, if not previously vaccinated. Males aged 22 through 26 years may be vaccinated.
- HPV4 is recommended for men who have sex with men through age 26 years for those who did not get any or all doses when they were younger.
- Vaccination is recommended for immunocompromised persons (including those with HIV infection) through age 26 years for those who did not get any or all doses when they were younger.
- A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 4 to 8 weeks (minimum interval of 4 weeks) after the first dose; the third dose should be administered 24 weeks after the first dose and 16 weeks after the second dose (minimum interval of at least 12 weeks).
- HPV vaccines are not recommended for use in pregnant women. However, pregnancy testing is not needed before vaccination. If a woman is found to be pregnant after initiating the vaccination series, no intervention is needed; the remainder of the 3-dose series should be delayed until completion or termination of pregnancy.

6. Zoster vaccination

- A single dose of zoster vaccine is recommended for adults aged 60 years or older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the U.S. Food and Drug Administration for use among and can be administered to persons aged 50 years or older, ACIP recommends that vaccination begin at age 60 years.
- Persons aged 60 years or older with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.

7. Measles, mumps, rubella (MMR) vaccination

- Adults born before 1957 are generally considered immune to measles and mumps. All adults born in 1957 or later should have documentation of 1 or more doses of MMR vaccine unless they have a medical contraindication to the vaccine or laboratory evidence of immunity to each of the three diseases. Documentation of provider-diagnosed disease is not considered acceptable evidence of immunity for measles, mumps, or rubella.

Measles component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who:
 - are students in postsecondary educational institutions,
 - work in a health care facility, or
 - plan to travel internationally.
- Persons who received inactivated (killed) measles vaccine or measles vaccine of unknown type during 1963–1967 should be revaccinated with 2 doses of MMR vaccine.

Mumps component:

- A routine second dose of MMR vaccine, administered a minimum of 28 days after the first dose, is recommended for adults who:
 - are students in a postsecondary educational institution,
 - work in a health care facility, or
 - plan to travel internationally.
- Persons vaccinated before 1979 with either killed mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection (e.g., persons who are working in a health care facility) should be considered for revaccination with 2 doses of MMR vaccine.

Rubella component:

- For women of childbearing age, regardless of birth year, rubella immunity should be determined. If there is no evidence of immunity, women who are not pregnant should be vaccinated. Pregnant women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health care facility.

Health care personnel born before 1957:

- For unvaccinated health care personnel born before 1957 who lack laboratory evidence of measles, mumps, and/or rubella immunity or laboratory confirmation of disease, health care facilities should consider vaccinating personnel with 2 doses of MMR vaccine at the appropriate interval for measles and mumps or 1 dose of MMR vaccine for rubella.

8. Pneumococcal (13-valent pneumococcal conjugate vaccine [PCV13] and 23-valent pneumococcal polysaccharide vaccine [PPSV23]) vaccination

- General information
 - When indicated, only a single dose of PCV13 is recommended for adults.
 - No additional dose of PPSV23 is indicated for adults vaccinated with PPSV23 at or after age 65 years.
 - When both PCV13 and PPSV23 are indicated, PCV13 should be administered first; PCV13 and PPSV23 should not be administered during the same visit.
 - When indicated, PCV13 and PPSV23 should be administered to adults whose pneumococcal vaccination history is incomplete or unknown.
- Adults aged 65 years or older who
 - Have not received PCV13 or PPSV23: Administer PCV13 followed by PPSV23 in 6 to 12 months.
 - Have not received PCV13 but have received a dose of PPSV23 at age 65 years or older: Administer PCV13 at least 1 year after the dose of PPSV23 received at age 65 years or older.

8. Pneumococcal vaccination (continued)

- Have not received PCV13 but have received 1 or more doses of PPSV23 before age 65: Administer PCV13 at least 1 year after the most recent dose of PPSV23; administer a dose of PPSV23 6 to 12 months after PCV13, or as soon as possible if this time window has passed, and at least 5 years after the most recent dose of PPSV23.
- Have received PCV13 but not PPSV23 before age 65 years: Administer PPSV23 6 to 12 months after PCV13 or as soon as possible if this time window has passed.
- Have received PCV13 and 1 or more doses of PPSV23 before age 65 years: Administer PPSV23 6 to 12 months after PCV13, or as soon as possible if this time window has passed, and at least 5 years after the most recent dose of PPSV23.
- Adults aged 19 through 64 years with immunocompromising conditions or anatomical or functional asplenia (defined below) who
 - Have not received PCV13 or PPSV23: Administer PCV13 followed by PPSV23 at least 8 weeks after PCV13; administer a second dose of PPSV23 at least 5 years after the first dose of PPSV23.
 - Have not received PCV13 but have received 1 dose of PPSV23: Administer PCV13 at least 1 year after the PPSV23; administer a second dose of PPSV23 at least 8 weeks after PCV13 and at least 5 years after the first dose of PPSV23.
 - Have not received PCV13 but have received 2 doses of PPSV23: Administer PCV13 at least 1 year after the most recent dose of PPSV23.
 - Have received PCV13 but not PPSV23: Administer PPSV23 at least 8 weeks after PCV13; administer a second dose of PPSV23 at least 5 years after the first dose of PPSV23.
 - Have received PCV13 and 1 dose of PPSV23: Administer a second dose of PPSV23 at least 5 years after the first dose of PPSV23.
- Adults aged 19 through 64 years with cerebrospinal fluid leaks or cochlear implants: Administer PCV13 followed by PPSV23 at least 8 weeks after PCV13.
- Adults aged 19 through 64 years with chronic heart disease (including congestive heart failure and cardiomyopathies, excluding hypertension), chronic lung disease (including chronic obstructive lung disease, emphysema, and asthma), chronic liver disease (including cirrhosis), alcoholism, or diabetes mellitus: Administer PPSV23.
- Adults aged 19 through 64 years who smoke cigarettes or reside in nursing home or long-term care facilities: Administer PPSV23.
- Routine pneumococcal vaccination is not recommended for American Indian/Alaska Native or other adults unless they have the indications as above; however, public health authorities may consider recommending the use of pneumococcal vaccines for American Indians/Alaska Natives or other adults who live in areas with increased risk for invasive pneumococcal disease.
- Immunocompromising conditions that are indications for pneumococcal vaccination are: Congenital or acquired immunodeficiency (including B- or T-lymphocyte deficiency, complement deficiencies, and phagocytic disorders excluding chronic granulomatous disease), HIV infection, chronic renal failure, nephrotic syndrome, leukemia, lymphoma, Hodgkin disease, generalized malignancy, multiple myeloma, solid organ transplant, and iatrogenic immunosuppression (including long-term systemic corticosteroids and radiation therapy).
- Anatomical or functional asplenia that are indications for pneumococcal vaccination are: Sickle cell disease and other hemoglobinopathies, congenital or acquired asplenia, splenic dysfunction, and splenectomy. Administer pneumococcal vaccines at least 2 weeks before immunosuppressive therapy or an elective splenectomy, and as soon as possible to adults who are newly diagnosed with asymptomatic or symptomatic HIV infection.

9. Meningococcal vaccination

- Administer 2 doses of quadrivalent meningococcal conjugate vaccine (MenACWY [Menactra, Menveo]) at least 2 months apart to adults of all ages with anatomical or functional asplenia or persistent complement component deficiencies. HIV infection is not an indication for routine vaccination with MenACWY. If an HIV-infected person of any age is vaccinated, 2 doses of MenACWY should be administered at least 2 months apart.
- Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, persons at risk during an outbreak attributable to a vaccine serogroup, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.
- First-year college students up through age 21 years who are living in residence halls should be vaccinated if they have not received a dose on or after their 16th birthday.
- MenACWY is preferred for adults with any of the preceding indications who are aged 55 years or younger as well as for adults aged 56 years or older who a) were vaccinated previously with MenACWY and are recommended for revaccination, or b) for whom multiple doses are anticipated. Meningococcal polysaccharide vaccine (MPSV4 [Menomune]) is preferred for adults aged 56 years or older who have not received MenACWY previously and who require a single dose only (e.g., travelers).
- Revaccination with MenACWY every 5 years is recommended for adults previously vaccinated with MenACWY or MPSV4 who remain at increased risk for infection (e.g., adults with anatomical or functional asplenia, persistent complement component deficiencies, or microbiologists).

10. Hepatitis A vaccination

- Vaccinate any person seeking protection from hepatitis A virus (HAV) infection and persons with any of the following indications:
 - men who have sex with men and persons who use injection or noninjection illicit drugs;
 - persons working with HAV-infected primates or with HAV in a research laboratory setting;
 - persons with chronic liver disease and persons who receive clotting factor concentrates;
 - persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A; and
 - unvaccinated persons who anticipate close personal contact (e.g., household or regular babysitting) with an international adoptee during the first 60 days after arrival in the United States from a country with high or intermediate endemicity. (See footnote 1 for more information on travel recommendations.) The first dose of the 2-dose hepatitis A vaccine series should be administered as soon as adoption is planned, ideally 2 or more weeks before the arrival of the adoptee.
- Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6 to 12 months (Havrix), or 0 and 6 to 18 months (Vaqta). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, administer 3 doses at 0, 1, and 6 months; alternatively, a 4-dose schedule may be used, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12.

11. Hepatitis B vaccination

- Vaccinate persons with any of the following indications and any person seeking protection from hepatitis B virus (HBV) infection:
 - sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 sex partner during the previous 6 months); persons seeking evaluation or treatment for a sexually transmitted disease (STD); current or recent injection drug users; and men who have sex with men;
 - health care personnel and public safety workers who are potentially exposed to blood or other infectious body fluids;
 - persons with diabetes who are younger than age 60 years as soon as feasible after diagnosis; persons with diabetes who are age 60 years or older at the discretion of the treating clinician based on the likelihood of acquiring HBV infection, including the risk posed by an increased need for assisted blood glucose monitoring in long-term care facilities, the likelihood of experiencing chronic sequelae if infected with HBV, and the likelihood of immune response to vaccination;
 - persons with end-stage renal disease, including patients receiving hemodialysis, persons with HIV infection, and persons with chronic liver disease;
 - household contacts and sex partners of hepatitis B surface antigen-positive persons, clients and staff members of institutions for persons with developmental disabilities, and international travelers to countries with high or intermediate prevalence of chronic HBV infection; and
 - all adults in the following settings: STD treatment facilities, HIV testing and treatment facilities, facilities providing drug abuse treatment and prevention services, health care settings targeting services to injection drug users or men who have sex with men, correctional facilities, end-stage renal disease programs and facilities for chronic hemodialysis patients, and institutions and nonresidential day care facilities for persons with developmental disabilities.
- Administer missing doses to complete a 3-dose series of hepatitis B vaccine to those persons not vaccinated or not completely vaccinated. The second dose should be administered 1 month after the first dose; the third dose should be given at least 2 months after the second dose (and at least 4 months after the first dose). If the combined hepatitis A and hepatitis B vaccine (Twinrix) is used, give 3 doses at 0, 1, and 6 months; alternatively, a 4-dose Twinrix schedule, administered on days 0, 7, and 21 to 30 followed by a booster dose at month 12 may be used.
- Adult patients receiving hemodialysis or with other immunocompromising conditions should receive 1 dose of 40 mcg/mL (Recombivax HB) administered on a 3-dose schedule at 0, 1, and 6 months or 2 doses of 20 mcg/mL (Engerix-B) administered simultaneously on a 4-dose schedule at 0, 1, 2, and 6 months.

12. *Haemophilus influenzae* type b (Hib) vaccination

- One dose of Hib vaccine should be administered to persons who have anatomical or functional asplenia or sickle cell disease or are undergoing elective splenectomy if they have not previously received Hib vaccine. Hib vaccination 14 or more days before splenectomy is suggested.
- Recipients of a hematopoietic stem cell transplant (HSCT) should be vaccinated with a 3-dose regimen 6 to 12 months after a successful transplant, regardless of vaccination history; at least 4 weeks should separate doses.
- Hib vaccine is not recommended for adults with HIV infection since their risk for Hib infection is low.

13. Immunocompromising conditions

- Inactivated vaccines generally are acceptable (e.g., pneumococcal, meningococcal, and inactivated influenza vaccine) and live vaccines generally are avoided in persons with immune deficiencies or immunocompromising conditions. Information on specific conditions is available at www.cdc.gov/vaccines/hcp/acip-recs/index.html.

TABLE. Contraindications and precautions to commonly used vaccines in adults^{1†}

Vaccine	Contraindications	Precautions
Influenza, inactivated (IIV) ²	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine; or to a vaccine component, including egg protein 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of Guillain-Barré Syndrome within 6 weeks of previous influenza vaccination Adults who experience only hives with exposure to eggs may receive RIV or, with additional safety precautions, IIV²
Influenza, recombinant (RIV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after previous dose of RIV or to a vaccine component. RIV does not contain any egg protein² 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever History of Guillain-Barré Syndrome within 6 weeks of previous influenza vaccination
Influenza, live attenuated (LAIV) ^{2,3}	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, or to a previous dose of any influenza vaccine In addition, ACIP recommends that LAIV not be used in the following populations: <ul style="list-style-type: none"> pregnant women immunosuppressed adults adults with egg allergy of any severity adults who have taken influenza antiviral medications (amantadine, rimantadine, zanamivir, or oseltamivir) within the previous 48 hours; avoid use of these antiviral drugs for 14 days after vaccination 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever. History of Guillain-Barré Syndrome within 6 weeks of previous influenza vaccination Asthma in persons aged 5 years and older Other chronic medical conditions, e.g., other chronic lung diseases, chronic cardiovascular disease (excluding isolated hypertension), diabetes, chronic renal or hepatic disease, hematologic disease, neurologic disease, and metabolic disorders
Tetanus, diphtheria, pertussis (Tdap); tetanus, diphtheria (Td)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component For pertussis-containing vaccines: encephalopathy (e.g., coma, decreased level of consciousness, or prolonged seizures) not attributable to another identifiable cause within 7 days of administration of a previous dose of Tdap, diphtheria and tetanus toxoids and pertussis (DTP), or diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Guillain-Barré Syndrome within 6 weeks after a previous dose of tetanus toxoid-containing vaccine History of Arthus-type hypersensitivity reactions after a previous dose of tetanus or diphtheria toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine For pertussis-containing vaccines: progressive or unstable neurologic disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella ³	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy,⁴ or patients with human immunodeficiency virus [HIV] infection who are severely immunocompromised) Pregnancy 	<ul style="list-style-type: none"> Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)⁵ Moderate or severe acute illness with or without fever Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination
Human papillomavirus (HPV)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Pregnancy
Zoster ³	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy,⁴ or patients with HIV infection who are severely immunocompromised) Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Receipt of specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination; avoid use of these antiviral drugs for 14 days after vaccination
Measles, mumps, rubella (MMR) ³	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component Known severe immunodeficiency (e.g., from hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, or long-term immunosuppressive therapy,⁴ or patients with HIV infection who are severely immunocompromised) Pregnancy 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever Recent (within 11 months) receipt of antibody-containing blood product (specific interval depends on product)⁵ History of thrombocytopenia or thrombocytopenic purpura Need for tuberculin skin testing⁶
Pneumococcal conjugate (PCV13)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component, including to any vaccine containing diphtheria toxoid 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Meningococcal, conjugate (MenACWY); meningococcal, polysaccharide (MPSV4)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Hepatitis A	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
Hepatitis B	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever
<i>Haemophilus influenzae</i> Type b (Hib)	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component 	<ul style="list-style-type: none"> Moderate or severe acute illness with or without fever

1. Vaccine package inserts and the full ACIP recommendations for these vaccines should be consulted for additional information on vaccine-related contraindications and precautions and for more information on vaccine excipients. Events or conditions listed as precautions should be reviewed carefully. Benefits of and risks for administering a specific vaccine to a person under these circumstances should be considered. If the risk from the vaccine is believed to outweigh the benefit, the vaccine should not be administered. If the benefit of vaccination is believed to outweigh the risk, the vaccine should be administered. A contraindication is a condition in a recipient that increases the chance of a serious adverse reaction. Therefore, a vaccine should not be administered when a contraindication is present.

2. For more information on use of influenza vaccines among persons with egg allergies and a complete list of conditions that CDC considers to be reasons to avoid receiving LAIV, see CDC. Prevention and control of seasonal influenza with vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP) — United States, 2014–15 Influenza Season. *MMWR* 2014;63(32):691–97.

3. LAIV, MMR, varicella, or zoster vaccines can be administered on the same day. If not administered on the same day, live vaccines should be separated by at least 28 days.

4. Immunosuppressive steroid dose is considered to be ≥ 2 weeks of daily receipt of 20 mg of prednisone or the equivalent. Vaccination should be deferred for at least 1 month after discontinuation of such therapy. Providers should consult ACIP recommendations for complete information on the use of specific live vaccines among persons on immune-suppressing medications or with immune suppression because of other reasons.


5. Vaccine should be deferred for the appropriate interval if replacement immune globulin products are being administered. See CDC. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2011;60(No. RR-2). Available at www.cdc.gov/vaccines/pubs/pinkbook/index.html.

6. Measles vaccination might suppress tuberculin reactivity temporarily. Measles-containing vaccine may be administered on the same day as tuberculin skin testing. If testing cannot be performed until after the day of MMR vaccination, the test should be postponed for at least 4 weeks after the vaccination. If an urgent need exists to skin test, do so with the understanding that reactivity might be reduced by the vaccine.

* Adapted from CDC. Table 6. Contraindications and precautions to commonly used vaccines. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices. *MMWR* 2011;60(No. RR-2):40–41 and from Atkinson W, Wolfe S, Hamborsky J, eds. Appendix A. Epidemiology and prevention of vaccine preventable diseases. 12th ed. Washington, DC: Public Health Foundation, 2011. Available at www.cdc.gov/vaccines/pubs/pinkbook/index.html.

† Regarding latex allergy, consult the package insert for any vaccine administered.





CDC
IMMUNIZATION
RESOURCES for
You & Your **PATIENTS**



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

FREE **CONTINUING EDUCATION**

Did you know you can get free Continuing Education for participating in CDC's immunization education programs?

www.cdc.gov/vaccines/ed/courses.htm

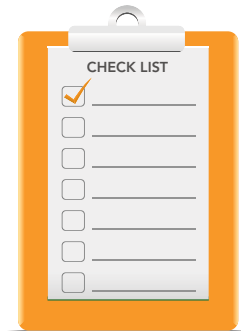
Immunization Guidelines and Recommendations

Immunization Schedules: The schedules of recommended vaccinations for all age groups are offered in several printable versions as well as an interactive tool and as a downloadable application for smartphone.

www.cdc.gov/vaccines/schedules/hcp/

Vaccine administration: Guidelines, screening questions and checklists for your patients, reference tables on contraindications and precautions, and comforting technique tools are available.

www.cdc.gov/vaccines/recs/vac-admin/



Vaccine storage and handling: Explore storage and handling videos, toolkits, and fact sheets to ensure your practice is storing and handling vaccines in accordance with ACIP recommendations. www.cdc.gov/vaccines/recs/storage/

Vaccine Information Statements (VIS): Federal law requires you provide VIS to patients before administering certain vaccines; VIS explains both the vaccine benefits and risks to your patients. You can find print-ready VIS at: www.cdc.gov/vaccines/hcp/vis/. You can find VIS translated into more than 40 languages on Immunization Action Coalition's website: www.immunize.org/vis/

Vaccine Adverse Event Reporting System (VAERS): The National Childhood Vaccine Injury Act (NCVIA) requires you to report certain adverse events that occur following vaccination. VAERS is a system for reporting those adverse events, as well as for analyzing data from those reports and making it available to the public. vaers.hhs.gov/

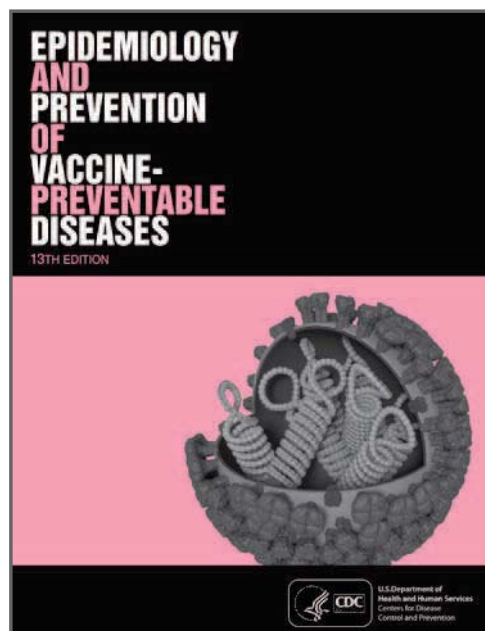
Epidemiology and Prevention of Vaccine-Preventable Diseases

(Pink Book): The Pink Book offers the most comprehensive information on vaccine-preventable diseases and recommendations for vaccine use.

www.cdc.gov/vaccines/pubs/pinkbook/index.html

You can order a hard copy of the book from Public Health Foundation.

bookstore.phf.org/store/ProductDetails.aspx?productId=27876



CDC Travel Vaccines: Visit CDC's travel vaccine web page to find out which vaccines your patients may need when traveling outside the United States.

wwwnc.cdc.gov/travel/destinations/list

You Call the Shots: You Call the Shots is a series of modules designed to provide training on vaccine recommendations, links to resource materials, and self-tests to assess learning.

www.cdc.gov/vaccines/ed/youcalltheshots.htm

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Nebraska State Immunization Information System (NESIIS)

Help Line

(888) 433-2510

Fax

(402) 471-6426

Website:

dhhs.nesiis@nebraska.gov

Vaccines for Children (VFC) Program Patient Eligibility Screening Record

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for 3 years or longer depending on state law. The record may be completed by the parent, guardian, individual of record, or by the health care provider. VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine. Providers using a similar form (paper-based or electronic) must capture all reporting elements included in this form.

1. Child's Name : _____
Last Name First Name MI

2. Child's Date of Birth: ___/___/_____

3. Parent/Guardian/Individual of Record: _____
Last Name First Name MI

4. Primary Provider's Name: _____
Last Name First Name MI

5. To determine if a child (0 through 18 years of age) is eligible to receive federal vaccine through the VFC and state programs, at each immunization encounter/visit enter the date and mark the appropriate eligibility category. *If Column A-D is marked, the child is eligible for the VFC program. If column E, F or G is marked the child is not eligible for federal VFC vaccine.*

	Eligible for VFC Vaccine				Not eligible for VFC Vaccine		
	A	B	C	D	E	F	G
Date	Medicaid Enrolled	No Health Insurance	American Indian or Alaskan Native	*Underinsured served by FQHC, RHC or deputized provider	Has health insurance that covers vaccines	**Other underinsured	***Enrolled in CHIP

**Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance. In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.*

*** Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.*

****Children enrolled in separate state Children's Health Insurance Program (CHIP). These children are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.*

Instructions for the Use of Vaccine Information Statements

Required Use

1. Provide a Vaccine Information Statement (VIS) when a vaccination is given.

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer, to any child or adult, any of the following vaccines — diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis A, hepatitis B, *Haemophilus influenzae* type b (Hib), influenza, pneumococcal conjugate, meningococcal, rotavirus, human papillomavirus (HPV), or varicella (chickenpox) — shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition vaccine information materials that have been produced by the Centers for Disease Control and Prevention (CDC):

- to the parent or legal representative¹ of any child to whom the provider intends to administer such vaccine, or
- to any adult² to whom the provider intends to administer such vaccine.

If there is not a single VIS for a combination vaccine, use the VISs for all component vaccines.

VISs should be supplemented with visual presentations or oral explanations as appropriate.

¹ “Legal representative” is defined as a parent or other individual who is qualified under State law to consent to the immunization of a minor child or incompetent adult.

² In the case of an incompetent adult, relevant VISs shall be provided to the individual’s legal representative. If the incompetent adult is living in a long-term care facility, all relevant VISs may be provided at the time of admission, or at the time of consent if later than admission, rather than prior to each vaccination.

2. Record information for each VIS provided.

Health care providers shall make a notation in each patient’s permanent medical record at the time vaccine information materials are provided, indicating:

- (1) the edition date of the Vaccine Information Statement distributed, and
- (2) the date the VIS was provided.

This recordkeeping requirement supplements the requirement of 42 U.S.C. §300aa-25 that all health care providers administering these vaccines must record in the patient’s permanent medical record (or in a permanent office log):

- (3) the name, address and title of the individual who administers the vaccine,
- (4) the date of administration, and
- (5) the vaccine manufacturer and lot number of the vaccine used.

Applicability of State Law

Health care providers should consult their legal counsel to determine additional State requirements pertaining to immunization. The Federal requirement to provide the vaccine information materials supplements any applicable State laws.

Availability of Copies

Copies are available in English and many other languages from CDC’s website at www.cdc.gov/vaccines/pubs/vis. Single camera-ready copies may also be available from State health departments.

Current VIS Editions

DTaP/DT: 5/17/07	Meningococcal: 10/14/11 [†]
Hib: 4/2/15	Pneumococcal (PCV13): 2/27/13 [†]
Hepatitis A: 10/25/11 [†]	Polio: 11/8/11 [†]
Hepatitis B: 2/2/12 [†]	Rotavirus: 4/15/15
HPV (Cervarix): 5/3/11 [†]	Td: 2/24/15
HPV (Gardasil): 5/17/13 [†]	Tdap: 2/24/15
HPV (Gardasil-9): 4/15/15 [†]	Varicella: 3/13/08 [†]
Influenza (inactivated): 8/19/14 [†]	Multi-Vaccine*: 10/22/14 [†]
Influenza (live): 8/19/14 [†]	
MMR: 4/20/12 [†]	
MMRV: 5/21/10 [†]	

*An optional alternative when two or more routine childhood vaccines (i.e., DTaP, hepatitis B, Hib, pneumococcal, or polio) are administered at the same visit.

[†]Interim

Reference 42 U.S.C. §300aa-26
April 15, 2015



Day	ID (initials or name or ID # etc.)	AGE	Vaccines/Status																								
			Medicaid (VFC)	No INS (VFC)	AI/AN (VFC)	*Underinsured (VFC)	INS (give private stock)	Rota Teq	Pediarix (DTaP, IPV, Hep B)	ActHIB	Prevnar 13	Hep A	MMR	Varicella	Kinrix	Tdap	Gardasil 9	Meningococcal (ACWY)	Meningococcal (Serogroup B)	Hep B	DTaP	IPOL	Flu Mist	Flu Shot			
2nd	J.D.	17	1												1	1	1	1									
3rd	A.B.	0		1				1	1	1	1																
7th	R.M.	5			1							1	1	1													
<p><u>This is a sample line listing.</u></p> <p>Please contact your Community Health Nurse or the NDHHS Immunization Program if you would like an electronic version that can be individualized for your clinic based on what vaccines brands you offer and if you are an FQHC, RHC, or deputized provider who can</p>																											
			TOTALS →			1	1	1	0	0	1	1	1	1	0	1	1	1	1	1	1	0	0	0	0	0	

RETURNED & WASTED VACCINE PROCESS

**EXPIRED
VACCINE
(UNOPENED)**



NESIIS
Check inventory, vaccine may be under expired tab.



NESIIS
Modify the QOH for doses previously administered as needed.



NESIIS
Print Transaction Summary for date after expiration choosing Doses Returned option.



Send in Returned Report with unopened expired or spoiled vaccine.

*** SPOILED *
VACCINE
(UNOPENED)**



NESIIS
Modify the QOH for doses previously administered as needed.



NESIIS
Modify the QOH for doses returned under manage inventory.



NESIIS
Print Transaction Summary choosing Doses Returned option.



Send in Returned Report with unopened expired or spoiled vaccine.

**** WASTED **
VACCINE
(OPENED SINGLE DOSES)**



NESIIS
Modify the QOH for doses wasted under manage inventory.



NESIIS
Print Transaction Summary choosing Doses Wasted option.



Send in Wasted Report at the end of the month with the monthly Transaction Summary report.

**** WASTED **
VACCINE
(OPENED MULTI-DOSE VIALS)**



NESIIS
Check inventory, vaccine may be under expired tab.



NESIIS
Modify the QOH for doses previously administered as needed.



NESIIS
Modify the QOH for doses wasted.



NESIIS
Print Transaction Summary choosing Doses Wasted option.



Send in Wasted Report at the end of the month with the monthly Transaction Summary report.

QOH = Quantity on Hand

* Spoiled vaccines are non-viable vaccines that have not reached the expiration date, such as a vaccine involved in a temperature excursion. *

** Wasted vaccines are vaccines that can not be returned such as the vial or syringe has been uncapped, or opened multi-dose vials that have expired or spoiled. **

Facility Name: _____

Pin #: _____

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7 Other or 13 Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4	Short-dated VFC dose was exchanged with private dose	11
Accidental use of VFC dose for a private patient	5	Accidental use of a Private dose for a VFC eligible patient	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6	Other – Describe:	13 Other
Other – Describe:	7 Other		

WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and submitted to the NDHHS Immunization Program once doses are replaced within a month from the borrowing instance. Email to DHHS.Immunization@nebraska.gov or fax to 402-471-6426.

Facility Name: _____

Pin #: _____

VACCINE BORROWING REPORT

Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): ___/___/___ to ___/___/___

VACCINE BORROWING REPORT TABLE

A Vaccine Type Borrowed	B Stock Used (VFC or Private)	C Patient Name	D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate Vaccine Stock was not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name:	Provider Signature:	Date:
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WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and submitted to the NDHHS Immunization Program once doses are replaced within a month from the borrowing instance. Email to DHHS.Immunization@nebraska.gov or fax to 402-471-6426.

REFRIGERATOR

FREEZER

35-46°F														≤5°F					When temps are out of range					
Day of Month	Time	Staff Initials	min	max		35	36	37	38	39	40	41	42	43	44	45	46	min		max		5	4	3≤
1			am																					
1			pm																					
2			am																					
2			pm																					
3			am																					
3			pm																					
4			am																					
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30			pm																					
31			am																					
31			pm																					

Temperature is too low! Document corrective actions to the right

Temperature is too high! Document corrective actions to the right

Temperature is too high! Document corrective actions to the right

- When temps are out of range
1. Put vaccines in proper storage conditions.
 2. Call NE Imm. Program at 402-471-6423.
 3. Call vaccine manufacturers to determine if vaccine was affected. Request documentation regarding vaccine viability.
 4. Document actions below. Actions for out of range temps (date, temp, action)

CHECKLIST FOR CERTIFICATE OF CALIBRATION/VALIDATION/TESTING REPORTS







A

If Certificate Identifies an Accredited Laboratory:



- ILAC/MRA Signatory body accredited Laboratory**

The Following Table lists the accredited laboratories

A2LA	L-A-B	ACLASS	IAS	PJLA	NVLAP
					

AND

- Name of Device (Optional)**
 - Model Number**
 - Serial Number**
 - Date of Calibration (Report or Issue Date)**
 - Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))**
-

B

If Certificate Does Not Identify an Accredited Laboratory:

- Name of Device (Optional)**
- Model Number**
- Serial Number**
- Date of calibration testing (Report or Issue Date)**
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/- 1F (0.5C))**
- Statement that calibration testing conforms to ISO 17025***

Vaccine Manufacturer Contact Information

Manufacturer/Website	Phone Number	Products (VFC & AIP vaccines)
<p>GlaxoSmithKline (GSK) www.gskvaccines.com</p>	<p>866-475-8222</p>	<p>BEXSERO® BOOSTRIX® ENGERIX-B® FLUARIX® FLULAVAL® HAVRIX® INFANRIX® KINRIX® MENHIBRIX® MENVEO® PEDIARIX® ROTARIX® TWINRIX®</p>
<p>Merck www.merckvaccines.com</p>	<p>800-637-2590</p>	<p>GARDASIL® GARDASIL®9 M-M-R®II PedvaxHIB® PNEUMOVAX®23 ProQuad® RECOMBIVAX HB® RotaTeq® VAQTA® VARIVAX® ZOSTAVAX®</p>
<p>MedImmune www.medimmune.com</p>	<p>877-633-4411</p>	<p>FluMist® Quadrivalent</p>
<p>Pfizer www.pfizerpro.com</p>	<p>800-438-1985</p>	<p>PREVNAR 13® Trumenba®</p>
<p>Sanofi Pasteur www.vaccineshoppe.com</p>	<p>800-822-2463</p>	<p>ActHIB® Adacel® DAPTACEL® DT Fluzone® IPOL® Menactra® Menomune® Pentacel® TENIVAC®</p>

Vaccine Storage Troubleshooting Record (check one) Refrigerator Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event <small>If multiple, related events occurred, see Description of Event below.</small>	Storage Unit Temperature <small>at the time the problem was discovered</small>		Room Temperature <small>at the time the problem was discovered</small>	Person Completing Report	
<small>When recording temperatures, indicate F (Fahrenheit) or C (Celsius).</small>					
Date:	Temp when discovered:		Temp when discovered:	Name:	
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title:	Date:
<p>Description of Event <i>(If multiple, related events occurred, list each date, time, and length of time out of storage.)</i></p> <ul style="list-style-type: none"> • General description (i.e., what happened?) • Estimated length of time between event and last documented reading of storage temperature in acceptable range (35° to 46°F [2° to 8°C] for refrigerator; -58° to 5°F [-50° to -15°C] for freezer) • Inventory of affected vaccines, including (1) lot #s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record) • At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer? • Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine? • Include any other information you feel might be relevant to understanding the event. 					
<p>Action Taken <i>(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)</i></p> <ul style="list-style-type: none"> • When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it “do not use” until after you can discuss with your state/local health department and/or the manufacturer[s].) • Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.) • IMPORTANT: What did you do to prevent a similar problem from occurring in the future? 					
<p>Results</p> <ul style="list-style-type: none"> • What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.) 					

Emergency Vaccine Management Plan

Provider Site Name _____

Provider Site Address _____

Primary Vaccine Coordinator _____

Emergency Phone # _____

Back-up Vaccine Coordinator _____

Emergency Phone # _____

Transporting Vaccine

- ❖ In the event of a power failure, vaccine will need to be moved to a pre-designated location. This procedure is for use in an emergency situation not routine transport.
- ❖ **See pages 33-36 of this 2016 Nebraska Immunization Program Provider Manual**
- ❖ Have coolers, frozen water bottles/frozen cold packs, bubble wrap, cardboard, and flashlights on hand
- ❖ All refrigerated vaccines can be transported in a cooler
 - Layer **conditioned** frozen water bottles or **conditioned** cold packs on bottom, then cardboard sheet, then bubble wrap then vaccine and a thermometer, then bubble wrap, then cardboard sheet, and top with **conditioned** frozen water bottles or **conditioned** cold packs. Be careful not to freeze vaccine!
 - Keep temperature between 35°F (2°C) and 46°F (8°C)
- ❖ Varicella and MMRV (ProQuad) need to be transferred on frozen cold packs with a thermometer and topped with frozen cold packs. MMR can be transported frozen.
 - Keep temperatures between -58° F (-50°C) and +5° F (-15°C)
- ❖ Once vaccine is transported to alternate refrigeration and freezer units keep vaccines at the proper temperatures

The back-up refrigerator and/or freezer unit is located at: _____

Phone number of alternate facility: _____

Signature of Primary Vaccine Coordinator: _____

* This plan must be initialed and updated annually

___/___/2016	___/___/2017	___/___/2018	___/___/2019
_____initials	_____initials	_____initials	_____initials

VACCINE TRANSPORT LOG: TEMPERATURE MONITORING

During Off-Site Clinics / Vaccine Transport

Acceptable Temps: 35° to 46° F or 2° to 8° C
5° or lower F or -15° or lower C

TEMPERATURES MUST BE DOCUMENTED EVERY HOUR WHILE VACCINE IS OUT OF MAIN STORAGE SITE

<u>Date</u>	<u>Time</u>	<u>REFRIGERATOR:</u> <u>Engel Cooler / Cooler</u> <u>Temperature</u>	<u>FREEZER:</u> <u>Engel Cooler /</u> <u>Cooler</u> <u>Temperature</u>	<u>Initials</u>	<u>Comments</u>

Initials & Signature: _____

Initials & Signature: _____

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies



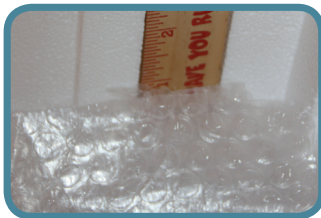
Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.



Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.



Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.



Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**



U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Distributed by

Visit www.cdc.gov/vaccines/SandH
for more information, or your state
health department.

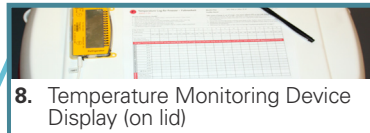
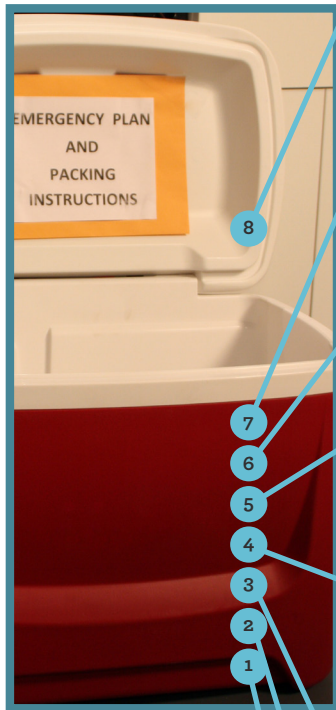
CS249275-I August 2015

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

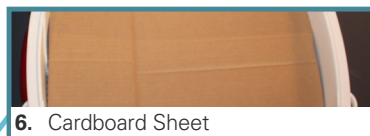
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.



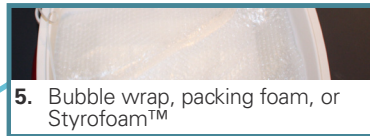
8. Temperature Monitoring Device Display (on lid)



7. Conditioned Water Bottles



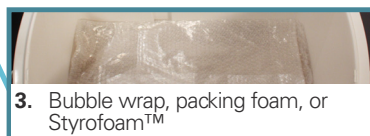
6. Cardboard Sheet



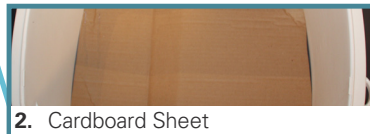
5. Bubble wrap, packing foam, or Styrofoam™



4. Vaccines, Diluents, and Temperature Monitoring Device Probe



3. Bubble wrap, packing foam, or Styrofoam™



2. Cardboard Sheet



1. Conditioned Water Bottles

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.

Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:

This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.