Vaccine Storage, Preparation, Administration, and Preventing Errors

National Adult Immunization and Influenza Summit

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Disclosures

- JoEllen Wolicki is a federal government employee with no financial interest in or conflict with the manufacturer of any product named in this presentation.
- I will not discuss any off-label uses for vaccines.
- The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.
- The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention or ATSDR.
Vaccine Administration Error

- Any preventable event that may cause or lead to inappropriate medication use or patient harm.
  Possible consequences include:
  - Inadequate immunological protection
  - Injury to the patient
  - Cost
  - Inconvenience
  - Reduced confidence in the health care delivery system

It is critical that ALL healthcare personnel take preventive actions to avoid vaccine administration errors.
Take preventive actions to avoid vaccine administration errors and establish an environment that values reporting and investigating errors and “near misses” as part of risk management and quality improvement.

Preventing Medication Errors

- The National Academy of Medicine recommends implementing proven medication safety practices:
  - Reducing reliance on memory
  - Standardization
  - Protocols and checklists
  - Monitoring error frequencies and correcting system problems associated with errors
Integrate storage, preparation, and administration best practices into your policies and procedures.

Common Vaccine Administration Errors

- Improper Storage
- Scheduling Errors
- Incorrect Preparation
- Administration Errors
- Wrong Patient
- Documentation Errors
Common Vaccine Administration Errors

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Store Vaccines at Proper Temperatures

Vaccines must be stored within the temperature range specified by the manufacturer.

**Ultracold** between -90°C and -60°C (-130°F and -76°F)

**Frozen** between -50°C and -15°C (-58°F and +5°F)

**Refrigerated** between 2°C and 8°C (36°F and 46°F)

The only way to know the temperature vaccines are exposed to is to measure and monitor it with a temperature monitor device.

Vaccines Storage and Handling Toolkit | CDC
### Equipment: Storing Vaccines

- Purpose-built units are recommended
- Household-grade units can be an acceptable alternative for refrigerated vaccines

**NEVER store any vaccine in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances.**

### Off-Site Facility or Temporary Clinic

- **Vaccine** that will be used at an off-site or satellite facility should be delivered directly to that facility.
- If delivery direct to the site is not possible, vaccine can be transported in a stable storage unit. CDC recommends:
  - Portable vaccine storage unit, such as a portable refrigerator unit
  - Qualified container and packout
- The total time for transport or transport + clinic workday should not exceed 8 hours unless guidance from the manufacturer differs.

**NEVER store any vaccine in a dormitory- or bar-style refrigerator + freezer unit under any circumstances.**
Temperature Monitoring Equipment

- Every vaccine storage unit and transport unit must have a temperature monitoring device.
- CDC recommends using a digital data logger (DDL) with:
  - Detachable buffered probe to best reflect vaccine temperatures
    › Probe buffered with glycol, glass beads, sand, or Teflon®
  - Alarm for out-of-range temperatures
  - Low-battery indicator*
  - Current, minimum, and maximum temperature display
  - Recommended uncertainty of +/-0.5° C (+/-1° F)
  - Temperature logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes
- DDL should have a Certificate of Calibration Testing.

Temperature Monitoring

- Check and record storage unit minimum and maximum temperatures at the start of each workday.
  - If the DDL does not read minimum/maximum temperatures, check and record the current temperature at least at the start and end of each workday.
- Record on temperature log:
  - Minimum/maximum temperature or current temperature
  - Date and Time
  - Name of person who logged the temperature
  - Any actions taken if a temperature excursion occurred

Temperature logs are available at
Off-Site Facility or Temporary Clinic

- Immediately upon arrival at the destination, place vaccines in an appropriate storage unit with a temperature monitoring device.
- If vaccines cannot be stored in an on-site storage unit, keep them in the portable vaccine storage unit.
- Use a transport temperature monitoring log to document temperatures:
  - At start and end of transport.
  - During clinic:
    › If using a DDL that records minimum/maximum temperatures, check and record temperatures each time the portable vaccine storage unit is opened.
    › If the TMD measures current temperatures only, place the probe as close as possible to the vaccines, and check and record temperatures hourly.
  - Keep the container closed as much as possible.

Common Vaccine Administration Errors

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Preparing Vaccines

- Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed.
- Follow strict aseptic medication preparation practices.
- Avoid distractions. Some facilities have a no-interruption zone, where health care professionals can prepare medications without interruptions.
- Prepare medications for one patient at a time.
- Always follow the vaccine manufacturer’s directions, located in the package inserts.

Expiration Date

- All products have an expiration date
- The expiration date is the final day that the vaccine can be administered
- Determined by the manufacturer
- Guarantees full potency and safety

Expiration Dates - Questions and Answers | FDA
Vaccines Storage and Handling Toolkit | CDC
Where to Find the Expiration Date

- Month, day, and year of expiration
- Month and year of manufacture
- QR Code, website, or phone number
- Month and year of expiration

Vaccines Storage and Handling Toolkit | CDC
Where to Find the Expiration Date

Month, day, and year of expiration

Month and year of manufacture

QR Code, website, or phone number

Month and year of expiration

Where to Find the Expiration Date

Exp 09/30/2023 12/2021

12/2021

Exp 12/2023

Exp 09/30/2023

12/2021

Exp 12/2023
**Where to Find the Expiration Date**

- Month, day, and year of expiration
- Month and year of manufacture
- QR Code, website, or phone number
- Month and year of expiration

**CDC recommends:**

- Checking vaccine expiration dates weekly
- Rotating vaccines so those with the earliest expiration dates are in the front of the storage unit. Use these first.
- Removing expired vaccines/diluents from storage units and areas where viable vaccines are stored.

**NEVER use expired vaccine or diluent!**
What is a Beyond-Use Date/Time (BUD)?

- BUD date or time is generated when a product is
  - Transitioned between storage states.
  - Altered for patient use.
- BUD period is set by the provider.
- BUD replaces but *does not extend* the expiration. Always use the earlier date or time.
- Only some vaccines have a BUD.

How is the BUD Calculated?

- The designated timeframe varies from product to product.
- Consult the vaccine’s package insert or Emergency Use Authorization (EUA) Fact Sheet for specific information about the BUD and instructions for calculating it.
## How is the BUD Calculated?

<table>
<thead>
<tr>
<th>December 2022</th>
<th>January 2023</th>
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<tr>
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<td>25 26 27 28</td>
<td>26 27 28</td>
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<tr>
<td>29 30 31</td>
<td>30 31</td>
</tr>
</tbody>
</table>

**Day 0: Punctured vial**

**Day 28: From puncture**

Never use vaccine after the beyond-use date/time!
Common Vaccine Administration Errors

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- Documentation Errors

Wrong Patient

- Verify the patient’s identity before administering vaccines.
- Educate staff on the importance of avoiding unnecessary distractions or interruptions when staff is administering vaccine.
- Prepare and administer vaccines to one patient at a time.
- If more than one patient needs vaccines during the same clinical encounter (e.g., parent with two children), assign different providers to each patient, if possible. *Alternatively, bring only one patient’s vaccines into the treatment area at a time, labeled with vaccine and patient name.*
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Scheduling Errors

- For children, especially infants, schedule immunization visits after the birthday.
Preventing Scheduling Errors

- Create procedures to obtain a complete vaccination history using the immunization information system (IIS), previous medical records, and personal vaccination records.
- Use standing orders, if possible.
- Post reference sheets for timing and spacing in your medication preparation area.
- CDC has vaccine catch-up guidance for DTaP, Tdap, Hib, PCV13, and polio vaccines to help health care personnel interpret the catch-up schedule for children.

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Knowledgeable staff is critical! Integrate vaccine administration training into orientation and other appropriate education requirements.

Strategies to Prevent Vaccination Errors: Knowledgeable Staff

- Before administering vaccines, all personnel who will administer vaccines should:
  - Receive competency-based training
  - Have knowledge and skills validated

- Integrate competency-based training into:
  - New staff orientation
  - Annual education requirements

Skills Checklist for Vaccine Administration [immunize.org]
COVID-19 Vaccine: Vaccine Administration Competencies Assessment Form-February 28, 2021 [cdc.gov]
In addition...

- Vaccines must reach the desired tissue to provide an optimal immune response and reduce the likelihood of injection-site reactions.
- A supply of needles should be available in varying lengths appropriate for the facility's patient population.
- Clinical judgment should be used when selecting needle length. Needle selection should be based on the:
  - Route of administration
  - Patient age
  - Gender and weight (for adults age 19 years or older)
  - Injection site
  - Injection technique

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Preventing Documentation Errors

- Do not use error-prone abbreviations to document vaccine administration. *For example, use NAS to document the intranasal route*—not IN, *which is easily confused with IM*.

- Use ACIP vaccine abbreviations.

- Change the appearance of look-alike names or generic abbreviations on computer screens, if possible.

Vaccination Resources for Healthcare Providers
CDC Vaccination Resources for Healthcare Providers

- Clinical Materials and Training Programs
- Schedules App
- Pneumococcal Vaccination App
- Pneumococcal Vaccine Timing for Adults
- Vaccine Catch-Up Guidance
- Storage and Handling Toolkit

Immunization Education & Training

- You Call The Shots
- Current Issues in Immunization Webinar (CIW)
- Immunization Courses
- Continuing Education
- Immunization MnMfa
- Pink Book Webinars
- Patient Education
- Provider Education Resources
- Quality Improvement Projects
- Workforce Improvement Projects

Related Link

- Vaccines & Immunizations
- ACS
- ACOI Recommendations
- Schedules

COVID-19 Vaccination Training Programs & Reference Materials

- Find a list of immunization training and educational materials, including tests and COVID-19 vaccine specific information.

You Call The Shots

Series of modules that explain the latest recommendations for vaccine use that include self-test practice questions.

Current Issues in Immunization

NetConference (CNCC)

Live. 1-hour presentations via conference call including question and answer session.

Immunization Courses

Webcasts and self-study education and training programs for healthcare personnel

Patient Education

Educational materials that complement personal education and advice for patients

CE Credit for Immunization Courses

A guide and video show how to obtain continuing education credit or print a certificate of attendance.

Quality Improvement Projects

Resources for providers seeking quality improvement projects that may be required for maintenance of certification.

Pink Book Webinar Series

1-hour webinars that explore the chapters of the Epidemiology and Prevention of Vaccine-Preventable Diseases (Vaccine Rates 

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Vaccines and Preventable Diseases

**PneumoReccs VaxAdvisor Mobile App for Vaccine Providers**

The PneumoReccs VaxAdvisor mobile app was updated on February 9, 2022, to reflect CDC's new adult pneumococcal vaccination recommendations.

Users simply:
- Enter a patient's age.
- Note if the patient has specific underlying medical conditions.
- Answer questions about the patient's pneumococcal vaccination history.

Then the app provides patient-specific guidance consistent with the immunization schedule recommended by the U.S. Advisory Committee on Immunization Practices (ACIP).

**Download the App Today**

Download PneumoReccs VaxAdvisor for free:
- [iOS device]
Pneumococcal Vaccine Timing for Adults

Make sure your patients are up to date with pneumococcal vaccination.

Adults ≥65 years old
Complete pneumococcal vaccine schedules

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Option A</th>
<th>Option B</th>
</tr>
</thead>
<tbody>
<tr>
<td>None*</td>
<td>PCV20</td>
<td>PCV15 ≥1 year†</td>
</tr>
<tr>
<td>PPSV23 only at any age</td>
<td>≥1 year → PCV20</td>
<td>≥1 year → PCV15</td>
</tr>
<tr>
<td>PCV13 only at any age</td>
<td>≥1 year → PCV20</td>
<td>≥1 year† → PPSV23</td>
</tr>
<tr>
<td>PCV13 at any age &amp; PPSV23 at &lt;65 yrs</td>
<td>≥5 years → PCV20</td>
<td>≥5 years† → PPSV23</td>
</tr>
</tbody>
</table>

* Also applies to people who received PCV7 at any age and no other pneumococcal vaccines
† Consider minimum interval (8 weeks) for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak (CSF) leak
‡ For adults with an immunocompromising condition, cochlear implant, or CSF leak, the minimum interval for PPSV23 is ≥8 weeks since last PCV13 dose and ≥5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥1 year since last PCV13 dose and ≥5 years since last PPSV23 dose

Shared clinical decision-making for those who already completed the series with PCV13 and PPSV23

<table>
<thead>
<tr>
<th>Prior vaccines</th>
<th>Shared clinical decision-making option</th>
</tr>
</thead>
</table>
| Complete series: PCV13 at any age & PPSV23 at ≥65 yrs | ≥5 years → PCV20 Together, with the patient, vaccine providers may choose to administer PCV20 to adults ≥65 years old who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 years old.

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Vaccine Catch-Up Guidance

CDC has developed catch-up guidance tools to assist healthcare providers in interpreting Table 2 in the child and adolescent immunization schedule.

- Pneumococcal Conjugate Vaccine (PCV) Catch-Up Guidance for Children 4 Months through 4 Years of Age. [3 pages]
- Haemophilus influenzae type b-Containing Vaccines Catch-Up Guidance for Children 4 Months through 4 Years of Age
  - Hib vaccine products: ActHIB, Pentacel, Hiberix, or unknown. [3 pages]
  - Hib vaccine products: PedsivaxHIB vaccine only [2 pages]
- Diphtheria-, Tetanus-, and Pertussis-Containing Vaccines Catch-Up Guidance for Children 4 Months through 6 Years of Age. [2 pages]
- Inactivated Polio Vaccine (IPV) [2 pages]
- Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines Catch-Up Guidance for Children 7 through 9 Years of Age. [2 pages]
- Tetanus-, Diphtheria-, and Pertussis-Containing Vaccines Catch-Up Guidance for Children 10 through 18 Years of Age. [2 pages]

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Vaccine Storage and Handling Toolkit

COVID-19 Vaccination Provider Requirements

The Vaccine Storage and Handling Toolkit has been updated with a COVID-19 Vaccine Addendum with information on Storage and Handling best practices for COVID-19 vaccines. All vaccination providers participating in the COVID-19 Vaccination Program must store and handle COVID-19 vaccines under proper conditions to maintain the cold chain as outlined in the toolkit and addendum.

This addendum will be updated with specific storage and handling information for each COVID-19 product. Please sign up for email alerts on this page to be notified when updates are made or check this website often.

For more information about COVID-19 vaccination provider requirements and resources on enrollment, ordering, and data in support of vaccination visit COVID-19 Vaccination Provider Requirements and Support | CDC

The 2021 Vaccine Storage and Handling Toolkit is a comprehensive guide that reflects best practices for vaccine storage and handling from Advisory Committee on Immunization Practices (ACIP) recommendations, product information from vaccine manufacturers, and scientific studies.

The toolkit has been updated for 2021 to clarify language including:

- Beyond use date (BUD)
- Routine maintenance for vaccine storage units
- New definition added to the glossary
- COVID-19 vaccine information
E-Mail Services and Websites

- Questions? E-mail CDC [nipinfo@cdc.gov](mailto:nipinfo@cdc.gov) or [CDC INFO | CDC](http://www.cdc.gov/cdcinfo/cdcinfo.html)
- Vaccines and Immunizations website [Vaccines and Immunizations | CDC](http://www.cdc.gov/vaccines/
- HCP education [Vaccines and Immunizations | CDC](http://www.cdc.gov/vaccines/
- Vaccinate with Confidence [COVID-19 Vaccine Confidence | CDC](http://www.cdc.gov/vaccines/
- Influenza [Influenza (Flu) | CDC](http://www.cdc.gov/influenza/
- Vaccine safety [Vaccine Information and Safety Studies | Vaccine Safety | CDC](http://www.cdc.gov/vaccine-safety/

Thank You!

Questions?

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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