Centers for Disease Control and Prevention

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

The National Academies Press

It is critical that ALL healthcare personnel take preventive actions to avoid vaccine administration errors.

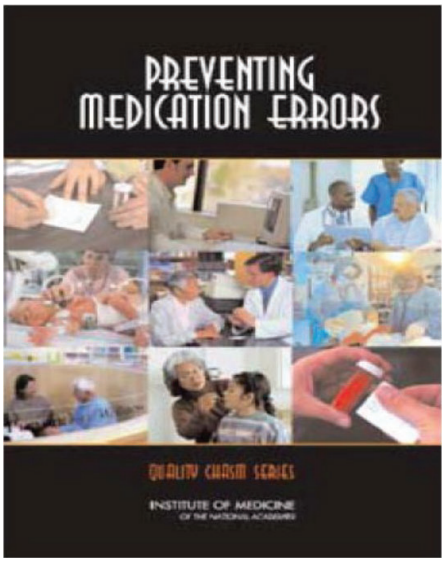
The National Academies Press

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.

The National Academies Press

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



The National Academies Press

Common Vaccine Administration Errors

- Improper Storage
- Scheduling Errors
- Incorrect Preparation
- Administration Errors
- Wrong Patient
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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)

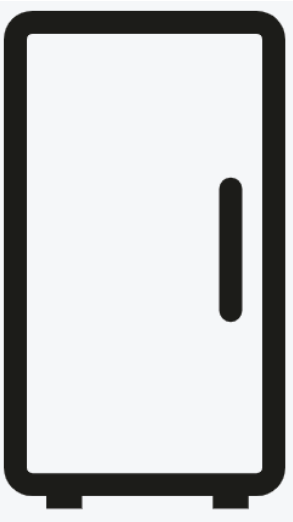
Frozen between
-50°C and -15°C
(-58°F and +5°F)

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.

Vaccines Storage and Handling Toolkit | CDC

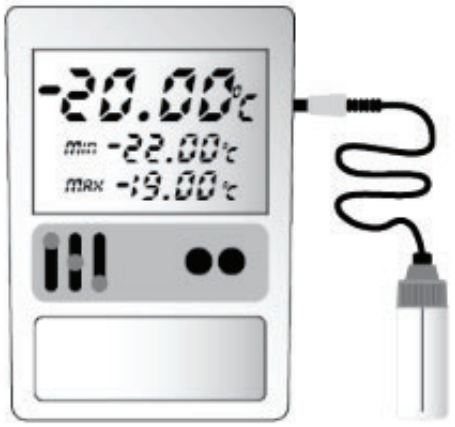
Off-Site Facility or Temporary Clinic

- 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 www.immunize.org and U.S. COVID-19 Vaccine Product Information | CDC

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.

Vaccines Storage and Handling Toolkit | CDC

CDC has a website dedicated to best practices for off-site clinics at Guidance for Planning Vaccination Clinics | CDC

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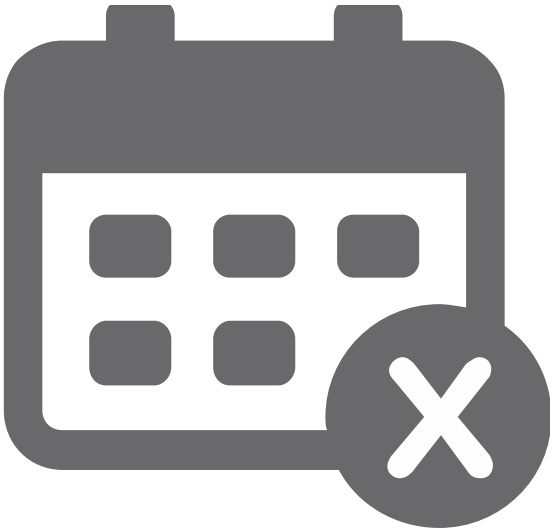
Preparing Vaccines

- 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.

Preparation infographics and videos are available at Storage unit temperature logs are available at CDC's Vaccine Administration Resource Library | CDC

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

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Vaccines Storage and Handling Toolkit | CDC

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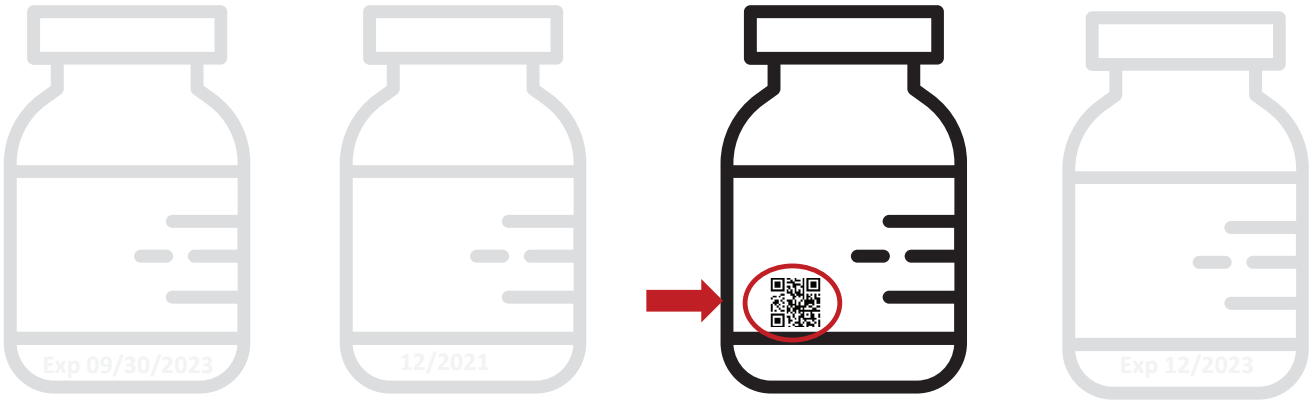

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Vaccines Storage and Handling Toolkit | CDC

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

NEVER use expired vaccine or diluent!

- 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.

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.

Vaccines Storage and Handling Toolkit | CDC)

CDC has BUD tracking labels for COVID-19 vaccines at U.S. COVID-19 Vaccine Product Information | CDC

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.

Vaccines Storage and Handling Toolkit | CDC

How is the BUD Calculated?

December 2022						
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	19	30	31

Day 0: Punctured vial

January 2023						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Day 28: From puncture

Vaccines Storage and Handling Toolkit | CDC

Common Vaccine Administration Errors

- Improper Storage
- Scheduling Errors
- Incorrect Preparation
- Administration Errors
- **Wrong Patient**
- 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.

Common Vaccine Administration Errors

Improper Storage

Scheduling Errors

Incorrect Preparation

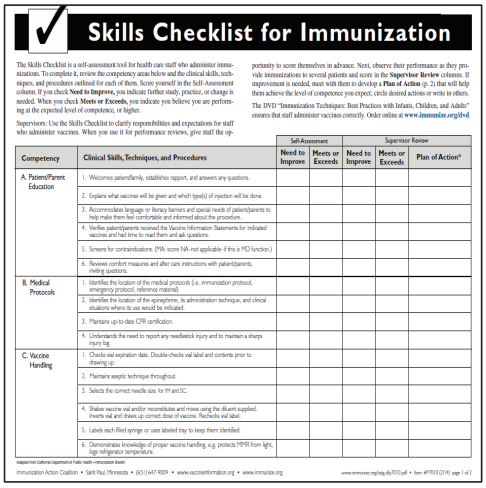
Administration Errors

Wrong Patient

Documentation Errors

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 Immunization

The Skills Checklist is a self-assessment tool for health care staff who administer immunizations. To complete it, review the competency areas below and the clinical skills, techniques, and procedures outlined for each of them. Score yourself in the Self-Assessment column. If you check **Need to Improve,** you indicate further study, practice, or change is needed. When you check **Meets or Exceeds,** you indicate you believe you are performing at the expected level of competence, or higher.

Supervisors: Use the Skills Checklist to clarify responsibilities and expectations for staff who administer vaccines. When you use it for performance reviews, give staff the opportunity to score themselves in advance. Next, observe their performance as they provide immunizations to several patients and score in the **Supervisor Review** columns. If improvement is needed, meet with them to develop a **Plan of Action** (p. 2) that will help them achieve the level of competence you expect; circle desired actions or write in others.

The DVD "Immunization Techniques: Best Practices with Infants, Children, and Adults" ensures that staff administer vaccines correctly. Order online at **www.immunize.org/ivd**

		Self-Assessment		Supervisor Review		
Competency	**Clinical Skills, Techniques, and Procedures**	**Need to Improve**	**Meets or Exceeds**	**Need to Improve**	**Meets or Exceeds**	**Plan of Action***
A. Patient/Parent Education	1. Welcomes patient/family, establishes rapport, and answers any questions.					
	2. Explains what vaccines will be given and which type(s) of injection will be done.					
	3. Accommodates language or literacy barriers and special needs of patient/parents to help make them feel comfortable and informed about the procedure.					
	4. Verifies patient/parents received the Vaccine Information Statements for indicated vaccines and had time to read them and ask questions.					
	5. Screens for contraindications. (MA: score NA-not applicable-if this is MD function.)					
	6. Reviews comfort measures and after care instructions with patient/parents, inviting questions.					
B. Medical Protocols	1. Identifies the location of the medical protocols (i.e. immunization protocol, emergency protocol, reference material).					
	2. Identifies the location of the epinephrine, its administration technique, and clinical situations where its use would be indicated.					
	3. Maintains up-to-date CPR certification.					
	4. Understands the need to report any needlestick injury and to maintain a sharps injury log.					
C. Vaccine Handling	1. Checks vial expiration date. Double-checks vial label and contents prior to drawing up.					
	2. Maintains aseptic technique throughout.					
	3. Selects the correct needle size for IM and SC.					
	4. Shakes vaccine vial and/or reconstitutes and mixes using the diluent supplied. Inverts vial and draws up correct dose of vaccine. Rechecks vial label.					
	5. Labels each filled syringe or uses labeled tray to keep them identified.					
	6. Demonstrates knowledge of proper vaccine handling, e.g. protects MMR from light, logs refrigerator temperature.					

Adapted from California Department of Public Health—Immunization Branch

Immunization Action Coalition • Saint Paul, Minnesota • (651) 647-9009 • www.vaccineinformation.org • www.immunize.org

www.immunize.org/catg.d/p7010.pdf • Item #P7010 (7/19) page 1 of 2

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

Common Vaccine Administration Errors

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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

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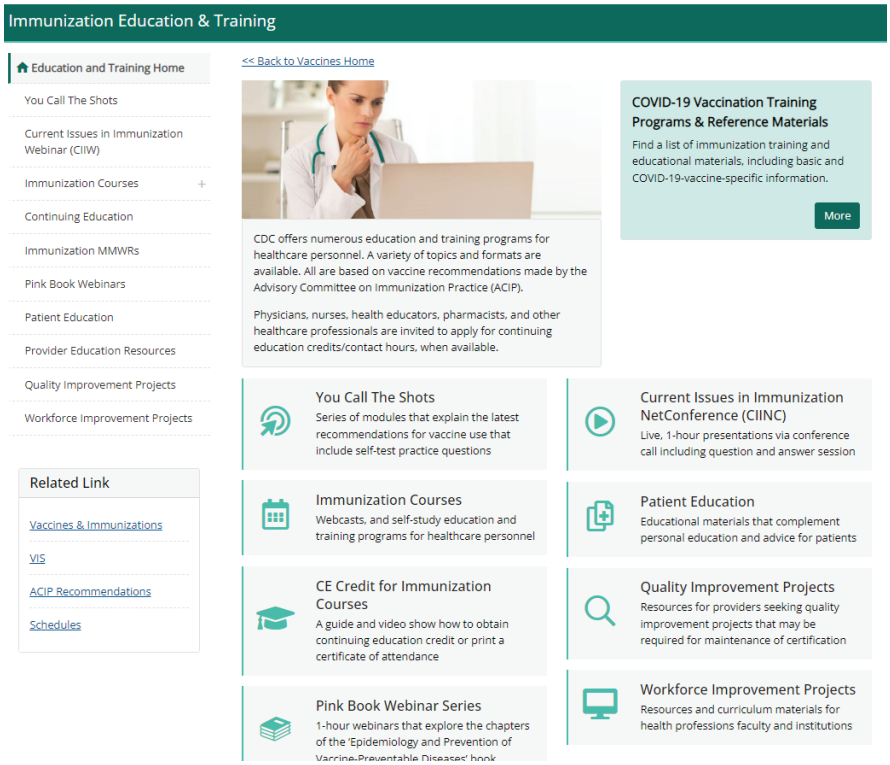

Vaccine Education and Training for Healthcare Professionals | CDC

CDC Vaccination Resources for Healthcare Providers

- Clinical Materials and Training Programs
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- Storage and Handling Toolkit

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CDC Vaccination Resources for Healthcare Providers

- Clinical Materials and Training Programs
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- **Pneumococcal Vaccination App**
- **Pneumococcal Vaccine Timing for Adults**
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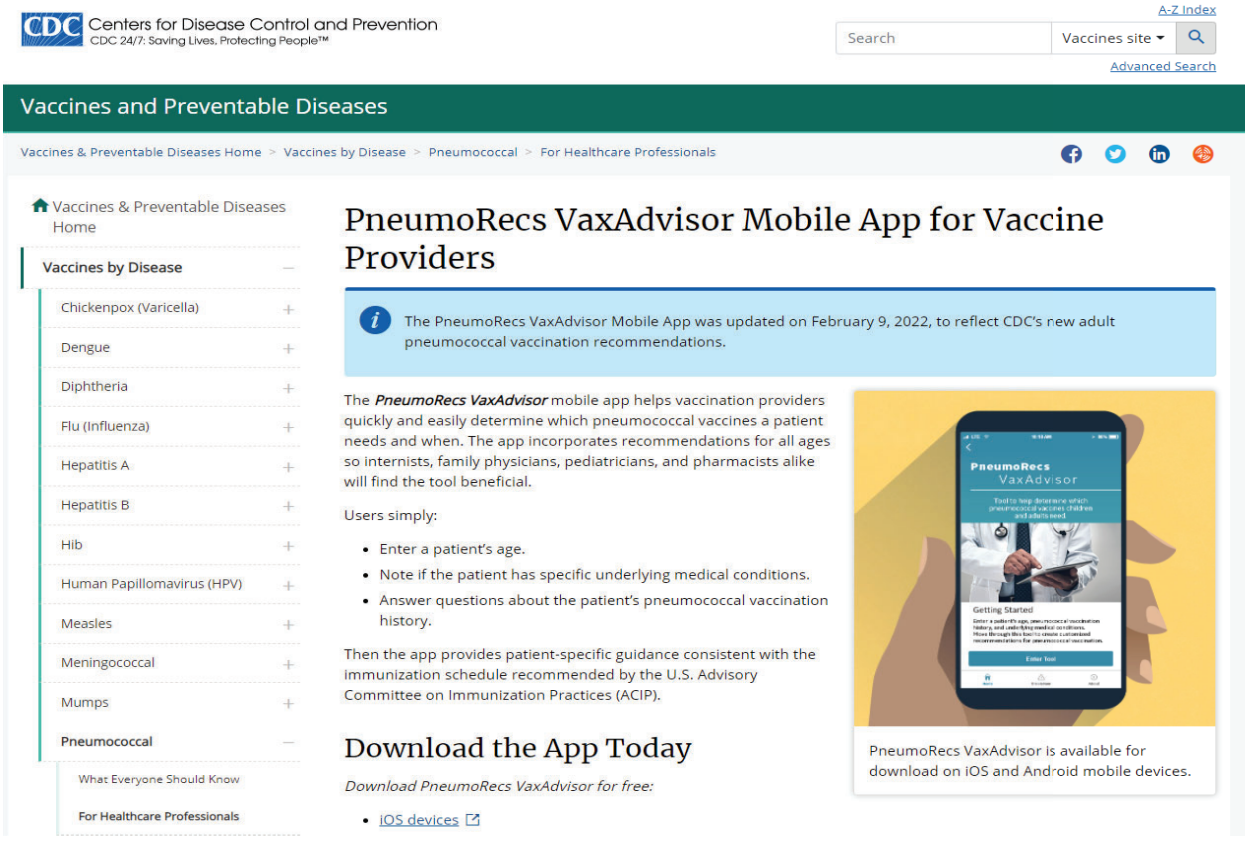

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Pneumococcal Vaccine Timing for Adults

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

Adults ≥65 years old
Complete pneumococcal vaccine schedules

Prior vaccines	Option A	Option B
None*	PCV20	PCV15 → ≥1 year† → PPSV23
PPSV23 only at any age	≥1 year → PCV20	≥1 year → PCV15
PCV13 only at any age	≥1 year → PCV20	≥1 year† → PPSV23
PCV13 at any age & **PPSV23** at <65 yrs	≥5 years → PCV20	≥5 years§ → PPSV23

* 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

Prior vaccines	Shared clinical decision-making option
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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CDC Vaccination Resources for Healthcare Providers

- Clinical Materials and Training Programs
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- **Vaccine Catch-Up Guidance**
- Storage and Handling Toolkit

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Vaccine Catch-Up Guidance

CDC has developed catch-up guidance job aids 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: PedvaxHIB 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

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CDC Vaccination Resources for Healthcare Providers

- Clinical Materials and Training Programs
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- Vaccine Catch-up guidance
- **Storage and Handling Toolkit**

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- Vaccine-Preventable Diseases

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

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Vaccine Storage and Handling Toolkit

Updated with COVID-19 Vaccine Storage and Handling Information
Addendum added September 29, 2021

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E-Mail Services and Websites

- Questions? E-mail CDC — nipinfo@cdc.gov or CDC INFO | CDC
- Vaccines and Immunizations website — Vaccines and Immunizations | CDC
- HCP education — Vaccines and Immunizations | CDC
- COVID-19 Vaccine clinical materials — U.S. COVID-19 Vaccine Product Information | CDC
- Vaccinate with Confidence — COVID-19 Vaccine Confidence | CDC
- Influenza — Influenza (Flu) | CDC
- Vaccine safety — Vaccine Information and Safety Studies | Vaccine Safety | CDC

Thank You!

Questions?

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.