COVID-19 Vaccinator
Training and Enrollment Refresher

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COVID-19 Vaccinator Training and Enrollment Refresher Slide Contents

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COVID-19 Vaccinator Training and Enrollment Refresher

- **This training and enrollment refresher is required for COVID-19 vaccination sites that registered with the Wisconsin Department of Health Services (DHS) prior to January 1, 2022.**
  - All staff who order, handle, and/or administer COVID-19 vaccines at vaccination sites registered with DHS prior to January 1, 2022 should complete this training refresher regimen, unless someone has recently completed the full list of COVID-19 training requirements within the last six months.
  - Complete the training refresher program by **watching this video** and **visiting the corresponding websites**. You can access the hyperlinks via the PDF copy of this slide deck that is in the invitation email sent to each location's primary and backup coordinator.
- **Please note**: Any new or existing staff who haven't completed the full list of COVID-19 training requirements **must** complete the full training process, rather than skipping to this training refresher.

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Attesting to Completing the Training Refresher

- Each location's primary and backup coordinators have received an email invitation to complete the COVID-19 Training and Enrollment Refresher attestation survey.
- The **survey is due within 30 days of receipt of the email invitation**. DHS will follow up if your location has not completed the survey before this deadline.
- Only **one** attestation survey submission is required on behalf of your location.

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Clinical Protocols and Administration Requirements

Review and follow the Centers for Disease Control and Prevention (CDC) Interim Clinical Considerations for the use of COVID-19 vaccines in the United States.

- Clinical Considerations should be reviewed on a regular basis.
- Within the webpage there are other relevant CDC and vaccination information links that all vaccination support staff should be familiar with.
- Do not distribute the information from the website in printed format, as content is frequently changing.

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Clinical Protocols and Administration Requirements

Appendices to the Interim Clinical Considerations

- Appendix A: Guidance for use of Janssen COVID-19 Vaccine
- Appendix B: People who received COVID-19 vaccine outside the United States
- Appendix C: People who received COVID-19 vaccine as part of a clinical trial
- Appendix D*: Vaccine administration errors and deviations
- Appendix E: Triage of people with a history of allergies or allergic reactions

*Please pay special attention to this appendix as it covers information that vaccinators frequently ask DHS about.

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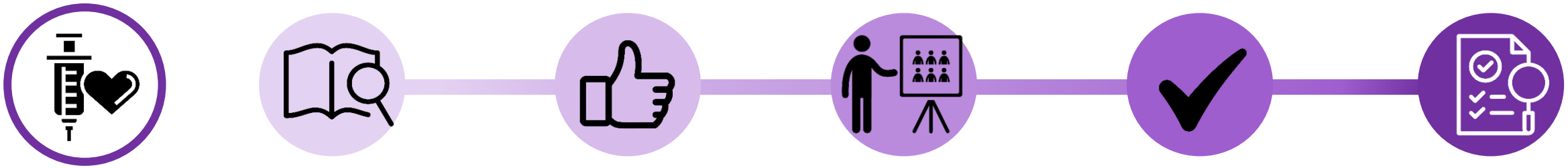
Clinical Protocols and Administration Requirements

Authorization Process for New Vaccine Use



New vaccine or use

VRBPAC* reviews clinical trial data

Official FDA authorization

ACIP** votes on recommendations

CDC director approval

CDC posts clinical considerations

Local health departments must wait for the Wisconsin Immunization Program Policy and Procedure Manual to be updated before they can administer the newly authorized vaccine. All other vaccinators can administer the newly authorized vaccine as soon as CDC posts the clinical considerations.

*VRBPAC = Vaccines and Related Biological Products Advisory Committee

**ACIP = Advisory Committee on Immunization Practices

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Clinical Protocols and Administration Requirements

- The Emergency Use Authorization (EUA) authority allows the Food and Drug Administration (FDA) to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear threats including infectious diseases, by facilitating the availability and use of medical countermeasures needed during public health emergencies.
- For additional information about COVID-19 vaccines, see the following FDA webpages:
  - COVID-19 Vaccines website
  - Emergency Use Authorization for Vaccines Explained
  - Infographic: The Path for a COVID-19 Vaccine From Research to Emergency Use Authorization (PDF, 723 KB)
  - Vaccine EUA Questions and Answers for Stakeholders
- *Recommended content*: Read on regarding the U.S. vaccine safety process or watch a five-minute video explaining the basics, if desired.

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Clinical Protocols and Administration Requirements

- Ask the following questions of the patient prior to administering COVID-19 vaccines:
  - How old are you?
  - Are you sick today?
  - Have you ever received a dose of the COVID-19 vaccine?
  - Do you have a health condition, or are you undergoing treatment that makes you moderately or severely immunocompromised? This includes, but is not limited to, cancer treatment, HIV, receipt of organ transplant, immunosuppressive therapy or high-dose corticosteroids, CAR-T-cell therapy, hematopoietic cell transplant (HCT), or moderate or severe primary immunodeficiency.
  - Have you received a COVID-19 vaccine before or during HCT or CAR-T cell therapies?
- Evaluate their responses and proceed with vaccine administration accordingly.

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Clinical Protocols and Administration Requirements

Know the 7 Rights of Vaccine Administration

1. The right patient
2. The right time
3. The right vaccine (and diluent)
4. The right dosage
5. The right route, needle, and technique
6. The right injection site
7. The right documentation

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Clinical Protocols and Administration Requirements

The Vaccine Adverse Event Reporting System VAERS is a passive reporting system. This means it relies on individuals to send in reports of their experiences. Anyone can submit a report to VAERS, including patients and their parents or caregivers.

Healthcare providers are **required by law** to report to VAERS:

- Any adverse event that occurs within the specified time period after vaccinations listed in the VAERS Table of Reportable Events Following Vaccination.
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine.

Healthcare providers are **strongly encouraged** to report to VAERS:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event.
- Vaccine administration errors.

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Vaccine Ordering Process and Best Practices

- Prior to ordering COVID-19 vaccine through the COVID-19 Vaccine Ordering Survey, providers should first check the Wisconsin COVID-19 Vaccine Exchange to see if another provider has vaccine to redistribute.
  - All providers are encouraged to offer and accept redistributed/unwanted doses, regardless of the probability of wastage.
  - Utilize the Vaccine Exchange if doses are needed on short notice.
  - Requesting vaccine through the Wisconsin COVID-19 Vaccine Exchange is the only way you can order doses in smaller increments than those provided by hubs or manufacturers.
- Ensure that other parties your location might exchange vaccine with have a Redistribution Form on file. DHS requires that all Wisconsin vaccinator organizations submit a Redistribution Form.

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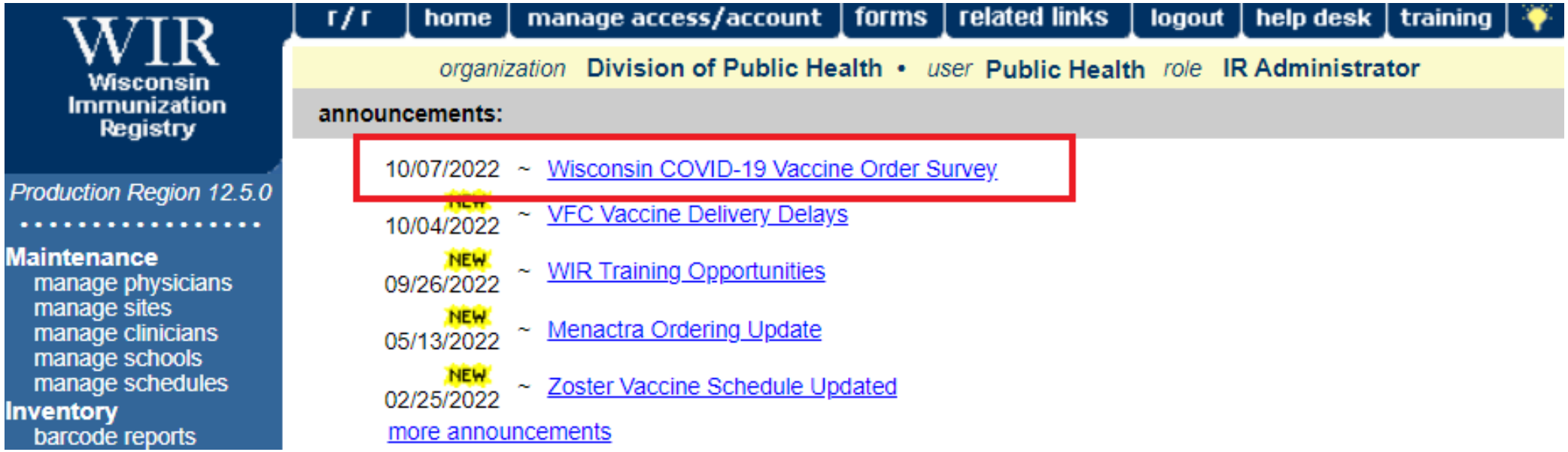
Vaccine Ordering Process and Best Practices

- Vaccination sites order COVID-19 vaccines through a survey.
- The link to the order survey can be found on the WIR **Announcements**, which is the first page shown after logging in:



Vaccine Ordering Process and Best Practices

- Direct ship order minimum: 100 doses for most vaccines.
  - Direct ship orders are processed weekly on Wednesdays.
  - Direct ship orders submitted after 12:00 p.m. on Tuesdays will be held and processed the following Wednesday.
- Hub order minimum: 30 doses.
  - Hubs process orders daily.
  - Providers can pick up emergency orders from a hub. Coordinate with your regional manager to arrange pickup.
- Whether a vaccine order gets shipped via hub delivery or direct ship depends on the vaccine type and the quantity ordered.

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Vaccine Ordering Process and Best Practices

- Make sure all contact and shipping information is current to avoid delays.
  - Keep COVID-19 Vaccinator Enrollment paperwork up-to-date, and ensure contacts and addresses are accurate in WIR.
  - Providers enrolled prior to January 1, 2022, can review and update registration responses on the Training and Enrollment Refresher Survey; personalized survey invitations are being sent vaccinators.
- Have one person submit orders to avoid duplication.
- If you submit an incorrect order, do not submit a duplicate order survey. Instead, email DHSCOVIDVaccinator@wi.gov to request a change.

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Vaccine Storage and Handling Requirements

- Digital data logger devices (DDL)
  - Each facility must obtain their own DDL for every cold storage unit being used to store COVID-19 vaccines.
  - On or around November 30, 2022, DDLs included with vaccine shipments will no longer work after the shipment is received. Shipment containers will no longer work for temporary storage.
- DDL devices should be placed in the center of the storage unit.
- Vaccinators must monitor and record temperatures daily using a temperature log.
  - The Immunization Action Coalition has developed a Temperature Monitoring Log and a Vaccine Storage Troubleshooting Record to support temperature monitoring and excursion activities.
  - Be ready to produce temperature monitoring logs upon your location's site visit.

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Vaccine Storage and Handling Requirements

- The CDC's Storage and Handling Toolkit provides a detailed overview of best practices and requirements to help safeguard the vaccine supply and ensure patients receive safe and effective COVID-19 vaccines.
- Food and beverages should **never** be stored in a cold storage unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them.
- Practice “first in/first out” inventory management for each product. Store older vaccines to the front of refrigerator or freezer units.
- **Never re-freeze thawed vaccine.**

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Vaccine Storage and Handling Requirements

- In some instances, vaccines must be used before the expiration date on the label.
- The beyond use date (BUD) is the date or time after which a vaccine should not be administered, stored, or transported. This date/time is outlined on the storage information in the vaccine manufacturer's storage and handling summary. See page 20 of the CDC's Storage and Handling Toolkit for details.
- The BUD replaces the manufacturer’s expiration date and should be noted on the label along with the initials of the person making the calculation. Examples of BUDs include:
  - Reconstituted vaccines have a limited period for use once the vaccine is mixed with diluent. Do not add diluent in until ready for use.
  - Multidose vials have a specified period for use once they have been punctured with a needle.
  - See next slide for details where to find BUDs and times for each COVID-19 vaccine manufacturer.

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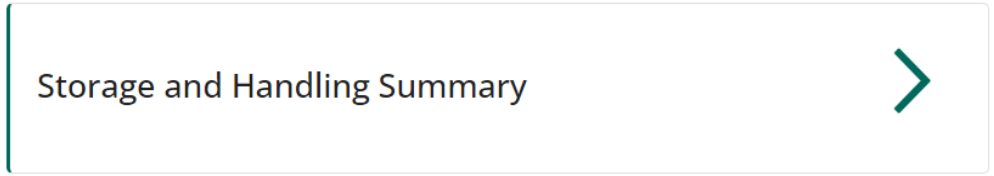
Vaccine Storage and Handling Requirements

Each COVID-19 vaccine manufacturer has unique guidelines for storage and handling, including the amount of time that both punctured and unpunctured vaccines can be stored and/or used at various temperature intervals.

Visit the CDC's U.S. COVID-19 Vaccine Product Information website to link to each of the manufacturer's storage and handling summaries:

1. Near the top of the webpage, click on the name of the vaccine manufacturer you wish to view: Janssen/J&J, Pfizer-BioNTech, Moderna, or Novavax.
2. Click on the **Storage and Handling** icon/link.

3. Select the link to the **Storage and Handling Summary.**



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Vaccine Inventory Management

- Continually monitor your vaccine inventory using the manufacturer lot lookup tools to help reduce administration errors:
  - Pfizer https://lotexpiry.cvdvaccine.com
  - Moderna https://modernacovid19global.com/vial-lookup
  - Novavax* https://us.novavaxcovidvaccine.com/hcp
  - Janssen/J&J* https://vaxcheck.jnj/
- Match the physical inventory on-hand to WIR inventory daily. Use appropriate reason codes in WIR when adjusting inventory. More information will be provided on the next slides.

*Janssen/J&J and Novavax vials purchased by the federal government are set to expire in early 2023. There are no plans to purchase additional doses of either vaccine type.

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Reporting Vaccine Wastage

- **When to complete and submit the Wastage Form F-02768**
  - Vaccine has expired per the **actual** manufacturer expiration date
    - Utilize the manufacturer lot lookup tools outlined on the previous slide
  - Once expired, WIR inventory moves to an "**EXPIRED**" status and can no longer be accessed by the provider
  - Submit completed Wastage Form to DHSCOVIDVaccinator@wi.gov
- **When to enter wastage in WIR**
  - Broken vial/syringe
  - Vaccine drawn into syringe, but not administered
  - Open vial, but not all doses administered
  - Expired per Beyond Use Date (BUD)
    - Example: The expiration date is moved up per the manufacturer's instructions because the vaccine has been thawed in the refrigerator for “x” number of weeks, **not** expired per the posted expiration date.
    - **Do not** change the expiration date in WIR to match the new beyond use date.

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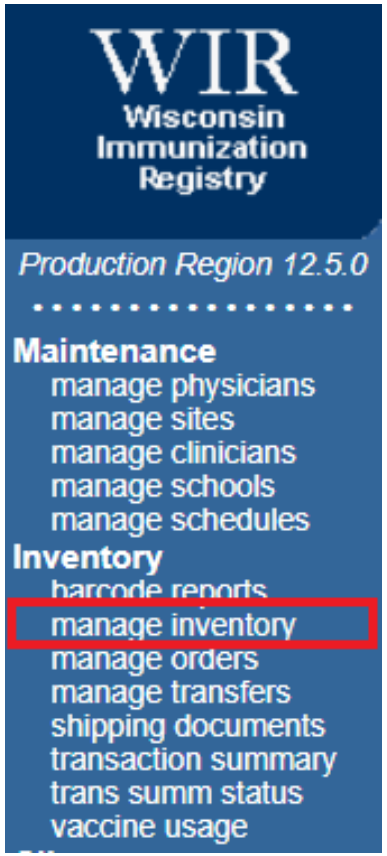
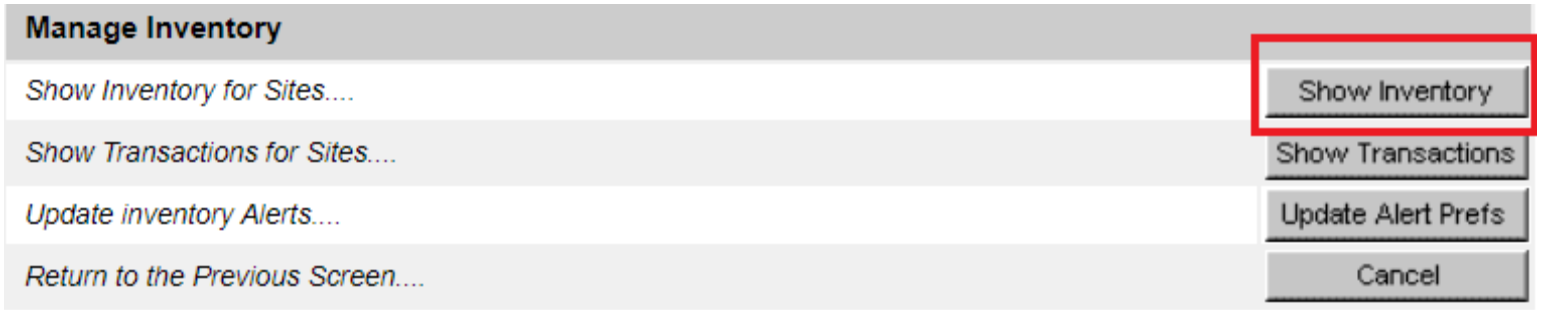
Entering Wastage in WIR

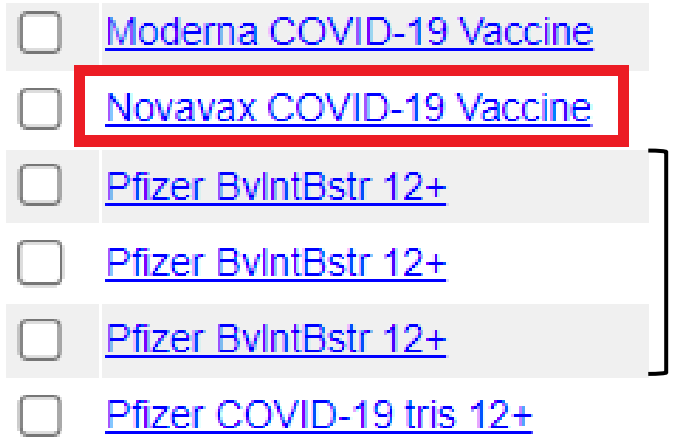
1) Click Manage Inventory → Show Inventory





Entering Wastage in WIR

2) Click the link of the vaccine **Trade Name** that you want to report as wastage. If there are multiple lots of the same vaccine, make sure to choose the one with the correct **Lot Number.**

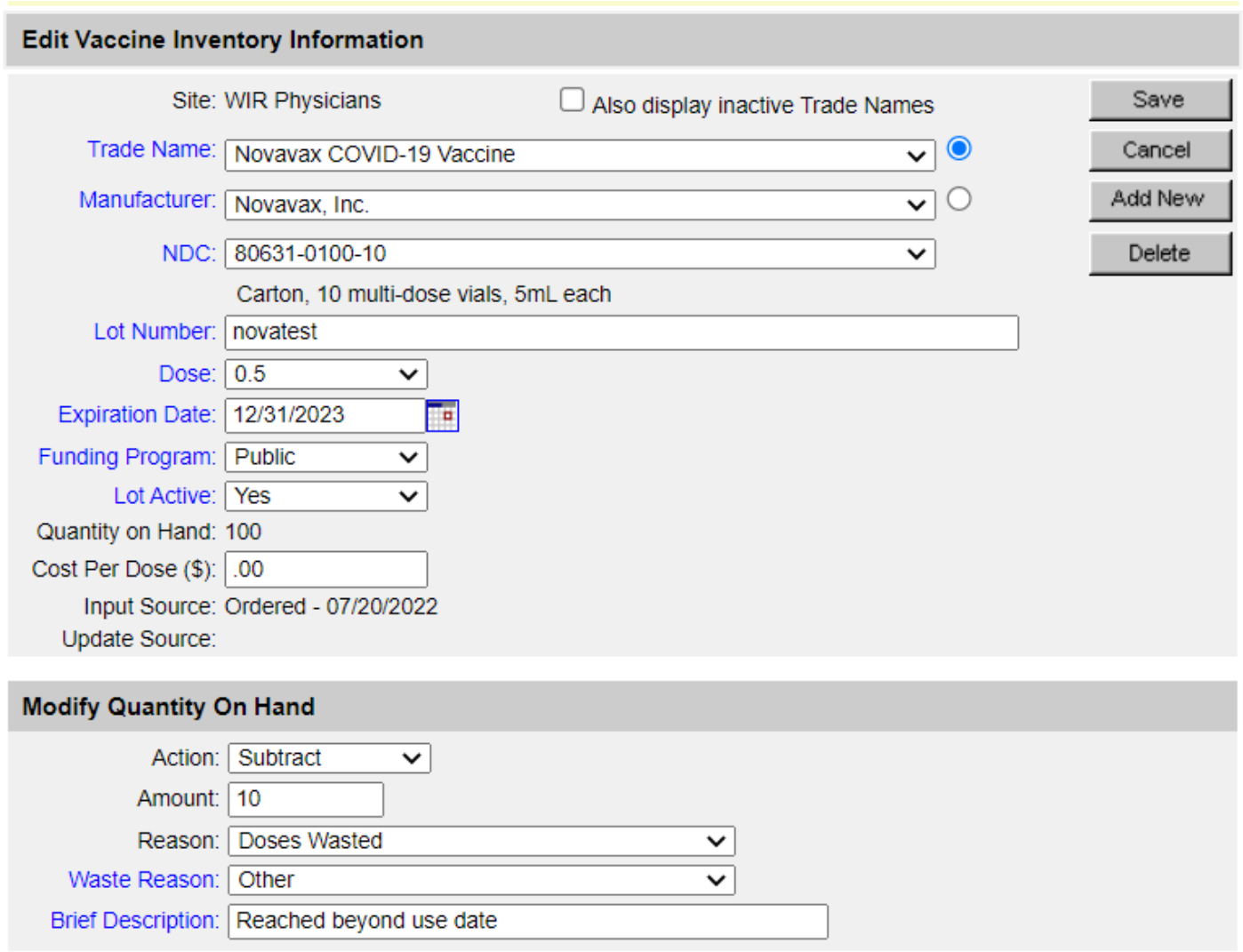


Choose the correct Lot Number

Entering Wastage in WIR

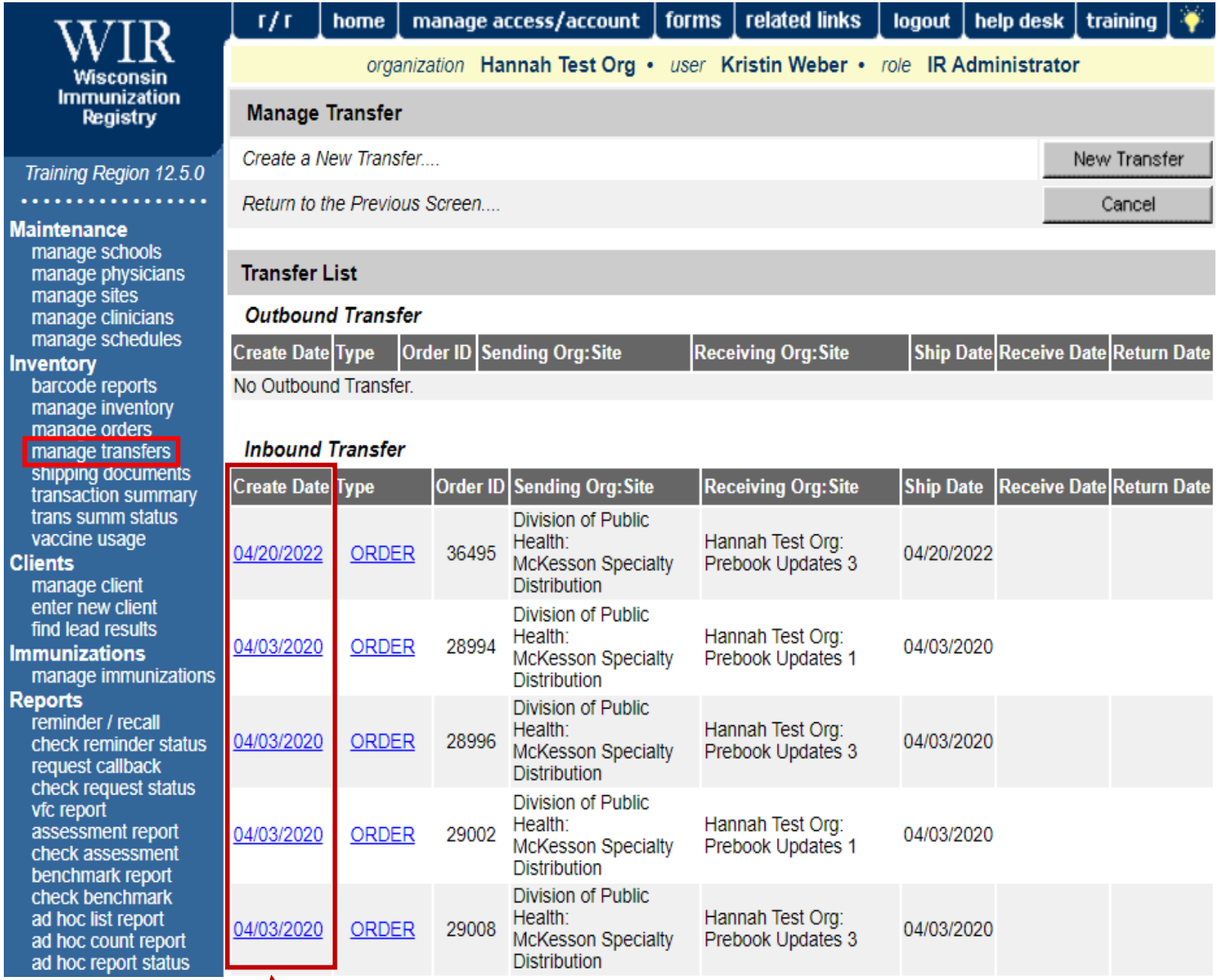
3) Enter **Action**, **Amount**, and **Reason** in the **Modify Quantity on Hand** section at the bottom of the screen.
   - If **Doses Wasted** is the reason, a **Waste Reason** is required.
   - If the **Waste Reason** is **Other**, a **Brief Description** is required.
   - Also use **Modify Quantity on Hand** to update inventory for **Doses Administered** and **Error Correction** when needed.

See the [COVID-19: General Guidance for Vaccinators webpage] for additional guidance on reporting vaccine wastage.



Accepting Transfers in WIR

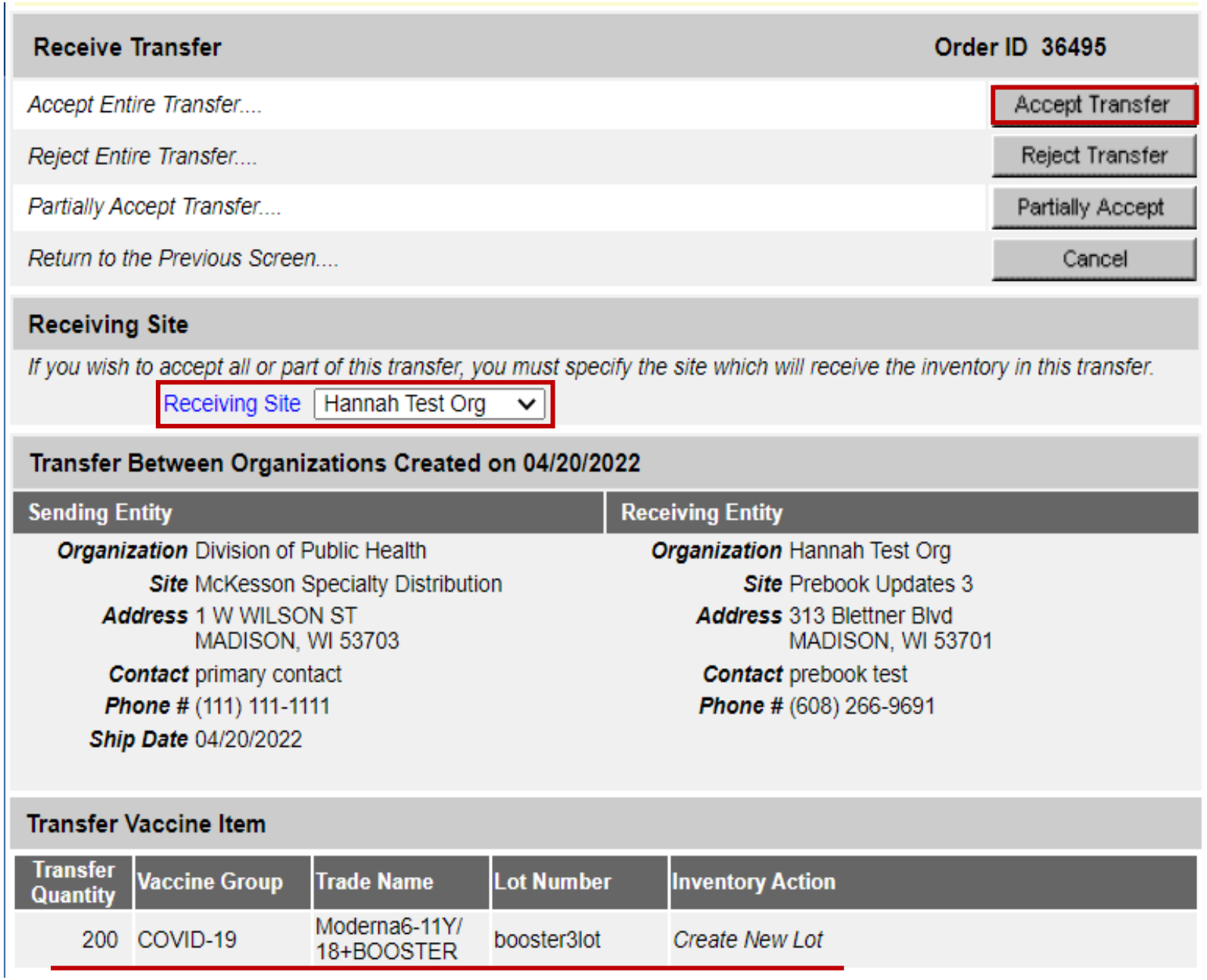
- When a vaccine is received from McKesson, a hub or another provider, the transfer **must** be accepted in WIR.
- Accepting an inbound transfer will automatically add the new vaccines directly to the provider's WIR inventory.
- Do **not** go into WIR inventory and manually enter the vaccine doses received.
- Accepting transfers in WIR ensures that lot numbers, expiration dates, and NDC numbers are correct.



Click the date link to go to the Receive Transfer screen.

Accepting Transfers in WIR

- On the Receive Transfer screen choose the correct receiving site from the dropdown menu. The new inventory will be added to this site.
- At the bottom of the screen, check the vaccine, quantity, and lot number to make sure it matches the physical inventory received.
- If everything is correct, click **Accept Transfer** at the top right of the screen.



Receive Transfer — **Order ID 36495**

Accept Entire Transfer....	Accept Transfer
Reject Entire Transfer....	Reject Transfer
Partially Accept Transfer....	Partially Accept
Return to the Previous Screen....	Cancel

Receiving Site

If you wish to accept all or part of this transfer, you must specify the site which will receive the inventory in this transfer.

Receiving Site: Hannah Test Org

Transfer Between Organizations Created on 04/20/2022

Sending Entity	Receiving Entity
Organization Division of Public Health	***Organization*** Hannah Test Org
Site McKesson Specialty Distribution	***Site*** Prebook Updates 3
Address 1 W WILSON ST MADISON, WI 53703	***Address*** 313 Blettner Blvd MADISON, WI 53701
Contact primary contact	***Contact*** prebook test
Phone # (111) 111-1111	***Phone #*** (608) 266-9691
Ship Date 04/20/2022	

Transfer Vaccine Item

Transfer Quantity	Vaccine Group	Trade Name	Lot Number	Inventory Action
200	COVID-19	Moderna6-11Y/ 18+BOOSTER	booster3lot	*Create New Lot*

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WIR COVID-19 Vaccine Best Practices

- Promptly accept all transfers in WIR so inventory remains up to date. **Never** manually enter new inventory in WIR.
- Document all doses administered within 24 hours of administration. Enter via the User Interface or Data Exchange, depending on provider practice.
- Reconcile COVID-19 vaccine inventory daily. Physical vaccine counts should match WIR inventory at the end of each clinic day.
- Submit wastage daily (if applicable) as part of reconciliation process.
  - Ensure all staff understand difference between BUD (wastage submitted in WIR) and actual expiration date (wastage form submitted) when reconciling inventory.
  - **Never** change an expiration date in WIR to match the beyond use date.

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Vaccination Clinic Planning Requirements

Vaccine providers should assess all people ordering, handling, and/or administering COVID-19 vaccines in Wisconsin using the CDC's Competencies Checklist.

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Patient Education Requirements

Providers should give each COVID-19 vaccine recipient:

- The age- and product-specific EUA Factsheet for Recipients and Caregivers. Copies of the most recent EUA Factsheets can be downloaded from each of the manufacturer's FDA webpages:
  - Pfizer-BioNTech COVID-19 Vaccines
  - Moderna COVID-19 Vaccines
  - Novavax COVID-19 Vaccine, Adjuvanted
  - Janssen COVID-19 Vaccine
- A COVID-19 vaccination record card.
  - Distribute a new card after the first dose in the primary series is administered or ask the patient to present their existing card where additional doses can be noted.
  - If a patient loses their vaccination record card, they should first call the provider/organization where they were vaccinated to request a replacement card.
  - If desired, any provider can look up the patient's vaccination record in WIR and issue a replacement card with the booster and primary series information.
  - Patients can also access their vaccination record using the public-facing links to the WIR immunization records portal. More information and links to the WIR records portal can be found on the DHS website.
  - Note: DHS cannot issue COVID-19 vaccination record cards.
- The V-safe information sheet.

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Patient Education Requirements

V-safe provides personalized and confidential health check-ins via text messages and web surveys so you can quickly and easily share with CDC how you, or your dependent, feel after getting a COVID-19 vaccine. This information helps CDC monitor the safety of COVID-19 vaccines in near real time.

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Pediatric Requirements for Ages 6 Months-11 Years

(For those vaccinating children in this age group)

- CDC recommends COVID-19 primary series vaccines for everyone ages 6 months and older
- CDC recommends COVID-19 updated (bivalent) boosters for everyone ages 5 years and older.
- COVID-19 vaccine dosage is based on age on the day of vaccination, not on size or weight.
- Children get a smaller dose of COVID-19 vaccine than teens and adults based on their age group.

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Pediatric COVID-19 Vaccination Schedule

Children 6 months-4 years old

Moderna

Primary → (4-8 weeks) → Primary

-OR-

Pfizer

Primary → (3-8 weeks) → Primary → (At least 8 weeks) → Primary

Children 5-11 years old

Moderna or Pfizer

Primary → (3-8 weeks (Pfizer) / 4-8 weeks (Moderna)) → Primary → (At least 2 months / After your last primary or booster dose) → Updated Booster

People 12 years and older

Moderna, Novavax, or Pfizer

Primary → (3-8 weeks (Novavax, Pfizer) / 4-8 weeks (Moderna)) → Primary → (At least 2 months / After your last primary or booster dose) → Updated Booster

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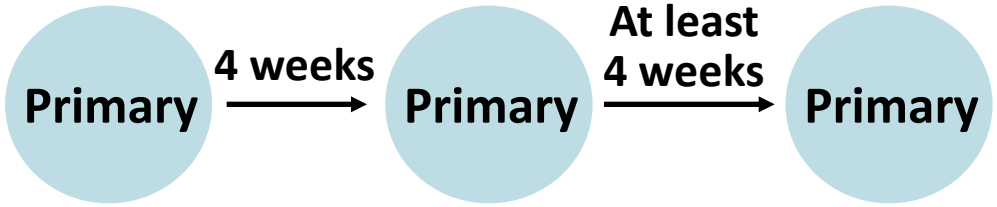
5-year-old children can only get a Pfizer-BioNTech booster. Children ages 6 years and older can get either a Pfizer-BioNTech or Moderna booster.

COVID-19 Vaccine Schedule for Children With a Weakened Immune System

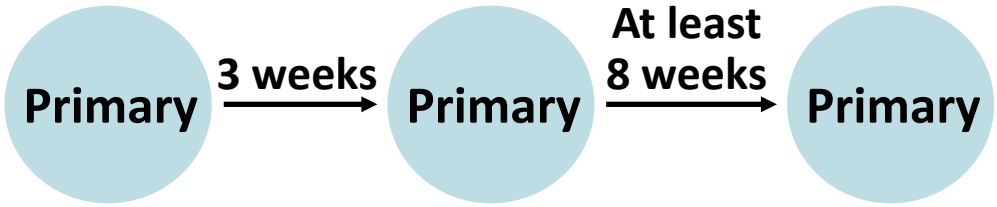
Children 6 months-4 years old

Moderna

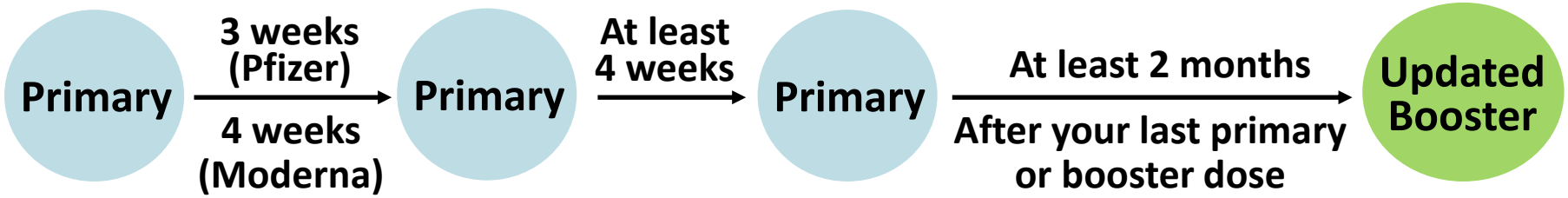


-OR-

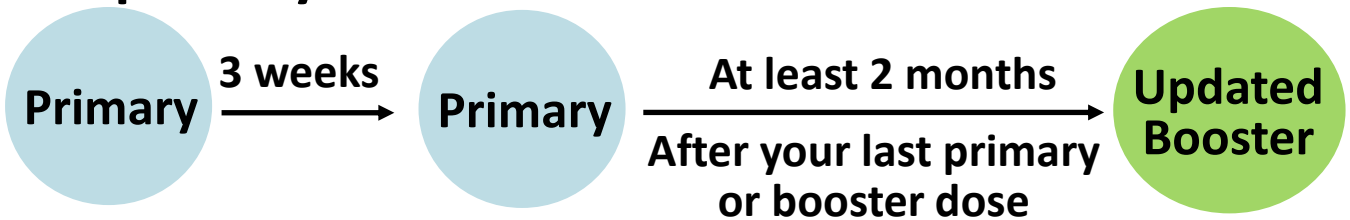
Pfizer



Children 5 years and older who received Moderna or Pfizer



People 12 years and older who received Novavax



For the most up to date schedules, see the CDC Interim Clinical Considerations.

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Pediatric Requirements

(For those vaccinating children in this age group)

- General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
- Needle length
  - Appropriate needle length depends on age and body mass. Injection technique is the most important parameter to ensure efficient intramuscular vaccine delivery.
  - For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue, but not so long as to involve underlying nerves, blood vessels, or bone.
  - Intramuscular injections are administered at a 90-degree angle to the skin, preferably into the anterolateral aspect of the thigh or the deltoid muscle of the upper arm, depending on the age of the patient.

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Pediatric Recommended Sites for Administration

(For those vaccinating children in this age group)

Below are the ACIP's intramuscular injection recommendations for children and youth as outlined on the DHS factsheet.

Age group	Needle length	Injection site
Children (birth-18 years)		
Neonates[a]	5/8 inch (16 mm)[b]	Anterolateral thigh
Infants, 1-12 months	1 inch (25 mm)	Anterolateral thigh
Toddlers, 1-2 years	1-1.25 inch (25-32 mm)	Anterolateral thigh[c]
	5/8[b]-1 inch (16-25 mm)	Deltoid muscle of arm
Children, 3-10 years	5/8[b]-1 inch (16-25 mm)	Deltoid muscle of arm[c]
	1-1.25 inches (25-32 mm)	Anterolateral thigh
Children, 11-18 years	5/8[b]-1 inch (16-25 mm)	Deltoid muscle of arm[c]
	1-1.5 inches (25-38 mm)	Anterolateral thigh

Visit CDC's website for more detailed information.

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Questions, Feedback or Concerns

Please contact DHSCOVIDVaccinator@wi.gov

Presentation Weblinks

Clinical Protocols and Administration Links

- Interim Clinical Considerations
- Appendices to the Interim Clinical Considerations
  - Appendix A
  - Appendix B
  - Appendix C
  - Appendix-D
  - Appendix E
- Medical Countermeasures
- COVID-19 Vaccines website
- Emergency Use Authorization for Vaccines Explained
- Infographic: The Path for a COVID-19 Vaccine From Research to Emergency Use Authorization
- Vaccine EUA Questions and Answers for Stakeholders
- U.S. vaccine safety process and 5-minute video about US vaccine safety process
- DHS factsheet - Vaccine Administration, P-03253 (covering the 7 Rights of Vaccine Administration)
- VAERS Table of Reportable Events Following Vaccination

Vaccine Ordering Process

- Vaccine Ordering Survey
- Regional Manager List
- Wisconsin COVID-19 Vaccine Exchange

Vaccine Storage and Handling

- Temperature Monitoring Log
- Vaccine Storage Troubleshooting Record
- CDC's Storage and Handling Toolkit
- U.S. COVID-19 Vaccine Product Information website

Vaccine Inventory Management

Lot Lookup Tools

- Pfizer https://lotexpiry.cvdvaccine.com
- Moderna https://modernacovid19global.com/vial-lookup
- Novavax* https://us.novavaxcovidvaccine.com/hcp
- Janssen/J&J* https://vaxcheck.jnj/

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Presentation Weblinks

Reporting Vaccine Wastage

- Wastage Form F-02768
- COVID-19: General Guidance for Vaccinators webpage

Vaccination Clinic Planning

- CDC's Competencies Checklist

Patient Education Links

- EUA Factsheets - downloaded from each of the manufacturer's FDA webpages:
  - Pfizer-BioNTech COVID-19 Vaccines
  - Moderna COVID-19 Vaccines
  - Novavax COVID-19 Vaccine, Adjuvanted
  - Janssen COVID-19 Vaccine
- DHS COVID-19 website: Your Vaccination Record
- V-safe information sheet
- CDC's COVID-19 Vaccine
- CDC's Safety of COVID-19 Vaccines

Pediatric Links

- CDC Interim Clinical Considerations
- General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP)
- Needle length
- DHS factsheet - Vaccine Administration, P-03253
- CDC's Vaccine Administration: General Best Practice Guidelines website

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