

COVID-19 Vaccine Information Brief

November 19, 2021

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Vaccine Information

- **FDA Expands Eligibility for COVID-19 Vaccine Boosters - VACCINATION CANNOT BEGIN UNTIL AFTER ACIP RECOMMENDATIONS ARE SIGNED BY THE CDC DIRECTOR**
- **COVID-19 Call Center Holiday Hours & COVID-19 Vaccine Redistribution - No Redistributions Nov 24-26**
- **COVID-19 Vaccine Emergency Use Instructions (EUI) Information and Resources**
- **Interim Clinical Considerations for Use of COVID-19 Vaccines - Updated**
- **New Community Toolkit for Addressing Health Misinformation**
- **Pfizer Pediatric Label Correction**
- **Pfizer Pediatric Storage and Handling - VACCINE CANNOT BE STORED IN THE FREEZER**
- **Moderna Shelf-Life Extension Update**
- Pfizer Pediatric Vaccine Expiration Date - Date on the label is NOT the expiration date
- IRIS Reminders for Healthcare Providers
- COVID-19 Vaccination Provider Resources
- Vaccine Expiration Date Resources
- Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training
- Vaccination Supplies
- V-Safe After Vaccination Health Checker

FDA Expands Eligibility for COVID-19 Vaccine Boosters

The FDA amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. The Centers for Disease Control and Prevention's (CDC) [Advisory Committee on Immunization Practices](#) will meet later today to discuss further clinical recommendations.

COVID-19 Vaccine Boosters for all individuals 18 years and older cannot begin until after ACIP recommendations are signed by the CDC Director.

Resources:

- [Moderna COVID-19 Vaccine](#)
- [Pfizer-BioNTech COVID-19 Vaccine](#)
- [COVID-19 Vaccines](#)
- [Emergency Use Authorization for Vaccines Explained](#)
- [News Release: FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations](#)

- [News Release: Coronavirus \(COVID-19\) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines](#)
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COVID-19 Call Center Holiday Hours and COVID-19 Vaccine Redistribution

The Iowa Department of Public Health will be closed November 24-26 and December 23-24, 2021. During this time, redistribution requests of COVID-19 vaccine will not be processed. The redistribution of COVID-19 vaccines and the physical transfer of vaccine between COVID-19 vaccination providers **MUST ONLY** occur after IDPH approval and IRIS transfer is complete. Inventory adjustments or redistribution of COVID-19 vaccine without IDPH approval may result in the loss of COVID-19 vaccine provider status and removal of COVID-19 vaccines.

The following are requirements for the redistribution of COVID-19 vaccine:

- Redistribution will **ONLY** be allowed between IDPH approved COVID-19 vaccine providers
- **Redistribution MUST be completed prior to physically transferring COVID-19 vaccine**
- Redistribution must be completed before administration of COVID-19 vaccine
- Redistribution will require completion of the COVID-19 Vaccine Redistribution Form and prior approval by IDPH; IDPH will approve all requests within 24 hours
- Immunization Program staff will initiate the transfer of doses in the initiating organization's IRIS account, and will accept the transfer of doses in the receiving organization's IRIS account
- Transferring provider is responsible for the physical transfer of vaccine and ancillary supplies
Receiving organization is required to document COVID-19 vaccine doses administered in IRIS

Questions regarding COVID-19 vaccine can be directed to 1-800-831-6293 ext. 1 or COVID19Vaccine@idph.iowa.gov.

COVID-19 Vaccine Emergency Use Instructions (EUI) Information and Resources

CDC issued Emergency Use Instructions (EUI) and updated its [clinical considerations](#) to allow the COVID-19 vaccine by Pfizer-BioNTech to be given as an additional primary dose or booster dose to certain people who completed a vaccine primary series with certain COVID-19 vaccines that are not authorized or approved by the U.S. Food and Drug Administration. This ensures that eligible people who were vaccinated outside of the U.S. with these vaccines, or who received certain non-FDA authorized or approved COVID-19 vaccines through participation in some clinical trials, can get an additional primary dose or booster dose of Pfizer-BioNTech COVID-19 vaccine.

The new guidance mirrors CDC's recommendations about who is eligible to receive [boosters](#) and [additional primary doses](#), allowing an additional primary dose of the COVID-19 vaccine by Pfizer-BioNTech in certain immunocompromised persons aged 12 years and older, and/or a single booster dose of Pfizer-BioNTech COVID-19 vaccine in certain adults 18 years and older who completed their primary vaccination with a non-FDA authorized or approved COVID-19 vaccines.

Although COVID-19 vaccines continue to work well to prevent severe illness, hospitalization, and death, including against the widely circulating Delta variant, we are starting to see reduced protection, especially among certain populations, against mild and moderate disease. It's important to note that this update only applies to a very small number of people. However, with cases of COVID-19 still high across the U.S. and globally, this update helps to ensure these individuals are better protected from the serious consequences of COVID-19.

Below is a list of resources and upcoming informational activities related to the recommendation:

- [EUI Healthcare Provider Fact Sheet and EUI Recipient/Caregiver Fact Sheet](#)
 - Updated [Clinical Considerations](#)
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Interim Clinical Considerations for Use of COVID-19 Vaccines - Updated

CDC released updated clinical guidance related to COVID-19 vaccines. The updated guidance can be found at [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States | CDC](#). Summary of recent changes (last updated November 16, 2021):

- Updated guidance in section on [People who received COVID-19 vaccine outside the United States](#)
- Updated guidance in section on [People who received COVID-19 as part of a clinical trial](#)

Related Links

- CDC: [Summary Document for Interim Clinical Considerations](#) (PDF)
 - CDC: [Summary Document for Interim Clinical Considerations poster](#) (PDF)
 - CDC: [COVID-19 Vaccine Administration Errors and Deviations](#) (PDF)
 - CDC: [COVID-19 Vaccine Administration Errors and Deviations poster](#) (PDF)
 - IAC: [Vaccines: COVID-19 main page](#)
 - IAC: [Ask the Experts: COVID-19 web page](#)
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U.S. Surgeon General Releases New Community Toolkit for Addressing Health Misinformation

U.S. Surgeon General Dr. Vivek Murthy has released a new toolkit to help community leaders stop the spread of health misinformation online and within their communities. The toolkit provides specific guidance and resources for health care providers, educators, librarians, faith leaders, and trusted community members to understand, identify, and stop the spread of health misinformation in their communities.

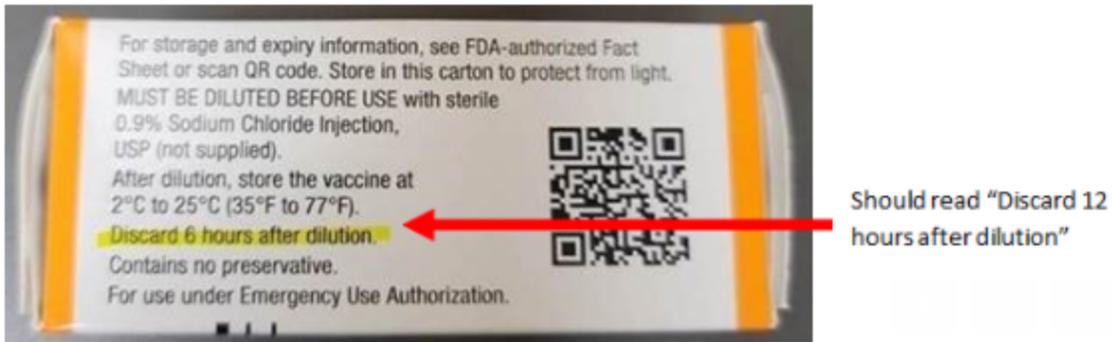
- [Community Toolkit for Addressing Health Misinformation](#)
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Pfizer Pediatric Label Correction

Labels on the Pfizer Pediatric (orange) vials were printed in the months prior to amendment of the EUA by the FDA. In anticipation of approval, the labels were printed, "Discard 6 hours after dilution." However, the FDA approved the vaccine for discarding 12 hours after dilution. This updated information is printed in the EUA and Fact Sheets as follows:

"After dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Fact Sheet supersedes the number of hours printed on vial labels and cartons."

CDC anticipates the label will eventually be updated, but please be aware that ALL Pfizer pediatric vaccine should be discarded 12 hours after dilution.



Pfizer Pediatric Vaccine Storage & Handling

- The product will be delivered in a newly updated product shipper at -80°C. The shipper is disposable and does not need to be returned to Pfizer. **The shipper CANNOT be used for vaccine storage.**
- The shipper box should be unpacked immediately upon receipt, as indicated on the carton.
- The contents must be placed in an ultra-cold freezer -90°C to -60°C or a refrigerator at 2°C to 8°C. **DO NOT PLACE THE PRODUCT IN THE REGULAR FREEZER.**
- Once the product arrives at the provider site, it can be stored for up to 10 weeks at 2 to 8°C and 6 months at ultra cold temperatures of -90° to -60°C.
- **Once open, doses in vials should be used within 12 hours.** Clinics should consider vial size (10-doses) and 12-hour time frame when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.

Storage and Handling

The table below indicates the length of time the pediatric vials can be stored at each temperature. Note, the 10 weeks in the refrigerator is **not** in addition to the 6 months in the freezer. All conditions for storage must be completed within the overall time frame for expiration. Once expired, the vaccine should be discarded regardless of storage conditions.

Storage Conditions	
Ultra Cold Freezer (-90°C to -60°C)	6 months
Freezer (-25°C to -15°C)	N/A
Refrigerator (2°C to 8°C)	10 weeks

Moderna Shelf-Life Extension Update

Moderna continues to update data regarding extension of expired doses. A total of 78 lots have been approved for extension, but challenges within IT systems have slowed the progress considerably.

Currently, 60 batches of Moderna vaccine have been processed for expiry extension and provide an additional 2 months of expiry. CDC expects this number to continue to rise in the days ahead. Moderna's look up tool remains the official indicator of product expiry and healthcare providers are highly encouraged to continue to monitor lot numbers at:

<https://www.modernatx.com/covid19vaccine-eua/providers/vial-lookup#vialLookUpTool>

REMEMBER: The Moderna vials must be maintained in the frozen state for the extension to be applicable (extension does not apply to thawed vials).

Pfizer Pediatric Vaccine Expiration Date

- Formulation does NOT have expiration printed on vial
 - Instead, each vial has the lot number and date of manufacture printed on the label
 - Date on the label is NOT the expiration date
 - **Expiration date of the Pfizer pediatric COVID-19 vaccine is 6 months from the manufacturer date**
 - Example: A vial with a manufacture date of 8/2021 includes August. It does not start in September. Expiration date would be Jan 31,2022
 - Pfizer does not have an expiration date look up tool for the pediatric COVID-19 vaccine
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IRIS Reminders for Healthcare Providers

Please contact the IRIS Help Desk with changes or corrections needed to patient records, such as date of birth errors, misspelled names or duplicate records. Healthcare providers should not refer patients to call the IRIS Help Desk for such requests. IRIS users should review patient demographics at each visit and make changes as necessary to the patient's address, phone number, and responsible person fields.

Healthcare providers should have a process for providing patients with their immunization record. In addition, patients may request their immunization record from the Iowa Department of Public Health by completing this [record request form](#). Please contact the IRIS Help Desk at 800-374-3958 with questions or for any clarification.

COVID-19 Vaccination Provider Resources

Pfizer-BioNTech and Moderna are offering new educational webinars open to all COVID-19 vaccination providers regarding new recommendations and products. Janssen (Johnson & Johnson) Vaccine informational materials online also have been updated. Details are listed below:

Pfizer Resources

These Pfizer-BioNTech COVID-19 vaccine educational materials and web pages have been updated:

- CDC: Clinical guidance and vaccine information for [Pfizer-BioNTech COVID-19 Vaccine](#)
- FDA: [Main page leading to Fact Sheets for Healthcare Providers and Fact Sheets for Recipients and Caregivers, specific to either age 5 through 11 years or age 12 and older \(PDF\) \(10/29/21\)](#)

Moderna Resources

These Moderna COVID-19 vaccine educational materials and web pages have been updated:

- CDC: Clinical guidance and vaccine information for [Moderna COVID-19 Vaccine](#)

- FDA: [Moderna EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) including the Full EUA Prescribing Information \(PDF\) \(10/20/21\)](#)
- FDA: [Vaccine Information Fact Sheet for Recipients and Caregivers Emergency Use Authorization \(EUA\) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 \(COVID-19\) in Individuals 18 Years of Age and Older \(PDF\) \(10/20/21\)](#)

Johnson & Johnson Resources

These Janssen COVID-19 vaccine educational materials and web pages have been updated:

- CDC: Clinical guidance and vaccine information for [Janssen COVID-19 Vaccine \(Johnson & Johnson\)](#)
 - FDA: [Janssen EUA Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\) including the Full EUA Prescribing Information \(PDF\) \(10/20/21\)](#)
 - FDA: [Vaccine Information Fact Sheet for Recipients and Caregivers Emergency Use Authorization \(EUA\) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 \(COVID-19\) in Individuals 18 Years of Age and Older \(PDF\) \(10/20/21\)](#)
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Vaccine Expiration Date Resources

Always be sure to check the manufacturer's website to obtain the most up-to-date expiration dates for COVID-19 vaccines. This is necessary for J&J vaccine as well as Moderna and Pfizer COVID-19 vaccines. It is important for healthcare providers to update vaccine expiration dates in IRIS. Questions regarding IRIS vaccine inventory and adjusting expiration dates can be directed to the IRIS Helpdesk at 800-374-3958.

For EUA COVID-19 vaccines that do not have a final expiration date, the CDC has set an expiration date of 12/31/2069 to serve as a placeholder date. Such vaccines have a dynamic expiration date, which can change over time as additional stability data become available. This placeholder date, which is far in the future, is intended to serve as a prompt for the provider to check the latest expiry information on the manufacturer's website. **It is important for healthcare providers to update vaccine expiration dates in IRIS.**

Janssen COVID-19 vaccine: The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Call 1-800-565-4008, or
- Go to www.vaxcheck.jnj/

Moderna COVID-19 vaccine:

The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:

- Scan the QR code located on the outer carton, or
- Go to www.modernatx.com/covid19vaccine-eua/

Pfizer Pediatric COVID-19 vaccine 5-11 years of age(orange cap):

- Pfizer does not have an expiration date look up tool for this vaccine
- Formulation does NOT have expiration printed on vial
- Instead, each vial has the lot number and date of manufacture printed on the label
- **Date on the label is NOT the expiration date**
- **Expiration date of the Pfizer pediatric COVID-19 vaccine is 6 months from the manufacturer date**

- Example: A vial with a manufacture date of 8/2021 includes August. It does not start in September. Expiration date would be Jan 31, 2022.

Pfizer COVID-19 vaccine: This vaccine product has an expiration date located on the vaccine vial.

CDC’s [COVID-19 Vaccine Expiration Date Tracking Tool](#) can help providers keep track of the expiration date by lot number.

J&J/Janssen		Moderna		Pfizer	
Lot Number	Expiration	Lot Number	Expiration	Lot Number	Expiration
204B21A	12/11/2021	005D21A	11/20/2021	EW0167	11/30/2021
211A21A	12/14/2021	006D21A	11/21/2021	EW0168	11/30/2021
212A21A	12/21/2021	007D21A	11/22/2021	EW0185	11/30/2021
213A21A	12/21/2021	020B21A	11/23/2021	EW0164	11/30/2021
		033B21A	11/26/2021	EW0177	11/30/2021
		021D21A	11/26/2021	EW0169	11/30/2021
		038D21A	11/27/2021	EW0178	11/30/2021
		036B21A	11/28/2021	EW0186	11/30/2021
		022B21A	11/28/2021	EW0176	11/30/2021
		022D21A	11/28/2021	EW0171	11/30/2021
		027D21A	11/28/2021	EW0180	11/30/2021
		023D21A	11/29/2021	EW0173	11/30/2021
		028D21A	11/29/2021	EW0181	11/30/2021
		024D21A	11/30/2021	EW0182	11/30/2021
		047D21A	11/30/2021	EW0179	11/30/2021
		020G21A	11/30/2021	EW0172	11/30/2021
				EW0187	11/30/2021
				EW0170	11/30/2021
				EW0165	11/30/2021
				EW0175	11/30/2021
				EW0183	11/30/2021
				FD7222	11/30/2021
				FD7210	11/30/2021
				FF2591	11/30/2021
				FD7220	11/30/2021

Pfizer COVID-19 Vaccine Medical Updates on Current & Immunization Site Training

Pfizer Vaccines US Medical Affairs continues to host daily *Medical Updates & Immunization Site Training for All Providers with a Focus on Emergency Use Authorization of the Pfizer-BioNTech COVID-19 Vaccine for Children 5 through 11 Years of Age*.

- In addition to Medical Updates, sessions will focus on the Storage, Handling, & Administration for currently available vaccine presentations
- These sessions will be updated to reflect new information and changes that evolve. Such updates will be identified at the start of each session and further explained during each presentation

Please click on the links below to join the sessions at the designated times.*

Date & Time	Password
Attendee link – November 22 – 5 PM ET	YKwPs6P85cH
Attendee link – November 23 – 5 PM ET	S4wspGuhN33
Attendee link – November 24 – 12 PM ET	iWpzpvHh667

Vaccination Supplies

The State of Iowa has recently obtained a limited quantity of individual 25 Gauge 5/8 inch safety needles, 1cc syringes, and a supply of combination 1 inch safety needles and 1 CC syringes. These vaccination supplies are available upon request by Local Public Health Agencies. These supplies are intended to be a back-up resource, the vaccine ancillary kits delivered with the vaccine will have 1 or 1^{1/2} inch needles, however IDPH is aware many prefer the 5/8 inch needles for the younger pediatric doses.

LPHAs should contact their [county emergency management coordinator](#) to request these supplies. County Emergency Managers will enter an individual WebEOC Mission for each LPHA requesting the needles and syringes.

V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

- V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese
- [V-safe after vaccination health checker website](#)
- [V-Safe Print Resources](#)
- [Vaccine Adverse Event Reporting System \(VAERS\)](#)