COVID-19 Vaccine Information Brief

September 27, 2021

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

IMPORTANT/NEW COVID-19 VACCINE INFORMATION:

- Pfizer Booster Dose Recommendations
- COVID-19 Vaccination Field Guide: 12 Strategies for Your Community
- Updated Quick Reference Guide for Healthcare Professionals
- MMWRs Released on COVID-19 Vaccine Effectiveness Studies

Pfizer Booster Dose Recommends for Adults 65+ and Specific At-Risk Groups

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted yesterday September 23, 2021 to recommend a booster dose of Pfizer's mRNA COVID-19 vaccine in certain populations. Individuals may self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered.

Effective immediately, CDC recommends:

- People 65 years and older and residents in long-term care settings should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.
- People aged 50–64 years with underlying medical conditions should receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series.
- People aged 18–49 years with underlying medical conditions may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.
- People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting may receive a booster shot of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after their Pfizer-BioNTech primary series, based on their individual benefits and risks.

These recommendations are ONLY for those who originally received two-dose series of Pfizer's COVID vaccine in the primary series. Booster doses might be recommended in the future for those who received COVID vaccines manufactured by Moderna or Janssen (Johnson & Johnson), or those who received a different mRNA vaccine for each dose in the primary series, but ACIP did not address these situations. **CDC will also evaluate with similar urgency available data in the coming weeks to swiftly make additional recommendations for other populations or people who got the Moderna or Johnson & Johnson vaccines.**

Many of the people who are now eligible to receive a booster shot received their initial vaccine early in the vaccination program and will benefit from additional protection. With the Delta variant's dominance as the circulating strain and cases of COVID-19 increasing significantly across the United States, a booster shot will help strengthen protection against severe disease in those populations who are at high-risk for exposure to COVID-19 or the complications from severe disease.

The FDA and the Advisory Committee on Immunization Practices (ACIP) have not approved the booster dose of COVID-19 vaccine. The FDA Vaccines and Related Biological Products Committee is scheduled to meet Friday,

September 17, 2021 to advise FDA on whether to authorize a booster dose of Pfizer vaccine for some or all adults. ACIP is scheduled to meet September 22-23, 2021. **Approval of booster doses is required by BOTH the FDA and ACIP prior to COVID-19 vaccine booster doses being administered. Health care providers can NOT begin administering booster doses beginning September 20, 2021. HHS provided September 20, 2021 as a planning date only.**

As a reminder, providers are responsible for adhering to all requirements outlined in the COVID-19 Vaccination Program Provider Agreement. Specifically, providers must administer COVID-19 vaccines in accordance with all program requirements and recommendations of CDC, the Advisory Committee on Immunization Practices, and the U.S Food and Drug Administration (FDA). This applies to both EUA and FDA approved COVID-19 vaccines. Accordingly, use of these products outside of those that have been approved and authorized by FDA (often referred to as "off-label use") is not recommended. It would violate the provider agreement and could expose providers to the following risks:

- Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims.
- Individuals who receive an off-label dose may not be eligible for compensation under the Countermeasures Injury Compensation Program after a possible adverse event.
- CDC has defined the scope of the CDC COVID-19 Vaccination Program in terms of how the USG-provided vaccines may be used in the program. Providers giving off-label doses would be in violation of the CDC Program provider agreement potentially impacting their ability to remain a provider in the CDC program.
- Administration fees may not be reimbursable by payers.

COVID-19 Vaccination Field Guide: 12 Strategies for Your Community

The Vaccine Task Force's Vaccine Confidence and Demand Team launched a new tool to support public health and community organizations, the **COVID-19 Vaccination Field Guide: 12 Strategies for Your Community**. The Field Guide offers evidence-based intervention strategies and real-world examples to increase COVID-19 vaccine confidence and uptake.

- COVID-19 Vaccination Field Guide: 12 Strategies for Your Community

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Updated Quick Reference Guide for Healthcare Professionals

The quick reference guide on the CDC website that provides basic information on the proper storage, preparation, and administration of all three vaccines. The document includes everything COVID-19 vaccine providers need to know about proper storage and handling and compares the requirements for all three vaccines in an easy to read, side-by-side format.

- Updated Quick Reference Guide for Healthcare Professionals

CDC MMWRs On Vaccine Effectiveness

The CDC MMWR released last Friday shows in a real-world study of vaccine effectiveness, all three COVID-19 vaccines authorized or approved in the U.S. provide strong protection against hospitalization for COVID19. Full vaccination was 93% effective against hospitalization for the Moderna Vaccine, 88% effective for the Pfizer-BioNTech Vaccine, and 71% effective for the Johnson & Johnson/Janssen Vaccine.

- Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID-19 Hospitalizations Among Adults Without Immunocompromising Conditions — United States, March–August 2021

Other research also shows COVID-19 vaccines offer protection against COVID-19-related hospitalization and emergency department/urgent care visits, even with the rise of the Delta variant. While vaccine effectiveness was lower among adults aged 75 years and older compared with younger adults, vaccination provides strong protection against severe COVID-19 illness.

- Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021

Another new CDC study further reinforces vaccine effectiveness against severe COVID-19. The study, which linked case surveillance and immunization data in 13 jurisdictions, showed when the Delta variant was widely circulating, people who were not fully vaccinated had at least 10 times higher risk of being hospitalized or dying with COVID-19 compared with people who were fully vaccinated.
Interim Estimates of COVID-19 Vaccine Effectiveness Against COVID-19–Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS-CoV-2 B.1.617.2 (Delta) Variant Predominance — Nine States, June–August 2021

Best Practices for Expired COVID-19 Vaccine

A significant amount of the J&J vaccine in the state expires in September. IDPH reminds providers to follow the best practices of regularly checking inventory for expired vaccines and removing expired inventory to prevent it from being administered. If the vaccine expires, remove it from the storage unit immediately to prevent staff from inadvertently using it.

Do not attempt to return the vaccine to the distributor. Instead, dispose of expired vaccine properly. Disposal must be done in accordance with local regulations with appropriate steps taken to ensure proper disposal. Dispose of expired vaccine vials (with remaining liquid) by placing them into the Sharps container and treating them as medical/biohazard waste. Do not draw up remaining liquid and dispose of it down the sink drain.

The CDC COVID-19 Vaccination Program Provider Agreement requires providers to report the number of doses wasted, unused, spoiled, or expired to IRIS. Healthcare providers can use the Adjusting COVID-19 Vaccine Inventory for Wastage instructions to account for wasted doses. IRIS staff are available to help manage IRIS inventory and capture vaccine wastage correctly by calling 800-374-3958.

COVID-19 Vaccine Shipping Cadence

The ordering cadence for Pfizer has changed from a 1-day to a 3-day window. IDPH orders COVID-19 vaccine on Thursdays. Pfizer ancillary kits are anticipated to arrive the following Monday and the vaccine delivery window is now Tuesday-Thursday.

Moderna and Johnson and Johnson COVID-19 vaccine may be delivered the following business day after IDPH places the order. CDC has stated to allow up to 2-3 business days for vaccine orders to arrive. Ancillary kits will arrive within a 24-hour window of the vaccine.

ACIP Authorizes Additional Vaccine Dose (3rd Dose) for ***Certain*** Immunocompromised Individuals

Currently, CDC is recommending moderately to severely immunocompromised people receive an additional dose of COVID-19 vaccine. The third dose should be the same product as the initial 2-dose mRNA COVID-19 primary vaccine series. **Fully vaccinated people with healthy immune systems or with conditions other than listed below, DO NOT need another dose of COVID-19 vaccine at this time. Administering an additional dose of COVID-19 vaccine to a healthy individual is outside the legal scope of the EUA and violates the COVID-19 Provider Agreement. The third dose recommendation only applies to mRNA COVID-19 vaccines, and does not include Johnson & Johnson's Janssen COVID-19 vaccine.**

It's important to note that individuals can self-attest and receive the additional dose wherever vaccines are offered.

Moderately to severely immunocompromised people include:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

Below is a list of resources related to the recommendation:

- Updated Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- New web page for consumers
- New web page for healthcare providers

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted yesterday September 23, 2021 to recommend a booster dose of Pfizer's mRNA COVID-19 vaccine in certain populations. Individuals may self-attest (i.e. self-report that they are eligible) and receive a booster shot wherever vaccines are offered.

Updated Guidance on Coadministration of COVID-19 Vaccine With Other Vaccines

COVID-19 vaccines and other vaccines may be coadministered without regard to timing. **If a patient is eligible, both the flu and COVID-19 vaccines can be administered at the same visit, as recommended by CDC and the Advisory Committee on Immunizations Practices (ACIP). In addition to the flu vaccine, the COVID-19 vaccine can be given at the same time as other vaccines.** Giving all vaccines for which a person is recommended to receive at the same visit is considered a best practice as it increases the probability people will be up to date on recommended vaccines. It also is an important part of immunization practice, especially if a health care provider is uncertain the patient will return for additional doses of vaccine. Both COVID-19 and flu vaccines have been shown to reduce illness, hospitalizations, and deaths.

CDC has extensive guidance for health care providers on coadministration of vaccines.

- When administering COVID-19 and flu vaccines during the same clinical visit, two different injection sites should be used, at least one inch apart from each other.
- If COVID-19 vaccines are administered at the same time as flu vaccines which might be more likely to cause a local injection site reaction (e.g., adjuvanted or high-dose inactivated influenza vaccines), the two should be administered in different limbs, if possible.
- Interim Clinical Considerations for Use of COVID-19 Vaccines|CDC

COVID-19 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 expirations 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 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
210A21A	9/25/2021	038B21A	9/25/2021	EW0207	9/30/2021
209A21A	9/25/2021	021B21A-1	9/26/2021	EW0203	9/30/2021
208A21A	9/25/2021	021B21A	9/26/2021	EW0201	9/30/2021
1816022	9/29/2021	033B21A	9/26/2021	EW0221	9/30/2021
1816024	9/29/2021	036B21A	9/28/2021		
1816027	9/29/2021	022B21A	9/28/2021		
1808986	10/2/2021	037B21A	10/1/2021		
1820095	10/2/2021	040B21A	10/2/2021		
1820096	10/21/2021	039B21A	10/2/2021		
1821282	10/21/2021	043B21A	10/3/2021		
1821281	10/21/2021	041B21A	10/4/2021		
1821286	10/21/2021	042B21A	10/5/2021		
1821288	10/30/2021	042B21-2A	10/5/2021		
1821287	10/30/2021	046B21A	10/6/2021		
		044B21A	10/6/2021		
		045B21A	10/8/2021		
		047B21A	10/9/2021		
		048B21A	10/9/2021		

COVID-19 Vaccine Access and Wastage Guidance

Take every opportunity to vaccinate every eligible person. As COVID-19 vaccine supply is more available, and opportunities to vaccinate Iowa residents may become more sporadic, focus should shift towards ensuring vaccination of all eligible persons even at the risk of wasting unused doses. The Department supports and encourages efforts to administer vaccine to all eligible individuals and is providing updated guidance on COVID-19 Vaccine Access and Wastage Guidance. The Department recommends every effort is made to vaccinate eligible persons who present at a vaccine clinic location. A multi-dose vial may be punctured to vaccinate one or more persons who present for vaccination. Ultimately, the remaining doses of vaccine in the vial may need to be wasted. At this point in Iowa's pandemic response, it is more critical to ensure people who want to be vaccinated are able to do so.

The CDC COVID-19 Vaccination Program Provider Agreement requires providers to report the number of doses wasted, unused, spoiled, or expired to IRIS. Healthcare providers can use the Adjusting COVID-19 Vaccine Inventory for Wastage instructions to account for wasted doses. IRIS staff are available to help manage IRIS inventory and capture vaccine wastage correctly by calling 800-374-3958.

Vaccinate with Confidence

Below are updated resources aimed at building confidence in COVID-19 vaccines.

- How to Build COVID-19 Vaccine Confidence in the Workplace
- Key Things to Know about COVID-19 Vaccines
- Frequently Asked Questions about Vaccination
- Vaccine Recipient Education

- Vaccine Communication Toolkit for Medical Centers, Clinics, Pharmacies, and Clinicians
- **Ad Council:** COVID-19 Collaborative Education Toolkit (Healthcare Provider Resources)
- **HHS:** COVID-19 Public Education Campaign Resources
- **HHS:** Talking Points for Health Care Leaders to Encourage Vaccine Confidence

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COVID-19 Vaccine and Clinical Information

General information about COVID-19 vaccine products for clinicians and healthcare professionals can be found on the COVID-19 Vaccination webpage.

Clinical information including FAQs, Contraindications and Precautions as well as Administrative resources can be found for each vaccine on their own product webpage.

- Pfizer-BioNTech COVID-19 vaccine
- Moderna COVID-19 vaccine
- Janssen/J&J COVID-19 vaccine
- COVID-19 Vaccine Quick Reference Guide
- Interim Clinical Considerations Summary Document

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)