IDPH IOWA Department of PUBLIC HEALTH
Protecting and Improving the Health of Iowans
Kim Reynolds, Governor | Adam Gregg, Lt. Governor | Kelly Garcia, Interim Director

# COVID-19 Vaccine Information Brief

October 27, 2021

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

## IMPORTANT/NEW COVID-19 Vaccine Information

- Interim Clinical Considerations - Updated
- Moderna COVID-19 Vaccine - **Do not puncture the vial stopper more than 20 times**
- Frequently Asked Booster Dose Questions
- Pfizer COVID-19 Medical Updates
- Moderna COVID-19 Medical Updates
- Indications for a Booster Dose Following Johnson & Johnson COVID-19 Primary dose
- Authorization of Heterologous (Mix-and-Match) Booster Dose
- COCA Call: What Clinicians Need to Know about the Recent Updates to CDC's Recommendations for COVID-19 Boosters
- Pfizer Pediatric COVID-19 Vaccination

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## Interim Clinical Considerations for Use of COVID-19 Vaccines

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 October 25, 2021):

- Updated guidance in section on Considerations for use of a COVID-19 booster dose
- New section added on Overview of COVID-19 vaccines recommendations
- Updated guidance in section on COVID-19 vaccine dosage and schedule
- Updated guidance in section on People vaccinated for prevention of COVID-19 outside the United States
- Updated guidance in section on COVID-19 vaccination and SARS-CoV-2 infection for People with prior or current SARS-CoV-2 infection; People with a history of multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A); People who received passive antibody products; and Vaccinated people who subsequently develop COVID-19
- New guidance on Considerations for COVID-19 revaccination in the section on Considerations for COVID-19 vaccination in moderately and severely immunocompromised people
- Updated Table in Appendix A: Vaccine administration errors and deviations- **Numerous changes**
    - **Intervals between vaccine dose**

      ***Primary series***

      Individuals who receive the second dose of an mRNA COVID-19 vaccine no more than 4 days before (referred to as the "grace period") or at any time after the recommended second dose date are considered to have completed the primary series. **If the second dose of a vaccine is given earlier than the 4-day grace period (i.e., the second dose is administered <17 days**

**[Pfizer-BioNTech] or <24 days [Moderna]), the second dose should be repeated. The repeat dose should be spaced after the dose given in error by the recommended minimum interval** (see Appendix A for more details).

***Additional dose***

The additional dose (i.e., third dose) of an mRNA COVID-19 vaccine should be administered at least 28 days after completion of the initial 2-dose mRNA COVID-19 primary (see Considerations for COVID-19 vaccination in moderately and severely immunocompromised people). **If the additional dose of an mRNA COVID-19 vaccine is given fewer than 24 days after the second dose (i.e., administered earlier than the 4-day grace period), the additional dose should be repeated. The repeat dose should be spaced after the dose given in error by the recommended minimum interval** (see Appendix A for more details).

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## Moderna COVID-19 Vaccine – Booster Dose Volume (0.25 mL) and Vial Presentation

Moderna COVID-19 Vaccine is authorized for emergency use to prevent COVID-19 in individuals 18 years of age and older. A booster dose was authorized on October 20, 2021, for specific populations described below.

**Primary Vaccination:** Each dose 0.5 mL

A primary series of this vaccine is two 0.5 mL doses administered intramuscularly 1 month apart. A third 0.5 mL primary series dose at least 1 month following the second dose is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

**Booster Vaccination:** One 0.25 mL dose

A booster dose may be administered intramuscularly at least 6 months after completing a primary series with the Moderna COVID-19 Vaccine to individuals:

- 65 years of age and older
- 18 through 64 years of age at high risk of severe COVID-19
- 18 through 64 years of age with frequent institutional or occupational exposure to SARSCoV-2

A single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the heterologous booster dose are the same as those authorized for a booster dose of the vaccine used for primary vaccination.

**Use of Multidose Vials of Moderna COVID-19 Vaccine**

Primary series doses of 0.5 mL and booster doses of 0.25 mL may be extracted from either vial presentation, preferentially using low dead-volume syringes and/or needles. When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from either vial presentation should not exceed 20 doses. **Do not puncture the vial stopper more than 20 times.** Once the vial has been punctured 20 times the remaining must be discarded.

At any time, if the amount of vaccine remaining in the vial cannot provide a full dose of 0.5 mL or 0.25 mL, discard the vial and contents. Do not pool excess vaccine from multiple vials.

Resources:

- Moderna COVID-19 Vaccine EUA

## Frequently Asked COVID-19 Vaccine Booster Dose Questions

**Q: Who is eligible to get a booster?**

**A:** For individuals who received a Pfizer-BioNTech or Moderna COVID-19 vaccine, the following groups are eligible for a booster shot at 6 months or more after their initial series:

- 65 years and older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work or live in high-risk settings

For the people who got the Johnson & Johnson COVID-19 vaccine, booster shots are also recommended for those who are 18 and older and were vaccinated two or more months ago. CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted on October 21, 2021 to recommend a booster dose of Johnson & Johnson COVID-19 vaccine.

**Q: Will booster shots be the same formulation as existing vaccines?**

**A:** Yes, COVID-19 booster shots are the same formulation as the current COVID-19 vaccines. **However, in the case of the Moderna COVID-19 vaccine booster shot, it is half the dose of the vaccine people get for their initial series.**

**Q: Can people mix and match vaccine brands for their booster shot?**

**A:** Eligible individuals may choose which vaccine they receive as a booster dose. Some people may have a preference for the vaccine type that they originally received and others may prefer to get a different booster. CDC's recommendations now allow for this type of mix and match dosing for booster shots.

**Q: Does this change the definition of "fully vaccinated" for those eligible for booster shots?**

**A:** No. At this time, people are still considered fully vaccinated two weeks after their second dose in a 2-dose series, such as the Pfizer or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.

**Q: Is it safe to co-administer COVID-19 vaccines with other vaccines, like flu?**

**A:** Yes, if a patient is eligible, both flu and COVID-19 vaccines can be administered at the same visit, as recommended by CDC and ACIP. In addition to the flu vaccine, COVID-19 vaccine can be given with other vaccines as well.

## Pfizer COVID-19 Medical Updates

Pfizer Vaccines US Medical Affairs will be hosting "Medical Updates" for its COVID-19 vaccine (with its partner BioNTech) on Tuesdays, at 5pm ET, and Thursdays, at 12pm ET, for the remainder of 2021. These sessions will be continuously 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.

Session topics, subject to change, may include:

- FDA indication and authorizations
- CDC/ACIP recommendations

- Packaging/presentation updates
- Storage, handling and administration
- Test your knowledge (Q&A scenarios for various storage & expiry conditions)

**October & November 2021 Sessions**
**Please click on the links below to join the sessions at the designated times.**

| Date & Time | Password |
|---|---|
| Attendee link – October 27 – 12 PM ET | 7c2gZCqcSz8 |
| Attendee link – October 28 – 12 PM ET | 9ywEun8Mjs7 |
| Attendee link – October 29 – 12 PM ET | cnRBrmGr324 |
| Attendee link – November 1 – 5 PM ET | g9ZmgHaip32 |
| Attendee link – November 2 – 5 PM ET | sJDZQERp325 |
| Attendee link – November 3 – 12 PM ET | 82qdN3PppPp |
| Attendee link – November 4 – 12 PM ET | Y4ZkXdh2bz7 |
| Attendee link – November 5 – 12 PM ET | rJSpNPts332 |

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## Moderna COVID-19 Medical Updates

Moderna will be hosting webinars for vaccination providers to learn more about the Moderna COVID-19 Vaccine booster dose, which has been authorized for emergency use in the United States. There will be no continuing education offered for this webinar. Please register at the link below for one of our available sessions.

**Webinar**: Important updates on the mRNA-1273 50 µg Booster Dose

- Thursday, October 28th at 12pm ET – Register here for Oct 28
- Thursday, November 4th at 3pm ET – Register here for Nov 4
- Thursday, November 11th at 12pm ET – Register here for Nov 11

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## CDC's Advisory Committee Recommends Johnson & Johnson Booster Dose for Adults

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted on October 21, 2021 to recommend a booster dose of Johnson & Johnson COVID-19 vaccine.

**Effective immediately, CDC recommends:**

- People aged ≥18 years who received a single dose Janssen primary series (1 dose) should receive a COVID-19 booster dose at least 2 months after completing the primary series.
    - J&J vaccine does not have eligibility criteria for the booster dose.

Resources:

- Janssen COVID-19 Vaccine EUA

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## FDA's Authorization of Heterologous (Mix-and-Match) Booster Dose

FDA amended the EUAs for COVID-19 vaccines to allow for the use of each of the available COVID-19 vaccines as a heterologous (or "mix and match") booster dose in eligible individuals following completion of primary vaccination with a different available COVID-19 vaccine. CDC's recommendations now allow for this type of mix and match dosing for booster shots. Heterologous dosing may be considered for the **booster dose** only.

**Intervals of Heterologous (Mix-and-Match) Booster Dose**

- Intervals should follow the interval recommended by the primary series.
- People who received a single dose Janssen primary series can receive a mRNA COVID-19 booster dose at least 2 months after completing primary series.
- If a Moderna vaccine booster is administered, the booster dose volume should be 50µg in 0.25ml (half-dose). Pfizer-BioNTech and Janssen booster doses are the same dose as primary vaccine. If an individual who is moderately to severely immunocompromised receives a primary dose of Janssen vaccine and receives a booster dose using Moderna, the 50µg dose should be used.

    - Example #1: Janssen COVID-19 Vaccine recipients 18 years of age and older may receive a single booster dose of Janssen COVID-19 Vaccine, Moderna COVID-19 Vaccine (half dose) or Pfizer-BioNTech COVID-19 Vaccine at least two months after receiving the Janssen COVID-19 Vaccine primary vaccination.

    - Example #2: Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 vaccine recipients falling into one of the authorized categories for boosters may receive a booster dose of Moderna COVID-19 Vaccine (half dose), Pfizer-BioNTech COVID-19 Vaccine or Janssen COVID-19 Vaccine at least six months after completing the primary vaccination.

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## Pfizer Pediatric COVID-19 Vaccination

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Oct 26th. The ACIP Is scheduled to meet November 2-3, 2021 to provide clinical recommendations.

**Pediatric Pfizer vaccinations for 5–11-year olds cannot begin until after FDA EUA approval and ACIP recommendations are signed by the CDC Director.**

**Pfizer Pediatric Vaccine Formulation**

- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a new product configuration with new packaging, new preparation, and a new national drug code (NDC).
- **The current product for adults and adolescents should not be used for children.**
- The Pfizer-BioNTech vaccine for 5–11-year-olds will be a two dose series. The ACIP will provide minimal interval recommendations at the November meeting.
- The packaging configuration will be 10-dose vials in cartons of 10 vials each (100 doses total) pending FDA authorization.
- COVID-19 pediatric vaccines will require diluent. The diluent will be provided with ancillary supplies which are configured specifically for use in children.
    - **NOTE: Reconstitution of the product for use on 5–11-year-olds uses a different volume of diluent than the adult formulation.**
- Diluent will be in 10mL vials; ancillary kits will provide 1 vial of diluent for every 1 vial of vaccine. Withdraw the needed amount of diluent and discard the remaining diluent in the vial.

**Vaccine Storage and 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.**
- 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.
- Pfizer COVID-19 pediatric vaccine cannot be stored in the freezer.
- Once open, doses in vials should be used within 6 hours. Clinics should consider vial size (10-doses) and 6-hour timeframe when scheduling children for vaccination, especially early in the program to minimize waste and optimize use of supply.