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 22, 2021

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

IMPORTANT/NEW COVID-19 Vaccine Information

- Indications for a Booster Dose Following mRNA COVID-19 Primary Series
- 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 COVID-19 Medical Updates
- Pfizer Pediatric COVID-19 Vaccination

Indications for a Booster Dose Following mRNA COVID-19 Primary Series

The Advisory Committee on Immunization Practices (ACIP) voted October 21, 2021 to recommend a booster dose following mRNA COVID-19 primary series. Individuals may self-attest (i.e., self-report that they are eligible) and receive a booster shot wherever vaccines are offered. In general, the same product used for the primary regimen should be used for the booster. **If a Moderna vaccine booster is administered, the booster dose volume should be 50µg in 0.25ml (half dose).**

Effective immediately, CDC recommends 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:

- People 65 years and older
- People 18 years and older who reside in long-term care settings
- People aged 18 years and older with underlying medical conditions
- People aged 18 years and older who work or live in high-risk settings

Resources:

- Moderna COVID-19 Vaccine EUA
- Pfizer COVID-19 Vaccine EUA

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

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.

CDC Clinician Outreach and Communication Activity Call: What Clinicians Need to Know about Recent Updates to CDC's Recommendations for COVID-19 Boosters

This COCA call will provide an overview of the most recent recommendations for administering COVID-19 booster vaccines. The Centers for Disease Control and Prevention will provide updates about the latest recommendations and clinical considerations for administering COVID-19 boosters, including an update on early safety monitoring for additional COVID-19 vaccine doses.

The slide set will be available under Call Materials on the COCA Call webpage. Continuing Education will not be offered for this COCA Call. Registration is not required.

Date: Tuesday, October 26, 2021
Time: 1:00 - 2:00 pm
Zoom link to join: https://www.zoomgov.com/j/1603968267
One tap mobile: US:+16692545252, 1603968267#, *581643# or +16468287666, 1603968267#, *581643#
Telephone: US: +1 669 254 5252 or +1 646 828 7666 or +1 669 216 1590 or +1 551 285 1373
Webinar ID: 160 396 8267
Passcode: 581643

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

October 2021 Sessions

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

Date & Time	Password
Attendee link – October 26 – 5 PM ET	vuPhUsbD258
Attendee link – October 28 – 12 PM ET	9ywEun8Mjs7

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.