IDPH IOWA Department of PUBLIC HEALTH
Protecting and Improving the Health of Iowans
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COVID-19 Vaccine Information Brief

October 15, 2021

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

IMPORTANT/NEW COVID-19 Vaccine Information

- Pediatric COVID-19 Vaccine Planning Assumptions
- COVID-19 Vaccines While Pregnant or Breastfeeding
- Reporting COVID-19 Vaccine Fraudulent Activities

Pediatric COVID-19 Vaccine Planning Assumptions

An Emergency Use Authorization (EUA) application for the Pfizer-BioNTech COVID-19 Vaccine for children 5-11 years old has been submitted to the FDA. The bullets below outline planning assumptions for planning COVID-19 vaccination programs for children <12 years old, pending FDA authorization and ACIP recommendations.

What is Known about COVID-19 vaccines for children < 12 year old:

- The Pfizer-BioNTech COVID-19 Vaccine for 5–11-year-olds will be a new product with new packaging and a new national drug code (NDC). Current products for adults and adolescents should not be used in children.
- The new product configuration will be 10-dose vials, in packages of 10 vials (100 dose total) pending FDA authorization. The product can be stored for 10 weeks at 2 - 8°C. There will also be changes to the product shipper.
- COVID-19 pediatric vaccines will require diluent, and this will be provided with ancillary supplies which are configured specific to new vaccine packaging and appropriate for use in children.
- The PREP Act has expanded scope of practice for pharmacists and pharmacy technicians nationwide to allow for provision of COVID-19 and influenza vaccinations to children ≥ 3 years old (please see: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf).

Planning Assumptions about COVID-19 Vaccine for children < 12 years old

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) is scheduled to meet on Oct 26th. Healthcare providers should be ready to vaccinate children 5-11 years old shortly thereafter pending FDA authorization and ACIP recommendations.
- Distribution of pediatric vaccines will begin once FDA issues the EUA, and vaccine administration will begin once the CDC Director makes a recommendation based on the ACIP recommendations.
- The minimum order amount will be 300 doses in the first week and 100 doses in subsequent weeks.

- Not all COVID-19 vaccination sites will need to receive pediatric vaccines. Vaccination providers that are most likely to vaccinate pediatric populations should be prioritized for initial dose availability, with provider types likely varying across communities (e.g., pediatric clinics, federally qualified health centers [FQHC], pharmacies, rural health centers [RHC]).
- Pharmacies participating in the Federal Retail Pharmacy Program (FRPP) will be able to order vaccine to select pharmacy locations increasing the number of locations children may go to get vaccinated.

COVID-19 Vaccines While Pregnant or Breastfeeding

COVID-19 vaccination is recommended for all people 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. Evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy has been growing. These data suggest that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems in women or men. Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people.

- COVID-19 Vaccines While Pregnant or Breastfeeding|CDC

COVID-19 Vaccine Fraudulent Activities

The U.S. Department of Health and Human Services Office of Inspector General is alerting the public about fraud schemes related to the novel coronavirus (COVID-19). Any incidents regarding COVID-19 healthcare fraud should immediately be reported to:

- HHS Office of Inspector General, 1-800-hhs-TIPS or www.oig.hhs.gov
- Federal Bureau of Investigation Electronic Tips Form: http://tips.fbi.gov

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New CDC Communication and Education Resources

- COVID-19 Vaccines for Older Adults
- COVID-19 Vaccines for Essential Workers
- COVID-19 Vaccines for Healthcare Personnel
- About COVID-19 Vaccine Delivered and Administration Data
- Customizable Content for School-Located Vaccination Clinics
- COVID-19 Vaccines for Teachers, School Staff, and Childcare Workers
- Connecting Long-Term Care Settings with Federal Pharmacy Partners

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FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meetings

The U.S. Food and Drug Administration announced a meeting of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss newly available data for the currently available COVID-19 vaccines.

- Pfizer COVID-19 vaccine for ages 5-11: Tuesday 10/26/21
  - View press release here

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 to recommend a booster dose of Pfizer's mRNA COVID-19 vaccine in certain populations. *It's important to note individuals can self-attest and receive the additional dose wherever vaccines are offered.*

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 may 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.**

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.

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. **The third dose recommendation only applies to mRNA COVID-19 vaccines (Moderna and Pfizer), 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 third dose recommendation:

- CDC web page for consumers
- CDC web page for healthcare providers

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

Best Practices for Expired COVID-19 Vaccine

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 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.

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)