

COVID-19

COVID-19 LIVE Event: Vaccine for 5- to 11-year-olds

November 10, 2021

COVID-19

Presenters:

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Sarah Bledsoe, PharmD, MSHA, CPHIMS, BCSCP, Senior Director of Pharmacy

Moderators:

Doug Blowey, MD, Medical Director/Chief Clinical Integration Officer, Integrated Care Solutions

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COVID-19 Vaccine Updates

Angela Myers, MD, MPH

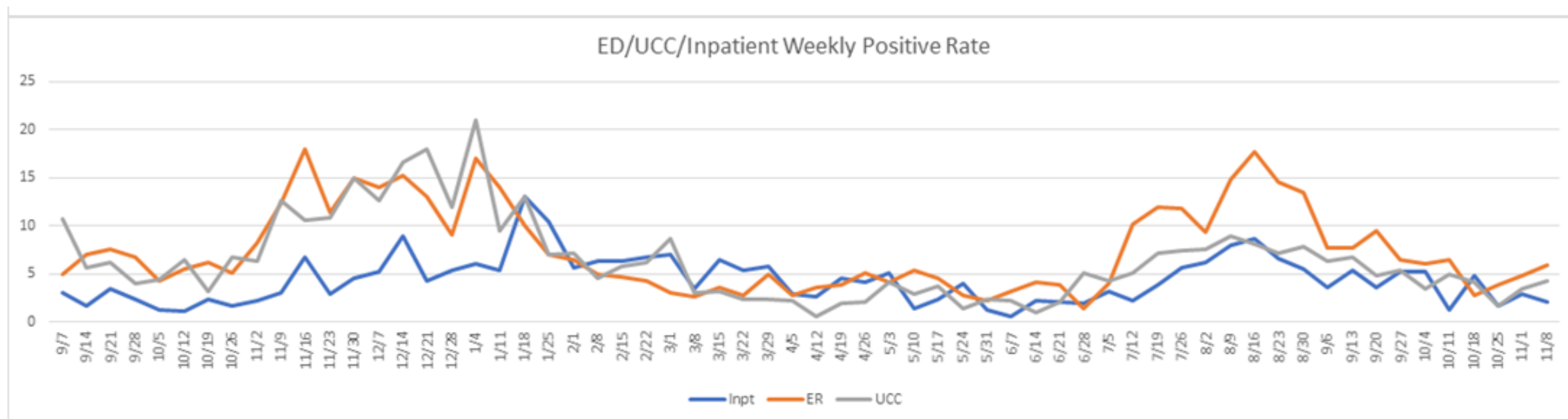
Director, Division of Infectious Diseases

Agenda:

- Update on COVID-19 vaccines in the pediatric population (5-11)
- Differences between the adult/adolescent formulation and the pediatric formulation
- Vaccine logistics and administration
- Q&A



CM COVID-19 Update



See positive testing results: <https://www.childrensmercy.org/health-and-safety-resources/information-about-covid-19-novel-coronavirus/covid-19-testing-at-childrens-mercy/positive-test-results/>

Pfizer BNT162b2 – Meets EUA Guidance for 5 to <12 Years of Age

Clear and Compelling Data



Data presented to ACIP

- Initial study had 2,268 participants (5-11 years old) stratified 2:1 vaccine vs. placebo (median follow up 2.3 mos)
- Equally balanced between girls and boys, 79% White, 6% Black, 7% Multiracial, 6% Asian, and 21% Latinx
- Local reactions were mostly mild or moderate, short-lived, and similar to 16- to 25-year-olds
- Systemic symptoms were mostly mild to moderate:
 - 39.4% fatigue, 28% headache, 9.8% muscle aches, 9.8% chills, 6.5% fever (uncommon)
- No serious adverse events (SAEs) were deemed to be related to vaccine (e.g., septic arthritis, epiphyseal fracture, foreign body ingestion)
- No cases of anaphylaxis, myo/pericarditis, Bell's palsy, or appendicitis

Source: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf>

Vaccine effectiveness in trial



Seroresponse criteria was met with a ≥ 4 fold increase in titer from baseline (pre-vaccine) as well as the immunobridging criteria.



Essentially no difference between the two age groups (5-11-year-olds vs. 16-25-year-olds) and a GMR of 10.4 (95% CI 0.93, 1.18).



Initial data show that children who had previous infection developed higher antibody titers than those who did not have previous infection.



VE reported as 90.7% (95% CI 67.7, 98.3) for COVID-19 infection 7 or more days after dose 2 with only 3 cases in vaccinated participants compared to 16 in unvaccinated.

Source: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf>

Estimated benefits for every million Pfizer-BioNTech COVID-19 vaccinations in children 5-11 years of age using recent incidence

Females 5-11 years

 **57,301** COVID-19 cases prevented

 **191** hospitalizations prevented

 **130** MIS-C cases prevented

 **60** ICU admissions prevented

Males 5-11 years

 **56,954** COVID-19 cases prevented

 **226** hospitalizations prevented

 **130** MIS-C cases prevented

 **72** ICU admissions prevented

Assumptions: Benefits accrue over **180 days (6 months)**; VE against symptomatic COVID-19: 90%; VE against hospitalization: 95%

Data Sources: COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic>. COVID Data Tracker https://covid.cdc.gov/covid-data-tracker/#trends_dailycases. COVID-Net https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html. All data are from the week ending on **9/11/2021**.

Source: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/08-COVID-Oliver-508.pdf> (slide 31)

Myocarditis Risk

- Myocarditis following COVID-19 vaccine is rare
 - Associated with less severe laboratory abnormalities compared to viral myocarditis
 - Faster return to normal heart function: <5 days for vaccine vs. 3+ weeks for infection
- Vaccine associated myocarditis: 40-50/million 2nd doses
- COVID-19 related myocarditis: 120,000/million infections
- MIS-C: 670,000/million cases

Sources:

https://www.cdc.gov/mmwr/volumes/70/wr/mm7027e2.htm?s_cid=mm7027e2_w

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/04-COVID-Oster-508.pdf> (slide 22)

Administration Errors

- Formulations of the Pfizer-BioNTech COVID-19 Vaccines are **NOT** interchangeable
 - If a child age 5–11 years inadvertently receives a 30 µg dose for their first dose, they should receive a single age-appropriate 10 µg dose for dose 2 & should be considered as having a completed primary series
 - If a child age 5–11 years inadvertently receives a 30 µg dose for dose 2, they should be considered as having a completed primary series

Source: <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/07-COVID-Woodworth-508.pdf> (slide 24)

Support and Resources

- [AAP COVID-19 Vaccine Toolkit](#)
- [CDC Pfizer-BioNTech COVID-19 Vaccine](#)

We are here to support your practice!

- CM Vaccine Clinics available for 5 years up to 22 years old:
cmkc.link/VaccineClinics
- Parent FAQ: cmkc.link/vaccineFAQ




Pediatric Vaccine Specifics


Sarah Bledsoe, PharmD, MSHA, CPHIMS, BCSCP
Senior Director of Pharmacy

Approval Pfizer-BioNTech COVID-19 in children ages 5-11 Vaccine









As we now know, the Pfizer-BioNTech COVID-19 Vaccine pediatric formula was just approved for children ages 5-11. Moderna and Johnson and Johnson are available for adults ages 18 and older.





FORMULATION: 5 Through 11 Years of Age
Pfizer-BioNTech COVID-19 Vaccine
Vaccine Preparation and Administration Summary



Administer the Vaccine

| | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Assess recipient status:</p> <ul style="list-style-type: none">• Screen for contraindications and precautions.• Review vaccination history.• Review medical considerations.  | <p>Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle* to withdraw and administer the vaccine. Ensure the prepared syringe is not cold to the touch. Check the age indications on the vial label, again, to ensure it is the correct formulation based on the age of the recipient.</p>  |
| <p>Choose the correct vaccine formulation based on the age of the recipient and equipment, including the correct needle size.</p> <ul style="list-style-type: none">• Check the age indications on the label. The vial for children 5 through 11 years of age has a orange cap and may have an orange border on the label. Do NOT administer vaccine that has a purple cap or purple bordered label on the vial to children younger than 12 years.• Use a new, sterile needle and syringe for each injection. Use 1 mL low-dead volume syringes to withdraw the vaccine. If sufficient low-dead volume syringes are not available, withdraw vaccine using a combination of low dead-volume syringes and non-low dead-volume syringes.  | <p>Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.</p>  |
| <p>Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.2 mL of mixed vaccine into the syringe.</p> <ul style="list-style-type: none">• Regardless of the type of syringe used, ensure the amount of vaccine in the syringe equals 0.2 mL.• If the amount of vaccine remaining in the vial  | <p>Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients older than 2 years of age (if tolerated).</p>  |
| | <p>Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle. As an alternative, the vastus lateralis muscle may be used.</p>  |
| | <p>Observe recipients after vaccination for an immediate adverse reaction:</p> <ul style="list-style-type: none">• 30 minutes: Persons with a history of:<ul style="list-style-type: none">» A contraindication to another type of COVID-19 vaccine product.» Immediate (within 4 hours of exposure) non-  |

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

| | Formulation for ≥12-year-olds (purple cap) | Formulation for 5–11-year-olds (orange cap) |
|---------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Age group | 12 years and older | 5-11 years |
| Vial cap color |  |  |
| Dose (mRNA concentration) | 30 ug | 10 ug |
| Injection volume | 0.3 mL | 0.2 mL |
| Fill Volume (before dilution) | 0.45 mL | 1.3 mL |
| Amount of Diluent* Needed per vial | 1.8 mL | 1.3 mL |
| Doses per Vial | 6 (after dilution) | 10 (after dilution) |

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)

Modified from: <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

Storage for Pfizer-BioNTech COVID-19 Vaccines

| | Formulation for ≥12-year-olds (purple cap) | Formulation for 5–11-year-olds (orange cap) |
|--------------------------------------------------|-----------------------------------------------|------------------------------------------------|
| Storage conditions | | |
| Ultralow temperature freezer (-90°C to -60°C) | 9 months | 6 months |
| Freezer (-25°C to -15°C) | 2 weeks | N/A |
| Refrigerator (2°C to 8°C) | 1 month | 10 weeks |
| Room Temperature (20-25°C): | 6 hours | 12 hours |

Date information for Vaccine

| | Formulation for ≥12-year-olds (purple cap) | Formulation for 5–11-year-olds (orange cap) |
|-------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| |  |  |
| Dating | Expiration Date | Manufacture Date |
| FDA Extended Dating | Yes | No |



Ordering COVID-19 vaccine

- Register as a [COVID Vaccine Provider Site](#)
- All vaccine comes from the state, we encourage you to order directly
- State is providing smaller order volumes
 - 300, hoping to offer in 100 doses soon
- Ancillary supplies come with shipment
- Order by Wednesday to receive the next week
- Children's Mercy can help

Observation

| Auto-Injector | Epinephrine Concentration | Patient Weight |
|--------------------------------------------------------------------|---------------------------|-------------------------|
| EpiPen® Auto-Injector Epinephrine, USP Auto-Injector 0.3 mg | 0.3 mg (0.3 mL) | ≥30 kg (≥66 pounds) |
| EpiPen Jr® Auto-Injector Epinephrine, USP Auto-Injector 0.15 mg | 0.15 mg (0.3 mL) | 15-30 kg (33-66 pounds) |

- Most patients require 15 min observation, some require 30
- Emergency plan available for anaphylaxis
- Emergency medications on hand
 - (EpiPen, EpiPen Jr., Benadryl)
- 1-800-GO-MERCY or EMS

Updated
Documents

Pfizer-BioNTech Fact Sheets (English) and FAQs

| Fact Sheet / FAQs | Vaccine Recipient Group | Last Updated |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------------|
| For Healthcare Providers | 12 years of age and older, purple cap (must dilute) | October 29, 2021 |
| For Healthcare Providers | 12 years of age and older, gray cap (no dilution) <i>This formulation is not yet available in the United States.</i> | October 29, 2021 |
| For Healthcare Providers | 5 - 11 years of age, orange cap (must dilute) | October 29, 2021 |
| For Recipients and Caregivers | 12 years of age and older | October 29, 2021 |
| For Recipients and Caregivers | 5 - 11 years of age | October 29, 2021 |
| Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine | All | November 4, 2021 |

FDA Comirnaty and Pfizer-BioNTech COVID-19 Vaccine

We are here to help!

- For questions or help with
 - Obtaining vaccine
 - Training for drawing up vaccine
 - Administering vaccine
 - Anything pediatric COVID-19 vaccine related

Email us:
physicianservices@cmh.edu



