COVID-19 Vaccines for 5- to 11-Year-Olds: WHAT WE KNOW NOW

Please join the Illinois Department of Public Health (IDPH) and the Illinois Chapter, American Academy of Pediatrics (ICAAP) for a webinar on

WEDNESDAY, OCTOBER 20 • 10:00AM

Register at https://illinoisaap.org/events/

Information current as of 10/19/21 and is subject to change.
Pediatric COVID-19 Vaccines: What We Know Now

Heidi Clark
Division Chief, Infectious Diseases
October 20, 2021
Information current as of 10/19/21

- Information shared is most up to date information we have from CDC.
- Information is subject to change, based on EUA issuance, ACIP and CDC recommendations, and evolving CDC guidance
- IDPH will continue to provide information to providers through SIREN alerts and webinars
Timeline for pediatric (5-11) authorization

- VRBPAC meeting 10/26
- ACIP meeting 11/2-11/3
- Anticipated first date of pediatric (5-11) vaccination 11/4/21
- Preordering begins this week
- Vaccine won’t ship until EUA issuance
- Vaccine cannot be administered until ACIP/CDC recommendations are issued
Pfizer-BioNTech COVID-19 Vaccines
PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL

<table>
<thead>
<tr>
<th>Description</th>
<th>Current Adult/Adolescent Formulation (1,170 and 450 packs)</th>
<th>Future Pediatric Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dilute Prior to Use</td>
<td>Dilute Prior to Use</td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td>12 years and older</td>
<td>5 to &lt;12 years**</td>
</tr>
<tr>
<td><strong>Vial Cap Color</strong></td>
<td>Purple</td>
<td>Orange</td>
</tr>
<tr>
<td></td>
<td><img src="image1" alt="Vial Cap Purple" /></td>
<td><img src="image2" alt="Vial Cap Orange" /></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>30 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td><strong>Injection Volume</strong></td>
<td>0.3 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td><strong>Fill Volume</strong></td>
<td>0.45 mL (before dilution)</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Amount of Diluent</strong>*</td>
<td>1.8 mL</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Doses per Vial</strong></td>
<td>6 doses per vial (after dilution)</td>
<td>10 doses per vial (after dilution)</td>
</tr>
</tbody>
</table>

**Storage Conditions**

- **ULT 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

**NOTE:** Use of the current adult/adolescent formulation (purple cap) to prepare doses for children 5 to <12 years old would result in an injection volume for the 10mcg dose of 0.1mL, which is both generally considered too small for typical IM injections and has not been studied.

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

**The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 5 to <12 years old.**

Q: Can the current adult/adolescent formulation (purple cap) be used to vaccinate children 5 to <12 years old once the vaccine is authorized for this age group?

A: No. For children under 12 years of age, you cannot use the current formulation and will need to use the future pediatric (orange cap) formulation.

**Purple Cap – Adult/Adolescent:** Authorized only for aged 12 years and older

**Orange Cap – Pediatric:** Future authorization for aged 5-to 12 years. A separate vaccine formulation specific for a 10mcg dose will be introduced.
Pediatric vaccine shipments

- New product configuration will be 10 dose vials in packages of 10 vials (100 dose trays)
  - Week one order minimum is 300 doses and increments of 300 doses
  - Subsequent week orders will be minimum of 100 doses and increments of 100 doses
- Providers are encouraged to consider second dose needs when planning their orders
- Adult/adolescent Pfizer vaccine will not ship the first week pediatric vaccine is being distributed
Get ready in I-CARE

• Prior to placing an order, ensure the following information is completed or updated:
  • Temperature logs for all appliances are up to date.
  • All data logger certificates of calibration are valid and not expired.
  • All temperature excursions have a vaccine incident report on file.
  • No expired vaccines are showing in the clinic’s inventory.
  • The clinic’s inventory in I-CARE matches the physical inventory.
  • The clinic’s inventory in I-CARE is not showing any negative balances.
  • Clinic must be open at least three days a week with at least four consecutive hours a day to be able to receive a delivery. Delivery hours must be entered and updated in I-CARE, including specifying if the clinic is closed during lunch or other hours, when placing orders through I-CARE.
Models for managing tray sizes

- Practices that are unable to utilize the number of doses distributed in a minimum order are encouraged to consider prudent inventory management:
  - Partner with other providers in a hub and spoke model
  - Utilize the Vaccine Matchmaker Tool
  - Work with your local health department to obtain smaller amounts of vaccine
- If you utilize these options, ensure you are familiar with proper cold storage and handling during transfers and complete the appropriate paperwork with IDPH so your inventory remains up-to-date
- Only transfer vaccine to providers with approved COVID-19 provider agreements (PINs start with “v”)

IDPH
Preparing for rollout

• Prepare all in your practice for rollout
• Communicate with parents about expectations
• Ensure staff are equipped and trained to respond to possible severe allergic reactions
• Consider co-administration of COVID-19 vaccines with influenza and other childhood vaccines, when appropriate
• Consider offering COVID-19, influenza, or other routine vaccines, as feasible, to additional eligible persons (e.g., siblings, family members, community members) when vaccinating the pediatric population
• Plan clinics according to timelines for authorizations and shipment of vaccines
  – Consider second dose timing when scheduling clinics
Other Considerations

• COVID-19 vaccines can be administered without regard to timing
• Reminder: Providers are required to report certain adverse events following COVID-19 vaccination to VAERS and support providers in encouraging parents or guardians to enroll their children in v-safe
  – Administration errors are reportable in VAERS
• Training will be required for all providers administering vaccine
• Vaccines.gov will have pediatric Pfizer listed separately from adult Pfizer
  • Please make sure to update your vaccine availability on vaccines.gov
• Please complete the pediatric vaccine readiness survey
COVID-19 VACCINES FOR CHILDREN

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Instructor of Pediatrics, Northwestern University Feinberg School of Medicine
COVID-19 Vaccines for Adolescents

- About 46% of 12- to 17-year-olds in the U.S. are fully vaccinated
  - Recently, the number of children being vaccinated each week is declining

![Daily Reported Administered Vaccine Doses, Ages 12+](chart.png)
Hot off the Press!!!
CDC MMWR Data for **Adolescents**

Vaccinate adolescents 12–18 years of age as soon as possible to prevent serious illness from COVID-19

CDC MMWR Early Release **10/19/2021** (Yesterday!)
https://www.cdc.gov/mmwr/volumes/70/wr/mm7042e1.htm?s_cid=mm7042e1_w
COVID-19 Vaccines for Adolescents

Lessons learned:

- Initial rush of “vaccine ready” children with a taper shortly after
- This taper is the where pediatricians and trusted messengers can impact vaccine decision making
- Families trust pediatricians
- Many parents feel most comfortable with their child receiving the vaccine in their medical home
- Logistical challenges and barriers to offering vaccine in primary care clinics
COVID-19 Vaccines for Children 5-11 will be available very soon...

- **October 26:** Pfizer-BioNTech vaccines for 5-11 year olds will be discussed by the FDA Vaccines and Related Biological Products Advisory Committee

- **Nov 2-3:** CDC Advisory Committee on Immunization Practices (ACIP) meets and reviews safety/effectiveness in the context of clinical and epidemiological risks of COVID in 5-11 year olds

- Pending FDA authorization and CDC recommendations, the vaccine will likely become available for children 5-11 (week of Nov 8th)

- Distribution of pediatric COVID-19 vaccine begins
COVID-19 Vaccines for Children

- AAP hopes providers will be prepared to engage the public immediately upon EUA issuance and recommendation of the vaccine for ages 5-11.

- Your strong recommendation as the child’s pediatrician matters most to parents.
Parents Are Most Likely To Trust Pediatricians To Provide Reliable Information About The COVID-19 Vaccine For Children

Percent of parents who say trust each of the following **a great deal or a fair amount** to provide reliable information about the COVID-19 vaccines for children:

<table>
<thead>
<tr>
<th>Source</th>
<th>Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Their child’s pediatrician</td>
<td>78%</td>
</tr>
<tr>
<td>The CDC</td>
<td>66%</td>
</tr>
<tr>
<td>Their local public health department</td>
<td>62%</td>
</tr>
<tr>
<td>Their health insurance company**</td>
<td>58%</td>
</tr>
<tr>
<td>Their employer*</td>
<td>53%</td>
</tr>
<tr>
<td>Their child’s school/daycare</td>
<td>44%</td>
</tr>
<tr>
<td>Other parents</td>
<td>38%</td>
</tr>
</tbody>
</table>

NOTE: *Among those who are employed and not self-employed. **Among those who are insured. See topline for full question wording.

Parents’ Intentions and Perceptions About COVID-19 Vaccination for Their Children: Results From a National Survey

Table 4: Parents’ Level of Trust in Sources of Information

<table>
<thead>
<tr>
<th>Sources of Information about COVID-19 vaccine, %</th>
<th>Trust Completely</th>
<th>Trust Mostly</th>
<th>Trust Somewhat</th>
<th>Do Not Trust</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child’s doctor</td>
<td>35.7</td>
<td>36.1</td>
<td>21.3</td>
<td>4.4</td>
<td>2.5</td>
</tr>
<tr>
<td>Child’s school or school district</td>
<td>9.9</td>
<td>23.4</td>
<td>35.6</td>
<td>17.5</td>
<td>13.6</td>
</tr>
<tr>
<td>Your local public health department</td>
<td>11.4</td>
<td>31.4</td>
<td>40.9</td>
<td>15.4</td>
<td>0.8</td>
</tr>
<tr>
<td>The CDC</td>
<td>21.1</td>
<td>29.0</td>
<td>29.5</td>
<td>19.8</td>
<td>0.7</td>
</tr>
<tr>
<td>AAP</td>
<td>18.6</td>
<td>29.1</td>
<td>35.0</td>
<td>15.1</td>
<td>2.3</td>
</tr>
<tr>
<td>Your close friends and members of your family</td>
<td>5.8</td>
<td>24.0</td>
<td>50.7</td>
<td>18.4</td>
<td>1.1</td>
</tr>
<tr>
<td>Your co-workers, classmates, other acquaintances</td>
<td>2.2</td>
<td>14.4</td>
<td>48.6</td>
<td>32.5</td>
<td>2.3</td>
</tr>
<tr>
<td>Social media (e.g., Facebook, Instagram, Twitter)</td>
<td>0.9</td>
<td>3.7</td>
<td>33.7</td>
<td>59.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Vaccine approval or development process, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government approval process for COVID-19 vaccine for child</td>
<td>9.3</td>
<td>30.0</td>
<td>28.3</td>
<td>32.4</td>
<td>—</td>
</tr>
<tr>
<td>Vaccine development process in general for child</td>
<td>12.8</td>
<td>34.1</td>
<td>29.0</td>
<td>24.1</td>
<td>—</td>
</tr>
</tbody>
</table>

Note: —, not applicable.

* The parent-child pair was the unit of analysis. Parents’ sampling weights were used in the analyses to account for design effects.
### Parents Whose Child's Pediatrician Recommended The COVID-19 Vaccine Are Far More Likely To Say Their Child Has Been Vaccinated

Thinking about your child between the ages of 12 and 17, have they received at least one dose of a COVID-19 vaccine, or not? IF NOT: As you may know, the FDA has authorized the Pfizer COVID-19 vaccine for use in children ages 12 and up. Thinking about your child between the ages of 12 and 17, do you think you will...?

<table>
<thead>
<tr>
<th>Option</th>
<th>Child is vaccinated</th>
<th>Get them vaccinated right away</th>
<th>Wait and see</th>
<th>Only if required</th>
<th>Definitely not</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child's pediatrician recommended vaccine</td>
<td>75%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not discuss/pediatrician did not recommend</td>
<td>31%</td>
<td></td>
<td>28%</td>
<td>11%</td>
<td>23%</td>
</tr>
</tbody>
</table>

NOTE: Among parents or guardians of children ages 12-17. April 2021 question wording: "Once there is a COVID-19 vaccine authorized and available for your child's age group, do you think you will...?" See topline for full question wording.


Kaiser Family Foundation, August 2021
COVID-19 Vaccines for Children

■ Despite this, only 1/3 of parents have talked with their pediatrician re: COVID-19 vaccine*

■ Leaves us with a large opportunity for outreach and connection surrounding COVID-19 vaccines

*Kaiser Family Foundation, August 2021
COVID-19 Vaccines for Children

■ Top concerns*:
  - Potential long-term effects (88%)
  - Vaccine side effects (79%)
  - Fertility concerns (73%)
  - Potential vaccine mandates for their children (65%)

■ Other concerns:
  - Why does my child need the vaccine? Kids aren’t affected by COVID-19
  - Trust in vaccine development and approval process, rushed
  - General apprehension due to young age, concern for long-term effects

*Kaiser Family Foundation, August 2021
Younger Age = Parents are Less “Vaccine Ready”

Parents’ response to the question, “If a vaccine against the coronavirus becomes available for children, do you plan to get [child’s name] vaccinated?”

SO WHAT CAN WE DO?
The goal is for children to be able to receive the COVID-19 vaccine in their medical home.
1. Parents **trust their child’s pediatrician**. Pediatricians are authorities and experts on vaccines.

2. Pediatric practices **have experience giving vaccines** to children.

3. After the initial surge of “vaccine ready” children, the hard work begins—**opportunities for conversation & intervention**.

4. Many adult-serving facilities and pharmacies will not feel comfortable vaccinating children. Many parents will not feel comfortable having their children vaccinated there either.

5. Elevating the role of pediatric offices in COVID-19 vaccine distribution will encourage an **increase in routine immunizations missed** during this pandemic.
   
   - Especially for clinicians who serve children/youth with special health care needs and those in under-resourced areas.
Logistical Challenges

- Obtaining and storing vaccine
- Obtaining the right amount of vaccine, avoiding waste
- Staffing – provider, RN, MA, front desk, etc
- Scheduling and outreach
- Documentation
- Reimbursement
- Provider/staff education
- Patient interest/demand matching supply
Planning Pearls

■ 1. Start preparing now: Enroll to administer COVID-19 vaccines with IDPH, CDPH, CDC, etc.
■ 4. Know other COVID-19 vaccination opportunities available in your community.

- Connect with your state immunization program for more information on COVID-19 vaccine distribution.
- Connect with other pediatric practices similar to yours.

@NinaAlfieriMD
Planning Pearls

■ 1. Start preparing now: Enroll to administer COVID-19 vaccines with IDPH, CDPH, CDC, etc.


■ 4. Know other COVID-19 vaccination opportunities available in your community.

• In clinic visits and with broader outreach to your patient population: Social media, texting, MyChart or however your practice reaches patients.

• Unify entire clinic staff around vaccination so families hear consistent messaging.

• Leverage pre-existing resources and handouts (see last slide).
Planning Pearls

■ 1. Start preparing now: Enroll to administer COVID-19 vaccines with IDPH, CDPH, CDC, etc.


■ 4. Know other COVID-19 vaccination opportunities available in your community.

• CDC released “Pediatric COVID-19 Vaccination Operational Planning Guide” (last slide).
• Consider staffing model – vaccine clinics vs offering anytime.
• Offering vaccine to entire families can increase population uptake of vaccine.
• Can co-administer COVID vaccine with others.
• Have a plan for anaphylaxis (extremely rare).
Planning Pearls

- 1. Start preparing now: Enroll to administer COVID-19 vaccines with IDPH, CDPH, CDC, etc.
- 4. Know other COVID-19 vaccination opportunities available in your community.

- Mass vaccination sites can help offload initial “vaccine ready” volume.
- Vaccines.gov/search/ search by product and zip code.
- Parents can also text their ZIP code to 438829 (GETVAX); or call 1-800-232-0233.

@NinaAlfieriMD
Summary

■ COVID-19 vaccines for children 5-11 are coming in the next few weeks.

■ Have a plan for vaccine access that is equitable and includes outreach to families and communities with concerns about the vaccine.

■ Now is the time to promote messaging to families about the importance of COVID-19 vaccination for children and adolescents and start planning vaccine logistics.
Thank you

■ Helpful Resources
  - ICAAP: COVID-19 Immunization Campaign
  - AAP: Critical updates on COVID-19
  - CDC “How to Talk with Parents about COVID Vaccination”
    https://www.cdc.gov/vaccines/covid-19/hcp/pediatrician.html
  - AAP: COVID-19 Vaccine - What Pediatricians Can do Now
  - CDC Pediatric COVID-19 Vaccination Operational Planning Guide:
  - Pfizer Peds One Pager:
  - Sign up for CDPH’s Health Advisory Network (HAN) Alerts:
    https://www.chicagohan.org/