Pediatric COVID-19 Vaccines

Training Supplement

November 5, 2021
Information current as of 11/04/2021

• Information shared is most up to date information we have from CDC.
• Information is subject to change based on evolving CDC guidance.
• IDPH will continue to provide information to providers through SIREN alerts and webinars.

• This presentation is not meant to be a complete training. Additional trainings are required and are shown later in this slide deck.
Preparing for Rollout
Preparing for rollout

• Prepare **all** in your practice for rollout
• Communicate with parents about expectations and address COVID-19 vaccine hesitancy
• Ensure staff are equipped and trained to respond to possible severe allergic reactions. Carry age-appropriate emergency supplies on hand.
• Consider co-administration of COVID-19 vaccines with influenza and other childhood vaccines, when appropriate
• Consider offering COVID-19, influenza, or other routine vaccines to additional eligible persons (e.g., siblings, family members, etc.) when vaccinating the pediatric population
Talking to Parents about COVID-19 Vaccination

- **How to Talk with Parents about COVID-19 Vaccination** web page provides information about the benefits of vaccination, vaccine coadministration, vaccine confidence, and more.

**How to Talk with Parents about COVID-19 Vaccination**

Tips for Pediatricians, Family Medicine Practitioners, Pharmacists & Other Pediatric Providers

Parents consider their child's healthcare providers to be their most trusted source of information when it comes to vaccines. You play a critical role in helping them understand the importance of COVID-19 vaccination and assuring them that COVID-19 vaccines are safe and effective.
Pediatric Vaccine Reporting on Vaccines.gov

- Updating vaccine inventory daily is required.
- Pfizer pediatric vaccine (age 5-11) can be added as reportable inventory in the COVID Locating Health Portal.
- Use the “Add Vaccine” option to add NDCs to your location to report inventory doses.
- Vaccines.gov will be updated to include a search field for the Pfizer BioNTech (age 5-11) vaccine.
- Guides for reporting inventory and public display information can be found on our Provider Resources page.
Formulations and Packaging
## Current and Future Pfizer Formulations

<table>
<thead>
<tr>
<th>Description</th>
<th>Dilute Before Use</th>
<th>Do Not Dilute</th>
<th>Dilute Before Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age Group</strong></td>
<td>12 years and older</td>
<td>12 years and older</td>
<td>5 through 11 years (&quot;Age 5y to - 1.2y&quot; on vial label)</td>
</tr>
<tr>
<td><strong>Vial Cap Color</strong></td>
<td>PURPLE</td>
<td>GRAY</td>
<td>ORANGE</td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>10 mcg</td>
</tr>
<tr>
<td><strong>Dose Volume</strong></td>
<td>0.3 mL</td>
<td>0.3 mL</td>
<td>0.2 mL</td>
</tr>
<tr>
<td><strong>Amount of Diluent Needed per Vial</strong></td>
<td>1.8 mL</td>
<td>NO DILUTION</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Doses per Vial</strong></td>
<td>6 doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
</tr>
<tr>
<td><strong>Emergency Use Authorization (EUA) Fact Sheet</strong></td>
<td>Click here</td>
<td>Click here</td>
<td>Click here</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Storage Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ultra-Low-Temperature (ULT) Freezer</strong> [-90°C to -60°C]</td>
</tr>
<tr>
<td><strong>Freezer</strong> [-25°C to -15°C]</td>
</tr>
<tr>
<td><strong>Refrigerator</strong> [2°C to 8°C]</td>
</tr>
<tr>
<td><strong>Room Temperature</strong> [8°C to 25°C]</td>
</tr>
<tr>
<td><strong>After First Puncture</strong> [2°C to 25°C]</td>
</tr>
</tbody>
</table>

¹ Diluent: sterile 0.9% Sodium Chloride Injection, USP. Bacteriostatic saline or other diluents must NOT be used.

² Regardless of storage condition, vaccine should not be used past the 9 month expiry (6 months printed on the vial plus additional 3 months).

³ Regardless of storage condition, vaccine should not be used after 6 months from the date of manufacture printed on the vial and carton.
Color-Coded EUA Fact Sheets for All Formulations are Updated

Current Formulation for ages ≥12 years.

Future Formulation for ages ≥12 years.

Current Formulation for ages 5 through 11 years
EUA Fact Sheets for Pfizer Pediatric Vaccine

- EUA Fact Sheet for Providers posted on 10/29/2021
  - COVID-19 Pfizer Pediatric Tris-sucrose Vaccine EUA Fact Sheet for Recipients
  - COVID-19 Pfizer Pediatric Tris-sucrose Vaccine EUA Fact Sheet for Providers
- The Pfizer Pediatric Vaccine for 5 through 11 years of age has an orange outline around the age group on the EUA fact sheet and elsewhere throughout the document.
Current Formulations:

<table>
<thead>
<tr>
<th>Vial Cap &amp; Label Border Colors</th>
<th>PURPLE</th>
<th>ORANGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Dilute Before Use</td>
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</tr>
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<td>Doses per Vial</td>
<td>6 doses per vial (after dilution)</td>
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</tbody>
</table>

**Storage Conditions**

- ULT Freezer (-90°C to -60°C)
  - 9 months**
  - 6 months***
- Freezer (-25°C to -15°C)
  - 2 weeks
  - DO NOT STORE
- Refrigerator (2°C to 8°C)
  - 1 month
  - 10 weeks
- Room Temperature (8°C to 25°C)
  - 2 hours prior to dilution (including any thaw time)
  - 12 hours prior to first puncture
- After First Puncture (2°C to 25°C)
  - Discard after 6 hours
  - Discard after 12 hours

Adult/Adelescent (ages 12 years and older) Purple Cap Vaccine and Pediatric (ages 5 to 11 years) Orange Cap Vaccine have many important differences in dosage, preparation, and storage. These are further described on the following pages.
Dosage and Preparation Differences

Key Differences:

- **Dose** - Orange cap dose is 10 micrograms
- **Dose Volume** - Orange cap dose volume is 0.2 mL
- **Diluent Volume** - Orange cap diluent volume needed is 1.3 mL
- **Doses per Vial** - Orange cap formulation has 10 doses per vial
Key Differences:

- **Storage and Handling** - Orange cap formulation may not be stored in a standard freezer.
- **Also**, note important differences in expirations after ultra-low freezer, refrigerator, or room temperature storage times.
- **Expiration after first puncture** - Orange cap formulation expires 12 hours, post-dilution.
Pfizer Pediatric Formulation Packaging

- Pediatric vials come packaged in cartons of 10 vials each.
- Vials come with a distinctive orange cap, orange striping on the label, and orange striping on the carton.
- Box dimensions: 37mm x 47mm x 89 mm.

The Adult/Adolescent formulations (current purple cap or future gray cap) should NOT be used to vaccinate children 5 through 11 years of age.
Manufacturer versus Expiration Date

- The date on the orange cap formulation are being notified that the date on the **vial** is the date of **manufacture**.
  - Note: this differs from the purple cap formulation vial label
- The date on the orange cap formulation vial label is **NOT** the expiration date.
- Pfizer does not have an expiration look-up tool.
- CDC will have clinical materials to assist with tracking expiration and beyond-use dates posted soon.
- The first shipments of vaccine included doses manufactured several months ago. Therefore, the expiration dates will be less than 6 months from receipt of the doses.
Manufacturer versus Expiration Date

Example:
• This vial shows a manufacturing date of 08/2021 (month+year)
• Manufacture date + 6 months = Expiration date
• The month of manufacture is included in the 6 months. In the image below, 08/2021 includes August. It does not start in September.
• The expiration date is January 31, 2022. The vial may be used from August 1, 2021 to January 31, 2022 if stored at appropriate temperatures per the EUA.
• If the orange cap formulation is not stored in ultra-low temperatures, it will expire prior to the 6 month expiration date.
Shippers and Storage and Handling
Shippers

• Pfizer orange cap vaccine will ship from Pfizer on dry ice.
• Shipping containers are smaller than the adult dose shippers.
• These shippers cannot be used for temporary storage.
• The contents **MUST** be removed from the shipper and placed in an **ultra-cold freezer** or a **refrigerator** as soon as it is received.
• An orange sticker has been added to the shipper boxes as a reminder not to store contents in a standard freezer.
Controlant Data Logger

• Shipping boxes will continue to contain a Controlant temperature monitor.
• Check the temperature monitor for any excursion warnings, turn the monitor off, and return it in the package provided.
• Be sure to add these sites to your safe sender lists so that you receive order, shipping, and temperature monitoring alerts:
  – cvgovernment@pfizer.com
  – Pfizer.logistics@controlant.com
  – onsitemonitoring@controlant.com
Pfizer Pediatric Cold-Chain Storage

- The table below indicates the length of time the pediatric vials can be stored at each temperature.
- Once product is thawed, do not refreeze.
- Note, the 10 weeks in the refrigerator is **not** in addition to the 6 months from the manufacture date in the ultra-low freezer. All conditions for storage must be completed within the overall timeframe for expiration.
- Expired vaccine should be discarded regardless of storage conditions.
- Do not store Pfizer pediatric vaccine in a standard freezer.

<table>
<thead>
<tr>
<th>Storage Conditions</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>ULT Freezer (-90°C to -60°C)</td>
<td>6 months</td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>N/A</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C)</td>
<td>10 weeks</td>
</tr>
</tbody>
</table>
Clinical Considerations
Pediatric Clinical Considerations

- Review all changes in the Interim Clinical Considerations for Use of COVID-19 Vaccines and related job aids: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

- Pediatric changes include but are not limited to:
  - Clinical recommendations and dosing, including recommendations for children that will turn 12 between their first and second doses in the primary series
  - Data from clinical trials
  - Reactogenicity and adverse events
  - Myocarditis and Pericarditis
  - Ingredient list, including information new tris-sucrose buffer information
  - Coadministration considerations
  - Vaccination of people with a history of MIS-C
  - Management of post-covid symptom
Important CDC Web Pages for Healthcare Professionals

• Information for Jurisdictions, Healthcare Providers, Pharmacists and Community Partners: COVID-19 Vaccination for Children 5-11 Years Old | CDC
  – More pediatric-specific information will be posted here as it becomes available.

• Interim Clinical Considerations for Use of COVID-19 Vaccines and related job aids: Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

• Pfizer BioNTech COVID-19 Vaccine brand-specific Information: Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC
  – Contains storage and handling information, sample screening forms, sample standing orders, preparation and administration information, and other resources.

• We expect the above resources to be updated for the Pfizer BioNTech COVID-19 Pediatric vaccine for ages 5 through 11 years sometime in the days after ACIP Recommendation.
CDC Clinical Resources will be updated soon to reflect Pediatric (age 5 to 11 years) dosing
CDC COVID-19 Vaccine Web Page for Parents and Guardians


• Site includes information on COVID-19 vaccine benefits, safety, side effects, and where to find a vaccine.
Training
Required Training and Education

• A variety of healthcare professionals and personnel will be needed to implement COVID-19 vaccination efforts. These include:
  – Experienced vaccinators (administered vaccine within past 12 months)
  – Vaccinators with past experience (administered vaccine >12 months ago)
  – Medical support staff qualified to prepare, store, handle, or transport vaccine
  – Administrative support staff qualified to store, handle, or transport vaccine

• See Chart for Training Competencies by professional qualification

• Some trainings are pending pediatric dose updates. Changes are expected in the coming days after ACIP recommendation.

• Complete the [COVID-19 Vaccine Administration Competencies Assessment Form (CDC)](https://www.cdc.gov/vaccines/healthcare/professional/education-training/COVID-19.html) for each staff member. Providers will be required to show documentation when a site visit is performed.
<table>
<thead>
<tr>
<th>Training or Core Competency</th>
<th>Healthcare professionals who have administered vaccine in the last 12 months</th>
<th>Healthcare professionals who are licensed to administer COVID-19 vaccine but have not done so in the last 12 months</th>
<th>Vaccination support workers (not licensed to administer vaccine) qualified to prepare, store, handle, or transport vaccine</th>
<th>Administration support staff qualified to store, handle, or transport vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC Training Module(s) for the vaccine product(s) in your facility</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td><strong>You Call the Shots: Vaccine Administration</strong> or other vaccine administration training completed within the last 12 months.</td>
<td>Required</td>
<td>Required</td>
<td>If preparing vaccine</td>
<td></td>
</tr>
<tr>
<td><strong>You Call the Shots: Vaccine Storage and Handling</strong> or other vaccine storage and handling training completed within the last 12 months.</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Relevant information contained in the <a href="#">EUA Fact Sheet(s) for Healthcare Providers</a> for the vaccine product(s) in your facility.</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
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<tr>
<td>Clinical considerations</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Storage and handling requirements</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
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<tr>
<td>Transport guidance</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Preparation requirements</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Administration requirements</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Anaphylaxis guidance</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Vaccination documentation and reporting requirements</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
<tr>
<td>Required and additional information for vaccine recipients</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
<td>Core Competency</td>
</tr>
</tbody>
</table>
Pfizer COVID-19 Vaccine Medical Updates

• Pfizer Vaccines US Medical Affairs is hosting training sessions for ALL providers and their staff on the current & potential new formulations of its COVID-19 vaccine.
• These sessions will be updated to reflect new information and changes as they evolve.
• Weblinks for future training sessions will provided at a later date.
# Pfizer COVID-19 Vaccine Medical Updates

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Password</th>
</tr>
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<tbody>
<tr>
<td>Attendee link - November 5 - 12 PM ET</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Attendee link - November 9 - 5 PM ET</td>
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</tr>
<tr>
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<td>Attendee link - November 24 - 12 PM ET</td>
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</tr>
</tbody>
</table>

Click the links to join the sessions at the designated times.

Preregistration is not required.
Pediatric COVID-19 Vaccine COCA Call 11/4/2021

Pediatric COVID-19 Vaccines: CDC’s Recommendations for COVID-19 Vaccine Primary Series in Children 5-11 years old

**When:** Thursday, November 4, 2021, 2:00 PM – 3:00 PM ET

Additional information and a recording of the call will be posted at: https://emergency.cdc.gov/coca/calls/2021/callinfo_110421.asp
Adverse Events and Managing Anaphylaxis
Preparing for Management of Anaphylaxis

The Interim Consideration: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination webpage has been updated to include considerations for children aged 5 to 11 years.

- Assure that staff are trained to recognize and respond to anaphylaxis in children aged 5 to 11 years.
- Facilities should ensure they have age and size appropriate emergency supplies on hand.
- Children <25 kg (55 lbs) require lower dosing of epinephrine for management of anaphylaxis.
- Pediatric autoinjectors are available in 0.15 mg and 0.30 mg doses. These will not be supplied through state or federal agencies but may be procured through your usual supply chain vendors.
Encourage Enrollment in V-safe

- **V-safe** is a smartphone app for reporting any side effects after getting the COVID-19 vaccine directly to the CDC.
- Parents or Guardians may enroll vaccinated children in v-safe.
Healthcare providers are **required** to report the following adverse events to the Vaccine Adverse Event Reporting System (VAERS):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events‡ (irrespective of attribution to vaccination),
- cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
- cases of COVID-19 that result in hospitalization or death.

‡See EUA Fact Sheet for Providers for definition of serious adverse events

Complete and submit reports to VAERS online [here](#).
Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the downloadable PDF. New!

Important: if you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.
Preventing Errors
Preventing Errors: Select Correct Vial for Age

• Check the vial label 3 TIMES to assure that you are administering the appropriate product for the patient age:
  – For Pediatric patients 5 through 11 years of age, verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states "Age 5y to < 12y."
Preventing Errors: Considerations to Ensure Vaccine is not Expired

Tip #1:

• Use Beyond Use Date labels while vaccine is in storage. This example is for the Purple Dose formulation. Check the CDC web site for a Pediatric Beyond Use Date label or create your own.
Preventing Errors: Considerations to Ensure Vaccine is not Expired

Tip #2:
- Mark the puncture information on the vial label
  - Record date and time of first vial puncture on the vial label.
  - Store between 2°C to 25°C (35°F to 77°F).
  - Discard any unused vaccine 12 hours after dilution.

Use within 12 hours after dilution.
Preventing Errors: Considerations to Ensure Vaccine is not Expired

Tip #3:
- Label drawn-up syringes with the vaccine information, lot number, and beyond use time (12 hours post dilution).
- The vaccine preparer should initial the label.
- Color code the label.
- Example syringe labels that you can create:
Preventing Errors:
Considerations for Time Outs & The 5 “Rights”

• Use a Time Out strategy
• More than one staff should inspect the vaccine vial for correct reconstitution, dose volume and labeling.
• Verify the Five Rights:
  – Right patient (including name and age)
  – Right vaccine
  – Right route
  – Right time
  – Right dose
• Triple check all vaccines before administration
Look-Alike-Sound-Alike Labeling

• Label vaccine storage containers, boxes and vials with Look-Alike-Sound-Alike (LASA) stickers.
  – Consider using the method you currently use for other LASA labeling.
  – If needed, pre-printed LASA stickers are available online or through your usual supply chains. Examples are shown below.
Preventing Errors:
Additional Considerations for Labeling and Storage

• Store unused vials or drawn-up syringes in a color-matched storage bin/container.

• Label the bin/container. This example is an example of a Pfizer COVID-19 vaccine storage and handling label for the purple cap formulation. Check the CDC web site for a Pfizer Pediatric Vaccine Storage and Handling label or create your own.
  – Tip: If you make your own, you can color-match the label.

• Store look-alike or sound-alike vaccines on different shelves in the cold-storage unit or in different cold-storage units.
Preventing Errors: Safety when Multiple Vaccine Formulations are Stored in the Same Facility

• Additional considerations if drawing up multiple brands or formulations of vaccine at a facility:
  – Draw them up in different areas. Label and color code those areas.
  – Label any drawn-up syringes with color-coded labels, as previously shown.
  – Label transport containers with color-matched labels.
  – Consider hanging posters or reminders on color-matched paper.
  – If any documentation is paper-based, consider printing information or forms on color-matched paper.
Contact Information

• To enroll in I-CARE: dph.immunizations@illinois.gov

• Pfizer Customer Service, Call 1-800-879-3477

• General Product Inquiries, Call 1-877-829-2619

• Pfizer Medical Information, Call 1-800-438-1985 or Visit PfizerMedicalInformation.com

• Controlant Customer Support: 1-701-540-4039

• Pfizer US Shipment Support: Call 1-800-666-7248
Details about vaccine

- As of 10/13, over 230 million doses of Pfizer vaccine have been given in the US with few serious adverse effects.
  - Most common side effects are temporary redness and pain at the injection site, fever, headaches and tiredness. Last 1-3 days.
  - Like with adults, the Pfizer-BioNTech vaccine should not be given to anyone with a history of severe allergic reaction to any component of the vaccine.

- The vaccine for 5-11 year olds is 1/3 of the dose of the vaccine for those 12 years and above.

- It is given the same way as other routine childhood vaccines.

- It is safe for children to get the COVID-19 vaccine with other vaccines.

- **ACIP Interim Clinical Considerations have been UPDATED (11/3):**
  
  https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#children
Should I vaccinate a 5-11 yo with…

- **Underlying medical condition → YES**
- **Previous COVID-19 infection → YES**
  - recommended for everyone ages 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity.
  - >7 million adolescents ages 12–15 years have been fully vaccinated with Pfizer-BioNTech COVID-19 Vaccine in the United States and in the general population there has been no safety concerns associated with vaccination of those who had prior infection.
- **Recent COVID-19 infection → YES**
  - Defer vaccination at least until the person has recovered from the acute illness AND they have met criteria to discontinue isolation (10 days after positive test if asymptomatic or 10 days after symptom onset, >24 post-fever). Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making.
- **History of MIS-C → YES**
  - The benefits likely outweigh a theoretical risk of an MIS-like illness for people who meet all of the following criteria: 1) Clinical recovery has been achieved, including return to normal cardiac function; 2) It has been ≥90 days since their diagnosis of MIS-C; 3) They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission; 4) Onset of MIS-C occurred before any COVID-19 vaccination.

https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic
For Chicago VFC Providers

- Pediatric formulation now included in CDPH vaccine ordering REDCap survey: [https://redcap.link/COVIDVaccineDistribution](https://redcap.link/COVIDVaccineDistribution)
- Complete by Tuesday at 5pm if you need to order 100 doses or less of Pfizer peds formulation.
  - Orders >300 should be delivered by the end of the week this week or next
- For small providers who wish to offer <100 doses of vaccines to their practices can pick up smaller quantities at our West Side office (2160 W. Ogden Ave)
  - But you must order OR email covid19vaccine@cityofchicago.org
## Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

<table>
<thead>
<tr>
<th></th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age group</strong></td>
<td>12 years and older</td>
<td>5-11 years</td>
</tr>
<tr>
<td><strong>Vial cap color</strong></td>
<td><img src="image1" alt="Purple cap" /></td>
<td><img src="image2" alt="Orange cap" /></td>
</tr>
<tr>
<td><strong>Dose (mRNA concentration)</strong></td>
<td>30 µg</td>
<td>10 µg</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 (before dilution)</strong></td>
<td>0.45 mL</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Amount of Diluent</strong>* Needed per vial</td>
<td>1.8 mL</td>
<td>1.3 mL</td>
</tr>
<tr>
<td><strong>Doses per Vial</strong></td>
<td>6 (after dilution)</td>
<td>10 (after dilution)</td>
</tr>
</tbody>
</table>

* 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
### Formulation and dosage

**Administration errors should be reported to [VAERS](https://www.vaers.org).** Unless allowable under the FDA EUA.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>If aged 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap) / COMIRNATY inadvertently administered, resulting in a higher-than-authorized dose.</td>
<td>Do not repeat dose.¹ If the dose given in error is the first dose, administer the second Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) dose 21 days later.⁵</td>
</tr>
<tr>
<td>If aged 12–17 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose.</td>
<td>In general, do not repeat dose. However, based on clinical judgement (e.g., the adolescent received two doses of incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) may be administered at an interval of 21 days after the dose given in error. If the dose given in error is the first dose, administer the Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) dose 21 days after the last dose in order to complete the primary series.⁵</td>
</tr>
<tr>
<td>If aged ≥18 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose.</td>
<td>Repeat dose immediately (no minimum interval) with the age-appropriate dose and formulation. If the dose given in error is the first dose, administer the second dose at the recommended</td>
</tr>
</tbody>
</table>

¹ For infants and children aged ≤2 years, repeat dose immediately.

⁵ For infants and children aged ≤2 years, repeat dose immediately; if the dose given in error is the first dose, administer the second dose at the recommended interval if ≥4 weeks have passed since the dose given in error.
Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

<table>
<thead>
<tr>
<th>Storage conditions</th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultralow temperature freezer (-90°C to -60°C)</td>
<td>9 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Freezer (-25°C to -15°C)</td>
<td>2 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Refrigerator (2°C to 8°C)</td>
<td>1 month</td>
<td>10 weeks</td>
</tr>
</tbody>
</table>

***Per FDA EUA, after dilution, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution. Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. The information in this Fact Sheet supersedes the number of hours printed on vial labels and cartons.***

## Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

<table>
<thead>
<tr>
<th></th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Interval</td>
<td>3 weeks (21 days)</td>
<td>3 weeks (21 days)</td>
</tr>
<tr>
<td>Additional primary dose</td>
<td>Moderate and severe immunocompromise</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Booster dose</td>
<td>Not recommended 12–17 years</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td>Recommended for certain groups ≥18 years*</td>
<td></td>
</tr>
</tbody>
</table>

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underlying medical conditions, or who work or live in high-risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices’ Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021
• Pediatric vials come packaged in cartons of 10 vials each.

• Each vial will be filled to 1.3mL before dilution. The pediatric formula will continue to require addition of 1.3mL of diluent (1:1 ratio) to yield 10 doses per vial.

• Unlike the adult shippers, these smaller shippers cannot be used for temporary storage. The contents MUST be removed and place in a refrigerator or ultra-cold freezer as soon as the order is received.

• DO NOT store Pfizer pediatric vaccine in a standard freezer.
Pfizer Vials and Expiration Dates: Label Information

- Pfizer COVID-19 Vaccine: 5 through 11 years formulation (orange cap)
  - Formulation does NOT have expiration printed on vial
  - Instead, each vial has the lot number and date of manufacture printed on the label
  - Date on the label is NOT the expiration date

- QR code on the Pfizer Pediatric Vaccine carton
  - Links to the EUA but does not provide information on expiration dates
Diluent and Inventory Reporting

**Diluent:** Orders of Pfizer pediatric vaccine include ancillary kits that contain 10mL diluent vials. While these vials appear to contain sufficient diluent for multiple vials, they **must only be used once**.
- Diluent vials are a one-time-use item and **should be discarded with the remaining content after each use**.
- For each vial of vaccine, extract 1.3mL of diluent from a single-use vial to reconstitute 1.3mL of vaccine. Do not be tempted to puncture diluent vials more than once.

**Reporting:** Pfizer pediatric vaccine (age 5–11) NDC can now be added as reportable inventory in the COVID Locating Health Portal. Use the “Add Vaccine” option to add these NDCs to your location to report inventory doses. **CDPH will be referring parents to this data source so please keep it updated.** Following ACIP recommendation, Vaccines.gov will be updated to include a search field for the Pfizer BioNTech (age 5–11) vaccine.
Ancillary Supplies – Needle length

• Though the table is typically recommended, remember that:
  • The deltoid muscle of the arm is the preferred site for an IM injection in a child >5yo
  • The Pfizer ancillary kits will only contain 1 inch length needles
  • No need to train new staff on when to use a 5/8 inch length needle

<table>
<thead>
<tr>
<th>Children, 3–10 years</th>
<th>22–25-gauge 5/8–1 inch (16–25 mm)</th>
<th>Deltoid muscle of arm³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>22–25-gauge 1–1.25 inches (25–32 mm)</td>
<td>Vastus lateralis muscle of anterolateral thigh</td>
</tr>
</tbody>
</table>

https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf
Ancillary Supplies: Epi pen

• Ancillary supplies provided with COVID-19 vaccination program for children DO NOT include Epi Pens or Epinephrine – *no anaphylaxis noted in clinical trials*.

• COVID-19 Vaccine providers are expected to supply Epi Pens or Epinephrine and assure this emergency equipment is available during administration of vaccine to children.

• Use the Immunization Action Coalition (IAC) handout as a standing order for management of vaccine reactions: [Medical Management of Vaccine Reactions in Children and Teens in a Community Setting](https://www.immunize.org/catg.d/p3082a.pdf)
Quick Training Resources

- **You call the shots**
  - Vaccine administration module
    - (Pediatric IM admin slides 72-74):
    - [https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html](https://www2.cdc.gov/vaccines/ed/vaxadmin/va/index.html)
  - Comfort and restraint techniques
    - (3yo and over @ 3:14)
    - [https://www.youtube.com/watch?v=r1dGpTCgerE](https://www.youtube.com/watch?v=r1dGpTCgerE)
  - Intramuscular (IM) Injection: Sites
    - (3yo and over @ 2:22)
    - [https://www.youtube.com/watch?v=PqSuCPnPeYE](https://www.youtube.com/watch?v=PqSuCPnPeYE)
**BEFORE**

Make a plan.

Talk to your child about getting the vaccine.

- Tell younger children on the same day as the vaccine.
- Give older children more time to ask questions. Talk with them about a plan for the vaccine so they feel in control.

[Links to documents provided]
Comfort and Restraint Techniques

Hold child on lap turned to the side
Secure child's arm
Place one arm around child
Place child's legs between thighs
Secure legs with other hand

child's legs near the parent's thigh. If the parent or adult is

https://www.youtube.com/watch?v=r1dGpTCgerE
**HOW TO HOLD YOUR CHILD WHILE SITTING UP ON YOUR LAP**

1. Inside arm tucked under adult’s armpit
2. Adult’s hand restrains outside arm close to the child’s body
3. Child facing the adult with legs straddled over the adult’s lap with adult hugging the child on their chest

**AFTER**

Show them praise and let them know what they did well. You can say things like:

- “You did it. I know you were really nervous about that.”
- “I’m so proud of you for telling us how you feel and for holding so still.”

[Graphic images of holding a child securely]

[Website link at the bottom]
CDPH Provider Ed Videos

• 11/1 (6:17) NEW Vaccine News You Can Use
  • https://www.dropbox.com/s/36o1sf930o6w6rc/Dr.%20F%20102921_video%201.mp4?dl=0

• 11/1 (2:01) NEW Parent-friendly answers: what does COVID in kids look like and why vax 5-11 now?
  • https://www.dropbox.com/s/ahpt4e7subycpz5/Dr.%20F%20102921_COVID%20in%20kids.mp4?dl=0

• 11/1 (1:45) NEW Epi data to answer why 5-11 now?
  • https://www.dropbox.com/s/m3s51r5ug0hc0l5/Dr.%20F%20102921_5-11yo.mp4?dl=0

• 11/1 (5:12) NEW Parent-friendly facts for the COVID Vaccine Ambassador
  • https://www.dropbox.com/s/o6c37nqorb0seox/Dr.%20F%20102921_vaccine%20Ambassador.mp4?dl=0
More CDC training

- Videos and infographics here: Vaccine Administration Resource Library | CDC
- Epidemiology and Prevention of Vaccine-Preventable Diseases at Pinkbook: Vaccine Administration | CDC includes strategies to decrease anxiety and procedural pain.
- COVID-19 vaccine webinar series includes a recorded, short webinar Administering More than 1 Vaccine on the Same Day: Clinical Considerations and a webinar on Clinical Considerations: Vaccinating Adolescents at COVID-19 Vaccine Webinar Series | CDC
  - A version for younger children should be posted soon
- All COVID-19 clinical materials are here: COVID-19 Vaccination Clinical and Professional Resources | CDC
- https://www.cdc.gov/vaccines/covid-19/training-education/index.html
HFS Billing info

- All HFS Coronavirus (COVID-19) Updates: https://www2.illinois.gov/hfs/Pages/coronavirus.aspx
- HFS' COVID-19 Fee Schedule uses Medicare rates: https://www2.illinois.gov/hfs/SiteCollectionDocuments/COVID19FeeScheduleAdd0004AEffective10042021Final.pdf
- Information on billing Federal HRSA for COVID-19 Testing, Treatment, and Vaccine Administration for the Uninsured: https://www.hrsa.gov/coviduninsuredclaim