

Pfizer-BioNTech COVID-19 Vaccination in 5-11 Year Old's

November 10, 2021

Housekeeping

How to Ask Questions

- Click on the icon found at the bottom part of your screen
- A box will open where you can type in questions, comments, indicate sound problems, etc.
- Use this throughout the webinar to ask questions

Slides & Recording

 This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccineprovider

Topics Covered

Public Health Problem

Safety and Efficacy

Updated EUA

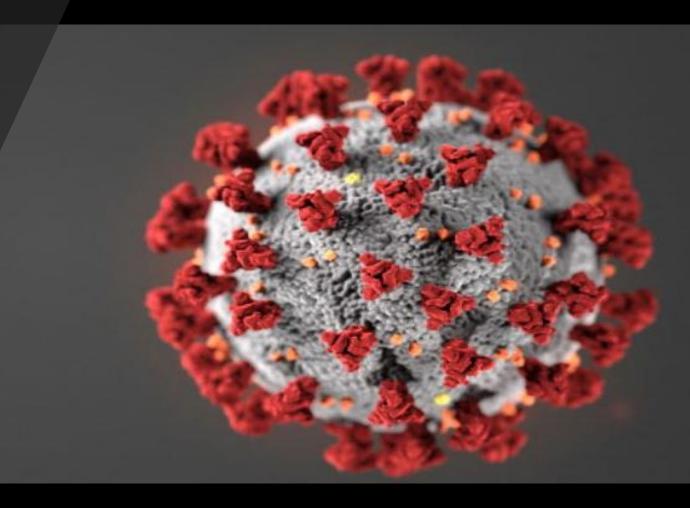
Clinical Considerations

Storage/Handling

Vaccine Preparation & Administration

Fact Check

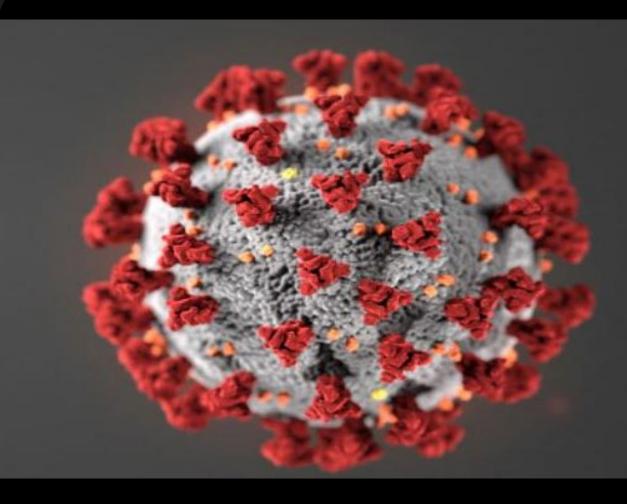
Public Health Problem



Public Health Problem: Summary of Evidence

- Children 5 through 11 years of age are at risk of severe illness from COVID-19
 - Over 1.9 million reported cases and greater than 8,300 hospitalizations through mid-October
 - Cumulative hospitalization rate similar to influenza season
 - Multisystem Inflammatory Syndrome in Children (MIS-C) most frequent among children 5–11 years
 - Other post-COVID conditions have been seen in children
- COVID-19 in children leads to missed school for themselves and their communities
- Wide use of an effective vaccine would reduce public health burden of COVID-19 in children 5 through 11 years of age

Safety and Efficacy



Safety: Reactogenicity Pfizer-BioNTech COVID-19 Vaccine, 5-11 Year Old's

- Local reactions (redness, swelling, pain at the injection site) and systemic reactions (fever, nausea/vomiting, headache, fatigue, chills, new or worsened muscle pain, new or worsened joint pain) were reported for 7 days following each dose
- 2.7% of vaccinated vs. 1.1% placebo arm had a local or systemic grade 3 or greater reaction after either dose
 - Most reactions were grade 3; 1 child in the vaccine arm had a grade 4 fever greater than 40.0° C; there were no other grade 4 reactions
 - Pain at injection site, fatigue and headache were the most common
 - More common after dose 2
- No deaths were reported among trial participants
- No cases of Myocarditis were reported among trial participants

Myocarditis: Estimated risks for every million Pfizer-BioNTech COVID-19 vaccinations in children 5-11 years of age

- Rates of myocarditis after vaccination in 5–11-year-olds unknown
- No cases occurred during clinical trials (n=3,082 with at least 7 days follow-up)
- Myocarditis after vaccination in 5–11-year-old population likely lower than rates seen in 12–15-year-olds
 - Underlying epidemiology of viral myocarditis varies greatly between children aged 5–11 and 12–17 years: substantially lower in children 5–11 years of age
 - Dose used in 5–11-year-olds (10µg) is a third of dose used in 12–15-year-olds (30µg)

Counseling: Pfizer COVID-19 Pediatric Vaccine

- With the participants in the 5 through 11 trials there were NO cases of myocarditis reported
 - The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Children Aged 5–11 Years — United States, November 2021 | MMWR (cdc.gov)
- Myocarditis/pericarditis after an mRNA vaccine is lower than the risk of myocarditis
 associated with COVID-19 infection in adolescents and adults
- People receiving mRNA vaccines, especially males ages <30 years, should be educated about the possibility of myocarditis/pericarditis following an mRNA vaccine
 - Seek care for symptoms of:
 - Chest pain, shortness of breath, feelings of having a fast-beating, fluttering, or pounding heart
- Most patients responded well to medicine and rest
- If you have any health problems after vaccination, report them to <u>VAERS</u>

COVID-19 Vaccines and Seropositivity

Data from Phase 3 Clinical Trial:

- 9% of children in clinical trial were baseline COVID-19 seropositive
- Post-vaccination antibodies higher in children who were baseline seropositive
- Rates of local and systemic reactions, as well as adverse events, were lower in children who were baseline seropositive

Data from U.S. Studies:

- Approximately 38% of children aged 5–11 years have evidence of prior COVID-19 infection based on seroprevalence estimates
- Prior infection can result in protection against infection but not 100% and likely decreases over time
- Children have a greater proportion of asymptomatic infection relative to adults
 - Asymptomatic infection can result in lower antibody levels than severe disease

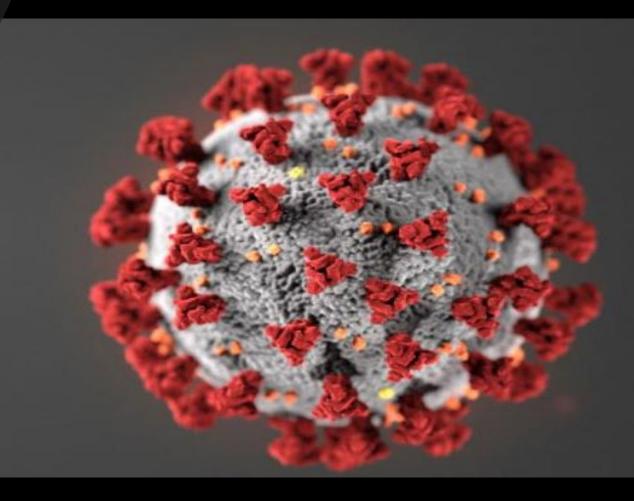
Vaccine Efficacy

- Vaccine efficacy against symptomatic lab-confirmed COVID-19 was 90.9% (95% CI: 68.3%, 98.3%)
 - 3 cases in the vaccine arm (N=1461; surveillance time: 369 person-years)
 - 16 cases in the placebo arm (N=714; surveillance time: 179-person-years)

Benefits and Harms Summary

- Clinical trial demonstrated Pfizer-BioNTech COVID-19 vaccine is safe, immunogenic and efficacious in children 5–11 years of age
 - Trial not powered to assess rate of rare adverse events; no cases of myocarditis in ~3100 vaccinated children
- Balance of benefits and risks varies by incidence of COVID-19
 - Largest benefits with higher incidence
- Benefit/risk balance favorable, regardless of seropositivity rates
 - While many children 5–11 years of age may be seropositive, unknown duration of protection for asymptomatic infection in children
 - Safety data reassuring in seropositive population

New EUA Fact Sheets



CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

Upcoming Noontime Knowledge: October 1, 2021 at 12:00 p.m. EST

Education Corner

Enrollment

Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

Pfizer

Moderna

Janssen (Johnson & Johnson)

EUA Fact Sheets

- · EUA Fact Sheet for Healthcare Professionals
 - 5 Through 11 Years of Age, Orange Cap (must dilute) UPDATED 10/29/21
 - 12 Years of Age and Older, Purple Cap (must dilute) UPDATED 10/29/21
- EUA Fact Sheet for Recipients
 - 5 Through 11 years of Age UPDATED 10/29/21
 - Spanish UPDATED 10/29/21
 - 12 Years of Age and Older UPDATED 10/29/21
 - Spanish UPDATED 10/29/21
 - Important: Print and provide the above EUA Fact Sheet to each COVID-19 vaccine recipient/caregiver in Michigan.
 - This version includes the information statement about the MCIR (as indicated in Michigan VISs). Per state law, patients/parents must be informed about MCIR.
- Translations 12 Years of Age and Older UPDATED 10/20/21
 - Chinese Simplified UPDATED 10/20/21
 - Haitian Creole UPDATED 10/20/21
 - Hmong UPDATED 10/20/21
 - Korean UPDATED 10/20/21
 - Spanish UPDATED 10/20/21
 - Tagalog UPDATED 10/20/21
 - Vietnamese UPDATED 10/20/21

Updated EUA Fact Sheets

www.michigan.gov/covidvaccineprovider

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

FOR 5 THROUGH 11 YEARS OF AGE DILUTE BEFORE USE

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 5 years of age and older.

This Fact Sheet pertains only to Pfizer-BioNTech COVID-19 Vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border and which is authorized for use to provide a 2-dose primary series to individuals 5 through 11 years of age. The vial labels state: Age 5y to <12y. The carton labels state: For age 5 years to <12 years.

Pfizer-BioNTech COVID-19 Vaccine which is supplied in a multiple dose vial with an orange cap and a label with an orange border, should not be used in individuals 12 years of age and older.¹

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

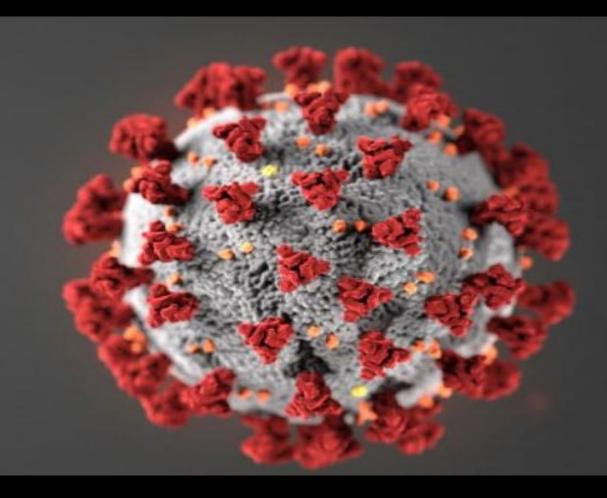
Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR PFIZER-BIONTECH COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

The Pfizer-BioNTech COVID-19 Vaccine is a suspension for intramuscular injection.

The Pfizer-BioNTech COVID-19 Vaccine, which is supplied in a multiple dose vial with an orange cap and a label with an orange border, is administered, after

Notwithstanding the age limitations for use of the different formulations and presentations lears to 12 years of age between their first and or either dose, either: (1) the Pfizer-BioNTech in individuals 5 through 11 years of age (each 0.2); or (2) COMIRNATY or one of the Pfizer-ed for use in individuals 12 years of age and IA) (gray and purple cap).

Clinical Considerations





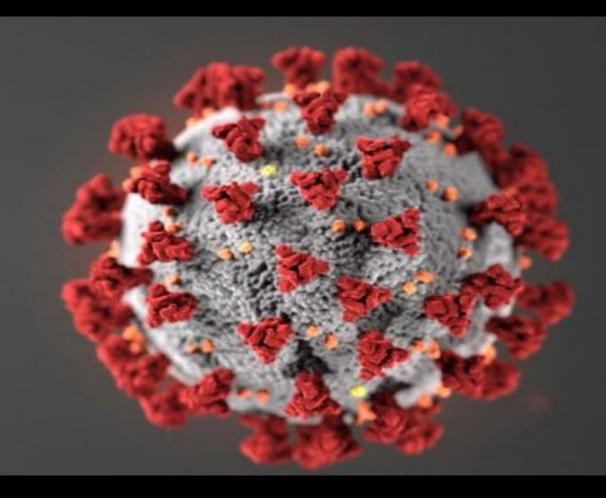
- Recommendations and clinical guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children aged 5–11 years including updated section on <u>Vaccination of children and adolescents</u>
- Updated guidance on COVID-19 vaccine dosing and schedule
- Updated guidance for myocarditis and pericarditis after mRNA COVID-19 vaccination in section on <u>Considerations for</u> mRNA COVID-19 vaccines: Pfizer-BioNTech and Moderna
- New guidance for people who received passive antibody products in section on <u>COVID-19 vaccination and SARS-CoV-2 infection</u>
- Updated guidance in section on People who received COVID-19 vaccine outside the United States
- Updated guidance in section on People who received COVID-19 as part of a clinical trial in the United States
- Updated guidance on <u>Considerations for COVID-19 vaccination in moderately and severely immunocompromised</u> people
- Updated guidance in section on Contraindications and precautions
- Updated Table in <u>Appendix A:</u> Vaccine administration errors and deviations
- Updated Appendix B: Triage of people with a history of allergies or allergic reactions
- Updated <u>Appendix C:</u> Ingredients included in COVID-19 vaccines

On This Page	
Purpose	Vaccination of children and adolescents
Overview of COVID-19 vaccine recommendations	Patient counseling
COVID-19 vaccine dosing and schedule	Considerations for mRNA COVID-19 vaccines: Pfizer- BioNTech and Moderna
Interchangeability of COVID-19 vaccine products	Considerations for Janssen COVID-19 Vaccine
People who received COVID-19 vaccine outside the United States	Contraindications and precautions
People who received COVID-19 vaccine as part of a clinical trial in the United States	Reporting of vaccine adverse events
Coadministration of COVID-19 vaccines with other vaccines	Laboratory testing Appendix A. Vaccine administration errors and deviations
COVID-19 vaccination and SARS-CoV-2 infection Vaccinating people with a known COVID-19 exposure or	Appendix B: Triage of people with a history of allergies or allergic reactions
during COVID-19 outbreaks	
Vaccinating people receiving medical care unrelated to COVID-19 or undergoing SARS-CoV-2 screening	Appendix C: Ingredients included in COVID-19 vaccines
Considerations for COVID-19 vaccination in moderately and severely immunocompromised people	Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vaccination
Considerations for use of a COVID-19 vaccine booster	References
dose	Previous Updates
Considerations involving pregnancy, lactation, and fertility	

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

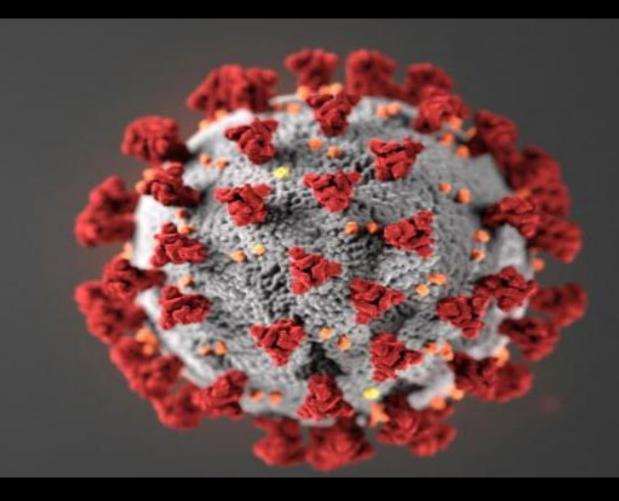
Who Can Receive Pfizer COVID-19 Pediatric Vaccine?



Pfizer COVID-19 Pediatric Vaccine Recipients

- Children with <u>underlying medical conditions</u> may be at increased risk for severe illness from COVID-19
 - Some children without underlying medical conditions may get severe COVID-19
- COVID-19 vaccine is recommended for everyone ages 5 years and older, regardless of underlying medical conditions
- People with known current COVID-19 infection should defer vaccination until the person has recovered from the acute illness AND met criteria to discontinue isolation
 - Serologic testing to assess for prior infection is **not** recommended for vaccine decision-making
- COVID-19 vaccine is recommended for everyone ages 5 years and older, regardless
 of a history of symptomatic or asymptomatic COVID-19 infection

Storage and Handling



Pfizer COVID-19
Pediatric
Vaccine Basics

Pfizer-BioNTech COVID-19 Vaccine, Multiple Dose Vial with Orange Cap and Label with Orange Border

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
5 through 11 years (Vial labels state: Age 5y to <12y)	Dilute with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

- Store vaccine in an ultra-cold freezer or refrigerator—Use Resources
 - Store in the original carton
 - Do not store in the thermal shipping container or a freezer
 - Do not refreeze thawed vaccine
- Pfizer COVID-19 Pediatric vaccine multidose vial—maximum of 10 doses per vial, based on EUA
- Administer as Intramuscular (IM) injection in the deltoid muscle
 - Anterolateral thigh may be used if needed
- Schedule 2-dose series separated by 21 days (3 weeks)

Orange Cap Storage Conditions

	Formulation for 5–11-year-olds (orange cap)
Storage conditions	
Ultralow temperature freezer (-90°C to -60°C)	6 months
Freezer (-25°C to -15°C)	N/A
Refrigerator (2°C to 8°C)	10 weeks

ORANGE CAP—Vial Storage Prior to Use

- Once received, frozen vials may be immediately transferred to the refrigerator at 2°C to 8°C (35°F to 46°F), thawed and stored for up to 10 weeks
- Alternatively, frozen vials may be stored in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 6 months
- Do **NOT** store vials at -25°C to -15°C (-13°F to 5°F)
- May also arrive at 2°C to 8°C (35°F to 46°F)
 - If received at 2°C to 8°C, they should be stored at 2°C to 8°C
- Ensure carton is updated to reflect the 10-week refrigerated expiry date
- Regardless of storage condition, vaccines should not be used after 6 months from the date of manufacture printed on the vial and carton

Once vials are thawed, they should not be refrozen

ORANGE CAP—Vial Storage During Use

Pfizer COVID-19 Vaccine Temperatures BEFORE and AFTER Puncture

Storage Temperatures: Before Puncture

May be stored at 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to dilution (including thaw time)

Storage Temperatures: AFTER dilution

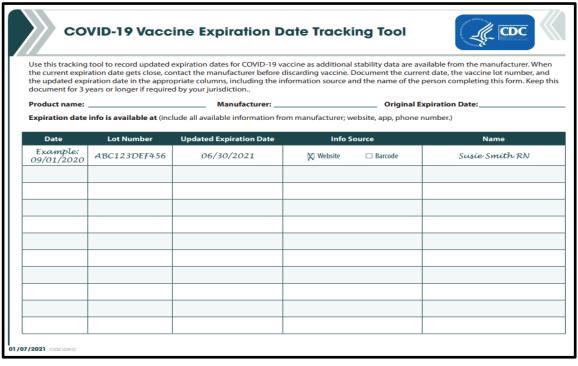
Vial should be held between 2°C to 25°C (35°F to 77°F), discard vial 12 hours after dilution

Discard any remaining vaccine after 12 hours

- If not previously thawed 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature up to 25°C (77°F) for 30 minutes
- Vial label/carton may state that a vial should be discarded 6 hours after 1st puncture
 - Information in the Fact Sheet supersedes number printed on vial labels and cartons

ORANGE CAP—Expiration Guidance

- Vaccine may be stored until the expiration date
- Expires 6 months after manufacture date
 - The manufacture date is printed on the **ORANGE CAP vial**
 - Count out 6 months, using the month printed on the vial as month 1
 - The vaccine expires on the last day of the 6th month



https://www.cdc.gov/vaccines/covid-19/downloads/expiration-tracker.pdf









November 2021



Month 5: December 2021



Month 6: January 2022

Expires



Pfizer-BioNTech COVID-19 Vaccine

Temperature Log for Frozen Vaccine Storage (Fahrenheit)



Store Pfizer COVID-19 vaccine between -13°F and 5°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below.

Save this record for 3 years, unless your state/local jurisdiction requires a longer time period.

Option 1: Minimum/Maximum (Min/ Max) Temperatures (preferred)

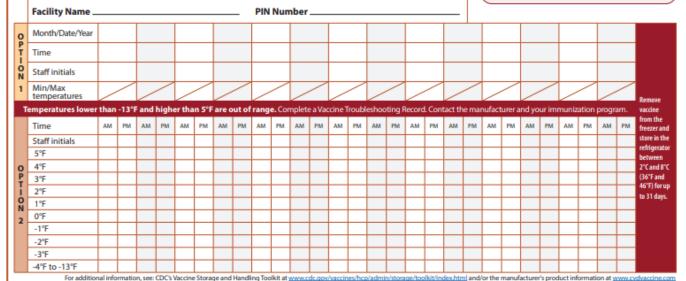
- Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
- Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature

- If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
- Document these temperatures by writing an "X" in the row that corresponds to the freezer temperature under the appropriate day of the month.
- 3. Review the continuous DDL temperature data daily.

If the temperature is out of range, TAKE ACTION!

- 1. Do NOT discard the vaccine.
- 2. Label the vaccine "Do Not Use."
- Complete the Vaccine Troubleshooting Record.
- Contact the manufacturer to determine under what conditions (frozen or refrigerated) to store the vaccine as quickly as possible.



07/09/2021 CS321570-

Adapted with appreciation from the Immunization Action Coalition (IAC) temperature log

- Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday
 - To determine if any excursions have occurred since the last temperature check
- For accurate temperature
 monitoring, use a digital data logger
 (DDL) with a detachable probe that
 best reflects vaccine temperatures
 (e.g., probe buffered with glycol,
 glass beads, sand, or Teflon®)



11/05/2021 CS321570-W

FORMULATION: 5 Through 11 Years

Pfizer-BioNTech COV

Storage and Handling Summary

Refrigerato

Before mixing, the vaccine may be stored in the refrigerator be contact the manufacturer for guidance. If directed to discard a guidance for proper disposal.

Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 Vaccine.

Temperature Monitoring

Ultra-cold freezer or refrigerator: Storage unit temperatures of the workday to determine if any temperature excursions har monitoring, use a digital data logger (DDL) with a detachable

 Ultra-cold temperatures: Use a probe designed specifically measure ultra-cold temperatures.

Check and record the temperature daily using CDC's temperat

Option 1 (preferred): Minimum/Maximum (Min/Max) Temperature

Most DDLs display min/max temperatures. Check and reco the min/max temperatures at the start of each workday.

Diluent

0.9% sodium chloride (normal saline, preservative-free) diluen guidance for storing the diluent.

Mixed Vaccine

- Once mixed, vials can be stored between 2°C to 25°C (35°F t 77°F) for up to 12 hours.
- Discard any remaining vaccine after 12 hours.

Disposal

11/04/2021 CS321570-X

Once vaccine has reached its expiration or beyond-use date, co If instructed to dispose of vaccine, dispose of the vial (with any your local and state regulations. Contact your jurisdiction's im <u>awardee-imz-websites.html</u>) for guidance.

CDC's Pfizer-BioNTech COVID-19 Vaccine materials https://www.cdc.cc
CDC's Vaccine Storage and Handling Toolkit https://www.cdc.cc
CDC's Pfizer Beyond-Use Date (BUD) labels https://www.cdc.gov
CDC's Freezer and Refrigerator Temperature Logs https://www.cdc.gov

For additional information, refer to the manufacturer's website

FORMULATION: 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine

Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations



Procedure

Follow storage and handling best practices outlined in CDC's Vaccine Storage and Handling Toolkit, COVID-19 Vaccine Addendum (https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storagehandling-toolkit.pdf), to maintain the cold chain when packing and transporting vaccine.

Transport Pfizer-BioNTech COVID-19 Vaccine with a temperature monitoring device in a:

- Portable ultra-cold freezer unit
- Portable refrigerator unit

Temperature monitoring:

At the start of transport

When transport concludes

 Container/packout qualified to maintain the recommended temperatures

Upon arrival at the clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Best Practices for Transporting mRNA Vaccines

- Protect vaccines as much as possible from drops, shocks, and vibration.
- To minimize movement, transport vials in the carton whenever possible.
- If individual, undiluted vials must be transported:
- Place vials with padding materials like bubble wrap or similar materials to prevent breaking.
- Secure storage containers during transport.
- Keep vaccine vials upright whenever possible.
- Protect from light.

General Information

- Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and personal protective equipment).
- ONLY unpunctured vials may be transported.

Record time and minimum/maximum temperatures:

Whenever the transport container is opened

- Unpunctured vaccine vials may be transported more than once.
- Transport thawed vaccine at refrigerated temperatures.
- Individual vials or partially filled trays must be transported at refrigerated temperatures.
- Vaccine stored at refrigerated temperatures should not be refrozen.
- Do NOT transport punctured vials or pre-drawn syringes

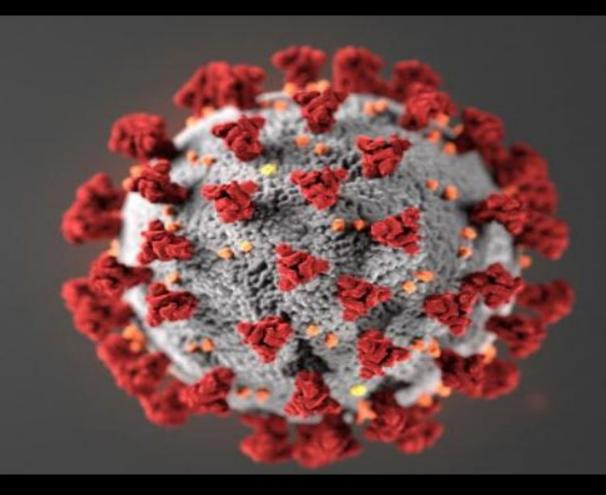
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CDC Pfizer COVID-19 Resource Page

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Vaccine Preparation & Administration



ORANGE CAP Dose Guidance

	Formulation for 5–11-year-olds (orange cap)	
Age group	5-11 years	
Vial cap color		
Dose (mRNA concentration)	10 ug	
Injection volume	0.2 mL	
Fill Volume (before dilution)	1.3 mL	
Amount of Diluent* Needed per vial	1.3 mL	
Doses per Vial	10 (after dilution)	

ORANGE CAP Dose Guidance Cont....

	Formulation for 5–11-year-olds (orange cap)
Number of doses	2
Interval	3 weeks (21 days)
Additional primary dose	Not recommended
Booster dose	Not recommended

Preparing the Vaccine—ORANGE CAP

- Before dilution, mix by inverting vaccine vial gently 10 times—Do not shake
- Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial
- Gently invert the vial 10 times to mix—Do not shake
- Record the 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.

Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials. Using a 21-gauge (or narrower) needle, withdraw 1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.



1.3 ml

Inject 1.3 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.



Using the mixing syringe, remove 1.3 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. **Do not shake.** If the vial is shaken, contact the manufacturer.



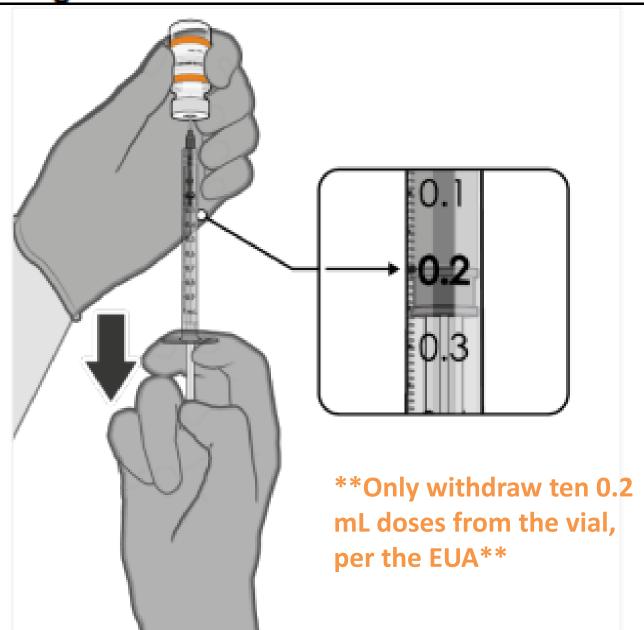
Note the date and time the vaccine was mixed on the vial.



Keep mixed vaccine between 2°C and 25°C (36°F to 77°F) for up to 12 hours. **Discard any unused vaccine after 12** hours. Do not return to ultra-cold freezer storage.



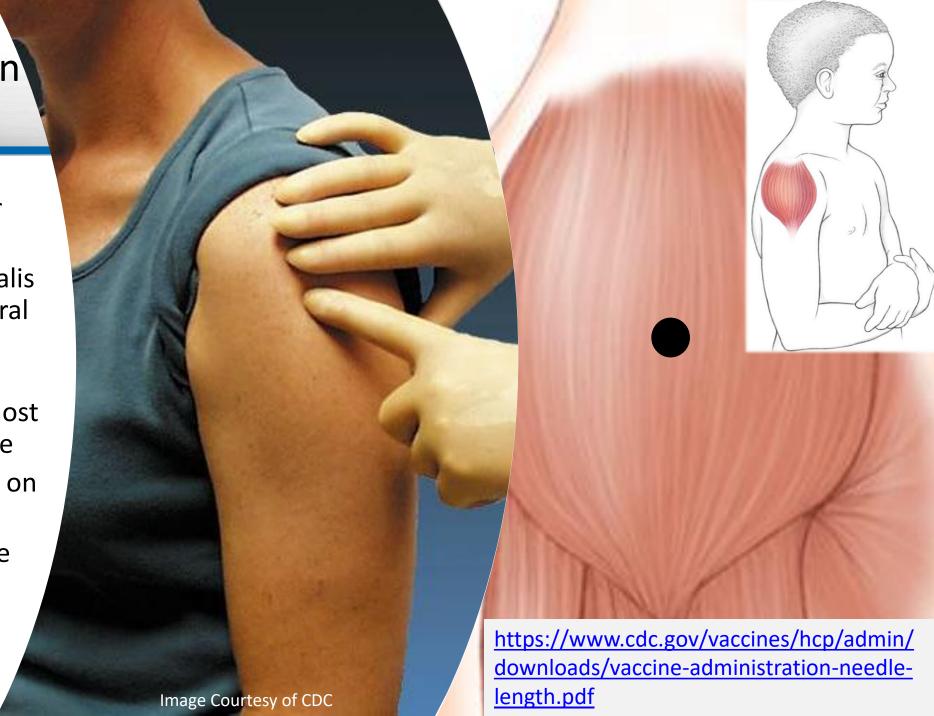
Orange Border - WITHRAWAL OF INDIVIDUAL 0.2 mL DOSES



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw <u>0.2 mL</u> of the Pfizer-BioNTech COVID-19 Vaccine preferentially using a low dead-volume syringe and/or needle.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and



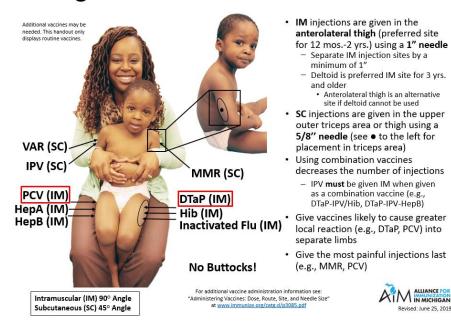
- Deltoid preferred site for 3 years and older
- May use the vastus lateralis muscle of the anterolateral thigh—use appropriate needle length
- Administer in thickest, most central part of the muscle
- Use needle length based on patient's age and weight
- Insert the needle into the muscle at a 90° angle



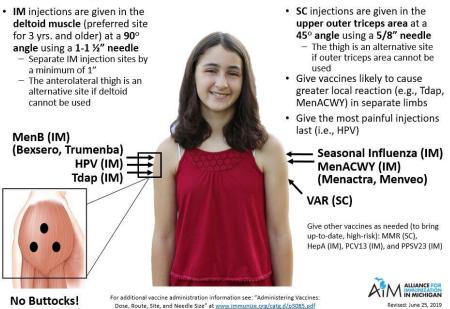
Coadministration

- COVID-19 vaccines may be administered without regard to timing of other vaccines
 - This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site
 - Separate injection sites by 1 inch or more

Giving All the Doses 12 Months and Older







Giving All the Doses

IN MICHIGAN

Revised: June 25, 2019

AIM: www.aimtoolkit.org

FORMULATION: 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine



Vaccine Preparation and Administration Summary

Contraindications and Precautions Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- Immediate allergic reaction to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness

For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at www.cdc.gov/vaccines/ covid-19/info-by-product/clinical-considerations.html. ¶An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

Management of Anaphylaxis

Be prepared to manage medical emergencies.

- Have a written protocol to manage medical emergencies following vaccination, as well as equipment and medications, including at least 3 doses of epinephrine, H1 antihistamine, blood pressure monitor, and timing device to assess pulse.
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

For more information, please see Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination at www.cdc.gov/vaccines/covid-19/infoby-product/pfizer/anaphylaxis-management.html.

Document the Vaccination

1/05/2021 CS321570-AA

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (i.e., immunization information system) for the jurisdiction as soon as a and no later than 72 hours after administration. Document each recipient's vaccine administration

■ Medical record:

- · Vaccine and the date it was administered
- · Manufacturer and lot number
- · Vaccination site and route
- · Name and title of the person administering the
- Personal vaccination record card (shot card): Date of vaccination, product name/manufacturer number, and name/location of the administering healthcare professional. Give to the vaccine recip
- Immunization information system (IIS) or "reg Report the vaccination to the appropriate state/le

Reporting Adverse Events

Healthcare professionals are required to report to the Adverse Event Reporting System (VAERS):

- Vaccine administration errors (whether associate adverse event [AE] or not)
- Serious AEs (irrespective of attribution to vaccina
- Multisystem inflammatory syndrome (MIS) in adults
- Cases of COVID-19 that result in hospitalization of
- Any additional AEs and revised safety reporting req per the Food and Drug Administration's conditions authorized vaccine throughout the duration of the

Adverse events should be reported even if the caus uncertain. Healthcare professionals are also encour report any clinically significant AEs that occur after administration. Submit reports to www.vaers.hhs.g

For additional information, see the vaccine manufacture product information at www.cvdvaccine.com.

For additional information on preventing, reporting managing mRNA COVID-19 vaccine administration see https://www.cdc.gov/vaccines/covid-19/info-b clinical-considerations.html#Appendix-A

*For the purpose of this guidance, an immediate allergic reaction is defi hypersensitivity-related signs or symptoms such as urticaria, angioede distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hou exposure to a vaccine or medication.

*Consider consultation with an allergist-immunologist to help deter patient can safely receive vaccination. Healthcare providers and hea may also request a consultation from the Clinical Immunization Safe COVIDvax Project https://www.cdc.gov/vaccine cisa/index.html. Vaccination of these individuals should only be don appropriate setting under the supervision of a healthcare provider e the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (incl) PEG allergy) have a precaution to Janssen COVID-19 vaccination. Peo previously received an mRNA COVID-19 Vaccine dose should wait at le
- People with a contraindication to Janssen COVID-19 vaccine (including) polysorbate allergy) have a precaution to mRNA COVID-19 vaccination

FORMULATION: 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary



Remove any significant air bubbles with the needle

still in the vial to avoid loss of vaccine. Use the same

Ensure the prepared syringe is not cold to the touch.

Check the age indications on the vial label, again,

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

Administer the vaccine immediately by intramuscular

(IM) injection in the deltoid muscle. As an alternative, the

Observe recipients after vaccination for an immediate

» A contraindication to another type of COVID-19

severe allergic reaction to a COVID-19 vaccine.

non-COVID-19 vaccine or injectable therapies

» Immediate allergic reaction of any severity to a

» Immediate (within 4 hours of exposure) non-

to ensure it is the correct formulation based on the

needle" to withdraw and administer the vaccine.

Bring the dose of vaccine from the designated

preparation area immediately to the patient

treatment area for administration.

vastus lateralis muscle may be used.

30 minutes: Persons with a history of:

age of the recipient.

age (if tolerated).

adverse reaction:

vaccine product.

Vaccine: Pfizer-BioNTech: 5 through 11 years of age (orange cap and orange bordered label) Use the correct formulation based on the age of the recipient

FORMULATION: 5 Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Preparation and Administration Summary

Diluent: 1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) Use a new vial every time.

Multidose vial: 10 doses per vial

General Information

Dosage: 0.2 mL

Prepare the vaccine using a NEW vial of diluent EVERY TIME. Discard the diluent vial and remaining diluent after mixing the vaccine.

Age Indications

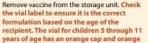
5 through 11 years of age

Schedule for Primary Series and Boosters

2-dose series separated by 21 days*

Prepare the Vaccine

Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.[†]



border on the label. Allow vaccine to come to room temperature. Vials can be held at room

hours before mixing.

liquid is discolored.

Before mixing, check the:

Age indications on the label

Any beyond-use dates/times

Expiration date of the vaccine and diluent

NEVER use expired vaccine or diluent. **NEVER**

use vaccine after the beyond-use date or times.

With the vaccine at room temperature, gently

invertivial 10 times. Do not shake the vial. If

the vial is shaken, contact the manufacturer.

may contain opaque particles. Do not use if

The vaccine is white to off-white in color and

temperature at room temperature for up to 12

» Anaphylaxis due to any cause. 15 minutes: All other persons

It is not necessary to change needles between drawing vaccine from a vial and injecting it into a recipient unless the needle has been damaged or co

0.2 mL

Dose Scheduling for Primary Series

Administer the Vaccine

Assess recipient status:

Review vaccination history

Review medical considerations.

including the correct needle size.

Screen for contraindications and precautions.

Choose the correct vaccine formulation based

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

vaccine using a combination of low dead-volume

volume syringes are not available, withdraw

syringes and non-low dead-volume syringes.

Cleanse the stopper on the vial of mixed vaccine

Regardless of the type of syringe used, ensure

the amount of vaccine in the syringe equals

If the amount of vaccine remaining in the vial

cannot provide a full 0.2 mL dose, discard the

Do NOT combine vaccine from multiple vials

with a new, sterile alcohol prep pad. Withdraw

0.2 mL of mixed vaccine into the syringe.

vial and contents

to obtain a dose.

on the age of the recipient and equipment,

Vaccination History† And		Then	Next Dos
0 doses		Give dose 1 today	Give dose 2 at le 21 days after do
1 dose (Pfizer-BioNTech	It has been at least 21 days since dose 1		Series complete no additional do
COVID-19 Vaccine)	It has not been at least 21 days from dose 1	No dose today	Give dose 2 at le 21 days after do
2 doses (Pfizer-BioNTech COVID-19 Vaccine) at least 21 days apart ⁶			Series complete no additional do

[†]COVID-19 vaccines may be coadministered with other vaccines, including simultaneous administration. When deciding whether to administer COVIDand other vaccines, providers should consider whether the person is behind or at risk of becoming behind on recommended vaccines. They should also person's risk of vaccine-preventable diseases (e.g., during an outbreak) and the reactogenicity profile of the vaccines.

Administer the 2nd dose as close as possible to the recommended interval of 21 days. It is not necessary to restart the series if the dose is given after t

Intramuscular (IM) injection in the deltoid muscle, The vastus lateralis muscle of the anterolateral thigh may be used.

Thawing Frozen Vaccine

- Vaccine stored at ultra-cold temperatures must be thawed before use.
- Thaw vaccine in the refrigerator or at room temperature:
- . Unpunctured vials may be stored in the refrigerator for up to
- Unpunctured vials maybe stored between 8°C to 25°C (46°F to 77°F) for a total of 12 hours prior to mixing (including
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date labels to track storage time at refrigerated temperatures.

Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine

other diluents to mix the vaccine

vials. Using a 21-gauge (or narrower) needle, withdraw 1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. Discard diluent vial and any remaining diluent every time. Do NOT use bacteriostatic normal saline or



Inject 1.3 mL 0.9% sodium chloride (normal saline. preservative-free) diluent into the vaccine vial.



Using the mixing syringe, remove 1.3 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.



Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. Do not shake. If the vial is shaken, contact the manufacturer.



Note the date and time the vaccine was mixed on the vial



Keep mixed vaccine between 2°C and 25°C (36°F to 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours. Do not return to ultra-cold freezer storage.



For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States at

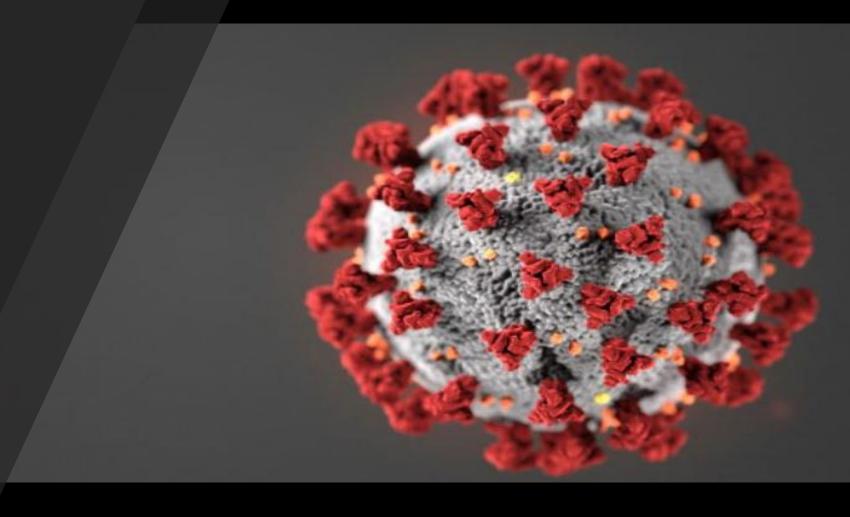
†Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

CDC Pfizer COVID-19 Resource Page

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

/05/2021

Fact Check



- NO. 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

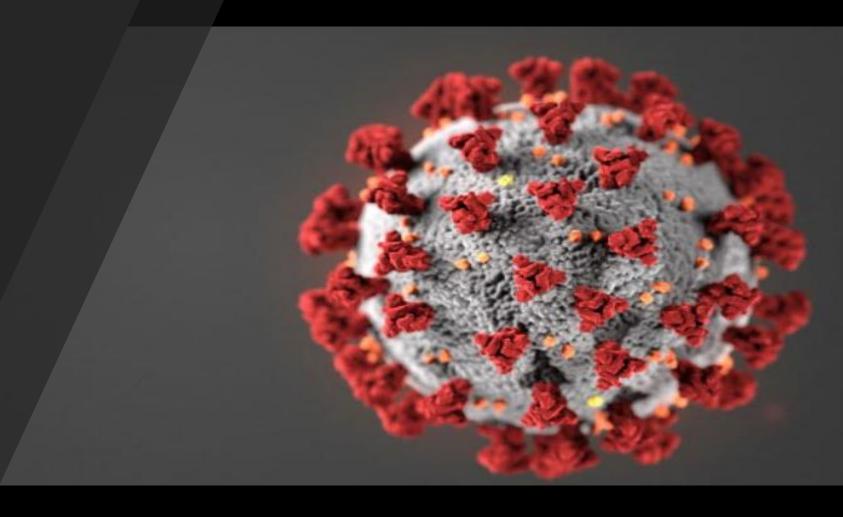
I just reconstituted one vial of vaccine and there is more diluent left over. Can I use that same diluent to reconstitute another vial of vaccine?

What dose and product do I use if a child is turning 12 years old between their first and second dose of the Pfizer vaccine series?

The dosage and product should be based on the **child's age on the day of vaccination.** Children aged 5 through 11 years should receive the 10 μ g Pfizer-BioNTech COVID-19 Vaccine (orange cap) formulation, and adolescents aged 12 years and older should receive the 30 μ g Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation. Therefore, if a child turns 12 years old between their first and second dose, they should receive the age-appropriate 30 μ g Pfizer-BioNTech COVID-19 Vaccine (purple cap) formulation or COMIRNATY for their second dose to complete their series.

- If a child turns from 11 to 12 years of age in between their first and second dose and receives the 5–11 years (orange cap) for their second dose, they do not need to repeat the dose, and this is not considered an error under the EUA.
- Children should receive the age-appropriate vaccine formulation regardless of their size or weight.

Resources



FORMULATION: 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine Standing Orders for Administering Vaccine



Vaccine	Diluent	Dosage (amount)/ Route
Formulation: 5 through 11 years of age	1.3 mL of 0.9% sodium chloride (normal saline, preservative-free) diluent	0.2 mL/IM injection

Purpose

 To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

 Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

Assess children 5 through 11 years of age for vaccination with Pfizer BioNTech COVID-19 Vaccine based on the following criteria:

- Primary-series vaccination
- If the recipient has never received a COVID-19 vaccine, administer 1 dose of Pfizer-BioNTech COVID-19 vaccine.
- If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, administer the second dose at an interval of least 21 days."
- If 2 doses of an mRNA vaccine have been administered, the child is considered fully vaccinated. No additional doses are
- Children with a history of myocarditis or pericarditis:
- If history is prior to COVID-19 vaccination may receive Pfizer-BioNTech formulation 5 thorough 11 years of age after the episode of myocarditis or pericarditis has completely resolved.
- ol f myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine, including Pfizer-Bio-NTech formulation for children 5 through 11 years of age. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccinesus.html@considerations-pfizer-biontech-moderna
- Educational materials on myocarditis/pericarditis are available at http://www.cdc.gov/coronavirus/2019ncov/vaccines/safety/myocarditis.html, www.cdc.gov/ coronavirus/2019-ncov/vaccines/safety/myocarditis.html

- Additional Clinical Considerations
- For children who received a COVID-19 vaccine that is not currently authorized or approved in the United States, guidance can be found at: html#not-authorized-vaccines
- Pfizer-BioNTech COVID-19 vaccine may be coadministered with other vaccines without regard to timing, including simultaneous administration.
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines-us, <a href="https://htt

Screen for contraindications and precautions

Contraindications:

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine (see https://www.dcc.gov/vaccines-us.html#Appendix-C for a list of vaccine components)

Precaution

Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.

- Immediate allergic reaction[§] to any non-COVID-19 or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots")
- This includes non-COVID-19 vaccines and therapies with multiple components and the component(s) that elicited the reaction is unknown
- Immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine
- Moderate to severe acute illness

"If the second dose is administered less than 17 days after the first dose (4-day grace period), the dose should be repeated. The repeat dose should be spaced at least 21 days after the improperly administered Pfizer-BioNTech dose.

⁹An immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms such as urticaria, angloedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.



FORMULATIONS: 5 Years of Age and Older

Pfizer-BioNTech COVID-19 Vaccine

Vaccine Dosage Chart



The table below summarizes dosage information based on age, dose and medical indications for Pfizer-BioNTech COVID-19 Vaccine formulations. Use this table in conjunction with the FDA Fact Sheet for Healthcare Professionals and CDC clinical materials.

- Use the correct formulation for the age of the recipient.
 Formulations are NOT interchangeable. Check the vial label to ensure you are preparing and administering the correct formulation based on the age of the recipient.
- 5 through 11 years of age: Orange cap and orange bordered label
- 12 years of age and older: Purple cap and purple bordered label
- Vaccine must be mixed BEFORE administering. Use 0.9% preservative-free normal saline diluent supplied in the ancillary supplies kit. Diluent is not packaged with the vaccine.
- All Pfizer-BioNTech vaccines are administered by intramuscular (IM) injection. The injection site depends on recipient's age:
- 5 through 11 years of age: Deltoid muscle (preferred)
- · 12 years of age and older: Deltoid muscle
- Vastus lateralis muscle in the anterolateral thigh may be used

PRIMARY SERIES DOSES

Primary Series (People 5 years of age and older)				
If administering	g Recipient's age Use Mix vaccine using Administer			
Primary series: Dose 1 or 2 (Separate by at least 21 days)	5 through 11 years of age	5 through 11 years of age formulation (orange cap)	1.3 mL of diluent*	0.2 mL
	12 years of age and older	12 years of age and older formulation (purple cap)	1.8 mL of diluent*	0.3 mL

Additional Primary Dose for Moderately and Severely Immunocompromised Persons				
If administering	Recipient's age	Use	Mix Vaccine Using	Administer
Any dose in the series (include the primary	5 through 11 years of age	An additional dose for moderately and severely immunocompromised children in this age group has NOT been authorized by FDA or recommended by CDC.		
2-dose series and an additional dose given at least 28 days after the primary series)	12 years of age and older	12 years of age and older formulation (purple cap)	1.8 mL of diluent*	0.3 mL

BOOSTER DOSES

Booster Doses				
If administering	Recipient's age	Use Mix vaccine using Administer		
Booster dose (at least 6	5 through 17 years of age	A booster dose in this age group has NOT been authorized by FDA or recommended by CDC.		
months after completing the primary series [†])	18 years of age and older ^{††}	12 years of age and older formulation (purple cap)	1.8 mL of diluent*	0.3 mL

^{0.9%} normal saline (preservative-free)

including the additional primary series dose for moderately and severely immunocompromised persons.

11/05/2021

CDC Pfizer COVID-19 Resource Page

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

RESOURCES

MICHIGAN IMMUNIZATION **CLINIC REQUEST FORM MICHIGAN INTERIM COVID-COVID-19 VACCINE** 19 VACCINATION STRATEGY **QUESTIONS AND ANSWERS PORTAL** FOR PARENTS 72 73 **TEENS AND COVID-19 COVID-19 VACCINES &** SOCIAL VULNERABILITY LOCAL HEALTH **VACCINES** FETAL CELLS 72 AND COVID-19 72 DEPARTMENT VACCINE INFORMATION ATTEND AN UPCOMING VACCINE TESTIMONIALS PROTECT MICHIGAN COVID-19 VACCINE COMMISSION TOWN HALL COMMUNICATION MATERIALS

Note: The Pfizer vaccine is approved by the U.S. Food and Drug Administration (FDA) for use in persons aged 16 and older, and is authorized under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in persons aged 5 to 15. The Moderna and Johnson & Johnson vaccines are authorized under an EUA for use in persons aged 18 and older. The emergency use of these products is only authorized for the duration of the COVID-19 emergency declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the Food Drug & Cosmetic Act unless the declaration is terminated or authorization revoked sooner.

PROVIDER GUIDANCE AND EDUCATION

Materials and information to support COVID-19 vaccine providers.

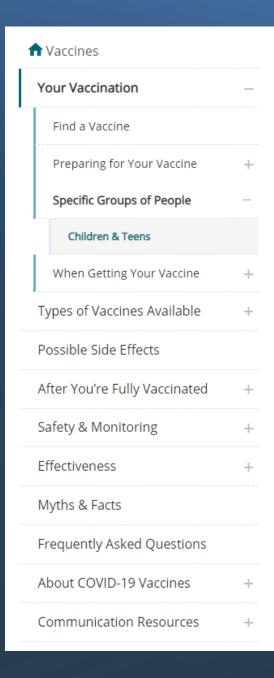
MORE INFORMATION

LTC PHARMACY PARTNERSHIP

This national initiative provides vaccine to priority groups in longterm care facilities.

MORE INFORMATION

www.michigan.gov/covidvaccine



COVID-19 Vaccines for Children and Teens

Updated Nov. 4, 2021 Languages ▼ Pi

Most Children and All Teens Can Get COVID-19 Vaccines

CDC recommends everyone ages 5 and older get a COVID-19 vaccine to help protect against COVID-19.

Authorized For	Pfizer-BioNTech	Moderna	J&J / Janssen
4 years and under	No	No	No
5–11 years old	Yes	No	No
12–17 years old	Yes	No	No
18 years and older	Yes	Yes	Yes

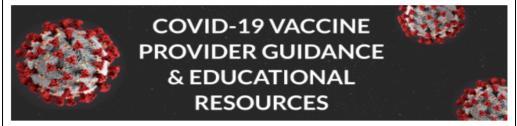
Widespread vaccination for COVID-19 is a critical tool to best protect everyone, especially those at highest risk, from severe illness and death. People who are fully vaccinated can safely resume many activities that they did prior to the pandemic. Children ages 5 years and older are able to get an age-appropriate dose of Pfizer-BioNTech COVID-19 vaccine. Learn more about what you and your child or teen can do <a href="https://www.whenfully.com/whenfully.







COVID-19 Vaccine Provider Guidance and Educational Resources



This webpage will house materials to support COVID-19 Vaccine Providers in successful implementation of the COVID-19 Vaccination Program. Be sure to "bookmark" this page and check back frequently for updates!

GENERAL COVID-19 VACCINE RESOURCES

Clinical Guidance for Michigan Providers Regarding Additional Dose of an mRNA COVID-19 Vaccine

Increasing Access to Vaccine Opportunities: Recommendations for Health Care Providers - Updated 6/18/21

COVID-19 Vaccines During Hospital Stays and Medical Appointments - Updated 6/14/21

COVID-19 Vaccination Clinic Preparation Checklist & Resource Toolkit - Updated 5/28/21

ACIP Recommendations for COVID-19 Vaccine

Interim Clinical Considerations for COVID-19 Vaccine

CDC COVID-19 Vaccine Resources for Healthcare Professionals

· Vaccine administration, storage and handing, reporting, and patient education for each specific vaccine

COVID-19 Vaccine Training Module

- Self-paced module with certificate of completion (no CE)
- MDHHS strongly recommends that all COVID-19 Vaccine Providers complete this training.

CDC HCP Vaccine Administration Resource Library

CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

Upcoming Noontime Knowledge: October 1, 2021 at 12:00 p.m. EST

Education Corner

Enrollment

Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

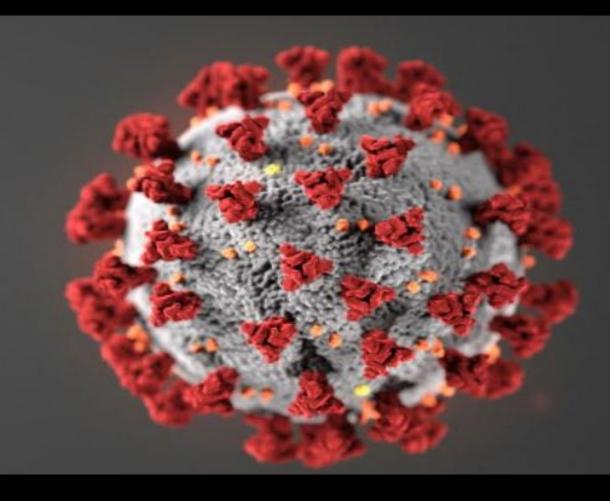
MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

Thank You!

Next "Noontime Knowledge" Update: TBD

Please watch your email for an updated link and topic!



www.michigan.gov/COVIDvaccineprovider