Pediatric COVID-19 Vaccines: CDC’s Recommendations for Pfizer-BioNTech COVID-19 Vaccine Primary Series in Children 5–11 Years Old

Clinician Outreach and Communication Activity (COCA) Call

Thursday, November 4, 2021
Continuing Education

- Continuing education is not offered for this webinar.
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  – Click on the “Q&A” button
  – Type your question in the “Q&A” box
  – Submit your question

▪ If you are a patient, please refer your question to your healthcare provider.

▪ If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.
Today’s Presenters

- **Sara Oliver, MD, MSPH**
  LCDR, U.S. Public Health Service
  Co-lead, Advisory Committee for Immunization Practices COVID-19 Vaccines Work Group
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- **Kate Woodworth, MD, MPH, FAAP**
  Advisory Committee for Immunization Practices COVID-19 Vaccines Work Group
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- **Kevin Chatham-Stephens, MD, MPH, FAAP**
  CDR, U.S. Public Health Service
  Pediatric Vaccine Readiness and Implementation Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention
Pfizer-BioNTech COVID-19 Vaccine in Children aged 5–11 Years Old

Sara Oliver MD, MSPH
COCA Call
November 4, 2021
COVID-19 Weekly Cases per 100,000 Population by Age — United States, March 1, 2020–October 10, 2021

>1.9 million cases among children 5-11 years of age

https://covid.cdc.gov/covid-data-tracker/#demographicsovertime
Proportion of Total COVID-19 Cases by Age Group — United States, March 1, 2020–October 10, 2021

Children 5-11 years are making up a greater proportion of total cases: **10.6%** of cases the week of October 10, 2021

https://covid.cdc.gov/covid-data-tracker/#demographicsovertime
Weighted Infection-Induced SARS-CoV-2 Seroprevalence By Age Group — 47 U.S. Jurisdictions, Sept 2021

- Seroprevalence in children aged 5–11 years: 38% (95% CI: 36–40%)
  - Higher than estimates among adults
  - Similar to estimates in children aged 12–17 years
- Range for jurisdiction-level estimates for children aged 5–11 years: 11%–61%*
- Estimates lower than jurisdictions previously presented
- Number of infections per reported case†:
  - General population: Median 2.4 (Range: 2.0–3.9)
  - Ages 0–17 years: Median 6.2 (Range: 4.7–8.9)

Data are preliminary and subject to change

*Restricted to 23 jurisdictions with ≥75 specimens from children aged 5–11 years:
†Jurisdiction-level May–June 2021 estimates restricted to jurisdictions that provided age data for >90% of individual cases: CA, IL, NV, NJ, NC, OH, SC, and TN
Cumulative Influenza- and COVID-19-Associated Hospitalizations Among Children Ages 5–11 Years

Annualized COVID-NET surveillance period: Oct 1, 2020-Sept 30, 2021

*Mitigation measures in place during 2020-2021

Flu 2017-2018  
Flu 2018-2019  
Flu 2019-2020  
Flu 2020-2021*  
COVID Oct 2020-Sep 2021*

9 pediatric influenza hospitalizations reported 2020-2021

*Mitigation measure in place during 2020–2021

Annualized COVID-NET surveillance period: Oct 1, 2020–Sept 30, 2021

†Influenza seasons: MMWR week 40 of the earlier year to MMWR week 18 of the later year. The COVID period: Oct 2020-Sep 2021 goes from MMWR week 40 of year 2020 to MMWR week 39 of year 2021. MMWR Week 53 for MMWR Year 2020 is combined with MMWR Week 52 for consistency with other years.

COVID-NET—California, Colorado, Connecticut, Georgia, Iowa, Maryland (entire state), Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

FluSurv-NET: California, Colorado, Connecticut, Georgia, Maryland (Baltimore Metropolitan Area), Michigan, Minnesota, New Mexico, New York, Ohio, Oregon, Tennessee, and Utah.

Children 5-11 years: 94 COVID-19 deaths* (1.7% of all deaths among U.S. children 5–11 years)

*Lag in reporting of deaths might result in underestimate
Summary
SARS-COV-2 epidemiology in children aged 5–11 years

- Children are at least as likely to be infected with SARS-CoV-2 as adults
  - Over 1.9 million reported cases; seroprevalence estimated ~38% among 5–11 years in Sept 2021
  - Infections in children less likely to be reported as cases than infections in adults

- Children 5-11 years of age are at risk of severe illness from COVID-19
  - >8,300 COVID-19 related hospitalizations as of mid-October
  - Cumulative hospitalization rate is similar to pre-pandemic influenza seasons
  - Severity comparable among children hospitalized with influenza and COVID-19, with approximately 1/3 of children 5–11 years requiring ICU admission
  - Multisystem Inflammatory Syndrome in Children (MIS-C) most frequent among children 5–11 years; 2,316 cases reported among this age group
  - Post-COVID conditions have been reported in children

- Secondary transmission from young school-aged children occurs in household and school settings
Other pediatric vaccine preventable diseases: Hospitalizations per year prior to recommended vaccines

<table>
<thead>
<tr>
<th></th>
<th>Hepatitis A¹</th>
<th>Varicella² (Chickenpox)</th>
<th>Influenza³</th>
<th>COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>5–14 years</td>
<td>&lt;20 years</td>
<td>5–17 years</td>
<td>5–11 years</td>
</tr>
<tr>
<td><strong>Hospitalization Burden</strong> (per 100,000 population)</td>
<td>&lt;1</td>
<td>4-31</td>
<td>30-80</td>
<td>25</td>
</tr>
</tbody>
</table>

¹ [https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm)
# Other pediatric vaccine preventable diseases: Deaths per year prior to recommended vaccines

<table>
<thead>
<tr>
<th></th>
<th>Hepatitis A(^1)</th>
<th>Meningococcal (ACWY)(^2)</th>
<th>Varicella(^3)</th>
<th>Rubella(^4)</th>
<th>Rotavirus(^5)</th>
<th>COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>&lt;20 years</td>
<td>11–18 years</td>
<td>5–9 years</td>
<td>All ages</td>
<td>&lt;5 years</td>
<td>5–11 years</td>
</tr>
<tr>
<td><strong>Average deaths per year</strong></td>
<td>3</td>
<td>8</td>
<td>16</td>
<td>17</td>
<td>20</td>
<td>66</td>
</tr>
</tbody>
</table>


Modeling the impact of COVID-19 vaccination in children ages 5–11 years

- Vaccination among 5–11-year-olds is expected to accelerate the decline in cases, reducing cumulative incidence nationally by an expected 8% (~600,000 cases) from November 2021 to March 2022.

- Vaccination of 5–11-year-olds would dampen, but not eliminate, a new variant emergence.

https://covid19scenario modelinghub.org/
COVID-19 Related K-12 School Closures by State, August 2, 2021 – October 22, 2021

<table>
<thead>
<tr>
<th>School districts closed</th>
<th>Total # schools closed*</th>
<th>Estimated # students affected*</th>
<th>Estimated # teachers affected*</th>
</tr>
</thead>
<tbody>
<tr>
<td>313</td>
<td>2,351</td>
<td>1,217,777</td>
<td>78,134</td>
</tr>
</tbody>
</table>

Data from the Unplanned School Closure Monitoring Project (DGMQ/CDC), ongoing research that uses systematic daily media searches (methods explained in https://doi.org/10.1371/journal.pone.0248925).

* Number of schools closed in district-wide closures, total number of students, and total number of teachers are estimated by matching the public school district ID or school ID with the district/school data for school year 2019/20 and private school ID with school data for year 2017/18 as obtained from the National Center for Education Statistics (https://nces.ed.gov/ccd/elsi/tableGenerator.aspx, accessed on Apr 20, 2021). Due to missing information in 2019/20 data, the total number of public school teachers in California is estimated using 2018/19 NCES data.
Indirect impacts of COVID-19 pandemic on children

- Worsening of mental or emotional health
- Widening of existing education gaps
- Decreased physical activity and increased body mass index (BMI)
- Decreased healthcare utilization
- Decreased routine immunizations
- Increase in Adverse Childhood Experiences (ACEs)
- Loss of caregivers
Children 5–11 years of age are at risk of severe illness from COVID-19
  – Over 1.9 million reported cases and >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 5–11 years of age
Benefits and harms assessments

- Data from Phase 2/3 clinical trial
- Potential benefits and harms in seropositive children
- Potential risk of myocarditis

GRADE= Grading of Recommendations, Assessment, Development and Evaluation
Symptomatic lab-confirmed COVID-19

- Pfizer-BioNTech COVID-19 vaccine phase 2/3 randomized controlled trial (RCT)*
- Randomized 2:1 vaccine to placebo (median follow-up time: 3.3 months)
- 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)
- The geometric mean ratio (GMR) for antibodies in 5–11-year-olds compared with 16–25-year-olds was 1.04 (95% CI:0.93, 1.18), and met the noninferiority criteria

*Unpublished, data obtained from sponsor
Serious adverse events (SAE)

- Pfizer-BioNTech phase 2/3 randomized controlled trial (RCT)*
- None of the SAEs were assessed by the investigator as related to study intervention.
- No deaths were reported in any trial participants

Initial Enrollment Group (median follow-up time: 3.3 months)
- 1 SAEs in 1 participants in the vaccine group (n=1518)
  - Limb fracture
- 2 SAEs in 1 in the placebo group (n=750)
  - Pancreatitis
  - Abdominal pain

Safety Expansion Group (median follow-up time: 2.4 weeks)
- 3 SAEs in 3 participants in the vaccine group (n=1591)
  - Infective arthritis (infection of the knee)
  - Foreign body ingestion of a penny
  - Epiphysial fracture
- 0 SAEs in the placebo group (n=788)

*Unpublished, data obtained from sponsor; randomized 2:1 vaccine to placebo
Reactogenicity, severe (grade ≥3)

- Pfizer phase 2/3 randomized controlled trial (RCT)* solicited events from participants or reported by their parent/legal guardian through electronic diaries for 7 days following each dose

- 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 after each dose
  - 2.7% of children in the vaccine arm vs 1.1% in the placebo arm had a local or system grade ≥ 3 reaction after either dose
    * Most reactions were grade 3; 1 child in the vaccine arm with had a grade 4 fever >40.0°C; there were no other grade 4 reactions
  - More common after Dose 2; pain at injection site, fatigue and headache were the most common

*Unpublished, data obtained from sponsor
Summary
COVID-19 vaccines and seropositivity

Data from Phase 3 clinical trial
- ~9% of children in clinical trial were baseline SARS-CoV-2 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 SARS-CoV-2 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\textsuperscript{1-4}
  - Asymptomatic infection can result in lower antibody levels than severe disease

Balance of benefits and risks by seropositive status

- Delta-wave surges of pediatric COVID-19 hospitalizations occurred even with seroprevalence ~38%, suggesting this alone is not sufficient to provide broad protection.
- Limited data on rates of reinfection in children.
- Protection against asymptomatic/mild infection important outcome in children.
  - Multisystem Inflammatory Syndrome in Children (MIS-C) typically occurs after asymptomatic or mild infection; post-COVID conditions can also occur after mild infection.
- No concerns identified in safety surveillance with seropositive adolescents and adults.
  - Individuals 12-64 years with seropositivity >30%.
- Vaccine recommendations that require serologic testing place unnecessary barriers.
- Limited data to estimate impact of vaccination of seropositive children, but risks minimal.
- Balance of benefits and risks **favorable** for vaccination of all children.
Estimated **benefits** for every million Pfizer-BioNTech COVID-19 vaccinations in children 5-11 years of age using **recent** incidence

<table>
<thead>
<tr>
<th>Females 5-11 years</th>
<th>Males 5-11 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔄 57,301 COVID-19 cases prevented</td>
<td>🔄 56,954 COVID-19 cases prevented</td>
</tr>
<tr>
<td>🏥 191 hospitalizations prevented</td>
<td>🏥 226 hospitalizations prevented</td>
</tr>
<tr>
<td>🍯 130 MIS-C cases prevented</td>
<td>🍯 130 MIS-C cases prevented</td>
</tr>
<tr>
<td>🛑 60 ICU admissions prevented</td>
<td>🛑 72 ICU admissions prevented</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Recent Epidemiology 5-11 years</th>
<th>Pandemic Average 5-11 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>🌟 58,204 COVID-19 cases prevented</td>
<td>🌟 18,549 COVID-19 cases prevented</td>
</tr>
<tr>
<td>🏥 226 hospitalizations prevented</td>
<td>🏥 80 hospitalizations prevented</td>
</tr>
<tr>
<td>🩸 132 MIS-C cases prevented</td>
<td>🩸 42 MIS-C cases prevented</td>
</tr>
<tr>
<td>⏰ 72 ICU admissions prevented</td>
<td>⏰ 26 ICU admissions prevented</td>
</tr>
</tbody>
</table>

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


Recent epidemiology data from the week ending on 9/11/2021. Pandemic average data are averaged for the entire pandemic through the week ending on 10/16/2021.
Vaccine-associated myocarditis

- Identified rates of myocarditis are based on data from adolescents and adults receiving 30ug dose of Pfizer-BioNTech COVID-19 vaccine
  - Dose in pediatric (5–11-year-old) age group: 10ug dose

- Rare event, but most common in males 12–29 years of age

- No cases of myocarditis occurred during the clinical trials with 5–11-year-olds
  - N=3,082 with at least 7 days of follow up reported
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)
Epidemiology of myocarditis in pre-COVID era

- **Children <18 years of age**
  - Annual incidence 0.8 per 100,000
    - In persons aged 15-18 years, 1.8 per 100,000 in 2015-2016
  - 66% male
  - Transplant 4-9%
  - Mortality 4-7%

Butts et al. *Pediatric Cardiology*. 2017
Sachdeva et al. *Am J Cardiol*. 2015
Estimated rates of myocarditis after vaccination in adolescents 12–15 years of age, per million second doses

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAERS</td>
<td>3.9</td>
<td>39.9</td>
<td>21.5</td>
</tr>
<tr>
<td>VSD</td>
<td>12.1</td>
<td>108.5</td>
<td>60.2</td>
</tr>
</tbody>
</table>

VAERS rates as of Oct 6th; VSD rates as of Oct 23rd. Both show risk after second dose, per million doses.
Benefits and risks of Pfizer-BioNTech COVID-19 vaccine for children 5–11 years of age

**Benefits**

- Prevention of COVID-19 cases
- Likely prevention of hospitalizations, MIS-C and deaths and post-COVID conditions
- Possible prevention of transmission
- Greater confidence in safer return to school and social interactions

**Risks**

- Myocarditis or other rare events after mRNA vaccines?
- Short-term reactogenicity
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
Parental surveys
Intent to have children vaccinated

- Among parents surveyed, 34–57% plan to get their children vaccinated\(^1-6\)
- 90% of parents ‘very worried’ their child would get COVID-19 reported intent to vaccinate their child, compared to 7% of parents ‘not worried at all’\(^5\)
- 82% of fully vaccinated parents reported intent to vaccinate their child, compared to 1% of parents who are unvaccinated/do not plan to get vaccinated\(^5\)
- Among parents of teens who discussed vaccination with their pediatrician, three-quarters of those whose pediatrician recommended vaccination say their child received at least 1 dose\(^6\)

4. Unpublished data from the CDC, the University of Iowa, and RAND Corporation Survey of Parents, September 2021
Values
Summary

- Among several polls of U.S. parents, about **half** of parents say they are likely to get their child vaccinated

- Many parents cite concerns for long- or short-term side effects such as fever, anaphylaxis or myocarditis in their decision to vaccinate their child

- Other factors that influence a parents’ decision to vaccinate include the parents’ vaccination status and provider recommendation
Work Group interpretation

- Vaccine policy decisions made on balance of known benefits and risks to individual
  - Other benefits (prevention of transmission; greater confidence in return to school/social interactions) and risks (extrapolation of myocarditis risk from other ages) part of a broader picture

- Experience with over >400 million doses of mRNA vaccines administered to people 12 years of age and older

- Benefits outweigh risks
  - Regardless of seropositivity rates, the benefit/risk balance still favorable
Possible impact with vaccination of 5–11-year-old

Prevention of COVID-19 cases

>90%

Likely prevention of COVID-19 related:

- Post-COVID conditions
  - MIS-C
  - Hospitalization
  - ICU
  - Death

Possibility for more social interactions and uninterrupted school
Possible impact with vaccination of 5–11-year-old

Possible prevention of transmission to vulnerable family members

Parental participation on work force may be more stable and predicable
Possible impact with vaccination of 5–11-year-old

Could result in lower transmission within schools and community

More confident return to in-person learning
Summary

Since the beginning of the COVID-19 pandemic, among U.S. children 5-11 years of age, there have been—

1.9 million cases

8,300 hospitalizations

2,316 MIS-C cases

94 deaths
Summary

Since beginning of the COVID-19 pandemic, among U.S. children 5-11 years of age, there have been—

1.9 million cases
8,300 hospitalizations
2,316 MIS-C cases
94 deaths

COVID-19 is now vaccine preventable
ACIP Vote – Interim Recommendation

The Pfizer-BioNTech COVID-19 vaccine is recommended for children 5–11 years of age in the U.S. population under the FDA’s Emergency Use Authorization.
Interim Clinical Considerations for COVID-19 Vaccine in Children Ages 5–11 Years

Kate Russell Woodworth, MD, MPH, FAAP
COCA call
November 4, 2021
Outline of Presentation

▪ The Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years
  – Formulation and dosing
▪ Vaccine recipients
  – Underlying medical conditions
  – Prior SARS-CoV-2 infection
▪ Patient and parent/guardian counseling
▪ Vaccine administration
Pfizer-BioNTech COVID-19 Vaccine Formulation and Dosing in Children Ages 5–11 years
# 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="image_url" alt="Purple cap" /></td>
<td><img src="image_url" alt="Orange cap" /></td>
</tr>
<tr>
<td><strong>Dose (mRNA concentration)</strong></td>
<td>30 ug</td>
<td>10 ug</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><strong>0.45 mL</strong></td>
<td><strong>1.3 mL</strong></td>
</tr>
<tr>
<td><em><em>Amount of Diluent</em> Needed per vial</em>*</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 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>

Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf
## Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

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<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
Vaccine Dosage

- Children should receive the age-appropriate vaccine formulation regardless of their size or weight.
  - As opposed to many medications, vaccine dosages are based on age and not size or weight.

- The dosage should be based on the child’s age on the day of vaccination.
  - If a child turns from 11 to 12 years of age in between their first and second dose and receives the 5–11 years 10 µg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error under the EUA.
Vaccine Recipients
Underlying Medical Conditions

- Children with underlying medical conditions may be at increased risk for severe illness from COVID-19\(^1\), however, severe COVID-19 can occur in children with and without underlying medical conditions.

- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, **regardless of underlying medical conditions**.


Current or Prior SARS-CoV-2 Infection

- People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) AND they have met criteria to discontinue isolation¹.
  - Isolation and precautions can typically be discontinued 10 days after positive test if asymptomatic or 10 days after symptom onset and after resolution of fever for at least 24 hours)

- Serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making².

Prior SARS-CoV-2 Infection

- COVID-19 primary vaccination would be 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\(^1\) and in the general population there has been no safety concerns associated with vaccination of those who had prior infection.

\(^1\)https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic
Limitations of Antibody Testing

▪ Antibody tests cannot determine when a person was infected.

▪ Antibody tests greatly vary in their sensitivity, particularly >3 months after infection.

▪ People can test positive on commercial antibody tests even after other markers of immunological response, such as neutralizing antibodies, have waned.

▪ At this time, there is no FDAAuthorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.
Counseling
Counseling: Expected Side Effects from Pfizer-BioNTech COVID-19 Vaccine

- Children may experience **fewer side effects** than adolescents or young adults\(^1\).
- Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection\(^1\).

- Expected side effects include
  - Local: pain, swelling, erythema at the injection site
  - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

- Routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
  - In general, Aspirin is **not** recommended for use in children and adolescents ≤18 years due to risk of Reye’s syndrome.

Counseling: Possible Risk of Myocarditis

- Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose.

- The observed risk is highest in males 12–29 years of age\(^1\).

- The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is **lower** than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults\(^2\).

---


FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine in children ages 5–11 years based on the determination that the benefits of COVID-19 vaccination outweigh risks in this population.

People receiving mRNA COVID-19 vaccines, especially males ages <30 years, should be made aware of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines.

- Seek care for symptoms of
  - Chest pain
  - Shortness of breath
  - Feelings of having a fast-beating, fluttering, or pounding heart

Any cases should be reported to VAERS

https://vaers.hhs.gov/reportevent.html
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, according to recommendations by age\(^1\).
  - Separate injection sites by 1 inch or more.
  - For older children (≥11 years), the deltoid muscle can be used.
  - For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

\(^1\)https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
Administration Errors

Updates will be posted at:


https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
What can you do for vaccine safety?

- Report adverse events following vaccination to VAERS even if you aren’t sure if the vaccination caused the adverse event
- Enroll yourself in v-safe
- Healthcare providers, encourage your patients to enroll in v-safe
- Parents and guardians, you can enroll your children in v-safe

Please get involved, your participation matters
Acknowledgements

- Sujan Reddy
- Mary Chamberland
- Sara Oliver
- Kathleen Dooling
- Sarah Mbaeyi
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- Matthew Oster
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- CISA
  - Karen Broder
  - Margaret Cortese

- Immunization Services Division
  - JoEllen Wolicki
  - Valerie Morelli
  - Elisha Hall
  - Andrew Kroger
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Planning for COVID-19 Vaccines for 5–11-Year-Old Children

Kevin Chatham-Stephens, MD, MPH
Pediatric Vaccine Planning and Implementation Lead
CDC Vaccine Task Force

CDC COCA Call
11/04/2021
Pediatric Vaccination Implementation Goals

- Enable access to and availability of vaccine providers where populations are most likely to seek vaccination (*reach the most*)

- Establish programming to ensure access to vaccine for vulnerable and underserved pediatric populations (*hard to reach*)

- **Minimize delays** between FDA\(^1\) authorization of pediatric vaccines and initial rollout of pediatric administration

- Disseminate **timely clinical guidance** to jurisdictions and providers

\(^1\)US Food and Drug Administration
## Approach for Reaching Children

**Augment existing public health infrastructure**

<table>
<thead>
<tr>
<th>Category</th>
<th>Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providers serving children aged 5-11 years and primary care</td>
<td>• Utilize primary care clinics, health departments, Federally Qualified Health Centers, etc. as trusted providers to vaccinate their patients</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>• Leverage broad pharmacy footprint to vaccinate children aged 5–11 years</td>
</tr>
<tr>
<td>School-located vaccination clinics</td>
<td>• Provide guidance on school districts partnering with health departments, pharmacies, and other pediatric providers to hold school-located vaccine clinics to expand access and promote equity</td>
</tr>
</tbody>
</table>


## Approach for Reaching Children

**Augment existing public health infrastructure**

<table>
<thead>
<tr>
<th>Category</th>
<th>Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children’s hospitals</td>
<td>• &gt;100 children’s hospitals across the United States will set up vaccination sites</td>
</tr>
<tr>
<td></td>
<td>• Critical part of efforts to provide access for children aged 5-11 years with underlying medical conditions</td>
</tr>
<tr>
<td>Temporary community clinics</td>
<td>• Leverage experience with adult and adolescent community vaccination clinics to complement other vaccine locations</td>
</tr>
</tbody>
</table>
Jurisdictions’ Plans to Use Different COVID-19 Vaccination Providers

- **Large pediatric providers:** 95% of jurisdictions reported VFC* enrolled providers would be providing COVID-19 vaccination to children under age 12 years.
- **VFC enrolled providers:** 86% of jurisdictions reported large pediatric providers would be providing COVID-19 vaccination to children under age 12 years.
- **Temporary vaccination clinics in the community:** 83% of jurisdictions reported pharmacists would be providing COVID-19 vaccination to children aged <12 years.
- **Temporary vaccination clinics co-located at schools:** 72% of jurisdictions reported school co-located vaccination clinics would be providing COVID-19 vaccination to children under age 12 years.

* Vaccines for Children Program
** Survey sent to 64 state and local health departments in late September. Responses are not mutually exclusive.
Where Jurisdictions Anticipate Most Children Will Be Vaccinated*

<table>
<thead>
<tr>
<th>Setting</th>
<th>Number of jurisdictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric providers</td>
<td>31</td>
</tr>
<tr>
<td>FQHCs/RHCs**</td>
<td>22</td>
</tr>
<tr>
<td>Health department</td>
<td>22</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>16</td>
</tr>
<tr>
<td>Children's hospital</td>
<td>9</td>
</tr>
<tr>
<td>School-located vaccine clinics</td>
<td>6</td>
</tr>
<tr>
<td>Temporary community clinics</td>
<td>4</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
</tr>
</tbody>
</table>

* Number of jurisdictions that ranked a setting or provider first or second from a list of 8 settings or providers

** FQHC = Federally Qualified Health Center; RHC = Rural health clinic
Parents’ Trusted Locations to Vaccinate Their 5–11-Year-Old Children*

% of respondents who selected location

- Regular doctor’s office or clinic: 62.8%
- Local pharmacy: 34.3%
- Another doctor’s office or clinic: 30.3%
- School with parent present: 25.4%
- Indoor vaccine clinic: 24.8%
- Outdoor vaccine clinic: 18.8%
- None of these: 15.9%
- School without parent present: 14.8%

*Unpublished CDC/RAND/University of Iowa data. 1,028 parents surveyed in late September/early October
CDC Support of Jurisdictional Readiness

- 2 jurisdictional readiness surveys
- Dissemination of planning resources:

CDC Support of Jurisdictional Readiness

- Guidance on, and support of, school districts partnering with pharmacies to conduct school-located vaccination clinics
- Listening sessions with public health, clinical, and other partners

How Schools Can Support COVID-19 Vaccination

Schools and school districts are consistently a large part of the daily life for many American children and families and uniquely positioned to teach about, link to, or even deliver COVID-19 vaccines.

On this page, the Centers for Disease Control and Prevention (CDC) provides action steps school leaders can take to support COVID-19 vaccine uptake and improve health literacy among staff, students, and families in their community. Which actions school districts decide to take will depend on state and local policies, health service infrastructure, and available resources.

Together, we can help our country reach COVID-19 vaccination goals.

6 Ways Schools Can Promote COVID-19 Vaccines

https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics/how-schools-can-support.html
Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)

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To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.
Joining the Q&A Session

- **Tom Shimabukuro, MD, MPH, MBA**
  Vaccine Safety Team Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- **Chris Duggar, BS, MPH**
  Vaccine Distribution, Awardee, and Partner Support Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention

- **Sujan Reddy, MD, MSc**
  Clinical Guidelines Team Lead
  Vaccine Task Force
  COVID-19 Response
  Centers for Disease Control and Prevention
Today’s COCA Call Will Be Available to View On-Demand

- **When:** A few hours after the live call ends
- **What:** Video recording
- **Where:** On the COCA Call webpage
  
  [https://emergency.cdc.gov/coca/calls/2021/callinfo_110421.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_110421.asp)
Next COCA Call

- **Topic:** What Clinicians, Pharmacists, and Public Health Partners Need to Know about Antibiotic Prescribing and COVID-19

- **Date:** Thursday, November 18, 2021

- **Time:** 2:00–3:00 P.M. ET

- **Website:** [https://emergency.cdc.gov/coca/calls/2021/callinfo_111821.asp](https://emergency.cdc.gov/coca/calls/2021/callinfo_111821.asp)
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Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.

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