Katherine Neas
Acting Assistant Secretary, Office of Special Education and Rehabilitative Services, Department of Education

Precious McKesson
Special Assistant, Office of Communications and Outreach, Department of Education

Dr. Kate Woodworth
Pediatrician and Medical Officer, Vaccine Task Force, Center for Disease Control and Prevention

Dr. Sara Bode
Chairperson-Elect, American Academy of Pediatrics Council on School Health
COVID-19 VACCINATIONS FOR CHILDREN WITH DISABILITIES
Vaccines for Children with Disabilities

- Commitment to Safe, In-person Learning for all students
- Concerns for children with underlying health conditions
- Return to School Roadmap guidance
- CDC guidance on tiered prevention strategies
Parent Engagement

Precious McKesson
Department of Education
Pfizer-BioNTech COVID-19 Vaccine in Children aged 5–11 Years

Kate Woodworth, MD, MPH, FAAP
Medical Officer
Vaccine Task Force, CDC COVID-19 Response

cdc.gov/coronavirus
### Evidence to Recommendations (EtR) Framework

<table>
<thead>
<tr>
<th>EtR Domain</th>
<th>Question(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Problem</td>
<td>• Is the problem of public health importance?</td>
</tr>
<tr>
<td>Benefits and Harms</td>
<td>• How substantial are the desirable anticipated effects?</td>
</tr>
<tr>
<td></td>
<td>• How substantial are the undesirable anticipated effects?</td>
</tr>
<tr>
<td></td>
<td>• Do the desirable effects outweigh the undesirable effects?</td>
</tr>
<tr>
<td>Values</td>
<td>• Does the target population feel the desirable effects are large relative to the undesirable effects?</td>
</tr>
<tr>
<td></td>
<td>• Is there important variability in how patients value the outcome?</td>
</tr>
<tr>
<td>Acceptability</td>
<td>• Is the intervention acceptable to key stakeholders?</td>
</tr>
<tr>
<td>Feasibility</td>
<td>• Is the intervention feasible to implement?</td>
</tr>
<tr>
<td>Resource Use</td>
<td>• Is the intervention a reasonable and efficient allocation of resources?</td>
</tr>
<tr>
<td>Equity</td>
<td>• What would be the impact of the intervention on health equity?</td>
</tr>
</tbody>
</table>

“The intervention” = Pfizer-BioNTech COVID-19 vaccine, given to children aged 5–11 years

“The problem” = COVID-19 among children aged 5–11 years
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
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

- **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
  - 94 COVID-19 deaths (1.7% of all deaths among U.S. children 5–11 years)
  - 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
  - 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**
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
Pfizer-BioNTech COVID-19 vaccine trial

- 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%)
- 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
Phase 2/3 trial: Children 5-11 years of age

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

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

- 2 SAEs in 1 in the placebo group (n=750)
  - Pancreatitis
  - Abdominal pain

- 0 SAEs in the placebo group (n=788)

*Unpublished, data obtained from sponsor; randomized 2:1 vaccine to placebo
Phase 2/3 trial: Children 5-11 years of age
Reactogenicity

- 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 within 7 days occurred in 86% vaccine recipients
  - Pain at the injection site most common

- Systemic reactions within 7 days occurred in 67% vaccine recipients
  - Fatigue and headache most common

- Severe reactions (grade ≥ 3 reaction) more common in vaccine recipients (2.7%) compared to placebo recipients (1.1%)
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%

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)
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
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
Locations Parents Trust to Vaccinate Their 5–11-Year-Old Children*

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

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

<table>
<thead>
<tr>
<th>Vial cap color</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>Age group</td>
<td>12 years and older</td>
<td>5-11 years</td>
</tr>
<tr>
<td>Dose (mRNA concentration)</td>
<td>30 ug</td>
<td>10 ug</td>
</tr>
</tbody>
</table>

Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf
<table>
<thead>
<tr>
<th></th>
<th>Formulation for ≥12-year-olds (purple cap)</th>
<th>Formulation for 5–11-year-olds (orange cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Interval</td>
<td>3 weeks (21 days)</td>
<td>3 weeks (21 days)</td>
</tr>
<tr>
<td>Additional primary dose</td>
<td>Moderate and severe immunocompromise</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Booster dose</td>
<td>Not recommended 12–17 years</td>
<td>Not recommended</td>
</tr>
<tr>
<td></td>
<td>Recommended for certain groups ≥18 years*</td>
<td></td>
</tr>
</tbody>
</table>

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

- The following links provide additional information about pediatric COVID-19 vaccination and school-located vaccination clinics
  - COVID-19 Vaccination for Children 5-11 Years Old | CDC
  - COVID-19 Vaccines for Children and Teens | CDC
  - Considerations for Planning School-Located Vaccination Clinics | CDC
  - Guidance for COVID-19 Prevention in K-12 Schools | CDC
  - Guide to On-Site Vaccination Clinics for School | WECANDOTHIS.HHS.GOV
  - Communication Resources for COVID-19 Vaccines | CDC
  - Frequently Asked Questions about COVID-19 Vaccination | CDC
HHS Resources

- Families of children with disabilities and special healthcare needs
Find COVID-19 Vaccines

5-digit Zip Code
Zip Code

Search Radius
25 miles

Vaccine Options

Pfizer-BioNTech (age 5-11)

Pfizer-BioNTech (age 12+)

Moderna (age 18+)

Johnson & Johnson/Janssen (age 18+)

Search for COVID-19 Vaccines

I'm looking for flu vaccines ➔
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.
This is Their Shot! COVID-19 Vaccination 5-11-Year-Olds

Sara Bode, MD, FAAP
Chairperson-Elect, American Academy of Pediatrics Council on School Health
The AAP recommends COVID-19 vaccination for all children and adolescents five years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.
Children and Adolescents have been significantly impacted by COVID-19

- Number of new child COVID-19 cases remains exceptionally high in the US.
- Children make up a growing percentage of hospitalized. Hospitalizations among unvaccinated adolescents 10x higher than fully vaccinated.

Benefits Outweigh the Risks

- Risk of myocarditis 16-18 times higher in patients with SARS-CoV-2 infection than non-infected individuals.
- Risk of myocarditis in individuals post-SARS-CoV-2 infection was 6-34 times higher compared to those who received mRNA
Vaccination - Access or Hesitancy?

**What is access?**

- Access to clinics
- Access to reputable information
- Access to trusted experts to ask questions

**What is hesitancy?**

- Strongly held beliefs - may include friend/family/community influence
- Feeling uninformed to ‘choose to act’
**ADDRESSING PARENTS’ CONCERNS: HEALTHYCHILDREN.ORG**

**COVID-19 Vaccine and Fertility**

What side effects might my child have after a COVID-19 vaccine?
By: Hina J. Talib, MD, FAAP

Does the COVID vaccine affect fertility?
By: Edith Bracho-Sanchez, MD, FAAP

Does the COVID-19 vaccine cause myocarditis?
By: Yvonne A. Maldonado, MD, FAAP

Can my child get a COVID vaccine with their other immunizations?
By: Shaquita Bell, MD, FAAP

---

**Ask the Pediatrician: COVID-19 Roundup**

**Question**

Who can parents trust most when it comes to COVID-19 and their children’s health?

**Answer**

A pediatrician, of course!

You’ve got plenty of questions. The internet has loads of answers. Unfortunately, though, there’s a lot of misinformation out there. For reliable, evidence-based information, turn to your child’s doctor.

Pediatricians just like yours have dedicated their time to answer parents’ most pressing questions about the COVID-19 vaccine. Whether your child is a toddler or a teen, you will find credible information that you can trust right here from pediatricians about COVID-19. Browse some of the latest questions and answers:

---

**COVID-19: Caring for Children and Adolescents with Special Health Care Needs**

By: Dorena Z. Kuo, MD, MPH, FAAP & Cara Coleman, JD, MPH

COVID-19 is surging with new and more contagious variants, putting children still too young for COVID vaccines at risk for infection. Children and youth with special health care needs (CYSHCN) may be at increased risk for more severe illness and complications. This includes children with chronic physical, developmental, behavioral or emotional conditions, disabilities, and those with medically complex conditions.

---

**Question**

Was the COVID-19 vaccine rushed?

**Answer**

No, the COVID-19 vaccine wasn’t rushed. There was a great sense of urgency worldwide, scientific attention and teamwork to help make the vaccine possible—and to save lives. An incredible amount of work went into the COVID-19 vaccine. We know that parents like you trust us to care for your children. That’s why we are here for families and ready to answer your questions about the COVID-19 vaccine.
Check out new science explainer videos on how mRNA vaccines work & how they were developed on AAP’s YouTube channel.

COVID-19 and kids: How mRNA vaccines work

How mRNA COVID-19 vaccines were developed
Reaching Families on Social Media

Follow AAP on social media:

@AmerAcadPeds on Twitter

American Academy of Pediatrics Facebook Page
**How Do I Prepare My Child?**

Is your child anxious about shots?

Try these tips:

- Preparation is KEY!! Describing the process from beginning to end
- Distraction techniques
- Use of ‘Buzz Buddies’
- Rewards are good!
Thank You!