



5-11 COVID-19 Vaccine Parents and Families Webinar

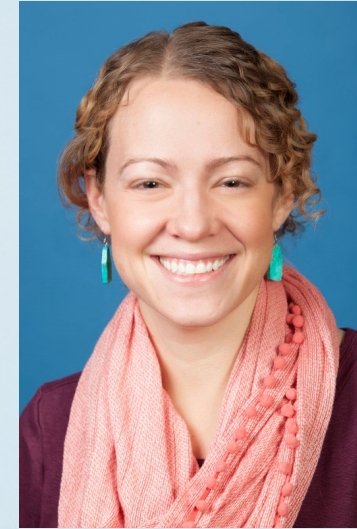
U.S. Department of Education
Centers for Disease Control and Prevention
American Academy of Pediatrics



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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

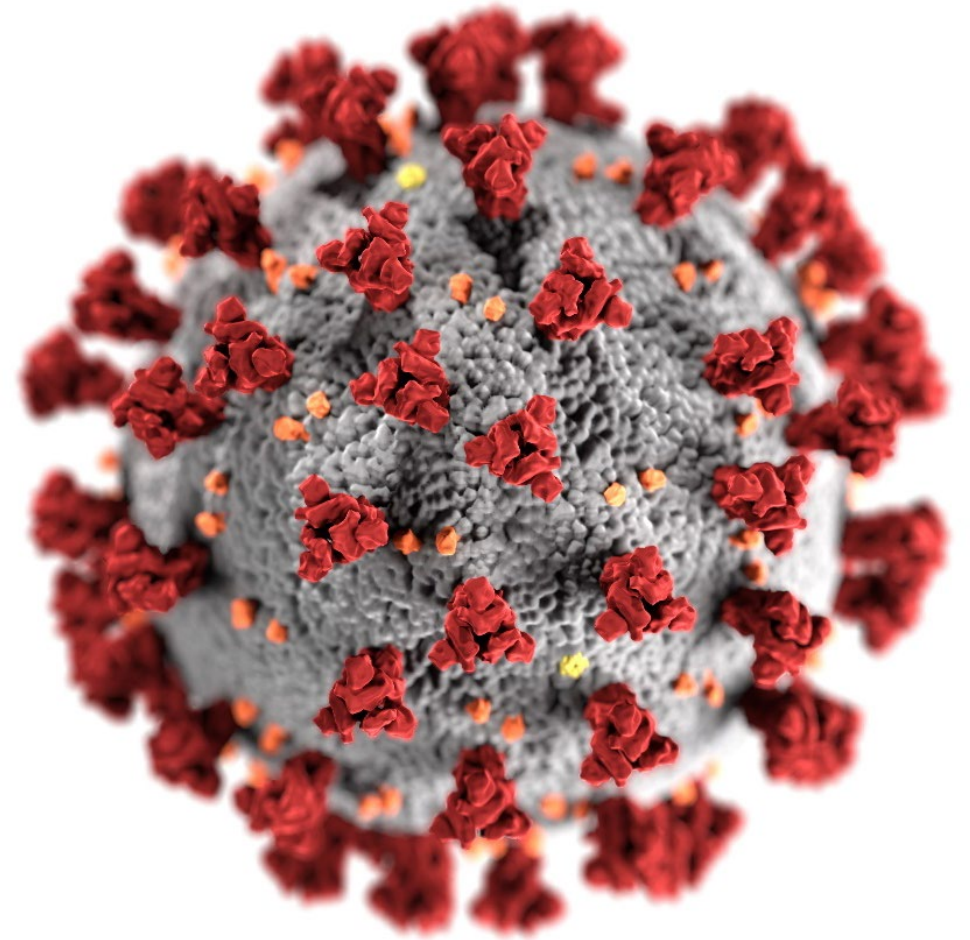
Precious McKesson
Department of Education

Pfizer-BioNTech COVID-19 Vaccine in Children aged 5–11 Years

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Medical Officer

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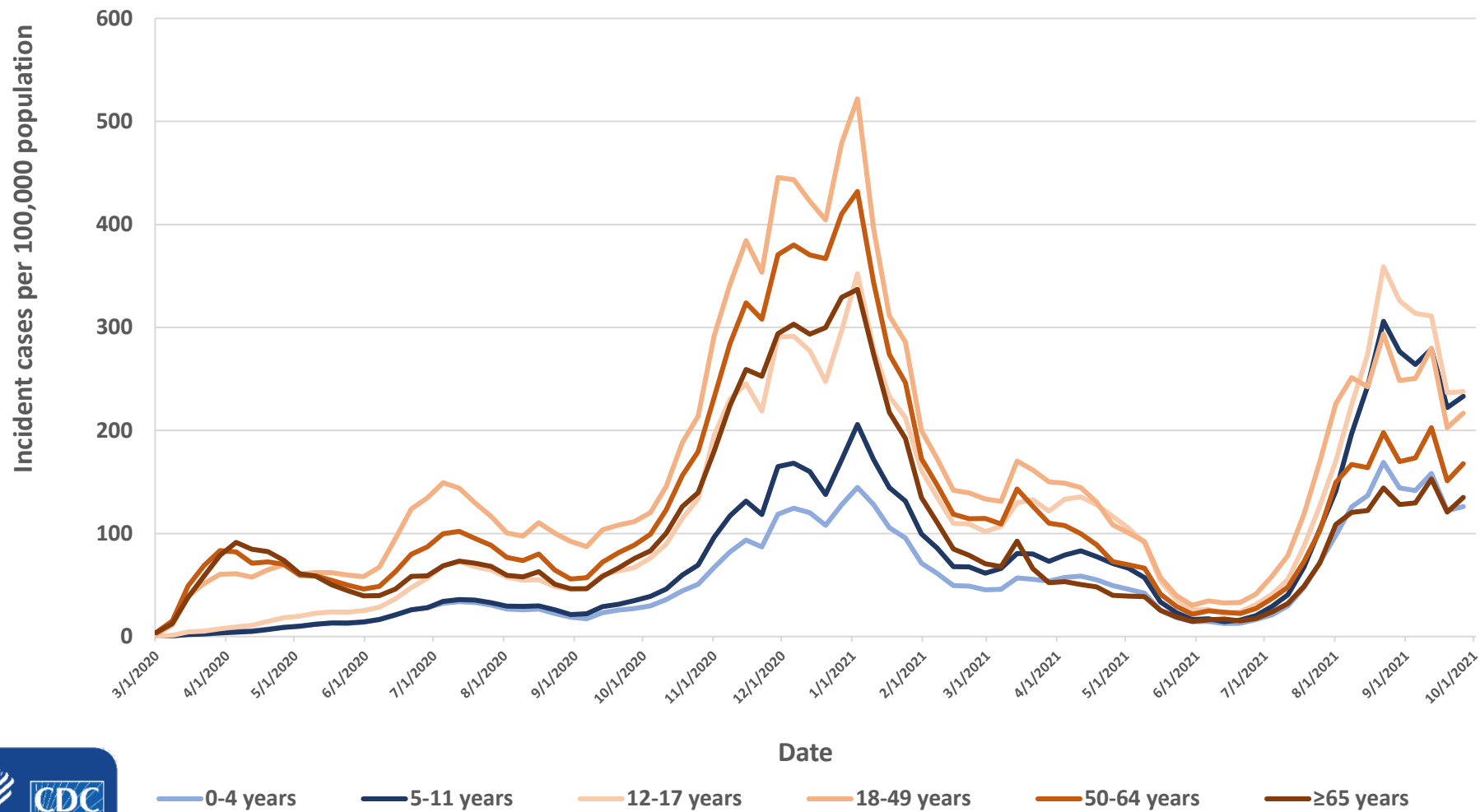
cdc.gov/coronavirus

Evidence to Recommendations (EtR) Framework

EtR Domain	Question(s)
Public Health Problem	<ul style="list-style-type: none"> • Is the problem of public health importance?
Benefits and Harms	<ul style="list-style-type: none"> • How substantial are the desirable anticipated effects? • How substantial are the undesirable anticipated effects? • Do the desirable effects outweigh the undesirable effects?
Values	<ul style="list-style-type: none"> • Does the target population feel the desirable effects are large relative to the undesirable effects? • Is there important variability in how patients value the outcome?
Acceptability	<ul style="list-style-type: none"> • Is the intervention acceptable to key stakeholders?
Feasibility	<ul style="list-style-type: none"> • Is the intervention feasible to implement?
Resource Use	<ul style="list-style-type: none"> • Is the intervention a reasonable and efficient allocation of resources?
Equity	<ul style="list-style-type: none"> • What would be the impact of the intervention on health equity?

“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**

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
 - 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)


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

Recent Epidemiology 5-11 years

 **58,204** COVID-19 cases prevented

 **226** hospitalizations prevented


 **132** MIS-C cases prevented

 **72** ICU admissions prevented

Pandemic Average 5-11 years

 **18,549** COVID-19 cases prevented

 **80** hospitalizations prevented

 **42** MIS-C cases prevented

 **26** ICU admissions prevented

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

Data Sources: COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic>. COVID Data Tracker https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.

COVID-Net https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html.

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.

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

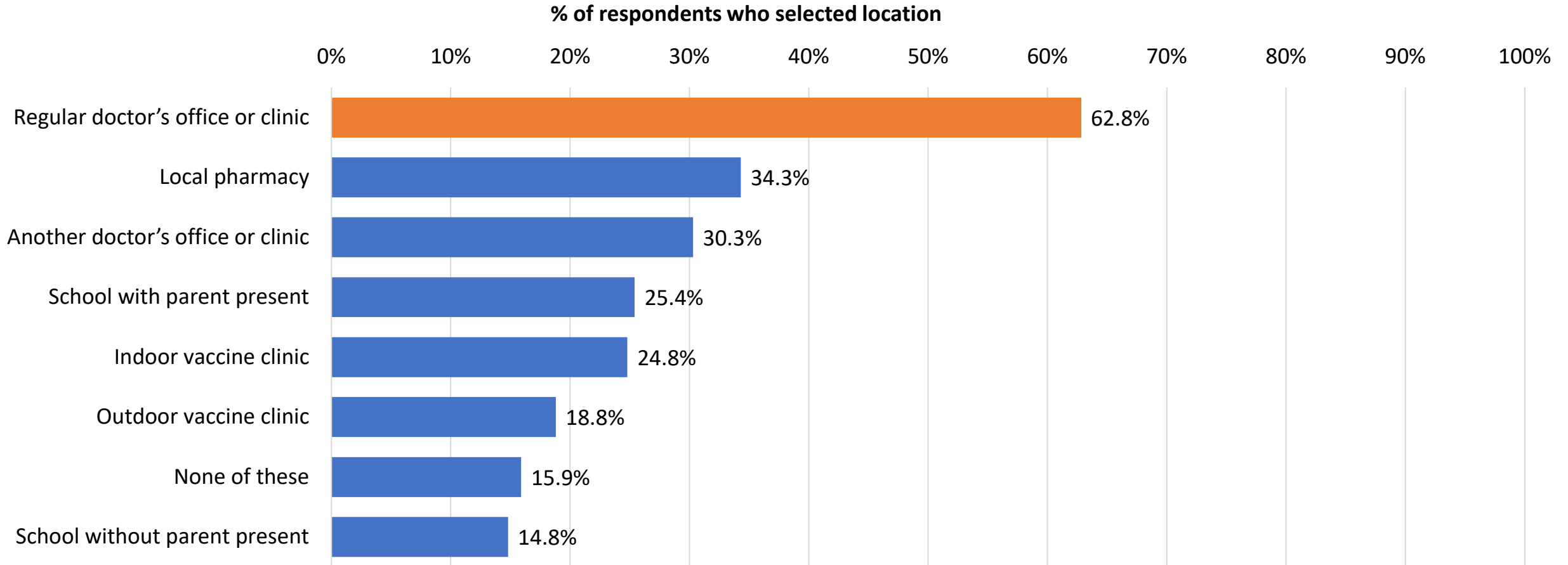
8,300 hospitalizations

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

Category

Approach



Providers serving children aged 5-11 years and primary care

- Utilize primary care clinics, health departments, Federally Qualified Health Centers, etc. as trusted providers to vaccinate their patients



Pharmacies

- Leverage broad pharmacy footprint to vaccinate children aged 5–11 years



School-located vaccination clinics

- 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



Approach for Reaching Children Continued

Augment existing public health infrastructure

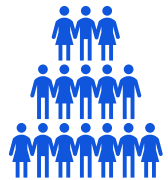
Category

Approach



Children's hospitals

- >100 children's hospitals across the United States will set up vaccination sites
- Critical part of efforts to provide access for children aged 5-11 years with underlying medical conditions



Temporary community clinics

- Leverage experience with adult and adolescent community vaccination clinics to complement other vaccine locations

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥ 12 -year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

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

*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
 - Disability Information and Access Line <https://wecandothis.hhs.gov/covid-19-vaccine-disability-information-and-access-line-dial>



Need help finding a COVID-19 vaccine in the U.S.? Call 1-800-232-0233 (TTY 888-720-7489)

Find COVID-19 Vaccines

Powered by **VaccineFinder**

5-digit Zip Code

Zip Code

Search Radius

25 miles



Vaccine Options

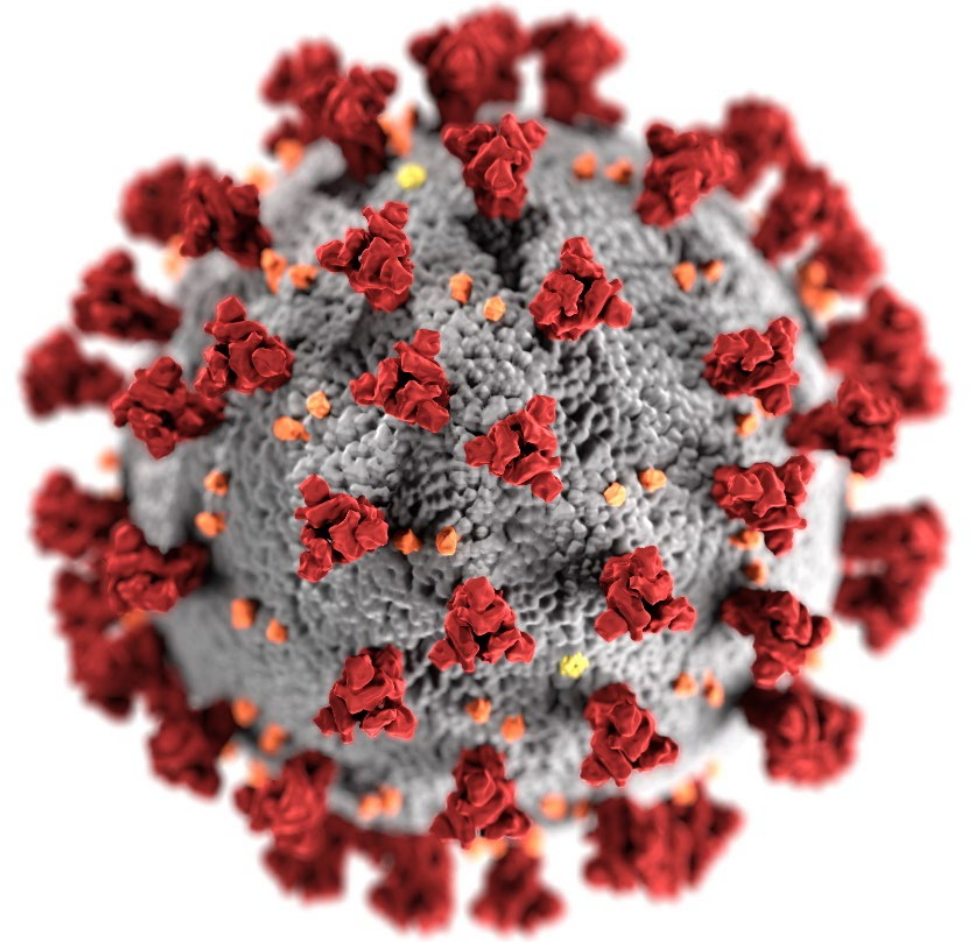
- Pfizer-BioNTech (age 5-11)
- Pfizer-BioNTech (age 12+)
- Moderna (age 18+)
- Johnson & Johnson/Janssen (age 18+)

Search for COVID-19 Vaccines

[I'm looking for flu vaccines →](#)



Thank you!



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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



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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.

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Why Vaccinate Children Against COVID-19?

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




Dr. Edith Bracho-Sanchez, Pediatrician, New York
aap.org
healthychildren.org


COVID-19 Vaccine and Fertility

Select Language ▾


Watch




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:



Dr. Stuart Berger, Pediatric Cardiologist
aap.org
healthychildren.org

Myocarditis and COVID-19

Watch

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

By: *Dennis Z Kuo, MD, MHS, 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?



Anisa M. Ibrahim, MD, FAAP

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.

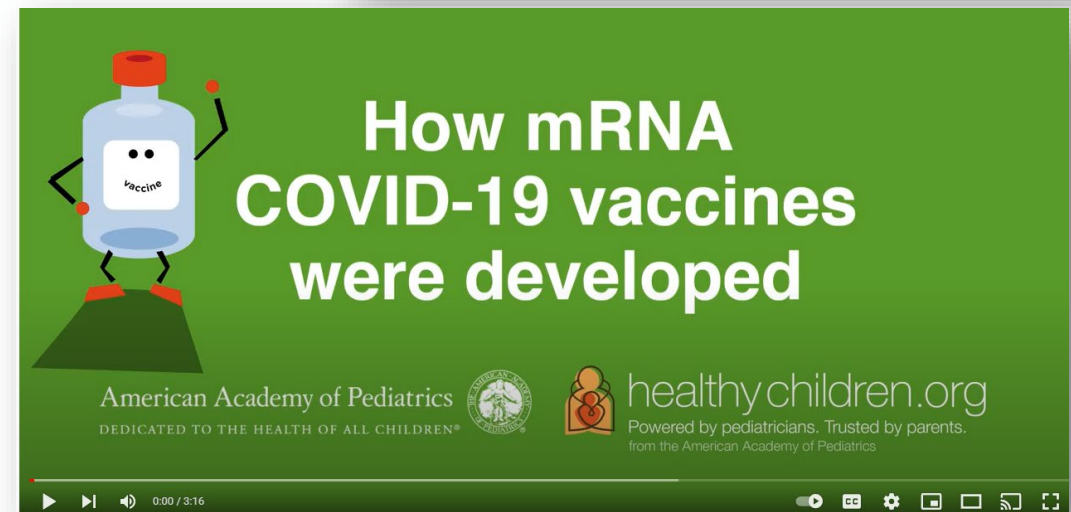
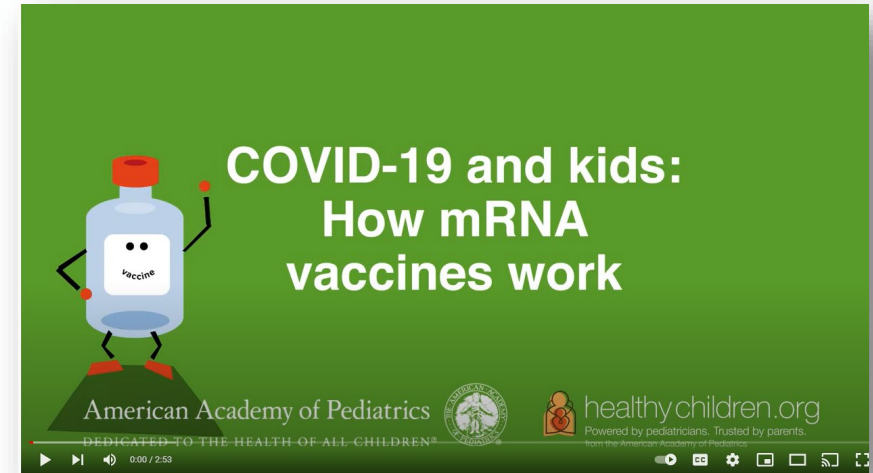
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Resources for Patients, Families, and Caregivers

Check out **new science explainer videos** on how mRNA vaccines work & how they were developed on AAP's YouTube channel

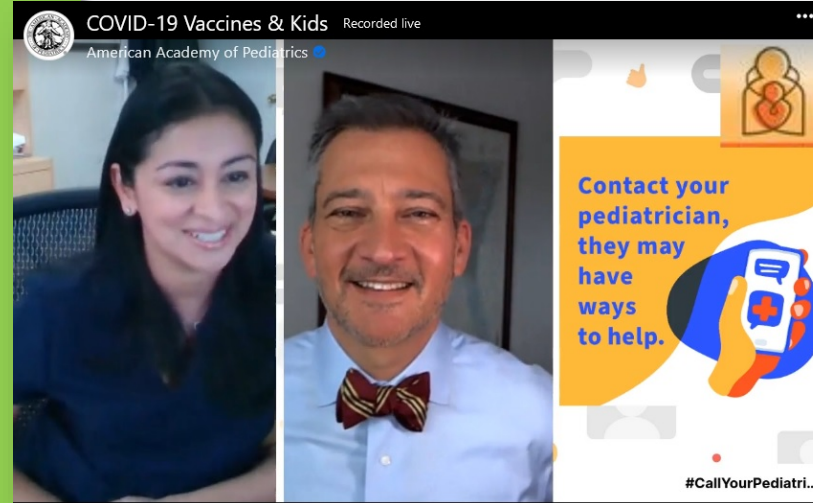


Reaching Families on Social Media

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!

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