



# **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.

# To Ask a Question

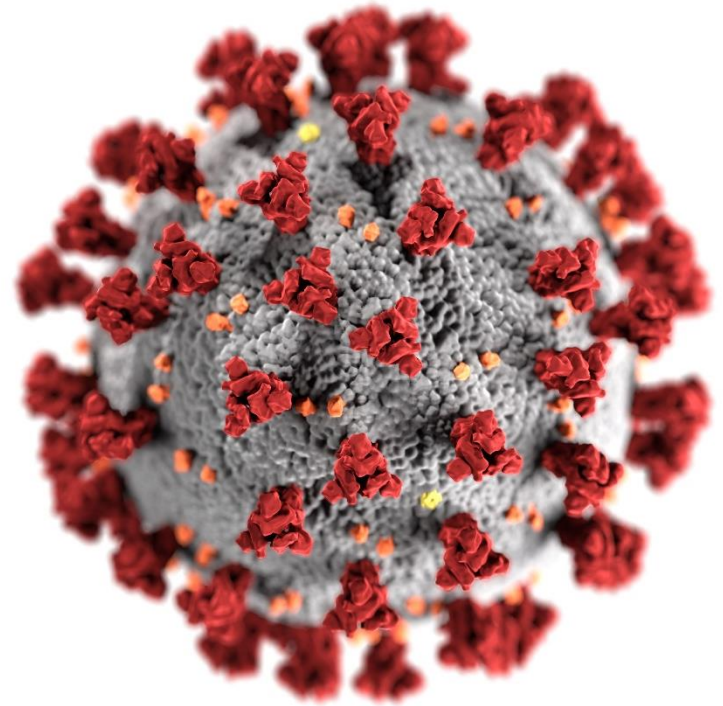
- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question
- If you are a patient, please refer your question to your healthcare provider.
- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email [media@cdc.gov](mailto: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

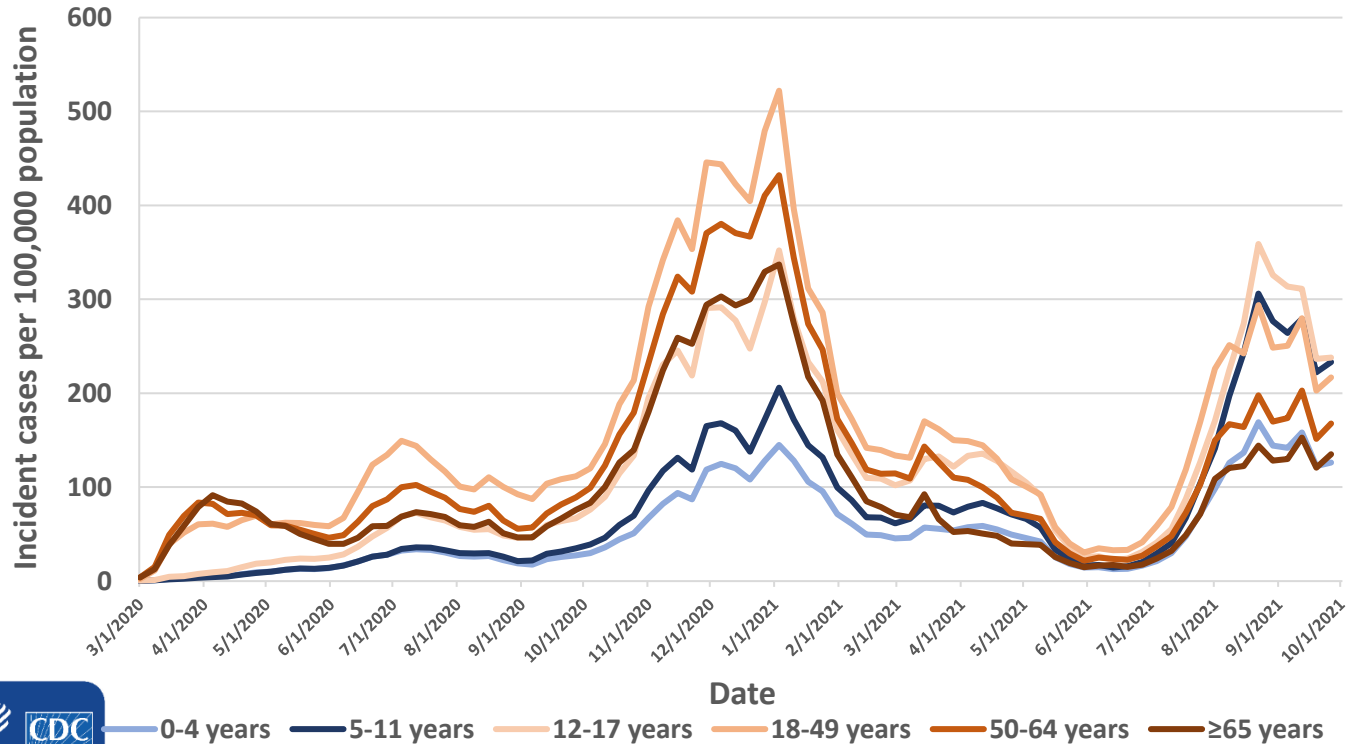
# Pfizer-BioNTech COVID-19 Vaccine in Children aged 5–11 Years Old

Sara Oliver MD, MSPH  
COCA Call  
November 4, 2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

# COVID-19 Weekly Cases per 100,000 Population by Age — United States, March 1, 2020–October 10, 2021

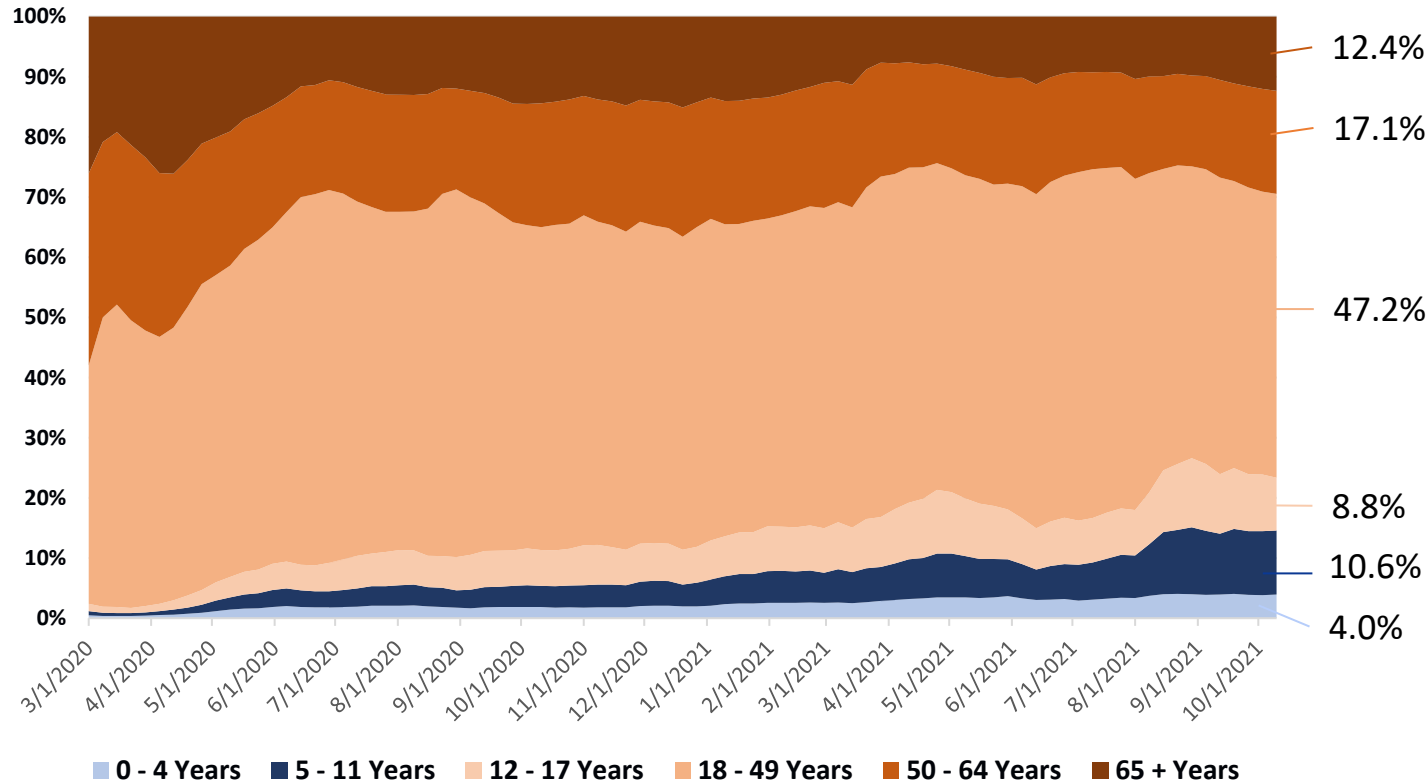


**>1.9 million**  
cases among  
children 5-11  
years of age



# Proportion of Total COVID-19 Cases by Age Group

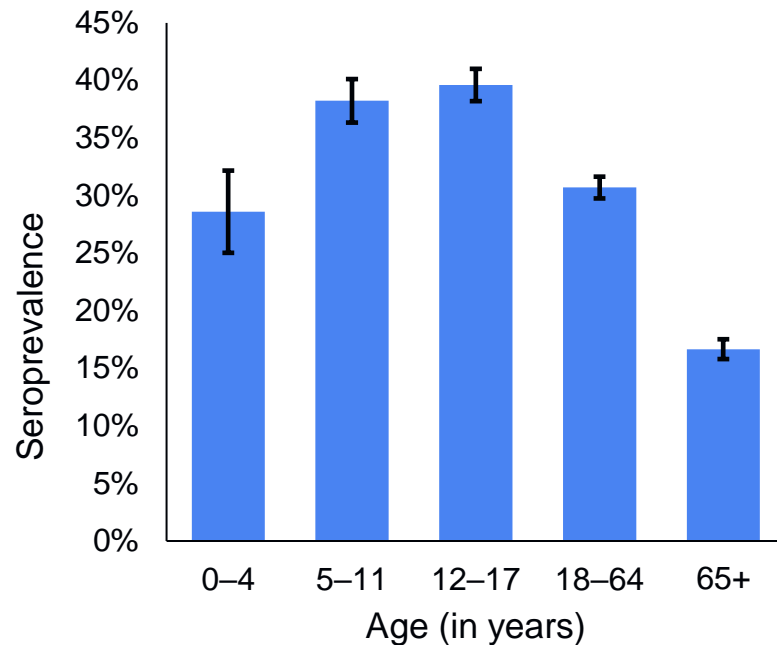
## — United States, March 1, 2020–October 10, 2021



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

# 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)



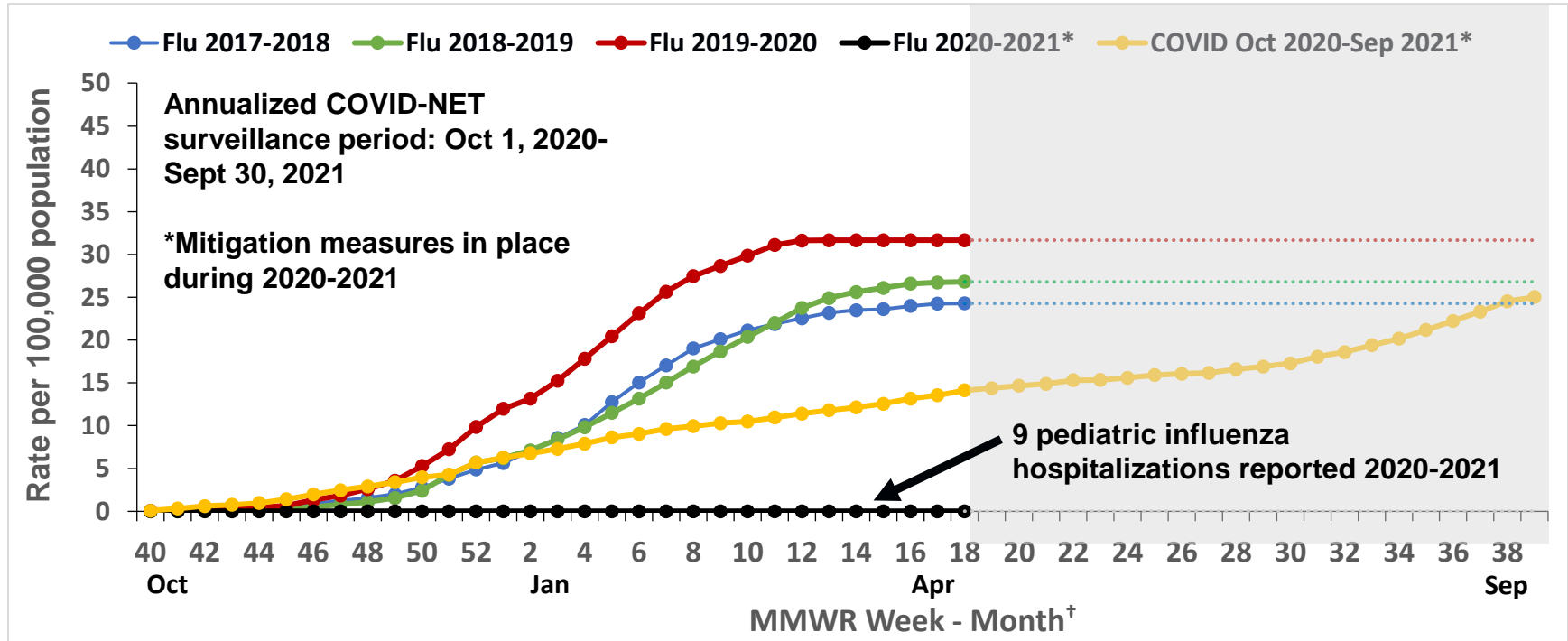
Data are preliminary and subject to change

\*Restricted to 23 jurisdictions with  $\geq 75$  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



\*Mitigation measure in place during 2020–2021

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

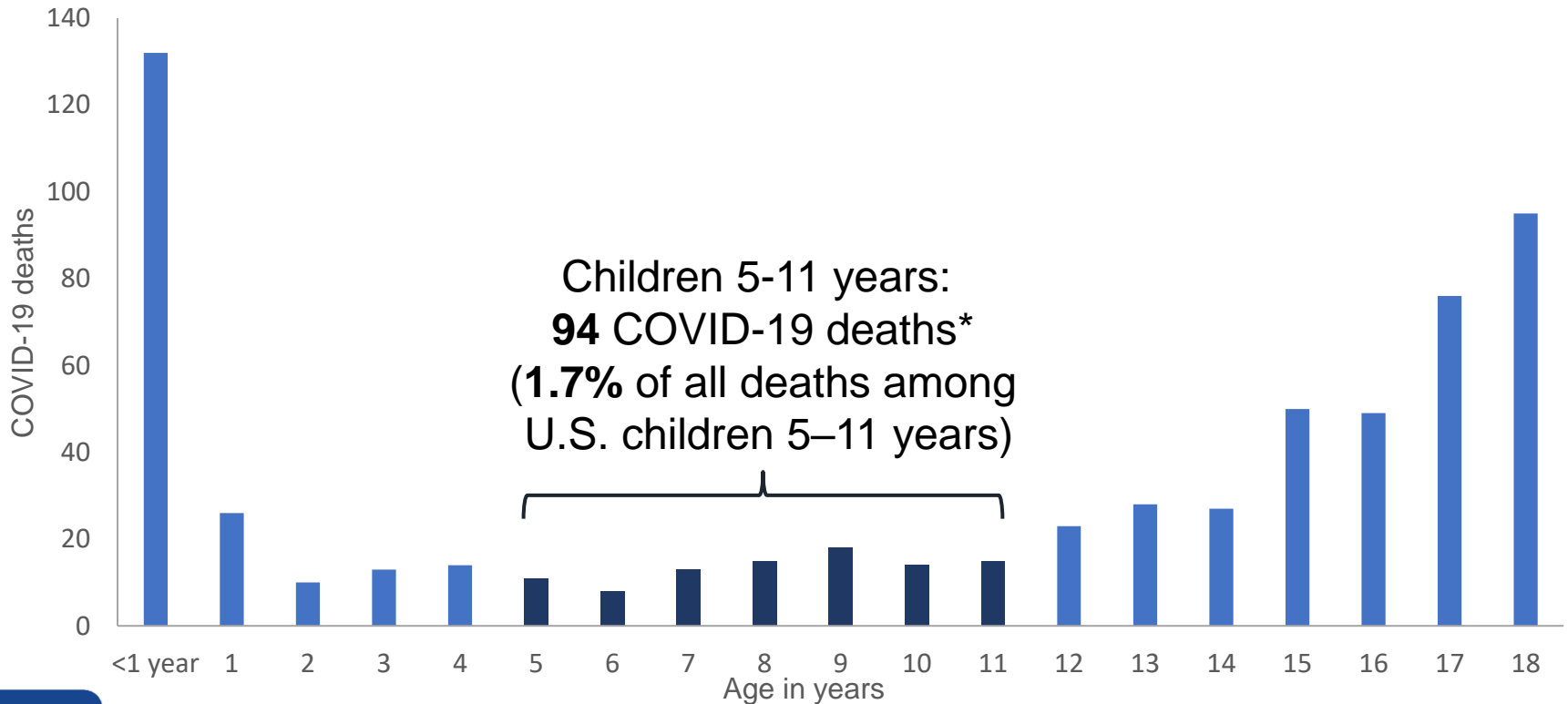
†Influenza seasons: MMWR week 40 of the earlier year to MMWR week 18 of the later year. The COVID period: Oct 2020–Sep 2021 goes from MMWR week 40 of year 2020 to MMWR week 39 of year 2021. MMWR Week 53 for MMWR Year 2020 is combined with MMWR Week 52 for consistency with other years.

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.



# COVID-19 Deaths by Age Group, NCHS

## — United States. January 1, 2020–October 16, 2021



\*Lag in reporting of deaths might result in underestimate  
<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>

# 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

	Hepatitis A <sup>1</sup>	Varicella <sup>2</sup> (Chickenpox)	Influenza <sup>3</sup>	COVID-19
Age	5–14 years	<20 years	5–17 years	5–11 years
Time period	2005	1988–1995	2003–2007	Oct 2020–Oct 2021
Hospitalization Burden (per 100,000 population)	<1	4-31	30-80	25

<sup>1</sup> <https://www.cdc.gov/mmwr/preview/mmwrhtml/ss5603a1.htm>

<sup>2</sup> Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970-1994. *J Infect Dis.* 2000;182(2):383-390. doi:10.1086/315714

<sup>3</sup> <https://www.cdc.gov/flu/weekly/weeklyarchives2007-2008/07-08summary.htm>

# Other pediatric vaccine preventable diseases:

## Deaths per year prior to recommended vaccines

	Hepatitis A <sup>1</sup>	Meningococcal (ACWY) <sup>2</sup>	Varicella <sup>3</sup>	Rubella <sup>4</sup>	Rotavirus <sup>5</sup>	COVID-19
Age	<20 years	11–18 years	5–9 years	All ages	<5 years	5–11 years
Time period	1990–1995	2000–2004	1990–1994	1966–1968	1985–1991	Oct 2020– Oct 2021
Average deaths per year	<b>3</b>	<b>8</b>	<b>16</b>	<b>17</b>	<b>20</b>	<b>66</b>

<sup>1</sup>Vogt TM, Wise ME, Bell BP, Finelli L. Declining hepatitis A mortality in the United States during the era of hepatitis A vaccination. *J Infect Dis* 2008; 197:1282–8.

<sup>2</sup>National Notifiable Diseases Surveillance System with additional serogroup and outcome data from Enhanced Meningococcal Disease Surveillance for 2015–2019.

<sup>3</sup>Meyer PA, Seward JF, Jumaan AO, Wharton M. Varicella mortality: trends before vaccine licensure in the United States, 1970–1994. *J Infect Dis*. 2000;182(2):383–390. doi:10.1086/315714

<sup>4</sup>Roush SW, Murphy TV; Historical comparisons of morbidity and mortality for vaccine-preventable diseases in the United States. *JAMA* 2007; 298:2155–63.

<sup>5</sup>Glass RI, Kilgore PE, Holman RC, et al. The epidemiology of rotavirus diarrhea in the United States: surveillance and estimates of disease burden. *J Infect Dis*. 1996 Sep;174 Suppl 1:S5–11.

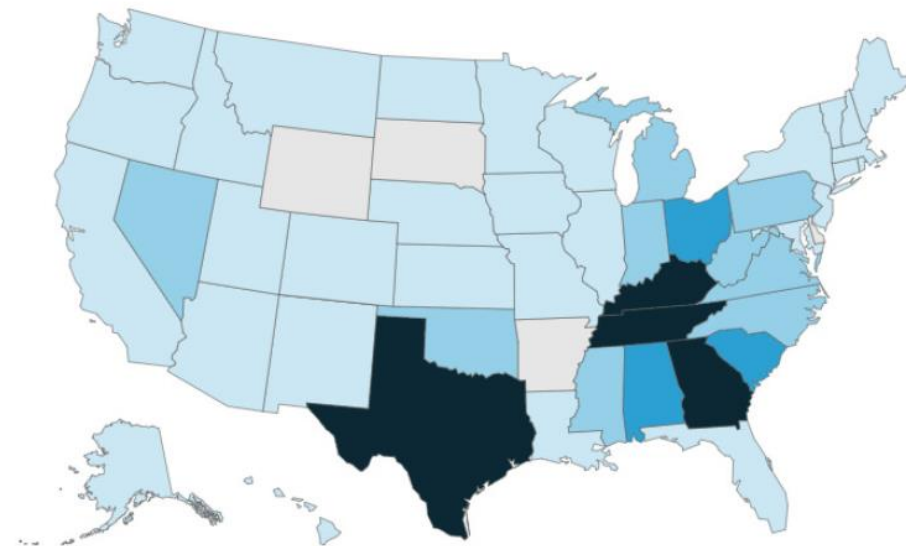
# Modeling the impact of COVID-19 vaccination in children ages 5–11 years

- 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

# COVID-19 Related K-12 School Closures by State, August 2, 2021 – October 22, 2021

School districts closed	Total # schools closed*	Estimated # students affected*	Estimated # teachers affected*
-------------------------	-------------------------	--------------------------------	--------------------------------

313	2,351	<b>1,217,777</b>	78,134
-----	-------	------------------	--------



# of Schools Closed 0 1 - 29 30 - 59 60 - 89 90 - 119 120 - 149 150 - 179 180+

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



# Public health problem:

## Summary of the available evidence

- **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

# 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**

# 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)

## Reactogenicity, severe (grade $\geq 3$ )

- 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  $\geq 3$  reaction after either dose
    - Most reactions were grade 3; 1 child in the vaccine arm with had a grade 4 fever  $>40.0^{\circ}\text{C}$ ; there were no other grade 4 reactions
  - More common after Dose 2; pain at injection site, fatigue and headache were the most common

# 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<sup>1-4</sup>
  - Asymptomatic infection can result in lower antibody levels than severe disease


1. Viner RM, Ward JL, Hudson LD, et al. [published online ahead of print, 2020 Dec 17]. *Arch Dis Child*. 2020;archdischild-2020-320972
2. Irfan O, Muttalib F, Tang K, Jiang L, Lassi ZS, Bhutta Z. [published online ahead of print, 2021 Feb 16]. *Arch Dis Child*. 2021;106(5):440-448
3. Dawood FS, Porucznik CA, Veguilla V, et al. [published online ahead of print, 2021 Oct 8]. *JAMA Pediatr*. 2021;10.1001/jamapediatrics.2021.4217. doi:10.1001/jamapediatrics.2021.4217
4. Poline J, Gaschignard J, Leblanc C, et al.. *Clin Infect Dis*. 2021;72(12):2215-2217. doi:10.1093/cid/ciaa1044

# 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

## Females 5-11 years

 **57,301** COVID-19 cases prevented

 **191** hospitalizations prevented


 **130** MIS-C cases prevented

 **60** ICU admissions prevented

## Males 5-11 years

 **56,954** COVID-19 cases prevented

 **226** hospitalizations prevented

 **130** MIS-C cases prevented

 **72** 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](https://covid.cdc.gov/covid-data-tracker/#trends_dailycases). COVID-Net [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html). All data are from the week ending on **9/11/2021**.



# 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](https://covid.cdc.gov/covid-data-tracker/#trends_dailycases). COVID-Net [https://gis.cdc.gov/grasp/COVIDNet/COVID19\\_3.html](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.

# 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)

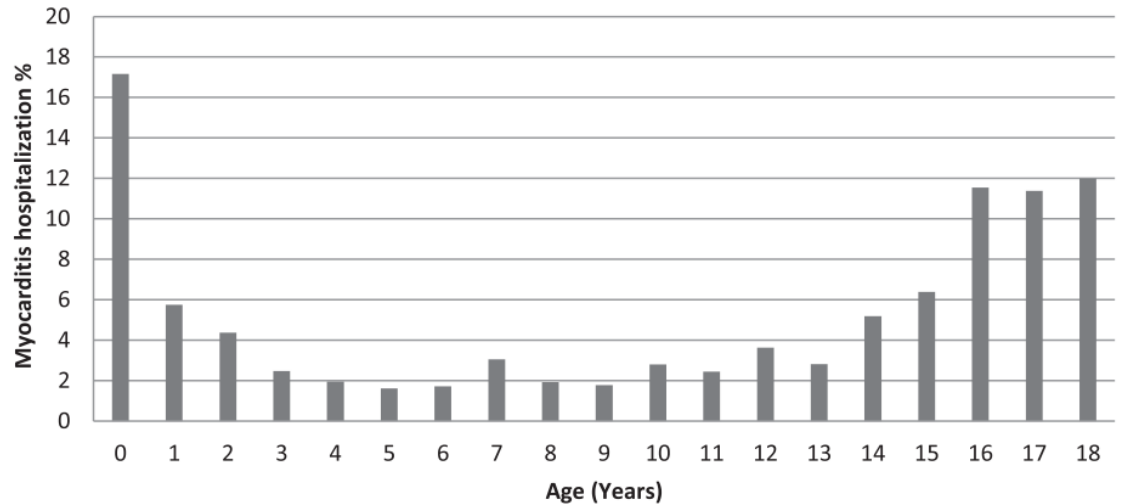
Myocarditis after vaccination in 5–11-year-old population likely **lower** than rates seen in 12–15-year-olds

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 (10 $\mu$ g) is a third of dose used in 12–15-year-olds (30 $\mu$ g)

# 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%



Vasudeva et al. *American J Cardiology*. 2021.  
Ghelani et al. *Circ Cardiovasc Qual Outcomes*. 2012  
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



	<b>Females</b>	<b>Males</b>	<b>Total</b>
<b>VAERS</b>	3.9	39.9	21.5
<b>VSD</b>	12.1	108.5	60.2

VAERS rates as of Oct 6<sup>th</sup>; VSD rates as of Oct 23<sup>rd</sup>. 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<sup>1-6</sup>
- **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’<sup>5</sup>
- **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<sup>5</sup>
- 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<sup>6</sup>

1. Szilagyi PG, et al. Parents' Intentions and Perceptions About COVID-19 Vaccination for Their Children: Results From a National Survey [published online ahead of print, 2021 Aug 3]. Pediatrics. 2021;e2021052335.

2. Ruggiero KM, et al. Parents' Intentions to Vaccinate Their Children Against COVID-19 [published online ahead of print, 2021 Jun 30]. J Pediatr Health Care.

3. Brennan M. In U.S., 55% Would Get COVID-19 Vaccine for Young Child. Gallup. September 28, 2021. Available at: <https://news.gallup.com/poll/354998/covid-vaccine-young-child.aspx> . Accessed October 1, 2021

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

5. Gallup Panel Poll. Available at <https://news.gallup.com/poll/354998/covid-vaccine-young-child.aspx>. Accessed September 29, 2021.

6. Lopes L, et al. KFF COVID-19 Vaccine Monitor: Available at: <https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-trends-among-children-school/> Accessed: October 1, 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

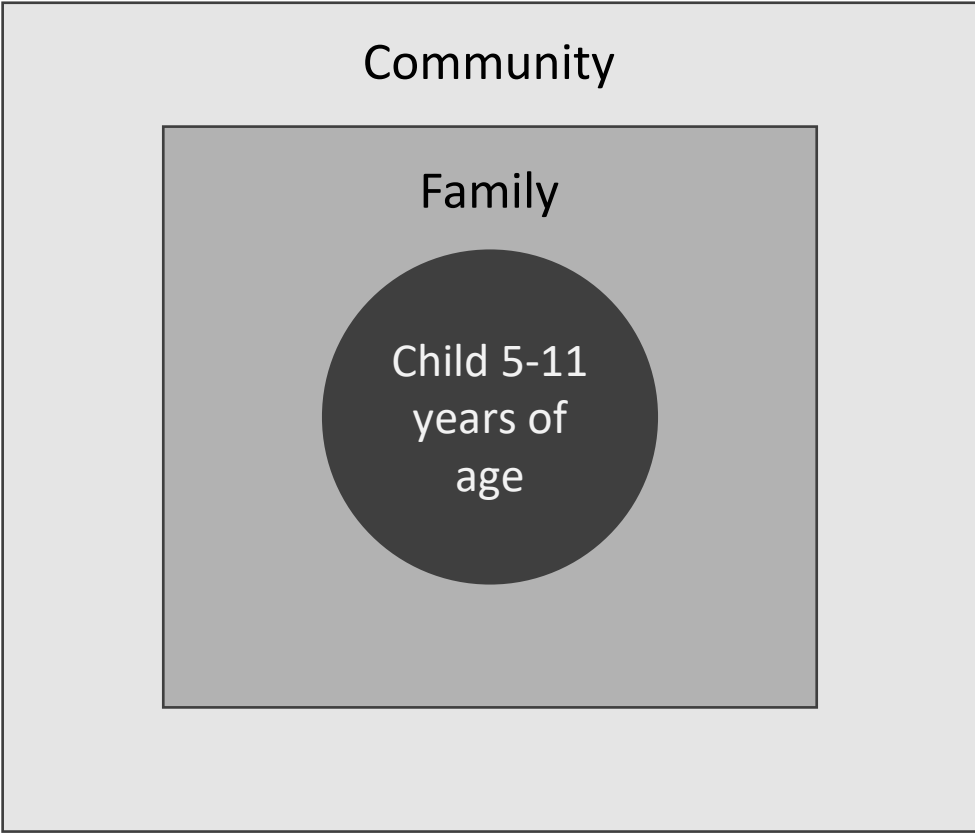
Possible prevention of transmission to vulnerable family members



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**

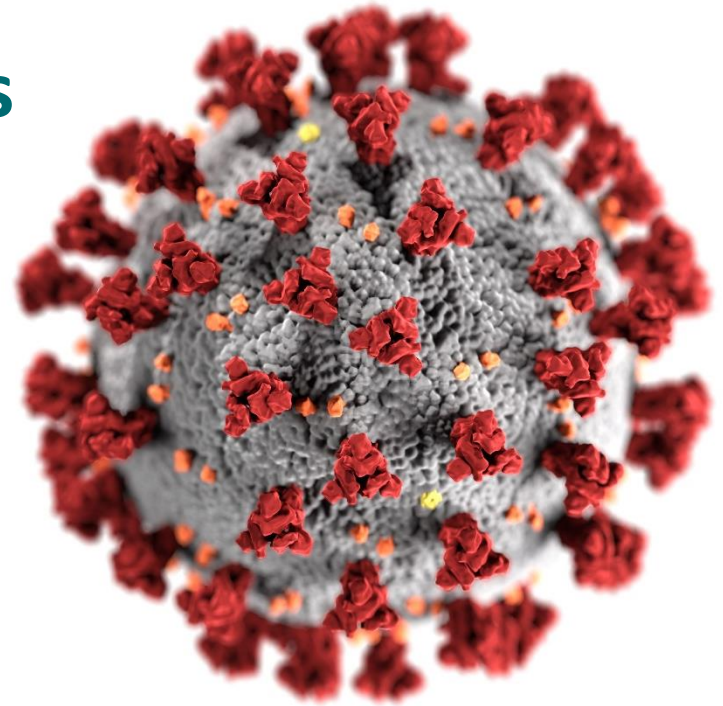
# ACIP Vote – Interim Recommendation

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



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)



# 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

	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
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

\*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

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

# 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.

# Vaccine Recipients





# Underlying Medical Conditions

- Children with underlying medical conditions may be at increased risk for severe illness from COVID-19<sup>1</sup>, 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.**

<sup>1</sup><https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#ChildrenAndTeens>

<sup>2</sup><https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>

# 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 isolation<sup>1</sup>.
  - 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-making<sup>2</sup>.

<sup>1</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html>

# 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<sup>1</sup> and in the general population there has been no safety concerns associated with vaccination of those who had prior infection.

<sup>1</sup><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 FDA-authorized 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<sup>1</sup>.
- Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection<sup>1</sup>.
- 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<sup>1</sup>.
- 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<sup>2</sup>.

<sup>1</sup>Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep 2021;70:977–982.

DOI: <http://dx.doi.org/10.15585/mmwr.mm7027e2>

<sup>2</sup>Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232. DOI: <http://dx.doi.org/10.15585/mmwr.mm7035e5>

# Counseling: Possible Risk of Myocarditis

- 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>



# Administration



# 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<sup>1</sup>.
  - Separate injection sites by 1 inch or more.
  - For older children ( $\geq 11$  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.

<sup>1</sup><https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>

# Administration Errors

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

## COVID-19 Vaccine

### Administration Errors and Deviations



A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This table provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, it includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors.

#### For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the [state immunization program](#) and/or [immunization information system \(IIS\)](#) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.

#### Interim recommendations for COVID-19 vaccine administration errors and deviations



# 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



**VAERS**

Vaccine Adverse Event Reporting System

<http://vaers.hhs.gov>



[vsafe.cdc.gov/en/](https://vsafe.cdc.gov/en/)

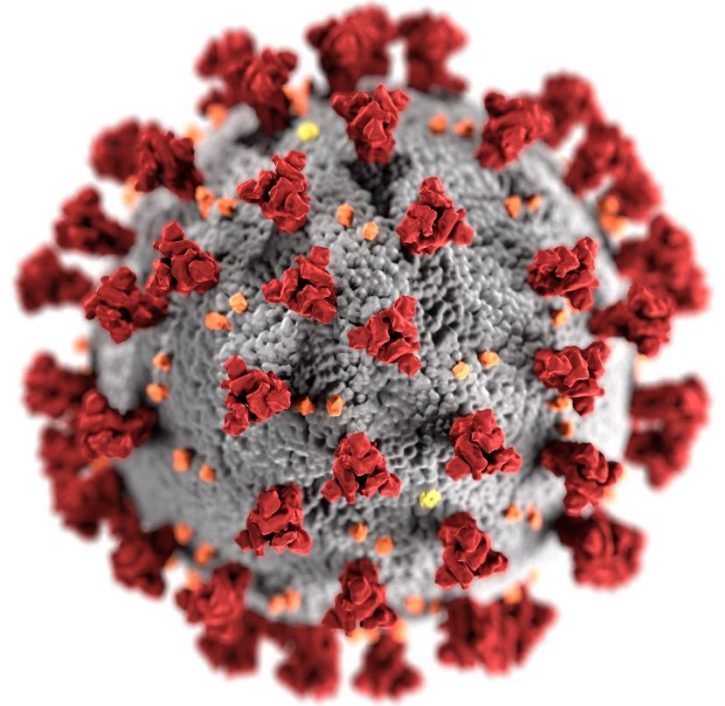
Please get involved, your participation matters



# Acknowledgements

- Sujan Reddy
- Mary Chamberland
- Sara Oliver
- Kathleen Dooling
- Sarah Mbaeyi
- Rachel Gorwitz
- Matthew Oster
- Jefferson Jones
- COVID-19 Response Epidemiology Task Force
- 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)  
TTY: 1-888-232-6348 [www.cdc.gov](http://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.



# Planning for COVID-19 Vaccines for 5–11-Year-Old Children

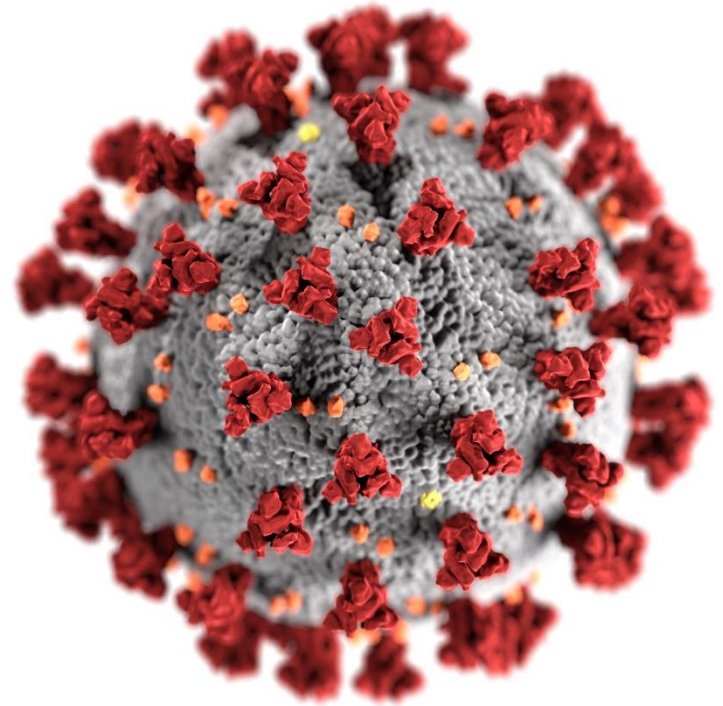
**Kevin Chatham-Stephens, MD, MPH**

Pediatric Vaccine Planning and  
Implementation Lead

CDC Vaccine Task Force

CDC COCA Call

11/04/2021



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)



# 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<sup>1</sup> authorization of pediatric vaccines and initial rollout of pediatric administration
- Disseminate **timely clinical guidance** to jurisdictions and providers



<sup>1</sup>US Food and Drug Administration

# Approach for Reaching Children

## Augment existing public health infrastructure

Category	Approach
	<p>Providers serving children aged 5-11 years and primary care</p> <ul style="list-style-type: none"><li>• Utilize primary care clinics, health departments, Federally Qualified Health Centers, etc. as trusted providers to vaccinate their patients</li></ul>
	<p>Pharmacies</p> <ul style="list-style-type: none"><li>• Leverage broad pharmacy footprint to vaccinate children aged 5–11 years</li></ul>
	<p>School-located vaccination clinics</p> <ul style="list-style-type: none"><li>• 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</li></ul>

# Approach for Reaching Children

## 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

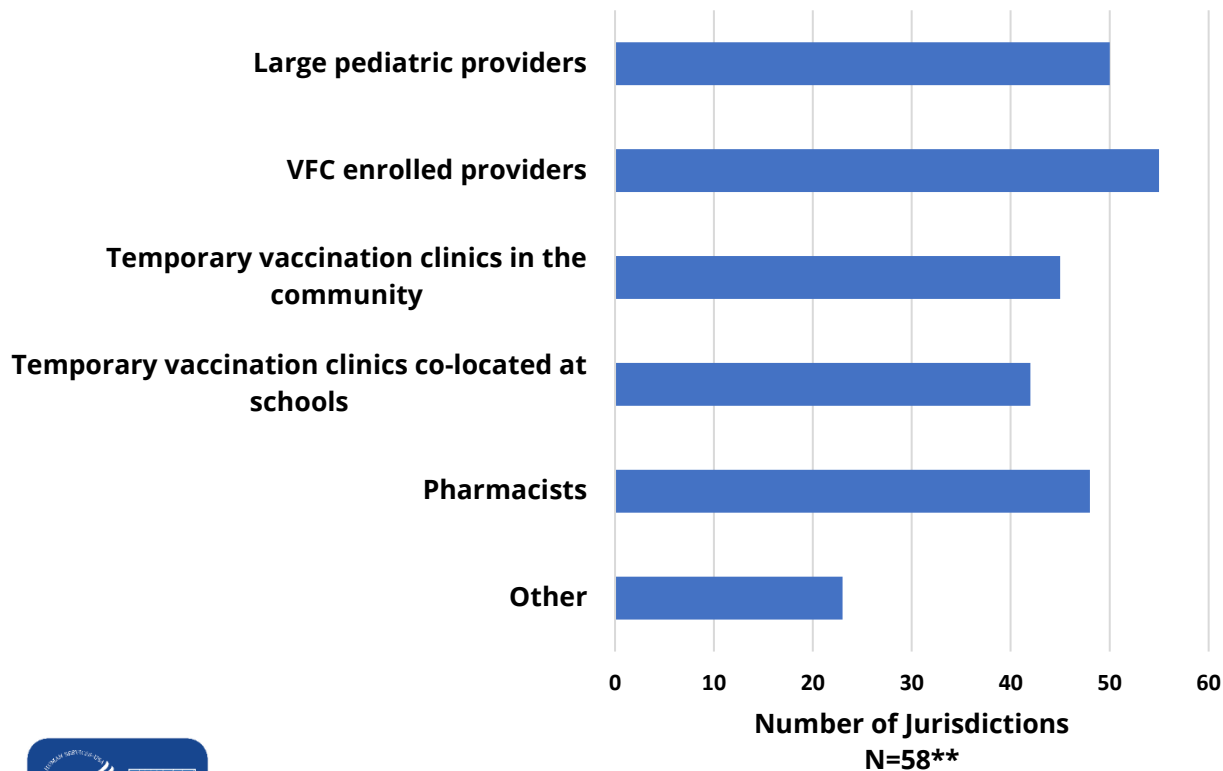


Temporary community clinics

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



# Jurisdictions' Plans to Use Different COVID-19 Vaccination Providers



**95%**

of jurisdictions reported **VFC\* enrolled providers** would be providing COVID-19 vaccination to children under age 12 years



**86%**

of jurisdictions reported **large pediatric providers** would be providing COVID-19 vaccination to children under age 12 years



**83%**

of jurisdictions reported **pharmacists** would be providing COVID-19 vaccination to children aged <12 years



**72%**

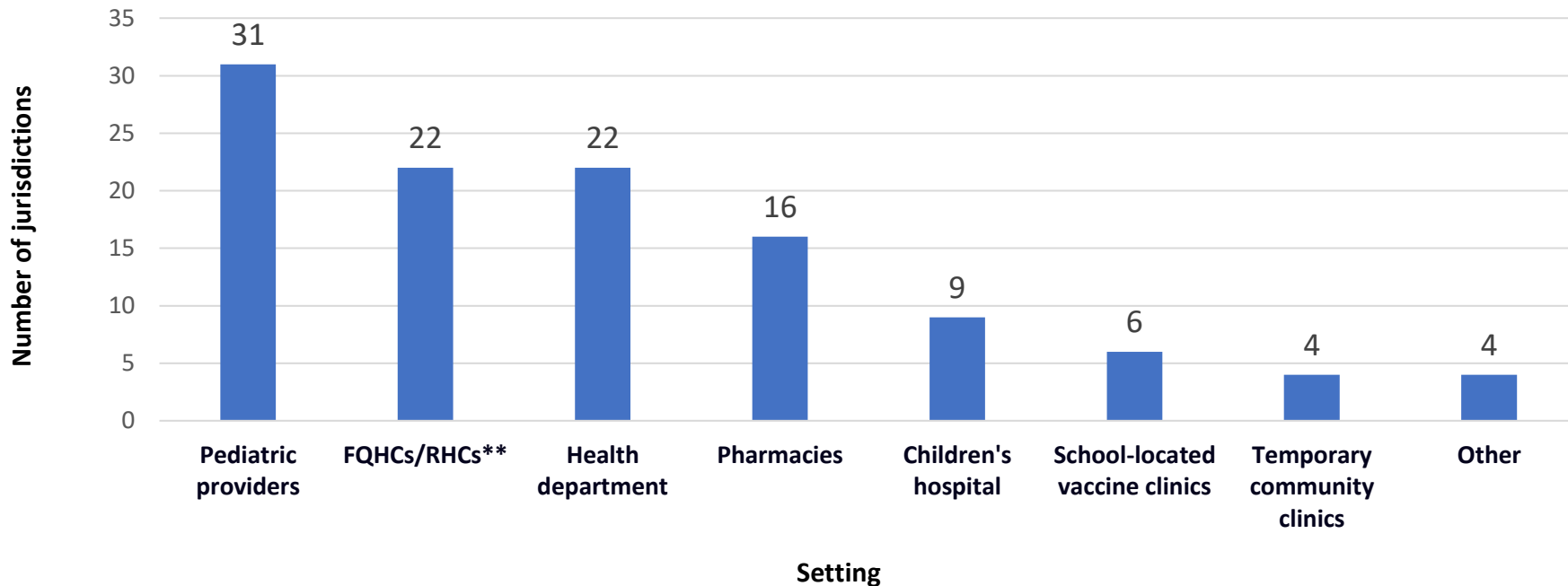
of jurisdictions reported **school co-located vaccination clinics** would be providing COVID-19 vaccination to children under age 12 years



\* 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\*

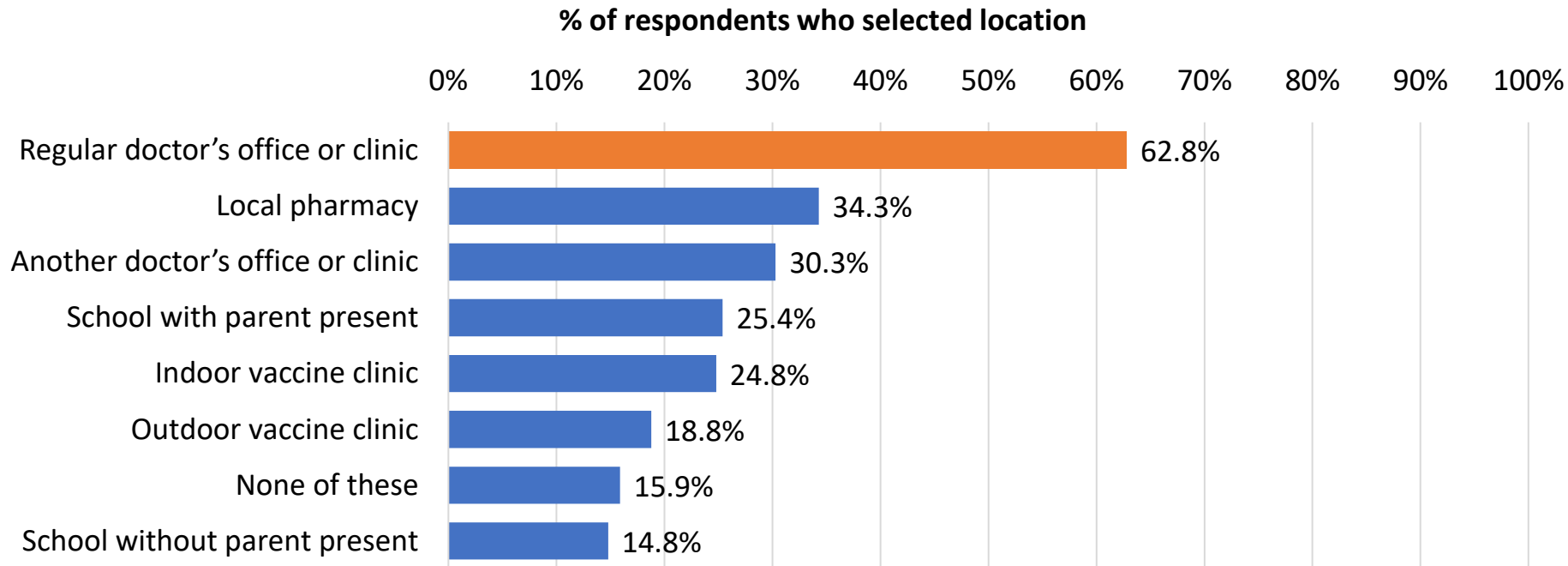


\* Number of jurisdictions that ranked a setting or provider first or second from a list of 8 settings or providers

\*\* FQHC = Federally Qualified Health Center; RHC = Rural health clinic



# Parents' Trusted Locations to Vaccinate Their 5–11-Year-Old Children\*



\*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:
  - Operational Planning Guide — <https://www.cdc.gov/vaccines/covid-19/downloads/Pediatric-Planning-Guide.pdf>
  - Preliminary information on Pfizer-BioNTech COVID-19 vaccines — <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

## COVID-19 Vaccination for Children 5–11 Years Old

Information for Jurisdictions, Healthcare Providers, Pharmacists and Community Partners

The U.S. Food and Drug Administration (FDA) has not yet authorized a COVID-19 vaccine for children age 5 to 11, and CDC's Advisory Committee on Immunization Practices (ACIP) has not yet made a recommendation on vaccinating this age group. CDC will update this web page when new information is available.

### On This Page

COVID-19 Vaccination Recommendations for Pediatric Populations

Clinical Resources for Vaccine Providers

Planning and Promoting COVID-19 Vaccination in Your Community

Clinical Training and Education

Supporting Data and Scientific Research

Information for Children with Developmental Disabilities



The federal government is committed to ensuring children age 5 through 11 have access to COVID-19 vaccines if authorized by the U.S. Food and Drug Administration (FDA) and recommended by CDC's Advisory Committee on Immunization Practices (ACIP).

Any COVID-19 vaccine for children age 5 through 11 is subject to the very same [multi-step testing and approval process](#) as all other COVID-19 and non-COVID-19 vaccines — including those routinely recommended for childhood vaccination.

This page shares up-to-date information and resources to aid in the planning for COVID-19 vaccination among children ages 5 to 11.

Information for  
Jurisdictions



Information for  
Healthcare Providers



Information for  
Pharmacists



Information for  
Parents and Caregivers



<https://www.cdc.gov/vaccines/covid-19/planning/children.html>



# 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.

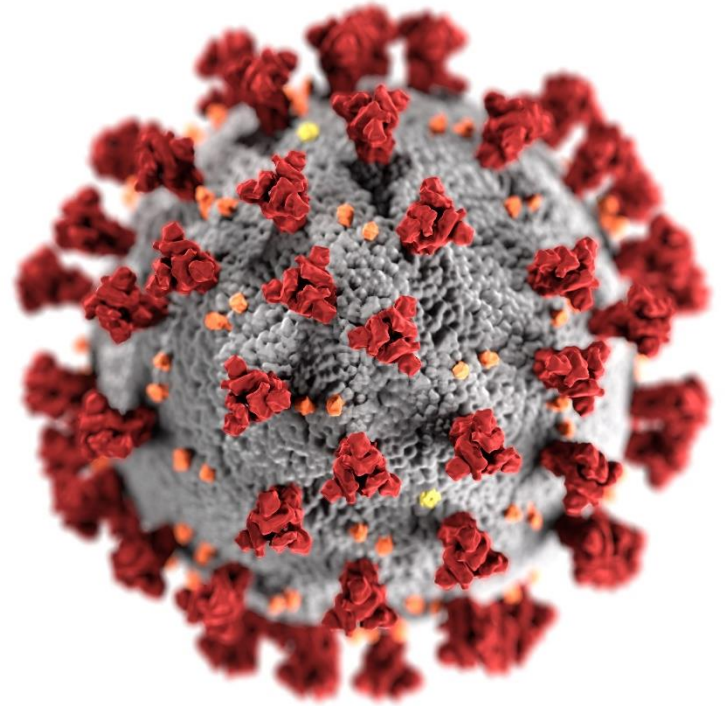
6 Ways Schools Can Promote COVID-19 Vaccines

<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)  
TTY: 1-888-232-6348 [www.cdc.gov](http://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.



# 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](mailto: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)

# COCA Products & Services



The logo for COCA Call features a blue horizontal bar with the text "COCA Call" in white. To the left of the bar are four icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle.

**COCA Call**  
CDC Clinician Outreach  
and Communication Activity

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.



The logo for COCA Learn features a green horizontal bar with the text "COCA Learn" in white. To the left of the bar are four icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle.

**COCA Learn**  
CDC Clinician Outreach  
and Communication Activity

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.



The logo for Clinical Action features a red horizontal bar with the text "Clinical Action" in white. To the left of the bar are four icons: a white eye in a blue circle, a white stethoscope in a red circle, a white syringe in a green circle, and a white biohazard symbol in an orange circle.

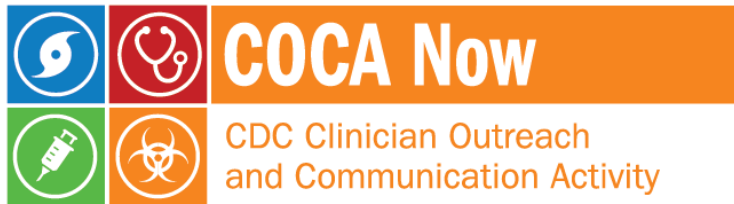
**Clinical Action**  
CDC Clinician Outreach  
and Communication Activity

As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

# COCA Products & Services



Monthly newsletter providing updates on emergency preparedness and response topics, emerging public health threat literature, resources for health professionals, and additional information important during public health emergencies and disasters.



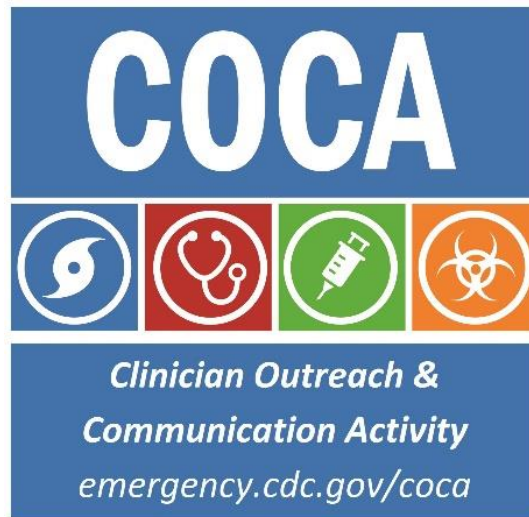
Informs clinicians of new CDC resources and guidance related to emergency preparedness and response. This email is sent as soon as possible after CDC publishes new content.



CDC's primary method of sharing information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.

# Join COCA's Mailing List

- **Receive information about:**
  - Upcoming COCA Calls
  - Health Alert Network (HAN) messages
  - CDC emergency response activations
  - Emerging public health threats
  - Emergency preparedness and response conferences
  - Training opportunities



[emergency.cdc.gov/coca/subscribe.asp](https://emergency.cdc.gov/coca/subscribe.asp)



# Join Us On Facebook!



The screenshot shows the Facebook profile for 'CDC Clinician Outreach and Communication Activity - COCA'. The profile picture features a diverse group of healthcare professionals. The cover photo shows a group of six smiling healthcare workers. The page includes a navigation menu on the left with options like Home, About, Posts, Photos, Events, and Community. The main content area shows a 'Status' section with a prompt to write something on the page, and a 'Posts' section with a recent event announcement: 'CDC Clinician Outreach and Communication Activity - COCA shared their event. October 31 at 1:18pm. Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM.' The right sidebar displays location information (Atlanta, Georgia), community statistics (21,420 likes, 21,217 followers), and an 'About' section with a map.

**COCA**

CDC Clinician Outreach and Communication Activity - COCA ✓  
@CDCClinicianOutreachAndCommunicationActivity

Home  
About  
Posts  
Photos  
Events  
Community  
Create a Page

Liked Following Share ... Sign Up

Status Write something on this Page...

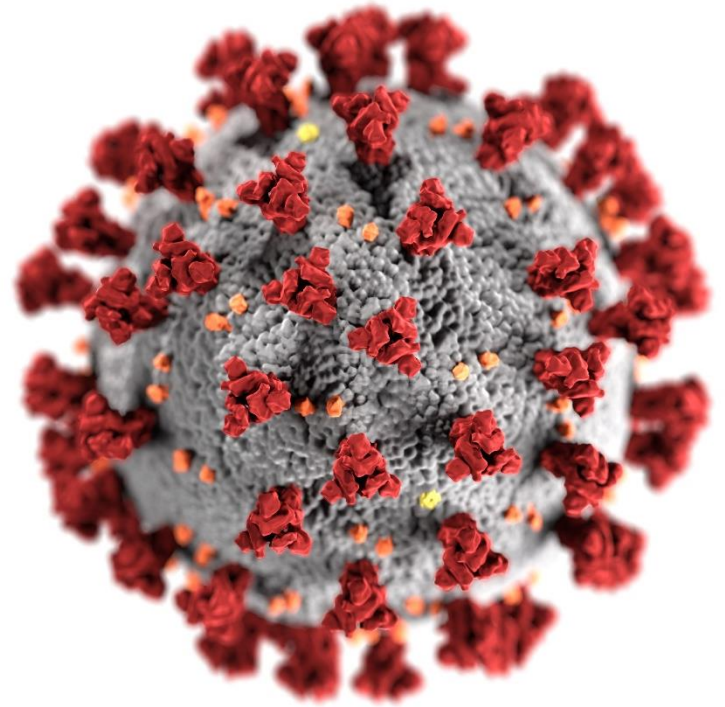
Posts  
CDC Clinician Outreach and Communication Activity - COCA shared their event.  
October 31 at 1:18pm · 🌐  
Clinicians, you can earn FREE CE with this COCA Call! Join us for this COCA Call November 7, 2017 at 2:00PM.

Government Organization in Atlanta, Georgia  
Community See All  
21,420 people like this  
21,217 people follow this  
About See All

**Thank you for joining us today!**



[emergency.cdc.gov/coca](https://emergency.cdc.gov/coca)



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

