



CDC/IDSA COVID-19 Clinician Call

November 6, 2021

Welcome & Introductions

Dana Wollins, DrPH, MGC

Vice President, Clinical Affairs & Guidelines
IDSA

- 78th in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

The Latest on COVID-19 Vaccination in Children Ages 5 to 11

Hosted in partnership with the American Academy of Pediatrics and the Pediatric Infectious Diseases Society

Pediatric COVID-19 Vaccines: Update on Recent Decisions and the Data Underlying Them



Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

The Pediatric Infectious Disease Perspective



Andi L. Shane, MD, MPH, MSc

Professor of Pediatrics, Division of Pediatric Infectious Diseases
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Pediatric COVID-19 Vaccine Implementation



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U.S. Centers for Disease Control and Prevention



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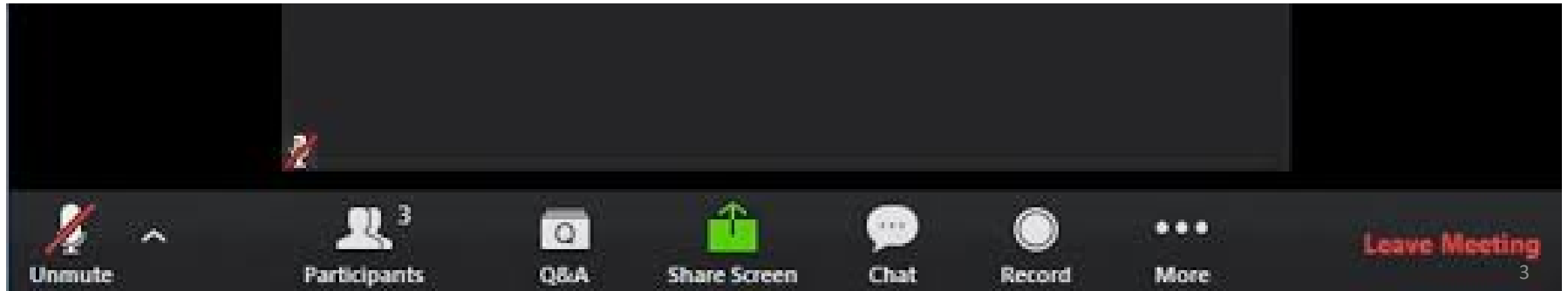
Lee Ann Savio Beers, MD, FAAP

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Question?
Use the “Q&A” Button



Comment?
Use the “Chat” Button



Peter Marks, MD, PhD

Director

Center for Biologics Evaluation and Research

U.S. Food and Drug Administration



Pediatric COVID-19 Vaccines

Peter Marks, MD, PhD
CDC-IDSA Webinar
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Pfizer Pediatric Demographics

10 microgram dose

Characteristic	Age 5-11 Vaccine (N=1518)	Age 16-25 Vaccine (N=537)	Age 5-11 Placebo (N=750)	Age 16-25 Placebo (N=561)
Female	47.4%	52.5%	48.9%	52.0%
Mean Age (years)	8.2	19.4	8.1	19.6
Median Age	8.0	18.0	8.0	19.0
Black	5.9%	8.8%	7.7%	8.9%
Hispanic/Latino	21.0%	20.9%	21.2%	18.7%
Comorbidity (yes)	20.6%	23.5%	20.3%	25.7%

Pfizer Pediatric Immune Response

10 microgram dose

Study Group	5-11 Years N=264 GMT (95% CI)	16-25 Years N=253 GMT (95% CI)	GMT Ratio [5-11 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)	Yes

Noninferiority is declared if the lower bound of the 2-sided 95% CI for the Geometric Mean Titer (GMT) Ratio is greater than 0.67 and the point estimate of the GMT ratio is ≥ 1.0 .

Pfizer Pediatric Efficacy

10 microgram dose

Endpoint	Vaccine 5-11 Years N=1305 Cases	Placebo 5-11 Years N=663 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	3	16	90.7 (67.7, 98.3)

Note the 2:1 randomization

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period; no severe cases were observed

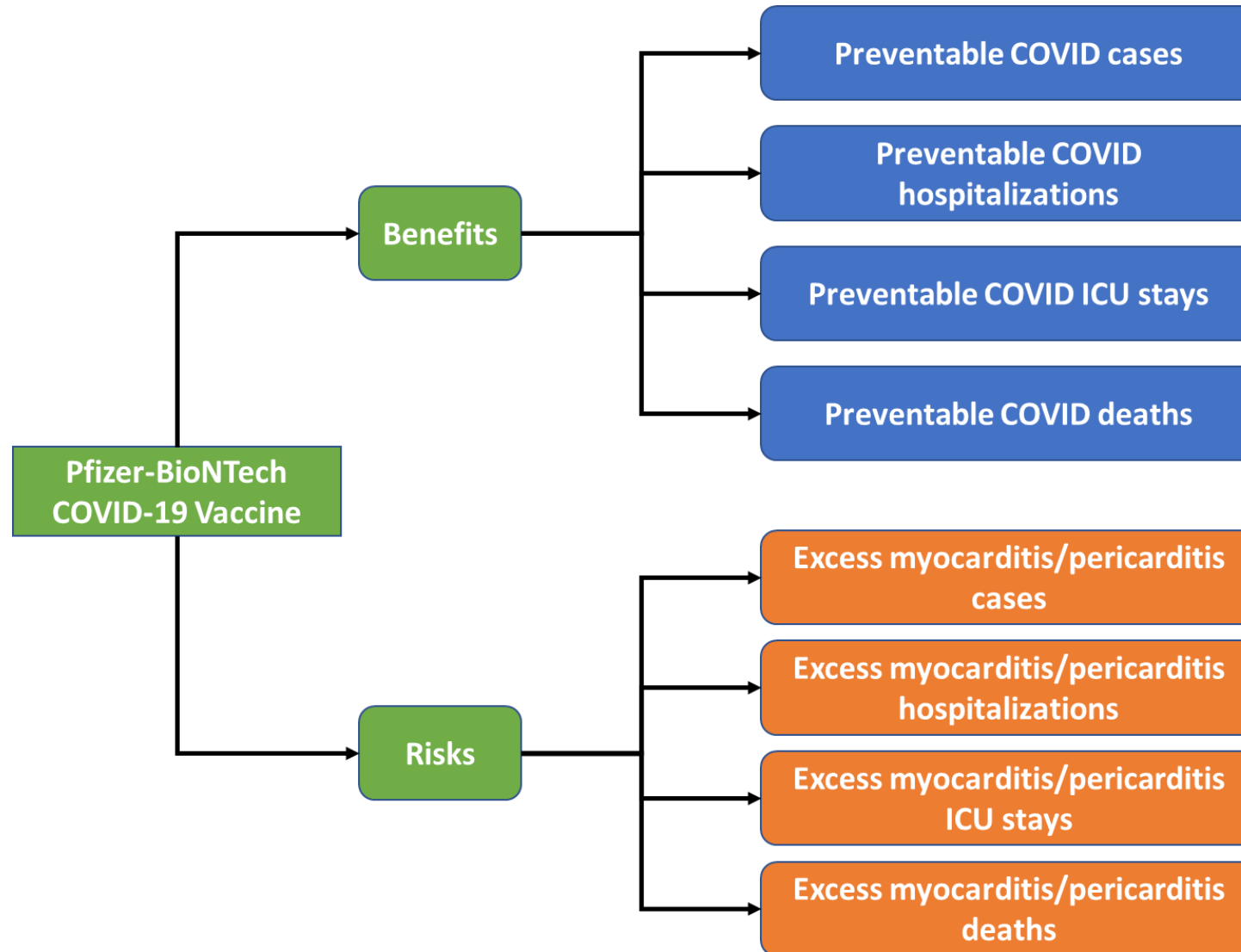
Pfizer Pediatric Safety

10 microgram dose

Characteristic	Age 5-11 Placebo Dose 2 (N=741)	Age 5-11 Vaccine Dose 2 (N=1501)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	29.5%	71.0%	77.5%
Fatigue	24.3%	39.4%	65.6%
Headache	18.6%	28.0%	60.9%
Muscle pain	7.4%	11.7%	40.8%
Chills	4.3%	9.8%	40.0%
Joint pain	3.6%	5.2%	21.9%
Fever	1.2%	6.5%	17.2%

Benefits and Risks Per 1 Million Fully- Vaccinated

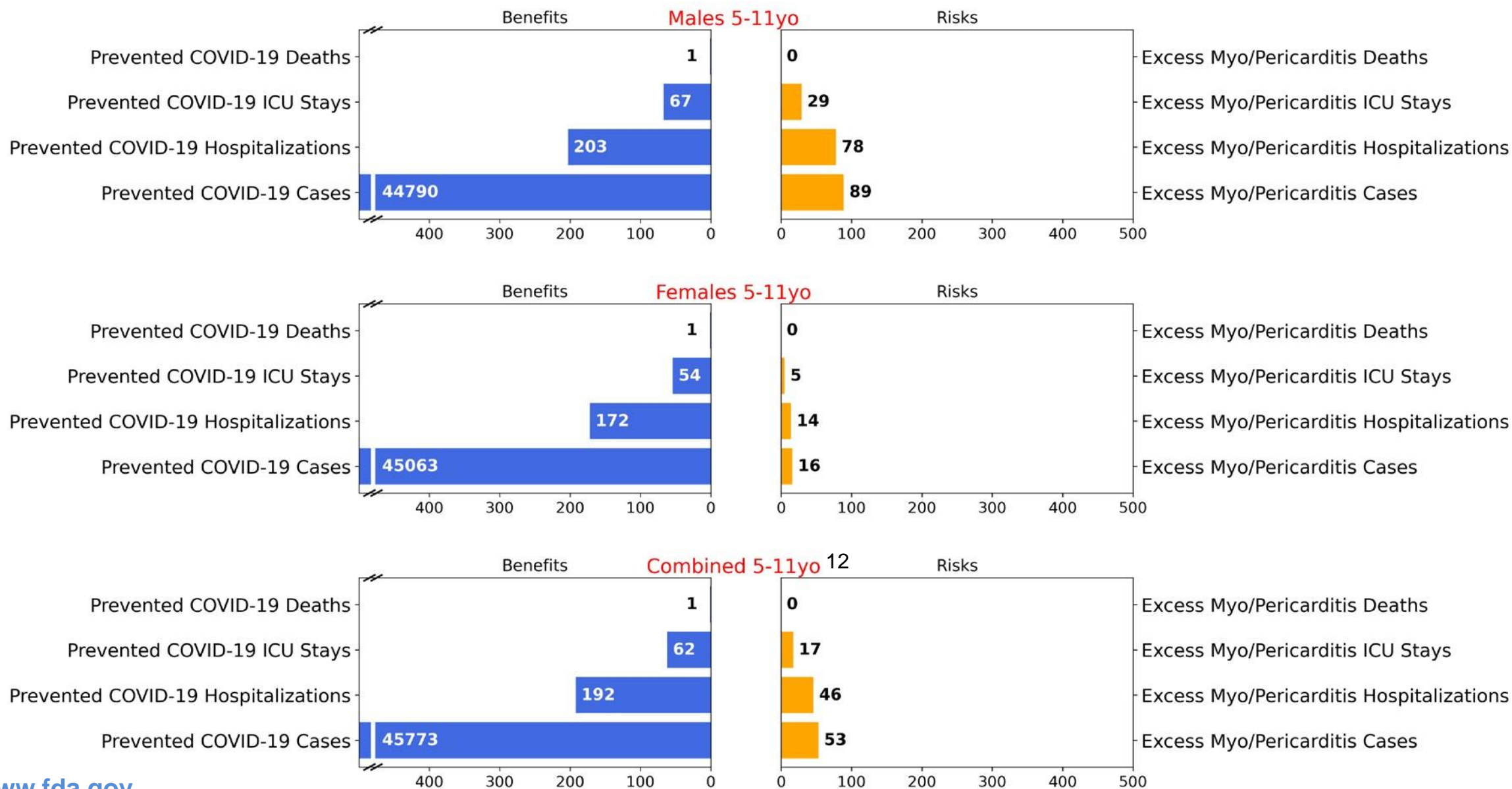
(Ages 5 to 11 years/male, female and all sexes)



Scenario 6

- COVID incidences the week of September 11, 2021
- Vaccine efficacy 70% against case and 80% against hospitalization
- Rate of excess myocarditis: 50% of OPTUM data for ages 12-15 years

Scenario 6: Cases Per 1 Million Fully- Vaccinated



COVID-19 Vaccines Younger Children

- Special considerations in children under 5 years
 - Determination of appropriate dose
 - Duration and number of children for safety follow-up
 - Benefit-risk considerations
- The various companies are conducting clinical trials
- Expecting data to FDA by early in 2022
- FDA will move quickly when data come in



U.S. FOOD & DRUG
ADMINISTRATION

Sara Oliver, MD, MSPH

LCDR, U.S. Public Health Service

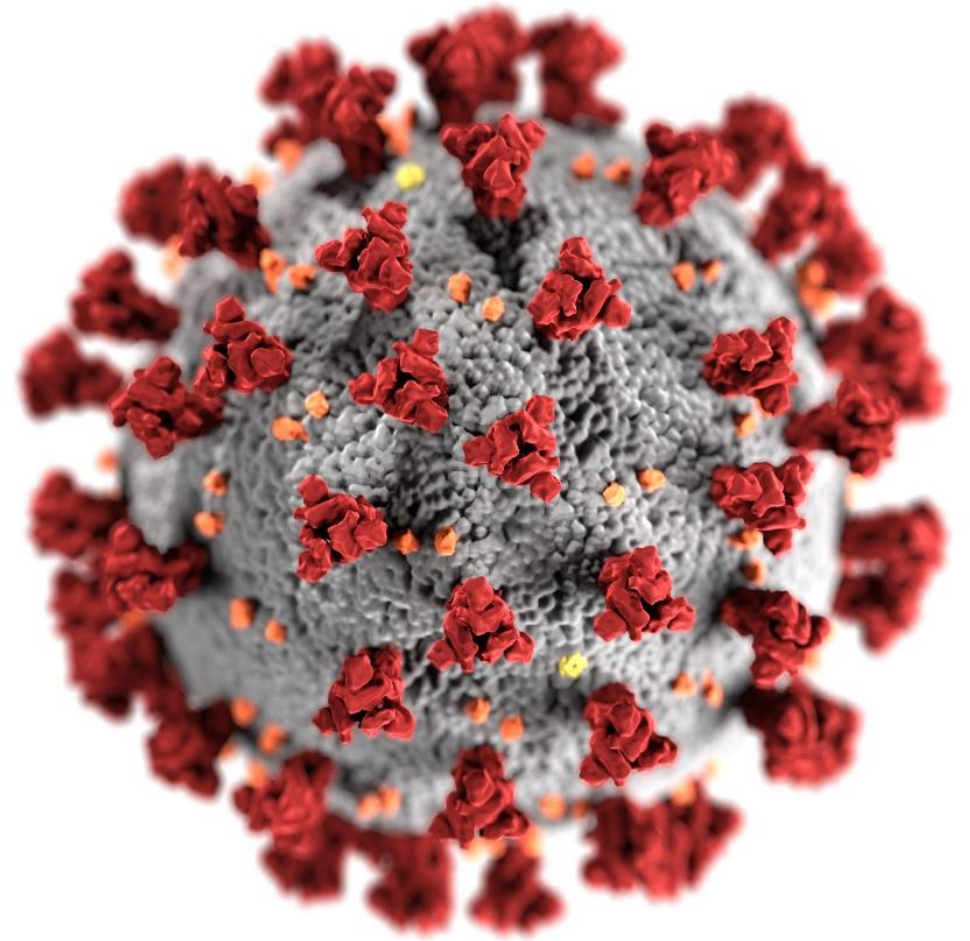
Lead, COVID-19 Work Group of the Advisory Committee on
Immunization Practices

U.S. Centers for Disease Control and Prevention



Pfizer-BioNTech COVID-19 vaccine in children aged 5–11 years

Sara Oliver MD, MSPH
IDSA
November 6, 2021



cdc.gov/coronavirus

Agenda: Tuesday November 1, 2021

- **Pfizer-BioNTech: BNT162b2 use in children aged 5-11 years** Dr. Gurtman (Pfizer)
- **PUBLIC COMMENT**
- **SARS-CoV-2 Epidemiology in Children** Dr. Jones (CDC)
- **Myocarditis in adolescents and young adults** Dr. Oster (CDC)
- **Vaccine safety surveillance in children** Dr. Shimabukuro (CDC)
- **Implementation of COVID-19 vaccine pediatric program** Dr. Chatham-Stevens (CDC)
- **Clinical considerations** Dr. Woodworth (CDC)
- **Evidence to Recommendations Framework** Dr. Oliver (CDC)

VOTE

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 adults¹⁻⁴
 - 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
 - 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 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

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

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)
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.

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.

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The Pediatric Infectious Disease Perspective

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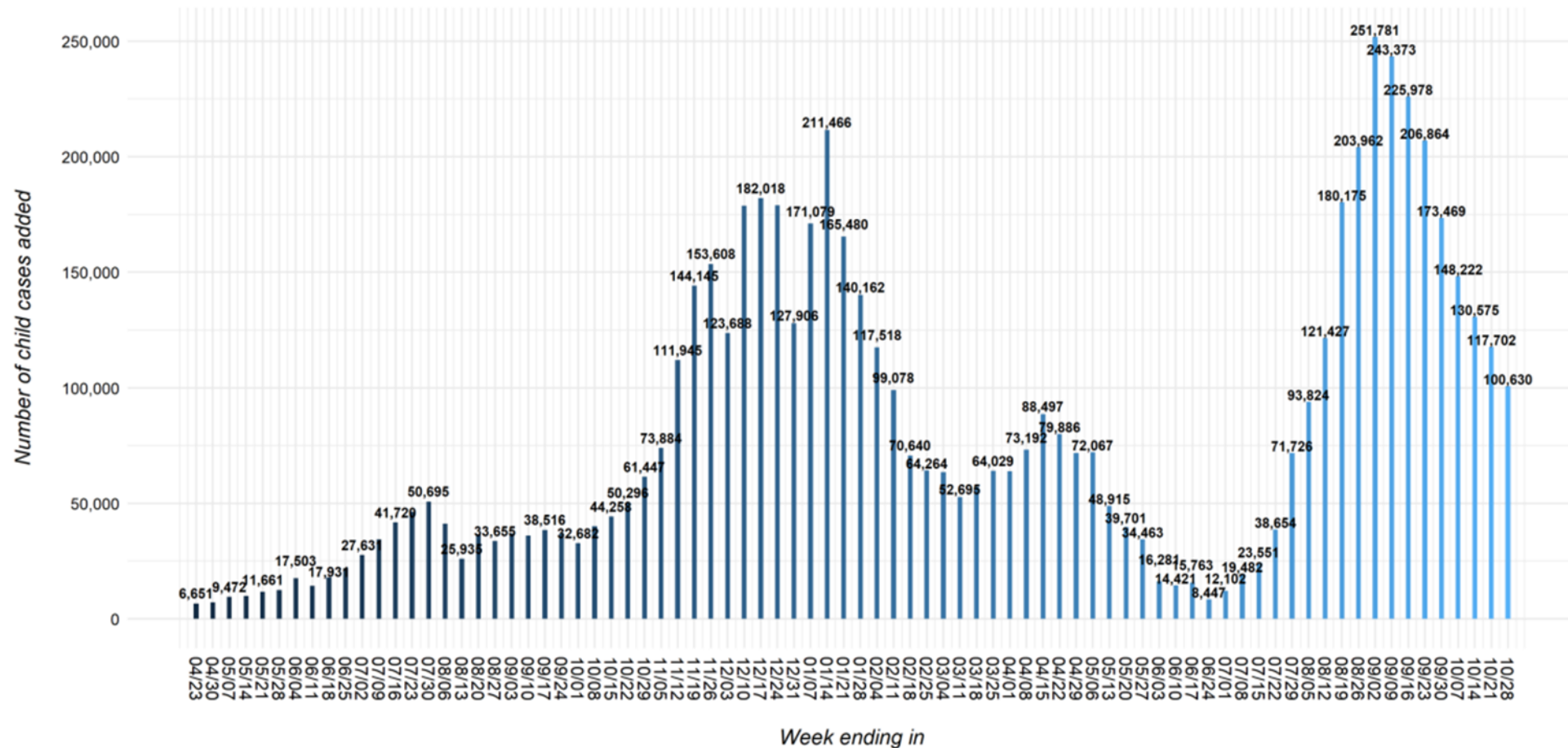
06 November 2021

Disclosures

- I am a voting member of the FDA VRBPAC but have not participated in any discussions or meetings related to COVID-19 vaccinations
- My employer has received funds for research in which I have participated from NIH and HHS
- I have received reimbursement for travel and lodging from the International Scientific Association for Probiotics and Prebiotics

The “Why” of Pediatric Vaccines: Epi April 2020-Oct 2021

Fig 6. United States: Number of Child COVID-19 Cases Added in Past Week*



* Note: 5 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20, WV as of 8/12/21

TX reported age for only a small proportion of total cases each week (eg, 3-20%); TX cumulative cases through 8/26/21

As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21

Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21

Due to available data and calculations required to obtain MA child cases, weekly estimates fluctuate (eg, on 10/28/21, there were 920 fewer cumulative cases)

See detail in Appendix: Data from 49 states, NYC, DC, PR and GU

All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children's Hospital Association



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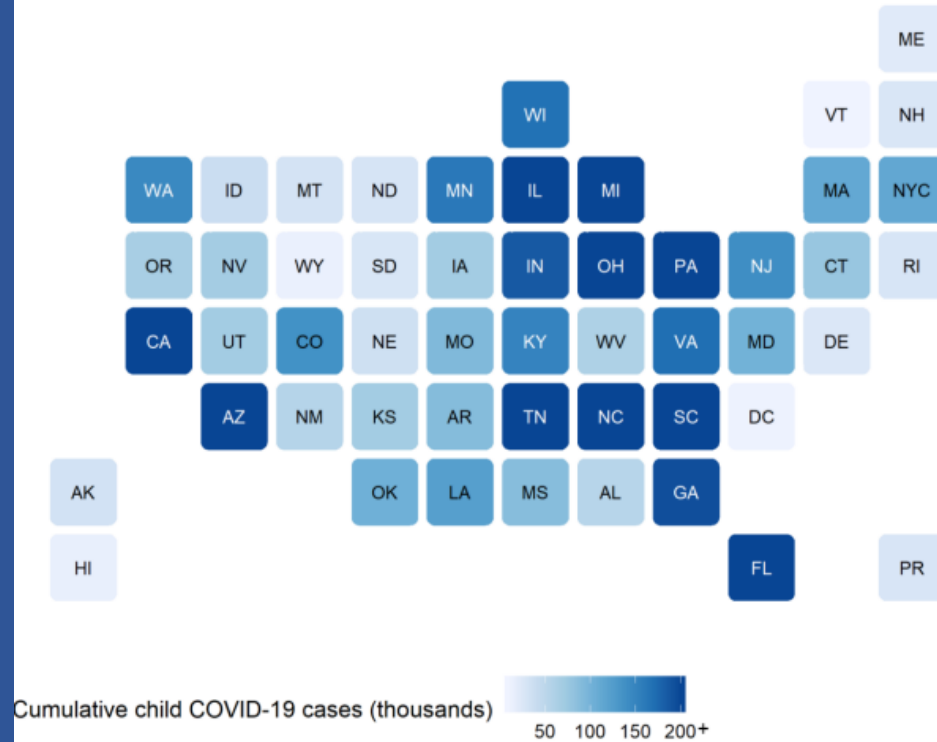


The “Why” of Pediatric Vaccines: Cumulative Cases

Fig 5. Cumulative Child COVID-19 Cases and Percent Increase in Child Cases

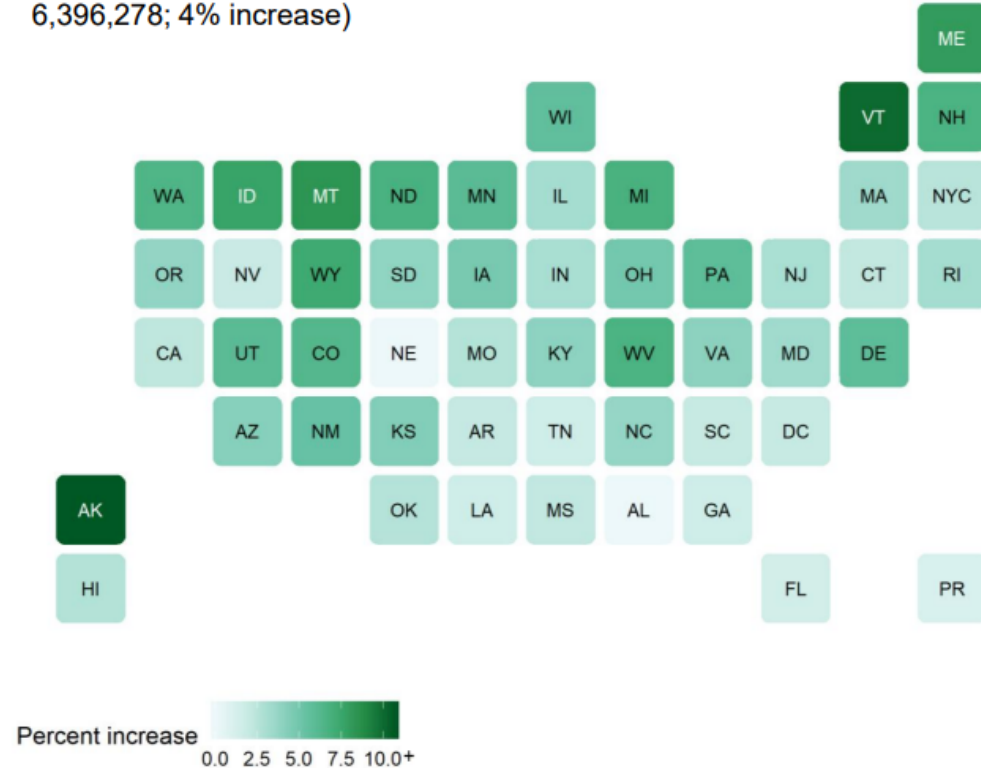
A. Cumulative Child COVID-19 Cases, 10/28/21

10 states with 200,000+ cumulative child cases



B. Percent Increase in Child Cases, 10/14/21-10/28/21

From 10/14-10/28, there were 218,332 child cases added (6,177,946 to 6,396,278; 4% increase)



See detail in Appendix: Data from 48 states, NYC, DC, and PR (TX excluded from figures)

All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children's Hospital Association

As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21

Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21



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The “Why” of Pediatric Vaccines: MIS-C

Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States

Since mid-May 2020, CDC has been tracking case reports of [multisystem inflammatory syndrome in children \(MIS-C\)](#), a rare but serious condition associated with COVID-19. CDC is working to learn more about why some children and adolescents develop MIS-C after having COVID-19 or contact with someone with COVID-19, while others do not.

Data on this page are reported voluntarily to CDC by each jurisdiction's health department. CDC encourages all jurisdictions to report the most complete and accurate information that best represents the data available in their jurisdiction. [Learn more about the data.](#)

Last updated with cases reported to CDC on or before November 1, 2021*

TOTAL MIS-C PATIENTS MEETING CASE DEFINITION*

5,526

TOTAL MIS-C DEATHS MEETING CASE DEFINITION

48

*Additional patients are under investigation. After review of additional clinical data, patients may be excluded if there are alternative diagnoses that explained their illness.

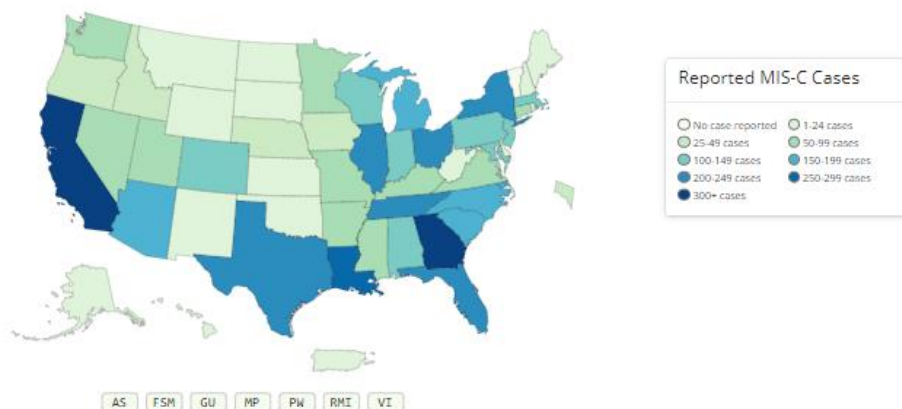
Summary

- The median age of patients with MIS-C was 9 years. Half of children with MIS-C were between the ages of 5 and 13 years.
- 60% of the reported patients with race/ethnicity information available occurred in children who are Hispanic/Latino (1,467 patients) or Black, Non-Hispanic (1,666 patients).
- 98% of patients had a positive test result for SARS CoV-2, the virus that causes COVID-19. The remaining 2% of patients had contact with someone with COVID-19.
- 60% of reported patients were male.

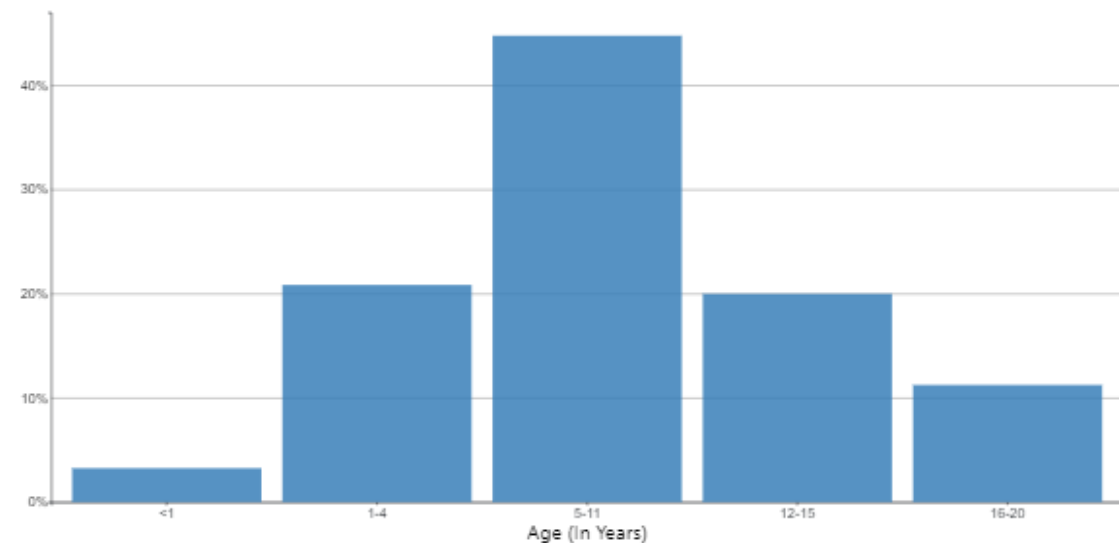
MIS-C Cases by Jurisdiction

Since reporting began in 2020, 52 U.S. jurisdictions (including 49 states, New York City, Puerto Rico, and Washington, DC) have reported at least one MIS-C case to CDC. Because of the small number of patients reported in some jurisdictions, this report includes case ranges instead of exact case counts from individual jurisdictions to protect the privacy of patients and their families.

Reported MIS-C Case Ranges by Jurisdiction, on or before November 1, 2021*



MIS-C Patients By Age Group



The “Why” of Pediatric Vaccines: COVID-19 Impact

CLINICAL IMPACT	NON-CLINICAL IMPACT
<ul style="list-style-type: none">• Interruption of routine healthcare• Decrease in immunization uptake• Increase in children with depression, anxiety, and mental health sequelae• “Elective” procedures canceled• Focus on COVID-19 resulting in missed non-COVID-19 diagnoses	<ul style="list-style-type: none">• Changes in routine → stress and isolation• Disruptions in learning• Lack of access to school-based services (nutrition, speech, occupational therapy, mental health services)• Missed life events• Housing and food insecurity• Increases in accidental and non-accidental trauma



ANXIETY

Panic attacks are discrete episodes, with an abrupt beginning and specific end.

SYMPTOMS

- Rapid heart rate
- Feelings of impending doom
- Feelings of being out of control
- Abdominal cramping



COVID-19

If you develop these symptoms, call your doctor or visit [cdc.gov/coronavirus](https://www.cdc.gov/coronavirus).

SYMPTOMS

- Fever
- Dry cough
- Trouble breathing
- Extreme fatigue



OVERLAPPING SYMPTOMS

- Chills
- Shaking
- Sweating
- Chest pain
- Hot flashes
- Shortness of breath

The “Why” of Pediatric Vaccines: Healthcare Encounters



- Subspecialty clinics and hospitals are the medical homes for some medically complex children
 - Parental trust
 - Normalize vaccinations as part of care
- Leverage healthcare encounters to administer vaccinations (Urgent Care, Emergency Departments, elective surgical procedures, inpatient care)
- Combine employee and hospitalized family vaccine campaigns to avoid waste



- **Unique ethical and clinical concerns; necessary for evaluation**
- **Balance risks of research with the need for safe and validated therapies**
- **Account for developmental and physiological differences in children of different ages**
 - **Age de-escalation for dosing, balancing efficacy and adverse effects**
 - **Consider regularly scheduled interventions**
 - **Informed consent/ assent**
 - **Contribute to science; receive monitoring**
- **Engagement of children in clinical trials**

Janell Routh, MD, MHS

CAPT, U.S. Public Health Service
Co-Deputy, Implementation Unit
CDC COVID-19 Vaccine Task Force
U.S. Centers for Disease Control and Prevention



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

Janell Routh, MD, MHS

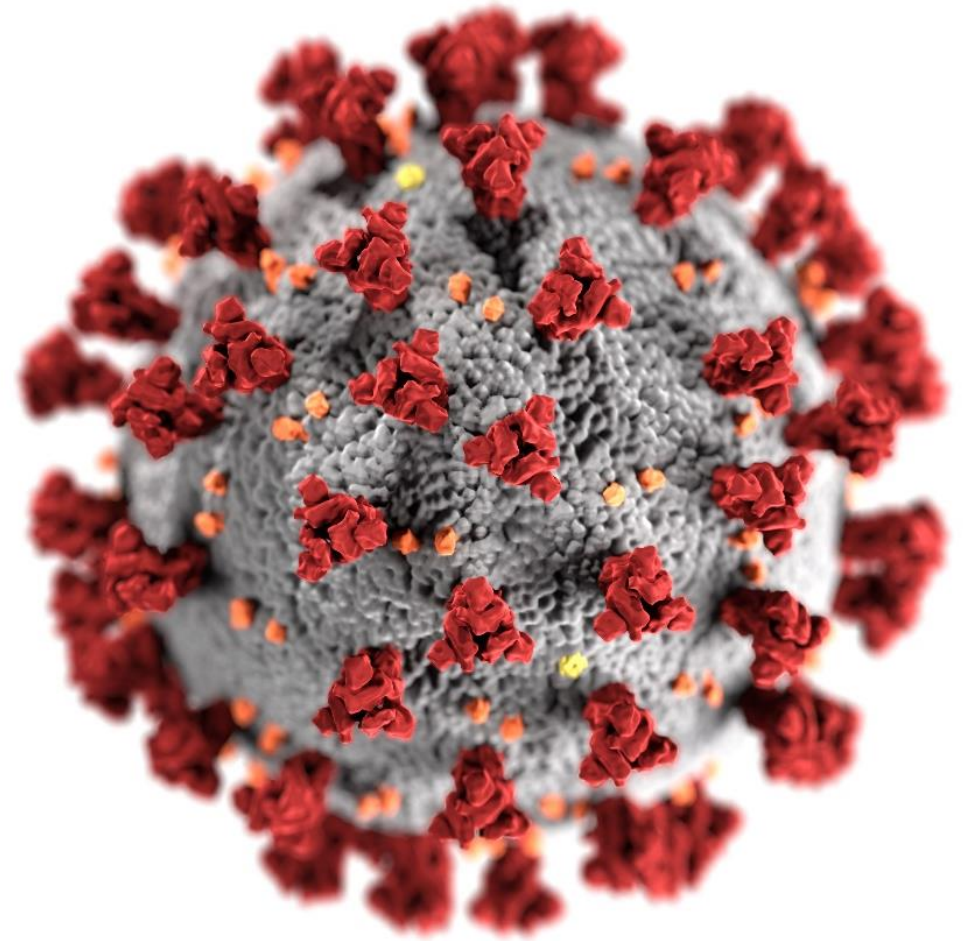
CAPT USPHS

Vaccine Task Force Co-Lead

CDC COVID-19 Response

CDC/IDSA COVID-19 Clinician Call

11/06/2021



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 FDA¹ authorization of pediatric vaccines and initial rollout of pediatric administration
- Disseminate **timely clinical guidance** to jurisdictions and providers



¹US Food and Drug Administration

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

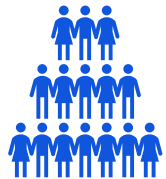
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Approach



Children's hospitals

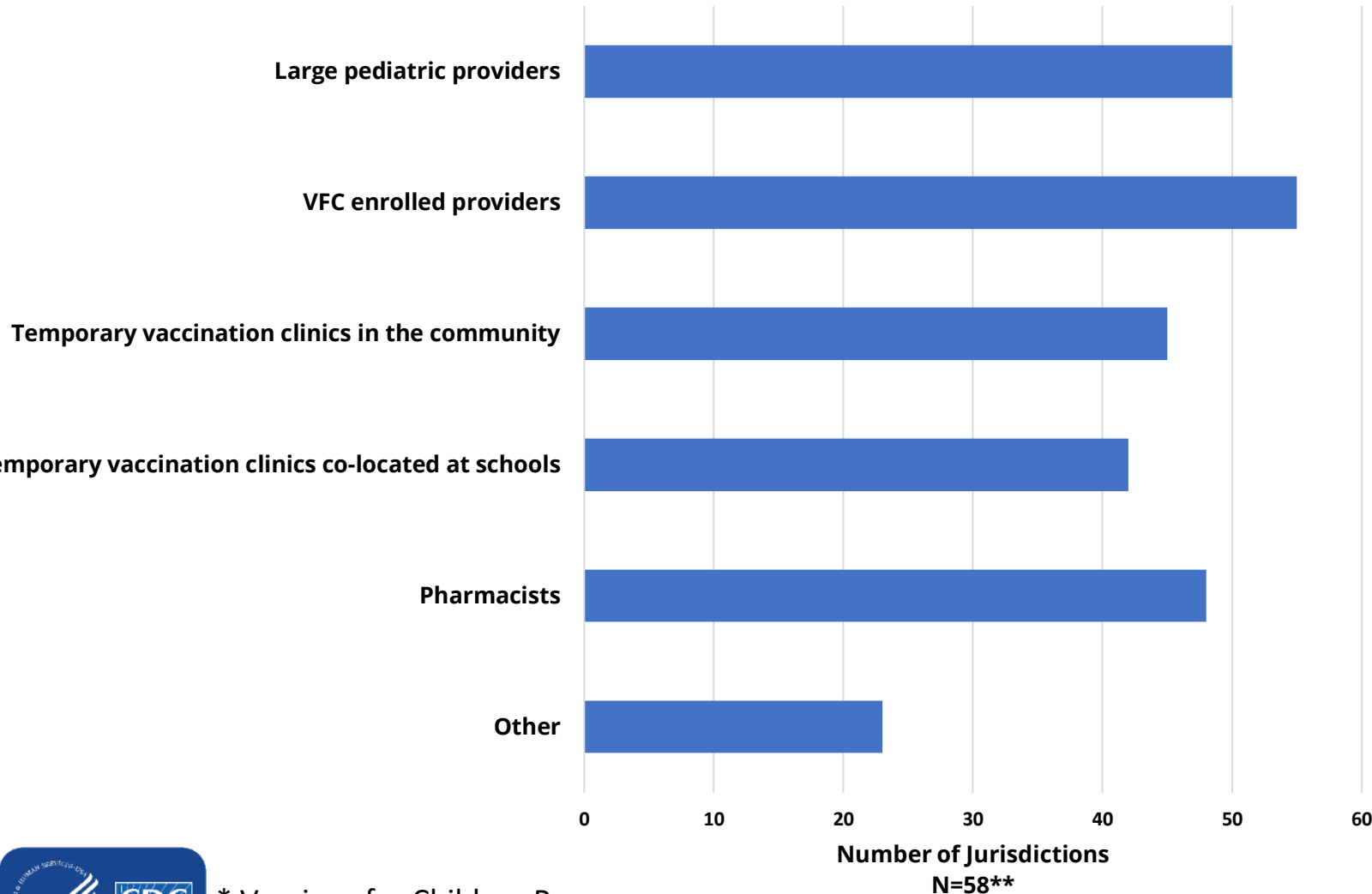
- >100 children's hospitals across the United States will set up vaccination sites
- Critical part of efforts to provide access for children aged 5-11 years with underlying medical conditions



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%

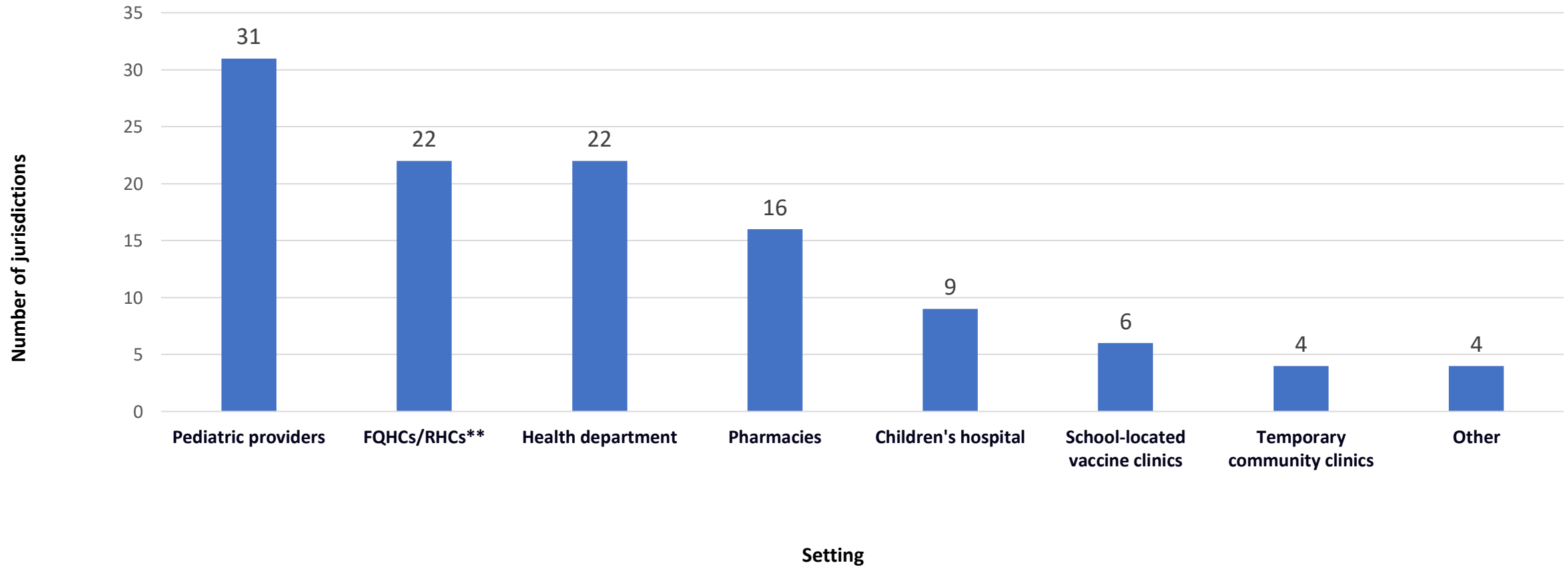
of jurisdictions reported **school co-located vaccination clinics** would be providing COVID-19 vaccination to children under age 12 years



* 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*

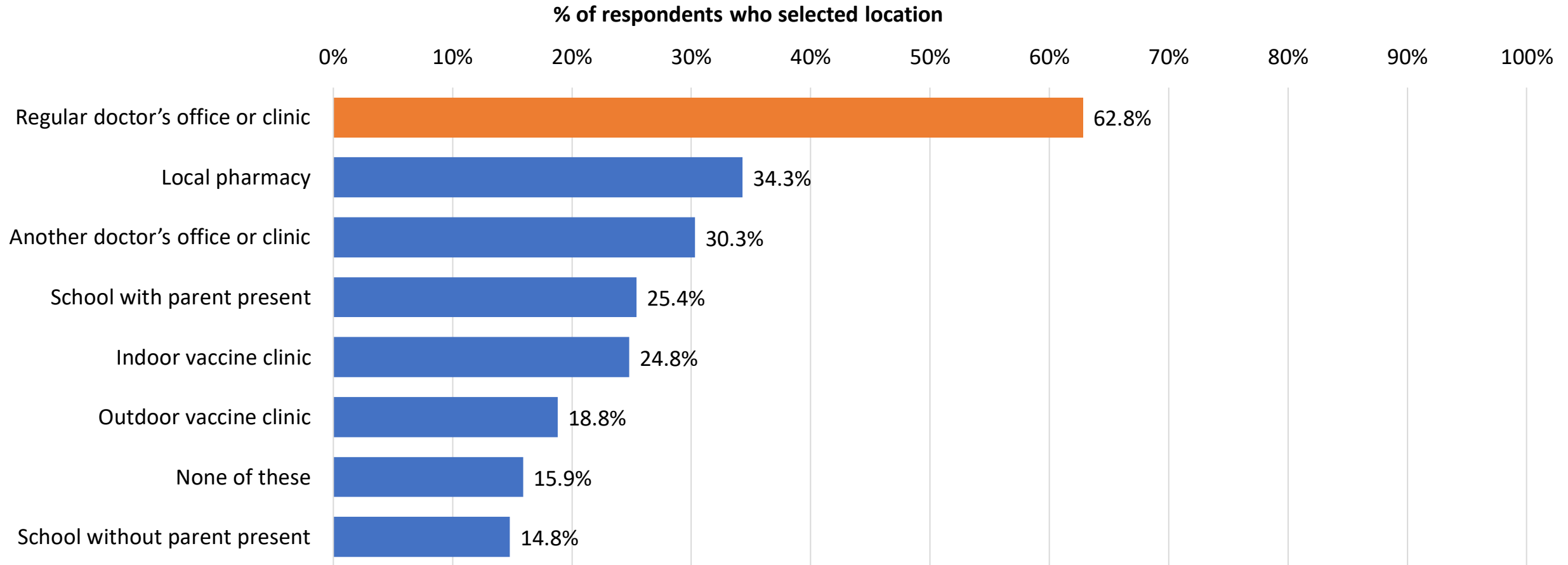


* Number of jurisdictions that ranked a setting or provider first or second from a list of 8 settings or providers

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



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

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>





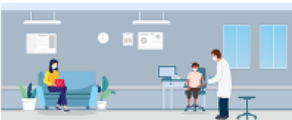
COVID-19 Vaccination for Children 5–11 Years Old

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>



How Partners Can Support the Pediatric Strategy



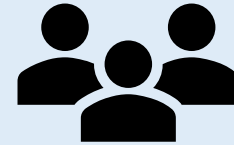
Identify Vaccine Champions

Identify trusted messengers who can speak to parents online or in-person about their decision to get their child vaccinated.



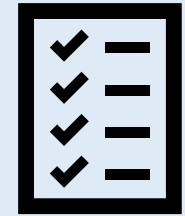
Provide Expertise

Provide expertise to pediatric providers and school staff on how to communicate effectively about COVID-19 vaccines.



Engage with Community

Engage with faith-based organizations, community organizations, youth groups, and school systems to communicate with children and families.



Provide Guidance

Provide guidance for how organizations can make vaccination events appealing to parents and how they can provide safe spaces for parents to ask questions.

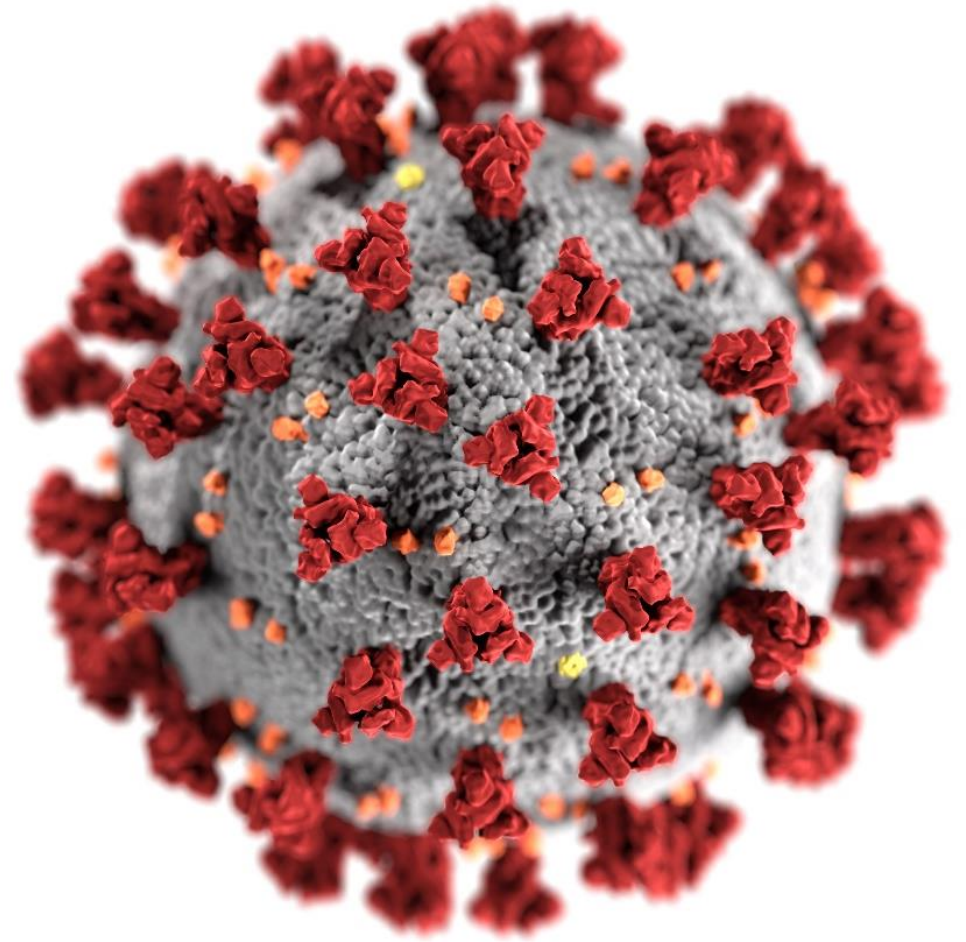
CDC Resources

- 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](#)



Thank you!

Happy to take questions



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.



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Health and Advocacy, Children's National Hospital



COVID-19 Vaccination Eligibility Expansion to 5-11-Year-Olds

Lee Savio-Beers. MD, FAAP
President, American Academy of
Pediatrics



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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

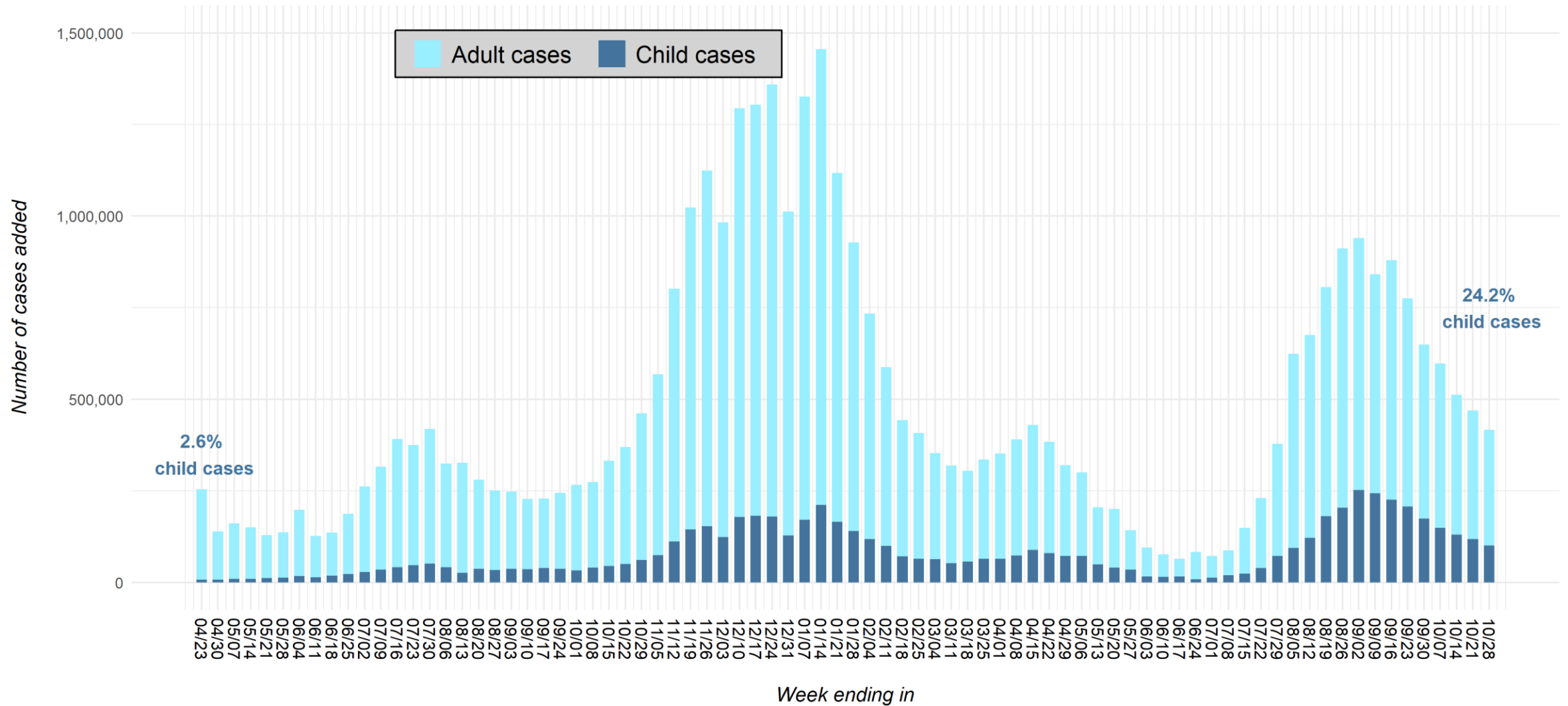
- Number of new child COVID-19 cases remains exceptionally high in the US.
- Children make up a growing percentage of hospitalized. Hospitalizations among unvaccinated adolescents 10x higher than fully vaccinated.
- Over 5,000 cases of multisystem inflammatory syndrome in children and about 50 deaths.
- Post-acute Sequelae of COVID-19: Long-term symptoms in children of any disease severity.

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 vaccine.



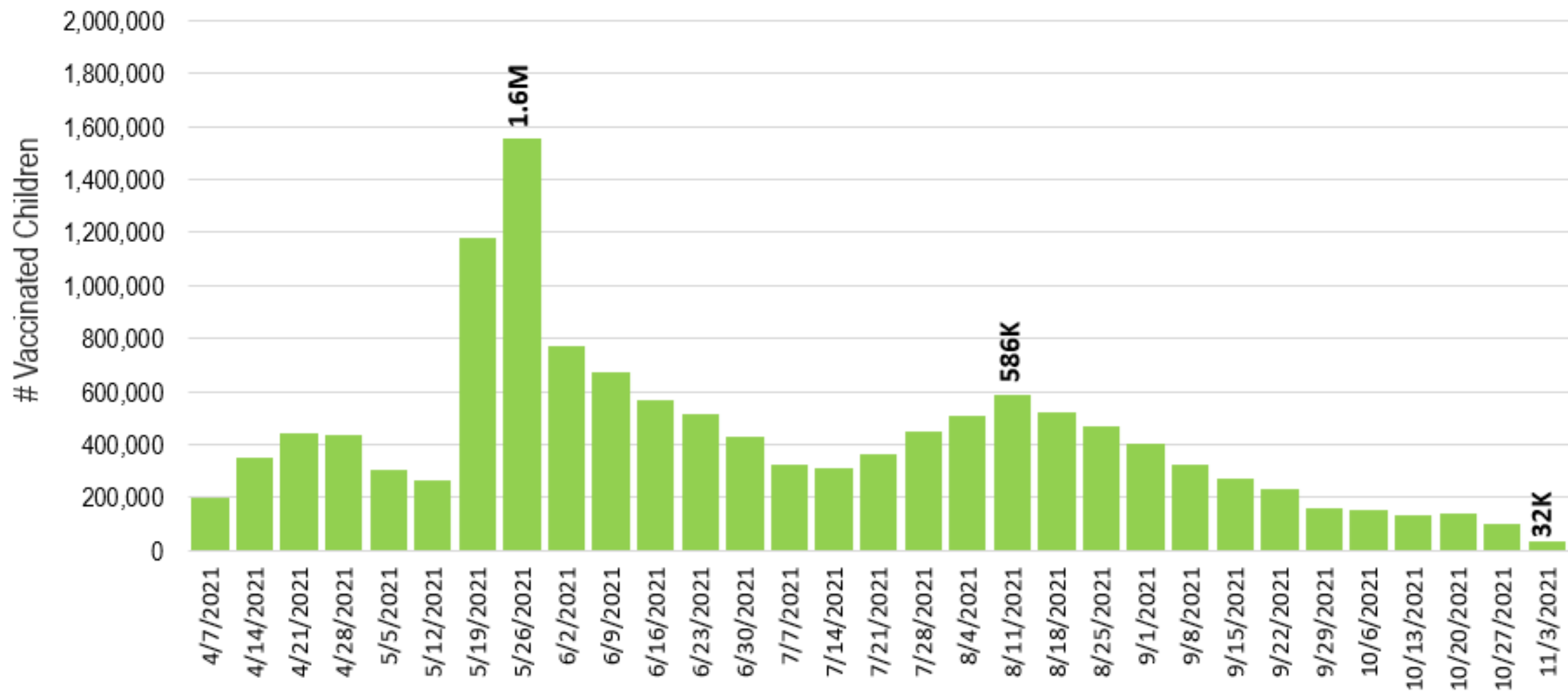
Fig 8. United States: Number of COVID-19 Cases Added in Past Week for Children and Adults*



* Note: 5 states changed their definition of child cases: AL as of 8/13/20, HI as of 8/27/20, RI as of 9/10/20, MO as of 10/1/20, WV as of 8/12/21;
 TX reported age for only a small proportion of total cases each week (eg, 3-20%); TX cumulative cases through 8/26/21
 As of 6/30/21, NE COVID-19 dashboard is no longer available; NE cumulative cases through 6/24/21
 Due to available data and changes made to dashboard, AL cumulative cases through 7/29/21
 Due to available data and calculations required to obtain MA child cases, weekly estimates fluctuate (eg, on 10/28/21, there were 920 fewer cumulative cases)
 See detail in Appendix: Data from 49 states, NYC, DC, PR and GU
 All data reported by state/local health departments are preliminary and subject to change; Analysis by American Academy of Pediatrics and Children's Hospital Association

Weekly Increase in the Number of Eligible US Children (Ages 12-17) Receiving Their Initial COVID-19 Vaccination

4.07.21 to 11.3.21



Source: AAP analysis of data series published by the CDC titled "Demographic Trends of People Receiving COVID-19 Vaccinations in the United States."

Vaccine implementation in 5 -11-Year-old Population

- Pediatricians' role in promoting vaccination among their patient population and in their community is critical
- Capacity to administer vaccine in pediatric offices is significant and increasing
- Community partnerships will strengthen vaccine delivery system
- Pediatricians – even when not vaccine administration sites – play important role in vaccine counseling and addressing vaccine hesitancy
- Considerations of Pfizer BioNTech Comirnaty[®] - Pediatric Formulation Use
 - Essential to use pediatric formulation

Resources for Practices

- Becoming a COVID-19 Vaccinator Video Series -
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/becoming-a-covid-19-vaccinator-video-series/>
- COVID-19 Vaccine Implementation in Pediatric Practices
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/covid-19-vaccine-implementation-in-pediatric-practices/>
- Considerations for COVID-19 Vaccination Clinics through Pediatric Practices
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/considerations-for-covid-19-vaccination-clinics-through-pediatric-practices/>

Talking With Parents, Caregivers and Patients

Pediatricians are encouraged to promote vaccination

- Ongoing, proactive messaging (ie, reminder recall, vaccine appointment/clinics)
- At every visit – can co-administer COVID-19 vaccines with those on the routine schedule, including annual influenza vaccine

Pediatricians are a trusted source of information

- Focus on the moveable middle
- Use a participatory format
- Incorporate Motivational Interviewing techniques with a strong personal recommendation



Ask permission to share

- *“You seem to have concerns about the vaccine. Well, that’s perfectly understandable – I’ve had a number of questions about it. Would you mind sharing what your particular concerns are?”*

Reflections

- *“I can hear that you’re concerned the vaccine could lead to problems down the road. Well, I completely get that – there’s a lot of information out there to digest. I’ve thought a lot about this and looked into it a great deal. Is it okay if I go over what I’ve found out?”*

Affirmations & myth busting

- *“I heard some of those same rumors myself, so I looked into it. It turns out that the possible association with infertility is a complete myth. It started with two doctors in Europe known to be antivaccine and spread from there. There is no truth to it, and experts agree that there is really no plausible way this vaccine would lead to infertility.”*

Autonomy support & personal recommendations

- *“What we know is that this virus is very dangerous for people of all ages, and it’s pretty clear to me the benefits greatly outweigh any potential risks. If he were my son, I would not hesitate to recommend this vaccine for him, and most of my patients now are getting the vaccine. Having said that, this is a decision that only you and your daughter can make. What do you think?”*

To Learn More About COVID-19 Vaccine Confidence Building, Access the Full “Effective COVID-19 Vaccine Conversations” PediaLink Course



<https://shop.aap.org/effective-covid-19-vaccine-conversations/>

Module 5 takes a deeper dive into putting evidence-based communication strategies into practice.



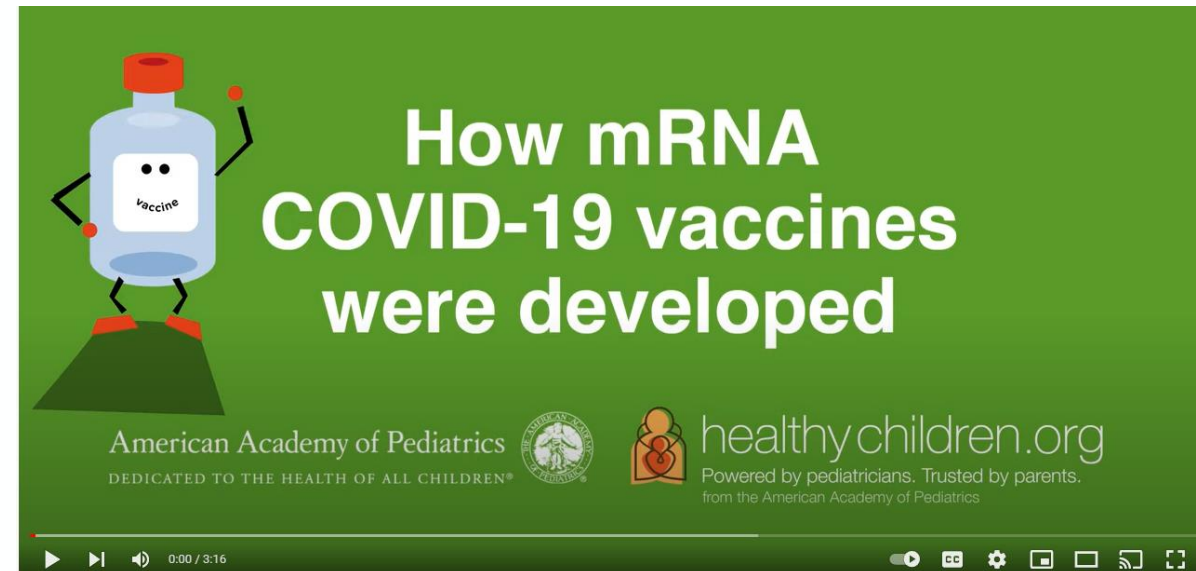
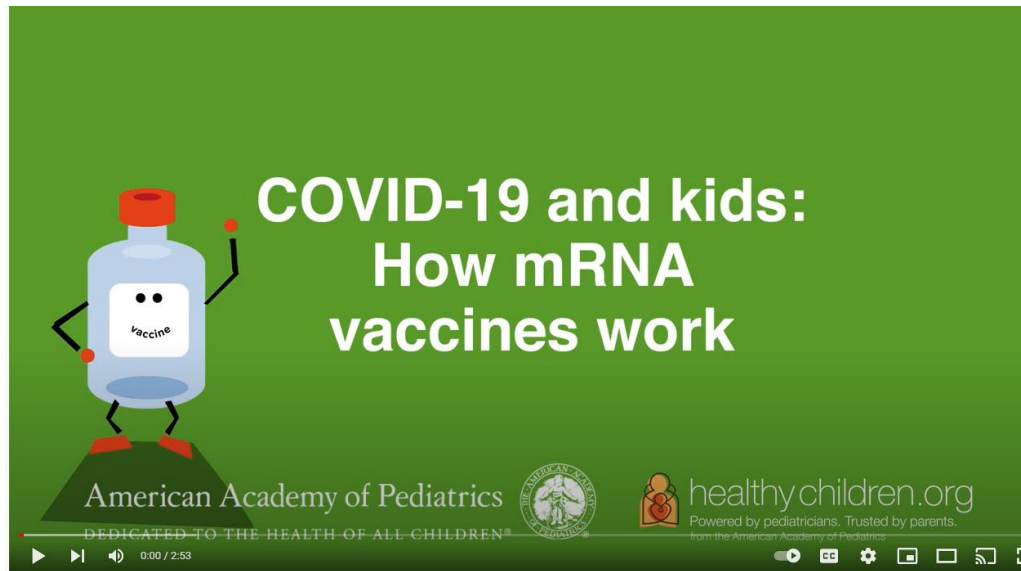
Resources for Patients, Families, and Caregivers

COVID-19 Vaccine Campaign Toolkit <https://www.aap.org/en/news-room/campaigns-and-toolkits/covid-19-vaccine-toolkit/>

HealthyChildren.org: [The Science Behind COVID-19 Vaccines: Parent FAQs](#)

Animated video on YouTube: [COVID-19 and kids: How mRNA vaccines work](#)

Animated video on YouTube: [How mRNA COVID-19 vaccines were developed](#)



AAP COVID-19 Information

Visit AAP.org Critical Updates on COVID-19 to find the following resources and more!

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/>

Immunizations Campaign Toolkit to promote vaccine confidence

<https://www.aap.org/en/newsroom/campaigns-and-toolkits/immunizations/>

Vaccine Information

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/>

Interim Clinical Guidance

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/>

COVID-19 Town Hall Series: Connecting with the Experts

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/connecting-with-the-experts/>

Children and COVID-19: State-Level Data Report

<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>





Thank You!

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Q&A/Discussion

Today's Links

- Slide 1 - This webinar is being recorded and can be found with the slides online at <https://www.idsociety.org/cliniciancalls>
- Slide 17 - <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html>
- Slide 20 - **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.
- Slide 24 - Modified from <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>
- Slide 26 - <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>
- Slide 32 - <https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%2010.28%20FINAL.pdf>
- Slide 33 - <https://downloads.aap.org/AAP/PDF/AAP%20and%20CHA%20-%20Children%20and%20COVID-19%20State%20Data%20Report%2010.28%20FINAL.pdf>
- Slide 34 - <https://covid.cdc.gov/covid-data-tracker/#mis-national-surveillance>
- Slide 46 - Operational Planning Guide — <https://www.cdc.gov/vaccines/covid-19/downloads/Pediatric-Planning-Guide.pdf>
- Slide 46 - Preliminary information on Pfizer-BioNTech COVID-19 vaccines — <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>
- Slide 46 - <https://www.cdc.gov/vaccines/covid-19/planning/children.html>
- Slide 47 - <https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics/how-schools-can-support.html>

Today's Links Continued

- Slide 49 – CDC Resources:
 - [COVID-19 Vaccination for Children 5-11 Years Old | CDC](https://www.cdc.gov/vaccines/covid-19/planning/children.html) - <https://www.cdc.gov/vaccines/covid-19/planning/children.html>
 - [COVID-19 Vaccines for Children and Teens | CDC](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Frecommendations%2Fadolescents.html) - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/children-teens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fvaccines%2Frecommendations%2Fadolescents.html
 - [Considerations for Planning School-Located Vaccination Clinics | CDC](https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics.html) - <https://www.cdc.gov/vaccines/covid-19/planning/school-located-clinics.html>
 - [Guidance for COVID-19 Prevention in K-12 Schools | CDC](https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html) - <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html>
 - [Guide to On-Site Vaccination Clinics for School | WECANDOTHIS.HHS.GOV](https://wecandothis.hhs.gov/guide-site-vaccination-clinic-schools) - <https://wecandothis.hhs.gov/guide-site-vaccination-clinic-schools>
 - [Communication Resources for COVID-19 Vaccines | CDC](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html#factsheets) - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/resource-center.html#factsheets>
 - [Frequently Asked Questions about COVID-19 Vaccination | CDC](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html) - <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>
- Slide 58 - Becoming a COVID-19 Vaccinator Video Series - <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/becoming-a-covid-19-vaccinator-video-series/>
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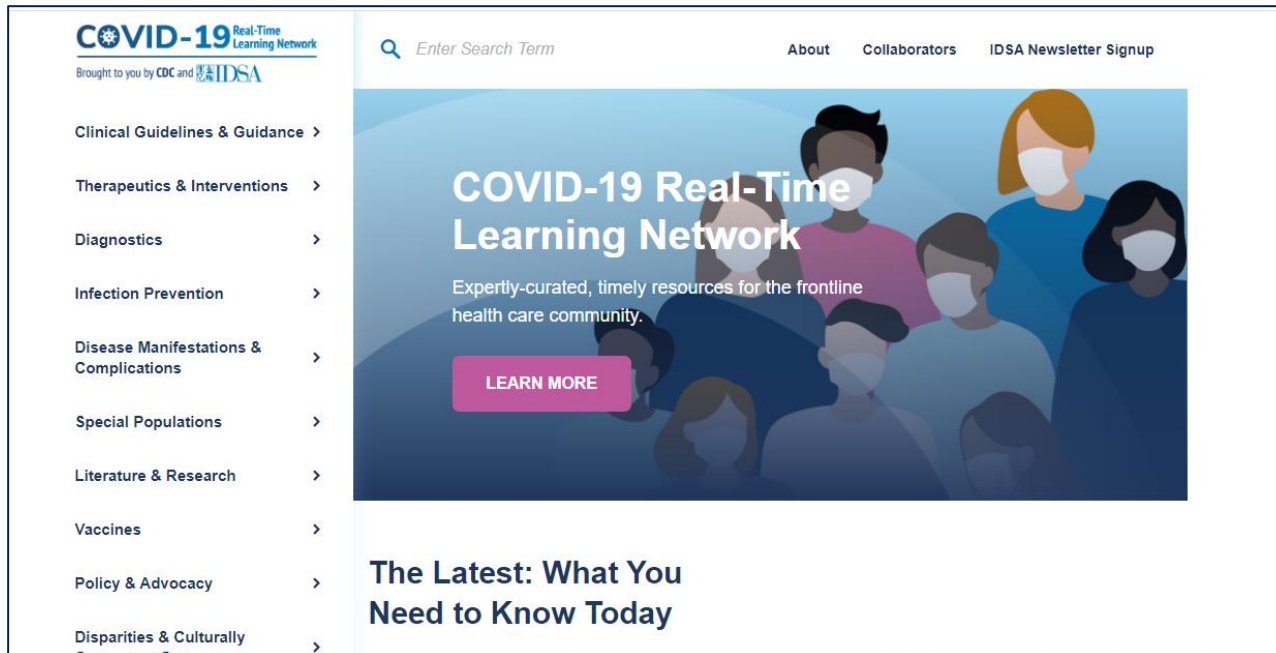
Today's Links Continued

- Slide 61 - <https://shop.aap.org/effective-covid-19-vaccine-conversations/>
- Slide 62 - COVID-19 Vaccine Campaign Toolkit <https://www.aap.org/en/news-room/campaigns-and-toolkits/covid-19-vaccine-toolkit/>
 - HealthyChildren.org: [The Science Behind COVID-19 Vaccines: Parent FAQs](#)
 - Animated video on YouTube: [COVID-19 and kids: How mRNA vaccines work](#)
 - Animated video on YouTube: [How mRNA COVID-19 vaccines were developed](#)
- Slide 63 - <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/>
<https://www.aap.org/en/news-room/campaigns-and-toolkits/immunizations/>
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/>
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/>
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/connecting-with-the-experts/>
<https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>

COVID-19 Real-Time Learning Network

Brought to you by CDC and IDSA

An online community bringing together information and opportunities for discussion on latest research, guidelines, tools and resources from a variety of medical subspecialties around the world.



Specialty Society Collaborators

American Academy of Family Physicians
American Academy of Pediatrics
American College of Emergency Physicians
American College of Physicians
American Geriatrics Society
American Thoracic Society
Pediatric Infectious Diseases Society
Society for Critical Care Medicine
Society for Healthcare Epidemiology of America
Society of Hospital Medicine
Society of Infectious Diseases Pharmacists

www.COVID19LearningNetwork.org

@RealTimeCOVID19

#RealTimeCOVID19

CDC-IDSA Partnership: Clinical Management Call Support

FOR WHOM?

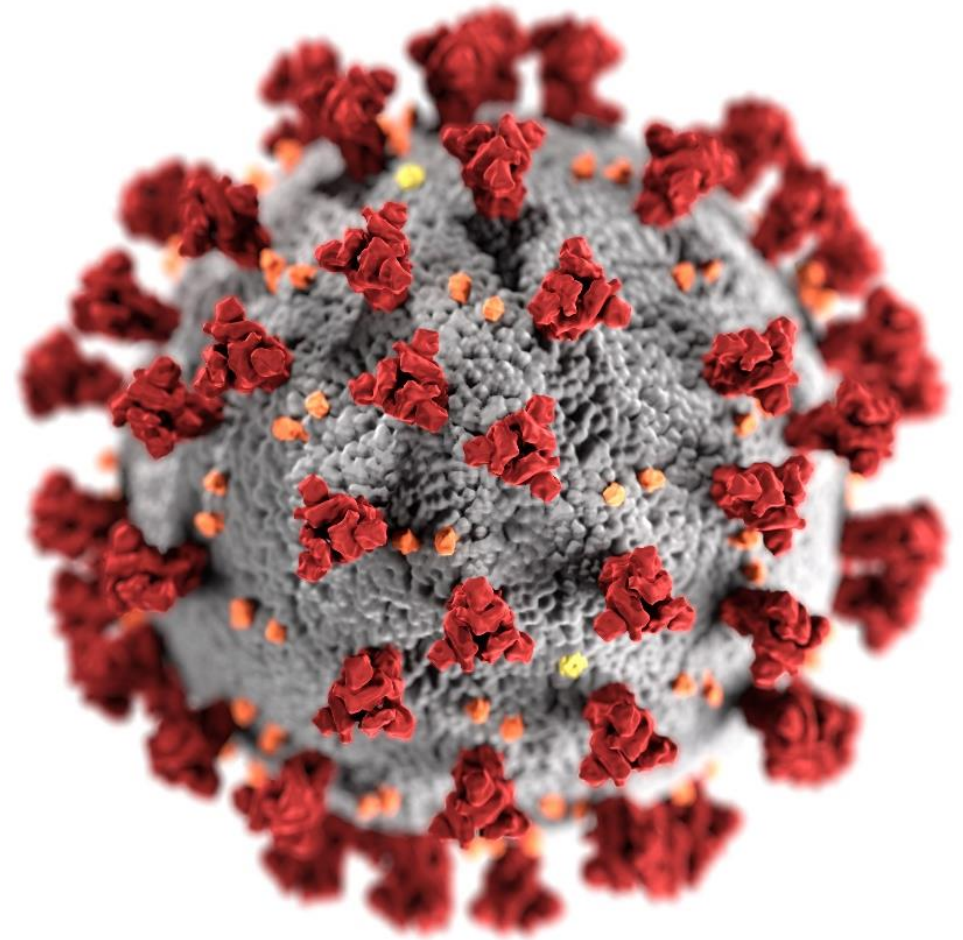
- Clinicians who have questions about the clinical management of COVID-19

WHAT?

- Calls from clinicians will be triaged by CDC to a group of IDSA volunteer clinicians for peer-to-peer support

HOW?

- Clinicians may call the main CDC information line at 800-CDC-INFO (800-232-4636)
- To submit your question in writing, go to www.cdc.gov/cdc-info and click on Contact Form



IDSA
Infectious Diseases Society of America

cdc.gov/coronavirus

Continue the
conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19



We want to hear from you!
Please complete the post-call survey.

Next Call:
Saturday, Nov. 20th

A recording of this call will be posted at
www.idsociety.org/cliniciancalls
-- library of all past calls now available --

Contact Us:

Dana Wollins (dwillins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)