



CDC/IDSA COVID-19 Clinician Call

May 15, 2021

Welcome & Introduction

Dana Wollins, DrPH, MGC

Vice President, Clinical Affairs & Guidelines
IDSA

- 66th 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.

Pfizer-BioNTech's COVID-19 Vaccine for Adolescents (12 to 15 Years of Age)

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



The Development of COVID-19 Vaccines

Peter Marks, MD, PhD

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



Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents

Kate R. Woodworth, MD, MPH

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Community Vaccine Implementation for Adolescents

Lee Ann Savio Beers, MD, FAAP

President, American Academy of Pediatrics
Professor of Pediatrics and Medical Director for Community Health and Advocacy,
Children's National Hospital



SARS-CoV-2 Vaccines in Children and Adolescents: Implications for the Future

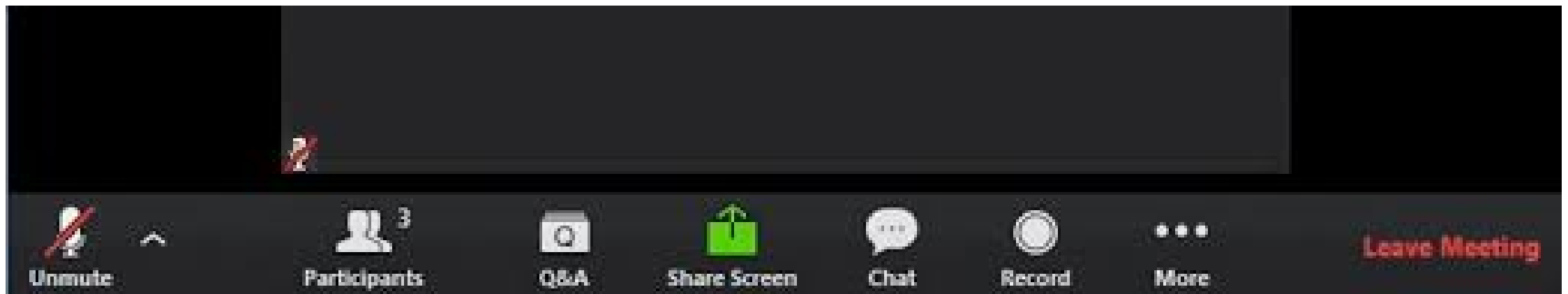
Janet A. Englund, MD

Professor of Pediatrics, University of Washington
Director of Transplant ID, Division of Pediatric Infectious Diseases,
Seattle Children's Hospital

Question?
Use the "Q&A" Button



Comment?
Use the "Chat" Button



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The Development of COVID-19 Vaccines

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IDSA Webinar

May 15, 2021

Vaccine Development – Accelerating the Process

- Clear guidance on expectations from products
- Facilitate early conversations with regulators
- Integrating different phases into one clinical trial
- Manufacture large quantities of product at risk
- Use optimal path to facilitate product availability



Biologics License Application (BLA)

- Biologics are licensed under both section 351 of the Public Health Service Act and the Federal Food Drug and Cosmetic Act
- Product must be safe, pure, potent, effective
- The standard used is that there is substantial evidence of efficacy from adequate and well-controlled clinical trials

Emergency Use Authorization (EUA)

- Put in place after 9/11 to ensure that potentially lifesaving medical products could be available to people in medical need when there is not an approved and available alternative
- The standard used is that the product “may be effective” and its “known and potential benefits outweigh the known and potential risks”



EUA for a COVID-19 Vaccine

- Must demonstrate clear and compelling efficacy in a large well-designed phase 3 clinical trial
- Careful evaluation of quality, safety, efficacy
- Public advisory committee meeting
- Enhanced post-deployment surveillance

Advanced Candidates – May 2021

- mRNA
 - BNT162b2 (Pfizer-BioNTech) – EUA granted Dec 11, 2020
 - mRNA-1273 (Moderna) – EUA granted Dec 18, 2020
- Non-Replicating Viral Vector
 - Ad26.COVS.S (Janssen) – EUA granted Feb 27, 2021
 - ChAdOx1 (Astra Zeneca-Oxford)
- Protein Subunit
 - NVX-CoV2373 (Novavax)
 - MRT5500 (Sanofi-Translate Bio)



Vaccine Trial Demographics

Vaccine	Pfizer-BioNTech (2 doses 21 d apart)	Moderna (2 doses 28 d apart)	Janssen (1 dose)
Total patients	43,552	30,350	39,321
Receiving vaccine	21,768	15,180	19,630
Receiving placebo	21,784	15,170	19,691
Black/African Amer.	9.8%	9.7%	17.2%
Hispanic/Latino	26.2%	20.0%	45.1%
At least age 65	21.4%	25.3%	20.4%



Vaccine Efficacy in Phase 3

Primary efficacy was determined against moderate and severe/critical COVID-19

Vaccine	Pfizer-BioNTech	Moderna	Janssen
Primary efficacy (vaccinated/placebo)	95% (8/162)	94.1% (11/185)	d14 66.9% (116/348) d28 66.1% (66/193)
Young population	<u>age 16-54</u> 95.6% (5/114)	<u>age 18-64</u> 95.6% (7/156)	<u>age 18-64</u> d14 63.7% (95/260) d28 66.1% (52/152)
Older population	<u>age 55+</u> 93.7% (3/48)	<u>age 65+</u> 86.4% (5/114)	<u>age 65+</u> d14 76.3% (21/88) d28 66.2% (14/41)
Severe COVID-19	1/9	0*/30	d14 14/60; d28 5/34

*One severe case reported 2 months after vaccination



Vaccine Safety in Phase 3

Second dose

Reaction (2 nd injection)	Placebo*	Pfizer-BioNTech		Moderna		Janssen	
		<55	55+	<65	65+	<60	60+
Injection site pain	14%	78%	66%	90%	83%	57%	33%
Fatigue	22%	59%	50%	68%	58%	44%	30%
Headache	21%	52%	39%	63%	46%	44%	30%
Muscle pain	10%	38%	29%	61%	47%	39%	24%
Chills	4%	35%	23%	48%	31%	N/A	N/A
Joint pain	8%	21%	19%	45%	35%	N/A	N/A
Fever	0.4%	16%	11%	17%	10%	13%	3%

*Average value across all studies, all doses, all ages



Pfizer Pediatric Demographics

Characteristic	Age 12-15 Vaccine (N=1131)	Age 16-25 Vaccine (N=537)	Age 12-15 Placebo (N=1129)	Age 16-25 Placebo (N=561)
Female	49.9%	52.5%	48.2%	52.0%
Mean Age (years)	13.6	19.4	13.6	19.6
Median Age	14.0	18.0	14.0	19.0
Black	4.6%	8.8%	5.0%	8.9%
Hispanic/Latino	11.7%	20.9%	11.5%	18.7%
Comorbidity (yes)	21.9%	23.5%	21.3%	25.7%



Pfizer Pediatric Immune Response

Study Group	12-15 Years N=190 GMT (95% CI)	16-25 Years N=170 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
Vaccine	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	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

Pfizer Pediatric Efficacy

Endpoint	Vaccine 12-15 Years N=1005 Cases	Placebo 12-15 Years N=978 Cases	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence from 7 days after Dose 2 in subjects without prior SARS-CoV-2 infection	0	16	100.0 (75.3, 100.0)

Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period

Pfizer Pediatric Safety

Characteristic	Age 12-15 Placebo Dose 2 (N=1078)	Age 12-15 Vaccine Dose 2 (N=1097)	Age 16-25 Vaccine Dose 2 (N=488)
Injection site pain	17.9%	78.9%	77.5%
Fatigue	24.5%	66.2%	65.6%
Headache	24.4%	64.5%	60.9%
Muscle pain	8.3%	32.4%	40.8%
Chills	6.8%	41.5%	40.0%
Joint pain	4.7%	15.8%	21.9%
Fever	0.6%	19.6%	17.2%



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ADMINISTRATION

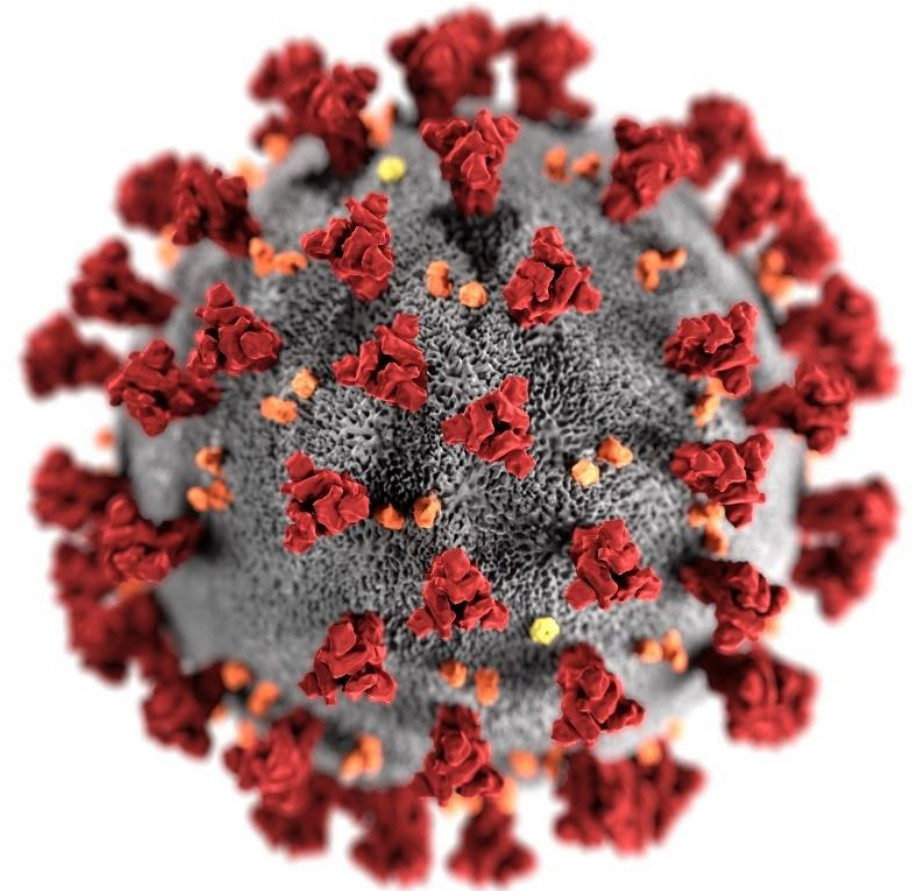
Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents

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Clinical Considerations for Pfizer-BioNTech COVID-19 Vaccination in Adolescents

Kate Woodworth, MD, MPH
May 15, 2021



ACIP Meeting

May 12, 2021



ACIP Vote – Interim Recommendation

The Pfizer-BioNTech COVID-19 Vaccine is recommended for persons 12–15 years of age in the U.S. population under the FDA's Emergency Use Authorization.

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021

Megan Wallace, DrPH^{1,2}; Kate R. Woodworth, MD¹; Julia W. Gargano, PhD¹; Heather M. Scobie, PhD¹; Amy E. Blain, MPH¹; Danielle Moulia, MPH¹; Mary Chamberland, MD¹; Nicole Reisman, MPH¹; Stephen C. Hadler, MD¹; Jessica R. MacNeil, MPH¹; Doug Campos-Outcalt, MD³; Rebecca L. Morgan, PhD⁴; Matthew F. Daley, MD⁵; José R. Romero, MD⁶; H. Keipp Talbot, MD⁷; Grace M. Lee, MD⁸; Beth P. Bell, MD⁹; Sara E. Oliver, MD¹

The Pfizer-BioNTech COVID-19 (BNT162b2) vaccine is a lipid nanoparticle–formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Vaccination

(GRADE) approach.[¶] The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥12 years under an EUA is interim and will be updated as additional information becomes available.

Clinical Considerations



Interim Clinical Considerations for COVID-19 Vaccines

- Recommendations apply to the use of the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA)
- Clinical considerations are being updated to include guidance for adolescents and recommendations regarding vaccine coadministration and vaccination after multisystem inflammatory syndrome in children (MIS-C) and adults (MIS-A)

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States



[Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination](#)

Reference Materials

[Summary Document for Interim Clinical Considerations](#) 

[Summary Document for Interim Clinical Considerations poster](#) 

[COVID-19 Vaccine Administration Errors and Deviations](#) 

[COVID-19 Vaccine Administration Errors and Deviations Poster](#) 

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Summary of recent changes (last updated May 14, 2021):

- Updated information for authorized age groups to include vaccination of adolescents ages 12-15 years with Pfizer-BioNTech COVID-19 vaccine.
- Updated information on coadministration of COVID-19 vaccines with other vaccines.

Coadministration

- COVID-19 vaccines were **previously recommended to be administered alone**, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns.
- However, **substantial data have now been collected** regarding the safety of COVID-19 vaccines currently authorized for use by FDA for use under EUA.
- Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that **immunogenicity and adverse event profiles are generally similar** when vaccines are administered simultaneously as when they are administered alone.

www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html

Coadministration

- COVID-19 vaccines and other vaccines **may now be administered without regard to timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days.

www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html

Coadministration

- It is unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.
- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers should consider:
 - Whether the patient is behind or at risk of becoming behind on recommended vaccines
 - Their risk of vaccine-preventable diseases (e.g., during an outbreak or occupational exposures)
 - The reactogenicity profile of the vaccines

Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

- The mechanisms of MIS-C and MIS-A are not well understood but include a dysregulated immune response to SARS-CoV-2.
- Children with MIS-C have high antibody titers to SARS-CoV-2; however, it is unknown if this correlates with protection against reinfection and for how long protective antibody levels persist.
- It is unclear if people with a history of MIS-C or MIS-A are at risk for recurrence of the same dysregulated immune response following reinfection with SARS-CoV-2 or in response to a COVID-19 vaccination.

Clinical Considerations for People with a History of MIS-C or MIS-A

- People with a history of MIS-C or MIS-A may choose to be vaccinated.
- Considerations for vaccination may include:
 - Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
 - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
 - Level of COVID-19 community transmission and personal risk of reinfection
 - Lack of safety data of COVID-19 vaccination following these illnesses
 - Timing of any immunomodulatory therapies

Clinical Considerations for People with a History of MIS-C or MIS-A

- Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A should consider delaying vaccination until they have recovered from illness and **for 90 days after the date of diagnosis of MIS-C or MIS-A**, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

Clinical Considerations for People with a History of MIS-C or MIS-A

Healthcare personnel or health departments can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.

www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Vaccine Safety Monitoring



VAERS is the Nation's Early Warning System for Vaccine Safety



VAERS

Vaccine Adverse Event Reporting System

Co-managed by
CDC and FDA

<http://vaers.hhs.gov>

A screenshot of the VAERS website. At the top left is the VAERS logo and the text 'Vaccine Adverse Event Reporting System' with the URL 'www.vaers.hhs.gov'. Below this is a navigation bar with five items: 'About VAERS', 'Report an Adverse Event', 'VAERS Data', 'Resources', and 'Submit Follow-Up Information'. The main content area has a heading 'Have you had a reaction following a vaccination?' followed by two numbered steps: '1. Contact your healthcare provider.' and '2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*'. Below this is a blue-bordered box with an 'Important' notice: 'If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.' Underneath is a Spanish version of the heading and steps. To the right of the text is a large image of a family (father, mother, and two children) looking at a laptop. Below the image is the text 'What is VAERS?'. At the bottom of the page are four tiles, each with an image and a title: 'REPORT AN ADVERSE EVENT' (with a description: 'Report significant adverse events after vaccination.'), 'SEARCH VAERS DATA' (with a description: 'Download VAERS Data and search the CDC WONDER database.'), 'REVIEW RESOURCES' (with a description: 'Find materials, publications, learning tools, and other resources.'), and 'SUBMIT FOLLOW-UP INFORMATION' (with a description: 'Upload additional information related to VAERS reports.').



Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
 - Uses text messaging and web surveys to check-in with vaccine recipients after vaccination
 - Participants can report any side effects or health problems after COVID-19 vaccination
 - Includes active telephone follow-up by CDC for reports of significant health impact

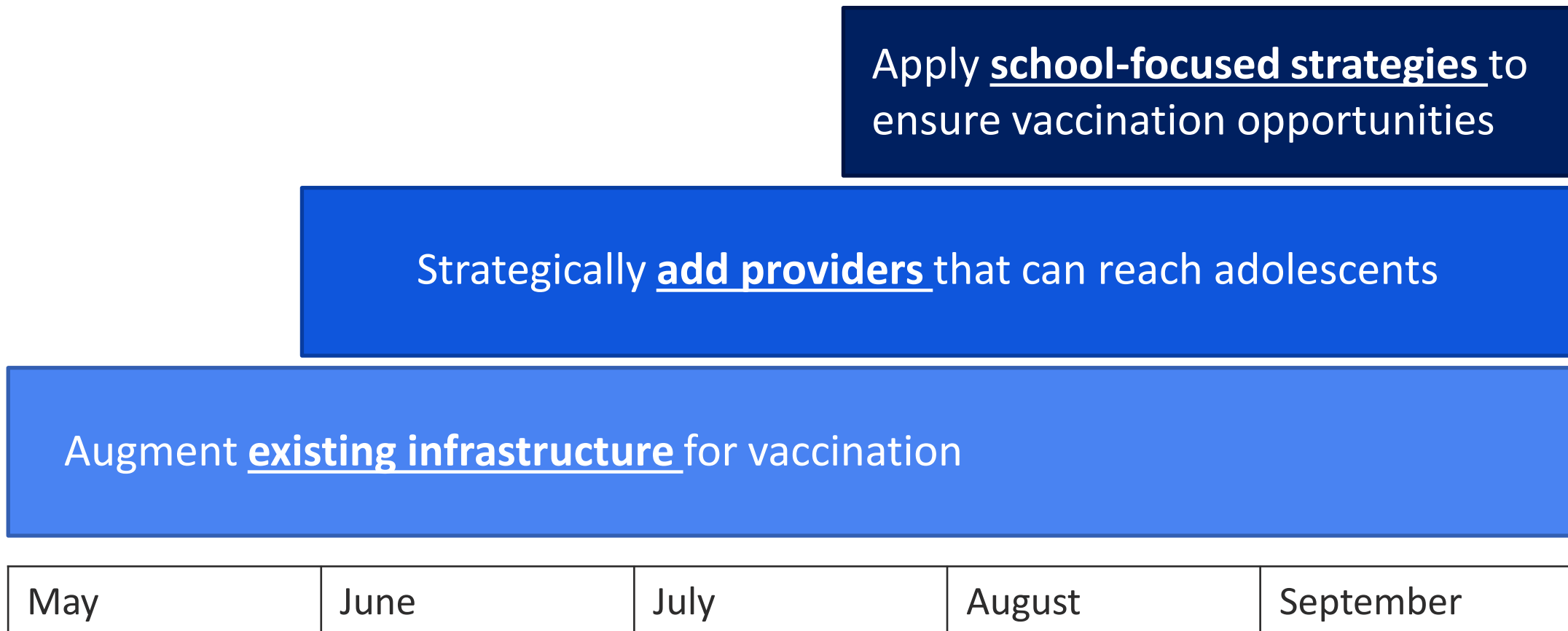


Implementation Considerations



Stepwise Approach to Increasing Vaccine Access for Adolescents

Adolescent
vaccination



Opportunities to Increase Equitable Access to the Pfizer-BioNTech COVID-19 Vaccine

- Pfizer-BioNTech COVID-19 Vaccine characteristics
 - Pfizer-BioNTech submitted new data to Federal Drug Administration supporting stability of vaccine when stored for up to one month (31 days) at 2-8°C¹
 - Strategies to efficiently utilize doses and support local redistribution, and smaller tray sizes would improve access (e.g., smaller providers, rural areas)
- Multipronged approach to improve access
 - Primary care providers serving adolescents, Federally Qualified Health Centers, rural health clinics, community health centers, children's hospitals, pharmacies, school-located vaccination clinics

1. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer

CDC Resources




Additional Tools

- Additional tools to identify persons with contraindications and precautions to vaccination

www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Pre-Vaccination Checklist for COVID-19 Vaccines


Information for Healthcare Professionals



Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

Pre-Vaccination Checklist for COVID-19 Vaccines



For vaccine recipients:
 The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name _____
 Age _____

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
• If yes, which vaccine product? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Another product _____			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
5. Have you received another vaccine in the last 14 days?			
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
8. Do you have a bleeding disorder or are you taking a blood thinner?			
9. Are you pregnant or breastfeeding?			

Form reviewed by _____ Date _____

12/21/20 CS921629-E
Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists
1

Interim Considerations

- Preparing for the potential management of anaphylaxis at COVID-19 vaccination sites

www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

The screenshot shows the CDC website page for 'Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites'. The page includes a navigation menu on the left with categories like 'Vaccines and Immunizations', 'For Parents', 'For Adults', 'For Pregnant Women', 'For Healthcare Professionals', 'COVID-19 Vaccination', 'For Immunization Managers', 'For Specific Groups of People', 'Basics and Common Questions', 'Vaccines and Preventable Diseases', and 'News and Media Resources'. The main content area features a title, a paragraph explaining that anaphylaxis is a severe allergic reaction, and a yellow warning box stating: 'Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine.' Below this, there is a section titled 'Observation period following COVID-19 vaccination' which lists observation times: 30 minutes for those with a history of anaphylaxis and 15 minutes for all other persons. Another section, 'Early recognition of anaphylaxis', lists symptoms such as respiratory distress, gastrointestinal issues, cardiovascular changes, and skin/mucosal reactions.

CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources**. Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- COVID-19 Vaccination: www.cdc.gov/vaccines/covid-19/index.html
- For Healthcare Professionals: www.cdc.gov/vaccines/covid-19/hcp/index.html

COVID-19 Vaccination

- Product Info by US Vaccine
 - Pfizer-BioNTech Vaccine**
 - Moderna Vaccine
 - Janssen/J&J Vaccine
 - EUA
 - FAQs for Healthcare Professionals
- Clinical Care +
- Provider Requirements and Support +
- Training and Education +
- Vaccine Recipient Education +
- Health Departments +
- Planning & Partnerships +
- Vaccine Effectiveness Research +
- Vaccination Toolkits +
- COVID-19 Vaccine Data Systems +
- Content Syndication +
- Vaccinate with Confidence +

Pfizer-BioNTech COVID-19 Vaccine

Summary of Recent Changes and Updates





Webpage content and individual PDFs are updated when there's new guidance concerning the Pfizer-BioNTech COVID-19 vaccine. Expand each section below to see a summary of new and updated items.

General Information Updates	+
Preparation and Administration Information Updates	+
Storage and Handling Information Updates	+


General Pfizer-BioNTech Vaccine Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine
 Diluent: 0.9% sodium chloride (normal saline, preservative-free)
 Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Dosing Information	+
Age Indications	+
Schedule	+
Administration	+


 EUA	 Interim Clinical Considerations
 Pfizer BioNTech Covid-19 Vaccine FAQs	 ACIP Recommendations

YOU CALL THE SHOTS



Vaccinating Adolescents

Vaccination can be a stressful experience. Adolescents may experience fear and anxiety, which if not addressed, can have long-term effects such as avoidance of needed health care throughout their lifetime. Your practices can positively impact adolescents' experiences and perceptions of vaccination. Consider strategies to manage pain and potential acute reactions.



COVID-19 Vaccine Communication Resources

- Toolkit for Medical Centers, Clinics, and Clinicians

www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

- Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit

www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html



CDC recommends vaccination for everyone 12 years and older to help protect against COVID-19.

Why does my child need a COVID-19 vaccine?

COVID-19 vaccines help protect kids from getting COVID-19. Getting a COVID-19 vaccine will also help keep them from getting seriously ill even if they do get COVID-19.

When should my child be vaccinated?

All kids who are 12 years and older should get a COVID-19 vaccine. If your preteen or teen hasn't gotten their vaccine yet, talk to their doctor about getting it as soon as possible.

Are COVID-19 vaccines safe for my child?

Yes. COVID-19 vaccination provides safe and effective protection against the virus that causes COVID-19. The COVID-19 vaccines have been used under the most intensive safety monitoring in U.S. history.

The Pfizer-BioNTech COVID-19 Vaccine is now available for everyone ages 12 and older. In the clinical trial for children ages 12 through 15, the Pfizer-BioNTech vaccine was 100% effective at preventing COVID-19 with symptoms. In addition, children's immune systems responded to the vaccine in a way similar to those of older teens and young adults. No safety concerns were identified in the clinical trial.

All authorized and recommended COVID-19 vaccines:

- are safe,
- are effective
- help protect from severe illness

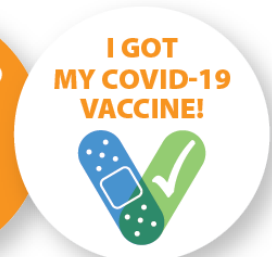
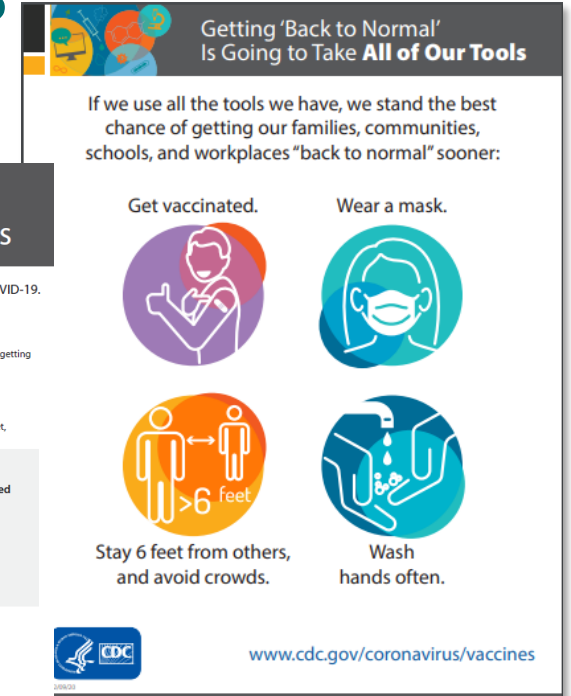
Before, during and after your child's vaccination

- Your child will need 2 shots given 3 weeks (21 days) apart to get the most protection.
- Tell the doctor or nurse about any allergies your child may have.
- Comfort your child during the appointment.
- To prevent fainting and injuries related to fainting, your child should be seated or lying down during vaccination and for 15 minutes after the vaccine is given.
- After your child's COVID-19 vaccination, you will be asked to stay for 15 minutes so your child can be observed in case they have a severe allergic reaction and need immediate treatment.



CS22388-B | 05/12/21

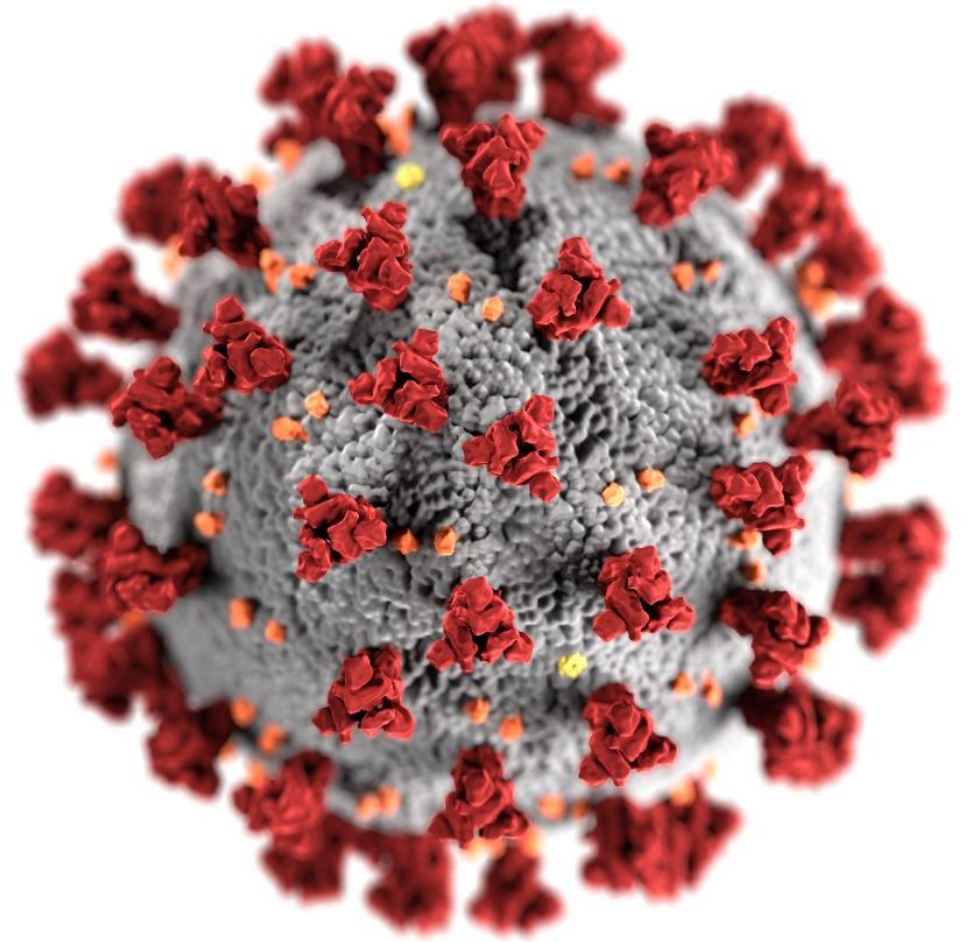
www.cdc.gov/cv



Your Patients Need to Hear from You!

- You are the most trusted resource for your patients in making health decisions. **Your strong recommendation to get a COVID-19 vaccine is one of the most important factors in your patients' decision to accept vaccination.**
- Engaging in Effective COVID-19 Vaccine Conversations
www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html

Thank you!



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

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



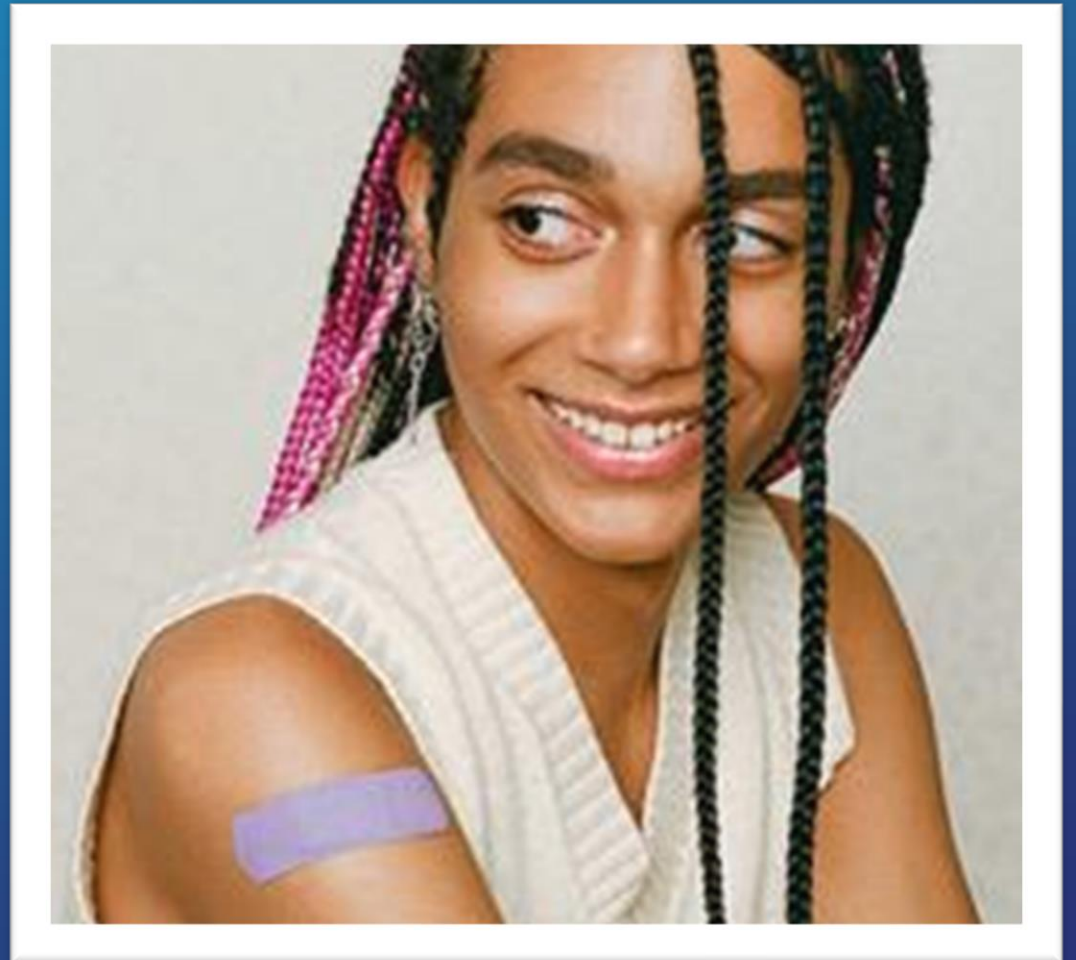
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Vaccination Implementation in Adolescents

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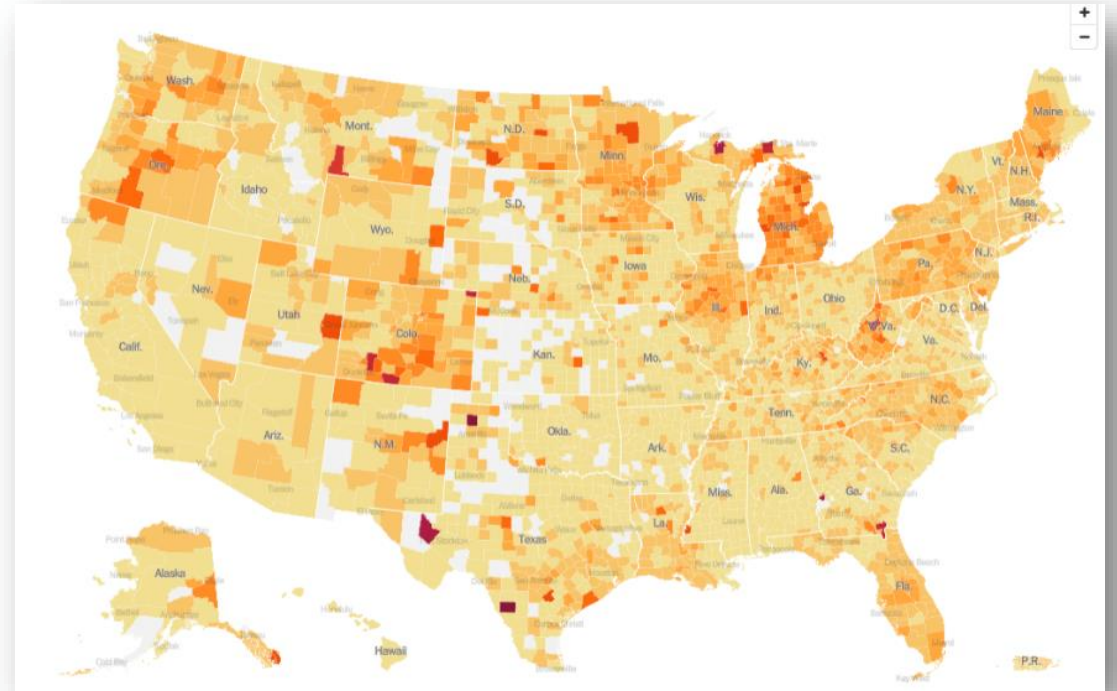
DEDICATED TO THE HEALTH OF ALL CHILDREN®



Children and COVID-19: State Data Report

A joint report from the American Academy of Pediatrics and the Children's Hospital Association

Summary of publicly reported data from 49 states, NYC, DC, PR, and GU



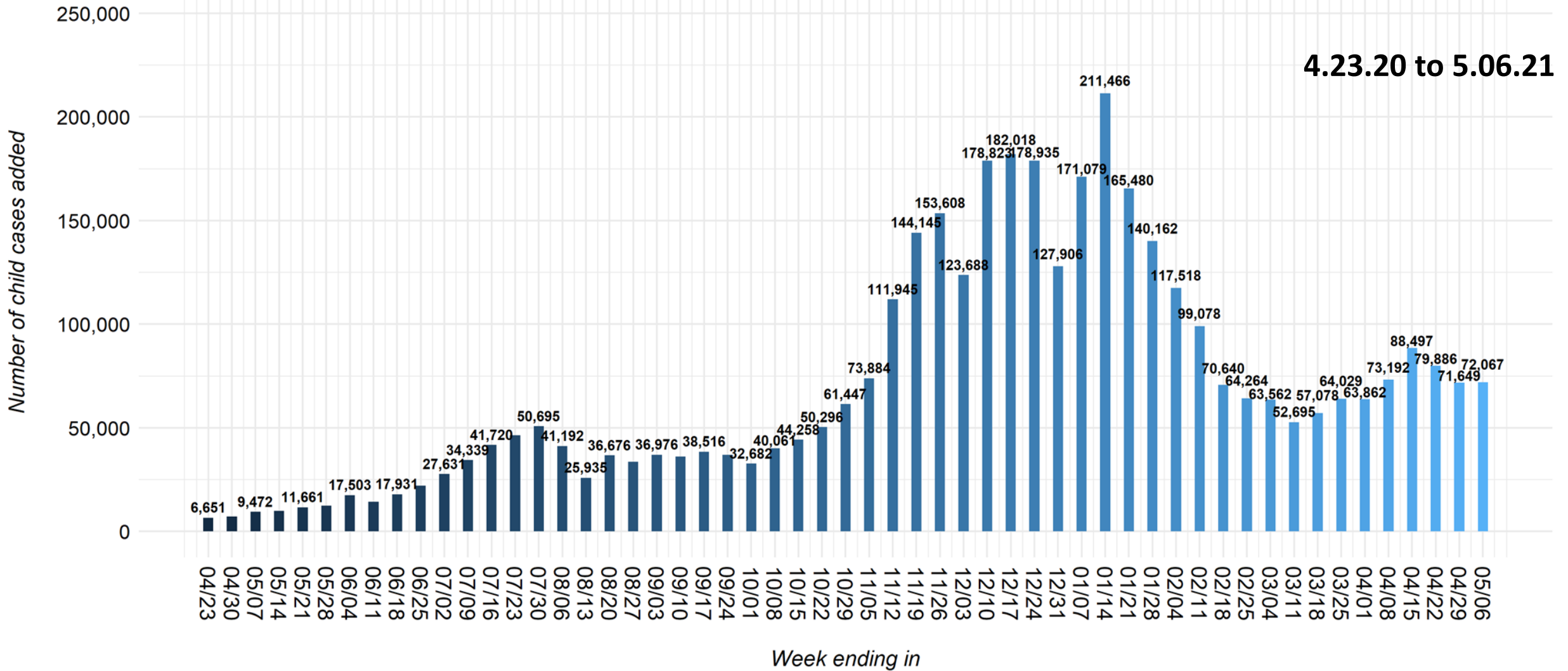
New report posted weekly on AAP.org

NYT 5.10.21 all ages

As of May 6, 2021 – 3,854,791 cumulative confirmed child COVID-19 cases

- An increase of over 72,000 new cases in the past week
- An increase of about 143,700 new cases in the past 2 weeks

United States: Number of Child COVID-19 Cases Added in Past Week

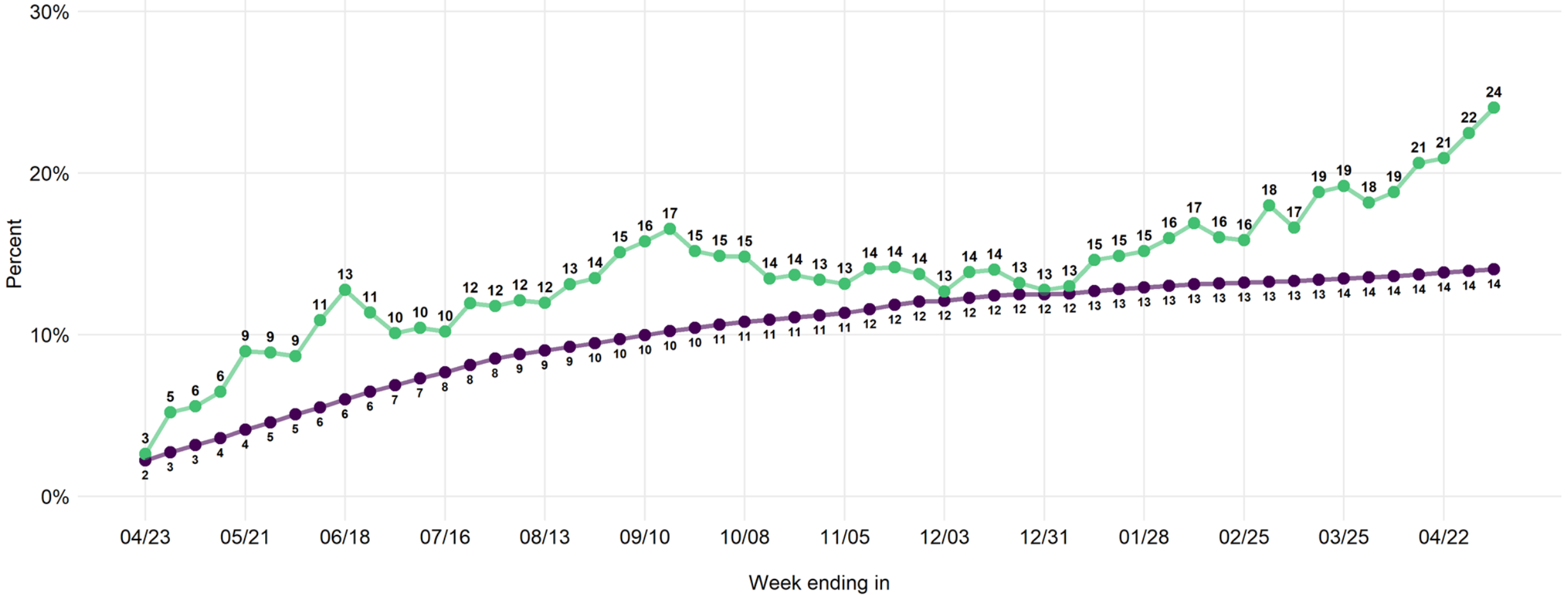


Source: AAP analysis of publicly available data from state/local health departments
 Note: 4 states changed definition of child cases: AL as of 8/13, HI as of 8/27, RI as of 9/10, MO as of 10/1
 TX reported age for only a small proportion of total cases each week (eg, 3-20%)
 As of 5/6/21, due to data revision and lag in reporting, RI experienced 30% increase in child cases (4,906 cases added)

Percent of COVID-19 cases that were children: Cumulative and for new cases in past week

● Percent children, cumulative ● Percent children, new cases in past week

4.23.20 to 5.06.21



Source: AAP analysis of publicly available data from state/local health departments
 Note: Analysis excludes data from Alabama and Missouri due to change in definition of 'child' case

Drop in Adolescent IZ Rates

- The pandemic has led to significant and sustained drops in immunization rates among teens.
- Routinely-recommended immunizations for adolescents **declined 26-46%** from March – November 2019 to March – November 2020.
 - Vaccines for Children
 - As of May 2, 2021, overall VFC provider orders (other than influenza) are down by **11.7 million doses** compared with 2019.
- Impacts are greater among Black and Latinx households and lower income children due to obstacles in receiving well child visits and vaccines.

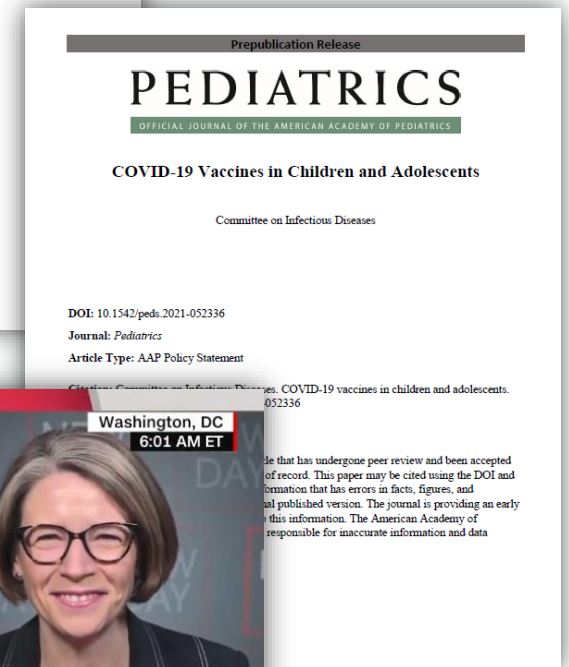
Source: Avalere analysis of 2019-2020 Commercial, Managed Medicaid, and Medicare Advantage claims using the Inovalon MORE2 Registry® and Medicare Fee-for-Service claims from a provider clearinghouse dataset maintained by Inovalon.

Source: <https://medium.com/rapid-ec-project/health-still-interrupted-pandemic-continues-to-disrupt-young-childrens-healthcare-visits-e252126b76b8>

Source: ACIP Meeting; May 12, 2021

NEW Policy Statement *COVID-19 Vaccines in Children and Adolescents*

- The AAP recommends COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications using a COVID-19 vaccine authorized for use for their age.
- Given the importance of routine vaccination and the need for rapid uptake of COVID-19 vaccines, the AAP supports coadministration of routine childhood and adolescent immunizations with COVID-19 vaccines.



Work with Federal Partners on Adolescent Vaccine Roll-out

- Educating families
- Getting vaccines to primary care providers
- Encouraging smaller tray sizes, extended shelf life in typical freezers
- 48% of VFC providers enrolled as COVID vaccine providers

Resources for Pediatric Practices

- **Becoming a COVID-19 Vaccinator**

Thursday (May 20) Webinar at 7:00 pm CT

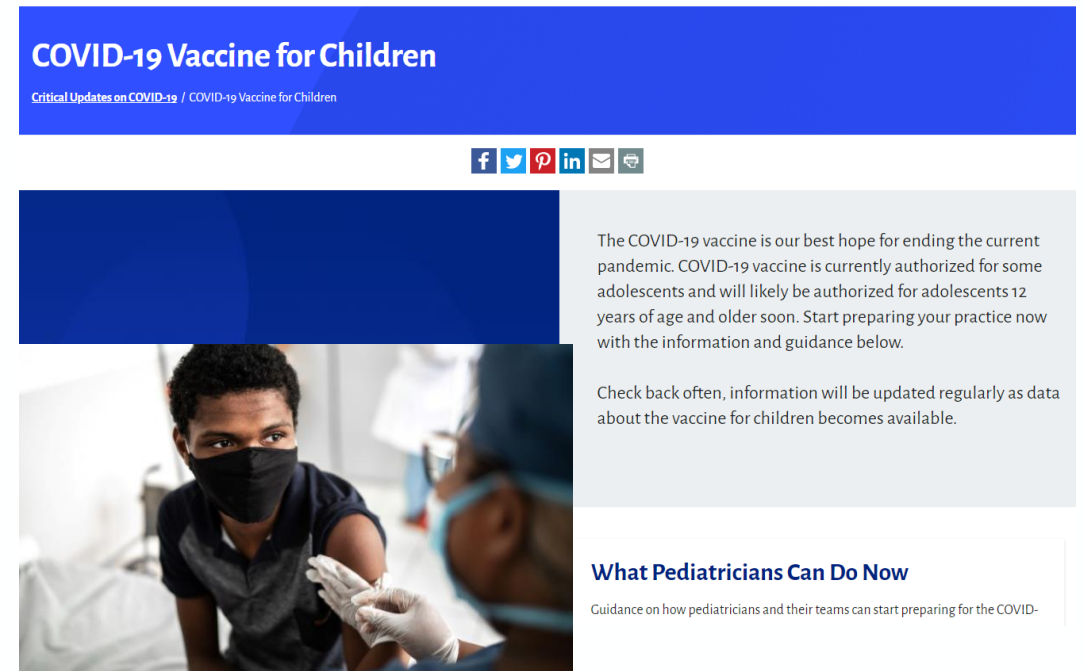
Practice Implementation in Pediatric Practices to share evidence-based strategies and best practices.

https://zoom.us/webinar/register/WN_8kYhuqX5Q8mZ5sbuzIR-5w

- **Website content on practice implementation**

- Standing orders
- Recall/reminder
- Vaccination-only visits
- Expansion of vaccination clinics (eg, drive thru, curbside, expanded hours)
- Community outreach and partnership
- Messaging to parents and families

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



The screenshot shows a webpage with a blue header containing the title "COVID-19 Vaccine for Children" and a subtitle "Critical Updates on COVID-19 / COVID-19 Vaccine for Children". Below the header are social media icons for Facebook, Twitter, Pinterest, LinkedIn, Email, and Print. The main content area features a photograph of a young boy wearing a black face mask, sitting in a chair while a healthcare professional in a blue surgical cap and mask administers a vaccine to his arm. To the right of the photo, there is text stating: "The COVID-19 vaccine is our best hope for ending the current pandemic. COVID-19 vaccine is currently authorized for some adolescents and will likely be authorized for adolescents 12 years of age and older soon. Start preparing your practice now with the information and guidance below." Below this text, it says: "Check back often, information will be updated regularly as data about the vaccine for children becomes available." At the bottom of the page, there is a section titled "What Pediatricians Can Do Now" with the subtitle "Guidance on how pediatricians and their teams can start preparing for the COVID-19 vaccine for children."

Promote Vaccine Confidence

- Utilize resources available from the AAP to build confidence in routinely recommended vaccines
 - www.aap.org/immunization (AAP Immunization Webpage)
 - <https://services.aap.org/en/news-room/campaigns-and-toolkits/immunizations/> (AAP Immunization Campaign)
- National AAP and local AAP chapter activities to address vaccine hesitancy and build vaccine confidence

#CallYourPediatrician

- Increase awareness among parents of need for routine health care for children, even during pandemic
- Educate parents on safety and infection control at practices
- Increase vaccination rates; ensure children receive timely care
- Help pediatricians weather financial downturn so they can remain in practice to care for children



COVID-19 Information for Families

New HealthyChildren.org Article:

Getting Your Child Ready for the COVID-19 Vaccine

<https://healthychildren.org/English/health-issues/conditions/COVID-19/Pages/Getting-Your-Child-Ready-for-the-COVID-19-Vaccine.aspx>

Updated:

- Ask the Pediatrician: When can children get the COVID-19 vaccine? <https://healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/when-can-children-get-the-COVID-19-vaccine.aspx>
- Ask the Pediatrician: My children want to have birthday parties with their friends but can't get COVID-19 vaccines yet. Is it safe? <https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Birthday-Parties-and-COVID-19.aspx>
- 5 Superpowers You Can Give Your Children <https://healthychildren.org/English/family-life/family-dynamics/Pages/Superpowers-Parents-Can-Give-Their-Children.aspx>
- The Science Behind the COVID-19 Vaccine: Parent FAQs <https://healthychildren.org/English/health-issues/conditions/COVID-19/Pages/The-Science-Behind-the-COVID-19-Vaccine-Parent-FAQs.aspx>
- COVID-19: What Families Need to Know <https://www.healthychildren.org/English/health-issues/conditions/COVID-19/Pages/2019-Novel-Coronavirus.aspx>



RESOURCES

- AAP Critical Updates on COVID-19

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

- “Becoming a COVID-19 Vaccinator” | Thursday, May 20 at 7 pm CT
Practice Implementation in Pediatric Practices Webinar – register here:
https://zoom.us/webinar/register/WN_8kYhuqX5Q8mZ5sbuzIR-5w

- #CallYourPediatrician Campaign Toolkit

<https://services.aap.org/en/news-room/campaigns-and-toolkits/call-your-pediatrician/>

- Immunization Campaign Toolkit

<https://services.aap.org/en/news-room/campaigns-and-toolkits/immunizations/>

- Strategies to Improve Immunization Rates

<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/Strategies-to-Improve-Immunization-Rates.aspx>

SARS-CoV-2 Vaccines in Children and Adolescents: Implications for the Future

Janet A. Englund, MD

Professor of Pediatrics

University of Washington

Director of Transplant ID

Division of Pediatric Infectious Diseases

Seattle Children's Hospital





SARS-CoV-2 Vaccines for Children and Adolescents: Implications for the future

IDSA Webinar May 15, 2021

Janet A. Englund, MD

Professor of Pediatrics, University of Washington
Pediatric Infectious Diseases, Seattle Children's
Hospital



Seattle Children's
HOSPITAL • RESEARCH • FOUNDATION



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PEDIATRIC EPIDEMIOLOGY



- Children represent ~22% of US population:
Sept-Oct, 2020: children represented 10% of COVID-19 + cases
April 2021: children represented 22% of COVID-19 + cases*
- Children are infected and transmit virus; household transmission likely most important route documented to date.**
- Younger children appear to have lower rates of infection and more likely to have minimal symptoms or be asymptomatic
- Mitigation strategies such as social distancing, school closures have decreased COVID-19 disease as well as other respiratory viruses in children- but as schools reopen, increased COVID-19 and resp. viruses noted.

* AAP & CHA report 4/29/21: **Laws RL et al Pediatrics 2020; Lewis NM CID 2020

DO CHILDREN SHED LESS VIRUS?

SARS CoV-2 Viral load (VL) kinetics in symptomatic children and adults

Univ. Geneva

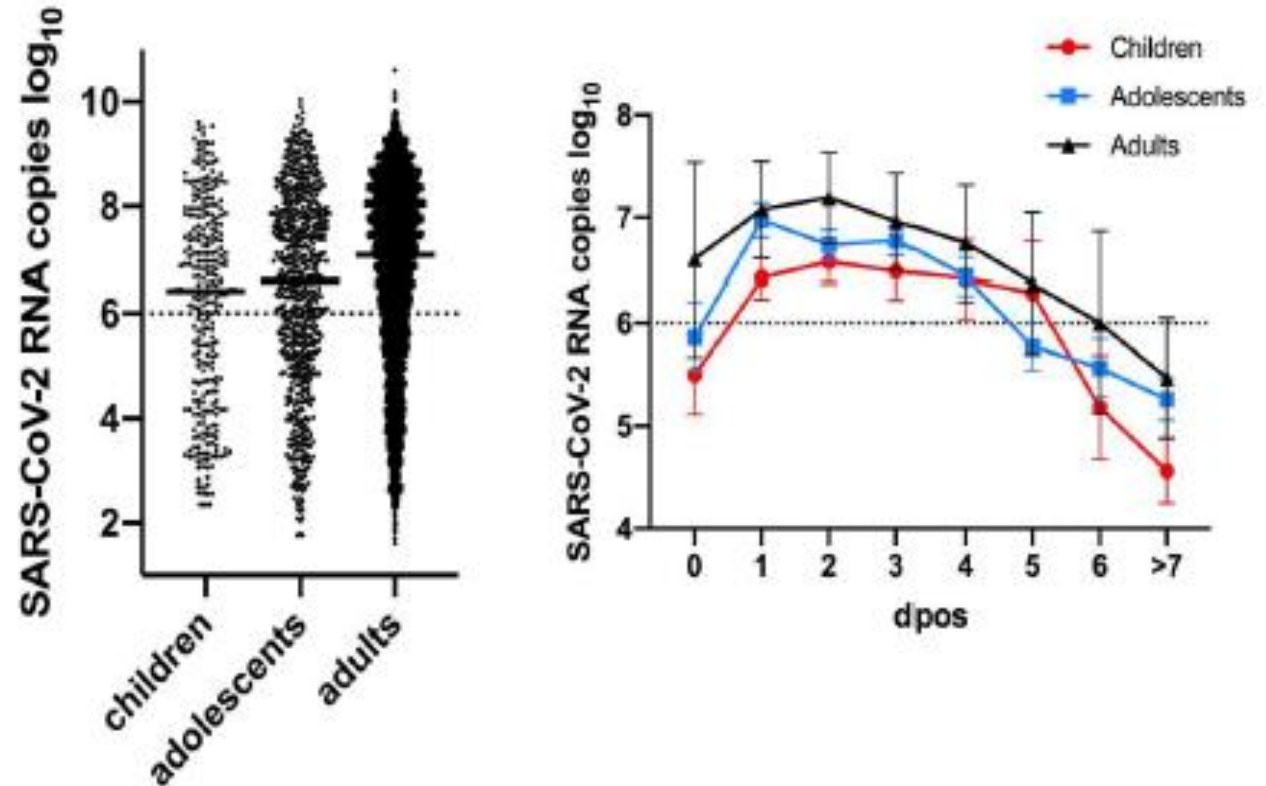
Prospective study of NP swabs from symptomatic patients:

- 279 children: 0-13 yrs
- 639 adolescents: 14-19 yrs
- 7109 adults: ≥ 20 yrs

VL in children <13 vs adol: NS

VL in children <13 vs adults: <0.01

Bellon et al.
Clin Inf Dis. 2021



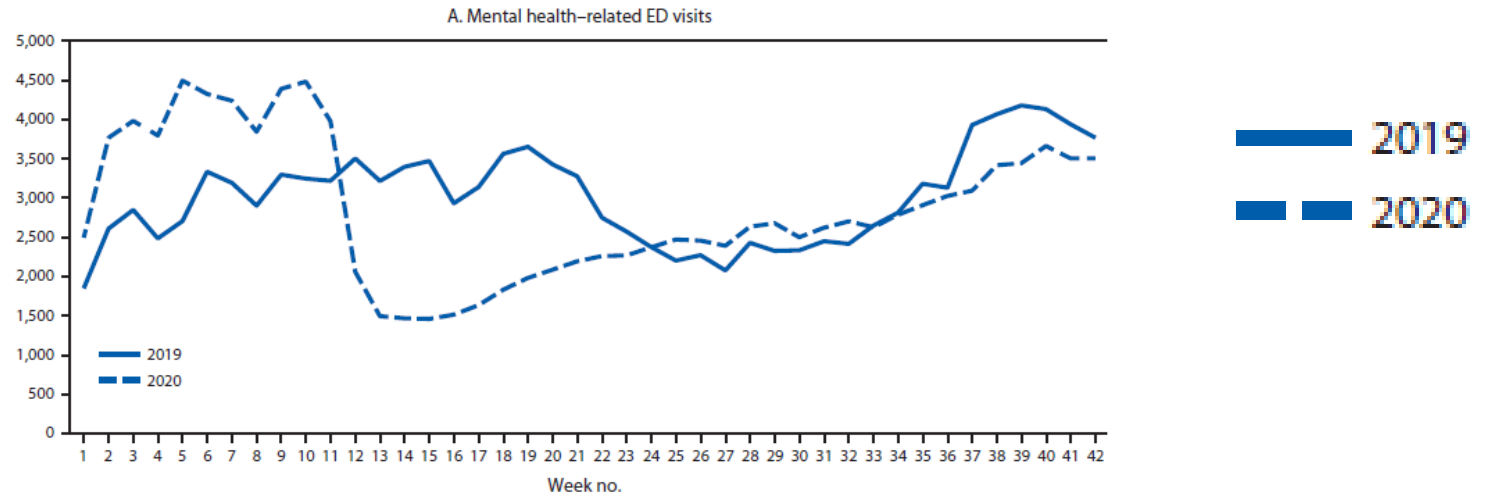
CONCLUSION:

Assuming that VL is a major driver in SARS-CoV-2 transmission, this data indicate that symptomatic pediatric and adolescent cases could transmit SARS-CoV-2.... during the first week of illness.

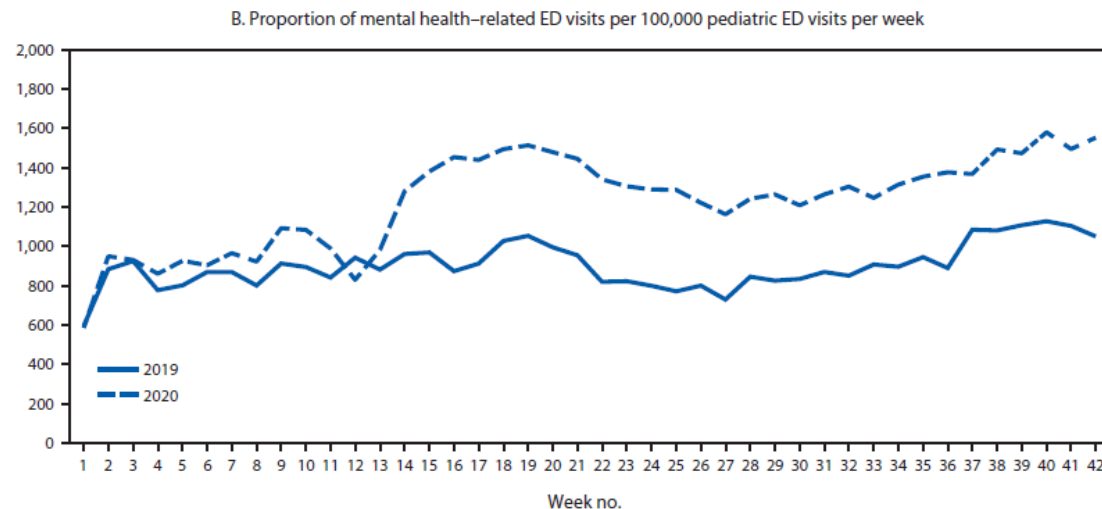
Impact of COVID-19 on Pediatric Mental Health

Mental Health–Related Emergency Department Visits Among Children Aged <18 Years During the COVID-19 Pandemic — United States, January 1–October 17, 2020

A. Mental Health-Related ED Visits in children < 18 years, 2020 vs 2019.



B. Proportion of mental health related ED visits per 100,000 pediatric ED visits per week.





STATUS OF COVID-19 VACCINE STUDIES IN CHILDREN

- **Pfizer-BioNTech mRNA vaccine:** Approved under FDA EUA and recommended by ACIP/CDC for ages 12 and up at 30 mcg dose;
 - Dose finding studies ongoing in ages 5-11 yrs
 - Planned Extension to ages 6M -5 yrs as a safety/immunogenicity study

- **Moderna mRNA vaccine:** Approved under FDA EUA and recommended by CDC for ≥ 18 at 100 mcg/dose
 - Clinical studies underway for children ages 12-18 yrs
 - Dose finding studies underway for children 11 yrs down to 6M, as a safety/immunogenicity study

- **Johnson & Johnson/ Janssen's AdV vector (nonreplicating vector) vaccine:** Approved under FDA EUA and recommended by CDC for ≥ 18 yrs
 - Clinical studies developed for adolescents and children
 - Current studies on hold

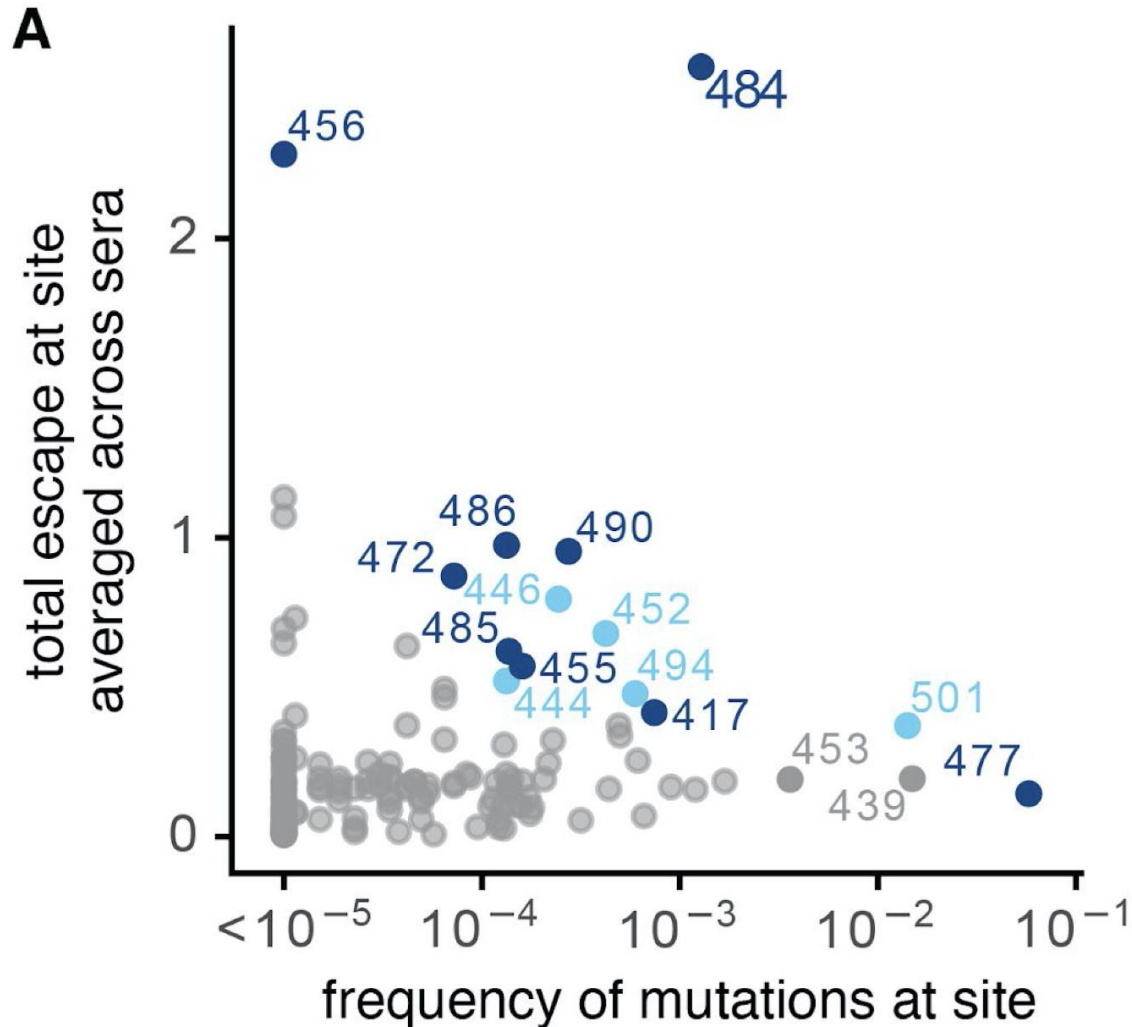
- **Novavax vaccine:** Nanoparticle vaccine of S protein + adjuvant; not yet under FDA EUA
Clinical studies underway in children 12- < 18 years *

* <https://www.fiercebiotech.com/biotech/novavax-delays-covid-19-vaccine-regulatory-submissions-again>

PUBLIC HEALTH CONSIDERATIONS FOR THE FUTURE

- Increasing adult vaccine uptake is leading to decrease incidence COVID-19 disease, loosening of social distancing and opening of schools
- Increasing social interaction in school and the community may increase spread in unimmunized populations, including children < 12 yrs
- Specific issues with vaccines for children:
 - When will FDA EUA vs. approval be obtained for younger children?
 - Vaccine mandates: if and how? d controversial
 - How will schools handle masking in classrooms and activities?
 - How can schools address diagnostic testing - especially if vaccinated children have lower viral loads,
 - How will we handle symptomatic respiratory disease if flu and RSV return, and there is no COVID-19 vaccine for children?

Effect of new variants on vaccine efficacy?



- Immune response to vaccines and protection from severe disease is not neutralizing antibody alone
- Early studies showing that the 484 variant escapes antibody, especially in those with lower levels of antibody
- mRNA vaccines can be redesigned very quickly to account for variants - example: Moderna has started clinical trials with variant vaccines; how do new variant vaccines impact vx access to children?

* Greaney AJ, et al: bioRxiv preprint

<https://doi.org/10.1101/2020.12.31.425021>;



Conclusions

- Children bear a large burden of the impact of COVID-19 due to both disease and society's response to disease prevention
- Children need COVID-19 vaccine to prevent infection, disease, and spreading of virus
- The Pfizer-BioNTech mRNA vaccine is safe and effective in children, with similar safety and improved immunogenicity compared to 16-24 year olds
- Testing of other COVID-19 vaccines in progress or likely to start soon in children < 18 years of age down to 6 mos.



Q&A and Discussion

Links and Resources

- Slides 6 -17: FDA - www.fda.gov
- Slide 23: MMWR ACIP Interim recommendations www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w
- Slides 25-31: Clinical Care Considerations - www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
- Slide 32: Clinical immunization safety assessment www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
- Slide 34: VAERS - <http://vaers.hhs.gov>
- Slide 35: V-Safe - www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
- Slide 38: FDA conditions for Pfizer BioNTech COVID-19 Vaccine - www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-allows-more-flexible-storage-transportation-conditions-pfizer
- Slide 40: Pre-vaccination Checklist - www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf
Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit: www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html
- Slide 41: Preparing for potential anaphylaxis after vac. - www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html
- Slide 42: CDC Resources COVID-19 Vaccination: www.cdc.gov/vaccines/covid-19/index.html
- Slide 42: For Healthcare Professionals: www.cdc.gov/vaccines/covid-19/hcp/index.html
- Slide 43: Toolkit for Medical Centers, Clinics, and Clinicians: www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- Slide 43: Pediatric Healthcare Prof. COVID-19 Vaccination Toolkit: www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html
- Slide 44 Engaging in Effective COVID-19 Vaccine Conversations - www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.html
- Slide 51: Pandemic disrupts young children's healthcare visits <https://medium.com/rapid-ec-project/health-still-interrupted-pandemic-continues-to-disrupt-young-childrens-healthcare-visits-e252126b76b8>
- Slide 54: Becoming a COVID-19 Vaccinator Webinar https://zoom.us/webinar/register/WN_8kYhuqX5Q8mZ5sbuzIR-5w
- Slide 54: AAP website content on practice implementation <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/covid-19-vaccine-for-children/>

Links and Resources (continued)

- Slide 55: AAP Immunization Campaign <https://services.aap.org/en/news-room/campaigns-and-toolkits/immunizations/>
- Slide 55: AAP Immunization Webpage - www.aap.org/immunization
- Slide 57: Getting your child ready for the COVID-19 Vaccine - <https://healthychildren.org/English/health-issues/conditions/COVID-19/Pages/Getting-Your-Child-Ready-for-the-COVID-19-Vaccine.aspx>
- Slide 57: When can children get the COVID-19 vaccine? <https://healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/when-can-children-get-the-COVID-19-vaccine.aspx>
- Slide 57: My children want to have birthday parties with their friends but can't get COVID-19 vaccines yet. Is it safe? <https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/Birthday-Parties-and-COVID-19.aspx>
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- Slide 57: What Families Need to Know <https://www.healthychildren.org/English/health-issues/conditions/COVID-19/Pages/2019-Novel-Coronavirus.aspx>
- Slide 58: AAP Critical Updates on COVID-19 <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/>
- Slide 58: #CallYourPediatrician Toolkit <https://services.aap.org/en/news-room/campaigns-and-toolkits/call-your-pediatrician/>
- Slide 58: Immunization Campaign Toolkit <https://services.aap.org/en/news-room/campaigns-and-toolkits/immunizations/>
- Slide 58: Improve Immunization Rates <https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunizations/Practice-Management/Pages/Strategies-to-Improve-Immunization-Rates.aspx>
- Slide 64: Novavax vaccine - <https://www.fiercebiotech.com/biotech/novavax-delays-covid-19-vaccine-regulatory-submissions-again>

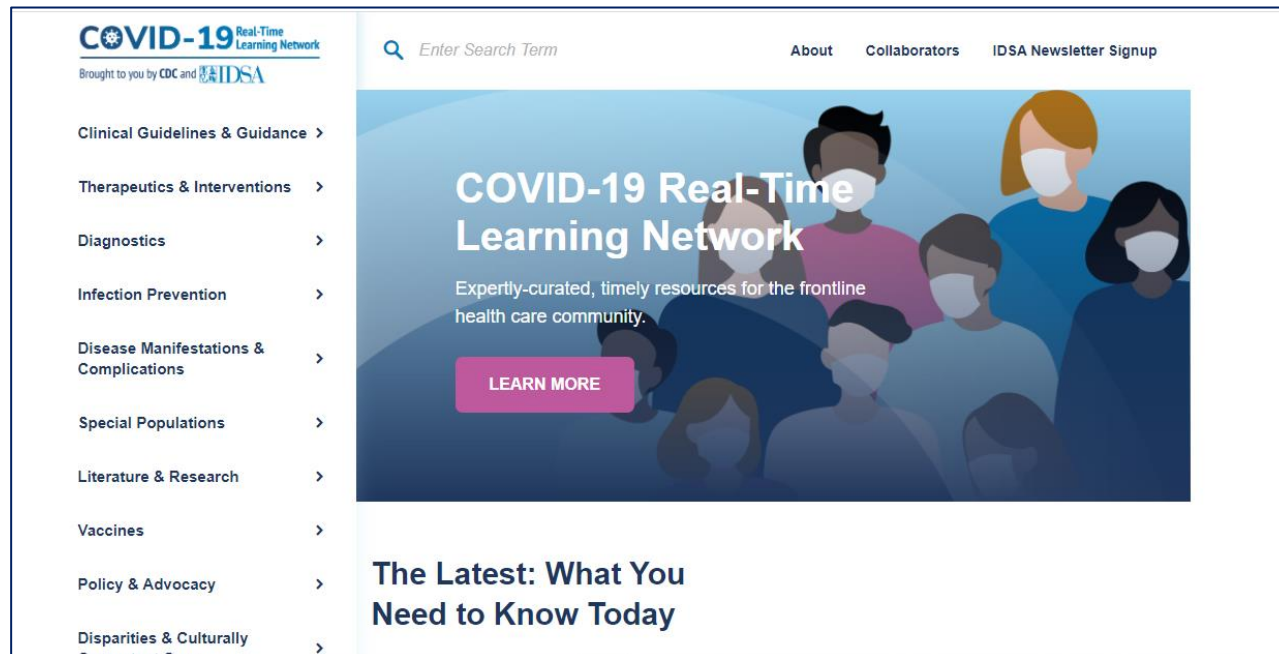
COVID-19 Real-Time Learning Network

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?

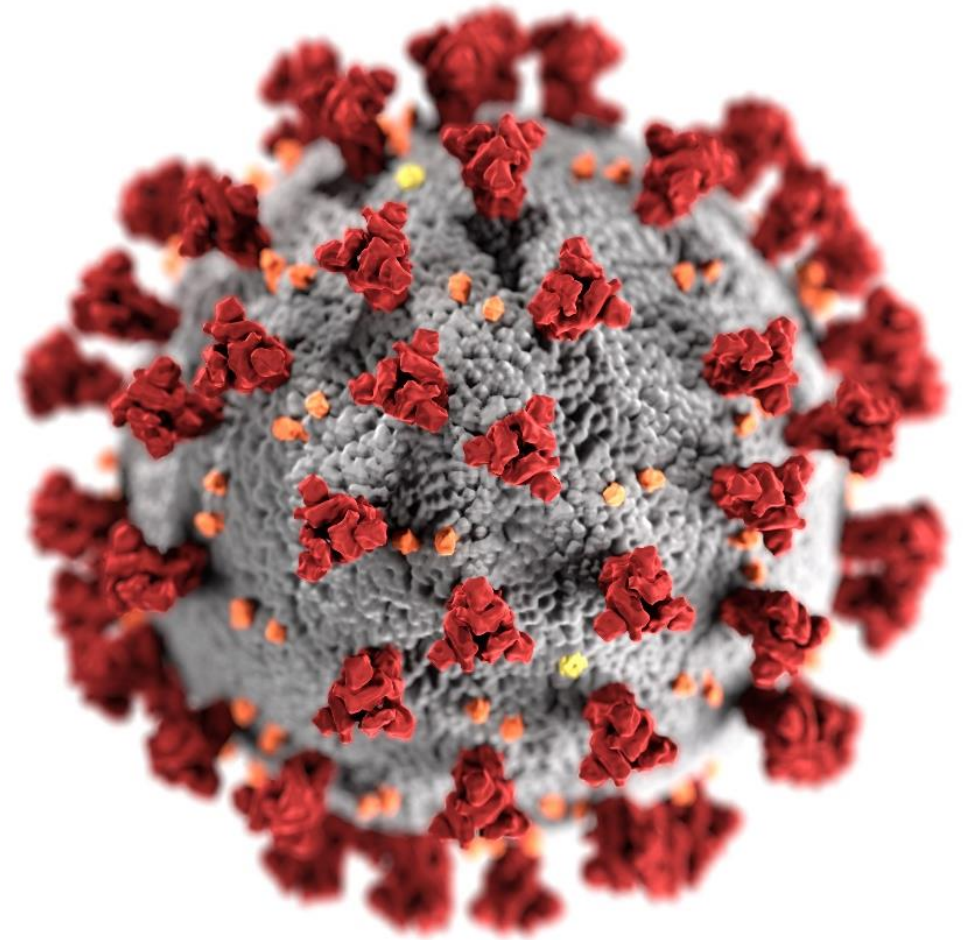
- Clinicians who have questions about the clinical management of COVID-19

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: **Sat., May 22**

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

Contact Us:

Dana Wollins (dwollins@idsociety.org)

Deirdre Lewis (dlewis@idsociety.org)