



Register Today

COVID CONVERSATION

Wednesday, May 26 at 6pm PT

American
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Program #6
Covid-19 Vaccine & Children



JASJIT SINGH, MD
Children's Hospital of
Orange County



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San Diego



Welcome to COVID Conversations

- All lines will be muted during the program
- Please use the Question-and-Answer box to communicate with the moderators
- Panelists will speak for approximately 15 minutes each, followed by moderated Q & A
- Webinar is being recorded and will be posted to the California Immunization Coalition website (<https://www.immunizeca.org/>) and the CIC YouTube page

<https://www.youtube.com/channel/UCklkZ1SZQNQLcpmNpeQpDAg>



Zoom Platform

- All participants will be in “listen only” mode. You should be able to hear through your computer audio – please make sure your speakers are not on mute.
- Dial in information was also sent with your confirmation email if you need to listen by phone.
- Technical difficulties during the webinar?
 - For assistance, please visit this link: <https://support.zoom.us/hc/en-us/articles/204484835-My-audio-is-not-working-on-iOS-or-Android>



Questions for Presenter?

- To ask a question or leave a comment use the question window
- Questions will be answered after the presentations
- Additional questions may be sent to info@immunizeca.org for email response after the webinar.





The California Immunization Coalition (CIC) is a statewide non profit dedicated to ensuring that all Californian's have access to lifesaving vaccines

American Academy of Pediatrics

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The AAP-CA is a partnership of the four local California AAP Chapters

AAP-CA is committed to the attainment of optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults living in California.



Today's Hosts and Moderators



Dr. Pia Pannaraj

- Associate Professor of Pediatrics, Molecular Microbiology and Immunology, Keck School of Medicine, University Southern California
- Director, Pediatric Immunization Advancement Laboratory, Division of Infectious Diseases, Children's Hospital Los Angeles
- Co-Chair, Emerging Issues Committee, California Immunization Coalition



Dr. Eric Ball

- Primary Care Pediatrician, CHOC Primary Care Network
- Board of Directors, American Academy of Pediatrics, California
- Co-Chair, Emerging Issues Committee, California Immunization Coalition



Today's Panelist

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Jasjit Singh, MD



Pediatric Infectious Diseases subspecialist Jasjit Singh, MD is Assistant Director of the division and serves as the Medical Epidemiologist for Children's Hospital of Orange County (CHOC) in California.

Dr. Singh received her undergraduate degree at Harvard University, and her medical degree from the Duke University School of Medicine. She completed her pediatrics residency at Cornell University Medical Center in NY, where she also served as Chief Resident, before completing her subspecialty fellowship training in Pediatric Infectious Diseases at Johns Hopkins Medical Center in Baltimore.

Dr. Singh's main interests are in the prevention of infection and vaccines, international health, and primary immunodeficiency conditions in children. She is active in clinical research, has presented her work at scientific meetings and has multiple publications. She has a passion for teaching medical students and residents, and gives frequent lectures at CHOC and in the community on a variety of infectious disease topics.

This past year's pandemic has brought new challenges for all of us in the field of infectious diseases. As we have sought to rise to the myriad demands on our clinical and administrative time, we have also aspired to be role models to our students, residents and junior faculty.

She and her husband enjoy doing medical missions abroad, and hope to do more in the years ahead.

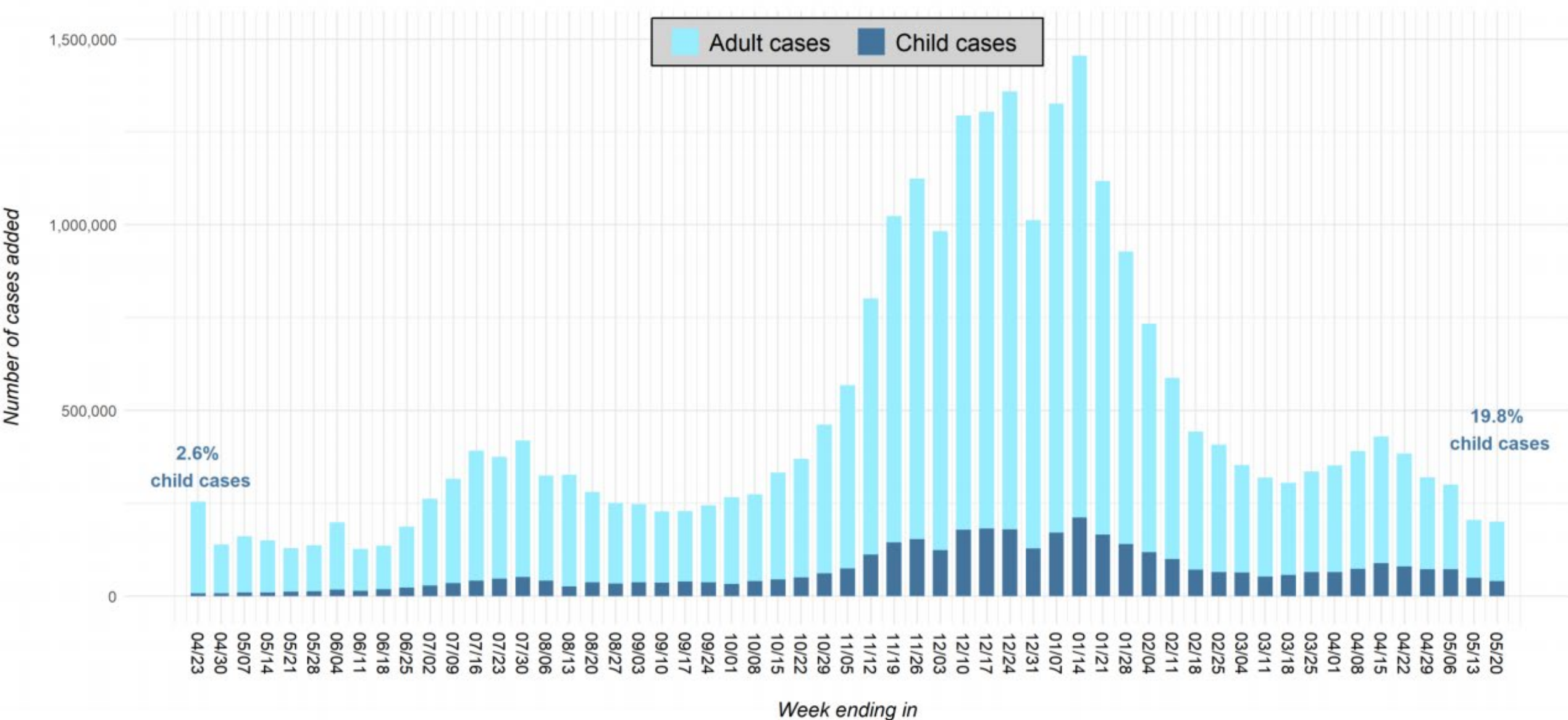
COVID and MIS-C in Children

Dr. Jasjit Singh

Objectives

- Review the epidemiology of Pediatric COVID-19
- Review the epidemiology of MIS-C
- Evaluate measures for why pediatric vaccination against SARS-CoV-2 is important
- Discuss successful operational strategies for schools

Fig 7. United States: Number of COVID-19 Cases Added in Past Week for Children and Adults*



* Note: 4 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; TX reported age for only a small proportion of total cases each week (eg, 3-20%)

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

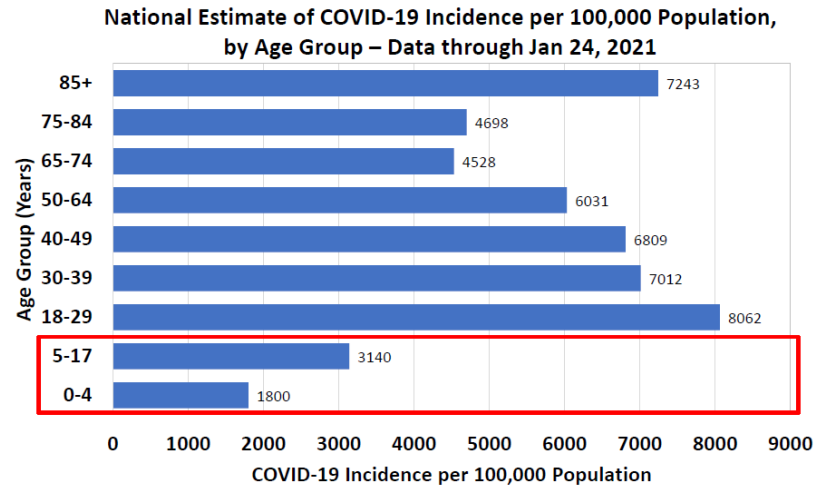


American Academy of Pediatrics
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Age Group Reported Incidence

COVID-19 Reported Incidence by Age Group: Lowest in Children <18 Years



Updated as of 1/24/21. Data are based on COVID-19 case-level data reported by state and territorial jurisdictions to CDC. The numbers are confirmed and probable COVID-19 cases as reported by U.S. states, territories, New York City, and the District of Columbia from the previous day.

<https://www.cdc.gov/covid-data-tracker/index.html#demographics>

- Approximately 300 deaths
 - Children represented around 0.06% of all COVID-19 deaths
 - About 0.01% of all child COVID-19 cases resulted in death

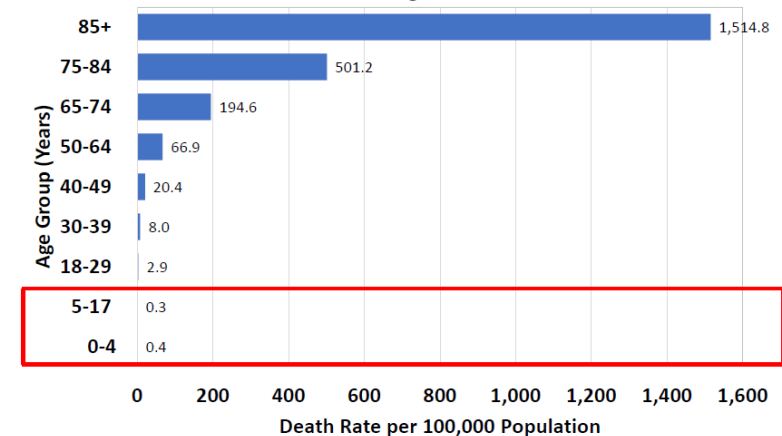


Source: AAP and CHA as of May 20, 2021

- 3,943,407 total child COVID-19 cases reported
- Overall rate: 5,239 cases per 100,000 children in the population
- Approximately 15,000 Hospitalizations
 - Children represented around 2% of total reported hospitalizations
 - About 0.8% of all child COVID-19 cases resulted in hospitalization

COVID-19 Mortality Rates Are Lowest Among Children <18 Years

National Estimate of COVID-19 Deaths per 100,000 Population, by Age Group – Data through Jan 24, 2021



Updated as of 1/24/21. Data are based on COVID-19 case-level data reported by state and territorial jurisdictions to CDC. The numbers are confirmed and probable COVID-19 cases as reported by U.S. states, territories, New York City, and the District of Columbia from the previous day.

<https://www.cdc.gov/covid-data-tracker/index.html#demographics>

Positive COVID-19 Patients by Location Tested

as of May 24, 2021

CHOC Orange

Age	Clinic	ED	OECs	Inpatient – ICU	Inpatient – NON ICU	Total
< 12 months	92	253	81	9	73	508
1 – 5 years	276	384	312	9	78	1,059
6 – 10 years	345	229	306	16	63	959
11 – 15 years	454	289	275	28	103	1,149
16 – 17 years	186	120	109	17	46	478
18 – 19 years	109	57	54	7	23	250
20 – 25 years	35	54	11	9	23	132
26 – 29 years	1	24	0	3	5	33
≥ 30 years	0	100	0	0	0	100
TOTAL	1,498	1,510	1,148	98	414	4,668

CHOC Children's Mission Hospital* = 17 Inpatients

*CHOC network ambulatory/ED patients captured in CHOC Orange data. CCMH ED are not captured.

CHOC tested a total of
32,959 patients.

Positivity Rate: 14.2%

as of May 24, 2021

Orange County Health Care Agency

as of May 19, 2021

Age	Total Cases Reported
0 – 17 years	26,738
18 – 24 years	35,334
TOTAL	62,072

CHOC Children's MIS-C Patients = 76



COVID-19 Treatment Options in Children

Source: Otto, W. and Chawla, R. FDA program spurs development of therapeutics for COVID-19 in children, adults, (April 2021), AAP News



Select therapeutics used to treat COVID-19 in children			
Product/drug	Company	Status	Patient population
Remdesivir	Gilead Sciences Inc.	FDA-approved	<ul style="list-style-type: none">Hospitalized children ages ≥ 12 years and weighing ≥ 40 kilograms (kg) requiring supplemental oxygen, invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO)
		EUA	<ul style="list-style-type: none">Hospitalized children < 12 years weighing 3.5-40 kg requiring respiratory support as above
Dexamethasone	N/A	Off-label use	<ul style="list-style-type: none">Hospitalized children (no age requirement) requiring supplemental oxygen, invasive mechanical ventilation or ECMO
Baracitinib	Eli Lilly and Company	EUA	<ul style="list-style-type: none">Hospitalized children ≥ 2 years requiring supplemental oxygen, invasive mechanical ventilation or ECMOGiven with remdesivir
Convalescent plasma	N/A	EUA	<ul style="list-style-type: none">Not the standard of care. Should be used only in clinical trials.
Bamlanivimab/etesevimab	Eli Lilly and Company	EUA	<ul style="list-style-type: none">Outpatients ≥ 12 years and weighing ≥ 40 kg with positive SARS-CoV-2 test results who are at high risk of progressing to severe COVID-19 and/or hospitalization*
Casirivimab/imdevimab	Regeneron Pharmaceuticals Inc.	EUA	
*Including body mass index ≥ 85 th percentile for age and gender, sickle cell disease, congenital or acquired heart disease, neurodevelopmental disorders, medical-related technological dependence or chronic respiratory disease that requires daily medication for control			

} Safety and Antibody Kinetics of COVID-19 Convalescent Plasma for the Treatment of Moderate to Severe Cases of SARS-CoV-2 Infection in Pediatric Patients, PIDJ May 2021

*Tocilizumab

Multisystem Inflammatory Syndrome in Children (MIS-C)

CDC MIS-C Definition

Case Definition for Multisystem Inflammatory Syndrome in Children (MIS-C)

- An individual aged <21 years presenting with feverⁱ, laboratory evidence of inflammationⁱⁱ, and evidence of clinically severe illness requiring hospitalization, with multisystem (≥ 2) organ involvement (cardiac, renal, respiratory, hematologic, gastrointestinal, dermatologic or neurological); AND
- No alternative plausible diagnoses; AND
- Positive for current or recent SARS-CoV-2 infection by RT-PCR, serology, or antigen test; or COVID-19 exposure within the 4 weeks prior to the onset of symptoms

ⁱFever $>38.0^{\circ}\text{C}$ for ≥ 24 hours, or report of subjective fever lasting ≥ 24 hours

ⁱⁱIncluding, but not limited to, one or more of the following: an elevated C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), fibrinogen, procalcitonin, d-dimer, ferritin, lactic acid dehydrogenase (LDH), or interleukin 6 (IL-6), elevated neutrophils, reduced lymphocytes and low albumin

Additional comments

- Some individuals may fulfill full or partial criteria for Kawasaki disease but should be reported if they meet the case definition for MIS-C
- Consider MIS-C in any pediatric death with evidence of SARS-CoV-2 infection

CDC MIS-C Data

Data through May 3, 2021

TOTAL MIS-C PATIENTS MEETING CASE
DEFINITION*

3742

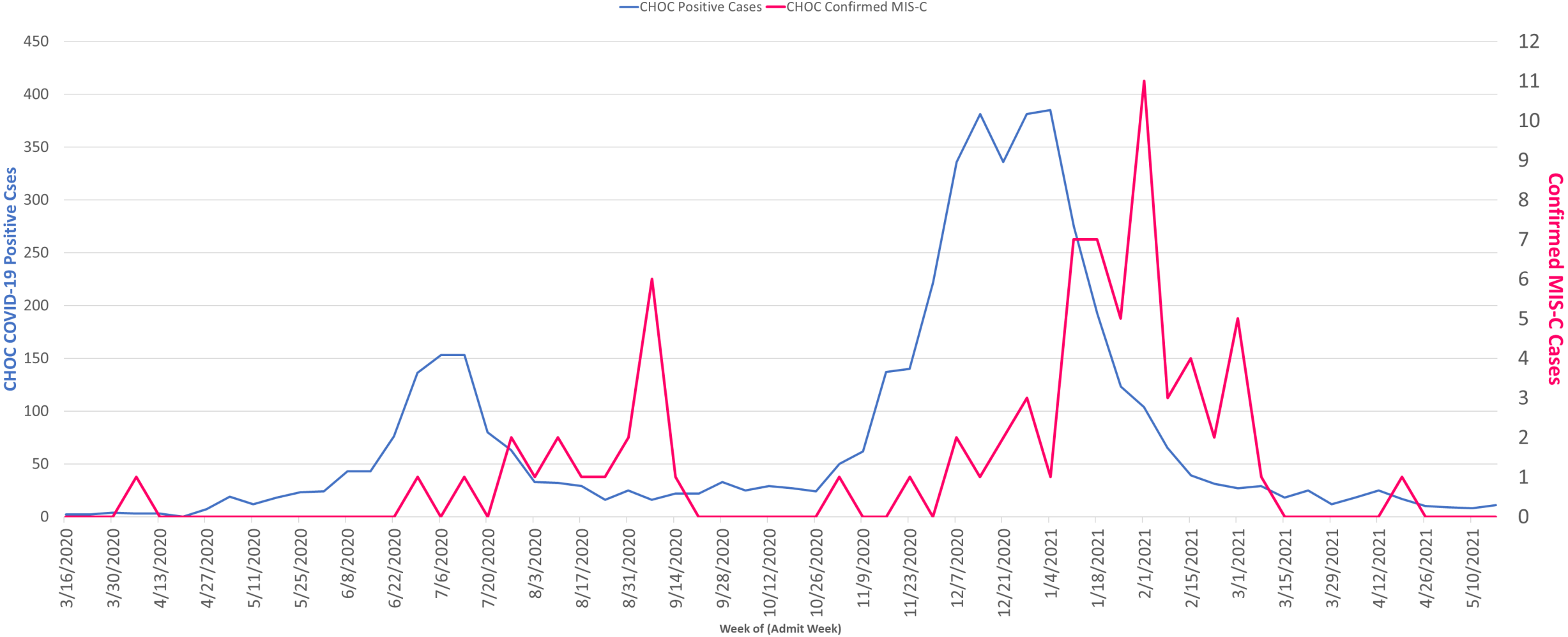
TOTAL MIS-C DEATHS MEETING CASE
DEFINITION

35

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

CHOC Orange COVID-19 Positive Cases and Confirmed MIS-C Cases

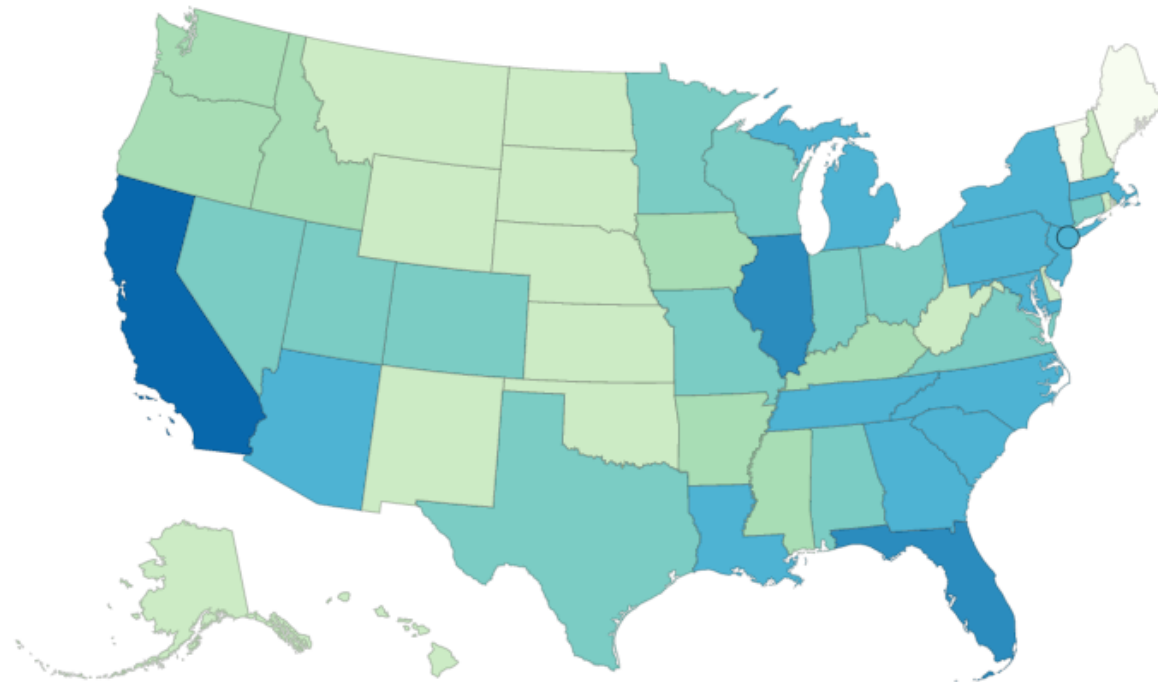
March 16, 2020 - May 24, 2021



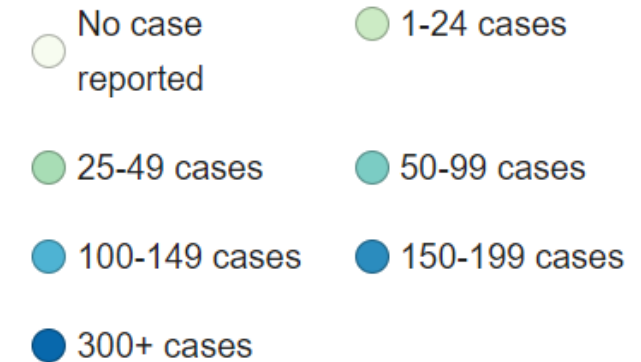
CDC MIS-C Data

Data through May 3, 2021

Reported MIS-C Case Ranges by Jurisdiction, on or before May 3, 2021*



Reported MIS-C Cases



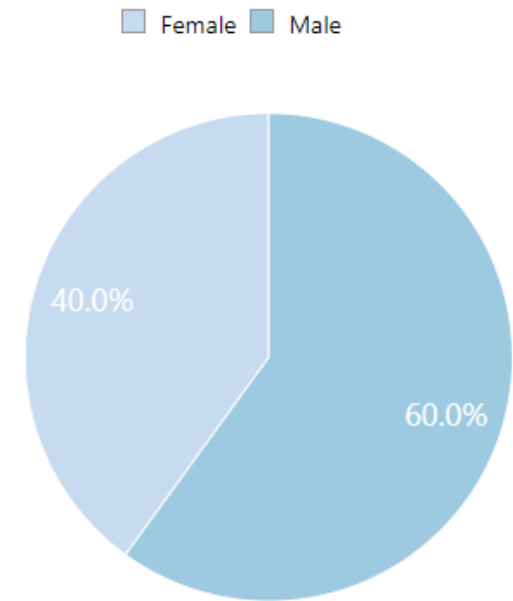
Territories **AS** **GU** **MH** **FM** **PW** **PR** **VI**



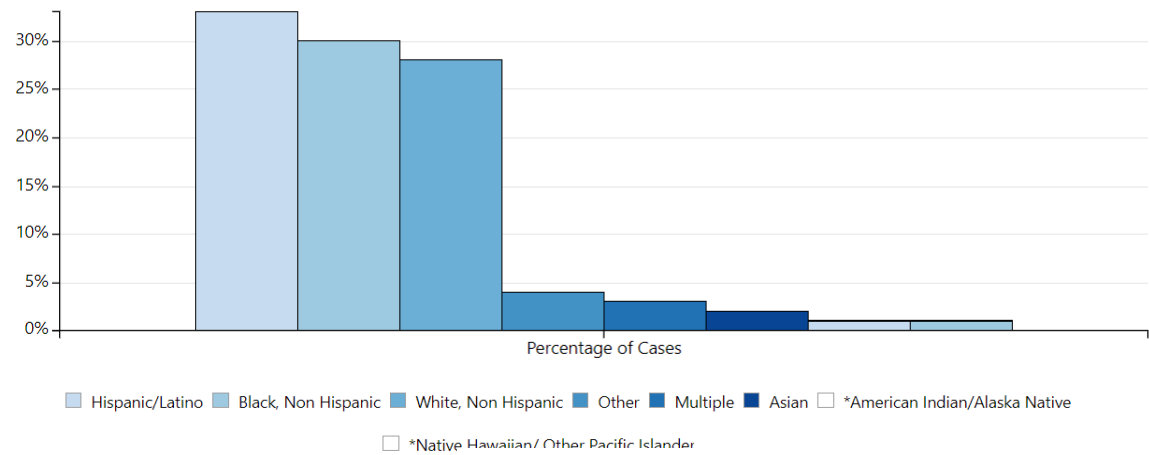
CDC MIS-C Data

Data through May 3, 2021

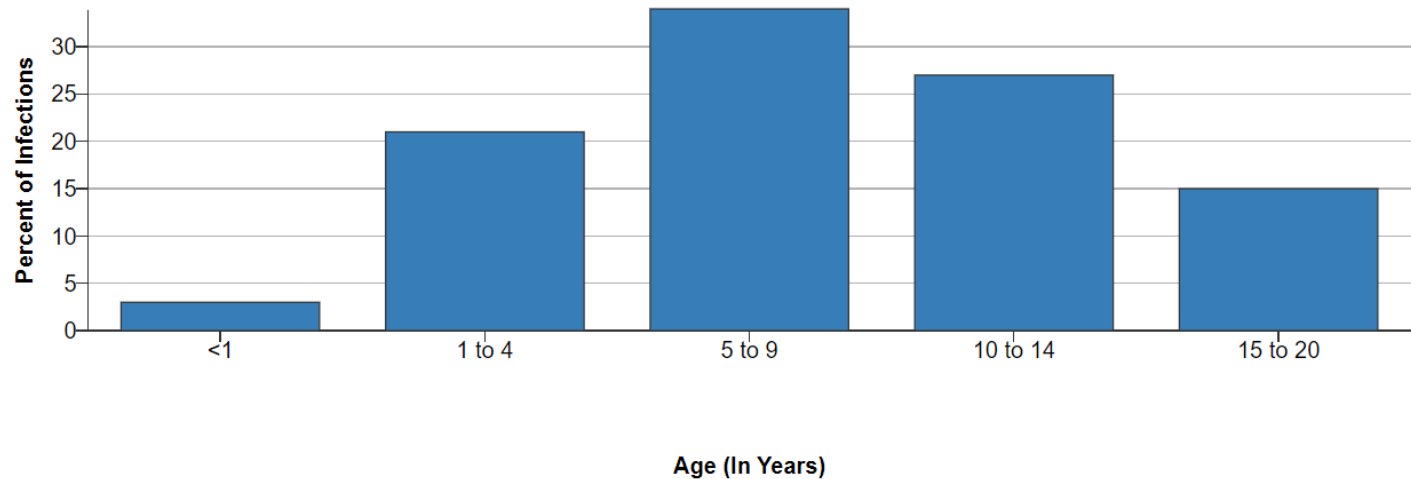
MIS-C Patients by Sex



MIS-C Patients by Race & Ethnicity



MIS-C Patients by Age Group



MIS-C Treatment Options in Children

“Among children with MIS-C, treatment with IVIG and methylprednisolone vs IVIG alone was associated with a more favorable fever course.”

Table 2. Primary and Secondary Analyses in the Propensity Score-Matched Cohorts

Outcomes	After propensity score matching		Absolute risk difference between groups (95% CI) [reference: IVIG alone]	Odds ratio (95% CI) [reference: IVIG alone]	P value
	No. (%)				
	IVIG and methylprednisolone (n = 32)	IVIG alone (n = 64)			
Primary outcome					
Treatment failure ^a	3 (9)	24 (38)	−0.28 (−0.48 to −0.08)	0.25 (0.09 to 0.70)	.008
Secondary outcomes					
Second-line treatment ^b	3 (9)	20 (31)	−0.22 (−0.40 to −0.04)	0.19 (0.06 to 0.61)	.004
Hemodynamic support ^{c,d}	2 (6)	15 (23)	−0.17 (−0.34 to −0.004)	0.21 (0.06 to 0.76)	.01
LVEF <55% ^c	2/12 (17)	14/40 (35)	−0.18 (−0.35 to −0.01)	0.20 (0.06 to 0.66)	.007
Duration of PICU stay, median (IQR), d	4 (2 to 5)	6 (4 to 8.5)	Reduction of days: −2.4 (−4.0 to −0.7)		.005

Source: Ouldali, N., et al. Association of Intravenous Immunoglobulins Plus Methylprednisolone vs Immunoglobulins Alone With Course of Fever in Multisystem Inflammatory Syndrome in Children, (2021) JAMA

Why do we need to vaccinate kids?

- COVID-19 has not been completely benign in pediatric patients:
 - Acute disease
 - MIS-C
 - Long-term complications and PASC
- They can still spread disease to others in the community.
- Needed for herd immunity
- Needed to avoid pockets in which the virus can continue to replicate, mutate and create variants
- Help open up the economy by allowing parents to return to work
- Go back to school!

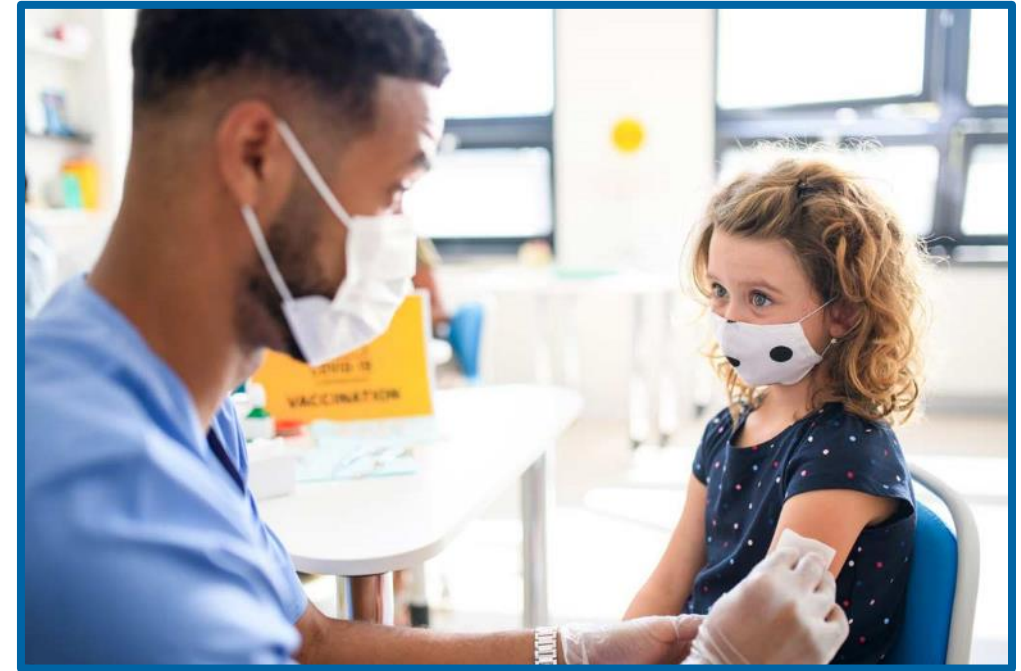


Image Source: CHLA

Returning to School



CDC's School Guidance for COVID-19

- Emphasizes 5 key prevention strategies:
 - consistent and correct use of masks,
 - physical distancing,
 - handwashing and respiratory etiquette,
 - cleaning and ventilation,
 - contact tracing in combination with isolation and quarantine.
- The guidance recommends layering two or more prevention strategies, with particular emphasis on universal use of masks and physical distancing.

Schools and SARS-CoV-2 Transmission

- Based on the data available, in-person learning in schools has not been associated with substantial community transmission.
- Evidence suggests that staff-to-staff transmission is more common than transmission from students to staff, staff to student, or student to student (UK, Australia), esp in younger children.
- When a combination of effective prevention strategies is implemented and strictly adhered to in the K-12 in-person learning environment, the risk of transmission in the school setting appears to be lower than or equivalent to the transmission risk in other community settings (Italy, Switzerland, Germany, NC, Chicago)

Physical Distancing

- Several studies from international settings (Norway, Switzerland, Australia, Italy, UK, Germany) have reported low levels of transmission with 1 meter between students in schools.
- The preponderance of the available evidence from U.S. schools (NC, Chicago, WI) indicates that even when students were placed less than 6 feet apart in classrooms, there was limited SARS-CoV-2 transmission when other layered prevention strategies were consistently maintained
- Greater physical distancing (at least 6 feet) should be prioritized whenever masks cannot be used (for example, while eating).
- Recommended physical distance between adults in schools is still 6 feet.
- Consistent with recommendations from WHO and the American Academy of Pediatrics, using a distance of at least 3 feet between students in classrooms could provide a feasible definition of physical distancing so long as other prevention measures are maximized.

CDC Operational Strategy for K-12 Schools through Phased Prevention

Updated May 15, 2021

- Evidence suggests that many K-12 schools that have strictly implemented prevention strategies have been able to safely open for in-person instruction and remain open.
- All schools should implement and layer prevention strategies and should prioritize universal and correct use of masks and physical distancing.
- Testing to identify individuals with SARS-CoV-2 infection and **vaccination for teachers and staff provide additional layers of COVID-19 protection in schools.**

Prevention Strategies by Level of Community Transmission			
Low Transmission ¹ Blue	Moderate Transmission Yellow	Substantial Transmission Orange	High Transmission Red
Elementary Schools Physical distancing: at least 3 feet between students in classrooms		Elementary Schools Physical distancing: at least 3 feet of distance between students in classrooms Cohorting ² recommended when possible	
Middle and High Schools Physical distancing: at least 3 feet between students in classrooms		Middle and High Schools Physical distancing: at least 3 feet of distance between students in classrooms Cohorting recommended when possible	Middle and High Schools Schools that can use cohorting: at least 3 feet of distance Schools that cannot use cohorting: at least 6 feet distance between students in classrooms ²
Sports and extracurricular activities Sports and extracurricular activities occur with at least 6 feet of physical distance to the greatest extent possible ⁶	Sports and extracurricular activities Sports and extracurricular activities occur with at least 6 feet of physical distance required ⁶	Sports and extracurricular activities Sports and extracurricular activities occur only if they can be held outdoors, with more than 6 feet of physical distancing ⁶	

Restarting Youth Sports as of February 23, 2021

THE ORANGE COUNTY REGISTER

SPORTS • HIGH SCHOOL SPORTS • News

High school football can begin in Orange County after clearing COVID-19 threshold

Players, coaches ecstatic after getting the green light to begin their season



Football players at Foothill High School in Tustin go through drills in their first real practice on Tuesday afternoon, February 23, 2021. They are among the Orange County football teams practicing now that the COVID-19 rates dropped to a level that such activity is allowed. (Photo by Mark Rightmire, Orange County Register/SCNG)

By STEVE FRYER | sfryer@scng.com | Orange County Register

PUBLISHED: February 23, 2021 at 12:27 p.m. | UPDATED: February 24, 2021 at 9:51 a.m.

Table: Youth and Adult Recreational Sports* Permitted by Current Tier of County

Widespread Tier 1†	Substantial Tier 2†	Moderate Tier 3†	Minimal Tier 4†
Outdoor low-contact sports <ul style="list-style-type: none"> • Archery • Badminton • Biking • Bocce • Corn hole • Cross country • Dance (no contact) • Disc golf • Golf • Ice and roller skating (no contact) • Lawn bowling • Martial arts (no contact) • Physical training programs (e.g., yoga, Zumba, Tai chi) • Pickleball (singles) • Rowing/crew (with 1 person) • Running • Shuffleboard • Skeet shooting • Skiing and snowboarding • Snowshoeing • Swimming and diving • Tennis • Track and field • Walking and hiking 	Outdoor moderate-contact sports <ul style="list-style-type: none"> • Baseball • Cheerleading • Dodgeball • Field hockey • Gymnastics • Kickball • Lacrosse (girls/women) • Pickleball (doubles) • Softball 	Outdoor high-contact sports <ul style="list-style-type: none"> • Basketball • Football • Ice hockey • Lacrosse (boys/men) • Rugby • Rowing/crew (with 2 or more people) • Soccer • Volleyball • Water polo Indoor low-contact sports <ul style="list-style-type: none"> • Badminton • Curling • Dance (no contact) • Gymnastics • Ice skating (individual) • Physical training • Pickleball (singles) • Swimming and diving • Tennis • Track and field • Volleyball 	Indoor moderate-contact sports <ul style="list-style-type: none"> • Cheerleading • Dance (intermittent contact) • Dodgeball • Kickball • Pickleball (doubles) • Racquetball • Squash Indoor high-contact sports <ul style="list-style-type: none"> • Basketball • Boxing • Ice hockey • Ice skating (pairs) • Martial arts • Roller derby • Soccer • Water polo • Wrestling

*This Table is not exhaustive, but provides examples of sports with different levels of contact so that the level of risk and appropriate Tier can be assessed for other sports.

†All sports permitted in lower tiers are also permitted in higher tiers.



Morbidity and Mortality Weekly Report (*MMWR*)

Mask Use and Ventilation Improvements to Reduce COVID-19 Incidence in Elementary Schools — Georgia, November 16–December 11, 2020

Early Release / May 21, 2021 / 70

Jenna Gettings, DVM^{1,2,3}; Michaila Czarnik, MPH^{1,4}; Elana Morris, MPH¹; Elizabeth Haller, MEd¹; Angela M. Thompson-Paul, PhD¹; Catherine Rasberry, PhD¹; Tatiana M. Lanzieri, MD¹; Jennifer Smith-Grant, MSPH¹; Tiffany Michelle Aholou, PhD¹; Ebony Thomas, MPH²; Cherie Drenzek, DVM²; Duncan MacKellar, DrPH¹ ([View author affiliations](#))

Summary

What is already known about this topic?

Kindergarten through grade 5 schools educate and address the students' physical, social, and emotional needs. Preventing SARS-CoV-2 transmission in schools is imperative for safe in-person learning.

What is added by this report?

COVID-19 incidence was 37% lower in schools that required teachers and staff members to use masks and 39% lower in schools that improved ventilation. Ventilation strategies associated with lower school incidence included dilution methods alone (35% lower incidence) or in combination with filtration methods (48% lower incidence).

What are the implications for public health practice?

Mask requirements for teachers and staff members and improved ventilation are important strategies in addition to vaccination of teachers and staff members that elementary schools could implement as part of a multicomponent approach to provide safer, in-person learning environments.

Morbidity and Mortality Weekly Report (MMWR)

COVID-19 Testing to Sustain In-Person Instruction and Extracurricular Activities in High Schools — Utah, November 2020–March 2021

Early Release / May 21, 2021 / 70

William A. Lanier, DVM¹; Kendra D. Babitz, MPP¹; Abigail Collingwood, MPH¹; Maggie F. Graul, MPH¹; Sydnee Dickson, EdD²; Lexi Cunningham, EdD³; Angela C. Dunn, MD¹; Duncan MacKellar, DrPH⁴; Adam L. Hersh, MD, PhD⁵ ([View author affiliations](#))

Summary

What is already known about this topic?

COVID-19–associated cessation of kindergarten through grade 12 in-person instruction and extracurricular activities can have negative social, emotional, and educational consequences for children.

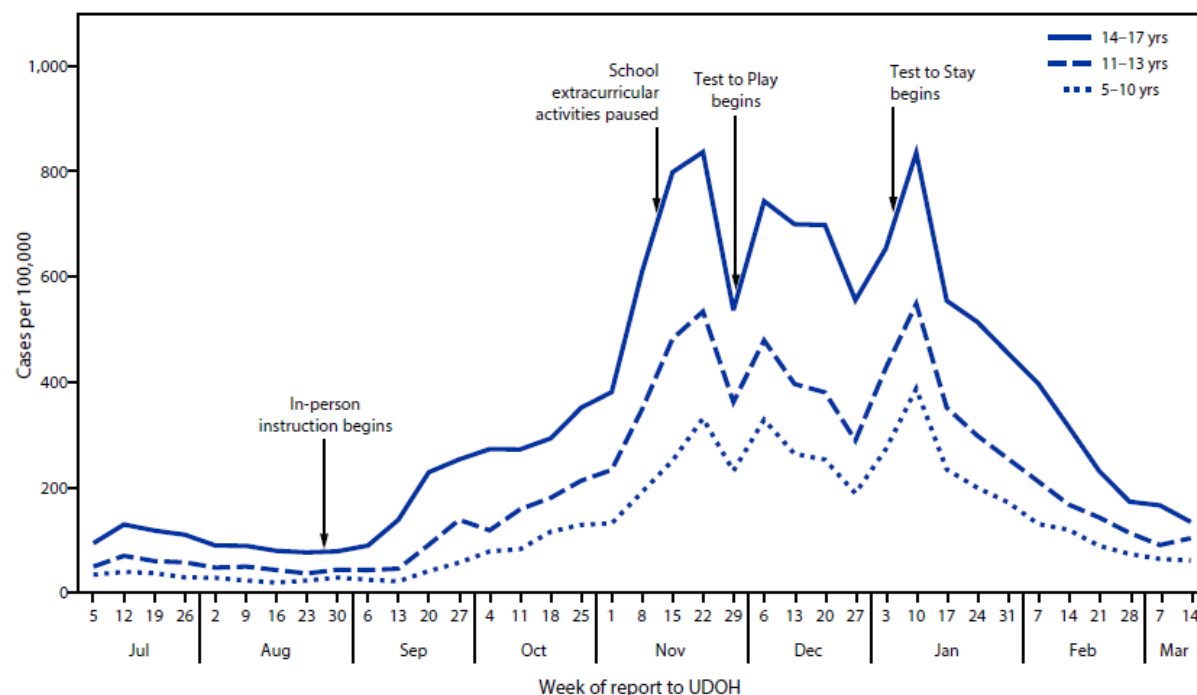
What is added by this report?

Utah implemented two high school COVID-19 testing programs to sustain in-person instruction and extracurricular activities. During November 30, 2020–March 20, 2021, among 59,552 students who received testing, 1,886 (3.2%) had a positive result. These programs facilitated the completion of approximately 95% of high school extracurricular competition events and saved an estimated 109,752 in-person instruction student-days.

What are the implications for public health practice?

School-based COVID-19 testing should be considered part of a comprehensive prevention strategy to identify SARS-CoV-2 infections in schools and sustain in-person instruction and extracurricular activities.

FIGURE 1. COVID-19 incidence* among children aged 5–10 years (N = 311,812), 11–13 years (N = 161,991), and 14–17 years (N = 209,578), by week — Utah, July 5, 2020–March 14, 2021†,§,¶,**



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

Early Release / May 14, 2021 / 70

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 ([View author affiliations](#))

[View suggested citation](#)

Summary

What is already known about this topic?

On May 10, 2021, the Food and Drug Administration expanded Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12–15 years.

What is added by this report?

On May 12, 2021, after a systematic review of all available data, the Advisory Committee on Immunization Practices made an interim recommendation for use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12–15 years for the prevention of COVID-19.

What are the implications for public health practice?

The Pfizer-BioNTech COVID-19 vaccine is the first COVID-19 vaccine approved for use in adolescents and has high efficacy against symptomatic COVID-19. Vaccination will be important to protect adolescents against symptomatic COVID-19 disease and to reduce community transmission of SARS-CoV-2.

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Today's Panelist

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Mark Sawyer, MD

Dr. Sawyer is a Professor of Clinical Pediatrics and a Pediatric Infectious Disease specialist at the UCSD School of Medicine and Rady Children's Hospital San Diego.

He is the medical director of the UCSD San Diego Immunization Partnership, a contract with the San Diego County Agency for Health and Human Services to improve immunization delivery in San Diego.

He is a past member of the American Academy of Pediatrics Committee on Infectious Diseases, the FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) and the CDC Advisory Committee on Immunization Practices (ACIP).

Recently he was recalled to VRBPAC to work on the EUA applications for Sars-CoV-2 vaccines.

COVID Vaccines in Children

MARK H. SAWYER, MD
UCSD SCHOOL OF MEDICINE AND RADY CHILDREN'S HOSPITAL SAN
DIEGO

Pediatric COVID Vaccine-The Questions



Do children need COVID vaccines?

Do COVID vaccines work in adolescents and younger children?

Are COVID vaccines safe in adolescents? What about younger children?

Where are children going to get COVID vaccines?

Do COVID vaccines cause MIS-C?

What about all the other pediatric vaccines that we are behind on?



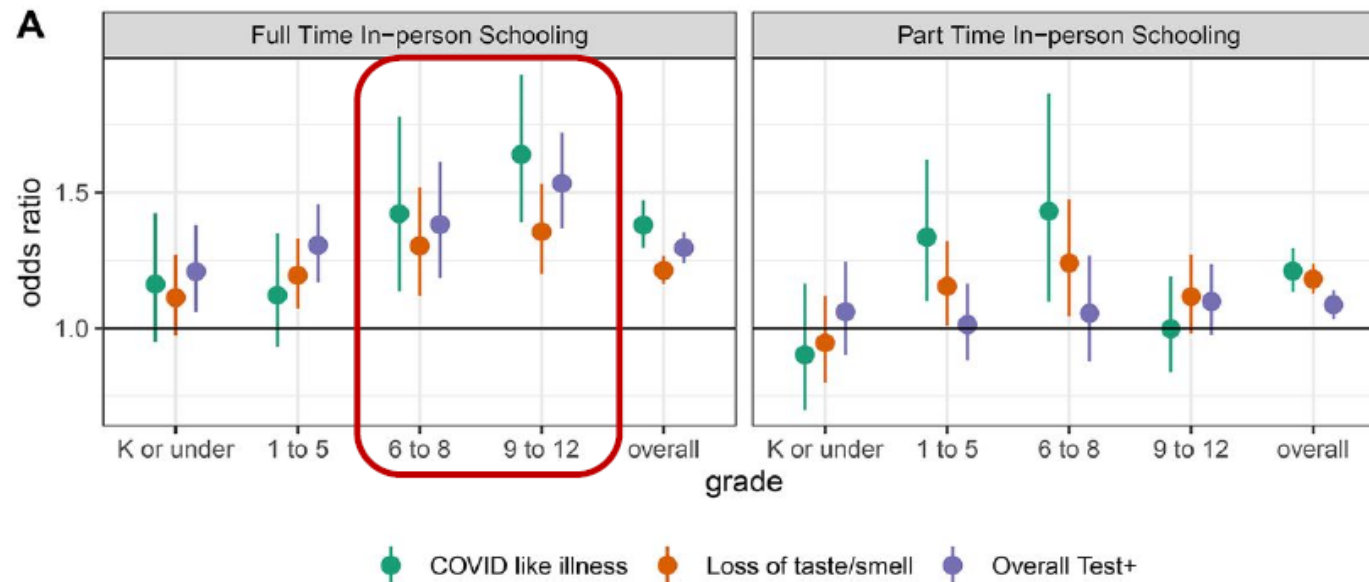
Do children
need COVID
Vaccines?

Serious COVID in Children

Age (years)	0-4	5-10	11-13	14-17
Hospitalization	4294	1983	1598	4007
ICU Admission	288	168	131	279
Death	52	30	27	69

Adolescents and Transmission of SARS-CoV-2

Adults living in a household with a child engaged in **full-time in-person school** had an **increase** in odds of reporting COVID-19 like illness, loss of taste/smell, or positive SARS-CoV-2 test within previous 14 days



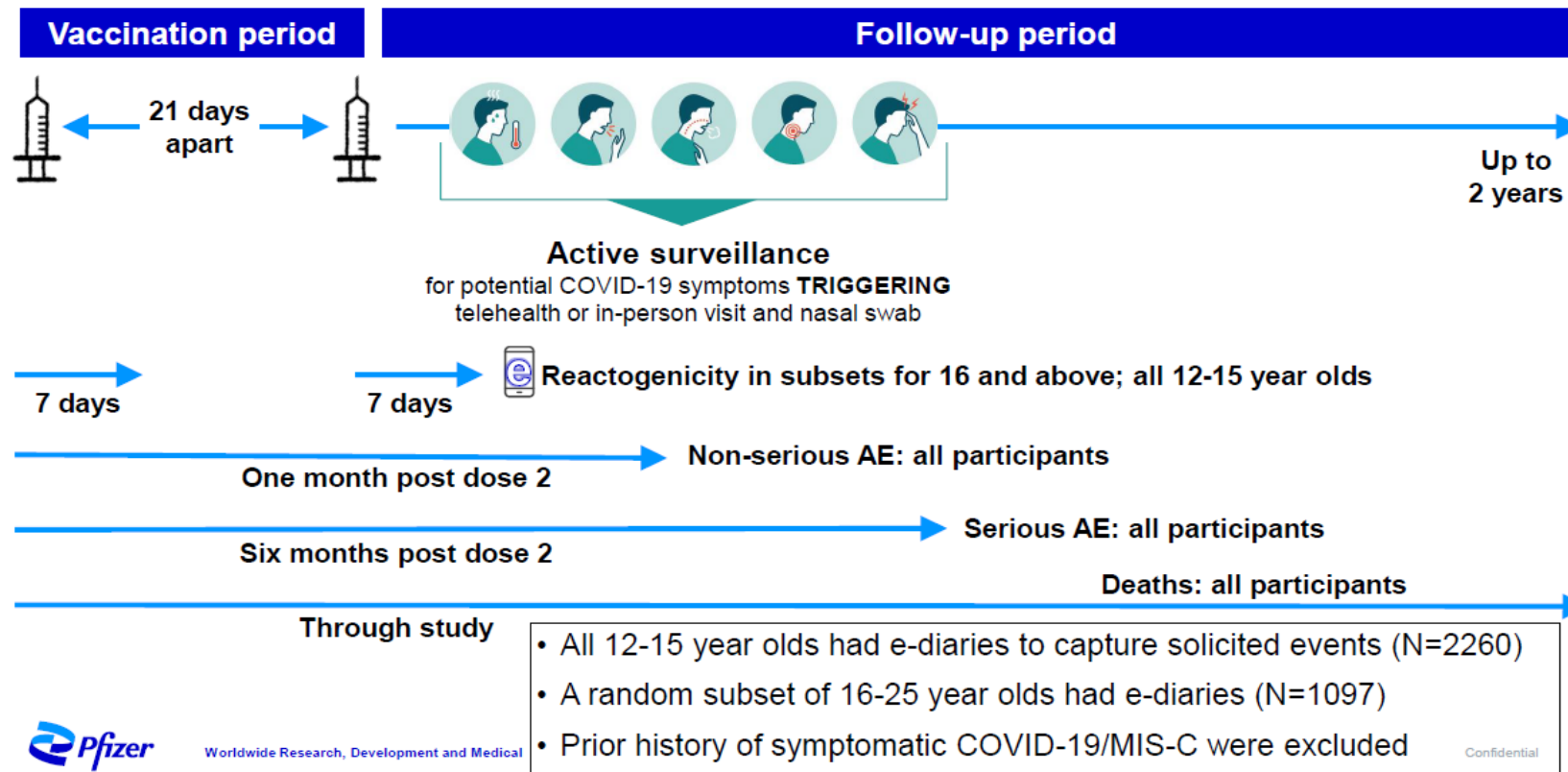
COVID-19-related outcomes compared to households with children not attending in-person school (reference), prior to adjustment for mitigation efforts



How well do the
Sars-CoV-2
vaccines work in
children?

Pfizer clinical trial-adolescents 12-15 years

Phase 2/3 Safety Schema – Started 27 July, 2020



Demography for 12-15 and 16-25 year olds (Safety population)

		BNT162b2		Placebo	
		12-15 Years (N=1131) n (%)	16-25 Years (N=1867) n (%)	12-15 Years (N=1129) n (%)	16-25 Years (N=1903) n (%)
Sex	Male	567 (50.1)	921 (49.3)	585 (51.8)	882 (46.3)
	Female	564 (49.9)	946 (50.7)	544 (48.2)	1021 (53.7)
Race	White	971 (85.9)	1443 (77.3)	962 (85.2)	1510 (79.3)
	Black or African American	52 (4.6)	189 (10.1)	57 (5.0)	179 (9.4)
	American Indian or Alaska native	4 (0.4)	32 (1.7)	3 (0.3)	18 (0.9)
	Asian	72 (6.4)	108 (5.8)	71 (6.3)	108 (5.7)
	Native Hawaiian or other Pacific Islander	3 (0.3)	10 (0.5)	0	3 (0.2)
	Multiracial	23 (2.0)	76 (4.1)	29 (2.6)	74 (3.9)
	Not reported	6 (0.5)	9 (0.5)	7 (0.6)	11 (0.6)
Racial desig.	Japanese	5 (0.4)	3 (0.2)	2 (0.2)	6 (0.3)
Ethnicity	Hispanic/Latino	132 (11.7)	604 (32.4)	130 (11.5)	575 (30.2)
	Non-Hispanic/non-Latino	997 (88.2)	1259 (67.4)	996 (88.2)	1322 (69.5)
	Not reported	2 (0.2)	4 (0.2)	3 (0.3)	6 (0.3)
Country	USA	1131 (100.0)	1333 (71.4)	1129 (100.0)	1364 (71.7)
	Others*	0	534 (28.6)	0	539 (28.3)



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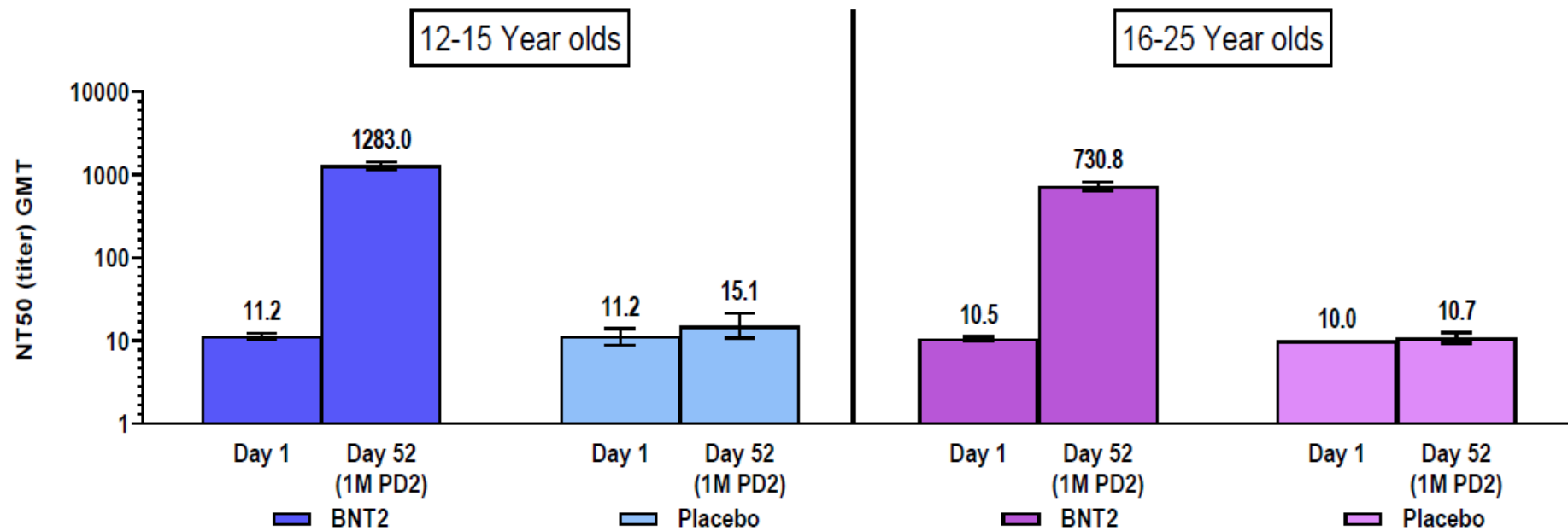
*Argentina, Brazil, Germany, South Africa, Turkey

Note: All 12-15 year olds from the US; ~72% of 16-25 year olds from the US

Confidential

4

Geometric Mean Titers: SARS-CoV-2 Neutralization Assay – NT50* – Subjects 12-15 and 16-25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population (All subjects)



*NT50 = 50% neutralizing titers



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First COVID-19 Occurrence From 7 Days After Dose 2

Subjects 12-15 Years of Age – Evaluable Efficacy Population

Subjects WITHOUT Evidence of Infection Prior to 7 days after Dose 2

Efficacy Endpoint	BNT162b2 (30 µg) N=1005		Placebo N=978		VE (%)	(95% CI)
	n	Surveillance Time (n)	n	Surveillance Time (n)		
First COVID-19 occurrence ≥7 days after Dose 2	0	0.154 (1001)	16	0.147 (972)	100.0	(75.3, 100.0)

- There were no severe COVID-19 cases

Total surveillance time: 1000 person-years for all subjects within each group at risk for the endpoint.
The analysis is descriptive; no hypothesis test



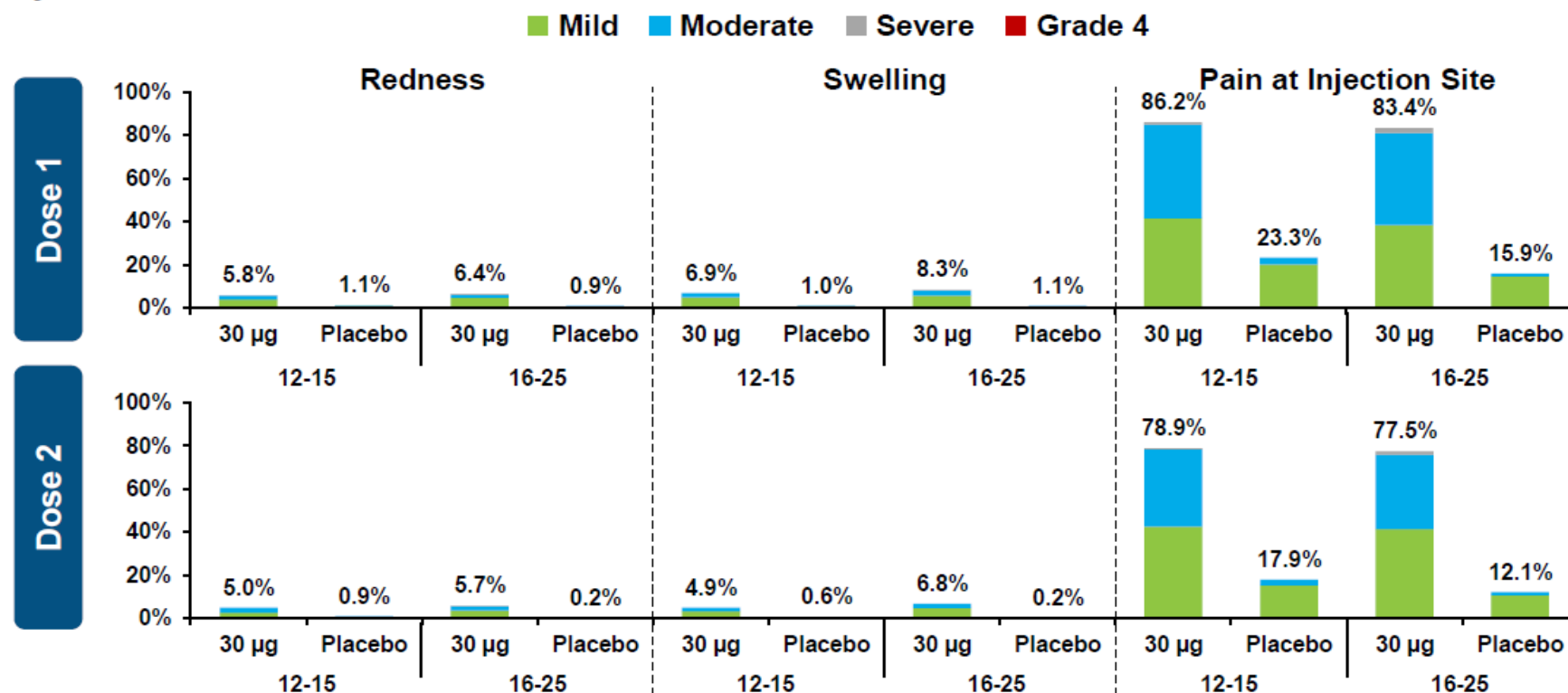
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Pfizer Sars-CoV-2 vaccine adverse events

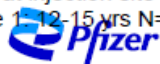
Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 12-15 and 16-25 Year Olds



Redness and swelling severity definition: Mild= >2-5cm, Moderate= >5-10 cm; Severe= >10 cm; Grade 4= necrosis

Pain at injection site severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization

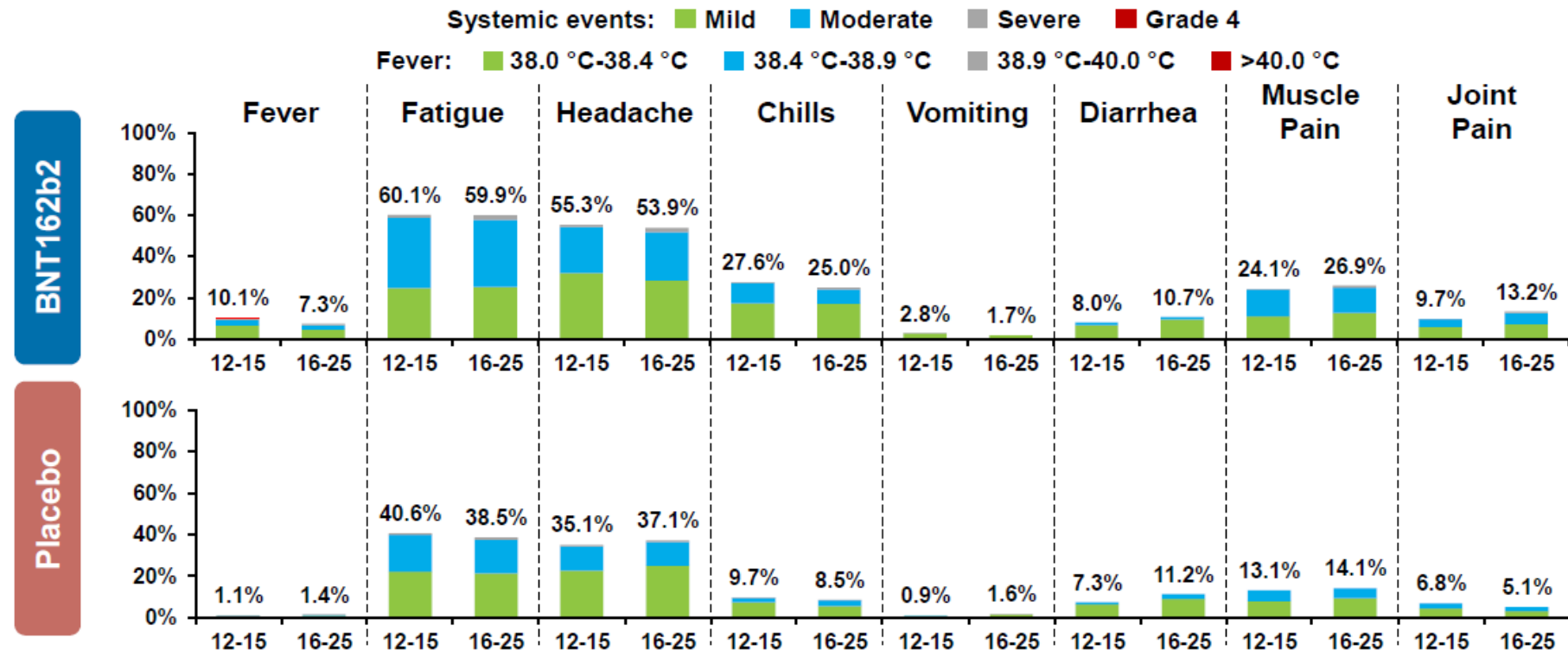
Dose 1: 12-15 yrs N=2254; 16-25 yrs N=1084 Dose 2: 12-15 yrs N=2175 16-25 yrs N=984



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Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 1 in 12-15 and 16-25 Year Olds



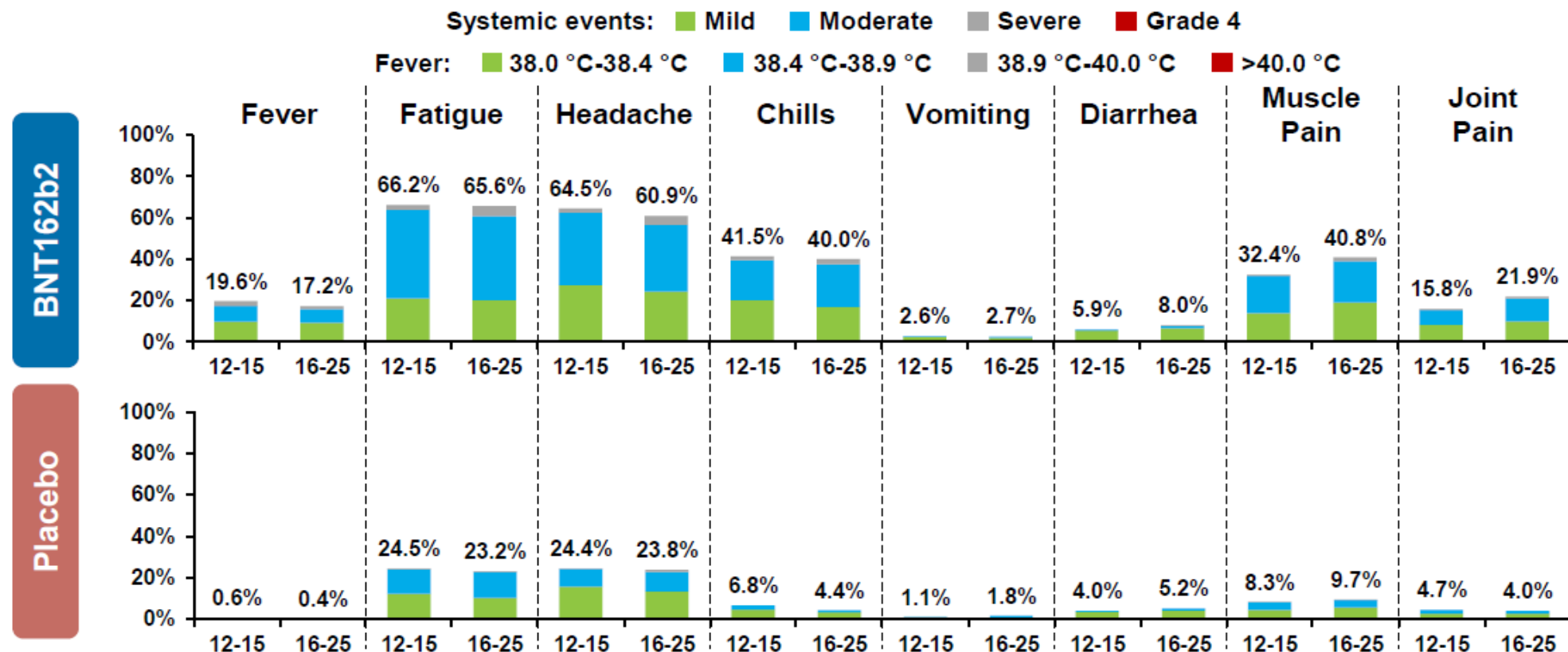
Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 time in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 1: 12-15 yrs N=2254; 16-25 yrs N=1084



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Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 12-15 and 16-25 Year Olds



Fatigue, headache, chills, muscle pain, joint pain severity definition: Mild=no interference; Moderate=some interference; Severe=prevents daily activity; Grade 4=ER visit or hospitalization
 Vomiting severity definition: Mild=1-2 times in 24h; Moderate=>2times in 24h; Severe=Requires IV hydration; Grade 4=ER visit or hospitalization
 Diarrhea severity definition: Mild=2-3 times in 24h; Moderate=4-5 times in 24h; Severe=6 or more times in 24h; Grade 4=ER visit or hospitalization
 Dose 2 12-15 yrs N=2175 16-25 yrs N=984



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Benefits and Harms:

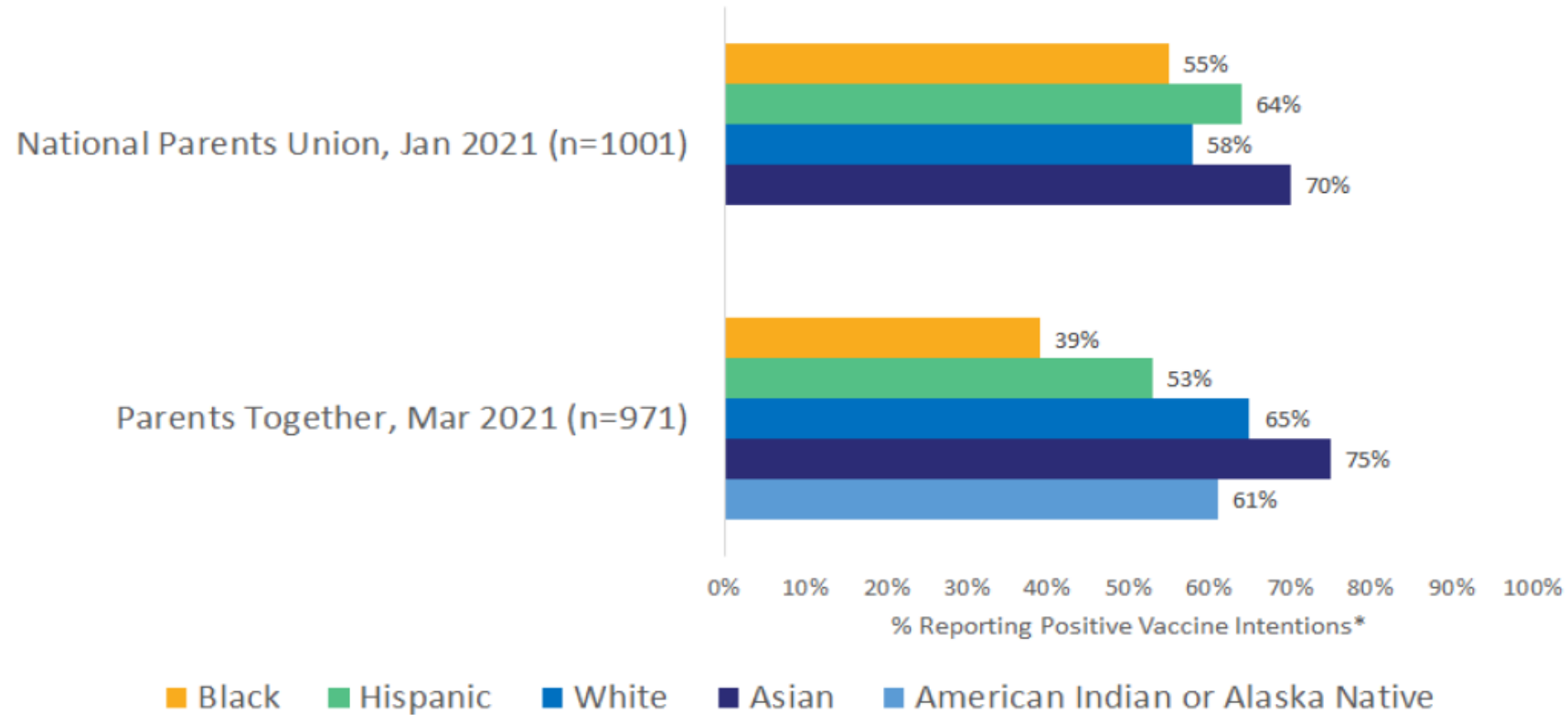
Summary of the Available Evidence: Harms

- No cases of anaphylaxis reported in the adolescent (12-15 years of age) study participants
- No cases of Bell's Palsy or facial paralysis reported in adolescents
- Among adolescents 12-15 years of age, 7 (0.6%) in the vaccine group had lymphadenopathy, compared to 1 (0.1%) participant in the placebo group
 - Most lymphadenopathy was local (arm or neck region), occurred on the same side as vaccination, and was reported within 2-10 days






Are parents
going to get
their children
immunized and
if so, where?

Values: Parents' Intent for Children to Receive COVID-19 Vaccine Varies by Race/Ethnicity



*Positive vaccine intentions includes persons reporting definitely or probably likely to get their child vaccinated.

Augment existing public health infrastructure and add new channels to vaccinate adolescents

	Category	Approach
	Primary care providers serving adolescents	Utilize primary care as trusted providers to notify, schedule, and vaccinate their patients, including managing routine immunizations, particularly as students return to school
	Pharmacies and HRSA sites¹	Leverage broad pharmacy footprint and HRSA sites to administer COVID-19 vaccine to adolescents rapidly, as with adults
	School-based vaccination	Partner with Federally Qualified Health Centers, pharmacies, public health, and adolescent provider networks to hold targeted programs at schools to ensure equity and coverage, particularly as students return

L. Health Resources and Services Administration (HRSA) sites including: Federally Qualified Health Centers (FQHCs), Rural Health Clinics, Community Health Centers

Consent

- The federal government does not have specific requirements for medical consent for vaccination.
- States/jurisdictions have medical consent laws that address the circumstances requiring and the processes for obtaining consent.
 - These laws vary across jurisdictions.
 - Providers may also be subject to policy requirements for consent within their own organizations.
- Sites administering vaccines should follow current state/jurisdictional policies and practices for other routine immunizations in this age group.

MIS-C

Multisystem
Inflammatory
Syndrome in
Children

Multisystem Inflammatory Syndrome in Children (MIS-C)

- Severe hyperinflammatory syndrome occurring 2-6 weeks after acute SARS-CoV-2 infection, resulting in a wide range of manifestations and complications
 - 60-70% of patients are admitted to intensive care, 1-2% die^{1,2}
- **3,742 MIS-C cases** have been reported to national surveillance as of May 3, 2021³
 - Median age of 9, with 21% (804) of cases occurred in adolescents 12-17 years
 - 63% of reported cases have occurred in children who are Hispanic/Latino or Black, Non-Hispanic
 - Estimated incidence of 1 to 8.5 MIS-C cases per million person-months

1. Feldstein LR, Tenforde MW, Friedman KG, et al. Characteristics and Outcomes of US Children and Adolescents With Multisystem Inflammatory Syndrome in Children (MIS-C) Compared With Severe Acute COVID-19. *JAMA*. 2021;325(11):1074-1087. doi:10.1001/jama.2021.2091
2. Belay ED, Abrams J, Oster ME, et al. Trends in Geographic and Temporal Distribution of US Children With Multisystem Inflammatory Syndrome During the COVID-19 Pandemic [published online ahead of print, 2021 Apr 6]. *JAMA Pediatr*. 2021:e210630. doi:10.1001/jamapediatrics.2021.0630
3. Health Department-Reported Cases of Multisystem Inflammatory Syndrome in Children (MIS-C) in the United States. <https://www.cdc.gov/mis-c/cases/index.html>

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 vaccines following these illnesses
 - Timing of any immunomodulatory therapies



All the rest.....

Routine adolescent vaccines

- Updated coadministration recommendations may facilitate catch up vaccination of adolescents.
- As of May 2, 2021, overall VFC provider orders (other than influenza) are down by **11.7 million doses** compared with 2019.
- This gap is largest in vaccines primarily given to adolescents.
 - Tdap – down **18.9%**
 - HPV – down **19.3%**
 - Meningococcal conjugate vaccine – down **15.1%**

Coadministration

- Due to the novelty of the COVID-19 vaccines, the previous recommendation was to administer COVID-19 vaccines alone, with a minimum interval of 14 days before or after administration of any other vaccine to better understand any adverse reactions.
- However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized by FDA for use under EUA.
- 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.

Coadministration

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

AAP Statement

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 (or vaccination in the days before or after) for children and adolescents who are behind on or due for immunizations ([based on the CDC/AAP Recommended Child and Adolescent Immunization Schedule](#)) and/or at increased risk from vaccine-preventable diseases.

COVID Vaccines in Children-Major Concerns

Severity of adverse events

Triggering of MIS-C

Co-administration with other vaccines

Further use of COVID Vaccines in Children

Both Pfizer and Moderna have already started clinical trials in younger children

- 5-11 year olds
- 2-4 year olds
- 6 month-23 month olds

Dose finding

Immunobridging serologic studies

Side effect profile

Careful monitoring for MIS-C

Questions and Answers



Evaluation

- At the end of this webinar an Evaluation will pop up on your screen.
- The evaluation should take approximately 5 minutes to complete.
- CIC utilizes the evaluation from our COVID Conversations to guide us in future endeavors as well as sharing the performance with our panelists.



Stay tuned for future COVID
Conversations

Thank you for your support and your participation!

You can find all previous Covid Conversations on our YouTube channel

<https://www.youtube.com/channel/UcklkZ1SZQNQLcpmNpeQpDAg>

www.ImmunizeCA.org/Covid-19-Updates