

HHP/HPH COVID-19 Community Webinar Series

Friday, November 5, 2021
12:00pm – 1:00pm

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Moderator

Andy Lee, MD

Medical Director, Hawai'i Health Partners
Chief of Staff, Pali Momi Medical Center
Hawai'i Pacific Health

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- Specific areas may not pertain directly to your clinical practice area and/or may not be applicable to your practice based on your existing workflows, infrastructure, software (e.g. EHR), and communications processes.

Webinar Information

- You have been automatically muted. You cannot unmute yourself.
- You will be able to submit questions via the Q&A section.
 - Due to time constraints, any unanswered questions will be addressed this week and posted on the HHP website
- A recording of the meeting will be available tomorrow on the HHP website and intranet.

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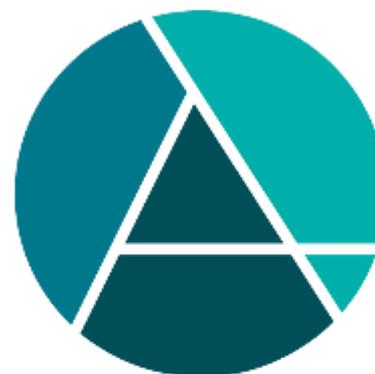
- You should have completed a brief questionnaire before joining today's live webinar.

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- Complete and submit evaluation survey that will be emailed to you within one week of the offering.
- Your CE certificate will be immediately available to you upon completion of your evaluation.
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Pediatric COVID-19 and COVID-19 Vaccination in 5-11 Year Olds



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Objectives

- Pediatric COVID-19 Updates:
 - Why vaccinate 5 to 11 year-old children?
- Pediatric COVID-19 Pfizer-BioNTech 5 to 11 year-old children:
 - How to vaccinate?
- To review questions and concerns about COVID-19 Vaccines

Pediatric COVID-19 in the US – As of October 28, 2021 (AAP)

Cumulative Number of Child COVID-19 Cases

- **6,396,278** total child COVID-19 cases reported
- **Children represented 16.6%** (6,396,278/38,496,700) of all cases
- Overall rate: 8,498 cases per 100,000 children in the population

Change in Child COVID-19 Cases

- **100,630** child COVID-19 cases were reported the past week from 10/21/21-10/28/21 (6,295,648 to 6,396,278)
- Children represented **24.2%** (100,630/416,059) of the weekly reported cases

Hospitalizations (24 states and NYC reported)*

- Among states reporting, children ranged from 1.7%-4.2% of their total cumulated hospitalizations, and 0.1%-2.0% of all their child COVID-19 cases resulted in hospitalization

Mortality (45 states, NYC, PR and GU reported)*

- Among states reporting, children were 0.00%-0.26% of all COVID-19 deaths, and 7 states reported zero child deaths
- In states reporting, 0.00%-0.03% of all child COVID-19 cases resulted in death

<https://www.aappublications.org>

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

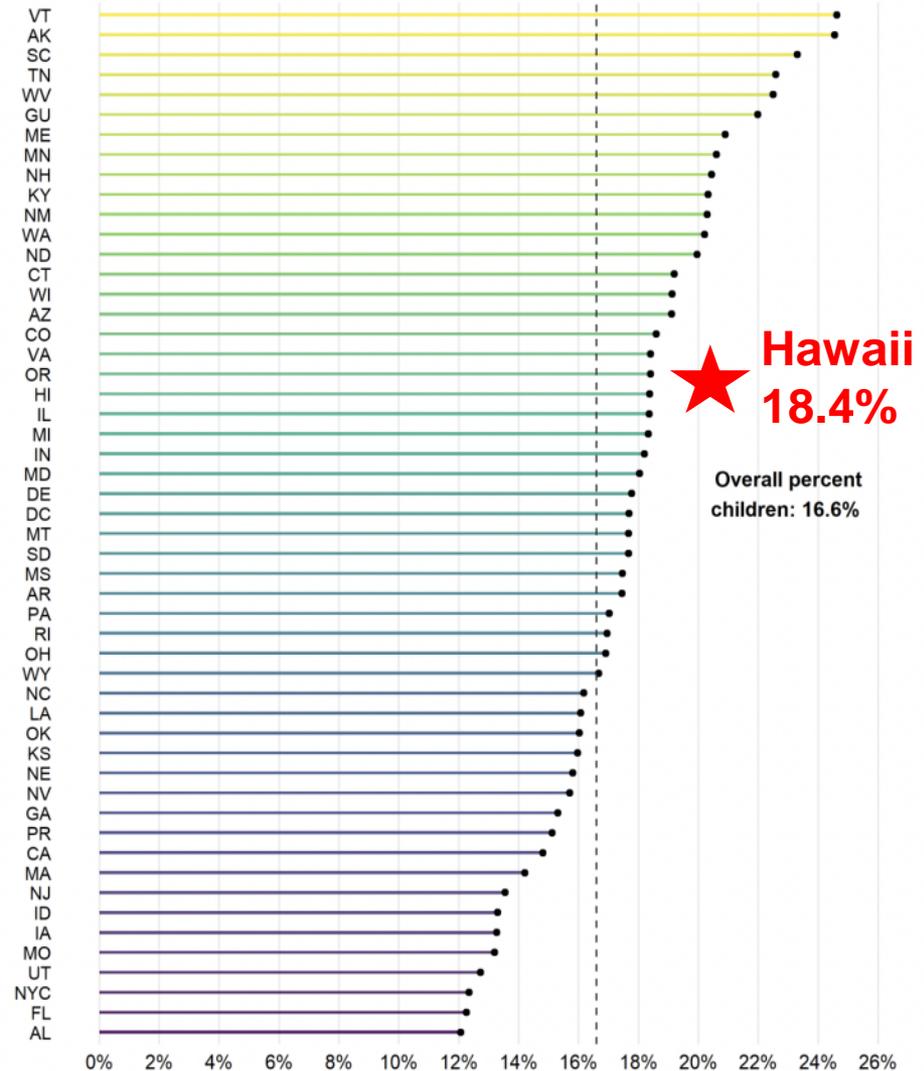
<https://health.hawaii.gov/coronavirusdisease2019/current-situation-in-hawaii/#agetrends>

Fig 3. Percent of Cumulative COVID-19 Cases that were Children: 10/28/21

- Children represented 16.6% (6,396,278/38,496,700) of all available cases
- Twelve states reported 20% or more of cumulated cases were children

**Cumulative cases/100,000 in Hawaii:
4967.5 per 100,000**

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



- Hawaii Child Population: 299,868
- 207,492 are Ages 0-11 years

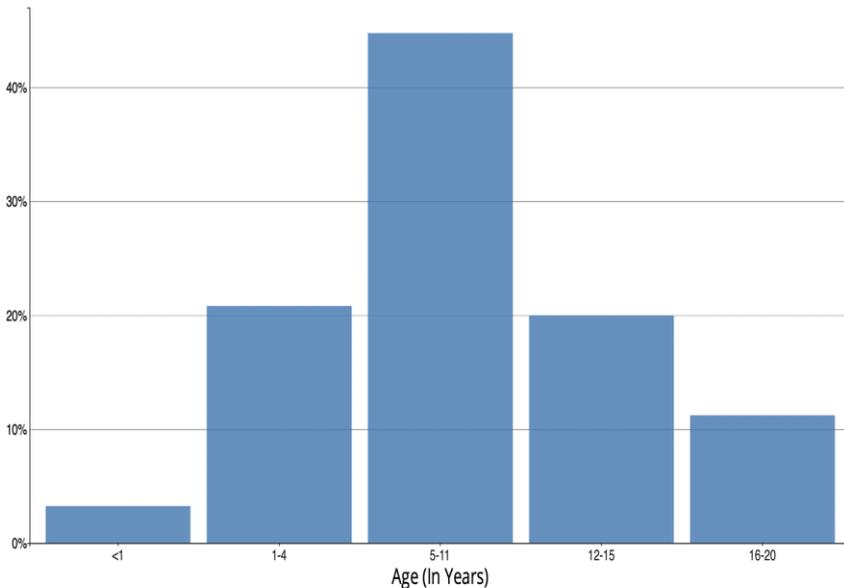


Multisystem Inflammatory Syndrome in Children (MIS-C) in US

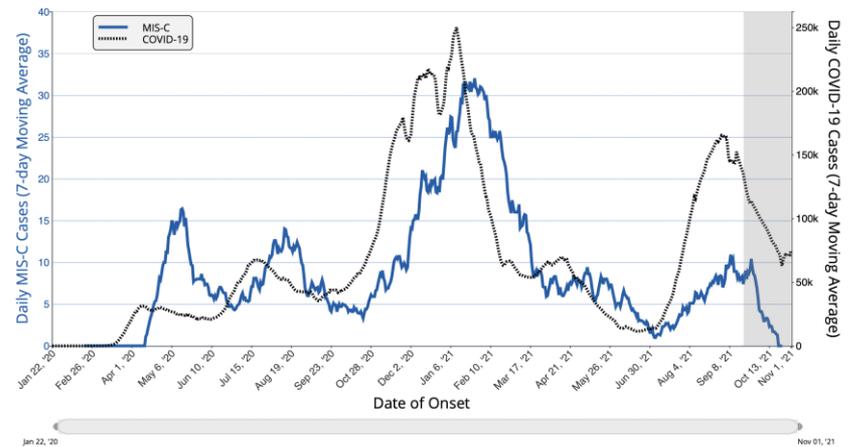
(Last updated by CDC November 1, 2021)

- **Total Confirmed Cases: 5526** (Increase in 309 cases from 10/4/2021)
- **Total Deaths: 48** (Up 2 from 10/4/2021)
 - The median age of patients with MIS-C was 9 years.
 - Half of children were between the ages of 5 and 13 years.

MIS-C Patients By Age Group



Daily MIS-C Cases and COVID-19 Cases Reported to CDC (7-Day Moving Average)



Number of included MIS-C cases: 5,525. The graph shows the 7-day moving average number of COVID-19 cases and MIS-C cases with date of onset between February 19, 2020 and October 18, 2021.

The grayed-out area on the right side of the figure represents the most recent 6 weeks of data, for which reporting of MIS-C cases is still incomplete. The actual number of MIS-C cases during this period is likely larger, and these numbers are expected to increase as additional case reports are incorporated. The scale for the Y-axis differs on the left and the right sides of the figure. The left Y-axis marks the number of daily 7-day average MIS-C cases in units of 5 with a scale of 0 to 40; the right Y-axis marks the number of daily 7-day average COVID-19 cases in units of 50,000 with a scale from 0 to 250,000. To protect patient privacy and ensure data stability, data are suppressed when the 7-day moving average is <1.

Date of onset was missing for 1 of the 5,526 cases.

<https://www.cdc.gov/mis-c/cases/index.html>

Long-COVID-19

- Post-COVID conditions have been seen in children and adolescents
- Symptoms continue 4 or more weeks after SARS-CoV2 infection
 - UK national survey found 7-8% children with COVID-19 continues symptoms >12 weeks after diagnosis
 - Can be mild to moderate and after MIS-C
- Can occur after mild or moderate COVID-19 or MIS-C
- **Most common symptoms:** Similar to adults, and include fatigue, headache, insomnia, trouble concentrating, muscle and joint pain, and cough

COVID-19 has affected Children in many ways...

Education

School Closures
Widening educational gaps
Fear in parents, students & teachers

Socialization

Isolation from friends and peers
Lack of adult interaction

Worsening Emotional and Mental Health

National emergency in children's mental health
Physical isolation, ongoing uncertainty, fear and grief

Physical Activities

Sports and Exercise

Extracurricular Activities

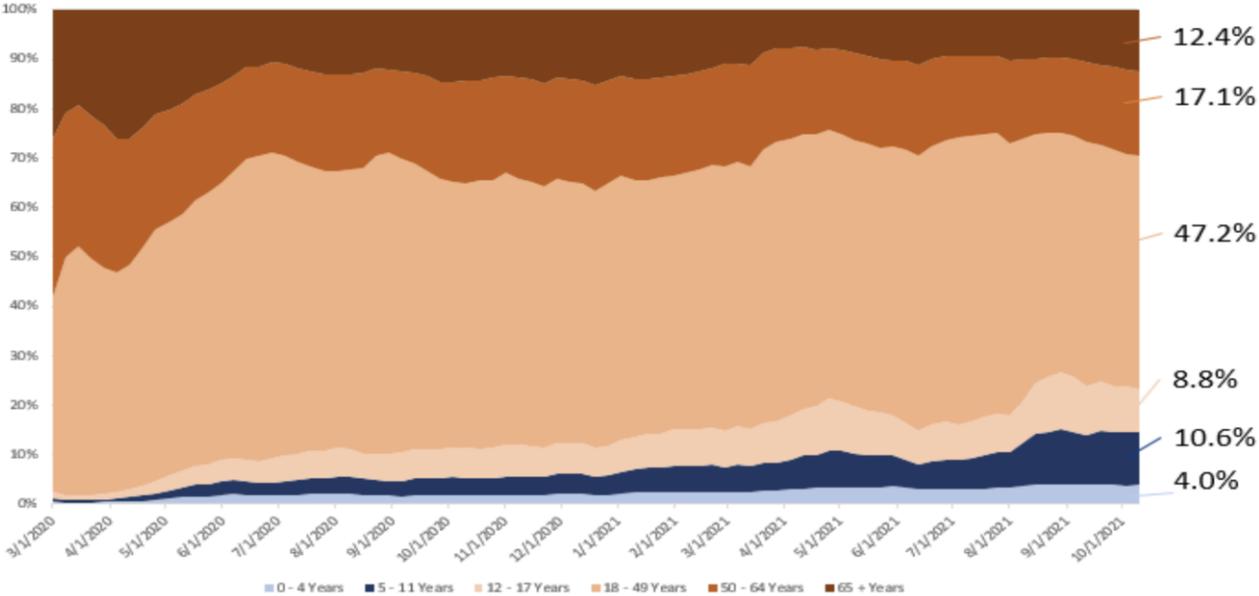
Orphans

140,000 Children have lost parent due to COVID-19

COVID-19 Epidemiology in Children 5 to 11 years old

- Over 1.9 million reported cases in Children 5-11 years of age
 - 10.6% of all cases
 - 8.7% of US population

Proportion of Total COVID-19 Cases by Age Group — March 1, 2020–October 10, 2021



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

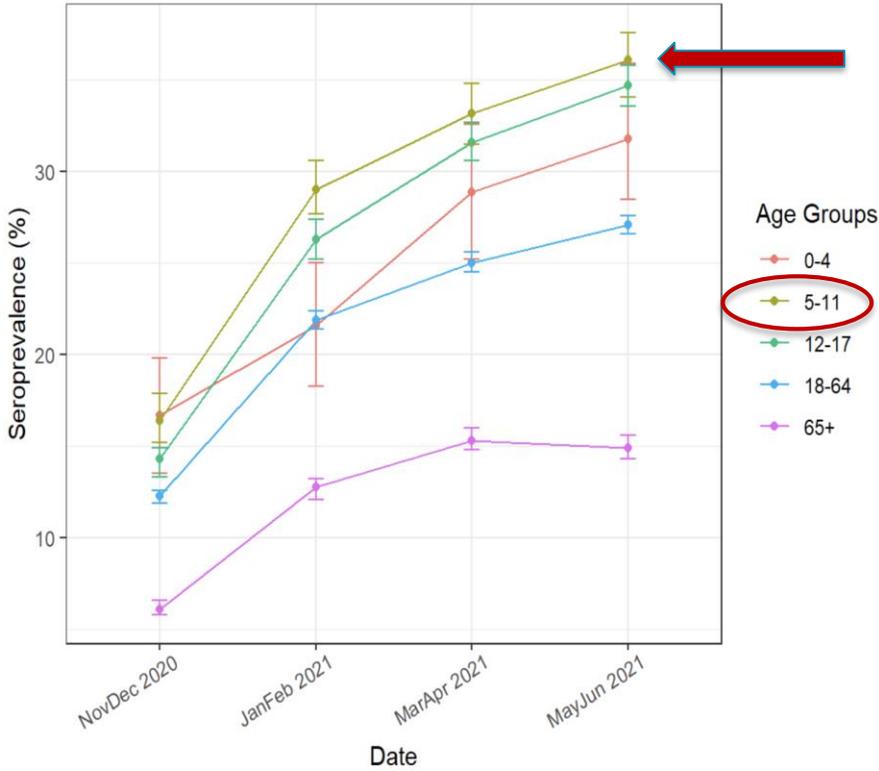
<https://covid.cdc.gov/covid-data-tracker/#demographicsovertime>

SARS-CoV2 Seroprevalence 42% for Children 5 to 11 Years Old

Weighted SARS-CoV-2 Infection-Induced Seroprevalence: 15 U.S. jurisdictions by Age Group, Nov 2020–Jun 2021

Seroprevalence may not represent the general population as these patients

- Children consistently have higher seroprevalence estimates than adults
- Age 5–11 have the highest seroprevalence, but confidence intervals overlap with other pediatric age groups
- Age 5–11 seroprevalence increased from 13% in Nov–Dec 2020 to 42% in May–June 2021
- Number of infections per reported case*:
 - General population: Median **2.4** (Range: 2.0–3.9)
 - Ages 0–17 years: Median **6.2** (Range: 4.7–8.9)

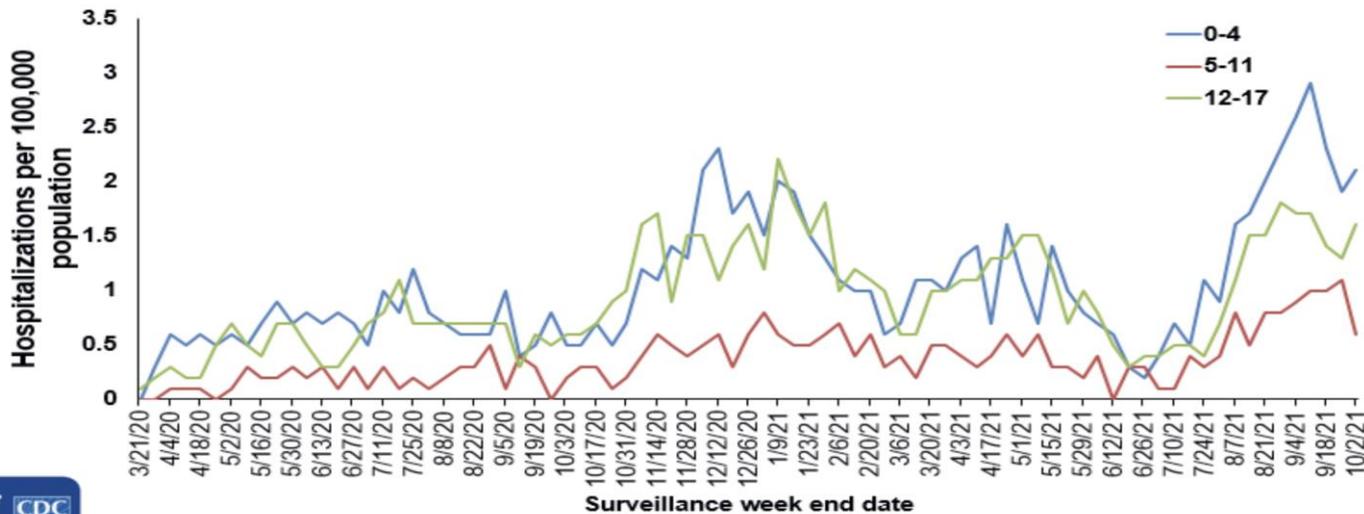


* Restricted to jurisdictions that provided age data for >90% of individual cases: CA, IL, NV, NJ, NC, OH, SC, and TN

COVID-19 Hospitalization in Children 5 to 11 years old

- Children 5-11 years of age are at risk of severe illness from COVID-19
- > 8,300 COVID-19 hospitalizations to date
- Approximately 1/3 of hospitalized children 5-11 years require ICU admission
- 32% of children 5-11 did **not** have underlying health conditions

COVID-19-Associated Weekly Hospitalizations per 100,000 — COVID-NET by age group, March 21, 2020–October 2, 2021



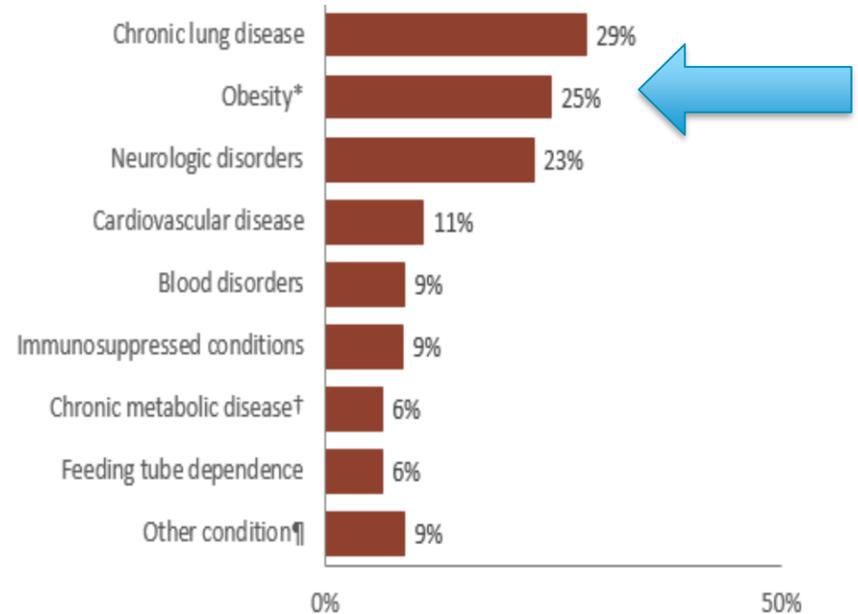
<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html>

Children Aged 5–11 Years Hospitalized with COVID-19— COVID-NET, March 2020–August 2021

Demographic and clinical characteristics

	N	(%)
Total	562	(100)
Age (yrs) – median (IQR)	8	(6–10)
Sex – Male	320	(57)
Race/ethnicity		
Black, non-Hispanic	207	(37)
Hispanic	177	(31)
White, non-Hispanic	124	(22)
Asian, non-Hispanic	23	(4)
Other, non-Hispanic	31	(6)
Severe disease[§]	200	(36)
≥1 underlying condition	381	(68)

Prevalence of underlying medical conditions



[§]Requiring intensive care unit admission or mechanical ventilation

*BMI (kg/m²) ≥95th percentile for age and sex based on CDC growth charts, ICD-10 codes for obesity, or obesity selected on case report form

†Includes type I and type II diabetes mellitus

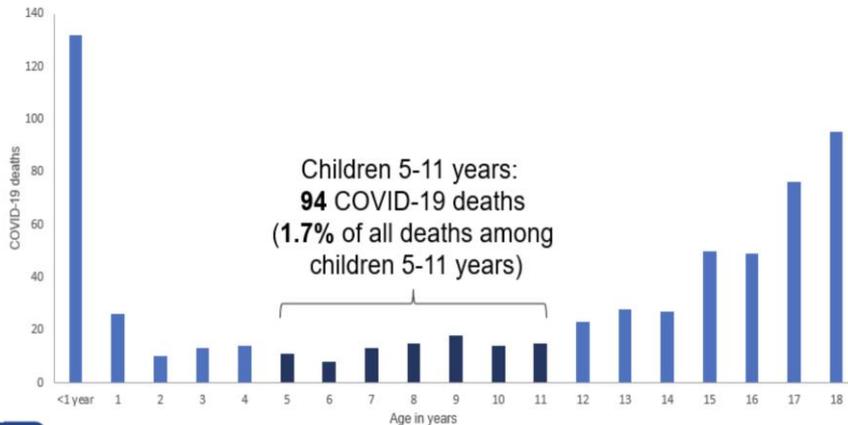
¶Includes gastrointestinal or liver disease; renal disease; rheumatologic, autoimmune, inflammatory conditions; abnormality of the airway

COVID-NET is a population-based surveillance system that collects data on laboratory-confirmed COVID-19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states. Methods described in: Woodruff RC, et al. Risk factors for Severe COVID-19 in Children. *Pediatrics*. ePub October 2021.



Pediatric Mortality in COVID-19

COVID-19 Deaths by Age Group, NCHS — January 1, 2020–October 16, 2021



<https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Counts-by-Age-in-Years/3apk-4u4f/data>

Leading Causes of Death in Children 5-11 Years of Age, NCHS, 2019

Causes of Death	Death (n)	Crude rate per 100,000
Accidents (unintentional injuries)	969	3.4
Malignant neoplasms	525	1.8
Congenital malformations, deformations and chromosomal abnormalities	274	1.0
Assault (homicide)	207	0.7
Diseases of the heart	115	0.4
Chronic lower respiratory diseases	107	0.4
Influenza and pneumonia	84	0.3
Intentional self-harm (suicide)	66	0.2
Cerebrovascular diseases	56	0.2
Septicemia	48	0.2

66 COVID-19 associated deaths in children 5-11 10/3/20-10/2/2021

Total population 5-17 years, 2019: 52,715,248

CDC NCHS WONDER Online Database. Accessed at <http://wonder.cdc.gov/ucd-icd10.html> on May 6, 2021

- Mortality: 94 deaths in children 5-11 years → 1.7% of all deaths
- Death # 8 in top 10 causes of death in children

MIS-C in Children 5 to 11 years

- MIS-C associated with COVID-19 most frequent among children 5-11 years
 - 2316 cases (**44%**) out of n=5217 in children aged 5-11 years from 2/19/2020 to 9/23/2021
 - Median age 9 years
 - Adjusted incidence estimates ~100-600 cases per million SARS-CoV2 infections
- **61%** occurred in children who are Hispanic/Latino or Black, Non-Hispanic
- Among children aged 5–11 years, **9 died (20% of MIS-C deaths)**

COVID-19 is a Vaccine Preventable Disease



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Vaccine Preventable diseases

Other pediatric vaccine preventable diseases: Hospitalizations per year prior to recommended vaccines

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

Other vaccine preventable diseases: Deaths per year prior to recommended vaccines

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

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

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

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

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

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

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

- Vaccination among 5–11-year-olds is expected to accelerate the decline in cases, reducing cumulative incidence nationally by an expected **8%** (~600,000 cases) from November 2021 to March 2022
- Vaccination of 5–11-year-olds would dampen, but not eliminate, a new variant emergence

<https://covid19scenariomodelinghub.org/>

COVID-19 Vaccination

Pediatric COVID-19 Pfizer-BioNTech 5
to 11-year-old Children:

How to vaccinate?

Cumulative Child COVID-19 Vaccinations

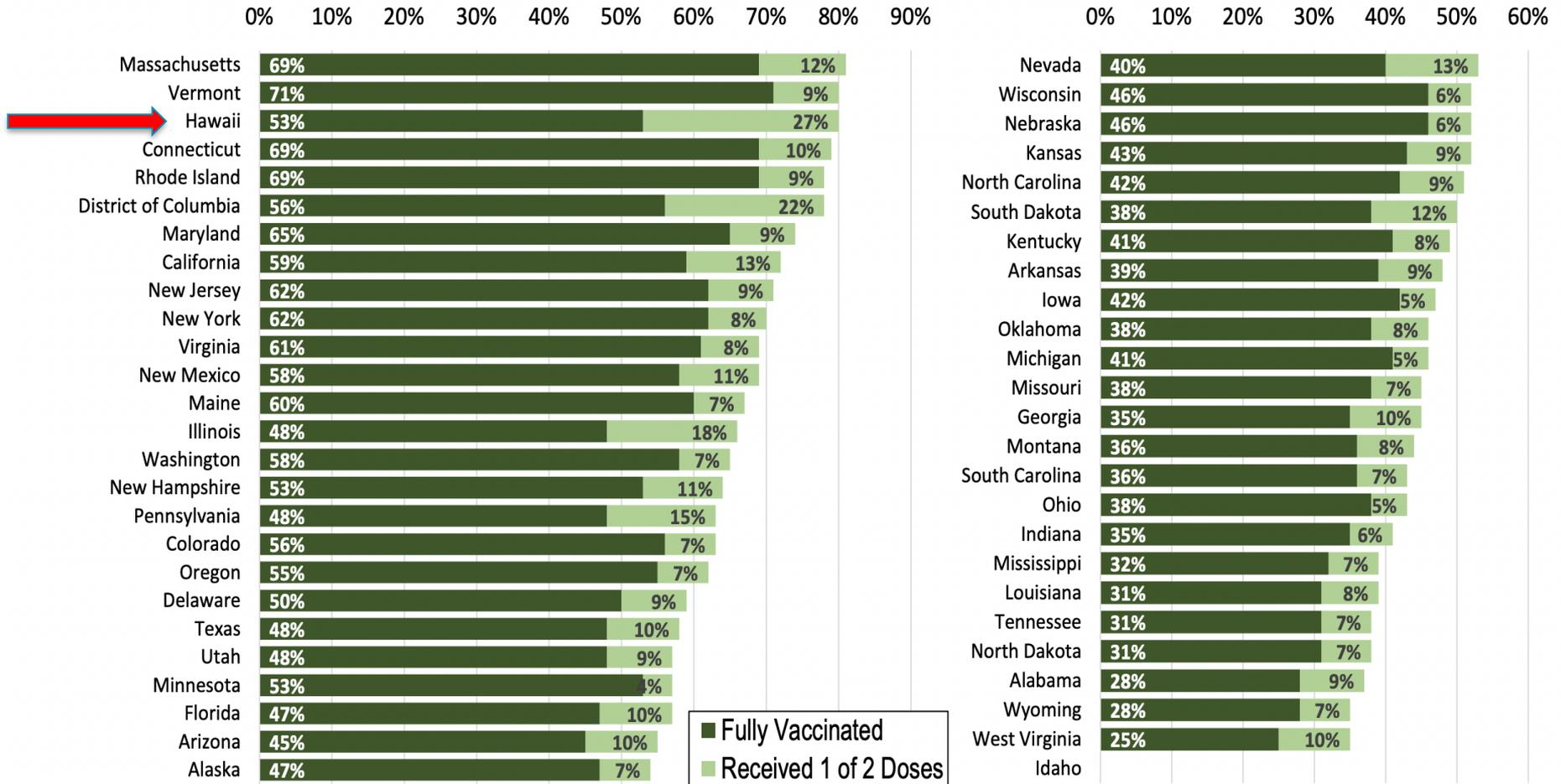
As of October 27, 2021, the CDC recorded:

- 13.6 million US children under age 18 have received **at least one dose** of COVID-19 vaccine:
 - Representing 58% of 12-17 year-olds
- 11.3 million of US children under age 18 are **fully vaccinated**:
 - Representing 49% of 12-17 year-olds

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

Proportion of US Eligible Children (Ages 12-17) Vaccinated Against COVID-19 by State of Residence

as of 10.27.2021



Source: AAP analysis of data series titled "COVID -19 Vaccinations in the United States, Jurisdiction". CDC COVID -19 Data Tracker (URL: <https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdiction>). Idaho information not available. Check state's web sites for additional or more recent information

ADVISORY COMMITTEE MEETING

Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement

OCTOBER 26, 2021

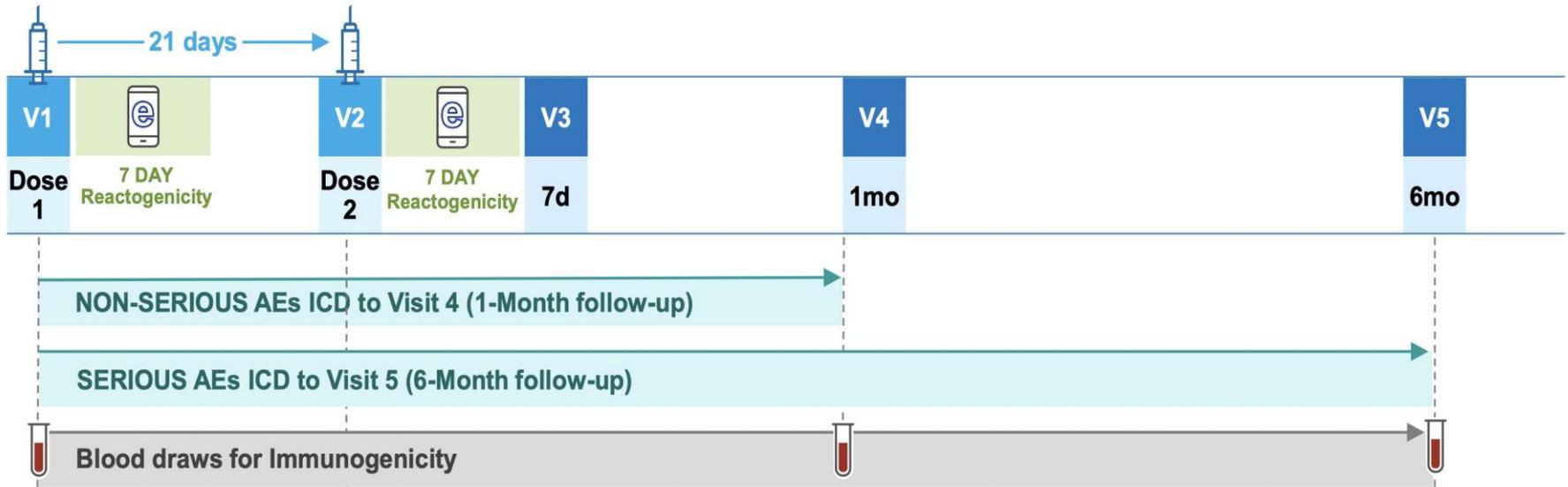
Scheduled

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October 26, 2021: VRBPAC Meeting Voting Question

Based on the totality of scientific evidence available, do the benefits of the Pfizer- BioNTech COVID-19 Vaccine when administered as a 2-dose series (10 µg each dose, 3 weeks apart) outweigh its risks for use in children 5-11 years of age?

Phase 2/3 Timelines of Participants 5 to <12 Years of Age Through 6 Months Post-dose 2

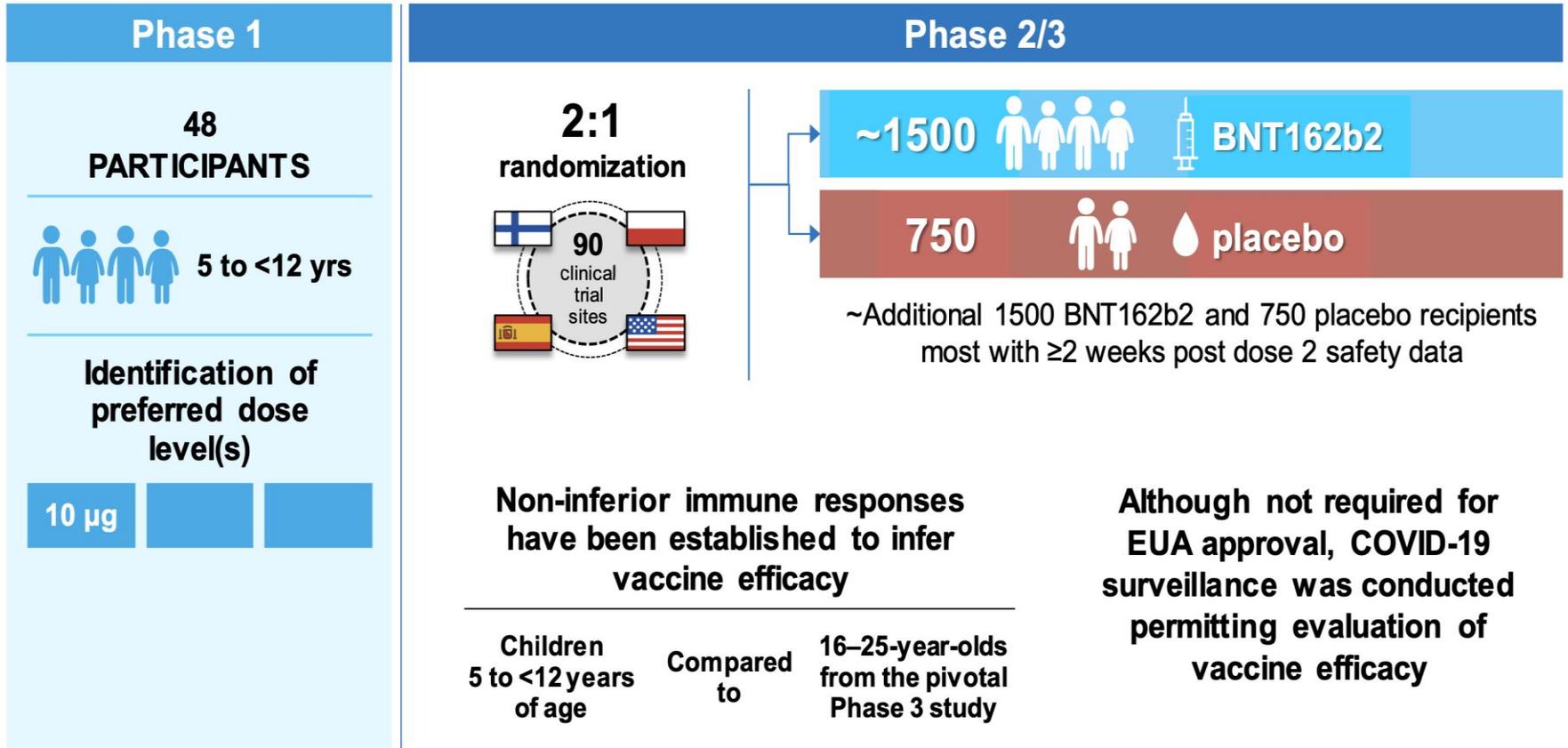


UP TO 2-YEARS

COVID-19/MIS-C Visit: triggered if a participant reports experiencing a COVID-19/MIS-C Symptom reported on the Illness diary or reported directly by the participants → potential COVID-19 Illness visit (telehealth/in-person visit + nasal swab) must be scheduled (optimally within 3 Days after illness onset)

CC-7

Pfizer-BioNTech Pediatric COVID-19 Vaccine BNT162b2: Study Overview: 5 to <12 Years



CC-8

Demographics for 5 to <12 Year Olds

Phase 2/3 Safety Population Initial Enrollment Group (N=2268)

		BNT162b2 (10µg) N=1518	Placebo N=750
Sex, n (%)	Male	799 (52.6)	383 (51.1)
	Female	719 (47.4)	367 (48.9)
Race, n (%)	White	1204 (79.3)	586 (78.1)
	Black or African American	89 (5.9)	58 (7.7)
	American Indian or Alaska native	12 (0.8)	3 (0.4)
	Native Hawaiian or other Pacific Islander	<1%	<1%
	Asian	90 (5.9)	47 (6.3)
	Multiracial	109 (7.2)	49 (6.5)
	Not reported	<1%	<1%
Ethnicity, n (%)	Hispanic/Latino	319 (21.0)	159 (21.2)
	Non-Hispanic/non-Latino	1196 (78.8)	591 (78.8)
	Not reported	<1%	<1%
Age at vaccination	Mean (SD)	8.2 (1.93)	8.1 (1.97)
	Min, Max	(5, 11)	(5, 11)
Obese, n (%)	Yes	174 (11.5)	92 (12.3)
Comorbidities ^a , n (%)	Yes	312 (20.6)	152 (20.3)

- a. Participants who had at least one of the prespecified comorbidities based on MMWR 69(32);1081-1088 and/or obesity (BMI ≥ 95th percentile)
- b. Obese is defined as a body mass index (BMI) at or above the 95th percentile according to the growth chart. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm.

CC-9

Phase 2/3 randomized, controlled trial

Included ~4,500 children 5 to 11 years of age

- 2,268 from the original group and 2,379 from the supplemental safety group

Two-dose regimen of 10- μ g doses administered 21 days apart, one-third of the 30- μ g dose used for people 12 years and older.

This dose level was carefully selected for use in the trial based on safety, tolerability and immunogenicity data evaluated as part of a dose-ranging study.

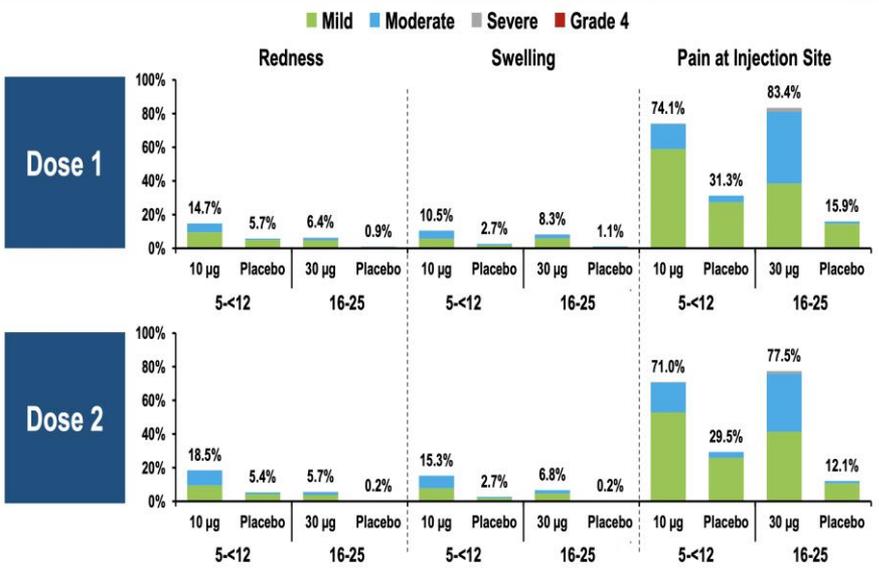
The Phase 2/3 trial showed a favorable safety profile, robust immune responses and a vaccine efficacy rate of 90.7% in participants without prior SARS-CoV-2 infection, measured from 7 days after the second dose.

The Data Monitoring Committee for the study has reviewed the data and has not identified any serious safety concerns related to the vaccine.

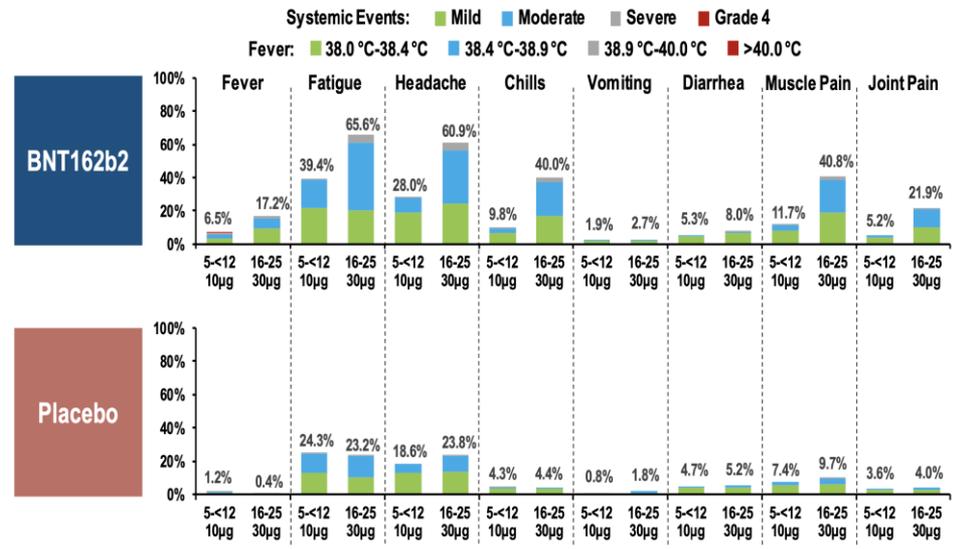
What are the Common Side Effects?

- Local: redness, swelling and pain at injection site
- Systemic: fever, fatigue, headaches, chills, vomiting, diarrhea, muscle pain and joint pain

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose in 5 to <12 and 16-25 Year Olds



Systemic Events, by Maximum Severity, Within 7 Days After Dose 2 in 5 to <12 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: 5-<12yrs N=2260; 16-25 yrs N=1064 Dose 2: 5-<12 yrs N=2242 16-25 yrs N=984

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: 5-<12 yrs N=2242 16-25 yrs N=984

Safety Conclusions 5 to 11 Year Olds

Reactogenicity was mostly mild to moderate, and short lived

Local reactions (redness, swelling) mild - moderate more common than 16-25 year olds

Systemic reactions (including fever) less common than 16-25 year-olds

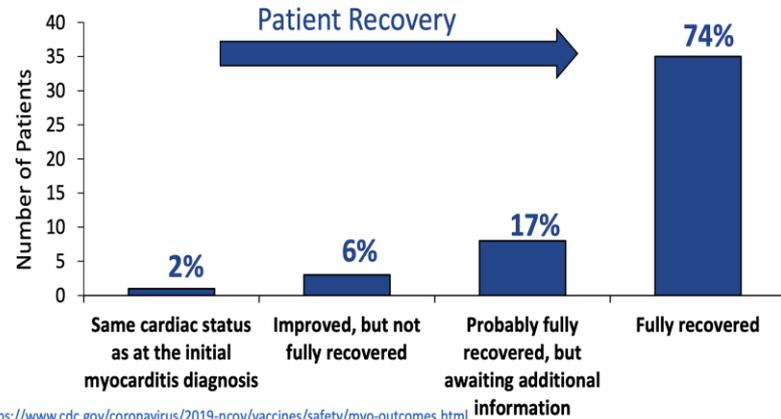
Observed Adverse Events profile did not suggest any safety concerns for BNT162b2 vaccination in children 5 to 11 years of age

Myocarditis – CDC presentation VRBPAC

- **No myocarditis cases were reported in the clinical trial**
- Vaccine-induced myocarditis is true safety signal, but rare
 - 877 cases among 12-29 year olds (out of more than 100,000,000 vaccinated)
 - 829 were hospitalized and 77% recovered
 - At the time of analysis, 5 people were in the ICU
 - No myocarditis cases reported and investigated by the CDC have resulted in death
- Not the same as Classic myocarditis
 - More mild form of disease, no reduction in ejection fraction

Cardiologist/healthcare provider assessment of recovery from myocarditis after COVID-19 vaccination by 3 months (n=47)

- 91% of cardiologists or healthcare providers indicated the patient was fully or probably recovered



- **Long term effects of vaccine-induced myocarditis**
 - Adolescents fully recovered from symptoms and arrhythmias ~35 days
- Potential role with genetics and hormones

VRBPAC Vote → FDA Outcome

- VRBPAC committee reviewed clinical data showing a **favorable safety profile and high vaccine efficacy of 90.7%** in children 5 to 11 years of age during a period when Delta was the prevalent strain
- 10- μ g dose level used in the trial for children 5 to <12 years of age was selected based on safety, tolerability and immunogenicity data
- Vote: 17 Yes, 1 Abstained
- **FDA granted Emergency Use Authorization 10/29/2021 for Pfizer-BioNTech COVID-19 Vaccine 5 to 11 year age group**

November 2, 2021: ACIP Policy Question 11-2-2021

- Should vaccination with Pfizer-BioNTech COVID-19 vaccine (2 doses, 10 µg, IM) be recommended for children 5-11 years of age, under an Emergency Use Authorization?
- Unanimous – Yes: 14
- CDC Director Approval of ACIP recommendations

Summary of Vaccine Safety

- Children may experience side effects, some systemic fewer than adolescents or young adults
- Children with prior infection may have fewer side effects
- Myocarditis: observed risk, highest males 12-29 years
- Risk of myocarditis or pericarditis after mRNA is lower than risk of myocarditis from SARS-CoV2 infection in adolescents/adults
- No Myocarditis/pericarditis in clinical trial 5-11 y n=3088
 - Not powered risk myocarditis
- Baseline myocarditis high in 12-17 years than 5-11 years
 - Monitor for myocarditis: Chest pain, SOB, fast beating heart
- Coadministration is okay
- If multiple vaccines, separate site by 1 inch or more

To Review Questions and Concerns About COVID-19 Vaccines



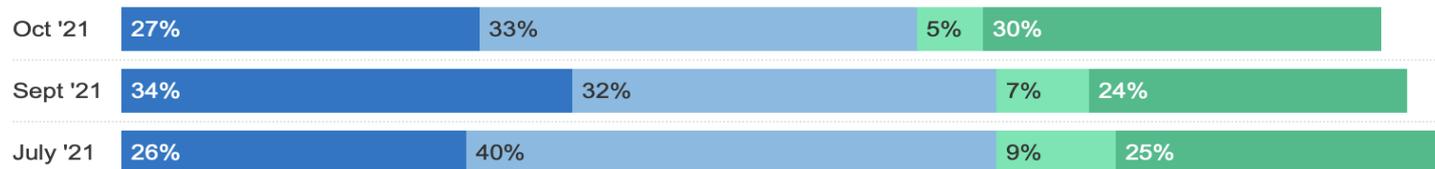
Parents Attitudes Towards COVID-19 Vaccinations For Children

Figure 1

Three In Ten Parents Say They Will Definitely Not Get Their 5 To 11 Year Old Vaccinated

Thinking about your child **between the ages of 5 and 11**, once there is a COVID-19 vaccine authorized and available for your child's age group, do you think you will get them vaccinated...?

■ Right away ■ Wait and see ■ Only if required ■ Definitely not



NOTE: Among parents or guardians of children ages 5-11. See topline for full question wording.

SOURCE: KFF COVID-19 Vaccine Monitor • [Download PNG](#)

[KFF COVID-19
Vaccine Monitor](#)

- 3 in 10 parents (27%) say “right away”
- A third of parents say they will “wait and see”
- 3 in 10 say they definitely won’t get their 5-11 year old vaccinated (30%)
- 5% say they will only do so if their school requires it

How is the 5 to 11 year old dose different? **1/3 of the adult dose: 10 µg**

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

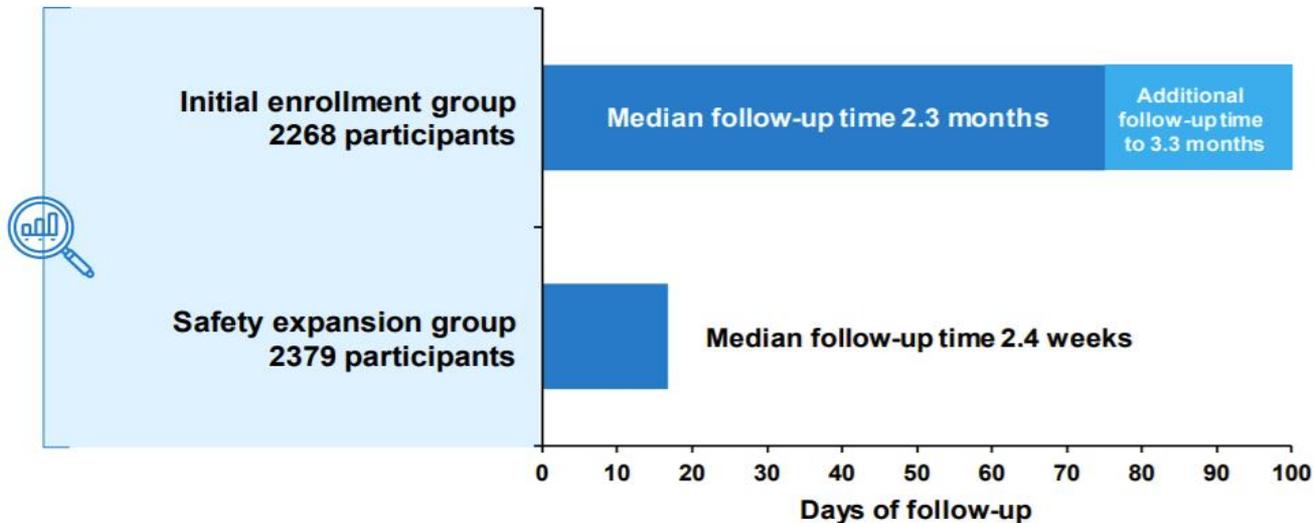
	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 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>

How Many Patients Were in the Clinical Trial?

- Two cohorts
- 2,268 trial participants (including 1,518 vaccine recipients) followed for at least two months past the 2nd dose
- Safety expansion group with additional 2,379 participants (1,500 vaccine recipients) followed for a median of 2.4 weeks after the second dose
 - Additional group per FDA's request “to allow for more robust assessment of serious adverse events and other adverse events of interest”

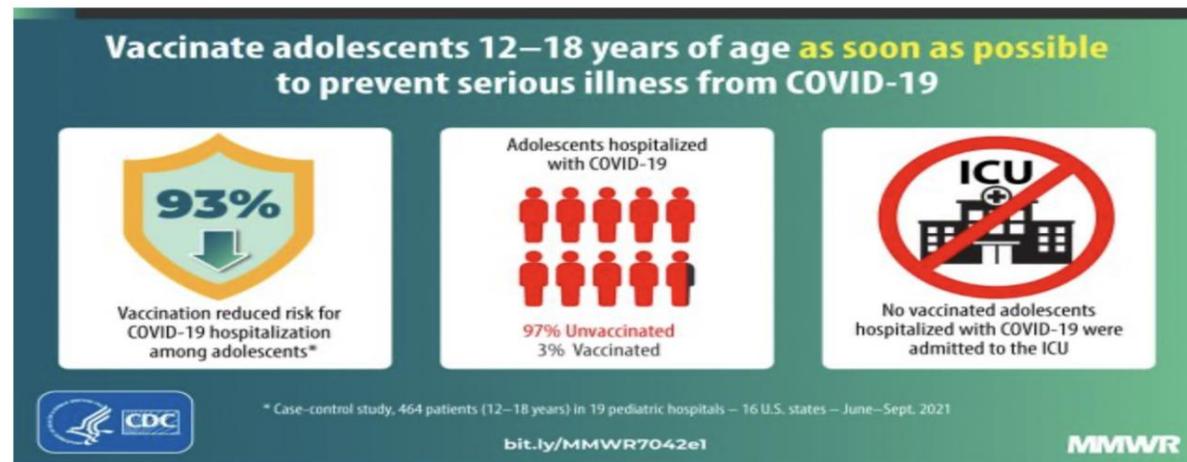


Why Vaccinate Children?

- To provide protection and prevent severe disease and hospitalization

COVID-19 Effectiveness in Hospitalized Adolescents 12-18 Years of Age

- Vaccine effectiveness of 2 doses of Pfizer-BioNTech vaccine against hospitalization during June - September 2021 was **93%** (95% confidence interval = 83%–97%)
- Among 179 COVID-19 patients:
 - Six (3%) vaccinated
 - 173 (97%) unvaccinated
- Pfizer-BioNTech 2 dose vaccine were highly effective in preventing COVID-19 hospitalization
- Vaccination to protect US youths against severe COVID-19



Olson SM, Newhams MM, Halasa NB, et al. Effectiveness of Pfizer-BioNTech mRNA Vaccination Against COVID-19 Hospitalization Among Persons Aged 12–18 Years — United States, June–September 2021. MMWR Morb Mortal Wkly Rep 2021;70:1483–1488. DOI: <http://dx.doi.org/10.15585/mmwr.mm7042e1external icon>.

Is the Vaccine Safe?

- Yes, the vaccine is safe and effective
- This vaccine has undergone the most stringent monitoring and data review
- Over 500 million COVID-19 doses of have been given
- 191.2 million people fully vaccinated

Ensuring COVID-19 Vaccine Safety in the US

Updated Sept. 28, 2021 Languages Print

Vaccine Safety and Monitoring

- COVID-19 vaccines were developed using science that has been around for decades.
- COVID-19 vaccines are safe—much safer than getting COVID-19.
- COVID-19 vaccines are effective at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it.



Millions of people in the United States have received COVID-19 vaccines under the most intense safety monitoring in U.S. history. CDC recommends you get a COVID-19 vaccine as soon as you can.

- VAERS: passive reporting system, doesn't establish or assess causality
- V-Safe app for COVID-19 – parent signs up for child on their account
- VSD – Vaccine Safety Data
- CISA – Clinical Immunization Safety Assessment Project (CD and 7 HCP)

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>

CDC Monitors Health Reports Submitted After COVID-19 Vaccination to Ensure Continued Safety

COVID-19 vaccines are part of the most intensive vaccine safety monitoring effort in U.S. history

Vaccine safety monitoring systems are used to check for potential vaccine safety problems (sometimes called adverse events) that may not have been seen during clinical trials. CDC uses new and established systems to actively monitor for possible adverse events related to COVID-19 vaccination. CDC and vaccine safety experts quickly assess unexpected adverse events to help guide U.S. vaccine recommendations.

VAERS

The **Vaccine Adverse Event Reporting System** is the nation's early warning system, used to monitor adverse events that happen after vaccination. Anyone can report possible health problems after vaccination to VAERS. CDC and FDA review the reports for unusual patterns that might indicate a vaccine safety problem needing deeper investigation. VAERS cannot determine if a vaccine causes an adverse event. CDC might use the CISA Project or VSD to conduct follow-up studies.

v-safe

People who receive a COVID-19 vaccine can enroll in **v-safe**, a new smartphone-based tool that provides quick health check-ins. People can share if they have side effects. CDC may call to check on people who report a health problem to get more information and submit a report to VAERS.

CISA Project

The **Clinical Immunization Safety Assessment Project** is a collaboration between CDC and seven medical research centers. CISA consults with U.S. healthcare providers and health departments about vaccine safety, conducts clinical research, and helps investigate safety issues.

VSD

The **Vaccine Safety Datalink** is a collaboration between CDC and nine healthcare organizations. Participating sites link patient vaccination and electronic health record data. CDC monitors the data for vaccine safety concerns and research opportunities.

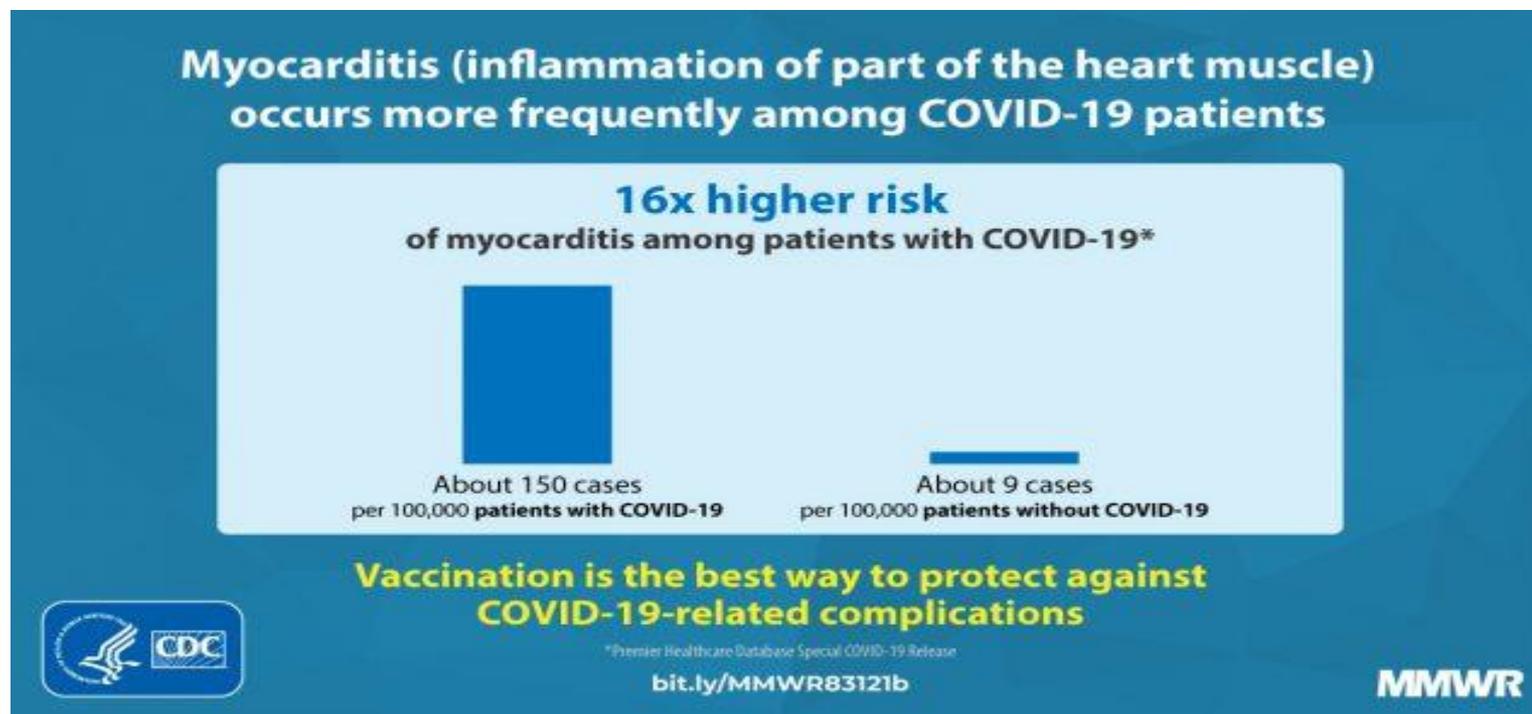
v-safe COVID-19 Pregnancy Registry

CDC invites some people enrolled in **v-safe** who received a COVID-19 vaccine shortly before or during pregnancy to participate in the **v-safe COVID-19 Pregnancy Registry**. CDC monitors information collected from participants to ensure the continued safety of COVID-19 vaccinations.

What about Myocarditis Associated with COVID-19 Vaccine?

- No cases of myocarditis or pericarditis were seen n=3082 in clinical trial for 5-11 year olds
 - Not powered to assess risk of myocarditis
- No myocarditis death linked vaccine in US: 3/9 classic myocarditis (bacteria/virus), 3 not myocarditis and 3 still in review
- Rare following receipt of mRNA COVID vaccine
- Usually after Dose 2, within 7 days
- Mild disease, symptoms resolve
- Higher risk of getting myocarditis from actual SARS-CoV2 infection
- Myocarditis can occur in adolescents and young adults

Myocarditis in COVID-19



- March 2020–January 2021
- Patients with COVID-19 had nearly 16 times higher risk of myocarditis compared with patients who did not have COVID-19

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

When should 5 - 11 year olds get the vaccine?

- The vaccination should not be delayed
- If an 11 year old has a birthday coming up, they should not wait for a higher dosage
- If a child turns from 11 to 12 years of age in between their first and second dose and receives 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 per the EUA

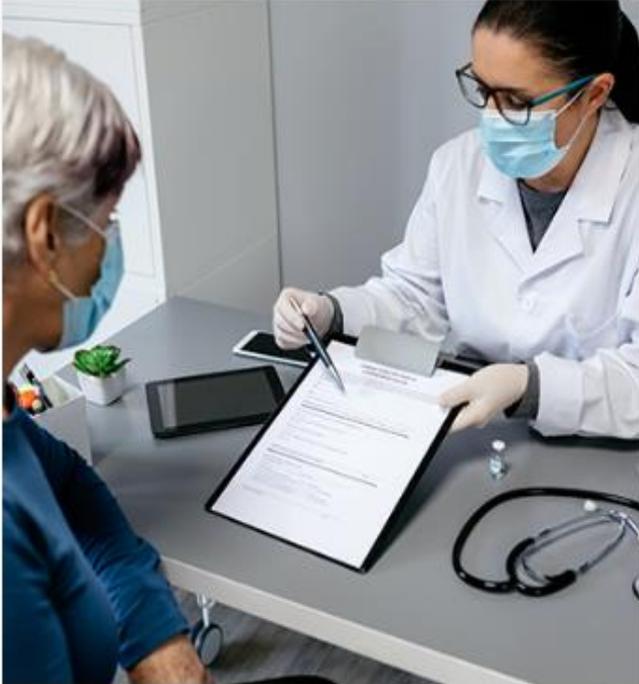
What should you do if 11 year old turns 12 years?

- Give the dose based on age at the time it is due

Can there be other vaccines give on same day of administration of COVID-19 vaccines?

- COVID-19 vaccines may be administered without regard to timing of other vaccines
 - This includes getting a COVID-19 vaccine with other vaccines on the same day
 - If multiple vaccines are administered at a single visit, administer each injection in a different injection site
 - 1 inch apart
 - Sites: Deltoid muscle of arm (preferred) or vastus lateralis of anterolateral thigh (alternative)

How do I become a COVID-19 Vaccine Provider?



- If you are a Healthcare facility or Primary Care Physician who would like COVID-19 vaccines to your patients, please complete the [COVID-19 Provider Form](#) below.
- Interested providers who complete the survey form, will receive an email from the Department of Health's Immunization Registry that will include three (3) items:
 - CDC COVID-19 Vaccine Program Provider Agreement – a fillable PDF
 - General Instructions and Tips
 - Creating your Digital Signature-ID Instructions
- [Step-by-step video on how to fill out the COVID-19 Provider Agreement](#)
- [Find out the Process and Flow for Enrollment](#)

COVID-19 Provider Survey Form

^^^ Click Here! ^^

<https://health.hawaii.gov/coronavirusdisease2019/for-clinicians/covid-19-vaccine/>

- **How do I order COVID-19 vaccines?**
 - After becoming an enrolled vaccine provider, the HDOH has a dedicated Distribution Team who will assist you as you order vaccines. Please contact the Hawaii Immunization Branch Call Center at (808) 586-8300 or toll-free at 1-800-933-4823 for additional assistance
- **What is the minimum amount of vaccines I can order?**
 - Pfizer: 6 doses
 - Moderna: 10 doses
 - Janssen: 50 doses
- **How are COVID-19 vaccines supplied?**
 - Vaccines are either supplied via redistributions from local COVID-19 vaccine providers who may have excess inventory on hand, or via direct-shipment from the vaccine manufacturer (Pfizer) or contracted CDC vaccine distributor (McKesson)
 - Note that it is possible for Pfizer and Moderna vaccines to be supplied via redistributions in quantities less than the minimum direct ship order amounts
- **Are there any training modules on how to administer COVID-19 vaccines?**
 - CDC COVID-19 Vaccine Overview and Best Practices, Pfizer, Moderna, and Janssen training modules can be accessed at <https://www2.cdc.gov/vaccines/ed/covid19/>

For more Provider FAQs:

<https://health.hawaii.gov/coronavirusdisease2019/files/2021/09/FAQ-for-COVID-19-Vaccine-Providers.pdf>

Summary: Why Vaccinate Children 5 to 11 years old?

- Children 5 to 11 years old can have severe COVID-19 requiring hospitalization (1/3 with no underlying health conditions)
- COVID-19 is 8th cause of death in children 5 to 11 years: 94 deaths (1.7% of all deaths amount children 5 to 11 years)
- 42% seroprevalence in children show history of COVID-19
- MIS-C rare but late hyperinflammatory condition affecting multiple organs
 - **44%** in children aged 5-11 years old
- Long COVID-19 – chronic condition more than 4 weeks
- Pediatricians are trusted providers, will be key to education to the “watch and see group”

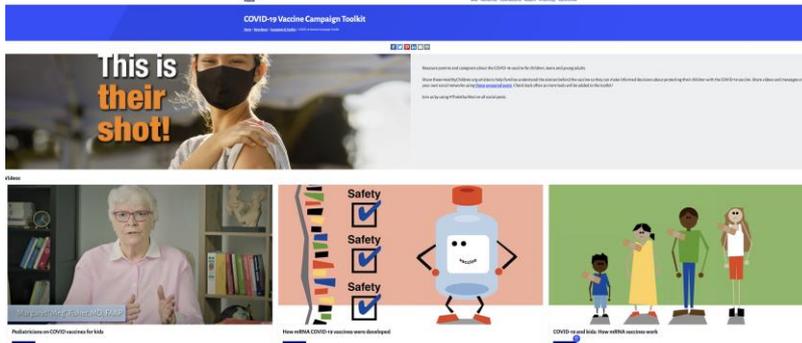
Summary: How to Vaccinate for COVID-19 in 5 to 11 Year Olds

- Safe and effective
- Produces good antibody response similar to adolescent & young adults
- 2 Dose COVID-19 Vaccine efficacy 90.7%
- Local side effects may occur in children
- Systemic side effects may occur but less than older adolescent/adult
- No cases of myocarditis or pericarditis were seen n=3082 (not powered to assess risk of myocarditis)
- Coadministration is okay, separate injection sites by 1 inch or more

COVID-19 is a Vaccine Preventable Disease

COVID-19 Resources/Data

- AAP Policy Statement/Toolkit



<https://www.aap.org/en/pages/covid-19-vaccines-in-children-and-adolescents-policy/>

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

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

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

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

CDC now recommends that children between the ages of 5 and 11 years receive the Pfizer-BioNTech pediatric COVID-19 Vaccine. Get more information and read [CDC's media statement](#).

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
- Presentation: Clinical Care Consideration Slides for Healthcare Providers

Summary of recent changes (last updated November 3, 2021):

- Recommendations and clinical guidance for use of Pfizer-BioNTech COVID-19 Vaccine in children aged 5–11 years including updated section on [Vaccination of children and adolescents](#)

FDA: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-October-26-2021-meeting-announcement#event-materials>

ACIP: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html>

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[What's this?](#)

Submit

Websites

AAP COVID Disease

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

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

AAP COVID vaccine information

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

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

AAP Policy

<https://www.aap.org/en/pages/covid-19-vaccines-in-children-and-adolescents-policy/>

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

CDC COVID Vaccines

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

FDA: <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement#event-materials>

ACIP: <https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html>

The Immunization Action Coalition: <https://www.immunize.org>

The Vaccine Education Center at Children's Hospital of Philadelphia: <https://www.chop.edu/centers-programs/vaccine-education-center>



Mahalo

HPH Vaccine Clinic Information



Melinda Ashton, MD

*Executive Vice President and
Chief Quality Officer*
Hawai'i Pacific Health



Shilpa Patel, MD

Associate Chief Quality Officer,
Hawai'i Pacific Health Medical

**HAWAI'I
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**HAWAI'I
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PARTNERS**

[COVID-19 Updates](#) / [Vaccine Update](#)

COVID-19 Vaccine: Oahu

Hawaii Pacific Health is working with the Hawaii Department of Health to administer the COVID-19 Vaccine and protect you and your loved ones.

We are currently scheduling appointments for individuals ages 5 and older.



Kapiolani Vaccine Clinic



Straub Medical Center Vaccine Clinic



Mobile Vaccine Clinic



Drive-through Vaccine Clinic



Kauai Vaccine Clinic



Frequently Asked Questions



When and Where to Get 5-11 year olds COVID-19 Vaccine

- The vaccine is available by appointment only for children ages 5-11 **at KMCWC and Straub Medical Center**
 - This week: Mon-Friday 8am - 4pm, and at KMCWC only: Saturday 8am – 4pm
 - Starting Monday 11/8: Mon - Friday 10am-6pm and at KMCWC only: Saturday 8am – 4pm
- **At Wilcox**, special clinic hours for children ages 5-11:
 - Friday, Nov. 5, from 2-5 p.m.
 - Additional dates through the end of November are also scheduled and posted online
- To schedule an appointment at one of these locations, visit www.hawaiipacifichealth.org/hph-covid-19-updates/vaccine-update.
- Adult vaccine continue to be provided at these sites. Walk-ins for first doses only, others by appointment.



Schedule a Mobile Vaccine Clinic Appointment on Oahu



Hawaii residents 5 years of age and older, please self-schedule below for the Mobile Vaccine Clinic.

Mobile Vaccine Appointments for ages 5-11 will start on 11/6/21

Please select your location:

I want to make a Vaccine Appointment for:

For immunocompromised individuals who are scheduling their third dose, the same mRNA vaccine (Pfizer or Moderna) should be used.

For eligible people who are scheduling their booster shot – either their third mRNA vaccine (Pfizer or Moderna) or their second Johnson & Johnson vaccine – you may choose any of the vaccines available at the site.

Parents are welcome to escort their child to their appointment. If you are unable, please complete the Department of Education consent form included with the pre-vaccination checklist provided in your upcoming appointment email that will be sent to you two days prior to your scheduled appointment or via the button below, and have your child bring it with them to their appointment.

Important Reminders

Only one appointment per qualified individual is allowed.

Preparing for Your Mobile Vaccine Clinic Appointment

Location

Various School and Community Locations

Please look for the mobile clinic schedule on this site when you schedule your appointment. Choose the location that's most convenient for you. Click the button below to view the full list of upcoming locations.

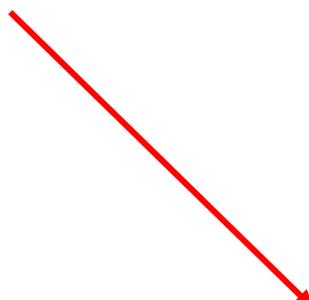
[VIEW FULL SCHEDULE](#)

Parking

Please look for designated visitor parking at each school or community location.

Vaccines for children ages 5-11 will be available at our **mobile vaccine clinic locations** on O'ahu with the HPH COVID-19 Vax Squad buses beginning Saturday, Nov. 6.

For a full schedule of upcoming mobile vaccine clinic locations, www.hawaiiPacificHealth.org/hph-covid-19-updates/vaccine-update, choose mobile vaccine clinic and click on



DOE and Other School Locations

Mobile vaccine clinics with our HPH **COVID-19 Vax Squad buses at O'ahu elementary schools.**

These vaccine clinics will be for students at these schools only, so scheduling will be managed by the school sites and information will be sent to parents from the individuals schools.

Drive Through Vaccinations

Two HPH **COVID-19 Vax Squad Drive Through** events on O'ahu:

- All days will be by appointment only: 8:30 to 4:45
- **Aloha Stadium** on Saturday and Sunday, November 13 and 14
 - Returning for second doses Saturday/Sunday, December 4/5
- **Kapolei High School** on Saturday and Sunday, November 20 and 21
 - Returning for second doses Saturday/Sunday, December 11/12
- We will also be able to offer adult vaccine doses by appointment

When and Where to Get 5-11 year olds COVID-19 Vaccine

- **At KMCWC and Straub Medical Center by appointment only**
 - This week: Mon-Sat 8am - 4pm, and at KMCWC only: Saturday, 8am – 4pm
 - Starting Monday 11/8: Mon – Friday, 10am-6pm and at KMCWC only: Saturday, 8am – 4pm
- **At Wilcox, special clinic hours for children ages 5-11:**
 - Friday, Nov. 5, from 2-5 p.m.
 - Additional dates through the end of November are also scheduled and posted online
- **To schedule an appointment at one of these locations, visit HawaiiPacificHealth.org/COVID19Vaccine**
- **At our **mobile vaccine clinic locations** on O‘ahu with the HPH COVID-19 Vax Squad buses beginning Saturday, Nov. 6.**
 - For a full schedule of upcoming mobile vaccine clinic locations, visit HawaiiPacificHealth.org/COVIDVaxSquad.
- **Mobile vaccine clinics with our **HPH COVID-19 Vax Squad buses at O‘ahu elementary schools.****
 - These vaccine clinics will be for students at these schools only, so scheduling will be managed by the school sites and information will be sent to parents from the individuals schools.
- **Two HPH **COVID-19 Vax Squad Drive Through** events on O‘ahu, by appointment only, from 8:30am-4:45pm**
 - **Aloha Stadium on Saturday and Sunday, November 13 and 14**
 - Second dose days on Saturday and Sunday, December 4 and 5
 - **Kapolei High School on Saturday and Sunday, November 20 and 21**
 - Second dose days on Saturday and Sunday, December 11 and 12

Q&A

Thank you!

- A recording of the meeting will be available afterwards.
- Unanswered question?
 - Contact us at Covid19Bulletin@hawaiiipacifichealth.org