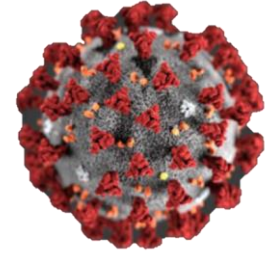


New Hampshire Coronavirus Disease 2019 Weekly Partner Call



November 4, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

Thursday noon-time partner calls will focus on science, medical, and vaccine updates with time for Q&A

Healthcare Provider & Public Health Partner Calls Have Been **Re-Scheduled** (to Avoid Holidays)

- Calls occurring on the **1st and 3rd Thursday** of each month from 12:00-1:00 pm (Next call will be November 18th)
- Webinar/call information (stays the same):
 - Zoom link: <https://nh-dhhs.zoom.us/j/94059287404>
 - Webinar ID: 940 5928 7404
 - Passcode: 353809
 - Telephone: 646-558-8656

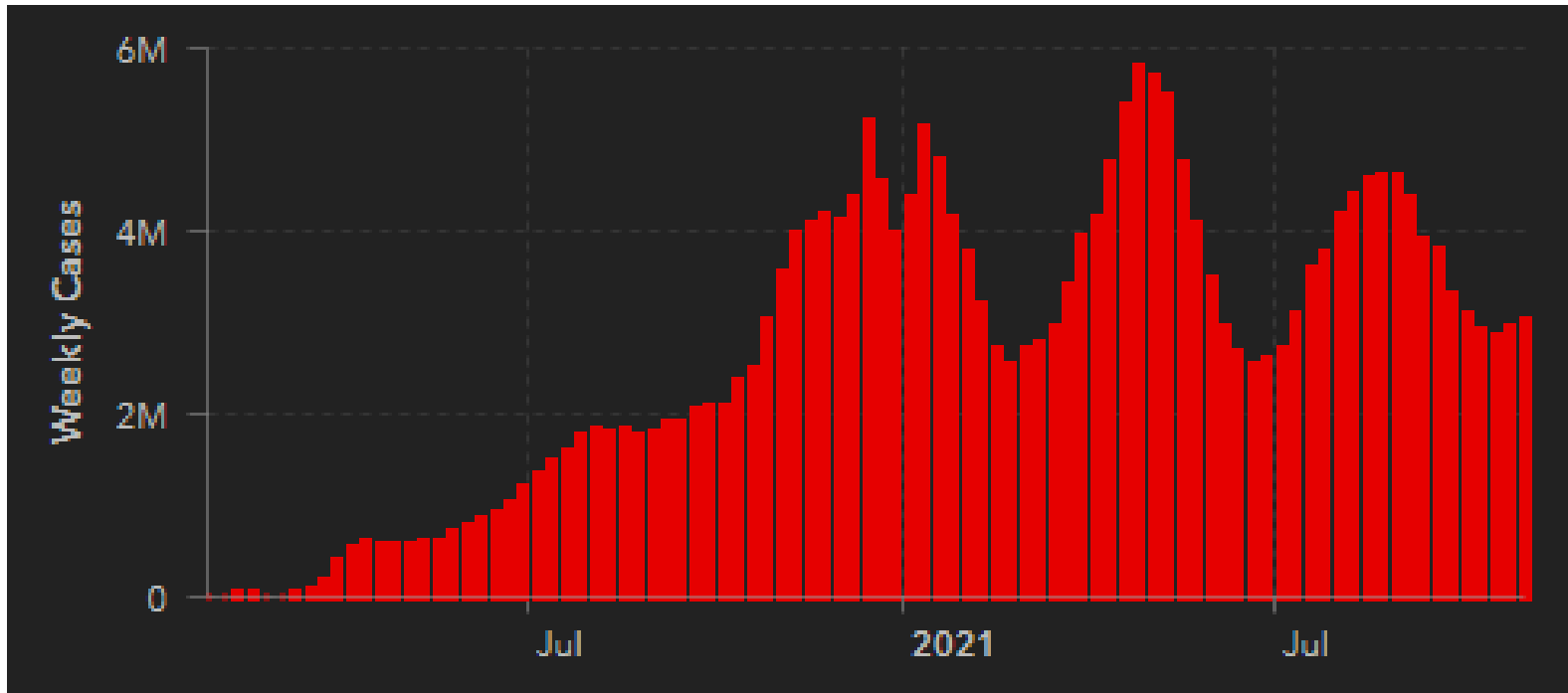
Agenda

- Epidemiology update – Dr. Daly
- Natural vs. vaccine induced immunity – Dr. Talbot
- COVID-19 vaccination for 5-11 year olds – Dr. Chan

Epidemiology Update

Global Epidemic Curve

- *248.2 million cumulative cases*



~3 million per week / ~450K cases per day

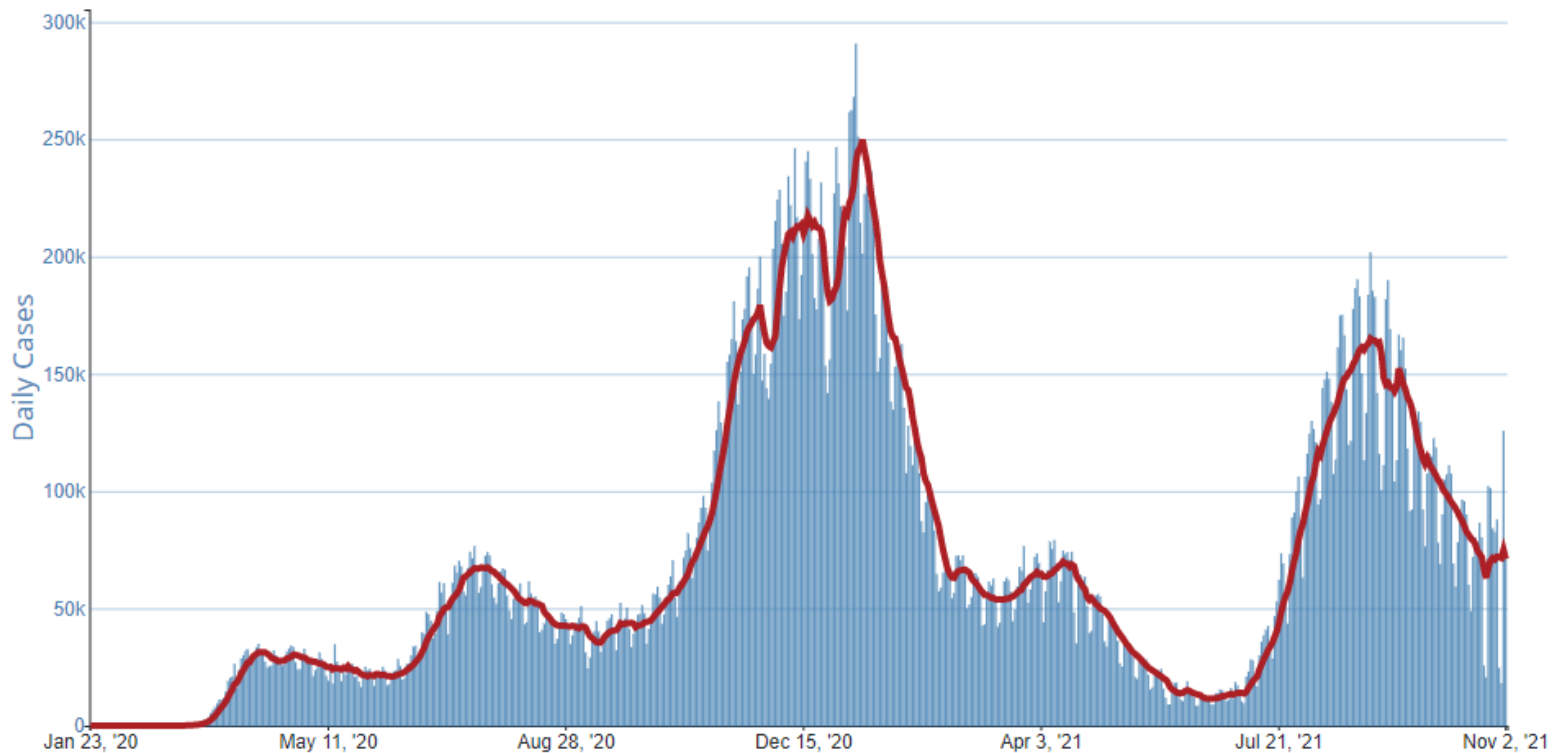
<https://coronavirus.jhu.edu/map.html>

U.S. Epidemic Curve

(new cases per day)

- *46.3 million cumulative cases*

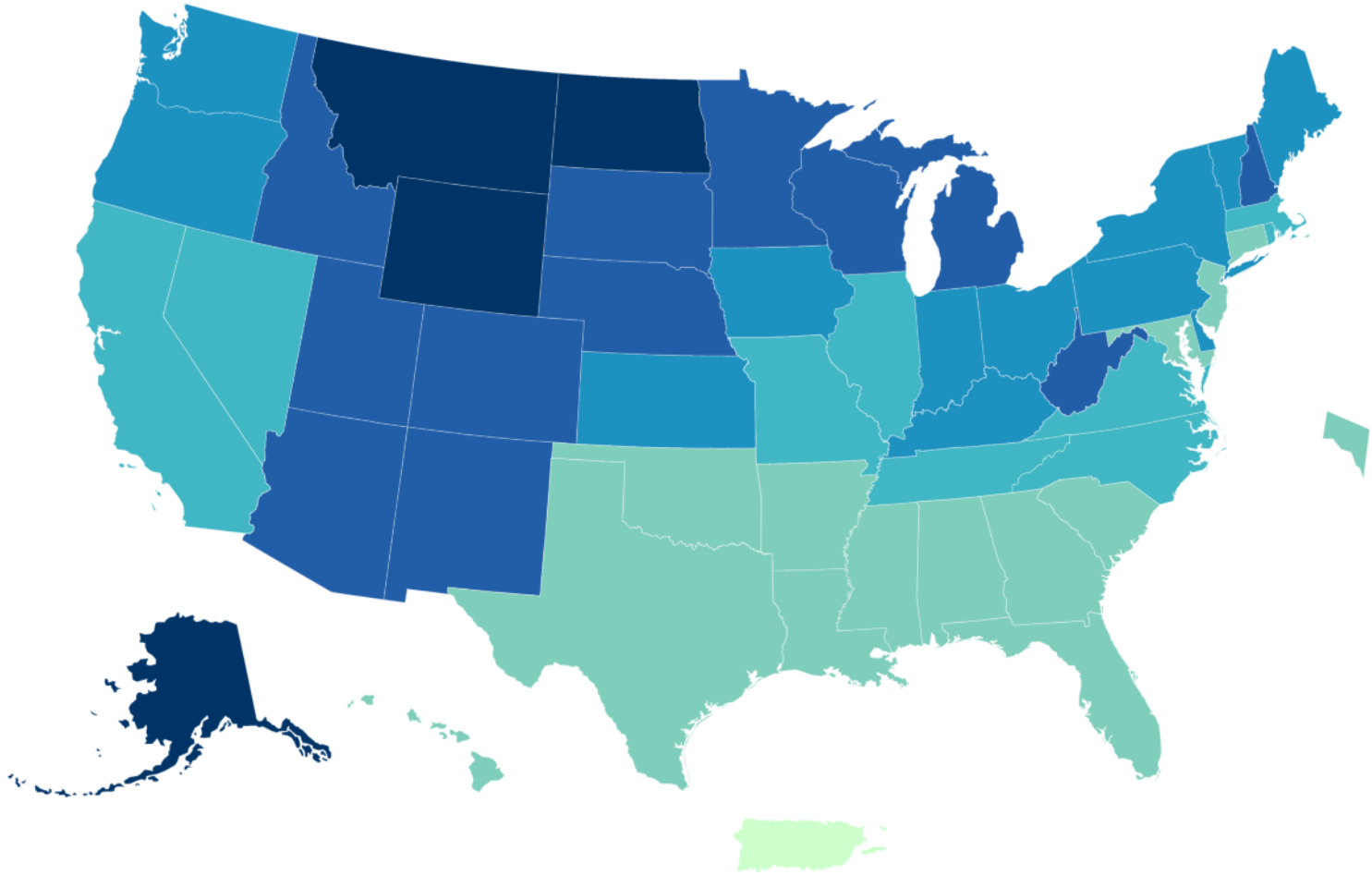
Daily Trends in Number of COVID-19 Cases in The United States Reported to CDC



7-day moving average: 75,000 cases per day

https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

US Hot Spots (7-day rate per 100,000)



Data not available ● 0 - 40.5 ● 55.5 - 102.2 ● 105.9 - 147.8 ● 169.0 - 242.3 ● 258.0 - 352.4 ● 443.2 - 570.9 ●

https://covid.cdc.gov/covid-data-tracker/#cases_community



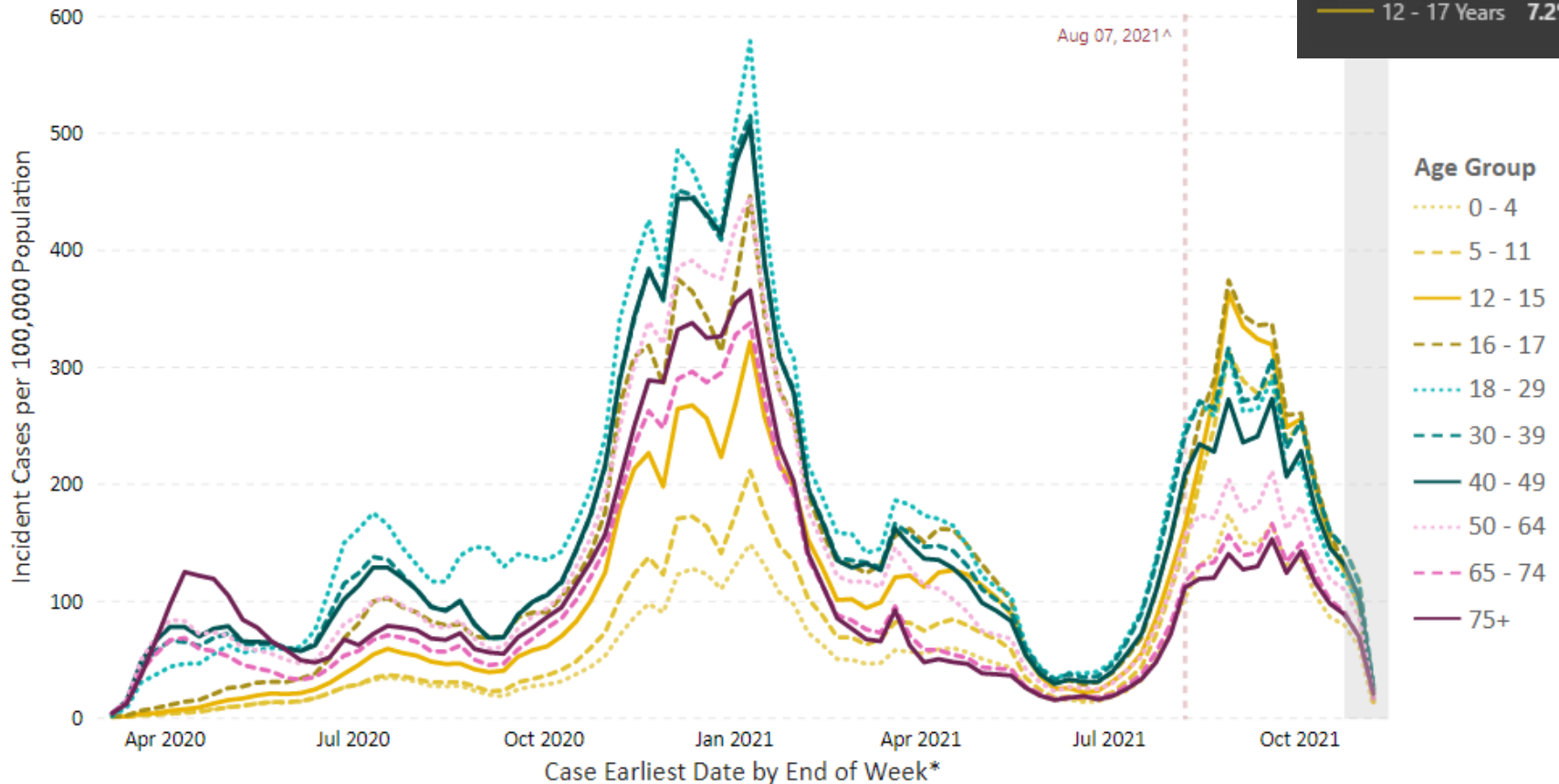
NH DIVISION OF
Public Health Services
Department of Health and Human Services

US Case Rates by Age Group

Region 1 Case Proportions

2021-11-06

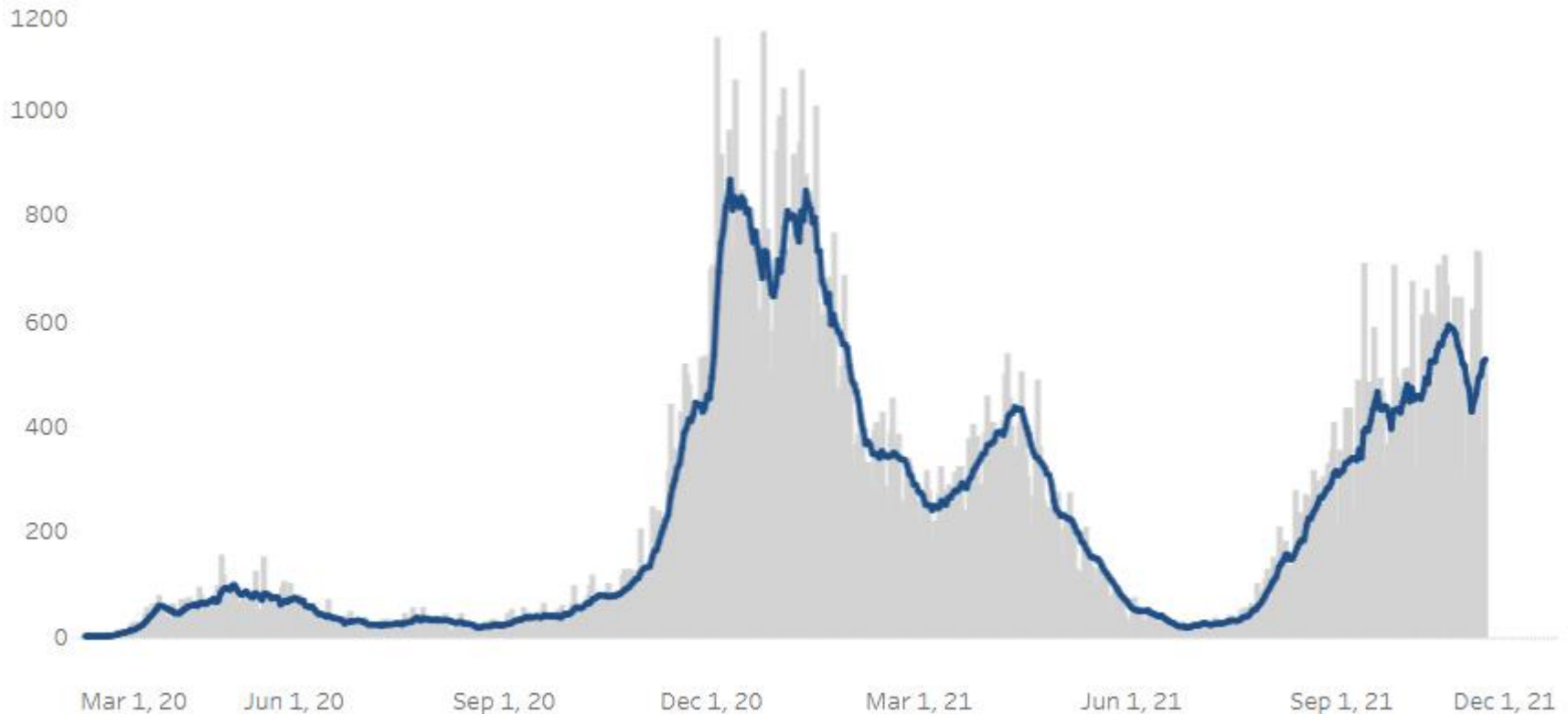
.....	0 - 4 Years	4.7%
- - - -	5 - 11 Years	11.6%
————	12 - 17 Years	7.2%



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

NH New Cases by Day

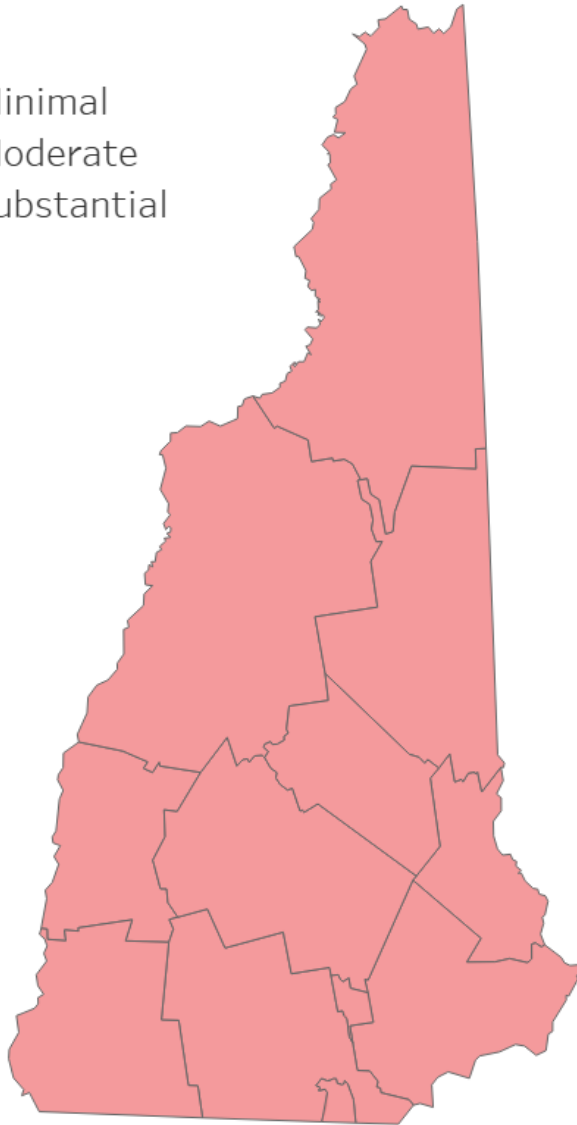
- *137,778 cumulative cases*



7-day moving average: 525 cases per day

<https://www.covid19.nh.gov/dashboard>

- Minimal
- Moderate
- Substantial



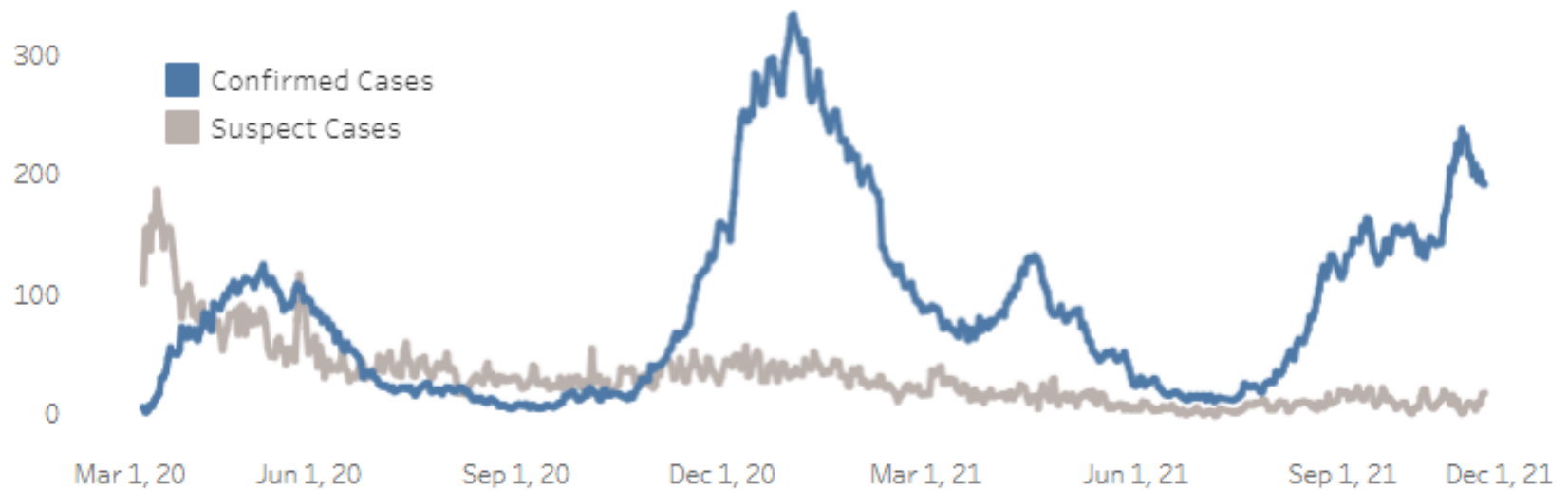
Community Level Transmission Metrics - Statewide (Not School Specific)

Level of Transmission	New Cases per 100k over 14 days	7-Day Total Test Positivity Rate
Substantial	512.2	6.4%

NH Levels of Community Transmission

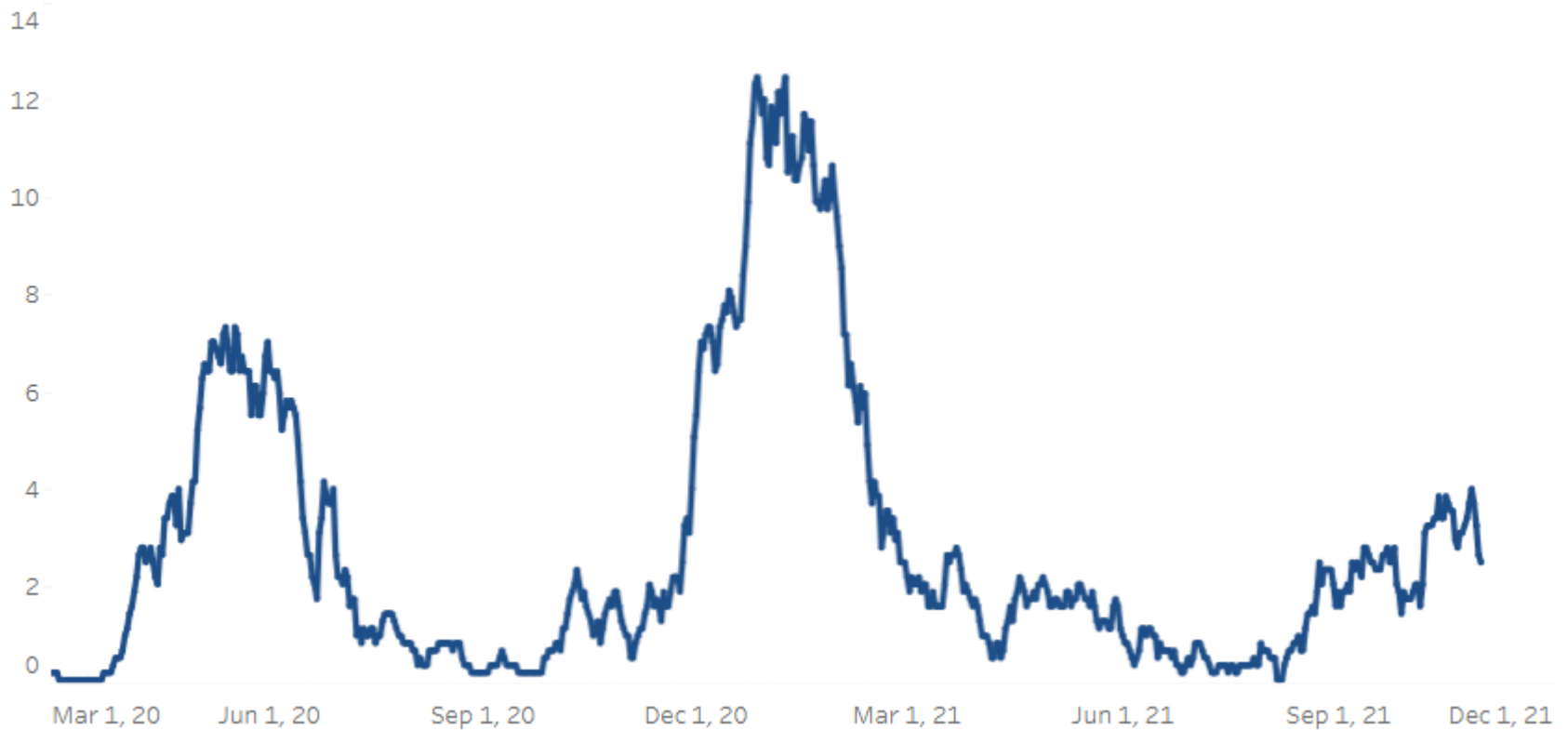
<https://www.covid19.nh.gov/dashboard/schools>

NH Hospitalizations



Current: 193

NH Deaths



Average: 2 – 3 per day

<https://www.covid19.nh.gov/dashboard/trends>

COVID-19 Clusters / Outbreaks

Total Onsite
Active Cases
242

Total Onsite
Recovered Cases
3,024

Current Onsite
Clusters
54

Current Onsite
Outbreaks
4

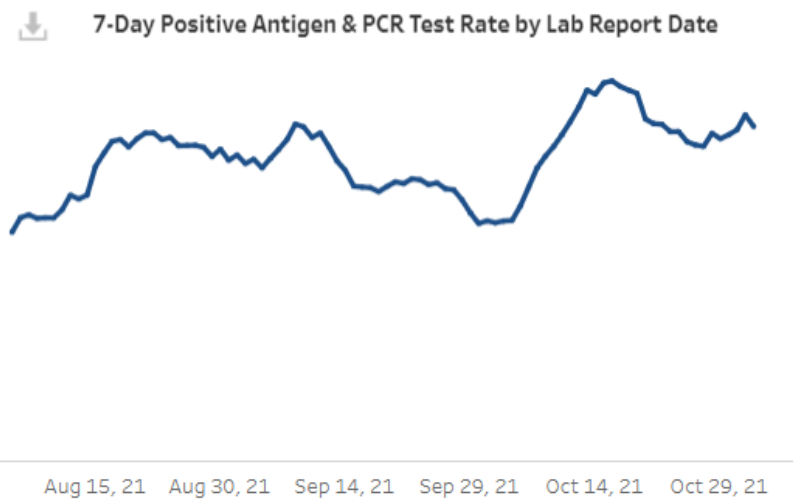
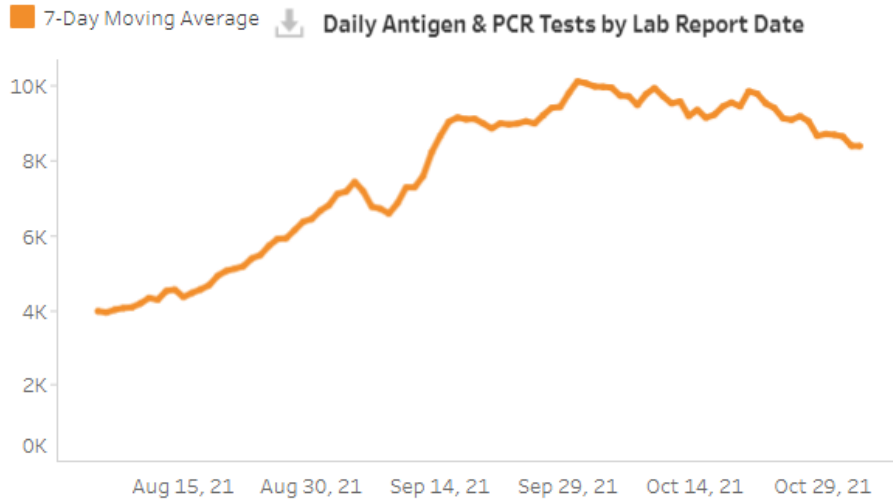
School Name	Active Cases	Recovered Cases	Cluster Count	Current Outbreak	Last Case Reported
Winnisquam Regional Middle School (Tilton)	18	17	2	Yes	11/02/2021
Trinity Christian School (Concord)	10	14	1	No	10/31/2021
Lancaster Elementary School (Lancaster)	7	43	0	No	11/02/2021
Barnstead Elementary School (Barnstead)	7	33	1	No	10/29/2021
Thorntons Ferry School (Merrimack)	6	8	1	No	10/28/2021
Kearsarge Reg. Elementary School - Bradford (Bradford)	5	6	1	No	11/01/2021
Southside Middle School (Manchester)	4	25	0	No	10/30/2021
Rundlett Middle School (Concord)	4	30	3	Yes	10/30/2021
Pine Tree Elementary School (Conway)	4	5	1	No	10/30/2021
Nute High School (Milton)	4	2	1	No	11/02/2021

Testing

58,718
Total Tests
Last 7 Days

3.9%
% of Population Tested
Last 7 Days

1 day
Median Time for Results
Last 7 Days



Average: ~8,000 tests per day (6.4% positive)

<https://www.covid19.nh.gov/dashboard/testing>

Natural vs. vaccine induced immunity

Three Questions

1. Should people with previous infection get vaccinated?
2. What is hybrid immunity?
3. Is nonCOVID mortality affected by COVID vaccine?



Natural Immunity

Should people with previous
infection get vaccinated?

Natural vs Vaccine Induced Immunity

Some unvaccinated individuals cite their own natural immunity from previous SARS-CoV-2 infection as reason to avoid vaccination

[MMWR](#) examined odds of hospitalization in 187 hospitals of VISION Network among adults presenting with COVID-19-like illness and compared odds of +PCR

1,020 unvaccinated, previously infected with 6,328 vaccinated, no previous infection

Infection or mRNA vaccination occurred 90-179 days earlier

Adjusting for sociodemographic and health characteristics, odds of hospitalization were 5.5 times higher (95% CI 2.75–10.99) in individuals who previously had COVID-19 compared to people fully vaccinated and no previous infection

Affirms Recommendation for Those Who Have Had SARS-CoV-2 Infections to Get Vaccinated

A study of hospitalized patients with symptoms similar to COVID-19* found...

Unvaccinated people with a previous infection were

**5x**
more likely to have a positive COVID-19 test
compared to vaccinated people†

*COVID-19-like illness hospitalizations 90-179 days after prior infection or full vaccination

†Received two doses of an mRNA vaccine and no previous infection

Get vaccinated
as soon as possible



bit.ly/MMWR7044e1

MMWR

CDC Science Brief, Oct 31 2021

- Review of > 90 published reports and pre-print studies on infection-induced immunity
- Data on vaccine-induced immunity is of higher quantity and quality
 - RCTs and prospective cohorts vs observational often retrospective studies
- Studies of infection-derived immunity limited to adults and those with symptomatic or severe disease

What We Know

- Recently fully vaccinated individuals and those recently infected both have low risk of subsequent infection for at least 6 months
 - Lab data suggest level of protection from previous infection may be reduced in mild disease or in response to certain variants
 - Elderly and immunocompromised may have less robust immune response and lower level of protection even within 6 months
- Antibody studies show that vaccination more consistently provides higher initial antibody levels than infection
 - Vaccination after infection provides high boost in antibody levels

Hybrid Immunity

Are people with previous infection at advantage following vaccination?

Hybrid Immunity

- Protection previously-infected individuals get when they are vaccinated
- Individuals who have recovered from COVID-19 tend to have stronger protection from subsequent infection after vaccination when compared to vaccinated people who had not been previously infected

In Qatar (Mostly Men <50)

VBT 65-82% Lower in Previously-Infected

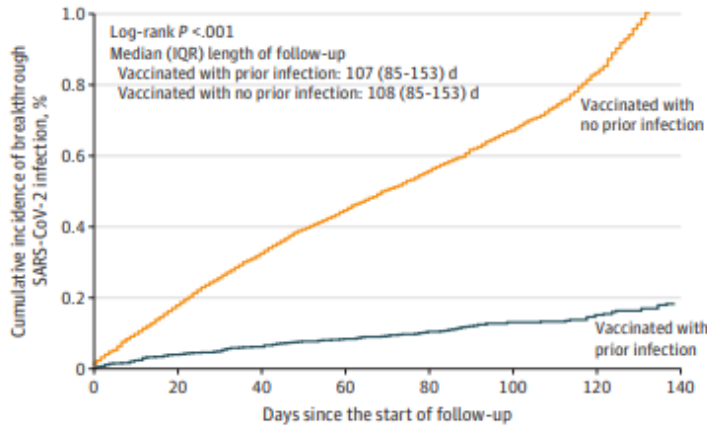
- 1,531,736 Qataris 14d after completion of mRNA series; 159,473 had prior COVID-19 infection
- Among Pfizer group:
 - 159 (0.16%) VBT with previous infection
 - 1 severe disease
 - 2,509 (0.86%) without previous infection
 - 26 severe disease, 2 critical
- Among Moderna:
 - 43 (0.07%) VBT with previous infection
 - 0 severe disease
 - 368 (0.22%) without previous infection
 - 1 severe disease

VBT cumulative incidence
0.15% with previous infection
0.83% for those without

VBT cumulative incidence
0.11% with previous infection
0.35% for those without

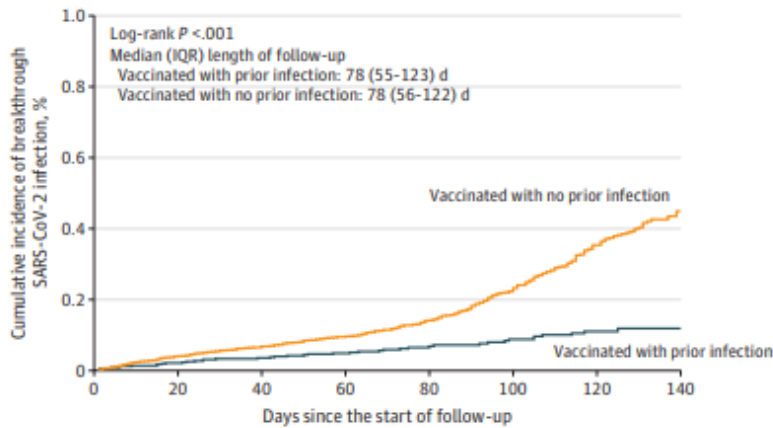
Figure 2. Cumulative Infection Incidence Among Matched Cohorts of BNT162b2-Vaccinated and mRNA-1273-Vaccinated Individuals With and Without Prior Infection

A Vaccination with BNT162b2



No. at risk ^a	0	20	40	60	80	100	120	140
Vaccinated with prior infection	99 226	96 960	93 683	85 593	80 822	58 258	36 385	29 650
Vaccinated with no prior infection	290 432	283 910	274 588	250 489	235 076	171 177	106 093	86 337

B Vaccination with mRNA-1273



No. at risk ^a	0	20	40	60	80	100	120	140
Vaccinated with prior infection	58 096	52 179	46 579	41 902	28 551	24 541	16 492	1 902
Vaccinated with no prior infection	169 514	152 478	136 504	127 722	82 960	72 662	49 144	5 566

Those infected $\geq 6m$ before their 1st vaccine dose had sig lower risk of reinfection than those infected $< 6m$ before 1st dose

Adjusted hazard ratio:

- 0.62 [95% CI, 0.42 to 0.92] for Pfizer
- 0.40 [95% CI, 0.18 to 0.91] for Moderna

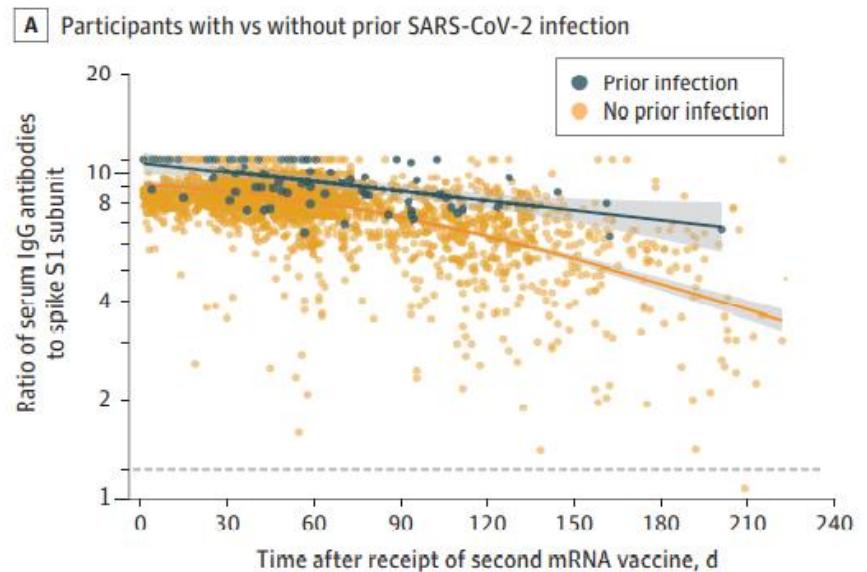
Antibody Durability After Vaccination Among HCWs With and Without Previous Infection

- Compared durability of spike IgG Abs in 3500 fully vaccinated HCWs at JHU with and without previous COVID-19 infection from June 2020 to Sep 3 2021
- Participants provided serum samples 14d after 2nd dose of mRNA vaccine and then again ≥ 90 d later
- Among 1,960 HCWs who gave serum samples, 73 (3.7%) had evidence of previous SARS-CoV-2 infection

Vaccinated HCWs with Previous Infection had Higher Ab Levels

Among vaccinated HCWs

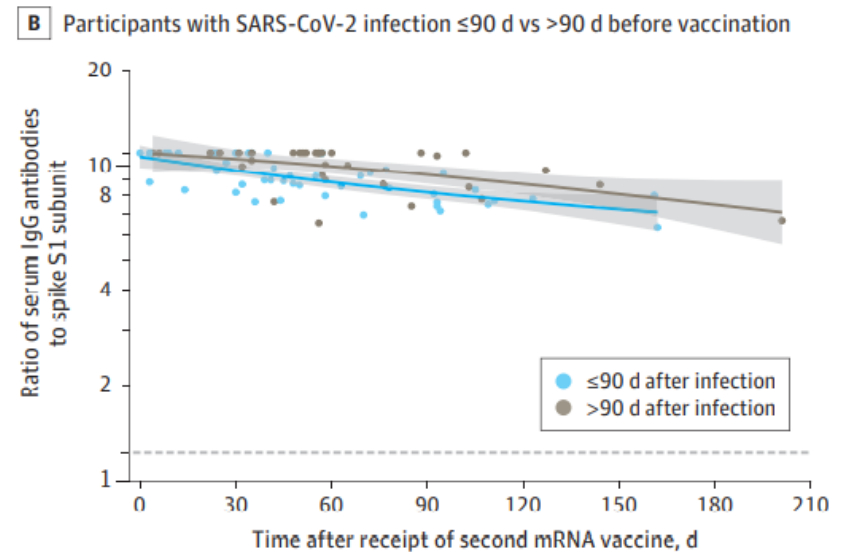
- WITHOUT previous infection, adjusted median Ab concentrations were 8.69 at 1m, 7.28 at 3m, and 4.55 at 6m after vaccination
- WITH previous infection, relative difference 14% at 1m, 19% at 3m, and 56% at 6m



Longer Interval Between Infection and First Vaccine Dose May Enhance Ab Response

Vaccinated HCWs infected > 90d before vaccination had higher adjusted Ab concentrations after vaccination than those infected within 90 days before vaccination

- 9% higher at 1m
- 13% higher at 3m



Off-Target Benefits of Vaccination

Is nonCOVID mortality affected
by vaccination?

Vaccination Protects Against COVID Death

- A [cohort study](#) of 19,625 Genesis nursing home residents found 7d mortality rates were lower among those who were vaccinated than unvaccinated (1st dose RR 0.34 [95%CI 0.22, 0.54]; 2nd dose RR 0.49 [95%CI: 0.34, 0.71])
- Now we have a population study of effects of vaccination on all-cause mortality risk

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70

October 22, 2021

COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021

Stanley Xu, PhD¹; Runxin Huang, MS¹; Lina S. Sy, MPH¹; Sungching C. Glenn, MS¹; Denison S. Ryan, MPH¹; Kerresa Morrissette, MPH¹; David K. Shay, MD²; Gabriela Vazquez-Benitez, PhD³; Jason M. Glanz, PhD⁴; Nicola P. Klein, MD, PhD⁵; David McClure, PhD⁶; Elizabeth G. Liles, MD⁷; Eric S. Weintraub, MPH⁸; Hung-Fu Tseng, MPH, PhD¹; Lei Qian, PhD¹

Does COVID-19 Vaccination Impact nonCOVID Mortality?

- Cohort study among ~11M persons ≥ 12 y enrolled in 7 Vaccine Safety Datalink (VSD) sites
 - VSD: research platform between CDC's Immunization Safety Office and 9 health care organizations for vaccine safety studies
 - Represents 3% US population
- Compared person-time
 - 6.4M vaccinated (3 EU vaccines) and 4.6M matched unvaccinated but who demonstrated health seeking behavior by getting flu shot in previous 2 years
- Endpoint was non-COVID mortality (because protective effect on COVID mortality already shown)
 - Non-COVID-19 deaths were those that did not occur within 30 days of an incident COVID-19 diagnosis or receipt of a positive test result for SARS-CoV-2 via PCR or antigen test

Vaccination Associated with Decreased non-COVID Mortality

3.5M Pfizer, 2.6M Moderna and 342,169 Janssen recipients

TABLE 2. Number of deaths and standardized mortality rate (deaths per 100 person-years) not associated with COVID-19 among COVID-19 vaccine recipients and unvaccinated comparison groups, by age, sex, and race/ethnicity — seven integrated health care organizations, United States, December 14, 2020–July 31, 2021

Characteristic	No. of deaths* (standardized mortality rate per 100 person-years)						
	mRNA vaccine				Janssen vaccine		
	Pfizer-BioNTech vaccine recipients [†]		Moderna vaccine recipients [†]		Unvaccinated comparison group [§]	Vaccine recipients [¶]	Unvaccinated comparison group [§]
After dose 1	After dose 2	After dose 1	After dose 2				
Overall**	1,157 (0.42)	5,143 (0.35)	1,202 (0.37)	4,434 (0.34)	6,660 (1.11)	671 (0.84)	2,219 (1.47)
Age group,^{††} yrs							
12–17	2 (0.01)	3 (0.01)	NA	NA	7 (0.01)	NA	NA
18–44	20 (0.02)	73 (0.02)	24 (0.03)	57 (0.02)	161 (0.07)	19 (0.04)	63 (0.08)
45–64	117 (0.16)	409 (0.13)	123 (0.16)	421 (0.17)	910 (0.51)	130 (0.25)	497 (0.66)
65–74	235 (0.79)	994 (0.62)	249 (0.63)	920 (0.58)	1,407 (2.13)	144 (1.49)	466 (2.77)
75–84	338 (2.32)	1,591 (1.89)	376 (2.00)	1,425 (1.77)	1,861 (6.34)	176 (5.59)	549 (9.13)
≥85	445 (7.90)	2,073 (6.85)	430 (7.16)	1,611 (6.57)	2,314 (18.76)	202 (15.35)	644 (23.76)
Sex^{§§}							
Male	587 (0.49)	2,584 (0.41)	640 (0.45)	2,352 (0.42)	3,265 (1.30)	326 (0.96)	1,102 (1.68)
Female	570 (0.35)	2,559 (0.29)	562 (0.30)	2,082 (0.28)	3,395 (0.96)	345 (0.75)	1,117 (1.31)
Race/Ethnicity**							
Hispanic	144 (0.36)	584 (0.29)	197 (0.35)	701 (0.33)	1,230 (1.07)	92 (0.91)	365 (1.24)
White, non-Hispanic	781 (0.47)	3,560 (0.39)	732 (0.39)	2,804 (0.37)	3,993 (1.17)	416 (0.85)	1,364 (1.58)
Asian, non-Hispanic	72 (0.23)	408 (0.23)	67 (0.18)	317 (0.21)	460 (0.78)	56 (0.83)	157 (1.09)
Black, non-Hispanic	84 (0.54)	300 (0.37)	130 (0.65)	340 (0.44)	623 (1.53)	65 (0.99)	187 (1.97)
Multiple races/Other/Unknown	76 (0.38)	291 (0.28)	76 (0.32)	272 (0.29)	354 (0.82)	42 (0.68)	146 (1.22)

Relative Risk for nonCOVID Mortality

TABLE 3. Adjusted relative risks for mortality of COVID-19 vaccine recipients and unvaccinated comparison groups*— seven integrated health care organizations, United States, December 14, 2020–July 31, 2021

Characteristic	Vaccine type, aRR, (95% CI)				
	Pfizer-BioNTech		Moderna		Janssen
	After dose 1	After dose 2	After dose 1	After dose 2	After dose 1
Overall[†]	0.41 (0.38–0.44)	0.34 (0.33–0.36)	0.34 (0.32–0.37)	0.31(0.30–0.33)	0.54 (0.49–0.59)
Age group,[§] yrs					
12–17	0.85 (0.38–1.90)	0.73 (0.33–1.64)	NA	NA	NA
18–44	0.37 (0.24–0.57)	0.36 (0.28–0.46)	0.46 (0.31–0.69)	0.38 (0.29–0.50)	0.55 (0.36–0.82)
45–64	0.35 (0.29–0.42)	0.28 (0.25–0.31)	0.31 (0.26–0.37)	0.33 (0.29–0.37)	0.40 (0.34–0.49)
65–74	0.39 (0.33–0.47)	0.32 (0.29–0.35)	0.32 (0.27–0.37)	0.28 (0.26–0.32)	0.50 (0.39–0.63)
75–84	0.38 (0.33–0.46)	0.32 (0.29–0.35)	0.32 (0.27–0.38)	0.29 (0.26–0.32)	0.58 (0.48–0.71)
≥85	0.46 (0.39–0.54)	0.39 (0.36–0.43)	0.38 (0.32–0.45)	0.35 (0.31–0.39)	0.68 (0.56–0.82)
Sex[¶]					
Male	0.41 (0.37–0.46)	0.35 (0.33–0.38)	0.36 (0.32–0.40)	0.33 (0.31–0.35)	0.52 (0.46–0.60)
Female	0.41 (0.36–0.45)	0.33 (0.31–0.36)	0.33 (0.29–0.37)	0.30 (0.28–0.32)	0.56 (0.49–0.64)
Race/Ethnicity^{**}					
Hispanic	0.36 (0.30–0.42)	0.29 (0.26–0.32)	0.33 (0.29–0.39)	0.31 (0.28–0.34)	0.58 (0.46–0.73)
White, non-Hispanic	0.44 (0.38–0.50)	0.37 (0.34–0.40)	0.35 (0.30–0.40)	0.32 (0.30–0.35)	0.53 (0.46–0.61)
Asian, non-Hispanic	0.31 (0.25–0.39)	0.32 (0.28–0.36)	0.23 (0.18–0.30)	0.27 (0.23–0.30)	0.68 (0.52–0.88)
Black, non-Hispanic	0.38 (0.31–0.47)	0.27 (0.24–0.31)	0.42 (0.35–0.49)	0.29 (0.25–0.32)	0.47 (0.36–0.63)
Multiple races/Other/Unknown	0.46 (0.36–0.60)	0.35 (0.30–0.41)	0.40 (0.30–0.51)	0.36 (0.30–0.42)	0.52 (0.38–0.71)

Limitations and Conclusion

- Observational, and individual-level confounders were not adjusted for
- Healthy vaccinee effects were found in all but youngest age group
- COVID-19 vaccinees may have been inherently healthier or engage in fewer risk behaviors
- Findings might not be applicable to the general population
- Conclusion: “This cohort study found lower rates of non–COVID-19 mortality among vaccinated persons compared with unvaccinated persons in a large, sociodemographically diverse population during December 2020–July 2021. There is no increased risk for mortality among COVID-19 vaccine recipients”

Three Questions

Q Should people with previous infection get vaccinated?

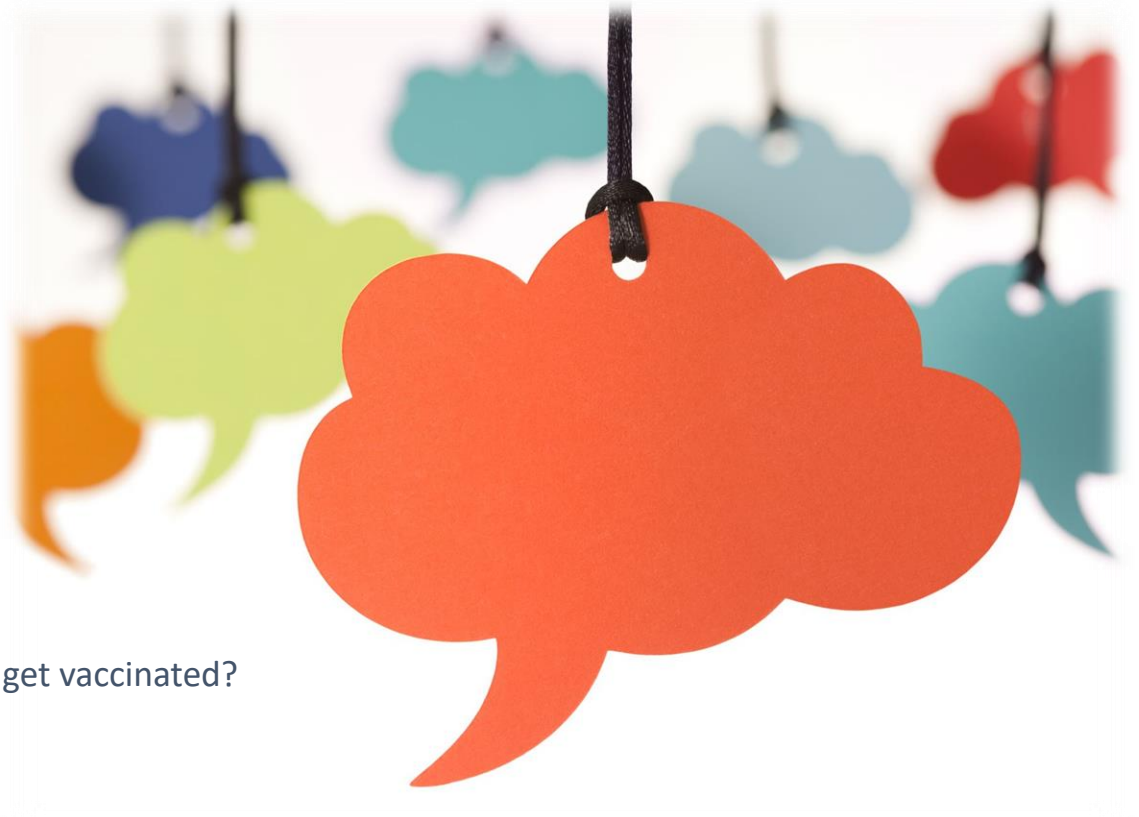
Answer: YES!

Q What is hybrid immunity?

Answer: Greater protection and antibody levels for those who had previous infection then get vaccinated

Q Is nonCOVID mortality affected by COVID vaccine?

Answer: Lower nonCOVID mortality in those vaccinated



Pfizer-BioNTech COVID-19 Vaccine for Children 5-11 Years Old ("pediatric vaccine")

COVID-19 Vaccination Now Authorized & Recommended for Children 5-11 Years Old

CDC Recommends Pediatric COVID-19 Vaccine for Children 5 to 11 Years

Media Statement

For Immediate Release: Tuesday, November 2, 2021

Contact: [Media Relations](#)

(404) 639-3286

Today, CDC Director Rochelle P. Walensky, M.D., M.P.H., endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine. CDC now expands vaccine recommendations to about 28 million children in the United States in this age group and allows providers to begin vaccinating them as soon as possible.

THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network
DHHS.Health.Alert@dhhs.nh.gov
November 3, 2021, Time 1500 (3:00 PM EDT)
NH-HAN 20211103



COVID-19 Pandemic, Update # 48 ***Pfizer-BioNTech COVID-19 Vaccine for Children 5-11 Years Old***

- The Pfizer-BioNTech COVID-19 pediatric vaccine (for 5-11 year olds) is a different formulation with different packaging and storage, dilution/preparation, and administration instructions
- Vaccine selection is based on age of the vaccine recipient on the day of vaccination (and NOT size or weight)
- New separate FDA [Fact Sheet for Healthcare Providers](#)
- New separate FDA [Fact Sheet for Recipients and Caregivers](#)
- Still a 2-dose series administered 21 days apart
- Dose is 10 mcg (0.2 mL after appropriate dilution)

Age Range	Dilution Information	Doses Per Vial After Dilution	Dose Volume
5 through 11 years (Vial labels state: Age 5y to <12y)	Dilute with 1.3 mL sterile 0.9% Sodium Chloride Injection, USP prior to use	10	0.2 mL

Dilution and Preparation Instructions

Pfizer-BioNTech COVID-19 Vaccine Vial with Orange Cap and a Label with Orange Border – VIAL VERIFICATION



✓ Orange plastic cap and label with orange border.

- Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has an orange plastic cap and a label with an orange border and states “Age 5y to < 12y.”

Pfizer-BioNTech Pediatric Vaccine Ingredients

- mRNA
 - Lipids:
 - (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
 - 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
 - 1,2-distearoyl-sn-glycero-3-phosphocholine
 - cholesterol
 - Sucrose
 - Tromethamine
 - Tromethamine hydrochloride
-
- The new pediatric formulation uses tromethamine (Tris) buffer instead of the phosphate buffered saline (PBS), and excludes sodium chloride and potassium chloride
 - Diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes sodium chloride to the dose
 - See CDC's [Appendix C](#) for comparison

Appendix C: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the [Pfizer-BioNTech](#), [Moderna](#), and [Janssen](#) COVID-19 Vaccines reported in the prescribing information for each vaccine.*

Description	Pfizer-BioNTech (mRNA) For persons aged 5-11 years (10µg dose) formulation	Pfizer-BioNTech (mRNA) For persons aged ≥12 years (30µg dose) formulation	Moderna (mRNA) For persons aged ≥18 years	Janssen (viral vector) For persons aged ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG:1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102:heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose		



Pfizer Vaccine Study: 5-11 Year Olds

- Study of 1,518 vaccine recipients and 750 placebo (saline) recipients in the Pfizer-BioNTech randomized, double-blinded, placebo-controlled clinical trial (Cohort 1)
 - 95% had safety follow-up for ≥ 2 months after dose #2 (normally FDA has required a median follow-up of at least 2 months)
- Safety data from an *additional* 1,591 vaccine recipients and 788 placebo recipients was included in review (Cohort 2); 71% had follow-up for at least 2 weeks after dose #2
 - Safety data on a total of 3,109 vaccine recipients
- Neutralizing antibody titers were compared one month after dose #2 in 5-11 year olds (10 mcg dose) vs. 16-25 year olds (30 mcg dose)
- Vaccine efficacy (VE) was assessed for prevention of lab-confirmed symptomatic COVID-19, starting 7 days after dose #2

Vaccine Safety: 5-11 Year Olds (Combined Cohorts 1 & 2: N=3,109)

- No concerning safety signals
- Serious adverse side effects occurred in 0.1% of vaccine recipients vs. 0.1% of placebo recipients
 - All serious adverse events reported in the study were unrelated to vaccination
 - No reports of myocarditis/pericarditis or anaphylaxis
 - No participant deaths
- Common vaccine side effects were common – fewer systemic side effects in 5-11 year olds (10 mcg dose) compared to older vaccine recipients (30 mcg dose)

Common Vaccine Side Effects

Injection Site Symptoms:

- Pain (84%)
- Redness (26%)
- Swelling (20%)
- Lymphadenopathy (<1%)

Systemic Symptoms:

- Fatigue (52%)
- Headache (38%)
- Muscle pain (18%)
- Chills (12%)
- Fever (8%)
- Joint pain (8%)

Neutralizing Antibody Titers Were “Non-Inferior”

Table 7: SARS-CoV-2 GMTs (NT50) at 1 Month After Primary Series – Immunobridging Subset - Participants 5 Through 11 Years of Age (Study 3) and Participants 16 Through 25 Years of Age (Study 2) – Without Evidence of SARS-CoV-2 Infection up to 1 Month After Dose 2 – Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine		GMT Ratio (95% CI) (5 Through 11 Years of Age/ 16 Through 25 Years of Age) ^{d,e}
		10 mcg/Dose* 5 Through 11 Years of Age n ^a =264	30 mcg/Dose [±] 16 Through 25 Years of Age n ^a =253	
Assay	Time Point ^b	GMT ^c (95% CI ^c)	GMT ^c (95% CI ^c)	
SARS-CoV-2 neutralization assay - NT50 (titer) ^f	1 month after Dose 2	1197.6 (1106.1, 1296.6)	1146.5 (1045.5, 1257.2)	1.04 (0.93, 1.18)

Abbreviations: CI = confidence interval; GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation; NAAT = nucleic-acid amplification test; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Vaccine Efficacy Estimate: 5-11 Year Olds

**Table 6: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection Prior to 7 Days After Dose 2 – Phase 2/3 –Children 5 Through 11 Years of Age
Evaluable Efficacy Population**

First COVID-19 occurrence from 7 days after Dose 2 in children 5 through 11 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine[±] 10 mcg/dose N^a=1305 Cases n^{1b} Surveillance Time^c (n^{2d})	Placebo N^a=663 Cases n^{1b} Surveillance Time^c (n^{2d})	Vaccine Efficacy % (95% CI)
Children 5 through 11 years of age	3 0.322 (1273)	16 0.159 (637)	90.7 (67.7, 98.3)

Note: Confirmed cases were determined by Reverse Transcription-Polymerase Chain Reaction (RT-PCR) and at least 1 symptom consistent with COVID-19 (symptoms included: fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting).

COVID-19 Vaccine Dosing and Schedule (CDC Summary Table)

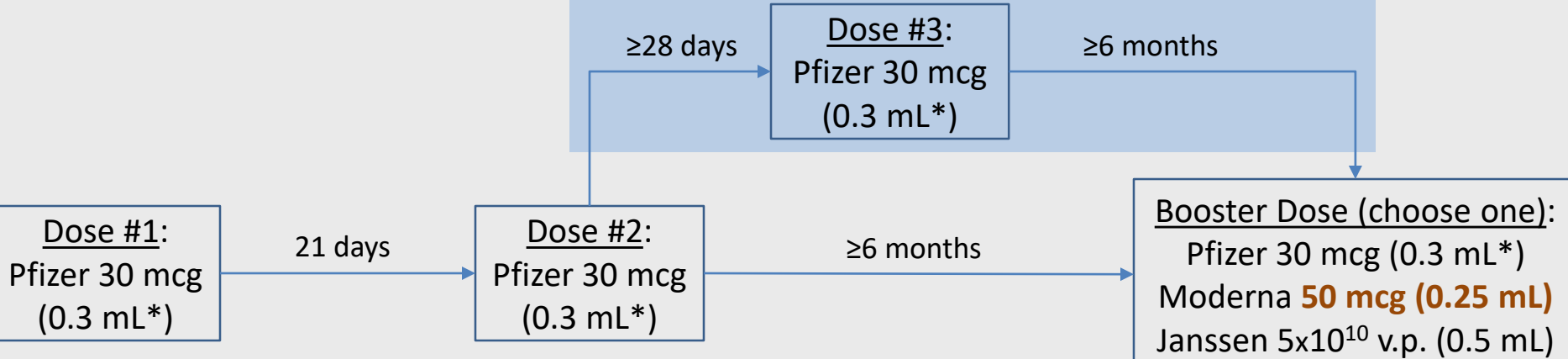
Primary and additional primary doses vaccine manufacturer	Age of recipient (years)	Vial cap color denoting formulation	Concentration of mRNA per primary dose	Primary dosage injection volume	Number of doses in primary series (interval between doses)	Additional primary dose in immunocompromised people (interval since 2nd dose)	Interval between last primary (including additional) to booster dose
Pfizer-BioNTech	5–11	Orange	10 µg	0.2 ml	2 (21 days)	Not recommended	Booster not recommended
Pfizer-BioNTech	12–17	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	Booster not recommended
Pfizer-BioNTech	≥18	Purple	30 µg	0.3 ml	2 (21 days)	1 (≥28 days)	≥ 6 months
Moderna	≥18	Not applicable	100 µg	0.5 ml	2 (28 days)	1 (≥28 days)	≥ 6 months
Janssen	≥18	Not applicable	5×10 ¹⁰ viral particles	0.5 ml	1 (Not applicable)	Not applicable	≥ 2 months

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

Pfizer-BioNTech (“Pfizer”) Vaccine Recs by Age

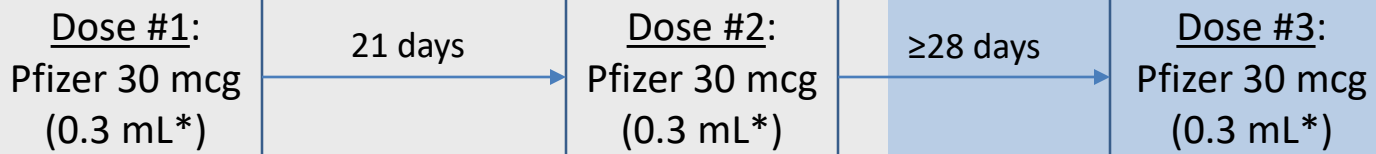
18+ Years of Age

Moderate-Severely Immunocompromised

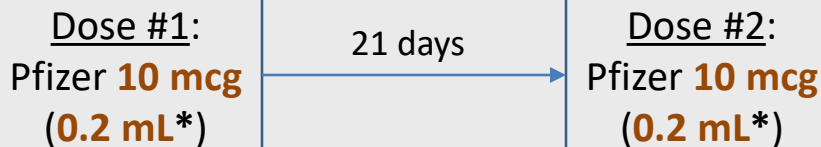


12-17 Years of Age

Moderate-Severely Immunocompromised



5-11 Years of Age



* Volume administered after appropriate dilution of multi-dose vial; vial prep and dilution differ for the different Pfizer formulations

Summary

- Healthcare providers need to closely review the new Pfizer-BioNTech pediatric vaccine storage, preparation/dilution, and administration instructions
- When vaccine recipients are being administered a COVID-19 vaccine, healthcare providers should start by verifying:
 - Purpose of vaccination (i.e., primary series vs. 3rd dose for immunocompromised vs. booster dose)
 - Verify the age eligibility of the vaccine recipient
 - Ensure the vaccine recipient is given the correct vaccine information (i.e., the FDA Fact Sheet for the appropriate vaccine product and age group)
 - Administer the appropriate vaccine, at the appropriate dose for indication and vaccine recipient age
- Review CDC's updated Interim Clinical Considerations for Use of COVID-19 Vaccines for more detailed guidance, including updates to COVID-19 vaccine contraindications and precautions

Updated Vaccine Contraindications/Precautions

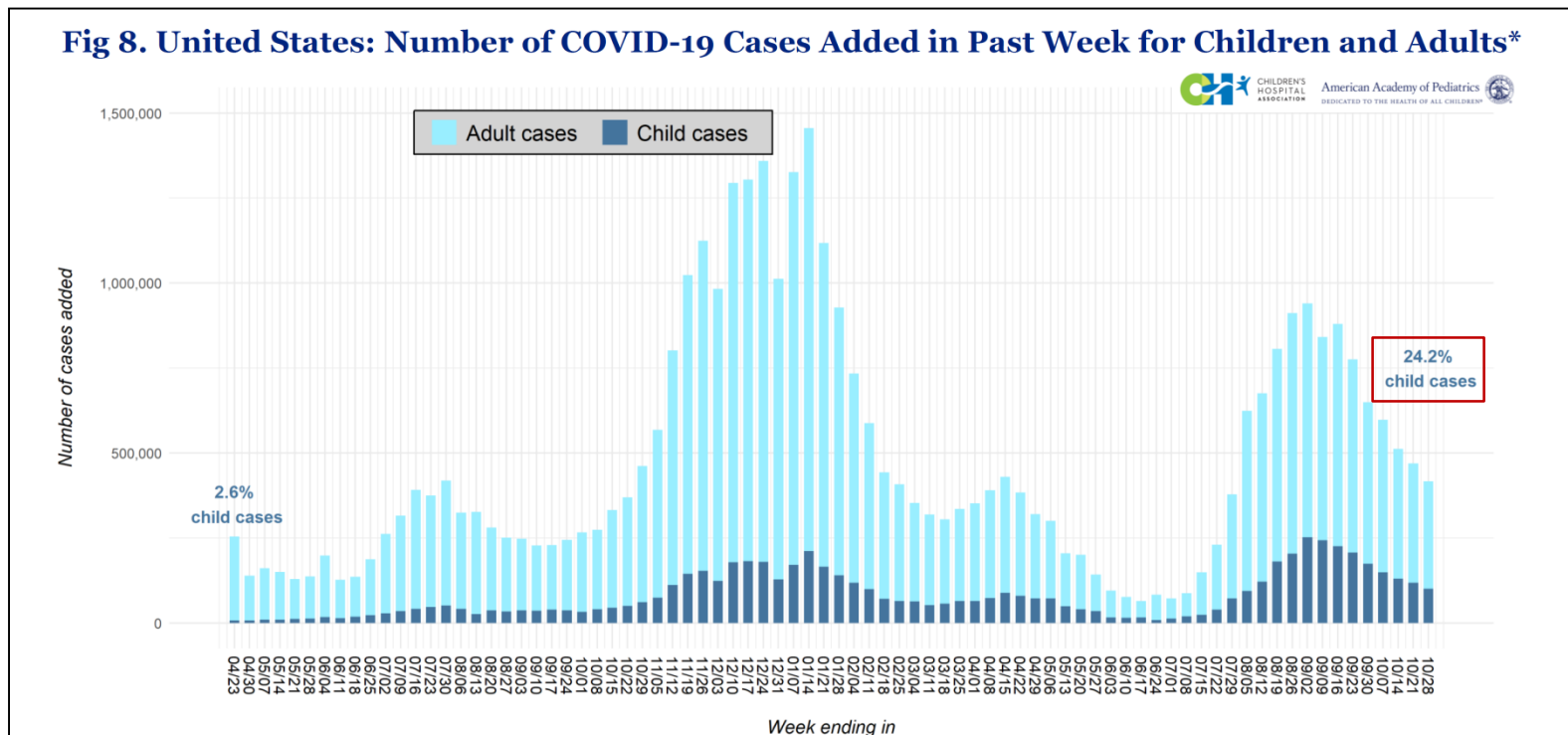
Appendix B: Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine^{1,2} • Known (diagnosed) allergy to a component of a COVID-19 vaccine¹ 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> • Any immediate allergic reaction³ to other vaccines (non-COVID-19) or injectable therapies⁴ • Non-severe, immediate (onset <4 hours) allergic reaction² after a previous dose of COVID-19 vaccine⁶ <p>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa⁵</p>	<p>Among people without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> • Allergy (including anaphylaxis) to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies, including anaphylaxis • Family history of allergies
<p>Actions:</p> <ul style="list-style-type: none"> • Do not vaccinate • Consider referral to allergist-immunologist • Consider other vaccine alternative if age appropriate^{1,5} 	<p>Actions:</p> <ul style="list-style-type: none"> • Risk assessment • 30-minute observation period if vaccinated • Consider referral to allergist-immunologist 	<p>Actions:</p> <ul style="list-style-type: none"> • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

Impact of COVID-19 on Children & Importance of Vaccinating Children

U.S. COVID-19 Infection and Mortality Data

- Over the entire pandemic, out of >36 million COVID-19 cases in the U.S., 15-16% have been in children under the age of 18 years (5% of cases have occurred in children 5-11 years of age)
 - More recently during Delta surge: ~25% of infections occurring in children under the age of 18 years (13% in children 5-11 years)



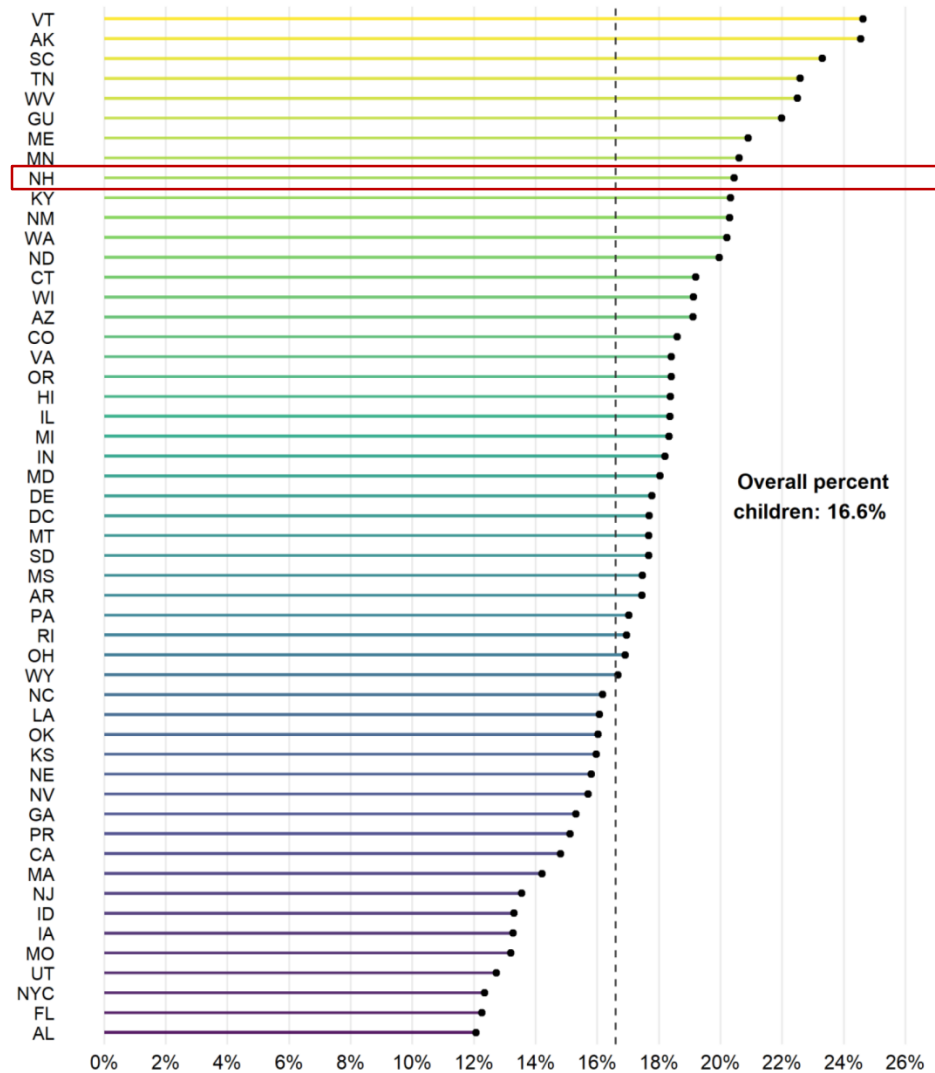
<https://covid.cdc.gov/covid-data-tracker/#demographics>

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

Proportion of Infections in Children by State

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

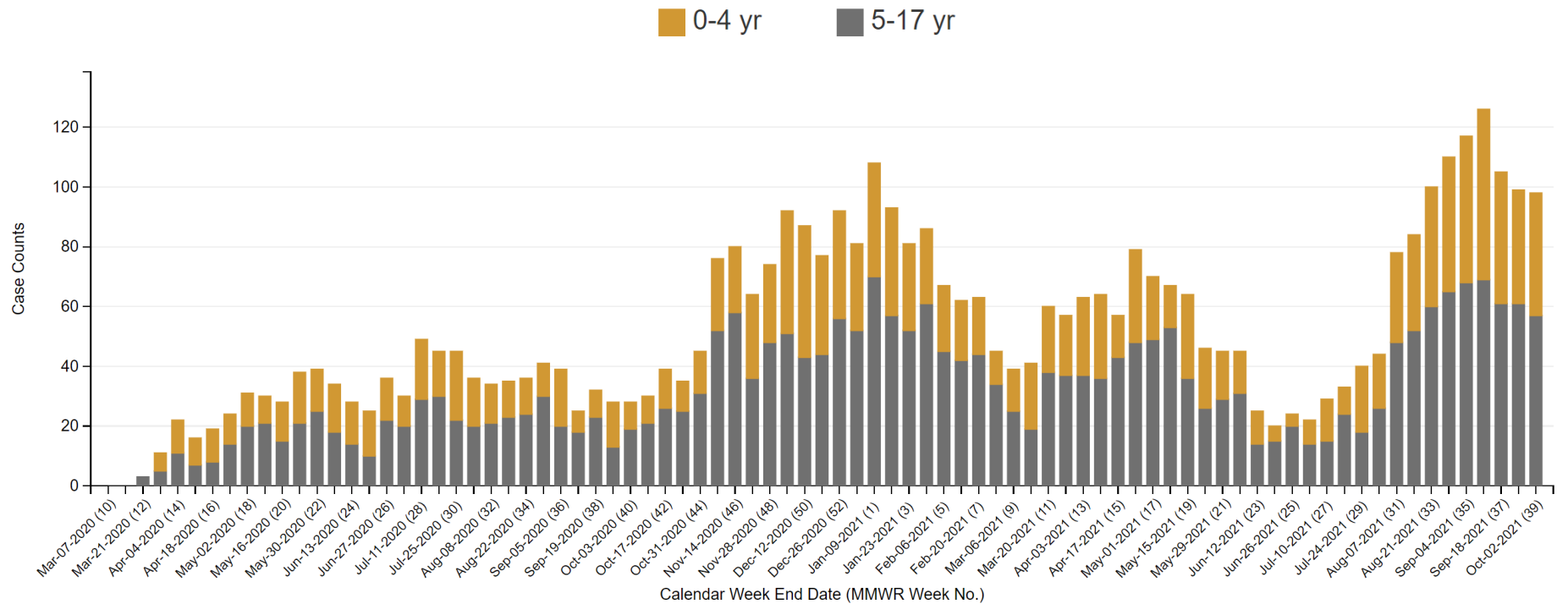


See detail in Appendix: Data from 48 states, NYC, DC, PR, and GU (TX excluded from figure)
 All data reported by state/local health departments are preliminary and subject to change
 Analysis by American Academy of Pediatrics and Children's Hospital Association
 As of 6/30/21, NE COVID-19 dashboard is 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



U.S. COVID-19 Hospitalizations by Age

Preliminary data as of Oct 23, 2021
COVID-19-Associated Hospitalizations by Age



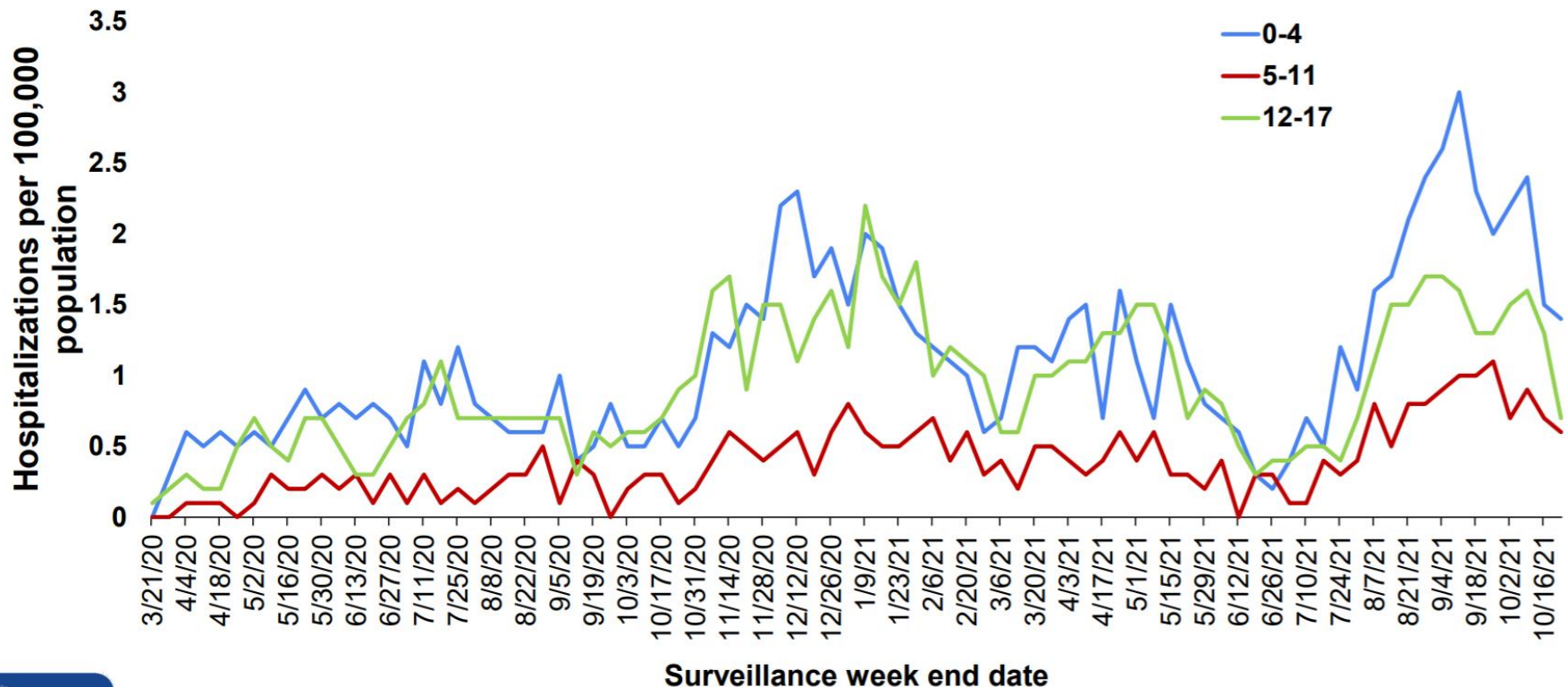
Cumulative case count by age group

	0-4 yr	5-17 yr	Total
2020-21	1647	2668	4315

<https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network>

U.S. COVID-19 Hospitalization Rates by Age

COVID-19-Associated Weekly Hospitalizations per 100,000 — COVID-NET by Age Group, March 21, 2020–October 23, 2021



<https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covid-net/purpose-methods.html>, Data are preliminary and subject to change

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-COVID-Jefferson-508.pdf>

Multisystem Inflammatory Syndrome in Children (MIS-C), United States

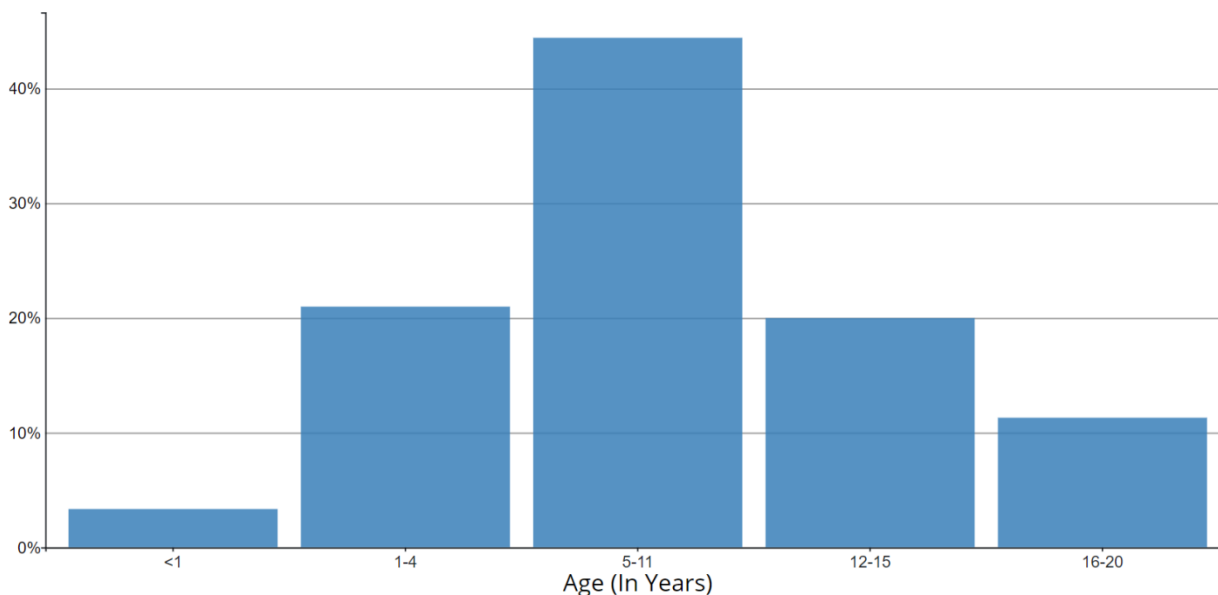
TOTAL MIS-C PATIENTS MEETING CASE DEFINITION*

5,217

TOTAL MIS-C DEATHS MEETING CASE DEFINITION

46

MIS-C Patients By Age Group



U.S. COVID-19 Infection and Mortality Data

- 805 deaths from COVID-19 reported in the U.S. in children <18 years of age, including 173 deaths in children 5-11 years of age (*still 0 deaths from COVID-19 in children in NH*)

Data from 624,628 deaths. Age group was available for 624,537 (99%) deaths.

Age Group	Percentage of deaths	Count of deaths	Percent of US population
0-4 Years	<0.1	256	6
5-11 Years	<0.1	173	8.7
12-15 Years	<0.1	205	5.1
16-17 Years	<0.1	171	2.5

COVID-19 Is a Vaccine Preventable Disease

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.

Indirect impacts of COVID-19 pandemic on children

-  - Worsening of mental or emotional health
-  - Widening of existing education gaps
-  - Decreased physical activity and increased body mass index (BMI)
-  - Decreased healthcare utilization
-  - Decreased routine immunizations
-  - Increase in Adverse Childhood Experiences (ACEs)
-  - Loss of caregivers

Importance of COVID-19 Vaccination

Possible impact with vaccination of 5–11-year-old

Prevention of
COVID-19 cases
>90%



Likely prevention of COVID-19 related:

Post-COVID conditions

MIS-C

Hospitalization

ICU

Death

Possibility for more social interactions
and uninterrupted school

Importance of COVID-19 Vaccination

Possible impact with vaccination of 5–11-year-old

Possible prevention of transmission to vulnerable family members



Parental participation on work force may be more stable and predictable

Importance of COVID-19 Vaccination

Possible impact with vaccination of 5–11-year-old



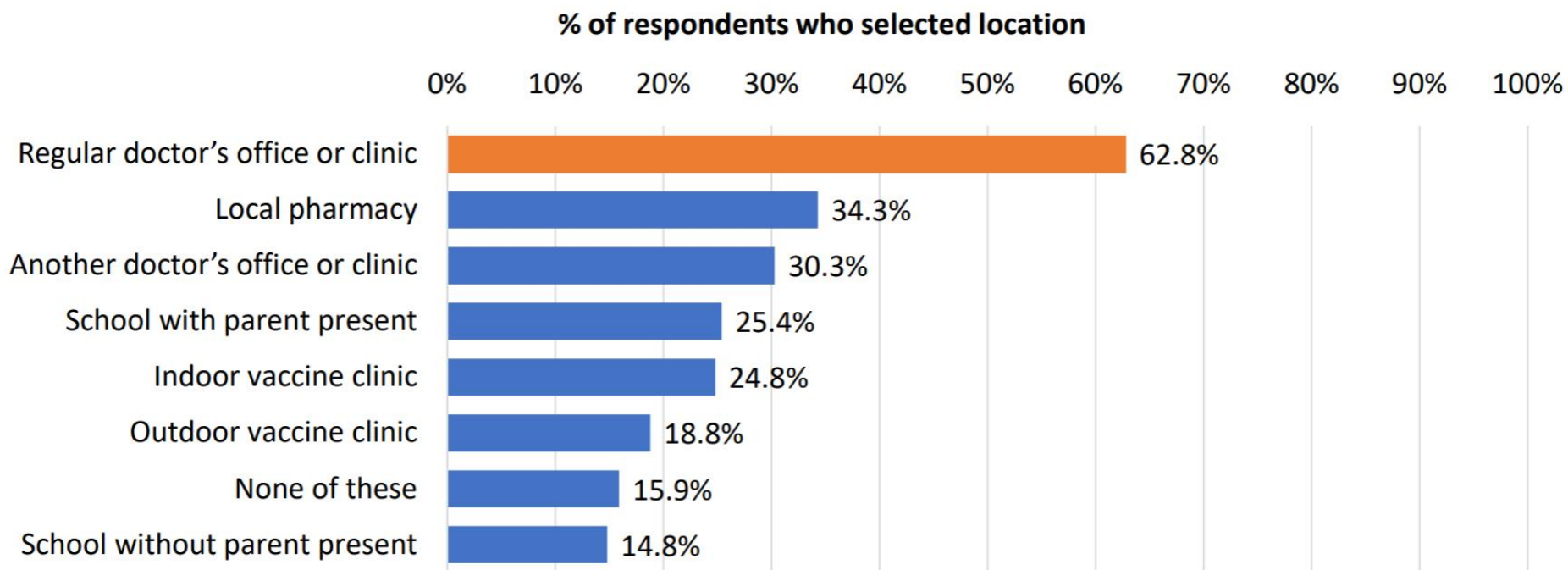
Could result in **lower transmission** within schools and community

More confident return to in-person learning

Summary

- COVID-19 vaccination in children age 5-11 years is safe and effective
- Achieving a high level of COVID-19 vaccination among children, adolescents, and adults is important to protect the individual's health and help relieve the direct and indirect impacts of this pandemic
- Go to vaccines.gov/search to find COVID-19 vaccination locations by specific vaccine product
- We need healthcare providers to enroll to become COVID-19 vaccine providers (see instructions [How to Become a COVID-19 Vaccine Provider](#))

Parents' Preferred Location to Vaccinate Their 5–11-Year-Old Children*



*Unpublished CDC/RAND/University of Iowa data. 1,028 parents surveyed in late September/early October

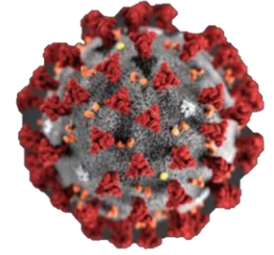


Q&A

Healthcare Provider & Public Health Partner Calls Have Been **Re-Scheduled** (to Avoid Holidays)

- Calls occurring on the **1st and 3rd Thursday** of each month from 12:00-1:00 pm (Next call will be November 18th)
- Webinar/call information (stays the same):
 - Zoom link: <https://nh-dhhs.zoom.us/j/94059287404>
 - Webinar ID: 940 5928 7404
 - Passcode: 353809
 - Telephone: 646-558-8656

New Hampshire Coronavirus Disease 2019 Weekly Partner Call



November 4, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

Thursday noon-time partner calls will focus on science, medical, and vaccine updates with time for Q&A