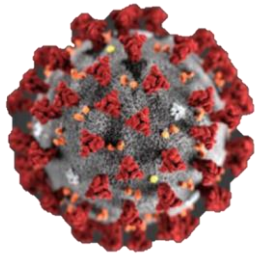


New Hampshire Coronavirus Disease 2019 Weekly Partner Call

August 19, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

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

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

Thursday Noon-Time Partner Call Schedule

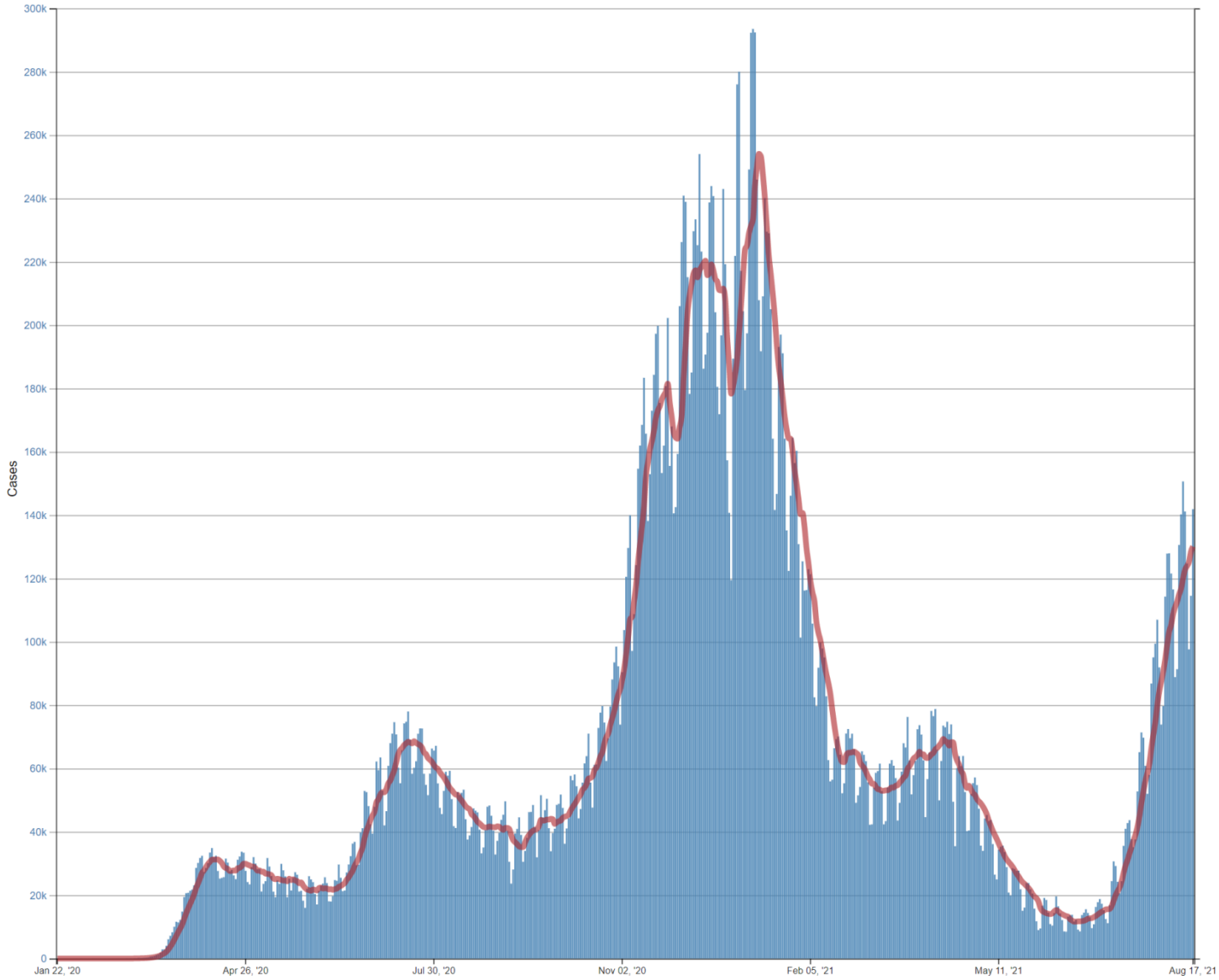
- We are changing our Thursday noon-time partner calls from scheduled/weekly to ad-hoc calls
- We will have calls as needed to discuss priority topics/issues – these will be announced through our HAN and on our healthcare provider website: https://www.covid19.nh.gov/resources/general-provider-covid-19-resources-and-information

Agenda

- Epidemiology update
- HAN Update #44: COVID-19 mRNA vaccine 3rd dose recommendations for people who are moderately to severely immunocompromised
- Federal HHS announcement about booster doses for people who received either the Pfizer or Moderna COVID-19 vaccines for their primary series
- Questions & Answers (Q&A)

Epidemiology Update

U.S. National Daily Incidence of COVID-19



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

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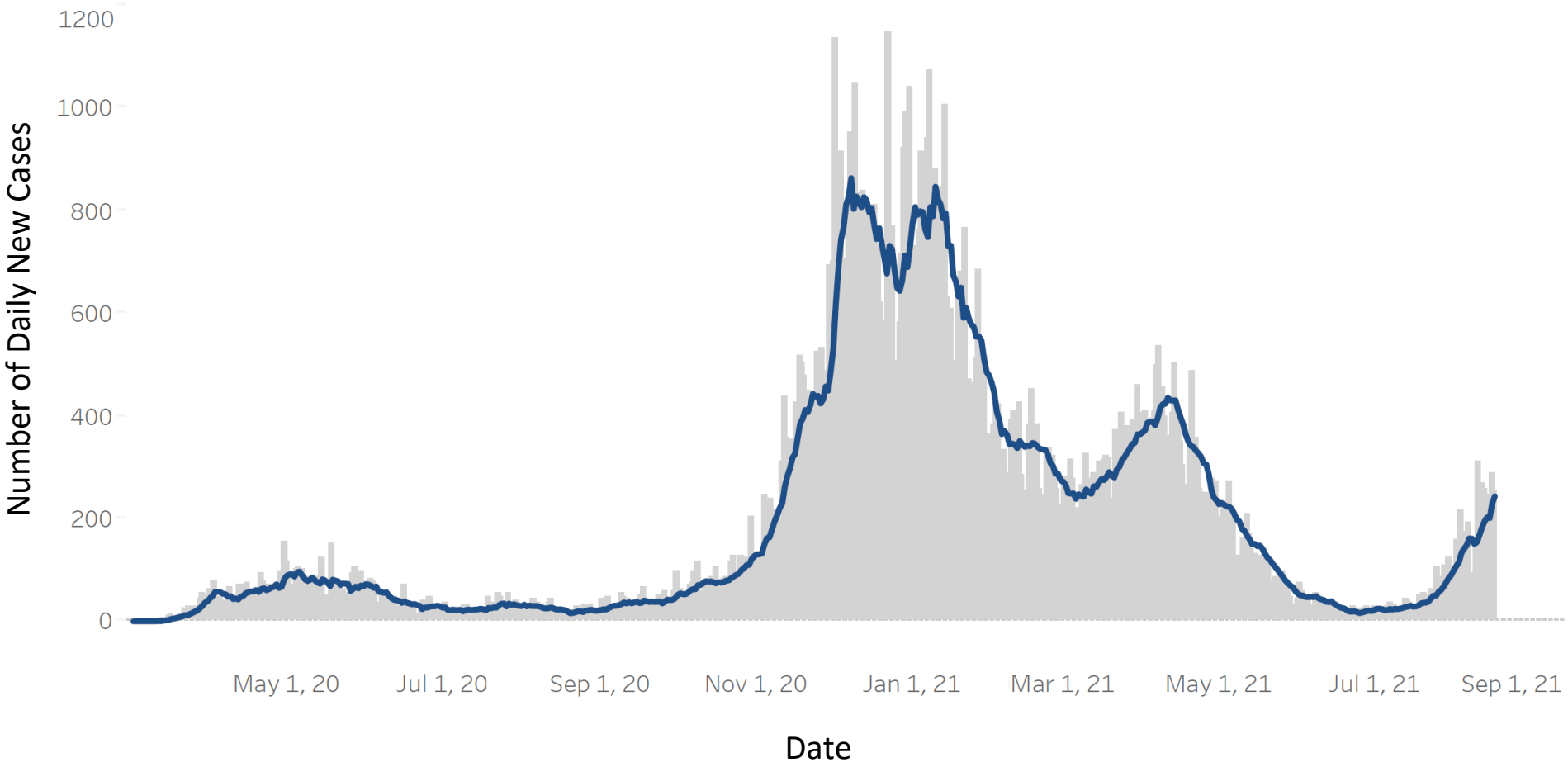
Number of New COVID-19 Cases per Day in NH



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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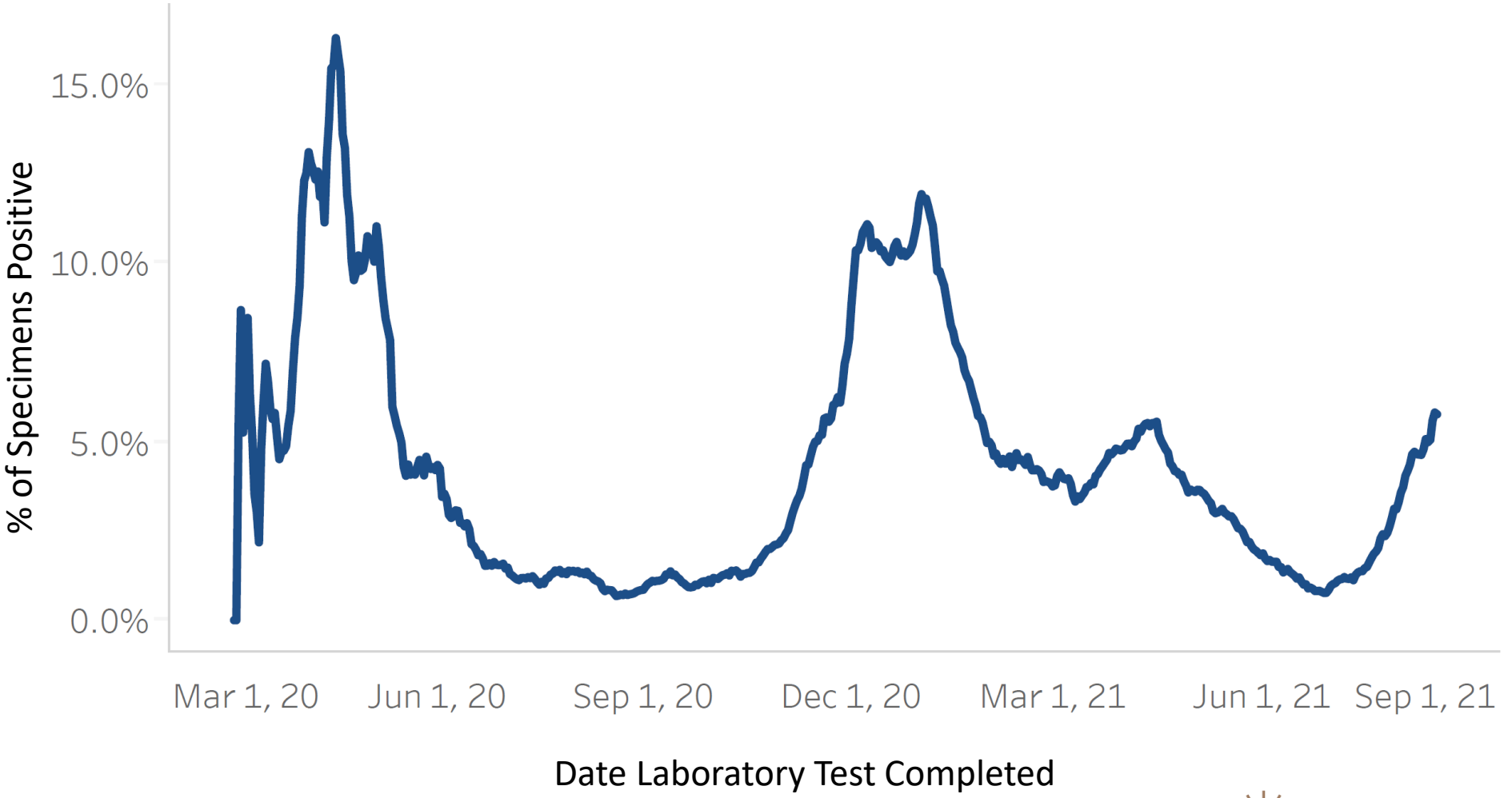
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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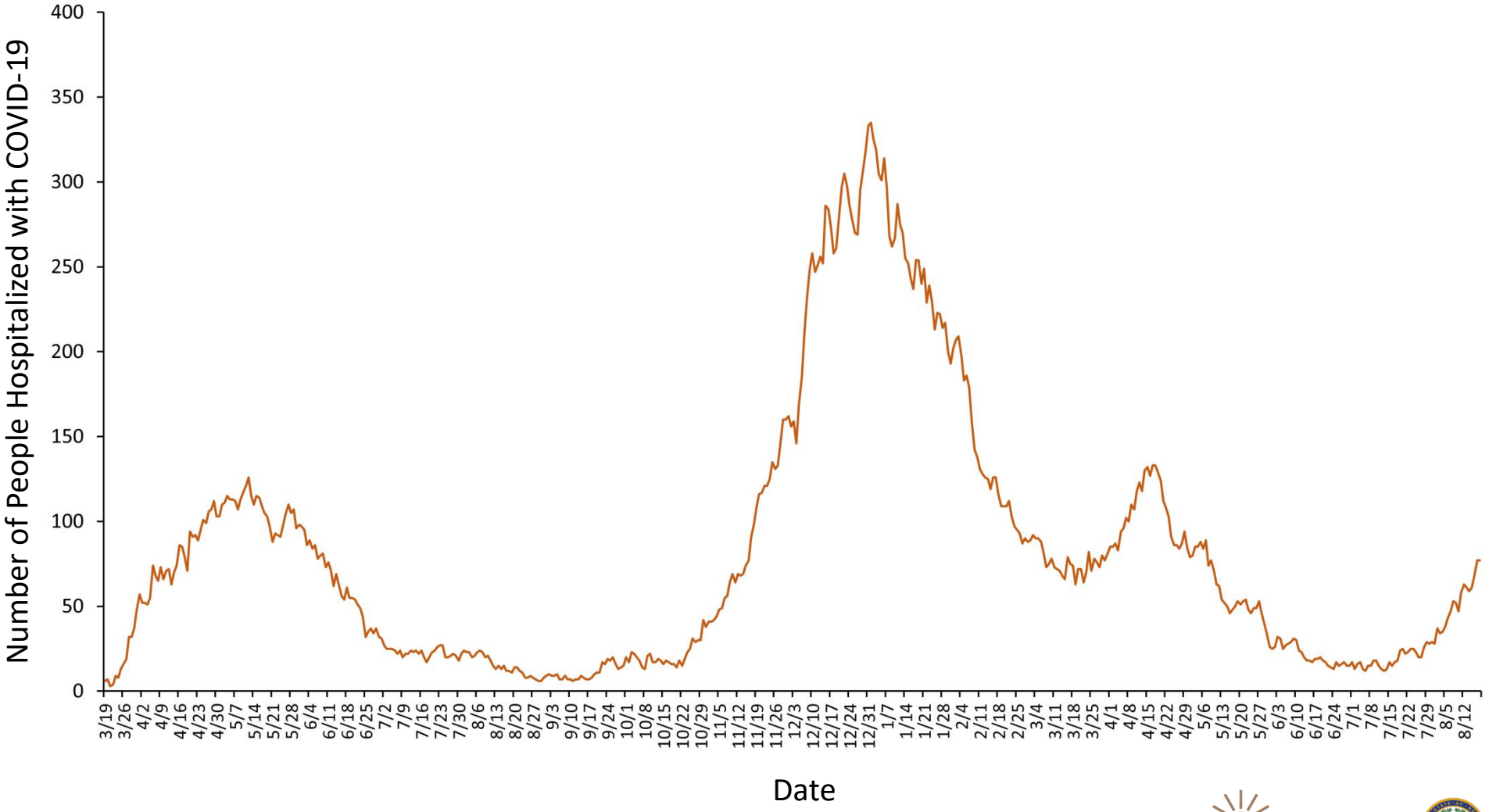
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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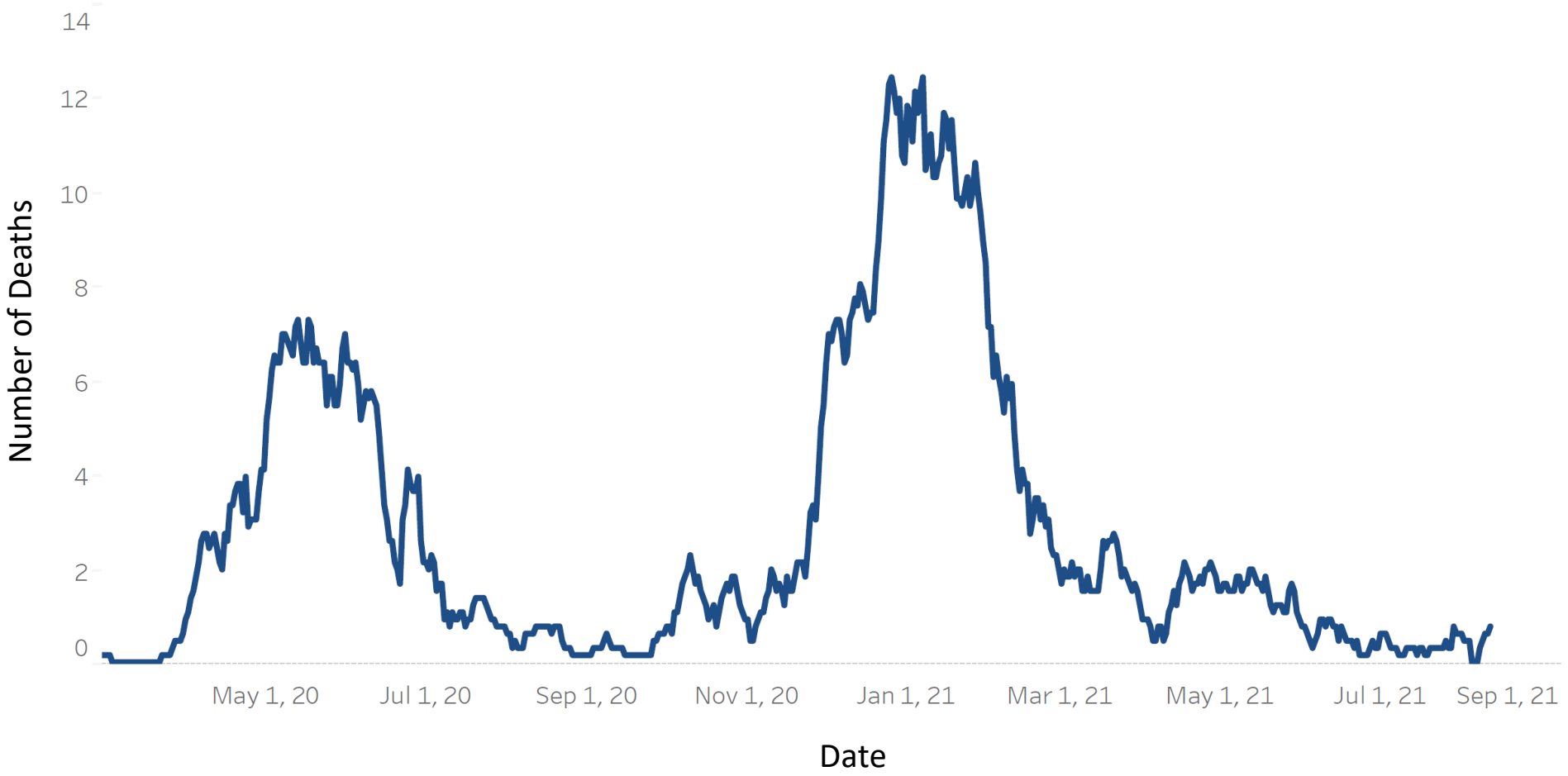
Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



https://www.nh.gov/covid19/dashboard/overview.htm#dash

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Level of Community Transmission in NH

Statewide Level of Transmission

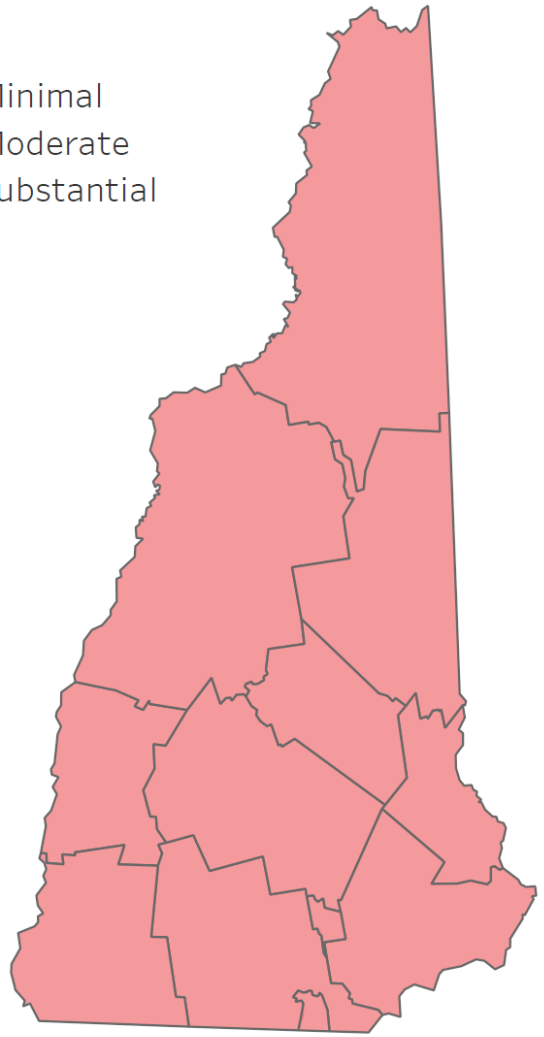
Substantial

New Cases per 100k over 14 days

204.7

7-Day Total Test Positivity Rate

5.8%



Data as of: 8/18/2021

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

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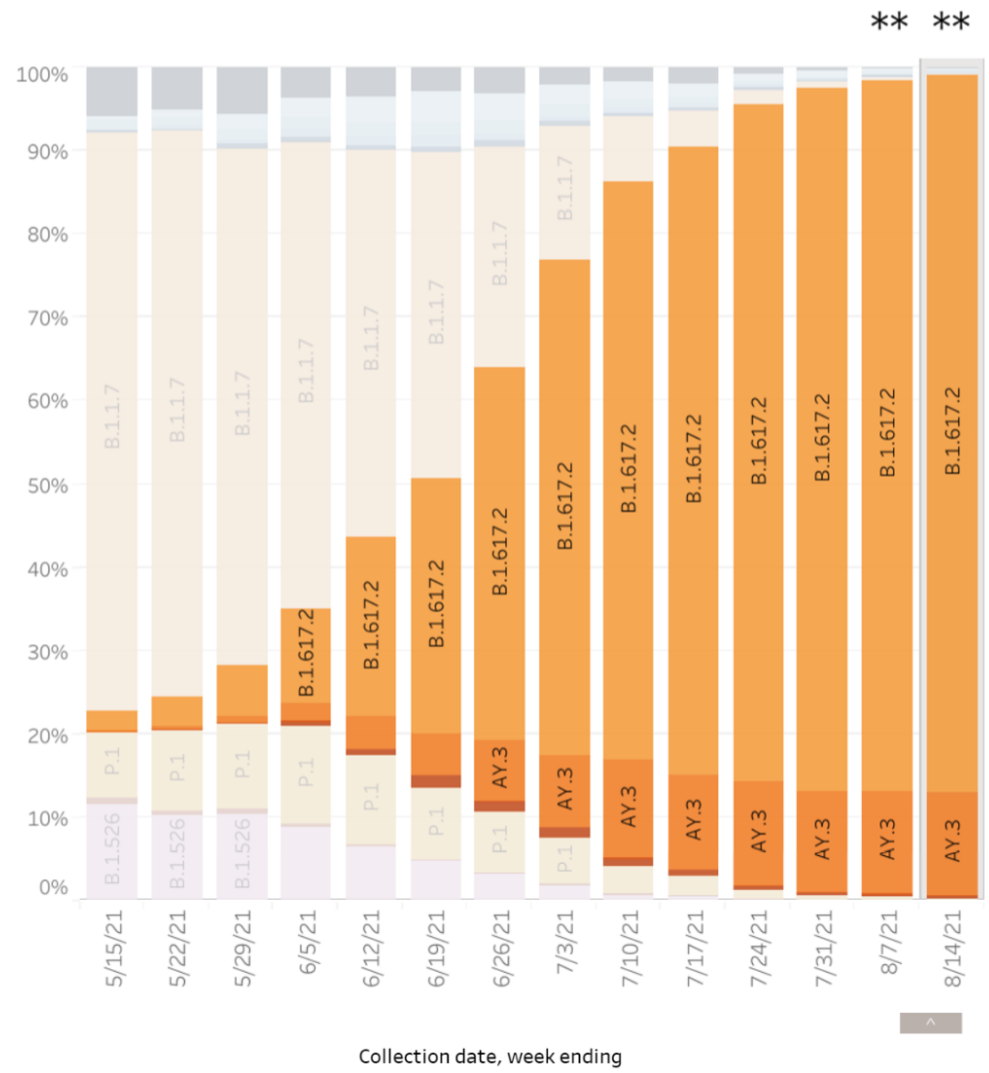
Variant Proportions in the U.S.

United States: 5/9/2021 – 8/14/2021



United States: 8/8/2021 – 8/14/2021 NOWCAST

USA

WHO label	Lineage #	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	0.3%	0.0-1.0%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	0.2%	0.0-0.7%
Delta	B.1.617.2	VOC	86.1%	82.6-89.4%
	AY.3	VOC	12.3%	9.1-15.7%
	AY.2	VOC	0.3%	0.0-1.0%
	AY.1	VOC	0.1%	0.0-0.2%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.0%	0.0-0.2%
N/A	B.1.621		0.4%	0.0-1.0%
	B.1.621.1		0.1%	0.0-0.5%
	B.1.628		0.1%	0.0-0.5%
	A.2.5		0.0%	0.0-0.2%
	B.1.626		0.0%	0.0-0.2%
	B.1.617.1	VOI	0.0%	0.0-0.2%
	B.1.617.3	VOI	0.0%	0.0-0.2%
Other	Other*		0.0%	0.0-0.2%

* Enumerated lineages are VOI/VOC or are circulating >1% in at least one HHS region during at least one two week period; remaining lineages are aggregated as "Other".

** These data include Nowcast estimates, which are modeled projections that may differ from weighted estimates generated at later dates

Sublineages of P.1 and B.1.351 are aggregated with the parent lineage and included in parent lineage's proportion. AY.3.1 is aggregated with its parent lineage AY.3. AY.4-AY.12 aggregated with B.1.617.2

https://covid.cdc.gov/covid-data-tracker/#variant-proportions

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Variant Proportions in NH, 8/5 – 8/18 (Last 2 Weeks)

- 187 positive specimens were sequenced:
  - Alpha (B.1.1.7): 18 (10%)
  - Beta (B.1.351): 0 (0%)
  - Gamma (P.1): 5 (3%)
  - Delta (B.1.617.2): 71 (38%)

HAN Update #44

Additional COVID-19 Vaccine Doses

- The following is important to understand CDC's recommendations about additional vaccine doses:
  - A 3rd dose after an initial 2-dose mRNA vaccine series is recommended for people who are moderately–severely immunocompromised because immunity from the primary series is likely to be insufficient (think of this as an extension of the primary series from a 2-dose to a 3-dose series)
  - Booster doses are for decreasing immunity over time after the initial/primary series, or due to circulating variants that cause the vaccines to be less effective

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-dose

Distributed by the NH Health Alert Network
Health.Alert@nh.gov
August 13, 2021 Time 2000 (8:00 PM EDT)
NH-HAN 20210813

NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs *for all*
Department of Health and Human Services

Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 44

mRNA COVID-19 Vaccine 3rd Dose Recommendations

- August 12th: FDA authorized use of a 3rd dose of the Pfizer and Moderna vaccines for immunocompromised persons
  - This authorization did NOT apply to the Janssen vaccine, or to people who received the Janssen vaccine as their primary series
- August 13th: CDC/ACIP recommended a 3rd dose of the either the Pfizer vaccine (for persons ≥12 years) or Moderna vaccine (for persons ≥18 years) after a 2-dose mRNA vaccine series, for people who are moderately or severely immunocompromised

Who Is Considered Moderately—Severely Immunocompromised?

- Conditions and treatments causing moderate—severe immunosuppression include, but are not limited to:
  - Active treatment for solid tumor and hematologic malignancies
  - Receipt of solid-organ transplant & on immunosuppressive therapy
  - Receipt of CAR-T-cell or hematopoietic stem cell transplant
  - Moderate or severe primary immunodeficiency disorders
  - Advanced or untreated HIV infection
  - Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents, TNF blockers, etc.

- A person's provider can make a determination about whether they can/should get a 3rd dose based on CDC guidance and other resources linked in CDC's guidance

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#considerations-additional-dose

Additional CDC/ACIP Recommendations

- 3rd dose should be the same mRNA vaccine product as the primary series
- An alternate mRNA vaccine product can be used if the primary series product is not known/available
- 3rd doses should be given at least 28 days after completion of primary series (minimum timeframe recommendation)
- Serologic/antibody testing to assess immune response prior to a 3rd dose is not recommended
- Patients seeking a 3rd dose outside their medical homes can self-attest to their immunocompromising condition

Healthcare Providers Recommendations

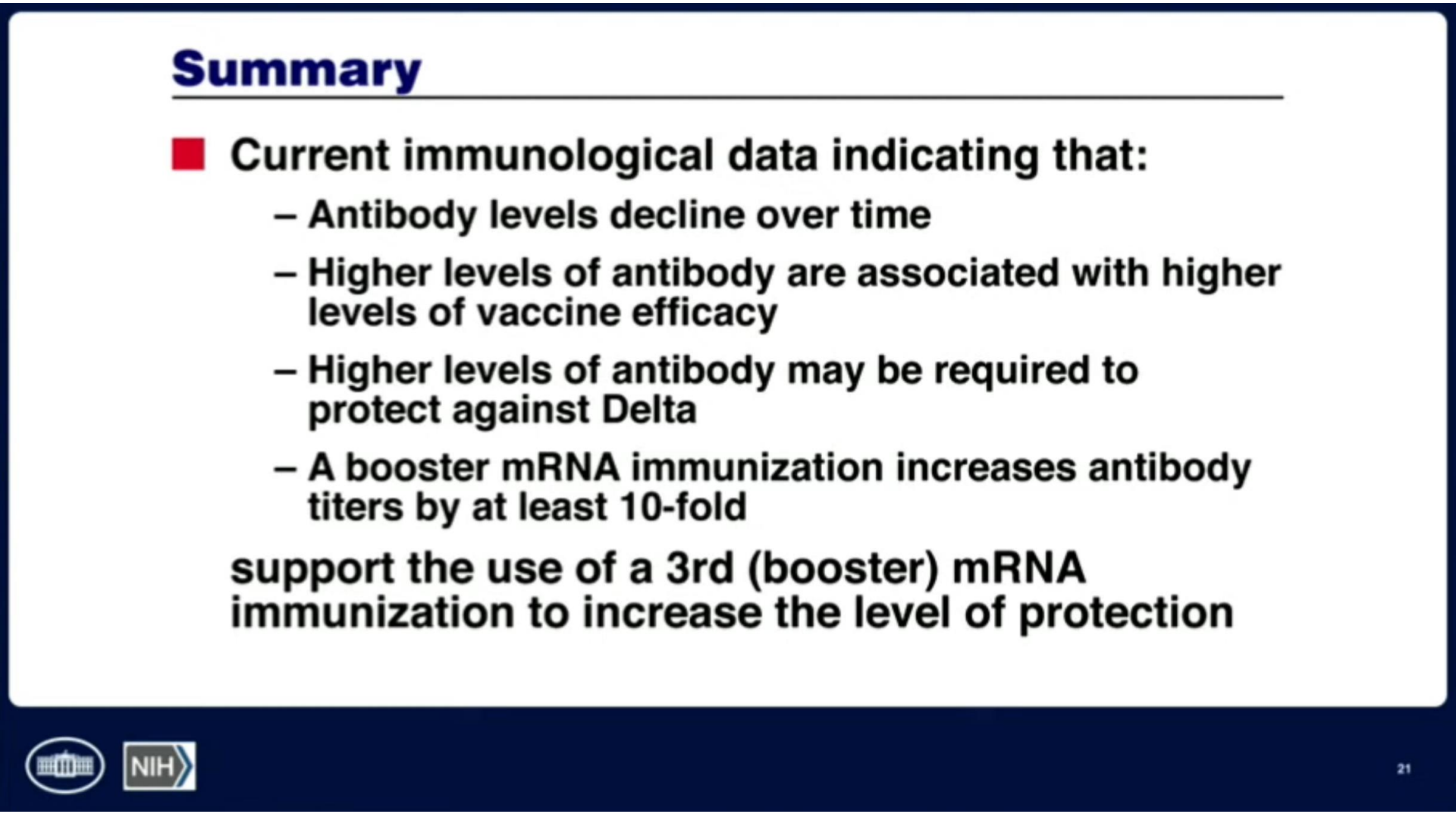
- Consider identifying, reaching out, and notifying your immunocompromised patients that they are recommended for a 3rd dose
- Work with your healthcare organization to get these patients vaccinated, or direct them to one of the many vaccination opportunities in your local community
- Even after a 3rd dose, immunocompromised persons remain at risk from COVID-19, so patients should be counseled to continue to take steps to protect themselves

COVID-19 Vaccine Booster Doses

Federal HHS Announcement, August 18th

- Planning on booster doses of Pfizer and Moderna COVID-19 vaccines to be administered starting September 20th
  - This is dependent on FDA vaccine approval/authorization allowing for booster doses, and ACIP recommendations
  - This does not apply to people who got the Janssen vaccine (which started distribution in March 2021)
- For people 18+ years starting 8 months after receiving their 2nd dose of the Pfizer or Moderna vaccine
- Initial booster doses will target people who were first eligible to be vaccinated in December 2020

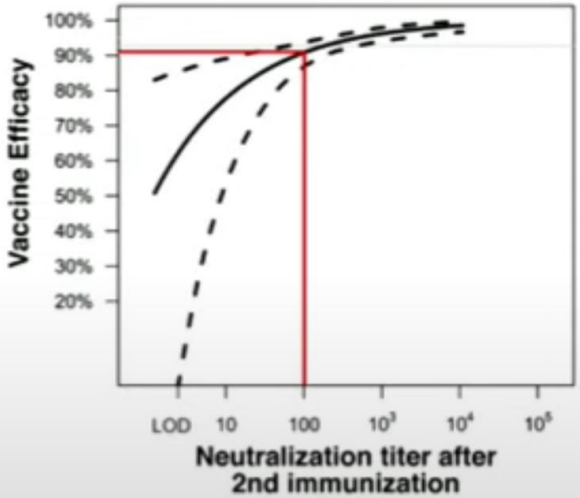
HHS Press Conference Explanation



HHS Press Conference Explanation

Higher Levels of Antibody Are Associated With Higher Levels of Vaccine Efficacy

Immune Correlates Analysis of the mRNA-1273 COVID-19 Vaccine Efficacy Trial



- Model of vaccine efficacy based on Moderna phase 3 study; 4 weeks after 2nd dose
- For serum neutralization titer of 100, vaccine efficacy was 91%

Source: Gilbert at al., Immune Correlates Analysis of the mRNA-1273 COVID-19 Vaccine Efficacy Trial: Pre-print on *medRxiv*

NIH

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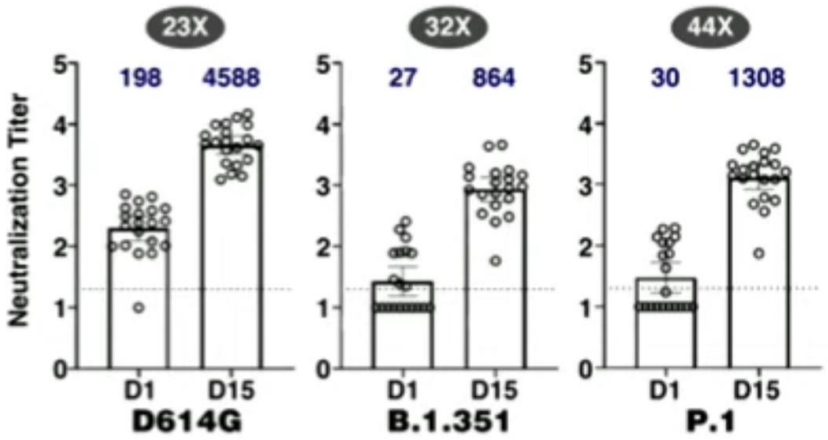
HHS Press Conference Explanation

A Booster mRNA Immunization Increases Antibody Titers by at Least 10-Fold

Immunogenicity After Boosting with Dose of 50ug of Moderna mRNA vaccine (boost given approx. 6 – 7 months after 2nd shot)



First columns: just before 3rd dose

Second columns: 15 days post-3rd dose boost

Reference: Preliminary Analysis of Safety and Immunogenicity of a SARS-CoV-2 Variant Vaccine Booster Wu et al., *medRxiv* preprint

20

What Do Real-World Vaccine Effectiveness Studies Show?

- Three new MMWR publications yesterday showed decreased overall vaccine effectiveness over time, but sustained high-levels of effectiveness at preventing severe disease
- It is unclear if the decrease in VE is due to natural waning of antibody response over time, or due to the more infectious Delta variant
  - These two important factors are unable to be separated in studies
- Before a brief overview of the new MMWR studies, first a review…

Vaccine Effectiveness (VE) Against Delta Variant

Country	Study Link	COVID-19 Vaccine	VE at Preventing Infection*	VE at Preventing Severe Illness**
United Kingdom	Bernal et al. NEJM; Stowe et al. khub	Pfizer-BioNTech	88%	96%
		AstraZeneca	67%	92%
Canada	Nasreen et al. medRxiv	Pfizer-BioNTech	85%	--
Scotland	Sheikh et al. Lancet	Pfizer-BioNTech	79%	--
		AstraZeneca	60%	--
Israel	Press Release	Pfizer-BioNTech	64%	93%

* Includes preventing "confirmed infection" and "symptomatic infection"
** Includes preventing hospitalizations and deaths (depending on study)

Preliminary estimates show that the Pfizer-BioNTech COVID-19 vaccine is:

- ~80% effective at preventing infection from the Delta variant
- 90-95% effective at preventing severe disease, including hospitalizations and deaths from COVID-19

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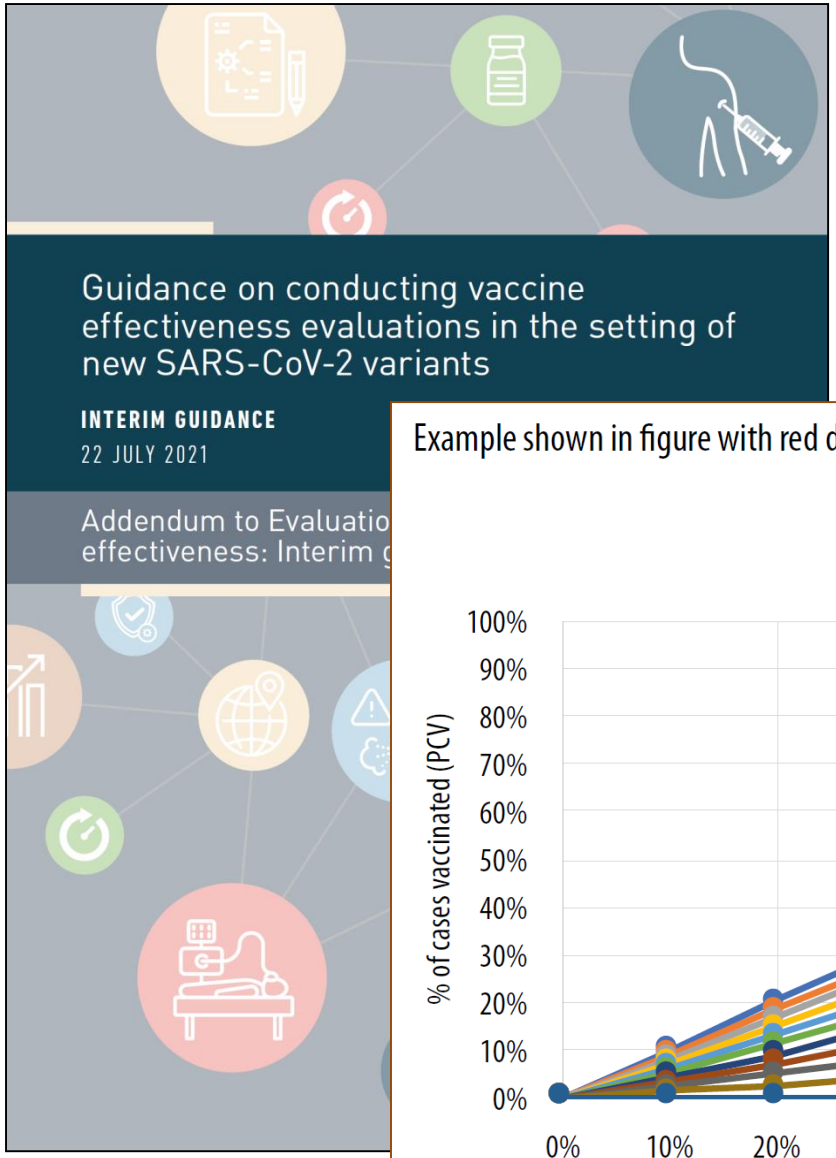
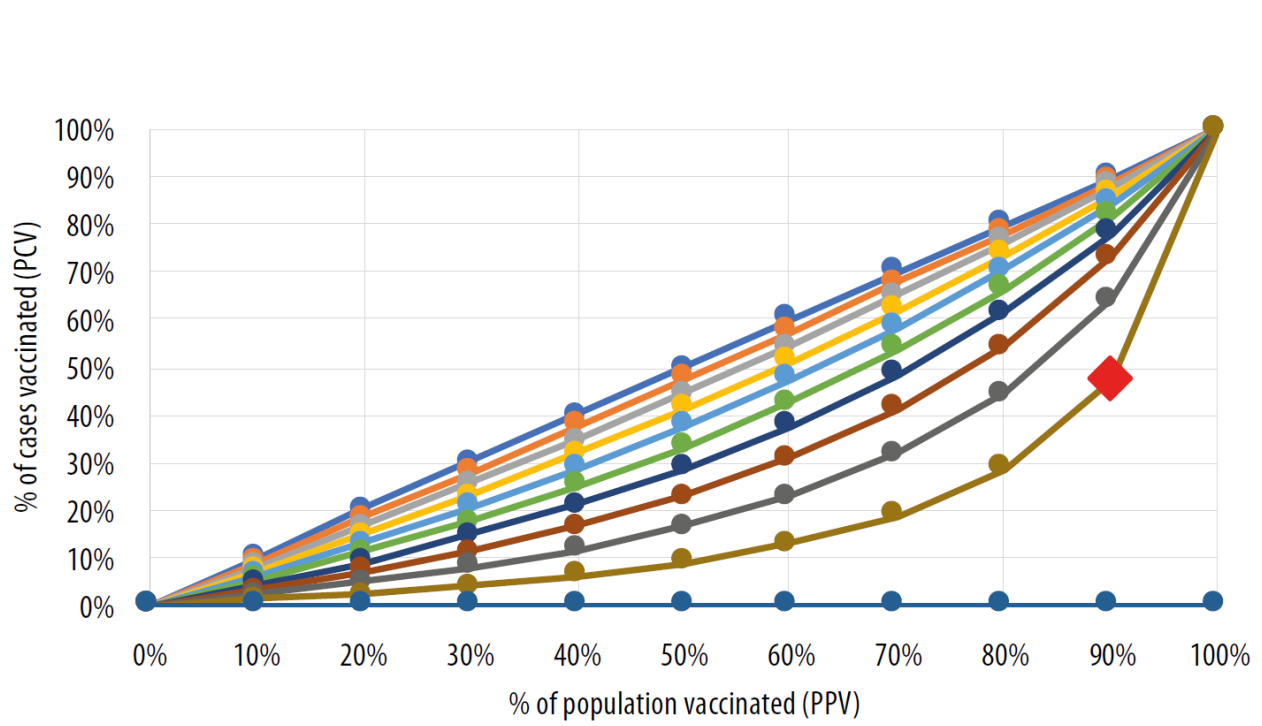
Qatar	Tang et al. medRxiv	Pfizer-BioNTech	54%	90%
		Moderna	85%	100%

- Other studies have shown decreasing VE over time temporally related to emergence of the Delta variant, but have not directly assessed VE against Delta variant



Example shown in figure with red diamond is the result for vaccine with 90% estimated VE and 90% PPV.



https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-variants-2021.1

Bulletin of the World Health Organization, 63 (6): 1055-1068 (1985)

Field evaluation of vaccine efficacy*

WALTER A. ORENSTEIN,[1] ROGER H. BERNIER
JAMES S. MARKS,[3] KENNETH J. BART,[1] & B

*This paper describes the epid
efficacy and recommends a practi
measles vaccine, the efficacy of w
methods are applicable to other va
the techniques are indicated.*

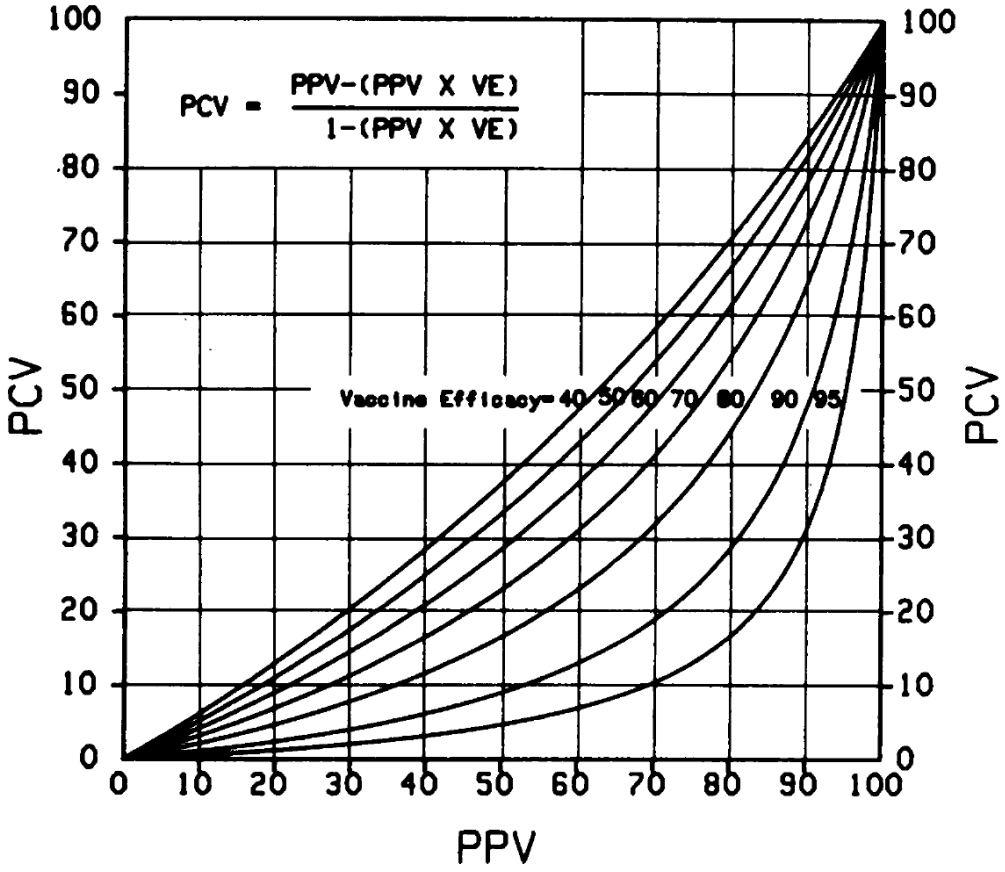
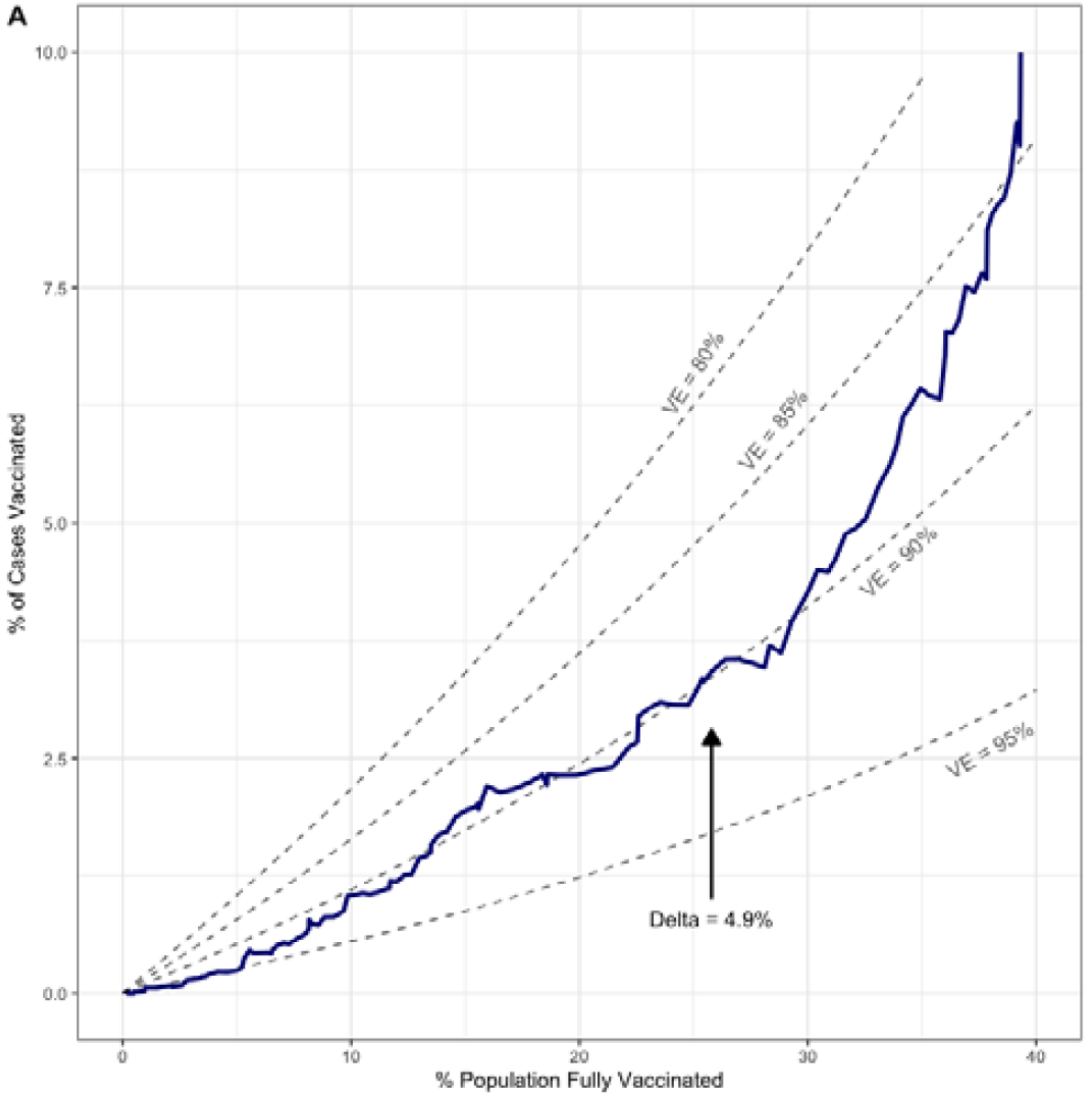


Fig. 1. The relationship between the percentage of cases vaccinated (PCV) and the percentage of the population vaccinated (PPV) for seven different percentage values of vaccine efficacy (VE).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536484/

Vaccine Effectiveness (VE) Progression, Utah

- Utah estimated VE from all vaccinations from January 16 – June 28
- VE declined from 90% in mid-May to 83% by the end of June
- Delta variant caused 70% of all infections in Utah by end of June



https://www.medrxiv.org/content/10.1101/2021.08.09.21261554v1

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Department of Health and Human Services

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
August 18, 2021

New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021

- Overall VE against infection decreased from 92% to 80%
- VE against hospitalization was stable from 92% to 95%
- Prevalence of the Delta variant increased from <2% to >80%

https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e1.htm?s_cid=mm7034e1_w

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
August 18, 2021

Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021

- Evaluated hospitalizations from 21 hospitals in 18 states
- VE of mRNA vaccines against COVID-19 related hospitalization was stable over a 24 week period
  - 2-12 weeks after receipt of dose #2, VE was 86%
  - 13-24 weeks after receipt of dose #2, VE was 84%

https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e2.htm?s_cid=mm7034e2_w

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
August 18, 2021

Effectiveness of Pfizer-BioNTech and Moderna Vaccines in Preventing SARS-CoV-2 Infection Among Nursing Home Residents Before and During Widespread Circulation of the SARS-CoV-2 B.1.617.2 (Delta) Variant — National Healthcare Safety Network, March 1–August 1, 2021

- Weekly data from CMS-certified SNFs or nursing homes are reported into CDC's National Healthcare Safety Network
- Evaluated VE for mRNA vaccines during three time periods:
  - pre-Delta (March 1 – May 9): 75%
  - Intermediate (May 10 – June 20): 68%
  - Delta (June 21 – August 1): 53%

https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e3.htm?s_cid=mm7034e3_w

Additional Comments on Study

- Main point from this study is that there was a decline in VE over the study period, consistent with other studies
- Specific VE estimates from this study are not generalizable: LTCF population is high-risk for spread of COVID-19 and had extensive testing requirements for aggressive case ascertainment (including asymptomatic infection)
- Did not distinguish between asymptomatic vs. symptomatic infections
- Reporting on resident vaccination status was voluntary during the pre-Delta period, but was required by CMS starting June 6th
  - "A bias indicator analysis was conducted, which indicated that VE was likely underestimated during the pre-Delta period"

Does the Decreased Vaccine Effectiveness Mean Everybody Needs a Booster Dose?

- Federal government is planning for boosters, possibly as early as September 20th
- Before this happens, the FDA needs to either fully approve/license COVID-19 vaccines or amend the EUA
- Then ACIP will meet and decide how/when to recommend booster doses of the vaccine
- Planning and discussion about how to deliver booster doses is currently underway

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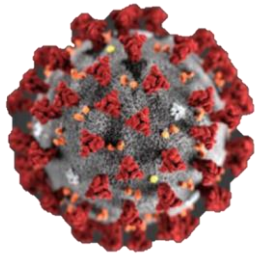

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