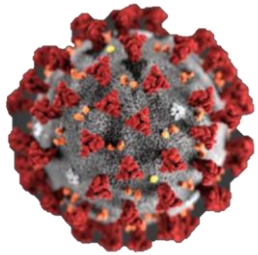


New Hampshire Coronavirus Disease 2019 Weekly Partner Call

August 12, 2021

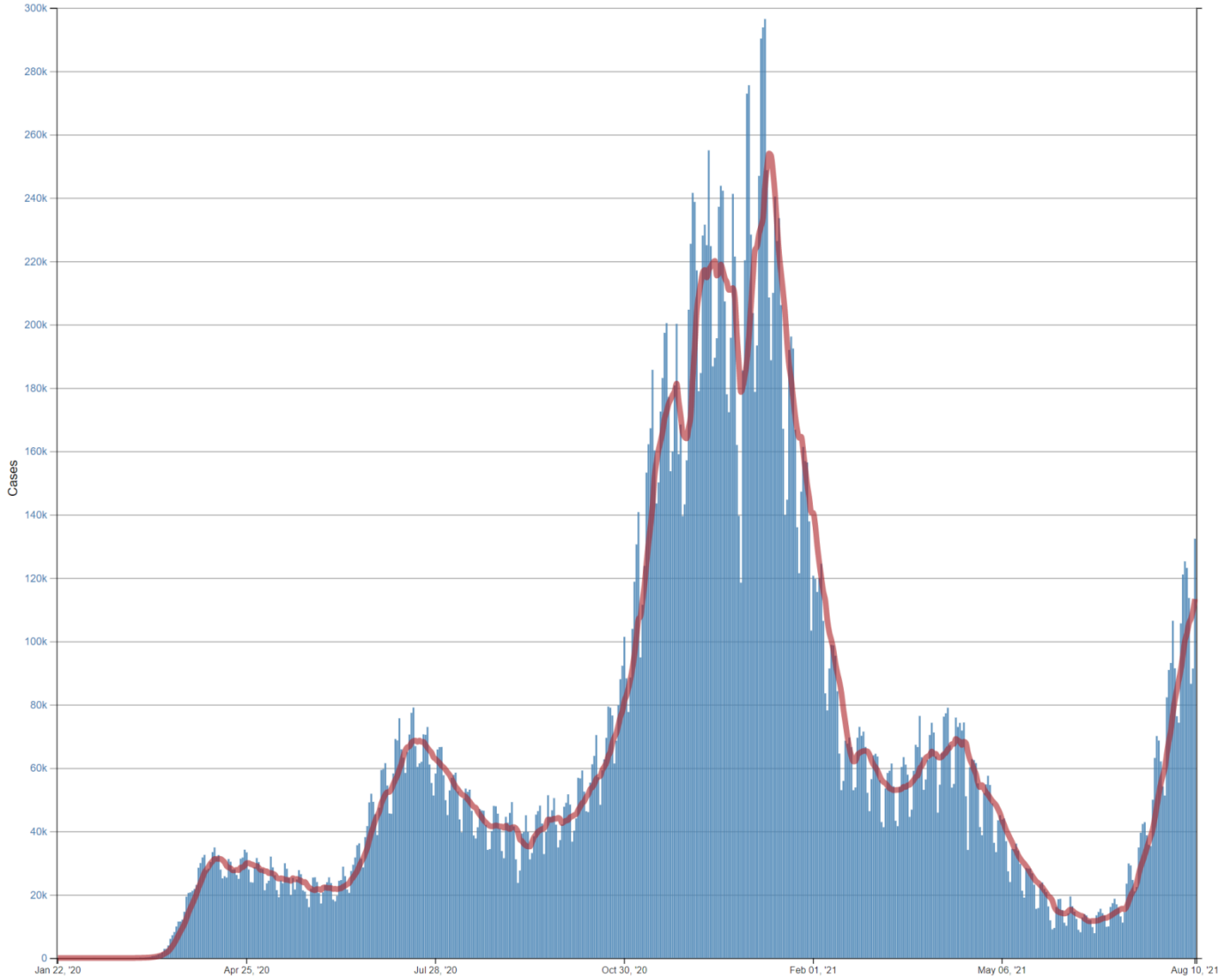
Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

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

Epidemiology Update

U.S. National Daily Incidence of COVID-19



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

NH DIVISION OF
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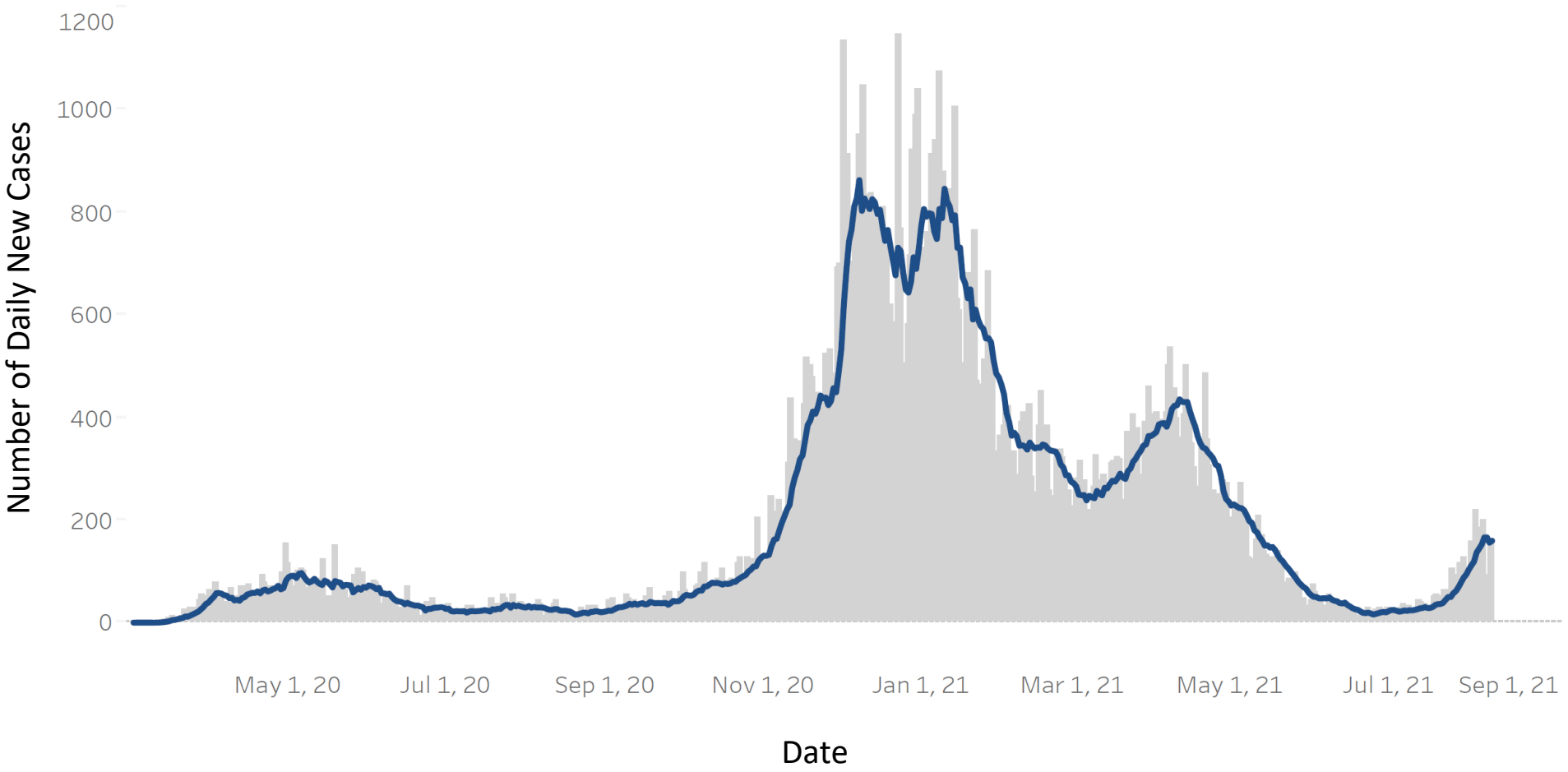
Department of Health and Human Services

Number of New COVID-19 Cases per Day in NH



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

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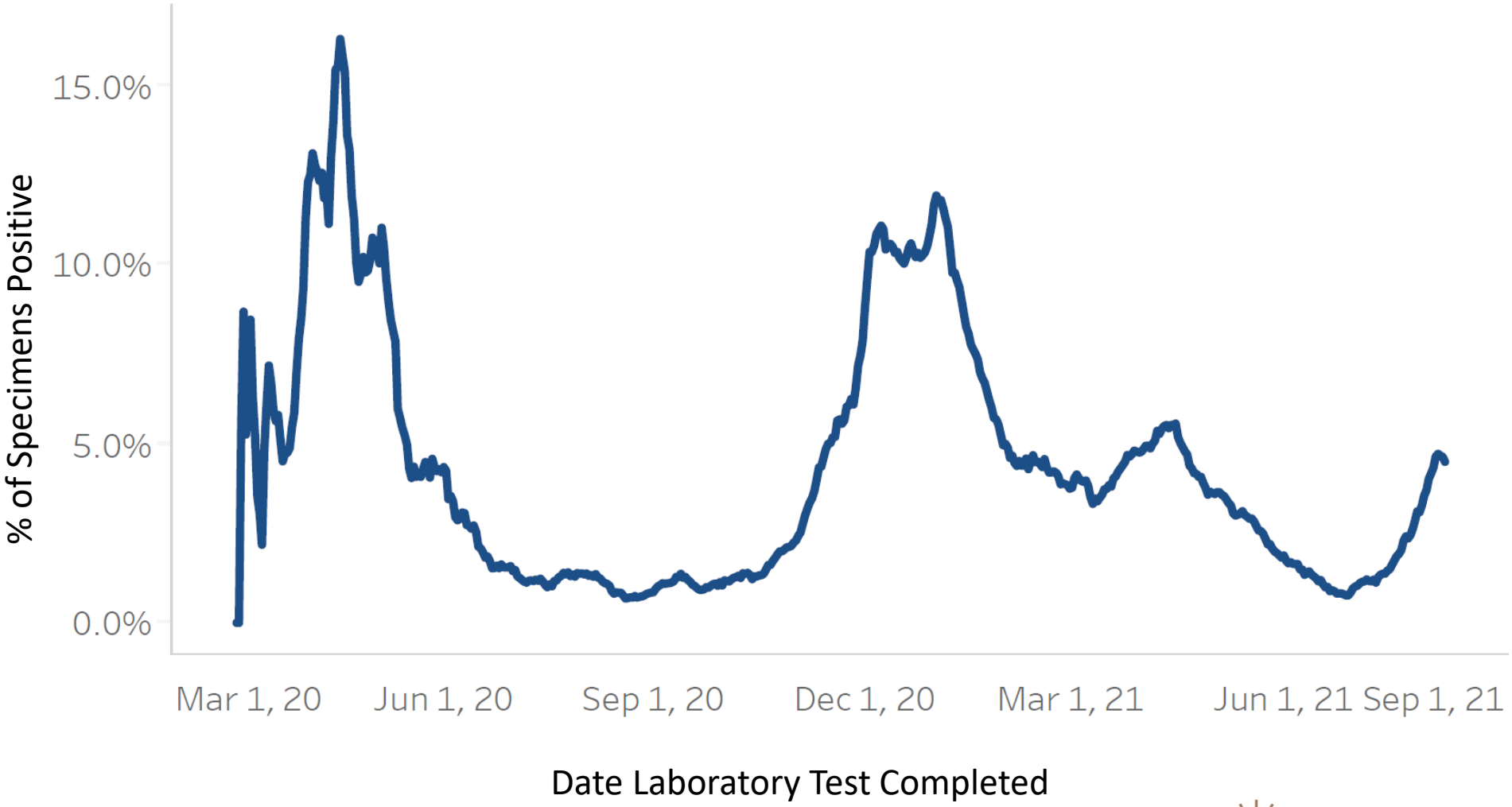
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



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

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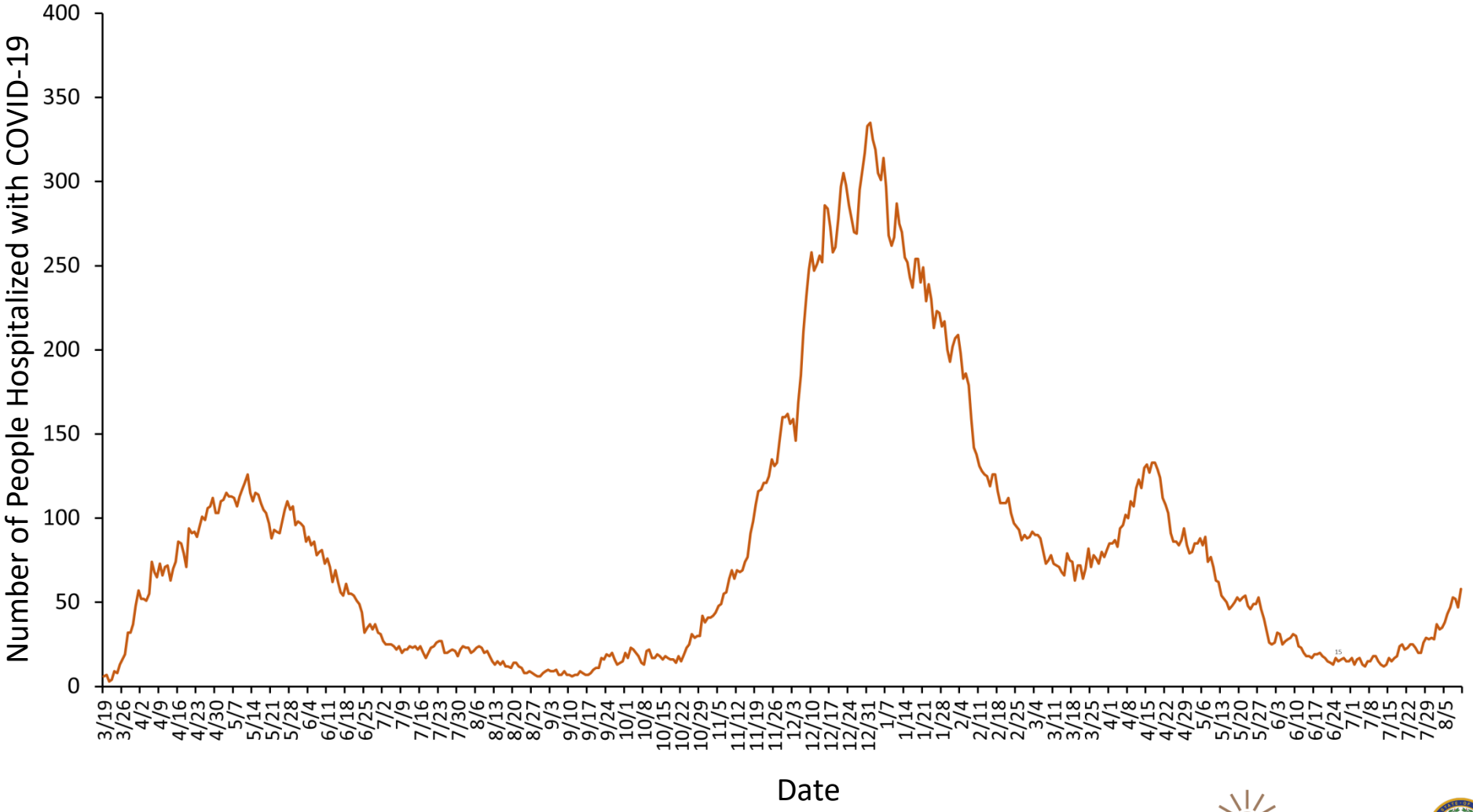
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



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

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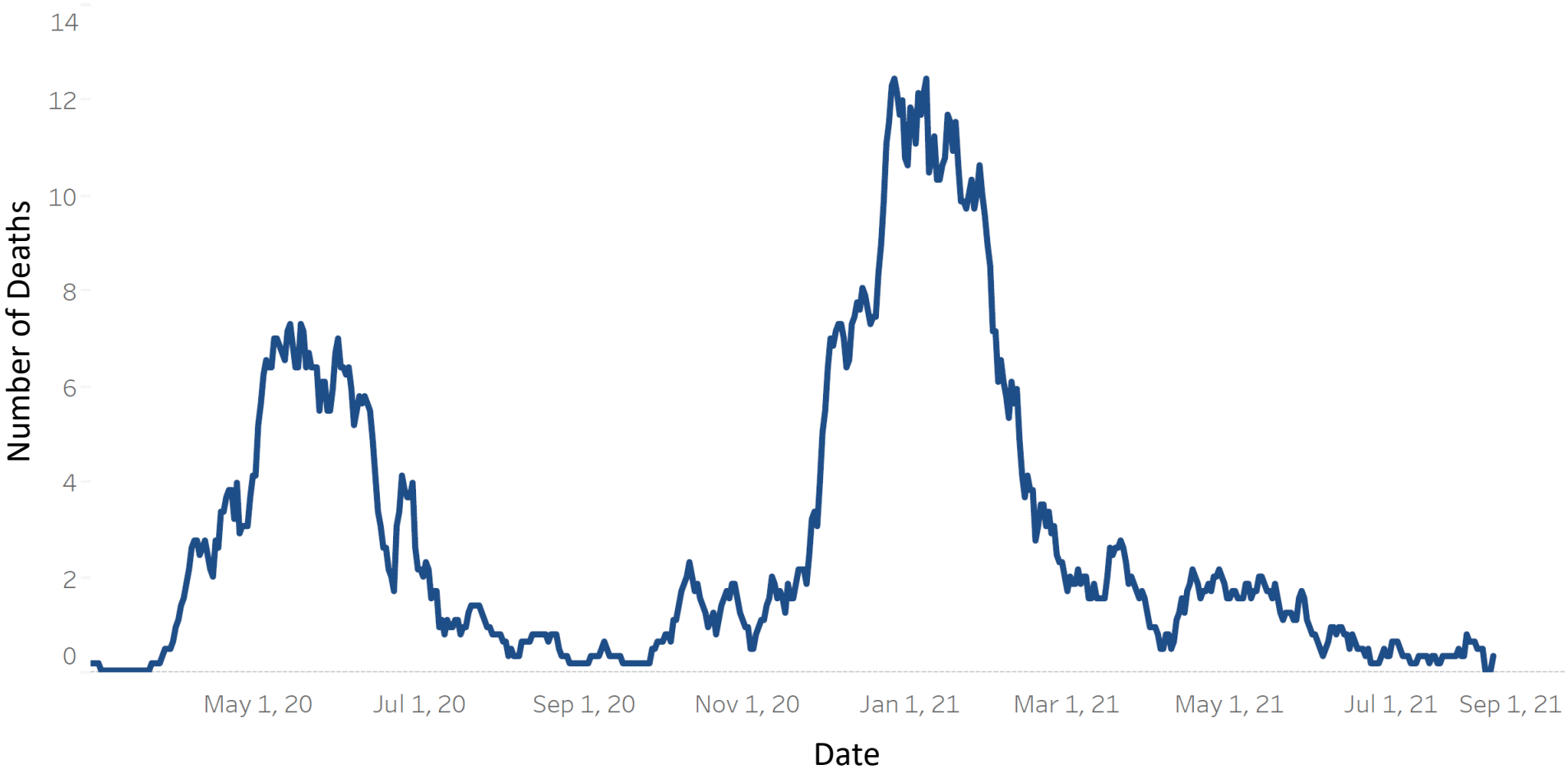
Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



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

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Level of Community Transmission in NH

Statewide Level of Transmission

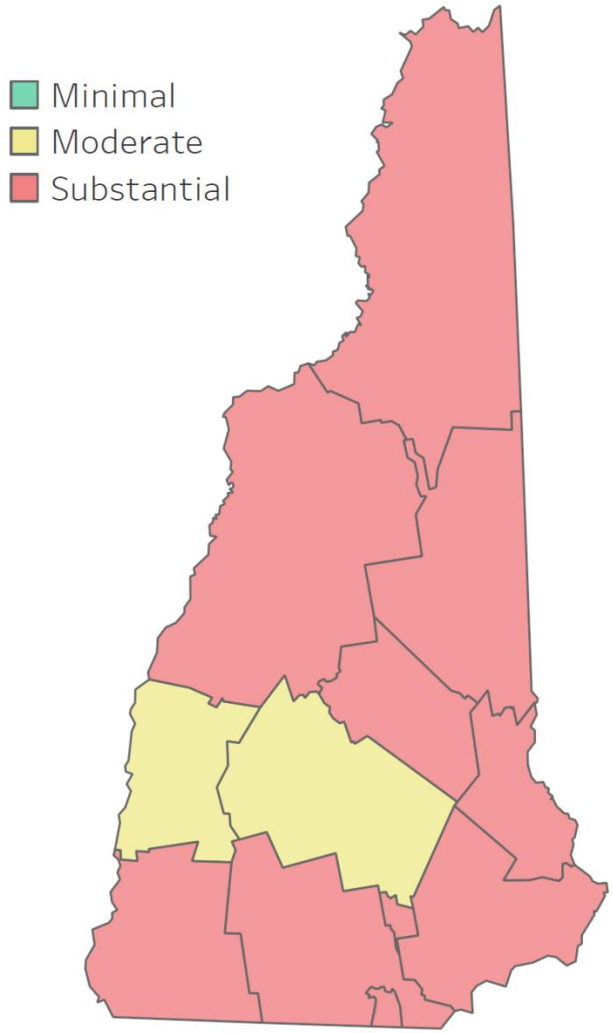
Substantial

New Cases per 100k over 14 days

143.5

7-Day Total Test Positivity Rate

4.5%



Data as of: 8/11/2021

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

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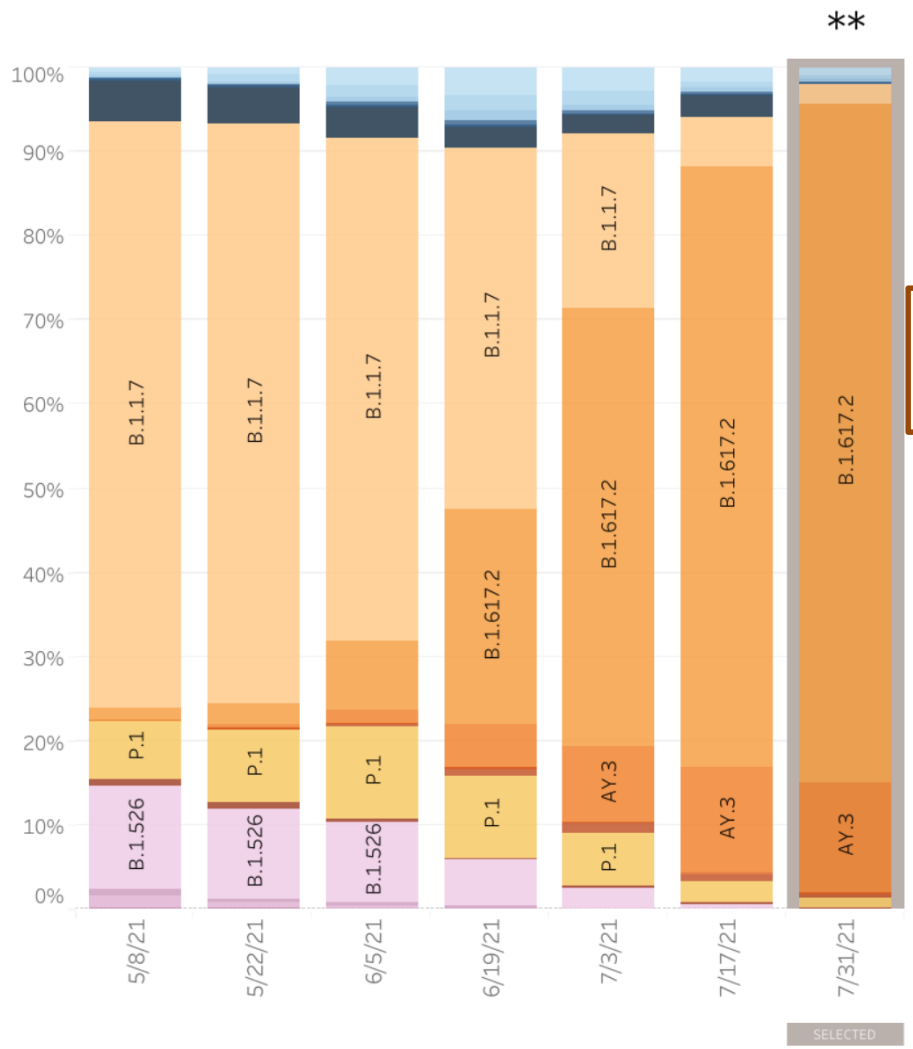
Variant Proportions in the U.S.

United States: 4/25/2021 – 7/31/2021

United States: 7/18/2021 – 7/31/2021 NOWCAST



Collection date, two weeks ending

USA

WHO label	Lineage #	Type	%Total	95%PI
Alpha	B.1.1.7	VOC	2.4%	1.0-4.0%
Beta	B.1.351	VOC	0.0%	0.0-0.2%
Gamma	P.1	VOC	1.1%	0.2-2.2%
Delta	B.1.617.2	VOC	80.6%	76.7-84.4%
	AY.3	VOC	13.1%	9.9-16.4%
	AY.2	VOC	0.6%	0.0-1.5%
	AY.1	VOC	0.1%	0.0-0.5%
Eta	B.1.525	VOI	0.0%	0.0-0.2%
Iota	B.1.526	VOI	0.2%	0.0-0.7%
	B.1.621		1.0%	0.2-2.0%
	B.1.621.1		0.3%	0.0-1.0%
	B.1.628		0.3%	0.0-1.0%
	Other*		0.2%	0.0-0.7%
	A.2.5		0.1%	0.0-0.5%
	B.1.626		0.0%	0.0-0.2%
	B.1.429	VOI	0.0%	0.0-0.2%
	B.1.427	VOI	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 (P.1.1, P.1.2, B.1.351.2, B.1.351.3) are aggregated with the parent lineage and included in parent lineage's proportion. AY.3.1 is agregated with its parent lineage AY.3.

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

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NH Variant Proportions, 7/29 – 8/11 (Last 2 Weeks)

- 186 positive specimens were sequenced:
  - Alpha (B.1.1.7): 20 (11%)
  - Beta (B.1.351): 0 (0%)
  - Gamma (P.1): 6 (3%)
  - Delta (B.1.617.2): 73 (39%)

Brief Review

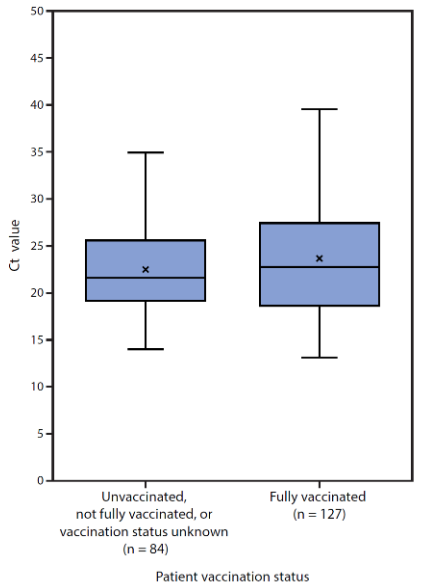
Vaccines Breakthrough (VBT) Disease due to Delta

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
July 30, 2021

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

- 469 cases among MA residents during “Independence Week” in Provincetown
- 74% was VBT
  - 90% Delta variant
  - 79% symptomatic
    - 5 hospitalizations, 0 deaths

FIGURE 2. SARS-CoV-2 real-time reverse transcription–polymerase chain reaction cycle threshold values* for specimens from patients with infections associated with large public gatherings, by vaccination status† — Barnstable County, Massachusetts, July 2021§



A commercial lab in Wisconsin reported a similar result (preprint)

https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

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Department of Health and Human Services

Pfizer-BioNTech VE Against Delta

Country	Study Link	VE at Preventing Infection*	VE at Preventing Severe Illness**
UK	Bernal et al. NEJM; Stowe et al. khub	88%	96%
Canada	Nasreen et al. medRxiv	85%	--
Scotland	Sheikh et al. Lancet	79%	--
Israel	Press Release	64%	93%

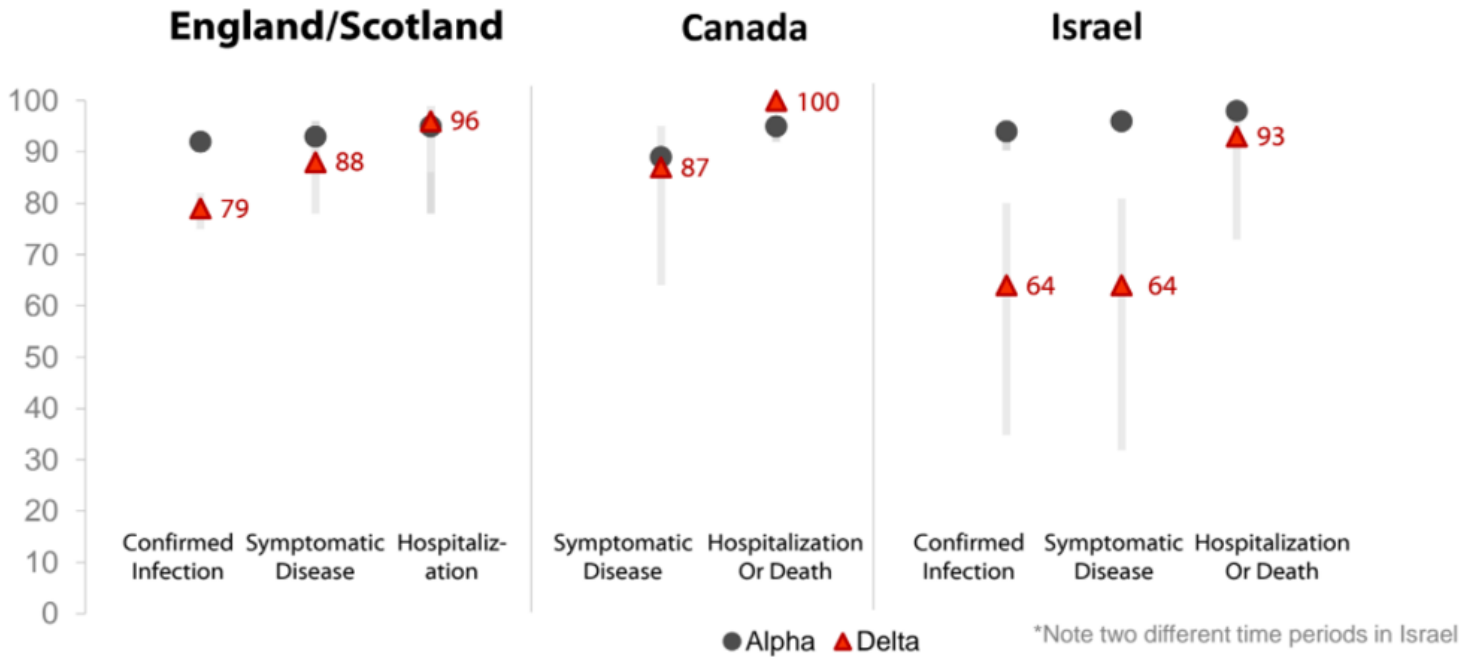
* Includes preventing "confirmed infection" and "symptomatic infection"
** Includes preventing hospitalizations and deaths (depending on study)

Preliminary estimates:

- ~80% effective at preventing infection
- >90% effective at preventing severe disease, hospitalizations, deaths

https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

Pfizer 2-Dose Vaccine Effectiveness for Alpha vs. Delta



Sheikh et al. Lancet (2021): https://doi.org/10.1016/S0140-6736(21)01358-1; Lopez Bernal et al. medRxiv preprint: https://doi.org/10.1101/2021.05.22.21257658; Stowe et al. PHE preprint: https://khub.net/web/phe-national/public-library/-/document_library/v2WsRK3ZlEig/view/479607266; Nasreen et al.medRxiv preprint: https://doi.org/10.1101/2021.06.28.21259420; https://www.gov.il/en/departments/news/06072021-04

19

[Internal CDC Presentation re Delta]

WHO VE Ongoing Systematic Review

- WHO's International Vaccine Access Center aggregating VE literature
  - Last review August 5
- New section added to highlight duration of protection not already part of VE estimate

#	Reference (date)	Country	Population	Dominant Variants	Vaccine product	Study Period	Descriptive Findings
1.	Mizrahi et al (July 31, 2021)	Israel	16+ year olds enrolled at Maccabi Health Services	Delta	Pfizer	June 1-July 27	The study compared the rate of breakthrough infection during June and July, when Delta was the dominant strain, between individuals who received 2 doses of the vaccine earlier this year to individuals who received two doses of the vaccine more recently, while adjusting for confounders. The authors report that persons vaccinated between January and February 2021 had a 53% (95% CI: 40-68%) increased risk of breakthrough infection in June and July compared to individuals vaccinated between March and April 2021. There was no difference by age groups 16-39, 40-59, ≥60 years. No unvaccinated persons were included in the study; thus vaccine effectiveness was not evaluated

Durability

mRNA Vaccines

PFIZER AND BIONTECH CONFIRM HIGH EFFICACY AND NO SERIOUS SAFETY CONCERNS THROUGH UP TO SIX MONTHS FOLLOWING SECOND DOSE IN UPDATED TOPLINE ANALYSIS OF LANDMARK COVID-19 VACCINE STUDY

Thursday, April 01, 2021 - 06:45am

- *Analysis of 927 confirmed symptomatic cases of COVID-19 demonstrates BNT162b2 is highly effective with 91.3% vaccine efficacy observed against COVID-19, measured seven days through up to six months after the second dose*
- *Vaccine was 100% effective in preventing severe disease as defined by the U.S. Centers for Disease Control and Prevention and 95.3% effective in preventing severe disease as defined by the U.S. Food and Drug Administration*
- *Vaccine was 100% effective in preventing COVID-19 cases in South Africa, where the B.1.351 lineage is prevalent*
- *Vaccine safety now evaluated in more than 44,000 participants 16 years of age and older, with more than 12,000 vaccinated participants having at least six months follow-up after their second dose*
- *The companies plan to share these results with worldwide regulatory agencies soon*

In interim report, among participants 6m after 2nd dose

- 91.3% efficacy against symptomatic disease
  - 850 cases in placebo group vs. 77 cases in vaccine group
- 95-100% efficacy against severe disease (CDC vs. FDA definition)
- Effective at preventing infection with B.1.351 variant

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious

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Comments (8

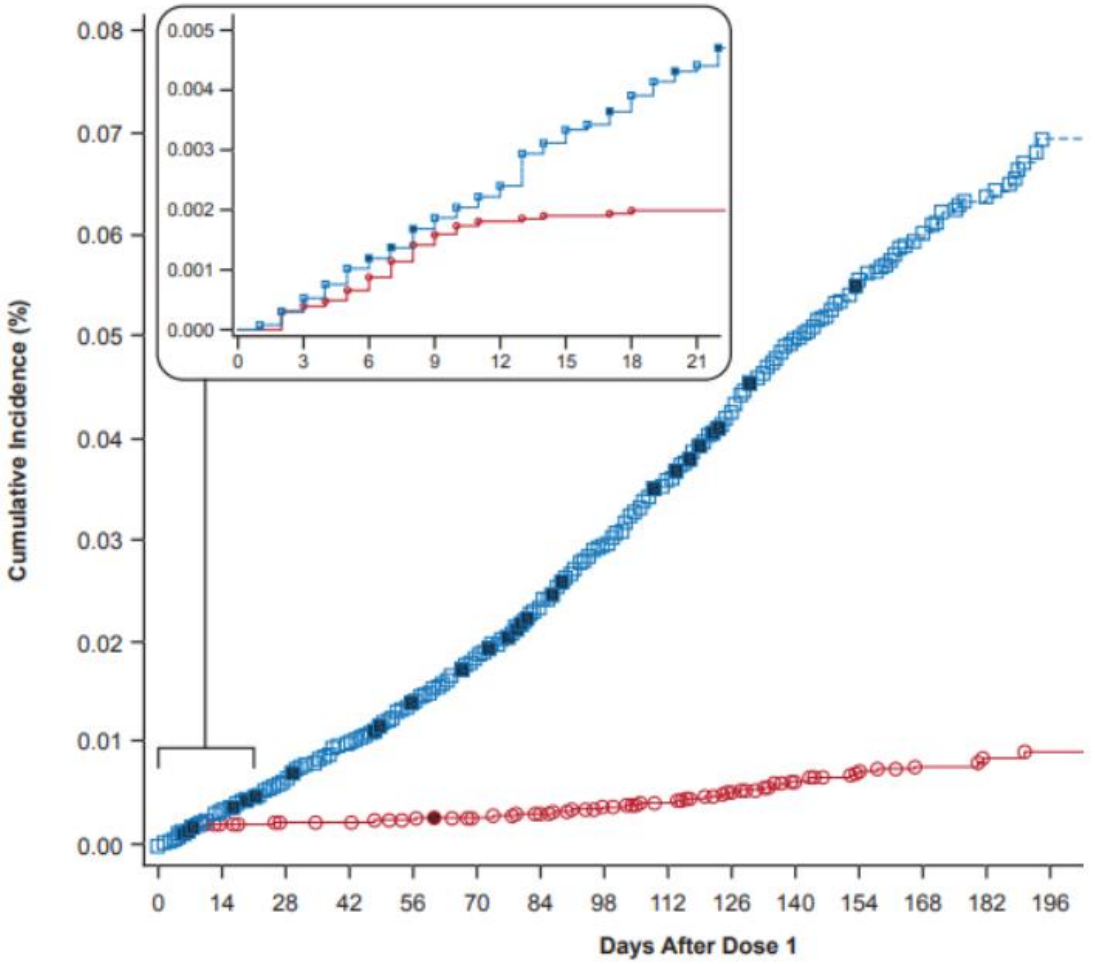
Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine

Stephen J. Thomas, Edson D. Moreira Jr., Nicholas Kitchin, Judith Absalon, Alejandra Gurtman, Stephen Lockhart, John L. Perez, Gonzalo Pérez Marc, Fernando P. Polack, Cristiano Zerbini, Ruth Bailey, Kena A. Swanson, Xia Xu, Satrajit Roychoudhury, Kenneth Koury, Salim Bouguermouh, Warren V. Kalina, David Cooper, Robert W. Frenck Jr., Laura L. Hammitt, Özlem Türeci, Haylene Nell, Axel Schaefer, Serhat Ünal, Qi Yang, Paul Liberator, Dina B. Tresnan, Susan Mather, Philip R. Dormitzer, Uğur Şahin, William C. Gruber, Kathrin U. Jansen, C4591001 Clinical Trial Group

doi: https://doi.org/10.1101/2021.07.28.21261159

- Among 42,094 participants ≥12 yo in ongoing placebo-controlled phase 2/3 efficacy trial in 6 countries, through Mar 13
- 6m post-2nd dose, 91.3% VE (95% CI 89-93.2) against lab-confirmed COVID-19
  - 81 cases among vaccinated, 873 among placebo
  - VE among subgroups by age, sex, race, ethnicity, presence of comorbid conditions, and country was generally consistent with overall population
    - 86-100% VE
  - 100% VE (95% CI 53.5-100) in South Africa with Beta predominant

- VE against severe disease 96.7% (95% CI 80.3-99.9)
    - 30 of 31 cases in placebo group



First COVID-19 Occurrence after Dose 1	BNT162b2 (N[a]=20,998) n1[b]	BNT162b2 (N[a]=20,998) Surveillance Time[c] (n2[d])	Placebo (N[a]=21,096) n1[b]	Placebo (N[a]=21,096) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall (≥12 years of age)	77	6.247 (20,712)	850	6.003 (20,713)	91.3	(89.0, 93.2)
Efficacy endpoint by subgroup						
Age group (years)						
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 55	52	3.593 (11,517)	568	3.439 (11,533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	266	2.417 (8208)	90.9	(86.3, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
Sex						
Male	42	3.246 (10,637)	399	3.047 (10,433)	90.1	(86.4, 93.0)
Female	35	3.001 (10,075)	451	2.956 (10,280)	92.4	(89.2, 94.7)
Race						
White	67	5.208 (17,186)	747	5.026 (17,256)	91.3	(88.9, 93.4)
Black or African American	4	0.545 (1737)	48	0.527 (1737)	91.9	(78.0, 97.9)
American Indian or Alaska Native	0	0.041 (186)	3	0.037 (176)	100.0	(–119.0, 100.0)
Asian	3	0.260 (946)	23	0.248 (934)	87.6	(58.9, 97.6)
Native Hawaiian or other Pacific Islander	0	0.015 (54)	1	0.008 (30)	100.0	(–1961.2, 100.0)
Multiracial	3	0.151 (518)	22	0.128 (476)	88.5	(61.6, 97.8)
Not reported	0	0.026 (85)	6	0.030 (104)	100.0	(2.8, 100.0)
Ethnicity						
Hispanic/Latinx	29	1.786 (5161)	241	1.711 (5120)	88.5	(83.0, 92.4)
Non-Hispanic/non-Latinx	47	4.429 (15,449)	609	4.259 (15,484)	92.6	(90.0, 94.6)
Not reported	1	0.032 (102)	0	0.033 (109)	–∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(–3874.2, 100.0)
South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(–0.1, 100.0)
USA	50	4.674 (16,046)	647	4.497 (16,094)	92.6	(90.1, 94.5)

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USA	50	4.674 (16,046)	647	4.497 (16,094)	92.6	(90.1, 94.5)

Efficacy Endpoint Subgroup	Vaccine Group				VE (95% CI)
	BNT162b2 (N=23,040)		Placebo (N=23,037)		
	No. of participants	Surveillance time (no. at risk)	No. of participants	Surveillance time (no. at risk)	
First COVID-19 occurrence after dose 1	131	8.412 (22,505)	1034	8.124 (22,434)	87.8 (85.3, 89.9)
After dose 1 to before dose 2	46	1.339 (22,505)	110	1.331 (22,434)	58.4 (40.8, 71.2)
After dose 1 to <11 days after dose 1	41	0.677 (22,505)	50	0.675 (22,434)	18.2 (−26.1, 47.3)
≥11 Days after dose 1 to before dose 2	5	0.662 (22,399)	60	0.656 (22,369)	91.7 (79.6, 97.4)
Dose 2 to 7 days after dose 2	3	0.424 (22,163)	35	0.422 (22,057)	91.5 (72.9, 98.3)
≥7 Days after dose 2	82	6.649 (22,132)	889	6.371 (22,001)	91.2 (88.9, 93.0)
≥7 Days after dose 2 to <2 months after dose 2	12	2.923 (22,132)	312	2.884 (22,001)	96.2 (93.3, 98.1)
≥2 Months after dose 2 to <4 months after dose 2	46	2.696 (20,814)	449	2.593 (20,344)	90.1 (86.6, 92.9)
≥4 Months after dose 2	24	1.030 (12,670)	128	0.895 (11,802)	83.7 (74.7, 89.9)

Using this data to advocate for boosters

Safety

- In >12,000 participants with >6 months of safety follow-up:
  - No new safety signals
  - No deaths related to vaccination
  - No cases of myocarditis
- Safety monitoring will continue per protocol
  - 2 years post-dose 2 for participants who originally received BNT162b2
  - 18 months after the second BNT162b2 dose for placebo recipients who received BNT162b2 after unblinding

What About Those With Prior Infection?

3% enrolled had evidence of previous SARS-CoV-2 infection (Ab, +PCR) at enrolment

- Among those who received vaccine, slightly higher reactogenicity after dose 1 and lower after dose 2

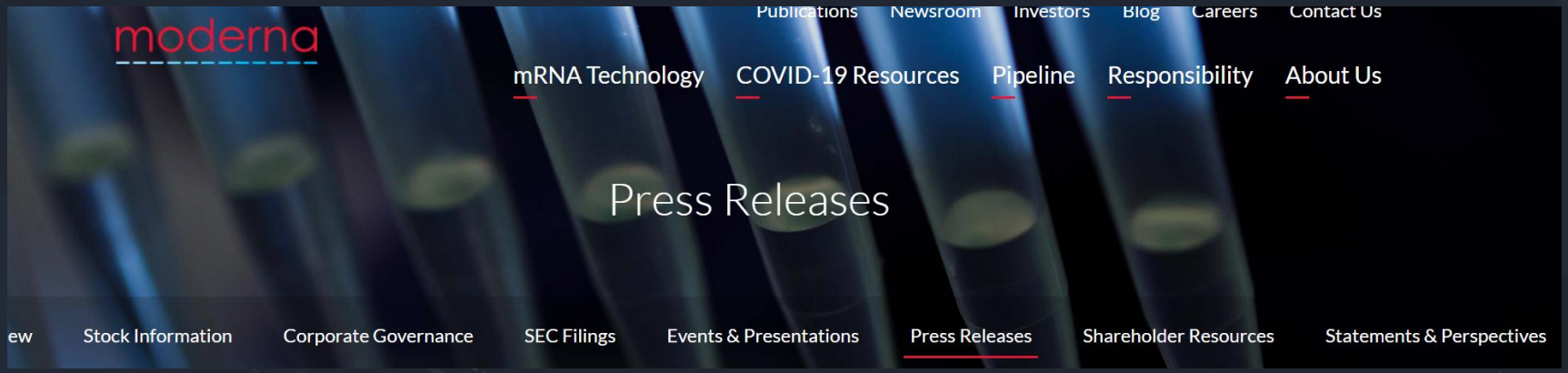
Among **placebo** recipients:

- If previous infection, 1.3% attack rate (7/542)
- If no previous infection, 4.7% attack rate (1015/21,521)
- ~72.6% protection by previous infection over 6m

Suggests less protection from prior COVID-19 disease itself than vaccination!

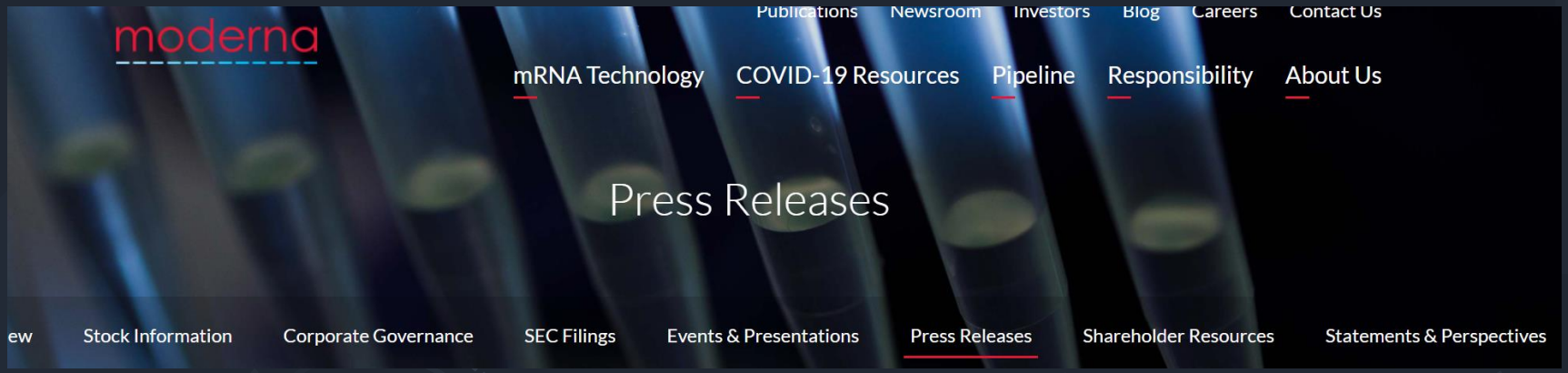
Vaccinating Previously Infected Protects Against Reinfection

- Among people previously infected with SARS-CoV-2, full vaccination provides protection from reinfection (MMWR)
- If previously infected but not vaccinated, you are 2.34 times (95% CI 1.58-3.47) more likely to get reinfected than those who were previously infected and vaccinated
- (Prior to Delta emergence)



Moderna Preliminary 6m Follow up

- Press release from 6-month follow-up of Phase 3 Moderna vaccine trial (n=28k)
- Median 6m after 2nd dose, vaccine efficacy
  - >90% against symptomatic (>900)
  - >95% against severe cases (>100)



Moderna Final 6m Follow up

- Press release from 6-month follow-up
- 6m after 2nd dose, vaccine efficacy
  - 93% against symptomatic
  - Pre-Delta
- Also advocating for booster

Boosters

Update toward readiness

Pfizer says it's time for a Covid booster; FDA and CDC say not so fast

By Maggie Fox, CNN

Updated 6:45 AM ET, Fri July 9, 2021

- "While protection against severe disease remained high across the full six months, a decline in efficacy against symptomatic disease over time and the continued emergence of variants are expected. Based on the totality of the data they have to date, Pfizer and BioNTech believe that a third dose may be beneficial within 6 to 12 months following the second dose to maintain highest levels of protection."
- Pfizer plans to seek an FDA EUA Aug 2021 for third dose
- Studying new version for variant booster

Global Booster Policies

Israel: ≥ 60 years or immunocompromised	France: elderly or immunocompromised	Germany: elderly, persons with underlying medical conditions, or previous AstraZeneca or Janssen/J&J vaccinees beginning Sept 1
UK: ≥ 50 years, persons with underlying medical conditions, or LTCF staff beginning fall	Russia: anyone 6m post vaccination	Hungary: anyone 4m post vaccination

WHO called for moratorium on booster shots until end of Sept, until at least 10% of each country's pop to be vaccinated

CDC, FDA, ECDC Do Not Recommend Booster for Fully Vaccinated Immunocompetent Persons

- Published data show overwhelming majority of severe illnesses are occurring in unvaccinated persons, not VBT
- ACIP has expressed opinion that 3 vaccine doses would be safe and beneficial among at least the most severely immunocompromised persons
    - In a US study conducted Mar-May 2021, ~44% of hospitalized VBT cases were among immunocompromised persons

When Will Booster Strategy Release?

Cannot make a dosing recommendation for vaccine that is not FDA-approved; vaccine manufacturers must apply for **EUA modification** to change dosing guidelines

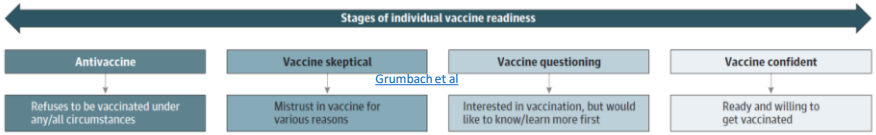
- Will require VE not just antibody boosts

FDA advises that a full US booster strategy expected early Sept: ACIP meeting Friday

- "Decision for those who are immunocompromised and face greater risk from the virus is expected sooner"

Benefits of Full Licensure

- KFF Poll: 3 in 10 unvaccinated adults (half of those in the "wait and see" group) say they would be more likely to get vaccinated if vaccines under EUA were fully approved
- Expected to spur employers to vaccine mandates
- Provide physicians greater latitude to prescribe additional doses for older adults or people with compromised immune systems



Grumbach et al

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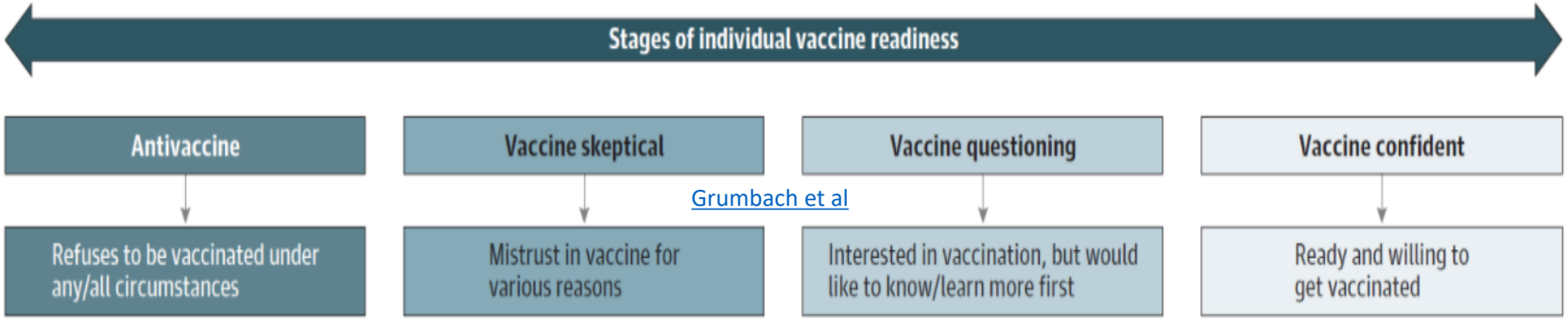

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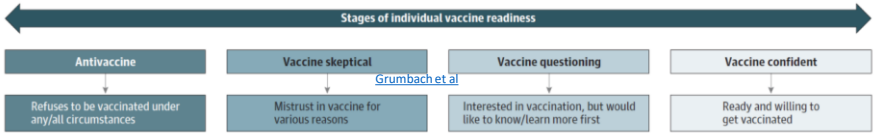
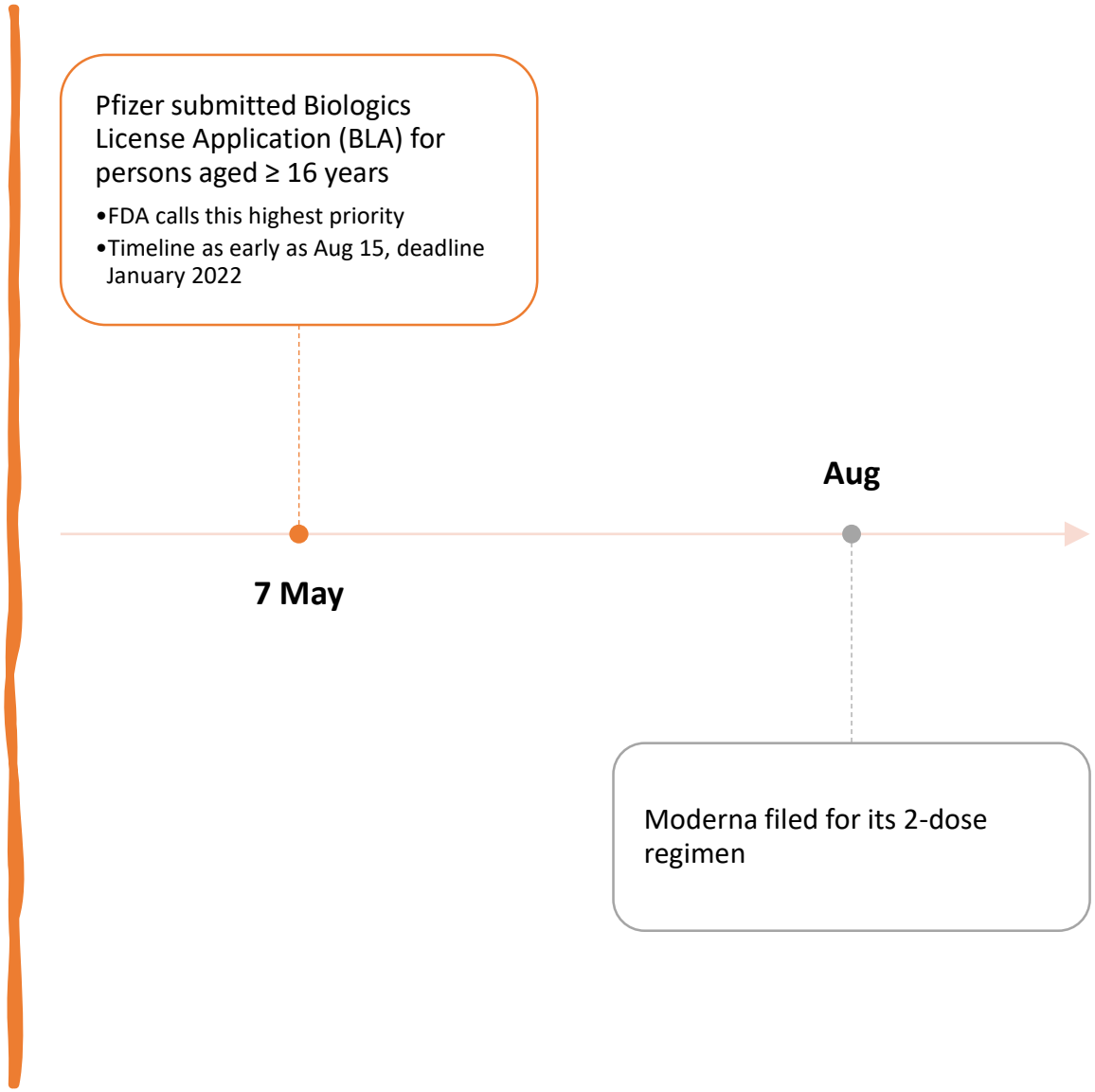


Status of the Path to Full Licensure

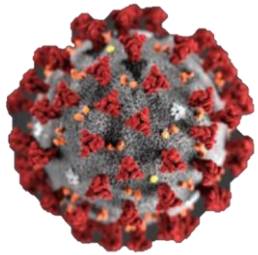


Get Vaccinated

- Unvaccinated people should get vaccinated
  - Prevents further variant emergence
    - Delta Plus is B.1.617.2.1 subset of B.1.617.2
    - Additional mutation (K417N) in spike protein
    - Same K417N mutation also in Beta, may help the virus evade immune response, including reduced susceptibility to some monoclonal antibody treatments
- Those with only 1 of 2-doses need 2, especially for full protection against Delta
  - Studies emerging regarding safe administration in patients with immediate reactions to first dose
  - www.vaccines.gov to find a vaccine

Summary

- All COVID-19 vaccines authorized in US are effective against COVID-19, including serious outcomes of severe disease, hospitalization, and death
- Available evidence suggests mRNA COVID-19 vaccines are highly effective against hospitalization and death for Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), and Delta (B.1.617.2)
    - Lower effectiveness against confirmed infection and symptomatic disease caused by the Beta, Gamma, and Delta variants compared with ancestral strain and Alpha variant
- Growing body of evidence indicates that people fully vaccinated with mRNA vaccine are less likely than unvaccinated persons to acquire or transmit it
    - Risk for VBT in fully vaccinated people clearly documented for Delta
    - Recommendation for boosters for immunocompromised expected within 48h



New Hampshire Coronavirus Disease 2019 Weekly Partner Call

August 12, 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