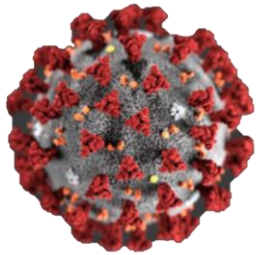


New Hampshire Coronavirus Disease 2019 Weekly Partner Call

December 16, 2021

Ben Chan
Elizabeth Talbot
Lindsay Pierce

Thursday noon-time partner calls 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

Healthcare Provider & Public Health Partner Calls

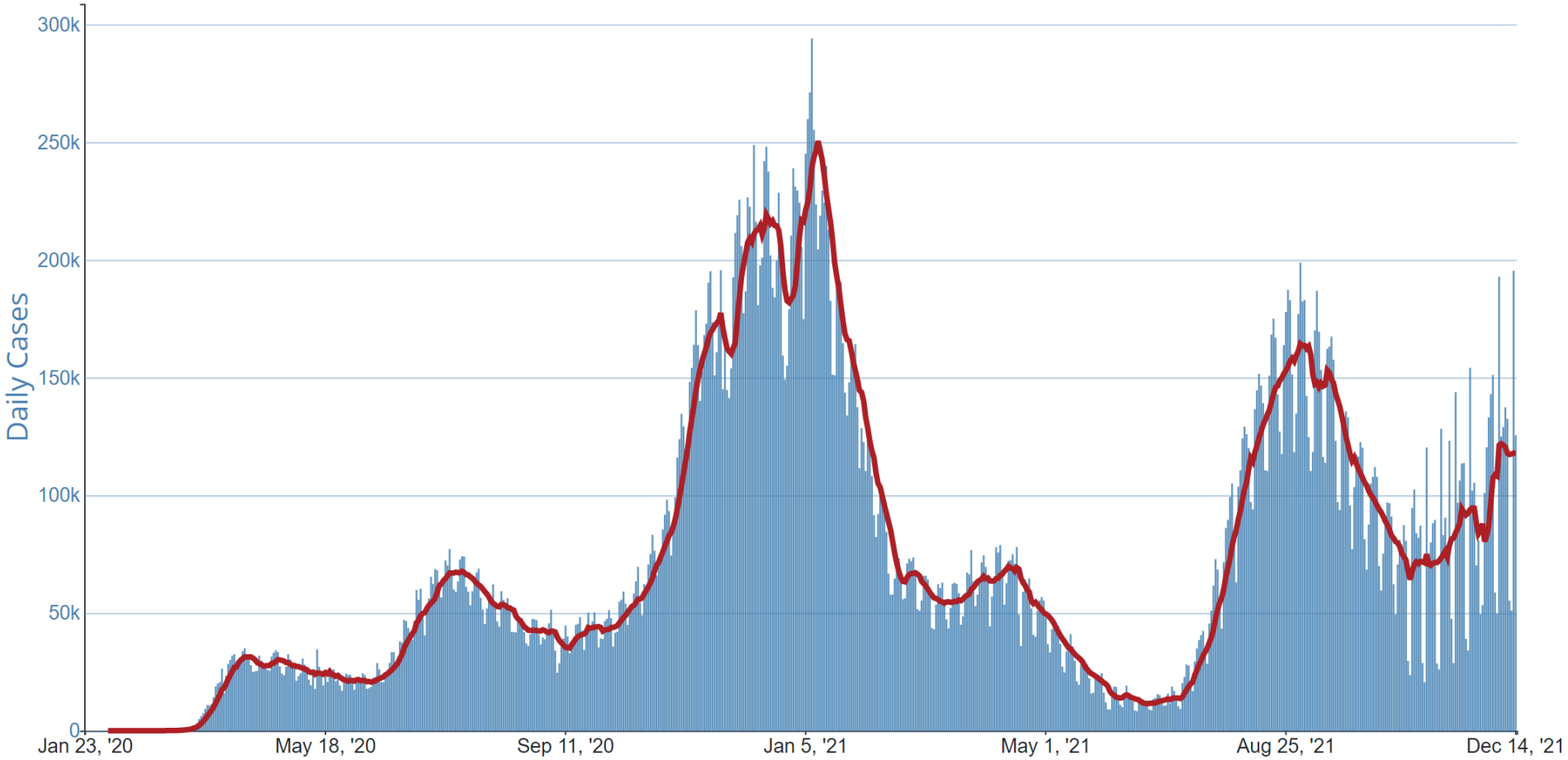
- **2nd and 4th Thursday** of each month from 12:00-1:00 pm (Next call will be January 13, 2022)
- Webinar/call information (stays the same):
  - Zoom link: https://nh-dhhs.zoom.us/s/94059287404
  - Webinar ID: 940 5928 7404
  - Passcode: 353809
  - Telephone: 646-558-8656

Agenda

- Epidemiology Update
- Omicron Variant and Vaccine Booster Update
- COVID-19 Treatment and PrEP Update
- 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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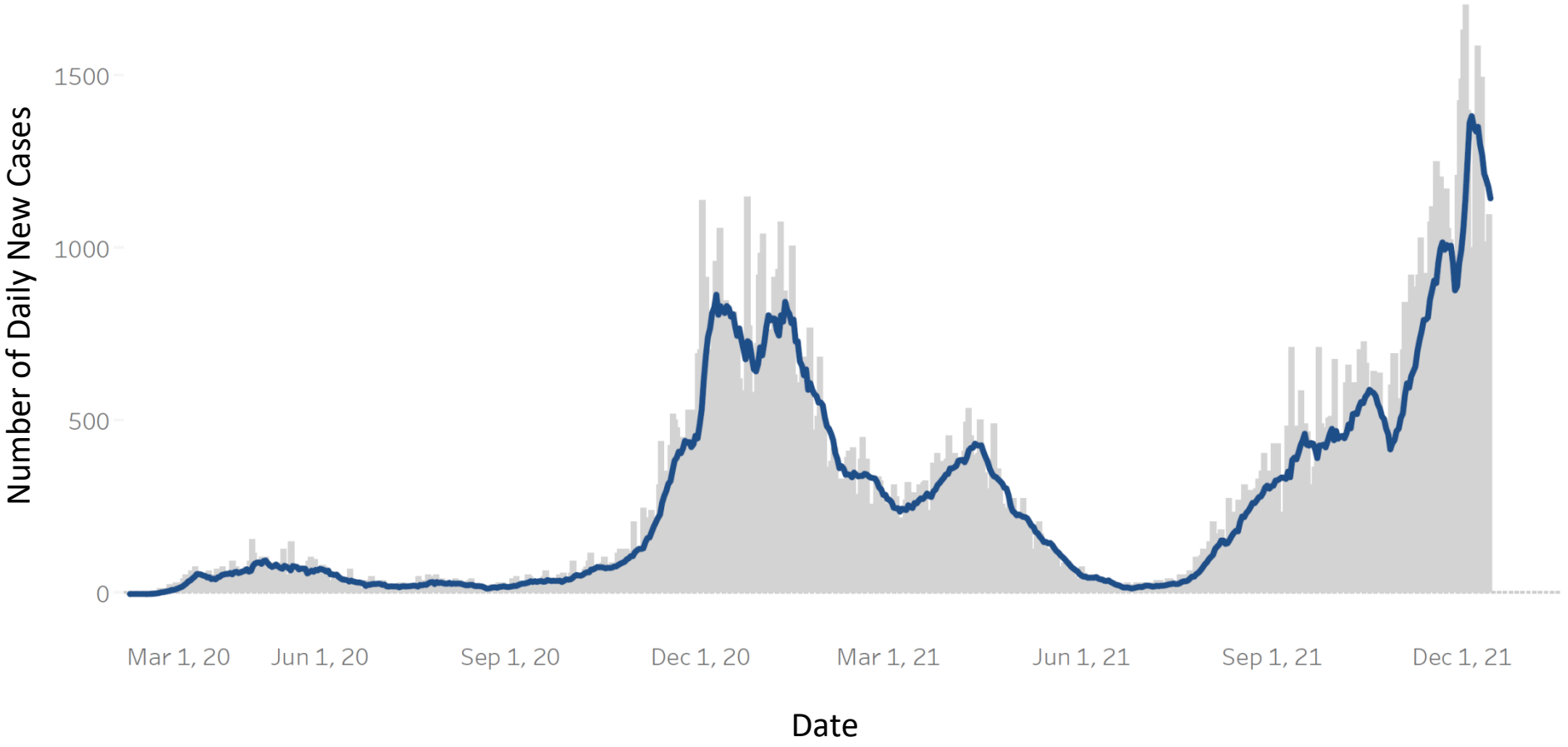
Number of New COVID-19 Cases per Day in NH



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

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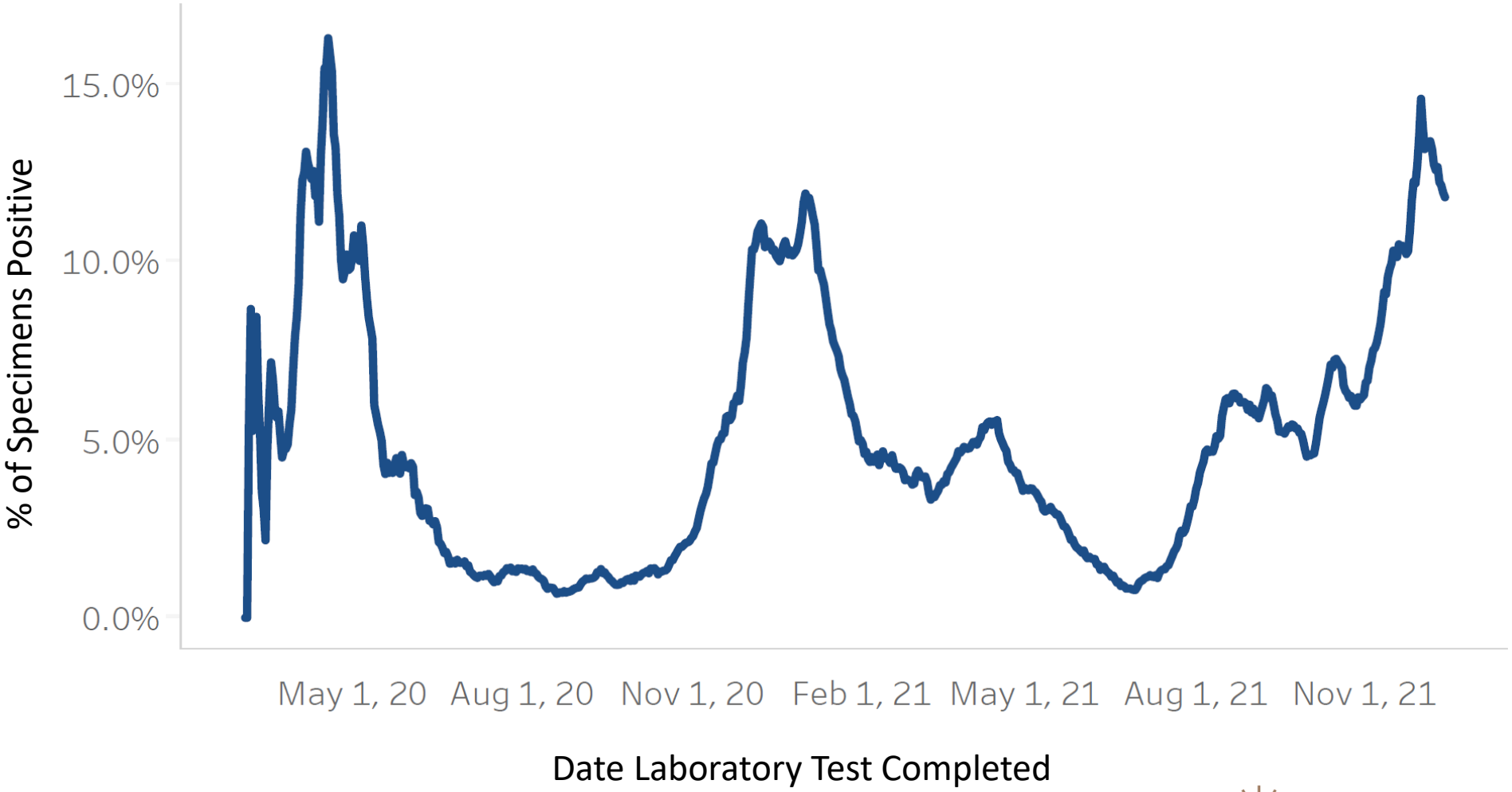
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



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

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Level of Community Transmission in NH

Statewide Level of Transmission

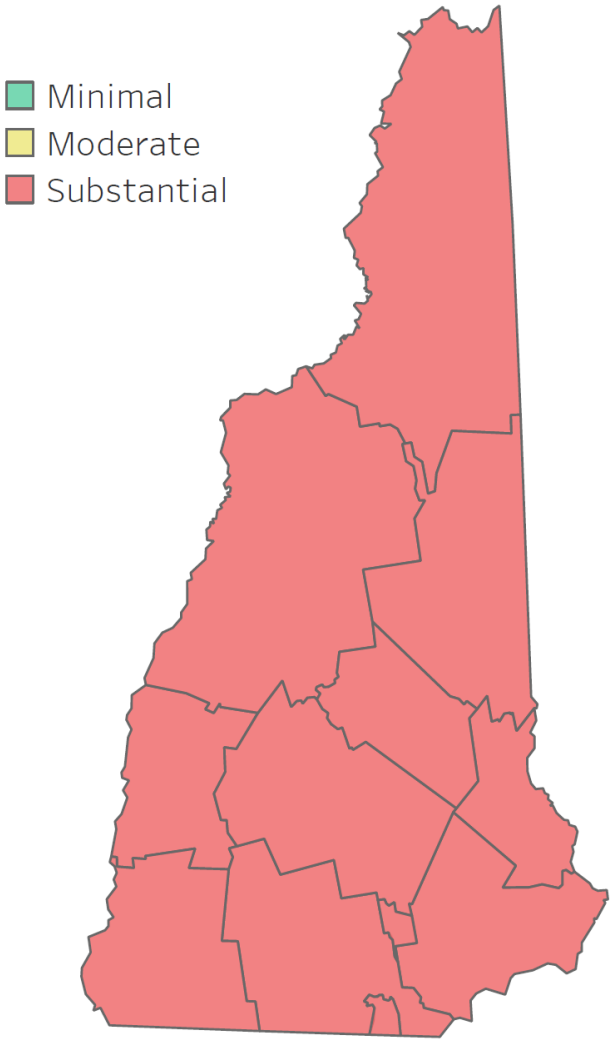
Substantial

New Cases per 100k over 14 days

1,280.2

7-Day Total Test Positivity Rate

11.8%



Data as of: 12/15/2021

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

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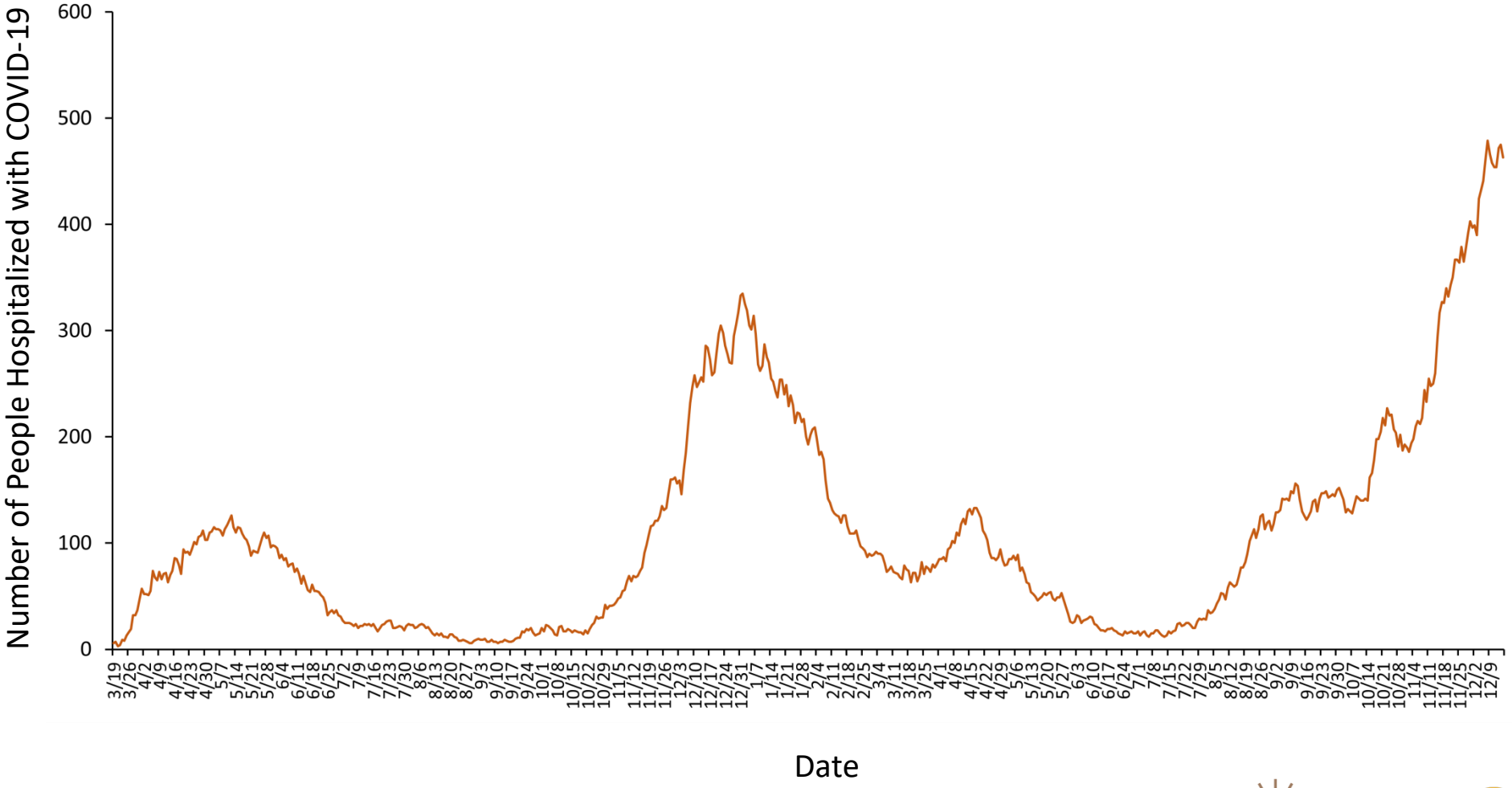
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



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

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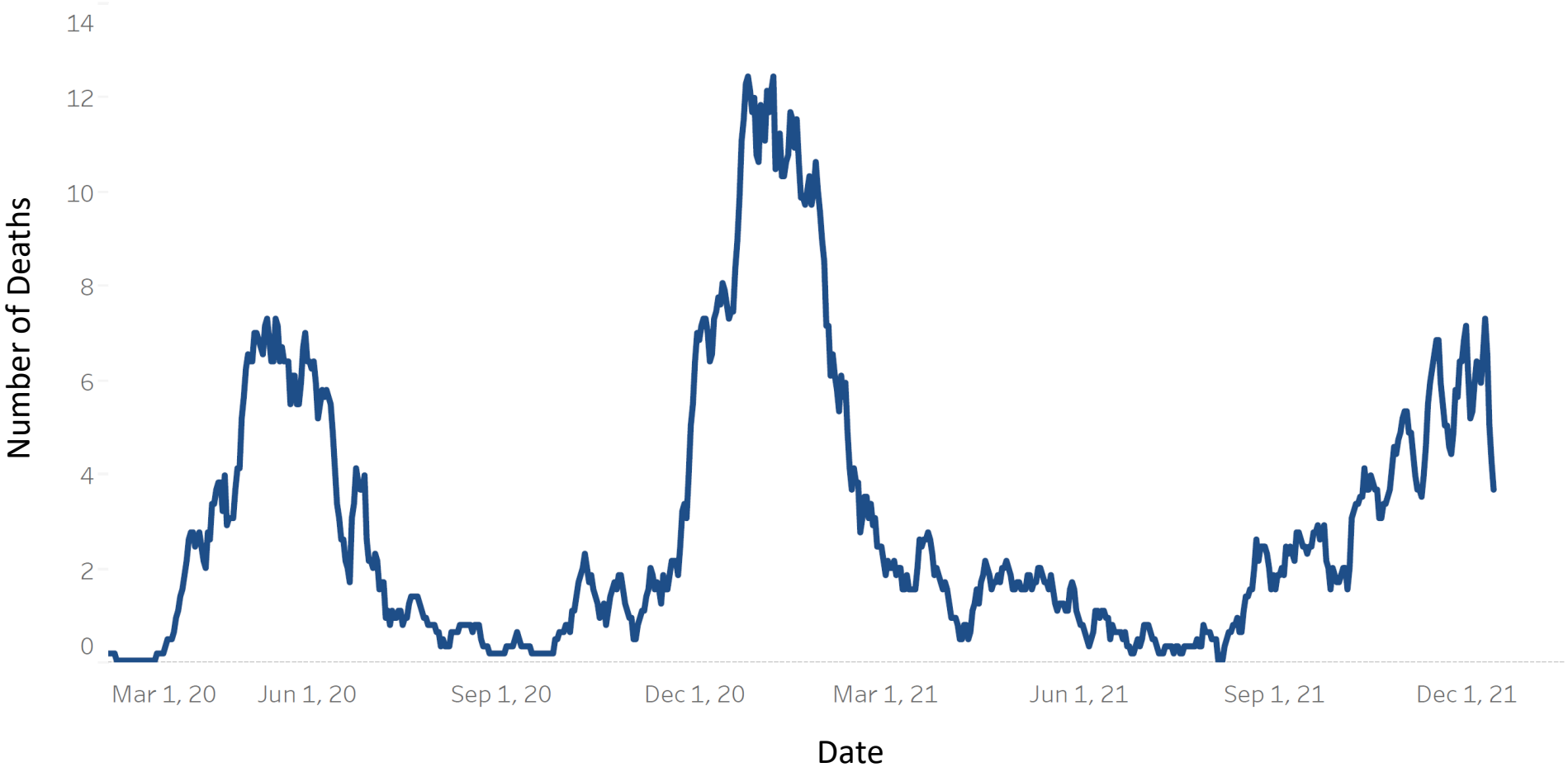
Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



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

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Omicron Variant and COVID-19 Vaccine Boosters

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Public Health Services
Department of Health and Human Services

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Protection against Covid-19 by BNT162b2 Booster across Age Groups

- Booster doses were approved for use in Israel for all persons 12 years of age or older by the end of August
- Quantified the booster effect in persons 16 years of age or older by comparing confirmed infections, severe illness, and deaths in persons with 2 doses vs. 3 doses (booster dose) of the Pfizer-BioNTech COVID-19 vaccine
- During Delta variant predominance

https://www.nejm.org/doi/full/10.1056/NEJMoa2115926

Confirmed Infections by Age Group

Age	Nonbooster Group	Booster Group	Nonbooster Group vs. Booster Group
			Rate Ratio (95% CI)
	no. of confirmed infections (no. of person-days at risk)		
≥60 yr	12,456 (22,803,132)	2833 (53,332,528)	12.3 (11.8–12.8)
50–59 yr	10,247 (12,735,098)	1011 (17,239,405)	12.2 (11.4–13.0)
40–49 yr	16,885 (16,560,386)	1157 (14,362,014)	9.7 (9.2–10.3)
30–39 yr	21,452 (19,338,294)	842 (9,541,493)	9.0 (8.4–9.7)
16–29 yr	22,441 (26,675,210)	317 (9,727,114)	17.2 (15.4–19.2)

https://www.nejm.org/doi/full/10.1056/NEJMoa2115926

Severe Illness and Deaths in Older Age Groups

Outcome	Age	Nonbooster Group	Booster Group	Nonbooster Group vs. Booster Group
				Rate Ratio (95% CI)
	yr	*no. of confirmed infections (no. of person-days at risk)*		
Severe illness	≥60	977 (22,135,011)	166 (46,668,795)	17.9 (15.1–21.2)
Severe illness	40–59	168 (27,599,399)	8 (25,890,717)	21.7 (10.6–44.2)
Death	≥60	288 (17,909,789)	34 (16,768,943)	14.7 (10.0–21.4)

https://www.nejm.org/doi/full/10.1056/NEJMoa2115926

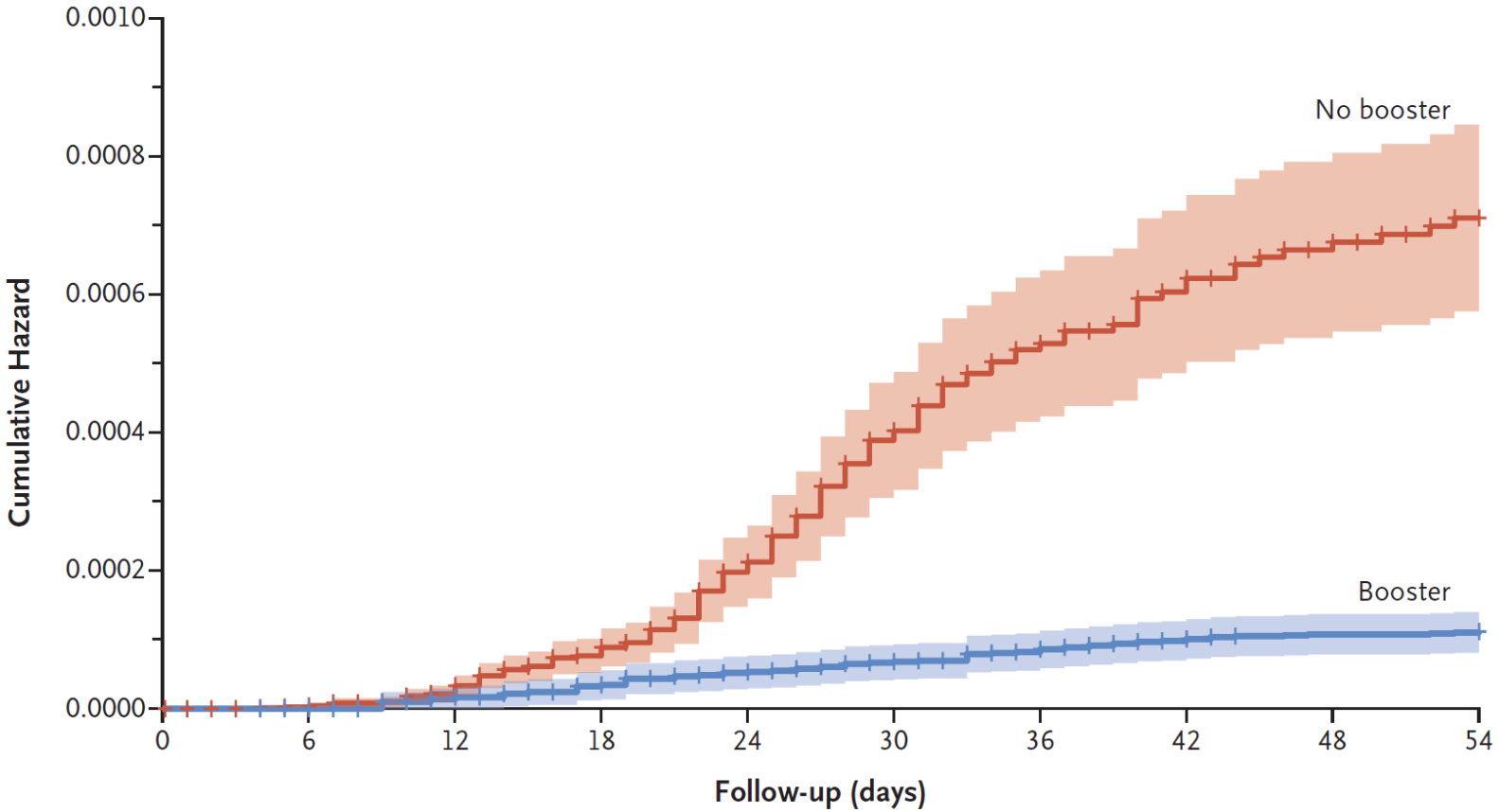
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

BNT162b2 Vaccine Booster and Mortality Due to Covid-19

- Another Israeli study of vaccine booster effect comparing mortality in people 50+ years of age who received 2 vs. 3 doses of the Pfizer vaccine
- During a period of high COVID-19 incidence with Delta variant
- People who completed a primary Pfizer COVID-19 vaccine series AND received a booster dose had a 90% lower COVID-19 mortality compared to those who did not receive a booster dose
- Based on a relatively short study period (54 days)

https://www.nejm.org/doi/full/10.1056/NEJMoa2115624



No. at Risk										
No booster	841,428	723,609	520,459	326,741	202,797	145,021	111,761	101,695	90,036	83,989
Booster	46,259	119,332	322,203	515,639	639,315	696,859	729,971	739,945	756,591	757,614
Cumulative No. of Events										
No booster	0	3	20	43	72	103	119	129	134	137
Booster	0	0	4	12	23	33	46	57	62	65

https://www.nejm.org/doi/full/10.1056/NEJMoa2115624

THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network
DHHS.Health.Alert@dhhs.nh.gov
December 13, 2021 Time 1400 (2:00 PM EDT)
NH-HAN 20211213

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

COVID-19 Pandemic, Update # 50

Omicron Variant and COVID-19 Vaccine Booster Update

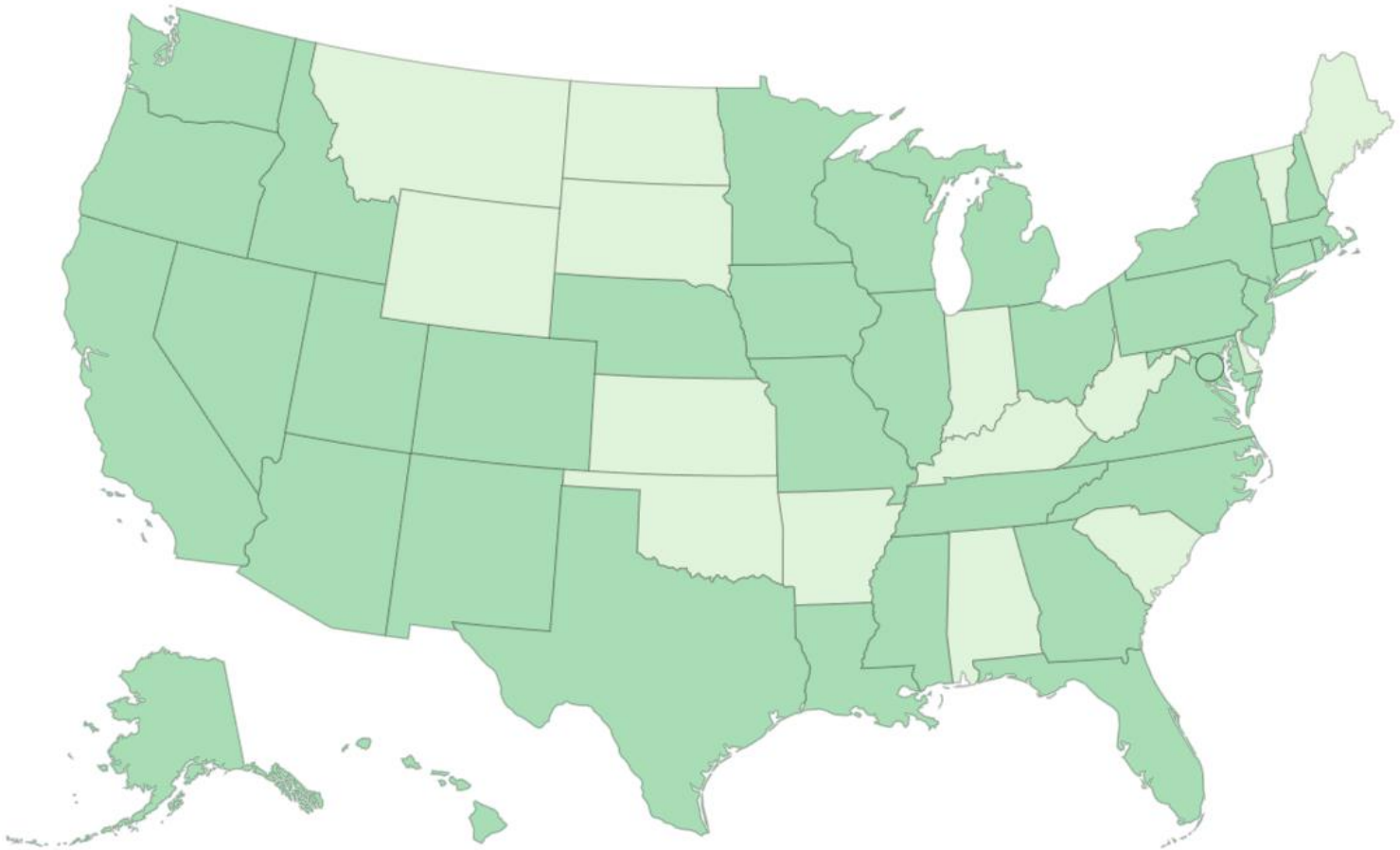
Key Points and Recommendations:

- NH Public Health Laboratories (PHL) has identified the first NH resident infected with the Omicron variant. This person is an adult from Cheshire County who traveled out-of-state and had a known exposure to another person with Omicron; this person was fully vaccinated but not yet boosted.

- The Omicron variant is predicted to be more infectious, resistant to certain therapeutics, and possibly evade vaccine- or infection-induced immunity. Preliminary laboratory-based studies are showing decreased vaccine- and infection-induced antibody neutralization of the Omicron variant (see Background section).

- COVID-19 vaccine booster doses are increasingly important:

States & Territories with Omicron Detections



Territories AS GU PR VI MP FM PW MH

https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html

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Summary of Early Omicron Studies

- Omicron appears to be more infectious
- Multiple studies are showing substantially decreased neutralizing antibody capability against Omicron variant in people with immunity from previous infection or vaccination (i.e. with a 2-dose mRNA vaccine series)
  - 10-40 fold reduction in neutralizing antibody titers against Omicron after a primary series vaccination (e.g., 2-dose mRNA vaccine)
- A 2-dose mRNA vaccine series in preliminary estimates is ~30-40% effective at preventing COVID-19 from Omicron
- A booster dose appears to substantially increases neutralizing antibody levels (but still lower than against other variants)
- One study reports that a booster dose increases vaccine effectiveness at protecting against COVID-19 from Omicron to ~75%

UK Health Security Agency

SARS-CoV-2 variants of concern and variants under investigation in England

Technical briefing 31

10 December 2021

- Studies of households have found a higher risk of transmission to household contacts from an Omicron index case compared to a Delta index case (not taking into account vaccination or prior infection status)
  - Risk of household transmission from Omicron index case compared to Delta: OR 3.2 (95% CI: 2.0-5.0)
  - Household secondary attack rate for Delta vs. Omicron: 11% vs. 22%, respectively

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040076/Technical_Briefing_31.pdf

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Department of Health and Human Services

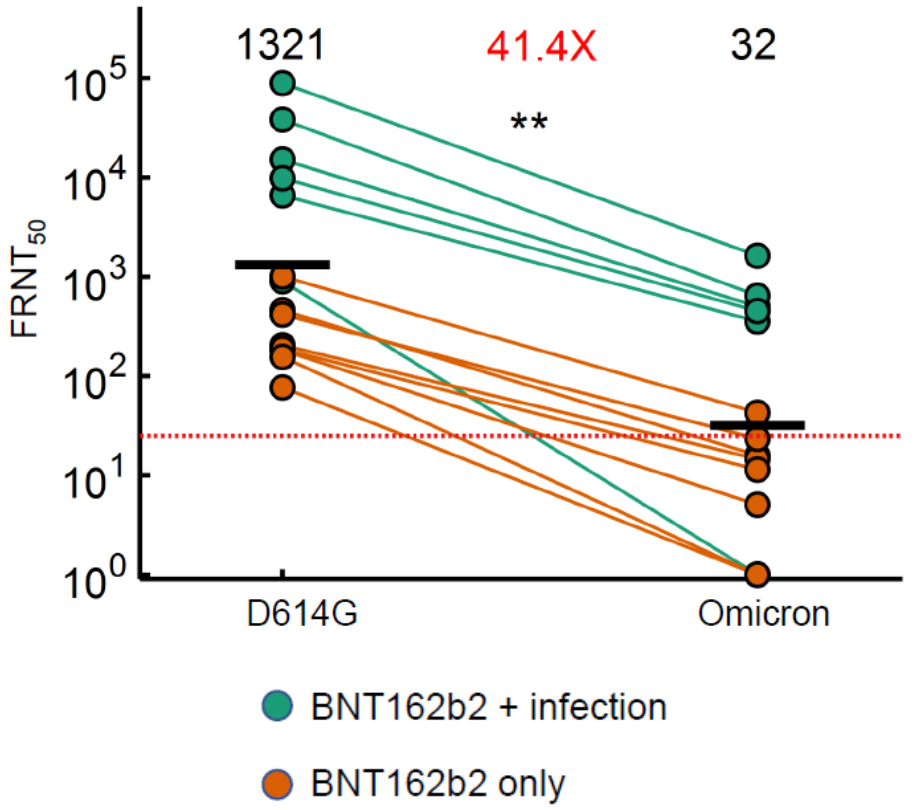
medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

SARS-CoV-2 Omicron has extensive but incomplete escape of Pfizer BNT162b2 elicited neutralization and requires ACE2 for infection

- Tested blood samples from 12 participants who were vaccinated with Pfizer vaccine
  - 6 participants had a + history of previous infection (green dots)
  - 6 participants had no history of previous infection (orange dots)
- Geometric mean neutralizing antibody titers showed a 41-fold decline for Omicron variant compared to D614G



https://www.medrxiv.org/content/10.1101/2021.12.08.21267417v2

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Department of Health and Human Services

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

SARS-CoV-2 B.1.1.529 variant (Omicron) evades neutralization by sera from vaccinated and convalescent individuals

- Tested neutralizing capability of sera from vaccinated and previously infected (convalescent) persons against Omicron:
  - Persons with previous Alpha, Beta, and Delta infections
  - Persons with primary vaccination with Pfizer, AstraZeneca and Moderna (“Spikevax”)
- Significant reduction in vaccine-induced antibody neutralization against Omicron compared to other variants (but some efficacy)
- Sera from convalescent persons failed to neutralize Omicron
- Better neutralization for infected + vaccinated persons

https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1

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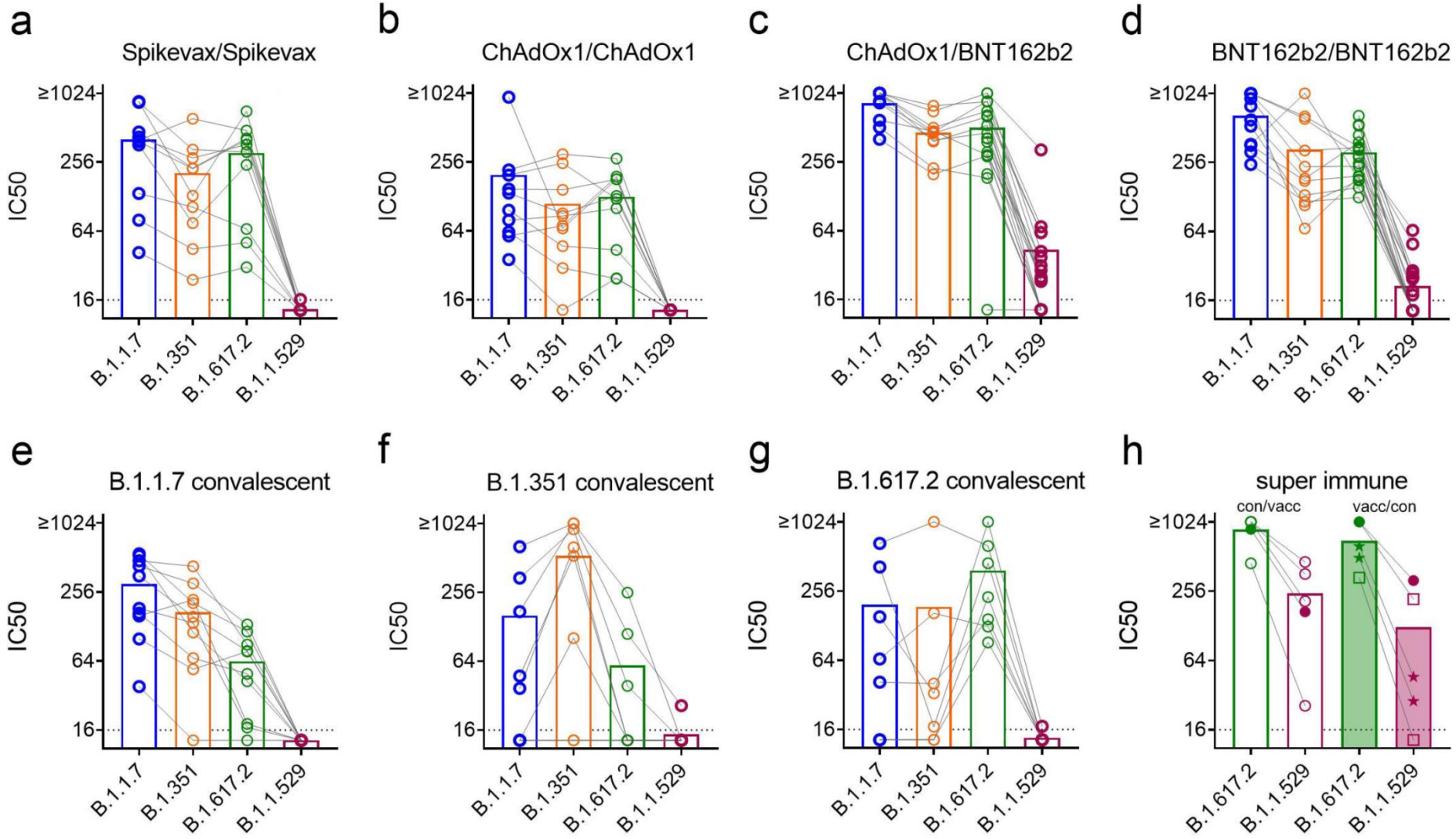

https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

Reduced neutralisation of SARS-COV-2 Omicron-B.1.1.529 variant by post-immunisation serum

- Neutralization antibody titers against Omicron were performed on blood from persons vaccinated with 2 doses of the AstraZeneca (n=22) or Pfizer (n=21) COVID-19 vaccines (none previously infected)
- In persons who completed 2-dose Pfizer vaccination: neutralizing Ab titers showed a 30-fold reduction against Omicron compared to earlier variant

https://www.medrxiv.org/content/10.1101/2021.12.10.21267534v1

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NEWS / Pfizer And BioNTech Provide Update On Omicron Variant

PFIZER AND BIONTECH PROVIDE UPDATE ON OMICRON VARIANT

Wednesday, December 08, 2021 - 06:54am

- Tested sera from vaccine recipients who received 2-doses: 25-fold reduction in neutralizing Ab titers against Omicron compared to wild-type virus
- Tested sera from VRs who received 3-doses (i.e., a booster): produced similar neutralizing Ab titers against Omicron as was observed after 2-doses against the wild-type virus
- A third dose also "strongly increases $CD8^+$ T-cell levels against multiple spike protein epitopes", the vast majority of which remain unchanged in the Omicron variant

https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant

medRxiv

THE PREPRINT SERVER FOR HEALTH SCIENCES

CSH Cold Spring Harbor Laboratory BMJ Yale

Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies

- Tested blood from the following vaccine recipient groups to compare neutralizing antibodies against Delta vs. Omicron:
  - Pfizer x2 doses
  - Pfizer x2 followed by a Pfizer booster 0.5 months later
  - Pfizer x2 followed by a Pfizer booster 3 months later
  - Moderna x2 doses
  - Moderna x2 followed by a Pfizer booster 0.5 months later
- Compared to Delta, neutralizing antibody titers against Omicron showed an ~10-40 fold reduced ability to neutralize the Omicron variant

https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v3

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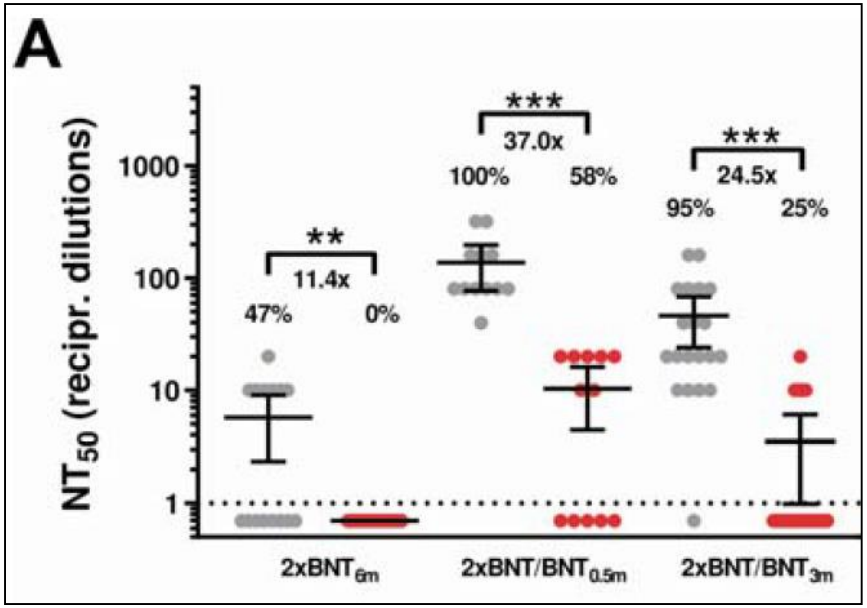
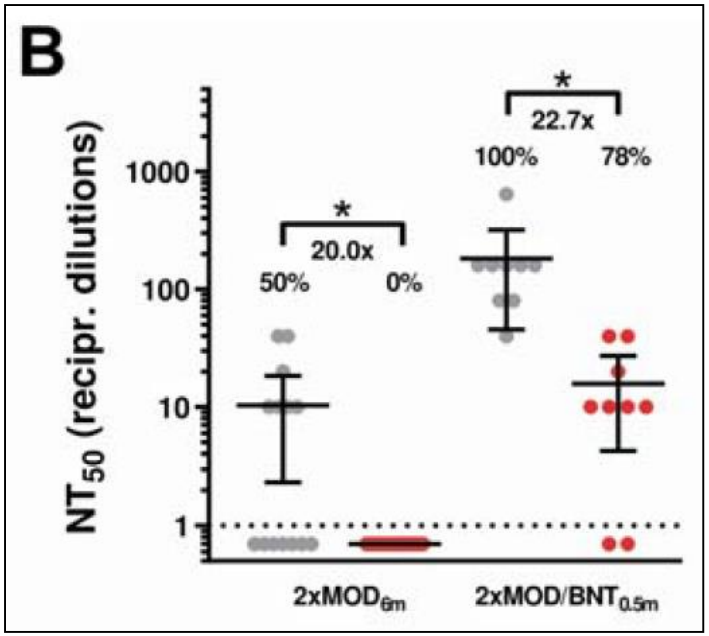
Group	Group size n
2xBNT	15
2xBNT / $BNT_{0.5m}$	12
2xBNT / BNT_{3m}	20
2xMOD	14
2xMOD / $BNT_{0.5m}$	9





https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v2

Cold Spring Harbor Laboratory

bioRxiv

THE PREPRINT SERVER FOR BIOLOGY

Improved neutralization of the SARS-CoV-2 Omicron variant after Pfizer-BioNTech BNT162b2 COVID-19 vaccine boosting

- Tested neutralizing antibody titers in blood from vaccinated participants after 2 doses (n=9) and 3 doses (n=4) of the Pfizer vaccine
- Omicron variant can be neutralized by blood collected from Pfizer vaccine recipients, optimally after 3 vaccine doses; however, neutralization is reduced

https://www.biorxiv.org/content/10.1101/2021.12.12.472252v1

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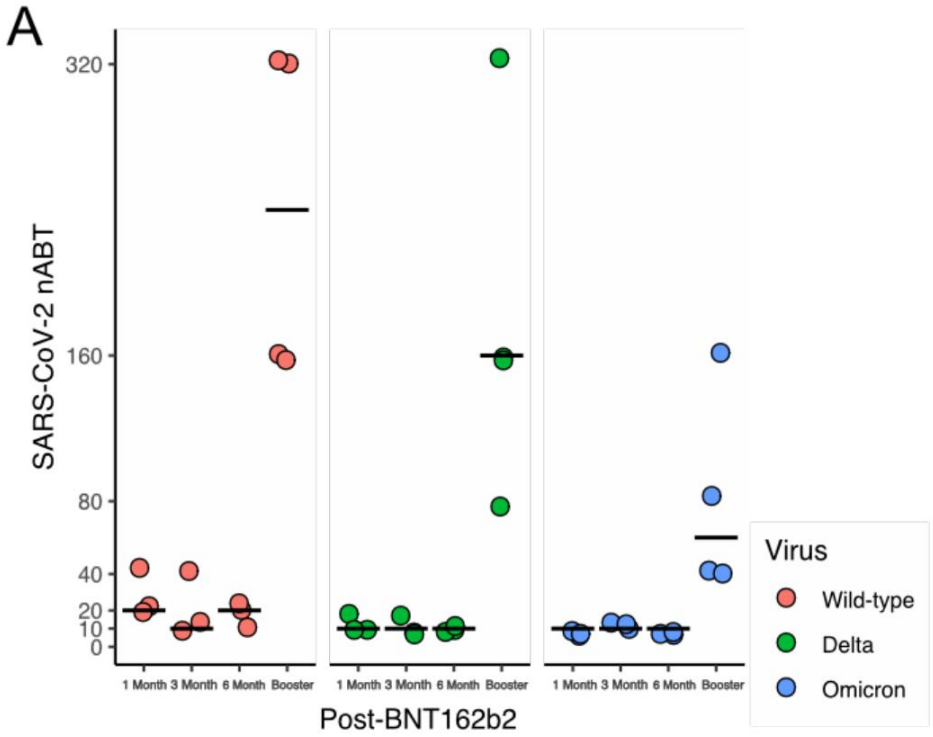
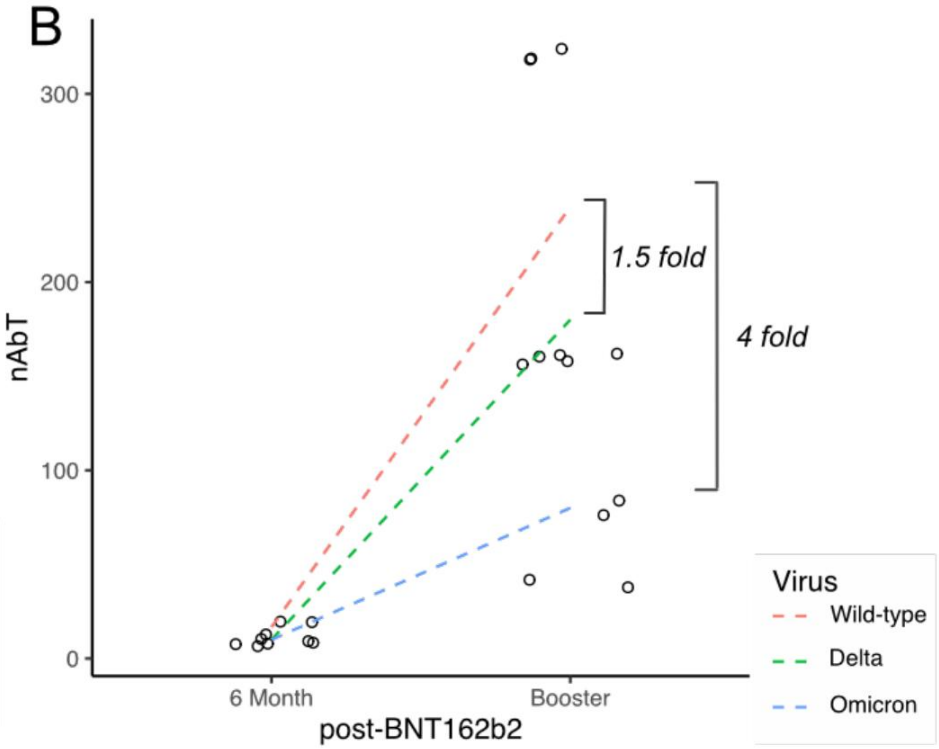
Department of Health and Human Services

A. Neutralizing Ab titers against variants at varying time points after vaccination



B. Neutralizing Ab titers 6 months after two vaccine doses compared to 1 month after booster dose



https://www.biorxiv.org/content/10.1101/2021.12.12.472252v1

Discovery

PRESS RELEASE - 14 DECEMBER 2021 13:47

Discovery Health, South Africa's largest private health insurance administrator, releases at-scale, real-world analysis of Omicron outbreak based on 211 000 COVID-19 test results in South Africa, including collaboration with the South Africa

- 2 doses of Pfizer vaccine: 70% protection against severe COVID-19; 33% protection against COVID-19 infection during Omicron wave (compared to unvaccinated)
- Risk of re-infection with Omicron is significantly higher

https://www.discovery.co.za/corporate/news-room#/pressreleases/discovery-health-south-africas-largest-private-health-insurance-administrator-releases-at-scale-real-world-analysis-of-omicron-outbreak-based-dot-dot-dot-3150697

UK Health Security Agency

SARS-CoV-2 variants of concern and variants under investigation in England

Technical briefing 31

10 December 2021

- Vaccine effectiveness against Delta and Omicron variants was estimated after 2 and 3 doses of the Pfizer vaccine (also analyzed data for AstraZeneca vaccine)
- Used both whole genome sequencing and S-gene target failure marker to identify Delta and Omicron variants
- Analysis included 56,439 Delta infections and 581 Omicron infections

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040076/Technical_Briefing_31.pdf

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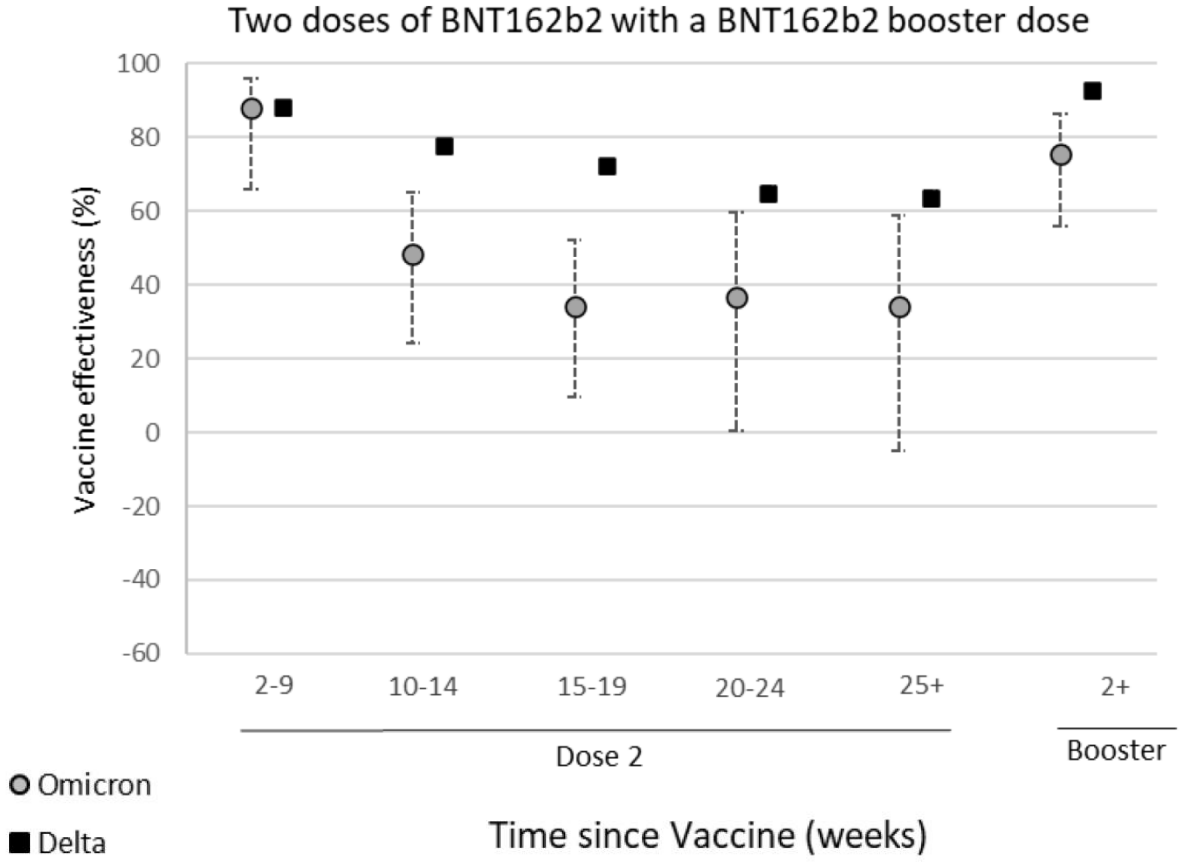
Vaccine Effectiveness: Symptomatic COVID-19



- 2 doses of Pfizer vaccine followed by a booster increased VE against Omicron variant to around 75%
- Based on low numbers of Omicron cases (uncertainty and imprecision in these estimates)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1040076/Technical_Briefing_31.pdf

Summary

- Multiple studies are showing substantially decreased neutralizing antibody capability against Omicron variant in people with immunity from previous infection or vaccination
- A 2-dose mRNA vaccine series in preliminary estimates is ~30-40% effective at preventing COVID-19 from Omicron
- A booster dose appears to substantially increases neutralizing antibody levels (but still lower than against other variants)
- One study reports that a booster dose increases vaccine effectiveness at protecting against COVID-19 due to Omicron to ~75%

Vaccine Booster Doses are Necessary

- December 9th: FDA authorized use of the Pfizer-BioNTech COVID-19 vaccine as a booster dose in 16-17 year olds
- CDC recommends:
  - All persons 18 years of age or older **should** receive a booster dose (heterologous dosing is allowed)
  - Persons 16-17 years of age **may** receive a booster dose (Pfizer-BioNTech COVID-19 vaccine only)
- NH DPHS recommends primary series vaccination for everybody 5 years of age or older, and a booster dose for anybody who is eligible (16 years of age or older)

COVID-19 Treatment and PrEP Update

COVID-19 Treatment and PrEP

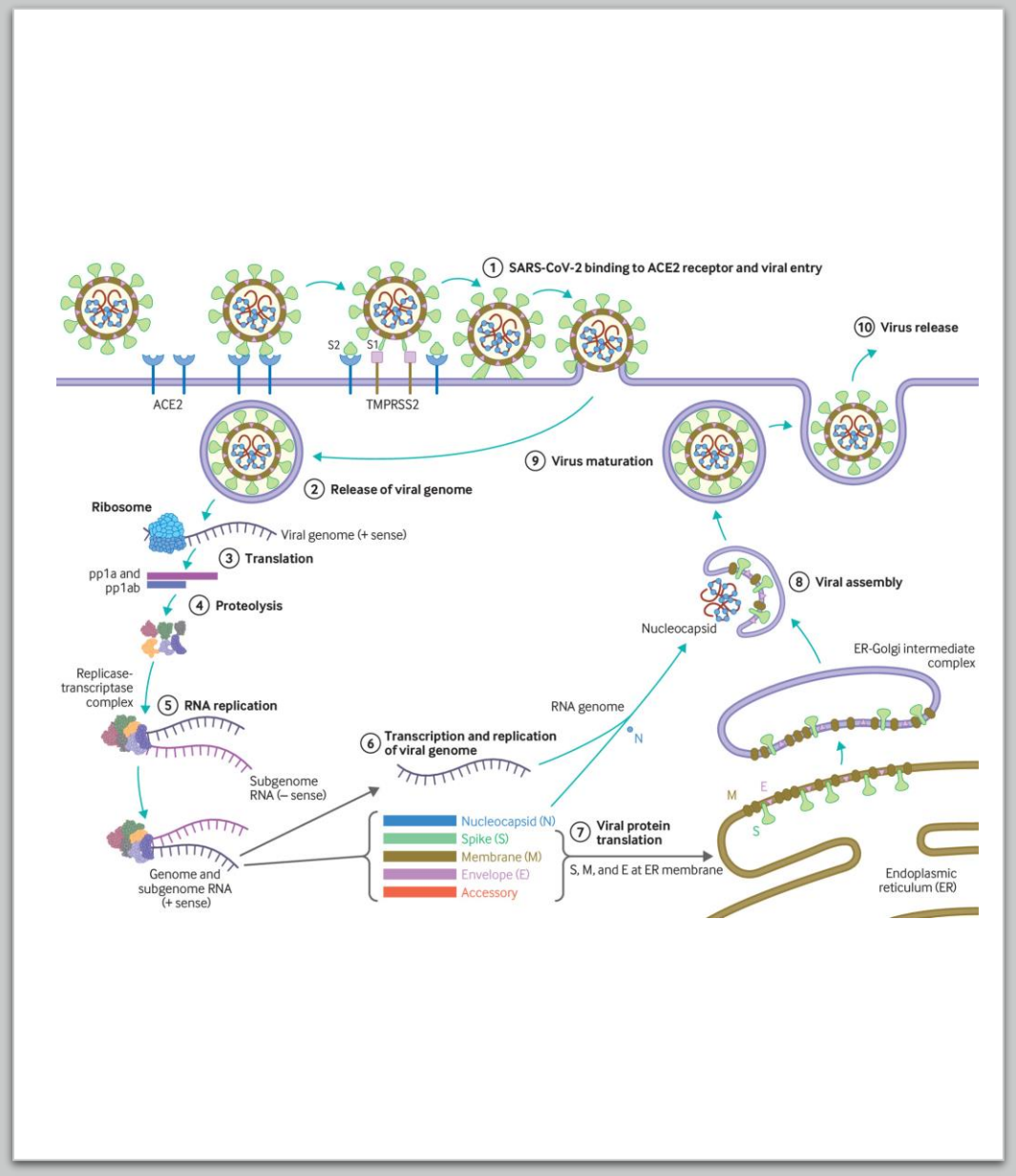
1. Paxlovid update
2. AZ's Evusheld: tixagevimab/cilgavimab

PAXLOVID™

Protease inhibitor nirmatrelvir given with ritonavir as treatment

Paxlovid Mechanism of Action

- Pfizer product
- Nirmatrelvir specifically designed SARS-CoV-2-3CL protease inhibitor with *in vitro* activity against all circulating SARS-CoV-2 VOCs and other coronaviruses
  - Combined with low dose ritonavir
- 3 pills Q12 5d



Cevik M, et al. Virology, transmission, and pathogenesis of SARS-CoV-2
BMJ 2020; 371 :m3862 doi:10.1136/bmj.m3862

FINAL ANALYSIS

Ph 2/3 Evaluation of Protease Inhibition for COVID-19 in High-Risk Patients (EPIC-**HR**)

Pfizer Press Release

Planned interim analysis of 1,219 of 3,000 planned unvaccinated adult nonpregnant outpatients in 359 locations who had confirmed mild-mod COVID-19, within 3 days of onset, at risk for progression to severe disease showed reduction of hospitalization by 89% through 28d post randomization. Similar if used within 5 days of symptom onset. AEs > placebo

Full 2,246 reduced risk of hospitalization or death by ~89%. Hospitalizations through 28d post randomization:

- 0.7% (5 of 697) Paxlovid recipients (no deaths)
- 6.5% (44 of 682) placebo recipients (9 deaths)

88% if 5 days

Relative hospitalization risk reduction 94% in patients ≥65 years

- 1.1% (1 of 94) Paxlovid recipients (no deaths)
- 16.3% (16 of 98) placebo recipients (6 deaths)

Incidence of AEs comparable in Paxlovid (23%) and placebo groups (24%), most mild

- Fewer SAEs: 1.6% vs 6.6%
- Fewer AEs leading to discontinuation of therapy: 2.1% vs 4.2%

In 499 patients, ~10-fold decrease in viral load at Day 5, relative to placebo

INTERIM ANALYSIS

Ph 2/3 Evaluation of Protease Inhibition for COVID-19 in Standard-Risk Patients (EPIC-**SR**)

Pfizer Press Release

Analysis of 80% of intended population of unvaccinated adults at low risk of hospitalization or death plus vaccinated adults who had one or more risk factors for progressing to severe illness failed to meet primary endpoint of increasing the sustained alleviation of self-reported symptoms for 4 consecutive days

Relative hospitalization risk reduction 70% nonstatistically significant (p=0.51) - no deaths either group

0.7% (3 of 428) Paxlovid patients were hospitalized

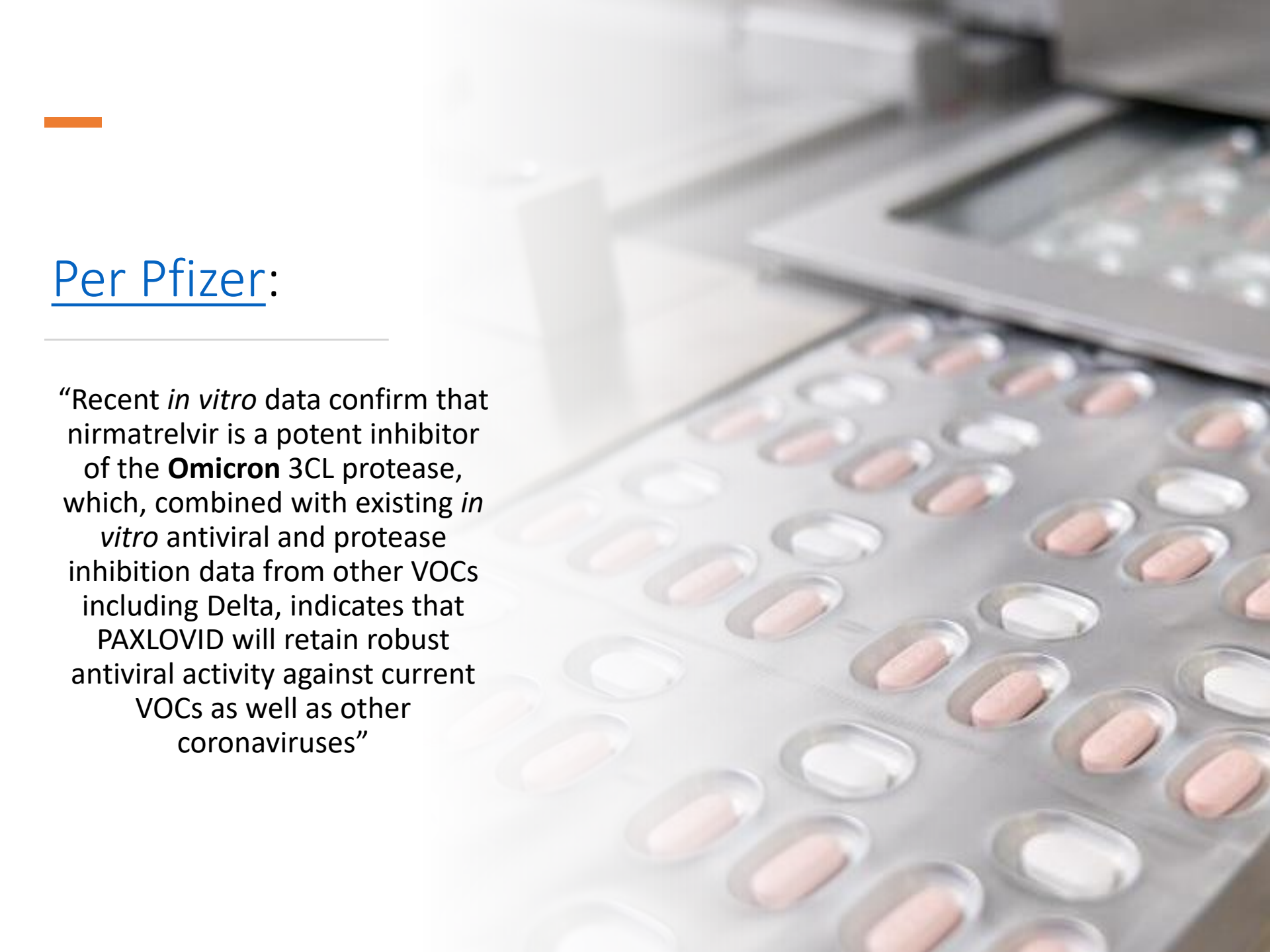
2.4% (10 of 426) placebo recipients

Rates of AEs similar between the drug and placebo (and same as EPIC-HR)

~10-fold decrease in viral load at Day 5, relative to placebo (and same as EPIC-HR)

Per Pfizer:

"Recent *in vitro* data confirm that nirmatrelvir is a potent inhibitor of the **Omicron** 3CL protease, which, combined with existing *in vitro* antiviral and protease inhibition data from other VOCs including Delta, indicates that PAXLOVID will retain robust antiviral activity against current VOCs as well as other coronaviruses"



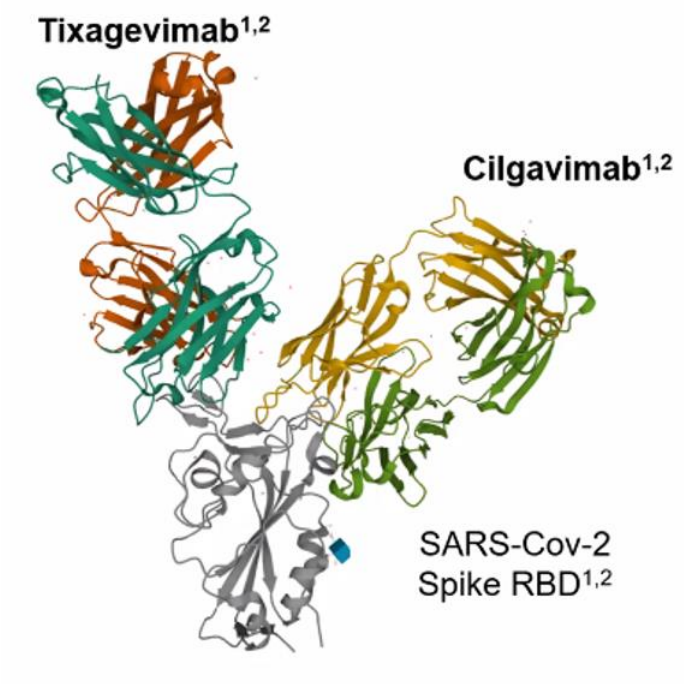
Next Steps for Paxlovid

- Nov 16: requested FDA EUA
- Complete EPIC-SR, especially vaccinated subpopulation analysis
- Complete Phase 2/3 EPIC-PEP (Evaluation of Protease Inhibition for COVID-19 in Post-Exposure Prophylaxis [for household contacts])
- USG purchased 10M courses for $5B and will distribute
- Pregnant/breastfeeding women and children?
- Combo therapies with other antivirals??

Evusheld

AstraZeneca's combination long-acting mAbs tixagevimab/cilgavimab for PrEP

Evusheld's mAbs Target the Spike Protein



- 2 human mAbs binding 2 distinct epitopes[3]
- Highly potent[4]
- Retained neutralizing activity against variants of concern[3]
- Intramuscular administration[5]
- Extended half-life (YTE modification)[5]
- Reduced FcR or C1q binding (TM)[5]
- Favorable safety profile[5]
- Efficacy was shown for pre-exposure prophylaxis in high-risk populations[5]

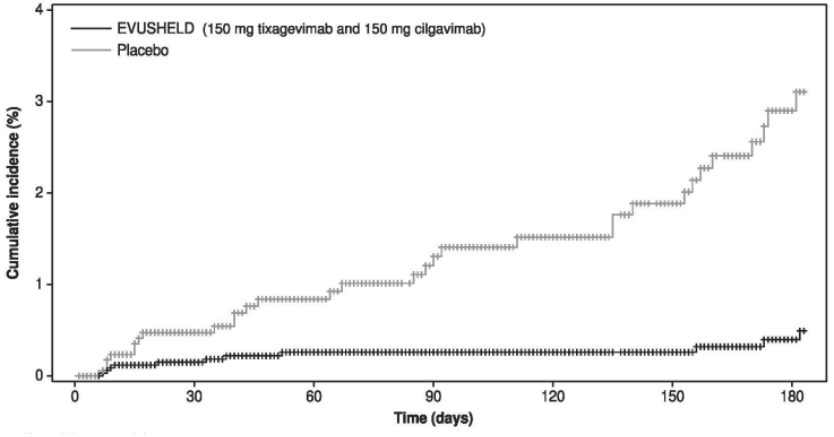
1. Sehnal D et al. *Nucleic Acids Res*. 2021;49:W431-W437; 2. Protein Data Bank. https://www.rcsb.org/. 7L7E. Accessed November 10, 2021; 3. Loo YM et al. Preprint published online. *medRxiv*. 2021; 4. Zost SJ et al. *Nature*. 2020;584:443-4493. 5. Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021.

PROVENT: Evusheld Efficacy and Safety

- **EFFICACY**[1]
  - Results from PROVENT, the Pivotal Phase III pre-exposure prophylaxis trial, showed EVUSHELD achieved a statistically significant reduction in the incidence of symptomatic COVID-19, the trial's primary endpoint.
    - EVUSHELD **reduced the risk of developing symptomatic COVID-19 by 77%** (95% CI: 46, 90; p<0.001), compared to placebo.
    - **Longer (median 6.5 month) follow-up showed a relative risk reduction of 83% (95% CI: 66-91) with EVUSHELD compared to placebo**
    - **More than 75%** of participants had co-morbidities, which include conditions that have been reported to cause a reduced immune response to vaccination.
- **SAFETY**
  - **EVUSHELD was well tolerated**, with no safety signals observed through 6 months[1]
  - At 6.5 month median follow-up, there were **no cases of severe COVID-19 or COVID-19-related deaths in those treated with EVUSHELD**. In the placebo arm, there were 5 cases of severe COVID-19 and 2 COVID-19-related deaths[1,2]

4220 participants

Med f/u 83d



Storm Chaser is SD PEP. Results in in FACT Sheet

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

Dec 8 FDA Issued an EUA for Evusheld

- **Dec 8, 2021** - U.S. Food and Drug Administration issued an Emergency Use Authorization (EUA) for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms [about 88 pounds]) who meet the following criteria:
- Are not currently infected with SARS-CoV-2 and have not recently been exposed to individual infected with SARS-CoV-2 AND
- Have either:
  - moderate to severe immune compromise due to a medical condition or due to taking immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination OR
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g severe allergic reaction) to a COVID-19 vaccine and/or component(s) of those vaccines

FDA EUA for Evusheld

Who is Immunocompromised?

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

Limitations and Contraindications

Limitations of Authorized Use:

- EVUSHELD is **not** authorized for **treatment** of COVID-19 or **post-exposure prophylaxis**
- PrEP with EVUSHELD is not a substitute for vaccination in individuals where COVID-19 is vaccination is recommended
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered ≥2 weeks after vaccination

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Contraindications

- EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD.

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Warning and Precautions

- There are limited clinical data available for EVUSHELD. Serious and unexpected adverse events may occur that have not been previously reported with EVUSHELD use.
- **Hypersensitivity Including Anaphylaxis:** Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour.
- **Clinically Significant Bleeding Disorders:** As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.
- **Cardiovascular Events:** A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

Cardiac SAEs

Table 3 Cardiac SAEs Regardless of Causality in PROVENT with Onset Prior to Day 183 Using the Median 6-Month Data Cut-off Date

	EVUSHELD N= 3,461	Placebo N= 1,736
Subjects with any cardiac SAE*	22 (0.6%)	3 (0.2%)
SAEs related to coronary artery disease or myocardial ischemia†	10 (0.3%)	2 (0.1%)
Myocardial infarctions‡	8 (0.2%)	1 (0.1%)
SAEs related to cardiac failure§α	6 (0.2%)	1 (0.1%)
SAEs related to an arrhythmia¶	4 (0.1%)	1 (0.1%)
Other (cardiomegaly, cardiomyopathy, and cardio-respiratory arrest)	3 (0.1%)	0

Cardiac Serious Adverse Events

In STORM CHASER (N= 1,121) no cardiac SAEs were reported (median follow-up approximately 6 months). Compared to PROVENT, the subjects in STORM CHASER were younger (median age 48 versus 57 years) and had fewer baseline cardiac risk factors (24% versus 36% with hypertension, 11% versus 14% with diabetes, and 3% versus 8% with cardiovascular disease in STORM CHASER versus PROVENT, respectively).

FDA Fact Sheet

SUPPLY/STORAGE | DOSING | PREPARATION | ADMINISTRATION

Each EVUSHELD co-packaged carton contains two vials

VIAL 1: Tixagevimab solution (dark grey cap), 150 mg/1.5 mL (100mg/mL)

VIAL 2: Cilgavimab solution (white cap), 150 mg/1.5 mL (100mg/mL)

Tixagevimab and cilgavimab are clear to opalescent, colorless to slightly yellow solutions

Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.

Discard any unused portion.

DO NOT FREEZE **DO NOT SHAKE**

Limited Initial Supply

HHS distributing 600,000 doses beginning this week

Pro rata basis, 50,000 doses QOW which equates to 216 for NH

NH DHHS will distribute fixed amounts to participating hospitals

Q&A

Healthcare Provider & Public Health Partner Calls

- **2nd and 4th Thursday** of each month from 12:00-1:00 pm (Next call will be January 13, 2022)
- Webinar/call information (stays the same):
  - Zoom link: https://nh-dhhs.zoom.us/s/94059287404
  - Webinar ID: 940 5928 7404
  - Passcode: 353809
  - Telephone: 646-558-8656