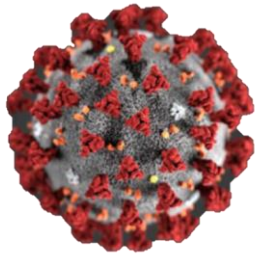

New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners

May 13, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

Thursday noon-time partner calls will focus on science, medical, and vaccine updates geared towards our healthcare partners

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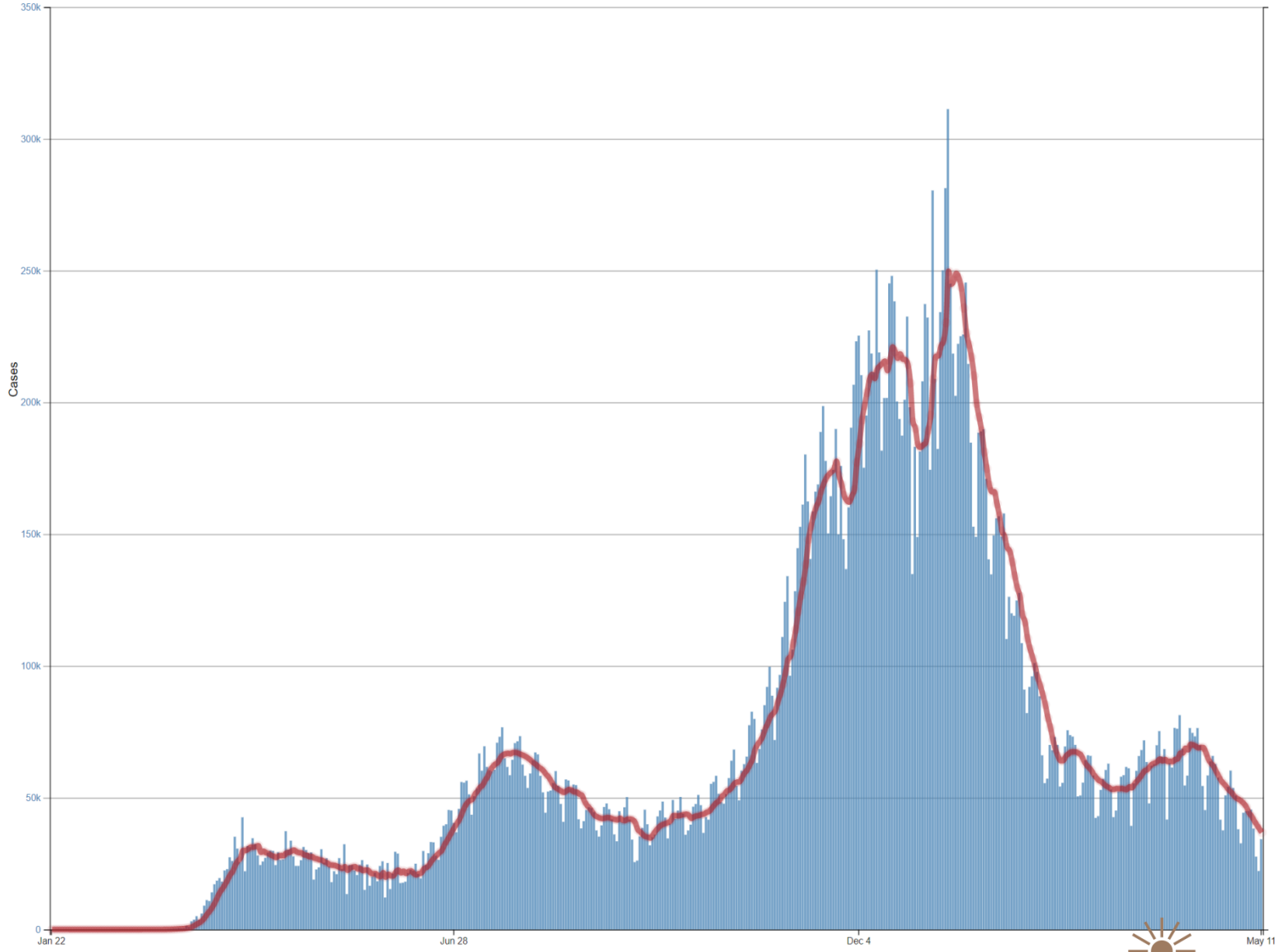
Department of Health and Human Services

Agenda

- Epidemiology Update
- Pfizer-BioNTech Emergency Use Authorization (EUA) for people aged 12-15 years
- NEJM Publication: Effectiveness of the Pfizer-BioNTech COVID-19 vaccine against the B.1.1.7 and B.1.351 variants
- Vaccine hesitancy resources
- Questions & Answers (Q&A)

U.S. National Daily Incidence of COVID-19



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

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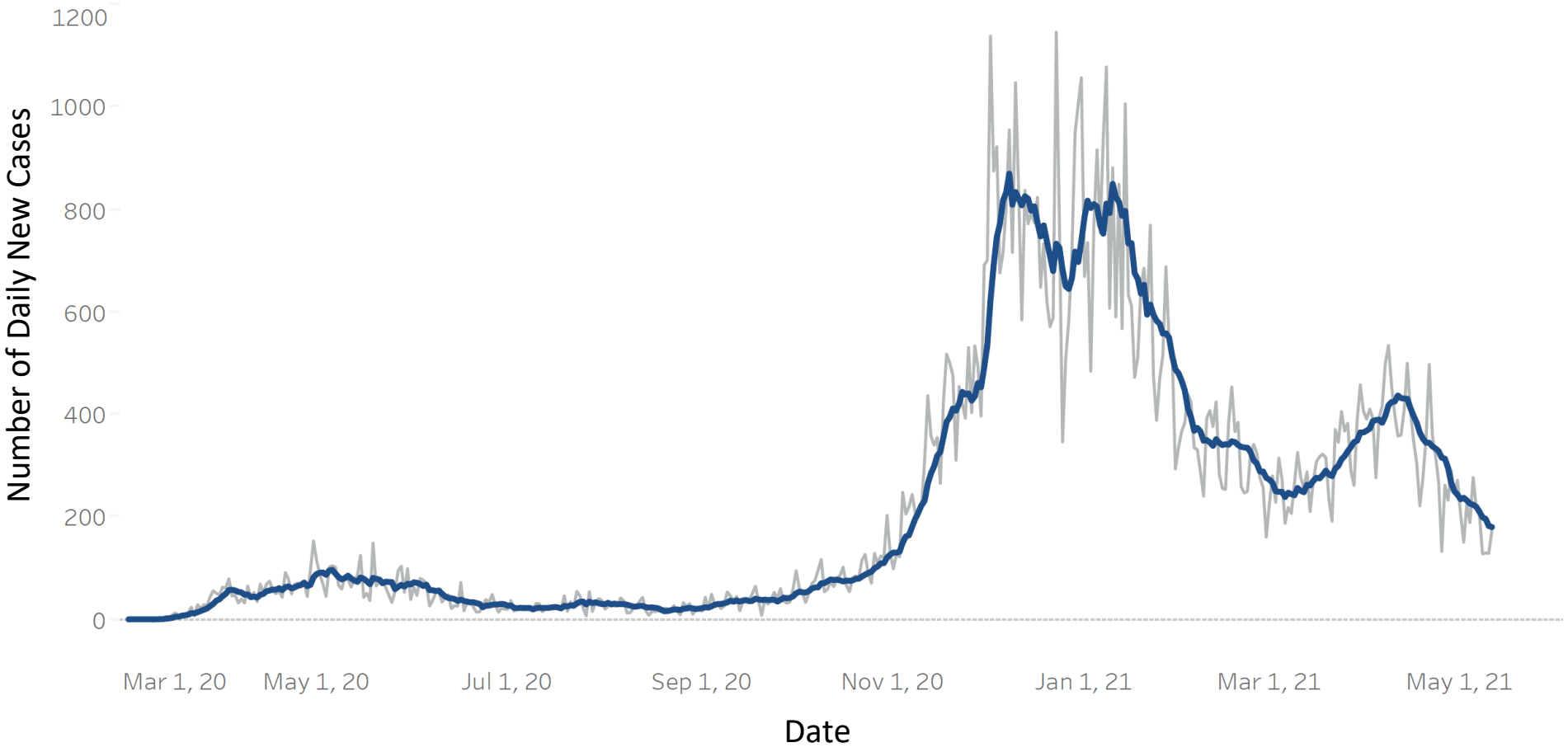
Number of New COVID-19 Cases per Day in NH



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

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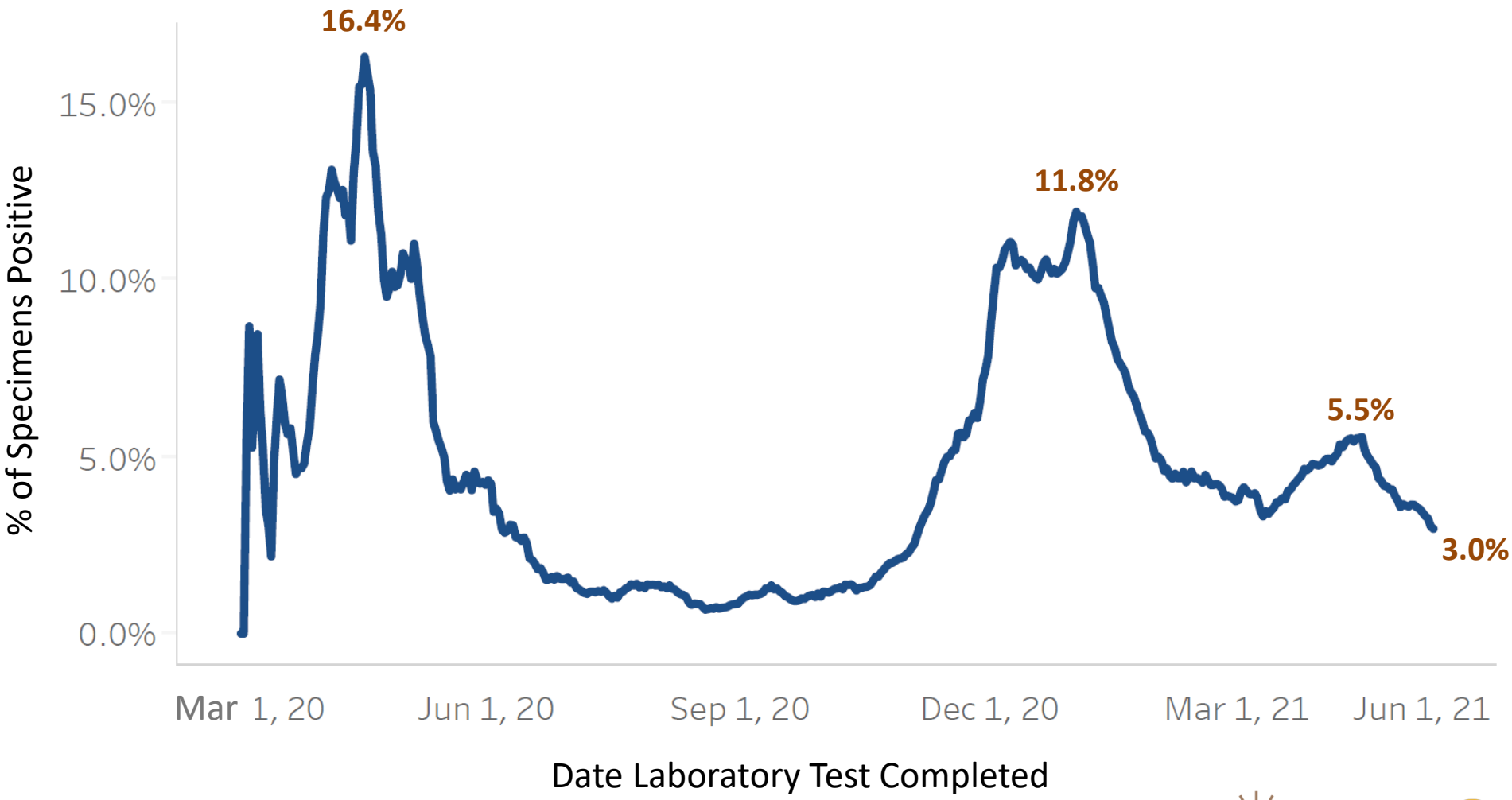
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



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

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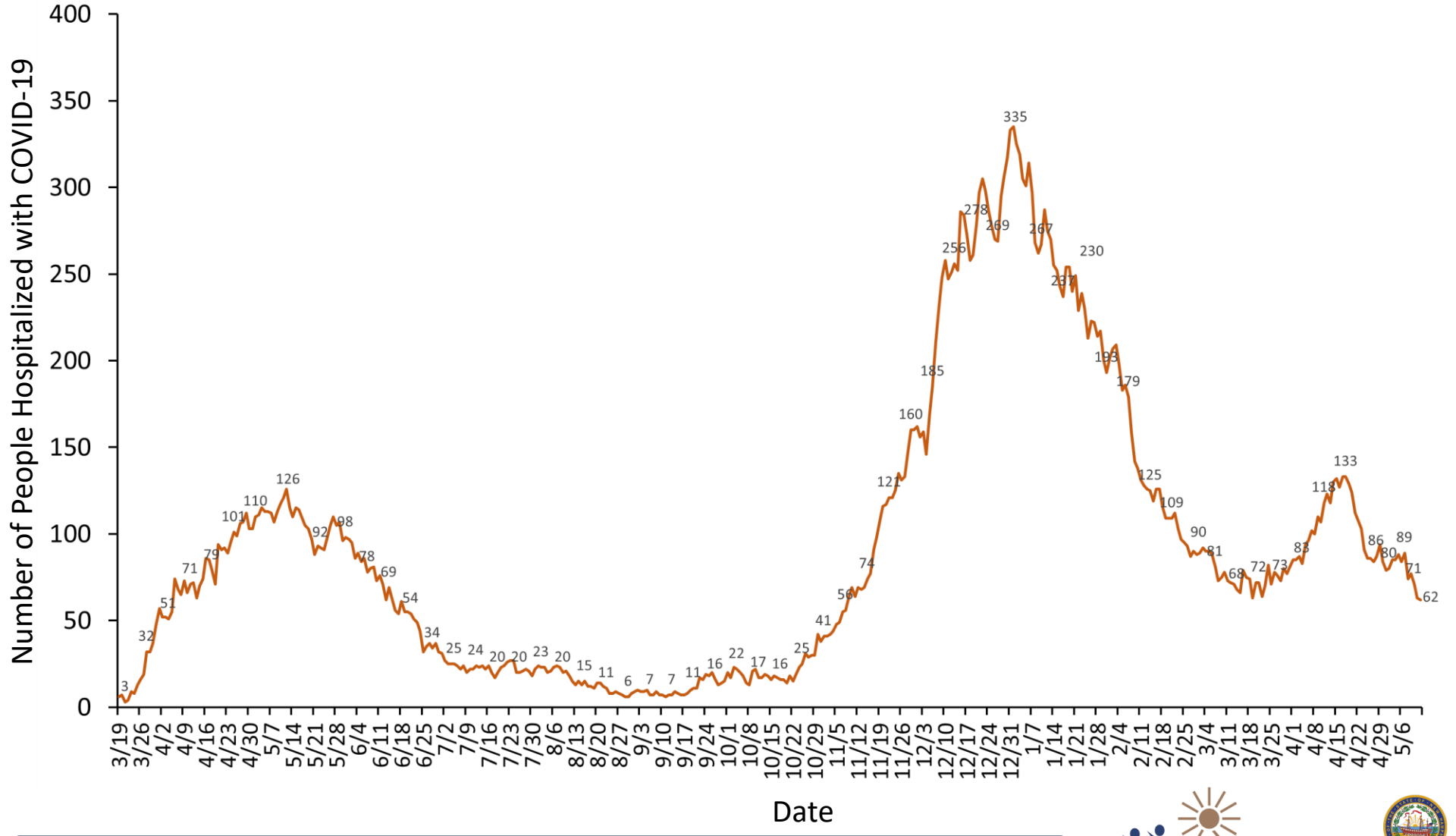
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



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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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Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization (EUA) in 12-15 Year Old Adolescents

THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network
Health.Alert@nh.gov
May 12, 2021 Time 1900 (7:00 PM EDT)
NH-HAN 20210512

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

Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 43

Pfizer-BioNTech COVID-19 Vaccine Authorized for 12-15 Year Olds

- Summary of Phase 3 clinical trial findings can be found in the updated FDA Fact Sheet for Healthcare Providers Administering Vaccine
- Studied 2,260 adolescents 12-15 years of age (1,131 vaccine vs. 1,129 placebo participants)

Vaccine Safety in 12-15 Year Olds

- No concerning safety signals
- Serious adverse side effects occurred in 0.4% of vaccine recipients vs. 0.1% of placebo recipients
- No notable patterns or “numerical imbalances” of serious adverse events between vaccine and placebo group participants were observed
- Common vaccine side effects were common

https://www.fda.gov/media/144413/download

Common Vaccine Side Effects

Injection Site Symptoms:

- Pain (91%)
- Swelling (9%)
- Redness (9%)
- Lymphadenopathy (<1%)

Systemic Symptoms:

- Fatigue (78%)
- Headache (76%)
- Chills (49%)
- Muscle pain (42%)
- Fever (24%)
- Joint pain (20%)
- Nausea (<1%)

https://www.fda.gov/media/144413/download

Neutralizing Antibody Titers Were “Non-Inferior”

Table 10: Summary of Geometric Mean Ratio for 50% Neutralizing Titer – Comparison of Adolescents 12 Through 15 Years of Age to Participants 16 Through 25 Years of Age (Immunogenicity Subset) –Participants Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population

		Pfizer-BioNTech COVID-19 Vaccine			
		12 Through 15 Years n[a]=190	16 Through 25 Years n[a]=170	12 Through 15 Years/ 16 Through 25 Years	
Assay	Time Point[b]	GMT[c] (95% CI[c])	GMT[c] (95% CI[c])	GMR[d] (95% CI[d])	Met Noninferiority Objective[e] (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)[f]	1 month after Dose 2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

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.

https://www.fda.gov/media/144413/download

Vaccine Efficacy Estimate for 12-15 Year Olds

Table 9: Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2: Without Evidence of Infection and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period, Adolescents 12 Through 15 Years of Age Evaluable Efficacy (7 Days) Population

First COVID-19 occurrence from 7 days after Dose 2 in adolescents 12 through 15 years of age without evidence of prior SARS-CoV-2 infection*			
	Pfizer-BioNTech COVID-19 Vaccine N[a]=1005 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=978 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI[e])
Adolescents 12 through 15 years of age	0 0.154 (1001)	16 0.147 (972)	100.0 (75.3, 100.0)

https://www.fda.gov/media/144413/download

Updated Guidance

- FDA Fact Sheet for Recipients and Caregivers
- FDA Fact Sheet for Healthcare Providers Administer Vaccine
- MMWR publication (Release will be Friday)
- CDC Clinical Considerations for Use of COVID-19 Vaccines (Update will be Friday)
- CDC Webinar "What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents"

Registration is Open!

https://www.vaccines.nh.gov/

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Pfizer-BioNTech Vaccination for 12-15 Year Olds

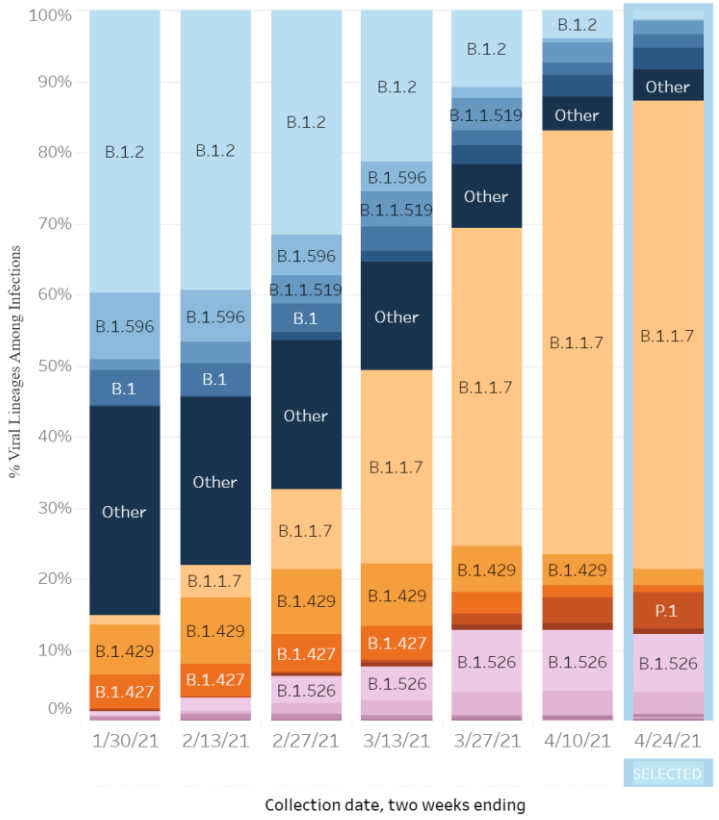
- Offered through multiple locations, including:
  - All State-managed fixed vaccination sites
  - Walgreens
  - Regional Public Health Network (RPHNs) targeted clinics (e.g., school-based vaccination clinics)
  - Hospital-based community clinics

Lineage	Variant name	Status
B.1.1.7	Variant of Concern 202012/01, or 501Y.V1	Emerged in Britain in December and thought to be roughly 50 percent more infectious. Now dominant in the U.S.
B.1.351	501Y.V2	Emerged in South Africa in December. Reduces the effectiveness of some vaccines.
P.1	501Y.V3	Emerged in Brazil in late 2020. Has mutations similar to B.1.351.
B.1.427, B.1.429	CAL.20C	Common in California and thought to be about 20 percent more infectious. Carries the L452R mutation.

Variants of Concern:
Evidence of increased transmissibility, disease severity, or reduced susceptibility

https://www.nytimes.com/interactive/2021/health/coronavirus-variant-tracker.html

Variant Proportions in the U.S.



https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html

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Qatar Mass Pfizer Campaign Dec 21

- Variants emerged
  - Mid Jan B.1.1.7 introduced
  - Mid Feb B.1.351 introduced
  - Feb 23 - Mar 18 50% B.1.351 and 44.5% were B.1.1.7
  - After March 7 ~ all were either
- As of Mar 31, 385,853 persons had received at least one vaccine dose and 265,410 had completed series

CORRESPONDENCE

Effectiveness of the BNT162b2 Covid-19 Vaccine against the B.1.1.7 and B.1.351 Variants

TO THE EDITOR:

May 5, 2021
DOI: 10.1056/NEJMc2104974

- Effectiveness (n=265,410) against any documented SARS-CoV-2 infection was
  - 89.5% against B.1.1.7
  - 75% against B.1.351
- Effectiveness against severe, critical, or fatal disease due to infection with any strain was 97.4%

More Reason to Get Vaccinated, Get Both, Avoid Variants

Table 1. Vaccine Effectiveness against Infection and against Disease in Qatar.

Type of Infection or Disease	PCR-Positive Persons		PCR-Negative Persons		Effectiveness (95% CI)*
	Vaccinated	Unvaccinated	Vaccinated	Unvaccinated	
	number of persons				*percent*
Infection					
PCR-confirmed infection with the B.1.1.7 variant†					
After one dose	892	18,075	1241	17,726	29.5 (22.9–35.5)
≥14 days after second dose	50	16,354	465	15,939	89.5 (85.9–92.3)
PCR-confirmed infection with the B.1.351 variant‡					
After one dose	1329	20,177	1580	19,926	16.9 (10.4–23.0)
≥14 days after second dose	179	19,396	698	18,877	75.0 (70.5–78.9)
Disease§					
Severe, critical, or fatal disease caused by the B.1.1.7 variant					
After one dose	30	468	61	437	54.1 (26.1–71.9)
≥14 days after second dose	0	401	20	381	100.0 (81.7–100.0)
Severe, critical, or fatal disease caused by the B.1.351 variant					
After one dose	45	348	35	358	0.0 (0.0–19.0)
≥14 days after second dose	0	300	14	286	100.0 (73.7–100.0)
Severe, critical, or fatal disease caused by any SARS-CoV-2					
After one dose	139	1,966	220	1,885	39.4 (24.0–51.8)
≥14 days after second dose	3	1,692	109	1,586	97.4 (92.2–99.5)

* Vaccine effectiveness was estimated with the use of a test-negative case–control study design,[2] with persons found positive by polymerase-chain-reaction (PCR) testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) serving as cases in the analysis and those found negative by PCR serving as controls. PCR-positive and PCR-negative persons were matched one to one according to age, sex, nationality, and reason for PCR testing. Vaccine effectiveness was calculated as described by Jackson and Nelson[2] (see the Supplementary Appendix).

† A B.1.1.7 infection was identified as an S gene "target failure" in an analysis conducted with the TaqPath COVID-19 Combo Kit platform (Thermo Fisher Scientific), with the criteria of a PCR cycle threshold value no higher than 30 for the genes encoding both the nucleocapsid protein (N) and ORF1ab but a negative outcome for the gene encoding the spike protein (S) applied. The median date of vaccination was March 1 for PCR-positive persons and February 28 for the matched PCR-negative persons.

‡ Because only B.1.351 and B.1.1.7 viruses were identified in viral genome sequencing in Qatar after March 7, 2021, the criteria used to identify a B.1.351 infection involved the complement of the criterion for S that was used to identify a B.1.1.7 infection — that is, any infection with a cycle threshold value no higher than 30 for the genes encoding N, ORF1ab, and S between March 8 and March 31 was regarded as a B.1.351 infection. The median date of vaccination was March 7 for the PCR-positive persons and March 1 for the matched PCR-negative persons.

§ Effectiveness against severe, critical, or fatal disease caused by PCR-confirmed SARS-CoV-2 infection was analyzed. The B.1.1.7 and B.1.351 variants were dominant in Qatar during the study period. Severe, critical, and fatal coronavirus disease 2019 (Covid-19) were defined on the basis of the World Health Organization criteria[3] for classifying SARS-CoV-2 infection severity and Covid-19–related death.

What are your own concerns?

Language that Works to Improve Vaccine Acceptance

Use These Words MORE:	Use These Words LESS:
The benefits of taking it	The consequences of not taking it
Getting the vaccine will keep you safe	Getting the vaccine is the right thing to do
A return to normal	Predictability/ certainty
Your family	Your community
Medical experts	Scientists/health experts
Research	Discover/create/ invent
Medical researchers	Drug companies
Damage from lockdowns	Inability to travel easily and safely
A transparent, rigorous process	The dollars spent; number of participants
Safety	Security
Pharmaceutical companies	Drug companies
Advanced/ groundbreaking	Historic
Vaccination	Injection/ inoculation
America's leading experts	The world's leading experts
Skeptical/concerned about the vaccine	Misled/confused about the vaccine

Framing the Challenge

- Ending pandemic requires us to vaccinate as many as possible
- The vaccines offer our best path toward saving lives, opening schools and businesses, and rebuilding our economy
- The decision to get vaccinated is a personal one that is influenced by many factors
- Research shows that Americans want unbiased facts about the safety and effectiveness of the vaccines – and information about whether vaccination is the right choice for them – from their doctor
- 10-15% still say they will probably not get the vaccine
- While numerous national and local efforts are attempting to address people's concerns, the single most influential factor will be a strong recommendation from a medical professional

HERE ARE 6 THINGS YOU CAN DO TO IMPROVE VACCINE ACCEPTANCE AMONG YOUR PATIENT FAMILIES.

1. **Lead by example.**
Get vaccinated and encourage your entire staff to be vaccinated.

2. **Prepare your health care team, pharmacy teams, and staff to have these conversations.**
Ask your staff members if they'd be willing to speak with their colleagues and patients about why they got vaccinated. All staff should be equipped to answer basic questions about COVID vaccines.

3. **Share educational materials widely.**
Post information in the waiting room, the staff break room, and common areas in your facility. Publish information on your website, intranet, and social media platforms. Include a way for people to contact you with questions.

4. **During patient visits, make the COVID-19 vaccine a new vital sign.** Ask every patient what their vaccination plan is. For those who say they will take it, make sure they know how and where to schedule an appointment. If they say they're not sure, discuss their concerns and answer their questions.

5. **Partner with your health department, employers, and others to engage with community members.** Collaborate with trusted messengers – like faith-based leaders, local employers, and other community leaders – to tailor and share culturally relevant messages and materials.

6. **Consider sending a letter or email to your patients.**
Start by expressing your concern for the health of your patients and their loved ones. Provide facts, refer them to additional resources, and offer to answer questions. See sample language on page 4.

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Practical Steps

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Messages That Work

Research shows people have said that these messages would make them more likely to get vaccinated for COVID-19

"The vaccines are highly effective in preventing illness -- even more effective than the annual flu vaccine."

"The COVID vaccine will help protect you from getting sick."

"The quickest way for life to return to normal is for most people to get vaccinated."

"Nearly all doctors who have been offered vaccine have taken it."

"Millions of people have been vaccinated safely. Tens of thousands of people participated in the phase 3 trials for the three authorized vaccines. After being fully vaccinated, no trial participants were hospitalized or died from COVID-19."

Guidance for Specific Concerns

ADDRESSING CONCERNS ABOUT SIDE EFFECTS:

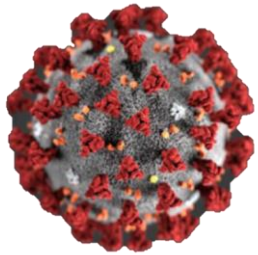
- *Severe side effects are rare and treatable. Minor side effects usually go away within a few days.*
- *No one can say for sure if there will be any long-term effects will be, but there is no reason to think there will be.*
- *The FDA and CDC will continue to monitor the vaccines for safety to make sure that even very rare side effects are identified.*

ADDRESSING CONCERNS ABOUT THE RAPID DEVELOPMENT OF VACCINES:

- *The COVID vaccines have been held to the same rigorous standards as other vaccines. The government didn't cut corners; it cut red tape to expedite the approval process.*
- *While the vaccines were developed quickly, they weren't created from scratch. Researchers have been studying and working with mRNA vaccines (Pfizer and Moderna) for decades, and scientists began creating viral vectors (Johnson & Johnson) in the 1970s.*
- *Viral vector vaccines have been used successfully to treat cancer and prevent diseases like the flu, Zika, and HIV; mRNA vaccines have been studied for the flu, Zika, rabies, and other diseases.*

Productive Conversations

- Use empathy and understanding: acknowledge the disruption that COVID-19 has caused in all our lives. Remind patients that getting vaccinated is the most important thing they can do to move back toward normal activities. Recognize that it's normal for someone to have concerns about a new vaccine for a new virus
- Acknowledge getting vaccinated is personal decision: your role is to provide info and answer questions so patients can make the decision that's right for them
- Clearly state what we know and don't know: don't overemphasize "potentials"
- Focus on benefits of getting vaccine: emphasize that the benefits exceed the risks
- Explain health risks of not getting vaccinated
- Make it personal: be prepared for "Did you (your family) get vaccinated?"
- Tell them you are open to talking again and encourage them to take one step



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