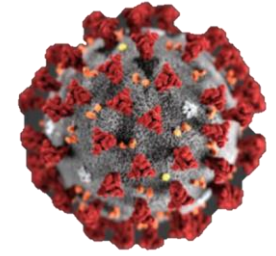


# New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners



April 1, 2021

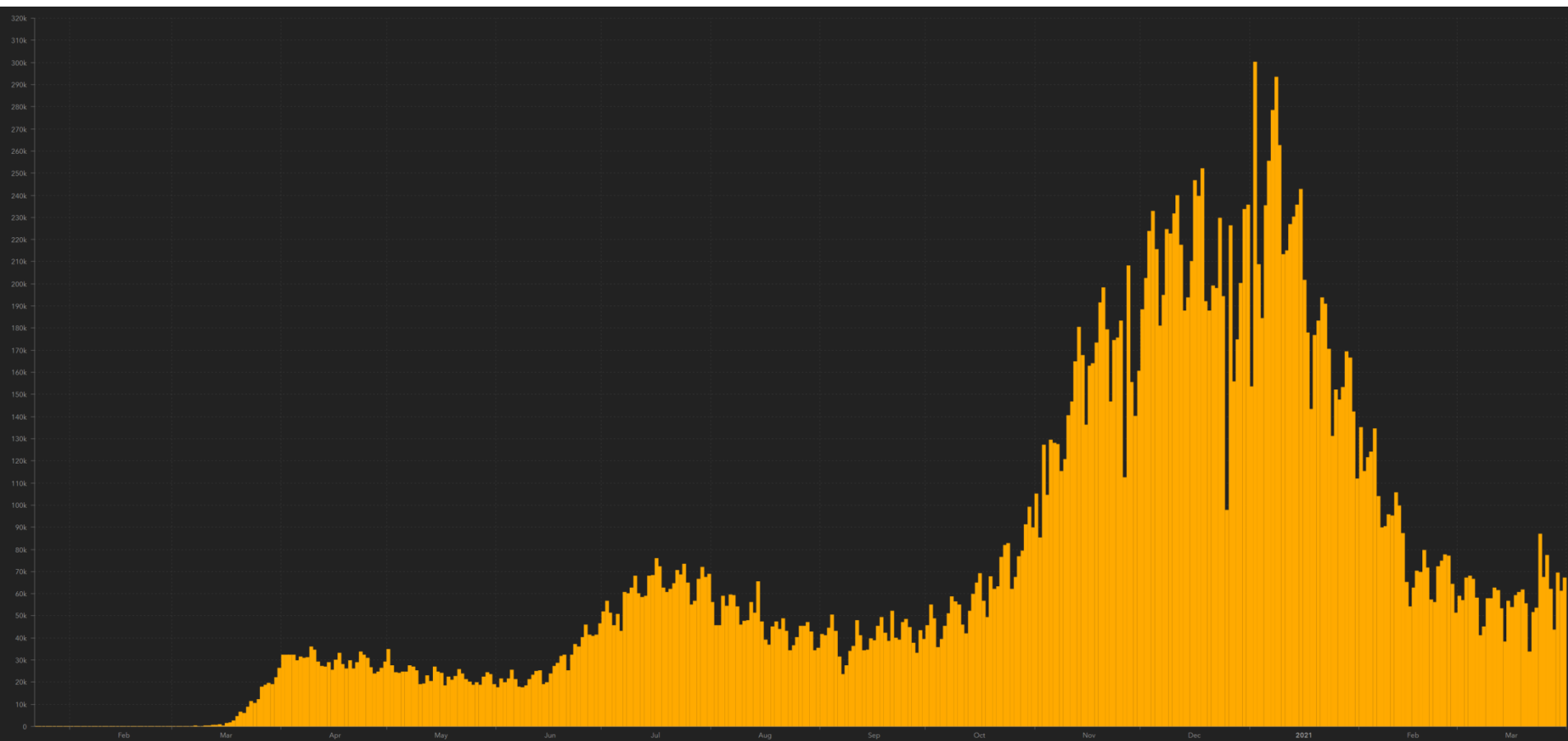
*Ben Chan  
Elizabeth Talbot  
Beth Daly  
Lindsay Pierce*

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

# Agenda

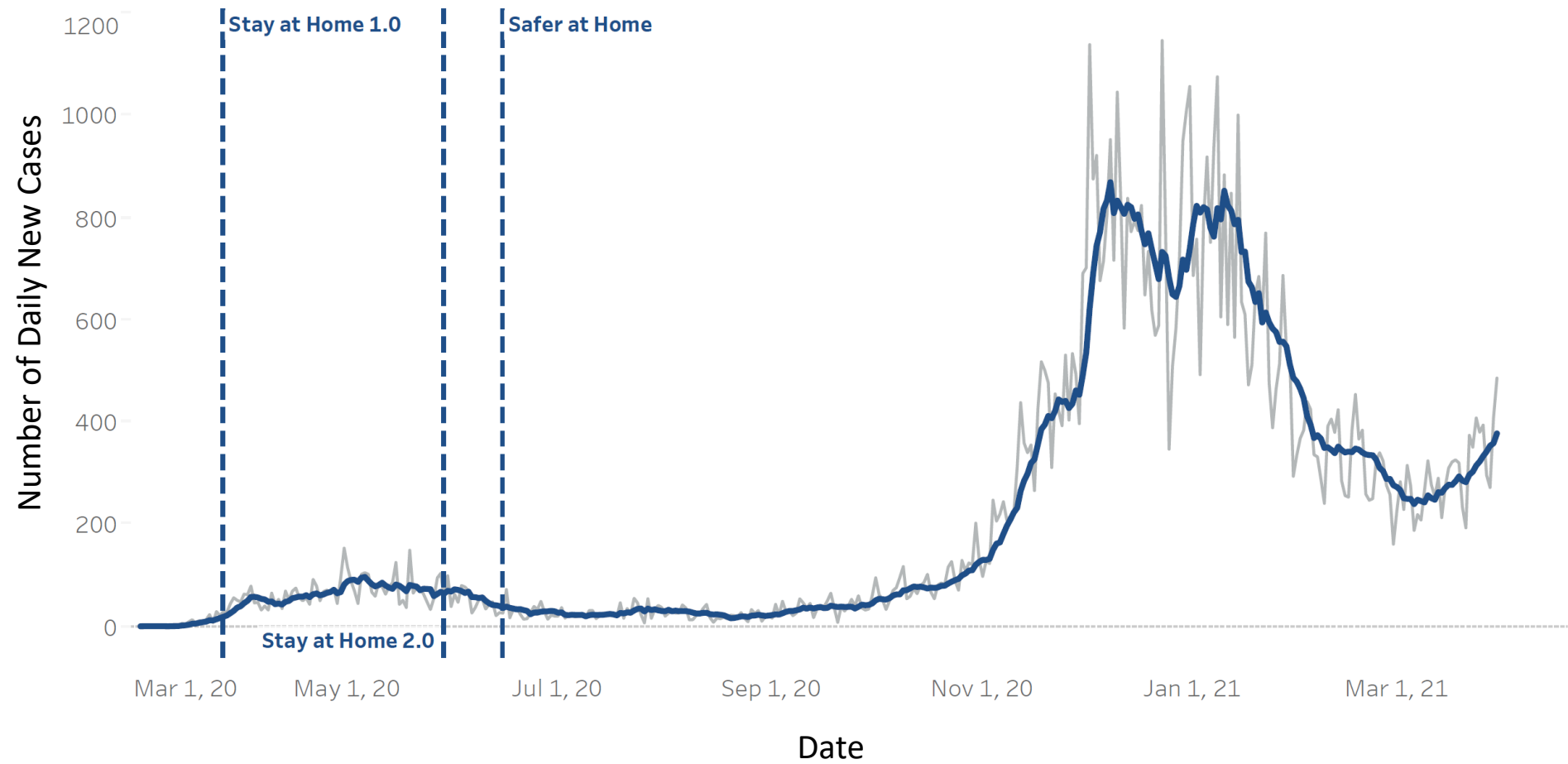
- Epidemiology Update
- MMWR: Provisional National Mortality Data
- Vaccine Effectiveness at Preventing Asymptomatic Infection & Real-World Vaccine Effectiveness
- Pfizer-BioNTech COVID-19 Vaccine Announcements
- Questions & Answers (Q&A)

# National Daily Incidence of COVID-19



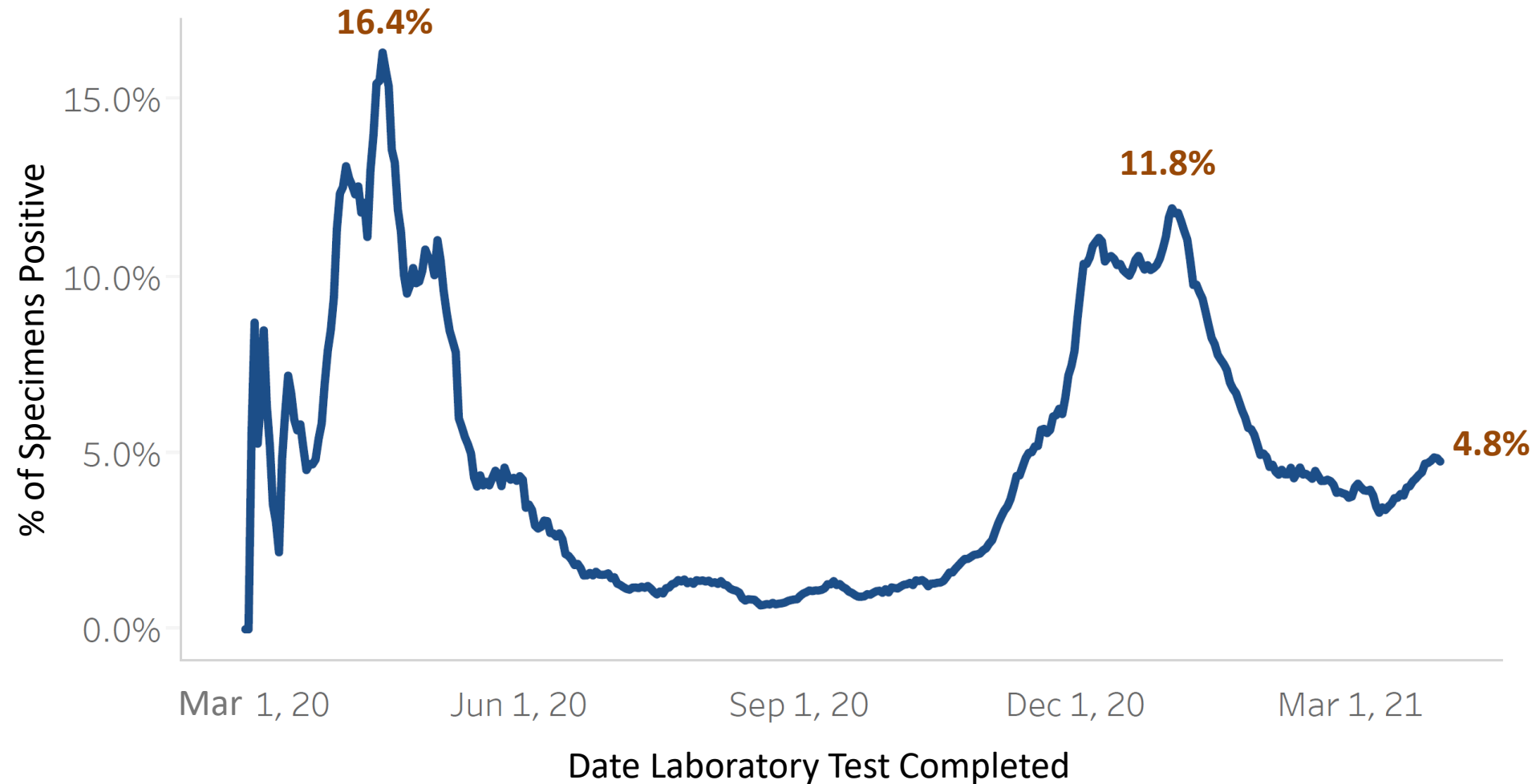
- More than 30.0 million cumulative cases in the U.S. (24% of all global infections)
- More than 552,000 deaths in the U.S. from COVID-19 (20% of all global deaths)

# Number of New COVID-19 Cases per Day in NH



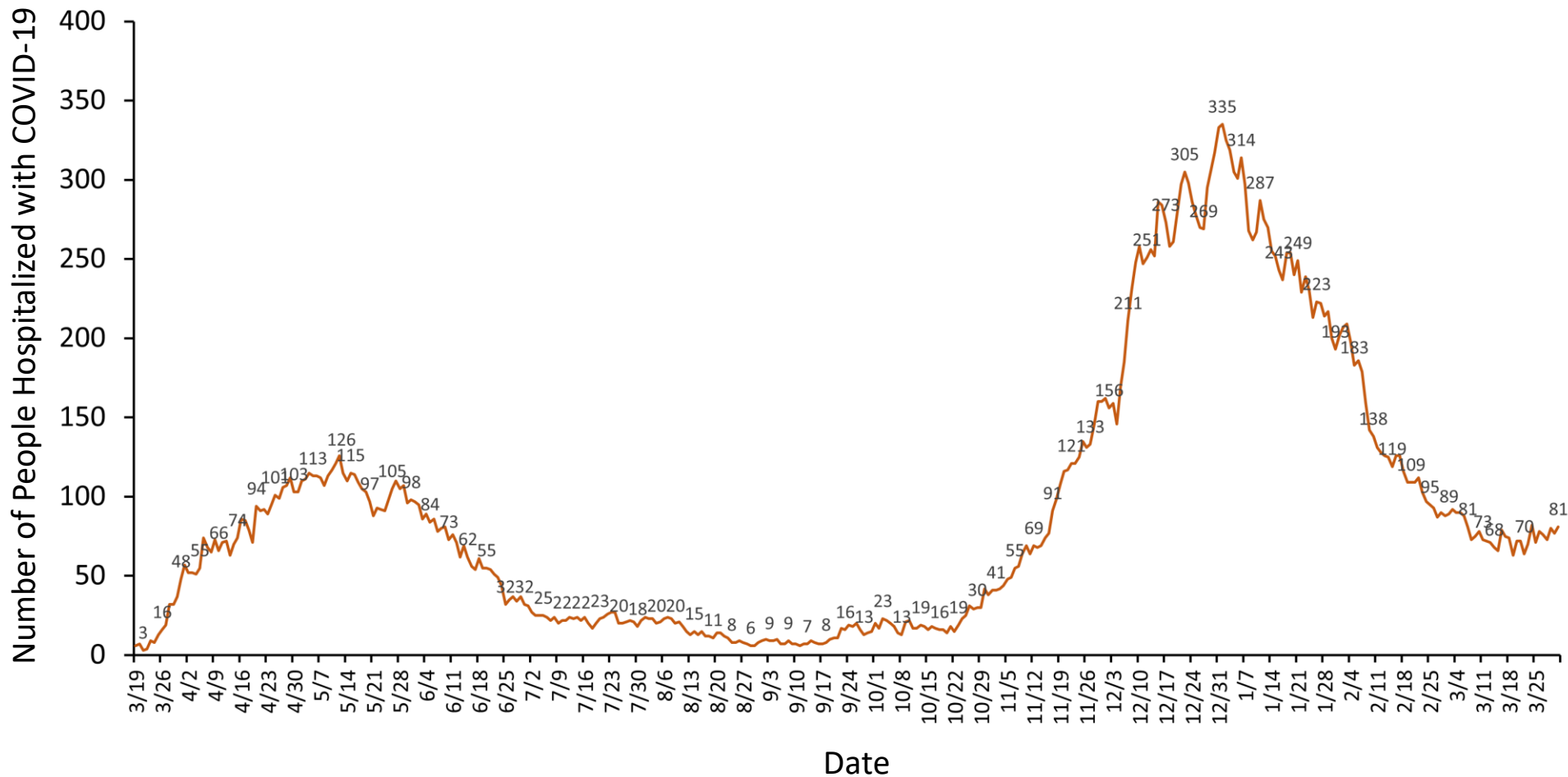
<https://www.nh.gov/covid19/dashboard/overview.htm#dash>

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



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

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

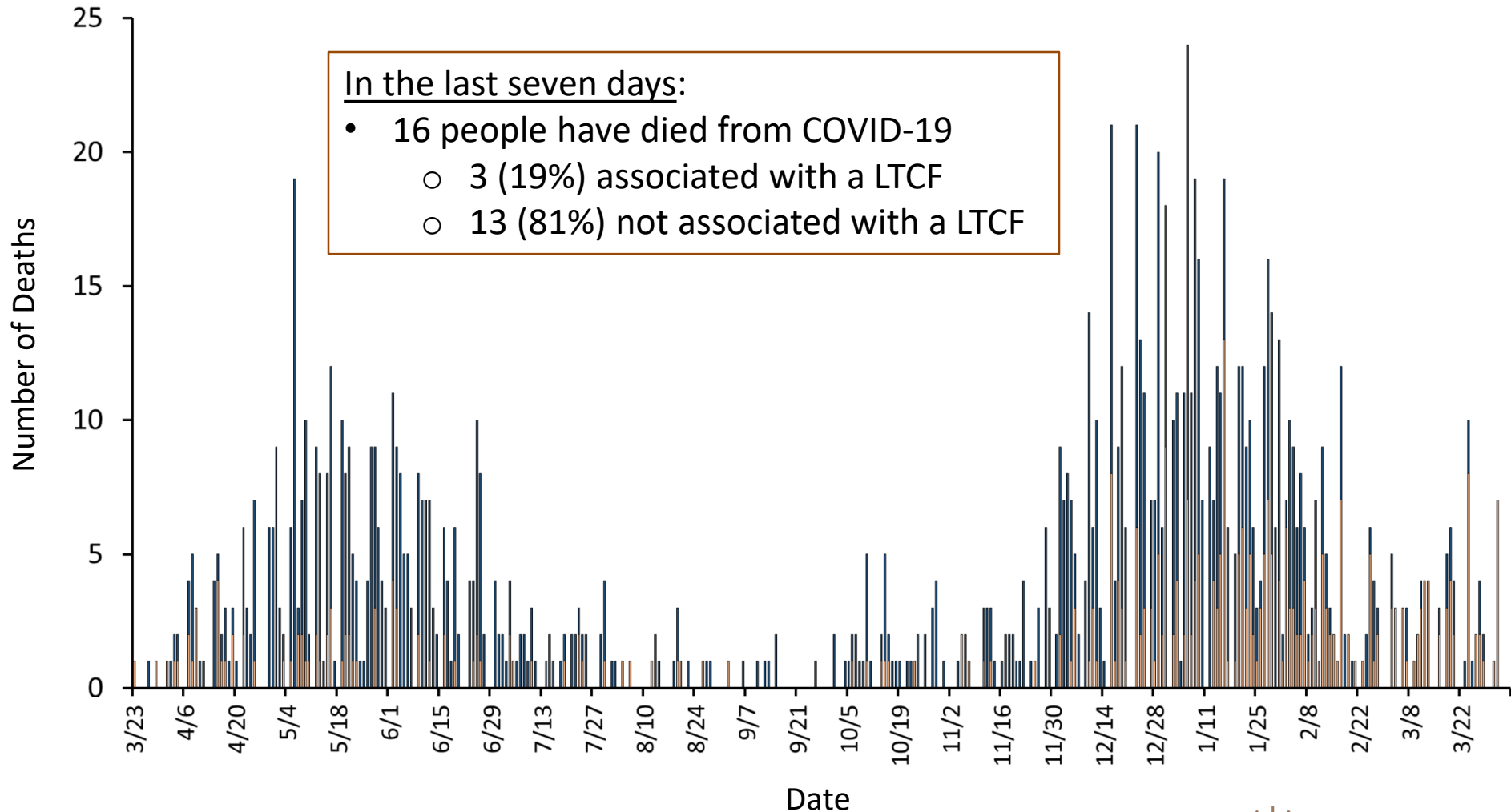


# Number of COVID-19 Deaths in NH by Report Date

■ Non-LTCF Associated    ■ LTCF Associated

In the last seven days:

- 16 people have died from COVID-19
  - 3 (19%) associated with a LTCF
  - 13 (81%) not associated with a LTCF



## Provisional Mortality Data — United States, 2020

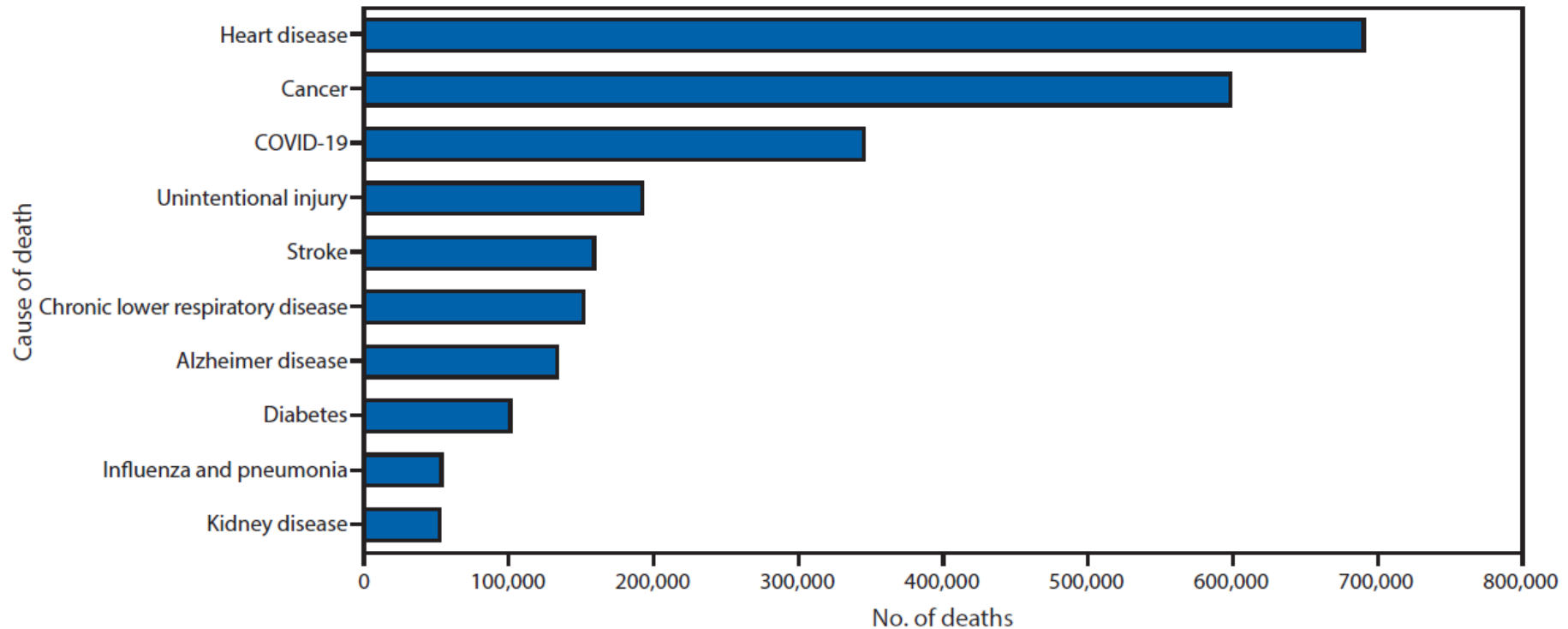
Farida B. Ahmad, MPH<sup>1</sup>; Jodi A. Cisewski, MPH<sup>1</sup>; Arialdi Miniño, MPH<sup>1</sup>; Robert N. Anderson, PhD<sup>1</sup>

- CDC analyzed preliminary National Vital Statistics System (NVSS) data on deaths occurring in the U.S. from Jan – Dec 2020
- Death rate increased for the first time since 2017
- Death rate increased 16% in 2020 compared to 2019



# COVID-19 is the 3<sup>rd</sup> Leading Cause of Death

FIGURE 2. Provisional\* number of leading underlying causes of death<sup>†</sup> — National Vital Statistics System, United States, 2020

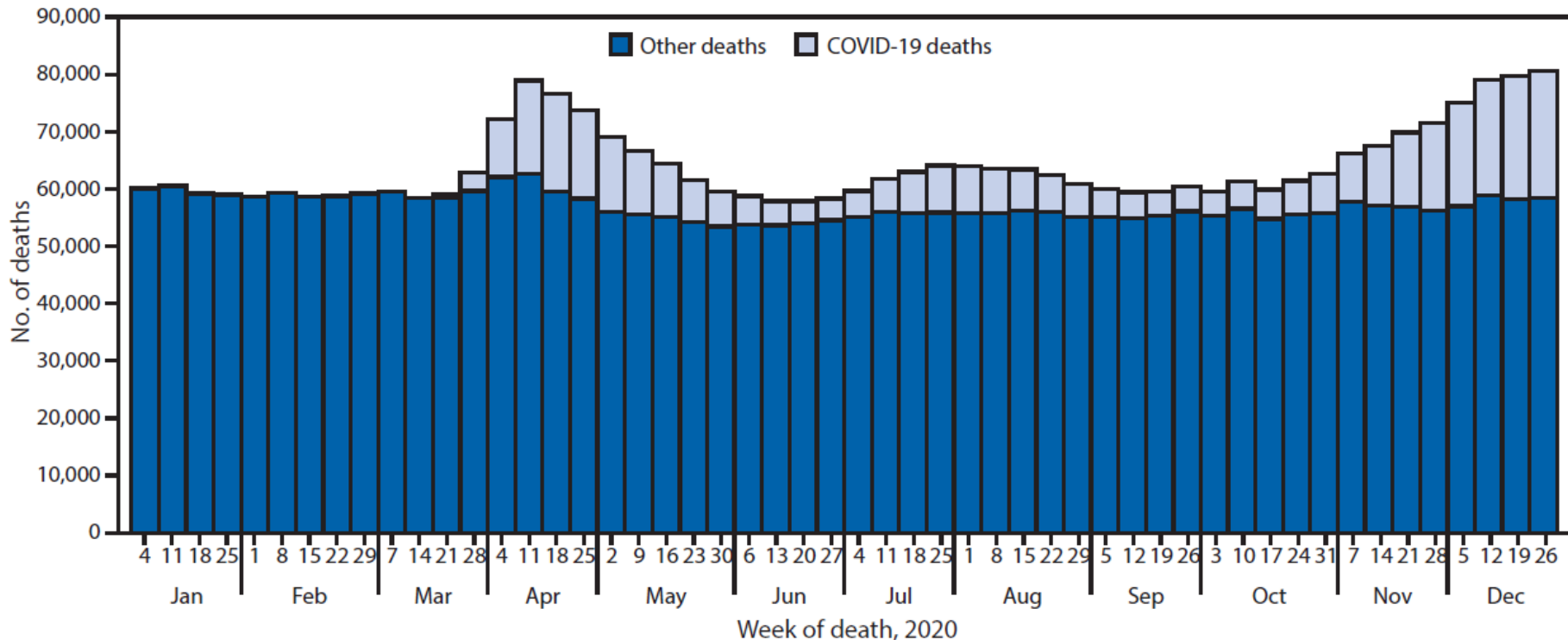


\* National Vital Statistics System provisional data are incomplete. Data from December are less complete due to reporting lags. Deaths that occurred in the United States among residents of U.S. territories and foreign countries were excluded.

<sup>†</sup> Deaths with confirmed or presumed COVID-19 as an underlying or contributing cause of death, with *International Classification of Diseases, Tenth Revision* code U07.1.

# Deaths Each Week

FIGURE 1. Provisional\* number of COVID-19–related deaths† and other deaths, by week — National Vital Statistics System, United States, 2020



\* National Vital Statistics System provisional data are incomplete. Data from December are less complete due to reporting lags. Deaths that occurred in the United States among residents of U.S. territories and foreign countries were excluded.

† Deaths with confirmed or presumed COVID-19 as an underlying or contributing cause of death, with *International Classification of Diseases, Tenth Revision* code U07.1.

# Vaccine Effectiveness at Preventing Asymptomatic Infection & Real-World Vaccine Effectiveness



# Moving From Vaccine Efficacy to Effectiveness

From Trials to Real World

A scanning electron micrograph (SEM) showing a textured, blue surface, likely a cell membrane, covered with numerous small, yellow, spherical particles. A few larger, blue, irregularly shaped structures are also visible on the surface. The background is dark, making the blue and yellow elements stand out.

## Vaccine Mitigation Impacts Unknown

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- Will not lead to an immediate end of need for mitigation strategies
  - Need to know if asymptomatic spread is reduced

# Asymptomatic Transmission

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- [CDC model](#) suggests that 59% of coronavirus transmission may come from people without symptoms
  - 35% pre-symptomatic and 24% never symptomatic
- Ability of vaccination to reduce asymptomatic transmission will be critical to ending the pandemic
- Primary endpoints of phase 3 trials were symptomatic COVID-19
  - [Moderna's phase 3](#), 62% reduction in risk of asymptomatic infection in vaccine group (0.10%), compared to placebo (0.27%)
  - [AstraZeneca](#) no reduction against asymptomatic infection 22-90d after 1<sup>st</sup> dose
  - VRBPAC analysis of JnJ's Phase 3 data reduced seropositivity by 74%
- Not knowing this severely limits the development of post-vaccination behavior recommendations and may contribute to vaccine hesitancy

# Patients Undergoing Pre- procedural Screening

[Tande AJ et al. Clin Infect Dis Mar 10 2021](#)

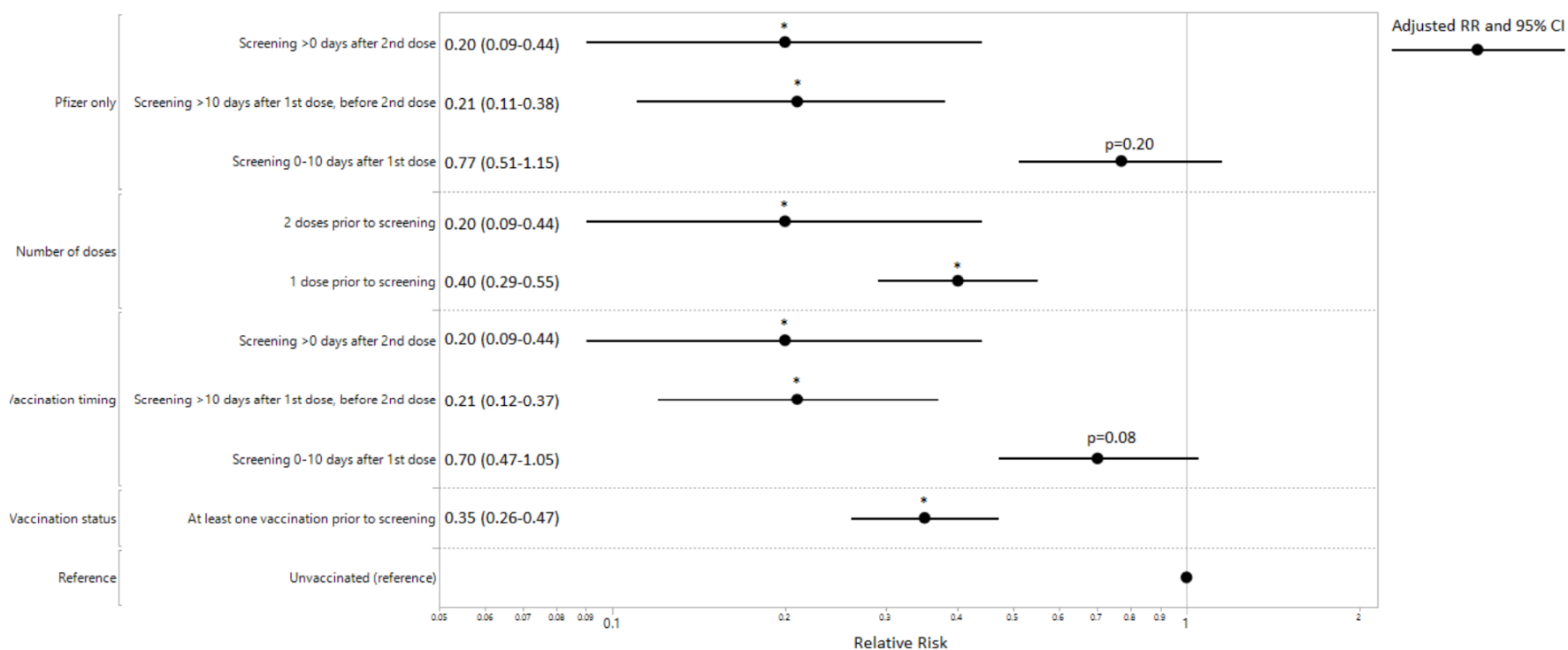
- Some healthcare institutions elected to require PCR testing for asymptomatic SARS-CoV-2 infection prior to surgery and medical procedures
  - Opportunity to compare vaccinated and not vaccinated
- Retrospective cohort study of consecutive, asymptomatic adult patients within Mayo
- All pre-procedural SARS-CoV-2 molecular screening tests
- December 17, 2020 - February 8, 2021
- Primary outcome was relative risk of a positive test among those who had  $\geq 1$  dose of either Pfizer or Moderna vaccine, as compared to persons without any vaccine

# Does mRNA Vaccination Reduce Asymptomatic Disease?

- In 39,156 asymptomatic individuals, mean (SD) age was 54.2 (19.7) years, 52.5% female
  - Median (IQR) time from 1<sup>st</sup> dose of vaccine to their molecular screening was 16 days
  - 23.5% screening tests in vaccinated group occurred among individuals had 2<sup>nd</sup> dose
- Positive tests in
  - 42 (1.4%) of 3,006 tests in vaccinated patients
  - 1,436 (3.2%) of 45,327 tests in unvaccinated patients
  - RR=0.44 95% CI: 0.33-0.60;  $p<.0001$
- Overall 72% risk reduction observed for any doses and 80% if 2<sup>nd</sup>. Compared to unvaccinated patients, risk of asymptomatic infection lower
  - >10 days after 1<sup>st</sup> dose (RR=0.21; 95% CI: 0.12-0.37;  $p<.0001$ )
  - Anytime after 2<sup>nd</sup> dose (RR=0.20; 95% CI: 0.09-0.44;  $p<.0001$ )
- Ct values available for 90.5 and 77.7% for vaccinated and unvaccinated: NS

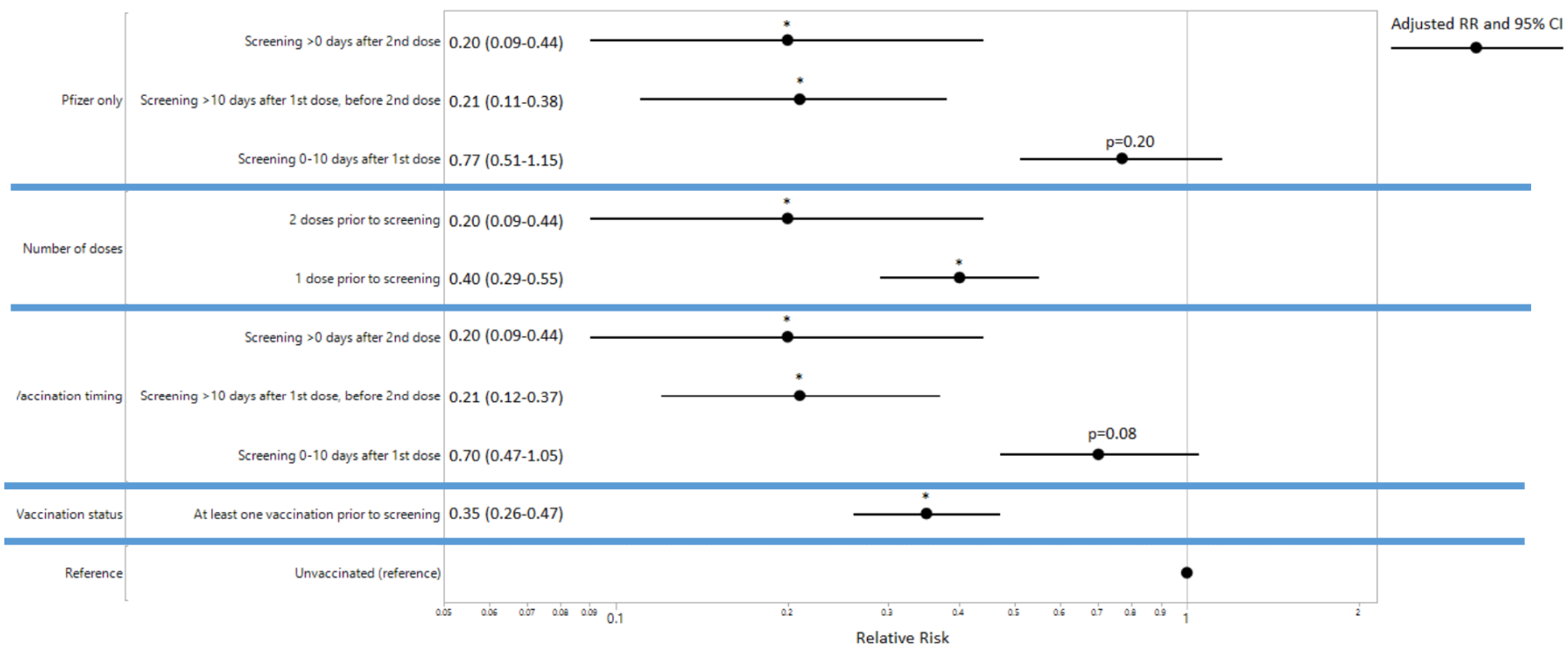


# Adjusted Relative Risk (with 95% Confidence Intervals) comparing pre-procedure COVID-19 molecular screening percent positive by vaccination status and timing



Relative risk was adjusted for age, sex, race/ethnicity, patient residence relative to the hospital (local vs. non-local), healthcare system regions, and repeated screenings

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# Vaccine Effectiveness Against Asymptomatic Infection

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- Real-world exploiting routine screening
- Scope of reduction consistent with phase 3 trial
- Mostly young white women
- Mostly Pfizer, few Moderna, no JnJ
- Major limitation is confounding based on risk behaviors: accessing vaccine and behaviors
  
- mRNA-based vaccine showed a significant association with reduced risk of asymptomatic SARS-CoV-2 infection, demonstrating impact of the vaccines on reduction in asymptomatic infections and presumably transmission

# Vaccine Efficacy & Effectiveness at Preventing Symptomatic and Asymptomatic Infection

- COVID-19 vaccine phase 3 clinical trials used symptomatic confirmed COVID-19 as the primary study endpoint
- Studies are emerging showing that the COVID-19 vaccines also prevent asymptomatic infection:
  - Studies specifically evaluating asymptomatic infection (identified through asymptomatic screening testing)
  - “Real-world” use observational studies (evaluating both symptomatic and asymptomatic infection combined)
- There is less data on the ability of people who are vaccinated and develop infection to spread that infection to others (i.e., data on transmissibility of infection from vaccinated persons)
  - One study in [medRxiv](#) shows lower viral loads in vaccinated persons who develop infection

# Vaccine Effectiveness at Preventing Asymptomatic Infection (% reduction in risk of positive test)

Vaccine	Study	Population	Vaccine Effectiveness after 1 Dose	Vaccine Effectiveness after 2 Doses
Pfizer	<a href="#">NEJM</a> Feb 24, 2021	Israel National Cohort*	29% - 52%	90%
Pfizer	<a href="#">Authorea</a> Feb 24, 2021	UK HCW Screening (Cambridge Hospital)	75%	No estimate
Pfizer	<a href="#">Clin Infect Dis</a> Mar 10, 2021	US pre-procedural screening testing	79% (adjusted estimate)	80% (adjusted estimate)
Moderna	<a href="#">NEJM</a> Feb 4, 2021	Moderna Phase 3 RCT	62%	No estimate
Janssen	<a href="#">FDA VRBPAC</a> Feb 26, 2021	J&J Phase 3 RCT (based on serology)	74%	N/A

\* Reported on persons “without documented symptoms, as an imperfect proxy for asymptomatic infection”

Note: studies use different time cut-offs for assessing effectiveness after vaccine dose, and different definitions of “asymptomatic” infection, so studies are not directly comparable

# Preventing Infection and Transmission

- COVID-19 vaccines are effective at preventing both symptomatic disease and asymptomatic infection
- Estimates of vaccine effectiveness at preventing asymptomatic infection appear to be in the range of 60-80% reduced risk based on limited early studies
- If vaccination prevents symptomatic disease and results in lower viral loads when a vaccinated person is infected, then vaccines will likely decrease the ability of that infected person to spread the virus to others
- We can decrease the risk even further when all people continue to wear a well-fitted face mask and practice physical/social distancing during this transitional period

**Interim Estimates of Vaccine Effectiveness of BNT162b2 and mRNA-1273  
COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Health Care  
Personnel, First Responders, and Other Essential and Frontline Workers —  
Eight U.S. Locations, December 2020–March 2021**

- Prospective cohorts of healthcare personnel, first responders, and essential frontline workers from 8 U.S. locations (AZ, FL, MN, OR, TX, UT)
- 3,950 participants with no prior documented infection
  - 63% received two mRNA vaccine doses
  - 12% received only one dose of an mRNA vaccine (at time of analysis)
  - 25% were unvaccinated
- People were tested for SARS-CoV-2 every week by PCR conducted on a self-collected mid-turbinate nasal swab

- 63% received the Pfizer-BioNTech vaccine
- 30% received the Moderna vaccine
- 205 (5.2%) of participants were infected
  - 89% had symptoms
  - 11% were asymptomatic
- Out of the 205 infections:
  - 161 occurred in unvaccinated individuals
  - 8 infections occurred in partially immunized persons ( $\geq 14$  days after first dose, but before 2<sup>nd</sup> dose)
  - 3 infections occurred in fully immunized persons ( $\geq 14$  days after second dose)
  - 33 were excluded due to “indeterminate” vaccination status



# Vaccine Effectiveness

TABLE 2. Person-days, SARS-CoV-2 infections, and vaccine effectiveness among health care personnel, first responders, and other essential and frontline workers, by messenger RNA immunization status — eight U.S. locations, December 14, 2020–March 13, 2021

COVID-19 immunization status	Person-days	SARS-CoV-2 infections		Unadjusted vaccine effectiveness*	Adjusted vaccine effectiveness*,†
		No.	Incidence rate per 1,000 person-days	% (95% CI)	% (95% CI)
<b>Unvaccinated</b>	116,657	161	1.38	N/A	N/A
<b>Partially immunized</b>	41,856	8	0.19	82 (62–91)	80 (59–90)
≥14 days after receiving first dose only <sup>§</sup>	15,868	5	0.32		
≥14 days after first dose through receipt of second dose	25,988	3	0.12		
<b>Fully immunized</b>					
≥14 days after second dose	78,902	3	0.04	91 (73–97)	90 (68–97)

**Abbreviations:** CI = confidence interval; N/A = not applicable.

\* Vaccine effectiveness was estimated using a Cox proportional hazards model accounting for time-varying immunization status.

† Hazard ratio is adjusted for study site.

<sup>§</sup> Participants received first dose but had not received second dose by the end of the study period.

# Summary

- The mRNA vaccines are “highly effective in real-world conditions” including at preventing both symptomatic and asymptomatic infection
- Other “real-world” vaccine effectiveness studies have similarly shown high mRNA vaccine effectiveness:
  - [Lancet Preprint](#): U.K. study of Pfizer-BioNTech vaccine in healthcare workers (72% effective after a single dose, 86% effective after the second dose)
  - [NEJM](#): Israel study of Pfizer-BioNTech vaccine in national mass-vaccination campaign (46%-60% effective after a single dose, 92% effective after the second dose)

# New Pfizer-BioNTech COVID-19 Vaccine Announcements

# 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

- Pfizer-BioNTech announced their COVID-19 vaccine was:
  - 91% effective measured up to 6 months after their second dose (850 cases in placebo group vs. 77 cases in vaccine group)
  - 95-100% effective against severe disease (based on CDC vs. FDA definition of “severe disease”)
  - Effective at preventing infection with B.1.351 variant – vaccine was studied in 800 participants in South Africa (B.1.351 variant predominant), and 9 cases were observed in placebo group vs. 0 cases in vaccine group

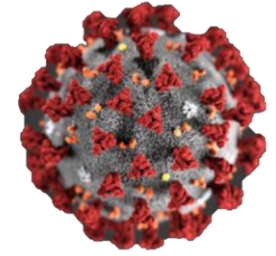
# PFIZER-BIONTECH ANNOUNCE POSITIVE TOPLINE RESULTS OF PIVOTAL COVID-19 VACCINE STUDY IN ADOLESCENTS

Wednesday, March 31, 2021 - 06:45am

- *In participants aged 12-15 years old, BNT162b2 demonstrated 100% efficacy and robust antibody responses, exceeding those reported in trial of vaccinated 16-25 year old participants in an earlier analysis, and was well tolerated*
- *The companies plan to submit these data to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as soon as possible to request expansion of the Emergency Use Authorization (EUA) and EU Conditional Marketing Authorization for BNT162b2*
- *The companies also provided an update on the Phase 1/2/3 study of BNT162b2 in children aged 6 months to 11 years*

- Pfizer-BioNTech announced their vaccine demonstrated 100% efficacy in participants aged 12-15 years of age (2,260 participants)
  - 18 cases in placebo group vs. none in the vaccine group
- Vaccination resulted in high SARS-CoV-2 neutralizing antibody levels (non-inferior to levels seen in participants aged 16-25 years of age)
- No safety concerns identified – side effects were consistent with those previously observed/reported

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



April 1, 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