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

February 4, 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

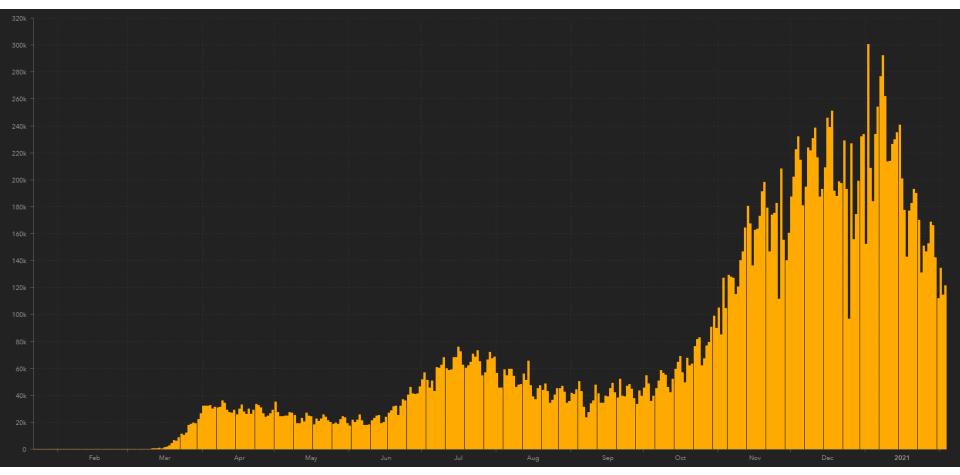


Agenda

- Epidemiology Update
- Johnson & Johnson COVID-19 Vaccine Update
- SARS-CoV-2 Variants of Concern (VOC)
- Testing for COVID-19 In Symptomatic Persons Previously Infected or Vaccinated
- Questions & Answers (Q&A)



National Daily Incidence of COVID-19

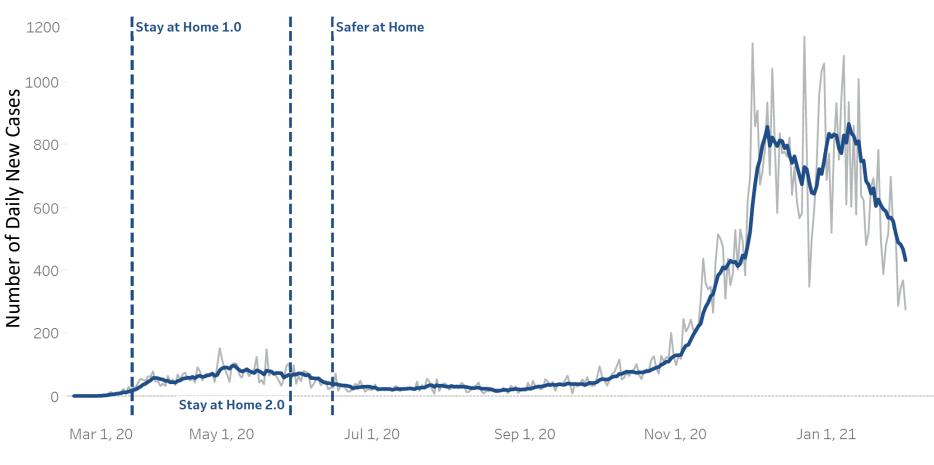


- More than 26.5 million cumulative cases in the U.S. (25% of all global infections)
- More than 450,000 deaths in the U.S. from COVID-19 (20% of all global deaths)



JHU COVID-19 Dashboard

Number of New COVID-19 Cases per Day in NH

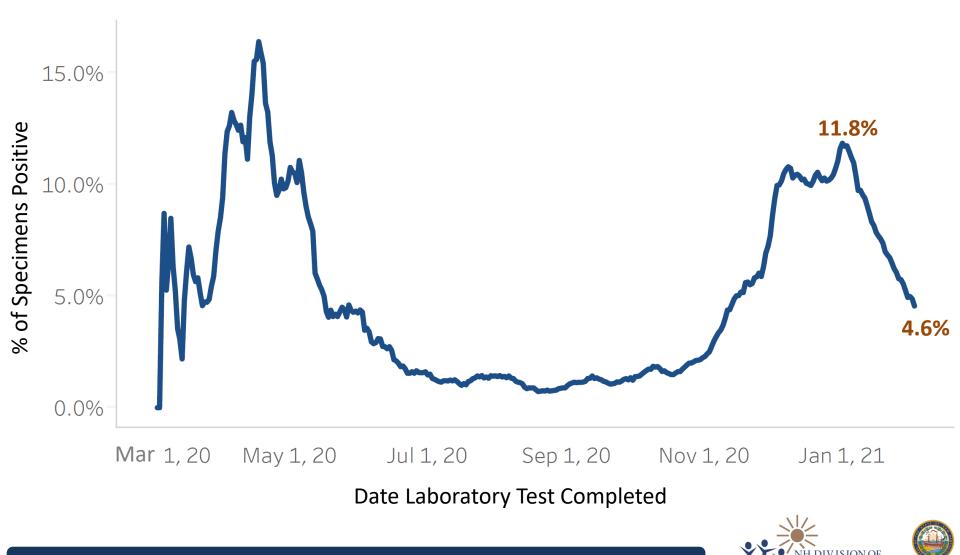


Date



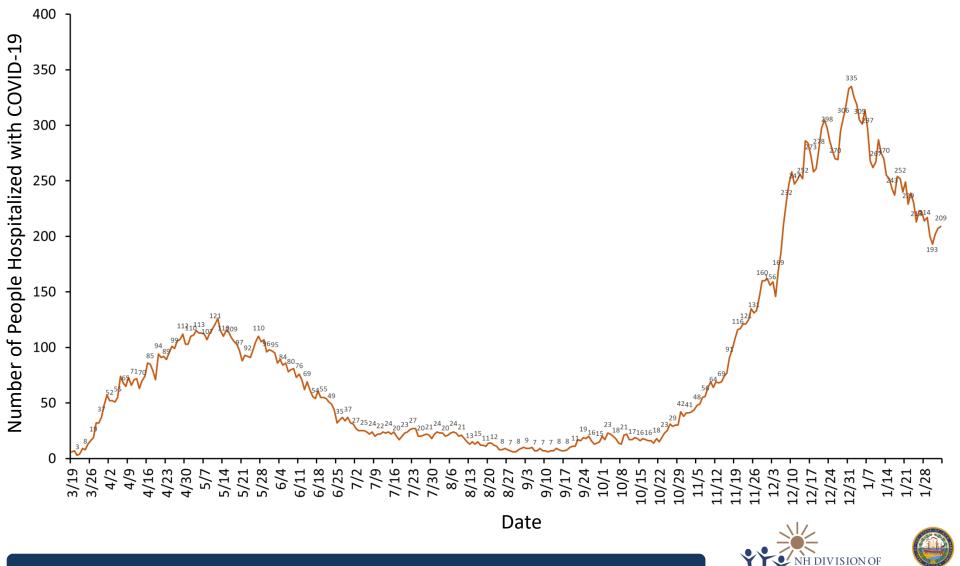
https://www.nh.gov/covid19/dashboard/overview.htm#dash

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



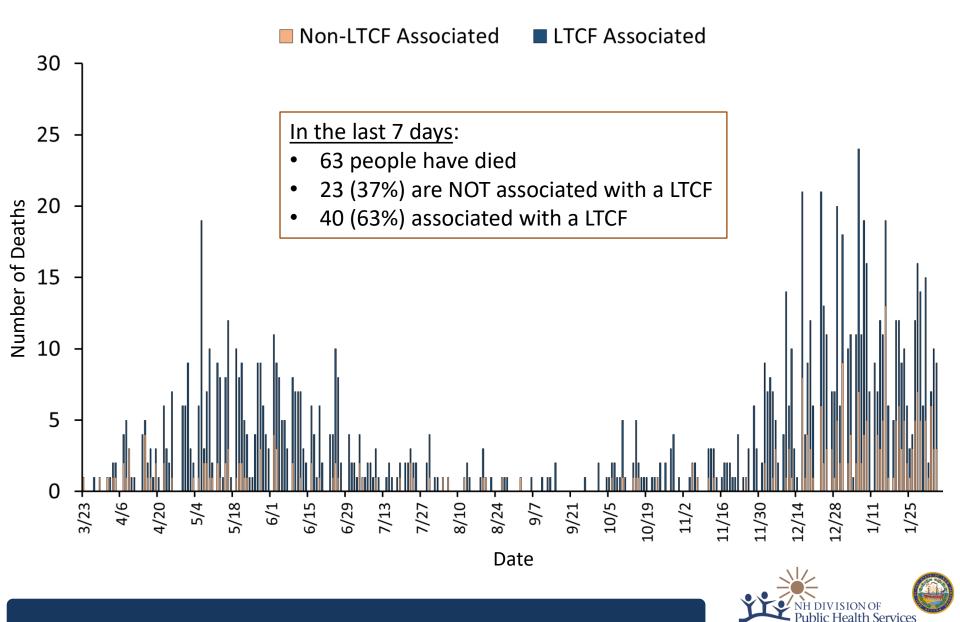
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Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



c Health Services

Number of COVID-19 Deaths in NH by Report Date



rtment of Health and Human Services

Johnson & Johnson COVID-19 Vaccine Update



Selected COVID-19 Vaccines

Platform		Developer	Status
لفس	Nucleic Acid	moderna	• 94% efficacy \rightarrow EUA
لاسم	(mRNA)	BIONTECH M	• 95% efficacy \rightarrow EUA
-	Adenovirus	Janssen T	• Phase 3 results \rightarrow likely Feb. 2021
	Vector	AstraZeneca	• Phase 3 results \rightarrow likely Mar. 2021
······	Recombinant Protein and Adjuvant	🥵 SANOFI 🎝	• Phase 2 starts \rightarrow Feb. 2021
*		Creating Tomorrow's Vaccines Today	• Phase 3 results \rightarrow likely Mar. 2021



Taken from Dr. Fauci's White House Press Briefing January 27, 2021

Johnson & Johnson's Ad26.COV2.S Vaccine

- Adenovirus serotype 26 (Ad26) vector recombinant, replicationincompetent adenovirus vector encoding the SARS-CoV-2 spike protein
- Same platform used in the Ebola vaccine: Ad26-based vaccines have been shown to be safe and highly immunogenic
- 1 dose, Refrigerated (not frozen)
- July 22nd: Started phase 1/2 trials (safety and immunogenicity)
- September 23rd: Phase 3 trial launched (adults 18 years and older)
 - November 15th: Initiated a 2-dose regimen phase 3 trial (ENSEMBLE 2 study) in parallel – two doses scheduled 8 weeks apart
- December 17th: Fully enrolled phase 3 trial with ~45,000 participants (ENSEMBLE study)
- January 29th (2021): Johnson & Johnson <u>announced</u> single-shot COVID-19 vaccine met primary endpoints in interim analysis of study data
- Pending submission to FDA for Emergency Use Authorization (EUA)



Preliminary Findings From Johnson & Johnson's Vaccine Study Analysis

- Single-dose of the Janssen Pharmaceutical COVID-19 vaccine
- Overall vaccine efficacy: 66% effective in preventing moderate to severe COVID-19 (28 days after vaccination)
 - 72% effective in the U.S.
 - 66% effective in Latin America
 - 57% effective in South Africa (95% of cases were due to B.1.351 variant)
- 85% effective at preventing severe disease across all regions (28 days after vaccination)
- Complete protection against COVID-related hospitalization and death (28 days post-vaccination)

https://www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints-in-interim-analysis-of-its-phase-3-ensemble-trial



Variants of Concern (VOC)



Issues with New VOCs

- Increased transmissibility/infectiousness
- Possible new variants might cause more severe disease; but more cases will translate to more hospitalizations and death even if no increased risk of severe disease
- Decreased immunity from previous infection
- Decreased immunity from COVID-19 vaccines



Lineage	Countries Reporting	Characteristics	
B.1.1.7	United Kingdom 80 Countries (see <u>WHO Sit Reps</u>) 541 cases in 33 U.S. states (see <u>CDC map</u>)	 Estimated in modeling study to be 50%+ more transmissible Public Health England report found no increased disease severity, but new <u>NERVTAG report</u> estimates possible increased risk of death ("realistic possibility" of increased risk) Possible small reduction in immunity from vaccination: Limited evaluation of sera from people vaccinated with Pfizer-BioNTech vaccine (bioRxiv study) & Modern vaccine (See announcement and bioRxiv study) found retained neutralizing activity against variant bioRxiv study found B.1.1.7 variant mutations resulted in small decrease in neutralizing ability of plasma from mRNA vaccine recipients Novavax (protein/adjuvant-based vaccine) reported vaccine efficacy of 89% in the UK in preventing symptomatic COVID-19 where B.1.1.7 variant was detected in over 50% of cases – efficacy by strain estimated to be 95.6% against original strain and 85.6% against B.1.1.7 strain 	
B.1.351	South Africa 41 Countries (see <u>WHO Sit Reps</u>) 3 cases in 2 U.S. states (see <u>CDC map</u>)	 Likely Increased transmissibility given epidemiology and findings of B.1.1.7 variant Still studying if new variant causes more severe disease More substantial decrease in immunity from previous infection or vaccination: bioRxiv study showed that mutations to the receptor binding domain (RBD) of the SARS-CoV-2 spike protein (particularly E484) can substantially reduce convalescent serum antibody binding and neutralization bioRxiv study showed that mutations in B.1.351 variant resulted in decrease neutralizing ability of plasma from mRNA vaccine recipients bioRxiv study found monoclonal antibodies were ineffective at neutralizing new variant; and 48% of convalescent plasma/sera samples (from people previously infected) had no detectable neutralization activity against variant (non-neutralizing antibodies showed better activity) About 1/3 of Novavax vaccine study participants had prior COVID-19 infection, and infection rate in placebo group was "not impacted by baseline anti-spike serostatus" (see webcast) Novavax (protein/adjuvant-based COVID-19 vaccine) reported vaccine efficacy of 60% in South Africa (60% in HIV-negative, 49% overall efficacy) in preventing symptomatic COVID-19 (B.1.351 variant detected in over 92% of cases), compared to 89% efficacy in UK Moderna reported a "six-fold reduction in neutralizing titers" observed with B.1.351 variant, but titers were "above levels that are expected to be protective" (see also bioRxiv study). Moderna is developing a "booster candidate" against the B.1.351 variant Johnson & Johnson reported that Phase 3 clinical trial (ENSEMBLE study) showed Janssen's COVID-19 vaccine (28 days post-vaccination) was 57% effective at preventing moderate-severe COVID-19 in South Africa (95% of cases due to variant) compared to 72% effective in the U.S. 	
P.1	Brazil 10 Countries (see <u>WHO Sit Reps</u>) 2 case in 1 U.S. state (see <u>CDC map</u>)	 Likely increased transmissibility given epidemiology and findings of B.1.1.7 variant Still studying if new variant causes more severe disease Likely decreased immunity from prior infection: <u>Lancet study</u> found resurgence in Manus Brazil after identification of P.1 variant in region, despite estimated 76% of population with previous infection. Vaccine-induced immunity likely diminished based on vaccine studies of B.1.351 variant (which has similar spike protein mutations) 	

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B.1.351

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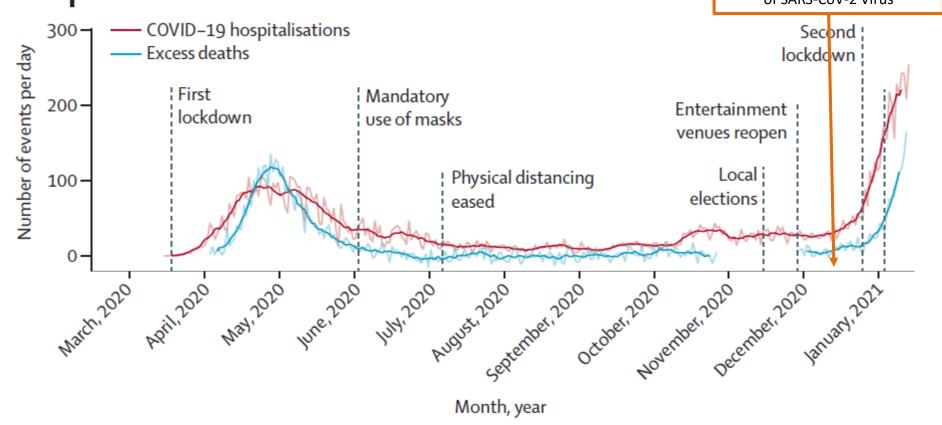
3 cases in 2 U.S. states (see <u>CDC map</u>)

- Likely Increased transmissibility given epidemiology and findings of B.1.1.7 variant
- Still studying if new variant causes more severe disease
- More substantial decrease in immunity from previous infection or vaccination:
 - bioRxiv study showed that mutations to the receptor binding domain (RBD) of the SARS-CoV-2 spike protein (particularly E484) can substantially reduce convalescent serum antibody binding and neutralization
 - <u>bioRxiv</u> study showed that mutations in B.1.351 variant resulted in decrease neutralizing ability of plasma from mRNA vaccine recipients
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2.1	Brazil 10 Countries	 Likely increased transmissibility given epidemiology and findings of B.1.1.7 variant
	(see <u>WHO Sit Reps</u>)	Still studying if new variant causes more severe disease
	2 case in 1 U.S. state (see <u>CDC map</u>)	 Likely decreased immunity from prior infection: <u>Lancet study</u> found resurgence in Manus Brazil after identification of P.1 variant in region, despite estimated 76% of population with previous infection.
		 Vaccine-induced immunity likely diminished based on vaccine studies of B.1.351 variant (which has similar spike protein mutations)



Resurgence of COVID-19 in Manaus, Brazil, despite high seroprevalence





https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00183-5/fulltext

Testing for COVID-19 in Symptomatic Persons Who Are Previously Infected or Vaccinated



THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network Health.Alert@nh.gov January 11, 2021 Time 1200 (12:00 PM EDT) NH-HAN 20210111



Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 33

COVID-19 Vaccination Allocation Plan Update Quarantine Guidance Update

Key Points and Recommendations:

 Regardless of prior infection or vaccination status, any person with new or unexplained <u>symptoms of</u> <u>COVID-19</u> still needs to isolate (<u>Isolation Guide</u>), and be evaluated for COVID-19 testing.



https://www.dhhs.nh.gov/dphs/cdcs/alerts/documents/covid-19-update33.pdf

Healthcare Provider Letter

To Whom It May Concern:

The above named patient was tested positive for COVID 19 on . He is immune to COVID 19 for 90 days from this date and should not be tested until after . If he develops any COVID symptoms during this time please know that it is not COVID 19 and treat accordingly.

If you have any questions please feel free to contact this office.



Problems and Inaccuracies

- Not a true statement: "He is immune to COVID-19 for 90 days from this date..."
 - Person has immunity, but is not "immune" (i.e., risk is low but not zero)
- Not a true statement: "He... should not be tested until after xx/xx/21"
 - Person should be tested, even within 90 days of prior infection or if person was previously vaccinated, if there is increased concern for COVID-19 (clinical judgement applies)
- Not a true statement: "If he develops any COVID symptoms during this time please know that it is not COVID-19"
 - People can be re-infected with SARS-CoV-2, even within 90 days of a prior infection. The only way to know if symptoms are due to COVID-19 is to test



Ask of Providers

- Use clinical judgement assess a person with symptoms, even if previously infected or fully vaccinated (assess symptoms, risk factors, time since prior diagnosis or vaccination, etc.)
- Test if someone has an increased risk for reinfection or exposure:
 - Immunosuppressed
 - Known exposure to someone with COVID-19
 - Recent travel (especially on public transportation or international travel)
- Test if someone has symptoms that might be more concerning for COVID-19 (e.g., fever, loss of taste/smell, worsening symptoms)
- If someone has no exposures or risk factors, mild singular or nonspecific symptoms, they may not need testing
- Clinicians must balance pre-test probability of disease with risk of false-positives (antigen testing) or identification of prolonged viral shedding (PCR testing) with repeat testing



Conclusion

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- End result may be appropriate i.e., the clinical assessment might indicate no need for testing due to very recent infection, no risk factors/exposures, and only mild symptoms (e.g., runny nose)
 - So person can return to school/work when afebrile and symptoms improving (per normal protocol)
- But the rationale in the letter is incorrect



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