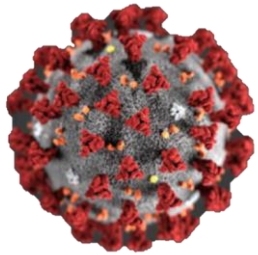


New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners

December 31 2020

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

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

Agenda

- Epidemiology Update
- Updated CDC Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines
- AstraZeneca COVID-19 vaccine update
- United Kingdom SARS-CoV-2 Variant of Concern (VOC 202012/01)
  - CDC Science Brief
  - London School of Hygiene and Tropical Medicine Modeling study
  - Public Health England matched cohort study
- Questions & Answers (Q&A)

THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network
Health.Alert@nh.gov
December 29, 2020, 2020 1300 (1:00 PM EDT)
NH-HAN 20201229

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

Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 31

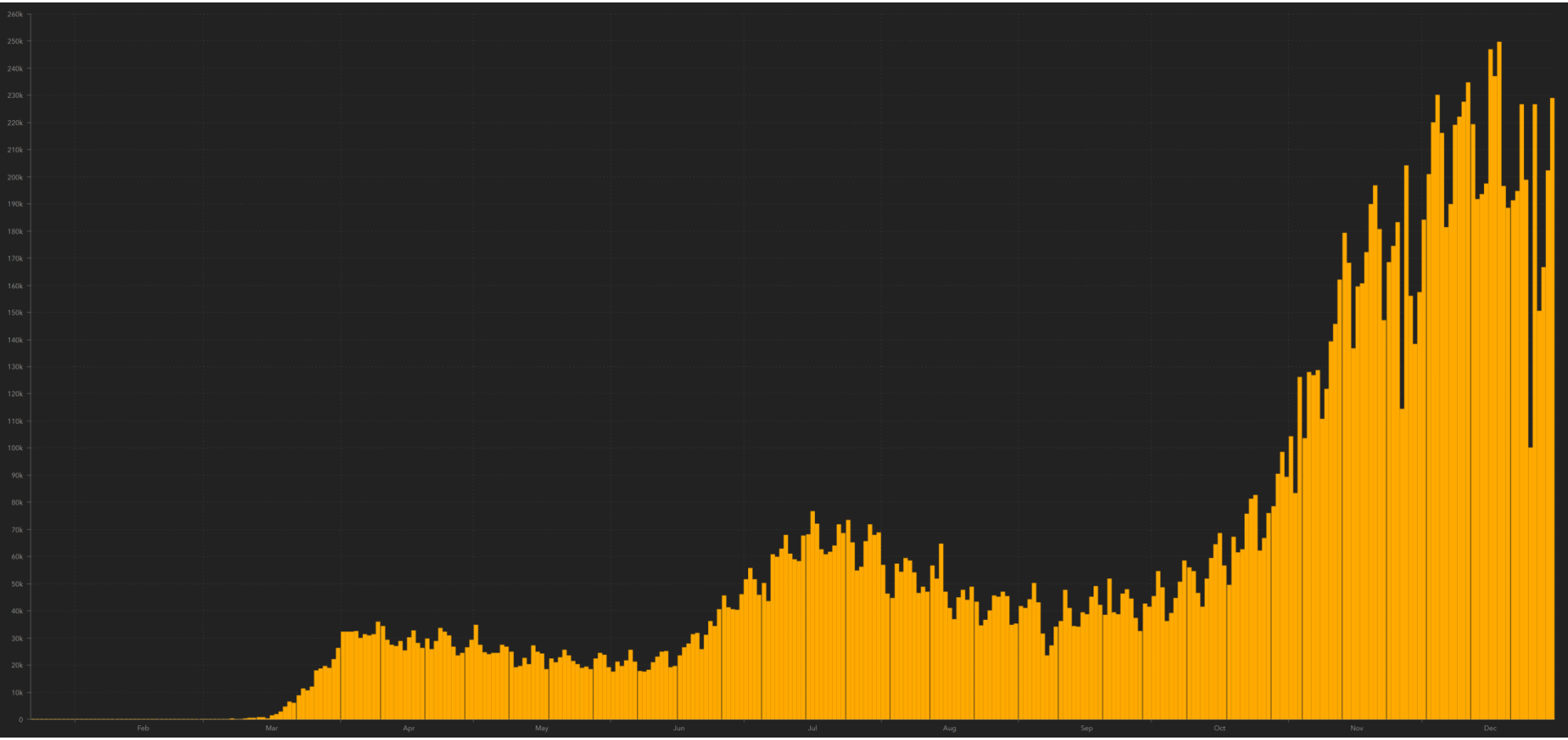
Instructions for Ambulatory Care Providers to Access Vaccine
Instructions for Enrolling to Become a Vaccine Provider

Registration:
Ambulatory care health workers at most risk must go to the following website to register: https://prd.blogs.nh.gov/dos/hsem/?page_id=10681.

This form must be completed by the individual being vaccinated. The individual will receive information about the vaccine, which must be reviewed prior to arrival at the vaccination clinic.

Scheduling:
Once DPHS receives the registration form, the registration will be reviewed and once approved (this may take several days and is contingent on vaccine supply) the individual will receive an email inviting them to schedule a vaccination appointment via email. Those without access to email will be contacted by phone. The email will come from no-reply@mail.vams.cdc.gov. Registrants should ensure that this email address is not blocked or sent to a spam filter.

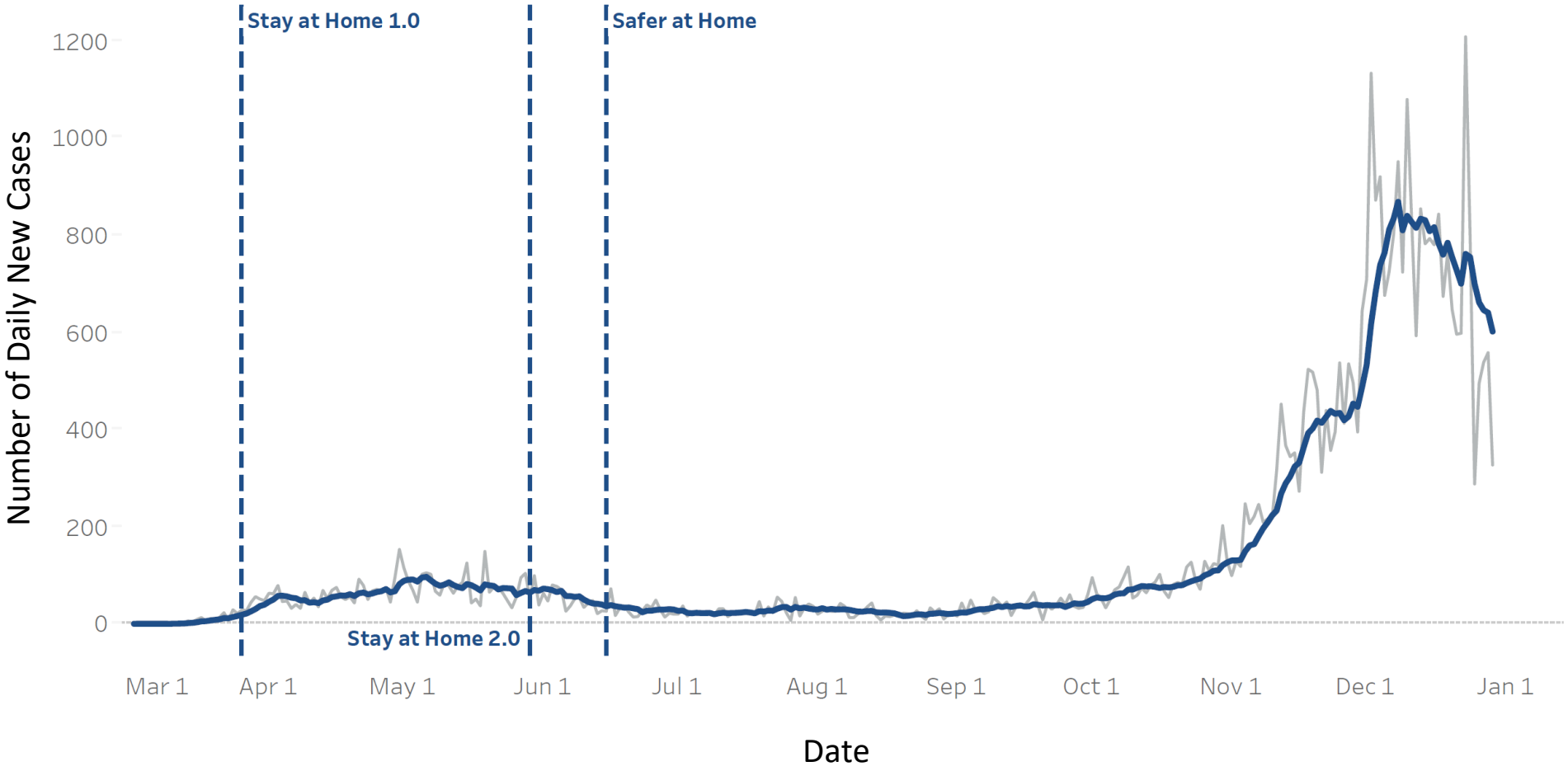
National Daily Incidence of COVID-19



JHU COVID-19 Dashboard

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

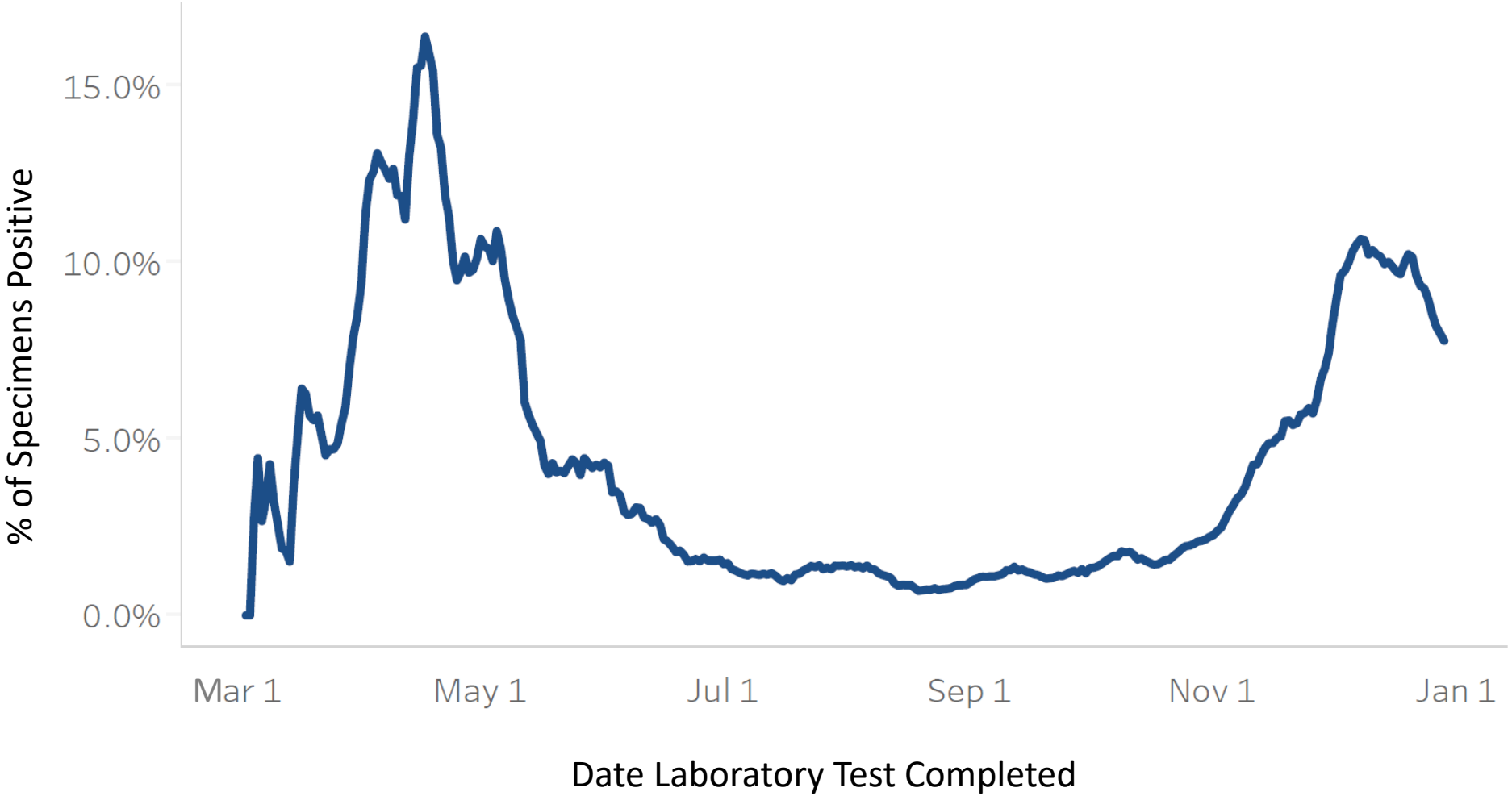
Number of New COVID-19 Cases per Day in NH



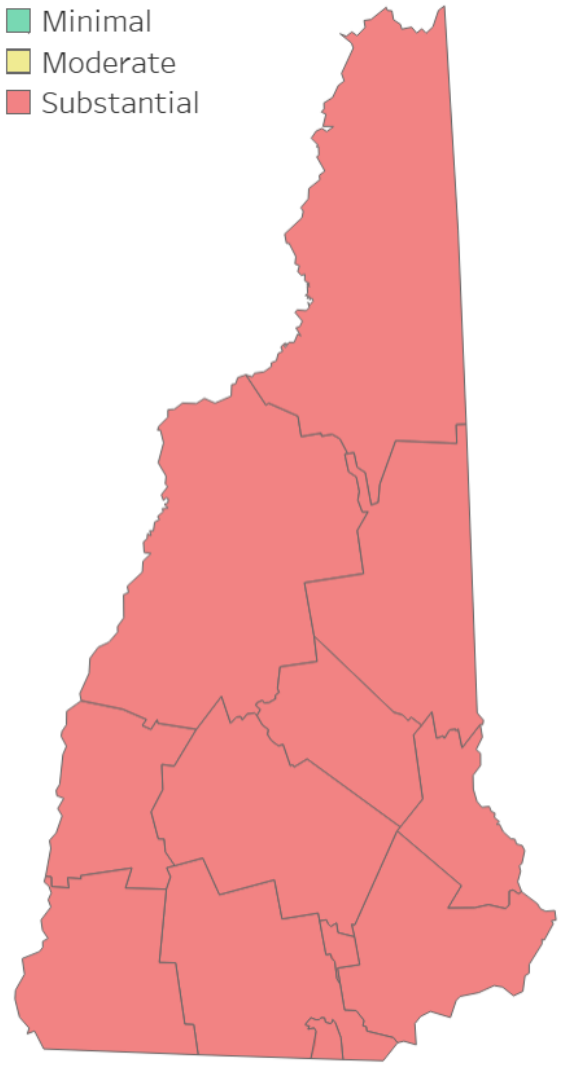
https://www.nh.gov/covid19/dashboard/overview.htm#dash

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

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



Level of Community Transmission



Level of Transmission

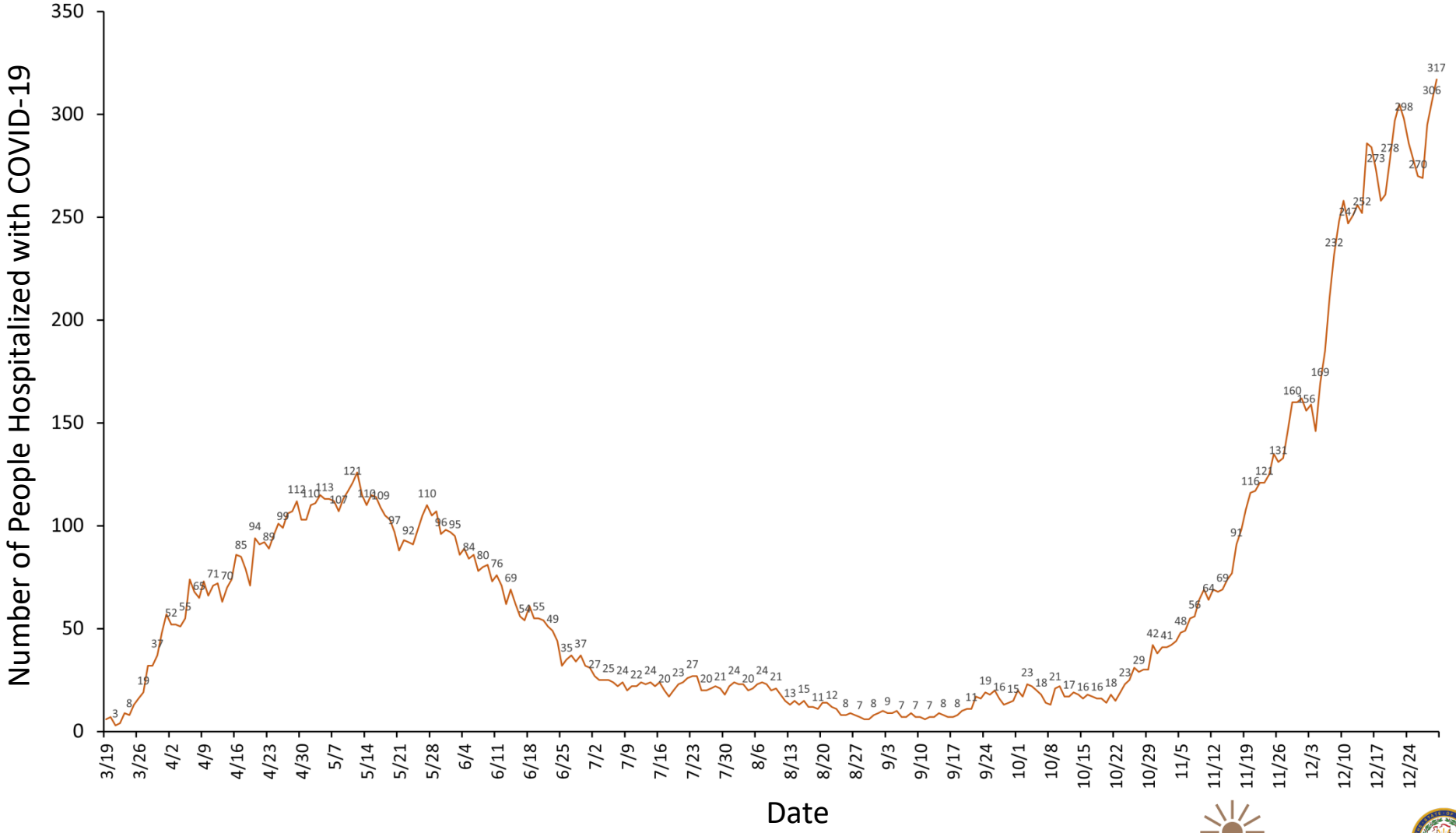
Substantial

New Cases per 100k over 14 days	New Hosp per 100k over 14 days	7-Day Total Test Positivity Rate
628.4	0.6	7.8%

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

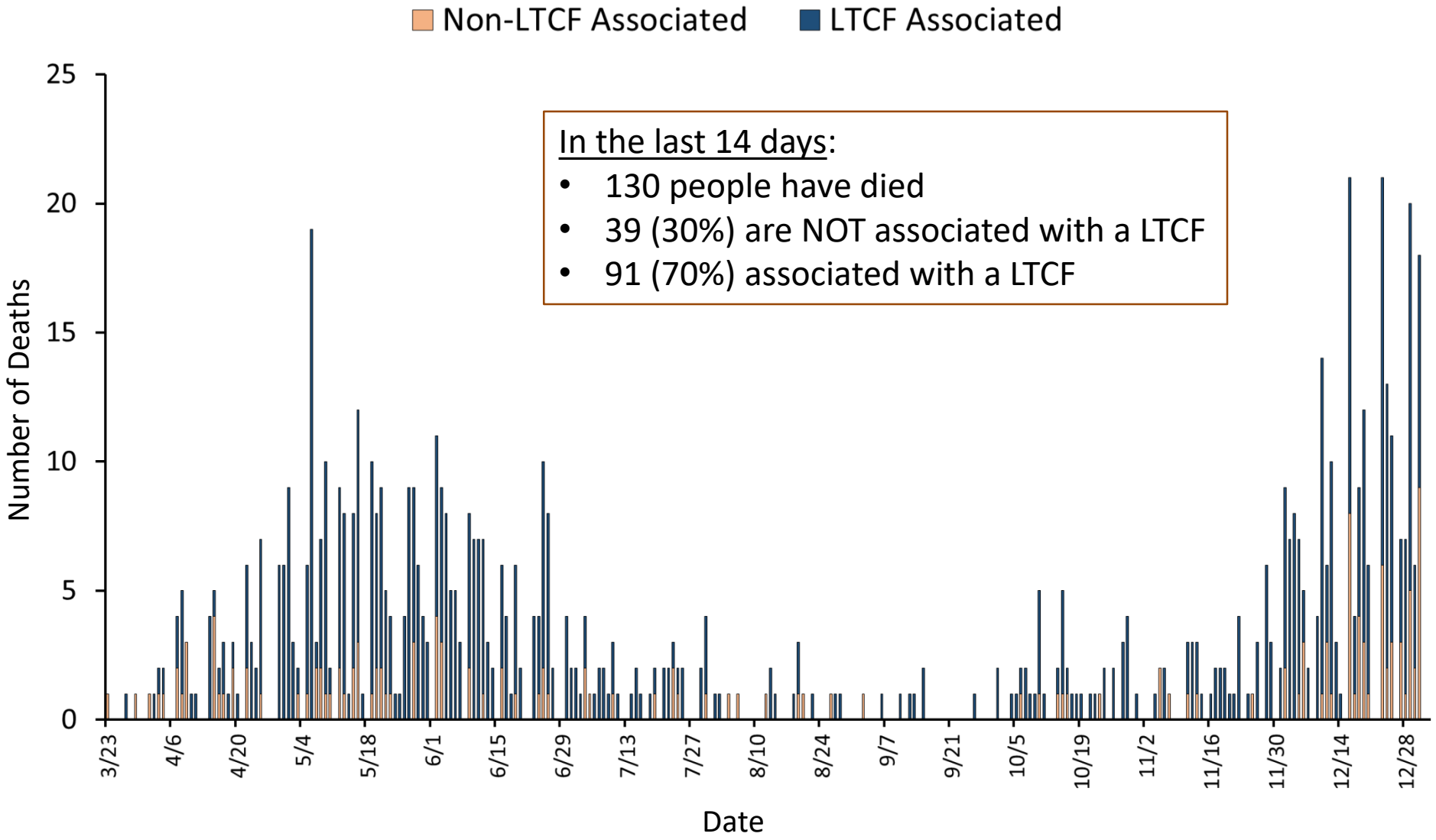
NH DIVISION OF Public Health Services
Department of Health and Human Services

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



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

Number of COVID-19 Deaths in NH by Report Date



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

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Summary of recent changes (last updated December 30, 2020):

- Additional information on antibody therapies and COVID-19 vaccination
- Information on COVID-19 vaccination and outbreak management
- Additional information on vaccination of immunocompromised persons
- Updates to contraindications and precautions to vaccination
- Information on COVID-19 vaccination and tuberculin skin testing

Distinguishing allergic reactions from other types of reactions

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Receive 2nd dose of mRNA COVID-19	No	Yes	Yes

https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp

Contraindications to mRNA COVID-19 vaccination

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
  - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp

Precautions to mRNA COVID-19 vaccines

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
- Unknown risks of developing a severe allergic reaction should be balanced against the benefits of vaccination
- Deferral of vaccination and/or consultation with an allergist-immunologist may be considered

https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp

Summary: Triage of persons presenting for mRNA COVID-19 vaccination

MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
ALLERGIES History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, or injectable therapies, such as: • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies **ACTIONS** • 30 minute observation period: Persons with a history of anaphylaxis (due to any cause) • 15 minute observation period: All other persons	**ALLERGIES** • History of any immediate allergic reaction‡ to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines† or polysorbate, as these are contraindicated) **ACTIONS:** • Risk assessment • Consider deferral of vaccination and/or referral to allergist-immunologist • 30 minute observation period if vaccinated	**ALLERGIES** History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines†: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components • Immediate allergic reaction‡ of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components^ (including polyethylene glycol)# • Immediate allergic reaction of any severity to polysorbate^# **ACTIONS** • Do not vaccinate# • Consider referral to allergist-immunologist

† Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

‡ Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

^ See Appendix A for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

https://emergency.cdc.gov/coca/calls/2020/callinfo_123020.asp

Other Important Updates

- COVID-19 Vaccination and TB testing (TST or IGRA)
- Inactive vaccines do not interfere with TB test results
- There is no immunologic reason to believe either a TST or IGRA would affect the safety or effectiveness of mRNA COVID-19 vaccines
- There is no data to inform the impact of the COVID-19 mRNA vaccines on either the TST or IGRA
- Therefore…

COVID-19 Vaccines and TST/IGRA

- Perform a blood draw (for IGRA) or place TST prior to COVID-19 vaccination (and then you can give the COVID-19 vaccine during same visit)
- If COVID-19 vaccination has been given and testing needs to be performed (baseline mTB testing), defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose series completion.

VUI/VOC 202012/01 or B.1.1.7

- Since 9/20, UK had rapid increase in cases in SE England, leading to enhanced virological investigations
- >50% belonged to new phylogenetic cluster
  - 23 mutations, 8 in spike protein
    - N501Y enhances viral binding to angiotensin-converting enzyme 2 receptor

VUI/VOC 202012/01

- Viruses constantly change through mutation leading to new variants, usually with no impact (e.g., D614G mutant)
  - This rate of emergence is faster than expected
- Preliminary analysis suggests that this variant is 1.4 to 1.7 times more transmissible
  - Increased reproductive number (R) 1.1 to 1.5
  - Estimated 70% more transmissible
- May be binding more easily to receptor cells, replicating more easily and driving higher viral loads, shedding longer

UK Variant Worldwide

- Already present in most European countries, Australia, RSK, and Canada
  - Travel restrictions in 40 countries
- Dec 29 CO reported first case
  - Patient in NG, in 20's, 50m SE of Denver, no travel history, no known contacts
  - Second NG member
- California also reported nontravel case, with symptomatic contact
- CDC "additional cases with the new variant will be detected in the United States in coming days"

Impact of VUI/VOC 202012/01

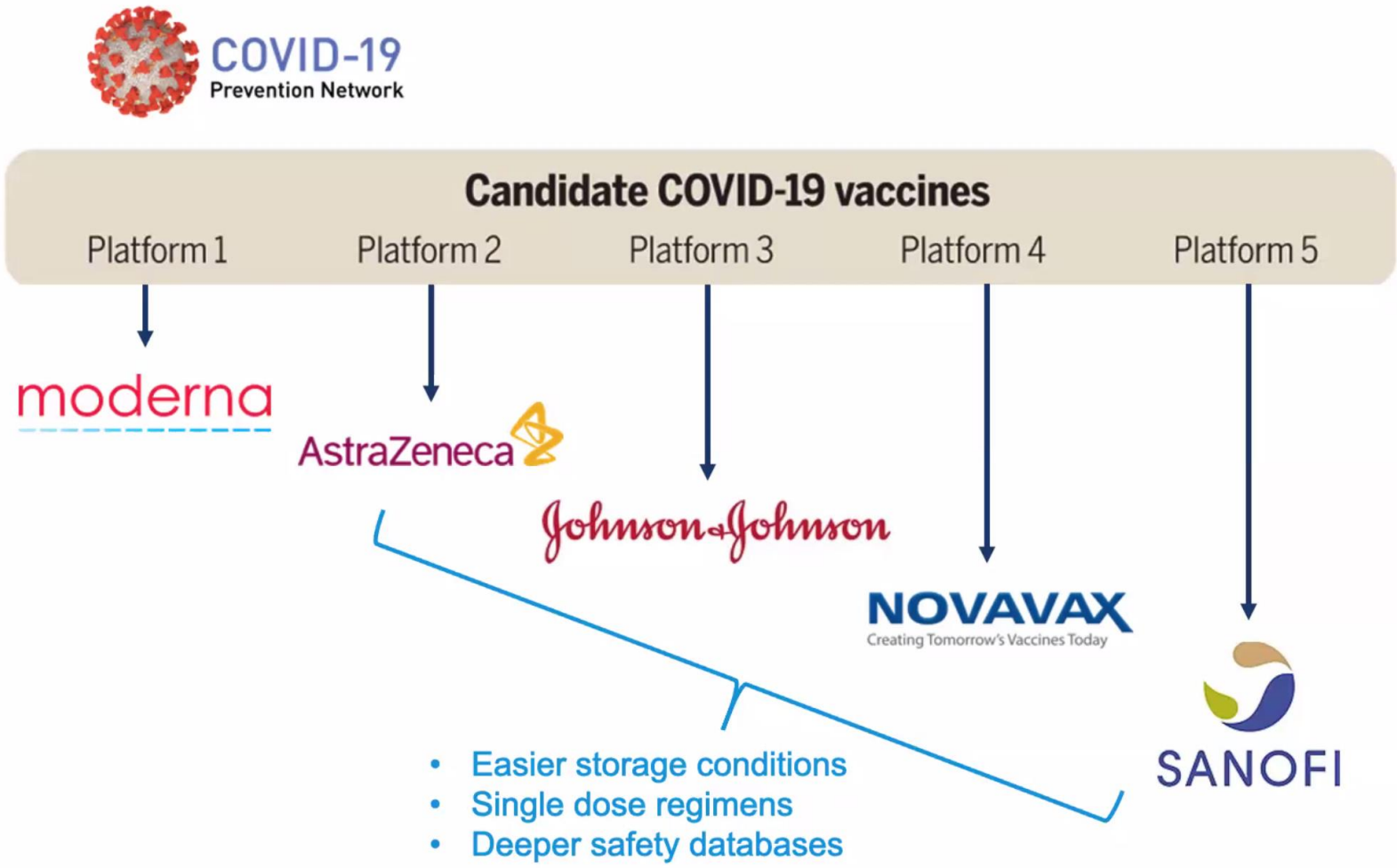
- No decreased utility of currently available treatments
- No decreased sensitivity of diagnostics
  - ThermoFisher TaqPath assay gives characteristic pattern (“S-target dropout”) when detecting this variant. This result does not adversely affect the performance of the test
- No increased severity
  - However, higher rate of transmission leads to more cases, which would increase hospitalizations and deaths
- No known lack of protection from previous infection

B.1.1.7 Vaccine Impact?

- Most experts not concerned
  - Poly-antibody response
- BUT it should be easy to update current mRNA vaccines
  - Relatively simple to change spike protein sequence

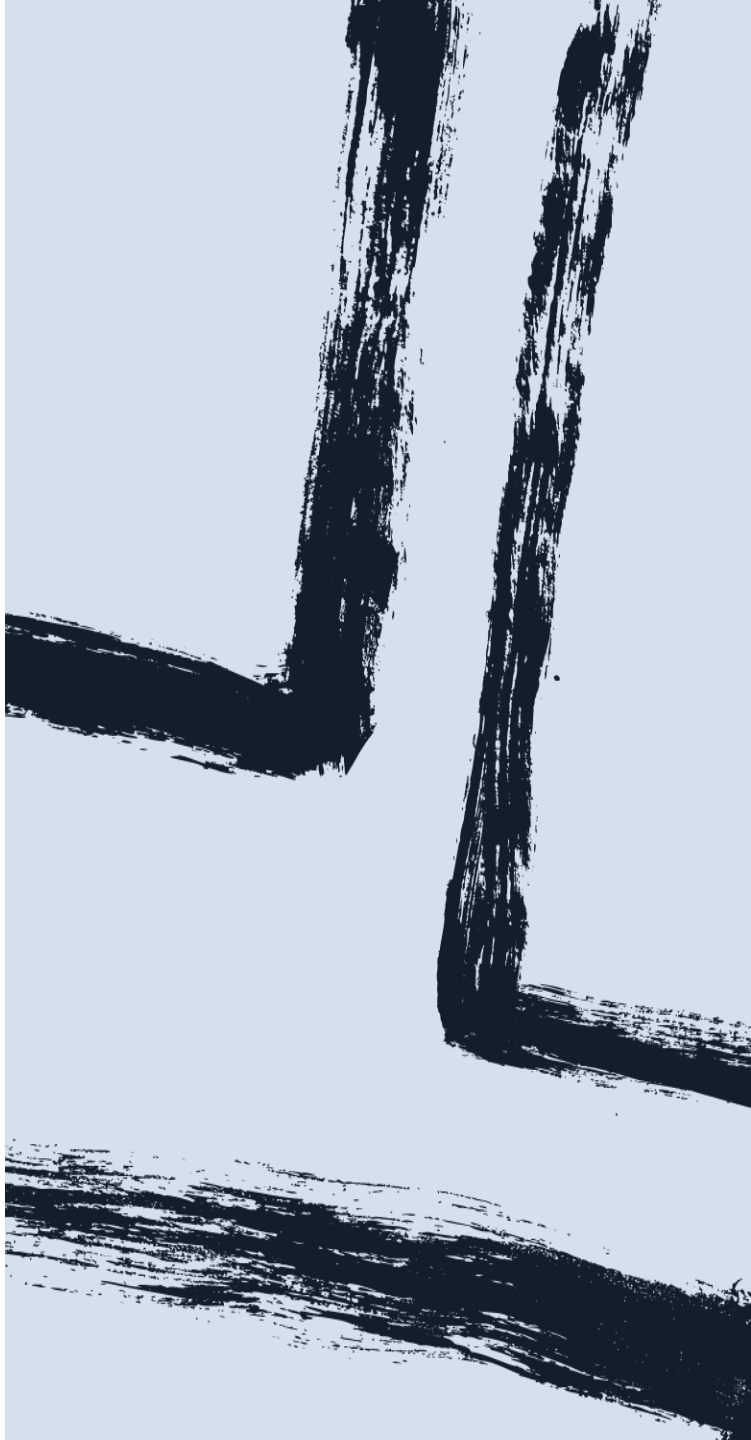
South Africa Variant 501Y.V2 or B.1.351

- Like the “UK variant,” preliminary data suggests that it may spread more easily and quickly than other variants. It has quickly become the predominant variant in parts of South Africa
- Much less is known


COVID-19
Prevention Network
Candidate COVID-19 vaccines
Platform 1
Platform 2
Platform 3
Platform 4
Platform 5
moderna
AstraZeneca
Johnson & Johnson
NOVAVAX
Creating Tomorrow's Vaccines Today
SANOFI
• Easier storage conditions
• Single dose regimens
• Deeper safety databases

Astra Zeneca / Oxford University

- AZD1222 ChadOx1 platform: chimpanzee adenovirus vectored vaccine
- Two doses spaced 4-12w for ≥18y
- Multiple trials grouped for analysis
  - Preliminary Nov 23
  - Well-tolerated but 3 cases transverse myelitis
  - Mistake in preparation



AZ/Oxford Data in Lancet 12/9/2020

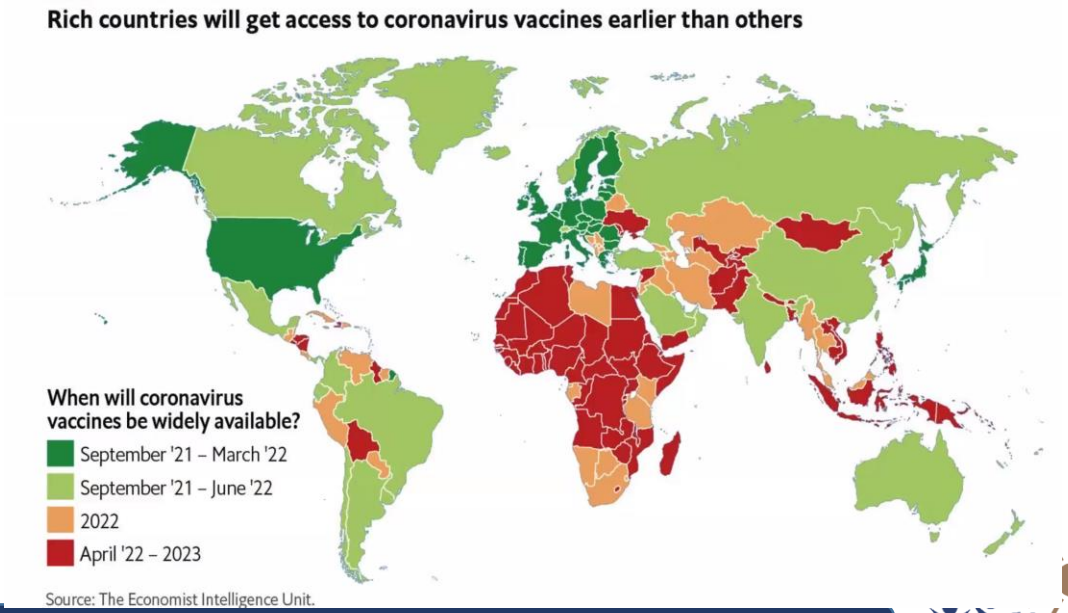
- 11,636 adults vaccinated with 2 doses in UK and Brazil
  - No severe disease or hospitalizations in pooled results
  - 70% effectiveness based on 131 (1.1%) symptomatic COVID-19 >14 days after second dose
    - 30 of 5,807 (0.5%) in vaccine group
    - 101 of 5,829 (1.7%) in control group given meningococcal conjugate vaccine or saline
- Subset in UK showed 70% averaged efficacy (N=11,636)
  - 62% effectiveness given 2 full doses of vaccine (N=8895)
  - *(90% given half then full doses (N=2741))*
- Serial PCR testing was performed and indicated 62% efficacy in preventing asymptomatic transmission

Nov 30 UK Regulatory Considerations of the AstraZeneca/Oxford Vaccine

- Approved 30 Dec with new interpretations:
  - Limited information for those ≥ 65y (<10% of subjects)
  - No serious adverse events
  - Higher efficacy of half dose regimen not substantiated
  - Efficacy data after a single dose not interpretable
- Experimental approach to immediately give as many persons as possible single dose rather than holding back supplies for second dose after 1 month
  - Mass vaccinations in soccer stadiums and racecourses
- FDA application at least 4 months away
  - Awaiting US trial that is almost completely enrolled

Global Hopes on the AZ Vaccine

- Advantages: can quickly produce, will cost few dollars per dose and easy to store for long periods
- Expected to be dominant worldwide for LMICs
- Manufacturing capacity of 3 billion doses in 2021



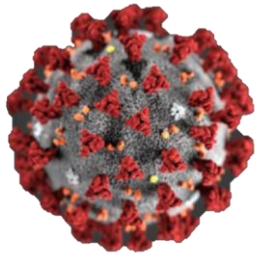
Re-Infection Re-Visited

- 31 case reports of reinfection
  - Mean 80-day interval
- Baseline anti-spike and anti-nucleocapsid antibody status of 12,541 Oxford Univ HCPs
  - 90.6% (11,364) neg and 9.4% (1265) pos antibody
  - Followed 31 weeks (med 200d neg, 139 pos)
- Identified 225 PCR positive
  - 223 in seroneg: 1.09 cases/100k at-risk days
    - 123 symptomatic
  - 2 in seropos: 0.13 cases/100k at-risk days
    - Both asymptomatic

https://www.nejm.org/doi/full/10.1056/NEJMoa2034545


Q.
A.

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



December 31 2020

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

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

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