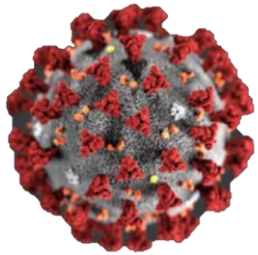


New Hampshire Coronavirus Disease 2019 Weekly Call for Healthcare Providers and Public Health Partners

January 7, 2021

Ben Chan
Elizabeth Talbot
Beth Daly
Lindsay Pierce

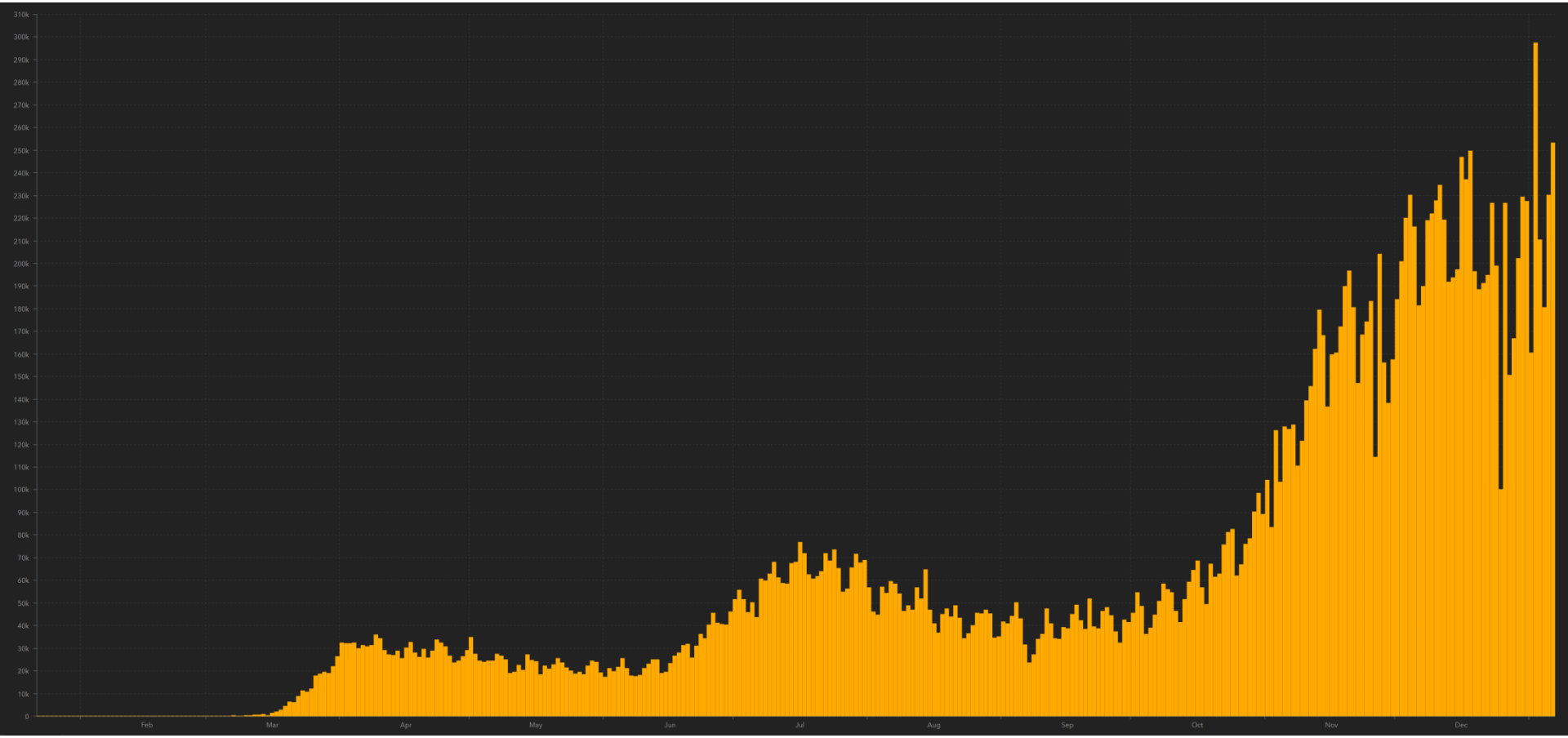
Thursday noon-time partner calls will focus on science, medical, and vaccine updates geared towards our healthcare partners

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

Agenda

- Epidemiology Update
- NH HAN #32 (recap from last week's call) – Update to CDC's clinical guidance on use of mRNA COVID-19 vaccines
- MMWR Publication: Anaphylaxis with COVID-19 Vaccines
- NH's Vaccine Allocation Plan Summary
- MMWR Publication: Antigen vs. PCR test comparison study
- Questions & Answers (Q&A)

National Daily Incidence of COVID-19



JHU COVID-19 Dashboard

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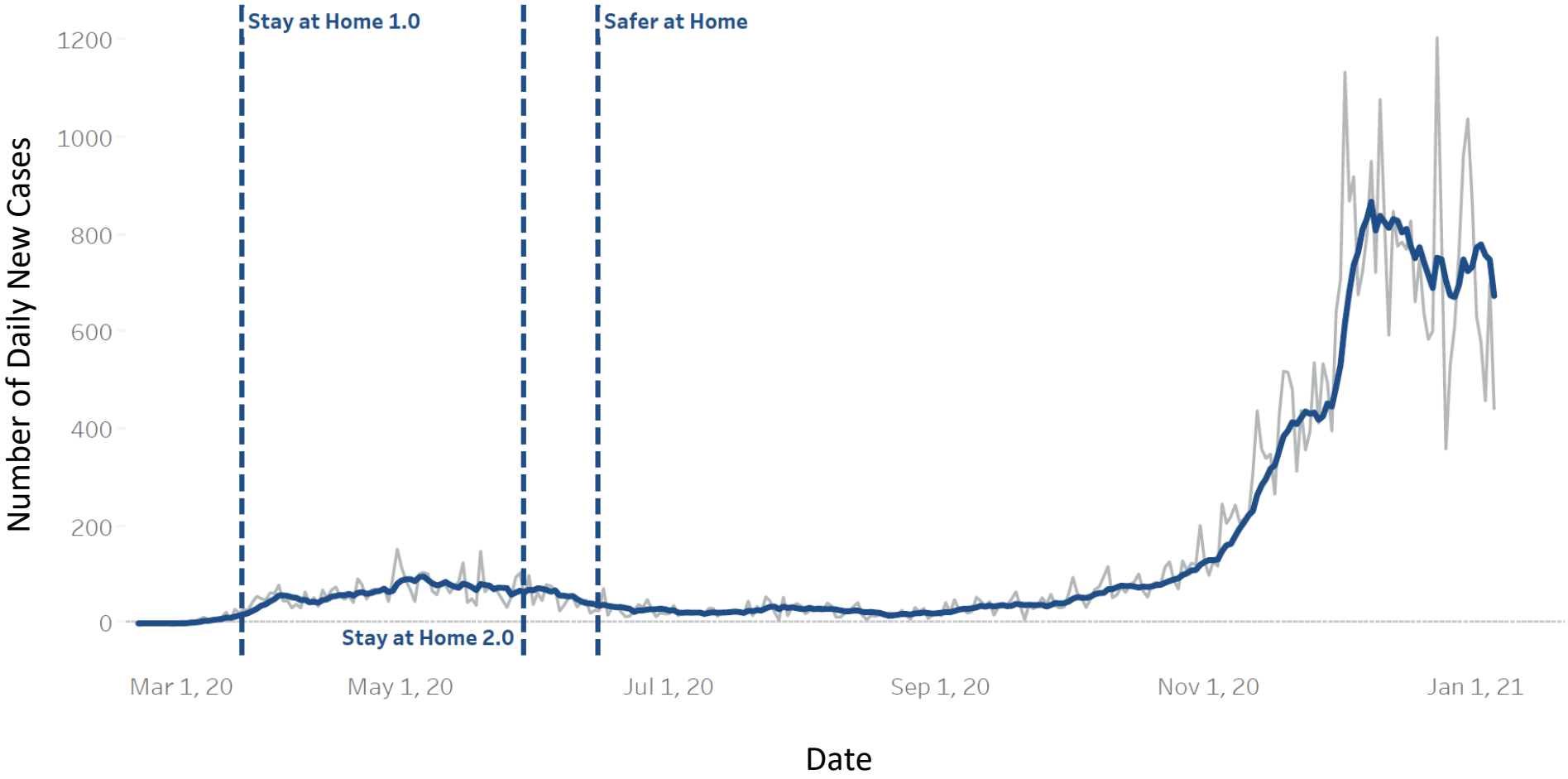
Number of New COVID-19 Cases per Day in NH



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

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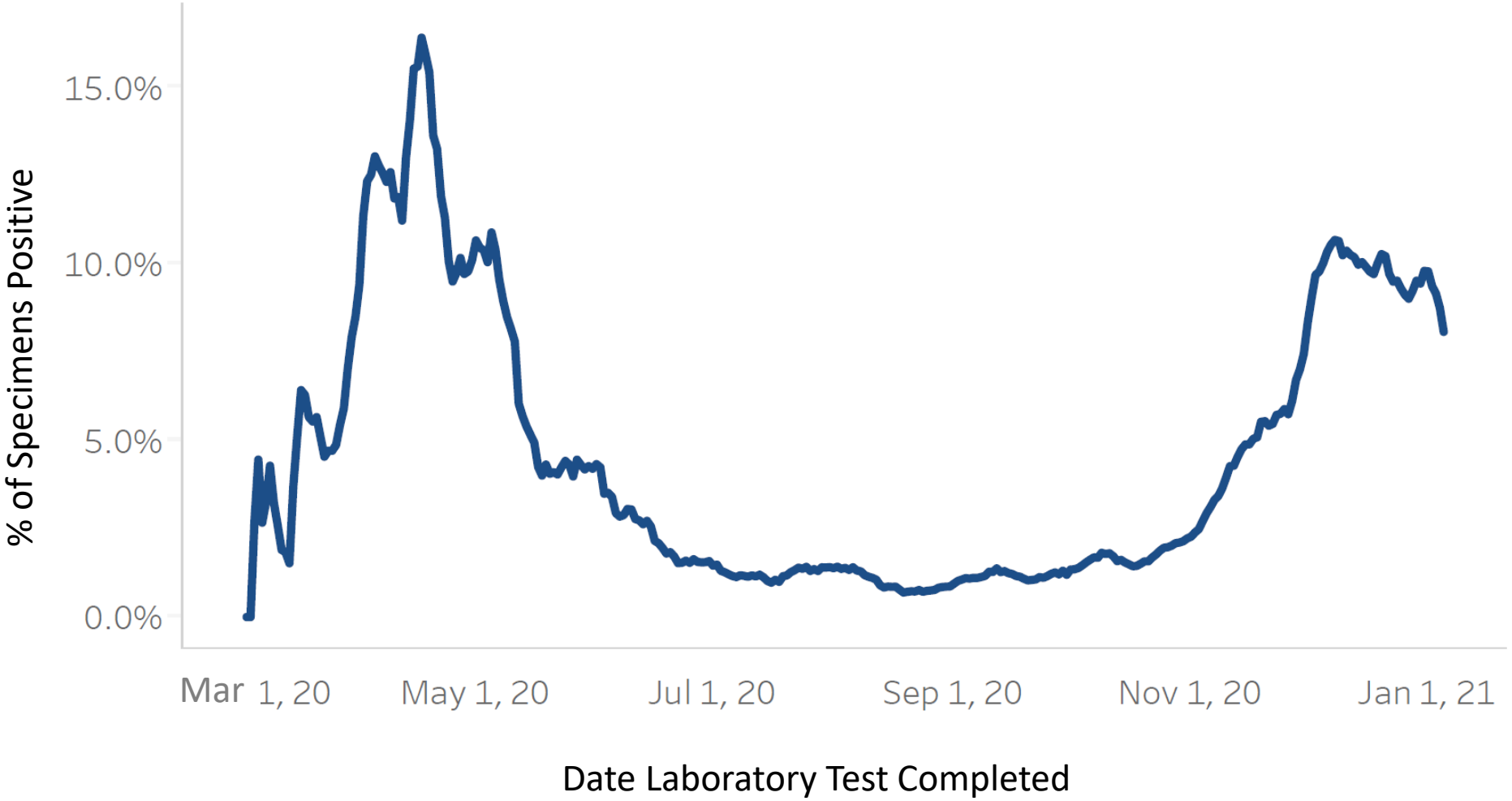
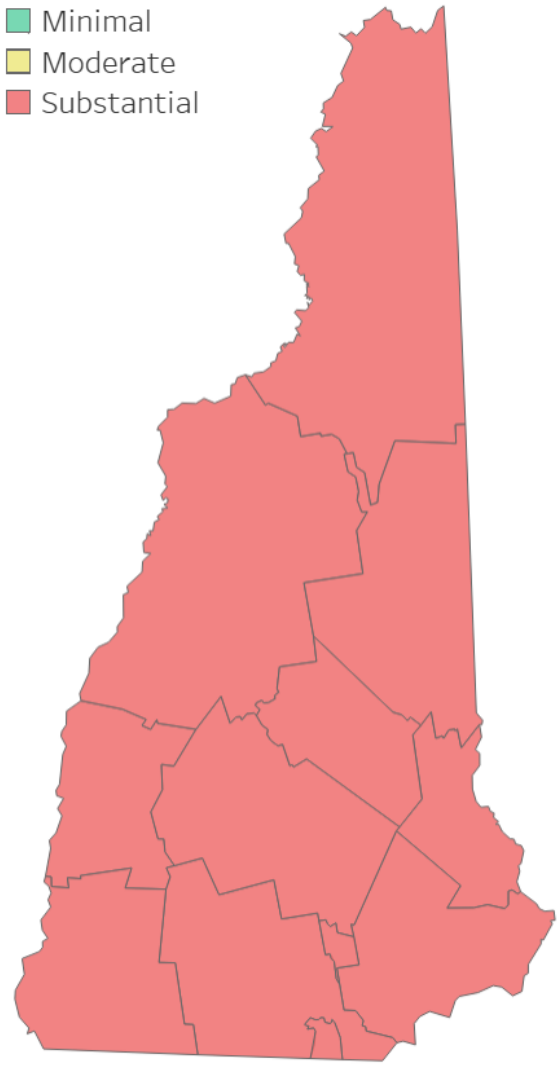
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



Level of Community Transmission



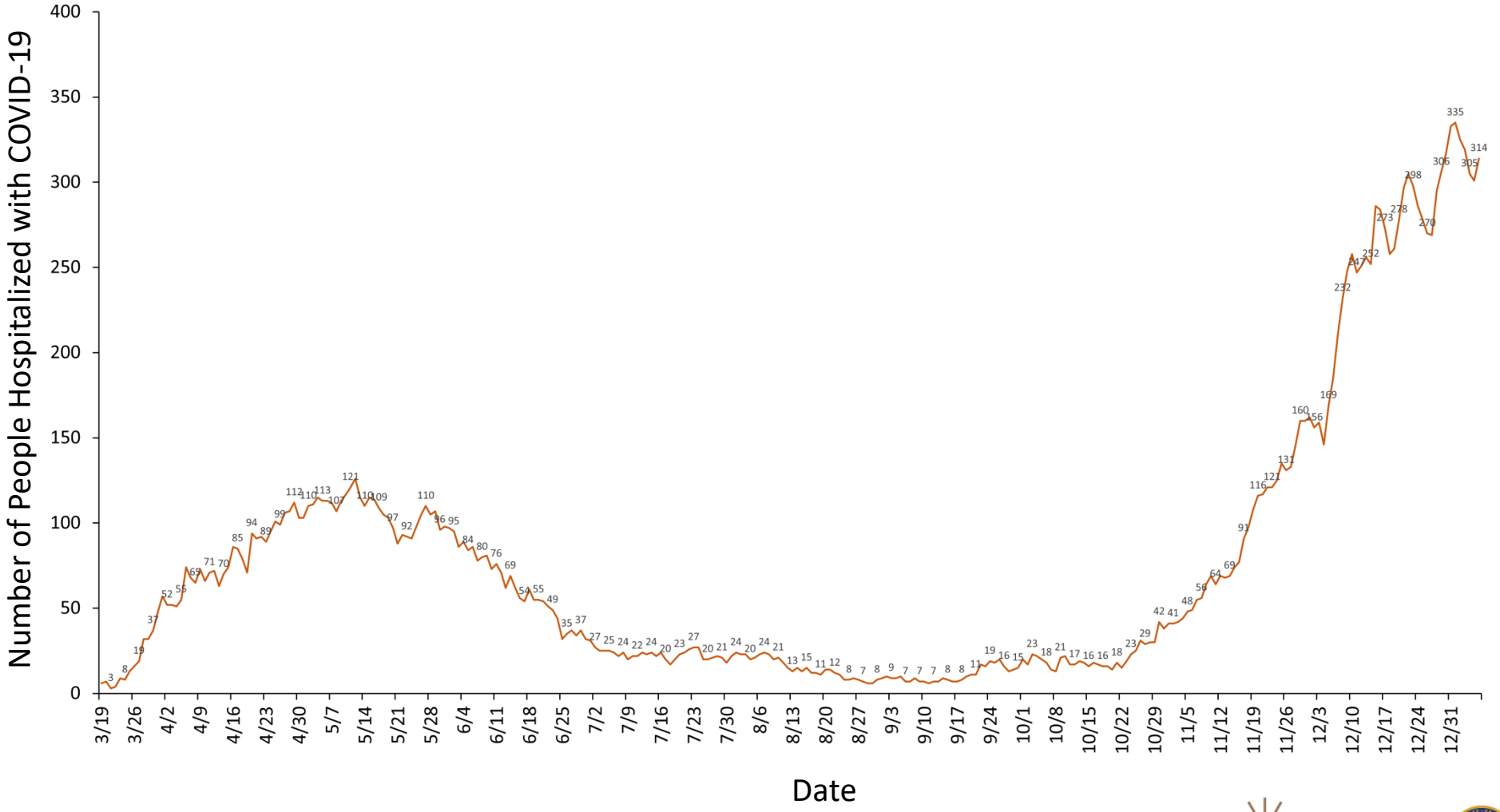
Level of Transmission

Substantial

New Cases per 100k over 14 days	New Hosp per 100k over 14 days	7-Day Total Test Positivity Rate
667.5	0.6	8.1%

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

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



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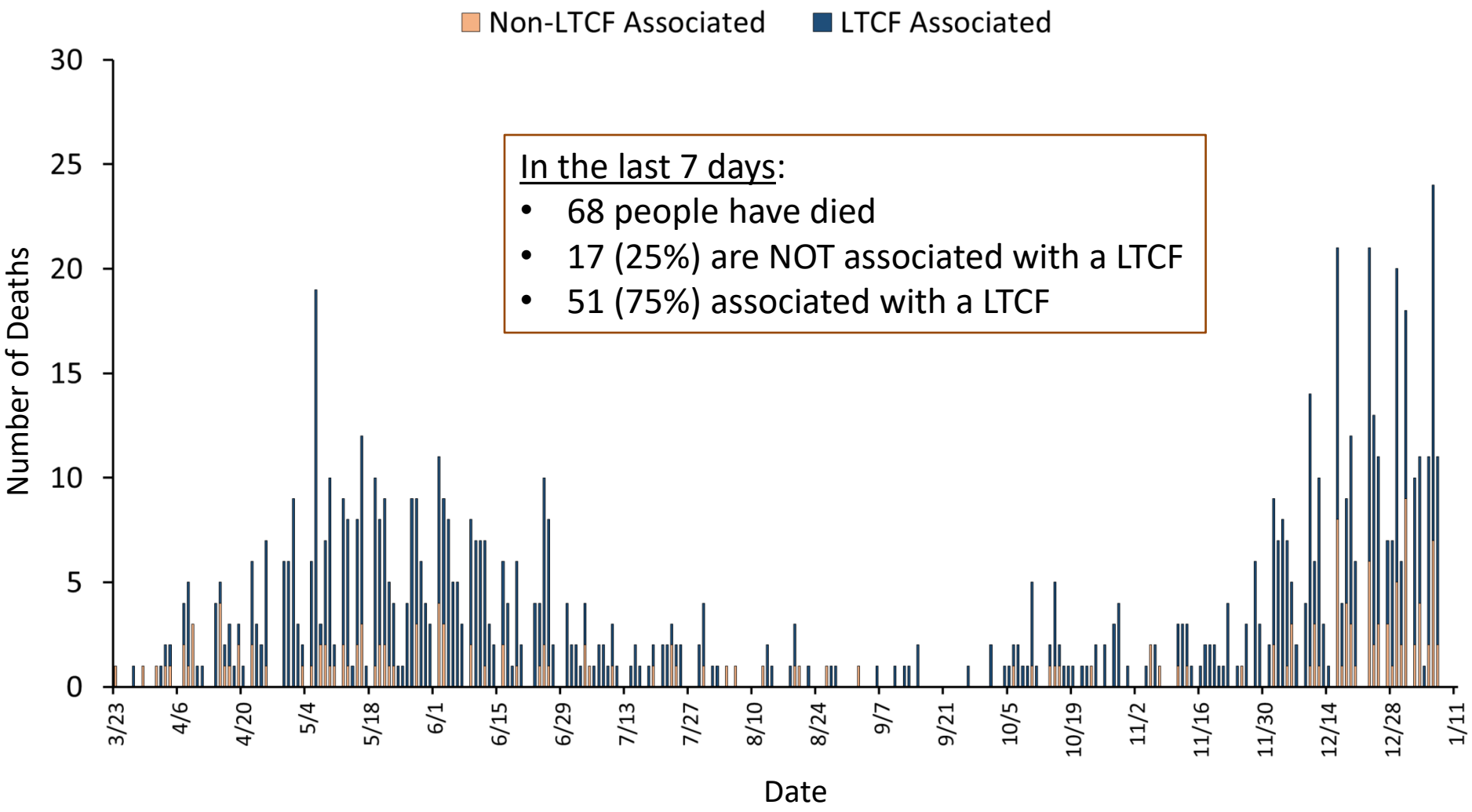
Number of COVID-19 Deaths in NH by Report Date



THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network
Health.Alert@nh.gov
December 31, 2020 Time 1700 (5:00 PM EDT)
NH-HAN 20201231

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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 # 32

CDC Updates COVID-19 Vaccine Clinical Guidance
Changes to Vaccine Contraindications and Precautions

Key Points and Recommendations:

- The U.S. Centers for Disease Control and Prevention (CDC) has updated their Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines; this includes updates to vaccine contraindications and precautions.
  - A CDC clinician webinar (12/30/2020) about these updates can be viewed here.
  - See the updated NH Division of Public Health Services (DPHS) COVID-19 Vaccine FAQs for Healthcare Providers and Public Health Partners (updated **12/31/2020**).
- Contraindications to administration of either the Pfizer-BioNTech or Moderna vaccine (i.e., people who should NOT receive the vaccines) include people who have a history of any of the following:
  - A severe allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient.
  - An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient.
  - An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving polysorbate – polysorbate is structurally similar to polyethylene glycol (PEG), which is an ingredient in both mRNA COVID-19 vaccines, so an allergic reaction to polysorbate could increase risk of an allergic reaction to the COVID-19 vaccines.

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

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
January 6, 2021

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020

CDC COVID-19 Response Team; Food and Drug Administration

- 1,893,360 doses of the Pfizer-BioNTech COVID-19 vaccine were administered from December 14th – 23rd
- 21 episodes of anaphylaxis – rate of 11.1 per million doses administered (influenza vaccine rate of 1.3 per million doses)
  - Median interval from vaccine receipt to symptom onset: 13 minutes (range 2 to 150 minutes)
  - 17 (81%) had a history of allergic reactions, including 7 (33%) with a history of anaphylaxis)

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf

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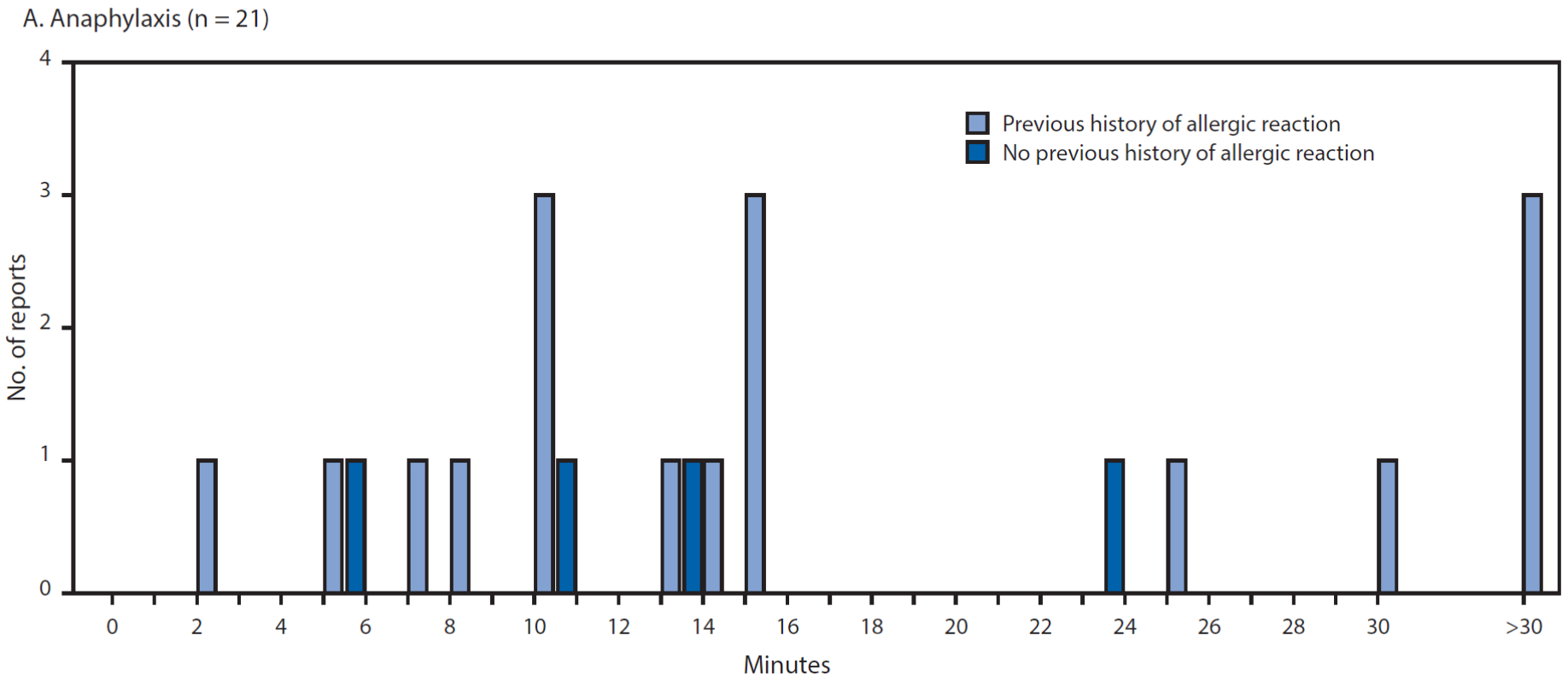
FIGURE. Interval (minutes) from vaccine receipt to onset of anaphylaxis (A)* and nonanaphylaxis allergic reactions (B)† after receipt of Pfizer-BioNTech COVID-19 vaccine — Vaccine Adverse Events Reporting System, United States, December 14–23, 2020



https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf

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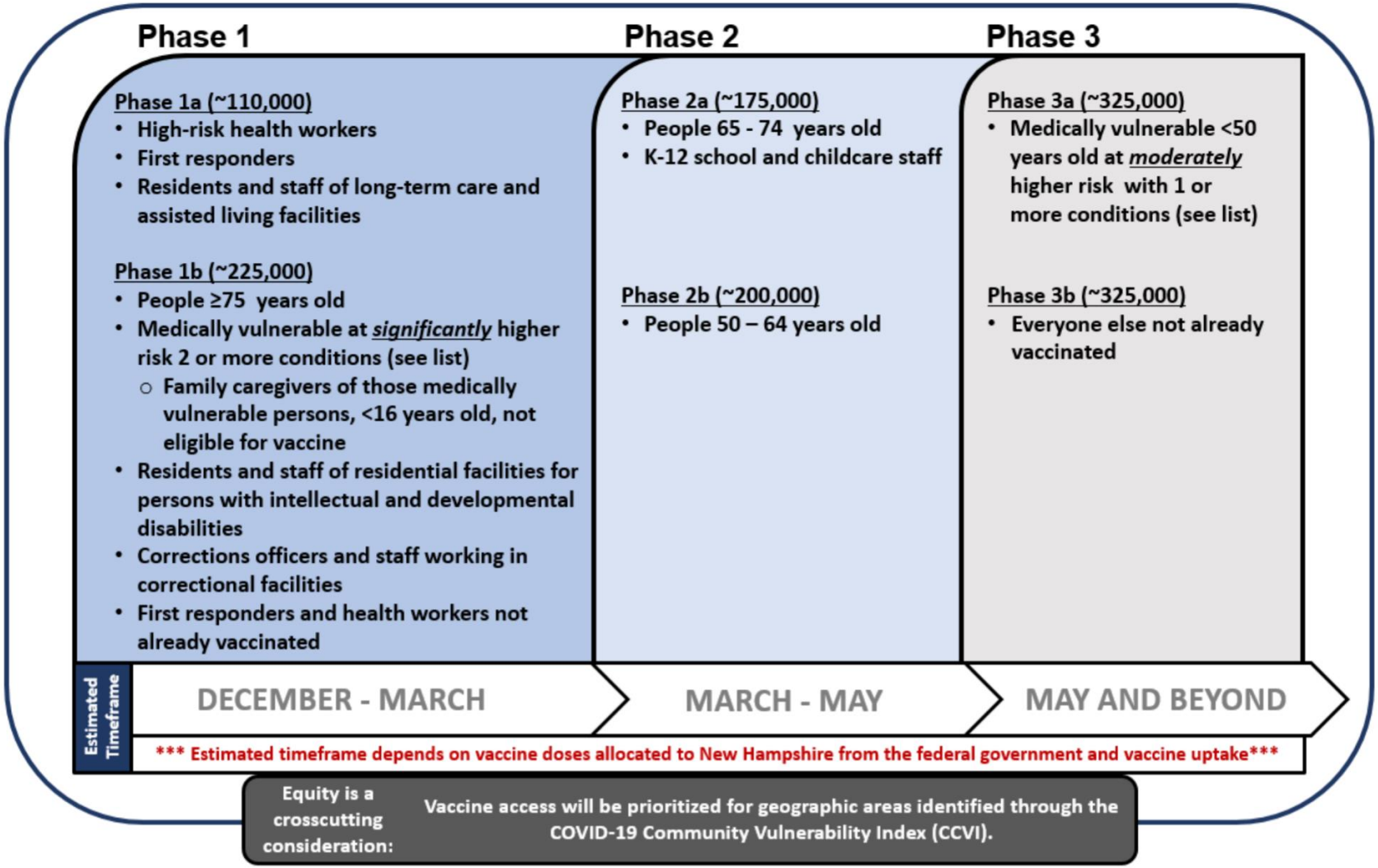
Summary

- Anaphylaxis to COVID-19 vaccines is a rare event
- No deaths have occurred from the COVID-19 vaccines (compared to 2,000+ deaths per day in U.S. from COVID-19)
- Screen for contraindications and allergies prior to vaccination
- Observation period after vaccination (15-30 minutes)
- Have necessary supplies on hand to manage anaphylaxis (IM epinephrine is the first-line treatment for anaphylaxis)

https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7002e1-H.pdf

Vaccine Allocation Plan Summary



https://www.dhhs.nh.gov/dphs/cdcs/covid19/documents/covid19-vaccine-allocation-plan-summary.pdf

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Vaccine Allocation Plan Summary

List Underlying Medical Conditions (adapted from CDC):

Phase 1b: Two or more conditions

Phase 3a: One or more conditions

- Cancer
- Chronic Kidney Disease
- COPD (Chronic Obstructive Pulmonary Disease)
- Down Syndrome
- Heart Conditions, such as heart failure, coronary artery disease, or cardiomyopathies
- Immunocompromised state (weakened immune system) from solid organ transplant
- Obesity (body mass index of 30 kg/m or higher but < 40 kg/m
- Severe Obesity (body > 40 kg/m)
- Pregnancy
- Sickle cell disease
- Other High Risk Pulmonary Disease
- Type 2 Diabetes Mellitus

Note: Flexibility is provided for a health care provider to vaccinate any patient whose primary care provider assesses a significant risk for severe illness due to any multiple co-occurring co-morbidities.

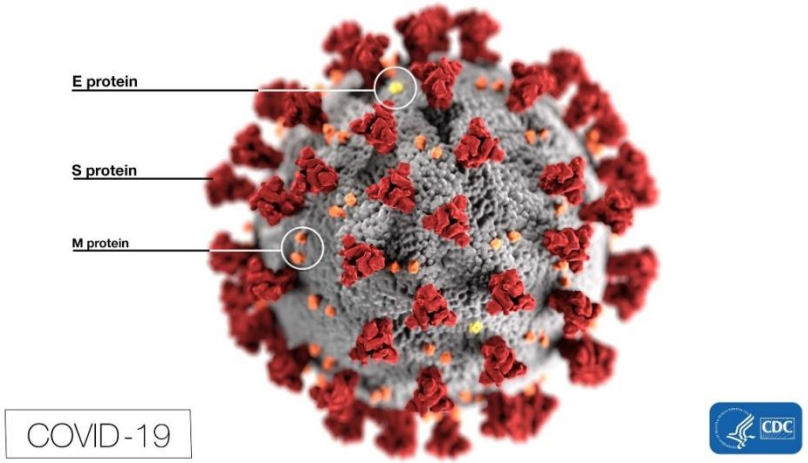
https://www.dhhs.nh.gov/dphs/cdcs/covid19/documents/covid19-vaccine-allocation-plan-summary.pdf

Phase 1b and Beyond

- Vaccine administration will occur through multiple pathways over the coming phases (Phase 1b and Beyond):
  - Hospitals and Long-Term Care Facilities
  - Pharmacy Partnership Program (PPP)
  - Public health mobile vaccination teams (Regional Public Health Networks)
  - Fixed vaccination sites (similar to our fixed testing sites around the State)
  - Other Healthcare partners that are able to take receipt, store, and administer vaccine
- We will communicate with the prioritized groups/persons through various mechanisms with instructions for how to register and where to go at the appropriate time.

SARS-CoV-2 Antigen Test Overview

- “Viral test” to identify the presence of the SARS-CoV-2 virus that causes COVID-19
- Detects proteins on/within the virus (vs. molecular tests which detect genetic material)
- Diagnose active/current infection



Antigen Tests: Advantages & Disadvantages

- Advantage:
  - "Point-of-care" and ease of use*
  - Increases access to testing
  - Results within 15-20 minutes
  - Lower cost
- Disadvantages:
  - Lower sensitivity and specificity (lower accuracy)
  - Increased risk of false-negative & false-positive results (and ensuing consequences)

*Note: testing process/procedure varies by manufacturer – some tests are simpler to use than others

Test Characteristics

- Sensitivity and Specificity are intrinsic test characteristics.
- Positive Predictive Value (PPV) and Negative Predicative Value (NPV) are impacted by prevalence of disease.
- Other factors affecting test accuracy:
  - Specimen collection (type of specimen, quality of specimen)
  - Time since infection or symptom onset
  - Contamination (procedural)

Morbidity and Mortality Weekly Report

Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses — Wisconsin, September–October 2020

- Quidel's Sofia SARS Antigen FIA test was compared to PCR testing (the "gold standard")
- Occurred on 2 university campuses in Wisconsin
- 1,098 paired nasal swabs including:
  - 871 asymptomatic persons (no symptoms of COVID-19 at time of testing)
  - 227 symptomatic persons (one or more symptoms of COVID-19)

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

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Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	7	14	21
	Negative	10	840	850
	Total	17	854	871

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	7	14	21
	Negative	10	840	850
	Total	17	854	871

- **Sensitivity**: 41.2% (Out of 17 positive PCR tests, 7 were also positive by antigen testing)
  - Antigen testing missed 10 infections (58.8%)

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	7	14	21
	Negative	10	840	850
	Total	17	854	871

- **Specificity**: 98.4% (Out of 854 negative PCR tests, 840 were also negative by antigen testing)
  - Antigen testing incorrectly identified 14 as positive (1.6%)

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	Negative	Total
Antigen Test Result	Positive	7	14	21
	Negative	10	840	850
	Total	17	854	871

- **PPV**: 33.3% (Out of 21 positive antigen tests, 7 were also positive by PCR)
  - 14 of the 21 positive antigen tests (66.7%) were incorrectly positive

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	7	14	21
	Negative	10	840	850
	Total	17	854	871

- **NPV**: 98.8% (Out of 850 negative antigen tests, 840 were also negative by PCR)
  - 10 of the 850 negative antigen tests (1.2%) were incorrectly negative

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Asymptomatic Testing (N=871)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	7	14	21
	Negative	10	840	850
	Total	17	854	871

- **Sensitivity**: 41.2%
- **Specificity**: 98.4%
- **PPV**: 33.3%
- **NPV**: 98.8%

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Positive Predictive Value (PPV)

- “Among asymptomatic participants… low PPV was observed despite a relatively high prevalence of SARS-CoV-2 in this population (5.2% prevalence overall; 2.0% among asymptomatic persons), suggesting that PPV could be even lower when using this antigen test among populations with lower expected SARS-CoV-2 prevalence.”

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	Negative	Total
Antigen Test Result	Positive	32	2	34
	Negative	8	185	193
	Total	40	187	227

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	32	2	34
	Negative	8	185	193
	Total	40	187	227

- **Sensitivity**: 80.0% (Out of 40 positive PCR tests, 32 were also positive by antigen testing)
  - Antigen testing missed 8 infections (20.0%)

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	Negative	Total
Antigen Test Result	Positive	32	2	34
	Negative	8	185	193
	Total	40	187	227

- **Specificity**: 98.9% (Out of 187 negative PCR tests, 185 were also negative by antigen testing)
  - Antigen testing incorrectly identified 2 as positive (1.1%)

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	Negative	Total
Antigen Test Result	Positive	32	2	34
	Negative	8	185	193
	Total	40	187	227

- **PPV**: 94.1% (Out of 34 positive antigen tests, 32 were also positive by PCR)
  - 2 of the 34 positive antigen tests (5.9%) were incorrectly positive

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	32	2	34
	Negative	8	185	193
	Total	40	187	227

- **NPV**: 95.9% (Out of 193 negative antigen tests, 185 were also negative by PCR)
  - 8 of the 193 negative antigen tests (4.1%) were incorrectly negative

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

Symptomatic Testing (N=227)

		PCR Test Result		
		Positive	**Negative**	**Total**
Antigen Test Result	**Positive**	32	2	34
	Negative	8	185	193
	Total	40	187	227

- **Sensitivity**: 80.0%
- **Specificity**: 98.9%
- **PPV**: 94.1%
- **NPV**: 95.9%

https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm695152a3-H.pdf

New Hampshire's Recommendations for Antigen Testing in Ambulatory Settings (1)

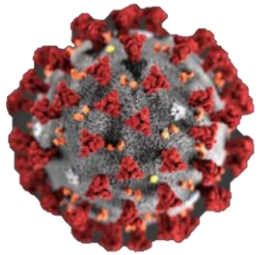
- We continue to recommend that antigen tests be used primarily in ambulatory/outpatient settings to test people with symptoms of COVID-19 (diagnostic purposes):
  - A positive antigen test in a symptomatic person should be treated as a true-positive and does not require PCR confirmation
  - Clinicians should use clinical judgement when deciding whether to confirm a negative antigen test in symptomatic persons – we recommend reflexing to PCR confirmation in high-risk or high-consequence settings, or if there is high suspicion of COVID-19 based on risk factors or symptoms (e.g., loss of taste or smell)
  - A negative test in a symptomatic person in a low-risk setting does not require PCR confirmation, and a person can return to school/work once fever-free off meds for 24 hours and other symptoms are improving

https://www.dhhs.nh.gov/dphs/cdcs/alerts/documents/covid-19-update23.pdf

New Hampshire's Recommendations for Antigen Testing in Ambulatory Settings (2)

- We do NOT recommend routine use of antigen testing for asymptomatic persons
- There are settings, however, where antigen testing in asymptomatic individuals may occur in consultation with public health, (e.g., LTCFs, State-sponsored screening/surveillance programs):
  - Any positive antigen result in an asymptomatic person should be confirmed with a PCR-based test as soon as possible after the positive result (ideally same day), but no longer than 48 hours after positive test (and person must isolate)
  - A negative test does not need PCR confirmation (especially if recurring testing is performed)

https://www.dhhs.nh.gov/dphs/cdcs/alerts/documents/covid-19-update23.pdf



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

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