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
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
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)
Level of Community Transmission

- Minimal
- Moderate
- Substantial

Level of Transmission: Substantial

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

https://www.nh.gov/covid19/dashboard/schools.htm#dash
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)
In the last 7 days:
- 68 people have died
- 17 (25%) are NOT associated with a LTCF
- 51 (75%) associated with a LTCF
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

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


CDC COVID-19 Response Team; Food and Drug Administration

- 1,893,360 doses of the Pfizer-BioNTech COVID-19 vaccine were administered from December 14\(^{th}\) – 23\(^{rd}\)
- 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
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

A. Anaphylaxis (n = 21)

[Bar chart showing the number of reports by minutes with categories for previous history of allergic reaction and no previous history of allergic reaction.]
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)
Vaccine Allocation Plan Summary

**Phase 1**
- **Phase 1a (~110,000)**
  - High-risk health workers
  - First responders
  - Residents and staff of long-term care and assisted living facilities
- **Phase 1b (~225,000)**
  - People ≥75 years old
  - Medically vulnerable at *significantly* higher risk 2 or more conditions (see list)
    - Family caregivers of those medically vulnerable persons, <16 years old, not eligible for vaccine
  - Residents and staff of residential facilities for persons with intellectual and developmental disabilities
  - Corrections officers and staff working in correctional facilities
  - First responders and health workers not already vaccinated

**Phase 2**
- **Phase 2a (~175,000)**
  - People 65 - 74 years old
  - K-12 school and childcare staff
- **Phase 2b (~200,000)**
  - People 50 - 64 years old

**Phase 3**
- **Phase 3a (~325,000)**
  - Medically vulnerable <50 years old at *moderately* higher risk with 1 or more conditions (see list)
- **Phase 3b (~325,000)**
  - Everyone else not already vaccinated

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***Estimated timeframe depends on vaccine doses allocated to New Hampshire from the federal government and vaccine uptake***

Equity is a crosscutting consideration: Vaccine access will be prioritized for geographic areas identified through the COVID-19 Community Vulnerability Index (CCVI).

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.

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 Predictive 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)
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)
Asymptomatic Testing (N=871)

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<thead>
<tr>
<th>Antigen Test Result</th>
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- **Sensitivity**: 41.2% (Out of 17 positive PCR tests, 7 were also positive by antigen testing)
  - Antigen testing missed 10 infections (58.8%)
Asymptomatic Testing (N=871)

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- **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%)
### Asymptomatic Testing (N=871)

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- **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
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<td>17</td>
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- **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

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- **Sensitivity**: 41.2%
- **Specificity**: 98.4%
- **PPV**: 33.3%
- **NPV**: 98.8%
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.”
Symptomatic Testing (N=227)

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<tr>
<td>Positive</td>
<td>Positive</td>
<td>32</td>
<td>2</td>
<td>34</td>
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<tr>
<td></td>
<td>Negative</td>
<td></td>
<td>185</td>
<td>193</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>40</td>
<td>187</td>
<td>227</td>
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- **Sensitivity**: 80.0% (Out of 40 positive PCR tests, 32 were also positive by antigen testing)
  - Antigen testing missed 8 infections (20.0%)
## Symptomatic Testing (N=227)

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- **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%)
Symptomatic Testing (N=227)

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- 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)

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- **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
Symptomatic Testing (N=227)

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

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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.

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)

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

January 7, 2021

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