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

January 14, 2021

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

• Epidemiology Update

• NH HAN #33

• **NEJM Publication**: Interim Results of Phase 1-2a Trial of Ad26.COV2.S Covid-19 Vaccine (Johnson & Johnson)

• Questions & Answers (Q&A)
National Daily Incidence of COVID-19
Number of New COVID-19 Cases per Day in NH

Number of Daily New Cases

Date

Mar 1, 20  May 1, 20  Jul 1, 20  Sep 1, 20  Nov 1, 20  Jan 1, 21

Stay at Home 1.0  Safer at Home

https://www.nh.gov/covid19/dashboard/overview.htm#dash
% of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)
In the last 7 days:

- 70 people have died (average: 10 people/day)
- 16 (23%) are NOT associated with a LTCF
- 54 (77%) associated with a LTCF
Removing quarantine requirement for people 14 days beyond their second dose of the COVID-19 vaccine (i.e., fully vaccinated), and people who are within 90 days of previously testing positive for COVID-19 (antigen or PCR test)

We continue to recommend against all non-essential travel (this is not a free-pass to travel)

Everybody needs to continue to follow all mitigation guidance (social distancing, avoiding group/social gatherings, wear face masks)

People with any new or unexplained symptoms of COVID-19 still need to isolate and seek out testing (even if previously vaccinated or infected)
• NH DPHS quarantine guidance for people who are fully vaccinated or previously infected with SARS-CoV-2 has been updated (Quarantine Guide). This guidance applies to the general public, businesses, schools, and healthcare facilities, including long-term care facilities (LTCFs) and assisted living facilities (ALFs). The following people do NOT need to quarantine after an unprotected exposure to a person with COVID-19, or after travel outside of New England:
  
  o A person who is 14 days beyond the second dose of their COVID-19 vaccine (i.e., 14 days after full vaccination).
  
  o A person who is within 90 days of a prior SARS-CoV-2 infection diagnosed by PCR or antigen testing.
    
    ➢ People with prior infection should be vaccinated to provide the highest level of protection against COVID-19.

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

• NH DPHS and CDC continue to discourage any non-essential travel, even for people fully vaccinated or previously infected because protection is not 100%, durability of immunity is still unknown, and there are new circulating strains of SARS-CoV-2 in other states and countries that are being investigated.
  
  o See NH DPHS travel guidance.
  
  o See CDC travel guidance.

• It remains possible that people who are fully vaccinated or previously infected could still acquire asymptomatic SARS-CoV-2 infection, or attenuated (milder) COVID-19. Therefore, even people who are fully vaccinated or previously infected need to continue to practice physical distancing, avoid social groups and gatherings, and wear face masks at all times when in public places and facilities. Healthcare providers should continue to follow all recommended infection control and personal protective equipment (PPE) guidance.
Johnson & Johnson’s Ad26.COV2.S Vaccine

- Adenovirus serotype 26 (Ad26) vector – recombinant, replication-incompetent 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)
- October 12th: paused for adverse event
- October 23rd: resumed recruitment
- December 17th: Fully enrolled phase 3 trial with ~45,000 participants (ENSEMBLE study)
  - November 15th: Initiated a 2-dose regimen phase 3 trial (ENSEMBLE 2 study) in parallel – two doses scheduled 8 weeks apart
- Preliminary results from the ENSEMBLE study are expected end of January

Interim Results of a Phase 1–2a Trial of Ad26.COV2.S Covid-19 Vaccine

- Cohort 1: participants age 18-55
- Cohort 3: participants age 65 years and older
- Given 1-dose or 2-doses (separated by 8 weeks)
- 5 vaccination groups:
  - Low-dose/Low-dose
  - Low-dose/Placebo
  - High-dose/High-dose
  - High-dose/Placebo
  - Placebo/Placebo

A. Solicited Adverse Events in Cohort 1

Systemic Symptom
- Any
- Fatigue
- Headache
- Myalgia
- Nausea
- Pyrexia

Grade 1  | Grade 2  | Grade 3  
---|---|---
Low dose | High dose | Placebo

Participants with Reaction (%)

B. Solicited Adverse Events in Cohort 3

Systemic Symptom
- Any
- Fatigue
- Headache
- Myalgia
- Nausea
- Pyrexia

Grade 1  | Grade 2  | Grade 3  
---|---|---
Low dose | High dose | Placebo

Participants with Reaction (%)
Level of antibody response (higher is better)

Upper limit of assay quantitation

Lower limit of assay quantitation

Day of antibody measurement

Treatment group; arrow indicates day dose was given

# in each group

Geometric Mean Concentration

% “seropositive” (titer above lower limit of quantitation)

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<tr>
<th>No. at Risk</th>
<th>Placebo/Placebo</th>
<th>Low Dose/Placebo</th>
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<tbody>
<tr>
<td></td>
<td>Day 1</td>
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• During 71 days of follow-up, antibody titers further increased and stabilized
• A 2\textsuperscript{nd} dose at day 57 (Cohort 1) further increased the antibody titer
• In elderly persons, the immune response after the first dose was modestly lower than in younger participants
Summary of Phase 1/2a Vaccine Trial

- Similar side effects compared to the COVID-19 mRNA vaccines
  - A higher percentage of younger participants had side effects
  - 60-80% of cohort 1 had systemic side effects (fatigue, headache, myalgia)
    - 15-40% of cohort 1 reported fever
  - 60-80% of cohort 1 had local side effects (primarily pain at injection site)
- A single dose led to almost 100% seroconversion with increasing and stabilizing titers up to day 71 after vaccination
- Unclear whether the elderly may benefit from a second dose (given lower antibody levels)
- Will need to wait for Phase 3 trial data to assess clinical efficacy at prevention of COVID-19 (possibly by the end of January or beginning of February) – studying both 1 and 2 doses of vaccine
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