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

March 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
- NH <u>COVID-19 HAN #36</u>: Janssen vaccine and CDC updates to vaccine contraindications and precautions
- Questions & Answers (Q&A)

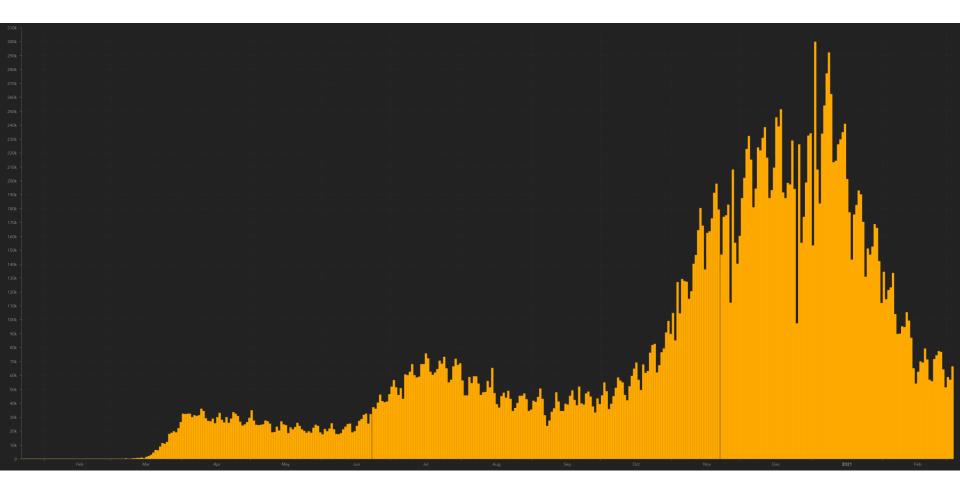


## **Key Clinical Resources Update**

- CDC <u>clinician webinar</u>: What Clinicians Need to Know About the Janssen COVID-19 vaccine
- CDC updated their <u>Interim Clinical Considerations for Use</u> of <u>COVID-19 Vaccines</u>
- NH DPHS updated the <u>COVID-19 Vaccine FAQs for</u> <u>Healthcare Providers and Public Health Partners</u>
- NH DPHS <u>Thursday Partner Call PPT slides</u> (2/25/21) for more details on Janssen COVID-19 vaccine study data



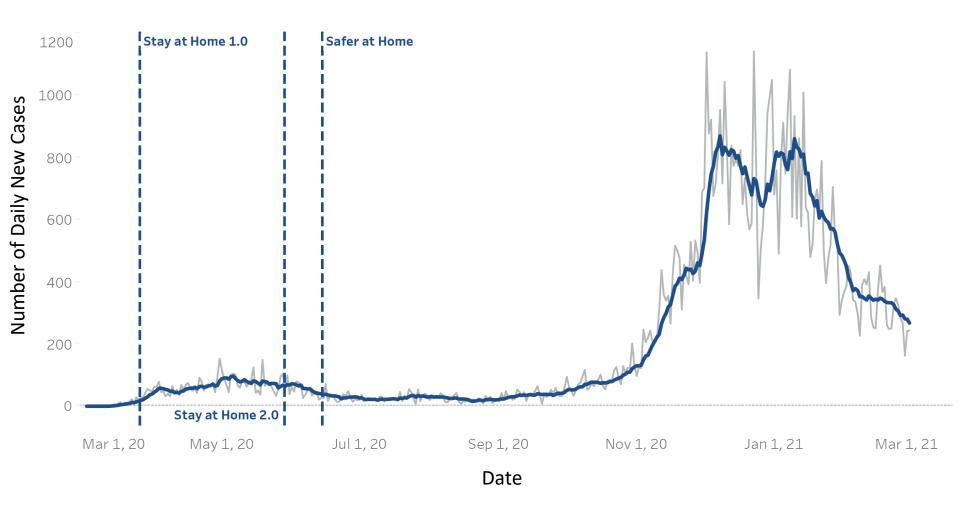
## National Daily Incidence of COVID-19



- More than 28.7 million cumulative cases in the U.S. (25% of all global infections)
- More than 518,000 deaths in the U.S. from COVID-19 (20% of all global deaths)

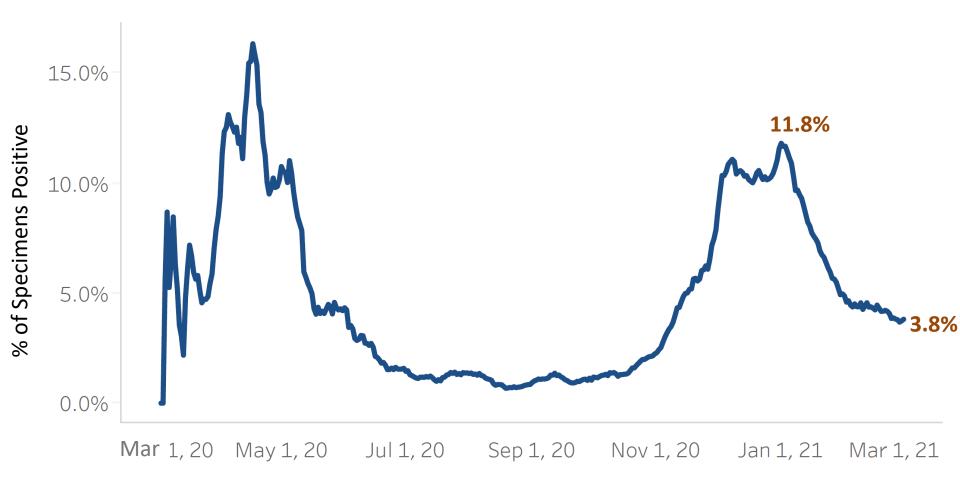


## Number of New COVID-19 Cases per Day in NH





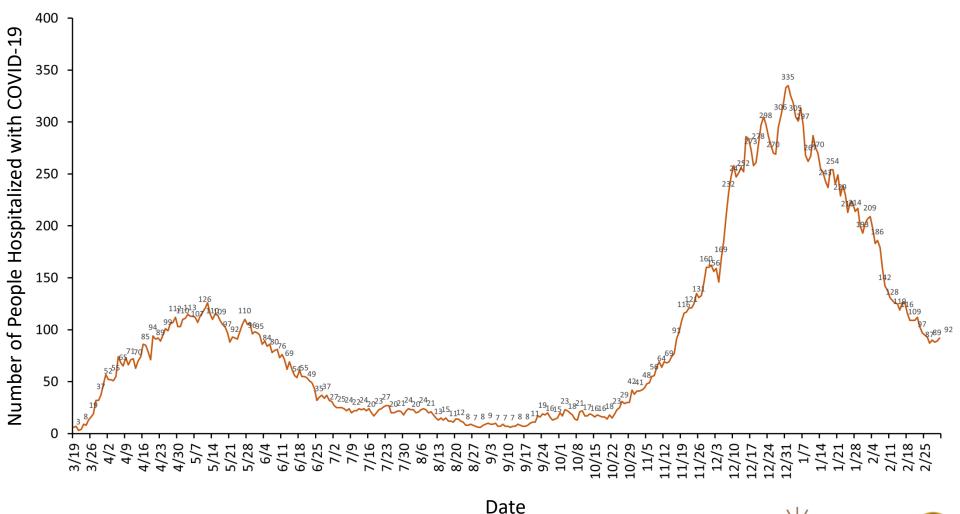
## % of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



**Date Laboratory Test Completed** 

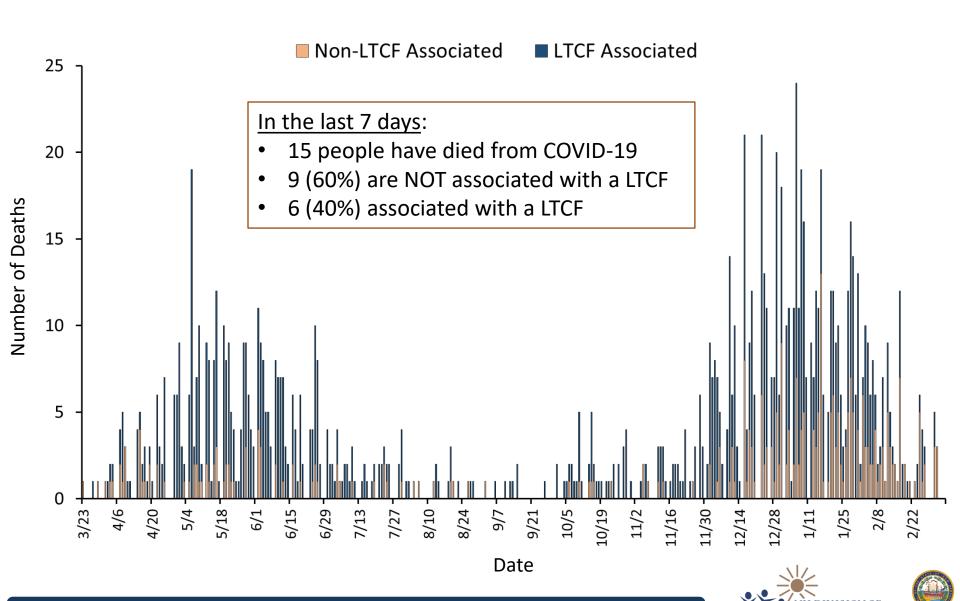


# Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)





## Number of COVID-19 Deaths in NH by Report Date

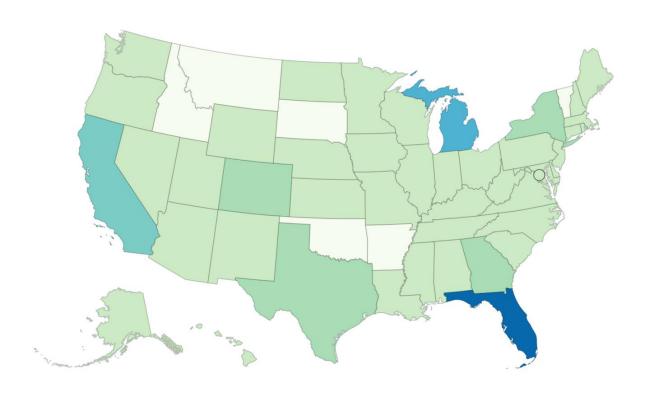


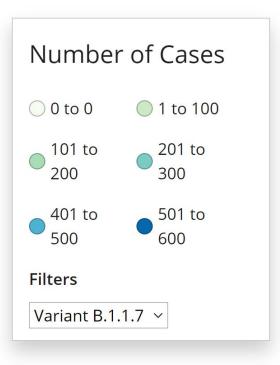
## Variants of Concern (Current as of 3/2/21)

Variant	Reported Cases in US	Number of Jurisdictions Reporting
B.1.1.7	2506	46
B.1.351	65	17
P.1	10	5



## Variant B.1.1.7



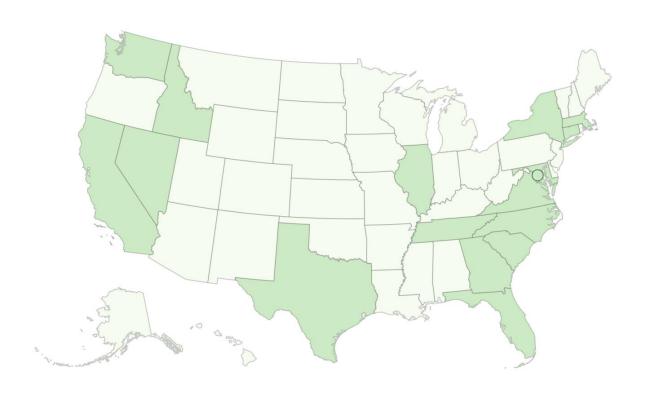


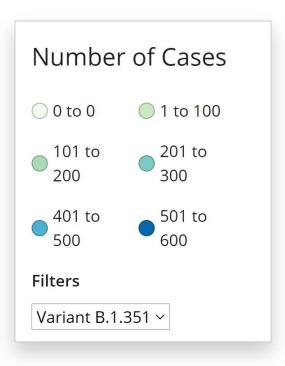
Territories AS GU MH FM MP PW PR VI





## Variant B.1.351



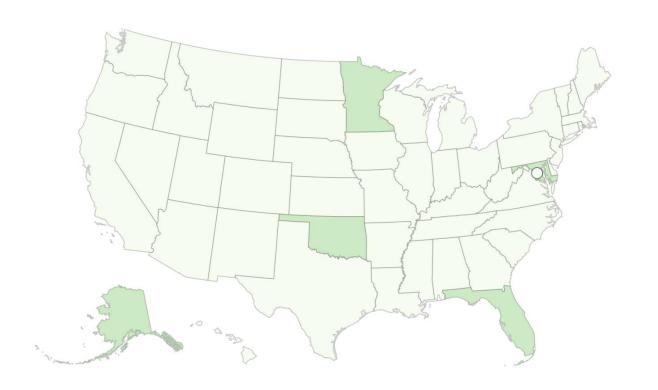


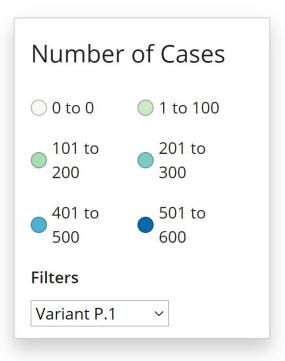
Territories AS GU MH FM MP PW PR VI





## Variant P.1





Territories AS GU MH FM MP PW PR VI





# Janssen COVID-19 Vaccine CDC's Updated Clinical Guidance on Use of COVID-19 Vaccines



## Janssen COVID-19 Vaccine: Overview

- Adenovirus vector vaccine that uses an inactivated ("replication-incompetent") adenovirus serotype 26 virus modified to carry the genetic code to our muscle cells to produce and express the SARS-CoV-2 spike protein that stimulates an immune response
- Single dose vaccine, stored at refrigerator temperatures
- This type of vaccine has been used in other vaccines that have been studied, including the Ebola vaccine (we have experience and safety and efficacy data from other vaccine studies)
- Common local and systemic side effects are similar to those seen with the Pfizer-BioNTech and Moderna vaccine
- No safety concerns identified, and the rate of serious adverse events was rare and the same between vaccine and placebo groups in the Janssen vaccine trial (about 0.4%)



## COVID-19 Vaccines: Key Messages

- Three currently authorized COVID-19 vaccines for use
- The CDC and ACIP do NOT express a preference for one vaccine over another
- All three COVID-19 vaccines currently authorized for use are effective at preventing disease, and have very high efficacy at preventing severe disease, hospitalizations, and deaths
- It is important for people to be vaccinated quickly and take the first available vaccine offered rather than wait for a specific formulation or manufacturer
- CDC has updated their guidance on COVID-19 vaccine contraindications and precautions for all COVID-19 vaccines



	Pfizer-BioNTech	Moderna	Janssen
Type of Vaccine	Modified mRNA	Modified mRNA	Adenovirus vector
Dosing	2-dose series Doses separated by 21 days	2-dose series Doses separated by 28 days	1-dose series
Overall Vaccine Efficacy (VE)	<b>95%</b> <sup>1,2</sup>	<b>94%</b> <sup>3,4</sup>	66% <sup>5</sup> ( <b>72%</b> in U.S. Population)
VE at Preventing Severe Disease	75% <sup>1,2</sup> (1 case vs. 4 cases) 92% <sup>6</sup>	100% <sup>3,4</sup> (0 cases vs. 30 cases)	<b>85%</b> <sup>5</sup> (5 cases vs. 34 cases)
VE at Preventing Hospitalization	87% <sup>6</sup>	limited numbers prevented calculation <sup>3,4</sup>	<b>100%</b> <sup>5</sup> (0 cases vs. 16 cases)
VE at Preventing Death	<b>84%</b> <sup>6</sup> Estimate at 21-27 days after 1 <sup>st</sup> dose; no data for efficacy following 2 doses	limited numbers prevented calculation <sup>3,4</sup>	100% <sup>5</sup> (0 deaths vs. 7 deaths)
Age Group Authorized to Receive Vaccine	16 years of age and older	18 years of age and older	18 years of age and older
Vaccine Ingredients	Messenger RNA (mRNA)     Lipids:         ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)         2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide         1,2-distearoyl-sn-glycero-3-phosphocholine         Cholesterol         Potassium chloride         Monobasic potassium phosphate         Sodium chloride         Dibasic sodium phosphate dihydrate         Sucrose	Messenger RNA (mRNA)     Lipids:         SM-102 (proprietary to Moderna)         Polyethylene glycol [PEG] 2000         dimyristoyl glycerol [DMG]         1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]         Cholesterol     Tromethamine     Tromethamine hydrochloride     Acetic acid     Sodium acetate     Sucrose	<ul> <li>Replication-incompetent adenovirus particles</li> <li>Citric acid monohydrate</li> <li>Trisodium citrate dihydrate</li> <li>Ethanol</li> <li>2-hydroxypropyl-β-cyclodextrin (HBCD)</li> <li>Polysorbate-80</li> <li>Sodium chloride</li> <li>Note: each dose may also contain residual amounts of cell proteins and/or DNA from cells that were used to grow the adenovirus vector (PER.C6 TetR cells)</li> </ul>

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Vaccine Ingredients	observational study in a natural vaccination setting  o 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide o 1,2-distearoyl-sn-glycero-3-phosphocholine o Cholesterol Potassium chloride Monobasic potassium phosphate Sodium chloride Dibasic sodium phosphate dihydrate Sucrose	ationwide  A (mRNA)  prietary to Moderna) glycol [PEG] 2000  dimyristoyl glycerol [DMG]  o 1,2-distearoyl-sn-glycero-3- phosphocholine [DSPC] o Cholesterol  Tromethamine Tromethamine hydrochloride Acetic acid Sodium acetate Sucrose	<ul> <li>Replication-incompetent adenovirus particles</li> <li>Citric acid monohydrate</li> <li>Trisodium citrate dihydrate</li> <li>Ethanol</li> <li>2-hydroxypropyl-β-cyclodextrin (HBCD)</li> <li>Polysorbate-80</li> <li>Sodium chloride</li> <li>Note: each dose may also contain residual amounts of cell proteins and/or DNA from cells that were used to grow the adenovirus vector (PER.C6 TetR cells)</li> </ul>

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## **Updated Contraindications and Precautions**

### Appendix B: Triage of people presenting for COVID-19 vaccination

#### CONTRAINDICATION TO VACCINATION

#### History of the following:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†
- Immediate allergic reaction\* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†

#### PRECAUTION TO VACCINATION

## Among people without a contraindication, a history of:

 Any immediate allergic reaction\* to other vaccines or injectable therapies‡

Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#

#### MAY PROCEED WITH VACCINATION

## Among people without a contraindication or precaution, a history of:

- 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:

- Do not vaccinate.
- Consider referral to allergistimmunologist.
- Consider other vaccine alternative.†

#### Actions:

- Risk assessment
- Consider referral to allergistimmunologist
- 30-minute observation period if vaccinated

#### Actions:

- 30-minute observation period: people with history of anaphylaxis (due to any cause)
- 15-minute observation period: all other people



## **COVID-19 Vaccine Contraindications**

- Don't administer a COVID-19 vaccine to a person with a history of:
  - A <u>severe</u> allergic reaction (e.g., anaphylaxis) after a previous dose of the COVID-19 vaccine or a component of the vaccine
  - An <u>immediate</u> allergic reaction\* of any severity after a previous dose of the COVID-19 vaccine or to a component of the vaccine (known/diagnosed allergy to a component)



### **COVID-19 Vaccine Precautions**

- Vaccination can occur, but there should be additional precautions taken if the person has a history of:
  - Any <u>immediate</u> allergic reaction\* to other vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), which does not meet criteria as a contraindication
- People with a "precaution" should be informed about the unknown risks of developing a severe allergic reaction to the COVID-19 vaccine, have a risk assessment performed by a provider, and discuss the potential risks/benefits of vaccination with their provider



## "Immediate Allergic Reactions"

- CDC defines an "immediate allergic reaction" as any
  hypersensitivity related signs or symptoms consistent with
  urticaria, angioedema, respiratory distress, or anaphylaxis that
  occurs within four hours following administration
- <u>Allergic</u> reactions after vaccination should be differentiated from <u>non-allergic</u> reactions such as vasovagal episodes and normal vaccine side effects; CDC has created a table (<u>Appendix D</u>) to assist providers



## Additional Clarifications on Vaccine Contraindications and Precautions

- A person with a contraindication to one mRNA COVID-19 vaccine should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna)
- A person with a history of an allergic reaction to a non-COVID vaccine or injectable therapy that contains multiple components, one of which is a component of a COVID-19 vaccine (such as polyethylene glycol or polysorbate) but in whom it is unknown which component caused the allergic reaction, is considered to have a <u>precaution</u> to COVID-19 vaccination; such persons can still receive an available COVID-19 vaccine with appropriate counseling and post-vaccination monitoring (30 minutes of observation)



## Additional Clarifications on Vaccine Contraindications and Precautions

- Persons with a contraindication to an mRNA vaccine, including a known/diagnosed allergy to polyethylene glycol (PEG) which is a component of both mRNA vaccines, have a precaution to receiving the Janssen vaccine the Janssen vaccine may be given, but referral to an allergist-immunologist should be considered
- Persons with a contraindication to the Janssen vaccine, including a known/diagnosed allergy to polysorbate which is a component of the Janssen vaccine, have a <u>precaution</u> to receiving one of the mRNA vaccines – an mRNA vaccine may be given, but referral to an allergist-immunologist should be considered



## Vaccines are NOT Interchangeable

- A person that starts a 2-dose series with one mRNA vaccine (Pfizer-BioNTech or Moderna), must complete the series with the same COVID-19 vaccine manufacturer
- However, a person who has received one dose of an mRNA vaccine but has an allergic reaction which prevents that person from receiving the second dose of the mRNA vaccine (i.e., vaccine contraindication) may be given the single-dose Janssen vaccine after at least 28 days have passed from receipt of the mRNA vaccine in order to be considered fully vaccinated against COVID-19 (with appropriate assessment, counselling, and precautions)



#### THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

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Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 36

Janssen COVID-19 Vaccine Receives FDA EUA

CDC Updates COVID-19 Vaccine Clinical Recommendations

Updated Vaccine Contraindications and Precautions

#### **Key Points and Recommendations:**

The U.S. Food and Drug Administration (FDA) has issued an <u>Emergency Use Authorization</u> (EUA) for use of the Janssen COVID-19 vaccine as a <u>single dose</u> in persons 18 years of age and older.



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