

## New Hampshire Coronavirus Disease 2019 Weekly Partner Call

September 30, 2021

Ben Chan Elizabeth Talbot Beth Daly Lindsay Pierce

Thursday noon-time partner calls will focus on science, medical, and vaccine updates with time for Q&A



#### Healthcare Provider & Public Health Partner Calls

- 2<sup>nd</sup> and 4<sup>th</sup> Thursday of each month from 12:00-1:00 pm (next call will be Thursday, October 14<sup>th</sup>)
- Webinar/call information:
  - Zoom link: <a href="https://nh-dhhs.zoom.us/s/94059287404">https://nh-dhhs.zoom.us/s/94059287404</a>
  - Webinar ID: 940 5928 7404
  - Passcode: 353809
  - Telephone: 646-558-8656



## Agenda

- Epidemiology update
- COVID-19 vaccine updates and forecasting (boosters, heterologous dosing, vaccines for children)
- CDC HAN: COVID-19 Vaccination for Pregnant People
- Questions & Answers (Q&A)

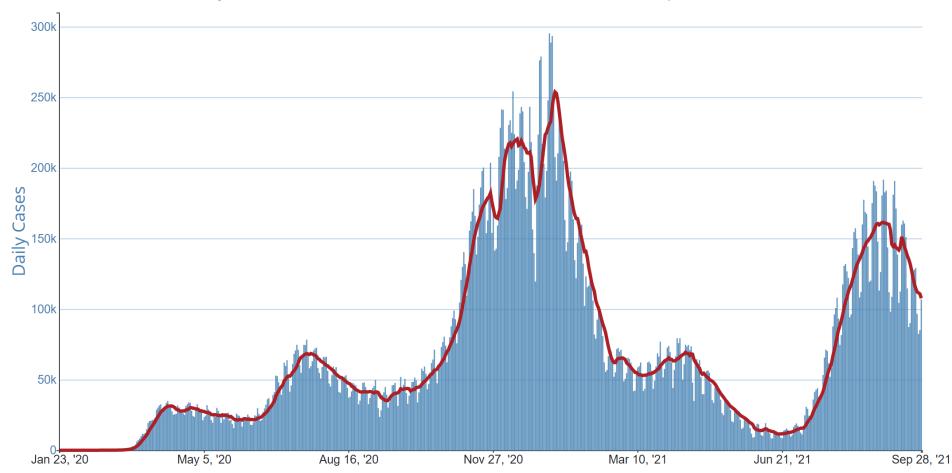


## **Epidemiology Update**



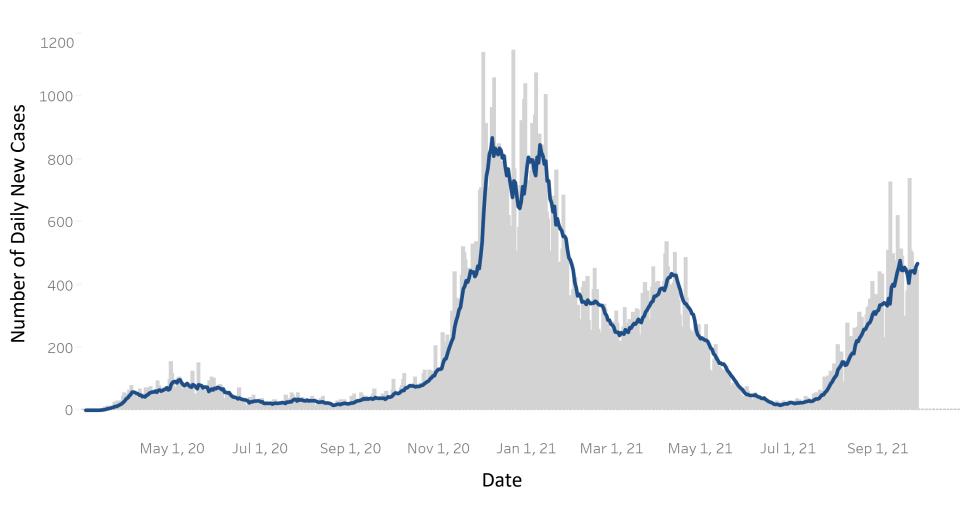
## U.S. National Daily Incidence of COVID-19

Daily Trends in Number of COVID-19 Cases in The United States Reported to CDC



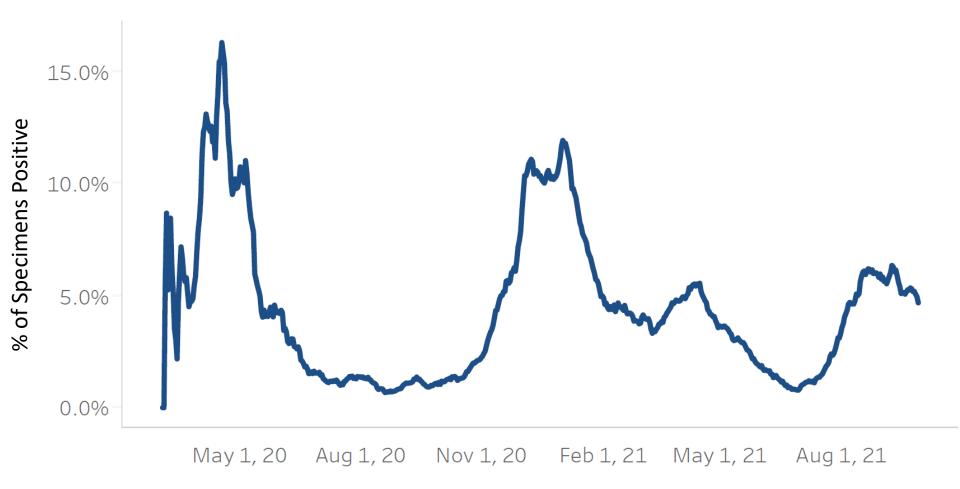


## Number of New COVID-19 Cases per Day in NH





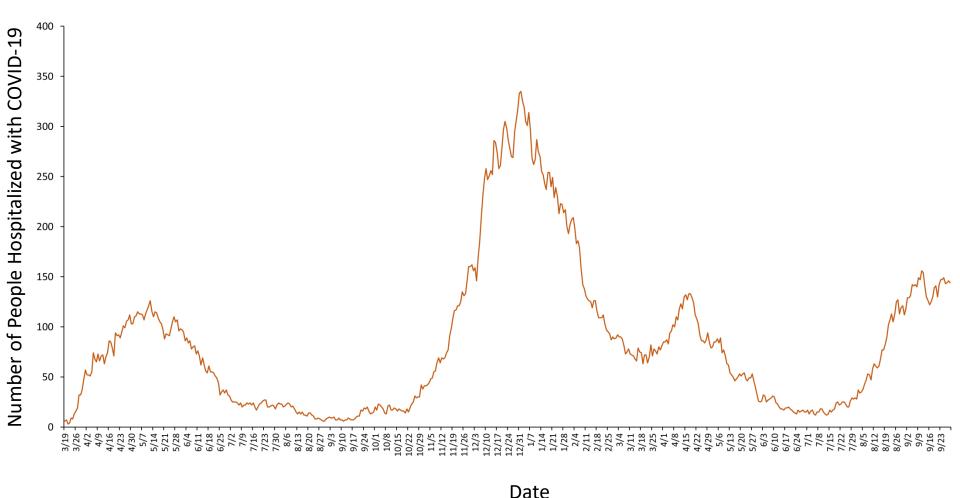
# % of Tests (Antigen and PCR) Positive for COVID-19 (7-Day Average)



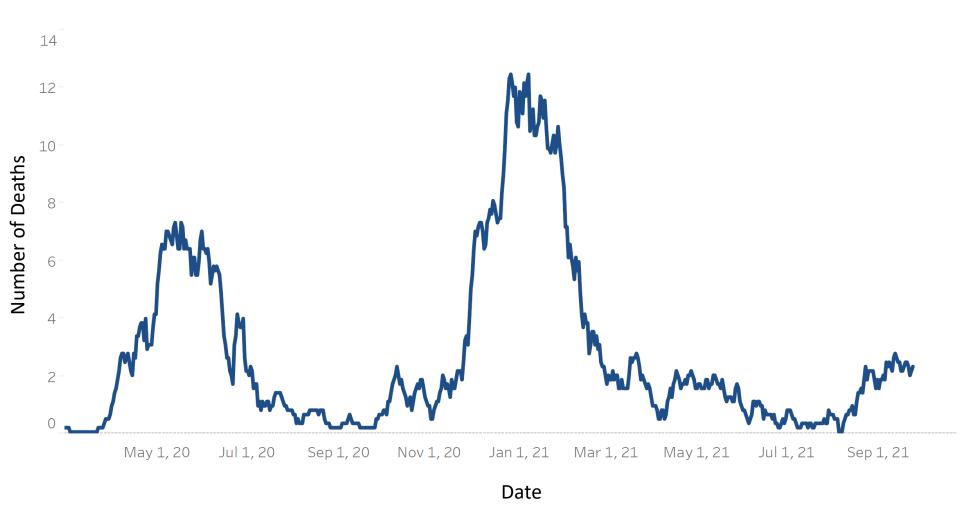
**Date Laboratory Test Completed** 



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



# Average Number of COVID-19 Deaths per Day in NH (Based on Date of Death)



# **COVID-19 Vaccine Updates**



Distributed by the NH Health Alert Network <a href="mailto:DHHS.Health.Alert@dhhs.nh.gov">DHHS.Health.Alert@dhhs.nh.gov</a>
September 24, 2021 Time 1730 (5:30 PM EDT) NH-HAN 20210924



## COVID-19 Pandemic, Update # 46 Pfizer-BioNTech COVID-19 Vaccine Booster Dose Recommendations

- On September 22<sup>nd</sup>, the U.S. Food and Drug Administration (FDA) <u>authorized</u> the Pfizer-BioNTech COVID-19 vaccine ("Pfizer vaccine") for use as a booster dose for certain people who have undergone their primary vaccination series with the Pfizer vaccine
- On September 24<sup>th</sup>, the U.S. Centers for Disease Control and Prevention (CDC) <u>recommended</u> the following for Pfizer vaccine booster doses:
  - People 65 years and older and residents in long-term care settings <u>should</u> receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completion of their Pfizer-BioNTech primary series (*formal recommendation for a booster*)
  - People aged 50–64 years with <u>underlying medical conditions</u> <u>should</u> receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completion of their Pfizer-BioNTech primary series (*formal recommendation for a booster*)
  - People aged 18–49 years with <u>underlying medical conditions</u> <u>may</u> receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completion of their Pfizer-BioNTech primary series, based on their individual benefits and risks (*permissive* recommendation based on an individual's own assessment of their risks and benefits)
  - 4. People aged 18-64 years who are at increased risk for COVID-19 exposure and transmission because of occupational or institutional setting <u>may</u> receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completion of their Pfizer-BioNTech primary series, based on their individual benefits and risks (*permissive recommendation* based on an individual's own assessment of their risks and benefits)



## CDC Framing and Messaging

#### Recommendation – Part 1

CDC recommends that the following groups **should** receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer-BioNTech primary vaccine series:

- People aged 65 years and older
- Residents aged 18 years and older in long-term care settings
- People aged 50–64 years with <u>underlying medical conditions</u>



https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html



## CDC Framing and Messaging

#### Recommendation – Part 2

CDC recommends that a booster dose of Pfizer-BioNTech's COVID-19 vaccine **should be made available** so that the following groups **may** receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer-BioNTech primary vaccine series, based on their **individual benefits and risks**:

- People aged 18–49 years with <u>underlying medical conditions</u>
- People aged 18–64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting



https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html



#### Additional Recommendations & Clarifications

- CDC has updated their <u>Interim Clinical Considerations for Use of COVID-19 Vaccines</u> with a new section: <u>Considerations for use of a Pfizer-BioNTech COVID-19 vaccine booster dose</u>
- A Pfizer vaccine booster is ONLY authorized and recommended for people who are at least 6 months beyond completion of a 2-dose primary series with the Pfizer vaccine
- Booster doses are not yet recommended for people who received the 2-dose Moderna series, or the 1-dose J&J Janssen vaccine
- A person is still "fully vaccinated" when they are 14+ days beyond receipt of the 2<sup>nd</sup> dose of the Pfizer or Moderna vaccines, or 14+ days beyond receipt of the singe dose J&J Janssen vaccine



## Remaining Questions and Issues

- When will booster doses be authorized and recommended for people who received the Moderna or J&J Janssen vaccine?
- Can different vaccine products be mixed (heterologous dosing)?
- When will vaccination be available to younger children?



### Moderna Vaccine Booster

- Moderna <u>announced</u> (September 1<sup>st</sup>) they had submitted data to FDA on use of the Moderna vaccine as a booster
- Reported findings:
  - Neutralizing antibody titers decreased at approximately 6 months (note: declining neutralizing antibody titers does not necessarily mean declining vaccine efficacy)
  - A booster dose increased neutralizing antibody titers "significantly above the Phase 3 benchmark" including for VOC
  - Safety profile after 3 doses was similar to that observed after 2 doses
- Moderna boosters could possibly be authorized/recommended by the end of October



### J&J Janssen Vaccine Booster

- Johnson & Johnson (J&J) <u>announced</u> (September 21<sup>st</sup>) findings/data from ongoing 1-dose and 2-dose studies:
  - A single shot provides "strong and long-lasting protection"
  - There was no evidence of reduced VE over the study duration, including when the Delta variant became dominant
  - Preliminary data on a "booster shot" administered either 2 months or 6 months after the first dose:
    - 2 month booster: antibody levels increased 4-6x higher than after a single shot; increased protection against symptomatic disease (94% protection in the U.S. study population), and against severe/critical COVID-19 (100% protection)
    - 6 month booster: antibody levels increased 9-12 fold higher than after a single shot
- Unclear when data will be published and/or submitted to FDA



## Heterologous (Mixed Vaccine) Dosing

- Data from other countries (e.g., UK) have shown potential benefit of heterologous dosing using AstraZeneca and Pfizer-BioNTech vaccines
- NIH is also conducting a clinical trial evaluating heterologous booster dosing in the U.S.
- FDA and CDC/ACIP could weigh in on heterologous dosing by the end of October



## Fauci says data from NIH's mix-andmatch Covid vaccine booster trials will soon be ready

PUBLISHED TUE, SEP 28 2021-3:04 PM EDT | UPDATED TUE, SEP 28 2021-8:33 PM EDT













#### KEY POINTS

- The National Institutes of Health is on the verge of concluding trials that mix initial vaccine doses from one manufacturer with booster shots from another manufacturer, Dr. Anthony Fauci said.
- Data on J&J's mix-and-match study could be ready within a week, while Pfizer's trial might be completed by mid-October, he said. Moderna's mix-and-match study data is already available.
- Though the CDC authorized Pfizer's booster for seniors and the medically vulnerable Friday, only recipients of Pfizer's first two doses are eligible for the third shot.



#### Pfizer-BioNTech Vaccine for 5-11 Year Olds

- Pfizer-BioNTech <u>announced</u> (September 28<sup>th</sup>) they have submitted data to the FDA on use of their vaccine in children 5-11 years old
- A formal submission to request EUA in this age group is expected "in the coming weeks"
- A summary of findings from 2,268 participants aged 5-11 years old administered a 2-dose series (10 mcg/dose) 21 days apart was announced (September 20<sup>th</sup>):
  - Vaccine was safe and well tolerated with the normal expected side effects observed (i.e., no safety concerns identified)
  - Antibody response was comparable to the response seen in older adolescents and adults
- Pfizer-BioNTech COVID-19 vaccine could be authorized/recommended for children 5-11 years of age by the end of October



## Summary

- Lots of changes possibly coming in the next several weeks including:
  - Booster doses for people who got their primary series with Moderna (and J&J Janssen vaccine?)
  - Heterologous dosing
  - COVID-19 vaccine availability for 5-11 year olds
  - Continued roll-out of Pfizer-BioNTech booster doses priority is still vaccinating the unvaccinated and giving boosters to highrisk groups, such as those 65 years of age and older
- All of this is dependent on data submission, and FDA and CDC/ACIP review



#### This is an official

#### **CDC HEALTH ADVISORY**

Distributed via the CDC Health Alert Network September 29, 2021, 12:00 PM ET CDCHAN-00453

## COVID-19 Vaccination for Pregnant People to Prevent Serious Illness, Deaths, and Adverse Pregnancy Outcomes from COVID-19

- 97% of pregnant persons hospitalized with COVID-19 are unvaccinated
- In the U.S., more than 125,000 infections in pregnant people have been reported, including more than 22,000 hospitalizations and 161 deaths
- Pregnant and recently pregnant women are at an increased risk for severe COVID-19, including hospitalization and death
- COVID-19 also increases the risk of adverse pregnancy outcomes, including preterm birth, NICU admission, and possibly stillbirth, pre-eclampsia, etc.
- Despite this increased risk, only ~31% of pregnant people are fully vaccinated before or during their pregnancy



### **CDC** Recommendations

- COVID-19 vaccines are safe and effective in pregnancy
- Providers should "strongly recommend" that people who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant, or who might become pregnant in the future get vaccinated
- These vaccine recommendations are consistent with <u>ACOG's</u>
   <u>Practice Advisory</u> and <u>SMFM guidance</u>
- Review CDC's HAN for more details and recommendations



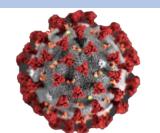
# Q&A



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