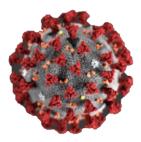
New Hampshire COVID-19 Healthcare Provider and Public Health Partner Call

February 10, 2022





NH COVID-19 HAN, Update #55



THIS IS AN OFFICIAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network <u>DHHS.Health.Alert@dhhs.nh.gov</u> February 3, 2022 Time 1700 (5:00 PM EDT) NH-HAN 20220203



COVID-19 Pandemic, Update # 55 Changes to COVID-19 Reporting and Surveillance

Key Points and Recommendations:

- Due to the increasing use of at-home COVID-19 tests and increased burden on providers of reporting individual infections during this Omicron surge, the NH Division of Public Health Services (DPHS) will track COVID-19 case incidence based on reports from 1) automated electronic laboratory test reporting; and 2) provider-collected point-of-care (POC) tests.
 - Providers, schools, childcare programs, etc. should stop reporting individual at-home tests (except when including persons with COVID-19 in a school's weekly aggregate report, as discussed below).
 - Providers and testing locations that hold a CLIA certificate are still required to report all COVID-19 test results (both positive and negative) under <u>CLIA regulations</u> and the federal <u>CARES Act</u>.
 - Provider-collected POC SARS-CoV-2 tests (e.g., antigen tests) should be reported as outlined in the NH DPHS <u>COVID-19 Rapid/POC Test Reporting Guidance</u>.
- Clinical details for new COVID-19-related hospitalizations and deaths should still be reported to DPHS using the <u>COVID-19 Case Report Form</u>.



School Weekly Aggregate Reporting Link is Now Live (for Data Entry Beginning 2/11)

COVID-19 School Dashboard

Guidance and Recommendations

<u>Responding to COVID-19 in K-12 Schools and Child Care Facilities</u> (February 7, 2022)

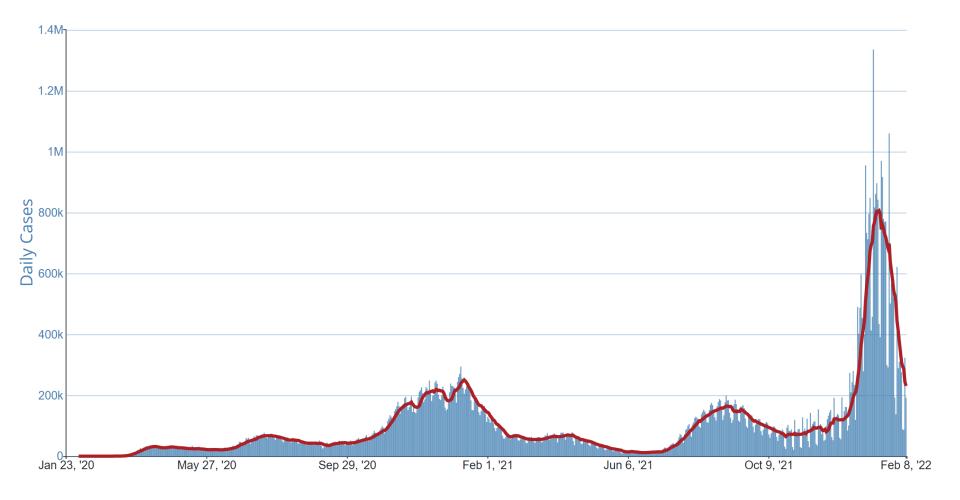
Weekly Aggregate Reporting Form for K-12 Schools and Colleges/Universities
Providers and testing locations that hold a CLIA certificate are still required to report all COVID-19 test results (both positive and negative) under
CLIA regulations and the federal CARES Act a. This means that in addition to weekly aggregate reporting, schools that conduct their own
COVID-19 testing under a CLIA certificate are still required to report all test results (see NH's COVID-19 Rapid/Point of Care Test Reporting
Guidance for healthcare providers).



Epidemiology Update



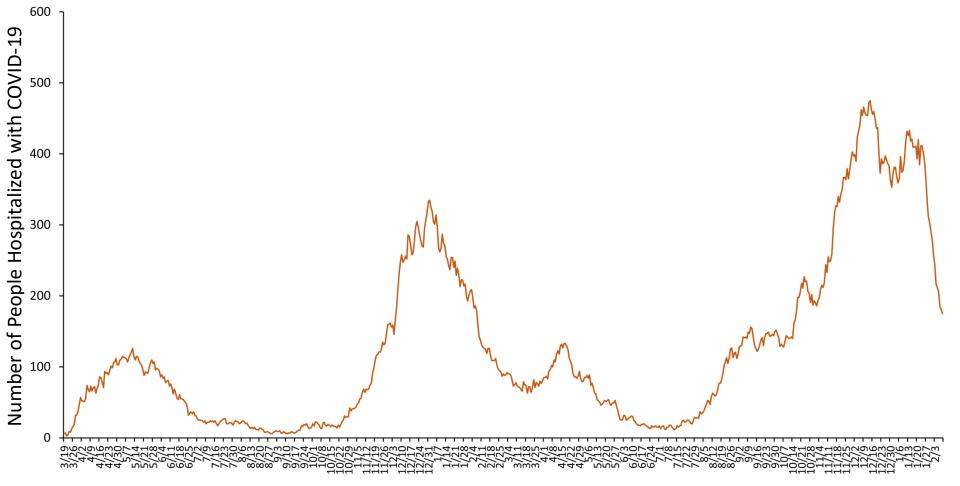
U.S. National Daily Incidence of COVID-19





https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

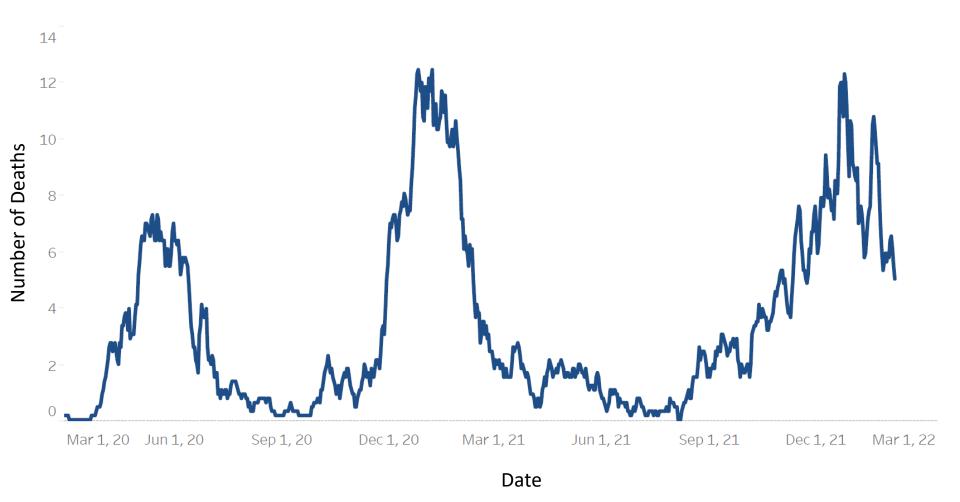
Number of People Hospitalized with COVID-19 Each Day in NH (Hospital Census)



Date



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





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

COVID-19 Vaccine for Children 6 Months Through 4 Years of Age





Pfizer and BioNTech Provide Update on Ongoing Studies of COVID-19 Vaccine

Friday, December 17, 2021 - 08:05am

While the study is ongoing and remains blinded, a pre-specified immunogenicity analysis was conducted on a subset of the study population one month following the second dose. Compared to the 16- to 25-year-old population in which high efficacy was demonstrated, non-inferiority was met for the 6- to 24-month-old population but not for the 2- to under 5-year-old population in this analysis. No safety concerns were identified and the 3 µg dose demonstrated a favorable safety profile in children 6 months to under 5 years of age.

Clinical study was amended to include evaluating a third dose administered at least two months after the second dose to provide high levels of protection



Pfizer and BioNTech Initiate Rolling Submission for Emergency Use Authorization of Their COVID-19 Vaccine in Children 6 Months Through 4 Years of Age Following Request From U.S. FDA

02.01.2022

- With pediatric COVID-19 cases surpassing 10 million and at the request of the FDA, the companies have submitted available data on the safety and efficacy of two 3 μg doses as part of a three-dose primary series for this age group to address the urgent public health need
- Companies plan to submit additional data on a third 3 µg dose in this age group in the coming months
- If authorization is granted, the Pfizer-BioNTech vaccine would be the first COVID-19 vaccine available for pediatric populations under 5 years of age

"If two doses are authorized, parents will have the opportunity to begin a COVID-19 vaccination series for their children while awaiting potential authorization of a third dose."



Vaccine Distribution is Imminent

- There has been no published data yet on Pfizer-BioNTech COVID-19 vaccine immunogenicity and efficacy
- The FDA Vaccine and Related Biological Products Advisory Committee (VRBPAC) is <u>meeting February 15th</u> to discuss authorization of the vaccine for children 6 months through 4 years of age
- Once the vaccine is authorized for use by the FDA, the CDC's Advisory Committee on Immunization Practices (ACIP) will discuss and provide medical recommendations
- Federal HHS is preparing to ship out COVID-19 vaccine product for this age group for delivery February 22nd (assuming FDA Emergency Use Authorization)



Pfizer-BioNTech COVID-19 Vaccine Products

PRELIMINARY – SUBJECT TO CHANGE PENDING REGULATORY GUIDANCE AND AUTHORIZATION/APPROVAL; CDC DOCUMENT – SHARED FOR JURISDICTIONAL PLANNING PURPOSES ONLY

	Current Products		Future Product
Age Indications ^a	12 years and older	5 through 11 years	6 months through 4 years ^d
Vial Cap Color and Label with Color Border	GRAY	ORANGE	MAROON
Preparation	Do Not Dilute	Dilute Before Use	Dilute Before Use
Amount of Diluent Needed per Vial $^{\rm b}$	Do Not Dilute	1.3 mL	2.2 mL
Dose Volume/Dose	0.3 mL/ 30 mcg	0.2 mL/ 10 mcg	0.2 mL/ 3 mcg
Doses per Vial	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
		Storage Conditions	
ULT Freezer (-90°C to -60°C) ^c	9 months	9 months	9 months
Freezer (-25°C to -15°C)	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator (2°C to 8°C)	10 weeks	10 weeks	10 weeks
Room Temperature (8°C to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to first puncture (including any thaw time)
After First Puncture (2°C to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours

^a Use the appropriate product based on the age of the recipient. ^b Diluent: Sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. ^c Regardless of storage condition, vaccines should not be used after 9 months from the date of manufacture printed on the vial and cartons. ^d The vaccine is currently under emergency use authorization review by the Food and Drug Administration (FDA) for children 6 months through 4 years old.



NH COVID-19 Vaccination Plans for Children 6 Months Through 4 Years of Age

- We need primary care practice providers and medical homes to take on the primary role of administering COVID-19 vaccine for this younger age group
 - Vaccine recommendations are best received by families when they come from a trusted healthcare provider
- A big THANK YOU to the many providers have already made this transition and are administering COVID-19 vaccine to their patients
- For those that have not yet had the opportunity to implement this into their practice, NH DHHS would like to support this transition



Benefits of Vaccination Through a Child's Medical Home

- Parents and caregivers are able to be individually counselled and have questions and concerns addressed
 - Includes discussion of medical recommendations and vaccine safety
- Ability to co-administer other childhood vaccines and perform routine well-child screenings
- Vaccination can occur in a medically appropriate setting with a healthcare team the child and family are familiar with
- Vaccine is administered by medical professionals experienced in childhood vaccination



Becoming a COVID-19 Vaccine Provider and Ordering Vaccine

- If you are not already vaccinating please see information on <u>How</u> to Become a COVID-19 Vaccine Provider
- NH currently has 105 pediatric and family practice providers actively administering COVID-19 vaccine
- A total of 10,200 doses of the new pediatric vaccine formulation (for vaccine recipients 6 months through 4 years of age) are available for providers to order during the first week
 - Please only order what you need for one week worth of vaccination; NH providers will have the ability to order more vaccine for delivery the following week



Role of the Regional Public Health Networks

- Primary care providers will serve as primary vaccinators for children in this age group
- The Regional Public Health Networks (RPHNs) will provide supportive services to providers

RPHN Responsibility	Pediatrician Office Responsibility	
Provide staff to support administrative functions	Provide office space	
Provide vaccine product and ancillary supplies	Advertise to patients/schedule if applicable	
Provide logistical support	Provide internet access, sharps disposal, etc.	
Obtain documented parental consent for administration as well as offering the ability to opt-out of NHIIS	Distribute paperwork to parents in advance	
Communicate and educate within community	Provide medical direction	
Document in NHIIS/VINI	Document in EHR/EMR	
Observe post-vaccination in non-clinical roles	Provide follow up care	



Other NH COVID-19 Vaccination Operations

- Our public health immunization section will continue to help "onboard" providers and clinics to be able to receive, store and administer COVID-19 vaccines
- The <u>mobile vaccine van</u> will continue to focus on vaccination of older and vulnerable populations
- <u>Vaccination fixed sites</u> will remain open at least through the end of March and continue to support COVID-19 vaccination in the community, but these sites will have a limited role in vaccinating very young children
- The ability of pharmacies to vaccinate children under 5 years of age is yet to be determined





