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Distributed by the NH Health Alert Network Health.Alert@nh.gov May 12, 2021 Time 1900 (7:00 PM EDT) NH-HAN 20210512



Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 43 Pfizer-BioNTech COVID-19 Vaccine Authorized for 12-15 Year Olds

- On May 10th, the U.S. Food and Drug Administration (FDA) updated their <u>Emergency Use Authorization</u> (EUA) for the Pfizer-BioNTech COVID-19 vaccine ("Pfizer vaccine") to allow use in people 12 years of age and older.
- The CDC's Advisory Committee on Immunization Practices (ACIP) met today (5/12) and voted to recommend use of the Pfizer vaccine in people 12 years of age and older who do not have a vaccine contraindication.
 - o Meeting information, including presented data, can be found online: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-05-12.html
- People can sign-up to schedule an appointment to receive COVID-19 vaccination through NH's online registration system at https://www.vaccines.nh.gov/; registration will be open for 12-15 year old vaccine recipients by tomorrow morning (5/13).
- The updated FDA EUA is based on study of the Pfizer vaccine in Phase 3 clinical trials in 2,260 adolescents 12-15 years of age (1,131 participants in the vaccine group, and 1,129 participants in the placebo group). Findings from this study are summarized in the updated FDA <u>Fact Sheet for Healthcare Providers Administer Vaccine</u> and include the following key points:
 - Common vaccine side effects in 12-15 year old participants were similar to other age groups and included local injection site pain (91%), swelling (9%), redness (9%), lymphadenopathy (<1%); and systemic symptoms such as fatigue (78%), headache (76%), chills (49%), muscle pain (42%), fever (24%), joint pain (20%), and nausea (0.4%)</p>
 - Serious adverse events were rare and reported in 0.4% of vaccine recipients vs. 0.1% of placebo recipients; there were no notable patterns or numerical imbalances in serious adverse events between the vaccine and placebo groups
 - Vaccine efficacy in 12-15 year old participants after 2 doses of the Pfizer vaccine was 100% (zero cases of COVID-19 in the vaccine group vs. 16 cases in the placebo group)
 - Neutralizing antibody titers in 12-15 year old participants compared to participants 16-25 years of age was "non-inferior", but 12-15 year olds did show a 76% higher geometric mean titer (GMT) of neutralizing antibodies compared to the older age group
- Please review the updated FDA and CDC guidance, including:
 - FDA Fact Sheet for Recipients and Caregivers
 - o FDA Fact Sheet for Healthcare Providers Administering Vaccine
 - A Morbidity and Mortality Weekly Report (<u>MMWR</u>) is planned for Friday 5/14 with further information about ACIP recommendations
 - o CDC is updating the Interim Clinical Considerations for Use of COVID-19 Vaccines (pending)
 - A CDC webinar "What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents" is occurring on Friday 5/14 from 2:00-3:00 pm; call information can be found at: https://emergency.cdc.gov/coca/calls/2021/callinfo 051421.asp

Weekly Partner Calls For:

Long-term care facilities and congregate living settings first and third Wednesdays from 11:45 am – 1:00 pm, in partnership with the NH Healthcare Association (NHHCA):

o Zoom link: https://zoom.us/j/511075725 Call-in phone number: (929) 205-6099

o Meeting ID: 511 075 725

Password: 092020

Educational and childcare partners first and third Wednesdays from 3:30 – 4:30 pm:

o Zoom link: https://nh-dhhs.zoom.us/j/98062195081

Call-in phone number: (646) 558-8656

Meeting ID: 980 6219 5081

Password: 197445

Healthcare providers and other public health partners every Thursday from 12:00 - 1:00 pm; these calls focus on new science, medical, and vaccine updates:

o Zoom link: https://zoom.us/s/94841259025

Call-in phone number: (646) 558-8656

Meeting ID: 948 4125 9025

Password: 003270

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- For any questions regarding this notification, please call the NH DHHS, DPHS, Bureau of Infectious Disease Control at (603) 271-4496 during business hours (8:00 a.m. 4:30 p.m.)
- If you are calling after hours or on the weekend, please call the New Hampshire Hospital switchboard at (603) 271-5300 and request the Public Health Professional on-call
- To change your contact information in the NH Health Alert Network, please send an email to <u>DHHS.Health.Alert@dhhs.nh.gov</u>

Status: Actual

Message Type: Alert Severity: Moderate Sensitivity: Not Sensitive

Message Identifier: NH-HAN 20210512 COVID-19 Update 43

Delivery Time: 12 hours Acknowledgement: No

Distribution Method: Email, Fax

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From: Benjamin P. Chan, MD, MPH; State Epidemiologist

Originating Agency: NH Department of Health and Human Services, Division of Public Health Services