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NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs *for all*
Department of Health and Human Services

Coronavirus Disease 2019 (COVID-19) Outbreak, Update # 29

Pfizer-BioNTech COVID-19 Vaccine Receives EUA, CDC and ACIP Issue Recommendations for Use

Key Points and Recommendations:

- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for use of the Pfizer-BioNTech COVID-19 vaccine as a 2-dose series (administered 3 weeks apart) in persons 16 years of age and older.
- Clinicians involved in handling, preparing, and administering the Pfizer-BioNTech COVID-19 vaccine must review the following FDA information and requirements before vaccinating:
    - FDA EUA for Pfizer-BioNTech COVID-19 vaccine
    - Fact Sheet for Healthcare Providers Administering Vaccine, which contains important information about who may receive the vaccine according to the EUA, preparation and storage information, administration instructions, and other specific instructions and mandatory requirements for health care providers
    - Fact Sheet for Recipients and Caregivers, which is the information that must be communicated and provided to all vaccine recipients or their caregivers prior to an individual receiving the vaccine
- The CDC's Advisory Committee on Immunization Practices (ACIP) has released Interim Recommendations for Use of the Pfizer-BioNTech COVID-19 vaccine.
    - More detailed clinical guidance will be available soon on the CDC website, Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine
    - Monitor CDC's COVID-19 Vaccination website for updates and resources
    - CDC is hosting a Clinician Outreach and Communication Activity (COCA) webinar, "What Every Clinician Should Know about COVID -19 Vaccine Safety" on Monday December 14, from 1-2 pm (Eastern Time)
- The Pfizer-BioNTech COVID-19 vaccine is an mRNA vaccine that contains a nucleoside-modified messenger RNA encoding the viral spike glycoprotein of SARS-CoV-2 formulated in lipid nanoparticles, which enable delivery of the mRNA into host cells where production and expression of the SARS-CoV-2 spike protein occur. The subsequent immune response to the viral spike protein antigen protects against COVID-19.
    - Vaccine was 95% effective at preventing symptomatic confirmed COVID-19 after 2 doses in the vaccine trial.
    - The most common side effects after vaccination involved local injection site reactions (84.1%), including pain, swelling, and redness. Other common systemic symptoms after vaccination included fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%). Symptoms were usually mild-moderate in severity, occurred within 1-2 days after vaccination, and resolved shortly thereafter.
    - There were not any specific safety concerns identified – serious adverse events were rare in the vaccine study. However, anecdotal reports of rare severe allergic reactions have been

reported during mass vaccination outside of clinical trials in persons with a previous history of severe allergic reactions.

- See the updated NH Division of Public Health Services (DPHS) COVID-19 Vaccine FAQs for Healthcare Providers and Public Health Partners (updated 12/13/2020)

- Contraindications to administration of the Pfizer-BioNTech vaccine (i.e., people who should NOT receive the vaccine) include a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Pfizer-BioNTech vaccine, or severe allergic reaction to any ingredient in the vaccine, which includes:
  - **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, and cholesterol), **potassium chloride**, **monobasic potassium phosphate**, **sodium chloride**, **dibasic sodium phosphate dihydrate**, and **sucrose**.
- Precautions to administration of the Pfizer-BioNTech vaccine include a severe allergic reaction (e.g., anaphylaxis) to any vaccine or injectable medical therapy (intramuscular, intravenous, or sub-cutaneous). Such persons should be informed of risks.
- Any vaccine recipient should be observed for at least 15 minutes post-vaccination. Persons with a vaccine precaution (i.e., history of anaphylaxis to any vaccine or injectable medication) should be observed for 30 minutes post-vaccination.
- Vaccine can be administered to people with underlying medical conditions (e.g., severely immunocompromised), and women who are pregnant or breastfeeding as long as the person does not have another contraindication to vaccination (i.e., history of severe allergic reaction to components of the vaccine) and they are included in the prioritized populations for vaccination. Such persons, however, are encouraged to first discuss the risks and benefits of vaccination with a primary care provider.
- Before and after vaccination, providers should:
  - Counsel vaccine recipients about expected systemic and local side effects; the individual should be given the Fact Sheet for Recipients and Caregivers before vaccination.
  - Encourage vaccine recipients to complete the 2-dose series even if the person develops post-vaccination symptoms to optimize protection (unless the person develops a contraindication to vaccination).
  - Advise that antipyretic or analgesic medications can be taken for treatment of post-vaccination symptoms; pre-vaccination prophylaxis is not recommended at this time.
  - Continue to counsel the vaccine recipient to follow mitigation measures after vaccination, including to:
    - ➢Avoid social gatherings and crowds of people, especially in indoor spaces
    - ➢Stay at least 6 feet from others when in public locations
    - ➢Wear a mask over the nose and mouth at all times when in public locations
    - ➢Avoid travel, even travel within the New England area
    - ➢Wash or sanitize hands frequently
- NH DPHS has developed Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics, which may serve as a resource for other organizations and providers. This guidance must be followed by Regional Public Health Network (RPHN) and State-managed vaccination clinics

operating under State medical direction and standing-orders, but the guidance can be adapted to fit local organizational context and policies.

- Clinicians must report any vaccination administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 to the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967, or online at https://vaers.hhs.gov/reportevent.html.
- NH's first allocation of the Pfizer-BioNTech COVID-19 vaccine is expected to arrive in State Monday December 14th. As previously announced in NH DPHS HAN #28, the initial shipment of vaccine is allocated to residents and staff at long-term care facilities and to hospitals to vaccinate their most at-risk health workers. Future shipments of vaccine will begin to be allocated to other Phase 1a high risk persons.
    - Ambulatory care health workers and first responders will be vaccinated at state-run fixed vaccination sites, which will be stood up by the end of December in locations across the state.
    - Ambulatory care health workers who are affiliated with hospital organizations may also be vaccinated through their hospital organization.

- 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 DHHS.Health.Alert@dhhs.nh.gov.

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Attachments: None