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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 # 30

Moderna COVID-19 Vaccine Receives EUA, CDC and ACIP Issue Recommendations for Use Update on Doses of Pfizer-BioNTech Vaccine in Multi-Dose Vials

Key Points and Recommendations:

- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for use of the Moderna COVID-19 vaccine as a 2-dose series (administered 28 days apart) in persons 18 years of age and older.
- Clinicians involved in handling, preparing, and administering the Moderna COVID-19 vaccine must review the following FDA information and requirements before vaccinating:
    - 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 Moderna COVID-19 vaccine.
    - **Updated** clinical guidance is also available on the CDC website Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the U.S.
    - Monitor CDC's COVID-19 Vaccination website for updates and resources, including more information about specific COVID-19 vaccines.
- The Moderna COVID-19 vaccine (similar to 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.
    - The Moderna vaccine was about 94% 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, including pain (92.0%), axillary swelling and tenderness in the vaccination arm (19.8%), swelling (14.7%), and redness (10.0%). Other common systemic symptoms after vaccination included fatigue (70.0%), headache (64.7%), muscle pain (61.5%), joint pain (46.4%), chills (45.4%), nausea/vomiting (23.0%), and fever (15.5%). Symptoms were usually mild-moderate in severity, occurred within 1-2 days after vaccination, and resolved shortly thereafter.
    - Compared to the Pfizer-BioNTech vaccine, the Moderna vaccine had a greater percentage of participants identified with axillary swelling and tenderness in the vaccination arm (19.8%), and more nausea and vomiting after vaccination (23.0%).

  - There were not any specific safety concerns identified – serious adverse events were rare in the vaccine study without significant differences between vaccine and placebo groups.

- See the updated NH Division of Public Health Services (DPHS) COVID-19 Vaccine FAQs for Healthcare Providers and Public Health Partners (updated **12/20/2020**)
- Contraindications to administration of the Moderna 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 Moderna vaccine, or severe allergic reaction to any ingredient in the vaccine, which includes:
  - 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
- Precautions to administration of the Moderna vaccine are similar to the Pfizer-BioNTech vaccine, and include a history of a severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable medication (including intramuscular, intravenous, or subcutaneous).
  - However, a person with a history of anaphylaxis to anything (including other vaccines, injection medications, oral medications, foods, or other substances or environmental exposures, etc.) should be informed about the unknown risks of developing a severe allergic reaction to the COVID-19 vaccines, and such vaccine recipients should be monitored for at least 30 minutes after vaccination (everybody else should be observed for at least 15 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 and they are included in the prioritized populations for vaccination. Such persons are encouraged to first discuss any questions and concerns, and the risks and benefits of vaccination with a healthcare provider.
- Before and after administering any COVID-19 vaccine, providers should:
  - Provide the Fact Sheet for Recipients and Caregivers specific to the COVID-19 vaccine being administered (see Pfizer-BioNTech Fact Sheet and Moderna Fact Sheet).
    - ➢ Translations of the Fact Sheet for Recipients and Caregivers can also be found on the FDA's Pfizer-BioNTech vaccine website (currently available), and FDA's Moderna vaccine website (forthcoming)
  - Counsel vaccine recipients about expected systemic and local side effects.
    - ➢ Depending on vaccine product (Pfizer-BioNTech vs. Moderna), approximately 80–89% of vaccinated persons develop at least one local symptom, and 55–83% develop at least one systemic symptom following 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

- Clinicians must report any administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and hospitalized or fatal cases of COVID-19 after vaccination to the Vaccine Adverse Event Reporting System (VAERS) by calling 1-800-822-7967, or online at https://vaers.hhs.gov/reportevent.html.
- See NH COVID-19 HAN #29 for details about the Pfizer-BioNTech COVID-19 vaccine. Below are some important updates:
  - While the FDA Pfizer-BioNTech vaccine Fact Sheet for Healthcare Providers Administering Vaccine reports 5 doses of vaccine in each vial after dilution, we are aware of unused vaccine remaining.
  - It is acceptable to use every full dose obtainable from each vial (including a possible sixth dose).
  - The ability to obtain a full sixth dose of vaccine from a vial depends on the type of syringe and needle used – syringes and needles with lower dead-space volume produce less vaccine wastage and allow for a possible sixth dose. If standard syringes or needles are used, then 6 doses may not be able to be extracted from a single vial.
  - Because the vials are preservative free, if the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume. Do NOT pool excess vaccine from multiple vials to create a full vaccine dose.
- See **TABLE** below for a comparative summary of the Pfizer-BioNTech and Moderna COVID-19 vaccines.

Table Comparing the Pfizer-BioNTech and Moderna COVID-19 Vaccines

	Pfizer-BioNTech Vaccine	Moderna Vaccine
Type of Vaccine	Modified mRNA	Modified mRNA
Dosing	2-dose series Doses separated by 21 days	2-dose series Doses separated by 28 days
Overall Vaccine Efficacy (prevention of symptomatic confirmed COVID-19)	95.0%	94.1%
Age Group Authorized to Receive Vaccine	16 years of age and older	18 years of age and older
Vaccine Ingredients	• Messenger RNA (mRNA) • Lipids: o (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) 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	• Messenger RNA (mRNA) • Lipids: o SM-102 (proprietary to Moderna) o Polyethylene 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
Side Effects (% reporting)	**Local injection site reactions**: • Pain (84.1%) • Swelling (10.5%) • Redness (9.5%) **Systemic reactions**: • Fatigue (62.9%) • Headache (55.1%) • Muscle pain (38.3%) • Chills (31.9%) • Joint pain (23.6%) • Fever (14.2%)	**Localized injection site reactions**: • Pain (92.0%) • Swelling (14.7%) • Redness (10.0%). • Axillary swelling & tenderness in vaccination arm (19.8%) **Systemic reactions**: • Fatigue (70.0%) • Headache (64.7%) • Muscle pain (61.5%) • Joint pain (46.4%) • Chills (45.4%) • Nausea/vomiting (23.0%) • Fever (15.5%)
Contraindications to Vaccination (do NOT vaccinate)	History of a severe allergic reaction (e.g., anaphylaxis) to a pervious dose of the COVID-19 vaccine or any ingredient in the vaccine.	
Safety Precautions	Any person with a history of a severe allergic reaction (e.g., anaphylaxis) to anything (including other vaccines, injection medications, oral medications, foods, or other substances or environmental exposures, etc.) should be informed about the unknown risks of developing a severe allergic reaction to the COVID-19 vaccines, and persons should be monitored for at least 30 minutes after	

	vaccination (everybody else should be observed for at least 15 minutes).	
Co-administration with Other Vaccines	COVID-19 vaccine should be administered alone and separated from other vaccinations by at least 14 days.	
Passive Antibody Therapy to Treat COVID-19	COVID-19 vaccine should NOT be given for at least 90 days after a person receives passive antibody therapy as treatment for COVID-19 (i.e., convalescent plasma or monoclonal antibodies).	
Pregnancy	Vaccine can be given, but patient should be counseled about the unclear risks and efficacy during pregnancy because COVID-19 vaccines haven't been extensively studied in pregnant women, but we believe the risk is low and there is benefit from the vaccine.	
Immunosuppression	Vaccine can be given, but patient should be counseled about the unclear risks and efficacy in people with immunosuppression because the vaccines haven't been extensively studied in people with significant immunosuppression and the vaccines may be less effective.	
NH DPHS Guidance	COVID-19 Vaccine Frequently Asked Questions (FAQs)	
CDC Guidance	Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines	
FDA Guidance and Resources	Fact Sheet for Healthcare Providers Administering Vaccine Fact Sheet for Recipients and Caregivers Translations of the Fact Sheet for Recipients and Caregivers (currently available)	Fact Sheet for Healthcare Providers Administering Vaccine Fact Sheet for Recipients and Caregivers Translations of the Fact Sheet for Recipients and Caregivers (forthcoming)

CDC: Centers for Disease Control and Prevention
COVID-19: Coronavirus Disease 2019
FDA: Food and Drug Administration
NH DPHS: New Hampshire Division of Public Health Services
mRNA: messenger ribonucleic acid

- 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