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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 # 32

CDC Updates COVID-19 Vaccine Clinical Guidance
Changes to Vaccine Contraindications and Precautions

Key Points and Recommendations:

- The U.S. Centers for Disease Control and Prevention (CDC) has updated their Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines; this includes updates to vaccine contraindications and precautions.
    - A CDC clinician webinar (12/30/2020) about these updates can be viewed here.
    - See the updated NH Division of Public Health Services (DPHS) COVID-19 Vaccine FAQs for Healthcare Providers and Public Health Partners (updated **12/31/2020**).
- Contraindications to administration of either the Pfizer-BioNTech or Moderna vaccine (i.e., people who should NOT receive the vaccines) include people who have a history of any of the following:
    - A severe allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient.
    - An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient.
    - An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving polysorbate – polysorbate is structurally similar to polyethylene glycol (PEG), which is an ingredient in both mRNA COVID-19 vaccines, so an allergic reaction to polysorbate could increase risk of an allergic reaction to the COVID-19 vaccines.
- Precautions to administration of either the Pfizer-BioNTech or Moderna vaccines include a history of an immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving another vaccine or injectable medication therapy (including intramuscular, intravenous, or subcutaneous injections), that does not meet criteria as a contraindication.
    - People with a vaccine precaution, and any person with a history of anaphylaxis due to any cause (including other medications, foods, 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 persons should be monitored for at least 30 minutes after vaccination (everybody else should be observed for at least 15 minutes post-vaccination).
    - People with concerning allergy histories are encouraged to consult with their primary care providers to help assess their allergy history, and the risks/benefits of COVID-19 vaccination.
- See CDC's Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines for more details and updates, including a table (Appendix C) to assist clinicians in differentiating an "immediate allergic reaction" from other commonly observed reactions following vaccination, which are not contraindications to receiving a second COVID-19 vaccine dose (including vasovagal reactions or other normal post-vaccination side effects).
- See **TABLE** below for a comparative summary of the Pfizer-BioNTech and Moderna COVID-19 vaccines with updated vaccine contraindications and precautions.

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	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)	People who have a history of any of the following should not be vaccinated with a COVID-19 vaccine: • A severe allergic reaction (e.g., anaphylaxis) to a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient. • An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving a previous dose of an mRNA COVID-19 vaccine or any vaccine ingredient. • An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving polysorbate.	

Safety Precautions	People who have a history of any of the following can still receive a COVID-19 vaccine, but should be informed about the unknown risks of developing a severe allergic reaction to the COVID-19 vaccine, and should be monitored for at least 30 minutes after vaccination if they elect to be vaccinated (everybody else should be observed for at least 15 minutes): • An immediate allergic reaction of any severity (defined as an allergic reaction within 4 hours) after receiving another vaccine or injectable medication therapy (including intramuscular, intravenous, or subcutaneous injections), that does not meet criteria as a contraindication. • A severe allergic reaction (e.g., anaphylaxis) due to any cause (including other medications, foods, substances, or environmental exposures, etc.).	
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	Fact Sheet for Healthcare Providers Administering Vaccine Fact Sheet for Recipients and Caregivers Translations of the Fact Sheet for Recipients and Caregivers

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