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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 # 36

Janssen COVID-19 Vaccine Receives FDA EUA
CDC Updates COVID-19 Vaccine Clinical Recommendations
Updated Vaccine Contraindications and Precautions

Key Points and Recommendations:

- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for use of the Janssen COVID-19 vaccine as a single dose in persons 18 years of age and older.
- There are now three authorized COVID-19 vaccines in the U.S., including the two mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna vaccines) and the new Janssen COVID-19 vaccine.
- The Janssen vaccine is an adenovirus vector vaccine that uses a modified inactivated ("replication-incompetent") adenovirus serotype 26 virus to carry the genetic instructions to our cells to produce and express the SARS-CoV-2 spike protein that stimulates an immune response.
    - The Janssen vaccine trial reported an overall vaccine efficacy of about 66% at preventing symptomatic COVID-19 after a single dose
        - In U.S. study participants, vaccine efficacy was higher with a reported efficacy of 72%, likely related to the fact that the vaccine protects less well against SARS-CoV-2 "variants of concern" present in other study countries
    - The vaccine was 85% effective at preventing severe COVID-19 and nearly 100% effective at preventing hospitalizations and deaths
        - The Janssen vaccine showed 82% efficacy at protecting against severe COVID-19 caused by the B.1.351 variant
    - Common side effects were similar to those seen with the Pfizer-BioNTech and Moderna vaccines and include localized symptoms (pain, redness and swelling), and systemic symptoms (fatigue, headache, myalgia, nausea, fever)
    - No specific safety concerns were identified, and serious adverse events were rare in the vaccine study without a difference between vaccine and placebo groups (0.4% of participants in both groups)
- CDC and the Advisory Committee on Immunization Practices (ACIP) have expressed no preference for any specific COVID-19 vaccine. **Encourage your patients to be vaccinated with the first available vaccine rather than wait for a specific formulation or manufacturer**.
- Persons involved in handling, preparing, and administering the Janssen 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, 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

- Clinicians should review the additional clinical resources and recommendations about use of the currently available COVID-19 vaccines:
  - CDC clinician webinar (**3/2/21**) about use of the Janssen vaccine
  - CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines (**updated 3/3/21**)
  - NH Division of Public Health Services' (DPHS) COVID-19 Vaccine FAQs for Healthcare Providers and Public Health Partners (**updated 3/3/21**)
- CDC's updated COVID-19 vaccine recommendations include important updates to vaccine contraindications and precautions:
  - Contraindication: Don't administer a COVID-19 vaccine to a person with a history of:
    - A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the COVID-19 vaccine or a component of the vaccine
    - An immediate allergic reaction* of any severity after a previous dose of the COVID-19 vaccine or to a component of the vaccine (known/diagnosed allergy to a component)
  - Precaution: A person can still be administered the COVID-19 vaccine, but there should be additional precautions taken if the person has a history of:
    - Any immediate allergic reaction* to other vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), which does not meet criteria as a contraindication
    - People with a precaution to vaccination can still receive the COVID-19 vaccine but they should be informed about the unknown risks of developing a severe allergic reaction to the COVID-19 vaccine, have a risk assessment performed by a provider, and discuss the potential risks/benefits of vaccination with their provider; such persons should be monitored for at least 30 minutes after vaccination (see additional guidance below)

  * An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria, angioedema, respiratory distress, or anaphylaxis that occurs within four hours following administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions such as vasovagal episodes and normal vaccine side effects; CDC has created a table (Appendix D) to assist providers
- Additional important guidance on COVID-19 vaccine contraindications and precautions:
  - A person with a contraindication to one mRNA COVID-19 vaccine should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna)
  - Persons with a contraindication to an mRNA vaccine, including a known/diagnosed allergy to polyethylene glycol (PEG) which is a component of both mRNA vaccines, have a precaution to receiving the Janssen vaccine – the Janssen vaccine may be given, but referral to an allergist-immunologist should be considered
  - Persons with a contraindication to the Janssen vaccine, including a known/diagnosed allergy to polysorbate which is a component of the Janssen vaccine, have a precaution to receiving one of the mRNA vaccines – an mRNA vaccine may be given, but referral to an allergist-immunologist should be considered

  - A person with a history of an allergic reaction to a non-COVID vaccine or injectable therapy that contains multiple components, one of which is a component of a COVID-19 vaccine (such as polyethylene glycol or polysorbate) but in whom it is unknown which component caused the allergic reaction, is considered to have a precaution to COVID-19 vaccination; such persons can still receive an available COVID-19 vaccine with appropriate counseling and post-vaccination monitoring (30 minutes of observation)

- COVID-19 vaccines are not interchangeable. A person that starts a 2-dose series with one of the mRNA vaccines (Pfizer-BioNTech or Moderna), must complete the series with the same COVID-19 vaccine manufacturer.
  - A person who has received one dose of an mRNA vaccine but has an allergic reaction which prevents that person from receiving the second dose of the mRNA vaccine (i.e., person has a contraindication to receiving an mRNA vaccine) may be given the single-dose Janssen vaccine after at least 28 days have passed from receipt of the mRNA vaccine in order to be considered fully vaccinated against COVID-19 (with appropriate precautions)
- See **TABLE** below for a summary of the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines.
- NH DPHS continues to promote our quarantine guidance that was posted in HAN Update #33. A person is not required to quarantine after an unprotected exposure to a person with COVID-19 or after travel outside of New England if the person remains asymptomatic AND the exposure or travel occurred in a person who is either:
  - 14 days or more beyond full vaccination (i.e., 14 days after receipt of the second dose of an mRNA vaccine, or 14 days after receipt of the single-dose Janssen vaccine) – NH's guidance for quarantine after full vaccination has no specified upper time limit
  - Within 90 days of a prior SARS-CoV-2 infection diagnosed by PCR or antigen testing
- Any person with new or unexplained symptoms of COVID-19 needs to isolate, be evaluated and considered for COVID-19 testing (even if that person is fully vaccinated or was previously infected), especially if there was an identified exposure or travel in the 14 days prior to symptoms onset.
- All fully vaccinated, or previously infected, persons should continue to follow currently recommended mitigation measures, including: wearing face masks, social distancing, avoiding social/group gatherings, limiting non-essential travel, etc.
- Any person participating in international travel who is exempt from quarantine upon return to NH (based on above criteria) still should be tested for asymptomatic SARS-CoV-2 infection per CDC international travel guidance, including testing on days 1-3 BEFORE travel, and testing again on days 3-5 AFTER travel (testing should be performed with a PCR-based test).
  - See NH COVID-19 Travel Guidance for additional information and recommendations, including testing recommendations for people who are required to quarantine after travel

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

	Pfizer-BioNTech	Moderna	Janssen
Type of Vaccine	Modified mRNA	Modified mRNA	Adenovirus vector
Dosing	2-dose series Doses separated by 21 days	2-dose series Doses separated by 28 days	1-dose series
Overall Vaccine Efficacy (VE)	**95%**[1,2]	**94%**[3,4]	**66%**[5] (**72%** in U.S. Population)
VE at Preventing Severe Disease	**75%**[1,2] (1 case vs. 4 cases) **92%**[6]	**100%**[3,4] (0 cases vs. 30 cases)	**85%**[5] (5 cases vs. 34 cases)
VE at Preventing Hospitalization	**87%**[6]	limited numbers prevented calculation[3,4]	**100%**[5] (0 cases vs. 16 cases)
VE at Preventing Death	**84%**[6] *Estimate at 21-27 days after 1st dose; no data for efficacy following 2 doses*	limited numbers prevented calculation[3,4]	**100%**[5] (0 deaths vs. 7 deaths)
Age Group Authorized to Receive Vaccine	16 years of age and older	18 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	• Replication-incompetent adenovirus particles • Citric acid monohydrate • Trisodium citrate dihydrate • Ethanol • 2-hydroxypropyl-β-cyclodextrin (HBCD) • Polysorbate-80 • Sodium chloride Note: each dose may also contain residual amounts of cell proteins and/or DNA from cells that were used to grow the adenovirus vector (PER.C6 TetR cells)

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%)	**Localized injection site reactions**: • Pain (48.6%) • Swelling (5.3%) • Redness (7.3%) **Systemic reactions**: • Fatigue (38.2%) • Headache (38.9%) • Muscle pain (33.2%) • Nausea (14.2%) • Fever (9.0%)
Contraindications to Vaccination (do NOT vaccinate)	See CDC guidance on COVID-19 vaccine contraindications and precautions, including Appendix B		
Precautions to Vaccination	See CDC guidance on COVID-19 vaccine contraindications and precautions, including Appendix B		
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; patient should be informed about limited data on safety of COVID-19 vaccines during pregnancy, but the COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus because the vaccines are all non-replicating vaccines and cannot cause infection, and there is benefit from the vaccination; see the ACOG Practice Advisory and CDC's Vaccine Considerations for People who are Pregnant or Breastfeeding		

Immunosuppression	Vaccine can be given, but patient should be counseled about the unknown safety profile and effectiveness of the vaccine in immunocompromised persons, the potential for reduced immune responses, and the need to continue to follow current mitigation guidance to protect themselves against COVID-19		
NH DPHS Guidance	COVID-19 Vaccine Frequently Asked Questions (FAQs) for Healthcare Providers and Public Health Partners		
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	Fact Sheet for Healthcare Providers Administering Vaccine Fact Sheet for Recipients and Caregivers Translations of the Fact Sheet for Recipients and Caregivers (pending publication)

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

References:

1. FDA. VRBPAC Meeting Briefing Document: Pfizer-BioNTech COVID-19 Vaccine. 2020 Dec 10. Available at: https://www.fda.gov/media/144245/download.
2. Polack et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. NEJM. 2020 Dec 31;383(27):2603-15. Available on NEJM website.
3. FDA. VRBPAC Meeting Briefing Document: Moderna COVID-19 Vaccine. Dec 17, 2020. Available at: https://www.fda.gov/media/144434/download.
4. Baden et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. NEJM. 2021 Feb 4;384(5):403-16. Available on NEJM website.
5. FDA. VRBPAC Meeting Briefing Document: Janssen COVID-19 Vaccine. Feb 26, 2021. Available at: https://www.fda.gov/media/146217/download.
6. Dagan et al. BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting. NEJM. 2021 Feb 24. Available on NEJM website.

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

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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

Attachments: None