TO: Vermont Health Care Providers and Health Care Facilities
FROM: Jennifer S. Read, MD, FIDSA; Medical Epidemiologist

General Information about the Pfizer-BioNTech and Moderna COVID-19 Vaccines

Two COVID-19 vaccines have received emergency use authorization from the U.S. Food and Drug Administration. A comparison of these two vaccines (type of vaccine, dosing, overall vaccine efficacy, age group authorized to receive vaccine, vaccine ingredients, and adverse events) is provided in the table.

	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 or older	18 years of age or 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
Adverse Events	**Local injection site reactions**: • Pain (84.1%) • Swelling (10.5%) • Redness (9.5%)	**Localized injection site reactions**: • Pain (92.0%) • Swelling (14.7%) • Redness (10.0%) • Axillary swelling & tenderness in vaccination arm (19.8%)

Adverse Events (continued)	**Systemic reactions**: • Fatigue (62.9%) • Headache (55.1%) • Muscle pain (38.3%) • Chills (31.9%) • Joint pain (23.6%) • Fever (14.2%)	**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%)

Vaccine recipients should be counseled about expected systemic and local side effects. Depending on vaccine product (Pfizer-BioNTech vs. Moderna), approximately 80–89% of vaccinated people develop at least one local symptom, and 55–83% develop at least one systemic symptom following vaccination. People who received the Moderna vaccine had a larger proportion of participants with: 1) axillary swelling and tenderness; and 2) more nausea and vomiting (when compared those who received the Pfizer-BioNTech vaccine).

The following information applies to both vaccines:

Contraindications and Precautions:

- Contraindication: History of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the COVID-19 vaccine or any ingredient in the vaccine.
- Precaution: 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 people should be monitored for at least 30 minutes after vaccination (everybody else should be observed for at least 15 minutes).

Providers should counsel COVID-19 vaccine recipients about expected local and systemic reactogenicity. Before vaccination, the **EUA Fact Sheet** should be provided to recipients and caregivers:

- Pfizer EUA Fact Sheet for Vaccine Recipients
  - Find translated versions
- Moderna EUA Fact Sheet for Vaccine Recipients (translations not yet available)

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events

- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal icon or by calling 1-800-822-7967.

Real-time **monitoring of vaccine adverse events** can be accomplished with registration (by the vaccine recipient) for V-safe.

No interchangeability of COVID-19 vaccines: COVID-19 vaccines are not interchangeable; the efficacy and safety of a mixed series has not been evaluated. If two doses of different mRNA COVID-19 vaccines are administered inadvertently, no additional doses of either vaccine are recommended at this time. Recommendations may be updated as further information becomes available.

Co-administration with other vaccines: A COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines.

Patient populations:

- **People with a history of SARS-CoV-2 infection:** Vaccination should be offered to people regardless of a history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Virologic or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making.

- **People with known current SARS-CoV-2 infection:** Vaccination should be deferred until recovery from acute illness (if the person had symptoms) and criteria have been met to discontinue isolation.

- **People who previously received passive antibody therapy for COVID-19:** There are no data on the safety or efficacy of COVID-19 vaccination in these people. Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

- **People with a known SARS-CoV-2 exposure:**

    - Community or outpatient setting: Defer vaccination until quarantine has ended.

    - Residents of congregate healthcare settings (e.g., long-term care facilities): May be vaccinated.

    - Residents of other congregate settings (e.g., correctional facilities, homeless shelters): May be vaccinated.

- **People with underlying medical conditions:** May be vaccinated if no contraindications to the vaccine.

- **People who are immunocompromised** (e.g., people with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications): These people may be at increased risk for severe COVID-19. Note that data are not currently available to establish safety and efficacy of this vaccine in these groups. These people may receive COVID-19 vaccine unless otherwise contraindicated. There is the potential for a reduced immune response.

- **People who are pregnant or lactating:** No data on these populations. Vaccine can be given, but patient should be counseled about the unclear risks and efficacy during pregnancy because COVID-19 vaccines have not been extensively studied in pregnant people, but we believe the risk is low and there is benefit from the vaccine.

REQUESTED ACTIONS:

1. Provide all patients with a copy of the EUA for the vaccine being administered.

2. Report all adverse events to VAERS.gov.

3. Encourage patients to register for V-safe, if interested, in order to support real time monitoring of vaccine adverse events.

If you have any questions, please contact the HAN Coordinator at 802-859-5900 or vthan@vermont.gov.

HAN Message Type Definitions
Health Alert: Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: Provides important information for a specific incident or situation may not require immediate action.
Health Update: Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service Message: Provides general correspondence from VDH, which is not necessarily considered to be of an emergent nature.