

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Patsy Kelso, PhD, State Epidemiologist

Guidance on Prioritization of Vaccination in Phase 1A and Moderna COVID-19 Vaccine Recommendations

Background

On December 30, the CDC released [Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#) that includes information on antibody therapies and COVID-19 vaccination, COVID-19 vaccination and outbreak management, updates to contraindications and precautions to vaccination

The COVID-19 vaccine developed by Moderna has received [emergency use authorization \(EUA\)](#) from the U.S. Food and Drug Administration. The [interim recommendation](#) of the Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) regarding the use of the Moderna COVID-19 vaccine has been issued. This recommendation for the Moderna COVID-19 vaccine should be implemented in conjunction with ACIP's [interim recommendation](#) for allocating initial supplies of COVID-19 vaccines, and Vermont priorities as outlined below. Additional resources include the [Fact Sheet for Healthcare Providers Administering Vaccine](#), and the [Fact Sheet for Recipients and Caregivers](#).

Prioritization of Vaccination

ACIP recommends the following two groups of people be offered vaccination in the initial phase of the COVID-19 vaccination program:

- Health care personnel (healthcare personnel comprise clinical staff members, including nursing or medical assistants and support staff (e.g., those who work in food or environmental services))
- Residents of long-term care facilities (LTCFs) (LTCFs include skilled nursing facilities, nursing homes, and assisted living facilities (vaccination may be offered first to residents and health care personnel in skilled nursing facilities because of high medical acuity and COVID-19-associated mortality among residents in these settings))

The Vermont Vaccine Implementation Advisory Committee further specified that, in Vermont, "health care personnel" includes:

- Long-term care staff who have direct patient contact.
- Health care workers (all classes including students and support personnel), primarily but not exclusively located in the Emergency Departments and Intensive Care Units, providing care to patients with COVID-19.
- Emergency Medical Services personnel with direct patient contact.

- Home health care clinical staff and caregivers who have contact with multiple patients or who are high-risk for serious illness from COVID-19.
- Any other health care providers and staff who have direct patient contact.

The definition of staff includes all health care providers who enter the facility, regardless of who employs them, as well as ancillary staff. Family caregivers are not included in this definition.

All 14 Vermont hospitals have been asked to provide vaccination to health care workers in their hospital-service area identified in this initial phase. To ensure equitable vaccine access for eligible health care personnel, vaccine distribution should be balanced between hospital-based and non-hospital-based personnel. Please note that those personnel who are exclusively seeing patients virtually do not meet the “direct patient contact” requirement to be eligible to receive vaccine in Phase 1A.

Individual hospitals will be reaching out to staff and health care workers in their area to schedule appointments. Health care providers and staff who have not heard from their local hospital by January 11, 2021 should reach out to the hospital.

While the COVID-19 vaccine supply is limited, hospitals may consider offering vaccine based on risk when prioritizing vaccination of health care providers and staff who have patient contact.

The Health Department recommends that individuals in the first tier should include:

- Health care providers and staff working in primary care, obstetrics and gynecology or dental practices
- Individuals working in inpatient settings with direct patient care who may not be employed by the hospital

Vaccine Distribution and Reporting Administration of the Vaccine

Vermont expects a weekly allocation of vaccine. The vaccine is shipped from Moderna’s distributor McKesson Specialty.

The next population groups to be prioritized in Vermont will be communicated in the coming weeks. The Vermont COVID-19 Vaccine Advisory Committee is reviewing new [CDC Advisory Committee Recommendation for Allocation of COVID-19 Vaccine](#) recommendations and Vermont specific data, prior to making a recommendation to the Health Department. It is not possible to predict when the next groups will be vaccinated due to uncertainty related to vaccine availability.

All immunizations in Vermont are required, by law, to be reported to the Vermont Immunization Registry (IMR). Per the CDC provider agreement for COVID vaccine, doses administered must be reported to the IMR within 24-72 hours of administration. All Vermont hospitals already have existing systems for reporting vaccinations to the IMR, and these same systems can be utilized for reporting COVID vaccine administration as long as they are within the 24-72-hour reporting requirement. As part of the COVID vaccine

provider enrollment process, the Health Department has engaged with any hospital needing to adjust their reporting mechanism to meet reporting requirements.

Efficacy

Most of the data regarding the Moderna COVID-19 vaccine comes from one large, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants (median age: 52 years, range 18–95 years). Interim results (using data from participants with a median follow-up of 2 months) indicated efficacy after 2 doses of 94.1% in preventing symptomatic, laboratory-confirmed COVID-19 among persons without evidence of previous SARS-CoV-2 infection. Efficacy also was high ($\geq 86\%$) across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Preliminary data suggest the Moderna COVID-19 vaccine may provide some protection against asymptomatic SARS-CoV-2 infection.

Safety

In the large clinical trial, reactogenicity symptoms (solicited local injection site or systemic reactions during the 7 days after vaccination) were frequent, but primarily mild to moderate.

The most common adverse events following 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%).

Systemic adverse events were more commonly reported after the second dose than after the first dose and were generally more frequent and severe in those aged 18-64 years than in those aged ≥ 65 years. Most local and systemic adverse events occurred within 1-2 days after vaccination and resolved in a median of 2-3 days. Severe (interfering with daily activity) local and systemic adverse reactions occurred more commonly in vaccine recipients (21.6%) than in placebo recipients (4.4%). Among vaccine recipients, 9.1% reported a grade 3 or 4 local injection site reaction and 16.5% reported a grade 3 or 4 systemic event.* Serious adverse events were observed in 1.0% of vaccine recipients and 1.0% of placebo recipients.** No specific safety concerns were identified according to age, race, ethnicity, underlying medical conditions or previous SARS-CoV-2 infection.

*Adverse events:

Grade 3: use of a prescription pain reliever or those preventing daily activity, fever (temperature 102.1–104.0°F [39–40°C])

Grade 4: those that require emergency department visit or hospitalization, temperature $>104^\circ\text{F}$ (40°C)

** Serious adverse events: any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, or results in persistent disability/incapacity.

Contraindications and Precautions using mRNA vaccines

While rare, anaphylactic reactions have been reported following vaccination with mRNA COVID-19 vaccines. Although investigations are ongoing, persons with a history of an immediate allergic reaction (of any severity) to an mRNA COVID-19 vaccine or any of its components might be at greater risk for anaphylaxis upon re-exposure to either of the currently authorized mRNA COVID-19 vaccines. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Recommendations for contraindications and precautions are described below. These recommendations may change as further information becomes available.

Contraindications

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose).

Additional information

Vaccination with the Moderna COVID-19 vaccine consists of 2 doses (100 micrograms, 0.5 mL each) administered intramuscularly 4 weeks apart.

Although the vaccine requires a freezer (-20 °C [-4°F]) for long-term storage, it is stable at refrigerator temperatures (2–8°C [35–46°F]) for up to 30 days after thawing.

The ACIP has recommended the use of the Moderna COVID-19 vaccine in persons aged ≥18 years for the prevention of COVID-19.

Persons initiating the Moderna COVID-19 vaccine should complete the 2-dose series. Both doses are necessary for protection; the efficacy of a single dose has not been evaluated.

The Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccine products; the safety and efficacy of a mixed-product series have not been evaluated.

Before vaccination, the [EUA Fact Sheet](#) should be provided to recipients and caregivers. Providers should counsel Moderna COVID-19 vaccine recipients about expected local and systemic reactivity.

Preparation of the Moderna COVID-19 vaccine for administration:

- The Moderna vaccine comes as a frozen liquid. **Do not dilute the vaccine.**
- Vaccine may be thawed in the refrigerator or at room temperature.
 - Thaw in refrigerator for 2 hours and 30 minutes
 - Thaw at room temperature for 1 hour
- With vial upright, gently swirl the vaccine before withdrawing each dose, **do not shake.** If vial is shaken, contact the manufacturer.
- Examine the vaccine. It should be white to off-white in color and may contain white particles. Do not use if the liquid contains other particulate matter or is discolored.
- Draw 0.5 mL for vaccine administration.
- After the first dose has been withdrawn from the vial, record the date and time on the label. Discard any unused vaccine after 6 hours. The vial should be refrigerated between doses.

COVID-19 vaccine information for health care professionals in Vermont is updated frequently and available at www.healthvermont.gov/COVID19-Vaccine-HealthPros.

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.gov> external icon or by calling 1-800-822-7967.

REQUESTED ACTION

Upon receipt of the Moderna COVID-19 vaccine, administer the vaccine expeditiously to anyone in the groups specified above without any history of severe allergic reactions to any component of the vaccine.

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.