

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

Initial Pfizer-BioNTech COVID-19 Vaccine Recommendations

Note: This Health Advisory is superseded by a [Health Advisory issued on December 24, 2020](#).

Background

The COVID-19 vaccine developed by Pfizer-BioNTech has received [emergency use authorization \(EUA\)](#) from the U.S. Food and Drug Administration. The EUA application for the Moderna COVID-19 vaccine will be reviewed on December 17, 2020 and if approved may be recommended by the Centers for Disease Control and Prevention (CDC) immediately thereafter. No other COVID-19 vaccine EUA applications have been submitted at this time. The [interim recommendation](#) of the CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of the Pfizer-BioNTech COVID-19 vaccine has been issued. This recommendation for the Pfizer-BioNTech COVID-19 vaccine should be implemented in conjunction with ACIP's [interim recommendation](#) for allocating initial supplies of COVID-19 vaccines.

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, environmental, and administrative 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 providers and staff (all classes including students and support personnel), primarily but not exclusively located in the Emergency Department 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 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. 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 4, 2021 should reach out to the hospital.

Hospitals seeking guidance to prioritize vaccination of health care providers and staff who have patient contact, while the COVID-19 vaccine supply is limited may consider offering vaccine based on risk. 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 Emergency Departments and inpatient settings with direct patient care who may not be employed by the hospital.

Vaccine Distribution

Vermont expects a weekly allocation of vaccine. The vaccine is shipped directly from the manufacturer to sites with ultracold storage (i.e., the Vermont Vaccine Depot, certain hospitals and the LTCF Pharmacy Partners (CVS, Walgreens, and HealthDirect)).

An ancillary supply kit will accompany the vaccine. The kit includes needles, syringes, alcohol prep pads, surgical masks, and face shields for vaccinators, COVID-19 vaccination record cards for vaccine recipients, and a needle selection information guide. Mixing kits with syringes, needles, and other needed supplies also will be included. Ancillary supply kits will not include sharps containers, gloves, or bandages. Additional personal protective equipment may be needed depending on vaccination provider site needs. In anticipation of a wider distribution of vaccine in the future, enrollment to be a Vermont COVID-19 vaccination provider is ongoing.

The next population groups to be prioritized in Vermont will be communicated during the week of December 20-26, after new recommendations are issued by CDC and examined by the Vermont Vaccine Implementation Advisory Committee. Work is underway to ensure wide, timely access to available vaccine.

Efficacy

Most of the data regarding the Pfizer-BioNTech COVID-19 vaccine comes from one large, randomized, double-blind, placebo-controlled Phase II/III clinical trial that enrolled over 43,000 participants (median age = 52 years, range = 16-91 years). Interim results (using data from participants with a median follow-up of 2 months) indicated efficacy of 95% in preventing symptomatic, laboratory-confirmed COVID-19 in persons without evidence of previous SARS-

CoV-2 infection. Efficacy also was high ($\geq 92\%$) across age, sex, race, and ethnicity categories and among persons with underlying medical conditions.

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. 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 18-55 years than in those aged > 55 years. Systemic adverse reactions had a median onset of 1-2 days after vaccine receipt and resolved in a median of 1 day. Severe (interfering with daily activity) local and systemic adverse reactions occurred more commonly in vaccine recipients than in placebo recipients. Among vaccine recipients, 8.8% reported any grade 3 or 4 event; the most common symptoms were fatigue (4.2%), headache (2.4%), muscle pain (1.8%), chills (1.7%), and injection site pain (1.4%). Serious adverse events were observed in 0.6% of vaccine recipients and 0.5% of placebo recipients and included medical events occurring at a frequency similar to that within the general population. No specific safety concerns were identified according to age, race, ethnicity, underlying medical conditions or previous SARS-CoV-2 infection.

Contraindication and Precaution

CDC considers a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or a severe allergic reaction to a previous dose as a contraindication.

CDC considers a history of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution but not a contraindication to vaccination. In persons who report a history of anaphylaxis to another vaccine (i.e., any other vaccine besides the Pfizer-BioNTech COVID-19 vaccine) or injectable therapy, a risk assessment should be conducted to determine type of reaction and certainty of information. These persons may still receive vaccination, but they should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination.

A history of mild allergic reaction to a vaccine or injectable therapy, such as urticaria alone without signs or symptoms of anaphylaxis, is not a contraindication or precaution to Pfizer-BioNTech COVID-19 vaccination. In addition, allergic reactions (including severe allergic reactions) not related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications [including the oral equivalents of injectable medications]) are not a contraindication or precaution to vaccination with Pfizer-BioNTech COVID-19 vaccine.

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other

persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions.

Additional information

Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 doses (30 micrograms or 0.3 mL each) administered intramuscularly 3 weeks apart. There is a 4-day grace period for administration of the second dose (i.e., administration at day 17-21). If more than 21 days since the first dose, the second dose should be administered at the earliest opportunity (but no doses need to be repeated). Persons initiating the Pfizer-BioNTech 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.

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

Preparation of the Pfizer-BioNTech COVID-19 vaccine for administration:

- Mix the vaccine using a NEW vial of diluent and a NEW vial of the vaccine EVERY TIME.
- Use only 1.8 mL of 0.9% sodium chloride (normal saline preservative) ONLY (do NOT use all the diluent in the vial). Do NOT use bacteriostatic normal saline or other diluents.
- CDC has provided interim guidance noting that given the public health emergency, it is acceptable to use every full dose obtainable (the sixth, or possibly even the seventh) from each vial. However, since these are preservative free vials, any further remaining liquid that does not constitute a full dose should not be pooled from multiple vials to create one.

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> or by calling 1-800-822-7967.

REQUESTED ACTION

Upon receipt of the Pfizer-BioNTech 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.