

TO: Vermont Health Care Providers and Health Care Facilities
FROM: Mark Levine, MD, Commissioner

Eligibility of Persons Immunized with a Non-FDA-Approved COVID-19 Vaccine to Receive a Primary Series of an FDA-Approved mRNA COVID-19 Vaccine

The U.S. Food and Drug Administration (FDA) has given Emergency Use Authorization (EUA) for the Moderna mRNA COVID-19 vaccine and the Janssen/Johnson & Johnson COVID-19 vaccine. The Pfizer-BioNTech mRNA COVID-19 vaccine has received full FDA approval for those age 16 and older, and EUA for those ages 12-15.

There are several other candidate COVID-19 vaccines for which an FDA EUA has not yet been given, including vaccines under study in the United States (e.g., the AstraZeneca vaccine and Novovax vaccines) and vaccines that have been licensed in other countries or approved by the World Health Organization (e.g., the AstraZeneca vaccine, the Sputnik V vaccine from Russia, the Sinovac vaccine from China, and others).

A few individuals in Vermont may have received vaccines licensed in other countries as part of working and living abroad. In addition, several hundred individuals in Vermont and the region have received COVID-19 vaccines as a volunteer in formal clinical trials of vaccine efficacy. We applaud the contributions of these individuals, many of whom are volunteers in the AstraZeneca vaccine trial conducted in Vermont at the University of Vermont Medical Center.

It is important to note that based on ethical research principles, these volunteers retain the choice to also receive an additional mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech). This decision should ideally be made in consultation and communication with the research study team so documentation is complete and effect on the original study data is captured.

In Vermont, both groups of people are currently eligible to receive Pfizer or Moderna mRNA vaccines. These individuals are able to receive the full primary series, although data may demonstrate that only a single dose is necessary.

[According to the U.S. Centers for Disease Control and Prevention](#), there are insufficient data upon which to recommend that persons who received the Janssen/Johnson & Johnson COVID-19 vaccine receive a dose of either the Pfizer-BioNTech or Moderna mRNA COVID-19 vaccine. Persons who received the Janssen/Johnson & Johnson COVID-19 vaccine will likely need a booster dose, and more data are expected in the next several weeks.

Primary care offices, pharmacies, and Vermont Department of Health pop-up vaccine sites will receive instructions clarifying that these individuals are eligible immediately for the COVID-19 mRNA vaccines. They should not be denied one of these approved vaccines if their original vaccine appears on a state or national registry.

REQUESTED ACTIONS:

Be aware of the eligibility of persons immunized with a non-FDA-approved COVID-19 vaccine to receive a primary series of an mRNA COVID-19 vaccine with an EUA (Moderna) or with full FDA approval (Pfizer-BioNTech).

Inform your patients who were part of a clinical trial to notify the clinical trial coordinator of their subsequent receipt of an mRNA 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.