

# Evaluation of COVID-19 Vaccine Effectiveness among Long-Term Care Facility Residents, Connecticut, 2021

## Background

Although currently authorized COVID-19 vaccines have been shown to be highly efficacious in preventing COVID-19 in study populations, effectiveness in long-term care facility (LTCF) populations is less certain. In addition, it remains unknown whether the vaccines prevent asymptomatic infection and transmission; this information is critical for making informed decisions about whether and how infection control guidance should be changed for vaccinated residents and resident populations. Current recommendations for controlling COVID-19 outbreaks in nursing homes, including extensive testing for asymptomatic SARS-CoV-2 infection, provide an opportunity to learn about vaccine effectiveness in this setting. Following initial distribution of the COVID-19 vaccine in LTCFs, CDC requested information from our state and local partners on evidence of continued transmission in these settings, including outbreaks. These efforts identified ongoing outbreaks at multiple LTCFs in Connecticut following delivery of the first or second dose of the vaccine. In collaboration with the CT DOH and EIP programs, we aim to assess the effectiveness of the COVID-19 vaccine in the context of ongoing transmission events.

## Primary Objectives

1. Estimate the effectiveness of a complete schedule (2 doses) of COVID-19 vaccine against SARS-CoV-2 infection in LTCF residents.
2. Estimate the effectiveness of a single doses of COVID-19 vaccine against SARS-CoV-2 infection in LTCF residents.

## Secondary Objectives

1. Estimate the effectiveness of a complete schedule (2 doses) of COVID-19 vaccine against symptomatic SARS-CoV-2 infection in LTCF residents.
2. Estimate the effectiveness of a single doses of COVID-19 vaccine against symptomatic SARS-CoV-2 infection in LTCF residents.

## Methods

We will conduct a cohort evaluation of vaccine effectiveness among residents of individual LTCFs in CT which are currently experiencing an outbreak of COVID-19 disease. All residents of select long-term care facilities (LTCFs) with exposure to the facility on or after the date of the first vaccination clinic will be eligible for this evaluation. The exposure of interest will be receipt of 1 or 2 doses of the COVID-19 vaccine. The outcome will be whether or not a patient meets the definition for a lab-confirmed case of SARS-CoV-2 infection. A cohort consisting of residents across multiple facilities will be investigated for feasibility.

## COVID-19 Case Definitions

Lab-confirmed SARS-CoV-2 infection



- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) using a molecular amplification or protein using an antigen-based test in a clinical or autopsy specimen.

Symptomatic, lab-confirmed SARS-CoV-2 infection

- A lab confirmed SARS-CoV-2 infection with new onset or increased severity of a clinically relevant symptom in any resident present on or after the first vaccine clinic and within 7 days before or 14 days after the positive test collection date

Asymptomatic, lab-confirmed SARS-CoV-2 infection

- A lab confirmed SARS-CoV-2 infection that does not have new onset or increased severity of a clinically relevant symptom in any resident present on or after the first vaccine clinic and within 7 days before or 14 days after the positive test collection date

SARS-CoV-2 Symptoms (new onset or increased severity):

- Fever (measured >100F or multiple >99F or subjective)
- Chills
- Rigors
- Myalgia
- Headache
- Sore throat
- Nausea or vomiting
- Diarrhea
- Fatigue
- Congestion or runny nose
- Cough
- Shortness of breath
- Difficulty breathing
- New olfactory disorder
- New taste disorder
- Anorexia
- Altered mental status

**Cohort Population**

Residents that resided within selected LTCFs during at least one or more rounds of facility-wide SARS-CoV-2 testing after the facility's first vaccination clinic date.

**Case Ascertainment**

Symptomatic and asymptomatic COVID-19 cases reported through Connecticut DOH surveillance data with onset or specimen collection dates on or after the date of the first vaccination clinic conducted at that facility will be included and regardless of the number of days that elapsed between vaccination and date of symptom onset or specimen collection for asymptomatic cases. The study period will continue

until 14 days following the last case identified as part of this outbreak. Facilities with frequent resident-wide surveillance testing following initial case identification will be preferred to ensure accurate and complete case-finding. Case classification will be determined using the definitions above. Some baseline demographic data to include co-morbidities will be collected on all residents regardless of case status as long as they were present on or after the first vaccine clinic.

### **Data collection**

Clinical and laboratory information, such as symptom onset date, duration of cough, COVID-19 symptoms, vaccination status, and test results will be collected for each case from each LTCF's electronic medical record system. Previous COVID-19 test dates and results for the 90 days prior to the date of the first vaccination clinic will be collected, if available, to assess the possibility that a previous infection could result in a positive test due to prolonged shedding or a negative test due to previously-acquired natural immunity.

### *Vaccination Status*

Vaccination date, type, and manufacturer, all cohort participants will be collected. Participants with incomplete vaccination history (e.g., missing or invalid doses, non-valid vaccination dates, etc.) will have vaccination verified with the Connecticut Immunization Information System.

### **Sample size estimation**

Assuming a vaccine effectiveness of 70% in a facility with 75% of residents vaccinated, we estimate that an attack rate of 25% will provide for a confidence interval width of 0.4.

### **Statistical Analysis**

The primary analysis will include all confirmed new cases in residents of selected LTCFs. The first 14 days following receipt of a COVID-19 vaccine dose will be excluded from the analysis. VE will be calculated using statistical methods appropriate for a retrospective cohort study. The primary outcome will be lab-confirmed SARS-CoV-2 infection. We will conduct this analysis in collaboration with partners in the Connecticut Department of Public Health and Emerging Infections Program.

Secondary analyses may include calculating VE of 2 doses compared with 0 doses against SARS-CoV-2 infection stratified by (1) symptomatic and asymptomatic cases and (2) hospitalized and non-hospitalized cases if sample size permits.

### **Ethical Considerations**

This activity was reviewed by CDC and will be conducted consistent with applicable federal law and CDC policy. The Humans Subjects Protection Office at CDC has determined this investigation to be public health surveillance and therefore no informed consent is required. In the event residents or their proxies are contacted to verify vaccination history, verbal consent will be obtained prior to conducting the interview. Risks to individuals include disclosure of personal identifying information (PII). To safeguard against disclosure of PII, all data will be collected using a unique identifier and PII will be de-identified. Paper abstraction forms will be maintained under lock and key. Data will be presented in aggregate and devoid of any personal identifiers.