

# COVID-19 Vaccine Breakthrough Case Investigation and Reporting



This page provides information and resources to help **public health departments** and **laboratories** investigate and report COVID-19 vaccine breakthrough cases.

- **[Vaccine breakthrough cases](#) are expected.** COVID-19 vaccines are effective and are a critical tool to bring the pandemic under control. However, no vaccines are 100% effective at preventing illness in vaccinated people. There will be a small percentage of fully vaccinated people who still get sick, are hospitalized, or die from COVID-19.
- [More than 115 million](#) people in the United States have been fully vaccinated as of May 10, 2021. Like with other vaccines, vaccine breakthrough cases will occur, even though the vaccines are working as expected. Asymptomatic infections among vaccinated people will also occur.
- There is some evidence that vaccination may make illness less severe for those who are vaccinated and still get sick.
- Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most SARS-CoV-2 [variants](#) currently circulating in the United States. However, variants will cause some vaccine breakthrough cases.

## What CDC is doing

CDC is leading multiple [vaccine effectiveness studies](#) to ensure COVID-19 vaccines are working as expected. In addition, CDC is coordinating with [state and local health departments to investigate SARS-CoV-2 infectionspdf icon](#) among people who received COVID-19 vaccine (called “vaccine breakthrough cases”) and identify patterns or trends in:

- Patients' characteristics, such as age or underlying medical conditions
- The specific vaccine that patients received
- Whether a specific SARS-CoV-2 variant caused the infections

## Defining a vaccine breakthrough infection

For the purpose of this surveillance, a vaccine breakthrough infection is defined as the detection of SARS-COV-2 RNA or antigen in a respiratory specimen collected from a person  $\geq 14$  days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.

## Identifying and investigating hospitalized or fatal vaccine breakthrough cases

As of May 1, 2021, CDC transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating only hospitalized or fatal cases due to any cause. This shift will help maximize the quality of the data collected on cases of greatest clinical and public health importance.

[Previous case counts](#), which were last updated on April 26, 2021, are available for reference only and will not be updated moving forward. State health departments report vaccine breakthrough cases to CDC. CDC now monitors reported hospitalized or fatal vaccine breakthrough cases for clustering by patient demographics, geographic location, time since vaccination, vaccine type, and SARS-CoV-2 lineage. Reported data include hospitalized or fatal breakthrough cases due to any cause, including causes not related to COVID-19.

To the fullest extent possible, respiratory specimens that test positive for SARS-CoV-2 RNA are collected for genomic sequencing to identify the virus lineage that caused the infection.

Some health departments may continue to report all vaccine breakthrough cases to the national database and can continue to submit specimens to CDC

for sequencing. However, CDC will focus its monitoring on reported hospitalized and fatal cases.

## Developing a data access and management system for reporting COVID-19 vaccine breakthrough cases

CDC developed a national COVID-19 vaccine breakthrough REDCap database where designated state health department investigators can enter, store, and manage data for cases in their jurisdiction. State health departments have full access to data for cases reported from their jurisdiction.

Ultimately, CDC will use the [National Notifiable Diseases Surveillance System \(NNDSS\)](#) to identify vaccine breakthrough cases. Once CDC has confirmed that a state can report vaccination history data to NNDSS, CDC will identify vaccine breakthrough cases through that system. At that time, the state health departments can stop reporting cases directly into the REDCap database. After this change, CDC will upload the available data reported to NNDSS into REDCap database for further review and confirmation by the state health department.

## Hospitalized or fatal COVID-19 vaccine breakthrough cases reported to CDC as of May 10, 2021

As of May 10, 2021, [more than 115 million people](#) in the United States had been fully vaccinated against COVID-19. During the same time, CDC received reports from 46 U.S. states and territories of vaccine breakthrough cases in patients who were hospitalized or died.

Total number of vaccine breakthrough infections reported to CDC

<b>Hospitalized or fatal vaccine breakthrough cases reported to CDC</b>
Female
People aged ≥65 years
Asymptomatic infections
Hospitalizations*
Deaths†

\*342 (30%) of 1,136 hospitalizations reported as asymptomatic or not related to COVID-19.

†42 (18%) of 223 fatal cases reported as asymptomatic or not related to COVID-19.

Previous data on all vaccine breakthrough cases reported to CDC from January–April 2021 are [available](#).

## How to interpret these data

The number of COVID-19 vaccine breakthrough infections reported to CDC likely are an undercount of all SARS-CoV-2 infections among fully vaccinated persons. National surveillance relies on passive and voluntary reporting, and data might not be complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases.

Data on patients with vaccine breakthrough infection who were hospitalized or died will be updated regularly. Studies are being conducted in multiple U.S. sites that will include information on all vaccine breakthrough infections regardless of clinical status to supplement the national surveillance.

## COVID-19 vaccines are effective

- Vaccine breakthrough cases occur in only a small percentage of vaccinated people. To date, no unexpected patterns have been identified in the case demographics or vaccine characteristics among people with reported vaccine breakthrough infections.
- COVID-19 vaccines are effective. CDC recommends that everyone 12 years of age and older get a COVID-19 vaccine as soon as they can.
- Based on what we know about COVID-19 vaccines, [people who have been fully vaccinated](#) can start to do some things they had stopped doing because of the pandemic.

For local health departments, healthcare providers, and clinical laboratories

For state health departments

How to send CDC sequence data or respiratory specimens from suspected vaccine breakthrough cases

Resources to support submitting breakthrough case data to CDC

- [COVID-19 vaccine breakthrough case investigation form pdf icon](#)[2 pages]
- [Information for laboratories COVID-19 vaccine breakthrough case investigation pdf icon](#)[2 pages]
- [Information for state and local health departments COVID-19 vaccine breakthrough case investigation pdf icon](#)[2 pages]

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- [Public health investigations of COVID-19 vaccine breakthrough cases protocol pdf icon](#)[10 pages]

For more information on COVID-19 breakthrough cases:

- [What You Should Know About the Possibility of COVID-19 Illness After Vaccination](#)
- [Previous COVID-19 Breakthrough Case Data](#)

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