


# 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 164 million** people in the United States have been fully vaccinated as of August 2, 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 infections**  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 data on all vaccine breakthrough cases reported to CDC from January–April 2021 are [available](#).

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 August 2, 2021

As of August 2, 2021, [more than 164 million people](#) in the United States had been fully vaccinated against COVID-19.

During the same time, CDC received reports from 49 U.S. states and territories of 7,525 patients with COVID-19 vaccine breakthrough infection who were hospitalized or died.

Hospitalized or fatal vaccine breakthrough cases reported to CDC	7,525	
Female	3,615	(48%)
People aged ≥65 years	5,557	(74%)
Asymptomatic infections	1,347	(18%)
Hospitalizations*	7,101	(94%)
Deaths†	1,507	(20%)

\*1,816 (26%) of 7,101 hospitalizations reported as asymptomatic or not related to COVID-19.

†316 (21%) of 1,507 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.
- People who have been [fully vaccinated](#) can resume activities that they did prior to the pandemic.

## For local health departments, healthcare providers, and clinical laboratories

- CDC encourages local health departments, healthcare providers, and clinical laboratories that identify a COVID-19 vaccine breakthrough case to:
  - Request the respiratory specimen be held for further testing.
  - Report the case to the state health department where the individual resides for further investigation and reporting to the national system.
- COVID-19 vaccine breakthrough cases that result in hospitalization or death should be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#) [↗](#).


## For state health departments

- If a possible vaccine breakthrough case is identified:
  - Request that the clinical or public health laboratory hold any residual respiratory specimens from the positive SARS-CoV-2 test.
  - Report the available case data to NNDSS, per normal procedures.
  - Review CDC's screening questions to assess whether the case meets the COVID-19 vaccine breakthrough investigation criteria.
- If the reported case meets those criteria, CDC encourages state health departments to:
  - Follow the steps for initiating a COVID-19 vaccine breakthrough case investigation.
  - Record the case in the COVID-19 vaccine breakthrough REDCap database.
- Because CDC would like to characterize the SARS-CoV-2 lineages responsible for COVID-19 vaccine breakthrough cases, including variants:
  - Report sequence results from a state public health laboratory, commercial reference laboratory, or academic laboratory by entering the PANGO lineage and GenBank or GISAID accession number into the COVID-19 vaccine breakthrough REDCap database.
  - If SARS-CoV-2 sequencing will not be performed locally and an acceptable clinical respiratory specimen is available, provide instructions for the testing laboratory to send the residual respiratory specimen to CDC.
  - For cases with a known RT-PCR cycle threshold (Ct) value, submit only specimens with Ct value  $\leq 28$  to CDC for sequencing. (Sequencing is not feasible with higher Ct values.)
  - If the Ct value is not known (e.g., positive by antigen test only or by a molecular test that does not provide a Ct value), the positive specimen may still be submitted to CDC for RT-PCR and possible sequencing.

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

- CDC would like to receive sequence data and respiratory specimens from COVID-19 vaccine breakthrough cases to assess the SARS-CoV-2 lineage, including variants. When a vaccine breakthrough case is identified, the health department will contact the laboratory to request that any residual respiratory specimen from the positive test be held for sequencing at CDC.
- The health department also will request the specimen ID numbers and the Ct value for positive RT-PCR results.
- If SARS-CoV-2 sequencing will not be performed locally and a specimen is available, the state public health laboratory should request the residual clinical respiratory specimen for subsequent shipping to CDC.
  - For cases with a known RT-PCR cycle threshold (Ct) value, submit only specimens with Ct value  $\leq 28$  to CDC for sequencing.

sequencing.

- If the Ct value is not known (e.g., positive by antigen test only or by a molecular test that does not provide a Ct value), the positive specimen may still be submitted to CDC for RT-PCR and potential sequencing.
- If your laboratory identifies a COVID-19 vaccine breakthrough case, please report it to your state health department so it can initiate the investigation with CDC.
- These instructions can also be found here: [NS3 Submission Guidance Documents](#) .

## Resources to support submitting breakthrough case data to CDC

[COVID-19 vaccine breakthrough case investigation form](#)  [2 pages]

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

For more information on COVID-19 breakthrough cases:

- [What You Should Know About the Possibility of COVID-19 Illness After Vaccination](#)
- [COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021](#)

Page last reviewed: August 5, 2021