

Transitioning national COVID vaccine breakthrough surveillance to focus on hospitalized and fatal cases

Starting May 1, CDC will transition from monitoring all reported COVID-19 vaccine breakthrough infections to identifying and investigating only vaccine breakthrough cases that result in hospitalization or death.

Rationale

- Given the large number of people being vaccinated in the United States and the high level of ongoing SARS-CoV-2 circulation, thousands of symptomatic vaccine breakthrough cases are expected even if the vaccines remain as effective as demonstrated during the clinical trials.
- Most vaccine breakthrough infections are asymptomatic or result in mild illnesses. Focusing on hospitalized and fatal vaccine breakthrough cases will help maximize the quality of the data collected on cases of greatest clinical and public health importance.
- Special studies are being conducted in multiple U.S. sites that will include vaccine breakthrough cases with milder illness and supplement the national surveillance data.

Transitioning

- Beginning May 1, CDC suggests that state and territorial health departments transition to reporting only vaccine breakthrough cases among persons who are hospitalized or die to the national REDCap vaccine breakthrough database.
- Given difficulties assessing causality, we request that you report all vaccine breakthrough infections that meet the case definition and occur among people who are hospitalized or die.
 - Questions regarding relatedness or causality are included in the database and can be used to clarify the relationship between the infection and hospitalization or death.
 - When available, we also ask that death certificates be uploaded for fatal cases, including previously identified deaths, to allow for a more standardized review.
- State and territorial health departments should continue to report the hospitalized and fatal cases into the existing national REDCap vaccine breakthrough database.
 - Some health departments may continue to report all vaccine breakthrough infections to the national database and can continue to submit specimens to CDC for sequencing. However, CDC will focus monitoring on reported hospitalized and fatal cases.
- Ultimately, CDC will use the [National Notifiable Diseases Surveillance System \(NNDSS\)](#) to identify vaccine breakthrough cases. At that time, the state health department can stop reporting cases directly into the national vaccine breakthrough REDCap database. CDC will upload the available data reported to NNDSS into the REDCap database for further review.
- More information at <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>

Vaccine breakthrough case definition

U.S. resident who has SARS-CoV-2 RNA or antigen detected on respiratory specimen collected ≥ 14 days after completing the primary series of an FDA-authorized COVID-19 vaccine.

Cases of heightened public health interest

A vaccine breakthrough case among persons who are hospitalized or die within 2 weeks of their SARS-CoV-2 positive test or as a result of COVID-19 disease after being fully vaccinated.