# COVID-19 Vaccine Breakthrough Case Investigation and Reporting

Updated June 23, 2022

## Technical Guide for Public Health Departments: Reporting and Analyzing COVID‑19 Cases by Vaccination Status

Since the beginning of the COVID-19 pandemic, many health departments have developed the capacity to routinely link COVID-19 case surveillance and immunization information system (IIS) data to monitor cases and deaths by vaccination status. This page provides information and resources to help **public health departments** report rates of COVID-19 cases and deaths according to vaccination status. It also provides guidance to health departments that are interested in reporting their data to CDC. COVID-19-associated hospitalizations by vaccination status are reported separately though the Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET).

Learn more about CDC's general information on COVID-19 case reporting.

On this page:

- How CDC works with health departments to monitor COVID-19 cases and deaths by vaccination status
- How to report COVID-19 data by vaccination status to CDC
- Best practices for analyzing patterns of COVID-19 according to vaccination status
- CDC definitions for analyzing COVID-19 cases and deaths by vaccination status

## How CDC works with health departments to monitor COVID‑19 cases and deaths by vaccination status

CDC collaborates with health departments that actively link immunization and case data to monitor rates of COVID-19 cases and deaths by vaccination status, including booster doses. Participating health departments voluntarily report their surveillance data to CDC. CDC analyzes the data and displays them as incidence rates and rate ratios on the COVID Data Tracker, which is updated monthly. CDC uses incidence rate ratios rather than percentage of vaccinated people among COVID-19 cases to display the data, because research has shown that rate ratios are more stable and directly related to vaccine effectiveness (see more under Best Practices below).

CDC analyzes surveillance data by vaccination status to:

- Monitor the impact of COVID-19 vaccination on rates of infection and death.
- Better understand patterns of COVID-19 among people who are vaccinated and unvaccinated.

Analyses of surveillance data can provide signals of potential changes in vaccine effectiveness. These signals can be confirmed through more robust, controlled vaccine effectiveness studies, which are ongoing at CDC.

# How to report COVID–19 data by vaccination status to CDC

Health departments that have created and validated data linkages between COVID-19 case surveillance and their IIS and would like to participate in the network of jurisdictions reporting their data to CDC should reach out to eocevent531@cdc.gov.

> To be included in routine aggregate analyses posted on CDC's COVID Data Tracker, a health department must be able to:
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> - Routinely link COVID-19 surveillance data to vaccination history data in IIS to allow accurate assessment of the vaccination status among people who test positive for SARS-CoV-2, the virus that causes COVID-19.
> - Identify cases in partially vaccinated people for exclusion or separate analyses.

Most health departments also have the ability to link to vital registration systems to confirm deaths due to COVID-19. However, health departments that are unable to link to vital registration systems can still report COVID-19 case data by vaccination status to CDC.

Currently, health departments may share COVID-19 case data with vaccine history to CDC via one of three data streams (in descending order of CDC preference):

1. Include data elements for vaccination history and positive specimen collection date with routine case data notifications to CDC using the COVID-19 Message Mapping Guide (MMG) through the National Notifiable Diseases Surveillance System (NNDSS), or by submitting the COVID-19 CSV reporting template.
2. Provide line-listed data for a limited set of data elements on cases and deaths among people vaccinated with a primary series with or without booster doses AND aggregate data on cases and deaths in partially vaccinated and unvaccinated people through monthly data upload to the Secure Access Management Service (SAMS).
3. Provide only aggregate data on COVID-19 cases and deaths according to vaccination status on a monthly basis directly through SAMS.

CDC is also interested in receiving sequence data on SARS-CoV-2 lineage among cases in people vaccinated with a primary series, with and without booster doses. If SARS-CoV-2 sequencing will not be performed locally and a specimen is available, the state public health laboratory can request that the residual clinical respiratory specimen be shipped to CDC. See instructions for submission and shipment of specimens for sequencing ⬚ to CDC.

# Best practices for health departments analyzing patterns of COVID–19 according to vaccination status

CDC reports **incidence rate ratios (IRRs)** rather than the percentage of vaccinated people among COVID-19 cases, hospitalizations, and deaths. An analysis published in *MMWR* demonstrated that IRRs are more stable and directly related to vaccine effectiveness, while the percentage of vaccinated people among COVID-19 cases rises with either increasing vaccination coverage or decreasing vaccine effectiveness. Interpretation of the proportion of vaccinated people among hospitalized and fatal cases may be further complicated in certain groups, such as older adults and people with comorbidities who have both higher risks of severe COVID-19 outcomes and higher vaccination coverage.

> **Best practices for accurate interpretation of cases, hospitalizations, and deaths by vaccination status**
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> - Limit analyses to the age groups that were vaccine-eligible during the analysis period. Failure to do so will result in comparing populations of vaccinated and unvaccinated people who have different age-related risks.
> - Exclude people who are partially vaccinated or analyze them separately, rather than combining them with people who are either fully vaccinated or unvaccinated, which would change rates and likely reduce IRRs.
> - Perform age-specific or age-standardized analyses to account for the different vaccination coverage levels and risks of infection, hospitalization, and death by age group.

- Perform analyses by week or month to account for changing vaccination coverage and disease incidence over time and to clarify changes in vaccine impact over time (e.g., related to emerging variants, waning population immunity).

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Published examples include: ⌄

- Johnson AG, Amin AB, Ali AR, et al. COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021. *MMWR Morb Mortal Wkly Rep* 2021;71:132–8. http://dx.doi.org/10.15585/mmwr.mm7104e2 ⧉
- Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1284–90. http://dx.doi.org/10.15585/mmwr.mm7037e1 ⧉
- Havers FP, Pham H, Taylor CA, et al. COVID-19–associated hospitalizations among vaccinated and unvaccinated adults ≥18 years—COVID-NET, 13 states, January 1–July 24, 2021. *medRxiv* [Preprint posted online August 29, 2021]. https://www.medrxiv.org/content/10.1101/2021.08.27.21262356v1 ⧉
- Rosenberg ES, Holtgrave DR, Dorabawila V, et al. New COVID-19 Cases and Hospitalizations Among Adults, by Vaccination Status — New York, May 3–July 25, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1150-5. http://dx.doi.org/10.15585/mmwr.mm7034e1 ⧉
- Griffin JB, Haddix M, Danza P, et al. SARS-CoV-2 infections and hospitalizations among persons aged ≥16 years, by vaccination status—Los Angeles County, California, May 1–July 25, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1170–6. https://doi.org/10.15585/mmwr.mm7034e5 ⧉

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**We note that several factors likely affect crude case rates by vaccination and booster dose status, which can challenge interpretation.**

Limitations include:

- Differences in the prevalence of previous infection among the unvaccinated and un-boosted groups.
- Variation in time since vaccination and waning protection.
- Differences in testing practices (such as at-home tests) and prevention behaviors by age and vaccination status.
- Variable data linkage completeness that might have resulted in misclassifications (e.g., booster doses not being linked to primary series).

# Definitions for COVID-19 cases and deaths by vaccination status

CDC uses the following definitions of COVID-19 cases by vaccination status for surveillance or analysis purposes. See CDC's recommendations for staying up to date on vaccination. For clinical considerations around COVID-19 vaccine primary series and booster vaccination, please see CDC's Interim Clinical Considerations.

**Vaccinated case with a primary series:** SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected ≥14 days after verifiably completing the primary series of an FDA-authorized or approved COVID-19 vaccine.

**Vaccinated case with a first additional/booster dose:** SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected in a person verified to have received a primary series and ≥14 days after receipt of one additional dose of any COVID-19 vaccine on or after August 13, 2021. (Note: this definition does not distinguish between vaccine recipients who are immunocompromised and are receiving an additional dose versus those who are not immunocompromised and receiving a booster dose.)

**Vaccinated case with a second additional/booster doses:** SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected in a person verified to have received a primary series and ≥14 days after receipt of two or more additional doses of any COVID-19 vaccine on or after August 13, 2021. (Note: this definition does not distinguish between vaccine recipients who are immunocompromised and are receiving an additional dose versus those who are not immunocompromised and receiving a booster dose.)

**Partially vaccinated case:** SARS-CoV-2 RNA or antigen detected in a respiratory specimen collected from a person who received at least one FDA-authorized or approved vaccine dose but did not complete a primary series ≥14 days before collection of a respiratory specimen with SARS-CoV-2 RNA or antigen detected.

**Unvaccinated case:** SARS-CoV-2 RNA or antigen detected in a respiratory specimen from a person who has not been verified to have received any COVID-19 vaccine doses before the specimen collection date.

**COVID-19-associated death:** Persons with a documented COVID-19 diagnosis who died and whose report the health department reviewed (e.g., using vital records, public health investigation, case interview, healthcare provider interview, medical record review, death certificate, autopsy) to make that determination. Per the interim guidance of the Council of State and Territorial Epidemiologists (CSTE), 🅿 ↗ this should include persons whose death certificate lists COVID-19 disease or SARS-CoV-2 as an underlying cause of death or as a significant condition contributing to death.

For more information on COVID-19 breakthrough cases and vaccine effectiveness:

- What You Should Know About the Possibility of COVID-19 Illness After Vaccination
- Rates of COVID-19 Cases and Deaths by Vaccination Status
- Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status
- COVID-19 Vaccine Effectiveness Research
- Monitoring COVID-19 Vaccine Effectiveness

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