

## COVID-19 Vaccine Breakthrough Reporting

COVID-19 investigation protocols change as new information and new resources become available. Please check the Washington State Department of Health website for the most current guidance on [SARS-CoV-2 vaccine breakthrough reporting](#).

### Background

A vaccine breakthrough case is defined as an individual with laboratory evidence of SARS-CoV-2 infection (detection of SARS-CoV-2 RNA or SARS-CoV-2 specific antigen), where the positive respiratory specimen was collected  $\geq 14$  days after completion of a primary vaccination series of an FDA-authorized COVID-19 vaccine.

Timely and thorough information on vaccine breakthrough cases is critical to our understanding of clinical and epidemiological implications of vaccine breakthrough, such as vaccine performance in persons with weakened immune systems, issues of vaccine degradation, and the potential for waning vaccine-induced immunity, as well as the impact of variants and their potential to bypass immunity provided by vaccines.

Washington State Department of Health (WA DOH) conducts surveillance for all vaccine breakthrough cases; however, WA DOH provides aggregate data on cases and deaths by week, age group, vaccination status, and vaccine product to the Centers for Disease Control & Prevention (CDC), which is included in the [CDC Vaccine Effectiveness & Breakthrough Surveillance dashboard](#). Only vaccine breakthrough cases with confirmed and probable case definitions are included in the WA DOH vaccine breakthrough reporting metrics.

### Case Evaluation

#### *Case Definition*

#### **Confirmed:**

SARS-CoV-2 RNA detected via a molecular amplification detection test or by sequencing results on a respiratory specimen **and** specimen collection date was  $\geq 14$  days after completing the primary series of an FDA-authorized vaccine

#### **Probable:**

Positive SARS-CoV-2 antigen test on a respiratory specimen **and** specimen collection date was  $\geq 14$  days after completing the primary series of an FDA-authorized vaccine

A case will be excluded from further investigation if any of the following is true:

- The case defining COVID-19 vaccination series included a vaccine that is not authorized or approved by the FDA or an age-appropriate CVX code (e.g., the case received only AstraZeneca and did not complete an FDA-approved/authorized vaccine series);
- The respiratory specimen that was positive for SARS-CoV-2 RNA or specific antigen was collected <14 days after completing the primary case defining vaccination series;
- The intervals between administered vaccines are too short (e.g., <17 days for Pfizer, <24 days for Moderna);
- Dates of administration are not available for administered vaccines;
- The case individual is not a Washington resident (e.g., non-US residents, residents of other US states or territories, or residents of tribal territories);
- Test results considered “false positive” based on subsequent negative results; and/or
- Test results corrected from positive to negative by laboratories.

Vaccination status at time of positive test can be found in both the WDRS “Clinical and Laboratory” Question Package and the Extended Variables Wizard in WDRS under the question: “Vaccination status at positive test”. Breakthrough cases will have the value “Completed primary series” for this variable. The VPD team will be updating this variable on a weekly basis. For a complete list of breakthrough cases by jurisdiction, you can also run the COVID-19 Vaccination Status Report in WDRS.

Previous breakthrough case classifications, defined by criteria that is no longer applied, are located in the “Clinical and Laboratory” Question Package (not in the Extended Variables Wizard): “Did the case meet COVID-19 vaccine breakthrough case definition?”. This variable is no longer being updated, as of June 28<sup>th</sup>, 2022.

## Reporting

### *Case Ascertainment*

Case ascertainment matches positive SARS-CoV-2 labs reported via the Washington Disease Reporting System (WDRS) to COVID-19 vaccine doses reported via the Washington Immunization Information System (WAIS). This process uses the following demographic information to find matches between the two data systems: first name, last name, middle initial, date of birth, sex at birth, phone number, and zip code. It identifies matches even when there are slight variations in the spelling of names or small errors in other demographic information, allowing more robust matching. Criteria used are:

- Has completed the full series of an approved, age-appropriate COVID-19 vaccine

- Fourteen days or more ( $\geq 14$  days) between positive SARS-CoV-2 test (PCR or antigen) and the last date of the series defining vaccine dose
- Appropriate minimum intervals documented between doses (e.g.,  $\geq 17$  days for Pfizer,  $\geq 24$  days for Moderna)
- Accountable county for the associated Coronavirus event in WDRS is not WA-99 (DOH OCDE)

Cases are excluded using these criteria so that those identified through active case ascertainment are guaranteed to be true breakthrough cases. Matching will be completed twice a week; vaccination status will be updated in WDRS by the end of the week. Linkages should be identified within three business days of positive lab entry or import into WDRS

## Contact information

If you have any questions about reporting, feel free to reach us:

By phone – 206-418-5500 (Monday through Friday, 8:00 a.m. – 5:00 p.m.)

By email – [vpd-cde@doh.wa.gov](mailto:vpd-cde@doh.wa.gov)

## Additional Resources

[WA DOH SARS-CoV-2 Vaccine Breakthrough Surveillance and Case Information Resource \(PDF\)](#)  
(updated monthly)

[SARS-CoV-2 Sequencing and Variants in Washington State report \(PDF\)](#) (updated monthly)

[WA DOH List of Notifiable Conditions](#)

[WA DOH COVID-19 Vaccine Breakthrough](#)

[CDC COVID-19 Vaccine Breakthrough Case Investigation and Reporting](#)

## COVID-19 Vaccine Breakthrough FAQ

### Active Case Ascertainment

*Q: What is the active case ascertainment process?*

Active case ascertainment for COVID-19 vaccine breakthrough cases is done by matching positive SARS-CoV-2 labs reported via the Washington Disease Reporting System (WDRS) to COVID-19 vaccine doses reported via the Washington Immunization Information System

(WAIS). WA DOH evaluations of this surveillance method have demonstrated that it identifies most vaccine breakthrough cases (at least 90 percent) occurring among state residents. However, it is important to be aware that some COVID-19 vaccine doses administered in Washington are not documented in WAIS. Examples of vaccinators that do not enter doses into WAIS are the military, the Veterans Administration, and some tribes. The active case ascertainment process finds matches between WDRS SARS CoV-2 labs and WAIS vaccine data using the following demographic information: first name, last name, middle initial, date of birth, sex at birth, phone number, and zip code. Criteria used are:

- Has completed the full series of an approved, age-appropriate COVID-19 vaccine
- Fourteen days or more ( $\geq 14$  days) between the collection date for the positive SARSCoV-2 test and last date of the series defining vaccine dose
- Only one documented dose for Janssen (Johnson & Johnson) vaccine OR only two documented doses for Pfizer or Moderna vaccine
- Appropriate intervals documented between doses (e.g.,  $\geq 17$  days for Pfizer,  $\geq 24$  days for Moderna)
- Accountable county is not WA-99 (DOH OCDE)

***These breakthrough case criteria and matching criteria may change over time to identify additional cases.***

*Q: How often will case classifications for vaccine breakthrough be updated in WDRS?*

Matching as described above will be completed twice a week on Tuesdays and Thursdays (excluding State Observed Holidays); vaccination status will be updated in WDRS by the end of the week. Linkages should be identified within three business days of positive lab entry or import into WDRS.

*Q: Are suspect cases (i.e., cases identified through at-home antigen testing) included in the DOH vaccine breakthrough metrics reporting?*

No. Cases identified through home testing are not included in Washington COVID-19 metrics on the state dashboard nor for vaccine breakthrough metrics.

*Q: Are epi-linked probable cases included in vaccine breakthrough metrics?*

No. Only cases that have tested positive either via PCR or antigen are included in vaccine breakthrough metrics.

*Q: How are reinfections that are also vaccine breakthrough cases accounted for?*

The following criteria are used to distinguish a new case from an existing case (i.e., distinguishing a reinfection):

- SARS-CoV-2 sequencing results from the new positive specimen and a positive specimen from the most recent previous case demonstrate a different lineage, OR
- Person was most recently enumerated as a confirmed or probable COVID-19 case with onset date (if available) or first positive specimen collection date for that classification >90 days prior, OR
- Person was previously reported but not enumerated as a confirmed or probable COVID-19 case (i.e., suspect), but now meets the criteria for a confirmed or probable COVID-19 case.

As of September 2021, cases meeting this reinfection definition will have new Coronavirus events created in WDRS in addition to their first Coronavirus event. If a case meets vaccine breakthrough case criteria, the vaccine breakthrough case classification will be added to whichever event(s) contain the breakthrough case defining positive lab result in WDRS.

Additional detail on distinguishing a new case from an existing case can be found in the [WA DOH Reinfection Investigation Protocol](#).

## Supplementary Passive Reporting

*Q: Are reports of vaccine breakthrough cases from LHJ passive reporting still accepted?* No, the Vaccine Breakthrough Team will no longer be accepting LHJ reported breakthrough cases. All breakthrough cases classified in WDRS are solely identified by our active case ascertainment linkage process.

*Q: Are reports of vaccine breakthrough cases from CREST still accepted?*

No, the Vaccine Breakthrough Team will no longer be receiving and reviewing vaccine breakthrough identified through CREST. Data from CREST typically only include verbal accounts of vaccinations, approximate dates of administration, and occasionally the type of vaccine administered. These data are self-reported, often incomplete, and are lacking the verification required to be included in Washington state metrics for vaccine breakthrough. Consequently, most reports of vaccine breakthrough cases received from CREST provide insufficient information to include the case in Washington state metrics. We expect that active case

ascertainment will capture most true breakthrough cases whose self-reported vaccination information is present in CREST.

LHJs wishing to continue capturing vaccine breakthrough reports via CREST for their own surveillance may continue to do so; however, these data will not be used by the DOH Vaccine Breakthrough for breakthrough surveillance. A specific view in CREST is available to LHJs wishing to see self-reported breakthrough cases captured via case investigations documented in CREST assessments. For access to that view please submit a request for access here: [CREST LHJ Help Request Submission Form](#).

*Q: What are some examples of vaccine information sources that won't be included in the active case ascertainment process?*

Vaccines administered through federal entities such as the Veterans Administration, federal corrections, the military, IHS and certain tribal entities, etc. may not be available in WA IIS. Individuals with vaccination information from these sources likely will not be captured through active case ascertainment. Additionally, cases with vaccines administered outside of Washington are not likely to be captured through active case ascertainment. If support is needed to verify doses given out-of-state, please reach out to the DOH Vaccine Breakthrough Team.

*Q: How can an LHJ that maintains their own internal vaccine breakthrough case list identify which cases were captured with active case ascertainment by DOH?*

For LHJs maintaining their own surveillance for vaccine breakthrough cases, cross referencing the classification assigned by DOH in the "Vaccination status at positive test" variable in WDRS will help to identify which cases were not captured by the active case ascertainment process.

## Miscellaneous

*Q: Will DOH continue to retrieve specimens from labs for all vaccine breakthrough cases for sequencing?*

No. Vaccine breakthrough cases were prioritized for whole genome sequencing from January 17, 2021 through September 9, 2021 to ensure that the distribution of variants detected among breakthrough cases could be continually monitored. Beginning September 10, 2021, sequencing for breakthrough cases is now part of random sampling by sentinel surveillance laboratories across the state.

For general whole genome sequencing questions, please reach out to: [wgs-epi@doh.wa.gov](mailto:wgs-epi@doh.wa.gov)

*Q: What are reporting requirements per 2023 WAC revisions?*

Health care provider and Health care facilities: none

Laboratories: none

## Updates

December 2022: Updated reporting for 2023 WAC revision

August 2022:

- Updated case ascertainment sections with a new breakthrough case definition that is standardized across DOH teams.
- Added information on the new vaccination status variable, “Vaccination status at positive test”, in WDRS, which is based on the new case definition implemented in June 2022.
- Updated the methodology used to link WDRS COVID cases to WAIS immunizations data.
- Updated the Supplementary Passive Reporting section.
- Removed “Appendix A: Vaccine Breakthrough Case Classifications in WDRS and Inclusion Vaccine Breakthrough Report” since it referred to a WDRS variable that is no longer in use by the DOH Vaccine Breakthrough team.

October 2021:

- Clarified confirmed and probable vaccine breakthrough case definitions.
- Added detail for active case ascertainment and passive reporting of COVID-19 reinfection cases in guidance and FAQ.
- Noted changes to prioritization of vaccine breakthrough specimens for whole genome sequencing.
- Clarified lack of requirement of vaccine documentation in WDRS for passive reporting.
- Updated classification used when vaccine documentation is missing from “Under investigation (pending)” to “Vaccine documentation incomplete/missing”.
- Added detail on exclusion criteria for false positives and lab results corrected from positive to negative.
- Added Appendix A to outline details of various breakthrough classifications in WDRS.

**September 2021:**

- Added clarifications to timeline for case classifications identified through active case ascertainment. Added link to CREST/SARA Help Log for CREST view requests.