

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

Timely and thorough information on vaccine breakthrough cases is critical to our understanding of the clinical and epidemiological implications of vaccine breakthrough, including 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) attempts to capture information on all vaccine breakthrough cases; however, the Centers for Disease Control & Prevention (CDC) only request information be reported for hospitalized and/or deceased cases. Only vaccine breakthrough cases with confirmed and probable case definitions are included in the WA DOH vaccine breakthrough reporting metrics.

Case Evaluation

Case Definition

Detection of SARS-CoV-2 RNA or antigen on a respiratory specimen* ≥ 14 days after completing the primary series of an FDA-authorized COVID-19 vaccine (where date of final vaccine dose is counted as day zero)

AND

Has not had SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected < 90 days before the most recent positive test (see [WA DOH COVID-19 guidelines](#) for evaluation for potential re-infection)

*An acceptable respiratory specimen includes a nasal swab, nasal wash, nasopharyngeal swab, oropharyngeal swab, saliva, sputum, bronchoalveolar lavage fluid, pleural fluid, or lung tissue.

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

1. The case defining COVID-19 vaccination series included a vaccine that is not authorized or approved by the FDA (i.e., the case received only AstraZeneca and did not complete an FDA-approved/authorized vaccine series);
2. The respiratory specimen that was positive for SARS-CoV-2 RNA or antigen was collected <14 days after completing the primary series;
3. The intervals between administered vaccines are too short (<17 days for Pfizer, <24 days for Moderna);
4. Lot numbers and/or dates of administration are not available for administered vaccines;
5. The case is not a Washington resident;
6. The case was recently positive for COVID-19, defined as a positive test <90 days prior to the positive test currently under investigation.

Reporting

Active Case Ascertainment

Active case ascertainment matches positive COVID-19 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 (>90 percent) vaccine breakthrough cases occurring among state residents, and substantially (up to 70 percent) more cases than passive case reporting alone. This process currently captures only cases with exact matches between WDRS and the WAIS using name and date of birth, and with COVID-19 vaccine doses and time intervals appropriately noted. Criteria used are:

- Has completed the full series of an approved vaccine
- Fourteen days or more (≥ 14 days) between positive COVID 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
- Lot numbers are listed for all case-defining vaccine doses
- No mixed or multiple doses (> two doses of any vaccine) are part of WAIS record
- No positive COVID-19 lab prior to the breakthrough defining lab
- Appropriate intervals documented between doses (≥ 17 days for Pfizer, ≥ 24 days for Moderna)
- DOH case classification for the associated COVID-19 event in WDRS is not “Ruled Out” or “Not Reportable”
- Accountable county for the associated COVID-19 event in WDRS is not WA-99 (DOH OCDE)

Cases are being excluded using these criteria so that cases identified through active case ascertainment are guaranteed to be true breakthrough cases. Matching will be completed daily Monday through Friday; vaccine breakthrough case classifications for confirmed and probable cases will be updated in WDRS the following business day. Linkages should be identified within three business days of positive lab entry or import into WDRS.

Passive Reporting

Passive reports of vaccine breakthrough cases are encouraged to be reported by local health jurisdictions (LHJ) if an LHJ is aware of breakthrough cases in their jurisdiction that the active case ascertainment process has not identified. Cases not identified through active case ascertainment are likely to be individuals whose vaccine doses are not in the WAIS, such as those administered out of state, through the military, Veterans Administration, etc. These cases must meet strict criteria for consideration:

1. Documentation that case has completed the full series of an approved COVID-19 vaccine
- 2. Lot numbers and dates of administration for administered vaccines must be provided**
3. Fourteen days or more (≥ 14 days) between positive COVID-19 test and last date of the series defining vaccine dose
4. Completed series of an FDA-approved vaccine with appropriate intervals (≥ 17 days for Pfizer, ≥ 24 days for Moderna)
5. DOH COVID-19 event classification is not “Ruled Out” or “Not Reportable”
6. Case must be a Washington resident
7. Source of vaccine information must be provided by LHJ
 - a. If using WAIS record not captured through active case ascertainment, person must be verified using name and DOB (and address if necessary) to ensure issues with fuzzy matching are avoided and SIDS ID must be provided
 - b. If using vaccine card or medical record, attach copy of vaccine documentation to WDRS whenever possible; this copy should show all required information

Any case missing source of vaccine information or lot numbers, or otherwise unable to be verified, will be classified as “under investigation” and returned with a request for complete information or an explanation why information could not be obtained.

Vaccine breakthrough metrics reports are published each Wednesday and include cases with specimen collection dates through the week ending two Saturdays prior to the publication date. Passive reports must be received by Friday at 5:00 p.m. before the publication week in order to be included in that week’s report.

LHJs can [report securely via REDCap](#). All reports must be made via line list and uploaded to the REDCap link. Line list templates are available for download at this link or can be obtained by emailing vpd-cde@doh.wa.gov. Required information is noted in the line list template.

Reconciling DOH Case Reports with LHJ Surveillance

For LHJs maintaining their own surveillance for vaccine breakthrough cases, cross referencing the case classifications assigned by DOH will help to identify which cases were not captured by the active case ascertainment process.

To view all cases with a case classification populated for vaccine breakthrough (using the variable ‘Did the case meet COVID-19 vaccine breakthrough case definition?’ in the Clinical and Laboratory question package), run a report from WDRS using ‘COVID-19 response’ as the Category and ‘COVID-19 Vaccine Breakthrough Cases’ as the report name.

Washington Disease Reporting System Production (Maven 6.0.10 Beta 2.9) Enter Case ID or Search Term...

Maven Reporting

Maven Reporting

Category: COVID-19 response

Select Report: COVID-19 Vaccine Breakthrough Cases

Description: Report to pull all cases where there is a response for 'did the case meet COVID-19 vaccine breakthrough case definition', using 'positive defining lab date SARS' as the report period

Positive defining lab date FROM [Required]*: MM/DD/YYYY

Positive defining lab date TO [Required]*: MM/DD/YYYY

County [Required - Use CNTRL for multi-select]*: Adams County, Asotin County, Benton County, Chelan County, Clallam County

Output Type: HTML

This report has been configured to run on the reporting database.

LHJs can use this report to compare WDRS event IDs from this report to the WDRS event IDs of vaccine breakthrough from their own surveillance systems. *Note: some case classifications are marked as “Under Investigation” pending receipt of additional information from the LHJ, and thus do not have a final classification for vaccine breakthrough. Please ensure that all reported information is provided according to the passive reporting criteria stated above, as this will assist in the proper classification of cases listed as “Under Investigation”.*

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

Additional Resources

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

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

[WA DOH List of Notifiable Conditions](#)

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

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

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 ([Washington Relay](#)) or email civil.rights@doh.wa.gov.

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 COVID-19 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 only captures cases with exact matches between WDRS positive COVID-19 labs and the WAIS using name and date of birth, and with COVID-19 vaccine doses and time intervals appropriately noted. Criteria used are:

- Has completed the full series of an approved vaccine
- Fourteen days or more (≥ 14 days) between the collection date for the positive COVID 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
- Lot numbers are listed for all case-defining vaccine doses
- No mixed or multiple doses are part of WAIS record
- No positive COVID-19 lab prior to the breakthrough defining lab
- Appropriate intervals documented between doses (≥ 17 days for Pfizer, ≥ 24 days for Moderna)
- DOH case classification in WDRS event is not “Ruled Out” or “Not Reportable”
- Accountable county is not WA-99 (DOH OCDE)

These breakthrough case criteria and matching criteria might 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 daily Monday through Friday (excluding State Observed Holidays); vaccine breakthrough case classifications for confirmed and probable cases will be updated in WDRS the following business day. 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.

Supplementary Passive Reporting

Q: What is the purpose of supplementary passive reporting?

Supplementary passive reporting provides a means for LHJs to report vaccine breakthrough cases within their jurisdiction, when the LHJ is aware that the active case ascertainment process is not likely to successfully identify and classify these cases. This passive reporting is intended to capture cases whose vaccination information is traditionally absent from the state immunization registry (e.g., individuals with vaccinations administered through the Veterans Administration, some tribal health clinics, Indian Health Service, federal corrections, the military, or when the person was vaccinated outside of Washington state) as well as cases missed in active case ascertainment because of issues like name/DOB mismatches.

Q: What is the information DOH needs for supplementary passive reporting?

Vaccine breakthrough cases are not required to be reported by local health jurisdictions (LHJ); however, passive reports will be accepted if an LHJ is aware of breakthrough cases in their jurisdiction that the active case ascertainment process has not identified. These cases must meet strict criteria for consideration:

1. Documentation that case has completed the full series of an approved COVID vaccine
- 2. Lot numbers and dates of administration for administered vaccines must be provided**
3. Fourteen days or more (≥ 14) days must have passed from date of last vaccine administration to the specimen collection date of positive test
4. A positive COVID-19 test must be documented in WDRS
5. Completed series of an FDA-approved vaccine with appropriate intervals (≥ 17 days for Pfizer, ≥ 24 days for Moderna, no interval for Johnson & Johnson)
6. DOH COVID-19 event classification is not “ruled out” or “not reportable”
7. Case must be a Washington resident
8. Source of vaccine information must be provided by LHJ (acceptable sources include IIS, medical record, and vaccine card)
 - a. If using IIS record not captured through active case ascertainment, person must be verified using name and DOB (and address if necessary) to ensure issues with fuzzy matching are avoided and SIIS ID must be provided
 - b. If using vaccine card or medical record, attach copy of vaccine documentation to WDRS whenever possible

Any case missing source of vaccine information or lot numbers, or otherwise unable to be verified, will be classified as “under investigation” and returned with a request for complete information or an explanation why information could not be obtained.

Q: Why should LHJs report vaccine breakthrough cases to DOH?

It is important that COVID-19 Vaccine breakthrough is well understood in all parts of Washington and the United States. Vaccine recommendations and other policy decisions use breakthrough case surveillance data for decision making and it is important that breakthrough case distribution and case attributes are available to public health officials.

This is why a process for passive reporting of breakthrough cases to be accepted will be maintained. That way, if an LHJ is aware of breakthrough cases within their jurisdiction that the active case ascertainment process will not successfully identify and classify, it can still be included in breakthrough metrics for the state.

DOH recognizes that there may be discrepancies between counties in terms of percentage of vaccine breakthrough cases captured; however, analyses performed by DOH indicate the majority of vaccine breakthrough cases among Washington residents will be captured by active case ascertainment, including a substantial increase in case finding compared to passive case reporting alone.

Q: How do LHJs report vaccine breakthrough cases to DOH that have not been captured by the active case ascertainment process?

LHJs can [report securely via REDCap](#). All reports must be made via line list and uploaded to the REDCap link. Line list templates are available for download at this link or can be obtained by emailing vpd-cde@doh.wa.gov. Required information is noted in the line list template.

Q: When should LHJs report vaccine breakthrough cases to DOH that have not been captured by the active case ascertainment process?

Vaccine breakthrough cases can be reported to WA DOH the REDCap Vaccine Breakthrough Reporting Submission Form. Passive reports must be received by Friday at 5:00 p.m. before the publication week in order to be included in that week's report. Vaccine breakthrough metrics reports are published each Wednesday and include cases with specimen collection dates through the week ending two Saturdays prior to the publication date.

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 whether a person says they were vaccinated, approximate dates of administration, and sometimes 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, Excel line list templates submitted to DOH via REDCap **must contain verified vaccine information including lot numbers of administered vaccines**. LHJs should directly report these cases to DOH. Suggestions for reconciling LHJ

vaccine breakthrough surveillance with cases identified through the WA DOH active case ascertainment process are included below.

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/SARA Help Log \(smartsheet.com\)](https://smartsheet.com/crest/sara-help-log).

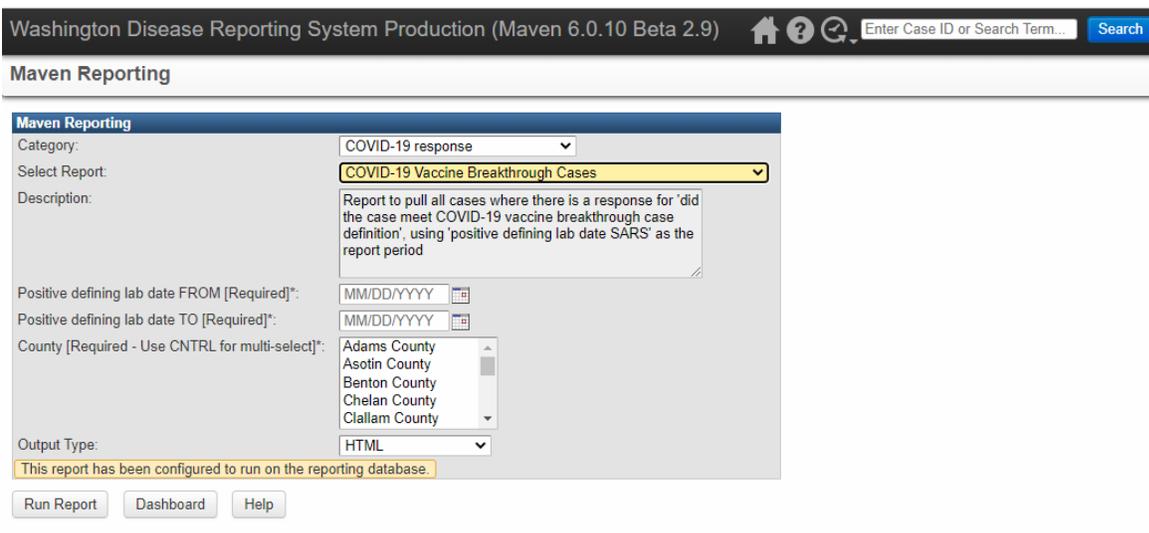
Q: What are some examples of vaccine information sources that won't be included in the active case ascertainment process?

Vaccines administered through federal entities such as the Veterans Administration, federal corrections, the military, certain tribal entities, etc. are generally not available in WA IIS and therefore will not be captured through active case ascertainment and would be candidates for supplementary passive reporting. Additionally, cases with vaccines administered out of Washington state not likely to be captured through active case ascertainment and would be candidates for supplementary passive reporting. 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 case classifications assigned by DOH in WDRS will help to identify which cases were not captured by the active case ascertainment process.

To view all cases with a case classification populated for vaccine breakthrough (using the variable 'Did the case meet COVID-19 vaccine breakthrough case definition?' in the Clinical and Laboratory question package), run a report from WDRS using 'COVID-19 response' as the Category and 'COVID-19 Vaccine Breakthrough Cases' as the report name.



LHJs can use this report to compare WDRS event IDs from this report to the WDRS event IDs of vaccine breakthrough from their own surveillance systems. *Note: some case classifications are marked as "Under Investigation" pending receipt of additional information from the LHJ, and thus do not have a final classification for vaccine breakthrough. For those cases to be properly*

classified, please ensure information is provided according to the passive reporting criteria stated above.

Q: Should vaccine breakthrough reports for suspect cases (i.e., cases identified through at-home antigen testing) be submitted to WA DOH?

No. Cases identified through home testing are not included in Washington COVID metrics, neither on the state dashboard nor for vaccine breakthrough metrics.

Q: Should vaccine breakthrough reports for epi-linked probable cases be made to WA DOH?

No. Only cases that have a positive SARS-CoV2 laboratory test result (either via PCR or antigen) can meet criteria for inclusion in vaccine breakthrough metrics.

Q: If an LHJ reports a vaccine breakthrough case based on a positive antigen test, and the case later becomes confirmed with a positive PCR test, should that information be updated by sending another report to DOH?

No, updates to laboratory information that affects COVID case classifications will be captured by DOH staff during other quality control processes; no other information is required once a case report containing all requested information has been submitted to DOH.

Miscellaneous

Q: How do we clear the vaccine breakthrough workflow for our county's cases?

The Vaccine Breakthrough Workflow in WDRS maxes out at 5,000 records. As a result, no new records can be added until more space is created by clearing records from the workflow. There are two ways to clear cases from an LHJ's workflow:

1. Check the box "Breakthrough reviewed by LHJ" in the Clinical and Laboratory Question Package, or
2. Check the box(es) next to reviewed cases in the workflow and then click the bulk action button "Breakthrough Reviewed" at the bottom of the workflow.

You may be able to request an LHJ-specific workflow for your own cases if you are actively using this workflow. Consider contacting DOH Agency COVID19 WDRS Developers at:

<COVID19WDRSDevs@doh.wa.gov> if you want to request a jurisdiction-specific workflow.

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

Yes; however, there are caveats. With increased testing volume locally and nationwide, many laboratories have decreased specimen retention periods, leading to missed opportunities for sequencing. Prompt reporting of breakthrough cases by LHJs will enable DOH staff to contact laboratories sooner.

Sentinel labs will continue to sequence all or a percentage of all eligible (Ct value[s] <30) positive tests. These sentinel labs include:

- Atlas Genomics
- Confluence Health
- Incyte Diagnostics
- Northwest Laboratories
- University of Washington

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

Updates

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.