COVID-19 vaccine breakthrough case investigations

Information for local health departments

Objective

Investigate SARS-CoV-2 infections among people who received COVID-19 vaccine to identify trends or clustering in patient characteristics, the administered vaccine, or the infecting virus.

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.

Exclusion criteria

SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected <45 days before the most recent positive test.

Screening questions to assess if case meets vaccine breakthrough investigation criteria

1. Received full primary series of an FDA-authorized COVID-19 vaccine (e.g., two doses of the Pfizer or Moderna mRNA vaccine)?
    a. **If YES, proceed to question #2**
    b. Stop if:
        i. No documented or reported COVID-19 vaccination
        ii. Received incomplete primary series of COVID-19 vaccine (e.g., 1 dose of Pfizer or Moderna mRNA vaccine)
        iii. Received a COVID vaccine that is not FDA-authorized

2. Respiratory specimen collected ≥14 days after receiving the last dose of an FDA-authorized COVID-19 vaccine tested positive for SARS-CoV-2 RNA or antigen?
    a. **If YES, proceed to question #3.**
    b. Stop if:
        i. No COVID-19 laboratory test result
        ii. Only a negative or equivocal test result
        iii. Only a positive result on another test type (e.g., antibody)
        iv. Only a positive result on another specimen type (e.g., serum)
        v. Positive specimen was collected <14 days after receiving the last dose of the COVID-19 vaccine

3. Known positive test for SARS-CoV-2 RNA or antigen on a respiratory specimen collected <45 days prior to the most recent test?
    a. **If NO or UKNOWN, proceed with case investigation on the next page.**
    b. Stop if:
        i. Documented SARS-CoV-2 RNA or antigen detected on a respiratory specimen collected <45 days before the most recent positive test.

Steps for initiating a COVID-19 vaccine breakthrough case investigation

1. Request the clinical or public health laboratory hold any residual specimens from the positive COVID-19 test (respiratory specimen, RNA extract, or viral isolate).
2. Report the available case data to MIDIS, per normal procedures.
    a. Attach vaccination records through either the imMTrax query or through manual entry of the vaccine.
3. Contact CDEpi at 406-444-0273 to report the possible case. A decision to send the specimen to CDC will be determined by DPHHS.
    a. When requested, forward the specimen to the Montana Public Health Laboratory for further analysis.
4. CDC may request further information regarding the case. CDEpi may reach out for missing information or other information necessary to investigate the case.