COVID-19 Vaccine Monitoring Systems for Pregnant People

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- Learn more about COVID-19 and pregnancy.
- Learn more about COVID-19 vaccination considerations for people who are pregnant or breastfeeding.

Monitoring COVID–19 Vaccine Safety during Pregnancy

CDC and the Food and Drug Administration (FDA) currently have five safety monitoring systems in place to capture information about vaccination during pregnancy and closely monitors that information reported to each system.

- **CDC and FDA**: Vaccine Adverse Event Reporting System (VAERS) ↗ — VAERS is a national system to which healthcare professionals, vaccine manufacturers, and the public can report possible side effects or health problems that happen after vaccination. Scientists investigate reports of events that are unexpected, appear to happen more often than expected, or have unusual patterns. The VAERS reporting form ↗ has a question to identify pregnant people (question 8). CDC clinicians review all pregnancy reports related to COVID-19 vaccinations.

- **CDC**: v-safe COVID-19 Vaccine Pregnancy Registry — **V-safe** is a smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. The v-safe COVID-19 Vaccine Pregnancy Registry is a registry to collect additional health information from **v-safe** participants who report being pregnant at the time of vaccination or a positive pregnancy test after vaccination. This information helps CDC monitor the safety of COVID-19 vaccines in people who are pregnant.

- **CDC**: Vaccine Safety Datalink (VSD) — VSD is a network of nine integrated healthcare organizations across the United States that monitor and evaluate the safety of vaccines. The system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination. Through VSD, CDC will study:
  - Weekly counts and rates of COVID-19 vaccination in pregnant people
  - Miscarriage and stillbirth that occurs among people who received COVID-19 vaccine during pregnancy
  - Adverse outcomes in pregnancy following COVID-19 vaccination, including:
    - Pregnancy complications
    - Birth outcomes
    - Infant outcomes for the first year of life (includes infant death, birth defects, and developmental disorders)

- **CDC: Clinical Immunization Safety Assessment (CISA) Project** — The CISA Project is a collaboration between CDC and seven medical research centers to provide expert consultation on individual cases of adverse events after vaccination and conduct clinical research studies about vaccine safety. CISA will implement a clinical research study on COVID-19 vaccine safety among pregnant people at three sites. The study will:
  - Enroll pregnant people who plan to receive COVID-19 vaccination; COVID-19 vaccines will be given as part of the study
  - Collect baseline maternal health information, including if they previously had COVID-19
  - Follow people during pregnancy and for three months after delivery
  - Follow babies through their first three months of life

- **CDC**: Birth Defects Study to Evaluate Pregnancy Exposures (BD-STEPS) — BD-STEPS is an ongoing study that collects information, including COVID-19 vaccination information, from people who have recently been pregnant to understand the potential causes of birth defects and how to prevent them.