



COVID-19

COVID-19 Vaccine Monitoring Systems for Pregnant People

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Pregnant and recently pregnant people are at an increased risk for severe illness from COVID-19 —including illness that requires hospitalization, intensive care, or a ventilator or special equipment to breath, or illness that results in death compared with non-pregnant people. Additionally, pregnant people with COVID-19 are at increased risk of preterm birth and might be at increased risk for other adverse outcomes. If you are pregnant, you can receive a COVID-19 vaccine.

Learn more about COVID-19 and pregnancy.

Monitoring COVID-19 Vaccine Safety during Pregnancy

CDC and the Food and Drug Administration (FDA) have safety monitoring systems in place to capture information about vaccination during pregnancy and will closely monitor that information. Learn more about COVID-19 vaccination considerations for people who are pregnant or breastfeeding.

- CDC and FDA: Vaccine Adverse Event Reporting System (VAERS) ☐ The
 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 new

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) 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 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) —
 This ongoing study 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.

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