COVID-19 Vaccine Monitoring Systems for Pregnant People

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Pregnant and Recently Pregnant People Are at Increased Risk for Severe Illness from COVID-19

CDC recommends COVID-19 vaccines for everyone ages 6 months and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. Although the absolute risks are low, pregnant and recently pregnant people are at an increased risk for severe illness from COVID-19, compared with non-pregnant people. Severe illness includes illness that requires hospitalization, intensive care, need for a ventilator or special equipment to breathe, or illness that results in death. Additionally, pregnant people with COVID-19 are at increased risk of preterm birth and stillbirth and might be at increased risk of other adverse pregnancy outcomes, compared with pregnant women without COVID-19.

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.