



#### COVID-19

## V-safe COVID-19 Vaccine Pregnancy Registry

Updated Feb. 25, 2022

COVID-19 vaccination is recommended for people who are pregnant, breastfeeding, trying to get pregnant now, or might become pregnant in the future. There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. The growing body of evidence about the safety and effectiveness of COVID-19 vaccination during pregnancy suggests that the benefits of receiving a COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy. CDC established the **v-safe** COVID-19 Vaccine Pregnancy Registry to learn more about this issue.

The registry is collecting health information from people who received COVID-19 vaccination in the periconception period (within 30 days before last menstrual period) or during pregnancy. The information is critical to helping people and their healthcare providers make informed decisions about COVID-19 vaccination. Participation is **voluntary**, and **participants may opt out at any time**.

#### Participation in the Registry

CDC is inviting people who received COVID-19 vaccination in the periconception period (within 30 days before last menstrual period) or during pregnancy to participate in the **v-safe** COVID-19 Vaccine Pregnancy Registry. **Pregnant people who would like to participate must be enrolled in v-safe.** If people enrolled in v-safe report that they were pregnant at the time of vaccination or after vaccination, the registry staff\* might contact them by phone to learn more. Even if you are no longer pregnant, you may still be eligible to enroll in the registry.

People who choose to enroll in the registry will be contacted by phone several times throughout their pregnancy for additional health check-ins. During these check-ins, they will be asked questions about their pregnancy and medical history. After delivery, participants might be contacted when their babies are about three months old. Participants will also be asked for permission to review their medical records to get a more comprehensive picture of their pregnancies. You can still enroll in the registry even if you don't give the registry permission to review your medical records. Personal information and responses in **v-safe** are confidential  $\square$  and will be protected to the full extent allowed by law.

\*Abt Associates has been contracted by the CDC to contact participants for CDC's **v-safe** COVID-19 Vaccine Pregnancy Registry.

#### V-safe and Registry Monitoring People Who Report Pregnancy

v-safe After Vaccination Health Checker Pregnant people reported, United States, as of February 22, 2022

203,353

v-safe COVID-19 Vaccine Pregnancy Registry Pregnant people enrolled, United States, as of February 22, 2022

17,082

As of February 22, 2022, more than 203 thousand **v-safe** participants have indicated they were pregnant at the time they received COVID-19 vaccination. CDC is currently enrolling eligible participants and analyzing data to better understand how COVID-19 vaccination affects pregnant people. As CDC learns more about the effects of vaccination during pregnancy, data

will be presented at the Advisory Committee on Immunization Practices (ACIP) meetings, which are open to the public, and in published reports.

\* The large difference between the number of people who self-identified as pregnant in **v-safe** and the number of people enrolled in the **v-safe** pregnancy registry is due to a number of factors. 1) There was a delay between rollout of COVID-19 vaccination and the launch of the **v-safe** pregnancy registry. 2) It takes time for registry staff to contact people who self-identify as pregnant in **v-safe**. 3) Not everyone who identified as pregnant in **v-safe** meets criteria to be in the registry. 4) The registry will only need to enroll a certain number of people who are vaccinated at different time points during pregnancy.

\*\*Recommendations for routine use of vaccines in children, adolescents, and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is a federal advisory committee to provide expert external advice and guidance to the CDC Director on the use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States.

# V-safe and the V-safe COVID-19 Vaccine Pregnancy Registry: What's the Difference?

**v-safe** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine. The **v-safe** COVID-19 Vaccine Pregnancy Registry is for **v-safe** participants who self-identify as pregnant at the time of vaccination or shortly thereafter (within 30 days of vaccination). The registry activities are in addition to the **v-safe** after vaccination health check-ins that participants receive via text message. Pregnant participants in the registry will be contacted to answer questions about their pregnancy and medical history. Participants will also be asked for permission to contact their healthcare provider(s).

**Note:** Participants are not paid for their participation, and not all people reporting pregnancy will be contacted to participate. Participation is completely voluntary, and you can opt out at any time. However, in general, many people feel good about participating in activities to help answer critical scientific questions, which can help inform recommendations for the public.

#### How CDC Is Using the Information

The information you provide will be combined with information from other participants in the registry. Together, this information will be evaluated and used to educate the public about how COVID-19 vaccination might affect pregnancy. In addition, this information will be used by CDC and the Food and Drug Administration (FDA) to guide recommendations on COVID-19 vaccination during pregnancy.

Specific health effects that scientists will be looking at include:

- Pregnancy outcomes, like miscarriage and stillbirth
- Pregnancy complications, like preeclampsia and gestational diabetes
- Problems with the newborn, like preterm delivery, poor growth, or birth defects

Your name and any identifying information will not be included In any reports. Your responses and personal information will be protected to the full extent allowed by law. Data for the registry are kept on a CDC system that employs strict security measures to keep personally identifiable information private.

## CDC May Need Permission to Contact Your Healthcare Provider

Having information on details, like medications or clinical laboratory results, can help provide a more complete picture of your pregnancy. Your healthcare provider(s) can help provide this information, which is important as we try to understand any potential effects of COVID-19 vaccination during pregnancy. If you choose not to give your permission for CDC to access medical records, you can still participate in the registry.

#### Vaccine Safety Monitoring in People Who Are Breastfeeding

Based on how these vaccines work in the body, the authorized COVID-19 vaccines are not thought to be a risk to lactating people or their breastfeeding babies. Although this project is not looking at potential effects during breastfeeding, other researchers across the nation are working to better understand the effects of COVID-19 vaccination in people who are breastfeeding.

## CDC Is Using Data from the Registry

CDC released the first U.S. data on the safety of mRNA COVID-19 vaccines administered during pregnancy based on analyses of data from three vaccine safety-related databases, including the v-safe pregnancy registry. The analyses did not identify any safety concerns for pregnant people who were vaccinated or for their babies. Additional follow-up is needed, particularly among those vaccinated in the first or second trimesters of pregnancy; however, these preliminary findings are reassuring. Thanks to the participation of thousands of people, information gathered through the v-safe COVID-19 Vaccine Pregnancy Registry is helping to build the evidence base about the safety of COVID-19 vaccination during pregnancy.

Data collected from the registry will also be regularly presented at the ACIP meetings, which are open to the public, and in published reports. However, gathering data on potential effects of COVID-19 vaccination during pregnancy is expected to take some time. People are being vaccinated at different times during their pregnancies. Given the natural length of pregnancy, it takes time to follow pregnancies and learn about any potential effects on babies. CDC is committed to sharing information learned about potential effects of COVID-19 vaccination during pregnancy as soon as possible.

#### How to Report Adverse Events

You or your medical provider can report any adverse events or health problems after COVID-19 vaccination to the Vaccine Adverse Event Reporting System (VAERS) by filling out a form that can be found on the VAERS website . FDA requires healthcare providers to report certain adverse events that occur after administering COVID-19 vaccine, but anyone can submit a report to VAERS. Reports to VAERS are invaluable to understanding the safety of COVID-19 vaccines as more people receive them over time. If you need further assistance with reporting to VAERS, please email info@VAERS.org or call 1-800-822-7967.

#### **Related Pages**

- COVID-19 Vaccine Safety and Monitoring
- > COVID-19 Vaccines While Pregnant or Breastfeeding
- > Benefits of Getting a COVID-19 Vaccine
- Myths and Facts about COVID-19 Vaccines

# More Information Protocol for the v-safe Pregnancy Registry ▶ Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons ☑