

## TERIS Summary

TERIS Agent Number: 6867  
Agent Name: **COVID-19 VIRAL VECTOR VACCINES**

Bibliographic Search Date: 12/2022

COVID-19 vaccines provide protection against the COVID-19 virus, SARS-CoV-2, and are administered by injection. Several different COVID-19 vaccines have been developed. Viral vector vaccines contain viruses engineered to deliver the spike protein of SARS-CoV-2 into the cell. Common vectors include non-replicating adenovirus or adeno-associated virus.

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**Magnitude of Teratogenic Risk to Child Born After Exposure During Gestation:** UNDETERMINED

**Quality and Quantity of Data on Which Risk Estimate is Based:** LIMITED

**Comments:** A SMALL RISK CANNOT BE EXCLUDED, BUT A HIGH RISK OF CONGENITAL ANOMALIES IN THE CHILDREN OF WOMEN IMMUNIZED WITH A COVID-19 VIRAL VECTOR VACCINE DURING PREGNANCY IS UNLIKELY.

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### Summary of Teratology Studies:

#### MAJOR CONGENITAL ANOMALIES

No congenital anomalies among the infants of 60 women who received a COVID-19 viral vector vaccine in the first trimester of pregnancy were reported to the Vaccine Adverse Event Reporting System (VAERS) (Moro et al., 2022).

#### PREGNANCY AND NEONATAL OUTCOMES

An increased frequency of adverse pregnancy outcomes, including pregnancy loss and preterm birth, was reported among 1574 women who received a viral vector COVID-19 vaccine during pregnancy compared to 11,866 women who received a mRNA vaccine while pregnant in a Korean retrospective cohort study, but no statistical comparisons were conducted in the study (Ahn et al., 2022). It is likely, however, that the higher rate of reported obstetrical complications among the viral-vector vaccinated group is due to a higher average maternal age.

Pregnancy and neonatal outcomes of 13 women who received a vector COVID-19 vaccine were similar to those of a propensity score-matched cohort of 399 pregnant women who did not receive any COVID-19 vaccines in pregnancy (Blakeway et al., 2022). Similarly, the incidence of neonatal death or NICU admission among 275 pregnant women who received a COVID-19 viral vector vaccine anytime during pregnancy and reported to the VAERS was no different from that expected in the general population (Moro et al., 2022).

#### ANIMAL TERATOLOGY STUDIES

Animal teratology studies of COVID-19 viral vector vaccines conducted by the manufacturer have not been published in the peer-reviewed literature.

#### Selected References:

(Each paper is classified as a review [R], human case report [C], human epidemiological study [E], human clinical series [S], animal study [A], or other [O].)

Ahn KH, Kim H-I, Lee K-S, Heo JS, Kim H-Y, Cho G-J, Hong S-C, Oh M-J, Kim H-J: COVID-19 and vaccination during pregnancy: a systematic analysis using Korea National Health Insurance claims data. *Obstet Gynecol Sci* 65(6):487-501, 2022. [E]

Blakeway H, Prasad S, Kalafat E, Heath PT, Ladhani SN, Le Doare K, Magee LA, O'Brien P, Rezvani A, von Dadelszen P, Khalil A: COVID-19 vaccination during pregnancy: coverage and safety. *Am J Obstet Gynecol* 226(2):236.e1-236.e14, 2022. [E]

Moro PL, Olson CK, Clark E, Marquez P, Strid P, Ellington S, Zhang B, Mba-Jonas A, Alimchandani M, Cragan J, Moore C: Post-authorization surveillance of adverse events following COVID-19 vaccines in pregnant persons in the vaccine adverse event reporting system (VAERS), December 2020–October 2021. *Vaccine* 40(24):3389-3394, 2022. [S]

## COVID-19 VACCINE PREGNANCY REGISTRIES

Healthcare providers are encouraged to suggest their patients enroll in the following registries:

#### V-SAFE

A registry collecting health information from people who received COVID-19 vaccinations in the periconception period or during pregnancy is being maintained by the Centers for Disease Control and Prevention. The registry attempts to assist individuals and healthcare providers to make informed decisions about COVID-19 vaccination.

Pregnant vaccinated people who would like to participate must complete a registration in v-safe (a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>). People who meet the conditions of the study will be contacted by the registry staff for additional details for enrollment in v-safe.

#### COVID-19 Vaccine Study

An observational pregnancy study by MotherToBaby has been established for women who received one or more doses of a COVID-19 vaccine during pregnancy or within one month prior to becoming pregnant. All study research will be performed via phone and office visits will not be required.

Additional information about the study can be found at MotherToBaby's COVID-19 Vaccines (<https://mothertobaby.org/ongoing-study/covid19-vaccines/>). Healthcare providers are encouraged to enroll such patients at <https://mothertobaby.org/join-a-study-form/>.

#### C-VIPER (COVID-19 Vaccines International Pregnancy Exposure Registry)

A registry collecting information from pregnant women who were vaccinated against COVID-19 during pregnancy and is maintained by Pregistry in Los Angeles, Calif. This registry evaluates obstetric, neonatal, and infant outcomes among women vaccinated during pregnancy to prevent COVID-19.

Healthcare providers may find additional information about this study at: <https://www.clinicaltrials.gov/ct2/show/NCT04705116>.

#### CANADIAN COVID-19 VACCINE REGISTRY FOR PREGNANT AND LACTATING INDIVIDUALS

A registry collecting information from women who are currently pregnant or breastfeeding regardless of vaccination status is maintained by the University of British Columbia in Vancouver, B.C., Canada and in partnership with other Canadian vaccine surveillance networks. The registry is a longitudinal survey monitoring the safety, effectiveness, and opinions related to the COVID-19 vaccine.

Healthcare providers may find more information about this registry at: <https://covered.med.ubc.ca/>.