



## COVID-19 Vaccination in Pregnant Women

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A recent study in the USA of a total of 35,691 pregnant participants 16 to 54 years of age from December 14, 2020, to February 28, 2021 [1] was conducted by using data from the v-safe pregnancy registry [2], "v-safe after vaccination health checker" surveillance system [3], and the Vaccine Adverse Event Reporting System (VAERS, a national spontaneous-reporting (passive-surveillance) system established in 1990 and administered by the US CDC and the US FDA) [4], the three US vaccine safety monitoring systems for characterization the initial safety of mRNA COVID-19 vaccines in pregnant participants [1]. Of 3,958 mRNA-vaccine (Pfizer/BioNTech vaccine, Moderna vaccine)-received-pregnant participants registered in the v-safe pregnancy registry, 115 (13.9%) of 827 completed pregnant participants had a pregnant loss and 712 (86.1%) had a live birth (mostly among third-trimester-COVID-19-vaccinated pregnant participants) [1]. Preterm birth (9.4%) and small-size-gestational age (3.2%) were the adverse neonatal outcomes [1]. The study revealed no neonatal death [1]. Spontaneous abortion (46 cases) was the most frequent event among 221 VAERS-reported-pregnancy-associated adverse events [1]. The study demonstrated although not directly comparable that the calculated proportions of COVID-19-vaccinated-completed-pregnant participants with adverse pregnancy and neonatal outcomes were similar to prior-COVID-19-pandemic-incidence reported in involved-pregnant women [1,5-16]. Chill, fever, headache, and myalgia were less frequent reported among pregnant individuals than

among nonpregnant participants, whereas injection-site pain was more frequent among pregnant participants [1]. Only 14.7 % of the v-safe-surveillance-system-identified-pregnant individuals had been contacted to offer pregnancy-registry enrollment at the time of this study-results analysis [1]. Rare pregnancy outcomes may be detected as the sample size increases contributing to additional reported-pregnancy outcomes due to small-sample-size and mostly-described-third-trimester-vaccination-neonatal-outcome preliminary registry data, thus, adverse pregnancy outcomes that might occur in relation to early-pregnancy exposures were not evaluated [1]. Follow-up is ongoing due to no early-COVID-19-vaccinated-pregnant individuals who have had live births had been captured in the updated v-safe pregnancy registry [1]. Non-recognized-very-early-pregnancy losses and after-greatest-risk-in-the-first-trimester-of-COVID-19-vaccinated-pregnant participants may contribute to non-reflecting the proportion of the exact postvaccination proportions among the pregnant individuals with spontaneous abortions [1]. Miscarriage was the most common pregnancy-specific condition after COVID-19 vaccination reported to the VAERS [1,17]. After maternal COVID-19 vaccination during the third trimester of pregnancy, emerging evidence has demonstrated transplacental transfer of SARS-CoV-2 (COVID-19) antibodies that might provide some levels of neonatal-and-maternal-COVID-19 protection [18-21]. Nevertheless, a direct comparison of pregnancy outcomes on the basis of timing of COVID-19 vaccination between some first-

and early-second-trimester pregnancies is urgently needed to define the proportion of spontaneous abortion in this study cohort [1]. VAERS do not demonstrate any clear safety signals related to neonatal or pregnancy outcomes and third-trimester-COVID-19 vaccination. Further evaluation of pregnancy, neonatal, maternal, and childhood outcomes related to maternal COVID-19 vaccination, pre-conception period, and earlier stage of pregnancy is needed for continuing monitoring [1], and the US CDC and the US FDA will closely monitor the information involving COVID-19 vaccination (Pfizer/BioNTech and Moderna vaccines) during pregnancy by safety monitoring systems [22]. The preliminary data from these systems via the early data external icon revealed no safety concerns for COVID-19-vaccinated-pregnant individuals or their babies [22]. When compared with non-pregnant individuals, pregnant and recently pregnant individuals are at a greater risk for severe COVID-19 illness although the overall risk of severe COVID-19 illness is low [22]. Increased risk of preterm birth and increased risk of other adverse pregnancy outcomes were found in COVID-19-pregnant people, compared with non-COVID-19-pregnant individuals, whereas there was no safety concerns in pregnant animals receiving a Johnson and Johnson/Janssen, Moderna, or Pfizer/BioNTech vaccine in several studies [22,23]. Currently, there are no data available on the effects on breastmilk production or excretion, effects of COVID-19 vaccination on the breastfed baby, and safety of COVID-19 vaccines in lactating individuals due to not including pregnant or breastfeeding individuals in the clinical trials for the COVID-19 vaccines currently authorized for use under and Emergency Use Authorization (EUA) in the USA [22,23]. Nevertheless, recent studies demonstrated that lactating individuals can receive a COVID-19 vaccine and also revealed that COVID-19-mRNA-vaccinated-breastfeeding persons had antibodies against SARS-CoV-2 (COVID-19) in their breastmilk [22,23]. Further studies are needed to identify what protection to baby provided by these antibodies [22,23]. Parents can receive a COVID-19 vaccine if currently trying to get pregnant or in the future [22]. As of April 21, 2021, in the interim, the WHO recommends COVID-19 vaccination in pregnant people when the benefits of COVID-19 vaccination to the pregnant people outweigh the potential risks (e.g., pregnant individuals at high risk of COVID-19 exposures, pregnant individuals with comorbidities that place them in a high-risk group for severe COVID) and continuing breastfeeding [23], <https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>). The WHO also recom-

mends both active and passive surveillance approaches to evaluate adverse events following immunization (AEFI) of COVID-19 vaccination, including during pregnancy [23].

In conclusion, being essential to find pregnancy, maternal, and neonatal outcomes, more longitudinal follow-up of larger subjects with earlier-pregnancy COVID-19 vaccination, and more vaccine platforms are needed due to unclear safety among mRNA-COVID-19-vaccine-received pregnant individuals.

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