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TO THE EDITOR

The article by Shimabukuro et al. 2021 presents preliminary safety results of coronavirus 2019 mRNA vaccines used in pregnant women from the V-Safe Registry.¹ These findings are of particular importance, as pregnant women were excluded from the phase III trials assessing mRNA vaccines.

In table 4, the authors report a rate of spontaneous abortions <20 weeks (SA) of 12.5% (104 abortions/827 completed pregnancies). However, this rate should be based on the number of women who were at risk of an SA due to vaccine receipt and should exclude the 700 women who were vaccinated in their third-trimester (104/127 = 82%). We acknowledge this rate will likely decrease as the pregnancies of women who were vaccinated <20 weeks complete but believe the rate will be higher than 12.5%. However, given the importance of these findings we feel it important to report these rates accurately. Additionally, the authors indicate that the rate of SAs in the published literature is between 10% and 26%.³⁻⁵ However, the upper cited rate includes clinically-unrecognized pregnancies,³ which does not reflect the clinically-recognized pregnancies of this cohort and should be removed.

Participant-Reported Outcome	Published Incidence* %	V-safe Pregnancy Registry† no./total no. (%)
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion <20 wk ¹⁵⁻¹⁷	10-26	104/127 (>82%) 827 (12.6) ‡
Stillbirth: ≥20 wk ¹⁸⁻²⁰	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk ^{21,22}	8-15	60/636 (9.4)¶
Small size for gestational age ^{23,24}	3.5	23/724 (3.2)
Congenital anomalies ^{25**}	3	16/724 (2.2)
Neonatal death ^{26††}	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.

† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. **A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.**

‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation.

§ The denominator includes live-born infants and stillbirths.

¶ The denominator includes only participants vaccinated before 37 weeks of gestation.

|| Small size for gestational age indicates a birthweight below the 10th percentile for gestational age and infant sex according to INTERGROWTH-21st growth standards (<http://intergrowth21.ndog.ox.ac.uk>). These standards draw from an international sample including both low-income and high-income countries but exclude children with coexisting conditions and malnutrition. They can be used as a standard for healthy children growing under optimal conditions.

Letter to Editor – Comment on “mRNA Covid-19 Vaccine Safety in Pregnant Persons”, Shimabukuro et al. (NEJM Apr 2021)

** Values include only major congenital anomalies in accordance with the Metropolitan Atlanta Congenital Defects Program 6-Digit Code Defect List (www.cdc.gov/ncbddd/birthdefects/macdp.html); all pregnancies with major congenital anomalies were exposed to Covid-19 vaccines only in the third trimester of pregnancy (i.e., well after the period of organogenesis).

†† Neonatal death indicates death within the first 28 days after delivery.

Kind Regards,

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1. Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *New England Journal of Medicine* 2021.

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