



the Centers for Disease Control and Prevention (CDC). Mention of a product or company name is for identification purposes only and does not constitute endorsement by the CDC or the Food and Drug Administration. The authors do not have any material conflicts of interest.

Disclosure forms provided by the authors are available with the full text of this letter at NEJM.org.

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3. Magnus MC, Wilcox AJ, Morken N-H, Weinberg CR, Håberg SE. Role of maternal age and pregnancy history in risk of miscarriage: prospective register based study. *BMJ* 2019;364:l869.

4. Goldhaber MK, Fireman BH. The fetal life table revisited: spontaneous abortion rates in three Kaiser Permanente cohorts. *Epidemiology* 1991;2:33-9.

5. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. *N Engl J Med* 2021;384:2273-82.

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On Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons

TO THE EDITOR: Shimabukuro et al. (June 17 issue)¹ reported preliminary data on the safety of messenger RNA (mRNA) Covid-19 vaccines in pregnancy from the v-safe surveillance system and pregnancy registry. They reported that among 827 participants with a completed pregnancy, the pregnancy resulted in spontaneous abortion by week 20 in 104 (12.6%), and the authors indicated that this proportion was similar to that in the general population. This calculated metric is misleading and does not reflect the real risk of spontaneous abortion.

As stated in the article, among the 827 participants with a completed pregnancy, 700 received their first eligible vaccine dose in the third trimester. These participants should be excluded from the calculation because they had already

passed week 20 when they received the vaccination. The risk of spontaneous abortion should be determined on the basis of the group of participants who received the vaccination before week 20 and were followed through week 20 or had an earlier pregnancy loss. Comparison with population-based rates of spontaneous abortion is complicated by the fact that women who are vaccinated at later times during early pregnancy have less time during which they are at risk for pregnancy loss; thus, a crude proportion is likely to underestimate the overall risk.²

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1. Shimabukuro TT, Kim SY, Myers TR, et al. Preliminary findings of mRNA Covid-19 vaccine safety in pregnant persons. *N Engl J Med* 2021;384:2273-82.
2. Sun H. Adjustment is required to calculate the risk of early pregnancy loss with COVID-19 infection or vaccination. *Am J Obstet Gynecol* 2021 August 3 (Epub ahead of print).

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THE AUTHORS REPLY: Sun appropriately raises questions about the proportion of women reporting spontaneous abortion in our recent article. We agree that the denominator used in that proportion — 827 completed pregnancies — is not an appropriate denominator for the calculation of a risk estimate or rate.

The number of spontaneous abortions (104) reflects data reported by the participants as of March 30, 2021, during telephone follow-up. In this preliminary report, follow-up information was missing for the majority of pregnancies in which exposure to vaccination occurred in early pregnancy. Among the 1224 women who had been vaccinated before conception or in the first trimester, follow-up through 20 weeks of gestation had been completed for only 204 pregnancies that were known to be ongoing and for 1 pregnancy that resulted in stillbirth. Among the pregnancies that had not yet reached 20 weeks of gestation, there were 10 pregnancies with other outcomes before 20 weeks of gestation, including 8 ectopic pregnancies and 2 induced abortions. For the other 905 pregnancies, follow-up had not occurred to establish whether these pregnancies were ongoing past 20 weeks of gestation. We have amended Table 4 in our earlier publication and have clarified the text.

Subsequently, we completed telephone follow-up for the 905 pregnancies and enrolled additional persons in the v-safe pregnancy registry. To determine the cumulative risk of spontaneous abortion from 6 to less than 20 weeks of gestation, we used life-table methods to perform an updated analysis, now reported in the *Journal*, involving 2456 women who received at least one dose of an mRNA Covid-19 vaccine before conception or before 20 weeks of gestation.¹ The estimated risks (14.1% overall and 12.8% in age-standardized analyses) are consistent with the risks of spontaneous abortion reported in the general population.¹

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1. Zauche LH, Wallace B, Smoots AN, et al. Receipt of mRNA Covid-19 vaccines and risk of spontaneous abortion. *N Engl J Med* 2021;385:1533-5.

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CORRECTIONS

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons (*N Engl J Med* 2021;384:2273-2282). In the Results section of the Abstract (page 2273), the third sentence should have read, “Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) were pregnancy losses and 712 (86.1%) were live births (mostly among participants vaccinated in the third trimester),” rather than “. . . of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester).” In the first paragraph of the Discussion section (page 2277), the parenthetical in the third sentence should have begun, “(i.e., preterm birth, small size, . . .)” rather than “(e.g., fetal loss, preterm birth, small size, . . .)” In Table 4 (page 2280), the double dagger symbol in the Spontaneous abortion row should have followed “Spontaneous abortion: <20 wk¹⁵⁻¹⁷.” The “Published Incidence” cell in the same row should have read “Not applicable,” rather than “10–26,” and the “V-safe Pregnancy Registry” cell should have read “104,” rather than “104/827 (12.6%).” In the table footnotes, the following content should have been appended to the double dagger footnote: “No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week-specific risk of spontaneous abortion.” The article is correct at NEJM.org.

mRNA Covid-19 Vaccines in Pregnant Women (*N Engl J Med* 2021;384:2342-2343). At the time of publication of preliminary findings in the Original Article related to this editorial, the number of spontaneous abortions was 104 and there was 1 stillbirth. However, no proportion could be determined for the risk of spontaneous abortion among participants vaccinated before 20 weeks of gestation because follow-up information was not yet available for the majority of those persons. The article has now been updated. In the fifth paragraph of this editorial (page 2342), the first sentence should have read, “Among 827 registry participants who reported a completed pregnancy, 104 experienced spontaneous abortions and 1 had a stillbirth,” rather than, “. . . a completed pregnancy, the pregnancy resulted in a spontaneous abortion in 104 (12.6%) and in stillbirth in 1 (0.1%); these percentages are well within the range expected as an outcome for this age group of persons whose other underlying medical conditions are unknown.” In the same paragraph, in the sentence beginning “Among live-born infants” (page 2343), the expression “were also consistent” should have read, “were consistent.” In the seventh paragraph, beginning “Given that,” the first sentence should have ended, “. . . limitations in their ability to draw conclusions about spontaneous abortions, congenital anomalies, and other potential rare neonatal outcomes,” rather than “. . . to draw conclusions about congenital anomalies and other potential rare neonatal outcomes.” The editorial is correct at NEJM.org.