

Increased risk of fetal loss after COVID-19 vaccination

Sir,

We read with interest the systematic review by Rimmer *et al.* (2023) and noted our manuscript (Thorp *et al.*, 2022) that reported significant harms to pregnant women and infants was omitted. We performed a population-based retrospective cohort study assessing rates of adverse events (AEs) after COVID-19 vaccines experienced by women of reproductive age, focusing on pregnancy and menstruation, using data collected by the Vaccine Adverse Events Reporting System (VAERS) database from 1 January 1998 to 30 June 2022. The proportional reporting ratio comparing AEs reported after COVID-19 vaccines with those reported after influenza vaccines is significantly increased (≥ 2.0) for COVID-19 vaccine for menstrual abnormality, miscarriage, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal cardiac arrest, fetal arrhythmias, fetal vascular malperfusion, fetal growth abnormalities, fetal abnormal surveillance, placental thrombosis, fetal death/stillbirth, low amniotic fluid, preeclampsia, premature delivery, preterm premature rupture of membrane, and premature baby death. When normalized by time-available, doses-given, or number of persons vaccinated, all COVID-19 vaccine AEs far exceed the safety signal on all recognized thresholds. Specifically for miscarriage we found the global relative risk for was 177 (95% CI 114.4–283.5) compared to influenza vaccination. We believe inclusion of our data in Rimmer *et al.* (2023) would correct a Type II error and lead to a conclusion of excess harm, necessitating a worldwide moratorium on the use of COVID-19 vaccines in pregnancy.

Conflict of interest

Authors have no conflicts of interest to declare.

James A. Thorp^{1,*}, **Claire Rogers**²,
Michael P. Deskevich³, **Stewart Tankersley**⁴,
Albert Benavides⁵, **Megan D. Redshaw**⁶, and
Peter A. McCullough⁷

¹The Wellness Company, Chief of Maternal and Pre-Natal Health, Gulf Breeze, FL, USA

²Concerned Doctors, Rome, GA, USA

³Independent Researcher, Boulder, CO, USA


⁴Concerned Doctors, Montgomery, AL, USA

⁵Verity Medical Foundation, San Jose, CA, USA

⁶Independent Researcher, Palmyra, MO, USA

⁷McCullough Foundation, Dallas, TX, USA

*Correspondence address. The Wellness Company, Chief of Maternal and Pre-Natal Health, 114 Highpoint Drive, Gulf

Breeze, FL 32561, USA. E-mail: jathorp@bellsouth.net  <https://orcid.org/0000-0002-7990-0620>

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<https://doi.org/10.1093/humrep/dead204>
Advance Access Publication Date: October 12, 2023

Reply: Increased risk of fetal loss after COVID-19 vaccination

Sir,

We read with interest the article by Thorp *et al.* (2022) published as a pre-print and in the *Journal of American Physicians and Surgeons* and their letter to the editor suggesting the need to include their data in our meta-analysis evaluating the risk of miscarriage following the use of SARS-CoV-2 COVID-19 vaccines (Rimmer *et al.*, 2023).

The authors present the findings of a simulation model that was constructed using data from the Vaccine Adverse Events Reporting System (VAERS) database in the USA between 1 January 1998 to 30 June 2022. The authors chose to construct a model estimating the total population who received either vaccine, the number of COVID-19 and flu vaccines doses given, and the incidence of adverse events globally. Interestingly, the authors decided to report the adverse events of COVID-19 vaccines compared to flu vaccines instead of simply reporting on the true incidence of adverse events reported on the VAERS database.

Clearly, any simulation model is subject to a high degree of bias when choosing the assumptions underpinning its construct. Thorp *et al.* seem to examine a hypothesis that COVID-19 vaccines are inherently more harmful than flu vaccines because they were rolled out rapidly. However, it is not clear how useful such a hypothesis or assumption would inform clinical practice.

Our meta-analysis simply reported on the true incidence of miscarriage and live birth following the use of COVID-19 vaccines. Therefore, the data reported in Thorp *et al.* does not meet the inclusion criteria for our meta-analysis.

Should the authors provide robust factual data on the true incidence of miscarriage following the use of COVID-19 vaccines, we would be more than happy to update our meta-analysis accordingly.