COVID-19 mRNA Vaccines in Pregnancy Summary

Current to April 2021

Safety Standards for Biologically Active Agents in Pregnancy

- Vaccines have traditionally been relatively biologically inactive, meaning they do not cause disease in and of themselves
- The COVID-19 mRNA vaccines train your body to produce the SPIKE protein, one of the main components of SARS-CoV-2 virus that causes sickness
- Good and standard medical practice requires that biologically active agents be PROVEN safe through years of clinical testing in randomized controlled trials BEFORE being administered to healthy people
- In addition to standard testing, agents being administered to pregnant women must undergo EVEN MORE testing to ensure that the agents will not harm the growth and development of the unborn child
- Testing should include careful monitoring of both pre-clinical and clinical adverse effects as even subtle changes can have long-lasting consequences

Assessing the Risk of Severe COVID-19

- Pregnant women were designated a COVID-19 high-risk group based, predominantly, on an analysis of the CDC COVID-19 registry published by the CDC in November 2020
- This study reported an increased risk of severe COVID-19 such as ICU admittance, ventilation, and death among pregnant women with symptomatic COVID-19 compared to non-pregnant women
- This analysis, although large and well recognized, was LIMITED by a focus on women with symptomatic COVID-19 and was based on a largely incomplete dataset of pregnancy and hospitalization outcome data
- Analyses from obstetrics units conducting universal testing show that the majority of pregnant women with SARS-CoV-2 were asymptomatic and other analyses showed no increase in severe outcomes in these women
- It is inappropriate to ascribe risk of severe outcomes of symptomatic pregnant women to asymptomatic pregnant women who are not at risk of severe outcomes especially when the treatments have not undergone rigorous safety testing and the alternative safe and effective therapies such as hydroxychloroquine are available

Examining Available Safety Data

- Six-month data from the randomized trials of the Pfizer mRNA COVID-10 vaccine showed that the vaccines dramatically increased the risk of any (298%) and severe (71.4%) adverse events relative to placebo in healthy adults an effect that extended to as many as 18% of vaccine recipients
- Active surveillance data from the V-safe registry in pregnant women, showed that COVID-19 vaccines increase concerning (grade ≥3) adverse effects in >13% of 2 dose recipients and caused fevers ≥38 °C in 8% and a temporal association between

cardiovascular, neurological, and immunological adverse effects and the vaccines has been reported after independent analysis of the VAERS surveillance system

- Authors of the V-Safe analysis reported a miscarriage rate of 13% that was based on 104 events among 827 completed pregnancies. However, authors subsequently withdrew the miscarriage rates and indicated that ongoing pregnancies should be analyzed before concerns regarding miscarriage could be ruled out
- A follow up sensitivity analysis of a larger number of early pregnancies showed that cumulative miscarriage rates followed the upper most boundary of risk for that group confirming concerns regarding an association between miscarriage and vaccination

Conclusion

- Asymptomatic pregnant women are not at an increased risk of severe outcomes from COVID-19 and safe treatment options to mitigate adverse outcomes are widely available
- Available short-term data from randomized controlled trials show that these vaccines cause clinical harm and pre-clinical and long-term effects are largely unknown as they have not been sufficiently monitored