

7 July 2021

A/Prof Benjamin Ong
Chairman
Expert Committee On Covid-19 Vaccination

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Dear A/Prof Ong

Inadequate Safety Evidence To Vaccinate Pregnant Women against Covid-19

In the Straits Times dated 21 June 2021, a study in the New England Journal of Medicine was cited by Prof Tan from KKH. He said, “findings indicate that there are no higher risks of adverse severe outcomes to mothers and their foetus, and that the vaccine is safe to take at **any point** of the pregnancy.”

Nevertheless, there are critical limitations of this study that call us to reconsider the policy to vaccinate pregnant women due to safety concerns.

Limitations Of The Study

- 1) **Short study duration** - it was a short 2.5 months (14 Dec 2020 to 28 Feb 2021) whereas it takes 9 months to make a baby. Neonatal outcomes are uncertain without a full duration of observation. The paper is titled “preliminary findings” because the data can change with time and “describe mostly neonatal outcomes from third-trimester vaccination”. The journal states that “more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes.”
(<https://www.nejm.org/doi/full/10.1056/nejmoa2104983>)
- 2) **Small sample size**
 - a. Of the 3,958 pregnant women who enrolled for this study, the data analysis was based on only 827 (20%) completed pregnancies at the time of publication. The actual sample size is 827 and not 3958.
 - b. The sample is weighted towards women vaccinated in their third trimester (700 women or **84.6%** of 827). Therefore, the authors’ conclusion: “Preliminary findings did not show obvious safety signals among pregnant women who received mRNA Covid-19 vaccines”, should **apply** to women vaccinated in their **third trimester**.
- 3) **Improper data methodology** - is not designed to compare the vaccine safety or risks by trimester.
 - a. Should not aggregate vaccination data of women across all trimesters and analyzed as a whole since the normal miscarriage rates are different in

different trimesters. The probability of miscarriage after 13 weeks is less than 1%. (<https://www.medicalnewstoday.com/articles/322634>). Moreover, we would be unable to compare normal miscarriage rates with any adverse events after vaccination for pregnant women.

A better study design would be a randomized clinical trial to compare two groups of matched pregnant women in the first trimester; one group receiving vaccinations and the other does not, and both groups are followed up to compare their subsequent rates of miscarriage and other pregnancy outcomes. We should separate trials for women in their second trimester and third trimester.

- b. At the cut-off time of the study's publication, only 11.2% or 127/1132 of women who were vaccinated in the first trimester, had completed their pregnancies (12 live birth and 115 pregnancy loss). It is premature to determine if vaccination in the first trimester is safe or not.

4) **Unknown foetal anomalies**

- a. Author states preliminary analysis “has limited information on other potential risks factors for adverse pregnancy and neonatal outcomes.” Any increase in miscarriages or foetal anomalies in women vaccinated during their first and second trimesters is unknown in these preliminary findings.
 - b. The data is mostly from third trimester pregnancies so the safety for foetal anomalies in the 1st and 2nd trimesters cannot be established. Moreover, for those who were vaccinated in their 3rd trimester and gave birth, birth defects may take months to a few years to manifest, such as reduced intelligence or physical co-ordination, autism etc.
- 5) **Misleading data** - Prof Tan mentioned that the 12.6% miscarriage rate in this paper falls within the background risk of 15% miscarriage rate. This is an inaccurate interpretation because 104 cases of miscarriage cannot be measured against 827 completed pregnancies, of which 700 of them are vaccinated in their third trimester. Table 4 tells us that miscarriages happen before 20 weeks (after 20 weeks it's called stillbirth). Data is vastly skewed towards the third trimester where less than 1% of miscarriages occur. Hence, **women vaccinated in their third trimester cannot be included here.**
- 6) **Possible misclassification and under-reporting in data collection:** “At the time of this analysis, just 14.7% of persons who identified as pregnant in the v-safe (smartphone app) surveillance system had been contacted”. Authors state that as with all participant reported surveys and platform, there may be classification mistakes whereby “**v-safe platform may include some reports from non-pregnant persons.**” They also acknowledge figures may be under-reported.
- 7) **Insufficient basis for safety** –“No obvious safety signals” from the conclusion of this preliminary study applied mostly to women vaccinated in the third trimester, and the one year outcome of the newborn is still unknown. It is **not a green light** for pregnant moms to sail into uncharted waters with unknown risks.

Hence, Singapore's mass vaccination for pregnant women in **all stages** of pregnancies **cannot** be based on this preliminary paper with severe, multiple limitations.

The WHO recommends vaccination of pregnant women in local epidemiological context. While we are concerned that pregnant women infected with Covid-19 would suffer higher risks of severe disease and miscarriages, the probability of infection is very low due to our very low community cases. At present, vaccination for pregnant women should be restricted to those who are at very high risk from Covid-19.

Without any proper study or randomised controlled trial done so far, are you not subjecting our pregnant women to a human trial with many unknown risks?

Therefore, we urge you to pause the vaccinating of pregnant women until studies are completed.

Thank you.

Yours sincerely

Concerned Parents and Mothers-to-be

██████████ (Mother)
██████████ (Pregnant)
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