UK Medical Freedom ALLIANCE

14 May 2022

Open Letter from the UK Medical Freedom Alliance to:

- Asma Khalil – Corresponding Author

Re: Request for Retraction of Nature Communications Paper "Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy"

The UK Medical Freedom Alliance is an alliance of medical professionals, scientists and lawyers who are campaigning for Informed Consent, Medical Freedom and Bodily Autonomy to be protected and preserved.

We are writing to you as the first and corresponding author of the recent publication in Nature Medicine entitled "Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy" [i].

- **The conclusions presented in your study have been publicised widely under headlines claiming that COVID-19 vaccination reduces the risk of stillbirths**[ii] [iii]
- **We argue that the data you have presented do not allow your conclusions and challenge your message of reassurance regarding COVID-19 vaccine effectiveness and safety in pregnancy**
- **The purpose of this letter is, therefore, to request an immediate retraction of your paper**

Indicating that evidence from 23 studies was evaluated, including a substantial number (117,552) of COVID-19 vaccinated pregnant women, gives an impression of validity of the analysis. However, your own description of your limitations within your paper and significant bias in the studies you evaluated precludes your conclusions, which are now widely propagated.

Below, we outline specifically why your conclusions are unjustified and scientifically invalid:

1. Risk of stillbirth

a. You describe the "*finding of a lower incidence of stillbirths in the vaccinated cohort*" of your analysis as important, although you also add that "*the observational nature of the original studies, significant statistical heterogeneity observed in the results and other probable confounders* ***should caution not interpret these results as causal***". This caution clearly got lost in the message that is now being circulated.

b. In your meta-analysis to evaluate the outcome of stillbirth, you appear to have included seven studies. You describe that one of these was "*at overall serious risk of bias, with the remainder at moderate risk*". Although your analysis claims a "*15% decrease in the odds of stillbirth*" based on your calculations, we completely fail in any attempt to verify this conclusion based on the papers you have quoted. **None of those studies examined stillbirths as their primary outcome, and none of them presented a result of reduced stillbirths following COVID-19 vaccination**.

c. **Four of the seven sources stated there was no statistically significant difference in stillbirths between vaccinated and unvaccinated pregnant women**[iv] [v] [vi] [vii].
   The remaining three present the following results:
   i. A retrospective cohort study of all pregnancies within a health system in Louisiana (US) over a short period between 15 June 2021 and 20 August 2021 assessed severe COVID-19 infection in vaccinated versus unvaccinated pregnant women as the primary outcome. They describe 6 stillbirths in the unvaccinated cohort of 8,760 women (0.07) and none in the vaccinated group of 1,332 with an odds ratio of zero[viii].
   ii. A retrospective cohort study assessed women who gave births after 24 weeks gestation in Israel between January and April 2021 with composite maternal outcome as the primary outcome. Intrauterine foetal deaths occurred in 5 cases (0.7%) in the vaccinated cohort (n=712) and 5 cases (0.5%) in the unvaccinated group (n=1063) with no statistically significant difference (p=0.52)[ix].
   iii. A study assessed 2002 women with a delivery event between 10 December 2020 and 19 April 2021 at a hospital within the Mayo Clinic Health System (US). There were no stillbirths in the vaccinated cohort (n=140) whilst 6 cases (0.3%) were recorded in the unvaccinated group (n=1862) with a non-significant p-value of 1[x].
d. **We demand that you immediately retract your paper or provide and publish a full and transparent explanation how you justify your conclusion that COVID-19 vaccination reduces the risk of stillbirths based on these studies**.

In addition to your conclusions regarding the risk of stillbirths, we take further issue with several claims made in your paper which include, but are not limited to, the following:

2. Risk of Miscarriages

a. You firmly conclude there is no indication that COVID-19 vaccination increases the risk of miscarriages. It appears that you are very keen to come to this conclusion as "*social media has been full of reports that have fuelled this concern*". Your meta-analysis appears to be based on two studies, both of which are at moderate risk of bias according to your paper. You describe that "*the number of exposures was small (N=4-43) and the vaccine types varied*" which is why you were unable to undertake quantitative synthesis.
b. Both studies you rely on for your meta-analysis compare women who suffered a miscarriage to those with ongoing pregnancies, according to their vaccination status within 3-5 weeks before assessment. This is a rather peculiar study design relying solely on post-hoc analysis with a narrow timeframe for vaccination to have occurred, and both studies also noted several significant limitations[xi] [xii].
c. **The data presented in your study do not support your statement regarding the risk of miscarriages after COVID-19 vaccination**.

3. Risk of myocarditis

a. We take grave issue with your comments regarding "*rare post-mRNA vaccination myocarditis*". Please consider the points below which challenge your statements:
   i. A recently published study on SARS-CoV-2 vaccination and myocarditis amongst 23 million residents of four Nordic countries found **between 4 and 7 excess events in 28 days per 100 000 vaccinees after BNT162b2 (Pfizer-BioNTech),** and between **9 and 28 excess events per 100 000 vaccinees after mRNA-1273 (Moderna)**[xiii]. This is clearly incongruent with your claim of an occurrence in 2 or even 10 per million.
   ii. The UK Government Information for recipients of Pfizer-BioNTech COVID-19 vaccine updated on 5 May 2022 states: "***There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with COVID-19 mRNA Vaccine BNT162b2.*** *These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur*." It also states that this may occur in up to 1 in 10,000 people[xiv].

b. **The association between myocarditis and COVID-19 vaccines has been officially acknowledged, and certainly for younger age groups the risks of COVID-19 vaccine adverse effects need to be very carefully considered**[xv] [xvi].

4. Clear bias towards supporting COVID-19 vaccine uptake in pregnancy

a. We argue that one of the main limitations of your paper is your clear bias towards your intention to promote COVID-19 vaccine uptake during pregnancy. This is blatantly evident in your introduction where you describe the variation in vaccine coverage as "*disappointing*" and lament the "*antivaccine disinformation*" as a cause of vaccine hesitancy. You state a priori and before presenting your results that the "*urgent need for vaccination of pregnant people cannot be overemphasised*".

b. **The validity of any study must be questioned when the significance of the results is already postulated in the introduction** and especially when the stated conclusions do no reflect any of the cautions and limitations which imply that the results are not as unambiguous as presented.

5. Quality of studies

a. You state there is "*an immediate need for high-quality robust information to investigate the outstanding questions about COVID-19 vaccination in pregnancy*", completely failing to acknowledge that no questions have actually been satisfactorily answered in clinical trials so far.

b. Your stated "*lack of experience with mRNA vaccine platforms outside research settings*" applied not just to pregnant women but to all humans until the mass vaccination campaign was rolled out in December 2020. As stated by the vaccine manufacturer Moderna: "***mRNA drug development***

has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines" [xvii].

c. **Pre-clinical studies regarding genotoxicity, carcinogenicity, reproductive and developmental toxicity, which would be particularly pertinent to establishing safety in pregnancy, have not been conducted by Pfizer**[xviii]. Pregnancy was an exclusion criterium for the regulatory clinical COVID-19 vaccine trials. Data regarding effects of COVID-19 vaccines in pregnancy are therefore solely dependent on post-marketing surveillance via passive reporting systems and retrospective, mostly observational cohort analyses, which are often subject to significant bias and limitations as those relied upon in your analysis.

d. **We completely agree with your call for studies that should be "*ideally prospective and controlling for bias*"**. A compound developed with completely novel technologies based on mRNA/DNA vectors and lipid nanoparticles, which has never previously administered to humans on such a large scale should have undergone rigorous and prospective safety studies BEFORE being recommended to pregnant women. **Clinical research standards dictate close and prolonged observation of trial subjects documenting any and all observed clinical effects following administration of the trial compound. This has not been done.**

e. Instead, the outcomes to be observed are being determined by the study protocols in post-hoc analyses with little or no stratification of gestational age at the time of vaccination, which is inappropriate to study unknown and unforeseen potential adverse effects and entirely inconsistent with the rigorous standards of clinical research. **The omission of well-designed clinical trials prior to approving COVID-19 vaccinations in pregnancy is a gross violation of research and clinical ethics**.

Conclusion & Requests

- Pregnant women have traditionally always been last to be included in trials for novel pharmaceutical compounds to ensure safety has been reliably demonstrated before exposing them to any unnecessary risks.
- **Pregnant women have never before been recommended to accept a treatment before the regulatory clinical trials of non-pregnant individuals have been completed**. There have been historic precedents of recommending insufficiently tested pharmaceutical products to pregnant women with disastrous consequences e.g. Thalidomide / Diethylstilbestrol.
- Your unequivocal statement that: "*The evidence supports recommendations advising COVID-19 vaccination in pregnancy*" constitutes the **promotion of an insufficiently tested and potentially unsafe product**, without any robust clinical data to support the claim.
- **Supporting the policies of COVID-19 vaccination for pregnant women, whilst ignoring or even denying the significance of growing numbers of serious adverse event reports**[xix]**, is therefore grossly negligent and irresponsible.**

- **We therefore appeal to you, in the interest of the health of pregnant women and their babies, that in future you conduct research without an a priori bias to promote a pharmaceutical product** examining the available data on their own merit without prejudice or pre-empting conclusions.

We thank you for reading and considering all the points made in this letter, trusting that you come to the only possible conclusion that **this paper must be retracted.**

We appeal to you to take immediate action, in accordance with the fundamental principle of ethical medicine to "first do no harm", as this issue is of utmost importance for the health of pregnant women and their babies.

We request you respond to us by 21 May 2022 to either confirm that:

1) **you are retracting your paper, or**
2) **you otherwise acknowledge receipt of this letter and respond to the points made therein as a matter of urgency.**

Yours sincerely

UK Medical Freedom Alliance

www.ukmedfreedom.org

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[i] https://www.nature.com/articles/s41467-022-30052-w
[ii] https://www.theguardian.com/world/2022/may/10/covid-vaccines-safe-for-pregnant-women-and-cut-stillbirth-risk-says-review
[iii] https://www.telegraph.co.uk/news/2022/05/10/unvaccinated-pregnant-women-urged-get-covid-jab-amid-stillbirth/
[iv] https://www.ajog.org/article/S0002-9378(21)00873-5/fulltext
[v] https://www.bornontario.ca/en/news/number-of-live-and-stillbirths-among-infants-born-in-ontario-by-covid-19-vaccination-status.aspx
[vi] https://jamanetwork.com/journals/jama/fullarticle/2782047
[vii] https://www.gov.uk/government/publications/covid-19-vaccine-weekly-surveillance-reports
[viii] https://journals.lww.com/greenjournal/Fulltext/2022/01000/Maternal_Outcomes_After_Severe_Acute_Respiratory.14.aspx
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[xix] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions