17 January 2022

Letter from the UK Medical Freedom Alliance to:

- Dr Sarah Stock – Corresponding Author

Re: Publication in Nature Medicine "SARS-CoV-2 Infection and COVID-19 vaccination rates in pregnant women in Scotland

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 "SARS-CoV-2 Infection and COVID-19 vaccination rates in pregnant women in Scotland" [i]. We acknowledge that this paper has been written with the purpose of encouraging vaccine uptake in pregnant women.

We have previously summarised our grave concerns about administering COVID-19 vaccines to pregnant women in Open Letters to the Royal College of Obstetricians & Gynaecologists (RCOG) and the Royal College of Midwives (RCM)[ii] and to the JCVI[iii], supporting a cautionary approach in view of the lack of robust and scientifically valid data regarding the effects and specifically the safety of COVID-19 vaccines in pregnancy.

The figures presented in your study will be publicised widely to encourage pregnant women to accept a COVID-19 vaccine. **We do not agree that the data you have presented allows your conclusions and are most concerned about your message of reassurance regarding vaccine effectiveness and safety**.

The purpose of this letter is therefore to request an immediate retraction of your paper. Below, we outline our specific reservations regarding definitions and assumptions of causality within your paper:

1. **Definition of cases**
   i. Your entire analysis is based on cases of SARS-CoV-2 infection as defined by a positive RT-PCR test. As you indicate, these tests may be carried out either to investigate the cause of an illness suggestive of COVID-19 or much more commonly as part of screening, which has become routine practice for all maternity admissions from 1 December 2020. Numbers of cases are therefore wholly dependent on numbers tested and not necessarily an indication of numbers of clinical COVID-19 disease.
   ii. You state that there were 5,653 cases of confirmed SARS-CoV-2 infections in pregnancy during the whole period of your study but then limit your analysis to 4,950 cases which occurred between 1 December 2020 and 31 October 2021. **It is entirely implausible that 87.6% of all cases since 1 March 2020 should have occurred after the height of the pandemic in 2020**. This must raise the suspicion that there is poor correlation between your definition of cases and clinical illness, implying that many of your cases had opportunistic positive tests instead.

iii. As cases will be exclusively defined by a positive RT-PCR test, they will occur more commonly amongst patients presenting themselves to hospital for any reason, as these will all be submitted to a test. Therefore, **your analysis relates to a specific cohort and cannot be extrapolated to the general population of pregnant women**, specifically those who do not seek healthcare and have no other reason to be tested. We note you point out yourself in your discussion that your data is descriptive and has not been adjusted for potential confounding factors. It is very possible that the reasons for testing the women in this cohort may have been because they were seeking health care. These reasons may have been entirely unrelated to COVID-19 disease but may very well have affected pregnancy outcomes.

iv. The definition of cases by a positive test alone is of particular concern in view of the **unreliability of these RT-PCR tests that have neither been validated nor standardized**. We have previously highlighted our concerns in an Open Letter to employers pertaining to the wide application and restrictions implemented as a result of possibly false positive RT-PCR tests[iv]. It is relevant for the interpretation of your data that RT-PCR test has not been validated[v] and is only under emergency authorisation for use in asymptomatic people. Of further concern are the issues of the numbers of expected false positive results being undefined as well as lack of standardisation.

a. False positive results

To enable determination of the ratio of false positive to true positive results, the false positive rate needs to be considered relative to the prevalence of disease in the population. According to the Office for National Statistics (ONS) on 12 December 2020, the prevalence of SARS-CoV-2 in the UK was around 1%. Assuming the false positive rate is around 1%, this means that 50% of all positive tests were false positives (i.e. 1,070,775 false positive tests out of the 2,141,551 total positive cases published by the government as of 23 December 2020). If the false positive rate was higher than 1%, false positive results would exceed true positives. Combined with high cycle threshold (Ct) values, the **probability of false positive test results may reach up to 97%**[vi].

b. Cycle threshold (Ct) values

It has been acknowledged in SAGE minutes that Ct values above 25 are unlikely to correlate with infectious disease[vii]. WHO guidance from January 2021 also stated that "*careful interpretation of weak positive results is needed. The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient's viral load*" [viii]. Data from an ONS survey, however, indicate that **samples are declared positive at very variable Ct values, often above 25**, which will have a direct impact on the number of reported cases at any time[ix].

c. Deviation from RT-PCR test manufacturer's instructions

The application of the RT-PCR test for SARS-CoV-2 in the UK has been highly inconsistent. Test kits utilised in the UK are intended to detect three separate gene fragments of SARS-CoV-2 in order to declare a positive result. Notwithstanding manufacturer's instructions, **it has been applied practice to identify cases via detection of only two, and increasingly also of only one gene fragment**. This clearly impairs the specificity, as the detected gene fragment in isolation may not be specific to the SARS-CoV-2 virus. This compromises reliability, inflates the number of positive cases and therefore renders the relevance of declared positive cases highly questionable[x].

We argue that any study based entirely on results of such an unreliable test cannot be expected to present clinically meaningful data.

v. The only indication of clinical data contained in your study refer to hospitalisation and critical care admission as well as adverse pregnancy outcomes, but the denominator exclusively relates to the specific cohort women who were tested for any reason, and many of them may well have presented themselves with a health issue or a pregnancy-related complaint.
You present no data at all regarding clinical COVID-19 disease.

2. Indications for hospitalisation and admissions to critical care

i. You correctly state that the cases of SARS-CoV-2 infection were "*associated with*" with hospital or critical care admissions. Although your conclusions appear to suggest this, this **association does not at all imply that any hospital or critical care admissions were indicated by COVID-19 disease**, as you mention yourself when describing the limitations of the study.

ii. Reasons for hospital or critical care admissions are not further defined or specified. As we elaborate above, the specific cohort of pregnant women in your study may be expected to be more likely to require hospital care, as many of them would have presented with a health issue before they were tested. The conclusion that pregnant women are more likely to require admission with SARS-CoV-2 infection is therefore not valid.

iii. The RCOG Information for Healthcare Professionals on COVID-19 in pregnancy updated on 11 January 2022 contains a comprehensive analysis regarding the risks of severe COVID-19 illness in pregnancy with an inconclusive summary stating "*these studies point to a possibly increased risk of severe disease from COVID-19 for pregnant women compared to non-pregnant women with COVID-19. However, the most consistent finding was of increased ICU admission rates for pregnant women, and this may in part be explained by a **lower threshold for ICU admission in pregnancy in general***" [xi]. This implies there may be confounding factors for the numbers of pregnant women admitted to ICU other than severity of COVID-19 disease, and it is plausible to consider that concern for mother and baby may prompt clinicians to err on the side of caution and escalate management sooner than they would for non-pregnant individuals.

iv. We note that according to your paper, to date, there has been "***one maternal death following SARS-CoV-2 infection in pregnancy in Scotland***". The UK Maternal Mortality rate from COVID-19 was quoted as 2.4/100,000 maternities (0.0024%) in the information from the RCOG.

3. Definition of "Unvaccinated"

i. We take serious issue with the definition of "unvaccinated" which includes those "*with one dose of vaccination ≤ 21d before the date of onset*" of COVID-19. We appreciate that the intent of this definition may be to allow immunity to develop so that best possible effectiveness may be demonstrated when presenting data, although Pfizer has claimed the known benefits of their vaccine includes: "*Reduction in the risk of confirmed severe COVID-19 any time after Dose 1"* [xii], and your study claims to focus on severe outcomes with the majority of your study population having received the Pfizer vaccine (79.4%).

ii. Classifying those who have received their first vaccine dose less than 3 weeks ago as unvaccinated fails to acknowledge the observation that a **higher incidence of SARS-CoV-2 infection may occur exactly in that interval, possibly as a result of vaccination**[xiii]. Such episodes

of infection and potentially illness will then be erroneously accounted for as occurring in unvaccinated individuals.

iii. The Pfizer vaccine has been shown to cause transiently decreased lymphocytes during the first three days after vaccination[xiv], and phase 2 trials of AstraZeneca demonstrated a similar reduction in neutrophils[xv]. The combination of **transient white cell depletion after COVID-19 vaccination** with the clinical observation of increased infection rates, and further evidence that vaccination triggers dramatic changes in immune cell expression but also influences several other health indicators including those related to diabetes, renal dysfunction, cholesterol metabolism, coagulation problems electrolyte imbalance[xvi] during this early time frame, suggests a signal that would not allow individuals within that period to be classified as unvaccinated.

iv. Whilst the MHRA Yellow Card system in the UK does not allow for analysis of the timeframe of the onset of adverse events after vaccination, this information is available from the Vaccine Adverse Event Reporting System (VAERS) in the US[xvii] where it appears that **66.6% of adverse events occur within 7 days**[xviii]. Anyone presenting to hospital within this period would be accounted for as unvaccinated in your study, which would therefore not allow for the collection of data of such potential vaccine-induced side effects.

4. <u>Consideration of timeframes & demographic variation in vaccine uptake</u>

i. The period your analysis focuses on starts from 1 December 2020. As you note, at that point pregnant women were not advised to be vaccinated unless they were classed as high-risk. It was not until 16 April 2021 that initial advice was reversed, and vaccination was recommended for all pregnant women. Due to this significant change in advice without any robust data demonstrating safety, many pregnant women will have remained hesitant to be vaccinated by the time the roll-out reached their age group, which for many would have been into June 2021, and there may have been a preference to delay vaccination until after the first 12 weeks of gestation. Therefore, according to your paper, vaccine coverage has been substantially lower among pregnant women compared to the general female population in the same age group, and **57.2% of all women delivering in October 2021 remained unvaccinated**. According to your data, this was the month with the highest coverage so far, so when analysing all data from 1 December 2020 onwards, that percentage would have been much higher.

ii. Your statement that 77.4% of SARS-CoV-2 infections in pregnancy occurred in the unvaccinated suggests that this group was disproportionately affected, when in fact this was probably a reflection of the total proportion of women who had not been vaccinated during your study period.

iii. Your study indicates that vaccine uptake was "*consistently lowest in younger (≤20 years) pregnant women and those living in the most deprived areas of Scotland*". It is well known that both teenage pregnancies[xix] and social deprivation increase the risks of maternal and neonatal complications[xx]. This is an essential confounding factor regarding your figures for hospital and critical care admissions that you have not accounted for in your analysis.

5. **Causality of SARS-CoV-2 infection in adverse outcomes**

   i. **The data you have presented without any statistical analysis does not allow the conclusion of causality between SARS-CoV-2 infection and adverse outcomes**, and you mention yourself that you had no "*access to detailed clinical records to assess whether COVID-19 directly or indirectly contributed to the preterm births and deaths*". It is entirely plausible that the differences you emphasise between pregnant women testing positive for SARS-CoV-2 and the general pregnant population relate to your cohort selection of women who were tested for any reason and often opportunistically when presenting themselves with any health issue. Your study gives no data regarding the number of women within your cohort who had clinical COVID-19 disease.

   ii. In the absence of any evidence of causality between SARS-CoV-2 infection and adverse outcomes, it therefore amounts to **pure speculation that COVID-19 vaccines would have had any effect on reducing those adverse outcomes**. No trial has investigated COVID-19 vaccines in pregnancy, and there is still no robust evidence from any clinical trial data, and certainly not from a "gold standard" randomised control trial (RCT), that COVID-19 vaccination reduces either hospitalisation or death[xxi]. There is no indication whatsoever that they would reduce adverse outcomes of pregnancy such as pre-eclampsia, pre-term labour or stillbirths. Your claim that your data "*support the importance of women being vaccinated in pregnancy*" is a mere assumption without any basis.

Pregnant women have traditionally always been the last to be included in trials for novel pharmaceutical compounds to ensure safety has been reliably demonstrated before exposing them to any unnecessary risks. **We suggest that a paper strongly promoting COVID-19 vaccine uptake to this particularly vulnerable group should have presented more comprehensive data and evidence regarding COVID-19 vaccine effectiveness and safety** as we highlight below:

COVID-19 Vaccine effectiveness

i. The latest COVID-19 infection fatality rate (IFR) figures from December 2021 in the table below, calculated by leading epidemiologist Prof Ioannidis and his team from analysis of 25 seroprevalence surveys across 14 countries, clearly demonstrate that **for the vast majority of the population, and those of reproductive age, this is not a life-threatening illness**[xxii].

Age	Infection Fatality Rate (IFR)
0-19	0.0013%
20-29	0.0088%
30-39	0.021%
40-49	0.042%
50-59	0.14%
60-69	0.65%
70+ (non-care home)	2.9%
70+ (all)	4.9%
Source: https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v2.full	

ii. The current COVID-19 variant of concern (Omicron) is associated with less severe illness, hospitalisations and deaths compared to previous strains[xxiii] [xxiv]. In addition, protection from COVID-19 vaccines against Omicron appears to be reduced[xxv]. This is acknowledged by the WHO[xxvi] and in a Technical Briefing by the UK Health Security Agency (UKHSA) dated 31 December 2021, which suggests that "***vaccine effectiveness against symptomatic disease with the Omicron variant is significantly lower than compared to the Delta variant and wanes rapidly***" [xxvii].

iii. This data emerges amidst mounting evidence of vaccine-induced immunity being short-lived[xxviii], as admitted by the Pfizer CEO Albert Bourla[xxix], with protection waning within 4-6 months. Recently published data from Denmark even suggests a potentially negative effect of the vaccines against COVID-19 infection[xxx]. Evidence from San Francisco / California reports that *"vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants"* [xxxi]. **A high proportion of cases infected with the Omicron variant also appears to occur in vaccinated individuals**, including in Scotland[xxxii] [xxxiii]. Meanwhile, it appears likely that most unvaccinated individuals would have had some exposure by now and acquired robust, comprehensive and long-lasting natural immunity, which has been shown in over 140 published studies to be far superior to the highly specific, limited and short-term vaccine-induced immunity[xxxiv].

In view of this evidence, we argue it is highly questionable whether at this time, women of reproductive age will derive any significant clinical benefit from vaccination. We would certainly not suggest that such a general recommendation without consideration of individual circumstances is justified.

COVID-19 Vaccine Safety

We take very serious issue with your statement regarding an "*established safety profile of vaccinations*".

i. The safety of COVID-19 vaccines cannot have been conclusively established as the regulatory trials have not yet been completed but have been compromised by allowing participants in the placebo group to cross over into the treatment arms[xxxv]. No data from completed clinical trials is available. Long-term effects on carcinogenesis, auto-immune disorders or fertility are entirely unknown.

ii. Many adverse reactions following the administration of COVID-19 vaccines have been reported to the MHRA in the UK[xxxvi]. In the report published on 13 January 2022, there were **over 1.4 million adverse reactions in the UK** from 431,482 reports (1 in 120 people injected), some of them extremely serious, including seizures, paralysis, blindness, strokes, blood clots and acute cardiac events. This report includes **1,932 fatalities**. There were 709 reports of adverse pregnancy outcomes (miscarriages / stillbirths) and 52,322 reports in the category of reproductive / breast disorders. It is widely recognised that only up to 10% of adverse events are officially reported, indicating that the actual number of adverse events is likely to be much higher.

iii. **Life-threatening adverse effects, such as blood clots and myocarditis[xxxvii], have been reported and listed as vaccine side-effects by regulators around the world, and the risks appear higher in young people including those of reproductive age.** The association between myocarditis

and COVID-19 vaccines[xxxviii] [xxxix] has been officially acknowledged, and certainly for younger age groups the risks of COVID-19 vaccine adverse effects are likely to outweigh their benefits[xl] [xli] [xlii] [xliii].

iv. **To claim established safety of COVID-19 vaccines in pregnancy amounts to complete speculation**. Small observational studies are not sufficient to reassure regarding the safety of this novel gene-based (mRNA or DNA viral vector) technology, that has never before been used in humans on such a large scale.

v. Most commonly quoted is the US Centers for Disease Control and Prevention (CDC) V-safe Covid-19 Vaccine Pregnancy Registry, a voluntary reporting system, collecting observational data of women who happen be pregnant at the time of vaccination[xliv]. Notably, only a fraction (less than 5%) of these women are formally enrolled (8,749 of 185,218 women as of 10 January 2022). Such a registry is not in any way comparable to robust, thorough, scientific evaluation and peer-reviewed evidence.

vi. Especially in pregnant women, who were not recruited into the ongoing regulatory clinical trials, adverse event reporting relies solely on post-marketing surveillance, which is carried out via passive reporting systems. For the MHRA reports to give an accurate reflection of the adverse event profile of COVID-19 vaccines, all members of the public and all doctors would be required to be fully aware of the Yellow Card System and when to submit a report. In reality, there is poor awareness of this scheme among both doctors and the public, potentially leading to a significant underestimate of the nature and the true number of adverse events and deaths.

We suggest there is no robust and scientifically valid basis for a claim of established safety of COVID-19 vaccines and would instead advise caution in view of the lack of data regarding effects of COVID-19 vaccines in pregnancy.

Conclusion & Requests

Your paper does not contribute to the evidence for effectiveness or safety of COVID-19 vaccines, as it intertwines the assessment of clinical outcomes with data on vaccine uptake and coverage. This is in the prior assumption that increasing vaccine uptake in the pregnant population should be advocated without even acknowledging the validity of reasons women may have to decline this intervention, especially when initial advice was for them to avoid COVID-19 vaccination in pregnancy, and the time it took to completely reverse this advice was less than half of a completed pregnancy, indicating that there could not possibly have been sufficient time to acquire enough robust data to reassure regarding the safety of this product.

We therefore appeal to you, in the interest of the health of pregnant women and their babies, that going forward you focus on research without bias to promote a pharmaceutical product that is and should still be under emergency use authorisation only, as clinical regulatory trials have not been completed and will not be satisfactorily accomplished anytime soon.

Your unequivocal conclusion that: "*Addressing low vaccine uptake in pregnant women is imperative to protect the health of women and babies*" amounts to a pharmaceutical promotion of an ineffective, insufficiently tested and potentially unsafe product without any clinical data to support it.

We thank you for your time to read and consider all the points made in this letter, hoping that you come to the only possible conclusion that this paper must be retracted.

We consider this to be of utmost importance for the health of pregnant women and their babies and appeal to you to take appropriate action according to the first principle of medicine to do no harm.

We will at this stage not publicise this letter further to give you time to respond and decide how you wish to proceed. However, we reserve the right to publish this letter more widely in due course, should we find that your study remains in the public domain and continues to be used to promote COVID-19 vaccination in pregnant women.

We request you respond by 24 January 2022 to either confirm that (i) you are retracting your paper or (ii) 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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