19th April 2021

Open Letter from the UK Medical Freedom Alliance to:

Prof Andrew Pollard – Chair of the Joint Committee for Vaccination and Immunisation (JCVI)

Prof Wei Shen Lim – Covid-19 Chair for JCVI

Dr Mary Ramsay – Head of Immunisation at Public Health England (PHE)

Mr Edward Morris – President of the Royal College of Obstetricians & Gynaecologists (RCOG)

Re: Covid-19 Vaccine Advice for Pregnant Women

The UK Medical Freedom Alliance are 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 wish to express our grave concerns regarding your latest advice that pregnant women "should be offered Covid-19 vaccine at the same time as the rest of the population, based on their age and clinical risk group"[i].

It appears this advice has been radically changed despite the continued lack of safety data in pregnant women. There are still no trial results or peer-reviewed evidence regarding pregnancy, and therefore the basis for this amendment appears entirely unfounded. It would seem that this change was prompted by "real world data from the United States" which apparently indicated that no safety concerns were raised in "around 90,000 pregnant women" who were vaccinated.

This "real world data" refers to the V-Safe Covid-19 Vaccine Pregnancy Registry[ii], in which 4478 pregnant women were enrolled as of 12th April 2021. The remaining 86,956 pregnant women were merely registered as having self-identified via a smart-phone based tool. No further information regarding any adverse events in this group have been published. We are incredulous that this information is supposed to reassure anyone regarding vaccine safety in pregnancy, when the period of observations has not even spanned half the length of a single pregnancy.

In addition, we have serious concerns that the published JCVI advice states that "all vaccines being used in the UK have undergone robust clinical trials" and question how a trial can be claimed to be "robust" that has not yet been completed. None of the current Covid-19 vaccine Phase 3 trials are due to complete until the end of 2022 at the earliest. It is also not consistent with a robust trial to unblind participants prior to completion and offer them transition into another trial arm[iii]. It is entirely misleading to include this statement in this particular guidance, as none of the trials have included pregnant women.

Pregnant women are still encouraged to "discuss the risks and benefits" of the Covid-19 vaccine with their clinician. Midwives and obstetricians are therefore being called upon to counsel women and answer their questions about Covid-19 vaccines. We have previously raised concerns, in an Open Letter to the Royal College of Obstetrics and Gynaecology (RCOG) and Royal College of Midwives (RCM)[iv], regarding the information sheet and decision aid for pregnant women considering vaccination against Covid-19, which has been endorsed by the RCOG and the RCM[v]. This information sheet is set out to facilitate the counselling process but contains no references to evidence. Whilst it ought to be factual and impartial, it is misleading in many places and in conclusion clearly biased towards advising some women to be vaccinated, stating that certain categories of women "should consider getting the vaccine".

Vaccine manufacturers have requested, and been granted, complete exemption from any liability for their products[vi] [vii]. Great onus therefore lies on professionals to counsel according to available scientific evidence, as they may otherwise be held liable, should adverse events occur, especially if these are serious. Great onus also lies on regulators and government officials to ensure that due process is followed, adhering to the first principle in medicine to do no harm.

We are therefore deeply disappointed at the claim that all vaccines used in the UK "have met the Medicines and Healthcare products Regulatory Agency (MHRA)'s strict standards of safety, effectiveness and quality", especially when this is supposed to refer to the use of Covid-19 vaccines in pregnancy.

Below, we elaborate why such a statement compels us to question the MHRA's "strict standards".

1) **Vaccine efficacy**
2) **Risks of Covid-19 in pregnancy**
3) **Vaccine safety**

1) Vaccine efficacy

The interim analyses of the currently ongoing vaccine trials, which are not due to be completed till at least the end of 2022, only indicate efficacy in reducing mild Covid-19 symptoms and not prevention of infection[viii]. There is no evidence from trials or peer-reviewed studies that Covid-19 vaccines reduce hospitalizations, deaths or prolonged symptoms[ix]. The statement in the guidance that "Covid-19 vaccines continue to save thousands of lives" is merely based on anecdotal observations or statistical modelling and is therefore misleading. It has been explicitly stated that infection is not prevented by the vaccines. The duration of any potential protective effect is currently also entirely unknown, as medium- and long-term immune responses have not been monitored.

The publicised effectiveness of up to 95% is a relative risk reduction, whilst data only indicate an absolute risk reduction to an individual of 0.4%[x]. Figures from Israel, the country with the highest vaccination uptake at present, indicate that numbers needed to vaccinate are 364 to prevent one PCR conversion, 490 to prevent one symptomatic case, 4004 to prevent hospitalization of one patient and 5014 to prevent hospitalization of one case with severe disease. To prevent one death, 25,940 people need to be vaccinated, at a cost of over $1million (assuming $20 per dose and two doses per person)[xi]. It is worth noting that Israel has recently reported a 40 times higher mortality rate compared to previous years and more deaths than would have been expected to occur related to Covid-19 in the same time frame.[xii] Israel has also had the highest excess mortality out of 26 countries over the last 5 weeks[xiii]. These figures suggest that, at least in the short term, the vaccines are not having a beneficial effect on severe disease or mortality.

2) Risks of Covid-19 in pregnancy

The information sheet endorsed by the RCOG/RCM does not quantify the efficacy of the vaccines, but clearly emphasizes the risks of Covid-19 in pregnancy, stating that "some pregnant women can get life-threatening illness" and advising women to "think about your risk of catching and becoming seriously unwell from Covid-19".

The JCVI guidance states that "the greatest risk factor for severe outcomes from COVID-19 is age", and it is well recognized that women of childbearing age are at very low risk, with an infection fatality rate of <0.05%. This is not the order of magnitude that is conveyed when the RCOG/RCM decision aid repeatedly mentions life-threatening illness.

According to the RCOG Information for Healthcare Professionals on Covid-19 in pregnancy, pregnant women are "not at increased risk of death from Covid-19" and the UK maternal mortality rate from Covid-19 is "2.2 hospitalized women per 100 000 maternities" (0.0022%)[xiv]. It states that they have a higher rate of intensive care unit (ICU) admissions but this "may reflect a lower threshold for admission to ICU, rather than more severe disease". Further, "there is currently no robust data from the UK comparing pregnant and non-pregnant women with Covid-19".

The information sheet also states that "preterm birth is more likely", without elaborating that these are iatrogenic preterm deliveries in 78% of cases[xiv]. It suggests that "age, ethnicity, BMI and underlying conditions" put women at "high risk from Covid-19" without quantifying any such risks. This relates to a meta-analysis which concluded that these risk factors are "associated with" hospitalization of pregnant women with Covid-19. There may be a variety of reasons for seeing these women hospitalized other than these being risk factors for severe Covid-19 symptoms, and it is misleading to suggest that these factors should prompt women to consider vaccination. The mortality rate in this meta-analysis was 0.02%, in line with the rate for all women of child-bearing age[xv].

The UK Government's Information for Health Care professionals advises that "Administration of the COVID-19 mRNA Vaccine BNT162b2 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus"[xvi]. We strongly recommend that any information sheet for pregnant women should include a referenced quantification of benefits and risks if its purpose is to aid decision making.

3) Vaccine safety

Pregnant women were not included in any vaccine trials, and therefore there is no published, peer reviewed, scientific evidence from clinical trials regarding safety in pregnancy, to the mother or baby. The JCVI guidance states that "available data on the Pfizer-BioNTech and Moderna vaccines provides confidence that they can be offered safely to pregnant women", failing to elaborate that this "data" is merely observational, relying on a passive reporting system that is neither robust nor thorough. The RCOG/RCM information sheet also states that "there is no evidence that the vaccines can cause harm to you or your baby".

The absence of evidence of harm cannot be taken as evidence or proof of safety.

The RCOG/RCM decision aid reassures that the vaccines "do not contain ingredients that are known to be harmful" but fails to inform that mRNA and DNA-vector vaccines have never previously received full regulatory approved for use in humans on this scale. It even compares the Covid-19 vaccines to other "non-live vaccines" recommended in pregnancy and refers to their safety. This completely fails to raise awareness of the fact that Covid-19 vaccines are based on a novel, gene-based mRNA or DNA biotechnology and are not comparable to any other established vaccines.

Advice from Public Health England previously stated that "the vaccines have not yet been tested in pregnancy, so until more information is available, those who are pregnant should not routinely have this vaccine. Non-clinical evidence is required before any clinical studies in pregnancy can start, and before that, it is usual to not recommend routine vaccination during pregnancy"[xvii]. More recent advice

conceded that "there are some circumstances in which the potential benefits of vaccination are particularly important for pregnant women" who may then "choose to have COVID-19 vaccine in pregnancy following a discussion with her doctor or nurse"[xviii]. Notably, no additional trials or published evidence on the safety of Covid-19 vaccines in pregnancy have occurred in the interim, to support this concession or in fact the most recent JCVI guidance.

In the absence of completed trial data, there are several reasons to have potential safety concerns over the effects of Covid-19 vaccines in pregnancy. Some of these relate to post-marketing reports and recent changes to guidance about certain types of vaccines, and some are based on previous experiences with mRNA vaccines.

Post-marketing reports

Several databases are capturing adverse events that have occurred in relation to the administration of Covid-19 vaccines.

- In the UK, the **MHRA** has reported a total of 626,087 adverse events, including 61 spontaneous abortions and 4 stillbirths, as of the 15 April 2021. 847 adverse events had a fatal outcome[xix].
- The **WHO** database records 527,790 adverse events and 3440 deaths as of the 18 April 2021[xx].
- The US Vaccine Adverse Event Reporting System (**VAERS**) database has recorded 2602 deaths relating to Covid-19 vaccines as of 8 April 2021[xxi], which is over ten times the average annual number of all vaccine-related deaths normally reported to VAERS (under 200 per year) in a period of only 3 months. 46% of these deaths occurred in people who fell ill within 48 hours of being vaccinated[xxii]. These must be taken seriously and cannot all be dismissed as coincidental.

Specifically, regarding the AstraZeneca vaccine, there have been reports of multiple cases of **cerebral venous thrombosis and thrombocytopenia** with fatal outcomes, leading to temporary suspension in 24 countries[xxiii], and subsequent advice to avoid this vaccine in the younger age groups, including women of childbearing age. The German Paul Ehrlich Institute justified their decision for suspension, indicating that seven such cases were reported, three of them fatal, when only one might have been expected to occur[xxiv]. The following week, a report noted a total of sixteen such cases in Germany, four of them with fatal outcome, and all but one occurring in women aged between 20 and 63 years[xxv].

The suspicion of a causal relation is plausible, as there is evidence of direct activation of the alternative complement pathway by SARS-CoV-2 spike proteins[xxvi], as well as papers demonstrating the potential of spike proteins to cause cell to cell fusion, forming syncytia, which may lead to endothelial damage and clot formation[xxvii]. As the production of spike proteins is induced by the all the vaccines, this has the potential to be a class effect[xxviii].

The European Medicines Agency (EMA) safety committee, after reviewing the data and declaring the AstraZeneca vaccine to be safe, while indicating that rare events cannot be ruled out, noted "concerns about the reports involving younger patients" with most cases affecting women[xxix]. They are also reviewing the reports of blood clots associated with the Johnson & Johnson Covid-19 vaccine that has led to the suspension of the vaccine in the US. The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is continuing its assessment of reported cases, convening an expert group in the context of a "safety signal" that warrants further investigation[xxx]. The EU Commission have announced that they will not be renewing the AstraZeneca or Johnson & Johnson vaccine contracts, and Denmark have stopped use of the AstraZeneca vaccine due to the safety concerns[xxxi].

UK Guidance on the AstraZeneca vaccine was revised very recently, and the situation is changing daily around the world. The possibility of further safety issues, including in pregnancy, cannot be ruled out. In

this climate, the precautionary principle must be invoked, and pregnant women should not be advised to subject themselves and their unborn babies to unknown risks, whilst giving them the impression that such advice is supported by robust scientific evidence.

Pregnancy is a known pro-thrombotic state. Although this is claimed not to increase the risks of vaccine-related thrombotic complications, the potentially added risks of thrombotic events through Covid-19 vaccines may be relevant not only to the health of the gravida but also to placental development and circulation. As of the 15th April 2021, 778 strokes and thrombolytic events have been reported to the MHRA, 570 events after the AstraZeneca vaccine but also 204 events relating to the Pfizer-BioNTech vaccine. This information is likely to be deemed significant by most people and therefore ought to be shared with pregnant women, according to the Montgomery ruling, that patients must be informed of any risks that "any reasonable person in the patient's position would be likely to attach significance to"[xxxii].

Previous experiences with mRNA vaccines

Attempts at developing a Coronavirus vaccine have been in progress for almost 20 years, since the emergence of SARS-CoV-1 in 2002, but have been unsuccessful, mainly due to serious safety issues in the animal trials[xxxiii]. These specifically related to an observed phenomenon where vaccinated animals developed a more severe and occasionally fatal disease on subsequent exposure to the pathogen[xxxiv]. **Antibody dependent enhancement** (ADE) has not been investigated for the Covid-19 vaccines, as animal trials were only limited, and its potential remains of significant concern[xxxv xxxvi].

Our Conclusions and Recommendations

None of the Covid-19 vaccines have received full regulatory approval but have instead merely been authorized for emergency use. The authorization has been given on the basis of interim data analyses of the ongoing trials, in which no pregnant women were included.

The JCVI guidance commits to "continue to closely monitor the evidence on COVID-19 vaccination in pregnancy" and to "update its advice as required". We assume that such monitoring refers to capturing MHRA data. The Yellow Card system that supplies data to the MHRA is a passive reporting system, which is not widely known to the public, and which is also not intuitive to the user, so many cases may go unreported.

It is misleading to present information and data captured via a smart-phone based tool as scientific research and evidence of safety, and this threatens to undermine the standards of evidence-based medicine that have always been upheld in the UK. In matters of life and death, especially with experimental products, it is imperative to rigorously uphold diligent scientific process.

Administering a Covid-19 vaccine to a pregnant woman should only occur as part of a clinical trial with rigorous monitoring systems in place. Currently, the RCOG/RCM information sheet does not even meet the Good Clinical Practice (GCP) criteria of information for patients considering participation in a trial, due to factual inaccuracies and omissions, whilst leading the reader towards an intended decision by the way benefits and risks are presented and emphasized.

We reiterate that **the first principle in medicine is to do no harm**. The current approach to advising pregnant women on Covid-19 vaccines is inconsistent with evidence-based medicine and the ethical and moral responsibility to protect pregnant women and their unborn babies from potential harm. In view of all our concerns listed above, we suggest in the strongest possible terms that the JCVI reviews and revises their advice with immediate effect.

We thank you for taking the time to read this letter and consider its contents. We request that you kindly acknowledge this letter and all the references within, and either confirm that appropriate amendments to published advice have been made or lay out the reasoning for not doing so.

UK Medical Freedom Alliance

http://www.ukmedfreedom.org

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