

**Open Letter from the UK Medical Freedom Alliance to:**

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Prof Tim Draycott – RCOG Vice president for Clinical Quality

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**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 highlight our concerns regarding the information sheet and decision aid for pregnant women considering vaccination against Covid-19, which has been endorsed by the Royal College of Obstetricians & Gynaecologists and the Royal College of Midwives<sup>i</sup>.

Midwives and obstetricians are being called upon to counsel women and answer their questions about Covid-19 vaccines. This information sheet is set out to facilitate this process. Unfortunately, it contains no references, and there is no more detailed guidance available for professionals.

As you may be aware, vaccine manufacturers have requested and been granted complete exemption from any liability for their products<sup>ii iii</sup>. 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.

An information sheet ought to be factual and impartial. In this case, 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”. This is at a time when no scientific data is available regarding the effects and safety of Covid-19 vaccines in pregnancy.

Below, we elaborate on specific concerns about this information sheet with regards to information on:

- 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 symptoms and not prevention of infection<sup>iv</sup>. There is no evidence from trials or peer-reviewed studies that Covid-19 vaccines reduce hospitalizations, deaths or prolonged symptoms<sup>v</sup>. 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%<sup>vi</sup>.

Figures from Israel, the country with the highest vaccination uptake, indicate that numbers needed to vaccinate are 364 to prevent 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<sup>vii</sup>. Incidentally, 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<sup>viii</sup>. Israel has also had the highest excess mortality out of 26 countries over the last 5 weeks<sup>ix</sup>.

The statement in the information sheet that “vaccination is effective in preventing Covid-19 infection” is not based on trial data or peer-reviewed evidence. It has in fact been explicitly stated that infection is not prevented by the vaccines. The duration of any potential protective effect is currently also entirely unknown, as immune responses have not been monitored.

## 2) Risks of Covid-19 in pregnancy

Whilst the information sheet does not question or quantify the efficacy of the vaccines, it clearly emphasizes the risks of Covid-19 in pregnancy, stating that “some pregnant women can get life-threatening illness” and advising to “think about your risk of catching and becoming seriously unwell from Covid-19”. This is repeated several times and is bound to prompt women’s concerns and worries.

According to the RCOG Information for Healthcare Professionals on Covid-19 in pregnancy however, 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%)<sup>x</sup>. It states 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”, and women of childbearing age have an infection fatality rate of <0.05%. This is not the order of magnitude that is conveyed when the decision aid repeatedly mentions life-threatening illness.

The information sheet also states that “preterm birth is more likely” without elaborating that these are iatrogenic preterm deliveries in 78%<sup>vi</sup>. 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 they 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<sup>xi</sup>.

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”<sup>xii</sup>. We would strongly recommend that any information sheet should include a referenced quantification of benefits and risks if its purpose is to aid decision making.

## 3) Vaccine safety

Counselling and consent taking ought to be mindful of Montgomery’s 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”<sup>xiii</sup>. This includes the information that nothing is known about the risks.

Pregnant women were not included in any vaccine trials, and therefore there is no data regarding safety in pregnancy. The information sheet however states that “there is no evidence that the vaccines can cause harm to you or your baby”.

**The absence of any evidence is not equal to no evidence of harm**, and therefore once again the information is misleading. It reassures that the vaccines “do not contain ingredients that are known to be harmful” but fails to elaborate that mRNA and DNA-vector vaccines have never previously received full regulatory approval for use in humans on this scale. The decision aid even compares the Covid-19 vaccines to other “non-live vaccines” and refers to their safety. It therefore completely fails to raise awareness of the fact that Covid-19 vaccines are based on a novel biotechnology and are not comparable to any other vaccines.

Advice from Public Health England states 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”<sup>xiv</sup>. Most recent advice concedes 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”<sup>xv</sup>. Notably, there has not been any additional evidence on the safety of the vaccines in pregnancy in the interim, to support this concession.

In the absence of the 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, some are based on previous experiences with mRNA vaccines, and some are theoretical, warranting further investigations.

#### 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 403,469 adverse events, including 35 spontaneous abortions, as of the 22<sup>nd</sup> March 2021. 585 adverse events had a fatal outcome<sup>xvi</sup>. The **WHO** database records 333,818 adverse events and 2435 deaths as of the 27<sup>th</sup> March 2021<sup>xvii</sup>. The Vaccine Adverse Event Reporting System (**VAERS**) database in the US has recorded 2050 deaths as of the 19<sup>th</sup> March 2021<sup>xviii</sup>. Whilst in previous years since 2010, less than 200 deaths have been recorded annually, related to all vaccines, ten times the number of deaths has been recorded within 3 months related to Covid-19 vaccines alone. 46% of these deaths occurred in people who fell ill within 48 hours of being vaccinated<sup>xix</sup>. It is clearly not satisfactory to dismiss all of these as coincidental.

Specifically, regarding the AstraZeneca vaccine, there have been concerns over a number of cases of **severe cerebral venous thrombosis** with fatal outcomes, leading to temporary suspension in 24 countries<sup>xx</sup>. 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<sup>xxi</sup>. The following week, a report noted 16 a total of such cases in Germany, four of them with fatal outcome, and all but one occurring in women aged between 20 and 63 years<sup>xxii</sup>. This is specifically the group that would include pregnant women. Investigators in Norway also suggested that a causal relation between such cases and the vaccine is likely<sup>xxiii</sup>.

The suspicion is plausible, as there is evidence of direct activation of the alternative complement pathway by SARS-CoV-2 spike proteins, and the production of spike proteins is intended to be induced by the vaccines<sup>xxiv</sup>. The European Medicines Agency (EMA) safety committee, after reviewing the data and declaring the AstraZeneca vaccine to be safe, although indicating that rare events cannot be ruled

out, noted “concerns about the reports involving younger patients” with most cases affecting women<sup>xxv</sup>. Such concerns would be specifically relevant for pregnant women. 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<sup>xxvi</sup>. Recommendations from the PRAC following their review ought to be awaited and included in any information, especially to young women who appear to be specifically affected by this risk.

Pregnancy is a known pro-thrombotic state, and the potentially added risks of thrombotic events through Covid-19 vaccines are entirely unknown. This is potentially relevant not only to the health of the gravida but also to placental development and circulation. This information is likely to be deemed significant by most people and therefore ought to be shared with patients, according to the Montgomery ruling.

#### 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<sup>xxvii</sup>. These specifically related to an observed phenomenon where vaccinated animals developed a more severe and occasionally fatal disease on subsequent exposure to the pathogen<sup>xxviii</sup>.

**Antibody dependent enhancement (ADE)** has not been investigated, as animal trials were only limited, and its potential remains of significant concern<sup>xxix xxx</sup>.

#### Theoretical concerns

There may be concerns that ovarian reserve may be affected by the vaccines as Pfizer has initiated a trial to specifically investigate this<sup>xxxi</sup>.

### **Conclusions and Recommendations**

It is important to be mindful that 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.

**Administering a Covid-19 vaccine to a pregnant woman should therefore only occur as part of a clinical trial** with rigorous monitoring systems in place. This 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.

**The first principle in medicine is to do no harm.** In view of all the concerns listed above, we would therefore suggest in the strongest possible terms that the information contained in this decision aid is reconsidered and amended 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 further either confirm appropriate amendments to the patient information sheet have been made or lay out your reasoning for not doing so.

UK Medical Freedom Alliance

<http://www.ukmedfreedom.org>

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- <sup>i</sup> <http://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-24-combined-info-sheet-and-decision-aid.pdf>
- <sup>ii</sup> <http://www.nejm.org/doi/full/10.1056/NEJMp2030600>
- <sup>iii</sup> <https://www.cnbc.com/2020/12/16/covid-vaccine-side-effects-compensation-lawsuit.html>
- <sup>iv</sup> <https://www.fda.gov/media/144245/download>
- <sup>v</sup> <http://bmj.com/content/bmj/371/bmj.m4037.full.pdf>
- <sup>vi</sup> <https://www.bmj.com/content/371/bmj.m4347/rr-4>
- <sup>vii</sup> <https://mises.org/wire/what-weve-learned-israels-covid-vaccine-program>
- <sup>viii</sup> <https://francesoir.fr/videos-debriefings/vaccination-en-israel-des-chiffres-de-mortalite-qui-interpellent-video>
- <sup>ix</sup> <https://www.euromomo.eu/graphs-and-maps>
- <sup>x</sup> <https://www.rcog.org.uk/globalassets/documents/guidelines/2021-02-19-coronavirus-covid-19-infection-in-pregnancy-v13.pdf>
- <sup>xi</sup> <https://www.bmj.com/content/370/bmj.m3320>
- <sup>xii</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/973884/Temporary\\_Authorisation\\_HCP\\_Information\\_BNT162\\_8\\_0\\_UK.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/973884/Temporary_Authorisation_HCP_Information_BNT162_8_0_UK.pdf)
- <sup>xiii</sup> <https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent>
- <sup>xiv</sup> <https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding/covid-19-vaccination-a-guide-for-women-of-childbearing-age-pregnant-planning-a-pregnancy-or-breastfeeding>
- <sup>xv</sup> <https://www.gov.uk/government/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy/the-safety-of-covid-19-vaccines-when-given-in-pregnancy>
- <sup>xvi</sup> <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions>
- <sup>xvii</sup> <https://www.vigiaccess.org> Search “Comirnaty”
- <sup>xviii</sup> <https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes>
- <sup>xix</sup> <https://childrenshealthdefense.org/defender/cdc-ignore-inquiry-death-injuries-covid-vaccine/>
- <sup>xx</sup> <https://www.forbes.com/sites/niallmccarthy/2021/03/16/which-countries-have-stopped-using-the-astrazeneca-vaccine-infographic/?sh=3da07e985592>
- <sup>xxi</sup> <https://www.pei.de/SharedDocs/FAQs/EN/coronavirus/suspension-astrazeneca/1-coronavirus-astrazeneca-why-vaccination-suspended.html>
- <sup>xxii</sup> <https://www.aerzteblatt.de/nachrichten/122311/Mindestens-14-Faelle-von-Hirnvenenthrombosen-in-Deutschland-gemeldet>
- <sup>xxiii</sup> <https://sciencenorway.no/covid19/norwegian-experts-say-deadly-blood-clots-were-caused-by-the-astrazeneca-covid-vaccine/1830510>
- <sup>xxiv</sup> <https://ashpublications.org/blood/article/136/18/2080/463611/Direct-activation-of-the-alternative-complement>
- <sup>xxv</sup> <https://www.cidrap.umn.edu/news-perspective/2021/03/european-regulators-say-astrazeneca-vaccine-safe-cant-rule-out-rare-events>
- <sup>xxvi</sup> <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-update-ongoing-evaluation-blood-clot-cases>
- <sup>xxvii</sup> <https://www.pnas.org/content/117/15/8218>
- <sup>xxviii</sup> <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0035421>
- <sup>xxix</sup> <https://pubmed.ncbi.nlm.nih.gov/33113270/>
- <sup>xxx</sup> <https://www.nature.com/articles/s41564-020-00789-5>
- <sup>xxxi</sup> <https://clinicaltrials.gov/ct2/show/NCT04748172>