18 May 2022

Open Letter from the UK Medical Freedom Alliance to:

- **Dame June Raine** - Chief Executive of the MHRA
- **Mr Edward Morris** - President of the Royal College of Obstetricians & Gynaecologists
- **Rebeccah Davies** - President of the Royal College of Midwives

Urgent Call to Re-evaluate COVID-19 Vaccine Advice for Pregnant Women

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 refer to our previous Open Letters dated 29 March 2021[i] and 19 April 2021[ii] in which we highlighted our serious concerns regarding advice being given to pregnant women in relation to COVID-19 vaccine efficacy, risk of COVID-19 in pregnancy and COVID-19 vaccine safety in pregnancy.

We are writing to re-emphasise our concerns which have been enforced by data that has come to light recently and over the course of the last year.

In addition to the details outlined in our previous letters, we elaborate below why we are now gravely concerned regarding the continued policies to vaccinate pregnant women against COVID-19:

1. Lack of Regulatory Trial Data in Pregnancy

a. Post-marketing data

Pregnancy was an exclusion criterium for the regulatory COVID-19 vaccine trials. Data regarding effects of COVID-19 vaccines in pregnancy are therefore solely reliant on post-marketing surveillance.

Recently released documents from Pfizer[iii] indicate that during the first three months of the vaccination program between 1 December 2020 and 28 February 2021, 42,086 adverse events were reported to the manufacturer, including 1,223 fatalities. Unfortunately, the number of vaccines administered during that period has been redacted in the released document and therefore no denominator is available.

Among those reports were 270 pregnant women, but pregnancy outcomes were only recorded for 32 cases as "*spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each)*". These data are insufficient for any analysis.

Pfizer has initiated a clinical trial specifically to investigate the effect of COVID-19 vaccination on ovarian reserve but this trial is not yet recruiting as of May 2022[iv].

b. Pre-clinical data

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[v]. "*Fertility, early embryonic development and embryofoetal development*" was only studied in

general toxicity studies with "*evaluation of male and female reproductive tissues*". No studies have been done on "*prenatal and postnatal development, including maternal function*". Consequently, in a **Public Assessment Report by the MHRA, last updated in June 2021, "*it is considered that sufficient reassurance of safe use of the vaccine in pregnant women cannot be provided at the present time*"** [vi].

In a document dated 11 January 2021 by the Therapeutic Goods Administration (TGA) of the Australian Department of Health[vii], the Advisory Committee on Vaccines (ACV) issued their recommendations regarding COMIRNATY (Pfizer COVID-19 Vaccine). The ACV recommended a review of the product information (PI), as previously cited in a letter responding to the application dated 23 October 2020 by Pfizer for the provisional registration of COMIRNATY in the Australian Register of Therapeutic Goods (ARTG)[viii]. The PI in this letter dated 24 January 2021 rates the product as "*Pregnancy Category B1*" stating: "*Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development*". The recommendation by the ACV included an amended rating as "*Pregnancy Category B2*", implying that studies in animals are inadequate or may be lacking, and a replacement of the above statement with: "*A combined fertility and developmental toxicity study in rats showed increased occurrence of supernumerary lumbar ribs in fetuses from COMIRNATY-treated female rats*".

With very few and limited pre-clinical studies available, it is notable that this amendment was deemed necessary within a very short period of time, highlighting the **ongoing uncertainty regarding as yet unknown potential adverse effects on pregnancy and the unborn foetus** and the need to keep this under the closest review[ix].

2. Lack of Clinical Trial Data in Pregnancy

a. Sources of clinical data

As pregnant women were excluded from the regulatory trials, widely publicised reassurance regarding the safety of COVID-19 vaccines in pregnancy has been largely based on retrospective and observational cohort analyses[x] [xi] [xii].

Commonly quoted as a source of reassuring information 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 to be pregnant at the time of vaccination[xiii]. Notably, whilst it was previously claimed that tens of thousands of women reported having no significant issues after vaccination in pregnancy, less than 5% of these women were formally enrolled (8,749 of 185,218 women as of 10 January 2022). As of 2 May 2022, only 23,779 women were enrolled. The most recent publicly accessible data analysis appears to be from September 2021[xiv]. Such a voluntary registry is not in any way comparable to robust, thorough, scientific evaluation and peer-reviewed evidence.

b. Absolute requirement for robust clinical data

The **COVID-19 vaccines are based on a completely novel technology** using mRNA/DNA vectors and lipid nanoparticles. Compounds based on these technologies have never previously been administered to humans on such a large scale as clearly stated by the manufacturers BioNTech and Moderna:

> "*To our knowledge, other than our COVID-19 vaccine and MRNA-1273, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA, the EMA or other comparable regulatory authority*." (BioNTech)[xv]
>
> "*No mRNA drug has been approved in this new potential class of medicines, and may never be approved as a result of efforts by others or us.* ***mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines***." (Moderna)[xvi]

Following the principles of Good Clinical Practice, completely novel compounds that have never previously been 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. Observation for possible effects on pregnancy should be continued for at least the length of a pregnancy including the postpartum period. **THIS IS NOT BEING DONE.** Therefore, policies of vaccinating thousands of pregnant women without strict protocols of clinical research have been deeply irresponsible.

c. Substandard quality of available studies

Instead of conducting prospective trials, outcomes to be observed in short-term studies are being determined by protocols in post-hoc analyses, with little or no stratification of gestational age at the time of vaccination. This approach is inappropriate to study unknown and unforeseen potential adverse effects and entirely inconsistent with the rigorous standards of clinical research.

We have previously written to the authors and editors of two UK-based studies that were clearly biased towards reaching the conclusions of affirming safety and efficacy of COVID-19 vaccines in pregnancy[xvii] [xviii]. These were then widely propagated to the public, despite the data contained in the studies not supporting those conclusions on close and meticulous analysis, as we clearly laid out in our letters[xix] [xx]. Indeed, the methodologies of both these papers were flawed to the point that we called for immediate retractions.

The omission of well-designed prospective clinical trials prior to approving COVID-19 vaccinations in pregnancy is a gross violation of research and clinical ethics. This is all the more concerning as there have been previous examples when new substances were indiscriminately administered to pregnant women with disastrous consequences (i.e. Thalidomide / Diethylstilbestrol (DES)).

3. Indications of Harm

Despite reassurances from observational studies, **there are now significant numbers of adverse events and adverse pregnancy outcomes being reported worldwide**. These can no longer be overlooked or denied but must be investigated as a matter of urgency.

a. Adverse event reporting

Especially in pregnant women who were not recruited into the ongoing regulatory clinical trials, **the recognition of adverse events relies solely on post-marketing surveillance** carried out via passive reporting systems.

In the UK, adverse reactions following administration of COVID-19 vaccines are supposed to be reported via the Yellow Card System of the Medicines and Healthcare products Regulatory Agency (MHRA). 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 **very poor awareness of this scheme and no publicised encouragement to report any side effects**, potentially leading to **reporting bias and a significant underestimate of the nature and the true number of adverse events and deaths**. It has previously been estimated that only up to 10% of serious adverse events are officially reported to the MHRA[xxi]. It is frequently claimed that these reports are not reliable but they are in effect the only tool applied for post-marketing surveillance of the COVID-19 vaccines, and more reliable data are simply not available.

i. MHRA

In the MHRA report published on 20 April 2022[xxii] there were **over 1.48 million adverse reactions in the UK** from 453,680 reports, including **2,096 fatalities**. One in 117 people vaccinated (0.85%) have reported an adverse event.

There were **1,184 reports of pregnancy conditions, including 797 miscarriages**, and 57,565 reports in the category of reproductive / breast disorders.

ii. VAERS

The Vaccine Adverse Event Reporting System (VAERS) database in the US has recorded **27,758 deaths** as of 29 April 2022[xxiii]. In 27.8% of cases, deaths occurred within 2 days of vaccination and in 39.4% within 7 days. For comparison, less than 200 deaths have been recorded annually, related to ALL vaccines in previous years since 2010.

There have been **3,197 reports of spontaneous miscarriages and also 314 foetal deaths and 132 stillbirths**[xxiv].

iii. Vigiaccess

As of 8 May 2022, the WHO Database Vigiaccess[xxv] listed 3,746,090 reports of adverse events in connection with a COVID-19 vaccine, including **18,892 deaths**.

There were 10,900 reports in the category "*Pregnancy, puerperium and perinatal conditions*", including **5,546 miscarriages, 200 stillbirths and 474 foetal deaths**. There were also 203,329 reports of reproductive system and breast disorders.

b. <u>Recent reports of increased adverse pregnancy outcomes</u>

i. Iceland

A recent publication from Iceland reported a notable **80% increase of stillbirths and neonatal deaths** in 2021[xxvi]. In 2020, there were 9 stillbirths and 17 in 2021. The number of stillbirths per 1,000 live births increased from 2.0 to 3.5. The average of stillborn babies per 1,000 live babies for the previous nine years (2011-2020) was 2 per 1,000. In 2021, there was a 75% increase compared to the previous nine years. Perinatal mortality increased by 82% (Fig 1).

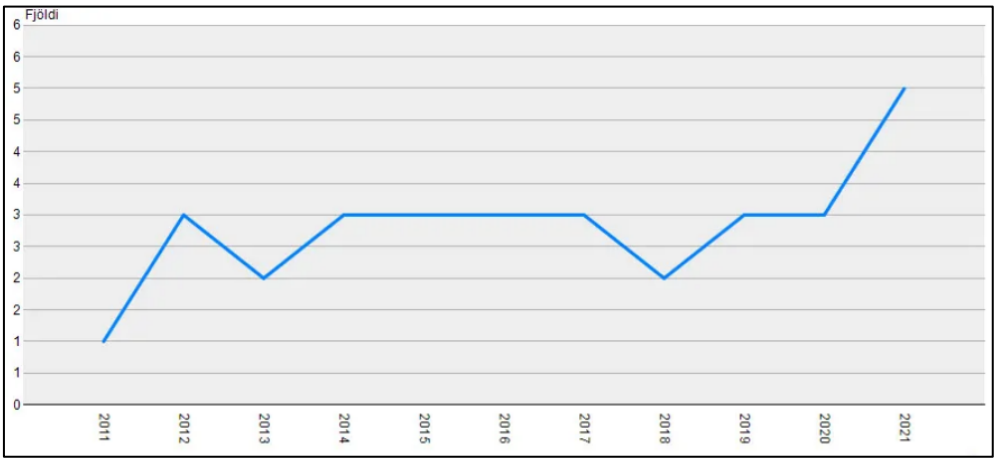

Fig 1 Perinatal Mortality in Iceland

ii. Scotland

In 2021 there was an investigation into an abnormal spike in **deaths of newborn babies** in Scotland, as the rate of 5.1 per 1,000 live births in September was significantly above average[xxvii]. There has been another spike in March 2022, of 4.6 per 1,000 births[xxviii]. Data from Public Health Scotland (PHS) clearly demonstrate these highly unusual spikes in neonatal deaths rates (Fig 2).

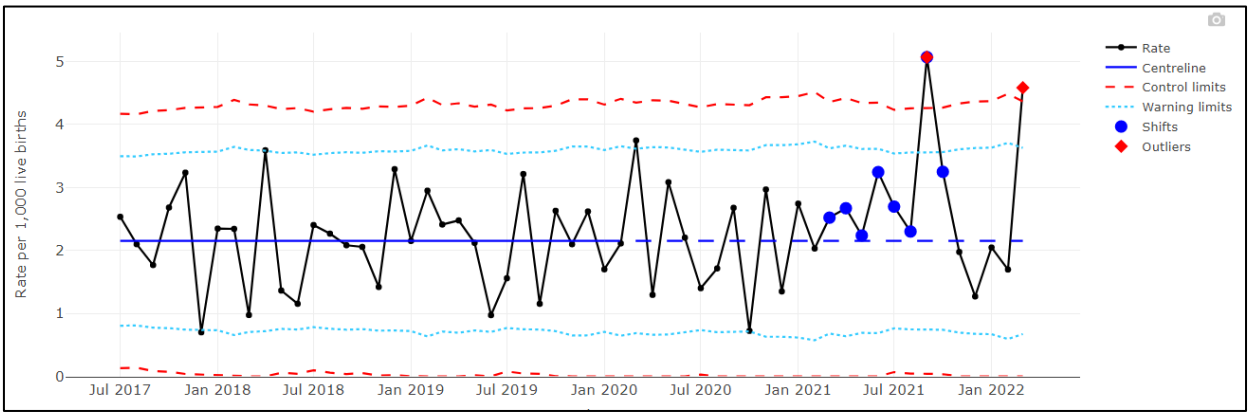

Fig 2 Monthly rates of Neonatal Deaths per 1,000 live births in Scotland (PHS Data)

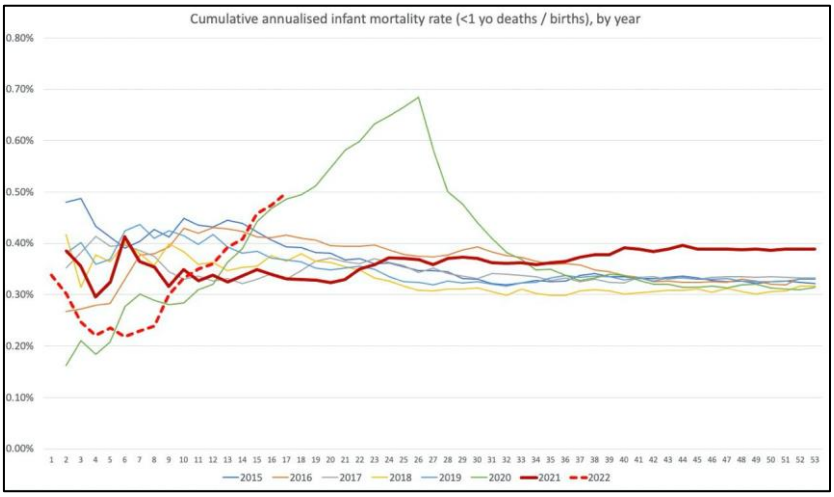

Fig 3 Cumulative annualised infant mortality (NRS data)

The cumulative annualised infant mortality rate (deaths of under 1-year olds per births) in Scotland showed a significant excess from the middle of 2021 onwards. Notably, these are cumulative data which usually stabilize at 0.3 - 0.33% towards the end of the year (Fig 3).

Data from PHS show a striking temporal correlation between COVID-19 vaccinations in pregnancy and rates of extended perinatal deaths (stillbirths and neonatal deaths) occurring in all pregnancies (vaccinated and unvaccinated) (Fig 4).

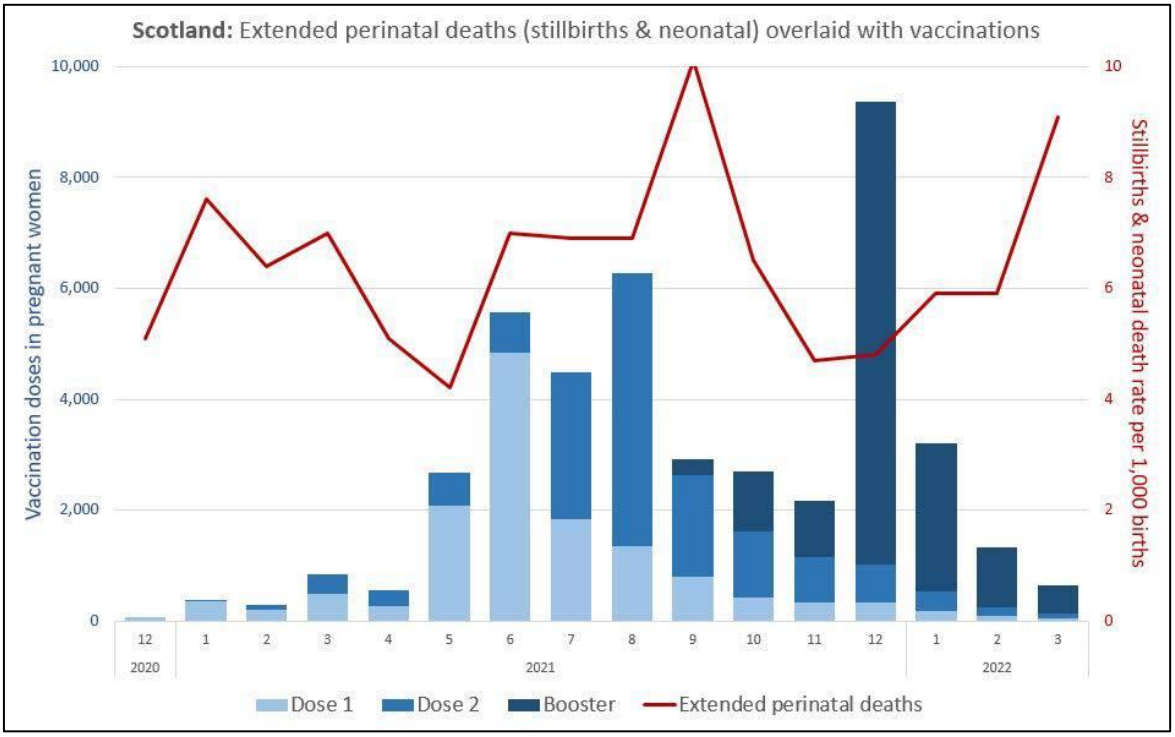

Fig 4 Rates of extended perinatal deaths and COVID-19 vaccinations in pregnancy (PHS data)

Whilst these reports of spikes in stillbirths, neonatal and infant mortality do not prove causality of the COVID-19 vaccines, the temporal association with the vaccine and booster rollouts must be acknowledged as a potential safety signal and prompt an immediate investigation.

Conclusion & Requests

- **Firm conclusions regarding the safety of COVID-19 vaccines in pregnancy are premature** as no well-designed prospective trials with sufficient length of follow-up have been conducted. Currently cited data do not stand up to scientific scrutiny.
- Among the available data of adverse events following COVID-19 vaccinations, there are **clear and undeniable safety signals** that must be investigated as a matter of absolute priority.
- Pregnant women have never before been recommended to accept a treatment even before the regulatory clinical trials of non-pregnant individuals have been completed. Until robust and transparent scientific evidence affirms the safety of these compounds which are based on completely novel technology, **the advice to vaccinate pregnant women must be revised and the rollout halted immediately to this cohort.**

- If you fail to acknowledge these safety signals, you must issue a public explanation as to why you do not consider these profoundly disturbing data worthy of an immediate and thorough investigation, without bias and pre-empting conclusions.
- You will be aware that vaccine manufacturers have requested and been granted complete exemption from any liability for their products[xxix] [xxx]. **Great onus therefore lies on regulators and professionals who are advising policies to scrutinise available scientific evidence, as they may otherwise be held liable** should adverse events occur, especially if these are serious.
- 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 is at this point grossly negligent and irresponsible.
- If you continue to advocate that COVID-19 vaccines should be administered to pregnant women, **we demand scientifically robust and transparent evidence for the safety and efficacy of COVID-19 vaccines in pregnancy**.

Thank you for reading and considering all the points made in this letter.

We trust that you will come to the only possible conclusion that COVID-19 vaccination in pregnancy must be halted immediately and only offered within the context of well-designed and prospective clinical research trials.

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 the utmost importance for the health of pregnant women and their babies.

UK Medical Freedom Alliance

http://www.ukmedfreedom.org

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[i] https://www.ukmedfreedom.org/open-letters/open-letter-to-royal-college-of-obstetricians-and-gynaecologists-and-the-royal-college-of-midwives-re-covid-19-vaccine-advice-for-pregnant-women
[ii] https://www.ukmedfreedom.org/open-letters/ukmfa-open-letter-to-the-jcvi-re-advice-that-covid-19-vaccines-should-be-offered-to-all-pregnant-women
[iii] https://phmpt.org/wp-content/uploads/2022/04/reissue_5.3.6-postmarketing-experience.pdf Page 12
[iv] https://clinicaltrials.gov/ct2/show/NCT04748172
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[xvii] https://www.nature.com/articles/s41591-021-01666-2
[xviii] https://www.nature.com/articles/s41467-022-30052-w
[xix] https://www.ukmedfreedom.org.org/open-letters/open-letter-from-ukmfa-to-dr-sarah-stock-and-editor-of-nature-medicine-re-claims-made-on-safety-of-covid-19-vaccines-in-pregnancy
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[xxii] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
[xxiii] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes
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