31 October 2022

Open Letter from the UK Medical Freedom Alliance to:

- **Dr Helen Mactier** – Retired Consultant Neonatologist
- **Healthcare Improvement Scotland**

Increase in Neonatal Mortality 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 write to you as the chair of the expert group to undertake a review of the significant increase in neonatal mortality across Scotland in the year 2021/22.

We write to appeal to you that you ensure that all possible factors which may have contributed to this increased neonatal mortality are indeed considered. Specifically, we appeal to you that the possibility of COVID-19 vaccination having a causative effect is not dismissed a priori.

It has been claimed that COVID-19 vaccinations are not worth considering in this context, as they have already been proven to be safe. We question the certainty of this statement and urge you to consider the following:

1) Lack of safety data

Pregnant women were excluded from the regulatory safety trials, and there are no trials or studies that cover even the duration of a pregnancy. COVID-19 vaccines were on the market for a mere 4 months, when they were declared safe. Potential adverse effects in neonates have not even been considered.

What is claimed to be reassuring safety data is largely based on post-marketing surveillance in retrospective and observational cohort analyses and registries, such as the CDCs V-safe COVID-19 Vaccine Pregnancy Registry. Voluntary registries are not equivalent to well-designed prospective clinical trials, as follow-up is inconsistent and incomplete. Clinical research standards dictate close and prolonged observation of trial subjects, documenting any and all observed clinical effects following administration of the trial compound. If pregnant women are being studied, observation should extend to the neonatal period and, especially in the case of a compound based on a completely novel technology, to childhood of the offspring and beyond. This has not been done.

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[i]. "*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 conducted on "*prenatal and postnatal development, including maternal function*"[ii]. Therefore, it cannot possibly be known whether it is safe to give these products to pregnant women.

2) Mechanisms of potential harm

We refer to our previous Open Letters to the Royal College of Obstetricians & Gynaecologists (RCOG) dated 29 March 2021[iii], 19 April 2021[iv] and 18 May 2022[v], 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.

It is worth noting the data tracking COVID-19 vaccination and infection in pregnancy in Scotland, which indicate that vaccination has not been effective in preventing infection but indeed suggest the opposite (Figure 1).

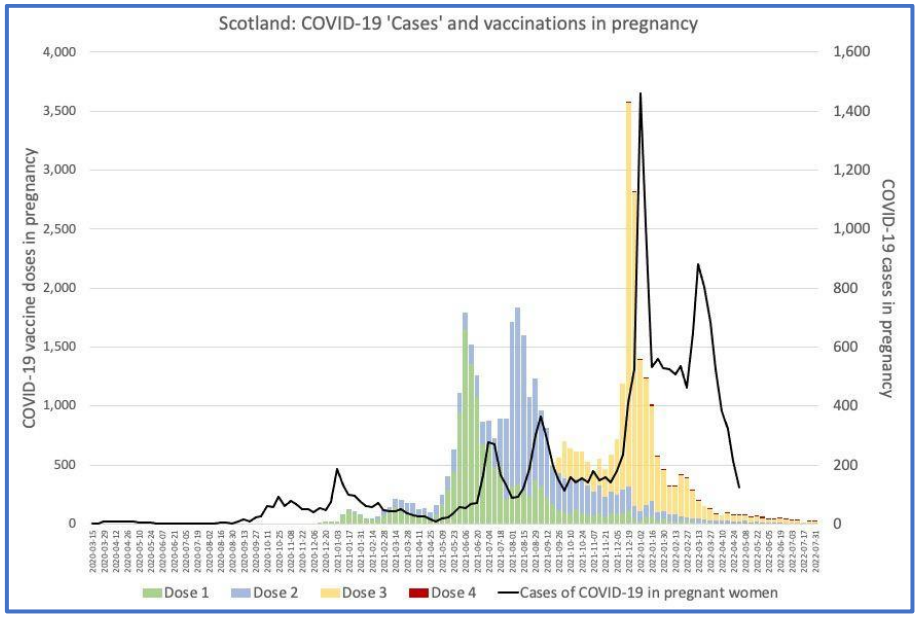

Figure 1

Pfizer's own pharmacokinetics studies[vi] showed that the lipid nanoparticles used to carry the mRNA are distributed to and accumulate in the ovaries at significant concentrations (Table 1)[vii]. Lipid nanoparticles are designed to cross even cell membranes, which otherwise create a barrier to certain substances, including the placental barrier. Potential ovarian toxicity of nanocarriers has in fact previously been warned about in a paper published 10 years ago[viii]. We have no knowledge of how much accumulates in maternal and also fetal ovaries, and what the potential effects may be on reproductive health, including that of the offspring.

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Sample	Total Lipid concentration (µg lipid equivalent / g [or mL]) (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170

Table 1

A recent research letter in JAMA Pediatrics[ix] highlighted that COVID-19 vaccine mRNA could be detected in breast milk. Clinical significance has not been investigated, but the conclusion advises caution against breastfeeding for the first 48h after vaccination, and previous studies have described adverse events in 7.1% of breastfed infants, which should give serious cause for concern[x].

A study published in PLOS Pathogens[xi] showed that in mice "the mRNA-LNP vaccine platform induces long-term immunological changes, some of which can be inherited by the offspring". The effect on the immune system in human offspring – including defence against infections as well as the propensity to allergies and autoimmune disorders – is at this stage completely unknown.

Concern regarding potential autoimmunity is also based on molecular mimicry [xii]. mRNA vaccines induce human cells to produce antigens (spike proteins) in order to elicit an immune response. Similarities between spike and human proteins may lead to an adverse autoimmune reaction. It is potentially relevant for pregnant women and their babies that the SARS-CoV-2 spike glycoprotein was found to share similarities with 27 human proteins that relate to oogenesis, uterine receptivity, decidualization, and placentation in a study published in the American Journal of Reproductive Immunology[xiii].

3) Safety signals

It must be acknowledged that high numbers of pregnancy-related adverse events, including miscarriages and stillbirths, have been reported to all four major databases for adverse event reporting (US - VAERS[xiv] / UK - MHRA Yellow Cards[xv] / Europe - EudraVigilance[xvi] / WHO - Vigiaccess[xvii]) (Table 2).

	VAERS	MHRA	Vigiaccess	EudraVigilance (Pfizer only)
Total Reports	1,424,789	464,072	4,429,975	1,132,795
Pregnancy / Puerperium / Perinatal			12,413	2876
Miscarriages	5055	821	5959	1994
Fetal deaths			548	150
Stillbirths	193	23	231	60
Data as of 10th October 2022				

Table 2

It is also worth noting that the spikes in neonatal deaths in Scotland have occurred in temporal association with COVID-19 vaccination (Figure 2). This correlation is particularly remarkable considering that not all pregnant women have been vaccinated.

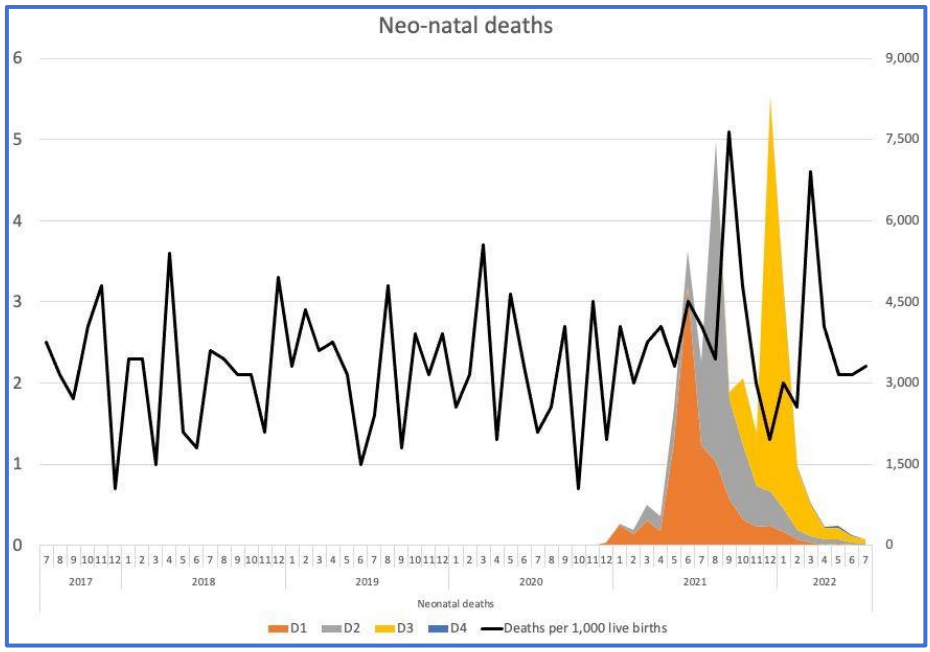

Figure 2

Whether or not COVID-19 vaccination is in any way related to the rise in neonatal mortality cannot possibly be known unless and until it is fully investigated without the bias that has afflicted most publications on this subject to date, which have sought to affirm safety without any basis in robust and reliable data. The need for investigation is urgent, especially as COVID-19 vaccination continues to be strongly recommended to pregnant women.

We therefore appeal to you, as chair of the expert panel instructed to investigate the rise in neonatal deaths, not to exclude the possibility that the COVID-19 mRNA vaccines, based on a completely novel technology never used in humans on a mass scale before, let alone in pregnant women, may be a major contributory or even causal factor in these tragic deaths.

Yours sincerely

UK Medical Freedom Alliance

http://www.ukmedfreedom.org

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[i] https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-02418-pgs-268-331.pdf

[ii] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/997584/COVID-19_mRNA_Vaccine_BNT162b2__UKPAR__PFIZER_BIONTECH_ext_of_indication_11.6.2021.pdf Pages 20/21

[iii] 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

[iv] 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

[v] https://www.ukmedfreedom.org/open-letters/ukmfa-open-letter-to-mhra-royal-college-of-obstetricians-gynaecologists-and-royal-college-of-midwives-re-urgent-call-to-re-evaluate-covid-19-vaccine-advice-for-pregnant-women

[vi] https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-02418-pgs-3-36.pdf

[vii] https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-02418-pgs-49-62.pdf

[viii] https://pubmed.ncbi.nlm.nih.gov/22361117/

[ix] https://jamanetwork.com/journals/jamapediatrics/fullarticle/2796427

[x] https://www.ncbi.nlm.nih.gov/sites/books/NBK565969/

[xi] https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1010830

[xii] https://pubmed.ncbi.nlm.nih.gov/35891400/

[xiii] https://pubmed.ncbi.nlm.nih.gov/34407240/

[xiv] https://medalerts.org/vaersdb/index.php

[xv] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

[xvi] https://dap.ema.europa.eu/analytics/saw.dll?PortalPages

[xvii] https://vigiaccess.org