Sicherheitsbedenken bezüglich: Covid-19-Impfungen in der Schwangerschaft

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Offener Brief an RCOG, RCM & UKHSA

An: Das Royal College of Obstetricians and Gynecologists (RCOG)

Royal College of Hebammen (RCM)

UK Health Security Agency (UKHSA)

Betreff: Sicherheitsbedenken bezüglich: Covid-19-Impfungen in der Schwangerschaft

COVID-19 Impfungen in der Schwangerschaft – wo sind die Beweise?

Geburtshelfer und Gynäkologen im Vereinigten Königreich vertrauen darauf und passen ihre Praxis gemäß den Richtlinien ihres Royal College (RCOG) an. Die jüngsten Ratschläge des RCOG standen jedoch in völligem Widerspruch zu allem, was sie selbst und akademische Institutionen über evidenzbasierte Medizin gelehrt haben. Dieser Rat lautet: COVID-19-Impfstoffe sind nicht nur sicher, sondern werden schwangeren Frauen dringend empfohlen.

Solche Ratschläge basieren nicht auf belastbaren Daten auf der Grundlage ethisch durchgeführter Forschung – und jeder, der medizinisch und akademisch ausgebildet ist, sollte sich ernsthaft damit auseinandersetzen.

Ethik der klinischen Forschung

Klinische Forscher, insbesondere bei der Durchführung von Studien zur Untersuchung von Arzneimitteln, sind verpflichtet, sich alle zwei Jahre über die Grundsätze der Guten Klinischen Praxis zu informieren, die den Nürnberger Kodex und die Deklaration von Helsinki beinhalten. Gemäß diesen Grundsätzen ist es unethisch, gegen ein Studienprotokoll zu verstoßen, indem unerwünschte Ereignisse nicht gemeldet werden (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428332/)[i] , indem Teilnehmer entfernt werden (https://www.realnotrare.com/post/maddie-de-garay)[ii]mit unerwünschten Ereignissen aus der Studie und durch vorzeitige Entblindung der Studienteilnehmer mit dem Ziel, das zu untersuchende Produkt allen zu verabreichen und damit die Studie effektiv zu beenden – wie dies alles in den COVID-19-Impfstoffstudien geschehen ist. Es ist unethisch, der Öffentlichkeit 75 Jahre lang den Zugang zu rohen Studiendaten zu verwehren und einen Teil davon erst nach einem Gerichtsverfahren zur unabhängigen Prüfung freizugeben [(https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/)iii] . Es ist

unethisch, die Schlussfolgerungen einer vorzeitig beendeten Studie auf gefährdete Gruppen zu extrapolieren, die nicht in der Studie vertreten sind – wie z. B. schwangere Frauen.

Aus offensichtlichen Gründen werden schwangere Frauen in der Regel von klinischen Studien ausgeschlossen. Das British National Formulary rät aufgrund fehlender Daten häufig vorsorglich von der Anwendung eines Arzneimittels in der Schwangerschaft ab. In der Schwangerschaft reicht der Mangel an Daten, um zögerlich zu sein. Zwei Beispiele aus nicht allzu ferner Vergangenheit erinnern uns daran, wie verheerend es sein kann, wenn schwangeren Frauen ein neues Produkt verabreicht wird: Thalidomid verursachte schwere Gliedmaßenschäden beim Fötus, und Diethylstilbestrol (DES) erhöhte das Risiko für bestimmte Krebsarten nach einer Exposition in utero, was eine lebenslange Überwachung für mehr als eine Generation erfordert. Es war in der Tat der Thalidomid-Skandal, der zur Einrichtung des britischen Yellow-Card-Systems für die Meldung unerwünschter Ereignisse führte. Doch plötzlich scheint das alles vergessen zu sein.

Mangel an belastbaren und zuverlässigen Sicherheitsdaten

Eine kürzliche öffentliche Kontroverse konzentrierte sich auf die am 16. August 2022 aktualisierten MHRA-Empfehlungen (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine)[iv] , in denen in den Schlussfolgerungen zur Toxizität festgestellt wurde, dass „eine ***ausreichende Bestätigung der sicheren Verwendung des Impfstoffs (mRNA BNT162b2 / Pfizer/BioNTech) derzeit nicht bereitgestellt werden kann*** “ und „ ***Frauen Auch Stillende sollten nicht geimpft werden***“. Die Regierung und die RCOG äußerten sehr schnell ihre Besorgnis über die Verbreitung dieser offensichtlichen Fehlinformationen und bekräftigten ihren Rat, dass schwangere Frauen sich impfen lassen sollten. Dieses Dokument stammt ursprünglich vom Dezember 2020, und daher wird behauptet, dass dieser Abschnitt veraltet ist. Es bleibt die Frage, warum dieser Abschnitt nicht geändert wurde, wenn dieses Dokument kürzlich aktualisiert wurde. Die Antwort ist natürlich, weil es

nichts zu aktualisieren gibt: Studien zur Genotoxizität, Karzinogenität, Reproduktions- und Entwicklungstoxizität, prä- und postnatalen Entwicklung wurden noch nicht durchgeführt.

Es kann unmöglich bekannt sein, ob es sicher ist, diese Produkte schwangeren und stillenden Frauen zu geben. Klinische Forschungsstandards schreiben eine enge und längere Beobachtung der Versuchspersonen vor, wobei alle und alle beobachteten klinischen Wirkungen nach der Verabreichung der Versuchssubstanz dokumentiert werden. Dies ist nicht geschehen. Es gibt keine Studien, die auch nur die Dauer einer Schwangerschaft dauern. COVID-19-Impfstoffe waren gerade einmal vier Monate auf dem Markt, als sich die anfängliche Empfehlung, sie in der Schwangerschaft zu vermeiden, um 180 Grad änderte und sie für sicher erklärt wurden. Mögliche Nebenwirkungen für die Nachkommen wurden noch nicht einmal berücksichtigt.

Es ist zutiefst unethisch, schwangeren Frauen eine völlig neue Verbindung in großem Maßstab ohne die strengen Protokolle der klinischen Forschung zu verabreichen, um nur zu sehen, was passiert, und dann so zu tun, als wäre dies Wissenschaft. Doch genau das ist geschehen.

Falsche Interpretation der verfügbaren Daten

Die Sicherheitsdaten basieren größtenteils auf retrospektiven und beobachtenden Kohortenanalysen und -registern, wie dem V-safe COVID-19 Vaccine Pregnancy Registry der CDC. Freiwillige Register sind nicht gleichbedeutend mit gut konzipierten prospektiven klinischen Studien, da die Nachverfolgung uneinheitlich und unvollständig ist, ohne Standardisierung oder Systematisierung und ohne Nachverfolgung der Teilnehmer.

Other data is from short-term studies where outcomes are determined in post-hoc analyses, with little or no stratification of gestational age at the time of vaccination. A large Canadian study (https://pubmed.ncbi.nlm.nih.gov/35964614/)[v] published in the Lancet concluded that "COVID-19 vaccines have a good safety profile in pregnancy" based on a follow-up period of a whole seven days. Conflicts of interest status

on this paper is notable. Publications are clearly biased towards reaching the conclusions of affirming safety and effectiveness of COVID-19 vaccines in pregnancy even when their study data do not allow such conclusions. The UK Medical Freedom Alliance (UKMFA) has published on their website open letters to the UK-based authors of two (https://www.ukmedfreedom.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)[vi] such studies (https://www.ukmedfreedom.org/open-letters/open-letter-from-the-uk-medical-freedom-alliance-to-professor-asma-khalil)[vii] with a critique of their conclusions. Both papers were widely propagated to the public.

The systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy (https://pubmed.ncbi.nlm.nih.gov/35538060/) [viii] was co-authored by the current president of the RCOG, who shared this headline with the RCOG membership: "COVID-19 vaccination associated with 15% reduction in stillbirths in pregnant women". The prompt within the message to "Find out more" linked not to the original paper for everyone to scrutinise and recognise the flawed methodology, but to the Guardian propagating the same headline. The work of Professor Norman Fenton (Professor of Risk Information Management) on the "statistical illusion of better pregnancy outcomes for vaccinated women" is worth considering for a comprehensive analysis of the available data (https://www.normanfenton.com/post/the-statistical-illusion-of-better-pregnancy-outcomes-for-vaccinated-women) [ix].

Currently, any quantitative assessment of the risks of adverse events in pregnancy is mostly stymied by the lack of reliable denominators, prohibiting accurate interpretation of existing data.

Shimabukuro et al published their preliminary findings of mRNA COVID-19 vaccine safety in pregnancy in the NEJM based on the V-safe registry (https://www.nejm.org/doi/full/10.1056/NEJMoa2104983) [x], reporting a

miscarriage rate of 12.6% – consistent with the general population. This was based on a denominator of 827 completed pregnancies. The conclusion was incorrect as only 127 women had been vaccinated in the first or second trimester, and so by definition the remaining 700 women could not possibly have had an early pregnancy loss.

According to post-marketing data from Pfizer, 42,086 adverse events were reported to the manufacturer during the first three months of the vaccination program. Amongst these were reports from 270 pregnant women. Only 32 pregnancy outcomes were recorded. This should have been but indeed was not a study with dedicated follow-up. This data was collected as part of post-marketing surveillance and is insufficient for comprehensive analysis.

Therefore, there are no reliable statistics at this time – but there are plausible mechanisms of potential harm and there are glaring safety signals.

Mechanisms of potential harm

Even if pregnant women were at increased risk from COVID-19, there are no conclusive data demonstrating that those risks are mitigated by vaccination. Regarding effectiveness, it is worth considering the data tracking COVID-19 vaccination and infection in pregnancy in Scotland, which does not indicate vaccination to have been beneficial, indeed it suggests quite the opposite (Figure 1).

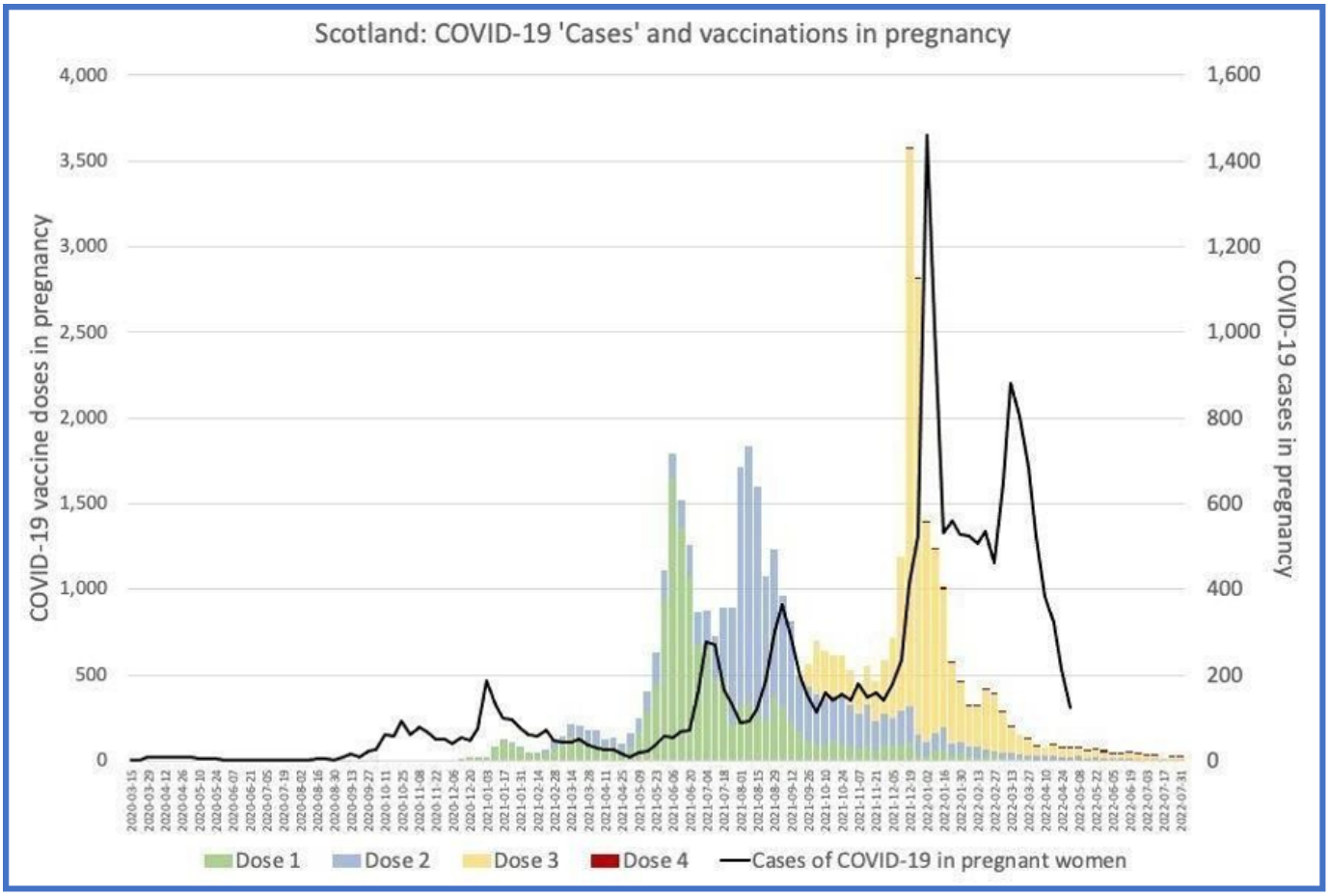

Figure 1 Scottish covid cases and vaccinations in pregnancy (https://publichealthscotland.scot/publications/covid-19-statistical-report/covid-19-statistical-report-28-september-2022/).

Independent of the potential risks to the pregnancy itself, there are now well-acknowledged risks of COVID-19 vaccines for women of childbearing age in general, including risks of cardiac and cardiovascular morbidities, which may well affect a pregnancy.

Pfizer's own pharmacokinetics studies (https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-%2002418-pgs-3-36.pdf) [xi] (https://www.hartgroup.org/wp-admin/post.php?post=8301&action=edit#_edn11) showed that the lipid nanoparticles used to carry the mRNA are distributed to and accumulate in the ovaries at significant concentrations (Table 1) (https://www.judicialwatch.org/wp-content/uploads/2022/04/JW-v-HHS-FDA-Pfizer-BioNTech-Vaccine-prod-3-%2002418-pgs-49-62.pdf) [xii] (https://www.hartgroup.org/wp-admin/post.php?post=8301&action=edit#_edn12).

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 highlighted that COVID-19 vaccine mRNA could be detected in breast milk (https://jamanetwork.com/journals/jamapediatrics/fullarticle/2796427) [xiv]. The clinical significance of this 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 (https://www.ncbi.nlm.nih.gov/sites/books/NBK565969/) [xv].

A study published in PLOS Pathogens (https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1010830) [xvi] 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 defense 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 (https://pubmed.ncbi.nlm.nih.gov/35891400/) [xvii]. mRNA vaccines induce human cells to produce antigens (spike proteins) in order to elicit an immune response. Similarities between spike protein and human proteins may lead to an adverse autoimmune reaction. It is potentially relevant for pregnant women 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 (https://pubmed.ncbi.nlm.nih.gov/35891400/) [xviii].

Safety Signals

Most concerning are the accumulating safety signals - and the apparent reluctance to fully investigate them. All four major databases for adverse event reporting (VAERS (https://medalerts.org/vaersdb/index.php) [xix] / MHRA Yellow Cards (https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions) [xx]/ EudraVigilance (https://dap.ema.europa.eu/analytics/saw.dll?PortalPages)[xxi] / WHO Vigiaccess (https://vigiaccess.org/)[xxii]) contain significant numbers of pregnancy-related adverse outcomes, including miscarriages and stillbirths (Table 2).

	VAERS	**MHRA**	**Vigiaccess (WHO)**	**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: Pregnancy-related adverse events on international databases

A study - currently in preprint - by Dr James Thorp (US specialist in feto-maternal medicine) compares pregnancy-related adverse outcomes (https://www.preprints.org/manuscript/202209.0430/v1) [xxiii] reported after COVID-19 vaccination to those reported after influenza vaccinations. Even considering the limitations of the study and the perhaps questionable validity of this comparison, the number of reports following COVID-19 vaccines of miscarriages, fetal chromosomal abnormalities, fetal malformation, fetal cystic hygroma, fetal cardiac disorders, fetal arrhythmia, fetal cardiac arrest, fetal vascular mal-perfusion, fetal growth abnormalities, fetal abnormal surveillance, fetal placental thrombosis, low amniotic fluid, and fetal death/stillbirth are extremely concerning.

In addition, there are reports of unexplained phenomena. Birth rates in the first half of 2022 appear to have fallen significantly in highly vaccinated countries in Europe based on official figures, with a decline of more than 4% in 15 countries and more than 10% in 7 countries (https://initiative-corona.info/fileadmin/dokumente/Geburtenrueckgang-Europe-DE.pdf) [xxiv]. The rates of cumulative annualised infant mortality in Scotland show 2021 as a significant outlier (Figure 2). As the data are cumulative, the variation usually evens out towards the end of the year, but not so in 2021. The rise mostly relates to spikes in neonatal deaths, which have occurred in temporal association with COVID-19 vaccination (Figure 3). This correlation is especially remarkable considering not all pregnant women were vaccinated.

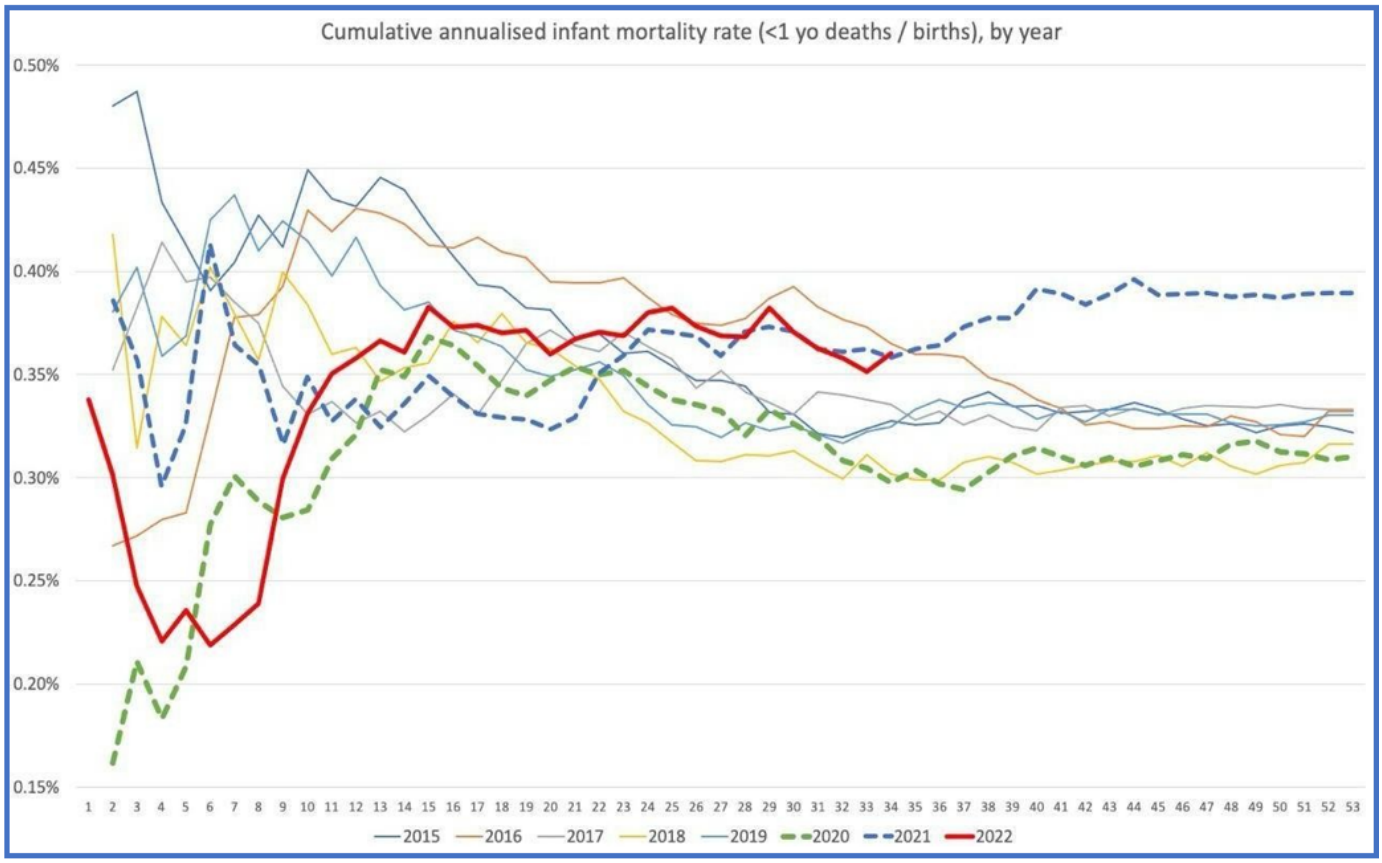

Figure 2 Infant mortality in Scotland (https://scotland.shinyapps.io/phs-covid-wider-impact/) 2015-2022

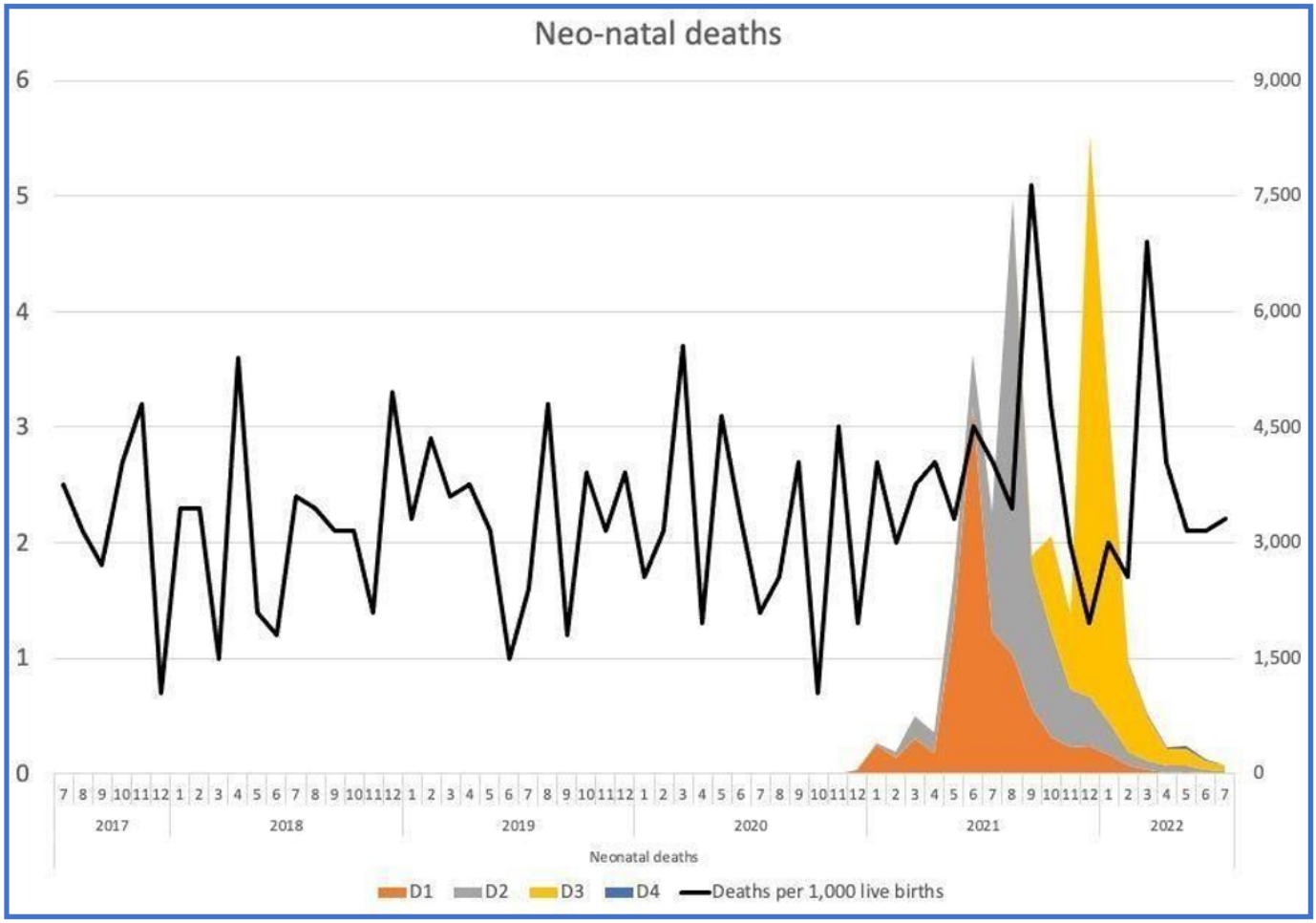

Figure 3 Neonatal (https://scotland.shinyapps.io/phs-covid-wider-impact/) deaths and COVID-19 vaccination (Dose 1-3) in pregnancy (https://scotland.shinyapps.io/phs-covid-wider-impact/) in Scotland

These spikes in neonatal deaths have been publicly acknowledged as concerning (https://www.bbc.com/news/uk-scotland-63097142)[xxv]. Dr Sarah Stock, expert in maternal and fetal medicine at the University of Edinburgh, commented in May 2022: "***The numbers are really troubling, and I don't think we know the reasons why yet***" but "***stressed the Covid vaccine, which studies have consistently shown to be safe in pregnancy, was not a factor (https://www.bbc.co.uk/news/uk-scotland-61448963)***" [xxvi]. This cannot possibly be known unless it is investigated without the bias that has afflicted most publications on this subject to date. The need for investigation is urgent, and whilst this should have been with clinical trials, there should now be a moratorium on COVID-19 vaccines to allow for meticulous retrospective analysis and re-evaluation.

If we continue to ignore these safety signals, we are not doing our due diligence to protect patients from harm. According to the principles of Good Medical Practice outlined by the General Medical Council, we are supposed to take action when we are concerned about compromised patient safety.

We are not just concerned but deeply disturbed and alarmed at the widespread distortion of science and the blatant omissions in the process of bringing a newly developed pharmaceutical product to market.

We have a collective duty to restore the principles of medical ethics to our practice and to clinical research to protect the most vulnerable groups from harm, and this includes pregnant women and their babies.

In the absence of data on long-term outcomes of mRNA COVID-19 vaccination in pregnancy for either women or their infants, vaccination of pregnant women should be paused while a full safety enquiry is conducted and until

results of long-term studies on animals as well as pregnant women and their offspring firmly and unequivocally establish that the benefits of vaccination clearly outweigh the risks to both mothers and babies.

We look forward to an early response to our concerns.

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[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428332/ (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9428332/)

[ii] http://www.realnotrare.com/post/maddie-de-garay (http://www.realnotrare.com/post/maddie-de-garay)

[iii] https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer- (https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/) vaccine-docs-2022-01-07/ (https://www.reuters.com/legal/government/paramount-importance-judge-orders-fda-hasten-release-pfizer-vaccine-docs-2022-01-07/)

[iv] https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid- (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine) 19/summary-public- (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine)assessment-report-for-pfizerbiontech-covid-19-vaccine (https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/summary-public-assessment-report-for-pfizerbiontech-covid-19-vaccine)

[v] https://pubmed.ncbi.nlm.nih.gov/35964614/ (https://pubmed.ncbi.nlm.nih.gov/35964614/)

[vi] https://www.ukmedfreedom.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 (https://www.ukmedfreedom.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)

[vii] https://www.ukmedfreedom.org/open-letters/open-letter-from-ukmfa-to-professor-asma-khalil (https://www.ukmedfreedom.org/open-letters/open-letter-from-ukmfa-to-professor-asma-khalil)

[viii] https://pubmed.ncbi.nlm.nih.gov/35538060/ (https://pubmed.ncbi.nlm.nih.gov/35538060/)

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