

24 January 2022

Open Letter from the UK Medical Freedom Alliance to:

- NHS Fertility Centres in Scotland – Aberdeen, Dundee, Edinburgh and Glasgow

Re: Scottish National Fertility Treatment Vaccination Policy (the “Policy”)

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.

1. Introduction of the Policy

From 23 December 2021, NHS fertility centres across Scotland began posting a “COVID-19 update” on their websites referring to various pregnancy statistics and then stating:

“In light of the above evidence, the speed at which the Omicron variant is spreading through communities and the safety of pregnant women and their babies, it has been nationally agreed that fertility treatment for unvaccinated women will be deferred with immediate effect.”^{i ii iii}

It is noted that the Dundee Fertility Centre uses very slightly different wording^{iv}, and the Aberdeen Fertility Centre^v instead cross-refers to a letter by Chief Medical Officer (CMO) Dr Gregor Smith, published on 7 January 2022^{vi}, in which he confirms the Policy.

The approach taken in the Policy is entirely disproportionate and amounts to unlawful discrimination, therefore exposing relevant decision-makers and other parties to significant legal liability. It is also of wider concern to society as it validates further unlawful discrimination in other NHS services based on vaccination status.

The purpose of this letter is to request that this Policy is terminated with immediate effect, failing which you are hereby put on notice of potential liability as detailed below and requested to respond to (i) this letter as a matter of urgency and (ii) the enclosed request for further information.

2. Extent of the Policy

It would appear that a person is currently considered “unvaccinated” for the purposes of the Policy unless they have had a third/booster COVID-19 vaccination or if it has been less than 12 weeks since their second dose. There is some ambiguity around the wording of the Policy and related frequently asked questions (FAQs) but it appears to imply both partners require to be vaccinated.

The Policy appears to apply to any couples undergoing any “fertility treatment” that may result in pregnancy (for example, provision of medication to induce ovulation) and not just IVF/ICSI treatments. It would also apply to women or couples who have frozen eggs or embryos at these centres. If an unvaccinated couple wanted to proceed with further treatment, it seems they would have to transport the fragile eggs and embryos for treatment elsewhere.

The Policy is presented as a deferral, and not a cancellation, of treatment. However, with no guarantees if or when the Policy will be revoked, or the criteria for doing so, this effectively amounts to a cancellation of NHS fertility treatment for persons who have chosen not to receive a COVID-19 vaccination, particularly where the woman is approaching the upper age limit of eligibility or is otherwise suffering from diminished ovarian reserve. The statement in the Policy that: *“Older women who have their treatment deferred, will have the deferral time added back on to their fertility journey to ensure that they do not lose out on eligibility for treatment due to their age”* will barely provide any reassurance or solution to these women as time ticks by, with many losing the opportunity to be biological parents. This is admitted by NHS Scotland stating that *“delays of several months may affect your chance of success once you are over 37 and especially if you are aged 40 or older.”*^{vii}

This is unlawful discrimination and is particularly despicable as it is preying on a vulnerable group in society.

3. Rationale for the Policy

It appears there are three elements being publicly relied on to justify the decision to implement the Policy. Each of these is considered in turn below.

a. Evidence about COVID-19 risks for vaccinated vs unvaccinated pregnant women

Two main sources of evidence are referred to in the Policy:

- The Scottish Intensive Care Society Report, published on 13 October 2021^{viii}, highlighted that of 89 COVID-19 positive pregnant women admitted to critical care between December 2020 and end of September 2021, 88 were unvaccinated, 1 was partially vaccinated, and none were fully vaccinated.
- The latest evidence from the UK Obstetric Surveillance System (UKOSS)^{ix} and the Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) report^x shows that unvaccinated pregnant women and their babies have died after admission to hospital with COVID-19, and 98 % of pregnant women in intensive care (ICU) with COVID-19 are unvaccinated. 88% of all women who have died during pregnancy or up to 6 weeks after birth were unvaccinated.

It is also noted that on 16 December 2021, the Scottish Government, Chief Medical Officer Dr Gregor Smith wrote to NHS Chief Executives highlighting recent updates to the Joint Committee on Vaccination and Immunisation (JCVI) advice on vaccinating pregnant women, namely that pregnant women should now be considered a clinical risk group and part of priority group 6 within the vaccination programme.

Without any further source evidence justifying that decision, this does not add to the data points noted above.

i. Interpretation of presented data

For correct interpretation of the figures and statistics quoted above, it is vital to consider the full context, which is not provided and seemingly not even considered.

Of particular relevance is the **time frame** that the data relates to. This is relevant because during that time frame the majority of pregnant women would have been unvaccinated. **A high percentage of women with adverse outcomes being unvaccinated is therefore not an indication of the unvaccinated being disproportionately affected but a reflection of generally low vaccine coverage in this population group.** It was only in April 2021 that the JCVI reversed the initial recommendation and vaccination was offered to all pregnant women. Due to the significant change in advice, many pregnant women will have remained hesitant to be vaccinated by the time the rollout reached their age group (for many women this would have been into June 2021), and there may have been a preference to delay vaccination until after the first 12 weeks of pregnancy. In a letter published on 18 August 2021, Dr Gregor Smith acknowledged that only a small proportion of pregnant women had been vaccinated^{xi} quoting “*over 4000 in Scotland*” which is a very small number compared to an average 3300 births per month (Data from National Records Scotland (NRS)). **It is therefore only natural that pregnant women in critical care as reported by the Scottish Intensive Care Society in September 2021 were predominantly unvaccinated.**

Further relevant information relates to the **primary reason for admission** (COVID-19 disease as opposed to other causes in the presence of a positive COVID-19 test) and the **extent of underlying comorbidities**. In order to be eligible for certain fertility treatments in the NHS women are required to have a body mass index (BMI) below 30. Consequently, the risk factor of obesity for severe COVID-19 disease^{xii} will not apply to the people impacted by the Policy.

ii. Risks of COVID-19 in pregnancy

We refer to our previous [Open Letters to the Royal College of Obstetricians & Gynaecologists \(RCOG\) and the Royal College of Midwives \(RCM\)](#)^{xiii} and to the [JCVI](#)^{xiv} where we assessed the evidence for the risks of COVID-19 in pregnancy and quoted the [RCOG Information for Healthcare Professionals on COVID-19 in pregnancy](#) (dated February 2021) stating that pregnant women are “*not at increased risk of death from COVID-19*”. The RCOG Information updated on 11 January 2022 contains a more comprehensive analysis regarding the risks of severe COVID-19 illness in pregnancy with an inconclusive summary stating “*these studies point to a possibly increased risk of severe disease from COVID-19 for pregnant women compared to non-pregnant women with COVID-19. However, the most consistent finding was of increased ICU admission rates for pregnant women, and this may in part be explained by a lower threshold for ICU admission in pregnancy in general*”, implying there may be confounding factors for the numbers of pregnant women admitted to ICU other than severity of COVID-19 disease^{xv}.

The UK Maternal Mortality rate from COVID-19 was quoted as 2.4/100,000 maternities (0.0024%).

We propose that it is entirely unscientific to analyse women with adverse outcomes by their vaccination status, especially in light of suggestions that current data on vaccination status is systematically miscategorised^{xvi}. Outcomes in cohorts of vaccinated versus unvaccinated groups matched by age and comorbidities, should be investigated instead. Figures currently presented should not be utilised to inform any policies.

b. The Omicron variant

The introduction of further restrictions appears to be officially justified by the recent emergence of yet another COVID-19 variant despite even early indications that Omicron is associated with less severe illness, hospitalisation and death compared to previous strains^{xvii xviii}. In addition, protection from COVID-19 vaccines against Omicron appears to be reduced^{xix}. This is acknowledged by the WHO^{xx} and in a Technical Briefing by the UK Health Security Agency (UKHSA) dated 31 December 2021, which suggests that ***“vaccine effectiveness against symptomatic disease with the Omicron variant is significantly lower than compared to the Delta variant and wanes rapidly”***^{xxi}.

This data emerges amidst mounting evidence of vaccine-induced immunity being short-lived^{xxii}, as admitted by the CEO of vaccine manufacturer Pfizer, Albert Bourla^{xxiii}, with protection waning after 4-6 months. Recently published data from Denmark even suggests a potentially negative effect of the vaccines against COVID-19 infection^{xxiv}. There is also evidence from San Francisco / California suggesting that *“vaccine breakthrough cases are preferentially caused by circulating antibody-resistant SARS-CoV-2 variants”*^{xxv}. A **high proportion of cases infected with the Omicron variant also appears to occur in vaccinated individuals**, including in Scotland^{xxvi xxvii}.

In view of this evidence, we strongly dispute that the Omicron variant constitutes a justification to impose vaccine mandates on anyone, let alone the vulnerable group of couples seeking fertility treatments.

In any event, the First Minister of Scotland made an announcement on 18 January 2022 removing the remaining additional restrictions which had been imposed in December 2021 (at a similar time to when the Policy was introduced), reflecting concerns about the Omicron variant at the time. During the announcement, the First Minister provided an update on positive trends in relation to Omicron and various data sources concluding: “So all of this is very positive news and comes as an enormous relief I am sure to all of us”. The First Minister also spoke of the *“improving situation”*^{xxviii}. It is noted that the Policy will be reviewed during February 2022 (or 1 March for Dundee) *“or earlier if appropriate”*. The Glasgow Royal Policy explicitly states that: *“Further information regarding the Omicron variant will continue to become available and any changes to current guidance will be communicated as soon as it becomes available.”*^{xxix} The data very much indicates that it is appropriate (and absolutely necessary) to reconsider matters earlier (i.e. immediately).

c. Safety of pregnant women and their babies

Considerations of safety must inherently relate to the overall health and well-being of pregnant women and their babies and not just to COVID-19 risks. As well as physical safety, mental wellbeing is particularly important for couples going through fertility treatments. Counselling services are offered to couples undergoing assisted conception in recognition of the stress that often accompanies a diagnosis of infertility and related treatment. Prior to certain procedures involving donor eggs, sperm or embryos, it is a Human Fertilisation and Embryology Authority (HFEA) regulatory requirement to meet with a counsellor. We strongly suggest that unvaccinated couples should remain entitled to these counselling services. Indeed, it is telling that in the version of the Policy and FAQs published by the Dundee Fertility Centre (Assisted Conception Unit), it is stated: *“We fully appreciate that this is very distressing news and may have come as a shock to read this new position re vaccination and treatment. If you think it might be beneficial to meet*

with our counsellor, please do not hesitate to contact us by email.” This is a *de facto* admission of liability that the Policy will cause affected couples significant distress.

i. The Policy is not aligned with previous advice given to couples trying to conceive

In December 2020, UK Government guidance was issued entitled *“COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding”*^{xxx}. The advice was described as precautionary, with reference to the new technology of this particular vaccine, and clearly stated that: *“if you are pregnant you should not be vaccinated – you can be vaccinated after your pregnancy is over”* and *“if you are planning to get pregnant in the next 3 months, you should delay your vaccination”*.

The guidance was updated several times, and the version dated 23 April 2021 had been significantly changed to now stating that *“pregnant women should be offered COVID-19 vaccines at the same time as people of the same age or risk group”*^{xxxi}. The only evidence offered to justify the departure from the advice only five months earlier was a reference to 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 be pregnant at the time of vaccination^{xxxii}. Notably, only a fraction (less than 5%) of these women are formally enrolled (8,749 of 185,218 women as of 10 January 2022). Such a registry is not in any way comparable to robust, thorough scientific evaluation and peer-reviewed evidence.

Especially in pregnant women, who were not recruited into the ongoing regulatory clinical trials, adverse event reporting relies solely on post-marketing surveillance, which is carried out via passive reporting systems (Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card System in the UK). 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 poor awareness of this scheme among both doctors and the public, potentially leading to a significant underestimate of the nature and the true number of adverse events and deaths.

We suggest that there is no robust and scientifically valid reason for the complete reversal of the initial guidance which advised caution in view of the lack of data regarding the effects of COVID-19 vaccines in pregnancy.

ii. Adverse reactions following the administration of COVID-19 vaccines

Many adverse reactions following the administration of COVID-19 vaccines have been reported to the MHRA in the UK^{xxxiii}. In the report published on 13 January 2022, there were **over 1.4 million adverse reactions in the UK** from 431,482 reports (1 in 120 people injected), some of them extremely serious, including seizures, paralysis, blindness, strokes, blood clots and acute cardiac events. This report includes **1,932 fatalities**. There were also 709 reports of adverse pregnancy outcomes (miscarriages / stillbirths) and 52,322 reports in the category of reproductive / breast disorders. It is widely recognised that only up to 10% of adverse events are officially reported, indicating that the actual number of adverse events is likely to be much higher.

Long-term effects of the COVID-19 vaccines are completely unknown at this stage, specifically effects on carcinogenesis, auto-immune disorders and on fertility. The effects on pregnancy and the developing foetus are also largely unknown as not studied in the regulatory trials. Specifically, a policy to vaccinate

couples who are already requiring fertility treatment would seem highly questionable when the potential effects of the COVID-19 vaccines on fertility have not been determined or even investigated.

iii. Potential concerns regarding COVID-19 vaccines prior to or in pregnancy

It is of particular note that the Phase 2/3 safety trials for the Pfizer COVID-19 vaccines, which began in February 2021, are not yet complete and have a trial end date of August 2022. In addition, several groups of pregnant women are excluded from these trials, including those who have previously been infected with SARS-CoV-2 or those with other medical or psychiatric conditions^{xxxiv}. Therefore, there are no trial data to reassure women that these vaccines are safe in pregnancy. In addition, some potentially concerning evidence has been emerging that should be cause for an immediate review of the recommendation to vaccinate pregnant women and those trying to conceive.

- Distribution of RNA- encapsulated lipid nanoparticles (LNPs)

The vaccine manufacturer Pfizer carried out a bio-distribution study finding that following administration of the COVID-19 vaccine, high concentrations of the LNPs used to deliver mRNA are found in the ovaries as well as liver, spleen and adrenal glands^{xxxv}. LNPs are potentially highly inflammatory^{xxxvi}, and their effect on ovarian function remains unknown at this stage.

- Menstrual disorders

The MHRA report up to 22 December 2021 included 50,565 cases in the categories of reproductive and breast disorders. An association between a change in menstrual cycle length and COVID-19 vaccination has recently been described in a prospective study^{xxxvii}, and there have been reports of women having altered cycles and heavier, painful periods^{xxxviii}. An article in the British Medical Journal (BMJ) suggested that this should be further investigated^{xxxix}, and the US National Institute of Health (NIH) is currently funding a study to assess the potential effects of COVID-19 vaccination on menstruation^{xl}.

- Miscarriages

A possible association of COVID-19 vaccination with pregnancy loss and miscarriage is currently a subject of speculation as this has not been properly investigated. A publication by the New England Journal of Medicine (NEJM) in April 2021^{xli} aimed to provide reassurance but had to later be corrected as the denominator in their calculations was incorrect^{xlii}. A re-analysis of the data by researchers from New Zealand^{xliii} did suggest there was a significant signal, and many cases have been reported to the MHRA.

In the absence of robust scientific evidence demonstrating the safety of COVID-19 vaccines specifically in early pregnancy, we suggest that it is unethical and irresponsible to offer and even mandate this medical intervention to women going to the lengths of interventional fertility treatments.

- Newborn and infant mortality

We highlighted in a letter dated 13 September 2021 to the Scottish Government and Chief Medical Officer a recent observation of an increased rate of neonatal deaths as well as a significant excess

in infant mortality in the second half of 2021 in Scotland^{xliv}. This has occurred against a background very significant excess mortality in the general population over the summer months in 2021 and correlates with the time period of the COVID-19 vaccine rollout to the younger age groups. We suggest that this must be investigated thoroughly as a matter of utmost priority. To date, we have not received any response that would provide reassurance regarding any cause for this excess mortality that is unrelated to the COVID-19 vaccines.

We expect you will be able to provide evidence showing how these safety concerns were considered prior to implementation of the Policy.

4. Notice of Potential Liability

We consider two possible core outcomes as a result of your decision to introduce the Policy.

Couples will either be coerced into vaccination to allow treatment to proceed (Outcome 1), or couples will assert their legal right to decline the offer of vaccination and will consequently not be able to proceed with treatment (Outcome 2). Both of these outcomes expose you to potential legal liability as outlined below:

a. **Outcome 1 - Couples will be coerced into vaccination to allow treatment to proceed**

There is a risk that COVID-19 vaccination may cause an adverse reaction to either partner of the couple in respect of issues pertinent to fertility or to their general health. You may be aware that vaccine manufacturers have been granted complete exemption from any liability for harms caused by their products. As the couple were not able to provide free and informed consent to the vaccination due to your coercive policy, liability for resulting harms rests with you for mandating this medical treatment.

Any risks associated with any medical intervention must be explicitly highlighted to the recipient and discussed in detail, especially if the recipient would not have accepted the medical intervention *but for* the imposition of it as a pre-condition for treatment. No medical intervention is ever 100% safe, and therefore fully informed consent, clearly defined in law, is always required. Mandating any medical intervention as a condition for access to fertility treatment is a form of coercion and denies the couple an opportunity to assess and appraise all available information and to weigh up the benefits and risks to them as individuals. It also puts a penalty or restriction on any couple declining a COVID-19 vaccine that is not consistent with ethical and lawful practice of medicine and indeed constitutes a violation of the principle of Informed Consent.

i. **Informed Consent**

Informed consent is the cornerstone of good, ethical medical practice and is firmly enshrined in the code of conduct issued by the General Medical Council (GMC), the Nursing and Midwifery Council (NMC), the NHS Constitution^{xlv}, as well as in UK^{xlvi} and International Law^{xlvii}.

The leading case in the UK concerning informed consent is the decision in the Supreme Court of Montgomery v Lanarkshire^{xlviii}. The Supreme Court concluded in this case that:

“An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of

any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments.”

“It is now well recognised that the interest which the law of negligence protects is a person’s interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body.”

The Universal Declaration on Bioethics and Human Rights 2005 states that “any preventive, diagnostic, and therapeutic medical intervention must only to be carried out with the prior, free, and informed consent of the person concerned, based on adequate information”.

Consent should be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice. An individual must be free to accept or refuse any treatment and their decision should be **voluntary and must not be influenced by pressure from medical staff**^{xlix}, friends, family or others. Informed means that “the person must be given all of the information about what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if the treatment does not go ahead”^l.

Furthermore, the Parliamentary Assembly of the Council of Europe passed Resolution number 2361 of 2021 on 27 January 2021^{li} which specifically stated:

- *Paragraph 7.3.1 - ensure that citizens are informed that [the COVID-19] vaccination is NOT mandatory and that no one is politically, socially, or otherwise pressured to get themselves vaccinated, if they do not wish to do so themselves;*
- *Paragraph 7.3.2 - ensure that no one is discriminated against for not having been vaccinated, due to possible health risks or not wanting to be vaccinated;*

Affected couples may seek recourse from you for any harms suffered as a direct result of your imposition of the Policy.

b. Outcome 2 - Couples will assert their right to decline the offer of vaccination and will consequently not be able to proceed with treatment

The Policy currently provides for treatment to be deferred and not cancelled, with a review in February 2022 or earlier if appropriate. The longer the Policy continues, the more likely an affected couple will be able to bring a successful damages claim. The passage of time for many couples will be the difference between them being able to get pregnant and not. Potential liability for this harm including loss of opportunity and any resultant pain and suffering, is likely to lie with you.

In all cases, regardless of future pregnancy outcome, this deferral will cause unjustified pain and suffering for the couples involved and will at the very least open up claims of solatium. At the other end of the spectrum, this may cause significant mental health decline for some couples which, in turn, may lead to the requirement for NHS services elsewhere to treat any resultant mental health conditions.

There are also those couples who will have previously had fertility treatment and may have frozen eggs or embryos in storage. If they wish to proceed with further treatment, they may have to transport the fragile

eggs and embryos for treatment elsewhere. The transportation itself would not be a risk-free process and could result in the unnecessary loss of eggs or embryos. You face the risk of liability for such losses.

i. Discrimination and human rights breaches

As well as the Policy being unethical, it amounts to unlawful discrimination based on vaccination status. It may also amount to a breach of the Equality Act 2010 by reason of the protected characteristics of pregnancy and/or disability.

The right to private and family life is protected under Article 8 of the European Convention on Human Rights. The Policy is an unwarranted and unlawful interference with this right^{lii}.

The World Health Organisation (WHO) promotes human rights in the field of health, with the following statement regarding equality and non-discrimination being of particular note:

*“Any discrimination, **for example in access to health care, as well as in means and entitlements for achieving this access**, is prohibited on the basis of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth, physical or mental disability, **health status** (including HIV/AIDS), sexual orientation ,and civil, political, social or other status, which has the intention or effect of impairing the equal enjoyment or exercise of the right to health.”* ^{liii}(Emphasis added).

It is noted that as an extension of human rights principles and as a matter of public law, UK citizens are entitled to access NHS services. Most of these citizens will be UK taxpayers funding the very service which they wish to access. **It is unethical and unlawful to withhold treatment in the present circumstances.**

ii. Right to receive care and treatment

The NHS Constitution sets out a number of Values and Principles that must be upheld. It is clear that the Policy is a direct breach of the following Values and Principles:

“You have the right to access NHS services. You will not be refused access on unreasonable grounds”;

“You have the right to receive care and treatment that is appropriate to you, meets your needs and reflects your preferences”;

“You have the right to be treated with a professional standard of care, by appropriately qualified and experienced staff, in a properly approved or registered organisation that meets required levels of safety and quality”;

“You have the right to be treated with dignity and respect, in accordance with your human rights”;

“You have the right to be protected from abuse and neglect, and care and treatment that is degrading”;

“You have the right to accept or refuse treatment that is offered to you, and not to be given any physical examination or treatment unless you have given valid consent. If you do not have the capacity to do so, consent must be obtained from a person legally able to act on your behalf, or the treatment must be in your best interests”;

“Respect, dignity, compassion and care should be at the core of how patients and staff are treated not only because that is the right thing to do but because patient safety, experience and outcomes are all improved when staff are valued, empowered and supported”.

5. Conclusion

We request that you respond by 31 January 2022 to either confirm that (i) you are withdrawing the Policy with immediate effect, or (ii) you otherwise acknowledge receipt of the letter and respond to the points made therein and the enclosed request for further information as a matter of urgency.

In the event of an unsatisfactory response and for the purposes of preservation of evidence in any future litigation, we will follow this letter up with formal Freedom of Information requests.

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Appendix: Requests for further information

Cc: Dr Gregor Smith – Chief Medical Officer for Scotland
Humza Yousaf – Scottish Cabinet Secretary for Health and Social Care
Human Fertilisation and Embryology Authority (HFEA)
Health Board Complaints Departments

ⁱ <https://www.nhsggc.org.uk/your-health/health-services/assisted-conception-service/covid-19/#>

ⁱⁱ <https://glasgowroyalfertilityclinic.co.uk/treatments-and-updates/updates-including-coronavirus-covid-19/>

ⁱⁱⁱ <https://services.nhsllothian.scot/edinburghassistedconceptionprogramme/Pages/COVID-19.aspx>

^{iv} <https://www.acundundee.org/news/treatment-deferral>

^v <https://www.aberdeenfertility.org.uk/>

^{vi} <https://www.gov.scot/publications/coronavirus-covid-19-fertility-treatment-for-unvaccinated-patients/>

^{vii} <https://www.nhsinform.scot/covid-19-vaccine/the-vaccines/pregnancy-breastfeeding-and-the-coronavirus-vaccine>

^{viii} <https://publichealthscotland.scot/publications/scottish-intensive-care-society-audit-group-report-on-covid-19/scottish-intensive-care-society-audit-group-report-on-covid-19-as-at-23-september-2021/>

^{ix} <https://www.npeu.ox.ac.uk/ukoss/publications-ukoss/results#2021>

^x <https://www.npeu.ox.ac.uk/news/2194-pregnant-women-now-a-priority-group-for-covid-19-vaccination>

^{xi} <https://www.gov.scot/publications/coronavirus-covid-19-letter-from-chief-medical-officer-on-pregnancy-and-vaccines/>

^{xii} <https://www.eurekalert.org/news-releases/938960>

^{xiii} <https://assets.website->

[files.com/5fa5866942937a4d73918723/6062f5749dcf7899999655dd0_UKMFA_Open_Letter_RCOG_RCM.pdf](https://assets.website-files.com/5fa5866942937a4d73918723/6062f5749dcf7899999655dd0_UKMFA_Open_Letter_RCOG_RCM.pdf)

^{xiv} https://assets.website-files.com/5fa5866942937a4d73918723/607ee895f5b16913aaca45b_UKMFA_Open_Letter_JCVI.pdf

^{xv} <https://www.rcog.org.uk/globalassets/documents/guidelines/2022-01-11-coronavirus-covid-19-infection-in-pregnancy-v14.3.pdf>



- xvi <https://www.researchgate.net/publication/357778435>
- xvii <https://www.sciencedirect.com/science/article/pii/S120197122101256X>
- xviii <https://pubmed.ncbi.nlm.nih.gov/34915975/>
- xix <https://news.sky.com/story/covid-19-omicron-less-likely-to-cause-severe-symptoms-but-effectiveness-of-booster-jabs-waning-for-some-says-ukhsa-12503005>
- xx <https://www.who.int/news/item/11-01-2022-interim-statement-on-covid-19-vaccines-in-the-context-of-the-circulation-of-the-omicron-sars-cov-2-variant-from-the-who-technical-advisory-group-on-covid-19-vaccine-composition>
- xxi <https://www.gov.uk/government/publications/investigation-of-sars-cov-2-variants-technical-briefings>
- xxii <https://www.nature.com/articles/s41467-021-26672-3.pdf>
- xxiii <https://t.me/STFNREPORT/9644>
- xxiv <https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full.pdf>
- xxv <https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v1>
- xxvi <https://www.westernjournal.com/cdc-announces-79-us-omicron-cases-occurred-vaccinated-individuals/>
- xxvii <https://www.heraldscotland.com/news/19843315.covid-scotland-case-rates-lowest-unvaccinated-double-jabbed-elderly-drive-rise-hospital-admissions/>
- xxviii <https://www.gov.scot/publications/coronavirus-covid-19-update-first-ministers-statement-18-january-2022/>
- xxix <https://glasgowroyalfertilityclinic.co.uk/treatments-and-updates/updates-including-coronavirus-covid-19/>
- xxx <https://web.archive.org/web/20201206233124/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> [Note: this uses the WayBack Machine to access historic web archives]
- xxxi <https://web.archive.org/web/20210426161536/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> [Note: this uses the WayBack Machine to access historic web archives]
- xxxii <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>
- xxxiii <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions>
- xxxiv <https://www.clinicaltrials.gov/ct2/show/NCT04754594>
- xxxv <https://www.naturalnews.com/files/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf>
- xxxvi <https://pubmed.ncbi.nlm.nih.gov/34841223/>
- xxxvii https://journals.lww.com/greenjournal/Fulltext/9900/Association_Between_Menstrual_Cycle_Length_and.357.aspx
- xxxviii <https://www.telegraph.co.uk/global-health/science-and-disease/covid-vaccines-linked-disrupted-menstrual-cycles-young-women/>
- xxxix <https://www.bmj.com/content/374/bmj.n2211>
- xl <https://www.nichd.nih.gov/newsroom/news/083021-COVID-19-vaccination-menstruation>
- xli <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8117969/#r15>
- xlii https://www.nejm.org/doi/full/10.1056/NEJMc210016?query=recirc_curatedRelated_article
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- xliv https://assets.website-files.com/5fa5866942937a4d73918723/61c1b50249ae1ffa69bd09a3_Open_Letter_UKMFA_Scottish_Mortality_Data.pdf
- xlvi <https://www.nhs.uk/conditions/consent-to-treatment/>
- xlvi <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>
- xlvi http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html
- xlvi <https://www.supremecourt.uk/cases/docs/uksc-2013-0136-judgment.pdf>
- xlix <https://www.nhs.uk/conditions/consent-to-treatment/>
- li <https://www.nhs.uk/conditions/consent-to-treatment/>
- li https://pace.coe.int/en/files/29004/html?_cf_chl_jschl_tk_=WP19CSyPM842Ilr6J1WLeXF4pvbnj1K5qnlzhYcHPqs-1641768146-0-gaNycGzNCSU
- lii <https://hudoc.echr.coe.int/eng?i=001-112993> COSTA AND PAVAN V ITALY, ECtHR, 28 August 2012, App. 54270/2010 - The judgement found that the Italian Statute on Assisted Reproduction (Law 40/2004), and particularly its prohibition to use *in vitro* fertilisation and pre-implantation genetic diagnosis to prevent the birth of children affected by genetically transmissible conditions, breached Article 8
- liii <https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health>

APPENDIX

Requests for further Information

- (a) Please provide copies of all records, notes, papers, data, research documents, expert evidence and other information relied on when making the decision to introduce the Policy.
- (b) With reference to (a), please provide all information considered in respect of possible COVID-19 vaccination risks to couples in respect of reproductive health, fertility, pregnancy and neonatal outcomes.
- (c) Please provide any information considered and decisions made about the Policy's impact on couple's mental health and access to fertility counselling services, including your criteria for offering these services
- (d) The JCVI's original advice in relation to vaccination in pregnancy and for those trying to conceive was as follows: *"if you are pregnant you should not be vaccinated – you can be vaccinated after your pregnancy is over"* and *"if you are planning to get pregnant in the next 3 months, you should delay your vaccination"*. Please provide all information relied on by you and/or the JCVI which led to the change of advice to offer the COVID-19 vaccination to all pregnant women.
- (e) With reference to the statistics taken from the Scottish Intensive Care Society Report dated 13 October 2021, please provide a breakdown of the data by month of admission, any underlying health conditions of such individuals and monthly breakdown of overall numbers pregnant women vaccinated vs unvaccinated during the relevant time period. Please provide an update for the statistics relied on up to, or as close as possible, to today's date.
- (f) With reference to the statistics taken from UK Obstetric Surveillance System (UKOSS) and the Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK), please provide a monthly breakdown of numbers of ICU admissions, maternal deaths, stillbirths and neo-natal deaths by vaccination status, together with confirmation of whether the mother or baby had any underlying health conditions, for the period March 2020 up to and including today's date. Please provide the 5-year average for ICU admission during pregnancy, maternal deaths, stillbirths and neo-natal deaths.
- (g) Please provide any information (including research, notes, data, analysis) held by you which pertains to the question posed by HFEA on their website "Can my clinic stop me having treatment if I haven't had a vaccine?" to include detail of any legal, ethical and practical considerations.
- (h) Please set out how you feel the Policy is compliant with the NHS Constitution and the NHS Values and Principles.