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Explainer on COVID vaccination, fertility, pregnancy and breastfeeding

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1. I heard that the COVID vaccine might reduce female fertility. Is this true?

No. In fact, multiple strands of evidence tell us that COVID vaccines do not reduce fertility.

Pregnant people were not included in the first round of trials, and participants were asked to avoid becoming pregnant, but nonetheless a number of people became pregnant by accident. The accidental pregnancies occurred equally across the vaccinated and the unvaccinated groups, which tells us that vaccines did not prevent pregnancy. The people who became pregnant have been followed closely, and have had normal pregnancies. You can find the accidental pregnancy data here (Moderna), here (Pfizer) and <a href=here (Janssen).

Vaccine	Control group			Vaccinated group		
·	Participants	Pregnancies	Miscarriages (rate)	Participants	Pregnancies	Miscarriages (rate)
Pfizer	18,846	12	1 (8%)	18,860	11	0 (0%)
Moderna	15,170	7	1 (14%)	15,181	6	0 (0%)
AstraZeneca*	4,830	43	14 (32%)	4,925	50	18 (36%)
Janssen (J&J)	21,895	4	1 (25%)	21,888	4	1 (25%)

^{*} Note that these pregnancy losses potentially include terminations reported as miscarriages, because the participant lives in a country in which termination of pregnancy is illegal. If the data from these countries is excluded, the pregnancy loss rate is 21% with the control and 14% with the vaccine.

Following the general rollout, we have been able to collect further data about the effect of the vaccines on human fertility. In a cohort of <u>2,126 couples trying to conceive</u> in the USA and Canada between December 2020 and September 2021, vaccination status in the female partner did not change the per cycle rate of conception. In IVF patients, COVID vaccination does not affect ovarian function, egg quality, fertilisation or clinical pregnancy rate. You can read these studies here (Aharon), <a href="here (Bentov), <a href="here (Safrai), <a href="here (Morris) and <a href="here (Orvieto). A study looking at ovarian reserve in fertile volunteers before and after vaccination found no change. You can read more <a href="here.

In the wider population, <u>4804 people</u> in the USA had reported post-vaccination pregnancies to the CDC by the end of March 2021 and by 31 July 2021 <u>10,178 people</u> in the USA who had had at least one

dose of the COVID vaccine had reported a pregnancy to one of the nine largest healthcare providers. In Ontario, by the end of June 2021, <u>712 people</u> had reported becoming pregnant after having received two doses of COVID vaccine.

The vaccine works by instructing our bodies to make antibodies that bind to a viral protein called Spike. This stops the virus from infecting our cells. The claim that the vaccine might reduce fertility came from the idea that there are proteins in the placenta that have some similarities with Spike, so the antibodies that block Spike might also attach to the placenta. But the viral and placental proteins are not similar enough that we would expect this to happen and laboratory studies have now confirmed that this is the case. You can read more about this here and here. If antibodies against Spike did cause problems for the placenta, we would expect to see miscarriages in pregnant people who become infected with COVID, and we don't see this. You can find studies here and here.

2. I am not pregnant, but I would like to have children later. Should I get the vaccine?

There is no evidence that the vaccine will reduce your chances of getting pregnant later and in the UK, the Royal College of Obstetricians and Gynaecologists says that "women trying to become pregnant do not need to avoid pregnancy after vaccination". In the USA, the CDC recommends that people who are trying to become pregnant or who may become pregnant in the future receive the COVID vaccine. For people in your position, there is no reason not to get the vaccine if you are offered it.

3. I heard that getting the COVID vaccine might cause changes to my period. Is this true?

After getting the COVID vaccine, <u>some people notice a change to their next period</u>, but because <u>periods vary naturally</u> it was initially difficult to tell whether the changes occurred because of the vaccine or by coincidence. We now have some evidence to suggest that some people experience a later than usual or heavier than usual period following vaccination, but this proportion is small compared to the number of people who experience these things in unvaccinated cycles, and the change is temporary.

A <u>study from the USA</u> looked at the periods of 2403 people before and after vaccination, compared to 1556 unvaccinated people. After the first dose of the vaccine, periods were not delayed; after the second dose, they were delayed on average by less than half a day. People who had both doses of the vaccine in a single menstrual cycle experienced a two-day delay to their next period, on average, but the timing of their cycle returned to normal within a further two cycles. You can read more here.

A <u>Norwegian study</u> of 6,000 people who have regular periods found that, in unvaccinated cycles, 37.8% of people report that their period is different from usual, and this increases to 39.4% after the first dose of the vaccine, or 40.9% after the second dose. The most commonly reported change was a heavier than usual period.

4. I heard that the COVID vaccine might reduce male fertility. Is this true?

No. In a cohort of <u>2,126 couples trying to conceive</u> in the USA and Canada between December 2020 and September 2021, vaccination status in the male partner did not change the per cycle rate of conception. And three studies looking at sperm quality before and after vaccination found that vaccination does not make any difference to sperm count or quality. You can read studies done on

people undergoing IVF <u>here</u> and <u>here</u>, and one done on volunteers who were not undergoing fertility treatment here.

For people who are concerned about male fertility, it is also worth considering that <u>COVID infection</u> <u>temporarily reduces male fertility</u>. This is in line with <u>a number of studies</u> that have found that COVID infection reduces sperm count and quality.

5. I am pregnant. What are the risks of catching COVID during pregnancy?

There are risks associated with catching COVID, particularly in the second half of pregnancy. Pregnant COVID patients are more likely to need intensive care than COVID patients who are not pregnant. Preterm birth and stillbirth are more common than normal in pregnant COVID19 patients, and their babies are more likely to be admitted to the neonatal unit. You can find a complete summary of all the data collected on this up to June 2021 here.

6. Does the vaccine prevent people from catching COVID during pregnancy?

Two studies from Israel have looked at how effective COVID vaccines are at preventing COVID infection specifically in pregnancy. Both found that the effectiveness of COVID vaccines in pregnancy are similar to their effectiveness in the wider population. You can read these studies here and here.

The vaccines are also very good at protecting against moderate and severe disease. In the UK, <u>between February and July 2021</u>, no-one who was pregnant and had had both doses of the vaccine was admitted to hospital, four pregnant people who had had one dose were admitted, and 738 who had not had the vaccine were admitted. <u>Between May and October 2021</u>, of 1486 pregnant people admitted to hospital with COVID, 1383 (96.3%) were unvaccinated and only 16 (1.1%) had received both doses of the vaccine. Of 230 who needed intensive care, 225 (97.9%) were unvaccinated and only one had received both doses of the vaccine. <u>A more recent study</u> looking at 79,148 births in Scotland between March 2020 and October 2021 found that 77.4% of COVID infections, 90.9% of hospital admissions and 98% of intensive care admissions during pregnancy occurred in those who were unvaccinated.

7. Can the COVID vaccine cross the placenta?

One study of 19 people who received the COVID vaccine during pregnancy could not detect any vaccine mRNA or spike protein in placenta or cord blood. You can read this study here. Babies of vaccinated mothers do not have any anti-spike IgM, indicating that the vaccines themselves do not cross the placenta. You can see the data on this here, here, with an explanation on the interpretation of the studies here.

Vaccination is also not associated with any placental pathology. You can read about this here.

8. Is it safe to have the COVID vaccine during pregnancy?

Yes. The safety of COVID vaccination in pregnancy is being monitored in a number of ways.

Passive monitoring schemes, such as Yellow Card in the UK and VAERS in the USA, collect information that doctors, patients and their families report. Neither of these schemes has detected adverse events occurring more often following COVID vaccination than they normally do in pregnancy. In the UK, on

the 16th August 2021, at which point 55,000 pregnant people had been vaccinated, the MHRA released a statement saying "there is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK, or any reactions to these vaccines, increase the risk of miscarriage or stillbirth. There is no pattern from the reports to suggest that any of the COVID-19 vaccines used in the UK increase the risk of congenital anomalies or birth complications." You can read the statement here. The Yellow Card reports are regularly updated and you can find them here. You can transcripts from White House Briefings on VAERS reports following vaccination in pregnancy here and here.

16 studies that actively track the outcomes after pregnancy have also been done, across five countries and 185,309 people vaccinated during pregnancy. None of these studies have found any increased risk of miscarriage, preterm birth, stillbirth or babies being born smaller than expected, or with congenital abnormalities, following COVID vaccination.

Registry studies recruit people at vaccination, track the outcomes of their pregnancies and compare the outcomes to those we normally see in pregnancy. In the USA, the V-safe pregnancy registry has examined the outcomes for 5,096 people vaccinated in pregnancy and their babies. The first report from V-safe found that, among 713 people vaccinated in pregnancy who had given birth by 30th March 2021, the rates of adverse events were the same as we normally see. A follow up study looking at outcomes of people vaccinated before 20 weeks of pregnancy found no increased risk of miscarriage following vaccination. A second follow up looking at 1634 births up to 13th September 2021 found that the rates of adverse events at birth remained normal.

The BORN Ontario registry comprises 64,234 people vaccinated during pregnancy in Ontario, Canada. Among the 31,343 who have already given birth, there was no increased risk of stillbirth, preterm birth or babies being smaller than expected for their gestational age. You can read more here and here a

Case-control studies identify people who experienced a certain adverse event and determine whether these people are more likely to have been vaccinated than those who did not experience the event. Two such studies have been done using 105,446 pregnancies (of which 31,080 had been vaccinated) in the USA's Vaccine Safety Datalink system. One of these found no concerning patterns linking COVID vaccination to stillbirth; the other found that people who experienced a miscarriage were no more likely to have received a COVID vaccine in the 28 days before they miscarried than those who did not miscarry. A case-control study looking at 18,950 pregnancies in Norway also found that people who experienced a miscarriage were no more likely to have received a COVID vaccine in the previous three or five weeks, that those who did not miscarry.

Seven cohort studies compared the outcomes at birth for babies born to people who were vaccinated, compared to those who were unvaccinated. All of these found no increased risk of adverse outcomes at birth associated with vaccination. Only one looked at miscarriage rates, but it also found no increased risk of miscarriage associated with vaccination. You can read these studies here (Goldshtein), here (Blakeway), here (UKHSA), here (Theiler), here (Wainstock), here (Lipkind) and here

(Goldshtein again). One of these followed babies for up to six months after birth and found no difference in the rates of serious illness or death between babies in the vaccinated and unvaccinated groups.

9. Will being vaccinated while I am pregnant give my baby any protection against COVID once they are born?

We have many reports showing that the protective antibodies your body makes after you are vaccinated (IgG) cross the placenta. You can read some of them here (first report), <a href="here (Gray), <a href="here (Mithal), <a href="here (Prabhu), <a href="here (Collier), <a href="here (Beharier), <a href="here (Zdanowski), <a href="here (Rottenstreich), <a href="here (Atyeo), <a href="here (Prahl), <a href="here (Shook), <a href="here (Sajadi), <a href="here (Yang) and <a href="here (Matsui).

Early reports suggest that vaccination in pregnancy is <u>about 61% effective</u> at protecting babies under six months old from hospitalisation with COVID.

10. Is the COVID vaccine recommended during pregnancy?

In the UK, the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives recommend getting vaccinated against COVID if you are pregnant. From the 16th December 2021, pregnant people are in a priority group for COVID vaccination, because of their increased risk.

In the USA, the CDC recommends that all pregnant people get the COVID vaccine.

11. I am breastfeeding. Should I get the vaccine if I am offered it?

There is no known risk associated with giving non-live vaccines whilst breastfeeding and no safety signals have appeared in breastfeeding people or their babies. In the UK, the Royal College of Obstetricians and Gynaecologists <u>recommends the vaccine to people who are breastfeeding</u> and in the USA, the CDC also <u>recommends that all breastfeeding people receive the COVID vaccine</u>.

On the 2nd September, the MHRA released a statement based on UK vaccine safety surveillance saying "There is no current evidence that COVID-19 vaccination while breastfeeding causes any harm to breastfed children or affects the ability to breastfeed." You can read the statement here. A study that asked 50 breastfeeding people to document any side effects in themselves or their babies found no severe adverse events. You can read this study here.

Two studies looking for vaccine mRNA in breast milk have been unable to detect it. You can read them here and here. A more recent study that first concentrated the mRNA from milk, was able to detect it at 2 parts per billion in 3 out of 10 milk donors. You can read this study here and an explanation of what 2 parts per billion means here. A study that looked for the chemical PEG, which is used to stabilise mRNA vaccines, in the breast milk of 13 people was unable to detect it. You can read this study here.

A number of studies have shown that the protective antibodies your body makes get into breast milk at high concentrations. You can read these studies here (Gray), here (Perl), here (Friedman), here (Romero), here (Collier), <a href="her

respond to COVID19 get into breast milk. You can read about this <u>here</u> and <u>here</u>. These antibodies and T cells are expected to give your baby some protection against COVID19, although more research is being done to find this out.

Revision history

Updated 24 January 2021 to include a trial-by-trial breakdown of the outcomes for participants who became pregnant during the trials.

Updated on 26 January 2021. Q3. "Following the publication of the data showing that the vaccine is safe in pregnant animals..." changed to "Following the publication of the interim data showing that the vaccine is safe in pregnant animals..." Q5 updated to more closely mirror the language of the JCVI report.

Updated on 3 February 2021 to incorporate developmental and reproductive toxicity studies using the Oxford/AZ vaccine in mice. I have also changed the link on the risks of COVID-19 infection during pregnancy to point to a living systematic review in the BMJ, which acts as a more comprehensive and up-to-date resource than the individual studies.

Updated on 10 February 2021 to add the safety data that has so far been collected in the USA and UK. **Updated on 19 February 2021** to add further safety data collected in the USA and UK.

Updated on 24 February 2021 to add an easy-reference table summarising the accidental pregnancy data.

Updated on 3 March 2021 to add the safety data that has been collected through V-safe in the USA, and to update the data that has been collected through the VAERS and Yellow Card schemes.

Updated on 4 March 2021 to add data about transfer of antibodies across the placenta and through breast milk following vaccination, and to add a link to my article at Nature Reviews Immunology.

Updated on 11 March 2021 to add data about accidental pregnancies in the Janssen vaccine trial, reformat to move the details of the accidental pregnancies to question 2, and new data about the effects of vaccination on antibodies crossing the placenta and into breast milk. I have also updated the VAERS data, to include data collected to 26 February.

Updated on 19 March 2021 to update VAERS data, collected to 11 March.

Updated on 23 March 2021 to add a new study on transfer of antibodies across the placenta, and to update the first preprint that came out on this to its final, published form.

Updated on 29 March 2021 to add a new study about the transfer of antibodies into breast milk and to update VAERS data, collected to 19 March.

Updated on 1 April 2021 to add another study looking at transfer of antibodies across the placenta following vaccination.

Updated on 5 April 2021 to reformat the answer to Question 6 and to add information about the UK's new active surveillance system.

Updated on 8 April 2021 to add another study showing that antibodies are transferred across the placenta following vaccination.

Updated on 9 April 2021 to update VAERS data, collected to 4 April.

Updated on 13 April 2021 to add another study showing that antibodies are found in breast milk following vaccination

Updated on 18 April 2021 to reflect the new advice in the UK that all pregnant people should be offered the vaccine, and to update VAERS data, collected to 8 April.

Updated on 22 April 2021 to incorporate the updated V-safe data.

Updated on 26 April 2021 to update VAERS data, collected to 16 April

Updated on 5 May 2021 to update VAERS data, collected to 3 May, and to add a new study on the immune properties of breast milk following vaccination.

Updated on 14 May 2021 to add a new study on antibodies crossing the placenta and entering breast milk following vaccination

Updated on 25 May 2021 to add a new study on antibodies crossing the placenta following vaccination **Updated on 28 May 2021** to add data to show that vaccines do not cross the placenta, and further data to show they don't cross into breast milk. Also added, data to show that they don't raise antibodies to the placental protein syncytin, and another study into the outcomes for babies whose mothers are vaccinated during the third trimester of pregnancy.

Updated on 2 June 2021 to add a study showing no placental pathology is associated with COVID vaccination.

Updated on 3 June 2021 to add two studies showing no impact of vaccination on fertility in IVF patients.

Updated on 4 June 2021 to add another study showing no impact of vaccination on pregnancy rate in IVF patients.

Updated on 7 June 2021 to update VAERS data, collected to 28 May.

Updated on 30 June 2021 to add a new study looking at antibodies and vaccine mRNA in breastmilk following vaccination

Updated on 13 July 2021 to add a new study on safety and efficacy of the Pfizer vaccine specifically in pregnant people

Updated on 15 July 2021 to add new information on the safety of COVID vaccination in pregnancy, collected in Ontario, Canada.

Updated on 22 July 2021 to add a pregnancy registry study from Israel, and another study showing that antibodies cross the placenta following vaccination

Updated on 26 July 2021 to add UKOSS data on COVID19 hospitalisations during pregnancy, and to reorder and reformat the document as some parts of it were getting out of hand!

Updated on 27 July 2021 to add another study showing no impact of vaccination on fertility in IVF patients, and to add studies about the effect of COVID19 vaccination on sperm quality

Updated on 10 August 2021 to add a new study on the safety of COVID vaccinations in pregnancy from the UK.

Updated on 12 August 2021 to add data from the V-safe datalink, showing that 1073 people who had completed their vaccinations had gone on to report pregnancies to their healthcare providers.

Updated on 13 August 2021 to add the follow-up study done in the V-safe pregnancy registry cohort, plus two new studies on antibodies in breast milk following vaccination

Updated on 18 August 2021 to add a statement from the MHRA on Yellow Card reports of vaccination during pregnancy, to the 16th August

Updated on 26 August 2021 to add another study showing transfer of antibodies into breast milk following vaccination

Updated on 3 September 2021 to add a statement from the MHRA on Yellow Card reports of vaccination in people who are breastfeeding, to the 25th August

Updated on 8 September 2021 to add a second study from Israel on the effectiveness of COVID vaccination specifically in pregnancy

Updated on 9 September 2021 to add a case-control study using Vaccine Safety Datalink data to show no association between miscarriage and COVID vaccination in the previous 28 days

Updated on 13 September 2021 to reflect a post-publication change to <u>this study</u>. Originally, they estimated miscarriage rates. In the update, they state the absolute numbers without an estimate of rate. Rates are now calculated in <u>a study on the same dataset</u>, with longer follow-up

Updated on 15 September 2021 to cite a review of studies about COVID and male fertility, rather than just one.

Updated on 27 September 2021 to add another study showing transfer of antibodies into breast milk following vaccination - although note that <u>this study</u> found that mRNA vaccines are rather better at doing this than the Janssen vaccine.

Updated on 29 September 2021 to add data from V-safe and Vaccine Safety Datalink presented at the ACIP meeting on September 23rd.

Updated on 14 October 2021 to add a new study showing that antibodies raised by vaccination do not bind the placental protein syncytin-1.

Updated on 22 October 2021 to add a case-control study from Norway showing no association between miscarriage and COVID vaccination in the previous three or five weeks.

Updated on 25 October 2021 to add updated fertility and pregnancy loss data published from the AstraZeneca trials

Updated on 19 November 2021 to add two new studies looking at the transfer of antibodies across the placenta following vaccination in pregnancy

Updated on 25 November 2021 to add new data released by UKHSA on birth outcomes of vaccinated vs unvaccinated people in the UK from January to August 2021

Updated on 30 November 2021 to add an Israeli study looking at outcomes at birth for those vaccinated in pregnancy, compared to those who were not vaccinated

Updated on 6 December 2021 to add a new preprint showing spike-specific T cells in breastmilk, and to update a preprint on the same topic to the paper, now published following peer review.

Updated on 10 December 2021 to add a new preprint showing that vaccination does not lead to the production of anti-Syncytin1 antibodies

Updated on 16 December 2021 to add a new preprint looking at the ability of mRNA COVID vaccines to cross the placenta

Updated on 17 December 2021 to add a new preprint looking at how long maternal anti-COVID IgG lasts in babies after birth

Updated on 22 December 2021 to add an update from the BORNOntario registry showing <u>no</u> <u>difference in the rate of stillbirths</u> between vaccinated and unvaccinated people in Ontario, January - October 2021

Updated on 28 December 2021 to add a new <u>preprint</u> looking at antibodies in babies following vaccination before pregnancy or while breastfeeding and <u>this study</u> on the safety of mRNA vaccination in those who are breastfeeding.

Updated on 5 January 2022 to add <u>recent data from UKOSS and MBRRACE</u> to the section on vaccine effectiveness in pregnancy and to tidy up and reformat the section on vaccine safety in pregnancy (but with no new data).

Updated on 6 January 2022 to add a <u>new cohort study</u> using data from the Vaccine Safety Datalink **Updated on 6 January 2022** to add a new section on COVID vaccination and menstrual changes with links to new studies from the USA and Norway.

Updated on 10 January 2022 to add a study looking at <u>ovarian reserve before and after vaccination</u> in fertile volunteers

Updated on 14 January 2022 to add new data on the safety and effectiveness of COVID vaccines in pregnancy <u>from Scotland</u>

Updated on 21 January 2022 to add a new study looking at <u>conception rates following COVID</u> infection and vaccination

Updated on 24 January 2022 to update from preprints to peer reviewed versions of articles, where these have become available, to update the systematic review on the risks of COVID in

pregnancy to <u>this newer one</u>, and to make the links to the studies on transplacental antibody transfer and transfer of antibodies to breast milk easier to navigate

Updated on 28 January 2022 to add a new study on <u>how COVID vaccination affects the success</u> of <u>IVF</u> and to change the link to the <u>UK HSA data</u> to the latest release

Updated on 11 February 2022 to add a new <u>cohort study</u> on vaccination in pregnancy, including six months of post-birth follow-up data

Updated on 15 February 2022 to update from the preprint to the peer-reviewed version of **Shook** et al

Updated on 16 February 2022 to add <u>the first study</u> looking at how effective vaccination in pregnancy is at protecting newborns from COVID