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Coronavirus (COVID-19) - Vaccination in pregnancy

Updated 5 August 2021

Information on vaccination against COVID-19 for pregnant and breastfeeding women and those considering pregnancy. Includes records on safety, fertility, pregnancy outcome, decision-making, accessibility and take-up of vaccination, exclusion of pregnant women from clinical trials, and parliamentary questions.

2021-07462

Acceptance of COVID-19 vaccination in pregnancy: a survey study. Levy AT, Singh S, Riley LE, et al (2021), American Journal of Obstetrics & Gynecology MFM vol 3, no 5, September 2021, 100399
No abstract available.

2021-07459

Anti-severe acute respiratory syndrome coronavirus 2 antibodies induced in breast milk after Pfizer-BioNTech/BNT162b2 vaccination. Kelly JC, Carter EB, Raghuraman N, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 1, July 2021, pp 101-103
Research letter exploring levels of SARS-CoV-2 antibodies in breast milk in lactating people undergoing COVID-19 vaccination. Results indicate sustained elevation of immunoglobulin G/immunoglobulin A levels in breast milk after Pfizer-BioNTech/BNT162b2 vaccination. (LDO)
Full URL: <https://doi.org/10.1016/j.ajog.2021.03.031>

2021-07458

Prioritization of pregnant individuals in state plans for coronavirus disease 2019 vaccination. Crane MA, Jaffe E, Beigi RH, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 1, July 2021, pp 95-99
Research letter exploring the number of states that prioritise pregnant women for COVID-19 vaccination and assessing the overall current eligibility of pregnant women to receive COVID-19 vaccinations across the United States. Results

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Patron: HRH The Princess Royal. The Royal College of Midwives Trust: A company limited by guarantee. Registered No. 01345335.



show that most states classify pregnant women as a priority group and pregnant women are eligible to receive vaccines in 50% of the country. (LDO)

Full URL: <https://doi.org/10.1016/j.ajog.2021.03.015>

2021-07456

Adverse effects of COVID-19 messenger RNA vaccines among pregnant women: a cross-sectional study on healthcare workers with detailed self-reported symptoms. Kadali RAK, Janagama R, Peruru SR, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) 9 June 2021, online

Research letter comparing the detailed side-effect profile of COVID-19 mRNA vaccines among pregnant and non-pregnant healthcare workers. Results indicate that side-effect profiles are similar between both groups and are non-life-threatening. (LDO)

Full URL: <https://doi.org/10.1016/j.ajog.2021.06.007>

2021-07388

NMC statement on new vaccination advice for pregnant women. Nursing and Midwifery Council (2021), London: NMC 3 August 2021

Statement from the Chief Executive and Registrar for the Nursing and Midwifery Council (NMC) on current COVID-19 vaccination advice for pregnant women. (LDO)

Full URL: <https://www.nmc.org.uk/news/news-and-updates/nmc-statement-vaccine-midwifery/>

2021-07385

Cord blood antibodies following maternal coronavirus disease 2019 vaccination during pregnancy. Mithal LB, Otero S, Shanes ED, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 2, August 2021, pp 192-194

Research letter investigating SARS-CoV-2 immunoglobulin G transfer from mothers to infants following COVID-19 vaccination during pregnancy. Results demonstrate that most pregnant women who received the vaccine in the third trimester had transplacental transfer of immunoglobulin G and antibody levels in the infant are equal to the mother. (LDO)

Full URL: <https://doi.org/10.1016/j.ajog.2021.03.035>

2021-07327

RCOG welcomes Chief Midwife's campaign encouraging pregnant women to get vaccinated. Royal College of Obstetricians and Gynaecologists (2021), London: RCOG 30 July 2021

England's chief midwife is encouraging pregnant women to get vaccinated, as new data shows that the overwhelming majority of pregnant woman who are being hospitalised with COVID-19 have not been vaccinated. (Author)

Full URL: <https://www.rcog.org.uk/en/news/rcog-welcomes-chief-midwives-campaign-encouraging-pregnant-women-to-get-vaccinated>

2021-07324

Pregnant women urged to get jab as majority unvaccinated. Mundasad S (2021), BBC News 30 July 2021

England's chief midwife has stepped up her call for pregnant women to get the Covid jab as soon as possible. (Author)

Full URL: <https://www.bbc.co.uk/news/health-58014779>

2021-07097

Brazil: Why are so many pregnant women dying from Covid?. BBC News (2021), BBC News 27 July 2021

Covid-19 has critically affected pregnant women in Brazil, with more than 1,000 deaths. One in five women that died from the virus didn't have access to an intensive care unit and one in three didn't have access to a ventilator.

So far Brazil has recorded more than 530,000 coronavirus related deaths and only 45% of the population has received at least one dose of the vaccine. (Author)

Full URL: <https://www.bbc.co.uk/news/av/world-latin-america-57974754>

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2021-06976

Coronavirus: Vaccination [written answer]. House of Commons (2021), Hansard Written question 35835, 19 July 2021 Nadhim Zahawi responds to a written question from Sarah Olney to the Secretary of State for Health and Social Care, regarding what the Government's guidance is on the number of weeks that should elapse between receipt of the first and second dose of the covid-19 vaccine for pregnant women; and what the evidence is behind that guidance. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-19/35835>

2021-06974

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 34581, 16 July 2021 Nadhim Zahawi responds to a written question from Marsha De Cordova to the Secretary of State for Health and Social Care, with reference to the number of pregnant women yet to receive a single dose of the covid-19 vaccine, what steps he is taking to help ensure that pregnant women are kept safe as covid-19 (a) infection rates increase and (b) restrictions lift. (Author, edited)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-16/34581>

2021-06957

Health chiefs encourage more pregnant women to get their COVID-19 vaccine. Public Health England (2021), London: PHE 22 July 2021

News item reporting that Health chiefs are encouraging more pregnant women to get their COVID-19 vaccine, as new data shows that 51,724 pregnant women in England have received at least one dose. (Author, edited)

Full URL: <https://www.gov.uk/government/news/health-chiefs-encourage-more-pregnant-women-to-get-their-covid-19-vaccine>

2021-06952

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 34580, 16 July 2021 Nadhim Zahawi responds to a written question from Marsha De Cordova to the Secretary of State for Health and Social Care, regarding the process for ensuring health professionals (a) are discussing with pregnant women the risks and benefits of the covid-19 vaccine and (b) have up to date information on the risks and benefits of the vaccine. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-16/34580>

2021-06946

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 32510, 13 July 2021 Nadhim Zahawi responds to a written question from Marsha De Cordova to the Secretary of State for Health and Social Care, regarding whether he is collecting data on the number of pregnant women and new mothers being vaccinated against covid-19. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-13/32510>

2021-06837

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 32512, 13 July 2021 Nadhim Zahawi responds to a written question from Marsha De Cordova to the Secretary of State for Health and Social Care, regarding what steps he is taking to (a) assess and (b) reduce covid-19 vaccine hesitancy among pregnant women. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-13/32512>

2021-06554

COVID unlocking will create 'perfect storm' for pregnant women, say maternity Colleges. Royal College of Obstetricians and Gynaecologists (2021), London: RCOG 15 July 2021

The Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) are warning

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that the easing of COVID-19 restrictions, due to take place on 19th July 2021, could be very detrimental to pregnant women, who tend to experience very severe symptoms of the disease, especially during the late stages of pregnancy, and also suffer poorer pregnancy outcomes such as premature labour, emergency caesarean section, pre-eclampsia and stillbirth. Both colleges are urging women to get vaccinated against the disease. Includes comments from Dr Edward Morris, President at the Royal College of Obstetricians and Gynaecologists, Professor Marian Knight, Professor of Maternal and Child Population Health at the University of Oxford, and Gill Walton, Chief Executive of the Royal College of Midwives. (JSM)

Full URL: <https://www.rcog.org.uk/en/news/covid-unlocking-will-create-perfect-storm-for-pregnant-women-say-maternity-colleges/>

2021-06521

Covid unlocking risk for pregnant women, say doctors. Price E (2021), BBC News 15 July 2021

News item reporting that the lifting of restrictions put in place by the UK government because of the COVID-19 pandemic is causing concern among doctors and midwives, who fear there will be an increase in infection among pregnant women. States that the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) have urged pregnant women to take up the offer of the vaccine, which is known to be safe in pregnancy, as the virus can be severe in the third trimester, owing partly to the increased pressure on the lungs by the growing fetus. Also states that the need for an emergency caesarean section is increased in women who give birth while infected, and the stillbirth rate, while still remaining low, is increased in this population group. (JSM)

Full URL: <https://www.bbc.co.uk/news/health-57840159>

2021-06399

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 29137, 7 July 2021 Nadhim Zahawi responds to a written question asked by Marsha de Cordova, regarding whether he will publish data on the number of pregnant and breastfeeding women who have had covid-19 vaccinations. (MB)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-07-07/29137>

2021-06194

COVID-19 Vaccination in Pregnancy: The Benefits Outweigh the Risks. Chavan M, Qureshi H, Karnati S, et al (2021), JOGC

[Journal of Obstetrics and Gynaecology Canada] vol 43, no 7, July 2021, pp 814-816

The rapid development of a vaccine to protect against SARS-CoV-2 infection and prevent coronavirus disease 2019 (COVID-19) has been a historic scientific achievement but has also raised many questions in the health care community about vaccine safety for patients who were not included in clinical trials. As mass immunization efforts have rapidly expanded, obstetricians across the globe now face the challenge of advising pregnant patients on whether they should receive the vaccine. (Author)

2021-06147

Coronavirus disease and vaccination during pregnancy and childbirth: a review of the Israeli perspective and experience. Hadar E, Dollinger S, Wiznitzer A, et al (2021), Journal of Maternal-Fetal and Neonatal Medicine 15 June 2021, online

Purpose of the study: To discuss selected aspects of our local and national experience in treating and vaccinating pregnant women with SARS-CoV-2 infection and COVID-19 disease.

Materials and methods: A comprehensive, retrospective review of COVID-19 parturients in our center as well as a detailed literature review of several aspects from the groundbreaking research done in Israel to investigate the direct

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obstetrical impact of COVID-19, indirect effect of the lockdown measures and the vaccination effort among pregnant women.

Results: The study shows our local and national experience in treating COVID-19 in pregnancy and the maternal and neonatal impact of vaccination in nationwide scale. We treated our first COVID-19 pregnant patient on April 4th, 2020 reaching a total of 193 pregnant women, with PCR-positive SARS-CoV-2 by 8th March 2021. Several studies from Israel have evaluated pregnancy-related outcomes of COVID-19, be it maternal, obstetrical or neonatal complications. We suggest that only in a small subset of severely ill mothers, intubated and otherwise respiratory or hemodynamically unstable, an emergency cesarean delivery should be considered, factoring gestational age, in order to assist maternal ventilation and circulation, as well as to avoid possible secondary fetal compromise due the maternal deterioration.

In addition, there is conflicting evidence as to the price of lockdown on obstetrical outcomes, i.e., not the direct medical impact of the virus, but rather the impact of the measures to contain its spread - mainly lockdowns, which has been a major tool in Israel to combat COVID-19.

Finally, we demonstrate to overall safety and efficacy of vaccination pregnant women and the beneficial impact on pregnancy outcome and neonatal gain of protecting antibodies.

Conclusion: The data emerging from Israel is overall reassuring, as for the association of COVID-19 with adverse pregnancy outcome and the possible protective effect of the vaccinations. Further, long term studies, should be conducted to answer the long-term maternal outcomes, as well and neonatal prognosis. (Author)

2021-06128

COVID-19 vaccination in pregnancy and postpartum. Brillo E, Tosto V, Gerli S, et al (2021), Journal of Maternal-Fetal and Neonatal Medicine 21 June 2021, online

Pregnant women were excluded from the initial phase 3 clinical trials of COVID-19 vaccines resulting in limited data on their efficacy and safety during pregnancy and postpartum. As a result, since December 2020, there has been conflicting advice from public health, governmental, and professional authorities on this matter. From the end of 2020 up to now, some consensus guidance has been published with a prevalent precautionary approach on the administration of vaccines in pregnant women, in breastfeeding ones, or for those who are planning a pregnancy (either spontaneously or with assisted technologies). After the first few months of vaccine administration in some countries, more permissiveness seems to prevail, although with inconsistencies. Some little indicative advice, their inconsistency around the world and their changes in a short time have probably disoriented both women and their health care providers and placed the burden of decision making upon women and their health care providers without information to assist in making an informed choice. We reviewed the COVID-19 vaccination guidance for pregnant and breastfeeding women published to date and evidence from cases of unplanned pregnancy during the course of vaccine trials, preclinical experimental and observational clinical studies, and discuss their implications. In this way, we have tried to identify the safety of COVID-19 vaccines for pregnant or breastfeeding women, and their offspring. (Author)

2021-05952

Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. Collier A-RY, McMahan K, Yu J, et al (2021), vol 325, no 23, 15 June 2021, pp 2370-2380

Importance Pregnant women are at increased risk of morbidity and mortality from COVID-19 but have been excluded from the phase 3 COVID-19 vaccine trials. Data on vaccine safety and immunogenicity in these populations are

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therefore limited.

Objective To evaluate the immunogenicity of COVID-19 messenger RNA (mRNA) vaccines in pregnant and lactating women, including against emerging SARS-CoV-2 variants of concern.

Design, Setting, and Participants An exploratory, descriptive, prospective cohort study enrolled 103 women who received a COVID-19 vaccine from December 2020 through March 2021 and 28 women who had confirmed SARS-CoV-2 infection from April 2020 through March 2021 (the last follow-up date was March 26, 2021). This study enrolled 30 pregnant, 16 lactating, and 57 neither pregnant nor lactating women who received either the mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) COVID-19 vaccines and 22 pregnant and 6 nonpregnant unvaccinated women with SARS-CoV-2 infection.

Main Outcomes and Measures SARS-CoV-2 receptor binding domain binding, neutralizing, and functional nonneutralizing antibody responses from pregnant, lactating, and nonpregnant women were assessed following vaccination. Spike-specific T-cell responses were evaluated using IFN- γ enzyme-linked immunospot and multiparameter intracellular cytokine-staining assays. Humoral and cellular immune responses were determined against the original SARS-CoV-2 USA-WA1/2020 strain as well as against the B.1.1.7 and B.1.351 variants.

Results This study enrolled 103 women aged 18 to 45 years (66% non-Hispanic White) who received a COVID-19 mRNA vaccine. After the second vaccine dose, fever was reported in 4 pregnant women (14%; SD, 6%), 7 lactating women (44%; SD, 12%), and 27 nonpregnant women (52%; SD, 7%). Binding, neutralizing, and functional nonneutralizing antibody responses as well as CD4 and CD8 T-cell responses were present in pregnant, lactating, and nonpregnant women following vaccination. Binding and neutralizing antibodies were also observed in infant cord blood and breast milk. Binding and neutralizing antibody titers against the SARS-CoV-2 B.1.1.7 and B.1.351 variants of concern were reduced, but T-cell responses were preserved against viral variants.

Conclusion and Relevance In this exploratory analysis of a convenience sample, receipt of a COVID-19 mRNA vaccine was immunogenic in pregnant women, and vaccine-elicited antibodies were transported to infant cord blood and breast milk. Pregnant and nonpregnant women who were vaccinated developed cross-reactive antibody responses and T-cell responses against SARS-CoV-2 variants of concern. (Author)

Full URL: <https://doi.org/10.1001/jama.2021.7563>

2021-05897

Maternal and neonatal SARS-CoV-2 antibodies assessment after mRNA maternal vaccination in the third trimester of pregnancy. Riviello C, Pontello V (2021), International Journal of Gynecology & Obstetrics 10 June 2021, online Brief report presenting the case of a healthy 42-year-old pregnant health care worker who received doses of the Pfizer vaccine at 31 and 34 weeks of gestation. The ratio between cord and maternal antibodies was 0.38 which may imply that placental transfer after vaccination is less efficient than in natural infection. (LDO)

Full URL: <https://doi.org/10.1002/ijgo.13783>

2021-05896

A forecast of maternal deaths with and without vaccination of pregnant women against COVID-19 in Mexico.

Lumbreras-Marquez MI, Fields KG, Campos-Zamora M, et al (2021), International Journal of Gynecology & Obstetrics 11 June 2021, online

Brief report forecasting excess maternal deaths for the second half of 2021 with and without vaccination of all pregnant women during May and June 2021. The authors predict that an 100% vaccination rate would result in the

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number of deaths falling from 993 to 885. (LDO)

Full URL: <https://doi.org/10.1002/ijgo.13788>

2021-05751

Coronavirus (COVID-19) Vaccination in Pregnancy. Information for healthcare professionals. Version 1.0. Royal College of Obstetricians and Gynaecologists (2021), London: RCOG 30 June 2021, 19 pages

This document is intended as temporary guidance on COVID-19 vaccination in pregnancy. It aims to summarise, in a format useful for maternity care, the evidence presented in existing COVID-19 vaccination guidance from the Public Health England/Department of Health Green Book,¹ as well as leaflets and information from Public Health England and the NHS. The document will be incorporated into the next version of the Royal College of Obstetricians and Gynaecologists (RCOG) Coronavirus (COVID-19) Infection in Pregnancy guidance expected to be published in autumn 2021. (Author)

Full URL: <https://www.rcog.org.uk/globalassets/documents/guidelines/2021-06-30-coronavirus-covid-19-vaccination-in-pregnancy.pdf>

2021-05747

Vaccine Update. Public Health England (2021), London: PHE no 322, June 2021

This special edition of Vaccine Update focuses on the COVID-19 vaccination programme and includes information on vaccine uptake, mortality rates and side effects. (LDO)

Full URL: <https://www.gov.uk/government/publications/vaccine-update-issue-322-june-2021-covid-19-phase-2-special-edition/vaccine-update-issue-322-june-2021-covid-19-phase-2-special-edition>

2021-05702

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 22032, 24 June 2021 Nadhim Zahawi responds to a written question asked by Fleur Anderson to the Secretary of State for Health and Social Care, regarding the assessment he has made of the potential merits of reducing the time between COVID-19 vaccine doses for pregnant women in line with priority groups 1 to 9. (LDO)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-06-24/22032>

2021-05661

EBCOG position statement on COVID-19 vaccination for pregnant and breastfeeding women. Martins I, Louwen F, Ayres-de-Campos D, et al (2021), European Journal of Obstetrics & Gynecology and Reproductive Biology vol 262, July 2021, pp 256-258

Covid 19 pandemic has led to significant mortality and long term morbidity globally. Pregnant women are at increased risk of severe illness from COVID 19 infection. There is an urgent need for all health authorities and Governments to offer vaccination to all pregnant women especially those with high risk pregnancy. (Author)

Full URL: <https://doi.org/10.1016/j.ejogrb.2021.05.021>

2021-05365

Pregnancy: Coronavirus [written answer]. House of Lords (2021), Hansard Written question HL832, 8 June 2021 Lord Bethell responds to a written question from Lord Balfe to Her Majesty's Government, regarding what plans they have (1) to increase the opportunity for pregnant women to have two doses of vaccinations by the time their pregnancy is full term by ensuring that that the NHS vaccination booking system allows them to book a second dose of vaccine eight weeks after their first, and (2) to ensure that any NHS-supported applications used to enable such bookings reflect that opportunity. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-06-08/HL832>

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2021-05348

COVID-19 vaccine acceptance among pregnant, breastfeeding, and nonpregnant reproductive-aged women. Sutton D, D'Alton M, Zhang Y, et al (2021), American Journal of Obstetrics & Gynecology MFM vol 3, no 5, September 2021, 100403

Background

Although mass vaccination against COVID-19 may prove to be the most efficacious end to this deadly pandemic, there remains concern and indecision among the public towards vaccination. As pregnant and reproductive-aged women account for a large proportion of the population with particular concerns regarding vaccination against COVID-19, this survey aims at investigating their current attitudes and beliefs within our own institution.

Objective

To understand vaccine acceptability among pregnant, non-pregnant and breastfeeding respondents and elucidate factors associated with COVID-19 vaccine acceptance.

Methods

We administered an anonymous online survey to all women (including patients, providers and staff) at our institution assessing rates of acceptance of COVID-19 vaccination. Respondents were contacted in one of three ways: by email, advertisement flyers and distribution of QR codes at virtual townhalls regarding the COVID-19 vaccine. Based on their responses, respondents were divided into three mutually exclusive groups: (1) non-pregnant respondents (2) pregnant respondents and (3) breastfeeding respondents. The primary outcome was acceptance of vaccination. Prevalence ratios were calculated to ascertain the independent effects of multiple patient-level factors on vaccine acceptability.

Results

The survey was administered from January 7, 2021 to January 29, 2021 with 1,012 respondents of whom 466 (46.9%) identified as Non-Hispanic White, 108 (10.9%) as Non-Hispanic Black, 286 (28.8%) as Hispanic, and 82 (8.2%) as Non-Hispanic Asian. The median age was 36 (IQR 25-47) years. Of all the respondents, 656 respondents (64.8%) were non-pregnant, 216 (21.3%) were pregnant and 122 (12.1%) were breastfeeding. There was no difference in chronic comorbidities when evaluated as a composite variable (Table 1). 390 respondents (39.2%) reported working in healthcare. Non-pregnant respondents were most likely to accept vaccination (457 respondents, 76.2%, $p < 0.001$) with breastfeeding respondents the second most likely (55.2%). Pregnant respondents had the lowest rate of vaccine acceptance (44.3%, $p < 0.001$). Prevalence ratios revealed all non-White races except for non-Hispanic Asian respondents and Spanish speaking respondents were less likely to accept vaccination (Table 3). Working in healthcare was not found to be associated with vaccine acceptance among our cohort.

Conclusions and Relevance

In this survey study of only women at a single institution, pregnant respondents of non-White or non-asian races were more likely to decline vaccination compared to non-pregnant and breast-feeding respondents. Working in healthcare was not associated with vaccine acceptance. (Author)

2021-05317

COVID-19 Vaccine Considerations during Pregnancy and Lactation. Blumberg D, Sridhar A, Lakshminrusimha S, et al (2021), American Journal of Perinatology vol 38, no 6, June 2021, pp 523-528

Editorial reviewing the published data and theoretical considerations of COVID-19 vaccination in pregnant and lactating women. Discusses the safety of mRNA and adenovirus DNA vaccines manufactured by Pfizer-BioNTech, Moderna and Janssen. (LDO)

Full URL: <https://doi.org/10.1055/s-0041-1726390>

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2021-05276

Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. Gray KJ, Bordt EA, Atyeo C, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) 26 March 2021, online

Background

Pregnant and lactating women were excluded from initial coronavirus disease 2019 vaccine trials; thus, data to guide vaccine decision making are lacking.

Objective

This study aimed to evaluate the immunogenicity and reactogenicity of coronavirus disease 2019 messenger RNA vaccination in pregnant and lactating women compared with: (1) nonpregnant controls and (2) natural coronavirus disease 2019 infection in pregnancy.

Study Design

A total of 131 reproductive-age vaccine recipients (84 pregnant, 31 lactating, and 16 nonpregnant women) were enrolled in a prospective cohort study at 2 academic medical centers. Titers of severe acute respiratory syndrome coronavirus 2 spike and receptor-binding domain immunoglobulin G, immunoglobulin A, and immunoglobulin M were quantified in participant sera (n=131) and breastmilk (n=31) at baseline, at the second vaccine dose, at 2 to 6 weeks after the second vaccine, and at delivery by Luminex. Umbilical cord sera (n=10) titers were assessed at delivery. Titers were compared with those of pregnant women 4 to 12 weeks from the natural infection (n=37) by enzyme-linked immunosorbent assay. A pseudovirus neutralization assay was used to quantify neutralizing antibody titers for the subset of women who delivered during the study period. Postvaccination symptoms were assessed via questionnaire. Kruskal-Wallis tests and a mixed-effects model, with correction for multiple comparisons, were used to assess differences among groups.

Results

Vaccine-induced antibody titers were equivalent in pregnant and lactating compared with nonpregnant women (pregnant, median, 5.59; interquartile range, 4.68–5.89; lactating, median, 5.74; interquartile range, 5.06–6.22; nonpregnant, median, 5.62; interquartile range, 4.77–5.98, P=.24). All titers were significantly higher than those induced by severe acute respiratory syndrome coronavirus 2 infection during pregnancy (P<.0001). Vaccine-generated antibodies were present in all umbilical cord blood and breastmilk samples. Neutralizing antibody titers were lower in umbilical cord than maternal sera, although this finding did not achieve statistical significance (maternal sera, median, 104.7; interquartile range, 61.2–188.2; cord sera, median, 52.3; interquartile range, 11.7–69.6; P=.05). The second vaccine dose (boost dose) increased severe acute respiratory syndrome coronavirus 2–specific immunoglobulin G, but not immunoglobulin A, in maternal blood and breastmilk. No differences were noted in reactogenicity across the groups.

Conclusion

Coronavirus disease 2019 messenger RNA vaccines generated robust humoral immunity in pregnant and lactating women, with immunogenicity and reactogenicity similar to that observed in nonpregnant women. Vaccine-induced immune responses were statistically significantly greater than the response to natural infection. Immune transfer to neonates occurred via placenta and breastmilk. (Author)

2021-05252

Care strategies before entering pregnant mothers to the operating room and after birth during COVID-19. Moghadam MY, Beigi-khoosani A, Merajikhah A (2021), British Journal of Midwifery vol 29, no 6, June 2021, pp 348-351

Provides an overview of care strategies for pregnant women in the perinatal period during the COVID-19 pandemic.

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Discusses vaccination and testing during pregnancy, isolation of the newborn baby and hygiene while breastfeeding. (LDO)

2021-05211

Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. Shimabukuro TT, Kim SY, Myers TR, et al (2021), The New England Journal of Medicine vol 384, no 24, 17 June 2021, pp 2273-2282

BACKGROUND

Many pregnant persons in the United States are receiving messenger RNA (mRNA) coronavirus disease 2019 (Covid-19) vaccines, but data are limited on their safety in pregnancy.

METHODS

From December 14, 2020, to February 28, 2021, we used data from the “v-safe after vaccination health checker” surveillance system, the v-safe pregnancy registry, and the Vaccine Adverse Event Reporting System (VAERS) to characterize the initial safety of mRNA Covid-19 vaccines in pregnant persons.

RESULTS

A total of 35,691 v-safe participants 16 to 54 years of age identified as pregnant. Injection-site pain was reported more frequently among pregnant persons than among nonpregnant women, whereas headache, myalgia, chills, and fever were reported less frequently. Among 3958 participants enrolled in the v-safe pregnancy registry, 827 had a completed pregnancy, of which 115 (13.9%) resulted in a pregnancy loss and 712 (86.1%) resulted in a live birth (mostly among participants with vaccination in the third trimester). Adverse neonatal outcomes included preterm birth (in 9.4%) and small size for gestational age (in 3.2%); no neonatal deaths were reported. Although not directly comparable, calculated proportions of adverse pregnancy and neonatal outcomes in persons vaccinated against Covid-19 who had a completed pregnancy were similar to incidences reported in studies involving pregnant women that were conducted before the Covid-19 pandemic. Among 221 pregnancy-related adverse events reported to the VAERS, the most frequently reported event was spontaneous abortion (46 cases).

CONCLUSIONS

Preliminary findings did not show obvious safety signals among pregnant persons who received mRNA Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes. (Author)

Full URL: <https://doi.org/10.1056/NEJMoa2104983>

2021-05210

COVID-19 vaccination in pregnancy and postpartum. Brillo E, Tosto V, Gerli S, et al (2021), Journal of Maternal-Fetal and Neonatal Medicine 19 May 2021, online

Aim

To identify whether COVID-19 vaccines should be administered in pregnant and breastfeeding women by reviewing the guidance and other evidence.

Methods

We reviewed the COVID-19 vaccination guidance for pregnant and breastfeeding women published to date and evidence from preclinical experimental and observational clinical studies, and discuss their implications.

Results

Pregnant women were excluded from the initial phase 3 clinical trials of COVID-19 vaccines resulting in limited data

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on their efficacy and safety during pregnancy and postpartum. As a result, since December 2020, there has been conflicting advice from public health, governmental, and professional authorities on this matter. From the end of 2020 up to now, some consensus guidance has been published with a prevalent precautionary approach on the administration of vaccines in pregnant women, in breastfeeding ones, or for those who are planning a pregnancy (either spontaneously or with assisted technologies). After the first few months of vaccine administration in some countries, more permissiveness seems to prevail, although with inconsistencies. At the moment, the results obtained by preclinical experimental and observational clinical studies suggest that the risks of the maternal COVID-19 outweigh the undocumented and hypothetical risks of the COVID-19 vaccines in pregnancy. Also, until two viral vector COVID-19 vaccines were associated with very rare thromboembolic events, all guidance had agreed that all approved COVID-19 vaccines could be administered in pregnancy. Actually, some concern has been expressed.

Conclusion

COVID-19 vaccines administered in pregnancy can reduce the risk of severe COVID-19 and their serious consequences for mothers and their offspring. However, many aspects remain to be clarified. (Author)

2021-05204

SARS CoV-2 (COVID-19) Current Pharmacotherapy for Mother and Infant. Thigpen J (2021), Neonatal Network: the Journal of Neonatal Nursing vol 40, no 3, May/June 2021, pp 175-182

The novel coronavirus disease 2019 (COVID-19), appeared in the United States over 1 year ago. This virus has a wide range of presentations, from being asymptomatic to causing severe acute respiratory syndrome, which can lead to death. It has led to a worldwide effort to find effective treatments, from repurposed medications to new discoveries, as well as the push to develop effective vaccines. As the race to fight this pandemic unfolds, this column provides what is currently available to combat this virus, how it has been utilized in the pregnant population, and what data have been made available about how these treatments affect fetal development and the neonate. (Author)

2021-05023

Expecto Patronum! Leveraging the Positive Force of COVID-19 Vaccines for Pregnant and Lactating Individuals.

Malinowski AK, Whittle W, Murphy K, et al (2021), JOGC (Journal of Obstetrics and Gynaecology Canada) 13 May 2021, online

For over a year, the world has been gripped by the coronavirus disease 2019 (COVID-19) pandemic, which has had far-reaching effects on society. The integrity of national health care systems has also been challenged, owing to shifts in guidance and misinformation. Although initial reports suggested that pregnant people were not at increased risk of severe COVID-19, current data arising from the “third wave” paint a much more concerning picture. In addition, pregnant and lactating people were excluded from vaccine trials, which has hindered the ability of health care professionals to provide evidence-based counselling regarding the safety and efficacy of the available vaccines in these populations. This commentary reviews the current data on the safety of COVID-19 vaccines in pregnancy. The evidence is clear that the risks of hospitalization and severe maternal and potentially fetal morbidity from COVID-19 in pregnancy far outweigh the very minimal risks of COVID-19 vaccination in pregnancy. (Author)

2021-04956

Maternal vaccines during the Covid-19 pandemic: A qualitative interview study with UK pregnant women. Brigden A, Davies A, Shepherd E, et al (2021), Midwifery vol 100, September 2021, 103062

Background

There is suboptimal uptake of recommended maternal vaccines (pertussis and influenza) during pregnancy in the UK. The Covid-19 pandemic has impacted healthcare services, and potentially vaccine coverage, and brought the need for

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new vaccines to be tested and rolled out.

Objectives

To explore: i) the impact of the Covid-19 pandemic on pregnant women's access to, and attitudes towards, routine maternal vaccines and; ii) women's attitudes towards testing Covid-19 vaccines on pregnant women and their personal willingness to take part in such a trial.

Design

Qualitative interview study with pregnant women in the Bristol and surrounding area (UK).

Methods

Semi-structured telephone/videoconference interviews were conducted (following a topic guide), transcribed verbatim and subjected to thematic analysis.

Results

Thirty-one pregnant women (selected for demographic range) were interviewed in April/May 2020. Participants felt the pandemic had elevated the importance of routine maternal vaccines, though women were concerned about safety management around appointment attendance. Women were wary of receiving a new Covid-19 vaccine, with most perceiving it as riskier than Covid-19 itself.

Conclusions

It is important to maximise the safety and efficiency of maternity appointments to encourage uptake of routine maternal vaccines, and to communicate this well. For pregnant women to gain a new vaccine or participate in a vaccine trial, they need to be convinced that the risk posed by the virus is greater than any risk of receiving a new vaccine. (Author)

Full URL: <https://doi.org/10.1016/j.midw.2021.103062>

2021-04866

Pregnant women's perspectives on severe acute respiratory syndrome coronavirus 2 vaccine. Carbone L, Mappa I, Sirico A, et al (2021), American Journal of Obstetrics & Gynecology MFM vol 3, no 4, July 2021, 100352

BACKGROUND

Since coronavirus disease 2019 vaccines have been distributed, a debate has raised on whether pregnant women should get the vaccine. No available data exist so far regarding the safety, efficacy, and toxicology of these vaccines when administered during pregnancy. Most of the Obstetrics and Gynecology societies suggested that pregnant could agree to be vaccinated, after a thorough counseling of risks and benefits with their gynecologists, thus leading to an autonomous decision.

OBJECTIVE

This study aimed to evaluate the attitude to coronavirus disease 2019 vaccination in pregnant and breastfeeding women in Italy.

STUDY DESIGN

A survey was made at the University of Naples Federico II and the Ospedale Cristo Re, Tor Vergata University of Rome, on pregnant and breastfeeding women asking their perspectives on the available vaccines after reading the recommendations issued by our national Obstetrics, Gynecology, and Neonatology societies. The questionnaire included 12 items finalized to evaluate general features of the women and 6 items specifically correlated to their attitudes toward the severe acute respiratory syndrome coronavirus 2 vaccination. Chi-square or Fisher's exact tests

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were used to compare group differences of categorical variables and Wilcoxon signed rank or Mann-Whitney U test for continuous variables. The study was approved by the institutional review boards of the University of Naples Federico II (ref. no. 409/2020) and the Ospedale Cristo Re, Tor Vergata University of Rome (ref. #Ost4-2020).

RESULTS

Most of the included women did not agree to eventually receive severe acute respiratory syndrome coronavirus 2 vaccine during pregnancy (40 [28.2%] vs 102 [71.8%]). Being pregnant was considered a determinant factor to refuse the vaccine prophylaxis (99 [69.7%] vs 43 [30.3%]; chi-square test=24.187; $P<.001$), even if a very large percentage declared to be generally in favor of vaccines (128 [90.1%] vs 14 [9.9%]; chi-square test=6.091; $P=.014$) and most of them confirmed they received or would receive other recommended vaccines during pregnancy (75 [52.8%] vs 67 [47.2%]; chi-square test=10.996; $P=.001$).

CONCLUSION

Urgent data are needed on the safety, efficacy, and toxicology of severe acute respiratory syndrome coronavirus 2 vaccines during pregnancy to modify this trend and to help obstetricians during the counseling. Furthermore, pregnant women should be included in future vaccine development trials to not incur again in such uncertainty.

(Author)

Full URL: <https://doi.org/10.1016/j.ajogmf.2021.100352>

2021-04665

COVID-19 vaccination: a guide for all women of childbearing age, pregnant or breastfeeding [Last updated 29 July 2021]. Public Health England (2020), London: Public Health England 6 December 2020

Information for all women of childbearing age, those currently pregnant or breastfeeding on coronavirus (COVID-19) vaccination. (Author)

Full URL: <https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding>

2021-04580

Vaccination: Children [written answer]. House of Commons (2021), Hansard Written question 5192, 21 May 2021 Jo Churchill responds to a written question from Mr Jonathan Lord to the Secretary of State for Health and Social Care, regarding what lessons he has learned from the covid-19 vaccine deployment that can be applied to the routine childhood immunisation programme. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-05-21/5192>

2021-04500

Maternity Colleges express concern over vaccine hesitancy in pregnant women. Royal College of Obstetricians & Gynaecologists (2021), London: RCOG 10 June 2021

Reports that the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) are urging pregnant women to seek advice from their health care professional about getting vaccinated against COVID-19, after the results of a recent survey conducted on social media revealed the majority of pregnant women declined the vaccine when it was offered to them. Concerns have been raised by the RCOG and the RCM following research which has shown pregnant women, particularly those in the third trimester, are at risk of becoming severely ill if they contract COVID-19, and this then increases the chances of prematurity and stillbirth. (JSM)

Full URL: <https://www.rcog.org.uk/en/news/maternity-colleges-express-concern-over-vaccine-hesitancy-in-pregnant-women/>

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2021-04498

US college covid-19 vaccine mandates don't consider immunity or pregnancy, and may run foul of the law. Block J (2021), BMJ vol 373, 2 June 2021, n1397

The requirement for vaccination with products under emergency use authorisation is new legal territory, finds Jennifer Block. (Author)

Full URL: <https://doi.org/10.1136/bmj.n1397>

2021-04135

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 7236, 25 May 2021 Nadhim Zahawi responds to a written question from Catherine West to the Secretary of State for Health and Social Care, regarding what steps his Department is taking to help ensure that pregnant women are supported to access to the covid-19 vaccine. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-05-25/7236>

2021-04013

Frequently asked questions for health-care providers providing care to pregnant patients and their newborns during the COVID-19 pandemic. Perinatal Services BC (2021), Vancouver: Perinatal Services BC 21 May 2021

Brief fact sheet aimed at health care providers on the care of pregnant women and their newborns during the COVID-19 pandemic. Includes information on women who have tested positive, placental pathology and vaccination. (LDO)

Full URL: <http://www.perinatalservicesbc.ca>

2021-03900

The Effects of the COVID 19 Pandemic on Vaccine Decisions in Pregnant Women. Gencer H, Özkan S, Vardar O, et al (2021),

Women and Birth: Journal of the Australian College of Midwives 19 May 2021, online
Background

Pregnancy is an important time for developing attitudes and beliefs about childhood vaccinations. Vaccinations are among the most effective way of preventing some infectious diseases. Discussions on vaccinations have increased due to the Covid-19 pandemic and there is an opportunity to give society correct information on vaccinations.

Aim

The aim of the study was to determine the opinions of pregnant women on vaccinations in pregnancy and childhood and the effect of the Covid-19 pandemic on these views.

Methods

The study was conducted as a cross-sectional study. The sample included 152 pregnant women. Data were collected through a 25-item online questionnaire created by the researchers.

Results

It was found in our study that 29.6% of pregnant women using forum websites exhibited hesitant attitudes towards vaccinations. The vaccine hesitancy rate was found to be high in pregnant women who said that their economic level was low and who worried about the risks of vaccination. The Covid-19 pandemic was reported to be the cause of a decrease in vaccine hesitancy in 28.9% of the participants.

Conclusion

The events surrounding the pandemic provided an opportunity to explain how pregnant women feel about

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vaccinations. Providing pregnant women with access to correct information from health workers may reduce the problem of trust, which is among the most important reasons for vaccine hesitancy. (Author)

Full URL: <https://doi.org/10.1016/j.wombi.2021.05.003>

2021-03845

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccination in Pregnancy: Measures of Immunity and Placental Histopathology. Shanes ED, Otero S, Mithal LB, et al (2021), *Obstetrics & Gynecology* 11 May 2021, online
Receipt of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination was not associated with placental histopathologic lesions. (Author)

Full URL: <https://doi.org/10.1097/AOG.0000000000004457>

2021-03791

Women perception of SARS-CoV-2 vaccination during pregnancy and subsequent maternal anxiety: a prospective observational study. Mappa I, Luviso M, Distefano FA, et al (2021), *The Journal of Maternal-Fetal and Neonatal Medicine* 13 April 2021, online

Objective

The use of Coronavirus 2 (SARS-CoV-2) vaccine in pregnant women is controversial and still not performed in Italy. Our objective was to evaluate the propensity of a population of Italian women to receive the vaccine and its psychological impact.

Methods

A prospective, observational study was performed on pregnant women attending Ospedale Cristo Re Università Roma TorVergata. A multi-section questionnaire was sent to each included woman on the first day of available SARS-CoV-2 vaccination. Part-A was finalized to acquire maternal characteristics and to test the women's perception of vaccinations in pregnancy and their fear-induced by vaccines. Part-B included the State-Trait-Anxiety-Inventory (STAI) a validated test for scoring trait anxiety (basal anxiety, STAI-T) and state anxiety (STAI-S). An abnormal value of STAI was considered when ≥ 40 . Comparisons of maternal variables were performed according to their vaccine attitude.

Results

The questionnaire was completed by 161 women (80.5% of the population considered). A positive attitude toward the vaccine was present in 136 (84.5%) women (positive) while the remaining 25.5% considered the vaccine not useful (negative). Among the former group 52.9% were favorable to obtain the vaccine during pregnancy despite the current national limitations, a percentage significantly higher ($p = .02$) than in the negative groups. Women with a negative attitude to the vaccine had a lower educational ($p = .002$) and employment level ($p = .016$) when compared to the positive group. In all the women a significant increase of STAI-S from STAI-T values was evidenced ($p < .0001$). The incidence of abnormal STAI T values (basal anxiety) was similar between the 2 groups ($p = .81$), while there was a significant increase of STAI-S values in the negative group (negative 88.0%; vs positive 63.4%; $p = .018$)

Conclusions

The majority of pregnant women considered have a positive attitude to SARS-CoV-2 vaccine. Vaccine campaign seems to increase the maternal level of anxiety and this increase is more marked with a negative attitude toward the vaccine. (Author)

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2021-03610

Pregnancy: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 1201, 13 May 2021
Nadhim Zawahi responds to a written question asked by Munira Wilson to the Secretary of State for Health and Social Care, regarding what steps he is taking to ensure that pregnant women are offered the Pfizer/BioNTech or Moderna COVID-19 vaccine. (LDO)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-05-13/1201>

2021-03598

Maternal and perinatal outcomes of pregnant women with SARS-CoV-2 infection at the time of birth in England: national cohort study. Gurol-Urganci I, Jardine JE, Carroll F, et al (2021), American Journal of Obstetrics & Gynecology 14 May 2021, online

Objective: The aim of this study was to determine the association between SARS-CoV-2 26 infection at the time of birth and maternal and perinatal outcomes.

Methods: This is a population-based cohort study in England. The inclusion criteria were women with a recorded singleton birth between 29th May 2020 and 31st 29 January 2021 in a national database of hospital admissions. Maternal and perinatal outcomes were compared between pregnant women with a laboratory-confirmed SARS-CoV-2 infection recorded in the birth episode and those without. Study outcomes were fetal death at or beyond 24 weeks' gestation (stillbirth), preterm birth (<37 weeks gestation), small for gestational age infant (SGA; birthweight <10th centile), preeclampsia/eclampsia, induction of labor, mode of birth, specialist neonatal care, composite neonatal adverse outcome indicator, maternal and neonatal length of hospital stay following birth (3 days or more), 28-day neonatal and 42-day maternal hospital readmission. Adjusted odds ratios (aOR) and their 95% confidence interval (CI) for the association between SARS-CoV-2 infection status and outcomes were calculated using logistic regression, adjusting for maternal age, ethnicity, parity, pre-existing diabetes, pre-existing hypertension and socioeconomic deprivation measured using Index of Multiple Deprivation 2019. Models were fitted with robust standard errors to account for hospital-level clustering. The analysis of the neonatal outcomes was repeated for those born at term (≥ 37 weeks' gestation) since preterm birth has been reported to be more common in pregnant women with SARS-CoV-2 infection.

Results: The analysis included 342,080 women, of whom 3,527 had laboratory confirmed SARS-CoV-2 infection. Laboratory-confirmed SARS-CoV-2 infection was more common in women who were younger, of non-white ethnicity, primiparous, residing in the most deprived areas, or had comorbidities. Fetal death (aOR, 2.21, 95% CI 1.58-3.11; $P < 0.001$) and preterm birth (aOR 2.17, 95% CI 1.96-2.42; $P < 0.001$) occurred more frequently in women with SARS-CoV-2 infection than those without. Risk of preeclampsia/eclampsia (aOR 1.55, 95% CI 1.29-1.85; $P < 0.001$), birth by emergency Cesarean delivery (aOR 1.63, 95% CI 1.51-1.76; $P < 0.001$) and prolonged admission following birth (aOR 1.57, 95% CI 1.44-1.72; $P < 0.001$) were significantly higher for women with SARS-CoV-2 infection than those without. There were no significant differences in the rate of other maternal outcomes.

Risk of neonatal adverse outcome (aOR 1.45, 95% CI 1.27-1.66; $P < 0.001$), need for specialist neonatal care (aOR 1.24, 95% CI 1.02-1.51; $P = 0.03$) and prolonged neonatal admission following birth (aOR 1.61, 95% CI 1.49-1.75; $P < 0.001$) were all significantly higher for infants with mothers with laboratory-confirmed SARS-CoV-2 infection. When the analysis was restricted to pregnancies delivered at term (≥ 37 weeks), there were no significant differences in neonatal adverse outcome ($P = 0.78$), need for specialist neonatal care after birth ($P = 0.22$) or neonatal readmission within four weeks of birth ($P = 0.05$). Neonates born at term to mothers with laboratory-confirmed SARS-CoV-2 infection were

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more likely to have prolonged admission following birth (21.1% compared to 14.6%, aOR 1.61, 95% CI 1.49-1.75; $P < 0.001$).

Conclusions: SARS-CoV-2 infection at the time of birth is associated with higher rates of fetal death, preterm birth, preeclampsia and emergency Cesarean delivery. There were no additional adverse neonatal outcomes, other than those related to preterm delivery. Pregnant women should be counseled regarding risks of SARS-COV-2 infection and should be considered a priority for vaccination. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.05.016>

2021-03526

Immunogenicity of COVID-19 mRNA Vaccines in Pregnant and Lactating Women. Collier AY, McMahan K, Yu J, et al (2021), JAMA (Journal of the American Medical Association) 13 May 2021, online

Importance Pregnant women are at increased risk of morbidity and mortality from COVID-19 but have been excluded from the phase 3 COVID-19 vaccine trials. Data on vaccine safety and immunogenicity in these populations are therefore limited.

Objective To evaluate the immunogenicity of COVID-19 messenger RNA (mRNA) vaccines in pregnant and lactating women, including against emerging SARS-CoV-2 variants of concern.

Design, Setting, and Participants An exploratory, descriptive, prospective cohort study enrolled 103 women who received a COVID-19 vaccine from December 2020 through March 2021 and 28 women who had confirmed SARS-CoV-2 infection from April 2020 through March 2021 (the last follow-up date was March 26, 2021). This study enrolled 30 pregnant, 16 lactating, and 57 neither pregnant nor lactating women who received either the mRNA-1273 (Moderna) or BNT162b2 (Pfizer-BioNTech) COVID-19 vaccines and 22 pregnant and 6 nonpregnant unvaccinated women with SARS-CoV-2 infection.

Main Outcomes and Measures SARS-CoV-2 receptor binding domain binding, neutralizing, and functional nonneutralizing antibody responses from pregnant, lactating, and nonpregnant women were assessed following vaccination. Spike-specific T-cell responses were evaluated using IFN- γ enzyme-linked immunospot and multiparameter intracellular cytokine–staining assays. Humoral and cellular immune responses were determined against the original SARS-CoV-2 USA-WA1/2020 strain as well as against the B.1.1.7 and B.1.351 variants.

Results This study enrolled 103 women aged 18 to 45 years (66% non-Hispanic White) who received a COVID-19 mRNA vaccine. After the second vaccine dose, fever was reported in 4 pregnant women (14%; SD, 6%), 7 lactating women (44%; SD, 12%), and 27 nonpregnant women (52%; SD, 7%). Binding, neutralizing, and functional nonneutralizing antibody responses as well as CD4 and CD8 T-cell responses were present in pregnant, lactating, and nonpregnant women following vaccination. Binding and neutralizing antibodies were also observed in infant cord blood and breast milk. Binding and neutralizing antibody titers against the SARS-CoV-2 B.1.1.7 and B.1.351 variants of concern were reduced, but T-cell responses were preserved against viral variants.

Conclusion and Relevance In this exploratory analysis of a convenience sample, receipt of a COVID-19 mRNA vaccine was immunogenic in pregnant women, and vaccine-elicited antibodies were transported to infant cord blood and breast milk. Pregnant and nonpregnant women who were vaccinated developed cross-reactive antibody responses and T-cell responses against SARS-CoV-2 variants of concern. (Author)

Full URL: <https://doi.org/10.1001/jama.2021.7563>

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2021-03458

Covid-19: Pregnant women should be offered Pfizer or Moderna vaccine, says UK advisory committee. Mahase E (2021), BMJ vol 373, no 8288, 19 April 2021, n1013

Pregnant women should be offered the Pfizer BioNTech or Moderna covid-19 vaccine at the same time as the rest of the population, with priority based on age and clinical risk group, the government's vaccine advisory committee has said. (Author)

Full URL: <https://doi.org/10.1136/bmj.n1013>

2021-03246

Advocate for the COVID-19 Vaccine for Pregnant and Breastfeeding Women. Spatz DL (2021), MCN - American Journal of Maternal/Child Nursing vol 46, no 3, May/June 2021, p 178

Many professional organizations and agencies have advocated for pregnant women and breastfeeding women to be offered the COVID-19 vaccine. Our breastfeeding expert, Dr. Spatz, reviews their recommendations and ways nurses can advocate for this population to receive the vaccine. (Author)

Full URL: <https://doi.org/10.1097/NMC.0000000000000719>

2021-03147

Covid and pregnancy - should you get the vaccine?. Foster L (2021), BBC News 7 May 2021

As the Covid vaccine is rolled out to younger age groups, what should you do if you're expecting a baby?

The guidance for pregnant people in the UK was changed last month following new data from the USA involving the Pfizer and Moderna vaccines. BBC News Health Reporter Laura Foster looks at what the science says. (Author)

Full URL: <https://www.bbc.co.uk/news/av/health-57013743>

2021-02984

Antibody Response to Coronavirus Disease 2019 (COVID-19) Messenger RNA Vaccination in Pregnant Women and Transplacental Passage Into Cord Blood. Prabhu M, Murphy EA, Sukhu AC, et al (2021), Obstetrics & Gynecology 28 April 2021, online

Coronavirus disease 2019 (COVID-19) vaccination in pregnancy induces a robust maternal immune response, with transplacental antibody transfer detectable in cord blood as early as 16 days after the first dose. (Author)

Full URL: <https://doi.org/10.1097/AOG.0000000000004438>

2021-02946

JCVI gives green light for pregnant women to be offered Covid-19 vaccine. Mitchell G (2021), Nursing Times 16 April 2021, online

Pregnant women will be offered the Covid-19 vaccine at the same time as their peers in the wider population following a change in guidance announced today. (Author)

Full URL: <https://www.nursingtimes.net/news/public-health/jcvi-gives-green-light-for-pregnant-women-to-be-offered-covid-19-vaccine-16-04-2021/>

2021-02918

Severe acute respiratory syndrome coronavirus 2 serology levels in pregnant women and their neonates. Kubiak JM, Murphy EA, Yee J, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 1, July 2021, pp 73.e1-73.e7

Background

Pregnant women and their neonates represent 2 vulnerable populations with an interdependent immune system that are highly susceptible to viral infections. The immune response of pregnant women to severe acute respiratory syndrome coronavirus 2 and the interplay of how the maternal immune response affects the neonatal passive

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immunity have not been studied systematically.

Objective

We characterized the serologic response in pregnant women and studied how this serologic response correlates with the maternal clinical presentation and with the rate and level of passive immunity that the neonate received from the mother.

Study Design

Women who gave birth and who tested positive for immunoglobulin M or immunoglobulin G against severe acute respiratory syndrome coronavirus 2 using semiquantitative detection in a New York City hospital between March 22, 2020, and May 31, 2020, were included in this study. A retrospective chart review of the cases that met the inclusion criteria was conducted to determine the presence of coronavirus disease 2019 symptoms and the use of oxygen support. Serology levels were compared between the symptomatic and asymptomatic patients using a Welch 2 sample t test. Further chart review of the same patient cohort was conducted to identify the dates of self-reported onset of coronavirus disease 2019 symptoms and the timing of the peak immunoglobulin M and immunoglobulin G antibody levels after symptom onset was visualized using local polynomial regression smoothing on log₂-scaled serologic values. To study the neonatal serology response, umbilical cord blood samples of the neonates born to the subset of serology positive pregnant women were tested for serologic antibody responses. The maternal antibody levels of serology positive vs the maternal antibody levels of serology negative neonates were compared using the Welch 2 sample t test. The relationship between the quantitative maternal and quantitative neonatal serologic data was studied using a Pearson correlation and linear regression. A multiple linear regression analysis was conducted using maternal symptoms, maternal serology levels, and maternal use of oxygen support to determine the predictors of neonatal immunoglobulin G levels.

Results

A total of 88 serology positive pregnant women were included in this study. The antibody levels were higher in symptomatic pregnant women than in asymptomatic pregnant women. Serology studies in 34 women with symptom onset data revealed that the maternal immunoglobulin M and immunoglobulin G levels peak around 15 and 30 days after the onset of coronavirus disease 2019 symptoms, respectively. Furthermore, studies of 50 neonates born to this subset of serology positive women showed that passive immunity in the form of immunoglobulin G is conferred in 78% of all neonates. The presence of passive immunity is dependent on the maternal antibody levels, and the levels of neonatal immunoglobulin G correlate with maternal immunoglobulin G levels. The maternal immunoglobulin G levels and maternal use of oxygen support were predictive of the neonatal immunoglobulin G levels.

Conclusion

We demonstrated that maternal serologies correlate with symptomatic maternal infection, and higher levels of maternal antibodies are associated with passive neonatal immunity. The maternal immunoglobulin G levels and maternal use of oxygen support, a marker of disease severity, predicted the neonatal immunoglobulin G levels. These data will further guide the screening for this uniquely linked population of mothers and their neonates and can aid in developing maternal vaccination strategies. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.016>

2021-02906

The coronavirus disease 2019 vaccine in pregnancy: risks, benefits, and recommendations. Stafford IA, Parchem JG, Sibai BM (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 224, no 5, May 2021, pp 484-495

The coronavirus disease 2019 has caused over 2 million deaths worldwide, with over 412,000 deaths reported in United States. To date, at least 57,786 pregnant women in the United States have been infected, and 71 pregnant women have died. Although pregnant women are at higher risk of severe coronavirus disease 2019-related illness,

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clinical trials for the available vaccines excluded pregnant and lactating women. The safety and efficacy of the vaccines for pregnant women, the fetus, and the newborn remain unknown. A review of maternal and neonatal coronavirus disease 2019 morbidity and mortality data along with perinatal vaccine safety considerations are presented to assist providers with shared decision-making regarding vaccine administration for this group, including the healthcare worker who is pregnant, lactating, or considering pregnancy. The coronavirus disease 2019 vaccine should be offered to pregnant women after discussing the lack of safety data, with preferential administration for those at highest risk of severe infection, until safety and efficacy of these novel vaccines are validated. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.022>

2021-02901

Balancing risks: making decisions for maternal treatment without data on fetal safety. Minkoff H, Ecker J (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 224, no 5, May 2021, pp 479-483

Challenges arise when treatment to improve maternal health brings the possibility of risk to fetal health. The coronavirus disease 2019 (COVID-19) vaccine is the most recent, but hardly the only, example. Because pregnant patients are often specifically excluded from trials of new therapies, this is often the dilemma that patients and providers face when considering new treatments. In this study, we used the COVID-19 vaccine as an exemplar to question the broader issue of how society, in general, and obstetricians, in particular, should balance obligations to pregnant women's right of access to new therapeutic agents with the physician's desire to protect the fetus from potential risks. We will argue that in almost all circumstances (with few exceptions, as will also be discussed), maternal benefit and respect for autonomy create the uncertainty that absent safety data bring. Consequently, if pregnant women choose to try new interventions and treatments, such as the COVID-19 vaccination, they should be offered those new regimens and their decision supported. In addition, we will argue that the right solution to avoid the dilemma of absent data is to include pregnant individuals in clinical trials studying new treatments, drugs, and other therapies. We will also discuss the basis for our opinion, which are mainstream obstetrical ethics, precedents in law (supreme court ruling that forbids companies to exclude women from jobs that might pose a risk to the fetus), and historic events (thalidomide). The ethical framework includes the supposition that sacrifice to improve fetal outcome is a virtue and not a mandate. Denying a pregnant patient treatment because of threats to their life can create absurd and paradoxical consequences. Either requiring abortion or premature delivery before proceeding with treatments to optimize maternal health, or risking a patient's own life and ability to parent a child by delaying treatment brings clear and significant risks to fetal and/or neonatal outcomes. With rare exceptions, properly and ethically balancing such consequential actions cannot be undertaken without considering the values and goals of the pregnant patient. Therefore, active participation of both the pregnant patient and their physician in shared decision making is needed. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.025>

2021-02900

Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients. Chervenak FA, McCullough LB, Bornstein E, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 224, no 5, May 2021, pp 470-478

The development of coronavirus disease 2019 vaccines in the current and planned clinical trials is essential for the success of a public health response. This paper focuses on how physicians should implement the results of these clinical trials when counseling patients who are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed about vaccines with government authorization for clinical use. Determining the most effective approach to counsel patients about coronavirus disease 2019 vaccination is challenging. We address the professionally responsible counseling of 3 groups of patients—those who are pregnant, those planning to become pregnant, and those breastfeeding or planning to breastfeed. We begin with an evidence-based account of the following 5 major challenges: the limited evidence base, the documented increased risk for severe disease among pregnant coronavirus

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disease 2019-infected patients, conflicting guidance from government agencies and professional associations, false information about coronavirus disease 2019 vaccines, and maternal mistrust and vaccine hesitancy. We subsequently provide evidence-based, ethically justified, practical guidance for meeting these challenges in the professionally responsible counseling of patients about coronavirus disease 2019 vaccination. To guide the professionally responsible counseling of patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed, we explain how obstetrician-gynecologists should evaluate the current clinical information, why a recommendation of coronavirus disease 2019 vaccination should be made, and how this assessment should be presented to patients during the informed consent process with the goal of empowering them to make informed decisions. We also present a proactive account of how to respond when patients refuse the recommended vaccination, including the elements of the legal obligation of informed refusal and the ethical obligation to ask patients to reconsider. During this process, the physician should be alert to vaccine hesitancy, ask patients to express their hesitation and reasons for it, and respectfully address them. In contrast to the conflicting guidance from government agencies and professional associations, evidence-based professional ethics in obstetrics and gynecology provides unequivocal and clear guidance: Physicians should recommend coronavirus disease 2019 vaccination to patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed. To prevent widening of the health inequities, build trust in the health benefits of vaccination, and encourage coronavirus disease 2019 vaccine and treatment uptake, in addition to recommending coronavirus disease 2019 vaccinations, physicians should engage with communities to tailor strategies to overcome mistrust and deliver evidence-based information, robust educational campaigns, and novel approaches to immunization. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.027>

2021-02893

Higher severe acute respiratory syndrome coronavirus 2 infection rate in pregnant patients. Lokken EM, Taylor G, Huebner EM, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 225, no 1, July 2021, pp 75.e1-75.e16
Background

During the early months of the coronavirus disease 2019 pandemic, risks associated with severe acute respiratory syndrome coronavirus 2 in pregnancy were uncertain. Pregnant patients can serve as a model for the success of clinical and public health responses during public health emergencies as they are typically in frequent contact with the medical system. Population-based estimates of severe acute respiratory syndrome coronavirus 2 infections in pregnancy are unknown because of incomplete ascertainment of pregnancy status or inclusion of only single centers or hospitalized cases. Whether pregnant women were protected by the public health response or through their interactions with obstetrical providers in the early months of pandemic is not clearly understood.

Objective

This study aimed to estimate the severe acute respiratory syndrome coronavirus 2 infection rate in pregnancy and to examine the disparities by race and ethnicity and English language proficiency in Washington State.

Study Design

Pregnant patients with a polymerase chain reaction–confirmed severe acute respiratory syndrome coronavirus 2 infection diagnosed between March 1, 2020, and June 30, 2020 were identified within 35 hospitals and clinics, capturing 61% of annual deliveries in Washington State. Infection rates in pregnancy were estimated overall and by Washington State Accountable Community of Health region and cross-sectionally compared with severe acute respiratory syndrome coronavirus 2 infection rates in similarly aged adults in Washington State. Race and ethnicity and language used for medical care of pregnant patients were compared with recent data from Washington State.

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Results

A total of 240 pregnant patients with severe acute respiratory syndrome coronavirus 2 infections were identified during the study period with 70.7% from minority racial and ethnic groups. The principal findings in our study were as follows: (1) the severe acute respiratory syndrome coronavirus 2 infection rate was 13.9 per 1000 deliveries in pregnant patients (95% confidence interval, 8.3–23.2) compared with 7.3 per 1000 (95% confidence interval, 7.2–7.4) in adults aged 20 to 39 years in Washington State (rate ratio, 1.7; 95% confidence interval, 1.3–2.3); (2) the severe acute respiratory syndrome coronavirus 2 infection rate reduced to 11.3 per 1000 deliveries (95% confidence interval, 6.3–20.3) when excluding 45 cases of severe acute respiratory syndrome coronavirus disease 2 detected through asymptomatic screening (rate ratio, 1.3; 95% confidence interval, 0.96–1.9); (3) the proportion of pregnant patients in non-White racial and ethnic groups with severe acute respiratory syndrome coronavirus disease 2 infection was 2- to 4-fold higher than the race and ethnicity distribution of women in Washington State who delivered live births in 2018; and (4) the proportion of pregnant patients with severe acute respiratory syndrome coronavirus 2 infection receiving medical care in a non-English language was higher than estimates of pregnant patients receiving care with limited English proficiency in Washington State (30.4% vs 7.6%).

Conclusion

The severe acute respiratory syndrome coronavirus 2 infection rate in pregnant people was 70% higher than similarly aged adults in Washington State, which could not be completely explained by universal screening at delivery. Pregnant patients from nearly all racial and ethnic minority groups and patients receiving medical care in a non-English language were overrepresented. Pregnant women were not protected from severe acute respiratory syndrome coronavirus 2 infection in the early months of the pandemic. Moreover, the greatest burden of infections occurred in nearly all racial and ethnic minority groups. These data coupled with a broader recognition that pregnancy is a risk factor for severe illness and maternal mortality strongly suggested that pregnant people should be broadly prioritized for coronavirus disease 2019 vaccine allocation in the United States similar to some states. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.02.011>

2021-02795

Vaccine Update. Public Health England (2021), London: PHE no 319, April 2021

This special edition of Vaccine Update includes information on COVID-19 vaccination guidelines and deliveries. It highlights the advice given to pregnant women about the risks and benefits of vaccination. (LDO)

Full URL: <https://www.gov.uk/government/publications/vaccine-update-issue-319-april-2021-covid-19-phase-2-special-edition/vaccine-update-issue-319-april-2021-covid-19-phase-2-special-edition>

2021-02705

Pregnancy: Employment [written answer]. House of Commons (2021), Hansard Written question 185871, 22 April 2021 Ms Nadine Dorries responds to a written question from the Secretary of State for Health and Social Care, with reference to the new advice on covid-19 vaccination for pregnant women from Public Health England issued on 16 April 2021, what steps he is taking to issue updated guidance for pregnant employees; and when that guidance will be available. (Author, edited)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-04-22/185871>

2021-02690

Coronavirus: Vaccination [written answer]. House of Commons (2021), Hansard Written question 137241, 13 January 2021

Nadhim Zahawi responds to a written question from Rachael Maskell to the Secretary of State for Health and Social Care, regarding what discussions he has had with Public Health England on requiring NHS and social care staff to have

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the covid-19 vaccine in order to keep patients and care residents safe. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-01-13/137241>

2021-02511

SOGC Statement on the COVID-19 vaccines and rare adverse outcomes of thrombosis associated with low platelets.

Society of Obstetricians and Gynaecologists of Canada (2021), Ottawa, Canada: SOGC 20 April 2021

Statement from the Society of Obstetricians and Gynaecologists of Canada (SOGC) on COVID-19 vaccination in pregnancy and rare adverse outcomes. SOGC supports the use of all available COVID-19 vaccines approved in Canada in any pregnancy trimester and during breastfeeding in accordance with regional eligibility. (LDO)

Full URL: https://sogc.org/common/Uploaded%20files/Latest%20News/EN_Statement-COVID-19_vaccines_rare_adverse_thrombosis.pdf

2021-02083

Pregnant women should be offered Covid vaccine. Anon (2021), BBC News 17 April 2021

Pregnant women should be offered a Covid jab when other people their age get one, the UK's vaccine advisers say. (Author)

Full URL: <https://www.bbc.co.uk/news/health-56778146>

2021-02064

Pregnant People's Paradox—Excluded From Vaccine Trials Despite Having a Higher Risk of COVID-19 Complications.

Rubin R (2021), JAMA (Journal of the American Medical Association) Vol 325, no 11, 16 March 2021, pp 1027-1028

This Medical News Quick Uptake discusses the evidence in favor of administering COVID-19 vaccines to pregnant individuals.

Full URL: <https://doi.org/10.1001/jama.2021.2264>

2021-02063

Involving Pregnant Individuals in Clinical Research on COVID-19 Vaccines. Bianchi DW, Kaeser L, Cernich AN (2021),

JAMA (Journal of the American Medical Association) Vol 325, no 11, 16 March 2021, pp 1041-1042

This Viewpoint from the National Institute of Child Health and Human Development emphasizes the need to use existing data sources and develop partnerships, infrastructure, and ethical and regulatory standards to generate data about the safety and efficacy of COVID-19 vaccination in pregnant individuals.

Full URL: <https://doi.org/10.1001/jama.2021.1865>

2021-02062

Pregnancy, Postpartum Care, and COVID-19 Vaccination in 2021. Rasmussen SA, Jamieson DJ (2021), JAMA (Journal of the American Medical Association) Vol 325, no 11, 16 March 2021, pp 1099-1100

This JAMA Insights review summarizes the epidemiology of SARS-CoV-2 infection in pregnant and lactating women, its effects on perinatal outcomes, and compiles guidance from the CDC, FDA, and obstetrics-gynecology specialty organizations on the safety of coronavirus vaccines during pregnancy and while breastfeeding.

Full URL: <https://doi.org/10.1001/jama.2021.1683>

2021-02061

COVID-19 Vaccination in Pregnant and Lactating Women. Adhikari EH, Spong CY (2021), JAMA (Journal of the American Medical Association) Vol 325, no 11, 16 March 2021, pp 1039-1040

This Viewpoint discusses the need for shared decision-making when counseling pregnant and nursing women about the unstudied benefits and risks COVID-19 vaccination, calling for rigorously designed studies with real-time,

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proactive data collection to establish evidence as quickly as possible about coronavirus vaccine safety in mothers and their infants.

Full URL: <https://doi.org/10.1001/jama.2021.1658>

2021-01597

'No evidence' Covid-19 vaccine will affect fertility, say unions. Ford M (2021), Nursing Times 21 January 2021
Leading unions have come together to put a stop to misinformation that appears to be circulating in relation to Covid-19 vaccines and fertility. (Author)

2021-01453

Coronavirus Disease 2019 (COVID-19) Vaccines and Pregnancy: What Obstetricians Need to Know. Rasmussen SA, Kelley CF, Horton JP, et al (2021), Obstetrics & Gynecology vol 137, no 3, March 2021, pp 408-414
Coronavirus disease 2019 (COVID-19) vaccines have begun to be distributed across the United States and to be offered initially to priority groups including health care personnel and persons living in long-term care facilities. Guidance regarding whether pregnant persons should receive a COVID-19 vaccine is needed. Because pregnant persons were excluded from the initial phase 3 clinical trials of COVID-19 vaccines, limited data are available on their efficacy and safety during pregnancy. After developmental and reproductive toxicology studies are completed, some companies are expected to conduct clinical trials in pregnant persons. Until then, pregnant persons and their obstetricians will need to use available data to weigh the benefits and risks of COVID-19 vaccines. Issues to be considered when counseling pregnant persons include data from animal studies and inadvertently exposed pregnancies during vaccine clinical trials when available, potential risks to pregnancy of vaccine reactogenicity, timing of vaccination during pregnancy, evidence for safety of other vaccines during pregnancy, risk of COVID-19 complications due to pregnancy and the pregnant person's underlying conditions, and risk of exposure to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and potential for risk mitigation. The Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and the Society for Maternal-Fetal Medicine have each issued guidance supportive of offering COVID-19 vaccine to pregnant persons. As additional information from clinical trials and from data collected on vaccinated pregnant persons becomes available, it will be critical for obstetricians to keep up to date with this information. (Author) [Erratum: Obstetrics & Gynecology, vol 137, no 5, May 2021, p 962]

2021-01267

Vaccine Update. Public Health England (2021), London: PHE no 316, January 2021
This special edition of Vaccine Update includes information on the safety of COVID-19 vaccination for pregnant and breastfeeding women. Also includes guidance on COVID-19 vaccination for health and social care workers. (LDO)
Full URL: <https://www.gov.uk/government/publications/vaccine-update-issue-316-january-2021-covid-19-special-edition/vaccine-update-issue-316-january-2021-covid-19-special-edition>

2021-01263

Vaccine Update. Public Health England (2020), London: PHE no 315, December 2020
This special edition of Vaccine Update includes resources and leaflets on COVID-19 vaccination for pregnant or breastfeeding women. (LDO)
Full URL: <https://www.gov.uk/government/publications/vaccine-update-issue-315-december-2020-covid-19-special-edition/vaccine-update-issue-315-december-2020-covid-19-special-edition>

20210125-14*

Vaccination: Coronavirus [written answer]. House of Commons (2021), Hansard Written question 137333, 13 January 2021

Ms Nadine Dorries responds to a written question from Marco Longhi to the Secretary of State for Health and Social

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Care, regarding whether his Department has made an assessment of the potential effect of covid-19 vaccines on fertility. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2021-01-13/137333>

20210108-2*

Coronavirus latest: Young women are the unlikely new face of vaccine resistance. Speed B (2020), iNews 6 January 2020

News item reporting that young women between the ages of 18 and 34 are the most likely population group to refuse the Pfizer/BioNTech COVID-19 vaccine, amid fears sparked by misinformation concerning damage to their fertility. States that no study has been undertaken to support this claim, and Dr Victoria Male, a lecturer in reproductive immunology at Imperial College London, has said that it is not usual for full fertility studies to be undertaken before vaccines and medications are rolled out because of the length of time this would take. States that this vaccine could be particularly important for women who are planning a pregnancy, because pregnancy and COVID-19 put pressure on the lungs and heart. (JSM)

Full URL: <https://inews.co.uk/news/health/coronavirus-latest-experts-debunk-vaccine-fertility-myths-women-819783>

20210106-21*

President's Corner: Introduction to ABM's Statement on Considerations for COVID-19 Vaccination in Lactation. Stuebe A (2021), Breastfeeding Medicine vol 16, no 1, January 2021, p 1

The recent emergency use authorization of novel mRNA vaccines to prevent COVID-19 is a triumph for science. Less than a year after the SARS-CoV-2 virus was first identified, we have a 95% effective vaccine in production. There is much to celebrate, and there is also a yawning gap: phase 3 trials of these novel mRNA-based vaccines excluded pregnant and lactating women. This void is the product of decisions made >40 years ago to exclude pregnant and lactating women from research, with the goal of avoiding any risk to the fetus or nursing child. In the short term, this strategy avoided liability; in the long term, it has left providers and patients without clinical data to make informed decisions. Without clinical data, the Academy of Breastfeeding Medicine relied on biological plausibility and expert opinion to craft a statement on considerations for mRNA COVID-19 vaccines during lactation. The available information is reassuring; however, pregnant and lactating people deserve better than plausibility to guide medical decisions. Henceforward, phase 3 clinical trials should routinely include pregnant and lactating participants. It is time to protect pregnant and breastfeeding individuals through research, not from research. (Author)

20210105-34*

Coronavirus disease 2019 vaccines in pregnancy. Craig AM, Hughes BL, Swamy GK (2021), American Journal of Obstetrics & Gynecology MFM vol 3, no 2, March 2021, 100295

As of December 1, 2020, nearly 64 million people have been infected with COVID-19 worldwide with nearly 1.5 million global deaths. The impact of this virus has continued to overwhelm hospital infrastructure and demanded remodeling of healthcare systems. With rising concerns for a third, and possibly the largest, wave of infected individuals, national leaders are continuing to seek avenues by which we can further limit disease transmission and prevent infection with the use of vaccination. To our knowledge, no clinical trial evaluating vaccines to prevent COVID-19 has included pregnant women. By December 2020, it's anticipated that the FDA will approve at least one or two mRNA-based COVID-19 vaccine under emergency use authorization (EUA) based on Phase 3 clinical trial efficacy data. Both Pfizer and Moderna have manufactured mRNA-based vaccines with 95% and 94.1% efficacy against COVID-19. [1, 2] AstraZeneca has manufactured a vaccine using a viral-vector demonstrating early efficacy as well and this next generation platform has previously been utilized with the Ebola vaccine and safely administered during pregnancy with an acceptable safety profile [3]. Approval of these vaccines will have a tremendous impact on the ongoing

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pandemic, yet there remains a lack of data for use of COVID-19 vaccine in pregnant women. In this article we seek to discuss the available data regarding treatment and prevention of COVID-19 in pregnancy and address the growing questions regarding how best to approach vaccine access and administration in the pregnant population. (Author)

Full URL: <https://doi.org/10.1016/j.ajogmf.2020.100295>

20210104-22*

Coronavirus: Vaccination [written answer]. House of Commons (2020), Hansard Written question 126063, 7 December 2020

Nadhim Zahawi responds to a written question from Alison Thewliss the Secretary of State for Health and Social Care, regarding what the Government's official advice is on covid-19 vaccination for people who are (a) pregnant and (b) lactating. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2020-12-07/126063>

20210104-21*

Coronavirus: Vaccination [written answer]. House of Commons (2020), Hansard Written question 124187, 2 December 2020

Nadhim Zahawi responds to a written question from Jim Shannon to the Secretary of State for Health and Social Care, whether it is his policy that (a) the elderly and (b) pregnant women will receive the covid-19 vaccine first. (JSM)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2020-12-02/124187>

2021-00859

Baby Care Units: Coronavirus [written answer]. House of Commons (2020), Hansard Written question 126073, 7 December 2020

Nadhim Zahawi responds to a written question asked by Vicky Foxcroft to the Secretary of State for Health and Social Care, regarding whether parents of babies in neonatal units will be given priority access to a COVID-19 vaccination. (LDO)

Full URL: <https://questions-statements.parliament.uk/written-questions/detail/2020-12-07/126073>

2021-00766

Equity in coronavirus disease 2019 vaccine development and deployment. Modi N, Ayres-de-Campos D, Bancalari E, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 224, no 5, May 2021, pp 423-427

The coronavirus disease 2019 pandemic exposed weaknesses in multiple domains and widened gender-based inequalities across the world. It also stimulated extraordinary scientific achievement by bringing vaccines to the public in less than a year. In this article, we discuss the implications of current vaccination guidance for pregnant and lactating women, if their exclusion from the first wave of vaccine trials was justified, and if a change in the current vaccine development pathway is necessary. Pregnant and lactating women were not included in the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. Therefore, perhaps unsurprisingly, the first vaccine regulatory approvals have been accompanied by inconsistent advice from public health, governmental, and professional authorities around the world. Denying vaccination to women who, although pregnant or breastfeeding, are fully capable of autonomous decision making is a throwback to a paternalistic era. Conversely, lack of evidence generated in a timely manner, upon which to make an informed decision, shifts responsibility from research sponsors and regulators and places the burden of decision making upon the woman and her healthcare advisor. The World Health Organization, the Task Force on Research Specific to Pregnant Women and Lactating Women, and others have highlighted the long-standing disadvantage experienced by women in relation to the development of vaccines and medicines. It is uncertain whether there was sufficient justification for excluding pregnant and lactating women from the initial severe acute respiratory syndrome coronavirus 2 vaccine trials. In future, we recommend that regulators mandate plans that describe the development pathway for new vaccines and medicines that address the needs of

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women who are pregnant or lactating. These should incorporate, at the outset, a careful consideration of the balance of the risks of exclusion from or inclusion in initial studies, patient and public perspectives, details of “developmental and reproductive toxicity” studies, and approaches to collect data systematically from participants who are unknowingly pregnant at the time of exposure. This requires careful consideration of any previous knowledge about the mode of action of the vaccine and the likelihood of toxicity or teratogenicity. We also support the view that the default position should be a “presumption of inclusion,” with exclusion of women who are pregnant or lactating only if justified on specific, not generic, grounds. Finally, we recommend closer coordination across countries with the aim of issuing consistent public health advice. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.006>

2021-00761

Inclusion of pregnant individuals among priority populations for coronavirus disease 2019 vaccination for all 50 states in the United States. Grünebaum A, McCullough LB, Litvak A, et al (2021), American Journal of Obstetrics & Gynecology (AJOG) vol 224, no 5, May 2021, pp 536-539

Research letter exploring whether pregnant women were uniformly included in priority COVID-19 vaccination phase one allocations across the United States of America. Results demonstrate substantial variations in how pregnancy is classified for COVID-19 vaccination. (LDO)

Full URL: <https://doi.org/10.1016/j.ajog.2021.01.026>

2021-00217

Pregnancy, breastfeeding and the SARS-CoV-2 vaccine: an ethics-based framework for shared decision-making.

Zipursky JS, Greenberg RA, Maxwell C, et al (2021), Canadian Medical Association Journal (CMAJ) vol 193, no 7, 16 February 2021, 202833

Proposes that women who are pregnant or breastfeeding should be offered the SARS-CoV-2 vaccine on ethical grounds, and discusses how health care providers and patients can use a shared decision-making approach to guide these discussions. (Author, edited)

Full URL: <https://doi.org/10.1503/cmaj.202833>

20201221-1*

SOGC Statement on COVID-19 Vaccination in Pregnancy [Reaffirmed 3 March 2021]. Society of Obstetricians and Gynaecologists of Canada (2020), Ottawa, Canada: SOGC 18 December 2020

Consensus statement from the Society of Obstetricians and Gynaecologists of Canada (SOGC) on COVID-19 vaccination in pregnancy. Recommends that the COVID-19 vaccine should be offered as the documented risk of not getting the vaccine outweighs the theorised risk of being vaccinated during pregnancy or while breastfeeding. (LDO)

Full URL: https://www.sogc.org/common/Uploaded%20files/Latest%20News/SOGC_Statement_COVID-19_Vaccination_in_Pregnancy.pdf

20201218-24*

Safety of COVID-19 vaccines when given in pregnancy [Last updated 30 April 2021]. Public Health England (2020), London: PHE 18 December 2020

This advice provides information on the safety of COVID-19 vaccines when given in pregnancy. It is designed for health professionals to share with women who were vaccinated before they knew they were pregnant. (Author)

Full URL: <https://www.gov.uk/government/publications/safety-of-covid-19-vaccines-when-given-in-pregnancy>

20201217-55*

COVID-19 vaccination and pregnancy. Royal College of Obstetricians and Gynaecologists (2020), London: RCOG 17 December 2020

Short news item reporting that the Royal College of Obstetricians and Gynaecologists is advising against the use of the

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new Pfizer-BioNTech COVID-19 vaccine in pregnancy and in breastfeeding women, until more information about it is available. (JSM)

Full URL: <https://www.rcog.org.uk/en/news/covid-19-vaccination-and-pregnancy/>

20201207-1*

COVID-19 vaccination: women of childbearing age, currently pregnant or breastfeeding [Last updated 19 May 2021].

Public Health England (2020), London: PHE 6 December 2020

Information for all women of childbearing age, those currently pregnant or breastfeeding on coronavirus (COVID-19) vaccination. (Author)

Full URL: <https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding>

20201127-1*

Maternal and child healthcare in India during COVID-19 pandemic. Paul P, Mondal D (2021), Midwifery vol 92, January 2021, 102865

Editorial discussing maternal and child healthcare in India during the COVID-19 pandemic. Highlights the high rates of maternal and infant mortality prior to the pandemic and outlines strategies to minimise further adverse outcomes.

(LDO)

Full URL: <https://doi.org/10.1016/j.midw.2020.102865>

20201028-22*

During the second wave of COVID-19, don't forget about influenza: a call to action. Atallah F, Minkoff H (2021), BJOG: An International Journal of Obstetrics and Gynaecology vol 128, no 1, January 2021, pp 12-13

Discusses the importance of improving influenza vaccine uptake in pregnancy, in particular as co-infection with COVID-19 may increase morbidity. (MB)

20200824-48*

Inclusion of pregnant women in COVID-19 vaccine development. Heath PT, Le Doare K, Khalil A (2020), The Lancet Infectious Diseases vol 20, no 9, September 2020, pp 1007-1008

Examines the issues involved in the inclusion of pregnant and lactating women in the development and deployment of COVID-19 vaccines. (MB)

Full URL: [https://doi.org/10.1016/S1473-3099\(20\)30638-1](https://doi.org/10.1016/S1473-3099(20)30638-1)

20200525-22*

Potential Maternal and Infant Outcomes From (Wuhan) Coronavirus 2019-nCoV Infecting Pregnant Women: Lessons From SARS, MERS, and Other Human Coronavirus Infections. Schwartz DA, Graham AL (2020), Viruses vol 12, no 2, February 2020, Article no: 194

In early December 2019 a cluster of cases of pneumonia of unknown cause was identified in Wuhan, a city of 11 million persons in the People's Republic of China. Further investigation revealed these cases to result from infection with a newly identified coronavirus, termed the 2019-nCoV. The infection moved rapidly through China, spread to Thailand and Japan, extended into adjacent countries through infected persons travelling by air, eventually reaching multiple countries and continents. Similar to such other coronaviruses as those causing the Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS), the new coronavirus was reported to spread via natural aerosols from human-to-human. In the early stages of this epidemic the case fatality rate is estimated to be approximately 2%, with the majority of deaths occurring in special populations. Unfortunately, there is limited experience with coronavirus infections during pregnancy, and it now appears certain that pregnant women have become infected during the present 2019-nCoV epidemic. In order to assess the potential of the Wuhan 2019-nCoV to cause maternal, fetal and neonatal morbidity and other poor obstetrical outcomes, this communication reviews the

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published data addressing the epidemiological and clinical effects of SARS, MERS, and other coronavirus infections on pregnant women and their infants. Recommendations are also made for the consideration of pregnant women in the design, clinical trials, and implementation of future 2019-nCoV vaccines. (Author)

Full URL: <https://doi.org/10.3390/v12020194>

20200515-7*

Consider pregnancy in COVID-19 therapeutic drug and vaccine trials. Whitehead CL, Walker SP (2020), The Lancet vol 395, no 10237, 23 May 2020, p E92

Correspondence urging researchers to afford pregnant women the same autonomy offered to other adults to decide about participation in clinical trials. (MB)

Full URL: [https://doi.org/10.1016/S0140-6736\(20\)31029-1](https://doi.org/10.1016/S0140-6736(20)31029-1)

20200501-1*

Vaccine Update. Public Health England (2020), London: PHE no 307, April 2020, pp 1-14

A special edition of Vaccine Update to mark World Immunization Week (WIW), which this year runs from 26th-30th April, and is the World Health Organization's annual celebration of immunisation, best practice, new advances and the work of immunisers, held with the aim of promoting the use of vaccines to protect people of all ages from disease, reflected in the name of this year's theme #VaccinesWork for All. In this, The International Year of the Nurse and Midwife, WHO and Public Health England acknowledge the crucial role played by nurses and midwives as advocates of vaccination throughout the life course. Includes sections on the delivery of immunisation services during the coronavirus pandemic, and vaccinations offered during the antenatal and postnatal periods. (JSM)

Full URL:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/882560/PHE_1165_2_VU_307_April_2020.pdf

20200429-36*

Protection by Exclusion: Another Missed Opportunity to Include Pregnant Women in Research During the Coronavirus Disease 2019 (COVID-19) Pandemic. Costantine MM, Landon MB, Saade GR (2020), Obstetrics & Gynecology vol 136, no 1, July 2020, pp 26-28

Coronavirus disease 2019 (COVID-19) is a novel infectious disease that started in Wuhan, China, and has rapidly spread all across the world. With limited ability to contain the virus and relatively high transmissibility and case fatality rates, governmental institutions and pharmaceutical companies are racing to find therapeutics and vaccines that target this novel coronavirus. However, once again, pregnant and breastfeeding women are excluded from participating in clinical trials during this pandemic. This 'protection by exclusion' of pregnant women from drug development and clinical therapeutic trials, even during epidemics and pandemics, is not unprecedented. Moreover, it is both misguided and not justifiable and may have excluded them from potentially beneficial interventions. This is another missed opportunity to obtain pregnancy-specific safety and efficacy data, because therapeutics developed for men and nonpregnant women may not be generalizable to pregnant women. Therefore, we recommend and urge the scientific community and professional societies that, without clear justification for exclusion, pregnant women should be given the opportunity to be included in clinical trials for COVID-19 based on the concepts of justice, equity, autonomy, and informed consent. (Author)

Full URL: <https://doi.org/10.1097/AOG.0000000000003924>

20200407-14*

Coronavirus Disease 2019 (COVID-19) Pandemic and Pregnancy. Dashraath P, Wong JJJ, Lim MXK, et al (2020), American Journal of Obstetrics & Gynecology (AJOG) vol 222, no 6, June 2020, pp 521-531

The current coronavirus disease 2019 (COVID-19) pneumonia pandemic, caused by the severe acute respiratory syndrome 2 (SARS-CoV-2) virus, is spreading globally at an accelerated rate, with a basic reproduction number (R0) of

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2 - 2.5, indicating that 2 - 3 persons will be infected from an index patient. A serious public health emergency, it is particularly deadly in vulnerable populations and communities in which healthcare providers are insufficiently prepared to manage the infection. As of March 16, 2020, there are more than 180,000 confirmed cases of COVID-19 worldwide, with over 7,000 related deaths. The SARS-CoV-2 virus has been isolated from asymptomatic individuals, and affected patients continue to be infectious two weeks after cessation of symptoms. The substantial morbidity and socioeconomic impact have necessitated drastic measures across all continents, including nationwide lockdowns and border closures.

Pregnant women and their fetuses represent a high-risk population during infectious disease outbreaks. To date, the outcomes of 55 pregnant women infected with COVID-19 and 46 neonates have been reported in the literature, with no definite evidence of vertical transmission. Physiological and mechanical changes in pregnancy increase susceptibility to infections in general, particularly when the cardiorespiratory system is affected, and encourage rapid progression to respiratory failure in the gravida. Furthermore, the pregnancy bias towards T-helper 2 (Th2) system dominance which protects the fetus, leaves the mother vulnerable to viral infections, which are more effectively contained by the Th1 system. These unique challenges mandate an integrated approach to pregnancies affected by SARS-CoV-2.

Here we present a review of COVID-19 in pregnancy, bringing together the various factors integral to the understanding of pathophysiology and susceptibility, diagnostic challenges with real-time reverse transcriptase polymerase chain reaction (RT-PCR) assays, therapeutic controversies, intrauterine transmission and maternal-fetal complications. We discuss the latest options in antiviral therapy and vaccine development, including the novel use of chloroquine in the management of COVID-19. Fetal surveillance, in view of the predisposition to growth restriction and special considerations during labor and delivery are addressed. Additionally, we focus on keeping frontline obstetric care providers safe while continuing to provide essential services. Our clinical service model is built around the principles of workplace segregation, responsible social distancing, containment of cross-infection to healthcare providers, judicious use of personal protective equipment and telemedicine. Our aim is to share a framework which can be adopted by tertiary maternity units managing pregnant women in the flux of a pandemic while maintaining the safety of the patient and healthcare provider at its core. (Author)

Full URL: <https://doi.org/10.1016/j.ajog.2020.03.021>

20200122-1*

Inadvertent vaccination in pregnancy (VIP) [Last updated 18 June 2021]. Public Health England (2010), London: PHE 1 May 2010

Advice for health professionals on pregnant women who are inadvertently vaccinated against coronavirus (COVID-19), chicken pox (varicella), shingles or measles, mumps, rubella. (Author)

Full URL: <https://www.gov.uk/guidance/vaccination-in-pregnancy-vip>

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