Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Professionally responsible coronavirus disease 2019 vaccination counseling of obstetrical and gynecologic patients

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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 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.

Key words: autonomy, becoming pregnant, beneficence, breastfeeding, clinical trials, counseling, COVID-19, informed consent, informed refusal, mRNA vaccines, pregnancy, professional ethics, SARS-CoV-2, shared decision-making, vaccination

Introduction

The coronavirus disease 2019 (COVID-19) pandemic has created a global health crisis, which requires effective prevention and treatment strategies on an unprecedented scale. The development of COVID-19 vaccines in the current and planned clinical trials is essential for the success of this public health response, which should be supported strongly by all physicians. This paper focuses on how physicians should

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implement the results of clinical trials when counseling patients who are pregnant, planning to become pregnant, breastfeeding, or planning to breastfeed about vaccines.

In December 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the following 2 vaccines for the prevention of COVID-19: the Pfizer-BioNtech vaccine for persons aged ≥16 years and the Moderna vaccine for persons aged ≥18 years.[1]

The EUA states that children and adolescents outside of these authorized age groups should not receive a COVID-19 vaccination at this time.

The US Centers for Disease Control and Prevention (CDC) mentions severe and immediate allergic reactions to a previous dose of a messenger RNA (mRNA) COVID-19 vaccine, its components, or to polysorbate as contraindications.[1] These individuals should not receive an mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it has been established that the individual can safely receive the vaccine.[1]

Pregnancy, attempting to become pregnant, and breastfeeding have not been deemed as contraindications for the mRNA vaccines, and the CDC stated that ". . . if pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated."[1]

American College of Obstetricians and Gynecologists (ACOG) recommends that COVID-19 vaccines should not be withheld from pregnant patients who meet the criteria for vaccination based on the recommended priority groups determined by the Advisory Committee on Immunization Practices (ACIP).[2] COVID-19 vaccines should be offered to lactating patients similar to nonlactating patients when they meet the criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.[3]

ACOG also stated that those ". . . considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients."[2]

Determining the most effective approach for this conversation is challenging. In this clinical opinion, we identified 5 major challenges and provide evidence-based, ethically justified, practical guidance for overcoming these challenges when counseling patients about COVID-19 vaccinations. Our aim was to be both clinically applicable and sensitive to the patients' concerns. We therefore addressed the counseling of 3 groups of patients——those who are pregnant, those planning to become pregnant, and those breastfeeding or planning to breastfeed.

Challenges With Counseling Patients

There currently is insufficient evidence from clinical trials about the safety and efficacy of the COVID-19 vaccines in pregnancy because pregnant women have been excluded from these vaccine trials. The theoretical risk of the COVID-19 vaccine must be assessed in the context of the documented increased risk for a severe COVID-19 disease course in pregnant women and their fetuses.[4] Immunization with inactivated virus vaccines or toxoids during pregnancy is not expected to be associated with an increased risk to the pregnant patient or the fetus.[5,6] In an overview of 17 systematic reviews reporting on maternal-fetal and neonatal outcomes after immunizations during pregnancy, no major safety concerns and risks were identified for any of the vaccines or outcomes of interest.[7] Statements from governments and professional associations regarding vaccination during pregnancy are inconsistent; false information and rumors abound. Some patients hesitate to become vaccinated, whereas others refuse vaccination.

Limited evidence base

Counseling pregnant patients about the efficacy and safety of COVID-19 vaccinations confronts the challenge that the clinical trials for the vaccines currently available excluded pregnant patients. Pregnant women are commonly excluded from vaccine and drug trials. A contributing reason for this exclusion is likely legal in nature instead of ethical in that vaccine and drug manufacturers might expose themselves to liabilities of injury to fetuses and future children that was allegedly caused by the administration of a vaccine or drug as a subject in a clinical trial. Vaccine and drug manufacturers have a corporate interest in preventing such a liability. This obstacle could be removed by legislation addressing clinical trial participation, which is long overdue. Such a policy change, however, is unlikely to occur soon enough for the inclusion of pregnant patients in ongoing or new COVID-19 vaccine trials.

The exclusion of pregnant patients from clinical vaccine trials causes there to be a lack of data from a clinical trial arm that would provide trial-based evidence for assessing both the efficacy and safety of COVID-19 vaccinations in pregnant patients and their offspring. To date, there are no efficacy or safety data specifically for the use of COVID-19 mRNA vaccines during pregnant or in lactating patients. Therefore, based on the absence of actual trial data, the risks to pregnant and fetal patients are unknown. There is, however, a large database of direct evidence on the potential safety of nonliving virus vaccines from the past experiences of subjects in the treatment arms of trials. There is also indirect evidence. The mRNA vaccines are nonliving virus vaccines. These do not use an adjuvant to enhance the vaccine efficacy. In addition, mRNA vaccines do not enter the nucleus and do not alter human DNA in the vaccine recipients. Therefore, ". . . the mRNA strand never enters the cell's nucleus or affects genetic material. . . ."[8] It is also unlikely that the mRNA will cross the placenta. In studies on mice vaccinated against the Zika virus, mRNA was shown to protect against placental damage.[9] This evidence suggests that the probable hypothesis about the use of the current nonliving COVID-19 virus vaccines in pregnant patients is that these are safe and efficacious. The CDC states that ". . . based on current knowledge,

experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus. . . .”[1] Clinical trials that include pregnant patients are needed to test this hypothesis. The FDA now encourages developers of COVID-19 vaccines to consider programs that might support the inclusion of pregnant subjects and subjects of childbearing potential to not avoid pregnancy early during the development.[10] For example, contrary to the current EUA approved vaccines, which excluded pregnant patients from their trials, the ongoing AZD1222 COVID-19 vaccine study does not specifically exclude pregnant subjects.

Documented increased risk of severe disease among pregnant coronavirus disease 2019 infected patients

Pregnant patients, especially those with comorbidities, are considered to be a higher-risk group for COVID-19 infection.[11,12] These patients are not more likely to become infected and the majority of pregnant patients have mild or asymptomatic infections. However, there are reports of a more severe disease course and other pregnancy complications if pregnant patients become infected.[13–19] There is therefore an increased potential for maternal deaths,[20–23] especially in low- to middle-income countries.[24] There are also disparate accounts of an increase in premature births,[23,25–27] premature cesarean deliveries,[28] and myocardial injuries[29,30] in addition to an increased risk for preeclampsia, cesarean delivery, and perinatal death in pregnant women with COVID-19 infections.[31] When compared with COVID-19 infected, nonpregnant peers, symptomatic pregnant patients may be at an increased risk for a more severe COVID-19 disease course.[32] Kim et al[33] reported an increased case fatality rate among critically ill pregnant patients, although there is variable information on the rate of intensive care unit (ICU) admissions for pregnant COVID-19 patients.[25,34,35] Vertical transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from the mother to the fetus has also been reported.[36,37] In addition, COVID-19 infections have been associated with increased placental inflammation and histopathologic abnormalities, fetal vascular malperfusion, and villitis, suggesting that the virus could impact perinatal outcomes through placental injury with possible adverse effects in the neonates.[38,39]

Black and Hispanic patients seem to be disproportionately more affected by SARS-CoV-2 infections, not only during pregnancy, and have an increased risk for admission to the ICU and receipt of mechanical ventilation, but not an increased risk for death.[32,40–42] Finally, Saccone et al[43] reported that among pregnant women, more than half of the respondents rated the psychological impact of the COVID-19 outbreak as severe and about two-thirds reported higher than normal anxiety.

Conflicting guidance from government agencies and professional associations

International government agencies and professional associations in Asia, Europe, the Middle East, and North America, and the World Health Organization (WHO) take different positions on the vaccination of pregnant patients (Table 1). The positions differ both on scientific and ethical grounds.

Some take an approach based on the ethical principle of respect for autonomy (Table 2). The CDC in the United States appeals implicitly to this ethical principle in the sense that information should be provided and the patients' questions should be addressed, but no recommendations are made.[1] The ACOG takes a similar position.[2]

Canada[47] and Ireland[51] state that the physician should explain that the risk to benefit ratio favors vaccination and that it should be offered. These positions assume that a vaccination is not contraindicated for pregnancy and that the clinical benefits outweigh the risks. The precautionary principle is not violated (Table 2). Therefore, according to these 2 recommendations, patients should decide for themselves without a recommendation being made.

Others take beneficence-based approaches and come to different conclusions (Table 2). Austria[48] states that vaccination is contraindicated for pregnancy and breastfeeding patients and that vaccination of the partners of pregnant patients should be a priority. France,[49] The Netherlands,[53] and Japan[55] take the position that vaccination should not be recommended for use during pregnancy. These positions assume that the risk to benefit ratio of the vaccination of pregnant patients is unfavorable and that it violates the precautionary principle.

In contrast, Germany[50] and The United Kingdom[52] take the position that vaccination should be offered only after a risk assessment. This position assumes that the risk to benefit ratio is favorable and therefore that the precautionary principle is not violated. The current evidence base supports the recommendation of vaccines. Israel states that “. . . priority will now be given to breastfeeding women, pregnant women and women who are planning to get pregnant.”[54]

The WHO[56] takes the position that there are insufficient data to provide guidance. Guidance should be delayed until the evidence base permits a more definitive assessment of the risk to benefit ratio. This position invokes the precautionary principle to manage uncertainty.

False information about coronavirus disease 2019 vaccinations

It is a disturbing reality that there is an abundance of false information available on the internet and provided by prominent public figures about vaccine use in general and in women specifically. For example, although there have been unfounded allegations of risks of infertility from COVID-19 vaccinations mainly on antivaccination blogs and websites and posted to social media,[57] the American Society for Reproductive Medicine (ASRM) published clinical recommendations debunking the myths of a potential impact of COVID-19 vaccination on fertility.[46] The ASRM encourages COVID-19 vaccination for those undergoing fertility treatment and pregnant and lactating patients according to the eligibility criteria.[46]

TABLE 1
Guidance from governments and professional associations

North American
United States: The United States Centers for Disease Control (CDC) states: "People who are pregnant and part of a group recommended to receive the COVID-19 vaccine may choose to be vaccinated. If they have questions about getting vaccinated, a discussion with a healthcare provider might help them make an informed decision."[1,44]
The American College of Obstetricians and Gynecologists states that: "COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups." And they also state that "COVID-19 vaccines should be offered to lactating individuals similar to nonlactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP."[2]
The Society for Maternal-Fetal Medicine (SMFM) states that: ". . . SMFM recommends that healthcare workers, who are considered prioritized for vaccination, be offered the vaccine if pregnant. . . ." And they also state that ". . . pregnant and lactating women who are otherwise eligible should be offered the vaccine."[45]
The American Society for Reproductive Medicine states that: "Patients undergoing fertility treatment and pregnant patients should be encouraged to receive vaccination based on eligibility criteria. Since the vaccine is not a live virus, there is no reason to delay pregnancy attempts because of vaccination administration or to defer treatment until the second dose has been administered. . . ." And they state, "A shared decision-making model between patients and providers should be used when considering vaccination and should take into consideration the ethical principles of autonomy, beneficence, and nonmaleficence."[46]
Canada: The Canadian Society of Obstetricians and Gynecologists of Canada (SOGC) states: "For individuals who are at high risk of infection and/or morbidity from COVID-19, it is the SOGC's position that the documented risk of not getting the COVID-19 vaccine outweighs the theorized and undescribed risk of being vaccinated during pregnancy or while breastfeeding and vaccination should be offered."[47]
Europe
Austria: The health ministry has said that COVID vaccination is contraindicated in pregnant and breastfeeding women but priority for immunization should be given to partners of pregnant women because of the severe disease history in pregnancy.[48]
France: The health ministry states: "Administration of the vaccine during pregnancy is not recommended (unless a high risk of severe form was identified during the prevaccination consultation), the safety data still being insufficient to inform about the risks of vaccination during pregnancy. . . ."[49]
Germany: the Robert Koch institute states: ". . . because there is insufficient experience, immunization in pregnancy and while breastfeeding is currently only recommended after individual risk-benefit assessment."[50]
Ireland: The Royal College of Physicians of Ireland states: "Pregnant healthcare workers are numerous in our workforce and their specific needs should be considered equally alongside their nonpregnant colleagues. Assessment of risk by the individual needs acknowledgment, and the pregnant woman should be able to choose vaccination if she falls into a priority group. Counseling by healthcare provider should balance available data on vaccine safety, risks to pregnant women from COVID-19 infection, and a woman's individual risk for infection and severe disease. While there is no data on breastfeeding, there is no known biologic mechanism to cause harm."[51]
United Kingdom: The Joint Committee on Vaccination and Immunization (JCVI), which previously said that pregnant women should not be immunized, now says (as of December 30, 2020) that: "Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy," and they state that ". . . the JCVI now advises that if a pregnant woman meets the definition of being clinically extremely vulnerable, then she should discuss the options of COVID-19 vaccination with her obstetrician and/or doctor. This is because their underlying condition may put them at very high risk of experiencing serious complications of COVID-19."[52]
The Netherlands: The National Institute for Public Health and the Environment of the Ministry of Health, Welfare, and Sport states: "Are you pregnant? If so, it is recommended to postpone the vaccination until after your pregnancy."[53]
Middle East
Israel: "Priority will now be given to breastfeeding women, pregnant women and women who are planning to get pregnant."[54]
Asia
Japan: "Pregnant women will not be given vaccination priority due to insufficient knowledge about vaccine safety and effectiveness for them."[55]
International
The World Health Organization states that, "…those pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider."[56]

ACIP, Advisory Committee on Immunization Practices; *COVID-19*, coronavirus disease 2019.

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TABLE 2
Ethical principles

Beneficence: Creates the ethical obligation to provide clinical management that in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment is predicted to result in a net clinical benefit for the patient.[50]
Respect for autonomy: Creates the ethical obligation to empower patients to make informed and voluntary decisions about the clinical management of their condition by providing them with information about the clinical management supported in beneficence-based clinical judgment.[49]
Precautionary: A "longstanding principle of public health: when in doubt about danger, we should err on the side of caution" by preventing danger.[57]

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Maternal mistrust and vaccine hesitancy

The influence of personal beliefs, mistrust among disenfranchised populations, and experiences with antenatal vaccination uptake is exacerbated during pandemic periods. Although the acceptance of vaccination should be a global norm, influences by historic, economic, or political factors can lead to vaccine hesitancy, for example the history of mistreatment of women of color in the United States. Vaccine hesitancy refers to the delay in acceptance or refusal of vaccinations despite the availability of vaccination services.[58]

The Informed Consent Process

Professional ethics in obstetrics and gynecology[59,60,61] provide practical tools to meet the challenges of counseling the following 3 groups of patients whom the obstetrician-gynecologist will encounter in clinical practice: those who are pregnant, plan to become pregnant, and those who are breastfeeding or planning to do so. The informed consent process implements the ethical principle of respect for autonomy, which calls for the obstetrician-gynecologist to empower patients with the information that they need to make informed decisions. The role of the physician in the informed consent process is to identify the clinically relevant information and assess it in an evidence-based clinical judgment, present this information and assessment to the patient, and explain the physician's evaluation. These steps empower patients to make informed decisions.

The informed consent process empowers the patient to make informed decisions when that process is based on her values and beliefs.[59] To support patients, they can be asked what is important to them, a question that has been shown to extract the patients' values.[62] Patients should also be asked to express any concerns they might have. The physician should listen attentively and respond to mistaken or incomplete information with a respectful explanation of what is known and the crucial distinction between documented and theoretical risks. Making a recommendation, as explained below, may help to allay the patients' concerns.

The informed consent process should be tailored specifically to each of the 3 groups of patients. For each, we identified the relevant clinical information and how it should be evaluated by the physician and, on this basis, how patients should be empowered to make informed decisions.

Counseling pregnant patients

The physician's evaluation

When counseling patients, physicians should use the available data to weigh the benefits of COVID-19 vaccines against the risks.[63] In evidence-based clinical judgment, the documented benefits and risks of COVID-19 vaccinations for use in pregnant patients count more than the theoretical risks and harms. The benefit of vaccination is prevention of COVID-19 infections and, consequently, the prevention of severe disease and mortality, and prevention of the transmission of COVID-19 to others. The risk of nonvaccination is not only severe COVID-19 and increased mortality, but also transmission of the virus to others. The complications of vaccinations for COVID-19 have been documented to be rare and clinically manageable. The fetal patient is not exposed to the documented risk, based on indirect evidence, nor is the breastfed newborn.[4,5,7] The mRNA strands are unlikely to cross the placenta and in mice models, mRNA Zika virus vaccines have been shown to protect the placenta.[8] The theoretical risks should not shape the informed consent process and the physician's evaluation that, when balanced, COVID-19 vaccinations confer significant clinical benefit. There is a consensus that receiving a recommendation for a vaccination from a healthcare provider is the most important factor in maternal decision-making, irrespective of the geographic or social context.[64–68] It follows that the physician should recommend a COVID-19 vaccination as soon as pregnant patients become eligible.

Empowering patients to make informed decisions

The patient should be informed that when COVID-19 occurs in pregnant patients, it can be severe and life-threatening at levels greater than those for nonpregnant patients. Vaccination has been demonstrated to reduce the risk of infection and, with it, the risk of serious disease and death. There is a very low incidence of complications following vaccination but these are transient and treatable. There is no evidence for an increased risk associated with the use of any nonliving virus vaccinations in the fetal and neonatal patient.[7] Patients should be informed of available data[63] and be encouraged not to base their decision-making solely on theoretical risk. The risk of complications, therefore, should be considered alongside the very significant advantage of preventing infection, preventing asymptomatic infections and potentially transmitting it to others, and preventing serious disease, long-term consequences, and death. For this reason, the physician should explain why vaccination is recommended.

Counseling patients who are breastfeeding or planning to breastfeed

The physician's evaluation

There is no evidence that vaccines contaminate breast milk. The biopsychosocial benefits for the neonatal patient are well established. SARS-CoV-2 antibodies have been detected in the breastmilk of infected patients and can potentially provide additional immunity to the newborn. The benefit of vaccination is unequivocal. Vaccination should be recommended.

Empowering patients to make informed decisions

The patient should be told that there is no evidence of harm to her baby from breastfeeding after receiving the vaccination and that there could be possible benefits for the newborn. Vaccination should be recommended.

Counseling patients planning to become pregnant

The physician's evaluation

The patients' information needs may differ. Some patients planning to become pregnant may be hesitant to accept vaccination. The reasons for vaccine hesitancy vary from person to person and community to community. Others may express concern or reject vaccinations based on false beliefs.

The physician's response should be professional, not personal. These patients should be treated with respect, paying special attention to patients influenced by false information that is now circulating on internet sites, which the patient may have visited or have been told about by others. Physicians should keep in mind that memory is created by repetition, irrespective of whether that which is repeated is true. This has the important implication that the physician should eschew prejudicial views about patients who express false beliefs. Instead, the physician should respond to a patient in need, in this case, in need of accurate information.

Other patients do not espouse false beliefs but are prudent about being risk averse with their planned pregnancies. Prudence is a virtue that calls for a patient to identify her legitimate self-interests, short-term and long-term, and to act to protect them. Prudential judgments should be evidence-based. Current evidence supports the view that legitimate self-interest in health and life are supported by timely vaccinations. The physician should point this out and ask patients to reconsider their judgments. Research about previous pandemics has supported the healthcare professional recommendation for maternal vaccination as an important factor that influences behavior.[69]

In ethical theory, patients who want others to be vaccinated but not themselves and who, therefore, want the benefits of herd immunity without vaccination are known as "free riders." This is a general problem with vaccinations, including childhood vaccinations.[70] The decision to be a free rider does not command respect because free riders want others to take risks without having to take those risks themselves. The physician should point this out and ask patients if they think that this is fair to those who accept vaccinations. Allowing the patients to consider this question empowers them to make an informed and responsible decision.

There is no evidence that the vaccination affects present or future fertility and the ASRM recommends that eligible patients who are planning to become pregnant should be vaccinated.[46] Patients planning to become pregnant typically do not want to impede their fertility and want the best outcomes for their pregnancies, both for themselves and their babies. Having false beliefs is incompatible with valuing these goals.

Empowering patients to make informed decisions

The goal should be empowering patients to recognize that they have mistakenly adopted false beliefs that, if acted on, would jeopardize their goals for their planned pregnancy. For patients invoking prudence, the physician should educate them as described above. The goal should be a patient who recognizes that her prudential judgment is not evidence-based. For free riders, the physician should ask them to reconsider as described above. The goal should be a patient who understands that the responsible decision is to become vaccinated.

When Patients Refuse Vaccination

Despite education, some patients, for whom there are no contraindications for vaccinations, will refuse the recommended vaccination. It is essential that their refusal should not be taken personally by the physician and that conversation with them should be respectful.

This is especially important in responding to decisions against vaccinations by patients of color. Their vaccine hesitancy or resistance may reflect both a personal and community history of mistreatment.

Patient refusal of COVID-19 vaccinations may be based on the fact that, as the CDC has stated, ". . . there are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people. . . ."[1] and based on the following statement by the ACOG: "there are no safety data specific to use in pregnancy."[2] This information is being used in some countries to deny pregnant women the opportunity to accept vaccination (Table 1). No pregnant patient wants to do anything "unsafe." When these statements are repeated during a counseling session, they may sound potentially scary, but using the term "safety" is too nonspecific as to what it means in the context of COVID-19 vaccination in pregnancy.

The physician should put the absence of safety data in pregnancy in its proper perspective. We know that giving COVID-19 vaccines to pregnant women will be effective in preventing COVID-19 disease and that without the vaccine, pregnant women are more likely to get sick, be admitted to the ICU, and possibly die if they become infected; that adverse pregnancy outcomes, such as premature births, are not more likely to occur because of the vaccine; and that the fetus is not more likely to have an adverse outcome because of the vaccine.

ACOG states that ". . . pregnant patients who refuse the vaccine should be supported in their decision."[2] This can be read to suggest that the physician should simply accept a patient's refusal,

which is not an adequate response. The physician has a strict legal obligation to satisfy the requirements of what is known as informed refusal.[59] Patients should be informed about the risks to themselves and others when they are not vaccinated. They are increasing their risk of becoming infected and becoming sick and infecting others, including their newborn child. This disclosure should be documented in the patient's record. Meeting these requirements also protects the physician's legitimate interest in reducing their liability. The ethics go further and create an autonomy-based ethical obligation to ask the patient to reconsider her vaccine refusal, including during any subsequent visits. During this process, the physician should be alert about vaccine hesitancy, ask patients to express their hesitation and reasons for it, and respectfully address them. For patients who affirm their vaccine refusal, the physician should accept and respect their refusal and offer an alternative of enrollment in current clinical trials of COVID-19 vaccines.

Conclusion

Evidence-based professional ethics in obstetrics and gynecology provides unequivocal and clear guidance.[59,60] There is evidence that a healthcare provider's recommendation for vaccination is the most important factor in maternal decision-making, irrespective of geographic or social context.[64–69] Physicians should use available data to weigh the benefits against the risks of COVID-19 vaccines[63] and they should, consequently, recommend COVID-19 vaccinations to all patients planning to become pregnant, all pregnant patients, and all patients who are breastfeeding or planning to breastfeed. Instead of using disease threat alone when recommending a vaccine, public health campaigns, which center on the protectiveness and safety of a maternal vaccine, may prove beneficial.[70] Minorities and especially African American patients continue to experience low vaccination uptake rates, stemming, at least in part, from years of bias in and mistrust of orthodox medicine, safety concerns, and environmental barriers to vaccine access.[71] To prevent the widening health inequities, build trust in the health benefits of vaccination, and encourage COVID-19 vaccine and treatment uptake, in addition to recommending COVID-19 vaccinations, physicians should engage with communities to tailor strategies to overcome mistrust and deliver evidence-based information, robust educational campaigns, and novel approaches to influenza immunization.[71,72]

Some statements from governments and professional associations concerning COVID-19 vaccinations implicitly adopt the approach of shared decision-making, a phrase often used without precision. Shared decision-making means that the physician should present information but make no recommendation.[73] This assumes that shared decision-making, in the sense of not making a recommendation, should guide counseling patients about receiving COVID-19 vaccinations, because of uncertain evidence about the net clinical benefit or risks of COVID-19 vaccinations. Shared decision-making in this sense and without making a recommendation should not guide counseling of patients about COVID-19 vaccination who are pregnant, breastfeeding or planning to breastfeed, and planning to become pregnant, because recommending COVID-19 vaccinations, we have shown, is justified on evidence-based and ethics-based grounds. ■

REFERENCES

1. Centers for Disease Control and Prevention. Interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States. 2021. Available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html. Accessed Jan. 7, 2021.

2. The American College of Obstetricians and Gynecologists. Vaccinating pregnant and lactating patients against COVID-19. 2020. Available at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19. Accessed Jan. 7, 2021.

3. Centers for Disease Control and Prevention. COVID-19 ACIP vaccine recommendations. 2020. Available at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html. Accessed Jan. 7, 2021.

4. Craig AM, Hughes BL, Swamy GK. Coronavirus disease 2019 vaccines in pregnancy. Am J Obstet Gynecol MFM 2021.

5. Global Advisory Committee on Vaccine Safety. Safety of Immunization during Pregnancy. A review of the evidence. 2014. Available at: http://www.who.int/vaccine_safety/publications/safety_pregnancy_nov2014.pdf. Accessed Jan. 27, 2021.

6. Pan American Health Organization. The Maternal and Neonatal Immunization Field Guide for Latin America and the Caribbean recommends the administration of Influenza (inactivated) and Tetanus/diphtheria vaccines. Washington, D.C. 2017. Available at: http://iris.paho.org/xmlui/bitstream/handle/123456789/34150/9789275119501-eng.pdf. Accessed Jan. 27, 2021.

7. Macias Saint-Gerons D, Solà Arnau I, De Mucio B, et al. Adverse events associated with the use of recommended vaccines during pregnancy: an overview of systematic reviews. Vaccine 2020 [Epub ahead of print].

8. Centers for Disease Control and Prevention. Understanding and Explaining mRNA COVID-19 Vaccines. Available at: https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html. Accessed Jan. 27, 2021.

9. Richner JM, Himansu S, Dowd KA, et al. Modified mRNA vaccines protect against Zika virus infection. Cell 2017;169:176.

10. Erbelding E. SARS-CoV-2 vaccines in pregnant women. Available at: https://www.nichd.nih.gov/sites/default/files/inline-files/NICHD Council_Erbelding_090720V2.pdf. Accessed Jan. 7, 2021.

11. Dashraath P, Wong JLJ, Lim MXK, et al. Coronavirus disease 2019 (COVID-19) pandemic and pregnancy. Am J Obstet Gynecol 2020;222:521–31.

12. Dhuyvetter A, Cejtin HE, Adam M, Patel A. Coronavirus disease 2019 in pregnancy: the experience at an urban safety net hospital. J Community Health 2020 [Epub ahead of print].

13. Rasmussen SA, Smulian JC, Lednicky JA, Wen TS, Jamieson DJ. Coronavirus Disease 2019 (COVID-19) and pregnancy: what obstetricians need to know. Am J Obstet Gynecol 2020;222:415–26.

14. Brandt JS, Hill J, Reddy A, et al. Epidemiology of coronavirus disease 2019 in pregnancy: risk factors and associations with adverse maternal and neonatal outcomes. Am J Obstet Gynecol 2020 [Epub ahead of print].

15. DeBolt CA, Bianco A, Limaye MA, et al. Pregnant women with severe or critical coronavirus disease 2019 have increased composite morbidity compared with nonpregnant matched controls. Am J Obstet Gynecol 2020 [Epub ahead of print].

16. Narang K, Szymanski LM, Kane SV, Rose CH. Acute pancreatitis in a pregnant patient with coronavirus disease 2019 (COVID-19). Obstet Gynecol 2020 [Epub ahead of print].

17. Gulersen M, Staszewski C, Grayver E, et al. Coronavirus disease 2019 (COVID-19)-related multisystem inflammatory syndrome in a pregnant womam. Obstet Gynecol 2020;2020.
18. Afshar Y, Gaw SL, Flaherman VJ, et al. Clinical presentation of coronavirus disease 2019 (COVID-19) in pregnant and recently pregnant people. Obstet Gynecol 2020;136:1117–25.
19. Figueiro-Filho EA, Yudin M, Farine D. COVID-19 during pregnancy: an overview of maternal characteristics, clinical symptoms, maternal and neonatal outcomes of 10,996 cases described in 15 countries. J Perinat Med 2020;48:900–11.
20. Hantoushzadeh S, Shamshirsaz AA, Aleyasin A, et al. Maternal death due to COVID-19. Am J Obstet Gynecol 2020;223:109.e1–16.
21. Martinez-Portilla RJ, Smith ER, He S, et al. Young pregnant women are also at an increased risk of mortality and severe illness due to coronavirus disease 2019: analysis of the Mexican National Surveillance Program. Am J Obstet Gynecol 2020 [Epub ahead of print].
22. Blitz MJ, Rochelson B, Minkoff H, et al. Maternal mortality among women with coronavirus disease 2019 admitted to the intensive care unit. Am J Obstet Gynecol 2020;223:595—e5.
23. Delahoy MJ, Whitaker M, O'Halloran A, et al. Characteristics and maternal and birth outcomes of hospitalized pregnant women with laboratory-confirmed COVID-19—COVID-NET, 13 states, March 1-August 22, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1347–54.
24. Amorim MMR, Soligo Takemoto ML, Fonseca EBD. Maternal deaths with coronavirus disease 2019: a different outcome from low- to middle-resource countries? Am J Obstet Gynecol 2020;223:298–9.
25. Papapanou M, Papaioannou M, Petta A, et al. Maternal and neonatal characteristics and outcomes of COVID-19 in pregnancy: an overview of systematic reviews. Int J Environ Res Public Health 2021;18:596.
26. Sentilhes L, De Marcillac F, Jouffrieau C, et al. Coronavirus disease 2019 in pregnancy was associated with maternal morbidity and preterm birth. Am J Obstet Gynecol 2020;223:914.e1–15.
27. Main EK, Chang SC, Carpenter AM, et al. Singleton preterm birth rates for racial and ethnic groups during the coronavirus disease 2019 pandemic in California. Am J Obstet Gynecol 2021;224:239–41.
28. Della Gatta AN, Rizzo R, Pilu G, Simonazzi G. Coronavirus disease 2019 during pregnancy: a systematic review of reported cases. Am J Obstet Gynecol 2020;223:36–41.
29. Pachtman Shetty SL, Meirowitz N, Blitz MJ, Gadomski T, Weinberg CR. Myocardial injury associated with coronavirus disease 2019 in pregnancy. Am J Obstet Gynecol 2021;224:229–32.
30. Mercedes BR, Serwat A, Naffaa L, et al. New-onset myocardial injury in pregnant patients with coronavirus disease 2019: a case series of 15 patients. Am J Obstet Gynecol 2020 [Epub ahead of print].
31. Di Mascio D, Khalil A, Saccone G, et al. Outcome of coronavirus spectrum infections (SARS, MERS, COVID-19) during pregnancy: a systematic review and meta-analysis. Am J Obstet Gynecol MFM 2020;2:100107.
32. Ellington S, Strid P, Tong VT, et al. Characteristics of women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-June 7, 2020. MMWR Morb Mortal Wkly Rep 2020;69:769–75.
33. Kim CNH, Hutcheon J, van Schalkwyk J, Marquette G. Maternal outcome of pregnant women admitted to intensive care units for coronavirus disease 2019. Am J Obstet Gynecol 2020;223:773–4.
34. Blitz MJ, Grünebaum A, Tekbali A, et al. Intensive care unit admissions for pregnant and nonpregnant women with coronavirus disease 2019. Am J Obstet Gynecol 2020;223:290–1.
35. Zambrano LD, Ellington S, Strid P, et al. Update: characteristics of symptomatic women of reproductive age with laboratory-confirmed SARS-CoV-2 infection by pregnancy status - United States, January 22-October 3, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1641–7.
36. Khalil A, Kalafat E, Benlioglu C, et al. SARS-CoV-2 infection in pregnancy: a systematic review and meta-analysis of clinical features and pregnancy outcomes. EClinicalMedicine 2020;25:100446.
37. Kotlyar AM, Grechukhina O, Chen A, et al. Vertical transmission of coronavirus disease 2019: a systematic review and meta-analysis. Am J Obstet Gynecol 2021;224:35–53.e3.
38. Patberg ET, Adams T, Rekawek P, et al. Coronavirus disease 2019 infection and placental histopathology in women delivering at term. Am J Obstet Gynecol 2020 [Epub ahead of print].
39. Sherer ML, Lei J, Creisher P, et al. Dysregulated immunity in SARS-CoV-2 infected pregnant women. medRxiv. Preprint posted online November 16, 2020. https://doi.org/10.1101/2020.11.13.20231373.
40. Joseph NT, Stanhope KK, Badell ML, Horton JP, Boulet SL, Jamieson DJ. Sociodemographic predictors of SARS-CoV-2 infection in obstetric patients, Georgia, USA. Emerg Infect Dis 2020;26:2787–9.
41. Emeruwa UN, Spiegelman J, Ona S, et al. Influence of Race and Ethnicity on Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection Rates and Clinical Outcomes in Pregnancy. Obstet Gynecol 2020;136:1040–3.
42. Andrasfay T, Goldman N. Reductions in 2020 US life expectancy due to COVID-19 and the disproportionate impact on the Black and Latino populations. medRxiv Preprint posted online September 15, 2020. https://doi.org/10.1101/2020.07.12.20148387.
43. Saccone G, Florio A, Aiello F, et al. Psychological impact of coronavirus disease 2019 in pregnant women. Am J Obstet Gynecol 2020;223:293–5.
44. Centers for Disease Control and Prevention. Vaccination considerations for people who are pregnant or breastfeeding. 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html. Accessed Jan. 7, 2021.
45. Society for Maternal-Fetal Medicine. Society for Maternal-Fetal Medicine (SMFM) Statement: SARS-CoV-2 Vaccination in Pregnancy. 2020. Available at: https://s3.amazonaws.com/cdn.smfm.org/media/2591/SMFM_Vaccine_Statement_12-1-20_(final).pdf. Accessed Jan. 7, 2021.
46. American Society for Reproductive Medicine. Patient management and clinical recommendations during the coronavirus (COVID-19) pandemic. 2020. Available at: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/covid-19/covidtaskforceupdate11.pdf. Accessed Jan. 27, 2021.
47. The Society of Obstetricians and Gynaecologists of Canada. SOGC COVID-19 resources. Available at: https://sogc.org/en/-COVID-19/en/content/COVID-19/COVID-19.aspx. Accessed Jan. 7, 2021.
48. Bundesministerium für Soziales, Gesundheit, Pflege und Konsumentenschutz. Empfehlung des Nationalen Impfgremiums zur Priorisierung von COVID-19-Impfungen: Version 1.0, Stand: 14.12.2020. Available at: https://www.aekktn.at/documents/e031f3c0-4066-11eb-a558-5254009ad2fe/Empfehlung%20des%20Nationalen%20Impfgremiums%20zur%20Priorisierung%20von%20COVID-19-Impfungen docx.pdf. Accessed Jan. 27, 2021.
49. Haute Autorite De Sante. Vaccination contre la Covid-19: la HAS définit la stratégie d'utilisation du vaccin Comirnaty. 2020. Available at: https://www.has-sante.fr/jcms/p_3227179/fr/vaccination-contre-la-covid-19-la-has-definit-la-strategie-d-utilisation-du-vaccin-comirnaty. Accessed Jan. 7, 2021.
50. Robert Koch Institute. AUFKLÄRUNGSMERKBLATT: Zur Schutzimpfung gegen COVID-19 (coronavirus disease 2019)—mit mRNA-Impfstoffen. Available at: https://www.rki.de/DE/Content/Infekt/Impfen/Materialien/Downloads-COVID-19/Aufklaerungsbogen-de.pdf?__blob=publicationFile. Accessed Jan. 7, 2021.
51. Royal College of Physicians of Ireland. Statement from the Institute of Obstetricians and Gynaecologists regarding pregnancy and breastfeeding, and vaccination against COVID-19. Available at: https://www.rcpi.ie/news/releases/statement-pregnancy-covid-19/. Accessed Jan. 27, 2021.
52. Royal College of Obstetricians and Gynaecologists. Updated advice on COVID-19 vaccination in pregnancy and women who are breastfeeding. 2020. Available at: https://www.rcog.org.uk/en/news/updated-advice-on-covid-19-vaccination-in-pregnancy-and-women-who-are-breastfeeding/. Accessed Jan. 7, 2021.
53. National Institute for Public Health and Environment. COVID-19 vaccination. 2021. Available at: https://www.rivm.nl/en/novel-

coronavirus-covid-19/vaccine-against-covid-19. Accessed Jan. 11, 2021.
54. Health ministry updates priority list for COVID-19 vaccines. 2020. Available at: https://www.jpost.com/breaking-news/health-ministry-updates-priority-list-for-covid-19-vaccines-652738. Accessed Jan. 11, 2021.
55. The Japan Times Ltd. Japan's COVID-19 vaccine plan prioritizes health care workers and older residents. 2020. Available at: https://www.japantimes.co.jp/news/2020/12/25/national/japan-vaccine-older-people/. Accessed Jan. 11, 2021.
56. World Health Organization. The Moderna COVID-19 (mRNA-1273) vaccine: what you need to know. Available at: https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know. Accessed Jan. 27, 2021.
57. WebMD LLC. Why COVID Vaccines are Falsely Linked to Infertility. Available at: https://www.webmd.com/vaccines/covid-19-vaccine/news/20210112/why-covid-vaccines-are-falsely-linked-to-infertility. Accessed Feb. 12, 2021.
58. World Health Organization. SAGE Working Group on vaccine hesitancy (March 2012 to November 2014). Available at: http://www.who.int/immunization/sage/sage_wg_vaccine_hesitancy_apr12/en/. Accessed Jan. 11, 2021.
59. McCullough LB, Coverdale JH, Chervenak FA. Professional ethics in obstetrics and gynecology. New York, NY: Cambridge University Press; 2020.
60. Chervenak FA, McCullough LB, Brent RL. The professional responsibility model of obstetrical ethics: avoiding the perils of clashing rights. Am J Obstet Gynecol 2011;205:315.e1–5.
61. Chervenak FA, McCullough LB. Academic physicians as factory workers: identifying and preventing alienation of labor. Am J Obstet Gynecol 2019;220:558–61.
62. McCullough LB, Wilson NL, Teasdale TA, Kolpakchi AL, Skelly JR. Mapping personal, familial, and professional values in long-term care decisions. Gerontologist 1993;33:324–32.
63. Rasmussen SA, Kelley CF, Horton JP, Jamieson DJ. Coronavirus Disease 2019 (COVID-19) vaccines and pregnancy: what obstetricians need to know. Obstet Gynecol 2020 [Epub ahead of print].
64. Wilson RJ, Paterson P, Jarrett C, Larson HJ. Understanding factors influencing vaccination acceptance during pregnancy globally: a literature review. Vaccine 2015;33:6420–9.
65. Myers KL. Predictors of maternal vaccination in the United States: an integrative review of the literature. Vaccine 2016;34:3942–9.
66. Lutz CS, Carr W, Cohn A, Rodriguez L. Understanding barriers and predictors of maternal immunization: identifying gaps through an exploratory literature review. Vaccine 2018;36:7445–55.
67. Poliquin V, Greyson D, Castillo E. A systematic review of barriers to vaccination during pregnancy in the Canadian context. J Obstet Gynaecol Can 2019;41:1344–55.
68. Yuen CYS, Tarrant M. Determinants of uptake of influenza vaccination among pregnant women - a systematic review. Vaccine 2014;32:4602–13.
69. Kilich E, Dada S, Francis MR, et al. Factors that influence vaccination decision-making among pregnant women: a systematic review and meta-analysis. PLoS One 2020;15:e0234827.
70. Chervenak FA, McCullough LB, Brent RL. Professional responsibility and early childhood vaccination. J Pediatr 2016;169:305–9.
71. Ferdinand KC, Nedunchezhian S, Reddy TK. The COVID-19 and influenza "Twindemic": barriers to influenza vaccination and potential acceptance of SARS-CoV2 vaccination in African Americans. J Natl Med Assoc 2020;112:681–7.
72. Bogart LM, Ojikutu BO, Tyagi K, et al. COVID-19 related medical mistrust, health impacts, and potential vaccine hesitancy Among Black Americans living With HIV. J Acquir Immune Defic Syndr 2021;86:200–7.
73. Chervenak FA, McCullough LB. The unlimited-rights model of obstetric ethics threatens professionalism. BJOG 2017;124:1144–7.