Professionally Responsible COVID-19 Vaccination Counseling of Obstetric/Gynecologic Patients

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Physicians should recommend COVID-19 vaccination to patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed.

Short Title

Counseling Patients about COVID-19 Vaccination

Abstract

The development of COVID-19 vaccines in current and planned clinical trials is essential for the success of this public health response. This paper focuses on how physicians should implement the results of these clinical trials: 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 counseling patients about COVID-19 vaccination is challenging. We address the professionally responsible counseling of three 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 five major challenges: the limited evidence base; documented increased risk of severe disease among pregnant COVID-19-infected patients; conflicting guidance from government agencies and professional associations; false information about COVID-19 vaccines; and maternal mistrust and vaccine hesitancy. We then provide evidence-based, ethically justified, practical guidance for meeting these challenges in professionally responsible counseling of patients about COVID-19 vaccination. To guide 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 current clinical information and why a recommendation of COVID-19 vaccination should be made and how this assessment should be presented to patients in the informed consent process with the goal of empowering them to make informed decisions. We also present a pro-active account of how to respond when patients refuse recommended vaccination, the elements of which are 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: The physician should recommend COVID-19 vaccination to patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed. To prevent widening health inequities, to build trust in the health benefits of vaccination and to 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 immunization.

Key Words

Beneficence, Breastfeeding, Clinical Trials, Counseling, COVID-19, Vaccination, Informed Consent, Informed Refusal, mRNA vaccines, Becoming Pregnant, Pregnancy, Professional Ethics, Autonomy, SARS-CoV-2, Shared Decision Making

INTRODUCTION

The COVID-19 pandemic has created a global health crisis that requires effective prevention and treatment on an unprecedented scale. The development of COVID-19 vaccines in current and planned clinical trials is essential for the success of this public health response, which all physicians should strongly support. This paper focuses on how physicians should implement the results of clinical trials: counseling patients who are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed about vaccines.

In December 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for two vaccines for the prevention of COVID-19: the Pfizer-BioNtech vaccine in persons aged ≥16 years and the Moderna vaccine in persons aged ≥ 18 years.[1] The Emergency Use Authorization states that children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

The U.S. Centers for Disease Control and Prevention (CDC) mentions as contraindications severe and immediate allergic reactions to a prior dose of mRNA COVID-19 vaccine, it's components or to polysorbate.[1] These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine.[1]

Pregnant women, those attempting to get pregnant, and breastfeeding women have not been deemed as contraindications to mRNA vaccines, and the CDC states 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]

The American College of Obstetricians and Gynecologists (ACOG) recommends that COVID-19 vaccines should not be withheld from pregnant patients who meet criteria for

vaccination based on Advisory Committee on Immunization Practices (ACIP) for recommended priority groups.[2] COVID-19 vaccines should be offered to lactating patients similar to non-lactating patients when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.[3]

The American College of Obstetricians and Gynecologists also states 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 Emergency Use Authorization for the prevention of COVID-19 by pregnant patients."[2]

Determining the most effective approach to this conversation is challenging. In this clinical opinion, we identify five major challenges and provide evidence-based, ethically justified, practical guidance for meeting these challenges in counseling patients about COVID-19 vaccination. Our aim is to be both clinically applicable and sensitive to patients' concerns. We therefore address the counseling of three groups of patients – those who are pregnant, those planning to become pregnant, and those breastfeeding or planning to breastfeed.

CHALLENGES TO COUNSELING PATIENTS

There is currently little evidence from clinical trials about the safety and efficacy of the COVID-19 vaccine in pregnancy because pregnant women have been excluded from these vaccine trials. The theoretical risk of the COVID-19 vaccine must be assessed in context of the documented increased risk of severe COVID-19 disease to both maternal and fetal health.[4] Immunization with inactivated 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 maternal-fetal and neonatal outcomes after immunizations during pregnancy, no major safety concerns have been identified and risks were not identified for any vaccine or outcome of interest.[7] Statements from governments and professional associations are inconsistent. False information and rumors abound. Some patients hesitate to become vaccinated; others refuse vaccination.

Limited Evidence Base

Counseling pregnant patients about the efficacy and safety of COVID-19 vaccination confronts the challenge that the clinical trials for currently available vaccines excluded pregnant patients. This is a common exclusion in vaccine and drug trials. A contributing reason for this exclusion is likely legal rather than ethical: vaccine and drug manufacturers might expose themselves to liability to injury to fetuses and future children that is alleged to have resulted from receiving a vaccine or drug as a subject in a clinical trial. Vaccine and drug manufacturers have a corporate interest in preventing such 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 continuing or new COVID-19 vaccine trials.

The exclusion of pregnant patients from clinical vaccine trials results in lack of data from a clinical trial arm that would provide trials-based evidence for assessing both the efficacy and safety of COVID-19 vaccination for pregnant patients and their offspring. To date, there are no efficacy or safety data specific to the COVID mRNA vaccine use in pregnant or 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 direct evidence base about potential safety from the experience of subjects in the treatment arms of trials and also from past experience with non-live vaccines. There is also indirect evidence. The mRNA vaccines are not live-virus vaccines.

They do not use an adjuvant to enhance vaccine efficacy. In addition, mRNA vaccines do not enter the nucleus and do not alter human DNA in vaccine recipients. As a result, "..the mRNA strand never enters the cell's nucleus or affects genetic material..".[8] and mRNA is unlikely to cross the placenta. In studies on mice vaccinated against ZIKA, mRNA was shown to protect against placental damage.[9] This evidence suggests that the probable hypothesis is that current COVID-19 non-live vaccines in pregnant patients 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 including pregnant patients will be needed to test this hypothesis. The FDA now encourages developers of COVID-19 vaccines to consider, early in their development, programs that might support inclusion of pregnant subjects and subjects of childbearing potential not avoiding pregnancy.[10] For example, contrary to the presently Emergency Use Authorization 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 COVID-19 infected Patients

Pregnant patients are considered a higher-risk group for COVID-19 infection, especially those with comorbidities.[11,12] These patients are not more likely to become infected and the majority of pregnant patients have mild or asymptomatic infection. However, if infected, there are reports of more severe disease and other pregnancy complications.[13,14,15,16,17,18,19] There is therefore an increased potential for maternal deaths,[20,21,22,23] especially in low- to middle-income countries.[24] There are disparate accounts of an increase in preterm births,[23,25,26,27] and an increase in preterm cesarean deliveries,[28] myocardial injuries,[29,30] as well as increased risks in

preeclampsia, cesarean delivery, and perinatal death.[31] Compared to COVID-19 infected nonpregnant peers, symptomatic pregnant patients may be at increased risk of more severe COVID-19 disease.[32] Kim et al. reported an increased case fatality rate of critically ill pregnant patients,[33] although there is variable information on ICU admissions for COVID-19 pregnant patients,[25,34,35] Vertical transmission of severe acute respiratory syndrome coronavirus 2 from the mother to the fetus has also been reported.[36,37] In addition, coronavirus disease has been found to be associated with 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 pregnant patients appear to be disproportionately affected by SARS-CoV-2 infection not only during pregnancy with increased risk for intensive care unit admissions and receipt of mechanical ventilation, but not death.[32, 40,41] 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 American, as well as the World Health Organization take differing positions. (Table 1) Positions differ on both 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: information should be provided and patients' questions addressed but no recommendations made.[1] The American College of Obstetricians and Gynecologists takes a similar position.[2]

Canada[47] and Ireland[51] state that the physician should explain that the risk-benefit ratio favors vaccination and that it should be offered. These positions assume that vaccination is not contraindicated for pregnant patients, i.e., the clinical benefits outweigh the risks. The precautionary principle is not violated. (Table 2). Therefore, according to these two 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 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 in pregnancy. These positions assume that the risk/benefit ratio of vaccination of pregnant patients is unfavorable and violates the precautionary principle.

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

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

False Information about COVID-19 Vaccinations

It is a disturbing reality that there is an abundance of false information available on the internet and from prominent public figures about vaccine use in general and in women

specifically. For example, while there have been unfounded allegations risks of infertility from COVID-19 vaccinations mainly on anti-vaccination 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, based on eligibility criteria.[46]

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. While acceptance of vaccination should be a global norm, influences due to historic, economic or political factors can lead to vaccine hesitancy, e.g., the history of mistreatment of women of color in the United States. Vaccine hesitancy refers to the delay in acceptance or refusal of vaccination despite availability of vaccination services.[58]

THE INFORMED CONSENT PROCESS

Professional ethics in obstetrics and gynecology[59,60.61] provides practical tools to meet the challenges of counseling the three groups of patients whom the obstetrician-gynecologist will encounter in clinical practice: those who are pregnant, those who 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 clinically relevant information and assess it in evidence-based clinical judgment, present this information and assessment to the

patient, and explain the physician's evaluation. These 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 elicit 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 patients' concerns.

The informed consent process should be tailored to each of the three groups of patients. For each, we identify 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.

Counselling Pregnant Patients

The Physician's Evaluation. When counselling patients, physicians should use available data to weigh the benefits and risks of COVID-19 vaccines.[63] In evidence-based clinical judgment, documented benefits and risks of COVID-19 vaccination for pregnant patients count more than theoretical risks and harms. The benefit of vaccination is prevention of COVID-19 infection and consequently severe disease and mortality, as well as preventing transmission of COVID-19 to others. The risk of non-vaccination is not only severe COVID-19 and increased mortality, but also transmitting the virus to others. The complications of vaccination with COVID-19 have been documented to be rare and clinically manageable. The fetal patient is not exposed to documented risk, based on indirect evidence, nor is the breastfed newborn.[4,5,7] mRNA is unlikely to cross the placenta and in mice models mRNA Zika vaccine has been shown to

protect the placenta.[8] Theoretical risks should not shape the informed consent process and the physician's evaluation that, on balance, COVID-19 vaccination confers significant clinical benefit. There is a consensus that receiving a recommendation from a health care provider for vaccination is the most important factor in maternal decision-making, irrespective of geographic or social context.[64,65,66,67,68] It follows that the physician should recommend COVID-19 vaccination as soon as pregnant patients become eligible.

Empowering Patients to Make Informed Decisions. The patient should be informed that COVID-19 occurs in pregnant patients, can be severe, and can be life-threatening at levels greater than those for non-pregnant patients. Vaccination has been demonstrated to reduce the risk of infection and with it of serious disease and death. There is a very low incidence of complications from vaccination but these are transient and treatable. There is no evidence of risk of any vaccination with a non-live virus to 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 worth taking to gain 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 the vaccine contaminates breast milk. The biopsychosocial benefits for the neonatal patient are well-established. CoV-2 antibodies have been detected in breastmilk in 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 breast feeding after vaccination and there could be possible benefits to the newborn. Vaccination should be recommended.

Counseling Patients Planning to Become Pregnant

The Physician's Evaluation. Patients' information needs may differ. Some patients planning to become pregnant may hesitate to accept vaccination. The reasons for vaccine hesitancy vary from person to person and community to community. Others may express concern or rejection based on false beliefs.

The physician's response should be professional, not personal. These patients should be treated with respect, especially attentive to patients influenced by false information that is now circulating on internet sites that the patient may visited or been told about by others. Physicians should keep in mind that memory is created by repetition, independent of whether what 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 in being risk averse about their planned pregnancies. Prudence is a virtue that calls for a patient to identify her legitimate self-interests, short-term and long-term, and 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 vaccination. The physician should point this out and ask patients to reconsider their judgments. Research regarding prior pandemics has supported that healthcare professional recommendation for maternal vaccination is an important factor influencing 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 vaccination, including childhood vaccination.[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 do accept vaccination. Offering the patients to consider this question empowers them to make an informed and responsible decision.

There is no evidence that 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 to 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 vaccination will refuse recommended vaccination. It is essential that their refusal not be taken personally by the physician and that conversation with them be respectful.

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

Patient refusal of COVID-19 vaccination 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 by 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 non-specific as to what it means in the context of COVID-19 vaccination in pregnancy.

The physician should put 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; that without the vaccine pregnant women are more likely to get sick, be admitted to intensive care, and possibly die if they become infected; that adverse pregnancy outcomes, such as preterm 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.

The American College of Obstetricians and Gynecologists 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 that they are taking for themselves and others by not being 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 liability. Ethics goes further and creates 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 the 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 health care 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 and risks of COVID-19 vaccines[63] and consequently they should recommend COVID-19 vaccination to all patients planning to become pregnant, all pregnant patients, and all patients who are breastfeeding or planning to breastfeed. Rather than 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, 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 widening health inequities, to build trust in the health benefits of vaccination and to 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 COVID-19 vaccination, because of uncertain evidence about net clinical benefit or risks of COVID-19 vaccination. 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 vaccination, we have shown, is justified on evidence-based and ethics-based grounds.

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Table 1: Guidance from Governments and Professional Associations

North American

United States: The 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 “ COVID-19 vaccines should be offered to lactating individuals similar to non-lactating 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 “…pregnant and lactating women who are otherwise eligible should be offered the vaccine.”[45]

The American Society for Reproductive Medicine (ASRM) 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 “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 non-maleficence.”[46]

Canada: The Canadian Society of Obstetricians and Gynaecologists 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 pre-vaccination 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 non-pregnant 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. Counselling 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 biological mechanism to cause harm.[51]

United Kingdom: The Joint Committee on Vaccination and Immunisation (JCVI), which previously said that pregnant women should not be immunized, now says (as of 12/30/2020) 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 "..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 (WHO) states that "Guidance on pregnant women in groups prioritized for vaccination before these urgently needed safety data are available will need to await information about the specific characteristics of the vaccines authorized for use, as well as the latest evidence on risks of COVID-19 for pregnant women and their children.[56]

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 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 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]