

Ethical Lessons Learned from the COVID-19 Pandemic in Perinatal Medicine

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ABSTRACT

The COVID-19 pandemic is unprecedented in our lifetime, especially in perinatology. The gold standard is to strongly recommend COVID-19 vaccinations to those trying to get pregnant, to those who are pregnant, and to those who are postpartum. When the benefits of vaccines far outweigh the risks, it is unethical to disseminate wrong information and discourage patients from becoming vaccinated. COVID-19 vaccinations and boosters prevent severe diseases and adverse pregnancy and neonatal outcomes. A pregnant patient's vaccination also protects the newborn infant because maternal antibodies protect the fetus and newborn. COVID-19 vaccinations and boosters in pregnancy are safe for the pregnant patient and her fetus. The three root causes of physician hesitancy—misapplication of therapeutic nihilism, misapplication of shared decision-making, and misapplication of respect for autonomy should not be ignored and need to be addressed. It is important that we heed Brent's insightful recommendations. Doing nothing with respect to vaccination is not an option, whether it applies to COVID-19 vaccines or to future pandemics. Physician hesitation is not an option. When there is sufficient evidence of vaccine safety and effectiveness without documented risks, vaccine recommendations before, during, and after pregnancy should be explicitly made to prevent maternal, fetal, and neonatal morbidity and mortality.

Keywords: Coronavirus disease 2019 vaccine, Maternal morbidity, Maternal mortality, Neonatal morbidity, Neonatal mortality, Patient rights, Preterm birth, Therapeutic nihilism, Vaccine counseling, Vaccine recommendations.

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INTRODUCTION

As of December 2022, there have been about 100 million coronavirus disease 2019 (COVID-19) cases in the United States (US), with about 1.1 million deaths.¹ There have also been well over 2,30,000 pregnant patients infected with COVID-19 in the US, with over 500 maternal deaths from COVID-19.²

Professional ethics in obstetrics is based on the ethical principles of beneficence, respect for autonomy, and justice and the professional virtues of integrity, humility, compassion, self-effacement, and self-sacrifice.^{3–5} The ethical principle of beneficence and the professional

The virtue of integrity are directly applicable tools for addressing the question posed in this paper.

The COVID-19 pandemic is unprecedented in our lifetime, especially in perinatology. In this publication, we will discuss

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important clinical ethical lessons we learned during the pandemic, including COVID-19 vaccination and physician hesitancy, ringfencing, and frameshifting.

HOW DOES COVID-19 AFFECT PREGNANCY?

Pregnancy in and by itself does not increase the likelihood of becoming infected with COVID-19. However, it should be no surprise when considering that the immune system is affected in pregnancy, that COVID-19-infected pregnant patients are sicker than nonpregnant patients, and that pregnant patients are at an increased risk for severe illness from COVID-19 when compared to those who are not pregnant. Those with COVID-19 infections during pregnancy are at increased risk for preterm birth (delivering the baby earlier than 37 weeks) and stillbirths and might be at increased risk for other pregnancy complications such as increased hospitalization, admission to an intensive care unit (ICU), or use of a ventilator or special equipment to breathe.⁶⁻⁹ When compared to those who are vaccinated, unvaccinated pregnant patients are at increased risk for ICU admissions, maternal morbidity, deaths, and pregnancy complications.¹⁰⁻¹²

COVID-19 VACCINES FOR PREGNANT PATIENTS

Infection prevention by social distancing and masking is the first step to preventing COVID-19 infection and its deadly sequelae. COVID-19 vaccines, which were introduced in the US in December 2020, have saved over 3 million lives in the US at the end of 2022.¹³ COVID-19 vaccination also prevents infections and decreases the risk of morbidity and deaths in pregnant patients.¹⁴

Getting fully vaccinated against COVID-19, and even more so after receiving a booster dose, saves lives. It's safe and effective.¹⁵ A recent review of six studies confirmed that COVID-19 vaccination prevented pregnant patients from Severe acute respiratory syndrome coronavirus 2 (SARSCoV2) infection and COVID-19-related hospitalization. The study showed that no adverse events of COVID-19 vaccination were found on pregnant, fetal, or neonatal outcomes.¹⁴ The benefits of receiving a COVID-19 vaccine in pregnancy far outweigh any known or potential risks of vaccination before,

during, and after pregnancy. There is no evidence that COVID-19 vaccines cause any fertility problems in patients or men or that the COVID-19 vaccine is harmful to either the nursing mother or the breastfed infant.¹⁶ In fact, patients receiving a COVID-19 vaccine show antibodies and T-cells which appear in the milk after maternal vaccination and likely protect the infant against COVID-19 infection.¹⁷

Within 2 months after COVID-19 vaccines were first introduced, there were no "red flags," according to Fauci.¹⁸ Although pregnant patients were not included in the initial COVID-19 vaccine trial in 2020, there were no increased serious adverse events for patients who were or became pregnant in the clinical trials of COVID-19 vaccines pregnant patients that would have warranted suspension of these trials. There was no documented theoretical risk of maternal, fetal, or neonatal harm, and there were no documented increased adverse outcomes in vaccinated pregnant patients. Consequently, Chervenak et al. outlined the ethical issues surrounding vaccination in pregnancy and they concluded that COVID-19 vaccination should be strongly recommended by providers to prevent severe maternal morbidity and death.¹⁹ Our clinically grounded, ethical justification for recommending COVID-19 vaccination to pregnant patients concluded that "physicians should recommend COVID-19 vaccination to patients who are pregnant, planning to become pregnant, and breastfeeding or planning to breastfeed."¹⁹ It took another 6 or more months for others to support that recommendation using a similar language we used 6 months previously.

We believe that early adoption of this position in 2021 would have subsequently prevented the ensuing months of physician hesitancy and, with it, many unnecessary maternal deaths and injuries in unvaccinated pregnant patients.

WHY ARE PREGNANT PATIENTS LESS VACCINATED THAN NONPREGNANT PERSONS?

On social media, misinformation and unfounded claims linking COVID-19 vaccines to infertility are widespread,

Table 1: Risk of COVID-19 infection vs benefits and risks of COVID-19 vaccination

<i>Risk of COVID-19 infection</i>	<i>Benefits of COVID-19 vaccination</i>	<i>Risk of COVID-19 vaccination</i>
Higher infection rate than nonpregnant	Prevents infection	Anaphylactic reaction
Higher maternal deaths	Prevents infection in others	Injection site pain and swelling
More ICU admissions	Prevents severe disease	Headache and Tiredness
More ventilation	Prevents preterm birth	Muscle aches and "fever"
More preterm births	Prevents fetal infection	Pregnant patients were not included in vaccine trials
More pregnancy loss	Prevents neonatal infection	Other vaccines have not shown adverse pregnancy outcomes
Infecting others	Antibodies in fetal and neonatal blood	No proven theoretical fetal risks
Infecting fetal patients	Antibodies in breast milk	No proven theoretical maternal risks
Long-term sequelae	Prevents long-term sequelae	Menstrual period changes

leading to vaccine skepticism among many men and patients of reproductive age.²⁰

Professional US organizations and other countries delayed recommending COVID-19 vaccinations for pregnant patients until mid to late 2021 and did not recommend it until there was clear evidence of increased maternal mortality from COVID-19 infections in late 2021. This is what's called "physician hesitancy."²¹

On 29th September 2021, the Centers for Disease Control (CDC) and prevention published a health advisory recommending urgent action to increase COVID-19 vaccination among patients who are pregnant, recently pregnant (including those who are lactating), who are trying to become pregnant now, or who might become pregnant in the future.²²

However, as of the end of 2022, the COVID-19 vaccine acceptance rate among pregnant patients remains lower than among nonpregnant patients, and more than one out of three pregnant patients in the US have not been fully vaccinated for COVID-19 before or during pregnancy, and only about 50% of nonhispanic pregnant Blacks have been fully vaccinated.¹

There are multiple factors influencing a woman's decision to get vaccinated, but the most common factor that influences patients to get vaccinated is a healthcare provider's recommendation.²³⁻²⁹ It is, therefore, an ethical imperative that physicians and others have a strong message and make a strong recommendation to pregnant patients and those trying to conceive to get vaccinated against COVID-19 (Table 1).¹⁹

"Physician hesitancy" occurs when physicians or their professional organizations do not recommend COVID-19 vaccination. Or it occurs when, while not clearly recommending against vaccination, physicians question both the safety and effectiveness of COVID-19 vaccines, therefore sowing doubt in patients and discouraging pregnant patients from accepting vaccination. Vaccine and physician hesitancy is a contributing factor to the present low vaccine acceptance rate by pregnant patients for COVID-19 and other recommended vaccines, and it is a major, unaddressed problem for the quality and safety of obstetric care.³⁰⁻³³

Disappointingly, there continues to be a proliferation of anti-vaccination proponents among physicians and other healthcare providers who actively discourage COVID-19 vaccinations (and often other vaccines). Some carry the mantle of healthcare providers, while others use the anti-vaccination movement for political purposes.

Physician hesitancy may have also been encouraged by inconsistent messaging to pregnant patients as well as the reluctance, until very recently, of physicians' professional organizations and publications not to recommend COVID-19 vaccination to pregnant patients, even though COVID-19 vaccinations to most other risk groups had already been recommended. As pregnant patients continue to

become severely ill or die from COVID-19, overcoming physician hesitancy has become urgent.

And though the CDC and most US states included pregnant patients as a risk group, several professional groups and societies initially said to only "offer" but not to recommend vaccination to be pregnant, therefore excluding the recommendation for COVID-19 vaccinations from pregnant patients.³⁴⁻³⁸ That approach was further elaborated by several publications that called for "shared decision-making" between a patient and her provider for offering (presenting vaccination as an option without the physician expressing a view on whether the patient should be vaccinated), but not recommending (expressing the view that the patient should be vaccinated), COVID-19 vaccination to pregnant patients.³⁹⁻⁴³

Well before the COVID-19 pandemic, Brent called for establishing successful vaccine programs for pregnant patients as the quintessence of preventive medicine. Maternal vaccination against COVID-19 is the best way not only to protect against maternal morbidity and mortality but also to protect the soon-to-be-born child and infant.^{10,44,45} As with other vaccines recommended in pregnancy, there are no known pregnancy-specific adverse effects of COVID-19 vaccines.

A recommendation by a physician or another health care professional is crucial to improve vaccine acceptance.^{10,19,21}

The American College of Obstetricians and Gynecologists and the Society for Maternal-fetal Medicine as well as the CDC hesitated to recommend COVID-19 vaccination recommendations to pregnant patients until the end of July 2021. In fact, pregnant patients were the only group who had been specifically excluded from these recommendations. At that time, it had become evident that there was a significantly elevated maternal mortality in unvaccinated pregnant patients.

In a review of COVID-19 vaccination in pregnancy, there were no concerning safety signals; specifically, no increase in fetal malformations,¹⁰ and studies indicated that the administration of the messenger ribonucleic acid vaccines resulted in a robust maternal humoral response. Although the antibody response to vaccination among pregnant patients has not been rigorously compared with the response among nonpregnant patients, there has been no reason to expect differences. Furthermore, maternal immunoglobulin G antibodies efficiently cross the placenta, resulting in relatively high titers in the fetus.¹⁰ There are no known or theoretical risks of COVID-19 vaccination of breastfeeding patients and there are no restrictions to the vaccination. Patients should be reassured that COVID-19 vaccines do not affect fertility, that COVID-19 vaccines cannot cause COVID-19 as none of them contains the live virus, that the COVID-19 vaccines do not interact with or alter genetic material, and that the vaccines do not contain any controversial substances.⁴⁶



PHYSICIAN HESITANCY IN NOT RECOMMENDING VACCINATION

There are three root causes of physician hesitancy and we identified how to reverse physician hesitancy by firmly recommending COVID-19 vaccines in pregnancy.²¹ Reversing the root causes of physician hesitancy remains an urgent matter of patient safety, not just during the COVID-19 pandemic but also for future outbreaks. The three root causes have their origin in clinical misapplications of important components of professionally responsible obstetric clinical judgment and practice:

- Clinical misapplication of therapeutic nihilism.
- Clinical misapplication of shared decision-making.
- Clinical misapplication of the ethical principle of respect for autonomy.

The first root cause of physician hesitancy is the misapplication of therapeutic nihilism in the clinical management of pregnancy. Therapeutic nihilism is defined as “skepticism regarding the worth of therapeutic agents, especially in a particular disease.”⁴⁷ Therapeutic nihilism is a powerful antidote to enthusiasm, the belief in clinical benefit in the absence of evidence.

The response to the clinical misapplication of therapeutic nihilism should be deliberative, beneficence-based clinical judgment. Therapeutic nihilism is justified when an intervention during pregnancy should be considered to result in significant net clinical harm. However, this did not apply to COVID-19 vaccination at the time of our 1st February 2021 publication in the American Journal of Obstetrics and Gynecology.¹⁹ The increased risks of severe maternal illness, ICU admission, and maternal, fetal, and neonatal death were already well documented early in 2021.⁶⁸ There were no “red flags” according to Dr Fauci¹⁸ and no increased serious adverse events for patients who were or became pregnant in the clinical trials of COVID-19 vaccines pregnant patients that would have warranted suspension of these trials. There was no documented theoretical risk of maternal, fetal, or neonatal harm, and there were no documented increased adverse outcomes in vaccinated pregnant patients. As the harms of COVID-19 disease in pregnancy were severe and immediate, and there were no documented safety concerns, deliberative beneficence-based clinical judgment supported the conclusion that vaccination should be recommended clearly as early as January 2021.

The second root cause of physician hesitancy is the misapplication of shared decision-making (in shared decision-making, the physician should not be directive but only offer and not recommend specific management).³ Shared decision-making has an important role in decision-making with patients when evidence is uncertain and is misapplied when it is taken to be the sole model for decision-making with patients. Shared decision-making has an important place when there are competing medically reasonable alternatives

for, and therefore uncertainty about, the management of the patient’s condition or diagnosis. For example, the obstetrician should offer both trials of labor and planned cesarean delivery after low transverse cesarean delivery. By contrast, shared decision-making is misplaced when making a recommendation is required, for example, when there is one medically reasonable alternative, for example, repeat cesarean delivery after classical cesarean delivery. This clinical judgment should be recommended and should be explained to the patient. She should be supported in her evaluation of it. In deliberative clinical judgment, not being vaccinated for COVID-19 was not a medically reasonable option for pregnant patients in February 2021, and it is not today.

The third root cause of physician hesitancy is the misapplication of the ethical principle of respect for autonomy. This ethical principle plays an indispensable role in decision-making with patients. It is misapplied when it is assumed that respect for autonomy requires physicians not to make recommendations and to defer to and implement patients’ decisions without exception.⁴⁸ Patient autonomy is enforced by making strong recommendations empowering pregnant patients to make informed decisions about COVID-19 vaccination. Pregnant patients report that their physician’s recommendations were the most important factor in their decision-making, especially as it relates to recommendations to get COVID-19 vaccines. It follows that making recommendations empowers pregnant patients to make informed decisions, belying the view that making recommendations is not compatible with respect for autonomy.

Currently, COVID-19 vaccination for pregnant patients is the standard of care and an ethical imperative. A pregnant woman’s refusal of vaccination should not be simply accepted by her physician. The legal requirement of informed refusal should be satisfied and documented, supplemented by the ethical requirement of respectful persuasion.

THE RISK OF DOING NOTHING

Well before the COVID-19 pandemic, Brent^{49,50} wrote several articles, such as one called—“Risks and benefits of immunizing pregnant patients: the risk of doing nothing.” Dr Brent laid out six beneficial points for immunizing pregnant patients or patients of reproductive age:

- To protect the mother, to protect the newborn and the infant, and to prevent diseases and complications of pregnancy.
- Preparation of vaccines against infectious agents that are known to result in reproductive pathology and congenital malformation if the infection of the mother occurs during pregnancy.
- To utilize vaccines used routinely to protect the nonpregnant population for administration during pregnancy.
- Utilization of vaccines to protect patients from diseases to which they are susceptible because of pregnancy.

- Utilization of vaccines for use before or during pregnancy, primarily to protect the newborn and infant via maternal transplacental antibodies.
- The prevention of intrauterine infection that has been alleged to initiate premature labor.

With the advent of COVID-19 Dr Brent's points are even more important. Doing nothing was and continues to be a clinical error. Hesitating to recommend the COVID-19 vaccine in pregnancy, despite clear evidence of harm to COVID-19-infected pregnant patients who were not vaccinated, and even though there was no evidence of potential harm from vaccination likely led to fewer pregnant patients accepting vaccination and subsequently the preventable increase in maternal mortality.⁵¹ Physicians and other healthcare providers should continue to strongly recommend COVID-19 and other safe indicated vaccinations to pregnant patients, those trying to get pregnant, those who breastfeed, and those who initially decline vaccination.

THE ONGOING NEED FOR RINGFENCING IN PERINATOLOGY

During the height of the COVID-19 pandemic, many hospitals worldwide have been overwhelmed by patients sickened by COVID-19. This often led to restrictions such as cancellation of family or doula visits and nonessential procedures and surgeries such as prenatal testing, prenatal visits, or *in vitro* fertilization to free up hospital resources. This further added to the strain pregnant patients and their families already had to endure. Many of the restrictions were not necessarily evidence-based. Only those changes should be made that are well supported in deliberative (evidence-based, rigorous, transparent, and accountable) clinical judgment response to the coronavirus pandemic.^{52,53} We argued for "ringfencing," which has its origins in the ringfences that are built to keep farm animals in and predators out or in finance, where it serves as a virtual barrier that segregates a portion of an individual's or company's financial assets from the rest. We believe that maternity resources, both human and physical, should be ringfenced from redeployment so that the capacity of labor and delivery units is not impaired and to ensure that women and their newborns continue to receive the safest possible care. The essential of putting women and children first during the coronavirus (and next) pandemic requires that hospitals sustain access by pregnant women and newborns to timely, effective, and safe prenatal and in-hospital care for the nonelective condition of pregnancy.

FRAMESHIFTING FROM INDIVIDUAL PATIENT-BASED CONCERNS TO POPULATION-BASED CLINICAL JUDGMENT

In addition to restricting services during the height of the pandemic, some hospitals also considered or actually moved obstetric services. This was often challenged by obstetricians

because of beneficence-based deliberative clinical judgment from the perspective of individual patient-based concerns. However, we believe that in a public health emergency, a frameshift from individual patient-based to population-based deliberative clinical judgment is required to meet the needs of the entire population of patients in the hospital.⁵⁴

An individual patient-based, beneficence-based deliberative clinical judgment is not an adequate basis for organizational policy in response to a public health emergency.

Instead, physicians, especially those in leadership positions, must frameshift to population-based clinical ethical judgment that focuses on the reduction of mortality as much as possible in the entire population of patients served by a healthcare organization. The challenges of obstetricians certainly include stress, and we emphasize that this additional stress originates in the sudden, unexpected ethical stress of having to shift from the professional commitment to meet each obstetric patient's needs individually to meet the needs of an entire population.

The COVID-19 is not the first and is surely not the last global pandemic. In case of overwhelmed hospitals, optimization and, if necessary, reassignment of hospital space are needed to care for all patients. When this happens, obstetricians should look beyond their perinatal patients. They should expand the concept of the professional virtue of integrity to include a population of patients at-large and not normally served by obstetrics. By moving obstetrics offsite, for example, deliberative clinical judgment focuses on the reduction of mortality as much as possible in the entire population of patients served by the hospital. This expanded concept of professional integrity should guide the response of obstetricians to future unexpected public health emergencies.⁵⁴

CONCLUSION

The COVID-19 pandemic is unprecedented in our lifetime, especially in perinatology. In this publication, we discussed some of the ethical lessons learned in perinatal medicine from the COVID-19 pandemic. The ethical principle of beneficence and the professional virtue of integrity is directly applicable tools for addressing the issues surrounding the COVID-19 pandemic.

The gold standard is to strongly recommend COVID-19 vaccinations to those trying to get pregnant, to those who are pregnant, and to those who are postpartum. When the benefits of vaccines far outweigh the risks, it is unethical to disseminate wrong information and discourage patients from becoming vaccinated. COVID-19 vaccinations and boosters prevent severe diseases and adverse pregnancy and neonatal outcomes. A pregnant patient's vaccination also protects the newborn infant because maternal antibodies protect the fetus and newborn. COVID-19 vaccinations and boosters in pregnancy are safe for the pregnant patient and her fetus. The three root causes of physician hesitancy—



misapplication of therapeutic nihilism, misapplication of shared decision-making, and misapplication of respect for autonomy should not be ignored and need to be addressed.

It is important that we heed Brent's insightful recommendations.^{49,50} Doing nothing with respect to vaccination is not an option, whether it applies to COVID-19 vaccines or to future pandemics. Physician hesitation is not an option. When there is sufficient evidence of vaccine safety and effectiveness without documented risks, vaccine recommendations before, during, and after pregnancy should be explicitly made to prevent maternal, fetal, and neonatal morbidity and mortality.

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