Pregnancy: Ethical Issues of Vaccine Refusal

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Good ethics start with good facts. To discuss the ethical dilemmas concerning COVID-19 vaccination during pregnancy, it is first required to analyze the medical-scientific available data regarding the outcome of COVID-19 infection during pregnancy upon the pregnant individual and upon the fetus and the efficacy and safety of COVID-19 vaccines upon both the pregnant individual and the fetus.

Medical-Scientific Aspects

COVID-19 Pandemic and Vaccination

The COVID-19 pandemic started in China in December 2019 and rapidly spread to over 200 countries worldwide. As of the beginning of March 2022, 446 billion people were infected, and over 6 billion people lost their lives due to the pandemic.

All preventative measures failed to stop the pandemic. Soon after its outbreak, it was clear that vaccinating the entire world population will be the most effective tool to fight the pandemic. As of the beginning of March 2022, over ten billion doses of COVID-19 vaccines have been administered worldwide. This constitutes over 62% of the world population.

Several COVID-19 vaccines, including the Pfizer-BioNTech and Moderna vaccines which are based on mRNA—a relatively new model of vaccines—have been successfully developed.

On 2 December 2020, the United Kingdom's regulatory agency (MHRA) gave temporary regulatory approval for the Pfizer-BioNTech vaccine, becoming the first country to approve the vaccine [1, 2]. On 11 December 2020, the FDA granted an

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J. G. Schenker et al. (eds.), *Hot Topics in Human Reproduction*, Reproductive Medicine for Clinicians 3, https://doi.org/10.1007/978-3-031-24903-7_3

emergency use authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. A week later, they granted an EUA for mRNA-1273, the Moderna vaccine [3].

Currently, 30 vaccines are authorized by at least 1 national regulatory authority for public use. Over 200 vaccines are undergoing clinical trials that have yet to be authorized.

COVID-19 Illness and Vaccination in Pregnancy

Globally, over 200 million individuals are pregnant each year. This creates a very significant and special group in relation to the pandemic and to vaccination.

Several studies demonstrated the risks of morbidity and mortality associated with COVID-19 in pregnancy on maternal and neonatal outcomes compared with not-infected pregnant individuals.

In a multinational cohort study, COVID-19 in pregnancy was associated with consistent and substantial increases in severe maternal morbidity and mortality, as well as neonatal complications when pregnant individuals with and without COVID-19 diagnosis were compared. Pregnant individuals with COVID-19 diagnosis were at higher risk for preeclampsia/eclampsia, severe infections, intensive care unit admission, maternal mortality, preterm birth, medically indicated preterm birth, severe neonatal morbidity index, and severe perinatal morbidity and mortality index. Asymptomatic pregnant individuals with COVID-19 diagnosis remained at a higher risk only for maternal morbidity and preeclampsia [4]. Several other studies corroborated these results [5–8]. In the United States, as of the end of February 2022, there were 182,847 infected pregnant individuals, 29,519 were hospitalized, and 285 died. Nearly all the COVID-19 cases among pregnant individuals to date have been among unvaccinated persons [9].

Studies have also documented serious consequences for the fetus and the newborn. These include stillbirth and early delivery due to maternal decompensation, leading to complicated neonatal courses and multiple neonatal deaths [6, 8].

Although pregnant individuals and their fetuses are at a higher risk of severe complications of COVID-19 infection, clinical trials for the available vaccines excluded pregnant and lactating women. Pregnant individuals were excluded from the initial phase 3 clinical trials of COVID-19 vaccines by Pfizer and Moderna.

Exclusion of pregnant individuals from clinical trials testing the safety and efficacy of COVID-19 vaccines is occurring even though, over the past two decades, several advisory bodies and ethics experts have issued recommendations for including pregnant individuals in clinical trials [10]. Hence, widespread failure to appropriately include pregnant women in vaccine research means that evidence about safety and efficacy in pregnancy has been limited and late in coming. As a result, in many countries, pregnant individuals have been denied the opportunity to receive COVID-19 vaccines that would have protected them and their offspring from the ravages of this disease.

Nonetheless, the consequences of the COVID-19 disease in pregnancy prompted many healthcare organizations and countries to support vaccination in pregnancy.

In Israel, the Ministry of Health and Vaccines Prioritization Committee recommended vaccination for pregnant individuals. Some jurisdictions in the United States are already offering the vaccine to pregnant individuals, including the District of Columbia, Pennsylvania, and Mississippi.

Professional societies, such as the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), the Society for Maternal-Fetal Medicine (SMFM), and the Royal College of Obstetricians and Gynaecologists (RCOG), all support COVID-19 vaccination in pregnancy since the benefits outweigh the risks [11, 12].

Based on the current available clinical data, vaccination during pregnancy has been proved to be effective and safe, both for the pregnant individual and for the fetus; the benefits of vaccination during pregnancy outweigh potential risks [13, 14].

Several studies discussed the attitude toward and knowledge of pregnant and nonpregnant individuals regarding the COVID-19 disease and vaccination and their effect on pregnant individuals, the fetus, and the newborn. These studies evaluated the sociodemographic characteristics, vaccination history, perception of risk for the COVID-19 pandemic, the impact of the COVID-19 pandemic, and acceptance or refusal of the COVID-19 vaccination during pregnancy.

The percentage of vaccine acceptance among pregnant women varied greatly among the surveys, ranging from 16 to 52% [15–18].

Most common refusal reasons were lack of data about COVID-19 vaccine safety in pregnant populations and the possibility of harm to the fetus. Pregnant individuals in the first trimester expressed higher acceptance of COVID-19 vaccination than those in the second and third trimesters [15]. Receipt of influenza vaccine during the previous season was associated with higher odds of vaccine acceptability [16].

Social-Ethical Aspects

Modern medical bioethics operates according to four fundamental principles: autonomy, beneficence, non-maleficence, and justice [19].

Beneficence is defined as the obligation of a physician to act for the benefit of the patient. The principle calls for not just avoiding harm but also to actively benefit patients and to promote their welfare.

Non-maleficence is defined as the obligation of a physician not to harm the patient.

The philosophical underpinning for autonomy is that all persons have intrinsic and unconditional worth and, therefore, should have the power to make rational decisions and moral choices, and each person should be allowed to exercise his or her wishes for self-determination.

The principle of autonomy became an overriding principle, and it replaced almost totally the long-standing patient–physician relationship based on paternalism. Nonetheless, as is true for all four principles, autonomy needs to be weighed against competing moral principles and in some instances may be overridden.

The evidence-based professional data presented in part Ib provides unequivocal and clear guidance: Physicians should recommend COVID-19 vaccination to persons who are pregnant.

The grave consequences resulting from COVID-19 infection during pregnancy, and the efficacy and safety of the vaccinations, constitute a prima facia moral obligation upon healthcare providers to advise, promote, and recommend vaccination at all stages of pregnancy. This is based on the moral principles of beneficence and non-maleficence.

Safety information on COVID-19 vaccines must be clearly communicated to pregnant individuals to provide reassurance and facilitate informed pregnancy vaccine decisions. Targeted interventions to promote COVID-19 vaccine uptake among ethnic minority and lower-income individuals may be needed [20]. Medical information about the safety, effectiveness, and benefits of vaccinations among pregnant individuals was found to increase the acceptance of vaccinations by 105.6% Polish patients and by 176% among Ukraine patients [18].

The strongest predictors of vaccine acceptance included confidence in vaccine safety or effectiveness, worrying about COVID-19 disease, belief in the importance of vaccines to their own country, compliance to mask guidelines, trust of public health agencies/health science, as well as attitudes toward routine vaccines [17].

Various terms are used to define the fact that certain people do not agree to be vaccinated: objection, hesitation, and refusal. Objection refers to a conscientious opposition to vaccines at large or to a particular vaccine; hesitancy refers to an attitude such as doubts or concerns [17]. Refusal refers to the end result of either objection or hesitancy.

Refusal and opposition to vaccines is not a new phenomenon. It appeared soon after the introduction of the first vaccine—the smallpox vaccine—in the eighteenth century.

The beliefs and arguments of the anti-vaccine movements have remained unchanged in the past two centuries, but new social media has facilitated the dissemination of information against vaccines [21].

There is a moral responsibility upon the pregnant individual to protect the fetus and her own health and well-being. Hence, the individual should accept the legitimate recommendation to be vaccinated.

Yet, based on the principle of autonomy, society ought to respect the right of an individual to make rational decisions and moral choices, and each person should be allowed to exercise his or her wishes for self-determination. Therefore, a pregnant individual who refuses to be vaccinated should not be coerced to do so.

Conclusions

COVID-19 can have severe consequences in pregnancy: evidence indicates that pregnant individuals with COVID-19 are at increased risk of severe illness and death, of giving birth to preterm babies, and potentially of other adverse pregnancy outcomes such as stillbirth.

COVID-19 vaccines are highly effective: They provide strong protection against severe illness and deaths. Pregnant individuals are likely to receive the same level of protection from the vaccines as nonpregnant people.

Safety data in pregnancy are increasing and are reassuring: Evidence on the safety of COVID-19 vaccines during pregnancy has been growing. To date, animal studies, monitoring of pregnant individuals who have received the vaccines, and experience using vaccines with similar components have not identified any pregnancy-specific safety concerns [14].

Based on the principles of beneficence and non-maleficence, it is the moral obligation upon healthcare providers to advocate, promote, and recommend vaccination for pregnant individuals.

Based on the principle of autonomy, a pregnant individual who refuses to be vaccinated should not be coerced to do so.

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