

COVID-19 vaccines in patients who are pregnant, are planning to become pregnant, are breastfeeding or are planning to breastfeed

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Abstract

The global health crisis created by the COVID-19 pandemic requires effective prevention strategies and therapeutic approaches at a worldwide scale. Regarding pregnant women, the observational studies have shown that pregnant patients have an increased risk of severe illness with intensive care unit (ICU) admissions, need for mechanical ventilation, death or adverse pregnancy course, with high risk of preterm birth and postpartum complications. It is challenging to counsel the pregnant patients about the efficacy and safety of the approved COVID-19 vaccines due to the lack of data from clinical trials. All worldwide international and national government agencies and professional associations take different position regarding the vaccination against COVID-19 in pregnant women, in those aiming to be pregnant and in breastfeeding patients. The solution to this public health issue is based on the development of COVID-19 vaccines in current and planned clinical trials. This paper aims to help physicians to implement the results of the clinical trials of COVID-19 vaccines by correctly inform, counsel and support patients who are pregnant, are planning to become pregnant, are breastfeeding or are planning to breastfeed.

Keywords: global crisis, COVID-19, vaccines, pregnant, breastfeeding, fertility

Rezumat

Criza sanitară globală cauzată de COVID-19 necesită aplicarea la scară largă a unor strategii complexe de prevenție și tratament. În ceea ce privește pacientele gravide, studiile observaționale desfășurate până în prezent au arătat un risc mai mare pentru o gravidă cu COVID-19 de a dezvolta forme severe de boală și complicații, cu o rată mai mare de internare la terapie intensivă, necesitatea ventilării mecanice sau chiar deces matern, precum și cu creșterea riscului de naștere prematură și de complicații postnatale. Este o mare provocare să poți sfătui corect o pacientă însărcinată în ceea ce privește administrarea vaccinului împotriva COVID-19 și eficacitatea și siguranța lui, întrucât nu există încă date suficiente. La nivel global, nu există o voce unică și care să emită recomandări, fiecare țară și fiecare organizație profesională având propriile puncte de vedere în ceea ce privește vaccinarea acestei categorii aparte a femeilor gravide, care alăptează sau a celor care plănuiesc să rămână gravide ori să alăpteze. Rezolvarea acestei probleme de sănătate are la bază continuarea studiilor și a dezvoltării vaccinurilor. Prin această lucrare, ne propunem să ajutăm doctorii să poată informa, consilia și oferi indicații corecte de vaccinare acestei categorii aparte de paciente, obținând astfel un grad ridicat de protecție împotriva îmbolnăvirii prin COVID-19.

Cuvinte-cheie: criză globală, COVID-19, vaccinare, gravide, alăptare, fertilitate

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Vaccinarea COVID-19 la pacientele care sunt gravide sau plănuiesc să rămână însărcinate, care alăptează sau își doresc să alăpteze

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Introduction

The global health crisis created by the COVID-19 pandemic requires effective prevention strategies and therapeutic approaches at a worldwide scale. The solution to this public health issue is based on the development of COVID-19 vaccines in current and planned clinical trials. This paper aims at helping physicians to implement the results of the clinical trials regarding COVID-19 vaccines by correctly inform, counsel and support patients who are pregnant, are planning to

become pregnant, are breastfeeding or are planning to breastfeed.

Food and Drug Administration (FDA) issued in December 2020 an Emergency Use Authorization (EUA) for the use of two vaccines for the prevention of COVID-19: the Pfizer-BioNtech vaccine in persons aged ≥ 16 years old, and the Moderna vaccine in persons aged ≥ 18 years old⁽¹⁾. These vaccines were recommended by the Advisory Committee on Immunization Practices (ACIP). Structurally, both vaccines are lipid nanoparticle-formulated,

nucleoside-modified mRNA vaccines encoding the pre-fusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19⁽²⁾. COVID-19 mRNA vaccines work by creating the “spike protein” (a surface protein of the virus which causes COVID-19), which is a harmless piece, basically teaching our body cells how to fight against the virus. The immune system will recognize this spike protein which is a “non-self” and will begin to build an immune response with antibodies like in the course of natural infection. The most important three things about mRNA vaccines are: firstly, they cannot give someone the disease because they do not use live viruses; secondly, they do not interact with the cellular DNA because they do not pass into the nucleus of the cells where the genetic material is kept; and thirdly, after the cells completely read the encoding message, the particle is destroyed by natural processes.

Regarding pregnant women, observational studies have shown that pregnant patients have an increased risk of severe illness, with intensive care unit (ICU) admissions, need for mechanical ventilation, extracorporeal membrane oxygenation (ECMO) or even death; or an adverse pregnancy course with a high risk of preterm birth and postpartum complications. Unfortunately, there are few data regarding the safety of COVID-19 vaccines in pregnancy. The main contraindications in COVID-19 vaccines stated by the the U.S. Centers for Disease Control and Prevention (CDC) are: severe and immediate allergic reactions to a prior dose of mRNA COVID-19 vaccine, to its components or to polysorbate⁽¹⁾. For these persons, is it needed an immediate evaluation by an allergist-immunologist⁽¹⁾.

Based on the limited data now available on the safety of mRNA COVID-19 vaccines, but from animal developmental and reproductive toxicity studies, there were no safety concerns demonstrated on pregnant mice vaccinated with the Moderna vaccine regarding embryonic and fetal development or postpartum development⁽²⁾. Based on the actual knowledge, mRNA vaccines are not live vaccines, therefore they are unlikely to harm the fetus or pose a risk for the pregnant woman, and due to the fact that it doesn't enter the cellular nucleus, it cannot modify or alter the DNA nuclear code, being also rapidly degraded by the normal cellular processes. However, there is a need for further studies regarding the safety and potential risks of the mRNA vaccines in pregnant women.

The mRNA vaccines are something new, but not unknown. The researchers have been studying and working with this technique for decades – they were also studied it before for the flu, Zika virus, rabies, and cytomegalovirus (CMV). Furthermore, vaccine researchers have used mRNA to trigger the immune system against specific cancer cells.

At this time, CDC recommends 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⁾, thus pregnant women, those who attempt to get pregnant and those who are

breastfeeding have no contraindication in receiving this vaccine.

Based on the Advisory Committee on Immunization Practices, the American College of Obstetricians and Gynecologists (ACOG) recommends that COVID-19 vaccines should not be refused to pregnant patients who meet the criteria for vaccination (i.e., healthcare personnel, associated comorbidities). The Advisory Committee on Immunization Practices is an organism that develops recommendations on how to use vaccines to control diseases in the United States. Afterwards, their recommendations are sent to CDC for approval.

CDC outlines pregnancy in the list of high-risk medical conditions for the prioritization of COVID-19 vaccine in pregnant women since the last updated on the 4th of February 2021⁽³⁾. The available data suggest that symptomatic pregnant patients with COVID-19 have a higher risk of severe forms and complications when compared with non-pregnant patients; if the pregnant patient associates other comorbidities, the risk is even higher⁽⁴⁻⁷⁾. Due to all of these new clinical data, CDC has included pregnancy as a risk factor for severe forms of COVID-19.

COVID-19 vaccines should be offered to breastfeeding patients similar to non-breastfeeding patients when they meet the criteria for receiving the vaccine based on prioritization groups outlined by ACIP⁽³⁾.

The Emergency Use Authorization issued by the FDA for the two mRNA vaccines states that: “If you are pregnant or breastfeeding, discuss your options with your healthcare provider”⁽³⁾. Considering that the available data regarding the safety and efficacy of the COVID-19 vaccines are limited, an informed and supported conversation between the patient and the medical team is needed⁽²⁾.

From 29 January 2021, EMA has authorized the use of the third COVID-19 vaccine in Europe, which is the AstraZeneca vaccine developed by the Oxford University in people above 18 years old (after the mRNA vaccines developed by Pfizer and Moderna); in the USA, it is expected to receive the FDA approval by this spring. The safety of the vaccine has been demonstrated across the four clinical trials in the United Kingdom, Brazil and South Africa. The AstraZeneca COVID-19 vaccine is also given as two injections into the arm, the second between 4 to 12 weeks after the first one. This is not an mRNA vaccine, being made up of another virus (from the adenovirus family) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. The adenovirus itself cannot reproduce and therefore it cannot cause the disease. Once inoculated, it delivers the gene of the spike protein of SARS-CoV-2. The cells will produce this protein and the person's immune system will recognize and treat this spike protein as foreign (non-self) and produce natural defenses (antibodies and T cells) against it. Also, in the AstraZeneca vaccine the data regarding safety during pregnancy are lacking; animal reproductive toxicity studies have not yet

been completed, but preliminary reproductive toxicity studies in mice do not show any toxicity or damages in fetuses⁽⁸⁾. Also, this technique isn't new and there are reassuring data from the use of Ebola vaccine which is based on the same technique.

Patients' counseling

Since pregnant patients were excluded from vaccination trials, there is limited information regarding the safety and efficiency of the vaccines at this patients' category. The theoretical risk of COVID-19 vaccine during pregnancy should be put in the balance with the risk of developing severe forms of the disease while being pregnant – in this context of the documented increased risk of severe COVID-19 for both mother and fetus health⁽⁹⁾. When taking an inactivated vaccine or toxoid vaccine during pregnancy, there is no expectation for adverse effects for both mother and fetus^(10,11). Saint-Gerons et al., in an overview of 17 systematic reviews reporting maternal-fetal and neonatal outcomes after immunizations during pregnancy with inactive vaccines, found no major safety concerns and risks⁽¹²⁾.

Limited data

It is challenging to counsel pregnant patients about the efficacy and safety of the approved COVID-19 vaccines due to the lack of data from clinical trials. Pregnancy represents common exclusion criteria for clinical trials due to legal and ethical liability. To date, there are no efficacy or safety data specific to the COVID-19 mRNA vaccine use in pregnant or breastfeeding patients and therefore the risks for mothers and fetuses remain unclear. But a parallel can be made with the large evidence from non-live vaccines about safety⁽¹²⁾: because mRNA vaccines are not live-virus vaccines, they don't enter the cellular nucleus and do not interfere with the DNA code and structure – “the mRNA strand never enters the cell's nucleus or affects genetic material”⁽¹³⁾.

Also, data from a past experience with mice vaccinated against Zika virus with an mRNA-type vaccine show that mRNA do not cross the placenta and it protects against placental damage⁽¹⁴⁾. Based on these data, CDC hypothesised that “experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus”⁽¹⁾. Certainly, this hypothesis must be certified by clinical trials including pregnant patients.

The risk of COVID-19 for the pregnant woman, the fetus and the newborn: what we know

CDC included pregnant patients on the list of high-risk medical conditions for COVID-19⁽⁴⁾. Regarding the susceptibility (how transmissible is SARS-CoV-2 to pregnant women compared with non-pregnant women), there is no information. What we know is that there are the same risk factors for contracting the virus, but it is unclear if a pregnant woman is more likely to get

COVID-19. Thus, although pregnancy does not increase the risk of acquiring SARS-CoV-2, it appears that there is a worse clinical course in pregnant patients when compared with non-pregnant patients of the same age – i.e., a risk for more severe forms, for complications, for ICU admissions, for ECMO, to be ventilated, even for maternal death^(7,15-20). There is an increased risk of maternal death⁽²¹⁻²⁴⁾, of preterm birth⁽²⁴⁻²⁸⁾, C-section⁽²⁹⁾, preeclampsia or of perinatal death⁽³⁰⁾. There are also reported cases of vertical transmission^(31,32). There is also proof that SARS-CoV-2 infection is associated with placental inflammation, fetal vascular malperfusion and villitis, all of these suggesting that the virus can impact the perinatal outcomes due to placental injury^(33,34). It is expected that a fetus from a mother with a severe form of COVID-19 will not do as well as a fetus from a healthy mother – there is a high risk of prematurity demonstrated and there are still inconclusive data regarding the risk of stillbirths.

There are also racial concerns regarding the severity of COVID-19, black and hispanic pregnant patients being more affected by the virus, with increased risk for ICU admissions^(35,36).

What are the government agencies and professional associations guidelines?

All worldwide international and national government agencies and professional associations take different position regarding the vaccination against COVID-19 in pregnant women, in those aiming to be pregnant and in breastfeeding patients. Some organizations issue recommendations based on ethics regarding the patient autonomy – i.e., CDC and ACOG in the USA states that information should be offered, but makes no recommendations: “People who are pregnant and part of a group recommended to receive the COVID-19 vaccine may choose to be vaccinated”^(1,37), “COVID-19 vaccines should not be withheld from pregnant individuals who meet the criteria for vaccination based on ACIP-recommended priority groups”, “COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet the criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP”⁽²⁾. The Society for Maternal-Fetal Medicine and the American Society for Reproductive Medicine recommend that healthcare workers who are pregnant and patients undergoing fertility treatment should be encouraged to receive vaccination based on eligibility criteria^(38,39).

The Canadian Society of Obstetricians and Gynecologists of Canada (SOGC) states that for patients who are at risk of infection or have comorbidities, the risk of not getting vaccinated and passing through the disease is worse than assuming the theoretical risk of doing the vaccine during pregnancy or breastfeeding⁽⁴⁰⁾.

In Europe, the policy of vaccination is different from country to country. There are some countries that consider pregnancy a contraindication for vaccination, such as Austria: “COVID-19 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⁽⁴¹⁾. The authorities from France state that “the administration of the vaccine during pregnancy is not recommended”⁽⁴²⁾, while in The Netherlands it is specified: “Are you pregnant? If so, it is recommended to postpone the vaccination until after your pregnancy”⁽⁴³⁾.

Germany and UK state that vaccination should be offered only after risk assessment^(44,45). The Medicines and Healthcare products Regulatory Agency (MHRA) in UK has authorised Oxford University/AstraZeneca’s COVID-19 vaccine for use since the 30th of December 2020. The Royal College of Obstetrics and Gynecology (RCOG) and the Joint Committee on Vaccination and Immunisation (JCVI) have updated the recommendations for using the Oxford University/AstraZeneca’s COVID-19 vaccine and the Pfizer/BioNTech vaccine for pregnant and breastfeeding women who meet other criteria for priority vaccination – i.e., clinically extremely vulnerable patients, frontline health or social care workers⁽⁴⁵⁾.

Israel states that “priority will now be given to breastfeeding women, pregnant women and women who are planning to get pregnant”⁽⁴⁶⁾. By contrast, Japan considers that vaccination should not be recommended in pregnancy⁽⁴⁷⁾.

The World Health Organization considers that there are not sufficient data regarding safety and efficacy and considers that guidance should be postponed until the evidence base permits a more definitive assessment of the risk/benefit ratio⁽⁴⁸⁾.

The Romanian Society for Obstetrics and Gynecology aligns with the international care standards and calls on the authorities not to restrict the access of pregnant women or of women who are breastfeeding to COVID-19 vaccination, since it is not restricted in other EU countries or in the USA⁽⁴⁹⁾.

The myths behind COVID-19 vaccines

There is an abundance of false information about COVID-19 and vaccines in the media and on the internet, and there are also many prominent anti-vaccine persons who speak loud false information and create panic. There is a strong false believe maintained on the internet about a link between infertility and COVID-19 vaccines, all these being combated by the American Society for Reproductive Medicine who encourages vaccination for those undergoing fertility treatments and for pregnant and lactating patients, based on eligibility criteria⁽³⁹⁾. The European Society of Human Reproduction and Embryology (ESHRE) states that “pregnant women should be informed about the lack of long-term human studies on COVID-19 vaccination, but should not be excluded from vaccination programmes”, and that “it seems prudent to postpone assisted reproduction treatments for at least a few days after the completion of vaccination”⁽⁵⁰⁾.

Ethics in obstetrics and gynecology

It is really challenging to provide professional counseling about COVID-19 vaccination to the ethically sensitive group of those who are pregnant, those who plan to become pregnant, and those who are breastfeeding or planning to do so. The informed consent should be based on the ethical principle of autonomy which means that the patient will decide what to do after being informed by the healthcare workers. The physician should inform and explain the patient and help him take an informed decision which is not based on personal beliefs or on media circulating myths.

Physicians should present data to weigh the benefits and risks of COVID-19 vaccines; the benefit is preventing the severe COVID-19 disease and its complications, as well as preventing the transmission of the disease to others. The post-vaccine complications are rare and clinically manageable. Regarding the fetus, based on indirect information, because mRNA does not cross the placenta, the fetus is not exposed to any risk. Also, the patient should be correctly informed about the risk of developing a severe, life-threatening form of disease during pregnancy at levels greater than those for non-pregnant patients.

The existing data regarding non-live virus vaccines use during pregnancy are reassuring that there is no evidence of risk for the fetus or mother.

Regarding patients who are breastfeeding or planning to breastfeed, there is no evidence that the vaccine contaminates breast milk⁽⁵¹⁾, considering that coronavirus antibodies were identified in breast milk in infected patients and so they can provide additional immunity in the newborn. The vaccination of those breastfeeding is beneficial and should be recommended.

Regarding fertility and vaccinations, although there are rumors, there is no evidence that vaccination affects the present or future fertility. The fertility societies recommend vaccination according to eligibility criteria.

Despite information, counseling and education, some patients will refuse to get vaccinated; they should be treated respectfully and their decision must be accepted. Their refusal may be based on the CDC state that “there are currently few data on the safety of the COVID-19 vaccines, including mRNA vaccines, in pregnant people”⁽¹⁾, or on the ACOG statement that “there are no safety data specific to use in pregnancy”⁽²⁾.

Conclusions

When combining ethics with evidence-based guidance for obstetrics and gynecology patients, it is hard to assess and to be unequivocal. The physicians should use the risk-benefit ratio when they recommend vaccination to pregnant women, to those who are planning to become pregnant and to those who are breastfeeding or planning to do so. When based on a vaccination campaign, the healthcare systems will center on prevention, protectiveness and safety. ■

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