

# Inclusion of Pregnant and Lactating Persons in COVID-19 Vaccination Efforts

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As cases of coronavirus disease 2019 (COVID-19) surge across the globe, the approval of vaccines is welcome news. These vaccines are likely our most powerful intervention to stem the tide of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections. However, it will take time, political will, and widespread public support to achieve vaccination rates high enough to control the pandemic. As the U.S. Food and Drug Administration issues emergency use authorizations for vaccines, the Advisory Committee on Immunization Practices is issuing recommendations about who should receive the vaccine and their priority for receipt (1). It is important to recognize where pregnant persons fit into this national framework. Health care workers, of whom as many as 300 000 may be pregnant, are in the highest-priority tier for vaccination and are currently being vaccinated. The next wave of vaccinations will be offered to persons with medical conditions, many of whom may also be pregnant.

Following the emergency use authorization of the Pfizer-BioNTech mRNA vaccine and the Moderna mRNA-1273 vaccine, the Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists offer the following recommendations. Pregnant persons should be offered the vaccine and should be encouraged to talk with their obstetric provider about their vaccination plan, although this is not a requirement for vaccination. Lactating persons should be encouraged to receive the vaccine. Persons planning to become pregnant should be encouraged to complete their vaccination series before conception to ensure that they are protected before pregnancy.

Here, we discuss the rationale supporting these recommendations. To appreciate why pregnant women are included in these early vaccination efforts, it is important to understand the interplay between pregnancy and COVID-19. Recent reports suggest that SARS-CoV-2 infection in pregnant persons is associated with increased risk for intensive care unit admission, invasive ventilation, extracorporeal membrane oxygenation, and death (2). Although the relative risks in pregnancy are increased, the absolute risks for severe disease are low, with about 1% of pregnant women in the United States requiring admission to an intensive care unit and 1.5 deaths per 1000 pregnant women with COVID-19 (2). Pregnant women with comorbid conditions, such as hypertension, diabetes, and obesity, may have excess risk for poor COVID-19 outcomes (3). Further, the same racial and ethnic disparities in COVID-19 outcomes seen in the general population are observed in the pregnant population (4). Some, but not all, studies have observed an association between COVID-19 and risk for preterm births and cesarean deliveries (5). Taken together, the evidence suggests that pregnant women with COVID-19 have higher risk than similar nonpregnant persons for poor health outcomes and that risks may also be higher for their babies. Thus, it

is critical that pregnant persons have the opportunity to be vaccinated if they would otherwise meet the criteria for vaccination. However, because pregnant women were excluded from COVID-19 vaccination trials, we have limited information about effectiveness and safety in this group.

That said, we do have some data to help inform discussion with pregnant persons. First, these vaccines contain mRNA encapsulated in a lipid nanoparticle that is delivered into host cells. The body's own host cells generate coronavirus spike proteins that stimulate antibodies against SARS-CoV-2. This activity occurs robustly in regional lymph nodes (6). There is no biological reason to suspect that this process is different during pregnancy, so we expect similar efficacy in pregnant and nonpregnant persons. Second, these vaccines contain no live virus or adjuvants that could affect the developing fetus. Further, available data about developmental and reproductive toxicity generated from rats administered the Moderna mRNA vaccine show no safety signals concerning female reproduction, fetal or embryonal development, or postnatal development (7). Finally, although COVID-19 vaccination has been associated with fever usually lasting less than 2 days, acetaminophen is acceptable treatment of fever in pregnancy, and vaccine-associated fever is no exception. Still, concerns will linger until human pregnancy data are available. Pregnancy-specific trials will provide data to address not only safety concerns, such as vaccine-associated miscarriage or fetal anomalies, but also vaccine efficacy for mother and possibly newborn through passively transferred antibodies. The Advisory Committee on Immunization Practices and the American College of Obstetricians and Gynecologists recommend that clinicians discuss with pregnant persons COVID-19 pregnancy risks, personal factors aside from pregnancy that may increase SARS-CoV-2 infection risk or disease severity, and benefits of and unknowns about vaccination. Information for providers to use when counseling, as well as patient information, has been developed (8).

The use of vaccines to protect pregnant persons and their newborns from infectious diseases is an integral part of routine obstetric practice. Seasonal influenza vaccine protects mothers from severe illness while protecting neonates in the first several months of life. The tetanus, diphtheria, and pertussis vaccine is given in each pregnancy between 26 and 34 weeks' gestation to protect mother and baby from pertussis. These vaccines provide the best protection against known devastating effects of these viruses and have excellent safety profiles established using animal data and epidemiologic studies in pregnant women (9, 10). In the case of COVID-19, time is of the essence. Preventing ongoing severe illness due to COVID-19 for reproductive-aged women, including those who are pregnant or postpartum, necessitates

a prompt response given our current knowledge about the efficacy and safety of these vaccines.

Of note, few if any vaccines are contraindicated in breastfeeding women; even the live vaccine for measles, mumps, and rubella is routinely recommended in nonimmune women after delivery regardless of lactation status. Clinicians should encourage women who are breastfeeding to receive the COVID-19 vaccine. Given the mechanism of action of mRNA vaccines, there is no reason for concern that vaccination would introduce virus into breastmilk.

Women who meet criteria for vaccination and are planning to become pregnant should be encouraged to complete the 2-dose vaccine before pregnancy. Doing so will afford them maximal protection once they become pregnant. Although the vaccine trials required pregnancy tests before study participation, pregnancy tests should not be required before COVID-19 vaccination. Data on the outcomes of the small number of women who became pregnant in the Pfizer-BioNTech and Moderna trials are not yet available because most of these pregnancies are ongoing.

In summary, safe and effective vaccines are now available to protect people from COVID-19 and help end this devastating pandemic. On the basis of what we know about the mRNA COVID-19 vaccines, as well as broader principles of how vaccines work and the safety of other vaccines during pregnancy and breastfeeding, it seems that pregnant and lactating women can be safely included in vaccination efforts. Clinicians should be prepared to discuss the issues outlined here with their pregnant and lactating patients, as well as with those who may be considering pregnancy.

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