

COVAX Maternal Immunization Working Group

Developed by the COVAX Maternal Immunization Working Group

As the pandemic continues to evolve globally, more evidence is emerging that suggests strong benefits of maternal immunization against COVID-19. Given the new data highlighting severe health consequences associated with the Delta variant for expectant mothers, many international institutions have strengthened calls for maternal immunization against COVID-19. Access to COVID-19 vaccination during pregnancy has varied significantly over the past few months, but many countries now recommend COVID-19 vaccination for pregnant and lactating women.

“Advances in maternal immunization science and implementation in times of COVID-19” Webinar Thursday, November 18th, 2021 • 7–11am PST / 3–6pm GMT

The COVAX Maternal Immunization Working Group is pleased to invite you to a webinar workshop. During the virtual session, we will critically review the key learnings from the COVID-19 pandemic and discuss their impact on future pandemic preparedness and maternal immunization vaccine development.

An agenda and official registration for the webinar are forthcoming from our events team (eventsregistration@gatesfoundation.org). For any questions on logistics please reach out to amanda.berzins@gatesfoundation.org.

Major Recent Studies on COVID-19 Vaccination in Pregnant Women

Vaccine Safety

- Researchers from the Instituto de Efectividad Clínica y Sanitaria and the U.S. Food & Drug Administration together with a group of maternal immunization experts have conducted a [rapid systematic review](#) of studies from mostly high-income countries, supported by the Bill and Melinda Gates Foundation, which found no evidence of COVID-19 vaccine safety concerns associated with pregnancy. This assessment supports existing guidelines from the WHO regarding COVID-19 vaccination recommendations for pregnant women.
- Researchers from the University of Washington conducted a prospective [cohort study](#) to investigate short-term reactions associated with COVID-19 vaccines among pregnant and lactating individuals primarily located in the United States. The study compared vaccine reactions among pregnant and lactating individuals to reactions among individuals of similar age and fertility intentions, finding that vaccines were well-tolerated among individuals who were pregnant, lactating, or planning pregnancy.

- Researchers from the U.S. Centers for Disease Control and Prevention (CDC) published a [Letter to the Editor](#) in the New England Journal of Medicine. The authors used the CDC v-safe COVID-19 vaccine pregnancy registry to understand the risk of spontaneous abortion after mRNA COVID-19 vaccination and found that the risk is consistent with the expected risk of spontaneous abortion.
- A U.S. research team has conducted a [cross-sectional study](#) on healthcare workers that found side-effects from mRNA COVID-19 vaccines were nonlife threatening and appeared to be similar when compared with nonpregnant women, with high acceptance of the second vaccine dose.

For resources on relevant policies, documents and publications, please visit
[COVAX Maternal Immunization Working Group](#)

COVID-19 in Pregnancy

- The Department of Obstetrics and Gynaecology at the Postgraduate Institute of Yashwantrao Chavan Memorial Hospital has published a [cross-sectional study](#) that found COVID-19 pneumonia puts obstetric patients at risk of poor maternal outcomes.
- The Department of Obstetrics and Gynecology at the Mayanei Hayeshua Medical Center of the Sackler School of Medicine, Tel Aviv University conducted a [retrospective cohort study](#) to assess the effect of COVID-19 on obstetric outcomes based on symptom status of pregnant patients at or near term. [The study](#) found that symptomatic COVID-19 patients at or near term were at an increased risk of general and neonatal adverse outcomes in comparison to asymptomatic COVID-19 patients and COVID-19-negative patients at or near term.
- A Canadian and Brazilian research team found that mortality was elevated in patients with COVID-19 when studying pregnant and recently pregnant women with SARS-CoV-2 infection and other severe acute respiratory infections in Brazil. The study found that mortality from COVID-19 and other respiratory infections was particularly present in regions where maternal mortality is already high.
- A British research team conducted a [national cohort study](#) using the UK Obstetric Surveillance System to understand the incidence, characteristics and outcomes of pregnant women hospitalized with SARS-CoV-2 infection. The study identified certain patient groups that had a higher incidence of symptomatic SARS-CoV-2 hospitalization. These groups include individuals who were overweight or obese, who were of an ethnic minority group, or who had a relevant medical comorbidity. Regardless of the mother's symptom status, pregnant women who were hospitalized with COVID-19 were more likely to have preterm births and babies born were more likely to be admitted to a neo-natal unit.
- The CDC COVID-19 Response Team in Atlanta has published a [retrospective cohort analysis](#) that found pregnant women with COVID-19 at time of delivery had higher risks for adverse pregnancy outcomes, maternal complications and severe illness than pregnant patients without COVID-19.

- A research team at the University of Alabama conducted a [retrospective cohort study](#) and found that the Delta variant of COVID-19 is associated with serious morbidity and adverse perinatal outcomes during pregnancy. All cases of hospitalized COVID-19-positive pregnant patients were individuals who were unvaccinated.

Vaccine Effectiveness

- The National Institutes for Health began an [observational study](#) in June 2021 to evaluate antibody responses in vaccinated participants and their infants, through its National Institute of Allergy and Infectious Diseases.
- A [prospective study](#) by researchers at NYU Langone found that pregnant women who are vaccinated against COVID-19 with mRNA vaccines pass high levels of antibodies to their babies. 100% of neonates in the study (n=36) had protective antibodies at birth and the highest levels of antibodies in cord blood were found in mothers who were fully vaccinated during the second half of their pregnancies.
- The results of an [observational cohort study](#) were published by a team of Israeli and American researchers. The researchers estimate that the mRNA COVID-19 vaccine has high effectiveness in pregnant women, at similar levels to the effectiveness estimated in the general population.
- An Israeli team of researchers conducted a [retrospective cohort study](#) and found that mRNA vaccination in pregnant women is associated with a significantly lower risk of SARS-Cov-2 infection when compared to patients with no vaccination.

Maternal Immunization Policies

The [COVID-19 Maternal Immunization Tracker](#) (COMIT) provides a global snapshot of public health policies that shape access to COVID-19 vaccines for pregnant and lactating women.

As of October 6, 2021, there are 51 countries that have an explicit recommendation that some or all pregnant women should receive vaccination. COVID-19 vaccination for pregnant women remains not recommended in 31 countries and not recommended but with exceptions in an additional 8 countries.

Current Recommendations

As of October 5, 2021



CDC: The CDC issued an urgent health advisory to increase COVID-19 vaccination among people who are pregnant, recently pregnant (including those who are lactating), are trying to become pregnant now, or who might become pregnant in the future. This recommendation and [health alert](#) comes amid data indicating [increased risk](#) of severe illness, death, and [pregnancy complications](#) for pregnant and recently pregnant people with COVID-19.



WHO: The WHO has issued [interim recommendations](#) that encourage vaccination in pregnant women who are at high risk of exposure to COVID-19 or have comorbidities that place them in a high risk group for severe COVID-19. The WHO also recommends vaccination in lactating women as vaccination is unlikely to pose a risk to the breastfeeding child.



RCOG: RCOG recommends COVID-19 vaccines in pregnant and breastfeeding women. Women may wish to consult their healthcare professional, although this is not a necessary step and pregnant women can receive a COVID-19 vaccine without prior discussion with a healthcare professional. RCOG notes that the Joint Committee on Vaccination and Immunization advises it is preferable for pregnant women in the UK to be offered Pfizer-BioNTech or Moderna mRNA vaccines, where available.



ACOG: ACOG [strongly recommends](#) vaccination of pregnant individuals and “encourages its members to enthusiastically recommend vaccination to their patients.” This recommendation comes amid a rise in COVID-19 cases due to the Delta variant and [low rates of vaccination](#) in pregnant people in comparison to non-pregnant people.



FDA: The FDA has granted approval to the Pfizer-BioNTech COVID-19 vaccine, which will now be marketed as Comirnaty. Although not required by the FDA, Pfizer has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes.



NHS: The NHS encourages pregnant women to get the COVID-19 vaccine as new data is released that shows nearly 20% of the most critically ill COVID patients in the U.K. are unvaccinated pregnant women. Nearly one in five COVID-19 patients receiving treatment through a special lung-bypass machine since July were unvaccinated expectant mothers.

Related News

Novavax and the **Serum Institute of India** [applied to the WHO](#) for emergency use listing for their COVID-19 vaccine on September 23. Approval for emergency use would be an important milestone as Novavax seeks to send doses to low and middle-income countries and begin distribution of doses through the COVAX facility.

Clover Biopharmaceuticals has found that their COVID-19 vaccine was 67% effective against COVID-19 and 79% effective against the Delta variant in a [large trial](#). Clover Biopharmaceuticals has an existing deal to supply up to 414 million doses through COVAX.

Country Experiences

India releases operational guidelines for vaccinating pregnant women against COVID-19

On July 2, 2021, after months of deliberation, the government of India released [operational guidelines](#) for vaccinating pregnant women against COVID-19, which apply to the three vaccines currently authorized in India: Covishield, Sputnik V, and Covaxin. These [new guidelines](#) were released after the country's second wave overwhelmed the healthcare system. [Pregnant women](#) have been [particularly affected](#) by the virus. Vaccines were approved for lactating and breastfeeding women in May, yet pregnant women were excluded from vaccination due to government concerns about safety, leaving them especially [at risk](#) of COVID-19-related hospitalization and death. Overall, vaccination has recently ramped up in India, with over 924 million shots administered and 225M individuals fully vaccinated as of [October 5](#).

Pan American Health Organization urges countries to prioritize pregnant and lactating women for COVID-19 vaccination

Carissa F. Etienne, Director of PAHO, [urged countries](#) to prioritize pregnant and lactating mothers for COVID-19 vaccinations: “We know that if pregnant women get sick, they have a higher risk of developing serious COVID symptoms, and more frequently require ventilation and intensive care, when compared to women who aren't pregnant. They also have a higher chance of delivering their baby early or pre-maturely.”

There are more than [270,000 cases of COVID-19](#) in pregnant women in the Americas. In Mexico and Colombia, COVID-19 is the leading cause of maternal deaths in 2021. Vaccine access varies greatly among countries, with 28% of people in Latin American and the Caribbean fully vaccinated, but less than 1% of the population in Haiti.

Canada urges pregnant women to get COVID-19 vaccine

New data from Canada finds that pregnant individuals are facing more hospitalizations than their non-pregnant peers. [Data has shown](#) that pregnant women are five times more likely to be admitted to hospitals for COVID-19 and 10 times more likely to end up in the ICU. The latest wave of COVID-19 is highlighting how COVID-19 is affecting pregnant women, with a [near doubling](#) of preterm births for mothers fighting COVID-19 versus the baseline population. The provincial health officer of British Columbia, Dr. Bonnie Henry, has [urged](#) pregnant women, breastfeeding mothers, and women wanting to become pregnant to get the COVID-19 vaccine.

Resources

Click on the logo of each organization to learn more.

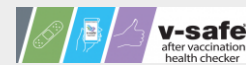


Royal College of
Obstetricians &
Gynaecologists

Royal College of Obstetricians & Gynaecologists:

[Guidance on COVID-19 vaccine, pregnancy, and breastfeeding](#)

Latest advice is that COVID-19 vaccines should be offered to pregnant women at the same time as the rest of the population, based on their age and clinical risk group.



CDC [v-safe Safety Monitoring and v-safe Pregnancy Registry](#)

As of October 4, more than 163,000 v-safe participants have indicated they were pregnant at the time they received COVID-19 vaccination, and 5,104 have enrolled in the v-safe COVID-19 Vaccine Pregnancy Registry.



London School of Hygiene & Tropical Medicine:

[COVID-19 Clinical Trials Tracker](#)

As of October 14, 2021, of 430 clinical trials for COVID-19 vaccines (ongoing and recruiting), only 5 studies include pregnant women.