



## COVID-19 vaccination in pregnancy

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Dear Editor,

The COVID-19 global pandemic, caused by the new SARS-CoV-2 Coronavirus, is still ongoing. A massive worldwide vaccination campaign began a few months ago [1]. Pharmacological therapeutic treatments are aimed at avoiding serious complications of the infection; antivirals directed against the SARS-CoV-2 virus are not yet available [2–4]. Certain population groups, such as the elderly and individuals with comorbidities, are at increased risk of severe infection. Evidence shows that pregnant women may also be at increased risk; this population category is particularly vulnerable to emerging infectious pathogens because of the alterations in immune and respiratory physiology that occur during pregnancy [5]. Therefore, preventing COVID-19 infection with vaccination can be important both for the mother and for the foetus. To date, vaccines with different mechanisms of action (e.g. mRNA, viral vector and protein subunit) are available, either authorised or investigational. Unfortunately, to date, clinical data supporting the efficacy and safety of COVID-19 vaccines in pregnant and lactating women are limited, due to the exclusion of pregnant women from pre-registration trials. For this reason, no clear recommendations about COVID-19 vaccination in pregnancy and lactation have been issued yet [6, 7]. The Center for Disease Control and Prevention (CDC) and the FDA have activated systems to monitor the safety

of COVID-19 vaccines during pregnancy and will closely monitor this information. Preliminary data from these systems are reassuring, and have not identified any safety concerns for pregnant people or their babies. In addition, the World Health Organization (WHO) suggests considering vaccinating pregnant women at high risk for infection (e.g. health care workers) or who have comorbidities. Recently, rare cases of thrombosis associated with thrombocytopenia have been identified following administration of viral vector COVID-19 vaccines [8]. Given that pregnant women have a higher rate of developing thrombosis than the general population [9], more clinical data in this patient population is warranted. There is a clear concern about receiving COVID-19 vaccination in pregnancy and lactation given the lack of efficacy and safety data from available vaccines in this patient population. Therefore, it is critical to derive post-marketing data to monitor the safety profile of these vaccinations for pregnant and lactating women in actual clinical practice through the implementation of rigorously designed studies.

### Declarations

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**Availability of data and materials** Full availability of data and materials.

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