Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

The need for a global COVID-19 maternal immunisation research plan

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There is evidence that COVID-19 threatens maternal and perinatal health. Pregnant women, especially in the second half of pregnancy, are at increased risk of complications—eg, severe pneumonia, hospitalisations, admission to intensive care unit, invasive mechanical ventilation—and death from COVID-19 compared with age-matched non-pregnant women.[1–3] Existing evidence also suggests that pregnant women with COVID-19 are at higher risk of having a preterm delivery and that their neonates are three times more likely to be admitted to hospital than those born to mothers without COVID-19.[4,5]

Pregnant women are not recognised as a high-priority group for COVID-19 vaccination, despite the risk of complications and poor perinatal outcomes.[6] Pregnant women were excluded from early COVID-19 vaccine research, resulting in a missed opportunity to generate safety and efficacy data, and potentially affecting whether pregnant women will receive the benefits of COVID-19 vaccines.

Reasonably, safety knowledge gaps lead vaccine developers to systematically exclude pregnant women from early clinical studies. However, preclinical and clinical data suggest an acceptable safety profile for most COVID-19 vaccines in development.[7–9] Furthermore, after emergency use authorisation for COVID-19 vaccines by the US Food and Drug Administration and support from the US Centers for Disease Control and Prevention[10] and the American College of Obstetricians and Gynecologists,[11] and a similar stance from the UK Joint Committee on Vaccination and Immunisation,[12] a substantial number of pregnant and lactating women are likely to be vaccinated if they also belong in high-priority risk groups for vaccination.

There is an urgent need for a proactive, global COVID-19 immunisation plan for the evaluation of COVID-19 vaccines in pregnant women in clinical trials before and after COVID-19 vaccine allocation. This plan should be based on a clear understanding of the effects of COVID-19 on pregnant women, the fetus, and the newborn baby (risks of the disease), as well as of the safety profile of COVID-19 vaccines (risks of the vaccine) and their efficacy. Such knowledge is needed for risk–benefit analyses to inform COVID-19 vaccine trials in pregnancy and the use of COVID-19 vaccines in pregnant women before and after regulatory approvals. The use of an approved vaccine in pregnant women needs to be supported by a favourable balance between the benefit and minimum risk for the mother and fetus, in the context of this pandemic. The collection of specific safety data in pregnancy is crucial to enable pregnant women and health-care providers to make informed decisions.

The criteria to be met by COVID-19 vaccine candidates for their evaluation and use in pregnancy need to be clearly defined. These criteria could include the completion of developmental and reproductive toxicology studies in appropriate animal models, and ascertainment of an acceptable reactogenicity profile with a low incidence of maternal fever after vaccination. Obtaining safety data in pregnancy is of particular relevance given the novelty of some of the COVID-19 vaccine platforms and adjuvants. Research protocols should include comprehensive and rigorous monitoring of maternal, perinatal, and infant safety endpoints, given the potential for obstetric and perinatal events and possible perception of an association with the vaccination. Immunogenicity information relevant to pregnancy is necessary, including documenting the immune response during pregnancy and the passage of vaccine-induced antibodies through the placenta and breastmilk, given the potential for infant protection through maternal immunisation.[13] Understanding the

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impact of maternal infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in different trimesters of gestation would help determine the optimal timing of vaccination to protect the pregnant mother from severe COVID-19 and its complications.

The perspectives of low-income and middle-income countries (LMICs) are also important for the evaluation and implementation of COVID-19 vaccines in pregnancy. COVID-19 cases and deaths in southeast Asia, Central and South America, and, to some extent, Africa[14] contribute a meaningful proportion of the global confirmed COVID-19 cases and deaths. The inclusion of pregnant women from LMICs in COVID-19 vaccine research is of relevance not only for individual benefit but also for overall societal benefit, because women of reproductive age are represented in essential groups in LMICs—eg, health-care providers, carers of children, and the workforce.

Globally, there are more than 213 million pregnancies every year, of which an estimated 190 million (89%) occur in low-resource settings,[15] where the risks of poor obstetric and perinatal outcomes are highest. The inclusion of pregnant women in COVID-19 vaccine research plans is imperative to provide informed, fair, and equitable opportunities for all pregnant women and their infants, and maximise the impact of COVID-19 vaccines worldwide.

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Azucena Bardají, Esperança Sevene, Clare Cutland, Clara Menéndez, Saad B Omer, Teresa Aguado, Flor M Muñoz

azucena.bardaji@isglobal.org

ISGlobal, Hospital Clínic, Universitat de Barcelona, Barcelona, 08036, Barcelona, Spain (AB, CM, TA); Manhiça Health Research Centre, Centro de Investigação em Saúde de Manhiça, Maputo, Mozambique (AB, ES, CM); Consorcio de Investigación Biomédica en Red de Epidemiología y Salud Pública, Madrid, Spain (AB, CM); Department of Physiological Sciences, Clinical Pharmacology, Faculdade de Medicina, Universidade Eduardo Mondlane, Maputo, Mozambique (ES); African Leadership in Vaccinology Expertise (ALIVE), Faculty of Health Sciences, University of the Witwatersrand, Parktown, Johannesburg, South Africa (CC); Yale Institute for Global Health, Department of Internal Medicine, Yale School of Medicine, Department of Epidemiology of Microbial Diseases, Yale School of Public Health, Yale School of Nursing, New Haven, CT, USA (SBO); Department of Pediatrics and Department of Molecular Virology and Microbiology, Baylor College of Medicine, Houston, TX, USA (FMM)

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