

In the race for coronavirus vaccines, don't leave pregnant women behind

By Carleigh Krubiner, Ruth R. Faden, and Ruth A. Karron

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Adobe

As several thousand people become newly infected each day with the novel coronavirus Covid-19, and some die of it, there are accelerated efforts to develop [new coronavirus vaccines](#)². The World Health Organization has activated its [R&D Blueprint](#)³, [new investments](#)⁴ are in the pipeline, and [multiple vaccine candidates](#)⁵ are expected to advance to clinical trials.

But as the world rushes to develop new vaccines against Covid-19, there is a real risk that pregnant women and their babies will not be among those who are able to benefit from them.

Ensuring there's a vaccine that can be offered to pregnant women is critical to health equity. While there are only [limited data](#)⁶ on how severe Covid-19 infection is in pregnancy, data from other coronaviruses suggest that pregnant women may face [more severe disease](#)⁷, [adverse obstetrical outcomes](#)⁸, and greater mortality from them. Development of coronavirus vaccines that pregnant women aren't able to use would be not only a tragedy but a grave injustice.

Yet if old paradigms persist, that is exactly what will transpire.

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Historically, the interests of pregnant women have not adequately featured in global responses to outbreaks and epidemics. Funders have not asked if the vaccine candidates they are investing in are suitable for pregnant women, and pregnant women have not been included in vaccine trials. The [absence of data](#)¹⁰ about the effects of vaccines during pregnancy has in turn resulted in [delays or outright denials of access](#)¹¹ to lifesaving vaccines, as evident in recent responses to Ebola outbreaks.

There is absolutely no reason for history to repeat itself. [Increasing recognition](#)¹² that this state of affairs is ethically unacceptable and [efforts to change](#)¹³ the status quo are underway. In 2019, the [PREVENT Working Group](#)¹⁴, which we co-lead, issued [22 specific recommendations](#)¹⁵ to promote equity for pregnant women and their babies in epidemic vaccine development and response. The implementation of even three or four of these recommendations will go a long way toward ensuring that pregnant women will not be left behind this time around.

Collecting data. Health information systems and infectious disease surveillance systems should ensure that data relevant to maternal, obstetric, and newborn health outcomes are routinely collected to inform scientific and public health responses to Covid-19 and similar coronaviruses.

The inclusion of pregnancy status in case-reporting forms from the WHO and [U.S. Centers for Disease Control and Prevention](#)¹⁶, among others, is a positive step toward systematically gathering this essential information and should be a model for how other public health agencies move forward in their own surveillance efforts. This information is needed to identify whether pregnant women and their offspring face elevated risks during outbreaks as well as to understand the risk-benefit profile of vaccines.

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[CDC expects 'community spread' of coronavirus, as top official warns disruptions could be 'severe'](#)¹⁸

Suitability for use in pregnancy. During development and investment decisions for vaccines against Covid-19, organizations investing in this pipeline should ensure that one or more of the vaccine candidates will be suitable for use in pregnancy. Early and ongoing investment in options that are most likely to be acceptable in pregnancy can pave the way for pregnant women and their offspring to realize benefits from vaccine candidates that ultimately prove successful — and help ensure that they, like other groups, will be protected against this new infectious disease threat.

Earlier non-clinical studies. With candidate Covid-19 vaccines accelerating rapidly toward clinical trials, vaccine developers should work with regulatory agencies and oversight authorities to determine what types of reproductive and developmental toxicology studies will be needed before enrolling pregnant women in later-stage trials. Because these types of non-clinical studies can take several months to complete, they should be started early in the

development process so pregnant women will not be barred from enrolling in vaccine trials with acceptable risk-benefit profiles.

Pregnant women should have opportunities. During this outbreak of Covid-19 — and in all future infectious disease outbreaks — large-scale efficacy trials for promising vaccines should assume that pregnant women are eligible to be enrolled *unless* the risks outweigh the benefits. To do otherwise is to incur a double injustice: denying pregnant women who might benefit from access to an experimental vaccine in an outbreak a fair chance to receive it, and denying all pregnant women the evidence base needed to make the right decision about access during a public health response.

Many of the Covid-19 vaccine candidates are using novel platforms or adjuvants. If these prove to be effective, they could become the norm for other kinds of epidemic vaccines. If pregnant women are not appropriately and fairly included in the evaluation of these novel “plug-and-play” platforms, the negative impacts on their future access to beneficial epidemic vaccines may extend far beyond the Covid-19 outbreak, leaving them unprotected against a wide array of infectious disease threats.

We don’t know how the risks pregnant women face from Covid-19 compare to the risks that other population groups face, and it is impossible to predict if a vaccine will be available in time to respond to this new threat. But we do know that pregnancy offers no protection against coronaviruses.

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Links

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