

Zika epidemic highlights need for priority vaccine research for pregnant women

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Credit: National Cancer Institute

The recent outbreak of Zika virus disease and its link to fetal development highlights the need for pregnant women and those of reproductive age to be a priority group for developing and evaluating new vaccines and vaccine guidelines for Zika and other emerging infectious diseases, say the authors of a new Viewpoint article in *JAMA*.

Three recent global infectious disease outbreaks - H1N1 influenza, Ebola and Zika have had specific implications for pregnant women and their unborn children, yet the global [public health](#) community lacks the best tools for dealing with this special group.

Public health policy and research must overcome several barriers to developing vaccines for pregnant women, say authors Saad B. Omer, MBBS, PhD, professor of global health, epidemiology and pediatrics at Emory University and Richard H. Beigi, MD, MSc, associate professor of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh Medical Center and chief medical officer at Magee-Womens Hospital of UPMC.

"These barriers are surmountable with concerted efforts and leadership," say the authors. "Strategic planning and action have allowed for advances in pediatric drug development and provide a good model. However, the time to act is now, before the next epidemic takes its toll."

Barriers include:

- The lack of a broadly accepted ethical framework and definition of risk for guiding clinical research during pregnancy, which has a limiting effect on both academic and industry-led [clinical trials](#). Institutional review boards often categorize research involving pregnant women as high risk without considering the balance between the benefits and the risks to both mothers and their unborn children. A pregnancy-specific ethical framework is needed to guide investigators and Institutional Review Boards (research ethics committees).
- A knowledge gap exists for vaccine responses in early pregnancy. Most of the current knowledge about vaccine responses comes from observational studies conducted in the latter part of pregnancy, with limited data available from the first and early

second trimesters or from randomized clinical trials. But since a substantial part of the harmful effects of Zika virus infection may occur in the early part of pregnancy, administering vaccines prior to pregnancy or early in pregnancy may be most beneficial, and more clinical research is needed for this time period.

- Consistent guidance on drug and vaccine labels is lacking for pregnant women. The Food and Drug Administration (FDA) recently issued the Pregnancy and Lactation Labeling Rule (PLLR), which creates clinically relevant and clear information on labels regarding risks and benefits for pregnant and lactating women and for males and females of reproductive age. However, the implementation of PLLR faces many logistical challenges. A "mock label" related to pregnancy and lactation is needed as a sample to help industry and public health leaders effectively phase in this new system. Clinicians who provide obstetrical care need to have clear explanations of the new categorization system.
- Standard definitions are needed for measuring outcomes when evaluating vaccine safety studies in pregnant women, a problem recently highlighted by the World Health Organization. The lack of standardization poses a problem as researchers try to merge data from different clinical trials that could optimize the evaluation of rare but clinically important outcomes such as microcephaly.
- More baseline data is needed for risk vs. benefit for emerging infections in different geographic locations, particularly in the context of other infections (such as malaria) that are associated with adverse birth outcomes.

Efforts to improve the quantity and quality of research in vaccines and drugs for [infectious diseases](#) in children could be translated into increased research for [pregnant women](#), the authors say. The Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act were enacted to address the lack of information available to prevent and

treat disease in children, and similar legislation could foster more research in pregnancy and pre-[pregnancy](#) and overcome the barriers to better vaccines and more effective clinical practices.

Provided by Emory University

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