Pregnant Women & the Zika Virus Vaccine Research Agenda: Ethics Guidance on Priorities, Inclusion, and Evidence Generation

The Policy

Synopsis

The Wellcome Trust [9], a global charitable foundation, funded the formation of the Ethics Working Group of ZIKV Research & Pregnancy [10] to analyze the ways in which pregnant women can be fairly and ethically included in Zika virus (ZIKV) vaccine research and development. This group formed in response to the recent rapid spread of ZIKV; their recognition of the general exclusion of pregnant women from vaccine research and development, including for ZIKV; and their acknowledgement that pregnant women at risk of contracting ZIKV have a particular interest in protecting the health of themselves and their offspring through mechanisms such as vaccines.

The working group developed a report entitled Pregnant Women & the Zika Virus Vaccine Research Agenda: Ethics Guidance on Priorities, Inclusion, and Evidence Generation [11], which is intended for various stakeholders in ZIKV vaccine research and development. These stakeholders include health organizations, policymakers, vaccine developers, researchers, health providers, patients, and human trials participants, among others.

The report first asserts three ethical imperatives of Zika virus vaccine research as they pertain to pregnant women:

1. "The global health and public health community should prioritize development of ZIKV vaccines that will be acceptable for use by pregnant women in the context of an outbreak;"
2. "The development of all ZIKV vaccines targeted to women of childbearing potential, whether expected to be acceptable for use in pregnancy or not, should include timely collection of data to inform judgments about safety and efficacy of administration in pregnancy;" and
3. "Pregnant women at risk of ZIKV infection should have fair access to participating in ZIKV vaccine trials that carry the prospect of direct benefit."

More broadly, the authors outline four ethical principles in regards to pregnant women’s participation in biomedical research:

1. "Pregnant women deserve an evidence base for the prevention and treatment of their illnesses equal to others as a matter of justice;"
2. "Pregnant women should not be categorized as a ‘vulnerable population’ for purposes of human subjects research review;"
3. "It is ethically permissible to conduct research with pregnant women that meets specific risk standards;" and
4. "Justice requires that pregnant women have fair access to research that offers the prospect of direct benefit."

The working group utilized these imperatives and ethical principles to develop fifteen recommendations regarding how relevant actors can safely and ethically include pregnant women and their interests in various stages of ZIKV vaccine research and development:

1. "Pregnant women should be affirmed as a priority population for ZIKV vaccines intended for use in areas experiencing ongoing transmission and in future outbreaks;"
2. "Financial and other in-kind resources should be allocated to fund and facilitate development of ZIKV vaccines that will be acceptable for use in pregnancy;"
3. "Incentives should be identified and utilized to encourage the development of ZIKV vaccines that will be acceptable for use during pregnancy;"
4. "Data should be collected regarding outcomes of safety and efficacy of vaccine administration during pregnancy;"
5. "Prospective studies should be conducted with pregnant women who receive the vaccine in public health and clinical settings to systematically collect data from them and their offspring;"
6. "Data should be collected regarding outcomes of safety and efficacy of administration during pregnancy from instances in which trial participants are unknowingly pregnant or become pregnant within a relevant window of time;"
7. "In the case that a vaccine is inadvertently administered to a pregnant woman, systematic collections and analyses of safety and efficacy data from them and their offspring should be carried out;"
8. "At least one expert in maternal health and one expert in pediatrics should be involved in vaccine research and development activities;"
9. "The perspectives of pregnant women should be taken into account in designing and implementing ZIKV vaccine trials in which pregnant women are enrolled or in which women enrolled may become pregnant;"
The Debate

Endorsements & Opposition

At present, there has not been any publicly reported endorsement or opposition to this report.
Regarding the broader issue of including pregnant women in clinical research trials, the following endorsements have been made:

- Dr. Kristine E. Shields[33] and Dr. Anne Drapkin Lyerly[29] stated in their 2013 *Obstetrics & Gynecology article* [34]: “We found the exclusion of pregnant women from industry-sponsored clinical trials to be common practice. Moving beyond reflexive exclusion and developing thoughtful criteria for inclusion of pregnant women in clinical research would likely advance the evidence base to inform treatment decisions during pregnancy and lead to better health outcomes for women and children.”

- A team of physicians and researchers from the US Food and Drug Administration and the National Institutes of Health stated in a 2013 *Women’s Health Issues* article [35]: “There is a clear and compelling rationale for increased pregnancy research in order to address the pressing therapeutic needs of pregnant women. Additionally, there is accumulating evidence that pregnancy provides a unique window into understanding fundamental mechanisms underlying observed links between a pregnant woman’s health and her later health and the health of her children. While pregnancy research raises myriad complex issues and challenges, its clinical value and its potential for generating new scientific knowledge about lifespan and intergenerational development demand that the challenges be met.”

- Dr. Ruth Macklin[36] stated in an article [37] in the *International Journal of Feminist Approaches to Bioethics* “Although no one questions the importance of preventing pregnant women, their fetuses, and their future children from avoidable harms that could be caused by experimental drugs, several reasons can justify the inclusion of pregnant women in a greater number of biomedical studies than current practice allows. The most compelling reason is the need for evidence gathered under rigorous scientific conditions, in which fewer women and their fetuses would be placed at risk than the much larger number who are exposed to medications once they come to market.”

Regarding the inclusion of pregnant women in vaccine research, the following opposition has been made:

- Dr. Matthew Memoli[38], director of the clinical studies unit in the Laboratory of Infectious Diseases at the National Institutes of Allergy and Infectious Diseases, stated in an interview [39]: “We always have to test these [vaccines] in a healthy population before we put pregnant mothers and their fetuses at risk.”

**Status**

The document was published in June 2017.

**Recommended Citation**


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