MedicalXpress

NIH launches large study of pregnant women in areas affected by Zika virus

June 21 2016

The National Institutes of Health and Fundacao Oswaldo Cruz-Fiocruz (Fiocruz), a national scientific research organization linked to the Brazilian Ministry of Health, have begun a multi-country study to evaluate the magnitude of health risks that Zika virus infection poses to pregnant women and their developing fetuses and infants. The study is opening in Puerto Rico and will expand to several locations in Brazil, Colombia and other areas that are experiencing active local transmission of the virus.

Zika virus is spread primarily through bites from infected *Aedes aegypti* mosquitoes, although other forms of transmission—notably, mother-to-child and sexual transmission—also occur. Active virus transmission currently is ongoing in 60 countries and territories. The virus has been linked to a spike in cases of microcephaly, a condition in which babies are born with abnormally small heads and possible neurological damage, sparking international concern. In addition to microcephaly, other problems have been detected in pregnancies and among fetuses and infants infected with Zika virus before birth, including miscarriage, stillbirth, absent or poorly developed brain structures, eye defects, hearing deficits, and impaired growth.

The Zika in Infants and Pregnancy (ZIP) study aims to enroll as many as 10,000 pregnant women ages 15 years and older at up to 15 sites. The participants will be in their first trimester of pregnancy and will be followed throughout their pregnancies to determine if they become infected with Zika virus and if so, what outcomes result for both mother

and child. The participants' infants will be carefully followed for at least one year after birth.

The National Institute of Allergy and Infectious Diseases (NIAID), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), and the National Institute of Environmental Health Sciences (NIEHS), all part of the NIH, are funding and conducting the study, along with Fiocruz.

"The full scope of the effect of Zika virus in pregnancy has not yet been fully determined," said NIAID Director Anthony S. Fauci, M.D. "This large prospective study promises to provide important new data that will help guide the medical and public health responses to the Zika virus epidemic."

"Zika virus has spread rapidly through the Americas," said NICHD Acting Director Catherine Y. Spong, M.D. "We anticipate that this study will provide important information on the link between Zika infection and pregnancy complications and inform strategies to help safeguard the health of mothers and their newborns."

"A mother's environment may be an important part of the Zika virus puzzle," said NIEHS Director Linda Birnbaum, Ph.D. "We've included environmental measures in the study and will also be evaluating nutrition and socio-economic status."

The researchers plan to compare birth outcomes between mothers who were infected with Zika virus and those who were not, documenting the frequency of miscarriage, preterm birth, microcephaly, malformations of the nervous system, and other complications. The researchers also seek to compare the risk of pregnancy complications among women who have symptoms of Zika virus infection and those who are infected but do not have symptoms. Additionally, the study will evaluate how the timing

of infection affects pregnancy outcomes and the role environmental influences, social determinants and other infections, such as dengue virus infection, may play on the health of the study participants and their newborns.

Women participating in the ZIP study will be monitored monthly for the duration of their pregnancies and then six weeks after delivery. They will have a physical examination and be asked to provide blood, urine, saliva and vaginal swab samples at study entry and at each monthly prenatal care visit. If the participants note that they will be receiving an amniocentesis in connection with their clinical care, the research team will arrange with the participant and her obstetrician to obtain a sample of the amniotic fluid to test for Zika infection. The participants will be instructed about the signs and symptoms of acute Zika virus infection and will be asked to notify their clinic immediately if they experience symptoms. Post-delivery, a breast milk sample, if available, will be obtained for Zika testing. Infants whose mothers consent to their participation in the study will be evaluated within 48 hours of birth and again at three, six and 12 months.

"This study, in partnership with NIH, is essential to elucidating the scientific complexity of the Zika virus," said Fiocruz President Paulo Gadelha. "It will be fundamental to developing prevention and treatment strategies against the disease."

It is important to note that the ZIP study is a research effort that is distinct from and complementary to public health registries underway in the United States (U.S. Zika Public Health Registry), Puerto Rico (Zika Active Pregnancy Surveillance System), and Colombia (SIVIGILA/Projecto Vez). These registries are population-based and collect observations from medical evaluations and testing with the intent of providing information for public health action.

For more information about the ZIP study, see Questions and Answers: The Zika in Infants and Pregnancy (ZIP) Study.

More information: www.niaid.nih.gov/news/QA/Pages/ZIP-QA.aspx

Provided by NIH/National Institute of Allergy and Infectious Diseases