

## CONGENITAL ZIKA SYNDROME: TIME TO CENTRALIZE DATA IN AN INTERNATIONAL REGISTRY

Alice Panchaud<sup>1,2,3</sup>, Patrick Gerardin<sup>4,5,6</sup>, Audrey Merriam<sup>7</sup>, Anna Gonc <sup>8</sup>,  
Didier Musso<sup>9</sup>, Manon Vouga<sup>10</sup>, Sonia Hernandez-Diaz<sup>1</sup>, David Baud<sup>11</sup>

<sup>1</sup>Epidemiology, Harvard T.H Chan School of Public Health, Boston, USA, <sup>2</sup>Swiss Teratogen Information Service, University of Lausanne and University Hospital, Lausanne, Switzerland, <sup>3</sup>School of Pharmaceutical Sciences, University of Geneva and Lausanne, Geneva, Switzerland, <sup>4</sup>P le Femme Enfant, Centre Hospitalier Universitaire, Saint Pierre, Reunion Island, France, <sup>5</sup>Centre for Clinical Investigation, Clinical Epidemiology, Saint Pierre, Reunion Island, France, <sup>6</sup>UU 134 Pimit, Cyroi, Universit  De La R union, Sainte Clotilde, France, <sup>7</sup>Division of Maternal Fetal Medicine, Department of Obstetrics and Gynecology, Columbia University Medical Center, New York, USA, <sup>8</sup>Department of Maternal Fetal Medicine, BC Natal, Hospital Cl nic Universitat De Barcelona, Barcelona, Spain, <sup>9</sup>Unit of Emerging Infectious Diseases, Institut Louis Malard , Tahiti, French Polynesia, <sup>10</sup>Institute of Microbiology, Faculty of Biology and Medicine, University of Lausanne and University Hospital, Lausanne, Lausanne, Switzerland, <sup>11</sup>Materno Fetal and Obstetrics Research Unit, Department "Femme M re Enfant", University of Lausanne and University Hospital, Lausanne, Switzerland

**Objective:** Nearly one year after the initial report on the increase in prevalence of microcephaly in Brazil, the magnitude of the risks of maternal–fetal Zika virus (ZIKV) transmission, the full composition of the spectrum of the congenital Zika syndrome (CZS), as well as potential associated co-factors remain to be defined. Moreover, the first follow-up data raised questions on long-term developmental outcomes of infants born with CZS or born after a potential intrauterine ZIKV exposure. A prospective cohort study aiming to answer the numerous questions regarding the risks linked to ZIKV in pregnancy with a global perspective is warranted.

**Method:** To address these key research questions, we have launched an international web registry to enroll anonymously pregnant women, at any gestational age, exposed to ZIKV (i.e., mosquito bite, unprotected sexual intercourse with a ZIKV infected person, or other) with or without positive ZIKV test results. Health-care practitioners contact the registry and provide information on their patients. Only well-documented cases enrolled before any additional screening are considered eligible (<https://epgl.unige.ch/zika-in-pregnancy-registry/>). Baseline information on sociodemographic characteristics and other risk factors is collected at enrolment. Follow-up information on pregnancy, fetal, and neonatal outcomes is gathered within 12 weeks after birth. The study population is stratified for analysis based on gestational age and prenatal screening test status at enrolment. Outcomes in pregnancies with a confirmed positive ZIKV test are compared with those in the reference group of pregnancies potentially exposed to the virus but with a negative test. The registry has been approved by Swissethics in June 2016.

**Results:** As of November 2016, 71 mother-infant pairs have been enrolled in the registry and 33 collaborators are entering data or ready to do so stemming from 20 different countries from both endemic and non- endemic areas. Efforts continue to increase enrollment for the purpose of enhancing the capacity to estimate the risk of maternal–fetal ZIKV transmission.

**Conclusion:** This centralized international dataset will allow researchers to acquire a comprehensive characterization of the risks associated to ZIKV maternal-fetal transmission and may serve as basis of inclusion for long-term follow-up of children born with congenital Zika syndrome or exposed to ZIKV prenatally.