

Title: International Shipment of Zika Samples from Brazil

Activities: Transport samples internationally; Develop or update data and specimen sharing policies

Stakeholders: World Health Organization; National and subnational health authorities

Phases: Surveillance and preparedness; Detection; Early response; Intervention

Years: 2016

Countries: Brazil

Agent: Zika

Case study prepared by: Emily Sherman, July 22, 2019

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On February 1, 2016, the World Health Organization (WHO) declared clusters of microcephaly and associated neurological disorders associated with the Zika virus (ZIKV) in Brazil a Public Health Emergency of International Concern (PHEIC).¹ Days later, United Nations and United States officials expressed concern over a lack of ZIKV samples being shared internationally by Brazil. By February 3, 2016, it was estimated that less than twenty ZIKV samples had been shared internationally. Researchers, however, needed more samples to definitively answer the critical question as to the relationship between microcephaly and ZIKV, and efficiently produce vaccines and diagnostic tests.²

International researchers consequently relied on strains of ZIKV from previous outbreaks. The Centers for Disease Control and Prevention (CDC) studied samples from the 2013 outbreak in French Polynesia, and researchers in England studied samples from the 2007 outbreak on Yap Island in the Federated States of Micronesia. However, without enough Brazilian samples, researchers were concerned they would be unable to effectively track potential mutations and evolution of Brazilian ZIKV.³

Brazil's biosecurity legislation inadvertently led to the difficulties in getting ZIKV samples out of the country. Brazil had been increasingly concerned with "bio-piracy", as foreign researchers

¹ Zahid Naeem. "Zika - Global Concern." *International journal of health sciences* vol. 10,3 (2016): V-VII.

² Maria Cheng, Raphael Satter, Joshua Goodman. "Few Zika Samples Being Shared by Brazil." *Associated Press*, 3 Feb. 2016, apnews.com/https://apnews.com/2db2a3581d2a42a08f5b031419cb09ed. Accessed 19 July 2019.

³ Cheng, et al. "Few Zika Samples Being Shared by Brazil," 3 Feb. 2016.

oftentimes took biological samples from the country, with limited to no benefit for Brazil, and had adopted a new biodiversity law in 2015.⁴ However, the regulations implementing this law, which would have governed the terms for the international transfer of samples, were not yet in effect meaning that sharing ZIKV samples outside of the country remained prohibited under domestic biosecurity law.

Brazil's 2015 biodiversity legislation had been created in accordance with the Convention on Biological Diversity's (CBD) and aligned with the Nagoya Protocol. The protocol states that genetic resources originating in a country are the property of that country, and that country may choose whether or not to share them with others. If resources are shared, it must be under mutually agreed terms. Moreover, equitable sharing of benefits from genetic resources are required between countries.⁵

The burden of Brazil's changing biosecurity and biodiversity laws on timely worldwide response to the ZIKV outbreak prompted the International Committee of Medical Journal Editors to address bio-piracy itself, announcing that studies may still be published after urgent data is made known to the public during a PHEIC.⁶ In doing so, it was hoped that Brazil would finalize its legislation so ZIKV samples could be shared worldwide.⁷ Some experts continued to place blame for the difficulties in sharing samples on research scientists who preferred to publish studies first and without competition, thus withholding samples for their own laboratories.⁸

Brazilian officials claimed that their laws did not hinder international accessibility to ZIKV samples. Two-thirds of samples collected in Brazil in collaboration with a team from the CDC were set to be sent back to the United States for analysis after approval by a medical review board. The World Health Organization (WHO) also reported that Brazilian legislation did not cause any problems related to a lack of sharing of ZIKV samples.⁹ However, after anonymous

⁴ Nurith Aizenman. "Scientists Say It's Time to End 'Parachute Research.'" *National Public Radio*, 2 Apr. 2016, www.npr.org/sections/goatsandsoda/2016/04/02/472686809/scientists-say-its-time-to-end-parachute-research. Accessed 19 July 2019.

⁵ Matthias Buck and Clare Hamilton, "The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity," *Review of European, Comparative and International Environmental Law* 20, no. 1 (2011): 47-48.

⁶ Marie-Paule Kieny, Vasee Moorthy, Daniela Bagozzi, "Public health: use open data to curb Zika virus," *Nature* 533, no. 7604 (2016): 469.

⁷ Ilaria Capua, "Data sharing: a code of conduct for data on epidemics," *Nature* 534, no. 7607 (2016): 326.

⁸ Esper Kallas and David O'Connor (2016), "Real-time sharing of Zika virus data in an interconnected world." *JAMA Pediatrics*; 170 (7): 633-634.

⁹ Dom Phillips, Nick Miroff, Lena Sun, "Brazil pushes back at Zika critics, finds new evidence of link to birth defect," *Washington Post*. 4 February 2016, https://www.washingtonpost.com/world/the_americas/brazil-pushes-back-at-zika-critics-finds-new-evidence-of-link-to-birth-defect/2016/02/04/22cfb4aa-cb47-11e5-b9ab-26591104bb19_story.html?noredirect=on&utm_term=.ef7e0b430973. Accessed 19 July 2019.

WHO officials complained that Brazilian laws did inhibit access to samples and data,¹⁰ the WHO announced a “data gap.”¹¹

By February 19, 2016, Brazil sent the U.S. CDC ZIKV samples, including tissue samples from two newborns with microcephaly and samples from two early miscarriages. Their mothers all showed symptoms of ZIKV. Analysis of these samples by CDC researchers through reverse transcriptase-polymerase chain reaction (RT-PCR) showed traces of ZIKV RNA and antigens in the brains of the newborns and in the placentas of the miscarriages: evidence of a link between ZIKV and microcephaly.¹²

Restricted shipment of ZIKV samples proved to be an ongoing issue during the outbreak. Sample sharing during disease outbreaks continues to present a challenge in disease events around the world. Addressing this challenge requires a united global response that establishes clear procedures and regulations for international sample transportation and sharing.¹³

Please include case study summary text below this line.

During early 2016, at the height of the Zika virus (ZIKV) outbreak, international researchers were anxious to get samples of the virus, in order to produce diagnostic tests, conduct scientific research, and contribute to the development of a vaccine. Existing Brazilian biosecurity legislation however complicated the ability to transport ZIKV samples outside of the country.

¹⁰ Cheng, et al., “Few Zika Samples Being Shared by Brazil,” 3 Feb. 2016.

¹¹ Jenny Barchfield and Mauricio Savarese, “After criticism, Brazil transferring Zika samples to US,” *Business Insider*. 5 February 2016, <https://www.businessinsider.com/ap-after-criticism-brazil-transferring-zika-samples-to-us-2016-2>. Accessed 19 July 2019.

¹² Roosecelis Brasil Martines, Julu Bhatnagar, M. Kelly Keating, et al., “Notes from the Field: Evidence of Zika Virus Infection in Brain and Placental Tissues from Two Congenitally Infected Newborns and Two Fetal Losses — Brazil, 2015,” *Morbidity and Mortality Weekly Report*, 2016, no. 65: 159-160.

¹³ Marion Koopmans, Xavier de Lamballerie, and Thomas Jaenisch, et al. (2018). Familiar barriers still unresolved—a perspective on the Zika virus outbreak research response. *The Lancet Infectious Diseases*. 19. 10.1016/S1473-3099(18)30497-3.