

Zika Virus: Current Outbreak and Ongoing Research Efforts

August 2016 Update

What is the Zika Virus?

The Zika virus is a tropical, mosquito-borne illness that is transmitted by the *Aedes* mosquito – the same type of mosquito that spreads Dengue, Chikungunya, and Yellow Fever.¹ Symptoms of the disease are usually mild, including fever, joint pain, rashes, and viral conjunctivitis (red/itchy eyes), and appear within a week of being exposed.² However, many people that are infected with Zika do not realize they are infected. The disease is rarely lethal.

While the main mechanism of Zika virus transmission is mosquitoes, the virus can also be transmitted from a pregnant mother to her baby during pregnancy or around the time of birth.³ According to the U.S. Centers for Disease Control and Prevention (CDC) there are now twelve confirmed cases of liveborn infants with birth defects in the U.S., including microcephaly.⁴ Microcephaly is a serious birth defect of the brain, where the baby's head is smaller than expected when compared to babies of the same age and sex.⁵ The CDC has now concluded that there is enough evidence to conclude that Zika virus infection during pregnancy is a cause of microcephaly and other brain defects.⁶ There have also been an increased number of people with Zika in Brazil who also have Guillain-Barré syndrome, a rare illness of the nervous system where a person's own immune system damages nerve cells.⁷ Scientists are continuing to investigate the association between this syndrome and the Zika virus.

In addition to being transmitted from the bite of specific mosquitoes and from mother to child during pregnancy, researchers have concluded that the virus is also transmittable through sexual contact.⁸ While the virus is known to linger in the blood for about a week, research is being conducted to determine how long the virus may linger in semen.

When was Zika discovered?

Zika was discovered in Uganda in the 1940s and, while the virus has circulated in various African and Southeast Asian countries over time, it was not until 2015 that Brazil experienced a major outbreak that has since expanded quickly and dramatically to other countries in Central and South America, as well as the Caribbean (including Puerto Rico and the U.S. Virgin Islands).⁹ As a result of the outbreak in 2015, scientists have learned the virus was much more harmful than previously thought, with the potential to damage the brains of fetuses and potentially cause a range of health and cognitive challenges. The World Health Organization officially declared a public health emergency in February 2016.

What can be done to prevent the spread of the virus?

The CDC has issued recommendations for travelers and those who reside in infected areas to prevent the spread of the virus by preventing mosquito bites.¹⁰ These include wearing long-sleeved shirts and long pants, staying indoors and using window/door screens, using Environmental Protection Agency (EPA)-approved insect repellents, pre-treating clothing and gear with permethrin (an insecticide), and sleeping under a mosquito net.

Because the potential mechanisms by which the virus spreads are still being explored, authorities are recommending special precautions for women who are pregnant and may become pregnant, including the use of condoms to prevent spread sexually transmitted infections.¹¹

As information on Zika is being updated rapidly, for the most up to date information, please see the CDC website (<http://www.cdc.gov/zika/index.html>).

Are there any current treatment options?

Currently there are no vaccines to prevent transmission of, or medicines to treat, the Zika virus.¹² Some of the known symptoms of the disease can be treated with common pain and fever medicines.¹³

What types of treatments are being developed?

Developing effective treatments for Zika is particularly challenging given how little is currently known. However, researchers are drawing on their experiences in responding to the Ebola epidemic as well as in examining vaccines and other treatments previously developed for viruses that are in the same family as Zika. An overview of selected areas of research by innovative biopharmaceutical companies is provided below.

Researchers are working on a number of vaccine candidates to prevent transmission of the Zika virus. Examples of some of the research initiatives underway by innovative biopharmaceutical companies include the following:

GlaxoSmithKline:¹⁴

- After completing a series of feasibility studies, GSK researchers are now preparing research studies for a new vaccine technology known as SAM (self-amplifying mRNA).
- Research into the new vaccine technology is being conducted in collaboration with the Vaccine Research Center at the National Institutes of Health.
- GSK is also working with global humanitarian organizations including Save the Children and AmeriCares, to support prevention and education efforts.

Inovio:

- The first clinical trial for a Zika vaccine is underway with Inovio's DNA-based vaccine given approval by the U.S. Food and Drug Administration to begin Phase I testing in June 2016.¹⁵
- The vaccine, which is being co-developed by GeneOne Life Sciences, demonstrated successful pre-clinical results and researchers expect preliminary results of the Phase I clinical trial before the end of 2016.
- Inovio CEO J. Joseph Kim noted that, "The beauty of this technological platform is that the vaccine is simply a DNA sequence developed in water," said Kim. "It cuts through all the difficult handling and complex development times of traditional vaccine approaches."¹⁶

National Institute of Allergy and Infectious Diseases (NIAID):¹⁷

- A clinical trial for a DNA-based Zika vaccine is underway as of August 2016.
- The vaccine uses a similar approach to a successful vaccine for West Nile virus. It includes a small, circular piece of DNA that codes for proteins of the Zika virus, allowing the immune system to learn to recognize and mount a response to virus-like particles without being exposed to the actual virus.

Sanofi Pasteur:¹⁸

- Researchers at Sanofi Pasteur have embarked on a Cooperative Research and Development Agreement with Walter Reed Army Institute of Research (WRAIR) on the co-development of a novel inactivated virus vaccine candidate.
- Building on the wealth of data from earlier WRAIR pre-clinical studies of the vaccine candidate, Sanofi Pasteur will create a clinical development and regulatory strategy.
- “In addition to exploring our own vaccine technology used in our new dengue fever vaccine, we are looking at other pathways to get a Zika vaccine into the clinic as soon as possible. Therefore, this exciting collaboration with the WRAIR creates the opportunity to rapidly move forward,” said David Loew, Executive Vice President, Head of Sanofi Pasteur.

Takeda:¹⁹

- Takeda has assembled an internal team to investigate how it can share its existing knowledge and infrastructure and work collaboratively to help advance the effort to develop a vaccine for Zika.
- Takeda currently has products in development for Dengue and Chikungunya, which may prove useful in informing Zika vaccine development.

Several other biopharmaceutical companies are in the early stages of research, including Johnson & Johnson, Pfizer, and Merck, examining whether their technologies or existing vaccines have the potential to inform development of a Zika vaccine. At least three additional vaccine candidates are in development by other biopharmaceutical companies and efforts to develop molecular tests to identify the virus are also under way.

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- ¹ <http://www.who.int/features/qa/zika/en/> (page updated June 20, 2016).
 - ² <http://www.cdc.gov/zika/about/overview.html> (page updated July 13, 2016).
 - ³ <http://www.cdc.gov/zika/pregnancy/question-answers.html> (page updated June 15, 2016).
 - ⁴ <http://www.cdc.gov/zika/geo/pregnancy-outcomes.html> (page updated July 21, 2016)

 - ⁶ <http://www.cdc.gov/zika/pregnancy/question-answers.html> (page updated June 15, 2016).
 - ⁷ <http://www.cdc.gov/zika/qa/gbs-qa.html> (page updated April 6, 2016).
 - ⁸ <http://www.cdc.gov/zika/transmission/index.html> (page updated June 17, 2016).
 - ⁹ <http://www.who.int/emergencies/zika-virus/history/en/>
 - ¹⁰ <http://www.cdc.gov/zika/prevention/plan-for-travel.html> (page updated June 24, 2016)
 - ¹¹ <http://www.cdc.gov/zika/prevention/index.html> (page update June 21, 2016)
 - ¹² <http://www.cdc.gov/zika/disease-qa.html> (page updated July 13, 2016).
 - ¹³ <http://www.who.int/features/qa/zika/en/> (page updated June 20, 2016).
 - ¹⁴ <http://www.gsk.com/en-gb/media/press-releases/2015/update-on-gsk-s-response-to-the-zika-virus-disease-outbreak/>
 - ¹⁵ <http://ir.inovio.com/news/news-releases/news-releases-details/2016/Inovio-Pharmaceuticals-and-GeneOne-Life-Science-Receive-Approval-for-First-in-Man-Zika-Vaccine-Clinical-Trial/default.aspx>
 - ¹⁶ <http://fortune.com/2016/01/28/zika-virus-vaccine/>
 - ¹⁷ <https://www.niaid.nih.gov/news/newsreleases/2016/Pages/Zika-Investigational-Vaccine.aspx>
 - ¹⁸ <http://sanofipasteur.com/en/articles/Sanofi-Pasteur-Signs-Research-Agreement-for-Zika-Vaccine.aspx>
 - ¹⁹ <http://www.takeda.com/news/featuredstories/actiontowardszika/>