



# TRENDS-in-MEDICINE

## BULLETIN:

### ZIKA VIRUS UPDATE

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by Lynne Peterson

In a teleconference with reporters, government officials discussed the status of the Zika virus outbreak – what they know, what they don't know, and what they want to find out.

#### Key highlights:

- There have been no local transmissions in the continental U.S., and no large outbreak here is expected, but increased reports of infected travelers are expected.
- A Phase I trial of a vaccine could begin this year. *This is probably HydroVax-001, which was developed for West Nile virus but never commercialized and has no pharma involvement – yet.*
- The FDA is reviewing blood supply and donor issues. *It wouldn't be surprising if the FDA banned blood donations for a few weeks after a person returns from an infected area.*

Anne Schuchat, MD, principal deputy director of the Centers for Disease Control and Prevention (CDC), explained that the virus is not new; it was first recognized in 1947, with the first outbreak in 2007 on a Pacific island, adding, “But what we are seeing in the Americas now is new.” She emphasized that this is a rapidly evolving situation.

There have now been ~1 million cases of Zika virus infection – spread by the *Aedes aegypti* mosquito, which also spreads dengue fever – in Brazil, and cases have now been reported in >20 countries in Central and South America. There have been 19 laboratory-confirmed cases in Puerto Rico, 1 in the U.S. Virgin Islands, and cases in 10 states and the District of Columbia. All of the continental U.S. cases were in travelers who contracted the virus outside the U.S., but it is not clear yet whether there was local transmission in Puerto Rico or the Virgin Islands.

Mosquito-borne infections are common, but what makes Zika so concerning is a suspected link between the virus and microcephaly (a serious brain defect) in newborns, leading Brazil to advise women not to get pregnant right now, and U.S. officials to warn against travel to affected countries, particularly by pregnant women and particularly in the first trimester when they may not even know they are pregnant. However, health authorities in Brazil have also seen an increase in Guillain-Barré, a rare neurological disorder that can last a few weeks to several months and can lead to paralysis. Dr. Schuchat said most people fully recover from Guillain-Barré, but it can take a few *years* to do so. Neither the microcephaly or Guillain-Barré links to Zika have been definitively proven.

Dr. Schuchat said Zika usually causes only a very mild illness or symptoms, and 80% of people who get infected never even have symptoms. When symptoms do occur, they usually last a few days to a week. Researchers are investigating whether there are other factors besides Zika that may have increased the risk of Zika to fetuses.

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Among the points Dr. Schuchat made were:

- So far, there has not been any local transmission in the U.S. – defined as a mosquito transmitting the virus from one person in the U.S. to another person in the U.S., but the CDC expects “a lot of travel-associated cases.”
- The number of reported U.S. cases is likely to go up because Zika has been added to the CDC list of notifiable conditions, so state labs must report them to the CDC.
- The diagnostic tests for Zika “are not as great as we would like them to be on availability or specificity...making sure immunity is to Zika and nothing else takes additional testing.”
- Dengue fever and chikungunya are also transmitted by the same mosquitos, but there have been no U.S. epidemics of those.
- Mosquito control is difficult.
- Outbreaks in the continental U.S. “will likely be limited...Based on our experience with other mosquito-borne viruses, we are not expecting really big, uncontrollable ones [with Zika].” She cited several reasons the risk of a major outbreak in the U.S. is lower than in Latin America:
  - U.S. urban areas are not as densely populated as Latin American areas affected.
  - The U.S. has more air conditioning and screens.
  - The U.S. has good mosquito control, but Dr. Schuchat added, “Community mosquito control may be difficult, and we need to identify better options.”
- CDC has one research partnership underway, with another starting soon.
- Brazil is now investigating whether infants born with neurological defects before monitoring for Zika began could have Zika-related defects.

In terms of **treatment**, Anthony Fauci, MD, director of the National Institute of Allergy and Infectious Diseases (NIAID), said:

- Research is taking many directions, including basic research, pathogenesis, diagnostic, vaccines, and therapeutics.
- Of importance is development of animal models and diagnostic platforms for rapid diagnosis and to distinguish infection from other viruses, especially dengue fever. He said, “These will be critical to reassure pregnant women in affected areas or returning from such areas.”
- There are already vaccine candidates, using existing platforms as a “jumping off point.” Dr. Fauci said at least two DNA-based vaccines are being explored, adding, “We will **not** have widely available, safe, and effective Zika vaccine this year or even in the next few years, though we may be able to being a Phase I trial this calendar year.” Dr. Fauci said NIH is already starting to make materials to get to GMP grade for this trial this year. He emphasized the use of vaccine platforms that can be adjusted for the virus-du-jour.
  - A live attenuated vaccine, building on work for dengue fever.
  - A strategy like was used with West Nile virus. This [platform] – HydroVax-001 (developed by researchers at the Oregon Health & Science University) – was found in a Phase I trial to be both safe and immunogenic. Dr. Fauci said that the vaccine did not go forward because no pharmas were interested in it. West Nile and Zika are both flaviviruses, so Dr. Fauci said that they feel that researchers can insert the Zika virus instead of the West Nile virus in the vaccine, adding, “We are already talking to a few companies to partner with us on advanced development.”
- NIH has called on the research community to help with funding areas of research specific to the Zika threat. He said NIH is spending \$97 million on research into this class generally, but couldn’t say specifically how much will be spent on Zika research. He did say that NIH will “be utilizing grantees and grants out there and immediately supplementing them...I imagine this will take resources...We want the community to get actively involved.”

*Can asymptomatic pregnant women have a baby with a Zika-associated birth defect?* Dr. Schuchat said that is unknown, but it is possible, and there are other viral conditions that can do that.

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*Does Zika infection confer immunity from future infection with Zika?* Dr. Schuchat said, “We think infection confers immunity, but we don’t know how long that lasts...We think it is likely one gets long-term protection, but we don’t know how long.”

*How high is the risk for Americans in the U.S.?* Dr. Fauci said, “There is essentially no risk at all [right now] because we don’t have local transmission in the U.S.” The regions of the U.S. most likely to see an outbreak are southern Florida and southern Texas.

*Asked about genetically-engineering mosquitos,* Dr. Schuchat said this is “very intriguing” but unproved on a large scale.

*Asked about reports of sexual transmission of Zika,* Dr. Schuchat said, “There is one reported case of Zika through possible sexual transmission. In another case, it was found in semen two weeks after infection...It is clear that it is primarily transmitted through the bite of an infected mosquito, and that is where we are putting the emphasis.”

*Asked about risks to the blood supply in the U.S.,* Dr. Schuchat said, “The FDA is looking at the issue of the blood supply, donors, and travelers. We know Zika is in the bloodstream very briefly. We don’t think it is there a long time. Most clear it in about a week, so this is an issue the FDA will be deliberating about re blood donors.”

*Is the Puerto Rican budget crisis affecting its ability to deal with Zika?* Dr. Schuchat said CDC has an installation there with ~40 staff members, which is working very closely with Puerto Rican health experts.

#### **In other Zika news that did not come from the teleconference:**

- There are reports that the Zika virus may have infected common mosquitos, not just the *Aedes aegypti* mosquito, which would increase the risk of spread.
- The World Health Organization (WHO) is convening an emergency meeting on February 1, 2016, to decide if the Zika virus outbreak should be declared a public health emergency. WHO director Margaret Chan, MD, DSc, said the virus is “spreading explosively” and the “level of alarm is extremely high.”
- Researchers from the University of Texas Medical Branch are involved in vaccine research. They collected samples in Brazil and are analyzing them in Galveston TX.
- GlaxoSmithKline reportedly is conducting feasibility studies on the use of its vaccine technology, and Sanofi reportedly is looking at whether its vaccine technology is applicable.

