

[GAO Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks \(Report\)](#)

Provides nonbinding recommendations to the Department of Health and Human Services concerning the United States government's response to the Zika virus.

Updated last **September 6, 2017**
for the 05/23/2017 Report.

WHAT IT DOES

The United States Government Accountability Office ([GAO](#)) produced a report of nonbinding recommendations, [Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks \(GAO-17-445\)](#) in response to a Congressional request to assess the 2016 United States Zika virus outbreak and the associated governmental response. In the report, the GAO examines and discusses the following three key considerations:

1. Current understanding about the epidemiology of the Zika virus, including challenges in conducting research about the virus;
2. Comparison of various diagnostic tests approved for Zika, including challenges in conducting these tests appropriately; and
3. Comparison of available mosquito control methods, including how the federal government can support those efforts.

After reviewing literature and agency documents, interviewing state and federal officials, and convening a meeting of Zika virus experts with the [National Academy of Sciences](#), the GAO named five [recommendations](#) for the Department of Health and Human Services (HHS) and its agencies.

The first two recommendations were intended for the Food and Drug Administration (FDA):

1. Allow for better comparison of diagnostic test information across different tests; and
2. Require manufacturers of diagnostic tests to identify the comparator assay (i.e., basis of comparison) they used to assess the performance of their diagnostic method.

The final three recommendations were intended for the Centers of Disease Control and Prevention (CDC):

1. Transparently provide CDC diagnostic tests to manufacturers who are in the final stages of receiving diagnostic test authorization;
2. Publicly list on the CDC website information about CDC-developed tests which are shared with public health laboratories; and
3. Provide to the public the background data used to create mosquito distribution maps.

RELEVANT SCIENCE

[Zika virus](#) is an emerging disease caused by a [Flavivirus](#). The virus is predominantly transmitted through the bite of the [Aedes aegypti mosquito](#), which inhabits much of the southern United States, as well as tropical and subtropical areas in Central America, the Caribbean, South America, Africa, the Pacific Islands, and Asia. The virus can also be [transmitted](#) through vaginal, anal, and oral sexual activity; through blood transfusions; and from mother to fetus during pregnancy. Infected persons can infect others even when they are not symptomatic, and it is unknown how long Zika virus can survive in a host.

Zika virus usually does not present [symptoms](#) in adults who are affected, but the 20% of infected persons who do become symptomatic most often experience fever, rash, headache, joint pain, pinkeye, and/or muscle pain.

[According to the CDC](#), there have been over 41,000 symptomatic cases reported in the United States since 2015. The vast majority of reported cases were in travelers returning from other affected countries, but both Florida and Texas reported cases that were presumed to have originated from local mosquito-borne transmission.

Although adult symptoms of Zika virus are relatively mild, Zika virus can be extremely harmful to a developing fetus if a pregnant woman is exposed. Zika virus exposure can result in fetal death, [microcephaly](#), and other abnormalities that are collectively known as [congenital Zika syndrome](#).

Currently, the FDA has not approved any diagnostic test for detecting Zika virus; however, 17 newly-developed [diagnostic tests](#) that utilize blood or urine samples to detect Zika infection have been authorized under [emergency use authorization](#) (EUA) by the FDA.

Much is still unknown regarding the nature of Zika virus and its potential long-term effects. There is currently no approved medication or vaccine available for Zika treatment or prevention, although [experts estimate](#) that over 40 vaccines are currently in various stages of development. The CDC's current prevention [recommendations](#) include avoiding mosquito bites, avoiding travel in areas where Zika virus is prevalent, and using condoms. The CDC also [advises](#) women to refrain from becoming pregnant for at least eight weeks after possible exposure.

RELEVANT EXPERTS

[Dr. Daniel A. Strickman, M.S., Ph.D](#) is a Senior Programs Officer for Vector Control in the Malaria and Infectious Disease Programs at the Bill and Melinda Gates Foundation and a fellow with the Entomological Society of America.

“This process is a welcome increase of US federal involvement in mosquito vector control and surveillance. Our current situation is largely fragmented, consisting of some areas with excellent service and others with no service whatsoever. The introduction of West Nile virus, chikungunya virus, and Zika virus into the United States is a reminder that a national system is required for public health.”

Relevant publications:

- Strickman, D., S. Frances, and M. Debboun. *Prevention of Bug Bites, Stings, and Disease*. Oxford: Oxford University Press. 2009.

BACKGROUND

Although Zika virus was [discovered in 1947](#), only a few major outbreaks have occurred since then, in places such as the Federated States of Micronesia, French Polynesia, Easter Island, the Cook Islands, and New Caledonia. However, in 2015 and 2016 an epidemic of Zika virus [spread](#) from Brazil to other parts of South America and North America, prompting the World Health Organization (WHO) to [declare](#) the virus a Public Health Emergency of International Concern in February 2016. The WHO lifted that declaration in November 2016, but [continues to warn](#) pregnant women about the potential risk of the virus.

ENDORSEMENTS & OPPOSITION

In an appendix, the GAO report contains a [statement](#) from HHS, as the parent organization of the CDC and the FDA, and their response to the five GAO recommendations.

The FDA concurred with both of the recommendations directed toward them; the CDC concurred with two of the three recommendations directed toward them (transparently provide CDC diagnostic tests to manufacturers who are in the final stages of receiving diagnostic test authorization; provide to the public the background data used to create mosquito distribution maps.) However, the CDC only partially concurred with the third recommendation directed toward them (publicly list on the CDC website

information about CDC-developed tests which are shared with public health laboratories).

Regarding this latter recommendation, the CDC said in the statement:

“CDC concurs with GAO’s recommendation to make this information available for all EUA [emergency use authorization] assays developed by CDC. CDC does not concur with GAO’s recommendation that CDC provide similar information for any CDC laboratory assays, including those that have not received EUA from the FDA. CDC does not distribute laboratory-developed assays that have some received EUA. In some circumstances, CDC shares laboratory-developed assay protocols (generally through scientific publications) and laboratory controls with partner public health laboratories to advance technical cooperation.”

STATUS

The final report was published on May 23, 2017. The recommendations are not legally binding.

RELATED POLICIES

On March 2, 2017, [Representative Darren Soto](#) (D-FL-9) introduced [H.R. 1310](#), the Strengthening Mosquito Abatement for Safety and Health (SMASH) Act. [Senator Angus King](#) (I-ME) introduced a parallel bill ([S 849](#)) on April 5, 2017. This act would support programs that focus on surveillance and control of mosquito-borne and other vector-borne diseases, including Zika virus. To date, the House version of the bill is still in committee; the Senate version of the bill has passed committee but has not yet received a vote by the full Senate.

POLICY HISTORY

Regarding the United States’s response to Zika virus, the GAO issued a report on March 2, 2016, titled [Preliminary Observations on the Zika Virus Outbreak](#).

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RECOMMENDED CITATION

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