

GAO Highlights

Highlights of [GAO-17-445](#), a report to congressional requesters.

Why GAO Did This Study

Zika virus disease can cause adverse pregnancy and neurological outcomes. Given this ongoing threat, GAO was asked to evaluate progress made and challenges faced by federal agencies in responding to the Zika virus outbreak in the United States.

GAO examined (1) information on what is known and not known about the epidemiology of the Zika virus, and any challenges with conducting surveillance and epidemiological studies, (2) characteristics of different diagnostic tests authorized during the outbreak, challenges test manufacturers and users faced, and the extent to which FDA and CDC followed their own communication guidance, and (3) the strengths and limitations of available mosquito control methods, and challenges federal agencies face supporting these efforts.

GAO reviewed literature and agency documentation, and interviewed federal and state officials about the Zika virus and the U.S. response. GAO also convened an expert meeting with the assistance of the National Academy of Sciences to discuss various issues surrounding the response to the Zika virus.

What GAO Recommends

GAO is making five recommendations to FDA and CDC, including that CDC establish a transparent process for providing test manufacturers access to diagnostic tests and FDA and CDC provide information to help ensure that users of diagnostic tests can compare performance. Agencies agreed with four recommendations but raised some concerns with the fifth. GAO has addressed these concerns in the report.

View [GAO-17-445](#). For more information, contact Chief Scientist Timothy M. Persons at (202) 512-6412 or personst@gao.gov.

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EMERGING INFECTIOUS DISEASES

Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks

What GAO Found

Since Zika virus disease was a newly emerging disease threat in the United States, and relatively little was known about the Zika virus prior to the 2016 U.S. outbreak, the Centers for Disease Control and Prevention (CDC), and the states were not fully equipped with needed information and resources at the beginning of the outbreak. This presented several challenges for Zika virus disease surveillance and research efforts, such as challenges related to establishing a national definition for reporting cases. Knowledge about Zika virus epidemiology has increased in the past year, including information about Zika virus disease incidence and distribution of cases, and its associated adverse health outcomes. Most of the 5,197 Zika virus disease cases reported by April 5, 2017 in the United States were associated with travel from affected areas outside the continental United States. Only two states had disease cases of local, mosquito-borne transmission—216 were in Florida and 6 in Texas. While much has been learned about the epidemiology of the Zika virus, many unknowns remain, including the actual number of infections and the full spectrum of outcomes.

The 16 Zika virus diagnostic tests authorized during the outbreak varied in their performance and operational characteristics. For example, they varied in their ability to detect the virus and provide accurate results. In developing the diagnostic tests, manufacturers faced challenges in several areas, including access to clinical samples and other authorized diagnostic tests for comparison purposes. Users of the tests also encountered challenges, including determining the most accurate test to use, and obtaining equipment needed to conduct the tests. Some manufacturers raised concerns about the difficulty in developing diagnostic tests that met the Food and Drug Administration's (FDA) requirements for Emergency Use Authorization and some users expressed concerns about selecting tests amongst those authorized. GAO also determined that CDC and FDA did not follow some of their guidance in communicating with users of diagnostic tests, including providing clear information that would have enabled users to more easily compare performance across different tests.

Mosquito control programs in the United States are implemented at state and local levels and are critical to mitigating the risks associated with the Zika virus. Control methods include applying pesticides, reducing available water sources for breeding, and using personal protection. Each method has its strengths and limitations. For example, some control methods are more effective at reducing mosquito populations while others help prevent individuals from mosquito bites. Similarly, each method has some limitations, for example, there is varied public opposition to the use of certain pesticides. CDC supports state and local mosquito control activities primarily by providing guidance on mosquito control methods and funding to support certain mosquito control efforts. Challenges federal agencies faced in supporting these activities include sustaining staff expertise in mosquito control during periods when there are no outbreaks, funding constraints, and effectively communicating information about the geographical distribution of mosquitoes that transmit the Zika virus.