

GAO Highlights

Highlights of [GAO-17-612T](#), a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives.

Why GAO Did This Study

Zika virus disease can cause adverse health outcomes. This statement summarizes the findings of GAO's May 2017 report that is being released concurrently on 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 challenges with conducting surveillance and epidemiological studies, (2) characteristics of different authorized diagnostic tests, 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 faced.

GAO reviewed documents and interviewed officials about the Zika virus response. GAO also convened an expert meeting with the assistance of the National Academy of Sciences to discuss various issues related to Zika virus.

What GAO Recommends

In its May report GAO made five recommendations to FDA and CDC, including that CDC establish a transparent process for providing test manufacturers access to diagnostic tests for comparison purposes and FDA and CDC provide information to help ensure that users of diagnostic tests can compare performance. The agencies agreed with four recommendations and partially with the fifth and identified actions to implement them.

View [GAO-17-612T](#). 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 Ensure Improved Response to Zika Virus Disease Outbreaks

What GAO Found

Since Zika virus disease was a newly emerging disease threat in the United States, 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 surveillance and research efforts, such as establishing a national definition for reporting cases. Knowledge about Zika virus epidemiology has increased in the past year, for example, its associated adverse health outcomes, and various modes of transmission. Most of the 5,197 Zika virus disease cases reported by April 5, 2017 across 49 states in the United States were associated with travel to affected areas outside the continental United States; only two states—Florida and Texas—reported local mosquito-borne transmission—216 were in Florida and 6 in Texas. The vast majority of the 36,504 cases reported in U.S. territories have been acquired through presumed local, mosquito-borne transmission in Puerto Rico. While much has been learned about the epidemiology of the Zika virus, many unknowns remain, including the actual number of infections in the United States and the full spectrum of short-term and long-term 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, having access to different tests, 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 consistently communicate sufficient information about 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 identified 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.