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and Investigations, Committee on
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Representatives

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EMERGING INFECTIOUS DISEASES

Actions Needed to Ensure Improved Response to Zika Virus Disease Outbreaks

Statement of Timothy M. Persons, Ph.D., Chief Scientist

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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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.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

Thank you for the opportunity to discuss our work on the federal response to Zika virus disease outbreaks, with particular focus on epidemiology, diagnostic tests, and mosquito control. Emerging infectious diseases, such as Zika virus disease, are an ongoing threat to the health and livelihoods of people and animals worldwide. Despite many advances in medical research and treatments during the past century, infectious diseases are still a leading cause of death worldwide. Our testimony today summarizes our report entitled *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks* which is being released today.¹ We have also issued several other reports on infectious diseases.²

Zika virus disease is caused by the Zika virus, which is spread to people primarily through the bite of an infected mosquito (*Aedes aegypti*). Many people with Zika virus infection will not have any signs or symptoms or will have only mild symptoms. The Zika virus attracted attention from health officials in the United States and abroad after associations were suspected between increases in reported cases of Zika virus infection and reported cases of microcephaly in newborns and other neurological syndromes in Brazil in 2015.³

Several U.S. federal agencies are involved in the response to Zika virus disease outbreaks. Specifically, the Centers for Disease Control and Prevention (CDC) collects data from states on reported cases of nationally notifiable diseases through surveillance systems. The Food and Drug Administration (FDA) oversees the safety and effectiveness of diagnostic tests. The Secretary of Health and Human Services (HHS) can make a declaration of emergency that can allow FDA to issue Emergency Use Authorization (EUA) of medical products to be used when adequate, approved, and available alternatives are lacking. FDA's website includes

¹GAO, *Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreak*, [GAO-17-445](#) (Washington, D.C.: May 23, 2017).

²For a full list of related reports please see [GAO-17-445](#).

³Microcephaly is a rare nervous system disorder that causes a baby's head to be smaller than expected and not fully developed, which can lead to impaired thought processes, delayed motor function, and other adverse outcomes.

a current list of available diagnostic tests and associated information about each test. FDA has authorized two different types of diagnostic tests for the Zika virus—molecular and serologic.⁴

Our May 2017 report and my statement today address (1) what is known and not known about the epidemiology of the Zika virus, and challenges in conducting surveillance and epidemiological studies, (2) characteristics of different Zika virus authorized diagnostic tests, challenges manufacturers and users of diagnostic tests have faced, and the extent to which CDC and FDA followed their own communication guidance concerning diagnostic tests during the recent U.S. outbreak, and (3) available mosquito control methods, their strengths and weaknesses, and challenges federal agencies face in assisting mosquito control efforts.⁵

For our May 2017 report, we reviewed agency documents including reports on Zika virus epidemiology, diagnostic testing guidance, agency documents on mosquito control, and information on all authorized diagnostic tests for Zika virus disease. We also interviewed the manufacturers of authorized tests, officials from key federal agencies and departments, selected state and local public health entities, and public health organizations responding to the domestic Zika virus outbreak. We also convened, with the assistance of the National Academy of Sciences, a meeting with 16 experts from federal and state governments, academia, and industry who combined knowledge of Zika virus epidemiology, diagnostic testing, and mosquito control, to identify and discuss experiences and challenges that arose during the Zika virus outbreak response. Additional information on our scope and methodology is available in our report. We performed the work on which this testimony is based in accordance with generally accepted government auditing standards.

⁴Molecular tests are used to detect genetic material in samples of bodily fluids such as serum and urine. Serologic tests are diagnostic tests that detect antibodies against the Zika virus.

⁵For the purpose of the report and this testimony, users of diagnostic tests include laboratory personnel, health care providers, and others in the medical and scientific communities.

Challenges to Gathering New Information about Zika Virus Epidemiology

Surveillance and research conducted during the recent Zika virus disease outbreaks around the world have established some new knowledge about the epidemiology of the Zika virus, including information about the incidence of the disease and the distribution of cases, and its associated adverse health outcomes. 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. Most of the 36,504 cases reported in U.S. territories have been acquired through presumed local, mosquito-borne transmission in Puerto Rico. According to the World Health Organization (WHO) and CDC, there is now evidence that the Zika virus causes microcephaly, brain abnormalities, and other birth defects and neurological disorders, based on the totality of evidence from current epidemiological and clinical studies.

Nevertheless, many unknowns about the Zika virus remain, including (1) the total number of people with symptomatic and asymptomatic infections, (2) the biological mechanisms, risks, reasons for geographic differences, and the full spectrum of outcomes associated with maternal-fetal transmission, (3) the presence and duration of the virus in different bodily fluids, and (4) the role of prior exposure to Zika and other closely related viruses in risk and severity of Zika virus disease outbreaks, and (5) the full spectrum of outcomes associated with Zika virus infection.

When the outbreak started in the United States, CDC, and state and local public health agencies, and public health organizations, faced some challenges in establishing and implementing surveillance systems for Zika virus disease and infection and its associated health outcomes. Challenges included establishing surveillance case definitions early in the outbreak when little was known about the Zika virus, timely communication of critical information that was rapidly evolving, and the lack of interoperability between surveillance systems. We also identified two key challenges for epidemiological research: (1) time and resources required for studies needed to establish association and causality between the Zika virus and associated health outcomes and (2) insufficient data and models for predicting the spread of the Zika virus.

Characteristics of Different Diagnostic Tests Varied, Manufacturers and Users Faced Several Challenges, and FDA and CDC Did Not Consistently Communicate Sufficient Information

By April 12, 2017, FDA had authorized 16 diagnostic tests for the Zika virus under EUAs, following a public health emergency declaration.⁶ In response to the Zika virus outbreak, CDC manufactured and received EUA from FDA for both molecular and serologic tests. We found that authorized diagnostic tests used for the recent Zika virus outbreak varied in their performance and operational characteristics. Molecular and serologic tests have different strengths and limitations, but some of the limitations can be mitigated by using the CDC algorithm.

It is important to recognize that a negative molecular test does not rule out Zika virus infection because the amount of virus in the sample could be too low to be detected at the time of molecular testing. Some scientists expressed concern over the limit of detection for the Zika virus by some authorized molecular diagnostic tests, which could have resulted in molecular testing missing Zika infections. CDC provided guidance intended to reduce the risk of inaccurate results by recommending that molecular tests should be further tested with a serological test. One critical issue with serological Zika virus disease testing is potential cross-reactivity – when antibodies to similar viruses react. For example, cross-reactions occur in the diagnostic tests for Zika and dengue because these viruses are closely related.

We identified challenges that manufacturers of diagnostic tests for Zika virus faced including: (1) lack of knowledge of biological aspects of the virus and immune response, (2) difficulty in accessing well-characterized clinical samples, (3) getting access to EUA tests for use as a comparator test, and (4) gaining cooperation with international entities.⁷

The first challenge manufacturers faced was uncertainty at the beginning of the outbreak about which sample type to use for molecular testing. For instance, the Zika virus had been found to be present longer in urine than in blood, but information on how long the virus could persist in different bodily fluids was still evolving making it difficult to develop diagnostic tests.

⁶FDA authorized 13 molecular tests and 3 serologic tests. According to FDA officials, they revoked one test, and as a result, 15 diagnostic tests are currently authorized.

⁷FDA recommends that manufacturers perform clinical evaluation studies that compare their tests to another “comparator” assay that is laboratory developed, an in-house test, or an EUA test.

Second, during the early stages of the outbreak there was a lack of well-characterized clinical samples for Zika virus diagnostic test development. Several manufacturers told us that there were insufficient quantities of available samples, and samples that were available were expensive.

Third, FDA recommends that manufacturers perform clinical evaluation studies that compare their new tests to another “comparator” assay (test).⁸ Similarly, a CDC document states that CDC should provide a consistent, fair, and transparent review process for all public-private initiatives, even during emergencies. According to CDC officials, the CDC developed EUA tests were not made available to some commercial manufacturers for use as comparator tests because these tests are distributed only to public health laboratories performing Zika virus clinical diagnoses. Moreover, according to CDC officials, in the early stage of the response CDC did not have the capacity to both adequately support public health laboratories and also supply commercial manufacturers with these tests. Ultimately, CDC distributed its tests to four manufacturers through technology transfers and we found that 2 of the 12 authorized molecular diagnostic test labels listed CDC’s test as their comparator test. However, one manufacturer told us their request to CDC for reagents to perform the CDC test as a comparator test was denied because they were a commercial manufacturer. CDC officials we spoke with were unclear of how the process to transfer authorized CDC tests to manufacturers originally started. *Standards for Internal Control in the Federal Government* state that agencies should document their operational processes to ensure that the organization meets its objectives.⁹ Without a clear and transparent process for distributing CDC diagnostic tests, CDC may not be able to support the development of capacity in the commercial sector to meet the needs during an outbreak.

Fourth, interacting with international entities to obtain samples and perform testing presented challenges for manufacturers. For instance, foreign countries have different laws that must be followed. A manufacturer we interviewed tried to bring equipment to perform a diagnostic test into another country for testing but it faced challenges getting the necessary import license.

⁸CDC was the first manufacturer to receive an EUA, and therefore the CDC test was the first authorized molecular test to which other manufacturers attempting to get EUA could compare their tests.

⁹GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: September 2014).

We also found that some diagnostic test users faced challenges complying with equipment requirements to perform tests as specified in the EUA labels, and determining the most accurate test. Moreover, although CDC officials told us that all states had at least one public health laboratory that had the equipment to run a CDC test, representatives from several laboratories we interviewed told us they had to acquire specific new specialized equipment to be able to perform a certain EUA diagnostic test.

An FDA document states that the agency should share information that is up-to-date, understandable, and easily accessible so diagnostic test users have some basis for choosing which medical products to purchase and use. We found that although performance characteristics are listed on individual diagnostic test labels, they are not available in a consolidated format. According to FDA officials, the agency began collecting information using reference samples because different manufacturers were using different types of samples and potentially different methods to determine the limit of detection of their tests. Until limit of detection data have been extracted and summarized from all the diagnostic test labels, it may be difficult and time-consuming for users to compare the performance characteristics and results of diagnostic tests.

Another challenge users faced was that without knowing the identity of the comparator test, it was more difficult for them to compare performance characteristics across different diagnostic tests and determine the most appropriate test for them to use. Experts at our meeting agreed that identifying the comparator test would make it easier to compare the risks and benefits of different Zika virus diagnostic tests. An FDA document recommends a clear description of all methods used and how and what data were collected when performing comparison testing, including a description of the comparator test. When we compared product labels for different molecular tests, we found that while labels listed the type of test used for comparison, 6 of 12 product labels did not list the identity of the test used for comparison. FDA officials stated that the comparator test for authorized diagnostic tests can either be another authorized test or a validated reference method, and that manufacturers are not required to identify the comparator test used. FDA staff told us they are concerned that labels identifying comparator tests could be used to make inappropriate claims or be misinterpreted by end users.

Standards for Internal Control in the Federal Government state that agencies are to communicate quality information externally through

reporting lines so that external parties can help an entity achieve its objectives and address related risks. CDC did not make publically available data comparing the performance characteristics of different CDC diagnostic tests that it distributed during the outbreak. CDC's website has information about the performance of its two authorized diagnostic tests but not the laboratory developed test it distributed. According to a HHS report, CDC did not provide information about one of its diagnostic tests because it could potentially create confusion and could have caused public health laboratories to discontinue use of an EUA test, and it had not done a comprehensive comparison of the two tests. Because CDC did not publicly provide performance information about its laboratory developed test—which was distributed to some public health laboratories—questions arose regarding the sensitivity of the two CDC tests.

Representatives of three scientific professional societies told us that information about the development and verification of CDC's diagnostic tests should be made available to the scientific and medical communities. Access to such data would provide transparency and allow for optimal patient care, according to these representatives. According to these scientific professional societies' representatives, the lack of access to data regarding test performance prevented laboratory professionals from making informed decisions about which test to adopt or recommend during the outbreak. Without including information on the performance characteristics of tests it is distributing, CDC cannot ensure that healthcare providers and the public have the information they need to make informed decisions about which test is best for their use.

In our May 2017 report we recommend that FDA consolidate information from individual diagnostic test labels and make it available in a form that enables diagnostic test users to more readily compare information across tests and require manufacturers of diagnostic tests to list the identity of comparator tests on their labels. We also recommend that CDC establish a transparent process to provide CDC diagnostic tests, on request, to manufacturers that are in the final stages of diagnostic test authorization, and include information on CDC-developed tests, including laboratory developed tests. HHS agreed with our recommendations for FDA to consolidate information about tests, require manufacturers to list the identity of the comparator assay, and that CDC establish a transparent process for distributing CDC-developed tests. In response to our recommendation to include information on CDC-developed tests distributed to public health laboratories, HHS partially concurred and provided clarifying information. HHS agreed that it should share

information on CDC-developed tests that have received EUA. However, regarding this recommendation, HHS did not agree with our recommendation that it should share information on CDC's laboratory-developed tests that have not received EUA because CDC is unable to provide detailed information on characteristics of these unstandardized tests. We maintain that sharing information about these laboratory developed tests that are used for comparison testing is important because of the concerns that were raised regarding the sensitivity of one of CDC's EUA tests. We recognize that laboratory-developed tests that have not received EUA are not standardized, but we believe that CDC can provide certain information on the performance characteristics and quality of these tests based on its knowledge about these tests. Sharing this information could help other diagnostic test users make informed decisions about which test to adopt or recommend. HHS also noted that CDC does not distribute laboratory developed tests that have not received EUA but shares them with public health laboratories. In response to this comment, we modified our recommendation to reflect this information.

Mosquito Control Methods Have Strengths and Limitations, and Federal Agencies Are Challenged in Assisting These Efforts

Different types of mosquito control methods are available in the United States and each has strengths and limitations. The methods can be combined with surveillance of the mosquito population, using an integrated approach (i.e., pesticide use, traps, public education programs, and others) to optimize the application of multiple control methods, depending on knowledge of mosquito biology and distribution.

Because Zika virus disease is not yet preventable by known drugs or vaccines, mosquito control is critical in mitigating risks associated with this disease. Mosquito control in the United States is implemented and overseen by state and local entities such as mosquito control districts and health agencies. CDC, through sources including the American Mosquito Control Association, identified over 900 entities in the United States that perform mosquito control; however, not all geographic areas in the United States are covered. Federal agencies may support such control entities with funding, subject matter expertise, and may regulate some control methods such as pesticides.

The federal government has a limited and indirect role in supporting mosquito control efforts, which are mainly implemented at the state and local levels. According to CDC documentation, the agency developed technical guidance and provided funding and technical assistance to support state and local mosquito control activities. We identified four challenges the federal government faced in supporting these mosquito

control efforts during the Zika virus outbreaks: (1) timing of the availability of resources and sustaining expertise, (2) communicating information about current mosquito distribution, (3) linking the effects of mosquito control to disease outcomes, and (4) having limited information about mosquito control entities.

Federal agencies faced challenges related to the cyclic nature of mosquito-borne diseases, including recruiting and maintaining expertise. According to CDC, when the disease fades, the jobs and resources also go away, so that the next time the disease appears, staff must be retrained or new staff trained. CDC officials also told us that mosquito control needs vary with seasonal cycles, resulting in periods of several months that require more resources followed by some periods when little or no resources are needed.

CDC also faced challenges in communicating the presence of mosquitoes in a manner that was clear and useful to different groups, such as mosquito control entities and the general public. CDC distributed maps of the estimated potential range of the primary Zika virus mosquito vectors on its webpages and in guidance, but imprecision in the maps can lead to confusion, according to some mosquito control officials. According to CDC officials, the maps allowed states to determine the level of effort needed for more precise mosquito surveillance as well as to show the public where they may encounter certain mosquito species. One mosquito control official told us of confusion about CDC's maps resulting from people failing to look at the qualifications stated in the map captions and mistakenly concluding that an entire state was infested with Zika virus vector mosquitoes. Further, detailed information about how the maps were created, including data sources and assumptions, was not posted on the CDC website or in documentation associated with the map. According to *Standards for Internal Control in the Federal Government*, management should use quality information to achieve the agency's objectives and should select appropriate methods to communicate externally the necessary quality information to achieve those objectives.¹⁰ This includes selecting appropriate methods to communicate externally, considering factors such as the intended recipients and the nature of the information being communicated.

¹⁰[GAO-14-704G](#).

Regarding information presented on CDC maps, experts we interviewed suggested including more details, such as collection records, measures of the stability of the mosquito populations, and areas of risk for transmission of mosquito-borne diseases. Without such context, CDC's maps could generate confusion about mosquito presence, resulting in concern among residents and public relations challenges, among other things. In our report we recommended that CDC provide details such as collection records, dates, and data limitations on posted and disseminated mosquito distribution maps to better inform mosquito control experts and the general public. HHS agreed with this recommendation.

CDC faced challenges in determining whether mosquito control efforts are associated with the reduction of mosquito-borne disease. For example, mosquito control entity officials told us that the entities' mosquito control efforts are not directly linked to disease reduction. Other challenges to analyzing the relationships between mosquito control methods and disease reduction include the dependence of transmission on factors such as weather, human susceptibility, and immunity.

CDC's capacity to develop a national strategy for mosquito control depends on its knowledge of mosquito control entities and their capabilities. We found that CDC relied on external sources to compile a list of mosquito control entities. CDC staff told us this list is likely to capture the larger, well-funded entities but may miss some smaller ones. Further, mosquito control capabilities in the United States vary by geographic area. A mosquito control official we interviewed agreed that variability in mosquito control entity capacities is significant. This variability makes it more challenging for CDC to determine the status of mosquito control efforts in different regions of the United States and to identify regions that may need technical guidance or assistance.

In conclusion, federal agencies can provide important information that can help users compare diagnostic tests and assist mosquito control efforts implemented at the state and local levels. Information on performance characteristics presented in each diagnostic test product label was not consolidated across available tests, were not consistently reported for diagnostic tests, and the identity of the comparator test was not listed on some labels, making it difficult for users to make informed decisions about which test to use or recommend to patients. The information that CDC included in its maps did not include sufficient details about its estimates of potential distribution of mosquitoes that can carry the Zika virus, which

made it difficult for mosquito control experts and the public to correctly interpret and use such data.

CDC developed the first two authorized diagnostic tests for the Zika virus and offers these tests to public health laboratories but not to some manufacturers. Such manufacturers additionally encountered difficulty acquiring authorized tests from other manufacturers. Without a clear and transparent process for distributing CDC-developed diagnostic tests to manufacturers, the agency may not be able to develop the capacity of the commercial sector to be able to meet the needs during an outbreak.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, this concludes my prepared statement. I would be happy to respond to any questions you may have.

For questions about this statement, please contact Timothy M. Persons, Ph.D., Chief Scientist, at (202) 512-6412 or personst@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals making key contributions to this statement include Sushil Sharma, Ph.D, Dr.PH, (Assistant Director), Ashley Grant, Ph.D, MPH, Hayden Huang, Ph.D., Amber Sinclair, Ph.D., and Penny Pickett, Ph.D.

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