GAO

Highlights of GAO-17-347, a report to congressional requesters

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Why GAO did this study

Infectious diseases continue to represent a threat to the health and livelihoods of people worldwide. Many infectious diseases can initially present with similar symptoms, making diagnosis challenging.

To address this challenge, federal agencies have identified technologies that can help diagnose infectious diseases by using multiplex assays—simultaneously testing for, or measuring, the presence of different pathogens. These technologies can also be deployed at or near the site of patient care. In this report, GAO discusses (1) the reported performance characteristics and costs of these technologies, (2) the technical challenges associated with multiplexing assays, and (3) the potential benefits and reported implementation challenges associated with these technologies.

To conduct this technology assessment, GAO reviewed Department of Defense (DOD), Department of Homeland Security (DHS), and Food and Drug Administration (FDA) documentation and scientific literature, and interviewed agency officials, developers and users of these technologies. GAO conducted site visits to eight developers identified by DOD and DHS market surveys. Experts convened with the assistance of the National Academies provided technical advice to GAO and reviewed a draft of this report. GAO incorporated their comments in the final report as appropriate.

View GAO-17-347. For more information, contact Chief Scientist Timothy M. Persons at (202) 512-6412 or personst@gao.gov.

TECHNOLOGY ASSESSMENT

Medical devices

Capabilities and challenges of technologies to enable rapid diagnoses of infectious diseases

What GAO found

Commercially available multiplex point-of-care technologies (MPOCTs) have a range of performance characteristics that describe, among other things, the ability of the technology to correctly identify the presence or absence of a pathogen. Some of these characteristics are used by the FDA to evaluate the technologies prior to approval; other attributes are considered by developers in designing and marketing their technologies. Technologies GAO examined have varying features such as physical size, number of diseases being tested for at the same time, and throughput – or the number of patient samples that can be simultaneously run. The amount of time it took for the technologies to return results to users ranged from 20 minutes to 2 hours. Among available technologies offered by the eight developers that GAO visited, procurement costs ranged from $25,000 to $530,000, and per-test operational costs ranged from $20 to $200.

Developers identified several technical challenges to developing multiplex assays that can slow MPOCT development and raise costs. For example, challenges include lack of patient sample access or reliable genetic databases for developing the assays. Modifying multiplex assays poses another challenge, because developers have to consider possible new interactions based on the modification and go through FDA review before the modified test can be marketed. Further, limitations in the number of targets—the part of the pathogen being detected—that can be detected, and identification of genetic targets used for detecting the pathogen, can constrain the performance of these technologies, in part as a result of design limitations.

Potential benefits of MPOCTs include improved patient health care and management, more appropriate use of antibiotics, improved ability to limit the spread of disease, and health care cost savings. However, developers and users disagreed on the strength of evidence showing the extent of MPOCT improvement on patient outcomes. Some stakeholders GAO spoke to identified the need for more clinical studies to establish the benefits of these technologies. Implementation challenges included reluctance by medical users to adopt these technologies, due to factors such as (1) lack of familiarity with such technologies, (2) costs and resources to use them, and (3) reluctance to order, and pay for, all of the tests for a given multiplex assay. Further, in some situations, positive test results for rare diseases are more likely to be false positives; thus systematic testing for such diseases may result in wasted resources to address all patients who test positive. Developers told us additional implementation challenges include the regulatory review process for getting approval or clearance to market their technologies. Another challenging aspect of the regulatory review process developers identified is in applying for waivers to allow untrained users to use their technologies. In some cases, selected developers believed that the performance by an untrained user may need to surpass the performance by trained users for such waivers. FDA officials confirmed that this could occur but nevertheless believed that their review process is necessary to ensure the technologies are safe and effective, while being accurate and simple to use when waived.