

Why GAO Did This Study

Bacterial infections have become more difficult, and sometimes impossible, to treat due to antibiotic resistance, which occurs when bacteria develop the ability to defeat the available drugs designed to kill them. Concerns about rising rates of resistance to available treatment options prompted the federal government to create the 5-year National Action Plan in 2015. The plan called for federal agencies to strengthen surveillance, advance the development of diagnostic tests and new antibiotics, and slow the emergence of resistant bacteria, among other things.

GAO was asked to review federal efforts to address antibiotic resistance. This report examines federal efforts and challenges related to (1) surveillance of antibiotic resistance, (2) the development and use of diagnostic testing to identify antibiotic resistance, (3) the development of treatments for resistant infections, and (4) appropriate antibiotic use. GAO reviewed literature and agency documents; interviewed agency officials and health care industry, drug industry, and other stakeholders; and held a meeting of international and U.S. experts to obtain their views.

What GAO Recommends

GAO is making eight recommendations to strengthen the federal response to combating antibiotic resistance. HHS concurred with seven recommendations and did not concur with one. More details are provided on the next page.

View [GAO-20-341](#). For more information, contact Timothy M. Persons at (202) 512-6888 or personst@gao.gov, or Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

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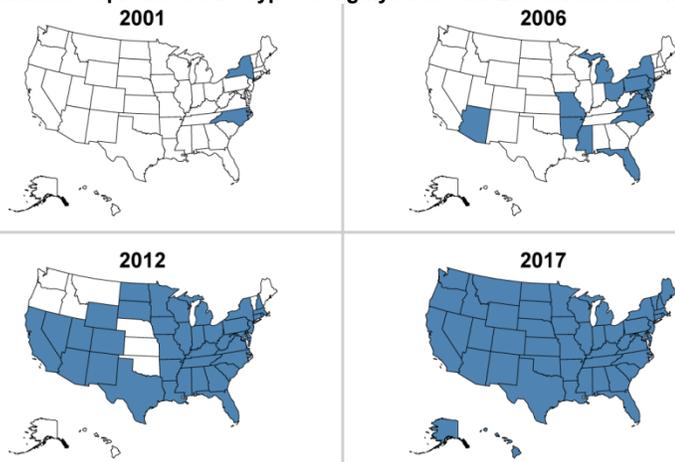
ANTIBIOTIC RESISTANCE

Additional Federal Actions Needed to Better Determine Magnitude and Reduce Impact

What GAO Found

The precise magnitude of the problem of antibiotic resistance is unknown. The Centers for Disease Control and Prevention (CDC) has made progress in expanding surveillance of infections from certain antibiotic-resistant bacteria in the United States and abroad but faces several challenges.

2001-2017 Cumulative Spread of One Type of Highly Resistant Bacteria in the United States



Source: Centers for Disease Control and Prevention (CDC). | GAO-20-341

Note: This figure tracks a type of carbapenem-resistant Enterobacteriaceae (CRE), which, according to CDC, is a "nightmare bacteria" resistant to nearly all available antibiotics. Shading indicates CDC confirmed the presence of these bacteria within that state in that year or a previous one.

CDC faces challenges in conducting surveillance for antibiotic resistance due to the limited data it is able to collect through various surveillance systems. For example, CDC's primary surveillance system for gonorrhea—which CDC classified as an urgent antibiotic resistance threat affecting over half a million patients annually—currently tracks only an estimated 1 to 2 percent of all U.S. cases and only in males. CDC has not fully evaluated the representativeness of the gonorrhea surveillance system's results. However, it could do so, for example, by comparing the trends in their limited sample population with trends it can establish in the overall U.S. population via additional studies. Such an evaluation could give CDC more confidence that the system's data accurately reflect national trends.

Federal agencies have taken steps to advance the development and use of diagnostic tests to identify antibiotic-resistant bacterial infections, but these efforts have limitations. For example, agencies have conducted some studies to establish whether testing can lead to positive health care outcomes, such as reduced rates of antibiotic-resistant infections. However, more such studies are needed, according to experts and agency officials. Without information to guide test usage, clinicians may not be able to select appropriate treatments for their patients. One reason for the insufficient number of studies is that Department of

What GAO Recommends

In response to the findings presented in this Highlights, GAO recommends that:

- CDC ensure that its evaluation of its surveillance system for antibiotic-resistant gonorrhea includes measures of the system’s representativeness of the U.S. population;
- HHS identify leadership and clarify roles and responsibilities to assess the clinical outcomes of diagnostic testing;
- HHS develop a strategy to further incentivize the development of new treatments for antibiotic-resistant infections, including through the use of postmarket financial incentives;
- HHS direct the CARB Task Force to include in its annual updates to the President plans for addressing any barriers preventing full implementation of the National Action Plan.

In addition, GAO is making four recommendations to address other CDC efforts in surveillance and reporting and to address FDA efforts in monitoring diagnostic tests.

HHS did not concur with the recommendation that it develop a strategy that includes the use of postmarket financial incentives to encourage the development of new treatments for antibiotic-resistant infections, citing its ongoing analysis to understand whether postmarket incentives should be included in such a strategy. GAO recognizes the complexity of this issue and maintains that this recommendation is warranted given that experts and others have called for additional postmarket incentives and the insufficiency of the current pipeline of new treatments for antibiotic-resistant infections.

Health and Human Services (HHS) agencies that are in a position to conduct or fund such studies—such as CDC and the Biomedical Advanced Research and Development Authority—disagree about what each agency should do. By clarifying roles and responsibilities, HHS agencies could more effectively address the need for more studies. The resulting studies could help demonstrate the value of diagnostic tests for antibiotic resistance, potentially increasing their use and improving patient care.

Experts warn that the current pipeline of antibiotics in development is insufficient to meet the threat of resistance. Several challenges impede the development of new treatments for resistant infections, notably inadequate return on investment for drug companies largely due to low prices and a limited patient population for whom these treatments would be appropriate. While HHS and Department of Defense agencies have provided financial premarket incentives to support antibiotic research and development, experts, federal officials and antibiotic developers agree that more postmarket incentives are needed to overcome the economic challenges. Advisory groups, including a presidential advisory council, and others have called for new postmarket incentives and identified multiple options for their design, including market entry rewards and reimbursement reform (see figure). However, HHS has not developed a strategy to further incentivize development of new treatments for antibiotic-resistant infections, and it may need to request authority and appropriations to create and implement certain types of incentives. Until such incentives are developed, more drug companies may exit the antibiotic development sector, and the pipeline of new treatments may continue to decrease.

Examples of Possible Postmarket Incentive Options to Encourage the Development of Antibiotics Identified by Advisory Groups and Others

Market entry reward A market entry reward could be awarded in addition to, or in replacement of, sales revenues		Reimbursement reform	
Lump sum payment	Transferable voucher	Licensing arrangement	Add-on payment
<ul style="list-style-type: none"> • Monetary reward paid to developers of new antibiotics • Could be paid over multiple years 	<ul style="list-style-type: none"> • Voucher that could be sold or auctioned and would confer additional market exclusivity for a different pharmaceutical drug 	<ul style="list-style-type: none"> • Antibiotic purchasing arrangement in which hospitals would pay a fixed fee to access the drug, which would allow them to use a certain number of doses 	<ul style="list-style-type: none"> • Payments to hospitals for use of certain antibiotics that are made in addition to the bundled payment the hospital already receives for a patient’s inpatient stay

Source: GAO summary of publicly available proposals. | GAO-20-341

Federal agencies have made several efforts to promote the appropriate use of antibiotics across health care settings through antibiotic stewardship—giving patients the right antibiotic at the right time, in the right dose, and for the right duration. However, key challenges remain. For example, federal agencies require only certain types of health care facilities to implement stewardship programs. In addition, CDC is limited in its ability to monitor and improve appropriate antibiotic use, in part because providers are not generally required to report antibiotic use data to a centralized database. The 5-year *National Action Plan for Combating Antibiotic-Resistant Bacteria* (National Action Plan) calls for strengthening antibiotic stewardship and for the timely reporting of antibiotic use data across health care settings. An executive order directs an interagency task force—the Combating Antibiotic-Resistant Bacteria (CARB) Task Force, coordinated by HHS—to provide annual updates to the President on, among other things, plans for addressing any barriers to full implementation of the National Action Plan. However, in its progress reports covering the first 4 years of the National Action Plan’s implementation, the task force did not identify plans to address barriers to expanding antibiotic stewardship programs or the collection of antibiotic use data. Until it does so, the government will not have reasonable assurance that it is fully implementing the National Action Plan and addressing antibiotic resistance.