Antibiotic Resistance

Additional Federal Actions Needed to Better Determine Magnitude and Reduce Impact

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2015 National Action Plan* (NAP) Five-Year Goals

1. Slow the emergence of resistant bacteria and preventing the spread of resistant infections;
2. Strengthen national One-Health surveillance efforts to combat resistance;
3. Advance the development and use of rapid and innovative diagnostic tests for the identification and characterization of resistant bacteria;
4. Accelerate basic and applied R&D for new antibiotics, other therapeutics, and vaccines; and
5. Improve international collaboration and capacities related to the first four goals.

*U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan)

Our Study Objectives Were Linked to NAP Goals

1. CDC's efforts to conduct surveillance of antibiotic resistance and any challenges to these efforts; (NAP Goal 2)
2. Federal efforts to advance the development and use of tests for diagnosing antibiotic-resistant infections; (NAP Goal 3)
3. Challenges to developing new treatments for antibiotic-resistant infections and federal efforts to address the challenges; (NAP Goal 4) and
4. Federal efforts to promote the appropriate use of antibiotics and any challenges that remain (NAP Goal 1)
5. International collaboration was implicit in all of our questions. (NAP Goal 5)

Overall Key Findings

Since the National Action Plan was released in 2015, federal agencies have made progress in addressing various facets of antibiotic resistance in the United States and abroad.

However:

- The precise magnitude of the problem of antibiotic resistance, and its trends over time remain unknown,
- Development and use of diagnostic tests face obstacles to robust clinical use,
- The industrial antibiotic pipeline is struggling from economic challenges, and
- Adoption of practices for appropriate use of antibiotics are limited by a variety of challenges

Major Findings: Surveillance

CDC has made efforts to collect and report information about antibiotic resistance, but it does not know the precise magnitude of the antibiotic resistance threat due largely to three challenges.

1. First, it faces limitations in data reporting and resistance testing from hospitals, as well as challenges ensuring that its resistant gonorrhea surveillance system is representative of the U.S. population.
2. Second, CDC faces challenges in reporting complete and timely information on the magnitude of and trends in antibiotic resistance.
3. Finally, CDC faces challenges to detecting resistance threats abroad.

Major Findings: Diagnostic Tests

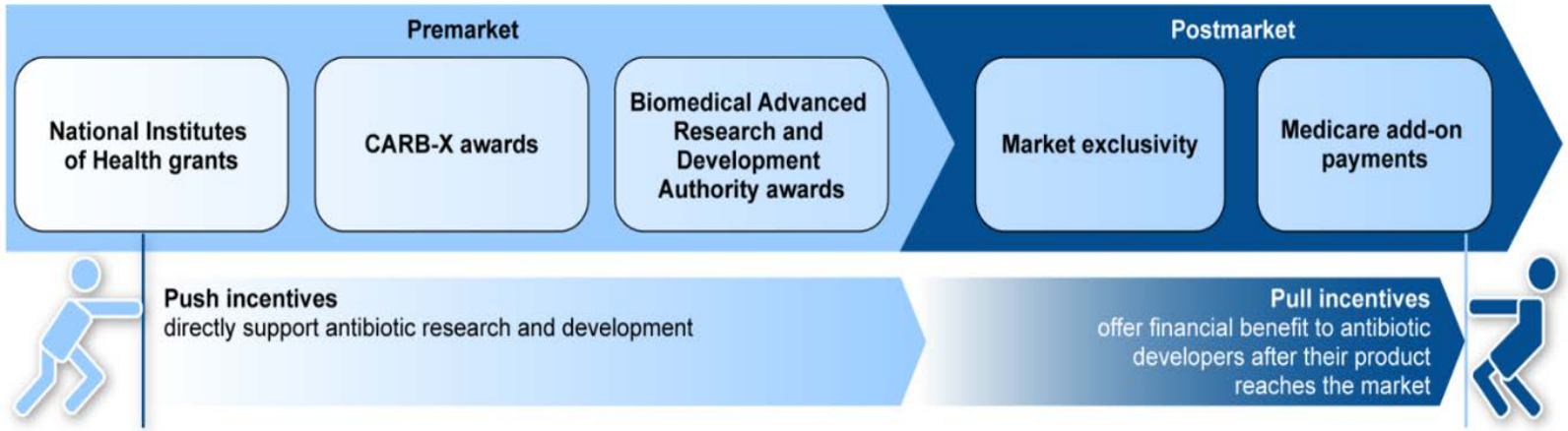
Federal agencies have helped advance the development of new FDA-authorized tests and the use of existing tests for diagnosing antibiotic-resistant infections, but these efforts face challenges to robust test adoption.

1. HHS and DOD have funded studies and taken other steps to advance testing, but they have not defined leadership, roles, and responsibilities to establish the clinical outcomes to support the use of such tests.
2. FDA has taken steps to advance testing; however, it has not regularly monitored test updates, including updates to “breakpoints” for distinguishing between susceptible and resistant bacteria.

Major Findings: Antibiotic Development

- Federal agencies currently incentivize antibiotic development, but economic challenges persist and threaten the antibiotic development pipeline.
- Experts have called for further focus on pull incentives to maintain the pipeline.

Currently Available Federal Push and Pull Incentives for Antibiotic Development



Source: GAO summary of information from the Department of Health and Human Services and literature. | GAO-20-341

Major Findings: Antibiotic Stewardship

- Federal agencies have undertaken several efforts to promote the appropriate use of antibiotics, but face challenges.
  - Federal efforts have been limited
  - Incomplete antibiotic use data limits CDC's ability to monitor appropriate use
  - Training may not improve prescribing behaviors

Source: GAO. | www.gao.gov

Major Findings: Addressing Barriers

The Combating Antibiotic-Resistant Bacteria (CARB) Task Force reports on progress on the National Action Plan, including plans to address barriers agencies face.

The CARB Task Force has not reported on barriers to implementing key Plan components, including expanding:

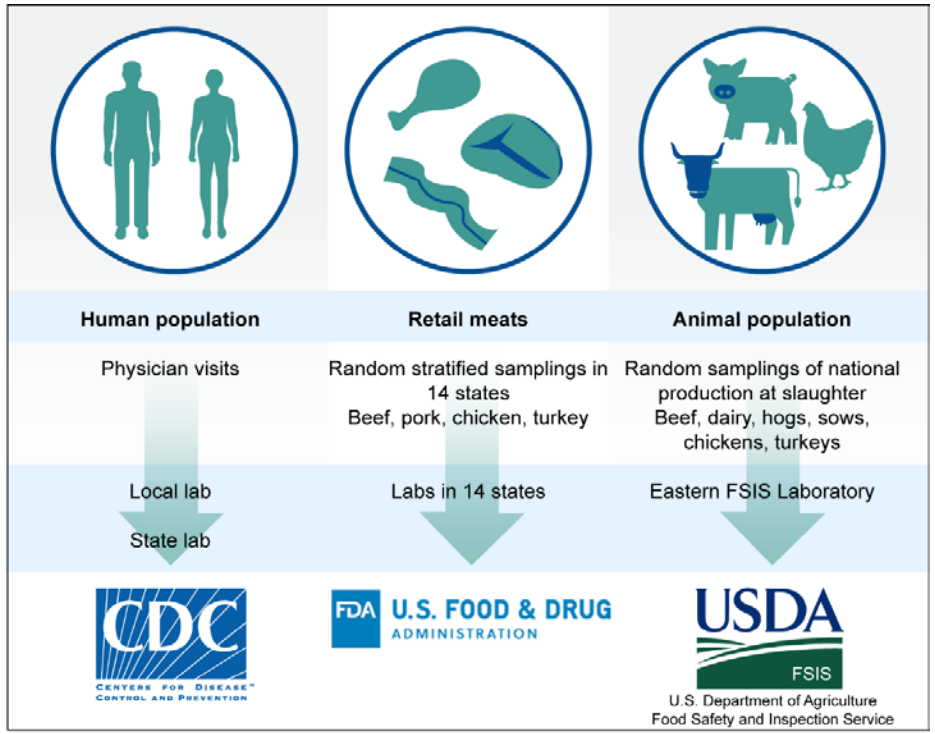
- A CDC program to strengthen response to resistant gonorrhea
- Stewardship programs across various health care settings
- Data collection on antibiotic use

Major Findings: Antibiotic Use in Animals

Federal agencies have improved data collection, but oversight gaps still exist.

- Drug labels for some antibiotics don't define duration of use.
- On-farm antibiotic use data collection is limited.
- FDA and USDA do not have metrics to assess impact of actions they have taken.

Other countries have taken actions, but some U.S. federal officials and stakeholders believe that similar U.S. actions are not feasible.

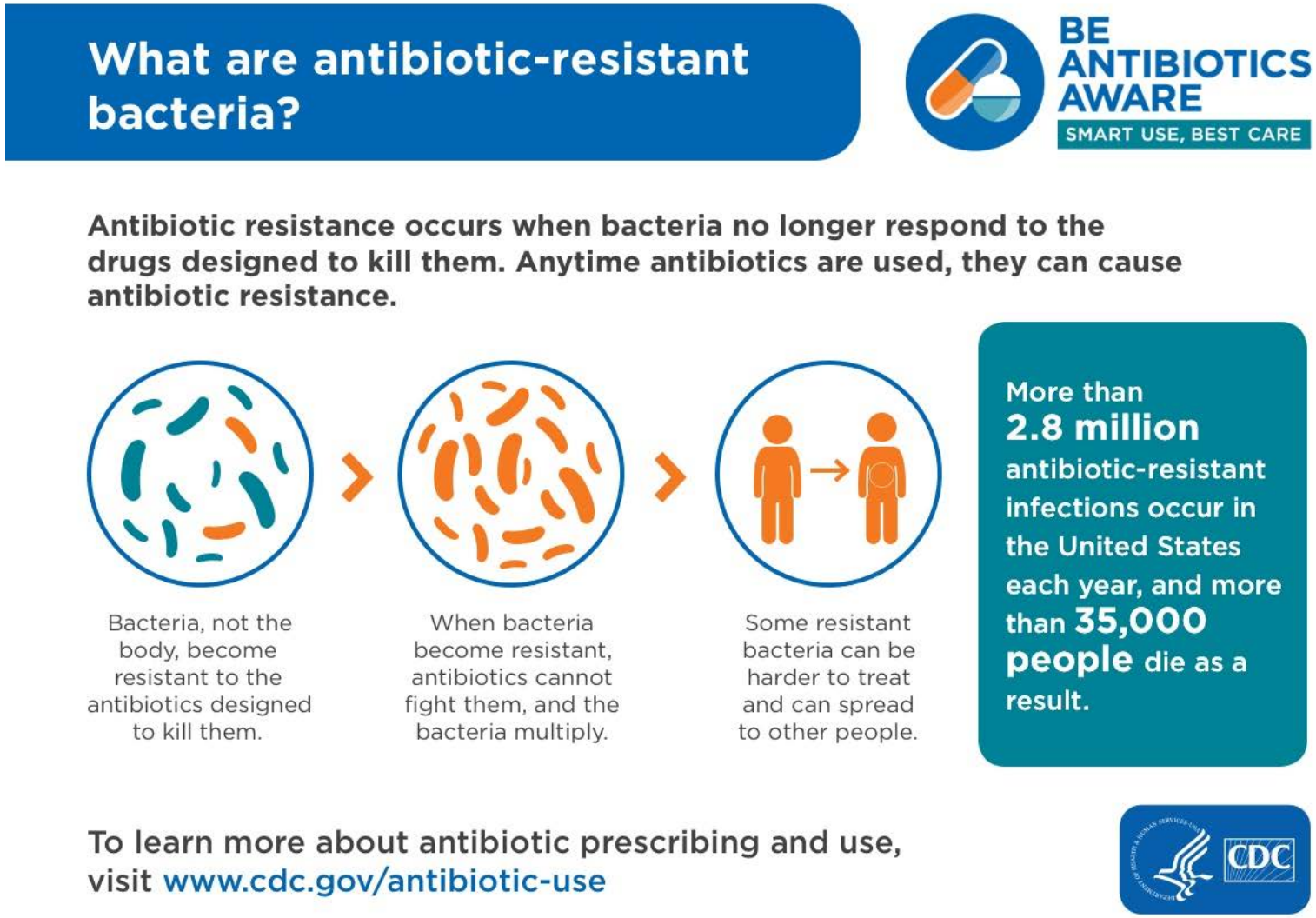


Source: Food and Drug Administration. | GAO-17-192

[*Note*: GAO notes the One-Health framework taken by the NAP and includes some of the animal perspective here since the scope of GAO-20-341 focused on human health.]

Conclusions

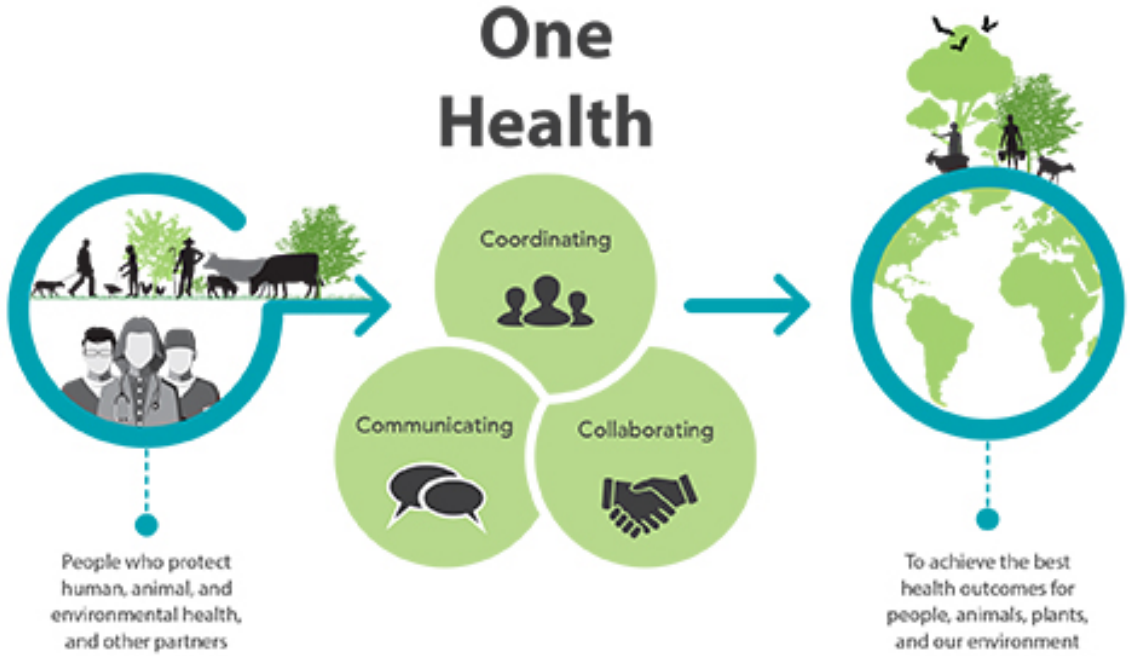
- Antibiotic resistance is a growing public health threat, and without urgent action common infections may become deadly threats.
- A concerted global effort from multiple stakeholders and countries is critical.
- Federal agencies have taken steps to improve surveillance, diagnostic testing, development of new treatments, and stewardship.



Source: Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP)

Conclusions (continued)

- However, HHS steps are lacking.
  - Until HHS develops a strategy to further incentivize development of new treatments through the use of post-market incentives, the pipeline of new treatments may continue to decrease.
- Without ensuring that barriers to implementing the National Action Plan are reported, the federal government will not have reasonable assurance that the Plan can be fully implemented.



Source: Centers for Disease Control and Prevention , National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

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