

PACCARB Overview

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All information is available at:

<http://www.hhs.gov/ash/advisory-committees/paccarb/index.html>

The opinions and views expressed in this informational presentation are my personal comments. As such, the presentation is not made on behalf of PACCARB nor in an official US Government capacity.

National Action Plan Goals (March, 2015)

Led by HHS, USDA and DoD

(other Departments also contribute)

1. Slow the emergence of resistant bacteria and prevent the spread of resistant infections.
 2. Strengthen national one-health surveillance efforts to combat resistance.
 3. Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria.
 4. Accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines.
 5. Improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control and antibiotic research and development.
- The *National Action Plan* divides the work under each goal into objectives, sub-objectives and Year 1, Year 3, Year 5 milestones.

Implementation of the National Action Plan will:

By 2020, implementation of the *National Action Plan* will lead to:

- major reductions in the incidence of urgent and serious threats, including carbapenem-resistant *Enterobacteriaceae* (CRE), methicillin-resistant *Staphylococcus aureus* (MRSA), and *Clostridium difficile*
- improved antibiotic stewardship in healthcare settings,
- prevention of the spread of drug-resistant threats,
- elimination of the use of medically-important antibiotics for growth promotion in food animals, and expanded surveillance for drug-resistant bacteria in humans and animals .

Other significant outcomes include:

- creation of a regional public health laboratory network,
- establishment of a specimen repository and sequence database that can be accessed by industrial and academic researchers,
- development of new diagnostic tests through a national challenge, development of two or more antibiotic drug candidates or non-traditional therapeutics for treatment of human disease

In addition,

- the effort to combat resistant bacteria will become an international priority for global health security.

Slow the emergence of resistant bacteria and prevent the spread of resistant infections

- Eliminate the use of medically-important antibiotics for growth promotion in food-producing animals and bring other agricultural uses of antibiotics, for treatment, control, and prevention of disease, under veterinary oversight.
- Identify and implement measures to foster stewardship of antibiotics in animals.
 - Sub-Objective 1.3.1: Develop, implement, and measure the effectiveness of evidence-based educational outreach to veterinarians and animal producers to advance antibiotic stewardship and judicious use of antibiotics in agricultural settings.
 - Sub-Objective 1.3.4: Develop appropriate metrics to gauge the success of stewardship efforts and guide their continued evolution and optimization.

Strengthen national one-health surveillance efforts to combat resistance (2)

- Enhance monitoring of antibiotic-resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain for food animals and retail meat.
 - Enhance surveillance of antibiotic resistance in animal and zoonotic pathogens and commensal organisms by strengthening the National Antimicrobial Resistance Monitoring System (NARMS) and leveraging other field- and laboratory-based surveillance systems.
 - Enhance collection and reporting of data regarding antibiotic drugs sold and distributed for use in food-producing animals.
 - Implement voluntary monitoring of antibiotic use and resistance in pre-harvest settings to provide nationally representative data while maintaining producer confidentiality.
 - Collect quantitative data on antibiotic-resistance and management practices along various points at pre-harvest, harvest, and processing stages, in collaboration with producers and other stakeholders, and disseminate information as appropriate.
- Develop, expand, and maintain capacity in veterinary and food safety laboratories to conduct standardized antibiotic susceptibility testing and characterize select zoonotic and animal pathogens.

National Action Plan: 180-day Review PAC Assessment (March, 2016)

PACCARB identified six overarching themes that will require further attention by the USG for the NAP and the efforts of the USG to have the strongest impact in combating antibiotic-resistant bacteria:

- **Fully embracing a One Health approach**
- **A lead federal champion of the CARB initiative**
- **Coordination of the federal response**
- **Resource allocation**
- **Development of critical partnerships**
- **Economic incentives for developing and deploying new diagnostic, preventive, and therapeutic tools**

Additional Information Slides follow this one

Presidential Advisory Council Combating Antibiotic-Resistant Bacteria

- The President's Council of Advisors on Science and Technology (PCAST) Report on Combating Antibiotic Resistance. (September, 2014)
- Executive Order 13676 directing federal agencies to implement the recommendations from the PCAST report, which includes creation of a federal interagency Task Force on Combating Antibiotic-Resistant Bacteria. (September 2014)
- Creation of the federal government's National Strategy (2014) and resulting National Action Plan (NAP) for Combating Antibiotic-Resistant Bacteria. (March 2015)
- Executive Order 13676 also directed the Secretary of the U.S. Department of Health and Human Services (HHS), in consultation with the Secretaries of the Departments of Defense (DoD) and Agriculture (USDA), to establish a President's Advisory Council on Combating Antibiotic Resistant Bacteria (PACCARB). (September 2015)

Mission Statement

- The mission of the PACCARB is to provide advice, information, and recommendations to the HHS Secretary regarding programs and policies intended to support and evaluate the implementation of the NAP, which will then be transmitted by the HHS Secretary to the President.

Membership

- 15 Voting Members (3 or 4 year appointment)
- 5 Non-voting Liaison Members
- 15 Ex-officio Members (USG agency representatives)

PACCARB Meetings

- ✓ September, 2015 – Overview of NAP, assignments
- ✓ March, 2016 – 180-day report on NAP progress
- ✓ June, 2016 – Incentives for Antibiotics, Diagnostics, Vaccines and Environmental Overview
- ✓ September, 2016 – Healthcare-associated infection prevention and Stewardship
- ☐ 2017 meetings – TBD

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Strengthen national one-health surveillance efforts to combat resistance (1)

- Develop, expand, and maintain capacity in State and Federal veterinary and food safety laboratories to conduct antibiotic susceptibility testing and characterize select zoonotic and animal pathogens.
 - Expand and maintain veterinary and food safety laboratory infrastructure for the identification of select zoonotic and animal health pathogens through the implementation of new diagnostic technologies (see also Goal 3) .
 - Accelerate and standardize antibiotic susceptibility testing and bacterial characterization for select zoonotic and animal health pathogens, coordinating with appropriate stakeholder groups .
 - Enhance communications and identify mechanisms for sharing and reporting antibiotic-susceptibility data on select zoonotic and animal health pathogens collected by veterinary diagnostic and food safety laboratories . These data should be stored in a centralized repository that can be linked with relevant public health databases, as appropriate, while maintaining source confidentiality .

Advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria.

- Develop and validate new diagnostics—including tests that rapidly distinguish between viral and bacterial pathogens and tests that detect antibiotic-resistance—that can be implemented easily in a wide range of settings.

Accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines.

- Conduct research to enhance understanding of environmental factors that facilitate the development of antibiotic-resistance and the spread of resistance genes that are common to animals and humans.
- Increase research focused on understanding the nature of microbial communities, how antibiotics affect them, and how they can be harnessed to prevent disease.
- Develop non-traditional therapeutics and innovative strategies to minimize outbreaks caused by resistant bacteria in human and animal populations.

Improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control and antibiotic research and development.

- Surveillance

- Collaborate with WHO, OIE, and other international efforts focused on the development of integrated, laboratory-based surveillance to detect and monitor antibiotic-resistance in relevant animal and human foodborne pathogens.
- Develop a mechanism for international communication of critical events that may signify new resistance trends with global public and animal health implications.

- Research and Development

- Establish and promote international collaboration and public-private partnerships to incentivize development of new therapeutics to counter antibiotic-resistance including new, next-generation, and other alternatives to antibiotics, vaccines, and affordable, rapidly deployable, point-of-need diagnostics.

- Prevention and Control

- Support countries to develop and implement national plans to combat antibiotic-resistance and strategies to enhance antimicrobial stewardship.
- Partner with other nations to promote quality, safety, and efficacy of antibiotics and strengthen their pharmaceutical supply chains.
- Coordinate regulatory approaches by collaborating with international organizations such as FAO and OIE to harmonize international data submission requirements and risk assessment.

New Task in March, 2016

Task assigned by HHS Secretary Burwell

- What is the best way to incentivize the development of therapeutics (including alternatives to antibiotics), rapid diagnostics, and vaccines for both humans and animals while maximizing the return on investment, and still encouraging appropriate stewardship, and access to products?

June 21-22, 2016 Meeting

- June 21 (Day 1) of the public meeting was dedicated to presentations from federal and non-federal stakeholders surrounding topic areas related to incentives for the development of vaccines, diagnostics, and therapeutics.
- June 22 (Day 2) was focused on the topic of the environment and antibiotic-resistance, in addition to a presentation regarding the new Food and Drug Administration's Guidance for Industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With Guidance for Industry #209."

September 19, 2016 Meeting

- September 19 –Prevention, Stewardship and Innovation activities were covered by government agency representatives for “lessons learned”
 - HICPAC (Healthcare Infection Control Practices Advisory Committee) - opportunities to collaborate
 - Stewardship actions in confined populations
 - Innovation activities in USDA and human-health agencies
 - December 13-15, 2016 USDA-OIE ATA meeting in Paris
 - <https://www.ars.usda.gov/alternativestoantibiotics/Symposium2016/contact.html>

Summary

- PACCARB provides recommendations to the HHS Secretary on the topic of AMR Actions as outlined in the US National Action Plan
- The Council has been in existence since September, 2015 and held 4 public meetings
- Notable accomplishments include a Review of initial NAP progress by the agencies, providing information on relevant topics such as environmental AMR, prevention, stewardship, antibiotic pipeline topics, veterinary regulatory updates, etc.