

USDA Inputs for Goal 2: One Health Surveillance

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USDA Agencies Contributing to Antimicrobial Resistance Work

- **Agricultural Research Service (ARS)**
- **Animal and Plant Health Inspection Service (APHIS)**
- **Food Safety and Inspection Service (FSIS)**
- **Agricultural Marketing Service (AMS)**
- **Foreign Agricultural Service (FAS)**
- **Economic Research Service (ERS)**
- **National Institute for Food and Agriculture (NIFA)**
- **National Agricultural Statistics Service (NASS)**

Objective 2.3

Develop, expand, and maintain capacity in veterinary and food safety laboratories to conduct standardized antibiotic susceptibility testing and characterize select zoonotic and animal pathogens.

Objective 2.3

Within one year:

USDA and FDA will assess current capacities and protocols within NAHLN and Vet-LIRN member laboratories and identify capacity development needs to support nationwide AR surveillance for zoonotic pathogens and pathogens of importance to animal health.

Objective 2.3

Within three years:

USDA and FDA will support capacity development in ten selected NAHLN and Vet-LIRN member laboratories by providing training in standardized methodologies for antibiotic-susceptibility testing.

Objective 2.4

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.

Objective 2.4

Within one year:

USDA will develop a plan for expanded monitoring of resistant bacteria throughout the food production continuum (e.g., pre-harvest, harvest, and processing of food products). On-farm sampling will be voluntary.

Objective 2.4

Within three years:

USDA will implement collection of data on antibiotic-resistance and management practices during pre-harvest, harvest, and processing of food products. On-farm sampling will be voluntary. This information will be used to monitor trends in drug-resistant bacteria and identify potential mitigation strategies for further investigation.

For Consideration

- **What is the appropriate role of molecular v. culture based surveillance and characterization for antimicrobial resistance?**
- **What is the appropriate investment mix for the government across the areas of agriculture versus human health and among research versus surveillance versus outreach/education?**
- **What are some solutions around obstacles (limited resources) existing for collecting antimicrobial use data and samples for characterizing antimicrobial resistance?**
 - **With limited resources, what would be a good model for a public-private partnership for collection of antimicrobial use and resistance data?**
 - **Other options?**

Thank You

Resources:

- **USDA AMR Action Plan: <http://www.usda.gov/documents/usda-antimicrobial-resistance-action-plan.pdf>**
- **Proposed initiatives from the USDA AMR Action Plan: https://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf**

FDA Activities to Strengthen National One-Health Surveillance Efforts to Combat Resistance (Goal 2)

William Flynn, DVM, MS
Deputy Director for Science Policy
Center for Veterinary Medicine
Food and Drug Administration

September 29, 2015

FDA's Center for Veterinary Medicine

- Component of FDA's Office of Foods and Veterinary Medicine
- Responsible for regulating animal drugs, devices, and food additives
- Works closely with CDC and USDA on coordinating National Antimicrobial Resistance Monitoring System (NARMS)
- Coordinates Veterinary Laboratory Investigation and Response Network (Vet-LIRN)
- Collaboration with Federal Partners critical to work on antibiotic resistance

FDA activity on Goal 2 focused on:

- **Objective 2.3:** Develop, expand, and maintain capacity in veterinary and food safety laboratories to conduct standardized antibiotic susceptibility testing and characterize select zoonotic and animal pathogens.
- **Objective 2.4:** 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.

Status of Goal 2 activities -

- **Objective 2.3:** FDA working with USDA to assess current capacities and protocols within the USDA NAHLN and the FDA Vet-LIRN member laboratories. Expanding capacity dependent on funding.
- **Objective 2.4:** FDA pursuing multipronged approach
 - Enhancing certain existing data elements, including
 - Antibiotic sales/distribution data
 - NARMS retail meat data
 - Collaborating with USDA and CDC on collection of on-farm data

Objective 2.4 Activities:

Enhanced sales data collection and reporting

- October 2014 – FDA began issuing enhanced annual summary reports on the sale and distribution of antibiotics approved for use in food producing animals
 - include additional data tables to provide more detailed information and to improve transparency
- May 2015 – Published proposed rule to revise annual antibiotic sales reporting requirements; includes proposed requirement to estimate sales by major food animal species

Objective 2.4 Activities: Expanded retail meat testing

- As part of the NARMS program, FDA is expanding retail meat testing in 2015-2016 by increasing the number of retail meats from 6,700 per year to 13,400 per year.
- NARMS has begun contributing bacterial isolates for whole genome sequencing and cataloging

Objective 2.4 Activities: Enhanced NARMS report and data availability

- In August 2015, FDA released its 2012-2013 NARMS Integrated Report. This report replaces FDA's annual NARMS Executive Summary report and highlights antimicrobial resistance patterns in bacteria isolated from humans, retail meats, and animals at slaughter.
- FDA also published online its collection of bacteria (enteric isolates) – *Salmonella*, *Campylobacter*, *Escherichia coli*, and *Enterococcus* – collected over the past 18 years as part of NARMS

Objective 2.4 Activities:

Addition of on-farm antibiotic use data

- On-farm data intended to augment existing data (e.g., sales, resistance data) to provide more comprehensive picture of antibiotic use practices.
- Important for assessing impact of implementing FDA's Guidance #213 (Goal 1.2)
- FDA, USDA, CDC working group formed to develop possible approaches for collecting on-farm

Objective 2.4 Activities: Data collection public meeting

- Jointly sponsored by FDA, USDA, and CDC
- September 30, 2015, Jefferson Auditorium, Washington, DC
- First opportunity to obtain public input on our ongoing effort to develop and implement plans for collecting additional on-farm antimicrobial drug use and resistance data.
- Public docket with 60-day comment period; comments received at public meeting and submitted to docket to be considered

In closing...

- Enhancing data collection on antibiotic use and resistance is critical for assessing impact of actions taken
- Such data is important for:
 - assessing the adoption of changes outlined in FDA's Guidance 213
 - gauging effect of stewardship efforts; guiding their continued evolution and optimization
- Resource limitations will present a challenge in collecting sufficient data to effectively assess progress over time
- Subject of the September 30 public meeting
- Input from the Advisory Council on this issue would be valuable

THANK YOU

PRESIDENTIAL ADVISORY COUNCIL ON
COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Goal 2: Strengthen National One-Health Surveillance Efforts to Combat Resistance

Detect, Protect & Innovate

Beth P. Bell, MD, MPH

Director

National Center for Emerging and Zoonotic Infectious Diseases

Centers for Disease Control and Prevention

Public Health Surveillance

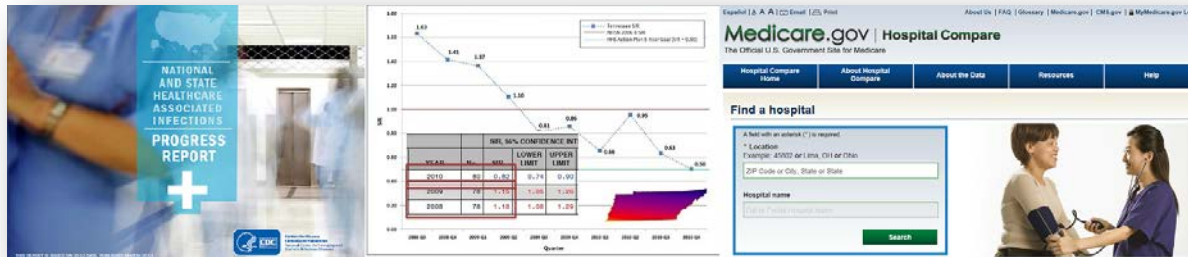
- Complementary data systems
 - Track different AR threats and aspects of those threats
 - Facilitate quality improvement
 - Define risk populations
- National and international laboratory expertise, testing, and diagnostic capacity
 - Identify types of resistance, especially novel forms
 - Provide reference testing and diagnostic capacity
 - Develop new detection methods

CDC's Major AR Surveillance Systems

Tracking Networks	Data Collected
<p>NHSN National Healthcare Safety Network</p>	<p>A system that collects and provides <u>data on infections and drug-resistance in healthcare settings</u>. Since NHSN collects data directly from healthcare facilities, it can provide facility-level information on healthcare-associated infections, antibiotic resistance, and antibiotic use.</p>
<p>NARMS National Antimicrobial Resistance Monitoring System</p>	<p>A national public health surveillance system that <u>tracks changes in the susceptibility of foodborne and other enteric bacteria to antibiotics of human and veterinary medical importance</u>. NARMS is a collaboration among CDC, FDA, USDA, and state and local health departments CDC tests bacterial isolates from humans, while FDA and USDA test isolates from retail meats and food animals.</p>
<p>EIP Emerging Infections Program</p> <p>Three main components within the EIP:</p> <ul style="list-style-type: none"> • ABCs: Active Bacterial Core surveillance • HAIC: Healthcare-Associated Infections-Community Interface • FoodNet: Foodborne Diseases Active Surveillance Network 	<p>A network of public health-academic-hospital collaborations in 10 states. It <u>provides access to bacterial and fungal samples for testing and detailed clinical case data</u>. The three main programs within EIP collect different types of resistance data:</p> <ul style="list-style-type: none"> • ABCs: clinical information and resistance data for bacteria that cause infections predominately in the community • HAIC: clinical information and resistance data for bacteria and fungi that cause infections at the intersection of healthcare and the general community • FoodNet: clinical and epidemiologic data on some human isolates in NARMS

CDC's National Healthcare Safety Network (NHSN)

- NHSN is a national surveillance and quality improvement system tracking infections in over 17,000 healthcare facilities nationwide
- NHSN is used by:
 - **Facilities across healthcare** to track HAIs and antimicrobial resistance, and direct prevention activities
 - **States** for public reporting and regional prevention
 - **CMS** for quality reporting and prevention initiatives
 - **HHS** to measure national progress

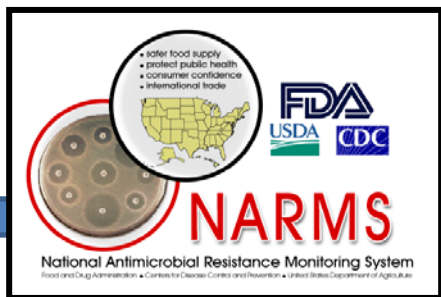


NHSN: Detect and Protect

Tracking Antibiotic Use and Resistance

- To date, 116 facilities have submitted at least 1 month of antibiotic use (AU) data to NHSN
 - VA lead collaborator; implementing hospital AU reporting in 48 hospitals
- Implementation of **NHSN's Antibiotic Use and Resistance (AUR) module** will support:
 - Hospital implementation of antibiotic stewardship programs and quality improvement efforts locally
 - Public health collection of antibiotic use and antibiotic resistance data from healthcare facilities to improve appropriate prescribing
 - National benchmarking to target improvements in antibiotic use and antibiotic resistance

National Antimicrobial Resistance Monitoring System (NARMS)



humans
CDC/NCEZID



54 health departments:
isolates from patients

retail meats
FDA/CVM



grocery stores in 14 states:
ground beef, chicken,
ground turkey, pork chops

animals
USDA/FSIS



slaughter and processing
facilities: cattle, chicken,
turkeys, swine

Search Options

Bacteria: *Salmonella* Serotype: Typhi Antibiotic: nalidixic acid From: 1999 To: 2013 States: All

Resistance By State (2013)

Set your search above, then press play to see changes in resistance over time.

Resistance by Year

Percentage resistant (0-90%) vs Year (1998-2014). 95% confidence interval (CI) is shown.

Quick Stats (based on current search)

4,616	Total <i>Salmonella</i> Typhi isolates tested
2,454	Total resistant to nalidixic acid

Please read this [disclaimer](#) before using these data.

Download

- [Download data related to your search](#)
- [Download all NARMS data](#)
- [Data dictionary](#)

Note: Downloadable isolate-level data are not available from all states.

CDC's Emerging Infections Program (EIP)

Early warning system for new and changing threats

- CDC funded network of 10 state health departments collaborating with local health departments, academic institutions, other federal agencies, laboratories, infection preventionists, and healthcare providers
- EIP population (~44 million) representative of the U.S. (e.g., age, gender, race, population density, percent at or below poverty level)
- Conduct surveillance on infectious disease, foodborne disease, influenza, HAIs, and antibiotic resistance to estimate national burden numbers
 - Estimated 722,000 HAIs in U.S. hospitals in 2011, or 1 in 25 patients
 - About 50% of all U.S. hospital patients in 2011 received at least one antibiotic
- Conduct applied research, e.g., risk factors and prevention strategies



CDC's Clinical & Environmental Microbiology Laboratory

- Serve as national and an international reference laboratory for antimicrobial susceptibility testing
- Provide reference testing and diagnostic capacity for pathogens causing HAIs and antibiotic resistant infections
- Develop and evaluate methods to reliably detect emerging antimicrobial resistance
- Conduct applied research on improved detection methods for HAIs
- Provide environmental microbiology methods for assessing contamination of healthcare environment

“Detect” Regional AR Laboratory Network

- The regional laboratory network would be able to:
 - More rapidly detect outbreaks caused by AR pathogens
 - Characterize resistance mechanisms
 - Track resistance trends
 - Identify emerging forms of resistance
- Partnerships will be critical to:
 - Link and communicate data with existing laboratories
 - Provide key isolates for research and development, including genomic sequencing

AR Isolate Bank

- Launched by CDC and FDA in June 2015 (CARB Year 3 milestone)
- Provides collections of bacteria to support research and development of new diagnostic tests and antibiotic drugs
 - Curated panels from the AR isolate bank can be used to challenge and design the next generation of clinical tests and therapeutic agents
- To date, bank contains over 160 isolates comprised of first collections of CRE and other multi-drug resistant gram-negative rods
 - CDC filled 26 orders from diagnostic test manufacturers, pharmaceutical companies, and academic researchers within 2 months of launch

National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB)

FY 2016 President's Budget

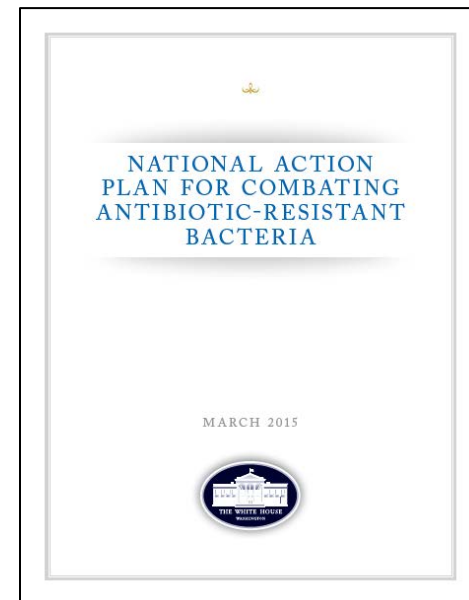
+\$264 million

- State HAI/AR Prevention (Protect) Programs
- Antibiotic stewardship activities
- Detect Network of AR Regional Labs

+\$14 million

- National Healthcare Safety Network (NHSN)

Supports implementation of CDC's activities under the National Strategy and National Action Plan



Thank you

GOAL 2: Strengthen National One-Health Surveillance Efforts to Combat Resistance

29 SEP 15

LTC Paige Waterman, MD
DoD AMR Lead

Armed Forces Health Surveillance Center - Global Emerging Infections Surveillance
and Response System



PRESIDENTIAL ADVISORY COUNCIL ON
COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Goal 2: DoD

- Centralized laboratory analyses saves money, time and provides reliable data for actionable surveillance efforts
- With more than 9.6 million beneficiaries worldwide and a global problem of AMR, DoD enhancements to its already well-developed laboratory and analytical processes and knowledge sharing with others will continue to improve quality of care and overall patient safety efforts

Goal 2: DoD



- MRSN (based at Walter Reed Army Institute of Research, or WRAIR)
 - Vast repository of clinically relevant isolates
 - Bioinformatics pipeline optimization including genetic characterization; translational database
 - Collaborative contributions to national molecular database (NIH/NCBI)

Goal 2: DoD



MRSN
Multidrug-resistant Organism Repository and Surveillance Network
Walter Reed Army Institute of Research



- Navy-Marine Corps Epi Data Center, Army Pharmacovigilance Center, and MRSN
 - Prepare enterprise-wide data entry to the CDC National Healthcare Safety Network (NHSN) on antibiotic susceptibility and use information
 - Will inform DoD Stewardship Policy and Procedures



Goal 2: DoD

- AFHSC-GEIS
 - Guiding One-Health work through its partner network as well as with own Food Safety-certified veterinarians

THANK YOU