



United States Department of Agriculture

USDA APHIS Proposals for Collection and Analysis of Antimicrobial Use and Resistance Data

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services
Science, Technology and Analysis Services

FDA Public Meeting, Washington, DC
September 30, 2015

USDA 2012 Stakeholder Workshop

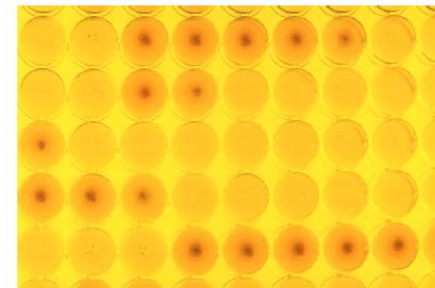
- Research
- Surveillance
- Outreach/education



Antibiotic Resistance Workshop Executive Summary

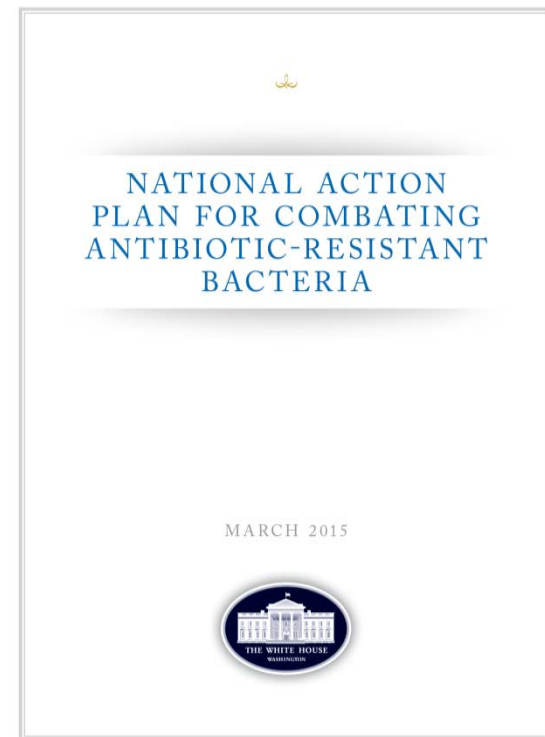
George Washington Carver Center
Beltsville, Maryland

May 15–17, 2012



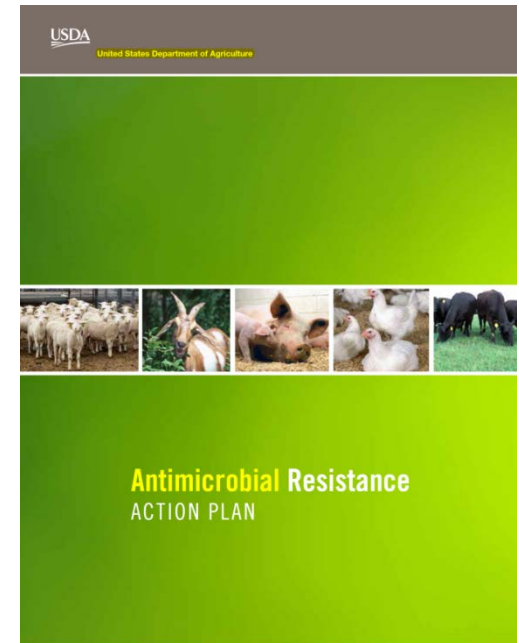
U.S. National Strategy and Action Plan for Combating Antibiotic-Resistant Bacteria

- Roadmap to confront AMR via multiple partners and stakeholders



USDA AMR Action Plan

- Describes how USDA proposes to obtain and disseminate science-based, actionable, quantitative antibiotic drug use information coupled with the development of resistance in food-producing animals and to relate this to livestock management practices.
- With stakeholders, address recognized knowledge gaps and develop effective, practical mitigation strategies that will help prolong the effectiveness of antibiotics to treat both people and animals.





USDA AMR Action Plan

Objectives

- Determine and/or model patterns, purposes, and impacts of antibiotic use in food-producing animals
- Monitor antibiotic drug susceptibilities of selected bacterial organisms in food-producing animals, production environments, and meat and poultry
- Identify feasible management practices, alternatives to antibiotic use, and other mitigations to reduce AMR associated with food-producing animals and their production environments

USDA-APHIS-Veterinary Services National Animal Health Monitoring System

- Established in 1985
- National studies of species/commodities
- Science- and health-focused
- Relate animal health to management practices, disease prevention and treatment, veterinary medical access and use
- Industry participation and engagement

Confidential Data Protection

- Confidential Information Protection and Statistical Efficiency Act (CIPSEA)
 - Federal Information Security Management Act of 2002
 - Confidentiality protections for data acquired from the public for statistical purposes
 - Disclosure punishable as a Class E felony
- NAHMS' data protection
 - Is a statistical unit
 - Data collected by NAHMS under CIPSEA is protected from disclosure for as long as the data exist
 - Personal identifying information is removed
 - Voluntary on-farm data are protected

NAHMS Proposed Initiatives

- To obtain and disseminate science-based and actionable information about antimicrobial use and resistance and relate this information to management practices
 - Informed by decades of surveillance, basic and applied research, education, and outreach by USDA
 - Effective mitigation strategies for AMR developed and animal producers advised on implementing these strategies
 - Emphases on public health and animal health outcomes and productivity
- Guided by U.S. CARB and USDA AMR Action Plans
- Stakeholders and partners integral to successful implementation

Proposed Study Types

- Longitudinal studies
- National commodity cross-sectional studies
- Focused studies and investigations
- Third party data

On-farm Longitudinal Studies

- Assess relationships between antimicrobial drug use and resistance over time on livestock and poultry operations
 - Investigate changes in resistance relative to use
 - Collect detailed use data and biological samples over multiple periods and relevant time frames
- Operations: beef feedlots, turkeys, broilers, swine
- Pathogens and commensals
 - *Salmonella*, *Campylobacter*, *Enterococcus*, and *E. coli*
 - AM susceptibility testing

On-farm Longitudinal Studies

- Voluntary participation
- Multi-year study periods
 - Preparation
 - Engage producers and producer groups
 - Enroll farms
 - Engage data and sample collectors
 - Multiple on-farm visits over 1.5 to 2 years
 - Collect AM use data and biologic samples
 - Analysis
 - Laboratory specimens – isolation and susceptibility testing
 - Use data
 - Examine temporal relationships between use and resistance

On-farm Longitudinal Studies

- Resource intensive
 - Time and funding
 - Potentially limit number of operations able to participate
 - Sample size will determine inference and precision

Veterinary Diagnostic Laboratory Data Longitudinal Study

- To monitor resistance profiles in animal pathogens from submissions to VDLs
 - Samples from clinically ill animals
 - May have had AM treatment
 - AMR profiles may differ from general population
- Data will be collated and analyzed
 - Examine patterns over multiple species and times
- Dissemination of information to veterinarians and producers may inform treatment decisions



Future Work with ARMS

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ARMS in the Future

- Another hog version in 2015
 - Operators surveyed January–March 2016
 - For 2015 practices and outcomes
- Can compare to 1998, 2004, 2009 versions
- Forms a baseline prior to FDA guidelines
- Normal cycle would bring another hog version for 2020 or 2021.

ARMS: Challenges for the Future

- Funding and costs
 - Affects sample size, questionnaire length, and number of versions
- Changes in farm structure and response
 - Survey response rate is 60 to 65% and maintaining
 - But response is inversely related to farm size, and production keeps shifting to larger farms
 - Can we keep large producers engaged?

Annual Antibiotic Use Survey

- To provide annual estimates of AM use in feed or water in multiple production types
- Monitor use trends relative to FDA Guidance #209 and #213
 - Currently no systematic survey data collected
- NAHMS developing surveys
- Voluntary on-farm participation
- CIPSEA data protection

Annual Antibiotic Use Survey

- Requires adequate participation at national scale to measure use changes
- Resources required to obtain reliable data
- Direct estimates of
 - Percentage of animals treated
 - Percentage of operations using products

Enhance Future NAHMS Studies

- Enhance periodic commodity surveys
 - Additional questions on AM use and practices
 - Link to sample collections on-farm for pathogens and commensals
 - Increase number and breadth of resistance testing
- Provide national population-based estimates
 - AM use practices
 - Pathogen prevalence
 - AST for pathogens and commensals

Focused NAHMS Commodity Studies

- NAHMS-type study outside of 5- to 7-year cycle
- Focus on specific AMR issues
 - Limit scope to address critical issues related to use or resistance
 - Limiting scope lowers producers' burden for participation and data collection
- Would lack the breadth and depth of typical commodity study

NAHMS Retrospective Study

Data Analyses

- Investigate trends within existing data collections
 - National Commodity Studies over multiple periods
- Archived data are available, accessible
- Analyses have been initiated
 - Internal
 - Academic partners
- Combining data from multiple cross-sectional surveys that may differ between studies
- Results help understand ways to standardize collection across species and over time

Third Party Data

- Evaluate existing producer-held AM use data
- Provide insights for comparisons with other data sources
 - Potential integration across multiple streams
 - Comparison with NAHMS data
- For large companies, if data already exist, may be more accessible than new data collection

Third Party Data

- Implementation framework
 - Access
 - Representativeness, validation
 - Analyses
 - Reporting
- Collaboration with academic partners

Conclusions/Moving Forward

- Implementing initiatives and recommendations will create a clearer picture of AM use/resistance
 - Includes internal and external checks for validity
- Prioritize with respect to resources
- Open to ideas and approaches
 - Public – private – academic partnerships
- Envision program will evolve over time
 - Baseline data required to investigate changes
 - Need to identify specific elements and sustained, stable, reliable data streams for tracking



Resources

- USDA-APHIS Proposed Initiatives
www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf
- USDA AMR Workshop
www.fsis.usda.gov/wps/wcm/connect/9ddc0b9c-af04-4ed4-b959-b7799ddbfe11/USDA-Antibiotic-Resistance-Workshop-Summary.pdf?MOD=AJPERES
- USDA AMR Action Plan: www.usda.gov/antimicrobial.html
- U.S. CARB National Strategy:
www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf

NAHMS Resource Materials and Contact Information

- NAHMS Reports online:
<http://www.aphis.usda.gov/nahms>
- NAHMS Reports printed available by request or to join mailing list
 - Email: Anne.L.Berry@aphis.usda.gov
- Further Information on Proposed Initiatives
 - Email: Kathe.E.Bjork@aphis.usda.gov