

Combating Antibiotic Resistant Bacteria (CARB) The Need for Data - The USDA Perspective

L. M. Granger D.V.M.
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

Antibiotics Council
Water and the Future of Animal Agriculture, Indianapolis, IN
March 23-26, 2015



National Perspective

- Global Health Security Agenda
- National Strategy for Combatting Antibiotic Resistant Bacteria (CARB)
- President's Council of Advisors on Science and Technology (PCAST)
- Executive Order
- USDA Roles
- APHIS Veterinary Services



United States Department of Agriculture

USDA Antibiotic Resistance Workshop

George Washington Carver Center Beltsville, Md.

May 15-17, 2012

<http://www.ars.usda.gov>

- Stakeholders included public health, consumers, and agriculture sectors
- Examine Trends
 - Antibiotic usage
 - AMR organisms
- Alternative Interventions and Strategies
 - Medical interventions
 - Management
- Economic Analyses
 - Policy impacts
- Outreach and Education
 - Surveillance
 - Research
 - Stewardship



Agriculture Stakeholders

- Antibiotic sales is a poor indicator of use across production modalities or species
- We need science to inform policy decisions – surveillance, research, stewardship (“judicious use”, “medically important”, “evidence based” => outreach and education
- There should be data driven risk assessments to inform policy
- Research and regulatory activities should be separated.

Non-Agriculture Stakeholders

- Public health and consumer sectors believe that the human health risk is best addressed by decreasing the overall use of antibiotics (amount)
- Advocate Better Hygiene and Management
- Less intensive animal agriculture
 - All in/All out management
 - Phase feeding
 - Split sex feeding
 - Artificial insemination
 - Specialization
 - Heifer rearing, pre-nursery, growers, finishers
- Market dynamics



Why do we need data?

“Something will be done to us....”

- The VFD is not designed to limit appropriate use of antibiotics.
- Bugs and drugs of interest must be decided upon.
- Standardized biograms
- Observational data will be important.
 - No data when resistant organisms are isolated to assess risks.
- Use data is only quantities reported sold.
 - @ 30% of the 80% reported is **ionophores**.
 - If 15% of the 80% is growth promotion and therapeutic use increases as does prevention – little real impact.



Food and Drug Administration (FDA)

- Collects amounts of antibiotics sold from most of the pharmaceutical companies and makes information available to the public
 - No information on species it is used
 - No information on exact amounts used
 - Dosage
 - No information on indications for use

USDA

- “USDA proposes to obtain and disseminate science-based, actionable, quantitative antibiotic drug use information coupled with information about the development of resistance in food producing animals and relate this to livestock management practices.”
- FDA:
 - relies on this information to inform its policy and regulatory decisions
 - taps into USDA extensive network of collaborative relationships for outreach

Public Policy

- Access to complete and correct information
- Accepted scientific methodology, analysis, and risk communication
- Ability and courage to challenge assumptions
- Understanding WYSIATI
 - Therapeutic Use vs “Production Use”

Preventative use (from FDA 213):

Judicious use includes a consideration by the veterinarian of relevant factors for determining the risk of a specific bacterial disease and for determining whether the use of medically important antimicrobials for prevention purposes is appropriate in a particular situation.

- (1) there is evidence of effectiveness,
- (2) such a preventive use is consistent with accepted veterinary practice,
- (3) the use is linked to a specific etiologic agent,
- (4) the use is appropriately targeted to animals at risk of developing a specific disease, and
- (5) no reasonable alternatives for intervention exist.

USDA Roles



- Surveillance
 - Monitor for use of antibiotics in food animals
 - Determine patterns of antimicrobial use in food producing animals, production types, species
 - Monitor antibiotic drug susceptibilities in bacteria, ecologic assessments, economic impacts of policy decisions
 - Risk assessments - animal to human
- Research and Development
 - Develop mitigations to reduce AMR
 - Alternatives to antibiotics, other technologies
 - Assessing the potential of transfer of genetic resistance elements
 - More complete data on potential environments that impact transfer of AMR genetic elements in food producing animals
- Education, Extension, and Outreach
 - Judicious use
 - Best practices
- Develop metrics to gauge progress



United States Department of Agriculture
National Institute of Food and Agriculture



The Animal and Plant Health Inspection Service

NAHMS

- Conducts monitoring and surveillance
- Collects information about antimicrobial use and biological samples on farms
- Evaluates epidemiologic relationships between farm management, antimicrobial use, and on-farm resistance patterns.

The best information relies upon systematic capture of diagnostic specimens and related information

National Animal Health Monitoring System (NAHMS)

- **Commodity studies**
 - Questionnaire
 - APHIS, ARS, and NASS
 - U.S. Code, Title 7, Section 2276 and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA)
 - Third party data
- **Enhancing NAHMS**
 - Ongoing longitudinal studies
 - More detailed data and biological samples
 - Model parameterization

The Agricultural Research Service

- The USDA's intramural research program.
- Area's of research:
 - investigating changes in the intestinal microbiome
 - investigating the mechanisms of the development of AMR
 - identifying and characterizing resistant bacteria
 - developing alternatives to antibiotics
 - understanding the impact of antibiotic administration on manure and the environment
 - describing the potential for transfer of AMR food borne pathogens or resistance genes from food animals through food processing to the consumer

Agricultural Resource Management Survey (ARMS)

- ARMS is an annual farm-level survey jointly administered by **ERS and NASS** with consultation from APHIS, others
- All surveys conducted are voluntary
- Focuses on farm finances
- Analyzes the impact of various production inputs and practices on production, costs, and revenues on farms.
- Modeling the expected market-level impacts on production and prices if certain antibiotic drugs used in livestock should be phased out.

Enhance NASS and ARMS Surveys

- ***Enhanced NASS and ARMS survey questionnaires with new and expanded questions about antibiotic drug use and related production practices.***
- National estimates of antibiotic drug use
- Related production practices
- Before and after the finalization of the FDA Guidance #213 and the accompanying changes to the Veterinary Feed Directive rule
- Effect on farm productivity, costs, and production practices
- Track adoption of production practices meant to replace antimicrobial use for growth promotion
- Enable better enable estimation of the quantities of antibiotics used in animal agriculture.
- Provide the FDA with valuable information regarding the impacts of its guidance.
- Identify critical areas for further focused, collaborative research and education/ outreach activities

Enhance NARMS

- Various biological samples could also be collected at slaughter and cultured for multiple bacteria (i.e., *Salmonella*, *Campylobacter*, generic *E. coli*, and *Enterococcus*).
 - Isolates could be tested for antimicrobial drug susceptibility.
 - Changes in microbial and resistance status in the slaughter plant could then be evaluated in light of contemporary on-farm antimicrobial use and management practices.



United States Department of Agriculture

Surveillance; research and development; and education, extension, and outreach.

- Because proposed activities are *voluntary*, USDA must closely cooperate with Federal, industry, commodity, and academic partners to implement *any* sort of plan.
- CIPSEA and Title 7, U.S. Code, Section 2276

Challenges

- Support by producers, veterinarians, commodity groups, others
- Coordination of the various Action Plans and agencies
 - This is progressing very smoothly
- Funding
- Regulatory process in the U.S., Paperwork Reduction Act
- *Develop the Action Plan* – cannot start this the wrong way.



Thank You





“In short, our culture resists the true values of the scientific way of knowing : we disdain observational patience leading to open minded description; we discourage eclectic methodologies; and we dismiss attentive care; failing to recognize the imperative, rather than the prerogative, nature of play.”

Lynn Margulis