

# Data Collection and Antimicrobial Stewardship

National Institute for Animal Agriculture (NIAA)  
8th Annual Antibiotic Symposium  
Overland Park, KS  
**November 13-15, 2018**

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# Outline

- Background
- Why collect data?
- What data do we have, and what data are needed?
- How will data be used?
- Summary

# Background

- FDA-CVM published the 5-year plan for ***Supporting Antimicrobial Stewardship in Veterinary Settings***<sup>1</sup> on 9/14/2018
- Three primary goals:
  - Align antimicrobial drug product use with the principles of antimicrobial stewardship
  - Foster stewardship of antimicrobials in veterinary settings
  - Enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals

<sup>1</sup><https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf>



# Background

- Overarching goal of FDA's ongoing efforts to support antimicrobial stewardship in veterinary settings:
  - Implement measures that address public health concern of antimicrobial resistance, while assuring animal health needs are met
- As of January 1, 2017:
  - All medically important antimicrobials for use in feed or water of food-producing animals require veterinary oversight
  - Growth promotion uses are no longer legal

# Why collect data?

Data is needed to:

- Assess the adoption of changes outlined in FDA GFI #213
- Help gauge the success of antimicrobial stewardship efforts and guide their continued evolution
- Assess potential associations between antimicrobial use practices and resistance

# What Data are Needed?

- Data on quantity of antimicrobials sold/distributed
- On-farm antimicrobial use practices
- Antimicrobial resistance data
- Animal health and demographic data

# Antimicrobial Sales for Food-Producing Animals

- Section 105 of the Animal Drug User Fee Amendments of 2008
  - Sponsors must annually submit information on sales and distribution of antimicrobial drugs approved for food-producing animals
  - FDA must publish summaries of that information and must report it in a manner consistent with protecting confidential business information
- As of 2016, sponsors must include a breakdown of estimated sales by species (4 major food-producing species)

# Antimicrobial Sales

- Value/Utility:
  - Provides an indicator of the overall quantity of antimicrobials entering distribution channels
- Limitations:
  - Sales are not indicative of actual use
  - Many drugs are approved for multiple species, have multiple indications, and multiple dosage regimens



# On-farm Antimicrobial Use Data



- Value/Utility:
  - Evaluates actual conditions of antimicrobial use
  - Opportunity to evaluate relationship between antimicrobial use and resistance
- Limitations:
  - Resource-intensive to collect representative and long-term data
  - Differences in the detail in farm-level records; no one uniform system for capturing this type of data

# On-farm Antimicrobial Use Data



- **FDA awarded two cooperative agreements in 2016**
- **Projects are to:**
  - Provide detailed antimicrobial use data that reflects actual on-farm use for 4 major food-producing species (cattle, swine, turkeys, chicken)
  - Provide baseline data for on-farm antimicrobial use (i.e., data prior to implementation of GFI #213)
  - Pilot methodologies for collecting, summarizing, and reporting antimicrobial use data from farms
  - Foster public-private partnerships/ collaboration
  - Leverage existing data systems and minimize burden and disruption to animal producers
  - Incorporate strategies for protecting farm/producer identity and other confidential information

# On-farm Antimicrobial Use Data



- Additional efforts – USDA-APHIS:
  - 2017 Antimicrobial Use Surveys (swine and feedlot cattle)
  - NAHMS studies
  - Proposed longitudinal studies

# Antimicrobial Use Measures (examples)



- Total # animals at risk of being treated in a population
- Total # animals treated
- Antimicrobial regimens actually used
- Kg of antimicrobials used (or sold)
- Time scale of reporting (# animal-days; calendar time, etc.)
- Production indices (kg meat produced, etc.)

# Antimicrobial Resistance Data



- Value/Utility:
  - Since 1996- NARMS has tracked changes in antimicrobial susceptibility of enteric bacteria in ill people (CDC), retail meats (FDA), and food animals (USDA)
  - Provides annual summaries of resistance trends
  - Collaborations on epidemiologic and microbiologic research studies
  - Recent improvements/expansions in NARMS
    - Interactive Data Displays
    - Whole Genome Sequencing (WGS) Data
    - Retail meat sampling expanded to include more states
    - Enhancements to animal sampling (cecal)
- Limitations:
  - Resistance data not linked to information on antimicrobial use in animals
  - Resistance data for animal pathogens not as available



# Animal Health and Demographics

- Value/Utility:
  - Provides context for assessing antimicrobial use information (i.e., appropriateness for extent of use, animal disease information)
- Limitations:
  - Availability of animal health data currently limited
    - USDA-APHIS NAHMS surveys and NASS provide animal demographics information; NAHMS provides some information about disease challenges at time of survey
    - Information generally only for reportable diseases

# How Will Data be Used?

- Quantities alone don't demonstrate stewardship
- Evidence is needed to demonstrate progress in antimicrobial stewardship in veterinary settings – what is our story?

# How Will Data be Used?

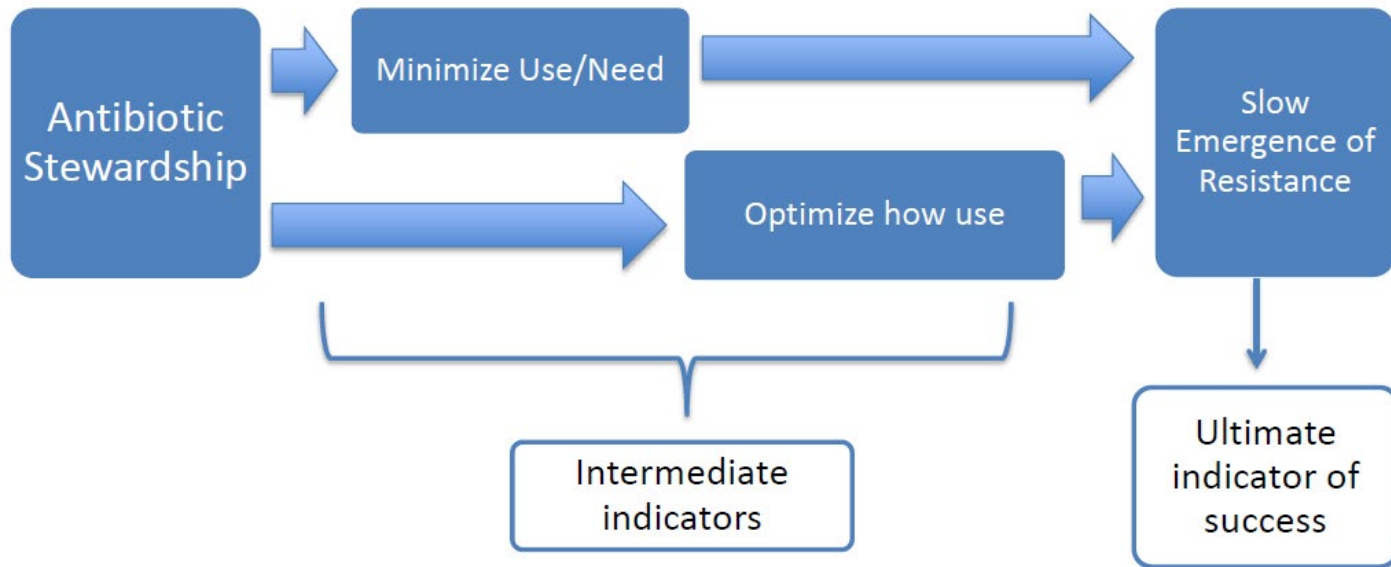
- CVM intends to publish a comprehensive assessment report
  - Integrates and analyzes available information to assess stewardship in veterinary settings
  - Includes data from various sources: cooperative agreements, sales and distribution data, animal health and demographics data, NARMS resistance data, USDA data captured through surveys/programs



# Challenges

- Mis-use of antimicrobial sales and/or use data
- How to best communicate progress
- Collaborative efforts of multiple stakeholders are crucial to continued progress
- Accurate and reliable data is critical, as is confidentiality for those who participate in providing data
- How do we create a long-term and sustainable system for antimicrobial use data collection?
- Relating antimicrobial use and resistance

# Monitoring Progress





# Summary

- Data from multiple sources are needed to provide a comprehensive and science-based approach to evaluation of antimicrobial drug use and resistance in animal agriculture
- Data will support the continued availability of safe and effective antimicrobials for use in treating animals and humans
- Ultimate goal is to reduce development of resistance while assuring that animal health needs are met



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