Summarizing and Reporting Data
A Proposed Framework

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

Bruce Wagner, PhD, Director, Center for Epidemiology and Animal Health, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Data Collection Public Meeting
September 30, 2015
Washington, D.C.
Topics

- Vision and purpose of report
- Overview of report outline
- Potential sources of information
- Next Steps
Vision of New Report

• A coordinated, interagency (USG) annual report with science-based information about antibiotic drug use and resistance in animal agriculture

• Integrate an array of information on animal demographics, animal health, drug use, and resistance to provide a comprehensive picture of antibiotic use practices in animal agriculture
Purpose of New Report

• These reports will:
  – Enhance transparency regarding antibiotic use practices in food-producing animals
  – Summarize data important for:
    • assessing the adoption of changes outlined in FDA’s Guidance 209 and 213
    • gauging the success of stewardship efforts and guiding their continued evolution and optimization
Overview of Report Outline

• Introduction
• Animal Health/Demographic Indicators
• Drug Use Indicators
• Antibiotic Resistance Indicators
• Discussion
• Appendices
Report: Introduction

• Background: include discussion of...
  – interagency process for formulating report
  – significance of resistance to human/animal health,
  – current antibiotic policies/initiatives
  – stewardship initiatives (including industry-sponsored)
  – relevant changes since last reporting period

• Objectives/Purpose
  – Describe/discuss purpose – as outlined in slide 4
Animal Health/Demographic Indicators

- Summarize available data on animal populations and disease incidence to provide context regarding:
  - Changes in animal populations
  - Occurrence of animal disease
- Such factors may influence antibiotic use
Drug Use Indicators

• Summarize data on extent and purpose of antibiotic use in various animal agriculture settings
• Could draw on several types of information including:
  – Sales/distribution data
  – Survey data on antibiotic use
  – other
Antibiotic Resistance Indicators

• Summarize available data on antibiotic resistance among foodborne bacterial pathogens and commensal bacteria including:
  – NARMS data (food and animal sources)
  – Potential on-farm data
  – Other

• Potential inclusion of animal pathogen data
Discussion Section

• In light of information summarized on animal demographics, animal health, drug use, and resistance
  – provide observations regarding antibiotic use practices in various animal agriculture settings
  – discuss resistance in relation to antimicrobial use
  – Identify areas of improvement and areas where further efforts are needed
Discussion Section

Assessing the adoption of changes outlined in FDA’s Guidance 209 and 213

Feed/water use of medically important antibiotics are:

- not being used for production purposes
- only being used for legitimate/appropriate therapeutic purposes
- only being used with authorization of licensed veterinarian
Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization

– assess extent to which use indicators align with stewardship/responsible use standards and industry best practices, in light of animal demographics and animal health indicators

– identify associations between antibiotic drug use practices and resistance
Discussion Section

Gauging the success of stewardship efforts and guiding their continued evolution and optimization (continued)

– discuss/highlight areas where further efforts may be needed

• informs Federal agencies in terms of policy development, research

• informs industry, academia, veterinary profession
Potential data sources

• Animal demographic information
  – USDA/NASS

• Animal health information
  – Enhance currently collected/summarized

• Drug Use Indicators
  – FDA (sales), USDA (on-farm use)

• Resistance Indicators
  – NARMS (FDA, USDA/FSIS)
  – On-farm (USDA/APHIS)
Potential data sources

• Animal demographic information
  – USDA Ag Statistics Annual Reports
    • Species-specific annual reports
    • Population statistics by animal type, geographic location etc.
    • Slaughter numbers
    • Live weights
Potential data sources

• Animal health information
  – Currently, limited data are available on disease incidence in animals (that may be a driver of antibiotic use)
  – Information on disease occurrence, distribution, key animal health events would be valuable
  – Important for interpreting antimicrobial use data

• Input needed on potential additional sources of this data
Potential data sources

Drug Use Indicators

• National cross-sectional studies
  – Percent of animals in national population receiving antimicrobials by drug class and reason for use
  – Percent of operations in the U.S. using antimicrobials by drug class and reason for use
Potential data sources

Drug Use Indicators

• Longitudinal studies
  – Number of animals receiving antimicrobials by class of antimicrobial and by reason for use
  – Dosage amount

• Other
Potential data sources

• Resistance Indicators
  – On-farm Resistance
  – USDA-NARMS (cecal, HACCP)
  – FDA-NARMS (retail meat)
Potential Data Sources

On-farm Resistance

• Percent of isolates resistant by class of antimicrobial and by organism
  – National cross-sectional studies
  – Longitudinal studies
  – Other (see APHIS AMR Initiatives doc)
Potential Data Sources
USDA-NARMS (cecal, HACCP)

• NARMS Annual Animal Report
  – Percent resistance by bacteria, drug, animal both pre- and post-chill

• NARMS Integrated Report
  – Genetic determinants of resistance (including those for drugs not labeled)
  – Resistance transfer mechanism (plasmid types and mutations)

• Research
  – Metagenomic data for surveillance of the animal antimicrobial resistome
Potential Data Sources
FDA-NARMS

- **NARMS Retail Meat Report**
  - Percent of resistant isolates by bacteria, drug, food commodity
- **NARMS Integrated Report**
  - Genetic determinants of resistance (including those for drugs not labeled)
  - Resistance transfer mechanism (plasmid types and mutations)
- **Research**
  - Metagenomic data for surveillance of the retail antimicrobial resistome
Report: Appendices

• Summary of relevant stewardship principles/standards (government, academia, veterinary, and industry-based)

• Additional information such as references, methods, data, lists of tables/figures, other reports/publications, etc.
Next Steps

• Data collection and reporting
  – Consider comments received today and submitted to the docket
    • Refine plan based on input
  – Will continue to seek public input
  – Goal to collect new on-farm data in 2016
    • Availability of resources a key factor
  – Goal to publish first integrated report in 2018