



Gathering Antimicrobial Use Data in Animals

NIAA Antibiotic Use and Resistance Symposium

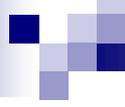
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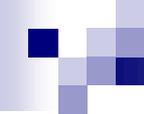
U.S. Food and Drug Administration (FDA)





Outline

- The Need for On-farm Use Data
- FDA's Judicious Use Strategy
- Existing Data on Use and Resistance
- NARMS Partners and On-farm Use Data
- NIMBioS
- Conclusions



The Need for On-farm Use Data

- Collecting additional information regarding on-farm antimicrobial use and resistance is a high priority.
- Meaningful metrics are needed to assess the impacts of different antimicrobial use practices on antimicrobial resistance, particularly related to stewardship and policy initiatives.

Refining Stewardship Principles

- Appropriate refinement of principles and regulatory policies for promoting antimicrobial stewardship in animal agriculture...
- requires improved understanding of the associations between on-farm use and resistance...
- which in turn requires long-term studies capturing the range of antimicrobial use patterns and resistance across different production classes.

Refining Stewardship Principles

Long-term Studies

- Long-term studies capturing the range of antimicrobial use patterns and resistance across different production classes

Improved Understanding

- Improved understanding of the associations between on-farm use and resistance

Appropriate Action

- Appropriate refinement of antimicrobial stewardship principles and regulatory policies

FDA's Judicious Use Strategy

- Policy Objectives:
 - Eliminate the use of medically important antimicrobials for production indications (such as “increased rate of weight gain” or “improved feed efficiency”)
 - Require veterinary oversight of therapeutic uses of these drugs in the feed and water of food-producing animals
- Timeline: 3 years (ends December 12, 2016)
- Important step towards addressing concerns about the use of antimicrobials in food-producing animals

Components of FDA's Strategy

■ Implement Changes

- Change labels (remove production claims, require vet oversight)
- Finalize VFD rule (current target Spring 2015)

■ Report progress

- Periodic progress reports (every 6 months)
- Evaluation at end of 3-year implementation period (December 2016)

■ Assess Impacts

- Continue collecting data (sales and resistance)
- Collect additional data (on-farm use and resistance)

■ Reinforce Stewardship

- Perform training/outreach to support new VFD rule
- Promote judicious use principles

Existing Data on Use and Resistance

- **NARMS:** Information on antimicrobial resistance among foodborne pathogens and commensal bacteria are reported for retail meats (FDA), animals at slaughter (USDA) and humans with clinical disease (CDC)
- **NAHMS:** The USDA Animal and Plant Health Inspection Service (USDA-APHIS) periodically collects antimicrobial use data on livestock and poultry operations as part of the National Animal Health Monitoring System (NAHMS). In addition, samples are collected to determine prevalence and characteristics (including antimicrobial resistance) of potential foodborne pathogens and commensal bacteria on the farm.
- **ARMS:** The USDA Economic Research Service (USDA-ERS) collects data on antimicrobial drug use periodically as part of the Agriculture Resource Management Surveys (ARMS).
- **U.S. National Residue Program:** The USDA-FSIS samples meat, poultry, and egg products for chemical contaminants including antimicrobial drugs.
- **ADUFA 105:** The FDA collects and reports annual data on the sale and distribution of antimicrobial drugs intended for use in food-producing animals aggregated by drug class under section 105 of the 2008 Animal Drug User Fee Amendments (ADUFA 105).

July 2012 ANPRM: Overview

- FDA solicited comments from the public on:
 - possible enhancements to the existing sales data collection requirements
 - how best to summarize sales data (within statutory parameters)
 - alternative methods for monitoring antimicrobial use in food-producing animals
- FDA believes that having additional information that provides a better understanding of the extent of use of medically important antimicrobial drugs in food-producing animals will support the implementation of the Agency's Judicious Use Strategy

July 2012 ANPRM: FDA's Responses

■ Annual Summary Reformat

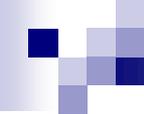
- September 2013 ANPRM - proposed additional tables
- Breakdown by medical importance and route/marketing status/presence of production claims

■ Rulemaking

- Drafting new regulation to codify the ADUFA 105 requirements
- Considering possible additional requirements

■ Antimicrobial Use

- Interagency group (FDA/CDC/USDA) formed to explore possible approaches for obtaining antimicrobial use data



Ongoing work of interagency group

1. Mapped the distribution of antimicrobials (medicated feeds vs. other products)
2. Reviewed the literature for analytic approaches that associate antimicrobial use and resistance
3. Surveyed the work other international programs have done to relate antimicrobial use and resistance
4. Submitted a NIMBioS Working Group proposal to develop analytic method to evaluate the association between shifts in antimicrobial use practices and antimicrobial resistance
5. Continuing to develop possible approaches for collecting on-farm data



Antimicrobial Distribution Channels

- Antimicrobial distribution channels are complex
 - Perhaps even more difficult to characterize than on-farm use (which would be more useful)

Analytic Approaches Associating Antimicrobial Use and Resistance

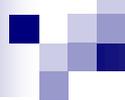
- There currently does not appear to be an analytic framework available to perform population-level analyses of antimicrobial use and resistance
 - Literature: some using in vitro, individual, and local scale; Range from purely descriptive to complex modeling
 - Other countries: some purely descriptive, a few attempt correlations (with methodological questions)
- The interagency group submitted a NIMBioS proposal...



NIMBioS

National Institute for Mathematical
and Biological Synthesis

- National Institute of Biological and Mathematical Synthesis
- Collaboration between
 - the National Science Foundation
 - the U.S. Department of Homeland Security
 - the U.S. Department of Agriculture
- Integrating modeling and mathematics with the biological studies



NIMBioS Working Groups: Overview

- Chosen to focus on major well-defined scientific questions at the interface between biology and mathematics that require insights from diverse researchers
- Typically meet 2-4 times over a 2-year period
- Participation is by invitation only, but meeting summaries are posted publicly

NIMBioS Working Group Proposal

- Title: “Evaluating the Association between Shifts in Antimicrobial Use Practices and Antimicrobial Resistance Resulting from FDA’s Risk Mitigation Strategy”
- Objective: Develop a systems approach to identify specific conceptual approaches, analytical methods, and quantitative data sources that are appropriate for associating population-level changes in antimicrobial use in livestock with population-level changes in antimicrobial resistance
- Status: First meeting 9/19/14 – 9/22/14

NIMBioS Working Group Proposal

- This NIMBioS Working Group will identify specific analytical methods and quantitative data that are appropriate for associating population-level changes in antimicrobial use in livestock with population-level changes in antimicrobial resistance
- The proposed work will identify strategic methods for data collection, analysis and synthesis to address research and regulatory questions and to efficiently allocate limited resources
- http://www-nimbios.nimbios.org/workinggroups/WG_amr

On-farm Use: Next Steps

- The Interagency group (FDA, CDC, and USDA) are developing possible approaches for enhancing current data collection efforts to provide additional on-farm information regarding antimicrobial use practices and resistance
- Expect to seek public input on approach in near future – potentially through public meeting
- Goal: start collecting new data in 2016 (before the end of GFI 213's 3-year implementation period)

Conclusions

- Useful baseline information is currently available on antimicrobial drug sales and antimicrobial resistance, but limited data are available regarding actual use
- Collecting additional information to link shifts in on-farm antimicrobial use practices with antimicrobial resistance data is a high priority
- A NIMBioS Working Group is developing an analytic approach for associating population-level changes in antimicrobial use in livestock with population-level changes in antimicrobial resistance

CVM AR Websites

- **Judicious Use of Antimicrobials:**

- <http://www.fda.gov/AntimicrobialJudiciousUse>

- **ADUFA 105 Reports:**

- <http://www.fda.gov/AnimalAntimicrobialSales>

- **NARMS**

- <http://www.fda.gov/NARMS>

Thank You

