APHIS Veterinary Services

USDA AMR Strategy

Federal Initiatives and the Impact on Producers, Industry, and States

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NIAA
November 5, 2015
Farm Foundation Public Meetings

- Feed mill operators
- Feed stores
- Drug manufacturers
- State regulatory agencies
- Veterinarians
- Farmers
- Minor species
FDA and USDA Partnership

• The FDA has implemented policy changes that will impact the way that antibiotics are used in animal production

  • Effective after December 2016

• Many stakeholders have raised the need for metrics to evaluate the impacts of the new FDA policies

• FDA and Veterinary Services will collaborate in developing a more robust picture of the way antibiotics are used in animal production systems
FDA Guidance for Industry #209

• Outlines AMR policy

• Describes two key principles:

  • **Principle 1**: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.

  • **Principle 2**: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.
USDA Surveillance, Data Collection and Analysis

Help define “good stewardship” and “judicious use”

Policy – complete correct information (data), scientific methodology, courage to challenge assumptions

Value – provide more specificity about actual conditions of use; assess associations between antibiotic judicious use practices and resistance

Limitations – resource intensive to collect representative data
• Assess the rate of adoption of changes outlined by FDA
• Gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization
Food and Drug Administration (FDA)

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

- Animal population
- Operations

≥ 70%
NAHMS Commodity Surveys

- Periodic (every 5-7 years)
- Cross-sectional
  - Snapshot of health and management practices at the time of the study
- 1-2 questionnaires are administered along with collection of biological samples
- Stakeholder driven
- Confidential and voluntary

Statistically based inference to larger population
Limitations of NAHMS Commodity Based Studies
Antimicrobial Use

• Provides information in terms of percent of animals receiving or percent of operations using a specific antibiotic and purpose for use

• Does not provide total kilograms used or animal daily doses

• Data are not collected in a timely way - collected every 5-7 years for each species dependent upon budget and resources
Enhancements to NAHMS studies

• Analysis of retrospective data from past NAHMS Studies
  – fully utilize existing data to meet current information needs.
• Use data currently unavailable in the U.S.
  – National estimates are needed to assess effects of FDA policy changes.
• Annual survey
  – to provide national estimates of antibiotic use in feed or water for feedlot cattle, broilers, swine, and, potentially, turkeys.

A sufficient number of operations could be sampled and tested for the presence of zoonotic pathogens (e.g., *Salmonella, Campylobacter*) and commensals (e.g., *Enterococcus, E. coli*) to provide national, population-based estimates on prevalence and antimicrobial resistance in these organisms.
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*Includes preparation of the OMB package as well as analysis and approval of the package by OMB. Data collection cannot begin until after OMB approval. At least 11 months are needed after submission of the OMB package to obtain OMB approval.

X=Work will occur during this quarter, depending on resources.
• AMR testing on samples from clinically ill animals
  • A centralized database would allow for collating AMR data across labs.
  • Monitor the continued usefulness of antibiotics against animal pathogens.
  • Inform producers and veterinarians when making treatment decisions.
• VET-NET / Pulse NET
  • Genetic resistance (genomics)
  • Sample testing methodologies and standardization of techniques
  • Identify pathogens of interest
Stewardship

• Stewardship is an ethic that guides behavior toward the responsible planning and management of resources.

• Stewardship is informed by an understanding of ecology (Gaia, endosymbiotic theory, self regulating, complex systems, autopoeisis)
  • Research
  • Surveillance
  • Outreach/education
Judicious use

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 is appropriate in a particular situation.

(1) There is evidence of effectiveness,
(2) 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.
Veterinarian‘s Responsibilities

Existing VFD regulation requires VCPR as defined by regulation for extralabel use of drugs (21 CFR 530) requires that a

“veterinarian may only issue a VFD for use in animals under his or her supervision or oversight in the course of his or her professional practice, and in accordance with all applicable veterinary licensing and practice requirements”
Veterinary Client Patient Relationship (VCPR) - Practical Implications

• Integral understanding of the management system
• Assume responsibility for animal care
• Focus appropriately on animal welfare, health and well being
• Timely site visits - Always examine the patient(s).
• Appropriate diagnosis/risk assessment/Tx
• Knowledge of animal feeding and nutrition
• Knowledge of approved drug combinations
Veterinary Feed Directive

- Greater veterinary oversight of feed use antimicrobials has raised concerns about VFD requirements - including:
  - Limited experience with process
  - Administrative burden concerns
  - Veterinary workforce limitations
  - Increase costs to producers
  - Impacts on feed industry
  - Impacts on animal health
  - A myriad of logistical challenges
Veterinary Shortage Areas

Loan Repayment Program - Status
Approved (825 counties)
National Veterinary Accreditation Program

- Veterinary Accreditation is a part of the veterinary education curriculum
- Education and outreach
- Judicious use
- VFD training

Could represent;
- Data stream
- Consistency Nationally
Stewardship of Medically Important Antimicrobial Drug Use in Food Animals

Understanding the FDA Guidances and Veterinary Feed Directive
Participants Role and Area of Interest

Role
- Producer: 19%
- Vet: 25%
- Nutritionist: 3%
- Feed Supplier: 5%
- University/Extension: 18%
- Gov Health Official: 10%
- Other: 8%
- Association: 7%

Area of Interest
- Beef-Feedlot
- Beef-Cow/Calf
- Pork
- Poultry
- Dairy
- Aquaculture
- Small Ruminants
- All Species
- Other

Source: 2015 Farm Foundation VFD Survey
N=333
Preparation for Implementation of VFD - Non-Producers

Preparation Actions

- 18% Talked to my clients
- 19% Attended meetings
- 19% Created process for managing VFD
- 10% Provided customers with guidances and implementation process
- 6% Not taken any steps
- 28% Does not apply

Source: 2015 Farm Foundation VFD Survey
N=202

Q: What actions have you taken to prepare for the implementation of the VFD:
Preparation for Implementation of VFD - Producers

Preparation Actions

- 32% Talked to my veterinarian
- 22% Attended meetings
- 20% Done research
- 15% Have implemented changes
- 6% Not taken any steps
- 5% Talked to my feed supplier

Q: What actions have you taken to prepare for the implementation of the VFD:

Source: 2015 Farm Foundation VFD Survey
N=51
Veterinarian/ Producer Relationship

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<tr>
<th>Relationship Description</th>
<th>Veterinarian</th>
<th>Producer</th>
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<tbody>
<tr>
<td>Make all animal health management decisions</td>
<td>12%</td>
<td>6%</td>
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<tr>
<td>Consultative advisor on animal health management</td>
<td>59%</td>
<td>41%</td>
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<tr>
<td>Consultative advisor on broad range of farm management</td>
<td>7%</td>
<td>5%</td>
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<tr>
<td>Minor input into animal health decision</td>
<td>5%</td>
<td>16%</td>
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<tr>
<td>Strictly clinical advice on as needed basis</td>
<td>17%</td>
<td>37%</td>
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Veterinarians and producers have differing opinions on the types of services that are provided by veterinarians.

Q: In general what type of service is provided by your veterinarian/to your clients:

Source: 2015 Farm Foundation VFD Survey

N=108
It’s almost an even split between those that have and have not had conversations around the guidances.

Q: Have your talked with your clients/veterinarians about these guidances? If no, when and how do you plan to have these conversations?

Source: 2015 Farm Foundation VFD Survey

N=131
I believe cattle producers will switch to injectable medications or not medicate at all, leading to misuse of injectable medications and/or higher death rates. The cost will go up, availability down and there will be animals that die when I can't get an antibiotic unless I can get hold of a veterinarian.

Increased dependency on the use of antimicrobials has led to decreased emphasis on stockmanship, stewardship and preventive medicine practices. Better control of antibiotics with the veterinary oversight.

We will be able to show the consumer the positive role antibiotics play in cattle production.

68% of producers view the impact on the negative side, while 63% of vets think it will have a positive impact.

Q: Please rate the impact these policies will have on the livestock industry: Q: Please describe these impacts

Source: 2015 Farm Foundation VFD Survey N=223
Impact on Day-to-Day Business Activities

The biggest impact will be increased paperwork and thus greater documentation and transparency.

Q: Please describe how these changes will impact your day to day business activities

Source: 2015 Farm Foundation VFD Survey
N=96
Level of Agreement on Impacts - Producers

- It will increase costs of veterinary care (4.18)
- I will have increased paperwork (4.18)
- It will increase cost of production (4.15)
- I will have decreased access to the antibiotics I need (3.59)
- It will cause me to make significant changes in my management practices (3.55)
- There will be an increase in sub-clinical disease (3.49)
- Antibiotics will be used more judiciously on my operation (2.92)
- Public perception of my operations will be improved (2.87)
- It will increase the amount of antibiotics used to treat disease (2.74)
- I feel positive about taking these steps in my operation (2.72)
- Overall use of antibiotics will decrease on my operation (2.69)

Source: 2015 Farm Foundation VFD Survey
Implementation of Changes – Impact to Business of Non-Producers

- Need for more communication/education: 3.12
- Increased paperwork: 3.25
- Increased demand for veterinary services: 3.66
- Improved public perception: 4.01
- Increased compliance costs: 4.34
- Reduced access to antibiotics: 4.41
- Reduced sales of total antibiotics: 5.21

Source: 2015 Farm Foundation VFD Survey
Summary

• Integrated production systems (swine/poultry), milking dairy, beef feeders and feed manufacturers report to understand the policies.
  • cow/calf may have challenges
• Impacts to minor species
  • heightened awareness of off label use could be major issue.
• Veterinarians are concerned about
  • compliance and liability,
  • how to serve their clients/patients.
• Measurement of success is a major issue
  • antibiotic use and antibiotic resistance.
California Senate Bill 27
Livestock: Use of Antimicrobial Drugs

Annette Jones, DVM
State Veterinarian and Director
Animal Health and Food Safety Services
California Department of Food And Agriculture
Veterinary Feed Directive Rule

Eliminates federal definition of veterinarian-client-patient relationship & defers to state (still must be a licensed veterinarian)

California v-c-p meets the federal standard:

California 16 CCR § 2032.1

(b) A veterinarian-client-patient relationship shall be established by the following:

(1) The client has authorized the veterinarian to assume responsibility for making medical judgments regarding the health of the animal, including the need for medical treatment,

(2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian is personally acquainted with the care of the animal(s) by virtue of an examination of the animal or by medically appropriate and timely visits to the premises where the animals are kept, and

(3) The veterinarian has assumed responsibility for making medical judgments regarding the health of the animal and has communicated with the client a course of treatment appropriate to the circumstance.

(c) A drug shall not be prescribed for a duration inconsistent with the medical condition of the animal(s) or type of drug prescribed. The veterinarian shall not prescribe a drug for a duration longer than one year from the date the veterinarian examined the animal(s) and prescribed the drug.
Monitoring

- Willing participants and respecting veterinary-client-patient confidentiality

- Authority to request and receive copies of VFD’s

- Information must be held confidential unless aggregated
  - Can be shared with VMB for enforcement of Practice Act or Federal entities if confidentiality will also be protected under federal law

- Report to the legislature January 1, 2019
Limits Use

- Medically important antibiotics labeled by FDA for over the counter (OTC) sales can still be obtained from retailers with prescription or VFD
  - Veterinary Food Animal Drug Retailer (B&P)
  - Retail License for Restricted Drugs (FAC)
  - May need regulations to add clarity

Violations

- Licensed veterinarian: Practice Act disciplinary sanctions
- Others: Up to $250/day; second violation up to $500/day
Limits Use

- Can only be used when in the judgement of a licensed veterinarian is necessary to treat, control and in some cases, prevent disease or infection

- Prevention / Prophylaxis
  - If related to surgery or medical procedure
  - If “in the professional judgement of a licensed veterinarian, it is needed for prophylaxis to address an elevated risk of contraction of a particular disease or infection”
  - If used to prevent disease beyond when related to surgery or medical procedure, *can not be used in a “regular pattern”*

- Can never use solely for weight gain or feed efficiency
“It ain’t what you don’t know that is the problem, it’s what you know for sure that just ain’t so.”

attributed to Mark Twain
Special Thanks – slides used with permissions

• Sheldon Jones
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Thank You