Goals and Objectives for Data Collection

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Outline

- Brief Background
- Why collect data?
- What data are needed?
- How will data be used?
Background

- Antibiotic resistance is a global problem affecting both humans and animals
- Given the complexities of antibiotic resistance, no single action can be taken to “fix” the problem
- Rather, it requires a long-term commitment to multiple actions, on multiple fronts, to monitor and address the problem
- Tracking progress is critical element
Guidance #209: Judicious Use Strategy

Describes two key principles:

1. Limit medically important antimicrobials to therapeutic purposes (i.e., those uses considered necessary for ensuring animal health)

2. Require veterinary oversight or consultation for such therapeutic uses in food-producing animals
Guidance #213: Implementation plan

- Finalized December 2013
- More detailed guidance on implementing key principles in Guidance #209
  - Established 3-year timeline
  - Defines medically important
Guidance #213: Objectives

- By January 1, 2017, the use of medically important antibiotics in food and water will:
  - Be limited to therapeutic purposes only
    - production (growth promotion) uses will no longer be legal
  - Require the authorization of a licensed veterinarian
    - Products used in water – change from OTC to Rx
    - Products used in or on feed – change from OTC to VFD
GFI #213: Important Milestones

Sept. 2015:
Public meeting on data collection strategy

Early 2016:
Finalize data collection plan

End of 2016:
All changes implemented by drug sponsors

Jan. 2017:
Changes in use practices begin

2018:
Publish first assessment of use practices

Aligning Affected Products (June 2014 - December 2016)

Assessing Impacts of Product Changes (December 2016 – Beyond)
Why collect data?

Without an intentional effort to assess the actions we take (e.g., GFI #213 changes), it will be difficult to know over time whether:

- actions taken are making a difference,
- actions taken need to be adjusted, or
- additional actions are needed?
Why collect data?

- Question can be considered at several different levels – that may require different types of data – varying in terms of difficulty to collect and assess.

- That is, actions/steps implemented can be assessed to determine if such actions are:
  1. Actually being adopted as intended
  2. Having the desired effect in terms of antibiotic use behaviors/practices (stewardship)
  3. Having the desired effect in terms of managing antibiotic resistance
Why collect data?

For example: assessing the implementation of veterinary oversight under GFI #213 could include examining indicators that can help us understand whether veterinary oversight:

1. is actually occurring as intended
2. is having the desired effect of fostering judicious use/good stewardship
3. is having the desired effect in terms of managing antibiotic resistance
Why collect data?

- Progress at each of these three levels i.e.,
  1) adoption
  2) impact on behaviors/practices
  3) impact on resistance

  is important and desirable…but

- Assessing impact at all levels is challenging – particularly impact on resistance
  - Attribution/other drivers of resistance
  - Predictability of bacteria
  - Longer term observations needed
Why collect data?

- In summary, data is needed to:
  - assess the rate of adoption of changes outlined in the FDA's GFI #213
  - help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization
  - assess associations between antibiotic use practices and resistance
What data are needed?

- Data is needed that provide indicators that actions/steps implemented are:
  1. Being adopted as intended
  2. Having the desired effect on antibiotic use practices
  3. Having the desired effect on antibiotic resistance

- Assessing progress at each of the above levels would require multifactorial approach

- Feasibility dependent on data availability
What data are needed?

A. Data on quantity antibiotics sold/distributed
B. On-farm antimicrobial use and resistance
C. Resistance data for pathogenic foodborne bacteria and commensal bacteria
D. Data on animal demographics/animal health
E. Data from FDA inspectional activities
What data are needed?

A. Data on quantity antibiotics sold/distributed
   - Data available - summary reports published since 2009
   - Annual summary substantially enhanced (Oct. 2014)
   - Rulemaking underway to obtain additional detail on animal species

Value - indicator of quantity of antibiotics entering distribution channels

Limitations – not actual use; not specific for species or indication of use
What data are needed?

B. On-farm antimicrobial use and resistance data

- Under development – limited data currently available
- Key focus of today’s meeting
- Implementation dependent on additional funding

*Value* – provide more specificity about actual conditions of use; opportunity to link use to resistance

*Limitations* – resource intensive to collect representative data
What data are needed?

C. Resistance data for pathogenic foodborne bacteria and commensal bacteria

- Data available – e.g., NARMS in place since 1996
- Enhancements made to animal sampling of NARMS
- Retail meat sampling expanded, WGS

Value – robust resistance database available

Limitations – resistance data not linked to information on antimicrobial use in animals
What data are needed?

D. Data on animal demographics/animal health
   - Some data available – animal demographic indicators
   - Limited animal health data currently available

Value – provides context for assessing antibiotic use information (e.g., appropriateness of extent of use)

Limitations – animal health data currently limited
What data are needed?

E. Data from FDA inspectional activities

- FDA program currently in place for inspecting licensed feed manufacturers
- Involves collaboration with state regulatory agencies
- As resources permit, plan to expand inspectional activity

Value – provides mechanism for inspecting VFD records; provides indicator of appropriate veterinary oversight of VFD feeds

Limitations – limited resources; large number of feed manufacturers
How will data be used?

- Proposed goal is to create a new USG Summary Report
  - Provide a summary of antibiotic drug use and resistance in animal agriculture
  - Integrates data on animal health, demographics, drug sales, resistance, and additional on-farm data…

- Focus of presentation this afternoon
In Summary -

Outcomes of data collection strategy include:

- Greater transparency regarding antibiotic use practices in food-producing animals
- Data for assessing the rate of adoption of changes outlined in FDA’s Guidance #213
- Data to help gauge the implementation and success of stewardship efforts and guide their continued evolution and optimization
- Better understanding of antimicrobial use practices associated with resistance
Thank You