

White Paper

New Science and Technology Tools for Antibiotic Stewardship

Information synthesized from the National Institute for Animal Agriculture's Symposium, "New Science and Technology Tools for Antibiotic Stewardship" conducted November 13-15, 2018, in Overland Park, Kansas. Full presentations are available online at www.animalagriculture.org.

DISCLAIMER: The information provided in this White Paper is strictly the perspectives and opinions of individual speakers and discussions at the 2018 Antibiotic Stewardship Symposium

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Background

The symposium, “New Science and Technology Tools for Antibiotic Stewardship”, conducted November 13-25, 2018, in Overland Park, KS, was the eighth annual antibiotic symposium hosted by the National Institute of Animal Agriculture (NIAA). The forum included participants from the United States, Canada, and Mexico, and brought together a range of stakeholders including producers, producer organizations and other industry leaders; veterinarians; public health professionals; representatives of pharmaceutical companies and technology companies; diagnostic laboratory representatives; researchers representing several universities; and United States regulatory officials from the FDA, CDC, and USDA. The overall goal was to present new information and talk about experiences in adapting to a rapidly changing business environment and marketplace, recognizing the efforts of the past and present, as well as the challenges of the future; discuss current research and science; and review methods of communicating to consumers. Through this discussion, the group was able to identify common values, provide a forum to share knowledge and experiences, and support honest dialogue in identifying areas of consensus with which to proceed into the future.

Over the last decade, antibiotic resistance has increasingly been in the public eye. Multi-drug resistant bacteria are becoming more common. Representatives protecting both animal and human health have been working for years to discover common ground and mutually beneficial solutions, and have been experiencing modest success. This symposium began eight years ago as animal agriculture talking to animal agriculture, and in the past seven years has grown and expanded to include human physicians, regulatory officials, pharmaceutical companies, technology companies, and others in the discussion. The discussion has evolved, and the majority of participants now approach the discussion with open hands instead of folded arms. This group has discovered the value of collaboration, stepping beyond our silos to advance the discussion from a One Health perspective, taking into account animals, people and the environment and the synergistic interactions between them. This symposium provided an opportunity for stakeholders to review our past successes, explore ongoing antibiotic resistance challenges, evaluate new science and technology in antibiotic stewardship and the fight against antibiotic resistance, and discuss how to continue moving forward.

The NIAA is a non-profit, membership-driven organization that unites and advances animal agriculture for the challenges facing animal agriculture industries (aquatic, beef, dairy, equine, goat, poultry, sheep and swine). NIAA is dedicated to furthering programs for the eradication of diseases that pose risk to the health of animals, wildlife and humans; promoting the efficient production of a safe and wholesome food supply for our nation and abroad; and promoting best practices in environmental stewardship and animal health and well-being.

The 2018 8th Annual Antibiotic Symposium was funded in part by Auburn University Food Systems Institute, the Beef Checkoff, Merck Animal Health, Norbrook Inc., Phibro Animal Health Corporation, USDA, United Soybean Board, and Zoetis.

Purpose and Design of the Symposium

The purpose of the symposium was to bring leaders from all parts of the animal agriculture industry to join with veterinarians, researchers and experts in human and public health, and regulatory officials to present new information and talk about their experiences in adapting to a rapidly changing business environment and marketplace. The objective was to recognize the progress in antimicrobial stewardship that has been made across the business and regulatory spectrum, identify and reinforce common values among diverse stakeholders, hear some of the latest developments in research and applications of developing science, discuss communication strategies to deliver highly technical and complex information to consumers, and look for areas of consensus as we move into the future.

Symposium Planning Committee

Co-chairs:

Dr. Eric Moore – Director of Technical Services, North America, *Norbrook Inc.*

Dr. Steven Solomon – Principal, *Global Public Health Consulting, LLC*

Committee Members:

Dr. Kevin Cummings – Associate Professor, Popular Medicine and Diagnostic Science, *Cornell University*

Dr. Laura H. Kahn – Research Scholar, *Princeton University*

Dr. Kerry Keffaber – Principal Advisor, *GLUE, LLC*

Mr. Jeff Morelli – Associate Director for Policy, Division of Foodborne, Waterborne, and Environmental Diseases, *CDC*

Ms. Amanda Raziano – Policy Analyst, *CDC*

Dr. Roger Saltman – Group Director, Cattle and Equine Technical Services, *Zoetis*

Dr. Dawn Sievert – Associate Director for Antimicrobial Resistance, Division of Foodborne, Waterborne and Environmental Diseases, *CDC*

Mr. Joe Swedburg – Board Chair, *Farm Foundation*

Symposium Topics and Speakers

(in order given at the symposium)

Welcome and Introductions

Nevil Speer, PhD, Chairman of the Board, *National Institute for Animal Agriculture*

Opening Address

Michael D. Apley, DVM, PhD, DACVCP, Professor, Production Medicine/Clinical Pharmacology, Frick Professorship, *Kansas State University*

Panel Discussion – Science Update: What’s New in the Rapidly Changing Science of Antibiotic Resistance?

Moderator Kerry Keffaber, DVM

Raised Without Antibiotics (RWA) and Implications for Animal Welfare

Sara J. Steinlage, DVM, MAM, Diplomate ACPV, Chief Veterinary Officer, *Elanco*

Antibiotic Usage in Beef Production – We Can’t Forget People

Randall Spare, DVM, President, *Ashland Veterinary Clinic*

AMR Research at the Agricultural Research Service

Roxann Brooks Motroni, DVM, PhD, National Program Leader for Animal Health, *USDA-ARS*

Role of the Gut Microbiome in Reducing Antimicrobial Use in Swine

Megan Niederwerder, DVM, PhD, Assistant Professor, *Kansas State University*

Panel Discussion – Let’s Be Practical: How Scientific Advances Are Being Used to Meet Consumers’ Needs and Ensure Public Health

Moderator Dawn Sievert, PhD, MS

Improving Stewardship in the Swine Industry

Heather Fowler, VMD, PhD, MPH, DACVPM, Director, Producer & Public Health, *National Pork Board*

How Scientific Advances are Being Used at Pilgrim’s Pride to Meet Consumers’ Needs and Ensure Public Health

Kendra M. Waldbusser, Global Head of Food Safety & Quality Assurance, *Pilgrim’s Pride Corporation*

How Scientific Advances Are Being Used in Academia to Meet Consumers’ Needs and Ensure Public Health

Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

Panel Discussion – Navigating the Maze: Providing Accurate and Trusted Information on Antibiotic Use and Resistance in an Increasingly Chaotic Information Environment

Moderator Steve Solomon, MD, FACP, FIDSA

Genetic Resistance and Data Sharing

Laura Goodman, PhD, Assistant Research Professor, *Cornell University*

Providing Accurate and Trusted Information on Antibiotic Use and Resistance in an Increasingly Chaotic Information Environment

Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

Communicating Your Science: What is it Really About?

Michael F. Dahlstrom, PhD, Associate Professor, Greenlee School of Journalism and Mass Communication, *Iowa State University*

Panel – Millennial Discussion

Moderator Sara J. Bohnenkamp

Panelists:

Amanda Butterfield, Beef Producer, Meyersfield, PA

Sean Stapleton, Veterinary Medical Student, *Cornell University*, Ithaca, NY

Elise Wade, Ag Communication Major, *Oklahoma State University*, TV Personality & Social Media Influencer, Stillwater, OK

Conal Gould, Director of Procurement, *Hello Fresh Canada*

Panel Discussion - Antibiotic Stewardship Update: What's New in the Ongoing Efforts to Ensure Optimal Antibiotic Use?

Moderator Dawn Sievert PhD, MS

Recent Activities in Human Medicine and Animal Agriculture

Kathy Talkington, Project Director, Antimicrobial Resistance, *The Pew Charitable Trusts*

Pew Farm Stewardship Work

Joe Swedberg, Board Chair, *Farm Foundation*

Antimicrobial Use and Resistance: Roadmap for 2018-2019

Michael Costin, DVM, Assistant Director, *Division of Animal & Public Health, AVMA*

Antibiotic Stewardship in Pork Production,

Liz Wagstrom, DVM, Chief Veterinarian, *National Pork Producers Council*

Meeting Consumers' Needs and Wants: How Purchasers and Retailers are Responding to Changes in the Marketplace

Ernie Meier, Director of Quality, U.S. Supply Chain Management, *McDonald's Corporation*

Panel Discussion – In the Beginning: How Producers and Retailers are Responding to the Changes in the Marketplace and Continuing to Provide a Safe and Abundant Food Supply

Moderator Eric Moore, DVM

Beef Industry Perspective

Joan Ruskamp, *J & S Feedlot*, Dodge, NE

Swine Industry Perspective

Karen Richter, *D K R Swine Farms*, Montgomery, MN

Dairy Industry Perspective

Brett Morris, *Partnership of Morrisland*, Ninnekah, OK

Poultry Industry Perspective

Hector Cervantes, DVM, MS, DACPV, Hon. MAM, Senior Manager, Poultry Technical Services, North American Region, *Phibro Animal Health*

FDA's New Efforts to Advance Antimicrobial Stewardship in Veterinary Settings

William T. Flynn, DVM, Deputy Director, Science Policy, *FDA Center for Veterinary Medicine*

Panel Discussion – More Than Numbers Part One: How the Animal Agriculture Food Supply is Using Data to Meet Consumers' Needs, Maintain the Health of the Industry and Address Public Health Concerns

Moderator Eric Moore, DVM

Building Consumer Confidence through Judicious Use of Antimicrobials

Mary Battrell, DVM, Staff Veterinarian, *Smithfield Hog Production*

What Do We Do with The Numbers?

Katie Hope, BS, DVM, Graduate Research Assistant, *Kansas State University College of Veterinary Medicine*

Pipestone Veterinary Group and Pipestone PART (Pipestone Antibiotic Resistance Tracker)

Joel Nerem, DVM, Veterinarian, *Pipestone Veterinary Services*

Panel Discussion – Knowledge Needs and Wants: What's New in Efforts to Provide Information on Antibiotic Use and Resistance to Different Audiences with Varied Interests

Moderator Steve Solomon, MD, FACP, FIDSA

What's New in Efforts to Provide Information?

Cheryl Stroud, DVM, PhD, Executive Director, *One Health Commission*

National Animal Health Monitoring System Antimicrobial Use Studies

Charles P. Fossler, DVM, PhD, Veterinary Epidemiologist, *USDA-APHIS-VS*

Antimicrobial Stewardship Statement

Ruaraidh Petre, Executive Director, *Global Roundtable for Sustainable Beef*

Communication During Outbreaks of Illness that are Linked to an Animal

Megin Nichols, DVM, MPH, Enteric Zoonoses Activity Lead, *CDC*

AMR Surveillance and Reporting at FSIS

Andrew Hudgens, MPH, Microbiologist, *USDA-FSIS*

Panel Discussion – More Than Number Part Two: How Reliable and Accurate Information Can Only Be Assured Through Trusted Collaborations that Protect Data from Misuse and Misappropriation

Moderator Roger J. Saltman, DVM. MBA

Data Collection for Infection and Resistance in Human Medicine – the Why, the What, & the How

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne and Environmental Diseases, CDC*

Challenges and Opportunities for Antimicrobial Use Data in Animals

Rick Sibbel, DVM, President and CEO, *Executive Veterinary and Health Solutions LLC*

Data Collection and Antimicrobial Stewardship

Susan J. Bright-Ponte, DVM, MPH, Veterinary Medical Officer, Antimicrobial Use and Resistance, *Office of Surveillance & Compliance, FDA Center for Veterinary Medicine*

Panel Discussion: Looking Ahead – Science and Data: How Might Scientific Advances and More Complete Data Help Achieve our Shared Goals

Moderator Rick Sibbel, DVM

Science and Data Needs

Brian Lubbers, DVM, PhD, Assistant Professor, *Kansas State University*

Merck Animal Health Antibiotic Research Efforts Targeting Antibiotic Alternatives

Judson Vasconcelos, DVM, PhD, Head, Veterinary & Consumer Affairs, *Merck Animal Health*

How Might Scientific Advances & More Complete Data Help USDA-APHIS Achieve Shared Goals

Larry M. Granger, DVM, Senior Leader of Antimicrobial Resistance, *USDA-APHIS*

Panel Discussion – Blockchain: Building a More Sustainable Supply Chain

Moderator Nevil Speer, PhD

What is Blockchain? IBM Food Trust Overview

Gary B. Rodrigue, Blockchain WW Food Safety Leader, *IBM*

Blockchain and Tyson Fresh Meats

John Gerber, VP, Cattle Procurement, *Tyson Foods* and Kevin Hueser, Senior VP, Beef Margin Management, *Tyson Foods*

Panel Discussion – Shared Solutions and Responsibilities: Building and Maintaining Trusted Collaboration Between Industry, Academia and Public Health

Moderator Nevil Speer, PhD

Public Health Perspective

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne, and Environmental Diseases, CDC*

Industry Perspective

Mark Gardiner, President, *Gardiner Angus Ranch*

Academia Perspective

Paul Plummer, DVM, Diplomate ACVIM-LA, Diplomate ECSRHM, Executive Director, *Iowa State University, National Institute for Antimicrobial Resistance Research & Education (NIARRE) Center*

Wrap Up

Nevil Speer, PhD, Chairman of the Board, *National Institute for Animal Agriculture*

Executive Summary

Antibiotic resistance creates a paradox. To reduce antibiotic resistance, we need to stop using antibiotics. However, without antibiotics, the practice of modern medicine collapses. Physicians and veterinarians have a responsibility to treat their patients when they're sick. As we can't cease antibiotic usage altogether, we need to figure out a way to optimize judicious use of antibiotics. The question isn't so much, "Does this patient need an antibiotic?" but rather "Do the benefits of antibiotic usage outweigh the risks of antibiotic exposure or of not treating this patient?" Drug choice, dose, and duration of use are key. And to make all of this work, human medicine, agriculture and veterinary medicine, and the pharmaceutical industry need to work together, across disciplinary boundaries, to describe a comprehensive One Health approach that takes into account the needs of humans, animals, and the environment. Communication and collaboration are essential to developing the successful strategies, policies, and implementation needed to control antimicrobial resistance.

The NIAA Antimicrobial Stewardship Symposium is in its 8th year, and in that time, much progress has been made. Many organizations have developed strategic plans; developed messages to communicate about antimicrobial stewardship; and partnered with diverse organizations to discuss concerns, find common ground, and implement practical actions to address antimicrobial stewardship. On the human side, there has been significant development of antimicrobial stewardship programs in hospitals, and there are developing programs in long term care facilities and private practice. On the animal side, producers and veterinarians have learned to work within the antimicrobial constraints of the USDA's Veterinary Feed Directive; the FDA has developed a comprehensive five year plan to address stewardship; and the major commodity industries are actively seeking and developing programs to further hone and reduce the use of antimicrobials in production agriculture. Human and veterinary medicine are learning from each other, as demonstrated by the AVMA's adoption of a set of core antimicrobial resistance principals developed initially by the CDC for use in human medicine. As the human medical and veterinary professions develop approaches to refine the practical use of antimicrobials, research into antimicrobial resistance mitigation has expanded to include everything from the role of the gut microbiome and genomics to innovative environmental management strategies.

As we move forward to approach antimicrobial resistance in animal agriculture, we need to keep the animal at the center of the discussion. For these animals, at their most basic, antimicrobials are animal welfare drugs. That said, producers from all facets of animal agriculture affirm that optimizing animal health minimizes the need for antimicrobials. A focus on genetics, nutrition, and health, as well as the care and comfort of the animals, comprises the best management practices that lead to healthier animals. This focus on best management practices is complemented by a research focus on prophylaxis and metaphylaxis for further improved health. Research into genetics, the gut microbiome, immunomodulation, and other emerging areas offers the promise of the addition of a multitude of additional tools in the disease-fighting toolbox, which will provide the alternatives necessary to accelerate the reduction of reliance on antimicrobials. And when all of the prevention efforts fail and the animal still gets sick, improved diagnostics support antimicrobial stewardship by providing timely guidelines for the use of antimicrobials, as well as identifying which antimicrobials to use.

Unfortunately, even as the agriculture industry has improved, perceptions of agriculture seem to have worsened. Consumers are confused by the variety of labels and claims, myths, and misconceptions that abound in the social ether. Often, no one speaks effectively about the industry's advances, and when they do, this communication is often misunderstood as consumers view it through the lens of their own values. We need to get the signal through the noise – offer transparency, build trust, and address the values the consumer brings to the table – only then can we move forward with the consumer.

In order to have the information to communicate to the consumer, we must have baseline and benchmark antimicrobial use data. Without a baseline, there is no comparison to demonstrate improvement. In veterinary medicine, Pipestone PART, NAHMS antimicrobial use studies, and FSIS antimicrobial sampling are all collecting data to provide this benchmark. Human medicine was able to demonstrate the value of benchmark data collection in addressing Hospital Associated Infections (HAIs). This data, collected through the National Health Safety Network (NHSN) was able to pinpoint specific correctable concerns, which allowed for the development of successful solutions and a greatly reduced national percentage of HAIs. Antimicrobial stewardship data collection is being built into the NHSN system. The takeaway message from all of this is that increased record-keeping and data collection leads to improved stewardship.

Finally, new research into One Health has continued to define the role of the environment in the question of the antimicrobial resistance landscape. The soil has its own microbiome, as does the ocean. Antibiotics are used on citrus crops. Novel solutions based on environmental interventions, from bacteriophages to managed ecosystem fermentation, contribute unique but much needed insight into antimicrobial resistance mechanisms. The environment is a late addition to the game, but as equally vital to the big picture as human or animal medicine.

We have made significant progress in the past few years. Human medicine, animal medicine, and the pharmaceutical industry have begun to approach the table together. We have much in common, and our antimicrobial resistance fates are inextricably entwined. We can't just address animals, or humans, or plants. Ongoing partnerships are crucial. There are no simple, easy solutions to the antimicrobial resistance problem, but with a willingness to coordinate, work together, and the incorporation of emerging scientific advances, we can get a handle on the problem and move forward into a less resistant future.

Presentation Highlights

Opening Address

Michael D. Apley, DVM, PhD, DACVCP, Professor, Production Medicine/Clinical Pharmacology, Frick Professorship, *Kansas State University*

Antibiotics come into the community through many different avenues. Doctors' offices, the local veterinarian, the neighborhood dentist, the critical access hospital, a long term care facility, the psychiatric hospital, and the feedlot are examples from just one small town in Kansas. Does the veterinarian or the physician think about the big picture of antibiotic stewardship when they're in the exam room with a critical patient? The further we get away from that exam room, the clearer the path forward becomes. But the exam room is exactly where we need to move stewardship.

Moral temptation involves a right and a wrong choice. An ethical dilemma consists of two right choices that conflict. This ethical dilemma is the real issue at the prescriber level. Take, for example, human bronchitis. Only one in five cases of bronchitis need and antibiotic to foster recover. But which one is the fifth one? The prescriber's ethical dilemma is to risk not treating a patient who truly needs antibiotics, versus treating the four who don't. The medical provider tends to err on the side of caution and prescribe those antibiotics. But for those with a detached view, it's easy to look at that decision and say it's wrong. We need to figure out how to bridge that gap, and move antibiotic stewardship into the exam room, in a way that won't harm the patient.

There are three failures in treating humans or animals that lead to antimicrobial resistance. The first is the failure to prevent the infection; the second is the failure to treat the infections with an affective antimicrobial; and the third, and most insidious, is the failure to protect against resistance, exposing the bacterial population to an antibiotic without actually treating the infection.

The Infectious Disease Society of America defines antimicrobial stewardship as:

"Antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Antimicrobial stewards seek to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains."¹

Antimicrobial stewardship may be straightforward to describe, but the systems in which it must be applied, like animal agriculture, are complicated. In the center of animal agriculture is efficiency and animal welfare, but the system involves multiple inputs, with food and environmental effects as the output. Food and environment join to affect human health, and food also affects the inputs, in the form of money. Antibiotics affect every aspect of the system (Figure 1).

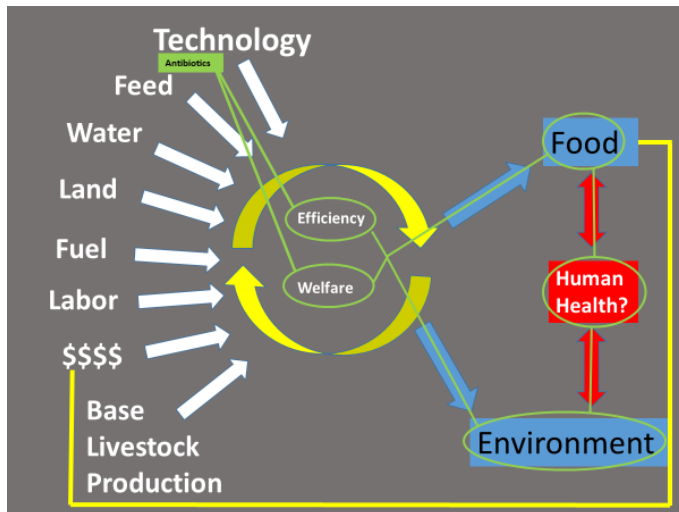


Figure 1. Inputs, outputs, and system interactions in animal agriculture²

The only way to address antimicrobial resistance in such a complicated system is through systems thinking. The United States National Action Plan for Combating Antibiotic Resistant-Bacteria³ and the Presidential Advisory Committee on Combating Antibiotic-Resistant Bacteria (PACCARB)⁴ are two entities employing a systems approach. Both advocate a One Health surveillance approach and support of collaboration and critical partnerships. The US National Action plan focuses on outcomes: accelerating development of rapid diagnostic tests and the progress of basic and applied research, while PACCARB focuses on how to achieve those outcomes: economic incentives, resource allocation, and a coordinated federal response.

Microbes don't respect boundaries. Relationships between humans, animals, and the environment are a central principal in the One Health systems approach to combating antimicrobial resistance. One Health must be seen as an organizing force, guiding discussion, connecting disparate parts of the system, and providing a lens through which to develop comprehensive combative strategies.

Panel Discussion – Science Update: What’s New in the Rapidly Changing Science of Antibiotic Resistance

Kerry Keffaber, DVM, MSC, moderator

Panel:

Sara J. Steinlage, DVM, MAM, Diplomate ACPV, Chief Veterinary Officer, *Elanco*

Randall Spare, DVM, President, *Ashland Veterinary Clinic*

Roxann Brooks Motroni, DVM, PhD, National Program Leader for Animal Health, *USDA-ARs*

Megan Niederwerder, DVM, PhD, Assistant Professor, *Kansas State University*

Raised Without Antibiotics (RWA) and Implications for Animal Welfare

Sara J. Steinlage, DVM, MAM, Diplomate ACPV, Chief Veterinary Officer, *Elanco*

In any conversation about antimicrobial resistance and animal agriculture, we need to ensure we keep the animal in the center of this discussion. Elanco Corporation views sustainable food animal production as the product of seven pillars addressing diverse aspects of animal agriculture. Antibiotic stewardship is one of these pillars, but the other six are diverse aspect of responsible animal production, including vaccination programs, biosecurity, nutrition, animal welfare, food safety mitigation, and environmental management (Figure 2).

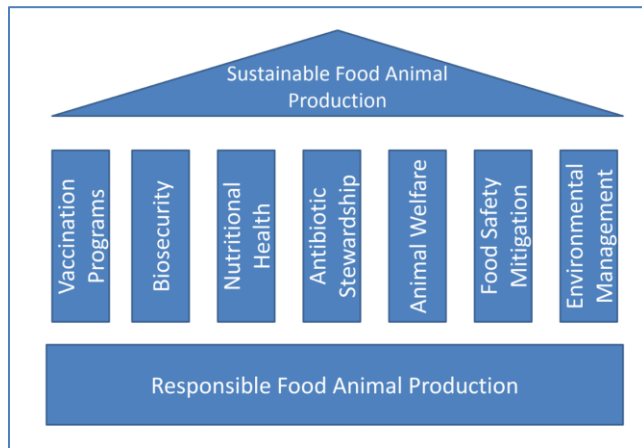


Figure 2. Seven pillars of sustainable food animal production⁵

Raised Without Antibiotics (RWA) is a consumer-driven movement in animal agriculture that has gained momentum in recent years. Consumers perceive that RWA production will positively impact animal health and welfare. A study by Dr. Dan Singer⁶ which surveyed more than 550 producers and stakeholders indicated that all producers and stakeholders felt that RWA slightly to significantly worsens animal welfare for both RWA and conventionally raised animals. However, the same survey group indicated that consumers think RWA slightly to significantly improves animal welfare in both RWA and conventionally raised animals. This study highlights a significant disconnect between animal agriculture professionals and consumers. This disconnect gives us a great opportunity to share what we do in animal agriculture, and educate the consumer about what really happens on the farm.

In reality, RWA compromises animal welfare. Broilers raised without antibiotics experience increased ammonia burns to the cornea, foot pad lesions, air sacculitis, and higher mortality than birds raised with the benefit of antibiotic therapy. Additionally, RWA compromises sustainability. Downtime between RWA flocks must be increased to prevent disease transmission from flock to flock, but in order to continue to meet demand with the increased downtime, flock numbers must be increased, which creates more demand for food and water, and more manure, to produce the same amount of food product as conventionally raised animals.⁷

To keep the animal at the center of the discussion, we need to take care that label or marketing outcomes, such as RWA, don't become more important than protecting the welfare of the individual animals. We need to do everything we can do to use antibiotics judiciously, but it is equally important to ensure we take care of the health and welfare of the animals entrusted to us.

Antibiotic Usage in Beef Production – We Can't Forget People

Randall Spare, DVM, President, *Ashland Veterinary Clinic*

There are 750,000 cow-calf operations in the United States. Most are small, with an average size of 40 cows. In 2016, the economic impact of these operations on beef production was \$67.5 billion. 80% of cow-calf operations are family or independently owned, and the average producer is 58 years old. Every one of these operations has a person that's connected to it. People raise cows for all sorts of reasons, from income to yard art, and all have different goals for their operation. Only 1.5% of antibiotics used in beef production are used in the cow-calf sector. And in this sector, management practices control the use of antibiotics. At the end of the day, every producer needs to understand that it is their responsibility to prepare that calf for a good, healthy life as it moves on from the ranch.

The veterinary feed directive has gotten veterinarians more involved with some of those ranches that didn't think they needed a veterinarian, offering an opportunity for education, partnership, and significant reduction in antibiotic usage. Defined management practices naturally reduce the use of antibiotics. Planned health practices such as vaccination, testing, and implementation of biosecurity practices all contribute to a healthier calf, and defined nutritional management, from gestational to colostral to post-weaning, support future growth and health. Critical events in a calf's life are the touchpoints where management choices can reduce antibiotic usage for months to come, and attention to genetics and handling practices support the calf as it moves through these life events. Choosing cows for calving ease, as well as low stress handling and supportive nutrition during weaning are prime management targets for reduction of antimicrobial use.

The producer is in control. Attention to genetics, docility, nutrition, and health support one simple goal: to make every day a good day in the life of a calf!

AMR Research at the Agricultural Research Service

Roxann Brooks Motroni, DVM, PhD – National Program Leader for Animal Health, *USDA-ARS*

The Agricultural Research Service (ARS) consists of 90 locations, 16 national programs, 25 ongoing antimicrobial resistance projects and a \$1.3 billion budget. ARS works with many USDA agencies and other federal agencies to coordinate research efforts around AMR. Four broad research areas addressed by the ARS are animal production and protection, crop production and protection, natural resources and sustainable agriculture systems, and nutrition, food safety and quality.

The mission of the ARS is to deliver scientific solutions to national and global agricultural challenges. The role of ARS in antimicrobial resistance research is to contribute solution-oriented, hypothesis driven research that benefits agriculture and ensures a safe secure food supply, as well as to perform basic and applied research that informs through peer-reviewed publication, subject matter expertise, and information sharing.

ARS researches many areas of antimicrobial resistance in agriculture. The USDA AMR action plan was developed in 2014. Three objectives delineate the areas of AMR research. The first is to determine and model purposes and impacts of antibiotic use in food producing animals, and research to inform this objective includes controlled feedlot style trials. Interestingly, observed antimicrobial resistance is similar between conventional and no antibiotic ever (NAE) cattle. The second objective is to monitor antibiotic drug susceptibilities of selected antimicrobial organisms in food-producing animals, production

environments, and meat and poultry. Research in this area has focused on development large scale monitoring technology for many different sample types, as well as forming collaborations to evaluate trends of antimicrobial resistance in developing countries. The third and final objective is to identify management practices, alternatives, and other mitigation strategies to reduce antimicrobial resistance associated with food-producing animals and their production environments. This objective is the focus of the bulk of antimicrobial resistance research. Vaccine and therapeutic developments such as the development of an effective vaccine for *Strep suis*, and environmental antimicrobial resistance mitigation strategies such as methods of treating manure to reduce the transport of antibiotics and resistant drugs into the environment, represent significant advances in antimicrobial resistance research.

As the UDSA and ARS examine the many problems facing agriculture today, including antimicrobial resistance, one of the most pressing identified needs is for transdisciplinary approaches that break down scientific silos. ARS has created the 'Grand Challenge' to address this need. To define and characterize the ARS Grand Challenge related to AMR, scientists from across ARS are coming together to answer three big questions: What research questions should and AMR ARS Grand Challenge address? How can ARS research inform risk assessments, surveillance and antibiotic stewardship activities? How can ARS better work with academia and industry to address these challenges? ARS is committed to reducing antimicrobial resistance in agriculture and fostering transdisciplinary relationships to support that goal.

Role of the Gut Microbiome in Reducing Antimicrobial Use in Swine

Megan Niederwerder, DVM, PhD, Assistant Professor, *Kansas State University*

The microbiome is the ecological community of commensal, symbiotic, and pathogenic microorganisms that share our body space.⁸ The typical medical approach to reducing disease is to eliminate harmful microbes, but the community of the microbiome encourages us to approach disease in a different way. Because the entire community of microorganisms are part of our normal flora, it is reasonable to ask if we can get the same effect of reducing pathogens by increasing beneficial microbes.

Many factors during the first three weeks in the life of a piglet affect the development of the ecological community that makes up the microbiome. These include mode of delivery, diet of the sow, diet of the piglets, microbiome of the sow, pathogen exposure, antibiotics used, handling, and stress.⁹

There are three main roles of the microbiome: absorption, metabolism, and storage of calories; providing a protective barrier; and development and regulation of immunity. All of these come into play in the interaction of respiratory pathogens with the gut microbiome. Infectious respiratory disease is a leading cause of morbidity and antimicrobial use in swine. In studies where pigs were co-infected with PRRSV and PCV2, increased microbiome diversity appears to be beneficial, and was associated with improved growth rate and improved clinical outcome.^{10,11}

If increased microbiome diversity is indeed beneficial, the next question was: how can we prophylactically modulate the microbiome to set the pig up for improved outcomes? Fecal microbial transplantation (FMT) is the process of transplanting feces from a healthy donor into a diseased or young individual.¹² The mechanism by which FMT works is largely unknown, but is thought to be associated with beneficial microbes and modulates the immune system. An experimental model transplanted fecal material into 3 week old piglets for 7 days prior to coinfection with PRRSV and PCV2.¹³ Piglets were followed for 42 days after coinfection. Findings at the conclusion of the study demonstrated a significant association between

FMT and protection against disease. FMT pigs experienced reduced clinical signs, antimicrobial use, mortality, and lung lesions. Research into FMT and the microbiome is a growing area.

FMT is beneficial for many diseases in humans, as well. FMT in humans has been demonstrated to aid in the resolution of recurrent *Colostridium difficile* infections, and evidence indicates that FMT is also beneficial for humans suffering from conditions such as inflammatory bowel disease (IBED) and irritable bowel syndrome. FMT has been used in several livestock species for several different conditions, and is associated with a broad benefit for the overall health of livestock animals.¹⁴ Potential applications of FMT include therapeutic, prophylactic, and immunogenic uses, and offer a potential new tool to combat disease and reduce antimicrobial resistance.

DISCUSSION

Dr. Kerry Keffaber of Glue, LLC asked Dr. Spare why everyone isn't using defined management and planned health practices?

Dr. Spare pointed out several reasons: tradition, economics, and a general feeling that this type of management doesn't apply to the specific operation. For the people who do add value through nutrition, genetics, health programs and breeding for temperament, the longer they own the animal the more likely they are to recoup the cost. Those producers that are economically driven will be the vanguard for this type of management, but not all cow-calf producers are economically driven. Those cattle owned by producers that are not driven by economics are the least likely to participate in defined management and planned health practices, and those cattle are going to require the most antibiotics. The veterinarian is the key in this relationship, and that veterinarian must understand how to engage with people, and help clients move toward better management and health practices.

Has the trend toward poultry raised without antibiotics has ever reversed?

Dr. Steinlage indicated that the industry has seen the trend increase sharply for about 9 years, but over last year it has begun to really plateau. Some producers have reversed their plans to raise chickens without antibiotics, and some quick service restaurants have reversed their decisions regarding antibiotic usage, and both the industry and retail food move toward a more holistic, one health approach. The pendulum seems to be swinging back to having the animal at the center of the discussion, and with that the importance of proper diagnosis, and treatment via judicious use of antibiotics, as well as prevention practices, have become a more significant consideration.

Kathy Talkington of the Pew Charitable Trusts asked Dr. Niederwerder about the cost of non-traditional therapies such as FMT and how the environment of the animal affects the health outcome after FMT.

Dr. Niederwerder indicated that the environment in which the transplantation occurs will influence outcome. Additionally, a major influence on the outcome of FMT is the donor. In that case, the question becomes, how do we identify the ideal microbiome for donation? At the moment, we don't have that definition, and this is one of the areas in which we have the most to learn. In terms of cost, any therapy should be completed when the animals are already being processed – both to reduce cost, in the form of labor, and to reduce stress, by minimizing the amount of handling animals receive.

Can we alter the microbiome by methods other than FMT?

Dr. Niederwerder listed prebiotics, probiotics, and postbiotics as additional methods to modulate the microbiome. In general, increased diversity is usually found to provide benefits, and transfer from the same species of animal is most likely to colonize. Probiotics may only consist of one or two species of microbes.

Dr. Peter Davies of the University of Minnesota asked Dr. Niederwerder about the potential for antimicrobial resistance (AMR) genes in the FMT material, and how that concern was balanced against the benefits?

Dr. Niederwerder allowed that her research did not measure the resistome within the transplant material they used. Anecdotally, there have been case reports of FMT in humans reducing the AMR genes within the recipient. However, in the future the resistome will likely need to be defined to ensure that resistant microbes are not inadvertently transplanted.

Dr. Rick Sibbel of Executive Veterinary and Health Solutions noted that he recently attended an AMR meeting in Morocco where one researcher presented work that indicated the microbiome is 70% genetic. His question for Dr. Niederwerder is regarding those genetics: is the difference between animals' microbiomes due to genetics, or is the microbiome changing the genetic response?

Dr. Niederwerder discussed that even among littermates from the same sow, there are likely microbiome differences. She believes that the genetics of the animal will affect microbial colonization and that the microbiome affects the genetic response.

Dr. Bradley Lawrence of Novus International, Inc asked Dr. Niederwerder if health outcome were improved because of a true impact on the viral response, or if it could be that the FMT simply affected feed intake?

Dr. Niederwerder believes it could be both, but leans toward the impact on viral response. In her research she saw less viral replication in pigs receiving FMT, as well as a more robust immune response, than pigs who did not receive FMT. She does think there could be some application of FMT in healthy animals that aren't challenged by disease, to increase feed efficiency.

Dr. Keffaber asked Dr. Motroni what the biggest barrier is to doing more research and learning more?

Her reply was the dearth of funding, and getting people to realize that there is an impact they could have in other research. If people can be moved out of their comfort zones, their expertise could be used in other areas to provide novel solutions.

Has Dr. Motroni done any research on diagnostics for different bacterial illness in animals to be able to better target therapy?

Dr. Motroni indicated that there is some current research in diagnostics toward developing better targets, as well as investigation into pen side diagnostics tests that could be utilized by veterinarians. Any time you're doing vaccine development, that research can simultaneously be looking at diagnostic targets.

The final discussion question was posed to Dr. Spare. How will producers be adequately reimbursed in cases where a calf's rearing affects price, as the calf raiser is some distance back down the supply chain?

Most cows move through multiple producers as they traverse the system from cow-calf to finishing. Dr. Spare replied that producers are adequately reimbursed to the level of inputs they're willing to put into the cow. If a baby calf is castrated at birth, and weaned before going to the sale barn, it's worth much more than a calf that's unweaned and uncastrated. The producers get to choose which market they want to join.

Panel Discussion – Let's Be Practical: How Scientific Advances Are Being Used to Meet Consumers' Needs and Ensure Public Health

Dawn Sievert, PhD, MS, moderator

Panel:

Heather Fowler, VMD, PhD, MPH, DACVPM, Director, Producer & Public Health, *National Pork Board*
Kendra M. Waldbusser, Global Head of Food Safety & Quality Assurance, *Pilgrim's Pride Corporation*
Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

Improving Stewardship in the Swine Industry

Heather Fowler, VMD, PhD, MPH, DACVPM, Director, Producer & Public Health, *National Pork Board*

As the Director of Producer and Public Health of the National Pork Board, Dr. Fowler oversees research as well as education and outreach activities as they relate to the broad topic of public health. Her presentation today gives an overview of the changes undertaken by the swine industry in response to scientific advances in antimicrobial resistance.

The National Pork Board was established under the Pork Promotion, Research and Consumer Information Act of 1985. Hand-in-hand with the National Pork Board is the Pork Checkoff program, which generates funds collected as a federally mandated fee per pig. Oversight is provided by USDA. It is specified in the Act that Pork Checkoff funds cannot be used for lobbying. The National Pork Board works together with the National Pork Producers Council and state organizations to support research, education, and promotion for and of the pork industry both domestically and internationally.

The National Pork Board believes in educating producers through a One Health approach. Inputs in the industry are spread across all three sectors of the one health framework. Producers work every day with pigs out in the barn environment and are conscious of the human health impacts in everything they do. Producers understand that their practices need to be sustainable if they are to pass the farm on to future generations. Responsible antibiotic use is part of this approach, and is summed up in the underlying theme of the current strategic plan: People, Pigs, Planet.

As far back as the early 1990s, swine veterinarians developed judicious antibiotic use guidelines. The 'Take Care – Use Antibiotics Responsibly' program was developed by Dr. Liz Wagstrom in 2005, and was a program directed at producers to ensure their judicious use of antibiotics. In 2007, the Take Care program was folded into PQA Plus® program. PQA had been started as a food safety program to address residue issues, but expanded to PQA Plus with the inclusion of antibiotic use guidelines and animal welfare

guidance as well as other topics. Guidelines for responsible antibiotic use comprise five tenets: decrease the need, provide measurable benefits, ensure advantages outweigh disadvantages, management practices promote responsible use, and maintenance of a valid veterinarian- client- patient relationship. The National Pork Board website (www.pork.org/antibiotics) provides a producer antibiotic resource center, where all antibiotic use resources are collected, as well as FAQs and additional clarifications from FDA regarding the Veterinary Feed Directive GFI #209 and #213.

Checkoff-funded research covers all areas of pork production, processing and human nutrition. Research funds are invested in animal welfare, environmental and production studies that help producers meet the challenges of responsible pork production.¹⁵ 2019 industry research areas in public health include antimicrobial use and resistance, MRSA, influenza, worker safety and health, and zoonotic disease. Antimicrobial use and resistance research is a continual and increasing focus for the industry, with dedicated research dollars in the annual budget.

2019 antimicrobial research priorities comprise preventative use of antibiotics at therapeutic doses, population versus individual antibiotic therapy, improvement of record keeping practices, and minimizing the need for use of antibiotics. Funded 2018 projects have investigated probiotics, replacement of dietary antibiotics, microbiota and piglet immunity, impact of antibiotic use patterns on AMR in PRRS infected swine, and antibiotic resistance gene diversity and mobility.

For producers who are considering raising pigs without antibiotics, the National Pork Board has developed a self-assessment tool, to help producers think about how NAE or RWA might look in their operation, and how they would continue to protect animal welfare (<https://www.pork.org/production/antibiotics/>).

Collaboration is key. Antimicrobial resistance is a One Health issue, and the National Pork Board strives to address AMR by doing what's right for people, pigs and planet. The National Pork Board has taken an active role in public health, and in its collaboration with diverse organizations the National Pork Board will continue to dedicate research dollars to judicious use of antimicrobials, as well as alternatives to the use of those antimicrobials.

How Scientific Advances are Being Used at Pilgrim's Pride to Meet Consumers' Needs and Ensure Public Health

Kendra M. Waldbusser, Global Head of Food Safety & Quality Assurance, *Pilgrim's Pride Corporation*

Pilgrim's Pride is a global chicken company, whose producers embrace a variety of different ways of growing chickens. Pilgrim's has more than 5000 farm partners, 34 hatcheries, 55 feed mills, and 52 processing plants on two continents, all in the business of producing 47 million birds per week.

All over the world, these production units engage in a vertical integration model, where chicks are supplied, eggs are hatched, and both replacement breeders and meat birds are raised, shipped, and processed. Traceability within this system is very easy, as all parts of the system, from hatchery to feed mill, are controlled by Pilgrim's Pride. Due to this traceability, it is a little easier for Pilgrim's to track antibiotic usage than many other animal agriculture enterprises. When a chicken comes to the Pilgrim's processing plant it has a defined use in two broad categories, grocery stores and food service. Different birds supply each of these market segments.

Pilgrim’s Pride asked their market research folks for data, but the data is very confusing because consumers are very confused. Words listed on chicken packaging like ‘natural’ and ‘hormone free’ lead to misconception and misunderstanding. Due to this background noise, it is difficult to determine what consumers want. However, determining what consumers need is relatively simple. What consumers need is what they’ll pay for.

For the last few years, what consumer will pay for is antibiotic free chickens. NAE and ABF chicken is quickly growing in both grocery and food service. From 2015 to 2016 ABF sales grew by 11%, and as of 2016, it was projected that in 2018 ABF will be worth more than \$1.1 billion.¹⁶

Currently about 45% of the US broiler supply are grown antibiotic free. However, if at any time in their 63 day lifespan they display any symptoms of illness and need medical treatment, they will be diverted to conventional channels at processing. Thus, very few birds are actually sold antibiotic free. (Figure 3.) The customer overwhelmingly needs just antibiotic-free breast meat, but ends up paying to support the entire antibiotic free growing system.

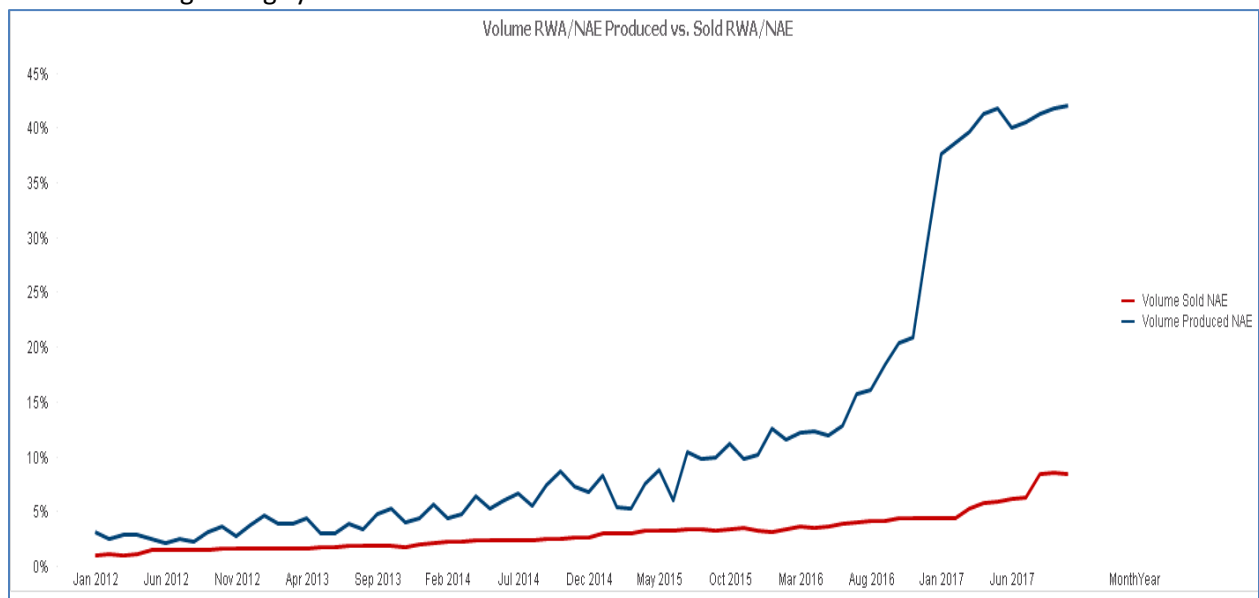


Figure 3. U.S. Broiler Supply: NAE production vs. NAE products sold.¹⁷

Earlier in the day Dr. Sara Steinlage was asked if she sees the trend toward RWA reversing. Dr. Steinlage mentioned she had seen this trend plateau in the past few years, and at Pilgrim’s Pride, the observation is the same. Consumers seem to be backing off their need for RWA chicken meat. Global chicken consumer trends indicate that antibiotic stewardship is viewed quite differently in Europe. Consumer want animals to be treated when they’re sick, and thus RWA is not really a need that consumers are willing to pay for. The United States seems to be heading in this direction as well.

Pilgrims is responding to consumer trends with practice leading toward responsible antibiotic use. Pilgrims understands that responsible use is not simply a reduction in usage, but rather a three-tiered approach, encompassing replacement of antibiotics with effective alternatives, reduction of the number of birds receiving treatment, and refinement of existing health support strategies through data. Four measures have been put in place to prevent use of the highest priority critically important antibiotics: control, analysis, food safety and evidence. Antibiotics are used only when absolutely necessary and then are used under veterinary supervision. There is a yearly review conducted into antibiotic used, their

utility, and the magnitude of their positive effects. During any medical treatment, withdrawal periods are strictly followed, and finally, when antibiotics are used, full written case notes including justification for the use of the antibiotics are provided.

There are many pillars of antibiotic stewardship. As Pilgrim's moves forward, these tenants guide and shape their policies. All of the players must be considered – different antibiotics have different uses in different parts of the world, and any change is felt globally from producer to processor. Consumers have needed to be re-educated to focus on animal welfare, not on the drugs themselves. Alternative prevention strategies, including breeding and nutrition, must be considered. Veterinary support has a huge role to play, and a big story to be told, but we need to be able to measure that support to tell the story. As they move forward, Pilgrim's will continue to follow one overarching tenant regarding antimicrobial use: 'As little as possible, as much as necessary.'

Are Being Used in Academia to Meet Consumers' Needs and Ensure Public Health

Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

With every purchasing decision, the consumer must juggle both the intrinsic and extrinsic factors of the product they are purchasing. Consumers have a right to expect that the foods they purchase are safe and of high quality, both intrinsic qualities, and to voice their opinions about government and industry procedures that ensure safe, high quality food. The ultimate responsibility for these procedures lies with the food industry, and in turn, industry needs standards from government that permit flexibility and efficiency in both the producing and marketing of foods.

The paradox of progress is that, as we move forward, we produce more problems. Higher economic growth and consumerism leads to more stress, people work more, and society falls behind. The better things become, the worse they are perceived. The more we know, the more we have to discover.

One example of significant progress within production agriculture is violative residues. In 1978 market hogs' violative residues were measured at 5.6% for antibiotics and 9.7% for sulfonamides. By 2016, there were no violative residues found in random sampling, and of more than 18,000 samples, only 0.02% tested positive for violative residues. This is a huge success and a huge advance, but no one talks about it. We need to communicate our successes!

A second example is the reduced incidence of foodborne pathogens. Over the past several years all meat borne pathogens except Salmonella and Vibrio have experienced substantial reductions. Salmonella, while not decreasing, has stayed the same, and Vibrio is associated with seafood, not other meats. In pork specifically, there are clear trends in the decrease of foodborne outbreaks, Toxoplasma in market hogs, human trichinella cases, and salmonella on hog carcasses. All of the evidence suggests that food has gotten safer over the past 20 years, but worsening consumer perceptions clash with this reality.

All of this is the backdrop for the antimicrobial resistance discussion. What really matters? Are food animal industries doing harm, and if so, how much? How are antibiotics used in food animals? How good is the evidence? Regardless of impact, industry has to do better. Across agriculture, industries are moving forward to reduce antimicrobial resistance because they know this is a really important area.

There are three general approaches to reduce the impact of antibiotic use in food animals on public health: reduce consumption of animal products, reduce contamination, and reduce selection pressure.

Reduced consumption has been in the conversation because consumers want it there. Competition in the protein markets is diverse and growing as the meat substitute market grows. One significant advantage of a 'no meat' burger is that it is certainly antibiotic free.

To reduce contamination of meat products, industry has introduced multiple hurdle technologies, ranging from the use of CO₂ and ozone to essential oils and plant extracts to protect meats. Preharvest control of pathogens has proved harder, as many pathogenic bacteria are found as normal flora and common commensals. Control at this point has been labelled as the 'holy grail' of antimicrobial reduction, but there has been little success in identifying reliable, repeatable interventions that substantially reduce bacterial prevalence at the point of harvest.

Finally, the most visible of the approaches to reduce antibiotic use is that of reducing selection pressure by reducing need, and restricting and optimizing use. Antimicrobial use in animals can be restricted or banned by regulations, but that loss generates a significant need for alternative products, to treat illness and protect animal well-being. Optimization of use focuses not on reducing use, but development of antimicrobial stewardship to ensure judicious use that balances resistance concerns with protecting animal health and food safety. Finally, the need for antibiotic use can be significantly reduced by improving housing, management, genetics and nutrition that improve host resistance to infection, and development of products to promote health, particularly in vulnerable populations such as neonates, recently weaned animals, and animals stressed by transport. We need to underline that this is not a new concept, but one that has been at the heart of veterinary medicine for decades.

What does the future look like? That's the question before us, and it will shape the picture of antimicrobial resistance as we move forward.

DISCUSSION

There is a lot of noise when talking to consumers. Where do we need to go to clearly communicate with them?

Ms. Waldbusser offered that Pilgrim's Pride has tried to use trade associations. However, they have been unable to get entire chicken industry to agree on the message, and when the different companies take different stances, it become even more confusing for the consumer. To begin with, they are trying to get a consistent message within Pilgrim's, but it is a difficult problem. Dr. Fowler explained that her industry has provided registered dietician tours for food service employees. They take people out onto the farm and show them how pigs are raised, then have a day where they demonstrate how to incorporate pork into a healthy diet. Additionally, they incorporate technology like YouTube and Food apps. Finally, Dr. Davies noted that it's hard to see much push on consumer education for food safety in the manner it used to occur in the past. The industry take is that consumers are telling industry they need to be more responsible. There are still a lot of food safety issues with improper storage handling, and cooking – but that's a difficult line to walk.

Dr. Fowler was asked where she sees the trend to RWA going?

The proportion of pigs that are RWA is very small, but she doesn't know the proportion. Producers are considering RWA as a potential market though, and that's why the National Pork Board has put together the Self-Assessment Tool.

Dr. Cervantes of Phibro Animal Health asked Ms. Waldbusser about the confusion created by the marketing department within the company. In his view the USDA has also contributed to the confusion by marketing the slogans ‘raised without hormones’, ‘raised without antibiotics’, and others. He feels their focus should be wholesome and fit for human consumption – not marketing slogans.

Ms. Waldbusser noted that the USDA is successful with marketing claims because consumers don’t trust big agriculture and they want someone else, like the USDA, to verify claims. The UK addresses this issue by providing much more transparency, from webcams to farm tours, and this is probably where we need to go in the United States. Both Ms. Waldbusser and Dr. Fowler indicated that reaching out to influencers on social media is important.

Finally, Sarah Sorcher of CSPI asked a question of Ms. Waldbusser. She hears from producers that they want people to come out and see what industry is doing, but she gets ‘ghosted’ a lot. She is also wondering if we’re focusing on the wrong stage of production – instead of processing, should we be paying more attention to the grandparent population upstream?

Ms. Waldbusser remarked that there would be a little hesitation from the contract growers to allowing visitors on farm, but we need to work in that direction, as we can’t say we have transparency and not let people on the farm. Ms. Waldbusser addressed the question of focus on the grandparent population by explaining that there is already a great deal of salmonella surveillance in primary breeders. She addressed the question of where the focus of antimicrobial resistance investigations should be by pointing out that the same strains of salmonella are seen all over the world, thus we should be looking at antimicrobial resistance globally, not just in our home country. Additionally, by-products of the poultry industry are used in not so obvious such as the aquaculture industry, where they are sold for fish protein. There is potential that this protein could be contaminated by AMR genes. Finally, consumers and others need to realize that just because a chicken is raised without antibiotics, it doesn’t mean that that chicken won’t harbor resistant salmonella. There are pressures beyond antimicrobials that lead to bacterial resistance.

Panel Discussion – Navigating the Maze: Providing Accurate and Trusted Information on Antibiotic Use and Resistance in an Increasingly Chaotic Information Environment

Steve Solomon, MD, FACP, FIDSA, moderator

Panel:

Laura Goodman, PhD, Assistant Research Professor, *Cornell University*

Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

Michael F. Dahlstrom, PhD, Associate Professor, Greenlee School of Journalism and Mass Communication, *Iowa State University*

Genetic Resistance and Data Sharing

Laura Goodman, PhD, Assistant Research Professor, *Cornell University*

Why do we need to genetically ‘predict’ antimicrobial resistance in animal health? The big data generated by bacterial sequencing has excellent correlation with sensitivity results and is actually much easier to use for surveillance than other methods. The data can also help with disease management.

A number of veterinary diagnostic laboratories have begun offering whole genome sequencing (WGS) of bacteria as a service. This is possible because of recent reductions in cost of the technology. It’s still not cheap, but it is not so expensive as to be inaccessible. Advantages are that the lab procedures are nationally harmonized, can confirm isolate relatedness, and are not restricted to particular panels of drugs. In a process called predictive genomics, large amounts of data provided by WGS can be used to predict serotype, virulence factors, and the antibiotic resistance gene (ARG) profile.

One reason veterinary diagnostic laboratories have WGS capacity is because of the FDA Vet-LIRN (Veterinary Laboratory Investigation and Response Network) CARB (Combating Antimicrobial Resistant Bacteria) surveillance project. 25 veterinary diagnostic laboratories across the country are systematically collecting animal isolates. In the 2017 pilot year, approximately 2000 isolates were collected. In 2018, isolate collection was expanded to include aquaculture isolates. WGS is done on a subset of these samples, and results have been uploaded into the National Center for Biotechnology Information (NCBI) database in near real-time. The system is integrated with the National Antimicrobial Resistance Monitoring System (NARMS), making this the first time that data from live animals has ever been entered into NARMS. The FDA and USDA are both doing CARB surveillance projects, focusing on different groups of bugs. Data entered into the system is coded, with all identifying information removed, as the goal is to look for national patterns not individual level identification. The tiered de-identification and coding system ensures confidentiality. The FDA project is working toward better representation of animal health in the NCBI database, and the more animal health isolates that are entered into the system, the better the predictions and disease management tools will be.

Using the data collected from the CARB surveillance project, one way of rethinking the antibiogram is by using the ARG heat map. The heat map represents all specific bacterial isolates collected from animal species, and maps their resistance. In one example, the heat map for veterinary *Salmonella* (Figure 4), the pattern demonstrates that most veterinary isolates contain no resistance genes, but there is one resistance stand-out, *Salmonella* Dublin. This method aids easily and visually in identifying resistant antibacterial strains.

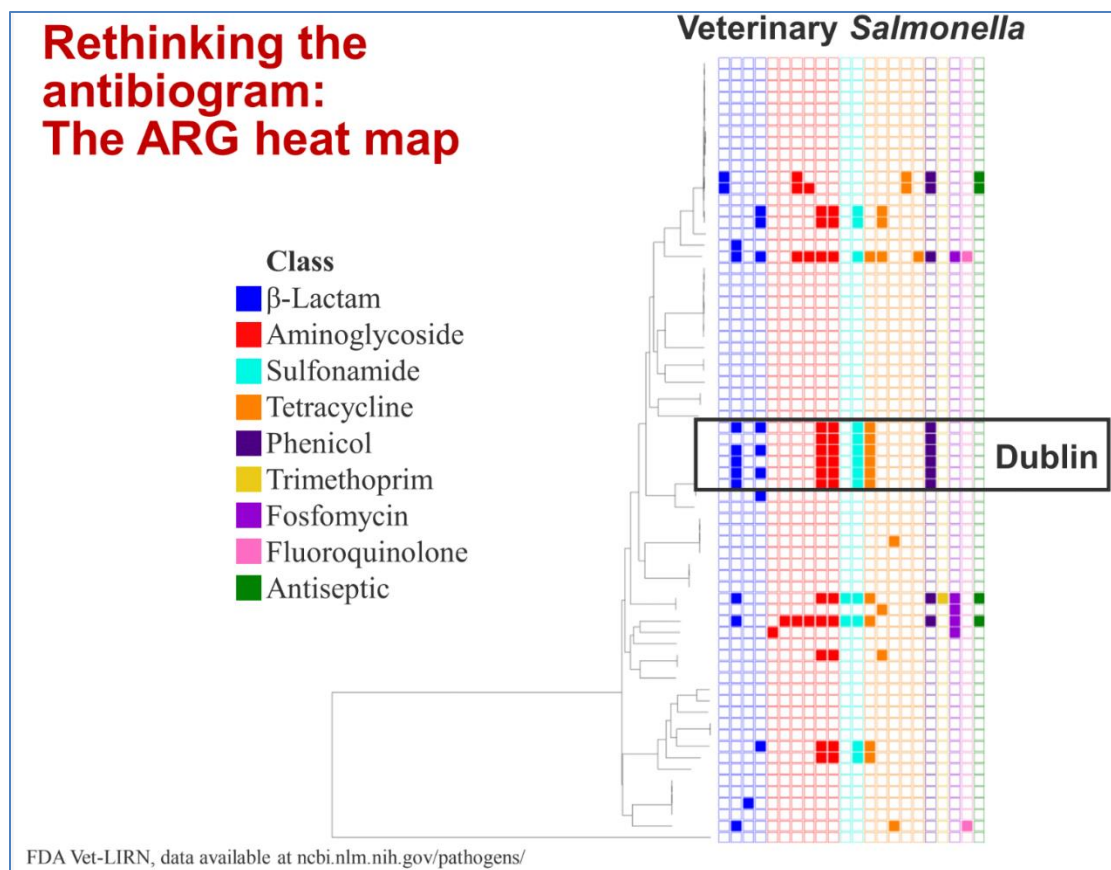


Figure 4. Antibiotic Resistance Gene (ARG) Heat Map for *Salmonella*^{18,19} Map generated using veterinary isolates collected in the 2017 FDA Vet-LIRN CARB surveillance project.

An additional metric we can look at is the distance between the veterinary isolate and human case isolates. One example from the 2017 dataset was a *Salmonella* Dublin with close similarity to a human isolate and a relatively high number of ARGs. This pattern is not surprising, however what interested researchers was that the isolate came from a cat. In fact, some of the most extreme resistance patterns seen came from companion animals, a fact that highlights the role of companion animals in antimicrobial resistance.

Cornell is the academic partner for the New York Integrated Food Safety Center of Excellence. In May 2018, the Center sponsored a meeting addressing One Health AMR data sharing. The executive summary from the meeting is available at <https://nyfoodsafety.cals.cornell.edu/resources/one-health-data-sharing/>. Data security, integrity, and confidentiality were discussed and are of utmost importance, and NARMS and NCBI were identified as best practice common databases. A tiered system with a 3rd party protector of identifiable information was proposed as one possible safeguard for confidentiality. Next steps for Cornell involve a pilot study with the New York Department of Health and providing guidance to other states to pursue similar initiatives.

The bottom line is that people and animals share pathogens, and pathogens share genes. By monitoring ARGs in animal populations, we can better protect both animal and human health as we move into the future.

Providing Accurate and Trusted Information on Antibiotic Use and Resistance in an Increasingly Chaotic Information Environment

Peter Davies, BVSc, PhD, Professor, *University of Minnesota*

In our increasingly noisy, polarized, and interconnected society, rational public discourse is a quaint idea. How do you get the signal through the noise? Accusations are simple; realities are complex. We live in a sound bite culture where detailed technical explanations simply don't garner attention. A complex defense is no defense, because you'll never get through the noise. Activists and journalists, but also professionals and scientists, all contribute to the noise. Knowledge and loyalty to the facts don't tend to be the focus of activists. While it is true that knowledge and loyalty are important and ignoring them is problematic, misinformation from the scientific community is even more damaging than the actions of misinformed or deliberately misleading activists.

Livestock-associated Methicillin-resistant *Staphylococcus aureus* (LA-MRSA) was first identified in Holland in 2004. It's been found in pigs and other food animals globally. Prevalence varies among countries, and there are other variants besides the ST398 MRSA originally found in the Netherlands. Human cases of infection with these food animal MRSA have been documented, but their occurrence is relatively uncommon compared to human MRSA. Even when humans are infected with food animal MRSA, the infections have mostly been non-invasive, and serious invasive infections have been very rare among healthy swine workers in regular contact with animal MRSA. However, despite the limited impact on public health to date, it has been a huge public relations problem in Denmark and Holland. LA-MRSA is now often raised as a consideration in permitting farm applications in the USA, despite the fact the robust studies in Denmark suggest minimal environmental risk.

Scientific publications on the neighborhood risk of LA-MRSA are inconsistent. Some studies suggest risk, but many of these studies exhibit flaws or limitations that undermine their findings. Data from one study in North Carolina reported elevated risk in one subgroup with moderate density of swine exposure, although groups with most exposure had numerically lower odds than groups with negligible swine exposure.²⁰ This conclusion arguably misrepresents the data, and added noise rather than clarity to the issue. Another study from Denmark also investigated MRSA and proximity of human residence to pigs. The study looked at high and low pig density areas and found no statistical difference in all MRSA infections between low and high pig dense areas. However, the paper concluded that MRSA was a major cause of human disease and serious public health challenge.²¹

Other studies indicate a negligible risk.²² In the US, several studies have confirmed that the prevalence of LA-MRSA is relatively low.²³ A study of human laboratories in Iowa indicated that just 0.2% of MRSA cases are livestock-associated, and in addition, less than 1% of methicillin susceptible strains are livestock-associated.²⁴

LA MRSA is a complex public relations issue. Unfortunately, lack of rigor in reporting and reviewing of some LA MRSA studies contributes more to the noise than the signal. In some cases, the noise has been amplified by press releases from Universities touting questionable conclusions of their researchers. Scientific authors, reviewers, editors, and universities all have a responsibility to fight misinformation and bias to produce a true, unbiased, objective signal.

Communicating Your Science: What is it Really About?

Michael F. Dahlstrom, PhD, Associate Professor, Greenlee School of Journalism and Mass Communication, *Iowa State University*

Science communication is an interdisciplinary field that looks at how scientific information is communicated, how audiences interpret this communication, and the effects of that communication on scientific understanding and acceptance.

Three tips for communicating scientific information are to avoid jargon, use analogies and metaphors that describe complexity through something familiar, and incorporate narrative examples that tell a story and increase relevance for the audience.

But how these tips are applied depends on the model of science communication utilized. The Deficit Model of Science Communication assumes that controversies about science are caused by deficit of scientific knowledge. Thus, the role of communication in this model is to educate the audience with facts, which will then speak for themselves and reduce the controversy. However, many studies show this model to be naive. Knowledge and attitudes about science are not necessarily correlated, and in fact, more accurate knowledge can actually lead to more polarization about the controversy.

Knowledge is important, but it is uninterpretable until applied to an underlying value system. It is this application that drives attitudes, behaviors, and acceptance of scientific technologies. And there are many competing values across audiences. For example, take the question of whether states should allow consumers to purchase raw milk. Science indicates that drinking raw milk significantly increases the risk of foodborne illness. One side of the controversy may hold the value of “keeping people safe” and use the science to promote their application of restricting raw milk to protect health. But another side may value “freedom of choice” and use the same science to promote their application of legalizing raw milk and allowing consumers the choice of engaging with the risk. Application of the same science to these two different values lead to different conclusions to the question of legalizing raw milk.

Audiences are not passive. They will seek out and interpret science according to their values. The only way to resolve socially contentious science issues is to articulate and discuss competing values and then see how the science can be applied in their service. This thinking leads to a more realistic model of science communication, the Public Engagement of Science Model. In this model controversies are not bad. They are a necessary function of the democratic process. The role of communication in this model is to incorporate accurate science into societal discussion about how best to apply science to meet societal values. It’s a two-way engagement between the expert and the public.

There are many ways to measure values. One example is the Cultural Theory of Risk that postulates that many of the conflicts around science are not actually about science at all, but rather about differences in aligning the desired solution to what an individual views as good societal structure. Individuals selectively pay attention to and interpret information in a way that expresses and reinforces their preferred way of life. Depending on the degree to which someone identifies as either an individual or with a larger collective, and the degree to which they view others in society as mostly equal or divided by hierarchy will result in different assumptions about how society works. Individuals who take more of an individualistic, egalitarian, hierarchical or fatalistic viewpoint will think about the same set of facts in a different way than other viewpoints based on those values.

The take home message is that audiences are not just sitting waiting for facts to come to them. They will apply their own values to the interpretation of the facts they learn. Messages must be interpretable according to those values. For effective scientific communication, you need to analyze your communications goal, the audience, why they care, how best to reach them, what values guide their interpretation of the message, and you need to earn their trust. It won't make science communication easier, but it will make it much more likely your message will be successfully received and really heard.

DISCUSSION

Dr. Heather Fowler of the National Pork Board noted that the National Pork Board and other agricultural organizations often deal with the media as a conduit to the public, but don't always have control of the message. Dr. Dahlstrom mentioned raw milk. Dr. Fowler's experience is that media will reach out to a public health veterinarian regarding the disease concerns related to raw milk and the science behind those concerns; but on the other side the media interviews someone who says raw milk cured his cancer. In this scenario public health comes off as the 'bad guy'. So how do we control the message?

Dr. Dahlstrom noted that there are many different contexts within communication. Dr. Fowler's example is one where you don't have much control over the message. A journalistic context can be hard because of this lack of control, but the more you know about media logic, the better you can give them information that fits what they're really looking for. However, it is also good to know whether you're working with a subject-specific journalist who really knows the subject, or a generalist who has no background in what they're being asked to cover. Knowing your journalists helps determine motivation and gives you better insight into the specific journalist's logic. Finally, if you know ahead of time the big issues surrounding your topic, you can address those and speak to the journalist's interest.

Cheryl Strad with One Health Commission commented that one of the huge One Health challenges is communication. We often talk past each other and miss each other's points. How can we have these conversations in a way that we understand what we're trying to tell each other instead of talking past each other?

Dr. Davies remarked that one of the problems is 'digestible bites' – shrinking a really broad issue into an understandable snapshot. Dr. Goodman added that it's important to engage with both sides, and understand where different stakeholders are coming from. Finally, Dr. Dahlstrom said that the biggest challenge he sees is the need for listening. Having a discussion where everyone gets to speak and is heard, and where there can be relationship building, is the only way to get to what the information is really about.

Sue Derain, a pharmacist at Auburn University, asked Dr. Goodman about e coli and antibiotic resistance in dogs. What sort of samples did she use, and were humans and dogs compared, or just dogs?

Dr. Goodman answered that a variety of sample type, including fecal, respiratory, urine, and other tissues, were examined. Current datasets don't indicate a link between veterinary *e coli* species and human samples. The NCBI database will generate a metric if it is there, but very few human samples have been associated with veterinary species.

Michael Apley of and Wendy Pinkerton of asked Dr. Dahlstrom about his discussion of the importance of audience values.

Dr. Apley agreed that the values are an issue, but wondered if maybe there is room for being direct in extreme cases such as anti-vaccination advocates or the raw milk movement. Dr. Dahlstrom asked him to consider his goal in communication. If the goal is to change minds, you must engage with the values. Many of these deeply held beliefs have nothing to do with the facts. Dr. Pinkerton offered that a reasonable approach may be to start with common value, instead of leading with the science? Dr. Dahlstrom agreed – if you want to change minds and opinions, the common ground is the values. That's where the trust starts to build. Competent information that's not trusted gets thrown out.

Panel – Millennial Discussion

Sara J. Bohnenkamp, moderator

Panel:

Amanda Butterfield, Beef Producer, Meyersfield, PA

Sean Stapleton, Veterinary Medical Student, *Cornell University*, Ithaca, NY

Elise Wade, Ag Communication Major, *Oklahoma State University*, TV Personality & Social Media Influencer, Stillwater, OK

Conal Gould, Director of Procurement, *Hello Fresh Canada*

How often do you touch antibiotics in your daily life?

The cow-calf producer allowed that even though she has a small cow-calf herd, 65% of them have never seen an antibiotic. Her farm is very focused on animal welfare, and they treat if necessary, but even then, over half of her cows have never received an antibiotic. The veterinary student still spends most of his days in lectures, but in those lectures the professors regularly talk about antimicrobial stewardship. The procurement director noted that he thinks about antibiotics every day, because of the consumers with whom he interacts. Additionally, his company does a lot of research on proteins, and antibiotics necessarily touch that research. Finally, the media influencer said she feels like she deals with the antibiotic issue daily, because she eats. However, she doesn't feel very educated regarding antibiotics and their stewardship, and she's curious to learn more.

Why do you feel like there's mistrust between millennials and food producers?

The panel notes several reasons, ranging from lack of transparency to a lack of knowledge that there is even a conversation to be had. Reasons coalesced around three main themes:

1) Lack of transparency.

Food production is very opaque. Generations older than millennials tend to 'not want to bother people' to provide the clarity and transparency that younger generations crave. In that void, those younger generations turn to You Tube and Netflix. But with these videos as their only window onto the food production industry, much of what is presented and internalized is negative.

2) Control of the narrative.

Most of the public story around beef production is told by journalists who focus on a narrow slice of that industry. The beef industry can tell their side of the story, but the challenge is for them to

tell it in a way that doesn't come across as defensive. Additionally, it's hard to describe the very complicated food production industry in a way that people who have no background in food production can understand. Food companies step into the communication gap with labeling claims, generating confusion to add to the narrowly focused non-industry story.

3) Two extreme ends of the spectrum are presented as the only alternatives.

The two extreme ends that are typically presented are conventional or No Antibiotics Ever (NAE). The conversation had not provided a clear definition of what might be in the middle. NAE seems to be a movement limited to the United States, and it seems like a public reaction to the food industry. There is room for considerably more clarity on this issue

Cow-calf producer Amanda Butterfield was asked about her recent attendance at a CDC meeting addressing antimicrobial use and stewardship. What was the most surprising thing that she took away from the meeting? What trends does she see with antibiotics, alternatives, and stewardship?

Amanda was most surprised at how disengaged the CDC was with what happens on the farm, although she allowed that the disengagement is changing. Additionally, the CDC is doing tremendous work to protect producers from disease that have huge ramifications for them, but that the common producer has no idea that this work is being done. We need to have these conversations – from both sides.

Amanda noted that much research is focused on preventing disease from occurring in the first place. Cargill is looking into microingredients and their role in priming the immune system, with the goal of reducing the need for use of antibiotics. Additional research is looking into epigenetics occurring in animal at the very small level. There are many products that will be coming onto the market designed to prevent, minimizing the need to treat.

Third year veterinary student Sean Stapleton was asked why, in the current climate, has he decided to go into food animal veterinary medicine?

When Sean was in undergrad, he became really interested in both humans and animal, and veterinarians fall right at that intersection. As far as getting involved in antimicrobial research, that was an accident. He happened to get to know an epidemiologist with a project looks at mathematical modeling and antimicrobial use in beef cattle. Through veterinary school and his research, he has come to the conclusion that it is important to find solutions that engage producers in a way that helps them to take ownership, and he wants to be part of that solution.

Hello Fresh Canada Procurement Director Conal Gould, was asked, as an outsider, what is the thing he's most noticed about antibiotics as he's started to visit farms? Also, what kinds of meat does Hello Fresh Canada source?

Conal pointed out that antibiotic usage isn't a bad thing. That may be obvious to everyone in the room, but as a consumer, he didn't really have a clear answer to that question. There is a lot of good stuff happening at the producer level, and that stuff falls somewhere between all or none antibiotic use. Visiting farms has really opened his eyes to what it's like to be a producer. Regardless of the type of producer, the business is often not very lucrative, and he has a new understanding for why producers might use antibiotics to improve feed efficiency. However, there are many passionate producers who really care about their animals, and care equally passionately about their consumers, and want to do right by both of them.

Hello Fresh Canada has decided to position themselves as a premium product. One of the things that defines a premium product is often NAE, for several reasons. It's a binary standard, making it easy to talk about. More importantly, NAE is often a proxy measure for better farming conditions. Those farms that are NAE tend to rely on better prevention to manage their herds, as the tool of antibiotic usage isn't available to them. This approach by Hello Fresh was met with initial skepticism, but the company has grown so much that producers now approach them about how to convert to NAE so that they can market their products that way through Hello Fresh. Their company's presence in the market has effectively doubled the size of the NAE market in Canada for poultry.

Finally, Elise Wade, who is identified as a media influencer, was asked why influencers are so important? Who are the key influencers we need to be engaging?

Influencers are important in this conversation about antibiotics because we're lacking a middleman. There is no one to translate between the uneducated and the industry, and influencers step in to fill that gap. Influencers are the people that get listened to. They don't necessarily get paid – often they want to go out and talk about what they're passionate about. This doesn't tend to be people in the industry, but those people can certainly fill these influencer roles, and that influence would be a huge step toward a more balanced conversation.

Panel Discussion - Antibiotic Stewardship Update: What's New in the Ongoing Efforts to Ensure Optimal Antibiotic Use?

Dawn Sievert, PhD, MS, moderator

Panelists:

Kathy Talkington, Project Director, Antimicrobial Resistance, *The Pew Charitable Trusts*

Joe Swedberg, Board Chair, *Farm Foundation*

Michael Costin, DVM, Assistant Director, *Division of Animal & Public Health, AVMA*

Liz Wagstrom, DVM, Chief Veterinarian, *National Pork Producers Council*

Ernie Meier, Director of Quality, U.S. Supply Chain Management, *McDonald's Corporation*

Recent Activities in Human Medicine and Animal Agriculture

Kathy Talkington, Project Director, Antimicrobial Resistance, *The Pew Charitable Trusts*

Antimicrobial resistance is a single problem that requires two solutions: stewardship to preserve the antibiotics we already have, and research to find new antibiotics and alternative therapeutic drugs. Pew Charitable Trust has focused on the stewardship component, and antibiotic stewardship is one of Pew's biggest issues. Stewardship entails the careful and responsible management of both to keep existing antibiotics effective and to avoid unintended consequences.

Human stewardship work has used compiled research data to provide concrete recommendations for a range of antibiotic use settings. The CDC has developed core stewardship components that have had a tangible impact on the uptake of stewardship in these different settings. Policy levers have helped drive that change. Between 2014 and 2016, United States acute care hospitals saw a 50% increase in the number of institutions fully implementing these CDC code components.²⁵ This uptick in hospital stewardship is due in part to the availability of defined stewardship goals that inform program evaluation.

Hospital accrediting agencies can require stewardship as part of accreditation requirements. Additionally, the Federal Department of Health and Human Services is in the process of adding a requirement for stewardship to Medicare participation for both hospitals and long term care facilities. Finally, Joint Commission Standards on Antibiotic Stewardship for inpatient facilities went into effect in 2017, and are continuously being improved.

The use of antibiotics in outpatient settings is harder to quantify, control, and develop policy interventions for. Pew, the CDC, and a panel of experts analyzed 2011 data from two national ambulatory surveys to determine that at least 30% of outpatient antibiotic prescriptions were unnecessary. This is benchmark data, and gives us a baseline for how to measure progress moving forward.

As human stewardship research and policy moves forward, the focus is on improved participation in stewardship programs, continuous improvement of stewardship recommendations, improved data reporting, and development of a better understanding of behavioral drivers and incentives for outpatient prescribers.

On the animal side of antimicrobial stewardship, in late 2018 the FDA released a Five Year Plan for supporting antimicrobial stewardship in veterinary settings. The plan will help provide the tools, resources, and information for continuous quality improvement, ensuring all antibiotic use falls under veterinary oversight, providing much needed antibiotic use data, and pushing for antibiotic labels to align with judicious principals. Significant research is needed in veterinary settings to determine how to reduce the need for antibiotics. Research into management practices, alternative products, and other strategies such as the employment of disease resistant breeds all contribute to answering this question.

It has been interesting hearing the challenges we're hearing throughout this conference. The series of interviews done by Pew indicate it's unclear what the expectations are and how we can move forward throughout the food chain with antibiotic stewardship – how its defined, across species, and up and down the food chain.

The Pew Charitable Trust is supporting work toward and understanding of the core components of a stewardship program in animals. There is an example of significant success on the human medical side of the equation, and those experiences highlight the core components as a way to level the playing field and make antibiotic stewardship expectations predictable. Once the process is started, continuous improvement is essential, but defining the core components is a particularly important first step.

Pew Charitable Trust will continue to advocate for increase funding in all sectors in order to support continued enhance stewardship work across agencies and sectors

Pew - Farm Foundation Stewardship Work

Joe Swedberg, Board Chair, *Farm Foundation*

One of the Farm Foundation's major initiatives is engaging the entire supply chain in discussion regarding antibiotic stewardship. The Farm Foundation in partnership with the Pew Charitable Trust has put together a team of internal and external experts to address antibiotic stewardship. This group's priorities and goals include discussing definitions, studying the most recently available research studies and industry information, exploring opportunities with antibiotic use in meat production, and trying to understand the scope of consumer needs.

The Farm Foundation brings food and agriculture together to discuss important issues, such as antibiotic stewardship. The Farm Foundation's antibiotic stewardship efforts began in 2015, the year that the VFD GFI #209 and #213 were initiated. The Farm Foundation hosted 12 listening sessions around the United States, giving producers, feed producers and processors a chance to directly interact with USDA and FDA officials. In 2016 the Farm Foundation initiated a national summit in Washing DC, as a response to survey data compiled from listening session attendees. This summit addressed gaps identified in the survey, especially the lack of access to veterinarians in rural areas and hobby farms in metro areas that tend to be out of the mainstream agricultural market loop. In 2017 the VFD became a reality, and the Farm Foundation brought together producer groups, pharmaceutical industry representatives, processors, and retailers/foodservice, to determine commonalities in face to face conversation. This diverse group has come together to write an overarching sustainability statement, and core components of a program to protect public and livestock health. They will be releasing the program information in December 2018. Finally, the Farm Foundation has recently started a Food and Agriculture Trade Resource Center²⁶ to bring clarity to trade discussions and enable productive debate and dialogue on trade policy issues.

Antimicrobial Use and Resistance: Roadmap for 2018-2019

Michael Costin, DVM, Assistant Director, *Division of Animal & Public Health, AVMA*

Dr. Costin is the staff consultant for the AVMA Committee on Antimicrobials. The AVMA believes antimicrobials are a very important part of the veterinarian's toolkit, and the organization is committed to judicious use and ensuring that antimicrobials remain available.

The AVMA formed Committee on Antimicrobials in 2015, consisting of 9 committee members, with the purpose of providing a primary resource to the AVMA on antimicrobial issues. In this capacity, the Committee promotes AVMA as a leader and trusted source of information; promotes antimicrobial stewardship and provides information and tools for AVMA members for antimicrobial stewardship.

In January 2018, the AVMA House of Delegates unanimously approved a definition of antimicrobial stewardship:

"Antimicrobial stewardship refers to the actions veterinarians take individually and as a profession to preserve the effectiveness and availability of antimicrobial drugs through conscientious oversight and responsible medical decision-making while safeguarding animal, public, and environmental health."²⁷

Additionally, the AVMA House of Delegates agreed upon Core Principals of Antimicrobial Stewardship. The Core Principals in veterinary medicine are modelled after the CDC Core Principals for Outpatient Clinics.²⁸ The AVMA Core Principals are:²⁸

- 1) Commit to stewardship
- 2) Advocate for a system of care to prevent common diseases
- 3) Select and use antimicrobial drugs judiciously
- 4) Evaluate antimicrobial drug use practices
- 5) Educate and build expertise
- 6) Take action

To promote acceptance and incorporation of the Core Principals in veterinary practice, and to assist practicing veterinarians in implementing them, the Committee has developed a Checklist of Core Principals. The AVMA Marketing and Communications Division is in the process of finalizing this checklist, and the AVMA is hoping to release this resource in early 2019.

The Committee on Antimicrobials has also developed a policy for the Definitions of Antimicrobial Use for Treatment, Control and Prevention. The Committee developed this policy through first reviewing many international definitions and then adjusting and refining those definitions in the context of how antimicrobials are used in the United States. The policy was recommended to the AVMA Board of Directors, and in November 2018, the Board of Directors adopted these definitions²⁹ as policy.

Antimicrobial prevention of disease (synonym: prophylaxis):

- 1) Prevention is the administration of an antimicrobial to an individual animal to mitigate the risk for acquiring disease or infection that is anticipated based on history, clinical judgement, or epidemiological knowledge.
- 2) On a population basis, prevention is the administration of an antimicrobial to a group of animals, none of which have evidence of disease or infection, when transmission of existing undiagnosed infections, or the introduction of pathogens, is anticipated based on history, clinical judgement or epidemiological knowledge.

Antimicrobial control of disease (synonym: metaphylaxis):

- 1) Control is the administration of an antimicrobial to an individual animal with a subclinical infection to reduce the risk of the infection becoming clinically apparent, spreading to other tissues or organs, or being transmitted to other individuals.
- 2) On a population basis, control is the use of antimicrobials to reduce the incidence of infectious disease in a group of animals that already has some individuals with evidence of infectious disease or evidence of infection.

Antimicrobial treatment of disease:

- 1) Treatment is the administration of an antimicrobial as a remedy for an individual animal with evidence of infectious disease.
- 2) On a population basis, treatment is the administration of an antimicrobial to those animals within the group with evidence of infectious disease.

In the past year, the Committee has also monitored legislative and regulatory proposals, including both state and federal legislation; been active in outreach and partnership, ranging from a joint statement developed with Canadian and European veterinarians, to providing recommendations to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), to participation in international and global stewardship conferences.

In 2019, the Committee on Antimicrobials plans to finalize the review, revision, and update the AVMA antimicrobial website, to be released early in the year. The Committee is actively planning the development of further antimicrobial stewardship resources, including toolkits, educational presentations, and factsheets. Finally, the Committee is monitoring and responding to federal register notices generated from the FDA's Five Year Plan.

The Committee remains committed and guided by the AVMA’s belief that antimicrobials are essential to the practice of veterinary medicine, and antimicrobial stewardship is the key to the continued availability of this irreplaceable medical resource.

Antibiotic Stewardship in Pork Production,

Liz Wagstrom, DVM, Chief Veterinarian, *National Pork Producers Council*

The pork industry has three national representations: the National Pork Producers Council (NPPC), the National Pork Board, and the National Association of Swine Veterinarians (AASV). The National Pork Producers Council is the advocacy arm of the pork industry, lobbying for reasonable regulation and legislation, and promoting international export marketing opportunities.

The ethical principles of the NPPC are highlighted in the We Care Responsible Pork Initiative, which promotes food safety, animal well-being, employee care, community outreach, and protection of both the environment and public health. (Figure 5).

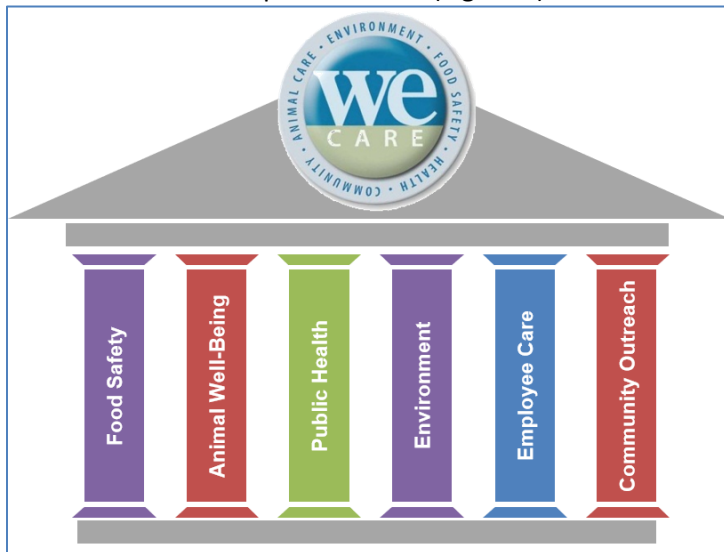


Figure 5. Components of the NPPC/Pork Checkoff ‘We Care’ Responsible Pork Initiative³⁰

Pork Quality Assurance (PQA) started to address residue problems in 1989. This began with ensuring pork producers had protocols in place to properly withdraw antibiotics no a ‘no violative residue’ level. Since then, PQA Plus has evolved to become a flagship education program. In 1999, PQA Plus began to address the appropriate use of antibiotics, making the pork industry and the AASV the first in animal agriculture to develop species-specific judicious use guidelines. In 2002, the National Pork Board issued a position statement declaring that food safety, protection of the environment, and promotion of animal well-being are essential in maintaining the effectiveness and availability of antimicrobials. The ‘Take Care – Use Antibiotics Responsibly’ Program was initiated in 2005, to build producer awareness and provide guidelines for the responsible use of antimicrobials. The Take Care program also marked the first time that the Pork Industry solicited input from the CDC. In 2007, the Take Care program and animal care were incorporated into PQA Plus. This newly expanded program incorporated on-farm assessments as a significant component for the program. PQA Plus is a voluntary certification program, but it is required by the major packers when accepting pigs for sale.

PQA Plus is revised every three years, to address the evolution of the industry and scientific and other advances, but the principles haven't really changed since 2005. The five responsible use principles of PQA Plus are³¹:

- 1) Take appropriate steps to decrease the need for the application of antibiotics
- 2) Assess the advantages and disadvantages of all uses of antibiotics
- 3) Use antibiotics only when they provide measurable benefits
- 4) Fully implement the management practices described for responsible use of animal health products into daily operation
- 5) Have a working veterinarian-client-patient relationship (VCPR) and follow the responsible antibiotic use guidelines.

In addition to the responsible use principles, PQA Plus provides six guidelines for responsible antibiotic use provide specific directives to support the responsible use principles.

In 2014, PQA Plus implemented the Common Swine Industry Audit. This is a standard audit, conducted by 3rd party auditors, and demonstrates compliance primarily by focusing on animal care, but also includes recordkeeping and other items.

Moving forward, the NPPC has agreed to definitions, core components, and guiding principles put forth through the Pew/Farm Foundation partnership. Domestic and International Efforts will address PACCARB, helping to elucidate the differences between veterinary and human medical practices; providing input to OIE, working with Codex to develop a code of practice to minimize antimicrobial resistance, and collaborating with WHPO, FAO, and the UN General Assembly.

The NPPC is committed to driving stewardship to minimize development and spread of antimicrobial resistance, in order to preserve effectiveness for both animal and human health. The NPPC is equally committed to retaining these antimicrobial tools, as an irreplaceable part of the management necessary to ethically grow pigs and produce safe and wholesome pork products.

DISCUSSION

A question followed up Kathy Talkington's discussion of the FDA five year plan, which will ensure antibiotic use falls under veterinary oversight, provide much needed antibiotic use data, and push for antibiotic labels to align with judicious principals. What is an example of a label on the animal side that does not represent judicious use?

Ms. Talkington explained that when the Pew Farm Foundation group looked at existing FDA labels, they discovered many of them didn't have duration limits. Additionally, some labels on antimicrobials for animal use have indications such as maintaining weight during times of stress. The Pew Farm Foundation group raised questions whether an indication such as weight maintenance is a medical indication.

Dr. Michael Costin mentioned bill Illinois S.B. 3429, Administration of antibiotics to food-producing animals. This bill requires veterinary prescription for medically important antibiotics and producer record-keeping and reporting of the use of those antibiotics.³² What group or funding was behind getting all antibiotic use for the last 12 months reported with no FOIA protection?

Dr. Costin clarified that this bill would require Illinois producers to file a report with the state, annually, for every animal they treat with antibiotics. The information would not have been protected from FOIA requests. The AVMA feels that this type of information belongs to the producer and should be protected. No organization was behind this bill – it was simply a proposed piece of legislation. The bill is still being discussed by the legislature, but the current session adjourns in early January 2019.

Definitions of stewardship and responsible use are abstract. When faced with treating an animal, how does a veterinarian choose among available antibiotics?

Dr. Costin noted that stewardship means prevention and the use of management practices that minimize the need for using antibiotics. Judicious use become a consideration when that well-managed animal still gets sick, and relies on correct diagnosis, efficacious drug choice, minimum effective dose, and minimum effective duration of treatment. Dr. Wagstrom indicated that full knowledge of the clinical history and antimicrobial susceptibility testing are paramount to the judicious use of antimicrobials. These are the tenets most veterinary students learn in microbiology class – it's just a question of incorporating them into veterinary practice,

Dr. Wagstrom was asked to describe the Trucker Quality Assurance (TQA) Program.

In 2001, the National Pork Board recognized the importance of bringing an animal to market in a healthy unstressed condition, and in response, developed a program targeting animal handling. The TQA program addresses issues such as the number of animals per group; how to move those animals with a minimum of stress; the use of electronic prods; and the cleanliness of the truck. The TQA program requires that every driver pass a test before that driver may transport animals. As of 2018, virtually every packer requires TQA training of their truckers.

Joe Swedberg commented that the Pew-Farm Foundation Antibiotic Discussion Group is a relatively new coalition, but the drivers behind antimicrobial stewardship efforts – producers, retailers, industry, and food service – have done much of the baseline work over the past two years that have enabled this group to come into being. What is new and exciting about this discussion group is that it is the first time groups of such diverse backgrounds and constituents have come together to develop a comprehensive approach.

Meeting Consumers' Needs and Wants: How Purchasers and Retailers are Responding to Changes in the Marketplace

Ernie Meier, Director of Quality, U.S. Supply Chain Management, *McDonald's Corporation*

McDonald's was started by Ray Crock 60 years ago, and his goal was to be a good citizen and a good servant to the community. Success in McDonald's Corporation has come to be defined as a 'three-legged stool' represented by the franchisees, the suppliers, and the company. Over 90% of McDonald's locations are franchises, which translates into 1800 owner-operators of 14,000 restaurants. These franchisees are key to business success, and the company is committed to the success of their franchises and those of future generations. Annual purchases for McDonald's amount to \$11 billion, including purchases of billions of pounds of beef, chicken, fish, and eggs. The beef supply chain entails 32 distribution centers, supplied by 33 packers and five grinders. All have met food safety and animal welfare standards set by the company. McDonald's serves 69 million meals daily – approximately every 12 days they serve the population of the United States.

Less than 2% of the current population is involved in animal agriculture. Customers want to know about their food. Sixty years ago, when McDonald’s was founded, beef came from local butchers, and buns from local bakers. Customers knew them personally. In our modern society, consumers are removed from those who grow and process their food - they are not connected to where it comes from. Many customers don’t believe McDonald’s burgers are 100% beef!

We have progressed from the age of manufacturing, through the age of distribution and information, to the age of the customer. Since the early 2000s, the empowered customer often knows more about your products than you do. Corporate obsession with supporting these customers is key to a successful business model. Research in 2007 into consumer perceptions and expectations³³ indicated that customers expect safe and reliable food. Having that food be fresh and customizable is a trend that is continuing to grow. Emerging trends and an expanding consumer palate demand global flavors, and finally, consumers are beginning to demand natural, minimally processed foods. Customers believe that what is fed to the animal is what they themselves are consuming – thus chemicals and processing are considered bad. (Figure 6).

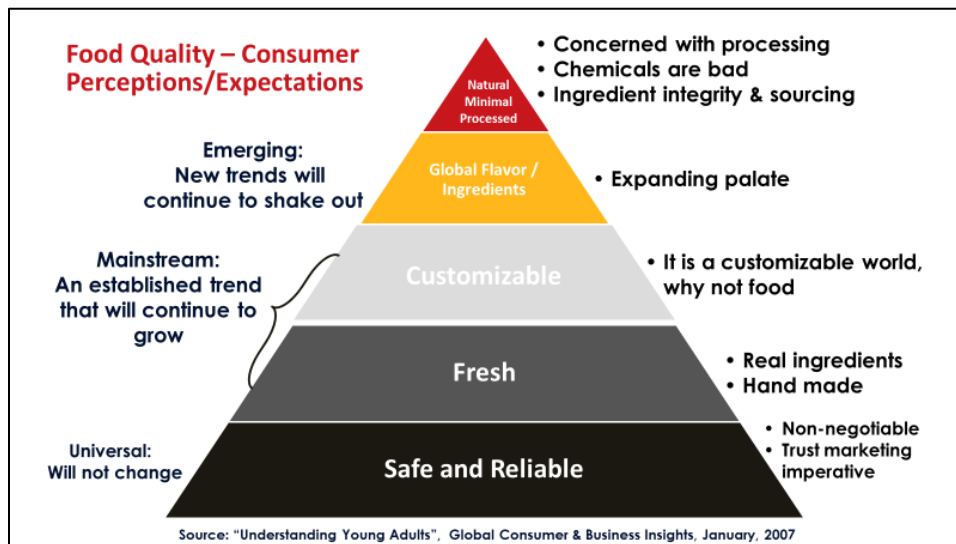


Figure 6: Consumer Perceptions and Expectations from “Understanding Young Adults”, Global Consumer & Business Insights, 2007.

McDonalds believe in the threes, such as economic, ethical, and environmental. The problem is, like many national and global companies, consumers don’t trust them. McDonald’s acknowledges there is much work to do to build back that trust with customers. Providing educational pathways for employees, continued support of Ronald McDonald educational charities, and other commitment help work to build this trust, but another huge component is the promotion of responsible use of antibiotics among their animal protein suppliers. In 2017, McDonald’s began to really promote the responsible use of antibiotics in all supply chains, basing that responsible use on the three R’s: refine, replace, reduce. Recently, ‘no antibiotics important to human medicine’ has been added to the consideration. They are working on a beef policy to be released within the next 12 months.

The new global food vision is that of food sourced responsibly. As one of the world’s largest food companies, McDonald’s can use their scale to drive continuous improvement and innovation in

responsible sourcing, to help realize a food supply where people, animals and the planet thrive. Key focus points are the ethical, promoting human rights and the health and welfare of animal; the economic, promoting economically viable farming; and the environmental, addressing climate change, preserving forests, protecting water resources, and reducing waste.

Today, what goes into food and how the animals that provide out protein are raised are what is important to customers. McDonald's is committed to providing this information to consumers, but for this information to be heard, consumers must trust in the restaurant, the retailer, and the producer to do what's right.

DISCUSSION

Mr. Meier has spent a good deal of time talking about consumer trust. Why doesn't the customer trust a company like McDonald's? Why doesn't the consumer trust animal agriculture?

Part of it is simply the size and scale of the company – customers have an inherent mistrust of large corporations. He thinks customers do trust the producer, but they don't necessarily trust those in the supply chain that are converting the producer's animals into meat protein. Dr. Lucas Pantaleon inquired if the use of Blockchain could increase the trust and transparency? Mr. Meier stated that the corporation is definitely looking into that. He thinks it would be great if McDonalds could trace their proteins using Blockchain.

What are McDonald's import practices and standard regarding imported beef?

McDonald's only imports frozen beef from Australia and New Zealand, and those producers and packers are required to adhere to the same practices as their counterparts in the United States. All fresh beef is sourced from the United States and Canada. Dr. Nevil Speer followed up by asking about McDonald's decision to source fresh, not frozen, beef at their United States restaurants. Mr. Meier admitted that he was initially against this change, but in the end the reason was to improve the quality of the burger. Fresh beef in the system allows restaurants to cook beef more consistently and thus better. It's the same formulation, but because the beef starts out fresh, restaurants are able to cook to order. This change did completely upend the supply chain, and required many modifications and equipment changes, as well as an increase in refrigeration (and reduction in freezer) space in restaurants. However, everyone got on board and they were able to make the switch to fresh beef in the United States earlier this year.

What percentage of McDonald's customers would be interested in knowing specific location in the ocean of fish filets?

The fish in the Filet of Fish sandwich is marine stewardship certified, which means they have to know where every fish comes from. He thinks customers are interested in knowing that the place where they buy their food is doing the right thing, but most won't want to go deeper into the details than that. They simply want to eat somewhere that makes them feel good.

How much noise and influence does McDonald's get from PETA and HSUS?

Mr. Meier commented that this sort of traffic is significant – organizations such as the visit the main offices once or twice a month. There was an active campaign against McDonalds from the Coalition (include

PETA and Mercy for Animals) recently. Partly in response to activist inquiries and demands, last year McDonald's started campaign for animals. They formed a council for animal welfare for poultry, and are building a key welfare indicator database. Suppliers will upload key welfare indicator metrics, and the council will be able to use this data to set benchmarks and target goals. McDonald's is also committed to conducting research into a slower growing breed of chicken and decreased stocking density, and will let the data drive their decisions. However, they have not yet committed to this chicken breed, and this was the part of the reason for the campaign by the Coalition. McDonald's is going to do the right thing – but they want to make sure they know what it is before they do it.

What's the process to involve producers in the decision-making process?

They are vertically integrated with suppliers with whom they have worked with for decades. They have seen a reduction in the overall antibiotic use in their supply chain since the introduction of the new 'no human medical antibiotics' policy. The Highly Pathogenic Avian Influenza (HPAI) outbreak helped strengthen biosecurity throughout the poultry supply chain, and that increase in biosecurity has improved management thus potentially allowed decreased use of antibiotics, supporting antibiotic stewardship.

How do you to communicate nuanced topics to customers?

When customers are buying food, they don't want to think about the animal it came from. Communication and marketing did extensive research to determine how to communicate to customers regarding what they're eating. They found that people do want to do research to find out about what they're eating, but not while they're eating it. Social media and websites can help get the message out.

McDonald's doesn't use antibiotics for growth promotion, but you don't really market it. Why? Other restaurant chains like Panera use this as a marketing tool.

Part of the reason for the lack of marketing is customer confusion. The poultry industry hasn't allowed antimicrobials for growth promotion for many years. 'No antibiotics important to human medicine' is also a difficult issue with markets, because it's not an easy message. The marketing department preferred the simple message of No Antibiotics Ever – but the bottom line is that the best thing for the animals it to allow the use of ionophores as a coccidiostat. Current policies have led to an overall reduction in the use of antibiotics, and McDonald's is not looking for never, ever in any programs. Their goal with antibiotics remains refine, reduce, and replace.

Panel Discussion – In the Beginning: How Producers and Retailers are Responding to the Changes in the Marketplace and Continuing to Provide a Safe and Abundant Food Supply

Eric Moore, DVM, moderator

Panelists:

Joan Ruskamp, *J & S Feedlot*, Dodge, NE

Karen Richter, *D K R Swine Farms*, Montgomery, MN

Brett Morris, *Partnership of Morrisland*, Ninnekah, OK

Hector Cervantes, DVM, MS, DACPV, Hon. MAM, Senior Manager, Poultry Technical Services, North American Region, *Phibro Animal Health*

Beef Industry Perspective

Joan Ruskamp, *J & S Feedlot*, Dodge, NE

Ms. Ruskamp and her husband have owned a Century Farm finishing operation. The operation has been transferred from her husband's great grandfather down to him. The layout of animal space on their operation is paramount to management and animal comfort. (Figure 7).



Figure 7. Aerial photo of J&S Feedlot, Dodge, NE.

Pens are spread out. A holding pond keeps nutrients on the farm, and a freshwater pond keeps water from running into the feedlot and provides a fishing venue. Approximately 100 acres of corn are grown on the farm utilizing the nutrients and water from the holding pond. Additionally, the corn crop on their farm utilizes smart seeds, which allows them to grow corn-on-corn each year with the ability to control pests with less pesticide.

Their operation has worked with Temple Grandin designs to institute low stress cattle handling. When cattle arrive the environment is quiet, and facilities have been upgraded to enhance calm movement. Animals move around a curve to find fresh hay, fresh water, and a place to lie down and socialize. They are continuously improving how they work with the animals so that they stay calmer and quieter.

J&S Feedlot is fortunate to work with a well-staffed veterinary clinic, as it means someone is always available to answer questions. The veterinary clinic has long provided protocols for antibiotic use, taking into account the correct fit for each situation. Ms. Ruskamp walks the pens every morning to observe the cattle and identify any that are not thriving. Identified cattle are brought up to a squeeze chute and 'examined', enabling identification of problem situations as early as possible. At the squeeze chute examination, management decides on the best course of action needed for that steer to return to full health as soon as possible and get back out to their pen-mates.

Computerized records with manually keyed in feed records have recently been updated. Feed records are now recorded as the feed is loaded and fed through the use of iPads which helps immensely with accuracy. They've always been meticulous, but they want to make sure the employees are doing the right

thing. Management use iPad out on farm, and this computerized system is able to ensure that the cattle are all getting exactly what they're supposed to be getting. The working environment on the farm is built on doing to right thing. Mistakes don't lead to reprimands, but rather to corrections.

Animals are fed a six step ration, with the initial ration using a higher roughage amount then a gradual move to higher energy amount from grain as the calf grows and adds muscle. Distillers grains match well with the rumen of their cattle, providing great protein, digestible fiber, and other good nutrition. These are used in the ration, as they support the rumen, and a happy rumen fights disease (and thus leads to decreased antibiotic and other medication use).

These animals do live outside, and the Nebraska environment hot and humid in the summer and snowy in the winter. Shade 'trees' and mist sprinklers provide relief from the elements in the summer, and prompt snow removal and metal windbreaks protect the animals in the winter.

At the end of the day everything they do is really about food. For generations her family has believed in the value of beef in the diet, and they are committed to providing the best, most nutritious beef possible.

Swine Industry Perspective

Karen Richter, *D K R Swine Farms*, Montgomery, MN

Ms. Richter and her family are third generation swine producers. She grew up on a farm that also produced dairy, and has been involved with agriculture her whole life. From that dairy background, she remembers daily milk samples being taken by the milk truck driver – responsible antibiotic use has been part of her whole life, too.

Her in-laws live on a 5th generation farm. Sustainability is ingrained in the day-to-day management. They are committed to keeping the farm in the family, and always looking at sustainability as a way to support and maintain the farm for future generations. For example, manure from hogs is a natural fertilizer, saving cost and supporting a sustainable environment. The manure is used to nourish the crops they raise for animal feed and biofuels.

Ms. Richter's farm has gone through many certification programs through the years -- national pork programs, requirements of packers, and voluntary programs for specific production practices. Many of these programs reinforce responsible antibiotic use, and that makes sense not only from an animal health standpoint, but also from an economic standpoint. Antibiotics cost money. They are used as directed by their herd veterinarian and only when necessary.

When she started in swine production, her sows were housed outside. They are now housed indoors, to better control their environment, protect from the elements, and protect from disease. Anyone working with the pigs wears barn-specific clothes, and showers in and out of all pig housing. Anyone traveling out of the country must wait several days before visiting the pigs. Visitors are recorded in visitor logs. All of these steps are taken to protect the health of the animals so that they don't have to use antibiotics or other medication. Also included in pig management are health protocols with robust vaccination programs. Herd health and biosecurity measures are implemented to protect the pigs from day one.

People that are two generations removed from the farm don't understand why we can't do it like we did in the 1950s, because they haven't experienced the day to day operation of the farm. Many consumers would like to see hogs outside in the fields, because it seems more 'natural'. But moving hog indoors protect the animal, and ultimately, provides a better environment and better health for the animal.

Everything they do, and all of the changes the Richters have implemented over the years, focus on the care, comfort and health of the animals.

The things that frustrate her – the challenges and fears that everyone in agriculture faces – are consumer misperceptions and myths. The myths have multiplied over the years because 98% of people are 2 or more generations removed from the farm. All of this has led to consumer lack of confidence in science and technology. It is very frustrating to her how science has become a four letter word. These myths and misperceptions lead consumers to a list of demands for which they simply cannot understand the ramifications. Those consumer demands, combined with the threat of foreign animal diseases, a shortage of large animal veterinarians, lack of funding for research, etc. etc. are things that frustrate and worry farmers.

Her farm exists for one reason: producing food. She serves the food they produce on her farm to her family, and she's proud and confident in the product she raises. And the product continues to improve, because of the evolving processes their farm has incorporated over the years, and continue to incorporate.

Dairy Industry Perspective

Brett Morris, *Partnership of Morrisland*, Ninnekah, OK

Mr. Morris retired from dairy in 2016, at which point he owned 65 head registered Holsteins. Dairy Farmers of America recommended him as the president of the National Cattleman's Beef Board – a position he proudly served and now he is the immediate past president.

While he no longer runs a dairy, Mr. Morris continues to run a beef and crop operation in partnership with his father - the Partnership of Morrisland. Their operation has 125 head of cow-calf angus pairs and includes a fertilizer company that strictly handles anhydrous ammonia. He also continues to own six dairy show cows, housed at Oklahoma State University.

Dairymen are overachievers. In the in 1940s, dairymen maintained four times as many cows as they do in 2018. However, the dairy industry produces much more milk now.

When he was in dairy, he always knew what they needed to do in the parlor. Antibiotics cost money, and he had to discard milk on treated cow. Those economic realities meant that his farm would do everything they could to prevent having to use antibiotics. This started with the calf, providing high quality colostrum, vaccinating calves at birth, and treating the navel with iodine to prevent infection. In the parlor, the biggest issue was mastitis control. Many preventative measures are currently in use, most commonly a pre and post teat dip with an antiseptic solution that kills bacteria. Additionally, lame cows eat less because coming up to the bunk to eat is painful, and this reduced feed intake translates to decreased milk production. He had the hoof trimmer come every 60 to 90 days, and could see an increase in milk percentages over the time in which hoof trimming was not a regular practice. Foot health was also supported by installing a foot bath coming out of the milking parlor, which helped fight the hairy foot warts that cause digital dermatitis. In short, his operation strived to do everything they could to prevent illness and injury.

For DHIA record-keeping, cows are tested every 30 to 45 days for milkfat and protein content, with an option to test SCC content, which can identify subclinical mastitis on the farm. When antibiotics must be used, withdrawal times are strictly observed, and lack of residues is confirmed by an on-farm antibiotic

test. Finally, the milk truck pulls samples before the milk is added to the load, to ensure a final time that there are no antibiotic residues in the milk.

Dairymen are stewards of the land. They strive to keep cows clean and cool, and continuously supplied with fresh water. They work with a nutritionist to ensure cattle are best supported in both production and health. Every preventative measure is incorporated to minimize the need for antibiotics. These cows are family. When all preventative measures are in place and an animal still gets sick or becomes lame, that animal will be treated to alleviate pain and suffering.

Poultry Industry Perspective

Hector Cervantes, DVM, MS, DACPV, Hon. MAM, Senior Manager, Poultry Technical Services, North American Region, *Phibro Animal Health*

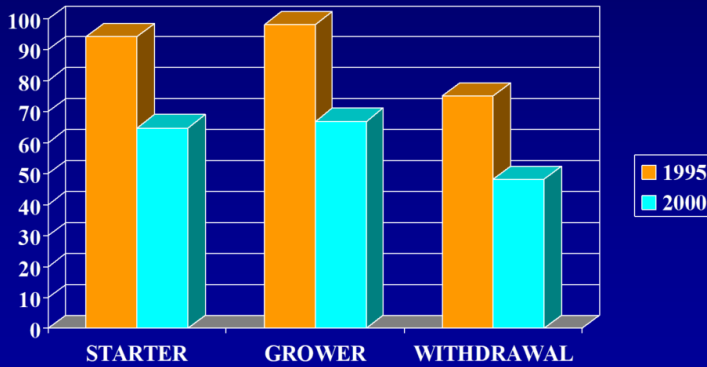
Dr. Cervantes is a poultry veterinarian, not a producer, but he has worked with a lot of producers. The poultry industry takes biosecurity very seriously, especially in the wake of the 2015 Highly Pathogenic Avian Influenza (HPAI) outbreak. Houses are automated and controlled by computer, but producers are still dedicated to checking on the chickens - usually three times per day.

Antimicrobials are used in poultry for therapeutic uses only: disease treatment, prevention and control. Growth prevention uses ceased in 2017 with the Veterinary Feed Directive. The poultry industry is extremely vertically integrated. Companies supply baby poultry to contract producers, and also supply feed, technical and veterinary support and at the end buy the poultry flocks. Contract producers are not allowed to give ANYTHING to their flock without approval from the poultry company. Poultry companies have nutritionists and veterinarians on staff. There is a strong veterinary-client-patient relationship (VCPR) and the veterinarians design vaccination and treatment protocols and visit farms regularly.

The majority of FDA approved drugs used in poultry production are antimicrobials. Antimicrobials are administered almost exclusively through the oral route, in water and feed. Commercial operations are overseen by licensed veterinarians, who develop health and disease prevention plans and oversee drug and antimicrobial use. Since 2014, the poultry industry has embarked on a collaborative program with USDA-NARMS to assess antimicrobial use and antimicrobial resistance at the farm level over time. Like all drugs used in commercial poultry operations, all medically important antimicrobials (MIAs) are used under strict veterinary oversight.

*The Judicious Use of Antimicrobials for Poultry Veterinarians*³⁴ was recently reviewed and posted on the American Association of Avian Pathologists (AAAP) and American Veterinary Medical Association (AVMA) websites. Different classes of antimicrobials have different relative importance to human medicine - and this is taken into account when prescribing. In 2002, the poultry industry had already achieved a significant decline in usage of in-feed antimicrobials (Figure 8). Current trends also demonstrate significant growth in chickens grown with No Antibiotics Ever (Figure 9).

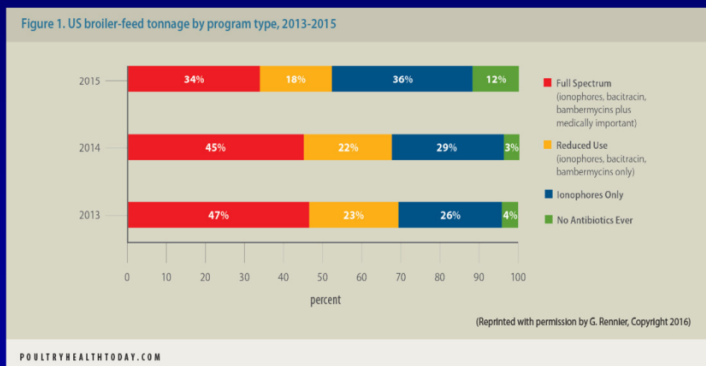
DOCUMENTED DECLINES ON USAGE OF IN-FEED ANTIMICROBIALS



Source: Chapman and Johnson, 2002, Poultry Sci. 81:356-364

Figure 8. Decline in use of in-feed antimicrobials in poultry, 1995 to 2000.

Programs that Restrict AMU in Broiler Production



Trends: 2013 – 2015, G. Rennie, 2016.

Figure 9. Poultry Industry trends from 2013 to 2015, including an increase in NAE (green bar).

Now nearly half of chickens are currently produced without antibiotics. However, as mentioned yesterday by Kendra Waldbusser, only about 8% are sold that way.¹⁴

Poultry producers have instituted a number of changes to reduce antibiotic usage. Sanitation and biosecurity have significantly improved. Best management practices have been instituted at breeder and broiler farms. Breeders are also vaccinated, with the goal of transferring protective passive immunity to progeny. At the hatchery many companies have ceased the practice of using massive antimicrobial treatment on day one, which means improved sanitation is extremely important. Chicken and turkey farms have also significantly improved sanitation and biosecurity, instituted best management practices,

and implemented vaccination programs to prevent immunosuppressive and respiratory diseases. Basically, the poultry industry is doing as much as possible to optimize the environment and boost immune status, so they don't need to use antimicrobials.

When best management practices are in place and protocols observed, but animals still get sick, antimicrobials are used judiciously. The AVMA definition and core principles for antibiotic stewardship are observed, and strive to follow the all-important triad of correct diagnosis, correct drug, and correct dosage.

DISCUSSION

What do we need to do when producers don't do the right thing? How do we handle that? How do we communicate that to the public?

Joan Ruskamp answered that the beef industry isn't vertically integrated, so producers are answering directly to the buyer. For cattle producers, only a few buyers exist. If those producers don't do the right thing, or project untrustworthy character, they cease to be trusted by the buyer. Additionally, the producer must demonstrate their commitment to 'doing the right thing' to their employees, if they want that ethic to spread throughout their ranch.

Karen Richter pointed to the processes in place – on-farm assessments, certification programs, and similar – that encourage producers to do the right thing. And if producers diverge toward unethical or unjust behavior, there are review panels in place to provide expert examination and recommendation to return to the right path. As with the beef industry, there are a limited number of customers to which producers can sell, so it is in their best interest to strive toward trustworthiness. Finally, if the assessments, review panels, and lack of buyers fails to persuade a 'bad actor' to change their ways, there are processes in place to address that behavior.

Brett Morris notes that Dairy Farmers of America (DFA) has a 'three strikes and you're out' policy. At the first 'strike', the error is pointer out to the producer. At the second 'strike', the producer is responsible for paying for half the load of milk. At the third 'strike', the producer is required to go before a panel and explain their behavior.

What is something you're proud of or some form of communication you've been doing to get your story out?

Joan Ruskamp uses farm tours – as many as they can – to get lay people out on the farm and educate them about how the beef industry works. Her most important comment about this process is that the producer must not only have nothing to hide, but also act like they have nothing to hide!

Karen Richter uses the many programs set into everyday production practices. Even though she's a small producer that relies on the same programs and science as the big producers. She also shares what she does – in the past this has been through tours – as much as biosecurity allows. Finally, she has been involved on many committees to address promotion, research, and producer education. The proactive approach of industry and organizations has helped to convey the positive aspects of the pork industry to consumers. There are opportunities out there. We must continue to strive to share what we do every day.

Brett Morris has also hosted tours. A couple of years ago hosted a dairy farm tour for children of a family physicians convention. They brought the kids on the farm to show what they do and how they take care of cows. One of the most-received comments from the kids after the even was that they really enjoyed learning about something for which they had no idea previously – it was much more fun than a science museum or aquarium.

Hector Cervantes is proud of the AAAP work with the AVMA to move the industry forward and the stewardship efforts which are reflected in the lack of any violative residues in any poultry product in the last 10 years. Additionally, adoption of new technologies like nipple drinkers, along with improvements in nutrition, ventilation, housing, management, and others, are changes of which the poultry industry can and should be proud.

FDA's New Efforts to Advance Antimicrobial Stewardship in Veterinary Settings

William T. Flynn, DVM, Deputy Director, Science Policy, *FDA Center for Veterinary Medicine*

There have been many changes, and much planning, addressing antimicrobial resistance (AMR) in the past few years, and FDA has been a central driver of that change. These changes began with Guidance for Industry (GFI) #209 and #213, progressed through the Veterinary Feed Directive (VFD) final rule, and have ultimately led to the September 2018 publication of the Five Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings³⁵. Today, Dr. Flynn will provide an overview of that Five Year Plan, but first, a few more details regarding the progress that has already been made.

Antimicrobial resistance is a complex issue. All uses, regardless of need, intent, or species are drivers of resistance. The approach to curbing this resistance must come from a One Health perspective if any lasting change is to be made. From the beginning, FDA's goal has been to implement measures that address public health concerns, while ensuring that animal health needs continue to be met.

GFI #209³⁶ laid out two key principles, designed to address the goal of slowing development of antimicrobial resistance: 1) Limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring animal health; and 2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. The strategy for implementing these two key principles is laid out in GFI #213³⁶. This strategy comprises seeking the voluntary withdrawal of production uses for medically important antimicrobials used in or on feed or water for food-producing animals, and changing the marketing status of antimicrobials to VFD or prescription only. The target date for implementation of GFI #213 was January 2017. GFI #213 formalizes the role of the veterinarian, ensuring that the veterinarian is included in the decision-making process.

The VFD is a framework for veterinary oversight of feed use drugs, established in 1996 with the Animal Drug Availability Act (ADAA)³⁷. In simple terms, VFD drugs are those intended for use in animal feed which require oversight by a veterinarian. The VFD designation is not limited to antimicrobials, although currently, all approved VFD drugs are antimicrobials. In 2000, the FDA finalized regulations for the authorization, distribution, and use of these VFD drugs.

The VFD Final Rule was updated in 2015, with changes designed to increase the efficiency of the process while continuing to ensure public health protection. With the full implementation of GFI #209 and #213 in January 2017, all medically important antimicrobials for use in feed require a VFD and those for use in drinking water require a prescription. Additionally, it is no longer legal to use these drugs for production (e.g. growth promotion) purposes.

As a result of GFI #209 and #213, 84 of 292 affected new animal drug applications were withdrawn. Of the remaining 208 applications, 93 applications for products intended for use in water were converted from over-the-counter (OTC) to prescription status, and 115 applications for products intended for use in feed were converted from OTC to VFD status. Production (e.g. growth promotion) indications were withdrawn from all 31 applications that included such indications for use.

All of this leads to the September 2018 Five Year Plan. This plan is meant to be a roadmap, outlining goals and objectives until 2023. The approach is divided into two phases, the first from 2019-2021, and the second from 2022-2023. These phases are a target for when work needs to be initiated, not completed. Additionally, the document is a living document, to be revised as necessary.

The FDA Five Year Plan has 3 main goals:

1. Align antimicrobial drug product use with the principles of antimicrobial stewardship
2. Foster stewardship of antimicrobials in veterinary settings
3. Enhance monitoring of AMR and antimicrobial drug use in animals

The first goal is product-oriented, with objectives of revising use in food-producing animals, developing a strategy for companion animals, and supporting new product development. There are three highlighted actions of this first goal. The first is to update appendix A of GFI #152³⁸, to support a risk assessment process for evaluating impact of antimicrobial drug use on AMR and define which drugs would be considered 'medically important'. The second is to bring non-feed and non-water uses of antimicrobials under the oversight of a veterinarian. The process for bringing this about includes a robust dialogue with stakeholders to develop an implementation strategy, and the target for developing a draft of the strategy is September 2019. The final highlighted action is to define appropriate durations of use of medically important antimicrobials used in feed or water for animals. This may be the most challenging of the three actions. It is important to note that an important step has been accomplished in that all products affected by this third action have already been brought under veterinary oversight. As with the second action, the process will involve extensive stakeholder input. The target for developing a draft implementation strategy for this initiative is September 2020.

The second goal, fostering veterinary stewardship, entails support of outreach and education, strengthening of compliance programs, and support for international outreach. Actions to support this goal include collaboration with federal, veterinary, producer and state organizations to disseminate information; and strengthening FDA-CVM compliance programs to support antimicrobial stewardship, by, among other things, incorporating a VFD inspection component into FDA's compliance programs.

The final goal is designed to enhance data collection. Objectives are to collect better data on actual drug use, enhance collection and analysis of AMR data, and increase data sharing and reporting across a range of partners. There are a number of actions intended to support these objectives. The first is collecting drug use data, which is a challenging issue given the limited infrastructure that currently exists in the veterinary sector. Currently funded cooperative agreements include two pilot studies that are generating data – the first in feedlot and dairy, and the second in poultry and swine. A second action area is enhancing

the NARMS program, expanding testing and improving the representativeness of the data captured by NARMS. A third action item is the publication of a comprehensive assessment report, integrating and analyzing all available information to assess stewardship in veterinary settings. The point of this action is to communicate to all stakeholders and to the public the progress that has come from veterinary antimicrobial stewardship efforts. Currently, much of the emphasis is on the quantity of antimicrobials sold or distributed for use in animals, but that number alone can be misleading, and isn't sufficient to fully describe the situation. We need a more comprehensive approach. This report is envisioned to encompass all available relevant data including data from cooperative agreement pilot studies, USDA survey data, NARMS resistance data, sales and distribution data, animal demographics including total biomass, and animal health data.

Significant progress has been made to advance antimicrobial stewardship. FDA is encouraged by this process and is committed to pursuing a collaborative approach moving forward. Antimicrobial stewardship requires the combined effort of many stakeholders, and more work is needed. The FDA is committed to working with all stakeholders and building on the progress that has already been made.

DISCUSSION

What are the challenges of communicating in a veterinary setting?

From the veterinary perspective, veterinarians are actively involved in being the gatekeeper, and in many cases also take on additional roles. The tools they need to fulfill these varied roles may not be well defined. From the producer perspective, some parts of the country have limited access to large animal veterinarians – but producers in these areas are still required to work with veterinarians in order to be able to use the drugs their animals need. How do they care for their animals and still fulfill VFD and stewardship requirements?

Panel Discussion – More Than Numbers Part One: How the Animal Agriculture Food Supply is Using Data to Meet Consumers' Needs, Maintain the Health of the Industry and Address Public Health Concerns

Eric Moore, DVM, moderator

Panelists:

Mary Battrell, DVM, Staff Veterinarian, *Smithfield Hog Production*

Katie Hope, DVM, Graduate Research Assistant, *Kansas State University College of Veterinary Medicine*

Joel Nerem, DVM, Veterinarian, *Pipestone Veterinary Services*

Building Consumer Confidence through Judicious Use of Antimicrobials

Mary Battrell, DVM, Staff Veterinarian, *Smithfield Hog Production*

As a staff veterinarian for Smithfield, Dr. Battrell's primary responsibilities are to care for the health and well-being of the animals, and to provide a safe and wholesome product to their consumers. These two

responsibilities are not in conflict, but if consumer confidence is to be maintained while retaining antibiotic availability, any antibiotics used must be employed judiciously and responsibly.

Starting in 2002, any product that goes on or near a Smithfield hog must first be approved by a veterinarian. This directive includes the 80% of hogs raised by contract growers and ranges widely enough to encompass products like marking paint, which must be edible. In addition to these protections, all Smithfield hogs and products consumed by these hogs have full traceability. Since 1996, a prescription is required to move any product from their buying co-op to their warehouse. This process has evolved to a computerized system, with lot numbers for each product item, making all products traceable to the specific farm, and to the barn within that farm.

Medication treatment charts are generated by Smithfield veterinarians, and reviewed at least quarterly. These treatment charts include everything that can go in or on a hog, and include name, dosage, mixing information, indications, and withdrawal. All medications are used strictly according to veterinarian instructions. Only products with animal labels are used. Withdrawal periods may be extended to satisfy international requirements. It could be argued that Smithfield is putting the company at a competitive disadvantage by implementing these requirements, but Smithfield is a large company and their reputation is extremely important, so they view these strict antimicrobial use policies as insurance against risk.

Documentation of all antimicrobial use is required of hog caregivers, and records are retained for three years. Verification of appropriate use is maintained on several levels from company to contract grower, internally through programs like Smithfield process verification, and externally through entities such as PQA Plus and 3rd party auditors.

The VFD has been incorporated into a system that has been in place at Smithfield for the past 20 years. Staff veterinarians have always worked with nutritionists to determine feed grade antibiotic usage, and records for this use are reviewed quarterly. More recently, the computer system is designed to prohibit feeds with certain medications to be issued to a farm without an active VFD.

A tremendous amount of time is spent at Smithfield teaching and training. Sick pig identification training is provided for caregivers on farms. Disease identification and sample collection training is undertaken by production staff, who collect and send out numerous diagnostic samples. The identifications from these diagnostic lab results lead veterinarians to better informed decisions on antimicrobial use, thus promoting antimicrobial stewardship. Finally, PQA Plus training and employee certification programs round out the training picture, providing a comprehensive educational regiment.

Smithfield does maintain a small number of antibiotic-free pigs. These pigs are on farms identified as high health, in low density areas with above average management. Pigs on these farms are managed to avoid the need for antibiotics, but they are treated if they become ill. Treated pigs are tagged in each ear and segregated at marketing. If a significant number of pigs on a farm require treatment, the farm is removed from antibiotic-free status and returned to conventional channels

“Good Food Responsibly” is not just a slogan. It defines the Smithfield approach comprehensively throughout the organization s and throughout all stages of production.

What Do We Do with The Numbers?

Katie Hope, DVM, Graduate Research Assistant, *Kansas State University College of Veterinary Medicine*

FDA Cooperative Agreements regarding antimicrobial use are currently in place for dairy, beef, pork, and chicken. Kansas State is working with the dairy and beef cooperative agreements. The beef-specific project is investigating feedyards. The feedyard project places no specific requirements on size or record system type. Types of record systems used by project producers include sales data, on-farm management software, and data from an intermediary management group.

In capturing use data, the feedyard project goals are to capture accurate, current, granular data coupled to cause. Ideally this data is easy to collect, as opposed to resource intensive. In the end, data should enable producers to benchmark. The specifics captured by this data include amount of drug used, duration of drug used, and number of animals exposed, and what you want to know dictates how you might optimize the specific data.

The best way to optimize disease treatment is by not using an antimicrobial in the first place. Approaching this optimization starts with a solid case definition, to allow for accurate disease diagnosis. This step is particularly important for producers who may be treating their own animals. Once disease is diagnosed, the next step is to look for efficacious, affordable non-antimicrobial alternatives. If these are available, use of an antimicrobial can be avoided altogether. If antimicrobials are necessary, then it is imperative that the veterinarian choose a drug appropriate for the disease. Duration of use of the drug should be continually re-evaluated, so that treatment is stopped as soon as the disease is under control.

At the same time as the animal is being treated for disease, it's important to look at why the disease occurred in the first place – investigating factors such as source of animals, weather, nutrition, genetics, and other management factors that may enable prevention of disease in the future.

Abbreviations for drug use data mentioned in papers are many, but all require some sort of estimate or assumption. Typically these estimates are based on use, dose, or weight. To describe a drug treatment regimen, five things are needed: product, amount, administration, interval, and route. If we strictly talk about total mg of use, we miss the other four aspects of the treatment regimen. Selection pressure is applied by total drug dose, but equally importantly by class of drug, type of dosing (one high dose versus multiple low doses), interval and route.

The main question when looking at antimicrobial use data remains, what do you want to know? However, to fully address animal health, one must look at the context of antimicrobial drug use. Investigating mechanisms of resistance development in both animals and humans, as well as determining how improved management, nutrition, genetics, education, and other intangibles can decrease the need to use antimicrobials in the first place, are crucial to a broad scope understanding of antimicrobial use and resistance development. If we are truly concerned about animal health, narrowly monitoring antimicrobial use without considering animal health is nonsensical.

Pipestone Veterinary Group and Pipestone PART (Pipestone Antibiotic Resistance Tracker)

Joel Nerem, DVM, Veterinarian, *Pipestone Veterinary Services*

Pipestone Veterinary Group is a private veterinary practice based in Pipestone, Minnesota, employing 40 veterinarians in 6 locations, with services provided in the United States, Asia, and Latin America. The majority of their clients are independent producers. Pipestone is a general veterinary practice servicing all types of animals, but a large portion of their business, and approximately 90% of their time, is pig farms. One of the services they provide is farm management service for sow production, and they have 75 sow farms, with 250,000 sows, currently under management.

The Pipestone Antibiotic Resistance Tracker (PART) was established in early 2017. PART's launch was timed to coincide with the Veterinary Feed Directive (VFD). As the VFD came on-line, Pipestone felt it was important to show leadership in the area of antibiotic stewardship. PART has two focuses: tracking antibiotic resistance; and demonstrating responsible antibiotic use. The PART program is a voluntary, subscription fee-based, producer program, entailing annual veterinary visits and quarterly reviews. 154 producers at 800 sites participate in PART annually, monitoring five million weaned pigs and three million market pigs. PART is solely funded by Pipestone and the subscription fees paid by producers. Pipestone also generates research and promulgates outreach related to PART and the data PART collects.

The first focus of PART is antibiotic resistance tracking. In the national discussion, the focus is on human health and food safety, and PART addresses those, but addresses livestock farms and animal health as well. Pipestone's approach to tracking antimicrobial resistance at the farm is both veterinary based and food safety based. The veterinary approach is traditional, with submission of collected samples from ill animals for diagnostic testing, and culture and sensitivity results guiding antibiotic selection. Collection and compilation of this data from hundreds of sites allows for identification of trends in resistance. Pipestone has defined a resistance diagram for five significant pathogens, and developed a relative resistance index based on those tests. According to this relative resistance index measurement, there has been no change in antibiotic resistance in hogs under Pipestone care in the past 18 years (Figure 10.) Independent results from hog diagnostic samples tested at Iowa State University demonstrate a similar lack of change in antibiotic resistance since 2003 (Figure 11).

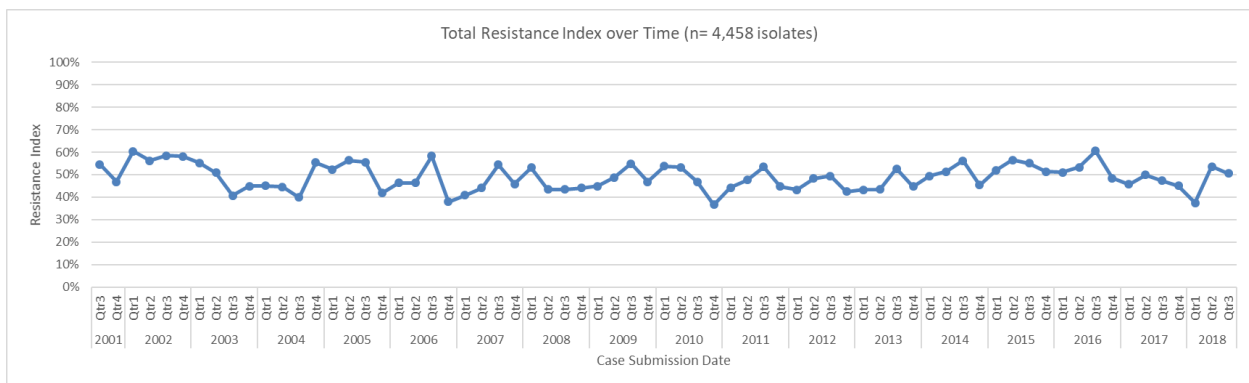


Figure 10. Resistance index in hogs under Pipestone care from 2001 to 2018.³⁹

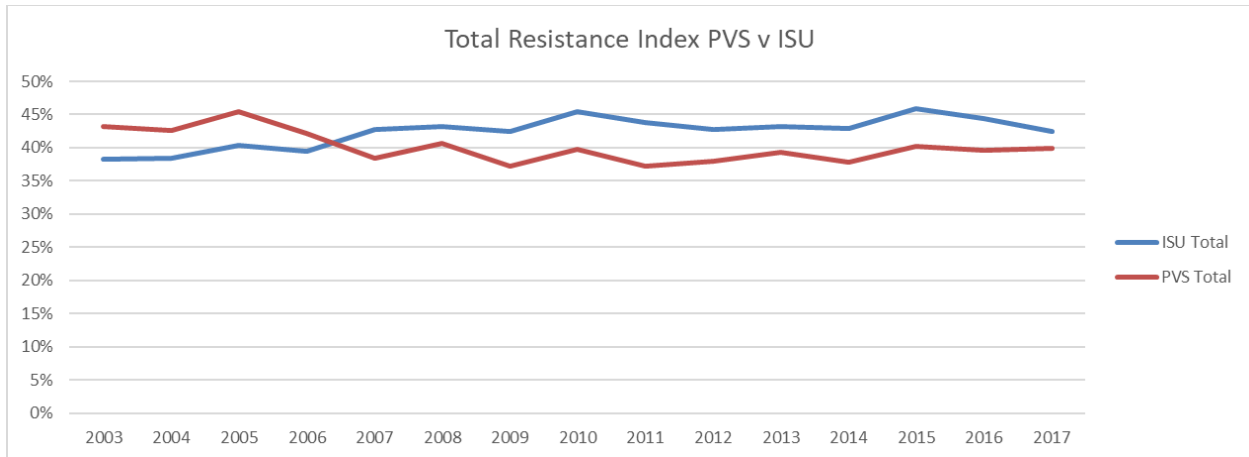


Figure 11. Resistance index in hogs under Pipestone care compared to hog diagnostic samples from Iowa State University, 2003-2017.⁴⁰

Pipestone’s current project is examination of antimicrobial resistance in sites other than on the farm. They have looked for bacteria in companion animal exam rooms, dirt from the playground in town, and the local wastewater treatment facility. Results of these investigations, comparing the swine farm to the wastewater treatment plant, playground dirt, and the companion animal exam room, have indicated that there is not a great deal of difference in bacteria collected, or the resistance of those bacteria, between sampling sites (Figure 12).

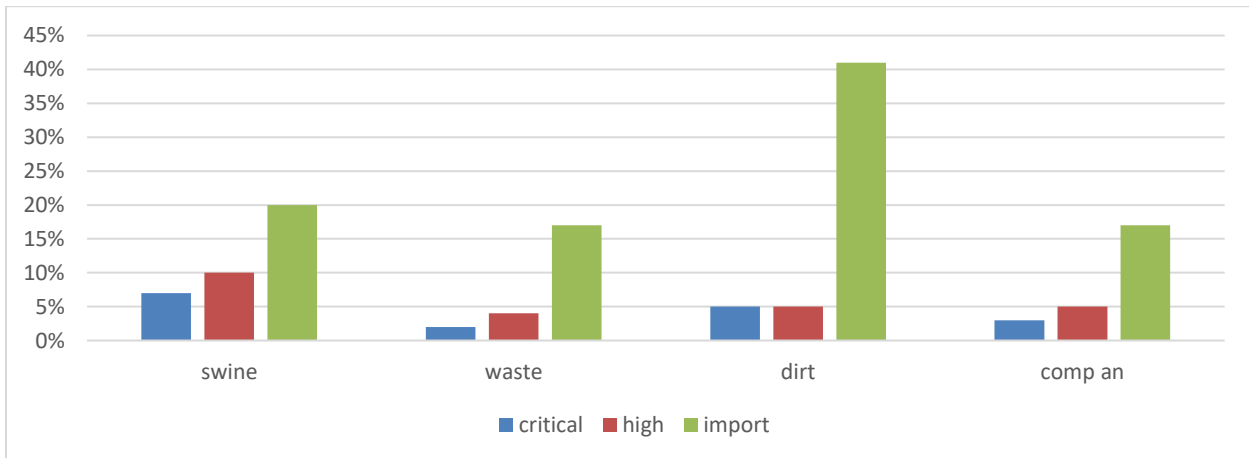


Figure 12. Comparison of AMR by class and site.⁴⁰ Critically important (*critical*), highly important (*high*), and important (*import*) classes are based on the FDA list of medically important drugs.⁴⁰ *swine* = swine farm, *waste* = wastewater treatment plant, *dirt* = playground dirt, and *comp an* = companion animal exam room

A second project just getting underway at Pipestone is in collaboration with the National Pork Board. This second project looks at phenotypic evaluation of the impact of antibiotic use protocols on AMR patterns over the lifetime of the pig. This project will look at antibiotic resistance development in minimal, moderate, and intensive antibiotic treatment groups of PRRS virus infected swine over a period of 23 weeks.

The second focus of PART is responsible antibiotic use practices. PART is the only public benchmarking antibiotic use platform for independent producers. Participation in the PART program supports producers as they strive to use antibiotics responsibly and ensures producers keep complete and detailed records of antibiotic use, review their antibiotic use protocols regularly with a veterinarian, and respond to the need for antibiotics with appropriate management decisions. Producers are provided with graphic usage by month data, for their farm as well as an average for all producers in the PART program. This data demonstrates to the producer where they fall on the spectrum of antibiotic usage (from least to most), and how they track over time. Grams per head is used as the metric (Figure 13).

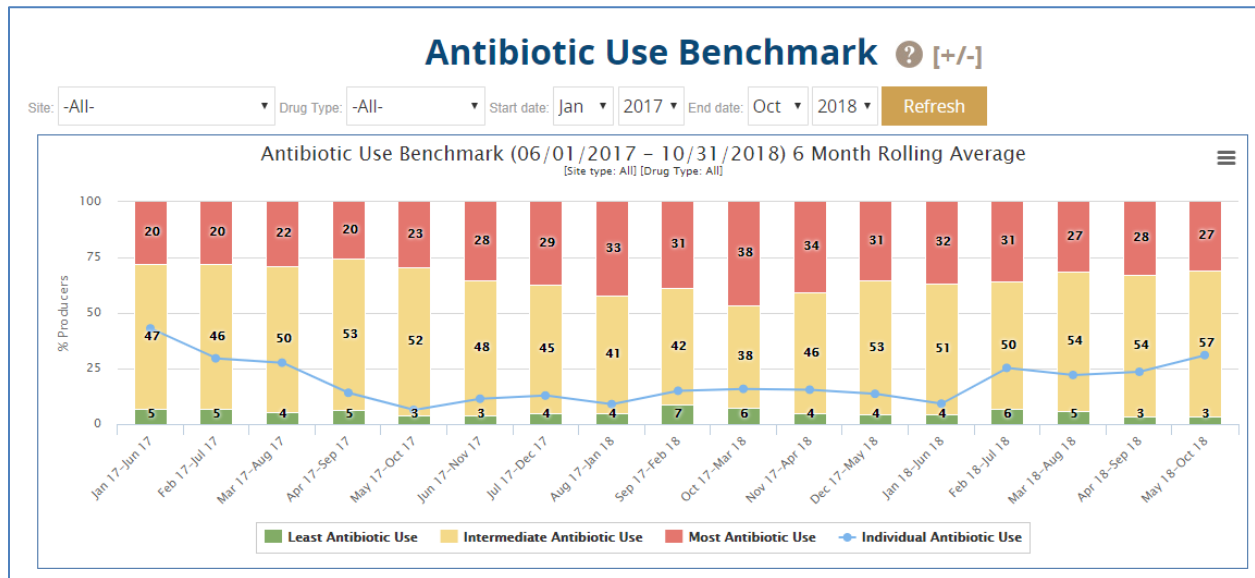


Figure 13. PART antibiotic use benchmark data comparing individual farm antibiotic use to all farm antibiotic use.⁴⁰

In the end, antibiotics are just one piece of the comprehensive approach to health. Other factors that must be considered range from facility design and biosecurity to disease status and vaccination to nutrition and air filtration. Pipestone strives to share compiled data and lessons learned broadly, through collaboration and outreach to organizations that range from Stanford Hospital to McDonald’s to the Minnesota Pork Producers Association.

DISCUSSION

Dr. Mary Battrell was asked about the difference in welfare for NAE hogs versus conventional hogs.

Antibiotic free hogs cost more to producer, mostly in average daily gain and feed conversion. However, the system does not allow for them not to get care. If the hogs need care, they receive it – they are just moved from NAE to conventional channels at that point.

Drs. Battrell and Nerem were both asked how they, as veterinarians, approach managing pig production since the VFD.

Dr. Battrell commented that all of her pigs are fed out of the company feedmill, so implementation of antibiotic use protocols and restrictions is fairly straightforward. For the other division of her company

dealing with toll mills it's a little more complicated. They have always evaluated their feed additives to determine benefit, and try to limit additives as much as possible. The frustration is that feedmills are designed to be efficient, and they don't like having any antibiotics in their feed because their addition requires a flushing cycle, reducing feedmill efficiency. For Dr. Nerem, the requirements put in place on their farms have had the intended effect. Required conversations between veterinarian and producer are now occurring when they might not have occurred before, and this has been a positive step for their practice. This increase in conversations has, however, required hiring more staff and spending more time with producers.

In a follow-up question for Drs. Battrell and Nerem, both were asked if they think there are less antibiotics used in their systems as a result of the VFD?

Dr. Nerem admitted he is not sure, because there was no good system for measurement before the VFD. His sense is that feed usage has declined, but has no numbers to back that up. He does think that bringing feedgrade use to the forefront has ushered in more elimination of disease by management. Dr. Battrell notes that antibiotic use in their system has declined, but she attributes that decline more to better pig health than to the VFD.

Finally, Dr. Michael Apley commented that within-system metrics are ok regardless of which measure because the goal is benchmarking, to recognize baseline and differences. Problems occur when moving between proteins, production systems, and countries. When moving to a broader system, the tendency is for everyone to use the metric that makes them look the best. Dr. Nerem's response was that measuring leads to responsible use, regardless of metric. It's really all about the pig, not the numbers.

Dr. Battrell's response was that she expects antibiotic use to fluctuate, based on the introduction of new disease strains. Every time a new disease strain surfaces, antibiotic use increases.

Panel Discussion – Knowledge Needs and Wants: What's New in Efforts to Provide Information on Antibiotic Use and Resistance to Different Audiences with Varied Interests

Steve Solomon, MD, FACP, FIDSA, moderator

Panelists:

Cheryl Stroud, DVM, PhD, Executive Director, *One Health Commission*

Charles P. Fossler, DVM, PhD, Veterinary Epidemiologist, *USDA-APHIS-VS*

Ruaraidh Petre, Executive Director, *Global Roundtable for Sustainable Beef*

Megin Nichols, DVM, MPH, Enteric Zoonoses Activity Lead, *CDC*

Andrew Hudgens, MPH, Microbiologist, *USDA-FSIS*

What's New in Efforts to Provide Information?

Cheryl Stroud, DVM, PhD, Executive Director, *One Health Commission*

One Health is a relatively new concept, and it is a ray of hope for the future. At its core, One Health is really about getting us out of our silos to interact with each other. A One Health lens is vital in addressing the comprehensive picture of animal, human, and environmental issues, from support of biodiversity to disaster relief to food security.

In research compiled by Princeton University professor Dr. Laura Kahn, reported in her book *One Health and the Politics of Antimicrobial Resistance*⁴¹, it is estimated that 700,000 deaths occur every year from antimicrobial resistance, and if we continue on the current trajectory, 10 million people will be dying per year by 2050. One of the takeaways from this same research is that AMR organisms in companion animals – our pets – are a significant source of resistance. AMR is also ubiquitous in the environment, housed in the soil microbiome. It can be argued that soil microbiota is just as important as gut microbiota. The soil microbiota and its effects on AMR are just beginning to be researched and understood.

Another new frontier of AMR research is the ocean microbiome. The animals that live in the ocean have never been given antibiotics, yet we find AMR organisms harbored within their bodies. The answer, in part, is runoff washing into the ocean, especially from countries where sanitation is questionable, countries which also happen to allow over the counter sales of antibiotics. The ocean is becoming a reservoir for exchange of antibiotic resistomes. Even citrus growers use antibiotics on their crops.⁴² We've released the dragon from the box – and it is going to be really hard to put back in.

Pollinators globally are really in trouble. They are covered by the VFD, and veterinarians treating hives and interacting in this sphere are essential to sustain and bolster the population. In the US, beehives are available to rent for crop pollination, and they're in high demand because there aren't enough bees left in the natural environment to complete the task. This has ramifications in agriculture both nationally and globally, and contributes to the lack of food security that has risen to crisis levels in countries such as the Central African Republic and Sudan. Food insecurity in countries such as these Republic contributes significantly to conflict and large scale security challenge.

OIE, FAO, and WHO comprise the One Health Tripartite.⁴³ Globally, partnership such as the One Health Tripartite are beginning to address the trifecta of animals, humans, and the environment in a comprehensive way. The Tripartite collaboration

‘recognize[s] that addressing health risks at the human-animal-ecosystems interfaces requires strong partnerships among players who may have different perspectives on some issues and different levels of resources.’⁴⁴

AMR requires out of the box thinking, and novel solutions. Approaches such as using bacteriophages and drugs to disrupt biofilm formation are novel proposals for replacement of antibiotics. Protocols for testing AMR differ across countries, and the Clinical and Laboratory Standards Institute is looking to standardize some of that testing so that we can all get on the same page. PATRIC (the Pathosystems Research Integration Center)^{44,45} provides resources for researchers. And a company in North Carolina, Integrated Biochem⁴⁶, has created a giant metal rumen that can digest organic waste in a process known as managed ecosystem fermentation, creating enzymes for use in other application.

Collaborations don't just magically happen - they start with relationships. And they are essential if we are to tackle AMR on the global scale and with the One Health lens that it demands.

National Animal Health Monitoring System Antimicrobial Use Studies

Charles P. Fossler, DVM, PhD, Veterinary Epidemiologist, *USDA-APHIS-VS*

The National Animal Health Monitoring System (NAHMS) was created in 1983, initially through universities. NAHMS conducted its first national study in 1990, and since then, has undertaken one to two studies per year. All of these studies collect information on health and management practices in U.S. livestock operations, designed to meet the needs of the livestock industry being studied. They are typically national in scope, and consist of one to two surveys, with incentives for producers to participate. Studies are designed to represent 70% of the operations and 70% of animals in a given commodity.

The USDA's Antimicrobial Resistance Action Plan AMR National Action Plan⁴⁷ includes several activities for APHIS to complete, including collecting antimicrobial use information for an antimicrobial use study. The data collection was completed in 2017, and included data from feedlot operations and nursery and grower/finisher pigs. Study objectives were:

1. Describe antimicrobial use practices in feed and water
2. Estimate percentage of operations administering and the percentage of animals receiving specific antimicrobials by reasons per use
3. Provide baseline data on antimicrobial use practices
4. Describe antimicrobial stewardship practices on production sites

Data collected was protected by the Confidential Information Protection and Statistical Efficiency Act (CIPSEA). Information on antimicrobial use practices for a period of 6 months in 2016 was collected from market pig operations in thirteen states. Information on antimicrobial use practices for a period of 12 months in 2016 was collected from feedlot operations in 22 states. Producers were asked about the primary reasons for antimicrobial use, as well as the average number of days treated. In addition, producers were surveyed about recordkeeping, Quality Assurance program participation, use of a veterinarian, and utilization of the veterinarian-client-patient relationship. Challenges in securing participation were a lack of ability to offer incentives for participation, and the fact that antimicrobial use is a sensitive topic. The data have not yet been released. NAHMS anticipates that reports will be available in the first half of 2019.

Dr. Speer asked Dr. Fossler if there is a plan for a NAHMS dairy study on antimicrobial use?

Dr. Fossler commented that he expects to see another NAHMS dairy study in the next few years, but he didn't know about a dairy study dedicated to antimicrobial use. NAHMS studies typically collect data on antimicrobial use.

Antimicrobial Stewardship Statement

Ruaraidh Petre, Executive Director, *Global Roundtable for Sustainable Beef*

The Global Roundtable for Sustainable Beef (GRSB) is a multi-stakeholder initiative, embracing the full supply chain and involving a range of constituents from producers and retailers to financial and pharmaceutical companies. GRSB promotes itself as the global overarching organization for the beef industry.

The GRSB's approach to sustainability is balanced and science-based, encompassing socially responsible, environmentally sound, and economically viable practices. Sustainability is based on continuous improvement, not capturing the best producers in the world but rather trying to move the bottom of the scale upwards. GRSB believes that raising the bottom of the range ultimately will have the most positive impact on global sustainability.

Regional and national GRSB roundtables are in place on six continents. A total of 500 companies and producer organizations are represented in GRSB's roundtables, representing 80% of cattle on feed in the United States and a significant part of the beef industry throughout the world. The most recently established roundtables have been established in Africa and Asia. Together, the United States, Africa, India, and China produce 40% of global beef. The United States produces 20% of global beef with just 6% of the global bovine herd. Africa, India, and China together also produce 20% of global beef, but with a much larger 60% of the global bovine herd.

GRSB developed five core principles that define sustainable beef: natural resources, people and the community, animal health and welfare, food, and efficiency and innovation. Criteria for sustainability are listed under each one. National groups take those and prioritize the ones that are most important in their own country, creating the metrics needed in their country to meet those principles.

In 2014, when GRSB released their sustainability statement, the single biggest issue on which the public commented was a need for antimicrobial stewardship. Antimicrobial stewardship is an integral part of animal health and welfare, clearly something the public is very concerned about, and inherently linked to sustainability. The GRSB Statement on Antimicrobial Stewardship is based on Tripartite guidance and industry consensus, and was published in June 2018.⁴⁸ The 2018 Tripartite⁴⁴ report highlights the fact that only 64 countries report following FAO-OIE-WHO recommendations to limit the use of critically important antimicrobials for growth promotion in animal production. Of these, 39 are high-income countries, mostly in Europe. By contrast, only 3 countries from Africa and 7 countries from the Americas have taken this important step to reduce the emergence of antimicrobial resistance. A total of 67 countries report having, at minimum, legislation in place to control all aspects of production, licensing and distribution of antimicrobials for use in animals. But 56 said that they have no guidelines at all regarding antimicrobials. The numbers cited in this report are an explanation of why, in addition to public comment, the GRSB decided it was important for the beef industry to have an antimicrobial stewardship statement.

In the Netherlands, antimicrobials were initially restricted very quickly, and the result was a 10% increase in mortality in calves, indicating adoption of use restrictions likely occurred too quickly to maintain animal health. However, over time mortality levels have returned to normal levels. Evidence from Europe indicates that reducing use of antimicrobials leads to a positive overall long-term impact, although it may not be perceived as such by producers, because operations using less antimicrobials are often less efficient. Building consensus was the hard part of developing a GRSB antimicrobial stewardship statement. GRSB members feared change and were afraid of being put out of business. A big producer concern was that the statement would affect macrolides – but that didn't happen. GRSB spent months trying to get this off the ground, and it wasn't easy, but in the end it was just a question of 'biting the bullet' and doing it. The antimicrobial stewardship statement promotes a tiered approach, employing use of antimicrobials of the least importance to human medicine first, employing those important to human medicine only if the lesser important antimicrobials prove ineffective. Several European members were adamant that no antimicrobial be used for feed efficiency, but in the end, ionophores remained allowed for use. The statement makes clear, however, that only ionophores, and no other antimicrobials, may be used for feed efficiency gains. The GRSB will continue to revise and refine the antimicrobial sustainability statement,

adjusting the living document as more research and policy results shape use recommendations and practices.

Communication During Outbreaks of Illness that are Linked to an Animal

Megin Nichols, DVM, MPH, Enteric Zoonoses Activity Lead, CDC

Virtually every day, crises and emergency risk communication is needed somewhere in public health. Providing information helps people make the best possible decisions for their health and well-being. There is a whole process regarding how communication occurs during an outbreak. The method, depth, and breadth of this communication may impact how we treat a patient, highlight why we are concerned about a specific pathogen, or warn consumers. However, in an outbreak situation, risk is a combination of hazard and outrage, and while we need to get information out quickly, we need to ensure that all communication is accurate, clear, concise, and planned.

One of the best ways to communicate to the public is by infographic. During an outbreak of human *Salmonella* infections linked to backyard chickens, CDC's 'Healthy Families and Flocks' infographic (Figure 14) avoided scare tactics, and highlighted a few important messages chicken owners need to know to stay healthy.

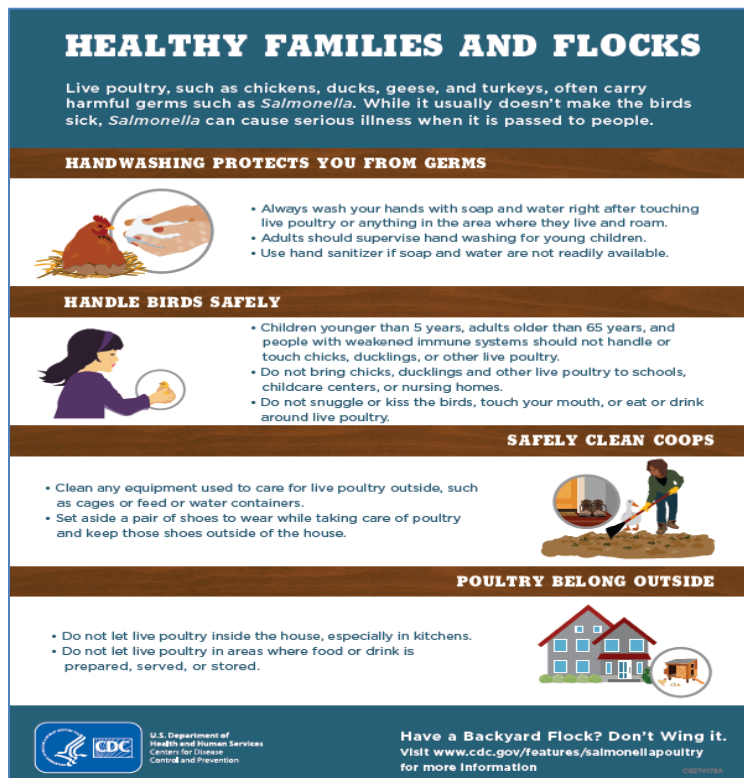


Figure 14. CDC *Healthy Families and Flocks* Infographic⁴⁹

This is a much better communication tactic than the media reported in the aftermath of the same outbreak, "CDC report crushes your chicken-kissing dreams". The report went viral, and may have included good messaging, but the takeaway for most people was, 'Don't kiss your chickens.'

Once communication occurs, reviewing response through venues such as web forums can help determine what messaging got through, what was missed, and what needs attention in the future. A selection of comments to a web forum during the *Salmonella* outbreak indicated members of the public ranged from understanding the messaging to completely missing the point.

Another outbreak example with significant communication needs was the recent outbreak of human *Campylobacter* infections linked to pet store puppies. This was a large multistate outbreak with an outbreak strain resistant to first line antibiotics. Traceback of puppies did not identify a single common breeder or supplier. Unlike the *Salmonella* outbreak linked to backyard poultry, which involved no resistant bacteria, AMR was a significant piece of this outbreak.

The resistance information was highlighted on the CDC website describing the outbreak, for several reasons. Many more infections in this outbreak were resistant than susceptible. Additionally, the infection strains were the same in puppies and in humans. The messaging from this outbreak highlighted three areas: the multi-drug resistance existed across subclades; the resistant bacteria were observed in both human and puppy isolates; and susceptibility testing and predicted resistance matched well. Medical providers looking for information on the outbreak needed to know to do susceptibility testing.

As the outbreak continued, the important questions became, ‘Where is this multi-drug resistance coming from?’ It was determined that 87% of puppies received antibiotics, either for prophylaxis alone, or for both treatment and prophylaxis. Messaging during the outbreak focused on recommendations for pet owners, pet store employees, healthcare providers, and veterinarians. (Figure 15). Medical providers and veterinarians alike were recommended to test for susceptibility before treating people or puppies for resistant *Campylobacter* infections.

Recommendations			
Pet owners	Pet store employees	Healthcare providers	Veterinarians
<ul style="list-style-type: none"> — Hand washing — Sanitation — When to seek veterinary care 	<ul style="list-style-type: none"> — Hand washing — Sanitation — Personal protective equipment — Food storage away from animal areas 	<ul style="list-style-type: none"> — Antibiotic resistance — Case management — Avoid antibiotics to which the outbreak strain is resistant 	<ul style="list-style-type: none"> — How to test for <i>Campylobacter</i> — Sanitation — Pet owner communication — Ill puppy should be examined by a veterinarian

Figure 15. Control recommendations: multi-drug resistant outbreak of human *Campylobacter* infections linked to pet store puppies.⁵⁰

CDC worked with trusted partners like the AVMA to disseminate the message, and in the end, articles written about the outbreak got the messaging right.

AMR Surveillance and Reporting at FSIS

Andrew Hudgens, MPH, Microbiologist, *USDA-FSIS*

Part of the mission of FSIS is to do inspection and sampling in order to characterize pathogens collected in the field. FSIS fits into the National Antimicrobial Resistance Monitoring System (NARMS) structure as it conducts random sampling of national production at slaughter. Three labs do PFGE (pulsed field gel electrophoresis), antimicrobial susceptibility testing, typing for salmonella species, and whole genome sequencing (WGS), testing thousands of samples annually. FSIS sampling programs collaborate with NARMS, and comprise samples from two sources: HACCP (Hazard Analysis and Critical Control Points) and cecal sampling. HACCP testing collects samples for salmonella and campylobacter. The additional, non-regulatory cecal sampling program expands sampling reach in order to better understand AMR. The cecal sampling program was initiated in 2013 and is voluntary. Initially cecal samples were tested by WGS for campylobacter and salmonella, but the program has also expanded to include enterococcus and E.coli testing. Antimicrobial resistance (AMR) for all samples is interpreted using NARMS strategy, which employs breakpoint criteria established by the Clinical Laboratory Standards Institute (CLSI) for salmonella, e. coli, and enterococcus, and epidemiologic cutoff values for campylobacter established by the European Committee on AST (EUCAST).

By collecting samples at the point of slaughter, FSIS is able to investigate how antimicrobials are being used and examine the fluctuations and trends in AMR of food-producing animals. The data collected at slaughter is moved into a labware system, and all subsequent analysis performed in tandem in order to validate results. Raw data collected is then compiled and presented in interactive visualizations, which is further interpreted and published in interactive surveillance reports.

An example of using AMR data to drive investigation is a 2018 linezolid resistance study.⁵¹ Linezolid resistance was only recently identified for the first time in bacteria collected from food producing animal in the United States. The resistance genes were initially isolated from cecal contents. Further characterization indicated an additional resistance gene, as well as resistance markers pointing to co-selection of resistance. Practically, this means that horizontal transmission into bacteria that cause human infections is a concern.

AMR surveillance and reporting is an important part of the mission of FSIS, and continues to drive new discoveries, more complete information, and new methods to tackle antimicrobial resistance.

DISCUSSION

Dr. Petre mentioned in his talk that calves in the Netherlands had suffered a 10% increase in mortality in the immediate aftermath of drastic reduction in livestock antimicrobial use. Was there any associated outcome in humans?

There was really no associated human outcome. Mortality in calves increase because of the restriction in use of antimicrobials, with little direct human effect. Anecdotally, the long term impact seems to be that they are now finding less resistant bacteria in the Netherlands.

Dr. Nichols was asked how big and how real the multi-drug resistant campylobacter issue was in the puppy outbreak?

Dr. Nichols pointed out that this was an instance where we saw the AMR bug in both puppies and people. CDC did ask if the bug was going from puppies to people. Using whole genome sequencing, CDC was able to determine that the antimicrobial resistance profiles in isolates from people and puppies were the same. This resistance profile is very rare and matched up with the antimicrobials being used in the puppies. This outbreak offered evidence of how antimicrobial use in animals could lead to antimicrobial resistance. CDC continues to monitor the situation closely and will report out any additional information.

Dr. Stroud was asked why we aren't paying more attention to MRSA in plants?

Dr. Stroud noted that the plant people need to be part of the conversation, and animal and human health advocates in the One Health realm are actively trying to recruit plant health advocates to the conversation.

Dr. Lucas Pantaleon asked Dr. Pete to describe how antimicrobial stewardship is implemented in developing countries?

One of the challenges in those countries is very limited access to veterinary services. An equally important challenge is the significant lack of oversight of antibiotic distribution. If the country has an export market, these two challenges can be addressed, for example, by employing paraveterinary services where veterinarians are unavailable. However, this represents a huge challenge, and needs a lot of investment.

An infectious disease pharmacist from Arkansas asked Dr. Stroud about accuracy in antimicrobial susceptibility testing.

Dr. Stroud noted that many times, by the time you get the sample to the lab, tissue characteristics have changed and testing is inaccurate. Treatment based on this inaccurate testing may not work, all because the time required to get the sample processed and to the lab changes the nature of the sample. More work needs to be done on early identification.

Panel Discussion – More Than Number Part Two: How Reliable and Accurate Information Can Only Be Assured Through Trusted Collaborations that Protect Data from Misuse and Misappropriation

Roger J. Saltman, DVM, MBA, moderator

Panel:

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne and Environmental Diseases, CDC*

Rick Sibbel, DVM, President and CEO, *Executive Veterinary and Health Solutions LLC*

Susan J. Bright-Ponte, DVM, MPH, Veterinary Medical Officer, Antimicrobial Use and Resistance, *Office of Surveillance & Compliance, FDA Center for Veterinary Medicine*

Monitoring Healthcare-Associated Infections at the National Level: CDC National Healthcare Safety Network (NHSN)

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne and Environmental Diseases, CDC*

Healthcare-associated infections (HAI) are infections such as central line-associated bloodstream infections, catheter-associated urinary tract infections, and surgical site infections. These and other HAIs are a longstanding and ongoing threat to patient safety, and both hospitals and the CDC have been working to make changes in HAI protocols, prevention, and response with the goal of improving patient outcomes and safety. The prevention of HAIs is a top priority for the United States Department of Health and Human Services (HHS). The HHS Steering Committee for the Prevention of HAIs was established in July 2008, and this committee has developed an Action Plan⁵² that provides a roadmap for HAI prevention. The Action Plan initially addresses hospitals, but over time, expands to all healthcare setting where HAIs may occur.

In response to the Action Plan, State health departments have moved to legislatively mandate certain HAI reporting; the Centers for Medicare and Medicaid Services (CMS) has instituted rules for HAI reporting as a condition of reimbursement; and healthcare systems have begun reporting HAIs and using the CDC National Healthcare Safety Network (NHSN). The NHSN is currently the nation's most widely used HAI tracking system. For those who use the system, it enables identification of infection prevention problems, provides benchmarking, offers a platform for compliance with federal and state reporting mandates, and generally drives national progress towards the elimination of HAIs. Reporting to the NHSN has grown exponentially, from 300 hospitals in 2008 to more than 17,000 facilities in 2015. These reporting facilities range from acute care hospitals to outpatient dialysis centers to skilled nursing facilities, and all are different, with different care modalities. The NHSN has expanded significantly to accommodate the various reporting and tracking needs of the range of institutions.

As an increasing number of healthcare facilities have begun to report to the NHSN, two main concerns of these facilities have risen to the forefront: staff reporting burden and consequences of storing sensitive data in an external system. Much of the bulk of reporting has fallen to infection preventionists, who find that in addition to the labor of increased manual data entry, there are frustrations in the many required data points that are not captured in medical records, and NHSN definitions that do not match those of the healthcare facility. Concerns relating to reporting and storage of data in an external system include security and confidentiality of both patient-level and facility-level data, and the potential negative publicity of publicly reported facility HAIs. Finally, with all of this reporting can come the unrealistic expectation of fixing the problems and 'getting to zero - an unreachable and unrealistic goal.

To address healthcare facility concerns about confidentiality, many layers of security have been built into the NHSN. The first hurdle, to get facilities to participate at all, was to assure them that sharing patient data within this secure system does not violate HIPAA. The system is protected by Secure Access Management Services (SAMS). Each facility participating in the NHSN is required to sign a 'consent to participate' agreement, which among other things, requires that only one facility administrator control system access. The healthcare facilities are in control of determining which data they will share with Group Users, when those data are shared, whether it is only certain parts of the data, and for what purpose (e.g., analysis and comparison across systems).

A specific set of standardized data elements are required for submission into NHSN. Electronic data collection, transmission, and sharing occur using the Health Level Seven International platform. This

platform is indispensable, for without it data are not interoperable and no analysis or comparison of data is possible. NHSN measures for data comparison have been submitted and approved through the National Quality Forum⁵³, which endorses data collection measures as evidence-based and valid.

Healthcare facilities of entering data into the NHSN benefit via both internal and external motivation. Standardized data and established metrics provide the data necessary for meaningful comparisons, as well as internal levels toward which to strive. Healthcare facilities are able to identify risks from practices, processes, and other transferring facilities to develop new preventative practices informed by the facility's own data. Potential negatives are turned into positives as facilities have begun to 'own' their data and make positive changes and improvements. External benchmarking allows facilities to know where they stand nationally. All of this has led to a tremendous reduction in HAIs, and ultimately, to healthier and safer patients.

The shared standardized data and metrics from contributing facilities are reported annually in a national integrated summary report: the National and State Healthcare-Associated Infections (HAI) Progress Report⁵⁴, which is available on the CDC website, along with the interactive patient safety ATLAS platform. Data are available for review at the state or regional level, but no further, which protects facility and patient data.

As reporting and data analysis needs continue to expand, the NHSN will continue to expand and change to meet these needs. Antimicrobial resistance and stewardship data collection and analysis capabilities are the most recently built into the system, to provide another powerful tool in the fight against antimicrobial resistance.

Challenges and Opportunities for Antimicrobial Use Data in Animals

Rick Sibbel, DVM, President and CEO, *Executive Veterinary and Health Solutions LLC*

Data in the context of antimicrobial resistance is for the greater good, or it should be; however, data in the context of animal agriculture is an asset that may be bartered. In the fight against antimicrobial resistance, there is an undeniable urge to compare human and animal data. We use many of the same drugs in humans and animals. Those drugs are used to combat bacterial infections that are often similar. Decisions to use antimicrobial drugs in both humans and animals usually have professional oversight. Health outcome objectives for both animals and humans are similar. And there are unintended consequences for both humans and animals of not using antibiotics, namely suffering and decreased quality of life.

However, record systems of animal antibiotic use, and economics, particularly in food producing animals, bear little resemblance to record-keeping and economic concerns for humans. Geographic diversity, age diversity, and production size diversity among and between animal species make it impossible to provide a one-size fits all approach to animal and antimicrobial stewardship. Human health is addressed on the individual level by well-defined data capturing systems and incentives, whereas animal health is addressed in agriculture production systems utilizing population level decisions in diverse settings. In human healthcare management systems, incentive systems work to encourage antimicrobial stewardship by providing a reward – and incentive – for following the steps required to earn the incentive. However, incentive systems don't work as well in production agriculture. Agricultural producers will not take those required steps if it means there is a chance they are jeopardizing the viability of their business. If they go out of business and thus have no animals, the antimicrobial stewardship is moot.

Agriculture needs to collect antibiotic use data in order to accurately characterize how well we use antibiotics and if we use them responsibly. The poultry industry is one success story in this realm, as through extensive data collection the industry has managed to move to raising 45% of all broilers without any antibiotics at all. However, there have been many concerns raised in the collection of antibiotic use data. For the poultry industry, concerns include the protection of producers who provide the data, and how to both blind and protect data collected to allow meaningful analysis.

The NAHMS national study was designed to collect meaningful data while protecting the privacy of those who provide that data. Five hallmarks of the NAHMS National Study have been defined: national scope, collaboration, voluntary, privacy, and scientifically based and statistically valid. This study really changes the way data are accessible and expands the access to this data. The Confidential Information Protection and Statistical Efficiency Act (CIPSEA) is of paramount importance, because without the protections it offers agriculture, producers will provide no data at all,

Every system of food production in the western world has massive amounts of data collection they can access. Increased recordkeeping is helping improve stewardship across the industry, but data at multiple hierarchical levels are needed for meaningful comparison, metric generation, and benchmarking. Biomass denominator is useful as a metric, but we need to be careful, and remember the end goal is to reduce human antimicrobial resistance, not to reduce the total amount of antibiotic used. Across the board reduction will not necessarily attain the goal of reduced human AMR, and will have unintended consequences for animals, both in their care and in their welfare. Decisions and resources in animal health for optimized antibiotic stewardship must focus on justified reasons for use. Collecting antibiotic use data in animal health involved multiple species with different routes of sales and distribution pathways. Many of the antibiotics used in these animals are of lesser importance to human health. Some antibiotics used in animal health have little record-keeping beyond the farm. The NARMS program should continue to focus on data collection and the associated record-keeping, and remain focused on public health and kept completely separate from any regulatory purposes or action. Changes to antibiotic administration in animal agriculture have led to greater veterinary oversight and record-keeping, and these records a providing the baseline from which to launch improved stewardship across the industry. Positive change is already occurring, and we must continue to protect privacy and offer valid data analysis to continue that change.

Data Collection and Antimicrobial Stewardship

Susan J. Bright-Ponte, DVM, MPH, Veterinary Medical Officer, Antimicrobial Use and Resistance, *Office of Surveillance & Compliance, FDA Center for Veterinary Medicine*

The FDA Five Year Plan for Supporting Antimicrobial Stewardship in Veterinary Settings³⁶ was released in September 2018. The Five Year Plan has three primary goals: to align antimicrobial drug use with principles of antimicrobial stewardship; to foster stewardship of antimicrobials in veterinary settings; and to enhance monitoring of antimicrobial resistance (AMR) and antimicrobial drug use in animals. The FDA's overarching goal for support of veterinary antimicrobial stewardship is to implement measures that address the public health concern of AMR while ensuring that animal health needs are met. As of January 1, 2017, with the implementation of Guidance for Industry (GFI) #213, all medically important antimicrobials used in feed or water are required to have veterinary oversight, and no medically important antimicrobials are approved for production uses, such as growth promotion.

Various data are necessary to assess the adoption of the changes outlined in GFI #213, to gauge the success of antimicrobial stewardship efforts and guide their evolution, and to assess associations between antimicrobial use practices and resistance. Examples of data needed include the quantity of antimicrobials sold and distributed, on-farm antimicrobial use practices, antimicrobial resistance data, and animal health and demographic data.

As per Section 105 of the Animal Drug User Fee Amendments of 2008, the FDA collects data on the annual sales and distribution of antimicrobial drugs approved for food-producing animals (which includes sales by species estimates as of 2016) and publishes annual summaries of the information. Antimicrobial sales data are useful as an indicator of the overall quantity of antimicrobials entering distribution channels; however, they do not provide information about actual use or context of use. Additionally, many drugs are approved for multiple species with multiple indications and varying dosage regimens, none of which sales data can adequately parse.

On-farm antimicrobial use data are much more important for assessing antimicrobial stewardship than sales data. As has been discussed, information only about quantity of antimicrobials used does not necessarily indicate presence or absence of good stewardship – there must be some information about the context of use. Antimicrobial use data can assist with evaluation of on-farm use conditions and practices (such as reasons for use, dose, and duration of administration) and offers the opportunity to evaluate the relationships between antimicrobial use and AMR. Unfortunately, antimicrobial use data collection is resource intensive and a lack of uniformity between producer records makes compilation and interpretation of these data very difficult. As described earlier in the conference by Dr. William Flynn, in 2016 FDA awarded two cooperative agreements, with a goal of collecting detailed antimicrobial use data that reflect actual on-farm use for the 4 major food-producing species, including baseline data for 2016 (*i.e.* prior to GFI #213 implementation). These agreements are intended to pilot methodologies for the development of standardized on-farm data collection, as well as incorporate strategies for protecting confidential information at the farm level. Additionally, as mentioned by Dr. Charles Fossler earlier in the conference, a different data collection project has been spearheaded by USDA-APHIS to distribute and compile over 1000 antimicrobial use surveys for swine and feedlot operators. Another source of data, prior NAHMS study data, can provide some measure of historical antimicrobial use. Finally, USDA has proposed longitudinal studies to evaluate on-farm antimicrobial use and development of AMR over time. There are many potential measures that could be tracked to provide useful metrics for assessment of current antimicrobial use practices and stewardship, and for informing future efforts to improve antimicrobial use. There is unlikely to be one perfect metric, as the choice depends on the defined objective for analysis, as well as some species-specific considerations. Examples of data that could be useful for tracking and assessment of antimicrobial use include the proportion of animals treated in a given population, the number of antimicrobial regimens used, the time scale of reporting, production indices and others.

In addition to tracking resistance trends, AMR data are important for providing information which could help guide antimicrobial stewardship efforts. Since 1996, NARMS has tracked changes in antimicrobial susceptibility of enteric bacteria in ill people, retail meats, and food animals, and compiled annual summaries of resistance trends. Recent improvements in NARMS provide interactive data displays, making the collected data more useful to the individual user; whole genome sequencing (WGS) data; expansion of retail meat sampling to more states; and the addition of cecal sampling to broaden collected data. Unfortunately, resistance data for all animal pathogens is not available, and resistance data in humans is not linked to that of animals. It is difficult to make, or disprove, any links between antimicrobial use practices and AMR in humans and animals.

Animal health and demographics data are important to provide context for assessing antimicrobial use information (e.g. appropriateness for extent of use, animal disease challenges, etc.). However, routine collection and availability of animal health data is currently limited in the U.S., making it difficult to assess background disease conditions and context of antimicrobial use and stewardship.

Evidence is needed to demonstrate progress in veterinary antimicrobial stewardship. FDA gets regular pressure from other organizations to provide updated information, and needs accurate data to fulfill those requests. FDA-CVM intends to publish a comprehensive assessment report that integrates and analyzes currently available information to assess stewardship in veterinary settings. The report will likely include data already mentioned, such as antimicrobial sales, available antimicrobial use data (e.g. from cooperative agreements), animal health and demographic data, NARMS resistance data, and USDA survey/program data. The challenges lie in the misuse of these data, and lack of agreed upon metrics with which to report progress.

Panel Discussion: Looking Ahead – Science and Data: How Might Scientific Advances and More Complete Data Help Achieve our Shared Goals

Rick Sibbel, DVM, moderator

Panel:

Brian Lubbers, DVM, PhD, Assistant Professor, *Kansas State University*

Judson Vasconcelos, DVM, PhD, Head, Veterinary & Consumer Affairs, *Merck Animal Health*

Larry M. Granger, DVM, Senior Leader of Antimicrobial Resistance, *USDA-APHIS*

Science and Data Needs

Brian Lubbers, DVM, PhD, Assistant Professor, *Kansas State University*

Which patient needs an antibiotic? The answer is binary – yes or no – and as a third party observer, it's easy to sit back and give an answer. It's a question that lends itself well to protocols and clinical practice guidelines. However, it's the wrong question to ask. The question we really should be asking is, "Do the benefits of antibiotic therapy outweigh the risks of antibiotic exposure or risk of not treating in this particular patient?" The answer is not binary, and it is not easy. This question is why antibiotic stewardship is difficult.

We need to define acceptable risk. Every person has a different tolerance for risk, and thus different acceptable risks. These are based on our age, life status, and countless other variables that define our individual lives. In the discussion of acceptable risk as it relates to antibiotic therapy and antimicrobial resistance, we have to consider the risk to the individual of not treating, the risk to society of treating, serious drug adverse events, and the negative outcomes from withholding therapy. Improved diagnostics can help to more specifically detect underlying disease and confirm diagnosis, allowing for specifically targeted treatment or avoidance of treatment in non-antibiotic responsive conditions. This confirmation reassures the prescriber, who often has the fear of the consequences of not prescribing antibiotics in cases where an antibiotic treatable diagnosis is unclear. This confirmation helps balance out the societal risks of treating with antibiotics, by limiting treatment to conditions that are truly responsive to antibiotics, thus eliminating over-prescribing. Effective adjunct or alternative therapies can further tip the

equation, and optimal dosing regimens can change the risk-benefit equation by providing smaller refined doses that minimize selection for resistance while still providing therapeutic benefits.

Is there a balance in dosing where we can change the dynamic to reduce the resistance pressure while still getting a good clinical outcome? One example of a dosing regimen that could be optimized is the therapy streptococcal pharyngitis. The duration of oral antimicrobial treatment of streptococcal pharyngitis is usually ten days. A scientific literature review reveals that the ten day therapy standard evolved without any scientific justification at all. The ten day standard exists because of history and the power of the number ten.⁵⁵ In a survey conducted by Dr. Lubbers that compared short versus long duration therapy for a variety of diseases, there was no difference in clinical outcome between short and long dosing regimens. (Figure 16). Shorter duration of antimicrobial therapy doesn't guarantee the promotion of less resistance than longer duration therapy, but it may, and it won't promote more.

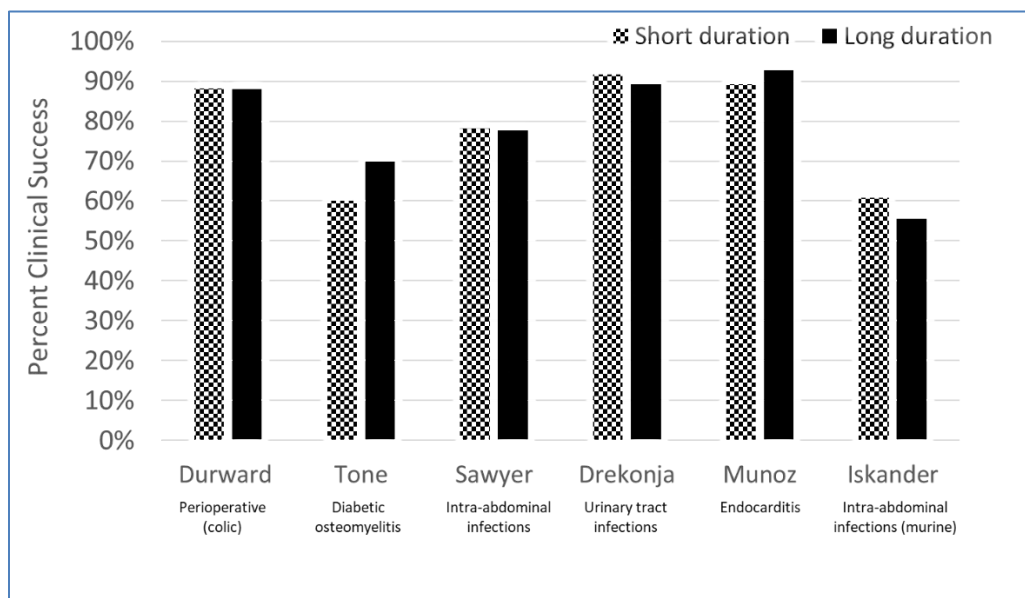


Figure 16. Comparison of clinical success of short versus long duration antimicrobial therapy regimens⁵⁶

Dosing regimens must balance the science and data needs. We need to be willing to go back, and challenge and question. Where does the recommendation come from? Does it make sense? Can we do better. It all comes back to the core tenants of antimicrobial stewardship: drug, dose, duration, and frequency.

Moving forward, we need to continually bear in mind this question: Is what we're currently doing based on good science? There are many efforts to answer the question of acceptable risk, but they're not being connected. We need to connect the findings and get the answers.

Merck Animal Health Antibiotic Research Efforts Targeting Antibiotic Alternatives

Judson Vasconcelos, DVM, PhD, Head, Veterinary & Consumer Affairs, Merck Animal Health

The aim of this panel is to talk about science, data, and shared goals. The shared goal, for everyone on this panel and everyone in this room, is the reduction of antimicrobial resistance. The science and data

are something that Merck can help with. They are a science-based company, and science and data are what they do every day. And Merck is very interested in being engaged with antimicrobial resistance.

Disease prevention is a top priority for Merck and is at the core of their business. Merck has made major investments in novel vaccines for livestock and companion animals. Research and development (R&D) is an ongoing investment, looking into solutions to treat, prevent, and control bacterial infections in animals. The company is not walking away from antibiotics, but they are doing that R&D into narrow spectrum antibiotics in non-shared classes with human health. In addition to antibiotics, however, Merck is looking into a wider range of tools with biologicals and technology. One new biological is Sequivity RNA Particle Technology, a unique groundbreaking technology that offers a tailored way to vaccinate animals. A new on-product technology is Whisper, a smart stethoscope that transfers lung sounds to a computer for analysis. This technology, currently available for cattle, removes the human error and improves diagnostic capability. In general, Merck is moving toward a more individual animal approach, to allow for more accurate, targeted diagnosis and treatment.

Merck's antimicrobial strategy moving forward is a multi-pronged approach, focusing on prophylaxis, metaphylaxis, and therapy. For the healthy animal, the best way to approach stewardship is to vaccinate. For at-risk animals, the answer is less black and white. Metaphylaxis started years ago in feedlot animals. But is there an alternative to mass use of antibiotics? For infected animals, there are currently no alternatives as good as antibiotics. This is why Merck continues to conduct research and development into the antibiotics of the future. However, Merck is also engaged to look for alternatives to antibiotics, for treatment, and especially for animals at risk. Merck, of course, also develops pharmaceuticals for human use, and the "One Merck" approach utilizes resources are focused across human and animal health R&D to identify new solutions and exploit all available knowledge.

The surveillance for bacterial resistance development the key to making evidence-based decisions. Continued participation in industry research activities including susceptibility testing and information dissemination, as well as advocacy for robust data collection and surveillance, all support the elucidation of this key. Merck also continues to look for alternative approaches, from bacteriophage and probiotic technologies to immunomodulation and microbiome modulation to pathogenicity blockers. These alternative pharmaceuticals support overall animal health, prepare the animal to fight disease, and provide specific and targeted therapy when it is needed.

So far, Merck sees promising trends, but hasn't come across anything that is a real breakthrough. There is nothing even close to true antibiotics as treatment for infected animal today. Regulatory uncertainty prevents them from moving faster, but conversations continue. Merck continues to balance concern for antimicrobial resistance with animal welfare, and is working to ensure that in the future, we still have our best tool available to fight disease.

How Might Scientific Advances and More Complete Data Help USDA-APHIS Achieve Our Shared Goals

Larry M. Granger, DVM, Senior Leader of Antimicrobial Resistance, *USDA-APHIS*

There are a few things we can all agree are common goals. We all want a better understanding of how antibiotic use relates to antimicrobial resistance. We want to demonstrate that agriculture participants are good stewards. We want to mitigate risks to human and animal health. We want to sustain and benefit the food chain and participate in the global agenda, and score well on gauges of the global (WHO,

OIE, and FAO) “core indicators”. And we want good public policy, based on complete and correct information, and scientific analysis.

Sometimes it’s necessary to use antibiotics. Antibiotic resistance has been a factor for as long as we’ve had antibiotics, and long before any antibiotic was used to treat people or animals. Antibiotic stewardship is an ethical consideration. If you’re the one that’s sick, or treating someone who is, you have a completely different opinion of antibiotic use from someone who isn’t. The decision to use antibiotics is guided by a critical understanding of all aspects of the affected biome; that is what defines judicious use. Physicians and veterinarians need data to inform their understanding. When we use antibiotics, we also need a baseline understanding of broad use parameters. Without data, we will never know if we’ve achieved our goals, or whether actions that reduced antimicrobial use were of value, or not. Data collection is also important to inform research efforts.

When resistance is augmented and none of the goals of treatment are achieved, that represents the worst case scenario. There have been times in the past we treated unnecessarily with antibiotics. Some of this has been easily remedied – the medicated milk replacer made necessary by substitution of cheaper indigestible plant-based proteins should not be justification for treatment with antibiotics – but some is more complicated, and the prescribed use is often based upon concern about the possibility of serious consequences from not treating. There may be better ways to address these concerns.

Antimicrobial resistance should convince us that more research and prevention investment is needed in agriculture. Animal health and productivity on the farm are technical goals, but there are other linked concerns, such as increased death loss in commerce, more carcass condemnations and higher disease incidence rates that may come with reduction in antibiotic use. All goals and concerns must be considered as we consider stewardship. Measures of effective stewardship and interventions need to assure efficiency in the economic system as well as assuring the best “One Health” outcomes. The economic system is not just a concern of the individual producer in the United States. AMR affects global marketability. Many countries in Europe have laws that promote zero antibiotic use in agriculture for anything except treatment of sick animals. AMR and global development goals are linked at the World Bank and through the collective efforts of NGOs like the FAO, OIE, and WHO.

We are in the midst of a revolution in medicine made possible by technology. Whole genome sequencing is a technology that gives us insight into how bacteria work, effectively characterizing the pathogen. Additionally, technology opens up a myriad of potential alternatives to antibiotics. CRISPR-Cas9 gene editing, probiotics, phages and quorum sensing chemicals are examples of potential alternatives that may be beneficial. Hormesis is a concept that needs exploration. There may be antibiotic uses and dosages that are effective with no associated increased resistance. When this is the case, antibiotic use achieves all of the goals we associate with use of alternatives to antibiotics. We should also consider that there may be other antibiotics that have the all the attributes we desire in the alternatives we seek, as is the case with ionophores.

Confidentiality protections meant to protect producer identity sometimes get in the way. Liability concerns prevent us from gathering the information needed to guide action. We’re losing an opportunity. In human medicine there are laws that protect the patient from privacy intrusion – we need to have something like that in place for agriculture.

Time changes all things, and it's not always bad. How we use antibiotics is one of those things. Our responsibility is to look at these tools, determine how to use them more effectively and more judiciously, and commit to monitor the effects of those changes.

DISCUSSION

Dr. Lubbers was asked what will it take for us to get the issues with antibiotic treatment duration, such as the historical ten day regiment for streptococcal pharyngitis?

The motto 'take the entire course of antibiotics' is starting to change to 'take as directed by your physician', which often translates to 'take until you feel better'. The first step is to challenge long held durations as appropriate. We are starting to ask these questions. A later step will be to show in clinical trials that three days is as effective as ten day. Those trials will give the prescriber confidence, and that confidence is what it will take to ultimately dispel the ten day myth.

What role will genomics or gene editing play in future advancements against antimicrobial resistance, and will the consumer accept those advancements?

Dr. Granger suggested that genomics and gene editing will play a significant role, especially as we start to look at the alternatives. What concerns Dr. Granger is the potential of substituting things we don't know much about for the great tools that are antibiotics. He doesn't want to return to the days of peddling snake oil. Dr. Vasconcelos noted that we have learned over the past few years that we need to be careful with how we frame new technology, starting with the names. We need to introduce new technology in a way that doesn't inspire more fear.

Dr. Granger was asked how to address remedies such as oregano oil that work, but aren't regulated. The allied industry has to skirt around what they do with things like oregano oil, because if they start talking about specifics, there is a fear it will start to be considered a drug and fall under FDA guidance, instead of being considered a feed additive. How does the industry avoid these sorts of products falling under FDA regulation?

Dr. Granger agrees that this is a sensitive issue. Some of the products we talk about as alternatives could be products regulated by the APHIS Center for Veterinary Biologics, which regulates biologics and diagnostic test kits. In the approval process for animal biologics, the Center for Veterinary Biologics requires products meet four criteria – pure, safe, potent, and effective. You could gather data under field trial conditions in a controlled way that is scientifically acceptable, then make that case to the regulatory system. This can be done with antibiotic approvals as well, but we cannot expect that investment to come solely from companies that produce these drugs.

Panel Discussion – Blockchain: Building a More Sustainable Supply Chain

Nevil Speer, PhD, moderator

Panel:

Gary B. Rodrigue, Blockchain WW Food Safety Leader, IBM

John Gerber, VP, Cattle Procurement, Tyson Foods

Kevin Hueser, Senior VP, Beef Margin Management, Tyson Foods

What is Blockchain? IBM Food Trust Overview

Gary B. Rodrigue, Blockchain WW Food Safety Leader, *IBM*

Stewardship and sound policy are based on complete and correct information. This information is where IBM's work lies. Mr. Rodrigue has had the opportunity three times in his career to work in disruptive, transformative technologies. The first was developing modems. The second was the development of semiconductors that enabled smartphone technology. The third is Blockchain. Blockchain is going to be just as disruptive as modems and smartphones, and it has the potential to change entirely how supply chain management works.

In 1995, communication was one to one, using media such as the postcard. This communication is inefficient, costly, and slow. Today, we expect communication to be instantaneous and bidirectional, such as that of social media. Blockchain provides this instantaneous, bidirectional information to a permissioned group of people. While Blockchain fulfills current expectations of communications, it's been held up empowered by trust and verification of data. An earlier iteration of Blockchain, bitcoin, was an unregulated, unpermissioned, resource intensive system. IBM's Blockchain is regulated and private, and is specifically developed by researchers and the community of users to include all of the elements needed for that community in a permissioned, private system. It is designed for the enterprise.

The current supply chain is complex, and inefficient. Participants are siloed, and every participant maintains their own ledger of transactions. These individual ledgers duplicate information used throughout the supply chain, as individual ledgers often hold the same information, but don't communicate. Aside from being inefficient, this system is expensive and vulnerable. If we can eliminate that redundancy and make that supply chain more efficient, while improving security and expense, everyone wins. Blockchain technology is evolving to enable connection of the elements of complex systems such as the food supply chain so that they can interact more seamlessly. Shared goals and trust in the system are vital to the success of Blockchain in managing complex systems.

The IBM Food Trust solution is a set of modules built for the industry, consisting of modules layered onto a basic platform. (Figure 17)

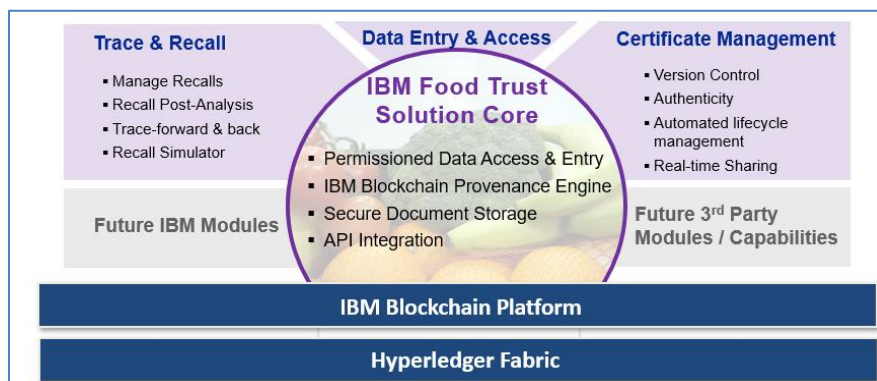


Figure 17. IBM Food Trust platform and modules.⁵⁷

IBM's Blockchain Platform and Hyperledger Fabric are the base, and you can think of them like a smartphone. The modules are like the apps you would download onto your smartphone. The current three modules are data entry and access, trace and recall, and certificate management. This system delivers

trusted information to those that need it to make informed decisions. As the system moves forward and evolves, additional modules may be added.

The idea is that the consumer wants this information – especially the next generation consumer. This next generation is going to demand to know the background of the commodities they consume. Blockchain technology can provide that background and assure the consumer that the product they have chosen possesses the characteristics they value. For suppliers that embrace this technology, this proof of background will lead to greater market share and the ability to charge a premium for that background information.

IBM believes there is an enormous amount of work to be done in adding and transmitting information throughout a network that needs that information instantaneously. They believe Blockchain will be the platform of choice. There is still an enormous amount of work that needs to be done in the modules that sit on this platform. This is a big data problem, and IBM is a big data company, equipped to address the challenges of big data. However, IBM is not a food company. Their partnership and collaboration with the food industry is key to making IBM Food Trust work.

Blockchain and Tyson Fresh Meats

John Gerber, VP, Cattle Procurement and Kevin Hueser, Senior VP, Beef Margin Management, *Tyson Foods*

Mr. John Gerber is the head cattle buyer at Tyson, generating transactions that comprise approximately seven million head of cattle per year, or 26,000 head of cattle per day. Tyson works with 4000 cattle feeder suppliers to maintain these cattle. As head cattle buyer, Mr. Gerber deals in the practical side of the business, identifying consumers and their specific needs, and buying the cattle that will fulfill those needs. The foremost consumer need is transparency. Who owned the cow herd or the feedyard? Tell me more about that producer? The consumer wants us to tell the story. They want to have a picture in their head of how the animal they are going to consume has lived its life. One way to generate this picture is through tours. Cactus Feedyard, a Tyson supplier, does about 100 consumer tours per year. Tyson would like to see more of this.

Excellent animal welfare is an additional key consumer desire. Consumers want to know that the animal they are purchasing has been treated well. In 2012, Tyson started the Farm Check program. This program demonstrates to the consumer that Tyson knows how an animal should be treated and is committed to animal well-being. Through this program, Tyson ensures audits of 5 to 10% of their supply every year. Producers in the program must pass a test, and their audits are third party verified. Feedyards were initially resistant, but over time they've become enthusiastic participants, and now vie to be the farm that gets picked for an annual audit.

All cattle buyers in Tyson are Beef Quality Assurance (BQA) certified. As of January 1, 2019, all beef suppliers will also be required to be BQA certified, in a program that includes elements of animal welfare as well as food safety. In the current consumer age, consumers expect and demand food safety. Recalls are expensive, both in time and reputation. Thanks to BQA and Farm Check, Tyson has not had a major food recall in recent history.

Consumers want traceability - they want to know where their food come from. Nationally, Mexico and Canada both have full traceability programs. The United State does not. Traceability is vitally important to control disease and the economic ramifications to which it leads – it allows us to narrow down disease

to smallest possible area to get on with business. Traceability opens up international markets, such as China, which will not buy U.S. beef without traceability assurances. Many of Tyson's producers are beginning to participate in traceability programs. In addition to controlling disease, traceability improves quality, and therefore improves beef demand. For calves with electronic identification, Tyson provides slaughter and carcass information back to the feeder. The consumer wants this information, too.

Sustainability is a new buzzword, throughout many sectors, not just beef supply. In addition to its animal welfare and food safety, Tyson is committed to a sustainable work force. Longer term employees lead to a better product. Tyson has committed to raising worker pay, ensuring worker safety, and improving of working conditions through mechanisms such as adding an extra break for shift workers. These changes come at a cost, but they are starting to see the return on investment. Worker retention rates have improved significantly.

Finally, the consumer demands responsible antibiotic usage. This responsibility is becoming ingrained throughout the Tyson supply chain. The only empty pens Mr. Gerber has seen lately are the sick pens. All of these focuses – transparency, animal well-being, food safety, traceability, sustainability, and responsible antibiotic usage – lead to a higher quality beef product. This product would not be possible without supplier collaboration and support. But Tyson and their suppliers need to continue to tell the story. They have a supply chain that 'does it right' – they just need to communicate that to the consumer.

An unusual aspect of Tyson that lends support to all of the things their consumers need and want, and verbalizes the focuses that have been described, is the Supplier Creed. The Supplier Creed addresses beef and pork producers, and it lays out a contract between Tyson and their suppliers that ensures company values are upheld on both sides of the relationship. The Suppliers Creed promises that Tyson will treat suppliers with respect and courtesy; strive for long term relationships; and foster collaboration with its suppliers. For their part, suppliers agree to strive for sustainability in animal well-being and the environment; and confirm that transparency is crucial and expected. This Creed is unique in the industry, and is something for which Tyson is very proud.

Mr. Kevin Hueser is the Senior Vice President for Beef Margin Management at Tyson. Pricing is inexorably tied to consumer demand. The relationship between buyer and seller has changed dramatically in recent years. Before 2010, the seller controlled the product, and the consumer – the buyer - controlled buying decisions only. Since 2010, however, the buyer has controlled the product. The customer now controls a great deal of the information that is shared about the product. The seller still gets to control the manufacturing practice, but consumers demand information on labels, do their own research on the product and its alternatives, and share information instantaneously with other consumers. Consumers have the bulk of the control, and Tyson has learned that if they don't meet consumer needs, the consumer will find someone else that will. It's not a matter of finding reasons they can't, but of finding solutions to the problems in the way of making it happen.

The definition of premium brands has changed dramatically. A generation ago, 'premium' meant fancy, expensive, and luxury. Today, 'premium' means transparent, local, complex flavors, natural, and knowing how that product was raised. Consumers are willing to pay for this 'premium' experience. Qualities such as natural, grass-fed, and non-hormone treated cattle (NHTC) resonate with the consumer. A big part of this is animal welfare. BQA is ahead of the curve in the respect. Tyson believes they have the best suppliers in the industry, and these suppliers are doing the right thing for the animals. Sick, unhealthy, or mistreated animals have never been profitable. The consumer has nudged the company to move to BQA certified. By 2020, in addition to suppliers and buyers, all transporters will be BQA trained as well.

Progressive Beef is the next-generation animal well-being program. A group of producers in Kansas, who have worked with Tyson for 25 years, formed the Beef Marketing Group to address a standard of behavior to market their cattle. That group began with the adoption of BQA, and evolved to the development of the Progressive Beef program. The three pillars of the Progressive Beef program are animal well-being, food safety, and sustainability – three significant areas that have been identified as consumer desires as well. E. coli outbreaks in the 1990s drove the food safety aspect to some degree. Reducing pathogens and recalls improves the safety of beef and drives sales. A big part of Progressive Beef, addressing not only food safety but the safeguarding of human health, is the responsible use of antibiotics. In terms of sustainability, the expectation is that program participants will keep the agricultural process sustainable by managing the environment responsibly. Actions such as managing the feedlot lagoon sustain not only the beef industry, but the environment in which producers and their family live.

The Beef Marketing Group gives a lot of tours, and many consumers have visited their feedyards. They talk about Progressive Beef as a way of differentiating themselves from other supplies. Tyson didn't buy the program, but has become a licensure, allowing Tyson to provide the program through a Quality Management System – encouraging all of their suppliers and the rest of the supply chain to join the program. Joining Progressive Beef is not simply a matter of taking a test and getting trained. It is a comprehensive, USDA certified audited program, with third party verification and formal audits to ensure the three pillars are being upheld. The message is that the suppliers care, and the goal is to increase consumer knowledge and trust in Tyson's beef production practices.

DISCUSSION

Consumers demand transparency, and the Blockchain platform can provide that – but the concern from producers is always liability. How do we reassure producers?

Mr. Hueser noted that we need to talk about the things that we're doing right. There is little liability in that, but we in agriculture have never been very good at talking about the good things. We have done an excellent job at educating the consumer about the bad things, which has served to make the consumer suspicious and more demanding of information. We need to shift the conversation.

The fear of liability has been around for a long time, but those fears in many cases are unfounded and exaggerated. With e. coli, there was a fear among producers that feedyards would get blamed for recalls – but that blame never materialized. The responsibility fell on the packer, and history has proven that it's pretty hard to point fingers at producers in those sorts of cases. We need to shift the focus of producers from fear of liability to the possibilities offered by transparency. One aspect, traceability, is not about finding and assessing blame, but rather about opening up market access. Transparency can actually protect the industry.

Mr. Gerber further addressed traceability, noting that the reason we haven't have traceability because the rancher didn't want it. But that tide is changing. The younger generation wants to show off what they have, and traceability offers a way to do that.

Mr. Rodrigue pointed out that we could have a whole conference about liability. However, if we can share information in a trusted manner, and can make that sharing instantaneous, we can move forward and progress. The old-fashioned way won't advance the industry. The consumer is driving this, and without

the consumer we would have no industry. If we can keep that in mind and collaborate to address consumer needs, that enables us to shift the conversation. The delivery of trusted information significantly diminishes liability. IBM is working with some governments that want to bring their whole animal protein industry onto the Blockchain platform. Consumers throughout the world are willing to pay a premium for this information, and that will not only increase margins, but likely increase market share. In China, consumers have shown that they're willing to pay 30% more – that's astronomical for this metric.

Is the Blockchain trust built on the idea that the data is viewable and auditable by all players in the Blockchain?

Mr. Rodrigue addressed this question. Data is not universally accessible. In order for the system to work, it must be – and is – a permissioned network. Several retailers use IBM Food Trust, from Kroger to Wal-Mart, and Tyson supplies all of those retailers. However, the information Tyson shares with Wal-Mart doesn't get seen by Kroger, or any other supplier. Selective permissions allow different users to see different data.

Are we going to run the risk of creating blockchain silos?

Dr. Rodrigue pointed out that the answer to not creating silos is interoperability, and IBM is spending a lot of time working on this idea. Returning to the phone analogy, interoperability is analogous to different phone networks (Sprint, Verizon, etc.) being able to talk to each other. For interoperability to work, it needs to be seamless to the consumer, trusted, and convey instantaneous information.

Who owns the Blockchain and sets permissions? Aggregated data in there would have a huge amount of value. Can't someone somewhere can see everything?

Dr. Rodrigue addressed this question. The person who puts information into the system retains ownership of the information. There are people designated as trust anchors. These are people who understand or give the permissions for who is going to see the data, so that the correct subsets of people see the correct subsets of data. If the trust anchor makes bad decisions or sets incorrect permissions, then there will be erroneous viewing of data. This is the idea of governance, and is one that IBM is working on.

All of the panelists have talked about what customers want, but that's often not the same as what consumers want. For commodity beef there is not a lot of information on the label – how is this information going to make it on the label in the future and is this going to be a branded product?

The two VPs from Tyson agree that that's a good question. Tyson often doesn't promote a packer brand – instead they promote a quality grade, service, and quality. As we move forward with traceability and Blockchain becomes more integral to the industry, Tyson is going to have to share more information, but at this point, they're not sure what this looks like.

How are we currently seeing technology applied?

For Tyson products, the consumer can read QT code on the product and see the whole supply chain. A pilot project on this was very successful, and is going into mainstream production. Another innovation they've explored is a visual journey through the farm that supplied the product, linked to the QR code. If the consumer viewing this journey likes the product, they can tip the specific farmer for that product. This is a way to promote sustainability, as well as address societal issues in poorer parts of the world.

Panel Discussion – Shared Solutions and Responsibilities: Building and Maintaining Trusted Collaboration Between Industry, Academia and Public Health

Nevil Speer, PhD, moderator

Panel:

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne, and Environmental Diseases, CDC*

Mark Gardiner, President, *Gardiner Angus Ranch*

Paul Plummer, DVM, Diplomate ACVIM-LA, Diplomate ECSRHM, Executive Director, *Iowa State University, AMR Research & Education Center*

Public Health Perspective

Dawn Sievert, PhD, MS, Associate Director for Antimicrobial Resistance, *Division of Foodborne, Waterborne, and Environmental Diseases, CDC*

Dr. Sievert is microbiologist and epidemiologist by training, and she has spent the last 17 years focused on antimicrobial resistance. Recently, she has seen a shift in the conversation, with many people coming to the table with outstretched hands instead of folded arms. We are concerned about those we care for. We want to be able to treat both animals and humans. And we recognize that every decision to use antibiotics should be actively evaluated, to ensure that the benefits outweigh the risks, both in terms of the potential to drive antimicrobial resistance and in terms of the ill effects of not treating.

In the course of the past three days of this conference, Dr. Sievert has identified three advancements that have been continually stressed and repeated throughout the conference: diagnostics, genetics, and communication. She is planning to take these ideas back to the CDC, to work on moving them forward, and developing relationships with other agencies to help move them, forward.

There are multiple pressures and drivers in resistance. Humans and animals have complex microbiomes, both commensal and pathogenic, and both carry resistance genes and plasmids. Because of these complex microbiomes and the resistance carried within them, the best protection is to minimize additional resistance acquisitions. In animals, this means thinking critically about animal husbandry and close congregation; in humans, it means focusing on healthcare interactions and, like animals, close congregation. We do know a lot about keeping healthy. Fresh air, clean water, a safe environment, a balanced diet, a healthy microbiome, a strong immune system, infection control, biosecurity, and judicious antimicrobial use when illness does arise are all known factors in maintaining health. We know it is hard to change behavior, to break the cycle and step out of a comfort zone, but advancement doesn't come without that leap. In order to make the most informed decisions about patient treatment (human or animal), we need improved decision-making tools, starting with better, faster, more affordable diagnostics.

There is much in common between human and animal medicine, not the least of which is the need to address antimicrobial resistance through a One Health lens. We can't address just humans, just animals, or just plants and expect to see a difference in circulating resistance - we are all in this together. Each facet needs to make advancements in our own area of expertise, but with ongoing collaboration and openness to ideas outside our realm of experience. There is no simple, easy solution – it will take support,

trust, patience, and perseverance. But building those ongoing partnerships, and getting to know each other better, leads to increased trust. This conversation, and these partnerships, have begun. We just need to continue and expand that growth.

Industry Perspective

Mark Gardiner, President, *Gardiner Angus Ranch*

Every animal is connected to a human. Animal agriculture is about people, having a safe product, and getting together to work towards that safe product. Beef might be the business of Gardiner Angus Ranch, but people are their passion, and they work every day to develop relationships and provide a safe product. The connection between cattle, people, the beef industry, and food is crucial.

The business philosophy at the Gardiner Ranch is to help customers reach their goals. Unhealthy cattle are not profitable for anyone. The ranch has a strong relationship with his veterinarian, and follows the veterinarian's recommendations, in terms of vaccinations, biosecurity, treatment, and really all things animal health. Gardiner Ranch works with national beef. They track their cattle and their customers cattle, and 98% of these cattle grade at choice or better. If customers don't grade 20% of cattle prime or above, they have a conversation about how to improve. Incentives are useful tools to get producers to do the right things. The best price comes with health and good genetics. You can build demand with trust, transparency, and a better product. From 1998 through 2018, Gardiner Angus Ranch customers marketed 92,000 head through U.S. Premium beef, receiving an average premium of \$94 per head, totaling \$8,676,420!⁵⁸ Healthy cattle with predictable genetics are profitable, and generate satisfied customers.

On March 6, 2017, wildfire struck the ranch, and 500,000 acres of 600,000 acres burned. But the ranch had capital in people and relationships. The bank offered a special line of credit and reduced the interest rate. American agriculture supported them. This is what's important: people matter; relationships matter; never stop teaching or learning.

Can we get better at what we do? Can we leave this place better than we found it? Absolutely

Academia Perspective

Paul Plummer, DVM, Diplomate ACVIM-LA, Diplomate ECSRHM, Executive Director, *Iowa State University, National Institute of Antimicrobial Resistance Research & Education (NIAMRRE) Center*

Alexander Fleming predicted and demonstrated the issue of antibiotic resistance even before the release of the first ever antibiotic, penicillin. The issue of resistance is not new. Do we have the tools we need to make the decisions to slow it down? Do we have the science, education, knowledge and resources?

"If we don't tackle this threat with coordinated action, antimicrobial resistance will take us back to a time when people feared common infections and risked their lives from minor surgery." *Director General of WHO*

In 2015, a group of researchers from Iowa State began to recognize that antimicrobial resistance (AMR) was a big issue. They began to build a consortium, inviting University of Nebraska – Lincoln, University of Iowa, Mayo Clinic, the USDA National Animal Health Center, and commodity stakeholders. The goal of this

consortium was to generate evidence-based antibiotic stewardship practices. The focus was on One Health – working outside silos together, to facilitate economically sound policy development. The consortium grew to a 150-plus-member regional group. At about this time, and AAVMC and APLU task force was in the process of evaluating what actions would have the most potential to be transformative in the fight against AMR. The task force identified formation of National Institute of Antimicrobial Resistance Research & Education (NIAMRRE) from this consortium as a priority transformative action.

Since late July 2018, members have been working to ramp up the regional consortium into a national institute. The mission of NIAMRRE will be to provide local, national, and international leadership in combating antimicrobial resistance; generate evidence-based solutions for antimicrobial stewardship; contribute to improvements in the health of animals, humans, and the environment (One Health); and facilitate economically and socially sound policy development and implementation. The vision is to drive collaborative and integrative research, education, and engagement to solve AMR challenges and benefit society using a One-Health approach.

The structure of NIAMRRE is complicated (Figure 18). The group is working on core focus areas, including epidemiology study design and data analysis; economic and social sciences; and laboratory core and virtual biorepository. The epidemiology and analysis core ensure the science generated is curated and not misleading, and the laboratory core will work to standardize lab work.

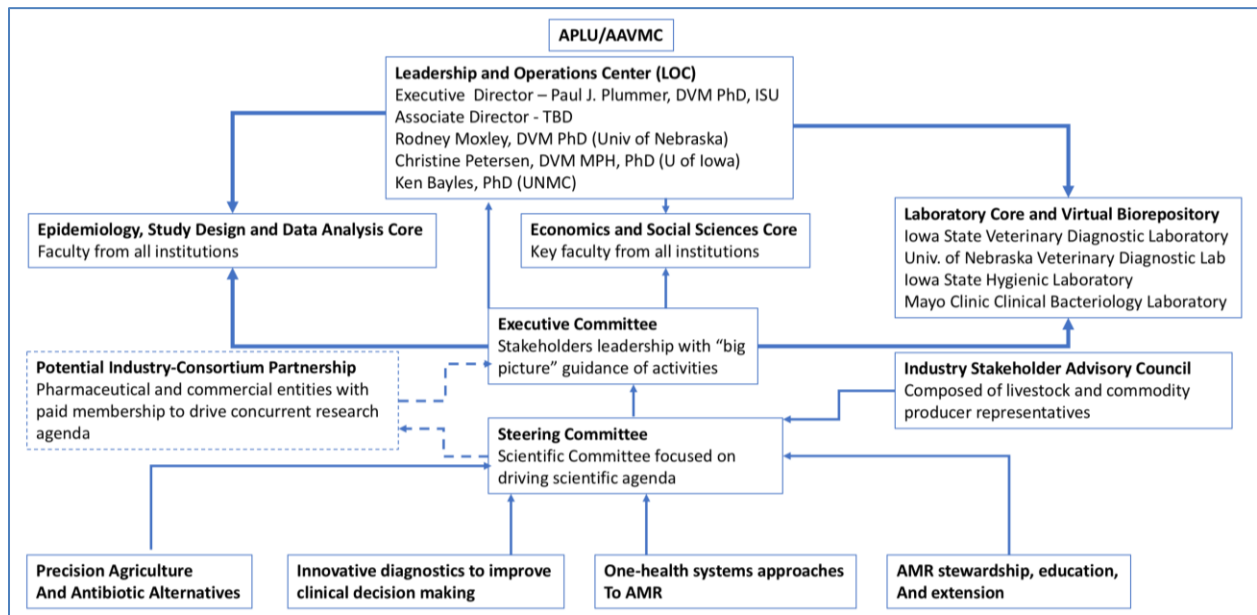


Figure 18. NIAMRRE Structure⁵⁹

NIAMRRE is building teams with proven expertise, to collaboratively lead local, national, and international antimicrobial stewardship efforts. It is an inclusive institute, independent of host and member institutions, and incorporating members from academia, community, and industry. The goal of this inclusivity is to identify shared, collaborative solutions that work for all members. Finally, NIAMRRE strives to generate accessible data, while maintaining confidentiality and liability protections.

NIAMRRE is first focusing on four main themes to foster antimicrobial stewardship: using precision agriculture approaches to animal agriculture management; improving clinical design through innovative,

rapid diagnostic testing capability; development of a systems approach to comprehensive monitoring; and promotion of antimicrobial stewardship through outreach and training. (Figure 19).

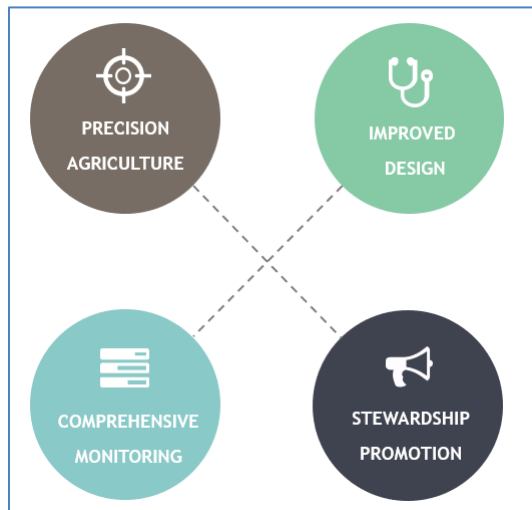


Figure 19. Four main stewardship themes of NIAMRRE⁶⁰

The next steps in the NIAMRRE development process are to ramp up the advisory committee, hire staff, stakeholder engagement to drive agenda and membership development, and identification of funding sources. Finally, NIAMRRE is becoming very active in governmental affairs, developing talking points in participating regularly in government discussions.

DISCUSSION

Mr. Gardiner was asked about his producers. Sometime producers get divided instead of joined in common progress – how do you deal with this with your producers?

Communication and transparency are key. Secluded, independent cattlemen tend to get secluded in their thoughts, and communication and collaboration is crucial to maintain progress. Mr. Gardiner believes is communicating with all partners, as well as potential adversaries that could affect the business. He’s taken a lot of criticism for communicating with the World Wildlife Fund, but he was able to open up communications with them by telling them he was afraid of them, and in the course of that communication, he has found out how professional they are and has been able to work with them.

Dr. Plummer was asked about funding for NIAMRRE. How will funding increases for NIAMRRE occur, and how can we help?

NIAMRRE membership has been working hard to think about funding mechanisms and sustainability. They are looking at a diversified portfolio. Members and entities that want to participate would have financial buy-in – not necessarily a big share, but this buy-in would ensure that people who have a vested interest in success have a financial stake in it as well. They are working on how to structure the buy-in process as win-win for the stakeholder and for sustainability. Another portion of funding will come through the membership process. Other streams of potential funding that have been identified include philanthropic avenues and advocating for appropriations to support their unique multidisciplinary multi-

institutional approach. Much of the initial governance is modeled on an NIH-funded antimicrobial resistance leadership group focused on human medicine.

Cheryl Stroud of the One Health Commission asked Dr. Plummer about bringing the College of Design in to develop infographics and other outreach materials.

The College of Design made Dr. Plummer's PowerPoint slides (see Figure 19 for an example). They became involved early in the consortium. For outreach, communication is huge, and in addition to the College of Design, the College of Journalism is involved. This has been a huge help in getting the word out.

Andy McCabe, the CEO of the Association of Veterinary Medical Colleges commented that before the institute, there was extensive research being done in these areas.

One pathway forward was just to continue along that road – but the consortium saw the opportunity to consolidate and benefit from multidisciplinary synergy. It's all about relationship-building and partnerships. Connections have been made that no one had thought of before, like that with the College of Design. This is an excellent opportunity to move forward with the One Health approach.

Wrap Up

Nevil Speer, PhD, Chairman of the Board, *National Institute for Animal Agriculture*

Antimicrobial resistance is a paradox. We can't stop using antimicrobials because they're incredibly effective, and without them, the practice of modern medicine collapses. However, every use of antimicrobials contributes to antibiotic resistance. Ideally, practitioners of both animal and human medicine should use antibiotics when necessary, but not when they're not necessary. For veterinarians, antibiotics are really animal welfare drugs. We have the responsibility of judicious usage, but also the responsibility to treat animals when they're sick, just as human physicians have a responsibility to treat humans.

Animal agriculture is the foundation of civilization. Antimicrobial resistance is a massive problem, and if we are too sequestered in our silos, it is a problem that is impossible to solve. Human medicine, the pharmaceutical industry, veterinary medicine, and animal agriculture all must work together to find solutions that work for animals, people, and the environment.

Footnotes

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- ² Image courtesy of Michael Apley
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- ¹⁶ Power of Meat – 2016
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- ¹⁹ Data available at <https://www.ncbi.nlm.nih.gov/pathogens/>
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