

Discussions of the Antimicrobial Use Task Force Executive Summary

Background

In the late 1990s, the AVMA recognized the potential for development and transmission of resistance as a result of veterinary antimicrobial use. The AVMA believed veterinarians should strive to optimize therapeutic efficacy and minimize resistance to antimicrobials to protect public and animal health, which prompted the AVMA to form the Steering Committee on Judicious Therapeutic Use of Antimicrobials (SCJTUA) in 1998. The outcome of the SCJTUA was the current AVMA policy titled "Judicious Therapeutic Use of Antimicrobials" and species-specific policies similarly titled also addressing judicious use.

Current Regulatory Oversight and Legislative Activities

The Food and Drug Administration (FDA) regulates the classification of antimicrobials in veterinary medicine. Antimicrobials are approved by the FDA for use in food animals for the therapeutic purposes of disease treatment, control, or prevention or for production uses such as improved rate of gain (growth promotion) and feed efficiency. Antimicrobials are further regulated by being classified as over-the-counter, prescription, or veterinary feed directive products for marketing and availability. Both legislation and the agency's initiatives suggest forthcoming additional restrictions on antimicrobial use in veterinary medicine.

AVMA Policies and Recent AVMA Statements

AVMA's current policy is very clear in terms of therapeutic uses of antimicrobials. The FDA, AVMA, and Codex Alimentarius Commission (the international standard setting body for food safety) define therapeutic uses as treatment, control, and prevention. While some groups use terms such as "non-therapeutic" or "sub-therapeutic," the AVMA has refrained from using such terminology because these terms are ill-defined and used inconsistently. The use of antimicrobials in production as well as the level of veterinary oversight that is needed for any antimicrobial use continues to be heavily debated. Recognizing that the scope of these debates is not limited to veterinary oversight of therapeutic uses of antimicrobials but extends into production uses, the AVMA Executive Board created and charged the Antimicrobial Use Task Force with clarifying the role of the veterinarian and level of involvement in all uses of antimicrobials.

Development of the Antimicrobial Use Task Force and Its Charge

In 2009, Resolution 3 (see Appendix A) was introduced at the 2009 Annual Session of the House of Delegates to revise the Judicious Therapeutic Use of Antimicrobials Policy. The revision, if approved, would state that one of the principles of judicious therapeutic use is that judicious use of antimicrobials should meet all requirements of a veterinarian-cl-

ent-patient relationship. The House of Delegates' Reference Committee #7 (Scientific Activities) recommended and the House approved referral of Resolution 3 to the Executive Board, which approved formation of an Antimicrobial Use Task Force (AUTF). The scope of the AUTF, as described in the entity description (Appendix B), was broadened by the Executive Board from that recommended by the HOD in order to address the veterinarian's role in *all* uses of antimicrobials, specifically to include the production uses of antimicrobials for growth promotion and feed efficiency.

The Task Force met twice in Schaumburg, Ill. A professional facilitator was invited to the second meeting to ensure balanced participation and assist in gaining consensus. Following two in-person meetings, two conference calls, the establishment of a subcommittee, and additional conference calls, the Task Force chair and staff provided a status update to the EB at its April 2010 meeting. The EB expressed its desire for a narrative report to be written by staff and available by the June 2010 meeting. Following receipt of the Task Force's report, the EB will then forward its recommendation to the House of Delegates.

AUTF Discussions

The Task Force attempted to clarify the veterinarian's role and level of involvement in all uses of antimicrobials. In its discussions, some members of the Task Force stressed the importance of recognizing that over-the-counter availability of antimicrobials does not equate to a complete lack of veterinary oversight of these drugs. Veterinarians are often involved in the use of antimicrobials, but the extent of involvement has been difficult to define and qualify. Given the shortage of food animal veterinarians, some members of the Task Force believed that over-the-counter availability of antimicrobials was essential in ensuring animal health, especially for therapeutic uses.

Conversely, concerns were discussed surrounding over-the-counter antimicrobial availability and growth promotion/feed efficiency uses in particular, and the perceived ability for the product to be used fairly arbitrarily and therefore injudiciously. Additional concerns surfaced regarding the use of antimicrobials in veterinary medicine that have human applications and were followed with suggestions for required veterinary oversight for those antimicrobial products. However, without clearly defining oversight, the idea could not be explored any further.

After thoughtful discussions on veterinary oversight, the Task Force universally agreed, "Veterinarians should be involved in the decision-making process for the use of antimicrobials regardless of the distribution channel through which the antimicrobial was obtained."

Following its discussions on the use of antimicrobials for growth promotion or feed efficiency, members of the AUTF came to consensus on several points:

- Veterinarians should be involved in the use of antimicro-

bials. Veterinarians should strive to improve their relationships with producers and clients as well as explore ways to better educate and communicate information on antimicrobial use.

- Although discussed and suggested by some members, there was no recommendation for additional veterinary supervision or oversight of antimicrobial use by those responsible for animal care. It was agreed that “oversight” could imply and engender additional regulation and responsibility without improving actual overall stewardship of antimicrobial use. Certain antimicrobials have no potential to impact human resistance patterns and therefore should not require additional veterinary oversight. Additionally, these products should be allowed to be used according to their labeled indications (including growth promotion and feed efficiency).
- It has been theorized that antimicrobials labeled for growth promotion or feed efficiency prevent subclinical disease and allow the animal to reach its full growth potential. Many agreed that in principle (with logistic barriers aside) drugs in this group that have been shown to have therapeutic efficacy (disease treatment, control, or prevention) should be reassessed and, if appropriate, relabeled accordingly. It was acknowledged that for disease prevention, the specific disease being prevented may not be easily identified from among the many that are probable and the mechanism by which antimicrobials promote growth could remain unknown. There was also the understanding that over-the-counter availability is not necessarily equivalent to a lack of veterinary oversight.
- Investigation of over-the-counter antimicrobials that potentially have a demonstrable human health risk is warranted and could be evaluated by a risk assessment.
- Demonstration of significant human health risk associated with over-the-counter availability of antimicrobials should trigger a requirement for additional veterinary supervision.

Improving Veterinary Stewardship

Recognizing that the charge of the AUTF was to evaluate veterinary oversight of all uses of antimicrobials, the AUTF explored ways to improve veterinary “stewardship.” Because no single definition of the term “oversight” was agreed upon, the Task Force had previously agreed to use the term “stewardship” for both its initial brainstorming sessions and its subsequent discussions.

While recognizing that no consensus was achieved regarding increased oversight, four processes that *might* enhance veterinary oversight emerged during discussions:

- Availability of antimicrobials only by prescription—A prescription-only process would require all antimicrobials to be authorized under a veterinary prescription or VFD. The current VFD process would require significant changes (such as electronic VFD forms, further education of veterinarians on the VFD process, and addressing other logistic barriers) to succeed as a mechanism to enhance veterinary stewardship. Additionally, the definition of VCPR may need to be further clarified and consistently

applied to other prescription products in addition to VFDs and extralabel drug use.

- Certification requirement for access to antimicrobials—Several ideas regarding certification emerged, including various types and levels of certification:
 - Similar to the pesticide applicator licensure process, an antimicrobial use licensure process could allow a producer to purchase antimicrobials after meeting certain requirements.
 - Veterinarians could be certified to indicate that there was a certain level of understanding regarding the judicious use of antimicrobials.
 - Producers could be certified by their veterinarian, indicating that there is a valid VCPR, and some sort of documentation could be issued to allow purchase of antimicrobials (nonspecific to a drug).
- Tiered approach—This approach would endorse a prioritization of important antimicrobials (in human health) and increase the levels of veterinary oversight accordingly.
- Electronic/telemedicine approaches—Electronic medical records, diagnostic reports, and other electronic media could be used to supplement on-farm visits by the veterinarian and still satisfy the requirements of a VCPR.

Status of the Science of Antimicrobial Resistance

The Task Force agrees that the use of antimicrobials can select for altered populations of bacteria and that resistant bacteria can be transmitted from animals to humans in several ways (including via food). Although the use of antimicrobials in humans is the major driver of human antimicrobial resistance, whether or not illness in humans due to resistant bacteria can also be linked to growth promotion or feed efficiency uses of antimicrobials in food animals continues to be debated. Some studies suggest a relationship between such use in food animals and human resistance trends, while other studies and risk analyses find no such relationship.

The AUTF came to consensus on the need for an evaluation and continued monitoring of health effects of veterinary-administered antimicrobials on both veterinary and human therapeutic efficacy. Therefore, the Task Force would be supportive of AVMA’s creation of an entity charged with performing a structured and systematic review of relevant data related to antimicrobial use in animals and its impact on animal and public health, recognizing that this undertaking would require significant resources.

Outcome

The Task Force discussed a wide variety of issues relative to its charge and objectives. The members agreed that there is a significant lack of data and a lack of understanding among the veterinary profession as well as the public and other stakeholders regarding the use of antimicrobials in food animal production. These gaps, coupled with inconsistent information from varying sources, clouds the decision-making process. Data gaps and differing interpretations drive distinct causal attributions and potentially contrasting conclusions.

While attempting to characterize the level of veterinary involvement as mandated by its charge, the Task Force found that terms such as veterinary “involvement,” “oversight,” and “stewardship” had no clear definitions. The only terms clearly understood and agreed upon by the Task Force are defined in federal regulations.

For example, “over the counter” refers to drug availability, not veterinary involvement. Prescription-only products place additional restrictions on drug availability on the prescription or other order of a licensed veterinarian. The Task Force discussed that restriction of antimicrobials to prescription-only use does not guarantee improved veterinary involvement or a valid VCPR, nor does it guarantee an improvement in judicious uses or resistance levels. Furthermore, attempts to require a veterinary prescription for all antimicrobials has the potential for multiple challenges and unintended consequences. Regarding stewardship, the Task Force could only agree that veterinarians should be involved in the use of antimicrobials but it could not characterize the level of involvement needed.

As previously stated, antimicrobial growth promoters are available as over-the-counter products and, as such, are sometimes perceived as an injudicious use of antimicrobials. Yet, some would argue that over-the-counter availability is not equivalent to lack of oversight and thus not necessarily injudicious. Along those same lines, as judicious therapeutic use has been defined by AVMA to only include treatment, control, and prevention, some may interpret that to mean growth promotion and feed efficiency uses are not judicious because they are excluded from the definition of therapeutic. An alternative interpretation would be that growth promotion and feed efficiency uses are simply not therapeutic, but no judgment is made on the judiciousness of such uses.

There were also a few philosophical components to the debate on the science of growth-promoting antimicrobials and how they should be used:

- One of the components hinges on the burden of proof. If clear evidence illustrating the harm to human health cannot be proven or if the harm to humans is insignificant, then continued use is appropriate given the societal

benefits of these products. Converse views were relayed among the Task Force, stating that if clear evidence illustrating no harm is lacking, then continued use still is inappropriate given the potential for human harm, regardless of the benefits.

- A second component surrounds the perceived quality of evidence. While there is a body of evidence that supports one position, or the opposing position, or even both, much of the end result is dependent upon an individual’s interpretation of the science and the preferred strategies. Attempts to remove growth promotion uses were seen by some as politically driven and not based upon scientific evidence, thus potentially secondarily impacting the ability to use antimicrobials for therapeutic purposes. Others among the Task Force indicated acceptance of the available data and viewed removal of these products as a logical way forward.

Conclusion

The AVMA Antimicrobial Use Task Force (AUTF) was convened to evaluate all uses of antimicrobials and clarify the veterinarians’ role in those uses. Following two in-person meetings and many conference calls, the Task Force identified that the issues surrounding antimicrobial use in veterinary medicine are multifaceted, involving highly complex information as well as a multitude of scientific unknowns. Yet, the Task Force also recognized a less technical component of the issue wherein learned professionals can evaluate the same data and come to differing conclusions. The Task Force offered an opportunity for exchange of information, and the members gained greater understanding for differing perspectives. The purpose of the report of the AUTF is to share the breadth of complexity of the issues and identify the many perspectives.

Upon the AUTF’s submission of its report to the EB, the EB will determine and forward its final recommendation to the House of Delegates for consideration at the 2010 Annual Session of the AVMA.

The AUTF will sunset at the close of the 2010 Annual Session of the House of Delegates.

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