Risk Assessment and Cost-Benefit Analysis Issues Associated With Antimicrobial Use in Food Animal Production

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Introduction

Risk assessment and cost-benefit analysis are two quantitative tools used in risk analysis and science-based decision-making. Generally, risk analysis is considered to be comprised of: 1) risk assessment, the process of identifying a hazard and evaluating the risk as the likelihood and magnitude of the consequences of an adverse event; 2) risk management, the pragmatic decision-making process concerned with regulating the risk; and 3) risk communication, the open exchange of information and opinions about risk, leading to better understanding and better management decision-making[1]. Cost-benefit analysis has been used in many fields and is currently used by government agencies to measure the impacts of alternative options in risk management decision-making.

The controversy regarding the public health risks associated with the use of antimicrobials in food animals has continued for over 25 years. This paper will posit, for discussion and dialog purposes only, one avenue by which a risk analysis of this issue might be developed to aid in assessing this controversy.

Risk Assessment

Risk assessments are best conducted by interdisciplinary teams, and in the case of antimicrobial use in food animal production, this team should include biological scientists, clinicians, chemists, toxicologists, and representatives from any other relevant science. Risk assessors and risk managers plan the assessment process together and determine the scope and scale of the assessment. The combination of assessors and managers assures that the risk assessment is conducted with management objectives in mind.

The risk assessment team formulates the issues to be addressed in the assessment. Key objectives of the assessment are to identify the risks associated with the use of antimicrobials in food animal production and determine the magnitude of each identified risk.

Risks associated with the use of antimicrobials:

Identified risks may include: development of resistance by human pathogens; development of resistance by animal pathogens; antimicrobial residues on food products; changes in the distribution of pathogen populations; and antimicrobials in animal wastes. Of foremost concern, undeniably, is the potential for development of antimicrobial resistance by human pathogens. The mechanisms by which this might occur have been examined and addressed extensively in the literature [2,3,4].

There may be risk differences with subtherapeutic versus therapeutic use of antimicrobials in food animal production. Differences in risks may depend on the pathogen type and class of compound, and may be related to the extent of resistance development, and the quantities of residues and pathogens found on food animal products and in food animal waste. Animal waste concerns are significant in the environmental arena, particularly with regard to organic farming practices.

Magnitude of identified risks:

Determining the probability of occurrence and the magnitude of each of these potential risks may prove to be very difficult, and in some cases, impossible due to the lack of information. Ideally, identifying the pathways of exposure to the risks combined with dose-response curves developed under well-controlled laboratory conditions would lead to quantitative estimations of risk. There are also confounding factors which should be considered to evaluate the relative risks associated with antimicrobial use in animals, particularly, how to compare and measure resistance that is developing as a result of antimicrobial use in humans. Data on this confounding factor are limited. In addition, data are limited on antimicrobial consumption, antimicrobial use in agriculture and the prevalence of resistant zoonotic pathogens in food animals and food of animal origin [5]. In general, quantification of the risks associated with the use of antimicrobials in food animal production may not be possible. In this case, a qualitative evaluation of risk may be all that can be presented to the risk managers or decision-makers at the present.

Risk Management

There are several regulatory alternatives available to diminish or control present and predicted risks associated with the use of antimicrobials in food animal production. The standard "default" option is "no change" in current licensing and registration of antimicrobials for this use. The

other option involves various combinations of restricting or eliminating subtherapeutic and therapeutic uses. Within this option is a spectrum of combinations of restrictions based on class of compound and pattern of use. There are trade-offs associated with each unique combination.

The overarching issues of risk substitution or trade-off in changes in antimicrobial use include, but are not limited to: 1) human health and welfare; 2) animal health and welfare; 3) quality and quantity of animal-derived protein; and 4) environmental concerns.

In the 1997 Report of the WHO Meeting, "The Medical Impact of the Use of Antimicrobials in Food Animals," it was stated that, "In light of shrinking public resources and the increasing need to conduct scientifically-substantiated risk assessments for prioritizing public health action, national policies on the use of antimicrobials in animals must balance the possible benefits to livestock production against the medical risk and public health consequences deriving from their use." The role that antimicrobials play in maintaining our current animal production practices has not been fully elucidated or quantified. The United States has a high quality, low cost, consistent supply of animal-derived protein as a result of these production methods. In addition, it has been proposed that current intensive production practices have reduced the environmental "footprint" of livestock production, freeing up land resources for other uses[6]. The use of antimicrobials in animal feed has reduced the toxic pollutant content of wastes, lowering methane, urea and ammonia. However, the use of antimicrobials also potentially changes the pathogen types and loads in wastes that may eventually be applied to crops for human or animal consumption. An associated concern is the impact on environmental flora that may result from antimicrobial or metabolite residues in animal wastes. Environmental concerns associated with the use of antimicrobials in food animals have not received comprehensive attention.

As previously mentioned, cost-benefit analysis (CBA) has long been used as a tool to aid in risk management decision-making and is now required in regulatory impact analyses of many Federal agencies. CBA allows for consideration of the economic impacts and the distribution of costs and benefits associated with alternative regulatory options. CBA does <u>not</u> serve as a sole decision criterion. What CBA does provide is a basis of comparison, in a common metric (i.e., dollars), of alternative options <u>within</u> a regulatory decision.

Factors that may be evaluated in a cost-benefit analysis of regulatory alternatives for antimicrobial use in food animal production include, but are not limited to: 1) human health care costs; 2) food availability for human consumption[7]; 3) food prices[7]; 4) production costs[7]; 5) level and distribution of farm income[7]; 6) trade impacts; 7) cost of new drug development; and 8) environmental impacts. The economic impacts of each of these factors, and the magnitude and distribution of the impacts, will differ for each regulatory alternative or combination considered.

Risk Communication

Risk communication is a tool to provide a forum for interchange among all those concerned about the risks identified in the assessment. It is important, for this publicly and politically sensitive issue, that we promote communication between health scientists, industry, government, consumer groups, and other interested parties in order to improve the decision-making process.

Summary

The use of antimicrobials in food animal production is a complex issue that needs comprehensive consideration. All perspectives are needed to make informed decisions regarding this issue. Risk assessment, risk management and risk communication, the triad of the risk analysis process, can promote better decision-making through communication amongst all parties, scientifically-sound characterization of the risks, objectivity, and transparency in the decision-making process.

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