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RISK ANALYSIS

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Risk analysis has emerged as an important tool for epidemiologists, a tool for supporting rational decision-making in the face of uncertainty and limited animal and human health resources. However, risk analysis, like case-control studies or cost-benefit analyses, represents a spectrum of applications which allow customization to fit the situation. Furthermore, the epidemiologist faces some unique challenges in communicating the process of risk analysis to potentially affected parties, including producers, politicians and the media.

We all practice risk analysis; we all make decisions after weighing the potential hazards, the likelihood of their occurrence, the implications should they occur, and the alternatives we have at our disposition. We personally examine both absolute risk levels and relative risks. We also incorporate these risk analyses into our personal cost-benefit analyses, ie, how we spend our money. In fact, most of us are very good at risk analysis or we wouldn't be alive today to enjoy our families, careers and accomplishments. Unfortunately, much of this "native" risk analysis is unconscious or at best, subjective and qualitative. Consequently, the methodologies that we successfully employ personally are difficult to pass on to the next generation or to apply to new situations where we need to explain or justify our decision-making process.

Systematic approaches to risk analysis have emerged from a number of fields, including engineering, manufacturing, toxicology, economics, the insurance industry and the exploration of space. Perhaps the first widely publicized application involved the nuclear power industry. Risk assessments have played an increasingly important role in the design and operation of nuclear power facilities and the policy response to accidents such as Three Mile Island and Chernobyl. Each of these applications of risk analysis has a slightly different set of guidelines and different applications. So why has risk analysis emerged as an increasingly important tool for epidemiologists and economists interested in veterinary medicine and animal health?

Two events stand out in explaining the increasing visibility of risk analysis for veterinary medicine: the emergence of Bovine Spongiform Encephalopathy (BSE) and the completion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). The BSE epidemic and potential linkage to human health is perhaps the most visible application of veterinary epidemiology in our lifetimes. As the epidemic grew, epidemiologic studies pointed to ruminant-derived meat and bone meal as the common source and set the stage for the regulatory actions which have proven effective in controlling the disease in cattle. Risk analyses, mostly qualitative in nature, were completed by countries anxious to avoid BSE in their own cattle populations. These analyses examined both the risk of importing BSE from affected countries and the risk of BSE occurrence domestically as a result of indigenous factors. The suggestion of potential links to human health has stimulated intense risk analyses activity worldwide on the implications of BSE contamination of the human food chain and on the alternatives for destroying BSE- affected or exposed animals and animal products.

The second major stimulus for risk analysis was the completion of the Uruguay round of the General Agreement on Tariffs and Trade (GATT) which led to the formation of the World Trade Organization (WTO). The Uruguay round considered agricultural trade for the first time and formulated guidelines for the development of animal health policies affecting trade (sanitary standards). These new guidelines, which came into effect in January of 1995, codified the importance of science as the foundation for sanitary requirements. Further, risk analysis was adopted as the tool for justifying animal health standards on a science basis. Countries were instructed to base their animal health import requirements on science as documented by risk analysis. The GATT encouraged harmonization of sanitary measures and recognized the International Office of Epizootics (OIE) as the global animal health standards. In addition, the GATT introduced the concepts of equivalence and transparency, emphasized for documented risk analyses in support of sanitary requirements. Risk analysis in the animal health arena is a logical outgrowth of epidemiology.

Risk analysis represents the application of our studies of the patterns of health and disease in populations by incorporation of this information into a decision-support framework. Risk analysis for animal health and disease

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incorporates systematic approaches to outlining agent, host and environmental risk factors, followed by a ranking or quantification of the likely contributions to overall risk from each of these factors. Just like other epidemiologic tools, risk analysis can utilize qualitative and quantitative methods. Risk analyses often use a combination of methods, as quantitative data may not be available for describing some key hazards. Nevertheless, approaches have been developed to provide numerical estimates which also incorporate the uncertainty of the estimators.

Risk analysis comprises hazard identification, risk assessment, evaluation of implications, risk management and risk communication. Hazard identification involves listing all of the things that might go wrong, ie, the hazards. Subsequently, risk assessment attempts to estimate the likelihood that each hazard will occur. Risk assessment is complemented by an evaluation of the implications should the hazard occur. Risk management involves outlining the options available to avoid hazards or minimize risks. The communication component of risk analysis occurs throughout the other processes by involving the affected people, organizations and industries. Usually risk analysis is not restricted to an assessment of health or disease outcomes alone, but is accompanied by some economic analyses, such as a cost-benefit analysis linked to the risk management options. Hazard identification is perhaps the easiest of these risk analyses processes for most people to understand and consequently is widely practiced.

Hazard identification involves listing of all the possible adverse outcomes for the disease situation under consideration. The process frequently starts with a subject matter expert outlining the worst case scenario or all of the possible events which might lead to disease. A scenario tree or flow diagram may be generated to demonstrate the relationship between specific hazards and the disease in question. The scenario tree allows the risk analyst to incorporate complex situations where a single hazard may be necessary but not sufficient to cause disease. The software package HandiStatus incorporates a hazard identification module to facilitate import risk analysis. The user defines the animal species and product involved plus the originating and receiving country. Based on the reported animal health status of the exporting and importing country, the software generates a list of potential diseases of concern for that animal or product. Unfortunately, hazard identification is frequently misrepresented as risk assessment, creating the impression that all of the hazards are imminent or of equal likelihood of occurrence. Hazard identification may not receive all of the attention it deserves because of the perception that the process is easy. However, if the risk analysis proceeds without a full accounting of the potential hazards, then the results may be flawed and the proposed risk management strategies ineffectual.

Risk assessment involves ranking or quantifying the likelihood that the hazards occur. Most risk assessments are qualitative, ie, hazards are ranked in general terms such as very likely, possible, or highly unlikely. The two applications of risk assessment most prevalent in veterinary medicine are Hazard Analysis-Critical Control Point (HACCP) and import risk analysis. Broader risk analyses in support of public policy decisions are becoming more frequent.

The HACCP concept was developed in the 1970's by the food industry to assure product safety. The HACCP process involves a systematic outlining of food production system from the raw materials to the consumer product in order to determine which procedures are most critical to controlling food safety. Beginning with a flow diagram of the food manufacturing process, the HACCP plan identifies potential microbial hazards and then examines which parts of the manufacturing are most critical. The HACCP concept also involves documentation of critical control points, incorporating quality assurance concepts to document the process. The HACCP concept has been applied by public health epidemiologists to the investigation of foodborne disease outbreaks.

Techniques for import risk analysis have been encouraged by the Uruguay round of the GATT. The OIE has outlined general principles for import risk analysis in the Animal Health Code. The OIE quantitative risk assessment model involves two factors: the probability of agent entry and the probability of exposure in the importing country. The probability of agent entry is defined as the likelihood of an infected animal or animal product entering the importing country. Estimation of this probability involves country factors for the exporting country and commodity factors for the animal or animal product being traded. The probability of exposure in the importing country relates to the nature of the agents of concern, the intended use of the importation and the human and animal demographics of the importing countries. These approaches to import risk analysis have been developed over the past 10 years through multinational collaboration.

Risk analyses to support domestic public policy are less standardized. Risk analyses of potential environmental impacts of animal diseases or their control have emerged in a number of countries, such as the current assessments of the risks associated with incineration of BSE-affected cattle carcases in the United Kingdom. Risk analyses of tuberculosis helped the United States formulate policies with regard to cattle feeding and movement practices.

Quantitative methods for describing the mathematical likelihood of the disease occurrence are gaining increasing attention. Software programs such as @RISK append to spreadsheets and allow manipulation of large amounts of data with complex scenario trees. These software packages facilitate uncertainty analyses, the incorporation of estimates of the uncertainty of the knowledge of specific data points into the risk assessment. New software also allows sensitivity analysis, consideration of the relative sensitivity of the scenario tree to variations in one specific factor or the implementation of specific risk management strategies. While generating numerical estimates of risk is inherently attractive to many, these quantitative risk analyses must be used with great caution. In general, the relative risk estimates are more useful than the absolute risk estimates. The absolute estimates are very model dependent and may create a false sense of security that we can state with certainty the risk.

Risk management is the obvious raison d'etre of risk analysis. Managing risk becomes more practical when all of the hazards are known and their contributions to the overall risk can be estimated. Incorporating economics into evaluation of risk management options allows decision-makers to focus on strategies where the greatest gains can be made at the least costs. Risk analyses also support holistic approaches to risk management where all of the potential hazards can be considered simultaneously.

Risk communications completes the risk analysis process and is perhaps the most important and most neglected. Few people fully understand the concept of risk, therefore successful risk communication is fraught with difficulty. All too often, the hazard identification and risk assessment are completed and the risk management decisions finalized before the affected parties are informed, eg, the "Decide, Announce, Defend" strategy. However, successful risk communication can involve the affected parties in all stages of the risk analysis. Each of us can contribute to the hazard identification. Once all of the affected parties are involved, they will take greater interest in the risk analysis and assume partial ownership for the outcome. Hazard identification is a very robust process, allowing all potential hazards to be included, even if the likelihood of their occurrence is minute. Successful risk communication may well be one of the most difficult challenges facing veterinary epidemiologists in the next decade.

In summary, risk analysis is a common sense approach to characterizing potential hazards and their likelihood of occurrence. Understanding all of the contributors to the overall risk facilitates cost-effective management strategies. Finally, involving all of the affected parties in the process increases the opportunity for successful risk management.