Quantitative Risk Assessment: An Emerging Tool for Emerging Foodborne Pathogens

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New challenges to the safety of the food supply require new strategies for evaluating and managing food safety risks. Changes in pathogens, food preparation, distribution, and consumption, and population immunity have the potential to adversely affect human health. Risk assessment offers a framework for predicting the impact of changes and trends on the provision of safe food. Risk assessment models facilitate the evaluation of active or passive changes in how foods are produced, processed, distributed, and consumed.

The changing epidemiology of foodborne diseases is a result of complex interactions and changes in pathogens, foods, food distribution, food consumption, and population immunity (1-3). Predicting the impact of a trend in one part of the food continuum presupposes understanding of the whole system. Aspects of the food processing and distribution system can amplify or attenuate the trend as it grows into a potential health hazard. While a full understanding of pathogen contamination, infection, and survival is difficult, a systematic approach to assessing the impact of the pathogen on health may improve the quality of public health decisions (4,5).

Quantitative risk assessment is a possible approach for designing programs to address emerging foodborne diseases. The use of risk assessment in environmental toxicology illustrates the potential advantages of applying quantitative risk assessment in a new field.

Risk Assessment Defined

The essence of microbial risk assessment is describing a system in which a microbial hazard reaches its host and causes harm. Risk assessment consists of four steps: hazard identification, exposure assessment, dose-response assessment, and risk characterization (6). The knowledge in each step is combined to represent a cause-and-effect chain from the prevalence and concentration of the pathogen to the probability and magnitude of health effects. In risk assessment, risk consists of both the probability and impact of disease. In this way, risk reduction can be achieved in either dimension—by reducing the probability of disease or by reducing its severity.

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Hazard Identification

In hazard identification, an association between disease and the presence of a pathogen in a food is documented. The information may describe conditions under which the pathogen survives, grows, causes infection, and dies. Epidemiologic and surveillance data, challenge testing, and scientific studies of pathogenicity also contribute information. Data collected during hazard identification are later used in exposure assessment, where the impact of processing, distribution, preparation, and consumption of the food are incorporated.

Exposure Assessment

Exposure assessment describes the pathways through which a pathogen population is introduced, distributed, and challenged in the production, distribution, and consumption of food. This step differs from hazard identification in that it describes a particular food-processing pathway. Depending on the scope of the risk assessment, exposure assessment can begin with pathogen prevalence in raw materials (e.g., a "farm-to-fork" risk assessment), or it can begin with the description of the pathogen population at subsequent steps (e.g., as input to a food-processing step). In any case, the intent of risk assessment is to track the pathogen population and estimate the likelihood of its being ingested by the consumer. By completing the pathway to the consumer, we incorporate the important issues of dose-response assessment.

Dose-Response Assessment

Dose-response assessment is used to translate the final exposure to a pathogen population into a health response in the population of consumers. This step is very difficult because of the shortage of data on pathogen-specific responses and because those responses depend on the immune status of the host (consumer). However, even limited knowledge of the shape and boundaries of a dose-response function can be informative in comparing the efficacy of alternate controls. The differences in response among various susceptible populations are important features in this step (7).

Risk Characterization

Risk characterization involves integrating the information gathered in the previous steps to estimate the risk to a population, or in some cases, to a particular type of consumer. In this step, by modifying the assumptions in the parameters of previous steps, we can study the effects of these alternate assumptions on ultimate health risk. Assumptions can be changed to study the impact of lack of knowledge and the potential gains through further research or to suggest the impact of a suspected trend. For this type of analysis, risk assessments are typically done in a computer environment to ease the computational burden and provide rapid responses to "what-if" questions using alternate assumptions and situations. Current spreadsheet applications and available "add-ins" allow generation of complicated probabilistic models that had previously only been available through expensive custom software.

Risk Assessment in Environmental Toxicology

In environmental toxicology, quantitative risk assessment has emerged as the predominant paradigm for describing the public health consequences of human exposure to environmental contaminants (8). Within this paradigm, existing situations are measured and compared according to a measure of population health risk. Similarly, proposed interventions are compared according to the reduction in population health risk that each intervention confers.

The adoption of risk assessment was primarily a result of legal and administrative challenges to regulatory authority during the 1970s (6). Regulatory agencies were required to provide a clear connection between an imposed regulation and an expected health benefit. If the expected health benefit could be quantified, the regulatory agencies were required to demonstrate that it was substantive. Quantitative risk assessment has since become widespread for different reasons. It is now used proactively to support decisions such as selection of waste treatment technologies, contaminated site cleanup operations, and state and municipal priority setting for public health initiatives.

The shift of environmental health issues into a framework of risk reduction opened the field to a broader set of analytic tools and prompted a broader spectrum of professionals to examine the complex problems in the field. Scientific societies have emerged with the sole mission of focusing on the general techniques of risk assessment and their role in public health decisions. In addition, environmental health risks can be compared with concurrent public health risks from other sources through the use of common measures. While this type of comparison is not always performed, scrutiny of the cost-effectiveness of various regulatory programs is increasingly required on the basis of risk reduction. Microbial food safety, as a relative latecomer to the field of risk assessment, can take advantage of its successes and failures and the wealth of constructive criticisms of frameworks, decisions, and methods for addressing pervasive uncertainties (4,8).

Opportunity for Technology Transfer to Microbial Health Risks

Quantitative risk assessment is an emerging tool in the field of microbial food and water safety (9-12). Recognizing the deficiencies of current approaches to evaluating the risk for human illness from pathogens in food, the Council for Agricultural Science and Technology recommended that risk assessment provide the basis for establishing food safety priorities and policies

(5). Because of recent initiatives advocating the widespread implementation of Hazard Analysis and Critical Control Points (HACCP) systems, quantitative risk assessment has been proposed as a means of providing health-outcome–based specification of microbial criteria for HACCP plans (12-14). Concurrently, international trade agreements have advocated that demonstration of increased domestic health risk (in a risk assessment) is the only acceptable basis for barriers to international trade in food (15-18). However, one of the most important benefits in the adoption of quantative risk assessment is improved understanding of the many factors that determine the safety of the food supply.

Some resistance to the adoption of risk assessment is likely. Good manufacturing practices and standard operating procedures carry a long history of reasonably safe production when properly applied. The return on investment in producing a quantitative risk assessment may not be high for an individual food company with a very conservative production process. However, good manufacturing practices and outbreak data are not particularly useful in predicting the impact of new products, newly recognized pathogens, and changes in food processing or in comparing international food systems. Whether changes in the food supply are planned (as in refocused inspection systems and minimally processed foods) or are occurring passively (as in changed pathogens, demographics, and consumer behavior), tools are required to assemble the information that describes the impact. Quantitative risk assessment may provide the only systematic means to interpret the impact of changes or trends before they become a source of epidemiologic data.

In a quantitative risk assessment of broad scope, there is a place for all the data from diverse information gathering activities relevant to microbial food safety. Recent analyses of pasteurized liquid egg (19) and ground beef contamination (20) incorporated evidence from farm-based studies of pathogen prevalence, technology assessments comparing decontamination methods, process-specific parameters of lot size and raw material mixing, growth and death models from predictive microbiology, monitoring studies of transportation and retail temperature control, and studies of consumption amounts and cooking preference.

By designing the quantitative risk assessment process as an intelligent information bank, we can develop a model to accommodate the breadth of available information. The model provides a focus for discussions among workers from diverse disciplines: farmers, veterinarians, food-processing experts, microbiologists, and consumer behavior experts. The model also allows for consideration and comparison of control strategies for which experimentation would be very difficult in a "live" environment. The impact, for example, of an aging population or a shift in cooking practices can be simulated by a variety of assumptions that reflect the extent of the change. By placing all of the information together, we can delineate gaps in knowledge and provide estimates of the benefits of proposed research.

The most obvious users for quantitative risk assessment as applied to microbial food safety are agencies responsible for food inspection, disease surveillance, and food standards. These agencies have the most to gain from models that incorporate existing and new data, capture knowledge of the relevant features of the food processing and distribution continuum, and capture knowledge of the variability in consumer behavior and immune system responses. If models are constantly updated and improved, decisions made to research, monitor, and control foodborne pathogens can be made with information that lends itself to multidisciplinary discussion and best describes what is currently known and unknown. Without such a model, there is little common ground for the type of collaboration often advocated for addressing the inherent complexity of foodborne disease.

Risk Assessment Case Examples

Two case examples illustrate the prospects of using risk assessment to support decisions regarding emerging foodborne diseases.

Escherichia coli O157:H7 in Ground Beef

A model of *E. coli* O157:H7 in ground beef has been developed to support comparative assessment of control strategies (20). The model describes the pathogen population from the production of ground beef (including carcass processing) to consumer cooking and consumption. The variability and uncertainty in the model are accommodated through the use of probabilistic representations for many of the parameters.

To generate a representative distribution of risk, the model is simulated many times with different values selected from the probability distributions. This is a technique known as Monte Carlo simulation (20-22).

While the direct output of the model is a distribution of health risk from eating ground beef hamburger patties, a more important use of the model is to describe the changes in health risk associated with changes in various parameters. By changing parameters describing, for example, pathogen prevalence and concentration in raw material, temperature abuse in transportation and retail, consumer cooking preference, infectious dose, and size of susceptible populations, we can study the impact of trends in disease risk factors. Because this model includes the farm-to-fork continuum, it is possible to assess the efficacy of interventions that would otherwise not be compared in the same analysis. In addition, the importance of improved data at different points in the process can be estimated.

Toxoplasmosis

A probabilistic model describing the incidence of toxoplasmosis was generated (23). While this model did not begin at the raw material level, valuable insights were gained in studying the impact of trends in exposure to *Toxoplasma gondii*. In congenital toxoplasmosis, the impact of maternal exposure to *T. gondii* depends on whether the mother has previously been infected (24). If this is the first exposure, the impact further depends on the trimester of pregnancy. If detected at an early stage and treated with certain drug therapies, the infection may have a smaller impact.

With such a model, the impact of varying risk factors can be studied. Since the most serious consequences of toxoplasmosis occur during pregnancy, a key variable is seroprevalence as a function of age. The protection offered by prior infection complicates disease therapy; a reduction in exposure to *T. gondii* could increase incidence of congenital toxoplasmosis by reducing the prevalence of immune women of childbearing age. This may be further complicated by changes in the age profile of pregnancy since younger women are less likely to have been exposed. In addition to the complexities of the population immunity profile, various trends in risk factors can be simulated, such as trends in cat ownership, consumption of implicated products, and the age distribution of pregnancy. The emergence of toxoplasmosis as one of the leading causes of death in the human immunodeficiency virus–positive population can be studied concurrently. The effectiveness of mitigation strategies (e.g., education and screening programs designed for pregnant women) can be compared to food-processing strategies intended to reduce overall exposure.

The model of *T. gondii* infection provides insight into the importance of detailed hazard identification to understand the complex mechanisms of disease, exposure modeling to understand the time-dependent nature of exposure, and intervention modeling to understand the potential negative consequences of a reduction in overall exposure. Moreover, the results underline the importance of performing all of the above tasks in the same overall exercise if the implications of trends and interventions are to be fully understood. It is unlikely that a sound decision could be made without a full microbial risk assessment involving modeling of the complex nature of population immunity and exposure.

Conclusions

One of the key benefits of quantitative risk assessment is the development of models describing the complex nature of pathogen populations in the food supply. Improved understanding of the efficacy of pathogen reduction is the most important side effect of this approach. Studies assessing the health impact of a foodborne pathogen often include extensive documentation of pathogen levels at unconnected points in the food and consumer pathway. In contrast, a microbial risk assessment based on a model provides a repository of knowledge describing health risk outcomes and control strategies. The model improves with each new related study and each critical review as more and more relevant data are uncovered. Furthermore, when a decision is required, a description of the system is already available in which assumptions and proposed interventions can be tested.

Initially, models can be expected to be crude. However, as a base for discussion, a model can be very effective at soliciting input from experts in the food industry and the public health community. Input from epidemiologists, microbiologists, and industry safety managers can be merged into the model until it represents the best available understanding of the interacting features of the food supply and their effect on the distribution of health risk. Once the model has been developed, the impact of various control strategies and trends can be simulated. Our current inability to compare control strategies at different points of the food supply chain is evidence of the need for a system-level understanding that will improve decision-making capacity.

Decisions to address foodborne pathogens cannot wait for scientific certainty. Large degrees of uncertainty require that decisions be made with great caution; however, there is no excuse for not making the best decision on the basis of available information. Model-based quantitative risk assessment can provide the decision-maker additional insights not typically evident in "piece-meal" considerations of data. The ability to represent the essentially probabilistic nature of emerging foodborne disease is another risk assessment attribute not typically achieved by traditional approaches.

Many gains in decision support can be achieved through model-based risk assessment. Given that many current concerns are focused on emerging pathogens, it may be timely to adopt risk assessment as a tool that is well equipped for studying changes and interventions in the race against pathogens.

References

1. Altekruse SF, Cohen ML, Swerdlow DL. Emerging foodborne diseases. Emerg Infect Dis 1997;3:285-93.
2. Hedberg CW, MacDonald KL, Osterholm MT. Changing epidemiology of food-borne disease: a Minnesota perspective. Clin Infect Dis 1994;18:671-82.
3. Smith JL, Fratamico PM. Factors involved in the emergence and persistence of food-borne diseases. Journal of Food Protection 1995;58:696-708.
4. Rodricks JV. Risk assessment, the environment, and public health. Environ Health Perspect 1994;102:258-64.
5. Foegeding PM, Roberts T, Bennett JM, Bryan FL, Cliver DO, Doyle MP, et al. Foodborne pathogens: risks and consequences. Ames (IA): Council for Agricultural Science and Technology (CAST) 1994; Task Force Report No.:122.
6. National Research Council. Risk assessment in the federal government: managing the process. Washington (DC): National Academy Press; 1983.
7. Gerba CP, Rose JB, Haas CN. Sensitive populations: who is at the greatest risk? Int J Food Microbiol 1996;30:113-23.
8. Commission on Risk Assessment and Risk Management. Framework for environmental health risk management. Washington (DC): The Commission;1997.
9. Jaykus L-A. The application of quantitative risk assessment to microbial food safety risks. Crit Rev Microbiol 1996;22:279-93.
10. Rose JB, Sobsey MD. Quantitative risk assessment for viral contamination of shellfish and coastal waters. Journal of Food Protection 1993;56:1043-50.
11. ILSI Risk Science Institute Pathogen Risk Assessment Working Group. A conceptual framework to assess the risks of human disease following exposure to pathogens. Risk Anal 1996;16;841-8.
12. Rose JB, Haas CN, Gerba CP. Linking microbial criteria for foods with quantitative risk assessment. In: Sheridan JJ, Buchanan RL, Montville TJ, editors. HACCP: an integrated approach to assuring the microbiological safety of meat and poultry. Trumbull (CT): Food Nutrition Press;1996.p.159-70.
13. Notermans S, Gallhoff G, Zwietering MH, Mead GC. The HACCP concept: specification of criteria using quantitative risk assessment. Food Microbiol 1995;12:81-90.
14. Buchanan RL. The role of microbiological criteria and risk assessment in HACCP. Food Microbiol 1995;12:421-4.
15. World Health Organization. Application of risk analysis to food standards issues. Report of the Joint FAO/WHO Expert Consultation 1995.WHO/FNU/FOS/Report No.95.3.
16. Hathaway S. Harmonization requirements under HACCP-based control systems. Food Control 1995;6:267-76.
17. Dawson RJ. The role of the Codex Alimentarius Commission in setting food standards and the SPS agreement implementation. Food Control 1995;6:261-5.
18. Hathaway SC, Cook RL. A regulatory perspective on the potential uses of microbial risk assessment in international trade. Int J Food Microbiol 1997;36:127-33.
19. Whiting RC, Buchanan RL. Development of a quantitative risk assessment model for *Salmonella enteritidis* in pasteurized eggs. Int J Food Microbiol 1997;36:111-26.
20. Cassin MH, Lammerding AM, Todd ECD, Ross W, McColl S. Quantitative risk assessment of *Escherichia coli* O157:H7 in ground beef hamburgers. Int J Food Microbiol. In press 1997.
21. Thompson KM, Burmaster DE, Crouch EAC. Monte Carlo techniques for quantitative uncertainty analysis in public health risk assessments. Risk Anal 1992;12:53-63.
22. Vose D. Quantitative risk analysis: a guide to Monte Carlo simulation modelling. New York: John Wiley & Sons, Inc.;1996.
23. Cassin MH, Lammerding AM, Paoli GM, McColl RS. Population response and immunity to *Toxoplasma gondii* [abstract]. In: Proceedings of the Annual Conference of the Society for Risk Analysis and International Society for Exposure Analysis; 1996 Dec 8-12; New Orleans, LA. MacLean (VA):Society for Risk Analysis. p. 129.
24. Dixon BR. Prevalence and control of toxoplasmosis - a Canadian perspective. Food Control 1992;3:68-75.