

Food Safety Research Consortium

A MULTI-DISCIPLINARY COLLABORATION TO IMPROVE PUBLIC HEALTH

Methodology Primer for the Foodborne Illness Risk Ranking Model

Background

The goal of the Food Safety Research Consortium (FSRC) is to improve how the U.S. food safety system works to reduce the threat of foodborne illness. To achieve this goal, the FSRC is developing decision tools that policymakers need to better identify and prioritize opportunities to reduce food safety risks and allocate government resources accordingly. As a first step, the FSRC is developing a computer risk-ranking model that will enable policymakers, risk managers, and risk analysts to compare and rank the relative public health impact of specific foodborne hazards, including appropriate measures of the economic impact of illness. This model, the Foodborne Illness Risk Ranking Model (FIRRM), is being developed jointly by Resources for the Future and the Department of Epidemiology at the University of Maryland School of Medicine, with guidance from other institutions within the FSRC. The goal of the project is not to produce a single risk ranking, but rather to provide a widely accepted and widely utilized tool that is transparent and objective and which will permit risk managers to compare risks using a variety of measures. FIRRM will help focus efforts to reduce illness because it will enable risk managers to focus data collection and analytical efforts, and eventually regulatory efforts and other food safety interventions, on the most important problems.

FIRRM, currently in a preliminary stage of development, is a user-friendly analytical tool for the comparison of the relative public health impacts of illness due to 28 major foodborne pathogens. For reasons of scope and due to limited time and resources, the model does not include waterborne illness or illness due to chemical hazards, though these will hopefully be added to future versions. Using the model, users can produce rankings by pathogen, by food, and by pathogen-food combination, according to five measures of the impact on public health: number of cases of illness, number of hospitalizations, number of deaths, monetary valuation of health outcomes, and loss of Quality Adjusted Life Years (QALYs). Rankings can be produced at the national level for the United States or, should data become available, for individual states, regions, or foreign countries.

In addition to allowing users to select the region and measures used for ranking, FIRRM allows users to modify many other settings. These settings include broad decisions about methodology (e.g., choosing which of three methods of food attribution to use), narrow decisions pertaining to specific modules within the model (e.g., selecting which years of data in a particular dataset to use), and changing specific values within the model (e.g., changing the value of a multiplier to account for unreported illness).

FIRRM is the first such comprehensive model to attribute the incidence of foodborne illness to specific pathogen-food combinations, to employ economic and QALY valuation, and to utilize Monte Carlo simulation to quantify the uncertainty of rankings and other results. In doing so, it

combines and furthers much of the research on the topic, including work by the Centers for Disease Control and Prevention (CDC), the USDA's Economic Research Service (ERS) and Food Safety and Inspection Service (FSIS), the FDA, the Center for Science in the Public Interest (CSPI), and others.

FIRRM is designed within the software application Analytica, a visual modeling and Monte Carlo simulation environment in which mathematical models are developed using functional influence diagrams. FIRRM includes a user-interface module and documentation, including user instructions, references to the literature, and technical explanations.

Approach

FIRRM utilizes a top-down epidemiological approach for estimating illness rather than a bottom-up microbiological or risk assessment approach. That is, FIRRM uses surveillance data on reported illnesses to estimate actual illnesses rather than the approach typically used in risk assessments in which microbial concentrations of pathogens in specific foods are modeled using dose-response functions to estimate the number of illnesses.

There are three primary reasons for this choice of approach. First, we are principally interested in ranking the impact to public health and thus need to start with data as close to these health outcomes as possible, rather than start with data on microbial concentrations in foods, which are removed from the eventual health outcomes. Second, utilizing the bottom-up approach would require separate risk assessments for each pathogen in each food item. As FIRRM includes 28 pathogens and over 40 food categories, this approach would require more than 1,000 individual risk assessments, a task well beyond the scope of this project. Third, when producing rankings in general, it is imperative that the values of items being ranked are computed as identically as possible to ensure that these values are comparable. Using surveillance data ensures that we are making the same assumptions for all pathogens and foods, rather than utilizing risk assessments by various researchers that may employ contradictory assumptions or methods. Quite simply, the top-down approach ensures an identical methodology across pathogens and foods.

There are limitations with the top-down approach, however. Although it is preferable for a big picture view of public health impacts, it is inadequate for further isolation of causes of illness. The top-down approach does not allow the model to account for cross-contamination between foods or misattributed illnesses actually caused by person-to-person transmission, waterborne pathogens, or environmental exposure. The food safety system is complex, and the model can be used to direct attention to those foods and pathogens that must be studied more closely and for which more extensive microbiological risk assessments should be performed.

FIRRM is organized into three major modules: (1) the estimation of foodborne pathogen incidence from surveillance data on cases, hospitalizations, and deaths, (2) the monetary and QALY valuation of pathogen-specific health outcomes, and (3) the attribution of pathogen incidence and valuation to food categories. A fourth module produces rankings of foods, pathogens, and pathogen-food combinations.

Estimations of Incidence

Before the annual incidence of foodborne illness can be estimated, the user must select the region for which to produce rankings. The current model utilizes national data, although there is the potential for incorporating data from specific states. The model includes a module to estimate incidence for the state of Maryland using that state's FoodNet surveillance data, though this module is not yet functional, pending authorization and access to data.

For national rankings, the default method for estimating the annual number of foodborne illnesses, hospitalizations, and deaths, is to use the methodology and data from Mead et al. (1999). Reported illnesses, hospitalizations, and deaths from surveillance and outbreak data are multiplied by pathogen-specific underreporting factors to obtain estimated illnesses, hospitalizations, and deaths due to each pathogen. These estimates are then multiplied by the percent of illnesses due to each pathogen assumed to be foodborne. The model also has the capability of allowing direct entry of incidence data from FoodNet and other data sources; efforts to obtain access to such data are ongoing.

Valuation of Health Outcomes

The FIRRM includes two methods of valuation: economic valuation and QALY valuation. For each pathogen, the model includes a symptom-severity outcome tree to organize the health outcomes of illnesses associated with that pathogen. Rates of hospitalization, of death, of acute health effects, and of chronic sequelae are used to estimate the likelihood of each health outcome in the tree, and thus, the number of annual cases of each health outcome.

The economic valuation of pathogen-specific health outcomes builds upon data and methods developed by ERS – namely, those described in Buzby et al. (1996), furthered in Buzby and Roberts (1996, 1997), and employed in the ERS online Foodborne Illness Cost Calculator (ERS 2003). The economic impact per case of each health outcome in each pathogen's symptom-severity outcome tree is estimated using either willingness-to-pay (WTP) measures or cost-of-illness (COI) measures (medical costs and productivity loss), according to user selection (COI is the default). The model includes COI estimates from ERS studies, as well as WTP values gleaned from an extensive literature search. The user may opt to change other settings as well, such as which Value of a Statistical Life (VSL) to use for mortality valuation and whether or not VSLs differ for children and adults. For each pathogen, the costs of each health outcome are summed to obtain an estimate of total annual monetary loss due to illnesses caused by that pathogen.

The QALY loss for each health outcome in each tree is estimated using the Quality of Well-Being (QWB) index. Each health outcome is assigned scores for the four QWB components (Mobility, Physical Activity, Social Activity, and Symptom/Problem Complex), which are then summed to obtain a QWB score. The QWB score is subtracted from the baseline QWB score, and the result is multiplied by duration of outcome, in years, to obtain QALY loss. The QALY loss of all health outcomes in each pathogen's tree are summed to obtain an estimate of total annual QALY loss due to illnesses caused by that pathogen.

Food Attribution

The estimated incidence and valuation of illnesses caused by each pathogen are attributed, by percentage, to a set of food categories, to obtain estimated incidence and valuation of illnesses caused by each pathogen-food combination. The food categories are based on those developed and used by CSPI. The table used to attribute illness and pathogens to foods includes a column for each pathogen and a row for each food category, in which each column sums to 100%, allocating all of the estimated illness associated with a pathogen to a food category. The user selects among three methodologies for creating this food attribution table: outbreak data, food consumption and contamination data, and expert elicitation.

Outbreak Method

The outbreak method (the default) is based on CSPI's compilation of data on outbreaks of foodborne illness, in which both the pathogen and food were isolated, and in which the cases from each outbreak could be sorted into one of the food categories. This data is based primarily on CDC data, but also includes outbreaks investigated by CSPI. The CSPI outbreak data is the only source of data available to trace reported illnesses due to a large number of pathogens to specific foods. The number of cases due to each pathogen-food combination is divided by the total number of cases of that pathogen to obtain attribution percentages for each pathogen-food combination. Some pathogens do not have adequate outbreak attribution data, in which case the pathogen is not attributed to foods.

Consumption and Contamination Method

The consumption and contamination method of food attribution is being developed specifically for this model. Basically, this method estimates annual per capita illnesses for each pathogen-food combination by multiplying the average amount of each food consumed per person per year by the likelihood that any given serving of that food will be contaminated with sufficient amounts of the pathogen to result in illness; attribution percentages are obtained by dividing the resulting estimates for each pathogen-food combination by the sum of all estimates for each pathogen. Annual per capita consumption of food is defined in the model by an upper and lower bound, where the upper bound is defined by "food disappearance" data from the ERS food consumption data system, and the lower bound is defined by "dietary recall" data from the USDA's Continuing Survey of Food Intakes by Individuals (CSFII). The major challenge comes in trying to estimate the likelihood that any given serving of food is sufficiently contaminated to cause illness. Contamination rates of specific foods by pathogen reported in the food microbiology literature are being used as a starting point for these estimates; however, there is the potential for incorporating more sophisticated data from individual food/pathogen risk assessments as they become available.

Expert Elicitation

The expert elicitation method uses the averaged results of expert responses to a survey developed and administered specifically for this project, in which experts were asked to attribute, by percent, the amount of illnesses due to each pathogen that were attributable to each food

category. The survey included 11 major pathogens in the model and also captured uncertainty bounds around their responses.

Calculation of Rankings

Foodborne pathogen incidence from the first module and valuation of pathogen health outcomes from the second module are multiplied by the food attribution percentages from the third module to obtain incidence and valuation by pathogen-food combination. The same food-attribution percentages are used regardless of measure of burden; that is, the percent of illnesses from pathogen X due to food A is the same as the percent of QALY loss from pathogen X due to food A.

The user selects the measure of burden by which to rank, though output tables report all five measures. When the CSPI outbreak data is used for food attribution, the rankings also report out the number of outbreaks recorded in the CSPI data for each pathogen-food combination, as an indication of uncertainty. In addition to ranking pathogen-food combinations, the model ranks pathogens (without attributing to food) and foods (summing by food across pathogens). The results of these three types of rankings can be viewed in the units appropriate to each measure, or as a percentage of the total of each measure. Output can also be viewed graphically.

Data Issues

Each of the three major modules of FIRRM is dependent on data, including data on the incidence of foodborne illness, on symptoms and severity of pathogen-specific illnesses, on the monetary costs of health outcomes, and on the attribution of illnesses to foods. The model is only as good as the data within it, and much work remains to be done to address data issues.

As FoodNet data are compiled and made available to researchers, questions of incidence and of which pathogens ought to be of most concern will begin to be answered with more precision. Food attribution data are more of a problem, however. At this time, the available data on the attribution of illnesses to specific pathogen-food combinations are almost entirely based on reported outbreaks; little work has been done to identify the pathogen-food combinations responsible for sporadic illness. In an attempt to identify data gaps, better define data needs, and raise awareness of the importance of food attribution data to addressing the problem of foodborne illness, FIRRM incorporates three different approaches to food attribution data. None of these approaches is ideal; indeed in our view none of them is as yet adequate to produce a risk ranking that could be used by decision makers. By including several different approaches, FIRRM highlights data gaps and suggests avenues to improve the data on food attribution.

Data on monetary valuation of health outcomes is also a concern. Cost of illness studies fully utilizing the methodology of symptom-severity health outcome trees have only been produced by ERS for four foodborne pathogens (*Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, and *Campylobacter jejuni*), though ERS has produced estimates for three additional pathogens (*Staphylococcus aureus*, *Clostridium perfringens*, and *Toxoplasma gondii*). Unlike surveillance data on incidence or food attribution, determining economic costs of health outcomes requires personal judgment in searching for and combining highly specific data that may not be readily

available. In short, the cost of illness studies required for each of the remaining 24 pathogens are complex and time consuming, and thus beyond the scope of this project. Furthermore, QALY valuation of pathogens is dependent on the symptom-severity stress and health outcome durations derived from the cost of illness studies. Therefore, only a small set of pathogens in the model currently include monetary or QALY valuation for rankings.

References

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