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## Knowing Which Foods Are Making Us Sick

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Over the past three years, *USA Today* has run a major story on a food safety problem almost every month. U.S. consumers may be a bit shell shocked by the barrage of headlines warning of foodborne pathogens (disease-causing organisms) or harmful chemicals. American consumers—as well as those in the agriculture and food processing industries—are undoubtedly asking, what next? Prediction is always difficult. Unfortunately, with foodborne illness it is even difficult to say which foods have been the biggest problem in the past. The reasons are actually as simple as these: the evidence gets eaten or thrown out, illness may follow food consumption by days or even years, and human memory, particularly when trying to remember what one had for dinner even three days ago, is frail. Just as unfortunately, it is important to know which foods caused the most illnesses in the past in order to reduce illness in the future.

This article focuses on foodborne illnesses caused by pathogens (bacteria, viruses, and parasites that can contaminate foods and cause illnesses). It explores why it is important to know which pathogens on which foods are causing illness in the U.S. and why we don't know more than we do about this relationship. It then looks at what is being done to improve our estimates of the numbers of illnesses associated with particular pathogens and foods and how federal agencies can use this knowledge to help improve food safety in the United States.

### Importance of Knowing Which Foods Are Riskiest

There are compelling substantive reasons—for all parties involved—to want to invest time and effort in developing information on the sources of foodborne illness. Consumers need to know how to handle foods safely, and many also would like information about the relative riskiness of particular foods to guide their purchase decisions. Produc-

ers would like to know whether the types of foods they produce are likely to be the next story on the front page of *The New York Times* so they can develop strategies to avoid potential financial risk. Supply chain managers want to know about the relative riskiness of the different sources of a product so they can appropriately weigh the costs and benefits of each source. Governments want to know about the relative riskiness of foods to effectively design laws and target efforts to protect the public from health risks.

There are also important procedural reasons for wanting quantitative data on the sources of foodborne illness—reasons related to assuring that regulations are actually needed and do not unfairly burden trade. Both industry and consumers are often concerned about special interests having undue influence on government agencies or about government agencies writing rules that favor one firm over another. To help assure that regulations are even-handed and serve their legislative purpose, the Administrative Procedures Act requires federal agencies to show a basis in fact for new regulations. Similar issues arise in international trade. Under the Sanitary and Phytosanitary Agreement that the United States signed as part of the Uruguay Round of trade talks, signatory countries are encouraged to adopt standards developed cooperatively through the international *Codex Alimentarius* Commission. If they choose to adopt stricter standards, they must be supported by scientific evidence or risk imposition of trade sanctions.

Government agencies in the United States and abroad rely on formal risk assessment as a primary means of understanding how health risks arise in the food supply. Risk assessment is a process of quantifying and modeling the pathway from contamination through exposure to health outcomes. It typically relies on dose-response relationships to predict illnesses or deaths. Risk assessment methods were initially developed in the context of managing chemi-

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cal and radiological hazards where dose-response relationships can be estimated using laboratory tests on animals and extrapolated to human populations. When efforts were made to extend this paradigm to microbial foodborne hazards in the early 1990s, it became apparent that the use of a dose-response function would be a stumbling block. Estimating a pathogen dose-response relationship is difficult because pathogens tend to be species specific, and human testing is considered to be unethical. An alternative is to estimate disease incidence from epidemiological data and then attribute it back to the source of infection—in other words, a *food attribution estimate*.

### **Determining Riskiest Foods is Difficult**

Despite the need for food attribution estimates, it is difficult to get them. There are two basic reasons for this. First, it is difficult to estimate the incidence of foodborne illness. Second, it is difficult to attribute these illnesses to their sources.

There is a great deal of uncertainty in estimates of the number of cases of foodborne illness in the United States, each year. This is not unique to the United States. Health statistics depend heavily on reporting by physicians and medical laboratories. Most cases of foodborne illness are probably mild and never show up at a doctor's office. When someone with foodborne illness does seek medical attention, the physician or medical laboratory may not report the illness to public health authorities. Even if a case of foodborne illness is reported to public health authorities, it may be identified only as a case of infectious disease not specifically foodborne infection. This results in significant underreporting of foodborne illness. The Centers for Disease Control scientists estimate that for many pathogens, only one in 38 cases of foodborne illness are reported (Mead et al. 1999).

There is even greater uncertainty about the food sources of foodborne illness. Food safety managers and public health officials need to know which pathogens on which foods are making people sick. Physicians can determine which pathogen made a patient sick by ordering a laboratory test. Often tests are not ordered because they are more useful for public health surveillance than for patient care. Even if a physician suspects that an illness is foodborne, it will typically be difficult to pinpoint the food. Individuals' ability to recall the foods they ate is notoriously poor. There may be a few days delay between infection and illness. Then it is a guess as to which food was actually associated with the illness. Again, there is usually no clinical reason to investigate the matter further.

### **Assessing the Riskiness of Foods**

In part in response to these reporting problems, CDC and state public health surveillance authorities have developed three major foodborne illness surveillance programs—OutbreakNet, PulseNet and FoodBorne Diseases Active Surveillance Network (FoodNet). While these systems provide information that is useful about the sources of foodborne illness, further work is needed to make them truly useful for food attribution in policy analysis.

The oldest of these three programs is OutbreakNet. An outbreak of infectious disease is the occurrence of multiple cases of illness associated with a single source of infection in a limited time period. An example is the recent peanut product-associated outbreak of *Salmonellosis*. The purpose of outbreak investigation is to gather information needed to stop the spread of an infectious disease outbreak. Like clinical data from visits to physicians, data from outbreak investigations is reactive, not proactive, in nature. But because the purpose is to prevent further spread

of the outbreak, the investigations do try to identify both the pathogen and the food sources involved. Sometimes, as in last summer's tomato and jalapeño pepper *Salmonella* outbreak, the fact that foods contain more than one ingredient, along with recall issues, pose challenges to investigators. OutbreakNet data collection is national in scope, but outbreaks are estimated to account for only about 10% of total foodborne illness, so the vast majority of foodborne illnesses are not captured by outbreak investigations. Further, studies show that cases of illnesses associated with outbreaks and those that are scattered, or sporadic cases of illness (the other 90% of foodborne illness), may not follow the same pattern of association with foods (Mead, et al. 1999).

OutbreakNet is now aided by PulseNet. PulseNet is a national network of state, local and federal public health laboratories with the capacity to genetically "fingerprint" foodborne pathogens using pulsed-field gel electrophoresis. Participating laboratories subtype (or "fingerprint") bacteria from suspect human and food samples. These genetic "fingerprints" are then entered into an electronic database. Both the laboratory and CDC analyze the database regularly looking for statistical patterns of multiple occurrences of the same pathogen. This system has increased the rate of outbreak detection over the conventional clinician reporting system. This is particularly important because the structure of the food supply has changed. With wide national and international distribution of food, outbreaks may involve small numbers of cases spread over wide distances—something conventional clinician based outbreak detection is less likely to pick up. But it also means that part of the apparent increase in outbreaks is an increase in detection.

FoodNet began in 1995 and is a collaborative program including CDC, 10 of the U.S.'s most active

state health departments, USDA and FDA. FoodNet conducts active surveillance of nine pathogens, and one syndrome. In addition, FoodNet conducts epidemiologic and population studies to better understand factors that may have contributed to illness. One example of an epidemiologic study that FoodNet uses is case-control studies which match a population of ill patients with statistically similar subjects who are not ill. Interviews are used to determine behaviors and consumption patterns within a specific time period. Statistical comparisons are used to identify factors that may have contributed to developing the illness. Though data provides valuable additional information for attribution assessments it also has limitations. As with outbreak investigations, dietary recall can be a problem. The fact that the number of states involved is small and the states self-select for participation may lead to biased estimates. In addition the fact that the studies tend to be fairly specific in focus, makes it difficult to use FoodNet data by themselves to gain an aggregate picture of the distribution of foodborne illness across the food supply. Expansion of FoodNet and PulseNet programs could provide better surveillance data on the sources of foodborne illness, but there is also a need for research and development targeted specifically at getting better attribution estimates

A number of efforts are underway within federal agencies to adapt this data or to create new data to meet the need for attribution estimates (Batz, et al. 2005). Most of these efforts are targeted at specific regulatory needs. For example, the Food Safety Inspection Service is working on attribution of *Salmonellosis* to food products under its jurisdiction using a sampling and genetic subtyping protocol developed in Denmark. CDC is working on two food-system-wide approaches, one based on outbreak case data that could be updated in real time, and another that relies on a blend

of outbreak and case-control study data. Microbiologists also continue to work on the problem of developing predictive dose-response models for human foodborne pathogens.

In the absence of hard data, judgment-based estimates are also used. Usually, this is done informally. Current estimates attributing the incidence of foodborne illness to specific pathogens rely heavily on the expert judgments of a group of researchers at the Centers for Disease Control and Prevention to fill gaps in the literature (Mead, et al. 1999). More formal methods are being developed. Evidence-based medicine has developed a set of criteria for evaluating studies through systematic literature reviews that are used to identify best clinical practices (Cochrane Collaboration, 2009). Risk analysis in environmental and safety policy has long relied on structured elicitation of expert judgment for subjective estimates of missing parameter values (Morgan and Henrion, 1990; Cooke and Schrader-Frechette, 1991).

### **What Do Experts Say about Food Risks?**

Recently, colleagues and I conducted an expert elicitation on foodborne illness source attribution as part of an effort to develop a foodborne illness risk ranking model for use in broad federal-level policy evaluation. Forty two of the country's leading food safety experts participated in the survey. These experts were able to draw on a broad range of knowledge to inform their judgments—knowledge of microbial ecology, food science, consumption patterns, and food handling practices as well as epidemiological data. For each of 11 prevalent foodborne pathogens, experts were asked to provide their best judgments of the percentage of cases caused by the pathogen that is associated with consumption of different food categories in a typical year (Hoffmann, et al. 2007a; 2007b). They were

also provided 90% credible intervals around their best judgments. The food categories spanned the food supply. We then applied these percentages to CDC estimates of the incidence of illness, hospitalization and death caused by each pathogen to estimate the cases of foodborne illness caused by the pathogen on different foods. These estimates were examined individually and aggregated to provide estimates of foodborne illness by food categories.

The purpose of the study was three-fold. First, we needed a consistent set of estimates—spanning all foods—of the association of foodborne illness with food consumption. Second, we aimed to capture information on sporadic illnesses as well as outbreaks. And third, we intended to assess the extent of agreement among experts and the degree of confidence that food safety experts have in their own understanding of the association between foodborne illness and the consumption of specific foods.

The most marked finding is the relatively high public health impact of a small number of pathogens and foods. Results from Mead et al. (1999) indicate that the three highest ranked pathogens account for 96.9% of all foodborne illnesses. Our results suggest that incidence is also highly concentrated by food. Four foods (produce, seafood, poultry and ready-to-eat meats) accounted for 60% of all illnesses, 59% of all hospitalizations and 46% of all deaths (Hoffmann et al. 2007a).

The results also show the importance of focusing public and private intervention efforts on particular pathogen/food combinations. A small number of food-pathogen pairs account for most of the public health burden from foodborne pathogens. Fifteen out of 121 food-pathogen pairs accounted for 90% of all illnesses; 25 pairs accounted for 90% of hospitalizations and 21 pairs accounted for 90% of deaths (Hoffmann et

**Table 1. Experts' Estimates of Foodborne Illness by Foods**

| Food Category            | % of total cases | % of total deaths |
|--------------------------|------------------|-------------------|
| Produce                  | 29.4             | 11.9              |
| Seafood                  | 24.8             | 7.1               |
| Poultry                  | 15.8             | 16.9              |
| Luncheon and other meats | 7.1              | 17.2              |
| Breads and bakery        | 4.2              | 0.6               |
| Dairy                    | 4.1              | 10.3              |
| Eggs                     | 3.5              | 7.2               |
| Beverages                | 3.4              | 1.1               |
| Beef                     | 3.4              | 11.3              |
| Pork                     | 3.1              | 11.4              |
| Game                     | 1.1              | 5.2               |
| Total                    | 100              | 100               |

Source: Hoffmann et al. 2007a.

al. 2007a). These food-pathogen pairs include foods and pathogens that do not rank highly if one were to rank all pathogens or all foods by themselves.

In this study we also develop a set of multiple measures of information uncertainty that can provide valuable guidance for setting priorities for research on attribution. The mean of the 90% credible intervals gives a measure of individual subjective uncertainty about the attribution estimates. Respondents come from a wide range of fields which may draw on different information sets or place different weight on different types of information. The variance of individual best estimates provides a measure of agreement among experts about best estimates. The variance of the credible intervals measures agreement about the level of uncertainty. Finally,

**Table 2. What Different Types of Uncertainty Tell Decision Makers**

| Case | Uncertainty Measure     |                        |                      |                                       | Characterization of Uncertainty   | Implication for Decisions   |
|------|-------------------------|------------------------|----------------------|---------------------------------------|---|---|
|      | Agreement among Experts | Individual Uncertainty | Agreement with Prior | Variability in Individual Uncertainty |   |   |
| 1    | high                    | low                    | high                 | low                                   | Agreement and confidence that the prior is correct.   | Act on the prior.   |
| 2    | high                    | low                    | low                  | low                                   | Confident consensus around an estimate other than the prior suggesting a credible alternative source of shared information.                   | Literature review, further expert consultation, and/or a literature-based risk assessment is likely to provide information needed to decide whether to act on the alternative estimate. |
| 3    | low                     | low                    | low                  | low                                   | Experts are highly confident in their judgments, but disagree. This might be due to differences in information used by different disciplines. | Conduct further consultation to determine the source of disagreement before acting.   |
| 4    | high                    | high                   | low                  | low                                   | Experts agree on alternative estimate, but are uncertain.   | May warrant further primary research.   |
| 5    | high                    | high                   | high                 | low                                   | Experts agree with prior, but are uncertain.  | May warrant further primary research.   |
| 6    | low                     | high                   | low                  | low                                   | Experts are highly uncertain and cannot agree on any estimate.  | A strong indication of a need for further research.   |
| 7    | low                     | high                   | low                  | high                                  | High variability in individual uncertainty, some are quite certain and others not.  | May give insight into where to start further research.  |
| 8    | low                     | high                   | high                 | low                                   | Illogical.  |   |
| 9    | low                     | low                    | high                 | low                                   | Illogical.  |   |

Source: Hoffmann et al. 2007b.



a comparison with attribution estimates based on outbreak case data measures the extent to which experts believe outbreak case data accurately captures food source attribution. Demographic data on the experts was used to test for systematic patterns in the measures.

Taken together these uncertainty measures provide a means of characterizing the quality of information available about attribution by pathogens, foods, and food/pathogen pairs (Hoffmann et al. 2007b). There are some food/pathogen pairs, such as *Vibrio* on seafood, where experts' best judgments are highly correlated with each other and with the outbreak-based attribution estimate, and their mean credible interval is narrow with low variance. There are others, like *Campylobacter* on produce where the mean and variance of the credible intervals are small, but the correlation between expert judgment and outbreak data is low. This is a case where experts agree that outbreak data does not provide a good attribution estimate, but have agreement based on other information. Then there are cases such as *Toxoplasma* on many foods where expert best estimates are not highly correlated with each other or the outbreak based estimate, and the mean and variance of the credible intervals are relatively high. Here there is evidence of poor information on attribution. This information on uncertainty on attribution provides part of the foundation for a value-of-information approach to deciding where to invest in further research and data collection on disease surveillance.

### Federal Food Safety Policy and Attribution Estimates

U.S. agencies are proposing to or are currently making use of food attribution estimates in a number of ways including risk-based inspections, health-based performance standards, and the rationalization of federal food

safety policy. In an effort to prioritize the use of limited inspection resources, FDA's Food Protection Plan includes risk-based targeting of inspection of both domestic plants and imports. USDA's Food Safety Inspection Service has also proposed risk-based inspections of domestic meat-processing and slaughter facilities. Both efforts have proven controversial. Consumer groups have expressed concern that a move from random or uniform allocation of inspection resources to risk-based allocation may not ensure product safety and that existing data are not adequate to support the shift. Consumer groups and others including the Government Accountability Office and the *Codex Alimentarius* Food Hygiene Committee would like to see HACCP regulations designed to meet specific public health goals. But this will require empirical estimates of the relationship between different levels of food contamination and foodborne illness. Source attribution estimates may play a role here (de Swarte and Donker, 2005).

### Closing Observations

One would think that every industrialized country would have good information on how foodborne illness is distributed across the food supply. But data on this relationship are more difficult to collect than one might imagine. Changes in international trade law have also made the collection of such data more crucial than it may have been in the past. Governments around the world, including the United States, have made a focused effort over the past 10 to 15 years to improve the quality of information on the distribution of foodborne illness across foods. Eventually, this information will help both government agencies and private firms do a more effective, more efficient job of protecting the public from foodborne illness. But for now, a great deal of work remains to be done.

### For More Information

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