An Approach to Ranking Microbial Foodborne Hazards

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Overview

- Background on the FSRC
- Conceptual Framework for Priority Setting
- The Foodborne Illness Risk Ranking Model
- Specific challenges:
  - Food categories
  - Food attribution approaches
  - Uncertainty and dependencies

Towards Risk-Based Food Safety

- Foodborne illness is a complex problem:
  - Many hazards in many foods
  - Diversity of health outcomes
  - Long production chain from farm to fork
  - Many players involved throughout chain
  - Complicated regulatory structure
- Numerous bodies (e.g. NAS/IOM, GAO) have called for a more science- and risk-based food safety system in the United States

In Turn, A Need for Tools

- Risk-based decision-making and priority setting rely on data-driven tools and analyses that treat the system as a whole
- Tools needed for:
  - Ranking risks
  - Prioritizing opportunities to reduce risk
  - Assessing the effectiveness of interventions
  - Allocating resources to maximize risk reduction
- Data access and integration at national and local level are key challenges

The Food Safety Research Consortium

- Formed in 2002 to develop analytic and decision tools towards a more risk- and science-based food safety system
- Interdisciplinary collaboration between 7 institutions, with steering committee members from each:

University of Maryland, Baltimore
- Mike Taylor (Chair)
- Glenn Morris Jr.
- Mike Batz (Executive Director)

University of California at Davis
- Juliana Ruzante

University of Georgia
- Mike Doyle

Iowa State University
- Helen Jensen

University of Massachusetts
- Julie Caswell

Michigan State University
- Ewen Todd

Resources for the Future
- Alan Krupnick

The Priority Setting Challenge

- Given a complex problem and finite resources, how best to target interventions and allocate resources to reduce illness?
- A Conceptual Framework for Food Safety Priority Setting: A set of principles set down to organize and guide decision tools and how they might fit together in a science-informed food safety system

The Conceptual Framework…

- Was developed through five focused workshops with researchers, decision makers and stakeholders from all sectors
- Is NOT methodologically prescriptive
- Is NOT intended to displace the other factors (social, political, market) that will continue to play a role in decisions

Some Key Principles

- Systems perspective
  - Foodborne illness results from the interaction of numerous factors, arising from farm to table, that affect both causation and prevention
- Practicality:
  - Needs of decisionmakers
  - Limitations of data
  - Financial and time costs of analysis
- Within the bounds of practicality:
  - Best available science
  - Transparency in assumptions & limitations
  - Flexible
- Re-evaluation:
  - Continuous or iterative evaluation

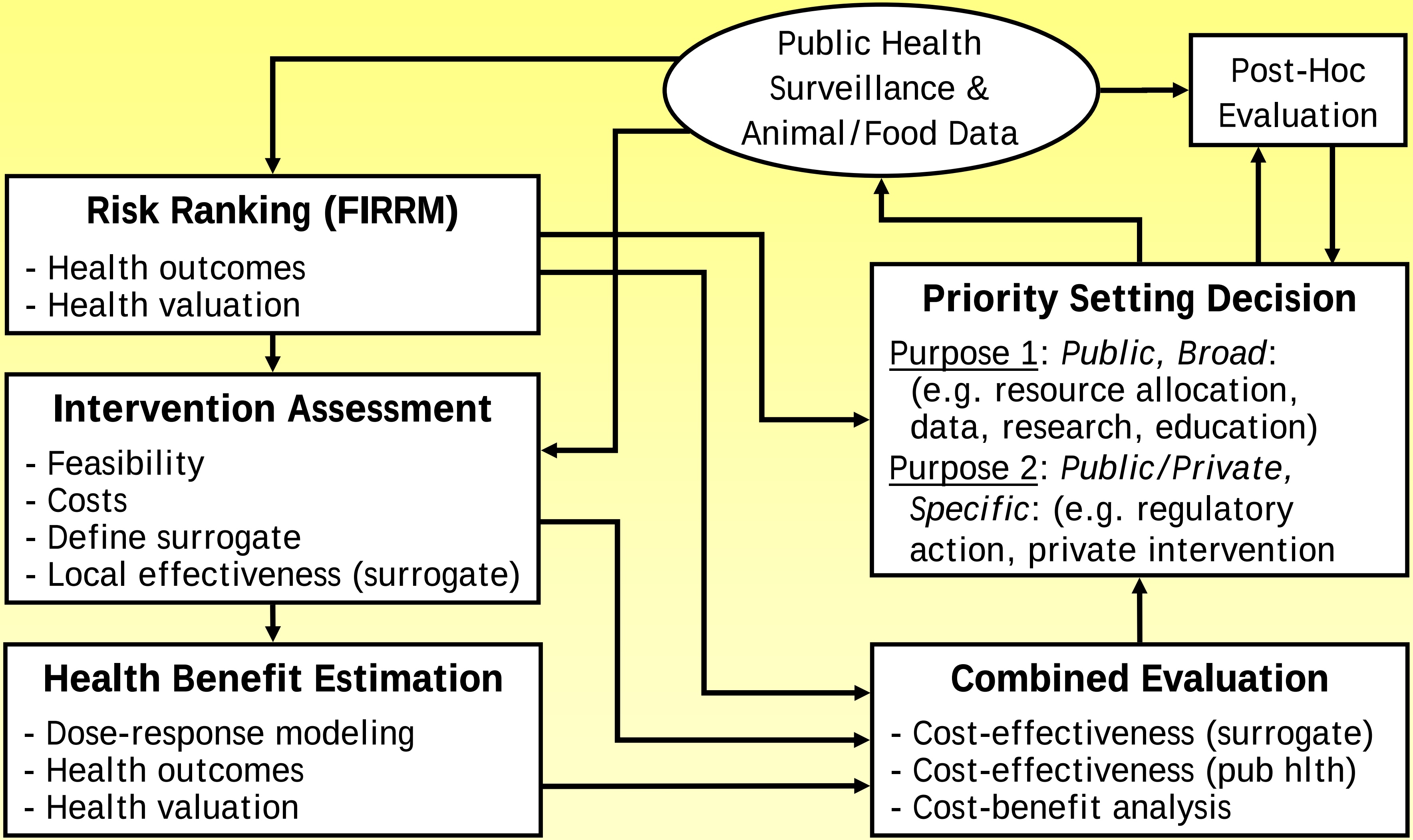
A Range of Decision Contexts

- Purpose 1: *broad, public sector* "resource allocation" –how to expend dollars, personnel, and other resources towards large array of hazards
- Purpose 2: *specific, public & private* "targeted risk management" – where and how best to act to reduce specific risks
- Approaches require different types of analysis and degrees of data-intensity

Four Analytical Elements

1. **Risk Ranking**
   Identify the most significant hazards from a public health perspective
2. **Intervention Assessment**
   Identify interventions and estimate their feasibility, effectiveness, and cost
3. **Health Impact Estimation**
   Compute public health effectiveness and benefits of interventions
4. **Combined Evaluation**
   Integrate information from other elements to inform decisions

The Conceptual Framework



Risk Ranking

- A first step in broad priority setting
- A risk ranking should be:
  - Data-driven when possible
  - Focused on public health endpoints
  - Based on integrated measures of public health impact (such as dollars or QALYs)
  - Inclusive of hazards - avoid the “streetlamp” effect of excluding hazards prematurely
  - Consistent across risk categories

Foodborne Illness Risk Ranking Model

- Need for a systematic approach to identify microbial hazards with the greatest public health impact
- FIRRM Project team:
  - UMB: Glenn Morris, Mike Taylor, Mike Batz, others
  - RFF: Alan Krupnick, Sandy Hoffmann, others
  - Iowa State: Helen Jensen
- Funded by RWJ (v1) and USDA CSREES (v2)

A Very Brief History of Risk Ranking

- Also known as Comparative Risk Assessment
- Historically, a deliberative process
  - Small number of experts/decision-makers
  - Diverse set of risk domains (health, ecosystem, socio-economic)
  - Use consensus to aggregate experts' preferences
- *Unfinished Business* (US EPA, 1987)
  - Ranked 31 National environmental issues
  - Followed by 8 EPA Regions, and most states
  - Fairly quiet for the past 10 years or so…

FIRRM Is Unlike Traditional CRA

- Empirical not deliberative
- Quantitative not qualitative
- Fewer and more similar risk domains
- Focus on differentiation within a single risk domain (microbial illness)
- Use of expert judgment is quite different
  - Used for input parameters only
  - Large panel survey for data, not consensus

Basics of FIRRM

- Ranks pathogen-food combinations, pathogens, and foods (summed over pathogens):
  - 28 pathogens
  - 13 food categories (46 sub-categories)
    - (11 food categories in v2)
  - 5 measures of annual public health impact:
    - Cases
    - Hospitalizations
    - Deaths
    - Monetary cost ($)
    - QALY loss

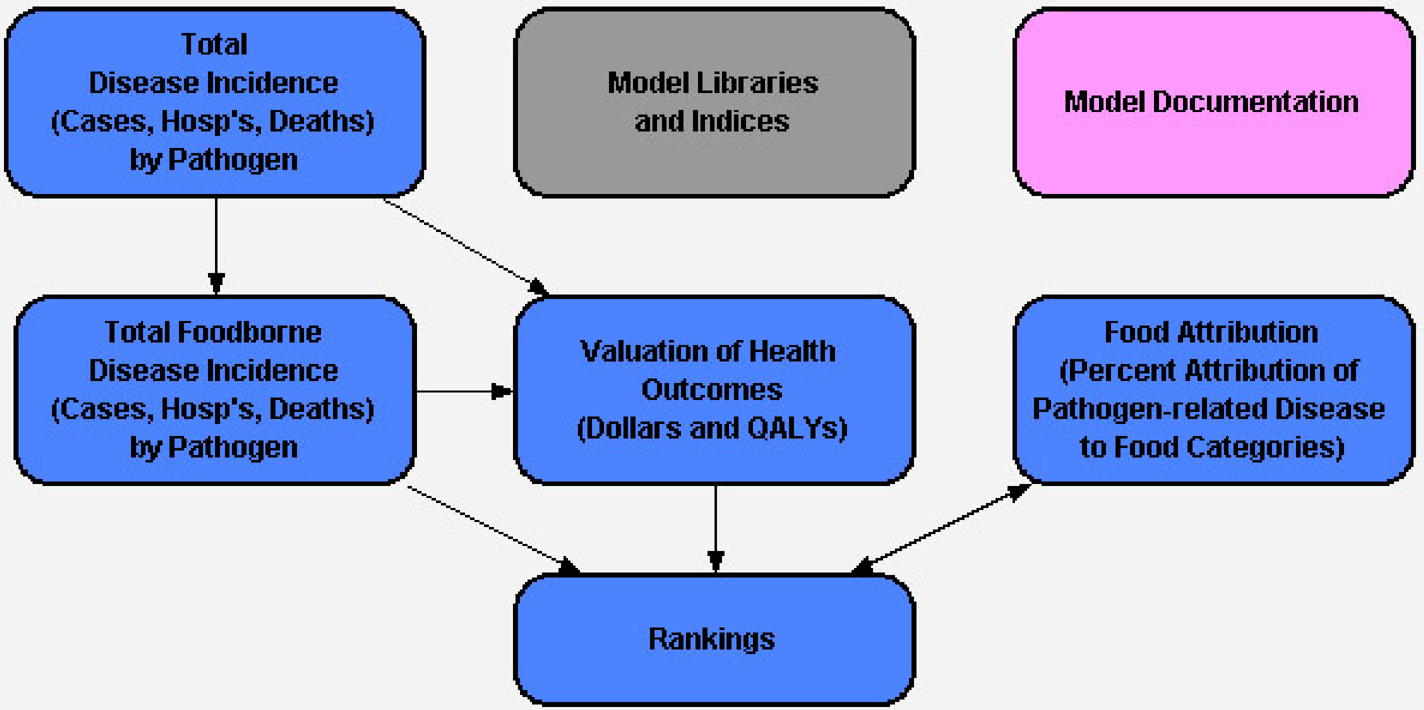
Analytica Enterprise - [Diagram - Model Structure]

File Edit Object Definition Result Diagram Window Help

Model Structure

FUNCTIONAL INFLUENCE DIAGRAM OF MODEL

As with all Analytica models, the Foodborne Illness Risk Ranking Model is composed of functional influence diagrams of model inputs, constants, assumptions, and outputs. Modules are composed of sub-diagrams that may include further modules. Arrows indicate data flow: an arrow from one variable to another indicates that the former is an input to the latter. Arrows between modules indicate that a variable, or variables, in one module are inputs to a variable or variables in another module. Not all data flow arrows are visible in all sub-diagrams, to make them easier to follow. Relationships between variables can still be followed through each variable's object window.



Model Design

- "Top-down" model that takes an epidemiological approach, working backwards from observed cases of disease to the hazard
- Integrates data from multiple sources:
  - Estimates of incidence of 28 pathogens based upon disease surveillance and underreporting factors
  - Health outcome trees of pathogen-associated illnesses, including hospitalization and death as well as chronic sequelae
  - Valuation, in dollars and QALYs, of health states in outcome trees
  - Attribution of pathogen-specific illnesses to food categories based on outbreak data and expert elicitation

Model Characteristics

- Not a predictive model
- Does not point to specific interventions
- Does not include chemical or other risks
- Built in Analytica
  - Graphical interface: point-and-click
  - Changeable assumptions
  - Uncertainty (Monte Carlo)
  - Documentation
  - Adaptability
  - Transparency (no secrets)
- Open and free to download/use/change

Incidence by Pathogen

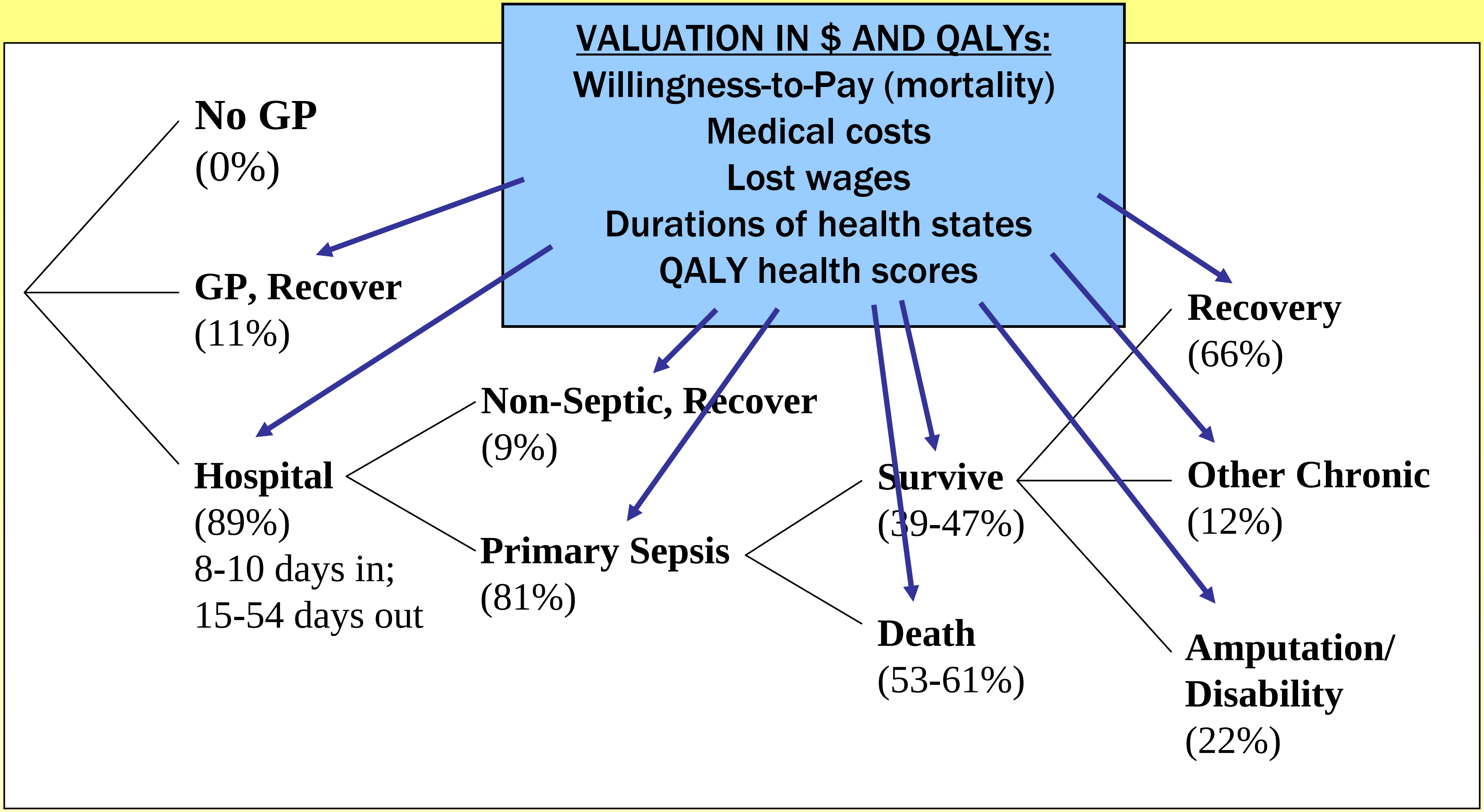
- **Estimates of incidence of 28 pathogens based upon disease surveillance and underreporting**
- **Based on data from FoodNet surveillance and studies, notifiable disease data, outbreak data, and from studies found in literature (e.g. Mead et al. 1999)**

Bacteria		**Parasites**
Bacillus cereus	*Salmonella* Typhi	*Cryptosporidium parvum*
Brucella	*Salmonella* nontyphoidal	*Cyclospora cayetanensis*
Campylobacter	*Shigella*	*Giardia lamblia*
C. botulinum	*Staphylococcus*	*Toxoplasma gondii*
C. perfringens	*Streptococcus*	*Trichinella spiralis*
E. coli O157:H7	*Vibrio cholerae* toxigenic	**Viruses**
E. coli nonO157 STEC	*Vibrio vulnificus*	Norwalk-like viruses
E. coli enterotoxigenic	*Vibrio* other	Rotavirus
E. coli other diarrheogenic	*Yersinia enterocolitica*	Astrovirus
Listeria monocytogenes		Hepatitis A

Integrated Measures of Health Impact

- Cases, hospitalizations, and fatalities are insufficient for comparing pathogens
- Pathogens have distinct:
  - Symptoms, severities, treatments
  - Hospitalization and fatality rates
  - Chronic sequelae
- The solution is valuation of health states using dollars or Health-Adjusted Life Years (HALYs)
  - Can aggregate across health states, compare distinct syndromes
  - Captures *preferences* about alternative health states
  - Can estimate the economic impact of foodborne illness

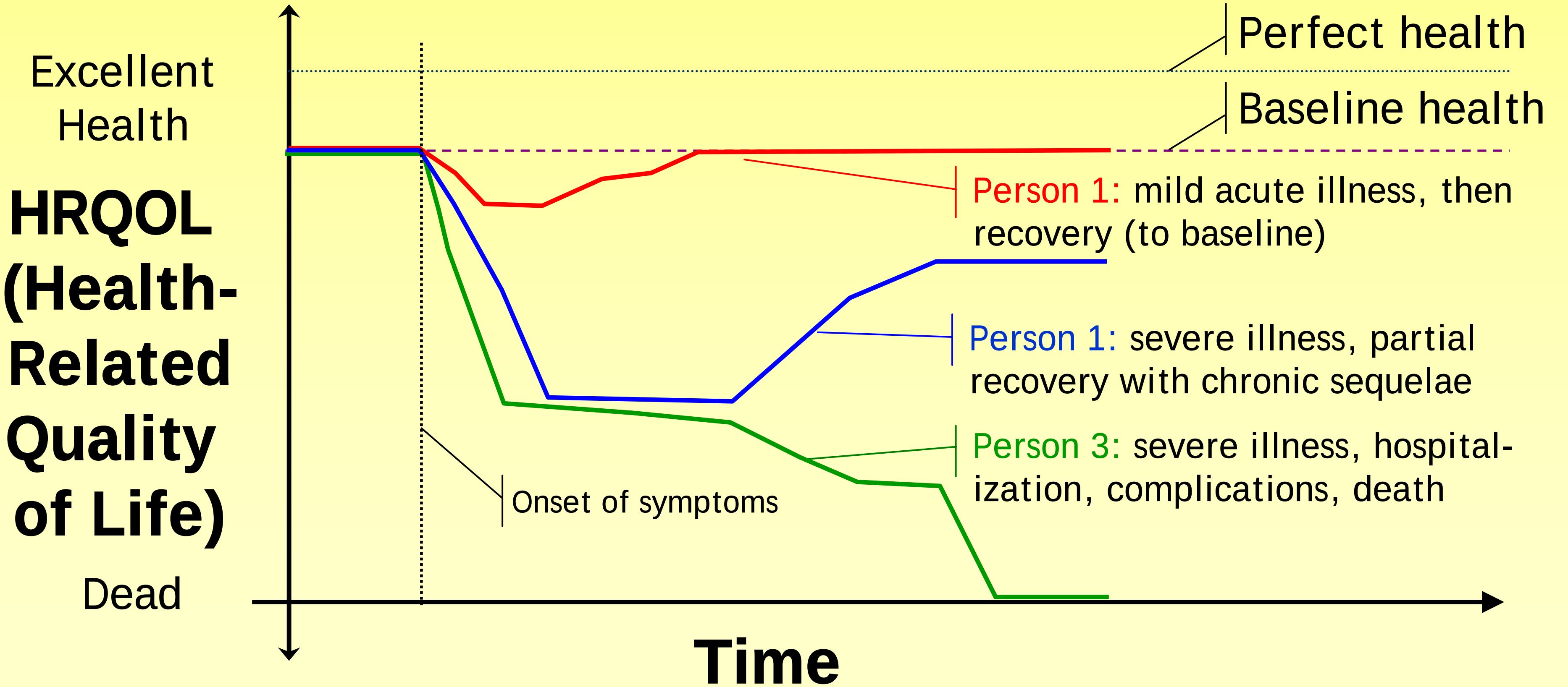
Valuation: *Vibrio vulnificus* example



Note: Because V. vulnificus infection results in severe symptoms, all symptomatic persons are assumed to receive medical treatment

Estimating QALYs

- Track HRQOL through stages of disease – compute loss of QALYs from population baseline (area between the curves)
- Multiple indices available to estimate HRQOL (we use QWB in version 1 and EuroQOL in version 2)



Food Attribution in FIRRM

- Our definition of "food attribution" is broad: for each pathogen, determine proportion (percentage) of foodborne cases in each food category

1000 foodborne cases of Pathogen A X

Food 1	10%
Food 2	5%
Food 3	30%
:	
:	
Food 10	15%
Food 11	10%
TOTAL	100%

=

Path-Food A1	100
Path-Food A2	5
Path-Food A3	300
:	
:	
Path-Food A10	150
Path-Food A11	100
TOTAL	1000

Food Attribution for Risk Ranking

- The systems approach: for broad prioritization (e.g. resource allocation), need to capture a broad coverage of foods
- Comparability: apples to apples
  - Consistency with attribution method across hazards
  - Use consistent food categories across combinations
  - Don't exclude important categories or foods
- Many approaches to attribution, but few data available for large number of pathogens and foods, leaving us with 2 primary sources:
  - Outbreak data
  - Expert judgment

Outbreaks and Experts

- **Outbreak Attribution:**
  - Pros: large dataset for many pathogens, straightforward data, can aggregate by decision rules
  - Cons: misrepresents sporadic cases, geographic & temporally inconsistent, driven by large events, selection bias in food identification
- **Expert Judgment:**
  - Pros: can reconcile disagreeing data & fill gaps, increasingly accepted as valid
  - Cons: not “data driven” in traditional sense, hard to detect biases, potential for circularity
- **Exposure Assessment:**
  - We attempted a simplified approach using contamination and consumption data, but data was too sparse across our scope of pathogens and foods

Food Categories

- Want risk categories to be logically consistent, administratively compatible, equitable, and compatible with cognitive biases*
- But food categories are non-obvious because there are many different ways to group things
  - Ultimately want to get at the many “contributing factors” along the farm-to-fork continuum but the big-picture view needs to simplify the picture into pathogens and foods

* *See:* Morgan et al. 2000. “Categorizing Risks for Risk Ranking,” *Risk Analysis* 20(1) 49-58.

Additional Food Categorization Factors

- **Complex foods:**
  - Foods as eaten usually include multiple ingredients - do we organize foods by complete dishes or composite ingredients?
- **Species vs Product:**
  - Should turkey slices be grouped with "poultry" or "luncheon meat?"
  - Is a tomato a fruit or a vegetable?
- **Origin of production:**
  - Do we need separate categories for imports?
- **Processing and preparation conditions:**
  - For ranking, does it matter how the food was produced (raw, fresh-cut, canned, etc), prepared (home, restaurant, caterer), or eaten (raw, cooked, reheated) at the big-picture level?
- **Fuzzy boundaries:**
  - Do you treat sprouts as a legume or similar to salad greens?
- **One size does not fit all:**
  - The best categories for ranking hazards may not match up to categories used in other data (e.g. food consumption data)

FIRRM (v2) Food Categories for Outbreaks

Poultry	Chicken Other Poultry Poultry Dishes Turkey
Beef	Beef Dishes Ground Beef Other Beef Raw or Cured Beef
Pork	Bacon / Ham Pork Pork Dishes
Other Meats	Other / Unknown Meat Other Meat Dishes Sausages & Deli Meats
Game	Game
Seafood	Finfish Other Seafood Seafood Dishes Shellfish
Dairy Products	Cheese Ice Cream Milk Other Dairy
Eggs	Egg Dishes Eggs

Fruit	Citrus Fruit Melons and Berries Other Fruit
Vegetables	Bean Dishes Canned Vegetables Herbs and Spices Legumes, Nuts, and Seeds Mixed Produce Other Vegetables Salad Greens and Sprouts Tomatoes & Mixtures
Sugars & Beverages	Alcoholic beverages Fruit Juices Non-alcoholic beverages Sugars and Sweets
Grain & Bakery	Bread Cakes and Pastries Other grain flour items Rice
Complex Foods	Deli Salads Desserts Other Complex Foods Other Meat Dishes Pasta and Pizza Sandwiches Sauces, Dressings, Oils

Food Categories and Binning Outbreaks

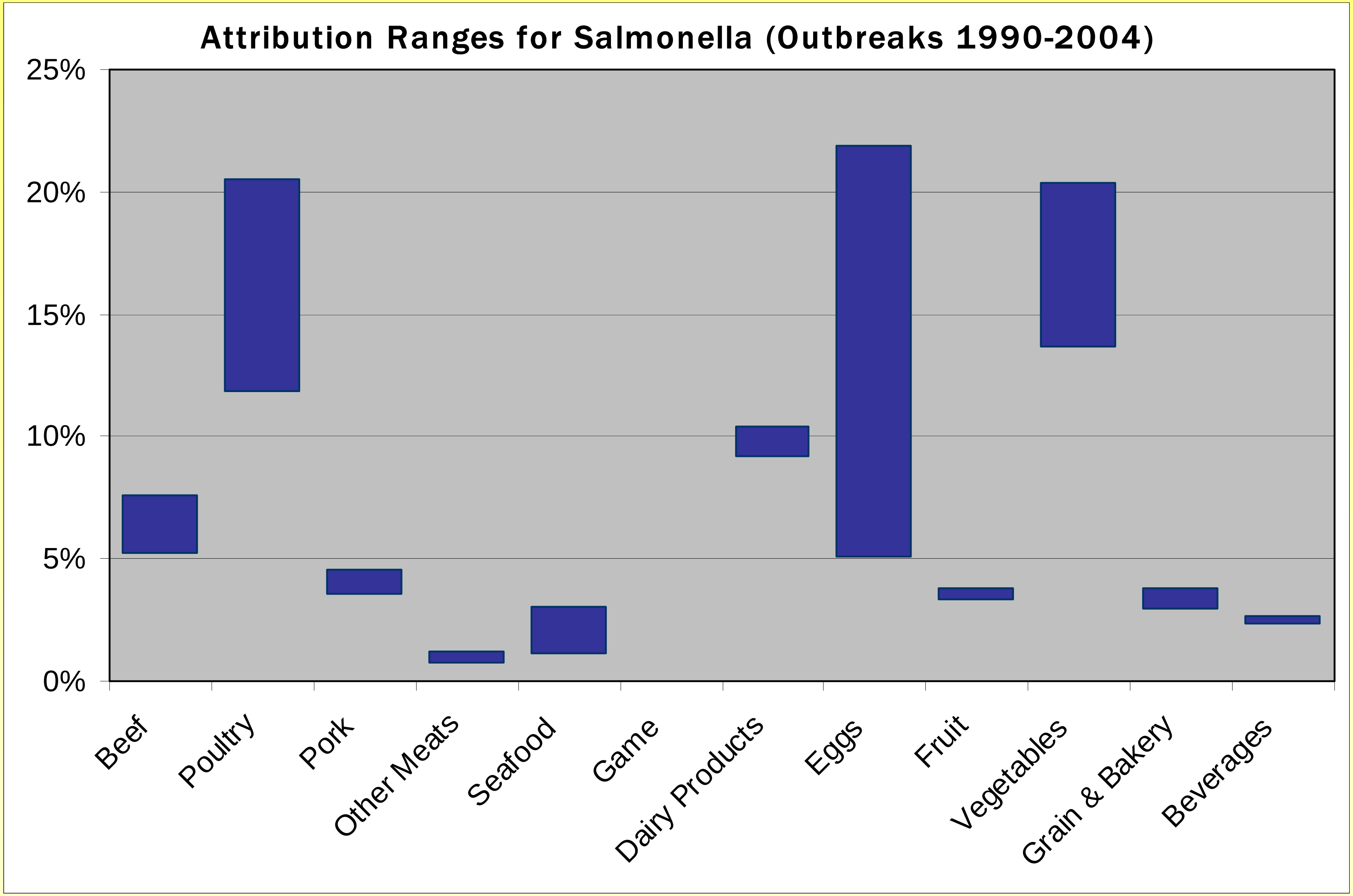
- Many foods as consumed are "complex" in that they include multiple ingredients - for some pathogens, as many as 50% of outbreaks may be due to complex foods
- How to handle? Sensitivity analysis approach:
  - Complex foods category: include or exclude
  - Binning choices: bin all multi-ingredient dishes into complex food category, or use less conservative approach to bin eligible outbreaks into the primary ingredient in the dish (e.g. omelette as egg)?

Complex Foods Example: Salmonella

Include/exclude?	With Complex Category		No Complex Category	
Binning option:	As Complex Food	By Primary Ingredient	As Complex Food	By Primary Ingredient
Beef	5%	7%	9%	8%
Poultry	12%	18%	20%	21%
Pork	4%	4%	6%	5%
Other Meats	1%	1%	1%	1%
Seafood	1%	3%	2%	3%
Game	0%	0%	0%	0%
Dairy Products	9%	9%	16%	10%
Eggs	5%	19%	9%	22%
Fruit	3%	3%	6%	4%
Vegetables	14%	18%	23%	20%
Grain & Bakery	3%	3%	5%	4%
Beverages	2%	2%	4%	3%
Complex Foods	41%	12%	--	--
Total	100%	100%	100%	100%

Multi-Source outbreaks excluded (single food vehicle only), 1990-2004

Uncertainty Due to Binning: *Salmonella*



Multi-Source outbreaks excluded, “complex foods” dropped from percentages.

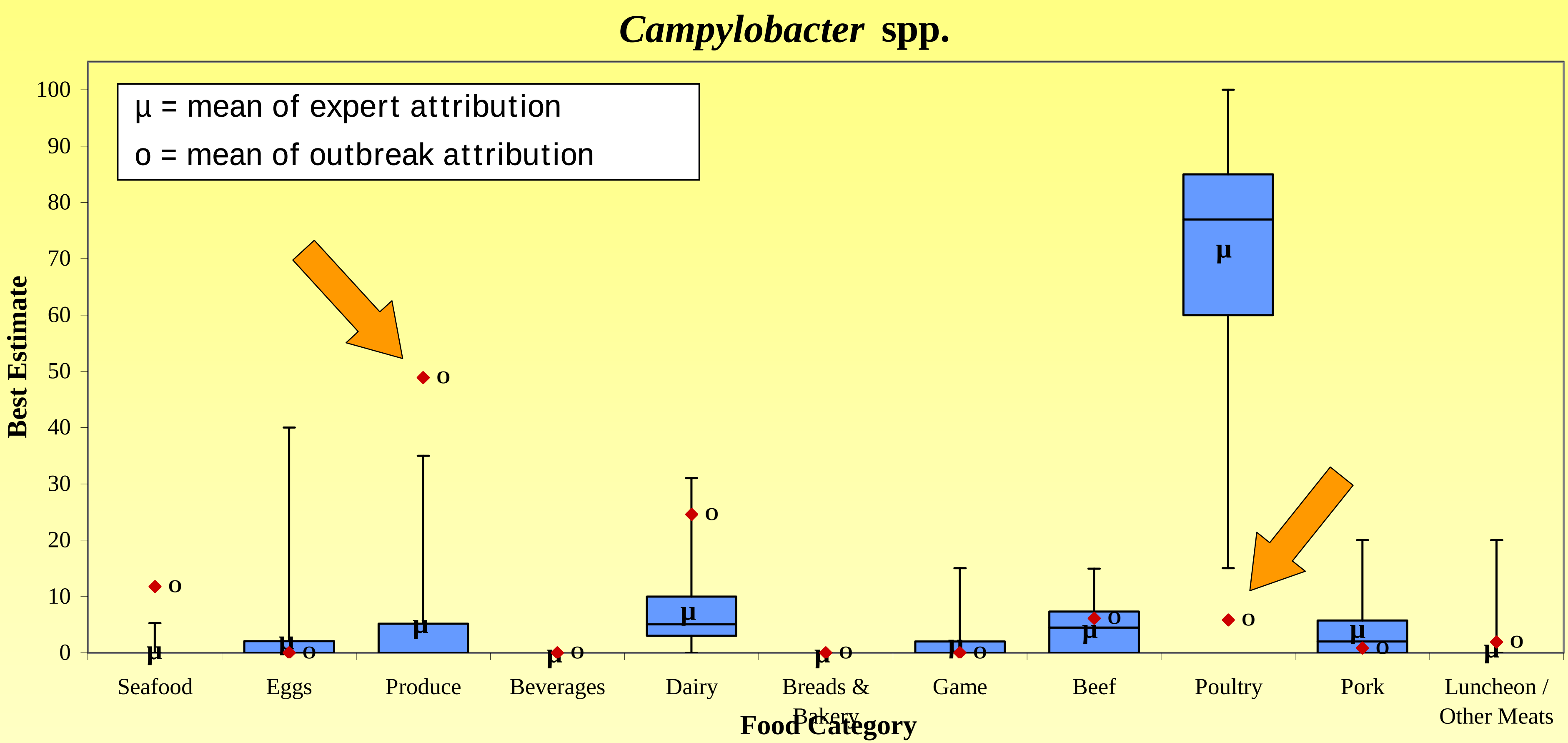
Food Attribution from Experts

- FSRC expert elicitation performed in 2003
  - 11 pathogens: FoodNet + Noro + Toxo
  - Best estimates, also low/high estimates
  - Self-assessed expertise, confidence in answers
- Survey administration
  - Mail survey, peer-reviewed set of respondents
  - 101 contacted, 45 completed: State/Federal Government (24), Academia/Research (14), Industry (3), Other (3)
- Forthcoming articles
  - "Using Expert Elicitation to Link Foodborne Illness in the U.S. to Food" Hoffmann S, Fischbeck P, Krupnick A, McWilliams M. *Journal of Food Protection*
  - "Informing Risk-Mitigation Priorities Using Uncertainty Measures Derived from Heterogeneous Expert Panels: A Demonstration Using Foodborne Pathogens." Hoffmann S, Fischbeck P, Krupnick A, and McWilliams M. *Reliability Engineering and Safety Systems*

Comparing Outbreaks and Experts

- For some pathogens, percentages are quite similar
- For others, percentages significantly different
- Outbreak data might have informed expert opinion
- Expert opinions might also reflect other data, such as case-control studies

Campylobacter: Experts & Outbreak



Major differences between outbreak data and expert judgments for Campylobacter

Note: preliminary data shown for illustrative purposes only

Attribution Affects Rankings: Example

Ranking pathogen-food combinations by number of annual hospitalizations	**Using Outbreak Data**	**Using Expert Judgment**
Norwalk-like viruses / Produce	1	4
Norwalk-like viruses / Unattributable or Other	2	5
Salmonella nontyphoidal / Eggs	3	6
Campylobacter / Produce	4	20
Norwalk-like viruses / Seafood	5	3
Salmonella nontyphoidal / Poultry	6	2
Toxoplasma gondii / Unattributable	7	25
Salmonella nontyphoidal / Produce	8	9
Campylobacter / Dairy	9	18
Campylobacter / Poultry	10	1
Norwalk-like viruses / Breads and Bakery	11	14
Listeria monocytogenes / Luncheon/Other Meats	12	10

Note: Preliminary results, shown for illustrative purposes only. Toxoplasma cannot be attributed via outbreaks (1 outbreak in dataset), but can be attributed via experts, thus the large number of unattributable hospitalizations by outbreaks are broken up by expert attribution.

Uncertainties and Dependencies

- Ranking results have wide uncertainty bands
  - Some pathogen-food combinations likely to be robust at top of list
  - But wide ranges may make it difficult to truly distinguish between “worst” and “almost worst”
- But distributions may be highly correlated
  - For example, underreporting multipliers may be very uncertain but are driven by the same variables across pathogens (e.g. likelihood of patient to see a physician, likelihood of stool sample, etc)

Conclusions

- Significant uncertainties, data gaps, and areas requiring subjective judgment
  - Food categories
  - Expert judgment for attribution
  - Choices of attribution approach
  - Valuation of mortality (VSLs)
- Nonetheless, we expect results to be informative and useful
- What is “good enough?”

Take Home Messages

- We should be striving for data-driven, empirical, and quantitative approaches
  - But incorporation of uncertainty is critical
  - We can learn a lot about future data collection needs and gaps in knowledge
- Consistency is crucial
- For microbial hazards, categorization and attribution to foods are major hurdles
- Expert judgment can be utilized in a focused manner to fill data gaps

Thanks

For more information on the Foodborne Illness Risk Ranking Model, including a downloadable version, visit the FSRC website:

http://www.rff.org/fsrc/

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