Food Safety and Inspection Service
Protecting Public Health and Preventing Foodborne Illness
An Assessment of Prevalence-based Models for Predicting Reductions in Illnesses Attributed to Microbial Food-Safety Policies

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When Are Qualitative Testing Results Sufficient To Predict a Reduction in Illnesses in a Microbiological Food Safety Risk Assessment?

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MS 15-042: Received 29 January 2015/Accepted 9 April 2015
Food Safety and Inspection Service:
Outline

• Framework for Quantitative Microbial Risk Assessment
• Motivation for simplifying models
• Analytic methods
• Results

- **Fundamental eqn for QMRA**

  \[ P(ill) = \int R(D) f(D) dD \]

- **Simplification for low doses**

  \[ P(ill) = \int \beta D f(D) dD = \beta D_{avg} \]


- **Simplification for prevalence-based**

  \[ P(ill) = P(ill \mid exp) P(exp) + P(ill \mid \overline{exp}) P(\overline{exp}) \]

  \[ = P(ill \mid exp) P(exp) \]

Do benefits from illnesses avoided outweigh industry costs for implementing a new regulation?

\[
\text{Public Health Benefits} = \Delta N_{\text{ill}} \times (\text{cost/illness}) \geq \text{Cost}
\]

Illness reductions are proportional to the current number of illnesses

\[
\Delta N_{\text{ill}} = K N_{\text{illnesses}}, \quad 0 \leq K \leq 1
\]
Total illness burden:

\[ N_{illnesses} = N_{servings} P(ill), \text{ where } P(ill) = \text{illness per serving} \]

The effect of a reduction in contamination is:

\[ \Delta N_{ill} = N_{servings} \left[ P_{baseline}(ill) - P_{new}(ill) \right] \]

\[ \Delta N_{ill} = \left[ 1 - \frac{P_{new}(ill)}{P_{baseline}(ill)} \right] N_{illnesses} \]

\[ \Delta N_{ill} = \left[ 1 - \frac{P(ill \mid exp)P_{new}(exp)}{P(ill \mid exp)P_{baseline}(exp)} \right] N_{illnesses} \approx \left[ 1 - \frac{P_{new}(exp)}{P_{baseline}(exp)} \right] N_{illnesses} \]

Desired risk assessment output
Food Safety and Inspection Service: Typical Food Safety Risk Assessment

- Growth
- Partitioning, Mixing, Cross-contamination
- Difficult to fill data gaps
- Growth or attenuation
- Cross-contamination, partitioning, attenuation
- Data collection by FSIS at slaughter or processing
- Is dose sufficient to cause illness?

$$f(\lambda)$$  
$$f(D)$$
• Risk assessments should be fit for purpose
  – Focused on risk management options
  – Readily implemented and communicated
  – Amenable to evaluating the effectiveness of implemented policies empirically

• Risk assessments should feature available data
• FSIS product sampling data
• CDC surveillance (FoodNet, FDOSS)
Food Safety and Inspection Service: FSIS Sample Collection and Testing

Sample Collection

Screening test for pathogen presence $P(\+)

Enumeration to determine levels $\lambda$
Food Safety and Inspection Service:
Summarizing FSIS testing data

log10 transformed *Campylobacter* concentration (cfu/ml)

Limit of Detection (L)

$P(-) = 0.54 \quad P(+) = 0.46$
FoodNet Illness (2013) = 7,277

\[
\{ 
\begin{align*}
600,000? \\
1,125,000? \\
2,000,000? 
\end{align*}
\]

The confirmed illnesses scale up to somewhere between 600,000-2 million salmonellosis cases (Scallan 2011). About 84% of these are from domestic food sources.

Data Sources: FoodNet & Scallan et al. (2011) Foodborne Illness Acquired in the United States—Major pathogens. *Emerging Infect. Disease*
FDOSS data are used to estimate the proportion of salmonellosis cases due to chicken consumption

Painter et al. (2013) Attribution of Foodborne Illnesses... *Emerging Infect. Disease*
Bayesian calibration determines which combinations of inputs and outputs “make sense” and updates parameters.

Prior distributions for intermediate processes are specified and the final distribution applied to dose-response.

\[ \Delta N_{ill} = N_{illnesses} \left[ 1 - \frac{P_{new}(ill)}{P_{baseline}(ill)} \right] \]
Illness reductions can be estimated by the process models, but....

Can we do something less complicated?

What if we only considered $P(+) + N_{ill}$?

A prevalence-based model is:

$$
\Delta N_{ill} = N_{ill} \left[ 1 - \frac{P_{new}(ill)}{P_{baseline}(ill)} \right] \approx N_{ill} \left[ 1 - \frac{P_{new}(+)}{P_{baseline}(+)} \right]
$$

$LOD$ can change relationship
Food Safety and Inspection Service:
Desired properties of prevalence-based model

• Simpler model is more transparent to reviewers and stakeholders
• For the given risk management question, any approximation should be conservative (i.e., predict fewer illnesses avoided)!
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Methods
• Use Bayesian process model as a “gold standard”

\[ \text{Calculate } P_{\text{baseline}}(\text{ill}) \text{ and } P_{\text{new}}(\text{ill}) \text{ via integration of DR function across exposure dose distribution} \]

• Compare illness reduction estimates from Bayesian process model and prevalence-based model for;
  – Range of reductions in contamination distribution
  – Different product-pathogen pairs
  – Different LOD’s

\[ H_0 : \left[ 1 - \frac{P_{\text{new}}(\text{ill})}{P_{\text{baseline}}(\text{ill})} \right] \geq \left[ 1 - \frac{P_{\text{new}}(+)\text{ }}{P_{\text{baseline}}(+)} \right] \]
Food Safety and Inspection Service: Datasets

• Product-Pathogen pairs considered:
  – *Campylobacter*-chicken (LOD=1 cfu/1 ml)
  – *Salmonella*-chicken (LOD=1 cfu/25 ml)
  – *E.coli* O157:H7- ground beef (LOD=1 cfu/325g)

• Data sources
  – HACCP ground beef samples (2007-2009, N=30,995)
Food Safety and Inspection Service: 
Modeling the effect of a new policy

• Reduce log-transformed mean of contamination distribution at production

\[ \lambda_{\text{baseline}} \sim \text{lognormal}(\mu, \sigma) \]
\[ \lambda_{\text{new}} \sim \text{lognormal}(\mu - \Delta, \sigma) \]

\[ \Delta = (0.1, 0.2, ..., 0.9, 1.0, ..., 1.9, 2.0) \]

2.3% reduction  90% reduction  99% reduction

• Baseline and new distributions determine the prevalence of positive samples
Food Safety and Inspection Service:
Illustration of calculations

Contamination at end of proc

$P_{\text{baseline}}(+) \approx 0.13$

$P_{\text{new}}(+) \approx 0.03$

$1 - \frac{P_{\text{new}}(+)}{P_{\text{baseline}}(+)} \approx 0.73$

Dose distribution and Dose-f

$P_{\text{baseline}}(\text{ill}) \approx 8.1 \times 10^{-7}$

$P_{\text{new}}(\text{ill}) \approx 1.0 \times 10^{-7}$

$1 - \frac{P_{\text{new}}(\text{ill})}{P_{\text{baseline}}(\text{ill})} \approx 0.88$
Results
Food Safety and Inspection Service: Chicken carcasses- *Campylobacter*: Reduction in average log-transformed mean

- Process model shows reduction in illnesses is nearly linear with reducing mean contamination at production
  - Most exposures occur in linear part of dose-response function
- Prevalence-based models predict lower reductions in illnesses consistently
  - Larger LOD=1 cfu/ml predicts greater reductions than smaller LOD=0.03 cfu/ml
  - Non-linear curves reflect dynamics of lognormal distribution’s tails
Prevalence-based model using LOD=0.04 cfu/ml is downward biased, but only slightly
  - This is the LOD used currently in FSIS
  - Detects 1 cfu per 25 ml

Prevalence-based model using LOD=1cfu/ml over-predicts reduction in illnesses
  - LOD is too far out in the tail of the lognormal distribution
  - Baseline would only find 0.5% of samples positive
• Process model reductions are more non-linear than other examples
  – substantial share of risk of human illness results from higher doses where the dose-response function is nonlinear

• Curves for process model and prevalence-based model using LOD=0.003 cfu/g are equal
  – This is the LOD used currently in FSIS
  – detects 1 cfu per 325 g
  – Using a higher LOD (0.015) slightly over-predicts illness reductions, but detection of positive samples would be exceptionally rare
Food Safety and Inspection Service:
Conclusions

• Prevalence-based model is reasonable
  – Prevalence-based model can over-predict true change in probability of illness per serving if LOD very high

• Agreement is highest for “rare” pathogens

• Prevalence-based model can be used in situations where enumeration data are not available
  – Substantial cost savings
  – Works in situations where enumeration data are too limited to fit $f(\lambda)$
Food Safety and Inspection Service: Implications for FSIS performance standards

• Historically, FSIS performance standards based on prevalence
  – if below avg, passing
  – if above avg, failing

• Recently, linked performance standards to public health goals
  – If prevalence across industry were to decline, what would be the public health benefit?

• Effectiveness of standards depends on compliance

• Projected public health benefits of performance standards may be conservative
Food Safety and Inspection Service:

Questions?