Towards an Interventions Assessment Model for E. coli O157:H7 in Leafy Greens

Applying the Conceptual Framework

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E. coli O157:H7 In Lettuce and Leafy Greens:
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The Public Health Challenge

- Complex problem, and finite resources
- The challenge, put simply:

How best to target interventions and allocate resources to reduce illness?
The Conceptual Framework...

- Informs the allocation of resources and efforts in ways that maximize risk reduction
- Considers the feasibility, effectiveness, and cost of risk reduction interventions
- Is NOT methodologically prescriptive, but specifies key principles
- Is NOT intended to displace the other factors (social, political, market) that will continue to play a role in decisions
A “Systems” Perspective

- Foodborne illness results from the interaction of numerous factors, arising from farm to table, that affect both causation and prevention.
- Thus, opportunities to reduce risk arise across the food system.
Key Principles

- **Practicality:**
  - Needs of decision-makers
  - Limitations of data
  - Financial and time costs of analysis

- **Within the bounds of practicality:**
  - Best available science
  - Grounded in “systems” understanding
  - Transparency in assumptions & limitations
  - Flexible

- **Re-evaluation:**
  - Continuous or iterative evaluation
A Range of Purposes

- **Purpose 1**: *broad, public*
  “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
Risk Ranking

- As a first step in broad priority setting, identify the most significant hazards

- 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
Intervention Assessment

- An analytical approach to identify the best intervention options:
  1. Identify “leverage points” in the farm-to-fork chain where intervention may be effective
  2. Compare interventions in terms of feasibility, cost, and effectiveness

- An “intervention” is defined as any action that results in reduction of risk: a regulation, a process change, a new technology, an educational campaign, etc

- Effectiveness in this context is defined locally, using a “surrogate” for public health, such as prevalence or enumeration
Questions to Guide Intervention Assessment

1. At which points across the farm-to-table spectrum could interventions be applied to reduce the risk of foodborne illness?
2. What technically feasible options are available at each point?
3. How effective are available interventions in reducing the risk of illness in surrogate terms?
4. What are the costs to government, industry, and consumers of implementing the intervention(s)?
5. Are there supply chain effects (changes in behavior up or down the supply chain from the intervention) that will significantly influence the effectiveness of interventions?
Modeling Interventions...

- Many choices of approaches, for example:
  - Farm-to-fork black box model based on regressions on epidemiologic data and parameters of the processing environment
  - Quantitative microbial risk assessment based on contamination data and predictive microbiology to estimate pathogen growth
  - Bayesian network based on conditional relationships between sampled data, parameterized through expert judgment
Secondary Impacts

- Ideally, intervention assessments should incorporate secondary impacts:
  - Intervening on one hazard may impact another
  - Some interventions may have adverse effects elsewhere in the chain
  - Models incorporating economic behavior will more fully represent real-world impacts of interventions
Health Benefit Estimation

- Examine interventions in explicit public health terms
- Translate surrogate-level effectiveness to public health effectiveness:
  - Dose-response models based on laboratory studies, natural experiments, or other data
  - Measured impacts of previous, similar interventions
- Inherent complexity in modeling
  - Food handling (subsequent to intervention)
  - Sensitive sub-populations
  - Antimicrobial resistance
Combined Evaluation

- Using results of other three analyses to examine and compare options
- Combine costs and impacts of interventions
  - Benefit-cost analysis
  - Cost-effectiveness (at surrogate level)
  - Cost-effectiveness (in public health terms)
- Sensitivity analyses
The Conceptual Framework

**Risk Ranking (FIRRM)**
- Health outcomes
- Health valuation

**Intervention Assessment**
- Feasibility
- Costs
- Define surrogate
- Local effectiveness (surrogate)

**Health Benefit Estimation**
- Dose-response modeling
- Health outcomes
- Health valuation

**Priority Setting Decision**
**Purpose 1**: Public, Broad: (e.g. resource allocation, data, research, education)
**Purpose 2**: Public/Private, Specific: (e.g. regulatory action, private intervention)

**Combined Evaluation**
- Cost-effectiveness (surrogate)
- Cost-effectiveness (pub hlth)
- Cost-benefit analysis

**Public Health Surveillance & Animal/Food Data**

**Post-Hoc Evaluation**
“Awesome Conceptual Framework for Prioritizing Opportunities to Reduce the Risk of Foodborne Illness, Man!”

- Now what?
Focusing on O157 in Lettuce (the thinking in June)

- Produce is an increasingly identified vehicle for outbreaks
- Recent O157 outbreaks in lettuce have clarified need for interventions but still a clear lack of direction
- Numerous risk assessments exist on meat, poultry, and animal products, while few such models have focused on produce products
Focusing on O157 in Lettuce (the thinking in November)

- The recent outbreak has highlighted the need for interventions
- Widespread agreement in the big picture
  - Multiplicity of potential routes of contamination
  - Serious knowledge gaps in most of these routes
- Nonetheless, we need to act NOW to make spinach and leafy greens safer
Short-term Action

- Consumers (retail, food service) driving growers to accept mandatory GAPs or BPs
- Market-driven requirements aren’t based on risk or science, as the science isn’t there, so they are “precautionary”
- These requirements may be overly aggressive, may focus resources on the wrong risks, and may not be protective
Long-term Planning

- We need to improve the science...
- ...But also need to improve the ability to assess the efficacy of risk reduction strategies
- To do this, we can take a systems view and begin to develop an integrated “model” to build up the assumptions and conditions that define the routes of contamination, that will allow us to assess interventions
Assessing Interventions in Produce

Some differences between raw produce and meats and produce:

- Reducing contamination to acceptable levels vs. preventing initial contamination
- Few pathways for contamination vs. numerous pathways for contamination
- Levels in product to be cooked vs. levels in product to be eaten raw
The Farm to Fork Continuum

The Supply Chain for Lettuce and Leafy Greens (simplified)
On-Field Contamination Pathways

- COWS
- MANURE
  - DIRECT CONTACT
  - SOIL AMENDMENTS
  - IRRIGATION WATER
  - FLOODING
  - WILD ANIMALS
  - AIR DEPOSITION
  - FARM EQUIPMENT
  - HUMAN CONTACT
  - SOIL → UPTAKE
  - LEAVES

- WILD ANIMALS
Determining Relative Risk

- Before we can identify interventions, we must establish the baseline.
- This means quantifying the risk associated with these pathways.
- All of these pathways are “possible” but which are more likely than others?
- If we cannot establish the “absolute risk” associated with any individual pathway, we might nonetheless be able to estimate the “relative risk” between pathways.
Pervasive Uncertainties

- All of these pathways are “possible” but which are more likely than others?
- The answer depends on many factors, for which the data (or the science) are unknown:
  - Levels in environment (water, ranches)
  - Transport/fate of pathogens in water sources
  - Distances/patterns of bacterial transport via wind
  - Persistence in soil
  - Effect of temperature, humidity, and other climate/weather variables on persistence or growth
  - Ability for internalization of bacteria
  - Consistency of composting for microbial decontamination
In the Face of Uncertainty

- By making a systematic attempt to quantify these pathways and build up the assumptions and conditions that drive the risk of these pathways, we can
  - Identify which gaps in data/knowledge are the most important
  - Build up the necessary foundation or framework to be able to compare the public health effectiveness of intervention actions
Questions for the Workshop

- Can we develop an “intervention assessment” model or set of analyses to prioritize opportunities to intervene to reduce risk?
- If this sounds too ambitious: can we organize the state of knowledge regarding O157 in leafy greens into an analytical framework that might be the foundation for assessing relative risk of pathways?
Questions for the Workshop

- As a starting point, can we agree on the most important pathways and the most important knowledge gaps?
- How can current/planned research and data collection fit into a systems model?
- What are the funding opportunities for this sort of multi-disciplinary modeling?
Thanks

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

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