

Impact of Traceability During Foodborne Illness Outbreaks

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Coordinated Outbreak and Response Evaluation (CORE) Network



- FDA's Coordinated Outbreak Response and Evaluation Network
- Manages Surveillance, Response, and Prevention activities related to incidents of illness linked to FDA-regulated human food, cosmetics, and dietary supplements
- Coordinating complex outbreak response activities across FDA, the States and CDC
- Responding to outbreaks where an in-depth investigation is needed



Federal Roles

- CDC:
 - Disease surveillance
 - Outbreak detection and investigation
 - Education and training of public health staff
- FDA & FSIS:
 - Food safety policies
 - Inspection and enforcement
 - Product recall and traceback
 - Investigation of farm and production facilities



Epidemiologic Data Collection Challenges

- Ill people interviewed 2-4 weeks after illness onset
- Commonly eaten foods such as leafy greens, chicken, and beef
- New foods may not be routinely asked about
- Stealthy ingredients such as onions, peppers, and spices
- Lack of brand/product information for produce and chicken and beef
- Identifying sub-clusters is critical



Outbreak Case Study:

Multistate Outbreak of *Salmonella* Newport Infections Linked to Onions

- 1,127 ill people (24% hospitalized, 0 deaths) from 48 states
- Utilized illness sub-cluster investigations to identify vehicle
 - Ingredients, like onions, difficult to implicate with patient recall alone
 - Early findings showed 9/9 sub-clusters served red onions
 - Utilized restaurant and other invoices to identify which red onions were supplied
- Single, common onion grower identified by FDA
- Traceback evidence led to the company voluntarily recalling onions starting on August 1, 3 weeks after the outbreak first detected
- Due to the way onions were grown and harvested, red, yellow, and white onion varieties were recalled



Outbreak Case Study:

Multistate Outbreak of Salmonella Newport Infections Linked to Onions

- Investigation Challenges
 - Difficult to identify the source when contaminated item is in a wide range of foods and is commonly eaten
 - Difficult to trace back and recall the many items affected and to provide easy public guidance
- Lessons Learned
 - Rapidly interviewing ill people to identify sub-clusters was critical
 - Focusing on sub-cluster investigations and traceback are a highly effective way of solving ingredient-driven outbreaks



Outbreak Case Study: Multistate Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Infections Linked to Raw Tuna

- 425 ill people (17% hospitalized, 0 deaths) from 28 states and DC
- Utilized several methods to evaluate the association between tuna and illness
 - A study to estimate the frequency of consumption of tuna among sushi eaters
- Traceback focused on fresh and frozen tuna supplied to 4 sub-cluster restaurants
 - Identified common ingredient used in spicy tuna supplied to all restaurants
 - The common product was a frozen raw nakauchi scrape yellowfin tuna from a single processing facility in India.



Outbreak Case Study: Multistate Outbreak of *Salmonella* Bareilly and *Salmonella* Nchanga Infections Linked to Raw Tuna

- FDA Import Alerts
 - All fresh and frozen tuna from Company A detained and screened upon entry to the US
- Product Recall
 - Company voluntarily recalled frozen raw tuna scrape
- Advice to the public and retailers





Traceback Challenges



- An ongoing outbreak; need to act fast
- Poor consumer recollection of consumption history and lack of specific product information
- Multiple product varieties and/or multiple ingredients identified
- Multiple sources of same product at points of sale (POS)
- Poor record-keeping at firms within the distribution chain
- Lack of a rapid and rigorous mechanism to link shipments (or item in a shipment) from farm to fork
- Varying tracing data across the supply chain



Outbreak Case Study:

Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Romaine Lettuce

- Traceback investigation was initiated on 11/18/19 that included 15 points-of-sale (POS)
- Traceback records were requested for all romaine lettuce available to cover the time period of 9/15/19 through 11/18/19
- Lack of lot code traceability for 13/15 POS
 - Took approximately 1 month to collect, analyze and identify growers that supplied the lettuce
 - For the 2 POS where lot codes were available, growers were identified within 24 hours or less
 - **Lot codes are not typically available during outbreak situations at POS**
- Broad public advisory was issued on 11/22/19
 - Most efficient way to ensure contaminated product was off the market

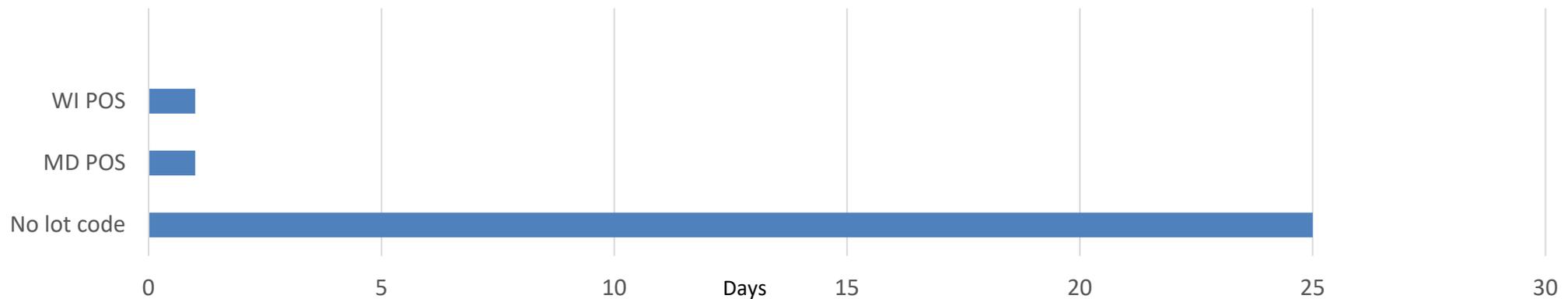


Outbreak Case Study:

Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Romaine Lettuce

Table 1. Traceback Initiation Dates for POS With and Without Available Lot Code Data Associated with *E. coli* O57:H7 Outbreaks Linked to Romaine Lettuce

	Traceback Initiation Date	Grower Identification Date
POS locations – no lot code data	11/18/19	12/13/19
MD POS location – lot code data	11/18/19	11/18/19
WI POS location - lot code data	12/4/19	12/5/19





Benefits of Better Traceability



- Access to specific KDEs creates efficiencies in the tracing process
 - FDA would likely be able to identify common product sources in approximately 5 to 7 days if lot code data is available at POS
- Authorities could have access to information for swifter product action
- Opportunity to better scope product actions
- Creates ability to have more refined record requests



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