Foodborne Outbreaks 101: Introduction to CDC’s Investigation Process for Multistate Foodborne Outbreaks

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Outbreak Investigation Process
A Changing Landscape: Foodborne Disease in the U.S.

- Food production and distribution has changed substantially over the last several decades
- Fewer producers, with wider distribution
- More “ready-to-eat” and industrially produced foods
- Has caused a shift in the types of outbreaks that occur
A Changing Landscape: Foodborne Disease in the U.S.

“Classic” Foodborne Outbreak

Disseminated Foodborne Outbreak
Detecting Outbreaks with PulseNet

- Subtyping enteric bacteria is essential to identifying highly disseminated outbreaks

- PulseNet laboratory network established in 1996
  - Over 80 participating laboratories in the US
  - 60,000+ isolates subtyped annually

- Bacteria collected from ill people undergo DNA “fingerprinting” using pulse-field gel electrophoresis (PFGE) and whole genome sequencing (WGS)

**Bacteria with the same “fingerprint” are more likely to come from a common source**
Detecting Outbreaks with PulseNet

- PFGE/WGS data from illness-causing bacteria are transmitted to CDC
- Monitored for temporal clusters
- PulseNet notifies epidemiologists to investigate clusters
Generating Hypotheses About the Source

- Demographics of ill people in the outbreak (age, sex, race/ethnicity)
- Geographic distribution
- Shape of the epidemic curve
  - Rapid ascent and descent?
  - Slow ascent and prolonged?
- Pathogen type and history
- Food exposure frequencies from initial interviews
Testing Hypotheses: How Do We Determine a Food is the Cause of an Outbreak?

- Three types of evidence used:
  - **Epidemiologic**: Association between illness and exposure
  - **Traceback**: Suspected food item converges on a common source of contamination
  - **Microbiologic**: Pathogen found in the food, farm or facility
Testing Hypotheses: Epidemiologic Evidence

Patterns in where and when people got sick, and past outbreaks caused by the same germ.

Interviews with sick people to look for foods or other exposures occurring more often than expected.

Discovery of clusters of unrelated sick people who ate at the same restaurant, shopped at the same grocery store, or attended the same event.
Testing Hypotheses: Epidemiologic Evidence

- “Are ill people eating any foods more often than we would expect?”

- What is done?
  - Ill people are asked about foods eaten before becoming sick
  - Compare to surveys of healthy people or non-outbreak cases
  - Other data used to corroborate reports (shopper cards, receipts)
  - Identify illness sub-clusters (multiple unrelated ill people with a common restaurant, event, institution exposure)

- Who’s responsible?
  - CDC coordinates questionnaire development and analyzes data nationally
  - State/local health departments interview ill people
Testing Hypotheses: Traceback Evidence

A common point of contamination in the distribution chain from farm to fork, identified by reviewing records collected from restaurants or stores where sick people ate or shopped.

Inspections in food production facilities, on farms, and in restaurants that identify food safety risks.
Testing Hypotheses: Traceback Evidence

- "Can most/all illnesses in the outbreak can be linked back to food coming from a common point of contamination?"

What is done?
- Product names and lot numbers collected from case-patients, if available
- Shopper card numbers and receipts document purchases
- Records (invoices, bills of lading) obtained to trace foods to their source

Who is responsible?
- State/local health departments get pertinent case-patient information to regulatory agencies
- State and/or federal regulatory agencies collect information further up the distribution chain to determine source
**FOOD & ENVIRONMENTAL TESTING**

The germ that caused illness is found in a food item collected from a sick person's home, a retail location, or in the food production environment.

The same DNA fingerprint linking germs found in foods or production environments to germs found in sick people.
Testing Hypotheses: Microbiologic Evidence

• "Can the same bacteria that is making people sick be found in the food or production environment?"

• What is done?
  – Testing leftover food items from patient homes / restaurants
  – Environmental and food sampling in the supply chain (e.g., farm, facility)
  – PulseNet data examined for routine food sampling programs (e.g., NARMS)

• Who is responsible?
  – State/local health departments collect leftover foods
  – Federal and state regulatory agencies test foods, conduct environmental assessments and sampling
Testing Hypotheses: Interpretation

- Making the link between a company or food item and an outbreak is not taken lightly
  - Implications for government credibility
  - Financial and brand impact on industry/companies

- All lines of evidence must be evaluated to make a determination
  - Want to be fast \textit{and} right
  - Avoid errors, but balanced by the need to stop ongoing risk
  - All three lines are not needed, and in rare circumstances, may rely on a single, strong line of evidence
Taking Actions to Prevent More Illnesses

- Regulatory agencies have several tools to stop outbreaks
  - Product recalls
  - Facility closures

- Industry actions to stop the outbreak can include:
  - Issuing consumer warnings and product recalls
  - Defining the scope of the contamination event
  - Halting production and/or correcting processes

- CDC’s role limited to publicly communicating about the outbreak source
  - Disseminating recall information
  - Providing specific, actionable advice
Confirming the Outbreak is Over

- CDC will close an investigation after reports of illness either stop or return to “expected levels”

- Other information is considered
  - Reporting delays for the pathogen and other factors that affect reporting (e.g., holidays)
  - Whether the source of contamination was known/mitigated
Public Communication
How CDC decides what to say and when to say it
Gaining and Maintaining the Public’s Trust

- Trust is essential for risk communication
  - Many risks are invisible (bacteria)
  - The information we have is often uncertain or incomplete
  - Much of the public cannot understand the information themselves

- Handle uncertainty with caution and clarity
  - Be clear about:
    - What we know
    - What we don’t know
    - What we’re doing to find out
Why CDC Communicates about Foodborne Outbreaks

#1 REASON:
Specific source identified & public can take action

Other reasons CDC may communicate include:
- State health department(s) communicate
- High risk group involved
- Deaths, high hospitalization rate
- Misinformation circulating
CDC’s Role in Public Communication

- As a non-regulatory agency, CDC’s role in taking actions to stop an outbreak is limited to posting outbreak notices
  - Since 2006, CDC has posted over 125 multistate foodborne outbreak notices on its website

- As the nation’s public health agency, CDC serves as the unofficial “spokesperson” for multistate outbreaks
Timing for Public Communication

- Communication to the public may be needed at any point, or it may never be needed
  - In 2017, CDC investigated over 220 multistate clusters; 14 outbreaks were communicated about publicly

- The decision about “when” typically occurs quickly
  - New information can trigger communication at any point in an investigation
Timing for Public Communication

- Posting a notice on the CDC website involves balancing many priorities:
  - Being “fast and right”
  - Input from partners
  - Science and plain language

- Often, CDC is not the first agency to “break the news”
  - We may wait to communicate until a company issues a recall so we can link to it and give specific advice about what not to eat
  - A state or local health department may issue press first
Questions to Consider

- Is the outbreak ongoing?
- What action step could people take to prevent illness?
- What is the shelf life of the food?
- Is the food item widely distributed?
- Is a vulnerable group affected?
- Are we seeing more severe illness than we would expect?
- What evidence links a food to illness?
Crafting the CDC Message

- Because our goal is to prevent additional illnesses, CDC’s most important message is crafting the advice for consumers.

- In order for our advice to lead to action, it needs to be:
  - Specific
  - Clear
  - Complete

- Identifying the company and its product(s) linked to an outbreak helps people take action.
Message Accuracy & Consistency

- Decision to post a notice is made jointly with partners
  - State and local health departments
  - Regulatory agency

- Discussion of communication plan with implicated firm

- Content for web posting shared in advance before posting
**Multistate Outbreak of *E. coli* O157:H7 Infections Linked to Romaine Lettuce**

**What's New?**
- Twenty-three more ill people from 10 states were added to this investigation since the last update on April 27, 2018. One death was reported from California.
- Three more states have reported ill people: Kentucky, Massachusetts, and Utah.
- The most recent illness started on April 21, 2018. Illnesses that occurred in the last two to three weeks might not yet be reported because of the time between when a person becomes ill with *E. coli* and when the illness is reported to CDC.

**At A Glance**
- Case Count: 121
- States: 25
- Deaths: 1
- Hospitalizations: 52
- Recall: No

**Highlights**
- Information collected to date indicates that romaine lettuce from the Yuma, Arizona growing region could be contaminated with *E. coli* O157:H7 and could make people sick.
  - For the latest information about the traceback investigation, visit the U.S. Food and Drug Administration (FDA) website.
- **Advice to Consumers:**
  - Do not eat or buy romaine lettuce unless you can confirm it is not from the Yuma, Arizona growing region.
  - Product labels often do not identify growing regions, so, do not eat or buy romaine lettuce if you do not know where it was grown.
Social Media

- Highlight advice
- Drive traffic to website
- Interact with consumers and answer questions
News Media

- Amplify message to larger audience
- Highlight investigation process
Outbreak Example

*E. Coli* O157 Infections Linked to SoyNut Butter
Days 1-3: Cluster Identification

- February 21: PulseNet and California notify CDC’s outbreak team of a cluster of *E. coli* O157 infections with a rare PFGE pattern

- February 22: CDC emails states to initiate multistate investigation
  - 7 cases in 4 states
  - Median age is 10

- February 23: First multistate conference call held
  - 10 cases in 4 states
  - Median age is 7
  - 4 cases of HUS
  - One illness sub-cluster identified at an Arizona daycare
Day 3: February 23

- How many illnesses and where?
  - 10 illnesses in 4 states

- Outbreak ongoing?
  - Yes

- Are illnesses severe?
  - 4 HUS cases

- Is a vulnerable group at risk?
  - Young children

- What evidence links a food to illness?
  - Epi: None
  - Traceback: None
  - Lab testing: None

- Is public communication needed?
  - High risk, low specificity
  - No advice to provide
  - **Decision:** Continue to investigate
Day 8: The First Epi Signal

- February 28: Maryland has a case that reported soy products on initial interview but not specifically soynut butter; Maryland plans to re-interview
Day 9: Epi Signal Strengthens

- Afternoon of March 1
  - Maryland case reports consuming Brand A SoyNut Butter, creamy variety
  - Arizona reports that a childcare center linked to 1 case serves this product

- Evening of March 1
  - Arizona reports that the childcare center linked to 3 cases serves Brand A SoyNut Butter
Day 10: March 2

- How many illnesses and where?
  - 12 illnesses in 5 states

- Outbreak ongoing?
  - Yes

- What evidence links a food to illness?
  - Epi: 100% (9/9) report Brand A SoyNut Butter; illness sub-clusters under investigation
  - Traceback: None, but specific product/brand named by cases
  - Lab testing: Pending

- Is public communication needed?
  - High risk, medium specificity
  - Firm identified, but no specific lots
  - Product testing pending
  - Advice to provide
    - Decision: Warn consumers not to eat Brand A soynut butter
Day 10: Warning the Public

- CDC and FDA inform the firm of the outbreak and that CDC will warn consumers to not eat any Brand A SoyNut butter products

- The evening of March 2, CDC sends a statement to media outlets warning people not to eat or serve these products
CDC, FDA, and states investigating multistate *E. coli* outbreak

CDC, FDA, and several states are investigating an outbreak of 12 illnesses of Shiga toxin-producing *E. coli* (STEC) O157:H7 reported from several states. Epidemiologic information collected to date indicates that [redacted] brand SoyNut Butter products might be contaminated with this harmful bacteria and are a likely source of this outbreak. CDC recommends that people not eat or serve these products. CDC will post additional details on its [outbreak website](http://www.cdc.gov/coli) on Friday, March 3.

The symptoms of STEC infections vary but often include severe stomach cramps, diarrhea (often bloody), and vomiting. Most people get better within 5–7 days, but some infections are severe or even life-threatening. [Hemolytic uremic syndrome (HUS)](http://www.cdc.gov/coli), a type of kidney failure, is a potentially life-threatening complication of *E. coli* O157 infection. Very young children and the elderly are more likely to develop severe illness and HUS than others, but even healthy older children and young adults can become seriously ill.

Contact your healthcare provider if you have diarrhea that lasts for more than 3 days, or is accompanied by high fever, blood in the stool, or so much vomiting that you cannot keep liquids down and you pass very little urine. More information about *E. coli* can be found at [www.cdc.gov/coli](http://www.cdc.gov/coli).
Days 11-12: Recalls and First CDC Web Posting

- March 3
  - Firm issues a recall of two best-by dates of Brand A SoyNut Butter
  - CDC web posting recommends consumers not eat and institutions not serve any Brand A SoyNut Butter

- March 4
  - Firm expands recall to two months of best-by dates to better cover the range of dates reported by ill people
Days 14-15: Initial Product Testing Results

- March 6
  - Oregon confirmed *E. coli* O157 in a sample of leftover Brand A SoyNut Butter collected from a patient’s home

- March 7
  - California reported that 2 samples of Brand A SoyNut Butter were preliminary positive
    - One leftover sample collected from a patient’s home
    - One intact retail sample
Illness Sub-cluster Investigations

- Childcare center in AZ served Brand A SNB & granola (3 people)
- Treatment facility in OR served Brand A SNB (2 people)
Traceback Investigation

- Brand A products were sold by Company B
- Company B used contract manufacturers to make products
  - Supplier C produced the soy nut butter itself
Day 15: March 7

- How many illnesses and where?
  - 16 illnesses in 9 states

- Outbreak ongoing?
  - Yes

- What evidence links a food to illness?
  - Epi: 100% (15/15) report Brand A SoyNut Butter, multiple illness sub-clusters
  - Traceback: Common supplier of soynut butter
  - Lab testing: Preliminary positives

- Is public communication needed?
  - Common supplier identified
  - Additional products not included in current warning
  - Decision: Warn consumers not to eat Brand A soynut butter and granola products

- Concern about the risk of other products produced by Company B, and the investigation continued
Days 11 to 23: Environmental Investigation at Supplier C

“Your Plant Manager stated he has never verified the accuracy of [the thermometer]”

“standing water and brown and black apparent filth was observed on the Processing Room Floor”

“You and your Plant Manager state you have not disassembled any SoyNut Butter processing equipment and all associated piping for cleaning and sanitizing since December of 2015.”

“Many of the mop and broom heads were stained black from apparent filth”

“Failure to perform microbiological testing…”

“There was no hot water to the handwashing sink and the two-compartment sink located in the Soy Nut Butter Processing Room…the hot water tank for these sinks has been out of repair for two years.”

“...product in your firm’s walk in cooler was observed with an apparent 3# diameter rodent defiled marking that penetrated the box and product. Additionally, apparent mold was growing on the surface of the butter.”

“An apparent fly infestation...small apparent flies and fly larvae, too numerous to count, were inside an unplugged chest freezer”
Public Warnings Expand

- March 10
  - Additional brands of SoyNut butter recalled
- March 24
  - Nutrition bars containing recalled SoyNut butter recalled

Advice to Consumers

- Consumers should not eat any variety or size of SoyNut Butter, granola, or Carb Not Beanit Butter, regardless of the date of purchase or the date listed on the container.
  - Even if some of the product was eaten or served and no one got sick, throw the rest of it away. Put it in a sealed bag in the trash so that children, pets, or other animals can’t eat it.
  - Check your pantry for recalled products. Some of these products have a shelf life of 2 years.
- Consumers should not eat recalled Yogurt Peanut Crunch Bars.
- Contact your healthcare provider if you think you or your child may have gotten sick from eating recalled products.
Further Developments in late March 2017

FDA Suspends Food Facility Registration of [Redacted]

No food may leave the facility for sale or distribution

March 30, 2017

Fast Facts

- On March 28, 2017, the FDA used authorities granted under the 2011 FDA Food Safety Modernization Act to suspend the food facility registration of [Redacted], because products manufactured in this facility may be contaminated.
- Soy nut butter manufactured by [Redacted] has been implicated in an outbreak of *E. coli* O157:H7.
- The FDA’s decision to suspend the registration of [Redacted] was prompted by the *E. coli* O157:H7 outbreak and the findings of FDA’s March 2017 inspection of [Redacted], which identified insanitary conditions that could lead to contamination with *E. coli* O157:H7 in finished products.
- No food can leave the [Redacted] facility for sale or distribution while the food facility registration is suspended.
Whole Genome Sequencing Results

- WGS shows that bacteria from ill people are closely related genetically
  - Even stronger evidence that all the infections are linked to a common source

- WGS shows that bacteria from ill people and SoyNut butter are closely related genetically
  - Further strengthens the evidence that this product is the cause of the outbreak
E. coli O157 Infections Linked to SoyNut Butter, 2017

At A Glance

- Case Count: 32
- States: 12
- Deaths: 0
- Hospitalizations: 12
- Recall: Yes

Map showing states affected, with bars indicating the number of cases by date of illness onset.
Outbreak is over, but is the risk?

- Outbreaks linked to products with long shelf lives pose special communication challenges
  - Public notices engage consumers, but interest declines when the outbreak ends

- Reports of recalled SoyNut Butter products available in stores and online weeks and months after the outbreak ended

Advice to Consumers

Although the outbreak investigation is over, illnesses may continue for some time. The recalled SoyNut Butter products have long shelf lives and may still be in people’s homes or in institutions. People who don’t know about the recalls could continue to eat the products and get sick. The recalled products are listed on the Recalls & Advice to Consumers page.
Conclusions
Industry Involvement in Investigation Process

Industry plays a critical role in multistate foodborne outbreaks

- **Hypothesis generation**: early consultation with industry experts can help narrow down suspects based on the timing and geographic distribution of illnesses

- **Hypothesis testing**: providing traceback data or sharing isolates from food/environmental testing can help confirm or refute a hypothesis

- **Pinpointing the cause**: working with regulatory agencies to scope contamination events and identify/correct the cause of contamination

- **Sharing lessons**: disseminating information learned during an outbreak and/or recall to others in industry
Industry Involvement in Public Communication

- Industry can help public health craft specific, actionable advice to consumers
  - You know how your product is labeled, where it’s sold, shelf life

- Industry can communicate directly with their customers
  - Robo-calls, printing recall notices on receipts, website announcements

- A company’s communications can provide another source of clear, accurate, and consistent messaging to the public
  - Press releases, social media
Conclusions about Investigation Process

- Detecting, investigating, and stopping multistate foodborne outbreaks is complex
  - Requires collecting and interpreting data from numerous places
  - Decisions are often made in the context of uncertainty
  - Need to be both “fast” and “right”

- Coordination is essential to ensure the right message is delivered at the right time to the right people
  - Clear expectations and internal communication key