

# How Epidemiological Evidence Drives Public Health Decision-Making and Interventions

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# Evidence and Decision Making

- **Outbreak investigation objective:**

**to initiate public health intervention  
as quickly as appropriate based on  
the evidence**

- **Outbreak examples include:**
  - Epi evidence indicates need for more **investigation**
  - Epi evidence supports **intervention**



# Types of Evidence

- Investigation partners contribute different types of evidence
  - Lab, Epi, Food Regulatory
- **Examples of epi evidence**
  - Food histories
    - Reported exposure to product
  - Historical PFGE pattern associations
  - Superficial product details (purchase locations, product descriptions)
  - Studies (descriptive or analytical)



# Types of Evidence

- **Examples of lab evidence**
  - Clinical isolates
  - Food isolates
  - PFGE
  - Historical PFGE pattern associations
- **Examples of regulatory evidence**
  - Distribution of product
  - Documentation - invoices, receipts, Bills of Lading, etc.
  - Environmental Assessments
  - Food samples (raw and finished products)



# Case Control Studies

- **Primary role: determine whether a particular exposure is significantly more common among outbreak cases**
  - Statistical output: odds ratio, p value
- **Considerations related to conducting case-control studies:**
  - Number of cases required to achieve statistical significance (power)
  - Time required to conduct study
    - Resource-intensive



# CDC FoodNet Data

- **Data source for “usual” levels of consumption/exposure in general population**
- **Population survey**
  - 10 sites cover 15% of the U.S. population; representative
- **Survey instrument**
  - Includes hundreds of closed-ended questions (Y/N)
  - Also, often used for hypothesis generation during outbreak investigations
- **Comparison of outbreak cases to general population**
  - Quick; often done early in an investigation
  - Success depends on outbreak exposure being included



# **Example 1: Retailer X Outbreak**

# Retailer X Outbreak: Overview

- *E. coli* O157:H7 outbreak strain
  - Common PFGE pattern combination
- Outbreak centered in MI and OH
  - Later involved other states
- Associated with Retailer X ground beef
  - Nebraska Beef ultimately recalled 5.3M lbs
- Case-control study conducted
  - **But first intervention preceded study**

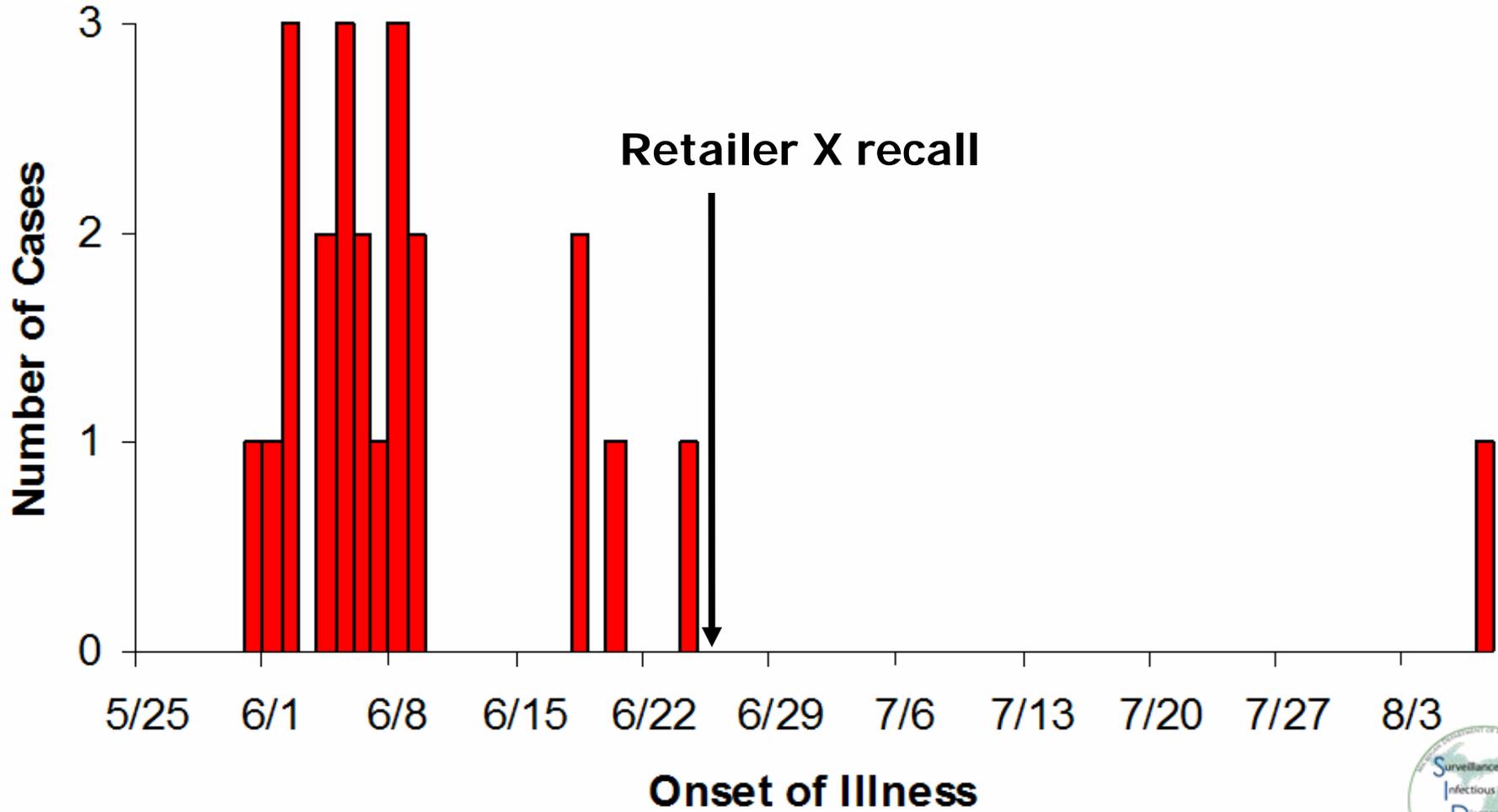


# Michigan Outbreak Summary

- **23 confirmed cases from 7 jurisdictions**
  - Oakland (7)      Washtenaw (4)      Saginaw (1)
  - Wayne (5)      Eaton (1)
  - Macomb (4)      Genesee (1)
- **Onset range: May 31 – Aug 7, 2008**
- **Ages: <2 – 75 years (median 17 years)**
- **Sex: 61% female**
- **13/23 (57%) hospitalized**
  - 1 confirmed, 1 probable (epi-linked) HUS



# Epi Curve – Michigan Cases



# Key Events 2008

- Jun 10 - Hospital notifies MDCH  
(severe case)
- Jun 16 - PFGE link to OH cases
- Jun 17 - Ground beef outbreak Q request
- Jun 18 - First MiHAN alert
  - First MDCH press release  
(reporting increase in cases,  
suspicion of ground beef)
- Jun 20 - CDC proposes CaCo study  
(**Friday afternoon**)



# Key Events 2008

- **Jun 23 - Ground beef STEC + in OH**
- **Jun 24 - 2 ground beef STEC + in MI (opened)**
  - **Preliminary CDC case control results**
  - **Second MDCH press release (reporting ground beef and Retailer X association)**
- **Jun 25 - Ground beef PFGE match to outbreak**
  - **Retailer X ground beef recall**
- **Jun 30 - Nebraska Beef (supplier) recall**
- **July 3 - Retailer X and Nebraska Beef recall expansions**



# Epi Evidence

- **As of June 18 (first press release):**
  - **8 MI cases match by PFGE (2 enzymes)**
    - 7 have been interviewed
    - 7 report home exposure to ground beef
    - **4 report undercooked ground beef**
  - 7 report shopping at Retailer X stores
    - 7 different locations in 5 counties
  - 5 report ground beef was from Retailer X



# Lab Evidence

- **At the conclusion of the investigation:**
  - **5 Retailer X ground beef samples collected from 5 MI case households**
    - 3 leftover portions (opened) – MDCH lab
    - 2 intact packages – USDA lab
  - **All 5 samples positive for the outbreak strain of *E. coli* O157:H7**
    - **16/16 subsamples (100%) were positive** from 3 samples tested by MDCH



# Retailer X Outbreak: Summary

- Outbreak strain caused severe illness
- **Intermediate interventions**
  - Retail-level recall followed by upstream (supplier) recall
    - May promote consumer recognition
- Shopper cards used to verify purchase date and exact item
  - USDA accessed records at store level
- Investigation partners' actions were somewhat independent of one another



**Example 2:**  
**(Most Recent) Sprouts Outbreak**

# Sprouts: Overview

- *Salmonella* Typhimurium outbreak strain
  - Rare pattern combination (new in MI)
  - Historical association with sprouts
- Outbreak centered in MI
- Associated with raw alfalfa sprouts
  - MI firm issued market withdrawal
- High-risk and rare exposure

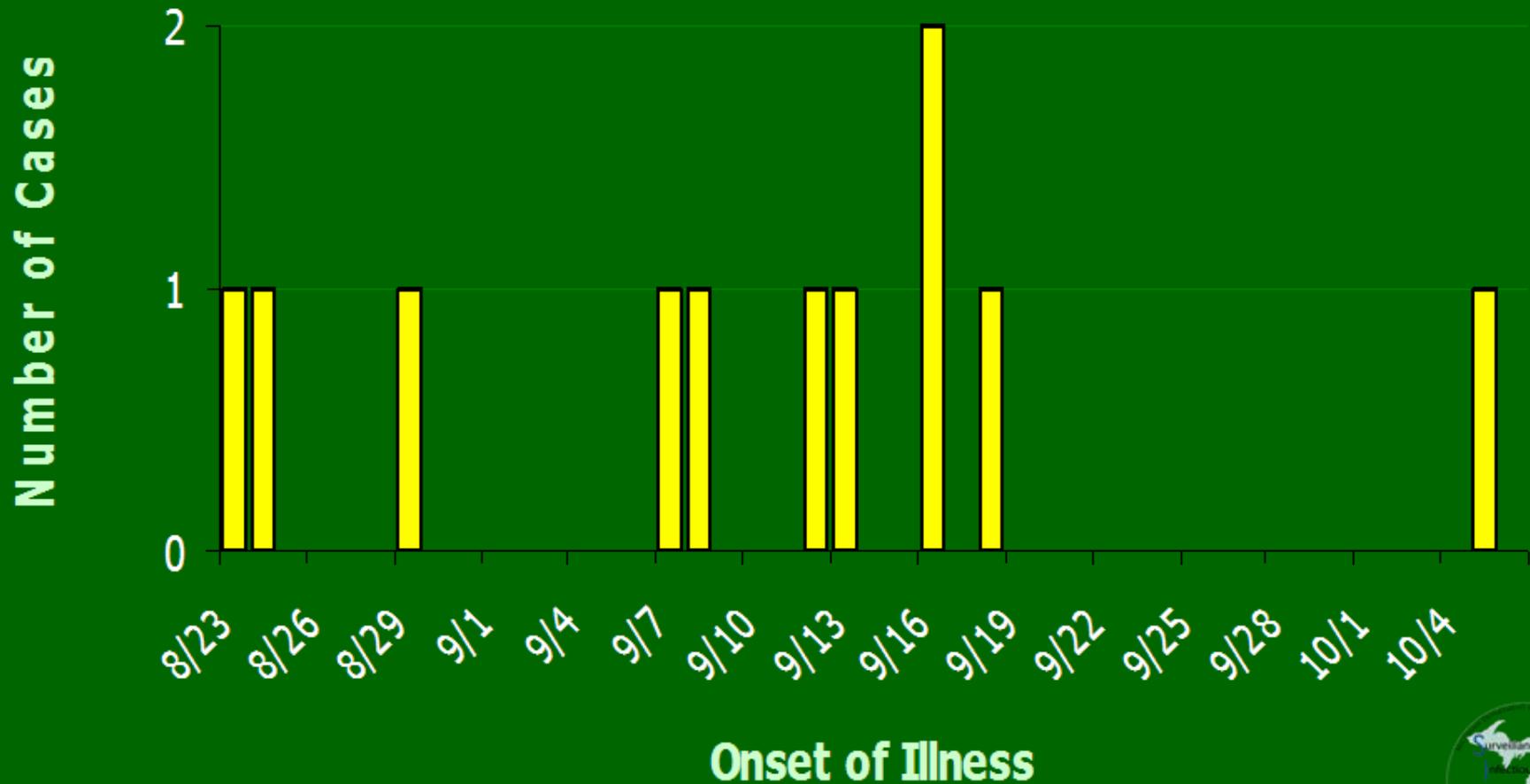


# Michigan Outbreak Summary

- 14 cases from 8 jurisdictions in MI
  - Oakland (3)      Washtenaw (1)      Kent (1)
  - Wayne (2)      Livingston (1)      Bay (1)
  - Macomb (4)      Genesee (1)
- 3 cases from other states
- Onset range: Aug 17 – Oct 5, 2009
- Ages: 11 – 59 years (median 28 years)
- Sex: **64% female**
- 2/14 (14%) hospitalized



# Epi Curve – Michigan Cases



# Key Events 2009

- Sep 9 – 3 MI cases PFGE match (2 report sprouts at Sandwich Shop A)
- Sep 17 – Cluster posted to PulseNet (MN, OH matches)
- Sep 18 – Other states contacted for epi histories
- Sep 23 – 3 of first 7 MI cases lost to follow-up
- Oct 1 – **CDC reports historical association with sprouts**
- Oct 2 – MDCH initial notification to MDA (3<sup>rd</sup> exposure)



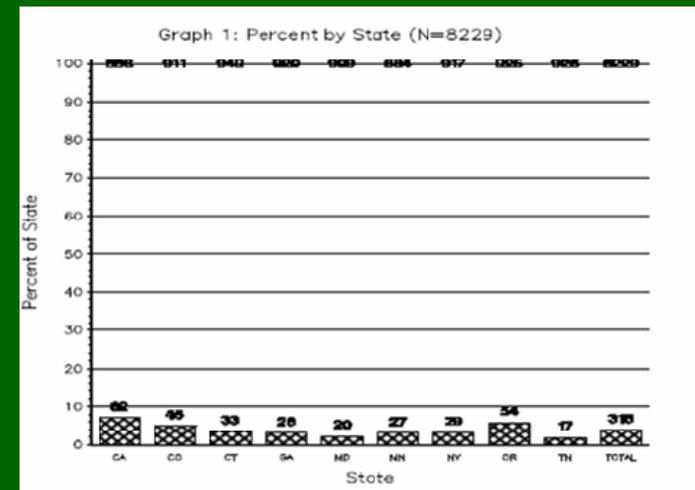
# Key Events 2009

- Oct 6 – MDCH reports new cases with sprout exposure
  - MDA starts traceback investigation
- Oct 7 – First draft of potential press release circulated
- Oct 8 – RRT deployment, surveillance samples collected at firm
- Oct 9 – Joint MDA/MDCH press release (reporting association)
- Oct 13 – Intensive sprout and seed sampling at firm
  - Firm issues press release announcing recall



# Epi Evidence

- As of October 6 (3 days before press release):
  - 10 MI cases match PFGE cluster
  - 5/5 cases asked report sprout exposure
    - Plus 1 questionable report (?timeframe)
  - 5 different Sandwich Shop A locations reported
- FoodNet 2002 data
  - **3.8%** gen. population ate raw alfalfa sprouts in a week period
- Prior sprouts outbreak



# Sprouts Outbreak: Summary

- Early communication/data sharing between MDCH and MDA epi
- Traceback was rapidly initiated (few cases)
  - Cooperation by Sandwich Shop A's corporate to provide data
- **Rare exposure** (FoodNet data comparison)
- History of outbreak strain pivotal
- RRT deployment – joint Food and Feed Response
  - Epi, Food, and Feed
- Proactive product sampling by MDA/RRT



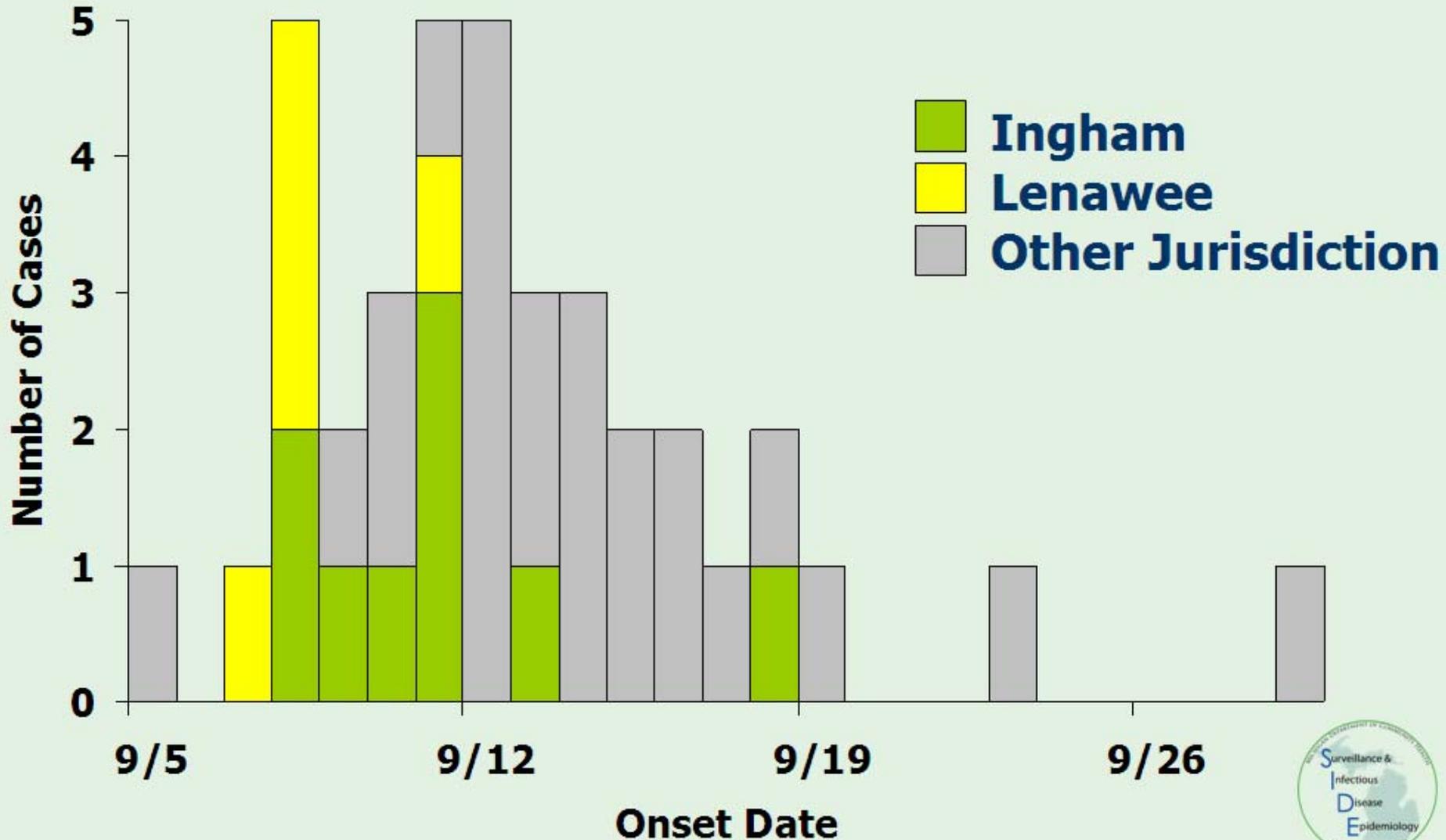
# **Example 3: Lettuce Outbreak**

# Lettuce Outbreak: Overview

- ***E. coli* O157:H7 outbreak strain**
  - Common pattern combination (top 10)
- **Outbreak centered in MI**
- **Associated with iceberg lettuce**
  - Lettuce processing stopped at MI firm
- **Great example of “three-legged stool”**
  - Lab, epi, and food regulatory



# Epi Curve – Confirmed Cases



# Michigan Outbreak Summary

- **38 confirmed cases from 9 jurisdictions**

Ingham (9)	Washtenaw (5)	Genesee (1)
Macomb (8)	Wayne (5)	Oakland (1)
Lenawee (5)	Kent (3)	St. Clair (1)
- **Onset range: Sep 5 – 21, 2008**
- **Age: <2 – 81 years (median 22 years)**
- **Sex: 63% female**
- **21/38 (55%) hospitalized**
  - 1 Hemolytic Uremic Syndrome (HUS)



# Key Events 2008

- Sep 12 - Lenawee County jail cluster reported
- Sep 15 - Ingham County (MSU) cluster reported
- Sep 18 - PFGE links MSU cases to outcounty cases
- Sep 19 - PFGE links jail to larger cluster
- Sep 25 - (see next slide)
- Sep 26 - MDCH press release reports association with Processor B's iceberg lettuce  
Processor B stops lettuce processing
- Oct 2 - IL case control study implicated iceberg
- Oct 7 - MSU case control study implicated iceberg



# September 25, 2008

- **Joint press conference held**
  - Ingham County, MSU, MDA, MDCH
  - Reporting outbreak, investigation efforts
- **Traceback results available:**
  - MDA determined Processor B was sole common supplier to MSU, jail
  - Independently, IL determined Processor B was supplier to IL restaurant cluster
- **MDCH launched case control study at MSU**





**Leaf Lettuce**



**Iceberg Mix**



**Mixed Greens**



**Romaine**



**Spinach**



**Shredded Iceberg**

Photos by Brenda Brennan and Shannon Johnson



# Lettuce Outbreak: Summary

- **Outbreak vehicle - common exposure**
  - Product details, traceback crucial
- **Short shelf life**
  - No product from outbreak period available for lab testing
- **Diverse investigation collaborations**
  - Groups had varying priorities
- **Mixed messages in the media**
- **Great example of “three-legged stool”**
  - Lab, epi, and food regulatory



# Conclusions

# Outbreak Factors

- **Agent involved**
  - **Salmonella vs. E. coli O157:H7**
- **Shelf life of product**
  - **Lettuce/sprouts vs. frozen ground beef**
  - **Availability to test implicated product**
  - **Likelihood of ongoing outbreak**
- **Rare or common exposure**
  - **Lettuce vs. sprouts**
- **Strain history**
  - **Past vehicle associations**



# Lessons from the Examples

- **Ask about known high-risk exposures**
  - e.g.: ground beef, sprouts, leafy greens
- **Pay special attention to rare exposures**
  - Especially when there are multiple reports
- **Product details may be crucial**
  - Particularly for common exposures



# Triggers often differ...

- **Partners may have to part ways**
  - **Mission of Agency**
  - **Available evidence in their possession**
  - **Legal restraints**
- **Partners may alternate taking lead**
  - **Evidence can take investigation so far**
  - **Lead may transfer to another agency**



**Objective:** to initiate public health intervention as quickly as appropriate based on the evidence



# Conclusions

- Evidence takes multiple forms
  - Lab (clinical, PFGE, product testing)
  - Epi (exposure hx, product details, descriptive or analytical)
  - Food Reg (traceback, enviro assess, distribution data)
- Evaluate consistency of **all available evidence** to drive decision-making
- Goal is to protect the health of the public



# Thank you

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