# Culture-Independent Diagnostics: Impact on Public Health

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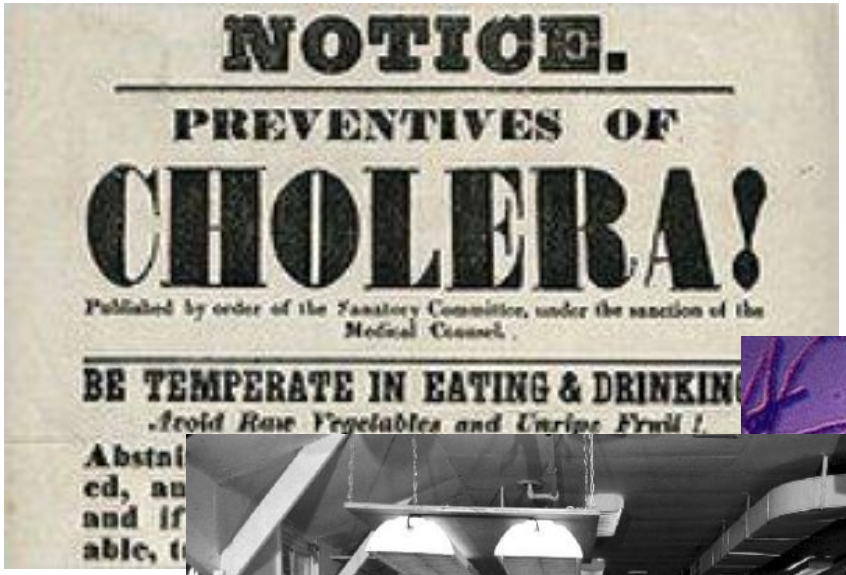
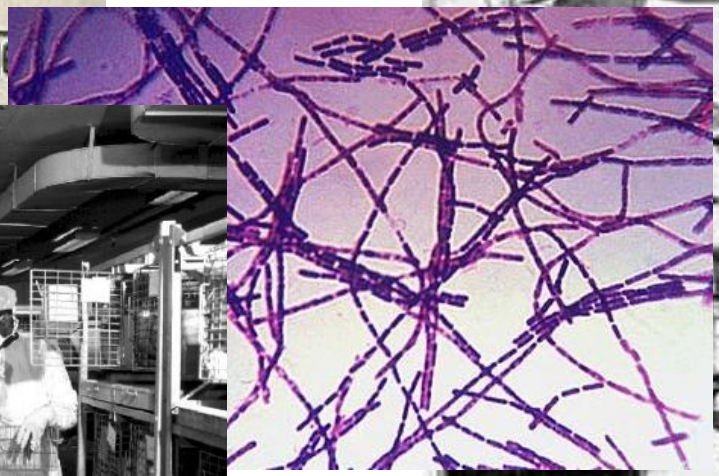
# Culture-Independent Diagnostics: Impact on Public Health

- Overview of issues
- Strategies for Public Health
- Regulatory role?

# Bacterial Culture







# Rapid Microbiology Tests

- Available for many conditions, many microbes
  - invasive, respiratory, sexually transmitted, and enteric diseases
  - bacteria, RNA/DNA viruses, parasites, fungi, toxins
- Multiple technologies (nucleic-acid based, antigen-based, metabolite based)
- Multi-analyte panels

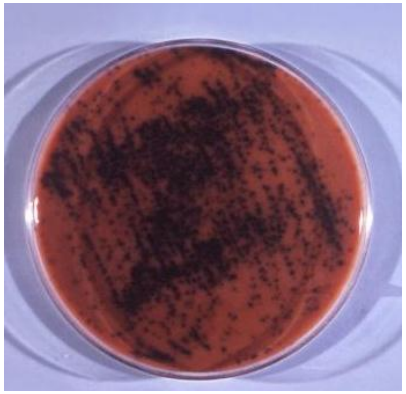
# Rapid / Culture-Independent Tests versus Culture

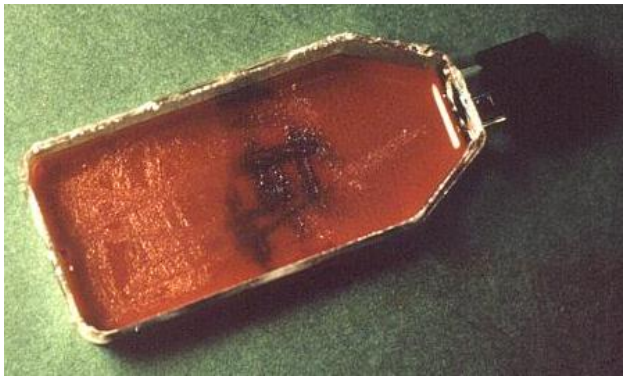
| | Culture | Rapid/culture-independent tests |
|---|---|---|
| **Speed** | Slow | Fast |
| **Infrastructure needed** | Significant | Minimal |
| **Expertise required** | Significant | Minimal |
| **Labor cost** | High | Low |
| **Cost of materials** | Low | High |

# Rapid / Culture-Independent Tests versus Culture

| | Culture or standard tests (e.g. microscopy) | Rapid/culture independent tests |
|---|---|---|
| **Sensitivity** | Gold standard | Low to high |
| **Specificity** | High | Low to high, almost always different |
| **Interpretation of positive findings** | Usually straightforward | Significant issues |
| **Range of pathogens detected** | All pathogens allowed by growth or test conditions | Limited to specific pathogen tested |
| **Allows for susceptibility testing & genotyping?** | Yes | Generally no |

# Demise of GC Culture





## Rapid NAA test:

- Fast (hours)
- Urine specimen (vs urethral swab)
- Includes *Chlamydia trachomatis*
- High sensitivity

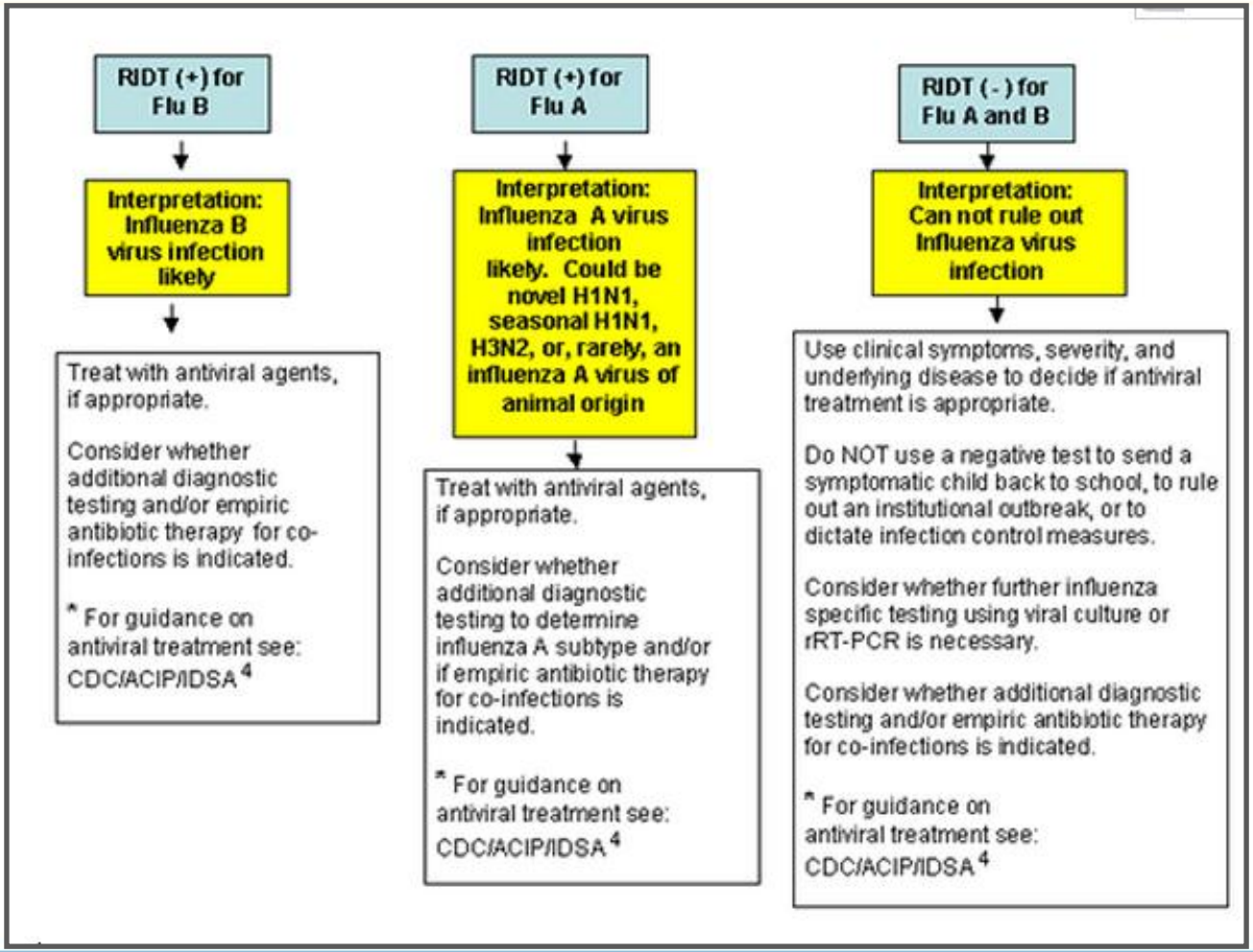
- No susceptibility data
- Specimen incompatible with culture
- Expensive
- Some concerns about false positives

Patient Management

## Medical reasons for laboratory testing

- Appropriate treatment
- Prevent unnecessary treatment or procedures

# Interim Guidance for the Detection of Novel Influenza A Virus Using Rapid Influenza Diagnostic Tests




http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm

CDC Home | Search | Health Topics A-Z

MMWR

Recommendations and Reports

October 16, 2009 / 58(RR12);1-14

# Recommendations for Diagnosis of Shiga Toxin--Producing *Escherichia coli* Infections by Clinical Laboratories

CDC Home | Search | Health Topics A-Z

MMWR

Weekly

September 29, 2006 / 55(38);1042-1045

# Importance of Culture Confirmation of Shiga Toxin-producing *Escherichia coli* Infection as Illustrated by Outbreaks of Gastroenteritis --- New York and North Carolina, 2005

*Escherichia coli* O157:H7 and other strains of *E. coli* that produce Shiga toxin are collectively known as Shiga toxin-producing *E. coli* (STEC). The current outbreak of STEC O157 infections associated with eating fresh spinach illustrates the importance of obtaining isolates to identify the source of the infections (*1*). Laboratory methods that do not require bacterial culture of stool specimens to identify STEC are being used increasingly by clinical diagnostic laboratories, sometimes without subsequent confirmation of a strain by isolating it in culture. This report describes findings from outbreaks of gastroenteritis in 2005 in New York and North Carolina in which clinical diagnostic laboratories initially used only non-culture methods to detect Shiga toxin (Stx). The findings highlight the importance of confirmation of Stx-positive stool specimens by bacterial culture for timely and reliable identification of STEC infections, including *E. coli* O157 and non-O157 STEC, to enable implementation of appropriate public health actions. An important part of that identification is

Patient Management

Disease Prevention

Patient Manage

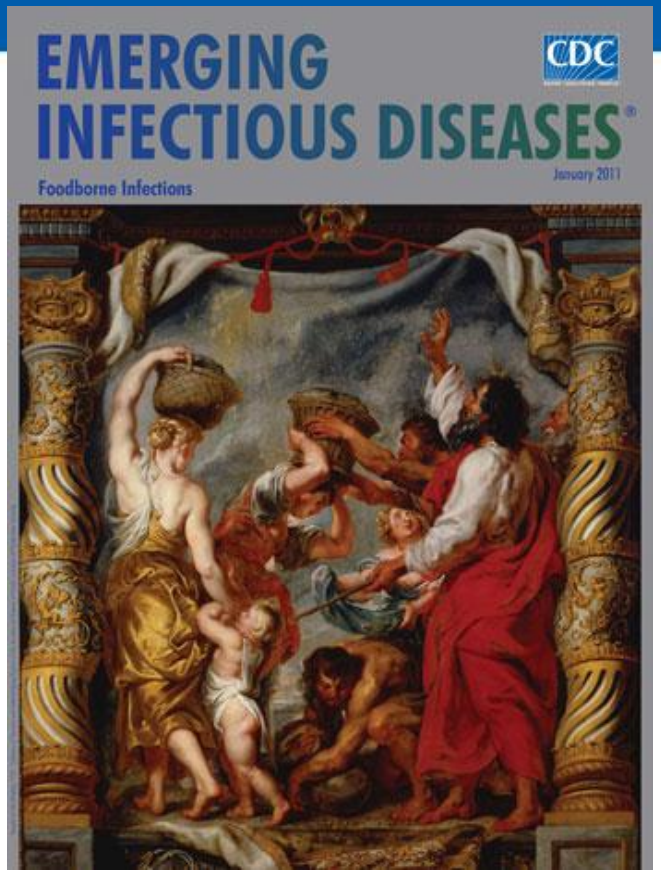
## Public health reasons for surveillance / outbreak investigation

- Limit transmission
- Control underlying problems
- Monitor trends → informed policy development

# Impacts

- Patient Management
- Public Health Programs
  - Requiring accurate case counts
    - Burden
    - Attribution
    - Trends
  - Isolate-requiring

# Estimates of Foodborne Illness




## Foodborne Illness Acquired in the United States—Major Pathogens

Elaine Scallan,[1] Robert M. Hoekstra, Frederick J. Angulo, Robert V. Tauxe, Marc-Alain Widdowson, Sharon L. Roy, Jeffery L. Jones, and Patricia M. Griffin

Estimates of foodborne illness
food safety policy and interventions.
tive and passive surveillance and ot
that each year 31 major pathogens
States caused 9.4 million episode
(90% credible interval [CrI] 6.6–12.
pitalizations (90% CrI 39,534–75,7
(90% CrI 712–2,268). Most (58%)
by norovirus, followed by nontyph
(11%), *Clostridium perfringens* (10
spp. (9%). Leading causes of hos
phoidal *Salmonella* spp. (35%), no
*lobacter* spp. (15%), and *Toxoplasm*
causes of death were nontyphoidal
*T. gondii* (24%), *Listeria monocytoge*
rus (11%). These estimates cannot
(1999) estimates to assess trends i
ods were used. Additional data and
can improve future estimates.

Estimates of the overall number o
illness are helpful for allocatin
tizing interventions. However, arri
is challenging because food may
by many agents (e.g., a variety of
sites, and chemicals), transmission
mechanisms (e.g., contact with ani
contaminated water), the proportio
by food differs by pathogen and h
and immunity), and only a small
are confirmed by laboratory testing
health agencies.

Laboratory-based surveillance
mation for assessing foodborne di

Author affiliation: Centers for Disease C
lanta, Georgia, USA

DOI: 10.3201/eid1701.P11101

Emerging I

RESEARCH

## Foodborne Illness Acquired in the United States—Unspecified Agents

Elaine Scallan,[1] Patricia M. Griffin, Frederick J. Angulo, Robert V. Tauxe, and Robert M. Hoekstra

Each year, 31 major known pa
United States caused an estimat
of foodborne illness. Additional e
caused by unspecified agents, incl
insufficient data to estimate agen
agents not yet recognized as ca
substances known to be in food b
nicity, and unknown agents. To est
nesses, we used data from surve
death certificates to estimate ill
and deaths from acute gastroent
nesses caused by known gastroe
proportions acquired by domestic
were similar to those for known p
then an estimated 38.4 million (9
19.8–61.2 million) episodes of dor
borne illness were caused by unsp
in 71,878 hospitalizations (90% C
1,686 deaths (90% CrI 369–3,338

Foodborne diseases are a sig
death in the United States. It
timated that each year, major kn
in the United States caused 9.4 m
borne illness, resulting in 55,961 h
deaths (*1*). (Hereafter, episodes o
as illnesses.) Although the numbe
these pathogens is substantial, t
only a subset of the total illnesses.

An additional proportion of fo
ably caused by a heterogeneous g
agents. First, many agents that ca

Author affiliation: Centers for Disease
lanta, Georgia, USA

DOI: 10.3201/eid1701.P21101

16 Emerging

COMMENTARY

## How Safe Is Our Food?

J. Glenn Morris, Jr.

How safe is our food? Put another way, how much illness in the United States is caused by foodborne pathogens? It sounds like a simple question. Getting a reasonable answer, however, is far from simple. The basic problem lies in the fact that only a small fraction of foodborne disease cases get reported through official (or unofficial) reporting systems. Calculating the "real" rate of foodborne illness requires development of models that use reported cases as a starting point to estimate underlying disease rates. Given the plethora of pathogens that can be transmitted through foodborne routes, this is a complex, and somewhat daunting, process. It is, however, necessary for assessing the safety of foods and developing strategies for disease prevention. The articles by Scallan et al. (*1*,*2*) in this issue represent the latest efforts to develop such estimates of the magnitude of foodborne illness in the United States.

In 1999, Mead et al. (*3*) published initial estimates of foodborne disease in the United States. This landmark undertaking was the first to provide a comprehensive compilation of data from a variety of sources, including the Centers for Disease Control and Prevention (CDC) and the medical literature. It resulted in the often-cited estimates that foodborne pathogens cause 76 million episodes of illness, 325,000 hospitalizations, and 5,000 deaths each year in the United States. (Hereafter, episodes of illness are referred to as illnesses.) During the past decade, these numbers have strongly driven ongoing efforts to implement or reform regulatory systems to protect the public from foodborne illness. However, some aspects of the methods have been criticized, particularly the high degree of uncertainty of particular parameters and thus of the results themselves (*4*–*6*). These concerns have led to requests for CDC to repeat and update the work of Mead et al., using better methods and parameter estimates that more closely reflect current realities.

Now, ≈11 years later, Scallan et al. have produced "Sons of Mead," which include substantial improvements to the methods used by Mead et al. and to the quality and timeliness of data (*1*,*2*). Scallan et al. should be commended, especially for 2 specific improvements: their advanced treatment of statistical uncertainty and variability and their transparent inclusion of voluminous appendixes of data, models, and assumptions. These authors followed the same basic approach as Mead et al. but chose to report their estimates in 2 articles. In the first article, they based their estimates of illnesses caused by 24 major pathogens (e.g., *Salmonella* spp., *Escherichia coli* O157:H7) primarily on data from the Foodborne Diseases Active Surveillance Network (FoodNet) and other pathogen-specific surveillance systems. In the second article, they estimated illnesses caused by unknown (or unspecified) pathogens by subtracting illnesses caused by known pathogens from the annual estimated number of cases of acute gastroenteritis in the US population and adjusting the result by the percentage assumed to be acquired domestically through food. If these 2 estimates are combined, as they were by Mead et al., the new totals are 47.8 million foodborne illnesses, 127,839 hospitalizations, and 3,037 deaths per year in the United States.

When one compares the 1999 and 2010 estimates (76 million vs. 47.8 million illnesses), the immediate response is to ask: Does this mean that food in this country is safer than it was 11 years ago? Unfortunately, the Scallan et al. articles do not enable us to answer this question. The methods, underlying assumptions, and parameter estimates used to generate these new numbers differ sufficiently from those used ≈11 years ago to preclude comparisons. In fact, if one looks simply at rates of overall gastrointestinal illness in the United States, based on FoodNet Population Surveys (*2*), one might infer that overall rates of acute gastrointestinal illness have increased during this period, from 0.49 episodes per person per year in 2000–2001, to 0.54 in 2002–2003, and to 0.73 in 2006–2007 (see [7] for a discussion of some methodologic issues with regard to the 2006–2007 survey). For the Scallan et al. articles, these 3 numbers were averaged to arrive at a rate of 0.6 episodes of acute gastroenteritis per person per year over the past decade. In contrast, Mead et al. used an estimate of 0.79 episodes of gastroenteritis per person per year, based on FoodNet data but also on older community surveys; they also used a somewhat different definition of acute gastrointestinal illness. This difference in estimated annual rates

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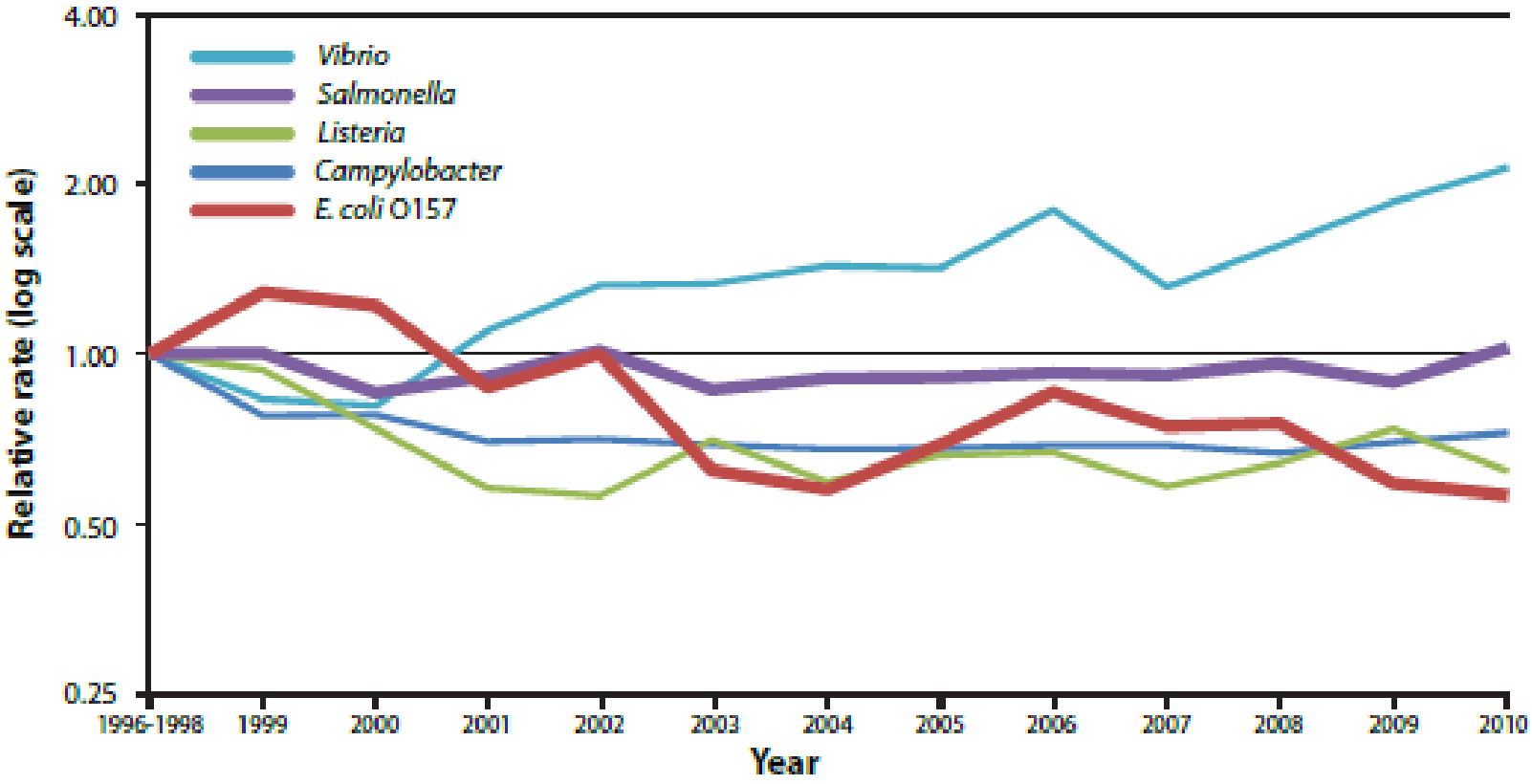
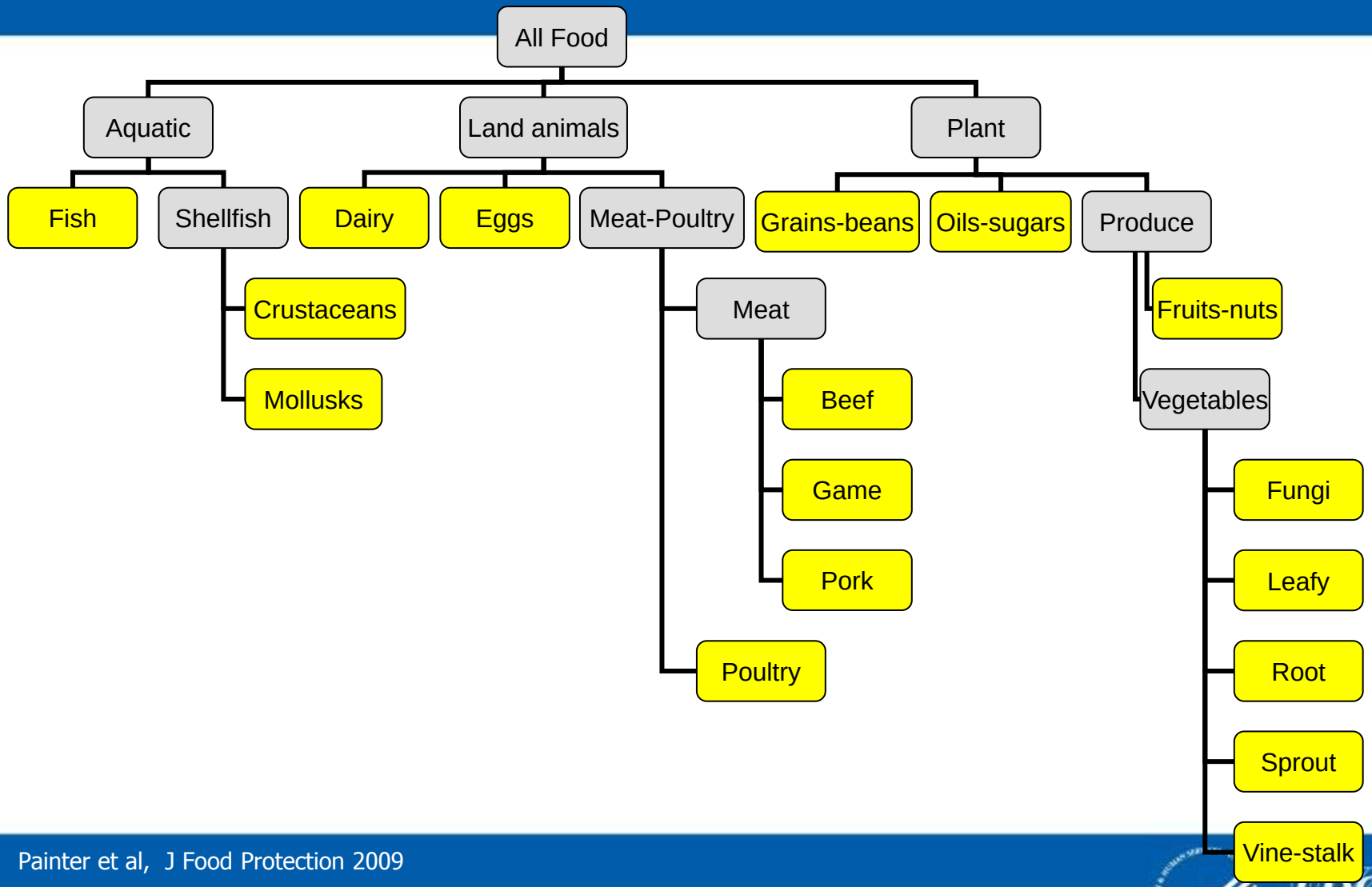
DOI: 10.3201/eid1701.101821

# Relative rates of laboratory-confirmed infections with *Campylobacter*, *E. coli* O157, *Listeria*, *Salmonella*, and *Vibrio* compared with 1996-1998 rates, by year – Foodborne Diseases Active Surveillance Network (FoodNet), United States, 1996-2010†




† The position of each line indicates the relative change in the incidence of that pathogen compared with 1996-1998. The actual incidences of these infections cannot be determined from this graph.

# Hierarchical scheme for categorizing foods into commodities




Painter et al, J Food Protection 2009

# Addressing CIDT: Burden, Attribution, Trends

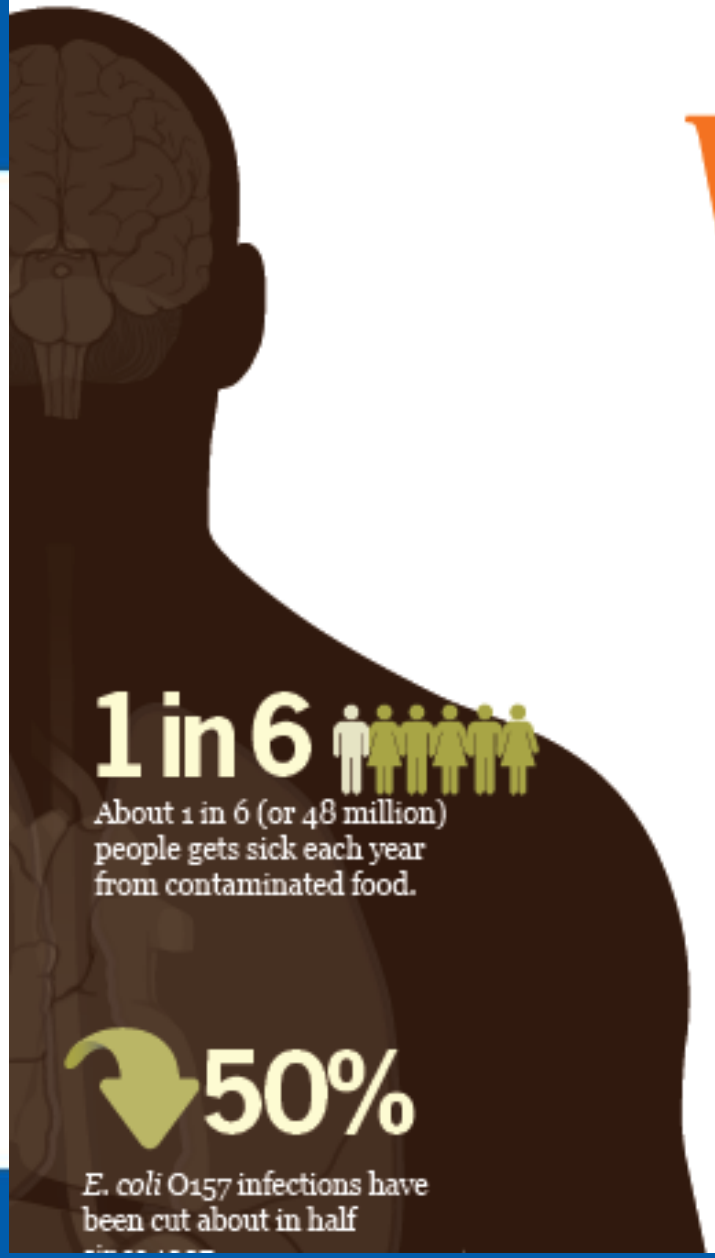
- Determine extent of issue
- Study test performance
- Redefine case definitions

# Impacts

- Patient Management
- Public Health Programs
  - Requiring accurate case counts
    - Burden
    - Attribution
    - Trends
  - Isolate-requiring
    - Subtype-based tracking programs
    - Susceptibility monitoring
    - Subtype-based attribution studies

# Selected Microbial Disease Agents Under Surveillance

| Agent | Public health surveillance | Isolate significance |
|---|---|---|
| *Salmonella spp.* | Subtype, AST | ++++ |
| Shigatoxin-producing *E. coli* | Subtype, AST | ++++ |
| *Listeria monocytogenes* | Subtype, AST | ++++ |
| *Mycobacterium tuberculosis* | Genotype, AST | ++++ |
| *Bordetella pertussis* | AST | +++ |
| *Neisseria meningitidis* | Subtype, AST | +++ |
| *Legionella pneumophila* | Subtype (outbreaks) | ++ |
| Influenza virus | Serotype, AST | ++ |
| *Neisseria gonorrhea* | AST | + |
| Methicillin-resistant *Staphylococcus aureus* | Subtype (outbreaks) | + |
| *Cryptococcus neoformans* | AST | ? |




CDC Vitalsigns™

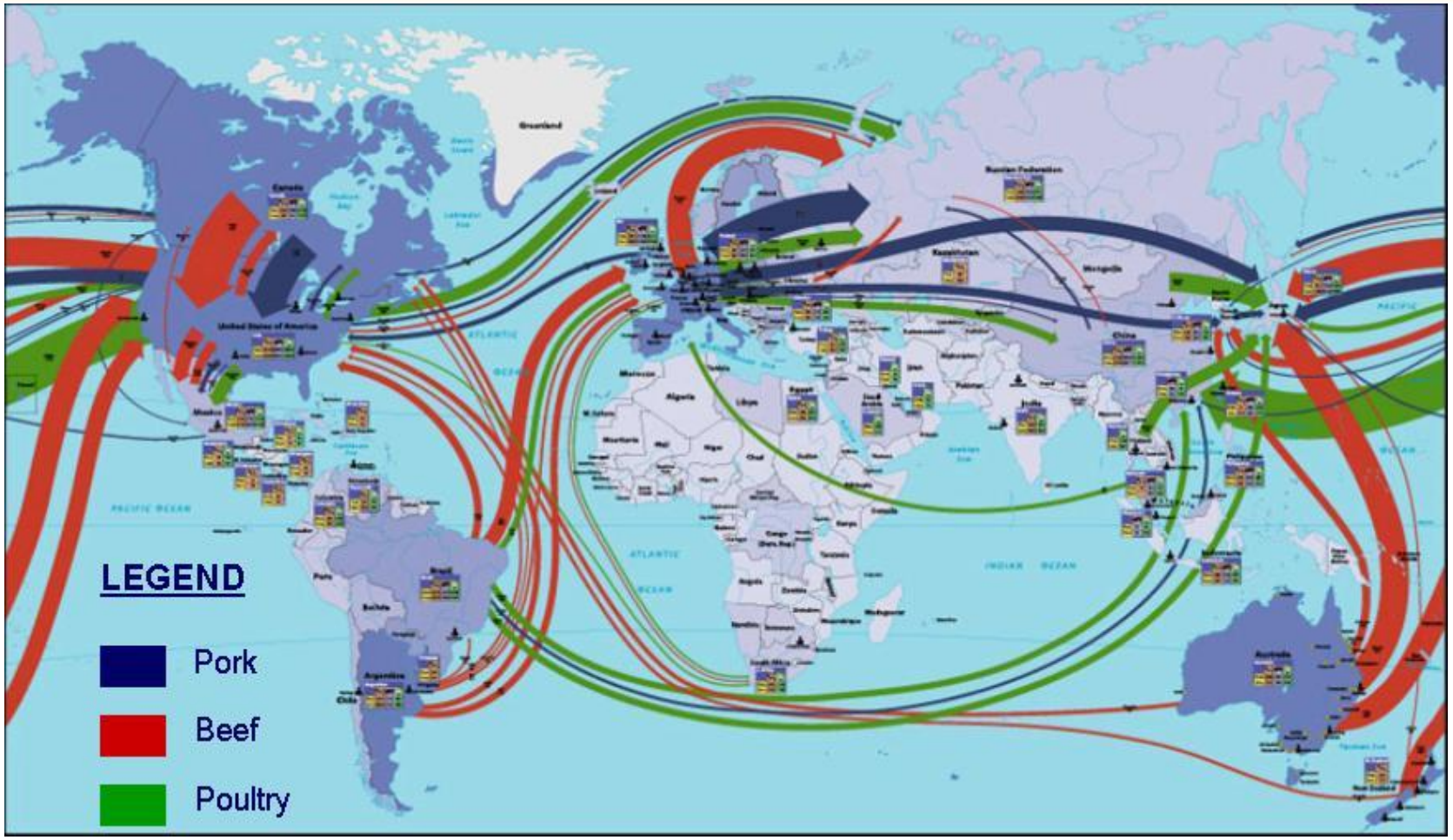
June 2011

# Making Food Safer to Eat

## Reducing contamination from the farm to the table

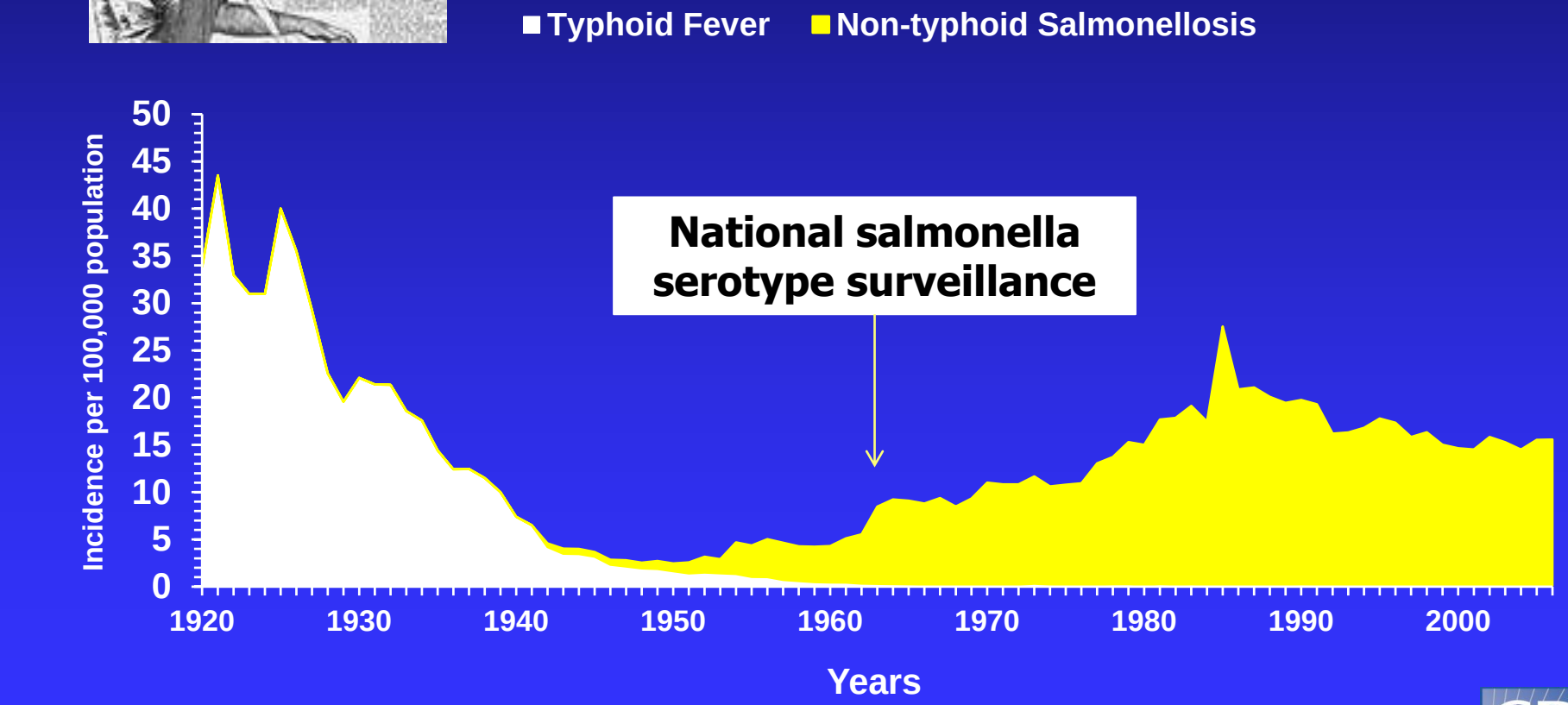
Each year, roughly 1 in 6 people in the US gets sick from eating contaminated food. The 1,000 or more reported outbreaks that happen each year reveal familiar culprits—*Salmonella* and other common germs. We know that reducing contamination works. During the past 15 years, a dangerous type of *E. coli* infection, responsible for the recall of millions of pounds of ground beef, has been cut almost in half. Yet during that same time, *Salmonella* infection, which causes more hospitalizations and deaths than any other type of germ found in food and $365 million in direct medical costs annually, has not declined. Each year, 1 million

# Global Meat Trade




Source: Center for Global Food Issues

# Nationwide reporting began in 1912
# Reported *Salmonella* infections in the United States, 1920-2006


CDC, National surveillance data

CDC
Centers for Disease Control and Prevention

# Salmonella Serotype Surveillance

Original Article

**A National Outbreak of *Salmonella enteritidis* Infections from Ice Cream**

Thomas W. Hennessy, M.D., Craig W. Hedberg, Ph.D., Laurence Slutsker, M.D., M.P.H., Karen E. White, M.P.H., John M. Besser-Wiek, M.S., Michael E. Moen, M.P.H., John Feldman, B.S., William W. Coleman, M.S., Larry M. Edmonson, M.P.H., Kristine L. MacDonald, M.D., M.P.H., and Michael T. Osterholm, Ph.D., M.P.H.

**N Engl J Med** 1996; 334:1281-1286 May 16, 1996

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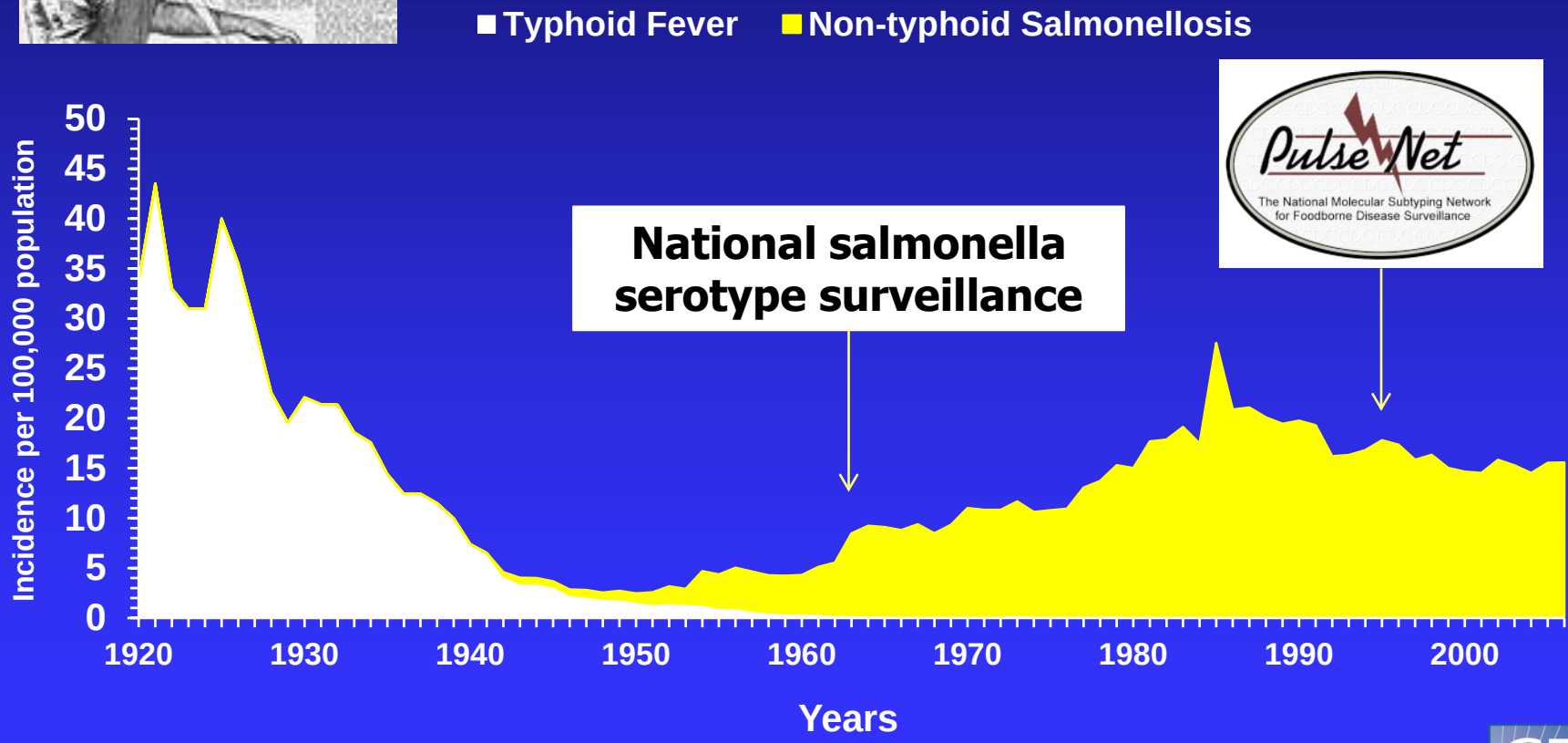


CDC, National surveillance data

CDC
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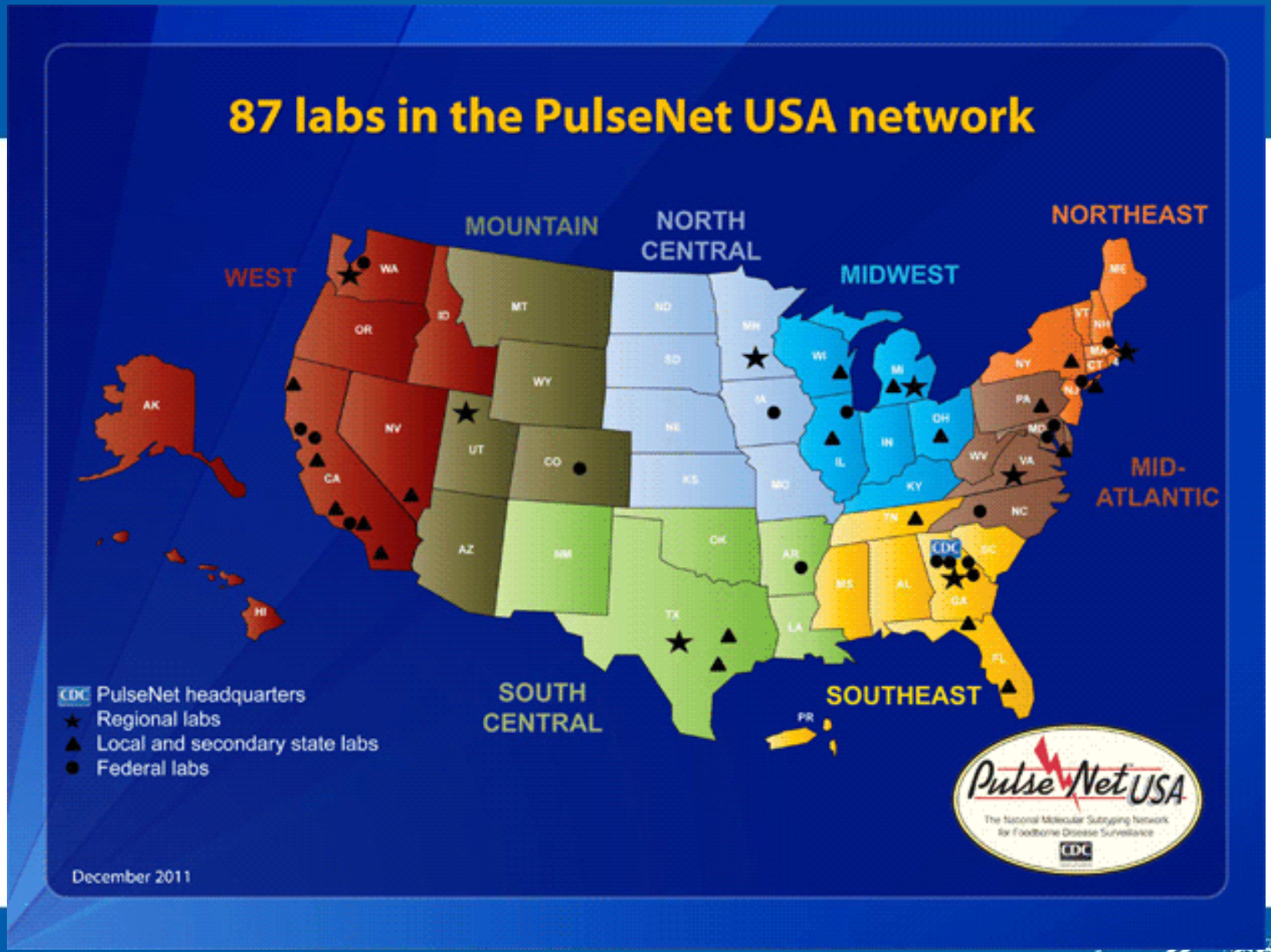

87 labs in the PulseNet USA network
WEST
MOUNTAIN
NORTH CENTRAL
MIDWEST
NORTHEAST
MID-ATLANTIC
SOUTH CENTRAL
SOUTHEAST
WA
OR
CA
AK
HI
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MS
MI
IN
KY
TN
AL
OH
WV
GA
FL
SC
NC
VA
PA
NY
MD
NJ
CT
MA
VT
NH
ME
PR
CDC
PulseNet headquarters
Regional labs
Local and secondary state labs
Federal labs
PulseNet USA
The National Molecular Subtyping Network for Foodborne Disease Surveillance
December 2011

# The decade's 10 biggest food-borne illness outbreaks (from CNN)

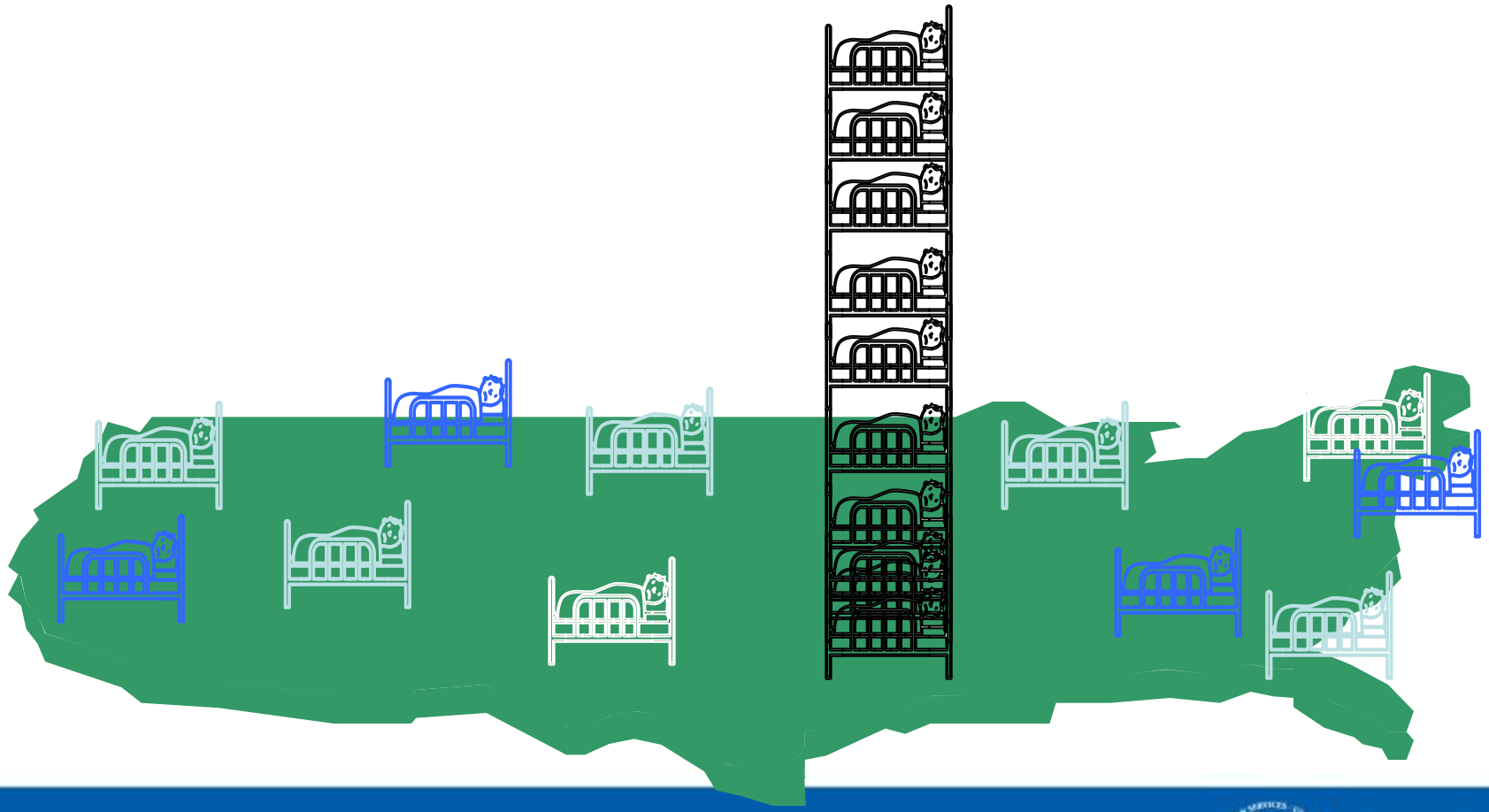
By **Jacque Wilson**, CNN
updated 8:00 AM EDT, Thu November 3, 2011

1. 2011: Cantaloupes (*Listeria monocytogenes*)
2. 2011: Turkey (*Salmonella*)
3. 2010: Eggs (*Salmonella*)
4. 2010: Celery (*Listeria monocytogenes*)
5. 2008: Jalapeno and Serrano peppers (*Salmonella*)
6. 2008 – 2009: Peanut butter (and peanut-containing products; *Salmonella*)
7. 2006: Spinach (bagged; *E. coli* O157:H7)
8. 2005 – 2006: Tomatoes (4 outbreaks; *Salmonella*)
9. 2004: Tomatoes (*Salmonella*)
10. 2002: Deli meat (*Listeria monocytogenes*)
11. 2001: Cantaloupe (*Salmonella*)

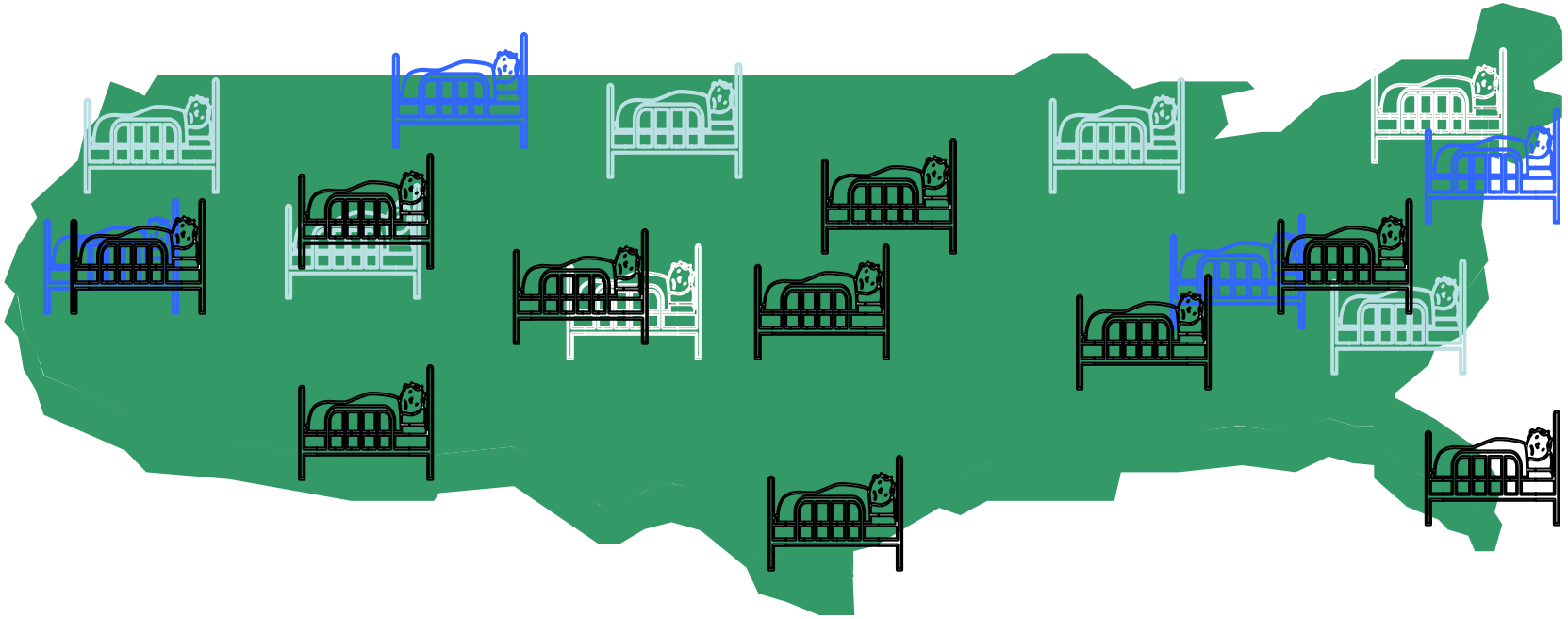
# Multistate Foodborne Outbreak Investigations, 2012 (so far)

- Ground Beef - *Salmonella* Enteritidis
- Live Poultry - *Salmonella* Hadar
- Live Poultry - *Salmonella* Montevideo
- Multistate Outbreak – *Escherichia coli* O145 Infections
- Live Poultry - *Salmonella* Infantis, Newport, and Lille
- Dry Dog Food - *Salmonella* Infantis
- Raw Scraped Ground Tuna Product - *Salmonella* Bareilly and *Salmonella* Nchanga
- Small Turtles - *Salmonella* Sandiego, *Salmonella* Pomona, and *Salmonella* Poona
- Raw Clover Sprouts at Jimmy John's Restaurants -*Escherichia coli* O26
- Restaurant Chain A - *Salmonella* Enteritidis

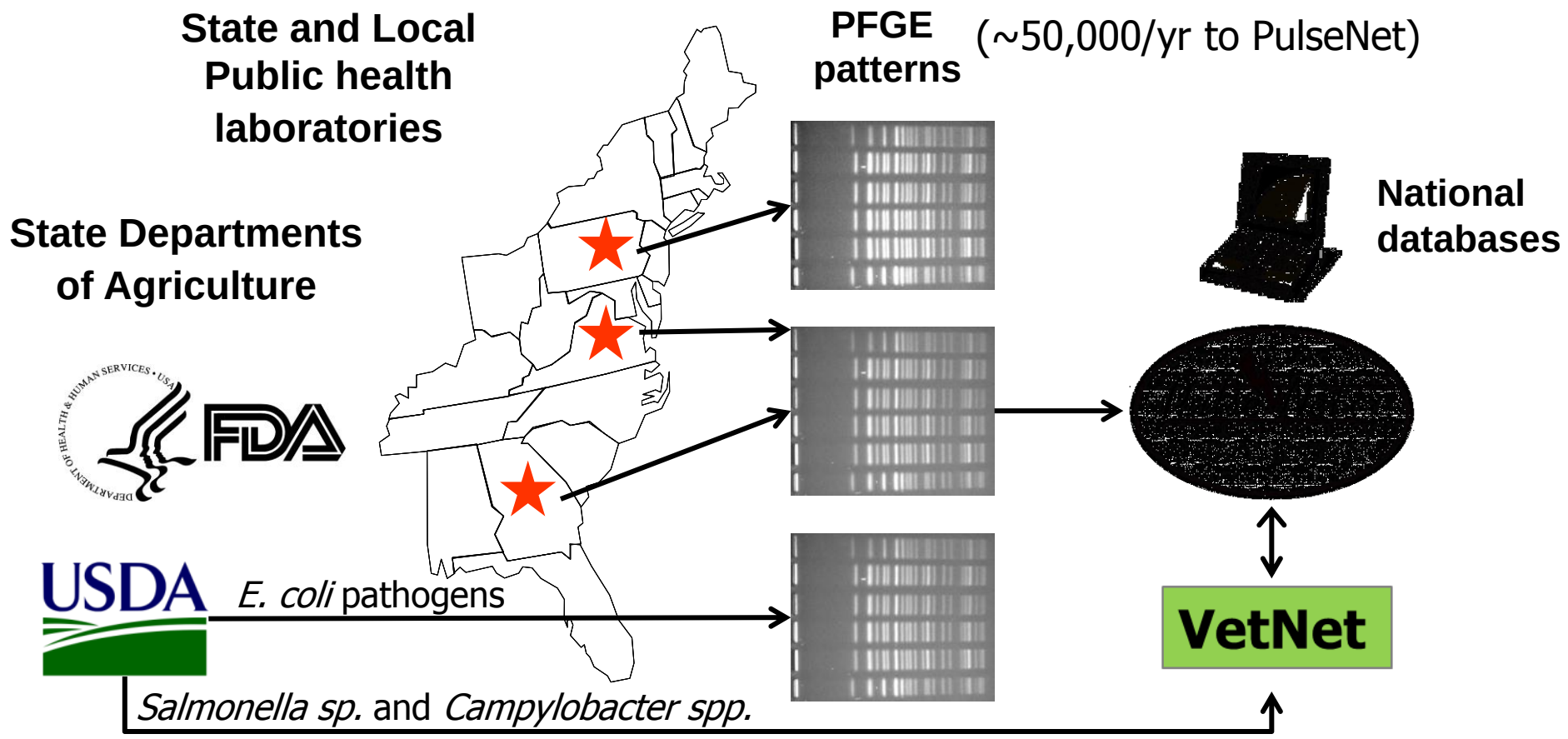
# A large outbreak in one place may be obvious



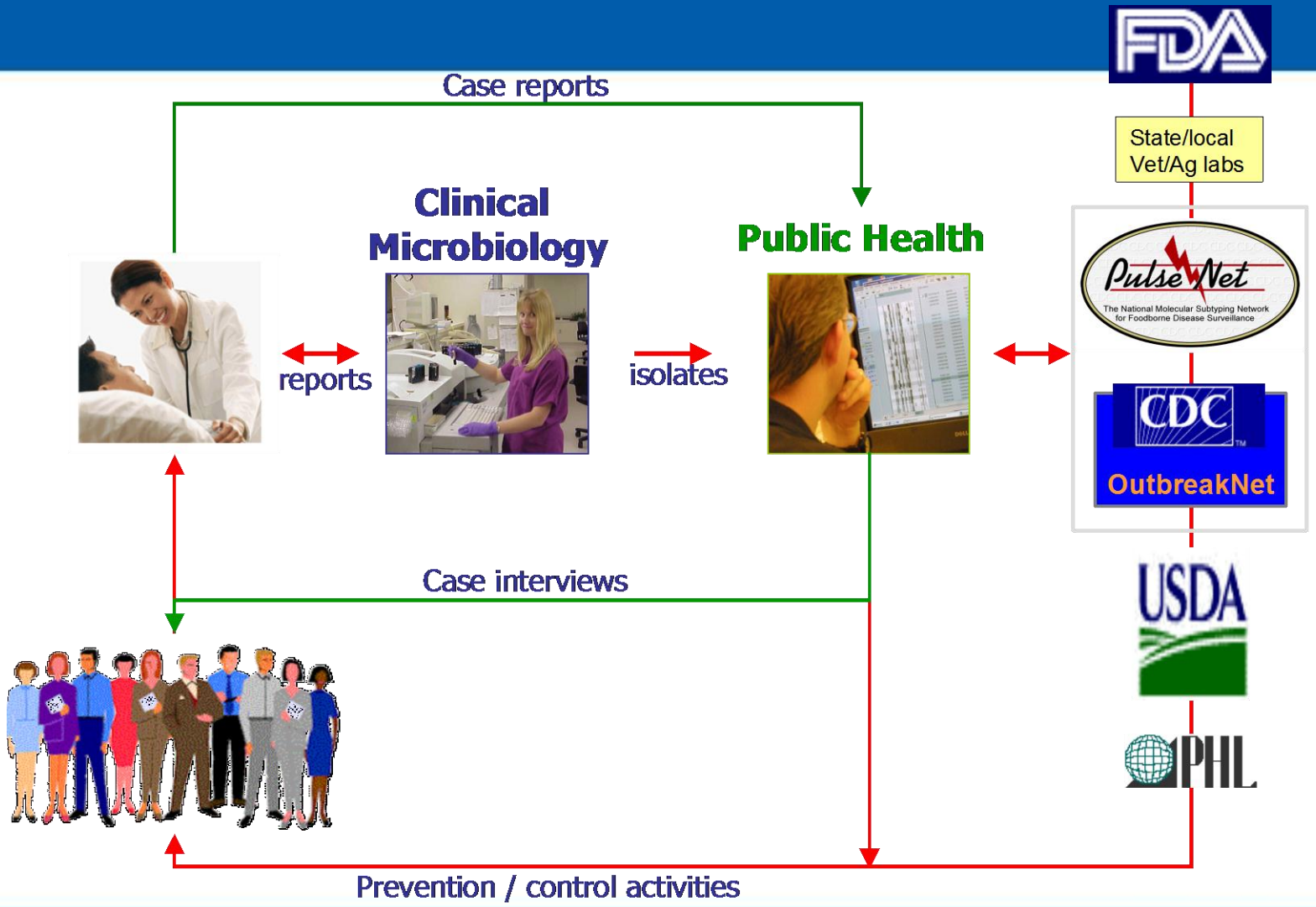
# An outbreak with persons in many places may be difficult to detect, unless cases can be linked



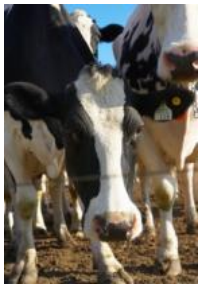
# PulseNet/VetNet Electronic Communication



# Pathogen Specific Surveillance



# Preventing Foodborne Disease

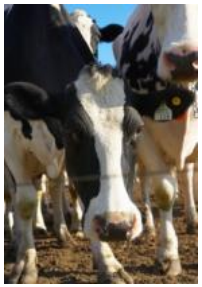


**Farm**

**Transport**
**Processing**
**Distribution**

**Preparation**

# Preventing Foodborne Disease



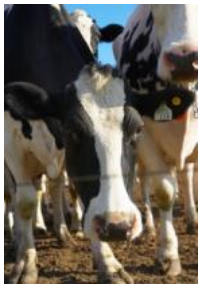
**Farm**

**Transport**
**Processing**
**Distribution**

**Preparation**

Disease surveillance

# Preventing Foodborne Disease



**Farm**

**Transport**
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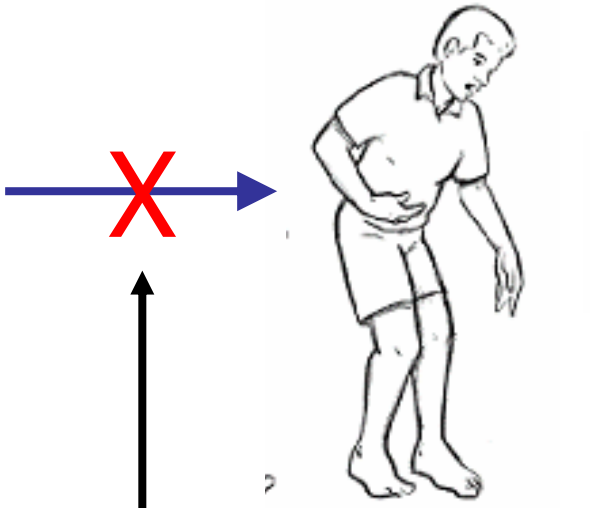
**Distribution**

**Preparation**

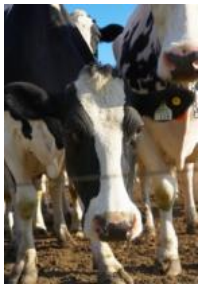


# Largest U.S. Food Recalls in which PulseNet Played a Prominent Role

| Year | Pathogen | Food | Amount recalled |
|---|---|---|---|
| **2011** | *Listeria monocytogenes* | Cantaloupe | Unknown |
| **2011** | *Salmonella* Heidelberg | Ground turkey products | >36,000,000 lbs |
| **2010** | *Salmonella* Enteritidis | Shell eggs | >500,000,000 eggs |
| **2010** | *Salmonella* Montevideo | Ready-to-eat Italian sausage products/pepper | >1,263,754 lbs |
| **2009** | *E. coli* O157:H7 | Cookie dough | 300,000 cases of product |
| **2009** | *Salmonella* Typhimurium | Peanut butter/peanut products | >3000 types of products |
| **2008** | *E. coli* O157:H7 | Ground beef | 5,300,000 Ibs |
| **2007** | *Salmonella* I 4,5,12:i:- | Frozen pot pies | Millions of pot pies |
| **2007** | *E. coli* O157:H7 | Frozen pizza | 5,000,000 pizzas |
| **2007** | *E. coli* O157:H7 | Ground beef (3 outbreaks) | 35,400,000 lbs |
| **2006** | *Salmonella* Tennessee | Peanut butter | 326,000,000 lbs |
| **2004** | *Salmonella* Enteritidis | Raw almonds | 13,000,000 lbs |
| **2003/'09** | *E. coli* O157:H7 | Blade Tenderized Frozen Steak | 865,046 lbs |
| **2002** | *Listeria monocytogenes* | Ready-to-eat poultry products | 27,400,000 lbs |
| **2002** | *E. coli* O157:H7 | Ground beef | 18,600,000 lbs |
| **2000** | *Listeria monocytogenes* | Ready-to-eat poultry products | 16,900,000 lbs |
| **2000** | *E. coli* O157:H7 | Ground beef | 1,100,000 lbs |
| **1998** | *Listeria monocytogenes* | Hot dogs, deli meats | 35,000,000 lbs |
| **1998/'08** | *Salmonella* Agona | Toasted oats cereal | >3,000,000 lbs |
| **1997** | *E. coli* O157:H7 | Frozen ground beef | 25,000,000 lbs |

Courtesy J. Besser

# Preventing Foodborne Disease



**Farm**

**Transport**
**Processing**
**Distribution**

**Preparation**

Disease surveillance

Limit ongoing illness

fix underlying problems

# Industries Stimulated to Change by PulseNet-Triggered Investigations

Peanut products

Ready-to-eat & "ready-to cook" foods

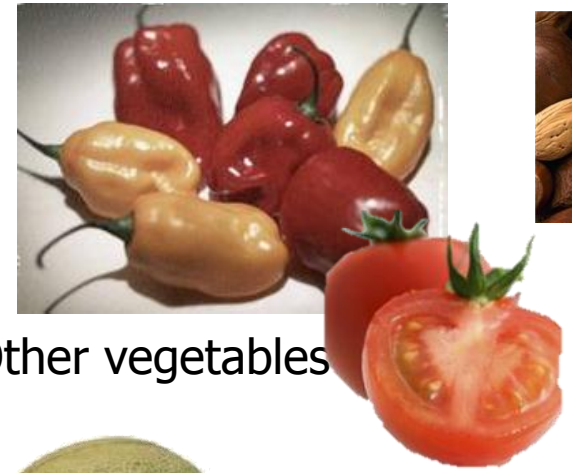
Eggs

Beef

Spices

Tree nuts

Leafy greens



Other vegetables

Sprouts

Mellon

Poultry

*"The foodborne disease surveillance system is to the food industry what radar is to automobile drivers – It is the "threat" of being caught that helps drive compliance with best safety practices."*

from Mike Doyle, Ph.D;
CDC Public Health Grand Rounds November 2009

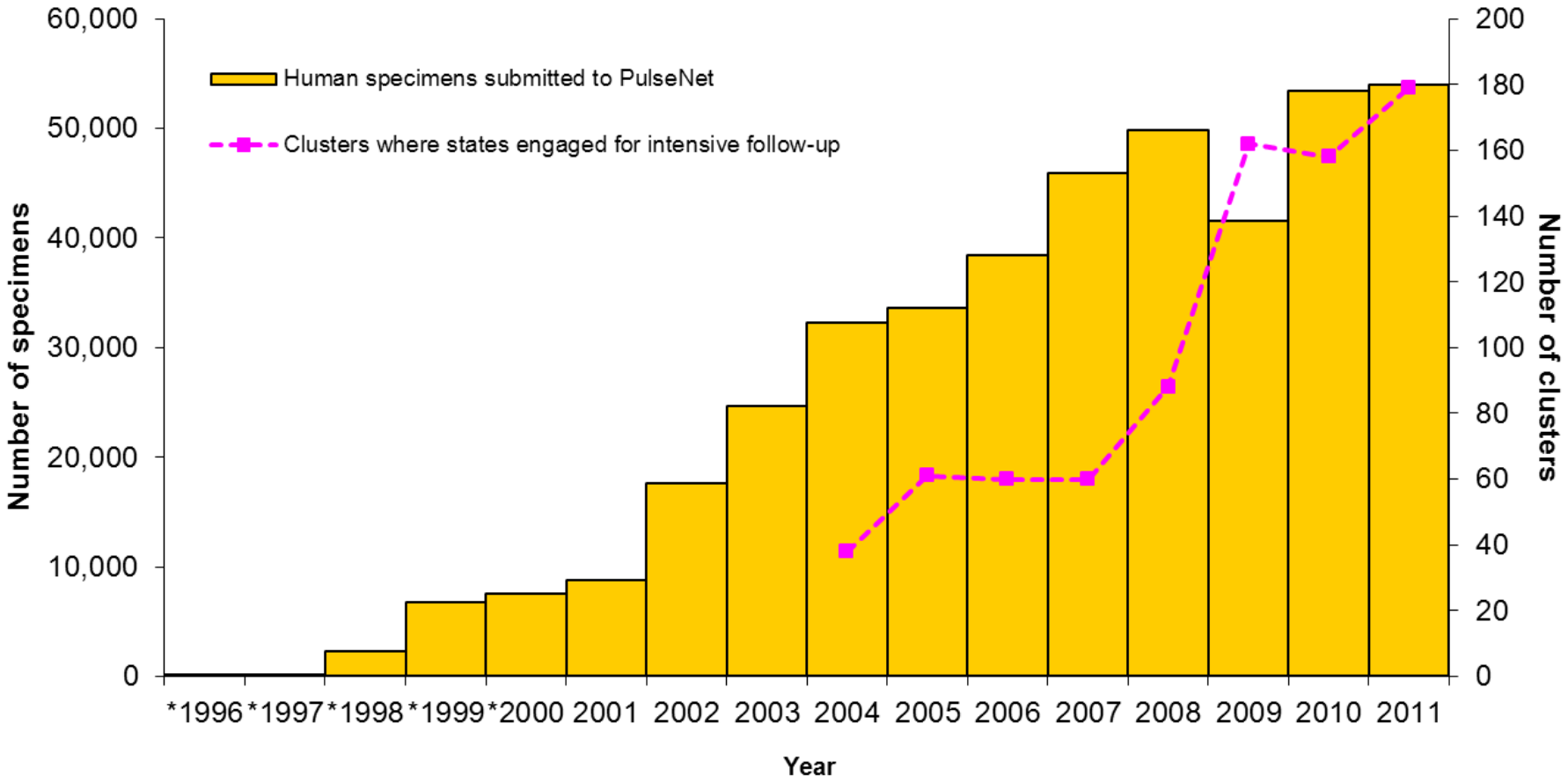
# Under-appreciated Sources of Infection

- *Salmonella* in reptiles and amphibians
- Multiple pathogens from live bird markets
- *Salmonella* from microbiology lab exposure
- *Salmonella* in "feeder" mice
- *Vibrio vulnificus* after fish handling
- *Salmonella* in baby chicks and ducks
- *Salmonella* in owl pellets
- STEC in petting zoos

# PulseNet Protocols

- *E. coli* O157
- Non-O157 STEC (VTEC)
- *Salmonella*
- *Shigella*
- *Listeria monocytogenes*
- *Vibrio cholerae*
- *Vibrio parahaemolyticus*
- *Campylobacter jejuni/coli*
- *Clostridium perfringens*
- *Clostridium botulinum*
- *Yersinia pestis*

# Bacterial isolates from humans uploaded to PulseNet USA, and identified clusters, 1996-2011†

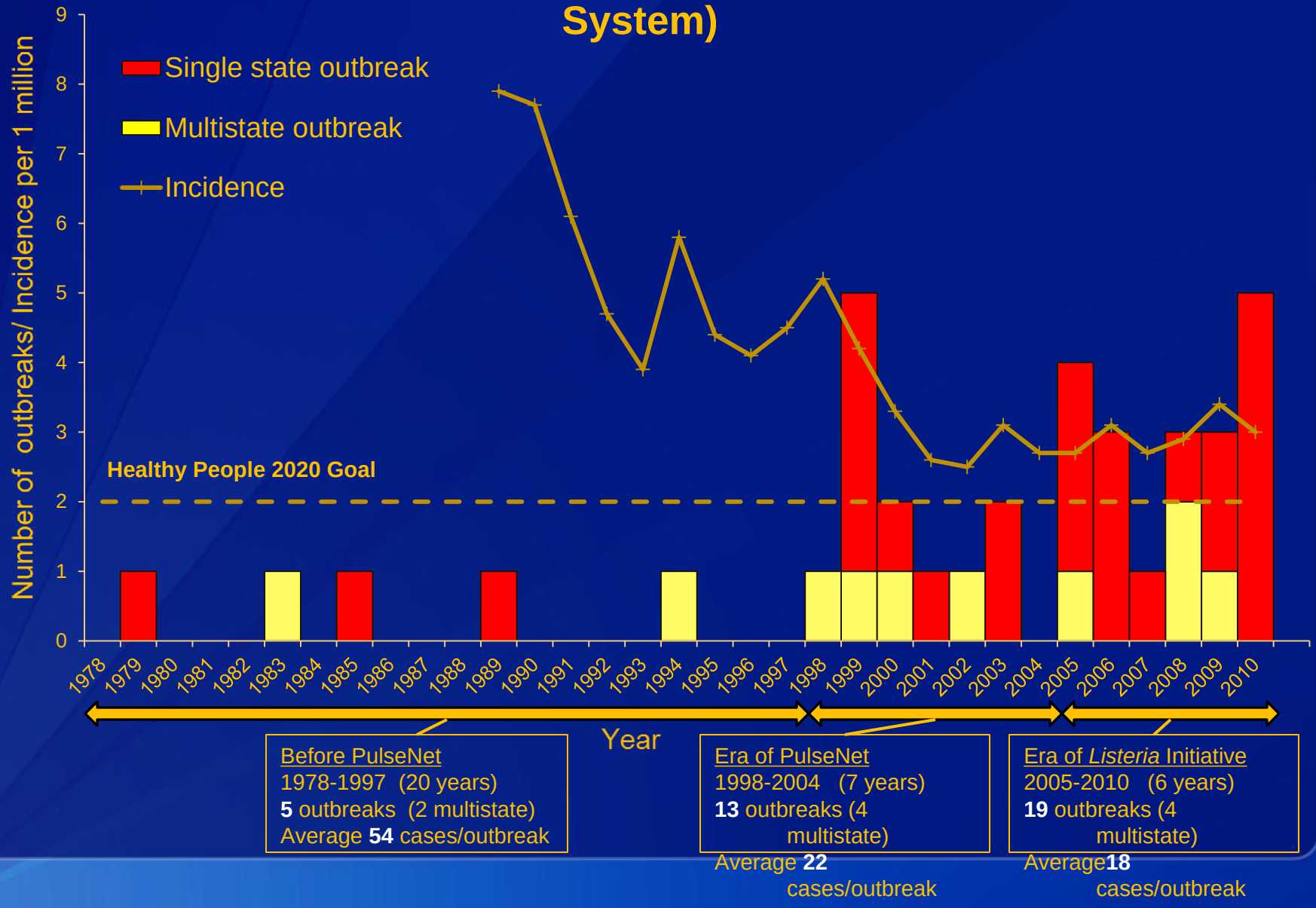



† Data are preliminary and subject to change
* data type information may not be complete for these years

# PulseNet-Based Surveillance

- **Each year PulseNet U.S.A. identifies**
  - ~1,500 clusters at local/state level
  - 200 multi-state clusters investigated

# Incidence and Outbreaks of *Listeria*, 1978-2010
## (from FoodNet and Foodborne Disease Outbreak Surveillance System)



*Dispatches*

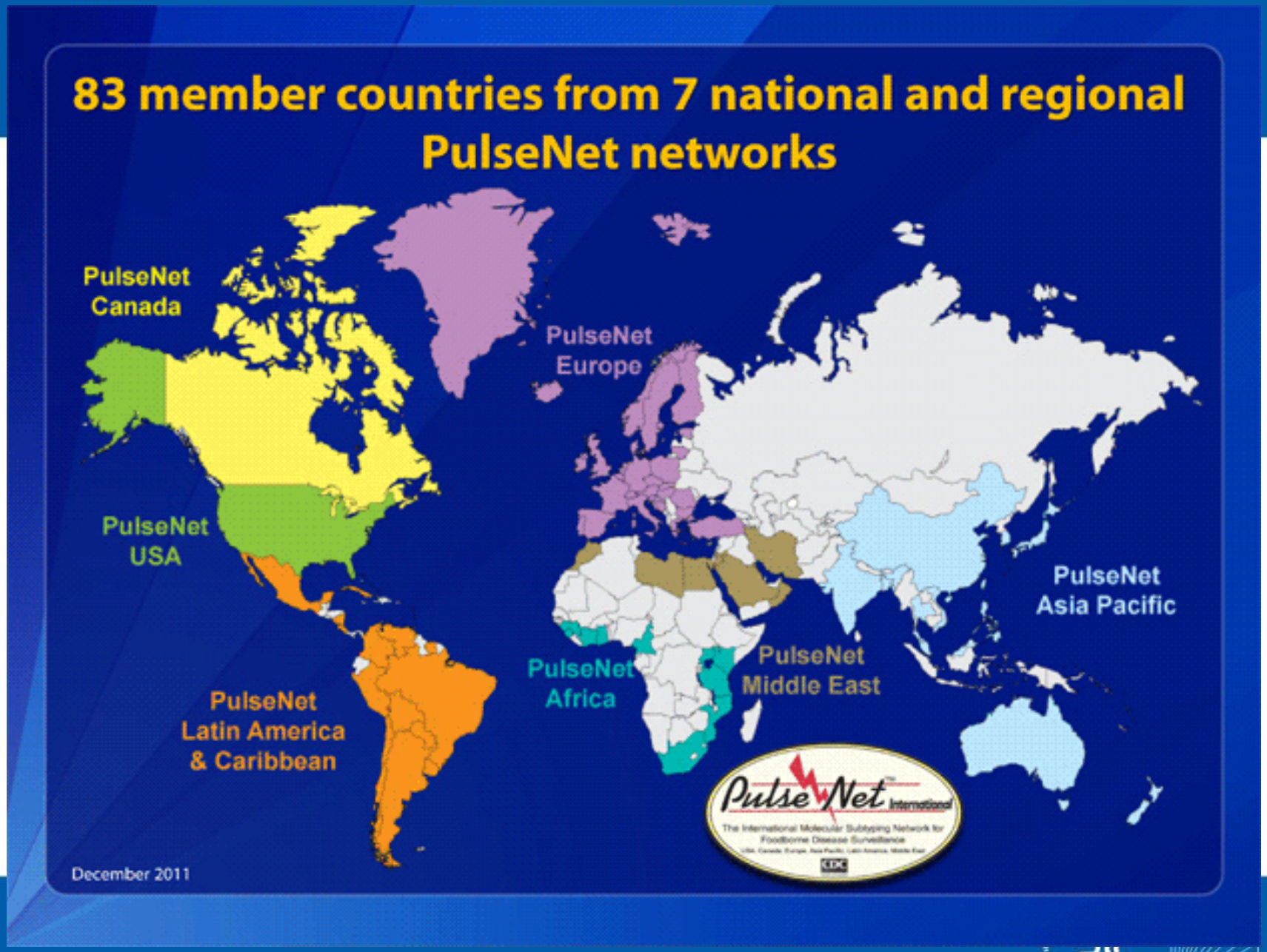
# Costs and Benefits of a Subtype-Specific Surveillance System for Identifying *Escherichia coli* O157:H7 Outbreaks

**Elamin H. Elbasha,* Thomas D. Fitzsimmons,*† and Martin I. Meltzer***

*Centers for Disease Control and Prevention, Atlanta, Georgia, USA; and †Colorado Department of Public Health and Environment, Denver, Colorado, USA

We assessed the societal costs and benefits of a subtype-specific surveillance system for identifying outbreak-associated *Escherichia coli* O157:H7 infections. Using data from Colorado, we estimated that if it averted five cases annually, the system would recover all its costs.

*Escherichia coli* O157:H7 infections pose a [illegible] nationally. After the outbreak was traced to the [illegible]


83 member countries from 7 national and regional PulseNet networks
PulseNet Canada
PulseNet Europe
PulseNet USA
PulseNet Asia Pacific
PulseNet Africa
PulseNet Middle East
PulseNet Latin America & Caribbean
PulseNet International
The International Molecular Subtyping Network for Foodborne Disease Surveillance
CDC
December 2011

## International outbreak of *E. coli* O157 infections linked to ground beef patties of a particular brand

CDC, October 26, 2007

A joint investigation between the Canadian Food
rtment of
ion Service
of a multi-
57:h7
n the USA,
anadian beef-producing firm. The outbreak was significant in

## International Outbreaks of shigellosis in Denmark and Australia in 2007 associated with imported baby corn from Thailand

By author name and date

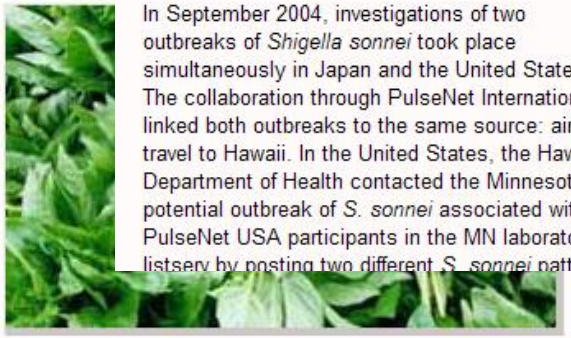
Two outbreaks of *Shigella sonnei* infections simultaneously detected in Denmark and Australia were found to be linked to the same baby corn packing house in Thailand. PulseNet played a key role in confirming this link when

## International outbreak of *Shigella sonnei* associated with air travel to Hawaii in 2004

By multiple authors, Japan Journal of Infectious Diseases, July 13, 2006

In September 2004, investigations of two outbreaks of *Shigella sonnei* took place simultaneously in Japan and the United States. The collaboration through PulseNet International linked both outbreaks to the same source: air travel to Hawaii. In the United States, the Hawaii Department of Health contacted the Minnesota Department of Health (MN) to inform them of a potential outbreak of *S. sonnei* associated with domestic and international air travel to Hawaii. PulseNet USA participants in the MN laboratory alerted the rest of PulseNet USA via the PulseNet listserv by posting two different *S. sonnei* patterns digested with XbaI that were obtained from

## International outbreak of *Salmonella* Senftenberg infection in 2007 associated with consumption of fresh basil imported from Israel

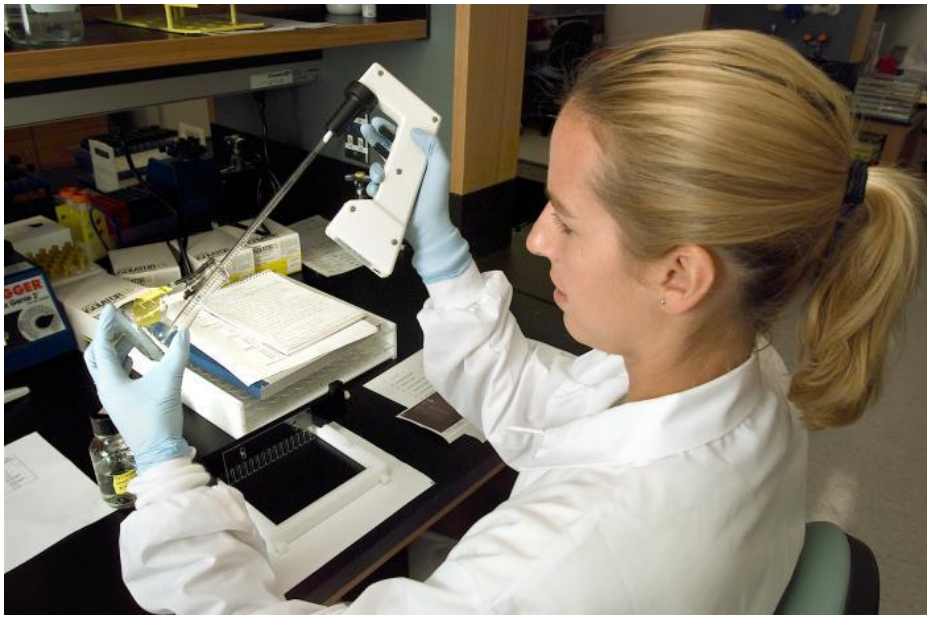


Multiple authors, Eurosurveillance, Volume 12, Issue 24, 14 June 2007

PFGE analysis performed according to the PulseNet *Salmonella* protocol by researchers in Europe and the United States, and shared through the PulseNet International network and the former European Enter-net, was instrumental in delineating this outbreak caused by *Salmonella* Senftenberg and confirming its source: fresh basil from Israel. Read original

# Current PulseNet Methods (PFGE and MLVA) are Isolate-Dependent

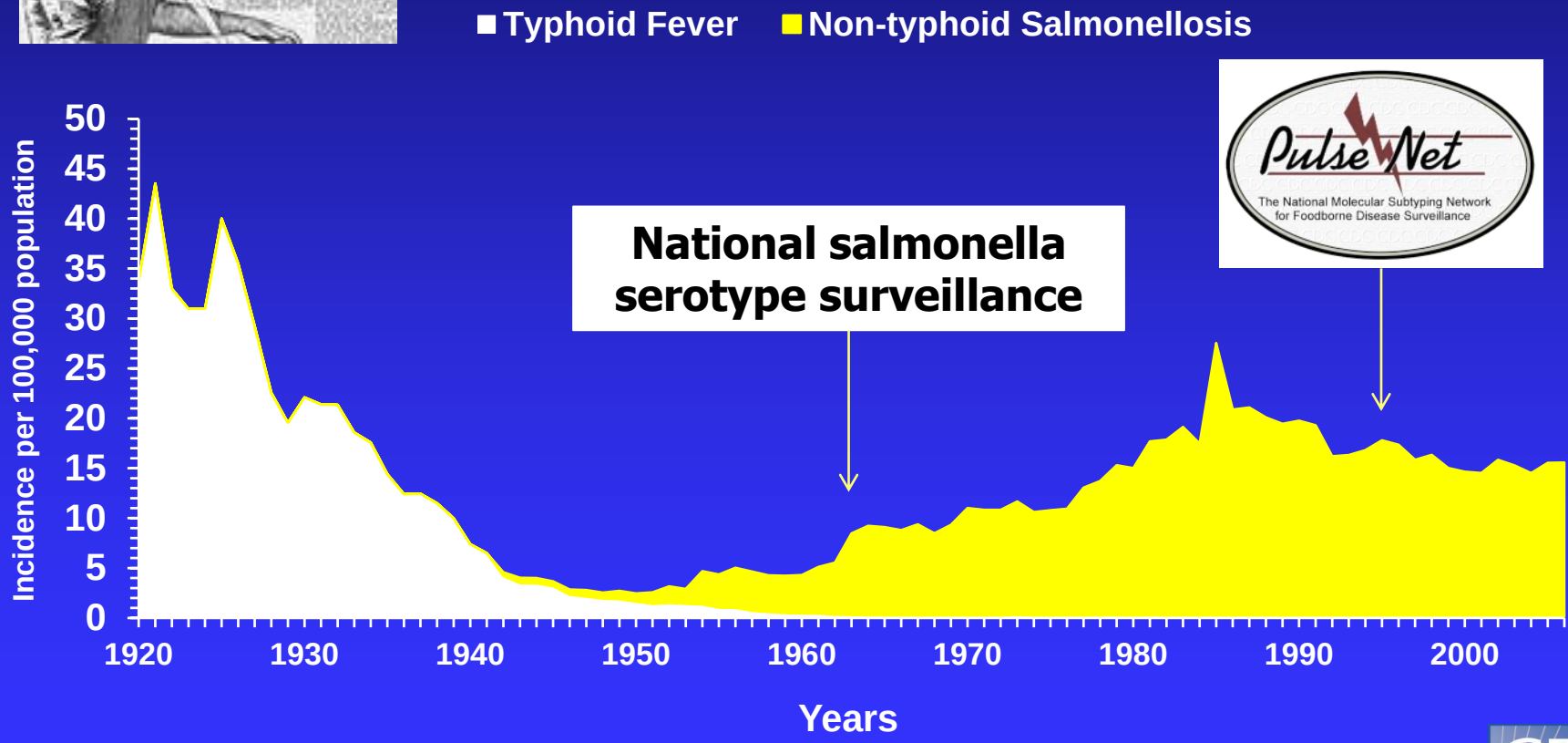
(Note: so is whole genome sequencing, and most other methods being considered)



# Companies with Multi-Analyte Gastro Panels in Development

- Luminex xTAG panel (in FDA clearance)
  - Bacteria (10)
  - Viruses (3)
  - Parasites (3)
- Verigene (research use only)
- At least 8 other companies have multi-analyte panels in various stages of development

# Nationwide reporting began in 1912
# Reported *Salmonella* infections in the United States, 1920-2006


CDC, National surveillance data

CDC
Centers for Disease Control and Prevention

# General Strategies to Address Issue

- Short-term: Preserve isolates
- Longer-term: Develop culture-independent pathogen characterization methods
- Very long-term: exploit paradigm shifting technologies

# Reflex Culture

Follow-up culture automatically initiated when positive culture independent-based laboratory test results are observed.

(possible when the specimen collected is compatible with culture)

# Short-term: Preserve isolates

- Work with medical industry to make new tests compatible with public health needs
- Consider public health impacts in the device licensure process
- Make reflex culture reimbursable?
- Modify State reportable disease rules
- Develop isolate recovery capacity for PHLs
- Sentinel culture-based surveillance?

# Longer-term: Develop culture-independent pathogen characterization methods

- Identify ID/subtype/virulence targets for direct molecular detection and characterization
- Exploit new technologies (metagenomics, single-cell sequencing)

# Opportunities

- Faster results (better exposure recall, faster intervention)
- Wider understanding of disease causation

# Questions

- How can the public health impact of certain test results be better emphasized as test systems are cleared by FDA?
- Are there ways in which the CLIA program can promote public health recommendations (e.g. supporting CDC guidelines and recommendations)?