



Culture-Independent Diagnostic Testing: Where Are We Now?

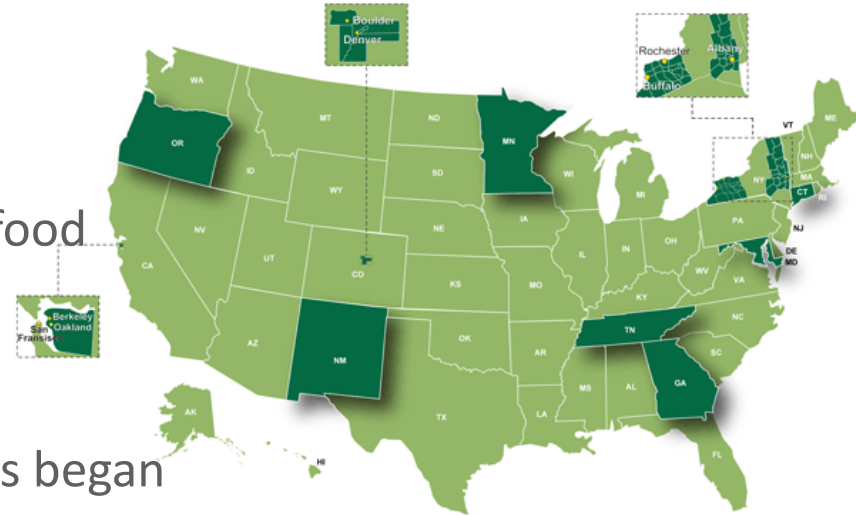
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**Epidemiologist, FoodNet, Enteric Diseases Epidemiology Branch
Division of Foodborne, Waterborne, and Environmental Diseases**

PulseNet/OutbreakNet Regional Meeting

Foodborne Diseases Active Surveillance Network (FoodNet)

- Collaboration among CDC, 10 state health departments, USDA-FSIS, and FDA
- Determine the burden of foodborne illness
- Monitor trends in the burden over time
- Population-based active surveillance for 8 pathogens commonly transmitted through food
 - *Campylobacter*, *Listeria*, *Salmonella*, Shiga toxin-producing *E. coli* (STEC), *Shigella*, *Vibrio*, *Yersinia*, and *Cyclospora*
- Surveillance for culture-confirmed infections began in 1996, expanded to CIDT+ infections in 2012



Laboratory Surveys

- Objectives
 - Supplement case data
 - Assess changes in diagnostic testing practices over time
- Biannual surveys of all clinical laboratories in FoodNet catchment
 - 5 questions per pathogen
 - Test methods, brand, reflex culture

1. During the past 6 months, has your lab changed testing methods used for detecting *Campylobacter*? (Yes/No)

2. Do you test stool specimens for *Campylobacter* on site at your laboratory? (Yes/No)
2a. If no, to which laboratories do you send specimens for *Campylobacter* testing?

3. How does your lab routinely identify *Campylobacter*? (check all that apply)

Culture on all specimens

Culture-Independent Diagnostic Test (CIDT) (e.g. EIA microplate or lateral flow immunoassays or PCR) on all specimens

3a. If *Campylobacter* is detected using a CIDT, do you attempt to culture the organism (i.e. reflex culture)? (Yes/No)

4. What do you submit to your public health laboratory?

Isolates

Stool samples

Broth

We do not routinely submit specimens for *Campylobacter* to the SPHL

5. Please indicate which culture-independent diagnostic test(s) your lab uses to detect *Campylobacter*

Stool immunoassay, such as EIA microplate or lateral flow assay

5a. If selected, which brand(s) do you use?

ProSpect *Campylobacter* assay (Remel);

PREMIER™ CAMPY assay (Meridian);

ImmunoCard STAT! CAMPY assay (Meridian);

Xpect *Campylobacter* assay (Remel);

Other antigen test (specify): _____

PCR

5b. If selected, which brand(s) do you use?

Luminex: xTAG® Gastrointestinal Pathogen Panel (GPP)

Hologic: Prodesse ProGastro SSCS assay

BioMerieux (BioFire): FilmArray Gastrointestinal (GI) Panel

Becton Dickinson (BD): BD MAX™ Enteric Bacterial Panel

Nanosphere: Verigene® Enteric Pathogens Test (EP)

Lab-developed test (LDT) (please specify gene target(s): _____)

Other culture-independent method (specify): _____

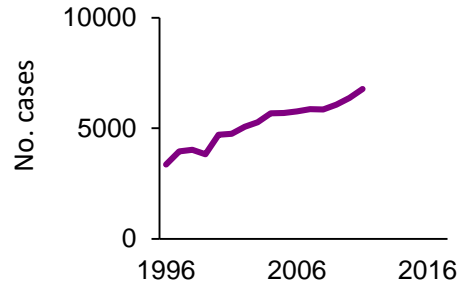
Challenges

- Surveillance
 - Need to change case definitions?
 - How do we interpret test results?
 - Increased case load? Need to prioritize interviews?
 - How do we interpret changes in incidence?
- Laboratory
 - Will clinical laboratories maintain culture? Will they reflex?
 - Increased or decreased specimen submission? Need to change rules?
 - Can SPHLs perform the reflex? How does that affect recovery?
 - How do we track and interpret results?

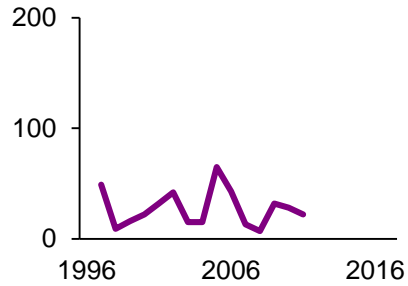


How have CIDTs affected case reporting?

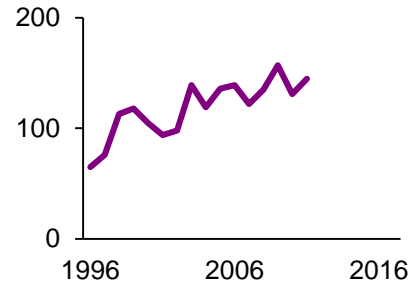
Campylobacter



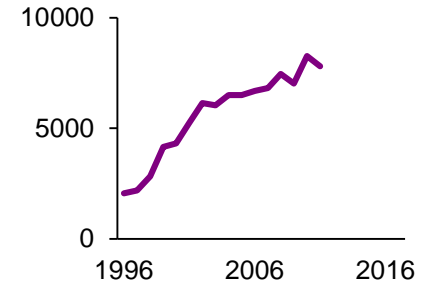
Cyclospora



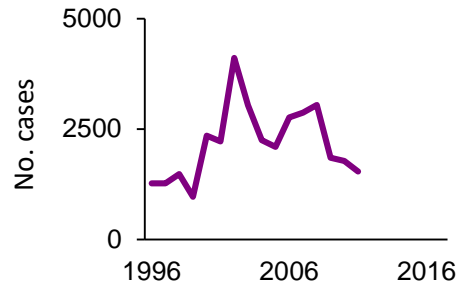
Listeria



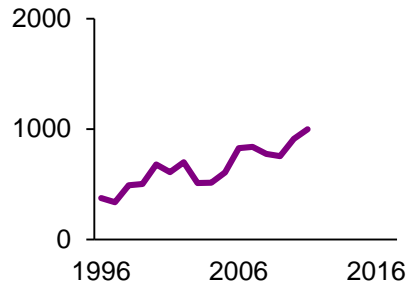
Salmonella



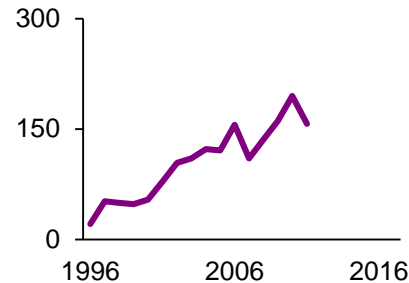
Shigella



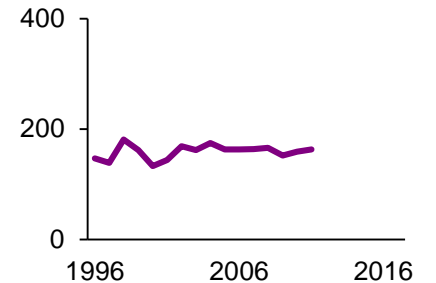
STEC



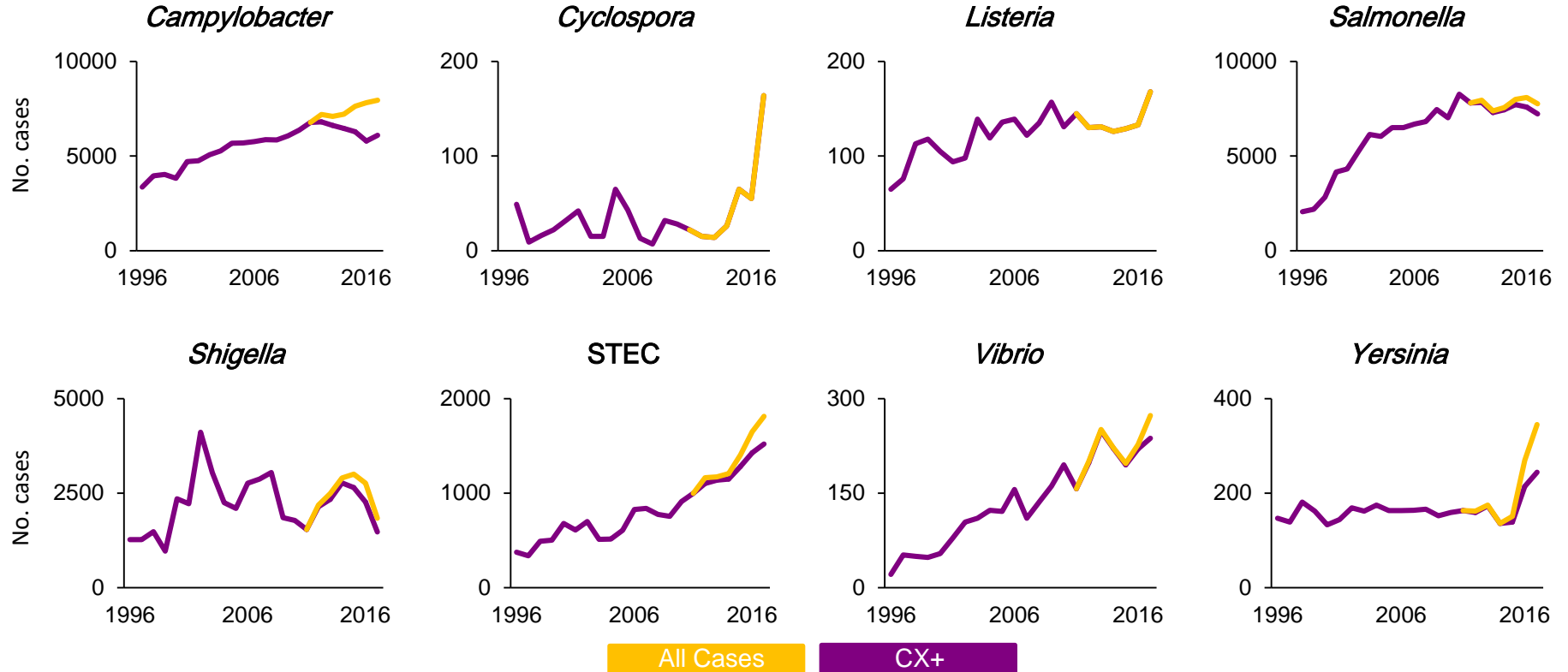
Vibrio



Yersinia

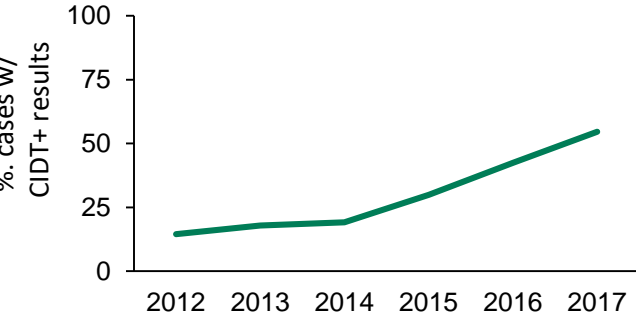


Increased case counts for all pathogens since 2012

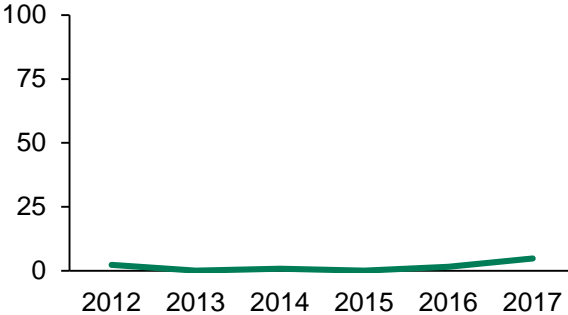


CIDT adoption varied by pathogen

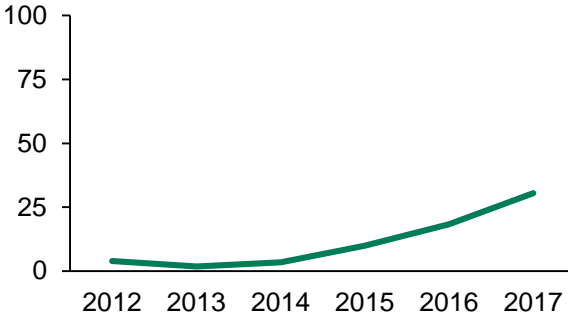
Campylobacter



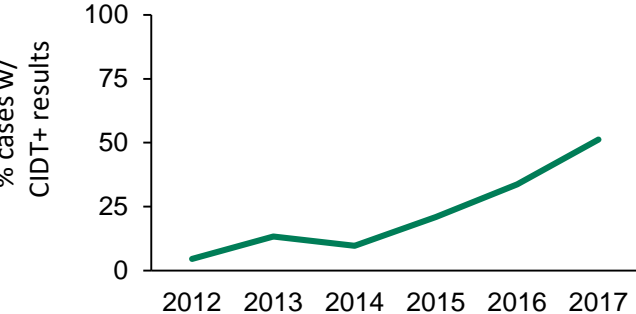
Listeria



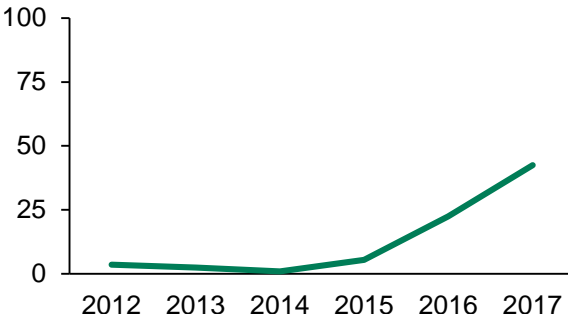
Salmonella



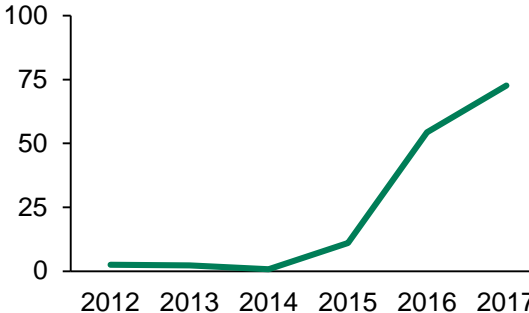
Shigella



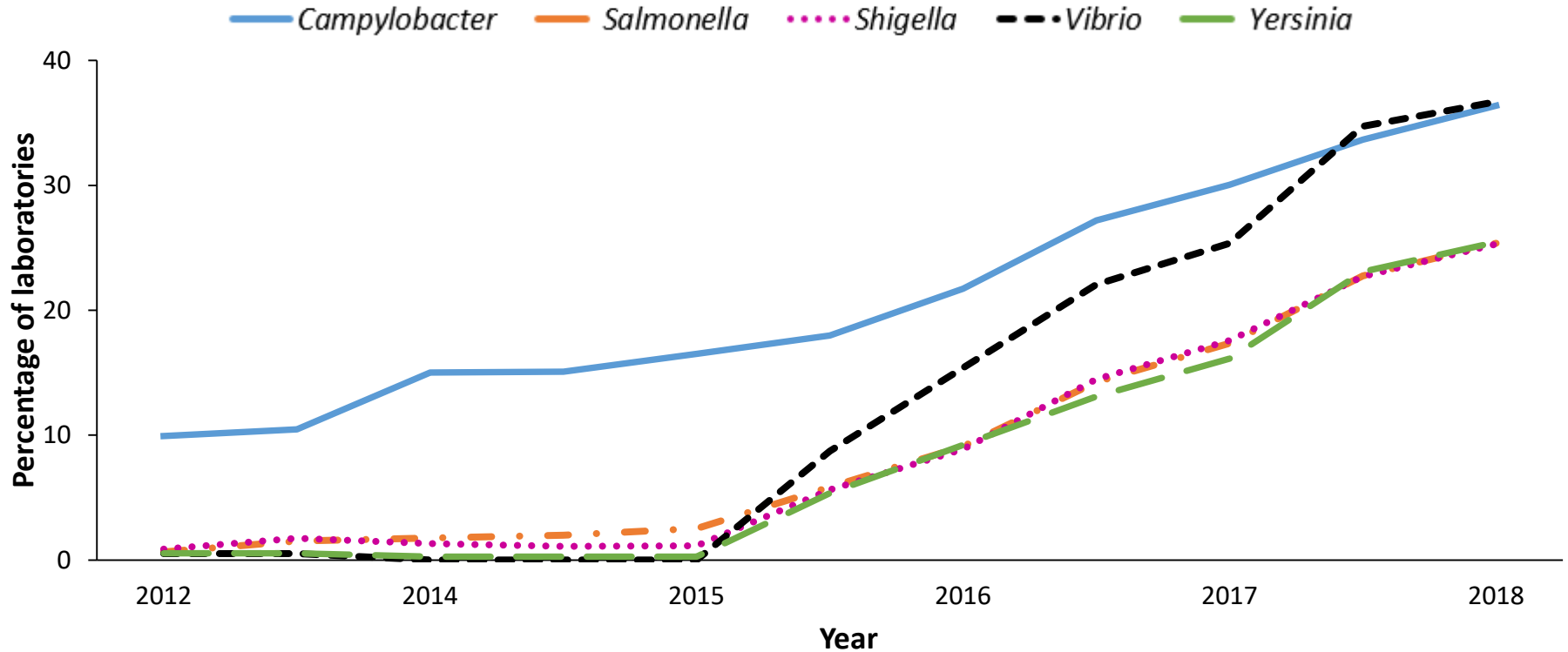
Vibrio



Yersinia



CIDT use increasing among clinical laboratories

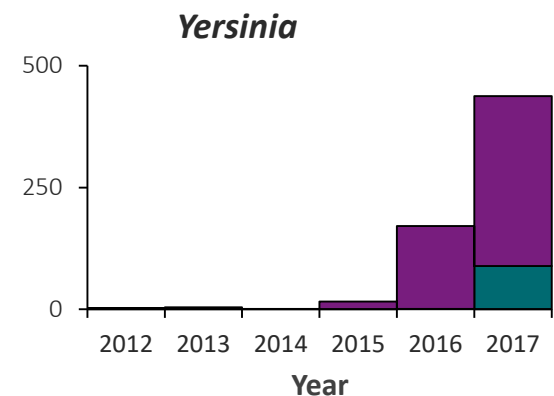
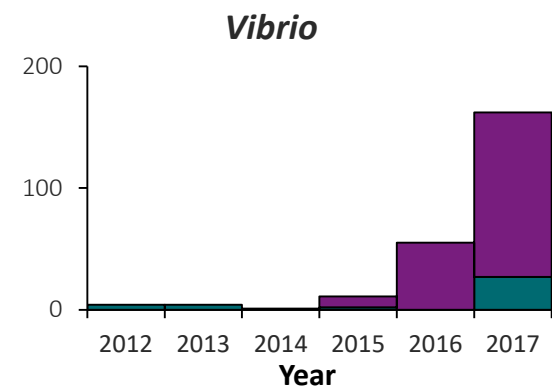
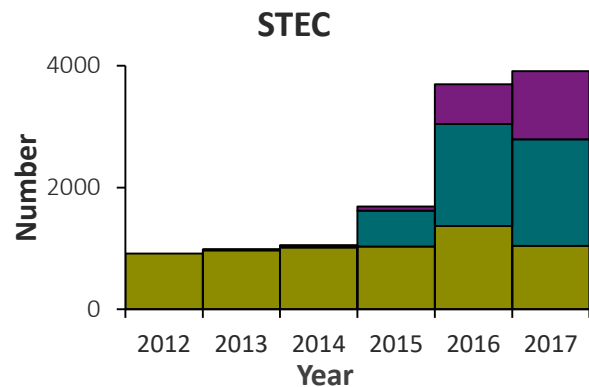
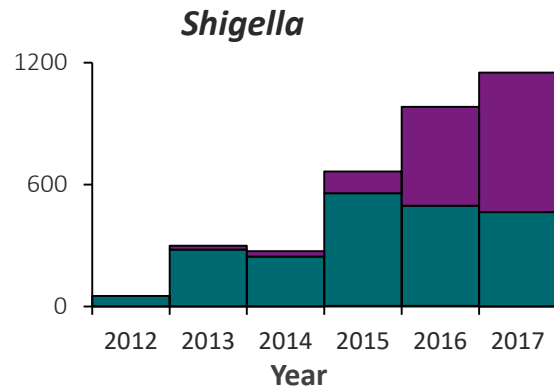
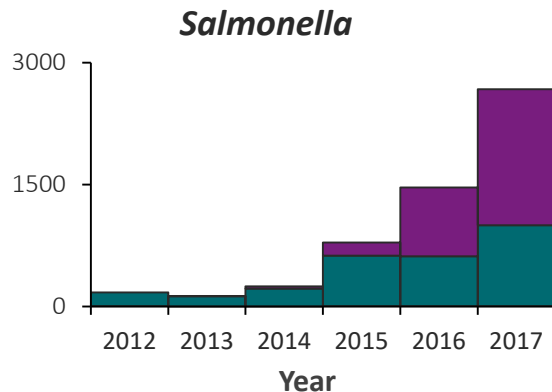
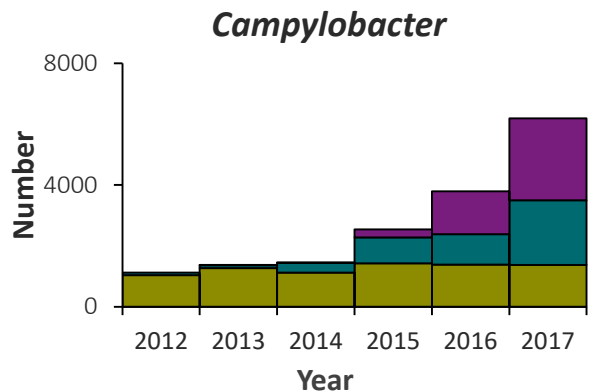


Recent increases were driven by syndromic panels

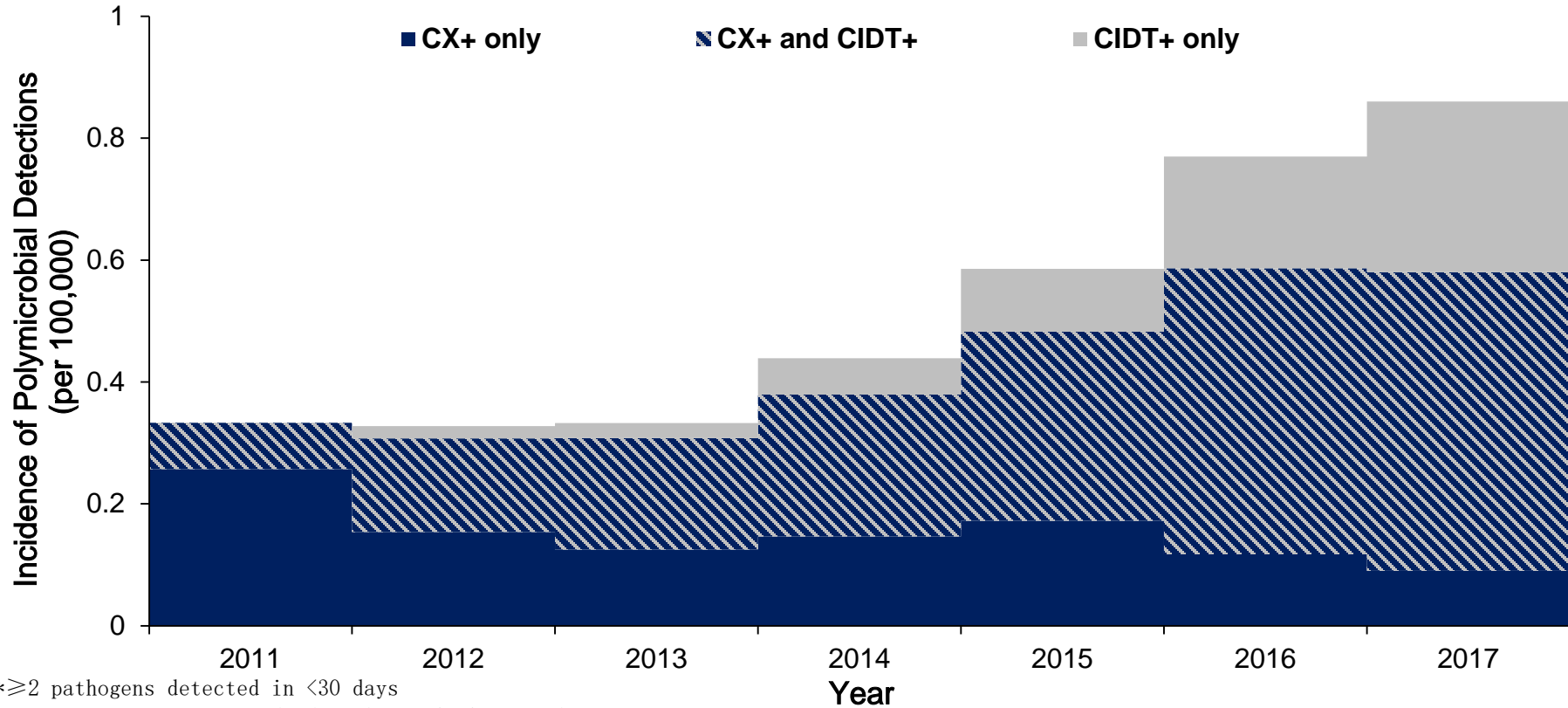
Antigen -based test

Locally-developed PCR test

DNA-based syndrome panel test



Increased panel use mirrors increase in polymicrobial detections

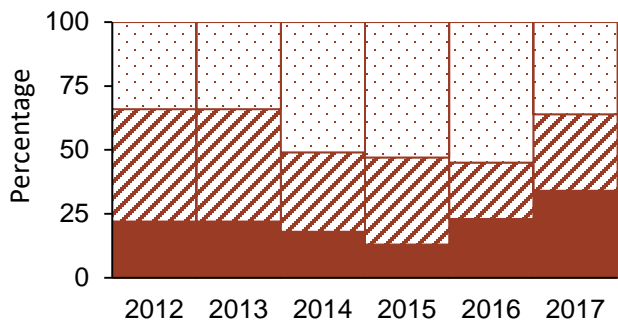


* ≥ 2 pathogens detected in <30 days
†CT, GA, NM, MD, MN, TN and selected counties in CA and CO

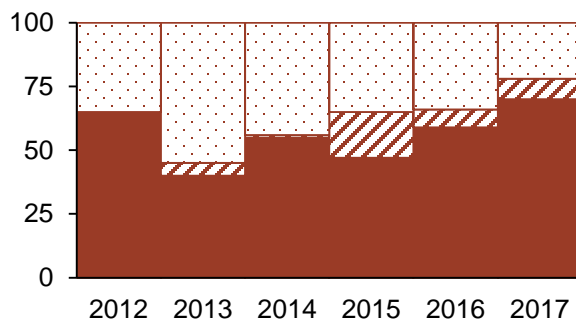
Reflex CX done frequently, but not often positive

■ Reflex culture positive ▨ Reflex culture negative ▩ Reflex culture not performed

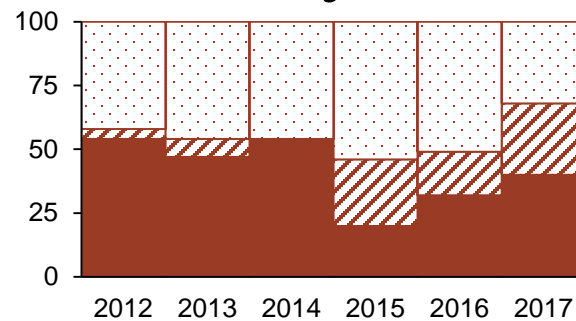
Campylobacter



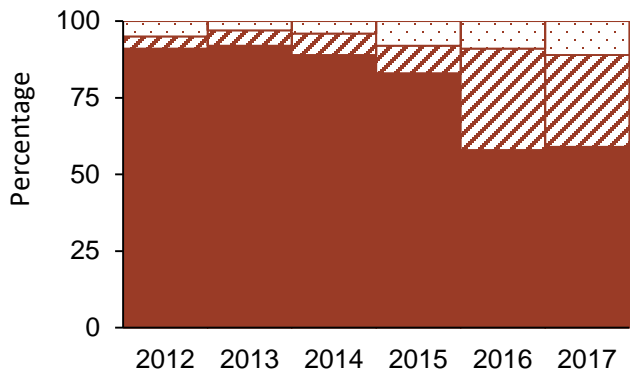
Salmonella



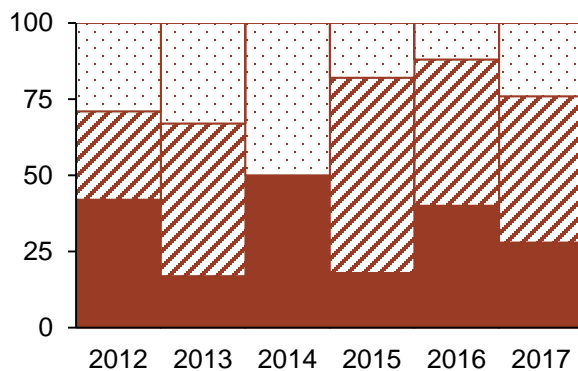
Shigella



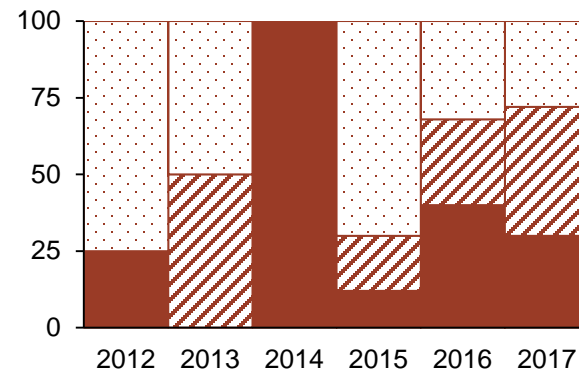
STEC



Vibrio

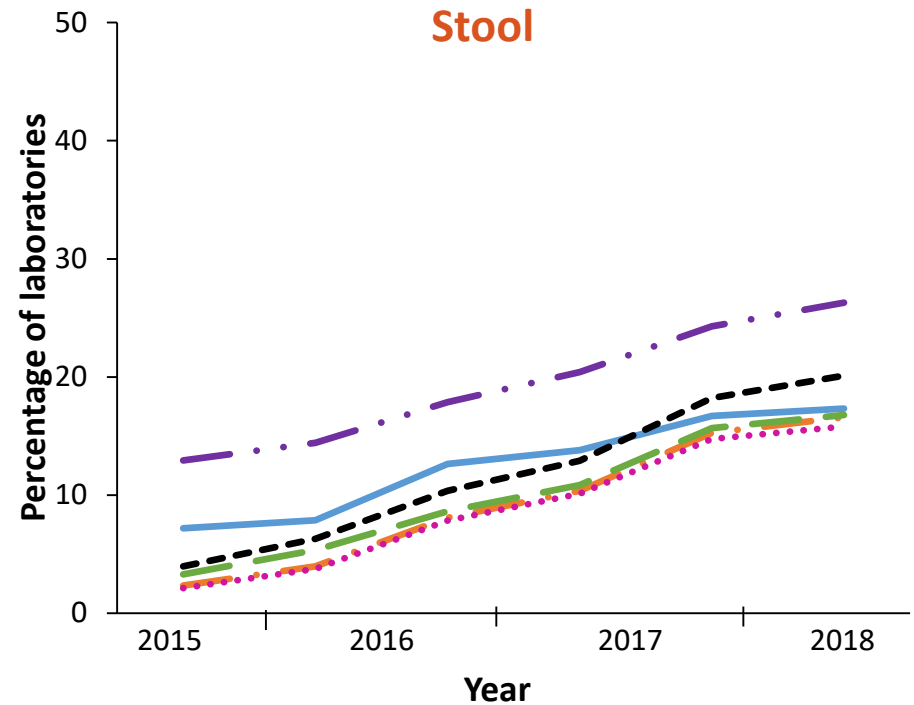
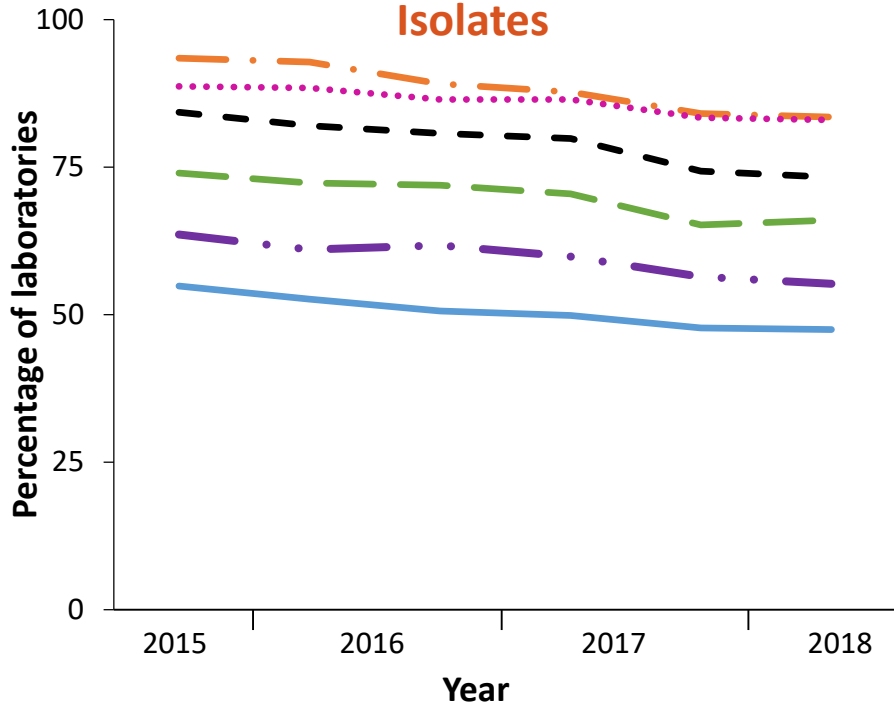


Yersinia



Isolate submission decreasing and while stool increasing

— Campylobacter — Salmonella Shigella — STEC - - - Vibrio — Yersinia



Surveillance Solutions

- Adapt surveillance and revise case definitions to capture CIDT+ cases
 - FoodNet revised definitions in 2012
 - National case definitions updated
 - *Campylobacter*, 2015
 - *Salmonella*, *Shigella*, *Vibrio*, 2017
 - STEC, 2018
 - *Listeria* and *Yersinia*, 2019
- Develop models to interpret incidence measures over time
 - Monitor healthcare provider testing practices
 - Estimate laboratory testing volume by test type

Laboratory Solutions

- Consider best approaches for obtaining isolates for species, subtype, and antimicrobial sensitivity characterization
 - Prioritize reflex culture
 - Update specimen submission regulations
- Survey clinical laboratories for testing practices

Unanswered questions require data & partnerships

- Collect epidemiologic and clinical data to better understand
 - Polymicrobial detections
 - Exclusion criteria
- Partner with industry to identify strategies to meet needs of both
 - Anticipate upcoming changes
 - Inform test interpretation

Acknowledgements

FoodNet Sites

California Emerging Infections Program

Connecticut Emerging Infections Program

Colorado Department of Public Health and Environment

Georgia Department of Public Health

Maryland Department of Health and Mental Hygiene

Minnesota Department of Health

New Mexico Emerging Infections Program

New York State Department of Health

Oregon Health Authority

Tennessee Department of Health

US Department of Agriculture Food Safety and Inspection Service

US Food and Drug Administration

US Centers for Disease Control and Prevention FoodNet Staff



For more information, contact CDC
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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

