16-ID-03

Committee: Infectious Disease

Title: Public Health Reporting and National Notification for Salmonellosis (non-typhoidal)

I. Statement of the Problem

Culture-independent diagnostic testing (CIDT), defined as the detection of antigen or nucleic acid sequences of the pathogen, is rapidly being adopted by clinical laboratories. For *Salmonella*, these are generally PCR-based testing methods which do not require a stool culture and thus do not yield an isolate. While concerted efforts are being made to ensure reflexive culture is performed at the clinical laboratory or the state or local public health laboratory, CIDT-positive reports are not always culture-confirmed. In 2011, CSTE updated the *Salmonella* case definition, classifying a positive CIDT result that is not culture-confirmed as a suspect case. Further modification of this case definition is needed to address the following two concerns:

1. These suspected cases are not being reported to national surveillance, and the number of positive CIDT reports is growing rapidly, leading to substantial under-ascertainment of laboratory-diagnosed cases.
2. Case definitions for bacterial enteric pathogens are not consistent. In the 2014 CSTE position statement for *Campylobacter*, a CIDT-positive report that is not culture-confirmed is classified as a probable case and is reported to national surveillance.

To prevent an increase in underreporting of salmonellosis cases and to make case definitions for enteric bacterial pathogens more consistent, this position statement proposes to change the case classification for a case with a positive *Salmonella* CIDT result from 'suspect' to 'probable.'

II. Background and Justification

Background:

An estimated one million cases of *Salmonella* infection occur annually in the United States. About 400 people die each year from *Salmonella* infection, with infants, the elderly and the immune compromised being at greatest risk. *Salmonella* is a leading cause of foodborne disease with multiple outbreaks detected each year. *Salmonella* surveillance in the United States has been in place for many decades. Ongoing surveillance of *Salmonella* infections is needed to detect and control outbreaks, to determine public health priorities, to monitor trends in illness, and to assess effectiveness of public health interventions.

Justification:

Surveillance data are essential for monitoring trends and detecting outbreaks. Methods for surveillance must keep pace with changing laboratory diagnostic methods.

- Use of CIDT to detect *Salmonella* has increased rapidly at clinical laboratories following FDA approval of several multiplex nucleic acid tests in 2014. As of March 3, 2016, FoodNet data indicate 29/426 (7%) of laboratories in the FoodNet catchment area are using CIDT. FoodNet has detected a 247% increase in the number of positive CIDT reports during 2015 (361) compared with 2012-2014.
- CIDT positive reports are not always culture-confirmed. This can be because the culture is negative at the clinical or public health laboratory, or because culture was not attempted.
- In 2015, 361 cases of salmonellosis positive (+) by CIDT and not culture-confirmed were reported to FoodNet. These cases represent 5% of all reported salmonellosis cases in the FoodNet catchment area which represents 15% of the US population.
- During 2012-2015, FoodNet received reports of 785 Salmonella CIDT-positive results for which culture was performed. Of those, 81% were confirmed by culture. This proportion varied by the specific CIDT used.
- The current case definition for salmonellosis classifies a CIDT-positive result without culture confirmation as a suspect case. These cases are not reported to CDC for use in national surveillance.

- The current (2014) case definition for campylobacteriosis classifies a CIDT-positive result without culture confirmation (PCR or antigen-based testing) as a probable case. These are transmitted to CDC for use in national surveillance.
- Some state health departments have barriers to investigating suspected cases. For example, some have rules that require local jurisdictions to investigate confirmed and select probable cases but not suspected cases. Increasing numbers of positive CIDT results that are non-culture confirmed, could affect outbreak detection and result in missed opportunities for control measures at the local level (such as worker exclusion).
- As the use of CIDT increases, counting only culture-confirmed cases will grossly undercount total number of laboratory-diagnosed salmonellosis cases. Public health case definitions must keep pace or surveillance will suffer.
- Underestimating the true number of *Salmonella* cases will affect the assessment of the impact of interventions to promote food safety. For example, in 2011, the Food Safety and Inspection Service of the United States Department of Agriculture implemented stricter pathogen reduction standards targeted at decreasing poultry-associated *Salmonella* infections and outbreaks. Also in 2011, the Food Safety Modernization Act gave the US Food and Drug Administration additional authority to regulate food facilities, establish standards for safe produce, recall contaminated foods, oversee imported foods, and requires CDC to strengthen foodborne disease surveillance and response to outbreaks. Under-ascertainment of salmonellosis due to exclusion of cases with positive CIDT results could result in false assessments of these and other interventions put in place to control salmonellosis.

This position statement proposes that positive CIDT results for *Salmonella* that are not culture-confirmed be reported as probable cases. Illnesses among persons who are epidemiologically linked to a confirmed, or probable case with supportive laboratory evidence, will be classified as probable cases.

III. Statement of the desired action(s) to be taken

1. Utilize standard sources (e.g. reporting*) for case ascertainment for salmonellosis. Surveillance for salmonellosis should use the following recommended sources of data to the extent of coverage presented in Table III.

Table III. Recommended sources of data and extent of coverage for ascertainment of cases of salmonellosis.

Source of data for case ascertainment	Coverage	
	Population-wide	Sentinel sites
Clinician reporting	X	
Laboratory reporting	X	
Reporting by other entities (e.g., hospitals, veterinarians, pharmacies, poison centers)	X	
Death certificates	X	
Hospital discharge or outpatient records	X	
Extracts from electronic medical records	X	
Telephone survey		
School-based survey		
Other _____		
2016 Template		

2. Utilize standardized criteria for case identification and classification (Sections VI and VII) for salmonellosis and add salmonellosis to the *Nationally Notifiable Condition List.*

☐ 2a. Immediately notifiable, extremely urgent (within 4 hours)
☐ 2b. Immediately notifiable, urgent (within 24 hours)
☒ 2c. Routinely notifiable

CSTE recommends that all States and Territories enact laws (statue or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications** to CDC.

3. CDC should publish data on salmonellosis as appropriate in *MMWR* and other venues (see Section IX).

CSTE recommends that all jurisdictions (e.g. States or Territories) with legal authority to conduct public health surveillance follow the recommended methods as outlined above.

Terminology:
* Reporting: process of a healthcare provider or other entity submitting a report (case information) of a condition under public health surveillance TO local or state public health.
**Notification: process of a local or state public health authority submitting a report (case information) of a condition on the Nationally Notifiable Condition List TO CDC.

4. State health departments should create a variable to distinguish CIDT-diagnosed probable *Salmonella* cases from probable cases that are epidemiologically linked to a culture-confirmed or CIDT-diagnosed case. This differentiation of probable cases will facilitate assessment of the impact of CIDT on surveillance.

5. Likewise, CDC should include a variable to distinguish CIDT-diagnosed probable cases from probable cases that are epidemiologically linked in the disease-specific Message Mapping Guide (MMG), to assess the impact of CIDT on surveillance.

6. State health departments should attempt to capture the type(s) of *Salmonella* testing performed for reported salmonellosis cases. This could include surveys of laboratory testing practices, capture of LOINC and SNOMED codes from electronic laboratory reporting, or other methods.

7. When available, *Salmonella* serotype characterization should be reported.

IV. Goals of Surveillance
To provide information on the temporal, geographic, and demographic occurrence of salmonellosis to facilitate its prevention and control.

V. Methods for Surveillance:
Surveillance for salmonellosis should use the recommended sources of data and the extent of coverage listed in Table III.

VI. Criteria for case identification

A. Narrative: A description of suggested criteria for case ascertainment of a specific condition.

Report any illness to public health authorities that meets any of the following criteria:

1. Any person with *Salmonella spp.* isolated from a clinical specimen.
2. Any person with *Salmonella spp*. detected in a clinical specimen using culture-independent diagnostic tests (CIDT).
3. Any person with diarrhea and who is a contact of a salmonellosis case or a member of a risk group defined by the public health authorities during an outbreak investigation.
4. A person whose healthcare record contains a diagnosis of salmonellosis.
5. A person whose death certificate lists salmonellosis as a contributing or underlying cause of death.

Other recommended reporting procedures

- All cases of salmonellosis should be reported according to state regulations.
- Reporting should be on-going and routine.
- Frequency of reporting should follow the state health department's routine schedule.

B. Table of criteria to determine whether a case should be reported to public health authorities

Table VI-B. Table of criteria to determine whether a case should be reported to public health authorities.

Criterion	Salmonellosis	
Clinical Evidence		
Clinically compatible illness		N
Healthcare record contains a diagnosis of salmonellosis	S	
Death certificate contains salmonellosis as a contributing or underlying cause of death	S	
Laboratory Evidence		
Isolation of *Salmonella spp*. from a clinical specimen	S	
Detection of *Salmonella spp*.in a clinical specimen using a CIDT	S	
Epidemiological Evidence		
Epidemiologically linked to a salmonellosis case		O
Member of a risk group as defined by public health authorities during an outbreak investigation		O

Notes:
S = This criterion alone is Sufficient to report a case.
N = All "N" criteria in the same column are Necessary to report a case.
O = At least one of these "O" (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.
* A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.

C. Disease-specific data elements

Clinical Information
- Reported symptoms and signs of illness
- Hospitalized

Epidemiological Risk Factors
- International travel in the 7 days prior to onsets
- Occupation/Industry/Place of Business, to include but not limited to:
    - Food handler
    - Child care center worker
    - Long term care facility worker
- Child care attendee
- Long term care facility resident
- Contact of a salmonellosis case

Laboratory Information

- Method(s) of laboratory testing (e.g., culture or CIDT [FDA-approved or not FDA-approved PCR or antigen-based test])
- Name of test and manufacturer, as available

VII. Case Definition for Case Classification

A. Narrative: Description of criteria to determine how a case should be classified.

Clinical Criteria
An illness of variable severity commonly manifested by diarrhea, abdominal pain, nausea and sometimes vomiting. Asymptomatic infections may occur and the organism may cause extra-intestinal infections.

Laboratory Criteria
Supportive laboratory evidence: Detection of *Salmonella* spp. in a clinical specimen using a CIDT.
Confirmatory laboratory evidence: Isolation of *Salmonella* spp. from a clinical specimen.

Epidemiologic Linkage
Probable: A clinically compatible case that is epidemiologically linked to a case that meets the supportive or confirmatory laboratory criteria for diagnosis.

Case Classification

Confirmed: a case that meets the confirmed laboratory criteria for diagnosis.

Probable: a case that meets the supportive laboratory criteria for diagnosis, OR a clinically compatible case that is epidemiologically linked to a case that meets the supportive or confirmatory laboratory criteria for diagnosis.

Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance:

A case should not be counted as a new case if laboratory results were reported within 365 days of a previously reported infection in the same individual.
When two or more different serotypes are identified from one or more specimens from the same individual, each should be reported as a separate case.

Comment:
The use of CIDTs as stand-alone tests for the direct detection of *Salmonella* in stool is increasing. Specific performance characteristics such as sensitivity, specificity, and positive predictive value of these assays likely depend on the manufacturer and are currently unknown. It is therefore useful to collect information on the type(s) of testing performed for reported salmonellosis cases. When a specimen is positive using a CIDT it is also helpful to collect information on all culture results for the specimen, even if those results are negative.

Culture confirmation of CIDT-positive specimens is ideal, although it might not be practical in all instances. State and local public health agencies should make efforts to encourage reflexive culturing by clinical laboratories that adopt culture-independent methods, should facilitate submission of isolates/clinical material to state public health laboratories, and should be prepared to perform reflexive culture when not performed at the clinical laboratory as isolates are currently necessary for molecular typing (PFGE and whole genome sequencing) that are essential for outbreak detection.

B. Classification Tables

Table VII-B. Criteria for defining a case of salmonellosis.

Criterion	Probable		Confirmed
Clinical Evidence			
Clinically compatible illness	N		
Laboratory evidence			
Detection of *Salmonella* spp. in a clinical specimen using a CIDT.		N	
Isolation of *Salmonella* spp. from a clinical specimen.			N
Epidemiologic evidence			
Epidemiologically linked to a confirmed or probable case of salmonellosis with laboratory evidence	O		
Member of a risk group as defined by the public health authorities during an outbreak investigation	O		
Criteria to distinguish a new case:			
Not counted as a new case if occurred within 365 days of a previously reported salmonellosis infection in same individual, (unless separate serotype as described below).		N	N
Report separate serotypes as distinct cases.			N
2016 Template			

Notes:
N = All "N" criteria in the same column are Necessary to classify a case. A number following an "N" indicates that this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion NOT present) is required for the case to meet the classification criteria, list the Absence of criterion as a Necessary component.
O = At least one of these "O" (One or more) criteria in each category (e.g., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case. (These "O" criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.) A number following an "O" indicates that this criterion is only required for a specific disease/condition subtype.

VIII. Period of Surveillance
Surveillance should be ongoing.

IX. Data sharing/release and print criteria

Notification to CDC of confirmed and probable cases of salmonellosis is recommended.

- Data will be used to determine the burden of illness due to *Salmonella*, trends in illness over time, assess the effectiveness over time of control programs, and monitor progress toward decreasing salmonellosis. Data may be used to compare cases across jurisdictions.
- Data may also be used to compare case numbers with information from other foodborne disease surveillance systems.

- Electronic reports of salmonellosis cases in NNDSS are summarized weekly in the MMWR Tables. Annual case data on salmonellosis is summarized in the yearly Summary of Notifiable Diseases. State-specific compiled data will continue to be published in the weekly and annual MMWR. All cases are verified with the states before publication.
- The frequency of reports/feedback to the states and territories will be dependent on the current epidemiologic situation in the country. Frequency of cases, epidemiologic distribution, importation status transmission risk, and other factors will influence communications.

X. Revision History

Position Statement ID	Section of Document	Revision Description
11-ID-08	Statement of the desired action(s) to be taken	ADDED recommendation that states and CDC add a variable to distinguish between probable cases with laboratory evidence and probable epi-linked cases.
11-ID-08	Section VII-A – Laboratory criteria	EDITED Detection of *Salmonella* spp. in a clinical specimen using a CIDT will meet criteria for probable rather than suspect case.
11-ID-08	Table VII-B – Probable laboratory evidence	EDITED Detection of *Salmonella* spp. in a clinical specimen using a CIDT will meet criteria for probable rather than suspect case. DELETED suspect case classification.

XI. References

1. Buchwald DS, Blaser MJ. A review of human salmonellosis: II. Duration of excretion following infection with nontyphi *Salmonella*.Rev Infect Dis. 1984 May-Jun;6(3):345-56.

2. Centers for Disease Control and Prevention (CDC).Case definitions for infectious conditions under public health surveillance. MMWR Recomm Rep. 1997 May 2;46(RR-10):1-55. Available from: http://www.cdc.gov/mmwr/preview/mmwrhtml/00047449.htm

3. Centers for Disease Control and Prevention (CDC). National notifiable diseases surveillance system (NNDSS): case definitions. Atlanta: CDC. Available from: https://wwwn.cdc.gov/nndss/case-definitions.html. Last updated: 2016 Feb. 3. Accessed: 21 March 2016.

4. Council of State and Territorial Epidemiologists (CSTE). CSTE list of nationally notifiable conditions. CSTE; August 2013. Available from: https://c.ymcdn.com/sites/cste.site-ym.com/resource/resmgr/CSTENotifiableConditionListA.pdf

5. Council of State and Territorial Epidemiologists (CSTE). 10-ID-13, P.S., Public Health Reporting and National Notification for Foodborne Outbreaks. 2010. http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/10-ID-13.pdf

6. Council of State and Territorial Epidemiologists (CSTE). 11-ID-08, P.S., Public Health Reporting and National Notification for Salmonellosis.2011. http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/11-ID-08.pdf.

7. Council of State and Territorial Epidemiologists (CSTE). 14-ID-09, P.S., Standardized Surveillance for Campylobacteriosis and Addition to the Nationally Notifiable Condition List. 2014. http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2014PS/14_ID_09upd.pdf.

8. Crim SM, Griffin PM, Tauxe R, Marder EP, Gilliss D, Cronquist AB, Cartter M, Tobin-D'Angelo M, Blythe D, Smith K, Lathrop S, Zansky S, Cieslak PR, Dunn J, Holt KG, Wolpert B, Henao OL; Centers for Disease Control and Prevention (CDC). Preliminary incidence and trends of infection with pathogens transmitted commonly through food - Foodborne Diseases Active Surveillance Network, 10 U.S. sites, 2006-2014.MMWR Morb Mortal Wkly Rep. 2015 May 15;64(18):495-9.

9. Cronquist AB, Mody RK, Atkinson R, Besser J, Tobin D'Angelo M, Hurd S, Robinson T, Nicholson C, Mahon BE. Impacts of culture-independent diagnostic practices on public health surveillance for bacterial enteric pathogens.Clin Infect Dis. 2012 Jun;54 Suppl 5:S432-9.

10. Huang JY, Henao OL, Griffin PM, et al. Infection with Pathogens Transmitted Commonly Through Food and the Effect of Increasing Use of Culture-Independent Diagnostic Tests on Surveillance — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2012–2015. MMWR Morb Mortal Wkly Rep 2016;65:368–371.

11. Iwamoto M, Huang JY, Cronquist AB, Medus C, Hurd S, Zansky S, Dunn J, Woron AM, Oosmanally N, Griffin PM, Besser J, Henao OL; Centers for Disease Control and Prevention (CDC). Bacterial enteric infections detected by culture-independent diagnostic tests--FoodNet, United States, 2012-2014.MMWR Morb Mortal Wkly Rep. 2015 Mar 13;64(9):252-7.

12. Medus C, Smith KE, Bender JB, Leano F, Hedberg CW. *Salmonella* infections in food workers identified through routine Public Health Surveillance in Minnesota: impact on outbreak recognition. J Food Prot. 2010 Nov;73(11):2053-8.

13. Medus C, Smith KE, Bender JB, Besser JM, Hedberg CW. *Salmonella* outbreaks in restaurants in Minnesota, 1995 through 2003: evaluation of the role of infected foodworkers. J Food Prot. 2006 Aug;69(8):1870-8.

14. Neill MA, Opal SM, Heelan J, Giusti R, Cassidy JE, White R, Mayer KH.Failure of ciprofloxacin to eradicate convalescent fecal excretion after acute salmonellosis: experience during an outbreak in health care workers. Ann Intern Med. 1991 Feb 1;114(3):195-9.

15. Pegues DA, Ohl ME, Miller SI. Salmonella Species, including Salmonella Typhi. In: Mandell GL, Bennett JE, Dolin R, editors. Principles and Practice of Infectious Diseases, 6th edition. Philadelphia: Churchill Livingstone; 2005.

16. Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerg Infect Dis. 2011 Jan; 17(1):7-15.

XII. Coordination

Agencies for Response

(1) Centers for Disease Control and Prevention
Thomas R. Frieden, MD, MPH
Director
1600 Clifton Road, NE
Atlanta, GA 30333
404-639-7000
Txf2@cdc.gov

XIII. Submitting Author:

(1) Alicia Cronquist, RN, MPH
Foodborne Disease Program Manager
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80246
303-692-2629
Alicia.cronquist@state.co.us

Co-Author:

(1) ☒Active Member ☐Associate Member

Sherri L. Davidson, MPH
Analysis & Reporting Branch Manager
Epidemiology Division
Alabama Department of Public Health
201 Monroe Street, Suite 1452
Montgomery, AL 36104
334-206-2050
Sherri.Davidson@ADPH.state.AL.US

(2) ☐Active Member ☒Associate Member

Aimee Geissler, PhD, MPH
Epidemiologist | CDR, US Public Health Service
Centers for Disease Control and Prevention | Atlanta, GA
Division of Foodborne, Waterborne, and Environmental Diseases
1600 Clifton Road, NE
Atlanta, GA 30333
Office: 404-639-7557
ihq5@cdc.gov