

## Research Paper

# Understanding the Relation between Establishment Food Safety Management and *Salmonella* Risk Factor Violations Cited during Routine Inspections

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MS 18-358: Received 27 July 2018/Accepted 30 October 2018/Published Online 28 January 2019

### ABSTRACT

Restaurants are a frequent setting for outbreaks and sporadic cases of *Salmonella*. The relationship among food safety management characteristics, compliance with procedures to reduce *Salmonella*-associated risk factors (as found during routine inspections), and the likelihood that an establishment has experienced a sporadic *Salmonella* case was assessed. Individual risk factor violations associated with *Salmonella* transmission pathways were identified by a literature review. Data from 546 routine inspection reports collected from July 2016 to June 2017, including 25 from restaurants that had experienced a sporadic case of *Salmonella*, were evaluated. In restaurants with certified food managers, there were fewer observations of *Salmonella* risk factor reduction procedures that were not in compliance. For establishments that had experienced sporadic cases of *Salmonella*, the person in charge at the time of an inspection was less likely to have been the establishment's official certified food manager of record (rate ratio = 0.4, 95% confidence interval = 0.2 to 0.8;  $P = 0.01$ ), and there was increased likelihood of being found out of compliance for prevention of contamination by hands (rate ratio = 3.7, 95% confidence interval = 1.4 to 8.1;  $P = 0.001$ ). The results of this study warrant future research on the dynamics of food safety management systems, the effect they have on risk factor violations cited on routine inspection results, and the risk for transmission of *Salmonella*. Analyzing routine inspection data as hazard surveillance may be useful to identify food establishments at a greater risk for transmitting *Salmonella* infections.

### HIGHLIGHTS

- Certified food managers reduce *Salmonella* risk factors on routine inspections.
- Sporadic *Salmonella* cases were associated with hand contamination compliance.
- Routine inspection data may serve as *Salmonella* transmission hazard surveillance.

Key words: Certified food manager; Food safety management; Person in charge; Routine inspections; Third-party auditors

The U.S. Food and Drug Administration (FDA)'s 2017 Food Code added the provision that “the PERSON IN CHARGE [PIC] be a certified FOOD protection manager [CFM] who has shown proficiency of required information through passing a test that is part of an ACCREDITED PROGRAM” (15). This provision was based on the demonstration that restaurants with a CFM had a reduced likelihood of experiencing an outbreak of foodborne illness and that restaurants in which the PIC was a CFM had fewer “out-of-compliance” observations during FDA's retail risk factor studies (7, 14). Further studies conducted by the Centers for Disease Control and Prevention (CDC)'s Environmental Health Specialist Network demonstrated that food establishments with CFMs were likely to have fewer critical violations on inspections and that managers and workers

certified in food safety were more likely to pass a food safety knowledge test (3, 4).

Certain food establishment management characteristics, including having a CFM, having the establishment's official CFM of record (CFMR) serve as the PIC, and using a third-party inspector, were recently shown to be associated with fewer observations of risk factor reduction procedures being found out of compliance during routine inspections (1). However, the relationship between food safety management characteristics and compliance varied by risk factor category. For preventing contamination by hands, the lowest out-of-compliance rates were found for inspections in which the CFMR was the PIC. However, for potentially hazardous food time and temperature violations, the use of a third-party inspector lowered out-of-compliance rates across all other categories of food safety management (1).

*Salmonella* is a leading cause of foodborne illness, and rates of infection in the United States have not declined in

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the past 20 years (5). Restaurants are a frequent setting for outbreaks and sporadic cases of *Salmonella* (8). This study was conducted to determine how food safety management characteristics affected risk factor violations previously associated with *Salmonella* outbreaks and to assess the relationship among food safety management characteristics, compliance in reduction of *Salmonella*-associated risk factors, as found during routine inspections, and the likelihood that an establishment had experienced a sporadic *Salmonella* case.

**Salmonella risk factor violations.** The Minnesota Food Code, Minnesota Rules chapter 4626, was adopted from the FDA in 1997 and contains the minimum design, installation, construction, operation, and maintenance requirements for all food establishments in Minnesota (11). These rules are the standards with which food establishments must comply in the handling, storing, preparation, and service of food to the retail food consumer (10). Five major risk factors from the FDA Model Food Code that are related to employee behaviors and preparation practices in retail and food service establishments have been identified as contributing to foodborne illness, generally: improper holding temperatures, inadequate cooking, contaminated equipment, food from unsafe sources, and personal hygiene. These five categories embody 32 contributing factors for foodborne illness outbreaks that are tracked by the CDC in the National Outbreak Reporting System: contamination of foods (15 factors), proliferation of bacteria in food (12 factors), and survival of bacteria in foods (5 factors) (2). In addition to the five major risk factors, the FDA has also established five key public health interventions to protect consumer health: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, time and temperature parameters for controlling pathogens, and the consumer advisory. Together, the five major risk factors contributing to foodborne illness and the five key public health interventions to protect consumer health are most important on the FDA Model Food Code Food Establishment Inspection Report. The inspection report form identifies 27 categories of risk factor violations that include 126 specific violations.

**Routine inspection reports.** The city of Bloomington environmental health inspectors conduct two unannounced routine inspections per year in medium- and high-risk food establishments, with follow-up inspections on items not in compliance (1). For routine inspections, an inspection report is prepared in accordance with Minnesota Food Code Minnesota Rules chapter 4626 that indicates whether the establishment is in or out of compliance and whether items were not observed by the inspector or were not applicable. All inspection reports indicate whether or not the establishment has a CFMR.

**Sporadic *Salmonella* inspection reports.** In Minnesota, *Salmonella* infections are required by law to be reported to the Minnesota Department of Health. People reported to have *Salmonella* infection are interviewed by department

staff about potential exposures during the 7 days before illness onset, including all food establishments patronized. The Minnesota Department of Health maintains surveillance data for all laboratory-confirmed *Salmonella* cases.

## MATERIALS AND METHODS

For this study, we looked at literature reviews and prior research studies that examined routine inspection results in relation to foodborne illness outbreaks to identify individual risk factor violations cited on the food establishment inspection reports that were specifically associated with *Salmonella* transmission pathways. These *Salmonella* risk factors were grouped by category following the FDA Food Inspection report form: demonstration of knowledge (1A through 1B), employee health (2A through 3D), good hygienic practices (4A through 5A), preventing contamination by hands (6A through 8G), approved source (9A through 12D), protection from contamination (13A through 15B), potentially hazardous food time and temperature (16A through 22A), consumer advisory (23), chemical (25A through 26S), and conformance with approved procedures (27B through 27F) (Supplemental Table S1).

Data on 546 routine inspections conducted from July 2016 through August 2017, for medium- and high-risk food establishments in the cities of Bloomington and Richfield, MN, were collected (1). This included a five-question supplemental questionnaire that was administered by the inspector at the time of the inspection to ascertain whether the food establishment had a CFMR, if the PIC at the time of the inspection was the CFMR, if the PIC was not the CFMR, whether they were a CFM, and whether the establishment used a third-party inspector to audit its food safety program. Results of the questionnaire and inspection reports were entered into Excel spreadsheets for analysis (1).

Restaurant exposure histories for 2016 and 2017, de-identified, sporadic *Salmonella* cases in the cities of Bloomington and Richfield, MN, were obtained from the Minnesota Department of Health. Twenty-five food establishments were identified that had experienced *Salmonella* cases that were not associated with outbreaks. Inspection results for these establishments were identified in the inspection result spreadsheet.

For statistical analysis of *Salmonella* risk factors and establishment management characteristics (Table 1), the percentage of observed risk factors out of compliance was compared for establishments with and without specific management characteristics (e.g., presence of a CFMR) (6). To evaluate the relationship between establishment management characteristics and the occurrence of sporadic *Salmonella* cases (Table 2), the percentage of sporadic *Salmonella* case inspections with the management characteristic was compared with the percentage of all inspections with the characteristic (6, 12). To evaluate risk factors for sporadic case exposures (Table 3), the proportion of sporadic *Salmonella* case inspections with observations out of compliance was compared with the overall proportion of inspections with observations out of compliance. Rate ratios and 95% confidence intervals were calculated for percentages of observations or inspections with observations out of compliance for establishment food safety management characteristics and food inspection risk categories (12).

## RESULTS

Of 126 total risk factor violations assessed during routine inspections, 48 (38%) were considered to be directly or indirectly associated with *Salmonella* transmission. These included 1 of 8 violations related to food managers,

TABLE 1. Percentage of *Salmonella* risk factor observations found out of compliance, by establishment food safety management characteristic, Bloomington, MN, 2016 to 2017<sup>a</sup>

Establishment food safety management characteristic, no. of observations by characteristic	<i>Salmonella</i> risk factor observations out of compliance (%)	Rate ratio for observations out of compliance (95% CI)
Establishment had CFMR		0.68 (0.61, 0.75)
Yes; <i>n</i> = 21,696	1,336 (6.2)	
No; <i>n</i> = 4,512	419 (9.3)	
PIC was CFMR		0.73 (0.66, 0.80)
Yes; <i>n</i> = 13,680	768 (5.6)	
No; <i>n</i> = 12,432	976 (7.9)	
PIC was CFM		0.82 (0.74, 0.90)
Yes; <i>n</i> = 19,536	1,244 (6.3)	
No; <i>n</i> = 6,480	501 (7.7)	
Establishment used third-party inspector		0.80 (0.73, 0.88)
Yes; <i>n</i> = 11,376	663 (5.8)	
No; <i>n</i> = 14,832	1,092 (7.4)	

<sup>a</sup> CFMR, certified food manager of record; PIC, person in charge.

6 of 11 violations related to employee health, 9 of 17 violations related to preventing contamination by hands, 15 of 23 violations related to protection from contamination, and 17 of 24 violations related to potentially hazardous food, time, and temperature.

For each food safety management characteristic (CFMR, CFMR as PIC, PIC is CFM, and use of a third-party inspector), the establishment had fewer observations of *Salmonella* risk factor reduction procedures out of compliance during routine inspections (Table 1). The rates for out-of-compliance observations for each of these characteristics ranged from 68 to 82% of the corresponding rates for establishments that lacked the food safety management characteristic. The lowest rate of out-of-compliance violations (5.6%) was for establishments in which the CFMR was the PIC. In contrast, 9.3% of *Salmonella* risk factor observations were found to be out of compliance when the establishment did not have a CFMR.

As previously reported (1) among all inspections, the great majority of establishments (82.8%) had a CFMR, as required by the Minnesota Food Code (Table 1). In slightly more than half of the inspections (52.6%), the PIC at the time of the inspection was the establishment's CFMR. Whether or not the PIC was the CFMR, for three-quarters of inspections (74.5%), the PIC was a CFM. For fewer than half of the inspections (43.4%), the establishment indicated

the use of a third-party inspector to audit food safety policies and procedures.

Of the 25 food establishments that experienced a sporadic case of *Salmonella*, the proportion of inspections in which the PIC at the time of the inspection was the establishment's CFMR was significantly lower than for all inspections combined (rate ratio [RR] = 0.4, 95% confidence interval [CI] = 0.2 to 0.8; *P* = 0.01). The PIC was the establishment's CFMR in less than one-third of these inspections (29.2%). For other food safety management characteristics, restaurants that experienced sporadic cases were similar to all inspections (Table 2).

For specific *Salmonella* risk factor categories, the percentage of inspections with observations out of compliance ranged from 15.9 to 83.5% for all inspections, and from 12.0 to 92.0% for inspections of establishments that experienced sporadic *Salmonella* cases (Table 3). The most common risk factor categories with inspection observations out of compliance were for protection from contamination (food inspection report items 13A through 15B; 83.5% of inspections), food time and temperature violations (items 16A through 22A; 54.2% of inspections), and prevention of contamination by hands (items 6A through 8G; 24.0% of inspections). Establishments with inspections out of compliance for prevention of contamination by hands were more likely to have experienced a sporadic case of *Salmonella* (RR = 3.7, 95% CI = 1.4 to 8.1; *P* = 0.001).

TABLE 2. Establishment food safety management characteristics, comparing 2016 to 2017 sporadic *Salmonella* cases to all 2016 to 2017 data in Bloomington, MN<sup>a</sup>

Establishment food safety management characteristic	Sporadic <i>Salmonella</i> case inspections by characteristic (%) ( <i>n</i> = 25)	2016 to 2017 inspections by characteristic (%) ( <i>n</i> = 546)
Establishment had CFMR	19 (76.0)	452 (82.8)
PIC was CFMR <sup>b</sup>	7 (29.2)	287 (52.6)
PIC was CFM	22 (88.0)	407 (74.5)
Establishment used third-party inspector	17 (68.0)	237 (43.4)

<sup>a</sup> CFMR, certified food manager of record; PIC, person in charge.

<sup>b</sup> Percentage of sporadic *Salmonella* case inspections when the PIC was the CFMR, compared with all inspections, rate ratio = 0.4, 95% confidence interval = 0.2 to 0.8, *P* = 0.01.

TABLE 3. Inspections with a *Salmonella* risk factor observation found out of compliance, comparing 2016 to 2017 sporadic *Salmonella* case inspections to all 2016 to 2017 inspections in Bloomington, MN

FDA food inspection risk factor category	Sporadic <i>Salmonella</i> case inspections with observations out of compliance (%)	2016 to 2017 inspections (%) with observations out of compliance
1A–1B: Certified food manager	6 (24.0)	94 (17.2)
2A–3D: Employee health	3 (12.0)	87 (15.9)
6A–8G: Prevent contamination by hands <sup>a</sup>	14 (56.0)	131 (24.0)
13A–15B: Protection from contamination	23 (92.0)	456 (83.5)
16A–22A: Food time/temp	16 (64)	296 (54.2)

<sup>a</sup> For 6A.8G, percentage of sporadic *Salmonella* case inspections with observations out of compliance, compared with all inspections, rate ratio = 3.7, 95% confidence interval = 1.7 to 8.1,  $P = 0.001$ .

## DISCUSSION

A growing number of studies have demonstrated that CFMs improve food safety practices in retail food establishments (1, 3, 4, 14). This, in turn, has been shown to reduce the risk of an establishment experiencing an outbreak of foodborne diseases (7). The results of this study extend these findings to suggest that CFMs improve food safety practices specifically related to *Salmonella* transmission. In addition, the occurrence of these risk factors may increase the likelihood of transmission of *Salmonella* in the establishment, even in the absence of an outbreak. In particular, establishments in which the CFMR was the PIC were less likely to have experienced a sporadic *Salmonella* case. Establishments found to have violations of procedures to prevent contamination by hands were more likely to have experienced a sporadic *Salmonella* case. It is not possible to confirm that the specific exposure led to the illness, and these cases were not associated with reported outbreaks. However, failure to properly wash hands may contribute to contamination with *Salmonella*.

Food workers can spread foodborne illnesses such as *Salmonella* in food establishments via hand contact with food and food contact surfaces. According to the CDC (5), a large percentage of foodborne disease outbreaks are spread by contaminated hands, and infected food workers have contributed to the propagation of *Salmonella* transmission during extended outbreaks of *Salmonella* in restaurant settings (9). Tambekar and Shirsat (13) found 100% reduction of *Salmonella* pathogens when hands were washed properly. Sporadic infections may occur if the frequency or level of contamination was below the threshold needed to cause an outbreak and no further amplification of the contamination occurred.

*Salmonella* infections within a food establishment are preventable in many cases. Unfortunately, prevention is more than just a one-step measure, such as washing hands. Pathogens can be spread through contaminated equipment, poor personal hygiene, improper holding and cooking temperatures, and employee illness. Collectively, if these factors are monitored and procedures and processes are evaluated on a consistent basis, foodborne illness in food establishments can be reduced.

The results of this study warrant future research on the dynamics of food safety management systems, the effect they have on risk factor violations cited on routine inspection results, and the risk for transmission of *Salmonella*.

Furthermore, analyzing routine inspection data as hazard surveillance provides a theoretical framework for future studies and may be useful to identify food establishments at a greater risk for transmitting *Salmonella* infections.

## ACKNOWLEDGMENTS

The authors acknowledge the cooperation received from the Bloomington, Minnesota, Environmental Health Department, which assisted in the data collection used in this study. We thank and acknowledge Dr. Laura Le at the University of Minnesota for assistance with the data analysis. Additionally, we acknowledge and thank Dr. Kirk Smith at the Minnesota Department of Health and Dr. Fernando Sampedro at the University of Minnesota.

## SUPPLEMENTAL MATERIAL

Supplemental material associated with this article can be found online at: <https://doi.org/10.4315/0362-028X.JFP-18-358.s1>.

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