

Research Paper

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

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ABSTRACT

Certified Food Manager (CFM) training can help ensure proper food safety practices for decreasing risk factor violations associated with foodborne illness. However, the effectiveness of food safety management also depends on the authority of the person in charge (PIC) and the added value of third-party inspectors auditing food safety policies and practices. To examine the effect of food safety management characteristics on risk factor violations cited on routine inspections, we evaluated results of 546 routine inspections in the cities of Bloomington and Richfield, MN, between 2016 and 2017. Food establishment management was characterized by the presence of a CFM of record for the establishment, whether the PIC was certified, and whether the establishment used a third-party inspector to audit food safety policies and practices. For each of these food safety management characteristics, the establishment had fewer risk factor observations that were out of compliance during routine inspections. The relationship between the establishment's food safety management characteristics and either the percentage of observations out of compliance or the inspections with observations out of compliance differed by risk factor category. For preventing contamination by hands, the lowest rates were found for inspections in which the CFM of record was the PIC. However, for potentially hazardous food time and temperature violations, establishments that used third-party inspectors had lower percentages of both observations and inspections out of compliance across all categories of management characteristics. The results of our study support the recommendations of the U.S. Food and Drug Administration regarding CFMs. However, our findings also suggest greater complexity in the characteristics of food safety management, which include the role of third-party inspectors and whether a CFM is acting in the role of the CFM of record.

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

With the publication of the 2017 Food Code, the U.S. Food and Drug Administration (FDA) (10) added the provision that “the PERSON IN CHARGE (PIC) shall 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.” This recommendation extends that from the 2013 Food Code that each food establishment have at least one CFM (9). The rationale for requiring the PIC to be certified was based on previous findings 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 (1, 6). The FDA retail risk factor study results have been corroborated by studies conducted by the Centers for Disease Control and Prevention Environmental Health Specialist Network (EHS-Net). In a 2007 study in Iowa, food establishments with certified kitchen managers were likely to have fewer

critical violations on their inspections (2). In a 2012 study in six EHS-Net sites, managers and workers certified in food safety were more likely to pass a food safety knowledge test than were those who were not certified (1). The authors found that food safety knowledge is complex and influenced by both restaurant and personal traits and that food safety certification promotes food safety knowledge for both managers and workers. The authors concluded that managers in both chain and larger food establishments may have greater food safety knowledge because they may have more resources for food safety training and because these managers focus on food safety more than do those in other food establishments.

An additional resource used by many restaurants is a third-party inspector to audit food safety policies and practices. These third-party inspections supplement the regulatory inspections and may be used for standardizing food safety performance across units in a chain or for other business purposes. Previous studies of CFMs have not included the potential impact of third-party inspections on the food safety performance of the establishment on risk-

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based inspections. The objectives of the present study were to evaluate the impact of an establishment's food safety management system, including the presence of CFMs and their role as PICs, and how the use of third-party inspectors influenced the number of observations found to be out of compliance during routine risk-based food safety inspections.

MATERIALS AND METHODS

The Minnesota Food Code, Minnesota Rule, section 4626.2010 (6) requires food establishments to have one full-time CFM who serves as the CFM of record (CFMR) with the licensing agency. The Minnesota Food Code requires the CFMR or other PIC to be present at all hours of operation. The PIC in any food establishment is the person who oversees the food establishment's daily operations and procedures. Although the CFMR is often the PIC, the Minnesota Rule does not require the PIC to be a CFM.

Although the PIC is not required to be a CFM, the Food Code requires the PIC be able to demonstrate knowledge of food safety factors that relate to their specific operations and responsibilities, such as: (i) foodborne illness prevention and personal hygiene, (ii) employee illness, (iii) food safety, (iv) food contact surface sanitation, (v) required food temperatures, such as cold holding, hot holding, cooking, reheating, and transportation of potentially hazardous foods, and (vi) hazards involved in consuming raw or undercooked meat, poultry, eggs, and fish (3). In addition to the PIC being able to demonstrate knowledge of food safety, he or she must also have a managerial control system in place for food practices within the food establishment. These food practices include but are not limited to exclusion of ill employees; proper hand washing; adequate cooking; proper cooling; proper cleaning and sanitizing of equipment and utensils; use of clean tableware at salad bars, buffets, and other self-service areas; receiving safe food; and restricting access of non-food handling personnel (3).

The present study was conducted to evaluate the establishment's food safety management based on the results of routine inspections from high- or medium-risk restaurants licensed and inspected by the City of Bloomington Environmental Health Division. In this city five license types can be issued to food establishments. License types I and II are issued to high- or medium-risk food establishments that use complex food processes such as cooking or cooling potentially hazardous foods, serving any raw or undercooked food products, and conducting any specialized processes such as curing of meat. Types I and II are differentiated by the number of meals or customers the establishment serves per day or how many seats the establishment has. Type III establishments are those with limited potentially hazardous foods and minimal food handling and preparation. Type IV and V establishments have minimal food handling and serve mainly prepackaged products. License types III, IV, and V were excluded from the study because of their low risk of foodborne illness.

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. Since January 2005, routine inspections have been based on program standards recommended by the FDA, the Minnesota Department of Agriculture, and the Minnesota Department of Health. For routine inspections, an inspection report is prepared in accordance to the Minnesota Food Code, Minnesota Rule chapter 4626 (6), which 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 the establishment had a CFMR.

For this study, data were collected for routine inspections conducted from July 2016 through August 2017. A five-question supplemental questionnaire was administered by the inspector at the time of the inspection to ascertain whether the food establishment had a CFMR, whether the PIC at the time of the inspection was the CFMR, whether the PIC was a CFM, and whether the establishment used a third-party inspector to audit its food safety program. For this study, a third-party inspector was defined as a corporate official or hired consultant who came to the establishment to audit the establishment's policies, procedures, and food safety practices independently of the official food safety inspection. The supplemental questionnaire was voluntary. Responses were partially verified by reviewing certificates, identification of specific courses taken, and reviews of auditor reports. Responses were attached to the health inspection report and submitted to the researcher.

Results of the questionnaire and inspection reports were entered into Excel spreadsheets. The following information was extracted for each establishment for the analyses: presence of a CFMR, PIC as the CFMR, PIC as a CFM, use of a third-party inspector, date of inspection, and compliance status for all risk factor observations. Each inspection was treated as an individual visit. For statistical analysis, risk factor observations were treated as dependent variables, and establishment management characteristics (e.g., presence of a CFMR) were treated as independent variables. Individual risk factors were grouped by category following the FDA Food Inspection Report Form (Supplemental Fig. S1): demonstration of knowledge (1A and 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), chemicals (25A through 26S), and conformance with approved procedures (27B through 27F). Data were analyzed using Excel version 16.10 (Microsoft, Redmond, WA), RStudio (7), and Epi Info 7 (3).

RESULTS

Food establishment inspection results were collected from 546 routine 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. Regardless of whether the PIC was a CFMR, during 74.5% of the inspections the PIC was a CFM. For fewer than half of the inspections (43.4%), the establishment indicated use of a third-party inspector to audit food safety policies and procedures.

For each of these food safety management characteristics (CFMR, PIC as CFMR, PIC as CFM, and use of a third-party inspector), the establishment had fewer risk factor observations that were out of compliance during routine inspections (Table 2). The rates for out of compliance observations for each of these characteristics were 73 to 80% of the corresponding rates for establishments that lacked the food safety management characteristic. The lowest rate of out-of-compliance observations (3.2%) was for establishments in which the PIC was the CFMR and the establishment used a third-party inspector (Fig. 1). In contrast, 5.4% of risk factor observations were out of

TABLE 1. Establishment food safety management characteristics during 546 routine inspections, Bloomington, MN, 2016 to 2017

Characteristic ^a	No. (%) of inspections		
	With characteristic	Without characteristic	ND ^b
Establishment had CFMR	452 (82.8)	94 (17.2)	0
PIC was CFMR	287 (52.6)	257 (47.1)	2
PIC was CFM	407 (74.5)	135 (24.7)	4
Establishment used third-party inspector	237 (43.4)	309 (56.6)	0

^a CFMR, certified food manager (CFM) of record; PIC, person in charge.

^b Inspections for which characteristic could not be determined.

compliance when the PIC was not a CFM and the establishment did not use a third-party inspector. Overall, the percentage of observations out of compliance decreased from 5.0% for establishments in which the PIC was not a CFM to 4.6% for establishments in which the PIC was a CFM but not the CFMR, to 3.7% when the PIC was the CFMR. For each of these food safety management characteristics, the percentage of observations out of compliance was lower when the establishment used a third-party inspector to audit their food safety policies and practices.

For specific risk factor categories, the percentage of observations out of compliance was 0.2 to 9.5% of observations and 0.2 to 87.9% of inspections with an observation out of compliance (Table 3). The most common risk factor categories with observations out of compliance were protection from contamination (food inspection report items 13A through 15B; 9.5% of observations and 87.9% of inspections), prevention of contamination by hands (items 6A through 8G; 6.5% of observations and 66.1% of inspections), and food time and temperature violations (items 16A through 22A; 5.6% of observations and 62.8% of inspections).

TABLE 2. Percentage of risk factor observations out of compliance by establishment food safety management characteristic, Bloomington, MN, 2016 to 2017

Characteristic ^a	No. (%) of observations		
	Total	Out of compliance	Rate ratio (95% CI) ^b
Establishment had CFMR			
Yes	56,952	2,336 (4.1)	0.76 (0.70, 0.83)
No	11,844	641 (5.4)	
PIC was CFMR			
Yes	36,162	1,357 (3.8)	0.76 (0.71, 0.81)
No	32,382	1,605 (4.9)	
PIC was CFM			
Yes	51,282	2,071 (4.0)	0.80 (0.74, 0.86)
No	17,010	864 (5.1)	
Establishment used third-party inspector			
Yes	29,862	1,068 (3.6)	0.73 (0.68, 0.78)
No	38,934	1,909 (4.8)	

^a CFMR, certified food manager (CFM) of record; PIC, person in charge.

^b CI, confidence interval.

The relationship between the establishment's food safety management characteristics and the percentage of inspections with observations out of compliance differed by risk factor category (Table 3). Inspections with violations related to CFMs, employee health, and protection from contamination were reduced for establishments where the PIC was a CFM. Having the PIC as the CFMR was associated with a reduction in violations for prevention of contamination by hands. In contrast, using a third-party inspector was associated with reductions in violations for approved sources, food times and temperatures, and chemical storage.

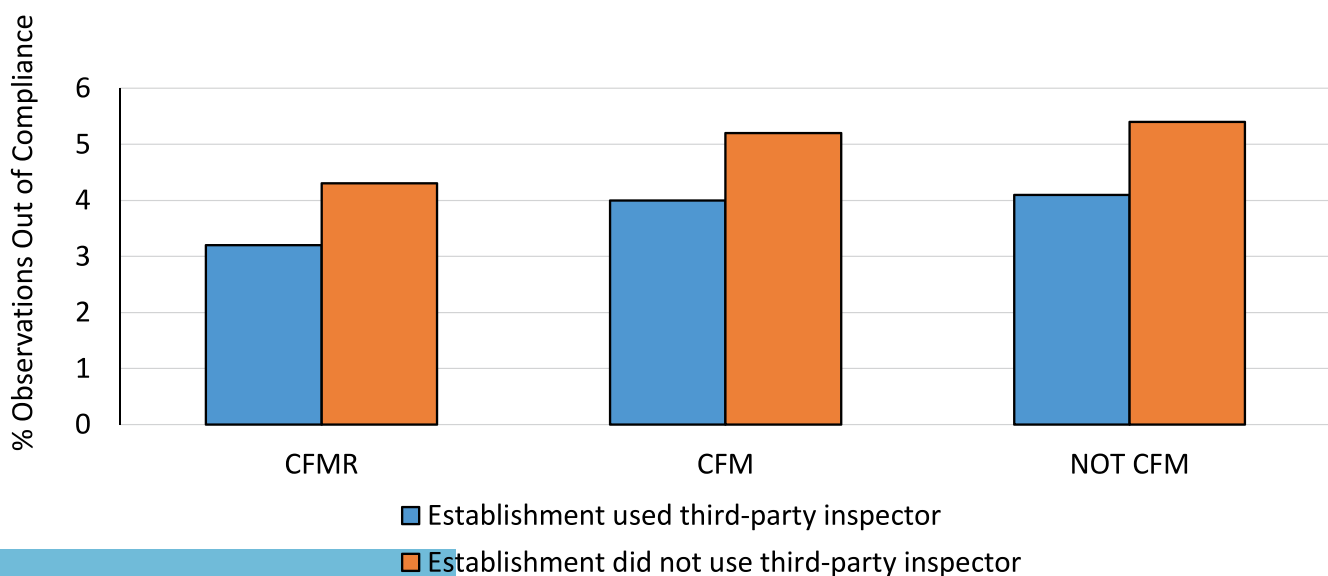


FIGURE 1. Percentage of risk factor observations found out of compliance by establishment food safety management characteristic, Bloomington, MN, 2016 to 2017.

TABLE 3. Percentage of inspections with risk factor observations out of compliance by FDA Food Inspection Report food risk factor category and establishment food safety characteristic, Bloomington, MN, 2016 to 2017

Risk-factor category	% inspections with observations out of compliance ^a			
	Total	PIC was CFMR	PIC was CFM	Third-party inspector
1A–1B: CFM	21.6	5.3*	15.7*	17.7
2A–3D: Employee health	17.2	11.9*	13.5*	13.9
4A–5A: Good hygienic practice	9.5	9.8	8.4	7.6
6A–8G: Prevent contamination by hands	66.1	60.4*	64.6	64.6
9A–12D: Approved sources	9.7	8.1	8.1	5.1*
13A–15B: Protection from contamination	87.9	84.2*	85.8*	86.5
16A–22A: Food time, temp	62.8	60.7	60.9	54.0*
25A–26S: Chemicals	33.5	34.0	32.2	21.9*
27B–27F: Conformance with approved sources	2.8	2.5	2.7	3.4

^a PIC, person in charge; CFMR, certified food manager (CFM) of record. Asterisks indicate values that are significantly different for the risk factor category ($P < 0.05$).

DISCUSSION

A series of FDA retail risk factor studies have revealed that CFMs improve food safety practices in retail food establishments (6), thus reducing the risk of an establishment being associated with an outbreak of foodborne diseases (1). The results of our study support FDA's general findings regarding the impact of CFMs. However, our findings also suggest a greater complexity in the characteristics of active managerial control to include the role of third-party inspectors and whether a CFM is acting in the role of the CFMR.

Active managerial control is a comprehensive food system that includes operators and staff who are knowledgeable about food safety issues and are responsible for controlling a retail food establishment's practices and procedures that ultimately affect the incidence of foodborne illness. According to the FDA, active managerial control embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification. Elements of active managerial control include but are not limited to CFMs, standard operating procedures for critical and complicated food preparation processes such as cooling, monitoring procedures, record keeping, employee health policies, employee food safety training, on-going quality control and assurance, and risk control plans. Our findings suggest that active managerial control such as CFMs as the PIC and third-party auditors could lead to the prevention, elimination, or reduction of foodborne illness risk factor observations during routine health inspections.

Prevention of contamination by hands appears to be more effective when the PIC is the CFMR rather than being a CFM without being the CFMR. This finding suggests that being the CFMR is associated with added authority or expertise that enhances the food safety performance of the establishment and is consistent with the CFMR being the general manager or proprietor in many establishments. Although third-party inspectors appear to have minimal impact on prevention of contamination by hands or other protection from contamination events, which may be dependent on direct supervision, the presence of these inspectors resulted in substantial reductions in the occurrence of potentially hazardous food time and temperature

violations. In these cases, the third-party inspectors may be enforcing corporate standards that may exceed minimum food safety standards. Thus, having a PIC with the authority of a CFMR appears to have greater impact on direct supervision activities in the establishment, whereas having a third-party inspector appears to have a greater impact on the effectiveness of temperature control policies and practices.

In keeping with the FDA's Food Code revisions for 2017 (10), local and state government agencies should require the PIC to also be a CFM. The PIC should be sufficiently trained to exercise the full authority of the establishment's management in supervising establishment food safety activities. The results of the present study also provide evidence that third-party inspectors increase the effectiveness of food safety policies and practices within a food establishment. Although it is beyond the scope of the Food Code to require third-party inspections, the Code does suggest that this type of consultation and auditing may reduce the establishment's risk of involvement in a foodborne illnesses event. Thus, establishments with sufficient resources should consider this enhancement to their food safety management systems, and environmental health agencies should consider providing these services for establishments that cannot afford them.

The results of this study warrant future research on the dynamics of food safety management systems to better understand the interactions between PICs with various levels of expertise and authority and third-party inspectors and the effect they have on risk factor violations cited on routine inspection reports.

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SUPPLEMENTAL MATERIAL

Supplemental material associated with this article can be found online at: <https://doi.org/10.4315/0362-028X.JFP-18-278.s1>.

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