Health Department Inspection Criteria More Likely To Be Associated with Outbreak Restaurants in Minnesota

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ABSTRACT

Millions of routine restaurant inspections are performed each year in the United States, and the Centers for Disease Control and Prevention has reported that a majority of foodborne illness outbreaks occur in restaurant settings. In an attempt to relate the data collected during inspections in Minnesota to illness likelihood, data from routine inspections conducted at outbreak restaurants were compared with data from routine inspections conducted at nonoutbreak restaurants. The goal was to identify differences in recorded violations. Significantly more violations were recorded at restaurants that had outbreaks. The majority of these violations were related to contamination in the facility and environment and to food handling procedures. Relative risks also were calculated for violations significantly more likely to occur at locations that had outbreaks of norovirus infection, Clostridium perfringens infection or toxin-type illness, and Salmonella infection. These three pathogens are estimated to cause the majority of foodborne illnesses in the United States. Meta-analysis of composited data for the three pathogens revealed 11 violations significantly more likely (α < 0.05) to be identified during routine inspections at outbreak restaurants than during inspections at nonoutbreak restaurants. Application of this information permits assessment of health department inspection data in a consistent fashion. This approach can help identify criteria more likely to be associated with outbreak locations and allow operators to focus on interventions that will have the most significant impact in higher risk establishments.

Restaurant locations in the United States are inspected based on guidance published by the U.S. Food and Drug Administration (FDA) in the Food Code (24), which is a uniform set of provisions that address the safety and protection of food offered at retail and in food service. The full Code was most recently issued in 2009; a supplement to the Food Code was issued in 2011 (25). The Food Code guidelines are designed to safeguard public health and ensure that food is not adulterated, and inspected locations are evaluated for foodborne illness risk factors and good retail practices. Application of the Code provisions varies by jurisdiction that differ in their requirements, frequencies of inspections, and scoring. Minnesota has its own state-specific version of the Food Code (16) which is based on the federal code, and for Minnesota licensed establishments, it is regulation. It consists of minimum design, installation, construction, operation and maintenance requirements for all licensed food establishments in Minnesota.

In an appendix to the Food Code, model form 3-A lists 54 standardized criteria or questions (24); these are summarized in Table 1. The form is provided as a tool, but its use is not mandatory. Criteria 1 through 27 are identified as foodborne illness risk factors and public health interventions, and criteria 28 through 54 deal with good retail practices. Some jurisdictions, including some in Minnesota, use the exact criteria detailed in this form in their restaurant inspections, whereas others have adopted slightly different versions by combining or rewording the criteria. Even though relatively similar criteria are evaluated during inspections, different tools are used to capture this information so comparison among different jurisdictions is difficult.

In Minnesota, various types of restaurant inspections are performed. These inspections differ by jurisdiction and specific situation in whether the inspections are announced. Based on the determined public health risk of the restaurant and the types of food served, the location is inspected periodically to ensure continued compliance with the Minnesota Food Code. As per Minnesota statute (20), routine inspections are performed at least annually at establishments that serve potentially hazardous foods that require extensive manual handling, cooking, cooling, etc. on the premises. Follow-up inspections are sometimes conducted several days to weeks after the routine inspection to ensure that previously identified serious violations have been corrected. Inspections also are conducted in response to patron complaints or potential foodborne illness outbreaks. These additional inspections generally are conducted on the same day that the complaint meets the criteria for launching an investigation, but the inspections could be
delayed up to a few days after initial notice of a potential concern is recorded (20). This approach to inspections is similar to that used in other states.

The Centers for Disease Control and Prevention (CDC) and the National Restaurant Association (17) track data related to restaurant meals. Close to half of consumers’ food dollars are spent at restaurants. The United States has nearly 1 million food establishments that serve an estimated 250 meals annually to each U.S. resident, for a total of more than 77 billion meals annually (14). The CDC reported that the majority (52%) of foodborne illnesses are attributed to traditional sit-down or fast food restaurant meals or ‘other’ restaurant meals (e.g., deli meals) (4). This figure does not include illnesses occurring in catering establishments because these facilities are categorized separately by the CDC. However, only a small number of the actual illnesses that occur are reported. Jones and Angulo (13) stressed that although reported outbreaks account for less than 3% of all foodborne illnesses in the time period they evaluated, restaurants are an important source of infection transmission. Gaining a better understanding of restaurants as foodborne disease pathways may help decrease overall illness incidence. If consumers believe that their illness may have occurred during one of these eating occasions, they can report the illness to the local health department.

Consumer complaints can signal that food service problems may exist, and these complaints may prompt an investigation by health inspectors. With epidemiological information from complaints available, the inspector often focuses the inspection on criteria associated with the typical causal pathways of the suspected illness agent. Generally, *Clostridium perfringens* infections or illness suspected to be caused by other bacterial toxins are related to temperature abuse; norovirus infections are associated with person-to-person contamination, and *Salmonella* infections are associated with a range of factors, including poor personal hygiene, food and surface contamination, temperature abuse, and failure to inactivate the organism (23, 26).

Previous research revealed that overall restaurant evaluation during health department routine inspections was not predictive of the likelihood of foodborne illness (6, 12, 18). However, certain violations were more likely to be identified during inspections of restaurants that had confirmed foodborne illness outbreaks (19). Many of these violations were associated with characteristic causal pathways for the responsible agents.

Because nearly 1 million restaurants are inspected on a routine basis at least annually, a large body of data is generated. An important research goal is to determine whether specific agent-associated violations that are more likely to be identified during outbreak investigation inspections are also found more frequently during routine inspections at restaurants that have had outbreaks. This association may help to determine whether the specific violations observed during routine inspections might be predictive of future concerns at an establishment. Comparing routine inspections done at outbreak locations with those done at nonoutbreak locations could reveal certain types of violations that are more likely to be associated with establishments that had outbreaks. This information could help public health agencies identify locations potentially predisposed to a foodborne outbreak and thus direct proactive preventative resources where they have the greatest need.

A previous study was conducted solely on outbreak restaurants (19). By focusing on routine inspections done at both outbreak and nonoutbreak chain and nonchain restaurants, the present study allowed comparison of these inspections to identify a set of common violations. Based on these data, a secondary goal was to develop a profile of a typical outbreak location, which could allow for identification of major, modifiable risks and to prioritize actions needed so that efforts can be focused appropriately.

**MATERIALS AND METHODS**

**Outbreak restaurants.** Data obtained from the Minnesota Department of Health (MDH) and various local health departments in jurisdictions across the state revealed 68 distinct restaurant-associated outbreaks of foodborne illness that occurred from 2005 through 2010 about which complete inspection information could be obtained. Inspection information was incomplete when locations had closed or forms were not completely filled out or had been lost.

**Nonoutbreak restaurants.** Data from routine inspections conducted at restaurants in Minnesota that had not had outbreaks between 2008 and 2011 were also gathered based on convenience sampling because these data were more complete.

**Mapping of violations.** Violations observed during these routine inspections at outbreak and nonoutbreak locations were recorded and compared with FDA Food Code form 3-A criteria (Table 1) (25) to determine to which criteria they were linked. Because the inspections had been conducted using different forms and schemes for collection of information, the same violations were denoted differently among jurisdictions. Mapping violations to this standard form made it possible to compare outbreak and nonoutbreak locations against a common platform with exactly matching violations.

**Data analysis.** Initial comparisons were made between all routine inspections conducted at outbreak and nonoutbreak locations. In this analysis, the outbreak locations included chain and nonchain restaurant locations, which were compared with nonoutbreak chain locations. Recorded occurrences of violations based on the FDA Food Code form 3-A were compared in two-proportion tests, and differences at the 95% significance level were determined.

Because the only types of nonoutbreak locations from which data were collected were chain locations, a comparison was also made using the subset of outbreak chain locations versus nonoutbreak chain locations. Because this comparison was considered more valid, more extensive analysis was done, which included a comparison of violations between these two types of locations to determine what violation patterns and repeats were observed. Fisher’s exact test (Excel 2007, Microsoft, Redmond, WA; and Minitab version 16.2.1, Minitab, State College, PA) was used for the analysis (because some proportions were small) to determine the significance of the differences in recorded violations. When significant differences were identified, relative risks were calculated. Recorded violations also were compared between routine inspections at each restaurant, split by outbreak type (norovirus infection, *C. perfringens* infection or toxin-mediated infections or illness suspected to be caused by other bacterial toxins are related to temperature abuse; norovirus infections are associated with person-to-person contamination, and *Salmonella* infections are associated with a range of factors, including poor personal hygiene, food and surface contamination, temperature abuse, and failure to inactivate the organism (23, 26).

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Because nearly 1 million restaurants are inspected on a routine basis at least annually, a large body of data is generated. An important research goal is to determine whether specific agent-associated violations that are more likely to be identified during outbreak investigation inspections are also found more frequently during routine inspections at restaurants that have had outbreaks. This association may help to determine whether the specific violations observed during routine inspections might be predictive of future concerns at an establishment. Comparing routine inspections done at outbreak locations with those done at nonoutbreak locations could reveal certain types of violations that are more likely to be associated with this standard form made it possible to compare outbreak and nonoutbreak locations against a common platform with exactly matching violations.

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illness, and Salmonella infection) and the total set of nonoutbreak locations.

Breaking down the data by types of outbreak resulted in data sets that were very small because relatively few outbreaks occurred. Therefore, a final analysis combined the individually calculated relative risks for outbreaks attributed to all three agents to develop an overall profile of the likelihood of any of these types of outbreaks. This meta-analysis of relative risk calculations was conducted using StatsDirect v. 2.7.8 (StatsDirect Ltd., Altrincham, UK). To check the validity of these identified core violations, sensitivity analysis was conducted by systematically changing the occurrence of violations to determine the effects of such changes on P values. The only violations that remained in the set were those whose P values remained at ≤0.05 under five different scenarios: the actual data, outbreak restaurant violation occurrence ± 1, and nonoutbreak restaurant violation occurrence ± 1.

RESULTS

The 68 outbreaks included in this study were linked to 63 separate restaurant locations; one location experienced three outbreaks (one attributed to two agents), and two locations each had two outbreaks. The total sample set included 44 outbreaks of norovirus infection, 13 outbreaks of Salmonella infection, and 11 outbreaks of C. perfringens infection or toxin-mediated illness. Toxin-mediated outbreaks, which are usually linked to temperature control issues, often are attributed to agents such as Bacillus cereus or Staphylococcus aureus, but the causal agent could not be definitely determined in the MDH investigations. Information about recent inspections was obtained from the identified affected locations. This information included the outbreak investigation inspections, the routine inspection conducted immediately after the outbreak, and preceding routine inspections performed at these same locations up to 4 years before the reported illnesses, for a total of 68 outbreak investigation inspections and 275 routine inspections at individual locations. Analysis in the present study focused on review of the routine inspections; the outbreak investigation inspections were evaluated separately (19).

The 63 individual outbreak locations were further characterized as chains and nonchain restaurants. For this study, based on the authors’ professional experience, a chain was defined as a restaurant that had more than 10 separate locations. Nearly two-thirds of the outbreaks occurred at nonchain locations. All of the locations that had more than one outbreak were nonchains. This subset of chain restaurants consisted of 22 locations with 22 outbreak investigation inspections and 75 routine inspections from 2005 through 2010. Table 2 describes these 22 locations that had outbreaks attributed to norovirus, Salmonella, and C. perfringens or a toxin. Only three Salmonella and C. perfringens infection outbreaks occurred at chain locations, whereas 21 of these outbreaks occurred at nonchain locations. In contrast, the number of norovirus infection outbreaks is more consistent between the chain and nonchain locations.

The data from nonoutbreak locations were collected from 91 chain restaurant locations, for a total of 172 individual routine inspection reports.

The initial analysis included all the routine inspection data, combining chain and nonchain locations that had outbreaks and comparing these data with that from chain locations that did not have outbreaks. There were no violations more likely to be recorded during routine inspections. The data from nonoutbreak locations were collected from 91 chain restaurant locations, for a total of 172 individual routine inspection reports. The data from nonoutbreak locations were collected from 91 chain restaurant locations, for a total of 172 individual routine inspection reports.
inspections at nonoutbreak locations than during routine inspections at outbreak locations. These findings present an interesting picture of the types of violations likely to be recorded at outbreak locations, and many of the nonchain outbreak locations were individually owned single locations. Fourteen violation types were significantly more likely to be recorded ($\alpha < 0.05$) during routine inspections at outbreak chain and nonchain locations than during routine inspections at nonoutbreak chain locations. For the most part, these findings mirrored the violations identified when chain locations alone were analyzed.

When violation types from routine inspections from the aggregated data set of chain and nonchain outbreak locations were compared with those from the chain nonoutbreak locations, some differences in the types of violations were observed, with an overall net of one more violation observed at the chain and nonchain outbreak locations. Among the mixed chain and nonchain outbreak locations, violation of criteria 13 (food separated, protected), 26 (toxic substances properly identified, stored, used), and 33 (approved thawing methods used) were recorded (data not shown).

Reported in Table 3 are the 13 violations significantly more likely to be found ($\alpha < 0.05$) during routine inspections at outbreak chain locations ($n = 75$) than at nonoutbreak chain locations ($n = 172$). Among the chain outbreak locations, violation of criteria 17 (proper reheating for hot holding) and 35 (food properly labeled; original container) were significantly more likely to occur in this group of restaurants than in chain and nonchain locations combined.

Taken together, the observed violations more likely to occur at outbreak restaurants than at nonoutbreak restaurants can be categorized. Generally, among the total violations, two (criteria 4 and 7; Table 1) or about 15% are related to personnel issues, eight (criteria 13, 17, 18, 20, 21, 31, 33, and 37; Table 1) or about 50% are related to food handling concerns, and six (criteria 26, 35, 42, 43, 47, and 54; Table 1) or 37% are related to the facility itself and the environment within which the food is prepared. When comparing these violation findings with contributing factors to foodborne illness as defined by the CDC (15), about two-thirds of those violations observed more commonly at outbreak locations fall into the “contamination” category, e.g., contamination of hands, surfaces, and food. The remaining violations are associated with “proliferation” or growth of pathogens because they are related to temperature abuse that can occur during preparation or storage.

### TABLE 2. Description of chain and nonchain restaurants that had outbreaks traced to a specific agent and their routine inspections, Minnesota, 2005 through 2010

<table>
<thead>
<tr>
<th>Type of outbreak</th>
<th>No. of routine inspections at outbreak locations$^a$</th>
<th>No. that had outbreaks</th>
<th>No. of routine inspections at outbreak locations$^a$</th>
<th>No. that had outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus infection</td>
<td>25</td>
<td>111</td>
<td>19</td>
<td>61</td>
</tr>
<tr>
<td>Salmonella infection</td>
<td>11</td>
<td>44</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>C. perfringens infection or bacterial toxin illness</td>
<td>10</td>
<td>45</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>46</td>
<td>200</td>
<td>22</td>
<td>75</td>
</tr>
</tbody>
</table>

$^a$ Inspection data from locations that had outbreak caused by more than one agent were counted in both outbreak types.

### TABLE 3. Specific violations observed more often in chains that had outbreaks than in chains that had no outbreaks, Minnesota, 2005 through 2010

<table>
<thead>
<tr>
<th>Criterion no. from FDA form 3-A</th>
<th>Criterion description</th>
<th>% of outbreak restaurants with violations ($n = 75$)</th>
<th>% of nonoutbreak restaurants with violations ($n = 172$)</th>
<th>Relative risk</th>
<th>95% CI$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>4$^b$</td>
<td>Proper eating, tasting, tobacco use</td>
<td>0.08</td>
<td>0.01</td>
<td>4.59</td>
<td>1.28–16.36</td>
</tr>
<tr>
<td>7$^b$</td>
<td>Bare hand contact procedure</td>
<td>0.15</td>
<td>0.05</td>
<td>2.8</td>
<td>1.23–6.32</td>
</tr>
<tr>
<td>17</td>
<td>Proper reheating for hot holding</td>
<td>0.027</td>
<td>0</td>
<td>Undefined</td>
<td>0.42–∞</td>
</tr>
<tr>
<td>18$^b$</td>
<td>Proper cooling time, temp</td>
<td>0.06</td>
<td>0.006</td>
<td>11.47</td>
<td>1.81–73.27</td>
</tr>
<tr>
<td>20$^b$</td>
<td>Proper cold holding temp</td>
<td>0.32</td>
<td>0.17</td>
<td>1.83</td>
<td>1.15–2.89</td>
</tr>
<tr>
<td>21</td>
<td>Proper date marking and disposition</td>
<td>0.11</td>
<td>0.034</td>
<td>3.06</td>
<td>1.10–8.51</td>
</tr>
<tr>
<td>31$^b$</td>
<td>Proper cooling methods</td>
<td>0.12</td>
<td>0.02</td>
<td>5.16</td>
<td>1.73–15.37</td>
</tr>
<tr>
<td>35$^b$</td>
<td>Food properly labeled, original container</td>
<td>0.18</td>
<td>0.14</td>
<td>3.53</td>
<td>1.87–6.64</td>
</tr>
<tr>
<td>37$^b$</td>
<td>Cross-contamination prevented</td>
<td>0.28</td>
<td>0.14</td>
<td>2.01</td>
<td>1.19–3.34</td>
</tr>
<tr>
<td>42$^b$</td>
<td>Utensils, equipment, linens</td>
<td>0.27</td>
<td>0.11</td>
<td>2.41</td>
<td>1.37–4.21</td>
</tr>
<tr>
<td>43$^b$</td>
<td>Single-use and single-service articles</td>
<td>0.19</td>
<td>0.02</td>
<td>10.7</td>
<td>3.40–33.98</td>
</tr>
<tr>
<td>47$^b$</td>
<td>Nonfood contact surfaces</td>
<td>0.37</td>
<td>0.11</td>
<td>3.38</td>
<td>2.03–5.63</td>
</tr>
<tr>
<td>54$^b$</td>
<td>Ventilation and lighting</td>
<td>0.32</td>
<td>0.19</td>
<td>1.72</td>
<td>1.09–2.68</td>
</tr>
</tbody>
</table>

$^a$ CI, confidence interval.

$^b$ Violations that maintained $P \leq 0.05$ after sensitivity analysis.
<table>
<thead>
<tr>
<th>Criterion no.</th>
<th>Criterion description</th>
<th>Relative risk</th>
<th>95% CI</th>
<th>Violation at outbreak/ nonoutbreak restaurants</th>
<th>Relative risk</th>
<th>95% CI</th>
<th>Violation at outbreak/ nonoutbreak restaurants</th>
<th>Relative Risk</th>
<th>95% CI</th>
<th>Violation at outbreak/ nonoutbreak restaurants</th>
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</thead>
<tbody>
<tr>
<td>3</td>
<td>Illness exclusion</td>
<td>8.60</td>
<td>2.5–29.4</td>
<td>0.3/0.035</td>
<td>0.47</td>
<td>0.08–20.0</td>
<td>0.016/0.034</td>
<td>0</td>
<td>0/0.03</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Proper eating, tasting, tobacco use</td>
<td>0</td>
<td>0–0.02</td>
<td>0/0.02</td>
<td>5.88</td>
<td>1.5–21.9</td>
<td>0.10/0.017</td>
<td>0</td>
<td>0/0.02</td>
<td>0</td>
</tr>
<tr>
<td>7</td>
<td>Bare hand contact procedure</td>
<td>7.70</td>
<td>2.8–20.6</td>
<td>0.4/0.052</td>
<td>2.20</td>
<td>1.0–5.6</td>
<td>0.11/0.05</td>
<td>0</td>
<td>0/0.05</td>
<td>0</td>
</tr>
<tr>
<td>13</td>
<td>Food separated, protected</td>
<td>0</td>
<td>0–0.04</td>
<td>0/0.04</td>
<td>2.75</td>
<td>10.3–7.7</td>
<td>0.11/0.04</td>
<td>0</td>
<td>0/0.04</td>
<td>0</td>
</tr>
<tr>
<td>18</td>
<td>Proper cooling time, temp</td>
<td>50</td>
<td>5.8–452.6</td>
<td>0.3/0.006</td>
<td>5.0</td>
<td>0.52–61.1</td>
<td>0.03/0.066</td>
<td>0</td>
<td>0/0.01</td>
<td>0</td>
</tr>
<tr>
<td>20</td>
<td>Proper cold holding temp</td>
<td>1.15</td>
<td>0.3–4.6</td>
<td>0.2/0.17</td>
<td>2.11</td>
<td>1.3–3.3</td>
<td>0.36/0.17</td>
<td>0</td>
<td>0/0.2</td>
<td>0</td>
</tr>
<tr>
<td>21</td>
<td>Proper date marking and disposition</td>
<td>2.80</td>
<td>0.4–39.2</td>
<td>0.1/0.035</td>
<td>3.66</td>
<td>1.15–9.41</td>
<td>0.11/0.03</td>
<td>0</td>
<td>0/0.02</td>
<td>0</td>
</tr>
<tr>
<td>31</td>
<td>Proper cooling methods</td>
<td>4.2</td>
<td>0.20–15.8</td>
<td>0.1/0.024</td>
<td>4.78</td>
<td>1.50–16.3</td>
<td>0.11/0.023</td>
<td>10.8</td>
<td>1.50–75.90</td>
<td>0.25/0.023</td>
</tr>
<tr>
<td>35</td>
<td>Food properly labeled, original container</td>
<td>5.30</td>
<td>2.1–13.3</td>
<td>0.4/0.075</td>
<td>3.02</td>
<td>1.50–6.10</td>
<td>0.20/0.075</td>
<td>6.58</td>
<td>2.18–20.09</td>
<td>0.5/0.076</td>
</tr>
<tr>
<td>37</td>
<td>Cross-contamination prevented</td>
<td>0.71</td>
<td>0.1–4.8</td>
<td>0.1/0.14</td>
<td>2.21</td>
<td>1.30–3.80</td>
<td>0.31/0.14</td>
<td>1.79</td>
<td>0.40–15.04</td>
<td>0.24/0.14</td>
</tr>
<tr>
<td>42</td>
<td>Utensils, equipment, linens</td>
<td>5.45</td>
<td>2.8–10.5</td>
<td>0.6/0.11</td>
<td>2.10</td>
<td>1.02–3.70</td>
<td>0.21/0.11</td>
<td>2.27</td>
<td>0.58–26.01</td>
<td>0.25/0.11</td>
</tr>
<tr>
<td>43</td>
<td>Single-use and single-service articles</td>
<td>29.4</td>
<td>8.0–103.3</td>
<td>0.5/0.017</td>
<td>8.82</td>
<td>2.40–30.20</td>
<td>0.15/0.017</td>
<td>0</td>
<td>0/0.02</td>
<td>0</td>
</tr>
<tr>
<td>47</td>
<td>Nonfood contact surfaces</td>
<td>2.72</td>
<td>0.9–9.3</td>
<td>0.3/0.11</td>
<td>3.73</td>
<td>2.40–30.20</td>
<td>0.41/0.02</td>
<td>0</td>
<td>0/0.1</td>
<td>0</td>
</tr>
<tr>
<td>52</td>
<td>Garbage and refuse disposal</td>
<td>0</td>
<td>0–0.08</td>
<td>0/0.08</td>
<td>0.87</td>
<td>0.25–2.90</td>
<td>0.066/0.076</td>
<td>0</td>
<td>0/0.4</td>
<td>0</td>
</tr>
<tr>
<td>53</td>
<td>Physical facilities</td>
<td>0.67</td>
<td>0.3–1.8</td>
<td>0.3/0.45</td>
<td>1.37</td>
<td>1.08–1.80</td>
<td>0.62/0.45</td>
<td>6.57</td>
<td>2.18–20.09</td>
<td>0.5/0.076</td>
</tr>
</tbody>
</table>

* Bold signifies those violation types significant by agent at 95% probability.
To evaluate further the data from chain locations, relative risks of the likelihood of a violation occurring at an outbreak location versus a nonoutbreak location were calculated. Generally, a relative risk value of \( > 1 \) indicates that an association exists, and a value of \( > 5 \) means that a relatively strong to strong association exists. Table 4 presents these data for the Salmonella, norovirus, and C. perfringens and toxin-mediated outbreaks.

Meta-analysis resulted in a subset of these data and development of an overall list of violation types more likely to be associated with outbreak restaurants in general. Thus, violations of criteria 17 (proper reheating for hot holding) and 21 (proper date marking and disposition) were dropped because in the sensitivity analysis the \( P \) values were not maintained at \( \leq 0.05 \). After these conservative analyses, 11 violation types remained (see Table 3) that provide a profile of an outbreak restaurant but are not specific to any of the three outbreak agents.

**DISCUSSION**

No violations were more likely to be observed at nonoutbreak locations; and when data from routine inspections at outbreak nonchain locations were removed from the comparison, different types of foodborne illness-related violations were identified. The net difference when comparing these data sets reveals that just one violation type was more likely to be found in the chain and nonchain outbreak locations. This finding may reflect the fact that programs in place across multiple locations that are part of a chain are likely to be different from those in place at nonchain single-location establishments.

The higher incidence of Salmonella and C. perfringens outbreaks at nonchain restaurants could indicate that chain restaurants may be better at managing risk factors related to these agents. They also may serve fewer menu items with preparation requirements that could lead to these types of outbreaks when mistakes are made. The data on norovirus suggests that this agent presents challenges that are inconsistently managed, regardless of the type of restaurant. Prevention of norovirus infection is difficult because of its association with food handlers’ behaviors, which can be challenging to manage. Because norovirus remains a top cause of foodborne illness, continued focus on its specific risk factors is encouraged.

Jin and Leslie (12) reported that chain restaurants develop reputations for good hygiene practices, which may provide ongoing motivation to maintain these standards. However, in the present study even though the total number of violations recorded during routine inspections were greater in the chain and nonchain locations together, these differences are probably not practically significant. Significantly more violations were recorded during routine inspections at outbreak locations than at nonoutbreak locations.

Jones and Angulo (13) reported that because cross-contamination and lapses in hygiene and sanitation practices were identified as factors leading to illness, improvements in these areas are needed. These authors cautioned that focus should be on areas where risks are modifiable and that adopted controls should be reevaluated periodically and with diligence to ensure that their focus remains appropriate. The violations observed in the present study that were more likely in outbreak locations cover a wide range of issues, with half related to the Food Code category “foodborne illness risk factors and public health interventions” (form 3-A, criteria 1 through 27) and the other half in the category of “good retail practices” (form 3-A, criteria 28 through 54) (25). This breadth emphasizes the need for attention to the entire food production system, not just foodborne illness risk factors. To better ensure restaurant food safety, improvements should be directed to a systems-based approach with active managerial control.

In the present study, relative risks were calculated for the violations significantly more likely to be observed at outbreak versus nonoutbreak chain locations. The calculated values help characterize the likelihood of a violation occurring at an outbreak location versus a nonoutbreak location. Under consideration was the incidence of specific violations during these inspections. Several violations occurred in more than one type of outbreak restaurant, indicating a broad spectrum of potential issues. Violations related to bare hand contact and utensil use were more indicative of lapses in implementation of basic prevention practices section of the Food Code form, which may be more indicative of lapses in implementation of basic preventative controls that support food safety programs. Similar results were obtained through examination of specific violations related individually to each agent.

The types of violations more likely to be observed during routine inspections at restaurant locations that had experienced norovirus infection outbreaks highlighted a wide range of concerns. Violations related to criterion 7 (no bare hand contact with food or use of sprayed alternate procedure) occurred more commonly among restaurants that had experienced norovirus infection outbreaks. Norovirus survives on the hands for extended periods. Because the fecal-oral route is a well-established transmission pathway for this pathogen (5), surviving norovirus particles present a significant risk. Bidawid et al. (1) demonstrated transfer of feline calicivirus, which is a norovirus surrogate recognized by the U.S. Environmental Protection Agency (22), from inoculated fingertips to ham, lettuce, and stainless steel. CDC data (15) indicated that bare hand contact was a contributing factor in 54% of reported norovirus outbreaks from 1998 through 2002, and others have reported poor hand washing compliance among restaurant workers (21, 27, 28). The present study confirmed that outbreak restaurants continue to experience issues with hand washing.
even when an outbreak is not occurring, and these issues have been detectable during routine inspections. Improvements in hand washing compliance are needed.

Five of the violations recorded during routine inspections of restaurants that had norovirus infection outbreaks were related to contamination of the food, utensils, equipment, single-use articles, nonfood contact surfaces, and physical facilities. Norovirus can survive for extended periods on surfaces, and studies with feline calicivirus revealed survival for up to 28 days at 20°C on dry surfaces. Proper cleaning and sanitization of surfaces and appropriate handling of other articles that could serve as vehicles for norovirus transfer are crucial elements of risk reduction practices in restaurants. Two other violations were related to employees eating or using tobacco inappropriately and food improperly separated and protected. Because food can also serve as a vehicle for norovirus infection, care must be taken to handle food in a sanitary manner. The other violations more likely to be observed during routine inspections at restaurants that had norovirus infection outbreaks were related to cold holding, date marking and labeling of food, and adequate ventilation and lighting. Although these violations are not related to the typical transmission pathways for norovirus, they may be more indicative of basic systematic failures in overall management of food safety related issues.

One violation that was not more likely to occur during routine inspections at restaurants that had norovirus infection outbreaks was proper use of illness reporting, restriction, and exclusion. This violation was associated with norovirus infection outbreaks in a previous study when outbreak investigation inspections and routine inspections at restaurants that had outbreaks were compared. Exclusion of ill workers may not be a focus during routine inspections, given that ill workers probably will not be present in the establishment at the time of the inspection. Because it is difficult to reliably assess the illness status of food handlers, this type of violation probably is more commonly assessed during foodborne illness outbreak investigations.

A wide range of issues were also suggested by examination of violations more commonly observed during routine inspections of restaurants that had Salmonella and C. perfringens infections or toxin-mediated illness outbreaks. The types of violations more likely to be found during routine inspections at restaurants that had Salmonella infection outbreaks were related to personnel illness, hand washing concerns, and problems with food cooling and labeling and management of utensils, linens, and single-use articles. The FDA reported that Salmonella contamination and infection outbreaks can be related to a variety of factors, including personnel, food, and surface contamination, temperature abuse, and failure to inactivate the organism. The violation types observed in the present study reflect these concerns. Similarly, violation of the criterion “proper cooling methods used; adequate equipment for temperature control,” which was more likely to be observed in C. perfringens and toxin-mediated outbreaks, is consistent with the expected causal pathway for this type of illness. The other violations related to proper labeling and garbage disposal may represent broader sources of contamination but may also indicate basic failures in overall management of food safety issues.

The numbers of inspection reports associated with Salmonella and C. perfringens infections and toxin-mediated outbreaks at chain locations were very low. To manage this limitation, a meta-analysis was conducted with the premise that each violation type was an independent study and that by combining the evidence from all three agents the data set would be much more robust. This analysis revealed a subset of core violations more likely to be found in outbreak restaurants. Eleven specific violations of the total possible 54 seemed to provide a profile of an outbreak restaurant. Because it is not known before an outbreak which agent will cause it, knowledge of the overall risk of the top three agents (norovirus, Salmonella, and C. perfringens) and toxins could permit identification of appropriately targeted interventions to prevent such an outbreak. Because the CDC reported that these three agents caused approximately 75% of confirmed and suspected foodborne illness outbreaks in 2008, an understanding of factors that may affect outbreaks due to these agents could have a significant impact on overall illness incidence. This list of factors could be used to assess whether a particular establishment may more closely resemble an outbreak location by determining how many of the 11 violations would be likely to be found during routine inspections.

With this combined-evidence approach, the factors identified in the present study agree with those reported elsewhere. Gormley et al. (10) found repeated concerns related to cross-contamination in an 18-year study. Patel et al. (18) also identified cross-contamination as an apparent factor in a Salmonella infection outbreak at multiple locations of a restaurant chain. Doménech et al. (7) reported issues with structural design conditions and sanitation were key weaknesses in the ability of food establishments to implement food safety programs. Several researchers have attempted to relate inspection scores to foodborne illness likelihood, and although findings are mixed, several types of violations more likely to be observed in outbreak locations were identified. Buchholz et al. (2) found that incorrect food storage and employee hand washing issues were predictors among other factors for an outbreak at a particular establishment. Hedberg et al. (11) reported that infected food handlers and bare hand contact with foods were the most commonly identified contributing factors to foodborne illness in a study of outbreak and nonoutbreak restaurants. Although in a Florida study inspection results were not considered to be predictive of future outbreaks, the authors did report that larger seating capacity was more likely to be associated with outbreaks. In an Iowa study, larger and full-service establishments were more likely to be cited for critical violations (3).

Despite this agreement with other study findings, the present study had several limitations, some of which have been described previously. To compile a robust data set for analysis, a decision was made to use outbreaks from only those restaurants about which complete inspection...
information could be obtained. This restriction resulted in inherent nonselection of other outbreaks, whose information might have provided different overall results. The variability among inspection results may sometimes be due to mistakes, loss of information, or jurisdictional and inspector differences. Violations often are categorized and reported differently, and assessment of behaviors is challenging. Behaviors may be modified by operators and others being inspected but then may change once the inspector departs. It also can be difficult to gauge operators’ policies, especially when personnel are able to provide the correct responses to questions designed to gauge knowledge and behavior. Not all foodborne illness risk factors can be observed during inspections.

The time of day that an inspection is conducted also can influence the reported findings. An inspection conducted during a busy meal time may reveal issues that are related to the hectic pace of work at that moment rather than true systematic failures. In Minnesota, some but not most inspections are announced, depending on the particular situation. When an establishment with limited hours is to be inspected, an appointment may be scheduled to ensure that the restaurant will be open when the inspector arrives. In an establishment with a history of cooling violations, an inspection should be scheduled to coincide with the time with the problematic process is typically performed. If an inspection is planned for a busy meal time, scheduling the visit may help to ensure that the manager or person in charge will have the necessary time to spend with the inspector. Inspections conducted after an outbreak might result in food safety improvements.

This study focused on outbreaks of foodborne illness in Minnesota and so may be subject to the limitations associated with this state’s food code regulations (16) and the types of violations that are recognized. However, these study results are believed to be applicable to other states because the findings emphasize that overall attention to food safety practices is needed but adoption of a more universally consistent approach would be beneficial. Data from other states should be evaluated to determine what differences if any might be detected.

Attention to specific types of violations may permit identification of a restaurant whose profile indicates a higher risk for foodborne illness. This at-risk location may not always be the same as that with the highest total number of violations, but the findings of this study suggest that a closer examination of the specific types of violations and comparison of these violations with the 11 criteria identified might be prudent. Inspections provide feedback to the operator concerning the effectiveness of the establishment’s process controls, thus enabling the operator to focus on interventions and programs that can have the greatest impact. Despite their limitations, restaurant inspections are a valuable tool that can be used to verify the existence of appropriate preventative controls and an active managerial control system.

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REFERENCES