A Risk-Based Food Inspection Program

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Abstract

The inspection of food facilities is a crucial public service designed to prevent foodborne illnesses among retail food consumers. To enhance the existing food inspection process in San Bernardino County, California, a risk-based food inspection program and assessment instrument has been developed and proposed. A literature review and interviews with health professionals were conducted to establish a baseline understanding of various inspection procedures currently being employed throughout the nation. San Bernardino subsequently developed an assessment instrument and attendant inspection schedules that reflect best practices. The proposed inspection model categorizes food facilities as high, moderate, or low risk according to food properties, service population characteristics, facility history, and predefined operational risks. The San Bernardino model supports health department decision making with respect to inspection resource allocation and also makes possible sliding permit fees that reflect the relative risk associated with each facility.

Introduction

Public health departments are responsible for ensuring the quality and safety of food provided by food facilities. Because of this responsibility, they need to adequately survey the risks imposed on consumers.

Inspections are an inherent component of surveillance because they have been demonstrated to prevent foodborne illness among consumers of retail food (Allwood, Lee, & Borden-Glass, 1999). Food facility inspections are, however, generally limited to characterizing food safety conditions at the particular time and day of the site evaluation. When inspections are combined with risk assessment, administrators receive value-added information, which promotes efficient use of human resources associated with inspection site visits. Risk assessment procedures take multiple risk factors into account to categorize food facilities by their level of relative risk. This categorization provides a standardized methodology for calculating the ideal number of inspections needed per year and for reducing or increasing individual permit fees according to identified risk levels.

The temporal and spatial variability of health risk factors at food facilities is well understood; thus, industry and governmental agencies have provided guidelines for assessing the most prevalent factors. These guidelines provide structure for inspection procedures. Hazard assessment and critical control point (HACCP) principles often provide the basis for risk-based inspections (Mortimore & Wallace, 1998). According to the definition given in the 2001 *Food Code*, risk-based inspections have a "jurisdiction prioritized inventory of establishments and set inspection frequency using a hazard assessment" (Food and Drug Administration, 2001).

The *Food Code* suggests that agencies using risk-based inspections conduct inspections from one to four times per year. Some state and local jurisdictions have elected to incorporate the *Food Code*'s suggestions for risk-based inspections in their entirety. Others, however, have developed their own processes for determining the priority and frequency of inspections. Some local jurisdictions such as Solano County, California, and the city of Plano, Texas, have risk-based inspection protocols that call for one to three inspections per year (Collins, 1995; Solano County, 2001).

A review of published literature reveals that a limited number of health departments have implemented risk-based inspection protocols that have deviated from published FDA processes and procedures. Two studies suggest that one to three inspections should occur each year (Riben et al., 1994; Zaki, Miller, McLaughlin, & Weinberg, 1997). A third study found that increasing the number of inspections from 6 to 12 did not result in increased performance scores (Bader, Blonder, Henriksen, & Strong, 1978). By contrast, a fourth study demonstrated that reducing the number of inspections from four to one per year led to a decrease in scores (Corber, Barton, Nair, & Dulberg, 1984). Because

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the number of published studies of risk-based inspection programs is limited, this article provides the reader an assessment of existing literature and a possible model for those seeking to include risk in their inspection programs and for agencies that desire to improve their current risk-based food inspection program.

Methods

To develop the San Bernardino County risk-based food inspection program, a literature and Internet search was conducted to determine the variables of risk that industry, government, and representative counties and state jurisdictions have considered when developing their respective, risk-based inspection programs. Personal conversations with health specialists at various county public health departments aided in the selection of literature and applicable Web-based Internet resources.

Results

Risk Categorical Systems

Assigning food facilities to risk categories supports prioritization of prevention and control measures. Jurisdictions that have implemented risk-based inspection programs commonly have employed one of two methods. The first method considers only one risk factor; the second considers multiple risk factors.

When only one risk factor is considered, facilities are ranked only by their inspection score (Centers for Disease Control and Prevention [CDC], 2004) or are categorized by levels of food preparation involved (Food and Drug Administration [FDA], 2001).

Food facilities can also be ranked according to relative risk, and in this case, multiple risk factors are evaluated. The factors include square footage of the facility, previous inspection scores, number of meals served per day, complexity of the menu, preparation of food for multiday use, egg-pooling practice, type of ownership, ethnicity of cuisine, population served, and foodborne-illness complaints (Buchholz, Run, Kool, Fielding, & Mascola, 2002). Another combination of risk factors that can be used for risk assessment involves types of food served, preparation steps required for these foods, volume of food, population served, and previous compliance history (Collins, 1995; Sonoma County, 2001).

Risk Factors

A risk assessment instrument has been developed for San Bernardino County (the instrument is available at http://www.llu.edu/llu/sph/ophp/documents/risk_figure.pdf). It provides a model for assignment of food facilities to various categories of risk on the basis of multiple risk factors. These factors include food properties, population at risk, food facility history, and food facility operational risks.

Food property risks involve foods that are capable of being a source of foodborne illness because of their chemical and physical characteristics. These characteristics include high protein and carbohydrate contents, neutral to slightly acidic pH, potential for violation of time-temperature requirements, and specific moisture and oxygen content that supports the growth of microorganisms (National Restaurant Association Educational Foundation, 2002). On the basis of these properties, four categories of food types have been included in the Food Facility Risk Assessment Instrument, with specific foods identified in each category.

At-risk populations are included in the Food Facility Risk Assessment because some individuals are more susceptible to contracting food illnesses than the general population is. The Food Safety and Inspection Service (FSIS) defines populations at risk as people who have pre-existing illnesses or health issues, including diabetics, individuals undergoing cancer treatments, HIV-positive individuals, and individuals on immuno-suppressive drugs (U.S. Department of Agriculture [USDA], 2004). This sub-population also includes people who are over 60 years of age with underlying diseases, pregnant women, neonates, and young children (USDA, 2004). The Risk Assessment Instrument contains two sections, one to assess patronage volume, and the other to evaluate the age category of typical consumers.

Food facility history evaluates two factors: 1) foodborne-illness complaints and 2) scores from routine inspections within the previous year. The category of complaint history includes one or more confirmed complaints within the last year. The score system used is predicated on 100 possible points, with cut points established at 90, 80, and 70. The assessment instrument has a category for individual restaurant inspection scores of 79 or less on a routine inspection within the past 12 months. There is also a category of 90 or above on two or more routine inspections in the last 12 months, which is included so that the system can reward food facilities that would normally be placed in a category of higher risk because of the intrinsic nature of the food facility. High-risk food facilities scoring 90 or above during the two most recent consecutive inspections would be reassigned to the moderate risk level. Likewise, moderate-risk food facilities with a score of 90 or above on their two most recent inspection would be reassigned to the low-risk category because of their demonstrated ability to consistently manage risk.

Operational risks are included in the Food Facility Risk Assessment Instrument because CDC has identified certain operational activities as risk factors for foodborne illnesses (FDA, 2004). Inspections in many jurisdictions, including health inspectors within the Food and Drug Administration, base their inspections on these 14 risk factors. The top five risk factors were selected because they could be clearly distinguished as contributing more than others toward foodborne illness. The San Bernardino Food Facility Risk Assessment Instrument includes the following risk factors: food from unsafe sources, improper holding/improper time and temperature, inadequate cooking, poor hygiene, and contaminated equipment/prevention of contamination.

Point System

A risk factor point system was developed to quantify the level of risk presented by each food facility. Several categories of risk were included to address risks from the types of foods served, risks associated with typical patron attributes, and risks associated with the history and operation of the food facility. The point value of each category was determined mainly from the literature (Collins, 1995) and from discussions with knowledgeable registered environmental health specialists.

Risk Categorization

Before food facilities are placed in risk categories, the ranges of point values for each risk level in the Food Facility Risk Assessment Instrument must be assigned and summed. Individual jurisdictions may see some variance because of differences in how food facilities are routinely inspected and scored; thus, each jurisdiction may need to make modifications to achieve best fit for its inspection system or type. To calculate the range for each risk level (high, medium, or low), the San Ber-

nardino County model suggests a procedure similar to that used by Solano County. After the inspectors complete the risk assessment instruments for individual food facilities, the total risk score for every food facility can be entered into a spreadsheet, where a frequency distribution of the scores can be displayed. Solano County reported score results that produced three separate bell-shaped curves, which they subsequently associated with high-, moderate-, and low-risk food facilities (Solano County, 2001).

Frequency of Inspections per Year

A method for determining the frequency of inspections was developed for use along with the Food Facility Risk Assessment Instrument. The authors, on the basis of their combined 17 years of food inspection experience, recommend that the high-risk facilities be inspected three times per year, the moderate-risk facilities be inspected two times per year, and the lowest-risk food facilities be inspected one time per year. It is important to note that risk assessment instruments for existing facilities should be completed every year to remain current with menu or operational changes.

Permit Fees

Ideally, fee-based permit systems should assess individual fees that are commensurate with the level of service provided. In other words, one standard fee is not fair to food service facilities that receive modest or minimal inspection services. San Bernardino County proposes a sliding scale based on the level of effort needed to offer adequate prevention services. One possibility is to charge high-risk facilities fees that cover approximately one-half of the total program costs; moderate-risk facilities, one-third; and low-risk facilities, one-sixth.

Discussion

Implementation of a risk-based, prevention-oriented inspection program has benefits. Such a system can effectively utilize personnel, management, and monetary funds (Collins, 1995; Wodi & Mill, 1985). Perhaps the greatest benefit is that it provides jurisdictions with a reasonable method of determining the frequency of inspections. A literature review indicates that the frequency of routine inspections is a determining factor for the outcome of inspections (Riben et al., 1994). The frequency of food facility inspections has been demonstrated to be positively associated with sanitation scores, a result that shows the importance of inspections (Allwood, Lee, & Borden-Glass, 1999).

Several publications have examined the issue of the ideal number of annual food inspections. FDA's 2001 *Food Code* suggests an inspection system in which food facilities are inspected one to four times a year (FDA, 2001). Some county or state jurisdictions implement this system. Many county and state jurisdictions, however, have designed their own systems, in which the frequency of inspections is based on other factors.

A review of the literature indicates that one or more inspections are needed per year. One study recommends that routine restaurant inspections should occur one to two times per year (Riben et al., 1994). Another found that an increase in the number of inspections per year from 6 to 12 did not improve the outcome of routine inspections (Corber et al., 1984). By contrast, other research has shown that some reduction in inspection scores occurs when the frequency of inspection is decreased from four times per year to one time per year.

Results from one study indicate that inspections of food facilities only once per year may not be sufficient (Bader et al., 1978). It should be noted, however, that one inspection per year may be adequate for some food facilities, while more inspections may be necessary for other facilities, depending on the level of risk associated with each establishment.

The proposed San Bernardino risk-based food inspection program recognizes the importance of previous inspection scores as a key indicator of the risk present in food facilities. The authors also chose to assume that other food risk factors needed to be considered along with previous inspection scores.

The proposed assessment model considers the risk factors that it is most important to identify during an inspection. The assessment instrument includes the following factors: food properties, population at risk and typical patronage, food facility history, and operational risks. The instrument takes multiple risk factors into account to give a balanced assessment of the risk present in food facilities, not only at the time of inspection, but also over the course of the year. Use of the instrument also provides incentive for food facilities to score well on the routine inspections. If a food facility has received a score of at least 90 on two or more routine inspections during the last 12 months, the facility is automatically placed in a lower risk category, which entails a reduced fee schedule.

The actions of some jurisdictions support the hypothesis that examining several risk factors will better assess the health risks present in food facilities. A 1995 study from the city of Plano, Texas, reports that the highest-risk facilities are inspected at least six times per year, with the moderate-risk facilities being inspected at least three times per year and the lowest-risk facilities being inspected one time per year (Collins, 1995). Regulations in Solano County, California, mandate that the highest-risk facilities be inspected three times per year, with the moderate-risk facilities being inspected twice per year and the lowest-risk facilities being inspected one time per year (Solano County, 2001).

The San Bernardino County Risk Assessment Instrument provides a system for calculating the frequency with which a food facility should be inspected according to its categorization as a high-, moderate-, or low-risk facility. These ranges are not determined on a pro forma basis, however. Ranges for the risk categories must be calculated for each county or jurisdiction.

In a comparable instrument for Plano, Texas, a "high-risk establishment" was defined as having a score of >70, a "moderate-risk establishment" was defined as having a score ranging from 50 to 69, and a "low-risk establishment" was defined as having a score of <49 (Collins, 1995). Alternatively, Solano County defines a "high-risk establishment" as having a score of ≥80, a "moderate-risk establishment" as having a score ranging from 38 to 79, and a "low-risk establishment" as having a score of ≤37 (Solano County, 2001).

Unlike its counterparts in Plano and Solano, San Bernardino County produces relative-risk categories that reflect the distribution of annually produced risk assessment scores. In the authors' experience, three reasonably distinct score distribution curves are produced, reflecting high, medium, and low risk, respectively. High-risk facilities are inspected three times per year, moderate-risk facilities are inspected two times per year, and low-risk facilities are inspected one time per year.

The authors anticipate rollout and implementation of the San Bernardino model in the near future. Evaluation models are currently under consideration so that efficiencies and other public health benefits accruing under the proposed system can be assessed.

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Conclusion

San Bernardino County has devised a risk-based food inspection model that can be used by agencies that desire evidenced-based decision making with respect to allocation of resources. The program includes a risk assessment instrument, which provides a vehicle for articulation of performance metrics. Agencies benefit through efficient use of inspection personnel, and the regulated community potentially benefits through reduced fee schedules as a function of performance and inspection results.

Acknowledgements: This publication was made possible through funding provided by the American Schools of Public Health Project #D3304-23/23 and Grant U50/CCU924359-01 from CDC.

Disclaimer: This article was supported in part by Grant #U50/CCU924359-01 from CDC. Its contents are solely the responsibility of the authors and do not necessarily represent the official view of CDC.

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