Introduction

Foodborne illness poses a significant risk to public health in the United States. The Centers for Disease Control and Prevention (CDC) estimates that each year in the U.S., 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne illnesses. Epidemiological investigation data indicate that the five major risk factors associated with most foodborne illness outbreaks are: (1) improper holding temperatures; (2) inadequate cooking; (3) contaminated equipment; (4) food from unsafe sources; and (5) poor personal hygiene.

The U.S. Food and Drug Administration (FDA) joins forces with state, local, tribal, and territorial agencies (SLTT) to ensure the safety of the nation’s retail food supply. In this endeavor, the FDA created the Food Code to assist SLTTs by providing them with a scientifically-sound technical and legal basis for regulating the retail and food service segment of the industry (restaurants, grocery stores, and institutions such as nursing homes). SLTTs can use the FDA Food Code as a model to develop, or update, their own food safety rules and ensure these rules are consistent with national retail food regulatory policy. In addition to various funding opportunities and the Food Code, the FDA aids with retail food safety regulation through the Voluntary National Retail Food Regulatory Program Standards (hereafter Retail Program Standards), the Food Safety Modernization Act, and the New Era of Smarter Food Safety.

The Retail Program Standards were developed in collaboration with federal, state, and local regulatory officials, retail food industry professionals, trade associations, academia, and consumers. The nine Retail Program Standards define a “highly effective and responsive retail food regulatory program” and serve as a framework for continuous quality improvement of SLTT retail food regulatory programs. Enrollment in the Retail Program Standards is designed to identify areas where a regulatory program can have the greatest impact on retail food safety, while assisting in identifying program areas in critical need of attention. In shifting the mode from response to prevention, the Food Code and the Retail Program Standards provide a strategically-sound framework to address the root causes of foodborne illness outbreaks.

Standard 9 of the Retail Program Standards prescribes a public health metric to demonstrate improvement in food safety for jurisdictions enrolled in the Retail Program Standards. The requirements define the process a jurisdiction can use to measure the success of its retail food regulatory program in enhancing food safety and public health in the community it serves. Success can be achieved by reducing the occurrence of foodborne illness risk factors through implementation of effective risk-based intervention strategies developed with retail food service operators. 

To conform with Standard 9, a jurisdiction must conduct a risk factor study, analyze the data collected, report the outcomes, and design targeted intervention strategies to reduce the occurrence of the risk factors that were identified. By tracking the occurrence of the five major risk factors and implementing targeted intervention strategies, food regulatory programs have a reliable and consistent method of monitoring food safety risks and identifying trends over time within the retail food industry. The results of the initial data collection for each of the facility types serve as the baseline measurement from which trends will be analyzed. The jurisdiction must also evaluate the effectiveness of the intervention strategies by conducting subsequent risk factor studies at least once every 60 months. A jurisdiction may either use routine inspection data or collect data separately when completing a risk factor study. A data collection instrument similar to the FDA Model Data Collection Form using the IN, OUT, NA and NO convention is required. If the jurisdiction uses a different collection form, the data it collects may be difficult to compare with data from the FDA National Foodborne Illness Risk Factor Studies or with data from other jurisdictions.

In 2021, the National Association of County and City Health Officials (NACCHO) and the Conference for Food Protection (CFP) conducted a study of local food regulatory programs’ risk factor intervention strategies. The study focused on Retail Program Standard 9 and risk factor studies conducted by local retail food regulatory programs enrolled in the Retail Program Standards. The study consisted of key informant interviews (KIIs) to identify and assess the implementation of risk factor interventions currently employed by local retail food regulatory programs. The local retail food regulatory programs that participated in the KIIs were asked questions about a variety of topics such as how they identified the risk factor(s) for their targeted intervention, the implementation of the intervention strategies, and the outcomes of their risk factor studies.
strategy, measurement of improvements resulting from the intervention, and challenges encountered.

The KIIs identified resources, processes, collaboration, implementation, and interventions as key components when selecting the risk factors targeted for improvement. Most jurisdictions targeted risk factors based on violations most frequently cited during retail food regulatory inspections. **Data collected during the KIIs showed the risk factor most often targeted by the study participants was poor personal hygiene.** When asked follow-up questions, KII participants indicated that personal hygiene for the purposes of their studies meant either: 1) employees observed working with exposed food or clean equipment and utensils while having persistent sneezing, coughing, runny nose, or watery eyes; or 2) employees observed eating, drinking, or smoking while preparing food.

**Methodology**

**Search Parameters**

For this research project, NACCHO and CFP staff utilized the listing of jurisdictions enrolled in the Retail Program Standards from FDA’s website updated through October 2020. Inclusion criteria specified local retail food regulatory programs that have completed more than one self-assessment and a corresponding verification audit of Standard 9. Ideal jurisdictions were those that had completed two risk factor studies with corresponding audits that verified conformance with Standard 9 over a time period where a trends report describing the effectiveness of the implemented intervention strategies is available.

**PARTICIPANT SELECTION PROCESS**

**Identifying potential participants**

- Project staff reviewed risk factor reports and data of local programs that had received at least two verification audits for Standard 9.
- Sample selections were made to represent a diverse range of jurisdictions (e.g., geographical regions, size of jurisdictions, access to resources, government structures, and rural versus urban).
- Inclusion criteria also specified jurisdictions that were recent applicants for the Crumbine Award where the applicant demonstrated implementation and outcomes of intervention strategies for conformance with Standard 9.
- Research project staff worked with NACCHO’s Research and Evaluation Team and consulted with the Retail Food Safety Advisory Group and the Retail Food Safety Regulatory Association Collaborative to finalize search parameters and criteria and to identify additional interview protocols.

- Thirteen jurisdictions met the criteria for study participation.
- Eight jurisdictions were identified to be eligible for interviews.

**About the Retail Food Safety Regulatory Association Collaborative**

The Collaborative is comprised of the following associations and agencies: the Association of Food and Drug Officials, the U.S. Centers for Disease Control and Prevention, the Conference for Food Protection, the U.S. Food and Drug Administration, the National Association of County and City Health Officials, and the National Environmental Health Association working together to reduce the incidence of foodborne illness. Our work focuses on a national strategy for the adoption of the latest editions of the Food Code, promoting and improving food safety culture, increasing enrollment and active participation and conformance with the Voluntary National Retail Food Regulatory Program Standards, improving foodborne illness outbreak investigations, improving food safety management systems at retail food facilities, and enhancing effective communications and sharing of best practices among retail food protection partners.
Thirteen jurisdictions met the criteria for study participation and 11 provided risk factor study reports. Nine jurisdictions were selected due to report completeness. Four jurisdictions had either an incomplete or missing risk factor study report. Eight jurisdictions were identified to be eligible for interviews.

Data Collection

DATA COLLECTION PROCESS

Interviewing KII participants
From May to September 2021, NACCHO and CFP conducted eight KIs with local jurisdictions of varying sizes and geographic regions.

Probing questions were used to ask about lessons learned to explore successes, challenges, and advice for other jurisdictions.

A follow-up questionnaire was used to solicit more specific information about some responses collected during the KIs.

Interview questions were developed in advance of the interview period and in consultation with the Retail Food Safety Advisory Group and the Retail Food Safety Regulatory Association Collaborative.

The interview questions were grouped into focus areas and aimed towards understanding the process that the jurisdictions followed; from collecting risk factor study data to creating targeted intervention strategies, implementing the strategies, and evaluating the effectiveness of the strategies.

NACCHO deployed the web-based questionnaire through Qualtrics® software, and NACCHO and CFP staff scheduled and conducted interviews using Zoom© software. The questionnaire and interview tools were the same for both categories of participants. Interviews were audio recorded with the verbal consent of participants and transcribed using an external transcription service. Following transcription, the questionnaire responses and interviews were analyzed by NACCHO using an in-vivo coding process in Excel©. Themes and subthemes were established following iterative expansion and consolidation of codes. These themes have been expanded upon in the results section of this study with both participant categories combined.

Study Limitations

This research study was limited by a small sample size of eight jurisdictions which may not completely reflect the experiences of all local retail food regulatory programs. The sample size was small because study participants were limited to jurisdictions that were enrolled in the Retail Program Standards, had confirmed conformance with Standard 9, and had received at least two verification audits. A larger sample size could potentially provide even more insight into identified themes and factors for risk factor interventions. Another limitation was the limited availability of written risk factor study reports. When project staff reached out to study participants for copies of their reports, some of the jurisdictions had data available but did not have this data developed into written reports. Additionally, some jurisdictions did not measure improvements between one risk factor study and a subsequent risk factor study. Standard 9 requires written reports and measurement of improvement following the implementation of interventions.
Another study limitation identified was a lack of response from the initial interview participants in a follow-up survey. Research staff sent a follow-up survey by email to all eight initial interview participants, and three responses were received, with two responses from the same jurisdiction.

Results

Research staff grouped the interview questions to address seven focus areas:

- Information on the risk factors that were studied.
- How risk factors from the study were identified for targeted intervention.
- How the intervention strategies were implemented.
- How the intervention strategies were evaluated.
- What the challenges were with implementing the intervention strategy.
- What factors were key to the effectiveness of the intervention.
- What lessons were learned.

Targeted Risk Factor Intervention Identification

The targeted interventions identified by the jurisdictions are representative of the following key public health interventions addressed by the FDA Food Code: demonstration of knowledge, employee health controls, controlling hands as a vehicle of contamination, and time and temperature parameters for controlling pathogens. Intervention strategies were used by the jurisdictions to target one or more of the following major risk factors: improper holding temperatures, poor personal hygiene, and contaminated equipment. Specific employee behaviors and preparation practices studied included handwashing/personal hygiene, temperature, cold holding, date marking, cooling, employee health/sick policy, food safety training, and contaminated equipment.

Six interview participants identified handwashing/personal hygiene or cold holding as one of the most common risk factors studied. When asked what aspects of handwashing were studied, participants identified behavioral aspects, such as employees not washing their hands when required, and issues with handwashing facilities and equipment, including not having the proper supplies available at a handwashing sink. The aspects of personal hygiene studied included employees experiencing sneezing, coughing, runny nose, or watery eyes and employees observed eating, drinking, or smoking while preparing food. Participants identified the following aspects of cold holding as a risk factor: issues with cold holding equipment resulting in improper holding temperatures, coolers being too full of food products or exceeding load line capacity, improper spacing of food products to promote air circulation, local regulations allowing cold holding of time/temperature control for safety (TCS) foods at 45°F (versus 41°F) or less, and TCS foods held at room temperature (not using time without temperature control as the public health control). Three interview participants identified date marking or contaminated equipment as one of the risk factors studied, two identified temperature or employee health/sick policies, and one identified cooling or food safety knowledge training as one of the risk factors studied.

To determine how targeted interventions were chosen, interview participants were asked to identify the risk factor information used to develop their intervention strategies. Seven interview participants chose risk factors based on frequently-cited violations, three utilized FDA-provided risk factor study data to identify targeted interventions, two used violations closely linked to foodborne illnesses, and one used behavior issues. One other method used was an internal evaluation or scoring system to identify most frequently cited risk factor violations. Additionally, some jurisdictions used multiple sources of information in the process of identifying targeted interventions.

The targeted risk factor interventions implemented by the study participants were compared to the intervention strategies included within, and recommended by, the FDA’s national risk factor studies/trend report. The most recent FDA risk factor study identified employee handwashing, cold holding, and cooling foods properly as the risk factors needing better control to improve food safety. This demonstrates that there is consistency among study participants and the FDA national studies for handwashing and cold holding as risk factors to target for intervention strategies.
**Intervention Strategy Implementation**

Participating jurisdictions determined the intervention strategy to implement using various approaches. Two interview participants indicated they selected a strategy found in FDA-provided resources, such as information from their Retail Food Specialist, the Retail Food Program Standards Resource Center on FoodSHIELD, or a strategy that had been successfully implemented by other jurisdictions and based on data from inspections. Two participants indicated they selected an intervention strategy after conducting a research review of best practices by agency staff and through a strengths/weaknesses/opportunities/threats (SWOT) analysis, resources shared within a Retail Food Program Standards Network, and resources acquired from another SLTT retail food program.

Collaboration with external consultants, key stakeholders, and other county and state health departments was also identified as a means of selecting the intervention strategy to implement.

When implementing effective intervention strategies, three interview participants identified training internal staff or creating/utilizing a food safety advisory group comprised of regulators, regulated entity representatives, and community members, as critical to guide the process.

> We used the data to show our staff where our issues could be in the field, and where the knowledge gaps were for the facility… It’s continual education of them on our training program, making sure we revisit with our senior and tenured staff members via team meetings and staff meetings to cover particular interventions.

Participants explained that the process of internal staff training to implement intervention strategies also involved the development of training materials and holding staff discussions to review strategies and get input from inspectors regarding any issues encountered. Staff training was conducted either by standardized supervisors or the team that developed the training material. Information covered during staff training included: (1) identifying why a risk factor is out of compliance – with emphasis on providing onsite education and educational materials for industry; (2) reviewing corrective action plans; (3) discussing active managerial control (AMC); and (4) making suggestions for the future. The source of information for staff training varied among interview participants to include benchmarked information created by researching other health departments in the nation and online information and handouts created by the jurisdiction, using the jurisdiction’s risk factor study, SWOT analysis and strategic plan, and FDA, state, and local food codes.

Other implementation efforts identified included creating a sample employee health policy for facilities to adopt, creating basic food safety guidelines in multiple languages for facilities, working with local media outlets such as television stations and newspapers for messaging, and incorporating AMC as part of the inspection process. Six interview participants distributed communication products, five participants had food safety information translated into other languages, and four participants created agreements or policies for distribution and increased educational efforts on the risk factor being targeted. Creation of toolkits for employees to use with regulated establishments was identified by two interview participants. When interview participants were asked to clarify if their jurisdiction assessed during inspections the extent a retail food establishment has incorporated AMC into their operations, the responses were mixed. Some additional implementation efforts identified included a food handler certification program, encouraging managers to lead by example, an external consultation program, a recognition program, and increased quality assurance.
Intervention Strategy Evaluation

Methods used to measure the effectiveness of the implemented intervention strategies varied among the interview participants. The most commonly identified tool for measuring effectiveness was the adoption of AMC by the food facility. One interview participant stated, “The adoption of AMCs was… a measurable outcome of the consultant intervention work.” When asked how AMC was measured by inspectors, interview participants indicated the need to look for proactive systems used to attain control of food safety during routine inspections. Food industry staff are trained on many subjects, including when and how to wash hands, proper set up of the three-compartment sink, toxic item storage, and using color coded cutting boards, and identifying a designated staff person to monitor employee hygiene, employee health information, and sanitary procedures. One jurisdiction identified a template used to measure the food industry’s progress toward implementing AMC and a training program for inspectors to observe and measure AMC to ensure consistency during inspections. Trained inspectors relied on AMC training materials when assessing the success of a retail food facility’s implementation. The inspector training program included training on looking for written food safety policies, training on policies, verification that the training has been conducted, and examination of any corrective actions implemented by the facility.

The success of the food industry’s implementation of AMC for the risk factor intervention strategy was determined through risk and performance assessment reviews conducted by one jurisdiction. This was a formal method of evaluation conducted annually to report on a results-based accountability performance measure: percent of food service establishments (FSEs) demonstrating FDA risk factor control measures to reduce foodborne illness. This measure captured the percentage of all FSEs found to be in compliance with risk factor control measures upon completion of all inspections in a 12-month period. This measure was assessed at one point in time at the end of each fiscal year. Using a risk- and performance-based assessment, food regulatory programs were able to identify FSEs that warranted more frequent inspections due to non-compliance. An FSE was in poor compliance if its historical performance assessment indicated an average of four or more risk factors and/or public health intervention items, or an average of four or more repeat violations of any type. A reduction in inspection frequency indicated an improvement in compliance.

The second most identified method used to evaluate intervention effectiveness was measurement of inspection scores and changes in compliance over time. Other methods included:

- Examining trends in compliance status for regulatory inspections conducted after implementation of the intervention strategy.
- Data collection over a long period of time.
- A holistic overview of all facilities that does not just target one particular risk factor.
- Use of a regular feedback form or questionnaire to clients (including evaluation questions on regular inspection forms).
- Using the baseline/risk factor survey.
- Using a results-based accountability model for inspections.
- Increasing inspection frequency for identified risk factors.
- Measuring outbreaks.
- Increasing inspection frequency for facilities identified in the study.

Jurisdictions were asked if routine inspection data was reviewed to identify trends in risk factor compliance status between risk factor studies. It was reported that supervisors are reviewing reports from software programs to: (1) monitor out-of-control risk factors identified during routine inspections; (2) identify risk factor trends related to conformance with Standard 5; (3) take a focused approach using inspection results for foodborne illness and outbreak investigations in a year; (4) collect risk factor compliance information for an annual review to identify trends; (5) communicate with food program management and staff in formal presentations; and (6) seek feedback from staff to identify improvements in partnership with industry for long-term control – with an emphasis on AMC and the use of risk control plans when needed. Additionally, jurisdictions interviewed stated that there are performance measures including a measure of compliance with risk factors.
Lessons Learned

Challenges with Implementing the Intervention Strategy

Lack of resources such as staffing, budget, and time were identified by six interview participants as a challenge with implementing a risk factor intervention strategy. Furthermore, five interview participants identified staff acceptance of the intervention and willingness to participate, as a challenge. Other notable challenges mentioned during the interviews included staff changes among SLTTs, state mandates, the long-term approach of the process, a lack of systems to pull and analyze data, hard-to-measure intervention strategies, and challenges related to COVID-19.

"We struggled with staff changing. We had an education campaign all mapped out, we implemented it, and then over the past year and a half we had multiple staff changes. So, it was really hard for us to gain footing with that. We're a smaller health department. We had, at that time, four inspectors. We had a turnover pretty much of everyone in five years besides [me]. So it was really hard.

Additional barriers to intervention implementation included lack of sustained behavior over a long period of time, difficulty creating unique interventions, size of county, management changes, and an iterative process requiring the constant update of practices.

Figure 1. Challenges with implementing risk factor intervention strategies

Respondents who participated in the KIs identified fifteen factors they deemed to pose challenges to implementing risk factor interventions.
Successes with Implementing the Intervention Strategy

Two significant factors that were key to the effectiveness of intervention strategy implementation were strong training programs, tools, and resources and the willingness of staff to participate in the intervention. Four interview participants stated that having strong training programs, tools, and resources was a key factor contributing to their success. One interview participant stated:

“You do have to train your staff effectively. Everyone does not do an inspection the same way, and that’s absolutely fine. But you have to make sure there is consistency and uniformity. Inspectors must all look at the same things and collect the same data in the end. And then you have to make sure they go out there and train the customers, the ones we’re inspecting, effectively.

Additional factors that were identified as enhancing the effectiveness of implementation included, measurable outcomes of implementation, the NACCHO mentorship program, a well written risk factor study, stakeholder input, and partnerships with State. Furthermore, data systems, education campaigns, making information easily accessible for customers, and enforcement mechanisms were identified as success factors for implementing effective intervention strategies.

Figure 2. Success Factors Key to the Implementation of Risk Factor Intervention Strategies

Respondents who participated in the KIls identified fourteen success factors that were key to the effectiveness of the implementation of risk factor interventions.

The interview results indicate that there is overlap between factors identified as challenges and those identified as key factors for an effective implementation of the intervention. For example, resources, staff buy-in, and data systems were identified as both a challenge and a key factor in effective implementation. Additionally, state mandates were seen as a challenge, while partnership with the state was identified as a key factor in effective implementation. Community engagement was also identified as a challenge, while stakeholder input was viewed as a key success factor.
Recommendations

Strategies to Support the Implementation of Targeted Interventions

Among interview participants, the most frequently identified recommendation for the effective implementation of targeted interventions was ensuring that retail program regulatory staff conduct uniform and consistent inspections.

“I think getting a system that works and getting your staff on an equal playing field is most critical. If you’re going to use the breadth of your staff, you want to have a system in place where everybody is doing evaluations consistently. Looking at the [Retail Program] Standards, train your staff so that everybody is very competent. If you add a new component, especially when you’re developing yourself, you need to make sure everyone on the staff is very fluent.”

Additionally, interview participants recommended collaboration within states or larger regions for data sharing, best practices, buy-in from decision makers, and creating a focused, time sensitive project to make the study fit a program already in place.

“Make things fit into what you already have. Try not to recreate but try to make things fit into what you already have so that it’s not as cumbersome. You’ve already got people going out to make inspections at the fair. You’ve already got restaurants being inspected by staff…”

Another notable recommendation was to establish sustainability of the program.

“One lesson [for me] is sustainability. My concern always has been that when I leave, will this continue? And so now, getting this new position, I now have two Food Managers. So, I’ve got a lot more managerial positions in my division. I’m incorporating these principles into their work plans, so it’s institutionalized.”

When interview participants were asked if they would recommend the use of a similar process and/or intervention strategy that their program implemented to other jurisdictions, 73% answered in the affirmative. Overall, most jurisdictions interviewed recommended doing a risk factor study and the subsequent implementation of a risk factor intervention. Additionally, a risk factor study report template that includes how the jurisdiction will, or has measured, the success of the intervention strategy was recommended for enrolled jurisdictions. As noted during the sample selection process, where 30% of the highly successful jurisdictions were found to have incomplete or missing risk factor studies, this requirement may not have the desired effect in local jurisdictions. Even some jurisdictions included in the study were unable to produce written risk factor studies. NACCHO’s and CFP’s interactions with these jurisdictions show that, even amongst jurisdictions who have achieved lasting conformance with the Retail Program Standards, risk factor studies are not being used by local jurisdictions to
identify public health metrics which can be used to evaluate the effectiveness of public health interventions in food regulatory programs. By creating a template or training programs aimed at standardizing the process of creating risk factor studies, identifying risk factors and evaluating the effectiveness of effective intervention strategies, we can help local food regulatory programs to monitor their progress in protecting public health.

**Conclusion**

Although challenges with implementing target intervention strategies were identified, the KII participants in this study acknowledged many success factors that were critical in effective intervention implementation (see Figure 2). The most frequently identified success factors were strong training programs, tools, and resources; and staff buy-in, or willingness, to participate in the intervention. Respondents described challenges such as staff changes, limited resources including budget and time, and difficulty sustaining long-term behavioral change, explaining how these factors were acting as barriers toward achieving effective interventions (see Figure 1).

Despite these identified challenges, the findings of this study highlight several recommended actions that can be taken by local, state, and federal leadership to reduce barriers to the successful implementation of targeted intervention strategies and improve food safety in the United States. For example, retail regulatory programs can aim to improve staff buy-in, collaborate with states or larger regions for purposes of data sharing, and establish long-term sustainability of the intervention program. It is also important for SLTTs to work towards conformance to Standard 9, as this Standard is key to having a foundational baseline of specific Program goals and intervention strategies that are both focused and intentional, to align with the other eight Retail Program Standards. Furthermore, the results of this study can serve as a baseline for the measurement of progress towards achieving effective intervention strategies within the retail food industry.
References


Acknowledgments

This study was completed with active support from the National Association of County and City Health Officials and the Conference for Food Protection, as well as input from members of the Retail Food Safety Advisory Group. This document was supported by the U.S. Food and Drug Administration (Grant Agreement # 5U18FD007056-02). Its contents are solely the responsibility of NACCHO and CFP and do not necessarily represent the official views of the sponsors.