**Study Protocol**

**Assessment of Ill Worker Policies Study**

**Revisions**

9/25/2020 – Revisions

* Participating sites - Franklin County, OH replaced California due to a new EHS-Net cooperative agreement being issued
* Attachment 3 – Manager interview was modified to incorporate questions about when a sick worker policy had been changed to account for any confounding effects from the COVID-19 pandemic
1. **Purpose**

This study is designed to determine if an educational intervention will result in restaurants either developing or enhancing their ill worker management plans. We will administer an educational intervention in a random sample of restaurants and assess ill worker management plans in those restaurants both before and after the intervention. We will also concurrently assess ill worker management plans in a group of control restaurants. If the data show that the intervention improved ill worker management plans, we will also administer the intervention in the control restaurants.

1. **Background**

Sick food workers contribute to about a third of restaurant-related outbreaks, and to 70% of restaurant-related outbreaks caused by norovirus, the most common cause of outbreaks. Additionally, 20% of food workers report having worked with foodborne illness symptoms (vomiting and diarrhea) in the past year. Clearly, ill food workers are a significant public health problem.

In its model Food Code, The Food and Drug Administration (FDA) provides specific recommendations for restaurants on managing ill workers. For example, the Food Code states that workers should not work with foodborne illness symptoms and that workers need to tell their managers when they are sick with foodborne illness symptoms. There is some evidence that the adoption of these provisions is linked with fewer foodborne illness outbreaks (Kambhampati et al., 2016). However, not all states have adopted these provisions of the Food Code, and not all restaurants implement these provisions when they have been adopted in their state.

For this study, we designed an educational intervention for restaurant management. The goal of this intervention is to inform restaurant managers about the FDA Food Code provisions concerning ill workers, provide information on the reasons that food workers report for working while sick, to provide model ill worker management plans, and to encourage restaurant management to develop their own ill worker management plan for the restaurant. The goal of this study is to evaluate the effectiveness of this intervention. The primary outcome of interest is whether the intervention improves/enhances a restaurants’ ill worker management plans.

1. **Primary Research Questions**
	1. Does the educational intervention lead to either the development or enhancement of ill worker management plans?

Measure: change in plans from before and after intervention implementation.

* 1. What is the frequency of food safety practices in restaurants to prevent the spread of illness from an ill worker?

Measure: frequency of restaurants with good food safety practices (e.g. limitations on bare hand contact with ready to eat food, cleaning policies, policies to respond to incidents of vomiting or diarrhea, etc.)

1. **Study Design**

4.1 Summary

This study will use a quasi-experimental, non-equivalent group, pre/post-test design. The study will have two groups of restaurants (intervention and control). In both restaurant groups, we will conduct a baseline assessment of the restaurants’ ill worker management plans. Study personnel will assess the plans through manager interviews and restaurant observations (Attachments 3 and 4). For the intervention restaurants, study personnel will provide the educational intervention (see section 5.5 and using Attachment 5) at visit 1 or the same visit as the baseline observation. The intervention will consist of a visit from study personnel, who will provide verbal information about ill worker management plans (e.g., the need to exclude ill workers from working; the need for cleaning protocols for when employees become ill). Study personnel will also provide and review a written guide on ill worker management plans (Attachment 5a).

Approximately three - six months later at visit 2, study personnel will conduct another assessment in both restaurant groups (Attachments 3 and 4). If the data indicates that the intervention is preliminarily effective, study personnel will then provide the intervention to the control restaurants. Approximately three - six months later, study personnel will then conduct the visit 3 in these control restaurants to determine the effectiveness of the intervention in these restaurants.

Participation in this study is voluntary and restaurant managers will be made aware of its voluntary nature. If a restaurant decides to no longer participate following the baseline assessment (1st visit), the restaurant will be dropped from the study and recorded as a ‘loss to follow up’.

4.2 Study Sites

This study will occur within the Environmental Health Specialists Network (EHS-Net). EHS-Net is a collaborative project of the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), and eight state and local public health departments (Franklin County Ohio, New York, New York City, Minnesota, Rhode Island, Southern Nevada Health District, Harris County Texas, and Tennessee). The state and local partners work with CDC to design, collect, and analyze data from these studies. The federal partners provide funding and input into study design and data analysis.

Investigators/Collaborators/Funding

|  |  |
| --- | --- |
| **Agency** | **Investigators/Collaborators** |
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| Franklin County, Ohio Public Health | Nichole Lemin, MS |  |
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| New York City Department of Health | Wendy McKelvey, PhD, MS |  |
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| Southern Nevada Health District | Lauren Diprete, MPH |  |
| Tennessee Department of Health | John Dunn, DVM, PhD |  |

Investigators include EHS-Net staff at each of the eight EHS-Net associated state and local health departments and CDC staff. Analysis will be conducted by CDC and EHS-Net staff. Funding for this study will be provided through the EHS-Net cooperative agreement.

4.3 Sample Size Determination

We anticipate recruiting twenty intervention and twenty control restaurants at each site (N=320). A power calculation was conducted assuming initial policy compliance rates of 20-50% and a power level of 80-90%. Based on these parameters, this study is sufficiently sized to detect if there is a difference between the intervention and control restaurants of approximately 15% or more (Figure 1).



Figure 1. Power Calculation

4.4 Sample Selection

Restaurants will be randomly selected, with equal probability, within their respective site, independent of other sites. This process will give each restaurant in a particular sampling frame the same probability of being selected for study participation. There are three reasons for employing this sampling strategy: reducing sampling error, maintaining equal representation by site, and ensuring generalizability within a site. First, as stated previously, the total target population of restaurants from all EHS-Net sites combined constitutes a highly heterogeneous group. To control for such heterogeneity in the total sample, restaurants will be stratified by EHS-Net site so they can be grouped into more homogeneous strata and then sampled within stratum independently. This reduction in heterogeneity of the total sample will lead to reduction in sampling error, which can improve representativeness of the selected sample and provide estimates (e.g., means) that tend to have less variability than estimates produced from samples that were drawn using the un-stratified, simple random sampling method. Second, with equal allocation of samples (40 restaurants per site), each EHS-Net site will have equal representation in the parameter estimates of the combined sample. An additional benefit is that even sites with small sampling frames will have sufficient data points to support their site-specific analyses. Third, by ensuring that the sampling of restaurants is done by an entity (CDC) separate from the data collectors (EHS-Net sites) and employing a random selection method, we are able to minimize the potential for selection bias. Parameter estimates or study findings obtained from an unbiased study sample could be generalized to the entire EHS-Net target population.

The average response rate across EHS-Net studies that used methods similar to the proposed study is 45% (Brown et al., 2014; Radke et al., 2016). We expect a similar response rate for the proposed study. Thus, we will need to contact approximately 712 restaurants to meet our target of 320 participating restaurant

1. **Implementation and Recruitment Plan**

Study personnel (health department environmental health specialists [EHSs]) will contact randomly-selected restaurants using multiple contact methods (e.g., by telephone, postcard, electronic mail, in person visit, and/or social media tools [Attachment 1 provides template language]) as appropriate for their site advertising the study. The multiple contact methods are intended to boost participation rates and contact methods used will be recorded on the participation log (Attachment 6). If a restaurant is willing to participate, they will be enrolled after either a telephonic or in-person discussion using the Manager Recruiting Script (Attachment 2). The EHS will set a mutually-agreeable time to interview a manager that has authority over kitchen workers (e.g., kitchen manager, general manager or owner). The EHS will also conduct an observation in the kitchen area and food worker restrooms.

Restaurants will be randomly assigned to either receive the intervention initially or be in the control group.

5.1 Visit– 1 (Baseline Visit)

At the first visit, for the intervention and control restaurants, study personnel will obtain consent and interview the restaurant manager (Attachment 3) regarding existing ill worker management plans and their content. During this visit, study personnel will also observe food workers and document practices that are used to minimize the risk of disease transmission if an employee were working while ill. The observation will focus on food worker hand hygiene (use of bare hands with food; hand washing practices), handwashing station supplies (presence of soap, running water, drying method), and supplies needed to clean-up after a vomiting or diarrhea incident. These are areas/practices that are routinely observed by EHSs during routine inspections (Attachment 4). For intervention restaurants, study personnel will then provide the intervention to the restaurant manager. The intervention will explain the importance of restricting or excluding ill workers and having cleaning policies and supplies to address vomiting/diarrheal incidents (Section 5.5 for specific talking points). Additionally, they will provide and review the guide (Attachment 5a) designed to assist in developing or modifying ill worker management plans. One month following the baseline visit/visit-1, study personnel will contact the intervention restaurants via phone or e-mail to determine if policies have been implemented and or modified, no information collection will be conducted. If they have not developed a plan, study personnel will encourage the restaurants to implement the changes to reduce the likelihood of ill workers continuing to work while ill. For the control restaurants, the manager interview and restaurant observation will occur using the same format as for the intervention restaurants. No intervention will be administered for the control group in this visit.

5.2 Visit– 2

Approximately three - six months or longer (depending upon the study site capacity to do an assessment and restaurant manager availability) after the baseline visit, study personnel will reassess both groups of restaurants with the same instruments (Attachments 3 and 4) used on the initial visit. This will include interviewing the manager about the ill worker management plans and their content. An observation (Attachment 4) will again be conducted to document procedures that are used to minimize the risk of transmission if an employee were ill. If preliminary data analysis shows success with the intervention restaurants, the intervention will be provided to the control restaurants at visit 2, followed by an additional assessment described below.

5.3 Visit – 3

The third visit is dependent upon and will only be conducted in control restaurants where the intervention was provided. This visit will be conducted telephonically and will only consist of the manager interview (Attachment 3). The purpose of this visit is to gather more evidence on the efficacy of the intervention in the control group.

The following table summarizes the study process.

|  |  |  |
| --- | --- | --- |
|  | **Intervention Restaurants** |  **Control Restaurants** |
| Manager Recruiting Script | ✓ | ✓ |
| **Visit -1** |
| Manager Interview | ✓ | ✓ |
| Restaurant Observation | ✓ | ✓ |
| Educational Intervention | ✓ | – |
| **Visit - 2** |
| Manager Interview | ✓ | ✓ |
| Restaurant Observation | ✓ | ✓ |
| Educational Intervention | – | ✓ |
| **Visit- 3 (Dependent on Visit – 2)** |
| Manager Interview | – | ✓ |

5.4 Preliminary Measure of Success of Intervention

The control and intervention arms of this study will be conducted simultaneously. If three or more restaurants per study site within the intervention arm have either developed or changed their practices for managing ill workers, the intervention will then be provided to all control restaurants that have not yet had their follow up (visit – 2) visit. No attempt will be required of the study personnel to re-engage control restaurants that have already had their second visit performed.

5.5 Intervention Talking Points

The intervention will be conducted by study personnel, senior experienced environmental health specialists. Given the knowledge and experience of this group, and the diversity of restaurant managers, study personnel will customize their presentation of the materials to meet the needs of the restaurant managers. Prior to conducting the research, all study personnel will meet to discuss implementation techniques and ensure that all study personnel are using the same talking points.

5.5.1 Preliminary Talking Points

* Lots of outbreaks are caused by ill food workers
* 1 in 5 Food workers reported working while sick with vomiting and diarrhea
* Infected food workers cause 70% of the reported norovirus outbreaks from contaminated food
* Humans are the reservoir for norovirus and may be asymptomatic
* Norovirus is spread from vomitus or fecal contamination from an infected person
* Excluding an ill worker is the best method to prevent contamination
* Good personal hygiene and limiting bare hand contact with food minimize the spread of contamination
* Contamination can persist on surfaces in the kitchen and dining room
* Different cleaners and sanitizers work for different types of contamination it is important to match them
* Employees report working while sick due to
	+ Staff shortages
	+ Not letting their co-workers down
	+ Need the pay
	+ Unable to find replacements
* All restaurants will eventually have an employee report that they are ill
* There are minimum code requirements that a restaurant is expected to meet, however they can do more to minimize the impact to their business and prevent foodborne illness
	+ Introduce guide with various strategies and draft procedures.
* If technological capacity exists, a site may show or direct a restaurant manager to FDA video testimonials of victims of foodborne illness
* <https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm345399.htm?source=govdelivery>
1. **Data Handling and Analysis**

*Analysis Plan*

 Analysis will be performed by the EHS-Net analytical workgroup (comprised of CDC and EHS-Net staff). The analysis of the data will proceed in several stages. The first stage of analysis will involve data cleaning, editing, and recoding. The data will be checked for accuracy and examined for inconsistencies. Frequency responses will be calculated for each variable to examine item non-response and extraneous responses. Variables with high item non-response or of poor quality will be discarded. The second stage will involve a descriptive analysis of the data set by running univariate frequencies and cross-tabulations for selected variables by demographic variables. Tests for association will be done using chi-square and t-tests. Analysis may also involve regression modeling of the data to examine any multivariable relationships and to control for confounding.

*Analysis Software*

 Software that will be used to analyze the data may include Microsoft Excel and SAS.

*Data Entry, Editing, and Management*

Data will be entered into a secured web-based information system designed specifically for this project using the REDCAP instance hosted by CDC’s National Center for Emerging, Zoonotic, and Infectious Diseases. User accounts will be issued to the EHS-Net investigator/collaborator in each state. Account privileges identify the data a specific user is authorized to access and the functions they are authorized to perform. Each EHS-Net investigator/collaborator is responsible for the administration of the system for his or her state, and includes user administration, correction and deletion of records. Data records are owned by the state entering the data. Each state must grant permission to other states or agencies who would like to use the data.

 The data entered into this system may only be analyzed, presented, or published following the EHS-Net publication procedures.

*Study Limitations*

The study is limited to the participating EHS-Net associated state and local health departments so ultimately it may not have overall generalizability to restaurants in other jurisdictions. Also, due to logistical concerns, the restaurants are further restricted to establishments that have a manager that can communicate in English, this may affect the applicability of the results to other non-English speaking restaurants. Furthermore, since this intervention has not been attempted before, we have made our best estimates on determining the proper sample size. It is possible that the study may be under-powered.

*Dissemination, Notification, and Reporting of Results*

 Results of data analysis will be published in professional journals and presented at meetings. They will also be available for state and local health departments to utilize in their efforts to identify and change certain retail food practices that may contribute to foodborne illnesses. Agencies may also disseminate reports to foodservice establishments where research was conducted.

1. **Risks Summary**

*Current Risks*

This study presents no more than minimal risk of harm to participants as the probability and magnitude of harm or discomfort anticipated in answering these questions are not greater in and of themselves than those ordinarily encountered in daily life. Participants in this study may provide business contact information if it is not already contained in the health departments records to aid in scheduling future visits.

*Future Risks*

No future risks exist since business contact information on the participation log (Attachment 6) will be destroyed once data collection is complete and only the coded identifier will be used for further analysis. These materials will be secured in locked cabinets until destruction.

*Benefits*

 The participating restaurants will receive information on the risks posed by sick food workers and the needs for developing enhanced employee health policies. The information learned from this study can be used to implement future ill worker interventions by local and state food safety programs leading to safer food.

1. **Informed Consent**

This project has been classified as research not involving identifiable human subjects. CDC institutional review board (IRB) approval is not required (Section 10) and informed consent is not required. However, to ensure that restaurant managers understand the voluntary nature of their participation and any potential risks and benefits we will obtain verbal consent prior to interviewing the manager (Attachment 3).

1. **Funding Information**

This study is funded by CDC as a project through the EHS-Net cooperative agreement.

1. **Institutional Review Boards**

 This project has been classified as research not involving identifiable human subjects. CDC institutional review board (IRB) approval is not required. This research study centers around restaurant food safety policies and practices, not about human subjects.

1. **List of Attachments**

Att. 1 – Study advertisement template

Att. 2 – Manager recruiting script

Att. 3 - Manager informed consent and interview

Att. 4 – Restaurant observation form

Att. 5 – Intervention Log

Att. 5a - Sick food worker toolkit

Att. 6 – Participation log

1. **References**

Brown, L. G., Le, B., Wong, M. R., Reimann, D., Nicholas, D., Faw, B., . . . Selman, C. A. (2014). Restaurant manager and worker food safety certification and knowledge. *Foodborne pathogens and disease, 11*(11), 835-843.

Kambhampati, A., Shioda, K., Gould, L. H., Sharp, D., Brown, L. G., Parashar, U. D., & Hall, A. J. (2016). A State-by-State Assessment of Food Service Regulations for Prevention of Norovirus Outbreaks. *J Food Prot, 79*(9), 1527-1536. doi:10.4315/0362-028x.jfp-16-088

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