

1 **Study Protocol**

2 **Assessment of Ill Worker Policies Study**

3 **Revisions**

4 9/25/2020 – Revisions

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

9 2/23/2022 – Revisions

- 10 • Added att. 3a – Manager interview with simplified consent language

11

12 **1. Purpose**

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

19 **2. Background**

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

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

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

36 **3. Primary Research Questions**

37

- 38 a. Does the educational intervention lead to either the development or enhancement of ill worker  
39 management plans?

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

- 41 b. What is the frequency of food safety practices in restaurants to prevent the spread of illness  
42 from an ill worker?

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

#### 4 4. Study Design

##### 5 4.1 Summary

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

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

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

##### 23 4.2 Study Sites

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

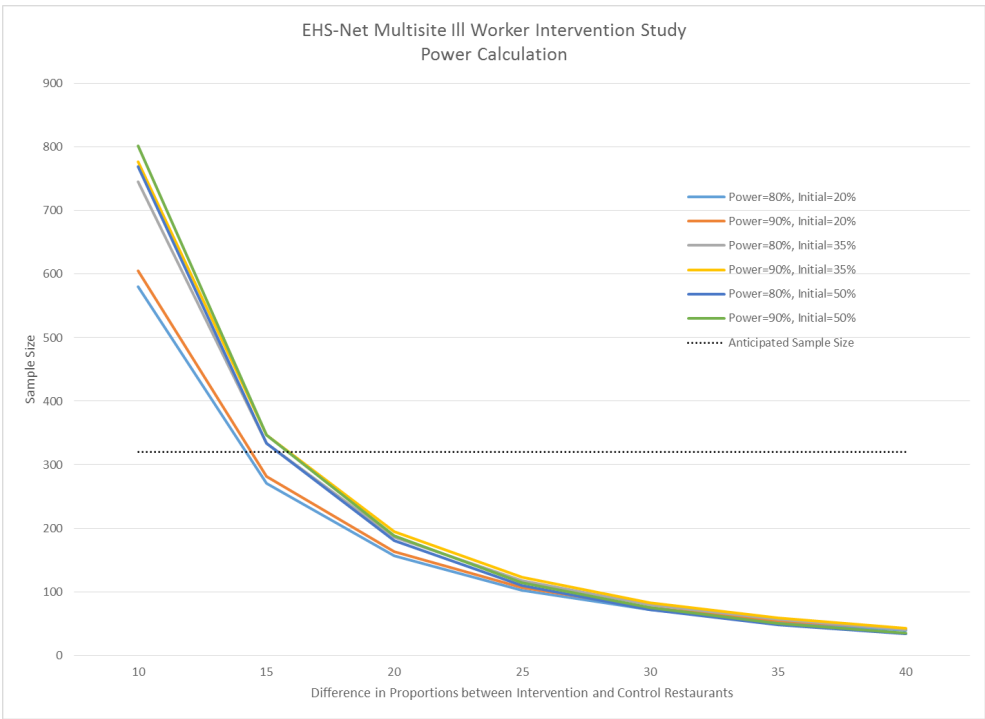
##### 32 Investigators/Collaborators/Funding

Agency	Investigators/Collaborators	
CDC	Adam Kramer, ScD, MPH	Laura Brown, PhD
Franklin County, Ohio Public Health	Nichole Lemin, MS	
Harris County, Texas Health Department	JoAnn Monroy, MPH	
Minnesota Department of Health	Kirk Smith, DVM, PHD	
New York City Department of Health	Wendy McKelvey, PhD, MS	
New York State Department of Health	Kristin Navarette, MD, MPH	
Rhode Island Department of Health	Ernest Julian, PhD, MA	
Southern Nevada Health District	Lauren Diprete, MPH	

1  
2 Investigators include EHS-Net staff at each of the eight EHS-Net associated state and local health  
3 departments and CDC staff. Analysis will be conducted by CDC and EHS-Net staff. Funding for this study will be  
4 provided through the EHS-Net cooperative agreement.  
5

6 **4.3 Sample Size Determination**

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



11  
12 **Figure 1. Power Calculation**

13 **4.4 Sample Selection**

14 Restaurants will be randomly selected, with equal probability, within their respective site, independent of other  
15 sites. This process will give each restaurant in a particular sampling frame the same probability of being selected  
16 for study participation. There are three reasons for employing this sampling strategy: reducing sampling error,  
17 maintaining equal representation by site, and ensuring generalizability within a site. First, as stated previously,  
18 the total target population of restaurants from all EHS-Net sites combined constitutes a highly heterogeneous  
19 group. To control for such heterogeneity in the total sample, restaurants will be stratified by EHS-Net site so  
20 they can be grouped into more homogeneous strata and then sampled within stratum independently. This  
21 reduction in heterogeneity of the total sample will lead to reduction in sampling error, which can improve  
22 representativeness of the selected sample and provide estimates (e.g., means) that tend to have less variability  
23 than estimates produced from samples that were drawn using the un-stratified, simple random sampling  
24 method. Second, with equal allocation of samples (40 restaurants per site), each EHS-Net site will have equal

1 representation in the parameter estimates of the combined sample. An additional benefit is that even sites with  
2 small sampling frames will have sufficient data points to support their site-specific analyses. Third, by ensuring  
3 that the sampling of restaurants is done by an entity (CDC) separate from the data collectors (EHS-Net sites) and  
4 employing a random selection method, we are able to minimize the potential for selection bias. Parameter  
5 estimates or study findings obtained from an unbiased study sample could be generalized to the entire EHS-Net  
6 target population.

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

## 10 **5. Implementation and Recruitment Plan**

11  
12 Study personnel (health department environmental health specialists [EHSs]) will contact randomly-selected  
13 restaurants using multiple contact methods (e.g., by telephone, postcard, electronic mail, in person visit,  
14 and/or social media tools [Attachment 1 provides template language]) as appropriate for their site advertising  
15 the study. The multiple contact methods are intended to boost participation rates and contact methods used  
16 will be recorded on the participation log (Attachment 6). If a restaurant is willing to participate, they will be  
17 enrolled after either a telephonic or in-person discussion using the Manager Recruiting Script (Attachment 2).  
18 The EHS will set a mutually-agreeable time to interview a manager that has authority over kitchen workers  
19 (e.g., kitchen manager, general manager or owner). The EHS will also conduct an observation in the kitchen  
20 area and food worker restrooms.

21  
22 Restaurants will be randomly assigned to either receive the intervention initially or be in the control group.

### 23 24 5.1 Visit- 1 (Baseline Visit)

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

### 43 44 5.2 Visit- 2

45 Approximately three - six months or longer (depending upon the study site capacity to do an assessment and  
46 restaurant manager availability) after the baseline visit, study personnel will reassess both groups of restaurants

1 with the same instruments (Attachments 3 and 4) used on the initial visit. This will include interviewing the  
 2 manager about the ill worker management plans and their content. An observation (Attachment 4) will again be  
 3 conducted to document procedures that are used to minimize the risk of transmission if an employee were ill. If  
 4 preliminary data analysis shows success with the intervention restaurants, the intervention will be provided to  
 5 the control restaurants at visit 2, followed by an additional assessment described below.

6 5.3 Visit - 3

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

10 The following table summarizes the study process.

	<b>Intervention Restaurants</b>	<b>Control Restaurants</b>
Manager Recruiting Script	✓	✓
<b>Visit -1</b>		
Manager Interview	✓	✓
Restaurant Observation	✓	✓
Educational Intervention	✓	-
<b>Visit - 2</b>		
Manager Interview	✓	✓
Restaurant Observation	✓	✓
Educational Intervention	-	✓
<b>Visit- 3 (Dependent on Visit - 2)</b>		
Manager Interview	-	✓

11

12 5.4 Preliminary Measure of Success of Intervention

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

18 5.5 Intervention Talking Points

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

24 5.5.1 Preliminary Talking Points

- 25 • Lots of outbreaks are caused by ill food workers
- 26 • 1 in 5 Food workers reported working while sick with vomiting and diarrhea
- 27 • Infected food workers cause 70% of the reported norovirus outbreaks from contaminated food
- 28 • Humans are the reservoir for norovirus and may be asymptomatic
- 29 • Norovirus is spread from vomitus or fecal contamination from an infected person

- 1 • Excluding an ill worker is the best method to prevent contamination
- 2 • Good personal hygiene and limiting bare hand contact with food minimize the spread of contamination
- 3 • Contamination can persist on surfaces in the kitchen and dining room
- 4 • Different cleaners and sanitizers work for different types of contamination it is important to match them
- 5 • Employees report working while sick due to
  - 6 ○ Staff shortages
  - 7 ○ Not letting their co-workers down
  - 8 ○ Need the pay
  - 9 ○ Unable to find replacements
- 10 • All restaurants will eventually have an employee report that they are ill
- 11 • There are minimum code requirements that a restaurant is expected to meet, however they can do
- 12 more to minimize the impact to their business and prevent foodborne illness
  - 13 ○ Introduce guide with various strategies and draft procedures.
- 14 • If technological capacity exists, a site may show or direct a restaurant manager to FDA video
- 15 testimonials of victims of foodborne illness
- 16 • [https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/](https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm345399.htm?source=govdelivery)
- 17 [IndustryandRegulatoryAssistanceandTrainingResources/ucm345399.htm?source=govdelivery](https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/ucm345399.htm?source=govdelivery)

18  
19

## 6. Data Handling and Analysis

### 20 *Analysis Plan*

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

30

### 31 *Analysis Software*

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

33

### 34 *Data Entry, Editing, and Management*

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

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

44

### 45 *Study Limitations*

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

#### 7 8 *Dissemination, Notification, and Reporting of Results*

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

### 13 **7. Risks Summary**

#### 14 *Current Risks*

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

#### 19 20 *Future Risks*

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

#### 24 25 *Benefits*

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

### 29 **8. Informed Consent**

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

### 34 **9. Funding Information**

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

### 36 **10. Institutional Review Boards**

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

### 40 41 **11. List of Attachments**

- 1 Att. 1 – Study advertisement template
- 2 Att. 2 – Manager recruiting script
- 3 Att. 3 - Manager informed consent and interview
- 4 Att 3a – Manager informed consent and interview
- 5 Att. 4 – Restaurant observation form
- 6 Att. 5 – Intervention Log
- 7 Att. 5a - Sick food worker toolkit
- 8 Att. 6 – Participation log

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10 **12. References**

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