

EHS-Net Hand Hygiene Study Protocol

I. Project Overview

Title

EHS-Net Hand Hygiene Study

Protocol Summary

Good hand hygiene is of critical importance in preventing the spread of illness in a food service environment. However, few studies have examined in detail the nature of personal hygiene policies and practices in food service establishments. The purpose of this study is to collect descriptive data on restaurant hygiene policies, environments, and food worker hygiene practices in restaurants, and to examine relationships among restaurant hygiene policies, environment factors, and hygiene practices. Data for this study will be collected through interviews with restaurant managers and observations of restaurant kitchen environments and workers. This is an Environmental Health Specialists Network (EHS-Net) special study. EHS-Net is a collaboration involving the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and eight Emerging Infectious Program sites (California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee); these partners have come together in an effort to better understand the environmental causes of foodborne illness.

Investigators/collaborators/funding

Investigators include EHS-Net staff at each of the eight EHS-Net sites. Funding for this study will be provided through EHS-Net.

II. Introduction

Literature Review/Justification

Foodborne illness is a significant public health issue—recent research indicates that foodborne diseases are a significant cause of illness in the United States and are responsible for substantial economic costs (Mead et al, 1999; Frenzen et al, 1999). Research also indicates that eating outside the home is associated with foodborne illness—epidemiological research has found that over half of reported foodborne illness outbreaks are associated with restaurants (Sulka & Huddle, 2003), and case control studies have found that people with foodborne illnesses were more likely to have eaten outside the home than were their non-ill controls (Hennessy et al, 1998; Kassenborg et al, 1998).

Research has also indicated that good hand hygiene is of critical importance in preventing the spread of illness in a food service environment--epidemiological investigations have consistently found that poor personal hygiene is a contributor to foodborne illness outbreaks in food service establishments (DHHS, 2001). Given the importance of food handlers' behavior to the prevention of foodborne illness, it is crucial to gain a better and more detail understanding of the hygiene practices of food service workers, and the factors that impact those practices. However, few studies have done this (Clayton and Griffith, 2004). Thus, the purpose of this study is to collect data on personal hygiene in food service establishments. Specifically, this study has two goals:

- 1) to collect descriptive data on food service establishment hygiene policies and environments, and food service worker hygiene practices, and
- 2) to examine relationships among restaurant hygiene policies, environmental factors, and food service worker practices.

Objectives

The primary objectives of this study are to describe hygiene policies, environments, and practices in food service establishments and to examine the relationships among hygiene policies, environments, and practices in food service establishments.

III. Procedures/Methods

Design

This study will use a cross-sectional design to collect information about hand hygiene practices, policies, and environments in restaurants. Information will be collected through an interview with the kitchen manager and through observations of the restaurant kitchen and of workers in the kitchen. The study will be performed by EHS-Net environmental health specialists (EHSs) who work in state health departments, and by EHSs who work in local health departments.

Data Collection

The EHS-Net specialists will contact randomly selected restaurant by telephone to determine their interest in participating in the study. If the restaurant is willing to participate, then the EHS-Net specialist will arrange a time to conduct the survey. For the interview portion of the questionnaire, the EHS-Net specialist will interview a manager with authority over the kitchen. For the observation portion of the survey, the EHS-Net specialist will observe the establishment kitchen, observing the environment and watching food preparation processes. The entire survey will take approximately two hours to complete.

All restaurant locations and study participants will remain anonymous. Restaurants will be assigned an ID number generated by the electronic database and no locations or names will be recorded.

Study Population

The catchment area for this study includes all or some of counties in each of the following eight states: California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee. Each state will select a convenient sample of counties from which to randomly select a minimum of fifty restaurants for the study. Only restaurants that meet the EHS-Net definition of a restaurant will be included in the study. A minimum of fifty restaurants in each of the eight states will yield a total study population of at least 400 restaurants. The study population will include all restaurants in the EHS-Net catchment area. Each state will include only one restaurant from each regional or national chain in its study population.

Study Timeline

The following table provides the estimated timeline for project activities.

Activity	Time Schedule
Conduct pilot	2 weeks after IRB approval
Conduct study	1-4 months after IRB approval
Analyze data collected	5-8 months after IRB approval

Informed Consent

A waiver of documentation of informed consent is requested in accordance with 45 CFR 46.117(c)(2). The proposed research meets the first criteria for waiver, as it 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. Additionally, as participants in this study will not be

providing personally identifiable information, activities for which written consent is not normally required outside the research context, the study also meets the second criteria for waiver.

Before conducting the study, we will obtain verbal informed consent from the restaurant manager. The environmental health specialist will read the manager a short introduction describing the purpose of the study and how the data will be used (See Appendix A). The interviewer will then ask the manager if he or she agrees to participate in the study. If the manager agrees, the interview will proceed; if the manager does not agree, the interview will cease.

Study Instrument

The data collection instrument was developed by EHS-Net specialists. The instrument consists of three sections: an interview section, an environment observational section, and a process observational section. In the interview section, the specialist will interview the establishment manager, or the person who has authority over the kitchen, about the restaurant and hand hygiene policies and practices. In the observation sections, the specialist will observe and record data on the environment and activities in the kitchen area. (See Appendix B).

Data Handling and Analysis

Analysis Plan

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. A frequency response will be done 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 (e.g. Independent vs. Chain restaurants). Tests for association will be done using chi-square and t-tests. Analysis may also involve regression modeling of the data to examine any multivariate relationships and to control for confounding.

Analysis Software

SAS system for windows version 8 will be used to analyze data.

Data Entry, Editing and Management

Data will be entered into a web-based information system designed specifically for this project. User accounts will be issued to the EHS-Net specialist 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 specialist is responsible for the administration of the system for his or her state, and includes user administration, correction and deletion of records. All data records are owned by the state entering the data. Each state has authority over its records and must grant permission to other states or agencies who would like to use the data.

Restaurant evaluation records will be assigned an identification number when submitted to CDC through this system. The name, address, and contact information for the restaurant will not be collected by the state during the evaluations. The only information collected and submitted to CDC will be the state and zip code in which the restaurant is located.

The data entered into this system may only be analyzed, presented, or published by permission of the states owning the data according to the EHS-Net publication procedures.

Bias in data collection, measurement and analysis

Given the nature of the study, the data are subject to interviewer bias and recall bias on the part of the interviewee.

Study Limitations

Data will be collected in those states participating in EHS-Net (California, Colorado, Connecticut, Georgia, Minnesota, New York, Oregon, and Tennessee). Therefore, findings may not be generalizable to the U.S. population as a whole. As mentioned above the data may be subject to interviewer and recall bias. This will be reported with the analysis of the data.

Dissemination, Notification, and Reporting of Results

Results of the analysis of the data will be published and presented in appropriate journals and meetings. State and local health departments may disseminate reports to the foodservice establishments in which evaluations were done if they so choose.

EHS-Net Hand Hygiene Data Collection Instrument

Appendix A: Manager Informed Consent Script

Let me give you a little background on why I'm here and what we are going to be doing. I'm working with _____ (state health department) on a research project designed to help us better understand restaurant policies and practices. Your restaurant was picked at random to be in this project. Participation in this study is voluntary. You can choose to stop at any time. If you don't want to be part of the study or if you change your mind later, nothing will happen to you. Whether you are part of the study or not will not affect your restaurant's grade on any health inspection.

We are doing this study to get a better understanding of restaurant policies and practices concerning hand hygiene. While I'm here, I'm going to ask you some questions about this restaurant's policies and practices, and I will observe your kitchen and some of your employees working. The questions in the interview do not ask anything private. If any of the questions make you uncomfortable you can choose not to answer them. The information we collect today will be combined with information from other restaurants in eight states. Your name and your restaurant's name will not be linked in any way to the information we collect, nor will they be included in any reports.

Do you have any questions?

If you have any questions at a later time, you can contact: (Local Contact Name). Their information is on this card. (Give them card)

Do you agree to be part of the study?

- Yes (Continue with the interview)
- No (Thank you for your time)

Okay, I'd like to interview you first, for about 20 minutes, and then I'd like to see your kitchen.

Appendix B: Study Instrument

Part B. Manager Interview

Date survey conducted: ____/____/2004

A. Manager Interview

Demographics of Establishment

1. Is this an independent establishment or a chain establishment?

- Independent
 Chain
 Unsure
 Refused

2. Approximately how many meals are served here daily? _____ Unsure Refused

Training and Certification

3. How many food workers work here, in total? _____ Unsure Refused

4. Do any food workers receive food safety training, such as a course or a class, or on-the-job training?

- Yes Unsure *If Unsure, skip to #7*
 No *If No, skip to #7* Refused *If Refused, skip to #7*

5. How many food workers have received food safety training? _____ Unsure Refused

6. Is food safety training for food workers, taught by...

a. your corporation or company?

- Yes Unsure
 No Refused

b. a private organization or consultant?

- Yes Unsure
 No Refused

c. a state or local regulatory agency?

- Yes Unsure
 No Refused

d. by kitchen employees, for example on-the-job training?

- Yes Unsure
 No Refused

e. by any other organization?

- Yes *If Yes, What organization? _____* Unsure Refused
 No
 Unsure
 Refused

7. How many kitchen managers work here, in total? _____ Unsure Refused

8. How long have you been a kitchen manager here? _____ Unsure Refused

9. How long have you been a kitchen manager altogether, including jobs at restaurants other than this one? _____ Unsure Refused

10. **Does your company policy require kitchen manager food safety certification?**
 Yes Unsure
 No Refused
11. **Are any kitchen managers food safety certified?**
 Yes Unsure *If Unsure, skip to #15*
 No *If No, skip to #15* Refused *If Refused, skip to #15*
12. **How many kitchen managers are food safety certified?** _____ Unsure Refused
13. **Are you food safety certified?**
 Yes Unsure
 No Refused
14. **Is food safety certification training for kitchen managers, taught by...**
- a. **your corporation or company?**
 Yes Unsure
 No Refused
- b. **a private organization or consultant?**
 Yes Unsure
 No Refused
- c. **a state or local regulatory agency?**
 Yes Unsure
 No Refused
- d. **by kitchen employees, for example on-the-job training?**
 Yes Unsure
 No Refused
- e. **by any other organization?**
 Yes *If Yes, What organization?* _____ Unsure Refused
 No
 Unsure
 Refused

Policies and Practices

15. **When handling food, do food workers here ever wear disposable gloves?**
 Yes Unsure
 No Refused
16. **Does this restaurant have a policy concerning when gloves are to be worn?**
 Yes Unsure *If Unsure, skip to #18*
 No *If No, skip to #18* Refused *If Refused, skip to #18*

17. What is the policy? (*Do not read answer choices- check all that apply*)

- Answer given
 Food workers must wear gloves at all times while working in the kitchen
 Food workers must wear gloves when handling ready-to-eat foods
 Food workers must wear gloves when handling raw meat or poultry
 Food workers must wear gloves when they have cuts or other skin injuries
 Other _____
 Unsure
 Refused

Note: When the worker has finished answering the question, ask one probing question: "Are there any other policies concerning when gloves are to be worn?"

18. Do new food workers learn when to wear and change gloves?

- Yes Unsure If *Unsure*, skip to #20
 No If *No*, skip to #20 Refused If *Refused*, skip to #20

19. How do new food workers learn about glove use? Do they learn about it with...

a. written instructions?

- Yes Unsure
 No Refused

b. with visual aids?

- Yes Unsure
 No Refused

c. a video?

- Yes Unsure
 No Refused

d. a verbal explanation?

- Yes Unsure
 No Refused

e. a demonstration?

- Yes Unsure
 No Refused

f. formal certification?

- Yes Unsure
 No Refused

20. Does this restaurant have a policy concerning handwashing?

- Yes Unsure
 No Refused

21. **What is the policy? (Do not read answer choices- check all that apply)**

- Answer given
- Hands must be washed after using the bathroom
 - Hands must be washed after touching bare human body parts other than clean hands or arms
 - Hands must be washed after coughing, sneezing, using a handkerchief, or tissue
 - Hands must be washed after using tobacco
 - Hands must be washed after eating or drinking
 - Hands must be washed after handling dirty equipment or utensils
 - Hands must be washed after handling raw meat, poultry, or seafood
 - Hands must be washed between working with raw food and ready-to-eat food
 - Hands must be washed before putting on gloves for working with food
 - Other _____
- Unsure
- Refused

Note: When the worker has finished answering the question, ask one probing question: "Are there any other policies concerning handwashing?"

22. **Do new food workers here learn how and when to wash their hands?**

- Yes Unsure If *Unsure*, Skip to #24
- No If *No*, Skip to #24 Refused If *Refused*, Skip to #24

23. **How do new food workers learn about handwashing? Do they learn about it with...**

a. written instructions?

- Yes Unsure
- No Refused

b. with visual aids?

- Yes Unsure
- No Refused

c. a video?

- Yes Unsure
- No Refused

d. a verbal explanation?

- Yes Unsure
- No Refused

e. a demonstration?

- Yes Unsure
- No Refused

f. formal certification?

- Yes Unsure
- No Refused

24. **Do employees log their handwashing activities in a handwashing log?**

- Yes Unsure
- No Refused

25. Are there any incentives to encourage employees to wash their hands?

- Yes If Yes, What are they? _____
- No
- Unsure
- Refused

26. Do you have a system for reminding employees to wash their hands- for example, a bell that rings periodically?

- Yes Unsure
- No Refused

27. In what other ways do you encourage handwashing?

(Check all that apply)

- Answer given
 - Signs in kitchen
 - I watch and remind them when necessary
 - There are punishments for poor handwashing practices
 - Other _____
- Unsure
- Refused

28. Do food workers here ever use hand sanitizers?

- Yes Unsure
- No Refused

29. Does this restaurant have a policy concerning hand sanitizer use?

- Yes Unsure If *Unsure*, skip to #31
- No If *No*, skip to #31 Refused If *Refused*, skip to #31

30. What is the policy? **(Do not read answer choices- check all that apply)**

- Answer given
 - Hand sanitizers are to be used at set intervals?
 - Hand sanitizers are to be used at the workers' discretion?
 - Hand sanitizers are to be used only in conjunction with handwashing?
 - Hand sanitizers are to be used when workers don't have time to wash their hands?
 - Hand sanitizers are to be used only with certain activities?
 - Other _____
- Unsure
- Refused

Note: When the worker has finished answering the question, ask one probing question: "Are there any other policies concerning hand sanitizer use?"

31. Do new food workers here learn about hand sanitizer use?

- Yes Unsure If *Unsure*, skip to #33
- No If *No*, skip to #33 Refused If *Refused*, skip to #33

32. How do new workers learn about hand sanitizer use? Do they learn about it with...

a. written instructions?

- Yes Unsure
 No Refused

b. with visual aids?

- Yes Unsure
 No Refused

c. a video?

- Yes Unsure
 No Refused

d. a verbal explanation?

- Yes Unsure
 No Refused

e. a demonstration?

- Yes Unsure
 No Refused

f. formal certification?

- Yes Unsure
 No Refused

33. Does this restaurant have any guarantees concerning how long customers will have to wait for their food? For example, some restaurants guarantee that orders will be out to the customer in 10 minutes or less, or the food is free.

- Yes Unsure
 No Refused

34. Please describe this guarantee. _____

35. Do you consider your kitchen under-staffed, staffed adequately, or over-staffed today?

- Under-staffed
 Staffed adequately
 Over-staffed
 Unsure
 Refused

We are asking this last set of questions to learn more about perceptions of foodborne illness in the foodservice industry. This is not a “test,” and answers will not be considered as ‘right’ or ‘wrong’. Note that unlike the previous questions, these questions in no way refer to the establishment in which you work.

36. Which of the following statements best characterizes where you think food gets contaminated with germs?

- Mainly BEFORE the food arrives at a restaurant?
 Mainly IN a restaurant?
 Equally BEFORE the food arrives and IN the restaurant?

 Don't know
 Refused

37. Which **two** of the following types of food do you think are most likely to be contaminated **BEFORE** they arrive at a restaurant? (*Show card*)

- Produce (raw vegetables and fruit)
- Red meat
- Poultry
- Eggs
- Dairy products
- Pre-prepared and package foods (e.g., in cans, jars and bags)
- Fish
- Shellfish

- Don't know Don't know Don't know
- Refused Refused Refused

38. Which **two** of the following do you think are important ways that food will get significantly contaminated **IN** a restaurant? Also note again, that this does **NOT** refer to your establishment. (*Show card*)

- Insects
- Food left too long at room temperature
- Food handled with bare hands before serving
- Food kept in dirty or poorly maintained fridge or freezer
- Out-of-date food
- Contaminated or dirty counters/utensils
- Through the air via poor ventilation

- Don't know Don't know Don't know
- Refused Refused Refused

39. Which **two** of the following germs do you think are the most **FREQUENT** causes of foodborne illness? (*Show card*)

- Campylobacter
- Clostridium perfringens
- Escherichia coli (E.coli)
- Hepatitis A virus
- Giardia lamblia
- Listeria
- Norovirus (or Norwalk-like viruses)
- Salmonella
- Shigella
- Staphylococcus

- Don't know Don't know Don't know
- Refused Refused Refused

40. Which *two* of the following germs do you think are the most **SERIOUS** causes of foodborne illness? (*Show card*)

- Campylobacter
 - Clostridium perfringens
 - Escherichia coli (E.coli)
 - Hepatitis A virus
 - Giardia lamblia
 - Listeria
 - Norovirus (or Norwalk-like viruses)
 - Salmonella
 - Shigella
 - Staphylococcus
- Don't know Don't know Don't know
 Refused Refused Refused

41. If a toilet door was left open after use, is there a reasonable risk that germs travel through the air to contaminate food?

- Yes
- No
- Don't know
- Refused

42. If someone who was sick with a stomach infection vomited in the presence of a second person (without splashing them), is there a reasonable risk that the second person will also become sick with the stomach infection?

- Yes
- No
- Don't know
- Refused

43. If someone who was sick with a stomach infection vomited on a food handling surface, but the vomit was then routinely cleaned up, is there a reasonable risk that the surface could still contaminate food?

- Yes
- No
- Don't know
- Refused

44. If someone who was sick with a stomach infection vomited on the floor **AT LEAST 6 FEET** from any foodhandling surfaces or food storage areas, and the vomit was cleaned up routinely, is there a reasonable risk that the surfaces or food could still be contaminated?

- Yes
- No
- Don't know
- Refused

45. If someone with vomiting and diarrhea is taken away from foodhandling duties but continues to have contact with customers (e.g. setting tables, working at cash till), is there a reasonable risk that that person will infect customers?

- Yes
- No
- Don't know
- Refused

46. Is there a reasonable risk that someone who was sick but has been completely recovered for one day, could still transmit the germs that made them sick through handling food improperly?

- Yes
- No
- Don't know
- Refused

Thanks for your help. Now I'd like to look around your kitchen and watch your workers work for a while.

B. Questions to be answered by specialist

1. FoodNet establishment type? (choose one)

- Quick Service
- Regular Sit-down Service
- Cafeteria/buffet

2. EHS -Net establishment type? (choose one)

- Prep Serve
- Cook Serve
- Complex

3. Who is collecting the data in this establishment? (choose all that apply)

- An EHS-Net state person not responsible for inspections in the establishment
- An EHS-Net state person responsible for inspections in the establishment
- A local person responsible for inspections in the establishment
- A local person not responsible for inspections in the establishment
- Other _____

4. How was the evaluation scheduled? (choose one)

- Along with an inspection
- In lieu of an inspection
- Independent of the inspection program

5. Is this establishment....

a.a sit-down restaurant?

- Yes
- No
- Unsure

b.a buffet establishment?

- Yes
- No
- Unsure

d.....a caterer?

- Yes
- No
- Unsure

e.a banquet hall?

- Yes
- No
- Unsure

f..... an institutional food service?

- Yes
- No
- Unsure

g.....an ethnic establishment?

- Yes *If yes, What ethnicity?*
 - Mexican
 - Italian
 - Chinese
 - Other _____
- No
- Unsure

Part C: Observation of Environment

1. Briefly describe your observation area. _____
2. Which of the following were included in your observation area:

<input type="checkbox"/> Sandwich preparation area	<input type="checkbox"/> Salad preparation area
<input type="checkbox"/> Raw meat/poultry preparation area	<input type="checkbox"/> Cook line
<input type="checkbox"/> Dessert preparation area	
<input type="checkbox"/> Other _____	
3. How many workers did you observe during the observation?
 - a. How many of those were wearing disposable gloves?
 - b. How many of those were eating?
 - c. How many of those were drinking?
 - d. How many of those were smoking or using tobacco products?
4. How many workers did you observe preparing RTE foods?
 - a. How many of those were wearing gloves?
 - b. How many of those were using a method other than gloves (utensils, tissue paper)?
5. How many workers did you observe preparing raw animal product?
 - a. How many of those were wearing gloves?
 - b. How many of those were using a method other than gloves (utensils, tissue paper)?
6. Did a manager/supervisor ask an employee to wash their hands?
 - Yes
 - No
 - Unsure
7. Did a manager/supervisor praise an employee for handwashing?
 - Yes
 - No
 - Unsure
8. Did an employee ask another employee to wash their hands?
 - Yes
 - No
 - Unsure

9. How much of the time during your observation was the manager/supervisor in the observation area?

*None or not very
much of the time* *Some of the time* *All of the time*

10. During your observation period, how busy was the kitchen?

Not very busy *Somewhat busy* *Very busy*

11. Are hand sanitizers in the kitchen?

- Yes
 No *If No, skip to #13*
 Unsure *If Unsure, skip to #13*

12. Where are they located? (Mark all that apply)

- By hand sink(s)
 By food preparation area(s)
 By customer service area(s)
 By wait station(s)
 Other _____

13. Are there glove supplies in the kitchen?

- Yes
 No *If No, skip to #15*
 Unsure *If Unsure, skip to #15*

14. Where are they located? (Mark all that apply)

- By hand sink(s)
 By food preparation area(s)
 By customer service area(s)
 By wait station(s)
 Other _____

15. How many signs are there about handwashing in the kitchen area? _____

16. Kitchen Hand Sink Questions

a. Was a hand sink(s) available in the work area?

- Yes
 No
 N/A

b. How many hand sinks were there in the kitchen area? _____

c. Was warm water available at the sink(s)?

- Yes
 No (Please specify number without _____)

- d. Was soap available at (or near) the sink(s)?
 - Yes
 - No (Please specify number without ____)
- e. Were paper or cloth drying towels available at (or near) the sink(s)?
 - Yes
 - No (Please specify number without ____)
- f. Was the hand sink(s) equipped with a foot pedal, knee pedal, sensor, or other method for hands free operation?
 - Yes
 - No (Please specify number without ____)

17. Restroom Hand Sink Questions

- a. Was a hand sink(s) available in the restroom(s) used by employees?
 - Yes
 - No If No, Skip to Part D
 - N/A If N/A, skip to Part D
- b. How many restroom hand sinks were there? _____
- c. Was warm water available at the sink(s)?
 - Yes
 - No (Please specify number without ____)
- d. Was soap available at (or near) the sink (s)
 - Yes
 - No (Please specify number without ____)
- e. Were paper or cloth drying towels available at (or near) the sink(s)?
 - Yes
 - No (Please specify number without ____)
- f. Was the hand sink(s) equipped with a foot pedal, knee pedal, sensor, or other method for hands free operation?
 - Yes
 - No (Please specify number without ____)

1. Describe what was happening during your observation. _____

2. Approximately how far, in feet, was the worker you observed from the nearest hand sink? _____

3. Was the hand sink in the line of sight of the food worker being observed? Yes No

4. During your observation period, how busy was the worker?

Not very busy Somewhat busy Very busy

5. How much of the time during your observation was a manager in a position to see the worker?

None or very little of the time Some of the time All of the time

6. During your observation, how visible was the worker to customers?

Not at all visible Somewhat visible Fully visible

7. During your observation period, how busy was the worker?

Not very busy Somewhat busy Very busy

Hand Hygiene Study Manual

I. Recruitment

A. Recruiting Procedure

We expect each state to collect data for this study in 50 restaurants. Each state will receive a list of randomly selected restaurants from the CDC and will use this list to obtain restaurant participants for this study. This restaurant list will be inflated by the beef study refusal and ineligible rates to ensure that each state will be able to meet the target of 50 restaurants. For example, if 25% of restaurants in a state refused or were ineligible (e.g., they were shut down, didn't meet the EHS-Net definition of a restaurant), we will provide that state with a list of 67 restaurants, expecting that approximately 25% (17) of the 67 would refuse to participate or would be ineligible to participate, and 50 would agree to participate.

When recruiting, please adhere the guidelines described below.

1. Make multiple attempts to contact restaurants.

Recruiters need to make a concerted effort to establish contact with any restaurant that they initially try to contact. This is important because there may be systematic differences between easy-to-contact restaurants and hard-to-contact restaurants. For example, easy-to-contact restaurants may be less busy, better staffed, or better run than hard-to-contact restaurants. As these systematic differences could impact hygiene issues in the restaurant, we want to be sure that hard-to-contact restaurants are represented in our sample as well as easy-to-contact restaurants. To ensure that every effort is made to contact all restaurants in the sample, please do the following:

- **Unanswered calls:** For unanswered calls make a minimum of 15 attempts over 5 days to reach an establishment.
 - **Answered calls:** For an answered call where no response was given (i.e. call back later) a minimum of 10 attempts over a minimum of 4 days should be made to the establishment to attempt to get a response.
- 2. Record all call attempts in the provided Call Tracking Log.** A Call Tracking Log designed to assist in keeping track of your calls can be found in back of this manual (p. 7). Please fill out the Call Log with the following information:
- Call Date
 - Call Time
 - Establishment Information
 - Attempt Number: The number of the attempt to call a particular restaurant
 - Results or Disposition of Call: No answer, Nonworking number, Told to call back, etc.
- 3. Record the final disposition of all restaurants in the Participation Log.** The Excel file called *HH Participation Log* should be used to keep track of the responses of the restaurants. Once you have made a final determination about a restaurant, fill out the Participation Log with the following information.
- **Sample ID #:** Sample ID number from the restaurant selection list
 - **Response Code:** Indicate the response you received from the restaurant using the following codes.
 - **UNABLE TO CONTACT/CLOSED (U):** Use this response code if you followed the protocol above for unanswered calls and do not ever make contact with a restaurant. Also use this code if you cannot find a working number for a restaurant or you determine that a restaurant is closed.
 - **NOT A RESTAURANT (N):** Use this code if you determine that the restaurant does not meet the EHS-Net definition of a restaurant. The following is the EHS-Net definition of a restaurant: An establishment that prepares and serves food to customers; institutions, food carts, mobile food units, temporary food stands, restaurants in supermarkets, and establishments that *only* cater are *not* included.
 - **REFUSED (R):** Use this code if you followed the protocol above for answered calls and make contact with a restaurant, but do not ever get a definitive response on participation. You will also use this code if you do make contact but the manager/owner declines to participate.
 - **CHAIN (C):** Use this code if a restaurant on your list is part of chain, and you have already collected data from a restaurant in that chain.
 - **PARTICIPATING (P):** Use this code if you are able to contact a restaurant, it meets the EHS-Net definition, it is not part of an already participating chain, and the restaurant agrees to participate.
 - **OTHER (O):** Something that does not fall into any of the other categories.

4. **Stop collecting data once you have collected data in 50 restaurants.** When you have collected data in 50 restaurants, you do not have collect any more data, even if you have restaurants on the list that you have not yet contacted.

B. Recruiting Script

Do not refer to the study as the Hand Hygiene Study. If you need to refer to the study by name, call it the Restaurant Policies and Preparation Study. Additionally, keep any descriptions of the study as general as possible. For example, you might say, “we are going to observe food preparation to learn about how food is handled in kitchens;” you would *not* say, “we are going to be observing handwashing.” We do not want the participants to change their normal behaviors, and one way we can do that is to keep them “blind” to the specific purpose of the study.

Below is a suggested recruiting script for calls to managers.

Hello this is _____ with the _____ Health Department. We are working on a research project that focuses on restaurant policies and practices and your location has been randomly selected to participate. The study consists of a brief interview with the manager and observation of food preparation. Please keep in mind this is not an inspection and participation is voluntary but we would really appreciate your participation. Could we schedule a time to come out and complete the survey?"

No → Thank you for your time.

Yes ↓

Great! I'll visit your restaurant for an hour and a half to two hours. Keeping in mind that a manager responsible for managing the kitchen must be available for the interview section, and that we would like to be there when food is being prepared, when would be a convenient time to schedule the visit?

Date: _____ Time: _____

Please call me at _____ if you need to cancel or re-schedule, or if you have any questions. Thank you.

II. Data Collection

Organizing Forms. We are keeping the data collected in this study anonymous, meaning that we do not want to be able to link any data collected to the restaurant from which the data came. Thus, once you complete your data collection, you will need to separate any identifying information on the restaurant from the restaurant's data. However, to ensure that we can link all the data from one establishment together, you should consider giving each data collection packet an ID number. *You would write this ID number in the top right-hand corner of each page of the data collection instrument.*

Part A. Informed Consent

Once at the restaurant, you will meet with the manager and obtain their informed consent. This script is included in the protocol.

Note: Throughout the data collection instrument, boxes (☐) indicate that there could be multiple answers to the question, while circles (○) indicate that there should be only one answer to the question.

Part B. Manager Interview

After obtaining informed consent, you will interview a *manager with authority over the kitchen*. Please follow the following guidelines.

1. General Guidelines

- For each survey question, you will read each question aloud and mark the appropriate response. Note that words that should be read aloud are in bold, while words you should not read aloud are not bolded.
- Answer choices should not be read aloud unless specifically noted.
- When reading answer choices, do not read the responses of “Don't know” or “Refused.”

- You should attempt to obtain an answer to each question in the interview; however, if you believe that the establishment manager is unaware or unsure of the answer to a question, the response should be recorded as “Don’t know,” and if the manager refuses to answer a question, the response should be recorded as “Refused.”

2. Specific Questions

- Please note and follow skip patterns present in questions 4, 11, 15, 16, 18, 20, 22, 25, 27, 28, 30, 32.
- *Question 10:* If you are in a state that requires certification, you may need to explain. For example, “even if your state didn’t require certification, would your restaurant require it?”
- *Open-ended questions:* Questions 17, 21, 26 are open-ended and could potentially generate a lot of responses. If responses fit into the provided categories, check the appropriate boxes. If not, check “Other” and describe the response. Although it would be tempting to simply provide them with the answer choices, we do not want to cue them as to what their policies *should* be, as that may impact their answers.
- *Questions 36-39:* Given the large number of answers to these questions, when you ask these questions, hand respondents the answer choices on a separate piece of paper (found on p. 10 of this manual) so that they can review them. Additionally, you are provided with three Don’t Know and three Refused options for these questions, as each of these questions is actually asking three questions. If a respondent provides you with only one answer, you will need to mark Don’t Know or Refused twice.
- *Questions 40-44:* When asking these questions, hand respondents the answer choices on a separate sheet of paper (found on p. 11 of this manual) so that they can review them.

Part C. Questions To Be Answered By Data Collector

This section contains several questions that the data collector should answer. The data collector should determine the FoodNet establishment type (Question 1) and the EHS-Net establishment type (Question 2), and describe the establishment (Question 5) through a survey of the restaurant and the menu. They should also indicate who is collecting the data (Question 3) and how the visit was scheduled (Question 4).

Part D. Observation of Environment

Once you have completed the manager interview, observe the kitchen environment and workers and record the data using the following procedure.

1. **Define your observation area.** Survey the kitchen and select an observation area in which you can observe a maximum number of workers in a short period of time (10-15 minutes). It may be that you can observe all the workers in the kitchen; however, you may have to limit your observation area depending on the size of the kitchen and the number of employees. Observe for a minimum of 10 minutes.
2. **Observe the workers in this area and answer questions 3-10.** The answers will be based on observations of the employees who are in the observation area at the time of your observation.
 1. This is designed to be a “snapshot” observation, so you will take one look at each employee and note what you need to note (are they wearing gloves, what are they doing). Thus, if the employees move around or switch tasks, the answers to these questions should be based on your first observation of the worker.
 - *Question 1:* Briefly describe your observation area—is it the entire kitchen or a portion of the kitchen? If a portion of the kitchen, which portion? This question is designed to supplement Question 2.
 - *Questions 4 and 5:* When answering questions about gloves and utensils, do not worry about whether or not the workers are wearing gloves or using utensils for the purposes of minimizing hand contact; simply record whether or not they are wearing gloves and using **utensils**. **If they are** wearing gloves and using utensils, you will count that twice—once for wearing gloves and once for using utensils.
 2. *Questions 6-10.* Attempt to answer these questions based on your observations. If you cannot, choose the *Unsure* option.
 3. *Question 9:* This question is subjective. For question 9, you will be focusing on the workers, not the manager. Thus, we do not want you to actually time how long the manager is around. Instead, answer this question based on your estimate of how long the manager is around

4. *Question 10*: This question is also subjective. Base your answer on the experiences you have had in restaurants.
3. **Survey the entire kitchen and answer questions 11-17.** Once you have observed the workers and answered questions 3-10, survey the *entire kitchen* to answer questions 11--17.
- *Questions 11*: This question refers both to bottled hand sanitizers, and sanitizing buckets or dips used for cleaning hands.
 - *Questions 11 and 13*: You will actively look throughout the kitchen for hand sanitizer, hand dips, and glove supplies. You will check by hand sinks, food preparation areas, and wait stations and other possible areas for hand sanitizers. If possible and appropriate, you will also look in drawers and cabinets. However, we want this to be answered by observation only, so you do not have to ask where the hand sanitizer and gloves are.
 - *Questions 16 and Questions 17*: You will examine all the sinks in the kitchen, and all the sinks in the restrooms that employees use (you may have to ask to determine these restrooms) to answer these questions. The determination of most of the answers to these questions is somewhat subjective. The answers should be based on the judgment and experience of the data collector. To assist in this, ask the following questions when completing this section.
 - 16b and 17b: Does the water feel warm to you?
 - 16c and 17c: Could the soap be accessed relatively easily?
 - 16d and 17d: Could the drying towels be accessed relatively easily?
 - If the answer to any of questions 16b-16e and 17b-17e is *No*, indicate that by choosing the No answer choice, and indicate in the provided blank for how many sinks the answer was No (for example, if 2 sinks did not have soap, you would enter 2).
 - If you cannot access a sink to determine the answer these questions, because it is blocked, for example, please indicate that by choosing the appropriate option, and indicating in the provided blank how many sinks you could not access.
 - You will only answer *Yes* to Questions 16a-16e and 17a-17e if the answer was *Yes* for every sink. For example, if you could access all the hand sinks and there was warm water at all the hand sinks, then the answer to Question 16b would be *Yes*. However, if there were 4 sinks, and there was warm water at 2 sinks, no warm water at 1 sink, and you could not access the other sink, you would check the box for *No*, and put a 1 in the blank to indicate that there was no warm water at 1 sink, and you would check the box for *Could not access sink to determine*, and put a 1 in the blank to indicate that you could not access one sink. You would not check *Yes* in this situation.
 - If it is clear that a sink is used for washing hands, although it is not technically a hand sink, include it when answering these questions.

Part E. Observation of Processes/Worker

1. **Once you have completed Part D, select one food worker** in the kitchen who is preparing food (e.g., cooking, slicing, etc.) and for whom you can observe hand movements unobtrusively. Try to ensure that the person you observe is not the person you interviewed.
2. **Record the time that you start observing** the food worker in the top left-hand corner in the space provided on the first observation sheet you use.
3. **Observe the food worker for 55-60 minutes and record data on their actions.**
 - During the first 10-15 minutes, do not record any information- just observe the worker, let him/her get used to you.
 - During the next 45 minutes, record information on the worker's hand movements. Specifically, you will note and record information on any instance in which the worker engages in any of the defined activities for which a handwash/glove removal or change should occur.

Activities for which a handwash should occur:

Prep	<u>Before</u> engaging in food preparation, including working with exposed food, clean equipment and utensils, and unwrapped single-use articles If this action occurs <u>immediately</u> after any of the actions for which a handwash is required afterward, do not record this action; only record the first one.
Gloves	<u>Before</u> putting on gloves for working with food If this action occurs <u>immediately</u> after any of the actions for which a handwash is required afterward, do not record this action; only record the first one.
RA	<u>After</u> handling raw animal product and before moving on to another task Raw animal product: Animal products that have not been cooked or processed. Includes uncooked eggs*, meat, poultry, and fish. *As we know that most restaurants work with un-pasteurized eggs, all uncooked eggs are included in this category. Additionally, we are <u>not</u> including dairy in this category.
RP	<u>After</u> handling raw produce and before moving on to another task Raw produce: Produce that has not been cooked or processed, such as fresh fruits and vegetables. This does <u>not</u> include ready-to-eat produce, such as raw, washed, cut fruits and vegetables that are placed on a line or whole raw fruits and vegetables that are presented for consumption such as at a buffet.
Cough	<u>After</u> coughing, sneezing, or using a handkerchief or disposable tissues and before moving on to another task
Eat	<u>After</u> using tobacco, eating, or drinking* and before moving on to another task *Drinking is acceptable if it occurs from a closed beverage container if the container is handled to prevent contamination of hands.
Dirty	<u>After</u> handling dirty equipment, utensils, or cloths and before moving on to another task
Body	<u>After</u> touching human body parts other than clean hands and clean, exposed arms and before moving on to another task
Other	<u>After</u> engaging in other activities which might contaminate the hands and before moving on to another task. This would include workers touching their clothes. If you use this category, briefly describe the activity.

- For each action observed, record the answers to each of the following 7 questions on the Observation Sheet.

Action?	Prep, Gloves, RA, RP, Cough, Eat, Dirty, Body, Other, Break*, Worker off**
Gloves worn?	Y=Yes; gloves were worn when action occurred N=No; gloves were not worn when action occurred Answer the question even if the action is <i>Gloves</i> , and it is likely that the answer will always be no.
Gloves removed?	Y=Yes; gloves were removed N=No; gloves were not removed NA=Not applicable; gloves were not worn
Hands placed under running water?	Y=Yes; hands were placed under running water N=No; hands were not placed under running water
Soap used?	Y=Yes; soap was used N=No; soap was not used NA=Not applicable; hands weren't placed under running water
How were hands dried?	P=paper towel H=hot air C=cloth towel CL=clothes O=other NOT=hands weren't dried NA=hands weren't placed under running water
Hand sanitizer used?	Y=Yes; a hand sanitizer or hand dip was used N=No; a hand sanitizer or hand dip was not used Should be answered even if hands were not placed under running water
If you cannot determine the answer to any of these questions, enter <i>U</i> for <i>Unable to Determine</i> in the appropriate space.	

- If worker leaves the observation area and you can no longer see them or follow them, enter *Break* in column 1 and leave all other columns blank. Resume your observation when the workers return to a point where you can observe them.
- If the worker's shift ends before you complete your observation, enter *Worker Off* in column 1, leave all other columns blank, and end observation.
- If an action that requires handwashing beforehand (e.g., putting on gloves) occurs immediately after an action that requires handwashing afterward (e.g., handling raw meat), you will record only the first action. In our example, you would record the raw meat (RA) action and would answer the glove, handwash, and sanitizer questions. You would not record the glove action.
- If the worker moves around the kitchen a lot, continue to observe him or her to the extent that you can without being obtrusive. For example, you may try to pick a place to stand that allows you to see the worker working in several different places. If the worker moves from one place to another permanently and you can't observe them in the new place, then follow the worker to the new place. Don't follow them to the restroom. We are trying to remain as unobtrusive as possible.
- If you are nearing the end of your observation period, and the worker has begun an activity that would require a handwashing afterward, try to stay through the end of the action to determine if they washed their hands or not. However, if the action is going to take a relatively long period of time, and you can't stay to determine the outcome, do not record that action.
- If you can't determine the answers to a question (e.g., you can't see whether or not the worker used soap when washing hands), indicate that by marking *U*, for *Unable to Determine*.
- You want to avoid telling the manager that you are going to be observing a specific person. If you are asked what you are doing focus on the fact that you are observing food preparation, not human behaviors.
- It may be helpful to take the Observation Summary with you into the field (p. 12 of this manual).

4. Record the time that you ended the observation in the top left-hand corner in the space provided. You will only need to do this on the first sheet, not every consecutive observation sheet.

5. Number Observation Sheets. You will likely use several observation sheets in each restaurant. We have provided you with two; but you may need to print off more. As you use them, number each sheet consecutively in the space provided under the left-hand side of the grid so that you can keep track of the order of the pages. For example, the sheet on which you record the first 15 events would be labeled page 1, and the second sheet, on which you record the next 15 events, would be labeled page 2.

6. Answer Questions 1-7.

- *Question 1:* Describe what the worker was doing.
- *Question 2:* Approximate how far the worker was from the nearest hand sink. If the worker moved around too much for you to determine this, mark the appropriate option.
- *Question 3:* Attempt to determine if a hand sink was in the line of sight of the worker. If you can not determine this, mark the appropriate option.
- *Questions 4-7:* These are subjective—use your experience in the restaurant and in other restaurants to answer these questions. If you cannot make a determination, mark the appropriate option.

III. Other

A. Answers to possible questions.

- “What are you doing?”
“Why are you watching me?”
“What are you looking for?”
We are trying to learn more about how food is prepared in restaurants. So we are watching food workers prepare food, and taking notes on what they do.
- “Why?”
In the long run, we hope to figure out how to make it easier for food workers to do what they need to do.
- “What are you going to do with your notes?”
They will be entered into a computer and analyzed along with other responses. We are not collecting any information that might identify you in any way.

Handout

Of the following types of food, which three do you think are most likely to be contaminated with germs that could cause foodborne illness BEFORE arrival at a restaurant?

- Produce (raw vegetables and fruit)
- Red meat
- Poultry
- Eggs
- Dairy products
- Pre-prepared and package foods (e.g., in cans, jars and bags)
- Fish
- Shellfish
- Unsure Unsure Unsure

Which three of the following do you think are the most common ways that food gets contaminated IN a restaurant?

- Insects (cockroaches, flies, etc.)
- Food left too long at room temperature
- Handling of foods that will not be further cooked (for ex., salads, sandwiches, already cooked food) by workers infected with germs
- Food kept in dirty or poorly maintained fridge or freezer
- Out-of-date food
- Contaminated or dirty food counters
- Contaminated or dirty air (from poor ventilation, from the toilet, etc.)
- Contaminated or dirty sinks, bowls, pans, utensils etc.
- Cross-contamination from other foods
- Contaminated or dirty water used for washing produce
- Unsure Unsure Unsure

Which three of the following germs do you think are the most COMMON causes of foodborne disease?

- Bacillus cereus
- Clostridium botulinum (botulism)
- Campylobacter
- Clostridium perfringens
- Escherichia coli (E.coli)
- Hepatitis A virus
- Giardia lamblia
- Listeria
- Norovirus (or Norwalk-like viruses)
- Salmonella
- Shigella
- Staphylococcus
- Unsure Unsure Unsure

Which three of the following germs do you think are the most SERIOUS causes of foodborne disease, with serious meaning that they have the most negative effects on health?

- Bacillus cereus
- Clostridium botulinum (botulism)
- Campylobacter
- Clostridium perfringens
- Escherichia coli (E.coli)
- Hepatitis A virus
- Giardia lamblia
- Listeria
- Norovirus (or Norwalk-like viruses)
- Salmonella
- Shigella
- Staphylococcus
- Unsure Unsure Unsure

Handout

If someone became sick with a stomach infection and vomited in the presence of a second person (without splashing them), how likely do you think it is that the second person would also become sick with the same illness?)

- Very likely
- Likely
- Unlikely
- Very unlikely

- Unsure

If someone who became sick with a stomach infection vomited on the floor *at least 6 feet* from any food handling or storage areas, how likely do you think it is that the food handling and storage areas could be contaminated with germs from the vomit?

- Very likely
- Likely
- Unlikely
- Very unlikely

- Unsure

If an employee who is sick with a stomach infection is removed from foodhandling duties but continues to have contact with customers, for example, through setting tables or working the cash register, how likely do you think it is that the employee could still infect customers with his illness?

- Very likely
- Likely
- Not likely
- Very unlikely

- Unsure

If an employee who was sick with a stomach infection has been recovered for one day, how likely do you think it is that the employee could still contaminate food he handled with the germs that made him sick?

- Very likely
- Somewhat likely
- Not likely
- Very unlikely

- Unsure

Cheat Sheet for Data Collection

- Select one food worker** in the kitchen who is preparing food (e.g., cooking, slicing, etc.) and for whom you can observe hand movements unobtrusively. **Record the time that you start observing** the food worker in the top left-hand corner in the space provided
- Observe food worker for 55-60 minutes.** During the first 10-15 minutes, do not record any information- just observe the worker, let him/her get used to you. During the next 45 minutes, record information on the worker's hand movements. Specifically, you will note and record information on any instance in which the worker engages in any of the identified activities for which a handwash/glove removal or change should occur afterwards.

These activities are:

Prep	Before engaging in food preparation, including working with exposed food, clean equipment and utensils, and unwrapped single-use articles
Gloves	Before putting on gloves for working with food
RA	After handling raw animal product and before moving on to another task
RP	After handling raw produce and before moving on to another task
Cough	After coughing, sneezing, using a handkerchief or disposable tissues and before moving on to another task
Eat	After using tobacco, eating, or drinking and before moving on to another task
Dirty	After handling dirty equipment, utensils, or cloths and before moving on to another task
Body	After touching human body parts other than clean hands and clean, exposed arms and before moving on to another task
Other	After engaging in other activities which might contaminate the hands and before moving on to another task

- During observation, record data on Observation Sheet.** Answer each of the following 7 questions.

Action?	Prep, Gloves, RA, RP, Cough, Eat, Dirty, Body, Other, Break*, Worker off**
Gloves worn?	Y=Yes; gloves were worn when action occurred N=No; gloves were not worn when action occurred Answer the question even if the action is <i>Gloves</i> , and it is likely that the answer will always be no.
Gloves removed?	Y=Yes; gloves were removed N=No; gloves were not removed NA=Not applicable; gloves were not worn
Hands placed under running water?	Y=Yes; hands were placed under running water N=No; hands were not placed under running water
Soap used?	Y=Yes; soap was used N=No; soap was not used NA=Not applicable; hands weren't placed under running water
How were hands dried?	P=paper towel H=hot air C=cloth towel CL=clothes O=other NOT=hands weren't dried NA=hands weren't placed under running water
Hand sanitizer used?	Y=Yes; a hand sanitizer or hand dip was used N=No; a hand sanitizer or hand dip was not used Should be answered even if hands were not placed under running water
If you cannot determine the answer to any of these questions, use the code <i>U</i> for <i>Unable to Determine</i> in the appropriate space.	

*If worker leaves the observation area and you can no longer see them or follow them, enter *Break* in column 1 and leave all other columns blank. Resume your observation when the workers return to a point where you can observe them.

** If the worker's shift ends before you complete your observation, enter *Worker Off* in column 1, leave all other columns blank, and end observation.

- Record the time that you ended the observation** in the top left-hand corner in the space provided.

5. Number pages. Number each observation sheet in the space provided in the lower left corner.

**EHS-Net Hand Hygiene Study
Hygiene Participation Log**

Instructions: For each selected restaurant, enter the sample identification number and the response code.
For restaurants that are ineligible or refuse, enter the reason for the ineligibility or refusal.

	Sample ID	Response Code: U=Unable to contact/Closed R=Refusal N=Not an EHS-Net restaurant C=Chain P=Participating O=Other	Reasons for Refusal/Comments
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2			
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