

# IRB Protocol for the EHS-Net Outbreak Prevention and Response Practices Study

## I. Project Overview

### Title

EHS-Net Outbreak Prevention and Response Study

### Summary

Norovirus is the leading cause of foodborne illness outbreaks in the United States and restaurants are the most common setting for these outbreaks. Prevention and control of restaurant-related norovirus outbreaks are critical to lowering the burden of foodborne illness. The purpose of this study is to assess restaurants' practices regarding outbreak prevention and response; and to assess relationships between food safety management systems and practices concerning norovirus outbreak prevention and response.

This is an Environmental Health Specialists Network (EHS-Net) multisite study. EHS-Net is a collaboration involving the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local health department sites (Franklin County, Ohio, Minnesota, New York, New York City, Rhode Island, Tennessee, Southern Nevada Health District, and Harris County, Texas); these partners have come together in an effort to better understand factors that impact food safety.

### Investigators

Investigators include EHS-Net staff at each of the eight EHS-Net sites.

### Background/Justification

Outbreak prevention and response practices are an important component of a restaurant's food safety management system. Norovirus is the leading cause of foodborne illness outbreaks in the United States. From 2009 to 2015, norovirus was the most common cause of single-etiology foodborne outbreaks (38%) and outbreak-associated illnesses (41%) (Dewey-Mattia, 2018; Hall, 2014). Restaurants are the most common settings of norovirus outbreaks (81%) (Hall, 2014), and almost half (46%) of restaurant-related outbreaks are caused by norovirus (Angelo, 2017). These data indicate that prevention and control of restaurant-related norovirus outbreaks are critical to lowering the burden of foodborne illness in the United States.

Norovirus is very contagious; food workers with norovirus infection can easily contaminate food and food contact surfaces. Additionally, vomit particles that travel through the air can contaminate the environment (e.g., food contact surfaces, tables, and chairs). Food safety practices play a vital role in preventing norovirus transmission in restaurants. Restaurants can reduce norovirus transmission by preventing food workers from working while ill, ensuring good worker hand hygiene, preventing worker bare hand contact with ready-to-eat food, and cleaning and disinfecting appropriately after vomiting events. Despite the importance of restaurant actions to norovirus prevention, we know little about the current state of restaurants' outbreak prevention policies and practices, especially related to norovirus. Thus, EHS-Net is proposing this study; it will identify gaps in restaurants' outbreak prevention policies and practices and identify food safety management system components associated with safe policies and practices.

This data collection supports the U.S. Department of Health and Human Services' Healthy People 2030 goal to "Improve food safety and reduce foodborne illnesses." The data collected through this study will inform intervention strategies to improve restaurants' norovirus outbreak prevention and response activities.

### Objectives

The purpose of this study is to assess restaurants' practices regarding outbreak prevention and response; and to assess relationships between food safety management systems and practices concerning norovirus outbreak prevention and response.

We will collect data on and analyze responses from the information collection on:

- a) Norovirus outbreak prevention and response practices, with a focus on employee health/ill workers, hand hygiene, cleaning, and cleaning after contamination events.
- b) General restaurant characteristics
- c) Food safety management systems (policies, training, monitoring)

This study supports the Division of Environmental Health Science and Practice's focus areas 1 and 2, as part of their scientific agenda. Objective 1 states: Identify and develop environmental health data sets, methodologies, and tools to assess exposures, health outcomes, and public health actions. This study will develop a dataset of policies and practices that assess exposures to norovirus in retail food establishments through ill food workers and contamination events. The dataset will also assess public health actions taken to control contamination in food establishments, such as understanding clean-up procedures after a contamination event or policies for working while ill. These efforts fall into 1.1.6, which addresses the prevention of environmental causes of foodborne illness outbreaks.

This study also supports Objective 3, which states: Conduct and support studies on environmental public health hazards, exposures, and health outcomes. This study is being conducted to assess a public health hazard, foodborne illnesses at retail food establishments. More specifically, the study focuses on policies and practices that reduce exposure to norovirus. This objective specifically mentions EHS-Net studies in 3.1.11 of the scientific agenda.

## II. Procedures/Methods

### Study Design

Data will be collected by environmental health specialists in participating EHS-Net sites. Restaurant managers and food workers are the respondents in this study. Data will be collected using: 1) a manager interview; (manager: a person that has the authority over kitchen workers: e.g., kitchen manager, general manager, or restaurant owner) 2) a food worker interview; and 3) a restaurant environment observation. 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.

Participation in this data collection is voluntary and anonymous, and every effort has been made to keep the data collection as short as possible and still meet the needs of the study objectives. Information on restaurant name and address will be maintained by each site to facilitate the site visit. Once the site visit has been recorded, the identifying information will be destroyed by each site by deleting any electronic keys or shredding paper keys. This information will not be recorded in the EHS-Net system.

### Study Population

EHS-Net is a collaborative project of the CDC, FDA, USDA, and eight state and local public health departments (Franklin County, Ohio; Minnesota; New York City; New York State; Rhode Island; Tennessee; Southern Nevada Health District, NV; and Harris County, TX.) The respondent universe is comprised of retail food establishments in selected geographical areas within the EHS-Net catchment areas. While the number of areas included in EHS-Net is small, they are demographically diverse and provide good geographical coverage of the U.S. (northeast, mid-west, south, and west). When the sampling methods outlined here for ensuring a representative sample in the current study are used, the results of the analyzed data can be used to generalize to the population of retail food establishments in the given EHS-Net site(s).

Restaurant lists will be obtained from the restaurant databases maintained by the EHS-Net sites. Restaurants inside a grocery store will be excluded from the list. CDC will use these restaurant lists to generate the sampling frame used to draw the sample for this study. Restaurants will be randomly selected, with equal probability, within their respective EHS-Net 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. 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 (50 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 staff) 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., 2016; Brown et al., 2014; Radke et al., 2016). We expect a similar response rate for the proposed study. Thus, in total, the EHS-Net sites will contact approximately 889 restaurants to meet our target of 400 participating restaurants.

Each EHS-Net site will enroll 50 restaurants in the study. Since there are no previously published (population) studies that have examined norovirus outbreak prevention and response practices in conjunction with organizational practices in restaurants, we are unable to determine whether this sample size will be able to support at least an 80% study power to detect statistical differences between study groups. Thus, data on expected prevalence of knowledge, attitudes, and practices between different groups of restaurants are not available as inputs for proper calculation of study sample size and power. Enrollment of 50 restaurants per EHS-Net site, totaling 400 restaurants for the entire study, is a reasonable sample size and follows the precedent of previous EHS-Net studies (Green et al., 2006; Kirkland et al., 2009; Sumner et al., 2011). Experience from prior EHS-Net studies also indicates that a sample size of 400 should be sufficient for the analytic purposes outlined below, since the analytic parameters are not likely to be considered rare (in distribution) events. Data collected from this study will provide the necessary information for sample size and power calculations for future studies.

### **Data Collection**

Each EHS-Net site will provide CDC with a list of all restaurants in their catchment area. This list consists of restaurant names, and it will serve as the sampling frame for the site. CDC will use a random number generator in SAS 9.4 to produce a random sample of restaurants from this restaurant list for each site. As we expect some restaurants will refuse to participate and some will be ineligible to participate, we will select more than the needed number of restaurants--100 restaurants for each site. Once they receive their sample list from CDC, data collectors in each site will contact restaurants with a recruitment script to recruit their participation in the study. If the manager is willing to participate, the data collector will arrange a mutually convenient time to conduct the data collection.

Data will be collected in the restaurants by the EHS-Net sites and may be accompanied by CDC staff. CDC staff will provide oversight to ensure data collection is consistent with training and study protocols. A certificate of confidentiality is needed because CDC staff will be involved in data collection and the staff may have knowledge of study participants. This would ensure that CDC would not release any business information that may have been obtained.

### **Study Instruments**

The following data collection instruments were developed through a collaborative effort between the CDC and the EHS-Net sites. Below is a description of the type of information to be collected with each method used.

- 1.) Manager interview: that has authority over kitchen workers (e.g., kitchen manager, general manager, or owner).
  - a. The data collector will obtain verbal informed consent and then conduct a face-to-face interview with a manager who has authority over the kitchen. This interview will include questions on restaurant general characteristics, and policies and practices related to employee health/ill workers and cleaning. This will take about 30 minutes to complete.
- 2.) Food worker interview

a. The data collector will obtain verbal informed consent from and then conduct a face-to-face interview with a worker of the manager's choosing. This interview will include questions about worker characteristics and policies and practices related to employee health/ill workers and cleaning, and worker perceptions and beliefs about working while ill. This will take about 15 minutes to complete.

3.) Restaurant environment observation

a. Data collectors will complete the restaurant environmental observation form, documenting worker hand hygiene and review employee health/ill worker and cleaning policies. These observations will not require interactions between the data collectors and restaurant staff and is estimated to take approximately 30 minutes.

**Projected Study Timeline**

Activity	Time Frame
Train EHS-Net sites on data collection	Within 1 month of OMB approval
Recruitment of restaurants	Within 2 months of OMB approval
Data collection	Within 8 months of OMB approval
Data entry and quality assurance	Within 10 months of OMB approval
Data cleaning	Within 16 months of OMB approval
Data analysis	Within 20 months of OMB approval
Manuscript development	Within 24 months of OMB approval

**Data Analysis**

*Analysis Plan*

The first stage of analysis will involve data cleaning. The EHS-Net administrator in each EHS-Net site and CDC staff will perform quality assurance procedures to check for data entry errors. We will first conduct analyses (frequencies, means, etc.) that describe study restaurants' prevention and response practices. We will also conduct analyses that describe the study restaurants' food safety management systems. To assess relationships between establishments' food safety management systems and practices concerning norovirus prevention and response, we will conduct multivariable regressions. These regressions will identify restaurant characteristics and food safety management system components that are related to good norovirus prevention and response practices. Additional descriptive analyses and multivariable regression will be performed where appropriate.

*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 data collector in each state. CDC staff will assign account privileges to users and the functions that they are authorized to perform. Each EHS-Net administrator is responsible for the administration of the system for his or her state, including actions such as user administration and correction and/or deletion of records.

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

*Study Limitations*

Data will be collected in those sites participating in EHS-Net. Therefore, findings will be generalizable only to restaurants in the EHS-Net sites. Additionally, the data may be subject to selection bias, interviewer bias, recall bias, and social desirability bias. These potential limitations will be described in any presentations or journal articles.

**Risks Summary**

The research procedures present no more than minimal risk of harm to participants, as the probability and magnitude of harm or discomfort anticipated in participating in these activities are not greater in and of themselves than those ordinarily encountered in daily life.

No future risks exist since call logs will be destroyed once data collection is complete.

**Benefits**

Although there are no immediate benefits to participants, the information learned from this study can be used to better understand outbreak prevention and response policies and practices. This information, in turn, can be used by CDC to further develop food safety prevention and intervention recommendations for environmental public health/food safety programs and the retail food establishment industry.

### **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 criterion for the waiver, as the probability and magnitude of harm or discomfort in participation are not greater in and of themselves than those ordinarily encountered in daily life. Additionally, as the research involves no procedures for which written consent is normally required outside the research context, the study also meets the second criterion for waiver.

Before conducting the study, we will obtain verbal informed consent from the restaurant manager. The data collector will read the manager a short introduction describing the purpose of the study and how the data will be used. The data collector 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.

Once a food worker is identified by the manager as a potential participant for the study, the data collector will read a brief recruiting and informed consent script to the worker. If the worker agrees to participate, the interview will proceed; if the worker does not agree, the data collector will ask the manager to help recruit another participant for the study.

We are requesting a waiver of written informed consent; thus, neither managers nor workers will have to read the informed consent scripts. Nevertheless, we conducted readability analyses of sections from each of the informed consent scripts. These analyses indicated that the scripts were at an 8th grade reading level.

### **Certificate of Confidentiality**

We will not collect identifying information on individuals, included interviewed managers and food workers. However, we will collect and keep data identifying information of the restaurants per the duration of the study. This information will be destroyed at the completion of the study.

Consistent with Section 301(d) of the Public Health Service Act, a Certificate of Confidentiality (CoC) applies to this research because this research is funded and supported by CDC and the activity constitutes research, and the research involves Human Subjects as defined by 45 CFR Part 46. The research involves information about an individual for which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Therefore, CDC and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive "identifiable, sensitive information" as defined by subsection 301(d) of the Public Health Service Act shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

CDC and its collaborators and contractors conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. CDC will ensure: 1) that any investigator or institution not funded by CDC who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of the Certificate; and 2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act. Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens.

All research subjects will be informed of the protections and the limits to protections provided by this Certificate through the informed consent process. All study staff who obtain consent from study subjects will be trained on how the Certificate protects the information collected and the limitations of the Certificate's protections.

#### **Funding Information**

Funding for this study will be provided by CDC EHS-Net through a cooperative agreement.

#### **Approvals from other IRBs**

Each EHS-Net site must submit this study to their local IRBs for an exemption determination.

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