

Supporting Statement Part A

**EHS-Net Outbreak Prevention & Response Practices
Study**

EHS-Net Generic Information Collection Request

OMB No. 0920-0792

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Supporting Statement - A

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Goal of the study: This study has two goals: 1) assess restaurant's policies and practices regarding outbreak prevention and response; and 2) assess relationships between restaurants' characteristics and food safety management systems and policies and practices concerning outbreak prevention and response.

Intended use of the resulting data: The data will allow identification of gaps in outbreak prevention and response policies and practices. It will also allow identification of restaurant management system components associated with better outbreak prevention and response policies and practices. This identification will inform intervention strategies to improve restaurants' outbreak prevention and response activities.

Methods to be used to collect data: The study will use a cross-sectional design. Methods will involve an interview with a restaurant manager and a food worker, and an observation of the restaurant.

The subpopulation to be studied: The sample will be from the population of restaurants in the Environmental Health Specialists Network (EHS-Net) catchment area (Minnesota; New York City; New York; Tennessee; Rhode Island; Franklin County, Ohio; Southern Nevada Health District; and Harris County, Texas). Restaurants participate voluntarily; they will be randomly sampled from the population.

How data will be analyzed: Initial analyses will involve descriptive statistics to assess policies and practices. Additional analyses will involve multivariable regressions to examine links between restaurants' characteristics and food safety management systems and policies and practices.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), is requesting Paperwork Reduction Act (PRA) clearance for a data collection entitled "EHS-Net Outbreak Prevention and Response Practices Study." This new data collection is being conducted using the generic information collection mechanism of the Environmental Health Specialists Network (EHS-Net; OMB No. 0920-0792, expiration 01/31/2025). EHS-Net is funded through CDC cooperative agreement EH20-001. The respondent universe for this data collection aligns with that specified for the EHS-Net generic information collection, that is, restaurants. Data will be collected by personnel in eight state and local health departments participating in EHS-Net. This data collection focuses on retail food establishment policies and practices concerning norovirus prevention.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

The EHS-Net program, developed by CDC, conducts studies designed to identify and understand environmental factors associated with foodborne illness outbreaks and other food safety issues (e.g., ill workers). These data are essential to environmental public

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health regulators' efforts to respond more effectively to and prevent future outbreaks and food safety-associated events.

EHS-Net is a collaborative project of the CDC, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and eight state and local public health departments (Franklin County, Ohio, Minnesota, New York, New York City, Rhode Island, Tennessee, Southern Nevada Health District, and Harris County, Texas). EHS-Net's funding to these state and local health departments, enables them to collaborate with CDC on study design, collecting study data, and co-analyzing study data with CDC. The federal partners provide funding and input into study design and data analysis. To date, EHS-Net has summarized its research efforts in over 30 publications (Attachment 2).

EHS-Net works closely and collaboratively with our federal partners at the FDA and the USDA to identify study topics, design the study, and ensure that the research is not overlapping with studies conducted by those agencies.

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 et al., 2018; Hall et al., 2014). Restaurants are the most common settings of foodborne norovirus outbreaks (81%) (Hall et al., 2014), and almost half (46%) of restaurant-related foodborne outbreaks are caused by norovirus (Angelo et al., 2017). These data indicate that prevention and control of restaurant-related foodborne norovirus outbreaks are critical to lowering the burden of foodborne illness in the United States.

Norovirus is very contagious; food workers with norovirus 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 restaurant characteristics and management system components linked 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.

2. Purpose and Use of the Information Collection

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The purpose of this study is two-fold: 1) assess restaurants' practices regarding outbreak prevention and response; and 2) assess relationships between restaurants' characteristics and food safety management systems and practices concerning norovirus outbreak prevention and response.

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

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

Data will be collected by environmental health specialists in participating EHS-Net health departments. Restaurant managers and food workers are the respondents in this study. Data will be collected using: 1) a manager informed consent and interview (Attachment 3); 2) a food worker informed consent and interview (Attachment 4); and 3) a structured establishment observation (Attachment 5).

The manager interview (Attachment 3) is necessary to gather information on restaurant characteristics, management systems, and practices. The food worker interview (Attachment 4) is necessary to gather information on worker characteristics and practices. The structured establishment observation by health department staff (Attachment 5) is necessary for collecting data on the restaurant characteristics and policies and practices.

EHS-Net is comprised of restaurants in selected geographical 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 statistical methods outlined here for ensuring a representative sample in the current study are used, the results of the collection can be used to generalize to the population of restaurants in the given EHS-Net site(s).

The data collected for this study can be used to understand gaps in restaurants' norovirus outbreak prevention and response policies and practices. It can also be used to understand restaurant characteristics and food safety management systems components that are linked with better policies and practices. This information can be used to inform and improve restaurants' norovirus prevention and response efforts. Federal, state, and local food safety programs can also use this information to inform their own efforts to prevent norovirus associated with the restaurants they regulate. The information can be used to develop food safety prevention, intervention recommendations, and tools for food safety programs and the restaurant industry. For example, if the study finds that manager certification is linked with better policies and practices, CDC can disseminate the information and encourage food safety programs and the restaurant industry to adopt kitchen manager certification. Ultimately, these actions can contribute to a decrease in norovirus associated with restaurants.

3. Use of Improved Information Technology and Burden Reduction

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The primary burden to respondents of participation in this study involves their participation in interviews. It is less burdensome for respondents to provide open-ended interview responses verbally than to have to type their responses into an electronic reporting system. Thus, we have chosen not to collect interview data electronically, but rather, collect the data through face-to-face verbal interviews with respondents. Data collectors will record the managers' and workers' responses on paper-and-pencil forms.

Participation in this data collection is voluntary, and every effort has been made to keep the data collection as short as possible and still meet the needs of the data collection.

4. Efforts to Identify Duplication and Use of Similar Information

This EHS-Net data collection will not be a duplication of effort. We have searched relevant scientific bibliographical databases (e.g., PubMed, Ovid, Agricola), attended national meetings (e.g., National Environmental Health Association, International Association of Food Protection), and consulted with other organizations (e.g., FDA, USDA-FSIS) concerning research on this topic. Few studies exist on this topic. We have consulted with both FDA and USDA and neither agency is conducting similar research.

5. Impact on Small Businesses or Other Small Entities

We expect that about half of the restaurants contacted for participation in this study will be small businesses. Given that small businesses are likely to have different experiences and practices than larger businesses, it is important that small businesses be included in this data collection. Short forms for small businesses will not be developed. Both large and small businesses will be presented with the same questions. We will, however, strive to hold the number of questions to the minimum needed for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

All participating restaurant workers will be interviewed once. If this data collection is not conducted, it will be more difficult for CDC, other federal, state and local food safety programs, and the food service industry to assess restaurants' practices concerning norovirus prevention. In turn, it will be more difficult to decrease the number of incidents of foodborne illness caused by restaurants' practices and for CDC to fully address the U.S. Department of Health and Human Services' Healthy People 2030 Goal to "Improve food safety and reduce foodborne illnesses." There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this data collection. This request fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

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In 2022, OMB renewed the EHS-Net GenIC package (OMB No. 0920-0792), and it now supports EHS-Net data collections until January 31, 2025. CDC is now requesting OMB approval of a new information collection under this program. Under the EHS-Net program generic clearance, an expedited review of EHS-Net data collections is enabled. Thus, no additional Federal Register notices are necessary, and the expected turn-around time for requested packages submitted under this clearance is six weeks or less.

This data collection focuses on identifying gaps in outbreak prevention and response policies and practices in restaurants. Data collection will allow us to identify restaurant management system components linked with better outbreak prevention and response policies and practices. This identification will inform intervention strategies to improve restaurants’ outbreak prevention and response activities. Personnel from the EHS-Net sites worked with CDC to develop this data collection in 2019. Additionally, FDA and USDA consulted on the data collection forms. Names and contact information are provided below.

2020-2025 EHS-Net Sites	
<p>Nicole Hedeem Epidemiologist Minnesota Department of Health Nicole.hedeem@state.mn.us 651-201-4075</p>	<p>Danny Ripley Food Inspector II Tennessee Department of Health Danny.ripley@nashville.gov 615-340-5620</p>
<p>JoAnn Monroy Food Safety Program Manager Harris County Health Department joann.monroy@hcpbes.org 713-274-6319</p>	<p>Lauren DiPrete Senior Coordinator Southern Nevada Health District DiPrete@snhdmail.org 702-759-1504</p>
<p>David Nicholas Chief Epidemiologist New York State Department of Health david.nicholas@health.ny.gov (518) 402-7600</p>	<p>Brendalee Viveiros Center for Food Protection Chief Rhode Island Department of Health Brendalee.Viveiros@health.ri.gov (401) 222-2749</p>
<p>Sarah Jensen Assistant Health Commissioner Franklin County Public Health sarahjensen@franklincountyohio.gov 614-525-6130</p>	<p>Wendy McKelvey Deputy Commissioner New York City Department of Health and Mental Hygiene wmckelve@health.nyc.gov 212-788-9641</p>
Federal Partners	
<p>Laurie Williams Consumer Food Safety Officer Food and Drug Administration Laurie.Williams@fda.hhs.gov</p>	<p>Gamola Fortenberry Epidemiologist USDA-Food Safety Inspection Service Gamola.fortenberry@usda.gov</p>

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

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10. Assurance of Confidentiality Provided to Respondents

The proposed project has been reviewed by the NCEH Information Systems Security Officer (ISSO) who has determined that the Privacy Act does not apply to this collection. Therefore, a system of records notice (SORN) will not be created. No assurances of confidentiality will be provided to respondents. Only anonymous data will be collected. To help ensure fidelity to data collection procedures, CDC will collect data in conjunction with site personnel in select restaurants. Since the previous PRA clearance, the NCEH Human Subjects Contact has determined that EHS-Net information collections are not human subjects research, and thus, do not require IRB review or approval.

No paper files will be delivered to CDC. Instead, data collectors will enter all paper-and-pencil responses into a web-based information system, the REDCAP data management system. All electronic data will be stored on secure CDC networks. Access to the data will be limited to those with a bona fide need-to-know in order to perform job duties related to the project. User accounts will be issued to the specialists who will serve as the administrator of the system for his or her own site. Through these password protected accounts, users will be granted privileges including entering and accessing data, and correction and deletion of records capabilities. As previously stated, all data records are owned by the site entering the data. Each site possesses ownership of its records and must grant permission to other sites or agencies who would like to use the data.

Information in identifying form will not be collected or transmitted to CDC. Data collectors will use a code to identify restaurants, but that code will not be linked to any identifying information.

Verbal consent will be obtained from respondents. The manager's informed consent script can be found at the beginning of the manager interview (Attachment 3); the food worker's informed consent script can be found at the beginning of the food worker interview (Attachment 4).

Participation in this data collection is voluntary, and respondents are informed of the voluntary nature of the data collection during recruiting and in the informed consent script.

Below is a description of the types of information to be collected with each method used.

- Manager interview- restaurant characteristics, food safety management systems, norovirus outbreak prevention and response practices
- Food worker interview- worker characteristics and practices
- Structured restaurant environment observation - restaurant characteristics, practices

11. Justification for Sensitive Questions

There are no sensitive questions in this data collection.

12. Estimates of Annualized Burden Hours and Costs

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Eight EHS-Net sites will collect data for this study; each site will collect data in 50 restaurants. Thus, there will be 400 manager respondents (50 restaurants * 8 sites). We expect a manager response rate of 45%; thus, we will need to contact 889 restaurant managers via a telephone recruitment script (Attachment 6) in order to meet our goal of 400 respondents. Each manager will respond to the script only once, and the average burden per response will be approximately 3 minutes (44 annual burden hours).

In restaurants that voluntarily agree to participate in this study, we will interview a manager about the restaurant's characteristics, policies and practices (Attachment 3). It is estimated that this will take approximately 25 minutes (167 annual burden hours). Following this, one food workers of the manager's choosing will be interviewed (Attachment 4); this will take about 15 minutes. We expected a worker response rate of 95% (421 workers* 15 minutes=105 annual burden hours). The health department workers will also complete a establishment observation in each location (Attachment 5). These observations will not require interactions between the data collectors and restaurant staff and are estimated to take approximately 35 minutes (233 annual burden hours.)

Table 12.1- Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Managers	Telephone Manager Recruiting Script	889	1	3/60	44
Managers	Manager Informed Consent and Interview	400	1	25/60	167
Food Workers	Food Worker Informed Consent and Interview	421	1	15/60	105
Observation	Restaurant Environmental Observation Form	400	1	35/60	233
TOTAL					549

The maximum total annualized cost of this data collection to respondents is estimated to be \$10,923 (See Table 12-2). This figure is based on an estimated mean hourly wage of \$17.81 for managers, \$14.32 for workers and \$24.30 for health department workers (These estimated hourly wages were obtained from the U.S. Department of Labor Bureau

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of Labor Statistics 2020 National Occupational Employment and Wage Estimates (https://stats.bls.gov/oes/current/oes_nat.htm).

12.2- Estimated Annualized Burden Costs

Respondent Type	Occupation Code	Occupation Title	Mean Hourly Wage	Respondent Type
Manager	35-1012	First-Line Supervisors of Food Preparation and Serving Workers	\$17.81	Manager
Food Worker	35-2021	Food Preparation Workers	\$14.32	Food Worker
EHS-Net Staff at Health Department	19-4042	Environmental Science and Protection Technicians, Including Health	\$24.30	EHS-Net Staff at Health Department

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

Costs to the government include a portion of the annual cooperative agreement to the EHS-Net sites that will collect the data and the costs of CDC personnel working on the data collection (A.14.1). The EHS-Net sites participating in this study receive equal funding, and we estimate that the sites will use approximately 20% of their cooperative agreement funds to conduct this data collection. We also estimate that one CDC staff member will spend approximately 50% of their time on this data collection.

The manager interview (Attachment 3) and worker interview (Attachment 4) forms will be available in both English and Spanish. The CDC Multilingual Services Team translated the English forms into Spanish at a one-time fee of \$919.79. Two of the EHS-Net sites are able to use the Spanish interview forms if needed.

14.1-Estimated Annualized Cost to the Federal Government

Expenditure	Cost	Measure	Total
Awards to sites (\$96,290 * 8 sites)	\$770,320	20%	\$154,064.00
CDC Salary (1 staff members)	\$100,000	50%	\$50,000
Translation services	\$919.79	100%	\$919.79
Total	\$871,239.79	-	\$204,983.79

15. Explanation for Program Changes or Adjustments

This is a new data collection associated with an existing generic clearance.

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16. Plans for Tabulation and Publication and Project Time Schedule

Table 16.1 provides the data collection activity schedule.

16.1 - Project Time Schedule

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

A detailed analysis plan can be found in Supporting Statement B (B.4).

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not requesting an exemption to the display of the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification for Paperwork Reduction Act.

References

- Angelo, K. M., Nisler, A. L., Hall, A. J., Brown, L. G., & Gould, L. H. (2017). Epidemiology of restaurant-associated foodborne disease outbreaks, United States, 1998-2013. *Epidemiol Infect*, 145(3), 523-534. doi:10.1017/s0950268816002314
- Dewey-Mattia, D., Manikonda, K., Hall, A. J., Wise, M. E., & Crowe, S. J. (2018). Surveillance for Foodborne Disease Outbreaks - United States, 2009-2015. *MMWR Surveill Summ*, 67(10), 1-11. doi:10.15585/mmwr.ss6710a1
- Hall, A. J., Wikswow, M. E., Pringle, K., Gould, L. H., & Parashar, U. D. (2014). Vital signs: foodborne norovirus outbreaks - United States, 2009-2012. *MMWR Morb Mortal Wkly Rep*, 63(22), 491-495.