

National Environmental Assessment Reporting System (NEARS)

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Revision

Supporting Statement Part B –

Collections of Information Employing Statistical Methods

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Part B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Statistical methods will not be used to select respondents for this data collection. All food safety programs in the United States (U.S.) will be invited to participate; however, participation is voluntary. Programs that participate in NEARS will report data on all outbreaks occurring in their jurisdictions. We expect that program participation will increase over time. However, until all eligible programs are participating, a limitation of our data will be that it applies to only those jurisdictions participating in NEARS.

State, local, tribal, and territorial food safety programs will report data into NEARS. There are approximately 3,000 such food safety programs in the U.S.

Although the data reported through this system are collected by food safety programs, they are not collected on food safety programs or personnel. Instead, they are collected primarily on foodborne illness outbreaks. Specifically, data collected by food safety programs during their investigation of foodborne illness outbreaks will be reported into NEARS. These data will provide information on environmental factors associated with outbreaks.

Data on all outbreaks occurring in the jurisdictions of participating food safety programs (the NEARS 'catchment area') will be reported to NEARS. Thus, we will be utilizing a convenience sample of voluntary participating programs and not obtaining a statistical sample. In the future, should a nationally representative program evolve, we may be able to generalize our data. Currently, we will describe the population of outbreaks solely in the NEARS catchment area and the environmental factors associated with them, and we will not generalize the data as nationally representative.

B.2. Procedures for the Collection of Information

Data Collection

Prior to collecting data, all food safety program personnel participating in NEARS will be encouraged to attend training for NEARS. These staff will be encouraged to attend a Skype Meeting (i.e., webinar) training session conducted by CDC staff (Attachment 4). This training is voluntary and will cover identifying environmental factors, logging in and entering data into the web-based NEARS data entry system, and troubleshooting problems. There will be no website, form, or presentation document associated with this training. Instead, CDC personnel will be

guiding participants through the NEARS data entry system. Attachment 4 contains a brief description of the training.

Although not a requirement, food safety program personnel participating in NEARS will also be encouraged to complete CDC's Environmental Assessment Training Series (EATS) (Attachment 5). This e-Learning course provides training on how to use a systems approach in foodborne illness outbreak environmental assessments. Participants acquire in-depth skills and knowledge to investigate foodborne illness outbreaks as a member of a larger outbreak response team, identify an outbreak's environmental causes, and recommend appropriate control measures. The course is presented in the context of a simulated virtual environment where participants can interact and practice the skills being learned. Attachment 5 contains a brief description of the training.

There are two data collection activities. For the first activity, participating food safety programs will record all their environmental assessment data using pen-and-paper form (Attachment 6) and then enter all their data into the secure NEARS web-based system (Attachment 7). The respondents for this activity are the food safety program personnel participating in NEARS. This activity will be done once for each outbreak.

The second activity is the manager interview that will be conducted at each establishment associated with an outbreak (Attachment 8). The respondents for this activity are the retail food managers of the outbreak establishments. Manager interviews are a routine part of outbreak investigations; however, food safety program personnel participating in NEARS conduct a structured interview, and will thus conduct their interviews slightly differently than they would if they were not participating in NEARS.

Data analysis results will be shared informally with participating sites through annual data summary reports and presentations during NEARS quarterly webinars. Results will also be shared with other stakeholders (e.g., NORS Team) and the food safety and environmental public health community through presentations at meetings and conferences, peer-reviewed publications in scientific journals, and possibly 'plain language' summaries on the CDC website. Results will be presented in aggregate form.

The results will be used to develop recommendations for food safety and environmental public health programs and the retail food industry. For example, if data collection identifies specific environmental antecedents associated with certain foodborne outbreaks, CDC can develop recommendations that address these unsafe policies and/or practices and disseminate the information to environmental public health programs and the retail food industry.

Quality Control Procedures

CDC personnel will periodically review the data from each site, and perform quality assurance procedures to check for data entry errors. They will provide reports to each program about the

quality of their data. CDC personnel will use these reports to highlight weaknesses in data and recommend ways to improve the quality of the data.

Potential Biases

The act of observing workers during environmental assessments may influence their performance and behavior on work-related tasks. In other words, the workers may not respond naturally when they know they are being observed. However, for the most part, those collecting these data will be experienced and will take measures (such as remaining unobtrusive and engaging in activities that will place workers more at ease) to minimize this bias when possible.

The manager interview data may be influenced by social desirability bias - the tendency for people to report greater levels of socially desirable behavior (such as safe food preparation practices) than they actually engage in, or to report their best behavior rather than their typical or worst behavior.

Any presentation of these data will acknowledge these potential biases and include a discussion of how they impact data interpretation.

B.3. Methods to Maximize Response Rates and Deal with No Response

Program Response

We have been and will continue to engage in activities to promote and encourage food safety program participation in NEARS. We have presented at multiple conferences attended by those responsible for outbreak investigation (e.g., National Environmental Health Association, Council to Improve Foodborne Outbreak Response, etc.). We will hold informational conference calls with programs interested in NEARS. During these calls, we will attempt to identify barriers to NEARS participation and address those barriers. Our goal is to achieve close to 100% participation in NEARS.

B.4. Test of Procedures or Methods to be Undertaken

Development of Revisions

A work group of experienced foodborne outbreak investigators and NEARS participants developed the proposed revisions to the instrument, after extensive discussion. Thus, the revisions and discussions were based on the collective experience and expertise of these investigators. For example, added questions were ones that these investigators have regularly used in the course of their investigations, and many of the clarification revisions were ones

investigators have had to regularly make in the field to obtain the desired data. Thus, although these revisions were not formally cognitively tested, we feel confident that the revisions will lead to improved flow and comprehension, and higher quality data. Nevertheless, we will regularly obtain feedback from NEARS users on the data collection instrument and experience, and routinely assess data quality, and will respond to any identified issues.

Future Revisions

The data collection instrument to be used for the NEARS was previously developed by the Environmental Health Specialists Network (EHS-Net) (See Attachments 6, 7, and 8). As food safety programs beyond the EHS-Net participants continue using the instrument, we expect that they will identify some components of the instrument that need revision. We expect these revisions to be minor. We plan to review respondents’ revision comments and questions on an annual basis to determine the nature and scope of requested revisions. Annual review of data may also reveal minor needed changes. Should we identify the need for changes to the data collection instruments, we will submit a nonmaterial or non-substantive change request to OMB for approval. For major changes to the instruments or methods, a full revision information collection request (ICR) will be submitted for Paperwork Reduction Act (PRA) clearance.

Data Analysis Plan

The three main goals of this data collection are to:

1. Describe foodborne illness outbreaks and outbreak responses.
2. Describe environmental factors (environmental antecedents and contributing factors) associated with outbreaks.
3. Describe the associations between environmental antecedents and contributing factors to outbreaks.

To address the first goal of this data collection, describe foodborne illness outbreaks and outbreak responses, we will conduct descriptive analyses (frequencies, means, etc.) to describe:

- outbreaks (Table B.4.1 contains the variables included in these descriptive analyses)
- outbreak responses (Table B.4.2 contains the variables included in these descriptive analyses).

Table B.4.1. Variables included in descriptive analyses of outbreaks

Question Number	Question	Justification
I_1	Did the exposure(s) take place in a single or multiple locations?	Describe where the outbreak took place.
I_2	Did the exposure(s) occur in a single state or multiple states?	
I_3	Did the exposure(s) happen in a single county/township/parish or multiple counties/townships/parishes?	

I_4	How many food service establishment locations within your jurisdiction were associated with this outbreak?	
I_5	How many environmental assessments conducted at foodservice establishments in your jurisdiction as part of this outbreak?	Describe whether environmental assessments were conducted.
I_5a	Why were no environmental assessments conducted in your jurisdiction as a part of this outbreak?	Describe barriers to conducting environmental assessments.
I_6	How many non-food service establishments within your jurisdiction were associated with this outbreak?	Describe whether any non-food service establishments were associated with the outbreak.
I_6a	How many environmental assessments were conducted at non-food service establishments in your jurisdiction as part of this outbreak?	Describe how many environmental assessments were conducted in non food service establishments.
I_7	Was a primary agent identified (suspected or confirmed) in this outbreak?	Describe the agent and serotype.
I_7a	What was the identified agent?	
I_7b	Was a serotype identified for this outbreak?	
I_7c	What was the identified serotype?	
I_8	Was this outbreak reported to a state or local Communicable Disease Surveillance Program?	This information will be used to help connect the NEARS data to existing epidemiological and laboratory data reported to the state.
I_8a	Select the state or local surveillance system(s) where this outbreak was reported.	
I_9	Was this outbreak reported to a national surveillance system?	This information will be used to help connect the NEARS data to existing epidemiological and laboratory data reported to other national surveillance systems.
I_9a	Select the national surveillance system(s) where this outbreak was reported and record the corresponding reporting number.	
I_10	Was a specific ingredient or multi-ingredient food suspected or confirmed in this outbreak?	Describe ingredients and foods associated with the outbreak.
I_10a	If an ingredient/food was not suspected or confirmed, explain why this outbreak was considered foodborne.	
I_11	Provide any comments that would help describe the foods involved in this outbreak.	
Va_1	What is the name of the suspected or confirmed ingredient / food vehicle?	
Va_2	Is this food a single specific ingredient or multi-	

	ingredient?	
I_11	Were any contributing factors identified in this outbreak?	Describe contributing factors to the outbreak.
VII_1	Which contributing factors was identified?	
VII_2	In your judgment, was this the primary contributing factor to this outbreak?	
VII_3	Briefly explain why this is a contributing factor in this outbreak.	
VII_4	When did this factor most likely occur?	
Va_3	Select the reason that best describes how this single specific ingredient or multi ingredient food was implicated in the outbreak.	Describes the type of information used to determine the food associated with the outbreak.
Va_4	Which best describes the food preparation process used for this specific ingredient or multi-ingredient food before consumption?	Describe the preparation of the suspected ingredient/food associated with the outbreak.
Va_5	During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures, as described by managers and/or workers?	Describe the circumstances of the outbreak.
Va_5a	How would those differing events best be characterized?	
V1_1	Describe the agent found in the sample.	Describe sample agents.
VI_2	Where was the sample taken?	
VI_3	Provide any other information about the sample.	

Table B.4.2 Variables included in descriptive analyses of outbreak responses

Question Number	Question	Justification
I_12	What activities were conducted during the outbreak investigation to try to identify the contributing factors?	Describe outbreak investigation activities.
I_13	Please rate the quality of communication between the food regulatory program and the communicable disease control program during this outbreak investigation.	Describe communication during the outbreak investigation.

I_16	Were any immediate control measures implemented for this outbreak?	Describe outcomes of the outbreak investigation.
I_16a	If control measures were implemented, briefly describe this measures.	
II_1	Date the establishment was identified for an environmental assessment	Describe how long it takes to respond to outbreaks with an environmental assessment.
II_2	Date of first contact with establishment management	
II_3	Number of visits to the establishment to complete this environmental assessment	Describe environmental assessment responses.
II_4	Number of contacts with the establishment other than visits to complete this environmental assessment	
II_7	Was a translator needed to communicate with the kitchen manager during the environmental assessment?	Describe whether language and communication are issues in collecting information for environmental assessments.
II_7a	Was a translator used to communicate with the kitchen manager?	
II_8	Was a translator needed to communicate with the food workers during the environmental assessment?	
II_8a	Was a translator used to communicate with the food workers?	
II_13	Were any samples taken in the establishment?	Describe sampling practices
II_13a	Where were they taken?	
II_13b	What foods or ingredients were sampled?	
III_1a	How long was the interview?	Describe the time from identification/contact until specific environmental assessment activities are conducted.
III_1	Date the manager interview was initiated	
IV_1a	How long was the observation?	
IV_1	Date the observation was initiated	

To address the second goal of this data collection, describe environmental factors associated with outbreaks, we will conduct descriptive analyses (frequencies, means, etc.) to describe

- environmental antecedents (see Table B.4.3 for the variables included in these descriptive analyses and their environmental antecedent classifications [economics, equipment, food, people, processes])
- contributing factors (examined by category: contamination, proliferation, and survival; see Table B.4.4 for the variables included in these descriptive analyses).

The list and descriptions of all contributing factors can be found in Attachment 3.

NEARS collects data on a number of environmental antecedent variables. These variables were chosen for inclusion in NEARS because existing hypotheses, theories or data suggest that they may be related to food safety and/or foodborne illness outbreaks.

Table B.4.3. Variables included in descriptive analyses of environmental antecedents

Question Number	Question	Justification	Classification
I_14	What were the environmental antecedents of this outbreak?	Describe the underlying causes of the outbreak.	Economics, Equipment, Food People, Processes
I_15	Briefly describe any other information about the underlying causes of the outbreak		
II_5	Facility type	Describe facility type.	Process
II_6	How many critical violations/priority foundation items were noted during the last routine inspection?	Describe critical violations.	Equipment, People, Process
II_9	Establishment type	Describe establishment type.	Process
II_10	Do customers have direct access to unpackaged food such as a buffet line or salad bar in this establishment?	Describe customer access to unpackaged food.	People
II_11	Does the establishment serve raw or undercooked animal products (example, oysters or raw shell eggs) in any menu item?	Describe whether this food safety risk exists and whether customers are notified of this risk.	Food, Process
II_11a	Is a consumer advisory regarding the risk of consuming raw or undercooked animal products provided?		People
II_11a1	Where is the consumer advisory located?		People
II_12	Which one of the options best describes the menu for this establishment?	Describe the establishment menu.	Food, Process
III_2	Is this an independent establishment or a chain establishment?	Describe establishment ownership.	People, Process
III_3	Approximately how many meals are served here daily?	Describe volume of business.	Economics, People, Process
III_4	What is the establishment's busiest day, in terms of number of meals served?		
III_5	Are any foods prepared or partially prepared at a commissary or other location?	Describe whether foods are prepared at commissaries.	Process

III_6	Other than daily specials, when was the last time food items were added to your menu(s)?	Describe whether food items have been added to the menu.	Food, People, Process
III_7	Approximately how long have you been employed as a kitchen manager in this establishment?	Describe manager experience.	People, Process
III_8	Approximately how long have you worked as a kitchen manager?		
III_9	How many kitchen managers, including you, are currently employed in this establishment?	Describe ratio of managers to workers (measure of worker supervision).	People
III_10	What language(s) do you and other managers in this establishment speak fluently?	Describe manager/worker communication/language barriers.	People
III_11	What languages do you and other managers speak at work?		
III_12	In your opinion, how well do you communicate verbally with your food workers, very well, somewhat well or not well at all?		
III_13	Do any kitchen managers receive food safety training?	Describe manager food safety training.	People
III_13a	How many kitchen managers have had food safety training?		
III_13b	What type of food safety training do kitchen managers (you) receive?		
III_14	Does this establishment require that kitchen managers have a food safety certification?	Describe food safety certification.	People
III_15	Are any kitchen managers, including you, food safety certified?		
III_15a	How many kitchen managers in this establishment, including yourself, are food safety certified by an ANSI accredited program such as ServSafe National Registry of Food Safety Professionals/Environmental Health Testing or Thomson Prometric?		
III_15b	How often is there a certified kitchen manager present during hours of operation?		
III_16	How many food workers do you have?	Describe staff size.	People, Process
III_16a	What language(s) do food workers in this establishment speak fluently?	Describe manager/worker communication/language barriers.	People
III_16b	What languages do food workers speak at work?		

III_16c	Do any food workers receive food safety training?	Describe food worker food safety training.	People
III_16c1	How many food workers have had food safety training?		
III_16c2	What type of food safety training do food workers receive?		
III_17	Does this establishment have a policy or schedule for	Describe cleaning and glove use policies.	Process
III_17a	Cleaning cutting boards?		
III_17b	Cleaning food slicers?		
III_17c	Cleaning food preparation tables?		
III_17d	After a worker or customer vomits and/or has diarrhea in the establishment?		
III_17e	Frequently touched customer surfaces?		
III_17f	Are any of these policies written?		
III_17f1	Which ones?		
III_18	Does this establishment have a policy for disposable glove use?		
III_18a	Does the glove use policy require that food workers wear gloves?		
III_18a1	When they have cuts or other injuries?		
III_18a2	When handling ready-to-eat foods?		
III_18a3	When handling raw meat or poultry?		
III_18a4	At all times while working in the kitchen?		
III_18b	Is the policy written?		
III_19	Does this establishment have a policy to take the temperature of any incoming food products?	Describe temperature taking policies.	Process
III_20	Excluding incoming products, does this establishment have a policy to take food temperatures?		
III_21	When food workers say they are ill, do you typically ask if they are experiencing certain symptoms?	Describe ill worker and sick leave policies.	Process, People
III_22	Does this establishment have a policy or procedures that requires food workers to tell a manager when they are ill?		
III_22a	Is this policy in writing?		

III_22b	Does this policy require ill workers to tell managers what their symptoms are?		
III_22c	Does this policy specify certain symptoms that ill workers are required to tell managers about?		
III_25c1	What are those symptoms?		
III_23	Does this establishment have a policy or procedure to restrict or exclude ill workers from working?		
III_23a	Is this policy in writing?		
III_23b	Does this policy specify the specific symptoms that would prompt excluding or restricting ill workers from working?		
III_23b1	What are those symptoms?		
III_24	Do any kitchen managers (including you) ever get paid when they miss work because they are ill?		
III_24a	How many kitchen managers get paid when they miss work because they are ill?		
III_25	Do any food workers ever get paid when work is missed because they are ill?		
III_25a	How many food workers get paid when they miss work because they are ill?		
IV_2	How many hand sinks are in the employee restrooms?	Describe availability of handwashing sinks, supplies and equipment, and handwashing and handwashing behavior	Equipment, People
IV_2a	Is warm water (minimum 100°F) available at all employee restroom hand sinks?		
IV_2b	Is soap available at (or near) all employee restroom hand sinks?		
IV_2c	Are paper or cloth drying towels or electric hand dryers available at (or near) all employee restroom hand sinks?		
IV_3	How many hand sinks are located in the work area?		
IV_3a	Is warm water (minimum 100°F) available at all hand sinks in the work area?		
IV_3b	Is soap available at (or near) all employee restroom hand sinks in the work area?		
IV_3c	Are paper or cloth drying towels or electric hand		

	dryers available at (or near) all hand sinks in the work area?
IV_4	If workers are observed washing hands, do the hand washes include water, hand cleanser, appropriate drying methods and are they for the appropriate length of time (approximately)?

IV_5	How many cold storage units are in the establishment?	Describe cold storage units and their temperatures.	Equipment
IV_5a	Which types of units did you observe?		
IV_6	Were any foods observed in cold holding?		
IV_6a	Were the temperatures of all foods measured in cold holding at 41°F or below?		
IV_7	Are any food workers using gloves while handling food?	Describe glove practices.	Equipment, People
IV_8	Is there a supply of disposable gloves available in the establishment?	Describe glove availability.	Economics, Equipment
IV_9	Are food workers using any methods besides gloves to prevent bare hand contact with ready-to-eat food?	Describe other bare hand contact prevention practices.	Equipment, people
IV_9a	If methods besides gloves are used: What methods?		
IV_10	Are any food workers handling ready-to-eat foods with bare hands?	Describe bare hand contact practices.	People
IV_12	Are there records to indicate that the temperatures of incoming ingredients are being taken and recorded?	Describe temperature taking and recording practices.	People
IV_13	Are there records to indicate that the temperatures of foods, excluding incoming ingredients, are being taken and recorded?		
IV_13	Is there any evidence of direct cross contamination of raw animal products with ready to eat foods?	Describe practices that could lead to cross contamination.	People, Process
IV_13a	Describe cross contamination evidence.		
IV_14	Were any hot foods observed in cooling?	Describe food cooling practices.	Process
IV_14a	What cooling method(s) are used?		
IV_14b	Were the cooling methods properly implemented?		
IV_15	Were any foods observed in hot holding?	Describe food holding and cooking practices.	People, Process
IV_15a	Were the temperatures of all foods measured in hot holding at 135°F or above?		
IV_16	Were any foods observed during cooking?		
IV_16a	Were the temperatures of all foods measured during cooking at or above the recommended temperatures?		
IV_17	Were any thermometers observed in food preparation areas to measure food temperatures?		
IV_17a	Were any thermometers observed being used?		
IV_18	Were any of these materials observed for	Describe cleaning practices.	People,

	cleaning/sanitizing food contact surfaces and in-place equipment?		Process
IV_18a	Are all wet wiping cloths stored in sanitizer solution between uses?		
IV_18b	Pick one sanitizer bucket (or bottle) and test sanitizer concentration. Is it in the proper range?		
IV_19	What does the establishment use to clean dishes, utensils, or other food equipment that is not cleaned in place?	Describe dishwashing practices.	Equipment, Process
IV_19a	Does the wash cycle reach the temperatures recommended for the mechanical washing machine?		
IV_19b	How is sanitization achieved?		
IV_191	Does the sanitizing cycle reach the temperatures recommended for sanitization?		
IV_19b2	Does the chemical sanitizing cycle have the required levels of chemical sanitizer recommended for the machine?		
IV_19c	What type of sink is used for manual washing?		
IV_19d	Are dishes, utensils, etc. washed, rinsed, and sanitized (either with heat or chemical) properly?		
IV_19d1	Is a sanitizing method properly implemented?		
IV_20	Did you observe signs and instructions posted in the establishment?		
IV_20a	Did any use pictures or symbols to communicate a message?		
IV_20b	What languages did you observe on signs or instructions posted for food workers?		
IV_21	Did you observe any of these items for responding to vomit and/or diarrheal incidents?	Describe equipment for cleaning after vomiting/diarrheal incidents	Equipment
IV_21a	Were any of these things located together?		
IV_24	Is a certified manager present at the time of data collection?	Describe manager training	People

IV_25	Does the written employee health policy or procedure....	Describe employee health policy	Process
Va_1	What is the name of the suspected or confirmed ingredient/food vehicle?	Describe and classify food ingredients linked with the outbreak.	Food
Va_2	Is this food a single specific ingredient or multi-ingredient?		
Va_3	Select the reason that best describes how this single specific ingredient or multi-ingredient food was implicated in the outbreak.		
Va_4	Which of the following best describes the food preparation process used for this specific ingredient or multi-ingredient food before consumption?		
Va_5	During the likely time the ingredient/food was prepared, were any events noted that appeared to be different from the ordinary operating circumstances or procedures, as described by managers and/or workers?	Describe and classify the food prep processes that the establishment used to prepare the suspected/confirmed vehicle.	Food, Process
Va_5a	How would these events best be characterized?		
Vb_1	Name of ingredient	Out-of-the ordinary events can lead to potential food safety risks. These data will identify and describe these events.	Economics, Equipment, Food People, Processes
Vb_2	If any information is present that shows this ingredient is an important food item or from an unapproved source or recall, describe.		
Vb_3a	Select poultry type		
Vb_3b	Select seafood type		
Vb_3c	Select beef, pork, lamb, other meat type		
Vb_3d	Poultry, seafood, beef, pork, lamb, other meat, Select best description of product upon arrival at the food service establishment		
Vb_3e	Dairy, Select best description of product upon arrival at the food service establishment		
Vb_3f	Eggs, Select best description of product upon arrival at the food service establishment		
		Describe and classify food ingredients linked with the outbreak.	Food, Process

Vb_3g	Plant or plant product, Select type
Vb_3h	Produce, Select produce type
Vb_3i	Plant or plant product, Select best description of product upon arrival at the food service establishment
Vb_3j	Describe other ingredient

To address the third goal of this data collection, describe the associations between environmental antecedents and contributing factors, we will conduct tests for association and logistic regression models.

Analysis will involve bivariate tests for association between individual environmental antecedent (explanatory) variables and the contributing factor (outcome) variables. Odds ratios will be calculated to assess the strength and direction of the bivariate relationships. For those bivariate associations found to be statistically significant at $p < .30$, the environmental antecedent variables will be used as candidate “predictors” to examine their multivariate relationships with the contributing factor variables. Multivariable logistic regression will be used to model for the effects that these environmental antecedent variables have in explaining the variations observed in the contributing factor variables. This type of analysis allows us to determine which environmental antecedents contribute to the presence of the contributing factor, and the relative degree of impact that each environmental antecedent has in the presence of that contributing factor. A separate model will be developed for each contributing factor analyzed.

Table B.4.5 describes the study questions designed to address this third goal of this data collection and the data collection variables designed to answer those questions. Note that we will likely create composite environmental antecedent variables based on the individual variables listed in the table.

Table B.4.5. Study questions and the data collection variables designed to answer those questions

Study Question	Environmental Antecedent Variables	Contributing Factors
How are specific environmental antecedents related to contamination contributing factors?	II_5, II_6, II_7 (a), II_8 (a), II_9, II_10, II_12, III_2, III_3, III_4, III_5, III_6, III_7, III_8, III_9, III_10, III_11, III_12, III_13 (a, b), III_14, III_15 (a, b), III_16 (a, b, c, c1, c2), III_17 (a, b, c, d, e, f, f1), III_18 (a, b), III_21, III_22 (a, b, c, c1), III_23 (a, b, b1), III_24 (a), III_25 (a), III_26 (a), IV_2 (a, b, c), IV_3 (a, b, c), IV_4, IV_7, IV_8, IV_9 (a), IV_10, IV_13 (a), IV_17 (a, b), IV_18 (a, b), IV_19 (a, b, b1, b2, c, d, d1), IV_20 (a, b), IV_21, IV_22 (a), IV_23, IV_24, IV_25	C1-C15
How are specific environmental	II_5, II_6, II_7 (a), II_8 (a), II_9, II_11, II_12, III_2, III_3,	P1-P12

antecedents related to proliferation contributing factors?	III_4, III_5, III_6, III_7, III_8, III_9, III_10, III_11, III_12, III_13 (a, b), III_14, III_15 (a, b), III_16 (a, b, c, c1, c2), III_17 (a, b, c, d, e, f, f1), III_19, III_20, IV_5 (a), IV_6 (a), IV_11, IV_12, IV_14 (a, b), IV_15 (a), IV_16 (a), IV_17 (a)	
How are specific environmental antecedents related to survival contributing factors?	II_5, II_6, II_7 (a), II_8 (a), II_9, II_11 (a, a1), II_12, III_2, III_3, III_4, III_5, III_6, III_7, III_8, III_9, III_10, III_11, III_12, III_13 (a, b), III_14, III_15 (a, b), III_16 (a, b, c, c1, c2), III_17, III_18, III_20, III_26 (a), IV_16 (a), IV_17 (a), IV_22 (a), IV_23	S1-S5

Table B.4.6 is a table shell that illustrates how we might analyze and present the data examining the bivariate relationships between specific environmental antecedents and the contributing factor of bare-hand contact with ready-to-eat food by a food worker who is suspected to be infectious (contributing factor C10).

Table B.4.6. Example Table Shell: Environmental antecedent variables associated with the outcome variable of whether the contributing factor of bare-hand contact with ready-to-eat food by an infectious food worker was identified, bivariate analyses

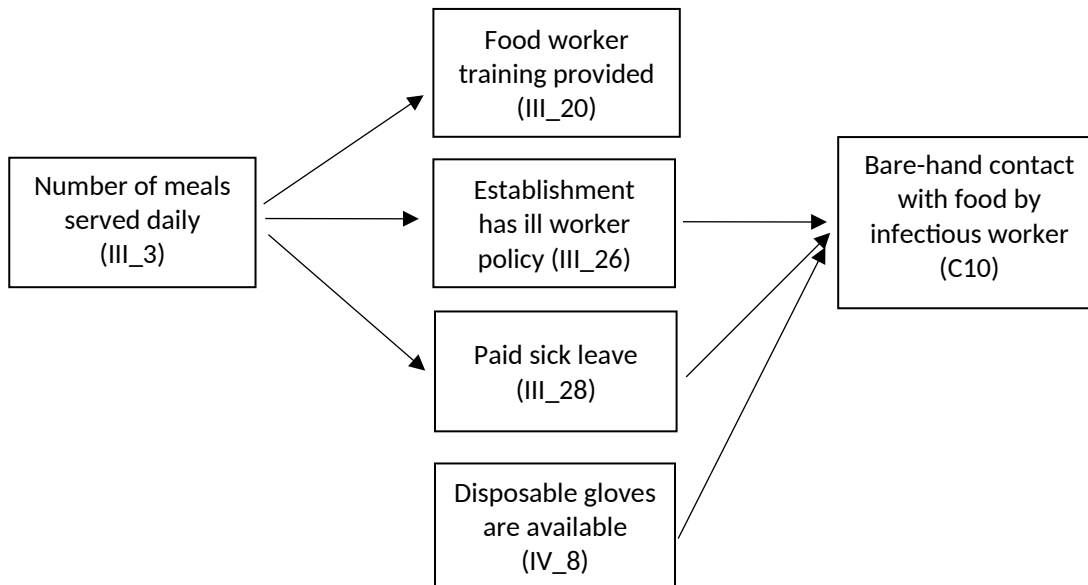
Environmental antecedent variables	Bare hand contact with food by infectious food worker (C10) identified as a contributing factor	
	OR (95% CI)	P
Number of meals served daily (III_3)		
<300	x.xx (ref)	.xxx
≥300	x.xx	
Food worker training provided (III_20)		
No	x.xx (ref)	.xxx
Yes	x.xx	
Paid sick leave provided (III_28)		
No	x.xx (ref)	.xxx
Yes	x.xx	
Establishment has ill worker policy (III_26)		
No	x.xx (ref)	.xxx
Yes	x.xx	
Disposable gloves are available in establishment (IV_8)		
No	x.xx (ref)	.xxx

Yes		x.xx	
Hand sink is available in work area (IV_2)			
No		x.xx (ref)	.xxx
Yes		x.xx	

OR=Odds Ratio, P=probability level

Below is an example figure demonstrating results from a multivariate analysis of the associations between environmental antecedents and the contributing factor of bare-hand contact with ready-to-eat food by an infectious food worker. This type of analysis allows us to determine the relationships among environmental antecedents and between environmental antecedents and contributing factors. It allows us to determine the direct and indirect effects of each environmental antecedent on the contributing factor. A separate model would be developed for each contributing factor analyzed.

Figure B.4.1. Example Figure - Environmental antecedent variables associated with the outcome variable of whether the contributing factor of bare-hand contact with ready-to-eat food by an infectious worker was identified, multivariate analyses



B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The following persons were primarily responsible for designing the instrument; however, Laura Brown and Adam Kramer will be primarily responsible for analyzing data.

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References

- Brown, L, Hoover, E, Selman, C, Coleman, E, Schurz Rogers, H. Outbreak characteristics associated with identification of contributing factors to foodborne illness outbreaks. *Epi Infect.* 2017;1:1-9.
- Dewey-Mattia D, Manikonda K, Hall AJ, Wise ME, Crowe SJ. Surveillance for Foodborne Disease Outbreaks — United States, 2009–2015. *MMWR Surveill Summ* 2018;67(No. SS-10):1-11.
- Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis.* 2011; 17:7–15.
- Scallan E, Griffin PM, Angulo FJ, Tauxe RV, Hoekstra RM. Foodborne illness acquired in the United States—unspecified agents. *Emerg Infect Dis.* 2011; 17:16–22.

Attachments

- Attachment 1A. Authorizing Legislation 42 U.S.C. § 241
- Attachment 1B. Authorizing Legislation 21 U.S.C § 2201
- Attachment 2. 60-day Federal Register Notice
- Attachment 3. Definition of Contributing Factors to Foodborne Illness Outbreaks
- Attachment 4. NEARS Food Safety Program Training Webinar
- Attachment 5. NEARS e-Learning on Environmental Assessment Foodborne Illness Outbreaks (screenshots)
- Attachment 6. NEARS Data Recording Instrument Word
- Attachment 7. NEARS Data Recording and Manager Interview Web Entry (screenshots)
- Attachment 8. NEARS Manager Interview
- Attachment 9. Research Determination Form