FoodNet Population Survey

Existing Collection In Use Without an OMB Control Number

Supporting Statement – Section A

April 11, 2016

Program Official/Project Officers

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- Goals of study
    a. Provide necessary data to estimate the burden of unreported and reported acute diarrheal illness in the catchment area, for use in modeling such burden in the United States more broadly.
    b. Assess the frequency of important exposures commonly associated with foodborne illnesses in the catchment area, for use in modeling such burden in the United States more broadly.
- Intended use of resulting data:
    a. Populating models designed to estimate prevalence of diarrheal illnesses in the United States
        - Assess efficacy of interventions implemented to reduce diarrheal diseases
        - Develop metrics for diarrheal disease food safety policies and programs
        - Estimate costs of diarrheal illnesses
        - Inform industry, academic and public health diarrheal disease research and food safety activities
    b. To provide estimates of food consumption and other exposures in the catchment area for use to guide generation of hypotheses during outbreak investigations
    c. To provide estimates of food consumption and other exposures in the catchment area to assist in the study of factors (e.g. specific foods, routes of exposure, settings, healthcare seeking behavior) associated with sporadic illness
    d. To provide data to estimate changes in healthcare seeking behavior and diagnostic testing practices (stool testing) for diarrheal illnesses in the catchment area
- Methods for data collection — Multi-mode survey (landline, cell phone, web, mail)
- Subpopulation to be studied — Residents of the FoodNet catchment area
- How data will be analyzed — Descriptive statistics and regression modeling

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Justification

1. Circumstances Making the Collection of Information Necessary

Background

Foodborne illnesses represent a significant public health burden in the United States. It is estimated that each year, 48 million Americans (1 in 6) become ill, 128,000 are hospitalized, and 3,000 die as the result of a foodborne illness[1]. Because foodborne illness poses a substantial public health challenge, food safety has been identified as one of CDC's ten "winnable battles", public health priorities with large-scale impact on health and with known, effective strategies to address them (See Attachment C).

The Foodborne Diseases Active Surveillance Network (FoodNet) is the principal foodborne disease component of CDC's Emerging Infections Program (EIP) (OMB: 0920-0978) and a collaborative project of the CDC, ten EIP sites (California, Colorado, Connecticut, Georgia, New York, Maryland, Minnesota, Oregon, Tennessee and New Mexico), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA). Since 1996, FoodNet has conducted active population-based surveillance for *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin-producing *Escherichia coli* O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* infections. The surveillance area includes 15% of the United States population (48 million persons). Data from FoodNet serve as the nation's "report card" on food safety by monitoring progress toward Healthy People 2020 objectives.

FoodNet determines the incidence of laboratory-confirmed infections for bacterial pathogens transmitted commonly through food. However, these reports represent only a subset of the number of cases of diarrheal illness that occur in the community. Most diarrheal illnesses are undiagnosed and, therefore, not reported. In order for a case of foodborne illness to be reported: the person must become ill, the ill person must seek and have access to medical care, a health care provider must obtain a specimen for microbial analysis from the ill person and submit the specimen to a laboratory, the laboratory must test for the pathogen and identify the pathogen, the laboratory must report the case to the local or state health department, and the case must be reported to CDC. Understanding the degree of underreporting that occurs at each of these steps is a critical piece in understanding the burden of foodborne illness in the surveillance area.

Evaluation of efforts to control foodborne illnesses can only be done effectively if there is an accurate estimate of the total number of illness that occur and if these estimates are recalculated and monitored over time. Estimates of the total burden start with accurate and reliable estimates of the number of acute gastrointestinal illness episodes that occur in the general community. To more precisely estimate the number of acute diarrheal illness and to describe the frequency of important exposures associated with illness, FoodNet created the Population Survey. The methods for this population-based survey of persons residing in the surveillance area is modeled after the BRFSS. Data are collected on the prevalence and severity of acute gastrointestinal illness (AGI) in the general population of the FoodNet geographic areas, describe common symptoms associated with diarrhea, and determine the proportion of persons with diarrhea who seek medical care. The survey also collects data on exposures (e.g. food, water, animal contact) commonly associated with foodborne illness. To date, five 12-

month cycles of the survey have been completed: 1996-1997, 1998-1999, 2000-2001, 2002-2003, and 2006-2007. By conducting the Population Survey in the same geographic areas served by FoodNet, it is possible to adjust pathogen-specific incidence of foodborne diseases for underdiagnosis resulting from medical care seeking and specimen submission and to link these data with other relevant information, including hospitalizations, deaths, and history of travel. Because FoodNet conducts surveillance at 10 US sites, these data are further adjusted for geographical coverage (online Technical Appendix).[1]

Data from the population survey have multiple uses. Information on AGI and health-seeking and testing behaviors, used in conjunction with foodborne disease surveillance, serve as the foundation of estimates of total number of foodborne illnesses in the United States summarized in publications by Mead et al, in 1999[3] and Scallan et al, in 2011[1]. Data on food exposures in the general public have proved invaluable to outbreak investigations. The ability to compare exposures reported by outbreak cases to the 'background' exposure in the general population allows investigators to more quickly pinpoint a source and enact control measures. More than two dozen manuscripts incorporating population survey data have been published[1,3-24].

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

2. Purpose and Use of the Information Collection

The objectives of the survey are:

a. Provide necessary data to estimate the burden of unreported and reported acute diarrheal illness in the catchment area, for use in modeling such burden in the United States more broadly.
b. Assess the frequency of important exposures commonly associated with foodborne illnesses in the catchment area, for use in modeling such burden in the United States more broadly.

The results of the survey will be used:

- To populate CDC's model designed to update estimates on total number of diarrheal illnesses and foodborne illnesses in the United States.
    i. The most recent estimates on total number of illnesses were published in 2011 and relied heavily data from the 2006-2007 population survey. The program has committed to publication of the new estimates by the year 2020. Data on AGI and health seeking behavior are a critical piece of these estimates and are not available from any other source. Data obtained from this population survey would be paired with data from active case surveillance conducted in these same sentinel sites to determine burden of disease from individual pathogens that cause foodborne illness.
    ii. Assessing trends in burden of disease in the surveillance catchment area can be used to assess efficacy of diarrheal disease prevention interventions and serve as metrics for food safety policies and programs.

[1] http://www.cdc.gov/foodborneburden/resources.html

iii. Estimates of diarrheal illnesses in these sentinel sites can be used to estimate morbidity, mortality, and costs of diarrheal illnesses.
iv. Estimates can be used to inform industry, academic, and public health diarrheal disease research and food safety activities.

- To provide estimates of food consumption and other exposures for use to guide generation of hypotheses during outbreak investigations.
    i. Information on food consumption in the general population of the FoodNet sites can be compared to foods that are mentioned by case patients during an outbreak. Having this readily available comparison group allows investigators to narrow the focus of their investigation thereby enhancing the timeliness of public health response.
- To provide estimates of food consumption and other exposures to assist in the study of factors associated with sporadic illness.
    i. Through routine, active surveillance, FoodNet collects standardized information on food and water consumption and environmental exposures from persons with *Salmonella* and *Campylobacter* within the FoodNet geographic areas. Collecting this same information from the general population in these FoodNet sites gives us a readily available comparison group which will allows us to identify potential risk factors to inform attribution estimates and as hypothesis to be tested in future research studies.
- To provide data to estimate changes in healthcare seeking behavior and diagnostic testing practices (stool testing) for diarrheal illnesses.
    i. These estimates are used to assess the number of persons in FoodNet geographic areas that sought medical care for diarrheal illnesses, and identification of the predictors of seeking care (e.g. illness duration, illness severity, gender, age, income). This estimate can be used to inform public health policy and preparedness.
    ii. These estimates are used to assess how many persons with diarrheal illness in FoodNet geographic areas provided a stool sample for identification and identifies predictors of stool sample providers (e.g. illness duration, illness severity). The current landscape of diagnostic practice for diarrheal illnesses is rapidly shifting. A stool sample is required for antimicrobial resistance testing, species determination, and serotype determination which are all used for outbreak detection.

The data from this collection are not designed to be nationally representative. Similarities between the US population and the surveillance network with respect to high-level demographic characteristics such as percent of the population that is Caucasian do not address potential relationships between geographic variables, health variables, and demographic characteristics. As such, CDC must always transparently articulate the limitations with respect to generalizability.

De-identified results will be made available in a public use data file. A link to data file will be posted to the CDC FoodNet website shared with participating state health departments and CDC programs, FDA, and USDA.

3. Use of Improved Information Technology and Burden Reduction

An integrated data collection platform that has been used in numerous surveys and can generate screens adapted for each data collection mode will be used by the contracting agency, ICF.[1] This approach offers several benefits including standardized skip patterns and logic rules, quotas, and databases across multiple modes; more efficient, accurate tracking and reporting across all survey modes; and complete flexibility for respondents (they can complete part of the survey by phone or web, return to the survey at a later time, and seamlessly pick up where they left off).
Hard copy forms will not be used, thereby reducing the time and resources needed for manual data entry. Data will be transmitted to CDC electronically.

4. Efforts to Identify Duplication and Use of Similar Information

FoodNet is a collaborative program coordinated within the Enteric Disease Epidemiology Branch (EDEB) in the Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) at CDC. EDEB and DFWED are responsible for surveillance and study of foodborne diseases in the United States. FoodNet Population Survey is unique in that within the survey population FoodNet has conducted active surveillance on 9 enteric pathogens, collecting demographic, geographic, testing practices, and outcome data. By pairing the population survey data with active case-based surveillance data collected from these same sentinel sites, we can more efficiently collect data needed to determine burden of disease from individual pathogens that cause foodborne illness.

Exploration of using BRFSS to collect some of this data was explored in 2013 and 2014. We submitted a questionnaire of 10 questions to be voted on for incorporation into the survey. In both years we received feedback from state partners that these questions were not in-line with the objectives of BRFSS as they were not behavioral objectives. BRFSS core survey (conducted on all participants) is a lengthy survey and in order to minimize burden on survey respondents, proposals of adding more than 10 are proposed as “optional” modules (conducted on selected participants). This optional module has to be approved by a minimum 70% of the states. Once approved implementation of the optional module is not mandatory, thus even though you achieved approval and funded for example a 10 question optional module at ($18,000/question), you have no guarantee that states will elect to implement your module. In 2010, BRFSS had 26 optional modules with a median of 5 questions per module. The median number of states that participated in each optional module was 5.0, limiting the ability to apply interpretation of the data obtained on a national level. In 2013, FoodNet staff surveyed state representatives at the BRFSS conference and only a minority of states (n=8) expressed interest in incorporating the module and all stated that it was too long. We submitted the optional module for approval, and only 59% of states voted for it to even be an option. This module would have only provided data for determining the burden of acute intestinal illness and would not have allowed us to achieve our other equally important objectives. In 2007 we were able to incorporate 2 questions into the BRFSS core survey that are included in our current population survey. This will allow for a baseline comparison for future efforts.

Other efforts such as National Health and Nutrition Examination Survey (NHANES) collect food consumption data, however the data collected by these efforts does not meet our needs. For example, NHANES does not meet our needs for 3 main reasons: the exposure history time

period (24hrs) and methodology (complete diary) compatible with the exposure history (7-14 days) and methodology (high risk exposures, targeted routes of exposures, balanced questionnaire of all food commodities) used for outbreak investigations and food source attribution. In summary no other groups collect the type and level of detailed information that is proposed in this study.

5. Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The purpose of this survey is to collect data that is not otherwise available. Specifically, without this data there would be:

- Inability to provide updated burden of foodborne illness estimates which have been requested by federal regulatory agencies,
- Reduced ability to conduct outbreak investigations because of a lack of information on current food consumption practices and other exposures.

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 with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

- A 60-day Federal Register Notice will be published in the Federal Register. Comments will be reviewed and incorporated, as appropriate, into the survey protocol and questionnaire.
- The development of this study was a collaborative effort among all agencies in the FoodNet program. The protocol and questionnaire has undergone extensive review and edits over the five cycles of administration. Prior to each cycle of the survey, the Population Survey working group, consisting of representatives from each of the partner agencies, was convened. This group was used to develop the survey content, which was then shared with all members of the FoodNet steering committee (including the FoodNet principal investigators) for approval. Current members of the working group include: (CDC) Allison Brown, Sarah Collier, Cindy Friedman, Katie Fullerton, Aimee Geissler, Laura Gieraltowski, Jennifer Hunter, Olga Henao, Ellyn Marder, Patricia Griffin, Scott Grytdal, Aron Hall, Michele Hlavsa, Mike Hoekstra, Kelly Jackson, Karen Neil, Thai-An Nguyen, Megin Nichols, Elaine Scallan, Robert Tauxe, Antonio Vieira, Matthew Wise, Ian Williams; U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS),) Wu San Chen, Kristin Holt, Janelle Krause, Amelia Kermis, Bonnie Kisler, Davi LaBarre, Maria Malagon; (U.S. Food and Drug Administration (FDA)) Michael Bazaco, Susan Lance, Marguerite Pappaioanou, Cary Parker, Katherine Vierk, Beverly Wolpert; (California Emerging Infections Program) Debra Gilliss,

Tanya Libby; (Colorado Department of Public Health and Environment) Elisha Wilson; (Connecticut Department of Public Health) Terry Rabatsky-Ehr, Connecticut Emerging Infections Program) Paula Clogher, Jim Hadler; (Georgia Division of Public Health) Nadine Oosmanally; (Maryland Department of Health and Mental Hygiene) Michelle Boyle, Jordan Cahoon; (Minnesota Department of Health) Amy Saupe; (New Mexico Emerging Infections Program) Sarah Lathrop, Cyndy Nicholson; (New York State Department of Health) Suzanne McGuire, Shelley Zansky;(Oregon Department of Human Services) Paul Cieslak, Beletshachew Shiferaw; (Tennessee Department of Health) Corrine Davis, John Dunn.

9. Explanation of Any Payment or Gift to Respondents

The contract developed by the survey implementation partner, ICF, includes a $2 to $5 pre-incentive, which has been shown to increase response rates by as much as 20 points. Details of payment to recipients are described in *Supporting Statement – Section B*.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act is not applicable since no identifiable information is being collected.

Individuals asked to provide information for the survey will be informed of the reason for collecting the information and how the information will be used. Participants are informed that study participation is completely voluntary and they may choose to decline study enrollment or to not answer any questions that they consider to be of a sensitive nature. There are no penalties for not participating. Participants may refuse to answer any of the questions or to discontinue the survey at any time. Consent and assent will be documented. All survey data will be kept secure. Names will not be collected. Analysis will be conducted at a summary level.

A statement of how data will handled will be read to each potential participant as part of the process of obtaining informed consent for participation in the study. Only the databases will be forwarded to CDC. Demographic information (e.g. age, sex) will be collected; individual names will not. Each record will be assigned a unique ID. Only summary information will be included in analysis and reports.

This study has been approved by the Institutional Review Board at CDC (Attachment E).

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Data collection will be for a total of 24 months. For each 12 month period, we anticipate an enrollment of 150 persons per site per month which will result in 18,000 interviews. In addition, there will be pilot interviews with up to 200 people. Each interview will take approximately 20 minutes (or 0.33 hours). This results in a total burden of 6,066 hours for 12 months of data collection, and 12,133 hours for the entire survey period.

Table A.12-1. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)

U.S. General Population	Attachment D. Pop Survey_ questionnaire_ Feb 2016	18,200	1	20/60	6,033
Total					6,0000

Annualized burden costs are summarized in the table below. These calculations assume the average hourly wage of $24.54 for all jurisdictions included in the FoodNet catchment area. Hourly rates were taken from the most recent publically available Current Employment Statistics of the Bureau of Labor Statistics and are based upon the average hourly earnings for October 2012 from the Current Employment Statistics survey conducted by the Bureau of labor Statistics (available at http://data.bls.gov/cgi-bin/surveymost).

Table A.12-2. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Average Hourly Wage Rate*	Total Cost Burden
U.S. General Population	Attachment D. Pop Survey_IRB approved questionnaire_April 2015	6,033	$24.54	$148,050
Total		6,033	$24.54	$148,050

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

There will be no direct costs to the respondents other than their time to participate in each survey.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The cost to the federal government includes the salary of CDC staff supporting the data collection activities and the money to support the contracting company for survey administration.

CDC staff will work with the contractor to oversee deliverables, obtain study data, and perform analysis. The costs will be spread over a period of four years. Year 1 will include activities such as obtaining OMB approval, working to set up the contract, analyzing feedback from 9 pilot interviews, and making any necessary revisions to the questionnaire. Years 2 and 3 will involve oversight of contractor during data collection, and receipt and analysis of preliminary data. Year 4 will involve analysis of final data and preparation of summary reports. The annualized cost will be $66,250; the total cost over 4 years will be $265,000.

An outside company (to be contracted through CDC) will have the primary responsibility for administration of this survey. In year 1, the contractor will provide expertise in survey design and implementation, work with CDC to define modes of administration, conduct focus testing of questionnaires, conduct pilot testing prior to the start of study, develop sampling weights, and program the survey instruments. The Contractor will also pre-test the questionnaire to assure the programming and questionnaire and skip patterns work properly. Finally, the Contractor will

be responsible for obtaining Institutional Review Board (IRB) review and approval prior to data collection, if necessary. In years 2 and 3, the contractor will collect the data, make changes as requested by the client, generate datasets to be used by CDC for analysis, and generate quarterly progress reports. In year 4, the contractor will generate the final dataset for the study per CDC specifications and generate a technical report summarizing the study. The cost of this contract is estimated to be $1,992,848 which will be spread out over 4 years in accordance with the stated deliverables. (Exact costs will not be available until after contractor is selected). Table A.14 shows the average cost for one year. A detailed estimate of costs is found in Attachment F.

The estimated cost to the federal government for one year is $564,462. Table A-14.1 describes how this cost estimate was calculated. Total cost over 4 years (set up, 2 years of data collection, analysis) is $2,257,848 (CDC staff: $265,000; contract: $1,992,848).

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Senior Epidemiologist(GS-13) Work with contractor to finalize development of instrument, pilot testing, renewal of IRB and OMB packages, receive and analyze data	1,000 (20 hours per week for 50 weeks/year)	$41.93	$41,930
Surveillance Epidemiologist (GS-9) Assist with data analysis and report preparation	1,000 (20 hours per week for 50 weeks/year)	$24.32	$24,320
Contract (1 year)			$498, 212
Estimated Total Cost of Information Collection			**$564,462**

15. Explanation for Program Changes or Adjustments

Although 5 cycles of the FoodNet population survey have been conducted, this request is the first for OMB. Initial burden estimates are based on responses from the 2006-2007 survey. CDC will use the Change Request mechanism to provide updates on any changes to the content of the survey for 2015-2016 and estimated burden per response.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of the survey will be shared with participating state health departments and CDC programs, available for public release through a summary report, and posted to the FoodNet website.

Analysis Plan

Preliminary data analysis will begin upon receipt of the first dataset from the contracting company (estimated to be one month after completion of the first 3 months of interviews) and continue with each subsequent dataset. Final analysis will be conducted after receipt of the final

study dataset containing information from the full 24 months. CDC staff will perform analysis using SAS v9.3. The analysis will consist of descriptive statistics and regression modeling, as appropriate.

Project Time Schedule

- ✓ Design survey questionnaire.....(COMPLETE)
- ✓ Receive IRB approval.....(COMPLETE)
- ✓ Prepare the request for task order proposal form.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Publish RFP, receive bids, and select contractor.....(COMPLETE)
- ❑ Pilot test survey questionnaire.....(1 month)
- ❑ Conduct survey.....(24 months)
- ❑ Collect, code, quality control, and analyze data.....(3 months)
- ❑ Prepare summary reports.....(3 months)
- ❑ Disseminate results/publication of findings.....3 months)

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

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List of Attachments

Note: Attachments are included as separate files as instructed.

- **Attachment A: Authorizing Legislation**
- **Attachment B: Federal register 60 day notice**
- **Attachment C: Winnable Battles Letter from CDC Director on Food Safety**
- **Attachment D: Pop Survey Cleared Questionnaire February 2016**
- **Attachment E. Protocol 1546 CDC Continuation Approval**
- **Attachment F: APHIR IGCE FoodNet Population Survey RFTOP v2**