State Health Department Reporting and Testing Practices: *Campylobacter* and Shiga toxin-producing *Escherichia coli* (STEC)

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Program Official/Project Officers

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Section A – 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 A. Winnable Battles**).

Campylobacter is a leading cause of bacterial foodborne disease with an estimated 1.3 million illness occurring annually in the US. The incidence of infection is highest in children <5 years. The incidence appears to be increasing; in 2012 rates reached their highest level since 2000. Although most infections are self-limited, *Campylobacter* infection can lead to reactive arthritis and Guillain-Barre syndrome.

Shiga toxin-producing *Escherichia coli* (STEC) is an important cause of bacterial foodborne disease and estimated to cause more than 260,000 cases each year. The highest incidence of infection occurs in children <5 years and overall rates have remained unchanged in recent years. Approximately 5–10% of persons diagnosed with STEC infection develop a potentially life-threatening complication known as hemolytic uremic syndrome (HUS).

Cases of *Campylobacter* and STEC are monitored at CDC through several surveillance systems. Two national passive systems, the National Notifiable Diseases Surveillance System (NNDSS) **(see Attachment B. NNDSS website)** and Laboratory-based Enteric Disease Surveillance (LEDS) **(see Attachment C. LEDS website)**, collect information from all states. The Foodborne Disease Active Surveillance Network (FoodNet) **(see Attachment D. FoodNet website)** is an active system that collects information from 10 states.

STEC is a nationally-notifiable disease and data from NNDSS and LEDS are routinely summarized and included in annual reports. STEC is being assessed because we recently put out lab testing guidelines and want to see if states are following them. We didn't choose other foodborne pathogens because they are already nationally notifiable so we know that the data we are getting are more consistent, and we don't have plans to use the information if it were collected on other pathogens.

Campylobacter is not nationally-notifiable, reporting to NNDSS and LEDS is inconsistent, and the quantity and quality of information varies greatly by state. Campylobacter is being assessed because states are not required to report Campylobacter and those that do may do so inconsistently. This means we do not have a complete and accurate picture of the data we are getting, and these data have not been routinely summarized. Instead, the epidemiology of *Campylobacter* in the US has largely been described based on data from FoodNet. Additionally, Campylobacter is a high incidence pathogen and is actually increasing in FoodNet data.

The Campylobacter data will feed into a summary of the Epidemiology of Campylobacter manuscript as well as inform our planning for Campylobacter activities going forward. STEC will help us to understand if the current guidelines are being used.

Cases of STEC and *Campylobacter* are considered to be confirmed cases if an organism is isolated by culture. In recent years, there has been a shift away from culture-confirmation in favor of rapid tests such as Enzyme Immunoassays (EIA), and molecular methods such as polymerase chain reaction (PCR). A large part of our FoodNet surveillance effort right now is focused on this issue and there are also working groups at the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE). This is a trend that we are seeing in infectious disease in general, not just enterics. For Campylobacter, in FoodNet, we saw an increase from 3.7% of labs using culture-independent (CI) methods in 2009 to 12% in 2012. In 2012, CI cases accounted for 12% of total Campy cases .

This change poses several issues for public health, including decreased ability to track changes in incidence rates over time and loss of isolates for subtyping or resistance testing. In addition, there has been reduced funding to state health departments for laboratory testing and disease reporting impacting their ability to perform these functions. These changes along with the inconsistencies in *Campylobacter* reporting result in an incomplete picture of surveillance at the national level. There is a need to systematically gather information on current practices in all states and territories which will enable us to form a comprehensive picture of surveillance, assess gaps, and develop recommendations that will improve public health's ability to track and respond to these infectious diseases.

For this current OMB data collection request, we plan to conduct a one-time data collection of foodborne disease epidemiologists at the state and territorial health departments and microbiologists at the state and territory public health laboratories. Information will be collected on current state and territory requirements for *Campylobacter* reporting and isolate submission, and testing practices for *Campylobacter* and STEC. Because less is known about *Campylobacter* surveillance at the national level, the majority of questions will be focused in this area.

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from foodborne disease

epidemiologists at the state and territory health departments and microbiologists at the state and territory health laboratories in all states, the District of Columbia, and US territories who have responsibility for *Campylobacter* and STEC surveillance or testing, acting in their official capacities. Data at the state, territorial, and local levels are used to identify and monitor health impact of the reportable conditions in those communities, measure trends, identify populations or geographic areas at high risk, plan prevention and control programs and policies, allocate resources appropriately, and evaluate the effectiveness of programs and policies.

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

Privacy Impact Assessment

Overview of the Data Collection System – The data collection consists of a SurveyMonkey ® web-based questionnaire that will consist of an epidemiologic (epi) module and a laboratory (lab) module. The epi module is designed to query epidemiologists at the state and territory health departments who report *Campylobacter* and STEC cases. Multiple choice questions will focus on current state or territory reporting requirements and practices for *Campylobacter* and STEC **(see Attachment E. Campy Data Collection Epi Instrument (word version)** and **Attachment F. Campy Data Collection Epi Instrument (online version)**. Examples of questions that will be asked include whether *Campylobacter* is notifiable, to which systems at CDC they report, and whether submission of specimens to the state or territory laboratory is required by law. The lab module is designed to query microbiologists at the state and territory public health laboratories that perform testing for *Campylobacter* and **STEC (see Attachment J. Campy Data Collection Lab Instrument (word version) and Attachment K. Campy Data Collection Lab Instrument (online version)**. Multiple choice and open-ended questions will focus on laboratory practices for *Campylobacter* at the state or territory level. Examples of questions include whether specimens are received at the lab for confirmation, whether the lab performs speciation, and which diagnostic tests are used.

The SurveyMonkey ® instrument was pilot tested by six epidemiology and microbiologists in FoodNet sites in CO, CT, NM, NY, OR and TN. Feedback from this group was used to refine questions as needed, ensure accurate programming and skip patterns and establish the estimated time required to complete the questionnaire.

Items of Information to be collected –

The data collection instrument consists of two modules and 36 questions total. The epi module (12 questions) includes 2 questions asking for contact information from the responder, 7 questions about *Campylobacter* requirements and reporting practices, 2 questions about STEC reporting practices, and a text field for any additional comments. Four questions have skip patterns. All questions are multiple choice with a text box for further explanation if the choice is 'Other'. The module is designed to take approximately 10 minutes to complete.

The lab module (24 questions) includes 2 questions asking for contact information from the responder, 17 questions about *Campylobacter* specimen submission and testing practices, and 4 questions about antimicrobial susceptibility testing for *Campylobacter*, and a text field for additional comments. Four questions have skip patterns. All questions are multiple choice with a text box for further explanation if the choice is 'Other'. The module is designed to take approximately 15-20 minutes to complete

Each responder will complete either the epi module or the lab module (but not both) depending on their professional duties.

Identification of Website(s) and Website Content Directed at Children under 13 Years of Age – The data collection system involves using a web-based questionnaire. Respondents will be sent a link directing them to the online questionnaire only (i.e., not a website). No website content will be directed at children.

2. Purpose and Use of the Information Collection

The objectives of the data collection are:

- To understand current reporting, specimen submission, and testing procedures and requirements for *Campylobacter* and STEC infections at the state and territory level
- To understand the extent to which state and territorial health laboratories are using culture-independent tests for *Campylobacter* diagnosis
- To understand the extent of antimicrobial susceptibility testing and PFGE for *Campylobacter* at the state and territory level

At CDC, the results of the data collection will be used:

- To improve *Campylobacter* surveillance at the national level by identifying reporting gaps in, and limitations of, current data collection
- To inform recommendations regarding the use of culture-independent tests for *Campylobacter* diagnosis
- To assess the impact of previous CDC recommendations to send Shiga toxin-producing broths to the state public health labs for STEC testing
- To understand state and territories' capacity and interest in conducting antimicrobial susceptibility testing and PFGE on *Campylobacter* isolates

The results of the data collection will be shared with the participating state and territorial health departments and laboratories via email and written report. The results will also be incorporated into a scientific publication describing the epidemiology of *Campylobacter* in the United States.

Privacy Impact Assessment

Individuals asked to provide information for the data collection will be informed of the reason for collecting the information and how the information will be used. Participants will be notified that their participation is voluntary through a written statement via email. All responses will be kept secure and IP addresses will not be collected. Identifiers will not be included in any published materials related to this study.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a SurveyMonkey ® web-based questionnaire allowing respondents to complete and submit their responses electronically. Web-based questionnaires reduce respondent burden by enabling them to easily access the questions and complete them at a convenient time and location. The questionnaire was designed to collect the minimum information necessary for the purposes of this project.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed data collection is unique. *Campylobacter* is not a nationally-notifiable disease and states are not required to report data to CDC. Therefore, CDC has not collected information on reporting and testing practices for *Campylobacter* from our state partners. In addition, due to the rapid uptake of culture-independent tests over the past year, if this information existed elsewhere it would be out-of-date. Finally, since the release of the MMWR guidelines recommending that Shiga toxin-producing broths be sent to state public health labs for STEC testing, no attempt has been made to ascertain the impact or implementation of these recommendations. The STEC questions in this survey will provide this information.

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

This request is for a one time data collection.

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

- Incomplete understanding of current practices regarding *Campylobacter* reporting practices and testing requirements at the state and territory level, potentially leading to misinterpretation of national data and impacting analysis and data-driven decision making
- Gap in information on current testing practices for *Campylobacter* and lack of ability to inform recommendations for use of culture-independent tests
- No information on the impact of previous CDC recommendations to send Shiga toxin-producing broths to state public health labs for STEC testing

- Incomplete understanding of the capacity for and gaps in *Campylobacter* speciation, antimicrobial susceptibility testing, and PFGE at state and territory health departments

There are no legal obstacles to reduce the burden. This is a one-time data collection.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of state and territory public health agencies will be speaking from their official roles. They will not be asked identifiable information.

This data collection is not research involving human subjects.

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

The estimate for burden hours is based on a pilot test by six public health professionals in FoodNet sites in CO, CT, NM, NY, OR and TN. Participants estimated that the time for reviewing

instructions, gathering needed information and completing the questionnaire was 10 minutes for the epi module and 15-20 minutes for the lab module. For the purposes of estimating burden hours, the upper limit of this range (i.e., 20 minutes) is used for the lab module.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for life, physical, and social science occupations. (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $24.22 is estimated for life scientists, which could include microbiologists and epidemiologists. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State/local/etc Epidemiologist)	55	1	10/60	9	24.22	$217.98
state/local/etc Microbiologist	55	1	20/60	18	24.22	$435.96
TOTALS	**110**	**1**		**27**		**$653.94**

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 complete each questionnaire.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government would be the salary of CDC staff supporting the data collection activities and associated tasks.

Questionnaires were prepared by CDC staff (FTE). A senior level FTE epidemiologist and microbiologist reviewed and approved the activities. The estimated cost to the federal government is $3,683.60. Table A-14.1 describes how this cost estimate was calculated.

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) Development of instrument, pilot testing, OMB package preparation, data collection, data analysis, report preparation	60	$34.34	$2,060.40
Senior Microbiologist (GS-14) Development of instrument, pilot testing, data collection, data analysis, report preparation	40	$40.58	$ 1,623.20
Estimated Total Cost of Information Collection			**$3,683.60**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this data collection will be shared with participating state and territory health departments and laboratories via email and written report. Results will also be included as part of a manuscript describing the epidemiology of *Campylobacter* in the United States which is currently in the planning phase.

Analysis Plan

Data analysis will begin upon completion of data collection. CDC FTEs and a student intern will perform the analysis using SAS 9.3. The analysis will consist of simple descriptive statistics to understand current practices.

Project Time Schedule

- ✓ Design questionnaire.....(COMPLETE)
- ✓ Develop protocol, instructions, and analysis plan.....(COMPLETE)
- ✓ Pilot test questionnaire.....(COMPLETE)
- ✓ Prepare OMB package.....(COMPLETE)
- ✓ Submit OMB package.....(COMPLETE)
- ❑ OMB approval.....(TBD)
- ❑ Gather responses.....(questionnaire available online for 3 weeks)
  - Reminder email at 7 and 20 days
- ❑ Collect, code, quality control, and analyze data.....(2 weeks)
- ❑ Prepare report.....(2 weeks)
- ❑ Disseminate results/publication of findings.....(4 weeks)

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.

LIST OF ATTACHMENTS – Section A

Note: Attachments are included as separate files as instructed.

- **Attachment A. Winnable Battles**
- **Attachment B. NNDSS website**
- **Attachment C. LEDS website**
- **Attachment D. FoodNet website**
- **Attachment E. Campy Data Collection Epi Instrument (word version)**
- **Attachment F. Campy Data Collection Epi Instrument (online version)**
- **Attachment J. Attachment H. Campy Data Collection Lab Instrument (word version)**
- **Attachment K. Campy Data Collection Lab Instrument (online version)**

REFERENCES

[1] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, Griffin PM: Foodborne illness acquired in the United States—unspecified agents. *Emerg Infect Dis* 2011, 17:16-22.
[2] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, Jones JL, Griffin PM: Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis* 2011, 17:7-15.
[3] Centers for Disease Control and Prevention (CDC).Incidence and trends of infection with pathogens transmitted commonly through food - foodborne diseases active surveillance network, 10 U.S. sites, 1996-2012. MMWR Morb Mortal Wkly Rep. 2013 Apr 19;62(15):283-7.