

Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics-

American Society for Microbiology

Request for Approval of New Data Collection

Supporting Statement A

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- Goal of study: To explore factors that may influence intended users of laboratory practice guidelines (LPGs)
- Intended use of resulting data: The ASM can define and use metrics to better inform their LPGs' creation, revision, dissemination, promotion, uptake and use. The collected survey data concerning an LPG for each of the following: reducing blood culture contamination (BCC), rapid diagnosis of blood stream infections (BSI), proper collection and transport of urine (UT), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* infection (CDI), will be analyzed to determine how the LPGs should be created/disseminated and promoted to address barriers observed with specific sub-groups of health professionals.
- Methods to be used to collect: A pre- and post-survey for an LPG that involves BCC and a separate pre-survey concerning a new LPG for BSI, UT, and CDI
- Subpopulations to be studied: Microbiology supervisors, laboratory directors, laboratory managers, and medical technologists
- How data will be analyzed: Cohort study; pre- versus post-dissemination of LPGs (for BCC) and pre-survey to inform LPG creation for BSI, UT, and CDI

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

This is a request for OMB approval of a new information collection, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics-American Society for Microbiology.” CDC is requesting a three year approval to collect the information. This information collection falls under the Title 42 Public Health and Welfare Authorization Legislation included as Attachment A.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) established minimum requirements for assuring the quality of laboratory testing in U.S. clinical laboratories. However, many laboratories voluntarily implement quality practices that go beyond the minimum standards required by CLIA regulation by identifying and adhering to relevant laboratory practice guidelines (LPGs). An “LPG” is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation.

The Centers for Disease Control and Prevention is funding three 5-year cooperative agreement projects collectively entitled “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics” under funding opportunity announcement number OE13-04. The overall purpose of these

cooperative agreements is to increase the effectiveness of LPGs that have public health impact by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs including: (1) non-laboratorians; (2) laboratorians, including medical laboratory technicians (2-year degree), medical technologists (4-year bachelor degree, also called “clinical laboratory scientists” or “medical laboratory scientists”), clinical laboratory directors, supervisors, and managers of clinical laboratories, and pathologists; and, (3) clinicians, including physicians and nurses. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG’s impact through better collection of information.

After an objective review process to score applications to a new cooperative agreement funding opportunity, “Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics,” the CDC selected three organizations that currently create and disseminate LPGs to support activities to improve the impact of their LPGs. The American Society for Microbiology (ASM), the Clinical and Laboratory Standards Institute (CLSI), and the College of American Pathologists (CAP), will each use at least two of their LPGs as models to better understand how to improve uptake and impact of these and future LPGs for their intended LPG users. In accordance with the funding opportunity announcement, the awarded organizations have selected model LPGs that concern laboratory testing for a disease or risk factor that has public health impact.

The CDC plans to submit separate packages to request OMB approval of new information collections for each of the three organizations involved in the overarching project: ASM, CLSI, and CAP. Separate submissions will be necessary for the overall project as each of the three organizations anticipate that their planning and activities timeline will differ. Moreover, it is anticipated that each of the three organizations will submit at least one additional request for OMB approval of a new information collection package at some time in the future. These future submissions will be asynchronous. This information collection request only concerns the ASM project.

Specifically, the ASM project will address four LPGs that are important to clinical testing and have a high public health impact: reducing blood culture contamination (BCC), rapid diagnosis of blood stream infections (BSI), proper collection and transport of urine (UT), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* (*C. difficile*) infection (CDI). The BCC LPG was published and it includes recommendations for the use of: 1) venipuncture over catheters as the preferred technique for sample collection in a clinical setting, and 2) phlebotomy teams over non-phlebotomist staff for collecting blood for culture. The BSI report examines the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections. This report will be published and recommendations will be developed based on additional information collected. Practices related to the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections were analyzed and approved recommendations will be published. Microbiological practices related to improving diagnosis and management of patients with *C. difficile* infection will be collected and analyzed, and recommendations will also be developed and published.

It is expected that as a result of sustained improvements in the process of creating and updating these clinical LPGs, public health, which depends upon accurate and appropriate laboratory testing guided by the use of LPGs, will also generally benefit, especially as organizations that create LPGs improve their

processes for evaluating and improving their impact. In order to improve the impact of LPGs, the ASM will develop metrics to assess the intended users' awareness and perceptions of the LPGs, and their laboratory practices to indicate adherence to practices recommended in the LPGs. Developing metrics will require collecting information from the intended users using surveys, and the intended respondents of ASM's surveys will include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists.

This work involves demonstration projects that will show how the concepts in the Institute of Medicine report "Clinical Practice Guidelines We Can Trust" which described how to improve dissemination and impact of LPGs by focusing on facilitators and impediments to LPG adoption, can be implemented through better metrics. The projects fit into CDC's translational science agenda because the activities will contribute towards the U.S. Department of Health and Human Services' Healthy People 2020 vision for "a society in which all people live long, healthy lives." This work supports one of the Healthy People 2020's missions to "improve practices that are driven by the best available evidence and knowledge" and several of the goals of Healthy People 2020 depend on accurate and reliable laboratory testing. It aligns with CDC's Science Impact Framework to promote translation of science into practice through disseminating science, creating awareness, catalyzing action, effecting change, and shaping the future. The ASM project is important because it links to the ultimate impacts of following evidence-based laboratory medicine practice guidelines for quality laboratory testing aimed to reduce 1) morbidity and mortality, 2) hospital length of stay and overall costs, 3) unnecessary antibiotic use and development of antibiotic resistant "super-bugs", 4) patient discomfort from repeat specimen collections or office visits, 5) healthcare associated infections, 6) delays in treatment, and 7) errors in diagnosis and treatment.

The BCC LPG "*Effectiveness of practices to reduce blood culture contamination: A Laboratory Medicine Best Practices systematic review and meta-analysis*" was published in *Clinical Biochemistry* (http://ac.els-cdn.com/S0009912012002998/1-s2.0-S0009912012002998-main.pdf?_tid=d910d3de-4808-11e4-8314-00000aacb35d&acdnat=1412016537_8f705e79d1ab745b8eade926135d7684). The expected publication and dissemination date for the BSI and UT LPGs is 2015 and the CDI is 2016. This cooperative agreement project will use surveys to collect information on LPG users' awareness, perceptions, and understanding of these guidelines in order to improve patient testing, their health, and, as a result, public health as a whole. Prior research has shown that some users are unaware of the recommendations for reducing blood culture contamination in hospitals. The BCC surveys will allow the ASM to better understand which laboratories and individuals are unaware of the BCC guideline, some of the barriers to their uptake of the recommendations, and the gaps in understanding the proper ways to collect blood for culturing. Because the BSI, UT, and CDI reports are not yet published, the ASM will conduct a baseline survey to determine current practices related to the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections; the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections; and improving diagnosis and management of patients with *C. difficile* infection, respectively, prior to dissemination of the LPGs.

As part of their cooperative agreement with the CDC, for this request of OMB approval of a new information collection, the ASM will need to collect baseline and post-dissemination information for the BCC LPG. For the remaining LPGs, BSI and UT with planned publication in 2015 and CDI in 2016, the ASM will conduct a baseline survey

2. Purpose and Use of Information Collection

There is a current lack of connection between the organizations that create and manage laboratory practice guidelines (LPGs) and the subsequent steps to ensure their eventual uptake and use. There are typically no metrics to evaluate changes in practices resulting from the LPG, nor ways to know what improvements would be warranted. Relevant data is undefined and unknown, with the exception of sales figures in some cases. Most LPGs are reviewed every few years to determine relevance and to assess whether they should be retired, updated, or entirely revised; these cycles provide regularly recurring opportunities to apply metrics. Unfortunately, useful data that could have been gathered is seldom collected. Targeted users are typically not asked whether they are aware of the LPG and, if they use it, how it might be improved, nor are data collected on why they chose not to use it or whether they modified it for uses. When it is time to review an LPG for revision or retirement, there is typically little information to inform the decision. In this context and given the stresses on the healthcare system caused by unnecessary and inappropriate testing, it is important for organizations that create and manage LPGs to better understand how to measure and increase impact of their LPGs.

The purpose for information collection is for the American Society for Microbiology to use the information about the four model LPGs (BCC, BSI, UT, and CDI) to identify gaps in their current approach for the creation, dissemination and uptake of their LPGs. Careful analysis of the information collected will allow the ASM to develop a comprehensive plan for improving future processes for LPG development and dissemination and allow them to demonstrate the value of using metrics to improve uptake and impact of their LPGs. With co-authors at CDC, collaborators at ASM will publish the results of this demonstration project to show other organizations that create LPGs that their impact can be enhanced by using metrics. Scientists at CDC will benefit from this work by improving our abilities to design and analyze survey questionnaires.

3. Use of Improved Information Technology and Burden Reduction

The survey(s) for the BCC guideline as well as the BSI, UT, and CDI guidelines with planned publication in 2015 and 2016 will be available in a SurveyMonkey® format hosted on the SurveyMonkey® website. The CDC Laboratory Response Network (LRN) Coordinator will email a letter to the Laboratory Director of the LRN Reference Laboratories, who will then email the sentinel, which include hospital and independent laboratories, in their states, and provide a hyperlink to access the survey tool online. We anticipate that approximately 4200 sentinel laboratories will be contacted and asked to complete the survey on-line. The email request will specify that the respondent should be a microbiology supervisor, and in the case where a microbiology supervisor is not employed, then either the laboratory director or laboratory manager will be asked to participate in each of the five unique surveys: BCC baseline, BCC post-dissemination, BSI baseline, UT baseline, and CDI baseline. Similarly, the ASM will also email the SurveyMonkey® hyperlinks for the five surveys, to each of their ClinMicroNet, DivCNet, and *ASM Clinical Microbiology Issues Update* newsletter listservs inviting ~828, ~1470, and ~1453 subscribers, respectively, to participate.

4. Efforts to Identify Duplication and Use of Similar Information

The ASM and CDC are confident that this project does not duplicate other efforts or existing data collections.

The CDC determined, following our review of the existing OMB-approved data collections located on the Office of Information and Regulatory Affairs, Office of Management and Budget website, that no surveys exist inquiring whether users of laboratory practice guidelines are aware of them and, if they use them, how they might be improved. In addition, they determined that there are no data on why these users chose not to adopt the recommendations or whether they made modifications before using them. There is little information available to inform guideline developers' decision on whether they should revise or retire guidelines. Furthermore, the CDC had consulted with numerous organizations that create LPGs, including ASM, CAP, and CLSI, and there was a consensus that they were not aware of all who actually use the laboratory guidelines, whether they are used in whole or part, and their perceptions of the guidelines.

5. Impact on Small Businesses or Other Small Entities

According to the U.S. Small Business Administration website (<http://www.sba.gov/content/what-sbas-definition-small-business-concern>), a small business concern is “one that is independently owned and operated, is organized for profit, and is not dominant in its field.” One example of a small business is one whose services' receipts do not exceed \$2.5 million.

While some survey respondents may be employed in relatively small laboratories, it is not possible to estimate exactly how many responding laboratories would be considered small businesses, as defined by the U.S. Small Business Administration's definition of a small business concern, because this information is not available to us. On the one hand, we would estimate that nearly all sentinel laboratories do not qualify as small businesses because they tend to be in high-volume settings, and typically include large hospital and independent laboratories. On the other hand, some of the sentinel laboratories may be smaller hospital or independent laboratories. If the response rate from these laboratories is approximately 80% as hoped, then there would be approximately 1680 (4200 x 50% small laboratories in LRN Reference Laboratories) x 80%) small businesses impacted, at maximum.

In order to reduce respondent burden for all respondents, including those working at smaller laboratories, a simple and accessible survey format will be used. The survey so will be accessible via the Internet, and an electronic link to the survey instrument will be provided respondents can easily access the survey at their convenience, either at home or in the office. The survey consists of questions that are short, written at a reading level appropriate to the target audience, and parsimonious. Respondents will not be asked to provide any extraneous information.

6. Consequences of Collecting the Information Less Frequently

The surveys for which we are requesting OMB approval will each (with the exception of the BCC survey, which will be administered twice) be fielded only once under the project plan.

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

This request fully complies with the regulation of 5 CFR 1320.5.

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

A. A 60-Day Federal Register Notice was published in the *Federal Register* on November 6, 2014, Vol. 79, No. 215, pp. 65967-65969 (Attachment B).

There were no public comments.

B. In 2014, the CDC Project Officers consulted survey design expert, Karen Wooten, to assure survey questions were carefully phrased and ordered.

The following provided consultation on survey design:

Karen Wooten, MA
Mathematical Statistician
Carter Consulting, Inc.
2310 Parklake Drive, NE, Suite 535
Atlanta, GA 30345
Phone: 770-939-2601
kgw1@cdc.gov

9. Explanation of Any Payment or Gift to Respondents

No remuneration will be paid to respondents.

10. Assurance of Confidentiality Provided to Respondents

The PRA Contact for this work, Division of Laboratory Systems Associate Director for Science, has reviewed this OMB application and has determined that the Privacy Act is not applicable. No patient health information is being collected. No contact information will be listed on any reports or summaries of findings. While each of the survey instruments contains a field where respondents may provide their email address, the identities of the respondents will not be shared with the CDC and will be used solely to send reminders to those who have not yet responded to the surveys. Moreover, a database of these email addresses will not be created and information that is submitted through SurveyMonkey® will be de-linked from any individually identifiable information. Neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. Results from these surveys will be reported in the aggregate.

10.1 Privacy Impact Assessment Information

Overview of the Data Collection System

On behalf of the ASM and the CDC, the Laboratory Response Network (LRN), which was founded by the CDC, will recruit laboratories that perform the kinds of testing affected by these LPGs to take the surveys. The LRN message system routinely alerts LRN laboratories concerning various important clinical and public health topics. Messages regarding ASM surveys will be worded as an invitation, not as a coercive request. Some states may opt not to recruit LRN laboratory participation, but because the issues are important to clinical and public health, we expect good participation by most states.

The CDC LRN Coordinator will email a letter, addressed from the ASM Project Manager, to the Laboratory Directors of the LRN Reference Laboratories (Attachment C1-C5/D1-D5 reminder letters). These ~55 LRN Reference Laboratory Directors will be asked to then email the sentinel laboratories, which include hospital and independent laboratories, in their states, and provide a hyperlink to access the survey tool online (Attachment E1-E5/F1-F5 reminder letters). SurveyMonkey® will host the online survey and be used as the information collection instrument and responses will be collected and maintained by ASM.

We anticipate that approximately 4200 sentinel laboratories will be contacted and asked to complete the survey on-line. The email request will specify that the respondent should be a microbiology supervisor, and in the case where a microbiology supervisor is not employed, then either the laboratory director or laboratory manager will be asked to participate in each of the five unique surveys: BCC baseline, BCC post-dissemination, BSI baseline, UT baseline, and CDI baseline.

The ASM will publicize the surveys and encourage participation by advertising the surveys in ASM's *Microbe*. (Attachment G1-G4) In addition, the ASM will also recruit, by emailing a letter containing the SurveyMonkey® hyperlinks for the five surveys to each of their ClinMicroNet (Attachment H1-H5/I1-I5reminders) and DivCNet (Attachment J1-J5/K1-K5 reminders) listservs inviting ~828 and ~1470 subscribers (comprised of laboratory directors as well as medical technologists), respectively, to take each of the five SurveyMonkey® surveys. Moreover, the ASM will email the same letter containing the SurveyMonkey® hyperlinks for the 5 surveys to ~1453 ASM *Clinical Microbiology Issues Update* newsletter subscribers (Attachment L1-L4), which include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists in a 25%:25%:25%:25% ratio, to invite them to participate. The *ASM Clinical Microbiology Issues Update* newsletter provides monthly updates on policy matters of concern to clinical microbiologists and is provided by ASM's Office of Public Affairs. These three listservs are used by ASM as a method for open communication among clinical microbiology laboratories to improve patient care.

Description of the Information to be Collected

The BCC survey (Attachment M1 (pre-survey) & M2 (post-survey)) is designed to collect information on laboratorians' current practices for collecting blood for cultures in order to reduce the overall rate of blood culture contamination. The survey includes questions on participant demographics, frequency the laboratories track the percentage of blood culture contamination, their awareness of or adherence to the guideline, facilitators and barriers to their adoption of the recommendations into their laboratory practice, and how they plan to use the recommendations. In addition, the BCC survey is designed to collect information on individual perceptions of the BCC LPG as well as requests for the participants' suggestions on how the LPG can be improved and what ASM and CDC can do to facilitate implementation of the recommendations and use of the guideline. The BCC baseline results will be compared to the post-survey responses to gauge if ASM's awareness efforts were effective and to identify barriers to adoption of LPG recommendations.

The BSI report, which will be published, examines the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections. Practices related to the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections were analyzed and approved recommendations will be published. Finally, information on the microbiological practices related to improving diagnosis and management of patients with *C. difficile* infection will also be published. Because the BSI, UT, and CDI reports are not yet published, ASM will conduct a baseline survey to determine current practices prior to dissemination of the LPGs. ASM plans to conduct post surveys for BSI, UT, and CDI that will require submission of a subsequent ICR in the future.

During the information collection process, responses will be kept in a secure, password-protected database. At the beginning of each survey, respondents are asked to provide their CLIA # and email address to ensure only one response per laboratory will be received and to follow-up with respondents to complete the survey if they have not already done so, respectively. All CLIA #'s and email addresses collected will be de-linked from the survey results and will not be stored in a database. ASM staff responsible for analyzing the results or writing the final report will have access to the database of survey responses. The surveys primarily ask for information regarding laboratorians' use of and opinions on laboratory testing practices related to reducing blood culture contamination (Attachment M1 & M2), rapid diagnosis of blood stream infections (Attachment M3), proper collection and transport of urine (Attachment M4), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* infection (Attachment M5). The surveys will be disseminated through a web-based survey system: SurveyMonkey®. No CDC staff or contractors will have direct access to any information collected by ASM. Importantly, the information collected will address voluntary practices that have no regulatory consequences. The information will be presented with findings in the aggregate, for example in peer-reviewed publications or presentations at scientific meetings. No personal or laboratory identifiers will be retained in the final survey dataset. The Privacy Act Checklist has also been included as Attachment M.

1. The surveys for this ASM project will inform participants that providing information is voluntary.
2. Because no laboratory or personal identifiers will be retained in the final survey dataset, the Privacy Act does not apply.
3. Survey responses received by the ASM will be stored in a secure, password-protected database.
4. If the information is shared with CDC for additional analysis, the survey responses will be stored in a secure, password-protected database at the CDC and ASM facilities.

11. Justification of Sensitive Questions

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and race and ethnicity will not be collected.

12. Estimates of Annualized Burden Hours and Costs

- A. The intended users of the ASM’s LPGs and respondents to their 5 surveys will include microbiology supervisors, laboratory directors, laboratory managers, and medical technologists.

The determination for the number of respondents for each of the four respondent categories is as follows:

Microbiology Supervisors

$$(4200 \text{ LRN labs} \times 50\%) + (0\% \text{ ClinMicroNet subscribers}) + (0\% \text{ DivCNet subscribers}) + (1453 \text{ ASM Clinical Microbiology Issues Update subscribers} \times 25\%) = 2463$$

Laboratory Directors

$$(4200 \text{ LRN labs} \times 25\%) + (828 \text{ ClinMicroNet subscribers} \times 99\%) + (1470 \text{ DivCNet subscribers} \times 60\%) + (1453 \text{ ASM Clinical Microbiology Issues Update subscribers} \times 25\%) = 3115$$

Laboratory Managers

$$(4200 \text{ LRN labs} \times 25\%) + (0\% \text{ ClinMicroNet subscribers}) + (0\% \text{ DivCNet subscribers}) + (1453 \text{ ASM Clinical Microbiology Issues Update subscribers} \times 25\%) = 1413$$

Medical Technologists

$$(0\% \text{ LRN labs}) + (828 \text{ ClinMicroNet subscribers} \times 1\%) + (1470 \text{ DivCNet subscribers} \times 40\%) + (1453 \text{ ASM Clinical Microbiology Issues Update subscribers} \times 25\%) = 960$$

According to the ASM, the burden hours per respondent who will be invited to participate in each of the BCC baseline and the post-dissemination surveys will not exceed 35 minutes (total of 70 minutes for both BCC baseline and post-surveys), and each of the BSI, UT and CDI baseline surveys will be 20 minutes. These time frames were specified based on ASM’s previous experiences conducting laboratory surveys.

Although the ~55 LRN Reference Laboratory Directors will not be invited to participate in any of the surveys, because they will each be asked to email an initial (Attachment E1-E5) and a reminder letter (Attachment F1-F5) to invite the sentinel laboratories to participate in each of the 5 surveys (BCC baseline, BCC post-survey, BSI baseline, UT baseline, and CDI baseline), they are also listed in the burden hours and cost tables. The amount of time it will take each LRN Reference Laboratory Director to email each of the initial and reminder letters with SurveyMonkey link included, is not longer than 5 minutes.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Microbiology Supervisors	BCC-baseline	2463	1	35/60	1437
	BCC-post	2463	1	35/60	1437
	BSI-baseline	2463	1	20/60	821
	UT-baseline	2463	1	20/60	821
	CDI-baseline	2463	1	20/60	821
Laboratory	BCC-	3115	1	35/60	1817

Directors	baseline				
	BCC-post	3115	1	35/60	1817
	BSI-baseline	3115	1	20/60	1038
	UT-baseline	3115	1	20/60	1038
	CDI-baseline	3115	1	20/60	1038
Laboratory Managers	BCC-baseline	1413	1	35/60	824
	BCC-post	1413	1	35/60	824
	BSI-baseline	1413	1	20/60	471
	UT-baseline	1413	1	20/60	471
	CDI-baseline	1413	1	20/60	471
Medical Technologists	BCC-baseline	960	1	35/60	560
	BCC-post	960	1	35/60	560
	BSI-baseline	960	1	20/60	320
	UT-baseline	960	1	20/60	320
	CDI-baseline	960	1	20/60	320
LRN Reference Laboratory Directors	BCC-baseline sentinel laboratory letter	55	1	5/60	5
	BCC-post sentinel laboratory letter	55	1	5/60	5
	BSI-baseline sentinel laboratory letter	55	1	5/60	5
	UT-baseline sentinel laboratory letter	55	1	5/60	5
	CDI-baseline sentinel laboratory letter	55	1	5/60	5
	BCC-baseline sentinel laboratory reminder letter	55	1	5/60	5

	BCC-post sentinel laboratory reminder letter	55	1	5/60	5
	BSI-baseline sentinel laboratory reminder letter	55	1	5/60	5
	UT-baseline sentinel laboratory reminder letter	55	1	5/60	5
	CDI-baseline sentinel laboratory reminder letter	55	1	5/60	5
Total					17275

B.

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate*	Total Respondent Costs
Microbiology Supervisors	BCC-baseline	2463	1	35/60	1437	\$35.92	\$51608.00
	BCC-post	2463	1	35/60	1437	\$35.92	\$51608.00
	BSI-baseline	2463	1	20/60	821	\$35.92	\$29490.00
	UT-baseline	2463	1	20/60	821	\$35.92	\$29490.00
	CDI-baseline	2463	1	20/60	821	\$35.92	\$29490.00
Laboratory Directors	BCC-baseline	3115	1	35/60	1817	\$51.23	\$93089.00
	BCC-post	3115	1	35/60	1817	\$51.23	\$93089.00
	BSI-baseline	3115	1	20/60	1038	\$51.23	\$53194.00
	UT-baseline	3115	1	20/60	1038	\$51.23	\$53194.00
	CDI-baseline	3115	1	20/60	1038	\$51.23	\$53194.00

Laboratory Managers	BCC-baseline	1413	1	35/60	824	\$37.76	\$31123.00
	BCC-post	1413	1	35/60	824	\$37.76	\$31123.00
	BSI-baseline	1413	1	20/60	471	\$37.76	\$17785.00
	UT-baseline	1413	1	20/60	471	\$37.76	\$17785.00
	CDI-baseline	1413	1	20/60	471	\$37.76	\$17785.00
Medical Technologists	BCC-baseline	960	1	35/60	560	\$37.76	\$21146.00
	BCC-post	960	1	35/60	560	\$37.76	\$21146.00
	BSI-baseline	960	1	20/60	320	\$37.76	\$12083.00
	UT-baseline	960	1	20/60	320	\$37.76	\$12083.00
	CDI-baseline	960	1	20/60	320	\$37.76	\$12083.00
LRN Reference Laboratory Directors	BCC-baseline sentinel laboratory letter	55	1	5/60	5	\$37.76	\$189.00
	BCC-post sentinel laboratory letter	55	1	5/60	5	\$37.76	\$189.00
	BSI-baseline sentinel laboratory letter	55	1	5/60	5	\$37.76	\$189.00
	UT-baseline sentinel laboratory letter	55	1	5/60	5	\$37.76	\$189.00
	CDI-baseline sentinel laboratory letter	55	1	5/60	5	\$37.76	\$189.00
	BCC-baseline sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00
	BCC-baseline sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00

BCC-post sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00
BSI-baseline sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00
UT-baseline sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00
CDI-baseline sentinel laboratory reminder letter	55	1	5/60	5	\$37.76	\$189.00
Total						\$ \$733478.00

* The hourly wage rate for the above table was taken from <http://www.mlo-online.com/ebook/201403/resources/6.htm>

The hourly wage rate for the respondents was calculated by taking the published salary on page 17 and dividing that by 2080 (working hours per year).

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

There are no capital and start-up costs nor operation and maintenance and purchase of services costs for this project.

14. Annualized Cost to the Government

The total annualized cost to the Federal government is comprised of three CDC Project Officers collaborating with and providing advice to the American Society for Microbiology project managers. The cost for each CDC staff is estimated by multiplying the percentage time contributed toward this project, per individual, and their respective pay rates based on the GS pay scale for Atlanta (<http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/atl.pdf>). The U.S. Department of Health and Human Services Human Resources is awaiting Office of Personnel Management guidance for implementation of the GP scale in order to make it publically available.

One individual with GP pay scale 15 step 4 (contributing 10% of their time) and three individuals with GSA pay scales of Grade 14 (2 people at a step 8 and 4, respectively, contributing 10% and the other person at a step 10, 1% of their time) are included in the annualized cost to the Federal government.

Federal Employee	% Time Contributed to Project	Pay Rate
Public Health Analyst	10%	\$124,608.00
Medical Officer	10%	\$210,704.00
Public Health Analyst	10%	\$111,138.00
Senior Health Scientist	1%	\$131,343.00
Total Annual		\$45,958.00
Cost		

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule

Activity

Letters sent to respondents

Time Schedule

1 - 2 months after OMB approval

Informal surveys (less than 9 people or by show of hands) may be conducted for BSI and UT. However, there isn't time to conduct a pre-survey.

1-2 months after OMB approval

BCC and BSI: 1 month after OMB approval.

UT: 3 months after OMB approval.

CDI: 7 months after OMB approval.

Data collection

BCC and BSI: 2-3 months after OMB approval

UT: 5-6 months after OMB approval.

CDI: 9-10 months after OMB approval.

Complete field work

BCC and BSI: 4 months after OMB approval.

UT: 10 months after OMB approval.

CDI: 14 months after OMB approval.

Validation

BCC and BSI: 5-6 months after OMB approval.

UT: 12 months after OMB approval.

CDI: 15-16 months after OMB approval.

Analyses

BCC and BSI: 7-9 months after OMB approval.

UT: 13-16 months after OMB approval.

CDI: 17-20 months after OMB approval.

Publication BCC and BSI: 18 months after OMB approval.
 UT: 28 months after OMB approval.
 C. diff: 36 months after OMB approval.

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

There are no exceptions to the certification.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.