Proficiency Testing in US Clinical Laboratories:
Perception, Practices and Potential for Expanded Utility

Request for Approval of New Data Collection
Supporting Statement B

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Contact:
Rex Astles, PhD
Division of Laboratory Science and Standards
Laboratory Science, Policy, & Practice Program Office
Centers for Disease Control and Prevention
1600 Clifton Rd.
MS F11
Atlanta, Georgia 30333
Phone: 404.498.2296
Fax: 404.498. 2219
Email: jda4@cdc.gov

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This is a request for OMB approval of a new data collection, Proficiency Testing Perception, Practices and Potential for Expanded Utility Interpretation. CDC is requesting a three-year approval to collect the data.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

This project is part of a cooperative agreement between the Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories (APHL). The primary focus is to conduct a systematic analysis to understand which types of laboratories follow proficiency testing (PT) good laboratory practices (GLPs) and to identify which kinds of laboratories could be targeted to promote PT GLPs. Based upon prior work conducted by APHL and CDC, it appears that many of these laboratories also use their PT results internally for quality improvement. Since laboratories already pay for PT materials, the use of PT for quality improvement purposes has the potential to further improve laboratory quality at no additional cost to US clinical laboratories.

Further, the Centers for Medicare & Medicaid Services (CMS) and CDC are currently collaborating to revise the Clinical Laboratory Improvement Amendments (CLIA), regulations to update the list of non-microbiological tests (analytes) for which PT is required, and to update the requirements for microbiology PT. Both of these changes are expected to have some impact on clinical and public health laboratories, but CDC has very little data to estimate the impact. Information to be collected concerning the perceived benefits and burden of performing PT will be needed to complete the regulatory impact analysis. The Department of Health and Human Services knows very little about the perceived benefits and burden of PT and this survey will provide an opportunity to learn about them.

This study will explore how the targeted laboratories use PT for GLPs, which may relate to independent variables that include laboratory testing volume and other characteristics of the laboratory or laboratory staff. For the laboratories that perform microbiology testing, the survey will ask a series of questions on the use of PT in microbiology and ways that it may be improved.

This research study will include administering a survey to help identify laboratories that would benefit from learning about additional uses for PT and providing information about PT GLP's to these laboratories in a strategic and targeted way.

The goal is to achieve at minimum a 80% response rate (29,840 out of 37,300 labs). APHL and CDC will strive to achieve a 80% response rate by promoting the survey through advertisements in laboratory trade publications, at professional meetings, and possibly through programs and laboratory accreditation organizations.

The cohort of laboratories surveyed will be all Certificate of Compliance and Certificate of Accreditation laboratories listed in the Centers for Medicare and Medicaid (CMS) Online Survey, Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information and practice characteristics for approximately all these laboratories.

The survey will be administered through a web-based survey system, specifically Survey Monkey. APHL will send each laboratory a postmarked letter explaining the survey and providing them with a link to log in to the survey with a unique identifier on their address label. Two weeks afterwards, APHL will follow-up with a postcard reminder which will also include that unique identifier on the address label.

2. Procedures for the Collection of Information

Survey Monkey is a commercial software system which supports compliance with Section 508 of the American Rehabilitation Act. Survey Monkey has been used successfully on many public health projects to collect survey data. Extensive internal testing of the survey questionnaire and associated field protocols will be performed prior to the actual launch of the survey.

The survey will include 26 questions. The questions will be multiple choice or Likert scale and one question will be open-ended.

Each of the 37,300 laboratories will receive a postal mailing on APHL letterhead. The mailing will contain a letter explaining the research purpose of the survey, and a link to access and complete the survey. The letter will describe the survey being fielded by CDC and APHL and will be signed by one credible official from the APHL.

Approximately 14 days after the initial postal mailing, APHL will send a follow-up post card as a reminder to the laboratories. The message will convey the same information contained in the first mailing including the purpose and website address to access the survey. All correspondence will be addressed to the laboratory director asking that they take the survey or share it with an appropriate staff member who can complete it.

Laboratorians will need to use one of two identifiers to log in to take the survey. The survey invitation and follow-up postcard will include a unique 8-digit log-in identifier on the address label which will correspond to their laboratory and enable the respondent to log in to the survey; alternatively, respondents can log in to the survey using their laboratory's CLIA number. Regardless of which number is used: the 8-digit unique identifier on the postal letter and postcard or the CLIA number, there will be a lock-out feature ensuring only one response per laboratory. This will also enable APHL to track the number of responses.

Both the 8-digit unique identifier on the mailings and the CLIA number will link the responses to the OSCAR database. The OSCAR database contains demographic information on each laboratory and will enable the APHL contractor to analyze the data by demographic criteria including: rural/urban setting, size and type of laboratory, and laboratory testing specialty.

When the survey field period closes after 1 month, the data will be cleaned and analyzed by the APHL contractor. The APHL contractor will also write a final report based on the findings. The final dataset will include one record for each originally sampled laboratory, whether or not a response was recorded. The APHL contractor will retain the survey results. However all identifying information including the CLIA number and alternative identification number will be removed before an analysis dataset is released and reported both for internal and external purposes. All raw data files minus the CLIA numbers and alternate identification codes will be provided to APHL and CDC for further analysis, if necessary.

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

As mentioned above, APHL will send out an initial postal mailing to establish credibility and provide detailed information on how to access the web survey. APHL will then follow up with a second mailing two weeks after the initial mailing as a follow-up reminder. The initial and follow-up mailings will provide the unique identification number on the address label in order to track responses. The web survey will be on-line for approximately 1 month, inclusive of 2 weeks after the final postcard reminder. In addition, respondents will also be able to log in to the survey using their CLIA number.

In addition, APHL will promote the survey through advertisements in laboratory trade publications, at professional meetings, and possibly through programs and laboratory accreditation organizations. As a token of appreciation for completing the survey, the respondents will also have the chance to enter a raffle to win one of 50 APHL teleconferences. The one-hour teleconference will be offered as either a live or recorded teleconference. The teleconferences will address relevant, contemporary issues in laboratory testing, and laboratories will have the opportunity to choose one that best meets their needs. All staff at the winning laboratory will be eligible to participate in the teleconference and to earn continuing education credits.

4. Tests of Procedures of Methods to be Undertaken

The analysis of the data will be comprised of reviewing and identifying trends related to differences related to demographic characteristics including: rural/urban setting, size and type of laboratory, and laboratory testing specialty. The APHL contractor will also run descriptive statistics on all of the survey questions to determine whether there are additional trends in the data that should be explored.

This study is the first to explore the use and perceived value of PT. Through the survey APHL and CDC hope to quantify how PT is used as a GLP by different types of laboratories. The goal is to use that information to guide efforts to develop educational materials and effectively target laboratory audiences.

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

Statistical aspects of the study have been reviewed by the individuals listed below:

John S. Hancock
Statistical Consultant
1445 Monroe Dr. NE Unit 27c
Atlanta Ga. 30324
Phone 404-713-4119
Email jhancock1944@yahoo.com