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

Clinical and Laboratory Standards Institute

Request for Approval of New Data Collection

Supporting Statement B

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

Respondents will be selected from several different sources and categorized into two respondent types, physician office laboratories (POLs) and laboratories in hospitals and clinics (HCs). Each of these groups of laboratory types will be asked for information regarding their awareness and use of one or the other laboratory practice guideline (HCs will be asked about *POCT12* and POLs about *POCT13*). A total of 30,000 respondents will be targeted with approximately 20,000 being identified from various sources available to the Clinical and Laboratory Standards Institute (CLSI) as outlined below (Table 1). The remaining 10,000 respondents will be identified by CDC from a laboratory demographic database. The overall breakdown for each of the two groups of laboratory types will be approximately 15,000 each for POLs and HCs.

The Clinical and Laboratory Standards Institute will solicit approximately 20,000 survey participants from physician office laboratories, Department of Defense laboratories, and hospitals that offer point-of-care glucose testing. Participants will be recruited by COLA, the Joint Commission and a Point-of-Care Coordinator network who have all agreed to distribute the link to the survey (Appendix C & Appendix D) in an email message (Appendix E & Appendix F), through their membership listserv. In addition, participants will also be solicited by email or postcard (Appendices G-L) through mailing lists purchased by CLSI from Clinscan and the American Hospital Association. Clinical sites offering point-of-care glucose testing in the Department of Defense medical system will also be asked via email to participate. None of these sources will require sampling.

An additional 10,000 laboratories, selected at random from a subset of sites included in a database of Clinical Laboratory Improvement Amendment (CLIA) certificate holders, the Online Survey Certification and Reporting System (OSCAR), will also be solicited. The OSCAR database contains the names and mailing addresses of over 200,000 HCs, POLs, and other types of testing sites. The database also contains information about the type of CLIA certificate that each laboratory holds (certificate of waiver, certificate of compliance, or certificate of accreditation), and the accrediting organization, such as COLA or the Joint Commission, for those laboratories with a certificate of accreditation.

Laboratories accredited by COLA and the Joint Commission will be excluded prior to sample selection from those selected from the OSCAR database to avoid duplication. Department of Defense laboratories are not included in OSCAR. The de-duplicated OSCAR database will then be stratified by certificate type, laboratory type (eg. hospital laboratory or POL), and census region (Northeast, Midwest, South, and West). The names and addresses of POLs with a CLIA Certificate of Waiver and hospital and clinic laboratories with a CLIA Certificate of Compliance will be proportionally allocated to two strata. The desired number of laboratories (8,000 POLs with a Certificate of Waiver and 2,000 clinical laboratories with a Certificate of Compliance) will be selected at random from each stratum.

Overall, the study sample will consist of about 15,000 POLs (expected *POCT13* users) and about 15,000 HCs (expected P*OCT12* users). This study will target a total of approximately 30,000 laboratories in order to obtain a sufficient number of completed surveys for efficient estimates and for the purpose of achieving an 80% or higher statistical power with the statistical tests.

Table 1- Summary of methods used to contact potential survey respondents

Organization/distribution list	**Number of recipients- lab type- LPG**	**Method of contact**
Clinscan	5,027 hospitals /clinics -*POCT12*	Email
COLA	5,000 POLs - *POCT13* 2,500 hospitals /clinics- *POCT12*	Email
Department of Defense	1,000 POLs- *POCT13* 1,000 hospitals/clinics - *POCT12*	Email
Point-of-Care Coordinators lists	250 POLs- *POCT13* 250 hospitals/clinics- *POCT12*	Email
The Joint Commission	1,600 hospitals/clinics- *POCT12*	Email
American Hospital Association	3,000 hospitals/clinics *POCT12*	Postcards
OSCAR database	8,000 POLs- *POCT13* 2,000 hospitals/clinics- *POCT12*	Postcards
Total	**29,627 laboratories**	
	- 15,377 – *POCT12*	
	- 14,250 – *POCT13*	

We plan to analyze responses from the subgroups of respondents (e.g., stratified by size of hospital, type of physician office or job title), and compare the differences between groups. To do this, we will need to obtain approximately 1,000 completed surveys for each of the subgroups in order to conservatively estimate an attribute (e.g., CLSI awareness) within 3% margin of error at a 95% confidence level.

The number of respondents indicated in the burden tables provided in Supporting Statement A was derived by estimating the number of participants from each contact list likely to find *POCT 12* or *13* of value (see table 2). We estimated the number of participants by job title from each contact list (e.g., Clinscan, COLA, Department Of Defense, etc.). We further stratified participants to setting; physician office laboratory (POL) versus hospital/clinic (HC). *POCT 12* is most relevant to hospital and clinical settings whereas *POCT 13* is most relevant to physician office laboratories.

Table 2- Estimated distribution of potential respondents across respondent categories in the burden table in Supporting Statement

	Number of Respondents in Burden Table (see Supporting Statement A)	Clinscan	COLA		Department of Defense		Point-of-Care Coordinators		Joint Commission	American Hospital Association	OSCAR	
		HC	POL	HC	POL	HC	POL	HC	HC	HC	POL	HC
POCT Coordinators	500						250	250				
Laboratory Directors	4276	1676	1000	500					200	500	400	
Laboratory Managers	4276	1676	1000	500					200	500	400	
Laboratory Supervisors	4276	1676	1000	500					200	500	400	
Medical	7800			1000	1000	1000			1000	1000	800	2000

Technologists												
Nurses	5000		1000								4000	
Medical Doctors	3500		1000							2000	2000	
Total	29628	5028	5000	2500	1000	1000	250	250	1600	3000	8000	2000

Legend:
HC= hospitals/clinics
POL= physician office laboratory

2. Procedures for the Collection of Information

Overview of the Data Collection System

The survey will contain instructions to direct it to the individual in each laboratory responsible for the development and revision of procedures for fingerstick glucose testing. This will help to ensure that only one response will be obtained for each participating laboratory or functional unit. Respondents include point-of-care coordinators, clinical laboratory directors, managers and supervisors, medical technologists, nurses, and medical doctors.

First and Third Surveys

A link to the survey (Appendix C & Appendix D) will be distributed to all targeted respondents either by email (Appendix E & Appendix F) or postcard (Appendices G-L). The CLSI will solicit participation from physician office laboratories, Department of Defense laboratories, and hospitals that offer point-of-care glucose testing. Participants will be recruited by COLA, the Joint Commission and a Point-of-Care Coordinator network, who have agreed to distribute links to the survey through their membership mailing lists. In addition, participants will also be solicited through mailing lists purchased by CLSI from Clinscan and the American Hospital Association. Clinical sites offering point-of-care glucose testing in the Department of Defense medical system will also be asked to participate through the Department of Defense Clinical Laboratory Improvement Program (CLIP). In order to obtain the needed number of respondents for a statistically valid study, additional laboratories, selected at random from a subset of laboratories included in a database of Clinical Laboratory Improvement Amendment (CLIA) certificate holders, will also be solicited.

Second Survey

The second survey (Appendix D) will occur approximately 4-6 months after the initial survey (Appendix C) and will only target respondents from the first survey who indicated that they were not familiar with *POCT12* or *POCT13* and therefore, will have received a complimentary copy of the appropriate LPG. It is expected that approximately 50% of all targeted respondents will not be familiar with POCT12 or POCT13. This survey will be the same as the first survey, but the respondents will be able to answer additional questions after they have reviewed the LPG. A link to the survey will be distributed to the email (Appendix F) addresses provided by these respondents during the first survey. Respondents that received a free copy of *POCT12* or *POCT13* following the first survey will also be contacted by email and asked to take the third survey (Appendix D).

Description of the Information to be Collected

The CLSI survey is designed to collect information on participant demographics, awareness of the CLSI, awareness of *POCT12* and *POCT13*, use of *POCT12* and *POCT13* in their laboratories, facilitators and barriers to their adoption of the recommendations into their laboratory practice, and questions about perceived value of the documents.

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

The response rate for all surveys will be maximized by repeated reminders using the same channel that will be used to distribute the survey (Appendices E-L). All targeted laboratories will receive an email (Appendix E pg1 & Appendix F pg 1) or postcard (Appendix G & Appendix J) approximately one month before distribution of the survey (Appendix C & Appendix D). This letter will describe the survey and our purpose for collecting the information. Another email (Appendix E pg 2 & Appendix F pg 2) or postcard (Appendix H & Appendix K) with a link to the survey will then be sent to the same targeted laboratories. We also plan to resend the link to the survey to all targeted laboratories approximately one month later to remind them of the survey (Appendix E pg 3, Appendix F pg 3, Appendix I, & Appendix L).

Response rates will be computed based on the *OMB Standards and Guidelines for Statistical Surveys* guidance document. The proportion of the sample that is represented by the non-responding laboratories in this project will be an indicator of potential nonresponse bias. If there is a lower response rate, an in-depth nonresponse bias analysis will be conducted.

4. Tests of Procedures or Methods to be Undertaken

The Fingerstick Glucose Survey will be pilot tested with 9 laboratory and healthcare professionals representing a diverse spectrum of the kinds of point-of-care coordinators, clinical laboratory directors, managers and supervisors, medical technologists, nurses, and medical doctors who work in the types of laboratories that perform glucose testing and monitoring, including hospital laboratories and physician offices or nursing homes that do not have an on-site moderate or high complexity laboratory. During pilot testing, the CLSI will identify volunteers to take the survey and then, collect impressions concerning any ambiguities or other concerns and finally follow up with phone calls if necessary. The CLSI will attempt to include a variety of geographical areas, including laboratories in smaller metropolitan areas, if possible.

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

The following provided consultation on survey design and will help analyze data:

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