Determining the Landscape of Quality Management Systems for Public Health Laboratories Performing Next-Generation Sequencing

CSTLTS Generic Data collection Request
OMB No. 0920-0879

Supporting Statement – Section B

Submitted: 6/4/2020

Program Official/Project Officer

Diego Arambula
Biologist
Division of Laboratory Systems
Center for Surveillance, Epidemiology, and Laboratory Services
1600 Clifton Rd.
V24-3
404.498.0691
DArambula@cdc.gov

Table of Contents

Section B – Data collection Procedures

1. Respondent Universe and Sampling Methods

The respondent universe for this generic information collection (GenIC) consists of 57 laboratory directors representing 57 state, local, or territorial public health laboratories (PHLs). All PHLs to be surveyed are affiliated with the Association of Public Health Laboratories (APHL) and have been previously identified by APHL as performing or starting to implement NGS-based testing; this eliminates the inappropriate surveying of laboratory personnel while ensuring representative PHLs are included in this data collection (1). Please see **Attachment A** for the list of respondents.

2. Procedures for the Collection of Information

Data will be collected via online survey and respondents will be recruited through a notification (see **Attachment D – Survey Invitation Email**) to the respondent universe. The notification email will explain:

- The purpose of the data collection, and why their participation is important
- Instructions for participating
- Method to safeguard their responses
- That participation is voluntary
- The expected time to complete the instrument
- Contact information for the project team

The invitation email, addressed from APHL and CDC, will be sent to the each PHL director and will contain a hyperlink that is unique to their laboratory. Each laboratory targeted in this GenIC has been previously surveyed by APHL and has been responsive to communications from APHL. One survey will be completed per public health laboratory (n=57) with the PHL Director serving as the primary respondent. If necessary, the laboratory director may gather information/input from quality managers or other laboratory personnel. Each laboratory will have six weeks to complete the survey and will only be considered non-responders if the survey has not been submitted by the end of that time period. One week after the invitation email has been sent, a reminder email (see **Attachment E – Reminder Email**) will be sent to the laboratory directors. One week prior to the closing of the survey period, another reminder email will be sent to the PHL directors (see **Attachment E – Reminder Email**). Qualtrics will be used as the survey platform.

Once the survey period has closed, de-identified, aggregated results from all participating PHLs will be transferred from secured APHL servers to CDC for analysis. Survey responses will be analyzed by descriptive and inferential statistics. Linking collected data to existing data sources by non-personal identifiers (i.e. laboratory characteristics) may be used to increase the overall utility of the data collection.

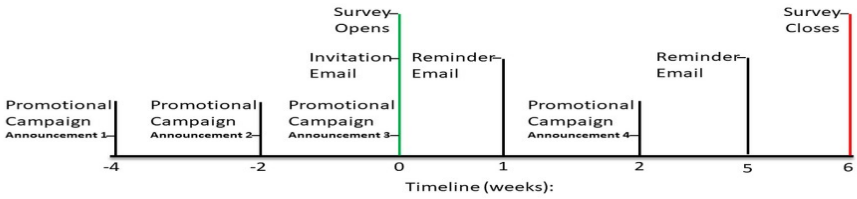
3. Methods to Maximize Response Rates Deal with Nonresponse

Although participation in the data collection is voluntary, the project team will make every effort to maximize the rate of response. The data collection instrument was designed with

particular focus on streamlining questions to allow for skipping questions based on responses to previous questions, thereby minimizing response burden.

Following the distribution of the invitation to participate in the data collection, (see **Attachment D – Survey Invitation Email**), respondents will have 30 business days to complete the instrument. Those who do not respond within 5 and 25 business days will receive reminder emails (see **Attachment E – Reminder Email**) urging them to complete the instrument. Those who do not respond within 30 business days from the invitation email will be considered non-responders.

Four weeks prior to sending the invitation email, APHL will announce and encourage PHL participation through a promotional campaign (**Attachment F** for promotional announcement 1 and 2, and **Attachment G** for announcement 3 and 4) in its weekly newsletter. These campaign announcements will occur biweekly for six weeks, see the below figure for a graphical representation of the timeline. The promotional campaign is primarily informative to raise awareness of the NGS Quality Initiatives products but will also serve as a reminder for solicited laboratories to complete the survey; please note that laboratories other than the 57 included in Attachment A will not be able to volunteer to participate in the online survey.



4. Test of Procedures or Methods to be Undertaken

The estimate for burden hours is based on a pilot test of the data collection instrument by two public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 40 minutes (range: 38 to 40 minutes). For the purposes of estimating burden hours, the upper limit of this range (i.e., 40 minutes) is used.

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

Collette Leaumont
Deputy Director for Science
Division of Laboratory Services
Centers for Disease Control and Prevention
2400 Century Center, V24-3, Atlanta, GA 30345

Office – 404.639.0838
chf3@cdc.gov

Rebecca Hutchins
Clinical Research Associate
Booz Allen Hamilton
1349 West Peachtree Street, NW, Suite 1400, Atlanta, GA 30309 Office – 404.909.5748
ibo7@cdc.gov

Oladayo (Dayo) Omosa
Evaluation Fellow
Division of Laboratory Services
Centers for Disease Control and Prevention
2400 Century Center, V24-3, Atlanta, GA 30345
Office – 404.498.2882
prp5@cdc.gov

Diego Arambula
Biologist
Division of Laboratory Services
Centers for Disease Control and Prevention
2400 Century Center, V24-3, Atlanta, GA 30345
Office – 404.498.0691
oco4@cdc.gov

Christin Hanigan
Sr. Specialist, Advanced Molecular Detection
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Office – 240.485.2748
Christin.Hanigan@aphl.org

Sudaba Parnian
Sr. Specialist, Monitoring and Evaluation
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700, Silver Spring, MD 20910
Office - 240.485.3854
sudaba.parnian@aphl.org

LIST OF ATTACHMENTS – Section B

Note: Attachments are included as separate files as instructed.

- **A. Attachment A – List of Public Health Laboratories Associated with APHL**
- **D. Attachment D – Survey Invitation Email**
- **E. Attachment E – Survey Reminder Email**
- **F. Attachment F – APHL Survey Promotional Campaign Announcement**
- **G. Attachment G – APHL Survey Promotional Campaign Announcement Post-launch**

REFERENCE LIST

1. Collins GS, Ogundimu EO, Altman DG. 2016. Sample size considerations for the external validation of a multivariable prognostic model: a resampling study. Stat Med 35:214-26.