

Rapid Influenza Diagnostic Testing Practices in Laboratories

Request for Approval of New Data Collection Supporting Statement B

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This is a request for OMB approval of a new data collection, Rapid Influenza Diagnostic Testing Practices in Laboratories. CDC is requesting a twelve month approval to collect the data.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The Survey of Rapid Influenza Diagnostic Testing Practices in Laboratories is a national systematic survey investigating rapid influenza diagnostic testing (RIDT) practices in clinical laboratories. The survey will be funded in full by the Office of Surveillance, Epidemiology, and Laboratory Services (OSELS) of the Centers for Disease Control and Prevention (CDC).

The survey covers basic laboratory demographic characteristics, specimen collection and processing, testing practices, reporting of results to emergency departments and other treatment facilities, reporting results to health departments, quality assurance practices, and methods of receiving updated influenza-related information. The majority of the questions request information about laboratory RIDT practices.

To date, no systematic study has been conducted to investigate how laboratories use RIDTs, how they report results, or how they interact with emergency departments or treatment facilities. The survey will be conducted on a national sample of clinical laboratories. There are no costs to respondents except their time. The total estimated annual burden hours are 1020.

The survey will be done by The Joint Commission (JC) as a part of a cooperative agreement with the CDC, Grant# 1U47OE000001-01, entitled "Strategies for Improving Rapid Influenza Testing in Ambulatory Settings". The survey will be administered by the Northern Illinois University Public Opinion Lab (NIUPOL), as a subcontractor to JC. A paper survey will be mailed to participant laboratories. Participant laboratories will be identified from two sources: The JC database and the College of American Pathology (CAP) database of accredited hospital laboratories. All identifiers will be removed regardless of the source. There are approximately 4,000 US hospitals the vast majority of which are Joint Commission- accredited. Approximately 2400 of those hospitals have labs that are accredited by the College of Pathology (CAP). The JC accredits another 1000 hospital based laboratories All 3,400 of these accredited hospital laboratories will be surveyed so that the sample will include 85% of the universe of hospital based accredited laboratories. Assuming a 60% response rate we anticipate receiving 2040 completed surveys. In order to estimate a given question response to within 5 percentage points of the true value with 95% confidence, using an anticipated population proportion of 0.50 (or expected proportion response of 50% on any given question), a sample size of at least 384 is required. Therefore, our sample should provide adequate data for statistical relevance.

Note: To estimate population proportion with specified absolute precision we used the following formula: $n = z^2_{1-\alpha/2}P(1-P)/d^2$ where n is the desired sample size, $z^2_{1-\alpha/2}$ is the square of the $1-\alpha/2$ point of the normal curve and α is the type I error rate (here assumed to be 0.05), P is the anticipated population proportion (0.50 gives the most conservative estimate of the sample size

and is used when the anticipated population proportion is unknown), and d is the half-width of the confidence interval desired (in the calculations $d=0.05$).

The survey data will be analyzed using descriptive statistics for an univariate analysis of the question responses; t-tests or Wilcoxon nonparametric tests, as appropriate, for continuous responses and chi-square tests for categorical responses to explore the relationship between pairs of survey responses, for example to relate quality assurance practices and procedures with the laboratory setting related to RIDT and confirmatory testing.

To address generalizability, a comparison will be conducted between a proportion of the laboratories of survey responders and non-responders. This will be used to determine if the sample appears to be representative. Demographic variables such as hospital size and geographic location will be compared. The analysis will determine if there are any significant differences between a sample of survey responders and non-responders. If there are no significant differences between these groups on the identified demographic factors, we can infer that a non-response bias does not exist. This would allow for study findings to be generalized to accredited laboratories. If a significant difference is found between responders and non-responders, this would imply that a non-response bias most likely exists and the generalizability of the findings would be limited. Those limitations would be acknowledged and describe in any reporting or interpretation of the data.

2. Procedures for the Collection of Information

The survey was designed by the JC with advice from their expert technical advisory panel to capture laboratory practices in RIDT testing. The questionnaire is composed primarily of short-answer closed-end items that will be answered by checking boxes. The survey will be pilot tested at eight hospital-based laboratories. Feedback will be used to determine the clarity of questions. We estimate that the typical respondent will require approximately 30 minutes to complete the questionnaire.

Each sampled laboratory will receive a postal mailing on JC letterhead. A cover memo that explains the purpose of the survey will accompany the questionnaire. The memo will explain that completing the survey is not, in any way, related to accreditation activities, and individual facility responses will be kept strictly confidential and not shared. The memo will contain a toll-free number for the survey contractors, to confirm legitimacy, obtain more information or request to be removed from the sample. The survey will be addressed to the Director of the laboratory and instructions will state that the survey should be completed by salient people within the laboratory. A postage-paid reply envelope will be sent in a 9"x12" envelope. Facilities will be allowed three weeks to complete and return the survey. After three weeks the NIUPOL will place follow-up calls to non-respondents to maximize the response rate. A second questionnaire mailing will be sent to those individuals who request one during the reminder calls.

NIUPOL will provide JC project staff with regular updates during the survey collection phase. These reports will log the cumulative number of completed surveys and detail any issues or problems that have emerged during the survey process, how the issues have been addressed, and the outcome. Project staff from JC and NIUPOL staff will discuss issues and determine the best approach to address any problems with the survey administration.

When the survey field period closes, NIUPOL will create an excel database. The final dataset will include one record for each originally sampled laboratory, whether or not a response was recorded. Each record will contain a disposition code indicating a completed case or a non-response. The aggregate data, with all identifiers removed, will be exported to the JC for data cleaning and analysis. The data will be analyzed by JC statistical staff using both descriptive and inferential statistics. The database will reside with the JC. The JC staff will interpret and report the results of the data analyses.

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

We will monitor survey response daily to gauge if the current active sample is likely to generate the required number of completed cases. If response is lower than estimated, two additional reminder calls will be made to non-responders by NIUPOL to enhance response rate. Based on past experience at JC and at CDC we typically get acceptable response from laboratories (average of 60%). However, a non-response bias analysis will be performed that will examine the demographic and practice characteristic variations between the *response* group and the *non-response* group. Our non-response bias analysis will compare the *response* versus the *non-response* group to assess any systematic bias attributable to non-response.

4. Tests of Procedures of Methods to be Undertaken

The first phase of data analysis will be a univariate analysis of all survey questions. This will be followed by bivariate analysis of laboratory demographic characteristics and practices vs. factors affecting the laboratories' interactions with the emergency departments and with the rest of their facility with respect to RIDT testing and results reporting. We will adjust for survey non-response and also include a post-stratification adjustment based on laboratory characteristics. The data will be analyzed using the SAS statistical package.

With the collection of at least 384 completed surveys, our analysis will be adequately powered to detect statistically significant responses. Additionally, we anticipate that we will have sufficient data to analyze differences attributable to such relevant variables such as type and size of laboratory, type of facility and other demographic characteristics, testing and reporting practices.

Our primary analytical goal is to determine RIDT practices in clinical laboratories that perform testing for emergency departments. The data will be used to provide information critical for designing a web-based RIDT practice and utilization course for clinicians.

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:

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