Survey of Influenza Rapid Diagnostic Test Practices in Laboratories

Request for Approval of New Data Collection
Supporting Statement A

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A. Justification

1. Circumstances Making the Collection of Information Necessary

The Survey of Rapid Influenza Diagnostic Testing Practices in Laboratories is a national systematic study investigating rapid influenza diagnostic testing practices in clinical laboratories. This will be a new collection. Influenza epidemics usually cause an average more than 200,000 hospitalizations and 36,000 deaths per year in the U.S. Respiratory illnesses caused by influenza viruses are not easily differentiated from other respiratory infections based solely on symptoms, and influenza viruses may adversely affect different subpopulations. The effective use of rapid influenza diagnostic testing practices is an important component of the differential diagnosis of influenza-like-illness in both inpatient and outpatient treatment facilities. Test results are used for making decisions about antiviral vs. antibiotic use, and in making admission or discharge decisions. In many cases, rapid influenza tests are the only tests that can provide results while the patient is still present in the facility. Thus, the appropriate use of the tests, and interpretation of test results is critical to the treatment and control of influenza. More than a dozen rapid tests have been approved by the U.S. Food and Drug Administration and are in widespread use. The reliability of rapid influenza tests is influenced by the individual test product used and the setting. Reported sensitivities range from 10-75%; while the median specificities reported are 90-95%. Other factors influencing accuracy are the stage (or duration) of illness when the diagnostic specimen is collected, type and adequacy of the specimen collected, variability in user technique for specimen collection or assay performance, and disease activity in the community. Given these and other collective findings, it is imperative for public health and for response planning that CDC develops sector-specific guidance and effective outreach to the clinicians on appropriate use of RIDT in their practices.

Previous studies by CDC of outpatient facilities showed that clinical laboratories usually perform the rapid tests for emergency departments, and provide results for both inpatient and outpatient treatment. Thus, understanding the use of rapid influenza testing in clinical laboratories, how the laboratories report results to emergency departments and treatment facilities and health departments, and what quality assurance practices are used will guide future efforts of the CDC to develop appropriate influenza testing guidelines and sector-specific training materials for clinicians and improve health outcomes of the American public.

The survey will cover 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 influenza testing practices. To date, no systematic study has been conducted to investigate how laboratories use these tests, how they report results, or how they interact with outpatient treatment facilities. This survey seeks to provide insight into how laboratories use and report the test results, assure quality of testing, and interact with treatment facilities, especially outpatient facilities. The survey will be conducted on a national sample of clinical laboratories.

For maximum relevance and utility, the data needs to be collected at the end of the current influenza season and before the next season.

The survey will be administered by the Joint Commission (JC). The data will be collected by the Northern Illinois University Public Opinion Laboratory (NIUPOL) under contract with the JC. After removal of identifiers, the data will be sent to the JC. The JC will analyze the data.

During the data collection process, respondent information will be kept secure. No IIF is being collected from respondents. The survey does not ask for any information related to individual patients. The survey primarily asks for information regarding laboratorians' work and processes. Survey responses will be submitted via a paper survey, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No patient identifiers will be retained in the final survey dataset.

2. Purpose and Use of Information Collection

The primary objectives are to:

1) Determine which rapid influenza diagnostic testing practices are used in clinical laboratories and especially in the laboratories that perform testing for emergency departments and outpatient facilities that use test results to treat patients and to make admission/discharge decisions.

2) Use information from this survey to inform the development of a rapid influenza diagnostic testing training program for clinicians, especially physicians, nurses, and other outpatient providers.

3) Use information from this survey in the development of sector-specific influenza testing guidelines for clinicians and health care workers in outpatient treatment facilities.

The Division of Laboratory Science and Standards will provide a final written report through cooperative agreement partners. The results of the work published in peer-reviewed journals and will be available to the public.

3. Use of Improved Information Technology and Burden Reduction

All data for this study will be collected via a paper-and-pencil questionnaire. A paper survey is being used because e-mail addresses are not available for all laboratory groups from which we are drawing the sample. For example, we do not have email addresses for the hospitals that are accredited by the College of American Pathology (CAP). In addition, many laboratory personnel, particularly those working in resource –poor settings do not have access to a computer during working hours. Both of these factors would tend to bias the study against resource-challenged laboratories. Since the survey is comprised of short-answer, checkbox – type questions, the burden, in terms of time required to answer the survey would be no more than the burden for an electronic survey.

4. Efforts to Identify Duplication and Use of Similar Information

This is a new program. Information has not been previously collected for this purpose. Previous studies of outpatient facilities showed that clinical laboratories usually perform the rapid tests for emergency departments, and provide results for both inpatient and outpatient treatment. Thus, understanding the use of rapid influenza testing in clinical laboratories, how the laboratories report results to emergency departments and treatment facilities and health departments, and what quality assurance practices are used will guide future efforts of the CDC to develop appropriate influenza testing guidelines and sector-specific training materials for clinicians and improve health outcomes of the American public.

To date, no systematic study has been conducted to investigate how clinical laboratories use these tests, how they report results, or how they interact with outpatient treatment facilities. This has been confirmed by consulting with experts in the CDC Influenza Division, at HHS, clinical experts at the JC and by checking electronic such as Medline/PubMed resources.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small business. The study is limited to hospital laboratories and we will not be sampling independent laboratories.

6. Consequences of Collecting the Information Less Frequent Collection

This is a one-time data collection.

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

There are no special circumstances.

8. Comments in Response to the Federal Register Notice/Outside Consultation

As required by 5 CDR 1320.8(d), a notice of this proposed data collection appeared in the Federal Register, June 8, 2011, Vol. 76, No. 110, pp. 33303-33304 (Attachment B). One non-substantive comment was received from the public.

<u>The following public comment was received:</u>

"Subject: PUBLIC COMMENT ON FEDERAL REGISTER FW: influenza spending OF AMERICAN TAX DOLLARS TO BENEFIT BIG PHARMA, BIG MEDICINE WITH BIG MONEY

CDC, IS A FRAUD. CDC NEEDS TO BE SHUT DOWN. IT WORKS ONLY FOR BIG PROFITEERS WHO WANT TO MAKE A FAST BUCK OUT OF HARMING AMERICA FOR BIG MONEY. CDC IS A COMPLETE AND UTTER FRAUD AS A HEALTH AGENCY.

JEAN PUBLIC ADDRESS IF REQUIRED"

CDC Standard response to the public comment was sent:

We received your comment and have forwarded it to the appropriate program. Thank you for your interest. CDC

9. Explanation of any Payment/Gift to Respondents

Not applicable.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by CIO who determined that the Privacy Act does not apply. During the data collection process, respondent information will be kept secure. No IIF is being collected from respondents. The survey does not ask for any information related to individual patients. The survey primarily asks for information regarding laboratorians' work and processes. Survey responses will be submitted via a paper survey, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No patient identifiers will be retained in the final survey dataset.

Data management will be closely monitored by the project staff. All responses will be entered in a secure database at NIUPOL. Ultimately, a data file without organization or individual identifiers will be sent in a secure electronic manner from NIUPOL to the JC project staff for analysis.

NIUPOL will initially have contact information for the directors of laboratories. No contact information will be shared with the JC or with CDC. Once the data collection has been completed, all names, addresses, and telephone numbers of contact persons will be destroyed, Participation in the survey is completely voluntary and participants will be notified of this. The information collected will be limited to operational processes and activities in the laboratory. No personal information or individually identifiable information will be collected. The data will be stored in a secure database on a password protected computer. Ultimately, the survey data results will be presented in aggregate form only; no individual laboratory-level data or personal information will be identified. All grant information will be maintained in a secure manner.

11. Justification for Sensitive Questions

No sensitive information will be collected.

12. Estimates of Annualized Burden Hours (Total Hours & Wages)

The participants will be taken from the JC data base and from the CAP data base of accredited hospital laboratories. There are approximately 4,000 US hospitals the vast majority of which are accredited by the JC. Approximately 2400 of those hospitals have labs that are accredited by the College of Pathology (CAP). The JC accredits an additional 1000

hospital based laboratories. Thus, 85% of hospital based labs are accredited by the JC or CAP. We will reach out to all 3400 laboratories (1,000 TJC and 2,400 CAP accredited). Surveys will be sent to laboratory supervisors with a request to respond within one month of receipt of the questionnaire. The NIU, contractors to the JC will place two reminder follow-up calls to all laboratories that do not initially respond to bolster response rate. Assuming a 60% overall response rate we anticipate receiving 2040 completed surveys. The survey takes 30 minutes for each participant to complete.

Estimated Annualized Burden Costs

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Hourly Wage Rate**	**Total Burden hours**	**Total Respondent Costs**
Clinical Laboratory Supervisors	Rapid Influenza Diagnostic Testing Practices in Laboratories	2040	1	30/60	$27.34	1020	27,886.80
Total							$27,886.80

Note: The salary for the clinical laboratory supervisor is taken from the Department of Labor Wage Reports (http://www.bls.gov/oes/current/oes292011.htm) for Medical and Clinical Laboratory Technologists.

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

There are no additional recordkeeping/capital costs.

14. Annualized Cost to Federal Government

Health Scientists will be creating the survey, collecting and analyzing the data, and reporting the results.

Type of Federal employee support	Total Hours	Hourly Wage Rate	Total Federal Costs
Health Scientist	104 (.05% FTE)	$56	$5,824
JC Project Manager (contractor)	208 (10% FTE	$45	$9,360
Contract Cost			$50,000
Total			$65,184

The average hourly wage rate is for a health scientist is estimated at the GS-14, step 6 Level, taken from the federal employee wage tables for the Atlanta area (http://www.opm.gov/oca/11tables/html/atl.asp).The hour wage for the Project Manager was taken from contractor estimates. There are no travel costs associated.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will begin as soon as clearance is received. The following is a timeline in months following OMB approval Administration, collection and cleaning and analysis are overlapping

Administer survey – Upon OMB approval
Data collection and cleaning – completed 3 months after OMB approval
Data analysis – completed 5 months after OMB approval

Following completion of the survey, data will be summarized into tables. Aggregate data will be reported to the CDC. Selected data of interest will be published by the JC.

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

Not applicable.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.