

**Quantitative Survey of Physician Practices in Laboratory Test Ordering and Interpretation**

***Request for Approval of New Data Collection  
Supporting Statement A***

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**Quantitative Survey of Physician Practices in Laboratory Test Ordering and Interpretation**  
***Request for Approval of New Data Collection***

This is a request for OMB approval of a new data collection, Quantitative Survey of Physician Practices in Laboratory Test Ordering and Interpretation. CDC is requesting a twelve month approval to collect the data.

**A. Justification**

**1. Circumstances Making the Collection of Information Necessary**

Background

The effective use of laboratory testing is an important component of the diagnostic process within physician practices. The field of laboratory medicine is undergoing rapid change with the continuing introduction of new tests, increased focus on evidence-based medicine, the deployment of Electronic Health Records, and the wide availability to physicians of electronic information resources, interactive diagnostic tools, and computerized order entry systems. To date, there has been no systematic study investigating how this rapid evolution in laboratory medicine is affecting primary care practice and if physicians are effectively incorporating laboratory testing innovations into their day-to-day practices. This proposed survey (Attachment C) follows a series of three qualitative focus groups involving nine or fewer primary care physicians: one concerning test ordering, one concerning communication with the lab and one concerning test interpretation. This survey will quantify the prevalence and impact of the issues identified within the focus groups. Understanding the relative importance of physician issues in the effective and efficient use of laboratory medicine in diagnosis will guide future efforts of the CDC to improve primary care practice and improve health outcomes of the American public.

Privacy Impact Assessment

*Overview of the Data Collection System*

The survey will be administered to physician respondents using a Web-based survey system administered by Altarum Institute, a non-profit health systems research organization. The Web-based survey system uses a standard commercial software package from the Datstat company; this system is widely used by survey researchers and includes extensive confidentiality protections. Physicians will receive an emailed message (Attachment E) explaining the purpose of the research and containing a link to the Web survey site. The Web-based survey system generates an internal and anonymous identifier that is used to track responses to the survey request, and up to three subsequent emailed reminders (Attachment E) are sent to non-responders. The identifier is internal to the survey system and is not exported with the completed data, thus protecting the anonymity of respondents. The Web-based survey site is designed to be visually appealing, easy to navigate, and is fully compliant with Section 508 of the Rehabilitation Act.

### *Items of Information to be Collected*

The information collected will be survey responses to a questionnaire (Attachment C) with topics related to physician laboratory interaction and utilization. Basic physician demographic characteristics will be collected including year of birth, gender, years in practice, physician specialty, professional memberships, practice size and practice setting. Other practice-related questions will include number and type of patients seen weekly. The majority of the questions request information about physician decision making processes involved in test ordering and interpretation. No sensitive information or personal health information is requested at any point in the survey.

### *Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age*

The information collection will not involve a website with content directed at children less than 13 years of age.

## **2. Purpose and Use of Information Collection**

The purpose of this information collection is to begin to acquire data on the extent and severity of issues that physicians face with clinical laboratory testing including the selection of appropriate laboratory tests and interpretation of test results. The findings of the survey will be used both to inform further interventions and studies into clinical laboratory utilization as well as raise awareness with publications, presentations, and other outreach among the physician community to improve laboratory test selection, test result interpretation, and patient care.

### Privacy Impact Assessment

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 physician's work and interaction with laboratories. Survey responses will be submitted via a Web-based survey system, and neither the survey operations staff nor subsequent data analysts will have access to the identities of the respondents. No patient nor physician identifiers will be retained in the final survey dataset.

## **3. Use of Improved Information Technology and Burden Reduction**

The survey will use the Internet for Web-based data collection, as most physicians have ready access to computer systems. Respondents will receive a survey notification letter (Attachment D) via ordinary postal mail, and the actual survey invitation will be sent via electronic mail (Attachment E), in order to reduce paper usage and shipping costs. All data will be stored in and accessed from an electronic data management system. No paper forms will be submitted to CDC.

## **4. Efforts to Identify Duplication and Use of Similar Information**

The CDC group that designed the original focus group research and has authored the quantitative survey questionnaire include professionals and leaders in the field of laboratory

medicine both in the public and private sectors; these experts include Brian Jackson, MD, John Hickner, MD, and Paul Epner, and their full associations are provided in Section 8 below. Large-scale literature reviews have been performed on the topics the survey intends to cover. The CDC Institute for Laboratory Medicine has been integrally involved in the design of the survey. Throughout a thorough review of all these sources of information, no work has been found to comprehensively study the physician attitudes and characteristics that this survey is designed to examine. We are confident that this work is sufficiently distinct as to not be duplicating other efforts.

### 5. Impact on Small Businesses or Other Small Entities

Some survey respondents will be physicians in small practices. For purposes of estimating the impact on small businesses, we have designated physicians in solo practice or in practice with one other physician as representing a small business. Approximately 35% of physicians fall into this category. Our overall target sample size is 1600, and therefore approximately 570 respondents could be characterized as a small business.

Distribution of Primary Care Physicians by Practice Size and Type*		Solo or 2 physicians	Group (3 or more)	Group /Staff HMO	Medical School	Hospital Based	Other	Total
Primary Care Physicians by Practice Type / Size	%	35.6	27.7	5.9	5.1	13.3	12.4	100
Sample Sizes: Total and by Practice Type/Size	1600	570	443	94	82	213	198	1600
* Source: 2004-2005 Community Tracking Study Physician Survey, Center for Studying Health System Change								

In order to reduce respondent burden for these and all respondents, a simple and accessible survey format will be used. The survey will be accessible via the Internet, using conventional software, and will be available for respondents to take at their convenience, either at home or in the office. The Web-based survey site will be available for several weeks and will accessible 24 hours per day. The questionnaire authors have reduced the survey length as much as possible, to reduce survey burden on respondents. Respondents are not asked to provide any extraneous information other than the core survey questions related to laboratory medicine practices.

### 6. Consequences of Collecting the Information Less Frequently

This survey will be fielded only once under the research plan.

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

There are no special circumstances that require the information to be collected in any of the formats identified, and the request fully complies with regulations.

### 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. As required by 5 CFR 1320.8 (d), a notice of this proposed data collection appeared in the Federal Register, Vol. 76, No. 26, pp. 6796-6797 on Tuesday, February 8, 2011 (Attachment B). One non-substantive comment was received from the public and no response was given.

B. The following individuals were consulted during the development of the study methods and data collection instruments.

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## **9. Explanation of Any Payment or Gift to Respondents**

In order to encourage response, physicians completing the survey will be offered the option of having Altarum Institute, the survey vendor, contribute \$10.00 on their behalf to their choice of one of several charitable organizations. The charitable organization choices will all be United States-based 501(c) non-profit organizations. This amount was selected to be sufficiently small as to not represent an undue compensation or possibly coercive influence on respondents.

## **10. Assurance of Confidentiality Provided to Respondents**

## Privacy Impact Assessment

- A) This information collection request has been reviewed by our PRA contact who has determined that the Privacy Act does not apply. Respondents included in the survey will be assigned anonymous identification codes; these codes will not contain identifying information and will be removed from the final dataset that is distributed to researchers for analysis.
- B) Survey responses received by Altarum Institute will be stored in a secure, password-protected database. As a task within construction of the final survey dataset for use by analysts and research, all identifying information will be removed by Altarum Institute technical staff.
- C) Since no identifiable information will be collected or used, consent will not be necessary.
- D) The survey will inform all respondents that all responses are voluntary.

### **11. Justification for Sensitive Questions**

Information on criminal behavior, sexual behavior and attitudes, alcohol or drug use, religious beliefs, and race and ethnicity will not be collected. Data security will be assured as described above.

### **12. Estimates of Annualized Burden Hours and Costs**

A. This survey program will collect a total of 1600 completed interviews, divided evenly between respondents who are Family Practice physicians (n=800) and General Internal Medicine physicians (n=800). Each physician will only be asked to respond once. Preliminary testing indicates that the average respondents will require 14 minutes to complete the entire questionnaire. In order to converge the final overall sample to 800 completed interviews from each type of physician (Family Practice and Internal Medicine), we will stratify the initial starting sample list by physician type and then construct a series of separate smaller replicate samples by type. These smaller replicates can be slowly released into the data collection process individually. Thus we can control the number of completed cases by managing the release of sample. If one physician type generates a higher response rate, then obtaining our target 800 completed cases would require fewer replicates. This is a common technique for telephone surveys, but it transfers directly to Web surveys as well.

#### **Burden Hours**

<b>Type of Respondent</b>	<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per Response (hours)</b>	<b>Total Burden Hours</b>
Family Practice Physicians & Internal Medicine Generalists	Laboratory Practices	1,600	1	14/60	373

Total	1600			373
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B. The total cost burden for respondents is estimated as follows: with a total annual burden of 373 hours, the total cost of the respondents' time to respond to the proposed survey is estimated to be \$31,612. The average hourly wage rate for Family Practice and General Internal Medicine physicians was obtained from the Bureau of Labor Statistics, Occupational and Employment Statistics Section May 2009 data (accessed December 10, 2010 at [http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)).

**Estimated Annualized Burden Costs**

Type of Respondent	Response Burden (hours)	Average Hourly Wage	Total Cost
Family Practice Physicians & Internal Medicine Generalists	373	\$84.75	\$31,612
Total			\$31,612

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers**

There will be no other annual cost burdens.

**14. Annualized Cost to the Government**

The total annualized cost to the Government of this survey is composed of CDC staff support and consultation throughout the design, survey administration, and analysis and reporting. CDC staff costs are estimated using the estimated hours of time of support and pay rates from the GS pay scale for Atlanta ([http://www.opm.gov/oca/11tables/html/atl\\_h.asp](http://www.opm.gov/oca/11tables/html/atl_h.asp)) and assumed an average pay rate of a grade 13 step 1 (\$40.97 per hour) among the four FTEs involved for a total of 90 hours plus \$950 in additional material costs.

Cost Component	Total Cost
CDC staff salaries and overhead	\$4,650
<b>Total</b>	\$4,650

**15. Explanation for Program Changes or Adjustments**

This is a new data collection.

## 16. Plans for Tabulation and Publication and Project Time Schedule

### Publication

Results from this survey are planned to be presented at national meetings and a manuscript containing the findings will be submitted to a peer-reviewed scientific journal. Manuscripts will include a discussion of potential biases and other limitations of the project. Additionally, results may be used for ongoing planning requirements of the CDC Laboratory Science, Policy, & Practice Program Office.

### Project time schedule

The Survey will be conducted as soon as possible following OMB approval. The following time schedule includes research steps through preparation and approval of the survey results final report; subsequent publication of results in peer-reviewed scientific journals is not included as part of the basic survey operations time schedule.

<b>Project Time Schedule</b>	<b>Date</b>
Finalize web survey programming	1 month after OMB approval
Obtain and construct sample	2 months after OMB approval
Start survey	4 months after OMB approval
Complete data collection	5 months after OMB approval
Initial data analysis results	6 months after OMB approval
Draft survey report	8 months after OMB approval
Finalize survey report	12 months after OMB approval

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

The proposed survey instrument will display the expiration date.

## 18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-I. No exceptions to certification are requested.