

technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

1. Proposed Projects

Survey of Laboratory Practices for Mycobacterium tuberculosis Drug Susceptibility Testing in the U.S.—New—As part of the continuing effort to support public health objectives of treatment, disease prevention and surveillance programs, the Public Health Practice Program Office (PHPPO), Division of Laboratory Systems seeks to collect information from both public health and private sector laboratories performing drug susceptibility testing on Mycobacterium tuberculosis. Tuberculosis is a continuing public health problem in the United States despite declining case

rates. Although public health efforts have brought multi drug resistant tuberculosis (MDRTB) under control, these MDRTB and other drug resistant isolates will continue to challenge laboratory support for TB control because of higher prevalence rates and potential for transmission in some segments of the U.S. population. To control this health problem, it is imperative that cases of tuberculosis are identified and placed on effective chemotherapy as quickly as possible. Information collected in the survey will be on test methods, drug concentrations, quality assurance, quality control and reporting practices. The survey will also collect information regarding the type of laboratories where testing is performed, the number of tests performed, testing for primary or secondary anti-tuberculosis drugs and turnaround time for reporting susceptibility test results to

the clinician and public health programs. This survey will provide CDC with information to facilitate standard use of drugs and concentrations tested, interpretation of test results, and laboratory reports so that the information for the clinician is consistent regardless of the laboratory performing testing. This 25-question survey will be mailed to 200 laboratories which are directly involved in Mycobacterium tuberculosis susceptibility drug testing. The amount of time required for completion of the survey will be 30-45 minutes for each respondent. The only cost to the respondent is the time involved in completion of the survey. Results of the survey will be published in a peer-reviewed journal and shared at national meetings to encourage the adoption of standard practices. There is no cost to the respondent.

No. of respondents	No. of responses per respondent	Hrs/response	Response burden
200	1	30/60	100

Dated: December 1, 1999.
Nancy Cheal,
Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-00-10]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork reduction Act of 1995, the Centers for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.
Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

1. Proposed Project

Evaluation of the diffusion of HIV and tobacco-use prevention education programs from national training to the community level—NEW—The National center for Chronic Disease Prevention and Health Promotion seeks OMB approval for an evaluation of the diffusion of CDC identified effective education programs from national training to the community level to be conducted from 2000 to 2002. The project aims to enhance the adoption and implementation of effective HIV and tobacco-use prevention programs. As such, it is directly related to the CDC FY 2000 performance plan to reduce smoking among young people 50% by 2003, and to reduce the incidence of HIV/AIDS through the dissemination of HIV prevention education programs. CDC will study the diffusion of three

prevention programs (2 HIV; 1 tobacco). Half of the participants attending the training will be randomly selected, by state, to receive additional technical assistance and diffusion action planning. This evaluation will follow two cohorts of respondents: *Cohort A* (Master Trainers and Coalition Leaders) includes education and public health agency administrators, health education trainers, and community organization and community media leaders who attended the national training and who will diffuse the program in their states and communities; *Cohort B* (Local Health Educators and Coalition Members) includes local administrators, teachers, and health educators in local health departments, schools, media groups, and community organizations, who attended a training provided by a Master Trainer/Coalition Leader. Cohort A will complete two 30-minute surveys at 6 months and 12 months post-training and also participate in one 90-minute focus group conducted by phone. Cohort B will receive one 45-minute survey six months after they have received training.
We assume that each Cohort A participant will, in turn, train 30 local health educators or coalition members (Cohort B). The total estimated cost to respondents is \$54,848 assuming an average wage of \$22.96 and \$22.58 for cohorts A and B respectively.

Respondents	Number of respondents	Number of responses per respondent	Burden per response	Total burden hours
Cohort A:				
HIV	57	3	0.83	142.49
Tobacco	40	3	0.83	99.99
Cohort B:				
HIV	1710	1	0.75	1282.50
Tobacco	1200	1	0.75	900.00
TOTAL	3007			2424.03

Dated: December 1, 1999.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day-00-11]

Proposed Data Collections Submitted for Public Comment and Recommendations

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Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports

Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

1. Proposed Projects

Survey of Laboratory Practices for Nucleic Acid Amplification Tests for Mycobacterium tuberculosis (M.tb NAA)—New—As part of the continuing effort to support public health objectives of treatment, disease prevention and surveillance programs, the Public Health Practice Program Office (PHPPO), Division of Laboratory Systems seeks to collect information from both public health and private sector laboratories performing nucleic acid amplification tests for Mycobacterium tuberculosis. Mycobacterium tuberculosis (TB) infection has reemerged as a significant public health concern in the United States. Since TB is easily transmitted, early detection of infection is imperative for control and prevention. CDC guidelines have advocated the use of the acid-fast bacilli smear (AFB), followed by culture, to confirm a diagnosis of tuberculosis. However, research and development have led to the design and marketing of nucleic acid amplification-based methods for the rapid detection of Mycobacterium tuberculosis (M.tb) directly from clinical sputum specimens. Since the FDA approval of two commercial M.tb NAA, CDC has become keenly interested in the analytic accuracy and clinical utility of these tests, especially from the standpoint of early detection and control of tuberculosis.

Literature reports indicate variability in sensitivities, specificities, and predictive values for M.tb NAA, depending on the experimental design, the population being studied, and the test methodology. Overall, both sensitivity and specificity are reported

to be relatively high compared with AFB smear and culture results. However, there are several important potential sources of error including contamination problems inherent to nucleic acid technology, cross-contamination with other mycobacteria, sub-optimal laboratory practices, and unknown factors. The use of M.tb NAA tests for rapidly diagnosis may be useful for controlling TB, particularly in high prevalence populations. However, the clinical utility and efficacy of M.tb NAA tests remains in question. Because of the uncertainty surrounding the analytical accuracy and clinical validity of the tests, the potential sources of error, and the subsequent potential expense of incorrect treatment.

The goal of the proposed project is to collect laboratory practice data, in conjunction with performance data, through a survey administered to current participants in the CDC's M.tb NAA Performance Evaluation Program, to determine if laboratory practices are associated with the risk of errors in these tests. Information collected in the survey will be on test methods, quality assurance, quality control and reporting practices, and test utilization. The survey will also collect demographic information regarding the types of laboratories where testing is performed. CDC will use this data as a primary source of critical information to develop laboratory guidelines and recommendations for performance and utilization of M.tb NAA tests. The only cost to the participants will be the time required to complete the survey, i.e., approximately 30 minutes each. The benefit of this data and the subsequent recommendations to public health will be the utilization of enhanced testing practices in the control and elimination of M. tuberculosis infection in the United States. There is no cost to the respondent.