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).

[FR Doc. 99–31742 Filed 12–7–99; 8:45 am]

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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

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 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.

No. of respondents	No. of responses per respondent	Hrs/response	Response burden
100	30	30/60	50

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

[60Day–00–09]

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 Projects

National Surveillance System for Hospital Health Care Workers (NaSH)—Reinstatement—National Center for Infectious Diseases (NCID)—has developed a surveillance system called the National Surveillance System for Hospital Health Care Workers (NaSH) that focuses on surveillance of exposures and infections among hospital-based health care workers (HCWs). NaSH (OMB 0920–0417) includes standardized methodology for various occupational health issues. It is a collaborative effort of the Hospital Infections Program, National Center for Infectious Diseases (NCID); the Hepatitis Branch, Division of Viral and Rickettsial Diseases, NCID; the Division of Tuberculosis (TB) Elimination, National Center for HIV, STD, and TB Prevention; the National Immunization Program (NIP), and the National Institute for Occupational Safety and Health (NIOSH).

NaSH consists of modules for collection of data about various occupational issues. Baseline information about each HCW such as demographics, immune-status for vaccine-preventable diseases, and TB status is collected when the HCW is enrolled in the system. Results of routine tuberculin skin test (TST) are collected and entered in the system every time a TST is placed and read; follow-up information is collected for HCWs with a positive TST. When an HCW is exposed to blood/bloodborne pathogen, to a vaccine-preventable disease (VPD), or to an infectious TB patient/HCW, epidemiologic data are collected about the exposure. For HCWs exposed to a bloodborne pathogen (i.e., HIV, HCV, or HBC) and for susceptible HCWs exposed to VPDs, additional data are collected during follow-up visits. Once a year, hospitals complete a survey to provide denominator data and every 2–5 years, the hospitals perform a survey to assess the level of underreporting of needlesticks (HCW Survey). Optionally, hospitals may collect information about HCW noninfectious occupational injuries such as acute musculoskeletal injuries. Data are entered into the software and transmitted on diskette to CDC. No HCW identifiers are sent to CDC. This system is protected by the Assurance of Confidentiality (308d).

Data collected in NaSH will assist hospitals, HCWs, health care organizations, and public health agencies. This system will allow CDC to monitor national trends, to identify newly emerging hazards for HCWs, to assess the risk of occupational infection, and to evaluate preventive measures, including engineering controls, work practices, protective equipment, and postexposure prophylaxis to prevent occupationally acquired infections. Hospitals that volunteer to participate in this system benefit by receiving technical support and standardized methodologies, including software, for conducting surveillance activities on occupational health.

This system was developed and piloted in large teaching hospitals (RFP–200–94–0834(P) and RFP–200–96–0524(P)). The first pilot included four hospitals and the second, five. After the refinement pilot in an additional 13 hospitals (PA–786 and interagency agreements), participation in NaSH became voluntary. The system is being made available to all acute-care hospitals in the United States wishing to participate voluntarily in the project. We anticipate no more than 100 hospitals participating by the end of fiscal 2000 and potentially 150 by fiscal 2002. To participate in NaSH, hospitals are required to provide information on all exposures to infectious agents, baseline information on the exposed HCWs, as well as the underreporting and hospital surveys.

A new component of NaSH will be a web-based surveillance for occupational exposures to blood that can be used by any health care facility and will meet OSHA requirements and needs mandated by national and state legislation. Referred to as ''NaSH Lite'', this module is an abbreviated version of the bloodborne pathogen exposure module. Data collected through NaSH Lite will help create a national database for benchmarking and for tracking trends in sharps-injuries as well as help health care facilities to record and prevent exposures. This module will be developed with OSHA input and in conjunction with state health departments. In addition, data collected through NaSH Lite will assist health care facilities to select, implement, and evaluate strategies (including safety devices) to prevent percutaneous exposures.