

Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (NSSAE)—Reinstatement with change—Division of Tuberculosis Elimination (DTBE), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Between October 2000 and September 2004, the CDC received reports of 50 patients with severe adverse events (SAEs) associated with the use of the two or three-month regimen of rifampin and pyrazinamide (RZ) for the treatment of LTBI; 12 (24%) patients died (Morbidity and Mortality Weekly Report 2003;52[31]:735-9). In 2004, CDC began collecting reports of SAEs associated with any treatment regimen for LTBI. For surveillance purposes, an SAE was

defined as any drug-associated reaction resulting in a patient's hospitalization or death after at least one treatment dose for LTBI. During 2004-2008, CDC received 17 reports of SAEs in 15 adults and two children; all patients had received isoniazid (INH) and had experienced severe liver injury (Morbidity and Mortality Weekly Report 2010; 59:224-9).

The CDC requests approval for a 3-year reinstatement with change of the previously approved National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection (OMB No. 0920-0773, expired April 31, 2011). The changes include a shortened data collection form and an increase in the number of respondents. This project will continue the passive reporting system for SAEs associated with therapy for LTBI. The system will rely on medical chart review and/or onsite investigations by TB control staff.

The purpose of this information collection request is to determine the annual number and trends of SAEs associated with treatment of LTBI and identify common characteristics of patients with SAEs during treatment of LTBI. Potential correspondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City,

Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for adverse event associated with LTBI treatment (NSSAE). The NSSAE form is completed for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. CDC will analyze and periodically publish reports summarizing national LTBI treatment adverse events statistics and also will conduct special analyses for publication in peer-reviewed scientific journals to further describe and interpret these data.

The Food and Drug Administration (FDA) collects data on adverse events related to drugs through the FDA MedWatch Program. CDC is collaborating with FDA in the reporting of SAEs. Reporting will be conducted through telephone, e-mail, or during CDC site visits. In this request, CDC is requesting approval for approximately 60 burden hours annually, an estimated increase of 36 hours from the previously approved 24 hours. This is due to an estimated increase of reports of SAEs after the publication of the MMWR report on SAEs in 2010. There are no costs to respondents other than their time to gather medical records to complete the reporting form.

**ESTIMATE OF ANNUALIZED BURDEN HOURS**

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Physicians .....	10	1	1
Nurses .....	10	1	4
Medical Clerk .....	10	1	1

Dated: October 7, 2011.  
**Daniel Holcomb,**  
*Reports Clearance Officer, Centers for Disease Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-12-11JJ]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under

review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

Evaluating Locally-Developed HIV Prevention Interventions for African-American MSM in Los Angeles—New—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Data on HIV cases reported in 33 U.S. states with HIV reporting indicate the burden of HIV/AIDS is most concentrated in the African American population compared to other racial/ethnic groups. Of the 49,704 African American males diagnosed with HIV between 2001 and 2004, 54% of these cases were among men who have sex with men (MSM). In Los Angeles County (LAC), the proportion of HIV/AIDS cases among African American males attributable to male-to-male sexual transmission is even greater (75%). In the absence of an effective vaccine, behavioral interventions represent one of the few methods for reducing high HIV incidence among African American MSM (AAMSM). Unfortunately, in the third decade of the

epidemic, very few of the available HIV-prevention interventions for African American populations have been designed specifically for MSM. In fact, until very recently none of CDC's evidence-based, HIV-prevention interventions had been specifically tested for efficacy in reducing HIV transmission among MSM of color. Given the conspicuous absence of (1) evidence-based HIV interventions and (2) outcome evaluations of existing AAMSM interventions, our collaborative team intends to address a glaring research gap by implementing a best-practices model of comprehensive program evaluation.

The purpose of this project is to test in a real world setting the efficacy of an HIV transmission prevention intervention for reducing sexual risk among African American men who have sex with men in Los Angeles County.

The intervention is a 3-session, group-level intervention that will provide participants with the information, motivation, and skills necessary to reduce their risk of transmitting or acquiring HIV. The intervention will be evaluated using baseline, 3 month and 6 month follow up questionnaires. This project will also conduct in-depth qualitative interviews with 36 men in order to assess the experiences with the intervention, elicit recommendations for improving the intervention, and to better understand the factors that put young African American MSM at risk for HIV.

CDC is requesting approval for a 3-year clearance for data collection. The data collection system involves screenings, limited locator information, contact information, baseline questionnaire, client satisfaction surveys, 3-month follow-up

questionnaire, 6-month follow-up questionnaire, and case study interviews. An estimated 700 men will be screened for eligibility in order to enroll 528 men. The baseline and follow up questionnaires contain questions about participants' socio-demographic information, health and healthcare, sexual activity, substance use, and other psychosocial issues. The duration of each baseline, 3-month, and 6-month questionnaires are estimated to be 60 minutes; the Success Case Study interviews 90 minutes; Outreach Recruitment Assessment 5 minutes; limited locator information form 5 minutes; participant contact information form 10 minutes; each client satisfaction survey 5 minutes.

There are no costs to the respondents other than their time. The total estimated annual burden hours are 1662.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per respondent (in hours)
Prospective Participant .....	Outreach Recruitment Assessment (screener) .....	700	1	5/60
Prospective Participant .....	Limited Locator Information .....	700	1	5/60
Enrolled Participant .....	Participant Contact Information Form .....	528	1	10/60
Enrolled Participant .....	Baseline Questionnaire .....	528	1	1
Enrolled Participant .....	Client Satisfaction Survey .....	224	3	5/60
Enrolled Participant .....	3 month follow up Questionnaire .....	420	1	1
Enrolled Participant .....	6 month follow up Questionnaire .....	400	1	1
Enrolled Participant .....	Success Case Study Interview .....	36	1	1.5

Dated: October 7, 2011.

**Daniel Holcomb,**

Reports Clearance Officer, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**Board of Scientific Counselors, Office of Infectious Diseases (BSC, OID)**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Time and Date: 8 a.m.-4:30 p.m., November 9, 2011.

Place: CDC, Global Communications Center, 1600 Clifton Road, NE., Building 19, Auditorium B3, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The BSC, OID, provides advice and guidance to the Secretary, Department of Health and Human Services; the Director, CDC; the Director, OID; and the Directors of the National Center for Immunization and Respiratory Diseases, the National Center for Emerging and Zoonotic Infectious Diseases, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, CDC, in the following areas: strategies, goals, and priorities for programs; research within the national centers; and overall strategic direction and focus of OID and the national centers.

Matters To Be Discussed: The meeting will include brief updates from OID and the three infectious disease national centers, a report from the OID/BSC Food Safety Modernization Act working group, and presentation of the recently released strategic framework for CDC's infectious disease programs. The main topic of the meeting will include a focused discussion, with breakout groups, on the changing roles and responsibilities for public health infectious disease laboratories and the challenges and opportunities related to new diagnostics,

other technologic advances, and a changing economic environment.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Robin Moseley, M.A.T., Designated Federal Officer, OID, CDC, 1600 Clifton Road, NE., Mailstop D10, Atlanta, Georgia 30333, Telephone: (404) 639-4461.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: October 6, 2011.

**Catherine Ramadei,**

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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