

Attachment B. *Federal Register* Notice, August 18, 2005, Volume 70, Number 159, Pages 48551-48553

collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Nurse-Delivered Risk Reduction Intervention for HIV-Infected Women—New-National Center for HIV, STD, and TB Prevention (NCHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: CDC is requesting a 3-year approval from the Office of Management and Budget (OMB) to administer a questionnaire and a one-on-one qualitative interview to HIV-infected women in the southern United States who are at risk for further transmission of the disease. This study is designed to adapt and evaluate an HIV transmission prevention intervention for the growing population of HIV-infected women in the South and to study factors associated with risk among women. The primary outcome will be a reduction in

sexual risk behavior as a result of a brief, nurse-delivered prevention intervention adapted for use with HIV-infected women in the South. The project will also conduct in-depth qualitative interviews of young, recently HIV-infected women to assess social and environmental factors that contribute to behavioral risk for HIV infection. The project addresses goals of the *CDC HIV Prevention Strategic Plan*, specifically the goal of increasing the number of HIV-infected persons who are linked to appropriate prevention, care, and treatment services. In addition, information from this research will inform future prevention interventions that encompass individual and contextual factors.

Approximately 550 women will be screened for eligibility to participate in the study, and a minimum of 330 women from one or two sites will be recruited and administered baseline and follow-up behavioral risk assessments in a randomized wait-list comparison design with a 6-month follow-up period. That is, the intervention and comparison group will complete an assessment at the baseline and in 6

months a follow-up assessment will be conducted to compare behavior change. Six months after the intervention group has been provided the intervention and follow-up, women in the comparison group will receive the intervention. The assessments will capture information on demographics, risk behaviors, attitudes, and knowledge related to HIV/STD transmission and prevention. Semi-structured qualitative interviews will be conducted with a subgroup of 25–30 young, recently-diagnosed participants following their participation in the intervention study. These interviews will explore behavioral, social, and contextual conditions that may have contributed to the women’s risk for HIV infection and ideas about preventing other women from becoming infected. The two behavioral assessments will take about 1 hour each to complete, the nurse-delivered intervention will take about 1 hour to complete, and the qualitative interviews will take about 2 hours to complete. The screening interview will take about 10 minutes to complete. There is no cost to respondents other than the time it takes them to participate.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Burden per response (in hours)	Total burden (in hours)
Women—screening interview	550	1	10/60	92
Women—assessment interviews	330	2	1	660
Women—intervention	330	1	1	330
Women—qualitative interviews	30	1	2	60
Total				1142

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Joan F. Karr,
Acting 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

[60Day-05-0573]

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 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and

Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-371-5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

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 or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Adult and Pediatric HIV/AIDS Confidential Case Reports (OMB Control No. 0920-0573)—Revision—National Center for HIV, STD, and TB Prevention (NCHSTP), Divisions of HIV/AIDS Prevention, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking a 3-year approval from the Office of Management and Budget (OMB) to continue data collection of the HIV/AIDS case reports. CDC is proposing to collect additional data on testing history for improved monitoring of HIV incidence (HIV testing history pre-test and post-test data collection forms), on specimen quality and

sequence information for drug resistance and HIV-1 subtype surveillance.

The National Adult and Pediatric HIV/AIDS Confidential Case Reports are collected as part of the HIV/AIDS Surveillance System. CDC in collaboration with health departments in the states, territories, and the District of Columbia, conducts national surveillance for cases of HIV infection and AIDS, the end-stage of disease caused by infection with HIV. HIV/AIDS surveillance data collection by CDC is authorized under Sections 301 and 306 of the Public Health Service Act (42 U.S.C. 241 and 242k).

Currently, 59 areas (states/territories/possessions) mandate and collect AIDS surveillance data. In addition, 43 areas currently mandate and collect confidential name-based surveillance data on HIV cases which have not progressed to AIDS in adults/adolescents and/or children using the HIV case report forms. We anticipate that over the next 3 years additional areas will mandate collection of name-based HIV surveillance data. Therefore, the estimated burden for the next 3 years is based on HIV case reporting in 59 areas. Respondents in this data collection are state, local, and territorial health departments. The purpose of HIV/AIDS surveillance data is to monitor trends in HIV/AIDS and describe the characteristics of infected persons (e.g., demographics, modes of exposure to HIV, clinical and laboratory markers of HIV disease, manifestations of severe HIV disease, and deaths due to AIDS). Because HIV infection results in untimely death and most often infects younger adults in the prime years of life, large amounts of federal, state, and local

government funding have been allocated to address all aspects of HIV infection, including prevention and treatment. HIV/AIDS surveillance data are widely used at all government levels to assess the impact of HIV infection on morbidity and mortality, to allocate medical care resources and services, and to guide prevention and disease control activities.

HIV/AIDS reports are sent to state/local health departments by laboratories, physicians, hospitals, clinics, and other health care providers using standard adult and pediatric case report forms. Areas use a microcomputer system developed by CDC (the HIV/AIDS Reporting System, HARS) to store and analyze data, as well as transmit encrypted data to CDC. A Public Health Information Network (PHIN) compliant HIV reporting system is currently in development and is scheduled to replace HARS by 2007.

This request to OMB includes one modification to both the Adult/Adolescent and Pediatric HIV/AIDS confidential case report forms. The forms to be used during this period will include an additional blank space in the top and bottom portions of the forms. Areas could then have the option of using this space to assign a form number. This form number would be for local use only and not be reported to CDC.

The burden estimate for this renewal includes estimated burden for evaluations of HIV/AIDS surveillance based on these forms. In addition, the burden estimate also includes forms that will be used to collect additional data on testing history for the purpose of estimating HIV incidence. The availability of a serologic testing

algorithm for recent HIV seroconversion (STARHS) allows surveillance systems to determine how many among a group of new diagnoses are from new infections. In order to derive a population-based estimate of HIV incidence based on data from those individuals who choose to have an HIV antibody test and who test positive (those reported to HIV surveillance systems), additional data are needed to assign statistical weights to individual STARHS results. These additional data include information on individual's reason for testing, the frequency with which he/she tests, place where he/she was tested, when he/she was most recently tested, when he/she was first tested, whether he/she has ever tested negative, and questions regarding use of HIV-related medicines.

The table also includes burden estimates of additional information on specimen quality and genotyping test results for drug resistance and HIV-1 subtypes as part of variant, atypical and resistant HIV surveillance (VARHS). These data will be reported to CDC by participating health departments for the purpose of calculating population-based estimates of prevalence of HIV drug resistance and HIV-1 subtypes among individuals with newly diagnosed HIV. These data are provided routinely by the testing laboratory to health departments requiring no additional data collection form.

No other Federal agency collects this type of national HIV/AIDS data. In addition to providing technical assistance for use of the case report forms, CDC also provides reporting areas with technical support for the HARS software. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Form	Number of respondents	Number of responses	Burden per response (in hours)	Total burden (in hours)
Adult Case Report: AIDS	59	814	10/60	8,004
Adult Case Report: HIV	59	809	10/60	7,955
Peds Case Report: AIDS	59	2	10/60	20
Peds Case Report: HIV	59	9	10/60	89
HIV Testing History Form Pre-test version	6	1,577	2/60	315
HIV Testing History Form Post-test version	24	1,577	2/60	1,262
VARHS	24	1,577	0.5/60	315
Total				17,960

Dated: August 11, 2005.

Joan F. Karr,

Acting 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

Technical Assistance to Rwandan Healthy Schools Initiative

Announcement Type: New.

Funding Opportunity Number: CDC-RFA-AA105.

Catalog of Federal Domestic

Assistance Number: 93.067.

Key Dates: Application Deadline: September 12, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under Sections 301(a) and 307 of the Public Health Service Act [42 U.S.C. 241 and 242], as amended, and under Public Law 108-25 (United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003) [U.S.C. 7601].

Background: Data from the 2000 Behavioral Surveillance Survey in Rwanda suggests that in-school youth are more likely to engage in early sexual activity than out-of-school youth, which makes secondary schools a natural and important focus for age-appropriate prevention and confidential, voluntary counseling and testing (CT) activities. In addition, behavior change messages or CT services have not yet systematically reached secondary-school students in Rwanda; while science lessons at the secondary level in Rwanda generally cover HIV/AIDS-related subject matter, content and presentation vary from school to school.

At present, confidential CT services in Rwanda are restricted primarily to health facilities, with limited availability in non-clinical settings. Schools have great potential to function as community resource centers for HIV/AIDS, particularly in those cases where, for multiple reasons, individuals are not presenting themselves for HIV testing at hospitals or health centers. When it has been used, mobile, confidential CT has proven to be a very effective approach in Rwanda; single-day testing campaigns have yielded as many as 12,000 persons tested.

With assistance from the World Bank, the United Kingdom, Department for International Development (DFID), the United Nations Children's Fund

(UNICEF) and other donors, the Rwandan Ministry of Education (MINEDUC) has recently completed the development of primary- and secondary-school curricula that integrate HIV/AIDS and life-skills lessons at each level of instruction. The Rwandan National Curriculum Development Center has approved the curricula and incorporated them into the training modules at Rwanda's teacher training colleges (TTC). The new textbooks will be distributed to schools in the near future. This is a valuable first step in ensuring that all students in Rwanda have an adequate knowledge base appropriate to their stage of physical, intellectual, and emotional development, with respect to HIV/AIDS prevention.

Purpose: As part of the President's Emergency Plan for AIDS Relief, HHS announces the availability of Fiscal Year (FY) 2005 funds for technical assistance to Rwanda's MINEDUC in launching a pilot initiative to develop secondary schools into community resources for confidential CT and the prevention of HIV/AIDS. The initiative, tentatively named the Healthy Schools Initiative, will take in two main interventions: (1) School-based, community, confidential CT offered via mobile testing units to secondary-school students, their parents and teachers, and surrounding communities; and (2) an innovative, age-appropriate prevention/behavior change campaign to focus on abstinence and parent-child communication. The grantee, to be selected on a competitive basis, will be responsible for collaborating closely with MINEDUC, HHS, the U.S. Agency for International Development (USAID), and other local agencies to ensure the successful planning, coordination, implementation and monitoring of the initiative.

Intervention 1: Counseling and Testing

Under the Healthy Schools Initiative, HHS will introduce free, confidential mobile HIV testing to secondary schools through a culturally appropriate public campaign to target teachers, upper level secondary-school students, their families and community members. Building on the enthusiasm expressed by the Rwandan Minister of Education about a sector-wide confidential CT campaign, the mobile testing intervention will roll out in a top-down fashion, by starting with public HIV tests for the Minister and other MINEDUC officials and then branching out to secondary schools through Free CT days. Free CT days will involve dispatching a mobile CT unit to secondary schools to provide free, confidential testing for teachers,

students, their families and community members. Prior to offering confidential CT at secondary schools, community preparation campaigns in school catchment areas will foster acceptance of community- and youth-centered confidential CT, and for people living with HIV/AIDS (PLWHA).

Both a "prevention for negatives" component and linkages to the national care and treatment program for HIV infected persons will facilitate appropriate follow-up for all individuals tested through the initiative. Age-appropriate information, Education, and Communication (IEC) materials that emphasize behavior change will go out to all individuals who test negative in an effort to encourage abstinence and faithfulness as the best means of prevention. The program will forge linkages with the Rwandan national care and treatment program to ensure access to care and treatment for individuals who test positive. Specifically, local referrals to clinics providing care and treatment to HIV infected individuals, and anti-retroviral therapy (ART) to those who are eligible, will be provided to any individual who tests positive for HIV at any testing site. In addition, educational materials on HIV, ARTs, and strategies for reducing transmission of HIV will be provided to individuals testing positive.

Given that Rwandan law and government policy currently require parental consent for the testing of youth under the age of 18, it is crucial that the program develop appropriate linkages between the initiative's prevention and confidential CT interventions to engender parental support for youth CT. Such linkages might include the integration of a module on confidential CT into the parent-child communication curriculum, extracurricular sensitization activities with parents about the importance of knowing one's serostatus at any age, or national advocacy activities coordinated with MINEDUC's HIV/AIDS unit.

Intervention 2: Prevention

As part of the President's Emergency Plan, HHS seeks to build on MINEDUC's achievements in developing primary and secondary HIV curricula by introducing a culturally and age-appropriate competence-based behavior-change curriculum to emphasize abstinence and parent-child communication about HIV/AIDS. The curriculum will be founded on the conviction that the key to behavior change lies in: (1) The delivery of innovative, age- and culturally appropriate messages about HIV/AIDS behavior change; (2) the continual