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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Simplified Procedures for Routine HIV Screening in Acute Care Settings

Announcement Type: New.

Funding Opportunity Number: 04156.

Catalog of Federal Domestic Assistance Number: 93.943.

Key Dates: Application Deadline: August 2, 2004.

Executive Summary

Approximately 250,000 people living with HIV in the United States are undiagnosed. Many persons with AIDS made multiple visits to hospitals, acute care clinics and managed-care organizations before their AIDS diagnosis, but were never tested for HIV. These encounters are missed opportunities for earlier detection of HIV infection. When HIV testing has been offered on a routine basis (independent of risk factors or symptoms suggestive of HIV) to patients in high-prevalence, high-volume acute care settings, many HIV-infected patients have been identified and the proportion of positive tests has often been equal to or greater than among publicly funded HIV counseling and testing sites and sexually transmitted disease (STD) clinics. Such findings suggest that broader implementation of routine HIV screening in high-prevalence health care settings is an important component of our national strategy aimed at identifying persons with undiagnosed HIV infection.

Many patients in high volume, high HIV prevalence acute care facilities that have implemented routine rapid HIV testing have not been offered HIV testing because of the limitations imposed by the required procedures and staffing. Many providers perceive pre-test discussions as too time-consuming. In addition, it may not be practical to commit sufficient staff to approach all patients to offer HIV testing and provide prior counseling during peak time periods. Prevention counseling may not be appropriate or feasible during many episodic or acute care visits. Thus, mandatory individual pretest counseling may be a barrier to offering HIV testing in these settings. Written brochures, when used to replace formal verbal pretest discussions, have been shown to increase the numbers of patients who can be offered HIV testing. In order to be successful in implementing routine HIV testing programs, pre-test procedures must be simplified to ensure that large numbers of patients can be screened for HIV in busy clinical settings.

The goal of this program is to examine changes in pre-test screening and education procedures which may increase the number of patients who test for HIV and who receive their results. The objectives of this program are to modify procedures and materials for providing pre-test information and to evaluate the feasibility, acceptability, and success of these simplified procedures at the participating site(s).

I. Funding Opportunity Description

Authority: This program is authorized under the Public Health Service Act, sections 301, 311, and 317 (42 U.S.C sections 241, 243 and 247(b)), as amended.

Purpose: The purpose of the program is to develop and evaluate simplified procedures and materials to improve the programmatic success of existing routine HIV screening projects in acute care settings. Simplified procedures are necessary to ensure that large numbers of patients can be screened for HIV in busy clinical settings. This program addresses the ''Healthy People 2010'' focus area(s) of HIV. Measurable outcomes of the program will be in alignment with one (or more) of the following performance goal(s) for the National Center for HIV, STD and TB Prevention (NCHSTP): Strengthen the capacity nationwide to monitor the epidemic, develop and implement effective HIV prevention interventions and evaluate prevention programs. In addition, this program addresses the Division of HIV/AIDS Prevention priorities: Develop new methods for diagnosing HIV infection.

Activities

Awardee activities for this program are as follows:

- Modify the facility's existing procedures for HIV pre-test education and recruitment in order to increase the number of patients tested and who receive their results, by developing materials or procedures such as brochures, posters, videos, or group waiting room activities to promote routine HIV screening and provide pre-test information.
- Continue to routinely offer rapid HIV testing to patients in the acute care center with the modified pre-test procedures.
- Assess the programmatic outcomes of the modified procedures (*e.g.*, number of patients offered testing, number of patients accepting testing, number of patients tested, number of newly diagnosed HIV infections, seropositivity rate among persons tested). Periodically provide CDC with these data.
- Assess patient and provider satisfaction with the modified procedures.
- Assess patient comprehension of pre-test messages delivered through modified materials relative to existing procedures.
- Utilize program data to revise the procedures to improve the project's effectiveness.
- Participate in conference calls, meetings, and site visits.
- Collaborate with CDC to disseminate the findings and details on modified procedures and materials.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Assist in the development and review of the modified pre-test counseling procedures, activities, and printed materials.
- Provide guidance and assistance in the development of data collection instruments as well as data management systems and procedures.
- Facilitate conference calls, grantee meetings, and site visits.
- Assist in the analysis and dissemination of findings.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: $120,000.

Approximate Number of Awards: One–Two.

Approximate Average Award: $60,000–$120,000 (This amount includes both direct and indirect costs).

Floor of Award Range: $60,000.

Ceiling of Award Range: $120,000.

Anticipated Award Date: September 1, 2004.

Budget Period Length: 12 months.

Project Period Length: one year.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as

documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations or by governments and their Bona Fide Agents, such as:

- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a State application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

CDC will accept and review applications with budgets greater than the ceiling of the award range.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

Eligibility will be limited to organizations that are currently conducting a systematic evaluation of the implementation of routine rapid HIV testing in high volume, high HIV prevalence acute care facilities. Facilities must have implemented procedures for routine, voluntary HIV screening with rapid HIV tests consistent with CDC's Program Announcement 01187, entitled, ''Routinely recommending HIV and STD Counseling and Testing in Ambulatory Care Clinics and Emergency Rooms'' (the program announcement and examples of protocols developed by successful applicants are available for review at [Web site]). Applicants must have conducted such a program for a minimum of four months by the time of application and collected data throughout this time period regarding the numbers of patients who were seen in the facility, were offered HIV testing, accepted testing, were tested, and were newly diagnosed with HIV. Only these facilities will have historical data regarding the barriers and outcomes of current procedures, which will be required for comparison to modified procedures.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: (770) 488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Application: You must submit a program narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 20 if your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed: Background and Need, Objectives, Methods, Monitoring and Evaluation, Timeline, Staffing, Budget Justification. The budget justification will not be counted in the stated page limit.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitaes, Organizational Charts, Letters of Support and commitment indicating the funding basis for the routine HIV screening program upon which this project will be based, etc.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.* If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

Application Deadline Date: August 2, 2004.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does

not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: (770) 488–2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed Federal assistance applications. You should contact your State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your State's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html.*

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

• Funds may not be used for the purchase of HIV testing kits. Funds are to be used for developing and evaluating modified procedures, not to provide the entire financial basis for the HIV screening program. Applicants must demonstrate that there is a mechanism in place to support routine HIV screening activities.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA—04156, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Background, Need, and Objectives (20 Points)

Does the applicant summarize pertinent data from ongoing activities and outcomes regarding the implementation of routine rapid HIV testing in acute care facilities? Does the applicant use existing programmatic data to identify goals and propose modifications consistent with the objectives of this project? Does the applicant identify potential alterations to the existing procedures that are likely to increase the number and proportion of patients tested for HIV? Does the applicant discuss the potential effectiveness of these modifications? Are goals and objectives for the program modifications and evaluations clearly stated? Are the objectives reasonable and measurable?

2. Methods (30 Points)

Are the proposed methods scientifically sound and appropriate to the program objectives and the time frame of the project period? Do they demonstrate an understanding of the issues to be addressed and evaluated? Are they feasible? Does the applicant describe how the proposed procedures differ from the existing pre-test activities and procedures conducted according to standard procedures? Will the proposed methods and changes accomplish the program goals? Are the methods designed to utilize feedback and revise and improve program effectiveness?

3. Monitoring and Evaluation (30 Points)

Does the applicant provide a plan for evaluating the effectiveness of the programmatic changes? Is the project designed in such a way that the assessment of satisfaction will not interfere with the assessment of programmatic outcomes of the new procedures? Can the outcomes be compared to those from the prior project activities?

4. Capacity (20 Points)

Does the applicant have sufficient facilities and the staff to conduct this project and the ability to train the necessary staff? Does the institution support a routine approach to HIV screening? Does the applicant demonstrate that a mechanism is in place to fund routine HIV screening activities, such that awarded funds will be used to develop and evaluate modified procedures rather than to provide the entire financial basis for the screening program per se?

5. Budget (Not Scored)

Is the budget reasonable and justification adequate for the proposed activities?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by NCHSTP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above.

In addition, the following factors may affect the funding decision: Preference will be given to organizations who have demonstrated their ability to implement and evaluate existing programs which evaluate the routine use of rapid HIV tests in high prevalence, high volume acute care facilities.

V.3. Anticipated Announcement and Award Dates

Awards will be issued on or about September 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR–4 HIV/AIDS Confidentiality Provisions
- AR–5 HIV Program Review Panel Requirements
- AR–6 Patient Care
- AR–7 Executive Order 12372
- AR–8 Public Health System Reporting Requirements
- AR–10 Smoke-Free Workplace Requirements
- AR–11 Healthy People 2010
- AR–12 Lobbying Restrictions
- AR–15 Proof of Non-Profit Status
- AR–24 Health Insurance Portability and Accountability Act Requirements
- AR–25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Additional Requested Information.

f. Measures of Effectiveness.

2. Financial status report and annual progress report no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2700.

For program technical assistance, contact: Sheryl Lyss, MD, Extramural Project Officer, Division of HIV/AIDS Prevention, National Center for HIV/STD and TB Prevention, 1600 Clifton Road, MS E–46, Atlanta, Georgia 30333, Telephone: (404) 639–2093, E-mail: *SLyss@cdc.gov.*

For financial, grants management, or budget assistance, contact: Julia Valentine, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488–2732, E-mail: *jvx1@cdc.gov.*

Dated: May 27, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Linkage to HIV Care Demonstration Project

Announcement Type: New.

Funding Opportunity Number: 04154.

Catalog of Federal Domestic Assistance Number: 93.941.

Key Dates:

Letter of Intent Deadline: June 18, 2004.

Application Deadline: July 23, 2004.

Executive Summary: Data from several studies indicate that 30 to 40 percent of persons with new HIV diagnoses are not linked to an HIV care provider within 12 months of their HIV diagnosis. However, such early, prompt linkage to care is important for the health of the infected person, as well as putatively that person's potential to infect others. A recently completed Antiretroviral Treatment Access Study(''ARTAS'') in four United States (US) cities indicates that providing case managers to help such newly diagnosed persons into care significantly increases the percentage of persons who see an HIV care provider once within six months and twice within twelve months after their initial HIV diagnoses. Such case management was also cost-effective (about one thousand dollars per additional person successfully linked). The purpose of this project is to test the feasibility of providing intensive case management to HIV-infected persons newly diagnosed at publicly funded clinics or testing locations throughout the U.S.

I. Funding Opportunity Description

Authority: Section 301(a) and 317(k)(2) of the Public Health Service Act, (42 U.S.C. 241(a) and 274b(k)(2)), as amended.

Purpose: The purpose of the program is to link HIV-infected persons recently diagnosed at publicly funded clinics in the U.S. to HIV care providers. The project is intended for communities with socio-economically disadvantaged HIV-infected persons. There are compelling personal and public health benefits to get recently diagnosed HIV-infected persons into care before they get sick. The personal benefits include delayed disease progression, early beginning of antiretrovirals, regular monitoring of their immunologic status (CD4+ cell count) and virologic status (HIV–1 RNA copies in plasma). The public health benefits include reducing HIV transmission due to earlier reduction in infectious HIV–1 RNA copies in the blood; and earlier entry into prevention for positives programs in clinical settings.

Data from the original linkage to care clinical trial ARTAS and from other research studies indicate that about 40 percent of socioeconomically disadvantaged HIV-infected individuals are not yet linked to clinical care within a year of their HIV diagnosis. The ARTAS research project showed that case managers trained in strengths-based case management methodology can facilitate entry into clinical care at a very reasonable cost. After one year, 64 percent of case managed participants and 50 percent of non-case managed participants were linked to care. Furthermore, the ARTAS model required only two to three face-to-face meetings on average with a case manager over a maximum of three months. The intent of the demonstration project is to determine how well ARTAS can be implemented locally. Data will be collected at each local site to determine success rates and costs to implement linkage case management.

The proposed project should specifically address the following objectives:

1. To assess and compare linkage to care rates in the existing referrals program with linkages rates after