III. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Elias A. Zerhouni, ''Statement of the Director to the House Subcommittee on Labor-HHS-Education Appropriations on the FY 2004 President's Budget Request,'' April 2, 2003.

2. National Institutes of Health, Roadmap Overview, September 2003.

3. Tufts Center for the Study of Drug Development, U.S. Pharmaceutical Industry Inflation-Adjusted R&R Expenditures and NCE Approvals, 1963–2002.

4. FDA, ''Innovation or Stagnation, Challenge and Opportunity on the Critical Path to New Medical Products,'' March 2004.

5. Tufts Center for the Study of Drug Development, ''Backgrounder: How New Drugs Move Through the Development and Approval Process,'' November 2001.

Dated: May 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11612 Filed 5–21–04; 1:17 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04195]

Strengthening the Masters-Level Public Health Training Program in Zimbabwe; Notice of Intent To Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to strengthen masters-level graduate training programs in public health to more comprehensively address the HIV/AIDS epidemic in Zimbabwe. The Catalog of Federal Domestic Assistance number for this program is 93.283.

B. Eligible Applicant

Assistance will be provided only to the University of Zimbabwe (UZ), with the assistance targeted to the Department of Community Medicine (DCM). No other applications are solicited.

The UZ/DCM MPH program is an applied epidemiology training program founded through a collaborative effort between the Ministry of Health and Child Welfare (MOHCW) and the UZ/DCM. During the past three years, the MPH Program has trained 37 personnel in its two-year course. It also trained approximately 416 district health team members in health information for district management leading to a Certificate in Health Information for District Management (CHIDM).

The UZ/DCM MPH program is the only MPH program in the country and the only graduate public health program providing core public health trainings. The purpose of this agreement is to build upon the success of the program and allow it to expand without compromising the quality of the training.

Zimbabwe is among the countries in the world most affected by HIV/AIDS: HIV prevalence is estimated to be approximately 25 percent, there has been a ten-fold increase in the number of TB cases, and up to 35 percent of the children may be orphaned by AIDS at the end of this decade. At the same time, the public health response to the epidemic in Zimbabwe is inadequate due, in part, to insufficient manpower in the Zimbabwe public health system and lack of sufficient expertise in HIV/AIDS. This training program will enable Zimbabwe to train and place epidemiologists who are better equipped to address epidemics.

C. Funding

Approximately $173,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before July 15, 2004, and will be made for a 12-month budget period within a project period of up to three years. Funding estimates may change.

D. Where To Obtain Additional Information

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For program technical assistance, contact: Shannon Hader, M.D., Director, CDC Zimbabwe, 38 Samora Machel Avenue, Harare, Zimbabwe, telephone: +263 4 796040, E-mail: *haders@zimcdc.co.zw.*

For budget assistance, contact: Shirley Wynn, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770–488–2696, E-mail: *zbx6@cdc.gov.*

Dated: May 17, 2004.

William P. Nichols,

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

[FR Doc. 04–11634 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04142]

BECAUSE Kids Count! (Building and Enhancing Community Alliances United for Safety and Empowerment); Notice of Availability of Funds-Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement BECAUSE Kids Count! (Building and Enhancing Community Alliances United for Safety and Empowerment) was published in the **Federal Register**, May 10, 2004, Volume 69, Number 90, pages 25899–25903. The notice is amended as follows: Page 25899, second column, change Letter of Intent Deadline to May 28, 2004 and change Application Deadline Date to June 23, 2004. Page 25901, second column, change Letter of Intent (LOI) Deadline to May 28, 2004 and page 25901, first column, Pre-Application Conference Call: change time from 9:30 a.m. Eastern time to 12:30 p.m. Eastern time.

Dated: May 18, 2004.

William P. Nichols,

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

[FR Doc. 04–11636 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04138]

Evaluation of the Use of Rapid HIV Testing in the United States; Notice of Availability of Funds-Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement Evaluation of the Use of Rapid HIV testing in the United States was published in the **Federal Register** April 1, 2004, Volume 69, Number 63, pages 17163–17166. The notice is amended as follows: Page

17163, first column, under ''Purpose'' change to, ''The purpose of the program is to evaluate how to rapid tests for HIV are being implemented and used across the United States in clinical practice, and identify potential opportunities to provide guidance to assist providers in making decisions on the appropriate use of these tests.''

Page 17163, second column under ''Purpose'' last paragraph, add ''Thus, rapid tests for HIV may be used in many different types of venues including physician office laboratories, clinics, hospital emergency rooms other departments, public health departments and non-clinical testing sites.''

Page 17163, third column, under ''Activities'' first bullet, change to, ''Provide leadership in developing a program to determine the national scope of rapid HIV test utilization, with a focus on utilization in the private sector, including the number and type of sites where rapid HIV tests are offered, the specific tests used, testing volume, purpose for testing, characteristics of patient populations tested, and other characteristics related to the sites where rapid HIV testing is being implement and used.''

Page 17163, third column, under ''Activities'' second bullet, change to, ''Evaluate how these tests are integrated into the health care delivery system, for example methods used for specimen collection and handling, results reporting, confirmation of preliminary positive rapid test results, and use of results by practitioners.''

Page 17163, third column, under ''Activities'' third bullet, change to, ''Catalog problems that sites have identified and reported using these tests, such as lack of follow-up on preliminary positives, false positive, or negative results, testing delivery issues, costs of testing, and difficulties with provision of training to testing personnel.''

Page 17164, III.1. Eligible Applicants, delete community-based organizations.

Dated: May 18, 2004.

William P. Nichols,

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

[FR Doc. 04–11633 Filed 5–21–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Testing for Primary HIV Infection in Seronegative Patients

Announcement Type: New.

Funding Opportunity Number: 04119.

Catalog of Federal Domestic Assistance Number: 93.943.

Key Dates:

Letter of Intent Deadline: June 23, 2004.

Application Deadline: July 23, 2004.

Summary: The technology for human immunodeficiency virus (HIV) screening tests has progressively improved over the first generation HIV–1 enzyme-linked immunoassay (EIA) tests licensed in 1985. Newer testing technology can identify infected individuals earlier in the course of their infection. Identifying individuals earlier in the course of infection holds the potential for reducing transmission, increasing diagnosis of infected persons, and improving health outcomes for infected individuals. Because of the high viral load during acute infection, the risk of HIV transmission through sexual and needle contact may be particularly high during this time period.

In both domestic (US) and international settings, methods have been piloted to demonstrate detection of HIV infection early in the course of infection. In these approaches, individuals were tested with standard antibody tests. Individual specimens from patients testing negative on initial screening tests were grouped into pools, which were tested by ribonucleic acid (RNA) amplification. Such pooling strategies have been demonstrated to identify persons with early HIV infection, or primary HIV infection (PHI), before they would have otherwise been identified with early generation, less sensitive EIAs.

Based on experiences reported in the medical literature, RNA screening for PHI appears to be feasible in a setting with moderate HIV prevalence, without anonymous testing, and with sufficient staff to contact those identified with PHI who do not return for their results. However, the utility and costs of screening for acute infection among other populations needs study. Issues include: (1) Whether testing for acute infection can be accomplished in real-time; (2) whether patients return for their test results, particularly those with non-reactive rapid HIV tests; (3) whether patients with PHI who do not return for test results can be contacted for followup; (4) whether identifying PHI increases the yield from partner contact and referral services (PCRS); and (5) whether the utility of the strategy differs in the context of anonymous testing.

Furthermore, pooled RNA testing must be compared not only to insensitive EIAs, but also to other methods that may identify HIV infection earlier than the insensitive EIAs, such as p24 antigen testing (positive approximately 5 days after RNA); third generation EIAs (positive approximately 10 days after RNA); or OraQuick testing (similar to third-generation EIAs). Laboratory results from multiple testing technologies can also be compared to determine potential laboratory criteria for identifying certain specimens which would warrant further testing for PHI (*e.g.*, supplemental testing if a single EIA is positive or if the Western blot is negative or indeterminate, or an EIA is in the ''grey zone'' as defined by signal/cutoff ratios less than 1.0, but greater than a specified threshold). The marginal utility of pooled RNA screening needs to be compared to these other methods of identifying earlier HIV infection.

Identifying persons with acute HIV infection can also serve as the basis for collecting longitudinal follow-up specimens from recently infected individuals, essential for developing, validating, and comparing potential HIV incidence assays.

In this program, specimens from all patients presenting for voluntary HIV testing will be tested with standard antibody tests (EIA or rapid test). Specimens that test antibody-negative on screening tests and those that test antibody-positive on screening tests but negative or indeterminate by confirmatory Western blot or immunofluorescence will be tested with multiple other testing technologies, including pooled nucleic acid testing, p24 antigen testing, a third generation EIA (if not already performed), and (for some specimens) OraQuick and Western blot (if not previously performed). (Please note that patients testing negative with tests performed on finger stick or oral specimens will only be able to participate in this project if venous blood samples are drawn.) Nucleic acid testing and p24 antigen testing must be performed in real-time so that results would be available as soon as usual confirmatory test results (typically two weeks). Demographic data, testing history, and information about self-perceived risk, recent exposures, and PHI symptoms would be collected on all patients who had preliminary evidence