

development of immunization staff and the enhancement of immunization program efforts.

## 2. Collaboration (15 points)

The extent to which organization includes representatives of immunization programs who are actively engaged in directing immunization program efforts, and who represent state and local immunization program efforts from all parts of the nation.

## 3. Understanding of the Project (15 points)

Extent to which the applicant understands the requirements, problems, objectives, complexities, and interactions required of this project

## 4. Objectives (15 points)

Degree to which the proposed objectives are clearly stated, realistic, time phased, and related to the purpose of this project

## 5. Operational Plan and Timetable (15 points)

The extent to which the applicant's plan to carry out the activities proposed is feasible and consistent with the stated objectives in this proposal. The extent to which the timetable incorporates major activities and milestones that are specific, measurable and realistic. Dates, tasks, and persons responsible for accomplishing tasks should be included.

## 6. Staff Capacity (15 points)

Extent to which the professional personnel proposed to be involved in administering this project and the professional personnel proposed to provide program leadership have the capacity to perform the work proposed. This would include individual qualifications with evidence of past achievements for staff identified.

## 7. Evaluation Plan (10 points)

The extent to which the evaluation plan appears feasible for monitoring progress toward meeting the stated project objectives. In addition to evaluating outcome-related project objectives, the plan should clearly describe how the grantee will use performance measures to track internal processes.

## 8. Budget (not scored)

The budget should be reasonable, clearly justified, and consistent with the intended use of funds.

## 9. Performance goals (not scored)

The extent to which the application will further the NIP performance goals

stated in the purpose section of this announcement.

## I. Other Requirements

### Technical Reporting Requirements

Provide CDC with original plus two copies of:

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. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status 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.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

### Additional Requirements

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the program announcement, as posted on the CDC Web site.

AR-10—Smoke-Free Workplace Requirements

AR-11—Healthy People 2010

AR-12—Lobbying Restrictions

AR-15—Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

## J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address: <http://www.cdc.gov>.

Click on "Funding" then "Grants and Cooperative Agreements."

For general 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 business management assistance, contact: Peaches Brown, Grants Management Specialist, Procurement and Grants Office, Centers for Disease

Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: (770) 488-2738, Email address: [prb0@cdc.gov](mailto:prb0@cdc.gov).

For program technical assistance, contact: Kenneth Sharp, Program Operations Branch, ISD, National Immunization Program, Mailstop E-52, 1600 Clifton Rd, Atlanta, GA 30333, Telephone number: (404) 639-8215, E-mail address: [ksharp@cdc.gov](mailto:ksharp@cdc.gov).

Dated: April 30, 2003.

**Edward Schultz,**

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

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BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[Program Announcement 03101]

### Active Surveillance for Pertussis— Surveillance for Vaccine Preventable Disease as a Foundation for Evaluating the Effectiveness and Impact of an Adolescent/Adult Pertussis Immunization Program; Notice of Availability of Funds

*Application Deadline:* June 5, 2003.

#### A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 317 and 2102 of the Public Health Service Act, 42 U.S.C. 247b and 300aa-2. The Catalog of Federal Domestic Assistance number is 93.185.

#### B. Purpose

The Centers for Disease Control and Prevention announces the availability of fiscal year (FY) 2003 funds to initiate a cooperative agreement for surveillance for pertussis in a defined geographic area to better characterize the epidemiology of pertussis disease across pediatric, adolescent, and adult age groups and to link disease surveillance with immunization registry data to evaluate vaccine effectiveness. Moreover, as licensure and recommendation of an adolescent/adult pertussis vaccine may occur in the United States in the near future, studies of the impact of this new recommendation could be conducted in this study site. The "Healthy People 2010" focus area is Objective 14: Immunization and Infectious Disease including 14.1 (Reduce or eliminate indigenous cases of vaccine-preventable diseases) and 14.24 (Increase the

proportion of young children and adolescents who receive all vaccines that have been recommended for universal administration for at least 5 years.)

The specific goals of this project include:

- Enhancing methods to evaluate the burden of pertussis disease across age groups.
- Developing improved methods for pertussis surveillance that could be applied in other areas.
- Evaluating the effectiveness of pertussis vaccination by linking disease surveillance with immunization registry data on vaccination coverage.
- Developing a study site that could be used to assess the impact of an adolescent/adult pertussis vaccine program.

Measurable outcomes of the program will be in alignment with the goals listed above.

### Background

The number of reported cases of pertussis in the United States has increased steadily from a historic low of 1,010 cases in 1976 to 7,867 cases in 2000. Despite high vaccination coverage in infants and children, pertussis is the only vaccine-preventable disease that has a reported increase in overall cases and infant mortality in the United States over the past decade. Adolescents and adults suffer significant morbidity; 12 percent to greater than 30 percent of persons with cough illness of at least one to two weeks duration have evidence of pertussis infection. The mean duration of cough in adolescents and adults has been estimated to be approximately eight weeks. It has been hypothesized that the incidence of pertussis in adolescents and adults is increasing and that this age group is a reservoir for circulation of *Bordetella pertussis* and transmission to infants, who have the highest morbidity and mortality.

The use of pertussis-containing vaccines has evolved since the first vaccine was licensed in the United States in 1914. Since becoming available in a combined vaccine with diphtheria and tetanus toxoids (DTP) in 1948, the vaccine has been widely used for routine childhood immunization. In 1991, acellular pertussis vaccine (DtaP) was introduced in the United States for the fourth and fifth booster dose. In 1997, DTaP was recommended for the entire five dose series (primary series plus booster doses) for children under six years of age. DTaP manufacturers and types have varied during their short history. Currently there are three different DTaP formulations (and one

DTaP-HepB-IPV) available in the United States. Many children receive more than one formulation of DTaP over the five dose vaccine series. Because the efficacy of products may differ, evaluating product specific vaccine efficacy requires good data on the specific vaccine administered; these data may be available in a vaccination registry.

The current passive surveillance system for pertussis lacks sensitivity. Pertussis incidence is thought to be underestimated by at least one to two orders of magnitude in some age groups. Diagnostic criteria and reporting of pertussis vary significantly from state to state and from year to year. Outbreak investigations and the occurrence of periodic epidemic years can also markedly affect reporting. For example, among adolescents aged 15–19 years, the reported national incidence was 3.6 per 100,000 in 1999. By contrast, the reported incidence rate for adolescents aged 15–19 years in Massachusetts (which uses serologic testing for diagnosis in persons over the age of 11) was 65.6 per 100,000 in 1999. In the epidemic year 1996, Massachusetts reported an incidence rate of 103 per 100,000 for adolescents in the same age group. Current data for pertussis in adults is even more limited. Thus, the variability in diagnostic testing and reporting makes the interpretation of the true incidence and trends in pertussis challenging.

A better understanding of the age distribution, transmission, and disease burden is critical to implement and evaluate an adolescent/adult immunization program in the United States. The ability to link immunization registry data to disease surveillance is also critical to evaluate vaccine efficacy and to assess trends in vaccine coverage and disease burden.

### C. Eligible Applicants

Applications may be submitted by public and non-profit private organizations and by governments and their agencies.

**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.

### D. Availability of Funds

Approximately \$325,000 is available in FY 2003 to fund one award. It is expected that the award will begin on or before September 15, 2003 and will be made for a 12-month budget period. The overall project period is five years with funding in years two through five dependent on availability of funds and

satisfactory progress achieving project goals.

### Recipient Financial Participation

Matching funds are not required for this program.

### E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities, and CDC will be responsible for the activities listed under 2. CDC Activities. The intention is for the Recipient and the CDC to work jointly and in collaboration in developing, executing and reporting on this project.

#### 1. Recipient Activities

The following section describes the expected activities of the recipient:

a. Establish population-based active surveillance for pertussis in geographic area with a well-defined population of at least 200,000 persons. Reporting sources should include all sites that provide inpatient and outpatient care to children, adolescents, and young adults. These include but are not necessarily limited to hospitals; emergency departments; pediatric, family practice, and internal medicine physician offices; public health clinics; urgent care centers; schools; and college health centers. Methods should be implemented to assure timely reporting of suspected pertussis cases, potentially including routine periodic contacts with reporting sources. Data should be collected from all suspected cases such that the descriptive epidemiology, risk factors, clinical course, therapy, and outcome of infection can be determined.

b. Enhance availability and use of laboratory testing to confirm the diagnosis of pertussis.

A range of laboratory tests should be available to confirm a pertussis diagnosis (e.g., culture, polymerase chain reaction (PCR), and serology). Strategies to facilitate widespread testing should be implemented. These may include educating reporting sources of the value and availability of testing, providing tests at no cost to the patient; facilitating transport of clinical specimens to the laboratory; and timely reporting of results.

c. Enhance the quality and scope of immunization registries in the surveillance area.

Activities to enhance quality include enrolling non-participating providers by facilitating ease of participation, and educating providers regarding the advantages of participation.

d. The applicant is also invited to propose a methodology for a pertussis

vaccine efficacy study or a case-control study of risk factors for infection that could be implemented in conjunction with surveillance.

If additional funding is identified, and at the discretion of CDC, epidemiological studies of risk factors or vaccine efficacy could be conducted as part of the scope of this project.

## 2. CDC Activities

CDC staff will collaborate in the following activities:

a. Collaborate in the development of surveillance strategies including consultation with staff experts on the clinical and laboratory diagnosis of pertussis.

b. Perform confirmatory laboratory testing for a sample of positive or negative laboratory tests.

c. Support registry evaluation and enhancement through consultation with staff experts on enhanced registry systems including immunizations registry computer programming experts.

d. Collaborate in the development and implementation of research activities under this agreement.

e. CDC staff experts on pertussis will provide educational training on the epidemiology, diagnosis, and treatment of pertussis as well as the limitations of the current national passive surveillance system.

## F. Content

The Program Announcement title and number must appear in the applications. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Applications will be evaluated on the criteria listed, so it is important to address them when describing the program plan. The narrative should be no more than 20 single-spaced pages and be printed on one side, with one-inch margins and a 12-point unredacted font.

The narrative should consist of, at a minimum, a Plan, Objectives, Methods, Evaluation, and Budget. The plan should address activities to be conducted over the entire five-year project period.

## G. Submission and Deadline

### Application Forms

Submit the signed original and two copies of PHS 398 (OMB Number 0925-0001). Adhere to the Errata Instruction Sheet (posted on the CDC web site) for PHS 398. Forms are available at the following Internet address: <http://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) at: 770-488-2700. Application forms can be mailed to you.

### Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time June 5, 2003. Submit the application to: Technical Information Management-PA# 03101, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341-4146.

Applications may not be submitted electronically.

### CDC Acknowledgement of Application Receipt

A postcard will be mailed by PGO-TIM, notifying you that CDC has received your application.

### Deadline

Letters of intent and applications shall be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received 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, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

## H. Evaluation Criteria

Applicants 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 section "B. Purpose" of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness shall be submitted with the application and shall be an element of evaluation.

Applications will be evaluated against the following criteria by a peer review group appointed by CDC:

### 1. Technical Approach to Implementing Surveillance (25 points)

The extent to which applicant provides a clear description of how the tasks described in the recipient activities would be accomplished. Specifically: (a) Extent to which applicant identifies all potential reporting sites in the surveillance area and presents strategies to enlist broad participation; (b) extent to which applicant provides a quality strategy to assure timely reporting of suspected cases; and (c) extent to which applicant proposes a feasible plan to make laboratory testing services widely available and to assure their widespread use.

### 2. Previous Experience (20 points)

The extent to which applicant provides information on the previous experience of the organization and project personnel that reflects an ability to complete the tasks listed in the recipient activities. Specifically, experience in disease surveillance; experience working with public and private medical care providers and hospitals in the surveillance area; and experience conducting culture, PCR, and serological laboratory tests. If applicant is not a State or local health department, experience working with the health department to conduct public health surveillance or other activities.

### 3. Quality of Diagnostic Laboratory Testing (15 points)

The extent to which applicant provides information on the quality of culture, PCR and serological methods that would be used for pertussis diagnosis. If such testing is not done currently, extent to which applicant can document that the proposed method is sensitive and specific for pertussis infection.

### 4. Quality of Immunization Registry and of the Plan to Enhance It (15 points)

Extent to which applicant documents presence of a functional immunization registry and the completeness of that registry. Quality of plans to enhance participation, completeness, and data accuracy.

### 5. Personnel Qualifications and Management Plan (15 points)

The extent to which applicant describes a staffing plan that demonstrates their understanding of the labor requirements to complete this scope of work and a management plan that describes their approach to managing this work, including subcontract management, if applicable. Includes identifying key staff, their roles

and responsibilities, and their professional experience (curricula vitae should be supplied in appendices).

**6. Understanding the Project Objectives (5 points)**

The extent to which the applicant demonstrates an understanding of the rationale of active surveillance for pertussis, the importance of laboratory testing to confirm diagnoses, and the role of immunization registries in assessing vaccine-specific coverage and facilitating epidemiological studies.

**7. Objectives (5 points)**

The extent to which the applicant describes the surveillance area; documents a population of greater than 200,000 persons; and describes the demographic characteristics of the study population. The extent to which the surveillance population reflects that of the United States.

**8. Human Subjects (Not Scored, However, an Application Can Be Disapproved if the Research Risks Are Sufficiently Serious and Protection Against Risks Is So Inadequate as to Make the Entire Application Unacceptable)**

The application should also adequately address the requirements of 45 CFR part 46 for the protection of human subjects. This should include the provision of the FWA number from the Office of Human Research Projection (OHRP).

**9. Budget (not scored)**

The applicant shall describe their proposed plan for managing the resources necessary to comply with the requirements specified in Section D. This shall include a description of the proposed person hours for each key individual.

**I. Other Requirements**

**Technical Reporting Requirements**

The grantee will provide CDC with the original plus two copies of:

1. *Semi-annual progress reports.* The results of the measures of effectiveness shall be a data requirement to be submitted with or incorporated into the progress report.
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

**Additional Requirements**

The following additional requirements are applicable to this program. For a complete description of each, see Attachment 1 of the announcement as posted on the CDC Web site.

- AR-1—Human Subjects Requirements
- AR-2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
- AR-10—Smoke-Free Workplace Requirements
- AR-11—Healthy People 2010
- AR-12—Lobbying Restrictions
- AR-14—Accounting System Requirements
- AR-21—Small, Minority, and Women-Owned Business
- AR-22—Research Integrity

Executive Order 12372 does not apply to this program.

**J. Where To Obtain Additional Information**

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC home page Internet address—<http://www.cdc.gov>.

Click on "Funding" then "Grants and Cooperative Agreements."

For general 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 business management and budget assistance contact: Peaches Brown, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341-4146, Telephone number: (770) 488-2738, E-mail address: [PRB0@cdc.gov](mailto:PRB0@cdc.gov).

For program technical assistance, contact: Gregory S. Wallace, M.D., Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop E-61, Atlanta, GA 30333, Telephone number: (404) 639-8715, E-mail address: [gsw2@cdc.gov](mailto:gsw2@cdc.gov).

Dated: April 30, 2003.

**Edward Schultz,**

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

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**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[Program Announcement 03047]

**Strengthening Blood Transfusion Services and Blood Safety in Tanzania; Notice of Availability of Funds**

**A. Authority and Catalog of Federal Domestic Assistance Number**

This program is authorized under sections 301, 307, and 317 of the Public Health Service Act, (42 U.S.C. 241, 2421, and 247b), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

**B. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a grant program to design an appropriate approach for strengthening blood transfusion services and blood safety in Tanzania.

The purpose of the program is to assess key needs and resources and to make recommendations for strengthening blood supply and transfusion services in Tanzania. This program is being performed specifically in Tanzania according to U.S. Congressional mandate for Department of State, United States Agency for International Development (USAID) implementation in response to the 1998 bombing of the U.S. embassy in Tanzania.

On August 7, 1998, terrorists carried out nearly simultaneous bombings of the U.S. Embassies, which were located in a residential area of Dar Es Salaam, Tanzania, and in downtown Nairobi, Kenya. Taken together, these bombings had their intended terrorist and disastrous effect: the occurrence of a large number of premature deaths, disabling injuries, and post-traumatic psycho-social stress among the victims directly affected and among their families and co-workers. In addition to an enormous adverse impact on innocent people, the bombings caused substantial damage to property and also revealed widespread weaknesses in the disaster preparedness, management, and response capabilities, including blood transfusion services.

In October 1998, at the request of President Clinton and Dr. Donna Shalala, then Secretary of the U.S. Department of Health and Human Services (HHS), Surgeon General Dr. David Satcher and a team of experts traveled to Kenya and Tanzania. Dr.