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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 733]

Year-Long Estimation of the Frequency of Bacterial Contamination of Blood Products in the United States

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of funds in fiscal year (FY) 1997 for a cooperative agreement program to conduct a year-long study to estimate the frequency of bacterial contamination of blood and blood products in the United States (U.S.).

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of Immunization and Infectious Diseases and HIV Infection. (For ordering a copy of Healthy People 2000, see the section Where to Obtain Additional Information.)

In addition, the Public Health Service (PHS) in Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States, emphasizes the need for identification and prevention of new and emerging infections. Some of these newly identified infections have been associated with the transfusion of blood and blood products. This announcement is related to the national identification of bacterially contaminated blood products in the U.S. blood supply and to ensuring the safety of the U.S. blood supply.

Authority

This program is authorized by Section 301(a) of the Public Health Service Act, as amended [42 U.S.C. 241(a)]. Applicable program regulations are found in 42 CFR Part 52, Grants for Research Projects.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

Eligible Applicants

Assistance will be provided only to national nonprofit organizations that coordinate multiple blood collection sites for the purpose of collecting and distributing blood and blood products nationwide. Status as a national organization will be determined if the organization coordinates blood collection sites in a majority of the States in the U.S. The applicant must indicate the number of States in which they coordinate blood collection sites. For nonprofit organizations, 501(c)(3) status is required. For-profit organizations are *not* eligible for this program.

Only national nonprofit organizations that coordinate the collection and distribution blood and blood products nationwide will be considered eligible applicants because of the need to generalize data to the entire nation and to ensure that no duplication of data occur. Only these organizations have the capability to initiate a nationwide study to develop standardized definitions of adverse transfusion reactions, to increase clinical nursing and medical staff awareness of these reactions and of bacterial contamination as a mechanism for these reactions, and to prospectively determine the rates of bacterial contamination of blood products (RBC, whole blood, and platelets) in the U.S.

Note: Effective January 1, 1996, Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 which engages in Lobbying activities shall not be eligible for the receipt of Federal funds constituting an award, grant (cooperative agreement), contract, loan, or any other form.

Availability of Funds

Approximately $150,000 will be available in FY 1997 to fund approximately two to three awards. It is expected that awards will range from $40,000 to $75,000 with an average award of $50,000. It is expected that awards will begin on or about August 1, 1997, and will be made for a 12-month budget period within a one year project period. Funding estimates may vary and are subject to change. No specific matching funds are required.

Use of Funds

Cooperative agreement funds shall *not* be used for the collection or delivery of blood or blood products. They will be used for developing: (1) educational materials, and (2) data collection materials and systems.

Restrictions on Lobbying

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352 (which has been in effect since December 23, 1989), recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying Congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, the FY 1997 HHS Appropriations Act, which became effective October 1, 1996, expressly prohibits the use of 1997 appropriated funds for indirect or ''grass roots'' lobbying efforts that are designed to support or defeat legislation pending before State legislatures. This new law, Section 503 of Pub. L. No. 104–208, provides as follows:

> Sec. 503(a) No part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress, * * * except in presentation to the Congress or any State legislative body itself.
>
> (b) No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1997, as enacted by the Omnibus Consolidated Appropriations Act, 1997, Division A, Title I, Section 101(e), Pub. L. No. 104–208 (September 30, 1996).

Background

Each year over 20 million units of blood products are transfused in the United States. Although safety has improved through improved donor screening and testing by the blood product industry in response to the human immunodeficiency virus (HIV)

epidemic, residual risk remains for the transmission of HIV and other emerging infectious pathogens. Some of these transfusion-associated pathogens and affected blood products include the transmission of *Trypanosoma cruzi*, the cause of Chagas' disease, by red blood cell (RBC) transfusion and hepatitis C virus by intravenous immunoglobulin product. Other emerging infectious pathogens, i.e., bacteria, also have been associated with transfusions and adverse reactions.

Approximately one death per million units transfused occurs due to transfusion-associated sepsis, a newly recognized and emerging problem (CDC, unpublished data). From 1986 through 1991, 16 percent (29/182) of transfusion-associated fatalities reported to the FDA were associated with bacterial contamination of blood products, including red blood cells (RBCs), whole blood, and platelets. Reports of sepsis and death after transfusion of blood products, platelets, and RBCs contaminated by bacteria have been increasing over the past decade. Since 1987, CDC has received anecdotal reports, from community sources and conversations with transfusion service personnel and clinical nursing and medical staff, regarding the bacterial contamination of blood products. These reports include 20 episodes of *Yersinia enterocolitica*-contaminated red blood cells (RBCs), including 12 deaths.

The Code of Federal Regulations (Title 21, Section 606.170[b]) requires only that fatal complications of blood collection or transfusion be reported to the Food and Drug Administration (FDA); thus, when non-fatal events are considered, the true incidence of infectious complications associated with the receipt of blood and blood products may be substantially underestimated. Lack of knowledge concerning the mechanisms of adverse transfusion reactions and transfusion-associated bacterial infection may be another reason for under-reporting. If blood products are not cultured after an adverse reaction, bacterial contamination of the product as a cause of the reaction cannot be definitely established. After a cluster of bacterial contamination of platelets occurred at one university hospital, medical staff were educated about adverse transfusion reactions and active surveillance for bacterial contamination of platelets was initiated; subsequently the number of platelet transfusion reactions reported monthly and the reported rate of bacterial contamination of platelets increased 31 (2.3/1000 to 72.4/1000 platelet pools) and 23 (0.3% to 7.7%) fold, respectively, in the following 22 month period.

A recent study from Germany estimated RBC bacterial contamination at approximately 0.5 percent and random donor platelet contamination at approximately 2.5 percent. Since the rates of bacterial contamination of different blood products in the U.S. is unknown, how the German rates compare with the bacterial contamination rates of blood products in the U.S. is unclear.

The existence of a significant number of transfusion-associated bacterial infectious events reported to CDC, the lack of known incidence of bacterial contamination of blood products in the U.S., and likely current underestimation of morbidity and mortality from these events, demonstrate the need to determine the incidence of transfusion-associated bacterial contamination of blood and blood products in the U.S. Therefore, this cooperative agreement is being established to initiate a study to develop standardized definitions of adverse transfusion reactions, to increase clinical nursing and medical staff awareness of these reactions and of bacterial contamination as a mechanism for these reactions, and to prospectively determine the rates of bacterial contamination of blood products (RBC, whole blood, and platelets) in the U.S. These results will aid in the study of the etiologic agents, risk factors, and outcomes associated with transfusion-associated bacterial contamination.

Purpose

The purpose of this cooperative agreement is to develop a pilot study with the national non-profit organizations that coordinate multiple blood collection sites to: (1) Determine the bacterial contamination rate of blood products; (2) identify donor risk factors for bacterial contamination of these blood products; and (3) determine the impact of transfusion of these bacterially contaminated blood products on the recipients.

The objectives of the cooperative agreement are:

1. To determine the rates of bacterial contamination of blood products, i.e., RBCs, pooled and apheresis platelets, and whole blood.

2. To describe risk factors of donors of bacterially contaminated blood products, i.e., prior or past medical history and prior exposures significantly associated with bacteremia at time of donation.

3. To determine health outcomes in recipients receiving bacterially contaminated blood products.

4. To describe underlying medical conditions of recipients that are significantly associated with death following receipt of bacterially contaminated blood products.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipients will be responsible for the activities under A., below, and CDC will be responsible for conducting activities under B., below:

A. Recipient Activities

1. Coordinate the collection of denominator data to include the number and types of blood products collected by the transfusion services, the number and types of blood products distributed by transfusion services, the number and types of blood products subsequently transfused.

2. Develop standardized definitions to include a microbiologic description of bacterially contaminated blood products and the clinical indicators to differentiate significant and insignificant transfusion reactions.

3. Collect numerator data to determine the bacterial contamination rate of blood products, to identify donor risk factors for bacterial contamination of these products; and, to determine the impact of transfusion of these bacterially contaminated blood products on the recipients.

4. Develop educational materials to increase clinical nursing and medical staff awareness of transfusion reactions.

5. Publish the study outcomes.

B. CDC Activities

1. Assist in the conduct of the study, including:

a. Collaboration in the development of study design.

b. Support recipients as a reference laboratory in confirmation of contaminating organisms, endotoxin and antibody testing.

2. Assist in the development of data management systems.

3. Collaborate in the coordination of data analysis, dissemination, and presentation of aggregated data from all recipients.

4. Collaborate in the publication of the study outcomes.

Technical Reporting Requirements

A narrative progress report is required semiannually. An original and two copies of all progress reports are due within 30 days after each semiannual reporting period. Progress reports should address the status of projects and progress toward project objectives and the goals of this cooperative agreement

as represented in the Purpose and Recipient Activities sections of this announcement.

An original and two copies of the financial status report (FSR) are required no later than 90 days after the end of the budget period. A final FSR is due no later than 90 days after the end of the project period. All reports are submitted to the Grants Management Branch, Procurement and Grants Office, CDC. Please address all reports or other correspondence to: Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–18, Room 300, Atlanta, Georgia 30305.

Application Content

Format

Pages must be clearly numbered, and a complete index to the application and its appendices must be included. Please begin each separate section on a new page. The original and each copy of the application set must be submitted unstapled and unbound. All material must be typewritten, single-spaced, with unreduced type on 8½″ by 11″ paper, with at least 1″ margins, headings and footers, and printed on one side only.

Application Narrative

All applicants must develop their applications in accordance with the PHS Form 5161–1 (revised 7/92, OMB Number 0937–0189), information contained in this announcement, and the instructions outlined below. Also, the narrative must be limited to 10 pages excluding appendices and should include the following:

1. The background and feasibility, need for funding, and willingness to collaborate with CDC in the conduct of the study.

2. The objectives of the proposed study which are consistent with the purposes of the cooperative agreement and are measurable and time-phased. The applicant should establish a specific and realistic plan of operation and timetable for all activities including development of methodology, development and dissemination of educational material, development and implementation of data collection instruments, collection of potentially contaminated blood products, laboratory identification of bacterial contamination of blood products, and data analysis.

3. The methods which will be used to accomplish the objectives of the study. Describe activities and methods already in place or planned, including capacity and experience to coordinate study efforts; assess quality of the project coordinators, facilities, and supporting resources; plan, coordinate, and maintain data collection and analysis; and disseminate information.

4. A budget which is reasonable and consistent with the purpose and objectives of the cooperative agreement funds. Please use standard form 424A, ''Budget Information'', provided with the PHS 5161–1 application. All budget categories should be itemized and individually justified.

5. A description of the project's principal investigator's role and responsibilities.

6. Documentation of eligibility status including: the number of States in which blood collection sites are coordinated; and, 501(c)(3) documentation of nonprofit status.

7. Establish a specific and realistic plan of operation and timetable for all activities.

8. Any other information that will support the request for technical and funding assistance.

9. Human Subjects: Whether or not exempt from the Department of Health and Human Services (DHHS) regulations, if the proposed project involves human subjects, describe adequate procedures for the protection of human subjects. Also, ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria: (Total 100 points)

1. The applicant's understanding of the purpose and objectives of the cooperative agreement and willingness to cooperate with CDC in the design, implementation, and analysis of the project. (20 Points)

2. The quality of the plans to coordinate and conduct the project with multiple blood collection sites, including a description of techniques for educational material, data collection, and data management. (20 Points)

3. The quality and feasibility of methods to accomplish objectives and required activities, including the provision of numerator and denominator data for the generalization of results nationally. The degree to which the applicant has met CDC requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes: (a) The proposed plan for inclusion of both sexes and racial and ethnic minority populations for appropriate representation. (b) The proposed justification when representation is limited or absent. (c) A statement as to whether the design of the study is adequate to measure differences when warranted. (d) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits will be documented. (30 Points)

4. How the study will be administered, including duties and responsibilities and time allocation of the proposed staff; and a schedule for accomplishing the program activities, including time frames. (15 Points)

5. A statement of the applicant's demonstrated capabilities and experience in conducting such a project. (15 Points)

6. The extent to which the budget is reasonable, clearly justifiable, and consistent with the intended use of cooperative agreement funds. (Not scored)

7. Human Subjects (not scored): If the proposed project involves human subjects, whether or not exempt from the DHHS regulations, the extent to which adequate procedures are described for the protection of human subjects. Recommendations on the adequacy of protections include: (a) Protections appear adequate and there are no comments to make or concerns to raise, (b) protections appear adequate, but there are comments regarding the protocol, (c) protections appear inadequate and the ORG has concerns related to human subjects, (d) disapproval of the application is recommended because the research risks are sufficiently serious and protection against the risks are inadequate as to make the entire application unacceptable, or (e) protections appear adequate that women, racial and ethnic minority populations are appropriately represented in applications involving human research.

Executive Order 12372 Review

This program is not subject to review by Executive Order 12372.

Public Health Systems Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283, Centers for

Disease Control and Prevention (CDC)—Investigations and Technical Assistance.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreements will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and form provided in the application kit.

Women, Racial and Ethnic Minorities

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian, Alaskan Native, Asian, Pacific Islander, Black and Hispanic. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, dated Friday, September 15, 1995.

Application Submission and Deadline

The original and two copies of the completed application PHS Form 5161–1 (revised 7/92, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–18, Room 300, Atlanta, Georgia 30305, on or before May 30, 1997.

1. Deadline

Applications shall be considered as meeting the deadline if they are either:

a. Received on or before the deadline date, or

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailings.)

2. Late Applications

Applications which do not meet the criteria in either 1.a. or 1.b. above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, information on application procedures, an application package, and business management technical assistance may be obtained from Locke Thompson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E–18, Room 300, Atlanta, GA 30305, telephone (404) 842–6595 or through the Internet or CDC WONDER electronic mail at: lxt1@cdc.gov. Programmatic technical assistance may be obtained from Matthew J. Kuehnert, M.D. or Marsha A. Jones, Hospital Infections Program, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), Mailstop E–69, Atlanta, GA 30333, telephone (404) 639–6413 or through the Internet or CDC WONDER electronic mail at: mgk8@cdc.gov.

You may obtain this announcement from one of two Internet sites: CDC's homepage at: http://www.cdc.gov or the Government Printing Office homepage (including free on-line access to the **Federal Register**) at: http://www.access.gpo.gov.

Please refer to Announcement Number 733 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report; Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report, Stock No. 017–001–00473–1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: April 22, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 720]

Epidemiology and Laboratory Capacity for Infectious Diseases

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1997 funds for a cooperative agreement program to ensure adequate capacity of local, State, and national efforts to conduct epidemiology and laboratory surveillance and response for infectious diseases.

CDC is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority area of Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

This program is authorized under sections 301(a) [42 U.S.C. 241(a)] and 317 [42 U.S.C. 247b] of the Public Health Service Act, as amended. Applicable program regulations are found in 42 CFR Part 51b, Project Grants for Preventive Health Services and 42 CFR Part 52, Grants for Research Projects.

Smoke-Free Workplace

CDC strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products, and Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.