DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 02073]

Traumatic Brain Injury(TBI) Follow-Up Registry and Surveillance of TBI in the Emergency Department (ED); Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Social Security Administration (SSA), announce the availability of fiscal year (FY) 2002 funds for a cooperative agreement for a TBI Follow-up Registry and Surveillance of TBI in the ED. This Program addresses the ''Healthy People 2010'' focus area for Injury and Violence Prevention. For a copy of ''Healthy People 2010'', visit the Internet site: *http://www.health.gov/healthypeople.*

The purpose of this program is to fund a follow-up registry that collects and analyzes information on outcomes of TBI and develop existing surveillance of TBI in the ED. The goal of both programs is to produce data of demonstrated quality that will be useful to State injury control programs and other State agencies, and document the longer term effects of TBI, including disability.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau, federally recognized Indian Tribal Governments, Indian Tribes, or Indian Tribal organizations, small, minority, and women-owned businesses.

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.

C. Availability of Funds

Approximately $565,000 (including direct and indirect costs) is available in FY 2002 to fund one award. It is expected that the award will begin on or about September 1, 2002 and will be made for a 12 month budget period, within a project period of up to three years. Funding estimates may change.

A continuation award within the approved project period will be on the basis of satisfactory progress as evidenced by required reports, the achievement of work plan milestones, and the availability of Federal funds.

1. Use of Funds

Funds awarded may not be used to supplant funds available from other sources to the recipient to conduct similar activities, not be used to provide patient care or management and, not to be used for construction purposes, rental of office space, or for the purchase or rental of furniture. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

D. 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).

1. Recipient Activities

a. Develop and implement a system for collecting data on pre-injury characteristics, information about acute and other care received and post-injury outcomes for a sample of people, including prisoners, identified through an existing TBI Surveillance System, and assess these outcomes at annual intervals. This includes identifying the sample, locating prospective participants and tracking them over time, abstracting pertinent medical record data, developing or modifying an existing questionnaire, and conducting telephone interviews.

b. Conduct hospital-based ED surveillance of TBI, consistent with standard definitions and methods for CNS surveillance, described in the current CDC ''Annual Data Submission Standards for Central Nervous System Injury Surveillance.'' (See Section J) This includes linking and unduplicating data obtained from emergency departments, including data elements that describe diagnosis, demographics, external cause, and survival status.

c. Convene meeting(s) of experts and others to advise on study goals, objectives, methods, and analysis of the data.

d. Compile follow-up data each year.

e. Analyze and interpret the data and report findings.

f. Evaluate the quality and completeness of the data.

g. Conduct yearly evaluations of the surveillance system to assess the predictive value positive and sensitivity of case ascertainment as well as the completeness and validity of the data collected.

h. Link surveillance activities and findings to State injury prevention and control activities.

i. Document the study methods.

j. Develop a research protocol with assistance from CDC for Institutional Review Board (IRB) reviews by all cooperating institutions participating in the research project.

2. CDC Activities

Provide technical assistance in conjunction with SSA where applicable and as necessary for effective project planning and management. Assist in the development of a research protocol for Institutional Review Board (IRB) review by all cooperating institutions participating in the research project.

a. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

d. Collaborate in the analysis of data and reporting of findings.

e. Provide technical assistance, as requested, to evaluate the surveillance system for completeness and validity.

f. Convene monthly conference calls with the recipient and SSA representative(s) to review progress.

g. Collaborate with the recipient and SSA representative(s) in the analysis of data on employment after TBI.

h. Participate in discussions with the recipient and SSA representative(s) on the feasibility of (a) tracking people with TBI who receive SSA, and (b) adding new questions on employment to the follow-up registry telephone interview.

E. Content

Applications The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the evaluation criteria listed, so it is important to follow the criteria in laying out your program plan. The narrative (excluding budget narrative and any appendices) should be no more than 30 double spaced pages, printed on one side, with one inch margins, and no smaller than 12 point unreduced fonts.

Number each page consecutively and provide a complete table of contents.

The narrative should include:

1. Executive Summary (one page, may be single spaced). This section should briefly summarize:

a. Amount of federal assistance requested;

b. Existing capacity;

c. Key objectives and activities proposed.

2. Proposal Narrative.

a. Introduction, statement of need, proposed goals and objectives, and program plan.

b. Existing program and capacity.

c. Proposed methods and activities.

d. Project management and project staff.

e. Proposed methods to evaluate the attainment of objectives.

3. Budget Narrative.

4. Human Subjects.

5. Appendices, which may include letters of commitment from key collaborators, resumes of key staff, brief summary reports of analyses of TBI surveillance data.

F. Submission and Deadline

Application

Submit the original and 2 copies of PHS 5161–1 (OMB Number 0920–0428). Forms are in the application kit and at the following Internet address: *www.cdc.gov/od/pgo/forminfo.htm* Application forms must be submitted in the following order:

Cover Letter
Table of Contents
Application
Budget information Form
Budget Justification
Checklist
Assurances
Certifications
Disclosure Form
HIV Assurance Form (if applicable)
Human Subjects Certification (if applicable)
Indirect Cost Rate Agreement (if applicable)
Narrative

On or before 5 p.m. Eastern Time, June 15, 2002, submit the application to the Technical Information Section 2920 Brandywine Road, Suite 3000, Atlanta, Georgia 30341.

Deadline

Applications shall be considered as meeting the deadline if they are received before 5 p.m. Eastern Time on the deadline date. Applicants sending applications 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.

Applications which do not meet the above criteria will not be eligible for competition and will be discarded. Applicants will be notified of their failure to meet the submission requirements.

G. Evaluation Criteria

Application

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC or Agency for Toxic Substance and Disease Registry ATSDR). Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of 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.) Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes:

A. The proposed plan for the inclusion of both sexes and racial and the 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.

Applications judged to be noncompetitive will be withdrawn from further consideration and CDC will promptly notify the principal investigator/Program director and the official signing or the applicant organization.

Awards will be determined by the Director of the National Center for Injury Prevention and Control (NCIPC) based on priority scores assigned to applications by the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP), consultation with NCIPC senior staff, and the availability of funds. All proposals will be reviewed using the current National Institutes of Health (NIH) priority scoring system to determine the technical and scientific quality of the proposal. Factors to be considered will include:

1. Need for data on TBI incidence and outcomes: The extent to which the applicant documents the need for the project to address a key public health issue and inform prevention and/or service activities.

2. Goals and objectives: The extent to which the project goals and objectives are relevant, specific, achievable, measurable, time-linked and can be addressed through the proposed methods.

3. Existing TBI Surveillance Program and Capacity: The extent to which the applicant describes an effective incidence surveillance system for TBI and provides the following:

a. Case definition for TBI.

b. Description of the source(s) of TBI case reporting.

c. Documentation of the timeliness and completeness of case ascertainment and other qualitative attributes of the system.

d. Summary of current surveillance data (i.e., 1999 or 2000).

e. Description of the prior usefulness of the system.

4. Capacity for conducting collaborative activities:

a. The analysis of employment data.

b. Adding employment questions.

c. The potential for tracking people with TBI receiving SSA assistance.

5. Methods and Activities:

a. The extent to which the proposed methods and activities can achieve the proposed objectives, consistent with the purposes of this Program Announcement.

b. The extent to which clear explanations of appropriate methods are described for the following: addressing case definition(s), case ascertainment, including identification and contacting of prisoners, TBI participant tracking, data elements, sources and availability of data, data collection, including methods for interviewing prisoners, protection of confidentiality, data processing and analysis, and a brief summary of methods for collaborative activities with the SSA.

c. The extent to which the operational plan and timetable are realistic, given available resources.

6. Management and Staffing:

a. The extent to which the scientific resources for project planning and data management/analysis are demonstrated within the applicant's organization or through collaboration with universities or other agencies.

b. The extent to which proposed staffing, staff qualifications and experience, and project organization indicate ability to accomplish the objectives of the program.

7. Evaluation:

a. The degree to which the applicant includes plans to evaluate the attainment of proposed objectives and the quality of the data collected.

b. The SEP shall assure that measures set forth in the application are in accordance with CDC's performance plans.

8. Human Subjects:

The extent to which the applicant adequately addresses the requirements of Title 45 CFR Part 46 for the protection of human subjects, including those in subpart C dealing with the protection of prisoners as research participants. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research.

This includes:

a. The proposed plan for the 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 or communities and recognition of mutual benefits.

9. Budget:

a. The extent to which the budget is reasonable, clearly justified, and consistent with stated objectives and proposed activities described in this announcement.

b. The extent to which the budget for collaborative activities with the SSA is clearly justified.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with:

1. An original, plus two copies, and a diskette copy of semi-annual progress reports.

2. Financial status reports, no more than 90 days after the end of each 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.

The following additional requirements are applicable to this program. For a complete description of each, see Attachment I of the announcement.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2010
AR–12 Lobbying Restrictions
AR–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR–22 Research Integrity

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317(k)(2) of the Public Health Service Act, [42 U.S.C.247b(k)(2)], as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where To Obtain Additional Information

This and other CDC announcements can be found on the CDC home page Internet address—*http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

The current CDC Annual Data Submission Standards for Central Nervous System Injury Surveillance can be obtained from Jacqui Butler at (770) 488–1496.

To obtain business management technical assistance contact: Nancy Pillar, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Suite 3000, Atlanta, GA 30341–4146, Telephone: (770) 488–2721, Fax: (770) 488–2777, Email address: *nfp6@cdc.gov.*

For program technical assistance, contact: Joseph Russel, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop F41, Atlanta, GA 30341–3724, Telephone: (770) 488–1042, Fax: (770) 488–4338, Email address: *nzr4@cdc.gov*.

Dated: May 2, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office, Center for Disease Control and Prevention.

Addendum

Background

TBI, a preventable disabling condition, is an important public health problem in the United States that is estimated to result in the annual occurrence of approximately 1,000,000 ED visits, 250,000 hospital admissions, 50,000 deaths, and the onset of long-term disability in more than 80,000 people.

TBI surveillance provides essential information for primary prevention (avoiding the occurrence of TBI) and valuable information for secondary prevention (mitigating the severity and sequelae of TBI). TBI surveillance also can provide a foundation for population-based TBI registries. Such registries enable the assessment of the burden of TBI related disability and provide essential information for planning programs to provide medical care and services for people with TBI sequelae. CDC has promoted TBI surveillance through funds provided to four States since 1995 (Program Announcement 526 in 1995 and Program Announcement 98022 in 1998) and eleven more States since 1997 (Program Announcement 716).

Although there are increasing data to describe the current incidence and etiology of TBI, little is known, on a population basis, about the outcomes and secondary conditions experienced by persons who survive traumatic brain injury. These outcomes include: their impairments, disabilities (also known as functional limitations or decreased activities), and participation restrictions, (including major roles such as work or school); the occurrence of secondary conditions (i.e., additional physical or mental health conditions that occurs as a result of having a primary disabling condition); and the need for and use of post-acute medical, rehabilitation, and other services. In fact, most of what is known about outcomes is based on studies that rely on case series methodology, small regional samples, and anecdotal reports. Greater understanding of these issues is important for several reasons: First, a better understanding of outcomes will add to our knowledge about the public health impact and societal costs associated with disabling injuries. Second, a better understanding of factors associated with increased risk of disability and decreased participation could lead to improved acute care and rehabilitation interventions aimed at reducing these adverse outcomes and secondary conditions. Third, little is known about the needs for services and barriers to receiving them following TBI.

In 1995, under Announcement 526—Part II, CDC funded one State (Colorado) to develop a full-scale population-based registry and follow-up study of persons with TBI (aged 16 years or older) to assess a wide range of outcomes and the need for, and barriers to receiving services in the year following injury, and in subsequent years. In 1998, under Announcement 98022—Part II, funding to Colorado was continued and a second state, South Carolina was funded to develop a similar registry, in collaboration with the Colorado project. In 2000, the Colorado project was completed and the SC project was continued.

Key References

U.S. Department of Health and Human Services. Healthy People 2010. Tracking.

Healthy People 2010. Conference Edition November 30, 1999.

Institute of Medicine. Enabling America Assessing the Role of Rehabilitation Science and Engineering. Brandt EN, Pope AM, Editors. National Academy Press, Washington, DC 1997. Published epidemiological studies of TBI are also reviewed in the section entitled ''Epidemiology of Traumatic Brain Injury in the United States'' located at the Internet Website of the CDC National Center for Injury Prevention and Control <*http://www.cdc.gov/ncipc/dacrrdp/tbi.htm*>.

Definitions:

Traumatic brain injury (TBI) and essential data elements for TBI surveillance are fully defined in CDC's Guidelines for Surveillance of Central Nervous System Injury. (For ordering a copy of the Guidelines, see Section J.—Where to Obtain Additional Information.)

Surveillance is the ongoing, systematic collection, analysis, and interpretation of health data necessary for designing, implementing, and evaluating public health programs.

Impairment: Any loss or abnormality of physiological, or anatomical structure or function.

Restriction in Activity (Disability): Any restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being.

Restriction in participation (Handicaps): a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfillment of a role that is normal (depending on age, sex, and social and cultural factors) for that individual.

A population-based follow-up system is defined as a system of ongoing registration of, and collection of information about, all or a representative sample of all cases of a condition in a defined population, such that cases can be related to the population base.

Elements of Disability:

Impairment: Any loss or abnormality of physiological, or anatomical structure or function.

Restriction in Activity (Disability): Any restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being.

Restriction in participation (Handicaps): a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfillment of a role that is normal (depending on age, sex, and social and cultural factors) for that individual.

[FR Doc. 02–11359 Filed 5–7–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics; ICD–9–CM E Code Revisions

AGENCY: National Center for Health Statistics, Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Notice.

SUMMARY: The National Center for Health Statistics has approved the following expansion to the External Cause Codes in the International Classification of Diseases, Ninth-Revision, Clinical Modification (ICD–9–CM). These ICD–9–CM E-Code revisions will become effective October 1, 2002. The official government version of the ICD–9–CM that will include all of the code revisions can be found on the ICD–9–CM CD–ROM available through the Government Printing Office. Guidelines for the use of the new E-codes will appear on the CD–ROM and on the NCHS website *http://www.cdc.gov/nchs/icd9.htm*.

E885.0 Fall from (nonmotorized) scooter
E922.5 Accidental injury caused by paintball gun
E955.7 Suicide/self-inflicted injury caused by paintball gun
E979.0 Terrorism involving explosion of marine weapons
E979.1 Terrorism involving destruction of aircraft
E979.2 Terrorism involving other explosions and fragments
E979.3 Terrorism involving fires, conflagration and hot substances
E979.4 Terrorism involving firearms
E979.5 Terrorism involving nuclear weapons
E979.6 Terrorism involving biological weapons
E979.7 Terrorism involving chemical weapons
E979.8 Terrorism involving other means
E979.9 Terrorism, secondary effects
E985.7 Injury caused by paintball gun, undetermined whether accidentally or purposely inflicted
E999.0 Late effect of injury due to war operations
E999.1 Late effect of injury due to terrorism

FOR FURTHER INFORMATION CONTACT: Donna Pickett, R.H.I.A., Co-chair, ICD–9–CM Coordination and Maintenance Committee, National Center for Health Statistics, CDC, telephone (301)–458–4200.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: May 2, 2002.

Alvin Hall,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); National Institute of Environmental Health Sciences (NIEHS)

The NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) *Expert Panel Report on the Developmental and Reproductive Toxicity of Methanol:* Notice of Availability and Request for Public Comments

Summary

Notice is hereby given of the availability of the *Expert Panel Report on the Developmental and Reproductive Toxicity of Methanol.* This report includes the summaries and conclusions of the expert panel's evaluation of the scientific data for potential reproductive and/or developmental hazards associated with exposure to methanol. The CERHR held this expert panel meeting in October 2001. CERHR is seeking public comment on these reports and additional information about recent, relevant toxicology or human exposure studies.

Availability of Reports

The expert panel report is available electronically on the CERHR web site (*http://cerhr.niehs.nih.gov*) and in printed copy by contacting the CERHR (PO Box 12233, MD EC–32, Research Triangle Park, NC 27709; telephone: (919) 541–3455; fax: (919) 316–4511; or e-mail: *shelby@niehs.nih.gov*).

Request for Public Comments

The CERHR invites public comments on the expert panel report and input regarding any recent, relevant toxicology or human exposure studies. The CERHR asks that all comments and other information be submitted to the