

2008-R-15

CIO Name: National Center for Chronic Disease Prevention and Control, Division of Cancer Prevention and Control

Project Title: A Retrospective Evaluation of Patterns of Care for American Indian and Alaska Native Men with Elevated Prostate Specific Antigen

Project Description and Objectives:

The Division of Cancer Prevention and Control seeks to conduct a feasibility study of patterns of follow-up care among American Indian and Alaskan Native (AIAN) men with elevated prostate specific antigen (PSA) tests. The pilot study will engender working relationships with Native groups, inform recruitment methods, as well as help to determine the burden of prostate cancer among this group.

Studies suggest that AIAN experience disparities in access to care for several acute and chronic conditions. Prostate cancer is the most frequently diagnosed cancer (70 per 100,000 men) as well as the second leading cause of cancer death (18 per 100,000) among American Indian men (1, 2). AIAN men present with more advanced disease at diagnosis, and have poorer relative survival compared with non-Hispanic white men (3, 4). Despite these disparities in diagnosis and outcome, there is no, or extremely limited, information on evaluation of elevated PSA or treatment of prostate cancer in AIAN populations.

The proposed project should use a retrospective design to develop a pilot feasibility study to evaluate patterns of care for male AIAN aged 50-85 years with elevated PSA tests. The study should explore how best to identify and recruit an "elevated PSA" cohort of AIAN men with suspected and confirmed prostate cancer into the study to gather data on follow-up care and treatment and assess the burden of and care for prostate cancer among AIAN men with elevated PSA.

Outcomes of the proposed study should include recommendations for identifying and reaching AIAN populations, guidelines and recommendations for working with AIAN organizations, and a description of appropriate methods to use for follow-up of AIAN men with elevated PSA tests. Identifying how to recruit and retain this underserved population into research studies and the

process of developing and maintaining relationships in the AIAN community through community-based participatory research techniques will inform both the literature and the field of public health about this important population.

Awardee Activities: Based on the project purpose and objectives, applicants should address the following issues:

1. Proposed plans and methodology for identifying and recruiting a cohort of 100 eligible participants with a goal of obtaining a minimum of 50 completed surveys.
2. Proposed inclusion criteria for the study population, i.e., AIAN men with a laboratory record indicating an elevated PSA.
3. Proposed plan for enrolling and retaining the study population in a survey of care.
4. A proposed survey indicating the type of questions that might be asked about follow-up care and treatment. At a minimum the survey should provide data on:
 - a. Rates of follow-up, including follow-up clinic visits with urologists and the proportion receiving prostate biopsies.
 - b. Among those with prostate biopsy-proven prostate cancer, determine the proportion who follow-up for treatment planning.
 - c. Among those with follow-up visits for newly diagnosed prostate cancer, determine treatments offered, treatments received, side effects following treatment, and surveillance.
 - d. For those with elevated PSA due to recurrent prostate cancer, document last visit to care provider for treatment or management of symptoms.
5. A description of how research findings will be analyzed and used to develop recommendations, guidelines, and interventions.
6. Timeline with specific, measurable, time-framed objectives for the 2-year project period.
7. Dissemination plan for the results of the study.

CDC Activities:

1. Provide expertise and knowledge in prostate cancer science, cancer disparities research, and community intervention research;
2. Provide technical assistance in the development of interview study instruments and protocol;

3. Facilitate/participate in dissemination of study findings via reports and peer-reviewed publications as well as presentations at conferences and meetings.

Special Requirements:

The role of external collaborators is central to this proposed work as the project must be conducted through those already known in the AIAN community (5). The external collaborators should have past and current experience working with the AIAN population and have pre-existing trusted relationships. This will facilitate the identification of study participants and coordination of study recruitment and follow-up among AIAN patients. The following criteria specific to this PEP will be used to determine the applicant's eligibility:

1. Established partnership with an AIAN organization with national reach.
2. Evidence must be provided in the form of a Letter of Support from the organization describing previous collaborations and/or the commitment to participate in the project that includes a description of the resources and infrastructure provided by the AIAN partner.

Additional Review Criteria:

In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this PEP will be considered in the review process:

1. Evidence of an infrastructure that will support community-based participatory research with AIAN population.
2. Experience in working with AIAN populations in research studies as evidenced by previous funding and/or publications.

Funding Preferences: None

Other Information: The following reference materials may be helpful in the preparation of the application:

1. Espey D.K., et al. Annual report to the Nation on the status of cancer, 1975-2004, featuring cancer in American Indians and Alaska Natives (draft in clearance).
2. American Cancer Society, Facts and Figures, 2007.
3. Gilliland F.D., Key C.R. Prostate cancer in American Indians, New Mexico, 1969 to 1994. J Urol, 1998. 159(3): p. 893-7; discussion 97-8.

4. Sugarman J.R., Dennis L.K., White E. Cancer survival among American Indians in western Washington State (United States). *Cancer Causes Control*, 1994. 5(5): p. 440-8.
5. Hodge F.S., Weinmann S., Roubideaux Y. Recruitment of American Indians and Alaska Natives into clinical trials. *Ann Epidemiol*, 2000. 10(8 Suppl): p. S41-48.

Project Period Length: No more than 2 years

Approximate Total Project Period Funding: \$400,000 (This amount is an estimate, and is subject to availability of funds and **includes direct and indirect costs, excluding the additional academic partner administrative costs.**)

Approximate Average Award: \$250,000 (This amount is for the first 12-month budget period, and **includes both direct and indirect costs, excluding the additional academic partner administrative costs.**)

Approximate Number of Awards: 1

NOTE: *Applications must not exceed either the stated Project Period Length or the Approximate Total Budget Period funding per year. Applications in excess of these limits will be considered non-responsive and therefore will not be reviewed.*