The activities of this NOFO are supported under Section 1706 of the Public Health Service Act, as amended (42 USC 300u-5). The eligible applicants (academic research centers) are further defined in Section 799B of the Public Health Service Act (42 USC 295p).

SPECIAL INTEREST PROJECT DESCRIPTION

Project Title

SIP25-001 Validating survey questions on prostate cancer screening including PSA testing and shared decision-making

Project Description

Several major professional societies including the United States Preventive Services Task Force (USPSTF) have issued prostate cancer screening recommendations which influence prostate cancer screening practices in clinical medicine (1-4). Survey-based questionnaires such as the National Health Interview Survey (NHIS) and the Behavioral Risk Factor Surveillance System (BRFSS) have been used to measure patient-reported receipt of prostate cancer screening (5-8). Although cognitive testing has been completed, the questions in these surveys have not been validated compared to a clinical gold standard (e.g. medical record review), such as if and when the patient received a prostate-specific antigen (PSA) test. For other cancer types, the concordance between self-report and electronic medical record verification varied widely depending on the cancer type (9). Therefore, it is difficult to determine the accuracy of survey results, such as the occurrence and timing of receiving a PSA test.

The primary purpose of this project is to provide a critical assessment of prostate cancer screening survey questions (e.g. questions asking about PSA-based screening) in NHIS and BRFSS and validate questions to most accurately assess if the US public is receiving prostate cancer screening services. For this primary purpose, the recipient will evaluate current survey questions on prostate cancer screening in NHIS and BRFSS, and (if these current questions are not sufficiently valid) modify existing questions or develop new questions, and then validate the modified or new questions. As part of this process, the recipient may need to identify a gold standard using real patient data, and use this standard to assess the validity and reliability of the current or proposed questions. The secondary purpose is to develop and validate questions related to shared decision-making (SDM) in the context of prostate cancer screening; this may include adopting and validating past survey questions related to SDM and prostate cancer screening. Because USPSTF and other professional organizations recommend SDM related to prostate cancer screening, assessing receipt of SDM is helpful in understanding if patients are receiving recommended cancer screening services. The recipient will then disseminate findings to make results available internally and to the public. Validated survey items can be used by CDC and the research community to better understand the prevalence of screening, impact of changing prostate cancer screening recommendations, occurrence of SDM, and disparities in screening. Validated survey items will help measure inequities in screening and inform efforts to improve disparities.

Project Objectives and Outcomes

Objectives: 1) To evaluate (validate) existing NHIS and BRFSS prostate cancer screening questions (such as receipt and timing of PSA-based testing). 2) If the current questions are not valid, propose and evaluate modified or new questions on prostate cancer screening. 3) Propose and evaluate survey questions assessing the receipt of SDM for prostate cancer screening; past survey questions assessing SDM may be utilized for this objective. Validating question should verify the accuracy of respondent understanding to questions and the accuracy of responses by using a clinical gold standard (e.g. electronic health record review).

Outcomes: A completed summary of findings from validation assessments of current and past BRFSS and NHIS prostate cancer screening survey items. A completed summary of new or modified BRFSS or NHIS validated measures for patient self-report prostate cancer screening survey items.

Healthy People 2030 Objectives
Reduce the prostate cancer death rate — C 08
Increase the proportion of adults who get recommended evidence-based preventive health care — AHS 08

Project Activities and Submission Requirements
Applications submitted in response to this SIP should present a **Research Plan** that addresses the following requirements listed below:

- Assess past research of peer-reviewed studies using NHIS and BRFSS prostate cancer screening questions (which would focus on studies evaluating the questions themselves but would also include studies using NHIS and BRFSS prostate cancer screening questions) and summarize current NHIS and BRFSS questions.
  Confirm or modify the wording of past questions and/or develop new questions for future survey-based questionnaires.
- Identify a clinical gold standard to validate prostate cancer screening questions.
- Perform cognitive (or related) testing on any substantially revised questions and on new proposed questions
- Validate patient responses to the new set of survey questions focusing on 1) PSA testing and 2) the occurrence of SDM for prostate cancer screening.
- Submit a report of findings.
- Propose recommendations for validated questions to include in future survey-based questionnaires. Identify 2-4 questions for each topic for surveys where only a small number of questions are possible.
- Disseminate results to CDC, NCI, and external audiences through various channels such as published reports or presentations

Study design and methods
Suggestions of methodology include evaluation of medical charts that would confirm patient receipt of a PSA test, review of electronic health records, review of electronic health record notes that detail the occurrence of SDM, observed interviews (might be more relevant to SDM), semi-structured interviews with patients or providers (might be more relevant to SDM), or another

validation standard chosen by the recipient (9-12).

Population of Focus
Population of focus includes individuals eligible for prostate cancer screening based on current recommendations. This includes individuals stated to be at high risk for prostate cancer (Black individuals and individuals with a family history of prostate cancer, according to the current USPSTF prostate cancer screening recommendations). By including Black individuals and individuals with a family history of prostate cancer, the project would be able to address populations at higher need of preventative health services related to prostate cancer (compared to an average risk population).

Collaboration/Partnerships
The recipient would need to partner with organizations who could help recruit subjects. This may include patients and health care organizations that can inform the study as well as help with recruitment.

Partnership with the CDC and National Cancer Institute (NCI) teams who manage the BRFSS and NHIS surveys is encouraged.

Recruitment Plan
The recruitment plan should describe sample size calculations, and how patients who are eligible for prostate cancer screening will be recruited.

Annual Action Plan
Provide a 12-month action plan using SMART goals and objectives to include a progressive timeline for completion of activities.

Evaluation Plan/Performance measurement
Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described. The evaluation plan must meet SMART goals and be consistent with the CDC evaluation framework (https://www.cdc.gov/evaluation/). A plan to evaluate data gathered as part of the research plan should be included.

Data Management Plan
If the applicant is collecting public health data, a standalone data management plan that addresses the 5 elements of AR-25 must be submitted the Other Plan(s) section of the application.
https://www.cdc.gov/grants/additional-requirements/ar-25.html

Dissemination & Translation Plan
Provide a dissemination plan that summarizes findings and provides recommendations of future directions of questions assessing prostate cancer screening. Dissemination in encouraged to include communication with CDC/NCI and publication of findings in peer-reviewed

publications. Audiences that should be reached include the public, patients, medical practitioners, policy makers, and public health researchers.

Public Health Impact
This project fills an evidence gap related to survey questions that address prostate cancer screening and SDM. Results will provide evidence of the strengths and limitations of currently available survey items on prostate cancer screening and SDM and guide future data collection on these topics. Having validated questions about prostate cancer screening can help surveys serve as important tools for monitoring impact of these changing recommendations on prostate screening trends. If new questions are proposed that replace recent questions, it will impact the ability of these surveys to monitor trends. However, if the project concludes that the older questions were not reliable, then new questions might be preferred. Alternatively, if the project concludes that these self-report questions are not valid or reliable for this purpose, then the impact of the study might be to deprioritize or discontinue these types of questions on the prostate cancer topics within NHIS and BRFSS.

Special Eligibility and Responsiveness
The following criteria specific to this SIP will be used to determine the institution's eligibility and responsiveness:

Special Eligibility Requirement: Access to the proposed study population(s); males of any age eligible for prostate cancer screening based on current recommendations.

Responsive Criteria:

The applicant must provide documentation, e.g., a letter of support or memorandum of agreement, demonstrating evidence of access to the study population and assuring access to the populations in which the study will be conducted.

Additional Review Criteria
In addition to the standard review criteria (Significance, Approach, Innovation, Investigators, and Environment) used to evaluate the scientific and technical merit of research applications, the following additional review criteria specific to this SIP will be considered in the determination of scientific merit and the priority score:

- Previous experience managing similar research projects, including validation of surveys, particularly cognitive testing.
- Evaluation if the proposed plan includes adequate sample size to achieve the study outcome.
- Evaluation if the proposed plan includes ability to include the population in focus (those eligible for prostate cancer screening, including high-risk groups).
- Previous experience conducting measurement validation studies, prostate cancer screening experience, and experience with conducting cognitive testing.

Funding Preferences
None

Research Plan Length and Supporting Material
The Research Strategy Section of the Research Plan is limited to a maximum of 12 pages. Supporting material included as appendices may not exceed 10 PDF (maximum of 30 pages) attachments. The appendices should include materials that show evidence of the applicant's ability to successfully conduct the proposed project and other evidence deemed necessary to support the contents of the proposal.
None

Availability of Funds
It is anticipated that approximately **$1,350,000** is available to fund **one** number of Prevention Research Center(s) for a **3-year** period of performance. The average award for each recipient is expected to be approximately **$450,000** for year one. The year one ceiling per recipient is **$450,000**. Funding may vary and is subject to change. Funding available includes direct and indirect costs.

Research Status
This project will be non-exempt research involving human subjects. It is anticipated that this project will require local IRB approval. Applicants should provide a federal- wide assurance number for each performance site.

OMB/PRA
OMB/PRA is not expected to apply

Award Administration
CDC staff will serve as consultants on this project, and will provide technical assistance, as requested, on project activities such as evaluation design, data collection and analysis, and data interpretation and dissemination of results. CDC staff may be co-authors on manuscripts. However, CDC staff will not have contact with human subjects or data collected from human subjects.

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SIP25-002 Prostate cancer active surveillance identification using electronic health records

Project Description.

A person can be categorized as a prostate cancer survivor when a prostate tissue biopsy confirms the presence of prostate cancer. Typically, low risk localized prostate cancer grows very slowly and, in many patients, may not progress to cause clinical symptoms or early mortality. Active surveillance (AS) is an ongoing regimen where the patient is closely monitored (e.g., with repeat prostate biopsy and PSA tests) to identify prostate cancer progression. Definitive treatment with intent to cure (i.e., radical prostatectomy or radiation therapy) is provided when progression is detected. Prostate cancer AS can help minimize complications or harms from unnecessary treatment with surgery or radiation therapy. Thus, men diagnosed with low risk, localized prostate cancer managed by AS can live longer, healthier lives. The American Urological Association (AUA) guidelines indicate clinicians should recommend AS as the preferred management option for prostate cancer survivors with low-risk, localized prostate cancer.[1] In the United States, community-based rates of AS have increased from 27% in 2014 to 60% in 2021, but with wide variation across practices and practitioners.[2] The use of AS is lower among African Americans and patients with lower incomes.[3-4].