

INTRODUCTION

Within the last decade, developments in novel treatments for a variety of cancers have emerged and are only continuing to grow at a rapid pace. Still, racial and ethnic disparities persist in clinical outcomes after a cancer diagnosis. There is clear evidence in the literature that minoritized populations and individuals from resource-deprived areas have been chronically excluded from clinical trials. The NCI Community Oncology Research Program (NCORP) is a national network that brings cancer clinical trials and care delivery studies to people in their own communities. By bringing cancer clinical research studies to individuals in their own communities, We aim to assess whether or not expansion of prostate cancer care by NCI designated cancer centers improve recruitment and retention of Black men. To answer this question, we will identify community sites that resulted from the recent expansion of NCI designated hospitals and evaluate if race distribution in the prostate cancer clinical trial profile has changed using an existing central NCI clinical trial database. We expect that there will be continued barriers to recruitment and retention of Black patients.

HYPOTHESIS AND SPECIFIC AIMS

Specific Aim 1: To determine the factors associated with participation/lack of participation of Black patients in research studies, including prostate cancer clinical treatment trials via a survey to be administered at community-site participants.

Hypothesis 1: Black people are more likely than Caucasians and other races to believe that research findings will expose them to unnecessary risks even when adjusted for age, socioeconomic status, and education level.

Specific Aim 2: To evaluate the perceptions of persons directly involved in the prostate cancer clinical trial enrollment process, including health care professionals (HCPs), on the enrollment of Black patients in clinical trials and how they communicate about trials.

Hypothesis 2: Investigators themselves limit minority participation and are less likely to ask minority patients to consider enrolling in clinical trials

Specific Aim 3: To analyze 10 geographically distributed NCI Community Oncology Research Program (NCORP) non-profit minority/community-based cancer centers to assess impact on clinical trial related activities

Hypothesis 3: Participation in NCI NCORP programs will have no impact on clinical trial related activities or access to quality cancer care.

BACKGROUND AND SIGNIFICANCE

Significance 1: With skewed enrollment and participation, conclusions of clinical trials may be questioned for how generalizable they may be to patients not fully represented in the trial cohort.

Significance 2: Differential patient referral to cancer clinical trials based upon race and ethnicity may be rooted in potential for bias and stereotyping among clinical and research professionals responsible for recruiting for cancer clinical trials and must be considered when developing strategies to increase minority enrollment

Significance: The NCORP program is intended to become a delivery model, with cancer care administered by multidisciplinary teams supported by patient navigators, that would reduce system inefficiencies while lowering cultural barriers to clinical trial participation. There are no studies to date assessing the effectiveness of these programs.

PROJECT METHODS

- Perform a cross-sectional analysis of demographic data from phase III and IV prostate cancer clinical trials completed between 2010-2016 within the current NCI databases
- Develop a provider and a patient questionnaire focused on variables predictive of clinical trial recruitment and retention
- Recruitment of study subjects from NCORP sites
- Distribution of provider survey to NCORP principal investigators
- Perform all analyses with STATA®, version 15.

PROJECT BUDGET

PROJECT BUDGET		Budget Item	
A Personnel		Faculty Salaries	
		Principal Investigator	\$58,000
		Co-Investigator	\$50,000
Staff Salaries			
		Research Coordinator	45,000
		Project Assistant	\$42,000
		Data Entry Clerk/Analysis Technician	48,000
Total Personnel Expenses			\$243,000
B Project Costs			
		IPads (20)	\$6,000
		Consumables	\$3,000
		Postage/Delivery	\$400
		Travel (Airfare+Lodging)	\$5,000
Total Project Costs			14,000
Total Direct Costs			257,000
		Indirect Costs (Overheads)	
	C	Max 15% of Direct Costs	38,550
Requested Grant			\$295,550

PROJECT TIMELINE

Table 1: Gantt Chart of Proposed Research Project Phases, Timing, and Team Members

Task	Team	Jan-March	April-June	Jul-Sep	Oct-Dec	Jan-March
Develop & Post Research Coordinator Position		█				
Dataset Construction			█			
Statistical Analysis				█		
Identify Project Champions			█			
Develop Interview Guide			█			
Develop Data Collection Forms/Survey Instruments			█			
Initiate Training and Implementation of Survey Tool Kit				█		
Conduct Needs Assessment and Site Inventory			█			
Recruit / Conduct Interviews					█	
Transcription and Analysis					█	
Triangulate/Integrate data					█	
Manuscript Prep/Submission						█

POTENTIAL PROBLEMS

- Low study accrual
- Inappropriate selection of the specific time points
- Response and question order bias

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