

**Prostate Cancer Detection Decision-Making
for Low-Income African American Men**

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Excess mortality due to prostate cancer among African American men is one of the most intractable cancer disparities. In the San Francisco Bay Area, incidence in this group is 40% higher and mortality is more than twice that for non-Hispanic White men. Research to increase early detection in this high risk group has stalled due to controversies surrounding the efficacy of the PSA test even though the equivocal studies that tested the PSA did not include adequate samples of African American men. Resulting national guidelines emphasize informed decision-making (IDM) prior to PSA testing, a process to elucidate a patient's values and preferences and to foster his understanding of the limitations of the test. Because African American men have disproportionately low literacy skills, it is not clear whether IDM is feasible or commonly practiced in settings where low-income men and/or those of low educational attainment access cancer screening such as health fairs and public health clinics. We propose first to ascertain current and best possible pre-screening communication practices in these settings. Second, because the PSA debate is largely due to over-treatment of low-risk disease and since 95% of PSA test results are normal, we will explore the feasibility of shifting the focus of IDM from screening to pre-biopsy counseling for the 5% of men with elevated PSAs. For this community-based participatory and mixed methods study, our specific aims are:

1. To document current practices in informed decision-making for PSA testing where uninsured, low-income and/or low-literacy African American men obtain screening in the SF Bay Area, and to explore the potential for effective IDM communication in these settings.
 - a. identify settings where low-income men may/do obtain PSA tests;
 - b. conduct in-depth interviews with 15 clinicians, 20 staff, and 20 patients regarding IDM and screening to ascertain key concepts, barriers, and facilitators, and to inform survey questions;
 - c. conduct 20 observations of community screenings to document the range of communication practices;
 - d. develop and field a web-based survey of clinicians to measure IDM beliefs and practices among 200 primary care doctors who report having patient populations that are 10-20% African American.
2. To assess the feasibility of pre-biopsy counseling (PBC) for African American men with an elevated PSA
 - a. document the current PBC practices through in-depth interviews with clinicians, staff, and patients in an organization that has pioneered this approach;
 - b. refine and pilot test a theory-based PBC protocol with 25-50 men found to have an elevated PSA;
 - c. explore system factors related to ease of access to PBC for men with elevated PSAs;
 - d. initiate a consensus process to establish county-wide guidelines for follow-up of prostate screening conducted in community settings.

II. RESEARCH STRATEGY

A. Significance

The excess burden of PCa borne by African American men should be treated as an urgent public health priority. Instead, early detection efforts have stalled in the face of questions regarding the mortality benefit of the PSA test and over-treatment of early stage disease following screening. Since the introduction of the PSA in the US, there has been a consistent decline of about 30% in PCa mortality overall,¹³ although the gap for African Americans persists.¹⁴ Statistical models have supported the role of PSA screening in the overall trend.¹⁵ While low-risk PCa has increased in the general US population, this is not true for low-income, uninsured men who consistently present with more advanced disease.^{16,17} Indeed, while the PSA debate focuses on the problems of over-diagnosis and overtreatment of men with screen-detected cancers, the greatest threats for low-income, uninsured men are under-detection and insufficient treatment.¹⁶

As the PSA debate continues, the universal emphasis on informed and shared decision-making has evolved with little regard for the implications for men of low health literacy or

time-pressured and often chaotic health care delivery settings. The Institute of Medicine defines health literacy as

“The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.”¹⁸ The definition of IDM (Box 1), when considered alongside a description of low health literacy (Box 2) reveals a deep chasm that poses yet another barrier to early detection of PCa in the highest risk groups. In fact, one study found African American PCa patients to be three times more likely to have low literacy skills than white men, and that men with low literacy skills were more than twice as likely to have a PSA level greater than 20 ng/mL at diagnosis compared with those of higher literacy.⁷ Indeed, in our community gatherings, men consistently ask “what is the prostate?” and “what does it do?”

The Centers for Disease Control has produced a brochure to assist African American men in IDM,⁶¹ but men of low literacy are less likely to attempt this process on their own. Yet the *practicality* of SDM as a standard of care, where clinicians

engage by eliciting patients’ values and preferences, has not been established. Studies of the general population reveal a mix of appropriate and inadequate implementation of SDM guidelines for prostate screening.¹⁹⁻²³ Research specific to African American men and the few studies that address health literacy found greater barriers and inadequate SDM.²⁴⁻²⁷ Among the conclusions is that patients’ ability to engage in SDM is determined by their literacy skills.²⁷ Thus far, research has not produced SDM strategies tailored for those who need it most: low-literacy African American men.²⁹⁻³⁰ To move beyond the current impasse, clinicians and policymakers need a clear understanding regarding if and how SDM can be used effectively with high-risk low-literacy men including identification of the optimal point in the early detection process for SDM.

B. Innovation

The novel features of this CBPR study include i) what is to our knowledge the first in-depth ethnographic exploration of prostate screening decision-making among low-literacy high-risk men in under-resourced settings; ii) development and feasibility testing of an approach to decision-making that shifts SDM *from the multitudes who get screened to the few* with elevated PSA levels; and iii) use of ancillary staff to reduce the time demands of SDM with low literacy patients for physicians. The use of an inductive approach and mixed methods, permitting examination of these issues from multiple perspectives, embeds this research in the real world of low income men and among the clinicians who provide their care. This is practice-based research, designed to emphasize external validity, the relevance and generalizability that enhance potential for translation into actual use.³¹ Finally, recognition of the multi-level nature of decision-making for PCa moves beyond the constraints imposed by data obtained only at the level of individual cognition, tapping influences

1. IDM defined: *the process patients go through to reach a healthcare decision by considering benefits, harms, risks; the match between these properties and personal values and preferences; understanding the uncertainty and limitations of a procedure.*¹⁰

2. People with *basic health literacy skills*, (22% of US adults) can read and understand a short pamphlet explaining the importance of a screening test. They would not be able to reliably perform intermediate level tasks [eg use a chart to find the age when children should receive a particular vaccine.] Most would have difficulty understanding typical patient education handouts or filling in health insurance applications. (An additional 14% of adults perform below the basic skill level.)⁵⁴

and dynamics which occur outside of individual awareness.³² This study is designed to produce findings with policy and practices implications and as the basis for a subsequent intervention trial.

C. Approach

i.) Context. Interviews and observations will take place in Alameda County (AC). The web-based clinician survey will include physicians from around the SF Bay Area. AC, on the Eastern shore of the San Francisco Bay, has 1.5 million residents. The largest city is Oakland which is 28% African American.³³ The major providers of screening to low-income men in AC include the Alameda County Medical Center (3 hospitals and 3 free-standing clinics); the Alameda Health Consortium (an association for eight federally-qualified community health centers that together serve more than 160,000 residents); Healthy Oakland (the first California licensed African-American faith-based Community Medical Clinic); the James A. Watson Wellness Center (an independent African-American health care center); and the Markstein Cancer Education and Prevention Center of Alta Bates Summit Medical Center. All have provided Letters of Support indicating willingness to participate including referral of patients with elevated PSAs. Letters have also been provided by the major associations of AC African American physicians, the Sinkler-Miller Medical Society and the St. Luke's Society. With its focus on African American cancer disparities, the leadership of the UCSF CAB and PEC draws heavily from Alameda County. PEC members have been actively involved with the conception and design of this study and will be integral to all aspects of implementation in accordance with principles of participatory research.³⁴

ii.) Conceptual framework. Our inductive ethnographic approach (described below), like grounded theory,³⁵ builds theory from data collected in the field rather than predetermining concepts and interactions. Following anthropologic tradition, we use broad conceptual frames to guide interpretation of our findings, particularly under Aim 1. These include health literacy as a social determinant of health (the lifelong forces and processes that influence ability to use health information)^{36, 37} and social context as defined by Pasick and Burke (the sociocultural forces that shape people's day-to-day experiences).³⁸ Briefly, this means that we are looking for relationships and institutional conditions that elucidate health literacy and reveal its influence on communication and decision-making as well as strategies that enable SDM in the context of low health literacy. For Aim 2, we will develop and test a counseling strategy that adapts "patient-centered communication functions and domains,"³⁹ operationalized in the "5As" model of behavior change (Assess, Advise, Agree, Assist, Arrange),⁴⁰ and Gaster's *Ask-Tell-Ask* approach²³ (see below, Counseling Protocol).

iii.) Methods Overview. The first aim of this study is designed to construct an initial understanding of real-world SDM for prostate screening that captures the multi-dimensional dynamics of patient-clinician-setting interaction in those environments where low-income high-risk men are likely to obtain the PSA test and to provide a preliminary estimate of prevalence of clinician communication practices, barriers, and perceptions. The purpose of Aim 2 is to assess the feasibility of an alternative that shifts the SDM effort from the 95% of men with normal PSA levels to the 5% whose test reveals an elevated PSA. Findings will be used to design a larger scale study to refine and test screening and follow-up communication strategies tailored for the setting/context and for men of low literacy. Under both aims we will blend qualitative and quantitative methods employing four "purposes of mixed methods research": i) triangulation (to attain convergence of results from different methods studying the same phenomenon; ii) complementarity (for elaboration and clarification from one method to another; iii) development (one method informs the other); and iv) initiation (to discover paradoxes and contradictions).²⁸ Using different forms of data from semi-structured interviews, surveys, and observations, we view our central questions from different perspectives that are triangulated in the analysis for a richer more complex understanding of phenomena^{41,42} that are in fact too complex for understanding on one dimension alone. We will use semi-structured interviews,⁴⁵ a protocol that allows participants to introduce substantive issues not anticipated by the interviewer and to address topics in their own words and manner.⁴⁶ These involve the use of open-ended questions and probes to elicit descriptive data and uncover new domains of interest. At the end of each patient interview, we will administer the REALM literacy measurement scale.⁴⁴

This process incorporates social and cultural context into analyses and illuminates factors of which informants may or may not be consciously aware. Pasick, Joseph and colleagues previously used such mixed methods to study the role of culture and social context in cancer screening⁶²⁻⁶⁵ interviewing scholars, community gatekeepers, and lay women and finding new understandings of and influences upon cancer screening among Latina and Filipina women that had not previously emerged from traditional health behavior research methods: "Tapping both lay and expert knowledge rather than lay knowledge alone can illuminate multiple dimensions of phenomena as well as explain why they occur."³² (Please see Table 1 which summarizes components of methods not detailed in the text.)

Table 1. Study Participants/Data Collection Methods/Objectives

Participant/Event	n	Methods	Objectives
Aim 1.			
- Clinicians who conduct PSA tests at events or in clinics - Staff where testing is offered free or at low-cost	20 20	- Invite MDs/Nurse Practitioners and auxiliary staff to participate in semi-structured interviews (30 min for MDs, 45-60 min for other staff)	- Document usual communication with patients prior to PSA test - Address known facilitators/barriers to SDM - Explore specific features of the setting and patient population that affect current prostate screening communication practices - Elicit clinician's vision of optimal process/context and how this could be achieved
- Patients	30	- On-site intercept: Invite male Afr Am patients, ages 45-70, to participate in 45-60 minute semi-structured interview following receipt of PSA or decision not to obtain the test	- Assess patient's healthcare decision-making preferences - Assess understanding of PCa and the PSA test - Document communication that occurred with clinician or staff regarding receipt of the PSA - Assess comprehension and satisfaction with information obtained - Explore extent to which decision to test/not to test was consistent with patient's values
- Screening events or hlth fairs where screening offered	200	- Record systematic observations of clinic procedures, interactions, and conversations in fieldnotes - Checklist for completeness/ consistency	- Document conversation topics; patient-provider rapport; question asking; whether provider checks for patient understanding; flow of conversation; if/how a testing decision is reached; immediate context e.g., patient or provider distraction
- Primary care clinicians	150	- Conduct 10-15 min structured web-based cross-sectional survey - Through the SF Bay CRN, recruit via email Bay Area primary care MDs with practices that include 10%+ African American patients	- Measure PSA test practices eg, proactively offer/only at patient request/conduct without offer; tailor by risk eg; Afr Am, family hx - Measure communication practices eg, standard approach (topics covered)/tailor to literacy, level of interest, questions/use of strategies to ascertain patient comprehension - Attitudes toward SDM/extent & nature of SDM practice; perceived barriers; satisfaction with skills - Measure degree of confidence in SDM skills - Information/training desired - Contextual factors (time, liability/ insurance considerations)
Aim 2.			
- African American men with elevated PSAs taking part in PBC	40	- Patients with elevated PSA - Patient attends counseling; session is audiotaped - Conduct 15-30 minute semi-structured post-counseling interview with patient - Conduct periodic counselor interviews - Patient phone interview 2 mos later	- Document patient participation rate (among those identified) - Post-counseling interview: Assess patient satisfaction, aspects that were helpful/not helpful, what was understood or unclear, confusing/intentions regarding follow-up/anticipated barriers and concerns. Administer REALM. - Phone interview: document follow-up process; assess patient understanding and satisfaction with decision/process.

Specific Aim 1. To document current practices in shared decision-making for PSA testing where uninsured, low-income and/or low-literacy African American men obtain screening, and to explore the potential for effective SDM communication in these settings.

a. Conduct in-depth interviews with 20 clinicians, 20 staff, and 30 patients regarding SDM and screening to ascertain key concepts, barriers, and facilitators, and to inform survey questions. Clinicians and clinic staff will be recruited from institutions serving low-income patients identified as described above beginning with the collaborators whose letters of commitment are attached. Probes will include whether clinicians recommend or bring up screening with some or all men, specifically addressing African Americans; whether doctors have points they consistently address and the extent to which they tailor the discussion and by patient characteristics. Probes will explore variations by culture and literacy. After hearing about their usual practices, we will show/read to them the elements of shared decision-making and inquire about the extent to which they use this approach, what they see as the strengths and limitations, and whether they regard it as relevant and feasible for their practice overall and for their African American patients specifically. Finally, respondents will be asked if they would consider adoption of some or all of the elements that they do not yet in use. We will probe for individual and organizational facilitators and barriers, and respondents' impressions of appropriateness for African American and low literacy men. Ms. Monica Allen, Project Coordinator, will conduct interviews with clinicians and staff, and Consultant Dr. Michael Huff, Co-Chair of our Prostate Committee, will interview African American male patients. Anthropologist and Co-Investigator Dr. Joseph will provide training and oversight for data collection.

b. Conduct observations of 200 men at community screenings to document SDM in these settings. We will observe ten men at each of approximately 20 prostate screening events offered in settings that include churches, clinics, and health fairs. We will look for explicit examples of pre-screening communication, aspects of the context that could be conducive to SDM and evident barriers. Some of our partners are known to have physicians on site and to ensure that a conversation is held with each man. However, the content of that conversation and what is likely and feasible in that context is unknown. We will assess the extent to which information on screening, diagnosis, and treatment of PCa is available and what form it takes. Data from observations will consist of detailed fieldnotes⁴⁷ that capture activities and discussions, including the tone and content of conversations as well as body language. In particular, interactions between men and clinicians will be documented. We will record systematic observations of procedures, interactions, and conversations using an Observation Checklist⁴⁷⁻⁴⁹ to ensure that key aspects of interactions and context are observed and described and to ensure consistency across the observers. The Checklist will include: (a) who is present prior to screening and how each participates e.g. family, staff, volunteers; (b) conversation topics; (c) patient-provider dynamics e.g., rapport, question asking; and (d) body language. Field notes will be elaborated electronically after the researcher leaves the event using the checklist. Observations will be conducted under Dr. Joseph's direction by PEC committee members, Ms. Allen, and Dr. Pasick.

c. Measure PSA test and SDM practices, preferences and confidence regarding SDM, barriers to SDM, and tailoring by race/ethnicity and health literacy in a survey of 150 providers whose practices have at least 10% African American patients. A list of community clinicians will be provided by the UCSF Clinical and Translational Science Institute's Clinical Research Network (CRN), one of the nation's oldest and largest practice-based research networks of community clinicians who are willing to participate in research. Known as the SF Bay CRN,⁵¹ the network maintains regular communication with 519 clinician members who work in over 100 distinct clinical settings, most serving ethnically diverse and underserved communities with hundreds of thousands of patient visits yearly. Member clinicians are ethnically diverse and often care disproportionately for minority patients. Overall, 70% work in outpatient settings, and 37% serve populations that are at least 20% African American. Of these, 21 reported that 50% or more of their patients are African American. In recent surveys, response rates greater than 50%-60% have been achieved. Eligibility criteria for our survey will include practices with at least 10% African American patients, provide outpatient care, and care to male patients ages 40+. This component will be led by Dr. Potter, Director of the SF Bay CRN.

The survey instrument will include items based on the SDM literature^{20,21,23,25,27} and questions informed by the qualitative data collected as described above. Table 1 summarizes items in the former category. In addition, characteristics of the practice setting and patient demographics will be collected. New items could include clinical vignettes⁵⁰ that depict patient characteristics and interactions we observed the qualitative phase of the study. From this survey we will estimate i) provider PSA test practices (e.g., automatically order test, only upon patient request, raise as option); ii) knowledge and use of shared decision-making strategies; iii) preferences and efficacy regarding SDM; and iv) extent to which communication is tailored for African American men compared to those of other race/ethnic groups and/or for patients of low health literacy. Most survey questions will be close-ended dichotomous or categorical 5-point Likert scale items (eg strongly agree/agree/unsure/ disagree/strongly disagree). We will look for bivariate associations in the above with setting characteristics (e.g., public health clinic vs private practice) or race/ethnic composition of the practice. Associations of dichotomous outcomes will be assessed by chi-square tests (for dichotomous or categorical characteristics) or single predictor logistic regression models (for continuous characteristics). For Likert scale outcomes, associations will be assessed using t-tests for dichotomous characteristics, ANOVA for categorical characteristics, and correlation for continuous characteristics. Logistic or linear regression models will be used for multivariable analyses. For the purposes of this exploratory analysis, all physician and practice-related characteristics with p-values of less than 0.20 in bivariate analyses will be retained in the multivariate regression models. Statistical tests will be two-sided with a significance level of 0.05. With a sample size of 150 respondents, we anticipate being able to estimate the mean response to Likert scale questions with reasonably narrow confidence intervals, e.g., a typical 5-point Likert scale might have an SD of 1.5 scale points; a 95% confidence interval would then have a half-width of less than 0.25 scale points. We will have 80% power to detect correlations as small as 0.23 between a Likert scale outcome and a continuous setting characteristic (e.g. proportion of minority patients in the practice). SAS software will be used for analyses.

Specific Aim 2. To assess the feasibility of pre-biopsy counseling (PBC) for African American men with an elevated PSA by pilot testing a theory-based PBC protocol with 40 men with a recent abnormal test.

Feasibility studies assess whether or not a given concept will yield a relevant and sustainable intervention, examining acceptability (how participants respond), implementation (can intervention be implemented as planned), and practicality (delivery in the face of resource constraints).⁵¹ Accordingly, we seek to answer these questions: What are the essential components of counseling following an abnormal PSA and prior to biopsy, particularly for low literacy men and how do men respond? How can men access PBC efficiently and effectively in under-resourced settings? Our objective is to devise a strategy that fits as seamlessly as possible into the context of healthcare delivery for low-income men. This pertains to components of the counseling conversation and characteristics of the counselor, where counseling is delivered, and how this process connects with delivery of screening. The formative phase for the PBC pilot will include interviews with staff and patients who took part in a preliminary form of PBC to guide protocol development, and development of recruitment procedures followed by implementation of the pilot test.

We will begin the process with a series of interviews with PEC member Leslie Paine, Manager of the Markstein Cancer Education in Oakland, who has overseen delivery of free prostate screening to approximately 900 men since 2002. Having observed the need, Ms. Paine developed a simple counseling protocol that she has provided over the past 9 years to 95 predominantly African American men with abnormal PSA tests. Sessions average 45 minutes and cover description of the prostate; review and explanation of the test result, all possible diagnoses, and causes for elevated PSA (checking to see if any could be the cause of the current test result); patient's responsibility for follow-up; recommended first step - repeat the PSA test; next steps and choices; and recommendation to discuss options with a doctor and where to seek follow-up care. A comprehensive record of Ms. Paine's experiences and insights will inform the PBC protocol.

For the pilot test, we will work with the aforementioned clinics and clinicians to recruit 40 men over 18 months with abnormal PSAs (the standard threshold is 4.0 ng/mL)⁵²⁻⁵⁴ as part of notification of their test results. It is likely that each setting will have unique requirements for the referral process. We will work with clinic staff to devise the most efficient method and to provide reminders and incentives to aid in identifying eligible patients. To protect patient privacy, the clinics will need to obtain patient consent to be contacted by our study. For community events, research staff will be present and will obtain participant consent at time of recruitment.

Counseling protocol. We will develop the PBC for the purpose of assisting African American men, particularly those of low health literacy, to understand their condition and their options, to prepare for discussion with their doctor in order to arrive at the decision that is best for them, to be motivated to follow through, and to have the information they need to obtain all appropriate services. Importantly, due to the increasing acceptance of active surveillance for men with low-risk prostate, men will be advised of the possibility that a diagnosis of cancer might not necessitate immediate treatment.⁵⁵ Key features will be emphasis on questions to ask the doctor and shared decision-making designed for those of low health literacy by use of "plain talk" (conversational language that greatly simplifies the words used⁵⁷), confirmation of patient understanding, and overload avoidance. We will draw on health communication theory and health literacy research to structure our protocol starting with the work of Gaster et al.,²³ who studied PSA screening communication and developed the "Ask-Tell-Ask Approach" which follows SDM principles for ascertaining patient values (explore baseline knowledge, elicit values: "Some people like to hear everything before making a decision....what would help you?"²³ Suggest ways other men have dealt with the choice. We will adapt this for the pre-biopsy discussion and to incorporate the "teach-back" concept from health literacy. Also known as the "show-me" method or "closing the loop,"⁵⁶ teach-back is a way to confirm what the patient understands by having them explain it back in their own words. As patient questions come up, and importantly where the counselor perceives that the patient may have a question he cannot himself articulate, a common problem, the counselor will proactively suggest questions. Together, patient and counselor will create a list to take to the doctor. Dr. Pasick has experience training counselors and information specialists in use of plain language and protocols that involve eliciting patient questions. She, Dr. Cooperberg, and Ms. Paine will collaborate on development of the protocol. Dr. Cooperberg, a urologist, will be involved throughout the development process to ensure technical accuracy and inclusion of issues and choices men should consider. Members of the Prostate Committee will review the protocol for appropriateness.

Institutional issues. A key feature of our protocol will be its design for delivery by ancillary clinic personnel rather than physicians in order to optimize (not eliminate) time subsequently spent with the doctor, and to reduce the significance of his/her SDM skills. It will be important for patients to feel that they can take his time in order to understand the situation and to ask questions. We estimate that counseling sessions will take 30-60 minutes. Our PBC pilot test will take place initially at the Markstein Cancer Education Center in the Alta Bates Summit Hospital where free screening is offered several times each year. If logistics are a problem, we will explore options including holding appointments at other clinics or counseling by phone. The latter is not

optimal but has been used when no other options are available. Drs. Pasick and Joseph are successfully delivering free genetic counseling by phone to low-income women who cannot travel to obtain this service in person; Dr. Pasick is collaborating with the Kaiser Division of Research to test nurse educator phone counseling with newly diagnosed cancer patients to inform them about clinical trials.

The path to large-scale implementation of a PBC intervention is not yet clear. One major challenge will be facilitation of easy access to this service for men who are screened all over the county. Should counseling be delivered centrally? Or should staff in various clinics be trained to provide counseling? Can a simple universal referral process be devised? Another critical challenge is the cost and benefit of counseling. How can PCB be funded on a long-term basis? Prostate Committee Chair and consultant to this study, Mr. Michael Shaw, Director of Men’s Health for Alameda County, will lead our inquiry on these topics. Under his leadership, the Committee is currently engaged in advocacy to increase access county-wide to the spectrum of PCa care. We will convene our committee and clinical partners at several points during this study to assess progress, identify challenges, and devise a vision for next phases including implementation.

iv) Data management and analyses. The number of participants for our qualitative methods is estimated according to our experience from similar studies in reaching *saturation* (the point at which no new information is obtained) and from established criteria: the quality of data obtained from each participant, the scope of the study, the nature of the topic, the qualitative method and study design.^{58, 59} As data collection proceeds, we may see the need for fewer or greater numbers of respondents. Ensuring that the information is adequately stored and managed is a central task. Audio-taped interviews will be transcribed. All participants will be assigned a code number, and all other identifying features will be removed from transcriptions. Transcripts will be produced in a format compatible with Atlas-ti software for qualitative analysis. This program facilitates analysis of qualitative data by allowing for multiple levels of coding, overlapping codes, and nested responses in qualitative data. We will use an iterative process of analysis by examining and re-examining the facts and meanings contained in our data to develop successively more refined ideas about domains of interest. Specifically, this process of analysis will involve: 1) the parsing of descriptive data according to themes; 2) the development of a set of taxonomic principles (a coding manual for significant influences on pre-screening communication) and subsequent classification (coding) of those themes; and 3) the identification of associations between themes and attributes of settings, clinicians, and patients. Coding is a central procedure in qualitative analysis in which passages of fieldnotes and interview transcripts are marked according to their substantive content to facilitate later analysis. Some codes are descriptive, e.g. “participation in decision-making,” “uncertainty about what to do” while others are more conceptual, such as “perception of risk” or “concepts of fate and early detection”. As data accumulate during the course of fieldwork, the coding scheme will evolve to reflect new insights and the accumulation of increasingly detailed information. Using the mixed method analytic approach called “concurrent triangulation,”⁶⁶ we will compare our various forms of data to determine if themes and results show convergence, differences, or some combination, weaving together a real-life portrayal of and processes for decision-making that contributes to reduction of the burden of prostate cancer borne by African American men.

v.) Project Organization. Dr. Pasick will assume responsibility for the overall scientific integrity of the study. She will supervise Project Coordinator, Ms. Allen and collaborate directly with co-investigators, Drs. Joseph, Potter, Cooperberg, and Ms. Paine for PBC. PEC Chair, Mr. Shaw and Co-Chair, Dr. Huff along with other Committee members, will provide input to all phases of the research and participate in data collection, interpretation, and reporting.

vi.) Timeline

		Year 1				Year 2			
		1	2	3	4	1	2	3	4
• Aim 1	Develop interview protocols/recruit respondents	■ ■	■						
	Conduct interviews		■ ■	■ ■ ■ ■					
	Conduct observations at community screening programs	■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	
	Analyze qualitative findings; develop clinician survey questions		■	■ ■ ■ ■	■ ■ ■ ■				
	Administer clinician survey					■ ■ ■ ■			
• Aim 2	Assess referral options & establish referral procedures	■	■ ■ ■ ■	■ ■					
	Implement PBC protocol/pilot test & post counseling surveys			■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■
	Analyses and reporting				■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■	■ ■ ■ ■