Physicians as Gatekeepers: Uncovering Barriers and Facilitators to Participation in a Prostate Cancer Prevention Intervention Clinical Trial

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Physicians as Gatekeepers: Uncovering Barriers and Facilitators to Participation in a Prostate Cancer Prevention Intervention Clinical Trial

by

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A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy Department of Anthropology College of Arts & Sciences University of South Florida

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Keywords: competing demands, research participation, organizational support, individual factors, structural factors

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Dedication

This dissertation is dedicated to my biggest fans and strongest supporters, my husband Scott and our children, Maren and Bryce. Scott—thank you for your patience, unwavering support and infinite confidence that I could do this! Maren and Bryce—thank you for your simple inspiration. I will be forever grateful for your push to “get to the next level,” and I hope that I always encourage you to do the same.
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Abstract

Clinical trials play an important role in advancing therapeutic and preventive care with many current modalities resulting from prior research. While prior research has described barriers to participation in therapeutic clinical trials, much less is known about barriers related to participation in trials aimed at prevention, prostate cancer prevention in particular. Physicians have been shown to play a critical role in access to trials; however, less is known about the individual and structural factors that influence their participation in prostate cancer prevention trials. This research provides rich ethnographic detail within the context of an ongoing trial. Research participants included physician/investigators who were either directly (serving as a co-investigator) or peripherally (referring patients for participation) involved in prostate cancer prevention intervention clinical trial (PCPICT), as well as those who were considered for participation but declined. Methods included open ended semi-structured interviews, participant-observation and a survey. Participants were recruited via direct inquiry, email and/or letter regarding participation. The results of this study show that individual and structural factors intersect,
influencing both the willingness and ability of physician/investigators to participate or refer patients for participation in a prostate cancer prevention intervention clinical trial. Individual factors such as explanatory views on prevention, notions of risk and uncertainty, shared decision-making and duality of roles appear to have a greater influence on the willingness of physicians to participate while structural factors such as staffing, other resources and time are more influential in regards to the ability to participate. This research served as a critical first step towards providing an in-depth understanding of the individual and structural factors that influence a physician’s participation in this type of trial. It builds from prior work where a better understanding of barriers and identification of successful strategies to overcome them was a noted void. The researcher identifies areas where additional research would be beneficial and provides applied recommendations for those considering the design of future cancer prevention intervention projects.
Chapter One:
Introduction

While completing my doctoral studies I was uniquely situated, also working as a project manager for a multi-site, cancer prevention intervention trial in the biomedical arena. During this time I often felt I was in a very liminal space, navigating the “rules” and languages of two very disparate worlds, wondering if they would ever intersect. My role as project manager had increased my awareness of the challenges inherent in the design, implementation and daily work of conducting a prostate cancer prevention trial. Simultaneously, my doctoral studies increased my skillset, providing a new perspective and toolkit with which to examine the world. My aim with this dissertation research was to show how the two worlds could indeed merge, with each informing the other.

This chapter will introduce the challenge of recruitment to cancer prevention clinical trials. The rationale for conducting this study will be described and the study objectives explained. The research questions and hypotheses will be introduced. The significance of the study and benefits of an anthropological perspective will then be
discussed. Finally the theoretical frame will be presented and an overview of the dissertation will be provided.

Statement of the Problem

Clinical trials are widely recognized in the medical and research communities for their role in advancing both therapeutic and preventative care (Baquet et al. 2009; Orozco 2009; Yates 2003) with many current modalities resulting from prior research. Chemoprevention, or the use of drugs, vitamins, or other agents to reduce the risk of, or delay the development or recurrence of cancer (National Cancer Institute 2011) is suggested as one of several means to reduce cancer incidence (Ford 2003). Enrolling an adequate number of patients, within a reasonable time period is particularly critical in chemoprevention trials (Sharp and Pentz 2004). Unfortunately, poor enrollment is common with less than twenty percent of subjects identified as eligible for cancer prevention trials actually recruited (Chlebowski et al. 2010; Kumar et al. 2011; Ruffin IV and Baron 2000).

Barriers to participation in therapeutic clinical trials have been well described (Hall et al. 2010); however, it is suggested that unique barriers present an ongoing challenge in the recruitment of healthy individuals as well as cancer survivors (Ford et al. 2009; Frayne 2001; Ott 2006) and overall less is known about the influences of
participation in clinical trials aimed at prevention. The identification of procedural, structural and infrastructural barriers is seen as critically important in order to evaluate the increasing number of new chemoprevention agents (Dilts and Sandler 2006). Referring physicians play a major role in accessibility to trials (Ford 2003, Kumar et al. 2011, Miller et al. 1998) and genuine commitment and trust have been identified as two critical components to a successful primary care/investigator relationship (Frayne 2001); however, less is known about the individual and structural factors that influence a referring physician’s participation in cancer prevention trials compared to therapeutic trials.

Significant challenges in recruitment to cancer prevention intervention trials exist. The need for studies of physicians’ attitudes and behaviors regarding clinical trial participation was identified by Swanson and Ward (1995) and though researchers responded with studies examining attitudes related to therapeutic clinical trial participation (Melisko et al. 2005), there remains a paucity of data specifically related to cancer prevention trials. Considering the important role of the physician in recruitment to prevention trials (Miller et al. 1998) and the status of health care professionals as gatekeepers for clinical trial participation (Probstfield and Frye 2011), an exploration of the structural and individual factors influencing their
involvement (or lack thereof) in cancer prevention intervention clinical trials is warranted.

Specifically related to cancer prevention clinical trials, Frayne et al. (2001) reported three areas of “physician-level” concerns including: 1) the dual role played as advocate for patient and research; 2) the threat to maintenance of the primary care relationship; and 3) the general philosophy of the physician towards prevention. Trial enrollment is likely the product of interactions between physicians’ beliefs and values, support from medical leadership (Somkin et al. 2005), access and other factors which have yet to be reported or explored. It is also likely that just as in the primary care setting, competing demands are a factor in recruitment to cancer prevention intervention clinical trials as well. Nguyen et al. (2005) suggested that the identification of barriers that prevent physicians from discussing research participation with their patients is a potential way to improve enrollment. Tailoring approaches to a specific practice area (academic vs. nonacademic) (Meropol et al. 2007) and the use of health maintenance organizations or managed care groups have been suggested as a ways to optimize participation while utilizing infrastructure that is already in place (Ruffin IV and Baron 2000).

Similar to the essential nature of physician involvement in the provision of preventive services, committed physician involvement has
been shown to be critical for successful recruitment to an ongoing prostate cancer chemoprevention trial (Kumar et al. 2011).

Additionally, the researchers recommended a more in-depth exploration of infrastructural level challenges, which may vary across research sites, in order to find solutions to current challenges in recruitment to this type of trial. Effective strategies to improve participation must consider the multiple competing demands (individual and structural factors) faced by physicians, as well as variants in practice area in order to succeed.

**Rationale and Significance**

This research served as a critical first step towards providing an in-depth understanding of the individual and structural factors that influence physician’s participation in a prostate cancer prevention intervention clinical trial (PCPICT). This timely work provides ethnographic detail within the context of an ongoing PCPICT. The results can be used to inform the design of future cancer prevention intervention trials which require multi-site participants reflective of our diverse population.

**Study Objective/Research Questions and Hypotheses**

I was interested in: a) exploring the factors that influence a physician’s participation in a PCPICT and b) identifying ways to improve collaboration between researchers and physicians, thus
improving the success of future projects. This study was designed to explore and document the individual provider level factors (such as notions of risk and shared decision-making, explanatory views on prevention, and duality of roles) and the structural (organizational and infrastructural) considerations that influence a physician/investigator’s participation in a PCPICT. Additionally, it included a consideration of how practice area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices) impacts the feasibility of participating in such a trial. The guiding research questions for this study were:

1) What individual factors influence a physician’s participation in a PCPICT?

2) What structural factors influence a physician’s participation in a PCPICT?

3) How do these factors vary depending on the practice site/area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices)?

The primary hypothesis was that both individual and structural factors intersect and influence both the willingness and the ability of the physician/investigator to participate or refer patients for participation in a PCPICT. Figure 1 shows the proposed model that undergirds the hypothesis tested in this study. Additionally, it was hypothesized that these factors will vary based on practice site/area
and the interactions will both facilitate and deter participation in these types of trials.

**Figure 1. Proposed Model: Individual and structural factors influencing physician participation in cancer prevention, intervention clinical trials**

- Dark blue boxes represent individual factors believed to impact the physician's participation in cancer prevention intervention clinical trials.
- Light blue boxes represent structural factors believed to impact the physician’s participation in cancer prevention intervention clinical trials.

**Benefits of an Anthropological Perspective**

The absence of anthropological contributions in this specific area suggested a void where further investigation to explore the role of physician/investigators as gatekeeper in a prostate cancer prevention intervention trial was warranted. The holistic anthropological
perspective can provide a deeper understanding of the issues, linking disparate views that might not otherwise be seen as influential or interrelated. Similarly, the proposed model attempts to capture these disparate factors of influence within this particular context. Lambert (2002) suggested that an anthropological perspective may facilitate an examination of the boundaries of a problem and provide useful insights to health research, particularly when considering the social and cultural dimensions of health, ill health and medicine. Additionally, since the knowledge and practice of “experts” is seen as locally variable, anthropologists in the healthcare setting can offer valuable insight to encompass the views, ideas and practices of not just lay participants but of professionals as well (Lambert 2002).

Ethnography, the hallmark methodology used by anthropologists, engages with others and their practices to better understand their local worlds (Kleinman 2006). Ethnographic research provides a rich, textured description of a phenomenon, providing insight into the views and experiences of a specific group (Abadie 2010). These methods are useful to tease out the data and information that contributes to deep knowledge and better awareness within a certain context. Anthropologists have previously used ethnography to explore community attitudes toward cancer and the impact of these attitudes on the implementation of messages from the
scientific community that were aimed at the adoption of lifestyle changes thought to reduce cancer risk. The research revealed that community members’ beliefs regarding cancer prevention were quite different from those presented by the scientific community and that community resistance to health messages were purposeful acts in response to a loss of control in power and social class (Balshem 1991).

In other work, Gregg and Curry (1994) examined cultural models for breast and cervical cancer among low-income African-American women and explored how these models may impact screening behavior. Their findings suggested that cancer models held by the patients and physicians differed substantially in regards to etiology, methods of cancer screening and prevention, as well as treatments for cancer and the authors suggested that mutual understanding between physicians and their patients is needed to improve screening rates (Gregg and Curry 1994). Though this work was completed some time ago it highlights the importance of mutual understanding between physicians and patients in regards to health care decision-making. Similarly, this reciprocal understanding may be relevant and influential when considering participation in a PCPICT.

Specifically in regards to the crisis in clinical trials, Hales et al. (2001) noted that a better understanding of the problem is needed for resolution of the current challenges. Similar to work by other
anthropologists, the use of a novel perspective to address a previously identified challenge was seen as beneficial in the design of this project. It was my hope that ethnography would add a new perspective not previously considered and provide a rich, textured description of the local context (Abadie 2010) surrounding a PCPICT, as well as insight into the views and experiences of the physician/investigators that are directly or are peripherally involved.

When considered as a vantage point to examine the current challenges of recruitment to clinical trials in general and cancer prevention intervention trials in particular, anthropology offered a valuable lens through which to better understand the complex and interrelated phenomena that influence this issue, particularly focusing on the critical role of physician/investigator. By using observation, participation and interviews, ethnography is useful to expand a model and discover associations between domains or variables (Schensul et al. 1999). Hemmings (2005) recognized the importance of the presence of medical anthropology within medicine, yet following an extensive review of the influence of anthropology on medicine spanning two decades, he concluded that unfortunately, medical anthropology continues to make little impact. Further clarifying, he noted that while medical anthropology has indeed helped to identify and articulate the problems of medicine, it has failed to provide
realistic solutions (Hemmings 2005). As such, with this research an anthropological perspective allowed for broad examination with an applied, solutions-oriented focus.

**Theoretical Frame**

Theory helps to explain, predict and interpret phenomena of interest and is important to understand potential links, confounding variables and the context in which a phenomenon does or does not occur (Bradley 2007). Thus, theory provides a framework, guiding the questions asked and ultimately answered in a research study (Bradley 2007; Creswell and Plano Clark 2011). The process for developing theory is diverse and depends on several factors including the topic of study, its context and the experience of the researcher (Bradley 2007). Schensul et al. (1999) stated that formative theory includes an issue or problem, in addition to some ideas about the components of the physical, social or institutional environment that may be associated with a problem. It may originate from preexisting information about the research community or topic, a review of the related literature, the prior experience of the researcher, or the experience of a local community. Thus, formative theory serves as a guide for the research and provides the opportunity to generate hypotheses from which observations can then be compared (Schensul et al. 1999). A theoretically informed focus helps ethnographers to
concentrate their fieldwork and to organize the information into a logical framework.

While designing this project, various theories and constructs were considered for their overall appropriateness in relation to the research goals. This included consideration of theories traditionally used within the field of anthropology as well as those utilized by researchers in other fields such as such as Political Economy of Health, Critical Medical Anthropology, the Ethnomedical Model, Explanatory Models, the Cultural theory of Risk, Notions of Risk, Clinical interaction and decision-making, Cancer Fatalism, Duality of Roles and the Theory of Competing Demands. Those theories and constructs that were determined to be most relevant to this project are expounded upon in Chapter Two, the Review of Literature within the context of the various research objectives. The overall intent was to let theory guide the methods chosen to answer the research questions, in order to contribute to a more in-depth understanding and provide applicable recommendations.

Physician involvement is thought to be essential for the provision of many services with the physician serving a critical link in the chain of events leading to the delivery of preventative services including cancer screening. The theory of competing demands has been used to recognize the multiplicity of factors that compete with the provision of
preventative services and influence their delivery by physicians in the primary care setting (Jaen et al. 1994). It is suggested that the primary components (physician, patient, and practice environment) are further influenced by factors such as attitudes, knowledge, expectations, practice organization and alternative demands. As a result, the multiple demands of the medical encounter “compete” with those related to prevention during the limited time available. The end result is that some but not all agenda issues may receive attention at the specific visit (Jaen et al. 1994) with preventative services often peripheral to other perceived priorities.

Nutting et al. (2001) also used this model to examine factors influencing physician recommendation for screening mammography. Interestingly, their findings suggest that the characteristics of the physicians, patients and the office visit were equally important in impacting the frequency of recommendation for mammography. Additionally, the authors suggested that effective strategies to improve the delivery of preventative services must go beyond physician education and performance feedback to consider the multiple competing demands faced by physicians and patients in order to prioritize services (Nutting et al. 2001). Prior to data collection, it was proposed that there is likely similar competition in the urologist’s office, when a patient receives the results of a prostate biopsy that
ultimately influences the likelihood that the recommendation is made to participate in a cancer prevention, intervention clinical trial.

In other related research, a case study by Joseph and Dohan (2009) was initiated with the expectation that multiple, competing demands vied for physicians attention and resources specifically as it relates to clinical trials recruitment. The authors proposed that some of these demands would encourage the recruitment of diverse patients while others would distract clinical investigators from these goals. Their findings suggested that enrollment in therapeutic cancer clinical trials was shaped by both biomedical and social factors (Joseph and Dohan 2009). Though focused more specifically on an examination of diversity in recruitment to treatment trials, there are certainly important findings that could be applied to a study examining individual and structural factors influencing a physician’s involvement in prostate cancer prevention, intervention clinical trial.

Biomedicine, broadly speaking, is a sociocultural system, with its own unique values, premises, and problems (Hahn and Kleinman 1983). As a part of the biomedical system, the realm of clinical trials is also a sociocultural system; and the specific arena of cancer prevention, intervention clinical trials yet another. The concept of competing demands was a logical and comprehensive starting point for this project; however, on its own the adequacy to examine all of the
potential sociocultural factors of influence at both the individual and structural levels was questionable. I also felt that it was likely that no single theoretical frame was adequate in isolation to fully explore the research questions. For this reason, an adaptation of the theory of competing demands that included a theoretically-grounded exploration of individual provider level factors (such as notions of risk and shared decision-making, explanatory views on prevention, and duality of roles) as well as structural level factors (such as practice area and organizational/infrastructural considerations); informed by the constant comparison of the similarities and differences of concepts that emerged in the field as suggested by Glaser and Strauss (1967), was proposed for this project. As previously noted, the theories and constructs that were thought to be influential and determined to be the most relevant are expounded upon in Chapter Two, the Review of Literature within the context of the various research objectives. Within this comprehensive frame, I was able to draw upon both micro and macro level factors to provide a more holistic understanding of the multitude of variables influencing the physician’s participation in a PCPICT.

**Organization of the Dissertation**

This research examines the intersection of competing demands, the individual and structural factors that influence both the willingness
and ability of physician/investigators to participate or refer patients for participation in a PCPICT. It extends the theory of competing demands into the anthropological literature and examines its relevance to a prostate cancer prevention intervention clinical trial. With the results, I was able to identify key findings useful for funding agencies and those designing prevention trials in the future. I also discuss opportunities and directions for future research.

The dissertation is divided into five chapters. Chapter Two provides a review of relevant literature. Chapter Three provides a brief overview of the setting of the current study in the context of the currently evolving health care arena in addition to the methods for data collection and analysis and a discussion of ethical considerations. Chapter Four contains the results of the dissertation reported according to the study objectives and research questions noted previously. Chapter Five is the discussion of the findings and is similarly organized by the study objectives and research questions. It also includes a discussion of the contributions to theory, applied anthropology and biomedicine (with application to future trials discussed); a consideration of limitations, reflections on familiarity in the research setting, a presentation of opportunities and discussion of dissemination and future directions, in addition to a conclusion.
Chapter Two:

Literature Review

Introduction

Prevention trials with a specific disease focus, such as cancer, may aim to prevent disease initially (primary prevention) or to prevent recurrence (secondary prevention) (National Institutes of Health 2011) and have been suggested as a sound medical strategy, particularly when resources are limited (Sharp and Pentz 2004). A growing body of research supports the reduction of cancer incidence through primary prevention (via lifestyle factors), early detection, and interventions with chemoprevention and vaccines (Ford 2003). Advances in the understanding of cancer biology and pathogenesis have identified molecular pathways that may serve as indicators for cancer risk, thereby providing the opportunity for prevention and early detection trials to play an important role in reducing the burden of this disease (Cox and McGarry 2003; Yates 2003). Well-designed cancer prevention studies are needed to validate molecular endpoints and their role in cancer prevention (Hall et al. 2010).

Adequate recruitment is essential for the completion of a clinical trial, whether preventative or therapeutic in nature (Lovato et al.
Poor accrual limits not only the advancement of science but the generalizability of cancer research (Ka'ano'i et al. 2004) and the societal benefit resulting from clinical trials is currently jeopardized due to declines in timely patient recruitment in all patient groups (Murthy et al. 2004; Probstfield and Frye 2011). Different from therapeutic trials, where treatment is for a disease or other adverse conditions already present, cancer prevention trials generally seek to enroll healthy, disease-free, asymptomatic individuals who may be at an increased risk for cancer due to a personal or family history of cancer or a pre-malignant condition (Hall et al. 2010; Hudmon et al. 1999). Additionally, the benefits from a prevention trial may be less readily evident than those of a therapeutic trial due to the desired outcome of disease prevention (Hudmon 1996). When the population is considered to be healthy, there is also an increased challenge and ethical responsibility to keep the participants healthy (Sharp and Pentz 2004). Despite the potential benefit of a reduction in disease burden, this expansion of medical research is not without its challenges (Lovato et al. 1997). Unique barriers are thought to present ongoing challenges to the recruitment of healthy individuals (Frayne 2001; Hall et al. 2010; Hudmon 1996; Korde et al. 2009; Lovato et al. 1997; Meropol et al. 2007; Ott 2006; Sample 2002; Tangrea 1997) and complex interactions between
participants, physicians, study designs and characteristics of the U.S. healthcare system are all suggested as barriers to participation in cancer prevention and control trials (Comis et al. 2000; Hudmon 1996; Ruffin IV and Baron 2000; Sample 2002; Tangrea 1997).

**Influence of Practice Area**

Since most cancer prevention trials are aimed at the general population, primary care physicians (PCPs) are considered by some to be the best source of referral for participation in these trials. However, Crosson et al. (2001) reported that PCPs prefer to defer cancer treatment to an oncologist and therefore may not discuss clinical trials opportunities with their patients, even if they are related to cancer prevention. Hall et al. (2010) found that oncologists were interested in referring patients to prevention trials, but did not have access to eligible (i.e., healthy) patients. These findings suggest that at least some of the variance in referral and participation rates may be attributed to the area of practice (generalist or specialist). Meropol et al. (2007) noted that tailoring approaches to a specific practice area (academic vs. nonacademic) may help to optimize participation. It is also noted that logistical barriers must be addressed and infrastructural support improved in order to increase participation and enrollment (Ford 2008; Ka'ano'i et al. 2004). These
notions required further exploration especially as they may relate to participation in a PCPICT.

Prevention trials also present access issues at the individual as well as institutional level, further contributing to the challenge of recruiting at risk populations (Korde et al. 2009). Clinical research opportunities are frequently associated with academic centers as opposed to community and other medical institutions and the opportunity to participate may not be a reality for all. Research done primarily in university or teaching centers may result in unintended subject bias due to the population seeking care there (Carbone et al. 2005) and increased availability within the community setting has been encouraged (Baquet et al. 2009). It is suggested that differential access to research opportunities due to structural or other barriers may disparately impact certain populations (Azevedo and Payne 2006; Murthy et al. 2004). Since the standard of care in many medical treatment regimens is the direct result of clinical research, this has implications for many conditions, including across the spectrum of cancer care from screening and prevention through diagnosis and treatment to survivorship.

Sharp and Pentz (2004) noted that a study must be representative of the population that the intervention would be applied to if proven efficacious. Thus, equitable access to trials is
important in order to reduce sample selection bias. This is a clear challenge when most recruitment occurs at academic medical centers and not within the community. Meropol et al. (2007) recommended increased accessibility within the community setting as one solution. This would likely be beneficial for a PCPICT as well, since potential healthy subjects are less likely to receive care at a specialty center. By improving accessibility within the community (via collaborations with physicians in private practice) such projects would be available to a greater number of individuals including those that are not receiving their care at academic or specialty centers. Hales et al. (2001) also reported that it may be less disruptive to enroll patients at their usual site of healthcare delivery then to refer them elsewhere. The literature from these sections informed the elaboration of the first study objective:

Consider how practice area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices) impacts the feasibility of participating in a PCPICT.

**Structural Considerations**

Organizational support and other health care system related factors are noted as predictors of enrollment as well as barriers to participation in treatment trials, with infrastructural support (including support staff) noted as critical (Roberts 2002; Ruffin IV and Baron 2000; Somkin et al. 2005). The development of systems that ease the
participation of the healthcare provider are suggested as opportunities to improve enrollment (Ford 2008). Infrastructure, realignment of incentives and compensation, and improved patient and physician navigation systems have all been suggested by surgeons as ways to improve their engagement in clinical trials (Al Refaie 2011). Though this research was with treatment trials, these factors likely affect enrollment for a PCPICT and were worthy of further examination.

Little research has been done to explore barriers in nonacademic environments (Nguyen et al. 2005); however, these settings have the potential to recruit a larger and more representative sample (Somkin et al. 2005) and the exploration of the structural dimensions that may impact the provision of trials in such settings has been identified as a research need (Baquet et al. 2008). Increased access to clinical trials via collaborations between non-academic, community settings and academic centers is suggested as a way to improve physician and health provider awareness about available trials and presumably a way to impact participation (Baquet et al. 2008; Colon-Otero et al. 2008). Ford et al. (2003) suggested that research results will come faster if clinicians and researchers can collaborate and promote studies. Frayne et al. (2001) suggested that recruitment to prevention trials may require a combined effort between oncology researchers, oncologists and primary care providers, and while the number of
cancer-prevention trials has increased, very little research has been
done to explore how investigators and primary care physicians may
coordinate efforts to recruit as well as retain subjects. Additionally,
Ruffin IV and Baron (2000) recommended further research to not only
better understand barriers unique to prevention trials but to identify
successful strategies to overcome them. The literature in these
sections informed the elaboration of the second study objective:

Explore and document structural (organizational and infrastructural)
considerations that influence participation in a PCPICT (with a
comparison of factors across types of sites).

Individual Considerations

Notions of risk/shared decision-making.

Risk is characterized by various disciplines in diverse ways, with
anthropologists traditionally viewing it as a cultural phenomenon
consider risk perception to be beliefs, attitudes, judgments and
feelings as well as the socio-cultural disposition that people adapt
towards both hazards and their benefits. The significance for this
project is that in the context of health-related risks, views about
expertise, scientific integrity, professional reliability and integrity and
the credibility of health-related messages are likely to be influenced by
the context in which judgments are made (Tansey 1999). While risk
may have varied meanings to different groups, all risk must be
understood within the larger social, cultural and economic context that it occurs (Douglas and Wildavsky 1982).

Hunt et al. (2006) reported that risk and “risk status” are complex notions that have multiple meanings and are understood differently by clinicians and patients. Their research highlighted the important (and often neglected) differences between epidemiological (the statistical associations within a population), clinical (the probability of the occurrence of a particular disease or outcome for an individual) and lay (signifying current or future illness) notions of risk and how these important differences may be ignored or treated as equivalent when they in fact are not (Hunt et al. 2006). Clinicians often discuss risk in clinically meaningful terms while patients must translate risk into terms that are personally meaningful and applicable to their unique circumstance. The authors explore how notions of risk impact patient’s decisions about prenatal genetic testing and suggest that failure to acknowledge the varied and often contrasting meanings of risk may impact communication and the ability of patients to make autonomous and informed choices about their care (Hunt et al. 2006).

Though not directly related, this research has the potential to inform when applied to a different context- the role of physicians in cancer prevention, intervention clinical trials. A consideration of the various meanings of risk and how they may be used by clinicians and
patients is important when examining the individual factors influencing a physician’s recommendation related to participation in a PCPICT. As observed by Hunt et al. (2006), risk may have multiple meanings which influence the evaluation of what is at stake as well as treatment options, and this may be an individual factor of influence when a patient has an abnormal yet non-cancerous biopsy result, ultimately influencing the likelihood that participation in a PCPICT is offered by the physician. Additionally, Hunt et al. (2005) found that when clinicians and patients have disparate starting points related to a perceived problem this greatly influences the options considered in regards to prevention or control and a shared decision making approach is recommended to arrive at the ideal decision for each individual situation. Since physicians are often recognized as a trusted source of health information (Crosson et al. 2001) and their input is frequently a key consideration in patient healthcare decision making (Roberts 2002), a better understanding of notions of risk and risk status and how this impacts physician recommendations and decision making for their patients was thought to be potentially relevant in regards to the decision to participate or refer to a PCPICT and further exploration was warranted. Attention to the varied meanings of risk may help both physicians and patients make truly informed decisions
about managing individual risk, specifically as it pertains to prostate cancer prevention and the opportunity to participate in a PCPICT.

**Explanatory views on prevention.**

Prior research has explored physician’s attitudes to the delivery of preventative interventions with a wide range of variance in importance seen, depending on the screening measure noted (cancer screening vs. blood pressure control) (Cornuz et al. 2000). This may have direct implications for interventions aimed at cancer prevention as well. Tangrea (1997) noted that physicians often play a critical role in deciding if a patient should enter into a trial and since they play an important role in the delivery of preventative services, it is possible that the gatekeeper role extends beyond preventative interventions to providing information about PCPICTs as well.

Interestingly, Hall et al. (2010) reported that the majority of oncologists (79.4%) were “not at all” or “a little” interested in offering cancer prevention trials to their patients, noting that medical training was focused on treatment of active disease and reducing its further burden, making it challenging to incorporate prevention trials into their practice. Chavez et al. (1995) noted the importance of including physicians in the analysis of the social and cultural construction of biomedical disease concepts since along with patients; they are considered actors in the ethnomedical belief system warranting an
analysis of their beliefs. The culture of biomedicine also determines how physicians make decisions within a certain context. For the purpose of this project and context, a consideration of the physician’s social and cultural construction of the concept of disease (cancer) prevention was thought to be important and further investigation of these concepts within the specific context of a PCPICT was included.

**Duality of roles.**

It is suggested that the varied and separate roles of physician/clinician and investigator may contribute to conflict related to the ultimate goals and populations targeted (Frayne 2001; Hales et al. 2001; Orozco 2009) and may be particularly salient in regards to cancer prevention intervention trials. Ka'ano'i et al. (2004) identified interference with the doctor/patient relationship, as well as conflict between the roles of clinician and research advocate as physician-related barriers to participation in cancer prevention clinical trials. The literature in these sections informed the elaboration of the third study objective:

*Explore and document individual provider level factors (such as notions of risk and shared decision-making, explanatory views on prevention, and duality of roles) that influence participation in a cancer prevention intervention clinical trial.*

The anthropological voice has been present in discussions and research in the area of cancer as well as that of clinical trials. The
literature reviewed for the initial stages of this project identified gaps in the research to date, particularly in regards to PCPICTs. These gaps, in addition to the lived experience that will be further detailed in the next chapter provided the impetus and direction for this research, to examine if prior findings resonated beyond those groups previously studied. Specifically, the limited anthropological contributions in this area provided the groundwork for an exploration of the role of physicians as gatekeeper and how various individual and structural factors intersect creating unique challenges for those investigators conducting PCPICTs.
Chapter Three:

Methods

Setting the Stage

There are several factors believed to be important to set the stage for this research project. While pursuing my doctorate, I also served as a co-investigator and project manager working at a National Cancer Institute (NCI) Comprehensive Cancer Center in Tampa, FL. Observations and challenges noted throughout the daily participation in this work were in large part, the impetus for the design of this dissertation research. More specifically, after appropriate channels for institutional approval were navigated, this project was considered a supplement or ancillary project to a currently ongoing prostate cancer chemoprevention clinical trial, *Phase II, Randomized, Double-blind, Multi-centered Study of Polyphenon E in Men with High-grade Prostatic Intraepithelial Neoplasia (HGPIN) and Atypical Small Acinar Proliferation (ASAP)* (IRB 105730). As such, resources, including access to the faculty and research sites participating in the parent study were available and helped to successfully facilitate the completion of this project. Funding for the time and travel to complete the data collection also allowed for completion without the need to
secure additional financial support. My experience conducting research in a familiar setting will be more fully discussed in Chapter Five.

The sample chosen for this study was physician/investigators who had been either directly (serving as a co-investigator) or peripherally (referring patients for participation) involved in the previously mentioned prostate cancer chemoprevention clinical trial, as well as those who have been considered for participation but declined. By considering the views of those that had been directly or peripherally involved (participants) as well as those that had not (non-participants), a better and more comprehensive understanding of the factors influencing the actors within their local context was sought. The research took place at current sites (n=8) of the prostate cancer chemoprevention clinical trial in the states of Florida, Illinois, Louisiana, and Minnesota. Participants in this PCPICT were thought to present a unique and important vantage point from which to obtain timely and relevant information about their current study participation and access was considered to be strength in the design of this research.

In order to reach a broader audience of physicians and elicit the opinions and experience of participants as well as non-participants in the PCPICT, I also sought to conduct research with urologists working
in private practice in the greater Tampa Bay area. The potential key personnel (n=21) from these sites had either inquired about participating in the trial or been asked to participate or refer subjects for participation but had not. The reasons for this were not well understood or documented, stimulating the interest in obtaining the views from this subset in addition to that of those who were currently participating in the clinical trial. Documentation of the lived experience via the methodologies that will be described more fully in the later part of this chapter helped me to explore in-depth the factors that influence the physician’s participation (or lack thereof) in the PCPICT, as well as factors that may influence possible future participation. It is the sincere hope that the findings from this exploratory research will directly contribute not only to the successful completion of the ongoing PCPICT but will also inform the design, development and implementation of future chemoprevention trials and with its applied focus help to address the bigger challenge of recruitment to clinical trials.

Also relevant to the results and discussion that will follow is the mention of an historical event and ongoing controversy, mention of both which was noted during data collection: 1) the passing of the Patient Protection and Affordable Care Act (PPACA) in March 2010
(Harrington 2010) and 2) the lack of uniformity in prostate cancer screening guidelines in the United States (Gomella et al 2011).

**PPACA.**

The Patient Protection and Affordable Care Act (PPACA) is considered the most significant social legislation passed in the United States since Medicare and Medicaid were enacted in 1965 (Harrington 2010) with the goals of expanding coverage, controlling health care costs, and improving the health care delivery system (Kaiser 2012). Changes related to expanded health insurance coverage will become effective in 2014 so the full effects have not been seen at the time of this writing. The market reform changes went into effect beginning in 2010, the possible impacts of which are already being noted by participants in this project.

**Prostate cancer screening.**

Prostate cancer has been said to present a public health dilemma with screening guidelines varying not only between countries but also within various medical organizations within countries such as the United States and a recent literature review by Gomella et al. (2011) suggested that there is indeed no standard of care for prostate cancer screening. As such, the lack of agreement in guidelines for prostate cancer screening is an issue that remains contested among practitioners in the field. This was noted during data collection and
clearly has implications for future prostate cancer chemoprevention studies since screening leads to the identification of those who may be eligible for participation in such a trial.

As previously noted, with this research the investigator was interested in: a) exploring the factors that influenced a physician’s participation in a PCPICT and b) identifying ways to improve collaboration between researchers and physicians, to improve the success of future projects. The research questions guiding this study were:

1) What individual factors influence a physician’s participation in a PCPICT?

2) What structural factors influence a physician’s participation in a PCPICT?

3) How do these factors vary depending on the practice site/area (specialty centers, academic center, VA medical centers, community offices)?

The primary hypothesis was that both individual factors such as notions of risk and shared decision-making, explanatory views on prevention, and duality of roles and structural factors such as institutional support and requirements, resources, time and patient pool intersect and influence both the willingness and the ability of the physician/investigator to participate or refer patients for participation in a PCPICT. Additionally, these factors were predicted to vary based
on practice site/area with the interactions both facilitating and deterring participation in these types of trials.

Based on the prior experience of the investigator and the resources at hand, this project was designed with a mixed-methods approach and was thought to have a good chance of success. By building on the relationships that were already established with physician/investigators that were participating in the ongoing PCPICT, the project was predicted to have legitimacy in the eyes of the key informants, helping to facilitate their acceptance and willingness to participate. Since I was conducting research in a familiar setting, the lack of consensus regarding possible objectivity and potential for role confusion associated with familiarity in the research setting is noted and this will be discussed in more detail as it specifically relates to this project, in Chapter Five. Entrée into the private practice arena was anticipated to be slightly more challenging; however, referral from a respected group member was predicted to increase acceptance and willingness to participate so that the data collection could be expanded to include the voices of as many private practice/community urologist offices as possible.

**Research Design**

Exploratory methods are particularly useful to examine domains which may be important to the research question, yet not much is
known. They are also useful to explore a phenomenon in greater depth, and to measure its prevalence. An exploratory design can also be useful to generalize the findings of a few individuals (Creswell and Plano Clark 2011). Mixed methods research is ideal to combine the exploration of qualitative methods and generalization of quantitative methods. This merger of modes of inquiry can provide more evidence and a more complete understanding than either method by itself with the strengths of one method often offsetting the weaknesses of the other (Creswell and Plano Clark 2011). Additionally, inductive inquiry allows for the emergence of processes and explanations that occur within the complex reality of life (Bradley 2007). Since this may not necessarily be the way a researcher would expect or predict them, inductive approaches are useful to examine provider perspectives that have received little or no previous attention (Hay and Craddock Lee 2009), such as the examination of provider perspectives related to participation in a PCPICT. In order to meet the objectives, this formative, exploratory study employed a mixed methods research design using qualitative, ethnographic (open ended semi-structured interviews and participant observation) and quantitative (survey) methods to examine the individual and structural factors that influence physician/investigators within the context of participation in a PCPICT.

Glaser and Strauss (1967) suggested that theory building is a
process of constant comparison of the similarities and differences between the concepts that emerge in the field. This approach assumes that theory is “grounded” in data, not specified at the onset of research and in its purest form there are no preconceived ideas of importance (Brod et al. 2009). Though it was virtually impossible to approach this project without any preconceived ideas of importance, based on the experiences that led me to choose this topic as well as the comprehensive review of the literature that was conducted, a grounded theory approach was useful to consider. This methodology has been suggested as a useful strategy to study the chronic illness experience (Charmaz 1990) and has also been utilized by anthropologists to study home birth (Cheyney 2008). Likewise it was an important methodology utilized with this research as well.

While challenges to recruitment in clinical trials have been well documented, the specific role of physicians in prevention intervention clinical trials was yet to be examined using ethnographic methods prior to this project and such methods can be especially useful to explore the cultural and social patterns and meaning within a particular context. Most notably, the hallmark iterative technique—the constant comparison of emerging concepts—was very important as fieldwork was conducted at the various sites for this project. The use of this technique allowed for the analysis or emerging themes and categories
while in the field, at times shaping the subsequent data that was collected and leading me in directions that were not anticipated, a benefit of this technique also noted by Charmaz (1990). This methodology was also useful when determining the point of saturation, when no new themes emerged from data collection (Guest et al. 2006).

Additionally, this approach allowed for an in-depth exploration of individual experiences and meanings related to cancer prevention and participation in cancer prevention intervention clinical trials while also paying attention to the larger and unavoidable structural factors that impact the practice of medicine, particularly as they relate to participation in a PCPICT. A better understanding of the specific “how’s” and “why’s” would not have been easily obtained through other methodologies and was necessary to glean a better understanding of all of the factors influencing this challenge and to inform future research efforts. Crabtree et al. (1998) utilized similar methodology (observation) to study the medical office as a whole system and explore competing demands within the primary care setting and noted physician and practice level constructs influencing the delivery of preventive services in this context. Similarly, Jaen et al. (2001) utilized mixed methods (observation, interviews and audits of medical records) to examine compliance with smoking cessation
practice guidelines in primary care practices. Their results documented that a smoking cessation agenda was frequently overridden by competing demands seen as a higher priority during the time limited visit (Jaen et al. 2001). Guided by formative theory, this novel project utilized anthropological methods to gain a greater awareness within a very specific context and explore the ways that the actors (physician investigators) are influenced by multiple competing demands both at the individual and structural level. I also attempted to seek solutions to overcome the current challenges faced in this very specific context: recruitment to PCPICTs.

**Sampling**

Structured purposive sampling techniques were employed to recruit physician/investigators who have been participants and non-participants in the ongoing prostate cancer chemoprevention clinical trial. During the design of the study, a pool of thirty potentially eligible participants was identified from the parent project, from various practice areas, as Table 1 describes.
Table 1. Subject Pool

<table>
<thead>
<tr>
<th>Practice Area</th>
<th># of Key informants</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-specialty (cancer) center</td>
<td>2</td>
</tr>
<tr>
<td>B-specialty (cancer) center</td>
<td>1</td>
</tr>
<tr>
<td>C-specialty (cancer) center</td>
<td>2</td>
</tr>
<tr>
<td>D-VA medical center</td>
<td>1</td>
</tr>
<tr>
<td>E-VA medical center</td>
<td>1</td>
</tr>
<tr>
<td>F-VA medical center</td>
<td>1</td>
</tr>
<tr>
<td>G-Academic/teaching hospital</td>
<td>1</td>
</tr>
<tr>
<td>H-Academic/teaching hospital</td>
<td>1</td>
</tr>
<tr>
<td>I-Private practice (community)</td>
<td>20</td>
</tr>
</tbody>
</table>

Eligibility Criteria

In order to participate, the following eligibility criteria were required: (1) Physician/investigators were involved or considered for participation in the prostate cancer chemoprevention clinical trial; (2) English speaking (as this is was the common language spoken by researcher and all participants); (3) Willing and able to provide informed consent; (4) Willing and able to participate in the open ended semi-structured interview and/or complete the survey. Any potential participant not meeting eligibility criteria one through four was excluded from participating.

Subject Recruitment

Participants were recruited via direct inquiry, using the recruitment letter/script found in Appendix A or B, depending upon their participation status in the ongoing clinical trial. Current participants (physicians/investigators) in the PCPICT were contacted
regarding participation directly via email or letter from me. Physicians that had inquired about participating in the trial or been asked to participate or refer subjects but declined (non-participants) and were not part of a local urological association were also contacted via letter from me. Physicians that had inquired about participating in the trial or been asked to participate or refer subjects but declined (non-participants) and were part of a local urological association were contacted first via email from the respected group member/key informant and then via letter from me. Prior to scheduling any interviews, all potential participants were contacted by me to confirm interest, eligibility and willingness to participate and the details of the meeting were arranged at that time. A written confirmation was provided as well as a reminder phone call or email the day prior to the scheduled meeting time.

**Methods and Data Collection**

**Open ended semi-structured interviews.**

Open ended semi-structured interviews are conducted to explore the multiple angles surrounding an issue and to discover the shared understandings of the participants (DiCicco-Bloom and Crabtree 2006) with a goal of achieving thematic saturation of key content areas. As power calculations and quantitative sample size estimations do not apply in qualitative research, Guest et al. (2006) noted that
nonprobabilistic, purposive sampling instead relies on saturation to
determine when enough data is obtained. Krueger and Casey (2009)
suggested this is the point where you have heard a range of ideas and
are no longer obtaining new information. When using a mixed
methods approach, Creswell and Clark (2011) suggested the use of a
small purposeful sample in the first phase and a larger pool of different
participants in the second phase of research to help minimize bias.

In terms of specific sample size necessary to reach thematic
saturation, there is a great deal of variation reported in the literature.
Romney et al. (1986) reported that small samples, with as few as four
individuals, can sufficiently provide complete and accurate information
within a particular cultural context, if the participants possess a degree
of expertise and competence about the domain of inquiry. A review
by Guest et al. (2006) showed that though numerous disciplines utilize
the term and encourage saturation of themes, few actually provided
guidelines for sample sizes using nonprobabilistic sampling. The point
at which the research findings have meaningful themes and useful
interpretations yet no new information or themes are observed usually
occurs within twelve interviews, but may occur with as few as six and
it is also suggested that saturation will be reached sooner, the more
similar participants are in their experience with the research domain
(Guest et al. 2006). According to Bernard (2011), sample size may
vary between ten and twenty knowledgeable sources, with the goal to uncover and understand the core categories in a cultural domain. Creswell and Clark (2011) suggested that the sample size should relate to the research question as well as the approach used and can vary widely between one and thirty.

For this project, open ended semi-structured interviews were aimed at eliciting individual and structural factors influencing the willingness and ability of physician/investigators to participate in a prostate cancer prevention intervention trial. They were also used to identify factors that may be unique to the various practice areas. The interview guide consisted of seventeen questions, developed by me and in collaboration with the dissertation committee and other researchers familiar with clinical trials, after an extensive review of the literature and with specific consideration of the objectives of this project in mind. Key informants were asked to describe challenges as well as share any suggestions to improve future collaborations. Based on strong existing relationships with the majority of participants at least a 50% acceptance rate was anticipated prior to the initiation of the data collection. The length of the interviews ranged from thirty to ninety minutes, based on the scope of information and responses shared by each interviewee.
**Participant observation.**

Participant observation or learning via exposure (Schensul et al. 1999) was also carried out at the various research sites, where possible as approved by the local IRB. This collection of data focused primarily on the interactions between the physician researcher and research team in order to better understand the internal working mechanisms of each facility and the process of research at the healthcare site. Observation occurred primarily in the backstage (Ellingson 2005) of the clinic environment where staff function “behind the scenes” and did not include any observations of provider-patient interactions. An observational checklist was designed to specifically note structural factors (such as use of a clinical trial alert system), noted previously in the literature as well as those observed by me to have an influence on participation in clinical trials, both therapeutic and prevention focused. The goal for this methodology was that it be utilized at a minimum of five sites (the non-VA medical center sites currently involved in the prostate cancer chemoprevention project), during routine site visits.

**Survey.**

The survey was developed by me in collaboration with the dissertation committee and other researchers familiar with clinical trials, after a review of the literature and with specific consideration of
the objectives of this project in mind. The survey was used to capture
demographic information such as years in practice, practice location,
prior clinical trial involvement, as well as elicit feedback related to
areas shown by other researchers to be factors in recruitment to
therapeutic and cancer prevention intervention trials such as impact on
primary role and time and financial constraints. By comparing current
responses across sites and to prior findings it was possible to
determine if similar factors are salient with those participating or
considered for participation in a PCPICT.

The participant survey was administered to the same key
informants (n=12) who were invited and agreed to participate in the
open ended semi-structured interviews. It was also offered to
urologists (n=19) working in private practice within the state of
Florida, primarily the greater Tampa Bay area that had inquired or
been invited to participate in the prostate cancer chemoprevention
clinical trial. Unfortunately direct access to the majority of these
individuals as originally planned was not possible due to an
unanticipated change in the functioning of local business group
(urologists working in private practice in the Tampa Bay area). Access
that was previously offered (invitation to visit a local urology group
meeting) was no longer possible. As a result, these potential
participants were first asked to complete the survey via email request
(including the survey link) from a respected group member/key informant and/or via an invitation letter (including survey and return stamped envelope) from me. A modification of the Dillman Total Design Survey Method (Hoddinott and Bass 1986) was employed to maximize response and follow-up postcards (including the survey link) were sent one week after the initial mail-out. This group was also offered the opportunity to participate in the open ended semi-structured interview as well if desired. Based on the established relationship with parent study participants and a strong relationship with a key informant and “insider” with access to this group of non-participating physicians, at least a 50% acceptance rate was anticipated. Table 2 reflects the planned methodology at each site.

Table 2. Planned Methodology by Site

<table>
<thead>
<tr>
<th>Practice Area/Research Sites</th>
<th># of Key informants</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>A- specialty (cancer) center</td>
<td>2</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>B- specialty (cancer) center</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>C- specialty (cancer) center</td>
<td>2</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>D- VA medical center</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>E- VA medical center</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>F- VA medical center</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>G- Academic/teaching hospital</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>H- Academic/teaching hospital</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>I- Private practice (community)</td>
<td>20</td>
<td>3, 1*</td>
</tr>
</tbody>
</table>

1-Open ended semi-structured interviews 2-Participant observation 3-Survey
*If agreeable
Data collection tools.

The Interview guide can be found in Appendix C, followed by the content matrix in Appendix D. The content matrix further delineates how the various questions helped to address the study objectives. After IRB approval and prior to the initial interview the guide was pre-tested with one researcher and two physicians familiar with clinical trials. Following the pre-test some questions were further divided into sub questions to ease future analysis. The overall content did not change and since no substantive revisions were needed, additional IRB approval was not required prior to the initial interview. The participant survey, consisting of nineteen questions, can be found in Appendix E and F. The observational checklist used during all participant-observation sessions can be found in Appendix G.

Data Quality and Management

To assure data quality: (1) I conducted all interviews; (2) interviews were audio-recorded (with permission) using an Olympus WS-700M digital voice recorder to ensure that no material was missed during analysis; (3) audio files were downloaded to a secure, personal laptop computer immediately following all interviews; (4) transcription occurred as quickly as possible (usually within twenty four hours) following the interview; (5) analysis was concurrent with data collection; and (6) all thematic analysis was conducted by me.
Detailed field notes were transcribed after each observation period and used to compare observations across sites including items such as the use of clinical trial alert systems, availability of dedicated research staff, and communication between staff related to potential eligibility to participate in a study, that were not collected by other means.

Survey data was entered directly into Qualtrics build 38768 (Qualtrics 2011) by the participants or captured on paper and transferred verbatim into Qualtrics by me. All data was stored on a secure, password protected, single access computer, to which only I have access.

**Data Analysis Plan**

**Qualitative.**

Open ended semi-structured interviews were audio-recorded and then transcribed verbatim by me with complete transcriptions completed in two to three hours, depending on the length of the interview. Each transcript was then reviewed for accuracy, organized by question and compiled into the research database. Information collected from the interviews was then analyzed for themes and patterns via analysis of recurring words and phrases to specifically address the study objectives and research questions. The constant comparative method was used to compare the views and experiences of respondents from across the various sites to help explain important
differences (Barbour 2001). Information from the observations was incorporated were relevant and appropriate throughout the discussion.

**Quantitative.**

As is standard in qualitative research, the demographic information collected via survey was summarized, using descriptive statistics to better describe the population as a whole (Kidd and Parshall 2000). This data is not linked in any way to the results of the semi-structured interviews or individual survey responses. The results from the interviews, observation and surveys was analyzed independently and integrated for the purposes of interpretation in order to address the objectives.

**Human Subjects**

This research adhered to professional guidelines and codes of ethics for the protection of human subjects. The purpose of the research was explained to all participants who were provided the opportunity to ask questions and voluntarily participate in the research prior to data collection. To ensure the confidentiality of all key informants, pseudonyms were assigned to all participants and research sites in the following format:

*interview number-site type-participation status* (01-S_P)

Site types were designated as specialty centers (S), academic centers (A), VA hospitals (V) or private practice/community (P). Participation
status was further delineated as participant (P) or non-participant (N). Prior to any subject recruitment, the study was approved for adherence to Human Subjects Protection by the University of South Florida Institutional Review Board (Pro #7442). A waiver of consent was received and though the informed consent document was reviewed prior to all interviews, a signature was not required. For those that completed the survey only, consent was implied with the provision of their responses. This project was also reviewed for scientific merit and approved by the Scientific Review Committee at the Moffitt Cancer Center, in Tampa, Florida prior to receiving IRB approval.

**Summary**

This chapter set the stage and described the impetus for this research. It then described the qualitative and quantitative methods utilized in this study to explore the factors influencing a physician’s participation (or lack thereof) in a PCPICT. The methods included open ended semi-structured participant observation and survey administration. This study adhered to professional guidelines and ethical standards to assure the protection of human subjects. Results will be presented in Chapter Four and Chapter Five will include a discussion of these results.
Chapter Four: Results

Introduction

The purpose of this analysis was to conduct a constant comparison of the similarities and differences between the concepts that emerged in the field during data collection (Glaser and Strauss 1967) and the literature presented in Chapters One and Two. The methods, study objectives, and research questions were guided by a consideration of the various theoretical frames and constructs noted in Chapters One and Two, in conjunction with the use of a grounded theory approach as discussed in Chapter Three. As previously noted, grounded theory methodology was also useful while collecting the data and at times led the discussion between researcher and participant in directions not anticipated, a benefit of this iterative technique, also observed by Charmaz (1990). This vantage point was considered advantageous in order to effectively examine the factors influencing physicians in their important role as gatekeeper to access to PCPICTs. An exploration of the disjuncture that exists between the desire to participate or refer participants and the reality of the cultural and social factors influencing participation in each local context was
constantly considered as data emerged. This allowed for an in-depth exploration of individual experiences and meanings related to cancer prevention and participation in cancer prevention intervention clinical trials within the context of the larger and unavoidable structural factors impacting the practice of medicine, particularly as they relate to participation in a PCPICT. The analysis was conducted with the goal of answering the research questions:

1) What individual factors influence a physician’s participation in a PCPICT?

2) What structural factors influence a physician’s participation in a PCPICT?

3) How do these factors vary depending on the practice site/area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices)?

Responses are organized by these questions and as they relate to the study objectives noted previously. Due to limitations that were unforeseen at the time of study design (lack of access to a local urology group meeting, as described in Chapter Three), there was an unanticipated change in the total sample size for some of the methods. Additionally, the distribution of participants from various settings was altered from the original research proposal. These modifications allowed the objectives, main research questions, and hypotheses to be addressed though possibly in a more limited manner. The final
analysis reflects the actual data collected from various methodologies, as illustrated in Table 3.

Table 3. Actual Methodology by Site

<table>
<thead>
<tr>
<th>Practice Area</th>
<th>Trial Participant</th>
<th># of Key informants</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>A- specialty (cancer) center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>B- specialty (cancer) center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>C- specialty (cancer) center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>D- specialty (cancer) center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>E- specialty (cancer) center</td>
<td>N</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>F- VA medical center</td>
<td>Y</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>G- VA medical center</td>
<td>Y</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>H- VA medical center</td>
<td>N</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>I- Academic center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>J- Academic center</td>
<td>Y</td>
<td>1</td>
<td>1, 2, 3</td>
</tr>
<tr>
<td>K- Academic and Private practice</td>
<td>N</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>L- Private practice (community)</td>
<td>Y</td>
<td>1</td>
<td>1, 3</td>
</tr>
<tr>
<td>M- Private practice (community)</td>
<td>N</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>N- Private practice (community)</td>
<td>N</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>O- Private practice (community)</td>
<td>N</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>P- Private practice (community)</td>
<td>N</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

1- Open ended semi-structured interviews 2-Participant observation 3-Survey
The results presented are divided into four sections. Section I describes the key informants. Section II reports on the qualitative, ethnographic findings obtained from the open ended semi-structured interviews. Section III reports on qualitative, ethnographic data obtained from the participant observation. Section IV reports on the quantitative data obtained from the completed surveys. A final summary concludes the chapter.

Section I- Key Informants

Qualitative.

The key informants for the open ended semi-structured interviews were physician/investigators who had been either directly (serving as a co-investigator) or peripherally (referring or asked to refer patients for participation) involved in the Phase II, Randomized, Double-blind, Multi-centered Study of Polyphenon E in Men with High-grade Prostatic Intraepithelial Neoplasia (HGPIN) and Atypical Small Acinar Proliferation (ASAP) (IRB 105730) trial. All interviews took place at a mutually agreeable location at a time that was not in conflict with the interviewee’s work responsibilities. In total twelve interviews were completed and the informants could be further stratified and described as nine participants and three non-participants in the larger/parent clinical trial. Demographic data was not collected for this portion of the project; however, based on survey responses, all participants were
male, ranging in age from 30 to >70. Informants were initially asked
describe the organization that they work for, and this is elaborated in
the following responses:

I work at an academic cancer center NCI designated we’re a
tertiary care referral center for patients with genitourinary
malignancies (01-S_P)

A federal hospital. Large volume. Many social disadvantaged
individuals. Significant proportion of minority patients (04-V_P)

We are not considered in the community (to be) a tertiary
medical center, or quaternary medical center. (The) perception
here (is) it doesn’t draw that patient population (for cancer
prevention research); we have to go out and get it. Some of the
things that are unique here is we have to go out and get
patients. If we were absolutely focused on clinical research, we
would go out and do that and we don’t really have the resources
to do that (07-P_N)

The hospital that I work at is closely affiliated with the academic
institution but they are not the same entity. It absolutely feels
more like an academic center than a community hospital
(10-A_P)

This is two parts organization. My own practice, it’s a private
practice but it’s not exactly like a regular community based
practice. We see more complicated cases, do more complicated
surgeries and see a lot of referrals from other urologists.
Basically it’s like an academic practice without being in
academia. We are part of bigger group, which has many
urologists. Everybody has his own office but we work as a group
we share some common business office and some ancillary
services (11-P_P)

Using the criteria originally defined by me, practice sites can be
categorized as follows: Specialty (n=5), Academic (n=2), Veterans
Affairs (n=3), Private practice (n=1), and both academic and private practice (n=1). By considering the views of those from the range of various practice sites that have been directly or peripherally involved in the trial (participants) as well as those that have not (non-participants), a better and more comprehensive understanding of the factors influencing the actors within their local context was possible.

Quantitative.

The key informants completing the survey included the twelve noted above that participated in an interview as well as four that did not (n=16). This group of four additional participants can be further described as physicians who had been invited to participate or refer patients for participation in the aforementioned PCPICT but had declined. Survey administration took place following the semi-structured interview for most respondents (n=8). Two surveys were completed by participants separately from the in person interview and later mailed to me. Four respondents (2 participants; 2 non-participants) completed the survey using the on-line format and two non-participants completed the survey and mailed it to me. As such, all responses were entered directly into Qualtrics by the key informants (n=4) or captured on paper and transferred verbatim into Qualtrics by me (n=12). In order to be able to make comparisons across groups, respondents were sub-divided into two groups,
participants in the PCPICT (n=10) and non-participants (n=6). As is standard in qualitative research, the demographic information collected via this methodology is summarized, using descriptive statistics to better describe the population as a whole (Kidd and Parshall 2000).

Participants.

These respondents (n=10) report a range of 6 to 32 (mean 15) years in practice. Medical specialty was reported as follows: urology (n=5), medical oncology (n=2), urologic oncology (n=2) and cancer prevention/epidemiology (1). Participants were also asked to report the country in which their primary medical training occurred with results as follows: United States (n=5), Turkey (n=1), Canada (n=1), Ireland (n=1), India and Great Britain (n=1) and Egypt and the United States (n=1). In terms of demographic information, all participants completing a survey were male, ranging in age from 30 to 70 years or older and specific of each category are found in Table 4 below.

Table 4. Participant Age (n=10)

<table>
<thead>
<tr>
<th>Age range</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-29</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>30-39</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>50-59</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td>60-69</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>70 years or older</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>
Ethnicity was self-reported as Not Hispanic or Latino (n=9), with 1 incomplete survey. In response to the question “How would you describe your race” participants were encouraged to select all categories that applied and answered as shown in Table 5.

Table 5. Participant Race (n=10)

<table>
<thead>
<tr>
<th>Race</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaskan Native</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Black or African American</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>7</td>
<td>70</td>
</tr>
<tr>
<td>Other, Egyptian, Middle Eastern</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

Non-participants.

Those non-participants (n=6) who completed the survey report a range of 2 to 28 (mean 13) years in practice. Medical specialty was reported as follows: urology (n=3) and radiation oncology (n=1) and it is noted that not all respondents answered all the survey questions.

Non-participants were also asked to report the country in which their primary medical training occurred with results as follows: United States (n=3) and Egypt (n=1), again with missing data noted. In terms of demographic information, all non-participants that the survey was sent to were male; however, not all respondents answered this question. Those completing a survey report an age range of 30 to 49 years, though incomplete data also was reported for this question.
Ethnicity was self-reported as Not Hispanic or Latino (n=3) and Hispanic or Latino (1) with incomplete responses to this question as well. In response to the question “How would you describe your race” participants were encouraged to select all categories that applied with three reporting their race as White while one reported as Black or African American. There were three non-responders for this question as well.

The surveys were designed to capture demographic information such as years in practice, medical specialty, and prior clinical trial involvement so as to better describe who is participating in the ongoing clinical trial. This is a first step at describing this specific population, since data on physician participation in prostate cancer prevention trials has not been previously reported in the literature. The surveys were also intended to elicit feedback related to areas shown by other researchers to be factors impacting recruitment to both therapeutic and cancer prevention intervention trials, such as impact on primary role as well as time and financial constraints. The survey data is not linked in any way to the results of the semi-structured interviews or individual survey responses.

Section II- Qualitative Findings

Verbatim transcripts of the open ended semi-structured interviews were analyzed by research objective and question, using
constant comparison and key words to identify themes and other findings. The first group of responses reported here relate to research question one (What individual factors influence a physician’s participation in a PCPICT?) and an exploration of the individual provider level factors - explanatory views on prevention, notions of risk and uncertainty, shared decision-making, and duality of roles - that influence participation in a cancer prevention intervention clinical trial).

**Individual provider level factors.**

Participants were asked what factors were influential to them personally when they made the decision to participate (or not) in a cancer prevention intervention clinical trial. Academic recognition and the ability to publish articles was noted by participants from a specialty center as well as academic/teaching hospital but not by those in private practice as noted with the following responses:

I think like anything, being in an academic institution - publication, participation in the study itself (01-S_P)

One gets the objective impressions of contributing to progress as well as getting academically recognized beyond personal satisfaction. I think also the data, the theoretical underpinning for the prevention trials or endeavors, ought to present in such a way that they raise interest and enthusiasm because that also facilitates selling the trial to the patients. Authorships and design (also) entice (04-V_P)

This suggests that motivations for participation could vary between the various practice sites. Interaction with those within the community
was also noted by one participant. Responses suggested a combination of the desire to work together yet also a warning of the potential for competition as the following response elaborates:

I think also having them (trials) readily available for your colleagues in the community (is important). To reach out to you, for participation and putting patients on trials is definitely something which is key because oftentimes they will call and they will ask is there a trial you can potentially do for that. There are certain other cancer centers in our community actively who have clinical trials in GU and other areas and really doing as good a job as we are opening trials. I think it’s important for us to be able to at the very least have comparable type studies and sorta keep up with the Jones’ (01-S_P)

One participant from a VA hospital simply noted the cost/benefit ratio as influential with the following response:

The likely benefit of the trial versus how much effort is at stake (02-V_NP)

Institutional support was noted by one participant in a specialty center:

Institutional support. (laugh) It goes back to that. That should be top on the list because our mission reads: contribute to the prevention and cure of cancer. So, it’s half of our mission. If you look at it from that perspective, half the resources should be allocated to that. Or a significant amount of resources should be allocated (03-S_P)

Personal interest/belief in prevention was noted by several physicians, at all types of institutions, as the following responses demonstrate:

I think from my perspective those are studies that should be done (03-S_P)
If it’s something that I’m interested in. If I don’t have any interest you obviously can see that there’s no sense in agreeing to something (08-A_P)

I can see where all this is going and how it makes sense. I understand what it’s for and so that’s the biggest thing for me to understand the trial where they are going with it, what it means. Secondly to make sure it has an endpoint that is of interest to me and that I well that it’s of interest to me that’s the main thing. It would be lovely if we could cure cancer and I wouldn’t have a job. I know that’s not going to happen but if we could do something that ultimately lead to less people having it then you know, that’s something I’m interested in too (10-A_P)

The possibility of prevention was noted as well as altruism and support for the cause was noted in the following responses:

Oh, that’s easy. Because prevention of a disease is always more attractive option than trying to treat the disease. At a minimum it might allow disease that’s a very, very early stage perhaps earlier than the traditionally defined clinical stage and I think that it will help certainly potential patients avoiding trouble or at least minimizing trouble down the road. I think, yes there is no question, prevention is better than therapy (04-V_P)

Well as a provider, honestly if it basically helps the fight against cancer in any way I think I would be a go anytime. Contributing to the fight against cancer is the most important (05-V_P)

We try to do trials that meet the greater need (12-S_P)

Additionally concerns for the patient were noted as evidenced by the following responses:

I think when it deals with prevention if the patients really not motivated and their concern is quite low I don’t really feel strongly that I would push for some sort of prevention trial but when patients are really quite motivated and specifically ask what can I potentially do to minimize my risk I think those are
suitable patient especially if they are compliant if they live fairly close to the institution. I think degree of commitment and interest is really ultimately the strongest predictor of how successful they will be compliant with participation (01-S_P)

Well, that’s like several things 1. Is it something I think the patients need? Is there a definite human need there for some help (06-S_P)

Must be patient friendly (07-P_N)

Scientific merit and feasibility were also noted as important as evidenced by the following comments:

And then #two would be, is it a good scientific question (06-S_P)

There must be a rational for prevention (07-P_N)

and #three is it feasible? (06-S_P)

The ability to enroll patients #1 (08-A_P)

Also noted as factors likely to influence participation at the individual level were the ability to stay current and provide patients access to new care as the following respondent explains:

I look for the trials to one, kinda keep me current plus. I mean current with medicine, but a little aware of what might be next. Not to get way far ahead of where I’m supposed to be making so many assumptions that I’m actually 5 years ahead of the rest of the world. We like trials where they bring in new medications not new that they are phase 1, we’re not too much on the phase ones we’re pretty much the new phase 2 things (12-S_P)

The most frequently noted response categories related to individual factors influencing participation in a PCPICT follow below in Table 6.
Table 6. Individual Factors of Importance (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Merit</td>
<td>S (1) A (2) V(2) P (2)</td>
</tr>
<tr>
<td>Personal Interest in Prevention</td>
<td>S (1) A (3) V(2)</td>
</tr>
<tr>
<td>Publication/Academic recognition</td>
<td>S (2) A (1) V (1)</td>
</tr>
<tr>
<td>Patient friendly</td>
<td>A (1) P(2)</td>
</tr>
<tr>
<td>Patient Need/Altruism</td>
<td>S (2) V (1)</td>
</tr>
<tr>
<td>Community engagement</td>
<td>S (1) A(1)</td>
</tr>
<tr>
<td>Feasibility</td>
<td>S (1) A(1)</td>
</tr>
<tr>
<td>Institutional Support</td>
<td>S (1)</td>
</tr>
<tr>
<td>Cost/ Benefit</td>
<td>V (1)</td>
</tr>
<tr>
<td>Who is running study</td>
<td>P (1)</td>
</tr>
<tr>
<td>Keep current</td>
<td>S (1)</td>
</tr>
<tr>
<td>Adequate funding</td>
<td>S (1)</td>
</tr>
</tbody>
</table>

S-Specialty Center A-Academic Center V-VA Hospital P-Private Practice

**Explanatory views on prevention.**

To solicit views on prevention, participants were asked about their general philosophy towards preventive medicine. Based on their responses there was wide variation in their interpretation of the question. Some participants spoke of preventive medicine in general as the following quotes reflect:

I think that as we embark in medicine today I think the emphasis is sort of moving away from treatment to prevention. We know that it’s more cost effective. We know from a society standpoint, if we can prevent something you’re much better. From a patient standpoint, obviously if you can prevent and not have to deal with actual malignancy, prevention is the ultimate goal. It’s what we strive for everyday. So I think that prevention is the future of medicine (01-S_P)

I think that’s the wave of the future..we talk about hypertension, diabetes, many of the cancers and now there is a better understanding for when one could intervene very early (03-S_P)
I think it should be the main focus of medicine. Better to prevent than have to treat (06-S_P)

The government wants to put a lot of money into it so there are opportunities for grants and research regarding it. I don’t see how you can be against preventative medicine (10-A_P)

Other spoke more specifically about cancer prevention as seen with the next responses:

I think there’s lots to do with preventive medicine for cancer. Unfortunately, most of the time we see and treat cancer when someone’s already got cancer (05-V_P)

Prevention is very important you know whether it is cancer or it is stones or whether it is infection you know that’s that will cut the health (care) cost, it will improve the patient well fare. When you wait for patient to be treated, there is nothing without a price whether it is a surgery or medications. Even you put the patient on medication, medicine has side effects too (11-P_P)

Some spoke more broadly about prevention while others noted specific types of interventions that they thought would be most beneficial as seen with the following responses:

My general philosophy is that for most chronic diseases like cancer, heart disease, cardiovascular disease, diabetes, the most important thing is physical activity and I know my personal philosophy is that we need to do more studies using intervention, using physical activity as intervention. And the second most important thing is diet. The studies investigating a healthy diet rich in vegetables, low in sugar, fat and salt, those kinds of things, that’s prevention. To me the most important ones are (those) that look at exercise and diet especially in young people, because once those habits get established and if you’re approaching 50 year old 60 year old people with prevention studies, it may be too late. They have already their BMIs already 35 or 40 and you know it’s not easy to get 50 60
70 year old people to get motivated to lose weight and start physical activity when all their lives they’ve been couch potatoes and not eating healthy, not doing enough physical activity. So my own personal belief (is) that those kinds of studies are very important (09-S\_N)

In general, I think that there’s a lot of screening and prevention that we do or call preventive medicine, when a lot of screening potentially may not show benefit for example: prostate cancer. There’s numerable studies that show benefit of prostate cancer screening but there’s probably equal as many or more that show there’s no benefit towards prostate cancer screening. And so why do I still offer prostate cancer screening to my patients? I think that if you can prevent a disease than you should, but how many lives or how many tests do you have to do to perform that before you know at least when it comes to screening (08-A\_P)

There’s a lot to do with preventing cancer with dietary habits, with having good food habits. So many things, day to day activities-exercise, good sleep at night. Things like that that which might sound ridiculous but they do in the long term diet I think plays a lot of role in cancer. So does exercise. So I guess that’s important (05-V\_P)

One participant suggested that prevention may work better in some situations than others:

It’s often a good idea. I don’t have a great philosophy. I think in certain situations it works really well other times it doesn’t it just depends on all the details of what you are trying to prevent (02-V\_NP)

Another participant challenged the definition of preventive medicine as well as wellness, posing the question of “when does prevention start” and suggested that prevention may need to be better defined, as seen in the following quote:
That’s a difficult question to answer. In the first place how do we define preventive medicine? It means that you know that something can go wrong. The issue is the definition of wellness. I think in oncology the most important thing is to change the image of cancer (for) the population (to) understand it’s a chronic disease which probably is a result of a chronic process of abnormalities which eventually lead to a malignancy or malignancies and therefore just like prevention of other diseases, nutritional changes, environmental changes, lifestyle changes, the same should be applied to preventing oncologic diseases and therefore the definition of when to start ought to be better defined. And the other issue is where does cancer prevention start? Could you start to detect molecular fingerprints of a micro subclinical cancer and prevent that from becoming a real problem? Is that prevention? Or is prevention trying to demonstrate that you prevent even the early oncogenic steps? It’s a matter of target of definitions. So it’s not so simple to design these studies (04-V_P).

Overall participants can be described as supportive of preventive medicine and a summary of the range of responses can be found in Table 7.

There was generally similarity in responses across all groups with themes such as cost effectiveness, preference of prevention to treatment and recognition of the value of prevention based on expanding medical knowledge noted. Several participants mentioned prevention as the “future” of medicine. Interestingly, some that were surgeons felt that their role in prevention was limited though could certainly see the value of prevention as the following response elaborates:
You know I constantly counsel my patients towards smoking cessation for example. (Those) that don’t have physicians want to treat their blood pressure and cholesterol and all that so I set them up and tell them they need to do that at their age, if it’s appropriate for that. But what do I do with my practice to prevent things? I guess I really don’t. So if asking what my philosophy is, I guess it is that I support it. It’s hard for a urologist to practice it but I do try and talk to them about smoking cessation and get them hooked up with appropriate primary care (07-P_N)

Table 7. Explanatory views on prevention (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supportive of it</td>
<td>S (3) A (2) V(2) P (2)</td>
</tr>
<tr>
<td>Prevention better than treatment</td>
<td>S (2) A (1) V(1) P (1)</td>
</tr>
<tr>
<td>Doesn’t work well for all cases, depends what trying to treat</td>
<td>V(1)</td>
</tr>
<tr>
<td>Future of medicine</td>
<td>S (2)</td>
</tr>
<tr>
<td>Challenging to define when prevention starts</td>
<td>V(1)</td>
</tr>
<tr>
<td>Challenging to design prevention studies</td>
<td>V(1)</td>
</tr>
<tr>
<td>Should be main focus of medicine</td>
<td>S (1)</td>
</tr>
<tr>
<td>Hard to practice in my arena</td>
<td>P (1)</td>
</tr>
<tr>
<td>Need more prevention studies because they are important</td>
<td>S (1)</td>
</tr>
<tr>
<td>I don’t see how you could be against preventive medicine</td>
<td>A (1)</td>
</tr>
<tr>
<td>Government has put a lot of money into it</td>
<td>A (1)</td>
</tr>
</tbody>
</table>

S-Specialty Center  A-Academic Center  V-VA Hospital  P-Private Practice

Following their initial response, participants were asked if what they stated was based on what they had learned in their training or was more influenced by their professional practice or even personal experience. The responses varied with most noting influence from one area or more as seen with the following responses:

I think I am more attuned to prevention then my training got me thinking about. I’ve evolved into more prevention (07-P_N)
It’s evolved since then. But, that question may be a little bit unfair because I went to med school in foreign county X. Let’s just say that, preventive health may not have been a priority there (08-A_P)

It’s pretty much what I’ve learned in my training. And it’s pretty much what life teaches you in a bit of time. You’ve seen people die and born in front of you and grow up into men and women in front of you and people who were adults when you were children you see them pass away by the time you are in this age that I am so it kind of gives you a broader perspective of life. Plus what I’ve learned in medicine as well. So both personal and professional influence the broader perspective (05-V_P)

Interestingly, there was varied commentary as to the past and current preventive training specifically with reference to American medical schools as the following statement:

Well, in the days that I trained we weren’t really taught about the importance of prevention, diet, exercise and all of that. More recently, they are becoming more into focus and in medical schools and in the scientific community. Fifteen years ago, people were very skeptical about diet and exercise so the accumulating data is clearly showing that these are very important for the past couple of decades. You know there’s more and more realization that you’ve got to make real changes (to prevent) disease, chronic disease. These are the things we have to change (09-S_N)

We don’t do a lot of preventive training (with our) surgical training. Med school yeah, in terms of primary care they talked about preventive strategies, not necessarily preventive medications or chemoprevention, things of that sort. Healthier living and eating and not smoking and not drinking and things of those sort. You know being fit, exercising. Those things are stressed and prevention from that point. Healthy lifestyles to prevent you from getting cancers and other disease but that’s about it (10-A_P)
A summary of the responses related to the influence of professional practice and personal experience on views about prevention follows in Table 8.

Table 8. Influence of personal and professional experience on views on prevention (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal</td>
<td>S (3) A (2) V(3) P (2)</td>
</tr>
<tr>
<td>Professional</td>
<td>S (3) A (2) V(3) P (2)</td>
</tr>
<tr>
<td>Changed over time</td>
<td>S (1) A (3) V(2) P (1)</td>
</tr>
</tbody>
</table>

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Following this, participants were asked to consider how they thought their philosophy towards preventive medicine may influence their willingness to participate in a PCPICT. Responses varied in specifics; however, there was some homogeneity with all participants noting at least some positive influence, regardless of their practice site as the following responses demonstrate:

- More and more, I am finding that prevention is probably one of the most important components in healthcare and to move it up in the agenda to be not the all encompassing but very, very important (03-S_P)
- I think it influences it in the positive for sure because I think it’s a good thing to be able to prevent disease processes from occurring in the first place (10-A_P)
- Well I’m absolutely for it, yeah. Being in the trenches, seeing what disease is at the other end, what is worth preventing (04-V_P)
Notions of risk.

Notions of risk came up in various responses, and were expressed as a means to determine who may be a good candidate to participate in a prevention intervention trial in general as suggested by one participant:

Probably the ideal patient is somebody who has a risk factor for a major disease and I think that’s the incentive for getting them involved in the first place (06-S_P)

As well as a consideration by clinicians as to when follow-up care may be provided, as the following response suggests:

The high risk feature on a path report might influence how aggressive we are together in terms of repeat biopsy. I might biopsy them at 6 months but most of the guys don’t get biopsied until a year after diagnosis. I’m not convinced that high grade PIN (prostatic intraepithelial neoplasia) is perfect just like PSA (prostate specific antigen) is not perfect. So I use PSA, the presence or absence of PIN. I use you know patient individual factors to say ok, when are we going to do another biopsy and I prepare them prior to initial biopsy that we may end up doing some more biopsies as time goes by (07-P_N)

As well as who may be offered or encouraged to participate in a prostate cancer prevention intervention trial as explained by another participant:

Depending on which condition it is, premalignant condition, if it’s something which has a significantly increased risk of cancer development I definitely think that they’re at a significant higher risk of cancer developing then I’m a little more strongly positive influenced or motivated to try to encourage patients to participate in a trial. I think that if it’s something which I think the risk is potentially increased but only slightly increased I think that I’m very clear to the patients in terms of what the likelihood
is of developing a condition and then sort of leaving it up to the patient based on how they feel whether they want to participate. I think I discuss it with them really keeping that specific relative risk really at the as an essential component of the discussion (01-S_P)

The interpretation of risk within the medical community and how it may influence participation in a prostate cancer prevention intervention trial was also discussed as the following responses elaborate:

You know the other thing that’s detrimentally affecting particularly prostate cancer I think is the ambiguity in the medical community about the significance of prostate cancer and the significance of prostate cancer treatment and if we can’t get our sh** together at the end of the day, patients think nothing why do I even have to prevent it? So, I think that we have to start from there but if the consumer thinks that prostate cancer is a non-entity then in reality why are we doing the study? That I think is probably the biggest nut for the consumer to swallow. They don’t realize the significance of prostate cancer. I as a surgeon feeling more and more pressure to discuss active surveillance with patients and so the consumer hearing that also feels perhaps more and more that they may have a cancer of little significance and that being said, do I need to do anything about it? (08-A_P)

I personally think one of the keys is the urologists, and how do they want to deal with the reporting of prostate biopsy showing PIN. One of them over there will refer because he just doesn’t say it’s benign we’ll see you in six months and recheck your PSA and exam. He will actually spend an extra minute and say it’s benign but there’s changes that I think you better go talk to them they have an interesting, and I do believe he uses the word interesting trial based on green tea. But he’s got three partners not a one of whom has ever sent anything over (12-S_P)
A summary of the various ways in risk was considered by the respondents can be found in Table 9.

Table 9. Risk (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influences who is offered/encouraged to participate in a trial</td>
<td>S (4) A (2)</td>
</tr>
<tr>
<td>Helps determine who is a good candidate to participate in PCT</td>
<td>S (3) A (1)</td>
</tr>
<tr>
<td>Perceived risk determines clinical care</td>
<td>S (1) A (1) P (2)</td>
</tr>
<tr>
<td>Physician’s perception of cancer risk</td>
<td>S (3) A (1)</td>
</tr>
<tr>
<td>Overall risk level (safety) of trial impacts</td>
<td>S (1) V (1)</td>
</tr>
<tr>
<td>Patients perceived risk and how it influences trial participation</td>
<td>P (1)</td>
</tr>
</tbody>
</table>

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**Uncertainty.**

Participants were asked to reflect upon times that they had decided to offer participation in a clinical trial and to consider how the possibility of uncertainty in the plan of care may have played a role in their decision to offer the trial. For those working at a specialty center, the possibility of uncertainty did not seem to play a role in the decision to offer the trial. One participant described the comprehensive approach taken when considering a patient for a trial and another noted that an unknown end is indeed the nature of research:

So you know depending on the patient, on their overall medical condition, their general well-being, I discuss it very clearly with them that we don’t truly know what the results are going to be of a study and potentially they may develop complications from the chemopreventive agent or the additional procedures that they need to undergo. I think it’s important not to sort of
minimize those and make it very clear that at the end of the day we don’t know what the results are going to be and it’s important to discuss with them the study design and what additional tests are going to need to be done and what the commitment is going to be from their end of things (01-S_P)

No. this is not a factor (03-S_P)

No, I think when you do research you don’t know what’s going to be the end (06-S_P)

Similarly, respondents from two academic institutions noted that familiarity with a study protocol helps to eliminate uncertainty as a factor of influence when offering a trial and one recognized that too much uncertainty could be a factor impacting participation as seen with the responses that follow:

No. I would say that I am if the studies that I enroll patients in, I for the most part know the study inside and out (so that uncertainty is minimized) (08-A_P)

I feel like I understand the protocol well enough in the beginning that I know what the plan is going to be so I don’t feel like there’s that much uncertainty. If there was that much uncertainty in the plan I probably wouldn’t participate (10-A_P)

Those from the VA medical centers had not experienced uncertainty in the plan of care though similarly to the prior comment, one participant did note that if present it could influence the likelihood of offering participation:

If there’s uncertainty then I think it’s less likely (that I would offer it). If it’s not a large uncertainty then it doesn’t matter. Only if it’s a big difference (02-V_NP)
If one has a large or sufficient patient population which might fit recruitment to studies, not offering the population access or studies shortchanges science (04-V_P)

Finally, those participants working in private practice noted that uncertainty in the plan of care was not a factor of influence when considering whether to offer trial participation to a patient. Instead they noted the absence of harm and similarity to usual treatment plan as more important as evidenced by the following statements:

No, I don’t think so. I think as long as the intervention isn’t gonna cause harm, I don’t think that that’s an issue (07-P_N)

It (participation) did not change my treatment plan. This is what I usually do. If I get a protocol that does not make sense to me I don’t participate but this particular study, it did not change the treatment plan. If a study design was completely different than my usual care it would impact my decision to participate (11-P_P)

Participants were then asked how has the possibility of uncertainty in the outcome associated with participation in the trial, played a role in their decision to offer the trial. There was little variation both between and within groups. Those participants working at a specialty center suggested that uncertainty in the outcome was not influential and even suggested the imperfection of medical knowledge, importance of rationale for a study and the suggestion that uncertainty is the nature of science as demonstrated in the following responses:
No, on the contrary because one of (the) things with prostate cancer is that most of the knowledge we have is imperfect and sometimes it can be erroneous and we are assuming that that knowledge is the real truth, which it is not (03-S_P)

You don’t want to do something just blindly, guessing or hoping this will do something, you need to have a rational for it (06-S_P)

It doesn’t really affect my participation because I think by definition that we know that there is uncertainty when you do research, otherwise why would you do the research if you were certain of the outcome? I believe only through clinical trials we’re going to find the truth so there is going to be uncertainty. That is a given. It’s the nature of science (09-S_N)

There was some heterogeneity in the response from those practicing at an academic center with one noting that uncertainty would influence the way a patient was counseled as well as noting his “patient first” perspective as the following responses demonstrate:

If there was uncertainty it would make it harder for me to counsel patients in an unbiased way. You have to dissect them, have to be interested enough in the trial and the outcomes to know. And, I guess I put my patients first always so I you know if the patients aren’t going to benefit, I won’t even look at those trials (08-A_P)

Another disregarded uncertainty as influential and similar to other respondents suggested that it was inherent to the nature of research:

(That’s) why it’s called a trial, we don’t know what is going to happen at all. No, that hasn’t influenced it at all. I would think that for prevention it would be less of an issue because we’re trying to prevent the disease process. If it works great; if it doesn’t we’re right back in same boat that you were in before. As long as doesn’t make it worse but we’re monitoring it to make sure it doesn’t make it worse (10-A_P)
Those at the VA sites also did not report uncertainty as a factor associated with participation in the trial and similarly to other respondents noted the importance of safety as evidenced by the following comment:

If there are no significant safety risks, no. Prevention is looking towards avoiding something which might be defined only once it comes up, while therapy you already have the target, it’s well defined. (When) preventing cancer, I think that the metrics are a little bit less well defined because ideally you should not prevent what we now define as established cancer (04-V_P)

Another respondent discussed honesty and communication with the patient as important means to deal with the possibility of uncertainty as noted in the following response:

I think if you are honest with your patient, with your potential recruit, upfront and tell them this is a possibility. You might get some side effect or if it’s a double blinded trial you may get a placebo or exact medicine we don’t know. So (this way) the patient knows they might or might not benefit or might get side effect or they might have to stop the medication, things like that. I think as long as you are up front from the very beginning I don’t think I see a problem with that. Patients understand (05-V_P)

One participant in private practice made similar comments to others regarding harm or risk with the following remark:

If it doesn’t help it’s not going to hurt, you know. I have no problem with doing that (11-P_P)
Various perspectives regarding uncertainty were noted during the interviews. A summary of the range of responses related to uncertainty follows in Table 10.

Table 10. Responses related to uncertainty (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not a factor</td>
<td>S (1) P (1) V(3)</td>
</tr>
<tr>
<td>Participation less likely if there is uncertainty</td>
<td>V(1)</td>
</tr>
<tr>
<td>Not an issue with cancer prevention studies</td>
<td>V(1)</td>
</tr>
<tr>
<td>Not an issue because understands study “inside and out”</td>
<td>A (1)</td>
</tr>
<tr>
<td>Uncertainty lessened because know what plan of care/course of treatment will be when on study</td>
<td>A (1)</td>
</tr>
<tr>
<td>No uncertainty if not significant safety risks</td>
<td>V(1)</td>
</tr>
<tr>
<td>Communication with the patient reduces uncertainty</td>
<td>A (1)</td>
</tr>
<tr>
<td>When you do research you don’t know what is going to be at the end</td>
<td>S (1)</td>
</tr>
<tr>
<td>There is uncertainty in research, it’s the nature of science</td>
<td>S (1)</td>
</tr>
<tr>
<td>Rational for prevention reduces uncertainty</td>
<td>S (1)</td>
</tr>
<tr>
<td>Uncertainty would make it hard to counsel in an unbiased way</td>
<td>A (1)</td>
</tr>
<tr>
<td>“That’s why it’s called a trial. We don’t know what is going to happen.”</td>
<td>A (1)</td>
</tr>
</tbody>
</table>

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**Shared decision-making.**

In an attempt to solicit perspectives regarding shared decision-making, participants were asked two separate lines of questions. One sought to address possible issues relevant to sharing decision-making with another provider, as may be necessary if a patient participated in a trial at a location away from their usual care. The other question dealt with how participation in a cancer prevention trial impacts the physician-patient relationship. First, participants were asked to
describe their thoughts about sending their patients to another facility to participate in a cancer prevention intervention trial. Participants were next asked about alternatives to referring their patients elsewhere such as having outside study staff come to their office or work place. Another alternative presented was the provision of support to train their own staff so that patients could participate in a cancer prevention trial but did not have to leave their usual office. Many considerations were noted by participants, with factors influencing all possible scenarios noted. A summary can be found in Table 11.

Table 11. Considerations when trial not available at site of usual care (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would consider referring out /would not be a problem</td>
<td>S (1) A (1) V (2) P (1)</td>
</tr>
<tr>
<td>If it was of significant benefit to my patient</td>
<td>S (2) A (1) P (1)</td>
</tr>
<tr>
<td>If the trial could take precedence over standard treatment</td>
<td>S (1)</td>
</tr>
<tr>
<td>If patient willing</td>
<td>V (1)</td>
</tr>
<tr>
<td>If supports future research</td>
<td>V (1)</td>
</tr>
<tr>
<td>The protocol must be logical</td>
<td>P (1)</td>
</tr>
</tbody>
</table>

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Themes that emerged were the importance of patient benefit, financial concerns, the detailed work of running a clinical trial, ownership and time. In particular, those that were agreeable or supportive of referring patients for participation at another site similarly identified themes such as the possibility of a positive experience or benefit for their patients and were agreeable to make
the referral due to and lack of availability at their own institution as the following responses demonstrate:

Yes, I would. I wouldn’t say no just for the sake because we don’t have something available here in our facility as long as the patient is happy doing that. If patient is willing and it helps, helps research for the future I would say yes, definitely yes (05-V_P)

Yeah. I wouldn’t mind that (08-A_P)

Absolutely. If I have a patient who is eligible for a prevention trial somewhere else and if I don’t have something for that population I would send them. Wherever there is a good study for the patient, we send them (09-S_N)

Yes, because it’s something you don’t offer here and they potentially could benefit from participating at another place (10-A_P)

I would be if I felt that the agent or the trial being considered was potentially quite appealing from a biological standpoint and I thought there may be a significant benefit to my patient (01-S_P)

The possibility of “losing” patients or having them “stolen” was noted by several participants. Variance occurred across the types of sites where participants worked, with those working at academic centers and in private practice more concerned than those working at specialty centers, as the following responses suggest:

No, in the sense that you are sending your patients somewhere else and they may not come back. So, why should they? It’s almost like saying that if you’re not cutting edge enough to have their research trial at your institution so why should I come back to you? (10-A_P)
One of the major reasons that people do not like to participate in the project done in centralized area is that they lose control of the patient (11-P_P)

Well, we don’t worry about people stealing our patients. I think that’s probably the big thing. So we wouldn’t mind sending them (06-S_P)

Comments by another participant suggest that the tenure of experience may also influence the likelihood that this is a concern:

You ask a guy like me, I’m not just beginning out in this business. I’m not as threatened by sending off as some might be. So no, I wouldn’t have trouble with that. If you talk to someone who’s trying to build a practice they might be less inclined to do that (12-S_P)

Concerns related to the coordination of all the details involved in referring patients outside the site of usual care was expressed in several different ways, in the following responses:

I’m always more in favor of keeping patients within my institution. All of us have a fear that when patients leave here, (are) sent out, they can be lost in the paperwork and the shuffle. Therefore, if there is an opportunity to have some coordinators come here and patients being managed on a trial and kept here that would definitely be more suitable or ideal (01-S_P)

It would find that to be overtly cumbersome. That’s nothing I would encourage (08-A_P)

I think that would be ok. The only problem I guess is just logistics. Who and when are they coming to visit the patient? You have facility fees involved, things of that sort that would have to be worked out on a higher level. Those things are important because if they’re occupying a clinical room then that means another patient is not there so potentially losing money.
It always comes back to money. I would much rather have it done here (10-A_P)

A summary of concerns that were noted when a trial was not available locally and referral to another site was possible are found in Table 12.

Table 12. Concerns related to referral to another site (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Logistics are challenging</td>
<td>A (1) V (1)</td>
</tr>
<tr>
<td>Losing patients to other providers</td>
<td>A (1) P (1)</td>
</tr>
<tr>
<td>Lack of transportation to other locations</td>
<td>S (1) A (1)</td>
</tr>
<tr>
<td>“Overtly cumbersome” nothing I would encourage</td>
<td>A (1)</td>
</tr>
<tr>
<td>Someone is going to be losing money</td>
<td>A (1)</td>
</tr>
<tr>
<td>I would much rather have it done here</td>
<td>A (1)</td>
</tr>
<tr>
<td>Volume of patients</td>
<td>P (1)</td>
</tr>
<tr>
<td>Complexity of the trial</td>
<td>P (1)</td>
</tr>
<tr>
<td>Adequacy of current staffing levels to support volume of work</td>
<td>S (1)</td>
</tr>
<tr>
<td>Patients “lost in shuffle” when “sent out”</td>
<td>S (1)</td>
</tr>
<tr>
<td>No concerns at all about this</td>
<td>V (1)</td>
</tr>
</tbody>
</table>

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The possibility of training current staff in order to keep the project at their own site was appealing, yet limitations were noted in the following responses:

It would be in theory. I know that some of the major constraints we have today is the number of research staff that we have and (the) ability for them to participate in all of our active trials. I think if we ever (are) to do that we would need to increase our research staff. If we did that then yes, that would definitely be suitable (01-S_P)

So from the research point of view you are better off sending your own people because they dot their I’s and cross their T’s. All the things that these people don’t care about. If you are not sitting next to me by the time the patient left half of the things I didn’t do because I am doing my own stuff (and forgot) (11-P_P)
Depends on what the trial is. I mean if it’s really complicated that’s one thing. If it’s not that complicated then I think we can handle that. A lot depends on if it involves a whole lot of technology, it just depends on the details (12-S_P)

With the following statement, one participant was quick to clarify that the concern was not related to training, but rather the lack of time:

The training is not a problem, the time to do it that’s the issue (02-V_NP)

Participants noted that these options were not mutually exclusive and may actually be complementary and/or interrelated as suggested by the following responses:

I think the three are not exclusive. They are complementary (03-S_P)

I think that they are interrelated, they are not exclusive. That they’ll occur even within the same site and there will be different reasons for why patients can or can’t be referred- distance, neighborhood, whatever (08-A_P)

Interestingly, one noted that prevention trials may not be appropriate for the patient population served at their facility, with the following response:

If you’re talking about prevention trials they don’t come up very often in our discussions because the people I am seeing already are sick, they already have cancer (09-S_N)

**Physician-patient relationship.**

The second line of questioning was designed to elicit feedback as to just how participation in a cancer prevention trial impacts the physician-patient relationship. Those participants who practice at
specialty centers all noted it as a positive experience with some indicating that it fostered trust, the sense of a common goal and allowed for the provision of involvement at a different and more holistic dimension, and allowed for a continuum of care as the following responses demonstrate:

I think it positively impacts it because patients are realizing you are trying to strive for minimizing their risk of cancer development that you are offering them treatments that they would potentially not be getting anywhere else so I think it fosters a degree of trust and of a common goal trying to be achieved (01-S_P)

I think it makes it better because it’s more holistic. (You) get involved with that particular person at a different dimension, a different perspective which is a perspective that many things many conditions can be prevented and we just scratching the surface of that. And that would make the relationship more solid because one is starting to know the patient very early. You know them for longer periods of time. There’s more continuation of care (03-S_P)

It was a positive, that’s about all I can say (06-S_P)

Any clinical trial I don’t think there is any negative effect on physician- patient relationship. You know most of my patients are participating in clinical trials they understand how important they are and some of them are very very happy that they are participating because they feel that not only are they potentially helping themselves but may be helping other people too through their participation (09-S_N)

Those at an academic institution also note a positive experience that allowed for a more comprehensive level of care as described in the following responses:
I speak of this only because of what I have heard from patients is that they are actually very happy to come to the university setting to hear about nutritional changes. Patients time and time again have made the comment that these are things that are not talked about with them at other institutions or whether it be in the community or what have you. Or they actually seek that they want that knowledge and I think that the fact that we do participate in these trials helps the patient physician relationship and it also lets the patient know on a different level that we are concerned about their overall health (08-A_P)

I think it’s a positive thing because you can tell the patient that you are participating in that type of a trial that kinda lets them know that you’re not just the surgeon that can’t wait to cut on you. It lets them know that you are interested in overall patient care and so this is something I can offer you besides just waiting for your next biopsy to come up. An opportunity to for me to intervene again, so there’s something I am interested in doing that might help you not need that intervention. So I think it’s a positive thing for the patients. I think they appreciate that (10-A_P)

Response from those participating from the VA medical centers was the most varied, yet also overall considered participation to have a positive and rewarding influence on the relationship as well as benefits to the patient in respect to contributions to the greater good as evidenced by the following responses:

Oh it’s wonderful because the patients are interested. Nobody wants to get sick. They would like as much as possible to participate. Once your patient is in trials even when participation is completed, I still see them in my research clinic and you know it’s actually (a) very good rewarding relation. Some get recycled; they enter new trials, similar disease spectrums. Oh
it’s very rewarding. Wonderful relationship with this patient. It’s fun. Absolutely (04-V_P)

I think patients by and large appreciate that as a physician you are trying to do something for the betterment of humanity. I think the patients feel good about it as well themselves because they feel that they are doing something which is helpful for the future generations. As a physician patient relationship I think it makes you feel good, that’s my personal feeling. You get to know them. They come every so often so you get to see them (and) often you develop a relationship with the patients. Both the physician and the patient know that it’s something which goes beyond the day to day activity, something for the betterment of humanity. (It’s) definitely a positive experience, different than the normal (05-V_P)

The participant working in private practice reports no change in physician-provider relationship and suggests that overall patient satisfaction is dependent on multiple factors as seen in the statement which follows:

Nothing changes. They depend upon the outcome you know; if the patients have good outcome and good experience they are happy. If they didn’t have a good experience they come back and express their dissatisfaction. Does (the) patient leave me because I sent him to the study? No. Is (the) patient mad at me because I sent him to the study? No. Some of them they feel that it is good, that it is better because they have more frequent check-up, more frequent lab work. Some of them see this as a risk and (some) as a reward you know? (11-P_P)

A summary of the impact of participation in a PCPICT on the physician-patient relationship can be found in Table 13.
Table 13. Impact of participation in PCPICT on physician-patient relationship (n=9)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Impact</td>
<td>S (2) A (2) V (2)</td>
</tr>
<tr>
<td>Doesn’t change/impact it</td>
<td>S (1) P (1)</td>
</tr>
<tr>
<td>Makes it better, more holistic</td>
<td>S (1)</td>
</tr>
</tbody>
</table>

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**Duality of roles.**

Prior research suggests a possible conflict when a provider plays the dual role of advocate for the patient and for the research. To address this, participants were asked how their ethical responsibilities as a physician change when a patient participates in a cancer prevention intervention trial. Many noted that ethical responsibilities did not change as seen in the following responses:

I don’t think they ever change. I mean I think that the patient comes first. I don’t think they ever change (08-A_P)

I don’t think they change at all. I have the same responsibilities. Whether they are in a trial or not you still are working under the same ethical premise I would think (02-V_NP)

One informant commented more specifically in relation to the ongoing trial and introduced the concept of risk. Additionally, he suggested that the goals of chemoprevention and therapeutic trials may be different as elaborated in the response below:

Good question. I think that they ultimately remain the same. One of the premises of being a physician is do no harm. So I think that you need to be very clear that when you discussing a chemopreventative trial that the goal remains the same as do no harm and potentially prevent cancer, but that there are risks.
Those risks are what you need to discuss, what those relative risks are in terms of percentages of the various complications you may have with them. So, I think your role as a physician doesn’t change but (patients) need to understand clearly you’re ultimately not knowing what the results are going to be for that specific intervention, which is a little bit different from when you treat a condition, when someone has a physical malignancy that you are treating. So, obviously you are earlier in the spectrum of disease but the goal is the same-minimizing the progression of a condition (01-S_P)

Several informants did reference the scientific merit of a study and how that may be a factor in minimizing any potential conflict related to duality of roles as seen in the following responses:

I think it’s part of the ethics of the practice of medicine. As long as the science is sound and makes sense (03-S_P)

Well, one has to be objective about the study design. If the study is well designed with appropriate controls; reasonable ethical eligibility criteria, does not push the envelope, does not promise hyperbolic outcomes I don’t see ethical issues, no (04-V_P)

One participant did not report ethical conflict; however, did make reference to the fact that a research participant may be treated differently than a non-research as seen in the statement which follows:

I am doubly careful about the patient because he has voluntarily agreed to do something which may have deleterious effects on him. So, I am doubly careful with my research patients to ensure that no harm comes to them and that’s true for any patient which we would deal with but more so with our cancer research patients. One does tend to be a bit extra careful with the details and everything else (05-V_P)
There was overall no variance in response across types of sites with informants from several referring to the Hippocratic Oath and physician’s responsibility to first do no harm. Interestingly, one physician working in private practice suggested a potential difference between pharmaceutical and prevention trials with the following remark:

I think that exists a certain extent in pharmaceutical trials where there’s dollars coming in. I suppose that the same could hold true for a prevention trial depending upon what the budget might or might not allow (07-P_N)

A summary of the responses related to changing ethical responsibilities is found in Table 14.

Table 14. Ethical responsibilities (n=9)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultimately remain the same, premise of being a physician is to “do no harm”</td>
<td>S (1)</td>
</tr>
<tr>
<td>They don’t change at all. I have the same responsibilities</td>
<td>V (1)</td>
</tr>
<tr>
<td>No ethical concerns as long as the science is sound and makes sense</td>
<td>S (1)</td>
</tr>
<tr>
<td>No ethical concerns as long as the study design is good</td>
<td>V (1)</td>
</tr>
<tr>
<td>“Doubly careful” with research patients to be sure no harm comes to them</td>
<td>V (1)</td>
</tr>
<tr>
<td>No change</td>
<td>P (1)</td>
</tr>
<tr>
<td>“They don’t ever change. The patient always comes first”</td>
<td>A (1)</td>
</tr>
<tr>
<td>They don’t change</td>
<td>S (1)</td>
</tr>
<tr>
<td>“I’m not sure they really do. You still have to be the doctor and do your best.”</td>
<td>S (1)</td>
</tr>
</tbody>
</table>

S-Specialty Center A-Academic Center V-VA Hospital P-Private Practice
Next, participants were asked to discuss any experiences related to role conflict when they played the role of advocate for the patient and for research simultaneously. Two responded yes and provided the following explanations:

I have, yeah. Some trials where I’m a PI and I’m discussing the study and I make it very clear to the patient what my role is in the study, I am really forthright about it. I tell them since I am the one that designed the study that obviously I may be a little biased that I think this study may be beneficial to you, but I make it very clear to them what the pros and cons are going to be and I make it very very clear to them that the end of the day whatever decision they make does not change ultimately how I treat them and they will ultimately get the best quality care they can but obviously (it) may vary depending on whether they participate or not (01-S_P)

I would say yes, you know when these LFTs (liver function tests) are elevated, how elevated? Is it elevated enough to take them off the study? Is the drug doing some harm? So yeah, every time there is something (like that) you have to consider (that) there’s conflict. It’s a balance, ok is he really being harmed or is he not being harmed? Is he being harmed enough to come off the study or not? Those kinds of things, I just make the decision that’s best for the patient. Always do what you think is best for the patient (10-A_P)

Others reported that they had not experienced conflicting roles commenting how factors such as financial interest and IRB oversight may be influential as noted in the following responses:

No, I think they come together and it comes with an understanding that the research is part of care and is an enhancer to the care (03-S_P)
I feel that my role is primarily being (an) advocate for the patient. So if I don’t see any conflict of interest or ethical problems participating in the research. I’m (honoring) my responsibility of being an advocate for my patient. I would do it if I were the patient myself so I don’t see any conflict there (09-S_N)

No, if I don’t have any financial interest or financial benefit and (it) is a study I am convinced to do, I don’t think it changes anything. Also (if) the study passes the IRB, you know that (it is ethical) (11-P_P)

While others noted that though they had not personally experienced role conflict, they could imagine how it was possible as the following responses illustrate:

I could see how that would happen, I haven’t really had any personal conflicts but I could definitely see how that could be an issue (02-V_NP)

Well, I think that there can be, I wouldn’t say coercion but motivation of interest on both sides, if one is willing to accept monetary advantages. Some people have to bring in their dollars for research resources and percentage of time and so forth that might be squeing a little bit the balance but for me personally that has not been an issue (04-V_P)

I have not personally, but I can see how that could happen. I’ll give an example: there’s a big group here in town who has a whole wing on their building that is dedicated to clinical research for profit so while it has not influenced me, I can see how that how that potentially could influence people (07-P_N)

A summary of the responses related to duality of roles and possibility of role conflict is found in Table 15.
Table 15. Duality of roles/role conflict (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td>When PI (Principal Investigator) that helped to design</td>
<td>S (1)</td>
</tr>
<tr>
<td>When labs abnormal</td>
<td>A (1)</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
<tr>
<td>Have not experienced</td>
<td>S (2) A (1) V(3) P (1)</td>
</tr>
<tr>
<td>As long as I don’t have financial interest or benefit</td>
<td>S (1) P (1)</td>
</tr>
<tr>
<td>Not if the study passes IRB</td>
<td>P (1)</td>
</tr>
<tr>
<td><strong>Can understand how it could be an issue</strong></td>
<td>S (1) V(2) P (1)</td>
</tr>
</tbody>
</table>

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**Changing relationships.**

Participants were also asked to describe changes that occur when a patient converts to research participant. On multiple occasions, the informants stated that the actual care of the patient did not change. However, specific changes were noted with the coordination of care, workload and documentation requirements, as the following responses demonstrate:

I think that when someone becomes a research participant there are more people involved in their active care so there is an additional component of coordination that needs to be involved (01-S_P)

There is a heck of a lot more paperwork. That’s I mean that’s really the main thing but you know typically we’re doing the same things for similar reasons (02-V_NP)

Well, once the patient becomes a research participant we have to follow everything that is written in the protocol to the minute detail because if we don’t do everything exactly as it’s written you get a lot of protocol deviations...That’s the only thing that
changes once a patient becomes a study subject. As far as patient’s care it never changes (09-S_N)

Additional comments hinted at necessary changes in the level of patient commitment or ownership of their care when participating in a trial, as the following responses suggest:

Their treatments or the way they are being cared for is more rigorous and requires more of a commitment from them as well (01-S_P)

Well I think it makes the patient take more ownership of the care and the other thing about prevention trials is that the ownership of the individuals care starts earlier down the continuum of care (03-S_P)

The importance of the relationship between the patient/research participant and the research team, as well as hints of possible changes in this relationship was suggested by the following responses:

You have to be willing to understand that the research subject is a special patient. For technical reasons there are certain (protocol) parameters that have to get fulfilled. One cannot cut corners and by the same token if the research team does not pay attention to the details and accommodate a patient, one ends up with noncompliance, drop outs, etc. So, the research patient has to be accommodated and (the team must) pay attention very very close because otherwise one loses him. One has to be flexible (04-V_P)

I’m trying to look for a change but the only thing I see sometimes is that the patient physician (bond) may become stronger (08-A_P)
Variance in response could not be associated with a specific site type as similar themes were noted by participants from specialty, academic, VA and private practice sites.

Participants were also asked to describe any changes that occurred when the research participant completed the study and converted back to patient again, at the time of study completion. Responses by all participants varied, with not all reporting changes. Themes that were noted ranged from possible changes in terms of trust to a reduction in paperwork and documentation requirements as evidenced by the following remarks:

Sometimes patients, if they’ve had side effects (they) may be a little bit skeptical about what you are offering them next. I think you need to discuss with them why their complication happened or ultimately outline for them what our treatment goals are going to be going forward. But there may be some challenges in terms of the trust (01-S_P)

Of course, once they if they are off study then you don’t have to worry about the deviations anymore. You just do your usual standard, good clinical practice (09-S_N)

We track them less because we don’t have to see them so often (10-A_P)

The most commonly noted change in the physician-patient relationship was a strong and lasting bond or attachment between the two as reflected in the following responses:
You get the impression that they have a stronger bond (08-A_P)

One gets attached to patient and patient gets attached to PI... I think it becomes almost like (a) family apparatus or relation, which it’s actually very rewarding. Very rewarding (04-V_P)

We do develop a good rapport once being a study subject and it carries on after they are off the study (05-V_P)

A summary of responses can be found in Table 16.

Table 16. Changing relationships (n=9)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>People (patients) are more involved in their care</td>
<td>S (1)</td>
</tr>
<tr>
<td>Additional coordination is required</td>
<td>S (1)</td>
</tr>
<tr>
<td>Trust may be challenged depending on what happens during the study</td>
<td>S (1)</td>
</tr>
<tr>
<td>Hope the patient becomes a better health consumer</td>
<td>S (1)</td>
</tr>
<tr>
<td>Patient-physician bond strengthened</td>
<td>A (1)</td>
</tr>
<tr>
<td>Keep them happy so they stay on the study</td>
<td>A (1)</td>
</tr>
<tr>
<td>PI-Patient attached like a family apparatus</td>
<td>V (1)</td>
</tr>
<tr>
<td>Nothing. We do the same things for similar reasons</td>
<td>V (1)</td>
</tr>
<tr>
<td>We develop a good rapport</td>
<td>V (1)</td>
</tr>
<tr>
<td>Patient is special and has to be accommodated or you will lose him</td>
<td>V (1)</td>
</tr>
</tbody>
</table>

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Preferred time of involvement.

Participants were then asked at which point in the research process they prefer to become involved, (i.e., conception/design, implementation, etc.). Those working at specialty centers all preferred to be involved early at the conceptual and grant writing stages as opposed to becoming involved later and gave very concrete and specific reasons for this as the following responses elaborate:
Early on. I think if possible at the conceptual level because I think it gives (me) the ability to give some input from a clinical standpoint in terms of what may be important to look at, what may be hindrances to the study itself (01-S_P)

As early as possible. Prevention is (a) very complex issue which requires a lot of multi disciplinary approach from the research (team), from the basic research, from the translation from the clinicians. And in order to develop a trial all have to be involved from the very beginning and not only to understand the trial better to be sure that it makes sense and to be sure that downstream when has been designed and more importantly implemented there is a very clear understanding of what the objectives are from the get go (03-S_P)

The earlier the better because if I’m going to be participating in a study I would like to be involved in the planning stages. You know, even writing the grant. Having more people involved early on you can identify pitfalls and potential problems or even assess feasibility better if you have people involved (then) (09-S_N)

The responses from those working at an academic center were more split with one experienced participating at all levels yet expressing benefits of participating early as well, especially with trials involving multiple sites as seen with the following response:

I have participated in all levels. The ones that I find the most valuable are the ones with design (of the study)... I think that it’s valuable that if you are thinking of involving 10 institutions that they all participate at design level or at least get input at design level (08-A_P)

This response was similar to those noted by physicians working at specialty centers. Another physician working at an academic center mentioned preferred involvement at the activation and recruitment
stage; however, noted that earlier involvement may be beneficial, as
seen with the response below:

I like...where I was brought in (to the project), kinda I guess
towards the end... because there’s less to do besides just enroll
the patients. But, I don’t think I would mind at all being
consulted earlier on regarding the clinical aspects that could
potentially play a role later on. My perception is just that the
physician probably was not as helpful as (he) could have been
(with this study) because (he was) so busy (10-A_P)

Those working at VA medical centers expressed the most variance in
their responses with one noting that it would depend on the trial yet
was unable to elaborate and provide more specific details for his
response. Another theme observed though not expressly stated,
seemed to be associated with tenure and prior experience as a
researcher as the following participant elaborates:

Well, I believe that after decades in the field, probably some
individuals like myself might be able to contribute some
impressions and some valuable details in the planning phase of
such projects. Not based on just lab experience (but from)
being in the trenches, seeing what disease is at the other end--
what is worth preventing and what perhaps is not worth
preventing (04-V_P)

One physician from private practice preferred to be involved with study
activation and initiation and not in the planning stages as seen with
the following response:

I like to join a study at the beginning. I don’t necessarily want to
be involved in study design (07-P_N)
The physician who has had tenure in both academia and private practice noted that several factors influenced when he would prefer to become involved:

It depends upon the study itself and the investigators and my degree of how much I know him how much I don’t. I have a big academic background so I don’t mind looking at a study (early on to provide input) (11-P_P)

Different from responses to the prior questions, there was greater heterogeneity between but not within the types of sites. A summary of responses follows in Table 17.

Table 17. Preferred time of involvement (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design/conception</td>
<td>S (4) A (1) V(1)</td>
</tr>
<tr>
<td>When initiating new sites, training and recruiting</td>
<td>S (1) A (1) P (1)</td>
</tr>
<tr>
<td>It depends on the trial</td>
<td>V(1)</td>
</tr>
<tr>
<td>“I’m a clinician. I want to be involved in the clinical part of it.”</td>
<td>V(1)</td>
</tr>
<tr>
<td>Analysis</td>
<td>S (1)</td>
</tr>
<tr>
<td>All depends on who the investigator is</td>
<td>P (1)</td>
</tr>
</tbody>
</table>

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**Future participation.**

I will remind the reader that participants were previously asked which factors were important to them when considering whether or not to participate in a cancer prevention intervention clinical trial. In the final question to address research question one, participants were asked what would help to increase the likelihood of participation in cancer prevention clinical trials in the future. This question was
designed to focus on factors at the individual, provider level not at the broader institutional or structural level. However, the responses addressed factors at both levels as well as some specifically related to their patients. I will focus on the individual factors here (though it is sometimes difficult to separate the two) and address the larger more structural issues in a different question.

Those participating from specialty centers especially discussed larger structural factors and also offered some solutions but none noted specific individual or personal level factors that may influence their participation in future trials. This could be a result of the fact that due to their high level of specialization (surgical and medical oncology) it is challenging to imagine a role for prevention with their particular patient populations. Responses from those at academic centers ranged from individual factors such as personal motivation or interest and patient factors to academic recognition as seen with the responses that follow:

I thought for a while there that if I... personally became more motivated towards nutritional treatment for disease that that might also drive my patients to do so too, but I didn’t necessarily see that panning off in that they would be participating in clinical trials. They may be taking matters into their own hands but why they’re not choosing (to participate), I don’t know why. Maybe because they don’t feel that the end product for them is tangible, that’s their lack of desire to participate. If there is something tangible they knew that they could say hey...I can hang my hat on this. But there’s no science there to support anyone making those statements so you can’t
make a leap of faith in order to try to get them to buy in (08-A_P)

I enjoy participating in the trials. I’m in academia so I enjoy being on the papers... So, certainly having publications...I mean the only reason to be involved besides your own personal interest if in academia is the fact that you can get your name on some papers and if you’re interested can be involved in some of these cutting edge evolving things. That’s what it is for me, just kinda the personal interest. I like research (10-A_P)

Larger, structural factors such as funding were also noted as influential by seen with the following response:

I think one of the most important factors is if I join as a co-investigator in a trial will there be enough funds for us to do the trial? ... And if the clinical trial is providing you that money then you know, I would be more inclined to participate and institutionally also they will not obviously support a study that’s underfunded. That’s one of the things they look at: does the study have funding? Adequate funding. So that’s number one and also ...the second thing that would be important to me is, is it something that I am interested in personally? You know if I’m interested personally in that clinical trial design or the intervention then I am more likely to participate in it... If I am not interested in the trial or don’t think it’s a good idea then obviously I am not likely to participate (09-S_N)

Responses from two participants not working in private practice provided potential insight into factors that may be influential to a physician who was, noting finances and perceived benefit of participation in the statements below:

I don’t know how you would incentivize a guy in private practice to participate in trials like this. It would almost have to be completely financial somehow. There are some big groups in the country who do participate in trials like that. They present it at meetings and they talk about how financially lucrative they can be. And a lot of those are pharma trials. Chemoprevention like
this I just don’t know how you would incentivize them because you have to have extra visits, you know for research and you have the IRB stuff to go through. I don’t know how you would incentivize them (10-A_P)

I think most of it would come down to what urologist’s perception of the benefit (whether or not he/she would be involved) (12-S_P)

In sharp contrast to factors suggested as influential to physicians working in private practice, those from the VA centers responded differently with both academic and scientific recognition as well as more altruistic factors suggested as likely to influence their future participation as seen with the following responses:

You know getting proper credit for contributing patients I think is important. It’s not money; it’s academic and scientific credit (04-V_P)

If the study appeals to my mind, that the study is going to be something good for the betterment for the future, in my little field. If I can kind of help things along or kind of change things fighting cancer that would be one of the factors. It really gets down to nuts and bolts, the crux, what is the study trying to achieve? Are we helping the future? Are we helping the cause, fighting against cancer? That is the bottom line. This would be the primary thing. Everything else is secondary (05-V_P)

One participant working in private practice noted some similar factors to those working in other areas with the following response:

I have to be interested in the type of cancer that we are trying to prevent so that’s number one. It has to be an organ system that I work with closely. Then the prevention itself has to have some rationale, something that seems reasonable and the last thing it has to be very simple. The other thing, I suppose it has to be somewhat appealing to patients (07-P_N)
Personal and professional interest in the topic of study, patient related factors and funding were all noted as important by participants. The range of responses regarding personal factors influencing future participation in a prevention clinical trial can be found in Table 18.

Table 18. Personal factors/future participation (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I must be personally interested in the trial</td>
<td>S (1) A (1)</td>
</tr>
<tr>
<td>Time</td>
<td>V(1)</td>
</tr>
<tr>
<td>“What is the study trying to achieve, will it help for the future?”</td>
<td>V(1)</td>
</tr>
<tr>
<td>More federal funding for prevention</td>
<td>S (1)</td>
</tr>
<tr>
<td>Must be patient friendly</td>
<td>P (1)</td>
</tr>
<tr>
<td>Must be a type of cancer that I am interested in preventing</td>
<td>P (1)</td>
</tr>
<tr>
<td>Must be an organ system that I work with</td>
<td>P (1)</td>
</tr>
<tr>
<td>“Fewer steps for the patient makes it more appealing to me”</td>
<td>P (1)</td>
</tr>
<tr>
<td>Will there be enough funding for me to do the trial?</td>
<td>S (1)</td>
</tr>
<tr>
<td>Publications</td>
<td>A (1)</td>
</tr>
<tr>
<td>Must be a trial that patients are interested in participating in</td>
<td>S (1)</td>
</tr>
<tr>
<td>Academic/scientific credit</td>
<td>V (1)</td>
</tr>
<tr>
<td>If it appeals to my mind and is for the betterment of the future</td>
<td>V (1)</td>
</tr>
<tr>
<td>Urologist’s perceived benefit</td>
<td>S (1)</td>
</tr>
<tr>
<td>There must be a tangible measure that the participants can see</td>
<td>A (1)</td>
</tr>
</tbody>
</table>

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**Structural level factors.**

The next participant responses are related to research question two (What structural factors influence a physician’s participation in a PCPICT?) and explore and document structural -organizational and
infrastructural- considerations that influence participation in a PCPICT, with a comparison of factors across types of sites.

**Influence of sponsor.**

Participants were asked to consider how organizational infrastructure may facilitate and constrain participation depending on the sponsor and to consider how some sponsors are preferred over others. There was great variance in the responses both within types of centers and when making comparisons across them. Disjuncture between organizational mandate and allocation of resources was noted by an informant from a specialty center:

> From the organizational level our mandate is to do research. There is a difference between what is expected and the resources provided and the expectation that we would have to provide the resources and the organization somehow is the coordinator of those resources without allocation of resource. I understand the organization needs to be fiscally conscious and to be sure that we carry the business but if the organization doesn’t allocate the resources that we would need on top of what our responsibility is to fund some of that research, they are not proportional (03-S_P)

The response from another key informant was suggestive of infrastructure related factors that may be influential when considering those physicians working in private practice, that are not participating:

> If I have to use my infrastructure, I don’t have anyone in the office so I have to go through the hospital or I have to hire someone. Hiring someone for a small project is not a good idea. You have to have the infrastructure, that’s why I think the
community guys shy away from research, there’s too much paperwork to do. Even through the paperwork, your examination is different, your documentation is different, your labs that you will draw is different (11-P_P)

Funding was reported as influential, serving as both an institutional barrier and facilitator to participating in research by several participants as the following responses elaborate:

A non-funded trial gets minimal effort from the clinical trials support staff (08-A_P).

The institution wants money coming in the door. So I think we’re getting away from research for the sake of research for sure but looking more at research that can pay because if it doesn’t pay it just can’t happen long term. There is just not enough money going around to pick-up the slack (10-A_P)

The pharma trials, they basically give more money to do it, so sometimes it is easier to find those resources that you need to get the job done (02-V_NP)

At the specialty centers there was a clearly stated preference for federally funded trials or those that had gone through some type of peer review as opposed to pharmaceutical trials as the following responses demonstrate:

So my experience has been typically trials that are organized at the federal level are typically pretty rigorous and well designed... when studies are done at (the) federal level a lot of the administrative type responsibilities are not necessarily present. It is easy just to put the patient on and then everything else is taken care of...the flow is a little bit smoother and the effort is a little bit less. We like to participate with some of the big oncology groups SWOG (South West Oncology Group) for example is one. I definitely think any studies that are being conducted directly through the NCI we actively try to participate in as well in urology, the SUO (Society of Urological Oncology),
has developed a consortium group ... and they have developed a couple of trials and I think those are trials we actively try to see if we can participate because we know that being open to lot of major cancer centers, accrual should be good...(the) likelihood of achieving accrual goals is definitely there (01-S_P)

Well our mandate of trials that are preferable are the investigator initiated trials which go through a(n) outside peer review, which is basically federal or it could be at the state level. Then you have the pharmaceutical sponsored trials and they are at different levels. Definitely, there’s discouragement of doing post marketing trials. But there’s a hierarchy of preference that’s the expectation and I think pretty much everybody knows about the expectation (03-S_P)

We always give precedence to studies that are NIH funded studies and investigator initiated studies and then if there is room then industry sponsored studies are supported. So NIH funded, grant funded studies, always take precedence and then followed by investigator initiated studies which may or may not be grant funded and then following them you have a drug company studies. Of course you know when the funding is getting tougher to get you may have more pharmaceutical studies but it doesn’t change the rules that we use to activate studies (09-S_N)

These types of trials were noted by other sites as well but for different reasons noted in the responses that follow, such ease of accommodation:

Federally funded studies are easier to get accommodated then commercial studies based on fiscal and intellectual property, legal (type) aspects. Some organizational related federal funds might be rather accommodated than others like VA cooperatives have priority over NIH/NCI studies and certainly over pharmaceuticals. VA cooperatives take precedence but without the infrastructure to necessarily support them (04-V_P)
Additionally, funding limitations at the federal level and the specific impact on clinicians interested in doing research locally were noted:

They say that they (the institution) want us to get federal grants because those are more prestigious, even sometimes they don’t quite pay as much by the time you get all the directs, indirects and those kind of things. At the same time, to get federal grants many times you have to have at least 40% dedicated research time and that makes a lot of clinicians not eligible. So, if we say we can’t get these big grants from the government because we don’t have research time, rather than give us more research time then I think the shift is just to say, well try to get these other grants the pharma grants, and such that don’t have that requirement (10-A_P)

A respondent also suggested that sometimes the prioritization of research projects shifts as seen in this response:

Well, for one thing it’s very hard to get federal funding now. At least in terms of RO1 type grants for investigator initiated (studies). The cooperative group trials are not such a problem. Our infrastructure has influenced that a little bit, we participate in SWOG and to do that we have to put in a certain number of patients in studies every year. Just recently our director gave notice to everybody that we are not putting enough patients on SWOG and to quit putting patients on the drug company sponsored studies unless there was really some unusual patient oriented circumstances. It does change over time because if we are doing really great on SWOG (as) in just a few years past then it was ok to go out and get the other sponsors (06-S_P)

The range of responses related to the influence of sponsor can be found in Table 19.
Table 19. Influence of sponsor (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a hierarchy of preference</td>
<td>S (1)</td>
</tr>
<tr>
<td>Investigator initiated then pharma trials</td>
<td>S (1)</td>
</tr>
<tr>
<td>Post-marketing trials discouraged</td>
<td>S (1)</td>
</tr>
<tr>
<td>We have a directive and it changes over time</td>
<td>S (1)</td>
</tr>
<tr>
<td>Currently cooperative group trials preferred over pharmaceutical trials</td>
<td>S (1)</td>
</tr>
<tr>
<td>NIH funded, investigator initiated then pharmaceutical</td>
<td>A (1)</td>
</tr>
<tr>
<td>Funded preferred over non-funded</td>
<td>A (1)</td>
</tr>
<tr>
<td>Institution just wants money coming in the door but federal are more</td>
<td>A (1)</td>
</tr>
<tr>
<td>prestigious</td>
<td></td>
</tr>
<tr>
<td>Federally funded are easier to get accommodated based on fiscal and</td>
<td>V (1)</td>
</tr>
<tr>
<td>intellectual property issues</td>
<td></td>
</tr>
<tr>
<td>There is no preference</td>
<td>V (1)</td>
</tr>
<tr>
<td>I don’t see a difference</td>
<td>V (1)</td>
</tr>
<tr>
<td>Not a good hierarchy, each department does its own thing</td>
<td>P (1)</td>
</tr>
<tr>
<td>Pharmaceutical can be easier because I don’t have infrastructure</td>
<td>P (1)</td>
</tr>
</tbody>
</table>

S-Specialty Center A-Academic Center V-VA Hospital P-Private Practice

Additional infrastructural barriers such as limited staffing and time were also noted by participants across several sites, as evidenced by the following responses:

We are assigned nurse coordinators and it appears that the nurse coordinators are always playing catch-up because they are so busy. And the institutional perception is that there are too many and they have to be rationed. So we have many studies that we want to get going and there is a push back institutionally because they say there are only so many nurse coordinators that you can use and you can allocate and you have to pay for it (03-S_P)

Faculty, they are all incredibly stretched thin. I think their limitation is similar to our limitation in terms of time (07-P_N)
One participant elaborated on the barrier of time in the following response:

It’s got to be a trial that a doctor is willing to remember. And then not only willing to remember but willing to spend some of their pressured time to bring up in the conversation with the patient. If it’s something where the doctor says I don’t mind you having that trial but he’s thinking to himself I don’t care about that then he’ll never offer it to anybody. Will be aware but barely remember. Will be aware of it and he would remember it on multiple choice questionnaire that it’s there but not probably not remember to spontaneously bring it up when he’s in front of it. And so you have to know the personalities of the doctors and what they are interested in doing (12-S_P)

This insight may be particularly relevant to those in a community or private practice setting and should be considered in the design of future prevention trials.

**Financial loss.**

Next, participants were asked about concerns related to financial loss if a patient moved care to participate in a prevention intervention trial as well as for suggestions to mediate if it was a concern. There was much heterogeneity in the responses both within and across groups as reflected in some of the responses from those working at a specialty center:

(Financial loss is) not really (a concern). I guess in theory there is but not really. I think ultimately that in prevention trials we really want to try to offer patients what we truly think biologically makes a lot of sense and as long as you continue following your patient I think that wherever a trial would be the most suited for someone is ultimately the best place for them to go (01-S_P)
Well it depends how you look at it...from the very bottom but irrational business level, yes because you are losing one patient but if you set up a system with the view of abundance in which you have scarce resources and the thinking is you need to rationalize more and keep the resources to yourself ...I think if you have a good trial, subjects will come in...with the complexities of the trial you can get it going (and) trials that you thought would not accrue at all you start (and get) 20-30% which is more than the zero percent. And I think if you have a well designed trial, well coordinated if you look from that perspective you could be adding, more enlarging than restrictive. So if looking at that bigger view then not just business model, if you have a bigger network it ultimately becomes advantageous then because it becomes available to more people (03-S_P)

No, not at all. For others, I don’t know of any way other than financial inducement (06-S_P)

As well the responses from those working at an academic center:

I’m an employee of the university I don’t feel a big loss if patients move. I look at it, and this is my opinion to the same extent if I think someone would be better served to have a treatment somewhere else, I’ll refer them there and so that being said, that’s probably bigger money loss then perhaps revenue generated through office visit for a clinical trial (08-A_P)

Yes. There’s no way I would send my prostatectomy patients to another facility. No way. The only thing I can think of is if it was a disease process that was not very easy to take care of or if it was something that like a lot of the community doctors didn’t want to deal with then that would be a good excuse for them to send the patient away and have someone else deal with it but prostate cancer for example is so pervasive. That’s potentially a big money maker. Not only for surgical reasons but you have the biopsy involved, you have the follow-up clinical visits to follow the PSAs. You know, all kinds of things so if you lose a prostate
Those working at a VA hospital had the most homogeneity within all groups, as well as the least concern regarding financial loss as evidenced by the following statements:

- Usually not. I mean I could see how there could be. At a VA there’s not, at all (02-V_NP)
- No. We have so much volume that they don’t care about that (04-V_P)

One participant hinted at the variance between clinical and business perspective, both of which cannot be ignored when planning future chemoprevention trials as the following quote demonstrates:

-(This) might be a little difficult question for me to answer because I don’t know the financials. At my level, I’m a plumber you know? What I do is a bit of urology or go to the operating room or go to clinic do my procedures and don’t think too much about the finance part of it. I guess no institution would like to lose a patient because more patients, more procedures, means more money. That’s as simple as that. From their point of view, it’s a different ball game altogether. From my side it’s entirely clinical and that’s finances. So we need to kind of merge the two, find a median path (05-V_P)

A participant from private practice provided insight into several issues including loss of control of the patient and financial concerns with the following response:

- It’s not, as long as they are coming back. If you look at bigger studies you know, you are not going not get the community involved within the design. But if you want to finish it early and get the cases, it’s your job to send it to them. You can do this
without them losing their control of the patient. The community physician does not like to give up the case because this is how they make their money (11-P_P).

These could be possible reasons for the lack of referrals from community physicians for the current trial. These reflections should be considered for future projects as well. A summary of the range of responses can be found in Table 20.

**Table 20. Financial loss (n=9)**

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I guess in theory there is but not really</td>
<td>S (1)</td>
</tr>
<tr>
<td>No</td>
<td>S (1)</td>
</tr>
<tr>
<td>It depends how you look at it</td>
<td>S (1)</td>
</tr>
<tr>
<td>At my level no but I don’t think too much about the finance part of it</td>
<td>V (1)</td>
</tr>
<tr>
<td>We have so much volume they don’t care about that</td>
<td>V (1)</td>
</tr>
<tr>
<td>Usually not</td>
<td>V (1)</td>
</tr>
<tr>
<td>I’m an employee of the university, I don’t feel a big loss if the patients move</td>
<td>A (1)</td>
</tr>
<tr>
<td>Yes</td>
<td>A (1)</td>
</tr>
<tr>
<td>Not a concern as long as they are coming back</td>
<td>P (1)</td>
</tr>
</tbody>
</table>

S-Specialty Center  A-Academic Center  V-VA Hospital  P-Private Practice

**Future participation-institutional perspective.**

The physician participants were next asked to consider factors from an institutional perspective that would increase the likelihood of participation in cancer prevention clinical trials in the future.

Responses were varied and though this question was designed to elicit factors from an institutional perspective, both individual and structural factors emerged as evidenced by the following responses:
(Having) dedicated staff. I think that’s the critical point, need to have dedicated staff (and) that institution feels is important to do prevention trials and allocate them. Institutionally (03-S_P)

Talking about developing cancer trials, we need more faculty in cancer prevention and control (06-S_P)

Being willing to set up and open dedicated clinical research units. Which means clinic space, clerical staff, study nurses, and research staff support with the regulatory process. Currently, everybody does it by himself or herself, the investigators. It stifles progress. There are lots of patients who are interested in trials but (there are) insufficient resources to help investigators bring trials to patients and accommodate patients in trials (04-V_P)

I’m not in that division (but) I think that the only thing that prevents them from doing more studies is the lack of funding. If they had more funding I think they would be doing more (09-S_N)

A summary of themes that developed included increased infrastructural support ranging from staff (both clinical research coordinators and faculty) to dedicated clinic space, as well as the necessity of funding and can be found in Table 21.

Also mentioned were the current economic climate and its impact on healthcare as well as the interconnectedness of clinical activity and research as evidenced by the following response from one participant:

I think that the financial climate...in the US overall right now is ...with the recession, plays a role because right now people aren’t going to the doctor much because they don’t have as much income. People are fighting for funded patients to come in. The clinical activity is what pays for research really... it keeps the
doors open and the research dollars don’t keep the doors open it’s the clinical dollars that do and so we’re encouraged to do more clinical activity and the thing that suffers of course is the things that don’t make money. Research typically doesn’t make the type of money, clinical does. So, that is not encouraged as much I don’t think as it could be. What is encouraged, I think sometimes are doing clinical trials that pay like some of the industry sponsored things. That’s more encouraged because that’s going to put some money in the bank so to speak. I don’t feel like there’s always a genuine interest in the research itself. I think it’s in the dollars that research can bring in. I think that clinical research is more of a priority because we do more clinical work here and then even a higher priority is doing clinical trials that pay (10-A_P)

Table 21. Institutional factors/future participation (n=12)

<table>
<thead>
<tr>
<th>Comment</th>
<th>Site Type (Frequency)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased advertising</td>
<td>S (1) V(1)</td>
</tr>
<tr>
<td>Dedicated staff</td>
<td>S (1) V(1)</td>
</tr>
<tr>
<td>Dedicated research units with dedicated research staff</td>
<td>V(1)</td>
</tr>
<tr>
<td>Increasing patient awareness about trials</td>
<td>V (1)</td>
</tr>
<tr>
<td>Financial incentives for the patients</td>
<td>V (1)</td>
</tr>
<tr>
<td>Less paperwork</td>
<td>V (1)</td>
</tr>
<tr>
<td>Need more cancer prevention faculty</td>
<td>S (1)</td>
</tr>
<tr>
<td>There has to be funding to pay it</td>
<td>A (1)</td>
</tr>
<tr>
<td>Less ambiguity regarding significance of the disease and it’s treatment in the medical community</td>
<td>A (1)</td>
</tr>
<tr>
<td>It’s ultimately going to depend on the urologist’s perception of the benefit.”</td>
<td>S (1)</td>
</tr>
<tr>
<td>The institution has to feel it’s important to do prevention trials</td>
<td>S (1)</td>
</tr>
</tbody>
</table>

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The importance of incentives and advertising were also noted by participants as the following responses demonstrate:

For (the) institution it would be an incentive to work harder and recruit more subjects (05-V_P)

I think making sure they are publicized more (01-S_P)
The final responses related to research question three (How do these factors vary depending on the practice site/area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices?) and consider how practice area may impact the feasibility of participating in a prostate cancer prevention intervention trial.

**Influence of the organization.**

Participants were asked to discuss how the organizational infrastructure both facilitates and constrains participation in research/clinical trials.

**Facilitation.**

Responses related to the facilitation of research included a consideration of the types of patients seen at each site and the appropriateness for them to participate in prevention clinical trials as the following responses demonstrate:

We see a fair portion of patients with unique clinical type dilemmas or genitourinary malignancies or premalignancies, which allow for participation in clinical trials and often times patients are seeking trials when they come to us (01-S_P)

There’s a big referral base to the University for treatment, so it gives an opportunity to accrue patients to clinical trials (08-A_P)

To the importance of integration of the research within usual clinical practices was also seen as important as evidenced by the following responses:
The research is actively integrated within our surgical practices (01-S_P)

The other thing that we have that works really well from an infrastructure standpoint is that we do actually discuss prevention (08-A_P)

These trials we’re doing you know are for disease processes that I’m going to be dealing with anyway so it makes sense. We can just work it in to the natural flow (10-A_P)

Also reported was the importance of having an environment that fosters research. The presence of support was expressed in various ways and includes staffing, regulatory affairs assistance and administrative backing, as the following responses suggest:

We have research staff that are present in our clinics (which) makes it that much easier to obtain consents and to conduct even questionnaires or surveys with patients. I think similarly we have an active list of our clinical trials and protocols that we’re that patients may be suitable for in the clinic, and therefore, anytime we see patients we attempt to see if they would be candidates for one of these trials. So, I think the whole environment is fostered to consider participation in studies when possible (01-S_P)

The organization has mechanisms including a clinical trial office which facilitates putting studies through to get the required regulatory requirements...we have a research nurse who also assists not only in carrying the trial through but putting it together and thirdly our mandate and one of our missions is to do research (03-S_P)

An IRB that helps us... research is encouraged by the dean; there are dean’s grants that are awarded yearly to facilitate and to encourage research. There’s an office of research affairs that basically makes sure that every research project that’s going here is functioning as it ought to and is compliant with you know
any standards that are put forth either nationally or locally by the IRB or the office of educational affairs to make sure they’re compliant (10-A_P)

The importance of building and maintaining positive relationships with physicians within the community was also noted, as reflected in the following comments:

I think we do try and maintain a good rapport with referring physicians in the community in order to keep them aware of what’s going on (08-A_P)

We also have “friendly physicians” who are not afraid of losing patients. We can keep the care within our system and the patients do not have to travel far (to participate in clinical trials) (12-S_P)

One participant noted that though infrastructure existed, this only allowed but did not help with the work of the study as seen with the following response:

There’s nothing really to facilitate in any way. There’s infrastructure: IRB, research office doesn’t actually help you do the study, it just allows you to do it (02-V_NP)

Another participant noted a lack of institutional support with the following response:

No particular efforts on behalf of institution to facilitate research…. the institution is not very facilitating (04-V_P)

**Constraint.**

More specific responses related to the how the organizational infrastructure constrains participation in research will now be
presented. The most frequently emerging theme, noted across all site types was time or lack thereof as noted in the following responses:

I think part of it is clinical volumes being such, sometimes it becomes difficult to take the time to discuss all of the various studies that you have available to patients. And sometimes with the volumes you don’t think about it or consider putting people on trial. So I think that it’s a little bit of two way street in the sense that being actively busy gives you opportunities to see more patients who may be suitable. Similarly (it) makes it difficult sometimes to actively try to recruit as many patients as possible for these studies (01-S_P)

Resources would be me actually having the time to focus on patient recruitment, patient identification and managing that piece of patient through a study. So when I say we lack resources we lack that type of resource. It’s not that I’m not interested but I’m pulled in too many directions. We’re a real small department and just don’t have that critical mass to do all things we need to do and still do a really quality job in clinical research in my book (07-P_N)

Time definitely. Time dedicated to the encounter...sometimes not having adequate support staff, clinical trial coordinators who are readily available. If you are scrapped for time and you know you potentially could accrue somebody, but yet you go to get somebody and they are not in the office because they are off site with someone else it’s like ok, we’ll make it a phone call then. I think that we all know that your best attempt at getting somebody is after the physician has talked to them and when they are there in the office and quite often if you can’t accrue on site, it’s going to be hard to accrue them over the phone or in any other way without it sounding as though it’s coercive (08-A_P)
Additional themes that emerged were documentation requirements, limited resources and financial related issues. As the quotes will demonstrate, there is often overlap in these factors:

There is this huge amount of paperwork. Essentially you have to have someone whose job it is to do the paperwork. It makes it logistically and monetarily harder to do it (02-V_NP).

High volume of nonresearch patients strains all resources—time, space, laboratory, radiological and pharmacy resources... (Research), it’s a side kick to the general operation of the hospital. It’s not a research institution. It’s accommodated on an individual base based also on available monetary resources (04-V_P).

We need more support.... More clinical trials personnel....more coordinators and regulatory (staff). It constrains because we don’t have enough staff. Lack of adequate personnel, it can slow things down. You need clinical trial support to help with screening, consenting, regulatory and also obviously once the patients are on study making sure everything is done right. In other words, the more clinical trials support you have the more patients you are likely to put (09-S_N).

I think it’s just that everybody is so busy clinically that it makes it difficult sometimes to participate in research to the extent that you could. We can’t make ourselves less busy, because need to be busy to pay the bills (10-A_P).

We have some infrastructure that could facilitate (research) if people wanted to do it. The problem, the difference between me doing this (and others in private practice) is that I send my cases (to you). I don’t need any financial support. This way I can participate as I want but don’t have to put investment into it (11-P_P).
**Then and now.**

Participants were also asked about participation in research at other institutions they had worked and to describe similarities and difference to their current place of employment. Not all had participated in research at other institutions. Those currently working at specialty centers noted some similarities in the responses below:

I think on the whole scheme of things the framework is essentially the same. We have research coordinators, we have research statisticians that we work with... clinical questions may vary but at the end of the day when you put them together it is close to similar. (That) made it that much easier (when I came here) (01-S_P)

(I am) coming Europe and North America because I came from Europe...I don’t see it as a whole lot of difference. Basically the bottom line is the same (05-V_P)

And differences were noted across most site types. Most commonly noted was variance in support staff and other resources as the following quotes suggest:

I will say that I think at the current institution there is less support staff. So I think PIs have to take a more proactive role and be involved with more of the day to days of how a study is conducted and the way it’s being registered and the way patients are followed and following specific end points or study (01-S_P)

At the previous VA I worked for (had) internal administrative constraints, a lower staffing to patient ratio, much more limited diagnostic services, availability, significantly inferior parking facilities for patients (04-V_P)

Well, at the NCI, it’s the government’s branch of medicine so resources were essentially unlimited while you were there because everything done there is done on protocol. So it’s
already approved so to speak ...it’s all intramural. It’s almost like having a credit card for research (10-A_P)

**Changing with the times.**

Those working in specialty centers also noted changes over time, most notably changes in funding as well as regulatory requirements as described in the following response:

As time goes by there is less and less and less money. (When I started) resources were almost limitless and you could do any research you wanted because there was a lot of money. Now money is very tight. (Previously) one could do research on almost anything and now it is more tough and one has to prioritize. The point is that there are less and less resources available (03-S_P)

Things have gotten more complicated for everybody now with HIPPA, IRB and all the regulations (06-S_P)

**Appropriateness.**

Participants were also asked if the trials that were available to them were appropriate for the population that they serve and to elaborate as to how this was or was not so. Emergent themes and factors considered were the appropriateness of available patients for trials, risk, resource demands, reception by potential participants and the ability to “work” the study in to the usual care routine as noted with the following responses:

We definitely should do a better job in looking at more innovative trials. About 10-20% of my patients are seen possibly for screening, they are somewhat more appropriate in a sense that they already are at the higher at the level where the risk of having prostate cancer is higher, and they are in the
system. There are biomarkers that one can use now to then define whether there is cancer or not (03-S_P)

Yes, so far. They are relatively low risk and did not require extraordinary resources for execution. Regarding prostate cancer prevention (we’ve had a) relatively good reception among potential candidates (04-V_P)

Yeah, I think so; it allows me to participate in research that has a translational bent and also be able to work it into my regular routine of seeing patients (10-A_P)

*Disruptions and integration.*

In the final question to address this objective and research question, participants were asked about their experience enrolling a patient into a clinical trial and encouraged to discuss any disruptions related to enrolling them at their current site of healthcare delivery as well as referring them elsewhere. In regards to enrollment at the current site of healthcare delivery, it is not generally seen as disruptive mainly due to the structure and resources already in place and integration with current or usual care. Enrollment in research was also seen as a way to provide a more comprehensive level of care. These results were reported across all site types, as seen with the responses below:

I think if you integrate it into your discussion when you see a patient and similarly as long as the logistics of the trial are such that you have research coordinators that are readily available (it is not disruptive). I really don’t think it hinders or impacts the flow of a clinic or how it’s integrated into your practice. In fact I
think it makes it that much more comprehensive and appealing to patients (01-S_P)

Not that disruptive if you have a good coordinator (02-V_NP)

The way we do it here, it’s not very disruptive. They come to the clinic and they have a problem already and we’re seeing them and the physician can say by the way we have this study (you may want to consider) (06-S_P)

I don’t think it disrupted my care with them at all because these particular trials didn’t affect what I did at all (10-A_P)

One participant clearly noted that it could be disruptive yet this was lessened with flexibility and dedicated staff as elaborated with the following comment:

Trying to fit (research patients) between other patients, in order to accommodate them or research candidate patients is often cumbersome. And (it) requires significant flexibility not just on my behalf but on other ancillary staff: study nurses, coordinators, secretary check-in check-out people, research pharmacy, labs, etc. We cannot have a research clinic every day. It’s not a research institution. The research patient has to be treated personally with special attention. (He) cannot be left to generic clinics and non dedicated staff. It backfires. (04-V_P)

Another participant expanded on the previously mentioned notion of time, as well provided a possible model to consider for future trials with this response:

I don’t know about the word disruptive but it takes more time. The current study is not disruptive for us because the person comes in who already has the time set aside for the conversation. Basically what happens is the urologist does the biopsies (and) when he gets the biopsy back and it shows that it’s PIN he’s going to do one of two things: he’s going to say that’s benign we’ll see you in 6 months just to follow up...or he’s
going to say well, it’s benign but you know it’s kinda worrisome we’ll send you over to the cancer center... they have some trials. But if one doctor was doing all that and they had three minutes to talk to you, their talk would be well it was benign see you in 6 months versus a long(er) conversation about green tea. You know which way they are going to have to go. Otherwise if they (spend) 45 minutes (instead of three) then however many people they were going to have to see in those 45 minutes, they are backed up (12-S_P)

In regards to referring patients to other sites for participation, there was vast heterogeneity in responses with positive and negative scenarios noted by respondents from all site types:

It involves much more effort... there’s more opportunities for things to go awry... any time you add variables that could go wrong, it can go wrong (01-S_P)

There are different types of constraints because they have to package the patient information including PHI and test results and so forth in such a way that it can be it becomes portable and sometimes there are hybrid situations. One has to be creative. One has to be willing to be flexible and work with all systems, but that’s the price for clinical research (04-V_P)

There’s a couple of variables there, it would depend on the facility where I am sending them to. How much confidence I have in that facility and I guess if I had to do that the best way I would do it is to speak to the person whom I am referring him to that facility so that he or she knows that I am getting a patient from XXX this is what he is supposed to be doing so that you know we communicate (05-V_P)

Some at risk populations, it is disruptive because they have to do something they wouldn’t normally do to be seen. So, it does change their daily routine (06-S_P)

It’s just an email and phone call to the coordinator. When you have a good coordinator, that’s easy to do. Patient doesn’t get lost they have one point person you know, they know exactly
what you need they send it to you. They call the patients. You know, the transition was smooth (11-P_P)

In closing, participants were asked if there was anything else that hadn’t been discussed that they felt was important for me to know. Perhaps most notably, the issue of limited time and the importance of infrastructure surfaced again as evidenced by the following responses:

No, I think the set up that we have here is very ideal. It makes it easy for me to do it. There’s really very little for me to do regarding the trial and that influences my participation more than anything else because I am busy taking care of patients. The last thing I want to do is have to do a lot of paperwork to keep people on the trials and so that would be the thing that made me not participate-if we somehow lost the infrastructure that we have I’d be less likely to participate because I just couldn’t keep up with all the paperwork (10-A_P)

Don’t underestimate how busy the doctors are. Another thing to consider for future prevention trials, that they have that dedicated slot, coming in to talk specifically about trial versus something being added on to what was already in place so if planning for future trials maybe keeping that type of thought process in place might help (12-S_P)

Also relevant was commentary related to increasing participation from the community at large as noted by this participant:

If you need bigger participation from the whole group it has to be a little but more organized. It has to be presented to the group and it may have to go through the research coordinator. If you want bigger, you are dealing with many urologists and every one of them sees 100-120 patients a week. If you want this volume you have to talk with the organization itself (11-P_P)
Additionally, they were asked if there any other factors that influenced their willingness or ability to participate in cancer prevention intervention trials that had not yet been discussed. Some respondents reinforced comments made earlier such as:

I think at the end of the day my drive to want to put patients on specific chemoprevention trials is believing that they are at increased risk of something developing and that ultimately from a biological standpoint (the) chemoprevention agent makes biological sense and is being given or administered at a time point where prevention is possible (01-S_P)

I think the willingness to participate in general with the practitioners is an understanding of what it means, prevention. Because many don’t understand it, that there are different levels of prevention. It could add to the quality of care, participating in those trials and (also) to understand the mechanisms of the drug because many don’t understand them (03-S_P)

Others noted regulatory challenges and difference in priorities that had not been noted previously as seen with the next response:

Well, there are organizational problems I guess you could say. Difficulty with the regulatory affairs certainly...difficulty dealing with people within the institution who don’t care about research and patient care. That’s a big one right there. And I think that’s getting more of an obstacle. It’s just the volume of work. It’s business versus patient care and research, totally trying to meet different ends. And then the whole regulatory thing, the HIPAA and all the regular stuff, it gets impossible (06-S_P)

Also not specifically noted previously was the influence of the physician’s interpretation of biopsy results and how this may influence participation in a cancer prevention clinical trial as described by one participant:
What makes or breaks whether a physician will even mention a trial is their interpretation of how significant the biopsy findings are. So if they think HGPIN - it’s benign it’s one thing. But (if) interesting finding- it’s going to be a whole different interpretation and sense of what needs to be done. And then I’m sure it’s also comes down to what the doctor’s interpretation of what the patient wants to hear. If you are going to design this type of trial I think you really need to get feedback from the people that are going to be involved in it, at least on a PIN sort of prevention trial. (And) the urologist because they’re the ones who do the biopsy, they’re the ones who interpret it. They’re the ones whose name is on the pathology report. And then it comes to how they interpret or respond to that, if they’re one that will that it’s not cancer so instead of yearly we’ll see him at 6 months or if they say whoa something’s starting up (12-S_P)

Possible challenges at the institutional level between the dual role as a surgeon and researcher and financial considerations were also noted in the following response:

Nobody is going to give a physician 40% research time, a surgeon, when I can go bill in a quarter what the grant is going to be for the whole 3-5 years. The institutions like, you gotta be kidding me, my surgeon’s going to the OR. I think that prevents a lot of good research from happening and it prevents a lot of physicians who have an interest in research from being able to pursue that as their career goes on. And, you have physicians who have done a lot of preparation in terms of research preparation and to be in academia who eventually fall out of academia for that very reason. The bottom line (is) I can’t get the grant because I’m too busy taking care of patients. And that’s what research is for, supposedly (10-A_P)

Finally, some comments shed light into the private practice arena, suggesting a role for future urological prevention studies, and noting future potential challenges when involving those physicians in private practice in future cancer prevention intervention projects:
A urologist can’t back down from the bread & butter urology that men need. So I have 2 groups of patients. I have patients that have cancer that I operate on and follow them along and guide them through that whole process and that’s what I like to do and that’s why I do what I do. But I’ve got this whole cohort of patients that I follow for prostate cancer screening and BPH and they come see me on a regular basis. They get to know me and how the practice is. I think definitely the group that I develop the relationship with over time is most appropriate place for a prostate cancer prevention trial. And so the cancer prevention, I don’t think should be focused on tertiary/cancer surgeon but more on my primary role as a urologist. So that’s where cancer prevention (needs to be) and with primary care doctors as well. But getting them interested, that’s a whole different story (07-P_N)

The important thing, the way to do that is you have to have a protocol that is logical. People like it and agree upon it and want to participate. One of the major reasons that people do not like to participate in the project done in centralized area is that they lose control of the patient (11-P_P)

**Section III-Qualitative, Ethnographic Findings from Participant Observation**

This collection of data focused primarily on the interactions between the physician and research team in order to better understand the internal working mechanisms of each facility and the process of research as it occurred at each local healthcare site. Observations were conducted in the backstage (Ellingson 2005) of the clinic environment, not in the presence of any patients or study participants. For consistency in data collection, an observational checklist was used to compare observations across sites and included items such as the use of clinical trial alert systems, the availability of
dedicated research staff, and communication between staff related to potential eligibility to participate in a study that were not collected by other means. During this time I was also fortunate to be able to engage in conversations with research coordinators, a research nurse, a regulatory specialist, a grant administrator and a research manager. I was also able to draw upon my familiarity and comfort level in the clinical arena and report on observations that were made beyond what was originally planned. Due to privacy and other considerations, this methodology was not utilized at VA medical centers or any private practice/community offices. At these sites this information was obtained when possible directly from the key informant during the semi-structured interview or via informal conversations with the parties noted above.

**Use of Clinical Trial Alert system (CTA).**

None of the specialty centers used a CTA system to alert practitioners about trials for which a patient could potentially be eligible. During the observations I had the opportunity to speak with coordinators and research nurses. When asked about the use of such a system, several expressed some concern that though a CTA may alert the physician regarding potential eligibility to participate in a trial (therefore increasing awareness), it would only be a starting point to enrolling a patient and would not eliminate the detailed screening for
eligibility that would follow and was usually completed by them, prior to physician involvement with the patients. Echoing comments from the coordinators and research nurses, the physicians also expressed reservation about the potential for a system (CTA) to accurately identify the appropriate patients for participation, noting that some element of human involvement would still be needed to verify the system’s results. Several physicians voiced an interest in this type of alert during the interview; however, also expressed skepticism as the following quote reflects:

(It) May be my own lack of exposure but I’ve never seen one that would work well, you have to pull together a lot of data points. Not saying it’s not possible, it’s just not easy (02-V_N)

Respondents from one center did note a “flag” that was supposed to be used to identify subjects currently participating in research projects. Not all staff at this facility was aware of this feature suggesting that it was not universally or consistently utilized. Another specialty center did not use a CTA; however, the participant noted that their recent transition to an electronic medical record (EMR) would make it easier to keep referring physicians abreast of what was happening with a patient that had been referred for clinical trial participation:

With the new electronic medical records and computerized scans you know you can do a lot just looking at that which should make it easier to stay in contact (12-S_P)
All respondents from VA sites reported that a CTA was not utilized and two out of the three also reported that a “flag” specifically identifying research patients was not in use. One VA site participant did report the use of such a system as the following response demonstrates:

I have patients details on the electronic medical record (EMR) (and) the first thing that pops up is (notification that) this is a research patient (05-V_P)

The physician at this site was not aware of how accurate or consistently this feature of the institution’s EMR was used. However; the responses suggest variance even within one type of system. The academic centers were not utilizing any form of CTA system or even an EMR at the time of data collection.

**Dedicated research staff.**

The importance of dedicated research staff cannot be understated as was evident from the interviews and observation conducted for this project. Participants at all sites noted the critical and valued role of research staff as the following responses demonstrate:

All that matters is who your research coordinator is. That’s basically 99% of it. The other things may differ a little but the research coordinator is all that matters (02-V_N)

I think the set up that we have here is very is ideal...(the coordinator) takes care of everything and there’s really very little
for me to do regarding the trial and that influences my participation more than anything else because I am busy taking care of patients. The last thing I want to do is have to do a lot of paperwork (10-A_P)

When you have a good coordinator, it’s easy to do (11-P_P)

Clinical trial coordinators were noted most often followed by regulatory support staff with participants often noting that without this support, participation in clinical trials would not be possible as the following response illustrates:

That would be the thing that made me not participate-if we somehow lost the infrastructure that we have I’d be less likely to participate because I just couldn’t keep up with all the paperwork (10-A_P)

There were various ways that this staff was structured and utilized depending on the site. Some were integrated within the surgical department while others were supported via a clinical research or other research department within the institution. Even within systems that would seemingly be similar (VA hospitals) there was no one way to participate in research. The participant in private practice did not have his own dedicated staff; however, noted that depending on the trial they were available via various scenarios allowing him to make participation in research projects a part of the comprehensive care that he provides to his patients.
**Communication between staff.**

During the time that participant observation was conducted there was minimal discussion between physician and research staff in regards to the possibility of participation or enrollment of specific patients in a clinical trial. In one instance a clinical trial coordinator made the physician aware that a patient was potentially eligible to participate in a clinical trial and then reminded him of the inclusion criteria before the physician entered the patient room. When research coordinators were observed in the clinic setting, it was noticed that they functioned very independently from the physician, relying more on communication from nursing and other staff (other coordinators, scheduling specialists, medical assistant, etc.) regarding patient status and other details necessary to identify patients that may be eligible to participate in a particular research study. In one specialty center there was a very collegial atmosphere between the research coordinators who often made each other aware of the specifics about a patient, which were then used to help determine potential eligibility.

At some sites it was difficult to discern if the minimal discussion with the physician could be attributed to the presence of an “outsider” with the usual flow of practice interrupted by my presence or if indeed this was the norm in that particular setting. Utilizing the observation
checklist as a guide, a summary of the data collected during actual observations can be found in Table 22 below.

Table 22. Participant observation (n=6)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Site type (times observed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of CTA</td>
<td>S (0) A (0)</td>
</tr>
<tr>
<td>Dedicated research staff</td>
<td>S (3) A (3)</td>
</tr>
<tr>
<td>Consideration of patient for participation in research study by physician</td>
<td>S (0) A (0)</td>
</tr>
<tr>
<td>Consideration of patient for participation in research study by other staff</td>
<td>S (4) A (0)</td>
</tr>
<tr>
<td>Communication between staff related to eligibility to participate in a trial</td>
<td>S (2) A (1)</td>
</tr>
<tr>
<td>Definitive plans to present a clinical trial to a patient</td>
<td>S (0) A(0)</td>
</tr>
</tbody>
</table>

**Beyond the checklist.**

During my time in the various clinics, observations were made that were not initially included on the observation checklist; however, further expanded my understanding of how research was conducted at each of the various sites. This helped to identify the variances at each location and to glean insight as to what best practices for a future trial may be. Of great interest to me was that though research infrastructure was in place in varying degrees at all of the sites where observation occurred, many of those involved in the work of research (nurses, coordinators, physicians) found the structure to be more prohibitive than helpful. This was mainly due to the many levels of documentation that needed to be completed at varying steps in the observation process.
research process. Though thorough documentation was recognized as necessary and important, many coordinators in particular felt that there were redundant steps that could be streamlined, resulting in a more efficient use of their time while still adhering to the necessary guidelines that are considered good clinical practice.

Also of interest was that though the study had a very specific list of inclusion and exclusion criteria that was to be used in identifying and pre-screening appropriate subjects for participation, one coordinator reported, “We have our own set of pre-inclusion criteria.” This was echoed by study teams at several of the sites who reported that things like overall health history and presence of other comorbidities, transportation, flexible job schedules (which would allow for adherence to required monthly study visits), family support, education level and perceived patient interest were often considered before the actual study inclusion/exclusion criteria were reviewed or the possibility of participating was presented to the patient. This unofficial set of criteria often eliminated potential subjects that otherwise may have been interested and/or eligible to participate in the trial. It is unclear from the data collected for this research how this ultimately impacted the screening and recruitment numbers reported by each site in the ancillary study; however, it did most likely result in the underreporting and elimination of potential participants.
A final observation was that research visits occurred primarily in one of two modes at the different sites. One model was that patients were identified by research coordinators or physicians and approached about participation in the trial in clinic on the same day that they were present in clinic for another reason. If approached then about trial participation, the result was often a conflict of time for all parties involved. If interested in participating, the visit was then extended and longer than the patient and staff had planned resulting in a competition for time and clinic space as well. The second model was that patients were identified in advance, while away from the clinic and then contacted about participation. If they expressed an interest and met initial criteria then a research specific visit was scheduled. Patients then came to the clinic for a future appointment where time and space were dedicated to them. The second model seemed to work more effectively in that the patient as well as the research team was better able to prepare for the visit. This lessened the competition for time and space at the initial visit. Subsequent visits were all arranged in advance and there seemed to be less competition for resources because of this.

An awareness of these additional factors may help to further identify the best sites for future cancer prevention trials and should be considered in the design of upcoming trials. Additional insights about
the overall clinic environment, the patient population at the various research sites and how each may influence future trials are found in Chapter Five.

**Section IV-Quantitative Data from Surveys**

**Participants.**

*Participants* were asked about involvement in clinical trials and all reported previous involvement in one or more (range: 3-100) clinical trials. Types of involvement ranged from recommending that a patient participate in a clinical trial to actually participating in the design of a clinical trial. The range of responses and more specific descriptions about the types of involvement are further described in Table 23. The reasons for involvement in clinical trials were also captured and the variance in responses can be found below in Table 24. The main reason noted for participating fell into four broad categories including altruism and benefit for patients (n=4), advancing medical science/scientific knowledge (n=4), education/keeping current (n=1) and personal interest in clinical trials (n=1). More specifically in regards to participation in prevention trials, *participants* reported prior participation in a range of 1-12 (mean=3.5) trials each. The reasons noted for participating in prevention trials are found in Table 25 and the main reason for
participation in prevention clinical trials verbatim as reported by participants can be found in Table 26 below.

Table 23. Types of involvement in clinical trials (n=9)

<table>
<thead>
<tr>
<th>Types of involvement in clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have participated in a clinical trial (therapeutic or prevention) in other ways. If so, please explain</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
<td>I have had patients inquire about clinical trials (therapeutic or prevention)</td>
<td>5</td>
<td>56</td>
</tr>
<tr>
<td>I have participated in the design and implementation of a clinical trial (therapeutic or prevention)</td>
<td>5</td>
<td>56</td>
</tr>
<tr>
<td>I have recommended patients participate in a clinical trial (therapeutic or prevention) administered by others.</td>
<td>6</td>
<td>67</td>
</tr>
<tr>
<td>I have had patients enroll at a clinical trial (therapeutic or prevention) at another location because it was not locally available.</td>
<td>7</td>
<td>78</td>
</tr>
<tr>
<td>I have recommended patients participate in a clinical trial that I administer.</td>
<td>8</td>
<td>89</td>
</tr>
</tbody>
</table>

Table 24. Reasons for involvement in clinical trials (n=10)

<table>
<thead>
<tr>
<th>Reasons for involvement in clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advancing Medical Science</td>
<td>8</td>
<td>80</td>
</tr>
<tr>
<td>Providing access to a novel treatment</td>
<td>9</td>
<td>90</td>
</tr>
<tr>
<td>To expand available services</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>Challenge</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Variety</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>To earn extra income for my practice</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>
Table 25. Reasons for participating in prevention trials (n=10)

<table>
<thead>
<tr>
<th>Reasons for participating in prevention trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advancing Medical Science</td>
<td>9</td>
<td>90</td>
</tr>
<tr>
<td>Providing the best possible care</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Providing access to a novel treatment</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>To expand available services</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>To earn extra income for my practice</td>
<td>1</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 26. Main reason for participating in prevention clinical trials (n=9)

<table>
<thead>
<tr>
<th>Main reason for participating in prevention clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advancing Medical Science</td>
<td>4</td>
<td>44</td>
</tr>
<tr>
<td>Interest in their effect</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Impact a premalignant condition before it develops into malignancy</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Prevent cancer suffering</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Prevent cancer</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>A personal belief in the benefits of prevention</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>To offer patient chance to prevent disease</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>Improve healthcare delivery for mankind</td>
<td>1</td>
<td>11</td>
</tr>
</tbody>
</table>

Somewhat in contrast to work by Weinberg et al. (2004) that reported survey participants would be much more likely to enroll patients to treatment than screening, diagnostic or prevention trials, this group of respondents was interested in participating in prevention trials for the reasons noted above. The factors influencing the participants and their decision to participate in any type of clinical trial are found in Table 27.
Table 27. Factors influencing participation in any clinical trial (n=10)

<table>
<thead>
<tr>
<th>Factors influencing participation in any clinical trial</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influence on clinical care process</td>
<td>6</td>
<td>60</td>
</tr>
<tr>
<td>Time</td>
<td>6</td>
<td>60</td>
</tr>
<tr>
<td>Financial Incentives</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Cost to you/your institution</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Paperwork requirements</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>Staffing</td>
<td>4</td>
<td>40</td>
</tr>
<tr>
<td>Concern for your patients well-being</td>
<td>7</td>
<td>70</td>
</tr>
<tr>
<td>Introduction of another care provider or decision maker</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Requirements of the research protocol</td>
<td>7</td>
<td>70</td>
</tr>
<tr>
<td>Institutional support</td>
<td>4</td>
<td>40</td>
</tr>
</tbody>
</table>

These factors reported by *participants* and noted in Tables 24-27 as influential in their participation in all types of clinical trials are similar to those previously reported in the literature such as the presence of incentives and disincentives (Cohen 2009; Yates 2003), staffing challenges (Meropol et al. 2007), documentation and paperwork requirements (Comis et al. 2000; Crosson et al. 2001; Orozco 2009; Weinberg et al. 2004) and the presence of research infrastructure or support (Al Refaie 2011; Somkin et al. 2005).

**Non-participants.**

*Non-participants* were also asked about their prior involvement in clinical trials and this ranged from addressing patient inquiries about clinical trials to participating in the design and implementation of trials. The responses related to involvement in all clinical trials can be found in Table 28.
Table 28. Types of involvement in clinical trials (n=4)

<table>
<thead>
<tr>
<th>Types of involvement in clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have had patients inquire about clinical trials (therapeutic or prevention)</td>
<td>3</td>
<td>75%</td>
</tr>
<tr>
<td>I have recommended patients participate in a clinical trial that I administer.</td>
<td>1</td>
<td>25%</td>
</tr>
<tr>
<td>I have recommended patients participate in a clinical trial (therapeutic or prevention) administered by others.</td>
<td>4</td>
<td>100%</td>
</tr>
<tr>
<td>I have participated in the design and implementation of a clinical trial (therapeutic or prevention).</td>
<td>1</td>
<td>25%</td>
</tr>
<tr>
<td>I have had patients enroll at a clinical trial (therapeutic or prevention) at another location because it was not locally available.</td>
<td>1</td>
<td>25%</td>
</tr>
</tbody>
</table>

Of those responding to survey question seven, two respondents reported participation in one or more therapeutic or prevention clinical trial while two reported no prior participation. Reasons for involvement in clinical trials as noted by respondents are found in Table 29 which follows.

Table 29. Reasons for involvement in clinical trials (n=2)

<table>
<thead>
<tr>
<th>Reasons for involvement in clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advancing Medical Science</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>To expand available services</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Challenge</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Variety</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>To earn extra income for my practice</td>
<td>1</td>
<td>50%</td>
</tr>
</tbody>
</table>

Similar to participants in the PCPICT, advancing medical science, expanding available services and earning extra income were all noted.
Additionally, *non-participants* note challenge and variety as two additional reasons for prior involvement in clinical trials. The main reasons noted for participation were to earn income for the practice (n=1) and advancing medical science (n=1).

Two *non-participants* reported that they have participated in prevention trials as an investigator or other study personnel noting the reasons shown in Table 30.

Table 30. Reasons for participating in prevention clinical trials (n=2)

<table>
<thead>
<tr>
<th>Reasons for participating in prevention clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>To earn extra income for my practice</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Providing the best possible care</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Advancing Medical Science</td>
<td>1</td>
<td>50%</td>
</tr>
</tbody>
</table>

The main reasons reported for previously participating in prevention clinical trials were earning extra income for the practice and providing the best possible care, which were different than the main reasons noted by *participants* who most commonly reported advancing medical science. This differential would benefit from further exploration if more direct inquiry (interviews) with non-participants was possible. Additionally, factors influencing the decision to participate in any type of clinical trial can be found in Table 31.
Table 3. Factors influencing the decision to participate in clinical trials (n=2)

<table>
<thead>
<tr>
<th>Factors influencing the decision to participate in clinical trials</th>
<th># responses</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Cost to you/your institution</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Paperwork requirements</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Staffing</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Concern for your patients well-being</td>
<td>1</td>
<td>50%</td>
</tr>
<tr>
<td>Institutional support</td>
<td>1</td>
<td>50%</td>
</tr>
</tbody>
</table>

Staffing, documentation and paperwork requirements, and research infrastructure or support are factors similar to those reported by the participants in the PCPICT and prior literature as discussed above. The concern for patient’s well-being is a factor influencing participation which has been previously identified by Weinberg et al. (2004).

Concerns related to time and cost were also identified in the interviews as the following quotes reflect:

I think that the biggest constraints are time (12-S_P)

As time goes by there is less and less and less money. (Previously) resources were almost limitless and you could do any research you wanted because there was a lot of money. Now money is very tight (3-S_P)

One respondent provided a reason for not participating in clinical trials, whether therapeutic or preventive in nature, writing in that “clinical trials not part of the practice model that I joined”. Unfortunately due to the nature of reporting via survey, this response could not be expanded upon; however, commentary from one participant may provide some perspective:
Most (physicians) are in private practice for a reason. If I was in private practice, I would have to think of myself as not as someone who is not interested in academics. I’m not interested in research. Why would I do this? (research) I got a tee time at (1), you know? I wouldn’t do it (10-A_P).

The various medical practice models and ability as well as desire to participate in clinical trials should be an additional consideration when determining future recruitment sites for prevention trials. The overall response rate to the surveys was not significant enough to consider additional analysis using SPSS. The results from the interviews and surveys were analyzed independently and will be integrated in chapter five for the purposes of interpretation in order to address the research objectives.

**Summary**

This was a formative, exploratory study conducted to provide an in-depth understanding of the individual and structural factors influencing a physician’s participation in a PCPICT, a topic with little documented research to date. A mixed methods research design using qualitative, ethnographic (open ended semi-structured interviews and participant observation) and quantitative (survey) methods was employed to examine factors of influence within the context of an ongoing PCPICT.

This chapter provided the results of the data that was obtained from the open ended semi-structured interviews, participant
observation, and survey methodology employed. Analysis was conducted in order to identify individual and structural factors influencing a physician’s participation in a PCPICT with a consideration of factors that may vary across practice site/area and to identify ways to improve collaboration between researchers and physicians to improve the success of this and future projects. The ethnographic detail within the context of an ongoing project that would not have been obtained via other means can be used to inform the design of future cancer prevention studies requiring multi-site participation in order to recruit participants reflective of our diverse population.
Chapter Five: Discussion and Conclusions

Introduction

This chapter discusses the responses of the physician/investigators who participated in the open ended semi-structured interviews, findings from participant observation where possible, as well as the results of the quantitative surveys as related to the research objectives, questions and hypotheses. The reader will be reintroduced to the model proposed initially as well as a modified version, reflecting the data collected with this study. The contributions of this research to theory, applied anthropology, and biomedicine will be elucidated. The implications of the research with recommendations for future cancer prevention clinical trials will be discussed and recommendations for future research directions will be presented. The limitations of this study will be delineated including those related to my vantage point and familiarity in the research setting prior to completing this work.

Research Question 1

This question attempted to explore and document individual provider level factors such as explanatory views on prevention, notions
of risk and uncertainty, shared decision-making, duality of roles, and other individual factors influencing a physician/investigator’s participation in cancer prevention intervention clinical trials. Physician involvement is thought to be essential for the provision of many preventative services with the physician serving a critical link in the chain of events leading to the delivery of preventative services (Jaen et al. 1994).

**Explanatory views on prevention.**

A personal interest and/or belief in preventive medicine and cancer prevention in particular were motivating factors for participants in this study and this was observed across all site types. As one participant remarked:

> I think that as we embark in medicine today I think the emphasis is sort of moving away from treatment to prevention. We know that it’s more cost effective. We know from a society standpoint, if we can prevent something you’re much better. From a patient standpoint, obviously if you can prevent and not have to deal with actual malignancy, prevention is the ultimate goal. It’s what we strive for everyday. So I think that prevention is the future of medicine (01-S_P)

Preventive medicine was recognized for its potential cost savings and preference over treatment of disease and participants had been influenced by their training as well as professional and personal experiences. This is exemplified in the following quote by one participant:
It’s pretty much what I’ve learned in my training. And it’s pretty much what life teaches you in a bit of time. You’ve seen people die and born in front of you and grow up into men and women in front of you and people who were adults when you were children you see them pass away by the time you are in this age that I am so it kind of gives you a broader perspective of life. Plus what I’ve learned in medicine as well. So both personal and professional influence the broader perspective (05-V_P)

Support of preventive strategies was also noted to positively influence the willingness to participate in the PCPICT though interestingly, some felt that their role in prevention was limited due to their role as surgeons:

The cancer prevention, I don’t think should be focused on tertiary/cancer surgeon but more on my primary role as a urologist. So that’s where cancer prevention (needs to be) and with primary care doctors as well (07-P_N)

This response mirrors work by Hall et al. (2010) who found that though oncologists were interested in referring patients to prevention trials, they felt that they did not have access to eligible (i.e., healthy) patients in order to do so. Similarly, as noted in the review of literature, Crosson et al. (2001) reported how the preference of primary care physicians (PCPs) to refer their patients to an oncologist for discussion of cancer treatment may extend to discussions related to cancer prevention trials as well. This perspective would benefit from further exploration prior to the design of future prostate cancer prevention intervention trials. A consideration of the most appropriate referral source for future studies is critical in an era of healthcare
reform and limited funding for research, to assure fiscal responsibility and that accrual goals are met in a timely fashion.

**Notions of risk and uncertainty.**

As previously noted in Chapter Two, anthropologists Douglas and Wildavsky (1982) consider risk perception to be the beliefs, attitudes, judgments and feelings in addition to the socio-cultural disposition that people adapt towards both hazards and their benefits. Risk perception grounded in culture and the cultural theory of risk is one way to interpret how and why individuals make judgments about danger, pollution, or threat (Tansey 1999). Since risk may have varied meanings to different groups, all risk must be understood within the larger social, cultural and economic context that it occurs (Douglas and Wildavsky 1982). This is an important consideration in a discussion about prostate cancer prevention and risk within the culture of biomedicine. In this study, risk perception and assessment were observed at two distinct levels, that of the patient, as the following quote demonstrates:

> If the consumer thinks that prostate cancer is a non-entity then in reality why are we doing the study? (08-A_P)

As well as that of the provider, as suggested in the following quote:

> I personally think one of the keys is the urologists, and how do they want to deal with the reporting of prostate biopsy showing PIN? What makes or breaks whether a physician will even
mention a trial is their interpretation of how significant the biopsy findings are (12-S_P)

Similar to risk and “risk status” as reported by Hunt et al. (2006), the “risk of cancer development” had multiple meanings that were understood differently by the physicians participating in this study. Although the patient voice was absent from this research, its influence in relation to study participation was mentioned by the participating physicians and cannot be ignored. In reality, the decision to participate or recommend that a patient participate in a cancer prevention trial is likely influenced by factors at both levels. A consideration at the patient level may be used to determine which patients would be willing (based on their perceived risk of disease) as well as those that could benefit (based on the provider’s interpretation of risk) from participation. A lack of consistency in the definition of risk within the medical community and ambiguity in the current management of prostate cancer and its precursors was noted as exemplified with the following statement:

You know the other thing that’s detrimentally affecting particularly prostate cancer I think is the ambiguity in the medical community about the significance of prostate cancer and the significance of prostate cancer treatment (08-A_P)

The overall subjectivity in determining risk is important to recognize, as it may influence trial participation as well.
Hales et al. (2001) noted that physicians may experience discomfort disclosing uncertainty in clinical management, as may be required as part of the participation in a clinical trial. Since this research was with a therapeutic trial, exploration in regard to cancer prevention, intervention trials was warranted. In this research, neither uncertainty in the plan of care nor the outcome associated with participating in the clinical trial was negatively influential. Uncertainty was seen as the “nature of science” with participants across sites offering suggestions (such as honesty and communication with patients) as a means to deal with the possibility of uncertainty.

**Shared decision-making.**

Similar to the findings of Hunt et al. (2005), disparate starting points related to the perceived problem (or lack thereof) and how to prevent or control it may greatly influence what treatment options are considered in this context as well. The lack of consensus and subjectivity in determining risk as noted above, in addition to variance in clinical priorities may influence the information and treatment options that are shared with each individual patient, as abnormal biopsy results are identified. This likely influences the process of shared patient decision-making between the patient and physician, as it relates to participation in prevention trials.
As would be anticipated considering the focus with this project, shared decision making was contemplated at the level of the provider. Questions were situated to elicit feedback related to various scenarios where research efforts may be coordinated with actors beyond their local site, in an effort to increase participation opportunities for their patients. Participants expressed a variety of responses and shared decision making was indeed a salient factor, but not in the ways anticipated by me during project design. Considerations such as logistics were pointed out as shown in the quote below:

The only problem I guess is just logistics (10-A_P)

As well as the importance of coordinating the details of care as one respondent noted:

All of us have a fear that when patients leave here, (are) sent out, they can be lost in the paperwork and the shuffle (01-S_P)

Also the importance of considering the benefit to the patient was mentioned:

If I have a patient who is eligible for a prevention trial somewhere else and if I don’t have something for that population I would send them. Wherever there is a good study for the patient, we send them (09-S_N)

And interestingly, the possibility of losing control of patients was mentioned as the following quote demonstrates:

No, in the sense that you are sending your patients somewhere else and they may not come back. So, why should they? It’s almost like saying that if you’re not cutting edge enough to have
their research trial at your institution so why should I come back to you? (10-A_P)

Heterogeneity in responses varied depending on the practice site as well as the tenure of experience. The following suggests that those with an established medical practice may be less concerned about losing control of their patients than those still in the process of establishing their practice:

You ask a guy like me, I’m not just beginning out in this business. I’m not as threatened by sending off as some might be. So no, I wouldn’t have trouble with that. If you talk to someone who’s trying to build a practice they might be less inclined to do that (12-S_P)

These findings are similar to prior work by Cornuz et al. (2000) who suggested factors such as age, gender, specialization, and the physician’s own health habits influenced the likelihood of preventative care.

**Duality of roles/role conflict.**

Hunninghake et al. (1987) suggested that clinical trials may be seen as a competing service to clinical care and noted challenges with role delineation and personal integrity when serving as both clinician and investigator. More recently, Ruffin IV and Baron (2000) suggested that conflict may arise between the physician’s role as care giver and that of scientist. The possibility that varied and separate roles may contribute to conflict related to the ultimate goals and populations
targeted in clinical research have also been noted by others (Frayne 2001; Hales et al. 2001; Orozco 2009). Ka'ano'i et al. (2004) identified conflict between the roles of clinician and research advocate as physician-related barriers specific to participation in cancer prevention clinical trials. Prior to this study, it was unclear how salient this was specifically in relation to a PCPICT.

Participants at all types of sites noted that their ethical responsibilities did not change when a patient participates in a cancer prevention intervention trial. One noted that this could be a unique difference between pharmaceutical (treatment) and prevention focused trials. In terms of role conflict, this had been experienced specifically in regards to participation in the ongoing trial by at least one participant working at an academic center when the course of action required by the protocol deviated from the usual care he would have provided, as he stated:

When these LFTs (liver function tests) are elevated, how elevated? Is it elevated enough to take them off the study? Is the drug doing some harm? So yeah, every time there is something (like that) you have to consider (that) there’s conflict (10-A_P)

For others, at all site types, it was not an issue with some noting protective stops in place such as the IRB oversight and lack of financial interest or benefit as possible factors contributing to the lack of conflict. This is reflected in the following quote:
No, if I don’t have any financial interest or financial benefit and (it) is a study I am convinced to do, I don’t think it changes anything. Also (if) the study passes the IRB, you know that (it is ethical) (11-P_P)

**Other factors of influence.**

Additional individual factors influencing the likelihood of participation in cancer prevention intervention trials were noted such as personal motivation and/or interest in research, scientific recognition and altruism. The following quotes provide examples of response from the participants:

It’s not money; it’s academic and scientific credit (04-V_P)

If the study appeals to my mind, that the study is going to be something good for the betterment for the future, in my little field (05-V_P)

These were noted by participants across all site types. In general, the participants were willing to consider multiple means of participation in trials such as patient referral to outside facilities, training their own staff and utilizing staff provided by the research sponsor in order to provide the best possible care options for their patients. Ka‘ano‘i et al. (2004) identified changes in the doctor/patient relationship as physician-related barriers specific to participation in cancer prevention clinical trials. This was not observed in this research and the impact of participation in the trial on the physician-patient relationship was
generally seen as favorable across all types of practice sites as the following responses demonstrate:

I think that the fact that we do participate in these trials helps the patient physician relationship and it also lets the patient know on a different level that we are concerned about their overall health (08-A_P)

It’s actually (a) very good rewarding relation. Some get recycled; they enter new trials, similar disease spectrums. Oh it’s very rewarding. Wonderful relationship with this patient. It’s fun. Absolutely (04-V_P)

**A glimmer of insight.**

Perhaps most informative for consideration in the design of future trials was insight by providers as to why physicians in private practice may be hesitant to participate in prevention trials:

I don’t know how you would incentivize a guy in private practice to participate in trials like this. It would almost have to be completely financial somehow...Chemoprevention like this, I just don’t know how you would incentivize them because you have to have extra visits, you know for research and you have the IRB stuff to go through. I don’t know how you would incentivize them (10-A_P)

The need to incentivize in some way, excessive regulatory requirements without the infrastructure such as adequate staffing to support the required work, a consideration of the benefit of participation as perceived by the urologist, and potential loss of control in decision-making were all important factors that were suggested to influence the likelihood of participation in a prostate cancer prevention intervention trial. These proposed barriers and facilitators to research
participation should be explored in further detail to improve the success of future endeavors.

**Research Question 2**

This question aimed to explore and document the structural (organizational and infrastructural) considerations that influence participation in a PCPICT and to provide a comparison of factors across types of sites.

**Resources and other support.**

As noted in the prior chapter, there was heterogeneity in the responses both within types of centers and when making comparisons across them. A disjuncture between the organizational expectation to participate in research and the resources provided was noted by an informant working at a specialty center, as he said:

> From the organizational level our mandate is to do research. There is a difference between what is expected and the resources provided (03-S_P)

Similarly, a participant in the VA system noted insufficient resources “stifling progress” in clinical research:

> Currently, everybody does it by himself or herself, the investigators. It stifles progress. There are lots of patients who are interested in trials but (there are) insufficient resources to help investigators bring trials to patients and accommodate patients in trials (04-V_P)

The presence of research infrastructure was a critical component noted by those in private practice as well. These findings are similar to work
by others (Roberts 2002; Ruffin IV and Baron 2000; Somkin et al. 2005) where organizational support and other health care system related factors were noted as predictors of enrollment as well as barriers to participation in treatment trials, with infrastructural support (including support staff) noted as critical.

Similar to work by Ka’ano’i et al. (2004), staffing and time constraints were potential infrastructural factors noted as important considerations influencing participation by these key informants. Funding not only to support research efforts but to contribute to the institution’s bottom line was noted as relevant across all site types though not as significant within the VA system. A clear preference to participate in funded research over non-funded research was observed across all site types. This was a more important factor than the actual sponsor at most sites though all noted a preference to participate in investigator initiated, federal or state and cooperative group trials over pharmaceutical trials. As evidenced by the following remark from a participant:

We always give precedence to studies that are NIH funded studies and investigator initiated studies and then if there is room then industry sponsored studies are supported (09-S_N)

Interestingly several reported changing priorities as a result of the current economic environment as the following responses demonstrate:
Of course you know when the funding is getting tougher to get you may have more pharmaceutical studies (09-S_N)

So, if we say we can’t get these big grants from the government … I think the shift is just to say, well try to get these other grants, the pharma grants and such that don’t have that requirement (10-A_P)

**Research Question 3**

Cancer clinical trials recruitment has historically occurred in academic settings (Nguyen et al. 2005), with community and nonacademic hospitals less likely to participate (Al Refaie 2011). Pinto et al. (2000) suggested a strategy for increasing enrollment in clinical trials is to improve communication and outreach with community physicians; however, it is also noted that increasing participation in screening and prevention activities would require more attention be given to logistical barriers and an increased awareness of cancer information and research services (Ka'ano'i et al. 2004). Since much, but not all, of the prior research has focused on therapeutic trials, this question was addressed by considering how practice area (specialty centers, academic centers, Veteran’s (VA) medical centers, community offices) may impact the feasibility of participating in a prostate cancer prevention intervention trial. The results from the various modes of data collected in this study suggest that for a variety of reasons, some sites may be better suited than others to participate in the prevention trials of the future.
The right place.

As previously noted, practice site influenced not only the facilitation of research (due to the absence or presence of infrastructure) but also the types of patients that were seen at each site. This is problematic since research done primarily in university or teaching centers may result in unintended subject bias due to the population seeking care there (Carbone et al. 2005). Additionally, since the opportunity to participate in trials may not be a reality for all, Azevedo and Payne (2006) have suggested that differential access to research opportunities due to structural or other barriers may disparately impact certain populations. The unavoidable reality that patient pool was influenced by other factors such as the presence or lack of insurance and unofficial “pre-inclusion” criteria at some sites warrants further exploration. This is especially important in the face of impending health insurance reform, since the standard of care in many medical treatment regimens are the direct result of clinical research. The reality of unequal access could have implications for many conditions and is not simply limited to the spectrum of cancer care.

All participants reported limits in access to the resources necessary to participate in research, even those specifically designated as research centers. This was reported by key informants during formal interviews as well as by other members of the research team.
during participant observation. Suaveness and creativity on the part of the physician/investigators made it possible for the current project to occur at their facility. Some respondents reported better support than others and a physician at one private practice site had found a way to access resources beyond his own in order to expand the types of services that were available and offer participation in clinical trials to his patients, despite the lack of his own research infrastructure, as described in the following response:

There’s a research coordinator at XXX Hospital. We can use her and that’s another way we can take advantage of (the) XXX IRB and their research coordinators. If I have to use my infrastructure, I don’t have anyone in the office so I have to go through XXX or I have to hire someone. Hiring someone for a small project is not a good idea. You have to have the infrastructure, that’s why I think the community guys shy away from research, there’s too much paperwork to do. It’s a lot of paperwork to do (11-P_P)

**The right time.**

Across all sites the common theme noted by all was time, broadly speaking, and the influence it had on their ability to participate in research as seen with the following responses:

The time to do it that’s the issue (02-V_NP)

I think their limitation is similar to our limitation in terms of time (07-P_N)

Don’t underestimate how busy the doctors are (12-S_P)
Time was seen as both a positive and negative influence on participation. When trial requirements were in-line or able to be incorporated into the usual schema of care this was seen as positive factor making participation more feasible as the following respondent explains:

It allows me to participate in research that has a translational bent and also be able to work it into my regular routine of seeing patients (10-A_P)

However, when time related to fitting a discussion about research into a time slot that was previously established for a clinical encounter; the time allotted by administration as dedicated for research (vs. clinical care); the time required to document research participation or even the time for a patient to see a research coordinator because they were present and readily available in the clinic, it was seen more as a negative factor of influence. Despite the negative time factors noted, this was not seen as a finite barrier making physicians unwilling to participate in this and future projects, yet is definitely a factor that should be considered in future trial design and resource allocation.

The ways in which conflicts for time and space were handled varied in each of the research sites; however, a consideration of the two models noted during participant observation may help to lessen the competition for time and space often reported by these key
informants, observed in the clinic and noted in prior research, further reducing this challenge in the future.

**A Comparison of Results**

When considering the quantitative results for a comparison of responses from those who are currently involved in the clinical trial and those that are not, similar responses were noted by both groups. Reasons for participation in clinical trials included advancing medical science, expanding available services, providing challenge and variety and earning extra income noted by participants in both groups. These results are similar to work by Crosson et al. (2001) who reported comparable reasons for participation in clinical trials. As would be expected based on total accrual, there was unequal representation between groups (participant and non-participant) with a greater number of participant responses in most categories.

The reasons noted for participating in prevention trials was also similar (advancing medical science, providing the best possible care, earning extra income for practice) among the groups. The participants also mentioned other motives such as providing the best possible care and access to a novel treatment. In terms of overall participation in any type of clinical trial, similarities between participants and non-participants included the influence of time, cost to individual or institution, paperwork requirements, staffing, concern for patients
well-being, and institutional support. Factors reported by participants but not non-participants also included the influence on the clinical care process, financial incentives, the introduction of another care provider or decision maker, and the requirements of the research protocol. Overall, the groups had more similarities than differences in this area and there was consistency when triangulating the findings generated by qualitative and quantitative means. One reason for the similarity in findings could be that though respondents were not currently participating in the PCPICT, most had participated in research previously. It is likely that a disjuncture between the individual willingness or interest in participating and limitations at the structural level (due to practice site, medical practice model or lack of infrastructure or resources) existed, ultimately influencing participation in the current PCPICT.

The primary hypothesis for this study was that both individual and structural factors intersect and influence both the willingness and the ability of the physician/investigator to participate or refer patients for participation in a PCPICT as shown in Figure 2:
Figure 2: Proposed Model: Individual and structural factors influencing physician participation in cancer prevention, intervention clinical trials

- Dark blue boxes represent individual factors believed to impact the physician’s participation in cancer prevention intervention clinical trials
- Light blue boxes represent structural factors believed to impact the physician’s participation in cancer prevention intervention clinical trials

Additionally, it was hypothesized that these factors would vary based on practice site/area and the interactions will both facilitate and deter participation in these types of trials. The results of this study show that the hypothesis is supported and that both individual and structural factors intersect, influencing the willingness and ability of physician/investigators to participate or refer patients for participation in a PCPICT. Individual factors such as explanatory views on prevention, notions of risk and uncertainty, shared decision-making
and duality of roles appear to have a greater influence on the *willingness* of physicians to participate while structural factors such as staffing, other resources and time are more influential in regards to the *ability* to participate. Though individual and structural factors did vary across sites to some degree, there was more heterogeneity among various physician/investigators than across the different site types. What was not examined in this project and would be a next logical step, is to further explore how willingness and ability was reflected in the actual accrual at the various sites participating in the PCPICT.

**Contributions to Theory**

An adaptation of the theory of competing demands that included a theoretically-grounded exploration of individual provider level factors (notions of risk and shared decision-making, explanatory views on prevention, and duality of roles) as well as structural level factors (practice area and organizational/infrastructural considerations) that as noted in previous chapters, were shown to be salient in other types of research, was proposed for this project. Within this framework, I was able to draw upon both micro and macro level factors of influence to provide a more holistic understanding of the multitude of individual and structural variables influencing the physician’s participation in a PCPICT. Jaen et al. (1994) proposed a three-part model to better
understand the delivery of preventative services in the primary care setting. Components of the model included the physician, the patient, and the practice environment. My research expanded this concept via mixed methods exploration to show that these factors are similarly influential in the delivery of services associated with participation in a PCPICT. Willingness and desire to participate on the part of the physician was unfortunately not always enough to result in actual participation since the ability to participate was influenced by constraints within the practice environment such as competing demands for time, space and personnel.

As noted previously, Joseph and Dohan (2009) suggested that enrollment in therapeutic cancer clinical trials is shaped by biomedical and social factors. Similarly, this research has revealed that these factors are also influential as physicians consider participation and enrollment in a PCPICT. Biomedical factors such as risk perception and scientific rationale; as well as social factors such as explanatory views on prevention, concerns for their patient’s well-being, and prior personal and professional experiences were reported as salient and influential by participants in this study. As with the prior research, the intersection of these individual, social and biomedical (physician and patient) and structural (practice environment) factors influences
not only the willingness but the ability of physician/investigators creating barriers as well as facilitators to participation in a PCPICT.

The factors of influence identified following a review of the literature and proposed in the original model were supported by the findings of this research. With the results of this study, a much better understanding of the intersection of these various factors within this particular context is now possible. As noted in the results section, individual factors such as explanatory views on prevention, notions of risk and uncertainty, shared decision-making and duality of roles appear to have a greater influence on the willingness of physicians to participate in a PCPICT. Structural factors such as staffing, access to other resources and time are more influential in regards to the ability to participate. This research did not examine how physician willingness and ability ultimately influenced actual recruitment to the PCPICT as compared to the project goals. This would be a valuable consideration and could add overall insight to better understanding the greater challenge of recruitment to prevention clinical trials within each of the four contexts. Further examination would also further delineate if some factors were more influential than others. The following, revised model (Model 2) demonstrates the interactions of the various individual and structural factors influencing these physicians as they function as gatekeepers in access to the PCPICT.
These factors served as both barriers and facilitators to the physicians as they considered participation in a PCPICT. The findings from this project show that factors previously shown to influence participation in therapeutic clinical trials are influential within the realm of prevention trials as well. Though all key informants were interested and willing to participate in the PCPICT due to individual factors, not all were able to due to the structural constraints of their specific practice environment. While this project focused on a very specific context- prostate cancer prevention intervention clinical trials- a consideration of these factors and how they may influence the willingness and ability of physicians to participate in other types of prevention trials should be considered by investigators that seek to design this unique and challenging type of study. Additional exploration of the intersection of
factors within each local environment would add additional insight and
investigators designing such projects are encouraged to consider how
the various factors may or may not be relevant depending on their
planned recruitment site (specialty center, academic center, VA
hospital, private practice).

**Contributions to Applied Anthropology**

This research provides an in-depth and nuanced understanding
of the individual and structural factors that influence a physician’s
participation (or lack thereof) in a PCPICT. It provides a novel
qualitative component within the context of an ongoing research
project, greatly contributing to the literature and expanding the theory
of competing demands into the field of anthropology and prevention
clinical trials. The results can be applied to inform the design of future
cancer prevention intervention trials which require multi-site
participation in order to recruit participants reflective of our diverse
population, in a timely and cost-effective manner. This is an area that
to the best of my knowledge has not been previously examined
specifically from an anthropological perspective. Anthropological
contributions in the arenas of cancer control, clinical trials, ethics, and
clinically applied anthropology were considered in the design of the
project; however, a direct comparison of my findings is not possible
due to the lack of analogous prior work. My project expands the
presence of the anthropological voice, making a contribution to this broad topical area while using a holistic perspective to address challenges previously identified by other disciplines. The results of this research provide novel insight and therefore answer Kleinman’s call (1985) for medical anthropologists to be able to consider the practical as well as theoretical aspects of health issues. By asking questions instead of making judgments as suggested by Barnett (1985), it helps to better understand why practitioners behave and believe as they do regarding PCPICTs. By considering physicians as actors in an ethnomedical belief system, an analysis of their beliefs and the social and cultural construction of biomedical disease concepts within a particular context was possible, as suggested by Chavez et al. (1995).

**Contributions to Biomedicine**

Kleinman (1985) noted that clinically applied anthropologists are able to consider the divergent views and visions of patients, professionals and the community, facilitating perspectivism and contributing to a broader understanding of all relevant issues. This project was able to elucidate the views and perspectives of professionals as they relate to participation in a specific type of clinical trial. Swanson and Ward (1995) identified the need for studies of physicians’ attitudes and behaviors regarding clinical trial participation, and prior to this work there was limited literature specifically exploring
the role of physicians as gatekeepers in access to PCPICTs. This project contributed to a gap in the literature and allowed for an in-depth examination of the individual experiences of the physician/investigators within the larger social and economic contexts in which health care is provided.

Al Refaie (2011) reported that infrastructure, realignment of incentives and compensation, and improved patient and physician navigation systems have been suggested by surgeons as ways to improve their engagement in clinical trials. These are also noted as important among the participants in this study. Similarly, Meropol et al. (2007) noted that tailoring approaches to a specific practice area (academic vs. nonacademic) may help to optimize participation. This research shows that overall the differing practice areas have challenges that are more similar than different.

**Application to future trials**

The analysis of these findings provides the opportunity to make suggestions that should be considered in the design of future prostate cancer prevention intervention clinical trials, and may be useful in the design of other types of prevention trials as well. Additionally, this research identifies and addresses the invisible barriers (named such due to the lack of formal evaluation or documentation previously) such as structural and infrastructural barriers, the identification of which
was suggested as critically important due to the increasing number of new chemotherapeutic agents needing evaluation (Dilts and Sandler 2006).

The urology clinic is a fast paced and ever changing environment. The clinical encounter is limited by both time and space resources, as observed during participant observation and reported by participants. Dedicated infrastructural support to provide for both may allow for the successful facilitation of future prostate cancer prevention research projects. A closer examination of the ways in which patients are identified and visits are scheduled may have a positive impact on future recruitment as well as result in a more efficient use of limited resources. The patient population at each clinical site influences the ability to meet recruitment goals, creating yet another structural challenge if there is a disjuncture between the two and as Sharp and Pentz (2004) note, the enrollment of adequate numbers of patients, within a reasonable time period is particularly critical in chemoprevention trials. An additional observation is that some of the types of sites where this project is taking place may not be ideal and should be reconsidered for future endeavors. Practitioners working in specialty and academic centers typically have a relatively small volume of low risk (cancer free) patients which is the population best served by a prostate cancer prevention intervention trial. Since the VA
hospitals function more as a primary care facility, there are a significantly greater proportion of potential patients available at these sites. Perhaps the best referral source is from within the community, urologists who are working to provide the “bread and butter” urology care to their patients over a life time and have an established relationship well before cancer diagnosis. Each of these sites has infrastructural challenges as noted previously and they must be considered within the greater health care structure as it continues to evolve. Finding ways to bridge paths of partnership with the community is highly recommended for the success of future cancer prevention studies. A summary of the main points from the key informants which should be considered by any investigator in the grant writing phase of a project follows:

1.) Future studies must make biological sense and be for a condition where the scientific rationale is clear and no ambiguity regarding the significance of treatment exists

2.) Protocol requirements must be closely in line with usual practice for the condition under study to minimize patient and physician burden

3.) Dedicated research time and personnel is highly desirable

4.) Partnerships with “friendly” community physicians must be forged to extend availability to a wider range of patients

5.) A collaborative project, available at the site of usual care delivery when possible with the urologist remaining key
decision maker (in partnership with patient and research team) is highly desirable

6.) Trial must utilize existing resources or provide for additional so that venture is at least cost neutral for the institutions involved

As previously noted, though willing to participate, those working in specialty and academic centers simply do not have access to the “healthy” and cancer free population that is needed for such a study. Finding ways to build relationships with community physicians where they are not threatened by collective work is imperative since these settings have the potential to recruit a much larger and more representative sample (Somkin et al. 2005). This will not only assure the best use of limited fiscal resources but also facilitate the recruitment of a wider and more diverse population, representative of those impacted by the burden of prostate cancer. As well, additional research should further explore more specifically what financial incentives would be considered necessary for those in private or community practice to participate in such a study as well as what infrastructure is or may be available to support their participation in prostate cancer prevention clinical trials.
Limitations

As with all research, this study is not without its limitations. What follows is a summary of obstacles as well as a brief discussion regarding non-participants.

1) This study included interviews with twelve physician/investigators currently participating or asked to participate in a prostate cancer prevention clinical trial as the primary research participants. Though the sample size was sufficient for this dissertation, it is not meant to generalize to all physician/investigators or even to all types of prevention intervention clinical trials, instead it was meant to describe the population within a particular context and provide implications and recommendations for future research.

2) Though some insight into possible reasons for non-participation can be gleaned from the responses provided by those who did participate, their responses should not be considered generalizable or reflective of the opinions of all non-participants. Soliciting this voice is incredibly important for the success of future prostate cancer prevention research projects.

3) Due to a poor response from community physicians, the sample size of “non-participants” from the private practice setting was limited. Despite the request to participate from a well-respected gatekeeper within this community, only 4 non-participant surveys and no interviews were completed. Though response was limited, those that did participate in the interviews and/or complete the surveys did provide some important insight that should be examined in future projects.

4) Non-random sampling was the primary means to recruit participants. The potential for bias in participant response exists due to the fact that all interviewees had a previously established working relationship with me prior to the time of data collection. Due to the specific nature of this project, this sample was
considered best qualified to address the research questions. Additionally, this association was thought to positively influence the willingness of the key informants to talk with me, as evidenced by the three interviews with non-participants that I was unable to complete. No physicians with whom a prior relationship did not exist were willing to be interviewed.

5) All key informants in this project were male and I am female. While this was unavoidable, it is unclear how this may have influenced the willingness to participate or the responses provided.

Certainly the most notably missing voice from this project was that of the physicians who did not agree to participate in the interviews or even complete the survey. Unfortunately due to a change in dynamics in the large, local urology group, I was unable to administer the survey in person as originally planned. The use of the modification of the Dillman Total Design Survey Method, using the letter/survey packet and a follow-up postcard provided little additional response (n=2). In person distribution may have increased the total number of surveys completed but it is unclear how it responses may have added to the depth of data collected since as noted in chapter four, little variance was noted between participants and non-participants, utilizing this methodology.

Reflecting on Familiarity in the Research Setting

Concerns about the familiarity of researchers in the research setting have been noted and include a lack of objectivity and possible
role confusion (Hanson 1994). Arguments have also been made that acting in familiar role as well as that of researcher may compromise objectivity (DiCicco-Bloom and Crabtree 2006). Additionally, the concern that motivates the research and potential to focus attention on a specific element or issue has been described as both a potential weakness and a strength when functioning as an “insider” (Hanson 1994:941) and Preston (1997) suggested that carrying out ethnography in a familiar culture has the advantages of access and familiarity of the setting. There is clearly not a consensus on this issue.

DiCicco-Bloom and Crabtree (2006) noted that establishing trust and finding out new perspectives is best done by reducing the hierarchy between informants and researchers therefore, it could be argued that this may be facilitated more easily in a research setting with some level of familiarity to the researcher. Hanson (1994) noted several positive aspects of familiarity including subjective knowledge and awareness of the cultural norms and values of the health care professionals involved in the study and suggest these strengths may be particularly salient when using qualitative methods. Researcher reflexivity is always essential to acknowledge power differentials and integrate reciprocity into the creation of new knowledge (DiCicco-
Bloom and Crabtree 2006) and this was of particular importance when “studying up” as this project required.

When considering my own agency and the possible constraints of working in a familiar setting, reflexivity, or the awareness that the production as well as distribution of knowledge is a social action (Hahn and Kleinman 1983) was critical during the completion of this dissertation project. While developing the study, familiarity in the research setting and with the challenges facing the project allowed me to truly apply anthropology to design a project that would provide a broader and more holistic perspective of the issues; providing data from the individual actors and within their local context that would not have been obtained without a mixed methods approach. Perspectivism and the ability to mediate between varying viewpoints on the same phenomenon was a valuable skill in the anthropologist’s toolkit that proved absolutely useful while arranging interviews and site visits and completing my work in the field. Conducting the participant observation was the part of the research process where reflexivity was perhaps the most important. I had to constantly interpret my findings based on observations, acknowledge power differentials and integrate reciprocity; however, the sum of my prior experiences as a clinician, research coordinator and project manager could not be completely avoided.
Once the actual data was collected, I was pleasantly surprised to experience an ease in separation between the professional experience prior to data collection, my role as scientist during data collection and the focus required to analyze and elicit the details necessary to answer the research questions. A keen awareness of my differing role and a more analytic focus during my time in the field while maintaining a collaborative approach as the research questions are addressed was of critical importance. The data that was collected was sorted and analyzed from my perspective, based on the totality of my experiences as is inherent to this type of research. Anthropological research is an interactive endeavor and this project resulted in exchanges between the key informants and researcher that were more rich and detailed than I could have hoped for. I am not sure that this result would have been the same, were I not considered to some degree, an insider. In this particular case, I believe that there were more strengths than weaknesses with familiarity with the research setting as I was able to build from existing relationships to focus on the specific details needed to address the study objectives and research questions. Buy-in to the project was not problematic and participants were more than willing to share their time and perspective as the key informants had the same vested interest in the parent trial’s success as I did.
Opportunities

The findings from this project offer several prospects to expand into other arenas for further research and provide suggestions for training and education related to clinical trials. These include, but are certainly not limited to contributions to other arenas of prevention research, development of improved patient-trial identification systems, and implications for physician education.

Prevention research.

Though this research focused on the specific context of a prostate cancer prevention intervention clinical trial, the findings are likely applicable to challenges observed in other areas of prevention research. Funding agencies, sponsors and investigators involved in the design and funding of such trials may benefit from a review of the six main findings reported previously, for applicability to their own local context.

Clinical trial alert systems.

With advances in technology and the increasing use of the electronic medical record (EMR), collaborations between researchers, information technology (IT) professionals and clinicians may increase the use of CTAs to improve the ease with which participants for all clinical trial types (therapeutic as well as prevention) are identified at various medical settings. Ultimately this could improve resource
utilization, minimize physician burden, boost enrollment and speed the rate at which new discoveries are tested for efficacy via clinical trials.

**Implications for physician education.**

Participants in this study had not received specific training or education related to clinical trials as part of their medical school curriculum. With few exceptions, most had not had any such training during their residency or surgical training either. Considering the importance of clinical trials to continuously improve the provision of medical care, providing an early introduction of the basic concepts, and laying the foundation of knowledge regarding clinical trials in medical school may be an effective means to improve understanding of physicians, ultimately improving future involvement in trials. This exposure could occur via workshops provided within the medical school curriculum or perhaps at conferences and other educational venues.

**Dissemination and Future Directions**

The dissemination of these findings is crucial to maximize the application as I intended at the outset of project design. This can occur through various channels including the preparation of an executive summary of findings, publication in peer-reviewed journals and presentation at scholarly meetings. An executive summary may be most useful to physicians already participating or interested in participating in prevention clinical trials as well as investigators.
involved in trial design. Publication in peer-reviewed journals could cater to two audiences, those more in the biomedical arena who may be interested in the application of the findings (such as trial sponsors, funding agencies and physician investigators) as well as to anthropological or other social science journals where the theoretical contributions may be more valued. Participation in scholarly meetings in both arenas could also increase the dissemination of results, thereby reaching a much broader audience.

On a more personal level, I envision future projects at several different levels. The “work” of research and how in reality it played out, varied greatly in the different spaces I visited. The physician clearly serves as a gatekeeper, often providing direct access to the potential research participant; however, a host of support is occurring in the backstage. This support varied greatly at each type of research site and additional research could explore in greater detail the valuable work of nurses, clinical trial coordinators and regulatory staff without which, the true work of research would not occur.

An additional expansion from this project is to attempt to capture the experiences of those physicians who are non-participants in research, either due to their current medical practice model or other barriers which have not yet been identified. I believe this work would be the most relevant in the private, primary care and specialty setting,
where potential prevention research patients are seen prior to the development of cancer and other such conditions. Relationships with “friendly” physicians in private practice was suggested by those at specialty centers as a way to increase participation in prevention trials so this could provide timely insight into the world of “non-participants” and specifically explore their willingness and ability to participate or refer patients for participation. Access would remain the largest challenge since just as was observed in the parent PCPICT, this group was challenging to reach in my study as well.

A final area of exploration would be to more closely examine the process of research within a particular setting to better understand the structural factors that influence a physician’s involvement in research. This is critical because support such as infrastructure and staffing ultimately impacts patient recruitment and the attainment of accrual goals to all types of clinical trials. Findings could contribute to an improvement in organizational support impacting the recruitment to and completion of prevention trials in a more timely and cost-effective manner. This may be most relevant in the VA setting, where some level of research infrastructure is already in place and a wide range of patients are seen for their primary medical care.
Conclusion

Using an applied anthropological perspective I examined the individual and structural factors influencing physician/investigators in their role as gatekeeper in access to a PCPICT. This research extends work by Probstfield and Frye (2011) to show that physicians also serve as gatekeepers for participation in a PCPICT, and provides valuable insights and information related to the reality that is experienced within each local context where study recruitment and participation take place. The results fill a void, building from prior work where Ruffin IV and Baron (2000) recommended further research to not only better understand barriers unique to prevention trials but to identify successful strategies to overcome them and used ethnographic methods to specifically explore the individual and structural factors of influence impacting physician/investigators in their role as gatekeepers. I was able to provide applied recommendations for researchers considering the design of future cancer prevention intervention projects as well as identify areas where additional research would be beneficial.
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Appendices
Appendix A. Recruitment Letter (current trial participants)

Month TBD, 2012

Dear Dr. ______________,

I am contacting you because of your involvement in the prostate cancer prevention trial: Phase II, Randomized, Double-blind, Multi-centered Study of Polyphenon E in Men with High-grade Prostatic Intraepithelial Neoplasia (HGPIN) and Atypical Small Acinar Proliferation (ASAP).

I am a student at the University of South Florida, interested in exploring the factors that influence physician’s participation in a prostate cancer prevention intervention clinical trial and identifying ways to improve collaboration between researchers and physicians, thus improving the success of future projects.

This letter is to invite you to participate in an additional research study: Physicians as Gatekeepers: Applying Anthropology for a New Perspective (eIRB#7442) which is being conducted in partial fulfillment of the requirements for the degree of Doctor of Philosophy and approved by the University of South Florida Institutional Review Board. The study consists of an interview and a brief paper or computer based survey. Both are designed to gain a better understanding of the factors that have influenced your participation in this project. The interview will be conducted at your convenience, off site and on your own time as may be required by your institutional guidelines.

Your expertise is very important and the results will inform my dissertation research as well as the design of future cancer prevention studies. In total, participation will take approximately ninety minutes of your time. To schedule a time for this interview, please contact me at 813-745-6046 or 813-507-7912. I look forward to speaking with you soon.

Kind regards,
Theresa Crocker, MS, RD
Doctoral Candidate, Department of Anthropology
University of South Florida
tomaszts@mail.usf.edu
Appendix B. Recruitment Letter (invited or inquired)  
Month TBD, 2012

Dear Dr. _____________,

I am contacting you because of your invitation to or prior interest in participating in the prostate cancer prevention trial: Phase II, Randomized, Double-blind, Multi-centered Study of Polyphenon E in Men with High-grade Prostatic Intraepithelial Neoplasia (HGPIN) and Atypical Small Acinar Proliferation (ASAP).

I am a student at the University of South Florida, interested in exploring the factors that influence physician’s participation this prostate cancer prevention intervention clinical trial and identifying ways to improve collaboration between researchers and physicians, thus improving the success of future projects.

This letter is to invite you to participate in an additional research study: Physicians as Gatekeepers: Applying Anthropology for a New Perspective (eIRB#7442) which is being conducted in partial fulfillment of the requirements for the degree of Doctor of Philosophy and approved by the University of South Florida Institutional Review Board. The first part of this study consists of a brief paper or computer based survey which should take no more than thirty minutes to complete. The completion of this survey will serve as affirmation of your agreement to participate in this portion of the project. The survey can be completed at your convenience so as not to interfere with your usual work duties. Additionally, you will have the opportunity to participate in a more in depth, interview at a later time, which will take approximately sixty minutes of your time. The interview will be conducted at your convenience, off site and on your own time as may be required by your institutional guidelines. Both are designed to gain a better understanding of the factors that have influenced your participation in this project.

Your expertise is very important. To schedule a time for the interview, please contact me at 813-745-6046 or 813-507-7912. I look forward to speaking with you soon.

Kind regards,
Theresa Crocker, MS, RD
Doctoral Candidate, Department of Anthropology
University of South Florida /tomaszts@mail.usf.edu
Appendix C. Interview Guide

Participant ID (Interview number-site type-P/NP): __________
Date: __________

“Thank you for taking the time to meet with me today. I know your schedule is busy and I really appreciate your willingness to share your expertise and experiences with me. Please keep in mind that there are no correct answers to these questions. I am truly interested in your responses to inform our current project and those in the future. Every part of this discussion is considered confidential. Your responses will be identified by using a unique code, not your name or any other identifying information. You can stop the interview at any time and there is no penalty if you stop taking part in this study. Do you have any questions?”

1. a. Can you tell me a little about the organization that you work for?
   b. Can you tell me about how the organizational infrastructure facilitates participation in research/clinical trials?
   c. Can you tell me about how the organizational infrastructure constrains participation in research/clinical trials?

2. a. When considering how the organizational infrastructure may Facilitate participation, can you talk about what differences may exist, depending on the sponsor of the trial? [probe: Federal government, State University, Community Hospital, Private Industry such as a pharmaceutical company]
   b. When considering how the organizational infrastructure may constrain participation, can you talk about what differences may exist, depending on the sponsor of the trial? [probe: Federal government, State University, Community Hospital, Private Industry such as a pharmaceutical company]
   c. How are some sponsors preferred over others?

3. a. Describe how have you participated in research at other institutions that you may have worked.
   b. Can you tell me about things that made it similar to where you currently work? [probe: are there things that made it better/worse, easier/more challenging?]
   c. Can you tell me about things that made it different from where you currently work? [probe: are there things that made it better/worse, easier/more challenging?]
4. Are the trials that are available to you appropriate for the population that you serve?
   a. If so, how is this so?
   b. If not, how is this so?

5. Please tell me your thoughts about sending your patients to another facility to participate in a cancer prevention intervention trial.
   a. Would this be acceptable to you [why or why not]?
   b. Would a preferred alternative be study staff coming to your office or workplace?
   c. How you feel about receiving support to train your staff so your patients could participate but stay at your office/workplace?

6. Tell me about your experience enrolling a patient into a clinical trial.
   a. In your experience, to what extent is it disruptive to do this at their usual site of healthcare delivery?
   b. How disruptive is it to refer them elsewhere?

7. a. Is there any concern of financial loss if patients move care to participate in a prevention, intervention trial?
   b. How salient is this concern?
   c. Are there ways this can be mediated so that more people can be involved in cancer prevention trials?

8. From the perspective of your institution, what would help to increase the likelihood of participation in cancer prevention clinical trials in the future? [probe: compensation, protected time, staff training or dedicated study staff, less paperwork, simplified approval process, personal interest in the trial]

So far we have talked about organizational or structural (bigger picture) influences, now I am interested more in individual or personal factors (those factors that are closer to home so to speak).

9. What factors are most important to you, when considering whether or not to participate in a cancer prevention intervention clinical trial? [probe: personal interest, participation in the trial design, authorship, meeting the needs of the community that you serve, other]

10. At what phase in the research process do you prefer to become involved?  [probe: design/initiation/training, analysis, results, other]
11. From your perspective, what would help to increase the likelihood of participation in cancer prevention clinical trials in the future? [probe: compensation, protected time, staff training or dedicated study staff, less paperwork, simplified approval process, personal interest in the trial]

12. a. Can you tell me about your general philosophy towards preventive medicine?
   b. Is this similar to what you learned in your training or different?
   c. Has this changed due to your professional experience?
   d. Has this changed due to your personal experience?

13. How does your philosophy towards preventive medicine influence your willingness to participate in a cancer prevention intervention trial?

14. Tell me about how participation in a cancer prevention trial impacts the physician-patient relationship? [probe: neutral, positive or negative?]

15. Thinking back to times when you have decided to offer participation in a clinical trial,
   a. How has the possibility of uncertainty in the plan of care associated with participation in the trial played a role in your decision to offer the trial? If so, can you tell me more about this?
   b. How has the possibility of uncertainty in the outcome associated with participation in the trial, played a role in your decision to offer the trial? Can you tell me more about this?

16. How do your ethical responsibilities as a physician change when a patient participates in a cancer prevention intervention trial?

17. Prior research suggests a possible conflict when a provider plays the dual role of advocate for the patient and for the research.
   a. Have you ever experienced this?
   b. Can you tell me about what changes when patient becomes research participant?
   c. Can you tell me about what changes when the study is done and the research participant becomes the patient again?

In this time together we have discussed both organizational/structural and individual factors that may influence your willingness and ability to participate in a cancer prevention intervention trial.
18. Is there anything else that we haven’t discussed that you feel is important for me to know about?

19. Are there any other factors that influence your willingness or ability to participate in cancer prevention intervention trials?
Appendix D. Content Matrix

*Explore and document individual provider level factors (such as notions of risk and shared decision-making, explanatory views on prevention, and duality of roles) that influence participation in a cancer prevention intervention clinical trial.*

5. Please tell me your thoughts about sending your patients to another facility to participate in a cancer prevention intervention trial.
   a. Would this be acceptable to you [why or why not]?
   b. Would a preferred alternative be study staff coming to your office or workplace?
   c. How you feel about receiving support to train your staff so your patients could participate but stay at your office/workplace?

9. What factors are most important to you, when considering whether or not to participate in a cancer prevention intervention clinical trial? [probe: personal interest, participation in the trial design, authorship, meeting the needs of the community that you serve, other]

12. a. Can you tell me about your general philosophy towards preventive medicine?
    b. Is this similar to what you learned in your training or different?
    c. Has this changed due to your professional experience?
    d. Has this changed due to your personal experience?

13. How does your philosophy towards preventive medicine influence your willingness to participate in a cancer prevention intervention trial?

14. Tell me about how participation in a cancer prevention trial impacts the physician-patient relationship? [probe: neutral, positive or negative?]

15. Thinking back to times when you have decided to offer participation in a clinical trial,
   a. How has the possibility of uncertainty in the plan of care associated with participation in the trial played a role in your decision to offer the trial? If so, can you tell me more about this?
   b. How has the possibility of uncertainty in the outcome associated with participation in the trial, played a role in your decision to offer the trial? Can you tell me more about this?
16. How do your ethical responsibilities as a physician change when a patient participates in a cancer prevention intervention trial?

17. Prior research suggests a possible conflict when a provider plays the dual role of advocate for the patient and for the research.
   a. Have you ever experienced this?
   b. Can you tell me about what changes when patient becomes research participant?
   c. Can you tell me about what changes when the study is done and the research participant becomes the patient again?

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*Explore and document structural (organizational and infrastructural) considerations that influence participation in a prostate cancer prevention intervention clinical trial (with a comparison of factors across types of sites).*

2. a. When considering how the organizational infrastructure may facilitate participation, can you talk about what differences may exist, depending on the sponsor of the trial? [probe: Federal government, State University, Community Hospital, Private Industry such as a pharmaceutical company]
   b. When considering how the organizational infrastructure may constrain participation, can you talk about what differences may exist, depending on the sponsor of the trial? [probe: Federal government, State University, Community Hospital, Private Industry such as a pharmaceutical company]
   c. How are some sponsors preferred over others?

7. a. Is there any concern of financial loss if patients move care to participate in a prevention, intervention trial?
   b. How salient is this concern?
   c. Are there ways this can be mediated so that more people can be involved in cancer prevention trials?

8. From the perspective of your institution, what would help to increase the likelihood of participation in cancer prevention clinical trials in the future? [probe: compensation, protected time, staff training or dedicated study staff, less paperwork, simplified approval process, personal interest in the trial]

10. At what phase in the research process do you prefer to become involved? [probe: design/initiation/training, analysis, results, other]
11. From your perspective, what would help to increase the likelihood of participation in cancer prevention clinical trials in the future? [probe: compensation, protected time, staff training or dedicated study staff, less paperwork, simplified approval process, personal interest in the trial]

Consider how practice area (specialty centers, VA medical centers, academic centers and community offices) may impact the feasibility of participating in a prostate cancer prevention intervention trial.

1. a. Can you tell me a little about the organization that you work for?
   b. Can you tell me about how the organizational infrastructure facilitates participation in research/clinical trials?
   c. Can you tell me about how the organizational infrastructure constrains participation in research/clinical trials?

3. a. Describe how have you participated in research at other institutions that you may have worked.
   b. Can you tell me about things that made it similar to where you currently work? [probe: are there things that made it better/worse, easier/more challenging?]
   c. Can you tell me about things that made it different from where you currently work? [probe: are there things that made it better/worse, easier/more challenging?]

4. Are the trials that are available to you appropriate for the population that you serve?
   b. If so, how is this so?
   c. If not, how is this so?

6. Tell me about your experience enrolling a patient into a clinical trial.
   a. In your experience, to what extent is it disruptive to do this at their usual site of healthcare delivery?
   b. How disruptive is it to refer them elsewhere?
Appendix E. Participant Survey (current trial participants)

PARTICIPANT QUESTIONNAIRE

Thank you for agreeing to participate in this project. This portion contains some general questions to provide a better idea of who we are working with and what your general research experience has been.

Please do not write any personal information (e.g. your name) on this form.

1. Please choose the site(s) that most closely represents your practice location:
   [     ] Academic Center/Teaching center
   [     ] Specialty Center, Please specify type ________________
   [     ] Private practice
   [     ] Veterans Affairs Medical Center
   [     ] Other (please specify) ________________

2. How many years have you been working at this location? [___|____]

3. How many years have you been in practice? [___|____]

4. What is your area of medical specialty? ______________________

5. In what country did your primary medical training occur? ______________________

6. In your practice, what has been your involvement in any type of clinical trial? Check all that apply.
   [     ] I have had patients inquire about clinical trials (therapeutic or prevention).
   [     ] I have recommended patients participate in a clinical trial (therapeutic or prevention) that I administer.
   [     ] I have recommended patients participate in a clinical trial (therapeutic or prevention) administered by others.
   [     ] I have participated in the design and implementation of a clinical trial (therapeutic or prevention).
   [     ] I have had patients enroll at a clinical trial (therapeutic or prevention) at another location because it was not locally
available. 
[   ] I have participated in a clinical trial (therapeutic or prevention) in other ways. ____________________________ 
[   ] I have never been involved in a clinical (therapeutic or prevention) trial.

7. How many clinical trials (therapeutic or prevention) have you participated in as an investigator or other study personnel? ________________

If none, please skip to question 14. 
If 1 or more, please continue to question 8.

8. What are your reasons for involvement in clinical trials? Check all that apply.

[   ] Advancing Medical Science
[   ] Providing access to a novel treatment
[   ] To expand available services
[   ] Challenge
[   ] Variety
[   ] To earn extra income for my practice
[   ] Other _____________________

9. What is your main reason for participating in clinical trials?
___________________________________________________
___________________________________________________
___________________________________________________

10. How many prevention trials have you participated in as an investigator or other study personnel? _____________________

11. What are the reasons for involvement in prevention clinical trials? Check all that apply.

[   ] Advancing Medical Science
[   ] Providing the best possible care
[   ] Providing access to a novel treatment
[   ] To expand available services
[   ] To earn extra income for my practice
[   ] Other _____________________
12. What is your main reason for participating in prevention clinical trials?

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

13. Which of the following factors influence your decision to participate in any type of clinical trial? Check all that apply.

[ ] Influence on clinical care process
[ ] Time
[ ] Financial Incentives
[ ] Cost to you/your institution
[ ] Paperwork requirements
[ ] Training and education
[ ] Staffing
[ ] Concern for your patients well-being
[ ] Impact on primary role
[ ] Introduction of another care provider or decision maker
[ ] Requirements of the research protocol
[ ] Institutional support
[ ] Other _____________________

After completion, please skip to question 16.

14. What are your reasons for not participating in clinical trials (therapeutic or prevention)?

Check all that apply.

[ ] Influence on clinical care process
[ ] Time
[ ] Financial Incentives
[ ] Cost to you/your institution
[ ] Paperwork requirements
Training and education
Staffing
Concern for your patients well-being
Impact on primary role
Introduction of another care provider or decision maker
Requirements of the research protocol
Institutional support
Other _____________________

15. What is your **main** reason for not participating in clinical trials (therapeutic or prevention)?

___________________________________________________
___________________________________________________
___________________________________________________
___________________________________________________

16. What is your gender?
[ ] Male
[ ] Female

17. What is your age?
[ ] 20-29
[ ] 30-39
[ ] 40-49
[ ] 50-59
[ ] 60-69
[ ] 70 years or older

**Note:** Please be sure to answer both question numbers 18 & 19 about your ethnicity and race.

18. How would you describe your ethnicity?
[ ] 1. Hispanic or Latino
[ ] 2. Not Hispanic or Latino

19. How would you describe your race?
**Select all that apply.**
[ ] 1. American Indian or Alaska Native
[ ] 2. Asian
[ ] 3. Black or African American
[ ] 4. Native Hawaiian or Other Pacific Islander
[ ] 5. White
[  ] 6. Other (please specify) ____________________
[  ] 7. More than one race (mark all that apply)

Thank you for answering these questions
PARTICIPANT QUESTIONNAIRE

Thank you for agreeing to participate in this project. This survey contains some general questions to provide a better idea of who we are working with and what your general research experience has been.

Please do not write any personal information (e.g. your name) on this form.

1. Please choose the site(s) that most closely represents your practice location:
   [ ] Academic Center/Teaching center
   [ ] Specialty Center, Please specify type ________________
   [ ] Private practice
   [ ] Veterans Affairs Medical Center
   [ ] Other (please specify) ________________

2. How many years have you been working at this location? [___|____]

3. How many years have you been in practice? [___|____]

4. What is your area of medical specialty? ________________

5. In what country did your primary medical training occur? ________________

6. In your practice, what has been your involvement in any type of clinical trial? Check all that apply.
   [ ] I have had patients inquire about clinical trials (therapeutic or prevention).
   [ ] I have recommended patients participate in a clinical trial (therapeutic or prevention) that I administer.
   [ ] I have recommended patients participate in a clinical trial (therapeutic or prevention) administered by others.
   [ ] I have participated in the design and implementation of a clinical trial (therapeutic or prevention).
   [ ] I have had patients enroll at a clinical trial (therapeutic or prevention) at another location because it was not locally
available.
[ ] I have participated in a clinical trial (therapeutic or prevention) in other ways.

[ ] I have never been involved in a clinical trial (therapeutic or prevention).

7. How many clinical trials (therapeutic or prevention) have you participated in as an investigator or other study personnel?

If none, please skip to question 14.
If 1 or more, please continue to question 8.

8. What are your reasons for involvement in clinical trials? Check all that apply.

- Advancing Medical Science
- Providing access to a novel treatment
- To expand available services
- Challenge
- Variety
- To earn extra income for my practice
- Other _____________________

9. What is your main reason for participating in clinical trials?

___________________________________________________
___________________________________________________
___________________________________________________
___________________________________________________

10. How many prevention trials have you participated in as an investigator or other study personnel?

11. What are the reasons for involvement in prevention clinical trials? Check all that apply.

- Advancing Medical Science
- Providing the best possible care
- Providing access to a novel treatment
12. What is your **main** reason for participating in **prevention** clinical trials?

__________________________________________________
__________________________________________________
__________________________________________________
__________________________________________________

13. Which of the following factors influence your decision to participate in **any** type of clinical trial? Check all that apply.

[ ] Influence on clinical care process
[ ] Time
[ ] Financial Incentives
[ ] Cost to you/your institution
[ ] Paperwork requirements
[ ] Training and education
[ ] Staffing
[ ] Concern for your patients well-being
[ ] Impact on primary role
[ ] Introduction of another care provider or decision maker
[ ] Requirements of the research protocol
[ ] Institutional support
[ ] Other _______________________

**After completion**, please **skip** to question **16**.
14. What are your reasons for not participating in clinical trials (therapeutic or prevention)?

Check all that apply.

[ ] Influence on clinical care process
[ ] Time
[ ] Financial Incentives
[ ] Cost to you/your institution
[ ] Paperwork requirements
[ ] Training and education
[ ] Staffing
[ ] Concern for your patients well-being
[ ] Impact on primary role
[ ] Introduction of another care provider or decision maker
[ ] Requirements of the research protocol
[ ] Institutional support
[ ] Other _____________________

15. What is your main reason for not participating in clinical trials?

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

16. What is your gender?

[ ] Male
[ ] Female

17. What is your age?

[ ] 20-29
[ ] 30-39
[ ] 40-49
[ ] 50-59
[ ] 60-69
[ ] 70 years or older

Note: Please be sure to answer both question numbers 18 & 19 about your ethnicity and race.
18. How would you describe your ethnicity?
   [ ] 1. Hispanic or Latino
   [ ] 2. Not Hispanic or Latino

19. How would you describe your race?
   Select all that apply.
   [ ] 1. American Indian or Alaska Native
   [ ] 2. Asian
   [ ] 3. Black or African American
   [ ] 4. Native Hawaiian or Other Pacific Islander
   [ ] 5. White
   [ ] 6. Other (please specify) ____________________
   [ ] 7. More than one race (mark all that apply)

20. If you would be interested in providing additional information related to your experiences with clinical trials, please provide the following contact information:

   Name: ________________________________
   Contact number: ______________________
   Best time to contact: _________________
   Email address: _______________________

   You will be contacted by the researcher to schedule a mutually convenient time to meet.
   Please note this information will be used for contact purposes only and will not be linked in any way to your responses.

   Thank you for answering these questions
Appendix G. Observational Checklist

**Research Site:**

**Date:**

**Time:**

<table>
<thead>
<tr>
<th>Y/N</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of Clinical Trial Alert System</td>
<td></td>
</tr>
<tr>
<td>Dedicated research Staff</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Observed</th>
<th>Not Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consideration of patient for participation in research study by physician</td>
<td></td>
</tr>
<tr>
<td>Consideration of patient for participation in research study by other staff</td>
<td></td>
</tr>
<tr>
<td>Communication between staff related to eligibility to participate in a trial</td>
<td></td>
</tr>
<tr>
<td>Definitive plans to present a clinical trial to a patient</td>
<td></td>
</tr>
</tbody>
</table>

Comments:
Appendix H. IRB Approval Letter
April 4, 2012

Theresa Crocker, M.S., R.D.
H Lee Moffitt Cancer Center
12902 Magnolia Drive
MRC-CANT
Tampa, FL 33612

RE: Expedited Approval for Initial Review
IRB #: Pro00000442
Title: Physicians as Gatekeepers: Applying Anthropology for a New Perspective

Dear Mrs. Crocker:

On 3/29/2012 the Institutional Review Board (IRB) reviewed and APPROVED the above referenced protocol. Please note that your approval for this study will expire on 3/29/2013.

Approved Items:
Protocol Document:
Dissertations Proposal 3.12.12

Consent Document:
Your study qualifies for a waiver of the requirements for the documentation of informed consent as outlined in the federal regulations at 45CFR46.117 (c) which states that an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: (1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

It was the determination of the IRB that your study qualified for expedited review which includes activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories outlined below. The IRB may review research through the expedited review procedure authorized by 45CFR46.110 and 21 CFR 56.110. The research proposed in this study is categorized under the following expedited review categories:
(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

As the principal investigator of this study, it is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB. Any changes to the approved research must be submitted to the IRB for review and approval by an amendment.

We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to human research protections. If you have any questions regarding this matter, please call 813-974-5638.

Sincerely,

John A. Schinka, Ph.D., Chairperson
USF Institutional Review Board