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Use of Semi-Structured Interviews to Explore Competing Demands in a Prostate Cancer Prevention Intervention Clinical Trial (PCPICT)

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Abstract

In this paper we report on findings from the first known study using qualitative methods to explore factors influencing physicians' participation in an ongoing federally-funded prostate cancer chemoprevention clinical trial. We sought to identify ways to improve collaboration between researchers and physicians and enhance the success of future projects and employed purposive sampling to recruit physician/investigators who were involved or invited to participate in the trial. Using the data from open-ended semi-structured interviews, we examined patterns in their languaging and created themes. We found that individual and structural factors served as barriers and facilitators to participation. Willingness and desire to participate in the trial (individual factors) were not always enough to result in actual participation due to practice environment (structural) constraints. Our research provides a better understanding of the complex intersection of factors in this setting and through our findings we extend the theory of competing demands into the arena of prostate cancer prevention clinical trials, moving the science towards solutions to current challenges in recruitment to this type of trial.

Keywords

Competing Demands, Barriers and Facilitators, Cancer, Screening and Prevention, Access to Participants, Open-Ended Semi-Structured Interviews

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In this paper we report on findings from the first known study using qualitative methods to explore factors influencing physicians' participation in an ongoing federally-funded prostate cancer chemoprevention clinical trial. We sought to identify ways to improve collaboration between researchers and physicians and enhance the success of future projects and employed purposive sampling to recruit physician/investigators who were involved or invited to participate in the trial. Using the data from open-ended semi-structured interviews, we examined patterns in their languaging and created themes. We found that individual and structural factors served as barriers and facilitators to participation. Willingness and desire to participate in the trial (individual factors) were not always enough to result in actual participation due to practice environment (structural) constraints. Our research provides a better understanding of the complex intersection of factors in this setting and through our findings we extend the theory of competing demands into the arena of prostate cancer prevention clinical trials, moving the science towards solutions to current challenges in recruitment to this type of trial. Keywords: Competing Demands, Barriers and Facilitators, Cancer, Screening and Prevention, Access to Participants, Open-Ended Semi-Structured Interviews

I, Dr. Crocker, conducted this research in partial fulfillment of the requirements for my doctorate in Applied Anthropology. During my doctoral program, I was uniquely situated, also working as a project director for a federally funded, multi-site, prostate cancer prevention intervention clinical trial (PCPICT). This resulted in the creation of a liminal space, often requiring navigation between the “rules” and languages of two very disparate worlds, biomedicine and anthropology, that seemed would never intersect. As the project director, I became increasingly aware of the challenges inherent in the design, implementation, and daily work of conducting a prostate cancer prevention trial. Simultaneously, through the requirements of the doctoral program, I experienced an increased skillset in which I acquired new perspectives and an expanded toolkit with which to examine the world. The overarching aim of my dissertation research was to show how the two worlds could merge, with each informing the other.

As project director, I had observed recruitment below goal at most sites participating in the PCPICT. Upon review of detailed screening logs, our team was able to delineate patient, protocol and infrastructure related barriers that were contributing (Kumar et al., 2012). Similar challenges to recruitment in chemoprevention clinical trials had been well-documented by others (Chlebowski, Menon, Chaisanguanthum, & Jackson, 2010; Ruffin & Baron, 2000). What we also recognized as an important influence in recruitment was the support of committed physicians (Kumar et al., 2012). Referring physicians had been recognized in other arenas for the major role they play in getting patients involved in clinical trials (Ford et al., 2003; Miller, Crabtree, McDaniel, & Stange, 1998). In fact, physician involvement is considered essential for the provision of much of today's healthcare, and physicians serve as a critical link in the chain of events leading to the delivery of preventative services including cancer screening (Jaén et al., 2001; Nutting et al., 2001). What had not been explored using qualitative methods, and was the driving force behind this project was the role of physicians as the "link" to participation in prostate cancer prevention intervention trials (as PCPICT gatekeepers).

Stange and Nutting (1994) used the theory of competing demands to describe the multiple factors competing for the provision and delivery of preventative services by primary care physicians. The main components (physician, patient, and practice environment) are thought to be 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 not all issues receive attention at a specific visit, with preventative services often peripheral to other priorities (Stange & Nutting, 1994). Competing demands have also been found to vie for physicians' attention and resources beyond the primary care arena. Joseph and Dohan (2009) report a similar influence in recruitment to therapeutic clinical trials. I began to wonder what role "competing demands" was playing in referral and recruitment to the PCPICT.

The dearth of literature on the interaction of these demands in the context of a prostate cancer prevention intervention clinical trial (PCPICT), a growing area of research with unique recruitment challenges, suggested a research gap. I wanted to explore the concept of competing demands as a factor influencing physician participation in the PCPICT. I proposed this starting point to explore the individual provider and structural level factors that were influencing participation in the PCPICT. This critical first would help to provide an in-depth understanding of the multitude of factors influencing a physician's participation. In turn, after identification we could focus on solutions. Therefore, the study objectives were to

- a) explore the factors that influence a physician's participation in the PCPICT and
- b) identify ways to improve collaboration between researchers and physicians, thus improving the success of future projects.

The research questions 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/are (specialty centers, academic centers, Veteran's (VA) medical centers, community offices)?

The research reported in this paper is a subset of qualitative findings from the larger mixed methods study, *Physicians as Gatekeepers: Uncovering Barriers and Facilitators to Participation in a Prostate Cancer Prevention Intervention Clinical Trial* (Crocker, 2013). In the larger study I employed an exploratory, mixed methods approach and used open ended semi-structured interviews, participant observation, and survey methods to elicit factors influencing participation in the PCPICT and identify factors that might be unique to the various practice areas.

I, Dr. Crocker, served as the primary investigator, data collector, and primary analyst. The secondary authors served as primary reviewers, guides, mentors, coaches, and motivators. The participants were colleagues as well as content experts, considered best qualified to help identify solutions. All involved in this project had a vested interest in contributing to a reduced burden of cancer.

Methods

Ethics Approval

Prior to subject recruitment, the hospital Scientific Review Committee reviewed and approved the research proposal for scientific merit and the University of South Florida Institutional Review Board approved it for adherence to Human Subjects Protection.

Recruitment and Description of Participants

To recruit the individuals considered best qualified to provide the desired information (Clark & Creswell, 2011), I employed structured purposive sampling. Using a recruitment letter, I invited physicians/investigators who were

- a) involved or invited to participate in the PCPICT and could provide insight into barriers and facilitators to participation;
- b) spoke English;
- c) were willing to provide informed consent and participate in the interview.

Participation was voluntary and there was no incentive provided.

Twelve physician/investigators were invited to participate and 12 interviews were completed (100% response rate). All participants were male. Practice areas as self-reported were specialty center (n=5), academic institution (n=2), Veterans Affairs hospital (n=3), private practice (n=1), and both academic and private practice (n=1). I assigned pseudonyms to ensure the confidentiality of all participants in the following format: *interview number-site type-participation status* (01-S_P). I designated site types as specialty centers (S), academic centers (A), VA hospitals (V) or private practice/community (P). Since not all physicians had actually referred patients to the PCPICT, they were also delineated as participant (P) or non-participant (N).

Rationale for Qualitative Design

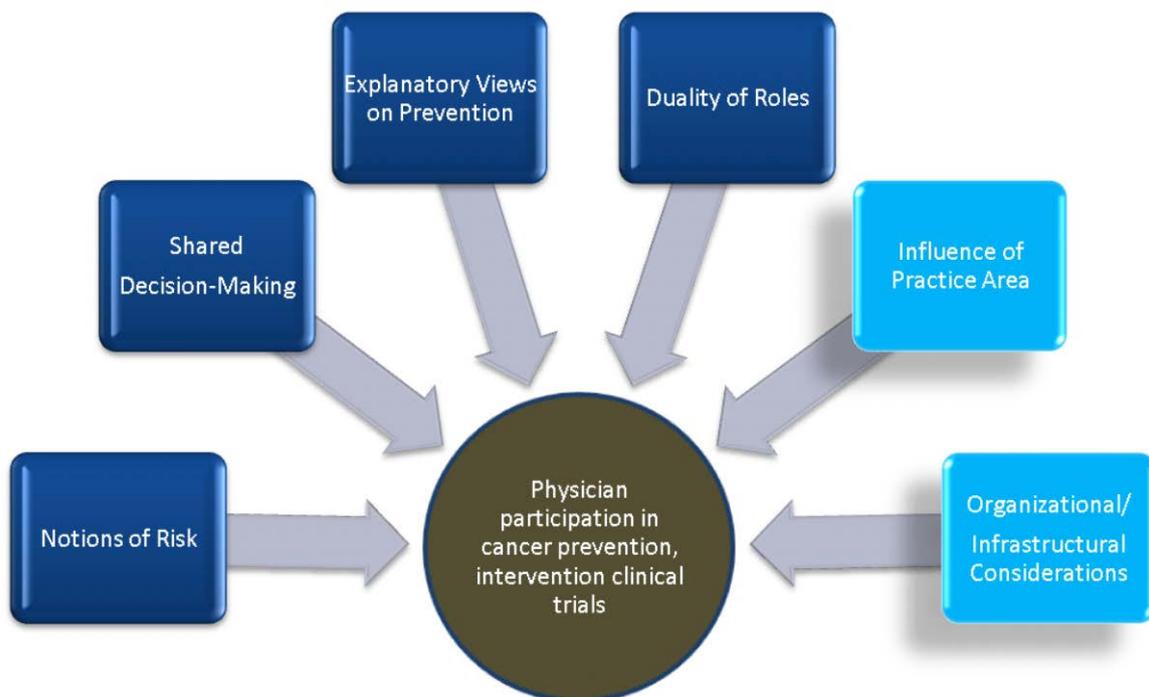
The project described in this article was aimed at exploring individual provider-level factors and structural considerations that influenced the physician/investigator's participation in the ongoing PCPICT. I was also interested in learning how practice area (specialty centers, academic centers, Veteran's [VA] medical centers, community offices) impacted the feasibility of participating in the trial. Qualitative inquiry is useful to improve the description

and explain complex, real-world phenomenon (Bradley, Curry, & Devers, 2007). It is also a way to engage with others and their practices to better understand a local world (Kleinman & Benson, 2006). This allows for insight into the views and experiences of a specific group (Abadie 2010) and contributes to deep knowledge and better awareness within a certain context.

Theoretical Frame

Following an extensive review of the literature, Figure 1 was developed and depicts the model of individual and structural factors thought to influence participation in the PCPICT. In addition to the review of literature, this adaptation of Stange and Nutting's (1994) Theory of Competing Demands was also based on the lived experience of the researchers as we had experienced physician's participation in the trial to date. As theory is modifiable, this was seen as a starting point and framework to guide the research (Bradley, Curry, & Devers, 2007).

Figure 1. Proposed Model: Individual and structural factors proposed to influence physician participation in the PCPICT



- 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

Data Collection

I used the model that included only the physician and practice components (not the patient), as a guide in the development of the interview guide. I developed the 19 question interview guide following an extensive literature review and with specific consideration of

the project objectives. This was considered important to obtain a holistic and comprehensive understanding of current influences. I also wanted to compare the lived experience of these participants with what has been reported previously in other related literature (see Crocker, 2013) to see if the factors of influence and experiences were similar. Since there were so many factors of influence reported in other arenas, the interview guide became quite lengthy. I needed a tool to be sure all of the questions ultimately addressed the research questions guiding the study. To accomplish this, I created a content matrix (see Appendix) with two distinct purposes in mind. Initially I used it to delineate how the various interview questions addressed the three research questions. This helped to avoid extraneous questions and assure that each research question was addressed. Prior to the initial interview, I pre-tested the guide with one researcher and two physicians who were not otherwise involved in the project but experienced with clinical trials. These interviews and related discussion took approximately 90 minutes per person. Following the pre-test I divided some questions into sub questions to ease future analysis. The overall content did not change and no substantive revisions or IRB review were needed.

Data Management and Quality

Most interviews took 60-90 minutes. The variation between the shortest and longest was based on the scope of information and responses shared by the interviewee. With each subsequent interview I became more proficient and comfortable navigating the interview guide. All research questions were addressed but not necessarily in the same order depending on the flow of the exchange which was more conversational and less rote as is common with semi-structured interviews compared to structured interviews. Whenever possible, interviews were transcribed within 24 hours of completion and prior to completing the next interview. Transcriptions were completed in 2 to 3 hours, depending on the length of the interview. I reviewed all transcripts for accuracy. Then I used the content matrix for a second purpose—as a guide to compile and organize responses into the research database. This was an organizational scheme to visually link the responses and the research questions.

To assure consistency in data collection I

- a) conducted all of the interviews;
- b) audio-recorded all interviews;
- c) downloaded audio files on a secure, password protected laptop computer immediately following all interviews;
- d) transcribed each interview verbatim as quickly as possible following the interview;
- e) analyzed the data immediately; and
- f) conducted a thematic analysis.

Data Analysis

I reviewed all 12 transcripts in their entirety for meaningful themes that were useful for interpretation. I used an integrated approach to qualitative analysis which allowed for application of the principles of inductive reasoning, constant comparison, and the use of conceptual and participant perspective codes during analysis (Bradley, Curry, & Devers, 2007). For example, when one physician was asked what was important for him when he considered participation in the PCPICT and he responded

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)

I was able to assign a conceptual code of *resources* and participant perspective code of *institutional support*. I could also integrate this response and compare it to other respondents' and prior research where organizational or infrastructure factors were also reported as influential.

I conducted analysis concurrently with data collection with the goal of comparing the similarities and differences between concepts that emerged in the field, as suggested by Glaser and Strauss (1967) and the literature review. I analyzed data from the interviews for themes and patterns via analysis of recurring words and phrases to specifically address the study objectives and research questions. I also used the constant comparative method to relate the views and experiences of respondents from across the various sites to help explain important differences and similarities (Barbour, 2001, Glaser & Strauss, 1967). This was particularly useful when assessing for variance in structural support at the different types of facilities (specialty centers, academic centers, Veteran's (VA) medical centers, community offices). For example, a physician from a specialty center reported, "There is a difference between what is expected and the resources provided [to do research]." Similarly, a physician with a private office in the community reported, "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."

This iterative technique led me in unanticipated directions, at times shaping the questions asked and the subsequent data collected. The result is a data set much richer than I ever could have anticipated. This benefit was also noted by Charmaz (1990).

Results

As recommended in mixed methods analysis and interpretation (Clark & Creswell, 2011), data from all sources (interview, observation and survey) were analyzed independently and integrated to address the overall study objectives. The results reported in this paper focus on the findings from the semi-structured interviews, related to the theory of competing demands as they were reported to influence participation in the PCPICT. These qualitative findings are reported thematically, as the individual and structural factors influencing participation in the PCPICT that were proposed during study design and confirmed during data analysis. This is the first time that I am aware that the theory of competing demands has been examined within the context of participation in a PCPICT. In the conclusion, the findings from this study are compared to prior research in other areas.

Individual Factors

In terms of individual provider level factors influencing participation in the PCPICT, the majority of participants reported the following as salient in regards to their participation: explanatory views on prevention (n=11), notions of risk (n=10) and uncertainty (n=7), and influence on the patient-provider relationship (n=8).

Explanatory views on prevention

I asked participants about their general philosophy towards preventive medicine. They reported that a personal interest and/or belief in preventive medicine and cancer prevention in particular were motivating factors for participation as the following responses suggest, “Prevention is very important you know whether it is cancer or . . . infection . . . that’s what will cut the health care [cost], it will improve the patient welfare. When you wait for patient to be treated, there is nothing without a price” and “. . . prevention of a disease is always a more attractive option than trying to treat the disease. I think, yes there is no question, prevention is better than therapy.” I noted this across all site types. The physicians also reported support of preventive strategies to positively influence their willingness to participate in the PCPICT: “I think the willingness to participate in general with the practitioners is an understanding of what it means, prevention.”

Notions of risk and uncertainty

I noted risk perception and assessment of risk at two distinct levels, that of the patient and that of the provider. Each served as consideration for participation in the trial. Notions of risk from the level of the patient was a means to determine who may be a “good” candidate to participate as suggested by one participant:

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)

Risk was also reported as influential in reference to physician participation in a trial, “What makes or breaks whether a physician will even mention a trial is their interpretation of how significant the biopsy findings are.” Uncertainty was seen as inherent to the business of science and medicine, and not seen as a deterrent to participation.

[That’s] why it’s called a trial, we don’t know what is going to happen at all. . . . If it works great; if it doesn’t we’re right back in same boat that you were in before. As long as [it] doesn’t make it worse, but we’re monitoring it to make sure it doesn’t make it worse. (10-A_P)

Influence on the patient-provider relationship

Physicians reported that participation in the PCPICT impacted the physician-patient relationship in a positive way: “You get the impression that they have a stronger bond” and “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.” They also reported that participation fostered trust, the sense of a common goal and allowed for the provision of involvement at a different and more holistic dimension, allowing for a continuum of care even after the study ends: “We do develop a good rapport once being a study subject and it carries on after they are off the study.” The factors reported above can be characterized as influencing the *willingness* of the physician/investigators to participate in the PCPICT and were reported as likely to be influential when future participation is considered as well.

Structural Factors

When considering the influence of structural factors on participation in the PCPICT, the presence or absence of infrastructural support, broadly described (n=9) and more specifically delineated as staffing (n=8) and funding (n=9) were mentioned by the participants. They also reported that limitations in time (n=8) were influential.

Infrastructural support

Physicians noted an interest in research participation: “There are lots of patients who are interested in trials.” However, the importance of infrastructure to support participation in these trials was considered necessary: “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.” Though recognized as critical to participation, inadequate support was noted across all site types as evidenced by the following responses” “(There are) insufficient resources to help investigators bring trials to patients and accommodate patients in trials” and

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 resources.
(03-S_P)

Staffing. More specifically, adequate staffing was recognized as critical, “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.” This infrastructural support was necessary to support the work required to meet regulatory and other requirements without competing with the needs of non-research patients and other responsibilities:

High volume of research 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)

Funding. Funding is another infrastructural consideration that was reported:

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. (10-A_P)

This ultimately impacts resource allocation as evidenced by the following responses, “[Certain 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” and “A non-funded trial gets minimal effort from the clinical trials support staff.”

Time. Finally, comments related to time cannot be ignored: “Don’t underestimate how busy the doctors are,” as limited time is seen as a constraint to participating in research.

“Time definitely. Time dedicated to the encounter . . . sometimes not having adequate support staff, clinical trial coordinators who are readily available. . .” “Faculty, they are all incredibly stretched thin. I think their limitation is similar to our limitation in terms of time.” This impacts participation in the trial:

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)

It also impacts recruitment as well, “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.” These structural factors acted as both barriers and facilitators in influencing the physician/researcher’s *ability* to participate in the PCPICT. They were also reported as likely to influence participation in future studies.

By constantly comparing the concepts and themes that emerged in the field (Glaser & Strauss, 1967) between participants at the various sites and to prior research findings, I was able to conduct an in-depth exploration of individual physician’s experiences and meanings related to cancer prevention and participation in cancer prevention intervention clinical trials. This also allowed me to consider the larger and unavoidable structural factors that impact the practice of medicine and influence participation in such a trial. I found that individual factors (such as explanatory views on prevention, notions of risk, and uncertainty and influence on the patient-provider relationship), in addition to structural factors (infrastructural support, staffing, funding, and time), both which have been identified by other researchers and in other contexts, are similarly influential within the realm of a PCPICT. Each served as barriers and facilitators to participation in the trial. In-depth exploration resulting from analysis of the qualitative data revealed that individual factors seemed to have a greater influence on the willingness to participate while structural factors were more likely to impact the ability to participate, as Figure 2 depicts. This revised model more clearly depicts the varying influence of each factor. The enhanced understanding of how individual and structural factors intersected to influence participation in the PCPICT will be useful for the design of future trials.

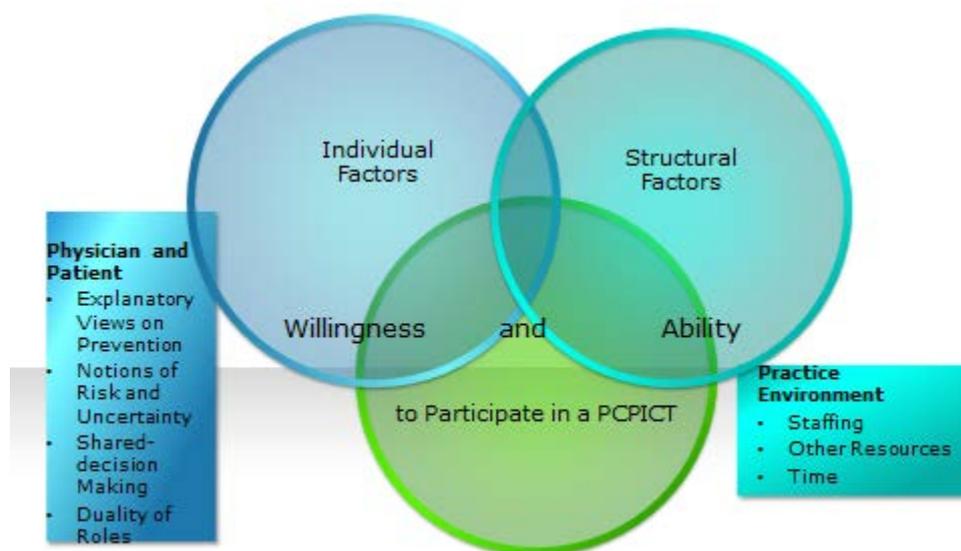
Practice Site/Area Factors

When considering the influence of individual factors on participation in the PCPICT, there was homogeneity in responses both within and across types of centers (i.e., specialty, academic, Veteran’s Affairs, academic, *and* private practice). A majority of key informants reported factors such as views on prevention, notions of risk, and influence on the patient-provider relationship as influential. In regards to structural factors, my analysis of the data suggested there was greater heterogeneity in the responses when making comparisons both within and across the types of centers. Participants at all site types expressed the critical need for research infrastructure. Physicians from all site types noted funding to support research efforts and contribute to the institution’s financial goals as relevant. Interestingly, this was not a significant barrier within the VA system. Time was seen as both a positive and negative influence on participation in the PCPICT. When trial requirements were in-line with or conducive to the physician’s usual schema of care for the condition under study, this was seen as a positive factor making participation more feasible. However, physicians stated that if trial requirements contrasted with usual care, or the time required for documentation purposes or to discuss research with a patient resulted in a conflict for a time slot that was

previously established for a clinical encounter, it was considered a negative factor of influence. Additionally, if the time allotted by administration for research competed with time for clinical care, lack of time was considered a significant barrier to participation in research. These barriers and facilitators to research participation, particularly the structural factors, should be explored in further detail to improve the success of future endeavors.

Patient population also falls within the realm of structural considerations influencing participation, at least in this PCPICT. “Patient” is also the third component noted as influential in the theory of competing demands. Considering the scope of practice of each participant (ranging from surgical oncology to routine urological care), and the practice environment in which their daily work occurs, it is not surprising that there was variation in the primary populations seen by each. Analysis revealed that some patients and practice sites were considered by the physician/investigators to be better suited for prevention type trials than others. This will be elaborated in a forthcoming publication.

Figure 2. Revised Model: Individual and structural factors influencing physician participation in the PCPICT



Discussion

In this paper I report qualitative findings from an ancillary study situated within the context of an ongoing PCPICT. The results can be used to inform the design of future trials. The findings suggest that individual and structural factors intersect, resulting in competing demands that influence the willingness and ability of physician/investigators to participate or refer patients for participation in the PCPICT. Individual factors such as explanatory views on prevention, notions of risk and uncertainty and influence on the patient-provider relationship appear to have a greater influence on the *willingness* of physicians to participate in a PCPICT. Structural factors such as staffing, access to resources, time and a patient population with the necessary diagnosis, many which are often beyond the physician/investigator’s control, are more influential in regards to the *ability* to participate. Similar to research conducted in other contexts (Klabunde et al., 2011), features of the various practice environments influenced involvement in the PCPICT, serving as both barriers and facilitators to participation.

I used the theory of competing demands to frame this research, drawing on micro and macro level factors of influence reported in other contexts to provide a more holistic understanding of the multitude of variables influencing participation in the PCPICT. This research expands the concept of competing demands from the primary care setting to the realm of cancer prevention intervention clinical trials. Factors identified as influential to the provision of preventative service such as the physician, practice environment, patient, attitudes, expectations and alternative demands (Jaén et al., 2001; Nutting et al., 2001) are similarly influential in the context of a PCPICT. Physician willingness and desire to participate was not always enough to result in actual participation. Notably, the ability to participate was influenced by constraints within the practice environment such as competing demands for time, space, and personnel as well as the patient population.

Limitations and Future Directions

I acknowledge benefits as well as potential concerns related to familiarity of the researcher in the research setting (DiCicco-Bloom & Crabtree, 2006; Hanson, 1994; Preston, 1997). With this project, it was beneficial to be able to provide firsthand knowledge of the challenges of an ongoing project and allowing for a research design that provided a broader and more holistic examination of the issues. It also afforded direct access to the physician/investigators who were willing to participate. The potential for bias in participant response and during data collection and analysis due to the fact that all interviewees had a previously established working relationship with me must be acknowledged. Reflexivity (Hahn & Kleinman, 1983) on my part helped to minimize any constraints or potential bias related to working in a familiar setting. Due to the specific nature of this project and the history of involvement, this sample was considered best qualified to address the research questions. The association positively influenced the willingness of the key informants to participate, as evidenced by the 100% participation rate.

Though triangulation of the data from all sources helped to corroborate the findings of the larger project, cross-checking for intercoder agreement would have additionally strengthened the interpretation of the qualitative portion of this exploratory study. The capacity to do so was limited by the resources available as this research was for a doctoral dissertation; however, since this was a study where I was embedded in ongoing relationships with the research participants, some have suggested that a single researcher is sufficient and preferred (Bradley, Curry, & Devers, 2007). This research focused on one very specific context-prostate cancer prevention intervention clinical trials- and was aimed at describing the physician's role as gatekeeper within this setting. My goal was to provide greater understanding of a specific lived reality and make recommendations for future research. It is recognized that due to the small sample size and specific context under analysis, results might not be generalizable to other research situations beyond the realm of PCPICTs. Expanding the study to a larger subset would be important to increase the strength of the conclusions beyond this setting. The findings reflect the perspective of only those who met the inclusion criteria. Some insight into possible reasons for non-participation in the PCPICT can be gleaned from the responses provided by those who were interviewed; however, their responses should not be considered reflective of the opinions of all non-participants. Soliciting this voice is important for the success of future prostate cancer prevention research projects. A consideration of the competing demands and intersection of factors within each local environment is encouraged. Additionally, the voice of the female physician is absent as all physician/investigators in the PCPICT were male.

This research did not examine how physician willingness and ability ultimately influenced actual recruitment to the PCPICT as compared to the project recruitment goals.

This would be a valuable next step, adding overall insight to better understanding the challenge of recruitment to prevention clinical trials within each of the four contexts. Additional examination could also delineate the relative influence of factors such as medical specialty, country of primary medical training, career stage, practice model, type of funding and internal research priorities, all which emerged as factors influencing participation in the PCPICT, via the various modes of data collection. Further exploration to more clearly describe the barriers and facilitators to participation among physician/investigators at all site types would help to minimize the influence of competing demands in future prevention trials. Finally, as previously noted, a discussion of competing demands typically includes the interaction of the physician, the patient, and the practice environment (Stange & Nutting, 1994). This project includes an exploration of only two of these components, the physician and practice environment. Though data emerged that can be associated with the patient component, additional research that captures the patient perspective as well as the experience of other members of the clinical research team would help to provide a more comprehensive understanding of all of the relevant issues influencing patient recruitment in this and other cancer prevention clinical trials.

Table 1. Summary of considerations for future studies

Key features	Explanation
Scientific Rationale	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
Minimal burden	Protocol requirements must be closely in line with usual practice for the condition under study to minimize patient and physician burden
Dedicated staff	Dedicated research time and personnel is highly desirable
Partnerships/Collaboration	Partnerships with “friendly” community physicians must be forged to extend availability to a wider range of patients
	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
Cost neutral	Trial must utilize existing resources or provide for additional so that the venture is at least cost neutral for the institutions involved

Conclusion

My results reveal that biomedical factors such as risk perception and scientific rationale in addition to social factors such as explanatory views on prevention, concerns for their patient’s well-being, and prior personal and professional experiences were salient and influential to participation in the PCPICT. As with prior research (Jaén et al., 2001; Joseph & Dohan, 2009; Nutting et al., 2001; Stange & Nutting, 1994), the intersection of these individual, social, biomedical, and structural factors influenced not only the willingness but the ability of physician/investigators, creating barriers as well as facilitators to participation in the PCPICT. These findings suggest that factors previously shown to influence participation in therapeutic clinical trials (Crosson, Eisner, Brown, & Maat, 2001) and cancer prevention trials (Hall et al., 2010) are similarly influential in the realm of a prostate cancer prevention intervention trial. The results of this study, allow for a better understanding of the

intersection of these factors within this particular context. A summary of main points, from the perspective of the key informants and to maximize the success of future studies is provided in Table 1.

This research contributes a qualitative component to an ongoing clinical trial, and expands the theory of competing demands into the arena of prostate cancer prevention clinical trials. Additionally, these findings move the science towards solutions to the current challenges in recruitment to this type of trial. I hope that the results will inform design, funding and implementation of future prevention clinical trials.

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Appendix

Content Matrix with Research Questions and Examples Questions from Interview Guide

Research question 1: What individual factors influence a physician's participation in a PCPICT?

Interview question 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]

Interview question 13:

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

Interview question 14:

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

Interview question 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?

Interview question 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?

Research Question 2: What structural factors influence a physician's participation in a PCPICT?

Interview question 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?

Interview question 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]

Interview question 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]

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

Interview question 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?

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