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Science in the Heartland: Exploring determinants of offering cancer clinical trials in rural-serving community urology practices

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Abstract

OBJECTIVE—Engaging community urologists in referring patients to clinical trials could increase the reach of cancer trials and, ultimately, alleviate cancer disparities. We sought to identify determinants of referring patients to clinical trials among urology practices serving rural communities.

METHODS—We conducted semi-structured qualitative interviews based on the Theoretical Domains Framework at non-metropolitan urology practices located in communities offering urological cancer trials. Participants were asked to consider barriers and strategies that might support engaging their patients in discussions about urological cancer clinical trials and referring them appropriately. Recorded interviews were transcribed and coded using template analysis.

RESULTS—Most participants were not aware of available trials and had no experience with trial referral. Overall, participants held positive attitudes toward clinical trials and recognized their potential roles in accrual, but limited local resources reduced opportunities for offering trials. Most participants expressed a need for increased human, financial, and other resources to support this

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role. Many participants requested information and training to increase their knowledge of clinical trials and confidence in offering them to patients. Participants highlighted the need to build efficient pathways to identify available trials, match eligible patients, and facilitate communication and collaboration with cancer centers for patient follow-up and continuity of care.

CONCLUSIONS—With adequate logistical and informational support, community urology practices could play an important role in clinical trial accrual, advancing cancer research and increasing treatment options for rural cancer patients. Future studies should explore the effectiveness of strategies to optimize urology practices' role in clinical trial accrual.

Keywords

urological cancer; clinical trials; physician recommendation; implementation science; community practice; cancer care delivery

1. INTRODUCTION

Major advances in treatment of urological cancers have been achieved due to successful completion of clinical trials.[1,2] National Comprehensive Cancer Network (NCCN) treatment guidelines for urological cancer care recommend consideration of available clinical trials as standard of care[3–6] as do American Urological Association guidelines for bladder[7] and prostate cancer.[8] Despite strong endorsement and proven contributions of clinical trials, 92% of adult cancer patients do not participate,[9] with even lower rates for underserved populations.[10–15] Rural cancer patients have recently received attention as an important underserved population.[16,17] Rural Americans constitute one-fifth of the US population and bear a disproportionate burden of cancer morbidity and mortality[18,19] and thus should be included in clinical trials. However, the degree to which rural cancer patients are adequately represented in cancer clinical trials is uncertain. Several studies suggest rural patients are underrepresented.[11,13–15] However, a more recent study, which pools multiple trials within one cancer cooperative group suggests that across all trials rural patients are adequately represented.[20]

Improved rural representation in some clinical trials may be the result of programs like the National Cancer Institutes' Community Oncology Research Program which has increased clinical trial participation among rural patients by extending clinical trials to community oncology practices.[20] However, the maldistribution of the oncology workforce[21] and the substantial proportion of cancer patients cared for by non-oncologists highlight the need for continued efforts to reach rural populations.[20]

One innovative strategy to maintain representation of rural populations is to integrate other cancer care providers into clinical trial efforts. Many specialists are involved in diagnosing and treating cancer. However, 20% of the US cancer burden is urologic,[22] making urologists a potentially valuable partner in increasing rural cancer patients' access to clinical trials. Although faced with similar maldistribution challenges demonstrated in the oncology workforce, urologists maintain a stronger hold in rural communities than oncologists: 11% of urologists serve rural communities compared to 3% of oncologists.[21,23]

Despite the high concentration of cancer within their specialty, urological cancer trials accrue patients more slowly than other cancer trials[24] Whether this is due to infrastructure limitations or unique barriers urologists face is unknown because relatively little research on physicians' participation in clinical trials include urologists.[12,24,25] Even less is known about the particular challenges faced by urologists practicing in *rural* settings. We sought to addresses these questions through in-depth exploration of factors influencing rural-serving urologists' offer of clinical trials.

2. MATERIALS AND METHODS

To structure this qualitative inquiry, we used the Theoretical Domains Framework (TDF), which synthesizes 128 theoretical constructs drawn from 33 theories into 14 constructs relevant to implementation behavior.[26] The TDF's 14 behavioral determinants are further summarized into three essential conditions of behavior change: capability, opportunity, and motivation.[27] *Capability* refers to individual's psychological and physical capacity to engage in intended activities. *Motivation* is defined as internal psychological processes that energize and direct behavior. *Opportunity* includes factors external to the individual that prompt or make behavior possible.[27]

We conducted semi-structured individual and group interviews on location in urology practices in communities across a rural state. To eliminate distance to trials as a distinct barrier,[28] we included only practices with access to urological cancer clinical trials through their hospital's affiliation with a state-wide infrastructure supporting clinical trials. To identify practices, we obtained a list of urologists from the state licensing board. We included all urologists with a non-federal, active license. We sorted urologists by county and excluded those in metropolitan counties (defined as population ≥50,000). We then identified non-metropolitan counties in which cancer cooperative group trials were offered through an outreach arm of the state's academic medical center. Urologists were included if their address was in, or adjacent to, the county in which trials were available. We verified urologists' practice affiliation via practice websites, directory listings, and phone calls to the practice. From the subset of urology practices with locally available trials, we excluded practices beyond a 4-hour driving radius from the university for the initial assessment. Practices were recruited by contacting individual urologists and obtaining agreement for the practice to participate.

Two interviewers visited each enrolled site to conduct individual and small group interviews with urologists and clinical and operational staff. Participants were provided study information and reviewed informed consent prior to participation. The research was approved by the Institutional Review Board of the University of Kansas Medical Center. Past accrual data on participating practices was obtained from the University's Cancer Center. Characteristics of the practice, including degree of rurality, practice type (solo/group; private/hospital-owned), size, ownership model, hospital size and resources were collected from participants, extant census data and American Hospital Association records.

All interviews were audio recorded and transcribed verbatim. Transcripts were imported into qualitative analysis software (NVivo[29]) after anonymization. We conducted template

analysis,[30] which uses a codebook to search for pre-defined themes and allows examination of emergent themes. The codebook was based on TDF constructs, with definitions and examples provided in previous literature,[31,32] and revised throughout the analysis. To assess sample size adequacy, we assessed interviews for saturation, a criterion commonly used in qualitative research.[33] After the initial round of data collection we reviewed transcripts to examine consistency in response across practices.

Twenty percent of transcripts were independently coded by two investigators and discrepancies resolved by consensus. Once coding was consistent among investigators, it was completed by a single investigator. Coded constructs were reviewed to identify subthemes.

3. RESULTS

3.1. Participant Characteristics and Trial Accrual

We identified 90 urologists with non-federal, active licenses, 72 of whom practiced in metropolitan communities. Of the remaining 18 non-metropolitan area urologists, 14 (grouped into 9 practices) had trials available through the University's outreach program in their local community; no trials were available near one urology practice. Three solo practices were located beyond the 4-hour driving radius, Of the six community urology practices meeting all inclusion criteria, four (67%) were enrolled. Non-enrollers consisted of one solo practice and one urologist practicing in a multi-specialty clinic. Responses were consistent across practices, indicating saturation had been achieved.Thus we did not contact the solo practices outside the driving radius. Across the four practices (two solo practices and two group practices), we completed interviews with seven physicians and 10 staff members, including nurses, practice managers and other support staff (Table 1). All participating practices were in non-metropolitan communities (population size <50,000) (Table 2). At the time of recruitment, six urological cancer clinical trials were available to community oncology programs in the centralized network. Two accruals to urological trials were attributed to these four rural communities' cancer programs, accounting for 7% of the academic center's annual enrollment, whereas three metropolitan community oncology programs accounted for 10% of accrual. We ascertained that both non-metropolitan accruals were obtained for a single study from a single community.

While all practices were in non-metropolitan communities, they differed in size and scope (Table 2). The two solo practices served small communities with populations less than 21,000. The two group practices were also in small communities (approximate populations 20,000 and 47,000), but both served as hubs for extensive outreach with multiple satellite sites (7 and 9 satellite clinics), covering up to nine surrounding counties, some more than two hours away, accessed via airplane.

3.2 Potential Determinants of Offering Clinical Trials

Urologists and their staff described many aspects of capability, opportunity and motivation in relation to their referring behaviors. However, opportunity determinants of trial referral were the most prevalent across all domains.

3.2.1. Opportunity—Both *environmental context and resources* and *social influences* were prevalent across all settings and practices. Many participants identified limited time and high workload as barriers to offering trials, which was heightened in the context of under-resourced rural practices. Participants perceived trial referrals requiring an investment of extra resources they could not allocate or secure on their own. They noted discussing trials with patients requires an extra time commitment from already overburdened physicians and staff, and expressed need for additional human resources to provide ongoing support. For example, one urologist commented:

> I think we have a good group of urologists here that are very interested in doing what's going to be best for that patient and the patient population. If it's good for them…it's a no brainer, but we do need to have the personnel.

Some suggested that any use of internal resources be incentivized financially. In addition to human and financial resources, participants expressed need for informational resources to support offering trials, such as brochures, videos, and internet sources to share with patients when introducing trials (Table 3, Resources).

> *You can always give them literature, but I'm not sure they read it, but they might be more apt to play a video and get the information that way*.

Despite having trials available in the immediate community, urologists were mindful of access limitations for patients living in more remote rural communities (Table 3, Environmental Context).

Social relationships also create opportunity, including influence from other providers at the cancer center, patients, and patients' friends and family. Among them, influence from other providers and cancer centers were most important. For example, urologists felt more comfortable referring patients to cancer centers and academic hospitals with positive reputations and to physicians they regard as knowledgeable and trustworthy (Table 3, Social Influences). Participants expected their usual cancer referral partners (academic urologists and local cancer centers) to have processes for clinical trials and preferred their patients receive information directly from trial personnel. They indicated they could be highly influenced by expanding their professional networks to include trial investigators.

> It's getting the people that are involved in developing the clinical trial in front of urologists themselves…maybe just when they developed a new one…talking to them, and basically selling their clinical trial to that doctor so that doctor, one, believes in it and, two, wants to recommend it to their patients.

Urologists perceived patients and their families to strongly influence their offer of clinical trials. They cared about anticipated patient reactions to their recommendation as well as patients' knowledge of and general perceptions about clinical trials. Some participants were mindful of social influence from patients' family members and expressed willingness to include relatives when engaging patients (Table 3, Social Influences).

3.2.2. Capability—In the capability domain, *knowledge* emerged as the most prevalent overarching construct, closely intertwined with *memory, attention, and decision processes,* and *psychological skills* Lack of awareness about clinical trials was frequently mentioned,

despite availability of urological cancer trials in each community, sometimes as close as the building next door. “We have to know what’s out there because…we simply don’t know what’s available.” Urologists and staff also lacked content and procedural knowledge about trials, which negatively impacts their confidence in presenting trials to their patients (Table 4, Memory, attention and decision processes). The few urologists who already offered trials described needing ongoing communication after referral. Existing trial information was hard to access and required high levels of cognitive processing to apply to patient care. They had inadequate reminder systems and requested systematic pathways to guide their *decision processes* in identifying and referring patients to trials.

Participants were aware of significant influences that physicians have on patient treatment decisions and believed urologists should have sufficient *knowledge* of clinical trials to feel confident about trial recommendations, which translates into *cognitive skills*, i.e., the ability to effectively explain and address questions about clinical trials, which they saw as an important prerequisite to offering trials. To increase *knowledge*, many participants expressed need for increased opportunities for basic training rather than being presented with full details about trials (Table 4, Knowledge).

3.2.3. Motivation—In the motivation domain, two TDF constructs, *social/professional role & identity* and *beliefs about consequences,* were most common. Regarding the *social and professional role*, urologists talked about how they view their role within the practice, relative to patients, and relative to other providers in the broader health system. Within the practice, urologists believe it is their responsibility to initiate conversations with the patient about clinical trials in the context of treatment counseling, rather than their staff. “[Talking about trials] is really part of giving the patient their options and making them aware of all of their options including trials.” That should first come from the physician. However, they do see a role for staff in helping them identify relevant trials for patients and further discussions they initiate. Several were conscientious of staff’s workload and were comfortable with, and willing to, delegate trial tasks to external resources such as cancer center trial staff. Urology staff see their role as reminding urologists about available trials, reinforcing doctor’s recommendations for trials, educating patients about trial options, and fielding questions about them (Table 5).

Urologists state they have a duty to maintain positive doctor-patient relationships and feel it is imperative that trial discussions not interfere. Some recognized it is a urologists’ duty to the patient and their professional obligation to discuss trials. Relative to other providers, urologists recognized their responsibility to be *aware* of trials, to refer patients to oncologists or urologists specializing in cancer for treatment options they cannot offer, but not being responsible for eligibility screening (Table 5, Professional Role). Many were comfortable referring patients to clinical trials rather than treating them, particularly when they had exhausted treatment options available to them. They likened trial investigators to other specialists they could refer to, envisioning they could instruct a patient to see a trial investigator for more information and “*then come back and talk with me about it.*” Urologists expect trial experts to send communication back about the referred patients’ eligibility and ultimate trial status. They also expect to discuss specifics of any co-management responsibilities as they feel the community urologist still has responsibility for

patients' care, irrespective of trial participation (Table 5, Professional Role). Because urologists in small communities interact with patients outside the clinic, they need to know the management plan, even if they are not responsible. Urologists who had referred patients to trials did not necessarily see their role diminishing once a patient enrolled in a trial. Community urologists also had additional expectations of trial investigators: to inform them about available trials both as periodic reminders and to increase their confidence in making referrals.

Regarding *beliefs about consequences*, participants who believed in benefits of clinical trials, such as advancing medicine, were more favorable toward offering trials (Table 5, Beliefs). Similarly, those who believe they are providing quality of care by offering clinical trials to their patients with limited treatment options were more receptive to recommending trials.

4. DISCUSSION

We sought to explore the opportunity, capability and motivation of rural-serving urology practices in offering clinical trials to their patients. Despite having trials available in their communities, participating practices had limited awareness of available trials because they lacked social connections with those conducting trials. They also lacked useable and actionable information about trial opportunities. Urologists and staff had limited capability to initiate trial discussions and no processes to integrate trials into their workflow. Nonetheless, rural urologists were motivated to offer trials because they see trials as extending available treatment options, which is aligned with their professional role. Further, they were receptive to interventions to help them offer trials to their patients. They perceive a need for education about trials to increase knowledge, improve confidence, and potentially advance their understanding of rural patients' concerns about and receptiveness to trials. Urologists indicated that dedicated resources are necessary and were receptive to external facilitation to achieve the goal.

Our findings confirm and extend previous work describing urologists' attitudes regarding cancer clinical trials.[24,25] In a national survey of urologists, participants reported holding positive attitudes about cancer clinical trials.[24] Those survey participants saw a wide range of benefits from clinical trial participation to their patients and their practice, and had no objections to trials based on philosophical, ethical, or business grounds, consistent with our findings. Similar to participants in our study, the survey participants, particularly those who did not currently participate in trials, lacked incentive to offer clinical trials, educational opportunities to learn about trials, and systems through which to enroll patients.[24] Previous literature has often characterized trial participation as potentially hindering the patient-physician relationship.[34,35] In slight contrast, our findings suggest that, *because* of the value urologists place on the patient-physician relationship, emphasizing how offering clinical trials may enhance that relationship could provide the missing incentive, especially to the extent urologists compete with other providers for patients.

Urologists in this study perceived that rural patients were less receptive to trials than non-rural patients, a finding consistent with other literature.[24,36] Indeed rural patients, whether

due to education, income, or distance, may be more reluctant to participate. It has recently been demonstrated that rural patients may participate in a representative fashion if sufficient resources are provided to support the recruitment effort.[20] Improvements in participation have been attributed to programs such as NCI's NCORP.[20] However, rural patients tend to have more negative attitudes toward trials. Thus, these efforts may need to be supplemented by direct outreach to rural populations featuring messages from their local healthcare providers.[36]

Low income patients, who are overrepresented in rural populations, are less likely to enroll in clinical trials and have a higher level of cost related concerns.[37] Cancer patients bear a high financial burden for their treatment costs.[38–41] Because treatment costs are the patient's responsibility and only clinical trial costs are paid by study sponsors, uninsured patients may have difficulty participating in clinical trials. However, even uninsured patients may have difficulty participating in clinical trials. Although treatment and study costs may be covered for most insured patients, clinical trial participation may involve slightly higher incremental out-of-pocket costs compared to regular cancer care.[42–45] Thus, urologists and staff should be educated on costs as well as benefits associated with participation in clinical trials and feel comfortable referring patients to trial specialists. Trial specialists should be able to accurately counsel patients, and may be able to help determine coverage and incremental costs, provide potential assistance,[44] and address patients' concerns so they can make informed decisions about trial participation.

Our results suggest environmental and staffing constraints may be additional limiting factors for urologists in rural practices. Although community urology practices across all geographic regions may be under-resourced, resource scarcity may be particularly important in non-metropolitan practices, which tend to be smaller groups or solo practices. Existing programs to extend trials to community urology practices (e.g., the Society of Urological Oncology-Clinical Trials Consortium) require practices to provide dedicated research personnel, limiting feasibility for solo and smaller group practices. However, in our study, urologists serving rural communities were willing to explore opportunities to collaborate with reputable cancer centers and regional oncologists. Delegation of tasks (beyond recommending a treatment path) fit well within self-perceived roles of urologists and their staff. Programs that provide external facilitators, rather than practice investment may generate greater uptake. Informational handouts or multimedia were welcomed and could be used to provide patient education deemed part of the urologist's responsibility, but beyond resources at hand.[46] If tailored to rural patients, these materials could further address barriers to participation.[46]

This study further extends previous work in two additional ways. First, we identified these rural urologists lack social networks with trial investigators who they and their staff perceive to be highly influential in encouraging them to offer clinical trials. Swanson et al. (2007) found a statically significant association between the urologist having an academic mentor who valued research and currently offering trials,[24] but did not investigate the potential role of trial investigators directly championing trials to urologists. Study participants highly value face-to-face contact with trial investigators, a strategy demonstrated to be effective among primary care physicians.[47] Second, offering clinical trials was consistent with rural

urologists' professional identity, as they perceive their job is to offer all appropriate treatment options to their patients. Because congruence of role identity with a new behavior is theorized to promote adoption of the behavior,[48] promoting the offer of clinical trials as an extension of available treatment options may further enhance uptake.

Based on these theoretically informed findings, we have identified several intervention components which may be effective in expanding the reach of cancer clinical trials to urological patients. First, disseminating information about available clinical trials to urologists is needed. Enriching dissemination efforts with face-to-face contacts from local study investigators and research personnel may increase integration of this information into patient care. Further, framing clinical trials as potential treatment option for all cancer patients and facilitating integration of reminders and support into the workflow at this junction may also aid implementation. Providing brief skills training at local and regional meetings that community urologists and their staff attend could increase confidence in offering trials. Developing adequate patient education materials about clinical trials in formats acceptable to rural populations could alleviate burden on urology practices and provide patients with consistent, accurate information that can facilitate their transition to the clinical trial expert. Finally, establishing clear communication about co-management responsibilities between the referring urologist and the clinical trial consult and ensuring feedback from cancer programs about eligibility screening and enrollment may foster urologists' willingness to try referrals. Figure 1 suggests a way that practices and stakeholders could work together.

4.1. Limitations and Future Research

The current study is not without limitations. We did not interview patients or their caregivers, and are unable to validate the patients' perspectives urologists described. Instead, we chose to focus on the physicians' offer of clinical trials. A large body of literature describes patients' barriers to clinical trial accrual and consistently finds that physician offer is highly influential in their decision to participate: Seventy percent of pattern variation for clinical trial enrollment is reported to be associated with physician effort to engage patients, and 73% of patients who enrolled in a clinical trial were motivated by their physician's recommendation.[12]

Participating practices were limited to rural counties in a single state. Results may not be generalizable to practices in metropolitan areas or other states. We limited our study to communities which had access to NCI-sponsored trials. Results may not be relevant for communities without these opportunities[28] or with only industry-sponsored trials.[49] Future research should validate findings among practices in a variety of geographic settings and should monitor the distance a patient must travel to participate in a trial. Further, because our qualitative methodology does not allow us to ascertain the magnitude of the impact these determinants may have on the offer of clinical trials, additional research to quantify the relative importance of these factors is warranted. A survey of a representative sample of urologists could address both the generalizability of these findings and help prioritize which determinants should be targeted for intervention. Including such items in the American Urological Association census, an extant survey with high response rates,[23] may be a

feasible approach to obtaining this data. Finally, we offer some potential interventions to address these disparities, but formal intervention mapping to identify interventions which can address these determinants is warranted.[50]

5. CONCLUSIONS

Rural-serving urology practices present important opportunities to increase cancer clinical trial accrual. With adequate relational, logistical and informational support, these practices could help advance cancer research and increase treatment options for urological cancer patients. Implementation strategies which address determinants of the clinical trial offer among rural urologists are potentially viable. Future studies should explore effectiveness of strategies to optimize rural urology practices' role in clinical trials accrual and assess the degree to which these findings apply to and impact other urology practices.

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HIGHLIGHTS

- Non-metropolitan community urology practices present important opportunities to increase cancer clinical trial accrual.
- Even in communities with available cancer clinical trials, practices have limited awareness of trials because they lack social connections with trial investigators.
- Rural-serving urologists were motivated to offer trials because they see trials as extending available treatment options, which is aligned with their professional role.
- Practices were receptive to interventions, including external facilitation, to help them offer trials to their patients.

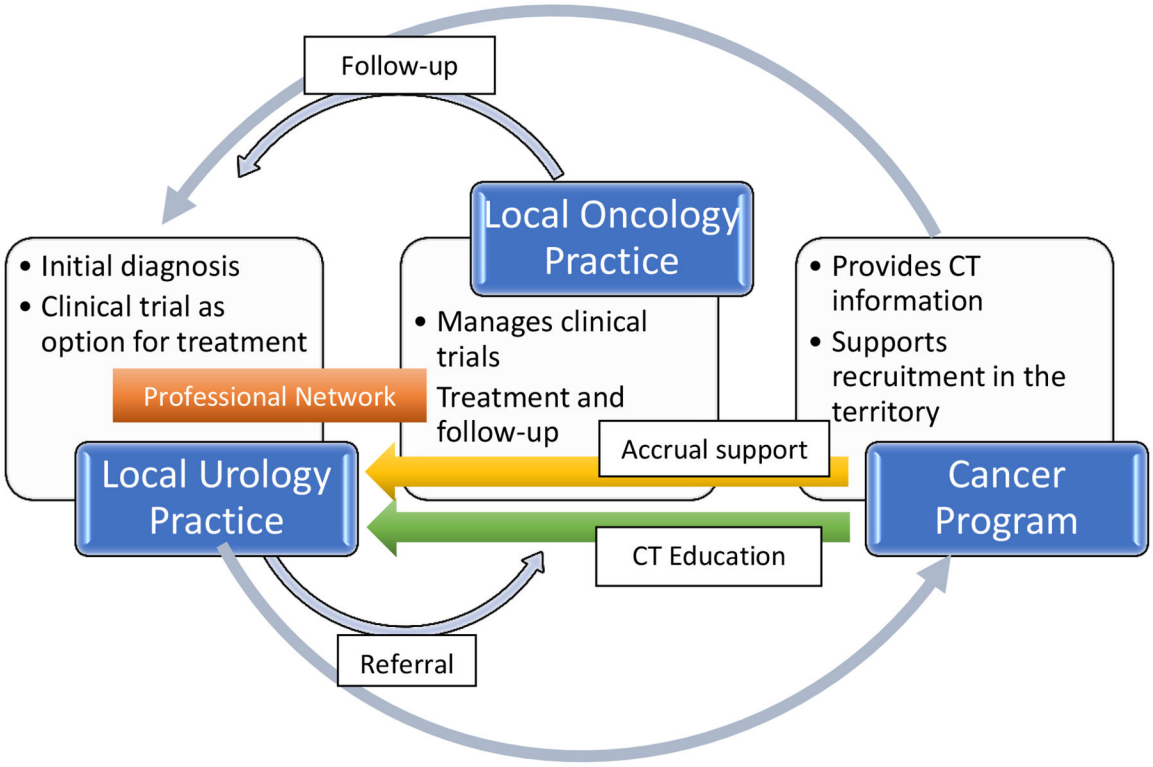

Figure 1.
Suggested patient and information flow to promote accrual to urologic clinical trials.

Table 1.

Characteristics of Participants

	Physician (n=7)		Staff (n=10)	
Gender				
Male	7		1	
Female	0		9	
Race/Ethnicity				
White	5		10	
Non-White	2		0	
	Mean	**Standard Deviation**	**Mean**	**Standard Deviation**
Age	53.6	16.21	44.9	9.97
Years in practice	7.6	12.69	19.1	9.48

Table 2.

Characteristics of Practices

	Count (N=4)
Practice Type	
Solo	2
Group	2
Affiliation	
Private	2
Hospital-Owned	2
Geographic locations	
Rural <2,500 population	0
Small Town (population = 2,500–9,999)	1
Micropolitan Area (population = 10,000–49,999)	3
Number of Employees	
< 5	1
5 – 9	1
10 – 14	1
≥ 15	1
Number of Physicians	
1	2
2–5	2
Local Hospital Bed Size	
<100	2
100 – 200	0
>200	2
Intensity-modulated radiation therapy Facilities	
Yes	4
Surgical Robot	
Yes	3

Table 3.

Illustrative Quotes of Opportunity Facilitators and Barriers

TDF Domains	Relevant Themes	Illustrative Quotes
Environmental Context	Environmental restrictions in rural communities reduce patient willingness to participate in clinical trials.	• They're driving two and half hours to get here. The last thing they want is more stuff. And they're having to drive here more than they want to anyway, and they lose a whole day just by coming to the doctor, they don't want to be bothered.
Resources	Trial referrals require additional human resources practices cannot attain on their own.	• I think we have a good group of urologists here that are very interested in doing what's going to be best for that patient and the patient population. If it's good for them…it's a no brainer, but we do need to have the personnel. First of all, we have to be made aware of the trial, who's going to fit into it, and then have the personnel to get it going. "
	Trial referrals require informational resources.	• I would do trials and I would try to push patients for trials.but we just need the resources. And I'm not asking for money for me, I'm just asking for resources. • Well, if you had a CD or somebody talking directly to the patient and explaining things.I think that would be a good way to get information to the patient. You can always give them literature, but I'm not sure they read it, but they might be more apt to play a video and get the information that way.
	Use of internal resources for trial referrals should be incentivized.	• Well, if there's time involved there should be money involved.but we've done a lot of things without being reimbursed over the years…
Social Influences	Urologists are willing to refer patients to cancer centers and physicians who are trustworthy.	• I send them to [university]..they're now one of the noted oncology places in America. I have no problem with that. • As long as I know them. Like Dr., Dr., Dr….those guys are good and I respect them, I have no trouble sending patients to them.
	Urologists rely on opportunities provided by usual referral partners	• How's [university] going to approach referrals up there? Are they going to say well we could do this or we could do the clinical trial in this area?
	Urologists prefer that to receive trial information directly from trial investigators.	• I really do think it's getting the people that are involved in developing the clinical trial in front of urologists themselves…maybe just when they developed a new one.talking to them and basically selling their clinical trial to that doctor so that doctor, one, believes in it and, two, wants to recommend it to their patients. I think that's probably more important than anything else… • That's what I think would work best, if when a new trial became available…whoever's starting it, if they came and actually got his time, talked to him and said if you have any patients for the next three months, six months.this is something that we're trying to get started, and just tell him what it is and what it's about. That would probably be the best thing.
	Urologists are influenced by patient reactions to their recommendation as well as their knowledge of and perceptions toward clinical trials in general.	• The majority of patients that perceive their cancers to be highly life threatening are open. The majority of patients who perceive their cancer to be unlikely to be quickly life threatening are less open to clinical trials. The prostate cancer patients on average are the least open to clinical trials in my experience, and I would also say that there are some people who just don't want to do something that's not proven. • Half of the patients in this area at least (are)…mostly farmers and I don't how much they can comprehend and know unless we really tell them point blank what they're going to go through, so.that could be one of the obstacles. • A lot of them have this idea when they hear it that, oh, the next greatest cure is just around the corner, and this is it. And I have one patient that sticks in my mind for sure because he got in there, and he was excited, and he got the control, and he was upset about it.

TDF Domains	Relevant Themes	Illustrative Quotes
		• The majority around here are on limited incomesand are going to say.what am I going to have to pay out of my pocket?
	Family members influence the referral processes.	• Sometimes you'll get a daughter that says well they need to go to so and so, that small town urologist doesn't know what he's talking about.

Table 4.

Quotes Illustrating Capability Facilitators and Barriers

TDF Domains	Relevant Themes	Illustrative Quotes
Knowledge	Community practices lack knowledge of existing trials.	• We have to know what's out there because honestly we don't,.we simply don't know what's available.
	Practices want to increase their knowledge of clinical trials through training and education.	• I think it would be good to have training and support so that we all have at least a basic understanding of what trials are available to our patients or that some of our patients are actually in trials but we don't necessarily know what that entails. Sometimes it's not even reflected in their chart that they were accepted into a trial unless you go through and read the oncology notes. • I think it would be helpful for continuity of care if nothing else just to know that your patient is in a trial and what kind of standards go along with that, even some of the labs that they're going to be having drawn or the CTs or imaging or whatever. Those things would be good to know. • At least the basics so that we can help answer questions if we need to. Of course we can always refer patients on to whoever it is that has that information but sometimes if you've developed a relationship with a patient as a physician or as a nurse and they trust you to give them information and they want to get it from you, they don't want to call someone they don't know and ask them so the more we know, the more we can help our patients know and understand what their options are.
Memory, attention, and decision processes	Self-made reminders some urologists use are not always effective.	• I keep lists on my desk of stuff I know is out there, but I'm sure I forget about it sometimes, or I'll come back and say, oh, shoot, they would have qualified for this, but I didn't know…
	Practices lack systematic pathways to manage trial information.	• If there was anything in place that was a constant reminder, I'm never against it. It's a function of taking the extra effort to dig and figure out.does this one meet the X, Y, Z criteria or whatnot.
Psychological skills	Practices want more knowledge of clinical trials so that they can effectively explain and answer questions for patients.	• When they (patients) start doing those studies, if they have any problem… they're not going to call the cancer center, they're going to call us. So we need to be prepared to know exactly how to answer them… • I guess any knowledge that I have about urological cancers in general including trials is helpful because the more I know about it, the more I'm able to educate other people. Our patients, even though they go into oncology, still typically follow with the urologist so it's not unusual that I could get a question about anything that had to do with their cancer including a trial so I would like to have information about trials. That would be helpful to me. • A lot of our patients are going to do whatever he (physician) tells them they should do, so.if he's going to recommend it to a patient, he knows he's recommending something that he wants to stand behind and recommend.

Capability determinant *Behavioral Regulation* was also discussed, but not included in the table.

Table 5.

Quotes Illustrative of Motivational Facilitators and Barriers

TDF Domains	Relevant Themes	Illustrative Quotes
Social/professional role & identity	Urologists and staff consider initiating trial conversation as their role while others also take part in the referring process.	• Honestly it would have to start with the physicians because that's where patients are going to get their initial information about a trial. But nurses are going to talk to patients and answer questions. We need to know what's going on with trials as well. • [Talking about trials] is really part of giving the patient their options and making them aware of all of their options including trials. That should first come from the physician.
	Urology staff see their role in offering clinical trials.	• If I'm aware of a certain patient that's great for this trial and maybe the doctors haven't thought of it, that's somebody that I'd bring up.
	Urologists see their role in following and co-managing patients on trial.	• You're still going to be seeing their CT scans after you took out their kidney, you're still going to be seeing them in clinic.
	Urologists feel responsible for maintaining positive professional relationship with their patients after the referral	• Of course, we can always refer patients on to whoever it is that has that information but sometimes if you've developed a relationship with a patient as a physician or as a nurse and they trust you to give them information and they want to get it from you, they don't want to call someone they don't know and ask them
Beliefs of consequences	Urologists with positive attitudes toward clinical trials were more likely to offer trials to their patients.	• I like clinical trials, and I think they are how we advance medicine…so I'm probably biased towards trying to get people signed up. • You don't always have a good outcome for them (patients) and so I think it's good to be able to give them options. • he (a patient)'s not going to make it. It would just be neat to have something to offer him.
Emotion	Urologists' emotion, mainly fear, influence their decision to offer trials.	• I think nationwide there's a perception that they're going to lose the patient.if they sign up on a clinical trial… • We're all human, I don't want to be embarrassed, so I don't want to bring up a topic and not know all the answers about it. So that's probably one of the things I'm probably a little reluctant to talk to them about clinical trials, because I don't know how the randomization is going to go, and I can't answer all their questions…

Other motivational determinants discussed included beliefs about capabilities, intentions, optimism, goal setting, and reinforcement.