ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY

ALLIANCE A191402CD

TESTING DECISION AIDS TO IMPROVE PROSTATE CANCER DECISIONS FOR MINORITY MEN

ClinicalTrials.gov Identifier: NCT03103321

A limited access study

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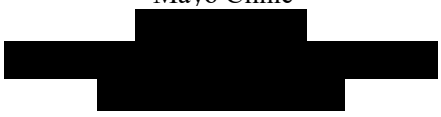

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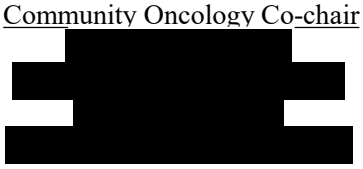
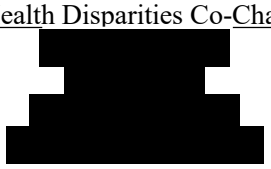
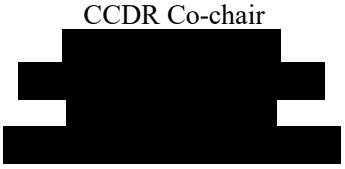


Health Disparities Co-Chair



CCDR Co-chair



GU Co-chair

Health Disparities

CCDR Committee Chair

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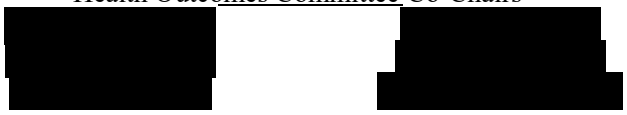

Primary Statistician

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Limited Access Institutions

ARM 1: Beaumont NCORP (Michigan), MI005 (ECOG, NRG, SWOG)
Greenville Health System (Greenville, SC), SC045 (NRG, SWOG)
Lewis Cancer and Research Pavilion at St. Joseph's, GA106 (ECOG, NRG, SWOG)
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Stroger/Cook County Hospital, IL042 (ECOG, NRG)

ARM 2: Aurora Saint Luke's Medical Center WI011 (ECOG, NRG)
Kaiser Permanente-Bellflower CA031 (NRG, SWOG)
Northwell Health, NY387 (NRG)
Ochsner Health System New Orleans LA007 (ECOG, NRG)
Virginia Commonwealth University, VA010 (ECOG, NRG)

ARM 3: Bronx Veterans Administration NY177 (NRG, SWOG)
Columbia University, NY024 (NRG, SWOG)
Lehigh Valley Hospital-Cedar Crest PA055 (ECOG, NRG, SWOG)
Montefiore Medical Center-Einstein, NY313 (ECOG, NRG)
University of New Mexico, NM004 (ECOG, NRG, SWOG)

ARM 4: Augusta University Medical Center, GA 020 (ECOG, NRG, SWOG)
Georgia NCORP, GA031 (ECOG, NRG, SWOG)
Hawaii NCORP, HI010 (NRG, SWOG)
Kaiser Permanente-Oakland, CA752 (NRG, SWOG)
LSU-Shreveport, LA017 (ECOG, NRG, SWOG)

Participants:
NCORP CCDR components of the Alliance (lead), ECOG-ACRIN, NRG, and SWOG NCORP Research Bases

Study Resources

Expedited Adverse Event Reporting [redacted]	**Medidata Rave® iMedidata portal** [redacted]
OPEN (Oncology Patient Enrollment Network) [redacted]	**Biospecimen Management System** [redacted]

Protocol Contacts:

A191402CD Nursing Contact

[redacted]

Protocol-related questions may be directed as follows:	
Questions:	**Contact (via email):**
Questions regarding patient eligibility, treatment, and dose modification:	Study Chair, Nursing Contact, Protocol Coordinator, and (where applicable) Data Manager
Questions related to data submission, RAVE or patient follow-up:	Data Manager
Questions regarding the protocol document and model informed consent:	Protocol Coordinator
Questions related to IRB review	Alliance Regulatory Inbox [redacted]

CANCER TRIALS SUPPORT UNIT (CTSU) ADDRESS AND CONTACT INFORMATION

For regulatory requirements:	**For patient enrollments:**	**For study data submission:**
Regulatory documentation must be submitted to the CTSU via the Regulatory Submission Portal. Regulatory Submission Portal: (Sign in at www.ctsu.org and select the Regulatory Submission sub-tab under the Regulatory tab.) Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately at [redacted] to receive further instruction and support. Contact the CTSU Regulatory Help Desk at [redacted] for regulatory assistance.	Please refer to the patient enrollment section of the protocol for instructions on using the Oncology Patient Enrollment Network (OPEN), which can be accessed at [redacted] Contact the CTSU Help Desk with any OPEN-related questions at [redacted]	Data collection for this study will be done exclusively through Medidata Rave. Please see the data submission section of the protocol for further instructions.
The most current version of the **study protocol and all supporting documents** must be downloaded from the protocol-specific Web page of the CTSU Member Web site located at [redacted] Access to the CTSU members' website is managed through the Cancer Therapy and Evaluation Program - Identity and Access Management (CTEP-IAM) registration system and requires user log on with CTEP-IAM username and password. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.		
For clinical questions (i.e., patient eligibility or treatment-related) see the Protocol Contacts, Page 2		
For non-clinical questions (i.e., unrelated to patient eligibility, treatment, or clinical data submission) contact the CTSU Help Desk by phone or e-mail: CTSU General Information Line – [redacted]. All calls and correspondence will be triaged to the appropriate CTSU representative.		
The CTSU website is located at [redacted].		

TESTING DECISION AIDS TO IMPROVE PROSTATE CANCER DECISIONS FOR MINORITY MEN

Eligibility Criteria (see Section 3.2)

Prostate biopsy within 4 months prior to registration showing
newly diagnosed prostate cancer, stage $T_{1-3}N_{0\ or\ X}\ M_{0\ or\ X}$ (see §3.2.1)
In addition, patients must have:
- Gleason score 6-10

Patients who have had a history of non-cutaneous malignancy in the previous 5 years are not eligible. Patients with history of non-melanoma skin cancer are eligible.

Scheduled prostate cancer consultation to be the first consultation after diagnosis (see §3.2.4)

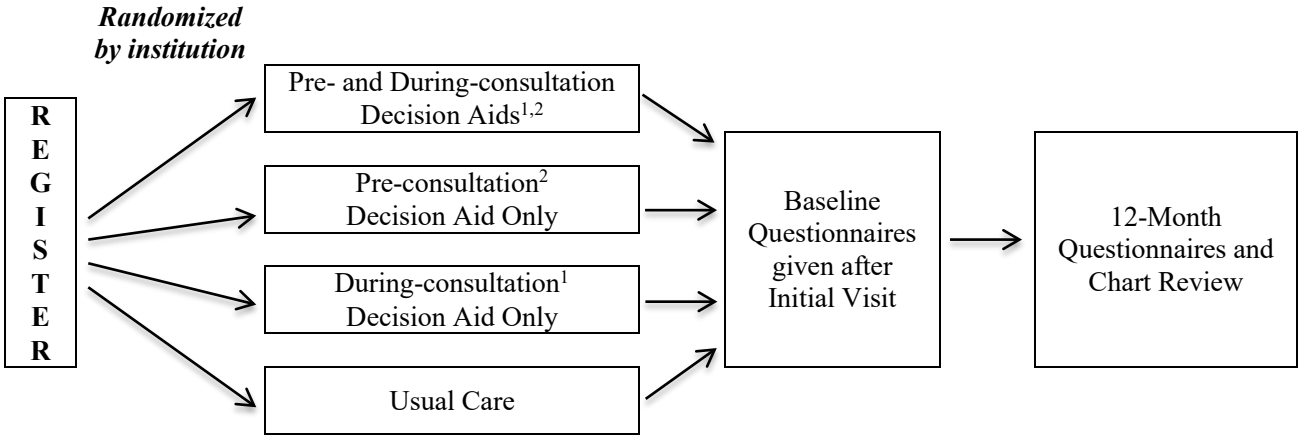
Patients may not be concurrently enrolled to another clinical trial for the treatment of cancer. Co-enrollment to biospecimen studies is allowed. Patients may be enrolled to other clinical trials after completing all of the baseline interventions and measures.

Must be able to read and comprehend English (see §3.2.6)

Age ≥ 18 years

Required Initial Laboratory Values
PSA < 50 ng/mL

Schema



1 "Prostate Choice" Decision Aid
2 "Knowing Your Options" Decision Aid

Please refer to the full protocol text for a complete description of the eligibility criteria and intervention plan.

Site personnel will be trained on the delivery of the intervention prior to the enrollment of any patients. This will consist of either video training and telephone conferencing or on-site training.

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1.0 BACKGROUND

1.1 Significance and rationale

Prostate cancer (PCa) treatment is a significant public health burden. Approximately 240,000 men were diagnosed with PCa and 28,000 died of this malignancy in 2011.[1] More than 81% of incident cases are localized PCa.[2] Clinical guidelines recommend active surveillance for many men with low risk prostate cancer, while radiation therapy and surgery are treatment options, for patients with intermediate (organ confined and Gleason score of 7) or high-risk disease (non-organ confined and Gleason scores 8-10).[3,4]

Men face difficult choices in making treatment decisions for prostate cancer that include important tradeoffs between functional outcomes and cancer control. Clinical guidelines recommend active surveillance, radiation therapy and surgery as acceptable treatment alternatives, especially for patients with intermediate disease (organ confined and Gleason score of 7) and radiation therapy and surgery for high-risk disease (non-organ confined and Gleason scores 8-10).[3,4] Surgery and radiation therapy provide similar mortality reduction but markedly different long-term urinary and sexual functional outcomes.[5-10] For every 20 patients undergoing radiation therapy or surgery, 6-10 will experience erectile dysfunction and 1-5 will have urinary incontinence.[8,10] Active surveillance for men with low-risk PCa (organ-confined and Gleason score 6), may avoid or delay the risks of adverse functional outcomes associated with treatment, but may also promote anxiety. Active surveillance is not a recommended option for high risk disease.

The predominant mode of addressing this excess burden of PCa to date has been through promoting screening in minority men; recent guideline changes suggest that this approach is no longer a viable option.[11] Tailoring treatment decisions for those patients with intermediate and high-risk PCa who may benefit most from definitive treatment, while informing patients with low-risk PCa about active surveillance and eliciting and respecting the values of all patients, represents a viable alternative strategy to reduce this excess burden.

PCa disproportionately affects African-American (AA) and American Indian/Alaska Native (AI/AN) men. Previous studies suggest that AA men have a higher incidence of more aggressive or advanced stage PCa and cancer-specific mortality compared to the general population.[12-15] Native Americans from the Northern and Southern Plains also experience disparities in PCa stage and survival comparable to AA men; PCa is also the second leading cause of cancer-related mortality in Native American men overall.[16,17] AI/AN men from these regions experience greater PCa mortality than non-Hispanic whites.[17] In Hispanic/Latino men disparities are less clear. In general, although national data do not suggest major outcome disparities in this group, local and regional studies, as well as patterns of care studies review pockets of disparities particularly related to delays in care or different treatment patterns for Hispanic/Latino men.[18-23]

Minority men experience disparities in prostate cancer knowledge, care patterns, and suffer from more functional outcome morbidity in prostate cancer. Combined, these compound known disease burden differences in these populations. Studies have documented lower levels of knowledge about PCa among African American men compared with other racial groups.[24] Historically, AA men are less likely to receive radiation therapy or undergo surgery, and more likely to receive "watchful waiting" or active surveillance, despite having a higher incidence of intermediate and high-risk PCa.[25-31] If rates of definitive therapy for minority patients with high-risk PCa were commensurate with the general population, the burden of the disease could arguably be reduced considerably. Conversely, minority men who do undergo definitive therapy are more likely to experience more treatment regret and greater functional outcome burden.[32,33] Although little research has been dedicated to treatment variation in Native American men, a recent report suggested that this underserved population also has lower rates of definitive treatment following a diagnosis of PCa.[16] These data suggest a precarious dilemma: on the one hand greater use of aggressive therapies could save lives, but could at the same time exacerbate existing disparities in functional outcomes associated with aggressive therapy.

Health system factors including poor patient-provider communication likely bias PCa treatment choices in all men, but particularly in minority men. For instance, minority men generally have decreased access to high quality hospitals and urologists for PCa.[28,34] If disparities from other conditions hold true, minority men may also experience implicit bias and suboptimal communication from their healthcare professionals.[35] While the socio-economic and cultural factors that contribute to disparities may differ for AA and AI/AN men, they all pass through health systems that likely share common delivery factors that adversely influence outcomes. The Institute of Medicine and other bodies have postulated that poor patient-provider communication likely mediate disparities.[36,37] Accordingly, patient-provider communication is a quality of care mediator of disparities that could influence appropriateness of care, i.e. whether some options are excluded, whether they are presented in a skewed fashion or in a manner where patient values are not consistently elicited or respected. Those with high-risk disease may not learn about all primary therapy options available, while those with low-risk disease may not learn about active surveillance. Moreover, if specialists do not share the full range of treatment options in the context of side effect information (such as erectile dysfunction or urinary incontinence) in the context of their current functional status, patients may elect for aggressive therapy without a full understanding of the relative merits of each therapy's cancer fighting benefits along with their immediate and long-term functional outcome implications.

Little research has addressed whether system interventions to improve patient-provider communication in prostate cancer can reduce disparities in patient knowledge and functional symptom burden while promoting adequate or enhanced cancer control through treatment patterns that are consistent with disease risk. Moreover, precious little data exist on whether interventions delivered on various health information technology platforms at key points in the care process can mitigate known disparities associated with patient-provider communication particularly in the confusing arena of prostate cancer. Thus, improving patient-provider communication related to risk disclosure along with elicitation of patient goals and preferences is a promising way to strike the right balance among oncologic benefits and treatment-related harms associated with different prostate cancer treatments for men facing an initial treatment decision.

Choice of PCa therapy represents a quintessential "preference-sensitive" treatment decision. Preference-sensitive decisions are those with significant uncertainty about net outcome benefit, where patient values and preferences are especially important to incorporate into treatment decisions.[38-40] In the absence of randomized trials suggesting which form of initial active therapy most reduces mortality, newly diagnosed patients and their physicians should carefully deliberate about the quality of life (QOL) implications and burdens of different primary treatments to reach a decision that embodies the principles of shared decision making (SDM). SDM is a model of evidence disclosure and values elicitation intended for preference-sensitive decisions and is endorsed by all major professional societies.[3,4,41,42]

Interventions to improve patient knowledge could plausibly reduce disparities in functional outcomes by facilitating mastery of experience and self-efficacy interventions that are most consonant with the most important or most distressing functional goals and symptoms. Consistent with the Biopsychosocial Model of Prostate Cancer Symptom Management,[43] we posit that interventions that help facilitate a collaborative, shared treatment decision consonant with the patient's most important goals will reduce known disparities in both knowledge as well as functional outcome burden (symptom distress).

Decision aids can improve patient knowledge and patient-provider communication by presenting risk information and helping elicit patient preferences. They improve knowledge and reduce treatment regret in prostate cancer treatment.[44-47] Decision aids can mitigate low literacy effects in disparities by decreasing the demands required for patients to make an informed treatment decision. They better align the task of decision making with the skills and abilities of patients.[48,49] In other clinical conditions, decision aids have been successfully used to reduce disparities in self-reported symptoms and patient knowledge.[50] Moreover, a recent systematic review entitled "Interventions to Improve Decision Making and Reduce Racial and Ethnic Disparities in the Management of Prostate Cancer" among screening eligible men suggests that educational programs can improve knowledge and interventions that proactively include discussion of quality of life can improve quality of life outcomes.[51] Educational interventions like these seem to have greater effect in men with less than a college education, thereby neutralizing disparities associated with education and literacy.[52] Thus, decision aids are a plausible health system intervention that could be delivered in the specialty care context to reduce disparities in knowledge and functional outcomes potentially mediated by poor communication, that will work even in patients with low health literacy. Existing prostate cancer treatment decision aids have a variety of features summarized below.

Author/ Date	Report Minority	Delivery Mode	Delivery Context	Pro-prietary	Tailor Risk	Comment
Davison & Degner 1997	No	Written Information package + consultation with nurse + (optional) audiotape of visit vs. Written information only	Inside specialty visit	N/A	No	Lower anxiety in the intervention group (p <.005)
Auvinen 2004		Extensive consultation with urologist + patient defined own role in decision making vs. standard treatment protocol	Inside specialty visit			20% fewer men chose surgery in the intervention group vs. the control group (63% vs. 85%)
Davison 2007		Personalized treatment information + generic video + written information vs. generic video + written information	Patient education center			No group differences
Holmes-Rovner 2005		Internet, audio, booklet	Focus groups; Inside specialty visit			Trend toward improved knowledge. Increase in discussion of surgery with physician (p=.02); 72% would take more active role in decision.
Van Tol-Geerdink 2008		Written decision aid	Inside specialty visit			Improved subjective and objective knowledge (p<.001) and accurate risk perception (p<.001). Patients took active decision-making role (p<.001). Greater satisfaction with quality of information (p=.002)
Onel1998		Video decision aid	Inside specialty visit			Increase in subjective knowledge; high level of participation in decision-making; high level of satisfaction with treatment choice.
Brink 2000		Interactive CD-ROM	Focus groups; Outside specialty visit			Increase in knowledge; increase in self-efficacy.
Kim 2001		Interactive CD-ROM	Inside specialty visit			High satisfaction with decision aid program
Davison 2003		Interactive computer program + individualized counseling session	Patient education center			Higher percentage of men assumed more active role than originally intended (p<.001); lower anxiety (p<.001) and depression (p=.018); partners also had lower anxiety (p<.001) and depression (p=.002).
Flynn 2004		Interactive CD-ROM	Outside specialty visit			Increased knowledge after decision aid (p<.001); decreased distress (p<.05); decrease in information needs after decision aid.
Schostak 2004		Personalized, multidisciplinary consultation	Outside specialty visit (interdisciplinary consulting service)			92.4% felt completely informed; patients had equal rates of surgery (43.4%) and radiation therapy (42.5%); 66% found consultation helpful.
Van Tol-Geerdink 2006		Written decision aid	Outside specialty visit			79% accepted greater involvement in decision-making; 75% chose lower radiation dose; fear of tumor recurrence and survival associated with choosing higher dose; fear of side effects associated with choosing lower dose
Isabaert 2008		Decision aid booklet	Inside specialty visit			More active involvement in decision-making; 46% found decision aid reassuring; 38% chose surgery; 48% chose radiation therapy; 12 % chose watchful waiting; 73% felt decision aid helped clarify personal preferences; 88% would use again.

From this literature one can surmise fairly consistent effects of decision aids on knowledge gain and involvement of men in decision making. Nevertheless, to our knowledge none have been tested on

tablet platforms, while also including minority men in sufficient numbers to make robust subgroup analyses, and that are freely available for use after the research is complete. Moreover, most of the above trials do not reflect recent evidence about the potential role of "active surveillance" in management of prostate cancer. Two decision aids fit that description: Prostate Choice and Knowing Your Options. Their features are described below. They each represent a synthesis of the best features of previous decision aids for delivery within or prior to the specialty visit, but have not yet been tested.

This study is the first to specifically test decision aids for PCa treatment decisions in a manner that deliberately over samples minority men in sufficient numbers to make inferences about their effects in these subgroups. Although no research that we are aware of has demonstrated that decision aids reduce disparities, we hypothesize that eliciting patient's baseline QOL information, more proactively involving them in shared decision-making process and then tailoring initial treatment recommendations to their disease severity and priorities can mitigate the negative excess burdens associated with treatment side effects.

1.2 Study Goals

The long-term goal of this research is to reduce the excess burden of prostate cancer and the morbidity associated with its treatments. The overall objective is to test feasible, effective tools that promote SDM for prostate cancer initial treatment decisions, and which improve those decisions in a manner that is risk-concordant and patient-centered for minority men. Our aim is to test the comparative effectiveness of two kinds of decision aids – during consultation and pre-consultation – alone and in combination to improve patient knowledge, symptom burden, and risk-concordant treatment utilization in localized prostate cancer.

1.3 Significance

This study will test the efficacy of decision aids in specialty practices that treat above average numbers of African American and Native American men and compare their impact in these populations to the general population within the infrastructure of the NCORP CCDR components. We hypothesize that decision aids will mitigate disparities related to poor patient-provider communication by improving knowledge, reducing burden of functional outcomes, as well as aligning treatment patterns with disease risk in these minority populations. This study is innovative because it tests newer tools, in newer formats, including within the clinical visit context, and with a novel trial design. It tests decision aids delivered within the clinical visit using a tablet format alongside a web-based decision aid delivered prior to the clinical visit. This study design represents a substantial departure from previous approaches by testing the comparative effectiveness of two prostate cancer decision aids in a 2x2 factorial cluster-randomized design within the NCORP CCDR components that looks at the individual and additive impact of those tools. This context will enable us to deliberately over-sample minority men. Knowing whether decision aids work at all, or which modes and contexts of decision aid delivery work best to improve communication are compelling health care delivery questions for the care of minority men facing the difficult choice of prostate cancer treatment. This study would be the first to bring decision aid research to the healthcare of Native American men; and would be only the second trial that we are aware of to test decision aids specifically in African American men. When complete, this strategy will produce significant generalizable inferences about the best way(s) to improve health service delivery to help address prostate cancer disparities.

1.4 Description of Interventions to be tested

Decision aids can be delivered within or prior to specialty visits using a variety of modes, including paper, tablet, and computer-based platforms. Decision aids delivered prior to the clinical visit prepare patients for decisions by providing information to have a basic understanding of facts discussed in a clinical consultation. Members of our team [redacted] have extensive

experience testing decision aids outside of the clinical visit. Most of the decision aid literature tests them prior to provider visits; these trials improve knowledge, but do not necessarily improve patient-provider communication.[44,45,53-55] The Mayo Clinic team typically tests decision aids for use with the clinical visit. These tools are minimal detail props to promote a better conversation. Several clinical trials of decision aids delivered within visits show improvement in patient knowledge comparable to tools delivered prior to consultation.[56,57] In contrast to tools delivered prior to the visit, tools delivered within a visit may promote better patient involvement in decision making. How the two forms of decision aid delivery might combine to improve outcomes is also uncertain. Despite the promise of decision aids, they are rarely used in specialty practice for prostate cancer and in-visit decision aids have never been tested as a tool to mitigate both disparities in knowledge as well as in functional outcomes for prostate cancer.

Whether in-visit and out-of-visit decision aids potentiate each other in enhancing decisional quality is an additional important unaddressed question that could inform eventual larger scale health services implementation strategies in underserved patient populations with PCa.

Our in-visit tool, Prostate Choice, is a decision aid for PCa treatment that incorporates the best available evidence in a literacy-sensitive, easy to use format for patients and providers delivered on a tablet device. Prostate Choice has a modular format that covers the key components critical to a high quality treatment decision for localized PCa. It personalizes each patient's PCa risk severity using evidence-based prediction tools,[16,17,58-65] and assesses pretreatment QOL using a validated instrument and elicits the importance of each dimension (urinary incontinence, erectile function) into the treatment decision.[66] It also reviews all treatment options for localized PCa, including surgery, radiation therapy and active surveillance, as well as estimates of treatment benefit for a reduction in PCa-specific mortality.[10] Moreover, it elicits patient preferences by enabling assignment of relative importance of different dimensions of QOL and disease control; it estimates each patient's overall life expectancy using Medicare life tables[67] (a strategy endorsed by clinical guidelines).[4,67] Upon completion of all modules, Prostate Choice provides a one page detailed summary, which can also be printed or emailed, as the foundation for future definitive treatment decisions incorporating individually tailored evidence-based risks, QOL and preferences as well as potential QOL implications regarding treatment.

Prostate Choice was developed with patients, physicians, and designers with experience in informed decision-making. In 2011 with the assistance of the Prostate Cancer Patient Advocate Core of the Mayo Clinic Prostate SPORE, Jon Tilburt, MD, MPH and Simon Kim, MD developed a tablet-based "app" to walk patients through the main categories of concern in early prostate cancer treatment. It is a touch-based interactive user experience that focuses on categories "Your Diagnosis," "Your Situation," "Your Priorities," "Your Treatments," and culminates in a summary combining all the categories. Each of the elements of Prostate Choice can be selected by patient or clinician. It is light on text, but shows numbers and elicits values to help facilitate a better conversation. It has been user-tested and found feasible and acceptable by patients and providers. Moreover, it has been further refined to ensure that it is at a Flesch-Kincaid 8th grade reading level. It conforms to basic decision aid quality criteria.[68]

Prostate Choice is designed to cultivate better conversations about treatment risks and benefits contextualized in the unique features of the patient's disease and life circumstance. It will be used in tablet form as part of the clinical conversation in whatever way the patient and physician decide. Both will be briefed on its functionality by study personnel prior to the visit.

Knowing Your Options: a Decision Aid for Clinically Localized Prostate Cancer, is designed for pre-visit use. Knowing Your Options: A Decision Aid for Clinically Localized Prostate Cancer, was developed by the Agency for Healthcare Quality and Research (http://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/prostate-cancer).[69] This non-proprietary web-based decision aid also uses the best available evidence and has been designed to be used in the out-of-visit/pre-visit setting. Similar to Prostate Choice, Knowing Your Options also allows for personalization for PCa severity in risk of cancer-specific mortality. It also queries patients about the

QOL issues regarding the different primary treatment options for PCa.[69,70] To our knowledge its efficacy has not been formally tested. All other decision aids for PCa treatment are proprietary, or do not reflect the most recent evidence.

Knowing Your Options was designed as consumer information for patients searching the internet directly. It is one of two currently available tools online that seek to summarize research evidence for patients. Development details are available at http://www.effectivehealthcare.ahrq.gov/ehc/decisionaids/prostate-cancer/.

Knowing Your Options was designed to lay out the basic facts of treatment choices for patients prior to their appointment with their doctor with more extensive written explanation. In this trial, the Knowing Your Options tool will be administered prior to initial consultations with urologists when eligible patients are presenting to discuss treatment options in the days leading up to/on the day of that consultation.

1.5 Design and Intervention Plan

Study population: Eligible patients from participating NCORP CCDR components will be enrolled. Men with self-reported racial/ethnic categories American Indian/Alaska Native, African American, Hispanic/Latino as well as all other races using existing 2010 Census definitions will be included. In addition to the Alliance NCORP CCDR sites, this study will be open to non-Alliance NCORP CCDR institutions interested in participating through the CTSU mechanism. Due to geographic clustering of African American and Native American populations, institutions will be selected preferentially if they can recruit at least half of their overall cohort from one of these two patient populations. We anticipate at least 8 sites preferentially accruing half of their participants as African American and another 8 sites who can preferentially recruit half of their participants as Native American. The trial will encourage Hispanic/Latino men to participate at all sites.

Randomization: In order to facilitate decision aid administration, enhance patient compliance, and avoid treatment arm contamination; we will perform a cluster randomized four-arm clinical trial.[70] We intend to test both during-consultation, pre-consultation and the combination of both during-consultation and pre-consultation evidence-based decision aids using a novel 2x2 factorial design in two key populations. A 2x2 factorial design breaks the combinations of during-consultation and pre-consultation decision aids into four treatment arms (cells): A) Prostate Choice in-visit combined with Knowing Your Options pre-consultation decision aid; B) Prostate Choice within specialty consultations and usual pre-consultation care; C) Usual during-consultation care and Knowing Your Options decision aid prior to the consultation; and D) Usual during-consultation care and Usual pre-consultation care.

In order to answer our question in a manner that preserves strong internal validity, a randomized design is preferred.[70,71] This approach allows inferences about effects with less concern about baseline imbalances between groups, confounding, or chance. We selected a cluster-randomized design to bring the rigor of the randomized design in line with the reality of every day practice. Furthermore, a cluster-randomized approach avoids contamination effects in the intervention arms.

Hence, randomization will be conducted at the participating site level instead of patient level. Participating sites will be randomized to one of the four arms. AA-oriented and AI/AN-oriented practices will be those capable of oversampling two of the three the minority populations we are targeting. Randomization will be designed in such a way that AA-oriented and AI/AN-oriented sites are distributed equally to the four arms of the study to prevent, as much as possible, one minority population from being recruited exclusively in only one or two of the intervention arms.

Recruitment: The greatest limitation to accrual feasibility is identifying AI/AN men with newly diagnosed, localized prostate cancer. National data suggest that conservatively 125 cases of prostate cancer occur annually among self-identified Native American men from the Northern Plains and Alaska.[17] We can identify 80% of those men (N = ~100), and approach 80% of them to participate per year (N = 80). We anticipate conservatively that because our intervention is a non-therapeutic

intervention limited to the office visit, 40% of eligible men at participating sites could enroll (n=40 per year for three years) in the Northern Plains and Alaska combined (this is a conservative estimate-most Mayo Clinic decision aid trials accrue 70% of patients approached). We have access to several urban sites from which to draw African American and Hispanic/Latino men, making their recruitment less difficult. The long term success of this line of research will hinge on decision aids being successfully used and their having a positive impact on patient knowledge and risk-concordant treatment decision making. Because of less geographic clustering, men of Hispanic/Latino ethnicity will be recruited from all study sites with a similar overall accrual target, reserving two slots minimum for them during the first year of accrual.

What if we do not accrue enough minority men? The primary outcome of this study is knowledge. Aggressive accrual targets for minority men are feasible, but there is no guarantee that they can be achieved. Suppose we only achieve accrual of half of the African American and American Indian/Alaska Native sample sizes and resorted to fill the remaining enrollment with men of self-described White/Asian race. Under this scenario (109 Hispanic/Latino, White, or Asian, 21 African American, and 21 American Indian/Alaska Native race) we would only be able to make the most preliminary (exploratory) inferences about differential outcomes in those subgroups, but our power to test our primary outcome, knowledge, would be preserved. (Part of such an exploratory analysis could include looking for White vs. all others differences, but such analyses are conceptually flawed and would be of limited utility.) Even under this scenario, this trial would make an important contribution to the literature on prostate cancer shared decision making and would represent the most robust minority representation of any such trial in North America to date.

2.0 OBJECTIVES

2.1 Primary objective

To test the comparative effectiveness of decision aids (DA's) on patient knowledge.

2.2 Secondary objectives

2.2.1 To test the impact of in-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.

2.2.2 To test the impact of out-of-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.

2.2.3 To test the impact of combined in-visit and out-of-visit DA's compared to both usual care and individual DAs on quality of life outcomes and treatment utilization.

2.2.4 To test the comparative effectiveness of DA's on minority men's knowledge.

2.2.5 To compare clinic time required to administer the DA's across arms.

3.0 PATIENT SELECTION

For questions regarding eligibility criteria, see the Study Resources page. Please note that the Study Chair cannot grant waivers to eligibility requirements.

3.1 On-Study Guidelines

This clinical trial can fulfill its objectives only if patients appropriate for this trial are enrolled. All relevant medical and other considerations should be taken into account when deciding whether this protocol is appropriate for a particular patient.

Although they will not be considered formal eligibility (exclusion) criteria, physicians should recognize that the following may seriously increase the risk to the patient entering this protocol:

- Psychiatric illness which would prevent the patient from giving informed consent.

3.2 Eligibility Criteria

___ **3.2.1 Documentation of disease:** Patients must have prostate biopsy within 4 months prior to registration showing newly diagnosed prostate cancer, stage $T_{1-3}N_{0\ or\ X}M_{0\ or\ X}$. In addition, patients must have:

___ • Gleason score 6-10

___ **3.2.2 PSA < 50 ng/mL**

___ **3.2.3 Patients who have had a history of non-cutaneous malignancy in the previous 5 years are not eligible.** Exception: Patients with history of non-melanoma skin cancer are eligible.

___ **3.2.4 Scheduled prostate cancer consultation to be the first consultation after diagnosis** (i.e. not a second-opinion or a consultation following previous discussions of treatment options).

___ **3.2.5 Patients may not be concurrently enrolled to another clinical trial for the treatment of cancer.** Co-enrollment to biospecimen studies is allowed. Patients may be enrolled to other clinical trials after completing all of the baseline interventions and measures.

___ **3.2.6 Patients with impaired decision-making capacity (such as with a diagnosis of dementia or memory loss) are not eligible for this study.** Since the primary outcome of the study is knowledge, including patients determined to have impaired decision-making capacity may confound analysis.

___ **3.2.7 Patients must be able to read and comprehend English.** Non-English-speaking patients may participate so long as an interpreter (e.g., family member, clinic staff, etc.) is present for consent, for the Decision Aid administration, and gathering of baseline and follow-up measures.

___ **3.2.8 Age ≥ 18 years**

4.0 PATIENT REGISTRATION

4.1 CTEP/DCP Registration Procedures

Food and Drug Administration (FDA) regulations and National Cancer Institute (NCI) policy require all individuals contributing to NCI-sponsored trials to register and to renew their registration annually. To register, all individuals must obtain a Cancer Therapy Evaluation Program (CTEP) Identity and Access Management (IAM) account [redacted]. In addition, persons with a registration type of Investigator (IVR), Non-Physician Investigator (NPIVR), or Associate Plus (AP) (i.e., clinical site staff requiring write access to OPEN, Rave, or TRIAD or acting as a primary site contact) must complete their annual registration using CTEP's web-based Registration and Credential Repository (RCR) [redacted] Documentation requirements per registration type are outlined in the table below.

Documentation Required	IVR	NPIVR	AP	A
FDA Form 1572	✔	✔		
Financial Disclosure Form	✔	✔	✔	
NCI Biosketch (education, training, employment, license, and certification)	✔	✔	✔	
HSP/GCP training	✔	✔	✔	
Agent Shipment Form (if applicable)	✔			
CV (optional)	✔	✔	✔	

An active CTEP-IAM user account and appropriate RCR registration is required to access all CTEP and CTSU (Cancer Trials Support Unit) websites and applications. In addition, IVRs and NPIVRs must list all clinical practice sites and IRBs covering their practice sites on the FDA Form 1572 in RCR to allow the following:

- Added to a site roster
- Assigned the treating, credit, consenting, or drug shipment (IVR only) tasks in OPEN
- Act as the site-protocol PI on the IRB approval

Additional information can be found on the CTEP website at [redacted] For questions, please contact the RCR Help Desk by email at [redacted]

4.2 CTSU Registration Procedures

This study is supported by the NCI Cancer Trials Support Unit (CTSU).

IRB Approval:

Each investigator or group of investigators at a clinical site must obtain IRB approval for this protocol and submit IRB approval and supporting documentation to the CTSU Regulatory Office before they can be approved to enroll patients. Assignment of site registration status in the CTSU Regulatory Support System (RSS) uses extensive data to make a determination of whether a site has fulfilled all regulatory criteria including but not limited to the following:

- An active Federal Wide Assurance (FWA) number
- An active roster affiliation with the Lead Network or a participating organization
- A valid IRB approval
- Compliance with all protocol specific requirements.

In addition, the site-protocol Principal Investigator (PI) must meet the following criteria:

- Active registration status
- The IRB number of the site IRB of record listed on their Form FDA 1572
- An active status on a participating roster at the registering site.

Sites participating on the NCI CIRB initiative that are approved by the CIRB for this study are not required to submit IRB approval documentation to the CTSU Regulatory Office. For sites using the CIRB, IRB approval information is received from the CIRB and applied to the RSS in an automated process. Signatory Institutions must submit a Study Specific Worksheet for Local Context (SSW) to the CIRB via IRB Manager to indicate their intent to open the study locally. The CIRB's approval of the SSW is then communicated to the CTSU Regulatory Office. In order for the SSW approval to be processed, the Signatory Institution must inform the CTSU which CIRB-approved institutions aligned with the Signatory Institution are participating in the study.

4.2.1 Downloading Site Registration Documents

Site registration forms may be downloaded from the A191402CD protocol page located on the CTSU members' website. Permission to view and download this protocol and its supporting documents is restricted and is based on person and site roster assignment housed in the CTSU RSS.

- Go to [redacted] and log in to the members' area using your CTEP-IAM username and password
- Click on the Protocols tab in the upper left of your screen
- Either enter the protocol # in the search field at the top of the protocol tree, or
- Click on the By Lead Organization folder to expand
- Click on the Alliance link to expand, then select trial protocol #A191402CD
- Click on LPO Documents, select the Site Registration documents link, and download and complete the forms provided.

4.2.2 Requirements for A191402CD Site Registration

- IRB approval (For sites not participating via the NCI CIRB; local IRB documentation, an IRB-signed CTSU IRB Certification Form, Protocol of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption Form, or combination is accepted).

4.2.3 Submitting Regulatory Requirements

Submit required forms and documents to the CTSU Regulatory Office via the Regulatory Submission Portal, where they will be entered and tracked in the CTSU RSS.

Regulatory Submission Portal: [redacted] → Regulatory Tab → Regulatory Submission Portal

When applicable, original documents should be mailed to:

[redacted]

Institutions with patients waiting that are unable to use the Portal should alert the CTSU Regulatory Office immediately at [redacted] in order to receive further instruction and support.

4.2.4 Checking Your Site's Registration Status

You can verify your site registration status on the members' section of the CTSU website.

- Go to [redacted] and log in to the members' area using your CTEP-IAM username and password
- Click on the Regulatory tab
- Click on the Site Registration tab
- Enter your 5-character CTEP Institution Code and click on Go

Note: The status given only reflects compliance with IRB documentation and institutional compliance with protocol-specific requirements outlined by the Lead Network. It does not reflect compliance with protocol requirements for individuals participating on the protocol or the enrolling investigator's status with the NCI or their affiliated networks.

4.2.5 Limited access information

Institutions that are interested in participating in this study must first contact the Study Chair, Jon Tilburt [redacted] to review study requirements and procedures and to identify who will be responsible for the study at their respective institution. See Section 13.1.

4.3 Patient Registration Requirements

- **Informed consent:** the patient must be aware of the neoplastic nature of his/her disease and willingly consent after being informed of the procedure to be followed, the experimental nature of the interventions being tested, alternatives, potential benefits, side-effects, risks, and discomforts. Current human subjects protection committee approval of this protocol and a consent form is required prior to patient consent and registration.
- **Patient completed booklets:** Patient questionnaire booklets are to be ordered prior to the registration of any patients. Patient completed booklets can be ordered by downloading and completing the booklet order form (located under the supplemental documents section of the A191402CD website) and faxing the form to Attn: Operational Support Clerk at [redacted] Samples of the booklets are found in Appendices I and II, which are to be used for reference and IRB submission only. They are not to be used for patient completion.

- **Institutional randomization:** Institutions will be randomized to one of four intervention arms:
  1) During- and pre-consultation decision aids
  2) Pre-consultation decision aid only
  3) During-consultation decision aid only
  4) Usual care

  The Alliance Statistics and Data Center will randomize institutions once an institution is interested and eligible to participate. All men enrolled at a site will receive the intervention to which the treating institution is randomized.

  Specifically, the lead study statistician will randomly assign the initial participating institutions to one of the arms before the study is activated. The randomization will be stratified by center type (i.e. which minority group, if any, the center is "targeting"); so that if for example, there were four initial centers which specialized in Native American/Native Alaskan men, each would be assigned to one of the four arms by randomly selecting one of the four repeatedly without replacement, each time assigning that center to one of the remaining arms. This will be done separately for all center types. For all of these centers, the lead statistician will obtain CTEP Institutional IDs (as well as IDs for affiliates, if any, that may be participating), and will then provide the Alliance randomization center with the initial set of CTEP IDs for each treatment arm.

  Thus, when a patient enrolls at one of the initial participating institutions, the CTEP ID of the center can be checked against the initial randomization list, which will determine which treatment that patient gets (and all patients at that center). In addition, the lead statistician will create a random sequence of arm assignments for additional institutions of each type that join after the study begins, so that whenever a new center joins the study, an arm will already have been determined for that center.

4.4 Patient Registration/Randomization Procedures

Patient enrollment will be facilitated using the Oncology Patient Enrollment Network (OPEN). OPEN is a web-based registration system available on a 24/7 basis. To access OPEN, the site user must have an active CTEP-IAM account (check at [redacted]) and a 'Registrar' role on either the LPO or participating organization roster. Registrars must hold a minimum of an AP registration type.

All site staff will use OPEN to enroll patients to this study. It is integrated with the CTSU Enterprise System for regulatory and roster data and, upon enrollment, initializes the patient in the Rave database. OPEN can be accessed at [redacted] or from the OPEN tab on the CTSU members' side of the website at [redacted] To assign an IVR or NPIVR as the treating, crediting, consenting, drug shipment (IVR only), or investigator receiving a transfer in OPEN, the IVR or NPIVR must list on their Form FDA 1572 in RCR the IRB number used on the site's IRB approval.

Prior to accessing OPEN, site staff should verify the following:

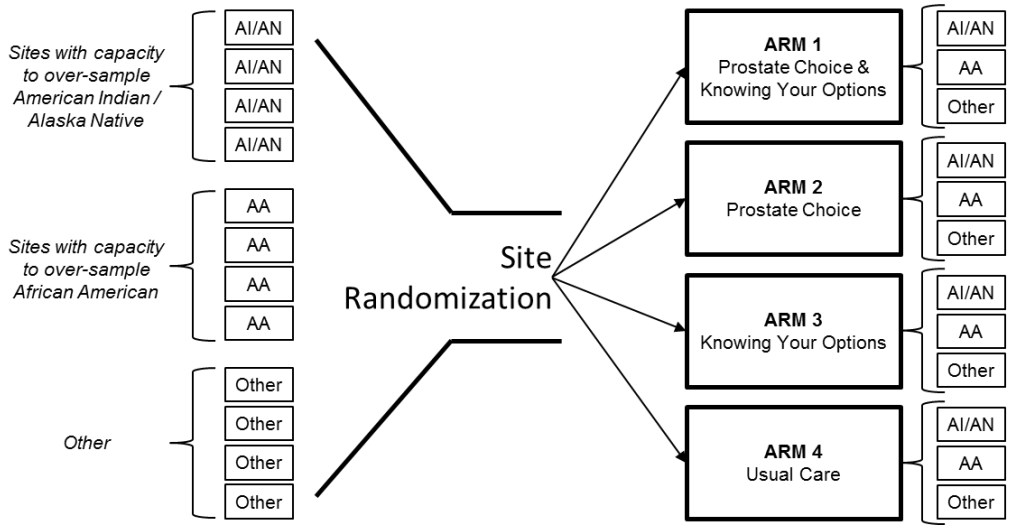
- All eligibility criteria have been met within the protocol stated timeframes.
- All patients have signed an appropriate consent form and HIPAA authorization form (if applicable).

Note: The OPEN system will provide the site with a printable confirmation of registration and treatment information. Please print this confirmation for your records.

Further instructional information is provided on the OPEN tab of the CTSU members' side of the CTSU website at [redacted] For any additional questions contact the CTSU Help Desk at [redacted]

4.5 Stratification and Treatment Assignments

While not formal stratification factors, randomization will be set up so that sites will the particular capacities to oversample minority populations will be distributed between the arms, as illustrated in the diagram below.



Grouping Factors/Treatment assignments:

Arm 1: Pre -and During Consultation Decision Aids

Arm 2: Pre-Consultation Decision Aid only

Arm 3: During Consultation Decision Aid only

Arm 4: Usual Care

5.0 STUDY CALENDAR

Laboratory and clinical parameters during treatment are to be followed using individual institutional guidelines and the best clinical judgment of the responsible physician. It is expected that patients on this study will be cared for by physicians experienced in the treatment and supportive care of patients on this trial.

Pre-Study Testing Intervals

- To be completed ≤ 28 DAYS before registration: History and physical.
- To be completed ≤ 90 DAYS before registration: PSA
- To be completed ≤ 4 MONTHS before registration: Prostate Biopsy

	Prior to Registration	Baseline*	12 months after baseline**
Test and Observations			
History and Physical	X		
Height	X		
Weight	X		
Prostate biopsy	X		
Chart Review			X(1)
Labs and Staging			
PSA	X		
QOL Instruments			
Baseline Questionnaire		X(2)	
One-year Questionnaire			X(3)

* To be administered following the surgical consultation

** +/- 6 weeks

1 At 12 months site staff will review the patient's chart from the 6-month point to the 12-month time-point, collecting treatment information and any pertinent events.

2 Includes the Prostate Cancer Treatment Questionnaire and the Decisional Conflict Scale. See Section 10.0 and Appendix I.

3 Includes Expanded Prostate Cancer Index Composite (EPIC-26) and the Decisional Regret Scale. See Section 10.0 and Appendix II. To be completed by the patient during a clinic visit. If no clinic visit is scheduled +/- 6 weeks from the 12-month time-point, study staff should mail the 12-month questionnaire with a self-addressed stamped envelope to the patient for him to complete at home and return by mail (see Section 8.3.1).

6.0 DATA AND SPECIMEN SUBMISSION

6.1 Data Collection and Submission

Data collection for this study will be done exclusively through the Medidata Rave clinical data management system. Access to the trial in Rave is granted through the iMedidata application to all persons with the appropriate roles assigned in Regulatory Support System (RSS). To access Rave via iMedidata, the site user must have an active CTEP-IAM account (check at [redacted] and the appropriate Rave role (Rave CRA, Read-Only, Site Investigator) on either the LPO or participating organization roster at the enrolling site.

Upon initial site registration approval for the study in RSS, all persons with Rave roles assigned on the appropriate roster will be sent a study invitation e-mail from iMedidata. To accept the invitation, site users must log into the Select Login [redacted] using their CTEP-IAM user name and password, and click on the "accept" link in the upper right-corner of the iMedidata page. Please note, site users will not be able to access the study in Rave until all required Medidata and study specific trainings are completed. Trainings will be in the form of electronic learnings (eLearnings), and can be accessed by clicking on the link in the upper right pane of the iMedidata screen.

Users who have not previously activated their iMedidata/Rave account at the time of initial site registration approval for the study in RSS will also receive a separate invitation from iMedidata to activate their account. Account activation instructions are located on the CTSU website, Rave tab under the Rave resource materials (Medidata Account Activation and Study Invitation Acceptance). Additional information on iMedidata/Rave is available on the CTSU members' website under the Rave tab at [redacted] or by contacting the CTSU Help Desk at [redacted] or by e-mail at [redacted]

A Schedule of Forms is available on the Alliance study webpage, within the Case Report Forms section.

Patient-completed questionnaire booklets for this study are to be ordered prior to the registration of any patients (see Section 4.4). Samples of questionnaire booklets are available in Appendices I and II for reference and IRB submission only. They are not to be used for patient completion. Booklets must be given to patients to complete and patients should be instructed to return the booklets to site staff either in person or by mail and site staff will enter patient and caregiver responses into Rave.

7.0 STUDY IMPLEMENTATION

7.1 Identification of participating institutions

It is expected that a majority of participating institutions will be identified prior to the activation of this study. However, recruitment of additional institutions will continue following activation of the study. Interested sites should contact the study chair, Dr. Tilburt to discuss the criteria listed in Section 13.1.

7.2 Site training

Before enrolling patients, each site randomized to one of three intervention arms must determine their desired mode of delivery for the decision aids (either by desktop computer or tablet). Sites that opt for tablet delivery of the decision aid will receive a tablet from the investigative team: Either by shipment or by hand delivery, depending on whether or not a member of the study team travels to the participating institution to provide personnel training.

Site personnel will be trained on the process of data collection and delivery of the intervention prior to the enrollment of any patients. This training will be provided either by video/telephone conferencing or by on-site training. consist of either video training and telephone conferencing or on-site training. The content of the training will consist of co-developing or adapting site-specific standard operating procedures (SOPs) that accommodate local site environments while maintaining fidelity to the particular study arm to which sites have been randomized. Training will be provided by a member of the study team from Mayo Clinic.

7.3 Site scheduling and clinic space requirements

Scheduling: Sites will need to determine the time needed to complete registration, pre-consultation decision aid interaction (for applicable study arms), and post-consultation questionnaire completion. Study coordinators will need to schedule patients to be present at the study site for sufficient time to complete pre- and post-consultation study items. Alternatively, sites must identify processes for pre- and post-consultation study requirements to be completed in very close proximity (1 business or less) to the visit.

Space requirements: Sites will need to identify and reserve an adequately private area near or adjacent to the patient waiting area. This space will be used to obtain patient consent for participation, obtain HIPAA authorization, and interact with the pre-consultation decision aid (for applicable study arms), and completion of the post-visit questionnaire.

Pre-consultation decision aid requirements: For study arms with the pre-consultation decision aid, this adjacent space must contain a computer terminal with internet access, or have wireless access provided to the room so that a tablet may be used.

During-consultation decision aid requirements: For study arms that will use the during-consultation decision aid, sites will need to ensure that exam rooms are provisioned with wireless internet access or contain a computer terminal with internet access. Either of these is needed in order for the physician to deliver the during-consultation decision aid.

Physician notification process: Sites should establish a local process for informing the participant's physician that the participant has completed pre-requisite study registration and intervention (where applicable). The physician will then be alerted to follow the during-consultation study procedures specific to his/her study site.

8.0 INTERVENTION

While it is expected that registration will occur on the same day as the initial surgical consultation, the intervention (surgical consult visit) must occur within 14 days following registration. Registration may occur after the surgical consult visit and patient completion of the Baseline Questionnaire, but must be completed no later than the same day as the consultation.

Participating sites will be randomized to Pre- plus During-Consultation decision aids, Pre-consultation decision aid only, during-consultation only decision aid, or usual care arms.

Arm A	Pre- and During Consultation Decision Aids[1, 2]
Arm B	Pre-Consultation[2] Decision Aid Only
Arm C	During Consultation[1] Decision Aid Only
Arm D	Usual Care

1 "Prostate Choice"

2 "Knowing Your Options"

8.1 Patient identification, scheduling, and consent

Sites should implement standard procedures for identifying eligible patients for this study. Patient eligibility will be determined locally by a combination of chart review and patient self-report. Clinical variables about the patients care germane to eligibility will be ascertained by site staff. Site staff must confirm with the patient that this is not a second opinion, and that this is the first face-to-face visit with the doctor to discuss treatment options. It is not required that patients know their diagnosis before the study is introduced to them.

Prospective patients who are informed about a new diagnosis of prostate cancer will be scheduled to receive a follow-up consultation with a physician to discuss treatment options. The scheduled prostate cancer consultation must be the first consultation after diagnosis (i.e. not a second-opinion or a consultation following previous discussions of treatment options). Physicians may consider referring patients to the study team for recruitment upon receipt of positive PCa biopsy results from the lab if the cancer diagnosis has already been disclosed by telephone or email.

It is critical that the site coordinator identify when this visit is scheduled, and plan to make contact (or arrange for the patient's physician to make contact) with the prospective participant before their scheduled consultation and inform them about the study. Participating institutions should implement a procedure for alerting the study coordinator when an eligible patient has been scheduled for the initial consultation. Institutional study coordinators will document all contact with all potentially eligible participants and indicate interest/non interest or "not approached."

If the prospective participant expresses interest in the study, the study coordinator should instruct the patient to arrive at their consultation appointment early enough (as determined by site-specific standard operating procedures) to complete all study-related activities. Patient consent may be obtained at any time up to and including the day of the consultation, but must be completed prior to any study-related activities. In addition, for sites randomized to the pre-consultation decision aid, time should be allowed for sufficient and unhurried patient interaction with the pre-consultation decision aid. All participants should also be informed that they will need to remain after the appointment to complete a short questionnaire (Baseline Questionnaire, see Appendix I).

8.2 Procedures for intervention on the day of the prostate cancer consult

8.2.1 Patient arrival

Following the completion of the consent and registration procedures, the study coordinator will greet and engage participant and escort them to a private area preferably near the waiting area.

8.2.2 Arms A and B only: Patient interaction with the pre-consultation decision aid

The study coordinator will lead the participant to a designated computer terminal or will provide a tablet with which the participant, in collaboration with a partner, if desired, may interact with the pre-consultation decision aid. Staff will be available for any technical issues that may arise.

8.2.3 Physician notification

The physician or appropriate clinical staff (e.g., physician assistant) will be notified when a participant has arrived and, if at an institution randomized to Arm A or B, that the patient has spent time with pre-consultation decision aid. The physician will thereby know to follow the study protocol.

8.2.4 Consultation

Arm A: The physician or appropriate clinical staff (e.g., physician assistant) will incorporate the during-consultation decision aid in his/her conversation with the patient about treatment choice. In addition, the physician or appropriate clinical staff will engage the patient regarding any questions by the patient about the pre-consultation decision aid. Site staff will record the time that the patient spends with the pre-consultation decision aid.

Arm B: Usual care, and the physician or appropriate clinical staff will engage the patient regarding any questions by the patient regarding the pre-consultation decision aid. Site staff will record the time that the patient spends with the pre-consultation decision aid.

Arm C: The physician or appropriate clinical staff will incorporate the during-consultation decision aid into his/her conversation with the patient about treatment choice.

Arm D: Usual care.

All Arms: At the end of the consultation, the physician will remind the patient that the study coordinator has post-visit (baseline) questionnaires for the patient to complete. The study coordinator will also assess the time for the consultation, which will be recorded in a separate field on the data collection forms. This will be defined as the time from when the physician enters the consultation room to when physician's consultative activities end (i.e., when the physician leaves the room OR when the patient is handed off to the CRA to complete post-consultation forms).

8.2.5 Baseline Questionnaire

After consultation with the physician, the study coordinator will escort the patient to a private area preferably near to the patient waiting area, and provide the Baseline Questionnaire for the patient to complete before leaving.

8.3 12-month follow up

Follow up to ascertain the patient's overall and disease specific quality of life and prostate cancer treatment regret will be conducted by site coordinators 12 months (+/- 6 weeks) after the patient's consultation.

8.3.1 Twelve-month follow-up questionnaire

If the patient has a scheduled follow-up visit within this window, he should be asked to complete the 12-month Follow-up Questionnaire during this visit. If no visit is scheduled, site staff will mail the Follow-up Questionnaire with a self-addressed stamped envelope to the patient for him to complete at home and return to the clinic by mail. If the questionnaire is not returned by mail within 4 days, the study coordinator will call the patient (up to 5 attempts) to remind him to complete and mail the questionnaire or he or she will offer the patient the opportunity to complete the questionnaire over the phone.

8.3.2 Twelve-month follow-up chart review

At this time site staff will also conduct retrospective chart review to ascertain treatment utilization and complete the follow-up form. Treatment utilization will be categorized by the type of treatment the patient had (surgery vs. radiation vs. active surveillance).

9.0 ADVERSE EVENTS

We do not anticipate any additional adverse events related to participation in this study beyond usual care.

If patients experience any emotional discomfort when completing the questionnaires, they may choose not to complete them and/or speak with the site staff. Patients experiencing any physical or psychological complications related to their standard of care treatment should discuss this with their treating physician.

10.0 MEASURES

10.1 Prostate Cancer Treatment Questionnaire (knowledge measure)

"The Prostate Cancer Treatment Questionnaire" is a 12-item instrument measuring respondent knowledge of key information deemed by clinicians to be critical for patients to successfully deliberate about preference of treatment for prostate cancer.

The questionnaire will be administered once, immediately after the consultation (post-consultation) and should take no more than 5-6 minutes to complete."

10.2 Decisional Conflict Scale (DCS)

The decisional conflict scale was developed and validated by O'Connor[72] as an instrument intended to "elicit 1) health-care consumers' uncertainty in making a health-related decision; 2) the factors contributing to the uncertainty; and 3) health-care consumers' perceived effective decision making". The low literacy version of this questionnaire will be used, and it contains 10 items answered on a 3 point scale (i.e., "yes," "unsure," "no") and may be adapted to specific health-care decision scenarios. Example questions include agreement with the following statements: "Did you know which options were available to you?" "Did you know the benefit of each option?" "Did you feel sure about what to choose?".

The questionnaire will be administered once, immediately after the consultation (post-consultation). It is estimated that it will take participants approximately 5-7 minutes to complete this questionnaire.

10.3 Expanded Prostate Cancer Index Composite Short Form (EPIC-26)

The Expanded Prostate Cancer Index Composite[66] measures health-related quality of life and returns summary scores for urinary, bowel, sexual, and hormonal domains with high test-retest reliability and internal consistency.

The questionnaire will be administered once; 12 months after the patient's initial consultation. The instrument contains 26 items, and will take approximately 10-15 minutes to complete.

10.4 Decisional Regret Scale

The Decisional Regret Scale[73] is a short, 5-item scale measuring "distress or remorse after a (health care) decision." The instrument has been validated in other decision aid studies.[74] Questions are answered on a 5-point agreement scale.

The questionnaire will be administered once; 12 months after the patient's initial consultation and will take approximately 1-3 minutes to complete.

11.0 END OF INTERVENTION

11.1 Duration of Treatment

The study intervention will take place in one day and follow-up assessments will occur at 12 months following the intervention.

11.2 Managing ineligible patients and registered patients who never receive protocol intervention

Definition of ineligible patients

A study participant who is registered to the trial but does not meet all of the eligibility criteria is deemed to be ineligible.

Follow-up for ineligible patients who continue with protocol intervention

Patients who are deemed ineligible after registering may continue the protocol intervention, provided the treating physician, study chair, and executive officer agree there are no safety concerns if the patient continues protocol intervention. All tests and data submission are to continue as if the patient were eligible. Notification of the local IRB may be necessary per local IRB policies.

Follow-up for ineligible patients who discontinue protocol intervention

For patients who are deemed ineligible after registering to the trial, who start the study intervention, but then discontinue the intervention, the same data submission requirements are to be followed as for those patients who are eligible and who discontinue study participation.

Follow-up for patients who are registered, but who never start study intervention

For all study participants who are registered to the trial but who never receive study intervention (regardless of eligibility), baseline and off-treatment notice data submission required. See the Data Submission Schedule accompanying the All Forms Packet.

11.3 Extraordinary Medical Circumstances

If, at any time the constraints of this protocol are detrimental to the patient's health and/or the patient no longer wishes to continue protocol participation, protocol participation shall be discontinued. In this event:

- Document the reason(s) for discontinuation of protocol participation on data forms.
- Follow the patient for protocol endpoints as required by the Study Calendar.

12.0 STATISTICAL CONSIDERATIONS

12.1 Study Design

This is a non-treatment study evaluating Decision Aids (DAs) for patients with newly diagnosed prostate cancer. For this trial, participating institutions are randomized, according to the racial distribution of the patient population, to treat patients to one of 4 treatment arms (see Schema). Patients will complete on-line DAs if not randomized to the Usual Care arm. All patients will complete a baseline knowledge questionnaire after the initial clinic visit and at 12-months following the surgical consultation.

12.2 Statistical Design and Analysis for the Primary Endpoint

Primary Endpoint: The primary outcome, knowledge, will be assessed by a standardized questionnaire (i.e., Prostate Cancer Treatment Questionnaire) administered once, immediately after the clinical consultation while the patient is still at the study site. The number correct from this 12-item measure will be reduced to a percentage of total number correct.

A different method for measuring our primary outcome, knowledge, proposing instead a pre-post approach was considered. However, several factors lead us to favor a one-time post-intervention measurement: 1) Our study's randomized design should control for differences in baseline effects; 2) a pre-post design could be confounded by learning effects associated with the baseline measurement since the baseline and post-intervention measurements would only be 1-2 hours apart. Such learning affects could lead to artificial improvements in our control group which could limit our ability to see "true" differences attributable to the intervention(s); 3) finally, a one-time measurement of knowledge will minimize burden to respondents, particularly during the consenting and baseline measurement period where we seek to impede clinical workflows as little as possible.

12.2.1 Analysis Plan

Although the randomization unit will be participating site, our inferential unit for statistical analysis will be the individual patient. Due to the potential for correlation among patients within the same site, a mixed effects regression model (also known as random effects model or multi-level model) will be utilized to examine the effects of the during-consultation Prostate Choice and the pre-consultation Knowing Your Options decision aids. Specifically, this model will contain a fixed intercept, a fixed effect for having received Prostate Choice, a fixed effect for having received Knowing Your Options, and a random, site-specific intercept to allow patients within the same site to be correlated. Baseline patient-level characteristics including race, ethnicity, severity of disease and site-level characteristics may be incorporated in this model if deemed appropriate. A similar approach will be utilized in the statistical analysis of secondary endpoints. Furthermore, descriptive statistics will be reported after incorporating cluster information, in particular, the empirical cluster size, and the observed intra-cluster correlation.

12.2.2 Sample Size and Power Considerations

Sample size and power calculation: We first consider power and sample size under the assumption that patients within the same site are uncorrelated**.** As this is unlikely to be the case in a group randomized trial, we will discuss the adjustment of the sample size estimate to account for this correlation between patients in the next subsection. A recent Cochrane review suggests that most patients can accurately answer 50% (standard deviation of 12%) of the questions asked of them.[70] On average, DAs increase that knowledge by 20% to 60% of questions asked being answered correctly, but 95% of trials show absolute knowledge increases of 10% or greater. We will consider an absolute 8% increase in knowledge as a clinically meaningful effect size for either during-consultation Prostate Choice or pre-consultation DA in this clinical trial. Note that the four arms of this study make up a 2 X 2 factorial design. Thus, it is natural to consider evaluating the decision aids using a two-way analysis of variance (ANOVA). In this case, the two factors in the ANOVA will be having received during-consultation Prostate Choice (yes or no) and having received pre-consultation DA (yes or no). We will consider simultaneously testing (at a significance level of 0.025 for each test) the main effects of the two decision aids as our primary analysis. That is, we will simultaneously test the null hypothesis that the average knowledge (i.e. the proportion of correct responses to questions) among those who received the pre-consultation DA is equal to that among those who did not (vs. an alternative that these two averages are not equal), and the null hypothesis that the average knowledge among those who received the during-consultation Prostate Choice is equal to that among those who did not (vs. an alternative that these two averages are not equal). A total sample of 100 patients (25 patients per arm) would give us approximately 85% power to detect a difference between those receiving pre-consultation DA and those not receiving pre-consultation DA, under the alternative that the average knowledge among those receiving pre-consultation DA is 58%, and that the average knowledge among those not receiving pre-consultation DA is 50%, using a two-sample t-test (with two-sided alternative) with a 2.5% significance level (this is equivalent to the F test for the main effects in the ANOVA). Under a similar alternative, the same can be said for the during-consultation Prostate Choice decision aid. Thus, if patients within each site were not correlated with each other, our target sample size would be 100 patients. There will be some, but insufficient power to detect an interaction between the two decision aids, but such effects are rare and not anticipated in this study. Therefore, we will not test for such an interaction in the primary analysis.

Sample size adjustment due to cluster randomization: As mentioned above, we do not believe that subjects within each site will truly be independent of each other. Thus, the application of the standard sample size calculation, as above, may lead to an underpowered study. Since we expect k=20 sites to participate in this clinical trial, we would need about m = 5 patients to be enrolled from each site (on average) to achieve a total enrollment of 100 patients. Assuming the intra-site correlation coefficient ρ will be approximately 0.1 (rather than zero) for all study sites, we must inflate the target sample size by a factor[71] of $1+(m-1)\rho=1+(5-1)*0.1=1.4$ to achieve comparable power to that in a patient-level randomized trial. This comes about as follows (we consider the pre-decision DA here, but the same derivation holds for the during-consultation Prostate Choice). Suppose the variance of knowledge (Y) is the same for all patients, and is equal to σ^2, and that n is our total sample size, with n/2 patients receiving the pre-consultation DA and n/2 not receiving the pre-consultation DA. Assuming no correlation between patients within the same site, the variance of the sample mean of knowledge among those receiving pre-consultation DA ($\bar{Y}_1$) will be $\sigma^2/(n/2)$, as will that for the sample mean of knowledge among those not receiving pre-consultation DA ($\bar{Y}_2$), and our test statistic would have the form $[(\bar{Y}_1 - \bar{Y}_2) - (\mu_1 - \mu_2)]/[\sigma^2/(n/2) + \sigma^2/(n/2)]^{(1/2)}$ (note that the denominator of this statistic simplifies to $[4\sigma^2/n]^{(1/2)}$). However, this is not a correct assumption in our case. In particular, suppose that we have 20 sites, and within each site, we have m (5) patients, between each of whom the

correlation is ρ (0.1) (meaning the covariance between any two patients in the same site is $\rho\sigma^2$). In this case, the variances of the sample means are not $\sigma^2/(n/2)$, but rather:

$$Var(Y_1) = Var(Y_2) = Var\left(\frac{1}{\left(\frac{n}{2}\right)}\sum Y_i\right)$$

$$= \frac{1}{\left(\frac{n}{2}\right)^2}\left[\left(\frac{n}{2}\right)\sigma^2 + (2)\left(\frac{\left(\frac{n}{2}\right)}{m}\right)\left(\frac{m!}{(m-2)!\,2!}\right)\rho\sigma^2\right]$$

$$= \frac{1}{\left(\frac{n}{2}\right)}\left[\sigma^2 + \left(\frac{1}{m}\right)m(m-1)\rho\sigma^2\right]$$

$$= \frac{1}{\left(\frac{n}{2}\right)}\left[\sigma^2 + (m-1)\rho\sigma^2\right]$$

$$= \frac{\sigma^2}{\left(\frac{n}{2}\right)}\left[1 + (m-1)\rho\right].$$

Thus, the denominator of our test statistic should actually be $[(4\sigma^2/n)(1 + (m - 1)\rho)]^{(1/2)}$. Therefore, if we replace the original sample size (n=100) with $n(1 + (m - 1)\rho = 100*1.4 = 140$ in the denominator of our original test statistic, we will have a test statistic which accounts for the correlation of 0.1 between subjects within each of the 20 sites. Hence, we will target an effective sample size of 140 patients (approximately 35 patients per arm, 7 patients per site). The total sample size may be further inflated by 20% to account for ineligible, cancel and loss to follow-up for longer term secondary outcomes and allow increased power to detect racial/ethnic differences. Therefore, a total number of 172 patients will be enrolled into this clinical trial. These 172 patients, recruited from 20 participating sites (about 9 patients per site) will receive the intervention (or control) to which their location is randomized.

Though we have chosen to power this study based on an absolute meaningful difference of 8%, we determined the necessary sample size for a range of meaningful differences. In each case, the target power was approximately 85% (thought it varied slightly, as we only considered sizes which were divisible by 20, given the number of expected sites) with joint main effect two-sided t-tests with two-sided alternatives at the 2.5% significance level. These sample sizes are as follows (not adjusted for ineligibility, cancel and loss to follow-up):

Meaningful Difference	**Total sample size without correlation within sites**	**Total sample size adjusted for correlation within sites**
4%	360	504
6%	180	252
8%	100	140
10%	60	84
12%	40	56

12.2.3 Study Operating Characteristics

Interim Analysis: An interim analysis will be used to test if intervention arm (either during-consultation Prostate Choice or Knowing Your Options pre-consultation DA) has produced better knowledge than the respective control arm. There will be 5 to 6 interim analyses conducted of this type before the final analysis with this plan. The O'Brien-Fleming boundaries[75] will be

used to determine statistical significance in this interim analysis. If any interim analysis is statistically significant, the DSMB may consider stopping the trial early due to demonstrated efficacy of the intervention arm.

Futility Analysis: This study will also be monitored for early stopping for futility. Repeated confidence interval approach[76] will be used to test futility. At each interim analysis, a 95% one-sided confidence interval on the difference of knowledge between the intervention and control arm will be computed. If the confidence interval does not cover the target alternative of 0.1 for one of these comparisons, the DSMB may consider stopping the trial early for futility.

12.3 Sample Size, Accrual Time, and Study Duration

12.3.1 Patient Population: In order to achieve higher minority accrual (at least 43 AA, and at least 43 AI/AN, and up to 86 White, and/or Asian), we will impose a restriction of at most 50% White and/or Asian participants at each site. Patient accrual will be restricted to AA and AI/AN minority once 50% White or Asian patients are enrolled. We are not oversampling Asian men (n=4) because there are no known disparities in this population. As patient recruitment is not blinded to site in the cluster randomization, we will encourage sites to identify patients prior to randomization and conduct recruitment by an individual independent from the one who delivers the intervention to reduce bias. We will recruit 172 patients (43 per arm).

In addition, in order to prevent imbalance between the arms, sites that over-accrue to the study may be asked to close the study at their institution. Finally, institutions will be given a recruitment goal of at least 2 men who report Hispanic/Latino ethnicity per site, and will be required to hold two slots for Hispanic/Latino participants for the first year of the study in hopes of accruing a similar number of Hispanic/Latino men. These slots will be released after the first year of the study if no Hispanic/Latino participants have been recruited at a given site.

12.3.2 Accrual Rate and Accrual Duration: Based on an estimated accrual rate of 10 patients per month across the 20 participating practices, we expect 1 year to identify and train participating practices, approximately 18 months to enroll patients into the clinical trial and another 18 months to collect follow-up outcomes and perform data cleaning and statistical analysis. The study duration of this clinical trial will be 4 years.

12.3.3 Primary Endpoint Completion Date for ClinicalTrials.gov Reporting: For purposes of ClinicalTrial.gov reporting, the Primary Endpoint Completion Date (PECD) for this study is the time the last patient registered has been followed for at least 12 months.

12.4 Supplementary Analysis Plans

12.4.1 Secondary endpoints

Secondary endpoints will be decisional quality, as measured by the DCS and Decisional Regret; clinical time required; patient QOL, which will be measured by questionnaires and converted into continuous summary scores using standard algorithms; and utilization, which will be categorized by the type of treatment the patient received, as determined by chart review at 12 months post-diagnosis. We will also consider the primary outcome of knowledge within only minority men (pooled) (defined as non-White or Hispanic White), as well as separately within the three racial subgroups. It is worth noting that some patients may receive a follow-up biopsy before these secondary endpoints are measured (at 12 months after first consultation), which could have a strong impact on their DCS and QOL scores. Thus, whether or not a patient receives a follow-up biopsy before 12 months (and the timing of this biopsy) will be taken into account when modeling these endpoints.

12.4.2 Secondary analyses

Decisional quality, average clinical time required, and patient QOL scores will be compared across DA types using linear mixed models similar to that used to assess the primary endpoint. In particular, this model will include fixed effects for Prostate Choice and Knowing Your Options and a random, site-specific intercept to allow for subjects within the same site to be correlated. Utilization will be compared across DA types using a generalized linear mixed model, again with fixed effects for having received Prostate Choice and having received Knowing Your Options and a random, site-specific intercept.

As mentioned above, the primary analysis will be re-implemented within only minority men as a secondary analysis. We anticipate enrolling approximately 80% minority men. It is worth nothing that, if this were the primary analysis, this sample would give us approximately 78% power to detect an absolute difference of 8% in knowledge for either of the decision aid main effects using a two-sample t-test (with two-sided alternative) with a 2.5% significance level (i.e. the same analysis/assumptions used to power the primary analysis).

As an additional secondary objective, we will explore whether the overall effects of interventions on patient knowledge, quality of life, and treatment utilization differ by racial/ethnic subgroups. Our sample size is driven by the primary outcome of knowledge. Oversampling of minority populations of interest will achieve a robust representation of these minority populations in our final sample, but we have not designed the trial to have sufficient power to ascertain subtle subgroup differences in knowledge and quality of life by race/ethnicity subgroups. These secondary analyses will be exploratory, because fully testing the racial/ethnic differences would require prohibitively large sample sizes, and the literature does not suggest a strong race-based rationale for large differences. If subtle but potentially important trends in subgroup differences are identified in these exploratory analyses, those findings could be used to justify a larger study examining a primary hypothesis related to racial/ethnic difference or could influence the design of subsequent culturally tailored interventions. At present, the science of decision aids and the state of the evidence surrounding racial/ethnic differences in the effect of decision aids would not support testing such a hypothesis as a primary endpoint.

12.5 Monitoring

12.5.1 Adverse Event Stopping Rules

This is a behavioral intervention, questionnaire-based outcome study (i.e., this is not a therapeutic study) and as such, no adverse event stopping rule will be developed (see Section 9.0).

12.5.2 Accrual Monitoring Stopping Rule

There is no formal plan to monitor for slow accrual. Meetings to assess recruitment will be conducted monthly. Regulatory DSMB reports will allow decisions to be made regarding stopping.

12.5.3 Other Monitoring

Conference calls (or webinars, if visual media is shared) will be arranged and conducted on an as-needed basis. These meetings will be led by the study chair, and will include the study statistician, protocol coordinator, institutional study coordinators and site investigators or their designees to monitor accrual, completeness of data collection, and safety.

12.6 Reporting

This study will be monitored by the Alliance Data and Safety Monitoring Board (DSMB), an NCI-approved functioning body. Reports containing efficacy, adverse event, and administrative information will be provided to the DSMB every 6 months as per NCI guidelines. Reports from these meetings will be made available to the study chair, statistician, and participating institutions.

Results Reporting on ClinicalTrials.gov: At study activation, this study will have been registered within the "ClincialTrails.gov" website. The Primary and Secondary Endpoints along with other required information for this study will be reported on ClinicalTrials.gov.

12.7 Inclusion of Women and Minorities

Because prostate cancer occurs primarily in men above the age of 50, recruitment of participants for this study will focus upon men aged 50 years and older. Since women and children are not subject to prostate cancer, they will be excluded from this study.

Racial Categories	DOMESTIC PLANNED ENROLLMENT REPORT				
	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/Alaska Native	0	43	0	0	43
Asian	0	5	0	0	5
Native Hawaiian or Other Pacific Islander	0	2	0	0	2
Black or African American	0	38	0	5	43
White	0	38	0	37	75
More Than One Race	0	3	0	1	4
Total	0	129	0	43	172

13.0 GENERAL REGULATORY CONSIDERATIONS AND CREDENTIALING

13.1 Limited Access requirements

Institutions that are interested in participating in this study must first contact the Study Chair, Jon Tilburt to review study requirements and procedures and to identify who will be responsible for the study at the institution.

Criteria for participation will be based on the following:

- Site must provide consultation to newly diagnosed prostate cancer patients
- Site must have providers willing to use a decision aid in patient consults
- Site must be able to recruit 8-10 patients over 2 years
- 2-3 of those recruited each year need to self-identify as being from one of two groups: American Indian or Alaska Native (i.e. can be "more than one race" with one of those races being American Indian/Alaska Native) OR African American
- Sites that see a lot of Hispanic/Latino patients are encouraged to participate, however the trial materials and outcome measures require English speaking capacity or assistance by an appropriate translator.

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15.0 MODEL INFORMED CONSENT FORM

Study Title for Study Participants:

Testing two decision aids on patient knowledge and communication when choosing a course of treatment for prostate cancer

Official Study Title for Internet Search on [redacted]

Alliance A191402CD: Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men

This research study is conducted by the Alliance for Clinical Trials in Oncology, a national clinical research group supported by the National Cancer Institute. The Alliance is made up of cancer doctors, health professionals, and laboratory researchers, whose goal is to develop better treatments for cancer, to prevent cancer, to reduce side effects from cancer, and to improve the quality of life of cancer patients.

What is the usual approach to discussing my treatment options?

You are being asked to take part in this research study that looks at whether computer tools (also called "decision aids") help prostate cancer patients better understand their treatment options and help patients talk about their treatment preferences with their doctors. Usually, patients who must make treatment decisions for prostate cancer discuss their options with their doctor. Their doctor explains available choices, answers questions, and offers his/her recommendation for the best treatment option. Doctor recommendations take into account the patient's age, health, and health goals.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to have the usual approach described above
- you may choose to take part in a different study, if one is available

Why is this study being done?

Discussing your options for treatment or observation of your prostate cancer is an important next step. The purpose of this study is to test whether the use of a decision aid (a visual aid with educational information) can improve patients' knowledge of their condition and options for treatment, and whether using a decision aid can help when talking with their doctor. The effects of two different prostate cancer decision aids will be tested in this study. One decision aid is called "Prostate Choice" and is used by patients during their visit with their doctor. The other decision aid is called "Knowing Your Options" and is used by patients before they visit with their doctor.

There will be about 172 men taking part in this study.

What are the study groups?

A computer will by chance assign your doctor's office or hospital to one of four groups in the study. This is called randomization. This is done by chance because no one knows if one study group is better or worse than the others. Neither you nor your doctor can choose the group you will be in. The four groups are:

- Group 1 will use both decision aids: one just before ("Knowing your Options"), and the other during your visit with the urologist ("Prostate Choice").
- Group 2 will use one decision aid ("Knowing your Options"), just before your visit with the urologist.
- Group 3 will use one decision aid ("Prostate Choice"), during your visit with the urologist.
- Group 4 will use neither decision aid, and you will have the usual discussion with the urologist described above.

If you are in Group 1 or Group 2, you will be asked to go to the clinic for your visit with the urologist early so that you will have time to use the decision aid.

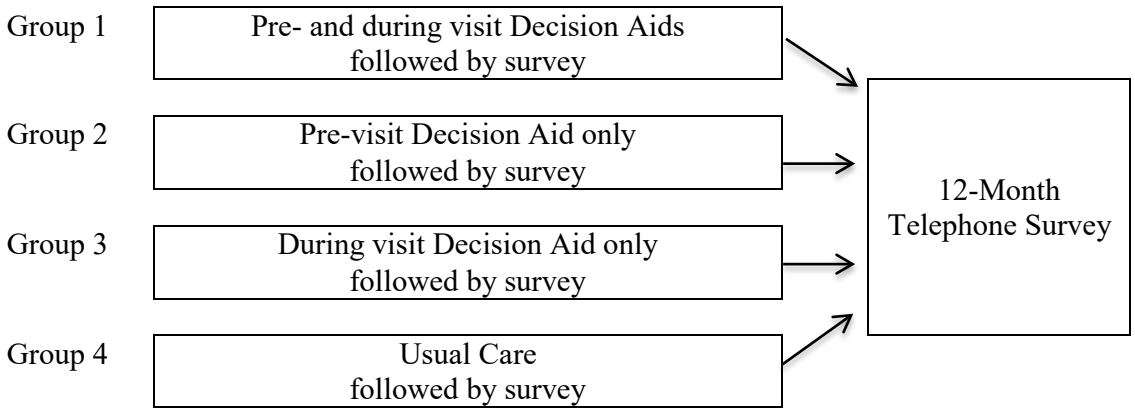
It is unclear whether there is any time difference between doctor visits for the different groups as a result of the decision aids.

All Groups: After your visit with the urologist, you will be asked to complete a survey about your treatment choice, your knowledge about your disease and treatment choices, and your experience in discussing treatment options. This survey should take about 10 to 15 minutes to complete.

All Groups: About 1 year after your visit with the urologist, if you have an appointment with him or her, you will be asked to complete another survey to ask you about your prostate cancer treatment choice and about the results of that choice. If you do not have an appointment with your urologist at this time, research staff from your doctor's office will mail to you the survey so that you can complete it at home. A stamped, addressed envelope will be provided with the survey. This survey should take about 15 to 20 minutes to complete.

In addition, after one year, research staff from your doctor's office will review your medical records to see what kinds of treatments you may have received for your prostate cancer (for example, surgery, or radiation therapy, or "watchful waiting").

Another way to find out what will happen to you during the study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How long will I be in this study?

You will participate in the study on the day of your visit with the urologist and then participate in the survey call 12 months after the visit.

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, you may need to have a history and physical to find out if you can be in the study if you haven't had one done recently.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions which you normally do not discuss. You do not have to answer any question that you do not want to during the surveys.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if a decision aid for prostate cancer treatment decisions will increase your knowledge of treatment options and help you talk with your urologist about your treatment preferences. It is also not known if a decision aid used before your doctor visit or during your doctor visit is more helpful. This study will help researchers learn how to better help people in the future who must make difficult treatment decisions.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor or IRB

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number).*
(Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)

What are the costs of taking part in this study?

There are no costs to you for taking part in this study. You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report

to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information from this study will be kept in the Alliance central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Alliance for Clinical Trials in Oncology
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The National Cancer Institute in the U.S.

The Alliance has received a Certificate of Confidentiality from the federal government, which will help us to protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of the study. The researchers involved in this project may not be forced to identify you in any legal proceedings (criminal, civil, administrative, or legislative) at the federal, state or local level. However, some information may be required by the Federal Food, Drug, and Cosmetic Act, the U.S. Department of Health and Human Services, or for purposes of program review or audit. Also, you may choose to voluntarily disclose the protected information under certain circumstances. For example, if you or your guardian requests the release of information about you in writing (through, for example, a written request to release medical records to an insurance company), the Certificate does not protect against that voluntary disclosure.

Where can I get more information?

You may visit the NCI Web site at [redacted] for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: [redacted]

A description of this clinical trial will be available on [redacted], as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

Contact for Possible Future Research Studies:

The researchers may decide to conduct further research in the future on decision aids for prostate cancer. They may want to contact you to learn more about your quality of life following prostate

cancer treatment and your long-term satisfaction with your treatment decision. They may also want to learn your opinions in the future about decision aids for prostate cancer

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the study.

Participant's signature_____

Date of signature_____

APPENDIX I BASELINE QUESTIONNAIRE BOOKLET

Prostate Cancer Treatment Questionnaire

Please check the TRUE or FALSE box for each statement based on your knowledge of prostate cancer treatments. If you are not completely sure, mark 'Unsure'.

		True	False	Unsure
1.	**Most prostate cancer spreads quickly to other parts of the body**	1☐	2☐	3☐
2.	**Other illnesses can make treating prostate cancer more difficult**	1☐	2☐	3☐
3.	**Some treatments are better than others at stopping prostate cancer**	1☐	2☐	3☐
4.	**Radiation therapy from a machine for prostate cancer requires weeks of daily treatments**	1☐	2☐	3☐
5.	**Radiation seed therapy for prostate cancer requires weeks of daily treatments**	1☐	2☐	3☐
6.	**Radiation for prostate cancer can cause rectal pain**	1☐	2☐	3☐
7.	**Surgery for prostate cancer can cause urine leakage**	1☐	2☐	3☐
8.	**For most men, radiation therapy for prostate cancer has no effect on urinary control**	1☐	2☐	3☐
9.	**Both surgery and radiation can decrease sexual function**	1☐	2☐	3☐
10	**Low-risk prostate cancer can be safely monitored**	1☐	2☐	3☐
11.	**After prostate cancer surgery, a man will go home with a catheter**	1☐	2☐	3☐
12.	**Hot flashes is a side-effect of hormone treatment**	1☐	2☐	3☐

Investigator developed.

Decisional Conflict Scale

My difficulty in making this choice

A. Which treatment option do you prefer? Please check one.

- ☐ Surgery
- ☐ Radiation (includes Brachytherapy, IMRT, proton beam)
- ☐ Active Surveillance (also called watchful waiting)
- ☐ Unsure

B. Considering the option you preferred, please answer the following questions:	Yes	Unsure	No
1. Do you know which options are available to you?	☐	☐	☐
2. Do you know the benefits of each option?.....	☐	☐	☐
3. Do you know the risks and side effects of each option?	☐	☐	☐
4. Are you clear about which benefits matter most to you?	☐	☐	☐
5. Are you clear about which risks and side effects matter most to you?.....	☐	☐	☐
6. Do you have enough support from others to make a choice?	☐	☐	☐
7. Are you choosing without pressure from others?.....	☐	☐	☐
8. Do you have enough advice to make a choice?	☐	☐	☐
9. Are you clear about the best choice for you?.....	☐	☐	☐
10. Do you feel sure about what to choose?.....	☐	☐	☐

APPENDIX II FOLLOW-UP (12-MONTH) QUESTIONNAIRE BOOKLET

Expanded Prostate Cancer Index Composite—Short Form (EPIC-26)

This questionnaire is designed to measure Quality of Life issues in patients with Prostate cancer. To help us get the most accurate measurement, it is important that you answer all questions honestly and completely.

1. Over the **past 4 weeks**, how often have you leaked urine?

☐ More than once a day
☐ About once a day
☐ More than once a week
☐ About once a week
☐ Rarely or never

2. Which of the following best describes your urinary control **during the last 4 weeks**?

☐ No urinary control whatsoever
☐ Frequent dribbling
☐ Occasional dribbling
☐ Total control

3. How many pads or adult diapers per day did you usually use to control leakage **during the last 4 weeks**?

☐ None
☐ 1 pad per day
☐ 2 pads per day
☐ 3 or more pads per day

4. How big a problem, if any, has each of the following been for you **during the last 4 weeks**?	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Dripping or leaking urine	☐	☐	☐	☐	☐
b. Pain or burning on urination	☐	☐	☐	☐	☐
c. Bleeding with urination	☐	☐	☐	☐	☐
d. Weak urine stream or incomplete emptying	☐	☐	☐	☐	☐
e. Need to urinate frequently during the day	☐	☐	☐	☐	☐

5. Overall, how big a problem has your urinary function been for you **during the last 4 weeks**?

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

6. How big a problem, if any, has each of the following been for you?	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Urgency to have a bowel movement	☐	☐	☐	☐	☐
b. Increased frequency of bowel movements	☐	☐	☐	☐	☐
c. Losing control of your stools	☐	☐	☐	☐	☐
d. Bloody stools	☐	☐	☐	☐	☐
e. Abdominal/ Pelvic/ Rectal pain	☐	☐	☐	☐	☐

7. Overall, how big a problem have your bowel habits been for you **during the last 4 weeks**?

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

8. How would you rate each of the following **during the last 4 weeks**?	Very poor to none	Poor	Fair	Good	Very Good
a. Your ability to have an erection?	☐	☐	☐	☐	☐
b. Your ability to reach orgasm (climax)?	☐	☐	☐	☐	☐

9. How would you describe the usual QUALITY of your erections **during the last 4 weeks**?

☐ None at all
☐ Not firm enough for any sexual activity
☐ Firm enough for masturbation and foreplay only
☐ Firm enough for intercourse

10. How would you describe the FREQUENCY of your erections **during the last 4 weeks**?

☐ I NEVER had an erection when I wanted one
☐ I had an erection LESS THAN HALF the time I wanted one
☐ I had an erection ABOUT HALF the time I wanted one
☐ I had an erection MORE THAN HALF the time I wanted one
☐ I had an erection WHENEVER I wanted one

11. Overall, how would you rate your ability to function sexually **during the last 4 weeks**?

☐ Very poor
☐ Poor
☐ Fair
☐ Good
☐ Very good

12. Overall, how big a problem has your sexual function or lack of sexual function been for you **during the last 4 weeks**?

☐ No problem
☐ Very small problem
☐ Small problem
☐ Moderate problem
☐ Big problem

13. How big a problem **during the last 4 weeks**, if any, has each of the following been for you?	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Hot flashes	☐	☐	☐	☐	☐
b. Breast tenderness / enlargement	☐	☐	☐	☐	☐
c. Feeling depressed	☐	☐	☐	☐	☐
d. Lack of energy	☐	☐	☐	☐	☐
e. Change in body weight	☐	☐	☐	☐	☐

Decisional Regret Scale

Please think about the decision you made about how to treat your prostate cancer after talking to your doctor. Please show how you feel about these statements by circling a number from 1 (strongly agree) to 5 (strongly disagree).

		Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1.	It was the right decision	1	2	3	4	5
2.	I regret the choice that was made	1	2	3	4	5
3.	I would go for the same choice if I had to do it over again	1	2	3	4	5
4.	The choice did me a lot of harm	1	2	3	4	5
5.	The decision was a wise one	1	2	3	4	5