University of California, San Francisco

DEPARTMENT OF DEFENSE US ARMY MEDICAL RESEARCH TRANSFORMATIVE IMPACT AWARD

Clinical Research Protocol

PIONEERING ADVANCES IN CARE & EDUCATION (PACE) - HDFCC #17553

Protocol Number:	#14-12951
Version Date:	8/9/2017
Investigational Product:	N/A
IND Number:	N/A
Development Phase:	N/A
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Approval:

2/3/2017

Peter R. Carroll, MD, MPH; Chair Dept. of Urology

Date

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PROTOCOL AGREEMENT

I have read the protocol specified below. In my formal capacity as Investigator, my duties include ensuring the safety of the study subjects enrolled under my supervision and providing the Department of Defense U.S. Army Medical Research with complete and timely information, as outlined in the protocol. It is understood that all information pertaining to the study will be held strictly confidential and that this confidentiality requirement applies to all study staff at this site. Furthermore, on behalf of the study staff and myself, I agree to maintain the procedures required to carry out the study in accordance with accepted GCP principles and to abide by the terms of this protocol.

Protocol Number: #14-12951

Protocol Title: Pioneering Advances in Care & Education (PACE) - HDFCC 17553

Protocol Date: 8/9/2017

8/9/2017

Investigator Signature *Date*

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LIST OF ABBREVIATIONS

ACS	American Cancer Society
AE	adverse event
AS	Active Surveillance
AUA	American Urological Association
BX	Biopsy
CAPRA	Cancer of the Prostate Risk Assessment score
CaPSURE	Cancer of the Prostate Strategic Urologic Research Endeavor
CFR	Code of Federal Regulations
CP	Choice Predisposition
CPS	Control Preferences Scale
CRF	case report form
CROM	Clinician-reported outcome measure
CRC	Clinical Research Coordinator
D&L	Diet and lifestyle
DMC	Data Monitoring Committee
DNA	Deoxyribonucleic acid
DoD-TIA	Department of Defense Transformative Impact Award
DSE	Decision Self-efficacy
DSI	Decision Support Intervention
DSMB	Data Safety Monitoring Board
DQI	Decision Quality Instrument
ECOG	Eastern Cooperative Oncology Group (ECOG) performance status
EPIC	Expanded Prostate Index Composite-26 items
FDA	Food and Drug Administration
FFPE	Formalin Fixed Paraffin Embedded
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICF	informed consent form
ICH	International Conference on Harmonisation

IEC	Independent Ethics Committee
IRB	Institutional Review Board
MaxPC	Memorial Anxiety Scale for Prostate Cancer (MAX-PC)
MRI	Magnetic Resonance Imaging
PCa	Prostate Cancer
PCa SCOPED	Prostate Cancer SCOPED Form (Situation, Choice, Objectives, People, Evaluation, and Decision)
PI	Principal Investigator
PIVOT	Prostate Intervention Versus Observation Trial
PSA	Prostate Specific Antigen
PROM	Patient-reported Outcome Measures
QL	Question List – Summary Form
QOL	Quality of Life
RNA	Ribonucleic acid
SAE	serious adverse experience
SSCa	Service Satisfaction with Cancer Care
SF-12	Short Form-12 (4-week recall)
TIBI-CaP	Total Illness Burden Index – Prostate Cancer
TRUS	Transrectal Ultrasound
US/UG	Up-staging / Up-grading

PROTOCOL SYNOPSIS

TITLE	DoD-TIA RCT PCa Decision Tool
SPONSOR	University of California San Francisco; Dept. of Urology
FUNDING ORGANIZATION	Department of Defense (DoD) U.S. Dept. of the Army Military Medical Research and Development
NUMBER OF SITES	4
RATIONALE	Current clinical-pathologic descriptions of prostate cancer (e.g. grade, stage, PSA) can be used to estimate a patient's risk of harboring more aggressive disease and the risk of recurrence post-therapy. However, there are limited data on how well patients understand this information and how this affects their management decisions. Decision support tools have been proposed to help men with prostate cancer through their decision process, yet most are not tailored to a patient's unique biology or preferences.[11] Our study evaluates the first decision support intervention that uses service learning (student) coaches as a low-cost workforce to administer a decision aid with personalized risk estimates based on patient tumor features. In a single-arm pilot study at UCSF, we found this intervention was feasible and acceptable, and associated with increased patient knowledge (IRIS #14-13332). We now propose to evaluate this decision support intervention in a multi-site clinical trial.
STUDY DESIGN	This is a site-randomized, cluster-crossover clinical trial of a decision support intervention (DSI) vs. usual care, among men with low prognostic risk prostate cancer, to assess differences in informed decision making (i.e., knowledge), anxiety, and decision quality and self-efficacy.
PRIMARY OBJECTIVE	To assess the impact of the DSI on **knowledge** (i.e., informed decision-making) regarding risks associated with different management strategies for prostate cancer, given one is diagnosed with low-risk prostate cancer.
SECONDARY OBJECTIVES	1). To assess the impact of the DSI on anxiety, decision quality and self-efficacy. 2). After the DSI or usual care, to compare choice of prostate cancer management / treatment selected.
NUMBER OF SUBJECTS	160 subjects enrolled, allowing for attrition (12) and non-response (12), leaving ~136 fully evaluable subjects.
SUBJECT SELECTION CRITERIA	Inclusion Criteria: A patient diagnosed with prostate cancer who meets the following criteria: 1. PSA <= 15 ng/ml

	1. Clinical stage cT1/2,N0,M0 2. Biopsy Gleason grade 2-6 OR (or 3+4 AND <=33% cores are positive for adenocarcinoma); a. A minimum of 10 diagnostic cores taken by a systematic directed approach. Sampling may be obtained by target TRUS or MRI imaging. 3. No treatment yet a. No previous radiation or simultaneous use of androgen deprivation b. Prior use of 5-alpha reductase inhibitor is allowed if they have been stopped for 6 or more months and biopsy performed when patient was not taking the drug. 4. English language proficient and ability to sign an ICF 5. Considered candidates for active surveillance at their institution by the treating urologist. Exclusion Criteria: Participants who have received any therapy for prostate cancer or who do not read/speak English or whose managing urologist does NOT deem them as a candidate for active surveillance.
TEST PRODUCT, DOSE, AND ROUTE OF ADMINISTRATION	Participants assigned to the intervention will receive Decision Support in the form of a decision aid+health coaching. The decision aid (delivered by internet and as a PDF document) provides participants with a report on options and outcomes as described in the literature; along with more tailored risk information. The tailored risk information will include their estimated risk of harboring more aggressive prostate cancer based on their clinical/pathologic features (i.e., "My Clinical Risk"). The DSI was developed and piloted at UCSF according to the International Patient Decision Aid Standards (see http://ipdas.ohri.ca/) (IRS# 14-13332), and incorporates tailored risk models developed and validated at UCSF and community sites [1]. The tailored models estimate a patient's risk of having more aggressive prostate cancer if, theoretically, one was to remove their prostate gland at that time (i.e., undergo surgery as active treatment) and have the entire gland reviewed (i.e., risk of up-staging or up-grading (US/UG)).
CONTROL PRODUCT, DOSE AND ROUTE OF ADMINISTRATION	Participants assigned to the control arm will receive usual care, including whatever information materials are provided to them by their urologist. (We will assess what materials they reviewed by surveying patients.)

DURATION OF SUBJECT PARTICIPATION AND DURATION OF STUDY	Subjects will be in an active study phase for approximately 4-6 weeks, depending on their scheduling with their local urologist. Within those six weeks, we will approach them about the study; if interested/consented, they will be asked to complete baseline surveys online (paper will be available if preferred); access the decision aid; and talk to the health coach; complete pre-visit surveys; meet with their urologist; and complete follow-up surveys. Once the participant has met with his urologist and made a management decision, he is done with the active intervention phase of the study, and will roll-over into an observational cohort component only of the study. In this phase, we will ask participants to complete surveys on their prostate cancer status and quality of life annually and allow us to access their medical chart to abstract data on their health and prostate cancer status.
CONCOMMITANT MEDICATIONS	Allowed: Participants may take any medications unrelated to their prostate cancer during the study. After their visit with their local urologist when they make a management decision, participants may follow any medical regimen for their prostate cancer. Prohibited: We will not enroll participants who have already received treatment for their prostate cancer.
EFFICACY EVALUATIONS	
PRIMARY ENDPOINT	• Knowledge regarding the risks and benefits associated with different management choices for men with localized/early stage prostate cancer.
SECONDARY ENDPOINTS	• Anxiety, decision self-efficacy, health-related quality of life. • Choice of prostate cancer management / treatment selection.
OTHER EVALUATIONS	Optional: In the future, we may consider banking saliva and FFPE tumor tissue from already performed biopsies for future research studies. Biospecimen donation will be optional.
SAFETY EVALUATIONS	There are not planned safety evaluations. The active phase of this behavioral intervention is brief, ~4-6 weeks. Participants will not be receiving any active treatment for their cancer during this phase. The main risks may be anxiety or confusion regarding the risks and benefits associated with their current diagnosis and decision ahead, and risk of loss to privacy by participating in a research study.
PLANNED INTERIM ANALYSES	As a behavioral intervention trial testing knowledge as the primary outcome, there an interim analysis is not planned.

STATISTICS **Primary Analysis Plan**	We will use univariate statistical tests (e.g., chi-square, t-test) and multivariate regression to assess the difference in the probability of the primary outcome between subjects randomized to the intervention and control arms for each site.
Rationale for Number of Subjects	Standard power calculations for chi-square tests to compare two proportions along with adjustments for potential correlation of responses within sites, missing data and attrition show that tests based on a sample of 136 subjects would have power to detect an alternative where the probability of the primary response increases from 0.5 in the control sites to 0.75 in the intervention sites. We will enroll 160 subjects to allow for attrition and survey non-response.

1 BACKGROUND

A critical public health need exists for **improved prognostic tools to distinguish aggressive from indolent prostate cancer** at diagnosis, and for **better support systems to guide patients in decision-making regarding management options**. Our proposal addresses both needs, and is poised to improve management of low-risk prostate cancer in the United States (U.S.) in the near term.

1.1 Overview of Non-Clinical Studies

Patients generally are at risk for both under-treatment and over-treatment relative to their personal priorities and the best available medical evidence [2-4]. This is certainly true in the case of low-risk prostate cancer patients, who are often over-treated with surgery or radiation relative to what they say they would have preferred if fully informed about all the options and outcomes, including the risks and benefits of active surveillance.

Decision support interventions tailored to specific clinical crossroads have increased patient self-efficacy, knowledge, question-asking, and satisfaction; and decreased decisional conflict, regret, anxiety, and distress [2, 5-17]. Such informed and involved patients tend to pursue less invasive treatment options than they might otherwise settle upon under usual care [18, 19].

However, in the area of prostate cancer, these decision support interventions have not provided personalized risk estimates to patients. The need for personalized risk estimates arises from the potential for an initially low-risk prostate cancer to be reclassified over time if it is not treated with surgery or radiation. Many patients and physicians avert that risk by erring on the side of active treatment (surgery or radiation) rather than active surveillance.

To reduce the risk of over-treatment, our team has developed individual risk prediction models that we have now integrated into our decision support intervention (DSI).

Decision support interventions must be delivered to patients in an effective and efficient manner. Our team has refined a comprehensive DSI, which prompts patients to review risk and other educational materials, as well list questions in writing for their physicians [7]. We have also refined a service learning workforce to deliver the intervention remotely, by internet and telephone, in a way that does not require clinics to modify their practices, and that leverages unpaid student interns receiving academic credit as part of their academic training [7].

Delivering such decision support should increase patient knowledge and question-asking, and these proximal outcomes should increase the proportion of men making informed decisions regarding their selection of active surveillance, surgery, or radiation for low-risk prostate cancer. This study will evaluate whether our intervention is feasible and effective in delivering individually tailored decision support to men prior to their first urology visit upon diagnosis with low-risk prostate cancer; and whether a higher proportion of men make informed decisions with less anxiety or decisional regret.

1.2 Overview of Clinical Studies

Not applicable

2 STUDY RATIONALE

Age-adjusted mortality rates have fallen nearly 40% since the start of the prostate specific antigen (PSA) screening era, and are at their lowest level in the past 80 years [20]. Prostate cancer remains the second leading cause of cancer mortality among men in the U.S.[20], but a wide array of novel diagnostic and therapeutic interventions promise to drive mortality rates down further.

The Prostate Intervention Versus Observation Trial (PIVOT) reported an early survival benefit for men diagnosed with high-risk disease (e.g., prostate cancer of high grade, stage, and/or PSA) treated with surgery rather than observation—but no benefit for men with low-risk disease [21, 22]. Moreover, all treatments entail risk of long-term quality of life (QOL) impacts (e.g. erectile dysfunction, incontinence) [23], and many men—often those opting for newer, technology-intensive treatments—ultimately express regret regarding their treatment decisions and low satisfaction with their clinical or QOL outcomes [24].

A growing consensus deems current rates of over-treatment of low-risk prostate cancer unacceptable, as the morbidity associated with avoidable interventions accounts for much of the suffering associated with prostate cancer in the U.S. [25]. One solution is to screen more selectively, to reserve treatment for men with aggressive cancer, and to guide those with indolent, lower-risk disease to active surveillance (AS)—i.e., careful monitoring with serial assessments and curative treatment at any sign of progression [26, 27]. Multiple factors underlie over-treatment of low-risk disease; key among them is the concern that a biopsy may not fully reflect tumor aggressiveness. The rate of biopsy under-sampling—i.e., a biopsy indicating low-risk characteristics for a tumor that ultimately proves to be higher grade or stage—is estimated at 20-30% [28].

Decision support tools have been proposed to help men with prostate cancer through their decision process, yet most are not tailored to a patient's unique biology or preferences [29].

Our study evaluates the first decision support intervention that uses service learning (student) coaches as a low-cost workforce to administer a decision aid with personalized risk estimates based on patient biology. In a single-arm pilot study at UCSF, we found this intervention was feasible and acceptable, and associated with increased patient knowledge.

2.1 Risk / Benefit Assessment

This study involves minimal risks not materially greater than those that may be experienced in usual care. Men receiving the DSI may not have yet been exposed to the level of detail contained in the decision aid. Some men might react negatively to the detail. However, generally decision support is not associated with harms such as anxiety or distress, and the coaching session is designed to help men absorb the information in the decision aid and write up questions in a question list. We cannot be sure that men will benefit directly, however the study will add important knowledge to our scientific understanding of how best to educate men about treatment options for early-stage prostate cancer. These insights could shape decision support for years to come. Therefore, the potential benefits outweigh the risks.

3 STUDY OBJECTIVES

3.1 Primary Objective

The primary objective is to increase the rate of *informed* decision-making among men with early-stage prostate cancer.

3.2 Secondary Objectives

Secondary objectives relate to assessing the effect of decision support on anxiety, decision self-efficacy, and decision quality, as measured by validated survey instruments, and management choice.

3.3 Optional Biospecimen Banking

In the future, we may also request archival leftover tumor tissue from a participant's recent prostate biopsy and saliva for banking for future research. If the scientific team were to decide to proceed with banking biospecimens we would do so based on tissue studies associated with the CaPSURE™ study (IRB # 10-00881) and its related sub-study CaPSURE Tissue (IRB# 13-12624).

4 STUDY DESIGN

4.1 Study Overview

This is a four-site, site-randomized, two-period, cluster-crossover design. 160 subjects are planned. Sites will be randomized in pairs to period 1 usual care or intervention. After all sites have met accrual goals, the pairs will cross over to intervention or usual care. In usual care, study participants will complete surveys and prepare for their visit as they usually would, and receive whatever education materials and counseling is normally provided by the sites. We will assess the materials and counseling received by surveying the patients about this. In the intervention, subjects will be contacted by the coordinating site (UCSF) and offered educational materials that include personalized risk estimates, along with coaching to help list questions for their upcoming visit with the urologist.

5 CRITERIA FOR EVALUATION

5.1 Primary Efficacy Endpoint

The primary endpoint is the proportion of patients who respond accurately to two survey items assessing whether they are more likely to die of prostate cancer or other causes (other causes are more likely); and whether waiting three months to make a treatment decision will affect their survival a lot; somewhat; or a little or not at all (a little or not at all is the correct answer).

Knowledge of these key facts is an important endpoint because patients often associate the word cancer with high mortality risks, and with urgency to act. Patients also often associate more invasive treatment with greater benefit.

In the case of early-stage, low-risk prostate cancer, patients should recognize that early-stage prostate cancer patients are more likely to die of other causes than prostate cancer; and that most can safely take three months to make decisions. This knowledge opens patients up to consideration of active surveillance along with surgery and radiation therapies.

Our intervention aims to educate patients about their (low) mortality risk and the time available for decision-making after their cancer diagnosis **before** they see their urologist for primary treatment counseling. Therefore, we will assess this endpoint just prior to the first urology appointment after a biopsy confirms early-stage low-risk cancer, and compare the usual care results to the intervention arm.

In preliminary studies at an academic medical center with highly educated patients, our intervention increased the proportion of patients responding accurately from 69% to 88%. Meanwhile, at our community sites, 52% of usual care patients responded accurately. We hypothesize that in our randomized controlled trial, we will see over 75% of patients respond accurately in the intervention arm, versus 50% in the usual care arm.

5.2 Secondary Efficacy Endpoints

We will assess the impact of our intervention on decision self-efficacy, decision quality, anxiety, and satisfaction, based on participant responses to validated surveys. We will also measure patient understanding of reclassification risk, based on a custom survey designed for this study. (Please see Table 2 for further details on study schedule)

We will measure decision self-efficacy before and after the intervention (before the medical appointment); to assure that the intervention is working as intended. In prior studies we and other researchers have shown that similar pre-consultation decision support interventions are associated with pre/post increases in decision self-efficacy. In the usual care arm, we will measure decision self-efficacy before the medical appointment.

We will measure decision quality, anxiety, and understanding of reclassification risk before and after the medical appointment. The study will record management or treatment approach selected by the participant.

We will measure satisfaction after the medical appointment.

5.3 Safety Evaluations

There are no anticipated clinical or physical risks associated with participation in this study. The primary anticipated risks associated with this study are losses to privacy, or anxiety or discomfort associated with the survey questions. Participants will be told that their participation is voluntary, and participants will be allowed to skip questions. The key questions that we want participants to answer (or be considered as having missing answers on primary outcomes) are 2 knowledge questions. In our sample size calculations, we will conservatively plan for around 10% missing responses (N~15) on our primary outcome, as well as 10% attrition (N~15 subjects) from consent to visit.

5.4 Other Evaluations

We will measure covariates that will inform exploratory analyses, including quality of life (SF-12 [30, 31], EPIC [32], diet and lifestyle (D&L) [33], decision self-efficacy (DSE), control preferences scale (CPS) [34], choice disposition (CP) [35], and demographics.

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6 SUBJECT SELECTION

6.1 Study Population

Subjects with a diagnosis of low-risk prostate cancer (PCa) who meet the inclusion and exclusion criteria will be eligible for participation in this study.

6.2 Inclusion Criteria

1. Male ≥18 years of age and newly diagnosed PCa (within 3-months).
2. Documentation of a low-risk PCa diagnosis as evidenced by clinical features of the following criteria:
    a. PSA test at diagnosis ≤15 ng/ml
    b. Localized PCa (cT1/T2,N0,M0)
    c. Biopsy Gleason grade 2-6 OR (or 3+4 AND <=33% cores are positive for adenocarcinoma)
        i. A minimum of 10 diagnostic cores taken by a systematic directed approach. Sampling may be obtained by target TRUS or MRI imaging.
    d. No treatment yet
        i. No previous radiation or simultaneous use of androgen deprivation
        ii. Prior use of 5-alpha reductase inhibitor is allowed if they have been stopped for 6 or more months and biopsy performed when patient was not taking the drug
    e. English language proficient and ability to provide ICF
    f. Managing urologist considers them a candidate for active surveillance
3. Written informed consent (and assent when applicable) obtained from subject and ability for subject to comply with the requirements of the study, including the ability to read and speak English.

6.3 Exclusion Criteria

Participants will be ineligible if they: 1) have pursued any active therapy for prostate cancer will be excluded; 2) are unable to read/speak English; or 3) if their managing urologist does NOT deem them as a candidate for active surveillance.

7 CONCURRENT MEDICATIONS

All subjects should be maintained on the same medications throughout the entire study period, as medically feasible, with no introduction of new chronic therapies.

7.1 Allowed Medications and Treatments

Standard therapy for non-prostate cancer conditions is allowed throughout the study. After the active intervention is completed and primary and secondary outcomes have been assessed (shortly after the visit with the managing urologist), the participant may pursue whatever

treatment he chooses for his prostate cancer. At this point, the participant will roll-over to an observation phase only.

8 STUDY TREATMENTS

8.1 Method of Assigning Subjects to Treatment Groups

The trial will use a randomized crossover design using 4 community-based urology sites. Two sites will be randomized to initiate the study in the 'decision support coaching intervention' arm while the remaining 2 sites will start in the 'usual care arm'. Each site will accrue 20 participants before crossing over to the alternate arm (see Figure 1). A total of 160 newly diagnosed men who are pre-treatment with low risk prostate cancer will be enrolled into the study. If the participating site is unable to meet the recruitment goal of 40 participants per site (for a final sample of 160 participants); the investigators may add sites to achieve the final study sample size of 160 during the funding period of this grant.

8.2 Blinding

The participating site will be randomized to DSI or usual care at study initiation and will crossover once they have met their accrual goal of 20 participants (see Figure 1). Patients recruited at each site will be blinded to the assignment of their site. Patients will be informed during recruitment and consent that the study will give surveys to assess patient knowledge and related outcomes at four sites, and examine how variations in patient education strategies are associated with patient survey responses. The clinic staff and physicians will NOT be blinded to the assignment; however, the primary outcome will be determined before the patient conducts their decision making consultation with the physician. The statistician will remain blinded to the randomization status of the sites during the analysis phase only.

8.3 Decision Support Intervention

Participants randomly assigned to the Intervention will receive access to our decision aid, developed following the International Patient Decision Aids Standards with the input of patients, family members, physicians, nurses, clinic staff, decision scientists, and clinical researchers [1]. After reviewing the decision aid, either via a secure website or a PDF file emailed to them (whichever is most convenient for them), patients will speak with a trained coach. The coach will review the decision aid screen by screen, or page by page, and write down any questions that the patient voices about the contents of the decision aid. The coach will then review the decision aid help text to address questions that are covered there, and save the remaining questions for the attention of the attending urologist at the upcoming visit. Specifically, the coach will save a word-processed document with the patient's questions for the physician, and send that file to the site study coordinator, who will print copies for the patient, family, and physician and make those copies available to all parties at the time of the clinic visit. Our surveys will also assess what other decision or communication aids the patient may have accessed on their own prior to the visit.

Our decision aid incorporates the following estimates:

- Survival and quality of life outcomes from the CaPSURE outcomes database for patients who underwent active surveillance, surgery, or radiation.

- Risk of reclassification ("upstaging" or "upgrading") based on demographic, clinical, and pathologic parameters using a model developed at UCSF and tested using UCSF and CaPSURE data.

8.3.1 Formulation of Control Product

The participants assigned to the control arm will be treated with usual care, including whatever information materials are typically provided to them by clinics (e.g. prostate cancer brochure from the American Cancer Society (ACS), American Urological Association (AUA) or their local institutions educational materials on diagnosis and treatment options). One of our surveys will assess what information materials each patient has seen prior to the visit.

8.4 Supply of Intervention at the Site

After patients are consented and enrolled in the study, intervention site coordinators will assure that they complete online or paper surveys, and will notify the coordinating site (UCSF) when these are complete. This will trigger the UCSF team to contact the patient by telephone and email, to communicate:

1. The Uniform Resource Locator (URL) for the decision aid
2. A PDF copy of the decision aid

The coach will also schedule a time for the coaching call, which is to occur before the urology visit.

During the coaching call, the coach will review the decision aid screen by screen or page by page; write down questions that the patient has for their doctor; and communicate those questions to the doctor via the site coordinator.

8.5 Measures of Intervention Compliance

Our interventionists (the coaches) will report on whether patients partially completed the coaching call; or fully completed the coaching call; or whether they never attended the coaching call.

9 STUDY PROCEDURES AND GUIDELINES

A Schedule of Events representing the required testing procedures to be performed for the duration of the study is diagrammed in Table 1.

Prior to conducting any study-related activities, written informed consent and the Health Insurance Portability and Accountability Act (HIPAA) authorization must be signed and dated by the subject. If appropriate, assent must also be obtained prior to conducting any study-related activities.

This is a site randomized study. Therefore, each site's health providers and staff will be aware of whether they are delivering the intervention or usual care at a given time.

9.1 Clinical Screening

Participants will be identified for eligibility to participate in this study by the coordinators (CRC's clinical research coordinators) at each site based by screening the medical charts. CRC's

will identify patients who have been recently diagnosed with low-risk prostate cancer, and provide a list to their site urologist(s) to ensure these patients are potential candidates for active surveillance. Those meeting eligibility criteria will be contacted by phone by the CRC for potential enrollment into this study. Introduction to the study and obtaining informed consent (IC) will use two methodologies:

1. **Phone based recruitment**: If the man expresses interest, the CRC will obtain verbal permission to be contacted by the data coordinating center at UCSF. The CRC will enter data into the REDCaP database case report forms (CRF) (specifically, the subject identifiers, and eligibility for study). The UCSF data coordinating center will send the paper-mode informed consent form (ICF), HIPAA and the baseline participant surveys to the man via traceable FedEx overnight mail.
2. **In person clinic recruitment**: If the patient is being seen in the clinic, the CRC will obtain the signed IC and will forward the original signed copy to the UCSF data coordinating center. The CRC will enter data into the REDCaP database CRFs. Specifically, the subject identifiers, eligibility for study, study biopsy results form, coach contact preferences, and appointment information forms. The UCSF data coordinating center will send the baseline participant surveys to the man via traceable FedEx overnight mail.

Those consenting will be asked to complete baseline surveys. Once those steps are complete, depending on the site's random assignment, the participant will either be asked to proceed with the Decision Support Intervention or standard informational brochure/s used in clinical care for men with newly diagnosed prostate cancer. The procedures associated with the DSI are described in section 8.3.

9.2 Outcome Assessments

Our primary and secondary outcomes will be assessed via surveys, according to the schedule in the Table 2.

9.3 Post-Intervention Clinic Visit

Participants will proceed to have their regularly scheduled visit with their urologist to discuss their management options. We will request participants to complete one additional survey after this visit as described in the Table 2.

9.4 Observational Cohort Component

After the participant has had his urologist visit where he makes a decision about management, he has completed the active intervention component of this trial and will automatically roll-over into the CaPSURE™ observational cohort. He will be mailed surveys approximately annually, which may ask about his health and prostate cancer status, health resource utilization, lifestyle habits, overall and prostate cancer-specific anxiety and quality of life. He may choose to withdraw or not complete these surveys at any time. We will also request permission to conduct clinical follow-up indefinitely by reviewing this medical chart or obtaining information on his health and prostate cancer status from his healthcare provider.

10 EVALUATIONS BY VISIT

10.1 Contact 1 Screening and Recruitment

Onsite research coordinator will screen for potential eligible participants in their electronic medical record (EMR) ~two weeks in advance of the scheduled consultation visit with the urologist. This includes approaching patients who are low-risk and have an upcoming appointment at the practice for initial treatment decision consultation with the urologist. This will be done by phone by the onsite CRC or in person during a clinic visit. The onsite CRC will discuss explain the study and if the patient agrees to consider participation they will notify UCSF data coordinating center to send a baseline study packet by traceable FedEx that includes informed consent, HIPAA and T_1 surveys (see Table 2. Summary of Patient-reported Outcome Measures (PROMs) and Time Points).

10.2 Contact 2.1 Obtaining Informed Consent

Includes: enrolling them; administering all baseline/pre-intervention surveys (e.g. SF-12, EPIC, demographics, brief lifestyle questions (e.g., smoking, physical activity), as well as choice predisposition (CP), decision self-efficacy (DSE) and control preferences scale (CPS)) [30, 32, 34, 35]. Site study coordinator alerts patient they must allow time before and after their visit to fill out surveys (on arrival and before leaving the clinic). Note this contact could conceivably be by telephone and the surveys could be filled out by Internet. After all surveys are complete, the site staff will enter the patient into the UCSF system to trigger a call from a student coach.

1. After obtaining the informed consent in REDCaP the CRC will complete the following forms in REDCaP:
    a. **Subject Identifier Form** in REDCaP and Registration Form in CaPSURE. This action assigns the subject a unique research ID and assignment to study arm (usual care vs, intervention) in REDCaP and CaPSURE secure websites.
    b. Complete **Study Eligibility Form**.
    c. Complete **Study Biopsy Form**. Record medical history, including: PSA at diagnosis; tumor stage; prostate volume; biopsy diagnosis date with primary and secondary Gleason grade; and ECOG performance score [36].
2. REDCaP will provide participant with the access to patient reported-surveys and demographics data.
3. If the participant opts for the paper-mode, the CRC will provide the participant with a paper packet of patient surveys.

10.3 Contact 2.2 Scheduling Intervention (intervention arm only)

Includes: Student coach contacts patient (by email or phone) to send PDF and URL of decision aid, and schedule a phone call for 3 days prior to the medical visit (see Appendix A).

1. The CRC will complete the following forms in REDCaP:
    a. Appointment Information Form
    b. **Coach Contact Preferences Form**

10.4 Contact 3 DSI Coaching (intervention arm only)

Includes: Student coach calls patient and conducts intervention interview, reviewing each screen of the decision aid, typing up patient questions for the doctor, and referring the patient to help text about the decision aid content. Student coach then sends question list to site coordinator to be printed and given to physician at the time of the appointment.

The student health coach will upload to REDCaP before the visit with the urologist.

a. A summary **Question List** (QL) **form** includes the following areas of concern generated by the participant and coach using the PCa SCOPED model [37]:
    i. Situation – clarifying facts about my condition
    ii. Choices (treatment) – Which options are available
    iii. Objectives – Clarifying my goals and priorities
    iv. People – Clarifying roles and responsibilities
    v. Evaluation – Clarifying how my choices affect my objectives
    vi. Decisions – Clarifying which choice is best and next steps
b. Complete and upload the **Prostate Cancer SCOPED model form**

10.5 Contact 4 Immediately Upon Arrival at Clinic for Urologist Consultation Visit

Includes: Immediately upon arrival, patient should fill out Time 2 surveys – e.g. on tablet or at a kiosk or on paper. These will include Decision Quality Instrument [38], Max PC [39, 40], DSE [35], Control Preferences Scale [34], Choice Predisposition [35], and Reclassification Risk Understanding. Clinic staff or site study coordinator should print question list and give copies to the patient/family and attending physician for use during the medical visit.

1. Print the QL and PCa SCOPED forms for review by the urologist.

10.6 Contact 5 Immediately After Clinic for Urologist Consultation Visit

Clinic staff or site study coordinator must ensure that patient should fill out Time 2 surveys – e.g. on tablet or at a kiosk or on paper:

1. These will include Decision Quality Instrument [38], Max PC [39, 40], Choice Predisposition [35], and Reclassification Risk Understanding.
2. Site coordinator also must ensure that physician fills out MD satisfaction survey.

The Schedule of Events table explains the procedures and role based responsibilities for the onsite CRC and the UCSF data coordinating research staff.

10.7 Contact 6 Post-visit Telephone Contact

At the study team's discretion, we may call patients to conduct a qualitative debrief of the intervention and medical visit. We will do this at the start of each period to ensure that we are surfacing qualitatively any unexpected issues with study structure or procedures. We will conduct these debrief calls until we are confident that study-related issues have been resolved.

10.8 Contact 7 Before Treatment Begins

The decision support intervention is complete at 10.7 and participant will be rolled into the CaPSURE disease specific registry for prospective follow up of management, recurrence status and survival status.

1. After consultation visit with the treating MD but before treatment is initiated the participant will be asked to complete the following surveys:
    a. Diet and Lifestyle survey [33, 41]
    b. Total Illness Burden Index – Cancer of the Prostate (TIBI-CaP) [42]
    c. Service Satisfaction with Cancer Care (SSCa) [43]

11 ADVERSE EXPERIENCE REPORTING AND DOCUMENTATION

11.1 Adverse Events

This is a behavioral medicine trial with no clinical investigations.

12 DISCONTINUATION AND REPLACEMENT OF SUBJECTS

12.1 Early Discontinuation of Study

A subject may be discontinued from study treatment at any time if the subject, the investigator, or the Sponsor feels that it is not in the subject's best interest to continue. The following is a list of possible reasons for study treatment discontinuation:

- Subject withdrawal of consent (or assent)
- Subject is not compliant with study procedures (i.e., does not complete coaching session before consultation visit with the treating urologist and therefore no decision aid is completed).
- Lost to follow-up
- Sponsor request for early termination of study

All subjects who discontinue study treatment will be encouraged to complete all remaining scheduled visits and procedures.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents.

12.3 Withdrawal of Subjects from the Study

A subject may be withdrawn from the study at any time if the subject, the investigator, or the Sponsor feels that it is not in the subject's best interest to continue.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice.

Reasonable attempts will be made by the investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents. As noted above, subjects who discontinue study treatment early (i.e., they withdraw prior to Contact 5) will not be administered further study surveys. Participants who withdraw before Contact 4 will be encouraged to attend their scheduled medical visit (see section 10.5).

12.4 Replacement of Subjects

Subjects who withdraw from the study will not be replaced. We will conduct our analyses on an intent-to-treat basis and will rely on multiple methods (including censoring and imputation) to examine the sensitivity of our findings to missing data.

13 PROTOCOL VIOLATIONS

A protocol violation occurs when the subject, investigator, or Sponsor fails to adhere to significant protocol requirements affecting the inclusion, exclusion, subject privacy, and primary endpoint criteria. Protocol violations for this study include, but are not limited to, the following:

Failure to meet inclusion/exclusion criteria

Failure to withdraw participant from the intervention arm in a timely fashion when the participant requests voluntary withdrawal from the study.

Failure to comply with Good Clinical Practice (GCP) guidelines will also result in a protocol violation. The Sponsor will determine if a protocol violation will result in withdrawal of a subject.

When a protocol violation occurs, it will be discussed with the investigator and a Protocol Violation Form detailing the violation will be generated. This form will be signed by a Sponsor representative and the Investigator. A copy of the form will be filed in the site's regulatory binder and in the Sponsor's files.

14 DATA SAFETY MONITORING

Not applicable

15 STATISTICAL METHODS AND CONSIDERATIONS

Prior to the analysis of the final study data, a Statistical Analysis Plan (SAP) will be written describing all analyses that will be performed. The SAP will contain any modifications to the analysis plan described below.

15.1 Data Sets Analyzed

All eligible patients who are enrolled in the study will be included in the analysis.

15.2 Demographic and Baseline Characteristics

We will compare several demographic and baseline characteristics between subjects in the intervention and control groups at baseline. These include age, race, and clinical characteristics such as prostate specific antigen.

15.3 Analysis of Primary Endpoint

The primary statistical analysis will compare the probability of correctly responding to the two knowledge survey questions between subjects randomized to the intervention and control sites using logistic regression. The primary predictor of the logistic model will be the binary, site-specific intervention indicator. We will also include site, time and intervention group by time interaction terms. Since randomization by site may not balance, all relevant sociodemographic and clinical characteristics of the subjects may be included in the models; we will also include other factors that are not balanced between the groups. We will assess balance by comparing means of continuous characteristics using two sample t-tests and by comparing categorical characteristics using chi-square tests.

15.4 Analysis of Secondary Endpoints

The statistical analyses of the secondary endpoints will follow the same regression model approach as with the primary endpoint using a regression model appropriate for the outcome type. For example, we will use linear regression to analyze continuous endpoints such as MaxPC and polytomous logistic regression for categorical endpoints of decision support intervention (DSI) coaching versus usual care.

15.5 Interim Analysis

Not Applicable

15.6 Sample Size and Randomization

We will base sample size calculations on the comparison of the probability of correctly responding to the two survey questions between subjects at the intervention versus control sites with a design effect correction to accommodate the potential correlation of responses within sites [44]. That is, we will inflate the sample sizes resulting from standard sample calculations for the comparison of two proportions by the design effect, 1 + (n-1)*rho, where n is the sample size per site and rho is the intraclass correlation coefficient of the primary binary response[45]. We are interested in detecting an alternative where the probability of the primary response increases from 0.5 in the control sites to 0.75 in the intervention sites. Standard power calculations for chi-square tests to compare two proportions [45] show that tests based on a total sample size of 116 would have power 0.8 to detect the alternative of interest. Since our study design involves 8 clusters (four sites measured in two time periods), our initial design would include 15 subjects measured in each site at each time. Preliminary data indicate that the intraclass correlation coefficient of the primary response is quite low within sites; the estimated intraclass correlation coefficient was less than 0.01. This estimate produces a design effect of 1.14 and we inflate the required number of subjects per site and time to 17 for a total sample size of 136.

Randomization: At baseline, this study will randomize two sites to the intervention and two sites to serve as controls. There are six possible assignments of two intervention and control sites in our study and we will generate a uniform (0,1) random number to select one of them.

16 DATA COLLECTION, RETENTION AND MONITORING

16.1 Data Collection Instruments

The Investigator will prepare and maintain adequate and accurate source documents designed to record all observations and other pertinent data for each subject treated with the study drug.

Study personnel at each site will enter data from source documents corresponding to a subject's visit into the protocol-specific electronic Case Report Form (eCRF) OR paper CRF when the information corresponding to that visit is available. Onsite CRCs will have access to a UCSF hosted REDCaP database (see https://redcap.ucsf.edu/index.php). The database will be partitioned by each site to maintain the confidentiality of site specific participants.

For eCRFs: If a correction is required for an eCRF, the time and date stamps track the person entering or updating eCRF data and creates an electronic audit trail. Paper-mode CRFs will be used only for PROMs which will be entered into the REDCaP database. *For paper CRFs:* If a correction is made on a CRF, the study staff member will line through the incorrect data, write in the correct data and initial and date the change.

The Investigator is responsible for all information collected on subjects enrolled in this study. All data collected during the course of this study must be reviewed and verified for completeness and accuracy by the Investigator. A copy of the CRF will remain at the Investigator's site at the completion of the study.

16.2 Data Management Procedures

The data will be entered into a validated database. The Data Management group will be responsible for data processing, in accordance with procedural documentation. Database lock will occur once quality assurance procedures have been completed.

All procedures for the handling and analysis of data will be conducted using good computing practices meeting FDA guidelines for the handling and analysis of data for clinical trials.

16.3 Data Quality Control and Reporting

After data have been entered into the study database, a system of computerized data validation checks will be implemented and applied to the database on a regular basis. *For EDC studies:* Queries are entered, tracked, and resolved through the EDC system directly. *For paper studies:* Query reports (Data Clarification Requests) pertaining to data omissions and discrepancies will be forwarded to the Investigators and study monitors for resolution. The study database will be updated in accordance with the resolved queries. All changes to the study database will be documented.

16.4 Archival of Data

The database is safeguarded against unauthorized access by established security procedures; appropriate backup copies of the database and related software files will be maintained. Databases are backed up by the database administrator in conjunction with any updates or changes to the database.

At critical junctures of the protocol (e.g., production of interim reports and final reports), data for analysis is locked and cleaned per established procedures.

All ICF, HIPAA, and/or paper-mode PROMs will be digitally archived and attached to the relevant section in the REDCaP database.

16.5 Availability and Retention of Investigational Records

The Investigator must make study data accessible to the monitor, other authorized representatives of the Sponsor (or designee), IRB/IEC, and Regulatory Agency (e.g., FDA) inspectors upon request. A file for each subject must be maintained that includes the signed Informed Consent, HIPAA Authorization and Assent Form and copies of all source documentation related to that subject. The Investigator must ensure the reliability and availability of source documents from which the information on the CRF was derived.

All study documents (patient files, signed informed consent forms, copies of CRFs, Study File Notebook, etc.) must be kept secured for a period of two years following marketing of the investigational product or for two years after centers have been notified that the IND has been discontinued. There may be other circumstances for which the Sponsor is required to maintain study records and, therefore, the Sponsor should be contacted prior to removing study records for any reason.

16.6 Monitoring

Not applicable

16.7 Subject Confidentiality

No raw / identifiable data from the study will be shared with the study sponsor, the Department of Defense U.S. Army Medical Research Transformative Impact Award group.

17 ADMINISTRATIVE, ETHICAL, REGULATORY CONSIDERATIONS

The study will be conducted according to the Declaration of Helsinki, Protection of Human Volunteers (21 CFR 50), Institutional Review Boards (21 CFR 56), and Obligations of Clinical Investigators (21 CFR 312).

To maintain confidentiality, all laboratory specimens, evaluation forms, reports and other records will be identified by a coded number and initials only. All study records will be kept in a locked file cabinet and code sheets linking a patient's name to a patient identification number will be stored separately in another locked file cabinet. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by the FDA. The Investigator must also comply with all applicable privacy regulations (e.g., Health Insurance Portability and Accountability Act of 1996, EU Data Protection Directive 95/46/EC).

17.1 Protocol Amendments

Protocol amendments cannot be implemented without prior written IRB/IEC approval except as necessary to eliminate immediate safety hazards to patients. A protocol amendment intended to eliminate an apparent immediate hazard to patients may be implemented immediately, provided the IRBs are notified within five working days.

17.2 Institutional Review Boards and Independent Ethics Committees

The protocol and consent form will be reviewed and approved by the IRB/IEC of each participating center prior to study initiation. Serious adverse experiences regardless of causality will be reported to the IRB/IEC in accordance with the standard operating procedures and policies of the IRB/IEC, and the Investigator will keep the IRB/IEC informed as to the progress of the study. The Investigator will obtain assurance of IRB/IEC compliance with regulations.

Any documents that the IRB/IEC may need to fulfill its responsibilities (such as protocol, protocol amendments, Investigator's Brochure, consent forms, information concerning patient recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB/IEC. The IRB/IECs written unconditional approval of the study protocol and the informed consent form will be in the possession of the Investigator before the study is initiated. The IRB/IECs unconditional approval statement will be transmitted by the Investigator to the Sponsor or designee prior to the shipment of study supplies to the site. This approval must refer to the study by exact protocol title and number and should identify the documents reviewed and the date of review.

Protocol and/or informed consent modifications or changes may not be initiated without prior written IRB/IEC approval except when necessary to eliminate immediate hazards to the patients or when the change(s) involves only logistical or administrative aspects of the study. Such modifications will be submitted to the IRB/IEC and written verification that the modification was submitted and subsequently approved should be obtained.

The IRB/IEC must be informed of revisions to other documents originally submitted for review; serious and/or unexpected adverse experiences occurring during the study in accordance with the standard operating procedures and policies of the IRB; new information that may affect adversely the safety of the patients of the conduct of the study; an annual update and/or request for re-approval; and when the study has been completed.

17.3 Informed Consent Form

Informed consent will be obtained in accordance with the Declaration of Helsinki, ICH GCP, US Code of Federal Regulations for Protection of Human Subjects (21 CFR 50.25[a,b], CFR 50.27, and CFR Part 56, Subpart A), the Health Insurance Portability and Accountability Act (HIPAA, if applicable), and local regulations.

The Investigator will prepare the informed consent form, assent and HIPAA authorization and provide the documents to the Sponsor or designee for approval prior to submission to the IRB/IEC. The consent form generated by the Investigator must be acceptable to the Sponsor and be approved by the IRB/IEC. The written consent document will embody the elements of informed consent as described in the International Conference on Harmonisation and will also comply with local regulations. The Investigator will send an IRB/IEC-approved copy of the Informed Consent Form to the Sponsor (or designee) for the study file.

A properly executed, written, informed consent will be obtained from each subject prior to entering the subject into the trial. Information should be given in both oral and written form and subjects (or their legal representatives) must be given ample opportunity to inquire about details of the study. If appropriate and required by the local IRB/IEC, assent from the subject will also be obtained. If a subject is unable to sign the informed consent form (ICF) and the HIPAA authorization, a legal representative may sign for the subject. A copy of the signed consent form

(and assent) will be given to the subject or legal representative of the subject and the original will be maintained with the subject's records.

17.4 Publications

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996.

17.5 Investigator Responsibilities

By signing the Agreement of Investigator form, the Investigator agrees to:

1. Conduct the study in accordance with the protocol and only make changes after notifying the Sponsor (or designee), except when to protect the safety, rights or welfare of subjects.
2. Personally conduct or supervise the study (or investigation).
3. Ensure that the requirements relating to obtaining informed consent and IRB review and approval meet federal guidelines, as stated in § 21 CFR, parts 50 and 56.
4. Report to the Sponsor or designee any AEs that occur in the course of the study, in accordance with §21 CFR 312.64.
5. Ensure that all associates, colleagues and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.
6. Maintain adequate and accurate records in accordance with §21 CFR 312.62 and to make those records available for inspection with the Sponsor (or designee).
7. Ensure that an IRB that complies with the requirements of §21 CFR part 56 will be responsible for initial and continuing review and approval of the clinical study.
8. Promptly report to the IRB and the Sponsor (or designee) all changes in the research activity and all unanticipated problems involving risks to subjects or others (to include amendments and IND safety reports).
9. Seek IRB approval before any changes are made in the research study, except when necessary to eliminate hazards to the patients/subjects.
10. Comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements listed in § 21 CFR part 312.

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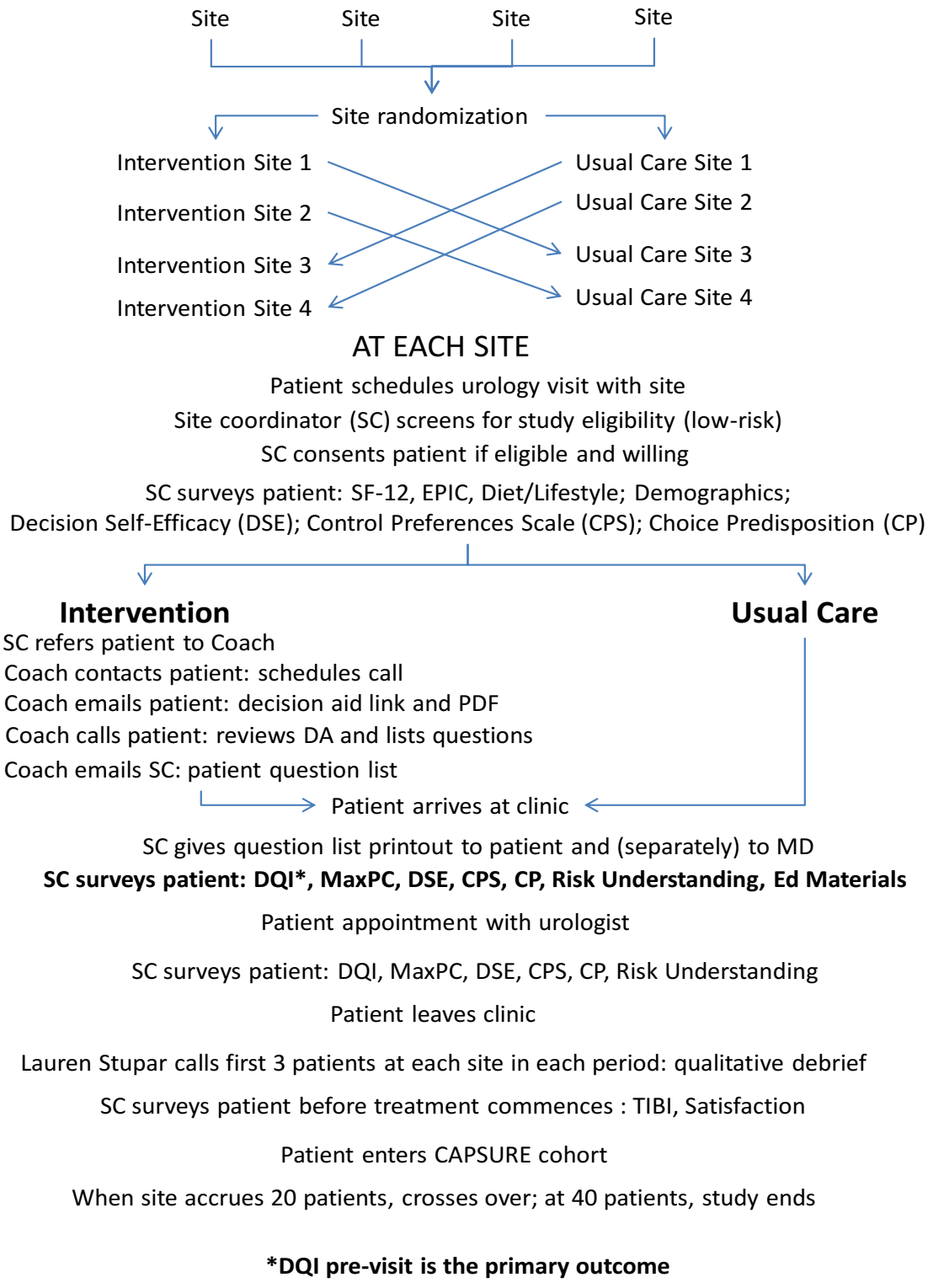
19 FIGURES AND TABLES

19.1 Figure 1. Decision Support Intervention Study Schematic



19.2 Table 1. DSI Trial - Schedule of Events[1]

Intervention Arm	Usual Care Arm
Screen and Recruit 1. Post "Diagnosis Confirmation" phone call by the physician or the clinical nurse, the onsite CRC will contact the patient about their eligibility and interest in participating in the decision support study. If they obtain verbal permission, will send them a packet of information with the Informed Consent (IC), HIPAA and T1 surveys via FedEx 2. Onsite CRC enters REDCaP CRFs: a. Subject Identifiers b. Eligibility for Study 3. Onsite CRC notifies UCSF data coordinating center to send FedEx package – this could be done by call or e-mail.	Screen and Recruit 1. Post "Diagnosis Confirmation" phone call by the physician or the clinical nurse, the onsite CRC will contact the patient about their eligibility and interest in participating in the decision support study and obtain verbal permission to send them a packet of information with the Informed Consent, HIPAA and T1 surveys via FedEx 2. Onsite CRC enters REDCaP CRFs: a. Subject Identifiers b. Eligibility for Study Onsite CRC notifies UCSF data coordinating center to send FedEx package – this could be done by call or e-mail.
Enters Decision Support Coaching Study	
T1: Obtain Informed Consent and HIPAA[2] Enter into REDCaP CRFs: 1. Study Biopsy Results 2. Appointment Information	T1: Obtain Informed Consent and HIPAA – Enter into REDCaP Enter into REDCaP CRFs: 1. Study Biopsy Results 2. Appointment Information
T1: Administer T1 surveys - paper or web-mode option Enter into REDCaP CRF:	T1: Administer T1 surveys – paper or web-mode option Enter into REDCaP CRF:

[1] Color grid for distribution of tasks associated with the study timed events:

Onsite Coordinator task
UCSF Data coordinating Center task

[2] If patient is recruited by phone by the onsite CRC, they will notify UCSF to send the paper ICF and HIPAA. The UCSF Data coordinating center will send paper regulatory documents to patient via FedEx. Patient signs and returns signed regulatory forms to UCSF via FedEx. UCSF CRC will scan ICF and HIPAA and attaches into REDCaP database. UCSF CRC will push e-mail to the onsite CRC to notify her/him that patient has consented. UCSF CRC will insure that both the site and the participant have a paper copy of the signed ICF and HIPAA. Upon receipt of a fully executed signed ICF and HIPAA form, the onsite CRC will enter information about the biopsy and the upcoming doctor appointment into REDCaP so the coach can begin the contact and coaching parts of the intervention.

Intervention Arm	Usual Care Arm
1. Consent and HIPAA Forms – UCSF to provide copies to site	1. Consent and HIPAA Forms – UCSF to provide copies to site
T2: Onsite CRC completes the following REDCaP CRFs: 1. Coach Contact Preferences This completes the onsite CRC referral to the coach	
Coach contacts patient and schedules coaching call	
Coach emails patient: decision aid (DA) link and PDF	
Coach calls patient: reviews DA and lists questions	
Coach emails CRC: patient question list	
Patient arrives at practice for consult visit with Urologist	
T3: CRC gives question list printout to patient (separately) and to MD	
T3: Patient completes T3 surveys before visit	T3: Patient completes T3 surveys before visit
Patient appointment with Urologist	
T4: Patient completes T4 surveys after visit	T4: Patient completes T4 surveys after visit
Patient leaves practice	
UCSF research staff call first 3 patients at each site for qualitative debrief	UCSF research staff call first 3 patients at each site for qualitative debrief
Before Treatment Commences	
T5: Patient completes T5 surveys	T5: Patient completes T5 surveys
Patient enters CaPSURE™ cohort	
Patient opts for Participation in the Diet & Lifestyle Sub-study of CaPSURE™	

19.3 Table 2. Summary Table of Patient-reported Outcome Surveys and Time Points

Instruments with Time Frame	# Items	Time (minutes)	Consent T1	Intervention T2	Pre-visit T3	Post-visit T4	Pre-treatment T5
Short Form 12 (SF-12)	12	10	X				
Expanded Prostate Cancer Index Composite (EPIC-26)	26	20	X				
Diet and Lifestyle	10	10	X				X
Patient Demographics (including weight, height, smoking)	6	5	X				
Demographics: Age at diagnosis (calculated from data entry by CRC)	1	1	X				
Control Preferences Scale (CPS)	1	2	X				
Decision Self-Efficacy (DSE)	1	2	X		X		
Choice Predisposition (CP)	2	3	X		X	X	
Access to patient education materials	6	3			X		
Access to Other Diagnostic Tests and External Interventions	6	5			X		
Decision Quality Instrument (DQI)	35	20			X	X	
Risk Reclassification Understanding	1	2			X	X	
Memorial Anxiety Scale for Prostate Cancer (Max PC)	4	5			X	X	
Service Satisfaction with Cancer Care	7	5					X
Total Illness Burden Index for Prostate Cancer – TIBI-CaP	27	10					X
Patient Debrief Telephone Interview (Based on the CIT)	*[3]	0-20					X*

[3] Qualitative Interview Debrief Interview Guide – See IRB application other study documents for interview guide. Applies only to DSI participant only and not to the usual care participant.

Instruments with Time Frame	# Items	Time (minutes)	Consent T1	Intervention T2	Pre-visit T3	Post-visit T4	Pre-treatment T5
Total Number of Items and Time to Complete Surveys	147	105	58|25		57|31	42|20	40|20-40

19.4 Table 3. Clinician-reported Outcome Measures and Time Points

Instruments with Time Frame for Administration	# Items	Time (minutes)	Consent T1	Intervention T2	Pre-visit T3	Post-visit T4	Pre-treatment T5
Physician Satisfaction	2	5				X	

19.5 Table 4. Interventionist-reported Outcome Measures and Time Points

Instruments with Time Frame for Administration[4]	# Items	Time (minutes)	Consent T1	Intervention T2	Pre-visit T3	Post-visit T4	Pre-treatment T5
Coaching Call Degree of Completion (study-specific; added to uTRAC)	2	2			X		

[4] Interventionist items are completed by the health coach.

20 APPENDICES

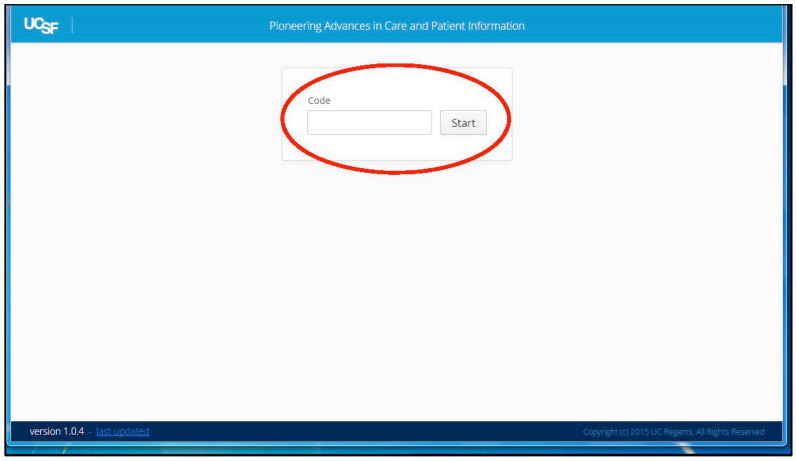
20.1 Appendix A. Coaching Intervention – Internet Access to DSI Tool

Appendix A. Coaching Intervention – Internet Access to DSI Tool

PATIENT INSTRUCTIONS FOR DECISION AID – Pioneering Advances in Care and Education

This document summarizes how patients may log in to review educational materials as part of a study. The study asks that patients review the materials prior to a telephone call with a health coach.

Note to patients: If you are not able to log in, you may simply review the contents of the PDF document "Patient-Specific Contents of Decision Aid -Pioneering Advances in Care and Education" that was included in the same email as these instructions. You may note any comments or questions on a piece of paper. If at any time you need assistance, please contact the coach who emailed you this document.



Before your coaching session:

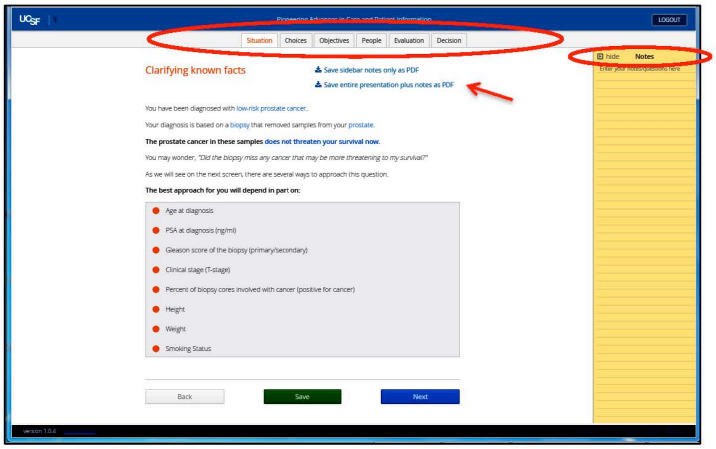
Go to your unique login page by following the link provided to you by the coach. It will look something like: menlikeme.org/#!/TIA012A000

Enter the six-letter Code (password) that the coach also provided for you.

Press on the Start button.

Patient Instructions for Decision Aid v20160601 Page A

Appendix A. Coaching Intervention – Internet Access to DSI Tool



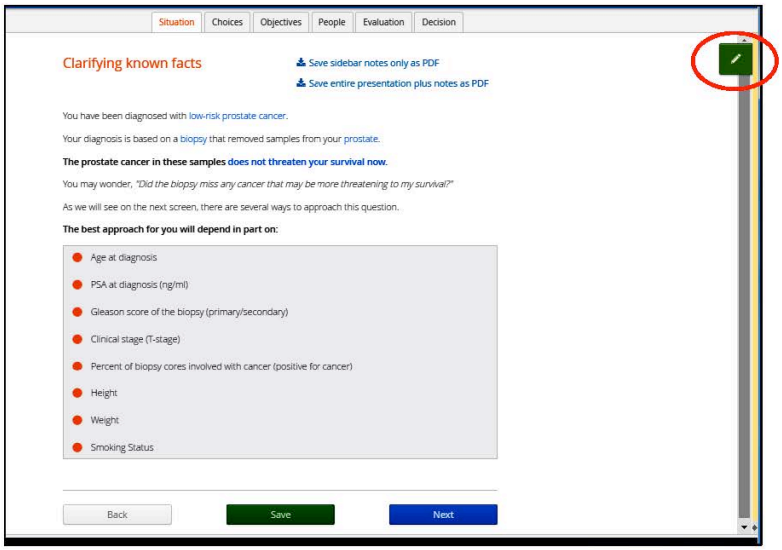
If all goes well, you should now be logged in. You can review the materials by navigating through the tabs from left to right. Click on a tab to see the information for that tab.

Please type any questions or notes you have in the section on the right side of each page. Each tab has its own place for questions and notes. The notes you type on one page, will only appear on that page. At any time, you can click on "Save sidebar notes only as PDF", near the top right of the screen to generate a complete list of all your questions and notes. The PDF file will be called "patient-decision-aid-notes". It will be saved to your computer's usual download location. You may also save a printable copy of the entire presentation, including your notes, by clicking "Save entire presentation plus notes as a PDF". The PDF file will be called "patient-decision-aid-presentation-and-notes".

Click the green "Save" button at the bottom of the screen before moving on to save your questions and notes. Click on the word "hide" if you would like to hide the Notes section. If you would like to view the Notes again, click on the green square that appears when the notes are hidden.

If you need assisstance, please contact the coach.

Appendix A. Coaching Intervention – Internet Access to DSI Tool



The first tab is called Situation. Please review the summary of your Situation and type any questions or notes in the Notes section on the right side of the screen. If the Notes section is hidden, you can open it up by clicking on the green square near the top right of the screen (circled in red above).

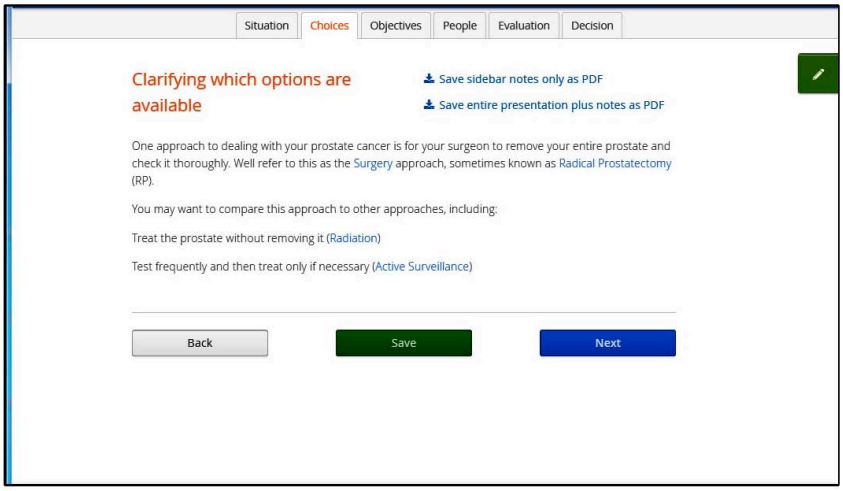
You may follow the links (indicated by blue text) for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

If you need assistance, please contact the coach.

Patient Instructions for Decision Aid v20160601 Page C

Appendix A. Coaching Intervention – Internet Access to DSI Tool



The second tab is called Choices. Please review the summary of your Choices and type any questions or notes in the Notes section on the right side of the screen.

You may follow the links for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

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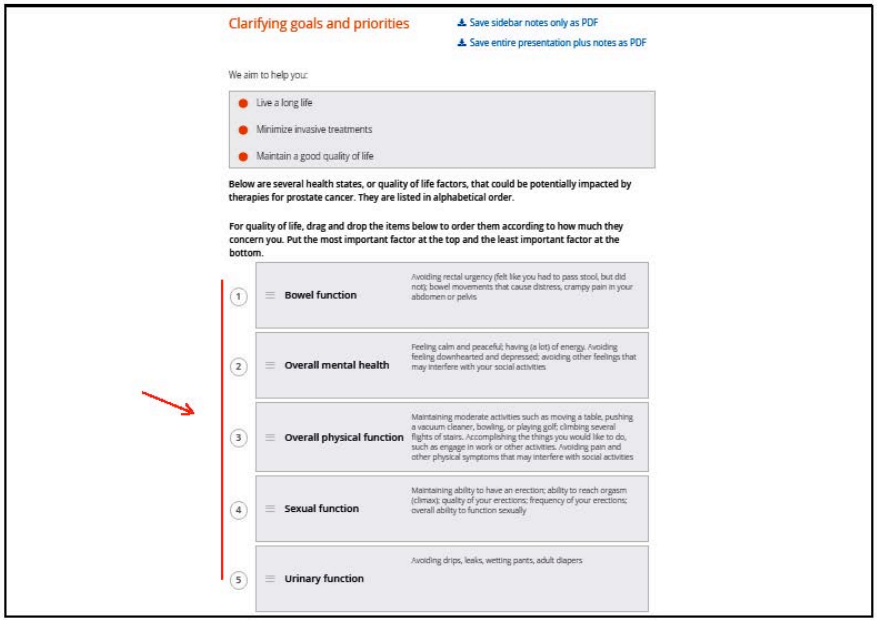
Appendix A. Coaching Intervention – Internet Access to DSI Tool



The third tab is called Objectives. Please review the Objectives section and rearrange the quality of life items into an order that reflects how much they concern you, with the area of highest concern at the top. If none of them stand out to you, you may leave them in the default order. They are listed in alphabetical order by default.

Also, please type any questions or notes in the Notes section on the right side of the screen. Click the green "Save" button before moving on to save your questions and notes.

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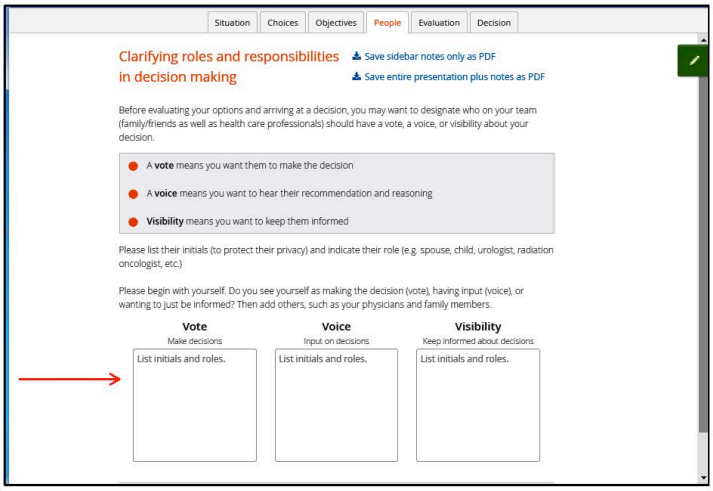
Patient Instructions for Decision Aid v20160601 Page E

Appendix A. Coaching Intervention – Internet Access to DSI Tool

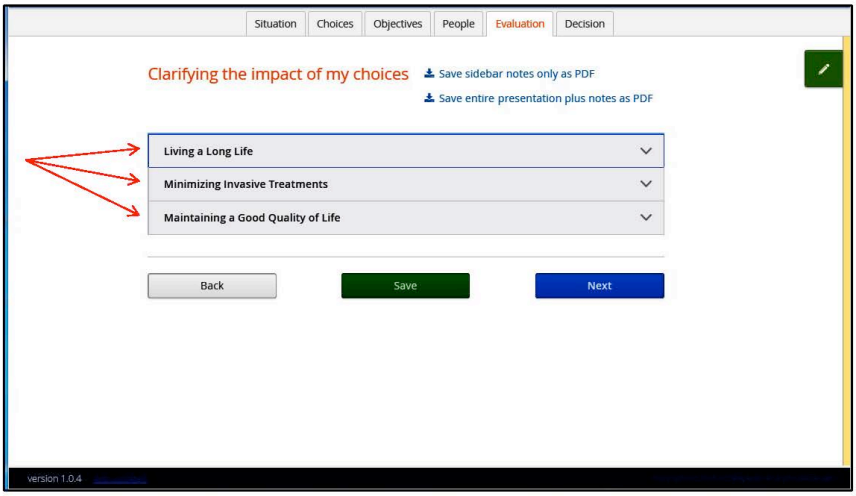


The fourth tab is called People. Please review the People section. In the boxes that indicate different level of involvement, list the initials (to protect their privacy) and indicate the role (e.g. – spouse, child, urologist, etc) of anyone who should be involved in treatment decision-making.

Also, please type any questions or notes in the Notes section on the right side of the screen. Click the green "Save" button before moving on to save your questions and notes.

If you need assistance, please contact the coach.

Appendix A. Coaching Intervention – Internet Access to DSI Tool



The fifth tab is called Evaluation. This tab has three expandable sections. If you click on the bar for each one, it will expand to show you more information underneath it. Please type any questions or notes about the Evaluation section in the Notes on the right side of the screen.

You may follow the links for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

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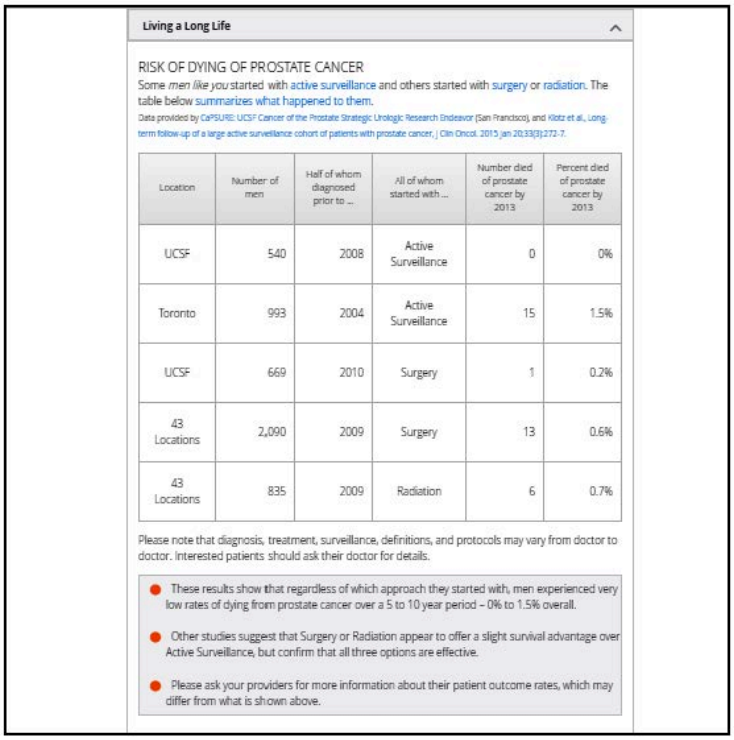
Appendix A. Coaching Intervention – Internet Access to DSI Tool



Living a Long Life

RISK OF DYING OF PROSTATE CANCER

Some *men like you* started with active surveillance and others started with surgery or radiation. The table below summarizes what happened to them.

Data provided by CaPSURE: UCSF Cancer of the Prostate Strategic Urologic Research Endeavor (San Francisco), and Klotz et al., Long-term follow-up of a large active surveillance cohort of patients with prostate cancer, J Clin Oncol. 2015 Jan 20;33(3):272-7.

Location	Number of men	Half of whom diagnosed prior to ...	All of whom started with ...	Number died of prostate cancer by 2013	Percent died of prostate cancer by 2013
UCSF	540	2008	Active Surveillance	0	0%
Toronto	993	2004	Active Surveillance	15	1.5%
UCSF	669	2010	Surgery	1	0.2%
43 Locations	2,090	2009	Surgery	13	0.6%
43 Locations	835	2009	Radiation	6	0.7%

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details.

- These results show that regardless of which approach they started with, men experienced very low rates of dying from prostate cancer over a 5 to 10 year period – 0% to 1.5% overall.
- Other studies suggest that Surgery or Radiation appear to offer a slight survival advantage over Active Surveillance, but confirm that all three options are effective.
- Please ask your providers for more information about their patient outcome rates, which may differ from what is shown above.

Please review the section called "Living a Long Life", and type any questions or notes in the section on the right side of the page.

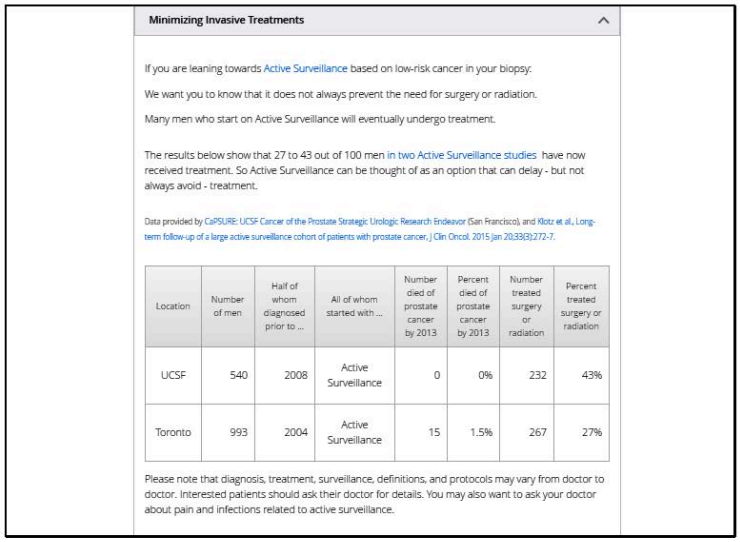
You may follow the links for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

If you need assistance, please contact the coach.

Patient Instructions for Decision Aid v20160601 Page H

Appendix A. Coaching Intervention – Internet Access to DSI Tool



Minimizing Invasive Treatments

If you are leaning towards Active Surveillance based on low-risk cancer in your biopsy:

We want you to know that it does not always prevent the need for surgery or radiation.

Many men who start on Active Surveillance will eventually undergo treatment.

The results below show that 27 to 43 out of 100 men in two Active Surveillance studies have now received treatment. So Active Surveillance can be thought of as an option that can delay - but not always avoid - treatment.

Data provided by CaPSURE: UCSF Cancer of the Prostate Strategic Urologic Research Endeavor (San Francisco), and Klotz et al., Long-term follow-up of a large active surveillance cohort of patients with prostate cancer, J Clin Oncol. 2015 Jan 20;33(3):272-7.

Location	Number of men	Half of whom diagnosed prior to ...	All of whom started with ...	Number died of prostate cancer by 2013	Percent died of prostate cancer by 2013	Number treated surgery or radiation	Percent treated surgery or radiation
UCSF	540	2008	Active Surveillance	0	0%	232	43%
Toronto	993	2004	Active Surveillance	15	1.5%	267	27%

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details. You may also want to ask your doctor about pain and infections related to active surveillance.

Please review the section called "Minimizing Invasive Treatments" and type any questions or notes in the section on the right side of the page.

You may follow the links for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

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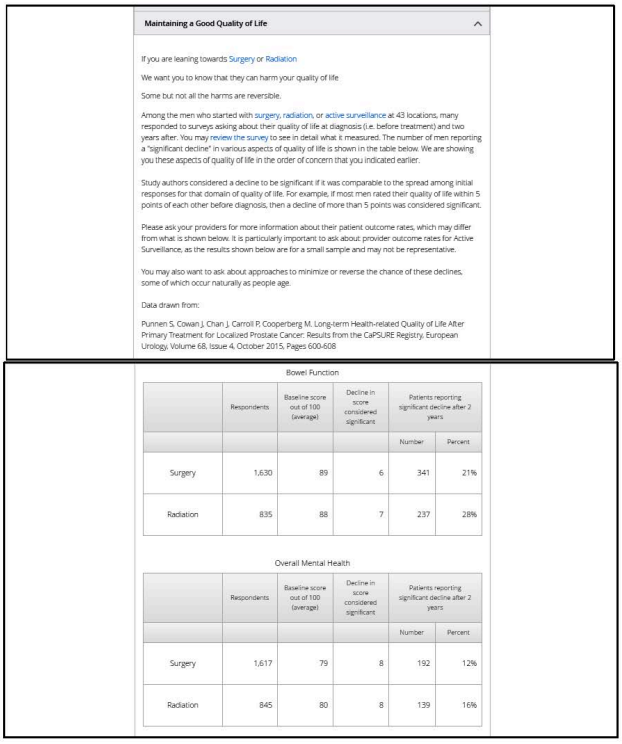
Appendix A. Coaching Intervention – Internet Access to DSI Tool



Maintaining a Good Quality of Life

If you are leaning towards Surgery or Radiation

We want you to know that they can harm your quality of life

Some but not all the harms are reversible.

Among the men who started with surgery, radiation, or active surveillance at 43 locations, many responded to surveys asking about their quality of life at diagnosis (i.e. before treatment) and two years after. You may review the survey to see in detail what it measured. The number of men reporting a "significant decline" in various aspects of quality of life is shown in the table below. We are showing you these aspects of quality of life in the order of concern that you indicated earlier.

Study authors considered a decline to be significant if it was comparable to the spread among initial responses for that domain of quality of life. For example, if most men rated their quality of life within 5 points of each other before diagnosis, then a decline of more than 5 points was considered significant.

Please ask your providers for more information about their patient outcome rates, which may differ from what is shown below. It is particularly important to ask about provider outcome rates for Active Surveillance, as the results shown below are for a small sample and may not be representative.

You may also want to ask about approaches to minimize or reverse the chance of these declines, some of which occur naturally as people age.

Data drawn from:

Punnen S, Cowan J, Chan J, Carroll P, Cooperberg M. Long-term Health-related Quality of Life After Primary Treatment for Localized Prostate Cancer: Results from the CaPSURE Registry. European Urology, Volume 68, Issue 4, October 2015, Pages 600-608

Bowel Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,630	89	6	341	21%
Radiation	835	88	7	237	28%

Overall Mental Health

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,617	79	8	192	12%
Radiation	845	80	8	139	16%

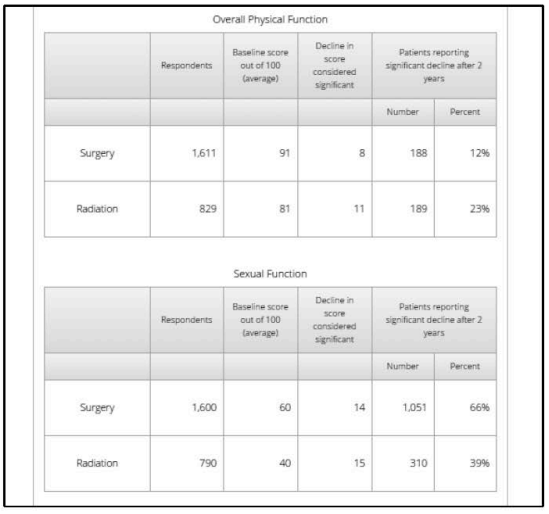
Please review the section called "Maintaining a Good Quality of Life", and type any questions or notes in the text box at the bottom of the page.

You may follow the links for additional help text. Be aware this will open a new browser window and you may need to return to the current window to continue the presentation.

Click the green "Save" button before moving on to save your questions and notes.

If you need assistance, please contact the coach.

Appendix A. Coaching Intervention – Internet Access to DSI Tool

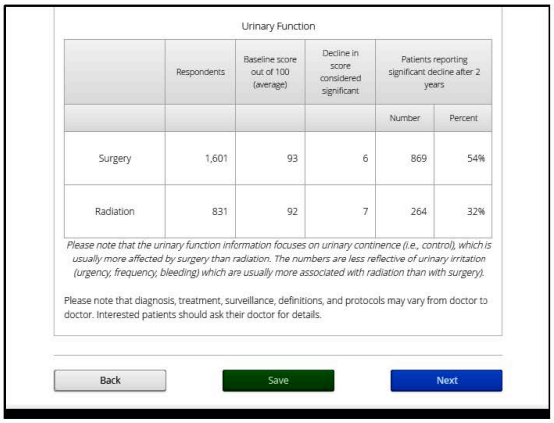


Overall Physical Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,611	91	8	188	12%
Radiation	829	81	11	189	23%

Sexual Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,600	60	14	1,051	66%
Radiation	790	40	15	310	39%



Urinary Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,601	93	6	869	54%
Radiation	831	92	7	264	32%

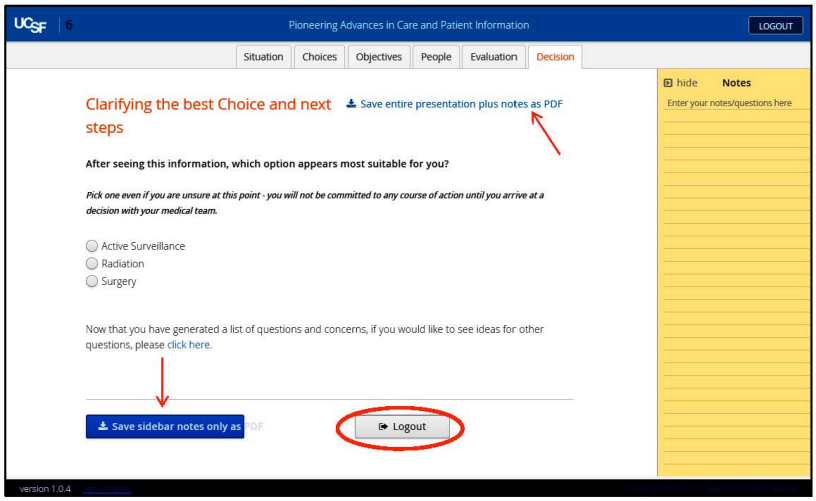
Please note that the urinary function information focuses on urinary continence (i.e., control), which is usually more affected by surgery than radiation. The numbers are less reflective of urinary irritation (urgency, frequency, bleeding) which are usually more associated with radiation than with surgery).

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details.

Back Save Next

[Continuation of "Maintaining a Good Quality of Life"]

Appendix A. Coaching Intervention – Internet Access to DSI Tool



The last tab is called Decision. Please review this Decision section and indicate which way you are leaning.

You may return to a previous section at any time by clicking on the tab for that section. If you need assistance, please contact the coach.

You may download a list of your questions and notes by clicking the blue button that says "Save sidebar notes only as PDF". This will download a PDF document named "patient-decision-aid-notes". It will be saved to your computer's usual download location. You may save a printable copy of the entire presentation, including your notes, by clicking "Save entire presentation plus notes as a PDF" near the top of the screen. The PDF file will be called "patient-decision-aid-presentation-and-notes"

Please click on the "Logout" button when you are all through.

20.2 Appendix B. Coaching Intervention – No Internet Access to DSI Tool [5]

[5] Appendices as referenced in section 10.3 of this protocol. These are examples of the Decision Aid that is sent to the participant by e-mail. If the participant does not have Internet access, a paper version is sent to the participant via paper-mode mail for them to follow along with during the coaching call, as illustrated in Appendix B.

Patient-Specific Contents of Decision Aid - Pioneering Advances in Care and Education

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1 - Situation

Clarifying known facts

You have been diagnosed with low-risk prostate cancer.

Your diagnosis is based on a biopsy that removed samples from your prostate.

The prostate cancer in these samples does not threaten your survival now.

You may wonder, "Did the biopsy miss any cancer that may be more threatening to my survival?"

As we will see on the next screen, there are several ways to approach this question.

Your clinical information at the time of diagnosis:

- Age at diagnosis: 40
- PSA at diagnosis: 4
- Gleason score of the diagnostic biopsy (primary + secondary): 3 + 3
- Clinical stage (T-stage): T1C
- Biopsy cores involved with cancer (positive for cancer): 2
- Total Biopsy Cores Taken: 12
- Prostate Volume at Diagnosis: 40
- Your height: 5' 10"
- Your weight at the time of diagnosis: 195 lbs 5 oz
- Your race (primary): Caucasian
- Your race (secondary, if any listed): Caucasian

Notes

2 - Choices

Clarifying which options are available

One approach to dealing with your prostate cancer is for your surgeon to remove your entire prostate and check it thoroughly. Well refer to this as the Surgery approach, sometimes known as Radical Prostatectomy (RP).

You may want to compare this approach to other approaches, including:

Treat the prostate without removing it (Radiation)

Test frequently and then treat only if necessary (Active Surveillance)

Notes

3 - Objectives

Clarifying goals and priorities

We aim to help you:

- Live a long life
- Minimize invasive treatments
- Understand the likelihood of needing treatment if you start with Active Surveillance
- Maintain a good quality of life

Below are several health states, or quality of life factors, that could be potentially impacted by therapies for prostate cancer. They are listed in alphabetical order.

For quality of life, drag and drop the items below to order them according to how much they concern you. Put the most important factor at the top and the least important factor at the bottom.

1. Bowel function - avoiding rectal urgency (felt like you had to pass stool, but did not); bowel movements that cause distress, crampy pain in your abdomen or pelvis
2. Overall mental health - feeling calm and peaceful; having (a lot) of energy. Avoiding feeling downhearted and depressed; avoiding other feelings that may interfere with your social activities
3. Overall physical function - maintaining moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf; climbing several flights of stairs. Accomplishing the things you would like to do, such as engage in work or other activities. Avoiding pain and other physical symptoms that may interfere with social activities
4. Sexual function - maintaining ability to have an erection; ability to reach orgasm (climax); quality of your erections; frequency of your erections; overall ability to function sexually
5. Urinary function - avoiding drips, leaks, wetting pants, adult diapers

Notes

4 - People

Clarifying roles and responsibilities in decision making

Before evaluating your options and arriving at a decision, you may want to designate who on your team (family/friends as well as health care professionals) should have a vote, a voice, or visibility about your decision.

- A vote means you want them to make the decision
- A voice means you want to hear their recommendation and reasoning
- Visibility means you want to keep them informed

Please list their initials (to protect their privacy) and indicate their role (e.g. spouse, child, urologist, radiation oncologist, etc.)
Please begin with yourself. Do you see yourself as making the decision (vote), having input (voice), or wanting to just be informed? Then add others, such as your physicians and family members.

Vote Make decisions	Voice Input on decisions	Visibility Keep informed about decisions

Notes

5 - Evaluation

Clarifying the impact of my choices

5a - Living a Long Life

RISK OF DYING OF PROSTATE CANCER

Some *men like you* started with active surveillance and others started with surgery or radiation. The table below summarizes what happened to them.

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Location	Number of men	Half of whom diagnosed prior to ...	All of whom started with ...	Number died of prostate cancer by 2013	Percent died of prostate cancer by 2013
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43 Locations	835	2009	Radiation	6	0.7%

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details.

- These results show that regardless of which approach they started with, men experienced very low rates of dying from prostate cancer over a 5 to 10 year period – 0% to 1.5% overall.
- Other studies suggest that Surgery or Radiation appear to offer a slight survival advantage over Active Surveillance, but confirm that all three options are effective.
- Please ask your providers for more information about their patient outcome rates, which may differ from what is shown above.

5b - Minimizing Invasive Treatments

If you are leaning towards Active Surveillance based on low-risk cancer in your biopsy:

We want you to know that it does not always prevent the need for surgery or radiation.

Many men who start on Active Surveillance will eventually undergo treatment.

The results below show that 27 to 43 out of 100 men in two Active Surveillance studies have now received treatment. So Active Surveillance can be thought of as an option that can delay - but not always avoid - treatment.

Data provided by CaPSURE: UCSF Cancer of the Prostate Strategic Urologic Research Endeavor (San Francisco), and Klotz et al., Long-term follow-up of a large active surveillance cohort of patients with prostate cancer, J Clin Oncol. 2015 Jan 20;33(3):272-7.

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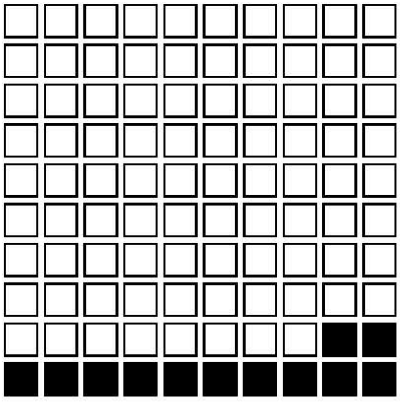
UCSF	540	2008	Active Surveillance	0	0%	232	43%
Toronto	993	2004	Active Surveillance	15	1.5%	267	27%

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details. You may also want to ask your doctor about pain and infections related to active surveillance.

5c - Understanding my likelihood of needing treatment if I start on Active Surveillance

You have previously reviewed the historical outcomes of men diagnosed with prostate cancer at UCSF, Toronto and the pooled results from 42 other sites. Each of these men, like you, had an initial biopsy (i.e., prostate tissue sample) that showed only low-risk cancer. In other words, your cancer appeared on biopsy to be small in volume, low-grade, early-stage, and with a PSA under 10. As you learned earlier, a biopsy is a sample of your prostate, and sometimes a biopsy of the prostate may under-estimate the full extent of the cancer. Only removing the entire prostate allows a full assessment. What if there was another way to estimate the extent of the cancer, without resorting to full removal of the prostate? Based on past outcomes from men with similar biopsy results as you, we can provide a statistical estimate that if you did have your prostate removed, your cancer would be found larger in volume, higher grade, or higher stage than expected based on the biopsy. It can be interpreted as an indicator of the chance that you may need treatment such as surgery or radiation at a later date if you start with active surveillance.

Men who start on active surveillance and later need treatment appear to have similar outcomes to those who start with treatment immediately.



88 out of 100
Predicted to have same volume, grade, and stage as on initial biopsy

12 out of 100
Predicted to have larger volume, higher grade, or higher stage and may need treatment at a later date if starting on active surveillance

5d - Maintaining a Good Quality of Life

If you are leaning towards Surgery or Radiation

We want you to know that they can harm your quality of life

Some but not all the harms are reversible.

Among the men who started with surgery, radiation, or active surveillance at 43 locations, many responded to surveys asking about their quality of life at diagnosis (i.e. before treatment) and two years after. You may review the survey to see in detail what it measured. The number of men reporting a "significant decline" in various aspects of quality of life is shown in the table below. We are showing you these aspects of quality of life in the order of concern that you indicated earlier.

Study authors considered a decline to be significant if it was comparable to the spread among initial responses for that domain of quality of life. For example, if most men rated their quality of life within 5 points of each other before diagnosis, then a decline of more than 5 points was considered significant.

Please ask your providers for more information about their patient outcome rates, which may differ from what is shown below. It is particularly important to ask about provider outcome rates for Active Surveillance, as the results shown below are for a small sample and may not be representative.

You may also want to ask about approaches to minimize or reverse the chance of these declines, some of which occur naturally as people age.

Data drawn from:

Punnen S, Cowan J, Chan J, Carroll P, Cooperberg M. Long-term Health-related Quality of Life After Primary Treatment for Localized Prostate Cancer: Results from the CaPSURE Registry, European Urology, Volume 68, Issue 4, October 2015, Pages 600-608

Bowel Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,630	89	6	341	21%
Radiation	835	88	7	237	28%

Overall Mental Health

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,617	79	8	192	12%
Radiation	845	80	8	139	16%

Overall Physical Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,611	91	8	188	12%
Radiation	829	81	11	189	23%

Sexual Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,600	60	14	1,051	66%
Radiation	790	40	15	310	39%

Urinary Function

	Respondents	Baseline score out of 100 (average)	Decline in score considered significant	Patients reporting significant decline after 2 years	
				Number	Percent
Surgery	1,601	93	6	869	54%
Radiation	831	92	7	264	32%

Please note that the urinary function information focuses on urinary continence (i.e., control), which is usually more affected by surgery than radiation. The numbers are less reflective of urinary irritation (urgency, frequency, bleeding) which are usually more associated with radiation than with surgery).

Please note that diagnosis, treatment, surveillance, definitions, and protocols may vary from doctor to doctor. Interested patients should ask their doctor for details.

Notes

6 - Decision

Clarifying the best Choice and next steps

After seeing this information, which option appears most suitable for you?

Pick one even if you are unsure at this point - you will not be committed to any course of action until you arrive at a decision with your medical team.

- ○ Active Surveillance
- ○ Radiation
- ○ Surgery

Now that you have generated a list of questions and concerns, if you would like to see ideas for other questions, please click here.

Notes

Appendix B. Coaching Intervention – No Internet Access to DSI Tool

We hope that the information obtained on this site will help you to be better able to participate with your health care providers in making informed decisions about your care. It is not a substitute for appropriate professional medical treatment or diagnosis. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read on this site. Except where explicitly stated otherwise, it is not intended as specific medical advice. Neither the Board of Regents nor its officers, agents or employees assume any legal liability or responsibility for the accuracy, completeness or usefulness of any information, apparatus, product or medical procedure described.

