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14. ABSTRACT Active surveillance (AS) is recommended for patients with low-risk prostate cancer to prevent overtreatment and maintain sexual and urinary functioning. However, approximately 90% of AS-eligible patients opt for curative treatment and 25-50% discontinue AS within 2-5 years without clinical evidence of cancer progression. Research is necessary to examine barriers and facilitators of informed decision-making and adherence to AS. We have conducted focus groups and personal interviews with patients (N = 33 patients) and care providers (N = 3) to examine barriers and facilitators of AS decisions and adherence. Factors that influence patients' decisions to opt for AS include trust in the physician's expertise, good intentions, and skills in detecting cancer progression in a timely manner, and avoidance of sexual and urinary deterioration associated with curative treatment. The partner's approval of AS played a significant role in the decision to opt for AS. Patient-provider communication and worries about cancer progression are major determinant factors of patients' AS decisions.					
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Introduction

To date, most newly diagnosed prostate cancers (PC) are low grade and low risk tumors that are confined to the prostate.¹ Active surveillance is a safe, evidence-based strategy to manage men with low-risk PC to prevent “overtreatment” and a decrease in quality of life associated with active treatment.² It involves close monitoring of the tumor with the intent to intervene with curative treatment (e.g., surgery) if disease progression is evident. In spite of the benefits of active surveillance, 90% of eligible patients opt for curative treatment.² Furthermore, 25% of patients discontinue the active surveillance protocol within the first 2 years, and 50% do so within 5 years without evidence of cancer progression.² Emotional distress related to the feeling of “doing nothing” while the cancer may be worsening, and changes in a patient’s treatment-related preferences and values are reported as the leading factors behind discontinuing active surveillance.³ Therefore, an intervention is urgently needed to address these issues. We propose to adopt for men on active surveillance an efficacious, symptom management intervention [Prostate Cancer Patient Education Program; PC^{PEP}], and assess its feasibility and acceptability.⁴ The PC^{PEP} was originally developed and tested for low-health literacy patients treated for early stage PC. It involves the provision of tailored modules and coaching using telehealth methods to reduce distress levels, enhance symptom management (e.g., urinary incontinence and impotence), and address unmet informational and supportive care needs during follow-up care. Prior studies found that the PC^{PEP} improved symptom management and self-efficacy beliefs among PC patients with low-health literacy.

As part of this adoption process (Phase 1), we will refine the *CPI-Prostate* modules and develop an Electronic Health Record (EHR)-based care plan for the patient and care provider. The *CPI-Prostate* program will consist of 4 modules: (1) enhanced education on active surveillance and follow-up care; (2) a tailored care plan for the patient and the provider delivered in a paper- and EHR-format; (3) a one-on-one, navigator-led session with the patient to discuss the care plan, and assess and address psychological distress and unmet needs; and (4) four navigator-led calls to continue the assessment of distress and needs, and to discuss updates to the care plan. We will conduct eight focus groups with 30 PC patients and 10 stakeholders to: (a) examine the barriers and facilitators of adherence to active surveillance, (b) explore patients’ unmet needs, and (c) inform the adoption process of the intervention modules, and the content and function of the EHR-based care plan. We will conduct usability testing to examine the utility of the penultimate version of the EHR-based care plan among 10 patients and stakeholders (50% PC patients) following NIH guidelines.

During the pilot feasibility and acceptability study (Phase 2), patients (N = 80) who are currently on active surveillance protocol will attend a 1-hour session with the navigator, followed by 4 navigator-led, follow-up calls. Outcome measures will be assessed at baseline (before the session), and at 1, 3, 6, and 12 months thereafter. The primary outcome will be the feasibility and acceptability of the intervention and adherence to active surveillance. Secondary outcomes are psychological distress, unmet needs, decisional regret, uncertainty, fear of cancer progression, quality of life, and satisfaction with care and communication. We hypothesize that the *CPI-Prostate* will be highly acceptable and feasible. Although the study is not designed to test for efficacy, we also hypothesize that patients who participate in the *CPI-Prostate* will report adherence to active surveillance, a significant decline in distress, unmet needs, and regret, and a significant improvement in quality of life and satisfaction with care and with communication from baseline to the 12-month assessment. These data will be used to power a future efficacy trial. Qualitative and quantitative statistical analyses will be used to examine the focus group input, the usability, feasibility, and acceptability testing, and changes in study outcomes (i.e., adherence, distress, fear, needs, quality of life, regret, and satisfaction) from the baseline (before the session) to 12 months after baseline.

This proposed research is innovative as it is the first time that a psychosocial and educational intervention will be used to increase adherence among PC patients on active surveillance. The use of EHR to convey and share follow-up care plans is also novel. The proposed research has high impact potential because it addresses an important problem in the care planning and symptom management of PC patients. It further has the potential to impact patients' quality of life as well as satisfaction with care and communication with providers. The potential for integration and dissemination in the clinic by existing patient navigation staff is high.

Keywords: Active surveillance, localized prostate cancer, treatment decision making, sexual and urinary function, unmet informational and supportive care needs, quality of life, adherence to active surveillance

Accomplishments

The study major goals are:

1. To adopt a successful, symptom management intervention (PC^{PEP}) for prostate cancer patients on active surveillance (Study Specific Aim 1). As part of the adoption process, we will: (Aim 1a) develop an Electronic Health Record-based care plan for the patient and the care provider; (Aim 1b) conduct focus groups and personal interviews with patients and stakeholders to examine the barriers and facilitators of offering, acceptance of, and adherence to active surveillance, and unmet needs; inform the refinement of the prostate cancer educational modules (e.g., educational pamphlets and the Navigator session and follow-up calls); and augment the content and function of the care plan; and (Aim 1c) conduct usability testing to establish the usability of the care plan software.
2. To evaluate the acceptability and feasibility of the program with prostate cancer patients on active surveillance in a small pilot study (Study Specific Aim 2).

What we accomplished of these goals during the study period: September 2015-Septmeber 2016

Phase 1: Patients' and Care Providers' Interviews/Focus Groups

We have successfully conducted focus groups and personal interviews with 32 patients and 3 care providers to examine patients' unmet informational and supportive care needs and barriers and facilitators of active surveillance from the patient's and provider's perspectives. We have exceeded our patient recruitment goal in Phase 1. Thirty-three patients have been recruited and either participated in focus groups or a personal telephone interviews with Dr. Mohamed. All of these patients are diagnosed with localized prostate cancer and are currently on active surveillance. These patients range in age from 41-79 years old. Median is 64.5 years and mean is 64.6 years. Nineteen patients identify as Caucasian, 1 as Asian, 2 as African American, and 11 are unknown. Fifteen patients are Non-Hispanic, 1 Hispanic, and 17 are unknown. Nineteen patients are married, 2 divorced, 9 single, and 3 unknown. (All patient demographics have been identified through EPIC and via audio records of the focus groups/interviews). The recorded interviews/focus groups have been transcribed by 2 Research Volunteers (Ms. Hamida Chumpa and Ms. Jeneera Hossain) and a Research Coordinator (Ms. Taleen Bolbolian); 20 hours effort each) and have been preliminarily analyzed by Dr. Mohamed. Results of the patient and provider focus groups and interviews have: (a) guided enhancement of the study materials (e.g., educational materials, navigation session, and follow-up care plan), (b) led to a poster depicting the study finding on "Treatment

Decision-making and Adherence to Active Surveillance in Prostate Cancer Patients” presented at the DoD-IPMACT conference in Baltimore, (c) a submission of a new DoD grant focusing on racial, cultural, and relationship factors affecting patients’ and their partners’ decision about active surveillance to the W81XWH-16-PCRP-HDRA, and (d) a manuscript (work in progress) describing unmet informational and supportive care needs of prostate cancer patients on active surveillance. Although we proposed to recruit 10 caregivers in Phase 1, we reached saturation (i.e., similar findings emerged regarding the perceived barriers and facilitators of active surveillance from the providers’ perspective) with 3 caregivers’ interviews.

Preliminary findings of both patient and provider focus groups and interviews showed that the majority of patients followed physicians’ recommendations (90%) and few searched the Internet for additional information on active surveillance (30%). Factors influencing patients’ decisions to opt for active surveillance include trust in their physician’s expertise, good intentions, and skills in detecting cancer progression in a timely manner, as well as avoidance of sexual and urinary deterioration associated with curative treatment options (e.g., surgery). The partner’s approval of active surveillance played a significant role in the decision to opt for active surveillance. Although, no desire to discontinue active surveillance or decisional regret was reported, participants reported increased anxiety at the time of clinical testing for cancer progression. Lack of information about follow-up care, active surveillance management plan, and delays in follow-up surveillance appointments also contribute to anxiety levels. Financial barriers to active surveillance emerged as a significant concern affecting patients’ ability to stay on active surveillance protocol in the future, despite being willing to continue active surveillance. These findings suggest areas for healthcare improvements including enhancing possible system-level determinants of trust, physician-patient communication and closeness, and shared decision-making.

Phase 1: Refinement of the patient educational materials, follow-up care plan, and the navigator session and follow-up protocol

We have successfully completed the design of the intervention modules including: a) a patient pamphlet to enhance patient understating of prostate cancer treatment options, active surveillance protocol, and the pros and cons of active surveillance as compared to other curative treatment options using high credible resources such as the National Cancer Institute Patient Education Publication and the American Cancer Society publications (attached); b) a follow-up care plan to inform patient about active surveillance follow-up protocol and provide information about support resources using the National Comprehensive Cancer Network, the American Society of Clinical Oncology, and the American Urologic Association guidelines on active surveillance and follow-up care (attached); and c) the navigator session and follow-up care to enhance patients’ emotional adjustment and adherence to active surveillance (attached). As proposed, we have built the patient navigator’s session using both the Prostate Cancer Patient Education Program (PC^{PEP}) framework, and Institute of Medicine guidelines on improving cancer survivorship. Currently, all intervention materials are ready for the usability testing and the feasibility pilot study (Phase II). We will be conducting soon the usability testing to examine the utility of the penultimate version of the EHR-based care plan among 10 patients and stakeholders (50% PC patients) following NIH guidelines. IRB approval for both the usability and feasibility study will be obtained from both Mount Sinai and the DoD before we conduct the usability testing and the feasibility pilot study (Phase II).

Opportunities for training and professional development the project has provided

Phase I of this project provided a great opportunity for the study PI (Mohamed) and her research team to understand the challenges and difficulties patients with prostate cancer face when making decisions about active surveillance. The project also provided the opportunity to collect patient qualitative data on their unmet informational and supportive care needs during the active surveillance management. The resulted data and information on these issues led to a submission of a new DoD grant focusing on examining racial, cultural, and dyadic relationship factors that contribute to the difficulties and challenges patients

face during both treatment decision making and active surveillance management (W81XWH-16-PCRP-HDRA; *under review*).

The project also provided several opportunities for training and professional development for both the PI and her research staff. Dr. Mohamed has developed more advanced skills in patient interviews and focus groups. During Phase I, Dr. Mohamed has interviewed and conducted focus groups with 33 patients on active surveillance and discussed their unmet needs and other sensitive issues such as sexual function and sexual relationship during active surveillance management as well as patient sexual orientation. The previous Research Coordinators (Ms. Bolbolian) have received and the new Research Coordinator (Ms. Goodman) will receive training on patient navigation and navigator session and follow-up calls. The two Research Volunteers (Ms. Hamida Chumpa and Ms. Jeneera Hossain) have received training by Dr. Mohamed to transcribe and organize Phase I qualitative data for analyses. This training has resulted in a poster depicting Phase I results presented at the DoD-IMPACT conference in August 2016, Baltimore. Participating in this conference has also provided Dr. Mohamed with the opportunity for to connect with the VA and Army prostate cancer community and DoD research community who provided quality feedback on the study first poster and ideas for future grants.

Phase II study (feasibility) will provide additional training and professional development opportunities for Dr. Mohamed and her team as Phase II study involves collection and evaluation of longitudinal data on intervention acceptability, feasibility, and usability (e.g., the timing, duration, type, and frequency of program modules and print materials used). Phase II results will also inform a future, large-scale RCT to examine the efficacy of the planned intervention. This will further improve Dr. Mohamed's career and professional progress in prostate cancer research.

Study results disseminated to communities of interest

Phase I study results have been shared with the research community. Our poster presented at the DoD-IMPACT meeting depicted the findings on patients' challenges and unmet needs during treatment decision making and active surveillance management. We are currently working on a manuscript describing the focus groups and interviews results. Additionally news about this study and our preliminary findings were published in our *Mount Sinai Urology Update* newsletter to inform both the Mount Sinai community and our patients about advances and options for cancer treatment.

Plan for the next reporting period to accomplish the study goals

The next reporting period will focus on evaluating the acceptability and feasibility of the program with prostate cancer patients on active surveillance in a small pilot study (Study Specific Aim 2). We plan to recruit 80 prostate cancer patients during the 24-month period and explore the acceptability and feasibility of the planned intervention.

Impact

The impact on the development of the principal discipline(s) of the project

Phase I focus groups and interviews results have been used to inform revisions and finalization of the intervention components and content. Patients reported unmet informational needs guided the development of the patient brochure (attached) and the revision of the follow-up care plan (attached). The navigator session and follow-up call (attached) have been designed to address major issues raised by patients during the focus groups and interviews (e.g., anxiety of having cancer, fear of cancer progression and future worries; attached).

The impact on other disciplines

Nothing to Report at this time. However, a significant impact of the intervention on other disciplines including patient psychological support during active surveillance management is expected. Phase II results will provide evidence for such an impact.

The impact on technology transfer

Nothing to Report at this time. However, a significant impact of the intervention on technology transfer as a result of using a follow-up care plan software is expected. Phase II results will provide evidence for such impact.

The impact on society beyond science and technology

Phase I results (patients and providers focus groups and interviews) have increased general knowledge about challenges and difficulties patients face during the treatment decision making and active surveillance management. Increased public awareness of issues that influence patients' decisions about active surveillance may lead to improved patient-physician communication about active surveillance and, thus, to an increased uptake of active surveillance among patients. This will reduce patient burden and cost of care and prevent unnecessary reduction of quality of life associated with curative treatment.

Changes/problems

During the first and second quarters of this awarded study, we have experienced some delay in hiring the study personnel (Research Assistant (15%); Research Coordinator (20%)) because of the limited fund allocated to these two positions. However, we have managed to resolve this issue. We have hired both Ms. Taleen Bolbolian (Research Coordinator) and Mr. Tung Ming Leung (Research Assistant) to join the study. Unfortunately, Ms. Taleen Bolbolian has left Mount Sinai on 1/7/2016 for a higher paying job. To resolve this problem, we have just Ms. Sarah Goodman to replace Taleen Bolbolian. We plan to train Ms. Goodman on the same HIPPA training and the conduct of the study that Ms. Taleen Bolbolian received before we start Phase II before we start recruiting patients for Phase II feasibility study.

The delay we experienced in hiring and training a Research Coordinator for this study led to a delay in starting Phase II (the feasibility study). However, we will increase patient recruitment for Phase II as we will be recruiting from 2 physicians (Dr. Tewari and Dr. Mehrazin) at Mount Sinai. Our most update patient medical data revealed that we have currently over 250 prostate cancer patients on active surveillance and our medical data show that more newly diagnosed patients at Mount Sinai now are opting for active surveillance compared to the 2 previous years (2014-2015). Thus, recruiting 80 patients during the remaining study period (2-year) will be feasible. Additional resources for patient recruitment are available via Mount Sinai affiliated hospitals including Mount Sinai-Queens and Mount Sinai-Beth Israel.

Products

Phase I Product:

Phase I products include the following:

- The study focus group/interview guide for patient and provider

- The study invitation letter
- The study flyer
- A modified ASCO Care Plan to fit with the requirements of Active Surveillance protocol
- The Active Surveillance Care Plan software (ongoing work)
- A table including definition of active surveillance and a description of active surveillance used in research and medical care (recommended by the research team).
- A folder including the most-updated literature on active surveillance and prostate cancer
- A database including > 250 active surveillance prostate cancer patients eligible for focus groups/interviews
- Outline for the navigator session

Phase II Product:

We have completed the design, refinement, and finalization of the feasibility study materials. The following materials are currently readily available for usability testing (care plan) and feasibility testing.

- Patient pamphlet
- Patient Follow-up Care Plan
- Navigator 1-hour session
- Navigator follow-up calls
- Study finalized outcome measures (pre- and post-intervention assessment; see Appendix E).

Participants and other collaborating organizations

Dr. Nihal Mohamed

Role Principal Investigator

Researcher Identifier: NIHALM (eRA Commons)

Nearest person month worked: 80 hours

Contribution to Project: Dr. Mohamed designed the study materials described above, worked with the ISMMS and DOD IRB to approve the study methodology and study materials, and met with the research team to review and edit protocols and regulatory documents.

Dr. Heather Goltz

Project Role: Co-Investigator

Researcher Identifier: hhhonore (eRA Commons), 0000-0002-2875-7764 (ORCID ID)

Nearest person month worked: 50 hours

Contribution to Project: Dr. Goltz met with the research team to review and edit protocols and regulatory documents, creating a study flyer, and reviewing and editing the focus group and interview guides. Dr. Goltz also created the first draft of the outlines of the navigator session.

Dr. David Latini

Project Role: Collaborator

Nearest person month worked: 3 hours

Contribution to Project: Dr. Latini met with the research team to review and edit protocols and regulatory documents, creating a study flyer, and reviewing and editing the focus group and interview guides

Dr. Joseph Kannry

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Kannry met with the research team to discuss the care plan software development and will schedule frequent meetings with the PI (Mohamed) and his research team to discuss progress in developing the plan and the software.

Dr. Ash Tewari

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Tewari met with the research team to discuss the study progress and will schedule frequent meetings with the PI (Mohamed) to discuss study update. Dr. Tewari also assisted with patient recruitment for Phase 1.

Dr. Reza Mehrazin

Project Role: Co-Investigator

Nearest person month worked: 3 hour

Contribution to Project: Dr. Mehrazin met with the research team to discuss the study progress and will schedule frequent meetings with the PI (Mohamed) to discuss study update. Dr. Mehrazin also assisted with patient recruitment for Phase 1.

Ms. Taleen Bolbolian

Clinical Research coordinator (and Phase 2 study Navigator)

Nearest person month worked: 60 hours

Contribution to Project: Ms. Bolbolian assisted with patient recruitment and scheduling of the focus groups and patient interviews. She has worked closely with Dr. Mohamed to update the literature on Active Surveillance, definitions, medical protocol, and the revision of the care plan. She has also participated in the online navigation training.

Mr. Tung Ming Leung (Research Assistant)

Nearest person month worked: 10 hours

Contribution to Project: Mr. Leung has been working closely with Dr. Mohamed to update the literature on Active Surveillance, definitions, medical protocol, and the revision of the care plan. He will also receive training on conduct of Phase II (e.g., patient recruitment, questionnaires, data collection, entry, cleaning, and organization for further analyses by the study biostatic person Dr. Benn).

Special reporting requirements

Not Applicable

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1. Appendices

Phase I

Appendix A

Focus Group Guide

Appendix B

User and Usability Testing

2. Phase II

Appendix C

The PCI-Prostate Program

Appendix D

Outcome Measurements

3. Publications and Conference Presentations

Appendix F

Poster presented at the DoD-IMPCAT Conference in Baltimore

Focus group guide

1. Introduction:

- a) Welcome
- b) Housekeeping business:
 - ✓ Taping, confidentiality
 - ✓ Informed consent
 - ✓ Refreshments
 - ✓ Rest room
- c) Purpose of focus group

2. Prostate cancer and follow-up care:

- a) Information about prostate cancer and follow-up care
- b) Barriers and facilitators of follow-up care

3. The CPI-Prostate Intervention:

- a) Background and aims
- b) Initial reactions and feedback

Focus Group Guide: Prostate Cancer Patients

Time: Between 90 and 120 minutes

This section describes the focus group (FG) guide and time plan of the focus groups of prostate cancer patients and stakeholders (i.e., physician- and non-physician-providers). Each group will include about 5 participants. The FG will explore issues related to prostate cancer follow-up care and barriers and facilitators of offering, acceptance, and adherence to active surveillance.

“Welcome everyone, my name is __ and I will moderate our group discussion today(the moderator also introduces the research assistant) --First, I would like to thank you all for agreeing to participate in our group discussion today. Your contribution will certainly help us understand a lot of issues related to your experience as prostate cancer survivors. We will ask you some questions about your follow-up care and difficulties and challenges you encountered as survivors. Please, don’t hesitate to talk and remember there is no right or wrong answer. It is also very important that you express your point of view about these issues we will discuss even if it is different from the other speakers’ point of views because everyone’s point of view is very important and unique. We would like to let every participant to have a chance to talk about his/her point of view, so....please give other participants a chance to speak. We also want to assure you that we take your privacy and confidentiality very seriously. Although these discussions will be recorded for later analyses and reports, your names and information will not appear in any reports or results and we will keep your records and information in a secured area where only the research team will have access to them. Before we start I would like to ask you to introduce yourself (you can use your first name, or any other name you want to use), and tell us a little bit about yourself. To cover all topics, we will need approximately 90 to 120 minutes. We will have a 15 minute break in the middle. Beverage and snacks will be served outside the room. Before we start, please introduce yourself..... (Participants introduce themselves.....).

SECTION I: Barriers and facilitators of active surveillance, follow-up care, and patients unmet needs

Focus Groups # 1- 2: Patients Focus Groups

First, let’s talk about what happened right after your prostate cancer diagnosis.....

- a. What did you know about active surveillance at that time? (Probes: what were the sources of this information, were you satisfied with the information you received, what other information about active surveillance you needed at that time).

- b. Describe the discussion you had with your doctor about active surveillance at that time (Probes: what information the doctor provided about active surveillance, what were the doctor's recommendations, how strong were these recommendations, did the doctor describe pros and cons of active surveillance, did the doctor discuss a follow-up care plan; what could have made this discussion better based on what you know now about active surveillance).
- c. What other prostate cancer management options you considered and why did you opt for active surveillance? (Probes: what was important for you to achieve with active surveillance? what about your feelings? How did being on active surveillance affect you emotionally? or in other ways?)
- d. What kind of difficulties and challenges you encountered with active surveillance (Probes: keeping doctor appointment, how the surveillance tests affected you physically and emotionally? What about the pain or fatigue?)
- e. [For patients who discontinued active surveillance] When was the time you decided to discontinue active surveillance? What made you make that decision at that specific time (Probes: emotional triggers, spouses or family members' recommendations, other issues)?
- f. [For patients who discontinued active surveillance] Now when you think about that time, do you regret discontinuing active surveillance? What could have helped you stay on active surveillance?
- g. [For patients who discontinued active surveillance] What other information, support, or help you would want to have before you had made your mind about discontinuing active surveillance?
- h. [For patients who are still on active surveillance] What helped you adhere to active surveillance all this time?
- i. Did you receive any other health care services from the time you opted on active surveillance (Probes: referral to a social worker, a psychologist, a dietician, a physiotherapist, etc)? Why? And who recommended it for you?
- j. As a prostate cancer survivor -- What are the most important things you would want to tell other prostate cancer patients about active surveillance and follow-up care?

SECTION I: Barriers and facilitators of active surveillance, follow-up care, and patients unmet needs

Focus Groups # 1- 2: Stakeholders Focus Groups

There is evidence that prostate cancer patients on active surveillance experience emotional distress and a significant proportion of these men may discontinue active surveillance because of its emotional impact.....as a care provider involved in prostate cancer health care.....we would like to get your feedback on issues that might be involved in patients' acceptance and continuation of active surveillance protocol.

- a. Describe potential provider-related factors that might influence the discussion about active surveillance during counseling? (Probes:, providers' characteristics, specialty, patient-provider relationship, attending to patients emotional and information needs)
- b. Describe potential patient-related factors that might influence the discussion about active surveillance during counseling? (Probes:, patients' age, literacy level, comorbidities, anxiety level, values and expectations)

- c. As a care provider, how do you think we can improve prostate cancer patients' adherence to active surveillance? (Probes: provision of full information, about active surveillance during counseling, utilization of decision making interventions, patient-provider communication, specialties)
- d. Describe potential barriers to patients' continuation of active surveillance from your own point of view as a provider (Probes: ambiguity of guidelines of active surveillance, familiarity with this approach, clinical practice; reliable transportation, language barriers, lack of insurance).
- e. Describe potential facilitators of patients' continuation of active surveillance from your own point of view as a provider (Probes: addressing patients' needs, improved providers' skills in eliciting patients' treatment-related preferences and values , provision of access to support resources).
- f. What resources are currently available for you as a provider that you think might improve offering, acceptance, and continuation of active surveillance (Probes: a social worker, a psychologist, a dietician, a physiotherapist, knowledge of community resources)

Closing (5 min)

Closing remarks
Thank the participants

SECTION II: Exploring the acceptability of the CPI-Prostate modules

Focus Groups # 3 - 4: Patients and Stakeholders

I am going to tell you about different ways care providers could reach out to and help prostate cancer patients increase their understanding about active surveillance and follow-up care. I would like you to let me know what you think about each of these different ways.

1. Follow-up Care Plan

- a) What do you think of this care plan? (copies of the care plans will be distributed during the focus groups to participants)
- b) Do you think this would be a good way to help patients increase their knowledge and make decision about active surveillance and follow-up care? If so, why? If not, why?
- c) Do you think this would be a good way to help patients talk with their care providers about their follow-up care? If so, why? If not, why?
- d) What would be the best way to get this care plan to prostate cancer patients?

2. A brochure describing active surveillance and the content and use of the care plan

- a. Do you think this would be a good way to help patients know more about active surveillance? or understand the content and use of the care plan? If so, why? If not, why?
 - b. What would be the best way to get this brochure to prostate cancer patients?
- 3. Internet-based care plan (e.g., Hospital-based patient-provider portals)**
- a. Do you know what a patient-provider portal is? Have you used it before? If Yes: Why? ; If No: Why?
 - b. Do you think this would be a good way to send the care plans and follow-up information to prostate cancer patients? If so, why? If not, why?
 - c. What would be the best way to get information about this internet-based care plans to patients?
- 4. A 1-hour meeting with a navigator to discuss the care plans and their update with patients**
- a. Do you know what a patient navigator is? Do you think this would be a good way to help prostate cancer patients increase their knowledge about active surveillance? If so, why? If not, why?
 - b. Do you think this would be a good way to help patients address other issues they may encounter following surgery? If so, why? If not, why?
 - c. What other issues important to you as a survivor that need to be addressed or discussed during this meeting? And why?
- 5. Follow-up calls with a navigator to discuss the care plans and their update with patients**
- a) Do you think this would be a good way to help prostate cancer patients adhere to active surveillance? If so, why? If not, why?
 - b) Do you think this would be a good way to help patients address other issues they may encounter while on active surveillance? If so, why? If not, why?
 - c) What other issues important to you as a survivor that need to be addressed or discussed during this meeting? And why?
- 6. A list of questions to ask your doctor about follow-up care and cancer- and surgery-related surveillance tests.**
- a. Do you think this would be a good way to help patients talk with their care providers about their follow-up care? If so, why? If not, why?
 - b. What questions you may want to ask your doctor about your follow-up care?

Closing (5 min)

Closing remarks
Thank the participants

APPENDIX B

USER AND USABILITY TESTING

User Testing Protocol: The EHR-based Survivorship Care Plan

Patients and Stakeholders

I. Introduction

Thank you for coming in today. We are asking individuals like you to help us by “trying out” content that will be part of a new educational program. Its purpose is to help prostate cancer patients on active surveillance learn about follow-up care, self-management of the disease, develop skills needed for self-care, and cope with problems that may arise. We will be asking you to examine some of the content and give feedback. Do you have any questions about this?

II. Post-Experience Questions: Patients and Stakeholders

[Ask following exposure to each component.]

- What do you think of _____?
- How would you change _____?
- Was _____ easy to use?
- Was there anything confusing about _____?
- Was _____ engaging?
- Did _____ seem relevant to your post-treatment experience?
- What do you think about the format? color? layout?
- Would you want to use _____?
- What do you like about it? What do you not like about it?
- How would you rate _____ on a 5-point scale with 1 being poor and 5 being good?

III. Post-Experience Questions: Stakeholders' input on plans for implementations and dissemination

- What is the best way to implement the program at _____?
- What is the best way to disseminate the program to other hospitals, clinics, out-patients nurse-led clinics, patients/caregivers advocacy networks, community care centers, primary care organizations, and consumer focused groups?
- What part of the implementation process may require modifications of the intervention/program?
- What part of the dissemination process may require modifications of the intervention/program?
- What outcome measures/methods that should be used to provide evidence of the success of the implementation and dissemination of the program?
- How to promote continuation of the implementation and dissemination of the program?
- How and with whom to construe a partnership approach to program implementation that pays attention to the program's contextual and methodological factors?

Usability Testing Protocol: The EHR-based Survivorship Care Plan

Patients and Stakeholders

Introduction

Thank you for coming in today. We are asking individuals like you to help us by “trying out” a new computer software program. Its purpose is to help prostate cancer patients on active surveillance learn about follow-up care, self-management of the disease, develop skills needed for self-care, and cope with problems that may arise. This session will help understand how people use the software of this program. It will also tell us if there are things we could improve to make the program better. Do you have any questions about this?

I will also ask you to do several tasks using the program so that we can see how you get around the site and find information. While you do these tasks, I will ask you to “think aloud”, or to talk about what you are doing. When you “think aloud”, I would also like you to talk about what you are thinking or feeling. We will be watching you and taking notes.

Do you have any questions or concerns? If there is anything you don't understand while we are doing this, you can ask me and I will try to explain what we are asking. At the end, I will ask you some follow-up questions.

I. Follow-up care plan information

Questions

- What would you do if you wanted to change your answer right here?
- What would you do if you wanted to change your answer to this item?
- What would you do if you wanted to go back to the previous page?
- What would you do if you wanted to print this page?
- What would you do if you send this page to someone?
- What would you do if you send a message about this page to your care provider?
-

II. Program Home Page

Questions

- Without touching on anything yet, if you were going to explore this page what would you do?
- Would you show me where to find _____ (based on answer to earlier answer)?
- Would you touch one of the resource links on this page?
- How would you go back to the Home Page?

III. End-of-Session Questions

- How did you find moving around the program? Does it seem easy or difficult? What makes it that way?
- Do you think some people would have problems using the program? What kinds of people? What kinds of problems?
- Would you like to make any other comments or suggestions about this program?

Appendix C

The *CPI-Prostate* Program

- **The Educational Module**
- **The Navigator Session and Follow-up Call Protocol**
- **Follow-up Care Plan**

Social Worker Navigator-Led Session: (60-90 minutes)

I. Introductions

a. Patient Navigator

“I want to welcome you to the prostate cancer surveillance study. I will be your patient navigator while you're on the surveillance study. Basically a PN is someone who is:

- a) Knowledgeable of the various aspects of prostate cancer, treatment options, symptoms, and when men are or are not appropriate for active surveillance
- b) Assists patients and their understanding of health information or understanding healthcare environment. Patients often receive care from multiple providers, organizations, and systems. This information is often complex and difficult to navigate. So, a patient navigator is someone who learns about the environment and helps you to understand the information and quickly navigate between providers and healthcare settings. I'm here to answer questions you may have and to be an advocate for you with your providers. PN can also help you to move from point A to point B and assist you with lining up your appointments for the same day. If you're having trouble understanding test results, PN can also work with your team to make sure you understand this information.”

“During your time on the study, you should feel free to call on me at any and there will be specific points in time that you will have to complete questionnaires, so, you can count on receiving a call from me about 1 to 2 weeks before each of those appointments to fill out questionnaires.”

b. Patient

“Mr. _____, thank you for agreeing to participate in the prostate cancer active surveillance study. As a participant on this study, we will be asking you to complete several activities over the next several months.”

Allow the participant time to briefly reflect on how/why they decided to participate in the study.

- *Prompt: “Can you tell me a little bit about how you heard about the study and decided to participate?”*
- *Active Listening and Empathetic Reflection: Reflect back on information the participant has provided to you, using short phrases from what they have just told you.*
- *Positive reaffirmation: Thank the participant again for contributing to PC research.*

c. Re-Introduction to Study and Protocols

“You have already consented to participate, but I just want to briefly go over the information about the study again before we get started.”

Purpose: “The Care Planning for PC Patients on Active Surveillance study is designed to collect information that the researchers will use to create an intervention for men like yourself who are on AS. Through this study, we are trying to understand why men such as yourself decide to participate in AS and also why men decide to end AS and opt for treatment.

- *Positive reaffirmation: “You are really doing the medical community and your peers a great service by helping us to understand AS better.”*

Participation: “What are you being asked to do? We are asking you to 1.5-2 hour group meeting and answer questions about your experience with AS, treatment decisions, and follow-up care. These meetings will be recorded, but you will not be identified by name in presentations or publications and only people involved in the research study will have access to your confidential information. You may speak as much or little as you like in the group and you may leave the study at any time.”

Compensation, Risks, Benefits: “You will not be paid to participate in this study. However, possible benefits to participating are that you may learn more about AS, treatment decisions and PC follow-up care. Also, you will have a place to discuss any potential distress or unmet needs you are experiencing while on AS. And lastly, you are providing an invaluable contribution to PC research by helping to guide design and research on a psychosocial intervention. Some questions may make you feel uncomfortable or anxious, but you do not have to share information you are not comfortable sharing. Your consent form has more information about your rights as a research participant and some resources and contact information.”

“Mr. _____, could you tell me what I said about the study in your own terms (or language or based on your own understanding)?”

“Do you have any questions about the information I provided to you?”

- *If “yes,” provide brief explanations, using as simple and clear language as possible.*
- *If “no,” proceed to next section.*

d. Re-affirmation of Consent to Participate in Study

“Mr. _____, just to confirm that we have your permission to proceed. Are you willing to participate in the study based on your understanding of what you will be asked to do during the study?”

- *If “yes,” proceed to next section.*
- *If “no,” offer to answer remaining questions or address concerns.*
 - *Active Listening and Reflection: “In thinking about what you just said, I hear the concerns you have expressed about [use short phrases from what they have just told youexamples still having cancer in the body, worries about missing progression].”*
 - *Positive Affirmation: If specific concerns relate to cancer in the body or missing progression, provide patient education: “I want to assure you that the researchers and clinicians take active surveillance very seriously. We know that the knowledge that cancer is still in your body can make you feel scared or anxious. This is why only prostate cancer that is low-risk for progression (growing larger) is considered appropriate for AS. Being eligible to participate in this study means that you have a relatively low chance that the cancer will grow quickly. While on AS, you will be monitored by your doctor. That means you may have PSA tests, biopsies, or other kinds of tests so that your doctor can detect any changes early. If there are changes, you and your doctor will talk about treatment options and find one that will work better for you.”*
- *If response is “firm,” provide information on how to revoke consent in writing to the PI and formally withdraw from the study.*
 - *Positive reaffirmation: Thank the participant for considering participating in the study and reinforce that you hope they will consider participating in studies in the future.*

II. Baseline Assessment

a. NCCN Distress Thermometer and Problem List for Patients

[Provide participant with laminated or paper copy of the Thermometer/List]

“Mr. _____ this is the National Comprehensive Cancer Network’s Distress Thermometer and Problem List for Patients. For the research study, we will use this tool to look at the amount of distress you have been experiencing in the past week, including today. You will circle the number that matches your distress level this week. Zero means you did not experience any distress at all this week and ten means that you are really distressed (you have extreme distress). Also, you will place an ‘X’ or ‘check’ next to any of the specific problems you have experienced over the past week, including today.”

“On the Thermometer, please circle the number that matches your distress and then select all of the specific problems on the checklist that you have experienced over the past week, including today.”

b. In-depth Discussion of Responses to Thermometer and Problem List

- i. Levels of Distress Identified
- ii. Unmet Needs Identified
- iii. Supportive and Empathic Feedback Provided to Participant

THE FOLLOWING ARE EXTENDED DIDACTIC EXAMPLES:

Example 1

i. Levels of Distress Identified

Participant selects the number 0 on the NCCN Thermometer, indicating “no distress.”

ii. Unmet Needs Identified

Participant then selects “yes” for the following issue(s) under the “Practical Problems” section of the Problem List: “transportation.”

iii. Supportive and Empathic Feedback Provided to Participant

“Mr. _____ let’s look at the NCCN Thermometer and Problem List. You circled “0” on the thermometer. Circling “0” generally means that over the past, including today, you have not felt any distress or worry. Would you say that is accurate in terms of how you have been feeling?”

- *If “yes,” proceed to discussions concerning the Problem List.*
- *If “no,” probe concerning what number more accurately describes the level of distress or worry they have been experiencing. Explain the meaning and proceed to the Problem List.*

“Mr. _____ in looking at the Problem List, I see that you selected “transportation” as something that has been a problem for you in the past week including today. Could you describe the problems you are having with Transportation?”

- *Active Listening, Reflection, and Positive Affirmation: “I hear your concerns about [problem(s) using short phrases from what they have told you] and believe I have some resources that might be helpful to you. The Social Work Resource Guide contains a lot of information concerning transportation as it is a common issue that impacts patients in our area.”* Select 2-3 resources that might be appropriate for the patient in terms of financial/insurance resources; geographic location of home, and other relevant factors. Start with any hospital-specific resources and then work your way outward/external. Make sure to educate patient on any referrals or documents they might need and whether you or they will make the call to initiate contact. You will return to this information when you cover the Resources/Referrals section of the Care Plan (see below). Check-in and use the “teach back” approach to ensure that the participant understands what you have discussed.

Example 2

i. Levels of Distress Identified

Participant selects the number 6 on the NCCN Thermometer, indicating “moderate distress.”

ii. Unmet Needs Identified

Participant then selects “yes” for the following issue(s) under the “Physical Problems” section of the Problem List: “changes in urination,” “fatigue,” “sleep,” and “sexual.” He then selects “fears” and “worry” under the “Emotional Problems” section and “dealing with partner” under the “Family Problems” section.

iii. Supportive and Empathic Feedback Provided to Participant

“Mr. _____ let’s look at the NCCN Thermometer and Problem List. You circled “6” on the thermometer. Circling “6” generally means that over the past, including today, you have a moderate amount of distress or worry. Would you say that is accurate in terms of how you have been feeling?”

- *If “yes,” ask the participant to briefly describe their experiences over the past week and proceed to discussions concerning the Problem List.*
- *If “no,” probe concerning what number more accurately describes their level of distress or worry; explain the meaning of the revised number; and ask participant to briefly describe their experiences during this time period. Next, proceed to the Problem List.*

“Mr. _____, in looking at the Problem List, I see that you selected “fears” and “worry” as things that have been a problem for you in the past week including today. Could you describe the problems you are having with fear and worry?”

- *Active Listening, Reflection, and Positive Affirmation: “I hear your concerns about [problem(s) using short phrases from what they have told you].”*

- Probe in terms of onset and duration of these problems by saying things like *“When did [problem(s)] occur?”* or *“How long have you been experiencing [problem(s)]?”*
- Next probe for potential precipitating or initiating factors by saying something like *“Did you notice anything going on at home or work or some other area of your life that might have brought this [problem(s)] on---if the patient has not indicated that they are cancer-related or began with the cancer diagnosis.”*
- Probe for potential unmet informational or resource needs. *“Are there things you have tried before that have worked for you?”* and then *“What do you think would be helpful to you, or that you might need, to solve this [problem(s)]?”* Listen carefully. It is “ok” to take notes.
 - Probe until you have covered all of the identified problems and any that may have emerged during the interview.
 - Note: A number of problems participants identify may cluster together due to prostate cancer, aging, previously diagnosed and emerging comorbid conditions, or some combination of these factors. For example, it would not be uncommon for participants to report issues with fatigue, sleep, and changes in urination (e.g., possible prostate changes producing sleep disturbances). Or, as another example, sex, worry, and dealing with partner (e.g., possible erectile dysfunction).
 - Remember to reassure the participant that not all physical symptoms are a sign of prostate cancer growing or spreading. Remind participants of AS principles (e.g., must be low-risk for progression/metastasis).
- Move towards appropriate resources and referrals. *“I believe I have some resources and/or referrals that might be helpful to you. The Social Work Resource Guide contains a lot of information concerning programs and services to address these issues, as they are common issue(s) that impact patients, particularly those who have been diagnosed with cancer. Additionally, since you are reporting some physical symptoms, I believe it would be a good idea to refer you to your urologist (or general practitioner depending on the symptoms) for a checkup.”*
 - Ask permission to refer, especially fee-for-service programs, before doing so in the Resource and Referral section. Select 2-3 resources that might be appropriate for the patient in terms of financial/insurance resources; geographic location of home, and other relevant factors.
 - Start with any hospital-specific resources and then work your way outward/external. Make sure to educate participant on any referrals or documents they might need and whether you or they will make the call to initiate contact. You will return to this information when you cover the Resources/Referrals section of the Care Plan (see below). The plan should include a timeline for follow-up and check-in, especially due to Thermometer score and the Emotional Problems the participant identified.

Example 3

i. Levels of Distress Identified

Participant selects the number 8 on the NCCN Thermometer, indicating “extreme distress.” **CAUTION: This score warrants close monitoring and a referral to Mount Sinai Social Work for assessment for suicide intent, resources, and referrals. Call Mount Sinai Social Work to deploy social worker or request immediate follow-up with participant.**

ii. Unmet Needs Identified

Participant then selects “yes” for the following issue(s) under the “Emotional Problems” section: “depression,” “worry,” and “loss of interest in usual activities.” They also select “dealing with partner” under the “Family Problems” section.

iii. Supportive and Empathic Feedback Provided to Participant

“Mr. _____ let’s look at the NCCN Thermometer and Problem List. You circled “8” on the thermometer. Circling “8” generally means that over the past, including today, you have a very high amount of distress or worry. Would you say that is accurate in terms of how you have been feeling?”

- *If “yes,” ask the participant to briefly describe their experiences over the past week and proceed to discussions concerning the Problem List.*
- *If “no,” probe concerning what number more accurately describes their level of distress or worry; explain the meaning of the revised number; and ask participant to briefly describe their experiences during this time period. Next, proceed to the Problem List.*

“Mr. _____, in looking at the Problem List, I see that you selected “fears” and “worry” as things that have been a problem for you in the past week including today. Could you describe the problems you are having with fear and worry?”

- *Active Listening, Reflection, and Positive Affirmation: “I hear your concerns about [problem(s) using short phrases from what they have told you].”*
- *Probe in terms of onset and duration of these problems by saying things like “When did [problem(s) occur?” or “How long have you been experiencing [problem(s)]?”*
- *Next probe for potential precipitating or initiating factors by saying something like “Did you notice anything going on at home or work or some other area of your life that might have brought this [problem(s) on---if the patient has not indicated that they are cancer-related or began with the cancer diagnosis.]”*
- *Probe for potential unmet informational or resource needs. “Are there things you have tried before that have worked for you?” and then “What do you think would be helpful to you, or that you might need, to solve this [problem(s)]?” Listen carefully. It is “ok” to take notes.*
 - *Probe until you have covered all of the identified problems and any that may have emerged during the interview.*
 - *Remember to reassure the participant that not all physical symptoms are a sign of prostate cancer growing or spreading. Remind participants of AS principles (e.g., must be low-risk for progression/metastasis).*

- **Note: A number of problems participants identify may cluster together due to prostate cancer, aging, previously diagnosed and emerging comorbid conditions, or some combination of these factors.**
 - **For example, it would not be uncommon for participants to report issues with worry or depression. However, if they score higher on distress and indicate suicidal ideation (e.g., saying things like they wonder if their family would be “better off without” them or expressing feelings of hopelessness), this is a RED FLAG.**
 - **Remember=Suicidal ideation (thoughts, feelings, talk) + Plan + Access (to means to commit suicide) + Low social support = Suicidal INTENT.**
 - **Initiate assessment for suicidal intent.**
- Move towards appropriate resources and referrals. *“I believe I have some resources and/or referrals that might be helpful to you. The Social Work Resource Guide contains a lot of information concerning programs and services to address these issues, as they are common issue(s) that impact patients, particularly those who have been diagnosed with cancer. Additionally, since you are reporting some physical symptoms, I believe it would be a good idea to refer you to your urologist (or general practitioner depending on the symptoms) for a checkup.”*
 - Ask permission to refer, especially fee-for-service programs, before doing so in the Resource and Referral section. Select 2-3 resources that might be appropriate for the patient in terms of financial/insurance resources; geographic location of home, and other relevant factors.
 - Start with any hospital-specific resources and then work your way outward/external. Make sure to educate participant on any referrals or documents they might need and whether you or they will make the call to initiate contact. You will return to this information when you cover the Resources/Referrals section of the Care Plan (see below).

III. EHR Personalized Care Plans

a. Treatment Summary Tailored to Study Participant

“Mr. _____, I would like to take a few minutes to explain the care plan document that will be placed in your electronic health record. This document will be updated as you continue through the AS study. The purpose of a “Treatment Summary” is to provide you with a convenient summary of any laboratory or medical tests, exams, biopsies, and treating physicians, specialists, and other care providers involved in your cancer surveillance. You will receive a copy for your records and you might find it useful to give a copy to your primary care provider, if you have one.”

b. Care Plan Tailored to Study Participant

“Mr. _____, this section of the care plan is the part that is very specific to you. When we meet and discuss how you are doing and what, if any, worry or problems you are experiencing, I will note them in this section. I will also place information about potential resources or referrals, along with contact information, in this section. Also, if you need routine (every day) care such as vaccinations (e.g., flu shots), annual physical exams, and other non-care-related care (e.g., for hypertension, diabetes), I will document that in this section, along with dates and contact information for those providers or specialists. Placing this information in the care plan provides you with one convenient place to document this non-cancer care to make sure we are addressing any needs you may have in these areas.”

IV. Resources and Referrals (R&R)

- a. R&R #1 Identified and Discussed with Study Participant (Addressing Unmet Needs)
 - b. R&R #2 Identified and Discussed with Study Participant (Addressing Unmet Needs)
 - c. R&R #3 Identified and Discussed with Study Participant (Addressing Unmet Needs)
- Move towards appropriate resources and referrals. *“As I previously mentioned, I have some resources and/or referrals that might be helpful to you. The Social Work Resource Guide contains a lot of information concerning programs and services to address these issues, as they are common issue(s) that impact patients, particularly those who have been diagnosed with cancer.”* Ask permission to refer, especially fee-for-service programs, before doing so in the Resource and Referral section. Select 2-3 resources per problem identified that might be appropriate for the patient in terms of financial/insurance resources; geographic location of home; and other relevant factors. Start with any hospital-specific resources and then work your way outward/external. Focus on free/low cost and close to their homes, when possible. Make sure to educate participant on any referrals or documents they might need and whether you or they will make the call to initiate contact.
 - Check-in and use the “teach back” approach to ensure that the participant understands what you have discussed.

V. Conclusion

a. Q&A

“Mr. _____, I just want to check in with you. We have covered a lot of information today. Do you have any questions concerning what we discussed today?”

- *If “no,” proceed to next section.*
- *If “yes,” offer to answer remaining questions or address concerns.*
 - *Active Listening and Reflection: “In thinking about what you just said, I hear the concerns you have expressed about [use short phrases from what they have just told youexamples still having cancer in the body, worries about missing progression].”*
 - *Positive Affirmation: If specific concerns relate to their level of participation, acknowledge and address their concerns. Reassure the participant that you will be available to them throughout the study to answer any questions they may have or clarify information.*

b. Congratulations for Participating in the Study and Concluding Remarks

“Mr. _____, I want to thank you again for agreeing to participate in the study. I know this represents a time investment, but I believe that your experiences on AS and the experiences of others like you, will help us to understand why people choose AS and stay on AS. I look forward to meeting with you again in the future.”

Materials for PN Session

- Laminated or paper copy of the NCCN Thermometer and Problem Checklist
- Laminated or paper copy of the Care Plan
- Pen
- Highlighter
- Multi-line telephone
- Laptop or Desktop PC with internet access
- Mount Sinai Social Work Resource Guide

Patient Navigator Notes

- Remember to maintain eye contact.
- Do smile and maintain a conversational tone.
- Do not judge (through verbal or non-verbal communication). The participant is a volunteer and their experiences should be respected even if you do not disagree with them.
- Maintain professional distance, but do not keep arms or legs crossed. This posture may convey being closed off or unfriendly to the participant.
- Watch your hand signals. For example, the U.S. sign for “ok” (thumbs up) may mean something quite different to others of different cultures or nationalities.
- Turn off your phone or pager during a PN session.
- Be mindful of the time, but don’t monitor the clock. This conveys to participants that you are bored or that they are unimportant.
- If you do not understand a comment that the participant has made, do not be afraid to ask them to repeat what they said or ask clarifying questions.
- Be prepared to explain information in multiple ways or formats to assist participants in understanding information.
- Be prepared for participants to occasionally show emotions like sadness, fear, grief, and so on. It is ok to take a moment and let them experience these feelings. You may say nothing or comforting words. Avoid phrases like “everything’s going to be ok” or “you’ll be fine.”

Suicide Risk Assessment and Crisis Intervention

If participants exhibit some of the following:

- Scores of “8” or higher on the NCCN Distress Thermometer
- Indicate issues in the “Emotional Problems” section of the Problem List
- Indicate suicidal ideation (e.g., saying things like they wonder if their family would be “better off without” them or expressing feelings of hopelessness)

These are RED FLAGS.

Simple Formula:

Suicidal ideation (thoughts, feelings, talk) + Plan + Access (to means to commit suicide) + Low social support = Suicidal INTENT.

Initiate assessment for suicidal intent!

Special Cases of Confidentiality

You should note that there are exceptions to participants' confidentiality that impact the study's ability to keep their information private. These include the following:

- Known or suspected abuse or neglect of a child
- Known or suspected abuse or neglect of an elderly (older adult)
- Known or suspected abuse or neglect of a person living with a disability

- Expressing thoughts of wanting to harm self or others

Social worker navigator-led follow-up calls: (60-90 minutes): 1, 3, 6, and 12 months

- Revisit the needs identified during the first session
- Assess if plan given has been followed
- Make alterations in plans or goals to help survivor achieve success
- Reward progress so survivor gets a WIN!!!!!!
- Assess distress and new needs emerged using the NCCN Thermometer and Problem List
- Assess coping skills and resources in place
- Provide emotional support and encouragement of adherence to follow-up recommendations
- Ask about outcomes of previous referrals and potential problems
- Encourage communication with providers and use of care plans/ Web-based educational tools/MyChart account, Question Lists,
- Make appointments for the next follow-up calls

Follow-Up Care Plan

Follow-Up Care Plan	
General Information	
Patient Name:	
Patient DOB:	Patient MRN:
Patient Phone:	Email:
Health Care Providers (Including Names, Institution)	
Primary Care Provider:	
Urologic Surgeon:	
Medical Oncologist:	
Nurse:	
Mental health/social worker:	
Nutritionist/dietician:	
Other (Therapist/Pharmacist, etc.):	
Treatment Summary	
Diagnosis	
Cancer Type/Location/Histology Subtype: Prostate Cancer	Diagnosis Date (year):
Stage: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Not applicable	
Gleason Score:	PSA at Diagnosis:
Current Medications:	
Medical Conditions:	
Allergies:	
Past major surgeries:	Date:
Clinical Trial: <input type="checkbox"/> Yes <input type="checkbox"/> No Name/Number:	
Active Surveillance Treatment	
Date Starting Active Surveillance:	
Last PSA Date and score:	
Last DRE:	
Last Biopsy:	
Other Therapy (chemotherapy, hormonal therapy, other) <input type="checkbox"/> Yes <input type="checkbox"/> No	
Follow-up Care Plan	
Schedule of Clinical Visits	
Coordinating Provider	When/How often
Cancer Surveillance or other Recommended Tests	

Coordinating Provider	Test	How Often
	PSA (Prostate Specific Antigen)	
	DRE	
	Biopsy	
	Other:	

Please continue to see your primary care provider for all general health care recommended for a man your age, including cancer screening tests. Any symptoms should be brought to the attention of your provider:

1. Anything that represents a brand new symptom;
2. Anything that represents a persistent symptom;
3. Anything you are worried about that might be related to the cancer coming back.

Possible late- and long-term effects that someone with this type of cancer and treatment may experience:
(Highlight those that apply)

- Decreased sex drive
- Enlarging breast tissue
- Erectile dysfunction
- Fatigue
- Hair loss
- Hot flashes
- Incontinence
- Increased body fat
- Loss of muscle mass
- Metabolic syndrome (increased blood pressure, blood sugar, cholesterol)
- Mood swings
- Osteoporosis
- Painful urination
- Rectal Pain
- Shortening of the penis
- Skin irritation or darkening
- Sterility
- Tiredness
- Trouble voiding or passing urine (urinary retention)
- Urinary frequency
- Other:

Cancer survivors may experience issues with the areas listed below. If you have any concerns in these or other areas, please speak with your doctors or nurses to find out how you can get help with them.

- | | | |
|---|---|---|
| <input type="checkbox"/> Anxiety or depression | <input type="checkbox"/> Insurance | <input type="checkbox"/> Sexual Functioning |
| <input type="checkbox"/> Emotional and mental health | <input type="checkbox"/> Memory or concentration loss | <input type="checkbox"/> Stopping Smoking |
| <input type="checkbox"/> Fatigue | <input type="checkbox"/> Parenting | <input type="checkbox"/> Weight changes |
| <input type="checkbox"/> Fertility | <input type="checkbox"/> Physical functioning | <input type="checkbox"/> Other |
| <input type="checkbox"/> Financial advice or assistance | <input type="checkbox"/> School/work | |

A number of lifestyle/behaviors can affect your ongoing health, including the risk for the cancer coming back or developing another cancer. Discuss these recommendations with your doctor or nurse:

- | | | |
|---|--|--------------------------------|
| <input type="checkbox"/> Alcohol use | <input type="checkbox"/> Physical activity | <input type="checkbox"/> Other |
| <input type="checkbox"/> Diet | <input type="checkbox"/> Sun screen use | |
| <input type="checkbox"/> Management of my medications | <input type="checkbox"/> Tobacco use/cessation | |
| <input type="checkbox"/> Management of my other illnesses | <input type="checkbox"/> Weight management (loss/gain) | |

Other comments:

Prepared by:

Delivered on:

A-2. Suggested Preventative Measures

Health Maintenance	Source
Bone health	Participate in regular weight bearing exercise (walking, strength training). Take recommended amounts of calcium and vitamin D. Talk with your provider about a vitamin D blood test. Monitor bone density.
Cancer screening	Annual physical exam with primary care provider Stay current on routine cancer screenings (gynecology, breast, colon, prostate, skin checks)
Cholesterol monitoring/management	Annual physical exam with primary care provider
Dental care	Biannual dental exam
Diabetic screening/management	Annual physical exam with primary care provider
Diet	American Institute for Cancer Research (AICR) www.aicr.org/ Make fruit and vegetables the basis for most of your meals and snacks. Consume healthy fats (olive oil, nuts) and avoid processed foods. Eat smaller portions of animal fats and proteins or eat them less often. Ask for referral to nutritionist/dietician
Exercise / Weight management	Adopt a physically active lifestyle. Do at least 30-45 minutes of moderate to vigorous activity at least 5 days/week. Request a referral for physical therapy for help setting goals and dealing with physical limitations.
Hypertension control	Annual physical exam with primary care provider
Mental health	Seek support as soon as you can after you receive your cancer diagnosis. There are a number of local in-person and online support groups, as well as the love and support of your partner, family, and friends. If you notice long periods of feeling hopeless or helpless about your situation or changes in sleeping patterns or energy level, consult your primary care provider for mental health resources in your community or use the resources below to find someone who can help you through the challenges of living through cancer.
Smoking cessation	Many cancer centers and other medical facilities offer smoking cessation programs. The most effective are those that combine behavioral counseling and medication to reduce the craving for cigarettes, and other tobacco products. Survivors should be offered referrals to help quit smoking at the time of diagnosis.
Vaccines	Annual physical exam with primary care provider

A-3. Selected Benefit Resources

Government Benefits	www.benefits.gov	Health coverage, including Medicaid
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	1-800-FED-INFO	
Medicare	www.medicare.gov 1-800-MEDICARE	Health coverage for seniors
Social Security	http://www.socialsecurity.gov/ 1-800-772-1213	Benefits for seniors and those with disabilities
Partnership for Prescription Assistance	http://www.pparx.org/ 1-888-477-2669 (888-4PPA-NOW)	Assistance obtaining prescription drugs
RX Assist's Patient Assistance Program Center	http://rxassist.org/patients/default.cfm E-mail: info@rxassist.org	Searchable database (drug name/ company prescription assistance program)
Employee Assistance Program (EAP)	Employee contact with the EAP is kept private. To learn more, ask your employer about your company's EAP. (This service is offered, for the most part, through large employer groups.)	EAPs help employees and their families deal with issues such as: <ul style="list-style-type: none"> • Short and long-term disability • Personal and emotional concerns • Legal and financial advice

A-4. Resources for Prostate Cancer Survivors and their Families

Area of Interest	Organization	Contact Information	Services
General Cancer Information and Advocacy	American Cancer Society (ACS)	http://www.cancer.org/Treatment/SupportProgramsServices/index (support services) http://www.cancer.org/cancer/prostatecancer/index (specific to Prostate) http://csn.cancer.org/ (Cancer Survivors Network)	Wide variety of services and supportive care for cancer survivors and their families.
	Cancer.Net™	http://www.cancer.net/portal/site/patient	Detailed patient information website of the American Society of Clinical Oncology® (ASCO); helps patients and families make informed health-care decisions.
	Cancer Support Community (CSC)	www.cancersupportcommunity.org 1-888-793-WELL	Global nonprofit group that gives support, education and hope to people with cancer and their loved

		e-mail: help@cancersupportcommunity.org	ones.
	Lance Armstrong Foundation - LIVESTRONG	www.livestrong.org 1-866-673-7205	Educational articles and videos
	National Coalition for Cancer Survivorship (NCCS)	www.canceradvocacy.org 1-888-650-9127	Advocates for quality cancer care; provides the Cancer Survival Toolbox to survivors, caregivers and clinicians at no cost.
Prostate Cancer General Information	Urology Care Foundation	http://www.urologyhealth.org	Advances urologic research and education and works with health care providers, researchers, patients and caregivers to improve patients' lives.
	Prostate Cancer Foundation	http://www.pcf.org/site/c.leJRiROrEpH/b.5699537/k.BEF4/Home.htm	PCF is a primary source for new standard-of-care and research information.
Cancer Survivorship	Institute of Medicine: From Cancer Patient to Cancer Survivor: Lost in Transition - video	http://www.youtube.com/watch?v=YhuqWM3dNAw	This short film by the Institute of Medicine features the stories of cancer survivors and supports the need for a Survivorship Care Plan.
	National Cancer Institute: The Facing Forward Series	http://www.cancer.gov/Publications/patient-education/facing-forward	A series of booklets designed to educate cancer survivors, family members, and health care providers about the challenges associated with life after cancer treatment.
Depression / Anxiety	American Psychosocial Oncology Society (APOS)	http://www.apos-society.org 1-866-276-7443 (Help Line)	Locate a mental health provider in your area.
	CancerCare	http://www.cancercare.org/ 1-800-813-HOPE (4673)	Gives free support services to those affected by cancer; programs include counseling, education, financial and practical help.
Incontinence, Urine Control, Supplies and Concerns	Dr. Leonard's Healthcare Catalog	www.drleonards.com 1-800-785-0880	On-line healthcare catalogue with incontinence products.

		www.nationalincontinence.com 1-800-998-1745	On-line incontinence supplies
Sexual Dysfunction	American Association of Sex Educators, Counselors, and Therapists (AASECT)	http://www.aasect.org	AASECT provides information and referrals for persons having difficulty with sexual issues from a variety of causes including cancer and chronic disease.

A-5. Selected Prostate Cancer Support Group Resources

Prostate Cancer Foundation (PCF) Support Group General Information	http://www.pcf.org/site/c.leJRIROrEpH/b.5856543/k.6599/Finding_a_Support_Group.htm	
Us TOO International	1-800-808-7866 www.ustoo.org www.inspire.com/inspire/group/us-too-prostate-cancer/ (Online community)	Us TOO International is a grassroots, non-profit prostate cancer education and network of over 325 support group chapters worldwide, providing men and their families with free information, materials and peer-to-peer support.
YANA- You Are Not Alone Now Prostate Cancer Support Site	www.yananow.org	Giving access to the stories of more than a thousand survivors, some diagnosed more than ten years ago
Malecare	212-673-4920 www.malecare.org www.outwithcancer.org (Online community) health.groups.yahoo.com/group/prostatecancerunder50/ health.groups.yahoo.com/group/prostatecancerandgaymen/ health.groups.yahoo.com/group/advancedprostatecancer/ (Malecare moderated email discussion lists)	Malecare is the largest all volunteer grassroots, non-profit men's cancer support and advocacy nonprofit in the United states. Malecare is unique in providing support groups focused on men presenting with advanced disease and for gay and bisexual men.
Imerman Angels	1-877-274-5529 www.imermanangels.org	Imerman Angels partners a person fighting cancer with someone who has beaten the same type of cancer.
Cancer Hope Network	1-877-467-3638	Matches cancer patients one-on-one with someone who has recovered

	www.cancerhopenetwork.org/	from a similar experience.
The Scott Hamilton CARES Initiative - 4th Angel Program	1-866-520-3197 www.4thangel.org	Free, national service which provides a one-to-one supportive relationship (phone or email based) to cancer patients and their caregivers.

A-6. Mount Sinai Health System Resources

Nutritionist

- We have a registered dietician who is available to discuss any nutritional concerns you may have, including an assessment of your current eating habits and advice on how to eat before, during, and after your cancer treatment.

Support Groups and Other Activities

- Our Social Work Department offers many disease-specific support groups and recreational activities. A monthly calendar of events is available in our Resource Room located on the 3rd floor of the Ruttenberg Center.

Creative Art Expression Group

- Patients, family members, caregivers and friends can channel their feelings through art, receive support, and surround themselves in a calm and creative space. Supplies are provided, yet group members can feel free to bring personal projects or materials.

Cancer Support Program for Men

- This program will work to match you with another male cancer patient who you can speak with individually in whatever format and with whatever frequency works for both of you.

Pet Therapy

- Patients (upon medical clearance) can receive visits from a certified pet therapy dog

Mindfulness Meditation, Guided Imagery and Relaxation

- A relaxation and meditation practice group open to patients, as well as Ruttenberg Center volunteers and staff

Therapeutic Massage

- A professional massage therapist is available to provide massages to oncology patients during treatment

If you or a loved one are interested in joining one the supportive groups or programs listed above, please contact Stephanie Pelosi, LCSW at 212.824.8762 for additional information.

Patient Representatives	212-659-8900 Monday-Friday, 9 am-5 pm	Patient Representatives assist patients and their families with any questions, complaints or concerns regarding their health care or any services, that other staff is unable to resolve. Patient representatives also provide information regarding patients' rights.
Department of Social Work Services	212-241-6800	
Department of Spiritual Care and Education	212-241-7262 infospiritualcare@mountsinai.org	
Patient Financial Services	212-731-3100 Monday-Friday, 9 am-5 pm 1-866-682-9380 (toll free)	
Integrative Urology and Wellness	http://www.mountsinai.org/patient-care/service-areas/urological-	Jillian Capodice, LAC

Program	conditions-and-surgery/areas-of-care/integrative-urology	Director, Integrative Urology and Wellness Program Tel: 212-241-9955 jillian.capodice@mountsinai.org
Smoking Cessation Program	If you are interested in participating, please contact our study coordinators at 212-241-2420.	If you are currently a smoker at least 50 years of age, and want to quit, the Mount Sinai Legacy Lung Screening and Cessation Program can assist you with the process. This project is a clinical and research program funded by a grant from The American Legacy Foundation that studies smoking cessation techniques in the context of CT screening for the detection of lung cancer and other tobacco-related diseases.

Appendix E

Phase II Feasibility Study Measurements

**A pilot Study to Enhance Care Planning for Prostate
Cancer Patients
on Active Surveillance**

<i>For official use only</i>	
ID	
MR #	
Assessment time-point	
Date	

Provisional Measurements of Demographic Information

Please complete the following questions:

1. How old are you? _____

2. What is your date of birth? ____ / ____ / ____ (Day / Month / Year)

3. What is the highest level of education you have completed?
 - Less than 8 years
 - 8 to 11 years (without graduation)
 - High school graduation/ G.E.D.
 - Vocation or technical school
 - Some college or university
 - Bachelor's degree
 - Graduate degree

4. Are you currently...
 - Never married
 - Married or living as married
 - Divorced
 - Separated
 - Widowed

5. What is your race or ethnic background?
 - Caucasian

- African American
- Hispanic
- Asian American
- Other (please specify) _____

6. Are you currently? (check ONE)

- Employed
- Unemployed
- Retired
- Other, specify _____

Please complete the following questions:

Provisional Measurements of Clinical History

1. When were you **diagnosed** with prostate cancer? (Month/Yr) _____

2. What treatment options you discussed with your doctor? (*check (✓) all that apply*)

1) ____ SURGERY

2) ____ EXTERNAL BEAM RADIATION

3) ____ BRACHYTHERAPY

4) ____ HORMONAL TX

5) ____ COMBINATION HORMONES/SURGERY

6) ____ COMBINATION HORMONES/EXTERNAL BEAM RADIATION

7) ____ COMBINATION HORMONES/BRACHYTHERAPY

8) ____ WATCHFUL WAITING

9) ____ Active Surveillance

3. Please give the month/year and result of your last three PSA tests since completing treatment for your prostate cancer...

PSA test (Month/Yr) _____ PSA Result _____

PSA test (Month/Yr) _____ PSA Result _____

PSA test (Month/Yr) _____ PSA Result _____

We are interested in how you view your overall health.

*Please circle **one** answer per question.*

	Poor	Fair	Good	Very Good	Excellent
4a. In general, how would you rate your overall health in the past year ...	1	2	3	4	5
4b. Compared to other people your age, would you say your overall health in the past year has been ...	1	2	3	4	5

5. Who has monitored your PSA level? (*check all that apply*)

- Family/Primary Physician
- Urologist
- Physician who treated my prostate cancer
- Surgeon at cancer center
- Radiation oncologist at cancer center
- Medical oncologist at cancer center

8b. How many months have you been on Active Surveillance?

_____months

_____ Don't Know

To the best of your knowledge, please tell me if you have any of the following health problems by answering yes or no to each. READ EACH HEALTH PROBLEM AND CODE YES OR NO.

HEALTH PROBLEM	YES	NO
a) Arthritis	1	0
b) Hypertension/high blood pressure	1	0
c) Heart disease	1	0
d) Emphysema	1	0
e) Chronic lung disease	1	0
f) Stroke	1	0
g) Diabetes	1	0
h) Fractured hip	1	0
i) Bladder control before your prostate cancer	1	0
j) Loss of eyesight	1	0
k) Hearing loss	1	0
l) Anemia	1	0
m) Asthma	1	0
n) Severe allergies	1	0
o) Stomach problems	1	0
p) Sexual or erectile dysfunction before your prostate cancer	1	0

32. What is your height? FT: ____/INCHES: ____ CODE "0" IF ZERO INCHES

33. What is your current weight in pounds: _____

34. Do you currently smoke? _____ Yes _____ No

34. Dis you smoke before? _____ Yes _____ No

The Intervention Evaluation

<u>STATEMENTS</u>	<u>STRONGLY AGREE</u>	<u>AGREE</u>	<u>DISAGREE</u>	<u>STRONGLY DISAGREE</u>	<u>DON'T KNOW</u>
The Program					
Increased my knowledge about health-care	1	2	3	4	9
Helped me talk to doctors/nurses about my health-care	1	2	3	4	9
Made me feel less anxious or upset about my health care	1	2	3	4	9
Made me feel more confident about my health care	1	2	3	4	9
Sort out what's important to me for dealing with my health care	1	2	3	4	9
Increased my knowledge about active surveillance	1	2	3	4	9
Helped me continue active surveillance	1	2	3	4	9
Helped me take care of myself	1	2	3	4	9
Helped me manage/control my symptoms (pain, fatigue, sexual dysfunction, urinary incontinence)	1	2	3	4	9
Taught me how to cope with the challenges of being on active surveillance	1	2	3	4	9

Taught me how to care for myself while being on active surveillance	1	2	3	4	9
Help me feel more confident about choosing the right stoma appliances and catheters	1	2	3	4	9
Helped me reduce my anxiety about active surveillance	1	2	3	4	9
Made me feel more anxious about active surveillance	1	2	3	4	9
Made me feel more confident in talking with my doctor about active surveillance	1	2	3	4	9

Would you recommend this program to other patients like you? (Please circle)

YES

NO

What is your best guess of how many minutes or hours you spent reviewing your care plan (Paper Copy) ?

1) TOTAL MINUTES: _____

2) TOTAL HOURS: _____

Have you used the care plan in your Patient Portal account? (Please circle)

YES

NO

What is your best guess of how many minutes or hours you spent reviewing your care plan (Patient Portal Account) ?

1) TOTAL MINUTES: _____

2) TOTAL HOURS: _____

What is your best guess of how many minutes or hours you spent discussing your care plan with your doctors or other providers?

1) TOTAL MINUTES: _____

2) TOTAL HOURS: _____

<u>STATEMENTS</u>	<u>STRONGLY AGREE</u>	<u>AGREE</u>	<u>DISAGREE</u>	<u>STRONGLY DISAGREE</u>	<u>DON'T KNOW</u>
The Navigator Session					
Increased my knowledge about my follow-up care	1	2	3	4	9
Helped me talk to doctors/nurses about my follow-up care	1	2	3	4	9
Made me feel less anxious or upset about my follow-up care	1	2	3	4	9
Made me feel more confident in how I deal with my care plan	1	2	3	4	9
Sort out what's important to me for dealing with the care plan	1	2	3	4	9

<u>STATEMENTS</u>	<u>STRONGLY AGREE</u>	<u>AGREE</u>	<u>DISAGREE</u>	<u>STRONGLY DISAGREE</u>	<u>DON'T KNOW</u>
The Navigator Phone Calls					
Increased my knowledge about my follow-up care	1	2	3	4	9
Helped me talk to doctors/nurses about my follow-up care	1	2	3	4	9
Made me feel less anxious my follow-up care	1	2	3	4	9
Made me feel more confident in how I deal with my care plan	1	2	3	4	9
Sort out what's important to me for dealing with the care plan	1	2	3	4	9

	Very much	Quite a bit	Some-what	A little bit	Not at all
1. How knowledgeable are you about active surveillance	5	4	3	2	1
2. How confident are you about continuing active surveillance	5	4	3	2	1
3. How difficult is it for you to be on active surveillance	5	4	3	2	1
4. How satisfied are you about your ability to continue being on active surveillance	5	4	3	2	1
5. Do you feel you need help with your emotion regarding being on active surveillance	5	4	3	2	1
6. How satisfied are you in general about your health care	5	4	3	2	1
7. How conformable are you talking about active surveillance or any related issues with your provider	5	4	3	2	1
8. How conformable are you talking about active surveillance or any related issues with other spouse/partner	5	4	3	2	1

HAD Anxiety and Depressive Scale

I feel tense or ‘wound up’:

- 3. Most of the time
- 2. A lot of the time
- 1. From time to time, occasionally
- 0. Not at all

I still enjoy the things I used to enjoy:

- 0. Definitely as much
- 1. Not quiet so much
- 2. Only a little
- 3. Hardly at all

I get a sort of frightened feeling as if something awful is about to happen:

- 3. Very definitely and quiet badly
- 2. Yes, but not too badly
- 1. A little, but it doesn’t worry me
- 0. Not at all

I can laugh and see the funny side of things:

- 0. As much as I always could
- 1. Not quite so much now
- 2. Definitely not so much now
- 3. Not at all

Worrying thoughts go through my mind:

3. A great deal of the time
2. A lot of the time
1. From time to time but not too often
0. Only occasionally

I feel cheerful:

3. Not at all
2. Not often
1. Sometimes
0. Most of the time

I can sit at ease and feel relaxed:

0. Definitely
1. Usually
2. Not often
3. Not at all

I feel as if I am slowed down:

3. Nearly all the time
2. Very often
1. Sometimes
0. Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach:

0. Not at all
1. Occasionally
2. Quite often
3. Very often

I have lost interest in my appearance:

3. Definitely
2. I don't take so much care as I should
1. I may not take quite as much care
0. I take just as much care as ever

I feel restless as if I have to be on the move:

0. Very much indeed
1. Quite a lot
2. Not very much
3. Not at all

I look forward with enjoyment to things:

0. As much as ever I did
1. Rather less than I used to
2. Definitely less than I used to
3. Hardly at all

I get sudden feelings of panic

3. Very often indeed
2. Quite often
1. Not very often
0. Not at all

I can enjoy a good book or radio or TV program

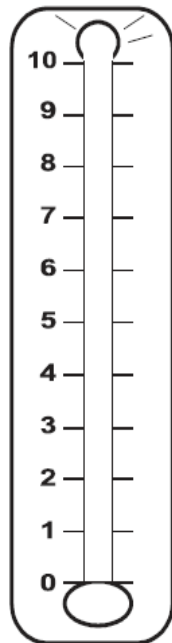
- 0. Often
- 1. Sometimes
- 2. Not often
- 3. Very seldom

The NCCN Distress Thermometer

SCREENING TOOLS FOR MEASURING DISTRESS

Instructions: First please circle the number (0-10) that best describes how much distress you have been experiencing in the past week including today.

Extreme distress



No distress

Second, please indicate if any of the following has been a problem for you in the past week including today. Be sure to check YES or NO for each.

YES NO Practical Problems

- Child care
- Housing
- Insurance/financial
- Transportation
- Work/school

Family Problems

- Dealing with children
- Dealing with partner
- Ability to have children

Emotional Problems

- Depression
- Fears
- Nervousness
- Sadness
- Worry
- Loss of interest in usual activities

- Spiritual/religious concerns**

YES NO Physical Problems

- Appearance
- Bathing/dressing
- Breathing
- Changes in urination
- Constipation
- Diarrhea
- Eating
- Fatigue
- Feeling Swollen
- Fevers
- Getting around
- Indigestion
- Memory/concentration
- Mouth sores
- Nausea
- Nose dry/congested
- Pain
- Sexual
- Skin dry/itchy
- Sleep
- Tingling in hands/feet

Other Problems: _____

The Need Assessment Measures

Psychological Needs (22 items)	No need, not applicable	No need, satisfied	Low need	Moderate need	High need
Fears about losing your independence	1	2	3	4	5
Fears about losing urine control	1	2	3	4	5
Fears about public embarrassments	1	2	3	4	5
Fears about losing self-respect	1	2	3	4	5
Fear about losing sexual potency/attractiveness	1	2	3	4	5
Confusion about why this has happened to you	1	2	3	4	5
Feeling bored and/or useless	1	2	3	4	5
Anxiety	1	2	3	4	5
Feeling down or depressed	1	2	3	4	5
Feelings of sadness	1	2	3	4	5
Fears about the cancer spreading	1	2	3	4	5
Fears about the cancer returning	1	2	3	4	5
Fears about pain	1	2	3	4	5
Anxiety about having any treatment	1	2	3	4	5
Fears about physical disability or deterioration	1	2	3	4	5
Accepting changes in your appearance	1	2	3	4	5
Worry that the results of treatment are beyond your control	1	2	3	4	5
Uncertainty about the future	1	2	3	4	5
Learning to feel in control of your situation	1	2	3	4	5
Making the most of your time	1	2	3	4	5
Keeping a positive outlook	1	2	3	4	5

Finding meaning in this experience	1	2	3	4	5
Feelings about death and dying	1	2	3	4	5
Concerns about the worries of those close to you	1	2	3	4	5
Changes in usual routine and lifestyle	1	2	3	4	5
Concerns about the ability of those close to you to cope with caring for you	1	2	3	4	5
Health system and information Needs (15 items)	No need, not applicable	No need, satisfied	Low need	Moderate need	High need
Waiting a long time for clinic appointments	1	2	3	4	5
Hospital staff to convey a sense of hope to you and your family	1	2	3	4	5
The opportunity to talk to someone who understands and has been through a similar experience	1	2	3	4	5
To be given written information about the important aspects of your care	1	2	3	4	5
To be given information (written, diagrams, drawings) about aspects of managing your illness and side effects at home	1	2	3	4	5
To be given explanations of those tests for which you would like explanations	1	2	3	4	5
To be adequately informed about the benefits and side effects of treatments before you choose to have them	1	2	3	4	5
To be informed about your test results as soon as possible	1	2	3	4	5
To be informed about cancer that is under control or diminishing (that is, remission)	1	2	3	4	5
To be informed about things you can do to help yourself get well	1	2	3	4	5
To be informed about support groups in your area	1	2	3	4	5
To be informed about the costs of your health care (e.g., stomal appliances and catheters)	1	2	3	4	5
To be informed about financial support with your care	1	2	3	4	5

To be informed about the companies that sell stoma appliances	1	2	3	4	5
To have access to professional counseling (e.g., psychologist, social worker, counselor, nurse specialist) if you/family/friends need it	1	2	3	4	5
To be treated like a person, not just another case	1	2	3	4	5
To be treated in a hospital or clinic that is as physically pleasant as possible	1	2	3	4	5
To be given choices about when you go in for tests or treatment	1	2	3	4	5
To have one member of hospital staff with whom you can talk to about all aspects of your condition, treatment, and follow-up	1	2	3	4	5
Physical and daily living Needs (7 items)	No need, not applicable	No need, satisfied	Low need	Moderate need	High need
Lack of energy/tiredness	1	2	3	4	5
Nausea/vomiting	1	2	3	4	5
Feeling unwell	1	2	3	4	5
Not sleeping well	1	2	3	4	5
Work around the home	1	2	3	4	5
Not being able to do the things you used to do	1	2	3	4	5
Help with stoma care	1	2	3	4	5
Help with catheters	1	2	3	4	5
Help with changing wet bed sheets	1	2	3	4	5
	1	2	3	4	5
Patient care and support (8 items)	1	2	3	4	5
Family or friends to be allowed with you in hospital whenever you want	1	2	3	4	5
More fully protected rights to privacy when you're at the hospital	1	2	3	4	5

More choice about which cancer specialist you see	1	2	3	4	5
More choice about which hospital you attend	1	2	3	4	5
Reassurance by medical staff that the way you feel is normal	1	2	3	4	5
Hospital staff to attend promptly to your physical needs	1	2	3	4	5
Hospital staff to acknowledge, and show sensitivity to, your feelings and emotional needs	1	2	3	4	5
Sexuality Needs (3 items)	No need, not applicable	No need, satisfied	Low need	Moderate need	High need
Changes in sexual relationships	1	2	3	4	5
Changes in sexual feelings	1	2	3	4	5
To be given information about sexual relationships	1	2	3	4	5
To be given information about changes in sexual function after treatment	1	2	3	4	5
To be given information about how to deal with changes in sexual function after treatment	1	2	3	4	5
To receive professional assistance with changes in the sexual function	1	2	3	4	5

Provisional Communication Need Assessment

	No need, not applicable	No need, satisfied	Low need	Moderate need	High need
Talk to the medical staff (e.g., physician, nurse) about cancer treatment and side effects	1	2	3	4	5
Talk to your family/friends about cancer	1	2	3	4	5

treatment and side effects					
Talk to other patients about cancer treatment and side effects	1	2	3	4	5
Talk to the medical staff about my worries and concerns	1	2	3	4	5
Talk to your family/friends about my worries and concerns	1	2	3	4	5
Talk to other patients about my worries and concerns	1	2	3	4	5

SF-12 Questions

8. I am now going to ask you some questions about your health. In general, would you say your health is:

- 1) ___ Excellent,
- 2) ___ Very Good,
- 3) ___ Good,
- 4) ___ Fair, or
- 5) ___ Poor?

9. Does your health now limit you in doing moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf; would you say:

- 1) ___ Yes, limited a lot,
- 2) ___ Yes, limited a little, or
- 3) ___ No, not limited at all?

10. Does your health now limit you in climbing several flights of stairs; would you say:

- 1) ____ Yes, limited a lot,
- 2) ____ Yes, limited a little, or
- 3) ____ No, not limited at all?

11. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health:

a) You accomplished less than you would like; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

b) You were limited in the kind of work or other activities; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

12. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems, such as feeling depressed or anxious:

a) You accomplished less than you would like; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

b) You did work or other activities less carefully than usual; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

13. During the past 4 weeks, how much did pain interfere with your normal work, including both work outside the home and housework; would you say:

- 1) ____ Not at all,
- 2) ____ A little bit,
- 3) ____ Moderately,
- 4) ____ Quite a bit, or
- 5) ____ Extremely?

14. How much of the time during the past 4 weeks have you felt calm and peaceful; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

15. How much of the time during the past 4 weeks did you have a lot of energy; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

16. How much of the time during the past 4 weeks have you felt downhearted or depressed; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

17. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities, like visiting friends and relatives; would you say:

- 1) ____ All of the time,
- 2) ____ Most of the time,
- 3) ____ Some of the time,
- 4) ____ A little of the time, or
- 5) ____ None of the time?

EPIC
The Modified Prostate Cancer Index Composite

The next set of questions ask about your urinary habits. When answering these questions, please consider only the last 4 weeks.

18. Over the past 4 weeks, how often have you leaked urine; would you say:

- 1 ____ More than once a day,
- 2 ____ About once a day,
- 3 ____ More than once a week,
- 4 ____ About once a week , or
- 5 ____ Rarely or never?

19. Which of the following best describes your urinary control during the last 4 weeks; would you say:

- 1 ____ No urinary control whatsoever,
- 2 ____ Frequent dribbling,
- 3 ____ Occasional dribbling, or
- 4 ____ Total control?

20. How many pads or adult diapers per day did you usually use to control leakage during the last 4 weeks: would you say:

- 1 ____ None,
- 2 ____ 1 pad per day,
- 3 ____ 2 pads per day, or
- 4 ____ 3 or more pads per day?

21. Overall, how big a problem has your urinary function been for you during the last 4 weeks; would you say:
- 1 ___ No problem,
 - 2 ___ Very small problem,
 - 3 ___ Small problem,
 - 4 ___ Moderate problem, or a
 - 5 ___ Big problem?

We now have a few questions about your bowel habits and abdominal pain. Once again, please consider only the last 4 weeks.

22. How big a problem, if any, has each of the following been for you: READ EACH STATEMENT IN COLUMN "A" AND THEN READ ALL RESPONSE CATEGORIES IN COLUMN "B".

A

B

STATEMENTS	No Problem,	Very Small Problem,	Small Problem,	Moderate Problem, or	A Big Problem ?
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1. Urgency to have a bowel movement; would you say:	0	1	2	3	4
2. Increased frequency of bowel movements; would you say:	0	1	2	3	4
3. Losing control over your stools; would you say:	0	1	2	3	4
4. Bloody stools; would you say:	0	1	2	3	4
5. Abdominal/Pelvic/Rectal pain; would you say:	0	1	2	3	4

23. Overall, how big a problem have your bowel habits been for you during the last 4 weeks; would you say:

1 ___ No problem,

2 ___ Very small problem,

3 ___ Small problem,

4 ___ Moderate problem, or a

5 ___ Big problem?

The next set of questions is about your current sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Please answer in terms of the past 4 weeks.

24. How would you rate each of the following during the last 4 weeks: READ EACH STATEMENT IN COLUMN “A” AND THEN READ ALL RESPONSE CATEGORIES IN COLUMN “B”, EXCEPT DK/NOTSURE.

A

B

STATEMENTS	Very Poor to None,	Poor,	Fair,	Good, or	Very Good?	DK/NOT SURE
1. Your ability to have an erection; would you say:	1	2	3	4	5	8
2. Your ability to reach orgasm (climax); would you say:	1	2	3	4	5	8

25. Overall, how would you rate your ability to function sexually during the last 4 weeks; would you say:

1 ___ Very poor,

2 ___ Poor,

3 ___ Fair,

4 ___ Good, or

5 ___ Very good?

8 ___ DK/NOT SURE

26. Overall, how big a problem has your sexual function or lack of sexual function been for you during the last 4 weeks; would you say:

1 ___ No problem,

2 ___ Very small problem,

3 ___ Small problem,

4 ___ Moderate problem, or a

5 ___ Big problem?

8 ___ DK/NOT SURE

The next series of questions ask about your hormonal function. Once again, please consider only the last 4 weeks.

27. How big a problem during the last 4 weeks, if any, has each of the following been for you: READ EACH STATEMENT IN COLUMN “A” AND THEN ALL RESPONSE CATEGORIES IN COLUMN “B”.

STATEMENTS	No Problem,	Very Small Problem,	Small Problem,	Moderate Problem, or	A Big Problem?
1. Hot flashes; would you say:	0	1	2	3	4
2. Breast tenderness/enlargement; would you say:	0	1	2	3	4
3. Change in body weight; would you say:	0	1	2	3	4
<u>A</u>	<u>B</u>				

28. Overall, how satisfied are you with the way your prostate cancer was treated, which can include watchful waiting; would you say:

- 1 ___ Extremely dissatisfied,
- 2 ___ Dissatisfied,
- 3 ___ Uncertain,
- 4 ___ Satisfied, or
- 5 ___ Extremely satisfied?

Satisfaction with Health Care – PATSAT32

Please answer all the questions yourself by circling the number that best applies to you. There are no 'right' or 'wrong' answers. The information that you provide will remain strictly confidential.

During your hospital stay, how would you rate doctors, in terms of:

Good (1) Poor (2) Fair (3) Good Very (4) Excellent (5)

- 1 Their knowledge and experience of your illness?
- 2 The treatment and medical follow-up they provided?
- 3 The attention they paid to your physical problems?
- 4 Their willingness to listen to all of your concerns?
- 5 The interest they showed in you personally?
- 6 The comfort and support they gave you?
- 7 The information they gave you about your illness?
- 8 The information they gave you about your medical tests?
- 9 The information they gave you about your treatment?
- 10 The frequency of their visits/consultations?
- 11 The time they devoted to you during visits/consultations?
- 12 The way they carried out your physical examination (took your temperature, felt your pulse,...)?
- 13 The way they handled your care (gave your medicines, performed injections,...)?
- 14 The attention they paid to your physical comfort?
- 15 The interest they showed in you personally?
- 16 The comfort and support they gave you?

During your hospital stay, how Poor Fair Good Very Excellent would you rate nurses, in terms of:

Good (1) Poor (2) Fair (3) Good Very (4) Excellent (5)

- 17 Their human qualities (politeness, respect, sensitivity, kindness, patience,...)?
- 18 The information they gave you about your medical tests?
- 19 The information they gave you about your care?
- 20 The information they gave you about your treatment?
- 21 Their promptness in answering your buzzer calls?
- 22 The time they devoted to you?
- 23 The exchange of information between caregivers?
- 24 The kindness and helpfulness of the technical, reception, laboratory personnel?
- 25 The information provided on your admission to the hospital?
- 26 The information provided on your discharge from the hospital?
- 27 The waiting time for obtaining results of medical tests?
- 28 The speed of implementing medical tests and/or treatments?
- 29 The ease of access (parking, means of transport,...)?
- 30 The ease of finding one's way to the different departments?
- 31 The environment of the building (cleanliness, spaciousness, calmness,...)?
- 32 In general, How would you rate the care received during your hospital stay?

Satisfaction with Communication

How much does it apply to you?	Not Much	A Little	A Fair	Much	Very
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				Amount		Much
1.	I find that doctors don't explain what they are doing to me	0	1	2	3	4
2.	I have difficulty asking doctors questions	0	1	2	3	4
3.	I have difficulty understanding what the doctors tell me about the cancer or its treatments	0	1	2	3	4
4.	I would like to have more control over what the doctors do to me	0	1	2	3	4
5.	I become nervous when I am waiting to see the doctor	0	1	2	3	4

Decisional Regret Scale

Please think about the decision you made regarding accepting active surveillance as your management option for your prostate cancer. Please read the following statements and select the response that reflects how you feel about that decision.

Strongly Agree (1); Agree (2); Neither Agree or Disagree (3); Disagree (4); Strongly Disagree (5)

- was the right decision
- I regret the choice that was made
- I would go for the same choice
- if I had to do it over again
- The choice did me a lot of harm
- The decision was a wise one

The Memorial Anxiety Scale for Prostate Cancer

Below is a list of comments made by men about prostate cancer. Please indicate by circling the number next to each item how frequently these comments were true for

you *during the past week*; not at all, rarely, sometimes, often.

Not at all (0) Rarely (1) Sometimes (2) Often (3)

1. Any reference to prostate cancer brought up strong feelings in me.
2. Even though it's a good idea, I found that getting a PSA test scared me.
3. Whenever I heard about a friend or public figure with prostate cancer, I got more anxious about my having prostate cancer.
4. When I thought about having a PSA test, I got more anxious about my having prostate cancer.
5. Other things kept making me think about prostate cancer.
6. I felt kind of numb when I thought about prostate cancer.
7. I thought about prostate cancer even though I didn't mean to.
8. I had a lot of feelings about prostate cancer, but I didn't want to deal with them.
9. I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind.
10. I was afraid that the results from my PSA test would show that my disease was getting worse.
11. Just hearing the words "prostate cancer" scared me.

II. For the next three questions, please indicate how frequently these situations have *EVER* been true for you.

Not at all (0) Rarely (1) Sometimes (2) Often (3)

12. I have been so anxious about my PSA test that I have thought about delaying it.
13. I have been so worried about my PSA test result that I have thought about asking my doctor to repeat it.
14. I have been so concerned about my PSA test result that I have thought about having the test repeated at another lab to make sure they were accurate.

III. Listed below are a number of statements concerning a person's beliefs about their own health? In thinking about the *past week*, please indicate how much you agree or disagree with each statement: strongly agree (0), agree (1), disagree (2), or strongly disagree (3). Please circle the number of your answer.

- 15. Because cancer is unpredictable, I feel I cannot plan for the future.
- 16. My fear of having my cancer getting worse gets in the way of my enjoying life.
- 17. I am afraid of my cancer getting worse.
- 18. I am more nervous since I was diagnosed with prostate cancer

The Mishel Uncertainty in Illness Scale

Please read each statement. Take your time and think about what each statement says. Then place an "X" under the column that most closely measures how you are feeling TODAY. If you agree with a statement, then you would mark under either "Strongly Agree" or "Agree." If you disagree with a statement, then mark under either "Strongly Disagree" or "Disagree." If you are undecided about how you feel, then mark under "Undecided" for that statement. Please respond to every statement.

1. I have a lot of questions without answers.

Strongly Agree; Agree; Undecided; Disagree; Strongly Disagree

2. I understand everything explained to me.

Strongly Agree; Agree; Undecided; Disagree; Strongly Disagree

3. The doctors say things to me that could have many meanings.

Strongly Agree; Agree; Undecided; Disagree; Strongly Disagree

4. There are so many different types of staff, it's unclear who is responsible

for what.

Strongly Agree; Agree; Undecided; Disagree; Strongly Disagree

5. The purpose of each treatment is clear to me.

Strongly Agree; Agree; Undecided; Disagree; Strongly Disagree

Appendix F

Publications and Conference Presentations

Poster Presented at the DoD- Impact

Title: Treatment Decision-making and Adherence to Active Surveillance in Prostate Cancer Patients

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Background/Objectives: Active surveillance (AS) is recommended for patients with low-risk prostate cancer (LrPC) to prevent overtreatment and maintain sexual and urinary functioning. However, approximately 90% of AS-eligible patients opt for curative treatment and 25-50% discontinue AS within 2-5 years without clinical evidence of cancer progression. Research is necessary to examine patients' unmet informational/supportive care needs and barriers and facilitators of informed decision-making and adherence to AS.

Methodologies: LrPC patients (N=28; mean age, 63.7 years, range: 54-74; 100% Caucasian) were on an AS protocol at the Icahn School of Medicine at Mount Sinai. Data was collected through focus groups, individual interviews, and chart review between January and May 2016. All focus groups and interviews were audio-recorded, transcribed, and analyzed using Atlas.ti software. Qualitative analyses used an immersion/crystallization approach to examine factors contributing to participants' treatment decision-making and continuation/discontinuation of AS.

Results: The majority of patients followed physicians' recommendations (90%) and few searched the Internet for additional information on AS (30%). Factors influencing patients' decisions to opt for AS include trust in their physician's expertise, good intentions, and skills in detecting cancer progression in a timely manner, as well as avoidance of sexual and urinary deterioration associated with LrPC treatment options. The partner's approval of AS played a significant role in the decision to opt for AS. Although, no desire to discontinue AS or decisional regret was reported, participants reported increased anxiety at the time of clinical testing for cancer progression. Lack of information about follow-up care, AS management plan, and delays in follow-up surveillance appointments also contribute to anxiety levels. Financial barriers to AS emerged as a significant concern affecting patients' ability to stay on AS protocol in the future, despite being willing to continue AS.

Conclusions: This study provides insight into patients' treatment decision-making and adherence to AS. We recommend further examination of these issues in ethnic minorities with LrPC and their partners. Psycho-educational interventions and specialist referrals are needed to provide information, regulate emotions, and enhance disease self-management.

Impact: This study has significant implications for LrPC care. Our findings suggest areas for healthcare improvements including enhancing possible system-level determinants of trust, physician-patient communication and closeness, and shared decision-making. Healthcare facilities may be able to adopt organizational changes promoting physician communication skills to increase trust and understanding of patients' and partners' values and preferences.

References

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