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Optimizing Active Surveillance in Low-Risk Prostate Cancer: a Pilot Study

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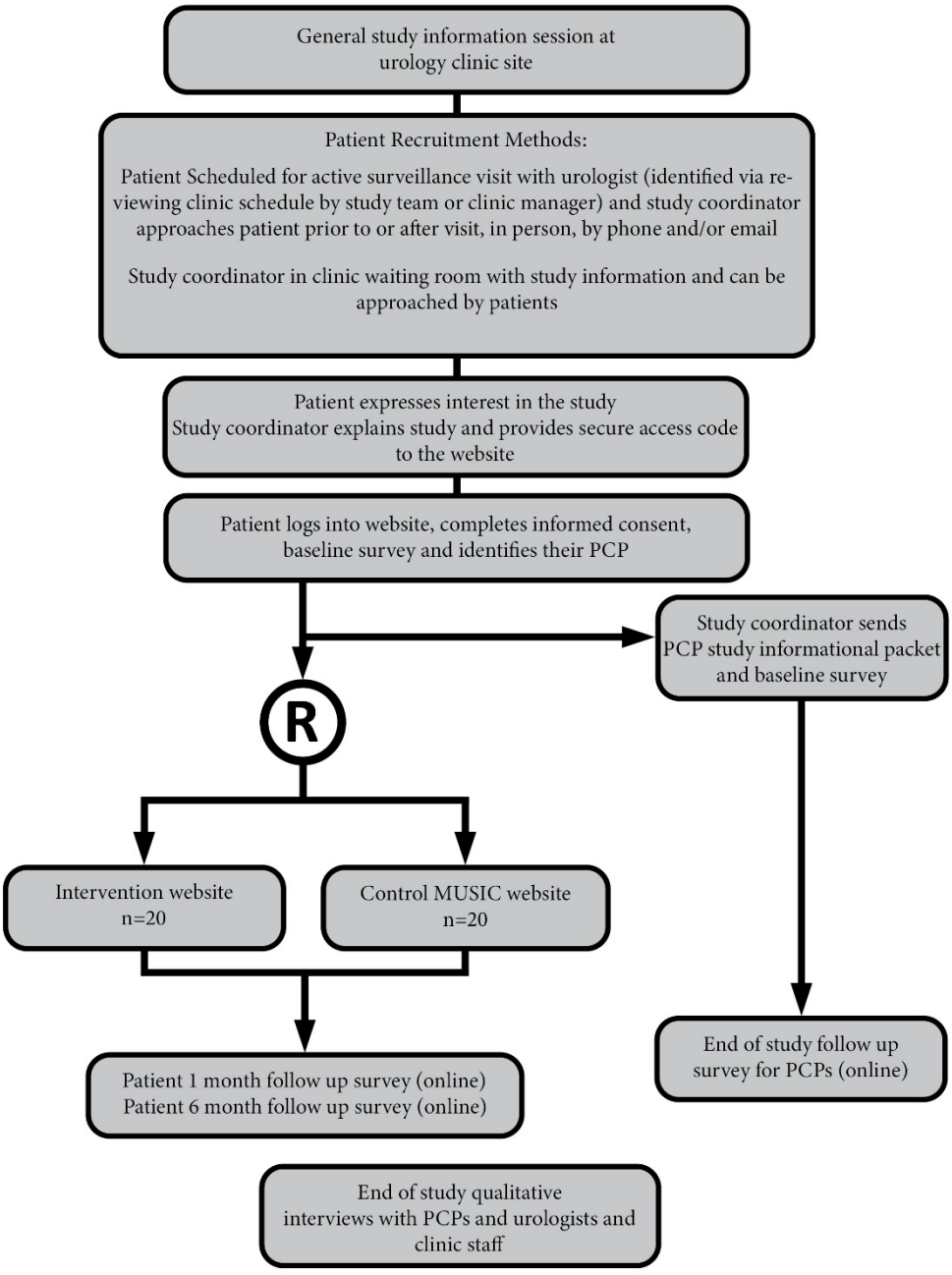
STUDY SCHEMA:



STUDY SUMMARY

The population of older and medically complex cancer patients is growing exponentially, calling for the involvement of primary care providers (PCPs) in team-based models to deliver high-quality care to cancer patients across the continuum. Team-based care is especially needed in light of the rapid growth in diagnoses of low-risk cancers (such as prostate, thyroid, and breast). Not only are these patients typically older and with more comorbidities, but treatment strategies are increasingly moving away from surgery and radiation to active surveillance. Because guidelines for low-risk prostate cancer now recommend active surveillance as the primary disease management strategy, it represents the ideal case for studying how to better engage PCPs. A key gap where PCP involvement can help is in improving adherence to active surveillance; though a growing number of men are choosing this strategy, adherence to active surveillance once chosen, both as a management strategy and to the follow-up protocols, remains suboptimal. Thus, it is critical to understand how to support men with low-risk prostate cancer to maximize adherence to active surveillance and importantly, how to effectively engage PCPs in low-risk cancer management.

The goal of this project is to perform a pilot evaluation of a patient-centered intervention that enables providers to support men on active surveillance to maximize adherence. Conducted in urology practices, this pilot will measure key patient-reported, provider-reported, and implementation outcomes. Successful completion of this work will inform a subsequent multi-center effectiveness-implementation hybrid design trial and ultimately will improve low-risk cancer management by effectively engaging PCPs in care delivery.

1 Objectives/Specific Aims

Aim: Perform a pilot evaluation of the intervention on key patient-reported, provider-reported, and implementation outcomes at urology practices. I will conduct a pilot evaluation of the impact of the patient-centered intervention on two key sets of outcomes.
Our primary outcome includes implementation measures (feasibility, acceptability) assessed via qualitative methods.
Our exploratory outcomes included patient-reported and PCP-reported measures including cancer-anxiety and preference for provider roles in team-based care delivery (patients), and coordination of care and skills (PCP) assessed via pre- and post-test survey study design.

Impact: This work fills a critical gap in supporting men with low-risk prostate cancer to maximize active surveillance adherence, and also lays the foundation for understanding how to effectively engage PCPs in low-risk cancer management. The study findings will provide the basis for a future R01 proposal to evaluate the effectiveness and implementation of a patient-centered tool integrated into primary care delivery systems to maximize active surveillance adherence.

2 Background and Significance

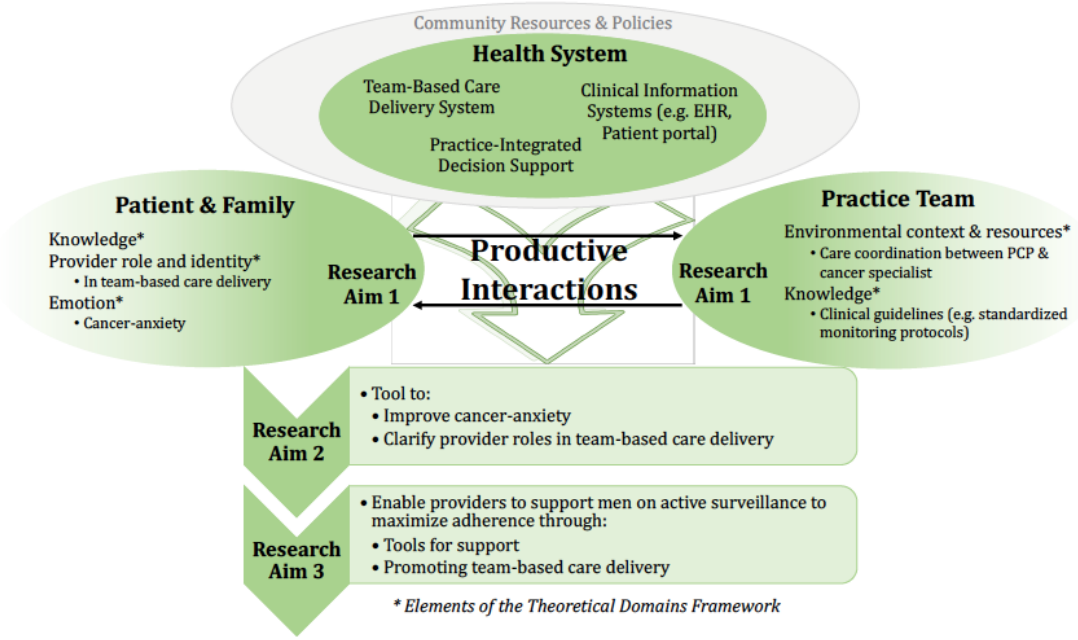
The rapidly growing number of older, medically complex cancer patients creates an urgent demand for increased primary care provider (PCP) involvement in cancer care. By 2040, nearly 75% of cancer patients will be 65 years or older and have a greater comorbidity burden.[1-3] Cancer specialists alone cannot meet the needs of this patient population.[4-6] Therefore, national organizations, such as the American Society of Clinical Oncology, are calling for team-based care models, where PCPs help cancer specialists provide coordinated care to their patients across the cancer continuum.[7-9]

Team-based care delivery is critical as the number of patients diagnosed with low-risk cancers is on the rise. Nearly 80% of newly diagnosed prostate cancers, 90% of thyroid cancers, and 20% of breast cancers are low-risk, with 5-year survival rates nearing 100%.[10-13] Often, these patients are also older and with a higher number of medical comorbidities. Low-risk cancers tend to be indolent where the harms from definitive treatment (with radiation or surgery) potentially outweigh the benefits, which has led to considering conservative treatments such as active surveillance.[14-16] In fact, for low-risk prostate cancer, guidelines now recommend active surveillance as the primary treatment strategy.[17-19] Over the past decade, an increasing number of men have chosen active surveillance, however, continued adherence after the initial choice remains sub-optimal.[20] Up to a third of men pursue definitive treatment even without their cancer progressing.[21-23] This is problematic because definitive treatment can lead to persistent sexual (e.g. erectile dysfunction), and urinary and bowel (e.g. incontinence) symptoms significantly impacting men's quality of life.[24-25]

Ensuring adherence to active surveillance for men with low-risk prostate cancer is challenging. Men endorse significant psychological distress, including discomfort in 'not doing anything' to treat their cancer and perceiving active surveillance as 'too risky' for fear of the cancer progressing.[22,26-29] Active surveillance requires routine clinical examinations, monitoring of prostate specific antigen levels and repeated prostate biopsies to assess tumor burden. However, standardized monitoring protocols vary, leading to significant variation in clinical practice; providers differ on what test to order, when to order the test, and how frequently to order the test. Furthermore, optimal

approaches delineating which provider—urologist or PCP—should be responsible for managing men on active surveillance do not exist.[17] Taken together, these contribute to men's distress with active surveillance adherence: not only does there appear to be uncertainty around determining how and when to pursue definitive treatment for cancer progression, but also which provider will ensure delivery of the appropriate follow-up care. Active surveillance for low-risk prostate cancer management serves as an ideal case study to evaluate how to effectively engage PCPs in team-based cancer care delivery.

Figure 1: Conceptual model for maximizing adherence to active surveillance. We adapt elements of the *Chronic Care Model*, where health system, patient and family, and practice team factors contribute to fostering productive interactions leading to improved outcomes.[30] Our model also incorporates the *Theoretical Domains Framework*, an implementation science framework used to identify behavioral determinants and support behavior change.[31]



PCP expertise in chronic disease management can be better leveraged to support adherence to active surveillance for men with low-risk prostate cancer. First, PCPs can capitalize on their knowledge of comorbidities to take care of these men who are often older and with complex medical needs.[26] Second, PCPs can leverage the longstanding, trusting relationships they have developed with patients to provide psychosocial support.[32-33] The *Chronic Care Model* identifies basic elements to improving care in health systems at organization, practice, and patient levels. We incorporate the Theoretical Domains Framework (TDF) within this model to identify behavioral determinants to inform intervention development to support achieving improved outcomes. Figure 1 outlines our conceptual model to how to ultimately maximize active surveillance adherence. This includes identifying the problem (characterizing patient/family and practice team level perspectives on determinants of active surveillance adherence) (Research Aim 1), applying the knowledge gained to design an intervention addressing identified gaps (e.g., self-management support for cancer-anxiety, clarifying provider roles in team-based care delivery) (Research Aim

2), and pilot evaluation of the intervention to maximize adherence (Research Aim 3).

Our prior work highlights barriers to effectively integrating PCPs in team-based cancer care and suggests areas for intervention. In a population-based survey of women with early-stage breast cancer, their PCPs and medical oncologists, we found significant variation in preferences for which provider—PCP or oncologist—should handle survivorship care.[34] When screening for secondary cancers, a service routinely performed in primary care, 94% of patients, 62% of oncologists and 57% of PCPs preferred the oncologist to handle this service. Using the same survey, we examined the influence of women's worry about breast cancer recurrence: we found that frequent worry was associated with preferring oncologists to handle multiple aspects of survivorship care otherwise routinely provided by PCPs and worry also drove women to prefer more extensive (but not necessary) breast cancer treatment.[35-36] Designing interventions to increase PCP involvement is critical to achieve high-quality cancer care.[37]

Therefore, the goal of this proposal is to characterize provider and patient factors influencing adherence to low-risk prostate cancer active surveillance to inform the development of a patient-centered intervention that enables providers to support men on active surveillance. This proposed work will identify new knowledge that will address gaps in evidence and aid in developing an intervention to improve active surveillance care.

3. Preliminary Data

Patient and provider perspectives on barriers and facilitators (determinants) to active surveillance care delivery. In Aim 1 of this study (HUM00175929), we conducted interviews with 15 patients and their partners, 15 urologists, and 19 PCPs. Guided by the Theoretical Domains Framework (TDF), interview questions probed about determinants to active surveillance adherence. Using qualitative analytic methods, several themes were discussed by providers (urologists and PCPs) and patients. These include knowledge and lack of clarity in provider roles in team-based care delivery. While providers discussed the importance of having an informed patient, patients reported not knowing what follow-up testing was required. Patients who understood what active surveillance entailed as a treatment strategy and were aware of the follow-up monitoring could then actively participate in their care. Both urologists and PCPs viewed urologists as being primarily responsible for active surveillance care and the PCP role to be supportive. PCPs were willing to be involved active surveillance management but wanted explicit guidance from the urologist. These themes informed the development of a web-based tool for patients to maximize adherence to active surveillance.

Expertise in intervention development and evaluation, and implementation science. In Aim 2 of this study (HUM00175929), we are currently developing a web-based tool to support patients on active surveillance to maximize adherence. Two specific interventions previously developed, and pilot tested by members of this team (*iCanDecide* and *ConnectedCancerCare*) provide the framework and basis for the intervention. Modules from both of these interventions will be adapted and refined for the tool developed in this study. First, *iCanDecide*, developed by Dr. Sarah Hawley, is an interactive breast cancer treatment decision tool for women with early-stage breast cancer considering locoregional and systemic treatment. The tool is comprised of knowledge-building and patient activation modules and includes a values-clarification and feedback exercise. Women who used the tool (vs. standard website) were more prepared and reported higher quality

with their decision. Second, *ConnectedCancerCare*, designed by Dr. Lauren Wallner, is a patient- and provider-level intervention targeting women with breast cancer as they transition from treatment to survivorship. The patient-facing website educates patients about breast cancer survivorship guidelines, clarifies provider roles in team-based cancer care, and provides patients with tailored tips to communicate with their oncologist and PCP. The tool also relays results to the patient's PCP and medical oncologist through personalized feedback letters. Women who used the tool (vs. static online survivorship care plan) were more likely to communicate with their PCP about provider roles and reported higher team-based cancer care knowledge scores.

4 Methods

4.1 Design

We aim to conduct a randomized controlled pilot trial to evaluate a patient-centered intervention on key implementation, patient-reported, and provider (PCP)-reported outcomes. We will recruit a total of 40 men with low-risk prostate cancer on active surveillance from urology practices. Patients will be randomized to an intervention (N=20 patients) which will involve a web-based tool with modules on active surveillance education, team based active surveillance care delivery and the role of the PCP, and self-management for cancer anxiety and worry. The control arm (N=20) will receive usual care. MUSIC urologists are all encouraged to refer their patients to the patient educational materials on the MUSIC website (http://www.musicurology.com/patientmaterials/). Patients in the control arm will be provided this link. Implementation outcomes (primary outcome) will be assessed via patient survey (1 month after study enrollment) and interviews with providers (at the end of the study). Patient-reported outcomes (exploratory outcome) will be assessed via survey 1 month and 6 months after study enrollment. PCP-reported outcomes will be assessed via survey upon study completion.

4.2 Subject Recruitment

Patient: We will use methods successfully used by members of this team (Drs. Hawley (HUM00062261) and Wallner (HUM00115786)) for subject recruitment. We will recruit 40 men with low-risk prostate cancer on active surveillance from the University of Michigan urology clinics. Eligible patients will be identified and recruited using several strategies including: 1) a study coordinator will review the EMR for patients with upcoming scheduled urology visits for active surveillance; 2) a clinic manager will provide a weekly list of patients with scheduled urology visits for active surveillance; 3) we will post flyers in the clinic waiting room with information about the study for interested patients; and 4) a study coordinator will sit at a table in the clinic waiting room with study flyers. In all cases, once a patient expresses interest in the study, a study coordinator will verify eligibility. The study coordinator will then discuss the following study materials with the patient (in-person if in clinic or over the telephone): an introductory letter describing the study and its risk and benefits, a $20 up-front cash incentive, link to website for the tool, log-in information, and $50 conditional incentive upon completion of the study. For patients in clinic, the study coordinator will provide patients with the option to view the tool website via laptop computer or iPad. When a patient visits the website, they will complete an electronic informed consent, provide their preferred contact information for follow-up (create an account), and complete a short baseline survey to collect data on the potential outcomes we anticipate will be influenced by the

intervention. Participants will then be able to use the tool. The study coordinator will verify subject's enrollment into the study via their completion of the consent form on the website and baseline survey.

PCP: All PCPs will be identified by patients in their baseline survey. The study coordinator will send an informational packet to the PCP and a baseline survey to the PCP (via email or mail), which will include an informed consent for the survey with the option to consent to recontact for qualitative interview purposes. If a PCP consents to be recontacted, we will email them at the end of the study, inviting them to participate in debriefing qualitative interviews. Verbal consent will be obtained at the beginning of the interview. We will offer a $50 eGift card or up-front Cash incentive for PCPs that complete the baseline survey, and another $50 eGift card for PCPs that complete the debriefing qualitative interviews.

Urologists and clinic staff: Urologists and clinic staff will be identified from the urology clinics that agree to participate in our study. At the end of the study, we will email all urologists and practice staff as appropriate, inviting them to participate in debriefing qualitative interviews. Verbal consent will be obtained at the beginning of the interview.

4.3 Eligibility Criteria

4.3.1 Patient Inclusion Criteria

1) 55 years old or older
2) Men diagnosed with low-risk prostate cancer currently on active surveillance
3) Men who identify having a primary care provider
4) Access and ability to use the Internet

4.3.2 Patient Exclusion Criteria

5) Men who are unable to read and/or speak English
6) Men with impaired decision-making capacity (such as with a diagnosis of dementia or memory loss)

4.3.3 PCP Inclusion Criteria

1) Identified by patient on baseline survey as their PCP

4.3.4 Urologist and Clinic Staff Inclusion Criteria (Qualitative Interviews Only)

1) Clinicians or staff at a participating urology clinic, including but not limited to MDs, APPs, and nurses

4.4 Intervention

Overview: The intervention is a patient-centered, web-based tool that will address determinants to active surveillance adherence. The aim of this pilot study is to determine whether the tool can improve patients' adherence to active surveillance.

Pre-intervention planning: We will apply a previously proven approach to prepare practices and inform providers of the pilot study.[37] At each practice site, we will conduct a 15-20 minute informational session for the urologists and clinic staff to engage them in the study. We will review the background leading to our pilot, including a general description of the landscape of the current problems with AS care delivery (e.g. coordination of care between PCPs and urologists, lack of clarity in provider roles for both providers and patients) and highlighting findings from our own data from Aim 1 characterizing determinants to AS care delivery. Additionally, during the session, we will review the study design and how the intervention will be deployed in each practice. Concerns and feedback received during the presentation regarding the intervention and/or study design will be incorporated prior to rollout of the intervention.

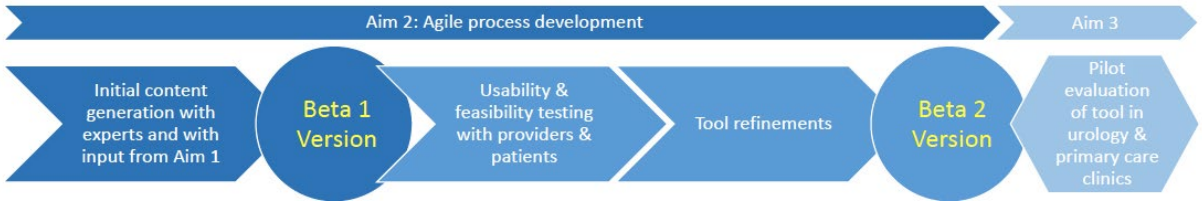
Content: The content of the web-based tool is informed by findings from Aim 1 (HUM00175929), adapts from the existing tools (*iCanDecide* and *ConnectedCancerCare*), and refined with input from clinical experts (urologists and PCPs). Similar to *ConnectedCancerCare*, our tool includes content on: a) eliciting patient's concerns about and expectations for active surveillance management; b) educating patients about key aspects of active surveillance as a management strategy (e.g. current recommendations for monitoring protocols); c) addressing problems with active surveillance care delivery (e.g. uncertainty with management, team-based care between urologists and PCPs) and providing *tailored* content for patients regarding d) managing cancer-anxiety, and e) clarifying provider roles in team-based active surveillance care delivery (Table 1).

Table 1: Anticipated tool content

Elicit	– Concerns regarding active surveillance – Provider role preferences in team-based care delivery	
Educate	– About active surveillance management	
Address	– Uncertainty with active surveillance management – Lack of care coordination between urologists and PCPs	
Manage	– Cancer-anxiety	*Tailored content*
Clarify	– Provider roles – Promote team-based care delivery	

Development: This will follow established CHCR methods for tool development (shown in Figure 2), using an agile process to plan (generate content), design (graphics and media), develop (programming) and test (stakeholder feedback on draft versions) the tool (currently ongoing, HUM00175929).

Figure 2: Steps to tool development



Provider summary: PCPs of patients randomized to the intervention website will receive a visit summary from the urologist. The study coordinator will addend the urologist's clinic note (most

recent clinic note from the time that the patient was recruited into the study) to specifically list the follow-up monitoring protocol for the patient on active surveillance. This includes the testing type and frequency and importantly, which provider (urologist or PCP) will be responsible for ordering and reviewing results. The study coordinator will pull the content for the addendum from the clinic note, however, if there is any uncertainty, the study coordinator will clarify with the urologist. Visit summaries will be routed through the electronic medical record for all PCPs within the same medical system as the urologist and for those PCPs outside the medical system, their contact information will be used to fax the visit summary. PCPs of patients in the control arm will not receive a visit summary.

4.5 Time and Events Table

All timepoints have a window of +/– 14 days. Please see Section 6 for details on data collection.

Patient Calendar	Day 1	Month 1	Month 6
Informed Consent	X		
Baseline Survey	X		
Intervention Access & Paradata collection	X		
Follow-up Surveys		X	X

PCP Calendar	Day 1	End of Study
Informed Consent	X	
Baseline Survey	X	
Intervention Access	X	
Follow-up Survey and Qualitative Interviews*		X

*Qualitative Interviews will be performed with a subset of PCPs who consent to be contacted.

Urologist/Clinical Staff Calendar	Start of Study	End of Study
Informational Session	X	
Qualitative Interviews (informed consent)		X

* The start of study refers to time prior to when patient recruitment begins when we will be conducting our pre-intervention planning. The end of study refers to the time after the intervention has been delivered to the patients. We specifically choose this time frame to conduct debriefing interviews with PCPs and urologists to allow providers to reflect on the totality of their experiences with patient(s) in the study.

5 **Measures**

We will collect key outcomes in this pilot study we believe will be impacted by the tool. Our primary outcomes include implementation measures of feasibility and acceptability.

Primary outcomes: implementation
Feasibility asks, “how well can this study be carried out within the clinical setting?” and will be defined by the successful recruitment of 40 patients. We will measure the proportion of men who consented to the study, successfully completed the baseline and follow-up surveys.

Acceptability asks the extent to which participants consider the intervention is agreeable. Patients in the intervention arm will answer questions (on a 5-point Likert scale) regarding the use of the tool including: a) the tool provided me the necessary information about being on active surveillance; b) the tool helped me know what tests I needed and when; c) the tool helped me understand what my PCP can do for my active surveillance; d) the tool was easy to use; e) the amount of time it took to go through the website; and f) I would recommend the tool to other patients. We will ask an open-ended question on if the tool should have any other features in future versions. We will additionally collect paradata such as user actions (clicks) and time spent on each webpage.

Exploratory outcomes: patient-reported and PCP-reported measures

Our exploratory outcomes include patient-reported and PCP-reported measures.

- Patient-reported measures will include knowledge of active surveillance (as a management strategy, follow-up protocols), cancer-anxiety, preferences for provider roles in team-based care (urologist vs. PCP), communication with providers, and utilization.
    - A limited number of survey questions will be verified with the medical record
    - No PHI will be recorded, only “yes/no” to specific questions outlined in the “6Month EMR verification CRF”
- PCP-reported measures will include knowledge about low-risk prostate cancer management, specifically with active surveillance and attitude and beliefs about coordination of care between urologists and PCPs and PCP skills in low-risk prostate cancer management.

The measures were selected after literature review, reflect our conceptual model, and were adapted from our prior work.

Patient-reported outcomes
We will collect patient-reported outcomes at baseline, at 1 month and 6 months after study enrollment for both the intervention and control groups.
a) demographics (age, race/ethnicity, marital status, highest education level attained, income, primary insurance) and medical history (year diagnosed with low-risk prostate cancer, year(s) on active surveillance, comorbidities).

b) knowledge of active surveillance as a management strategy: will be assessed as true/false statements

c) knowledge of active surveillance follow-up protocol: will be assessed as true/false statements

d) cancer anxiety: we will use the Memorial Anxiety Scale for Prostate Cancer which is a validated survey that measures prostate cancer anxiety, PSA anxiety and fear of recurrence of prostate cancer.

e) preferences for provider roles in team-based care (urologist vs. PCP):
Which provider would you prefer to manage the following aspects of your active surveillance care? Urologist vs. PCP vs. Shared (PCP and urologist both should share the responsibility)

-Ordering my PSA test to monitor for my cancer progression
-Checking to see if I am anxious or worried about my cancer
-Helping me manage my anxiety or worry about my cancer
-Making sure I schedule my follow-up urology appointment
-Ordering and helping me understand my follow-up test results for my active surveillance

f) communication with providers: we will ask patients about their communication with both their urologist and PCP. All responses will be on a 5-point Likert scale.
With urologist:

-I am confident discussing any questions or concerns I have about active surveillance with my urologist
-I am likely to reach out to my urologist about any questions or concerns I have about active surveillance

With PCP:

-I am confident discussing any questions or concerns I have about active surveillance with my PCP
-I am likely to reach out to my PCP about any questions or concerns I have about active surveillance

g) utilization (to be only asked at 6 month follow-up survey): we will ask patients about their AS follow-up including visits to the urologist and PSA testing

-have you seen your urologist since your last visit (y/n)?
    -if not, do you intend on seeing your urologist?
        -if yes, do you have an appointment scheduled?
-have you had a follow-up PSA from the time of your last visit (y/n)?
    -if not, do you intend on getting a follow-up PSA?
        -if yes, do you have a PSA test ordered?

PCP-reported outcomes:
We will collect PCP-reported outcomes at baseline and/or upon study completion for all PCPs.
a) demographics (age, race/ethnicity), training (year residency completed), practice characteristics (setting, size), and patient panel characteristics (number of days PCP is in clinic, number of patients seen on a typical clinic day)

b) knowledge about low-risk prostate cancer management, specifically with active surveillance

c) coordination of care between urologists and PCPs: we will ask PCPs about their perceptions on coordination of care with urologists. All responses will be on a 5-point Likert scale.

Thinking about how you deliver follow-up care for men who are on active surveillance for their low-risk prostate cancer, how often do you:

-Receive a summary from the urologist with detailed recommendations for follow-up care
-Receive information from the urologist in a timely manner
-Communicate with the urologist about which physician will follow the patient for their cancer care
-Discuss with the patient whether you or the urologist will follow them for their cancer care

d) skills in low-risk prostate cancer management: will ask PCPs about their perceptions on skills to manage men with low-risk prostate cancer on active surveillance. All responses will be on a 5-point Likert scale.

-PCPs have the skills necessary to provide care related to the effects of low-risk prostate cancer or its treatment (e.g. monitoring for late- or long-term effects)
-PCPs have the skills necessary to monitor men on active surveillance for the progression of low-risk cancer
-PCPs should have the primary responsibility to monitor men on active surveillance for the progression of low-risk cancer
-PCPs are better able than cancer specialists to provide psychosocial support
-In general, PCPs should be a key part of the patient's care team for their low-risk prostate cancer

6 Procedures

6.1 Data Collection

Patient baseline survey: Patients are asked to complete a baseline survey after they have enrolled in the study. All patients will receive an automated email reminder 7 days after starting the baseline survey if the survey remains incomplete, and up to 5 phone contacts from the study coordinator within 14 days if the survey remains incomplete.

Patient Follow-up survey: The study coordinator will employ a modified version of the Dillman method to encourage survey response:

- One month and 5 months from completion of the baseline survey, patients will receive a 1-week advance email alert to complete the follow-up survey
- 2-3 weeks after the initial automated follow-up survey notification, site staff will begin calling individuals who have not completed the survey. The purpose of these calls is to clarify questions, explain confidentiality procedures, and encourage participation. At least 5 calls will be made to reach the patient, including nights and weekends as necessary.
- If patient is unable to be contacted, the study team will conduct additional tracing to try and find updated contact information.
- 2 weeks later, if patient still has not completed the survey and has not opted out, site staff will send a reminder postcard encouraging online survey completion.
- For those who remain non-responders after 2 additional weeks, a second survey notification email will be sent.

- 2 weeks later, if still unsuccessful, study team will make additional attempts to encourage survey completion via phone calls and reminder letters. This will continue to occur every 2-3 weeks until attempts to convert survey response have been exhausted. Our study team has been engaged in survey work for decades and will utilize our wealth of expertise to determine when further attempts to convert response are likely to prove useless. Study team will cease efforts if a patient opts out. As surveys are returned, study team will review for missing data. If items appear to be inadvertently missed (as opposed to intentionally skipped), staff will contact patients to obtain the missing information.

PCP baseline survey: Once identified, site coordinator will send PCPs an informational study packet describing the intervention through mail/email. PCPs will be asked to complete a baseline survey (received with their informational study packet). An automated email reminder will be sent 7 days after starting the baseline survey if the survey remains incomplete, and up to 3 phone contacts from the study coordinator will be made within 1 month if the survey remains incomplete.

PCP Follow-up survey: The study coordinator will employ a modified version of the Dillman method[38] to encourage survey response:

- One month from completion of the study, PCP will receive an advance email alert to complete the follow-up survey.
- 2-3 weeks after the initial automated follow-up survey notification, site staff will begin calling PCPs who have not completed the survey. The purpose of these calls is to clarify questions, explain confidentiality procedures, and encourage participation. At least 5 calls will be made to reach the PCP.
- If the PCP is unable to be contacted, the study team will conduct additional tracing to try and find updated contact information.
- 2 weeks later, if PCP still has not completed the survey and has not opted out, site staff will send a reminder postcard encouraging online survey completion.
- For those who remain non-responders after 2 additional weeks, a second survey notification email will be sent.
- 2 weeks later, if still unsuccessful, study team will make additional attempts to encourage survey completion via phone calls and reminder letters. This will continue to occur every 2-3 weeks until attempts to convert survey response have been exhausted.

Qualitative interviews: The study coordinator and/or PI will conduct interviews each with 2-3 PCPs and 2-3 urologists and clinic staff as appropriate at the end of the study to understand whether the tool was useful (both to them as providers supporting their patient and to patients), to discuss barriers and facilitators to implementation of the tool into their clinical practice (e.g., how well was it incorporated into their usual clinical care?), and receive general feedback on improvements to inform future implementation of the tool. Interviews will be conducted via Zoom or phone.

6.2 **Data Management**

The website applications that CHCR develops are hosted and managed on virtualized servers provided by Michigan Medicine HITS.

All servers and the back-end databases (for data storage) are password protected. The server runs the RedHat Linux Enterprise operating system. Security patches and updates are downloaded and installed automatically. Each server is also protected by firewalls to restrict network access to the server. The data collected from participants is stored separately from the application (per Standard Practice Guidelines) on databases also acquired from Michigan Medicine HITS.

Servers and databases used by CHCR includes the safeguards required by HIPAA and may be used to maintain Protected Health Information. The system that CHCR develops goes through an independent security review with Michigan Medicine Information Assurance. This review includes requirements such as: a code review, vulnerability scans, and penetration testing (to determine if there are any hackable risks).

When a participant accesses the study website, content will be transmitted securely using the Transport Layer Security (TLS) protocol, the same protocol used to protect financial and other personal information when transmitted from a web site to a user's browser. This prevents anyone else on the network from intercepting and viewing the content that is being provided by or to the participant.

The intervention platform will collect survey data from patient and relative participants throughout their use of the website. This will include:

- Information entered by patient participants during personalization of the intervention
- Patient contact information, entered during account creation
- Provider contact information, entered by patients during the invitation process
- Patient baseline and follow-up survey data

The website also automatically tracks and records paradata such as user actions (clicks) and time spent on each webpage.

Patient baseline, 1 month and 6 month surveys: Patient surveys will be hosted via UM Qualtrics and patients will be asked to complete the applicable survey at baseline, 1 month and 6 months. Patients will be invited via email to complete the electronic survey. All digital records produced will be de-identified and stored in the University of Michigan DropBox system, a secure and password protected online document storage system. These files will only be accessible to the PI and study staff.

PCP baseline and follow up surveys: PCP surveys will be hosted via UM Qualtrics and PCPs will be asked to complete the applicable survey at baseline and end of study. Participants will be invited via email to complete the electronic survey. All digital records produced will be de-identified and stored in the University of Michigan DropBox system, a secure and password protected online document storage system. These files will only be accessible to the PI and study staff.

PCPs also have the option to request a paper survey. Site coordinators will send the paper survey through the mail if requested, including a self-addressed stamped envelope to return the

completed survey. Paper surveys will be de-identified and stored in a locked cabinet only accessible to study staff. These surveys will be entered into the Qualtrics system and will be destroyed as soon as the data is verified.

Qualitative interviews: All digital records (Zoom recordings, transcripts or any other digital forms of data) produced outside of the CHCR system will be de-identified and stored in the University of Michigan DropBox system, a secure and password protected online document storage system. These files will only be accessible to the PI and study staff.

7 Data Analysis

7.1 Analysis Plan

As this is a pilot study to examine feasibility and acceptability and inform development of the final study protocol and intervention, the analytic plan is mostly descriptive in nature and no formal statistical testing is planned.

Feasibility will be defined by the successful recruitment of 40 patients. In addition, we will assess the proportion of men recruited who complete the baseline and follow-up surveys.

Acceptability: we will describe the distribution of each of the six measures of acceptability. For any measure with a mean score <3, we will use this information to inform future adaptations of the tool to improve acceptability. Similar to what we have done in our prior studies (HUM00192638, HUM00115786), we will create a summary score of acceptability by averaging the responses to the six items; a score of >=3 will indicate the tool was acceptable to the patient. We will describe the distribution of the summary score and calculate the proportion of patients with a score of >=3.

Exploratory outcomes: we will explore several secondary patient-reported and PCP-reported outcomes including patient – knowledge, cancer anxiety, provider role preferences, communication with providers, utilization and PCP – knowledge, coordination of care and skills in low-risk prostate cancer management. We will summarize each measure using descriptive statistics. We will then use chi-square tests or two-sided t-tests as appropriate to compare the measures between patients in the intervention and control arms and PCPs in the intervention and control arms.

Interviews: all interviews with providers and clinic staff will be audio-recorded and transcribed by a professional service. The study team, including the PI, will review all transcripts to identify what patients and providers noted as working or not working with the intervention. Overall themes related to usefulness of the tool and barriers and facilitators to implementation in clinic will be described, and these will then be used to adapt future iterations of the tool and guide its implementation to broader clinical settings. We will use NVivo statistical software to conduct our qualitative analyses.

8 Protection of Human Subjects

This study expects no more than minimal risk as the primary potential risk to our study participants is breach of confidentiality of personally identifiable information (PII) and/or protected health information (PHI). This risk is low, given the strategies the research team will implement to minimize risk of breach of confidentiality to participants. Data will be deidentified before being shared between study members when feasible; consent will be obtained prior to any use of identifiable data; shared data will be kept to the minimum required to accomplish the work and will be transmitted securely; IRB approvals will be obtained; all staff involved in this work will complete and maintain protection of human subjects training; and the staff involved will be restricted to the minimum number necessary to conduct the work.

Patient participants will be offered a $20 up-front cash incentive, and a $50 eGift card upon completion of the 1-month and 6-month follow-up survey. Qualitative interview participants (PCPs, urologists and clinic staff) will also be given a $50 eGift card upon completion of the qualitative interview.

9 Data and Safety Monitoring

This study will be monitored in accordance with the NCI approved University of Michigan Rogel Cancer Center Data and Safety Monitoring Plan.

The study team will meet every six months or more frequently depending on the activity of the protocol. The discussion will include matters related to the safety of study participants (SAE/UaP reporting), validity and integrity of the data, enrollment rate relative to expectations, characteristics of participants, retention of participants, adherence to the protocol (potential or real protocol deviations) and data completeness. At these regular meetings, the protocol specific Data and Safety Monitoring Report form will be completed and signed by the Principal Investigator or by one of the co-investigators.

Data and Safety Monitoring Reports will be submitted to the University of Michigan Rogel Cancer Center Data and Safety Monitoring Committee (DSMC) every six months for independent review.

10 Adverse Event Reporting

Adverse events related to this study are not expected. However, any adverse events resulting from research procedures will be reported to IRBMED per institutional guidelines.

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12 Appendices

Memorial Anxiety Scale for Prostate Cancer (MAX-PC)©18-Items

YOUR FEELINGS ABOUT PROSTATE CANCER AND PSA PROSTATE SPECIFIC ANTIGEN TESTS

We would like to better understand how patients cope with aspects of their treatment for prostate cancer and the medical tests frequently involved in their care.

I: 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, or Often.

	Not At All	Rarely	Sometimes	Often
1. Any reference to prostate cancer brought up strong feelings in me.	0	1	2	3
2. Even though it's a good idea, I found that getting a PSA test scared me.	0	1	2	3
3. Whenever I heard about a friend or public figure with prostate cancer, I got more anxious about my having prostate cancer.	0	1	2	3
4. When I thought about having a PSA test, I got more anxious about my having prostate cancer.	0	1	2	3
5. Other things kept making me think about prostate cancer.	0	1	2	3
6. I felt kind of numb when I thought about prostate cancer.	0	1	2	3

7. I thought about prostate cancer even though I didn't mean to.	0	1	2	3

	Not At All	Rarely	Sometimes	Often
8. I had a lot of feelings about prostate cancer, but I didn't want to deal with them.	0	1	2	3
9. I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind.	0	1	2	3
10. I was afraid that the results from my PSA test would show that my disease was getting worse.	0	1	2	3
11. Just hearing the words "prostate cancer" scared me.	0	1	2	3

II. For the next 3 questions, please indicate how frequently these situations have *EVER* been true for you.

	Not At All	Rarely	Sometimes	Often
12. I have been so anxious about my PSA test that I have thought about delaying it.	0	1	2	3
13. I have been so worried about my PSA test result that I have thought about asking my doctor to repeat the test.	0	1	2	3
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 the test results were accurate.	0	1	2	3

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 Disagree, Disagree, Agree, or Strongly Agree. Please circle the number of your answer.

	Strongly Disagree	Disagree	Agree	Strongly Agree
15. Because cancer is unpredictable, I feel I cannot plan for the future.	0	1	2	3
16. My fear of having my cancer getting worse gets in the way of my enjoying life.	0	1	2	3
17. I am afraid of my cancer getting worse.	0	1	2	3
18. I am more nervous since I was diagnosed with prostate cancer.	0	1	2	3