Revision History of Project Research Protocol

Version	Summary of Revisions Made	Rationale
Version 1 11-25-2019	Original	
Version 2 05/05/2020	Procedures updated to include option to complete activates online	Need to address COVID-19 restrictions to meet with patients
Version 3 09/30/2020	Item #4: Clarify the use of MS One Drive to share project files and data among the research team, and update text to address clinical sites requirements.	Request of ORSP to include a note about the system used to share documents/data with team members. Request of clinical sites to include a note in patients' electronic records regarding their participation in the study

Study Title: Fostering Shared Decision-Making about Prostate Cancer Screening among Clinicians and African American men

Sponsor: NIMHD (2U54MD007595): April 2019 - Dec 2023

Grantee: Xavier University of Louisiana (XU)

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XU-IRB #: 684, full IRB approval granted Dec 18, 2019. Version 2 ammendment approved May 7, 2020
Clinical Trial Registration #: NCT03869216

Clinical sites: Clinics offering annual physicals and preventive care:
1. University Medical Center New Orleans (UMCNO): Tulane Internal Medicine
2. Tulane downtown: Internal Medicine Clinic, Living Well Primary Care Clinic, LaSalle Med-Peds Clinic
3. Tulane uptown: Uptown Square Multispecialty Center
4: Tulane Metairie: Lakeside Specialty Clinic, Heart & Vascular Primary Care Clinic
Updates to respective IRBs and regulatory Committees will be submitted to all sites joining the study

Study Objective: Advance the translation path of implementing the shared decision-making (SDM) process regarding prostate specific antigen (PSA) screening in the clinical setting.

Study design: *Behavioral* randomized clinical trial (under new NIH definition) to compare the efficacy of an educational intervention (training) vs usual care in increasing patient engagement in SDM and the quality of the provider-patient SDM process (Clinical Trials Registration: NCT03869216).

Study Outcomes: The primary outcome will be the extent to which patients and clinicians engage in SDM during the medical encounter following receipt of the intervention or control. Two secondary outcomes include *Patient quality of decision-making process* (knowledge, decisional confidence, self-efficacy, and satisfaction) and *Preference-congruent decision making* to examine whether patient preferences for or against receiving PSA-based screening align with care received (actual receipt of PSA test, extracted from the electronic medical record).

Subjects: 200 African American men, 40-69 years old, with NO diagnostic of prostate cancer, who are receiving primary care (annual physicals and preventive care) at the clinical sites during the project period (2020-2023).

Intervention: Patients will be randomly assigned to receive a 30-45 minute online educational intervention (n=100) or control group (n=100). Patients receiving the training will learn about prostate cancer (risk, screening, diagnoses and treatment), PSA-based screening (benefits, risks, harms, and guidelines), and SDM process (options, perceptions, preferences, actions). In order to measure the application of the SDM process in the clinical setting (primary outcome), patients will discuss the PSA test with their respective primary care provider (PCPs) during a medical wellness visit (annual checkup). The conversation will be audio-recorded, after patient/PCP's asent, and evaluated to identify the application of the different components of the SDM process. If the audio-recording is not authorized, the patient and PCP will complete an evaluation survey about the encounter. Patients will complete online surveys at enrollment (baseline), during the training (pre-post test), and 3-months after medical encounter (follow-up).

Enrollment: Searches in electronic medical records will be conducted to pre-screen and invite (mail, calls, and emails) elegible patients and their respective PCPs to join the study. Patients will complete in-person or online consent and HIPPA authorizations. PCPs' will complete an online baseline survey and provide implicit consent to join the study.

RESEARCH PROTOCOL

Study Title: Fostering Shared Decision-Making about Prostate Cancer Screening among Clinicians and African American men

1. Study aim, background, and design

Despite years of aggressive prostate cancer (PrCa) screening practices and declines in mortality in the U.S., African American men (AAM) still have the highest PrCa incidence and mortality rates. Not only is PrCa the most common cancer in AAM but a substantial proportion of AAM have earlier age of onset, increased proportion of clinically advanced disease, and increased mortality from PrCa compared to white men. The 2018 U.S. Preventive Services Task Force (USPSTF) prostate cancer screening guidelines recommend that providers and patients engage in shared decision making about prostate-specific antigen (PSA)-based screening (Grossman et al, 2018). Through shared decision making, primary care providers (PCPs) can empower patients to understand their personal risk and the benefits, harms, and uncertainty of PSA-based screening in order to make an individualized decision as to whether screening is right for them.

African Americans in U.S. represent 12.6% of the total population, but they represent 32% of Louisiana population and 60% of the New Orleans area (U.S. Census, 2010). Louisiana has the 2nd highest incidence and 7th highest mortality rate of PrCa in the U.S. (Giancola et al, 2016; Maniscalco et al, 2017). We have a unique and timely opportunity to continue our efforts to address barriers to cancer health literacy and shared decisions among African Americans and leverage the application of the USPSTF guidelines.

The proposed study is a behavioral randomized clinical trial (RCT) to advance the translation path of implementing the shared decision-making (SDM) process regarding PSA-screening during clinical encounters. The RCT involves 200 African American male (AAM) patients who are receiving care at the respective clinical site during the project period. The aims of this study are to: 1) assess the efficacy of the intervention in increasing patient engagement in SDM, 2) assess the efficacy of the intervention in improving the quality of the provider-patient SDM process, and 3) evaluate the acceptability of the intervention and procedures through a process evaluation.

The study will compare an intervention for AAM patients versus a usual care control group. The intervention will use multimedia educational training materials to increase patients' understanding of prostate cancer (risk, screening, diagnoses and treatment), PSA-based screening (benefits, risks, harms, and guidelines), and shared decision making process (options, perceptions, preferences, actions). Patients will be randomly assigned to the intervention or control group. A battery of instruments will be applied in several intervals during the study period to collect pre-post and follow-up data. Generalized linear mixed models will be used to test our hypotheses that 1) the intervention will increase provider-patient engagement in SDM and 2) patients in the intervention arm will have higher decision confidence and satisfaction, and preference-congruent decision making than those in the control group. ANOVAs and chi-square tests will assess group differences on PCPs and patient characteristics.

2. Subject Population

Participants: During the study period we expect to recruit 200 male patients who: 1) self-identify as African American; 2) are 40-69 year old; 3) are currently a patient of a study clinical site; and 4) are able to read and understand spoken English (5th grade level). Patients will be excluded if they have 1) history of prostate cancer, or 2) medical conditions that inhibit them to complete any aspect of the intervention. Half of these participants (n=100) will be randomly assigned to the intervention arm (educational program about prostate cancer risks, screening and decision making), and the other half (n=100) will be randomly assigned to the control arm (usual care).

3. Study procedures

Project total duration is five years (April 2019 - Dec 2023). In general, we have revised and updated the study procedures, educational intervention, recruitment strategies, and assessment materials in year 1, and will begin enrollment in year 2. Assessment of the comparative effectiveness of the intervention will occur during years 2, 3 and 4 (clinical trial). Follow-up of study outcomes, evaluation of the acceptability of the intervention, and manuscripts preparation will occur in year 5.

Pre-screening of potential participants and invitation to join the study: Research team, working closely with clinic staff, will review patient rosters and medical records to identify all potentially eligible patients (African American men, 40-69 years old, with no prostate cancer diagnosis). This step requires a HIPPA weaver to prescreen potential participants. Contact information (name, address, phone numbers and emails) will be extracted from the medical records to a digital file. This data will be used to fill out an invitation letter and/or email (Appendix 1) that research team will send to those eligible patients. Eligible patients who are at the clinic for other reasons will be invited personally by clinical staff and/or research team, and given a copy of the letter, if they are interested on the study. Flyers (Appendix 2) will be posted in the different clinical sites participating in the study and available to pick up in the clinic waiting rooms.

Additionally, clinicians (MDs, residents, nurses, etc.) providing primary care services to potential patients will be identified through the patient medical records and their contact information (name, email, and phone) will be extracted (entered in a digital file). An email (Appendix 3) introducing the study procedures and including a link to the Physician-Collaborator Background Survey (Appendix 4) well be sent by project investigators, clinical sites directors and/or department chairs to all the primary care providers (PCPs) identified.

Patients enrollment, consent and baseline (Visit #1): In this visit, patients will a) sign, in-person or online, the consent (Appendix 6A or 6B) to participate in the study including authorization to audio-record a clinical encounter and HIPPA (Appendix 7A or 7B) authorization to access medical records; and b) complete baseline surveys (Appendix 8A). Research team will send letters and/or emails (Appendix 1) to potential participants including basic information about the project; a personalized link to the electronic consent and baseline surveys; and contact information in case that participants want to review the consent, have questions, and/or prefer to setup a face-to-face meeting to complete the procedures. Follow-up phone calls (Appendix 5) will be made to those who have not enrolled or opt-out.

- For those completing the visit <u>face-to-face</u>, and based on participant preferences and time and transportation constraints, the meeting could be scheduled at the private offices of research personnel, at the respective clinic, or in a specific place chosen by the patient where privacy may be preserved. In this case, the consent (Appendix 6A) and HIPPA (Appendix 7A) forms will be completed on paper and signed copies will be given to participants to keep.
- For those completing the <u>visit online</u>, the consent will be presented on a set of questions and short answers extracted from the consent form (Appendix 6B) and a link to the entire consent will be available so participants can read and save the entire document before continuing with the consent process. The online consent requires electronic signature for the consent and HIPPA (Appendix 7B) authorization. Patients can sign the documents by signing their name using the finger, mouse or stylus pen.

After completing the consent, surveys and training, patients will receive a $40 electronic gift card as compensation for the time spent and any expenses incurred during the visit (transportation, parking, Internet and phone services, etc.)

Educational intervention procedures (online training): Patients randomly assigned to the intervention arm will complete an online educational program (Appendix 9) to enhance knowledge about prostate cancer and risks, and application of shared decision making (SDM) skills. Patients will complete the training immediately after enrollment and baseline (Visit #1). Research team will send an email (Appendix 1) to participants including a personalized link to the training and respective surveys (Prostate Cancer Knowledge, Intention-to-Screen questions, Evaluation of Training and Decision Aid Questions, Appendix 8D), and contact information in case that participants have questions or need help to navigate the site. Patients in the control arm will be given instructions to complete the training once the entire study procedures are completed (6-months after enrollment).

Patients and Primary Care Providers (PCPs) medical encounter (Visit #2): In order to measure the application of the SDM process during the clinical setting, patients will discuss the PSA screening with their respective primary care provider (PCP) during a medical wellness visit (annual checkup). Each week, research team will send a reminder (email and/or phone call) to all enrolled patients having scheduled wellness visits in that week, and their respective Primary Care Providers (PCPs).

This visit may be conducted online or face-to-face, as follow:

Online visit: This wellness visit will take place online. The clinical sites have available telehealth services including Zoom videoconference that are HIPPA compliant. An email to schedule the virtual visit (Appendix 1) will be send by Research team to the respective Patient/PCP. Patients who prefer this option will receive instructions on how to proceed. At the beginning of the meeting, the patient and PCP will confirm that they are in a place where privacy may be preserved and that authorize to audio-record the encounter. If the audio-recording is authorized, the research team member will start the recording. If the audio-recording is not authorized or possible, after the encounter the PCP will rate the conversation using the online evaluation form (Physician-Collaborator Patient Evaluation, Appendix 4) and the patient will complete the online post-encounter surveys (Intention-to-Screen questions, Shared Decision Making Questionnaire, and Decisional Self-efficacy – Appendix 8B). Once the encounter and evaluations are completed the PCP and patients will receive the respective electronic gift card ($50 and $40) for the time spent and any expenses incurred during the visit (transportation, parking, Internet and phone services, etc.).

Face-to-face visit: This wellness visit will take place in the PCP's consultation room at the respective clinical site and will be audio-recorded after patient/PCP's consent. At the beginning of the encounter the research assistant will ask authorization to record the conversation. If the audio-recording is authorized, the research assistant will start the recording. If the audio-recording is not authorized, the research assistant will bring an evaluation form (Physician-Collaborator Patient Evaluation, Appendix 4) for the PCP to rate the conversation. Once the encounter is completed the research assistant will pick up the recorder or the respective evaluation form and will give the PCP a $50 electronic gift card as appreciation for the time spent. Immediately after the encounter the patient will complete the post-encounter surveys (Intention-to-Screen questions, Shared Decision Making Questionnaire, and Decisional Self-efficacy – Appendix 8B) and will receive a $40 electronic gift card as compensation for the time spent and any expenses incurred during the visit (transportation, parking, Internet and phone services, etc.).

Follow-up procedures (Visit #3): At 3-months after the medical encounter (visit #2) patients will complete brief post-intervention surveys (Prostate Cancer Knowledge, Decisional Confidence, Satisfaction with Decision, and Intention-to-Screen questions) and an additional questionnaire about the acceptability of the intervention and procedures. These surveys (Appendix 8C) may be completed online or face-to-face, as follow:

- **Online visit:** Research team will send an email (Appendix 1) to participants including a personalized link to the follow-up surveys including contact information in case that participants have questions.
- **Face-to-face visit:** These surveys will be administrated by the research team in a face-to-face meeting that will be scheduled immediately after the medical encounter (visit #2).

After completing the surveys, patients will receive a $20 electronic gift card as compensation for the time spent and any expenses incurred during the visit (transportation, parking, Internet and phone services, etc.). Additionally, research team will check each year the medical records of each participating patient to see if they have had or not received a new PSA exam during the study period (Jan 2020-Dec 2023).

Duration: The entire study procedures for each patient may be completed in around six months, including follow-up (Table 1). It is expected that consent and baseline survey (visit #1) will take about 15 to 30 minutes to fill out. Intervention patients will take around 30-45 minutes completing the educational program, including the pre- and post-tests. The PCP/Patient medical encounter (visit #2) will take around 1 hour according to the clinical site schedules and including time needed for patient to complete the respective surveys. Patients' follow-up assessment (visit #3) will take around 15-20 minutes.

Measures and Outcomes. Outcomes will be assessed using different measures (Appendices 4 and 8) and across different post-intervention intervals: immediately after the clinical encounter (visit #2), and at 3-month (±15 days; visit #3). The primary outcome will be the extent to which patients and clinicians engage in SDM during the patient-clinician encounter (visit #2) following receipt of the intervention or control, evaluated using the Shared Decision Making Questionnaire (SDM-Q). Two secondary outcomes will include: 1) *patient quality of decision-making process*, assessed at baseline (visit #1), immediately after the patient-clinician encounter (visit #2), and at 3-months post intervention (visit #3) using a composite score of the following scales: Prostate Cancer Knowledge, Decisional Confidence, Decisional Self-efficacy, and Satisfaction with Decision, and 2) *Preference-congruent decision making* to examine whether patient preferences for or against receiving PSA-based screening, assessed with Intention-to-Screen questions at baseline (visit #1) and immediately after the clinical encounter (visit #2) align with care received during the subsequent 3 months (physician orders of PSA screening and actual receipt of PSA screen will be extracted from the electronic medical record). The acceptability of intervention and procedures (Tertiary outcome) will be accessed with a structured questionnaire (Appendix 8) to rate the acceptability of the enrollment process, the delivery of the intervention, and their overall satisfaction with the study that patients will complete at the 3-months follow-up (visit #3). Additionally, patients in the intervention arm will complete an evaluation of the educational intervention and the decision aid questions included in the training (Appendix 8D).

Below is the **Study Design Schema** about the randomization of patients and assessment for both the intervention and the control arms (Figure 1) and the **schedule of activities** and measures to be completed (Table 1).

Figure 1: Study Design Schema

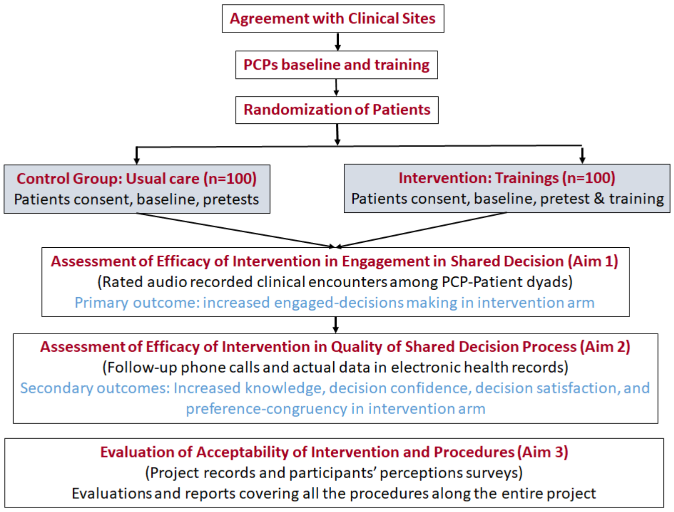

Table 1: Study activities and measures to be completed

Visit	Timeline	Procedure	Outcome	Measures

Visit #1 Consent & Baseline (15-60 min)	After initial contact with patient	Review/sign consent and HIPPA forms		• Consent form • HIPPA authorization form
		Complete baseline assessment	**Secondary outcome:** *Patient quality of SDM*	• Prostate Cancer Knowledge • Decisional Confidence • Satisfaction with Decision • Decisional Self-efficacy
			Secondary outcome: *Preference-Congruent DM*	• Intention-to-Screen questions • PSA screening orders and actual receipt of PSA screen, extracted from the electronic medical record
Intervention (30-45 min)	Before visit #2	Patients in intervention arm: complete training		• Prostate Cancer Knowledge • Intention-to-Screen questions • Decision aid questions • Evaluation of training
Visit #2 Medical encounter (approx. 1 hour)	During 3 months after visit #1 and intervention	Complete medical encounter	**Primary outcome:** *Patient and clinicians engagement in SDM*	• Shared Decision Making-Patient • Shared Decision Making-PCP • Intention-to-Screen questions • Decisional Self-efficacy
Visit #3 Follow-up (15-20 min)	3 months after visit #2	Complete follow-up assessment	**Secondary outcome:** *Patient quality of DM*	• Prostate Cancer Knowledge • Decisional Confidence • Satisfaction with Decision
			Secondary outcome: *Preference-Congruent DM*	• Intention-to-Screen questions • PSA screening orders and actual receipt of PSA screen, extracted from the electronic medical record
			Tertiary outcome: *Acceptability of intervention and procedures*	• Acceptability of Intervention • Intervention Appropriateness • Feasibility of Intervention

4. Risks

<u>The risks to the patients as participants are minimal</u>.
All patients will be asked information regarding their self-identified race/ethnicity, as well as cancer screening (i.e. having or not a prostate exam). The discomfort anticipated with some of these questions is similar to that experienced when completing a form in the doctor's office.

Patients in the intervention arm will receive information regarding prostate cancer and risks and may suffer discomfort and feel embarrassed because of some images included in the training, such as the ones showing the prostate location in the human body (Appendix 9, page 2). However, it is expected that any adult patient having routine clinical visits may be exposure to similar images at any time during their lives.

Although patients will have been physically and mentally prepared for the clinical encounter, it is possible that they will suffer discomfort and feel embarrassed because of the clinical encounter. It is not possible to avoid these risks and patients will be clearly informed about them. However, these are the common risks experienced by any person having routine clinical visits and it is expected that any man may face these decisions at any time during their lives.

The research does not have any impact on the rights and welfare of participants. No personal information (name, address, phone, emails) will be kept about invited patients refusing to join the study. However, those refusing to participate in the study will be asked reasons for no participation. Aggregated data about those refusing to participate will be reported in the study procedures and manuscripts. On the other hand, patients completing the project activities will receive training and monetary compensation for the time spent and any cost incurred for their participation.

There is minimal risk of loss of privacy. There is the potential for loss of confidentiality: 1) Participants' personal information (name, phone, email and address) will be collected and used to contact them along the study timeline. 2) Patients medical records will be examined to find history of PSA screenings, and 3) the clinical encounters will be audio-recorded to rate the application of the shared-decision making (SDM) during the clinical encounter. Although appropriate efforts will be made to protect the privacy of patients' identifiable information, any accidental disclosure would not place participants at risk or harm.

Procedures to minimize identified risks:

Participants considering the interventions offensive, risky, embarrassing, or not appropriated to their cultural beliefs, may stop participating at any time. No additional information about these participants will be collected when they stop participating.

Codes will be assigned to each patient participating so it is possible to match pre-tests and post-tests with real performance during the clinical encounters but at the same time protect patients' privacy. Codes will be assigned by research personnel once the consent form is signed (visit #1) and will be recorded, instead of names, in all study records (surveys, medical encounter, intervention, etc.). Names, address, email and phone numbers will be used by research team only to contact the participants. Qualtrics, the software to capture and store project data, uses Transport Layer Security (TLS) encryption for all transmitted Internet data and has the functionality to ensure the confidentiality of survey results. Microsoft OneDrive, which uses encryption for files (at-rest and in-transit), was approved by Xavier Office of Technology Administration to share project files among the research team.

The patient informed consent process includes authorization to audio-record the clinical encounter and the HIPAA authorization to access health records. Only contact information (name, address, phones and email) and PSA screenings (having or not PSA screening) will be extracted (entered to a digital file) from the medical records and patient will be identified with the respective code assigned. Only authorized research personnel (listed in the IRB application) will have access to the medical records. Audio recording of the clinical encounter, where PSA screening is discussed, will be rated by research personnel. Audio files will be password protected, kept in secured computers for 6 months after the medical encounter (visit #2), and then deleted. No copies of these audios will be made. However, clinicians participating in the medical encounter may write a note into the respective patient health record about the decision of ordering or not the PSA test as part of the decision making process.

Private information (name, address, phone, email and having or not PSA screenings) will be collected in separate control sheets (digital files) and available only to the research team (personnel listed in the IRB application) and always kept confidential. Digital files will be kept in the password-protected systems and personal computers locked in secure offices and/or other places. Intervention results will be reported in aggregate by role (clinician/patient), age, education, race (clinicians only), gender (clinicians only), etc. It would not be possible to identify the participant with any particular response.

5. Benefits

This study has the following benefits to participants or society in general:

- **Individual:** Patients completing the intervention will increase their awareness and gain knowledge regarding prostate cancer risks and the harms/benefits of different screening methods. After the evaluation of the intervention, those patients randomized to the control condition (usual care) will be invited to complete the intervention (training) so they will not be at a disadvantage.

- **Scientific**: This study will provide evidence supporting the impacts of current prostate cancer screening guidelines to the African American men as well as the applicability of shared decision making (SDM) during the clinical encounters.

- **Social:** Educational interventions addressing cultural perceptions, risks and misconceptions about prostate cancer screening may have a positive impact in African American men's and clinicians' approach to screening and early diagnosis of prostate cancer.

- **Organizational:** Shared decision making is considered a standard of person-centered care in clinical practice (National Quality Forum, 2018). More specifically, shared decision making about PSA screening is included in the list of recommended improvement activities in the Merit-based Incentive Payment System (MIPS), Quality Payment Program (CMS, 2019). Educational interventions fostering shared-informed-decisions about prostate cancer screening may have a positive impact on the quality of clinical services provided and patient-clinician communications, which may increase African American men's trust and satisfaction with the healthcare system.

6. Remuneration

Patients will receive up to $100 compensation for completing the entire procedures. Clinicians may receive $50 compensation for each audio-recorded medical encounter with their respective enrolled patients. These compensations are given as token of appreciation for the time that patients and PCPs spent participating in the study, and include any expenses that may be incurred by the patients when attending the study visits (transportation, parking, Internet and phone services, etc.)

7. Academic or Extra Credit

N/A

8. Costs

There will be no costs to the subject for participating in this research study.

9. Alternatives

The alternative is that patients do not have to participate in the study and will continue to receive care as usual.

10. Consent process and documentation

Patients will be invited to voluntarily join the study and complete the intervention. No personal information will be kept about those not willing to participate. However, those refusing to participate in the study will be asked reasons for no participation. Aggregated data about those refusing to participate will be reported in the study procedures and manuscripts. Written informed consent will be obtained (in-person or online) for all patients enrolling in the study. Patient consent includes authorization to audio-record the clinical encounter (Appendix 6A and 6B) and the HIPPA authorization to access medical records (Appendix 7A and 7B). During the enrollment (Visit #1, see study procedures), members of the research team will be available (by phone, email or in-person) to answer any question prospective participants may have about the study procedures, consent process, and the risks and benefits of the intervention so they are fully knowledgeable about the expectations regarding their participation. Enough time will be given to each participant to read and ask questions. Participants who do not complete the enrollment in one week will be contacted again to confirm if they decide to participate.

11. References

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12. List of Appendices

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