A multi-modal, physician-centered intervention to improve guideline-concordant prostate cancer imaging

Funding Agency: VA HSR&D

Principal Investigator/Study Chair: Danil Makarov, MD, MHS

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Abstract

Almost half of Veterans with localized prostate cancer (the most common non-cutaneous malignancy among US men) undergo inappropriate, wasteful imaging. Before widespread PSA screening, most incident cases were advanced, requiring radiographic staging before treatment. In recent years, most new prostate cancer cases have been clinically localized; there is near unanimous agreement that routine radiographic staging is obsolete. While there have been efforts to curb this practice, imaging use to stage low-risk prostate cancer remains high. Past studies by our research team have shown that physicians, not patients, are the drivers of inappropriate imaging. The objective of this study is to develop and implement an intervention to improve guideline-concordance across all populations – to decrease inappropriate imaging and increase appropriate imaging in prostate cancer patients. Building off previous research, this study will evaluate three multi-level interventions implemented in 10 VHAs across the US. A Clinical Order Check in CPRS will be used when a physician attempts to order imaging on a patient with the following characteristics: male, diagnosis of prostate cancer or prostate biopsy performed within six months of the current date, serum PSA<20ng/mL (those with higher PSAs all require imaging). The order check will not appear for imaging ordered for men with CPT codes associated with prostate cancer treatment in the past year as the intervention is tailored to address incident prostate cancer cases. Physicians will either be able to reverse their imaging order or opt out and explain the reason for doing so. Audit and feedback will be used to provide individual imaging feedback on prostate cancer imaging performance to physicians. This will be collected from Oncotrax and validated in CAPRI. Feedback will be given quarterly and will include recommendations by the PI. Finally, academic detailing will take place at each institution at the initiation of the intervention and every three months thereafter. In the event that the study team is unable to physically travel to the institution a Zoom meeting will be conducted covering the detailing agenda. The outcomes of interest are facility-level utilization of inappropriate and appropriate imaging, physician-level utilization of inappropriate and appropriate imaging, physician attitudes regarding prostate cancer imaging and the intervention, as well as the net cost of implementing a physician behavioral intervention.

List of Abbreviations

CAPRI – Compensation and Pension Record Interchange
CDW – Corporate Data Warehouse
CFIR – Consolidated Framework for Implementation
CPRS – Computerized Patient Record System
FIML – Full information maximum likelihood
HERC – Health Economics Resource Center
PHI – Protected health information
TDF – Theoretical Domains Framework
VACCR – Veterans Affairs Central Cancer Registry
VANYHHS – VA New York Harbor Healthcare System
VHA – Veterans Health Administration
VINCI – VA Informatics and Computing Infrastructure

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1.0 Study Personnel

- **Principal Investigator/Study Chair:** Danil V. Makarov, MD, MHS
- **Co-Investigators:**
    - Scott Sherman, MD, MPH – VA New York Harbor
    - Craig Tenner, MD – VA New York Harbor
    - Steve Zeliadt, PhD – VA Puget Sound
    - Heather Gold, PhD – NYU School of Medicine
    - Michele Shedlin, PhD – NYU Rory Meyers College of Nursing
- **Advisor:**
    - Scott Braithwaite, MD, MSc – NYU School of Medicine
- **Collaborators:** There will be a site PI at each of our 10 participating VA Hospitals. They all are members of the Urology Department at their respective institution.
    - John Leppert, MD, MS – VA Palo Alto Healthcare System
    - Jeremy Shelton, MD, MSHS – VA Greater Los Angeles Healthcare System
    - Christopher Tessier, MD – VA Portland Healthcare System
    - Atreya Dash, MD VA Puget Sound Health Care System
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2.0 Introduction

Almost half of Veterans with localized prostate cancer receive inappropriate, wasteful imaging. The VHA Blueprint for Excellence prioritizes increasing operational effectiveness. Prior studies seeking to limit inappropriate imaging did not assess barriers and achieved mixed results. Our team has explored the causes of guideline-discordant prostate cancer imaging and found that 1) patients with newly diagnosed prostate cancer have little concern for radiographic staging but rather focus on treatment, 2) physicians trust imaging guidelines but are apt to follow their own intuition, fear medico-legal consequences, and succumb to influence from colleagues who image frequently.[1] In spite of such discrepant views, most VHA physicians suggested or supported a large-scale effort to improve imaging use across VHA.

We propose a multi-site, stepped wedge, cluster-randomized trial to determine the effect of a physician-focused behavioral intervention on VHA prostate cancer imaging use, the Prostate Cancer Imaging Stewardship (PCIS) intervention. The multi-level intervention, developed according to the Theoretical Domains Framework (TDF), combines traditional physician behavior change methods with novel methods of communication and data collection. The intervention consists of three components: 1) a system of audit and feedback to clinicians informing individual clinicians and their sites about how their behavior compares to their peers' and to published guidelines 2) a program of academic detailing with the goal to educate providers about prostate cancer imaging, and 3) a CPRS Clinical Order Check for potentially inappropriate imaging. The intervention will be introduced to 10 participating geographically-distributed study sites.

We will assess imaging rates for all months from the start of data collection (March 1, 2018) prior to the intervention go live-date and 3 months following the intervention. The study's specific aims seek to understand the effects of the intervention on 1) facility-level prostate cancer imaging rates, 2) physician experience with and perceptions of the intervention and its implementation, and 3) the costs of both implementing the intervention and affecting change in imaging use.

This project seeks to describe and analyze the implementation of a behavioral intervention to improve prostate cancer care. This theory-based intervention builds on prior work identifying barriers to guideline-concordant prostate cancer imaging in VHA (CDA 11-257) and addresses these at three levels: individual (audit and feedback with VHA Cancer Care Cube data), facility (academic detailing) and system (CPRS Order Check). The team will assess the intervention's cost impact and providers' experiences in preparation for a subsequent large-scale VHA implementation project optimizing the operational effectiveness of prostate cancer imaging across VHA. The current application is an opportunity to leverage VHA's state-of-the-art, integrated healthcare delivery system to implement a carefully designed, theory-based behavioral intervention to reduce harmful, inappropriate care, increase appropriate care to those who truly need

it, and simultaneously save money for the healthcare system.

The study will explore the existence of a causal association between a behavioral intervention and facility-level guideline-concordant imaging. Prior analyses of prostate cancer imaging guideline implementation efforts were either retrospective[2] or lacked a control group.[3] Their results may be affected by unmeasured confounding or secular trends. Employing a multi-site, stepped wedge cluster-randomized trial will allow determination of whether an intervention is causally linked with changes in imaging behavior.[4]

3.0 Objectives

- **Aim 1: To determine whether a multi-modal, physician-focused behavioral intervention can improve facility-level guideline-concordant utilization of prostate cancer imaging.**
    - *H 1.1:* A physician focused intervention will decrease facility-level utilization of guideline-discordant imaging among low-risk men because it will address the causes of inappropriate imaging.
    - *H 1.2*: A physician-focused intervention will increase facility-level utilization of guideline-concordant imaging among high-risk men because it will actively promote imaging among patients who need it most.

- **Aim 2: To use mixed methods to explore physician influence on guideline-concordant imaging**.
    - *H 2.1:* Physicians who finished residency training more recently will be more likely to perform guideline-concordant imaging than their more experienced peers.
    - *Objective 2.1*: Through semi-structured interviews, the research team will explore physicians' experiences with and perceptions of the intervention and how those perceptions relate to prostate cancer imaging use.

- **Aim 3: To determine the cost and cost impact of a physician-focused behavioral intervention to improve guideline-concordant prostate cancer imaging.**
    - *H 3.1*: The costs of the intervention (including physician time) and increased guideline-concordant imaging will be offset by savings made in reducing guideline-discordant prostate cancer imaging.

4.0 Resources and Personnel

Management of the study will take place at VA New York Harbor Healthcare System (VANYHHS), the primary site. The intervention will be delivered to 10

participating geographically-distributed, high volume prostate cancer treatment sites. Urology Chiefs at each site have agreed to participate, share expertise, support staff and space with our team. All administrative work, study planning, and data analysis will be done at VANYHHS. The PI Danil Makarov, MD, MHS; 2 Co-Investigators: Craig Tenner, MD and Steve Zeliadt, PhD, and the research staff members (Project Manager, Data Manager, and Research Coordinator) will have access to identifiable information.

Danil V. Makarov, MD, MHS, Principal Investigator
As the Principal Investigator of the study, Dr. Makarov will oversee all aspects of the study including providing guidance to all co-investigators, study staff and site PI's. Additionally, he will provide the Performance Measurement/Audit and Feedback to each urologist and travel to each site to conduct Academic Detailing.

Scott Sherman, MD, MPH, Co-Investigator
Dr. Sherman will provide both high level and logistical guidance on behavior change intervention implementation for a multi-site study.

Craig Tenner, MD, Co-Investigator
Dr. Tenner will be responsible for leveraging his expertise to build strong relationships with the local IT departments and to assist with the order check implementation and analysis.

Steve Zeliadt, PhD, MPH, Co-Investigator
Dr. Zeliadt will be responsible for the high level quantitative analysis and work with both the Data Manager and Research Staff to ensure that collection, cleaning and analysis are all aligned.

Heather Gold, PhD, Co-Investigator, WOC-VA NY Harbor
Dr. Gold will apply her expertise in analyzing large datasets, her history working with the team on prostate cancer imaging studies, and her prior research analyzing the cost-effectiveness of cancer treatments to this study. She is responsible for overseeing the cost-effective analysis of this study.

Michele Shedlin, PhD, Co-Investigator, WOC-VA NY Harbor
Dr. Shedlin will take the lead role in designing all interview and survey instruments and qualitative data analysis. She will also conduct in-depth qualitative interviews at each site following the intervention.

Site Principal Investigators, 10 participating VA sites
Site PIs at each location have committed to creating Local Clinical Advisory Committees, which will comprise the Site PI, Urology Chief, a local IT representative, and a local Research Assistant. The Site PI is responsible for maintaining quarterly meetings with the Local Clinical Advisory Committees, in addition to maintaining regular contact with PI and project manager. The urologists serving as Site PIs and Urology Chiefs will also have the opportunity to enroll in the study as participants (one site-PI is a non-urologist oncologist, Dr. Andrew Liman, and will not participate as a study subject).

Research Assistants, 10 Participating VA Sites
The Research Assistants will work directly with the Site PIs to ensure that the intervention components are carried out efficiently. The Research Assistants will act as a liaison at the participating VA site, submit the appropriate IRB documents for their respective sites (including R&D committee requirements), as well as complete other administrative responsibilities associated with the study.

Scott Braithwaite, MD, MSc, Advisor
Dr. Braithwaite will serve as an advisor for the project. He will help strategize research directions during periodic meetings, assist with writing manuscripts and dissemination of results. He will have no access to identifiable information or data.

Hilary Oliphant, MHA, Research Manager
The research manager will manage this project by creating and managing grant budgets, overseeing project-related contracts, facilitating the hiring and credentialing process for project staff, and communicating with project PIs and staff to achieve research goals. Additionally, she will oversee other aspect of the study including staffing and training.

Shannon Ciprut, MHS, Project Manager, WOC- VA NY Harbor
The project manager will serve as the primary liaison with research staff at participating sites. She will lead local project staff at VA NY Harbor in study activities, including participant ment, and lead and maintain regular communications between all parties involved including: study sites, research staff, and the PI. She will administer surveys to provider participating and collect results for analysis and may conduct interviews. She will also assist the data manager in data analysis and presentation.

Dawn Walter, MPH, Data Manager, WOC- VA NY Harbor
The Data Manager will ensure data integrity and security and will conduct preliminary analyses through active participation in the study, beginning in the earliest stages, to ensure the creation of secure, accurate, efficient, and epidemiologically sound data environments. This individual will work closely to train the Research Coordinator and provide expertise with these datasets throughout the study.

Matthew Kelly, Research Coordinator
The Research Coordinator will aid the research staff in coordinating the study. This individual will work closely with the data manager to extract key data points from chart review to compile a dataset of results. The RC will be responsible for supporting the team by assisting with regulatory approvals, including IRB; coordinating with Site Research Assistants; and providing necessary administrative support to the project. He will attend weekly check-ins with the PI and the Project Manager.

Centralized Transcript Services Program

For the qualitative portion of the study, transcripts (text of interviews that have been audiorecorded) will be generated by the Centralized Transcript Services Program. CTSP is an internal VA service available to investigators as part of the

Informatics Decision Enhancement & Analytical Sciences (IDEAS2.0) initiative funded through HSR&D at the VA Salt Lake City Health Care System (PI: Susan Zickmund, PhD). All identifying participant information will be removed before the transcription service has access to the secure project folder.This service is internal at the VA. Interviews that have been audio-recorded will be stored on a VA secure research drive prior to transcription.

5.0 Study Procedures

5.1 Study Design

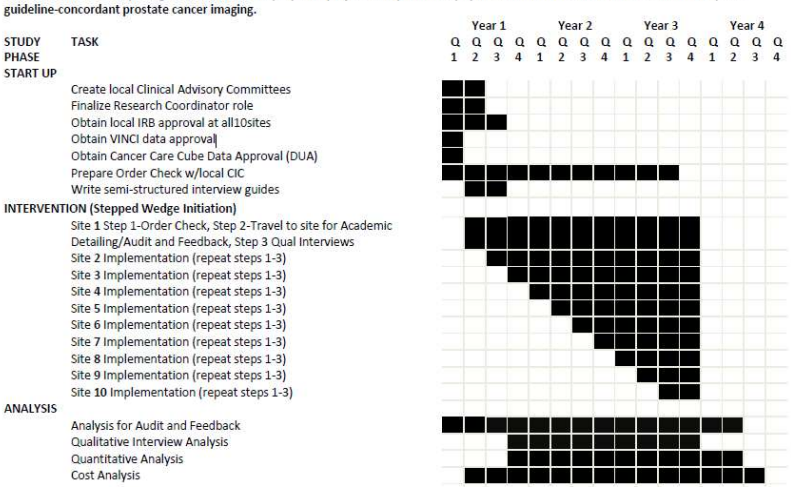
This study aims to utilize both quantitative and qualitative methods to evaluate the combination of our three proposed evidence-based interventions. The study will evaluate three complementary, multi-level interventions for improving the rates of guideline-concordant prostate cancer imaging at VHA. This theory-based strategy was developed based on preliminary data exploring barriers and facilitators to guideline-concordant prostate cancer imaging[5] subsequently mapped to effective behavior change interventions.[6,7]

To frame implementation of our intervention at the 10 committed study sites and to inform sustainability and dissemination of our findings, we used the Consolidated Framework for Implementation Research (CFIR), a compilation of existing implementation theories offering an overarching typology to promote implementation theory development and verification about what works in which setting and why. CFIR is composed of 5 domains: Intervention characteristics, Inner Setting, Outer setting, Individuals Involved, and Implementation Process. Each domain has within it between 4 and 12 constructs. The domains and constructs most relevant to the current project include Intervention Characteristics (Evidence Strength & Quality, Trialability, Adaptability, Complexity, and Cost), Inner Setting (Networks, Culture), Outer Setting (Peer Pressure, External Policies), Individuals (Knowledge, Self-Efficacy, Individual stage of change), and Process (Planning, Engaging, Executing, and Evaluating). Qualitative analysis in Aim 2 will use a CFIR-based interview guide to explore participant experience and guide subsequent dissemination.

Using a stepped wedge cluster-randomized design, the first time point will be a baseline measurement, where none of the study sites initiate the intervention. This is a single direction cross-over randomized trial where every site serves, at some point, as both control and an intervention site.[4] This will allow for an accurate and fair reading of baseline imaging measures at each site. Table 1 shows a chart outlining the proposed project timeline.

At subsequent time points, study sites initiate the intervention. The time at which each site initiates implementation of the intervention is randomized. Due to the staggered nature of the intervention, in the site randomized to receive the intervention first it will be ongoing for 33 months and the last site will receive a 6 month intervention. The 6 month minimum duration of each intervention component is consistent with prior implementation literature.[8-10] A stepped wedge design is particularly useful when an intervention must be administered on a community scale (e.g. a Clinical Order Check) or for other financial, logistic, or ethical reasons.[11] Guaranteed access to the intervention has been a powerful recruitment tool.

Table 1. Gantt chart depicting the timeline of the proposed project to implement a physician-focused behavioral intervention to improve guideline-concordant prostate cancer imaging.



The three interventions that each site will receive are: audit and feedback, academic detailing, and a clinical order check. Each method is described in detail below.

Audit and Feedback: Audit and feedback is an effective, individual-level intervention for changing healthcare provider behavior, resulting in small but potentially clinically important benefits.[9,12] Audit and feedback addresses the intervention functions of education, persuasion and incentivization, all of which are important for addressing beliefs about capabilities and consequences, knowledge, and social influence determined to be significant in our preliminary work.[13,14] We will provide quarterly feedback on prostate cancer imaging performance to every participant at each study site; feedback will be given to each provider individually and will include his or her individual-level data as well as aggregated data for the local institution (for which there are more than 3 providers included in the aggregated sample, including both participants and non-participants) and VHA as a whole as collected from Oncotrax and validated using CAPRI. The data will be reviewed during a brief group meeting between the Site PI and participants at the clinic, arranged at their discretion, and will include specific recommendations for overall performance improvement from the Site PI for the site as a whole, based on the aggregate reports. Site PIs will receive de-identified individual level rates, so long as there are more than 3 participants enrolled at that site (including the Site PI). Individual participants will only see individualized reports for themselves. Participants who are not serving as Site PI will not have individual-level data for their colleagues and will not be aware of any other individual enrollment status.

Academic detailing: Academic detailing (also known as educational outreach) is an

individual and facility-level intervention consistently shown to affect provider behavior.[8,12] This strategy addresses the intervention functions of persuasion, modeling, and education which are effective methods for affecting behaviors driven by beliefs about capabilities, knowledge, social influences, beliefs about consequences, and environmental context and resources.[13-15] The academic detailing sessions will take place at the initiation of the intervention and then regularly thereafter as determined by the local investigative team throughout the intervention period. The initial session will be performed by a member of the primary investigator team along with the local site PI; subsequent sessions will be performed by the local site PI to encourage sustainability. During the meeting, the representative from the investigator team will follow a script explaining that the visit is part of an experimental program to provide physicians and providers with up-to-date, unbiased information about imaging to stage prostate cancer.[8,16] The representative will review summary information from the NCCN and AUA prostate cancer imaging guidelines and encourage the provider participants to modify their ordering behavior to comply with those guidelines.[17] **Appeals based on fear or coercion will be avoided**. Improvement of clinical care will be emphasized above cost considerations. Providers will be encouraged to participate in the educational exchange and to discuss specific problem cases. Summaries of the guidelines and their URLs will be left with providers. A sample agenda for the visit will include:

1. Review prostate cancer imaging guidelines.
2. Demonstrate the clinical reminder.
3. Mention the audit and feedback.
4. Answer any questions.

Subsequent academic detailing sessions may occur in-person, by phone, or over e-mail. At the discretion of the site-PI, sessions may take place during regularly scheduled department meetings. Attendance at these sessions will not be mandatory. Because of this, it is possible that non-participating providers may be exposed to the academic detailing sessions, should these occur during department-wide meetings. There will be no requirement to stay, and there will be no indication of who is enrolled and who is not at these sessions.

Clinical Order Check: A Clinical Order Check is an evidence-based, systems-level method to affect behavior change.[10,18-20] It addresses the intervention functions of education, enablement and incentivization which are effective methods to change behaviors driven by beliefs about capabilities, knowledge, social influences, beliefs about consequences, and environmental context and resources; all significant domains that have been established in our preliminary work.[5,21,22] All VA facilities currently use locally adapted clinical reminders. We will adapt the Order Check currently in use at VANYHHS (implemented by Drs. Makarov, Sherman and Tenner) and adapt it for implementation at other study sites with guidance from their local Clinical Advisory Committee. This strategy is technologically simple, straightforward, and is considered to be a best practice within the VA IT community.[23] As at VANYHHS, the reminder will be self-explanatory and non-intrusive to workflow. Reminder specifics include:

1. Selection criteria: The Clinical Order Check will appear when a patient has the following characteristics:

i. *Male sex*

ii. *Diagnosis* of prostate cancer or prostate biopsy performed within 6 months of the current date

iii. *Serum* PSA<20 ng/mL. Those with higher PSAs all require imaging.

iv. *Imaging Modality:* Provider selects: bone scan or axial imaging of abdomen or pelvis

The order check will not appear for imaging ordered for men with CPT codes associated with prostate cancer treatment in the past year as the intervention is tailored to address incident prostate cancer cases.

2. Content – Based on consultations with our local physician leaders and administrators, we agreed on the following text for the Order Check: "Imaging not recommended to stage men with PSA<10, Gleason<7, and clinical stage <T3. Imaging recommended for high-risk cancer. Excessive imaging may harm patients and waste resources." Below the popup screen are references supporting the recommendation. Local site advisory committees will have the opportunity to modify this text according to their practice needs and culture.

3. Opt out – Providers may override the recommendation against ordering and are asked to explain their reasons for doing so. (The local IT representative, as part of the Local Clinical Advisory Committee, will be able to pull these responses from CPRS, in addition to the number of times the Opt Out option was utilized during the intervention period. Public Key Infrastructure (PKI)-encrypted email through VA Outlook will be used to share de-identified Clinical Order Check results between local IT representatives at participating sites and the central research staff. PKI is a VA-approved software used to secure the delivery of electronic services to VA employees, contractors, and business partners. The IT personnel will provide the reasons why participating providers have overridden ("opted out") the order check and the quantity of times the pop-up was overridden by participants during the intervention period. VA Outlook is secure and PKI-encrypted emails are only accessible to those who have been granted access. It is only accessible on the VA network and requires VA network ID and password.

This feature will be implemented at the institution-level, and it will not be possible for the order check to distinguish among providers by enrollment status. Providers who are NOT participating in this study will need to simply click ("x") out of the pop-up notification to proceed with their orders.

Additional quantitative measures: Three validated instruments will be administered prior to the initiation of the intervention to all subjects at participating sites as one collective pre-intervention survey. The Organizational Readiness to Change Assessment (ORCA scale)[24], Evidence Based Practice Attitudes Scale[25] (EBPAS), and a Self-Assessment of Contextual Fit[26] will be given before the intervention is initiated, along with a demographic questionnaire. The first set of instruments assesses organization strengths and weaknesses to support implementation of evidence based practices as well as a provider's feelings towards adopting new practices The CFIR constructs that are captured through this measurement are: evidence strength & quality, structural characteristics, characteristics of the individual, networks and communication, culture, compatibility, incentives & rewards, goals & feedback, leadership engagement, planning, and reflecting. After the intervention, another survey consisting of two additional validated instruments will be distributed to all participants: the Adoption of Information Technology Innovation-Compatibility Subscale[27],Level of Success Instrument[28], and a modified Self-Assessment of Contextual Fit.[26] These will measure the degree to which employees feel new technologies are compatible with their work, how successful the adoption of an innovation was, and the contextual fit of the PCIS intervention with the clinical department environment. The ORCA scale will also be administered within the post-intervention survey. The CFIR constructs of compatibility and penetration will be measured through these tools. These surveys will be deidentified for analysis.

Qualitative Component: We will be conducting a qualitative piece to assess participant opinions of the proposed intervention and how those perceptions relate to prostate cancer imaging use, among a subsample of the frontline provider study participants (N=25-40). This will consist of in-depth, semi-structured interviews. At the end of the intervention one-on-one, in-depth semi-structured interviews will take place with a participant and a member of the research team in person or by phone, using a CFIR-based interview guide. We will also invite participating site-PIs and urology chiefs to participate in this qualitative component. In addition to the standard interview guide, we will also ask a short series of questions exclusively to all participating Urology Chiefs and site PIs (N=20-30) to explore institutional and managerial perspectives of implementation and attitudes towards sustainability of the intervention. We will continue interviews until we reach thematic saturation.

5.2 Recruitment Methods

Provider Recruitment:

We have letters of commitment from the Urology Chiefs at all sites with their approval and agreement to take part in this study. Providers from all 10 participating VAs who have the capability of ordering imaging and treat patients with and at-risk of prostate cancer will be invited to participate including those with VA clinical privileges with WOC status. We will attempt to enroll all urologists at the participating study sites, including the Chiefs and Site PIs (N=160; (10

Chiefs and 150 frontline practitioners)We will also invite all, Physician Assistants, Nurse Practitioners, and other urology providers who order imaging and treat prostate cancer patients at participating sites to enroll (bringing N close to 200).

Participation in the study is completely voluntary. The section Chiefs will have no knowledge of the extent to which providers from their clinic enroll in the research or not, as participation will be kept confidential among the research team. Responses to quantitative and qualitative surveys and interviews will be de-identified and kept confidential and reported as aggregate. Participation will not affect employment at the VA, nor will it affect professional standing in any way including any academic appointments.

Some aspects of the intervention are provider-specific while others are institution specific. We will study 2 samples of physicians: Site PIs and Urology Chiefs as well as frontline staff physicians. There are 20 Chiefs and Site PIs (2 at each site) and around 150 frontline urologists (full-time, part-time, and WOC) at the 10 sites (range = 3-20). There are around 200 potentially eligible providers at all 10 sites. We will also study other types of providers who have the ability to order imaging and care for patients with prostate cancer at VA including: Nurse Practitioners, and Physician Assistants, and other urology providers.

The central research staff, the PI, and the Site-PI will collectively send informational e-mails to all eligible providers through VA Outlook. Eligible providers will have the opportunity to express interest or opt out of further study communications. Next, the central research staff, PI, and Site-PI will send recruitment emails that will include a study information sheet as an attachment. Eligible providers will have an opportunity to express interest, ask questions, communicate with study team members, or opt out of further study communications. Study contact information will be included in the e-mail to accept all inquiries related to the study and to go over the study and all items related to consent over the phone. The recruitment e-mail will contain a unique link, generated by the VA REDCap system, that will direct them to a portal within which the participants may designate consent. The study team will follow-up with non-responders by e-mail and by phone. Immediately following the consent page, the pre-intervention survey will appear. The study team will follow-up with participants who have consented but who have not filled out the survey by e-mail, one week following the indication of consent, and each week consecutively thereafter for up to 3 weeks (and a maximum of 3 survey reminder e-mails).

During the first academic detailing session, a member of the research staff and the PI will travel to each study site as part of a project kick-off meeting. Since the session will take place at the LSI's discretion, it is possible that this will occur during a Grand Rounds session or regular departmental meeting. In this case, there may be providers present who are eligible for the study but have not enrolled. During the session, the PI and study team member will let all site

providers that although the study has begun, eligible providers may still opt to enroll in the study. The PI and study team member will invite any unenrolled, eligible providers to contact the study team by phone or by e-mail if they opt to participate at a later time. This will be conducted through a general announcement to the group as a whole, to avoid singling anyone out or identifying any participants. The providers may approach the study team in-person during the visit or contact them later on, at their discretion. The study team will bring hard copies of the study information sheet to the meeting should anyone express interest or request the information. The study team will also bring hard copies of the REDCap consent portal and pre-intervention survey. If providers express interest and willingness during the site visit, the providers may fill these out in-person and return to either a local study team member or visiting central team member. The study team will also provide self-addressed stamped envelopes for providers who wish to enroll but fill out the paperwork at a later time. Providers may return these envelopes to the local site team or mail themselves to the central research team, whichever is most convenient. The central research team will enter the paper-based responses in REDCap. Upon doing so, the study team will shred the paper-based versions of the survey. The study team may also re-send study information sheets and the REDCap consent portal by e-mail to anyone who requests it. The enrollment status of meeting attendees will not be shared or discussed.

Study participants will consent for the qualitative of the study during the informed consent process for the study as a whole. Participants will be reminded of this effort and invited to participate by email sent from the NY Harbor research team. An effort will be made to recruit Urology Chiefs (n=10), site PIs (n=10), and a subset of frontline practitioners (about 20-30). Reminder e-mails (up to 3 e-mails in 3 consecutive weeks following the initial contact) will be sent to non-responders and include requests to schedule interviews to occur either in-person or by phone. Recruitment phone calls may also be made to participants' listed phone numbers to non-responders from e-mail. Up to 3 phone call attempts may be made in 3 consecutive weeks following the initial contact; following the maximum attempts of contact, recruitment efforts will cease.

For the qualitative interviews, we will recruit 20 to 30 participants across the sites, in addition to urology chiefs and Site-PIs in order to reach theoretical saturation. Interviews will cease following team consensus of theoretical saturation. Participants will be invited to schedule an interview in-person or by phone. The study team initially plans to enroll about 30 participants beyond the Site-PIs and Urology Chiefs for interviews. Interviews and analyses of transcriptions will be ongoing throughout the qualitative portion of the study. Interviews will either cease early or continue enrolling until theoretical saturation has been achieved. Interviews that have been scheduled in advance will still occur. If a participant agrees to an interview after the team has ceased qualitative data collection, then an interview will not occur.

After the intervention period, participants will receive an e-mail from the study team requesting participation in the post-intervention survey. The e-mails will contain new, unique links for distribution and self-initiated access to the surveys. Up to 3 follow-up emails will be sent to participants who did not complete the surveys in the 3 consecutive weeks following the initial contact regarding these instruments.

Participants will not be compensated for their participation in this study. Participation in this study will not influence employment. The 10 Chiefs have already agreed for their departments to participate in this study but will still give informed consent to participate as individual study subjects. Similarly, the 10 Site PIs, none of whom are Chiefs, will be invited to participate in the study. The Urology Chiefs will have no knowledge of the extent to which staff members in their department elect to participate in this study.

Subject Recruitment:

Prostate cancer patients will not be contacted directly for participation in this study and the research team will not have any direct interaction with patients, however the NYHHS team will have access to personal health information. The Cancer Registry is an online tool used by cancer registrars to create and maintain a VA cancer patient database. Oncotrax assists registrars in saving information on diagnosis, treatment, and survival for newly diagnosed cancer cases. These data are used in quality improvement and research studies as well as in incidence and trends analysis. A waiver of HIPAA authorization and a waiver of informed consent will be secured to identify patients in the VHA OncoTrax data in CDW using the ICD-9 code 185 or the ICD-10 code C61 for prostate cancer. Patients will be excluded if they have a history of prior malignancy, are over the age of 85, diagnosed at autopsy or by death certificate, died within 3 months of diagnosis, or not having data on at least one of the following: PSA, clinical stage, or Gleason score.

5.3 Informed Consent Procedures

Informed consent will be obtained from all providers who agree to participate at the 10 study sites at the beginning of the study. The consent process details the study procedures, including the interventions, as well as the expectations of the participating providers including participation in completion of surveys and interviews. The study team is requesting a waiver of documentation of informed consent for provider participants, as this study involves very minimal risk and would not require informed consent outside of research. The recruitment process will be conducted remotely by the central site.

The Site PI will identify eligible prostate cancer providers including urologists, PAs and NPs. Research staff members will identify email addresses through the

VA directory as needed. The Site PI will send an informational e-mail to all eligible providers to briefly explain the purpose of the study intervention and an overview of participation. Eligible providers will have the opportunity to reach out to the Site PI or research team member with any potential questions or to express preliminary interest. The email will clearly state that participation is voluntary and will not affect employment at VA.

One week following the informational e-mail, the central research team will follow-up with a recruitment email to those who have expressed interest and those who did not respond to the informational email. The team will contact each of the eligible providers by email (VA Outlook) and invite them to participate in the study through recruitment email with an information sheet attachment. The consent process will be conducted using a REDCap-based electronic consent portal. The consent portal will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users. Potential participants will participate in the consent process by e-mail approach from the study team, with an invitation for self-initiated access of unique link to consent portal and survey on personal portable electronic devices using web-links. Self-initiated accessing of consent portal may occur in clinic or at home; however, VA REDCap is accessible only on the VA network and login requires valid VA network ID.

Upon receipt of the recruitment e-mail, potential participants will have the opportunity to speak to a study team member to go over study procedures and ask questions. Potential participants may also opt out of future study communications upon request. The central research team and/or the Site RA will schedule either a phone call (if NY Harbor individual) or in-person (if Site RA) meeting to discuss the study procedures and to provide an opportunity for the provider to ask questions about the study and process of consent upon the request of the potential participants and to non-responders by e-mail. Contact information will also be provided (email and phone) for prospective participants to contact a member of the key study personnel with questions, prior to consent. All individuals who will have the ability to obtain informed consent have extensive human subjects' research experience. All individuals obtaining consent will be members of the research team who are designated and approved for doing so. All members of the research team have completed numerous VA research trainings as well as CITI Human Subjects Protection training. Communications including the information sheet will explicitly state that this study is purely voluntary, and there is no obligation to participate. If providers decline participation, there will be no consequences. Communications will state that this study will have no effect on employment status and their supervisor will not be aware of his/her decision to participate or not.

Participant indication of consent will be obtained using a typed signature, to be submitted through the REDCap portal. The information sheet will be included as an attachment with the recruitment email. If, when the study team speaks with potential participants, they don't remember or cannot locate the information sheet, the study members will confirm the best email address to send it to them and re-send it for reference. If a participant does consent to the study, REDCap will send an automated completion notice that will include the information sheet as an attachment. If a provider declines participation, or requests to no longer be contacted regarding this study, the study team will not contact that individual again. Follow-up emails will be sent one week after initial contact to those who do not respond. Up to 3 follow-up emails will be sent to non-responders. The central research team will make phone calls to the numbers listed in the VA directory in attempt to reach individuals who did not respond to emails. The research team will end follow-up after 2 unsuccessful phone calls to non-responders.

The research team will re-send the REDCap consent portal after the intervention has begun if a non-participating provider requests to be included in the study during or following the study kickoff site visit. The research team may send one follow-up email or follow-up phone call as necessary, and all recruitment efforts for providers at the given site will cease at that time.

Study team members will record and receive verbal consent to audio record from participants for interviews that occur over the phone through Micrososft Teams. Participants in the qualitative portion of the study will have already consented by agreeing to participate in the study during the recruitment process.

Informed consent will not be required of patients due to a waiver of HIPAA authorization and a waiver of informed consent. There will be no active participation of patients in this study; the study team will access patient electronic health records in order to monitor trends in imaging among prostate cancer patients.

5.4 Inclusion/Exclusion Criteria

Provider Criteria

- Inclusion criteria
    - Urology Chiefs and attending urologists employed through the VA (full-time, part-time, WOC) at one of the 10 participating sites; Physician Assistants and Nurse Practitioners employed through the VA at one of the 10 participating sites that work in the respective urology clinics
    - Providers may be any gender or race/ethnicity
    - Qualitative portion only: Urology Chiefs and/or frontline staff physicians; participating PAs & NPs having cared for at least 5 men with incident prostate cancer within the previous 6 months

- Exclusion criteria
    - Urology Residents

In efforts to avoid potential coercion, Urology Residents are excluded from the study due to the hierarchical culture of surgical training program in addition to preliminary findings that imply that they strictly adhere to attending preference.[29]

Patient Criteria
Patients will not be directly recruited into the study. We will obtain a waiver of HIPAA authorization and informed consent to analyze electronic health records of patients at the 10 participating sites.

5.5 Study Evaluations

Screening
Physicians and other eligible providers will be identified based on their employment in the Urology sections at the 10 participating sites. Urology Chiefs and local site-PIs have already been identified.

Questionnaires

Prior to the initiation of the intervention, immediately following the e-consent process, all provider participants will be asked to complete a demographic questionnaire as well as validated survey measures. The demographic questionnaire will ask providers questions about age, race/ethnicity, and details about their time as urologists/providers, such as years in practice and training focus. Full, Part-time, or WOC VA status of the providers will be determined administratively. After the demographic questionnaire the participants will complete the ORCA scale,[24] and the EBPAS scale.[25] When the intervention is complete three additional measures will be administered to participants: Adoption of Information Technology Innovation-Compatibility Subscale,[27] Level of Success Instrument,[28] and a Self-Assessment of Contextual Fit.[26] Participants will also complete the ORCA scale again as a pre/post measure. The research staff will prepare the VA-approved REDCap portal for virtual distribution and collection of results. The staff will provide access information via VA Outlook to distribute the survey instruments electronically, including unique links to unique portals to collect data from each participant. REDCap is a secure, VA-approved web application that facilitates the collection and entry of research data. The main research staff at NY Harbor will be able to access the questionnaire results directly through the secure REDCap project account. The main research staff will have exclusive access to this account. As per VHA Record Control Schedule 10-1 8300.6, collection of records will be cutoff at the end of the fiscal year after completion of the research project, and results will be destroyed 6 years after cutoff. All responses collected will be deidentified. Results will be reported as aggregate. Individual responses will not be shared with the Urology Chiefs, and the Urology Chiefs will not be aware of who has completed the survey or not.

Qualitative Interviews

Qualitative interviews will be conducted using an interview guide developed using CFIR. The aim of the interviews is to understand the acceptability and sustainability of the intervention. There is a section on the interview guide that is specifically for the Urology Chiefs and Site PIs, as leaders of this project. These questions explore the institutional perspectives of intervention implementation and attitudes towards sustainability of the intervention. An investigator along with a member of the main research staff will travel to each of the participating sites to conduct the interview in-person, or the interviews will be held over the phone by a member of the central investigative team (investigator or staff member). Data from the interview will be collected through the VA Microsoft Teams application and uploaded to a secure internal research drive for transcription.

Additionally, the central research team will collect ongoing qualitative data from site research team members about the implementation of the intervention every 6 months post commencement via informal phone interviews. Demographic information of LSIs and Local Rcs will be recorded.

All evaluation materials are included as a separate attachment with the protocol.

5.6 Data Analysis

All data will be managed at VANYHHS by the Data Manager, Research Coordinator, and Project Manager. They will collect, clean, and analyze datasets. Other members of the main study team will analyze aggregated or de-identified data. Statistical analyses will be performed using the SAS 9.1.3 Service Pack 4 statistical package (SAS Institute, Cary, NC) and Excel 2010 (Microsoft Corporation, Seattle, WA). Qualitative data will be analyzed using NVivo 10 (QSR International). REDCap is a secure, VA-approved web application that facilitates the collection and entry of research data. A private, password protected REDCap project will be created for this study. Study team members will ascertain the input data from the questionnaire as well administered to participants. REDCap not only stores data but can generate descriptive statistics. Site-specific results will be deidentified and will not be shared with anyone beyond the central research team. Specifically, only aggregated data will be shared with Chief or Site PI. Site-specific information will be collected for analysis purposes only; results will be reported as aggregate.

Quantitative Analysis

Quantitative data for this study is from VHA's Corporate Data Warehouse (CDW). VINCI, VHA's secure data environment will be used to identify prostate cancer patients in CDW as well as their imaging tests, demographic information, and clinical history. The VINCI team will extract required data from CDW tables and create a work environment for our team on secure VINCI servers in Salt Lake City. VSSC's Cancer Care Cube (CCC) will be used to generate timely data for Audit and Feedback. CCC permits rapid access to

accurate nationwide VA cancer registry data[30] from the clinical OncoTrax system, uploaded once monthly. To address potential reporting delays, we will check the validity of the Oncotrax data by comparing them with CAPRI data biweekly - a focused review of about 200 charts a week. In further efforts to avoid delays due to lags in CDW data availability, the local IT specialist will run a reoccurring monthly report in CPRS in attempt to identify patients diagnosed with prostate cancer in real-time. The results will yield patient name, SSN, and presumed date of prostate cancer diagnosis. The IT specialist will send the results of these queries to the central research team via PKI-encrypted email on VA outlook periodically. If the IT specialist at a site is unavailable to produce these reports, another member of the Local Clinical Advisory Committee will send either a list of newly diagnosed prostate cancer patients or a list of patients receiving prostate biopsies at that site via PKI-encrypted email to the central research team. The central research team will verify and validate this data using concentrated chart review within CAPRI. Due to local practice differences at the Madison VA only, the central research team is unable to verify receipt of imaging in CAPRI, such as bone scan or CT, (our primary outcome) without access to the local consult notes in CPRS. Therefore, the central research team will verify eligibility status of patients sent from the initial local CAC data pull. The central research team will send this confirmed list back to the local research coordinator via PKI-encrypted email for verification of imaging receipt and date of imaging. The local research coordinator will ascertain the imaging order and status via local consult notes in local CPRS system. The local research coordinator will then send the confirmation of imaging completed, type of imaging, and date received via PKI-encrypted email to the central research team. This will serve as a supplemental source of data to improve data validity, accuracy, and quality for both feedback reports and overall imaging rates. The study team will collect the following data from CAPRI: date of birth, zip code, marital status, race/ethnicity, Gleason score, date of diagnosis, PSA, clinical stage, date of medical appointments, diagnostic procedures/treatment, imaging ordered, and treating provider. This will guarantee the fidelity of the data used for Audit and Feedback and provide insight into the timing with which data from each individual site are updated for future projects. CCC data will be stored securely in VINCI where it will be linked to CDW when necessary. We will request remote CAPRI access to all 10 study sites for the central research data team from the National Information Security Officer (ISO) following Central IRB approval.

The sample size of 10 study sites was determined to ensure appropriate power for our primary outcome: differences in the rate of inappropriate prostate cancer imaging. For the sample size calculation of a stepped wedge trial, the key variables are the number of clusters (i.e., sites), I; the number of distinct time points or intervals being compared, T; and the number of outcome observations per time point, *N* (i.e., the number of individual patients with the outcome per cluster, per time interval).[4] We assume the model, $Y_{ij} = \mu + \alpha_i + \beta_j + X_{ij}\theta + e_{ij}$, where α_i is a random effect for cluster *i* such that $\alpha_i \sim N(0, \tau^2)$, β_j is a fixed effect corresponding to time interval *j*, X_{ij} is an indicator of whether the intervention has been implemented in cluster *i* at time *j* (1=intervention; 0=control), θ is treatment effect and $e_{ij} = \sum_k e_{ijk}/N$ are independent and identically distributed $N(0, \sigma^2)$

and $\sigma^2 = \sigma^2{}_e/N$. Let Y_{ij} be the mean for cluster *i* at time *j*. Assume testing the hypothesis $H_0: \theta = 0$ versus $H_A: \theta = \theta_A$, where θ_A is the treatment effect size. The approximate power for conducting a 2-tailed test of size alpha is $power = \Phi\left(\left(\theta_A/\sqrt{Var(\hat{\theta})}\right) - Z_{1-\alpha/2}\right)$ where Φ is the cumulative standard normal distribution function, $Z_{1-\alpha/2}$ is the $(1-\alpha/2)th$ quantile of the standard normal distribution function and $\hat{\theta}$ is the estimated effect size. The estimated number of patients exposed to the intervention will be 750, compared to 750 control patients, which will provide sufficient power for even modest improvements in imaging rates among low-risk men. Assuming 10 time periods (Q2-Q11), an estimate for baseline imaging among men with low-risk prostate cancer of 40% in the usual care group, and a decrease to 20% guideline-discordant imaging (absolute difference of -0.20), 10 clusters (sites), 15 patients with low-risk prostate cancer per quarter x 10 study sites x 10 quarters is estimated to impact 1500 total patients out of 6000 patient charts reviewed (a conservative estimate based on analysis of VINCI data), an alpha of 0.05, and a coefficient of variation of 0.40, accounting for clustering, we would estimate having a power of >0.999. This is a conservative estimate in terms of the expected effect of the intervention on prostate cancer imaging rates and assumes a high coefficient of variance with outcomes highly correlated with site. A more conservative post-intervention rate of imaging of 28.7% would reduce power to 0.80.

Similarly, we estimate that we will have sufficient power to detect increases in appropriate imaging among men with high-risk prostate cancer. Assuming 10 time periods (Q2-Q11), an estimate for baseline appropriate imaging of 66% in the usual care group, and an increase to 86% (for an absolute difference of +0.20), 10 clusters (sites), 5 at patients with high-risk prostate cancer per quarter (a conservative estimate based on analysis of VINCI data), alpha of 0.05, a coefficient of variation of 0.40, we estimate power of 0.89.

We will also perform exploratory, individual-level analyses. If providers consent to participate in the study, then these imaging outcomes will be linked to their survey and qualitative data. For non-participants, imaging patterns alone (with no additional data) will be analyzed in a de-identified manner.

Qualitative Analysis

Qualitative data will add depth and detail, complementing the other findings to explain and illustrate quantitative results. In-depth interviews at the conclusion of the study will explore providers' experiences with the intervention and explain the important implementation-related domains from CFIR.[22] The exploratory nature of this component will permit the identification of new ideas and inform the generation of inductive hypotheses regarding factors motivating guideline-concordant imaging. We will also ask a short series of questions exclusively to all Urology Chiefs and Site PIs (N=20) to explore institutional and managerial perspectives of implementation and attitudes towards sustainability of the intervention.[31] Data gathered will be critical to the plan to

disseminate the intervention to other VAMCs nationally. We anticipate recruiting a subset of approximately 20-30 frontline providers across the 10 participating study sites in order to reach theoretical saturation. There are 79 practicing urologists at all 10 sites (10 Chiefs and 67 frontline practitioners) so we anticipate no difficulties in reaching our recruitment goal. Qualitative results will be analyzed using NVivo software (QSR International). NVivo will allow for the organization, coding, and analysis of interview transcripts. Results obtained from these triangulated quantitative and qualitative components will be integrated,[32,33] a key procedure in mixed methods analysis. Demographic information will be collected from participants to aid in the analyses.

Cost Analysis

Clinical care cost data will be accessed primarily through the Health Economics Resource Center (HERC) Average Cost File. HERC has created estimates of the cost of all VA health care encounters that have taken place since October 1, 1998. These data are accessible approximately 6-8 months following end of the fiscal year. These data will allow for comparable standardized prices to be applied across all VHA facilities for all follow-up care activities. Cost data will also be obtained from billable private insurance claims. VHA's Medical Care Recovery Program attempts to collect for care performed at VHA when a VA user has private insurance. We will identify subjects in our cohort who have billable private insurance and flag these subjects for exclusion in sensitivity analyses as they may be likely to be more reliant on community care than VA-users without private billable insurance. Preliminary analysis in VISN20 identified that out of a cohort of 260,743 subjects, 17,141 (6.6%) had billable insurance. This variable is available in the CDW.

We will also estimate the cost of implementing the intervention using methods described by Liu et al. in their paper documenting organizational costs for implementing a depression care quality improvement intervention into VHA primary care practices.[34] These methods allow for the documentation of organizational costs associated with the implementation effort itself, not just the costs associated with changes in patient care, whose calculation we describe above. We will collect data on participant hours and intervention related activities directly related to the implementation effort. Implementation costs are related to travel, clinical informatics, training sessions, conference calls, development of training materials, email communication, and any other activities spent counseling, training, or supporting personnel at the study sites. Participants will include any individual (provider, study staff, administrator) participating in the implementation project. Data sources used for estimating costs will include interviews, surveys, e-mail communications, project schedules, meeting minutes, project cost records, and government salary information. Costs will be estimated based on length of interviews and surveys, email word count, time of telephone calls, and government travel budgets based on calculated reference ranges for such expenses, as described by Liu et al.[34]

Outcomes

The study's Primary Outcomes determined from the above data sources will be:

Specific Aim 1

1. Facility-level utilization of bone scan or abdominal/pelvic CT or abdominal/pelvic MRI among men with newly diagnosed, low-risk prostate cancer. (Inappropriate Imaging)

2. Facility-level utilization of bone scan or abdominal/pelvic CT or abdominal/pelvic MRI among men with newly diagnosed, high-risk prostate cancer. (Appropriate Imaging)

Specific Aim 2

1. Provider-level utilization of bone scan or abdominal/pelvic CT or abdominal/pelvic MRI among men with newly diagnosed, low-risk prostate cancer. (Inappropriate Imaging)

2. Provider-level utilization of bone scan or abdominal/pelvic CT or abdominal/pelvic MRI among men with newly diagnosed, high-risk prostate cancer. (Appropriate Imaging)

3. Provider attitudes regarding prostate cancer imaging guidelines and the behavioral intervention

Specific Aim 3

1. Net cost of implementation of physician behavioral intervention VHA. This file will be used to quantify facility-level workforce and imaging technology.

Facility-level descriptors will be obtained from the 2009 VHA Oncology Services Survey.[35] As part of the Office of Patient Care Services initiative to conduct systematic program reviews, Oncology Services conducted a survey of cancer care services in VHA.

Missing Data
Missing data has the potential to affect the validity of our results. We foresee 4 potential sources for missing data and propose strategies to deal with them.

1. Improper transcription into Oncotrax and CCC: to overcome this, we will train our centrally-located, full-time Research Coordinator to identify missing data fields and search for this information in CAPRI. We expect the study to follow 60 patients from 10 sites per quarter, or a manageable 12 patients per business day.
2. Patients seeking care in the private sector through the Veterans Choice Act: Fortunately, when the VA pays for imaging tests, they are indicated in CAPRI. Outside healthcare providers have to send back the statement to collect payment so this information will be manageable to track.[36]
3. Patients seeking care in the private sector through Medicare: Dr. Zeliadt found 67% of veterans with an elevated PSA followed up within VHA in the subsequent 24 months.[37,38] We assume that follow-up will be improved among men with a

cancer diagnosis already having chosen to undergo prostate biopsy within VHA. At the completion of the study, we will request CMS records using VIReC's CMS-VA linkage to identify any missing studies performed by a Medicare provider.[39]

4. Patients seeking care in the private sector through private insurance: there is no reliable way to ensure completeness of these data. We will review CAPRI notes for documentation of outside care but may not be able to confirm that none took place. This phenomenon should occur with equal frequency in the control and the intervention sites and should bias our results to the null.

In spite of our best efforts, it is likely that some data will remain missing. The full information maximum likelihood (FIML) method will be used to handle missing data as a less stringent assumption of missing-at-random will be made. Simulation studies have shown that no other missing data handling method performs better than the FIML regardless of the mechanism by which the missing data are generated.[40,41]

5.7 Withdrawal of Subjects

Participants will be able to withdrawal any point if they so choose without any consequences. Withdrawal from this study will have no impact on employment at the VA. Enrollment status in this study will remain confidential among personnel involved in the Research team. However, any data collected up to that point may still be utilized.

6.0 Reporting

While this study is less than minimal risk, there is the possibility of loss of data confidentiality. Adverse events and serious adverse events are not likely to occur due to the nature of this intervention. The intervention does not entail greater than minimal risk to either provider participants or their patients. If a reportable event such as an unanticipated problem or protocol deviation should occur among the research team, the PI will be notified immediately. Research staff will record and document all details related to the event. The PI will determine if the event meets criteria to report to IRB, and this decision will be documented, signed, and dated by the PI. In the unlikely event that an adverse event occurs at one of the intervention sites, the Site Research Assistants will report it to the Site PI immediately. The Research Coordinator at each site will be responsible for documenting the details of the event, in addition to contacting the main site research staff. The Site PI will determine if the event meets criteria to report to the IRB. This decision will be documented and the central research study team as well as the main PI will be notified. It is unlikely that findings will reveal results that affect participants' health or welfare in this study. There are no safety conditions that trigger immediate suspension of the research that we anticipate.

7.0 Privacy and Confidentiality

There is minimal risk associated for patients involved with this study. This study will use patient PHI. It is necessary to have access to PHI in order to determine the rates and trends in prostate cancer imaging across the study sites. There is a risk of breach in confidentiality; however, multiple safeguards are in place to ensure information security. Only members of the study team performing data analysis, the Research Coordinator and Project Manager, will have access to central data PHI and patient records. Only the designated member of the LCAC will access the locally generated data reports. A variety of precautions will be taken to ensure the security of patient data. PKI-encrypted email will be used to transmit patient data. PKI is a VA-approved software used to secure the delivery of electronic services to VA employees, contractors, and business partners. PKI-encrypted emails are only accessible to those who have been granted access and are only accessible on the VA network requiring a VA network ID and password. Patient PHI will be stored on password protected, secure sever.

The VA's informatics and computing infrastructure (VINCI) will be used to store and analyze data. Individual investigators and multiple databases may lack sufficient resources to ensure consistency and quality control, or a long-term commitment to data storage and access. Therefore, there are less consistent standards for the protection of Veterans data, data quality, and data access compared to a centralized repository. A centralized research data repository, such as the VA Informatics and Computing Infrastructure (VINCI), offers a number of important advantages: Consistent, defined, and transparent security and standards for access to data; a common point of entry for all investigators who use the data; tools for analysis and reporting; tighter and more consistent control over the standards and quality of the data included; and the ability to standardize and update terminology and format as technology and methodology improve. VINCI is a partnership between the VA Office of Information Technology (OI&T) and the Veterans' Health Administration Office of Research and Development (VHA ORD). VINCI provides the storage and server technologies to securely host suites of databases integrated from select national data. These servers reside at the Austin Information Technology Center (AITC), located in Austin, Texas. To ensure the protection of Veterans data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200.12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO). Access to VINCI resources will be approved in accordance with the requirements of National Data Systems (NDS), VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, and all other applicable VA and VHA policies and regulations. Researchers and Operations staff will access the data along with the tools for analysis and reporting in the secure, virtual working environment through a certified VHA network computer using the VA INTRANET (NOTE: VINCI is not accessible through the INTERNET). If not working within a VA or VHA hosted office environment containing VA network access,

researchers may access VINCI through an approved Virtual Private Network (VPN) and Remote Desktop application. The remote computing environment will enable data analysis to be done directly on VINCI-CDW servers located at the Austin Information Technology Center, thus keeping all data from being transmitted to local PC hard drives or servers.

VA REDCap is specifically designed for human subjects research. It is installed and accessibly only on VA network, and login requires VA network ID. The application is also housed on VINCI server. REDCap is a mature, secure web application for building and managing online surveys and databases. The VA REDCap portal is intended to be used by authorized VA network users for viewing and retrieving information only. Each member of the main study site research staff has their own individual password-protected account on REDCap that was granted by the VA REDCap support team. It is located explicitly through the VA intranet. This study will have a project file that will be accessible only to authorized REDCap users on this study team at the main research site. VA REDCap login can be accessed at: https://vhacdwweb05.vha.med.va.gov/. Provider privacy will also be maintained. All questionnaires and survey item individual responses will not be shared with any personnel beyond the central research staff. The responses will be directly entered into the secure REDCap project site. Participating providers at each site will have access to their own individual imaging rates in addition to aggregate institution results, through a report created by the data team . The main site Research staff will send the reports through VA outlook email. Participating providers will not be able to view other provider-specific data corresponding with other individual participants. In sites that have more than 3 providers, the Site PI will have access to de-identified individual level rates to improve context, clarity, and goals for the group feedback meetings. Individual participants will receive institutional level data reported as an aggregate, conditional that there are >3 employed providers in the department to be included, in order to protect confidentiality. The Chief of Urology will not be aware of which staff members are enrolled, which study activities have been completed, or the content of individual responses. Identities of participating individuals for in-depth interviews following the intervention will be confidential and will remain within the central study research team in order to feasibly conduct the interview. The data collected will be analyzed and reported as aggregate for reporting of results and future manuscripts. Identities of participants in this portion of the study will not be shared with the Site PIs. Chiefs and other participants will not be aware who has been interviewed (other than themselves, if they chose to participate). Qualitative data reported will retain anonymity of the respondents. The site of the participant will be retained so that the central team members are able to analyze themes among sites by imaging volume (for example, “low imaging sites” versus “high imaging sites”). This information will only be reported as aggregated themes. Participation in this study will not influence or affect employment at VA.

Interviews that have been audio-recorded will be stored on the VA desktop of approved study team. Interviews will be recorded during phone call interviews, and will be recorded by the VA Microsoft Teams application in real time. Microsoft Teams is a

collaboration software that combines chat, meetings, calling, collaboration, application integration, and file storage into a single interface. We will use the application to create a meeting with dial-in information and will record the meeting directly through the application on VA secure desktop. Interviews will be de-identified and uploaded onto the secure NY Harbor research server and will be made available to the VA HSR&D Centralized Transcript Service Program (CTSP), an HSRD-funded initiative for qualitative studies at the VA (PI: Dr. Susan Zickmund). Approved staff from the VA Salt Lake City (VASLC) will transcribe the audio files. The VASLC has a Professional Transcription Service available to VA sites and monitored by their own IRB. The audio recordings to be transcribed by VASLC staff will be labeled by the subject's unique alphanumeric code and saved behind the VA Firewall in the main study site's secure shared project folder. The VASLC transcription staff will be given access to a sub-folder within the study team's secure project folder to be created especially for this exchange. Approved study staff will place a copy of the audio files in this folder for an approved VASLC transcriptionist to access for the purposes of transcription. The VASLC transcriptionist will transcribe each interview verbatim and save the completed transcript in the sub-folder using the same alphanumeric code. No data (audio files, in process transcripts, or completed transcripts) will leave the NY Harbor secure research server. As completed transcripts become available, approved study staff will move these files from the transcription sub-folder into another sub-folder that is only accessible to study staff, where they will be stored and accessed for qualitative analyses. We will collect site information within the demographic questions to be retained for analysis. This will be anonymized when reporting results and will be kept confidential within the NY Harbor research team.

Project research data will only be used by authorized study personnel for the exclusive purposes of this project. PHI or passwords associated with data for this project will never be recorded or shared. Only designated VA research personnel will have access to data stored on VINCI, REDCap, and the secure VA research folder. If an individual is no longer part of the research team, the present study team will submit a modification through Central IRB to remove that individual from the study personnel. All passwords will be changed following a change in personnel, and only shared among authorized study team members via secure communication. The ISO and Privacy Officer will be notified within one hour if improper use or disclosure should occur.

8.0 Communication Plan

Communication between the main site and the 10 participating sites is integral to the success of this study. As the study sites are spread across the country, it is critical that the Site PIs and their study team members stay in contact with the main site. Frequent check-ins and open lines of communication will ensure that the study is conducted according to the IRB-approved protocol. The main site is committed to helping the local sites with any aspect of study startup as well as continuing reviews or any other subsequent IRB and regulatory submissions. The main site research team will have regular weekly meetings to check-in with the PI, in addition to other research and administrative task-specific meetings that will regularly occur.

The main study PI plans to have biannual meetings with the local Site PIs. One will occur in-person while the PIs attend national urologic conferences, such as the American Urological Society annual meeting, and another meeting will occur over a telephone conference line, approximately 6 months later.

Local Site PIs have committed to creating Local Clinical Advisory Committees comprising the Site PI, Urology Chief, a local IT representative, and the Site Research Assistant. Local PIs and Research Assistants are responsible for scheduling and maintaining these meetings. These committees will meet quarterly to discuss the progress of the intervention. After each Local Clinical Advisory Committee notes and any updates will be delivered to the main site research staff. The project manager and research staff will call to check-in with the site Research Assistants after each Local Clinical Advisory Committee meeting and will set up remote meetings via conference or videoconference calls as needed. The central research staff may also participate in these LCAC meetings by calling in.

Once a site has been randomized into the intervention, each participating provider will receive a quarterly audit and feedback report from the central research staff. This report will contain individual-level imaging data as well as data collected on imaging for their institution as a whole.

Communication between Site PIs and Local Clinical Advisory Committee with participating providers at their clinic regarding the progress, status, and results are also an integral component to the implementation and effectiveness of the intervention components. The Site PI and Site Research Assistant will have regular communication via presentations, emails, department meetings and any other regular activities that occur at the given site for clinical operations to encourage optimal participation in the project (clinical order check, audit and feedback, academic detailing) and to enhance data results. The coordinating staff will also document use of these communications to aid in continual monitoring of implementation.

If any changes are made to the protocol or any other documents relating to the IRB, a message will be sent to the Site PIs as well as the Site Research Assistants.

9.0 References

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