Project Title:

MyPath: A Patient-Centered Web-Based Intervention to Improve Reproductive Planning for Women Veterans

(Alternative IRB Protocol Title: Improving Outcomes for Women Veterans Using a Patient-Centered Web-Based Decision Tool)

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Abstract

High rates of medical and mental health comorbidities result in elevated risks of poor maternal and neonatal outcomes among women Veterans compared to their civilian counterparts. While proactive planning and optimization of physical and mental health prior to pregnancy can mitigate these risks, nearly 40% of pregnancies among Veterans are unintended.[1] National guidelines recommend routine delivery of patient-centered reproductive planning services in primary care, including assessment of reproductive goals followed by tailored contraceptive and/or preconception counseling, to reduce unintended pregnancy and improve pregnancy outcomes. Only 38% of women Veterans at risk of pregnancy, however, report having contraceptive or preconception health discussions with their primary care provider in the past year.[2]

We developed "MyPath," a novel patient-facing web-based decision support tool, to address gaps in reproductive planning services in VA primary care. MyPath's objectives are to help women Veterans consider their reproductive goals, increase their knowledge, align contraceptive and pregnancy timing decisions with their goals and health needs, and engage in shared decision making with providers. In pilot testing among 58 Veterans, use of MyPath prior to clinic visits was highly acceptable to Veterans and increased reproductive planning discussions compared to usual care without increasing providers' perceived workload. We aim to study MyPath in a pragmatic randomized trial to assess efficacy and collect implementation data.

Specific Aims:

1) Aim 1 will test the effect of the MyPath tool used by women Veterans before primary care visits on occurrence of reproductive planning discussions with shared decision making (primary outcome), patient-provider communication self-efficacy, and contraceptive decision quality, compared to usual care;

2) Aim 2 will test the longer-term effect of MyPath on contraceptive utilization, unintended pregnancy, and preconception health behaviors, compared to usual care;

3) Aim 3 is an implementation process evaluation, including quantitative and qualitative data collection to identify implementation barriers and facilitators and intervention costs.

Exploratory analyses will examine effect modification of Aim 1 and 2 outcomes by race/ethnicity, age, visit modality (in-person or virtual) and provider practice-type (Women's Clinic or non-Women's Clinic).

Methodology:

This study is a randomized controlled trial that is clustered at the provider level among up to 100 women's health primary care providers and their reproductive-aged women Veteran patients at up to 16 sites. The trial will investigate the effect of our web-based decision support tool on occurrence of reproductive planning discussions with shared decision making, reproductive knowledge and decision quality, and contraceptive and preconception health behaviors.

Enrolled patients scheduled to see intervention providers will receive a text message containing the MyPath link prior to their visits; enrolled patients scheduled to see a control arm provider will receive usual care. We will assess outcomes among a minimum of 456 women Veterans by either telephone or online immediately after their scheduled visit, as well as by telephone at 3- and 6-month follow up timepoints. We will also collect data to describe implementation barriers and facilitators using quantitative methods, including cost analysis, and qualitative methods, including interviews with Veterans, providers, and clinic leaders. We will use best practices for the conduct and reporting of this type of trial as detailed in the CONSORT guidelines.

List of Abbreviations

AMVAHCS – VA Amarillo Healthcare System

AVAHCS – Atlanta VA Health Care System

CDC – Centers for Disease Control and Prevention

CDW – VA Corporate Data Warehouse (repository of electronic health record-based clinical and administrative data)

Co-I – Co-Investigator

COIN – VA Center of Innovation for Veteran-Centered and Value-Driven Care

CTVAHCS – VA Central Texas Healthcare System

DVAHCS – Durham VA Health Care System

ELVAHCS – VA El Paso Healthcare System

HSR&D – VA Health Services Research & Development

LSI – Local Site Investigator

MEDVAMC - Michael E. DeBakey Veterans Affairs Medical Center (Houston, Texas)

OVAHCS- Orlando VA Health Care System

PBRN – Practice-Based Research Network

PHI – Personal Health Information

PI/SC – Principal Investigator/Study Chair

RA – Research Assistant

RCT – Randomized Controlled Trial

RLP – Reproductive Life Planning

SDM – Shared Decision Making

STVHCS – VA South Texas Healthcare System

VA – Veterans Affairs

VAECHCS – VA Eastern Colorado Health Care System

VANTHCS – VA North Texas Healthcare System

VAPSHCS – VA Puget Sound Health Care System

VAPHS – VA Pittsburgh Healthcare System

VASDHCS – VA San Diego Healthcare System

VASLCHCS – VA Salt Lake City Health Care System

VATVCBHCS – VA Texas Valley Coastal Bend Healthcare System

VINCI – VA Informatics and Computing Infrastructure

VSSC – VHA Support Service Center

WTVAHCS – VA West Texas Healthcare System

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1.0 Study Personnel

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Study Sites

The study will be conducted at three engaged sites:

- VA Puget Sound Health Care System (VAPSHCS); LSI: Lisa Callegari
- VA Salt Lake City Health Care System (VASLCHCS); LSI: Jessica Johnson
- VA Pittsburgh Health Care System (VAPHCS); LSI: Deirdre Quinn

In addition, study staff will recruit, consent, and enroll VA staff and patients remotely from up to thirteen additional non-engaged sites that are part of the VA women's health Practice-Based Research Network (PBRN).

2.0 Introduction

Delivery of high-quality reproductive healthcare for women Veterans is a national priority[3, 4]. The number of women Veterans of childbearing age using VA healthcare increased 2-fold over the past 15 years[5]. Women VA-users under the age of 35, those most likely to experience pregnancy, demonstrated an even more dramatic 3-fold rise in numbers over that timeframe[5]. Through system-wide efforts including training women's health providers[6] and creation of comprehensive Women's Health Clinics offering integrated gender-specific and general primary care[7], VA has made substantial progress in delivery of reproductive health services. Despite these advances, however, suboptimal contraceptive use, high rates of unintended pregnancy, and low rates of receiving contraceptive and/or preconception counseling underscore significant ongoing unmet reproductive health need among women Veterans[1, 2].

Although Veterans have access to the full range of prescription contraceptive options at low or no cost[8], data published by study investigators indicate that nearly 40% of pregnancies among women Veterans are unintended, similar to the age-adjusted general population[1]. Unintended pregnancy, defined as pregnancy that is unwanted or occurring earlier than desired, is independently associated with adverse health outcomes[9] as well as negative impacts on women's economic and social wellbeing[10] and an estimated $4.5 billion dollars annually in healthcare costs in the US[11]. Additionally, unintended pregnancy often precludes opportunities for health optimization prior to pregnancy[12]. This is of particular importance in women Veterans who have a higher prevalence of potentially modifiable risk factors for poor maternal and neonatal outcomes compared to their civilian counterparts, including medical comorbidities[13, 14], mental health conditions[15] and psychosocial stressors[16].

The Centers for Disease Control and Prevention (CDC)[17] and other national organizations[18, 19] recommend routine delivery of reproductive planning services in primary care to improve reproductive decision making and outcomes. Reproductive planning services include assessment of women's childbearing desires and goals followed by individualized contraceptive and/or preconception counseling to address women's goals and needs[17]. Beyond advocating for increased delivery of reproductive planning services, national organizations also emphasize the importance of patient-centeredness in reproductive planning counseling and care[17, 18]. A

key component of patient-centered counseling is shared decision making (SDM), a two-way process of communication between patients and providers that incorporates patients' goals, values and preferences into the decision making process[20, 21]. SDM in contraceptive counseling is preferred by women[22-24], including Veterans[25], and is associated with increased rates of contraceptive continuation and use of effective contraceptive methods[26-28].

Delivery of patient-centered reproductive planning services happens infrequently in primary care outside[29, 30] or within VA[2]. As the vast majority of basic reproductive healthcare in VA is provided in primary care rather than specialist gynecology care[31], provision of reproductive planning counseling and services by VA primary care providers is essential. In a large national survey, however, only 38% of Veterans at risk of pregnancy reported discussing contraception and/or preconception health with their primary care provider in the past year[2]. Of additional concern, studies indicate that key elements of patient-centered counseling, such as active listening and eliciting women's values and preferences, are often absent in reproductive planning encounters in VA[25, 26, 32]. Patient-level barriers to high-quality reproductive planning counseling identified in qualitative work by Dr. Callegari include women Veterans' perceived low self-efficacy to request this counseling and perceived lack of time in visits. Veterans' low self-efficacy is linked to negative past experiences of reproductive health counseling in the military and VA, including gender-based discrimination and dismissal of reproductive health concerns, resulting in fears that reproductive planning conversations will not be valued by VA providers[25].

Existing interventions have had limited effect on increasing delivery or patient-centeredness of reproductive planning services. Prior efforts to increase reproductive planning counseling and services include use of a paper-based "Reproductive Life Planning (RLP)" tool created by the CDC over 10 years ago[12, 33]. The RLP tool was developed without an explicit evidence- or theory-based process, however, and recent studies suggest that its content does not address the complexity of women's actual reproductive health decision making[34, 35]. Other efforts to improve reproductive planning services in primary care, such as clinical decision support systems in the electronic medical record, have had similarly limited effects[36, 37]. These prior studies suggest that additional research is needed to identify effective strategies for increasing the quantity and quality of reproductive planning services in primary care.

The MyPath intervention is a theory-based, state-of-the-art web-based decision support tool. Patient-facing decision tools have been shown to promote SDM and to improve decision quality; preliminary data also suggests improvements in clinical outcomes such as medication continuation and adherence[20]. Our research team utilized an evidence-based and theory-informed process to develop MyPath, a patient-facing web-based tool designed to be used prior to primary care visits to help women Veterans (1) consider their reproductive goals, (2) improve their knowledge about fertility, contraception, and preconception health risks, (3) align contraceptive decisions with their preferences and goals, and (4) engage in SDM with providers. The tool also offers users the option to email a "summary page" of their questions and choices to themselves to use at an upcoming medical appointment.

From April to August 2017, we conducted a non-randomized pilot study of MyPath (n=30) with a historical pre-intervention control group (n=28) in VA Seattle and VA American Lake Women's Health Clinics. Veterans spent an average of 11 minutes using MyPath. Acceptability of MyPath

was high among both women Veterans and providers. All Veterans (100%) felt that MyPath was useful for thinking about one or more topic areas (menstrual cycle/fertility, preconception health, contraception), 97% agreed they gained new information from using MyPath, and 93% would recommend MyPath to other women Veterans. Providers reported that MyPath did not significantly increase their workload and 83% would like their patients to use it in the future. Our pilot data demonstrate that MyPath is highly acceptable to women Veterans and has potential to increase reproductive planning services and decision quality using a low-intensity, scalable approach. Further research is needed to establish whether MyPath is efficacious at increasing the quantity and quality of patient-provider communication, increasing effective contraceptive use, and increasing pre-conception health behaviors.

3.0 Objectives

Our overarching hypothesis is that MyPath will increase patient-centered reproductive planning discussions and improve contraceptive decision quality, leading to improved reproductive behaviors and health outcomes for women Veterans receiving primary care at VA. To test this hypothesis, we will conduct a randomized controlled trial (RCT) at up to 16 sites, clustered at the provider level among up to 100 providers and their reproductive-aged women Veteran patients, guided by the following aims:

Aim 1. To test the effect of MyPath on the occurrence of reproductive planning discussions with SDM (primary outcome), compared to usual care. Secondary outcomes include the impact of MyPath on communication self-efficacy and measures of contraceptive decision quality (knowledge, decisional conflict, values concordance).

Aim 2. To test the effect of MyPath on clinical outcomes at 3 and 6 months after the index visit including contraceptive utilization (continuous contraceptive use, use of effective methods) and unintended pregnancy, compared to usual care. Exploratory outcomes will include behaviors to modify preconception health risks.

Aim 3. To identify potential barriers and facilitators to implementation by collecting process and cost data and conducting qualitative interviews with Veterans, providers, and clinic leaders, with the goal of facilitating future implementation in partnership with Women's Health Services if MyPath is found to be effective.

Exploratory analyses will also look for effect modification of Aim 1 and 2 outcomes by race/ethnicity, age, visit modality (in-person or virtual) and provider practice-type (Women's Clinic or non-Women's Clinic).

In addition, we plan to obtain covariate and outcome data in VA Corporate Data Warehouse (CDW) from the electronic health record to collect some demographic and covariate variables and inform future implementation studies. We will compare self-reported reproductive health outcomes of participants (collected at 3- and 6-months) with reproductive health data from the

electronic health record to assess for agreement and identify possible CDW structured data that would be used as outcomes for larger-scale implementation studies.

4.0 Resources and Personnel

Study investigators are located at four VA sites (including the three engaged study sites, plus VA Greater Los Angeles). Study staff will recruit, consent, and collect data remotely from providers and patients at up 16 VA sites (including the three engaged sites as well as up to thirteen non-engaged PBRN sites described below). In addition, we have a contract with a software company for maintenance of the web-based decision tool. The contracted software company will have no access to identifiable data or personal health information (PHI) and will not be involved in study analysis.

The two co-investigators who are not LSIs (Karin Nelson at VAPSHCS and Alison Hamilton at VA Greater Los Angeles) will have access to aggregate-level, de-identified data only.

Study Sites

The study will be conducted at three engaged sites:

- VA Puget Sound Health Care System (VAPSHCS); LSI: Lisa Callegari
- VA Salt Lake City Health Care System (VASLCHCS); LSI: Jessica Johnson
- VA Pittsburgh Health Care System (VAPHCS); LSI: Deirdre Quinn

In addition, study staff will recruit, consent, and enroll VA staff and patients remotely from up to 13 non-engaged sites that are part of the VA women's health PBRN. Site contacts listed below serve as PBRN site leads. They are not engaged in the research study, but provide periodic guidance on recruitment methods and other site-specific questions as they arise. Additionally, site contacts serve as a liaison between study staff/investigators and site leadership:

Non-Engaged Sites

Site	Women's Health Site Contact	Site Status
VA Eastern Colorado Health Care System (VAECHCS) in Denver, CO	Kim Chen, MD	Obtained facility level approvals and currently enrolling
Michael E. DeBakey VA Medical Center (MEDVAMC) in Houston, TX	Deleene Menefee, PhD	Obtained facility level approvals and currently enrolling
Durham VA Health Care System (DVAHCS)	Karen Goldstein, MD, MSPH	Obtained facility level approvals and currently enrolling
Atlanta VA Health Care System (AVAHCS)	Ursula Kelly, PhD, ANP-BC, PMHNP-BC	Obtained facility level approvals and currently enrolling

Orlando VA Health Care System (OVAHCS)	Georgine Lamvu, MD, MPH	Obtained facility level approvals and currently enrolling
VA San Diego Healthcare System (VASDHCS)	Karuna Ahuja, MD	Obtained facility level approvals and currently enrolling
VA Amarillo Healthcare System (AMVAHCS)	Juli McNeil, MSSW, LCSW	Pursuant to facility-level approvals, will begin enrollment
VA Central Texas Healthcare System (CTVAHCS)	Juli McNeil, MSSW, LCSW	Pursuant to facility-level approvals, will begin enrollment
VA El Paso Healthcare System (ELVAHCS)	Seigrid Nixon, MD	Obtained facility level approvals and currently enrolling
VA South Texas Healthcare System (STVHCS)	Araceli Revote, MD	Obtained facility level approvals and currently enrolling
VA North Texas Healthcare System (VANTHCS)	Juli McNeil, MSSW, LCSW	Pursuant to facility-level approvals, will begin enrollment
VA Texas Valley Coastal Bend Healthcare System (VATVCBHCS)	Juli McNeil, MSSW, LCSW	Pursuant to facility-level approvals, will begin enrollment
VA West Texas Healthcare System (WTVAHCS)	Juli McNeil, MSSW, LCSW	Pursuant to facility-level approvals, will begin enrollment

Key Study Personnel

Name	Role	VA Site	PHI Access	Recruit/ Consent / Data Collection	Analysis
Lisa Callegari, MD, MPH	PI/SC, LSI	Seattle	Y	Y	Y
Karin Nelson, MD, MSHS	Co-I	Seattle	N	N	Y
Deirdre Quinn, PhD, MSc, MLitt	Co-I, LSI	Pittsburgh	Y	N	Y
Jessica Johnson, MD	Co-I, LSI	SLC	Y	N	Y
Alison Hamilton, PhD, MPH	Co-I	Los Angeles	N	N	Y

Non-Key Overall Study Personnel

Name	Role	Location	PHI Access	Recruit/ Consent/ Data Collection	Analysis
Samantha Benson, MPH	Study Manager	Seattle	Y	Y	Y
Siobhan Mahorter, MPH	Research Coord.	Seattle	Y	Y	Y
Leslie Taylor, PhD	Biostatistician	Seattle	N	N	Y
Scott Coggeshall, PhD	Biostatistician	Seattle	N	N	Y
Jeff Todd-Stenberg, PhD	Data Requisitioner	Seattle	Y	N	N
Rachel Hunter-Merrill, MA	Data Analyst	Seattle	Y	N	Y
Vyshnika Sriskantharajah	Data Manager	Seattle	Y	N	Y
George Sayre, PsyD	Qualitative Methodologist	Seattle	N	N	Y
Deirdre Quinn, PhD, MSc, MLitt	Research Consultant	Pittsburgh	Y	N	Y
Kristen Rice, MPH	Research Assistant	Pittsburgh	Y	Y	Y
Aarthi Yogendran	Research Assistant	Seattle	Y	Y	Y
Amy Alcantara	Research Assistant	Salt Lake City	Y	Y	Y
Shannon Mitchell	Research Assistant	Pittsburgh	Y	Y	Y

Caroline Merkel	Research Assistant	Seattle	Y	Y	Y
Na'imah Muhammad	Research Assistant	Seattle	Y	Y	Y
Christine Sulc	Research Assistant	Seattle	Y	Y	Y
Theresa Neinas	Research Assistant	Seattle	Y	Y	Y

Services Performed by Outside Contractor

The software development company Nitid Bit, LLC, will perform maintenance and updates to support the web-based decision tool, MyPath, and will store MyPath analytics data (which is not identifiable). The decision tool was built by Nitid Bit using prior VA research funding. The contractors will manage de-identified analytic data on use of the tool (e.g. time spent on each section of the tool) but will not have access to any PHI.

5.0 Study Procedures

5.1 Study Design

Experimental Design

For Aims 1, and 2, we will use a cluster randomized trial design with clustering at the provider level to study the efficacy of MyPath delivered via text message to patients prior to primary care appointments at VA. The unit of randomization is the provider. This approach allows us to optimize efficiency while minimizing the risk of bias and contamination. Specifically, randomizing providers rather than patients addresses the contamination concern that providers interacting with patients who use MyPath may be exposed to the Summary Page from the tool highlighting patients' goals and preferences, which could alter communication with patients who have not used the tool.

After enrollment, providers will be randomized to **intervention arm** or **usual care arm** with a 1:1 allocation ratio. Randomization will be stratified by the clinic practice-type (Women's Clinic vs. non-Women's Clinic) and study site (Seattle, Salt Lake City, Pittsburgh, and the additional non-engaged PBRN sites: Atlanta, Denver, Durham, Houston, Orlando, San Diego, Amarillo, Central Texas, El Paso, South Texas, North Texas, Texas Valley Coastal Blend, and West Texas). We will include stratification by clinic practice-type because we expect providers located in Women's Clinics may communicate about reproductive planning differently than providers in other primary care settings.

Women Veterans will be identified for recruitment if they have a scheduled primary care appointment with an enrolled study provider, are 18-44 years old, and have no CDW evidence of impaired decision-making or a past procedure that would result in infertility (e.g., hysterectomy, oophorectomy, or sterilization). Those patients will be screened, consented, and enrolled approximately one week before their scheduled appointment. Recruitment will take place over the course of 18 months.

Intervention: The MyPath intervention is designed to promote guideline-recommended care and best practices for reproductive health care. As such, MyPath itself is a variation of usual practice. Providers randomized to the intervention arm will receive the link to the MyPath tool, a brief orientation to MyPath by telephone, a brief conversation guide (Attachment T), and a wearable button (Attachment U) and card (Attachment V) prompting patients to bring up MyPath during their appointment. Study staff may also identify and send publicly available clinical resources for reproductive health counseling or decision making when requested. Study staff will contact providers in the intervention arm approximately every six months (via phone, email or MS Teams message) to provide updates on the study and offer support and advice regarding the MyPath tool. Providers in the control/usual care arm will not be provided any education or information about the intervention, will be asked not to disseminate MyPath to their patients during the study recruitment phase, and will provide usual care.

Enrolled patients scheduled to see intervention providers will be sent a text message prior to their appointment through the existing national VA VetText program (see letter of support from Dr. Callegari's IIR grant application, Attachment B). The text message will include a brief invitation to use MyPath along with a link to the tool. Participants will be asked whether they consent to receive text messages from VA that include PHI, a practice that the VetText program uses to be able to send additional details about appointments in text messages. Participant consent will be documented in their study record. In the MyPath pilot study, patients spent an average of 11 minutes using the MyPath tool. The MyPath tool can be accessed at va.mypathtool.org using a mobile device or Google Chrome web browser. Screens shots from each main section of MyPath may be reviewed in the attached MyPath Intervention Overview (Attachment C).

Blinding: All recruitment for providers and patients will be done via telephone and email by study Research Assistants (RAs). Consent and survey data collection for the trial for both providers and patients will be done via telephone by RAs. Survey data collection for the patient post-visit survey will either be done through a Qualtrics online survey that will be sent to patients via a VA-approved Qualtrics one-way text message, or completed via telephone by RAs. RAs will remain blinded to the intervention and control arm assignment of *providers* throughout the period of study data collection. RAs will remain blinded to the intervention and control arm assignments of *patients* until the end of the post-visit survey, after Aim 1 outcomes have been assessed. The final questions of the post-visit survey for patients will assess adherence to the intervention (i.e., use of the MyPath tool), which will unblind RAs to each patient's study arm when the patient reaches that point in the study. Because RAs will never be made aware of which patient is scheduled to see which provider, the unblinding of patients' study arms at the end of the post-visit survey will not result in RAs being unblinded to providers' study arms.

Use of Administrative Data: Survey data will be supplemented with medical record data housed in CDW to describe the study population, assess some study covariates, and compare outcomes assessed by survey with outcome data available in CDW as described in the Administrative Data Sources and Codes document (Attachment D).

For Aim 3, we will collect both qualitative and quantitative data to understand barriers and facilitators to the implementation of the MyPath intervention in VA clinical practice. This aim will be guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework, a widely used implementation framework incorporating both individual- and organizational-level elements[38].

Qualitative: Up to 30 intervention arm patients will be interviewed after their post-visit survey about their experiences using MyPath. Intervention arm providers will be interviewed at the close of patient recruitment about their experiences in the study and about potential barriers and facilitators to implementing MyPath in clinical practice. Up to 15 clinic leaders will be interviewed at the close of patient recruitment about potential barriers and facilitators to implementing MyPath in clinical settings.

Quantitative: Quantitative data collection to assess reach will include intervention adherence by patient participants (i.e., the proportion of patients in the intervention arm who used the intervention). Analytic data from the software developers hosting MyPath will be obtained. Analytic data will verify self-reported use of the tool, quantify time spent using the tool, and describe which pages of MyPath are most visited to better understand the reach of MyPath among women receiving the intervention. Women in the intervention group will be assigned a personal code consisting of two words and a number when they access MyPath, and MyPath analytic data will be linked to this code. Linkage of the code will be maintained in a crosswalk behind the VA firewall. Lastly, process data will be collected to estimate costs of implementing the intervention, including time spent training intervention arm providers, costs of disseminating the tool, and costs of software

Study Population

Providers: We will enroll up to 100 primary care providers who have seen at least 30 unique reproductive-aged women in the past year. Providers will be recruited across the 9-16 study sites. Trainees who must staff with attending providers (e.g. residents and medical students) will be excluded from participation. After patient recruitment is complete, we will invite intervention arm providers to complete qualitative interviews for Aim 3 about their experiences seeing patients who used the tool.

Patients: We anticipate enrolling approximately 456 women Veteran patients (not to exceed 570 patients) scheduled to see enrolled providers over the course of 18 months of recruitment. We aim to recruit approximately 15 patients scheduled to see each study provider, for a cluster size of 15 and a total sample size of 456, though depending on enrollment rates and in efforts to balance the number of patients in study arms, additional patients may be enrolled up to a maximum of 570. Up to 30 intervention arm Veteran participants will be interviewed for Aim 3. They will be purposively sampled for variety in characteristics such as intervention adherence, race/ethnicity, age, parity, provider in a women's clinic vs non-women's clinic, and site/geographic location.

Clinic Leaders: We will enroll and interview up to 20 clinic leaders who work with enrolled providers for Aim 3.

Potentially vulnerable groups that may be included in our patient population because we are not specifically excluding them include employees or students; economically and/or educationally disadvantaged persons; and patients that identify as racial or ethnic minorities. It is unlikely that study eligible patients will be illiterate or have limited English language proficiency as these are requirements of military service enrollment. Pregnant women will be excluded from the study because the MyPath intervention is designed for non-pregnant women. Additional groups that will be excluded include women who are not capable of pregnancy (e.g., with known infertility for reasons such as hysterectomy or tubal sterilization), who are not interested in receiving information about birth control or planning for pregnancy, and women who are older than 44, as fertility and risk of pregnancy drops significantly over this age.

Minimizing Anticipated Risks

Risks to VA employees (providers and clinic leaders): The primary risk of the study to VA employees is the potential of disclosure of confidential or sensitive data. Although unlikely, employees may experience discomfort while completing self-report surveys or qualitative interviews. In addition, providers may perceive additional burden due to seeing patients who have used the MyPath tool. We anticipate this burden to be minimal, however, as no providers in our pilot study felt that that MyPath added significant burden and some providers felt that MyPath made counseling more efficient because patients were informed about their options. The following strategies will help minimize risks to employees:

- The Seattle Health Services Research & Development (HSR&D) Center of Innovation (COIN) has developed extensive security measures (discussed below in section 7.0) to minimize the risk of disclosure of confidential or sensitive data.
- Steps will be taken to minimize the risk of invasion of privacy. Employees will be sent a recruitment email, which will include the study information sheet. This email will invite employees who do not wish to be contacted further about the study to opt-out of further contact/recruitment efforts by responding to the email.
- When reached by telephone for recruitment, consent, and enrollment, study staff will discuss the voluntary nature of study participation with employees, emphasizing that their choice of whether to participate will not affect their employment or work environment.
- All participants will be informed by study staff that they may choose not to answer any questions for any reason.
- All participants will be informed that they may choose to withdraw from the study at any time.

Risks to patients: The MyPath tool is a variation of normal care and designed to promote guideline-recommended reproductive healthcare, including assessment of reproductive goals,

contraceptive care, and preconception care. The expected benefit is an increase in the likelihood that women Veteran patients receive national guideline-recommended care. The primary risk of the study to VA patients is the potential of disclosure of confidential or sensitive data. Although unlikely, patients may experience discomfort while completing the MyPath tool, self-report surveys, or qualitative interviews. The following strategies will help minimize risks to patients:

- The Seattle HSR&D COIN has developed extensive security measures (discussed below in the "Data Security Measures" section 7.0) to minimize the risk of disclosure of confidential or sensitive data.
- Steps will be taken to minimize the risk of invasion of privacy. Initial contact with prospective participants will be via an introductory study mailing, which will include the study information statement and a postage-paid post card that patients may return to opt-out of further contact by the study team.
- Recruitment emails will emphasize the voluntary nature of the study. When prospective participants are reached by telephone for recruitment, consent, and enrollment, study staff will discuss the voluntary nature of study participation with patients, emphasizing that their choice of whether to participate will not affect the care they receive at VA or the benefits for which they are eligible.
- All participants will be informed by study staff that they may choose not to answer any questions for any reason.
- All participants will be informed that they may choose to withdraw from the study at any time.
- Although unlikely, some respondents may find some questions intrusive or offensive or may become distressed. To minimize this risk, study personnel will be trained in how to communicate with patients regarding reproductive and sexual health and remind participants about their rights as listed above (to withdraw from the study or skip any question). Any participant who experiences distress or any adverse reaction as a result of any study questions will be given information about who to call to talk in more detail. They will be provided with resources as listed in the attached Crisis Protocol (Attachment E).

Analysis of Risk vs. Benefit

VA Employees: Employee participants may benefit from this research in several ways. First, employee participants may gain satisfaction from participating in a research project designed to improve the quality of care for reproductive-aged women Veterans. In Dr. Callegari's previous work, providers felt that preconception and contraception care are essential to the health and well-being of their Veteran patients and were enthusiastic about offering feedback regarding barriers and facilitators to providing reproductive planning services in the primary care setting. Participation could provide VA providers and staff a sense that they are contributing to important quality improvement work. Further, a number of providers in the MyPath pilot study felt that the

tool made their counseling more efficient because patients were more informed about their options. Providers in the intervention group during the study, and providers in the control group after the study if the intervention is continued, could thus benefit from more efficient counseling experiences.

Patients: Veteran participants may benefit in several ways from the study. From Dr. Callegari's previous work, women Veterans of childbearing age generally perceive significant gaps in care related to pregnancy planning and contraception counseling in VA primary care. In prior qualitative work, Veterans were enthusiastic about efforts on the part of VA to improve these services. Women Veteran participants may benefit from knowing that they are contributing to research efforts to improve delivery and quality of VA care. Women Veteran participants in the study intervention arm may benefit by knowledge gained, improved quality of their reproductive decisions, improved communication with their providers, and improved health behaviors after using the MyPath tool. Women Veterans in the control arm will not benefit from the MyPath intervention during the study but could benefit from implementation after the study, if the intervention is found to be effective. Veteran participants will also receive monetary incentives to compensate their time.

Balance of Potential Risks and Benefits: These potential benefits outweigh the minimal risks related to loss of privacy and confidentiality and of discomfort when discussing health or operational matters, which are no greater that those encountered by employees and VA patients in daily life.

Protection for Vulnerable Populations

All VA employees will be informed that their participation is voluntary and that opting out will not affect their employment, work environment, or benefits in any way.

It is likely that patients from vulnerable populations will be included in our datasets, such as employees or students; economically and/or educationally disadvantaged persons; and patients who identify as racial/ethnic minorities. We do not anticipate the intervention or participation in the study evaluations will pose any additional risks to these populations. Should members of these groups be included, we anticipate that they will be adequately protected by the above strategies of risk minimization.

Data Repository/Data Banking

Due to a CIRB determination in January 2024, data collected under a Waiver of HIPAA Authorization cannot be deposited into a data repository or registry; thus, these activities have been discontinued. No study data (past or future) collected under this protocol will be deposited into a data repository or registry and participants will no longer be asked if they would like to store their data for future use in a data repository and registry.

5.2 Recruitment Methods

Sample Size

Providers: Up to 100 providers will be enrolled for Aims 1 and 2, and all intervention arm providers (up to approximately 38) will be invited to complete the qualitative interview at the end of the patient recruitment/enrollment phase.

Patients: no more than 570 patients will be enrolled for the RCT, and up to 30 intervention-arm patients will complete the qualitative interview after the post-visit survey.

Clinic Leaders: Up to 35 clinic leaders will complete qualitative interviews at the end of the patient recruitment/enrollment phase.

Identifying and Recruiting Study Participants

Providers: Providers from each study site will be identified as potentially eligible for study recruitment using data available through CDW. These data will be accessed by our data requisitioner using the VA Informatics and Computing Infrastructure (VINCI). Recruitment emails will be sent to potentially eligible providers by study staff (see attached email, Attachment F). Recruitment emails will include a study information statement for providers (Attachment G) and will instruct providers to respond if they do not wish to be contacted about participation in the study. Opt-out responses from providers will be collated by the study manager. Recruitment lists will be made available to study RAs at least one week later. RAs will contact providers by telephone, email, and MS Teams messenger. Screening, consent, and study enrollment will occur over the telephone (see attached script, Attachment H). No more than 3 voice messages, 3 emails, and 3 MS Teams direct/instant messages will be sent by study staff to potentially eligible providers that have not opted-out of study contact.

Patients: After study providers have been enrolled, the data requisitioner will pull lists of all potentially eligible VA patients (women ages 18-44 without medical record evidence of infertility) empaneled to enrolled providers. Recruitment letters will be mailed to these patients (Attachment I) by the study manager or research coordinator at the start of the study. Recruitment letters will include a study information statement for patients (Attachment J) and a postage-paid opt-out postcard (Attachment K) which patients may return by mail if they do not wish to be contacted further about study participation. The data requisitioner will pull lists of potentially eligible patients assigned to enrolled provider primary care panels again at 6 and 12 months into the patient recruitment phase and recruitment letters will be mailed to any new patients (those not previously mailed a recruitment letter). The study manager and research coordinator will track any opt-out postcards in the patient crosswalk database so that no further contact will be made with those patients.

During the active patient recruitment phase of the study, the data requisitioner will pull weekly lists of potentially eligible VA patients (same criteria as above) that are scheduled to see enrolled study providers during the following week. In-person, telephone, and video-conferencing appointments will be eligible study visits. The study manager, research coordinator, or database manager will match these lists against the patient crosswalk database to remove any patients to whom a recruitment letter was never sent, who returned the opt-out postcard, who already enrolled in the study, or who have declined participation or withdrawn from the study previously.

Those vetted recruitment lists will be distributed to the study RAs, who will make contact with patients prior to their appointments by email (for screening, when email addresses are available) and subsequently by telephone (for screening, consent and enrollment; see attached script, Attachment L).

- **Email recruitment:** To provide Veterans a second opportunity to opt-out of the study, RAs will send an unencrypted email from a designated study email account (to which only study staff have access). The recruitment email will introduce Veterans to the study and invite them to complete a confidential online questionnaire (using the Qualtrics online survey program) as a means of opting-in or opting-out of being contacted about the study and screening for eligibility. The study information statement (which was previously mailed to all potentially eligible participants; Attachment J) will also be made available as a downloadable document within the online Qualtrics recruitment survey. The recruitment email does not contain the Veteran's name or other PII, and contains no statements that could be used to infer anything about the Veteran's health status. This strategy of recruiting Veterans by email is Veteran-centered because it allows Veterans who may have received the mailing many months ago, and who may have forgotten details or changed their mind about the study in the intervening time, to reconsider whether they are interested in the study and let us know before receiving recruitment calls.
- **Telephone recruitment:** If we fail to receive an opt-out (by mail, Qualtrics survey, or telephone) from a Veteran at 7 days from the Veteran's appointment date, we will contact the Veteran by telephone to invite them to learn more about the study and consider participating.

Study RAs will be responsible for recruiting, consenting and collecting data from patients at all study sites. To avoid overlap, RAs will be assigned specific shifts when they will be responsible for conducting recruitment calls/emails, and survey phone calls. RAs will document contact attempts and call outcomes in a shared recruitment list (stored on a secure VA server) to avoid overlap and ensure recruitment is synchronized. Additionally, the Study Manager and/or Study Coordinator will provide daily oversight and coordination to ensure accuracy.

Clinic Leaders: Potentially eligible clinic leaders will be identified by study co-investigators at engaged study sites and site contacts at non-engaged study sites. Recruitment emails will be sent to potentially eligible clinic leaders by the study team (see attached email, Attachment M). Recruitment emails will include a study information statement for clinic leaders (Attachment N) and will instruct clinic leaders to respond if they do not wish to be contacted about participation in the study. Opt-out responses will be collated by the study manager. Study staff conducting qualitative interviews will contact clinic leaders up to 3 times by telephone, 3 times by email, and 3 times by MS Teams instant/direct message for recruitment purposes. Screening, consent, and enrollment will happen over the telephone (see attached script, Attachment O).

Payment

Providers and Clinic Leaders: VA employees will not receive payment for participation in the study.

Patients: Enrolled patients will receive $25 by electronic funds transfer from VA or receive a $25 Amazon gift card after completing three of the study surveys (baseline, at 3 months, and at 6 months), and, when applicable, after completing a qualitative interview. Enrolled patients who complete the post-visit survey after their scheduled primary care appointment will receive $50 by electronic funds transfer from VA or a $50 Amazon gift card. This means that patients can receive up to $125 for completing all study surveys for Aims 1 and 2, and an additional $25 if invited to do a qualitative interview for Aim 3. Payments will be initiated after each completed study survey or interview; thus, patients will be paid for partial study participation. We will give Veterans the option of receiving a gift card or an electronic fund transfer from VA as payment for their study participation. VA electronic fund transfer payments are distributed through the VA Austin payment center. If a Veteran would like to receive their payment by electronic funds transfer and they have not previously filled out VA Form 10-091, Veterans have the option to complete a paper VA Form 10-091 (returned by mail) or complete VA Form 10-091 online through the VA's online Customer Engagement Portal. If a Veteran chooses to receive their payment as an Amazon gift card, these will be mailed by the study team or sent as a gift card claim code in an unencrypted email from the study email account. No Veteran identifiers would be included in the email (Attachment Z). Veterans may experience a delay in receiving electronic funds transfer payments for up to 6 months due to processing time.

5.3 Informed Consent Procedures

Study Staff Involved in Screening, Consent, and Enrollment:

Screening, verbal consent, and enrollment of providers and patients will be conducted by study RAs following the attached scripts (Attachments H and L). Study staff who will conduct qualitative interviews (investigators, study manager, or research coordinator) will conduct screening, verbal consent, and enrollment with clinic leaders before the qualitative interview following the attached script (Attachment O). The PI/SC will be responsible for ensuring that all study staff are up-to-date on VA-required human subjects protection trainings. The PI/SC and study manager will provide further specific training on obtaining verbal consent during a study orientation that will be provided to RAs, which will include role playing verbal consent scenarios.

Waiver of Documentation of Consent for Entire Study:

Because the study poses minimal risk to participants, and because recruitment and enrollment would not be feasible in-person for all participants, we are requesting a waiver of documentation of consent for the entire study. Verbal consent procedures will be conducted over the telephone by study staff after recruitment emails or physical letters with opt-out option are sent to potentially eligible participants.

Study staff obtaining verbal consent will be trained in consent processes, including to understand the importance of consent processes being interactive and non-coercive. Study staff obtaining verbal consent will be trained not to continue with the consent and enrollment if they have any reason to believe that a potentially eligible participant is not able to provide informed consent at the time of the telephone call.

Alteration of Consent During Patient Enrollment:

We are asking for an alteration of consent processes during patient enrollment, to include withholding the specific topics addressed by the intervention from eligible patients until after they have enrolled and attended their scheduled appointment. We will obtain prospective agreement from patients for this alteration during the consent process. We also propose using a small number of unnecessary screening questions to obfuscate the specific purpose of the study at the time of screening. Once patients have completed their scheduled appointment, and before any outcomes are assessed in the post-visit survey, patients will learn about the information that was withheld from patients using the Deception Debrief Script (Attachment P). Patients will learn about the information that was withheld from them either from the RAs if they complete the post-visit survey by telephone, or at the beginning of the post-visit survey if they complete the survey online via Qualtrics. We are proposing this minimal alteration in consent procedures because discussing the specific topics addressed by the tool and intervention with eligible patients could prime patients in the control arm to discuss reproductive planning with their medical provider during their scheduled appointment. Since the occurrence and the quality of reproductive planning discussions between patients and providers is our primary outcome, we hope to minimize the extent to which we prime control arm patients to discuss these topics.

Withheld Information and Prospective Agreement: As detailed in the patient information statement (Attachment J) and during verbal consent processes (Attachment L), we will inform potentially eligible patients that this study is trying to improve the primary care that women Veterans receive and is evaluating a web-based decision tool designed for women Veterans. The purpose of the intervention will be described as helping women Veterans get the most out of their primary care visits and make informed health care decisions. We will inform patients that we are interested in studying whether the intervention affects the type and quality of discussions patients have with their providers and their decisions. We will state that we are choosing not to reveal the specific topics addressed by web-based tool until after enrolled patients have seen their medical provider so that we do not influence what they decide to discuss with their providers. Patients will be informed before they decide whether or not to enroll in the study that the specific purpose of the study and the specific topics addressed by the intervention will be revealed after they have seen their provider and before we ask them any questions about their medical appointment.

Added Screening Questions: We will screen patients on the inclusion and exclusion criteria detailed below in section 5.4. Screening questions may also be found in the patient survey instruments (Attachment Q) and in the patient screening and consent script (Attachment L). In addition to asking potentially eligible patients whether they would like information about pregnancy and birth control, we will also ask if they are interested in receiving information about other health-related topics, including sleep, healthy weight, pain, smoking cessation, and stress management. Including those additional, unnecessary screening questions will reduce the extent to which eligible participants are primed to discuss pregnancy and birth control with their providers and will help to maintain the obfuscation of the specific topics covered by the intervention until after they have received the intervention or seen their provider.

Analysis of Potential Risks to Patients: An alteration to consent procedures such as what we propose may pose additional risks to patients. Patients may feel discomfort once the full details of the study purpose are revealed to them and may decide they no longer wish to participate after the study purpose is revealed to them. We are taking the following measures to reduce the risks that our proposed alteration poses:

- The withholding of information about the study purpose will be made clear in the study information statement and by RAs doing screening, consent, and enrollment. Patients can choose whether or not to enroll in the study knowing that this information will not be revealed to them until after their scheduled appointment.

- We will provide as much information about the study as possible without revealing that our outcomes are related to reproductive planning. All information provided in the study information sheet and by RAs about the study will be accurate. No inaccurate or misleading information about the study will be provided to patients.

- The withheld information will be revealed to participants using the Deception Debrief Script (Attachment P) as soon as withholding the information is no longer necessary to the conduct of the study. This will be after they have attended their medical appointment and before the post-visit survey. Participants will be offered the opportunity to ask any questions they have and will be asked if they are comfortable continuing to participate in the study.

- Patients will be screened and included in the study only if they say they are interested in receiving information about pregnancy planning and/or birth control (see inclusion and exclusion criteria in section 5.4), which means the intervention is concordant with the patients' desires for information. This reduces the likelihood that enrolled patients will find the MyPath intervention or the purpose of the study to be intrusive or offensive.

- The additional, unnecessary screening questions are not of a sensitive nature, and patient answers to the additional screening questions will not be recorded or stored as part of study datasets.

5.4 Inclusion/Exclusion Criteria

Providers:
Inclusion Criteria:

- Primary Care Provider (MD, Nurse Practitioner, Physician Assistant) at a study site
- Designated as a Women's Health Provider [defined in VA directive 1330.01 as primary care providers who have demonstrated proficiency (e.g. pelvic exams and pap smears) in women's health and who have at least 10% of their panel comprised of women]
- Completed appointments with at least 30 unique female patients ages 18-44 in the past year at a study site. If a study site does not have enough providers who meet this

criterion and are willing to enroll in the study, the study team may reduce the minimum to 15 unique female patients ages 18-44 in the past year at a study site. (pulled from CDW)

Exclusion Criteria:

- Previous involvement as provider in MyPath pilot work (identified by PI/SC)
- Medical trainee (e.g., resident physician or medical student)
- Self-report that they have plans to leave VA, go on extended leave, retire, stop primary care practice, or change VA site in the 18 months following their enrollment

Patients:

Inclusion Criteria:

- Female (obtained via CDW)
- 18 – 44 years old (obtained via CDW)
- Has a scheduled VA medical appointment with an enrolled study provider and plans to attend the appointment at the time of enrollment (obtained via VSSC and/or CDW)
- Interested in receiving information or talking with their provider about pregnancy planning and/or birth control
- At least one valid telephone number available in medical record (obtained via CDW)

Exclusion Criteria:

- Medical record history of hysterectomy, bilateral oophorectomy, female sterilization, or diagnosed infertility for another reason
- Self-reported history of hysterectomy or bilateral oophorectomy
- Self-report of not having a uterus or ovaries (e.g. transgender women), which precludes the capacity to become pregnant
- [For VAPSHCS patients] Self-report of completing MyPath decision tool previously (e.g. during pilot study or Quality Improvement work).
- Unable to communicate in English
- Impaired decision making (by ICD code, from CDW)
- Currently pregnant
- Self-report that they have opted out of VA text messages, or that they are unable to receive text messages

Clinic Leaders:

Inclusion Criteria:

- Managerial role in a VA clinical setting where at least one enrolled provider practiced during study data collection

Exclusion Criteria:

- none

5.5 Study Evaluations

Providers:

Screening: During screening, we will determine whether potentially eligible providers meet the eligibility criteria for participation in the study by reviewing inclusion and exclusion criteria. The list of provider screening variables is included as part of the attached Provider Survey Instrument (Attachment R).

Demographic and Practice Characteristics Survey: Providers complete a brief demographic and practice characteristics survey prior to randomization. The list of demographic and practice characteristics variables is attached as part of the Provider Survey Instrument (Attachment R).

Aim 3 Qualitative Interview: After completion of patient enrollment, intervention arm providers who participate in the qualitative interview will be invited to do a 15-20 minute qualitative interview. During the interview, providers will be asked questions about their experience providing care to women receiving the MyPath intervention and facilitators and barriers to implementing MyPath in clinical practice (see attached interview guide, Attachment S).

Patients:

Screening: During screening, we will determine whether potentially eligible patients meet the eligibility criteria for participation in the study by reviewing inclusion and exclusion criteria. We will ask additional screening questions in service of obfuscating the specific purpose of the study until after patients have attended their medical appointment (as discussed above in section 5.3). All screening questions are detailed in the Patient Survey Instruments (Attachment Q).

Intervention: Intervention arm participants will be asked questions after their scheduled visit about whether they accessed and used the MyPath website prior to their visit. They will also be assigned a personal code at the start of the MyPath tool. We will then ask participants to provide the personal code at the post-visit survey so that we can obtain analytic information on their use of the tool after the fact. Analytics collected using this method will include the length of time the patient stayed on the MyPath webpage, which modules they used, and whether or not they navigated to the MyPath summary page. MyPath can be viewed at va.mypathool.org and the MyPath Intervention Overview (Attachment C) includes example screen shots from each main section of the web-based intervention.

Study Surveys (baseline, post-visit, 3 months, 6 months): Veterans in both the control and intervention arms will complete a demographic and health survey at baseline (at the time of enrollment), a post-visit survey, a 3-month survey, and a 6-month survey. The baseline, 3-month and 6-month surveys will be completed via telephone with a study RA utilizing VA REDCap for data collection.

The post-visit survey will primarily be completed online. Veterans will be sent a VA-approved Qualtrics one-way text message with a link to complete the post-visit survey online after their appointment. Veterans will receive no more than 5 additional brief Qualtrics one-way text messages within the three weeks following their primary care appointment to remind them to complete the post-visit survey. If the Veteran does not complete the post-visit survey online, RAs will reach out to the Veteran via telephone and utilize VA REDCap for the post-visit survey data collection.

- One-way text message that will be sent to Veterans to complete the post-visit survey online via Qualtrics:

  It's time to complete your VA study survey:

  [Link to Qualtrics Survey]

  Thanks for contributing! Questions? Call 206-716-5901

- Example reminder one-way text messages that will be sent to Veterans to complete the post-visit survey online via Qualtrics:

Reminder: It's time to do the next survey for the women Veterans study: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Don't forget to complete the next VA study survey to receive $50: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Please complete this survey for "Improving Outcomes for Women Veterans": [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Reminder: It's time to do the next survey for the women Veterans study: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Don't forget to complete the next VA study survey to receive $50: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Don't forget to complete your VA survey by MM/DD to receive $50! [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Survey reminder! Your responses will help VA improve care for women Vets. [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Reminder from VA! Please complete this study survey ($50 compensation) [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX

Please complete this survey for “Improving Outcomes for Women Veterans”: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Reminder: Submit your next survey to help improve women Vets’ healthcare: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Reminder: Submit survey to support women’s health at VA and receive $50: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Please complete VA women’s health study survey by MM/DD to receive $50: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX
Reminder: Help the VA improve care for women Vets and receive $50: [Link to Qualtrics Survey] Questions? Call 206-XXX-XXXX

All survey questions assessed at each timepoint are provided in the attached Patient Survey Instruments (Attachment Q) and summarized below.

- Baseline survey: Demographics, pregnancy intentions, and whether the patient is at risk of unintended pregnancy (UIP) will be assessed. Baseline preconception health risks will be assessed.

- Post-visit survey: The primary outcome of the occurrence of a reproductive planning discussion with SDM and the secondary outcomes of communication self-efficacy and family planning knowledge will be assessed among all participants. Secondary outcomes relating to contraceptive choices and decisions will also be assessed post-visit among the subgroup at risk of UIP. Whether participants discussed preconception health risks or received any services related to preconception health risks identified at baseline will be assessed among participants considering pregnancy. At the end of the post-visit survey we will ask questions related to use of the intervention for Aim 3, including collecting the users’ assigned personal codes as described above.

- 3- and 6-month surveys: Changes in pregnancy goals and whether the patient continues to be at risk of UIP will be assessed. Secondary outcomes relating to contraceptive use and unintended pregnancy will be assessed among the group remaining at risk of UIP. Preconception health behaviors, an exploratory outcome, will be assessed.

Aim 3 Qualitative Interview: Intervention arm patients who participate in the qualitative interview will be asked questions about their experience receiving the MyPath text message, using or not using the MyPath intervention, and using any other similar health-related tools previously (see interview guide, Attachment S).

Clinic Leaders:
Brief Demographic Survey and Qualitative Interview: Clinic leaders who complete the qualitative interview will be asked questions about their experience having the MyPath intervention provided to patients in their clinic and facilitators and barriers to implementing MyPath in clinical practice. See attached interview guide (Attachment S).

5.6 Data Analysis

Aims 1 and 2 - Sample Size:
Sample size and power calculations are based on our primary outcome, occurrence of reproductive planning discussion between patient and provider with shared decision making (SDM), and rely on formulas specified for use in cluster randomized trials accounting for non-use of the tool in the intervention group and attrition.[39] We estimate that the baseline prevalence of discussions of contraception and/or preconception health among women who could potentially become pregnant will be 50%, based on estimates from the nationally-representative VA ECUUN study and our pilot study.[2] Based on field testing, we estimate that 30% of women participants enrolled in the intervention arm who receive the text with the MyPath link will not actually view the tool and the sample size calculation will thus account for this estimated non-use. Assuming a kappa coefficient of 0.01 and attrition of 5%, a sample of 456 patients (approximately 15 patients for each of 30 providers) will yield 80% power in 2-sided tests with a type-1 error rate of 5% to detect a 20-percentage point increase in reproductive planning with SDM to 70%. This difference is clinically meaningful and consistent with what we observed in our pilot (22% increase).

Aims 1 and 2 - Missing data and subject dropouts:
For the 3- and 6-month follow-up periods, we assume 20% attrition (15% lost to follow up and 5% who either become pregnant or change to desiring pregnancy). This is a conservative estimate based on 7% attrition at 3-months in our pilot. All appropriate efforts will be made to avoid missing data, including monitoring of missingness and subject dropout rates by the PI and study manager or research coordinator biweekly during the study data collection phase. The research coordinator will investigate causes and remedies. For key analysis variables that have 15% or more missing values, we will analyze factors that are associated with having a missing value and perform a sensitivity analysis using multiple imputation to allow an unbiased analysis for all subjects.

Because informative missingness would violate the covariate-dependent missing at random (CDMAR) assumption of the standard multiple imputation procedure, we will conduct sensitivity analyses in which we multiply impute missing data under plausible informative missing data mechanisms – in particular, lower contraceptive continuation rates among participants with missing values of this outcome, in one or both arms. In all analyses, we will check for departures from model assumptions.

Aims 1 and 2 - Outcome Analyses:

Intention to Treat: Primary analyses of treatment effects will be intent-to-treat, with participants analyzed in the groups to which they were originally assigned irrespective of whether or not they received the intervention. Therefore, participants who "cross-over" from their assigned study arm will be analyzed in their originally assigned group. Participants will be withdrawn/removed from the study and excluded from analysis after enrollment in either of these circumstances:

- Participants who do not attend their scheduled visit with the study provider after enrollment (and thus have an undefined outcome for patient-provider reproductive planning discussion).
- Participants who find out they are pregnant during their enrollment visit (and thus would have been ineligible had this been known prior to enrollment).

Secondary analysis will utilize causal inference methods (e.g., using instrumental variables) to estimate the treatment effect between participants who actually used the MyPath tool vs. those who did not (i.e., accounting for adherence).

Analytic Subgroups: Certain secondary outcomes will be analyzed only among a pre-defined cohort/subgroup of participants. Assignment to these groups is made at patient screening/enrollment (pre-intervention). Definitions of the full sample and analytic subgroups are as follows:

- **The full sample:** includes all individuals who are eligible for and enrolled in the study based on inclusion/exclusion criteria (capable of pregnancy with no prior history of hysterectomy, oophorectomy, sterilization, not currently pregnant, interested in receiving information about either pregnancy planning or birth control, and able to receive VA text messages).
- **At risk of unintended pregnancy (UIP):** a subgroup of the full sample defined as having had sex with a man in the past 12 months who has not had a vasectomy and not currently seeking pregnancy. Outcomes related to contraception will be assessed in the subgroup at risk for UIP.
- **Considering pregnancy:** a subgroup of the full sample who are considering or ambivalent about pregnancy in the next few years. The exploratory preconception health behaviors outcomes will be assessed in this subgroup.

Description of the study populations: Provider, patient, and clinic leader participants will be described through summary statistics of demographic characteristics, and for providers, practice characteristics.

Aim 1 Primary Outcome: The analysis for our primary outcome of patient-provider discussion of reproductive planning with share decision making (SDM) will be assessed post-visit in **the full sample**. For our Aim 1 primary outcome analysis, we will use a mixed effects logistic regression model to test whether the odds of occurrence of reproductive planning with SDM is significantly different in the intervention versus control arm post-visit. In addition to estimating the odds ratio, we will also estimate the difference in predicted probabilities between the intervention and control group.

Covariates to be included in adjustment models are as follows:

- Study site (categorical)
- Clinic practice-type (binary) – Women's Clinic Y/N
- Visit Type (virtual/telephone vs. in-person)
- Patient Age (categorical)
- Patient Race/ethnicity (categorical)
- Patient Household Income (categorical)
- Patient Marital Status (categorical)
- Patient Parity (categorical)
- Mental Health Diagnosis (one or more, binary)
- Medical Comorbidity (one or more, binary)

Aim 1 Secondary Outcomes: Secondary outcomes for Aim 1 will be assessed post-visit. Secondary outcomes assessed **in the full sample** include provider-patient communication self-efficacy and reproductive planning knowledge. Secondary outcomes assessed **in the subgroup at risk of UIP** include contraceptive decisional conflict, values concordance, and contraceptive method decision. We will use a mixed effects logistic regression model to test whether these outcomes are different in the intervention versus control arm post-visit.

Aim 2 Secondary Outcomes: Secondary outcomes for Aim 2, including continuous contraceptive use, consistent contraceptive use, and unintended pregnancy, will be assessed at 3- and 6-month follow up **in the subgroup at risk of UIP**. We will use a mixed effects logistic regression model to test whether outcomes differ between groups. For continuous and consistent contraceptive use outcomes, we will adjust for self-reported pre-study contraceptive use (measured at the post-visit survey).

Exploratory Preconception Health Behaviors: These outcomes will be assessed among a subgroup of study participants considering pregnancy in the next few years or who are ambivalent about pregnancy (unsure). Preconception risk factors will be measured at baseline and using medical record data, and behaviors to modify those risk factors will be assessed at post-visit, 3-months, and 6-months.

Exploratory Analyses of Interaction Effects: **For Aim 1 and 2 outcomes,** we will assess modification of the effect of assignment to the intervention by the following 4 pre-specified factors: age, race/ethnicity, visit modality (in-person or virtual) and clinic type (Women's Health Clinic yes/no). We will assess evidence for effect modification by adding the effect modifier and its interaction with the treatment assignment indicator to the primary analysis models specified above.

Exploratory Analyses of Patient-Centered Contraceptive Outcomes: Recognizing that pregnancy intentions may fluctuate and participants in the subgroup at risk of UIP may decide that they wish to pursue pregnancy during the study timeframe, we will create "goals-concordant" measures for both continuous contraceptive use over 6 months and consistent contraceptive use at 6 months. Goals-concordant continuous contraceptive use will be defined as non-continuous use among women who desire pregnancy now; any continuous use outcome among women who are not trying but would be okay with pregnancy; and continuous use among women who desire pregnancy later, never, or who are not sure. Goals-concordant

consistent contraceptive use will be defined as no method or inconsistent use among women who desire pregnancy now; no method, inconsistent use or consistent use among women who are not trying but would be okay with pregnancy; and consistent contraceptive use among women who desire pregnancy later, never, or who are not sure.

In addition, we will create a "goals-concordant" reproductive behaviors outcome at 6 months, combining consistent contraceptive use and folic acid supplementation. Goals-concordant reproductive behavior will be defined as taking folic acid among women who desire pregnancy now; taking folic acid or consistent contraceptive use among women who are not trying but would be okay with pregnancy or who are unsure; and consistent contraceptive use among women who desire pregnancy later or never.

Aim 3 – Analysis Plan

Quantitative analyses will involve both MyPath analytics data and estimated cost data and will provide summary statistics such as total cost estimates, means or medians (e.g., of time spent using the tool), and proportions (e.g., of participants who used the tool, or who used specific components of the tool), etc. These analyses will be descriptive.

The qualitative interviews will be recorded, transcribed, and analyzed. Transcripts will be analyzed using inductive and deductive content analysis, which will allow us to obtain specific information about implementation barriers and facilitators as well as capture unanticipated themes and previously unidentified factors[41]. We will (1) deductively develop *a priori* codes based on the specified RE-AIM domains in Table 8, and (2) inductively create emergent codes to capture data that do not fit *a priori* codes. Two trained coders will independently code all transcripts. For each group separately (Veterans, providers, clinic leaders), we will begin with an initial codebook using our *a priori* codes and then add codes as they emerge[42, 43].To maintain the iterative process even as the final codebooks are applied, open codes will continue to be developed and added to the codebooks. Transcripts coded before addition of the new codes will be reexamined with the updated codebooks to ensure consistency. All analyses will be facilitated by use of ATLAS.ti software. Code output will be reviewed and discussed amongst the investigator team to identify common themes within and across groups.

Staff Analysis Responsibilities and Involvement:

The PI/SC and study biostatisticians are responsible for overseeing the analysis of all Aim 1 and 2 outcomes. The VA-employed study data analyst will be responsible for carrying out Aim 1 and 2 analyses in VA computing space, using STATA, SAS or R software packages. The PI/SC and Qualitative Methodologist are responsible for overseeing the analysis of all Aim 3 qualitative interviews. The PI/SC, study manager, research coordinator, and qualitative methodologist will be involved in the Aim 3 qualitative data analysis, including coding and synthesis of qualitative findings. Qualitative analysis will be facilitated by Atlas.ti software housed in VA computing space.

Co-I and Collaborator involvement: Study co-investigators will collaborate with the Puget Sound team to do analysis for the study. Co-Is will be involved to inform high-level analysis planning and preparation of findings for publication or presentation. Non-LSI Co-Is, including Karin

Nelson and Alison Hamilton will have access to de-identified data only, and will not have access to any participant PHI.

5.7 Withdrawal of Subjects

As discussed above in the Intention to Treat approach of section 5.6, we plan to withdraw participants from the study after enrollment under two circumstances. Both of these criteria will be assessed at the start of the post-visit survey and withdrawal would happen before assessment of any study outcome measures. The patient information statement (Attachment J) details the circumstances in which a patient could be withdrawn from the study. Participants will be removed from the study and excluded from analysis after enrollment in either of these circumstances:

- Participants who do not attend their scheduled visit with the study provider after enrollment (and thus have an undefined outcome for patient-provider reproductive planning discussion).
- Participants who find out they are pregnant during their enrollment visit (and thus would have been ineligible had this been known prior to enrollment).

Research participants may withdraw from the research at any time by notifying an RA or LSI. Participants may withdraw permission for the research team to access their medical record data by notifying an RA or LSI in writing. RAs and LSIs will notify the PI/SC, study manager, and research coordinator of any withdrawals. The PI/SC, study manager, research coordinator, or database manager will set the status of the participant to “Withdrawn/Do not contact” in the patient crosswalk, preventing further contact for study follow-up. There will be no consequences to the participant if they choose to withdraw from the research.

6.0 Reporting

No Serious Adverse Events (SAEs) are expected as a result of this study. The intervention will deliver guideline-concordant information and care. Other study procedures, including telephone surveys and qualitative interviews are minimal risk. Participants in this study will not receive any information or be asked questions outside of what they are recommended to receive in guideline-concordant primary care.

We will adhere to CIRB requirements for reporting of unanticipated problems, such as breach of confidentiality or loss of study documents containing PHI. CIRB requires reporting of these problems in writing within 5 business days.

We will adhere to CIRB requirements for reporting of adverse events (AEs) at continuing review and at study closure. As detailed in the crisis protocol (Attachment E), RAs will report any adverse patient reactions to survey questions to the PI/SC, their LSI, and the study manager as soon as possible.

Quarterly meetings with study investigators and study personnel will occur to discuss issues such as study progress, modifications, documentation, recruitment, retention, data analysis and confidentiality and to address any issues or concerns as they arise. These meetings will be overseen by the PI/SC.

Given the minimal risk to study participants from this intervention that delivers guideline-concordant health information, we propose a Data Safety Monitoring Plan, with the frequency of data monitoring as outlined in Table 3 below.

Table 3. Data Monitoring

Data type	Frequency of review	Reviewer
Subject accrual (adherence to protocol inclusion/exclusion)	Bi-Weekly	PI/SC and Study Manager or Research Coordinator
Adverse event rates	Bi-weekly	PI/SC and Study Manager or Research Coordinator
Protocol adherence (use of tool in the intervention group)	Bi-weekly	PI/SC and Study Manager or Research Coordinator
Data quality, including missingness	Bi-Weekly	PI/SC and Study Manager or Research Coordinator

7.0 Privacy and Confidentiality

Description of PHI used in study

PHI of study participants will be collected from three main data sources. The sources and identifiable data fields that will be collected are described below.

- CDW or other Electronic Health Record repository for patient data (Aims 1&2):

  Identifiable information about patients will be obtained from CDW or its replacement database following the Cerner electronic medical record transition (Scheduled for October, 2020 in Seattle, WA). A list of CDW data fields and electronic health record codes used for the study is provided in the Administrative Data Sources and Codes document (Attachment D). The study data requisitioner will pull data as described below, using the VA Informatics and Computing Infrastructure (VINCI). Data will then be saved in the study data folder on the secure VA network.

  Recruitment:

  Providers: Names and VA facilities of potentially eligible providers will be pulled from CDW. These PHI fields are necessary for confirming eligibility for recruitment, to look up the provider contact information in the VA Outlook Global Address Book for recruitment purposes, and to identify the provider site and practice type (women's health clinic vs. non-women's health clinic) of providers for randomization purposes.

  Patients: Before study recruitment begins, and at 6 and 12 months into study recruitment, we will pull lists of potentially eligible patients assigned to enrolled providers' panels. These are the patients to whom we will mail recruitment letters. The lists will include patient names and mailing addresses. Real SSNs will be accessed as they are necessary to look up patient medical records in CDW in order to determine potential subject eligibility and later to pull and match data from CDW to the patient-reported data as described below. SSNs are also required by the VA R&D Purchasing and Fiscal office to process subject payments. We will send unencrypted recruitment emails with no sensitive information to Veterans up to two weeks prior to the patient's appointment and will notify recipients not to reply to the email. We instead provide two ways for Veterans

to contact us with questions or to tell us they are not interested in the study: first, they may complete the Qualtrics survey (unique link embedded in the email) which asks them if they would like to be contacted by the study team by phone (or not); second, they may call the study manager at the number listed in the email.

Covariate and Outcome Variables:

We will pull data to describe the enrolled patient population, include in our analysis models (covariates) and compare reproductive health outcomes (preconception health and contraceptive use) between survey and medical record data. These CDW variables will be pulled for all enrolled patients (see Administrative Data Sources and Codes, Attachment D). The relevant reproductive health fields will not be identifiable or contain PHI; however, patient SSNs will be used to pull the CDW data for enrolled participants and link it to patient-reported data collected during the study. Once that matching is complete, SSNs will only be stored in the study crosswalk and not in the analytic datasets.

- Joint Legacy Viewer (JLV) for viewing medical record and confirming appointment status: For enrolled Veteran participants who are not reachable for the Post-Visit survey, study staff will review their medical record using the JLV application to confirm whether the Veteran attended or did not attend their appointment and if so, whether pregnancy was diagnosed at that visit. Veterans who did attend their appointment and have no pregnancy diagnosis documented at the visit will be included in analyses (with missing outcome values) per our intent-to-treat approach. Veterans who did not attend their appointment or who had a pregnancy diagnosed at their appointment will be withdrawn from the study and excluded from analyses (i.e., they are handled in the same way as Veterans reached for the post-visit survey).

  In addition, for Veterans not-reachable for the Post-Visit survey, but who are included in analyses (because they did attend their visit and were not pregnant), study staff may use JLV to abstract details about the study-associated visit for analysis. These details include whether a discussion about reproductive health or any referrals or new prescriptions relating to reproductive health were documented as part of the visit. These data will be recorded using an abstraction form (Attachment

- VSSC for patient recruitment: Identifiable information about patients will be obtained from VSSC for the purposes of patient recruitment. During the active patient recruitment phase, weekly recruitment lists of potentially eligible patients scheduled to see an enrolled provider will include patient names, dates of birth, real SSNs, telephone numbers, email addresses, VA facility, and upcoming appointment dates. These are the lists that will be used by RAs to contact and screen patients by telephone and email, as well as to consent and enroll patients by telephone.

- VA Outlook Global Address Book (Aims 1-3): The contact information of potentially eligible providers and clinic leaders will be obtained via the VA Outlook Global Address Book for recruitment purposes.

- Audio recorded qualitative interviews (Aim 3): Interviews with employees and patients will take place over the phone or via MS Teams. No names or other identifiers will be included on audio recordings or in transcripts; however, voiceprints themselves are considered identifiable.

Data Security Measures

A number of steps will be taken to ensure confidentiality and data protection throughout the study to minimize risk breach of privacy or confidentiality to VA employees (providers and clinic leaders) and Veteran participants.

Data Storage

Physical Documents/Data: Physical study documents containing any PHI or de-identified data will be stored in offices at HSR&D centers at each of the three engaged study sites within locked filing cabinets. Physical documents will not be removed from VA badge-access protected or locked office areas and will be stored in a locked filing cabinet. At each site, the LSI will be responsible for ensuring that only approved study staff have access to any physical study records stored this location.

Electronic Documents/Data: Electronic study data aside from MyPath analytics data (addressed below) – including all protected health information (PHI) and de-identified analytic datasets – will be stored in secure, password protected study folders and/or SQL databases on the Seattle HSR&D network or within the secure VA VINCI workspace. Access will be restricted to the study team. Study staff at VASLCHCS and VAPHS will be provided access to these Seattle HSR&D study folders, which will be accessible through the VA network. Protected health information will not be disclosed, copied, transmitted by email, or transmitted in total or in part to anyone not connected with the approved protocol and not approved by the VA (via a Data Use Agreement, if necessary) to access the identifiers. All data will be secured in accordance with Puget Sound Center of Innovation for Veteran-Centered and Value-Driven Care (COIN) policy, according to VA regulation requirements set forth by the Veterans Health Administration (VHA) Handbook 1200.12. To ensure confidentiality and protection of subject data, data will only be analyzed and stored electronically on secure servers at the COIN or within secure VA VINCI workspace. Anti-virus protection is maintained on all servers and workstations at the COIN office. All workstations and servers are physically secured in locked offices, reside behind the VA firewall, and fully participate in Windows NT security. The study data folder will be further safe-guarded against unauthorized access by network user login authentication controls, including strong password requirements that will only be given to IRB-approved study staff. In no case will patient identifiers or data be provided to any person or entity outside the IRB-approved study team, and we will ensure that all study results are presented in a way that no individual can be identified.

MyPath Analytics Data: Analytic data for the MyPath tool, including participants' use of the tool and time spent on each section of the tool, will be stored on a server maintained by Nitid Bit, LLC, the developers of the MyPath tool. Enrolled patients in the intervention group who use MyPath will be assigned a personal code consisting of two words and a number at the time of MyPath use that is not identifiable. Participants will have the option to save this code to their personal device, if they wish. Analytic data will be stored on the non-VA MyPath server by this personal code without any identifying information. The analytic data, which **will not have any identifiers**, will be encrypted and transferred to a secure VA server by the software developer team prior to any analysis. At the end of the post-visit survey, study staff will request that women share their personal codes. The personal codes will be linked to participants' Study ID and identifying information only behind the VA firewall in a secure crosswalk separate from the data. Users who choose

to email their MyPath “summary page” to themselves may enter their email address into the tool but that information is immediately deleted and is not saved in any database.

Storage and Security of Audio Recordings: Interviews will be audio recorded using a VA approved audio recording method. VA-approved physical audio recorders, insofar as they are used, will be kept physically secure and stored in a locked filing cabinet. If and when such a device is taken to another location, the device will be secure on the study staff who uses it. Regardless of the audio recording method used, study staff will download digital recordings to the study data folder on the secure VA network, after which the interviewer will delete the data from its original storage location, as soon as is feasible following an interview. For transcription services, we intend to use the VA Central Transcription Services Program (CTSP) and thus plan to transfer the audio files via the secure VA network. Interview transcripts will be stored in the study data folder on the secure VA network. All recordings and transcriptions will be labeled using study IDs only.

Crosswalk separating identifiers from analytic data (Aims 1-3):

We will maintain crosswalk files linking study identifiers to study IDs and MyPath personal codes in Excel or similar format (e.g., Access database). We will create three separate crosswalks: one for providers (Aims 1 and 2), one for patients (Aims 1 and 2), and a third for qualitative interviewees (Aim 3). Lists of four-digit Study ID numbers will be generated randomly using STATA software and assigned to participants as they are enrolled. After study data collection is complete, identifiers will be scrubbed from files used during data collection (e.g., REDCap database and recruitment lists) and the crosswalk files will become the only files linking PHI to participant study IDs (e.g., study analytic datasets will not contain identifiers).

During study recruitment, the patient crosswalk will include information on all potentially eligible patients to whom recruitment mailings were sent so that any opt-out postcards can be tracked and weekly patient recruitment lists can be checked (by the study manager, database manager, or research coordinator) against the crosswalk to ensure that no patients are contacted by telephone for recruitment inappropriately. Entries in the patient crosswalk for non-enrolled potentially eligible patients will be removed at the end of study recruitment, and all remaining patient and provider recruitment lists will be destroyed at that time. Thus, only PHI on enrolled study participants will be retained after the conclusion of the active patient recruitment phase.

The crosswalks will be password protected and kept in a separate folder from the analytic datasets within the study data folder on the secure VA network. Only CIRB-approved study staff will have login access to the folder containing the study crosswalk files.

Analytic datasets will not include SSNs, names, dates of birth, appointment dates, or other identifiers. Only aggregate data will be presented to external audiences.

Staff Training and Data Access:

The PI/SC will hold overall responsibility for ensuring that all study staff have received training in VA data security procedures and protection of PHI.

The PI/SC, study manager, research coordinator, data requisitioner, and database manager at the PI/SC site will have access to study identifiers, including the study crosswalks and

recruitment lists. The LSIs and RAs at VAPHS and VASLCHCS will have access to site-specific provider and patient recruitment and follow-up lists but will not have access to the study crosswalk files. The site-specific recruitment and follow-up lists will be stored in separate, password protected sub-folders so that the LSIs and RAs from each engaged site will have access only to their site-specific recruitment and follow-up lists.

The study biostatisticians and co-investigators who are not LSIs will have access to de-identified analytic datasets and analysis files, but not to any files containing PHI. The data analyst will have access to PHI for the purposes of data cleaning and ongoing data quality monitoring, which will occur prior to de-identifying the datasets.

The PI/SC and study manager or research coordinator will be responsible for notifying CIRB of removal of any study staff who no longer work on the study or need access to study data files and removing study folder access for staff who no longer require access.

8.0 Communication Plan

The study PI/SC will be the point of contact for ensuring that any deviations from the protocol or Unanticipated Problems will be promptly reported and communicated to CIRB. The PI/SC is also responsible for communicating any unanticipated problem that may impact the conduct of the study and any protocol, document, or study procedure changes to LSIs and RAs at all engaged sites.

Prior to the start of study enrollment, the PI/SC and overall study manager will host an interactive orientation for all study staff involved in data collection (RAs and research coordinator) about the study protocol, including study recruitment, screening, consent, enrollment, data collection, participant withdrawal, study communication, and data security procedures. The study manager will be responsible for storing documentation of R&D-required staff trainings for all study staff who have access to the study data folder. The PI/SC will hold study meetings at least quarterly during data collection phases of the study. All study staff will be included on meeting invitations, and at least one study staff from each engaged site will be required to attend each study meeting. These meetings will be a forum during which study progress, successes, challenges, problems, and potential solutions can be discussed. Topics for discussion will include study communication methods, updates or changes to study procedures, screening and recruitment rates, follow-up rates, data quality, and adverse events. Email will be used to communicate changes, updates, and any problems between study staff and the PI/SC between study meetings. RAs and the research coordinator will be instructed to raise routine questions and challenges they encounter during study recruitment and data collection with their LSI and the overall study manager. The LSI and overall study manager will both be jointly responsible for responding to RAs and for raising issues to the attention of the PI/SC as needed. All study staff will be instructed to notify their LSI, the overall study manager, and the PI/SC without delay in the case of any adverse event, protocol deviation, loss of study data, breach of confidentiality, or other unanticipated problem. The PI/SC will be responsible for notifying the VA Puget Sound Information Security Officer and Privacy Officer immediately after becoming aware of any breach of secure data or improper use or disclosure of study data.

The PI/SC and overall study manager at VAPSHCS will be the points of contact for CIRB and will be responsible for ensuring the study obtains and maintains CIRB approvals. LSIs at each engaged site will be responsible for obtaining local R&D approval for the study. The PI/SC will

work with the local study contacts at the non-engaged sites to notify the Associate Chief of Staff of Research at each non-engaged site about the study.

The study PI/SC assumes primary responsibility for oversight of study logistics; data collection; data analysis; and synthesis of findings into feedback reports. The PI/SC will assume responsibility for ensuring the study meets overall project deadlines and adheres to the proposed timeline; communication with study team members and participants about study events and results; and timely reporting of study findings to operational stakeholders, VA researchers and the scientific community.

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