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

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Improving Outcomes for Women Veterans Using a Patient-centered Web-based Decision Tool

Veteran Information Sheet

Researchers:	**Phone Numbers**
Lisa Callegari, MD, MPH, Principal Investigator	(206) 277-3129
Sam Benson, MPH, Study Manager	(206) 277-4177
Siobhan Mahorter, MPH, Study Coordinator	(206) 764-2206

Researchers' Statement:

You are receiving this information sheet because you **may** be asked to participate in a research study at VA in the next one to two years. The principal investigator of this study is located at VA Puget Sound in Seattle, Washington and additional study staff are located at VA medical centers in Salt Lake City, Utah and Pittsburgh, Pennsylvania. Primary care providers at VA facilities in Washington, Utah, Pennsylvania, North Carolina, Georgia, Texas, Colorado, Florida, and California are participating in the study as part of the national Women's Health Practice Based Research Network.

The study is to test whether a brief, web-based decision tool can help increase women Veterans' knowledge and help them to be prepared for primary care visits at VA. You are receiving this information sheet because you have a primary care provider who is part of the study. Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled. We will plan on enrolling up to 570 women Veteran patients that are being seen by these providers.

VA staff may contact you about this study about one week before you have a scheduled appointment with a primary care provider who is part of the study. At that time, we will tell you more about the study and answer questions you have. You may choose whether to be in the study at that time. You are welcome to contact the study staff now or at any time if you have questions.

WHY IS THIS STUDY BEING DONE?

We are testing a web-based decision tool that was designed specifically for women Veterans. The tool gives women Veterans information to empower them to be prepared and to get the most out of their visits with their medical providers about certain health topics. We are interested in whether the web-based tool affects the types and quality of discussions that women Veterans have with their primary care providers. We are also interested in whether women Veterans are more likely to make health decisions that are in-line with their values and goals for their health after using the tool.

Since we are studying whether the web-based tool might improve discussions you have with your provider, we won't tell you exactly what topics it is about until later in the study. If we told you now, we think it could influence what topics you want to discuss with your provider, which would make it harder to tell what effect the tool itself has. If you enroll in the study, we will tell you the specific goals of the study and of the tool and invite you to ask questions after you have had your appointment and before we continue with the study.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

We may contact you before a scheduled primary care appointment at VA. If you decide to be in the study, we will ask you some questions about your health, living situation, and demographic characteristics at that time. Then you will be assigned either to receive nothing out of the ordinary, or to receive a text message with a link to the web-based tool before your upcoming appointment. Whether you will receive the text message or not depends on which provider you are going to see. If you receive the text message with a link to the tool, we ask that you visit the website before your appointment. In a prior research study involving the tool, women Veterans used it for 11 minutes on average.

If you do not attend your scheduled medical appointment or if you find out you are pregnant at your appointment, we will withdraw you from the study before you complete any more surveys. Otherwise, after your appointment, we will ask you to complete one online survey, and up to two telephone surveys. The online survey will be sent to you shortly after your scheduled appointment and will take about 30 minutes. If you're unable to complete the survey online, study staff will call you to complete the survey by telephone. The second and third surveys, if you are eligible for them, will be by telephone at 3 and 6 months after your appointment, and take about 15 minutes each. The surveys will ask questions about topics like what you discussed at your medical appointment, aspects of your health history, your health goals, any health-related behaviors you decided to change as a result of your appointment, and any changes in your living situation. The topics addressed in the survey questions are similar to those you might discuss in a medical appointment with your doctor.

At the end of the study, we will gather information from the VA medical record for all patients in this study. We will look at information related to women's health. We will tell you more about the specific information we would like to obtain after your visit with your provider. This information will be used to help us design future research studies about women's health.

We plan to invite a small number of people in the study who receive the link to the tool to do 30-minute telephone interviews with study staff after they've had their appointment and completed the second survey. It would involve talking with study staff about your experience using the web-based tool. We will review additional details about the interview with you if you are selected to do the interview.

You may choose whether or not to be in the study. If you decide to be in the study, we will keep your identity and participation in the study confidential. There are no right or wrong answers to any of our questions. You can choose to withdraw from the study or skip any question or component of the study for any reason. Doing so will not impact the care you receive at VA.

ARE THERE ANY RISKS OR DISCOMFORTS?

Some of the questions we will ask may feel intrusive or personal. We will ask questions about your health, goals for your health, health behaviors, demographic characteristics, and living situation. You may skip any question you do not wish to answer.

Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that someone could find out that you are in this study and could find out information about you. As described below, the researchers have taken a number of steps to prevent this from happening.

ARE THERE ANY BENEFITS?

You may not benefit directly from being in this study. Participants who receive the link to the tool will receive information that may help them make decisions about and discuss health topics with their provider. One potential benefit to everyone in this study is having the opportunity to share your experiences as a woman receiving care at VA. We hope to use the information we gather in this study to improve the quality of care that other women Veterans receive.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information we collect will be kept confidential and not disclosed outside of the VA unless required by law or regulation. When we present results of the study, we will include only de-identified data, so you will not be linked to any of your survey answers or quotations.

Your privacy is important to us. To make sure no one other than study personnel can match you to your data, we will use a unique study code to label your study data. We will not place any identifiable information on any research data, which includes the surveys and interview recordings. We will keep a master list that links study participants' names to study codes separate from the study data in a secure VA database with restricted access. All study documents will be stored in locked filing cabinets in VA research offices or on a protected VA computer network.

Usually, only study personnel will have access to the identifiable information that we collect from you; however, the Office of Human Research Protections and other study monitors may have access to identifiable records as part of auditing and monitoring the research.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

Yes. Study participants will receive a payment of $25 after three of the study surveys, (the baseline, 3-month, and 6-month surveys) and will receive $50 after completing the online post-visit survey (which happens shortly after their scheduled primary care appointment). Participants who complete an interview will receive an additional $25. That means that you could earn up to $125 for completing all study surveys, and an additional $25 if you are invited to do the interview. You may choose how to receive a payment (as an electronic transfer into your bank account from VA or an Amazon gift card that is mailed or emailed to you by the study team). If you choose to receive an electronic funds transfer into your bank account from VA, the VA may take up to 6 months to process those payments and you may have to complete a form about your bank account information and submit it to the VA.

WHO CAN I TALK TO ABOUT THIS STUDY?

If you have any questions about the study purpose, procedures, risks, discomforts, possible benefits, choices available to you, or your rights as a research subject after reading this Information Statement, please contact one of the researchers listed at the top of this statement.

You may contact the VA Central Institutional Review Board (CIRB) Office at **877-254-3130** if you:

- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

An IRB is an independent body made up of medical, scientific, and non-scientific members, who ensures the protection of the rights, safety, and well-being of subjects involved in research.

We very much appreciate your consideration. Thank you!