Preliminary Implementation of an Informational Nudge to Improve Heart Failure Prescribing

NCT05986695

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KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by VA's Office of Research and Development, Health Services Research and Development (HSRD) grant. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn the effectiveness of a multicomponent 'nudge' strategy. Your participation in this research will last up to 3 hours for interviews and/or focus groups over the period of 6-8 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

A person may want to volunteer to participate in this study as the information may contribute to generalizable knowledge about quality improvement. *For* a *complete description of benefits, refer to the Detailed Information section of this form.*

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may NOT want to volunteer for this study due to the small risk of loss of privacy and/or confidentiality. *For* a *complete description of risks, refer to the Detailed Information section of this form.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you chose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study [redacted] at the Tucson Arizona VA. If you have questions, suggestions, or cancerns regarding this study or you want to withdraw from the study his contact information is: [redacted]

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn the most efficient and effective way of guideline-concordant heart failure care. In order to accomplish this, we need your perspective regarding the multicomponent 'nudge' strategy to change prescriber behavior.

HOW LONG WILL I BE IN THE STUDY?

The Southern Arizona VA Health Care System agreed to participate in this study. This research study is expected to take approximately 18 months. Your individual participation in the project will take up to three hours total for an electronic survey, interviews and/or focus groups over the period of 6-8 months.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

You will be contacted by a study team member to arrange for the survey {<10 minutes), interviews and/or focus groups. You will be interviewed and/or participate in the focus groups that will enable you to provide your perspective regarding the project.

After the project begins, the multicomponent nudge strategy will be implemented throughout the Southern Arizona VA Health Care System. Additional interviews and/or focus groups will be available for you to provide further feedback regarding the nudge strategy.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

Study participants are expected to:

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

- Uncomfortable during the interview: you may be uncomfortable during the interview. If this is the case you can request that the question be skipped or to stop the interview
- Confidentiality, privacy and data security: All data will be handled as confidentially as possible and in accordance with all laws, regulations, and VA directives. The research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office and/or a password-protected computer file. The research records will be kept in a password protected computer file that only the study team has access.

All your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any presentations or publications from this information will not identify you.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Photographs, audiotaping, or videotaping
The study team has explained that by signing this Informed Consent Document, you are voluntarily and without separate compensation authorizing voice recording(s) to be made of you by the Southern Arizona VA Health Care System while you are participating in this study.

The audio recording will occur during the MS Teams interview and/or focus group session. The VA Centralized Transcription Services Program in Salt Lake City, UT will provide the transcription services. The said voice recording is intended for the following purposes: transcribing the audio recording of your interviews/focus groups for analysis.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to stop being audio recorded and may withdraw your consent for up to a reasonable time before the voice recording is used.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct benefit to you; however, your participation in this study may benefit your knowledge of cardiology best practices and quality of HF care may improve. In addition, your participation in this study may help us understand how to better treat Veterans who suffer from heart failure.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

All data will be handled as confidentially as possible and in accordance with all laws, regulations, and VA directives. The research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office and/or a password-protected computer file. The research records will be kept in a password protected computer file that only the study team has access.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name and gender.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office {GAO); HSRD, VA Centralized Transcription Services Program, the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment, or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

There is no payment being offered for participation.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE **DAY:**

[redacted]

AFTER HOURS:

[redacted]

DO I **HAVE TO TAKE PART IN THE STUDY?**

Participation is voluntary. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled.

As a VA employee, refusal to take part in the study will in no way influence your employment, ratings or subsequent recommendations. You may discontinue taking part at any time without any penalty or loss of benefits.

There are no consequences of your decision to withdraw from the research.

Data already collected prior to your withdrawal may continue to be reviewed by the study team, but cannot collect further information, except from public records, such as survival data.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

You should contact the following with any questions, complaints, and concerns about the research or related matters.

Research questions: [redacted]

Complaints or concerns: Patient Advocate at [redacted]

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Southern Arizona VA Health Care System Institutional Review Board. This is the Board that is responsible for overseein the safet of human ants in this study. You may call the IRB Administrator at [redacted]
- if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms. _____(study team member) has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I **agree to participate in this research study as has been explained in this form.**		
Participant's Name	Participant's Signature	Date