Models of Primary Osteoporosis Screening in Male Veterans

NCT04079868

March 28, 2023

Participant Name:	**Date:**
Study Title: Models of Primary Osteoporosis Screening in Men	
Principal Investigator: Cathleen Colón-Emeric, MD, MHS	**VAMC**: Durham

Please read this form carefully. It tells you important information about a **voluntary** research study. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. It is important that you understand the information on this form. If you would like to check that this study is approved by the Durham VAMC's Institutional Review Board, please call the research office at (919) 286-6926 or (888) 878-6890, extension 6926.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to test different models of osteoporosis screening and treatment adherence on fracture risk in older men.

You are being asked to participate in this research study because your Patient Aligned Care Team (PACT) cares for men who are eligible for osteoporosis screening.

A total of 39 PACT teams are being recruited for this study, approximately 24 in the Durham VA Health System and 15 in the Hunter Holmes McGuire VA Medical Center.

WHAT IS THE EXPERIMENTAL PART OF THIS RESEARCH STUDY?

Initially, PACT teams are assigned to 1 of 3 different models of organizing osteoporosis screening and management for their patients who are at high fracture risk. However, to decrease the amount of time burden during COVID-19 PACT teams who are assigned to PACT practice management team will be re-randomized to either Bone Health Service arm or the Control (Usual care).

WHAT PROCEDURES, DRUGS, OR TREATMENTS ARE INVOLVED IN THIS RESEARCH STUDY?

If you agree to participate in this research study, then your PACT team will be randomly assigned to an osteoporosis screening model. Using a procedure like flipping a coin, you will have a 50/50 chance of being assigned to one of these groups:

Control– You will be given the current VA Undersecretary Guidelines for primary osteoporosis screening, and patient education materials about osteoporosis. You and your team will continue to screen for and manage osteoporosis as you are currently doing.

Bone Health Service Model – Your patients will have osteoporosis screening, education, and follow-up managed centrally by the bone health team. You will have the opportunity to opt out of the service for patients for whom it is not appropriate, and approve medication orders, but are not responsible for most activities.

1. The Bone Health Nurse (BHS RN) will identify eligible patients in your team, and contact them via letter and/or telephone. If they agree they will be scheduled for DXA. Patients meeting treatment thresholds will be referred to the Bone Health MD for e-consult.
2. The Bone Health MD generates an e-consult containing recommendations for additional laboratory evaluation (if needed) and treatment; you will be listed as a co-signer on this note. If you agree to the recommendations, you co-sign the note.
3. If you agree to the recommendations, you co-sign the note. The BHS RN then contacts the patient to provide education and shared decision making, and places orders for your co-signature. If you do not think treatment is appropriate for your patient, you can opt out of the program by making an addendum.
4. All patients initiating oral bisphosphonates will be called by the BHS RN at 1, 6, and 12 months to identify adherence barriers. Patients with medication nonadherence identified during these calls will be offered an additional educational telephone or group visit.

Step in Process	Control	Bone Health Service (BHS)
Selection for screening	Discretion of provider	BHS RN queries RDW quarterly
Scheduling screening	Provider orders; MSA or Veteran phone call to radiology	BHS RN orders and coordinates scheduling with Veteran
Quantify risk from DXA results, determine if they meet treatment threshold	Discretion of provider	BHS RN and BHS MD based on FRAX risk
Shared decision-making with Veteran	Provider by phone or at next primary care visit	E-consult to provider, BHS phone call with Veteran, decision- tool sent to patient
Ordering treatment	Provider	BHS RN with provider co-signature
Adherence	Discretion of	BHS RN telephone follow-

monitoring	provider	up and personalized barrier assessment
Intervening when non-adherence detected	Discretion of provider	BHS RN uses adherence algorithm, educational visit

Re-Contact: After 2 years, you will be asked if you are interested in participating in a survey through VA REDCap to describe how well osteoporosis screening and adherence promotion is working for your patients. You will be asked about the model's impact on you and your PACT team.

I agree to be re-contacted: ☐ Yes ☐ No

CAN I REFUSE TO BE IN THIS RESEARCH STUDY OR WITHDRAW AT A LATER TIME?

Absolutely. You do not have to join this or any other research study. If you do join and later change your mind, you may quit at any time. If you withdraw from the study, no new data about you or your patients will be collected. If you refuse to join or if you withdraw from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled. This will not affect your relationship with or treatment by the Veterans Health Administration (VHA) or your rights as a VHA patient. You will still receive all the medical care and benefits for which you are otherwise eligible.

WHAT OTHER OPTIONS DO I HAVE?

Taking part in this study is your choice. You have the option not to participate.

HOW LONG WILL I BE IN THIS RESEARCH STUDY?

Your PACT will be in this study for 2 years.

WHAT ARE THE RISKS AND DISCOMFORTS OF PARTICIPATING IN THIS RESEARCH STUDY?

- We will collect information about you, your PACT team members including age, race, sex, and how long you have worked in the VA. While we will make every effort to keep this information private, there is a risk of loss of confidentiality.
- The osteoporosis care model you are assigned may alter the team's work flow, which may affect the work environment.
- If you experience discomfort that you think may be related to the research, you can call the study team.

WILL I BENEFIT FROM TAKING PART IN THIS RESEARCH STUDY?

You may not personally be helped by taking part in this study, but your participation may lead to knowledge that will help others. We will determine which model of osteoporosis screening is most effective in decreasing fracture risk for Veterans, and how they impact PACT providers and staff. This will help VA improve care for its Veterans in the future, while supporting PACT teams.

DOES PARTICIPATION IN THIS RESEARCH STUDY COST ANYTHING?

There will be no costs to you for any of the research treatment or research testing done as part of this research study.

WILL I RECEIVE ANY COMPENSATION (MONEY OR OTHER) FOR TAKING PART IN THIS RESEARCH STUDY?

You will not receive compensation for taking part in this research study.

WHAT WILL HAPPEN IF I AM INJURED WHILE PARTICIPATING IN THE RESEARCH STUDY?

The VA will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the Durham VAMC or arrangements may be made for contracted care at another facility. Every reasonable safety measure will be taken to protect your well-being. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at 919-286-6957.

WILL MY CLINICAL OR OTHER RESEARCH TEST RESULTS BE SHARED WITH ME?

We will let you know of any important discoveries made during this study which may affect you or your willingness to participate in this study.

WILL THE RESULTS OF THIS RESEARCH STUDY BE SHARED WITH ME?

At the end of the study, you will receive your patients' screening and adherence rates, along with facility rates for comparison. You will receive a summary of the study results, including which screening models are most effective in reducing fracture risk.

DO ANY OF THE RESEARCHERS HAVE A FINANCIAL INTEREST RELATED TO THIS RESEARCH STUDY?

VA Health Services Research and Development is sponsoring this study, and provides salary support for some study staff. None of the researchers have a financial conflict of interest related to this study.

HOW WILL MY RESEARCH DATA BE PROTECTED AND SECURED?

1) Paper study data will be stored in the Durham VA Geriatric Research and Clinical Center (GRECC) in a locked file. Electronic study data will be stored on Durham VA servers in restricted access folders.
2) Only approved study staff will have access to the data.
3) To avoid inadvertent disclosure, data will not be transmitted outside of the VA, except when paper consent forms are transported to the Durham VA GRECC.
5) Your research records will be maintained and destroyed according to VHA records retention requirements.

WILL ANYONE ELSE HAVE ACCESS TO MY RESEARCH DATA?

If results of this study are reported to others, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your research records may be reviewed by Durham VA staff who are responsible for the safe conduct of this research. We may also provide your research records to federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of the Inspector General (OIG), and the Office of Research Oversight (ORO). We will not share any information with these groups outside the VHA unless they agree to keep the information confidential and use it only for the purposes related to the study. Any information shared with these outside groups may no longer be protected under federal law. These groups may disclose your information to other groups. If the sponsor receives identified information, it is then the sponsor, and not the VA, who is responsible for the security of the information.

WHERE CAN I FIND OTHER INFORMATION ABOUT THIS RESEARCH STUDY?

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHO DO I CONTACT IF I HAVE QUESTIONS OR CONCERNS ABOUT THE RESEARCH STUDY?

If you have questions about the research or need to talk to the study team, you can contact Dr. Colón-Emeric at (919) 660-6932 during the day or at (919)-970-0235 at night. If you have questions about the research or your rights as a research participant, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service at (919) 286-0411, extension 177632.

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AFFIRMATION FROM PARTICIPANT

My rights as a research participant have been explained to me, and I voluntarily consent to participate in this study. I have received an explanation of what the study is about and how and why it is being done. I authorize the use and disclosure of my identifiable information as described in this form. I will receive a signed copy of this consent form.

Participant's Signature	**Date**
Signature of Person Obtaining Consent	**Date**