

The Impact of Family History and Decision Support on High Risk Cancer Screening

1. If leaving a message on an answering machine:

Hello, this is [your name]. I am calling from the (Durham or Madison) VA Medical Center for [patient's name] to tell you about a study you might qualify for. Please call me back at [number]. Thank you. Do not leave any PHI in your message.

2. If leaving a message with a person other than the patient:

"This is [your name] from the (Durham or Madison) VA Medical Center. May I speak with [patient's name]? Could you please have him return my call? My number is XXX-XXXX." If the person asks for more information about the call, say, "I'm calling about a research study he might qualify for. Will he be available to talk to me about it` anytime in the next week or so?" If the patient will not be available in the next week or two, mark the patient status as "Unable to Contact." If the patient is physically unable to talk on the phone, make the patient status as "Ineligible – unable to use phone."

3. If patient is available to talk:

Hello, this is [your name]. I am calling from the (Durham or Madison) VA Medical Center. Recently, we mailed you a letter about a research study on collecting family health history to improve cancer screening and referrals. Would you like to hear more about the study? ?

No: Okay. I will take your name off of our list. I appreciate your taking the time to let me tell you about the study. It would be really helpful for us to know reasons why people would not be able to participate. If you don't mind, can I ask why you declined to participate? (write down answer) Thank you for your time. Good-bye.

Yes: Go to 4.

3a. If patient indicates no family history of cancer or other disease: Having a family history of disease is not required for participation in this trial. We are interested in seeing how the family health history screening tool improves colorectal cancer screening and referrals. Would you like to hear more about the study?

No: Okay. I will take your name off of our list. I appreciate your taking the time to let me tell you about the study. It would be really helpful for us to know reasons why people would not be able to participate. If you don't mind, can I ask why you declined to participate? (write down answer) Thank you for your time. Good-bye.

Yes: Go to 4.

4. Yes: Great! I'll go ahead and tell you a little bit more about it. The Durham/Madison VA is conducting a research study concerning collecting and providing family health history information to your primary care doctor to improve your care. Joining this research study may improve how cancer screening recommendations are made for yourself, other veterans, and your family members. It may also help or improve the VA health system to provide better care.

If you join this study, you will enter information about the health of you and your family members into a secure website called MeTree. This may take 20-30 minutes. Then, you will receive a report documenting your family health history that you can keep, along with personalized recommendations. Your doctor is also participating in this study, and will receive a copy of this report to discuss with you.

The Impact of Family History and Decision Support on High Risk Cancer Screening

If you are interested, the first thing we'll do is go through the consent process by phone. For this, I will explain the study in detail and answer any questions you have. Once you have consented to be in the study, I will let you know which of two groups you will be in. Whether you are in group 1 or 2 has been determined by a process like flipping a coin. In Group 1, you will fill out the MeTree family history tool in the next couple of weeks. In Group 2, we will call you back to fill out the MeTree family history tool in 12 months.

No matter which group you are in, you will get to decide whether you want to fill the MeTree family history tool online on your own or make an appointment to do it in person. The MeTree family history tool is online and can be accessed from any computer or tablet. If you prefer to fill it out in person, then we will set up an appointment to meet an hour prior to your scheduled appointment with your primary care provider.

To make it as easy as possible to fill out the MeTree family health history tool, I will mail you a brochure and a worksheet to help you collect information from your family members. If you decide to do it online, I will also send you an access code, password.

We will pay you \$50 via check or electronic fund transfer after you have completed MeTree., and we will review your medical record 12 months later to see if your doctor did recommend any additional cancer screenings. There are also brief phone surveys to be completed after MeTree, that ask follow-up questions about your healthcare and experience with the study.

Do you have any questions? (Answer)

In order to participate, I will have to ask you some screening questions to see if you are eligible for this study. It will take about 20 minutes. I will ask some questions about sensitive information including your date of birth and your medical history. Your responses are kept confidential by using a study ID. We will not disclose any identifiable information to anyone outside our study team. You can stop answering any questions at any time. Your refusal to answer questions will not negatively affect any relationship you have with the VA medical center or your VA benefits.

Is it ok for me to ask you the screening questions now?

No, do not recontact: Okay. I appreciate your taking the time to let me tell you about the study. It would be really helpful for us to know reasons why people would not be able to participate. If you don't mind, can I ask why you declined to participate? (write down answer) Thank you for your time. Good-bye.

No time now, call back: Okay. When is a good time to call you back? We'll give you a call then. Thank you for your time.

Yes: Go to 5.

5.. For the following 6 questions, the highlighted answer is the answer needed for eligibility. At the first question where the patient is ineligible say: I'm sorry, but you are ineligible for the study because [reason]. I appreciate your taking the time to let me tell you about the study. Good-bye. Also mark the "No" next to the "Patient eligible?" question.

The Impact of Family History and Decision Support on High Risk Cancer Screening

a) Do you have any knowledge of your family health history for any first or second-degree blood relative? This would include your biological children, parents, siblings, nieces/nephews, aunts/uncles, grandparents, or half-siblings.

i. Yes No

b) Are you planning to relocate or leave the VA healthcare system in the next 12 months?

i. Yes No

c) Are you a patient of (*insert PCP name*)?

i. Yes No

d) How old are you?

i. Age 40-64 Yes Age <40 or >64 No

e) Cognitive screener

These next questions are a little different. They ask you to use your memory. I am going to name three objects. Please wait until I say all three words then repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Now, don't write them down. Please repeat these words for me: APPLE – TABLE – PENNY. (*Interviewer may repeat names 3 times if necessary but repetition not scored.*)

Did patient correctly repeat all three words? Yes No

| | Incorrect | Correct |
|---------------------------------|-----------|---------|
| g. What year is this? | 0 | 1 |
| h. What month is this? | 0 | 1 |
| i. What is the day of the week? | 0 | 1 |

What were the three objects I asked you to remember?

| | | |
|----------|---|---|
| j. Apple | 0 | 1 |
| k. Table | 0 | 1 |
| l. Penny | 0 | 1 |

Total Score: 3 or less 4 or more

The family history collection tool asks about cancer of the colon and rectum. The following questions are about sigmoidoscopy and colonoscopy, two tests to check for colon cancer. Both tests examine the colon using a narrow, lighted tube that is inserted in the rectum.

The Impact of Family History and Decision Support on High Risk Cancer Screening

With both:

- You may be given medicine through a needle in your arm to make you sleepy.
- You may need someone to drive you home.
- You may need to take the rest of the day off from your usual activities.

Sigmoidoscopy only examines the lower part of the colon while Colonoscopy examines the entire colon.

Have you ever had a sigmoidoscopy?

yes no

If yes, how long has it been since your last sigmoidoscopy?

3 or less 4 or more years

Have you ever had a colonoscopy?

yes no

If yes, how long has it been since your last colonoscopy?

3 or less 4 or more years

If you are eligible for the study, can you commit to entering your family health history information into the MeTree website either within the next 30 days, or in 12 months? This involves 20-30 minutes at your computer, or setting up a time to meet with a study team member at the VA.

Yes No

Can you also commit to completing up to two brief 5-10 minute phone surveys about your experience with the study?

Yes No

Patient eligible? Yes No

Yes: go to 6.

No: I'm sorry, but you are ineligible for the study because [reason]. I appreciate you taking the time to let me tell you about the study. Good-bye

6. It looks like you are eligible for our study. Before agreeing to participate, there are some important things I have to mention.

The Impact of Family History and Decision Support on High Risk Cancer Screening

This telephone consent will take the place of a written consent to be in the study. Over 31/2 years, we will enroll and collect data from up to 600 participants in this study. Your participation will be limited to entering your family health history information into MeTree on your own or in person and completing a survey. The survey asks about screening that you have had for cancer and other health problems. We will look in your medical record to see if you receive any cancer screening in the 12 months after you use MeTree.

You are not required to take part in this study: your participation is entirely voluntary.

You can refuse to participate now or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment.

If you want to withdraw from the study, you can do this by writing the Principal Investigator. Instructions for doing so will be on the HIPAA Authorization form that we provide to you.

You may not personally be helped by being in this study, but your participation may lead to knowledge that will help others.

If you are a patient and decide you do not want to be in this study, your decision will not affect your treatment in any way. You will continue to receive usual care for high blood pressure from your doctor, whether or not you are in this study.

If during the study any information reveals depression or other major clinical findings, your primary physician will be notified immediately.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent.

Your medical records will be maintained according to this medical center's requirements. However, there is a possibility that the Office for Human Research Protections (OHRP), the Office of Research Oversight (ORO), the Institutional Review Board (IRB), or the Department of Veterans Affairs may inspect the records.

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

Some veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

Eligibility for medical care is based upon the usual VA eligibility policy and is not guaranteed by participation in a research study.

In case of illness or physical injury resulting from participation in this study, you are entitled to medical care and treatment, except if the illness or injury is due to noncompliance (not following study instructions) by you. This care may be

The Impact of Family History and Decision Support on High Risk Cancer Screening

provided by the VAMC or arrangements may be made for contracted care at another facility.

The VAMC has not set aside compensation payable in the event of physical injury or illness resulting from participation in this study.

In case there are questions, concerns, or complaints regarding this research study, you can call the study Principal Investigator or one of the study doctors. I will give you their phone numbers at the end of this call so you can write them down. If any medical problems occur in connection with this study the VA will provide care.

Further information about compensation and medical treatment may be obtained from the medical administration service at this VA medical center. I will give you their number at the end of the phone call.

If you have questions about the research or your rights as a research subject, would like to obtain information, offer input, or have other concerns or complaints, you may contact the administrative officer of the research service. I will also give you that number at the end of this call.

Do you have any questions? (address)

As a reminder, your family history data will be entered into the MeTree program. This tool was developed and lives on a Duke computer behind the Duke firewall and meets all VA security standards. Identifying information, such as your name or address, will not be entered into the program. Your family history data will be combined with family history data collected from other patients and maintained indefinitely by Duke for future research about how diseases are passed down in families. All other data collected during this study, including identifying information and any health data abstracted from your VA medical record, will be kept in VA files only. If you decide not to bank your family health history information at Duke, then you cannot take part in this study. Do you voluntarily consent to participate in this study?

YES NO

No: Okay. I appreciate your taking the time to let me tell you about the study. It would be really helpful for us to know reasons why people would not be able to participate. If you don't mind, can I ask why you declined to participate? (write down answer) Thank you for your time. Good-bye.

I certify that the patient consented verbally to participate in this research study.

**Name of Person Obtaining Verbal Telephone
Consent** **Date**

Now I will see whether you will fill out MeTree now or in 12 months. This determination has been done using a process like flipping a coin.

The Impact of Family History and Decision Support on High Risk Cancer Screening

If patient's PCP randomized to the delayed condition: You will complete MeTree 12 months from now. There is little risk associated with waiting to do this because colorectal cancer takes 7-10 years to develop. During the next 12 months, we will not contact you again. In 12 months, we will call you to ask you to fill out the MeTree family health history tool. In case I can't reach you at this number, is there someone else who would know how to contact you? (Collect contact information). We can also send you study reminders by text message or secure messaging through MyHealtheVet. What do you prefer for us to use to contact you? (if requesting text messages): Can you confirm a cell phone number that is able to receive text messages?

If patient's PCP randomized to the immediate condition: You will complete MeTree now. Do you have access to a computer or tablet to complete the MeTree survey?

If yes: Great. I will be mailing you a packet with a brochure and a worksheet that tells you what information to collect from your family before you fill out the tool, which will make it easier. We will also send an access code and password so that you can access the website by text or by mail. Please look for your packet in the mail. If you have any questions or issues when completing the survey, please give me a call at [xxxxx]. I can also send you the login information by text message. Can you confirm a cell phone number that is able to receive text messages?

If no: I can meet you before an upcoming appointment. It looks like you have a clinic appointment on [date/time]. I need to meet with you at least 1-hour prior to this appointment. [Schedule appointment]. Great, we will plan to talk again on (appointment date/ time).

Now I am going to give you some important phone numbers. Please get a pen or pencil to write them down.

If you have any general questions about the study, please call me at (number ext____).

If you would like to talk to one of the study Investigators, you can call if in Durham: the Principal Investigator Dr. Goldstein at (number) during the day or page her at xxx after hours.
in Madison: the Principal Investigator Dr. Voils at (number) during the day or the study doctor Dr. XXX at (number) after hours.

If you would like to call the Research Office to confirm that this is a VA-approved study, please call (919) 286-0411 ext. 7632 (in Durham) or (number) in Madison.

I want to thank you for taking the time to talk to me today and for your willingness to participate in this research project. Talk to you soon! Good-bye.