Integrated Approach to Patient and Family Engagement for Advance Care Planning for Vulnerable Older Adult Within an Accountable Care Organization (ACO)
NCT03609658
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IMPACT Study—Information Sheet for Intervention Group

Hi my name is_____. I am a Nurse Navigator with *(list the department and/or physician the Nurse works with/for*). I am affiliated with the Department of Internal Medicine Gerontology at Wake Forest School of Medicine. I am calling on behalf of Dr. Jennifer Gabbard to invite you to participate in a research study.

The purpose of the study is to find better ways to engage patients in discussing their goals and values related to their health care with their family doctor/ provider through advance care planning. Sadly because of accidents or illness, 3 out of 4 people will be unable to make some or all of their own medical decisions at some time in their life. Therefore, this study encourages people to talk with their families and their family doctor/provider about their overall desires for future care and to choose someone who could make medical decisions for them if they ever have an accident or became too sick to make them on their own.

Participating in this study is completely voluntary. You do not have to participate in this study. This study will involve answering a few questions about advance care planning over the phone, scheduling a visit to meet with your family doctor/provider to further discuss your answers, and complete the Patient Engagement survey after you meet with your family doctor/provider. We ask that you bring a trusted love one with you to that visit, preferably whoever you think could make medical decisions for you if you are unable to make your own decisions (i.e if you ever become so sick you can't make your own decisions). Please be aware that this type of visit may require a standard copayment as per your insurance requirements.

WILL YOU BE PAID FOR PARTICIPATING?
Payment is available for participating in this study. You will receive a $25 gift card that will be mailed to you after you complete the Patient Engagement survey.

WHAT ARE THE RISKS OF THE STUDY?
The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff. There is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

BENEFITS
There are not any benefits to participating in this study.

WHAT ABOUT MY HEALTH INFORMATION?
In this research study, any new information we collect from you and information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: answers to questionnaires and whether you ever go to the emergency department or are admitted to the hospital.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Jennifer Gabbard that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Jennifer Gabbard, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By agreeing to participate in this study you give us permission to use your Protected Health Information for this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?
Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or in the event of a research-related injury, contact the study investigator, Jennifer Gabbard, MD at [redacted] after hours.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this information sheet.

By answering the questions that follow, you are agreeing to participate in this research study.