NCT00106080

Improving the Quality of End-of-Life Communication for Patients With COPD

Patient Consent Form

July 11, 2007

Department of Veterans Affairs

RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: Improving the Quality of End-of-Life Communication for Patients with COPD

Principal Investigator: David H. Au, MD MS **VAMC** VA Puget Sound Health Care System, Seattle(663)

Researchers:

David H. Au, MD, MS	Principal Investigator	Health Services Research and Development (HSR&D), VA Puget Sound Health Care System (VAPSHCS)	206-764-2504
Stephan D. Fihn, MD, MPH	Co-Investigator	HSR&D, VAPSHCS	206-764-2651
J. Randall Curtis, MD, MPH	Co-Investigator	Division Pulmonary and Critical Care Medicine, University of Washington (UW)	206-731-3356
Donald Patrick, PhD	Co-Investigator	Professor of Health Services Research, UW	206-616-2979
Paula Diehr, PhD	Co-Investigator	Professor of Biostatistics, University of Washington	206-543-1044
Ruth Engelberg, PhD	Co-Investigator	Division Pulmonary and Critical Care Medicine, UW	206-731-3356
Christopher Bryson, MD	Co-Investigator	HSR&D, VAPSHCS	206-764-2430
Vincent S. Fan, MD, MPH	Co-Investigator	HSR&D, VAPSHCS	206-764-2504
Bradford Felker, MD	Co-Investigator	HSR&D, VAPSHCS	206-764-2007
Laura Cecere, MD	Co-Investigator	HSR&D, VAPSHCS	
Mary McDonell, MS	Project Director	HSR&D, VAPSHCS	206-764-2460
Edmunds Udris, MPH	Project Coordinator	HSR&D, VAPSHCS	206-764-2558
Idamay Curtis, BA	Research Assistant	HSR&D, VAPSHCS	206-277-1954
Jared LeClerc	Research Assistant	HSR&D, VAPSHCS	206-277-4153
Liza Mathias	Research Assistant	HSR&D, VAPSHCS	206-277-6739
Brianna Moss	Research Assistant	HSR&D, VAPSHCS	206-277-6739
Dawn Sakaguchi	Research Assistant	HSR&D, VAPSHCS	206-277-4153

SUBJECT'S IDENTIFICATION (I.D. plate or give name-last, first, middle)

APPROVED

JUL 1 1 2007

UW Human Subjects Review Committee

RECEIVED
Human Subjects Division

JUL 0 6 2007

UW

VA FORM APR 1991 (RS) **10-1086**

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The goal of this study is to improve how doctors talk with their patients about the care they may want to receive in the future. You are being asked to participate in this study because you may have a condition called chronic obstructive pulmonary disease (COPD). Our interest lies mainly in patients with your type of lung disease. We hope to find better ways for doctors to talk with patients about the care patients would want if they became very ill. You were selected because of the type of lung disease that you have, not because we believe that you will become very ill. But by taking part you will help us learn more about how to improve the ways doctors talk with their patients who have lung diseases, such as chronic bronchitis, emphysema and chronic obstructive pulmonary disease (COPD).

PROCEDURES

If you choose to be in this study, the doctor who takes care of your lung disease will either provide care to you as usual, or he/she will be chosen to be in the test group. If your doctor is in the test group, he/she will receive information you have given us about your preferences for medical care. You will also be offered the option of choosing someone who you wish to make decisions for you, if you become so ill that you cannot make your own decisions. This person is called a surrogate.

First, a research assistant will ask you some questions and have you complete 11 questionnaires. The research assistant will ask you questions about your education, job, health symptoms, and communication preferences. More specifically, communication preferences refer to questions about preferences and types of care that you may want to receive toward the end of life. These include questions like: "Would you like to discuss with your doctor, the kinds of treatments you want if you get too sick to speak for yourself?" "Would you want resuscitation, or CPR, if your heart were to stop beating?" as well as possible scenarios regarding personal preferences toward end of life care while in a coma and unable to interact with your surroundings. **These scenarios are designed to stimulate conversation and are not meant to reflect your current condition.** In addition, you will be asked to answer a wide range of questions like: "What was the highest grade you completed in school?" "I panic or get afraid when I cannot catch my breath" (true or false). You are free to refuse to answer any questions you do not wish to answer. The questionnaires will take approximately 60 to 90 minutes, and can be done over the telephone, in your home, or at your next VA appointment, whichever is most convenient for you. A research assistant will help you to fill out the questionnaires.

You will also be asked to perform a short lung test called a "Spirometry" test, if you have not had one in the last year. This test measures the amount of air you are able to blow into a tube. The spirometry test can be done at your home, or at the VA Hospital, whichever is most convenient for you. Your doctor has probably already prescribed a bronchodilator inhaler for you, and you should not use this inhaler in the 2 hours before the test. You will be asked to perform the test twice, once before you use a bronchodilator and another after you have used 2 puffs from a bronchodilator inhaler. The spirometry will take approximately 20 minutes.

If you see a doctor who has been selected to be in the test group, the information that you provide to us will be shared with the doctor who takes care of your lung disease. From the information you provide, your doctor will receive a brief summary of your preferences, facilitators and barriers to end-of-life communication along with suggestions to aid in a discussion. Your doctor will not have direct access to the information you provide to us. You will also have the option of sharing the information with your surrogate (if you have chosen one). Also, we will meet with you during your next clinic visit with your doctor, and give you a letter summarizing your preferences to give to your doctor. It will be up to you and your doctor to decide if you want to do anything else with that information. If your doctor is not in the test group, we will not share the information with your doctor. Questions that ask about your satisfaction with the care your provider gives you will not be shared with your doctor. Questionnaires will not be placed in your medical records.

Two weeks after this clinic visit, we will ask you to complete 3 of the original 11 questionnaires over the telephone. We expect this session to take 30-45 minutes. Your total time being in this study will be about six months. If you move out of the area, or become too ill to complete questionnaires, you would be removed from the study. This would not affect the care you receive.

We will also look at your medical records to gain further information about your health condition and medications. We wish to look at your medical records for up to ten years from the date you begin this study. This is because we would like to see how you're doing after the study ends and how we're doing with your clinic visits, hospital stays, and medication use. If at any time you decide to cancel your permission to let us look at your medical records, you can call us at (206) 764-2558. To make the cancellation official, write to Ed Udris, VAPSHCS, HSR&D (152), 1660 South Columbian Way, Seattle, WA, 98108.

RISKS, STRESS, OR DISCOMFORT

Answering questions about end of life will require you to think about illness and death. These questions can cause discomfort for some people. Some people find the questions personal or upsetting and may feel that the questions are an invasion of privacy. You may refuse to answer any questions.

There are no known physical risks for the spirometry test. You may already have been prescribed a bronchodilator, and the dose (2 puffs) for this test is very low. As with any drug, there may be unexpected side effects. There will be no other direct physical risks to you from being in this study, and you and your doctor will continue to make all decisions regarding your care.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you decide not to participate in this study it will not affect the care you receive. You will still continue to see the same providers and receive the same high quality care.

BENEFITS OF THE STUDY

You may not benefit from this study. But by taking part you will help us learn more about how to improve the ways doctors talk with their patients who have lung diseases, such as chronic bronchitis, emphysema and chronic obstructive pulmonary disease (COPD).

OTHER INFORMATION

Other than medical providers who have regular access to your medical record, your identity will be kept confidential. For the purposes of this study, only your provider and study personnel will be allowed to see any information collected. Questionnaires and interviews you completed for this study will not be part of your medical records.

The following people or groups may know that you are in this study:

- the research team members
- VA (to monitor studies)
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) for payment of subjects or for tests done outside of the VA
- the study sponsor
- government agencies that regulate research such as the Food and Drug Administration (FDA) or the Department of Health and Human Services (DHHS)
- the VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies

A number will be used to identify you. Personal data (such as your name, address or telephone number) will be kept apart from the information collected during the interviews. Only the research study staff will have access to the file that connects each person's study number and personal data. The file linking each person with his or her number will be destroyed ten years after all patient participation has been completed or no later than 12/31/2016. This will be after the results of the study have been collected and reviewed. There will be no direct costs to you for participating in this study. We will mail you $10.00 two weeks after you complete the study as a partial reimbursement for your time.

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. You may withdraw your permission for us to review your records at any time; however doing so will terminate study participation. If you want us to stop using your records, please contact Ed Udris, Project Director, VA Puget Sound Health Care System at (206) 764-2558.

If you are injured as a direct result of taking part in this study, you will be treated at no cost to you. Veterans who are injured because of being in this study, may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured, may receive payment under the Federal Tort Claims Act.

QUESTIONS

Please call Ed Udris, Project Coordinator at (206) 764-2558, if you have any questions regarding this information.

Printed name of researcher	Date	Signature of researcher	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Date	Signature of subject	Date
Printed Name of Witness	Date	Signature of Witness	Date

APPROVED

JUL 1 1 2007

UW Human Subjects Review Committee

NCT00106080

Improving the Quality of End-of-Life Communication for Patients With COPD

Clinician Consent Form

July 11, 2007

Department of Veterans Affairs

RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: Improving the Quality of End-of-Life Communication for Patients with COPD

Principal Investigator: David H. Au, MD MS **VAMC:** Seattle (663)

Researchers:

David H. Au, MD, MS	Principal Investigator	Health Services Research and Development (HSR&D) VA Puget Sound Health Care System (VAPSHCS)	206-764-2504
Stephan D. Fihn, MD, MPH	Co-Investigator	HSR&D, VAPSHCS	206-764-2651
J. Randall Curtis, MD MPH	Co-Investigator	Division Pulmonary and Critical Care Medicine University of Washington	206-731-3356
Donald Patrick, PhD	Co-Investigator	Professor of Health Services Research University of Washington	206-616-2979
Christopher Bryson, MD	Co-Investigator	HSR&D, VAPSHCS	206-764-2430
Vincent S. Fan, MD	Co-Investigator	HSR&D, VAPSHCS	206-764-2292
Laura Cecre, MD	Co-Investigator	HSR&D, VAPSHCS	206-680-0280
Mary McDonell, MS	Project Director	HSR&D, VAPSHCS	206-764-2460
Edmunds Udris, MPH	Project Coordinator	HSR&D, VAPSHCS	206-764-2558
Idamay Curtis	Research Assistant	HSR&D, VAPSHCS	206-277-1954
Jared LeClerc	Research Assistant	HSR&D, VAPSHCS	206-277-4153
Liza Mathias	Research Assistant	HSR&D, VAPSHCS	206-277-6739
Brianna Moss	Research Assistant	HSR&D, VAPSHCS	206-277-6739
Dawn Sakaguchi	Research Assistant	HSR&D, VAPSHCS	206-277-6739

Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called 'informed consent.' We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

We are trying to determine whether providing information to clinicians about communicating with patients about end-of-life decisions and medical treatment preferences can improve the quality of communication for patients with COPD. You are being asked to participate because, according to VA electronic medical records, one or more of your patients may have a clinical diagnosis consistent with chronic obstructive pulmonary disease (COPD), chronic bronchitis or emphysema. It is because of your patients' diagnosis that you, as their provider, have been selected to participate. Please note that these

SUBJECT'S IDENTIFICATION (I.D. plate or give name-last, first, middle)

APPROVED
JUL 1 1 2007
UW Human Subjects Review Committee

RECEIVED
Human Subjects Division
JUL 0 6 2007
UW

RECEIVED
Human Subjects Division
JUL 0 6 ...

VA FORM APR 1991 (RS) **10-1086**

patients will also be asked to participate in the study.

PROCEDURES

This randomized controlled trial will take place in the Primary Care and Pulmonary Clinics at the VA Puget Sound Health Care System, Seattle and American Lake. As a provider who takes care of patients with lung disease, you will be randomly selected to either provide care as usual (no research intervention) or to participate in the test group. You, your patient, and possibly the patient's surrogate, may or may not be given information from the team regarding the patient's opinions about communication and end-of-life preferences for medical treatment. Although there may be no direct benefit to you personally from participating in this study, if one of these systems of care works better than the other, we hope that it will be implemented in other VAs so all patients with COPD will receive better care. If you agree to participate in this study, you will be one of an estimated 120 participating Primary Care/Pulmonary Providers in the VA Puget Sound Health Care System.

Once enrolled, we anticipate you'll participate in the study for approximately 30 months. At the end of that period we'll send you a letter thanking you for your participation.

We will ask you to complete a brief questionnaire annually, plus two brief questionnaires before and after one clinic visit for each enrolled patient. We will ask you questions about how comfortable you are having end-of-life discussions with your patients. For example, we will ask, "How prepared do you feel about breaking bad news to a patient about his or her illness?" or "How prepared do you feel discussing end-of-life decisions, such as DNR decisions, with a patient?" You do not have to answer every question. We anticipate that the questionnaires will take approximately 5 minutes to complete. For purposes of randomization, we will ascertain provider specialty, clinic panel size, and years since training. The information that you provide to us will not be shared with anyone outside of the study and will only be reported in aggregate, non-identifiable form.

For those of you selected randomly to be in the test arm of the trial, feedback reports based on information provided by your patient will be delivered to you prior to a scheduled clinic visit. It will be up to you and your patient to decide if you want to do anything else with that information. For those not in the test arm, we will not provide any feedback regarding your patient's treatment preferences. You will not receive information about how your patients rate the quality of your care or communication.

We may also ask your patient to undergo spirometry, if they meet the study criteria for chronic lung disease but have not had spirometry in the past 12 months. We will either refer patients to the Pulmonary Function Test Lab, or have our research assistants perform the test in the patient's residence, whichever is most convenient for the patient.

We wish to examine whether there is any benefit to collecting this questionnaire information and presenting it to medical decision makers and providers. You are free to refuse to answer any questions or questionnaires. It is important for you to understand that, in all cases, you will continue to make all decisions regarding your patients' medical care.

RISKS, STRESS, OR DISCOMFORT

The risks to you of this study are very small. You will either provide 'usual care' or you will get information about your patient's feelings about communication and medical treatment preferences. You and your patient will make all final decisions regarding your patient's care. You may ask the research staff any questions regarding the study or the questions you are asked. You are free to refuse to answer any questions. If the questions become too burdensome, you are free to withdraw from the study at your sole discretion at anytime.

There will be no direct physical risks to you from being in this study. As patients' primary care provider, you and your patient will continue to have ultimate decision-making authority in the provision of care. The only other potential risk to you is a loss of confidentiality due to researchers having access to your data from the questionnaire. This is standard for such research, this risk is minimal, and confidentiality will be protected by locking up all paper records, password protecting all computer files and keeping computers in a locked office. Confidential study ID numbers will be used in the analyses, and the data analysts will not have the key. Any data presented will be in aggregate form such that no individual can be identified. Only study personnel will be allowed to see any information collected. Your identity will be kept confidential.

BENEFITS OF THE STUDY

You may not benefit from this study. But by taking part you will help us learn more about how to improve the ways doctors talk with their patients who have lung diseases, such as chronic bronchitis, emphysema and chronic obstructive pulmonary disease (COPD).

OTHER INFORMATION

Provider level data will be used for study purposes only, and will not be used for any promotional, disciplinary or evaluative purposes. Additionally, direct provider identifiers will not be shared outside of project staff. To ensure that all primary and secondary analyses are completed, provider identifiers will be kept indefinitely, as long as patients are followed.

The following people or groups may know that you are in this study:

- the research team members
- VA (to monitor studies)
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with the VA to conduct research) for payment of subjects or for tests done outside of the VA
- the study sponsor
- government agencies that regulate research such as the Food and Drug Administration (FDA) or the Department of Health and Human Services (DHHS)
- the VA committees that oversee research, including the Institutional Review Board that oversees the safety and ethics of VA studies

There are no financial incentives nor directs costs to you from participating in this study. You may refuse to take part in this study or to answer any questions you do not wish to answer. If you choose not to take part in this study, your work status will not be affected in any way. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw from this study, please contact Ed Udris, Project Director, VA Puget Sound Health Care System at (206) 764-2558.

QUESTIONS

Please call Ed Udris, Project Coordinator, at (206) 764-2558 if you have any questions regarding this information.

Printed name of researcher	Date	Signature of researcher	Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, I can ask one of the researchers listed above. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject	Date	Signature of subject	Date
Printed Name of Witness	Date	Signature of Witness	Date

Please ask a co-worker to witness your signature by signing on the witness line.

APPROVED

JUL 1 1 2007

UW Human Subjects Review Committee