Information Sheet

Study Title: Validating the Use of Frailty Measurements to Predict Care Expectations and Deteriorations in Quality of Life Among People with COPD: A Prospective Cohort Study

OHSN-REB Number*:* 20200048-01H

Study Doctor: Sunita Mulpuru, Respirology, 613-798-5555 ex 72772

Funder: Canadian Institutes of Health Research & Canadian Lung Association

INTRODUCTION

You are invited to participate in this study because you have chronic obstructive pulmonary disease (COPD). Please read this document carefully and ask any questions you may have.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

Our team would like to improve your health and experience with care at The Ottawa Hospital. The purpose of this study is to evaluate the use of frailty measurements to gain a better understanding of patients' care preferences as well as to predict deteriorations in patient-reported outcomes.

The standard or usual treatment for COPD is focused on disease-specific metrics. We are proposing the use of an evaluation tool that would help doctors evaluate the non-pulmonary complications of COPD and your overall well-being to further improve the care you receive at the hospital. The results may be used as a guide for future care of patients with COPD.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 120 people will take part in this study, from the Respirology outpatient clinic of The Ottawa Hospital. This study should take two years to complete and the results should be known in about two and a half years.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to complete a survey (online) prior to each scheduled visit (baseline, 6 months and 12 months) or complete the survey with a member of the study team during your telephone study visits. During the first telephone visit, you will be asked questions on care preferences and your overall health.

During the 6-month and 12-month telephone visits, you will discuss, with a member of the study team, changes in your health since your last visit, your frailty, and answer questions on your overall health

Surveys

For each study visit, you will be asked to complete a survey. You will have the option to complete the survey before the scheduled telephone study visit or complete it during your telephone visit. If you agree to complete the survey before your visit, you will receive an email with a link to the survey.. The purpose of these surveys is to collect some information on your quality of life, your lung health, and your well-being.

The first survey will also include questions on your preferences of care interventions (e.g. lung rehabilitation, meal assistance programs).

If you complete the surveys before the study visit, each visit will take approximately 5 minutes, and approximately 10 minutes if you decide to complete the survey with a member of the study team during your telephone study visit.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Even though you may have provided information on a questionnaire, these responses will not be reviewed promptly by your health care team. If you wish them to know this information, please bring it to their attention.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

As a participant, you will be expected to:

- Answer survey questions prior to or during your scheduled telephone visits
- Participate in **three** telephone study visits with a member of the study team (baseline, 6 months, and 12 months visits).

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study will last for about two years. Your participation in the study will last for 1 year from your initial visit with the study team.

You will be asked to participate in three study telephone visits with the study team, at baseline, 6-months, and 12-months

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no anticipated risks in participating in this study.

You may become uncomfortable while discussing your experiences. You may choose not to answer questions or leave the interview at any time if you experience any discomfort.

You might not like all of the questions that you are asked on the surveys. You do not have to answer any questions that make you feel uncomfortable.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive any direct benefit from your participation in this study. However, your participation will help the research team understand whether this evaluation tool can help improve the care and experience for patients like yourself.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

The study doctors and study staff will only collect the information they need for this study.

Records identifying you at this center will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Ottawa Health Science Network Research Ethics Board who oversees the ethical conduct of this study.
- Ottawa Hospital Research Institute to oversee the conduct of research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your participant code, sex, and age.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be published and presented to the scientific community at meetings and in journals.

Your de-identified data from this study may be used for other research purposes. If your study data is shared with other researchers, information that links your study data directly to you will not be shared.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor may be informed by the study team that you are taking part in the study.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical trial/study will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

This research study can be found on the above listed website by using the clinical trial registration number [insert clinical trial registration number]

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

At the end of each study visit, you will receive, by mail, a $20 gift card to a coffee shop at the end of each study visit (total of 60$) as a token of appreciation for your time.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let a member of the study team know. The results of this study will be available on the clinical trial registry.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By participating in this study, you do not give up any of your legal rights against the study doctor, or involved institutions for compensation, nor does this form relieve the study doctor and their agents of their legal and professional responsibilities.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr Sunita Mulpuru	613-798-5555 ex 72772
Principal Investigator Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. Please contact The Ottawa Health Science Network Research Ethics Board, Chairperson at 613-798-5555 extension 16719.