

PCOM Letterhead

[Substitute same from participating institution and, of course, change Department, PI, and Co-Investigators]

Department of Neuroscience, Physiology and Pharmacology

215-871-6880

PATIENT INFORMED CONSENT FORM

Title of Study: Pennsylvania Study of Chronic Obstructive Pulmonary Exacerbations (PA-SCOPE) Phase 2: Impact of Easy Access to Preventive Care for Impending Acute Chronic Obstructive Pulmonary Disease (COPD) Exacerbation

Patient Name: _____

Patient ID#: _____

IRB Protocol#: _____

Purpose of Study:

The purpose of this study is to find out if easy and early access to medical advice and treatment for a COPD (Acute Chronic Obstructive Pulmonary Disease) flare-up will:

- Reduce the need for a patient to be admitted to a hospital for treatment
- Decrease the number of flare-ups
- Make the flare-up less serious
- Improve lung function, quality of life, and ability to carry out daily activities

You are being asked to participate in this study because you have been hospitalized for a COPD (Acute Chronic Obstructive Pulmonary Disease) flare-up at some time in the last one to three months.

Principal Investigator:

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Co-Investigators:

David Kuo, DO, Department of Family Medicine

Director

PCOM Healthcare Center – Roxborough Division

5830 Henry Avenue, Philadelphia, PA 19128

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Attending Physician
PCOM Healthcare Center – Cambria Division
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The information in this consent form is being given to you to help you decide if you want to take part in a research study. This study is sponsored by the Pennsylvania Department of Health. PCOM is receiving payment for performing this study.

Purpose of Study

Chronic Obstructive Pulmonary Disease (COPD) is a disease of the lungs caused mainly by smoking. In Pennsylvania, chronic [occurring for a long time] respiratory lung diseases are the 4th leading cause of death. COPD flare-ups (exacerbations) are to lung disease like a heart attack (myocardial infarction) is to coronary artery disease. These COPD flare-ups usually include shortness of breath, coughing and mucous (sputum) production. Unlike heart attacks, however, not as much is known about the causes, symptoms, treatments, and results of treatments.

The number of patients being admitted to the hospital for COPD flare-ups is increasing. About half of all patients discharged from the hospital for COPD flare-ups are readmitted within six months. It is believed that where patients live and go for medical care, what their income is, and what race they are can affect their chance of developing a COPD flare-up. New information suggests that patients who live in a rural (country) area or who are treated in a community hospital which does not have medical students, interns or residents are more likely to be admitted for a COPD flare-up and remain in the hospital for a longer time than other patients (those who live in the city and go to a hospital that also teaches medical students, interns and residents). There is, however, not much research on how to stop and/or reduce COPD flare-ups.

The purpose of this study is to find out if easy and early access to medical advice and treatment for a COPD flare-up will:

- Reduce the need for a patient to be admitted to a hospital for treatment
- Decrease the number of flare-ups
- Make the flare-up less serious
- Improve lung function, quality of life, and the ability to carry out daily activities

You are being asked to participate in this study because you have been hospitalized for a COPD flare-up at some time in the last one to three months.

Description of the Project

This is Phase 2 of the PA SCOPE Study. This study will test a method to determine whether COPD flare-ups in patients can be reduced. The intervention is a 1-800 phone number that patients with early signs of COPD flare-up will learn to call for advice and changes in treatment. Using this phone number will also increase contact with primary care physicians, and allow a member of the health team to call the patients back to see how they are doing.

This research study will be conducted at several hospitals and healthcare centers in Pennsylvania; 400 patients who have been recently hospitalized for a COPD flare-up in the last one to three months will be asked to enroll.

PCOM expects to enroll approximately 75 patients. Five visits, once every six months, will be in your doctor's office:

Study subjects of Dr. Kuo at Roxborough Healthcare Center: 215-483-3800

Study subjects of Dr. Venditto at Inter-Med: 215-871-6337

Study subjects of Dr. Williams-Page at Cambria Healthcare Center: 215-578-3300

For one of the first visits, you will also need to go to the:

Temple Lung Center (study subjects of Dr. Barbara Williams-Page)

7th Floor, Parkinson Pavilion

Temple University Hospital

3401 North Broad Street

Philadelphia, PA 19140

215-707-3336

Or

Roxborough Memorial Hospital (study subjects of Drs. Kuo and Venditto)

5800 Ridge Avenue

Philadelphia, PA 19128

215-487-5572

Your participation in this study will last two years and will include 3½ hours for Visit 1 plus 1 hour for each of the next four visits for a total time over two years of 7 ½ hours.

A table that contains the Schedule of Procedures is pictured below. Details for each visit begin after the table.

PHASE 2 SCHEDULE OF PROCEDURES

| Procedure | Enrollment | 2 week Phone Contact | 6 months | 12 months | 18 months | 24 months |
|---|-------------------|-------------------------------------|-----------------|------------------|------------------|------------------|
| Visit | 1 | 1A | 2 | 3 | 4 | 5 |
| Informed Consent | X | | | | | |
| History & Physical | X | | X | X | X | X |
| Randomization | X | | | | | |
| Diary Distribution | X | | | | | |
| Peak Flow Meter Distribution | X | | X | X | X | |
| Diary and Peak Flow Meter Instruction | X | X | | | | |
| Diary Collection | | | | | | X |
| Demographic Questionnaires | X | | X | X | X | X |
| Quality of Life Questionnaires^A | X | | X | X | X | X |
| Full PFTs w/ABG^B | X | | | | | |
| Six-minute Walk Test with Oxygen Titration^C | X | | | | | |

A – Quality of Life questionnaires: Modified Outcomes Study Short Form 36 (SF-36), St. George’s Respiratory Questionnaire (SGRQ), the Shortness of Breath Questionnaire (SOBQ), the Quality of Well-Being Scale (QWB).

B – PFTs = Pulmonary Function Tests

ABGs = Arterial Blood Gas – Performed at Temple Lung Center of Roxborough Memorial Hospital

C – Performed at Temple Lung Center or Roxborough Memorial Hospital

Visit 1: Screening

You will undergo the following procedures to determine your eligibility:

1. A medical history will be obtained, which will: smoking history; presence of other health problems; history of influenza and pneumococcal vaccination; history of drug abuse; current medical therapy (bronchodilators, steroids,

oxygen); history of pulmonary rehabilitation; emergency room visits and hospitalizations during the last year for your COPD; medical care and coverage (insurance, primary care, specialist care); previous pulmonary function tests; and occupational and environmental exposures.

2. Demographic information will be recorded, which will include age, gender, employment, income, education and marital status
3. A physical exam will be performed
4. Quality of Life and Functional Status Questionnaires will be given to you to complete
5. **PFTs: Pulmonary (Lung) Function Testing**
These tests will take place in your local Pulmonary Function Lab (Temple Lung Center or Roxborough Memorial Hospital) and will take about 3½ hours. Lung function testing measures the amount of air in your lungs and how well you can move that air by blowing forcefully into a machine. Your lung function will be measured before and after you use your inhaled bronchodilator medicine. During the test, you will be asked to breathe in and out of a mouthpiece while a machine measures the amount of air you are breathing.
6. **ABG: Arterial Blood Gas sample:** Approximately ½ teaspoon of blood will be taken from a blood vessel in your wrist (first choice) or arm and the amount of oxygen and carbon dioxide in the sample will be measured.
7. The tests described below involve walking while monitoring your symptoms and your need for extra oxygen. The type of test you undergo will depend on your condition.
 - **Six-Minute Walk Test:** The time required for this test will vary but will last approximately 6 minutes. The test will be conducted in an enclosed hall that is 60 feet long, and will be marked with start and end points. Before the test, you will be asked to sit quietly for 10 minutes. You will then walk back and forth between the start and end points as many times as you can in a 6-minute period. You may stop and rest if you need to, but you must remain where you are until you can begin walking again. During the test, you will also be asked questions to grade your degree of breathlessness. You must try to walk as much distance as you possibly can during these six minutes. Your oxygen level can be monitored, and oxygen can be used if your oxygen level drops.
 - **Oxygen Titration Test:** This is a low intensity exercise test that lasts approximately 4 minutes. You will walk on a treadmill at the rate of 1-2 miles per hour, beginning without oxygen. As your oxygen level drops, you will be given extra oxygen. The amount of extra oxygen you need during exercise will be determined by this test.

Visit 1: Enrollment and Randomization

1. If you meet the eligibility requirements and agree to participate in the study, you will be randomized (like the flipping of a coin) to be in the **interventional** or **non-interventional** group. You have a 50% chance of being randomized to either group. Patients randomized to the non-interventional control group will get the COPD “standard of care” without telephone access to the Call Center.

2. Treatment Protocol for **ALL** Study Participants:
 - a) Regardless of which treatment group to which you have been randomized, you will receive this medical care through your primary care physician. The physician does not have to be a PA SCOPE Study doctor. This includes:
 - 1) Medications: bronchodilators, inhaled and/or oral steroids, and antibiotics when needed
 - 2) Long-term oxygen therapy if needed
 - 3) Offered enrollment into an outpatient pulmonary rehabilitation program
 - 4) Receive influenza and pneumococcal vaccinations
 - 5) Be encouraged to stop smoking and offered participation in outpatient smoking cessation programs.
 - b) **ALL** subjects will also receive a Peak Flow and Patient Diary, and instructions will be given for their use. You will record the following information into your diary every day in the morning between the hours of 6 AM and 11 AM:
 - 1) Peak Expiratory Flow (PEF)
 - 2) Activity score
 - 3) Heart and respiratory rates
 - 4) Symptoms, including temperature
 - 5) Weight
 - c) **ALL** patients will be instructed to report to the nearest Emergency Room if they feel a sudden worsening of their symptoms
 - d) **ALL** patients will be called 2 weeks after enrollment to see if they have any questions about the use of their diary
3. Additional Treatment Protocol for Patients in the **Interventional Group**:
 - a) If you are randomized to the interventional group, you will be provided with 24 hour, 7 days a week, access to COPD study nurses through a 1-800 Call Center at the Temple Lung Center. If you are in the interventional group, you will call a 1-800 Call Center phone number if you have worsening COPD symptoms. The directions for symptoms to report will be given to you by the study staff. The Call Center will be answered by study nurses who will (1) provide immediate advice to manage the worsening symptoms (for example, changes in drug therapy or dosing), (2) contact your primary care provider immediately via fax, and (3) follow-up with you 24 and 96 hours later by phone.
 - b) If you have been prescribed antibiotics and corticosteroids, you will be given separate special instructions regarding side effects of bronchodilators, antibiotic use, and high blood sugar (hyperglycemia), which is associated with prednisone use. If you have a history of diabetes, glucose testing of the urine will be prescribed.
4. Additional Information for Patients in the Standard-of-Care Group: If you are randomized to the standard-of-care group, you will be encouraged to call your

primary doctor for any worsening in your breathing symptoms per your doctor's usual instructions.

THE FOLLOWING VISIT INSTRUCTIONS APPLY TO ALL STUDY PARTICIPANTS:

Visit 2 – Six-Month Follow-Up: This visit should last approximately 1 hour. You will visit your study doctor in order to:

- Review your medical history, including your current medications
- Assess for any adverse events
- Record any previously unrecorded COPD flare-ups, urgent physician visits, Emergency Room visits, or hospitalizations since the previous visit
- Review your demographic information
- Receive a physical exam
- Review your diary
- Review your peak expiratory flow (PEF) technique and replace the peak flow meter (if necessary)
- Complete the Quality of Life questionnaires

Visit 3 – One-Year Follow-Up: This visit should last approximately 1 hour. You will visit your study doctor in order to:

- Review your medical history, including your current medications
- Assess for any adverse events
- Record any previously unrecorded COPD flare-ups, urgent physician visits, Emergency Room visits, or hospitalizations since the previous visit
- Review your demographic information
- Receive a physical exam
- Review your diary
- Review your peak expiratory flow (PEF) technique and replace the peak flow meter (if necessary)

Visit 4 – Eighteen-Month Follow-Up: This visit should last approximately 1 hour. You will visit your study doctor in order to:

- Review your medical history, including your current medications
- Assess for any adverse events
- Record any previously unrecorded COPD flare-ups, urgent physician visits, Emergency Room visits, or hospitalizations since the previous visit
- Review your demographic information
- Receive a physical exam
- Review your diary
- Review your peak expiratory flow (PEF) technique and replace the peak flow meter (if necessary)
- Complete the Quality of Life questionnaires

Visit 5 – Final Visit – Two-Year Follow-Up: This visit should last approximately 1 hour. You will visit your study doctor in order to:

- Review your medical history, including your current medications
- Assess for any adverse events

- Record any previously unrecorded COPD flare-ups, urgent physician visits, Emergency Room visits, or hospitalizations since the previous visit
- Review your demographic information
- Receive your diary
- Complete the Quality of Life questionnaires
- You will return the electronic diary

Description of Any Foreseeable Risks or Discomforts

Blood Sample

When blood is drawn from an artery (blood vessel) in your wrist or arm, you may have discomforts like pain and lightheadedness (feel like you may pass out). There is a small risk of bleeding, bruising and/or infection at the puncture site. Also, for a few minutes, the blood vessel may have a spasm (become a bit smaller) which may cause some temporary pain. The total amount of extra blood that will be drawn because you are participating in this study ½ teaspoon.

Lung Function Tests

Discomfort is unusual during lung function testing, but some people may feel dizzy and/or get a headache during the test.

Quality of Life Questionnaires

You may be uncomfortable giving information about your symptoms and how it affects your life. Your questionnaire will stay with your study file in the study doctor's office. Only your study identification will be used with the answers you provide on these questionnaires. You have the option of leaving answers blank if they make you feel uncomfortable.

Six-Minute Walk Test or Oxygen Titration Test

You may experience fatigue, dizziness and increased shortness of breath. These conditions are usually temporary and resolve on their own. Your oxygen level will be monitored during this time, and oxygen may be given to you if it is needed. The test may be shortened if you cannot walk for the full six minutes.

Description of Benefits

While early intervention may improve the overall quality of life, functional status, lung function, and length of life, you may not personally benefit from your participation in this study. However, if the results of this study show that earlier access and intervention are successful in preventing serious COPD flare-ups, the overall COPD management for patient like you may be improved.

Alternative Procedures

The alternative procedures to this study are that you will be care for as is standard of care for your COPD condition.

Confidentiality Statement

All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. You understand that medical records and data generated by the study may be reviewed by the PCOM Institutional Review Board (IRB), the Temple IRB, the PA SCOPE Coordinating Center, Pennsylvania Department of Health and the United States, and Office of Human Research Protections (OHRP) to assure proper conduct of the study and compliance with federal regulations. You understand that the results of this study may be published. If any data are published, you will not be identified by name.

Voluntary Participation Statement

You understand that your participation in this study is entirely voluntary, and that refusal to participate will involve no penalty or loss of benefits to you. You may discontinue your participation at any time without penalty or loss of benefits.

Compensation Statement

You understand that you will receive a gift coupon for \$25.00 for participation in this study upon completion of your questionnaires at Visit 1 and every 6 months. This will add up to five gifts for a total of coupons valued at \$125.00. You will then select a gift (or gifts) of your choice from a gift list that will be given to you. You can not trade this coupon in for cash.

Institutional Contact

If you have any questions about your rights as a research subject, you may contact the PCOM IRB Vice-Chair Virginia Salzer, PhD, at 215-871-6476.

If you have any questions about research-related injuries, you may contact your physician as follows:

Study subjects of Dr. Kuo at Roxborough Healthcare Center: 215-483-3800

Study subjects of Dr. Simelaro at Inter-Med: 215-871-6337

Study subjects of Dr. Williams-Page at Cambria Healthcare Center: 215-578-3300

Standard Injury Statement

You understand that if you sustain an injury as a result of participation in this study, only physicians' fees and medical expenses not covered by your medical and hospital coverage or other third party coverage will be paid at no cost to you. You understand that financial compensation for such injuries is not available. You understand that you have not waived any of the legal rights that you would otherwise have as a participant in an investigational study.

Costs Statement

You understand that the physician's fees, blood draws, or blood tests required by the study will be provided at no cost to you. You understand that the physician's fees and tests considered to be part of the standard care for your condition will be billed to you in the usual manner.

Termination Statement

Your participation is voluntary and you may refuse to participate or may discontinue participations at any time during the entire duration of the study without penalty or loss of benefits to which you are otherwise entitled. In addition, you may be removed from the study by the doctor without regard to your consent if you need additional treatments, do not follow the study plan, experience a study-related injury, or for administrative reasons.

Statement of Significant New Findings

Any new important information, which develops during the course of the study, which may influence your willingness to continue participation in the study, will be made available to you.

Pennsylvania Study of Chronic Obstructive Pulmonary Exacerbations (PA-SCOPE) Phase 2: Impact of Easy Access to Preventive Care for Impending Acute COPD Exacerbation

Final Statement and Signature

This study has been explained to me, I have read the consent form and I agree to participate. I have been given a copy of this consent form.

Patient's Name (printed)

Patient's Signature

Witness Signature

Signature of Person Conducting
Consent Discussion

Investigator Signature