

Date: January 20, 2015,
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Application Number: IRB00054456

JHM IRB - eForm A – Protocol

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1. Abstract

The transition from hospital to home is a high risk period for patients. One out of 5 patients suffer an adverse event shortly post their discharge with about a third of those deemed preventable. Poor patient and family readiness for discharge is associated with increased use of emergency department (ED) and hospital services post discharge. Transitional care interventions to support patients being discharged from the hospital, have been shown to reduce ED visits and re-hospitalizations and. These interventions focus on the 30 days post-discharge period, addressing medication and outpatient follow up issues.

In this study, we propose to develop and evaluate a comprehensive patient and family-centered transitional care intervention to improve patient-centered outcomes among hospitalized patients with Chronic Obstructive Pulmonary Disease (COPD). COPD patients commonly experience severe symptoms, and frequently visit the ED or are hospitalized. The study will answer the following: Among patients hospitalized due to a COPD exacerbation, would patient/family engagement in a hospital-initiated three month transitional care program that addresses the patient’s bio psychosocial needs and advances the patient/ family caregiver disease management skills, improve patient health-related quality of life, and reduce use of acute care services, compared to ‘usual care’? Would this program improve family caregiver coping skills and reduce their stress?

The study will be conducted as follows: 1) Intervention components and materials will be developed by a team that includes patients, caregivers, inter-professional team (physicians, nurses, respiratory therapists, case managers, social workers), and healthcare leaders. The intervention plans will be informed by state of the art COPD self- management interventions along with input from focus groups (FGs) and stakeholder input. 2) The study intervention will be pilot tested and refined based on additional input from patients, families, and key stakeholders. 3) A randomized single- blinded trial will be conducted to measure intervention impact on patient outcomes compared to 'usual care'. Our primary study outcomes are the change in disease specific quality of life and combined number of hospital and ED visits per

patient over the 6 months post discharge. Other study measures include patient survival, symptom burden, and experience of care; and, family caregiver stress, and coping skills.

2. Objectives (include all primary and secondary objectives)

The study will test the following main hypotheses:

We hypothesize that compared to usual care, at 3 and 6 months post discharge, the study intervention will: a) Improve patient health-related quality of life and survival, and reduce their use of hospital and ED visits; b) result in improved patient experience, activation, self-efficacy, and self-care behaviors; and c) result in improved family caregiver's preparedness for caregiving and coping skills.

To test this hypothesis, we will accomplish the following specific aims:

1) Develop and pilot test a Patient and Family-centered Transitional Care Intervention (PFI) to empower and build capacity of COPD patients/family caregivers, and advance their disease management, problem solving, and coping skills. The PFI builds on state-of-the-art interventions for COPD management and offers tailored services to address individual patients' bio psychosocial needs. The PFI starts early during hospital stay and continues for 3 months post discharge

2) Conduct a single-blinded randomized controlled trial among 240 COPD patients (120 in each group), admitted to one academic medical center, (Bayview Medical Center) to test the effects of PFI compared to usual care on health-related quality of life; survival; and, use of ED and hospital services

3) Evaluate PFI impact on the patient experience, activation, self-efficacy, and self-care behaviors

4) Evaluate intervention process and impact on family caregiver self-efficacy, stress, and coping skills.

3. Background (briefly describe pre-clinical and clinical data, current experience with procedures, drug or device, and any other relevant information to justify the research)

Nearly 8% of the US population was admitted to a hospital at least once in 2010, accounting for nearly 37 million hospitalizations. The transition from hospital to home is a high risk period for patients. One out of 5 patients suffers an adverse event shortly after their discharge from the hospital. Poor patient readiness for discharge is associated with increased use of emergency department (ED) and hospital services shortly post discharge. Among the more frequently hospitalized patients are those with Chronic Obstructive Lung Disease (COPD). COPD is a prevalent condition and according to NHANES III national survey data about 14% of adults age 25-75 have COPD disease. Patients with COPD suffer from high mortality, morbidity,

symptom burden, and functional limitations that influence their quality of life. COPD is the fourth leading cause of death in the US and about 75% of total costs for treating COPD are spent on treating acute exacerbations mostly in the hospital setting. In 2000, COPD resulted in 1.5 million ED visits, 726,000 hospitalizations, and 119,000 deaths. COPD is also a leading cause for re-hospitalizations with about 20 % of patients re-hospitalized within 30 days. Significant healthcare disparities exist among COPD patients with patients residing in low income areas and blacks experiencing higher number of hospitalizations than patients residing in high income areas and white patients, respectively. Psychosocial distress, single marital status, and the need for social services intervention are all associated with higher re-hospitalization rates among COPD patients. Depressive symptoms among these patients are associated with higher mortality and symptom burden and poorer physical and social functioning.

Transitional care studies have sought to improve patients' readiness for discharge via multiple intervention approaches including employing transition coaches, nurse educators, and case managers who would take the time to educate and support the patients within the hospital and post discharge. Many of these studies have focused on measuring 30 day readmission rates and the interventions usually last up to when follow up with primary care providers is anticipated. A recent systematic review on transitional care interventions among patients admitted with acute myocardial infarction and stroke highlighted the need for longer term studies with more focus on patient centered outcomes including mortality, quality of life, and functional status. Transitional care interventions that focus on COPD patients are very few. A recent stakeholder's workshop including patients and families prioritized research on 'integrated healthcare strategies during transitions in care' as a number one priority for COPD research. Furthermore, an official report of the American Thoracic Society called for more studies on integrated care for COPD patients highlighting the need for patient-centered holistic approaches for care that take into account individual patient needs and preferences as opposed to 'one size fits all' approaches.

4. Study Procedures

- a. Study design, including the sequence and timing of study procedures
(Distinguish research procedures from those that are part of routine care).

The study will be conducted in two phases: Phase 1 is the intervention development and pilot testing phase, and phase 2 is the randomized controlled trial phase and the assessment of the experience with study intervention, as well as review of implementation barriers, and lessons learned.

Phase 1 started with intervention development (phase 1a), followed by pilot testing and refinement of interventions (phase 1b). **Phase 1a** involved intervention development with all key stakeholders and holding focus groups and interviews to inform intervention development and elicit feedback on intervention plans. **Phase 1b** involved pilot testing of the intervention with ~10 patients and refinement of intervention based on feedback from patients, their family members, and their clinical team. **Phase 1** is currently near completion and has been approved

by the JHU IRB under application number NA_00090518. We are submitting Phase 2 for approval as a new application.

Phase 2 involves rigorous testing of the study intervention in a randomized controlled trial (RCT) at 4 hospital units (Med A, Med B, PCU and Bridgeview) within Johns Hopkins Bayview Medical Center. We plan to consent and enroll 240 persons who meet the initial eligibility criteria of hospitalization due to a COPD related condition. Patient participants who consent to the study will be randomized to one of two study arms; 1) Intervention or, 2) Usual Care, and then complete a baseline assessment, which will inform tailoring of the intervention to patient needs and engagement level. Patients will have a 50/50 chance to be in either arm of the study. Usual Care in this study includes the routine hospital and transitional care services offered to patients admitted at Johns Hopkins Bayview medical units. Please refer to Table 1 comparing intervention with usual care.

Table 1. Integrated Patient Family Intervention: Education and Behavioral Features compared to Usual Care

Intervention Features	Usual Care	Study Intervention
Assessing patient needs and preferences	Standard assessment on hospital admission	Bio psychosocial assessment including barriers to care
Response to patient needs	Variable. Based on the involved practitioner/s and their time availability	Follows a standard COPD nurse protocol that includes checklists for each COPD nurse encounter with the patient with proactive identification and addressing of barriers to care in collaboration with the rest of the healthcare team
Advancing COPD self-management skills	Very limited. Inpatient- General advice delivered by primary nurse and other clinicians to the patient during the hospital stay; outpatient services highly variable.	Comprehensive disease management intervention that utilizes motivational interviewing principles and engages both patient and family caregiver , starting during hospital stay, and continuing for 3 months
Discharge plan education	Brief verbal education delivered by patient nurse to the patient with print out of discharge instructions. The quality of verbal communication may vary based on nurse practice and time demands. Family caregiver presence during discharge planning education is variable	In addition to the ‘usual care’ services, the COPD nurse will ensure that the patient/family understands the discharge instructions and able to follow through on the treatment plan
Post discharge follow up	Transition support services include those of a nurse transition guide (substituted by a home healthcare visiting nurse for high risk patients) that would provide follow up for one month post discharge	Close follow up with a ‘COPD nurse Transition Guide’ over 3 months post discharge, in collaboration with a social worker as applicable. The sessions include both patient and caregiver (whenever available) and would focus on COPD self-management skills, addressing barriers to care, and facilitating access to social support and community based services.

The current application is for Phase 2 of this study.

Phase 2 of this study will continue to follow Patient Family Engagement and Community-Based Participatory Research (CBPR) approach to engage patients/families and all key stakeholders throughout all phases of the research as “experts”. This enhances interventions’ relevance to the patients and healthcare decision makers and increases the potential for intervention sustainability and wide spread dissemination.

Study Participant Recruitment for Phase 2

For phase 2 of the study, there are two types of participants: (1) patient participants who are COPD patients admitted to Johns Hopkins Bayview Medical Center (JHBMC) with an acute COPD exacerbation, (2) caregivers of patient participants. We will be utilizing Hospital-based recruitment to enroll patients for this study. We plan to use patient census and diagnosis lists that are maintained by the hospital to identify in a timely manner potentially eligible hospitalized patients as early as possible during their hospital stay. This recruitment approach has proved successful in Phase 1b of this study (NA_00090518) . For patients who are hospitalized with COPD Exacerbation or COPD- related symptoms at one of 4 Bayview medical units (MedA, MedB, PCU, Bridgeview), a study team member will contact the patient’s provider to determine whether the patient’s clinical status allows them to participate in the study. Patients who are clinically stable will then be approached by a study team member who will inquire about their interest in participating and obtain written consent in the privacy of their own room. (Attachment A).

Once a patient is consented to participate in the study, a baseline assessment will be conducted and they will be randomized to usual care or intervention arm. If a patient is randomized to the study intervention arm, the patient will be asked by the study interventionist if they are willing to invite a family caregiver (or close friend) who is involved in their medical care to participate in this study. If the patient agrees to invite a caregiver, the interventionist will ask for the patient’s permission to directly contact the caregiver and inform them about this study. This approach for recruitment of family caregiver will help reduce the burden on sick hospitalized patient participants and offer a successful recruitment method for caregivers. Earlier studies involving caregivers have successfully utilized this method. (See supplemental materials by Bowen et al. and Albert et al. attached). The interventionist will approach the family caregiver in person while at the hospital or via phone (if caregiver is away from hospital for an extended period) and using a prepared script will inform them about the study (Attachment B), check if they are interested in participating, and obtain their written consent (Attachment C). Recruitment materials describing the study will be used as needed to facilitate the recruitment process for patients and caregivers. (Attachments D and E)

Intervention Description

The aim of phase 2 is to conduct a randomized controlled trial to evaluate the impact of a patient and family-centered transitional care program which we have named the BREATHE program. The BREATHE program stands for Better Respiratory Education and Treatment Help Empower. The BREATHE program will offer the following:

- 1) Individualized transition support services to help ensure that the patient (and family caregiver if available) are prepared for discharge, understand the discharge plan of care, and receive post discharge follow up to help meet their needs
- 2) Tailored COPD self-management education and support program that starts during the hospital stay and continues post discharge in the community setting
- 3) Facilitated access to community based services.

The intervention will be delivered by a specially trained COPD Nurse Transition Guide. The intervention involves both patients and family caregivers (if available), is literacy adapted, and follows a tailored approach based on patient needs, priorities, and preferences. Table 1 depicts the study intervention features and description.

Table 2. Intervention Features and Description

Intervention Features	Components	Description
Transition Support	- Assign a COPD Transition Guide who will follow the patient throughout the transition period	- A ‘COPD nurse’ will serve as a specialized transition guide who will follow the patient during their hospital stay and up to 3 months post discharge. The COPD nurse is a registered nurse with at least 2 yrs of homecare experience. - The COPD nurse will work with the patient, family-caregiver, and their healthcare team (inpatient and outpatient providers). - The COPD nurse is trained in motivational interviewing techniques, patient and family-centered communication, and COPD treatment and self-management techniques.
	Baseline assessment and response to patient needs and priorities	- Conduct baseline patient and family-caregiver assessment.* - The COPD nurse reviews assessment findings with the patient, communicates main findings to the inpatient team and outpatient medical providers, and follows up on how patient needs are being met.
	Attention to discharge	- The COPD nurse helps the patient and family caregiver understand the hospital discharge plan, checks on their ability to follow it, and addresses any barriers interfering with their ability to do so.
	Post discharge follow up	- Follow up by the COPD nurse over 3 months via home visits and/or phone. - Referral to a community-based clinical social worker if the inpatient workup reveals complex psychosocial needs including poor living conditions, and need to access mental health or substance abuse treatment services. - Provision of a telephone number that the patient can call to in case they would like to talk to a medical provider AND they do not have a physician who is following them yet post discharge.
COPD self-management education and support program	- Comprehensive disease management intervention that engages both patient and family caregiver - Program is tailored to patient activation level, patient priorities, , and current health	- Program delivered by the COPD nurse and applies motivational interviewing techniques. - Starts during hospital stay and continues over 3 months - Aims to reinforce the following COPD self-management behaviors: Taking medications correctly and regularly; Recognizing exacerbations and following provided action plan; Practicing breathing exercises and energy conservation techniques; Maintaining an active lifestyle including going to pulmonary rehabilitation if indicated; Seeking help and support services as needed; Stopping smoking (if smoker) - Offers tools for patient and family caregiver to work together to support patient in adopting and maintaining above self-management

	behaviors	activities/behaviors
Facilitated access to services	- Provision of information about local social support and community resources and help to patient and caregivers in accessing those	- A local resource guide will be available to the COPD nurse to use and share with patients and family caregivers - The COPD nurse will provide patients and family caregivers with information about social support and community resources according to their needs and will help them in accessing those. - The COPD nurse will be able to seek advice of a social worker about other services as needed.

Intervention Procedures

. The intervention involves the following:

- The COPD nurse (study interventionist) visits the patient while at the hospital, talks to them and their family caregiver (if available), reviews patient information, and their baseline assessment (refer to data collection below). The COPD nurse will then communicate with the patient's medical providers as needed about any surfaced patient needs and barriers to care.
- The COPD nurse ensures that the patient (and family-caregiver when available) understands the hospital discharge plan and how to use their medications and inhaler treatments.
- The COPD nurse will educate the patient and family caregiver about early signs of COPD exacerbations that require them to seek medical opinion in 24 hours, as well as signs that the patient need to seek medical attention immediately. This education is summarized in the form of an action plan that is printed on a magnet material and will be given to the patient before they leave the hospital. The patient and family caregiver will be asked to hang this magnet on their fridge for easy visibility.
- The COPD nurse initiates a tailored program for patient (and family- caregiver when available) on COPD self-management, starting at the hospital and continuing for 3 months post discharge. The program will be delivered during a series of hospital and home visits. If the patient is uncomfortable with having the COPD nurse visit them at home, alternative plans will be made for follow up meetings at the healthcare facility, via phone, or both.

Program tailoring will occur based on the patient baseline knowledge of COPD, their self-management skills, and their individual needs and priorities. Session frequency and pace of education will be tailored based on the patient's activation level as measured by Patient Activation Measure (PAM) score. Patients with low PAM scores will have more frequent sessions, starting with the patient's own role in caring for their health. The program will be delivered as a series of small steps and easily attainable goals so that the patients may experience initial successes and build confidence in moving further in the program. The program goals is that by the end of the intervention period, the patient participants will gain knowledge on COPD; causes, signs and symptoms of its exacerbation. He/she will be able to perform different types of breathing exercises and will be able to correctly use their inhalers and medical devices (if applicable). The patient will pace their activity and utilize energy conservation techniques and breathing exercises to cope with breathlessness. They would also gradually increase their exercise

schedule, as well as pursue smoking cessation and pulmonary rehabilitation programs, if applicable. (See Attachment F-Patient Education Materials) .

- The COPD nurse follows a motivational interviewing approach to engage and activate patient (and family-caregiver) and enable them to manage the patient's health condition beyond the 3 months intervention period
- The COPD nurse will help the patient access available services (e.g. health services, transportation services, nutrition services, medication coverage plans) based on their needs. If the patient has mental health problems, substance abuse problems, or poor social support (e.g. no family/friends), the patient will be referred to a clinical social worker who will facilitate their access to treatment and social support services as applicable.

In this study, the COPD nurse will not directly provide medical care to patient participants. Instead, participants will receive medical care from their inpatient and outpatient care providers. Medical therapy to treat COPD and any other co-morbidity will, accordingly, be the responsibility of the patient participant and his or her medical providers. No blood testing or collection of biological samples will be done for the study participants. Outcomes and covariates data will be collected primarily via surveys and interviews, a spirometry test, as well as information from the patient medical records. (See below)

Data Collection for Phase 2:

Patient participants will be interviewed, by a trained study team member 1) in person at day 2-4 of index hospitalization and, 2) via phone, within 1 week post discharge and at 1, 3, and 6 months post their index hospitalization discharge. The baseline assessment collects demographic information, information about their bio-psychosocial status, as well as their COPD knowledge, COPD self-management skills, patient activation, and health literacy levels. (See Attachment G- BREATHE REDCap Grid and Instruments; Attachment H- Study Assessments Tables). As part of the study assessment, a spirometry test will be conducted while patient is in the hospital, and information will be collected post discharge on whether the patient has visited the ED or been re-hospitalized. If so, information about the name of ED or hospital will be collected and patient's permission to check the medical records for that visit will be obtained to determine whether the visit was COPD-related.

Patient participant data will be entered by a study team member via tablet directly into a secured research database (Research Electronic Data Capture- REDCap). We will also collect data from caregiver participants who will be surveyed upon enrollment, and at 3 and 6 months post discharge to assess their self-efficacy, stress and coping, and experience with the intervention. The caregiver assessments will be conducted by the COPD nurses and via a self-administered survey which will be returned to the study team via postal mail.

As a quality control measure, we will audio-record the interactions of the study interventionist at 20% of the patient encounters and a random sample of those audio recordings will be reviewed for implementation of motivational interviewing principles and adherence to protocol. The patients and family-caregivers will be reminded at the start of each conversation/session that it will be audio-recorded and will be informed that they may choose not to have the audio-recorder on or ask that it be stopped anytime during the session. The audio files will be saved on a secure password protected Hopkins drive directly after session

conclusion. The drive will only be accessible to the PI and designated team members and stored files will be kept for 7 years in accordance with the DHHS regulations and would then be destroyed.

- a. Study duration and number of study visits required of research participants.
There are two types of study activities for patient participants in phase 2 of this study : 1) Data collection activities which will be similar for both study arms and include an in person interview during hospital stay, followed by phone interviews to collect data post discharge and at 1, 3, and 6 mons . These interviews will take 30-45 mins. 2) Intervention activities, only for those randomized to intervention arm, which will include a combination of prescheduled encounters and ‘check in’ contacts as needed based on patient needs and preferences. The COPD nurses will aim towards conducting a minimum number of 6 or 12 prescheduled outpatient sessions over a 3 months period based on the patient activation measurement score (PAM score). Patients with low activation levels will be offered 12 sessions as opposed to 6 sessions for patients with high PAM score (the PAM score reflects patient activation status) . The number of sessions may be increased as needed and agreed upon by the patient, caregiver, and COPD nurse. All visits will be conducted at the patient participant’s home (with the caregiver(s) present whenever possible). If the patient does not want the COPD nurse to visit them at home then the visit will be conducted at a Bayview facility or via phone. Caregiver participants will be asked to meet in person at least once with the COPD nurse. This meeting can take place at the hospital, the patient participant’s home, his or her own home, or a Bayview facility. After this initial meeting, the COPD nurse will invite them to join the prescheduled encounters with their family member. Caregivers’ time preferences will be taken into consideration as much as possible to facilitate their participation. (See Attachment I- COPD nurse protocol and Attachment J- Local Services Guide Table of Contents).
- b. Justification of why participants will not receive routine care or will have current therapy stopped.
N/A - The intervention will be delivered in addition and in coordination with existing usual care services
- c. Justification for inclusion of a placebo or non-treatment group.
N/A
- d. Definition of treatment failure or participant removal criteria.
Participants may be removed from the study if they are a threat to the COPD nurse, if there is a change in health or mental status that meets the study exclusion criteria, or if they become homeless or unable to reach.
- e. Description of what happens to participants receiving therapy when study ends or if a participant’s participation in the study ends prematurely.
N/A

5. Inclusion/Exclusion Criteria

Eligibility criteria:

- a) Admitted with a diagnosis of an acute COPD exacerbation; OR has a previous COPD diagnosis* AND receiving treatment to control COPD symptoms – (e.g. nebulizer treatment, prednisone course, ...) in the current hospitalization
- b) Age > 40 and >10 pack-yrs smoking
- c) English speaking
- d) No terminal illness (i.e. less than 6 months life expectancy) that is non-COPD related
- e) No severe cognitive dysfunction determined based on their ability to follow instructions (can provide informed consent)
- f) Has a home address (i.e., not homeless)
- g) Anticipated discharge back to home (rather than to Hospice or long term nursing home placement)

* COPD diagnosis: (ICD9 codes 491.x (chronic bronchitis), 492.x (emphysema), 493.2 (chronic obstructive Asthma), and 496 (COPD, unspecified))

6. Drugs/ Substances/ Devices

- a. The rationale for choosing the drug and dose or for choosing the device to be used.
N/A
- b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
N/A
- c. Justification and safety information if non-FDA approved drugs without an IND will be administered.
N/A

7. Study Statistics

This is a randomized study to demonstrate the effectiveness of an integrative multilevel intervention for improving patient-centered care delivery among patients with chronic obstructive pulmonary disease (COPD). Due to the nature of the intervention, patients and their medical providers will not be blinded, but data collectors and outcomes assessors will be blinded.

Study Endpoints:

- Primary Endpoints

1) The primary outcome will be the difference between study groups in the total combined number of COPD-related re-hospitalizations and ED visits.
We expect that intervention group will have a lower combined number of COPD-related re-hospitalizations and ED visits.

2) Another primary endpoint will be the difference between study groups in the change in quality of life measured by the Saint George's Respiratory Questionnaire score.

The Saint George's Respiratory Questionnaire (SGRQ) is a self-reported disease-specific, health-related quality of life (QOL) questionnaire. It was developed to measure the impact of COPD on a person's life.

We expect that the intervention will have a positive influence on patients' quality of life measured by the Saint George's Respiratory Questionnaire (SGRQ), leading to a better change in SGRQ scores (SGRQ at 6 months post discharge minus SGRQ at 1 week post discharge) in the intervention group. Here “better” means more improvement or fewer declines in quality of life.

- Secondary Endpoints

- Difference between study groups in 6-month mortality rate.
- Difference between study groups in the time to first re-hospitalization, first ED visit, or death after discharge, whichever comes first.

- Safety Endpoints

Safety will be evaluated with summary of adverse events.

Sample size

This study will accrue 240 patients from 4 medicine units in one hospital during a recruitment period of 16 months. Intervention will last for 3 months, and patients will be followed up to 6 months post discharge. To guide our sample size calculation, we refer to publications on related research where the authors used the combined number of COPD-related hospitalizations and ED visits per patient as primary outcome to evaluate interventions with patient population and intervention intensity that are similar to ours.

In [1], the reported cumulative combined number of COPD-related hospitalizations and ED visits per patient was 0.45 per patient in the usual care and 0.2 per patient in the intervention arm, after 6 months into the study. Based on this, we estimated our sample size to detect such a difference, with 80% power and a probability of type I error of 0.05 (two-sided). Assuming that the nesting of patients within units would introduce some within unit correlation that would decrease the efficiency of our estimators, we will incorporate a variance inflation factor of 20% for this consideration. In addition, to account for mortality and patients dropping out of study, based on what was reported in [1], we assumed a patient completion rate of 88%, and 6-month mortality rate of 11%. Under these assumptions, the estimated sample size needed was a total of 120 patients per arm. This results in a total of 240 patients that will undergo randomized trials throughout the whole study.

In addition, in [1], the authors observed that based on patients' completed Saint George's Respiratory Questionnaire, after 12 months into the study, respiratory health

status worsened by an average of 6.4 points in the usual care arm, and by 1.3 points in the intervention arm, resulting in a difference of 5.1 with a 95% confidence interval of [2.5, 7.6]. Assuming similar effects at 6 and 12 months, with our proposed sample size – 120 patients per arm – we can approximately obtain a power of 82% with a probability of type I error of 0.05 (two-sided).

Statistical analysis

Descriptive statistics will be calculated to summarize patients' characteristics in all four units. Comparability of the intervention arm and the control arm will be assessed with regard to pre-intervention socio-demographics and health status measures. We will identify and determine possible necessary adjustment for some baseline attributes accordingly. Two-sample t test will be performed to investigate the difference in two means for continuous variables, Fisher's exact test or Chi-squared test will be used to investigate the difference in proportions for binary or categorical variables, two-sample Poisson test will be conducted to examine the difference in count or rate data. The comparison results will be presented in a table, with p-values reported. Historically, patient gender, age, race, education and severity of illness have been identified as important attributes and are usually adjusted for in the model.

Further statistical analyses will explore the association between intervention assignment and each of the outcomes. Outcomes of the control arm and the intervention arm will be compared first by two-sample t test, Fisher's exact test/Chi-squared test, or two-sample Poisson test, based on the data types of the outcomes.

The preliminary statistical analyses will be followed by regression analyses; using generalized linear models with link functions chosen that are specific to the data types of the outcomes. The data will have a two-level structure, being defined by individual patient nested within units. To address the potential influence of unit-level attributes on patient-level outcomes, we will model the variable "unit" as a fixed effect.

- Combined number of COPD-related re-hospitalizations and ED visits.

Combined number of COPD-related hospitalizations and ED visits per patient is a count variable. We will use a Poisson or Negative Binomial regression model (generalized linear model with a log link) to analyze the effect of intervention assignment on this outcome, adjusting for units, and relevant patient baseline characteristics such as patient gender, age, race, education, and severity of illness.

- Change in the Saint George's Respiratory Questionnaire score

A linear regression model will be used to assess the intervention effect in change in the Saint George's Respiratory Questionnaire score, adjusting for units, and relevant patient baseline characteristics such as patient gender, age, race, education, and severity of illness.

- 6-month mortality rate

A logistic regression model will be used to assess the intervention effect on 6-month mortality rate, adjusting for units, and relevant patient baseline characteristics such as patient gender, age, race, education, and severity of illness.

- Time to first re-hospitalization, first ED visit, or death, whichever comes first.

Cox proportional hazards model will be used to assess the intervention effect in terms of time to first event, adjusting for units, and relevant patient baseline characteristics such as patient gender, age, race, education, and severity of illness.

[1] Disease Management Program for Chronic Obstructive Pulmonary Disease, A Randomized Controlled Trial. Kathryn L. Rice, Naresh Dewan, Hanna E. Bloomfield, Joseph Grill, Tamara M. Schult, David B. Nelson, Sarita Kumari, Mel Thomas, Lois J. Geist, Caroline Beaner, Michael Caldwell, and Dennis E. Niewoehner. American Journal of Respiratory and Critical Care Medicine 2010 182:7, 890-896.

8. Risks

- a. *Medical risks, listing all procedures, their major and minor risks and expected frequency.*

Medical risks are minimal as patients and providers will be in control of the treatment plan. No procedures or medical treatments will be provided to the study participants.

A Data Safety and Monitoring Board will be established for the study. The Board will have 3 researchers and a patient advocate. The researchers have many years of experience in clinical management of COPD, research methodology, and community based research. The patient advocate has worked for multiple years with the COPD Foundation. The board will meet four times a year during the intervention period. The Board will have the responsibility for monitoring study data for evidence of adverse effects attributable to study intervention.

- b. *Steps taken to minimize the risks*

There is a possible risk of loss of privacy and psychological risk to participants because of being embarrassed with their home environment when the nurse interventionist visits them. To address this and reinforce sound self-management principles, the purpose of the home visits will be clarified and the approach would be that of partnering with patients and caregivers to help self-manage their COPD, address any problems that they currently have that influence their health, and help them live better. Also, we will ask patient participants and their family- caregiver if they prefer to meet at the healthcare facility or via phone instead of at their own home and will follow their stated preference. Additionally, we will have an alternate

plan to meet patients at healthcare facility or contact them via phone when participants who do not want to be visited at home.

There is also a risk that as the patient and family caregiver become more activated and gain more expertise in disease self-management they may rely more on themselves and the nurse interventionist and delay contact with their healthcare providers. To address this we included in the program an action plan that directs patients and family-caregivers to the symptoms for which they should seek immediate attention from their medical providers. The action plan will be reviewed by study interventionist with the patient at each of the intervention sessions.

c. *Plan for reporting unanticipated problems or study deviations.*

Unanticipated problems will be reported as per severity. Severity will be judged based on a predetermined grading system. A log will be kept for unanticipated problems as well. Study deviations will be tracked in a log and reported to the IRB per IRB specified guidelines.

Any participant deaths that occur within 30 days of receiving a study intervention, whether expected or unexpected, will be promptly reported in accordance with JHM policies, except when the death meets one of the exceptions to prompt reporting criterion.

d. *Legal risks such as the risks that would be associated with breach of confidentiality.*

There are risks for breach of confidentiality that we would address by taking all possible measures to secure patient personal information and restrict access to it to trained study team members. There may also be risks associated with having the study nurse visit the patient participants at their home to deliver the study intervention. However, the study nurse interventionists will be trained home visiting nurses who are Johns Hopkins Homecare Group employees who are specially assigned to perform the role of a COPD nurse transition guide and will follow the JHU and Hopkins Homecare policies and procedures in regards to professional conduct. Their work on this study is within the scope of the normal duties that home care visiting nurses perform.

e. *Financial risks to the participants.*

If the intervention resulted in patients seeking more follow up services post discharge, patients could incur more out-of-pocket medical expenses. However, these medical services would be within recommended guidelines for care and therefore, would be expected to produce benefits that far outweigh the risks.

9. *Benefits*

a. *Description of the probable benefits for the participant and for society.*

Participants in both study arms will benefit from the educational materials provided in this study at enrollment time (in case of intervention arm participants) or 6 months post enrollment (in case of usual care arm participants). Participants in the intervention arm will also benefit from COPD nurse services including transition support and facilitated access to community based resources and services post hospital discharge. Benefits may include improved quality of life, reduced symptoms, and reduced need for acute care services. Caregiver participants (enrolled in intervention arm only) will also benefit from study educational materials, resource lists, and COPD nurse support and guidance.

There are large societal benefits from this study. COPD is a prevalent health condition, resulting in significant mortality, morbidity, reduced quality of life, and staggering healthcare costs. The study aims to develop and test interventions to engage and empower COPD patients and their family caregivers to better manage this health condition, improve health-related quality of life, and prevent hospitalizations and ED visits.

10. Payment and Remuneration

- a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

Each patient and caregiver will be compensated a total of \$100 and \$80, respectively, for their time and participation in the study. This compensation will be paid in the form of a check over the course of their study participation. All patient participants will also be provided with a tabletop fan at time of enrollment to this study.

11. Costs

No financial costs.

There will be a time investment of 30-60 mins at baseline, post discharge, 1, 3 and 6 months for interview and survey completion activities. Participants will be offered compensation (as listed above) in return for this time investment. There will also be a time investment for participants as they engage in education and support sessions with the nurse interventionist. This aspect of the study is beneficial to the participants, as they will be learning valuable disease management skills that they will benefit from well after the study intervention is over.

Table 1 Covariates

Variable	Hospital	One week post discharge	1 month post	3 months post	6 months post	Measure/Instrument description
Age, Gender, Marital Status, Race/Ethnicity, Living alone Y/N	<input type="checkbox"/>					
FEV1 and FEV1/FVC		<input type="checkbox"/>				Performed during hospital stay
Addiction to drugs or alcohol, mental health dx.	<input type="checkbox"/>					CAGE questionnaire; Coded diagnosis at index hospitalization
Education, Income, Occupation, Insurance	<input type="checkbox"/>					
Health Literacy	<input type="checkbox"/>					One item question on ease of filling of medical forms
mMRC Dyspnea Scale	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	One item
Medical hx. (Ht, Wt, previous PFTs, oral steroid use, class of inhaler treatments)	<input type="checkbox"/>					Medical record
Number of hospitalizations in prior 1 year to index hospitalization	<input type="checkbox"/>					Patient/Caregiver self-report,
Time since last hosp. (in mons)	<input type="checkbox"/>					Patient/Caregiver self-report
No. of years since receiving COPD diagnosis	<input type="checkbox"/>					Patient/Caregiver self-report
Length of stay at index hospitalization		<input type="checkbox"/>				Calculated based on dates of admission and discharge
Smoking status	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Yes/ No, pack-yrs, readiness to quit using 4 stages
Patient reported social / family support	<input type="checkbox"/>				<input type="checkbox"/>	ENRICHED instrument
Home oxygen use	<input type="checkbox"/>				<input type="checkbox"/>	No oxygen/ oxygen continuously/oxygen with activity and/or sleep.
Depression treatment	<input type="checkbox"/>					One item on receiving treatment for depression: currently, during past 2 years, never
Health status	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Self-report

Functional status	<input type="checkbox"/>			<input type="checkbox"/>	Katz Index of Independence in Daily Living
Patient anxiety and distress			<input type="checkbox"/>	<input type="checkbox"/>	Hospital anxiety and distress scale (HADS)
Cognitive status	<input type="checkbox"/>				Minicog
Co-morbidities	<input type="checkbox"/>			<input type="checkbox"/>	Charleson co-morbidity index at baseline Patient self- report at 6 months on new heart conditions or cancer
Major life events				<input type="checkbox"/>	Loss of caregiver, change in living status, new health conditions or terminal diagnosis, other

Table 2 Patient Outcomes

Variable	Hospital day 2	One week post discharge	1 month post	3 months post	6 months post	Measure/Instrument description
Satisfaction with Care			<input type="checkbox"/>			Overall satisfaction from HCAHPS <ul style="list-style-type: none"> • Rate hospital • Recommend to a friend
Readiness for discharge			<input type="checkbox"/>			Care Transition measure (CTM-3)
Missed appointments			<input type="checkbox"/>	<input type="checkbox"/>		Percentage of patients who missed post-hospitalization follow-up appointment. Yes/No question. If missed, re-check at 3 months.
Patient Activation	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Patient activation measure (PAM)
Self-efficacy	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Understanding COPD Questionnaire (Section A-18 items)
Self- care behaviors: Physical activity, Change in smoking status, Use of breathing techniques, Use of positions of ease	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Select questions from Understanding COPD questionnaire, change in smoking status, physical activity (2 items)
Medication Adherence	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Morisky Adherence Scale (4 items)
Patient report on hospital and outpatient care process		<input type="checkbox"/>		<input type="checkbox"/>		Were barriers to care addressed, meds explained, reviewed use of medical devices esp. inhalers, questions answered, concerns addressed. At 3 months: Ask about outpatient providers seen.(Who?How often seen?) AND whether patients has to pay co-pay fees. If so,how much per visit?
Patient perceptions of caregiving	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	Perceptions of caregivers' support and their preparedness to assist with COPD management; caregiving activities received
Participation in pulmonary rehabilitation	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Percentage of patients enrolled in pulmonary rehabilitation • Mean number of sessions attended per week

Post hospitalization ED visits and readmissions (COPD - related and all cause)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Measure: Average number of visits per patient in the 6 months post discharge (calculated as Combined ED and hospitalizations; ED only; Hosp. only). Based on patient self-report (Y/N ; circumstances/reasons for seeking these services) followed by medical records confirmation
COPD - specific quality of life <ul style="list-style-type: none"> Overall disease specific quality of life Impact on daily activity Impact on psychosocial well-being 		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	St. George's Respiratory Questionnaire (SGRQ)
General quality of life			<input type="checkbox"/>		<input type="checkbox"/>	12 items - Medical Outcomes Study (MOS-SF-12)
COPD – related and all - cause mortality		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Information from caregivers, Hospital and ED records, Dept of Maryland Vital Statistics (for 'lost to follow up' participants)

Table 3 Family

Variable	Hospital day 2	One week post discharge	1 month post	3 months post	6 months post	Measure/Instrument description
Baseline assessment		<input type="checkbox"/>				Age, gender, employment, relationship to patient, other caregiving responsibilities, health status, distance from patient home, transportation means, involvement in caregiving/caregiving activities
Family – caregiver preparedness for caregiving		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	Preparedness for caregiving scale (8) Adapted Understanding COPD questionnaire (6)
Caregiver stress		<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	Stress related to helping (1), Zarit stress index(4), Ways of Coping Questionnaire (seeking social support subscale) (8)

Table 4 Intervention

Variable	Hospital day 2	One week post discharge	1 month post	3 months post	6 months post	Measure/Instrument description
Patient and family reactions to intervention			<input type="checkbox"/>	<input type="checkbox"/>		Satisfaction with program services; usefulness of program materials
Implementation process measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Measures fidelity to intervention protocol (encounter checklists, referral to support services); Use of motivational interviewing techniques (based on a random set of audio recordings).



COPD Nurse Interventionist Protocol

Table of Contents:

1. Patient assignment to COPD nurse interventionist
2. Nurse Visit goals and notes
 - a- First Hospital Visit*
 - b- Follow up In-hospital (Interim) Visits*
 - c- Pre-discharge Hospital Visit*
 - d- Follow up Outpatient Encounters*
3. Frequency of Outpatient Follow up Encounters
4. Describing COPD nurse role to patients
5. Describing BREATHE program to patients
6. Intervention flow chart

Patient assignment to COPD nurse interventionist



- The COPD nurse will be notified via e-mail about new BREATHE study patient around 12 noon (and at 3pm as applicable)
- The COPD nurse on call that day will log into REDCap , assign the patient to themselves, and review the baseline assessment summary report (referred to in REDCap as ‘Patient Information summary report’) , within 4 hours of E-mail notification (unless weekend)

Nurse Visit goals and notes

a. First Hospital Visit:

The COPD nurse accepting the patient (will be referred to as ‘ the primary COPD nurse’) will visit the new patient as soon as possible after E-mail notification to maximize opportunity to work with the patient before the day of hospital discharge.

The goals for first visit are to:

- Get acquainted with the patient, describe the COPD nurses’ team approach to care, as well as yourself as person who is there to help rather than to ‘tell them’ what they should do (i.e. more of a partnership approach) .
- Describe the BREATHE program and COPD nurse role



- Learn from patient how the COPD nurse can be most helpful to them
- Understand patient needs
- Explore whether the patient has a caregiver and connect with the caregiver
- Agree on follow up plan

During this visit, the COPD nurse will:

- Introduce herself to the patient (and any caregivers if present). Introduce the BREATHE program and the COPD nurse role. Please refer to sections 4 and 5 of this protocol for suggested language. **Recall that the spirit of this program is to help engage the patient and family caregiver.** Low activated patients need a confidence boost so always good to reinforce, praise, and help address barriers to care. We have to convey that the patient and caregiver : 1) Play an important role in their health and their future ability to live a better life; 2) We believe in their ability to succeed; 3) We are there to help them succeed but only they can make that happen! To do this , we need to help patients experience some successes no matter how small and build their confidence. To facilitate above we need to help patients set small achievable goals (taking very small steps and setting mini-goals. When they achieve those, praise (in a respectful manner (watch out for inadvertently coming across as condescending or paternalistic) and reinforce. That would help motivate low activated patients, build their confidence, and keep them moving forward.
- Provide study binder and talk about program visit frequency based on patient's PAM score (low PAM, aim for 12 encounters post discharge; hi



PAM, aim for 6 encounters post discharge. You may have more contacts with patients in both groups if you, the patient, or the caregiver felt the need for it).

- Ask permission to ask few questions that will help them work with the patient better then proceed to conduct a brief biopsychosocial assessment

Here are suggested question to help engage and inform the COPD nurse about their individual status:

- Tell me about your recent health problem? What happened?
What brought you to the hospital? What do you think started this?
- What is your understanding of your health condition? What worries you the most?
- What is most important to you?
- How can I (the COPD nurse) be most helpful to you?
- What are your goals if your health worsens? Do you have advance directives?
- What do you do when you feel breathless? (Inquire on who they seek healthcare from)



Also, inquire as possible about their home environment and their social support system.

- Ask patient whether they have a family caregiver (CG) who “helps them with their healthcare”, and whether they would approve of having that caregiver join the study. **If there are caregiver/s in the room ask to speak with the patient in private (without caregiver present) beforehand so that the patient can speak up freely.** Seek patient’s approval to contact the caregiver of their choice and obtain their contact information from the patient. Seek to obtain 3 CG contact numbers and a mailing address.
- If caregiver available with the patient in hospital → a) obtain oral consent from CG (give CG a copy of the written consent), b) agree on time for a meeting with them (referred to later as Caregiver meeting) to obtain written consent and conduct baseline caregiver assessment.
- If CG not at the hospital→ 1) ask patient if ok to call the CG from their room so s/he may introduce you to the CG, 2) inform CG about study, 3) obtain oral consent (refer to IRB approved oral consent script) and schedule time



for an in person meeting to go over written consent and baseline

assessment. If you cannot reach CG at the time, seek to call them as soon as possible.

- Check with patient on: 1) preferred location/method for future visits (home, via phone, at Holabird Ave. facility) , 2) preferred tel. number and two back up/ emergency numbers to reach them, 3) mailing address , 4) preferred communication approach – TELEPHONE (note down best time to reach)/TEXT/E-MAIL
 - If CG is present, check with them as well on their own contact information and communication approach preferences as described for patient above.
- Schedule first outpatient follow-up visit. (Engage designated CG in scheduling that follow up visit time whenever possible to maximize opportunity that both patient and CG are present)
- **Document patient visit note in Meditech** so other healthcare team members can read it. (**Remind health team that they can read your notes in Meditech**)



- **Communicate any pressing surfaced issues/barriers** to care that need to be addressed early during hospital stay **to the patient nurse and case manager as needed.**
- **Complete checklist in REDCap.**

b. Follow up In-hospital (Interim) visits:

Visits will be held in the patient room with the patient participant alone or with their family caregiver if they are available to join the visit. Time can vary from 20 - 90 mins depending on the patient's clinical state, level of comfort, and preference. **Aim for a daily visit by one of the COPD nurses unless the patient is anticipated to stay more than 7 days** (which allows for the first, interim, and pre-discharge hospital visit to be conducted by the primary nurse). **Plan to visit hospital patients in the afternoon** as their rooms will have less traffic then allowing for quieter visits. CGs are also more likely to be available then.



The goals for follow-up in-hospital visits are:

- Start COPD self-management education with patient and caregiver focusing on the following priority areas for pre discharge education: Medication list and reasons for using each medicine, pursed lip breathing, inhaler use technique, and action plan .
- Identify patient priorities for post hospital discharge visits and need for help at home
- Work with patient’s inpatient healthcare team to address patient needs

During this visit, the COPD nurse will:

- Remind patient that the COPD nurses will “team up”/cover for each other when one is not available to maximize the ability to support and teach patients while still at the hospital.
- COPD nurses will document all their hospital visits in Meditech and fill in respective checklist in REDCap.
- The “Primary” as well as the “Covering” nurse will check each other’s documentation in Meditech and in REDCap prior to meeting the patient to remain updated on what their COPD nurse colleague has already done.



- Start preparing patient for discharge (to reduce education on discharge day). Focus on:
 - Medication list and inhaler technique
 - Pursed- lip breathing exercises
 - Pulmonary rehabilitation (if eligible)
 - Smoking cessation (if needed)- patient may need Nicotine replacement prescriptions
 - Transportation (if needed)- patient may need forms for public transportation filled out. COPD nurse to work with hospital staff for this .
 - Oxygen (if needed)be sure there is consideration for portable oxygen as well
- Communicate with the patient’s healthcare team as needed (hospital unit case managers/hospitalists (pager)/admitting physician/caring physician) to address any needs that may have surfaced while reviewing baseline assessment and talking to the patient.
- Ensure patient/caregiver understand the discharge plan



- Notify outpatient provider about patient's enrollment and let them know that you will route your note in Epic to them (or fax it to their office if they have no access to Epic)
- Discuss action plan: Educate the patient and family caregiver about early signs of COPD exacerbations that require them to seek medical opinion in 24 hours, as well as signs that the patient need to seek medical attention immediately. This education is summarized in the form of an action plan (with green, yellow, and red zones) that is provided in the patient binder. Ask patient to hang on their fridge for easy visibility. Review action plan with patient and caregiver and ask patient participants and their CGs to fill in the blanks with names and contact information.
- If primary nurse is seeing the patient on this visit, remind about post-discharge visit plan (Home/Telephone/Bayview Healthcare facility)



c. Pre-discharge visit:

The goals for pre-discharge visit are to:

- Check patient's demonstration on pursed lip breathing technique and inhaler use. (If not done at interim visit)
- Check whether patient and caregiver feel ready for discharge and address concerns
- Communicate with outpatient provider/s scheduled for post-discharge follow up and share your notes with them.
- Confirm post-discharge follow up plan with patient. Fill in medication list form. Ensure that they understand and agree to plan.
- Resolve any anticipated issues with transportation or patient ability to obtain/afford medications.
- Agree on follow up plan /post-discharge visits/ preferred communication /contact numbers etc.

d. Follow up home visits and/or phone calls:

The goals for follow-up home visits are to:

- Continue COPD self-management program. **Follow motivational interviewing principles and tools to achieve the following behavioral goals: Taking meds correctly; Staying active; Applying breathing techniques as needed; Avoiding irritants; Conserving energy/ pacing to manage daily activities. If patient is still a smoker, continue to help them**



advance on the 'readiness to quit ladder' towards successful smoking cessation.

- Reassess patient priorities at end of each visit and fill in on MY Roadmap form
- Review any patient or caregiver needs or concerns. Address barriers to care (e.g. transportation, help with oxygen supplies, etc...)
- Review medications, inhaler treatment, and action plan
- If patient on oxygen, check if they have portable oxygen devices that allow them to leave their home.
- Help patients prepare their questions/queries for their follow-up visit with pulmonologist and/or PCP.
- Work /coordinate to have joint conversations with the caregiver ; help patient and the caregiver work together to manage COPD

During these visits the COPD nurse will:

- Assess whether the caregiver is able to join in on any/each of the visits that the COPD nurse will hold with the patient. The COPD nurse will work with the patient and their caregiver- to the extent that the latter is capable of joining the patient-nurse conversation. **The nurse will aim to contact the CG via phone while the patient is still at the hospital and plan to meet them in person at least once early during the 3 months intervention period.**
- Discuss, educate and support patients so that at the end of the 3 months (with the help of their CGs) they may be able to meet the COPD Self-management Education Program Goals.
 1. Describe COPD, its causes, and treatment options.
 2. List 'things' that cause/exacerbate own symptoms of breathlessness.



3. Demonstrate appropriate use of their inhalers* (plus nebulizer and oxygen devices as applicable).
 4. Recognize signs and symptoms of an acute exacerbation and follow an action plan to seek treatment promptly. (Achievement of this goal will be assessed via teach back for signs and symptoms, reflection on their own most recent exacerbation and what contributed to its occurrence, and development and posting of an action plan at home.)
 5. Demonstrate ‘pursed lip’ and ‘belly’ breathing* and verbalize steps taken to cope with breathlessness and anxiety
 6. Follow a plan to gradually increase physical activity aiming to a target of 30 mins of activity three times per week, as tracked via a patient-kept log
 7. Describe what pulmonary rehabilitation programs involve and summarize how it may benefit COPD patients
 8. If smoker, stopped smoking (as measured by self-report) or is contemplating to stop (as measured by moving upwards on the readiness to quit ladder)
 9. Will be able to ask important questions for the medical providers during future visits (example: rescue medication, FEV1 etc.)
- Key support services that the COPD nurse will facilitate access to as applicable include :
 - transportation
 - medication cost coverage options
 - support groups and peer hotline
 - rehab programs
 - accessibility to medical providers and oxygen devices support
 - Mental health referrals



The COPD nurse may consult the BREATHE program local resource guide or Healthify for existing resources/services.

- To review medications:
 - a) The COPD nurse will ask patients/caregivers to bring out their current COPD treatment medications/ inhalers.
 - b) The nurse will then help the patient and caregiver fill out a record of those medications with simple instructions for reasons for taking each and how to take.
 - c) The nurse will also teach the patient how to use their inhalers, nebulizer machines, and oxygen supply devices as applicable.
 - d) The nurse will confirm patient comprehension and skills via use of 'Teach Back' and 'Show Me' techniques.

e. Final visit

The goals of the final visit are:

- Review of COPD self-management – 'putting it all together'
- Certificate of completion

During this visit the COPD nurse will:

- Assess patient's ability of self-management
- Hand over the certificate of completion to patient and caregiver
- Fill in respective end of program checklist in Recap.



Frequency of Outpatient Follow up Encounters

The table below shows the approximate schedule for post hospital discharge encounters with patients and caregivers. The exact timing of visits may vary based on patient/ caregiver availability and logistical issues. However, **the aim is to conduct a minimum number of 12 patient encounters over 3 months period with low activated patients and 6 encounters with highly activated patients.** This number may be increased or supplemental phone calls may be added as needed per COPD nurse, patient, or caregiver needs.

	MONTH 1				MONTH 2				MONTH 3			
	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
High PAM score	X	X		X		X			X			X
Low PAM score	X	X	X	X	X	X	X	X		X		X
	X*	X*		X*	X*							



All 'X's indicate in person visits unless indicated otherwise. X* indicate a telephone follow up call. The arrows indicate deferring telephone calls for 3 weeks ONLY IF they patient is also receiving Home Health services.



Describing COPD nurse role to patients

The COPD nurse is member of the healthcare team who will help them learn ways to cope with their COPD and breathe easier. The nurse will educate them about their discharge plan and work with them on specific areas that can help them to manage COPD after they leave the hospital.

The nurse will work with them and their caregiver to make sure they have the information and the confidence they need to take care of COPD symptoms and cope with those in a way that allows them to live better and have a good quality of life. The nurse will also help the patient and caregiver connect with any community services that they may need such as transportation. The nurse will provide them with her telephone number so they can call her with any questions or concerns. Nurse should also help patient/caregiver identify who to call after usual business hours.

Introducing BREATHE Program to Patients

- Greetings ... I am [name] the COPD nurse here to introduce myself to you. I will work with you and any family members that you may like to involve in your care. I have home health experience and training in COPD management.
- This is my colleague (photo)....., the other COPD nurse in the BREATHE program. I will be your “primary nurse” and she will be “covering” for me



when I am not on call in the hospital. Both of us will work with you as a team while you are in the hospital.

- I will work with you for 3 months after you leave the hospital so we make sure you have what you need to manage COPD at home.
- With your permission, I will also work with one of your family members (or your caregiver) and we can go over COPD information together so you're your caregiver feels they know enough to help you cope with COPD.
- We will discuss with both of you COPD, its treatment, breathing techniques that can help you breathe better. We will also talk about how to conserve your energy and pace yourself so that you do not run out of breath very fast. We will together go over educational materials that can help you cope with COPD.
- We can also work together on getting you to a slow and gradual start of gentle physical activity to help make you feel stronger over time. We can also talk about programs that are available for COPD patients like you in the community such as lung training programs if you would like.
- We can talk about anxiety symptoms that can come when someone is short of breathe and how to deal with those. We can also about several other topics based on what you think is important to you at this stage. (can show agenda setting form- MY Roadmap)
- If you have a problem, like if you have some type of service needs. Let's say some people might have issues with transportation, things like that, we will also help to connect you with community
- Before you leave the hospital and shortly after, we will go over your discharge plan and make sure to address any questions that you may have.
- I would visit you at home. If you are uncomfortable having somebody come visit your home, we can plan on talking on the phone or meeting at Bayview facility.
- Your binder with education materials and information about resources will be given to you to keep so that after the three months are over, you have all of this information at your fingertips.