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Structured COPD Discharge Education and Quality of Life: A Feasibility Evaluation

Patricia B. Conley, RN MSN PCCN

A dissertation submitted to the faculty of the Medical University of South Carolina in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the College of Nursing

November 2016

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## Acknowledgements

I would like to thank my committee members for their guidance, Dr. Teresa Kelechi, Dr. Lynne Nemeth, Dr. Martina Mueller, and Dr. Brian Mieczkowski for his pulmonary expertise. The knowledge and feedback I have received from your mentoring has been invaluable in the development of my dissertation, conducting the clinical study, and summarizing the results. This educational achievement is one of many stepping stones to my goal of becoming a clinical nurse scientist. I am also grateful to Katherine Bright and Erin Klintworth, whose support helped facilitate my study's submission through the institutional review board (IRB) process in being approved.

In addition, I want to thank Jackie DeSouza, Paige Baker, LaGayle Heflin, Tien Nguyen, Ruth Woronick, and all the staff on the Progressive Care Unit for their assistance in this study. I would like to express my appreciation to Jennifer Feeback and Sharon Stawinski from the Research Operating Committee for their work and support of my dissertation study.

To my son, Zachary for his avid support and constructive criticism which have always been a source of incredible wisdom to me in my research. For all those who supported my journey in becoming a bedside research scientist, including my sister, Mary. In honor of my parents, the late Edward and Annette Conley whose inspiration is best reflected by Louis Pasteur's quote, "*Science knows no country, because knowledge belongs to humanity, and is the torch that illuminates the world.*"

## Abstract

**Background:** Multiple internal and external factors are responsible for the development and progression of chronic obstructive pulmonary disease (COPD). Noxious stimuli such as cigarette smoking and other air borne pollutants set off the ongoing inflammatory process of COPD resulting in air flow limitation and lung tissue destruction.

**Objectives:** Examination of inflammatory mediators of COPD and risk factors that coincide with hospital admission for AECOPD. The aim of this dissertation was to conduct a feasibility study to implement an educational intervention for hospitalized patients and evaluate their quality of life (QOL), using the RE-AIM framework to evaluate outcomes.

**Design:** This dissertation includes three papers: a principle-based concept analysis on inflammatory mediators related to COPD, an integrative review of the psychometric instruments used to measure risk factors for hospitalization among patients with COPD, and a feasibility study using the American Lung Association's modified COPD Action Plan to instruct patients with COPD on identifying early signs of an exacerbation and when to seek medical care. In addition, quality of life perceptions were evaluated using the World Health Organization-BREF (WHOQOL-BREF) before hospital discharge and 30 days post discharge via phone call.

**Conclusions:** COPD is a complex chronic disease with an insidious onset by inflammatory mediator(s) or genetic origin. The episodic acute exacerbations of COPD (AECOPD) are responsible for high healthcare utilization and perceptions of low quality of life. The feasibility study results suggest implementation of the American Lung Association modified COPD Action Plan can be carried out as discharge instructions and

QOL evaluated using the WHOQOL-BREF questionnaire. Positive ratings and comments on the delivery and content of the COPD Action Plan were found in a small sample of participants who responded to follow up.

## Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most common chronic diseases in the United States (US) with approximately 13.6 million individuals diagnosed with COPD and an equal number undiagnosed (Healthy People 2020, 2012). The physical, psychological and economic burden of living with COPD negatively affects quality of life (QOL) of patients and their caregivers. COPD is the third leading cause of death in the US, and management of the disease remains suboptimal (National Institutes of Health, 2013).

Due to complex ongoing inflammation, COPD is a progressively deteriorating lung disease. Ongoing exposure to noxious sources of inhalational irritants from cigarette smoking, occupational exposures, and outdoor air pollution perpetuate an inflammatory cascade and ultimately lead to airway airflow limitation (Barnes, 2016). COPD is an insidious respiratory disease due to chronic and acute episodes of inflammation.

Acute exacerbation of COPD (AECOPD) is defined as acute flares of inflammation that frequently lead to hospitalization for patients with COPD. Risk factors involving hospitalization for patients with COPD include: comorbidities, past hospitalizations, low forced expiratory volume in one second ( $FEV_1$ ), socioeconomic status (urban and rural), physical functional ability (ambulating, bathing and dressing), psychological aspects of anxiety, and depression impacting QOL (American College of Chest Physicians, 2012; Conley & Gregoski, 2015). AECOPD is the third most common cause of hospital readmissions within 30 days post discharge. The incidence of recidivism is likely to occur in patients with comorbidities or those with more serious COPD disease (Panettieri, 2013).

For both patients and the health care system, there is tremendous financial responsibility, with an estimated \$50 billion spent annually in consumption of health care resources and other costs due to work absences (American College of Chest Physicians, 2014; Jalota & Jain, 2016; Jennings et al., 2014;). Complicating matters, approximately 20% of individuals discharged from US hospitals are readmitted within 30 days (Centers of Medicare and Medicaid, 2014), and Centers of Medicare and Medicaid (CMS) withhold compensation to hospitals for these readmissions, costing an average of \$130,000 to each US hospital. A more effective chronic care management process is critically needed by the US acute care system (Centers of Medicare and Medicaid, 2014; Polster, 2015).

This dissertation is composed of three papers that link the complex etiology of inflammation in COPD to the risk factors among individuals hospitalized with COPD and the need for an educational intervention. Potentially, an educational intervention could reduce morbidity and mortality and improve perceived QOL. The first paper is a principle-based concept analysis that examines inflammatory mediators involved in triggering the onset and chronic progression of inflammation in COPD. The paper highlights the risks of being exposed to external factors (indoor, outdoor pollution, and smoking) and internal factors (aspects related to the inflammatory process and genetics) responsible for COPD exacerbations (Barnes, 2016). This concept analysis of what causes inflammation in COPD by inflammatory mediators is a stepping stone to understanding the acute exacerbations of COPD (AECOPD). The paper has been accepted for publication.

The second paper, which has been published, is an integrative review of the risk factors associated with hospital admission related to COPD and highlighted the need to assess patients with COPD for the risk of readmission (Conley & Gregoski, 2015). Examining the best methods to measure risk factors for developing COPD complications leading to hospital readmission, as well as assessing for QOL perceptions of patients hospitalized with COPD, is essential to improving care and QOL for these patients. Therefore, it was determined that a concise instrument is needed to assess risk factors for hospital admission of patients with COPD (Conley & Gregoski, 2015; Kansagara et al., 2011).

The concept analysis of inflammatory mediators and integrative review of risk factors for hospitalization among patients with COPD served as groundwork for the dissertation study. Consequently, the third paper is from the dissertation study, which investigated an education model prior to discharge. The goal of this study was to educate hospitalized patients with COPD to recognize early changes in their condition. Accordingly, learning to identify changes at the onset, most times, signals the need to contact a medical provider or to seek more advanced medical care in order to prevent further morbidity and mortality of recurrent COPD acute exacerbations. The study evaluated the feasibility of implementing the American Lung Association (ALA) COPD Action Plan to provide an individualized, disease specific discharge education to patients with COPD and evaluate QOL using the World Health Organization-BREF (WHOQOL-BREF) (ALA, 2013; WHOQOL-BREF, 1997). Distinctly, the goal was to increase patients' knowledge of changes in respiratory symptoms and related effects of COPD and of when to seek prompt medical care. Such knowledge may decrease occurrences of

AECOPD and hospital admissions of patients with COPD, as well as improve QOL perceptions by participants (Choi, Chung, & Han, 2014; Mitchell et al., 2016).

A structured action plan, delivered individually, may help overcome obstacles to teaching patients with COPD, many of which are related to the diverse needs and backgrounds of patients, making it essential to deliver discharge instructions one-to-one, nurse to patient (Hanania, 2012; Sheppard et al., 2013, Polster, 2015). Also, it is common for patients with COPD to experience anxiety and depression related to breathlessness episodes and decreased functional abilities that impair perceptions of QOL (Coventry, Gemmell & Todd, 2011; Ries, 2006). As a result, the modified COPD Action Plan was selected because it is a concise format for educating patients on self-management and symptom control, and because it has an easy-to-understand format. The instructions are organized in color zones to illustrate how patients should self-assess how they feel, ranging from good day (green), bad day (yellow), and when there is an urgent need for medical care (red). Thus, the plan highlights the need to promptly act on changes in symptoms that signal the need to contact or seek professional health care (American Lung Association, 2013; Effing et al., 2012). Additionally, this plan is familiar to pulmonary medical providers due to the widespread use of these types of asthma action plans. Next, QOL before and after discharge from the hospital was measured with the WHOQOL-BREF. The WHOQOL-BREF was selected because it is a reliable and validated instrument with 26-items measuring physical, psychological, social, and environmental domains (Skevington, Lofty & O'Connell, 2004).

To measure feasibility of this discharge clinical procedure, the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework was

used to evaluate delivery of the action plan as a discharge teaching tool via the 30 day follow up phone call after discharge (Glasgow, Vogt & Boles, 1999). **Reach** included recruitment and retention of the sample population of participants with COPD hospitalized on a Progressive Care Unit (PCU). **Effectiveness** was measured by outcome of the participants' perception of benefit of the COPD Action Plan based on a 30 day follow up survey and qualitative results. PCU nurse completion of a questionnaire on perception of benefit involving the discharge intervention to participants with COPD was evaluated. The survey completed by a PCU nurse was used to evaluate acceptance and feasibility by the PCU nurse trained to instruct participants on the COPD Action Plan. **Adoption** was evaluated by PCU nursing staff (rated responses) and participants' perception of willingness to adopt the discharge clinical procedure (rated responses, 30 day outcomes of health care utilization and QOL outcomes). **Implementation** of the clinical procedure was appraised by consistency in delivery (fidelity) of the COPD discharge procedure assessed by observation and based on feedback from participants and the nurse's recommendations. **Maintenance** of the discharge procedure for patients with COPD (survey and qualitative results) to be used hospital-wide will be determined following completion of this study (Carnerio et al., 2010; Glasgow, Vogt & Boles, 1999).

Overall, the long term objective of this dissertation study was to, first, provide a specific strategy to address the educational needs of patients with COPD in the acute care setting and, second, identify issues of participants that are associated with their QOL (National Institute of Nursing Research, 2013; Scott, Baltzan, Dajczman, & Wolkove, 2011). Evidence suggests that reducing dyspnea or improving ways to cope with breathlessness, such as learning pursed lip breathing, improves QOL (Feldman, 2013).



Additionally, support networks by phone or online help patients cope with anxiety and depression. Future studies should address ways to teach patients to conserve their energy that could potentially improve perceived QOL related to impaired activity tolerance from dyspnea.

#### Research Question

What is the outcome of using the American Lung Association COPD Action Plan in terms of self-rated knowledge and assessment of QOL in a cohort of patients discharged from a Progressive Care Unit after hospitalization for an AECOPD or COPD?

#### Gaps in Knowledge

Based on a review of the literature, research evidence is limited regarding outcomes of specific patient education instruments delivered during hospitalization and evaluating QOL (Almago & Castro, 2013; Mularski et al., 2012). Compared to COPD action plans, action plans for asthma have been studied more extensively for their educational impact on respiratory symptoms and self-management outcomes. Jalota and Jain (2016) report that 400 asthma action plans have been investigated as to their effectiveness in teaching self-management of symptoms compared to 69 studies on COPD action plans. Their findings on asthma action plans indicated effectiveness in prevention of more severe asthma exacerbations. COPD action plans may be beneficial to patients in acquiring knowledge, increasing confidence in managing their lung disease, and making decisions when to contact health care providers.

Few studies have evaluated the most effective evidence-based action plans that teach specific self-management to guide discharge education for hospitalized patients with COPD. Further evidence is needed on outcomes of improved self-management,

such as through early recognition of symptoms, prompt medical care, reduced hospital readmissions, and improved perceived QOL post discharge (Bischoff et al., 2011; Effing et al., 2012; Jennings et al., 2014). Sunde et al. (2014) implemented a prospective clinical intervention study using a multidisciplinary COPD-Home model to teach individualized self-management skills and provide support from other health care professionals. Also, Sunde et al. (2014) described the outcome strengths of the model being integrated care and continuous reinforcement of self-management skills to improve COPD. Sunde and colleagues pointed out that evidence is needed to support effectiveness and impact on QOL (Sunde et al., 2014). Moreover, given obstacles to teaching patients with COPD, many of which are related to the diverse needs and backgrounds of patients, it is essential to deliver individually tailored discharge instructions (Hanania, 2012; Polster, 2015; Sheppard et al., 2013).

Using a COPD self-management education plan for outpatients in a prospective study, using a parallel group, by Labrecque et al. (2011) found a decrease in emergency department (ED) visits measuring participants per year ( $p = 0.002$ ). In addition, hospitalizations were reduced ( $p = 0.17$ ). Researchers attributed the nonsignificant result to the specific definition of ED visits being 24 hours or less, and improved health-related quality of life (HRQOL) in patients with COPD at 12 months ( $p < 0.001$ ). Scott and colleagues (2011) compared knowledge of COPD and information needs of outpatients and in hospital patients with COPD using two questionnaires. Reported results showed a positive correlation between prior COPD learning and high school education ( $p < 0.05$ ). Also, a positive correlation was found from prior COPD instructions and lower Lung Information Needs Questionnaire (LINQ) score ( $p < 0.01$ ) (Scott et al., 2011).

Researchers Choi, Chung, and Han (2014) conducted a cross-sectional descriptive study on outpatients in a COPD clinic and found adherence to an action plan reduced unplanned hospitalizations ( $p = 0.001$ ).

Trappenburg et al. (2011) conducted a multicenter randomized controlled trial on outpatients, to test the effectiveness of administering personalized COPD action plans to reduce exacerbation recovery time and every three days completed the Clinical COPD Questionnaire (CCQ) to measure health status. Their results based on the CCQ scores indicated above the minimal pertinent difference 0.4 points ( $p < 0.01$ ) (Trappenburg et al., 2011). Other researchers carried out a randomized controlled trial to assess the impact of a comprehensive intervention for patients with COPD discharged from the hospital (Ko et al., 2016). What the researchers found, based on the intervention group, was a reduction in hospitalization for AECOPD ( $p = 0.047$ ) and decreased length of stay (LOS) ( $p < 0.001$ ) (Ko et al., 2016). Ko et al. (2016) were not able to provide evidence as to what particular intervention was most effective.

Furthermore, Krishnan and researchers found that multidisciplinary educational action programs, not disease specific, included evaluation of QOL, physical exercise, and follow up phones calls to patients after discharge, decreased hospitalizations (Krishnan et al., 2015; Nelson & Pulley, 2015). In addition, findings were investigated from comprehensive discharge programs that *bundle* interventions (education, exercise, and follow up phone calls after discharge) such as Project Better Outcomes through Optimizing Safe Transitions (BOOST) for COPD patients. Results showed improved outcomes, fewer hospitalizations, and increased QOL. Mularski et al. (2012) examined comparative effectiveness research for patients with COPD. They called for collaboration

among researchers, clinicians, payers, and policymakers in broadening methodologies such as repeating performed effectiveness designs that examine longitudinally over time positive and negative outcomes, as well as expense (Mularski et al., 2012).

In summary, the findings point to a need for conformity of a statistically proven effective COPD discharge instructions delivered (either written, audiovisual, or electronic tablet-based) to improve self-management among patients with COPD (Choi et al., 2014, Mularski et al., 2012; Sawyer et al., 2016; Schafer et al., 2015). Future studies are needed that detail implementation, content of instructions, and are individualized based on assessment of prior participant knowledge of self-management and evaluation of QOL. (Effing et al., 2012).

#### Design and Method

The study took place on a 24-bed Progressive Care Unit (PCU) at an urban hospital. Descriptive statistics will report the demographic data and participant characteristics. The Wilcoxon signed-ranks test will be used to compare QOL domain scores of participants before hospital discharge and again from the 30 phone call reevaluation of QOL. Qualitative data was obtained from the participants during the 30 day call back which was pulled out from open ended comments. These comments were read and reviewed with my qualitative mentor and the prevailing themes were categorized.

#### Theoretical Framework

Socio-Ecological Model (SEM) was used to guide the paper involving risk factors for hospitalization of patients with COPD and development of the structured discharge educational protocol and QOL evaluation. Application of SEM for the feasibility study

was appropriate because it recognizes the interconnectedness in layers of influence for patients with COPD (Centers for Disease Control and Prevention, 2015). The framework consists of multiple levels of influence which include: the *individual*, their knowledge, motivation and skills; *interpersonal relationships* that consists of, family, friends and social network; *organizations*, involving environmental factors such as air pollutants indoors and outdoors, smoking first hand or second hand. In addition to *community resources composed* of connections and support between organizations in the community, and home. *Public policies* embody the laws to support and protect individuals and communities (CDC, 2015). The SEM provided a relevant framework to create an educational solution to instruct critically ill hospitalized patients with COPD on self-management skills to identify and manage respiratory symptoms as well as to evaluate their perceptions of QOL.

### Conclusion

This dissertation explored the concept of inflammation using a principle-based concept analysis to examine inflammatory mediators related to the onset of chronic and acute inflammation in COPD. The concept analysis of recent findings involving inflammatory mediators revealed that further investigation is needed, in order to clearly define the triggers to inflammation. Furthermore, research is essential to discover what preventive measures or pharmacological antagonists to inactivate the triggers involving inflammation in COPD.

The second paper describes the psychometric measurements that have been used to determine how best to identify and predict patients with COPD who are most at risk for AECOPD that results in hospitalization and rehospitalization, especially within 30

days following discharge for the same. Clearly, this integrative review illustrated how many studies used several instruments to assess risk factors for hospitalization among patients with COPD. Rational for using numerous measurements to determine risk factors for hospital admission was attributed to the multifactorial entity of COPD that includes severity of disease, psychosocial, and socioeconomic factors of each individual. Producing a valid and concise instrument to pin-point at risk patients with COPD for hospital admission in the critical care setting would be valuable.

Culmination of the principle-based concept analysis paper on inflammatory mediators in COPD and integrative review of risk factors for hospitalization for AECOPD among patients with COPD was the premise for the structured discharge feasibility study. This study was designed and conducted to examine delivery of the modified ALA COPD Action Plan, assess QOL using the WHOQOL-BREF, and evaluate outcomes using the RE-AIM Framework. Recruitment of the goal sample population was met, but possible barriers to retention of participants in the 30 day follow up that was low, which could be attributed to lack of compliance and socioeconomic barriers. Adoption was evaluated by the participant and one trained PCU nurse responses, which was limited due to the small follow-up sample (n =13).. The participants, who were reached via phone call on the 30 day follow-up, reported low healthcare utilization which may indicate gained knowledge of taking their prescribed respiratory medication and keeping scheduled appointments after hospital discharge. There was no difference in scores taken in hospital and 30 day follow-up by phone using the WHOQOL-BREF, calculated with the Wilcoxon signed-ranks test. The WHOQOL-BREF has documented reliability and validity, but for this critically ill patient population,

it was imperative for the PI to read and record the answers for the participants.

Implementation in the delivery of the COPD Action Plan to participants was feasible based on the response from the PCU nurse and the PI. Taking the strengths from the outcomes of this feasibility study, the PCU clinical manager approved use of the modified ALA COPD Action Plan as discharge instructions for patients with COPD.

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Manuscript I

Inflammatory Mechanisms Associated with COPD: A Principle-Based Concept  
Analysis

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Accepted for publication in *Nursing2016 Critical Care*

## **Abstract**

**Aim:** To report a principle-based concept analysis of inflammatory mediators related to chronic obstructive pulmonary disease (COPD).

**Background:** In patients with COPD, acute and chronic inflammation within the bronchi cause luminal narrowing from mucosal edema, smooth muscle contraction and mucus production that contributes to gas exchange impairment. Shortness of breath and limited exercise tolerance are common symptoms of COPD. The mediators that trigger acute inflammatory responses and perpetuate chronic inflammation in COPD have been investigated on a molecular, cellular, and global physiologic level. The exact mediators of inflammation have not been conclusively determined.

**Design:** Principle-based method of concept analysis.

**Methods:** Systematic review of the literature in 2015 using the MeSh words “pulmonary disease, chronic obstructive” AND MeSh words “inflammation mediators” in only English were searched in PubMed, CINAHL, Cochrane, Medline and Google Scholar.

**Results:** The concept of inflammation continues to evolve. There are now numerous inflammatory mediators linked to COPD. Four principles are used to conduct the concept analysis of inflammation in COPD: linguistic, logical, epistemological, and pragmatic. The final analysis retained 15 articles.

**Conclusions:** This paper provides insight regarding the concept of inflammation within COPD by developing epistemology on the exact factor(s) triggering inflammation. The global impact of this debilitating disease and high level of health care utilization calls for a collaboration among health care providers and researchers.

**Relevance:** Nursing has a pivotal role in caring for patients with COPD and conducting research on mediators of inflammation related to COPD. Further research is needed to discover definitively mediators that perpetuate of this serious lung disease in order to improve outcomes. Such outcomes would identify the prevention strategies and develop treatments that could better target the detrimental effects of this inflammation.

**Keywords:** COPD lung inflammation, pulmonary disease, chronic obstructive and inflammation, inflammatory mediators of COPD

## **Introduction**

Inflammation has a historical and scientific background related to lung inflammation which can best be understood using the lens of the principle-based concept analysis. A documented history identifies and describes inflammation dating as far back as 2000 years ago. Medzhitov, a professor of immunology, defined inflammation as a process triggered by tissue injury or infection, which elicits the recruitment of plasma proteins and leukocytes to the affected site.<sup>1</sup> Having knowledge of the phenomenon involving inflammation for nurses is necessary due to the impact on many aspects of providing care (teaching patients avoidance of precipitating factors), education (instructing patients on prescribed anti-inflammatory medications), and research (for evidence-based practice). Therefore, evidence-based knowledge, regarding causes related to the altered inflammatory process involving COPD that results in air flow limitation, is essential for health care professionals.<sup>2</sup> Understanding the science identifying the triggers of mechanisms causing inflammation associated with COPD can be translated to the importance of avoiding pollutants. Sources of pollutants can include: being a smoker or exposure to second hand cigarette smoke, occupational, indoor, or outdoor sources. Other sources encompass being in close proximity to industrial or high traffic areas, or during times there are high ozone alerts.<sup>1-3</sup>

The principle-based concept analysis is a blueprint to build on the clinical understanding of inflammation for the underpinning of professional nursing practice and other health care professionals. Penrod and Hupcey's four principles: epistemological, pragmatic, linguistic, and logical will be used to assess the level of maturity for the concept of inflammation.<sup>6</sup> While inflammation is on one hand

beneficial, as in the process of wound healing, it can be detrimental when it causes swelling in bronchial tubes making breathing and air exchange difficult.<sup>7</sup> Over time, chronic inflammation leads to destruction in the lung tissue results in COPD. In health care, timely and accurate identification of an acute exacerbation of COPD (AECOPD) involving an acute inflammatory response is critical. AECOPD occurrences causes more frequent coughing with many times increased production of sputum, worsening activity tolerance related to difficulty breathing, and further dyspnea (breathlessness) could ultimately result in respiratory failure (Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD)).<sup>8</sup> The seriousness of COPD is documented by the National Institutes of Health as being the third leading cause of death in the United States and the fourth leading cause of death globally.<sup>7,9-11</sup>

## **Background**

Inflammation has been poignantly referred to as the old flame, but without the actual fire. This means that inflammation can cause similar pain and discomfort as a burn, but not be caused by an actual burn from a fire. The term ‘edema’ carries over to today as being part of a common descriptive involving inflammation that began with Hippocrates in the 5<sup>th</sup> century BC, in which he described edema being part of the healing process following tissue injury.<sup>12</sup> During the 1<sup>st</sup> century, Celsus, a Roman encyclopedist, defined the four signs of inflammation with the terms: “*rubor, et tumor cum calore et dolore*” meaning redness and swelling with heat and pain (p. 958).<sup>13</sup> A fifth component was added by a Greek physician Galen, to the signs of inflammation, “*function laesa*” that described impaired function of an affected extremity (p. 104).<sup>14</sup> Elie Mechnikoff, a zoologist, discovered the outcome in “leukocyte recruitment and phagocytosis of

microorganisms involving human protection against inflammation, infection, and immunity” (p. 3257).<sup>15</sup> This finding propelled the understanding of inflammatory process for treatment.<sup>1,15</sup> Scott et al. pointed out that the definition of inflammation has dramatically changed since the origin of its use almost 2000 years ago.<sup>16</sup> Currently, the meaning of inflammation is determined by how it is assessed “clinically, microscopically at the cellular or molecular level” (p.248).<sup>16</sup>

Inflammation related to COPD is manifested in several forms. The onset of COPD is most commonly a progressive form that is insidious and continuous, as compared to the critical manifestation that occurs in acute exacerbations of COPD (AECOPD). The first form of inflammation contributes to the ongoing downward spiral of worsening restrictive air flow condition in the lungs. In the acute form, the impact to the pulmonary system is so severe that most patients do not fully recover. The concept of inflammation is knowingly linked to physiological mediators responsible for COPD, but they are still not completely understood. There is heterogeneity in the scientific evidence for mediators as the culprit for the abnormal inflammatory pathophysiology in COPD.<sup>17</sup>

### **Data sources**

A review of the literature was performed to carry out the principle-based concept analysis of inflammation which produced information on the scientific findings pertaining to mediators for inflammation in patients with COPD. Multiple data base search engines were used to obtain articles related to inflammatory mediators in COPD. PubMed, CINAHL, Google Scholar, Cochrane via EBSCO interface, and Medline via EBSCO interface was searched using the following MeSH terms: “pulmonary disease, chronic obstructive” AND MeSH terms “Inflammation-Mediators.” Inclusion criteria



and results from each data base: adults, adults with COPD, mouse models examining causes of inflammation related to COPD. Exclusion criteria included pediatric studies and those delivering treatments or interventions for lung inflammation.

A systematic review was conducted to obtain studies for use in the principle-based concept analysis which included 15 articles in the final data set. Abstracts were reviewed and study types ranged from those having adult humans and mouse models.

### **Antecedents**

A concept analysis of inflammation requires an understanding involving the antecedents of inflammation. Antecedents of inflammation in COPD involve a precursor or stimulus from which an individual is exposed to such as cigarette smoke first hand, second hand, or some type of air pollution. The stimulus in most cases is the trigger for mediators that set into motion the detrimental inflammatory activity, described by the Latin term “*inflammare* (to set on fire)” the Latin term.<sup>16</sup>

### **Attributes**

The characteristic attributes of inflammation include: redness, warmth, swelling, pain, and limited function.<sup>18</sup> For COPD, chronic inflammation is attributable to breathlessness especially on exertion and poor activity tolerance. In an AECOPD, an individual can exhibit some of the following clinical signs and symptoms of increased difficulty breathing (dyspnea) or breathlessness, increased frequency of cough, productive cough with colored sputum (yellow, green or sometimes blood tinged).<sup>7</sup> Moreover, building on the historical roots of inflammation, its antecedents as well as the attributes, we gain an understanding when conducting an assessment of a patient’s respiratory function. Classification of

airflow limitation in COPD individuals is measured by spirometry that calculates the volume of air an individual can exhale from their lungs following a maximum inspiration.<sup>8</sup> The Global Initiative for COPD established the measurement of forced expiratory volume in one second (FEV<sub>1</sub>) being less than 70% as a marker of COPD.<sup>8</sup> Table 1.

### **Linguistic principle**

To fulfill the linguistic principle, a concept needs to have consistency in its use and meaning.<sup>6</sup> Therefore, from the analysis of the linguistic principle the meaning of inflammation found in COPD is used consistently throughout the literature, in that it results in air flow limitation.<sup>19</sup> Scientific evidence is not uniform surrounding the physiological process of mediators attributable to the dysfunctional inflammatory process in COPD. Irregularity exists in the evidence on mediators of how they cause acute exacerbations of COPD and the chronic progression of the disease, is still being investigated. Table 2. The literature reflects how empirical measurements have evolved in an effort to establish uniformity in quantifying the symptoms that are a consequence of inflammation. Calculating the degree of severity involving airflow limitation, as described by GOLD, is an indirect quantitative measurement that reflects the effects of inflammation. GOLD employs a classification of COPD severity ranging from mild to severe. Mild COPD is classified as forced expiratory volume in one second (FEV<sub>1</sub>) “post-bronchodilator use  $\geq$  80% predicted to severe FEV<sub>1</sub>  $<$ 30% predicted” (p. 9).<sup>8</sup>

Use of a standardized instrument that has a scale with clinical descriptions to quantify clinical features of patients having respiratory difficulty would promote distinctions in severity of respiratory distress. Such a standardized instrument to assess a

patient in the acute and critical care setting would be valuable. Being able to rate the severity of dyspnea could add to the objectivity of a respiratory assessment of patients with COPD, especially for patients who are unable to describe their symptoms due to altered cognition or effects of hypoxia or hypercapnia.<sup>20</sup>

### **Logical principle**

A concept is logical if it maintains its framework within the limits of theory application.<sup>6</sup> Sources in the literature cited external inflammatory factors from cigarette smoking to ozone levels. What the literature confirmed to be uncertain was that various precipitating pathophysiological sources elicit a variety of identified mediators. Some mechanisms identified to be accountable for inflammation in COPD include the alteration in Sirtuin1 Protein Coding gene in the circadian molecular clock rhythm of cigarette smokers.<sup>21</sup> Other researchers found proteases in agricultural dust from enclosed animal feeding sites and household mite dust to be mediators.<sup>4</sup> Consistently, the literature cited external inflammatory factors being predominately cigarette smoking as the most common noxious stimuli eliciting cellular and molecular mechanisms responsible for inflammation found in COPD.<sup>22-24</sup> Barouchos et al found tumor markers were related to inflammation of COPD and the degree of disease severity.<sup>25</sup> Haw and colleagues reported from their research an increase in tumor necrosis factor-related cell self-destruction (apoptosis) induced ligand (TRIAL), a cytokine to be the key in the abnormal inflammatory pathology in COPD.<sup>26</sup> Other researchers found exposure to cigarette smoking resulted in an abnormal reaction of causing an increase in Tc17 cells which scientists related to inflammation related to COPD.<sup>27</sup>

Another study identified pathogenic microorganisms in sputum to be linked to inflammation in COPD.<sup>5,28</sup> Increased levels of pigment epithelium-derived factor (PEDF) correlated with inflammation involved in COPD and decreased FEV<sub>1</sub>.<sup>29</sup> Other studies revealed the amount of progranulin in sputum, the loss of glycerol dehydratase-positive *Lactobacillus*, and nuclear factor kappaB as factors related to lung inflammation in COPD.<sup>30-32</sup> In addition, it has been found that precipitating sources such as ozone air pollution elicits a variety of identified mediators that can cause an alteration in circadian rhythm. This disruption in the circadian rhythm was found by researchers which resulted in a cascade reaction from pro-inflammatory mediators causing inflammation in COPD.<sup>3</sup> Therefore, identification of which specific mediators of inflammation are responsible and how the process becomes ongoing and acute in COPD would help enable development of more effective treatment.<sup>8,33</sup>

In particular, critically ill hospitalized adults with COPD are a vulnerable population who depend largely on the nurse and medical staff when it comes to identification on potential causes of an ECOPD. Causes of ECOPD can range from infection, an external source (smoke or air pollution) in the environment, or an acute progression of the disease. No theoretical framework specific to mediators signaling inflammation causing COPD was found in the literature. Theories that are available focus on the care of symptoms and functional disability subsequent to COPD. Coleman et al. addressed the use of the Chronic Care Model with its aim to improve patient to physician and nurse relationship for better patient outcomes.<sup>34</sup> Nursing's essential role in care of these patients encompasses carrying out interventions, education, and reassessment of outcomes. These aspects are important in order to promote health

through prevention (avoidance of noxious airborne pollutants), recovery when there are exacerbations, and to help reduce severity of ECOPD as well as further decline in their pulmonary status.

### **Epistemological principle**

A concept that has a sound epistemological principle is clearly defined and discernible from other concepts.<sup>6</sup> Inflammation, as a concept related to COPD, is defined as chronic inflammation of airways and lung tissue that alters gas exchange.<sup>35</sup> Characteristic clinical features that can be indirectly measured and described, including dyspnea, cough, and limited activity tolerance. The degree of COPD severity can be graded as established in guidelines by GOLD.<sup>8</sup> Clinical features such as air flow limitation that define COPD are also shared by other pulmonary diseases. Air flow limitation is also present in asthma, cystic fibrosis, and constrictive bronchiolitis.<sup>36</sup> The mediator(s) that is responsible for air flow limitation among these pulmonary diseases is what is different. Distinctly, impaired air flow limitation creates shortness of breath and decreased activity tolerance.<sup>37</sup> In COPD, there is no definite set of mediator(s) that can be pinpointed as being attributable to the abnormal inflammatory process.

Shortness of breath also referred to as difficulty breathing or breathlessness is common attribute of COPD. Some patients describe these acute episodes of shortness of breath as near death experiences.<sup>38</sup> Others have made an effort to quantify the degree of shortness of breath. One instrument that patients can rate their level of shortness of breath is the Borg scale that gives patients a range of 0 to 10, with 0 being no effort in breathing and 10 maximal feeling of difficulty breathing.<sup>17</sup>

Impaired functional endurance in patients with COPD is another predominate clinical attribute. Decreased activity tolerance impacts individuals with COPD in their ability to ambulate, do grocery shopping, and as the disease progresses getting to the bathroom or kitchen become a major hurdle. Two measurements of shortness of breath include the Borg visual analog scale that scores level of dyspnea from 0 (none) to 10 (severe).<sup>39</sup> Another instrument to measure activity tolerance includes body mass index, degree of air flow obstruction and dyspnea, and exercise capacity index (BODE).<sup>40</sup>

### **Pragmatic principle**

The concept needs to be relevant in the realm of scientific inquiry in order to fulfill the criteria for the pragmatic principle.<sup>6</sup> Here the concept of inflammation is known to be a process that occurs as a result of infection, tissue injury from various airborne noxious stimuli, or para-inflammation that is likely responsible for autoinflammatory diseases.<sup>1</sup> Most currently cellular and molecular mediators are being found as the culprit of inflammation found in COPD. In the disease process of COPD, inflammation is defined for what it is; abnormal and chronic, with acute episodes involving the peripheral airways and lung parenchyma.<sup>19</sup> Additionally, to fulfill the pragmatic principle, a concept must be well-operationalized, in that it can be measured. Therefore, to examine the consequences of inflammation involving COPD, indirect measurements can be obtained by using the following parameters: results of arterial blood gases, pulse oximeter readings, observational assessment for degree of respiratory distress, activity tolerance, and level of consciousness. Inflammation in COPD is not completely a mature concept since at this time the responsible mediators that trigger the inflammatory

process are not all completely understood. Also, there are a lack of universal standards to measure inflammatory mediators, based on the evidence found in the literature.

## **Results**

This paper uncovers the gap of what mechanisms are responsible for the chronic and acute inflammatory process related to COPD. Oh and Sin proposed that phenotyping patients with COPD could help target which specific mechanisms are linked to an individual's cause of inflammation.<sup>19</sup> Despite a multitude of different mediators reported in the studies, the findings are not conclusive. The implications of external, internal factors along with genetic implications play a role in mediators that malfunction causing airway inflammation in COPD. Therefore, gaining knowledge of the mechanisms for the inflammation process gives a deeper foundation to the concept of inflammation. Nurse research scientists have a pivotal role in collaborating with other researchers in the discovery of mechanisms in COPD inflammation, as well as treatment modalities.<sup>41</sup> It is important to recognize that the analysis of inflammation is fluid, since science is a dynamic process with new discoveries in pathogenesis that can improve assessment and treatment modalities for those with COPD.

## **Conclusion**

The principle-based concept analysis provided a rigorous process to examine the principles that comprise the concept of inflammation. No consistent theoretical definition was found for mediators responsible for the abnormal inflammation in COPD. Each principle was examined based on the empirical data found in the literature illustrating the heterogeneous nature of mediators connected to the altered pathophysiology of inflammation among patients with COPD. Emphasis on further scientific research is

needed by nurses, physicians, respiratory therapists, and bench scientists to work together in phenotyping individuals with COPD in order to identify the specific mediator(s) eliciting and perpetuating the destructive inflammatory process. In the future, phenotyping could be linked to treatments aimed at specific identified mediators which could be more effective in slowing the chronic inflammation in COPD and helping to prevent AECOPD occurrences.

### **Relevance to clinical practice**

- Identification of the attributes, antecedents, and outcomes of inflammation in COPD is essential to the clinical practice of nurses caring for these patients. The principle-based concept analysis of inflammation, as evidenced by various mediators, is the foundation of further research.
- A historical and scientific background provides a comprehensive framework to problem solving of this debilitating lung disease that is an international health burden. Nurses working together with other health care disciplines and scientists have the potential to improve health care delivery and quality of life for individuals with COPD.



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**Table 1. Inflammation in COPD: Conceptual Components**

Antecedents	Attributes	Consequences
<p>Abnormal inflammation in COPD result of various causes: noxious stimuli such as air pollution (outdoor, indoor, and occupational), cigarette smoke, and <math>\alpha_1</math> antitrypsin deficiency (an inherited disorder).</p> <p>Noxious stimuli or genetic disorder that trigger inflammatory mediators in lung tissue resulting in COPD.</p> <p>Exacerbations of COPD from bacterial, viral infections, or airborne pollutants.</p>	<p>Airway inflammation that is chronic and contributes to the progressive decline of lung function.</p> <p>Acute ECOPD episodes signals a worsening of the disease progression.</p> <p>Cough with or without sputum, dyspnea, and impaired exercise tolerance.</p> <p>Phenotypes of COPD: mixed COPD-asthma, emphysema-hyperinflation, and chronic bronchitis.</p>	<p>Acute exacerbation of COPD: acute impaired gas exchange (hypoxia and/or hypercapnia), respiratory failure, need for supplemental oxygen delivery, ventilator assistance (mechanical ventilation or bi-level positive airway pressure (BiPAP)).</p> <p>Anxiety and depression contributes to perceived impaired quality of life Increase in morbidity and mortality.</p> <p>Social and financial burden to the healthcare system in the United States and globally.</p>

**Table 2. Observation Instrument to Assess Dyspnea - Respiratory Failure<sup>20</sup>**

Mild Shortness of Breath	Moderate Dyspnea	Severe Dyspnea	Respiratory Failure
Respiratory rate 22-26/minute	Respiratory rate 28-32/minute  Slight labored respirations  Retractions (chest)	Fearful Facial expression  Respiratory rate 33 to >/min  Labored respirations/Nasal flaring  Diaphoretic	Respirations: severe labored, grunting or apneic periods  Cyanotic: lips, nail beds, mucus membranes
Severity Score = 1	Severity Score = 2	Severity Score = 3	Severity Score = 4



Manuscript II

An Integrative Review: Psychometrically Tested Instruments of Risk Factors Predicting  
Hospitalization Involving Adults with Chronic Obstructive Pulmonary Disease

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## Instruments Measuring Risk Factors Predicting Hospitalization for Chronic Obstructive Pulmonary Disease: An Integrative Review

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Received: 10-15-2013

Accepted: 10-30-2013

Published: 12-08-2013

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### Abstract

#### Introduction

The purpose of this paper is to determine which psychometric instruments have been used to identify risk factors to predict hospitalizations in patients with chronic obstructive pulmonary disease (COPD).

#### Methods

An integrative literature review was conducted on published studies carried out in the United States (US) and internationally, measuring risk factors related to hospital admission and readmission for COPD from 2002 to 2015. An extensive search was done using electronic databases PubMed, CINAHL, MEDLINE, and Google Scholar to find studies published in English, adults 18 years and older. Systematic manual searches produced additional empirical studies.

#### Results

Of the 29 studies screened from electronic data bases the literature search (n = 6) and systematic manual searches (n = 9) met the criteria. The outcome yielded (n = 15) articles that met the criteria, reflecting heterogeneity in types of measurements involving clinical data, psychosocial, and socioeconomic variables in the final data set.

#### Conclusions

This integrative review found a multitude of psychometric instruments for assessing risk factors for COPD admission, which highlights the need for a comprehensive and concise instrument to identify patients at risk for future hospital admissions in the acute care setting. Due to a limited number of studies examining risk factors related to COPD admission, the literature search span was conducted from 2002 to 2015.

**Keywords:** COPD; Admission; Risk Assessment; St. George's Respiratory Questionnaire; Quality of Life

## Introduction

When a patient with COPD comes to the emergency department (ED) for treatment, a tenuous balance exists in deciding, in less critical exacerbations of COPD (ECOPD), whether or not to admit the patient? Starting 2015 new regulations stipulating what is paid from healthcare funds has increased the need for better predictors for hospitalization [1]. Medicare and Medicaid Services define a hospital readmission as an admission within 30 days for the same diagnosis [2]. Based on new regulations by the Centers for Medicare and Medicaid, (section 3025 of the Affordable Care Act, section 1886q) individuals who are readmitted to the hospital for an acute exacerbated COPD, the hospital will not be paid or not paid in full for that hospitalization [2]. Medicaid and Medicare are government-sponsored healthcare programs in the United States (US) with stipulations on payment which includes who is covered and how much will be paid for in health services [2]. Adding to this dilemma, published studies on measurements to identify risk factors related to hospitalization for individuals with COPD, reveal there is no consensus on what measurement instruments best predict hospitalization [3-6].

## The Study Design

The aim of this integrative review of the literature is to present findings from studies using instruments to determine risk factors predicting hospitalization among patients with COPD. COPD is a disease with worse implications among individuals of urban, low socioeconomic status. These vulnerable individuals are more likely to have high risk factors with frequent hospitalization or readmission for the same previous diagnosis of COPD [4, 7, 8]. Risk factors can be measured and can predict the likelihood of patients with COPD being hospitalized or readmitted (either of these being the result) for treatment of their COPD. For this integrative review a *theoretical definition of risk factors for hospitalization of patients with COPD will include identified variables that are related to physical, functional, psychological, and socioeconomic status. An operational definition of risk factors for hospitalization for patients with COPD having dyspnea and hypoxia, can be obtained by collecting data using scales that determine most causative risk factors related to patients with COPD hospitalizations.*

## Search Method

Due to a limited number of studies examining psychometric measures of risk factors related to COPD admission, the literature search span was conducted from 2002 to 2015. Two search strategies were conducted to identify articles describing instruments that measure risk factors for hospital admission and readmission to the hospital for COPD or exacerbated COPD treatment. Inclusion criteria: human, English, adults 18 year of age and older; risk factors for COPD admission. Exclusion criteria: studies that used an intervention and those using a machine-learning method such as Random Forest (due to

lack of external cross-validation). The first search from 2002 to 2014 used MEDLINE, CINAHL, PubMed and the Cochrane Library. The search terms used for each database included MEDLINE: confounding variables (epidemiology), pulmonary disease, chronic obstructive, risk assessment, hospitalization, inpatients; patient discharge; risk factors; epidemiologic measurements; CINAHL: research instruments, pulmonary disease, chronic obstructive independent variable, risk assessment, hospitalization, inpatients, patient discharge education; PubMed: hospital predictors, chronic pulmonary disease, COPD, hospitalization, unplanned readmission, risk of admission, readmission; MeSH terms: hospitals; hospital; predictors; pulmonary disease, chronic obstructive, and the Cochrane Library: risk factors; predictors; chronic obstructive pulmonary disease; hospitalization; instruments to measure. MEDLINE: risk assessment, pulmonary disease, chronic obstructive produced 716 articles. CINAHL: risk assessment, pulmonary disease, chronic obstructive found 144 articles. PubMed: pulmonary disease, chronic obstructive MeSH and risk factors MeSH found 23 articles. From these searches, a total of 883 articles, 6 articles were obtained that met the inclusion criteria for adults 18 years and older; having COPD, male or female, and studies published in the US or other countries available in the English language.

A second search strategy was conducted using the same inclusion criteria to increase the number of studies measuring risk factors; hospital admission and readmission to the hospital for COPD treatment using MEDLINE, CINAHL, PubMed, Cochrane, and Google Scholar. Google Scholar searched with phrase: "COPD predictive instrument for hospital admission" and the phrase "St. George's Respiratory Questionnaire to measure risk factor COPD and hospitalization" between 2002 to 2015 articles. A total of 13,283 articles were obtained and screened. Articles were selected if they met the inclusion criteria for adults 18 years and older; having COPD, male or female, hospital admission for COPD, risk factors predictive of hospital admission, and studies published in the US or other countries available in the English language. Sixty-seven pages were screened and 8 articles were obtained from hand searches of the retrieved Google references. In addition, one article met criteria from MEDLINE.

## Search Outcome

In total, 15 studies were included from the search strategy that met the inclusion criteria. The select sample of studies were from the following countries: Canada, India, Portugal, Scotland, Singapore, Spain, United Kingdom (UK), and the United States (US). Type of studies included: prospective (n=11), case control (n=1), observation (n=1), longitudinal (n=1), and historical cohort (n=1). Quality appraisal used The Center for Evidence-Based Medicine Levels of Evidence to evaluate and rate the level of evidence for each study [9]. Table 1.



Table 1. Instruments to Determine Risk Factors for Hospital Admission among Patients with COPD

Instrument/references	Research subjects/Theoretical framework	Description	Method of Measure	Validity/Reliability	Findings/Level of evidence
1  [10].	<p>Patients with COPD from an outpatient clinic at a single university-affiliated hospital.</p> <p>N = 127</p> <p>Mean age +/- SD: 70.9 years +/- 8.3</p> <p>Male/Female 116/11</p> <p>Exacerbation of COPD (ECOPD) defined as dyspnea, sputum production, or sputum purulence.</p> <p>Theoretical Framework not mentioned</p>	<p>Historical cohort study</p> <p>BODE Index 9 was calculated for all patients during the 4 week enrollment period.</p> <p>GOLD scale: Four stages of COPD severity compared to BODE Index scores.</p>	<p>Outcome measure- number of hospital admission for COPD during the follow-up.</p>	<p>Poisson regression model used to quantify and compare the relationship between FEV<sub>1</sub> and BODE scores with number of hospital admissions.</p> <p>BODE score significant effect on number of hospital admissions:</p> <p>Incidence rate ratio 1.20; 95% confidence interval 1.15 to 1.25;</p> <p>p &lt; 0.001; FEV<sub>1</sub> % of predicted on number of hospital admissions (incidence rate ratio, 0.08, 95% CI, 0.04 to 0.16); p &lt; 0.001.</p>	<p>Findings from a follow-up of 16.2 months (mean): 47% of patients had one hospital admissions and 17% died (result of respiratory failure). BODE Index better predictor of COPD hospitalization than FEV<sub>1</sub> alone. BODE Index better predictor for hospital admission (pseudo r<sup>2</sup> was 0.16) than GOLD staging of COPD severity.</p> <p>Levels of evidence: 2b</p>

<p>2</p> <p>Standardized data collection instrument for predictors of hospital admission for ECOPD. Tools: GOLD, Glasgow Coma Scale (GCS) and Charlson Comorbidity Index (CCI).</p> <p>[4].</p>	<p>16 public health: emergency departments (ED).</p> <p>N = 2,487</p> <p>72.8 mean age, 91% males</p> <p>1,537 (61.8%) were admitted to the hospital and 950 (38.2%) were discharged.</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective multicenter cohort study</p> <p>Standardized data collection: demographic items, assessed compliance to prescribed treatments, level of consciousness per GCS 15 and no less, paradoxical breathing and/or resting dyspnea, use of accessory muscles, lower extremity edema, respiratory rate, blood pressure, heart rate, oximetry and/or arterial blood gases.</p> <p>Interview 7 days post-discharge and for patients admitted to the hospital; interview before discharge to assess: level of support at home, assistance with self-care, severity of dyspnea, physical activity, baseline treatment, comorbidities using CCI, and number of hospital admissions for ECOPD the previous year.</p>	<p>Data from standardized data instrument predictive of hospital admission as compared to GOLD guidelines.</p> <p>Compare results of the standardized data collection tool to GOLD recommendations.</p>	<p>Multivariate analysis of factors predictive of ECOPD hospital admission.</p> <p>The predictive capacity for the model: Area under the curve 0.89 and 0.83.</p> <p>Previous hospital admission for ECOPD (OR 2.03, 95% CI 1.32 - 3.11); resting dyspnea (OR 3.05, 95% CI 2.39 - 3.88); altered PaCO<sub>2</sub> &gt; 65mmHg (OR 6.90, 95% CI 4.03 - 12.09).</p> <p>Goodness of fit for the tool at ED arrival and decision time achieved p values 0.66 and 0.10 in the Hosmer Lemeshow test, respectively.</p>	<p>Results for factors most predictive of hospital admission: 3 or more hospitalizations for ECOPD in last year, resting dyspnea, altered dyspnea, partial arterial carbon dioxide pressure (PaCO<sub>2</sub>) at time of ED arrival.</p> <p>Results of standardized data instrument indicated agreement in part with GOLD recommendations.</p> <p>Levels of evidence: 1b</p>
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<p>3</p> <p>Evaluation of COPD longitudinally to identify predictive surrogate endpoints (ECLIPSE), St. George's Respiratory Questionnaire (SGRQ-C), and GOLD.</p> <p>[11]</p>	<p>Adults: 40 - 75 years of age</p> <p>N = 2,138 in cohort</p> <p>Female % = 35%</p> <p>Male % = 65%</p> <p>Theoretical Framework not mentioned</p>	<p>Longitudinal evaluation: follow up at 3 months, 6 months, and every 6 months after, for a sum of 3 years, to predict surrogate endpoints.</p> <p>Examined time to first incidence of hospital admission.</p>	<p>Kaplan-Meier curves and Cox proportional hazard regression adjusted for confounders. ECLIPSE, SGRQ-C, and GOLD results.</p>	<p>Summary of rate per person per year (PPPY).</p> <p>Hazard ratio 2.71, 95% CI, 2.24 – 3.29, <math>p &lt; .001</math> for highest risk: previous hospitalizations for exacerbations,</p> <p>Hypercapnia <math>p &lt; 0.1</math>, CI 0.84- 5.63, poor quality of life <math>p &lt; 0.05</math>, CI 1.03-5.41. Hosmer-Lemeshow Goodness of fit test model well calibrated <math>p &lt; 0.85</math>.</p>	<p>Total 1,452 hospitalizations for ECOPD.</p> <p>Highest risk for admission: previous hospitalization for exacerbation of COPD. Moderate risk: severe airflow limitation, older age, poor general health, severity of emphysema, and leukocytosis.</p> <p>Levels of evidence: 1b</p>
<p>4</p> <p>Baseline clinical data, SGRQ, Hospital Anxiety and Depression Scale (HADS), CCI, Carstairs index (socioeconomic deprivation), and social support measured with self-report instrument, Enhancing Recovery in Coronary Heart Disease (ENRICHD) Social Support Inventory (ESSI).</p> <p>[7]</p>	<p>Adults COPD patients admitted for AECOPD to one of 3 acute hospitals UK referred to nurse led Early Discharge Services (EDS)</p> <p>N = 79</p> <p>Age = 65.3 +/- 9.9</p> <p>Male % = 44(56)</p> <p>Female % = 35 (44)</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective cohort</p> <p>Impact of psychosocial risk factors for readmission followed by EDS after AECOPD and follow up one year after</p>	<p>Physiologic risk factors: baseline 3 and 12 months. Lung function (FEV<sub>1</sub>), comorbidities, incidence of previous hospital admissions, medications, sociodemographics, SGRQ), HADS, Carstairs index (low social class, lack of car, unemployment, and overcrowding), and social support with ESSI.</p>	<p>Univariate logistic regression analysis of baseline psychosocial factors (SGRQ, HADS anxiety, ESSI, and Carstairs). Age, lung function, and greater proportion with readmissions (compared to those not readmitted) revealed significance <math>p &lt; 0.05</math>.</p> <p>Cox regression using FEV<sub>1</sub> % adjusted for age and sex as predictor for AECOPD, alone was significant predictor of time to readmission or death (hazard ratio 0.97, 95% confidence interval 0.95 to 0.99, <math>p = 0.003</math>).</p>	<p>Age, lung function, and previous hospital admission strongest predictors of readmission for AECOPD. Researchers noted that the HADS does not measure for panic attacks which is a documented experience of many COPD patients.</p> <p>Levels of evidence: 3a</p>

<p>S</p> <p>SGRQ, demographic data, socioeconomic data, and nutritional parameters. State-trait anxiety inventory (STAI-5/T).</p> <p>[13]</p>	<p>Adults with moderate to severe COPD (FEV<sub>1</sub>/FVC &lt;/ 70, FEV<sub>1</sub> &lt;/ 50%) with high consumption (HC) of health care services; emergency care and hospital admission</p> <p>N = 32 cases, age 72 years +/- 7</p> <p>N = 32 control, age 71 years +/- 9</p> <p>N = 64</p> <p>All males, mean 72 years of age</p> <p>Theoretical Framework not mentioned</p>	<p>Case-control</p> <p>Cases with COPD-HC of health care services required in one year was defined as: 1) 2 or more hospitalizations, 2) 3 or more emergency visits, or 3) one admission and 2 emergency visits</p>	<p>Demographic data: distance from hospital (kilometers)</p> <p>Clinical data: respiratory symptoms, comorbidities, and any complications related to COPD. Dyspnea assessed by Mahler's baseline dyspnea index (BDI)</p> <p>Socioeconomic data: 1) low socioeconomic index and limited education &lt; 10 years, 2) intermediate socioeconomic level, 3) high socioeconomic &gt; 14 years education, medium to high income (Prescott, et al, 1999).</p> <p>Anxiety, health-related quality of life scored with SGRQ, nutritional parameters</p> <p>Therapeutic aspects: forced spirometry, resting arterial blood gases, maximal respiratory muscle pressures, and 6-min walking test.</p>	<p>Logical regression</p> <p>Fisher t-test to compare means after conducting Kolmogorov-Smirnov test. Statistically significant difference of variables in groups, Pearson correlation (r) of quantitative data and Spearman correlation (r<sub>s</sub>) on qualitative data.</p> <p>SQRQ scores: symptoms and impact, p &lt; 0.01 and activity p &lt; 0.05</p> <p>Inhaled salmeterol multiplied risk of having COPD-HC 27.4 (95% CI 2.4 – 308.1).</p>	<p>Independent predictors of high incidence for hospital services (emergency care and admissions): treatment with salmeterol, presence of cardiac arrhythmias, and impaired health-related quality of life (increased SGRQ) scores.</p> <p>Levels of evidence: 3a</p>
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<p>6</p> <p>Data for this study partly obtained from National Emphysema Treatment Trial (NETT) a randomized controlled trial of volume reduction surgery vs continued medical treatment conducted among 17 clinics throughout the US (1998 to 2002). Tools: shortness of breath questionnaire (SOBQ), SGRQ, and 6-minute walk.</p> <p>(Fan, Ramsey, Make, &amp; Martinez, 2007)</p> <p>United States</p>	<p>Adults with emphysema, severe air flow limitation (<math>FEV_1 &lt; / 45\%</math> predicated) and had finished 6 to 10 weeks of pulmonary rehab program prior to randomization.</p> <p>N = 1, 218</p> <p>N = 614, randomized to medical therapy</p> <p>Mean age 66.5 years, 64% males.</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective cohort</p> <p>Subjects had emphysema with severe airflow limitation (<math>FEV_1 &lt; / 45\%</math> predicted).</p>	<p>Demographics, BMI, pulmonary function, arterial blood gases, x-ray results, dyspnea SOBQ, SGRQ, 6 minute walk, exercise capacity, medication use, history of exacerbations, and comorbidity.</p>	<p>Multivariable logistic regression to estimate risk of E COPD</p> <p>Compared predictive models used AUC and associated standard error and 95% CI were compared.</p> <p>AUC in original dataset: 0.70 vs 0.59. <math>p = 0.0001</math></p> <p>Control group had statistically higher mean <math>PaCO_2</math> [45.1 +/- 7.7 vs 49.6 +/- 7.8 mmHg, <math>p = 0.03</math>].</p>	<p>Predictive ability in the final tool SOBQ significantly better than using <math>FEV_1</math> alone.</p> <p>Levels of evidence: 1a</p>
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Cite this article: Conley P. Instruments Measuring Risk Factors Predicting Hospitalization for Chronic Obstructive Pulmonary Disease: An Integrative Review. *J J Pulmonol*. 2015, 1(3): 016.

<p>7</p> <p>Measured risk factors for readmission after hospital discharge for ECOPD, which included quality of life indicators using tools: GOLD, Beck-Depression Inventory, Graffar Scale, and SGRQ.</p> <p>(Carneiro, Sousa, Pinto, Almeida, Oliveira, &amp; Rocha, 2010)</p> <p>Portugal</p>	<p>Adults 84.4% male, median age 68 years of age +/- 12.4, stage IV 51%, and median total SGRQ 50.6</p> <p>Percent who resided in Domicile in the Porto district (second largest urban area in Portugal) = 70%</p> <p>N = 45</p> <p>Questions read to illiterate subjects who were not able to read.</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective study</p> <p>Subjects hospitalized with ECOPD (2006-2008) defined as an acute change in baseline per Anthonisen et al. (1987) criteria and GOLD criteria.</p>	<p>Questionnaire:</p> <p>Demographics, risk factors for COPD (smoking and smoking burden), asthma, workplace exposure, family history of non-malignant lung disease, and co-morbidities. 1) Clinical and functional evaluation, GOLD criteria to classify disease severity. 2) QOL per SGRQ. 3) evaluation of any depression using Beck Depression Inventory-Short form, 4) Social Status-evaluated with Graffar Scale, 5) COPD treatment before hospital admission.</p>	<p>Pearson correlation test (r) and nonparametric Spearman correlation test (R) to examine correlation of variables.</p> <p>AUC for model = 0.68.</p> <p>High SGRQ scores reflected worse QOL related to depression (R = 0.69; p = 0.02). FEV<sub>1</sub> inversely related to a worse score of depression (r = -0.48; p = 0.054).</p>	<p>Findings revealed a link between depression and a high SGRQ total score, related to a poor quality of life. Small sample size noted.</p> <p>Levels of evidence: 1c</p>
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<p>8</p> <p>To determine if clinical risk factors and QOL risk factors as measured by questionnaire: Seattle Obstructive Lung Disease (SOLDQ) scored at baseline on patients who were followed for 12 months follow-up was predictive of hospitalization</p> <p>(Fan, Curtis, Tu, McDonnell, &amp; Fihn, 2002)</p> <p>United States</p>	<p>Adults assigned to one of seven primary care clinics of Veterans Affairs (VA) medical centers</p> <p>N = 3,282 (COPD and asthma)</p> <p>Male = 96.3%</p> <p>Race, white = 85.7%</p> <p>Age mean = 65.6 years (10.9)</p> <p>Theoretical framework not mentioned</p>	<p>Prospective cohort</p> <p>Subjects part of Ambulatory Care Quality Improvement Projects (ACQUIP) multi-center, randomized controlled trial and enrolled in the general medicine clinics at seven Department of Veterans Affairs (VA) hospitals.</p>	<p>Completed a health inventory, SOLDQ, and CCI. Distance of patient to hospital (per zip codes), smoking status, employment status, pulmonary function testing (PFT) results, age, marital status, and hospitalization based on International Classification of Disease, ninth revision (ICD-9) for COPD and respiratory infection.</p>	<p><math>\chi^2</math> for categoric variables. Logistic regression for QOL scores modeled as predictor variables.</p> <p>Hospitalization for COPD: c-index, 0.706; Hosmer-Lemeshow, 7.9; <math>p = 0.4</math>); lowest quartile SOLDQ for physical function 6.0 (95% CI, 3.1 to 11.5); long term steroid use (OR, 2.8; 95% CI, 1.6 to 4.9). Prior hospitalization for COPD (OR, 4.5; 95% CI, 2.2 to 9.2).</p>	<p>SOLDQ disease specific for COPD QOL measurement (especially physical function impacting lower QOL) found to be an independent predictor for hospitalization for COPD and mortality.</p> <p>Levels of evidence: 1c</p>
<p>9</p> <p>Factors associated with hospital admission from ED for ECOPD using a standard protocol. Post hoc comparison of admissions to assess agreement with GOLD guidelines.</p> <p>[3]</p>	<p>Cohort study of patients matching (9 indications for hospital admission) Global Initiative for COPD (GOLD) guidelines. Adults, median age 69 years.</p> <p>48% men</p> <p>52% women</p> <p>White = 178/76</p> <p>African American = 37/16</p> <p>Hispanic = 16/7</p> <p>N = 233</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective multicenter cohort, observational</p> <p>COPD patients seen in ED for treatment of ECOPD, defined as increased shortness of breath, worsening cough, or change in sputum production, &gt;/ 55 years of age, and able to give consent.</p>	<p>Hospital admission defined as a patient admitted to an inpatient unit with diagnosis of COPD, emphysema, or chronic bronchitis). Data collected: clinical findings, COPD history, symptoms described prior to admission, respiratory rate, comorbidities, new diagnosis of arrhythmia, and zip code.</p>	<p>Multivariate logistic regression to examine independent factors associated with hospital admission. Hosmer-Lemeshow and AUC for final model.</p> <p>The area under the receiver operator curve (ROC) was 0.80 for the multivariate model and the Hosmer-Lemeshow test demonstrated a good fit (<math>p = 0.81</math>). No significant two-way interactions in the final model. 61% admission rate (95% CI = 56% to 66%).</p>	<p>Findings: age, female gender, higher pack-years of smoking, recent use of inhaled corticosteroids, self-reporting of decreased activity in past 24 hours, elevated respiratory rate in ER, and concurrent diagnosis of pneumonia increased risk of admission.</p> <p>Levels of evidence: 1c</p>



<p>10</p> <p>Variables predictive of hospital admission 2 months after emergency room visit, in patients with ECOPD.</p> <p>GCS, CCI, and socioeconomic data.</p> <p>[14]</p>	<p>Adults:</p> <p>N = 2,336 (patients with index ED visit)</p> <p>N = 1,537 admitted to the hospital</p> <p>N = 950 discharged home</p> <p>Male = 2,125 (91%)</p> <p>Female = 207 (8.8%)</p> <p>Mean age years = 72.5, +/- 9.64</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective cohort</p> <p>Subject seen in one of 16 hospitals among Spanish National Health Service. COPD defined by FEV<sub>1</sub>/FVC &lt; 70%</p>	<p>Date collected in ED socioeconomic, respiratory status (arterial blood gases: pH, pCO<sub>2</sub>, and O<sub>2</sub>, respiratory rate, and dyspnea at rest), level of consciousness (GCS), and presence of disease conditions recorded using CCI.</p>	<p>Univariate analyses based on patient's condition in ED (admitted to the hospital or discharged home).</p> <p>X<sup>2</sup> and Fischer exact tests used to test for statistical significance among proportions.</p> <p>Predictors of admission to an intermediate respiratory care unit or intensive care unit with long-term home oxygen use or noninvasive mechanical ventilation elevated pCO<sub>2</sub> and decreased pH at time of ED arrival. AUC 0.87 in derivation sample and 0.89 in validation sample.</p> <p>Previous ECOPD admission in past year (OR 1.98 &amp; 2.33); pCO<sub>2</sub> on ED admission (OR 2.02 &amp; 2.90); number of ED visits within one week of index ED visit (OR 5.14); dyspnea level one week after index ED visit (OR 2.66 &amp; 1.40); and predictors for short term admission (AUC 0.82).</p>	<p>Collecting data at time of ED visit can be used to predict short term hospital admission. AUC could be improved.</p> <p>Patients admitted to the hospital during index ED visit: baseline FEV<sub>1</sub>, % ECOPD related hospitalization in previous year, severe baseline dyspnea, and dyspnea one week after index ED visit were predictors for short term readmission (AUC 0.73).</p> <p>Levels of evidence: 1c.</p>
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<p>11</p> <p>Examined risk factors for hospitalization and death secondary to COPD.</p> <p>Medical Research Council (MRC) dyspnea scale.</p> <p>Airway questionnaire 20 (AQ20).</p> <p>(Schembri et al.,2009)</p> <p>Scotland</p>	<p>Adults</p> <p>N = 3,343</p> <p>Females = 1657, 49.6%</p> <p>Males = 1686, 50.4%</p> <p>Patients screened from clinical network during yearly visits.</p> <p>Age 70 -79 years, 1,112/33%</p> <p>Median follow-up was 1.9 years</p> <p>Theoretical framework not mentioned</p>	<p>Prospective observational</p> <p>Inclusion criteria for COPD: FEV<sub>1</sub> &lt; 80% of the predicted value (greatest of pre and post bronchodilator values) and FEV<sub>1</sub> / FVC &lt; 70%</p>	<p>Demography: gender, age, deprivation score, smoking status, and history, body mass index (BMI).</p> <p>Severity of COPD and quality of life</p>	<p>Proportional hazard model (CI 95%) used to identify significant risk factors. Risk scores for predictors were described as 3 times the logarithm for the hazard ratios.</p> <p>Based on Hazard ratio (95% CI): Prior respiratory admission (2.68, 2.27 – 3.36); Dyspnea score (5 worse) (4.37, 2.74 – 6.95); BMI underweight (1.23 (0.94 – 1.61); Base FEV<sub>1</sub> &lt; 30, (1.8, 1.39 – 2.32).</p> <p>Statistically significant identified risk factors for hospitalization and death (p &lt; 0.05).</p>	<p>387 (54%) hospitalized once</p> <p>160 (22%) hospitalized twice</p> <p>168 (24%) hospitalized more than twice</p> <p>Risk factors (p &lt; 0.05) low BMI, worsening MRC dyspnea score, increasing age, decreased FEV<sub>1</sub>, previous respiratory or cardiovascular hospital admission, and use of prednisone predictive of poor outcomes.</p> <p>Influenza vaccine protective.</p> <p>Levels of evidence: 1c</p>
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<p>12</p> <p>Hospital readmission for acute exacerbation of COPD (AECOPD), SGRQ, CCI, Cognitive status Pfeiffer Questionnaire, Katz Activities of Daily Living Scale, Social Resources and Yesavage Scale.</p> <p>(Almagro et al., 2006)</p> <p>Spain</p>	<p>Adults</p> <p>N = 129</p> <p>Age = 72 years, +/- 9.2</p> <p>Men = 120/93%</p> <p>Women = 9/7%</p> <p>Admitted to acute care teaching center</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective</p> <p>Subjects FEV<sub>1</sub> &lt; 70%</p> <p>Admitted for AECOPD: worsening breathlessness and change in mental status related to hypercapnia.</p>	<p>Questionnaire: regular treatment; number of medications. Health-related quality of life questionnaire (Spanish version of SGRQ), Dyspnea visual analog scale, CCI, Cognitive status Pfeiffer Questionnaire, Katz Activities of Daily Living Scale, Social Resources scale of Older American Research and Service Center, socioeconomic data, and presence of depression per Yesavage Scale (short version).</p>	<p>Multivariate model used:</p> <p>Qualitative variables analyzed: <math>\chi^2</math> test or Fisher's exact test.</p> <p>Quantitative variables: Student's t-test or non-parametric test: Mann-Whitney.</p> <p>Hosmer-Lemeshow Goodness of fit test indicated model calibrated (p = 0.85): readmission significantly related to previous hospital admission, hypercapnia at discharge, and poor quality of life.</p> <p>21 (16.3%) readmitted within one month.</p> <p>45 (34.9%), 53 (41.1%), and 75 (58.1%) at 3, 6, and 12 months readmitted.</p> <p>Mean length of stay 30.1 +/- 24.2 days.</p>	<p>Statistically significant scores on dyspnea scale ATS p &lt; 0.02, high number readmission in past year for ECOPD p &lt; 0.0001, high PaCO<sub>2</sub> p &lt; 0.005.</p> <p>SGRQ scores of readmitted patients significantly worse scores on: activity, impact on daily life, and distress due to respiratory symptoms.</p> <p>Levels of evidence: 1c</p>
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<p>13</p> <p>Predictors for hospital admission for ECOPD among ED patients.</p> <p>Structured ED interview with patient or family member.</p> <p>Canadian Triage and Acuity Scale (CTAS), respiratory rate (RR) clinical data, demographic variables, and Anthonisen criteria.</p> <p>(Rowe et al., 2009)</p> <p>Canada</p>	<p>N = 501</p> <p>55.5% (n= 278) male</p> <p>Median age 71 years</p> <p>Race: white 94.7%</p> <p>Theoretical Framework not mentioned</p>	<p>Prospective cohort</p> <p>AECOPD</p> <p>Participants (or family) presented to one of 16 EDs with ECOPD and answered an ED structured interview and a telephone interview completed 2 weeks later.</p>	<p>Clinical characteristics: BMI, high school graduate, smoking history, health care use (primary care provider, ED use, and hospitalizations), admitting diagnoses, comorbidities, lung function (FEV<sub>1</sub>), and arterial blood gas (ABG)</p>	<p>Bivariable analyses for dichotomous variables tested by chi-square test, bivariable analyses for continuous variables performed by Mann-Whitney U test.</p> <p>Multivariable logistic regression (MLR) model used. P value statistically significant at 0.05.</p> <p>Hospital admission significantly associated with 2 previous COPD admissions in past 2 years (OR = 2.10; 95% CI = 1.24 to 3.56), receiving oral corticosteroids for COPD (OR = 1.72; 95% CI = 1.08 to 2.74), having Canadian Triage &amp; Acuity Scale score 1-2 (OR = 2.04; 95% CI = 1.33 to 3.12) and additional ED treatments, mostly oxygen and IV magnesium (OR = 3.95; 95% CI = 2.45 to 6.35).</p> <p>Hospital admission: 49.3 (95% CI = 44.9% to 53.9%). Goodness of fit assessed by deviance value, 1.23, indicating a reasonable fit.</p> <p>No significant difference in sex, education level, primary care support between admissions or discharge groups.</p>	<p>50% of patients hospitalized 62% scored Anthonisen criteria I or II, 73.4% FEV<sub>1</sub> &lt; 50%</p> <p>Predictors for hospitalization: past COPD history, EDs being usual site for COPD care, p &lt; 0.001 and treatment received adjunct to COPD treatment in ED p &lt; 0.001.</p> <p>Levels of evidence: 1c</p>
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Cite this article: Conley R. Instruments Measuring Risk Factors Predicting Hospitalization for Chronic Obstructive Pulmonary Disease: An Integrative Review. J Pulmonol. 2015, 1(3): 016.

<p>14</p> <p>Role of anxiety, health status, and depression as risk factors for COPD rehospitalization.</p> <p>[15]</p>	<p>N = 406</p> <p>Participants from university hospitals of 5 Nordic countries.</p> <p>Male/Female age 69.2 years mean, +/- 10.5</p> <p>Female = 51.2</p> <p>Male = 48.8</p> <p>Theoretical framework not mentioned</p>	<p>Prospective study (multicenter)</p> <p>Patients had been admitted with AECOPD defined as change in baseline condition, so severe, acute hospital admission required.</p> <p>Met GOLD criteria for stage I or higher.</p>	<p>Data collected from pulmonary units at discharge:</p> <p>SGRQ, HADS, and questionnaire</p>	<p>Chi-squared and unpaired t-test used.</p> <p>Time until readmissions tested by Kaplan-Meier survival analysis and Cox regression.</p> <p>Linear regression used to analyze correlation between health status and psychological status.</p> <p>Readmission within 12 months = 60.6%, patients had lower lung function and health status. Hazard ratio (HR, 95% CI) = 0.82 (0.74 – 0.90) predicted FEV<sub>1</sub> and 1.06 (1.02 – 1.10) per 4 units increase in sum SGRQ score.</p> <p>Readmission within 12 months = 60.6%, patients had lower lung function and health status. Hazard ratio (HR, 95% CI) = 0.82 (0.74 – 0.90) predicted FEV<sub>1</sub> and 1.06 (1.02 – 1.10) per 4 units increase in sum SGRQ score.</p> <p>Previous hospitalizations (HR 95% CI: 1.98 (1.42 – 2.76) independent related to increased risk of hospitalization (2 previous hospitalizations). Significant correlation between total SGRQ score and total HAD score (r = 0.38; p &lt; 0.001)</p> <p>Significant interaction between health status and psychological status related to risk of readmission (p = 0.002).</p>	<p>COPD patients having poor health status discharged after hospital admission, the risk of rehospitalization was higher in patients with anxiety.</p> <p>Low FEV<sub>1</sub> and poor health status discovered as being important risk factors for readmission.</p> <p>Levels of evidence 1c</p>
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<p>15</p> <p>Factors related to hospitalization of patients with acute exacerbation of COPD (AECOPD). Structured questionnaire administered by physicians to hospitalized patients for acute ECOPD, after they were clinically stable.</p> <p>[16]</p>	<p>N = 73</p> <p>Participants included those with AECOPD admitted to the hospital.</p> <p>Male = 96%</p> <p>Age in years = 60 +/- 9</p> <p>History of previous hospitalization = 59%</p> <p>Comorbidities = 46%</p> <p>Theoretical Framework not mentioned</p>	<p>Observation study</p> <p>AECOPD defined by World Health Organization-Government of India as ongoing deterioration of patient's condition from stable baseline to acute occurrence of symptoms that require a change in medication (Jindal, Gupta &amp; Aggarwal, 2004).</p>	<p>Data from structured questionnaire during hospitalization, body mass index (BMI), smoking, symptoms, comorbidities, spirometry, and outcomes during hospitalization.</p>	<p>Univariate analysis conducted on variables. Variables found significant were put into a step-wise multivariate regression analysis. Statistically significant risk factors found were: FEV<sub>1</sub> peak expiratory rate, sputum purulence, history (in past year) of previous hospitalization, and comorbidities.</p> <p>Risk factors identified as statistically significant for COPD hospital admission, p value significant p &lt; / 0.05: peak expiratory flow rate p = 0.046, FEV<sub>1</sub> p = 0.03, sputum purulence p = 0.039, previous hospitalization in past year p = 0.048 and comorbidities p = 0.041.</p>	<p>Authors report this is the first study in northern India to examine COPD risk factors for hospitalization. Tuberculosis (10%), smoking 97%.</p> <p>Low FEV<sub>1</sub> is a predisposing risk factor for mortality from COPD.</p> <p>Levels of evidence: 1c</p>
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Note. Body mass index (BMI), air flow obstruction, dyspnea (score from the modified Medical Research Council (MRC), and exercise capacity (distance walked in 6 minutes (BODE index), Global Initiative for Chronic Obstructive Lung Disease (GOLD), Glasgow Coma Scale (GCS), Charlson Comorbidity Index (CCI), evaluation of COPD longitudinally to identify predictive surrogate endpoints (ECLIPSE), St. George's Respiratory Questionnaire (SGRQ), Graffar Scale (socioeconomic score), Hospital Anxiety and Depression Scale (HADS), Carstairs index (socioeconomic deprivation), enhancing recovery in coronary heart disease (ENRICHED) social support inventory (ESSI), State-trait anxiety inventory (STAI-S/T), shortness of breath questionnaire (SOBQ), Beck-Depression Inventory, Anthoisen criteria determining severity of COPD, Seattle Obstructive Lung Disease Questionnaire (SOLDQ), Airway questionnaire 20 (AQ20), Cognitive Status Pfeiffer Questionnaire, Katz Activities of Daily Living Scale, Yesavage Scale (short version to evaluate the presence of depression), Canadian Triage and Acuity Scale (CTAS).



Levels of Evidence (Oxford Centre for Evidence-based Medicine – Levels of Evidence, March 2009) [13]

Table 2. Level of Evidence
1a Systematic reviews of random controlled trials, different populations. Prospective cohort.
1b Individual random controlled trial, single population
1c All or none case series
2a Systematic reviews of cohort studies (same type)
2b Individual retrospective cohort study
2c Outcomes research-ecological studies
3a Systematic reviews of same type of case-control studies, better studies
3b Individual case control study with limited population
4 Case-series with low quality cohort and case-control studies
5 Expert opinion with no specific critical appraisal, or based on physiology

### Synthesis

Of the fifteen studies included in the integrative review, numerous instruments were identified as measuring for risk factors predictive for hospital admission or readmission of COPD, exacerbated COPD, or patients with acute exacerbated COPD. Deciphering the validity and reliability of the instruments used to measure risk factors for COPD admission was as multifaceted problem given the different types that existed across studies. Specific reports of reliability and validity are typically not reported but we assume that these attributes are subsumed within the statistical tests conducted, especially for reliability. As a result reliability and validity are reported together. Statistical analysis of measurements used in the studies were done in order to determine risk factors, which focused on the predictive capacity of variables related to hospitalization for exacerbated COPD. In other words, all of these studies examined the predictive validity of exacerbated COPD hospitalizations using multiple variables.

Reliability is necessary for validity to be established [17,18]. However, the nature of COPD progression makes it difficult for reliability to be independently established. The study conducted by Vidal et al. had the highest statistic value predictive for COPD hospitalization amid the studies included in the review (4). The accuracy in the model to measure to predictive risk factors for hospitalization among patients with COPD was reported as being the area under the curve (AUC) 0.89. An outcome such as this, would indicate a clinical classification of the measurement tool as 'good' in predicting an admission for COPD [19]. One study in the review reported being the first to use measurements to determine risk factors in their country, consequently stability of these measures has not been estab-

lished [15]. Multiple studies demonstrated the correlation between episodes of exacerbated COPD and accelerated disease progression, which in turn increase the incidence of repeated future hospital admissions, and mortality [11, 13]. As COPD patients experience exacerbations, deterioration impacts their quality of life, which is additionally challenged by those who have a low socioeconomic status, lack of social support, smoking, body mass index (BMI) being abnormally high or low, including the implications of experiencing anxiety, and depression [13].

### Results

Across studies multiple complexities and diverse models were used to measure risk factors. The BODE Index: BMI, degree of airway obstruction measured by forced expiration in one sec (FEV<sub>1</sub>), dyspnea (modified Medical Research Council questionnaire (mMRC), and exercise capacity measured by a 6-minute walk (6MWD), is a multidimensional score of COPD disease severity. Using the BODE index and other select clinical variables included, revealed a significant effect on predicting the number of COPD hospital admissions (95% Confidence Interval, 1.15 to 1.25; < 0.001) [10]. Despite the BODE index being valuable to clinicians because it evaluates major indicators for hospital admission, many times the 6MWD it is not a useful instrument in the acute care setting.

In contrast, Coventry et al. from the United Kingdom measured variables with five different instruments to examine potential risk factors for COPD admission: baseline clinical data, St. George's Questionnaire (SGRQ), Hospital Anxiety and Depression Scale (HADS), Charleston Comorbidity Index (CCI), Carstairs index (socioeconomic deprivation), and Enhancing Recovery in Coronary Heart Disease (ENRICH) that included a social support inventory [12]. Utilizing numerous tools was a common finding in all the studies. Expecting health care professionals to complete numerous scales is unrealistic, in order to determine COPD risk factors for hospitalization. The dilemma of finding a valid and reliable tool to measure risk prediction for COPD hospital admission is compounded by the regulation set by Medicare and Medicaid (2014) readmission penalty regarding reimbursement [2]. Such a regulation indiscriminately imposes a judgment, presuming a lack of quality care and services among hospitals and the health care professionals [20].

There was limited reporting in the studies about their feasibility, but all had strengths in measuring risk factors. Table 2. Some of the specific strengths of the studies relied on the combination of instruments used and the inclusion of clinical, functional status, socioeconomic, and psychosocial components. Additionally, limitations of the integrative review was the heterogeneity of the different instruments used to capture the most predictive risk factors.

Table 3: Validity and Reliability of Instruments for Risk Factors

Study Name	Constructs/Instruments		
<p>1</p> <p>Ong, K. C., Earnest, A., &amp; Lu, S. J. (2005). A multidimensional grading system (BODE index) as predictor of hospitalization for COPD. <i>Chest</i>, 128(6), 3810-3816. doi: 10.1378/chest.128.6.3810</p>	<p>A multidimensional grading system BODE Index (body mass index, airflow obstruction, dyspnea (score from the modified Medical Research Council (MRC), and exercise capacity (distance walked in 6 minutes) scores for each as predictor of hospitalization for COPD and Global Initiative for Chronic Obstructive Lung Disease scale (GOLD).</p>	<p>4</p> <p>Coventry, P. A., Gemmell, I., &amp; Todd, C. J. (2011). Psychosocial risk factors for hospital re-admission in COPD patients on early discharge services: a cohort study. <i>BMC Pulm Med</i>, 11, 49. doi: 10.1186/1471-2466-11-49</p>	<p>Baseline clinical data, St. George's Questionnaire (SGRQ), Hospital Anxiety and Depression Scale (HADS), Charleston Comorbidity Index (CCI), Carstairs index (socio-economic deprivation), and social support measured with self-report instrument, Enhancing Recovery in Coronary Heart Disease (ENRICHD) Social Support Inventory (ESSI).</p>
<p>2</p> <p>Vidal, S., Gonzalez, N., Barrio, I., Rivas-Ruiz, F., Bare, M., Blasco, J. A., . . . Quintana, J. M. (2013). Predictors of hospital admission in exacerbations of chronic obstructive pulmonary disease. <i>Int J Tuberc Lung Dis</i>, 17(12), 1632-1637. doi: 10.5588/ijtld.13.0177</p>	<p>Body mass index, airflow obstruction, dyspnea (score from the modified Medical Research Council (MRC), exercise capacity (distance walked in 6 minutes scores for each) (BODE index), GOLD, standardized data collection tool for predictors among patients with exacerbated COPD, and Glasgow Coma Scale.</p>		<p>Authors reported the CCI for comorbidity had a predictive validity in outcomes for readmission and death.</p> <p>Charlson ME, Pompei P, Ales KL, Mackenzie CR: A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. <i>J Chronic Dis</i> 1987, 40:373-383.</p>
<p>3</p> <p>Mullerova, H., Maselli, D. J., Locantore, N., Vestbo, J., Hurst, J. R., Wedzicha, J., . . . Anzueto, A. (2014). Hospitalized Exacerbations of Chronic Obstructive Pulmonary Disease: Risk Factors and Outcomes in the ECLIPSE Cohort. <i>Chest</i>. doi: 10.1378/chest.14-0655</p>	<p>ECLIPSE procedure (evaluation of COPD longitudinally to identify predictive surrogate endpoints), St. George's Respiratory Questionnaire (SGRQ-C), and GOLD.</p>	<p>5</p> <p>Soler, J. J., Sanchez, L., Roman, P., Martinez, M. A., &amp; Perpina, M. (2004). Risk factors of emergency care and admissions in COPD patients with high consumption of health resources. <i>Respir Med</i>, 98(4), 318-329.</p>	<p>SGRQ, demographic data, socioeconomic data, and nutritional parameters. State-trait anxiety inventory (STAI-S/T).</p>

Cite this article: Conley P. Instruments Measuring Risk Factors Predicting Hospitalization for Chronic Obstructive Pulmonary Disease: An Integrative Review. *J Pulmonol* 2015, 1(3): 016.

<p>6</p> <p>Fan, V. S., Ramsey, S. D., Make, B. J., &amp; Martinez, F. J. (2007). Physiologic variables and functional status independently predict COPD hospitalizations and emergency department visits in patients with severe COPD. <i>Copd</i>, 4(1), 29-39.</p> <p>doi: 0/15412550601169430</p>	<p>Data for this study partly obtained from National Emphysema Treatment Trial (NETT) a randomized controlled trial of volume reduction surgery versus continued medical treatment conducted among 17 clinics throughout the US (1998 to 2002). Tools: shortness of breath questionnaire (SOBQ), SGRQ, and 6-minute walk.</p>	<p>8</p> <p>Fan, V. S., Curtis, J. R., Tu, S. P., McDonell, M. B., &amp; Fihn, S. D. (2002). Using quality of life to predict hospitalization and mortality in patients with obstructive lung diseases. <i>Chest</i>, 122(2), 429-436.</p>	<p>Clinical risk factors and QOL risk factors as measured by questionnaire: Seattle Obstructive Lung Disease (SOLDQ) scored at baseline on patients who were followed for 12 months follow-up was predictive of hospitalization. Short-form-36 questions of QOL.</p> <p>The SF-36 was completed by patients, reported as a reliable, valid, and responsive measure containing 36 questions that can be used to calculate a physical component summary (PCS) score and a mental component summary (MCS) score.</p> <p>Ware JE Jr, Gandek B. Overview of the SF-36 Health Survey and the International Quality of Life Assessment (IQOLA) Project. <i>J Clin Epidemiol</i> 1998; 51:903-912</p>
<p>7</p> <p>Carneiro, R., Sousa, C., Pinto, A., Almeida, F., Oliveira, J. R., &amp; Rocha, N. (2010). Risk factors for readmission after hospital discharge in chronic obstructive pulmonary disease. The role of quality of life indicators. <i>Rev Port Pneumol</i>, 16(5), 759-777.</p>	<p>Measured risk factors for readmission after hospital discharge for ECOPD, which included quality of life indicators using tools: GOLD, Beck-Depression Inventory, Graffar Scale, and SGRQ.</p> <p>SGRQ was stated to be properly validated in Portuguese to assess QOL.</p> <p>Jones PW, Quirk FH, Baveystock CM, Littlejohns OA. Self-complete measure of health status for chronic airflow limitation. The St. George's Respiratory Questionnaire. <i>Am Rev Respir Dis</i> 1992; 145:1321-1327.</p>		



<p>9</p> <p>Tsai, C. L., Clark, S., Cydulka, R. K., Rowe, B. H., &amp; Camargo, C. A., Jr. (2007). Factors associated with hospital admission among emergency department patients with chronic obstructive pulmonary disease exacerbation. <i>Acad Emerg Med</i>, 14(1), 6-14. doi: 10.1197/j.aem.2006.07.034</p>	<p>Factors associated with hospital admission from ED for ECOPD using a standard protocol. Post hoc comparison of admissions to assess agreement with GOLD guidelines. Family income estimated using zip codes and insurance status categorized by private or commercial.</p> <p>The BODE index was reported to have been validated in predicting risk of death and hospital admission in patients with COPD who are stable.</p> <p>Ong KC, Earnest A, Lu SJ. A multidimensional grading system (BODE Index) as predictor of hospitalization for COPD. <i>Chest</i>. 2005; 128:3810-6.</p>	<p>11</p> <p>Schembri, S., Anderson, W., Morant, S., Winter, J., Thompson, P., Pettitt, D., . . . Winter, J. H. (2009). A predictive model of hospitalisation and death from chronic obstructive pulmonary disease. <i>Respir Med</i>, 103(10), 1461-1467. doi: 10.1016/j.rmed.2009.04.02</p>	<p>Examined risk factors for hospitalization and death secondary to COPD. Medical Research Council (MRC) dyspnea scale, Airway questionnaire 20 (AQ20),</p>
<p>10</p> <p>Quintana, J. M., Esteban, C., Garcia-Gutierrez, S., Aguirre, U., Gonzalez, N., Lafuente, I., . . . Rivas-Ruiz, F. (2014). Predictors of hospital admission two months after emergency department evaluation of COPD exacerbation. <i>Respiration</i>, 88(4), 298-306.</p> <p>doi: 10.1159/000365996</p>	<p>Variables predictive of hospital admission 2 months after emergency room visit, in patients with ECOPD,</p> <p>Glasgow Coma Scale, Charlson Comorbidity Index, and socioeconomic data.</p>	<p>12</p> <p>Almagro, P., Barreiro, B., Ochoa de Echaguen, A., Quintana, S., Rodriguez Carballeira, M., Heredia, J. L., &amp; Garau, J. (2006). Risk factors for hospital readmission in patients with chronic obstructive pulmonary disease. <i>Respiration</i>, 73(3), 311-317.</p> <p>doi: 10.1159/000088092</p>	<p>Questionnaire: routine treatment at home; number of medications. Health-related quality of life questionnaire (Spanish version of SGRQ), Dyspnea visual analog scale, Comorbidity used Charlson Index, Cognitive status Pfeiffer Questionnaire, Katz Activities of Daily Living Scale, Social Resources scale of Older American Research and Service Center, socioeconomic data, and presence of depression per Yesavage Scale (short version). Airway questionnaire 20 (AQ20), structured questionnaire to assess home medications.</p>

<p>13</p> <p>Rowe, B. H., Villa-Roel, C., Guttman, A., Ross, S., Mackey, D., Sivilotti, M. L., ... Borgundvaag, B. (2009). Predictors of hospital admission for chronic obstructive pulmonary disease exacerbations in Canadian emergency departments. <i>Acad Emerg Med</i>, 16(4), 316-324. doi: 10.1111/j.1553-2712.2009.00366.x</p>	<p>Structured ED interview with patient or family member. Canadian Triage and Acuity Scale (CTAS), respiratory rate (RR). Anthoniessen et al. (1987) criteria used to define exacerbation of COPD. Clinical characteristics: BMI, high school graduate, smoking history, health care use (primary care provider, ED use, and hospitalizations), admitting diagnoses, comorbidities, lung function (FEV<sub>1</sub>), and arterial blood gas (ABG). Visual analog scale and dyspnea Scale of American Thoracic Society, functional dependence assessed with Katz Activities of Daily Living Scale, Social Resources Scale of the Older American Research and Service Center, and Yesavage Scale (short version) to evaluate the presence of depression.</p>
<p>14</p> <p>Gudmundsson, G., Gislason, T., Janson, C., Lindberg, E., Hallin, R., Ulrik, C. S., ... &amp; Bakke, P. (2005). Risk factors for rehospitalisation in COPD: role of health status, anxiety and depression. <i>European Respiratory Journal</i>, 26(3), 414-419.</p>	<p>Data collected from pulmonary units at discharge:</p> <p>SGRQ, Hospital Anxiety and Depression scale (HAD) and Questionnaire.</p> <p>HAD questionnaire is reported in previous studies to have fairly high validity for psychiatric morbidity.</p> <p>Wilkinson MJ, Barczak P. Psychiatric screening in general practice: comparison of the general health questionnaire and the hospital anxiety depression scale. <i>J R Coll Gen Pract</i> 1988; 38: 311-313.</p>
<p>15</p> <p>Mohapatra, P. R., &amp; Janmeja, A. K. (2010). Factors associated with hospital admission in patients with acute exacerbation of chronic obstructive pulmonary disease. <i>Indian J Chest Dis Allied Sci</i>, 52(4), 203-206.</p>	<p>Structured questionnaire administered by physicians to hospitalized patients for acute ECOPD, after they were clinically stable. Data collected from structured question during hospitalization, body mass index (BMI), smoking, symptoms, comorbidities, spirometry, and outcomes during hospitalization.</p>

**Table 2.** Constructs/instruments used in each study to determine risk factors for COPD admission. Report on validity and reliability of instruments with supporting citation.

#### Discussion

Based on the initial literature results of 14,166 articles, 15 articles were selected that ranged in statistical rigor for determining risk factors most predictive of hospitalization for COPD or acute exacerbation of ECOPD. In addition, the studies clearly represent the global health crisis that COPD poses to patient:

diagnosed with this disease and the health care system that cares for them. One of the limitations of this study was that out of the articles measuring risk factors for exacerbated COPD hospital admission, most were from studies conducted outside of the US (80%). This is a limitation since other countries differ in health care practices and resources from the US. In addition, there was no consistency in the clinical data collected and the instruments used. The strengths of the studies revealed the correlation of past hospitalizations, low FEV<sub>1</sub>, measuring socioeconomic, and psychological aspects of anxiety and depression impacting the QOL of COPD patients.

Among these publications no theoretical frameworks were included, which could be the result of the studies being heavily influenced by physicians, who take more of a non-theoretical physiological approach to research. Random Forest (RF) was utilized in several studies found in the search but were not included because it employs a machine learning method where fit is almost always obtained irrespective of the clinical reliability and validity of the model [5, 21]. Other researchers conducted retrospective studies that did not meet the inclusion criteria. One such study was the Medicare Provider Analysis and Review (MEDPAR) files during the years 2006 and 2010 that included: California, Illinois, Florida, New York, Ohio, Pennsylvania, and Texas to detect risk factors for COPD hospital admission. Their findings revealed increasing use of hospitalization and common prevalent risk factors being congestive heart failure (CHF), patients who were indigent, sicker, lack of support, and low education level contributing to the vulnerability of this population [6].

### Conclusion

COPD is a serious global health issue with a dynamic relationship involving patients' socioeconomic status, self-rated quality of life, disease severity, comorbid factors, and geographic location. Due to the intricate problem of COPD and the fragile equilibrium of risk factors that predispose patients to being admitted to the hospital, finding one measurement instrument to identify the key potential risk factors is a daunting feat to accomplish. Access to valid and reliable instruments to measure risk factors employed by those health care professionals entrusted with the care of patients with COPD, needs to embody gestalt clinical assessment skills and follow an empirically sound predictive model [14, 18, 22].

The time is now, to create a comprehensive, efficient, and effective psychometric instrument that can measure risk factors in real-time to address this vulnerable COPD population [4, 15, 22, 23]. Use of the Socio-Ecological Model would provide a framework of four essential domains to be measured: individual (clinical, psychosocial, and socioeconomic factors); relationships (family, significant others); community setting (environment); and society (economic and social policies) [24, 25],

Research to establish statistically sound evidence of a new prediction model will bridge the gap in evidence-based practice for these patients. Therefore an instrument created with the Socio-Ecological Model and a baseline of common risk factors could be customized to meet the unique needs of populations in their geographic locations and susceptible attributes. Such an instrument could then be generalizable on a national and potentially international level. A COPD risk factor instrument, that could be used in the ED or when hospitalized patients have stabilized, would have the potential to improve outcomes, as well as conserving health care resources [10,23,24,26,27].

### Acknowledgements

The authors would like to thank Lisa Kerr, PhD, and Kitty Serling, MLS for their guidance and support.

### Funding

This research received no funding to write this paper and there are no conflicts of interest.

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Manuscript III

Structured COPD Discharge Education and Quality of Life: A Feasibility Study

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## Abstract

**Background:** Discharge instructions for hospitalized patients with chronic obstructive pulmonary disease (COPD) are essential to promote improved health outcomes, reduce incidence of rehospitalization, and improve perception of quality of life (QOL).

**Objectives:** This study evaluated the feasibility of implementing the American Lung Association's modified COPD Action Plan and assessment of QOL among participants hospitalized for an acute exacerbation of COPD (AECOPD) or COPD.

**Methods:** A feasibility study was conducted on a cohort of critically ill participants with COPD hospitalized on a Progressive Care Unit. Nurses were trained to deliver the modified COPD Action Plan, and the Principal Investigator administered the World Health Organization Quality of Life-Brief (WHOQOL-BREF) questionnaire to assess QOL before discharge and 30 days after discharge via phone call. RE-AIM (Reach, Effectiveness-Adoption, Implementation and Maintenance) Framework was used to evaluate outcomes.

**Results:** In hospital enrollment (n = 50 participants); 13 completed both the in-hospital and 30-day follow-up assessments. There was in hospital dropout (n = 1), reported deaths on 30 day follow-up (n = 2) and those not reached by phone (n = 34). Participants' answer to whether self-management skills were learned from the action plan (12; 92.3% answered "Yes"). WHOQOL-BREF scores were compared using the Wilcoxon signed-ranks test; there were no statistically significant difference between in hospital and 30 day follow-up scores.

**Conclusions:** Administration of COPD instructions can increase patient satisfaction in receiving self-management instructions from an action plan near time of discharge based

on a small follow-up sample. There was no significant change in QOL scores obtained from the follow-up group in this study. *Keywords:* COPD, action plans, education, self-management, quality of life

## **Introduction**

Chronic obstructive pulmonary disease (COPD) is a progressive inflammatory lung disease that results in airflow limitation, which is treatable but presently not curable (Celli et al., 2015). The physical, psychological and economic burden of living with COPD negatively affects the QOL of patients and their caregivers. COPD is the third leading cause of death in the United States, and management of the disease remains suboptimal (National Institutes of Health, 2013). Tremendous financial responsibility exists for both patients and the health care system, due to the high consumption of resources (Jennings et al., 2014). The average US hospital readmission rate within 30 days post discharge for COPD is reported at 20.2%, and Centers of Medicare and Medicaid (CMS) have established penalties in financial reimbursement to hospitals for these readmissions, necessitating more effective chronic care management for these patients (Centers of Medicare and Medicaid, 2014). Action plans are strategic instructions used to help nurses educate patients on disease entities and symptoms with information on appropriate actions to take. A goal of action plans, as in COPD, is to teach self-management skills in order for patients to prevent delay in seeking care and worsening outcomes of morbidity and mortality (Sanchez et al., 2016).

Based on the diverse needs and backgrounds of patients with COPD, it is essential to deliver discharge instructions individually (Hanania, 2012; Sheppard et al., 2013). A compounding factor, however, is that many individuals with COPD, are of low-socioeconomic status (City Data, 2015; Gershon, Dolmage, Stephenson & Jackson, 2012). Low-socioeconomic status encompasses lack of education, economic resources, and occupational risks (Gershon, Dolmage, Stephenson & Jackson, 2012). Thus, concise



discharge instruments are needed to specifically provide COPD self-care instructions to improve QOL (Kansagara et. al, 2011). Incorporating consideration of compounding factors such as comorbidities, socioeconomic status, and anxiety mostly related to breathless episodes, into discharge instructions is critical to gaining effectiveness and satisfaction in the delivery of nurse-patient education to patients with COPD (Coventry, Gemmell, & Todd, 2011; Polster, 2015).

The purpose of this study was to evaluate the feasibility of implementing the American Lung Association (ALA) modified COPD Action Plan (page 1 of 2) as a systematic discharge education of patients with COPD and to assess their QOL using the WHOQOL-BREF (ALA, 2013; WHOQOL-BREF, 1997). This structured discharge plan targeted patients with COPD receiving care in an acute care setting.

### **Gap in Evidence**

Based on the literature, there is a growing body of evidence to support the effectiveness of specific patient education and discharge instructions, such as the use of action plans, delivered during outpatient visits or hospitalization (Almago & Castro, 2013; Mularski et al., 2012). For example, action plans for asthma have been studied for their educational impact on respiratory symptoms and self-management outcomes. In a meta-study, Jalota and Jain (2016) report that 400 asthma action plans have been investigated as to their effectiveness in teaching self-management of symptoms compared to data published from 69 studies on COPD action plans. These findings on asthma action plans indicated effectiveness in prevention of more severe asthma exacerbations but little information was available on QOL. In comparison, researchers concluded COPD action plans are likely to be effective if they are patient-centered and COPD-

specific, take into account comorbidities, and have a multidisciplinary approach (Jalota & Jain, 2016).

### **Mixed Evidence: Benefits, Inpatient or Outpatient, Evaluation of QOL**

Similarly, COPD action plans are beneficial to patients, but they too are limited in outcomes on QOL, based on a review of action plans and the role of antibiotics in self-management for patients with AECOPD (Jalota & Jain, 2016). Bischoff et al. (2011) reported use of a COPD action plan given to 252 participants who also received either hospital-based exercise or home-based exercise for patients in a one year prospective cohort study. Reduced ECOPD recovery time (0.0001) was reported but the action plan did not impact unplanned healthcare utilization (OR 0.94, 95% CI 0.49 to 1.83) (Bischoff et al., 2011). There was no report of QOL evaluation as noted by Bischoff et al. (2011). Sanchez-Nieto et al. (2016) conducted a multicenter, randomized study that taught self-management skills to 85 outpatients, providing one group teaching session and then subsequent individual teaching sessions. QOL was assessed using the COPD Assessment Test (CAT), ( $p = 0.286$ ). Findings reported by Sanchez-Nieto et al. (2016) included incidence of hospitalization for ECOPD in comparing control group (CG) to intervention group (IG) decreased, 52 versus 42.

**Benefits of COPD education.** Findings from a prospective study conducted over a one year period, used a COPD self-management education plan, by Labrecque et al. (2011). The same researchers reported 57 outpatients with stable COPD showed a decrease in emergency department (ED) visits compared to 45 patients who did not receive instruction ( $p = 0.002$ ) (Labrecque et al., 2011). Hospitalizations were reduced in the education group, but this finding was not statistically significant ( $p = 0.17$ ), and

improvements in health-related quality of life (HRQOL) ( $p < 0.001$ ) were observed. Similarly, Scott and colleagues (2011) compared knowledge of COPD and information needs of 38 inpatients and 43 outpatients with COPD diagnosed 9 +/- 7 years prior and measured these outcomes using two questionnaires. Reported results showed a positive correlation between prior COPD learning and high school education ( $p < 0.05$ ), and a positive correlation was found from prior COPD instructions and lower Lung Information Needs Questionnaire (LINQ) score ( $p < 0.01$ ). The need for further education on diet and self-management was identified. No measurement of QOL was reported by Scott et al. (2011).

In cross-sectional descriptive study, Choi, Chung, and Han (2014) taught 126 participants with COPD during clinic visits how to care for their respiratory condition and prevent ECOPD. Results suggested improved adherence to an action plan and reduced unplanned hospitalizations ( $p = 0.001$ ). QOL measured with St. George's Respiratory Questionnaire (SGRQ) results mean (standard deviation) 37.79 +/- 18.99. Trappenburg et al. (2011) conducted a multicenter randomized controlled trial to test the effectiveness of administering personalized COPD action plans to reduce exacerbation recovery time in 233 patients. Patients were recruited during scheduled outpatient visits ( $n = 111$ ) in the individualized action plan and ( $n = 122$ ) usual care. SGRQ was used to report QOL in this study ( $p = 0.42$ ). Every three days participants completed the Clinical COPD Questionnaire (CCQ) to measure health status, starting as out-patients and then at home or if they were hospitalized. Results of the CCQ scores indicated improvements in health status related to a decrease in exacerbations ( $p \leq 0.01$ ). Ko et al. (2016) carried out a randomized controlled trial to assess the impact of a comprehensive intervention for

patients recently discharged from the hospital for AECOPD. Compared to the control group that received standard instructions, the group receiving the intervention experienced a reduction in hospitalization for AECOPD ( $p = 0.047$ ) and decreased length of stay (LOS) ( $p \leq 0.001$ ). The investigators did not report what particular aspect of the intervention was most effective.

Sanchez-Nieto et al. (2016) conducted a randomized controlled trial that enrolled 89 patients, who months prior, had either been hospitalized for ECOPD or treated in the emergency department (ED). These researchers found incidence of ECOPD, in the intervention group, decreased from 52 to 42 (Sanchez-Nieto et al., 2016).

Fan et al. (2012) conducted a randomized controlled trial of patients with COPD who had been hospitalized within 12 months prior to enrollment for COPD. The comprehensive program educated 209 participants in the intervention group to self-initiate antibiotics and prednisone for ECOPD and 217 in the usual care group. When it was identified that the mortality rate was higher in the intervention group 28 compared to 10 receiving usual care the study was stopped (Fan et al., 2012). This outcome was not defined but surmised that participants in the intervention group may have been over confident in self-treatment and delayed seeking medical care.

### **Best Practice Discharge Models: Reducing Hospital Readmissions and Improving Outcomes**

The COPD Foundation held a multi-stakeholder National COPD Readmissions meeting in 2013 to establish evidence-based practices to reduce hospital readmissions. Krishnan et al. (2015) reported that no specific evidence-based COPD educational instruments were produced from this meeting. Evidence-based programs were identified

to educate on disease symptoms and actions to take, as well as scheduling post-hospital office appointments included: Society of Hospital Medicine's (SHM), Project Re-Engineering Discharge (RED), Care Transitions Intervention, Project Better Outcomes through Optimizing Safe Transitions (BOOST), and the Transition Care Model. Providing an individualized approach to educating self-management for patients with COPD was emphasized along with identification of comorbidities such as congestive heart failure (CHF) and diabetes (DM) which pose challenges to self-management of COPD (Krisman et al., 2015).

Furthermore, findings were reported from several studies that multidisciplinary educational action plans which included evaluation of QOL, physical exercise, and follow up phone calls to patients after discharge, decreased hospitalizations (Krishnan et al., 2015). Evidence of these comprehensive discharge programs revealed *bundle* interventions (education, exercise, and follow up phone calls after discharge) such as BOOST for COPD patients, reporting a 2% 30-day hospital readmission reduction (Krisman et al., 2015). Incidentally, BOOST does not include home visits. Results reported improved outcomes, fewer hospitalizations, and increased QOL (Hansen et al., 2013).

Mularski et al. (2012) examined comparative effectiveness research for patients with COPD reporting gaps in evidence on effective education strategies such as proper instruction on use of inhalers, setting follow-up appointments after discharge and evaluating QOL. They called for collaboration among researchers, clinicians, payers, and policymakers in broadening methodologies such as repeating performed effectiveness

designs that examine longitudinally over time positive and negative outcomes, as well as expense (Mularski et al., 2012).

COPD action plans are promising to patients with COPD, helping them acquire knowledge, increase their confidence in managing their lung disease, and deciding when to contact health care providers. However, few studies have confirmed whether specific action plans for COPD delivered as discharge instructions are an effective approach to reduce hospital admissions and influence quality of life (Bischoff et al., 2011; Effing et al., 2012; Jennings et al., 2014). Future studies are needed that detail implementation and content of instructions (pharmacological and nonpharmacological), and how discharge instructions could be individualized based on assessment of prior participant knowledge of self-management and evaluation of QOL (Effing et al., 2012; Mularski, 2012; Polster, 2015).

As important as it is to assess outcomes on health, it is equally as important to assess the feasibility of instructional models and their uptake during discharge. Another consideration, is a need for uniformity in delivering COPD discharge instructions (either written, audiovisual, or electronic tablet-based) to improve self-management among patients with COPD (Choi et al., 2014; Mularski et al., 2012). The present study sought to provide an initial understanding of the feasibility of delivering one type of action plan to critically ill patients with COPD and whether there are perceived benefits on QOL. Specifically, the aims of this study were to 1) evaluate the feasibility of implementing the COPD modified Action Plan as part of the discharge instructions for patients with COPD or an exacerbation of COPD (ECOPD), hospitalized on a PCU;

2) compare QOL measured using the WHOQOL-BREF valid instrument and patient response scores before discharge, and at 30 days post discharge; and 3) explore discharged patients perceptions related to the action plan, regarding whether or how this instrument assisted them to gain knowledge of self-management with COPD (e.g., number of hospitalizations, emergency department (ED) visits, etc.). Outcomes of this feasibility study were measured with the RE-AIM Framework.

### **Theoretical Framework**

The Social Ecological Model (SEM) was used to guide the development of the structured discharge educational protocol and QOL evaluation for the present study because SEM recognizes the interconnectedness in layers of influence for patients with COPD (Centers for Disease Control and Prevention, 2015). The framework consists of multiple levels of influence which include: the *individual*, his/her knowledge, motivation and skills; *interpersonal relationships* that consists of family, friends and social network; *organizations*, involving environmental factors (home or work) such as air pollutants indoors and outdoors. Additionally, *community resources* are composed of connections and support between organizations in the community and home. *Public policies* embody the laws to support and protect individuals and communities (Glasgow, Vogt & Boles, 1999). The SEM provided a schematic design as to the interrelationships of factors to be considered when this discharge intervention was developed to teach hospitalized patients with COPD self-management skills and evaluate their perceptions of QOL.

## **Research Question**

What is the outcome of using the ALA COPD Action Plan in terms of self-rated knowledge and assessment of QOL in a cohort of patients discharged after hospitalization for an AECOPD or COPD?

## **Methods**

### **Study Design**

This prospective feasibility study used the ALA COPD modified Action Plan for discharge instructions to evaluate the outcome on patients hospitalized for an AECOPD J44.1 International Classification of Diseases (ICD) or for another illness, or had COPD J44.9 ICD as a secondary diagnosis. In addition, QOL was assessed using the WHOQOL-BREF questionnaire before hospital discharge and 30 days via phone call, after hospital discharge. The study was conducted over six months (May, 2016 to October, 2016) in a 24-bed PCU at a hospital in Kansas City, Missouri. Prior to this study there was no formalized COPD action plan in place for nurses to review and provide to patients with COPD on discharge from the hospital. The study received expedited approval from the Medical University of South Carolina's institutional review board (IRB) and the hospital's research operating committee. Informed consent was obtained from all participants.

### **Setting, Sample and Recruitment**

Participants were recruited from a 24-bed PCU located in an urban area of western Missouri that serves a population 473,000 of racially diverse individuals (City Data, 2013). Among this population, most patients live within a 150 mile radius of the hospital in the urban and surrounding area (Research Medical Center, 2016). City data



(2015) reported that 14.3% of Kansas City residents live with income below the poverty level, as compared to 11.7% for the whole state. It was anticipated that retention of the sample would be a challenge in the 30 day follow-up based on follow-up in previous studies at the hospital where the study was conducted (Feeback, 2015). The original sample size of 25 was doubled to 50 to obtain adequate data to evaluate the feasibility of this study (Billingham, Whitehead & Julious, 2013).

A majority of this population with COPD have multiple comorbid conditions: renal disease, diabetes, congestive heart failure, and depressive symptoms (Maters, 2014). Inclusion criteria included adults: 18 years-of-age and older, discharged to self-care, home (independently or with family/significant other), have a primary or secondary diagnosis of exacerbation of AECOPD (J44.1 ICD) or COPD (J44.9) International Classification of Disease (ICD-10, 2011), score 15 on the Glasgow Coma Scale, understand and speak English, have access to a working phone, and have an address to receive mail. Exclusion criteria consisted of patients with a tracheostomy, not able to talk or communicate using BiPAP (noninvasive bi-level positive airway pressure ventilation) during the day or on mechanical ventilation. (Table 1. Provides the inclusion and exclusion criteria for enrollment of participants). The Principal Investigator (PI) screened potentially eligible patients with COPD from a daily census sheet, invited those who met the inclusion criteria to participate, and obtained informed consent from those who agreed. Demographic characteristics measured: age in years, gender, race, smoking status, home oxygen use, body mass index (BMI) in kg/m<sup>2</sup>, marital status, home support, education level, employment status, primary and secondary diagnosis ICD-10 codes were collected from participants and/or their medical record.

## **Measures**

**RE-AIM.** To measure feasibility of this discharge instruction, the RE-AIM framework was used (Glasgow, Vogt & Boles, 1999). Assessment of feasibility was evaluated over various time points, such as after delivery of the action plan via the 30 day follow-up phone call post discharge. **Reach** included recruitment and retention of the sample population of participants with COPD hospitalized on a Progressive Care Unit (PCU). **Effectiveness** was measured by assessing participants' perceived benefits of the COPD Action Plan, based on 30 day follow up feedback (survey and qualitative results). A trained PCU nurse completed a questionnaire on how beneficial the discharge intervention was perceived for participants with COPD and answered questions to evaluate acceptance and feasibility of the action plan. **Adoption** was evaluated by PCU nursing staff (rated responses) and participants' perception of willingness to adopt the discharge clinical procedure (rated responses and 30 day outcomes of health care utilization and QOL outcomes). **Implementation** of the clinical procedure was appraised by consistency in delivery (fidelity) of the COPD discharge procedure, given direct observation, feedback from participants, and the nurse's recommendations.

**Maintenance** will be determined following completion of this study's results from the trained PCU nurse and participants' evaluations of the COPD Action Plan as an approved institutional discharge procedure for patients with COPD (survey and qualitative results).

**Quality of life.** WHOQOL-BREF questionnaire includes 26 items that were read and completed by the PI with the participant (Appendix II). The questionnaire assesses QOL in four domains: physical, psychological, social relationships, and environment (World Health Organization, 2014). WHOQOL-BREF questionnaire was selected for its

documented sound psychometric properties and diverse application with adults sick and well, and tested in 23 countries from the general population consisting of hospital, rehabilitation, and outpatient settings (Skevington, Lotfy, & O'Connell, 2004).

Validation of the psychometric properties of this assessment instrument has been verified in a cross-cultural adult survey (n = 11,830). Cronbach's *a* was acceptable ( $p > 0.7$ ) for internal consistency reliability. The analysis was based on Multi-Trait/Multi-Item Analysis Program (MAP). Construct validity based on Pearson correlations (one-tailed test) between domains for the total sample was strong, positive, and highly significant ( $p < 0.0001$ ) (Skevington, Lotfy & O'Connell, 2004, p. 305).

Hawthorne, Hermann & Murphy (2006) reported guidelines for interpretation of WHOQOL-BREF domain scores from two studies of adults in the community categorized by gender, years of age, and health status. General norms for the WHOQOL-BREF were: 73.5 (SD, 18.1) physical domain, 70.6 (SD, 14.0) psychological wellbeing, 71.5 (SD, 18.2) social relationships, and 75.1 (SD, 13.0) environment. Differences in WHOQOL-BREF domain scores were significant when reported by health status and decreased by 50% compared to those in excellent health (Hawthorne, Hermann & Murphy, 2006).

Each participant was sent a postcard 14 days following discharge to remind them of the 30 day follow-up phone call. (Figure 1). Participants were asked questions by the PI via 30 day follow up phone call to determine feasibility of the discharge protocol and satisfaction.

## **COPD Discharge Education: COPD Action Plan and Monthly Calendar**

The modified COPD Action Plan provides three classifications for patients to daily self-identify changes in respiratory symptoms and takes action based on changes in their respiratory condition (American Lung Association, 2013) (Table 2). Color zones included: 1) Green Zone, patient is doing well/action take daily medications, 2) Yellow Zone, patient is having a bad day/action: use immediate relief inhaler, call health care provider immediately if symptoms worsen, 3) Red Zone, need for urgent medical care/action: call #911 immediately and use immediate relief inhaler until help comes.

A monthly calendar was given to each participant to record daily with a check next to the symbol representing the following: respiratory condition and well-being described per ALA color zones, hospitalizations, ED visits, phone calls to health care provider, etc. (Table 3). The calendar was to be returned after the 30 day follow up call to the participant, in a hospital addressed stamped envelope provided by the PI.

### **Procedures for COPD Discharge Education**

Three PCU nurses who volunteered to deliver the COPD discharge instructions were trained individually. Nurses were informed about the purpose of the study and entire study flow. The PI provided a standardized script for use with each participant in this study to the nurse volunteers, and demonstrated the process of administering the discharge action plan. The nurses were notified when patients enrolled and consented in the study, and then requested to deliver the discharge education close to the time the participant was to be discharged or on the day of discharge. The modified COPD Action Plan was read to participants the day of or before discharge by the PI or trained nurse. The participant was asked to “teach-back” in their own words, to describe what each zone

represented in symptoms and the action to take. This clinical procedure took place in the privacy of the participant's hospital room.

Participants were provided with a monthly calendar to document daily symptoms, and were instructed how to complete it. The PI administered the WHOQOL-BREF questions after the modified COPD Action Plan instructions had been reviewed with each participant. A copy of the action plan was then given to the participant to take home and place in a prominent place as a guide to daily self-assessment.

As a component of the feasibility evaluation the trained PCU nurse who delivered the action plan completed an evaluation form on adoption and implementation of this discharge procedure. The evaluation was done two days after they conducted the discharge education. (Table 4)

### **Delivery of COPD Action Plan**

The Principal Investigator (PI) obtained lists of potentially eligible patients with COPD from a unit census sheet. Patients meeting inclusion criteria were invited to enroll in the study. Those who agreed to participate, signed the informed consent.

The PI read the WHOQOL-BREF questionnaire to the participants and recorded their responses. Next the PI read the information to be filled in daily on the monthly calendar by the participant. Then the participant's address was recorded on a postcard to be sent to him or her 14 days after discharge as a reminder of the 30 day follow up via phone call. Participants received \$5.00 gift card following completion of the instructions and responding to WHOQOL-BREF questionnaire. Data were entered into a Research Electronic Data Capture (REDCap) database, a secure web-based data management system used for data capture from research studies (REDCap, 2015). The PI followed up

with each participant by telephone, 30 days after discharge to collect data from the monthly calendar, namely the number of office visits (scheduled and unscheduled), emergency department visits, and hospitalizations. The WHOQOL-BREF questionnaire was re-administered to participants and responses recorded by the PI. Participants' scores of satisfaction were obtained related to their perceived satisfaction with the delivery of action plan instructions and to evaluate their perceived gain in knowledge regarding self-management skills to care for their COPD. After questions were answered, a \$5.00 gift card and stamped hospital addressed envelope was sent to the participant to return the completed calendar.

## **Data Analyses**

### **Quantitative data**

All data were collected by the researcher and directly entered into the Research Electronic Data Capture (REDCap) study database. Statistical analyses were then performed using the Statistical Package for the Social Sciences (SPSS) 23.0 (IBM SPSS, Armonk, N.Y.). Descriptive statistics were calculated for each variable. For continuous variables, means, standard deviations (SD), medians, and minimum and maximum values were calculated. For categorical variables, counts and percentages were calculated.

The WHOQOL-BREF scoring methodology was guided by a published handbook (WHOQOL-BREF, 1996). Missing data were handled appropriately, < 20% of raw scores missing in a domain resulted in no domain score. Domain scores were calculated from item raw scores for each characteristic and each domain in accordance with the scoring methodology. The calculation to transform each domain score was done with an algebraic equation. Each item in the domain had a response score from 1 to 5, on a Likert scale.

The actual raw score was subtracted by the lowest possible raw score of that participant and then divided by the possible raw score range, next that sum was multiplied by 100. Scores were transformed linearly 0 to 100. The transformation score with calculated in REDCap before exporting into SPSS.

WHOQOL-BREF in hospital scores were compared to the 30-day follow-up assessment domain scores by using the Wilcoxon signed-ranks test. Wilcoxon signed-ranks test was used to compare the ranks from four QOL domains of participants who completed the WHOQOL-BREF in hospital after the modified COPD Action Plan education session and to 30 day follow up via phone call after discharge. Differences were considered statistically significant if the test statistic had a probability level of 0.05 or lower. In addition, a 95% confidence interval was calculated for all of the mean difference scores. The two sample *t*-test was used to compare the sample that completed the QOL questionnaire domains (physical, psychological, social relations, and environment) in hospital and 30 day follow-up via phone call.

### **Qualitative data**

This study utilized qualitative description to analyze the verbal data obtained from participants during the 30-day call back, as open ended comments (Sandelowski, 2000). The question to obtain verbal text, was the first among the survey and QOL questions asked. The PI and a qualitative mentor read and reviewed all of the comments. Having two researchers review the open-ended comments increases the trustworthiness and confirmability (Krefting, 1991). The expertise of the PI being a bedside nurse on the PCU for greater than ten years (prolonged engagement) helped to establish trustworthiness among the participants (Krefting, 1991). The external audit of the data

(participant responses) appraised by a senior qualitative mentor who verified confirmability of the themes that emerged. All data for verbal responses (n =10) was transcribed in writing by the PI on a hard copy of the WHOQOL-BREF during the follow-up phone call, which was then kept in each participants' file to provide an audit trail. The construct was measured by face validity, a subjective form of validity, pertaining to the question and responses by participants. The construct of interest measured satisfaction and benefit of participants receiving self-management instructions from the modified COPD Action Plan. There were no test-retest measurements to provide evidence for reliability of this question.

## **Results**

### **Demographics and Participant Characteristics**

A total of 68 patients were approached, 50 agree to participate, 50 were enrolled and 13 completed the 30 day follow up phone call. (Diagram I Illustrated the sample population by Consolidated Standards of Reporting Trials (CONSORT). Demographic characteristics (Table 5) of the sample were: age (mean, 64.5 year; SD, 9.5 years), range was 49 years to 84 years, and gender: 26 (52%) females and 24 (48%) males. Of race there were, 18 (36%) were African American/Black and 32 (64%) White. Among participants, 19 (39.6%) answered, 'yes' to smoking status and 29 (60.4%) answered, 'no'. Those who used home oxygen, reported, 'yes' 19 (39.6%) and 'no' to home oxygen use 29 (60.4%). Body mass index (BMI) in kg/m<sup>2</sup> recorded on participants, minimum 13.9 and maximum 70.0, (mean, 24.4; SD, 11.4). Marital status was self-reported by participants as: 28 (56%) single, married 17 (34%), and divorced 5 (10%). Having home support, participants who lived with someone assisting them with activities of daily



living, 14 (29.2) 'yes' and 34 (70.8%) 'no'. Education level was reported as followed: some high school 34 (69.4%), some college 10 (20.4%), completed college 4 (8.2%), and graduate school 1 (2.0%). Employment status of those not working 41 (83.7%) and those working 8 (16.3%). Documented primary and secondary diagnosis with International Classification of Diseases (ICD-10) codes were collected from participants' medical record. Primary diagnoses included: acute respiratory failure 10 (20%), AECOPD 4 (8%), Healthcare-Associated Pneumonia 4 (8%), acute and chronic respiratory failure 3 (6%), acute or chronic respiratory failure 3 (6%), and ECOPD 3 (6%). Secondary diagnoses were documented as followed: COPD 19 (38%), ECOPD 13 (26%), AECOPD 7 (14%), and hypoxia 2 (4%).

There were a total of 37 dropouts. One participant dropped out while in the hospital, who did not complete the WHOQOL-BREF questionnaire after being enrolled, while 34 others did not complete the 30-day follow-up assessment, and 2 deaths were reported during the 30-day follow-up via phone assessment.

**Feasibility Assessment.** The RE-AIM framework was used to evaluate five dimensions, beginning with **reach**, and defined as recruitment and retention. (Table 6). The target sample of 50 participants were recruited, however only 13 were retained. Of the patients that dropped out or could not be contacted at the 30 days visit; 1 dropped out in the hospital, 2 died and 34 were not able to be reached by phone call on follow-up, or refused to complete the 30 day follow-up survey and WHOQOL-BREF reassessment due to not feeling well or being busy. **Effectiveness**, defined as outcomes and perception of benefit, was assessed with the following question, "Do you think the discharge action plan taught you to better take care of your respiratory symptoms and when to seek help?" Participant

responses were yes 12 (92.3%) and no 1 (7.7%) participant response was “It didn’t cure me.” Satisfaction with the modified COPD Action Plan and delivery by participants was rated, high 4 (30.8%), moderate 9 (69.2%), and low 0 (0%). Based on qualitative comments from participants on 30 day follow-up, three themes emerged from the comments. 1) *Perceptions about Delivery of the modified COPD Action Plan* reflected an appreciation of knowledge gained, two responses, “Person to person is always good” and “No one (before) took the time to go over this with me. I appreciate it.” 2) Participants discussed feeling better related to *Improved Self-Management Skills* with a participant stating, “Doing exceptionally well. Eating healthy and stopped smoking,” and another “Great.” 3) *Consequences of Decline related to COPD*, “When real hot out, slow deep breaths still don’t help.”

One trained PCU nurse completed a follow-up survey. The response from the PCU nurse on “rated acceptability and ease of delivery of action plan,” was moderate because the nurse said based on each patient’s existing knowledge of COPD self-management, educational background and general well-being, more explanation of the action plan instructions may be needed for some patients. Reply by the PCU nurse to, “Do you see this action plan as a benefit for future patients with COPD?” Response was ‘Yes’. (Table 7).

**Adoption** was evaluated by rated responses and 30 day outcomes of health care utilization and QOL outcomes. Wilcoxon signed-ranks test of median QOL scores indicated no statistical significance among domains (score of differences between means in hospital and 30 day follow-up). The following are the domain scores (mean in hospital, mean 30 day follow-up and  $p$  value): physical (49.3; 55.8;  $p = .78$ );

psychological (64.8; 70.8;  $p = .40$ ); social relations (60.0; 55.8;  $p = .79$ ), and environment (70.2; 72.4;  $p = .59$ ) Participants rating of satisfaction with action plan and delivery was high, 4 (30.8%), moderate, 9 (69.2%), and low, 0(0%). Health care utilization post hospital, 30 day follow-up: number of ED visits: 12 (99%) no ED visits and 1 (1%) ED visits for an insulin reaction. The number of reported hospitalizations following discharge, 12 (99%) no hospitalizations and 1(1%) hospitalized 2 days for COPD. Number of times participants called #911 since discharge was, 0 (100%), number of office visits reported were, 5 (40%) no visits, 7 (55%) had scheduled visits, and 1 (5%) had an office visit not related to COPD. (Table 8). **Implementation** was evaluated on consistency in delivery (fidelity) of the COPD discharge procedure, feedback from participants, and the nurse's recommendations.

Survey outcome of PCU trained nurse responses, post administration of the modified COPD Action Plan rating for length of time to deliver the action plan" answer by the PCU nurse was '15 minutes'. The PI observed the PCU nurse's consistency (fidelity) according to scripted dialog in delivery of the COPD discharge procedure. Only one trained PCU nurse was observed due to limitation in availability of nurses when participants were enrolled in the study and ready to receive the discharge instructions.

**Maintenance** was the final dimension to determine feasibility of the study. The discharge intervention could be considered a potentially strategic intervention using the ALA modified COPD Action Plan but use of the WHOQOL-BREF demonstrated no significant evidence in change of scores from in hospital to 30 day follows up via phone call.

**Quantitative findings (QOL).** Of the 30 day follow-up calendars, 2 were returned completed with the following results: participant (1) green was marked for good day = 88% (28 days out of 32 total days recorded), yellow marked for some problems breathing = 0.5% (2 days out of 32) and 3% (2 days out of 32, nothing was recorded). Participant (2) green marked = 64% (18 day out of 28 total days recorded), yellow marked = 36% (10 days out of 28). SPSS was used to calculate results on the transformed domains in hospital (n = 49) and on 30 day follow-up (n = 13). Scores below 70 would be considered a perceived low QOL, as indicated by the interpretation of WHOQOL-BREF scores from Hawthorne, Herrman & Murphy (2006). The participants who completed the study on 30 day follow up (n = 13) rated social and physical domains as the lowest rated of the four domains, each with a mean 55.8, which is considered a low perceived QOL.

The Wilcoxon signed-ranks test indicated that there was no significant difference in QOL between in hospital and 30 day follow up of 13 participants. Thus, the null hypothesis is retained, as there is no difference between the ranks of in hospital QOL and 30 day discharge follow-up QOL scores. Since the sample (n = 13) of participants retained who completed the study was small, the standard deviation and the 95% confidence interval (CI) of the difference in mean scores (in hospital and 30 day follow-up) was calculated to determine amount of difference. Wilcoxon signed-ranks test was used to calculate the z scores. CI and z score results of QOL domains were: physical (CI -7.3, 10.0), z = -.28; psychological (CI -5.4, 15.0), z = -.85, social; (CI -11.9, 9.4), z = -.27; environment (CI -10.6, 5.8), z = -.54.

The WHOQOL-BREF mean score differences between in hospital scores and 30 day follow via phone call scores were, physical (+1.4) and psychological (+4.8) indicated an increase in both domain scores though not statistically significant. Increase in the mean score could indicate participants being more active at home, experiencing some physical improvement. The psychological domain had the greatest increase in mean score (+4.8) of the 4 domains but was not statistically significant. This possibly reflects participants feeling better mentally being at home in familiar surrounds and for some being near family or loved ones. Social mean domain difference in score of (-1.3) might reflect participants with less or no social support at home, as 17 (34%) participants reported being single. Environment score (-2.4) may indicate poor air quality if exposed to smokers or poor housing conditions. Differences in social and environment mean domain scores were not statistically significant.

### **Qualitative findings (30 Day Follow Up)**

Participants were called at their requested time and day in accordance with the PI availability, which was scheduled with the PI during the in hospital portion of the study. Comments were evaluated from 10 out of the 13 participants who offered responses to the first question asked during the 30 day phone follow up. Overall, most participants were weak and become short of air (dyspneic) during phone call, and would simply answer the rated questions for evaluation of the action plan and QOL questions. The comments were summarized into themes relevant to the question concerning, *satisfaction with receiving self-management instructions from the COPD Action Plan*. From the analysis of the data, words used by participants, three prevailing themes emerged as previously described. Since there was a small sample of participants who completed the

30 day follow-up call, and 10 out of 13 providing responses to one question, resulted in a scant amount of text to analyze. Minimal responses from participants were due to them being weak and dyspneic from their COPD, and for many, having comorbidities.

### **Discussion**

Overall findings from the study indicated the targeted PCU population was able to be recruited; administration of the modified COPD Action Plan was achievable by a trained PCU nurse and the PI. Obtaining participants QOL scores could be obtained when the PI read and recorded them at the bedside. The study had limited feasibility due to lack of retention in the 30 day follow-up. There were no significant differences from the QOL questionnaire mean scores before hospital discharge compared to 30 day follow-up per phone call. Even though a small sample of participants completed the study (n =13), they reported positive satisfaction ratings with the instructions from the action plan. Only one reported being hospitalized for a health issue not related to COPD. In addition, from the qualitative data in the follow-up, three themes surfaced as described in qualitative findings.

Although much emphasis has been made about the correlation of QOL to outcome measures of patients with COPD, there is inconsistency and lack of significant findings from self-management instructions on QOL. Ko et al. (2016) reported, in their comprehensive intervention for patients recently discharged for an AECOPD, the intervention group showed a decrease in hospital readmissions and at 12 months a mean improvement of -6.9 points in total St. George's Respiratory Questionnaire (SGRQ) measuring health-related QOL. In comparison, researchers who used a COPD Action Plan found adherence to instructions was negatively associated with unplanned

hospitalizations but findings indicated no significant relationship with QOL scores (Choi, Chung & Han, 2014). Trappenburg et al. (2011) found that use of an action plan, teaching increased knowledge among patients to identify symptoms of ECOPD, did not decrease healthcare utilization or improve health-related QOL. Bischoff et al. (2011) and researchers studied the impact of using a COPD action plan for recognition of ECOPD symptoms, along with standing orders for prednisone and antibiotics, did not include an evaluation of QOL. The lack of statistical improvement in QOL scores from the findings of this feasibility study and other published studies that examined QOL, begs the question, are most patients with COPD so impaired by their health (COPD and comorbidities) and/or their socioeconomic status that they do not perceive QOL improvement?

Gaining insight into the perceptions of the participants was important to examine in relationship to the delivery of the COPD Action Plan, because the findings are relevant to the feasibility of the study. Participants' verbal acknowledgment in gaining real life self-management skills that could help improve their QOL, may also decrease their risk of hospitalization or rehospitalization for an AECOPD. Maintaining privacy and nurse to participant interaction of the discharge protocol may have helped promote learning and satisfaction in the survey outcome measures, but no improvement in the QOL domain scores. Establishing trust among participants in their interaction with the PI, was a goal, in order that they would feel comfortable to ask questions and share their comments.

Furthermore, the literature reports inconsistency on the content and benefit of education for patients with COPD, being disease specific or general as found in discharge models such as Re-Engineered Discharge (RED) toolkit. The RED discharge model has

minimal instructions on actions for patients to take related to disease symptoms for COPD (RED, 2016). Bischoff et al. (2011) reports limited positive outcomes using a written COPD action plan, from which there was no decrease in healthcare utilization among participants. Fan and researchers (2012) reported their study being stopped because of a high mortality rate in the intervention group than usual care group, of those who received self-management instructions (pharmacological and nonpharmacological). Such outcomes could indicate giving participants' options to initiate pharmacological interventions for self-management of developing ECOPD symptoms can be potentially detrimental.

While previous research suggests a need for ongoing communication with participants to support the action plan instructions, no time frames have been established (Bischoff et al., 2011). This study noted that patients reported satisfaction related to implementation of the ALA modified COPD Action Plan, as noted in comments and ratings from patients. The trained PCU nurse in our study found the action plan to be a reasonable protocol to administer to patients with COPD before or on the day of discharge. Therefore, we conclude that the COPD discharge protocol using an action plan is partially feasible in the acute care setting, but follow-up via phone call lacked feasibility, as shown by the insufficient retention of participants. Dropouts in follow-up were an anticipated obstacle from previous studies at this hospital that did phone follow-up. The high dropout number rate could be a consequence of this population being high risk for multiple reasons: the severity of their COPD disease, comorbidities, socioeconomic factors, and unstable home environment. When participants were called for the 30 day follow-up, some refused to complete the survey and questionnaire stated



the following reasons; “I’m moving right now,” “I don’t feel well,” “Can I answer the questions for my husband (participant)?” and another participant was too drowsy. Also, participants did not all want to answer the question rating satisfaction with their sexual activity and for some it created a distraction (they wanted to go into detail).

Key components of this feasibility study merit future consideration and evaluation: 1) determining the optimal timing for delivering COPD instruction, at least one day before discharge, 2) determining the effectiveness of a 15 to 20 minute patient education session to provide , concise content of ALA modified COPD Action Plan instructions, 3) evaluation of a more concise QOL instrument and 4) reconsideration of large incentives (\$10 gift card) or meeting participants at office or clinic visits for follow-up communication and evaluation from participants.

The PI sitting down next to each participant to deliver the instructions, nurse to participant, provided an opportunity for participants to ask questions, which in some cases enabled valuable teaching. In several cases the participants reported having difficulty getting appointments when they developed abnormal, non-emergent respiratory symptoms (increased dyspnea or colored sputum production). In these instances, participants were instructed on options to seek medical attention such as urgent care centers or the emergency department. The instruction session was preemptive to help most participants identify the connection between waiting too long to receive medical attention and hospitalization. Likewise, participants were able to see the resulting detrimental effects of smoking or other airborne (indoor or occupational) inhalation irritants that may have led to their hospitalization, in some cases an AECOPD or respiratory failure. Depending on participants’ educational and reading level, reading

comprehension was not assessed, reading to the participants insured the instructions of the action plan was conveyed, and a teach-back assured understanding. Participants allowed the PI to read the QOL questionnaire while holding it in front of them and recording their answers, since most were weak and dyspneic. Implementing an action plan on the day of discharge or a day before was best completed the day before discharge, when participants were not waiting for a ride and rushing to leave the hospital to go home. Potential moderators affecting the outcomes of this study included: literacy of participants, time spent sitting at the bedside to deliver the action plan and obtaining responses from the QOL questionnaire, gift card, nurse to participant interaction, privacy of the participants' room, severity of COPD, and time frame presenting information in most cases the day before discharge.

WHOQOL-BREF is a 26-item comprehensive instrument to evaluate QOL. The WHOQOL-BREF was selected for its documented validity and reliability to evaluate QOL and is among one of the more brief questionnaires available. Comparing the WHOQOL-BREF to St. George's Respiratory Questionnaire (SGRQ) that is a 50-item questionnaire and a shorter version of SGRQ, which is a 40-item questionnaire; the WHOQOL-BREF has fewer questions. Due to the fact that this patient population suffers with dyspnea resulting in limited endurance and ability to concentrate in order to take in information or answer questions, a shorter questionnaire of 5 to 6 questions would be more realistic to administer. Studies that examined action plans to educate on self-maintenance of COPD primarily used the SGRQ to evaluate QOL (Ko et al., 2016; Trappenburg et al., 2011) Development of such an instrument will require testing for validity and reliability. A wide spread of BMI results possibly reflected on the low end

(13.9 Kg/m<sup>2</sup>), a lack of nutritional intake and at the high end (70.0 Kg/m<sup>2</sup>), the probable consequence of poor food choices or availability, along with inactivity due to poor endurance from breathlessness caused by COPD. The primary diagnosis of acute respiratory failure could reflect participants delay in seeking medical care for changes in their respiratory condition and in some cases is an indication of the severity of their condition and/or impact of comorbidities.

The ALA modified Action Plan delivered for each participant was part of their overall discharge instructions. Each participant still received the standard discharge instructions, to include review of action and side effects of their home medication list and teaching on any other comorbidities. The \$5.00 gift card given to each participant who completed the in hospital part of the study and when the 30 day follow-up was completed by phone, was acknowledged by many participants as an incentive to enroll and participate in the study. Despite the gift card, partly given as an incentive and acknowledgement of respect for participants' time, there were a large number of dropouts. Consideration should be taken in providing follow-up education and evaluation of QOL done as part of a post hospital office visit instead of a phone call.

Selection of a QOL questionnaire with fewer questions may be more useful in this critically ill patient population. Presenting the outcomes of the qualitative and quantitative findings from this research will be communicated to administration, in order to gain approval for the action plan to be used as an approved institutional discharge procedure for patients with COPD.

## **Limitations**

Throughout the study it was noted that almost all the participants would ask to have the study commence right after they agreed and signed the consent. Subsequently, most of the trained PCU nurses were not immediately available to administer the instructions from the action plan, except in one case. This is due to patient priorities on this busy PCU. One of the three trained nurses was available to deliver the COPD modified action plan and the PI completed the QOL questionnaire. Overall, there was a lack of retention in 30 day follow up. Despite the PI calling participants, at their requested time (sent on 14 day postcard with a date) and sometimes twice, to answer the follow up questions, they either did not answer the phone or a message was left or they did not want to complete the survey and QOL questionnaire. One participant stated on the second call back, "I don't feel well right now, please call back." In some case there was no answer and a message was left, with no return call from the participant or a recording was given that the phone was no longer in service. During the 30 day follow-up phone calls to participants, few comments were obtained. Participants would simply answer the questions repeated from the WHOQOL-BREF and the additional 6 questions on satisfaction with the discharge education. For this reason only 10 verbal responses were available for the question on satisfaction of the COPD instructions. Selection of a QOL questionnaire with fewer questions may be more useful in this critically ill patient population. Also, participants were sent hospital addressed stamped envelopes to return the completed calendars, from which only two calendars were returned. Minimal compliance to completing the calendar from participants is likely due to their impaired condition from COPD and other coexisting conditions. Adding more tasks for the

participants to do beyond self-assessing their respiratory symptoms was apparently not a reasonable expectation. Due to the small sample size on follow-up and the specific patient population being those with COPD hospitalized on a PCU, there is limited generalizability for applicability of the findings.

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## Conclusions

This feasibility study establishes the ground work toward implementation of the ALA modified COPD Action Plan to be used for discharge instructions teaching self-management skills to patients with COPD in the acute care setting. Based on findings from various studies reported in the literature on COPD action plans or education, there are inconsistencies in their use, with mostly no specific information given on the content of instructions, while some included pharmacological (steroids and antibiotics) and nonpharmacological (pursed lip breathing) self-treatment for worsening respiratory symptoms. The literature has little evidence in examining the use of COPD action plans on patients in the acute care setting with high acuity, high risk populations, and those with comorbidities. In addition, reports of findings from researchers revealed inconsistent results of improvement on QOL following implementation of self-management instructions (Choi, Chung & Han, 2014). Many of the studies were conducted on those in the outpatient setting or after discharge with stable COPD or patients with COPD but not having other major comorbidities such as cardiac disease, making this feasibility study unique and challenging (Labreque et al., 2011; Ko, et al., 2016, Trappenburg et al., 2011). The PCU participants were found to have ‘some high school’ education (35%), majority were single (56%) and those not employed were (84%). City Data (2015) reports the population where this study was conducted, has the lowest income level in the state. Therefore, the SEM used as the theoretical framework for this study provided a sound platform for developing this study and bringing to light the factors impacting this population with COPD.

The principle-based concept analysis of inflammation involving COPD manuscript and the integrative review of instruments measuring risk factors predicting hospital admission manuscript for patients with COPD created a closely linked scholarly look at COPD in its complexity and highlighted the areas in need of future research.

Evaluation of QOL following administering discharge instructions needs to be included, with consideration of alternate follow-up contact such as meeting participants at office visits or clinic visits. Future studies are needed to examine outcomes using a larger sample size, to include other hospital units and compare a different COPD action plan. Comparison of two different COPD action plans would be necessary to include in the study design ethically, because standard of care prior to this study did not include any written COPD action plan for patients. Delivering a structured individualized action plan may help overcome stumbling blocks that includes, lack of specific written instructions to teach patients self-management of their COPD and a copy for the patient to take home.

#### Lessons Learned and Next Steps

The modified COPD Action Plan was well received by the findings from participants who completed the 30 day follow-up survey. Participants reported no readmissions for AECOPD (or COPD) on follow-up. No significant changes were found in comparison of the mean domain scores from the WHOQOL-BREF questionnaire. There were several limitations observed in this study, one being a large dropout of 34 participants after discharge, indicating a lack of retention and thus, poor follow-up. A shortfall in follow-up after discharge from the hospital was likely related to moderator variables, primarily severity of COPD (primary admitting diagnosis acute respiratory failure (10, 20%) and socioeconomic factors (City Data, 2013). The other limitation was

participants requested the instructions from the action plan and QOL questionnaire be administered soon after they were enrolled. Trained PCU nurses were most of the time not available to provide the action plan instructions. Since the study was conducted on a PCU, the results are limited in generalizability to other patient populations.

Lessons learned from this study is that the patient population with COPD receiving care on the PCU are critically ill and have little reserve, physically (dyspnea, weak) and psychologically (anxious, depressed) that could have impacted adherence to follow-up. Participants were eager in general to receive education from the modified ALA COPD Action Plan and had little difficulty giving accurate teach-back of the zones and appropriate action to take. Some participants asked for alternative resources if they could not get an appointment with their physician when they felt their respiratory symptoms worsening. This was an opportunity to inform participants of alternative resources, for example to seek care from urgent care centers located near their homes. Even though there were limitations, this feasibility study contributes to evidence that providing education to patients with COPD in the in the acute care setting is beneficial. Improvements in follow-up included reduced ED visits for COPD and empowerment of patients gaining knowledge in identification of changes in respiratory symptoms, as evidenced by patient satisfaction scores. Benefits of implementing self-management COPD instructions in the acute care setting include patients making the connection of a change in their respiratory symptoms and the need for hospital care. In some cases, family or friends were available to be included in the instructions was another benefit. This study gained support from nursing colleagues, who were eager to contribute by carrying out this research intervention. The next step is to obtain funding to conduct a

larger randomized clinical trial with multiple hospital units to compare implementation of the modified ALA COPD Action Plan and another COPD action plan and include follow-up with participants during scheduled office visits.

**Table 1. Inclusion and Exclusion Criteria**

<b><i>Inclusion</i></b>	<b><i>Exclusion</i></b>
Adults 18 years-of-age and older Discharged to self-care, home (independently or with family/significant other) Primary or secondary diagnosis of exacerbation of COPD (ECOPD), J44.1 International Classification of Disease (ICD-10) (2011) Score of 15 on the Glasgow Coma Scale Understand and speak English Have access to a working phone Have an address to receive mail	Patients with a tracheostomy, not able to talk or communicate Using BiPAP (noninvasive bi-level positive airway pressure ventilation) during the day or on mechanical ventilation

**Table 2. American Lung Association – COPD Action Plan**



**MY COPD ACTION PLAN**

It is recommended that patients and physicians/healthcare providers complete this action plan together. This plan should be discussed at each physician visit and updated as needed.



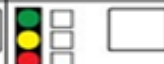


































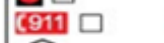







































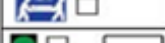










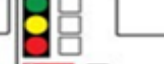























The green, yellow and red zones show symptoms of COPD. The list of symptoms is not comprehensive, and you may experience other symptoms. In the "Actions" column, your healthcare provider will recommend actions for you to take based on your symptoms by checking the appropriate boxes. Your healthcare provider may write down other actions in addition to those listed here.

Green Zone: I am doing well today	Actions
<ul style="list-style-type: none"> <li>• Usual activity and exercise level</li> <li>• Usual amounts of cough and phlegm/mucus</li> <li>• Sleep well at night</li> <li>• Appetite is good</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Take daily medicines</li> <li><input type="checkbox"/> Use oxygen as prescribed</li> <li><input type="checkbox"/> Continue regular exercise/diet plan</li> <li><input type="checkbox"/> At all times avoid cigarette smoke, inhaled irritants*</li> <li><input type="checkbox"/> _____</li> </ul>
Yellow Zone: I am having a bad day or a COPD flare	Actions
<ul style="list-style-type: none"> <li>• More breathless than usual</li> <li>• I have less energy for my daily activities</li> <li>• Increased or thicker phlegm/mucus</li> <li>• Using quick relief inhaler/nebulizer more often</li> <li>• Swelling of ankles more than usual</li> <li>• More coughing than usual</li> <li>• I feel like I have a "chest cold"</li> <li>• Poor sleep and my symptoms woke me up</li> <li>• My appetite is not good</li> <li>• My medicine is not helping</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Continue daily medication</li> <li><input type="checkbox"/> Use quick relief inhaler every ____ hours</li> <li><input type="checkbox"/> Start an oral corticosteroid (specify name, dose, and duration) _____</li> <li><input type="checkbox"/> Start an antibiotic (specify name, dose, and duration) _____</li> <li><input type="checkbox"/> Use oxygen as prescribed</li> <li><input type="checkbox"/> Get plenty of rest</li> <li><input type="checkbox"/> Use pursed lip breathing</li> <li><input type="checkbox"/> At all times avoid cigarette smoke, inhaled irritants*</li> <li><input type="checkbox"/> Call provider immediately if symptoms don't improve*</li> <li><input type="checkbox"/> _____</li> </ul>
Red Zone: I need urgent medical care	Actions
<ul style="list-style-type: none"> <li>• Severe shortness of breath even at rest</li> <li>• Not able to do any activity because of breathing</li> <li>• Not able to sleep because of breathing</li> <li>• Fever or shaking chills</li> <li>• Feeling confused or very drowsy</li> <li>• Chest pains</li> <li>• Coughing up blood</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Call 911 or seek medical care immediately*</li> <li><input type="checkbox"/> While getting help, immediately do the following: <input type="checkbox"/> _____</li> </ul>







\*The American Lung Association recommends that the providers select this action for all patients.

The information contained in this document is for educational use only. It should not be used as a substitute for professional medical advice, diagnosis or treatment. THE AMERICAN LUNG ASSOCIATION DOES NOT ENDORSE ANY PRODUCT, DEVICE OR SERVICE, INCLUDING ANY PARTICULAR COPD MEDICATION OR TREATMENT DEVICE. For more information, visit [www.Lung.org](http://www.Lung.org) or call 1-800-LUNG-USA (1-800-586-4872) © 2015 American Lung Association

Table 3. 30 Day Follow-Up Calendar

30 DAY FOLLOW UP CALENDAR						
MONTH _____						
SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>
 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>	 <input type="checkbox"/>
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**NOTES :**

 = good day	 = Hospitalized
 = some problems breathing	
 = need help now	 = Emergency Room Visit
 = called for help	

**Table 4. PCU Nurse Evaluation on COPD Action Plan**

<p>1. PCU nurses rate <u>acceptability and ease</u> of delivery of action plan:</p>	<p>(3) High _____                  (2) Moderate _____                  (1) Low _____</p>
<p>2. Fits in with discharge instructions normally given to patients, please rate:</p>	<p>a. Good, fits into routine of patient care (3)                  b. Somewhat of an added burden to deliver to participant (2)                  c. An imposition to daily nursing activities (1)</p>
<p>3. How much time to deliver action plan?</p>	<p>a. 10 minutes                  b. 15 minutes                  c. 25 minutes</p>
<p>4. Do you see this teaching plan as a benefit for future patients with COPD?</p>	<p>a. Yes                  b. No                  c. Somewhat</p>



**Table 5. Demographics Characteristics of Participants on PCU**

	Minimum	Maximum (Mean+/-SD)
Age in years (n = 50)	49	84 (64.5/9.5)
	Descriptive	Frequency/Percent
Gender	Female 26 (52%)	Male 24 (48%)
Race	AA (African American or Black)	18 (36%)
	W (White)	32 (64%)
Smoker	Yes 19 (39.6%)	No 29 (60.4%)
Home oxygen	Yes 19 (38%)	No (62%)
Body Mass Index (BMI) Kg/m <sup>2</sup>	Minimum 13.9	Maximum 70.0 (24.4/11.4)
Marital Status	Single	28 (56%)
	Married	17 (34%)
	Divorced	5 (10%)
Home support	No	14 (29.2%)
	Yes	34 (70.8%)
Education	Some high school	34(69.4%)
	Some college	10(20.4%)
	Completed college	4 (8.2%)
	Graduate school	1 (2.0%)
Employed	No	41 (83.7%)
	Yes	8 (16.3%)
<b>Primary diagnosis</b>		
<b>International Classification of Diseases- 10<sup>th</sup> revision (ICD-10)</b>	Frequency	Percent
Acute respiratory failure J96.20	10	20%
Acute exacerbation of COPD (AECOPD) J44.1	4	8%
Healthcare-Associated Pneumonia (HCAP) J18.9	4	8%
Acute and chronic respiratory failure J96.20	3	6%
Acute on chronic respiratory failure J96.22	3	6%
Exacerbation of COPD (ECOPD) J44.1	3	6%
<b>Secondary diagnosis</b>		
COPD J44.9	19	38%
Exacerbation of COPD (ECOPD) J44.1	13	26%
Acute exacerbation of COPD (AECOPD) J44.1	7	14%
Hypoxia R09.02	2	4%

**Table 6. RE-AIM: Results to Determine Feasibility of Study**

RE-AIM Dimension	Measurements	Results/Comments
<p><b>Reach</b> Feasibility to recruit predetermined goal sample size of PCU participants (n = 50).</p>	<p>-Initial recruitment (n =50) in hospital and total of 37 dropouts.</p>	<p>Diagram 1. -Retention: (n = 13) completed in-hospital study</p> <p>-30 day follow up via phone calls (n = 13), this attrition was attributed in part to the impaired condition of the participants from COPD, comorbidities, as well as socioeconomic factors.</p>
<p><b>Effectiveness (measured by outcomes and perception of benefit)</b> Participants' perceived benefits of the COPD Action Plan, on 30 day follow up (survey and qualitative results).</p> <p>One <b>trained PCU nurse</b> completed a questionnaire of rated and perceived benefit of the discharge intervention for participants with COPD.</p>	<p>-Based on qualitative comments from participants, three themes emerged from the comments.</p> <p>-Rated questions on satisfaction with discharge protocol by participants</p> <p>-Trained nurse. The COPD Action Plan</p>	<p>1. <b>Perceptions about Delivery of COPD Action Plan</b> reflected an appreciation of knowledge gained, two responses, "Person to person is always good" and "No one (before) took the time to go over this with me. I appreciate it." 2. Based on participants feeling better related to <b>Improved Self-Management Skills</b> with a participant stating, "Doing exceptionally well. Eating healthy and stopped smoking" and another "Great." 3. <b>Consequences of Decline related to COPD</b>, "When real hot out, slow deep breaths still don't help."</p> <p>Do you think the discharge COPD Action Plan taught you to better take care of your respiratory symptoms and when to seek help (n = 13) Yes = 12 (92.3%) No = 1 (7.7%)</p> <p>Gave moderate rating for acceptability and ease in delivery of the action plan (need to accommodate level of comprehension for each patient).</p>
<p><b>Adoption</b> Individuals willing to implement discharge instructions (one setting) Rated responses and 30 day outcomes of health care utilization and QOL outcomes</p>	<p>-QOL results determined no significant change in domain scores. Table</p> <p>-Participants scores/ g satisfaction</p>	<p>Wilcoxon signed-ranks test of median QOL scores indicated no statistical significance among domains (score of differences between means in hospital and 30 day follow-up: Physical +1.4 Psychological +4.8 Social -1.3 Environment -2.4 Rate satisfaction with COPD Action Plan and delivery: High = 4 (30.8%) Moderate = 9 (69.2%) Low = 0 (0%) Health care utilization at hospital, 30 day follow-up: Number of Emergency Department Visits: 12 (99%) no ED visits 1 (1%) ED visits for insulin reaction Number of Hospitalizations: 12(99%) no hospitalizations 1(1%) hospitalized 2 days, COPD Number of times called #911 since discharge: 0 (100%) none Number of office visits: 5(40%) no visits 7(55%) scheduled visits 1(5%) problem (not COPD related)</p>

RE-AIM Dimension	Measurements	Results/Comments
	<p>-Trained PCU nurse scores/ratings</p>	<p>30 day follow-up calendar, 2 were returned completed with the following results: Participant (1): green was marked for good day = 93% (28 days out of 30 total days recorded), yellow marked for some problems breathing = 7% (2 days out of 30) and 3% (2 days out of 32, nothing was recorded). Participant (2): green marked = 64% (18 day out of 28 total days recorded), yellow marked = 36% (10 days out of 28).</p> <p>Acceptance and ease of delivery of the action plan, rated moderate. Recommended each patient needs individualized instruction based on their knowledge level. "Fits in with discharge instructions normally given to patients" was given the highest rating 'good'.</p>
<p><b>Implementation</b> Consistency in delivery (fidelity) of the COPD discharge procedure, feedback from participants, and the nurse's recommendations.</p>	<p>-Trained PCU nurse score supported implementation (based on one delivery of action plan).</p> <p>-Observed consistency in delivery (fidelity) of the COPD discharge procedure</p>	<p>Do you see this action plan as a benefit for future patients with COPD? Response was 'Yes'.</p> <p>Length of time to deliver the action plan" was scored '15 minutes'.</p> <p>-Delivered COPD Action Plan per scripted dialog, as observed by PI. Only one trained PCU nurse was observed due to limitation in availability of nurses when participants enrolled to receive discharge instructions.</p>
<p><b>Maintenance</b> Determined following completion of this study, based on quantitative and qualitative results of the COPD Action. Plan as an approved institutional discharge procedure for patients with COPD</p>	<p>-Results will be submitted to hospital management.</p>	<p>-Clinical manager of PCU is planning to use ALA COPD Action Plan on unit. Use of the action plan institutional-wide will be determined.</p> <p>-Obtain grant funding to compare ALA COPD Action Plan and another action plan in a randomized study done on multiple units in the hospital.</p>

**Table 7: 30 day Follow-up Phone Interview with Participates**

1. Do you think the discharge COPD Action Plan taught you to better take care of your respiratory symptoms and when to seek help? Comments: Yes:      No:
2. Level of satisfaction with delivery of COPD Action Plan.  (3)Highly satisfied ____ (2) Moderate satisfaction ____ (1) Low satisfaction____
3. Number of ED visits:
4. Number of hospital admission in the last 30 day after discharge:
5. Number of office visits: scheduled                  unscheduled
6. WHOQOL-BREF questionnaire administered:

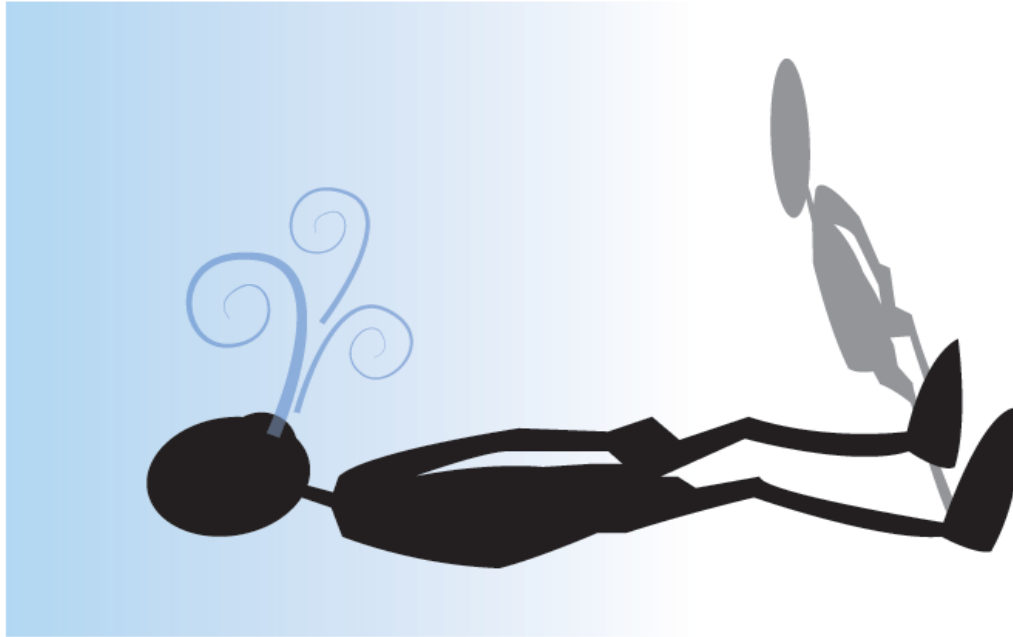
**Table 8: WHOQOL-BREF Domain Scores**

	In hospital  N = 49  Mean ±SD (Median)	In hospital (sample with follow-up only)  N = 13  Mean ±SD (Median)	30 day follow-up  Mean (Median) SD  N=13  Mean ±SD (Median)	Difference Between in- hospital means and 30 day follow-up  N= 13  Mean ±SD	95% Confidence Interval	Z Score*  Test statistic	<i>p</i> values*
<b>Physical domain score</b>	49.3 ±16 (50.0)	54.4 ±15.6 (57.1)	55.8 ±21.4 (53.6)	+1.4 ±14.3	(-7.3, 10.0)	-.28	<i>p</i> = .78
<b>Psychological domain score</b>	64.8±16.7 (66.7)	66.0 ±17.1 (66.7)	70.8 ±18.9 (79.2)	+4.8 ±16.8	(-5.4, 15.0)	-.85	<i>p</i> = .40
<b>Social Relations domain score</b>	60.0±20.3 (66.7)	57.1 ±18.3 (58.3)	55.8 ±21.4 (50.0)	-1.3 ±17.6	(-11.9, 9.4)	-.27	<i>p</i> = .79
<b>Environment domain score</b>	70.2±14.6 (71.9)	74.8 ±12.2 (78.1)	72.4 ±12.4 (68.8)	-2.4 ±13.5	(-10.6, 5.8)	-.54	<i>p</i> = .59

\*Wilcoxon Signed Ranks Test



Figure 1. Postcard: Reminder of 30 Day Follow-Up Phone Call



Hello,

This is a reminder of your 30 day follow up phone call! Please have your calendar filled out as best as you can and with you during the phone call on:

Date \_\_\_\_\_  
Time \_\_\_\_\_

*Thank You!*

Principal Investigator, Pat Conley, RN MSN  
PCCN (PhD student)  
Research Medical Center  
Medical University of South Carolina

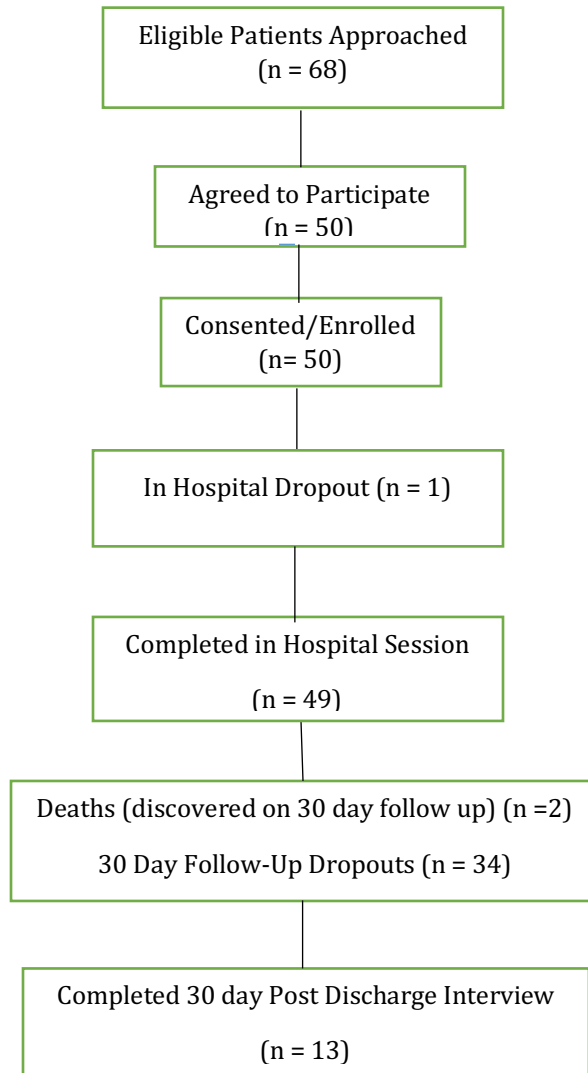
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**Diagram 1. Consolidated Standards of Reporting Trials (CONSORT)**



## LICENSE AGREEMENT



This License Agreement is between American Lung Association (“ALA”), with its principal place of business at 1301 Pennsylvania Avenue NW, Suite 800, Washington, DC 20004 and Patricia Conley, RN MSN PCCN/Medical University of South Carolina/Research Medical Center (“You”). You have asked for permission to use certain materials owned by ALA in your research project or study. ALA grants your request subject to the following terms and conditions. Your signature below indicates your agreement to comply with all the terms and conditions outlined below.

### **Nature of Research Project or Study (the “Study”):**

Chronic Obstructive Pulmonary Disease (COPD) discharge action plan and perception of quality of life issues (QOL). The research study is part of my PhD program of study at the Medical University of South Carolina, School of Nursing.

### **ALA Materials to be Use in the Study:**

- COPD Action Plan

### Reference

American Lung Association. (2013). <http://action.lung.org/site/DocServer/action-management-plan.pdf>. (Retrieved 8/30/2015).

### **How the ALA Materials will be Used in the Study:**

The COPD Action Plan (ALA, 2013) will be used to in a research study as part of a discharge instruction guide presented verbally to each patient in the privacy of their hospital room. Also, each patient will be given a copy of the Action Plan to take home. The study and this ALA Action Plan will need to be approved for use by the Institutional Review Board at the Medical University of South Carolina and Research Medical Center.

### **Time Period for Use of ALA Materials:**

The time period could be estimated 12 months (September, 2016 to September, 2017).

### **Your Contact Information (Name, Title, Address, Phone and Email):**

Patricia Conley, PhD Student  
10017 E. 68<sup>th</sup> Terrace  
Raytown, Missouri 64133  
Cell: 816-509-2676 and Home: 816-356-9863  
[conleyp@musc.edu](mailto:conleyp@musc.edu)



Appendix II: Institutional Review Board Letter of Approval



**Institutional Review Board for Human Research (IRB)  
Office of Research Integrity (ORI)  
Medical University of South Carolina**

**Harborview Office Tower  
19 Hagood Ave., Suite 601, MSC857  
Charleston, SC 29425-8570  
Federal Wide Assurance # 1888**

**APPROVAL:**

This is to certify that the research proposal **Pro00051799** entitled:

**Structured COPD Discharge Education and Quality of Life: A Feasibility Evaluation**

Submitted by: **Patricia Conley**

Department: **Medical University of South Carolina**

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Original Approval Date: **3/28/2016**

Approval Expiration: **3/27/2017**

Type: **Expedited**

Chair, **IRB-I - Medical University of South Carolina**

**Mark Hamner\***

**Statement of Principal Investigator:**

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

**\*Electronic Signature:** *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Appendix III: Research Medical Center Approval

**RESEARCH MEDICAL CENTER  
Clinical Studies Research Operations Committee (ROC)  
Approval Form**

<b>Clinical Study Name</b>	Structured COPD Discharge Education and Quality of Life: A Feasibility Evaluation	<b>Name of PI</b>	Patricia Conley, RN, MSN (PhD student)
<b>Clinical Study Number</b>	N/A	<b>Name of Sponsor</b>	Medical University of South Carolina

**Approvals:** By signing below, you hereby authorize the clinical study to be conducted at Research Medical Center pending receipt of outside IRB approval.

  
\_\_\_\_\_  
Jacqueline Desouza-Van Blaricum, CEO

3/3/2014  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Jennifer Feeback, Director/Clinical Research

2/25/2016  
\_\_\_\_\_  
Date

Comments:

\_\_\_\_\_  
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## Appendix IV: Consent Form

Page 1 of 4  
Version Date: 05/23/2015

### Medical University of South Carolina CONSENT TO BE A RESEARCH SUBJECT

**TITLE OF RESEARCH:** Structured COPD Discharge Education and Quality of Life: A Feasibility Evaluation

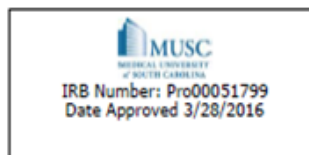
#### A. PURPOSE OF THE RESEARCH

You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your investigator or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of this study is to examine the outcome of providing discharge instructions on taking care of your COPD. You are being asked to participate in this study because you have COPD. The investigator in charge of this study is Patricia Conley, RN MSN PCCN (PhD student). The study is being done at one site (Research Medical Center). Approximately 50 people will take part in the study.

#### B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You will be given discharge instructions on the day of or near your discharge date. These discharge instructions are part of the American Lung Association's COPD Action Plan. As part of your discharge instructions, you will be given information about how to identify changes in your respiratory symptoms and how to manage these symptoms.
2. After you are given the discharge instructions, you will be asked questions about the effect of COPD on your life. You will also be asked to provide a home address and working phone number where you can be reached after discharge.
3. Following the discharge instructions and questions on about COPD on your life you will be given a calendar to daily check for 30 days how you feel and if you have to seek any medical care after discharge.
4. Your medical record will be reviewed to gather information about the following demographic data: age, gender, race/ethnicity, top 3 admitting diagnoses, body mass index (BMI), home support/lives with someone or alone, smoking status (yes or no), marital status (married, single, divorced, other), zip code, educational background, and employment status/occupation.



5. After discharge, you will receive a follow up phone call about 30 days after discharge. During this phone call, you will be asked questions about the effect of COPD on your life. These will be the same questions asked prior to discharge.
6. If you answer the questions when you are called 30 days after discharge you will be asked to return the calendar in an addressed stamped envelope when you receive your second gift card.

#### C. DURATION

Participation in the study will take 2 sessions (15 minutes) in the hospital before you are discharged and one phone call to you at home to answer questions (15 minutes) 30 days after discharge.

#### D. RISKS AND DISCOMFORTS

There is minimal risk for a loss of confidentiality of your personal information as a result of participation in this study. To prevent the loss of confidentiality of personal information, your information will only be accessible to study team members.

#### E. BENEFITS

A potential benefit of participation in the study is that receiving this discharge education may improve your COPD self-management skills and quality of life.

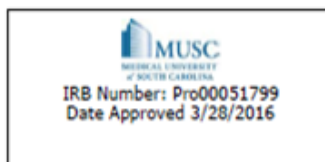
#### F. COSTS

There will be no cost to you as a result of participation in this study.

#### G. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be given a \$5.00 gift card for participating in the discharge instructions and answering questions regarding quality of life related to having COPD. Then 30 days after discharge you will be called on the phone to answer the same questions on quality of life and how the discharge instructions may have helped you take care of your COPD. You will be given a second \$5.00 gift card if you complete this portion of the study, mailed to the address you provide. In the event the card is lost or stolen, there will not be a replacement.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds \$600.00 in a calendar year, you will be issued a Form 1099.



#### H. ALTERNATIVES

Your alternative is to not participate in this study.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of Research Medical Center, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

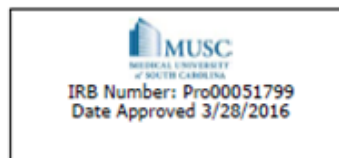
The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

#### Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Patricia Conley (816) 276-3400.

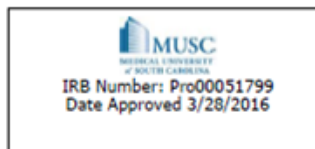
If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.



*If you wish to participate, you should sign below.*

_____ Signature of Person Obtaining Consent	_____ Date	_____ Signature of Participant	_____ Date
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## Appendix V: HIPAA Form

Page 1 of 6 (as of 11/1/2014)

Standard HIPAA Authorization

### Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to the Medical University of South Carolina (MUSC) to use or disclose (release) your health information that identifies you for the research study described here:

**Study title: Structured COPD Discharge Education and Quality of Life: A Feasibility Evaluation**  
**This study will examine the use of the COPD Action Plan and participants answers to quality of life questions.**

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment;
- Parents of minor children is less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Federal and state agencies and MUSC committees having authority over the study such as:
  - The Institutional Review Board (IRB) overseeing this study;
  - Committees with quality improvement responsibilities;
  - Office of Human Research Protections;
  - Food and Drug Administration;
  - National Institutes of Health; or
  - Other governmental offices, such as a public health agency or as required by law.

MUSC is required by law to protect your health information. By signing this document, you authorize MUSC to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.



You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, MUSC may still use or disclose (release) health information already obtained about you as necessary to maintain the integrity or reliability of the research study. If you revoke this Authorization, you may no longer be allowed to participate in this research study. To revoke this Authorization, you must write to:

*Patricia Conley, RN MSN PCCN (PhD student at Medical University of South Carolina.  
Research Medical Center~ 4West/PCU 2316 E. Meyer Blvd. Kansas City, MO 63123*

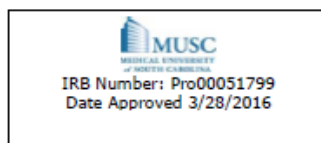
You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

You will be given a copy of this Authorization. This Authorization will expire at the end of the research study. If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at 843-792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

[SIGNATURE PAGE TO FOLLOW]









## NOTICE OF PRIVACY PRACTICES

### MUSC Organized Health Care Arrangement (OHCA)

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." We collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.

#### HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. **For treatment.** Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.
2. **To obtain payment.** We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.
3. **For health care operations.** We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.
4. **For public health activities.** We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.
5. **Victims of abuse, neglect, domestic violence.** Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.
6. **Health oversight activities.** We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.
7. **Judicial and administrative proceedings.** Your PHI may be released in response to a subpoena or court order.
8. **Law enforcement or national security purposes.** Your PHI may be released as part of an investigation by law enforcement.
9. **Uses and disclosures about patients who have died.** We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.
10. **For purposes of organ donation.** As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.
11. **Research.** We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.



IRB Number: Pro00051799  
Date Approved 3/28/2016

**12. To avoid harm.** In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

**13. For workers compensation purposes.** We may release your PHI to comply with workers compensation laws.

**14. Marketing.** We may send you information on the latest treatment, support groups and other resources affecting your health.

**15. Fundraising activities.** We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

**16. Appointment reminders and health-related benefits and services.** We may contact you with a reminder that you have an appointment.

**B. You may object to the following uses of PHI:**

**1. Hospital directories.** Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

**2. Information shared with family, friends or others.** Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

**3. Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

**C. Your prior written authorization is required (to release your PHI) in the following situations:**

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

**1.** Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

**2.** Psychotherapy notes.

**3.** Any circumstance where we seek to sell your information.

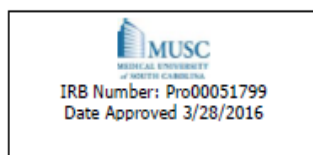
**WHAT RIGHTS YOU HAVE REGARDING YOUR PHI**

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

**A. The Right to Request Limits on How We Use and Release Your PHI.** You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

**B. The Right to Choose How We Communicate PHI with You.** You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

**C. The Right to See and Get Copies of Your PHI.** You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for



copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

**D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI.** This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

**E. The Right to Amend Your PHI.** If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

**F. The Right to Receive a Paper or Electronic Copy of This Notice:** You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

**G. The Right to Revoke an Authorization.** If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

**H. The Right to be Notified of a Breach.** If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

#### HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

#### HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.

#### PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

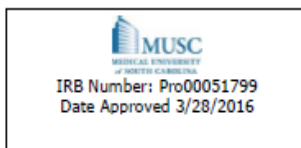
If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue / MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

#### CHANGES TO THIS NOTICE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: <http://www.musc.edu/privacy>.

#### EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.  
Revised September 2013.



Appendix VI: Letter of Permission from Journal

**RE: Inclusion granted**

**November 17, 2016**

**Dear Dr. Patricia Conley,**

Warm Greetings!

Thank you for mail. Please proceed to include it. We apologize for the delay in response.

Please feel free to let us know for further assistance.

Regards,

**Neil Jacobson**

Jacobs Journal of Pulmonology

Jacobs Publishers

9600 Great Hills

Trail # 150w

Austin, Texas

78759(Travis County)

E-mail: [pulmonology@jacobspublishers.international](mailto:pulmonology@jacobspublishers.international)

APPENDIX VII: Letter of Permission from the US WHOQOL Center

Thank you for your interest in the World Health Organization Quality of Life — BREF US English Version Instruments.

We distribute the WHOQOL-BREF U.S. English Version free of charge as electronic files.

Any questions can be directed to:

US WHOQOL Center

Attn: Instrument Distribution Coordinator

University of Washington, Department of Health Services  
Box 359455

Seattle, Washington, USA 98195-9455

Phone: (800) 291-2193

Fax: (206) 616-3135

Email: seaqol@u.washington.edu

Although this information isn't required, we would also appreciate a short description of how you plan to use the instrument. The information would be used to enhance the effectiveness of future instruments or revisions.

Sincerely,

Instrument Dissemination Coordinator, US WHOQOL Center

Name (First, Last, Title):

Patricia Conley, RN MSN PCCN

Today's Date:

09/15/2015

Organization:

Medical University of South Carolina

Mailing Address (Street, PO Box):

10017 E. 68th Terrace

City, State (if USA), Postal Code:

Raytown, MO, 64133

Country (if outside USA):

Phone 1:

816-509-2676

E-mail:

conleyp@musc.edu

Study Name:

Feasibility Study of a COPD Discharge Protocol

Sample Population:

Hospitalized Critically Ill Patients

Estimated Sample Size:

30

Estimated Study Start and Completion Dates:

03/01/2015

Brief Description of Project:

The aim of the study in general is to evaluate the outcome of patients subjective score on gained knowledge, hospital readmission, emergency room visits, and calls to the doctor. In addition, the score of the patients self rating on quality of life (QOL) will be evaluated, hoping that the discharge instructions will improve their perception of having a better QOL.

### **User Agreement for the WHOQOL-BREF Instrument**

*Please read the following information carefully*

The UNIVERSITY OF WASHINGTON distributes the **WHOQOL-BREF** and its translations available in the following languages: U.S. English

**Therefore, User and UNIVERSITY OF WASHINGTON agree as follows:**

#### **1. UNIVERSITY OF WASHINGTON's obligations**

UNIVERSITY OF WASHINGTON shall deliver the original **WHOQOL-BREF** and/or the translations requested by "User" subject to the following conditions:

§ The translations requested are available, and

§ The present agreement is duly completed and signed by “User”

## 2. “User”’s obligations

### 2.1 No modification

“User” shall not modify, abridge, condense, adapt, recast or transform the **WHOQOL-BREF** in any manner or form, including but not limited to any minor or significant change in wordings or organization in **WHOQOL-BREF**, without the prior written agreement of UNIVERSITY OF WASHINGTON, which agreement shall not be unreasonably withheld or delayed.

### 2.2 No translation

“User” shall not translate **WHOQOL-BREF**, without the prior written agreement of **Dr. Donald Patrick**.

### 2.3 No reproduction

“User” shall not reproduce the **WHOQOL-BREF** except for the limited purpose of generating sufficient copies for use in investigations stated hereunder and shall in no event distribute copies of the **WHOQOL-BREF** to third parties by sale, rental, lease, lending, or any other profit-making means.

### 2.4. Publication

In case of publication of study results, “User” shall cite (1) “Bonomi AE, Patrick, DL., Bushnell, DM, Martin M (2000). Validation of the United States' version of the World Health Organization Quality of Life (WHOQOL) instrument. *Journal of Clinical Epidemiology*, 53(1), 13-17.” in reference section of the publication. (New publications may be added and older ones deleted).

### 2.5 Provision of data

All data, results and reports obtained by, or prepared in connection with the **WHOQOL-BREF** shall remain the User’s property. However, UNIVERSITY OF WASHINGTON may request the User to share data, results and reports obtained through the use of the **WHOQOL-BREF**, which request User can accept or reject in its sole and unfettered discretion. UNIVERSITY OF WASHINGTON shall ensure the anonymisation of such data at three levels, by the removal of: any patient identification, any university or company identification and any therapy name. UNIVERSITY OF WASHINGTON will classify and reorganize such anonymous data and therefore, shall hold all intellectual property rights regarding these data when and if submitted to the data pool.



UNIVERSITY OF WASHINGTON may provide such reorganized data to third parties, for analysis in education, research, consulting, and specifically for the evaluation of cross-cultural equivalence and development of reference values for this **WHOQOL-BREF** or for any other similar project.

## 2.6 Payment

### 2.6.1 Royalty fees (Authors)

The use of the **WHOQOL-BREF** is free of author's royalty fees.

### 2.6.2 Distribution fees (UNIVERSITY OF WASHINGTON)

The use of the **WHOQOL-BREF** in studies is not subject to a distribution fee.

### 2.6.3 Invoicement

For the use of the **WHOQOL-BREF**, this completed user agreement shall suffice as invoicement.

## 3. Copyright Infringement

The **WHOQOL-BREF** was developed by the World Health Organization at The University of Washington. The World Health Organization holds copyright over the WHOQOL and all its present and future translations. Each new translation will be made available to third parties once it is available, through the World Health Organization, under the conditions described in the present document.

If, at any time during the term of this agreement, « User » learns of any infringement by a third party of any Intellectual Property Rights in connection with the **WHOQOL-BREF**, « User » shall promptly notify UNIVERSITY OF WASHINGTON. UNIVERSITY OF WASHINGTON shall notify such infringement to **Authors**. **Authors** will decide to institute or not proceedings against the infringing party.

## 4. Confidentiality

All and any information related to the **WHOQOL-BREF** including but not limited to the following: information concerning clinical investigations, creations, systems, materials, software, data and know-how, translations, improvements ideas, specifications, documents, records, notebooks, drawings, and any repositories or representation of such information, whether oral or in writing or software stored, are herein referred to as confidential information. Likewise, any information provided by User to **Authors** relating to this Agreement, including information provided in this Agreement, shall be treated as confidential information.

In consideration of the disclosure of any such confidential information to the other, each party agrees to hold such confidential information in confidence and not divulge it, in whole or in part, to any third party except for the purpose specified in this agreement.

## **5. Use of name**

It is agreed that UNIVERSITY OF WASHINGTON shall not disclose, whether by the public press or otherwise, the name of “**User’ or institution**”, to any third party to this agreement except to the copyright holder(s) of the **WHOQOL-BREF**.

## **6. Liability**

### **6.1 In case of breach of contract**

In the event of total or partial breach by UNIVERSITY OF WASHINGTON of any of its obligations hereunder, UNIVERSITY OF WASHINGTON’s liability shall be limited to the direct loss or damage (excluding loss of profit and operating losses) suffered by “User” as a result of such breach and shall not include any other damages and particular consequential damages.

### **6.2 In the scope of the use of the “Questionnaire”**

Under no circumstances may **Authors** or UNIVERSITY OF WASHINGTON be held liable for direct or consequential damage resulting from the use of the **WHOQOL-BREF**.

### **6.3 In the event of non-renewal of this Agreement**

In the event of non-renewal of this Agreement by UNIVERSITY OF WASHINGTON for any cause or failure by UNIVERSITY OF WASHINGTON to conclude a new agreement with “User” upon the expiry of this Agreement, UNIVERSITY OF WASHINGTON will have no liability for payment of any damages and/or indemnity to “User”.

## **7. Term and termination**

This agreement shall be effective as the date of its signature by “User” and shall continue for a term of 10 (ten) years at least or until the term of the study above mentioned in SUMMARY OF THE STUDY.

Either party may terminate this Agreement immediately upon providing written notice to the other party in the event of: (a) the other party’s unexcused failure to fulfil any of its material obligations under this Agreement or (b) upon the insolvency or bankruptcy of, or the filing of a petition in bankruptcy or similar arrangement by the other party. User may terminate this Agreement for any reason upon 90 days written notice.

Upon expiration or termination of this Agreement UNIVERSITY OF WASHINGTON may retain in its possession confidential information it acquired from **WHOQOL-BREF** while under contract. The obligations which by their terms survive termination, include,

without limitation, the applicable ownership, confidentiality and indemnification provisions of this Agreement, shall survive termination.

### **8. Assignment**

This Agreement and any of the rights and obligations of “User” are personal to the “User” and cannot be assigned or transferred by “User” to any third party or by operation of law, except with the written consent of UNIVERSITY OF WASHINGTON notified to “User”.

### **9. Separate Agreement**

This Agreement holds for the above mentioned study only. The use of the **WHOQOL-BREF** in any additional study of the “User” will require a separate agreement **without additional fees, unless significant updates have been added to the user manual (new edition, etc.)**.

### **10. Entire Agreement, Modification, Enforceability**

The entire agreement hereto is contained herein and this Agreement cancels and supersedes all prior agreements, oral or written, between the parties hereto with the respect to the subject matter hereto.

This Agreement or any of its terms may not be changed or amended except by written document and the failure by either party hereto to enforce any or all of the provision(s) of this Agreement shall not be deemed a waiver or an amendment of the same and shall not prevent future enforcement thereof.

If any one or more of the provisions or clauses of this Agreement are adjudged by a court to be invalid or unenforceable, this shall in no way prejudice or affect the binding nature of this Agreement as a whole, or the validity or enforceability of each/and every other provision of this Agreement.

### **11. Governing law**

This Agreement shall be governed by and construed in accordance with the laws of the State of Washington. Any disputes will be adjudicated first through the UNIVERSITY OF WASHINGTON and subsequently through courts in the State of Washington.

Acceptance of Terms of User Agreement:

I have read and agree to the terms listed in the user agreement above.

You have completed the user permission form for the WHOQOL-BREF and are now free to download the instrument and scoring information at <http://depts.washington.edu/yqol/WHOQOL-BREF>

Thank you for your interest in the WHOQOL-BREF!

