

Patient Education and Medication Adherence in Chronic Obstructive Pulmonary Disease:
The Effects of Education Related To Exacerbation Events

Submitted by

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GRAND CANYON UNIVERSITY

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Abstract

The purpose of this direct practice improvement project was to identify if an educational intervention regarding medication adherence would decrease exacerbations events 30 days post intervention compared to 30 days pre intervention, in 60-80 year old patients with chronic obstructive pulmonary disease (COPD). Thirty-one patients participated in this project and the Morisky Medication Scale-8 (MMAS-8) was used to determine patient's adherence. McNemar's chi-squared analysis was calculated to compare pre and post exacerbation events and statistical significance was noted for a decrease in exacerbation post educational intervention ($p = .049$). Pearson's chi-squared analysis was calculated for age, gender and level of education regarding medication adherence. Statistical significance for age was noted ($p = .029$) regarding patient's stopping medication because it made them feel worse (older elders [71-80 years of age] were significantly higher). Clinical significance was obtained regarding gender ($p = .056$) and stopping medications because patients felt better and females were found to have a greater incidence in this area than males (females: 93.8% and males, 66.7%). There were no statistically significant findings regarding medication adherence and level of education. Imogene King's Theory of Goal Attainment guided this project.

Keywords: adherence, COPD, chronic obstructive pulmonary disease, exacerbations, non-adherence, pharmacotherapy

Dedication

This project is dedicated to my loving husband, Noah, who always knew I could, to my children, Joseph and David, who have learned that a mommy is many things and working hard gets you to live your dream, and to my parents whom I know would be beyond proud.

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Chapter 1: Introduction to the Project

Managing chronic illnesses can be challenging for both patient and practitioner. The goals of management for any chronic illness are to control the disease and its symptoms, in order to limit declining health status, maintain quality of life and produce optimal outcomes. However, there are challenges that present barriers to care for both the patient and the provider that require consideration when caring for patients with chronic illnesses. Medication non-adherence is a factor that plays a substantial role in the challenges faced by the patient and the provider.

The literature is abundant with the various causes of chronic obstructive pulmonary disease (COPD) exacerbations; however, non-adherence to pharmacotherapy is a common cause and is a crucial aspect of treatment and the course of disease. The focus of this project was to determine if patients who are non-adherent to medication therapy for COPD will have a reduction in COPD exacerbations 30 days post educational intervention.

Patient education is a foundation of nursing science, particularly now, as health care is evolving to have a greater focus on out patient management. This practice improvement project focused on patients with COPD who are non-adherent to pharmacotherapy and used the teach-back technique to educate patients on the importance of adherence. Once the educational intervention occurred, each patient's status was monitored to determine if exacerbation of COPD resulted during the 30 days post intervention. The chapter will also include highlights of the project's methodology and design and discuss how the project could contribute to advancing scientific knowledge. Lastly, terms were defined

and acknowledgement of assumptions, limitation and delimitations associated with this project were noted.

Background of the Project

COPD is a chronic and progressive illness that causes airway obstruction, inflammation and limits airflow, which are the catalysts for subsequent respiratory symptoms, known as exacerbations (Bentsen, Rokne, & Wahl, 2012). COPD and its exacerbations can be a serious detriment to a patient's morbidity and mortality. Therefore, pharmacological management of this chronic illness is key in maintaining health status, quality of life and lung function. Pharmacotherapy is a cornerstone in the management of COPD and requires that the patient and provider remain in concert with the goals of treatment.

Medication adherence is suspect for older patients with COPD, as disease duration is usually longer and risks of comorbidities, adverse side effects, and polypharmacy are contributory to non-adherence (Khodour, Hawwa, Kidney, Smyth, & McElnay, 2012). Non-adherence leads to suboptimal outcomes and is a detriment to health status, health related quality of life, and overall morbidity and mortality. It also contributes to increased utilization of health care resources like increased provider and emergency room visits and hospital admissions (Khodour et al.).

Health literacy is the degree to which an individual can obtain, process and understand health information required to facilitate appropriate health choices (Sewell & Thede, 2013). It has been noted that more than 89 million Americans have insufficient ability to effectively understand and complete medical treatments and participate in their health care (Tamura-Lis, 2013). Subsequently, health literacy has been noted to have a great

deal of impact on medication adherence (Tamura-Lis). Poor health literacy is major component that is predictive of poor health and poor health outcomes (Sewell & Thede). Therefore, patients' understanding of how to take their prescribe medication is an important factor in medication adherence and is equally important assessment by the provider.

Problem Statement

It is not known to what degree the use of teach-back technique, as an educational intervention in patients 60-80 years of age with COPD, will affect the number of exacerbations that occur during the 30 day period post education. It has been clearly identified in the literature that COPD is a chronic illness that is progressive and without a cure (Fromer, 2011). Management of COPD requires adherence to pharmacotherapy to slow progression of disease and decrease exacerbation events that worsen respiratory symptoms, which effect morbidity and mortality. Exacerbation of COPD is the leading cause of hospital admissions in older adults and is the cause of 120, 000 deaths per year in the United States (Schnell et al., 2012). It is predicted that in 2020 it will be the 3rd most common cause of death in the United States (Schnell et al.). Because of the unpredictability of COPD exacerbation, it is often difficult to treat and is often unreported and untreated (Berkoff et al., 2014). Therefore, health status deteriorates quickly due to disease progression and can end in repeated hospitalizations and sometimes death (Berkoff et al.). Moreover, this causes a significant economic burden and impact on society regarding utilization of health resources and on patient quality of life due to sub optimal outcomes (Pasquale, Sun, Song, Hartnett & Stemkowski, 2012). For hospitals, reimbursement issues continue to mount as Centers for Medicare and Medicaid have now

established 30-day readmission penalties under the Affordable Care Act (Tiep, Carlin, Limberg, & McCoy, 2015). Tiep et al. (2015) also note that health literacy can affect patient's understanding of their diagnosis and treatment and those who are health literate have better compliance in treatment and outcomes.

This project will contribute to solving the issue of medication non-adherence and increased exacerbations by helping to identify how education can foster patient's understanding of their pharmacotherapy and afford positive patient outcomes. This project will also focus on educating patients regarding their COPD medication adherence and look to determine if decreased exacerbations occurred post education.

Purpose of the Project

The purpose of this quantitative pretest-posttest project was to ascertain if an educational intervention using teach-back technique would decrease COPD exacerbations over a 30-day period post intervention compared to 30 days pre educational intervention. This project focused on COPD patients 60-80 years of age followed as outpatients in a private pulmonary practice located in south Florida.

Age was defined by date of birth and gender will be defined as male or female. Level of education was noted as elementary school, high school, college and graduate education. Adherence was measured by using the Morisky Medication Adherence Scale-8. The number of exacerbations were measured pre and post educational intervention and data was obtained from the patient's medical record. Exacerbation was defined as any change in respiratory status that required an intervention by a healthcare provider via telephone, office visit, emergency department visit and/or hospital admission.

Exacerbations that occurred during the 30 days prior to and the 30 days post-educational intervention were noted.

This project will contribute to nursing science the best practices that will foster self-management and patient centered care in patients with COPD. It will also provide understanding of the importance of education and its impact on patient adherence to pharmacotherapy, which is an essential component in the management of COPD.

Clinical Question

The question posed is in regards to COPD patients, 60-80 years of age who are non-adherent with their medication regimen. Does the use of teach-back technique decrease the number of exacerbation events during a 30-day period post educational intervention as compared to the 30-day period prior to using the teach-back technique? Patients with COPD may have many contributing factors that lead to medication non-adherence. This project hoped to associate educational intervention regarding medication non-adherence using the teach-back technique and the number of exacerbations that occur during the 30 days pre and 30 days post educational intervention. This project also aimed to discover if there is an additional correlation between age, gender, race and level of education and exacerbation events pre and post educational intervention.

Advancing Scientific Knowledge

COPD is a leading cause of morbidity and mortality globally and is often managed sub-optimally (Wortz et al., 2013). With the current and continued growth of the aging American population, coupled with the recommendations from the Institute of Medicine to provide patient centered, self-managed care, understanding best practices that will facilitate the best patient outcomes is crucial in the delivery of care in patients with

chronic illnesses like COPD (Wortz et al.). There is no cure for COPD but as with all chronic illnesses, the objective is to focus on healing (Rubenstein, Gross, Hulton, Strang & Wasserbauer, 2014). Goals of care associated with chronic illness are consistent with maintaining or improving self-care capacity, effective disease management, prevention of complications, delay deterioration and decline of the patient, and achievement of the highest quality of life (Rubenstein et al.).

Self-management requires patients to have educational and supportive interventions by providers, which allow patients to increase and improve their skill in managing their illness (Wortz et al., 2013). Self-management is evident when discussing medication adherence and patient education. In order for patients to achieve medication adherence, a process that includes behavioral changes, regular follow-up, problem solving and goal setting must occur (Wortz et al.). The literature is rich in describing how education fosters patient's self-management to maintain these care goals.

The gap in the literature regarding how patient education plays a role in medication adherence and subsequent decrease in exacerbation events remains an important aspect of patient care that should be considered, particularly regarding goals of care, treatment and outcomes. Lareau and Hodder (2012) explain that poor adherence to pharmacologic treatment in COPD patients, particularly in the elderly, leads to increased morbidity and decreased quality of life for patients. Therefore, it is important for providers to evaluate, reassess and educate patients to improve outcomes (Lareau & Hodder). Gellad, Grenard and Marcum (2011), performed a systematic review regarding medication adherence in the elderly. The authors noted that there were few studies that addressed non-financial barriers to medication non-adherence in the elderly. Moreover, the authors concluded that

education of patients regarding their disease process could help minimize counterproductive behavior and promote treatment adherence (Gellad et al.). This project will address the need in practice to educate COPD patients regarding non-adherence to pharmacotherapy, by utilizing the teach-back method to decrease in the overall number of exacerbation events over a 30-day period.

The self-management approach to care aligns closely with Imogene King's Theory of Goal Attainment (TGA). King's TGA explains that the nurse, the patient and the environment all interact and impact patient and provider outcomes (University of the Philippines, 2011). Additionally, goal setting is a key element in assuring optimal outcomes for patients with chronic illness. Therefore, this project hoped to demonstrate that educational efforts that are geared to meet patient needs and engage both patient and provider in methods to address medication adherence will be accomplished with the use of King's theory. Medication adherence is a significant factor in patients with COPD to produce successful outcomes. However, mutual recognition of adherence issues by the patient and the practitioner is equally important in goal setting. Identifying possible issues associated with medication adherence and providing subsequent education for patients, allow the patient and the practitioner to set goals directed towards adherence and potentially lead to improved outcomes. King's TGA develops a framework to establish mutual goals between the patient and the practitioner, resulting in patient self-management, empowerment and satisfaction. King's theory is significantly relevant for this project simply because the onus is on patient needs and preferences regarding care but also strives to encompass a collaborative relationship between the patient and the provider (Caceres, 2015). This project will advance the TGA because it will provide an

understanding the how the nurse/patient relationship is an important factor in patient education and subsequently, positive patient and provider outcomes. It was also demonstrate that goal achievement can occur with empowering patients with knowledge that is meaningful and understandable to them.

Significance of the Project

This practice improvement project will be significance if a positive significance is noted between education and decreased exacerbation events. This will support critical importance in the relationship between patient education and positive patient outcomes. It also confirms the patient-provider relationship and its effects on patient outcomes are a part of patient success. Moreover, this project's focus supports the continued movement towards patient centered care and self-management in the care of COPD, which stems from patient education.

Patient education is an indispensable component of self-management and causes changes in patient behavior due to knowledge, which results in improved patient outcomes that are related to quality of life and health status (Kaptein, Fischer, & Scharloo, 2014). Using evidence-based practices, like teach-back, will facilitate educational approaches that encourage patient decision-making and self-management. This is an important consideration in the provision of care for those with chronic illnesses like COPD. It is also imperative for nurses to understand and develop best practices to enhance patient care beyond the acute care setting in order for patients to thrive in the community. This project will present data that will continue to support the use of patient

education, which is a cornerstone in nursing, and show that positive clinical outcomes can be the result of patient education.

This project aligns with other research because it stresses how education regarding medication adherence can improve outcomes in COPD patients. Shrestha et al.(2015) investigated patient adherence patterns in the management of COPD and factors that affected adherence to prescribed treatment. The authors found that non-adherence to treatment regimens can be affected by patient's poor understanding of their illness and medication adherence. Additionally, Gellad et al. (2011) performed a systematic review regarding medication adherence in the elderly. Among the findings noted, the authors found that educating patients promoted medication adherence in this population and improved patient outcomes.

Rationale for Methodology

The goal of this project was to determine if an educational intervention, using teach-back technique, influenced changes in behavior regarding medication adherence and therefore, decreased COPD exacerbation events. The quantitative data provided statistical evidence to determine if the post educational intervention decreased exacerbation events. There is also correlational data to determine if age, gender, and level of education influenced exacerbation events. Use of the MMSA-8 determined patients' adherence levels and further data analysis explored if level of adherence affected the number of exacerbation events.

Quantitative methods are based on something that can be exactly measured and uses numbers and statistics as a basic element of analysis (University of Wisconsin Madison, 2015). Components of quantitative methods are considered objective, and use deductive

reasoning to synthesize data that has a concise and narrow focus (University of Wisconsin Madison). Additionally, statistical analysis of the results yields a broad answer that can be discussed, published and can lead to further research (Shuttleworth, 2009).

Nature of the Project Design

A pretest-posttest design will be utilized for this project. This type of design is primarily used for the purpose of comparing groups and/or measuring change resulting from experimental treatments (Dimitrov & Rumrill, 2003). This approach was selected because observations pre and post educational intervention will be made regarding the number of exacerbation events of one group. With the pretest-posttest design there is more structure because there is only one group being observed and careful measurement is done before applying the intervention and then once again measured after the intervention occurs (Dartmouth University, n.d.).

Patients between 60-80 years of age, followed by a private pulmonary office in south Florida, who were diagnosed with COPD, completed the MMAS-8 to determine adherence or non-adherence to medication therapy. Once patients were deemed non-adherent, patients were taught the importance of medication adherence, using teach-back technique, and were followed 30 days post intervention, to determine the number of exacerbations experienced. This was compared to the number of exacerbations experienced by patients during the 30 days prior to educational intervention.

Demographic data that included age, gender and level of education was also correlated with non-adherence.

Definitions of Terms

This project used the following terms operationally. Defining these terms allowed for better understanding by the reader.

Adherence. The act of doing what is required by rule or belief (Merriam-Webster Dictionary, 2015). For the purpose of this project adherence relates to consistently taking medication as prescribed.

Chronic obstructive pulmonary disease (COPD). Chronic obstructive pulmonary disease is a lung disease categorized by chronic obstruction of airflow that interferes with normal breathing and is not curable and is progressive in nature (World Health Organization, 2016).

Exacerbation. Exacerbation is deterioration of COPD that manifests with worsening respiratory symptoms that include shortness of breath, wheezing, increase of phlegm and/or cough (American Thoracic Society, 2015). For the purpose of this project, exacerbation will be identified via telephonic triage, urgent office visit, emergency department visit and/or a hospital admission. Any one of these occurrences will be considered one exacerbation.

Health literacy. Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions (U.S. Department of Health and Human Services, n.d.).

Health related quality of life (HRQoL). The functional effect of a medical condition and/or its consequent therapy upon a patient and encompasses physical and occupational

function, psychological state, social interaction and somatic sensation (International Society for Quality of Life Research, 2016).

Level of education. The progression from very elementary to more complicated learning experience (Stack Exchange, 2015).

Non-adherence. The act of not doing what is required; lack of adherence (Merriam-Webster Dictionary, 2015). For the purpose of this project, non-adherence is considered not taking medication as prescribed, for any given reason. This includes forgetting, choosing to stop, not taking according to the healthcare providers order, including dosage and times per day.

Patient centered care. Patient centered care is care that is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions where clinicians and patients work together to produce the best outcomes possible (Barry & Edgman-Levitan, 2012).

Pharmacotherapy. Treatment of disease by means of drugs (MediLexicon, 2016).

Self-management. Self-management has been defined as “the systematic provision of supportive interventions designed to increase patients’ skills in decision making, problem solving, utilizing resources, and taking action” (Young, et al., 2015, p 1043).

Teach-back technique. A way for the healthcare provider to ensure patients understand aspects of their medical care and treatment by asking patients to explain, in

their own words, and re-teaching until the patient is able to fully grasp concepts (Teachbacktraining.org, 2016).

Assumptions, Limitations, and Delimitations

Assumptions. There were many assumptions noted by the investigator. It was assumed that the diagnoses made by the physicians were correct and were recorded correctly in the chart and the patient population in the project required education regarding medication adherence. It was also assumed that those patients who participated in this project did not understand the importance of medication adherence in relation to COPD and were non-adherent with their medication regimen for COPD due to lack of education. It was assumed that exacerbations are related to medication non-adherence. Lastly, it was assumed that this population represents the current situation in south Florida.

Limitations/delimitations. Limitations included the fact that the sample size was small and the use of a convenience sample could be subject to selection bias. The number of patient's that came to the office with a diagnosis of COPD during the time of the project was not controlled or predetermined by the investigator. The stage of disease, length of diagnosis and comorbidities were not considered and could reflect bias due to concomitant medication or concurrent disease (Indrayan, 2012). The participants may have experienced the Hawthorne effect, and responses of participants may have been biased, as they knew they are being studied (Indrayan). Participants smoking history, race and comorbid conditions were not considered and could be reflective of alternate causes of non-adherence. This data can be generalized to older Americans with COPD but may be difficult to generalize to younger populations. The possibility of missed events could

have occurred and may not reflect exact numbers of pre and post educational exacerbation events. This could have been a result from patients being treated at different hospitals, failure to report incidents to staff/physicians and failure of staff/physicians to document events. Lastly, exacerbations that did occur could also be contributed to other factors other than non-adherence to medications, like comorbid conditions and disease progression.

Summary and Organization of the Remainder of the Project

This chapter has detailed how chronic obstructive pulmonary disease is a progressive and pathological condition of the respiratory system, effecting millions worldwide. COPD and its subsequent exacerbations cause decreased quality of life and health status, and is a huge contributing factor to patient's morbidity and mortality, particularly when pharmacotherapy is suboptimal (Bettoncelli et al., 2014). Pharmacological management is an essential component of care for this patient population, however, as with any chronic illness, non-adherence can be a barrier that can have a negative impact on patient outcomes (Lareau & Hodder, 2014). Negative patient outcomes can be costly and lead to poor resource utilization and economic strain on the healthcare infrastructure (Pasquale et al., 2012). Additionally, health literacy can also influence non-adherence to pharmacotherapy. Patients with poor health literacy, particularly those with chronic illness, have been shown to demonstrate worse symptom management, have lower health status and are less likely to self-manage their care and comply with treatment recommendations (Sadeghi et al., 2103). However, patients that have been exposed to enhanced education for medication adherence have been noted to benefit from the intervention (Sadeghi et al.). Therefore, assessing medication adherence and re-educating

patients who are deemed non-adherent may be a factor in optimizing outcomes for patients.

The aim of this project was to use quantitative methods to identify patients with COPD who are non-adherent in their pharmacotherapy for their disease management. Once identified, patients were educated using the teach-back method. Post education, the number of COPD exacerbations were noted for 30 days and compared to the number of exacerbations experienced during the 30 days pre-education, utilizing the pretest-posttest design. Correlational data analysis examined age, gender, race, and level of education to understand if relationships existed regarding adherence and exacerbation events.

The following chapters will provide an in depth understanding of this project improvement and its process. Chapter two will present a current review of the literature that will highlight factors that are pertinent in COPD management. Discussion will include the various causes of exacerbation, the role pharmacotherapy plays in treatment of COPD, the economic consequences regarding utilization of resources and the burden of COPD exacerbation and lastly, the impact of health literacy and education on COPD and exacerbation. Chapter two will also discuss the principles of Imogene King's Theory of Goal Attainment and how it will be utilized to guide this project improvement.

Chapter three will describe the methodology process of this project. Discussion will include statement of the problem, the use of quantitative methodology and the use of the pretest posttest design for data analysis. It will also provide details regarding the population and sample and will include how the data was gathered for this investigation and the steps that lead to the implementation of this project. Lastly, Chapter Three will discuss ethical considerations and limitations and assumptions of this project. Chapter

Four will provide detailed information on data analysis. This information will discuss the types of analysis used and report the results of this project. It will include written and graphic summaries. Lastly, Chapter 5 will interpret findings of this project and provide discussion of how the findings are relevant in current literature and practice. It will also provide how these results may impact nursing and clinical practice and will make recommendation for practice and further research areas.

Once IRB approval was obtained, the gathering of patients for the project improvement began in April 2016. All data were collected by April 2016, and was followed by data analysis. As of May 2016, the project was completed and was ready to be presented and defended.

Chapter 2: Literature Review

Medication adherence is crucial to the management of chronic illness, especially those with chronic obstructive pulmonary disease (COPD) (Scullion, 2010). Although COPD cannot be cured, appropriate management with pharmacotherapy can slow disease progression, reduce frequency of exacerbation and improve patients' overall quality of life (Blanchette, Gross & Altman, 2014). In order for pharmacotherapy to be affective, medications must be taken as prescribed. According to the World Health Organization, approximately 50% of the general population are adherent to treatment for chronic disease (Clyne et al., 2011). Patient adherence to treatment in COPD management is considered crucial in optimizing disease management. Poor adherence is commonly seen in this patient population and yields outcomes associated with increased morbidity and mortality (Scullion, 2010). COPD is a chronic and difficult condition that worsens over time; therefore, adherence to treatment is necessary to enhance quality of life, and co-morbidity (Bettoncelli et al., 2014). The purpose of this project was to ascertain if an educational intervention using teach-back technique decreased COPD exacerbations over a 30-day period post intervention compared to 30 days pre educational intervention.

This chapter will provide an overview of COPD, its effects globally and in the United States and identify those at greater risk. Further discussion will focus on the aging population and COPD and challenges faced by this patient population including aspects of disease burden, non-adherence and health literacy. Additional discussion will address causes of COPD exacerbations, the importance of pharmacotherapy in the management of COPD, the economic burden the COPD causes to healthcare and utilization of health care resources and how health literacy effects outcomes. Each of these themes will

support the association with poor medication adherence and the benefits of patient education as an intervention, using the teach-back, to increase adherence and decrease morbidity associated with exacerbation. The use of Imogene King's Theory of Goal Attainment provided the framework to note that patients and providers who recognize and reach mutual goal attainment will likely result in the attainment of successful outcomes regarding medication adherence including overall health and quality of life in those with COPD.

To identify appropriate studies to support how education regarding medication adherence influences COPD exacerbations, an extensive literature search was done using Google Scholar and Grand Canyon University Library (GCU) databases. The use of GCU's library database included CINAHL, Cochrane Library, Joanna Briggs Institute, OVID, Pro Quest Nursing and Allied Health Source, and PubMed. This literature search used peer reviewed articles published from 2010 to 2015, and included search words of COPD, chronic obstructive pulmonary disease, COPD and the elderly, COPD and the elderly morbidity and mortality, COPD exacerbations, COPD exacerbations and medication adherence, COPD exacerbations and the elderly, teach-back and COPD, teach-back and medication adherence, medication adherence, pharmacotherapy and health literacy.

Background of the Problem

Chronic obstructive pulmonary disease (COPD) is a global health care concern that has proven to have significant impact on morbidity, mortality and healthcare resources (Sadeghi, Brooks, Stagg-Peterson, & Goldstein, 2013). It is currently estimated that more than 3 million people succumb, worldwide, to COPD, with men and women being

equally affected (World Health Organization, 2015). According to the COPD Foundation (2015), COPD affects over 24 million Americans and in all 50 states.

Since 2008, COPD has been deemed the third leading cause of death in the United States and is the only disease that has shown to have an increasing rate regarding those affected (Blanchette et al., 2014). The CDC reports that 15 million Americans have been diagnosed with COPD and more than 50% of adults with COPD were unaware of their diagnosis, indicating that actual numbers of those affected may be higher (Centers of Disease Control and Prevention (CDC), 2015). Those most at risk for COPD are Caucasians, women, older adults, individuals with lower educational levels, those in a lower socioeconomic status, and former and current smokers (CDC).

COPD is characterized as a progressive, irreversible disease process that is associated with airflow limitation related to an abnormal inflammatory response of the lungs (Suissa, Dell'Aniello, & Ernst, 2012). According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, patients that exhibit dyspnea, chronic cough or sputum production or have a history of exposure to risk factors like smoking or air pollutants are likely to have a diagnosis of COPD (DiBonaventura et al., 2012).

As the U.S. population ages, there is an expected substantial growth of older Americans between 2012 and 2050. The projected estimate of those 65 and older by 2050 is 88.7 million, which is double the 43.1 million in 2012 (Ortman, Velkoff, & Hogan, 2014). As of 2013, 3.4 million persons celebrated their 65th birthday, having an average life expectancy of an additional 19.3 years (Administration for Community Living, 2012). It is likely that the COPD burden will become more evident in this population with time. The Centers for Disease Prevention and Control (2015) reports that adult COPD

patients are more likely to not be able to work, face activity limitations and use special equipment compared to their counterparts without COPD.

Exacerbation of COPD is characterized by worsening symptoms associated with COPD (dyspnea, mucous production, cough and/or wheeze) and requires immediate medical attention. COPD exacerbations are key factors in disease evolution, functional decline, health care utilization and cost burden (Fromer, 2011). The aim of COPD management is early identification of these symptoms and provide care that is proactive that includes maintenance pharmacotherapy to reduce exacerbation events, and decrease the physical and resource utilization associated with exacerbation (Fromer).

Exacerbation events cause progression of disease, particularly as exacerbations become more frequent (Anzueto, 2010). Frequent exacerbation (two or more per year) increases dyspnea, reduce exercise capacity and have proven to have a greater decline in health status for patients (Anzueto). There is an increased risk of morbidity, particularly related to poor adherence to treatment in COPD (Scullion, 2010). It has also been noted that the more severe the exacerbation the longer the recovery time, causing patients to experience further deterioration in health and quality of life over time (Anzueto, 2010).

Medication adherence is a key part of COPD management that not only manages symptoms but also provides patients the ability to maintain quality of life and decreased morbidity and mortality associated with COPD (Scullion, 2010). The elderly are most susceptible to non-adherence due to factors associated with aging, gender, co-morbidities, patient and provider relationship, socioeconomic factors, complexity of treatment and health literacy (Albertson, Harper, Murin & Sandrock, 2015). The cause of non-adherence is multifaceted and its burden is evident in both the patient and in resource

utilization. According to the National Heart, Lung and Blood Institute, the economic burden to the U.S. healthcare system regarding utilization of resources for this population is estimated at \$29.5 billion dollars annually, with \$13.2 billion spent on hospital care, \$5.5 billion spent on provider services and \$5.8 billion spent on pharmacotherapy (Pasquale, Sun, Song, Hartnett, & Stemkowski, 2012).

Non-adherence is associated with two types of behaviors called intentional and non-intentional non-adherence (Bryant et al., 2013). Intentional non-adherence is purposeful cessation or decrease in use of therapy during symptom remissions and is often related to mistaken interpretation of the disease and the objectives of treatment (Bryant et al., 2013). Unintentional non-adherence refers to patients that do not adhere to treatment due to circumstances beyond their control, like cognitive issues, physical disabilities, and complicated polypharmacy schedules (Bryant et al.).

Health literacy is a major factor associated with non-adherence in pharmacotherapy. The World Health Organization defines health literacy as the “cognitive and social skills that determine the motivation and ability of individuals to access, understand and use information to promote good health” (Sadeghi et al., 2013, p 73). This would include the aptitude to read text and numerical information and evaluate material for health-related conditions (Sadeghi et al.). In the United States, half of the adult population has low health literacy, which is associated with poor health outcomes (Sudore & Schillinger, 2009). Health literacy presents a greater challenge in older adults secondary to issues with cognition and polypharmacy (Sudore et al.). It is crucial to detect non-adherence in patients with COPD, and equally important to determine health literacy in patients in order to maintain adherence to pharmacotherapy. Since the goals of pharmacotherapy are

to reduce decay of lung function, severity and number of exacerbation events and number and length of hospitalizations (Bettoncelli et al., 2014), education can be tailored to the patient to meet the needs for successful management of COPD. The elderly and those with chronic illnesses are more likely to be in poorer health when health literacy is an issue (Sadeghi et al).

The teach-back technique has been established as an effective method to educate and engage patients and clarifies the learner's perception of instructions by identifying gaps in understanding (Peter et al., 2015). Using teach-back, patients and providers are engaged in their learning and patients are asked to explain or demonstrate learning after instruction (Dantic, 2014). If the patient is unable to provide appropriate understanding, they are re-educated until mastery occurs, allowing effective self-management for patients with COPD (Dantic). Teach-back has been found to be a valuable and effective resource when counseling patients with varying literacy levels (Betts, 2013).

Theoretical Foundation/Conceptual Framework

Imogene King's Theory of Goal Attainment (TGA) will be the conceptual framework used to guide this direct improvement project. King's theory was developed in the early 1960s and its focus was to describe patient growth within a dynamic and interpersonal relationship to attain certain goals (Pretiprin, 2015). Moreover, King's focus was to cultivate a framework that would be the basis of a theory to emphasize the *why* of nursing (Caseres, 2015). Additionally, King's TGA is composed of three interacting systems that are called personal (individual), interpersonal (provider and patient) and social (society that includes family, work, church) (University of the Philippines, 2011). Each interacting system contains concepts that embody each system. King (2007) explains that

the interaction of the individuals within the systems demonstrates the interactions of humans in their social world and these systems do not change.

The personal system concepts include perception, self, growth and development, body image, space and time. These are fundamental in understanding a human being's response to events, however, perception is considered pinnacle as it navigates behavior of the individual (Gonzalo, 2011). According to King, individual perception of self, body image, time and space influences responses and an individual's growth and development over their lifespan affects their self-perception. The following, noted by The University of the Philippines (2011), highlights each concept of the personal system.

- Perception: a method of systematizing, understanding and transforming information that represents one's reality and influences behavior
- Self: a combination of thoughts and feelings that make up a person's awareness of self
- Growth and Development: changes that occur in human beings that are related to genetic and life experiences which permit one to move toward maturity
- Body Image: how one sees self
- Time: the time between one event and another event
- Space: the physical area called territory that exists in all directions
- Learning: acquiring information

The interpersonal system concepts include interactions, communication, transaction, role and stress (Gonzalo, 2011). The University of the Philippines (2011) explains the concepts of interpersonal systems as follows:

- Interactions: two or more persons (dyads, triads and four or greater are small or large group) engaged in reciprocated verbal and nonverbal activities that are goal oriented
- Communication: the way human relationships develop and are sustained
- Transaction: The process where communication between humans achieve goals
- Role: the actions that are usual of a person within a social system
- Stress: human interaction with the environment that retains equilibrium for growth, development and performance. Energy and information exchange occurs to sustain regulation and control of stressors amid the person and environment
- Coping: How to manage stress

The transaction process will not change, however, the ways in which communication and interaction occur does change because of multiple technologies available (King, 2007). However, the transaction process helps individuals and groups set goals that lead to outcomes that represent quality care and evidence based practice (King).

Lastly, the social system demonstrates how the nurse interrelates with others, including the patient. Those who are part of the relationships share common objectives, principles and interests and institute the guidelines of conduct and action that maintain

values and roles (University of the Philippines, 2011). The concepts of the social system as described follows:

- Organization: Made up of humans with specific functions and positions who utilize resources to achieve personal and organizational goals
- Authority: this is a transactional course of action where members are reciprocal in accepting the authority of those within an organization
- Power: Where one or more individuals impact others in a situation
- Status: Where one is in regard to others in a group or organization
- Decision making: A process that is organized with the ultimate outcome of attaining a goal
- Control: Being in charge

A pilot study done by Choure et al. (2015), examined how to improve nurse knowledge of post myocardial infarction rehabilitation at hospitals in Indore, India through a new self-instructional module. A convenience sample of 60 nurses was recruited and answered pre and post questionnaires regarding post MI patients in cardiac rehabilitation. Post questionnaires were answered after nurses completed a self-instructional module on cardiac rehabilitation. The literature review explains that Indians are at a 3-4 times greater risk to have heart disease than Americans and myocardial infarction (MI) presents a tremendous burden on morbidity, mortality and health care resources. From a clinical perspective, patients that receive cardiac rehab have an increased likelihood to maintain their health and achieve positive outcomes. Therefore, assessing nurses' knowledge regarding cardiac rehab for post MI is crucial for patient care and outcomes. The use of Imogene King's Theory of Goal Attainment guided this

study to emphasize that mutual goal setting leads to transaction, which represent life situations where people enter as active participants and change in the process of the experience. The process of transaction leads to goal attainment.

The research found that staff nurses had significant improvement in their knowledge after the self-instructional module and found scores improved from a mean pretest score of 8.27 to a mean posttest score of 23.18 ($p > 0.0001$). There was no difference in knowledge when years of experience or education level were considered. It was concluded that educational opportunities that were taken helped nurses provide better care to patients because of their increased knowledge of current practices.

King's theory is clearly relatable to this project of utilizing education to reinforce medication adherence, with the goal of potentially decreasing exacerbation events. According to Caceres (2015), King viewed the nursing process (assessment, diagnosis, planning, implementation and evaluation) as a fundamental component to goal setting and goal-attainment in the nurse patient relationship. The nursing process determines how nurses, with their patients, prioritize, meet and sustain mutual goals that also promote patient empowerment, self-management and positive outcomes (Caceres).

King's theory supports the patient and provider as separate but interacting entities (Caceres, 2015). Understanding the rationale for patient non-adherence, the provider and patient can work together using the teach-back technique to reach the goal of patient adherence and decrease exacerbation events. Recognition of individual needs, roles, and goals is continuous and mutual in order to reach goal attainment (Caceres). TGA is unique in that it identifies there will be differences between dyads but provides the dynamics to navigate those differences via transaction in order to reach mutual goal

attainment (Caceres). Education using teach-back is a way to allow for the patient and provider to engage in the personal, interpersonal and social systems of King's theory and utilize the various concepts within each system. Although King's TGA is considered a nursing theory it can be easily used among the multiple disciplines across the healthcare continuum.

Understanding that medication adherence is key to successful patient outcomes requires recognition by patient and practitioner. Identifying potential barriers to adherence will allow the patient and practitioner to set goals to increase adherence and improve outcomes. Using the teach-back method can be an effective tool in patient adherence secondary to poor health literacy. Using King's Theory of Goal Attainment will provide a framework that will establish mutual goals and satisfaction between patient and practitioner.

Review of the Literature

Exacerbation is part of the disease process of COPD, and its root cause can be varied. Many factors are critical to consider in the management of patients with COPD. The four points discussed in this literature address potential reasons for exacerbation, the role and goals of pharmacotherapy in COPD, the economic burden related to poor medication adherence leading to progression of COPD including exacerbation, and how health literacy impacts adherence to medication regimens and patient outcomes.

Potential reasons for exacerbation. Reasons for exacerbation can vary from patient to patient. Despite these variations, exacerbation takes its toll on patients in terms of health status, quality of life and overall progression of disease (Rubenstein et al., 2014). The following studies will highlight potential causation of exacerbation and will help to

gain insight on how to better combat this issue for patients with COPD. This is pertinent to the project because exacerbation events can possibly be averted or decreased with medication adherence and health literacy regarding disease and pharmacologic interventions.

In a prospective study by Perera et al. (2007), 73 patients with a mean age of 68.3 years were recruited to assess airway and systemic inflammation in the stable, exacerbation and recovery period in COPD. The study examined airway (FEV1) and systemic markers (C-reactive protein) and their contribution to recurrent exacerbations 50 days post exacerbation event (patients were seen at time of exacerbation, prior to treatment, then at day 7, 14 and 35). It also examined the evolution of airway and systemic markers in regard to exacerbation frequency. The researchers explored if continuing exacerbation systems were related to increased inflammatory state that contributed to recurrence and non-recovery from exacerbations. The researchers looked to see if continuing exacerbation symptoms were related to increased inflammatory state that contributed to recurrence and non- recovery from exacerbations. The researchers found that exacerbation frequency is associated with impaired health status ($p=0.03$) and decreased response to therapy ($p< 0.31$), contributing to continued systemic inflammation and subsequent recurrent exacerbation. Strengths and weaknesses were not presented in this study.

A Canadian retrospective study used a healthcare database to identify patients hospitalized for the first time for a COPD diagnosis (Suissa, Dell'Aniello, & Ernst, 2011). An inception cohort of 73,106 patients was developed to examine patients with severe COPD exacerbations and their association with mortality. The patients were

captured from 1990-2005 and were followed until death or March 31, 2007. The mean age of participants was 75.4 years of age. The researches sought to describe the long-term effects of severe COPD exacerbations over time and their relationship to mortality. The study's results noted that occurrence of severe exacerbation worsened the course of disease, increased the number of successive exacerbations and subsequently after each severe exacerbation, mortality rate increased with every new exacerbation. A strength of the study was the use of an inception cohort that provided the ability to compare patients at different points in time. Limitations noted were the possibility of selection bias, lack of information regarding severity of symptoms, airflow limitation and exercise tolerance and limited inclusion to those over 55 years of age.

Wong et al. (2014) highlighted in their literature review that COPD and repeated exacerbations lead to gradual debilitation in patients and quality of life. They also discuss how self-management can improve these aspects for patients with COPD. The goal of this study was to explore perceived requirements and expectations of patients concerning lifestyle, management and adaptation of their COPD. The qualitative study with a focused group discussion, conducted in Malaysia by used a convenience sample of 18 patients and 18 physicians, to investigate unmet needs of patients with COPD that could potentially improve their quality of life. The mean age of participants was 72.3 years of age. The study's key findings were patients exhibited lack of knowledge regarding COPD, subsequent causes of COPD, and misinformed beliefs regarding COPD. Overall poor knowledge regarding COPD was noted and breathlessness was thought to be a result of large meals and not associated with the disease process. There were three noted limitations of this study. All participants were male and only expressed male viewpoints,

patients were recruited via primary and chest clinics and those patients from the chest clinic could have represented greater severity of disease and due to the qualitative nature of the study, results could not be generalized. The strength of the study was the utilization of local physicians and their views, which was not previously studied.

An additional qualitative study in Sydney, Australia by Kirby et al. (2014) explored patient's experiences to determine the extent of their integrated care when presenting to the emergency department or their healthcare provider. It also explored healthcare provider perceptions regarding patient needs. The researchers discussed in their literature review the importance of providing care that is integrated and patient centered for COPD patients. They also noted that good communication between patient and provider leads to timely care. The goal of the study was to explore patient experiences after seeking care at the emergency department or their healthcare provider to determine the extent of integrated care for their COPD.

Kirby et al. (2014) used a convenience sample of 21 patients (12 admitted and 9 not admitted) that were interviewed regarding the integration of their care and communication with their healthcare providers. The mean age of patients was 68.1 for non-admitted patients and 72.3 for admitted patients. Health care providers involved in the care of admitted patients were also interviewed but providers caring for non-admitted patients were asked to fill out an interview information sheet. The results noted that all patients reported a poor understanding of their COPD and stated their shortness of breath was not related to COPD but to asthma. A common theme was patients often attributed their shortness of breath to heart related problems and often waited to seek help for their dyspnea until they perceived it as serious enough to seek treatment. Healthcare providers

found that integration of care was adequate in the inpatient setting but acknowledged they were lacking between inpatient and outpatient settings. The limitations in this study noted that there was no general practitioner (GP) perspective regarding integration of care for COPD and that patients seeing more than one GP could be a barrier to integrative care. Patients also perceived unavailability of GP appointments on short notice and therefore may have increased hospital use for treatment.

Tsiligianni, Kocks, Tzanakis, Siafakas, and van der Molen (2014) conducted a systematic review of the literature and a meta-analysis of 171 studies to explore factors that could positively or negatively affect health status and/or quality of life in COPD patients. The researches explained that because the burden of COPD differs in patients, the Global Initiative for Chronic Obstructive Lung Disease (GOLD), which grades severity of disease, may not be the only indicator. Quality of life (QoL) is a measure to determine burden and is described as the ability of a patient to enjoy normal activities. The aim of the systematic review was to examine the literature to discuss factors that may influence COPD quality of life or health status.

Tsiligianni et al. (2014) determined that although smoking and pack years were important factors regarding health status, there were conflicting results regarding the impact of smoking and showed a weak correlation between smoking and health status. The study did show that ex-smokers and smokers had significant differences in health status regarding improvement in respiratory symptoms after smoking cessation. Weight was also a factor regarding health status in COPD patients. The study noted that both underweight and overweight patients had a decrease in health status related to dyspnea and obese patients had worsening respiratory symptoms coupled with a decrease in

exercise capacity. Limitations were noted to be the small number of studies included and some correlations made in the study could be artificial due to heterogeneity between questionnaires.

In a prospective study of 95 patients conducted by Ferrari, Tanni, Caram, Naves, and Godoy (2011) the researchers' aim was to verify predictors of health status at baseline and after three years in COPD patients. They discussed in their literature review that COPD leads to co-morbidity and affects QoL and health status, noting the purpose of these measurements is to address the wide range of effects from COPD that include both physical, emotional and psychological realms. Patients were evaluated by body composition, pulse oximetry, the six-minute walk distance, Modified Medical Research Council dyspnea scale (MMRC) and the St. George's Respiratory Scale (SGRS). The BODE (BMI/airflow obstruction/dyspnea/exercise capacity) index was also calculated and the GOLD standard was used in staging disease (stage I: mild disease and stage IV: severe disease). The study found that patients with increase in stage of disease demonstrated poorer results on both the BODE index and the SGRS indicating greater symptoms associated with exacerbation ($p < .0001$). Limitations of the study noted that evaluations of depression and anxiety were not included, despite knowing that psychological factors have important impact on COPD patients and therefore could have influenced results.

A cross-sectional observational study by Chiu et al. (2014) studied 1,054 patients over a 6-month period to identify beliefs or behaviors related to treatment adherence and to assess the association between asthma control and adherence. The review of literature discussed the importance of medication adherence to decrease disease burden in asthma

and how patient perceptions of disease and treatment play a significant role in adherence. They continue to note that the understanding of these perceptions is crucial for healthcare providers to achieve positive outcomes for their patients regarding treatment and overall outcomes. The population of patients studied ranged from 18 years and older and were on maintenance inhaler therapy for their asthma. Patient data was obtained by questionnaires that consisted of a 12-item Likert questionnaire regarding beliefs and behaviors of patients. The additional questionnaires were the eight point Morisky Medication Adherence Scale (MMAS-8) to assess medication adherence, the Asthma Control Test (ACT) which assess level of asthma control in the previous 4 weeks of visit and lastly, the Standardized Asthma Quality of Life Questionnaire (AQLQ-S), to assess quality of life during previous 2 weeks of visit. The researchers reported that although 72.5% of the study population reported they understood their disease well, 35.7% were unsure about the effectiveness of their inhalers and 32.8% found that taking medication more than once daily was inconvenient. The study also noted that 39% of the subjects reported apprehension regarding using their inhaler in public and 25 % preferred oral medication. The research concluded patients with better asthma control had significantly better clinical outcomes, as they were more compliant with their treatment, had better understanding of their disease and subsequently had less exacerbations ($p= 0.001$).

Study limitations were reported as having a small population and data regarding medication adherence, asthma control and quality of life were self-reported and collected in one visit, which may be a cause for recall bias (Chui et al., 2014). Additionally, no health literacy assessment was performed to understand if patients fully understood the

questionnaires and patients were recruited from a specialty clinic. Therefore, asthma control may have been underestimated.

Omachi, Sakar, Yelin, Blanc, and Katz (2012) conducted a cross sectional study to examine the association between health literacy, health status and outcomes for patients with COPD. The study recruited patients from a previous study in 2001 that randomly sampled patients via telephone interviews (random digit dialing) across the continental 48 states. Patients' ages ranged from 55-75. Patients were followed longitudinally annually, with a retention rate of 80% for 8 years. In 2006, there were 161 patients left in the cohort and an additional 375 were interviewed from the Northern California area. There were 386 subjects that reported a diagnosis of COPD from a medical doctor. From this cohort, 277 subjects participated in this study published in 2012.

The literature review discussed the importance of understanding the disease and treatment processes and its relationship with poor outcomes in COPD patients (Omachi et al., 2012). The researchers explained that nearly half of U.S. adults have limited health literacy skills and this issue has been connected with underuse of preventive therapies, poor self-management and poorer outcomes in patients with chronic diseases like COPD.

Health literacy was examined using a 3 item Likert questionnaire that addressed frequency needed assistance to read hospital materials, frequency of difficulty in understanding and learning about their medical condition and confidence in filling out medical forms. Higher scores were indicative of better health literacy (Omachi et al., 2012). They found that poorer health literacy was associated with COPD-related

emergency department visits, hospitalizations and seeking medical advice for treatment of worsening respiratory symptoms in 50.1% of the sample ($N=140$), $p<0.05$).

Limitations of this study were the study was conducted in English only and consisted of a primarily white cohort, which limits generalization (Omachi et al., 2012). The research relied on self-reporting to identify healthcare resource consumption over a 12-month period and recall accuracy could have been improved with a shorter time period being measured. The researchers also noted that the health literacy scale used did not demonstrate normal distribution but distribution was thought to not change the findings and health literacy was measured indirectly.

Kale et al. (2015) used data from a prospective, longitudinal, multi-site observational study that examined associations between cognition, health literacy and self-care care in patients with COPD. There were 235 patients that participated and were recruited from outpatient clinics in New York City and Chicago between 2011 and 2013. Eligible patients were ≥ 55 years, spoke English and/or Spanish and were formally diagnosed with COPD by a physician. Health literacy was measured by utilization of the Short Test of Functional Health Literacy in Adults (S-TOFHLA) (available in English and Spanish), which is a 40-item tool that measures reading comprehension and numeracy. Scores range between 0-36, noting a score ≤ 23 was categorized as low. The researchers explained in their review of the literature health literacy is significantly linked to self-management and positive patient outcomes, particularly in patients with chronic disease and low health literacy can have a profound negative impact on patient and provider.

The research found that 66% of patients had a S-TOFHLA < 23 and associated this finding with racial minority, married, lower socio-economic status and have lower level

of education ($p < 0.001$) (Kale et al., 2015). They also found that patients with low health literacy were less informed regarding the chronic component of COPD and were equally more inclined to experience symptoms related to COPD ($p = 0.003$).

Limitations of this study were noted as predominantly representative of a greater proportion of women and racial minorities and may not be generalizable to suburban and rural communities (Kale et al., 2015). Additionally, the sample may have underestimated the actual proportion of low health literacy, as health literacy may have been a catalyst in patient participation. There was also no causal relationship that determined low health literacy and disease beliefs or health literacy and adherence via health beliefs.

Noting the various causes of COPD exacerbation, it can be considered that assisting patients in understanding their disease and treatment could potentially thwart exacerbation event and potentially limit their frequency and/or severity. Due to these findings, positive patient outcomes, sustained quality of life, and health status could potentially be increased.

The previous articles documented potential reasons for COPD exacerbations that included poor understanding of COPD and medications, repeated exacerbations, latter stage of disease, poor communication between patient and provider, and life style issues like continued tobacco use and poor nutrition. Additionally, these articles noted that exacerbations increased when patient's perception regarding inconvenience of medication schedules and social stigma associated with medication use (specifically inhalers) occurred. These themes are relevant to this practice improvement project because they identify barriers that prevent positive outcomes and stabilize COPD and its subsequent exacerbations. Therefore, assessing patient understanding of COPD and

pharmacotherapy is needed in order to provide and tailor education to meet the specific patient deficit(s) with the goal of decreasing exacerbation events and maintaining optimal health.

Pharmacology in COPD: Goals of treatment. Pharmacological therapy in COPD is a keystone in maintaining lung function, quality of life and health status. It is an important aspect of care that the patient and provider understand these goals and the role pharmacotherapy plays. It is essential for the provider to ensure efficacy and appropriateness of care and for patients to feel comfortable and informed with their treatment. This is relevant to the project as adherence to pharmacotherapy is a key aspect in patients with COPD and understanding and adhering to their regimens is the focus of this project.

Make, Dutro, Paulose-Ram, Marton, and Mapel (2012) conducted a retrospective analysis of medical and pharmacy claims from 19 health plans across the United States from July 2004 through June 2005. Patients 40 years and older with at least one inpatient or 2 outpatient claims coded for COPD were included, totaling 42,565 patients with commercial insurance and 8,507 Medicare patients. The researchers discuss in the review of the literature how pharmacotherapy advances have shown significant improvement in the management of COPD and have contributed to better diagnosis and treatment strategies. The goals of these strategies are to increase cognizance of COPD and improve patient outcomes.

The researchers found that overall, patients in both cohorts were undertreated and had suboptimal management of their COPD pharmacologically (Make et al., 2012). The research noted that oral corticosteroid steroids (30.1% for commercially insured and

20.9% for Medicare) and short acting beta agonists (30% for commercially insured and 25.5% for Medicare) were the most commonly filled respiratory medications and antibiotics and/or antimicrobials were the most frequently given non-respiratory medications. Moreover, patients in either group did not receive maintenance medications, noting in the commercial group, 66% received no maintenance medications, 59.1% were not prescribed any medication and 7.2% received only SABAs (n=28,206). In the Medicare group, 70.9% received no maintenance medications, 66.0% were not given any COPD medications and 4.9% were given SABAs (n=6,376). The researchers also found that that the majority of patients (98.7% commercial and 96.4% Medicare) had a mean of 11.3 and 11.5 (for commercial and Medicare patients respectively) office visits in the year the study was conducted. Additionally, 19.4% of Medicare patients and 13.9% of commercial patients were hospitalized at least one time for COPD (53.9% of Medicare patients and 39.8% of commercial patients were hospitalized for any reason overall).

Limitations of this study were the COPD diagnosis was extracted from a coded diagnosis and not from spirometry and therefore could not confirm diagnosis (Make et al., 2012). It is also possible that medication usage was under-reported due to the study period of one year and newly diagnosed patients at the end of the study did not have sufficient time to start medication. The estimation of medication as days supplied (calculated by using recommended daily dose) could be incorrect if patients were on unusual doses. There was no accountability for prescriptions that were filled but not taken nor was there a way to account for patients who received sample medication.

A systematic review by Ágh et al. (2015) was conducted to obtain an improved understanding of the association between medication adherence and health related quality

of life (HRQoL) and how each has a reciprocal relationship in patients with the COPD diagnosis. The literature review discusses that in real world conditions, medication adherence is estimated between 20-60%. Subsequently, non-adherence possess negative effects on those with COPD, causing frequency of exacerbations and hospitalizations and mortality.

Seven studies were included in this systemic review that included 5 prospective cohort studies and 2 cross-sectional studies that ranged from 1995 to 2013 (Ágh et al., 2015). The study suggests non-adherence may not have a clear impact on HRQoL and this may be related to negative effects from pharmacotherapy, which may cause daily life limitations and social stigma of inhaler use. However, improved HRQoL may also be a reason patients with COPD are non-adherent and find the benefits on not taking medication may temporarily outweigh health deterioration.

There were several limitations from this study that were noted (Ágh et al., 2015). This systematic review included only studies published in English and peer-reviewed journals from MEDLINE. Although studies that evaluated associations between medication adherence and HRQoL were included, there was exclusion of non-pharmacological interventions in the treatment of COPD.

A cross sectional, observational study done by Ágh, Inotai, & Mészáros (2011), looked to approximate adherence to respiratory medication and detect aspects linked to adherence in patients with chronic obstructive pulmonary disease. Patients were recruited from an outpatient clinic in Hungary, referred by 4 general practitioners and one pulmonologist between March and November 2009. A sample of 170 patients were included in the study who had a diagnosis of COPD for 1 year prior to participating in the

study, were over 40 years of age and were maintained on drug therapy. The review of the literature discussed the impact of COPD globally and its heavy economic burden on health care systems while stressing that poor pharmacotherapy adherence in patients with COPD may increase exacerbation and result in poor health and higher health care costs. Lastly, the literature review noted that medication adherence and HRQoL are 2 factors that are crucial in measuring success of drug therapy. Health related quality of life may have a negative and positive affect on non-adherence and this relationship may be reciprocal.

Ágh et al. (2015), used post bronchodilator spirometry and a self-reported 2-part questionnaire, which was mailed to patients. The questionnaires included were the Morisky Medication Adherence Scale (MMAS) and the EurQol 5-dimension questionnaire (EQ-5D). Results indicated that adherence to respiratory medication is low with a 58.2% adherence rate ($p < 0.005$). Older patients, females and patients with moderate stage of disease displayed more adherent behaviors and patients who smoked and had complex medication regimens were found to have less adherent behaviors ($p \leq 0.001$). The most common cause of non-adherence was forgetfulness and feeling worse from respiratory pharmacotherapy (51.2% and 41.8% respectively).

The study's limitations stated that self-reporting can overestimate actual adherence (Ágh et al., 2015). The use of postal services for the MMAS and EQ-50 have not been validated; these questionnaires are based on self-reporting and therefore could not make assurances that subjects did not have help in completing them. Lastly, HRQoL and

medication adherence changes over time so conducting a longitudinal study may have provided more reliable data.

Braido et al. (2013), conducted a literature review of randomized control trials (RCTs) evaluating health related quality of life and health status (HRQoL/HS) from patient reported outcomes (PROs). A total of 51 trials that included long acting beta agonists (LABA) and long acting anticholinergic (LAMA) met inclusion criteria and the RCTs used were RCTs published until 2012 on this subject matter.

The review of the literature noted that decrease HS and HRQoL are frequently issues in patients with COPD, therefore, assessing PROs is often beneficial and frequently achieved with the use of questionnaires to help in understanding appropriate pharmacotherapy, particularly from a patient perspective and preference (Braido et al, 2013). This remains consistent with the recommendation from the GOLD guidelines.

Braido et al. (2013), found that the use of bronchodilators were crucial in improving PROs of patients in regard to HS and HRQoL and their efficacy. It was also determined that patients who were prescribed higher dosages of bronchodilators did not have improved outcomes and that may be related to patient's perspective there was associated increased burden and more challenging therapies. Lastly, combination therapy of LABA and LAMA proved more effective than individual therapy.

Limitations noted explained that in these studies patients were often on concomitant drugs (Braido et al., 2013). Therefore the use of inhaled corticosteroids could indicate the effects of bronchodilators were greater than noted. This would need further investigation.

A Korean retrospective study done by Kim et al. (2014), examined the effect of inhaled long acting bronchodilators in patients newly diagnosed with COPD as of 2009.

A total of 77,480 newly diagnosed COPD patients were identified using databases from the Korean Health Insurance Review and Assessment Service (KIRA) and used in this study. Additional inclusion criteria included patient's with a primary or secondary diagnosis of COPD, >40 years of age and used one or more COPD medications at least two times in one year. Medications included long acting and short acting beta agonists (LABA/SABA), oral corticosteroids, inhaled corticosteroid (ICS), short acting and long acting muscarinic antagonists (SAMA/LAMA), methylxanthines and systemic beta agonists. Patients were separated into 3 groups consisting of inhaled short acting bronchodilators (SA-B, including ICS: n=5173), inhaled long acting bronchodilators (LA-B: n=12,115) and oral medications (OM, no bronchodilators or ICS: n=60, 192).

The literature review indicated that COPD is a global health problem and causes severe restriction of daily activities, increases mortality and is responsible for heavy utilization of health care resources (Kim et al., 2014). The literature had shown the advantages of inhaled long acting bronchodilators in reduction of exacerbation and improvement of health status and quality of life, however the efficacy in actual practice is unclear.

The study results showed that the LA-B group lower rates of re-hospitalization, lessened emergency visits and decreased use of medical resources ($p<0.001$) (Kim et al., 2014). The SA-B and OM groups had greater emergency room visits when compared to the LA-B group as well as hospitalizations ($p<0.001$).

Limitations noted that risk factors associated with exacerbation was not available, and the focus was on newly diagnosed COPD patients (Kim et al., 2014). The definition of COPD was subjective and was defined by researchers parameters for inclusion. The

amount of women in the study was higher than men and it is uncertain if gender has influence in reporting of symptoms or seeking treatment and due to the reimbursement of medications in Korea, prescribing can be related to lung function testing and the use of LA bronchodilators.

The previous articles have demonstrated that pharmacotherapy is crucial in the management of COPD. It is an important factor in patient outcomes, health status and quality of life. Stressing the importance of optimal, appropriate and simple treatment regimens is imperative for providers, however, it is equally important that patients adhere to their treatment regimens. This theme is relevant to this practice improvement project because it underscores the important role pharmacotherapy and adherence play in

maintaining optimal patient outcomes by reducing exacerbation, slowing the progression of COPD and maintaining quality of life.

Economic factors. As previously discussed, COPD and exacerbations of COPD have been associated with increased utilization of resources like readmissions to hospitals, use of emergency room services and physician visits. Understanding that adherence is linked to better utilization of resources and a decreased incidence of morbidity is an important factor in care for this patient population, particularly regarding cost containment for patients and decreasing resource utilization burden on the health care systems.

Blasi et al. (2014), conducted a secondary data analysis in Lombardy, Italy that examined healthcare administrative databases to update the approximated burden of COPD in Italy. In the study, 15,857 participants were enrolled from January 1, 2006 until December 31, 2006 and followed until December 31, 2009 or until their death or migration outside Lombardy. Inclusion criteria consisted of patients who were ≥ 40 years of age and hospitalized for at least one COPD exacerbation during 2006 (date of admission was date of inclusion to the study).

Blasi et al. (2014) explained in their literature review that exacerbations of COPD vary in intensity of worsening respiratory symptoms requiring medication and/or hospitalization. As disease progression occurs exacerbations increase in occurrence and severity and can lead to serious debilitation to quality of life, pulmonary function and lifespan, elevating the burden to healthcare systems.

The data revealed that annual rate of exacerbation averaged 3.2 per person and found that for this patient population, 34% of health care money spent was attributed to care for COPD exacerbations with the major cost related to hospitalizations (Blasi et al., 2014).

COPD patients with a history of exacerbation accounted for a higher mean yearly per patient cost than patients without an exacerbation history. Patients whose past exacerbations were considered severe had the highest cost per patient annually.

Limitations of this study were potential failure to include milder exacerbation events (Blasi et al., 2014). Additionally, capturing patients admitted to hospitals that did not have severe events and an underrepresentation of patients who exhibited less frequent exacerbations. Lastly, in the analysis of fiscal consequence, there was no data to represent indirect costs or costs that related to emergency room and/or general practitioner visits.

Dalal et al. (2012), conducted a retrospective observational study using a claims database that stored data from 90 different managed care health plans, totaling 60 million lives. The patient profile consisted of 80% commercial, 2% Medicare and 3% Medicaid. Data was collected from January 1, 2003 through March 31, 2009 and was comprised of patients with moderate COPD exacerbation who had not had maintenance therapy prior to the study, which totaled 21, 524 patients (Dalal et al.). The aim of the study was to compare COPD outcomes between patients beginning fluticasone propionate-salmeterol (FSC) versus anticholinergics (AC) following a moderate COPD exacerbation.

Dalal et al. (2012) discussed in the literature review that COPD and its effects on morbidity and mortality and noted that COPD is considered to be the 3rd leading cause of death in the U.S. It explained that total costs of COPD sustains a huge economic burden with costs estimated to almost 50 billion dollars annually and are related to severity of disease, noting that severe exacerbation costs 2.6 times more to care for than a non-severe event. The GOLD standard provides staging of disease and with staging, pharmacotherapy is initiated to obtain the best outcomes for patients, which includes

maintenance therapy. The TORCH study recommends the use of maintenance therapy and when used in conjunction with inhaled corticosteroids, reduction in exacerbation rates can occur.

The results noted that 1 in 4 patients received maintenance therapy for their mild exacerbation and suboptimal treatment consistently lead to increased exacerbation events and therefore, have the ability to decrease costs of care and utilization of resources (Dalal et al., 2014). The study showed that patients who had maintenance therapy with FSC had a 42% lower risk of exacerbation than those prescribed AC ($p=0.04$). However, patients prescribed FSC incurred higher pharmacy costs but those prescribed AC incurred higher medical costs ($p < 0.05$).

The study did report limitations (Dalal et al., 2014). Due to capturing data from a claims database, lung function could not be determined and patients could exhibit variations of severity not related to patients with moderate COPD. Patients with asthma were not excluded, as the conditions are similar and difficult to separate without clinical data. Patients who were hospitalized could not be stratified due to the small population size. Using data claims, misclassification bias may have existed and lastly, the results can only be generalizable to the population of COPD patients enrolled in commercial managed care as well as criteria for the inclusion to the study.

Pasquale et al. (2012), conducted a retrospective analysis from a large national health plan that primarily serves the Medicare population. Inclusion criteria consisted of patients from age 40 through 89 years who were part of the plan for 24 months or more, had 2 separate insurance claims for a COPD diagnosis that included bronchitis and had pharmacy claims for COPD maintenance pharmacotherapy between January 1, 2007 and

March 31, 2009. The total participants were 8,554 patients with a mean age of 70.1 years of age.

Pasquale et al., (2012), discussed that COPD and disease progression often is associated with exacerbation, increase in poor outcomes, worsening lung function, morbidity and mortality. As previously discussed, the researchers noted, according to the National Heart, Lung and Blood Institute, annual expenditures for acute episodes of COPD in the U.S. is approximately 29.5 billion dollars. It was also noted that early detection and treatment of exacerbation is a cornerstone of improved outcomes but in actuality, 50% exacerbations remain undertreated and unreported.

The study found that patients with increased severity of disease, greater cost and utilization of resources were incurred ($p < 0.0001$) (Pasquale et al., 2012). The study also noted that reduction of exacerbation (By 2 or more) could yield a savings of \$5,125 annually and \$11,599 in general health care expenditures.

This study noted few limitations. Clinical data regarding COPD were unavailable with the use of claims information (Pasquale et al., 2012). The researchers also disclosed there were no causal inferences gathered due to the use of multivariate regression modeling.

Toy et al. (2010) conducted a retrospective study that used a large database that covered 8.4 million people (7.6 million under 65 years of age and 800,000 over 65 years of age) in the U.S. from 1999-2006 regarding medication claims of a group of retirees and employees from 40 self-insured Fortune 500 companies. To compile healthcare cost experienced by these patients the researchers used the 2005 Medical Expenditure Panel Survey (MEPS), which provides cost information at the patient level that includes

insurance and patient payments for services. The total number of patients in the sample was 55,076.

The researchers discussed in their literature review that COPD is a disease that is associated with airflow limitation and is progressive in nature (Toy et al., 2010). Prevalence is increasing and the economic burden continues to increase with a total cost of COPD was \$42.6 billion in 2007 in the United States. With the variety of medication regimens available to help manage disease and symptoms, there remains issues with adherence and contributes to morbidity, mortality, hospitalizations, poorer quality of life and increased resource use. Medication adherence has been associated with age, cost, comorbid conditions, and complex pharmacologic therapies. The aim of the study was to examine adherence levels of patients prescribed inhaled pharmacotherapies and the association between adherence, dosing frequency, healthcare usage and cost effects of greater adherence.

Results from the study showed that higher adherence was associated with daily dosing versus multi dosing ($p < .0001$) and higher adherence caused less utilization of resources and decreased cost after treatment initiation in one year ($p < .0001$) (Toy et al., 2010). Limitations of this study were several according to the authors. The use of claims to determine adherence did not represent actual taking the medication and/or taking them correctly, therefore leads to bias. The ability to measure COPD severity could not be accomplished by direct observation due to the use of claims and analysis was limited to patients beginning treatment for COPD and therefore would not have included patients

with severe disease. Lastly, data costs were calculated by using MEPS and may not be accurate to actual costs.

A systematic review conducted by van Boven et al., (2013), aimed to assess the economic and clinical t of non-adherence to COPD pharmacotherapy. Searching PubMed and Web of Science databases, studies were retrieved from inception of the database until 2012. Using search terms that were combinations of COPD and impact on clinical and economic outcomes the studies included were peer-reviewed, full text, in English and were original studies. Twelve studies were deemed appropriate for this review.

The literature review for this study was brief but highlighted the valor of pharmacotherapy for COPD patients (van Boven et al., 2013). Pharmacotherapy has shown to decrease symptoms and prevent exacerbation but adherence is the key in effective outcomes. Suboptimal adherence is a real world issue for this patient population and is frequently a consequence of preventable morbidity and mortality.

The main findings of this systematic review were non-adherent patients were more likely to experience decrease in quality of life, mortality, increased admissions to hospitals and decrease in productivity (van Boven et al, 2013). The study also noted that patients who were adherent had incurred a decrease in total medical costs associated with their health care but noted that adherence would likely increase costs in pharmacotherapy.

Study limitations were acknowledged since some were observational they were not suited to account for causal effects of non-adherence (van Boven et al., 2013). There was no use of unpublished, non-English studies and due to the variety of studies included it

was difficult to synthesize evidence for meta-analysis. Prescription records could not account for actual adherence or correct use of medication.

Dalal, Christensen, Liu, and Riedel (2010), conducted a retrospective analysis to estimate direct patient costs (patient and plan) of COPD management among patients with commercial insurance in the United States. Using a database for medical and pharmacy claims that comprised of diverse enrollees of approximately 14 million people, along with data from the 2006 MEPS (previously discussed), patients were selected from January 1, 2006 through December 31, 2006 with ICD-9 codes consistent with COPD being the primary diagnosis (Dalal et al.). Other inclusion criteria consisted of patients 40 years and older, part of the plan for the entire year of the study and have race and ethnicity data obtainable. Total patients were 37,089 patients included in the study (19,641 outpatients, 13,833 urgent outpatients, 1,231 ED patients, 1,547 admitted patients and 837 ICU patients).

The researchers discussed in the literature review the progressive and irreversible nature of COPD and how features of the disease vary (Dalal et al.). Exacerbation is a disease consequence that can attribute to mortality, decreased quality of life and comorbidity and strict management is crucial for this patient population to control symptoms and disease progression. Additionally, direct costs related to morbidity that results from COPD in the U.S. is anticipated to be \$29.5 billion as of 2010, hospitalizations being 45% of those direct costs and pharmacotherapy as 20%. The need to examine patient and plan costs needs to be published.

The results of this study indicated that costs of care were elevated in conjunction with the level of care patients required, indicating the cost of an ICU admission was three

times the cost of a regular admission ($p < 0.001$) (Dalal et al., 2010). Average ICU expenditure was \$40,311 versus a standard admission at \$12,459; however, outpatient management was noted at \$754.

The limitations of this study were the use of claims is not reliable for diagnosis and patient encounters may have been subject to miscoding and also provide limited information regarding pharmacotherapy while hospitalized (Dalal et al., 2010). Also, indirect costs are not clearly indicated and overall costs may not be exact. Although this data concentrated on commercially insured patients in a managed care plan, race, health status and treatment patterns were not able to be determined and could not be considered factors that could influence outcomes. The generalizability of the study may be limited to managed care patients.

A pilot study conducted in the Netherlands, published in 2014, aimed to understand the outcomes related to an on demand system (where patients scheduled outpatient appointments as needed) regarding health, expenses and healthcare utilization (Berkoff et al., 2014). These researchers conducted a prospective randomized controlled trial using patients ≥ 40 years of age, had tobacco use for ≥ 10 pack-years and were diagnosed with \geq stage 2 COPD (per GOLD standards) from a teaching institution. Patients were randomized to obtain balanced demographics and disease stage, with enrollment beginning on October 10, 2007 and culminating on October 12, 2009. One hundred patients had 2 year follow up (49 in the on-demand group and 51 in the control group).

Patients included in the on-demand group had one set appointment annually and patients controlled their outpatient follow up. The control group had fixed office appointments dictated by the pulmonary physician. Both groups were assessed at baseline

for spirometry (after using bronchodilators) and past and current use of tobacco was also noted (Berkoff et al., 2014). At intervals of 6 months, 1 year, and 2 years patients completed the Clinical COPD Questionnaire (CCQ), the St. George's Respiratory Scale (SGRS) and the Short Form-36 (SF-36) via mail and further information was extracted from pharmacists and general practitioners regarding utilization at the conclusion of the study. Pulmonary visits and events of exacerbation were identified via the institution's computer database.

The study results found that in both groups patients experienced a decrease in health grade but was reduced in the on-demand subjects. However, the differences were insignificant with the exception of symptoms ($p = .04$) (Berkoff et al., 2014). Patients in the on-demand group versus the control group had significantly better symptom control on the SGRS and SF-36 questionnaires after 24 months ($p = .10$). Regarding utilization, the on-demand group used their GPs less but their pulmonary nurse practitioners more than the control group despite similar numbers of exacerbation events ($p = 0.003$). Total costs were lower in the on-demand group but did not reach statistical significance.

Limitations of the study were few. There was no account for skipped visits and the use of a pilot study captured a small sample size and was exploratory in nature (Berkoff et al., 2014). Other limitations included gaps in information at commencement of the study, the inability to obtain data regarding health grades in the control group patients who were misplaced from follow up and 2 patients failed to meet inclusion criteria regarding tobacco history.

A retrospective cohort study conducted by Hussey et al. (2014), looked to determine the association between continuity of care, cost of care and episodes of hospitalizations,

emergency department incidents and complications for patients with chronic disease who have Medicare, from 2008 and 2009. Using a random sampling of 5% of insurance claims of fee for service Medicare (part A and B) insured patients, inclusion criteria required patients to be over 65 years at the start of 2008 and have Medicare part A or B for 2 years. Data from 2008 the Bice-Boxman Continuity of Care (COC) Index (0= patient was seen by a different provider for each visit and 1=all visits billed by a single provider), was used to measure continuity of care in patients with congestive heart failure (CHF) (n=54,488, chronic obstructive pulmonary disease (COPD) (n=76,520) and diabetes mellitus (DM) (n=166,654) with a total cohort of 241,722.

Hussey et al. (2014), explained that patients with chronic illness have been subject to issues with care coordination that often causes less than optimal care and results, especially related to cost, outcomes and experiences. As healthcare evolves, coordination of care is of utmost concern and new care models and approaches to care are developing, however, the effects are not understood regarding coordination of care.

The results of this study found patients with all three chronic conditions demonstrated consistent findings in regard to high levels of continuity, low incidence of hospital utilization and use of emergency room visits (Hussey et al., 2014). Patients had similar results for COC noting that continuity was consistent (CHF: .55, COPD: .60 and DM: .50), and these results show an association with resource utilization of health care. High levels of COC were shown to have decreased odds of patients being admitted, ED visits and having complications associated with their primary condition, comorbidities and patient safety ($p < 0.0001$). Decreased costs per episode were also associated with higher

COC index scores regarding hospitalizations, ED visits and complications for all three chronic illnesses.

Limitations of this study included that this information may not be generalizable to younger populations with other health insurances and claims databases could not measure severity of illness due to lack of clinical data (Hussey et al., 2014). Additionally, because of cross-section analysis, causality could not be addressed and patients that did not have a primary care provider enrolled in the study had lower COC scores and had lower visit counts.

The previous articles are reflective in noting that patients who have chronic illnesses, like COPD, are at risk to have poor adherence to treatment and follow up, experience poor outcomes with subsequent increased utilization of health care resources. These include admissions and readmissions to the hospital, increase in emergency room use and increase in physician utilization. These factors, which stem from medication non-adherence, increase health care expenditures as well as burden the health care system for this patient population. This theme is relevant to this practice improvement project because understanding patients' needs, beliefs and capacity to understand their disease process and the significance of medication adherence in their disease process is crucial in achieving optimal outcomes for patients as it will decrease the burden on health care resources and subsequently decrease costs to manage COPD patients. Perhaps patient education could be an aspect to remedy this gap in patient care and aid in the reduction of health care expenditures.

Health literacy and impact on adherence. Health literacy is currently an important issue in the health care arena. Often misunderstood, health literacy is the ability in which

individuals have the capacity to obtain, process, and/or understand basic health information and services needed to make appropriate health decisions. Faced with the current evolution of healthcare, it is an important aspect to consider in patient care, as it empowers patients and fosters a stronger role for them to partner with providers in navigating their care. Particularly in chronic disease, patients require understanding of their diagnosis and management to reach optimal levels in their health and sustain those outcomes. This aspect is crucial to the project as it looks to connect adherence to treatment plans in order to decrease exacerbation events through education.

A systematic review conducted by Gellad, Grenard, and Marcum (2011) used 9 articles after searching PubMed and PsychINFO from January 1998 to January 2010. Four studies used pharmacy claims to evaluate adherence, two studies used pill count/electronic monitoring and three studies used other methods to evaluate adherence. The articles searched focused on U.S. elderly ≥ 65 years of age. The aim of this research was to ascertain barriers to medication that were non-financial among the elderly. The literature review indicates the use of pharmacotherapy in older adults is done with the goal of improving QoL, extend expectancy and manage disease processes. However, non-adherence is a commonality in this patient population and often is represented by varied rationale and factors but remains the cause of negative outcomes regarding health.

Results of the research discovered that medication adherence is a complex behavior and it is difficult to identify a clear rationale for barriers, however, this research noted that barriers can be categorized by patient-related-factors, drug-related factors and other factors (Gellad et al., 2011). Health literacy was found to be a significant patient-related issue and was associated with low medication adherence and noted that health literacy

skills are more important when taking medications as directed and filling prescriptions appropriately.

The limitations of this study included the use of two data bases, the inclusion of other studies could have been missed, and studies with null effects could have been unpublished leading to potential publication bias (Gellad et al., 2011). Lastly, the inclusion criteria were restricted and therefore results can only be generalized to the specific population targeted.

A systematic review done by Zhang, Terry and McHorney (2014), looked to approximate the effect size of the association among health literacy and medication adherence. Articles were searched via 6 databases, (CINAHL, IPA, MEDLINE OVID, PubMed, PsycInfo and Web of Science) ranging from 1966 through May 2013 with 35 articles accepted.

The literature review explained that poor medication adherence is a serious barrier for patients to achieve successful outcomes in the management of chronic disease, leading to disease progression, morbidity and mortality (Zhang et al., 2014). Non-adherence is costly, not only in health parameters but causes economic consequences for patients, employers and the health system in terms of increase utilization of emergency departments, hospitalizations and out patient visits. The researchers noted that with the passing of the Affordable Care Act, there is greater attention toward improving health literacy and to ensure high levels of care and outcomes.

The study found that increased health literacy levels are statistically significant to improved medication adherence (noted in 6 diseases and 35 samples) (Zhang et al., 2014). The study also suggests that increased health literacy in patients could be one

mechanism in a larger strategy to improve medication adherence as health literacy alone may have a limited impact on medication adherence. They also found patient beliefs could influence medication adherence, however health literacy may influence patient beliefs.

The study limitations noted that health literacy was measured by instruments and did not represent the relationship between medication adherence and health numeracy, reliability and comprehension (Zhang et al., 2014). Health literacy was measured on materials that were read and was not applicable to verbally presented information. Bias could have been introduced as estimated assigned p values in the absence of actual p values occurred. Lastly, the generalizability of the study is limited to other countries as the predominant number of studies were conducted in the United States (Zhang et al., 2014).

A systematic review done by Bryant et al. (2013) aimed to examine the effectiveness of strategies to increase medication adherence for COPD management and medication adherence in general. The literature review discussed that patients with COPD have an elevated non-adherence to medication related to medication type, dosing schedule, patient traits and appropriate usage. They continued to discuss the patterns of behavior regarding medication non-adherence as intentional and non-intentional (previously discussed in the introduction of this paper), noting that the most common causes for unintentional non-adherence is polypharmacy, due to the complexity of medication regimens. However, other motives that are consistent with non-adherence have been related to poor awareness and understanding of COPD, medication therapies and high rates of depression (often associated with COPD). The researchers discussed that multiple interventions that

include education, supportive care counseling and self-monitoring, may increase adherence.

Medline and Cochrane Library were searched using terms COPD or emphysema or pulmonary emphysema or chronic bronchitis or obstructive lung disease and medication adherence/compliance (Bryant et al., 2013). There were seven studies that met inclusion criteria and were used for this systematic.

The researchers found that all studies in the review noted focused on patient education and counseling (Bryant et al., 2013). Additionally they found that improving provider abilities in these capacities resulted in better satisfaction and health outcomes for patients. Simplifying medication routines and altering dosing schedules were also linked to improvement in adherence. This study described that patient education and tailoring patient regimens to meet the patients' capacity to understand lead to improved patient outcomes.

Limitations of the study were found to be related to the use of only peer-reviewed publications and due to the diversity of measures used to evaluate medication compliance, meta- analysis was not done (Bryant et al., 2013). Lastly, the studies used focused only on pharmacological adherence and did not consider non-pharmacological interventions.

A cross-sectional, observational study conducted by Street and Haidet (2010), looked to determine physicians' awareness of patient's health beliefs, communication, patient-provider relationship and demographic factors that are linked with physician understanding of patients' perceptions of illness. A convenience sample of 207 patients and 29 primary care physicians from 10 outpatient clinics were recruited. Once the

patient and provider consulted, each were asked to complete the 19 item, CONNECT instrument that measures 6 domains of an individual's perceptions about their health condition.

The literature review for this study noted that the foundation of patient centered care is recognition of their health beliefs, values and preferences (Street & Haidet, 2010). These concepts can influence patient's health literacy. Addressing this aspect of patient care allows for understanding patients' level of health literacy in order to modify care plans and education to the patient's needs. Therefore, increasing patient understanding and satisfaction with care and fostering adherence to treatment. The study found that physician's had a relatively poor understanding of patients' health ($p= 0.001$). The study also found that when physicians were with patients who actively asked questions, discussed concerns and opinions regarding their care, physicians had an improved understanding of their patients' health beliefs ($p= 0.001$). Lastly, the study suggests that ethnicity may impact on physician understanding. Amid African American and Hispanics, physician understanding was poorer compared to Caucasians ($p=0.013$, $p=0.075$ respectively).

The authors noted that there were several limitations of the study (Street & Haidet, 2010). They did not measure if exactitude of physician understanding was due to post-consultation results nor was physician pre-consultation evaluations considered. Additionally, racial concordance was not balanced between patients and physicians and the physicians in this study represented various types of practices.

White, Garbez, Carroll, Brinker, and Howie-Esquivel (2013), looked to determine if hospitalized patients with heart failure (HF), educated with teach-back technique, were

able to retain self-care learning material and if this was associated with lessened hospital admissions. White et al. conducted a prospective cohort study of 276 patients (276 in hospital and 188 post-hospitalization) over 65 years of age, who had been admitted for HF over a 13-month period (July 2009 through August 2010) were included in this study. Using the teach-back method for patient education, recall was assessed during hospitalization and 7 days after discharge (via telephone). Patient education lasted between 15 to 120 minutes and 4 teach-back questions were asked regarding diuretic name, when to report weight gain, food to avoid and identifying 3-4 warning symptoms that would require provider contact.

The review of the literature explained that as of 2009, HF is a chronic disease that affects 5.8 million people in the U.S. with associated costs of \$37.2 billion annually, which is the largest Medicare source of spending (White et al., 2013). The ratio of risk is 1 in 5 to be diagnosed with HF and there will be a likely rise in numbers affected. HF is the leading cause of readmission and is usually related to patient failure to follow medication regimens, adhere to nutritional restrictions and delay treatment and these actions lead to readmission. Current guidelines from the American Heart Association and the Joint Commission have stressed the benefits of patient education and its preventative impact regarding patient activities. The researchers reported that studies have demonstrated the effective use of teach-back technique and have shown that with further education, patients seem to master information needed to correctly understand health information.

The study found that patients were able to correctly reply to the pre-determined teach-back questions 84.4% during hospitalization and 77% at follow up, and those who

answered correctly shared similar characteristics (White et al., 2013). Overall understanding was considered excellent, despite the patients' age and disability, however, patients observed had the most difficult time with understanding when to report weight gain. Patients who received longer education times also did better with recall ($p < .001$). The 30-day readmission rate (all cause) was noted to be 14.9% but the HF rate was only 3.3% and trended towards significance ($p = .15$).

Limitations noted from this study consisted of several according to the authors. There was no control group and therefore comparisons could not be considered (White et al., 2013). Teach-back was already being used at the institution for HF patients and readmission rates were very low. Eighty-eight patients were lost to follow up teach-back due to demise, illiteracy, transfer to another institution, inability to contact patient, and/or refusal to participate. An important consideration is the reliability of teach-back. Due to the interactive nature of the technique, bias can occur when the educator understands the patient's limitations regarding retention of subject matter, and can provide additional education until learning is accomplished.

Kiser et al. (2012) conducted a randomized control trial of 99 COPD patients to discover the impact of literacy sensitive self-management intervention on inhaler technique scores to verify if results vary by literacy. Patients were randomly selected ($n = 67$ intervention group) for one to one (using teach-back) self management learning or usual care with the intervention focus on inhaler use, discontinuing tobacco use and

utilizing a COPD action plan (Kiser et al.). Subjects in both groups were similar except the control group had a higher percentage of patients with lower health literacy.

Kiser et al. (2012), discussed that the literature indicates that literacy skills in patients with COPD regarding disease are commonly found to be inadequate and are associated with increased morbidity, mortality, poor disease management and readmission (Kiser et al.). As self-management can be difficult, literacy plays a crucial role in maintaining health and avoiding exacerbations that may increase mortality and morbidity (Kiser et al.). Inhaler therapy is a common pharmacotherapy in COPD patients. Due to variation in technique for usage, proper technique is key to successful patient outcomes and is associated with adequate health literacy skills.

Thirty minute, one-to-one sessions, using the teach-back technique to provide step-by-step instruction regarding inhaler was carried out, using manufacturer recommendations (Kiser et al., 2012). Teach-back sessions were conducted at baseline and follow-up occurred 2-8 weeks post intervention. There was noted improvement in both groups regarding technique regarding MDI usage (all patients had MDI inhalers) with a smaller increase for those in the intervention group ($p < 0.001$). Diskus subjects ($n=41$; $n=14$ usual care and $n=27$ intervention) showed no differences but did show trending to improvement in the intervention group (.09 versus 0.4, $p= 0.18$), furthermore, when comparing literacy subgroups, those with higher literacy levels, technique improvement were greater in the intervention group ($p=0.001$). Of the 27 Handihaler subjects ($n=11$ usual care and $n=16$ intervention), the intervention group had better mean improvement

scores from baseline, but were not statistically significant from the usual care group ($p=0.14$).

Limitations of this study were that characteristics of non-participants were not collected and therefore can decrease generalizability (Kiser et al., 2012). The research assistant was noted as such and could cause bias in interpretation. The inhaler checklist was not validated as it was specifically created for this study and follow up time was varied and could affect results of those with longer follow up times. Lastly, the study did not account for differences in Diskus and Handihalers.

Press et al. (2011) conducted a Phase II, blocked randomized stratified control trial with the aim of the study comparing brief intervention technique (BI) to teach-to-goal technique (TTG) (teach-back) in regard to effectiveness. Adult patients (18 and older) who were hospitalized and physician diagnosed with COPD or asthma, totaling 50 patients (BI: $n=26$ and TTG: $n=24$) were included and recruited from July 2009 through April 2010. During hospitalization TTG patients were assessed for baseline knowledge and had repeated assessment and intervention of their inhaler technique and did so until mastery was demonstrated. BI patients were also assessed for baseline knowledge, however, they were trained with verbal information and given a copy of written directions (no demonstration). Follow up occurred 30 days post hospitalization via 10-minute telephone interviews noting if patients had any emergency room visits, hospitalizations or deaths within this period for any reason.

The literature review discussed the importance of medication adherence and methods used to improve self-management in patients pending discharge from hospital with COPD and/or asthma. Asthma and COPD are common chronic respiratory diseases that

require intense self-management in order to improve outcomes (Press et al., 2011).

Patients with COPD and asthma often misuse their inhalers and education to rectify this care issue could improve patient outcomes and prevent adverse events. This study relates to health literacy as it uses TTG and BI methods to teach patients. Each is unique but the use of TTG allowed for repeated assessment and intervention until mastery was demonstrated. This method takes in to account patient's understanding and looks to have the patient master the information, therefore, increasing their health literacy.

Results of this study indicated that although both groups improved, TTG took three times longer (mean of 6.3 minutes compared to 2 minutes for BI), but TTG patients had significantly lowered scores regarding misuse of inhaler post education (MDI: TTG 13% and BI 46% $p=0.01$; Diskus: TTG: 25% and BI: 80 %, $p=0.05$;) (Press et al., 2011). BI participants were eight times more likely to experience a post discharge health event (TTG: 5% BI:40%, $p=.0.02$) (Press et al., 2011).

Limitations of the study notes that patients were lost to follow up (39 remained) and not all post hospitalization events were noted (Press et al., 2011). Of those events noted all were self-reported. Literacy and vision were not tested and could have played a role in the study's outcomes. Results were inconsistent between MDI and Diskus inhaler use. The results of this study may not be generalizable because enrolled subjects were high-risk and consisted of a high percentage of minorities from one urban academic center who spoke English and were given only English educational supplements.

A qualitative descriptive study conducted in Canada by Draaistra, Singh, Ireland, and Harper (2012) examined perceptions of patients' roles in goal setting in a spinal cord injury (SCI) rehabilitation program. Inclusion criteria consisted of patients > 16 years

that sustained either traumatic or non-traumatic SCI within the last 6 months which resulted in permanent injury. Thirteen patients were included in this study from a regional rehab facility affiliated with a tertiary care academic teaching hospital.

Draaistra et al. (2012), discussed the input from governmental expectations regarding patients involvement in their rehabilitative process and noted that improved patient outcomes are achieved with increase in health literacy, self-management and decision making from patients. It was also discussed the importance of the healthcare team to collaborate with the patient to foster the patient's goal setting and attainment, however, in real practice this may not be the case and may hinder the patient. It was noted that efficiency of care is crucial to decrease patient stay as well as foster timely independence and aid in goal setting.

Draaistra et al. (2012) identified four themes associated with goal setting from this cohort as visioning, redefining, brainstorming and rebuilding. These findings are representative that effective interactions promote successful transactions that foster goal attainment. Visioning is first and represents patients' identification of overall goals prior to admission and barriers and non-barriers to goals are also identified here. Lack of knowledge was identified as a barrier to goal attainment during visioning. Redefining is second and is where patients redefine goals with health professionals upon admission. Patients have input in goal setting, prioritize goals and achieve a sense of accomplishment. Barriers to goal setting identified here include discomfort in setting goals, lack of knowledge regarding prognostic outlook and "reality check" regarding prognosis that comes from goal setting. Brainstorming is third and occurs when knowledge is shared regarding participant's progress. A sense of familiarity is achieved

with team members and role definition is established. Barriers identified here are lack of action, and lack of communication. Rebuilding is last and consists of personal determination, team support and a sense of community is developed. Barriers identified here include diminished personal resources, lack of timely communication and feelings of vulnerability.

The researchers found that during each theme, King's theory is consistently part of the process. During visioning, the interacting of personal and social systems is apparent. As personal and social systems become unstable because of lack of knowledge regarding outcomes, expectations, and goals, hope remained an important part of the visioning process for patients. During redefining, interpersonal and personal systems interact as the team defines specific goals entering rehab. Here is where patients rely on health professionals to help in goal formation, however, professionals must acknowledge their own perceptions to foster autonomy in their patients to make their goals. During brainstorming, social interaction occurs and both the patients and the team communicate comfortably and become in tune to their interpersonal roles. Lastly, rebuilding is where transaction occurs, as this is when mutual goals are set between the patient and the team to reach successful goal attainment.

Limitations of the study include the use of only one urban facility, which reduces transferability of findings (Draaistra et al., 2012). Additionally, maintaining privacy of participants reduced the ability to provide details of the subjects and therefore limited

transferability to other populations. Age groups were not well represented and marital status was included to comprehend spousal /partner support.

The above articles support that education and health literacy are components that are interdependent and are needed to address patient education and understanding of their disease process and treatment regimens. It is imperative that education for patients be included in the plan of care as it has been shown to support positive patient outcomes, particularly in patients with chronic illnesses. However, these articles note that education must be instituted at the patient's capacity to understand the information they need to have successful outcomes. These themes are relevant to this practice improvement project because an educational intervention, using the teach-back method, will be used to potentially decrease exacerbation events and foster positive patient outcomes. Understanding the capacity of patients' ability to comprehend information being taught is a very key element in educating patients.

Summary

Chronic obstructive pulmonary disease is a chronic disease that brings with it many challenges. Its effects are seen globally and is now ranked as the fourth leading cause of death worldwide and expected to rise to third by 2030 (Ingebrigtsen, 2013). COPD is considered irreversible obstruction of the airways that is progressive, and debilitating (Afonso, Verhamme, Sturkenboom, & Brusselle, 2011). Although it is a preventable and a treatable disease, its effects are detrimental causing decreases in quality of life and health status and prevalence rates increase with age (Fotoukian, Shahboulaghi, Khoshknad, & Mohammadi, 2014). In the U.S., COPD is the only common cause of

mortality that has increased over the last 40 years compared to decreases in heart disease and infectious diseases (Stanley, Gordon, & Pilon, 2013).

As previously noted in this chapter, the United States will have an increase in the elderly population and likely to yield an increase in those diagnosed with COPD. Due to these factors, the need to examine outcomes of elders with COPD regarding medication adherence is needed. Moreover, examining how elders and medication adherence affect outcomes will likely support the need to provide appropriate treatment to decrease exacerbation and stabilize lung deterioration, utilize educational resources that address patient's capacity and need, while reassessing their knowledge, and reeducating as indicated will improve health literacy. In concert with the literature, encompassing proper pharmacotherapy and initiating education regarding medication adherence in the care of elders with COPD will likely decrease healthcare costs and utilization of resources.

Treatment and maintenance of COPD requires pharmacologic intervention and with some patients, changes in lifestyle to combat tobacco and alcohol use, malnutrition or obesity, sedentary lifestyle and management (Taggart et al., 2012). These risk factors place them at higher risk of having comorbid conditions (Taggart et al.). Since COPD patients are likely to experience other comorbid conditions, they are confronted with complex pharmacotherapy regimens (Schnell et al., 2012). It has been reported in the literature that 94% of patients with COPD have at least one other comorbid diagnosis (Schnell et al.).

Subsequently, patients with COPD often have issues of non-adherence regarding pharmacotherapy and poor adherence is often related to poorer outcomes for this patient population. Adherence to long-term therapy is challenging to many with chronic illness

(Senzaki, 2015). However, poor adherence to drug therapy in COPD increases the likelihood of symptom manifestation, poor health, decreased quality of life, increased morbidity and mortality and increased utilization of health care resources (Carr-Lopez et al., 2014). Adherence is crucial in producing positive patient outcomes and must be addressed for patient success. Adherence can be intentional, where patients contemplate risks and benefits of therapy and consciously decide not to take medication (Carr-Lopez et al.). However, unintentional adherence is also possible and is related to patients forgetting to take their medication (Carr-Lopez et al.). Despite the root cause, the goal is adherence and to foster patient's self management and empowerment.

Imogene King's theory of goal attainment is useful in providing patients and practitioners the opportunity to set and achieve mutual goals pertaining to medication adherence. Considering external and internal factors that influence goal achievement, King's theory is an ideal framework that focuses on the total patient and provider environment and how satisfaction of goal attainment can be mutually set and achieved. The foundation of King's theory recognizes that goals vary according to individuals, however, establishing communication and relationships between provider and patient, goals can be developed and met, placing emphasis on the patient's needs (Caceres, 2015).

The literature review supports the use of quantitative methods with a pretest-posttest design that will be used for this study. A majority of the literature review is comprised of quantitative studies that have explained the causes of exacerbation, supported the importance of pharmacotherapy in the treatment of COPD, the associated increased costs and burden to the health care system when treatment is not optimal associated with medication non-adherence, as well as the use of education in fostering improved patient

outcomes while understanding that a patient's health literacy is key in delivering health information. Many of the studies also acknowledge that elders are at greater risk of being diagnosed with COPD, and often experience decreased quality of life and poor outcomes related to their disease and medication non-adherence. Many of the studies discussed in the literature review have also used surveys and questionnaires to obtain data regarding patients and medication adherence, like the MMAS-8 scale, which will be used in this project. These were all considerations when determining variables and a population to investigate. Therefore, the value of this project is that may add additional data in understanding the impact patient education has regarding medication adherence in management of COPD exacerbations and positive patient outcomes.

Exacerbation is worsening of respiratory symptoms that include dyspnea, cough, wheezing and phlegm production and is the fall out from non-adherence, which leads to suboptimal health outcomes (Gadkari & McHorney, 2012). Patients often require hospitalizations and acute changes in pharmacotherapy to maintain respiratory status (Tanabe et al., 2011). Exacerbations adversely influence lung function and leads to worsening of disease, worsening of quality of life, poorer prognosis and socioeconomic expenditures (Tanabe et al.). It can also lead to more frequent and severe occurrences of exacerbation events (Hurst et al., 2010). It has also been reported that health literacy plays a role in adherence to pharmacotherapy. Patients with COPD often have misconceptions and various beliefs regarding diagnosis, disease process and treatment. Therefore, self-management of chronic illness is compromised in patients with low health literacy and these patients often rely on their healthcare provider for information via oral communication (McCarthy et al., 2012). The literature has demonstrated that patients are

unsatisfied with this type of interaction when medical language is used and find it difficult to understand words that they are not familiar with (McCarthy et al.). Therefore, it is crucial to tailor education to the patient's capacity in order to reach goals of adherence and have optimal patient outcomes.

Using education, specifically teach-back technique, has shown to be a successful approach in patient education regarding medication adherence. Using teach-back gives the patient and the practitioner the opportunity to establish a partnership in care and fosters patient-provider communication and patient-centered care (Small et al., 2015). Teach-back fosters patient learning by teaching them about their disease and disease management using their own words (Senzaki, 2015). Once instructed, patients are asked to repeat what they have learned and are re-taught as indicated until mastery occurs. It is an effective tool in the assessment of patient retention of health information (Senzaki). Teach-back is an educational approach that may not only increase medication adherence in COPD patients but may decrease exacerbation events due to educating patients. Therefore, education using the teach-back method, may improve patient understanding and increases their health literacy.

Teach-back is a way to close the loop between educating patients, the patient's understanding or health literacy, and best health outcomes (University of Washington School of Nursing, 2014). It is a way to present educational material that is meaningful to patients because it allows the patient to have information explained, checked to see if understanding is achieved and then have the patient repeat the information in their own words to ensure full understanding (University of Washington School of Nursing, 2014).

The last step is to re-explain to the patient if reiteration of information is not correct or unclear, until the patient achieves mastery (University of Washington School of Nursing).

Chapter 3: Methodology

Chronic obstructive pulmonary disease is a chronic disease that has been highly associated with medication non-adherence in the elderly (Scullion, 2010). In order for patients to maintain lung function and sustain quality of life, it is crucial that patients adhere to their prescribed regimen (Scullion).

The purpose of this quantitative pretest-posttest project was to ascertain if an educational intervention using teach-back technique decreased COPD exacerbations. This project focused on COPD patients 60-80 years of age followed as outpatients in a private pulmonary practice located in south Florida. Using teach-back technique, these patients were re-educated regarding the importance of medication adherence. Post education, patients were monitored for one month to determine if utilizing teach-back technique regarding medication adherence influenced the number of exacerbation events compared to number of events one month prior to teach-back technique. This chapter will discuss the methodology used to implement this direct improvement project in regard to design, sample selection. Further discussion will provide instrument use and its validity and reliability and how the data will be analyzed. Lastly, limitations and ethical considerations regarding this project will be provided.

Statement of the Problem

There is evidence to suggest that poor education and low health literacy are components that contribute to medication non-adherence. It is crucial in COPD patients understand their disease process and medication regimen are complimentary in order to prevent exacerbation events associated with COPD. Therefore, this project improvement provided the opportunity to assess patient adherence and associate if the teach-back

technique that was used to educate patients was an effective method to improve medication adherence and therefore, decrease exacerbation events.

Clinical Question

The clinical question posed is in COPD patients, 60-80 years of age who are non-adherent with their pulmonary medication regimen, does the use of teach-back technique influence the number of exacerbations events over a 30-day period post teach-back intervention compared to 30 days pre teach-back intervention? The independent variable is the teach-back method. The dependent variables are the number of COPD exacerbations one month prior to teach-back technique and the number of COPD exacerbations one-month post teach-back technique. Discussion regarding methodology, design, data collection and instruments are noted in separate sections.

Project Methodology

This project used a quantitative methodology to determine if education, using the teach-back method, decreases exacerbation events, pre and post education, in patients with COPD who have been found to non-adherent with their respiratory pharmacotherapy regimen. The quantitative approach focuses on gathering numerical data and generalizing it across groups of people or to explain a particular phenomenon (University of Southern California, 2016). Quantitative methodology can also examine the relationships among variables and tests a theory or explanation by a specific hypothesis (Creswell, 2014). Quantitative methods are pre-determined and utilize instrument-based questions like surveys or questionnaires. This method contrasts qualitative or mixed methods methodology. Qualitative methods look to find meaning of a phenomenon from views of the participants and are more subjective in nature and tend to give a *feeling* to data

collected (Creswell). Mixed methods approach is a combination of both qualitative and quantitative data allowing results to be generalized but also focuses on the perspective of the participants (Creswell).

The use of quantitative methodology was chosen because the focus of the project was to determine if an educational intervention could change behavior regarding medication adherence and effect patient outcomes regarding exacerbation. Quantitative research is used to determine the relationship between one thing (an independent variable) and another (a dependent or outcome variable) in a population. Quantitative research designs are either descriptive, where subjects are usually measured once or experimental, where subjects are measured before and after a treatment (Hopkins, 2008). The use of a questionnaire is appropriate for and supportive of quantitative research as it is a rigid tool that allows the data collected to be expressed in numerical terms (The Open University, n.d.) This ideology in is in concert with the goals of quantitative research.

Project Design

The project design used was a pretest-posttest design. In pretest-posttest design, the group of patients will be evaluated pre teach-back intervention and post-teach back intervention to ascertain if there was a change in outcomes. Pretest-posttest designs are the favored method to compare and measure the degree of change occurring as a result of treatments or interventions (Shuttleworth, 2009). Pretest-posttest design aligns with quantitative methodology because it looks to associate the intervention of the independent variable to produce the observed changes in the values of the dependent variable (Creswell, 2014). This is appropriate to use in quantitative research because quantitative research is most often about quantifying relationships between or among the

independent variable(s) and the dependent or outcome variable (Sousa, Driessnack, & Mendez, 2007).

The use of the Morsiky Medication Adherence Scale-8 was provided to patients that consented to be a part of the project to collect data regarding adherence. Upon completion of the MMAS-8 scale, scores were calculated. Once a patient was deemed non-adherent, patients received education regarding adherence to their respiratory pharmacotherapy via teach-back technique. Patients were monitored one-month post-educational intervention to assess if exacerbation occurred. A chart review also examined the number of exacerbation each patient experienced patient 30 days pre-educational intervention. The results were analyzed using McNemar's chi-squared test. Patient demographics included age, gender and level of education and were extracted from the medical record and/or from the participant via a survey sheet. Demographic data was correlated to outcomes calculating Pearsons chi-squared.

Population and Sample

Patients in this project will be recruited from a private pulmonary practice in south Florida. This was a convenience sample of patients 60-80 years of age with a diagnosis of COPD for at least one month, prescribed at least one COPD medication, who speak English and were deemed non-adherent with their medication after completing a survey questionnaire. This specific patient age group was chosen due to the increasing aging population and their increased risk to be diagnosed with COPD. Additional inclusion criteria consisted of patients having ICD-10 codes reflective of a COPD diagnosis.

Patients that were currently stable with COPD or were experiencing exacerbation symptoms were included.

Patients were recruited on a voluntary basis during office visits that occur during a two-week period. All patients that choose to participate were informed of the project and its purpose and signed consent prior to participation. Patients were provided an explanation that inclusion or refusal to participate would not change or affect their care. The sample size was determined by the number of patients with a COPD diagnosis, seen in the pulmonary office during a two week time period consisting of 8 days (no patients were recruited on Wednesdays). The physicians of this practice agreed and consented to have their practice participate in this project (see Appendix E).

Data was collected by the investigator and used identifying information as patient initials and also assigned each patient a number, beginning with 1, in the order in which they were seen. Data was kept in a locked office at the investigator's home and on the investigator's locked personal computer. Information will be kept for 5 years. Only the investigator had access to raw data and the statistician saw data that was identified by unique identifiers and not patient names.

Instrumentation

Data collected on the survey included nominal data for age, race, and number of COPD medications and categorical data regarding gender and level of education. Additionally, the number of exacerbation events were recorded regarding events that occurred one-month pre intervention and one-month post intervention. This included exacerbations that were treated/identified telephonically, in an office visit, emergency room visit, or hospitalization. The survey sheet included an area for patient initials,

medical record number and unique identifier. Age, race and number of COPD medications were recorded on separate lines along with gender and level of education. Pre and post education exacerbation events were also recorded on separate lines and how the event was identified was checked. Please see Appendix B for the survey.

The second portion of data collection was the Morisky Medication Adherence Scale Survey (MMSA-8) to determine patient adherence. Questions 1 through 7 concentrate on possible reasons non-adherence could occur. Questions ask if patients sometimes forget to take medication, stop their medication for other reasons than forgetting, stop their medication due to negative side effects, stop medication for travel or leave home and forget them, was medication taken the day prior to office visit, stop medication if patients do not feel like they need it due to feeling well, and if taking medications is an inconvenience. These 7 questions require yes or no responses and are given a score of one for a no response and zero for a yes response. Question 8 poses the question of remembering to take medication and the difficulty in remembering. It is scaled on a 5 point Likert scale with 0 meaning all the time, 1 meaning usually, 2 meaning sometimes, 3 meaning once in a while and 4 meaning rarely/never. Adherence is deemed as follows: Low adherence= <6, medium adherence=6-8 and high adherence= 8. For the purpose of this project, non-adherence will be defined as anything less than 8.

To calculate scores there is the need to reverse the code response in a positive direction for item number 5 and standardize the code for item 8 (0-4), resulting in a scale from low adherence to high adherence (Morisky, 2015). Item 8 is divided by 4 when

calculating a summated score. This procedure standardizes the 5-point Likert scale. The total scale has a range of 0 to 8.0. Please see Appendix C.

Validity. The validity of the MMAS-8 is well established in the literature and has been tested and used globally in various studies. This adherence measure was designed to facilitate the identification of barriers to and behaviors associated with adequate adherence to chronic medications. In 2008, the MMAS-8 was developed as a modified version of the original, which looked at 4 questions (Tan, Patel, & Chang, 2014).

The English-language MMAS-8 is a reliable and valid tool, and its psychometric assessments encompass testing for its reliability, concurrent and predictive validity and its concordance with pharmacy provision data (Ashur, Shamsuddin, Shah, Bosseri, & Morisky, 2015). It showed a significant correlation with the original MMAS-4, which reinforces its concurrent validity. The scale's predictive validity was reinforced by testing the relationship between medication adherence as measured by the scale and several medication adherence-related measures. The single dimension structure of the MMAS-8 was supported using factor analysis, where all of its items loaded on 1 component, with a minimum factor loading of 0.425. Additionally, the concurrent and concordance validity of the MMAS-8 were supported using pharmacy refill medication adherence data.

This questionnaire was administered to all patients that fit inclusion criteria and answers were patient specific. There were no changes or adaptations made to the questionnaire and it was written in English. The investigator assisted patients who required assistance in completing the questionnaire if the patient asked for assistance.

Reliability. The MMAS-8 has been utilized globally to determine medication adherence. In a previous study, the scale has been determined to be reliable ($\alpha= 0.83$) and

significantly associated with blood pressure control ($p < 0.05$) in low income, mostly minority and underserved individuals with hypertension (low adherence levels were associated with lower rates of blood pressure control) (Holt et al., 2012). This questionnaire will be administered to all patients that fit inclusion criteria and answers will be patient specific. There were no changes or adaptations made to the questionnaire and it was written in English. The investigator assisted patients who required/requested assistance in completing the questionnaire.

Data Collection Procedures

The project began once IRB approval was received from Grand Canyon University. One week prior to patients coming to the office, the investigator identified those patients who were scheduled to meet the pulmonologists by their ICD-10 codes to ensure a diagnosis of COPD. Once identified, the patients initials were placed on a data survey sheet with age, gender and level of education noted (if not present in the medical record, patient were asked). The number of medication(s) were noted and then reaffirmed with the patient/caregiver and recorded on the survey sheet. The patient's medical record was used to identify the number and type of exacerbation events that took place one month prior to the office visit and was also documented on the survey sheet.

Patients who were identified to have a diagnosis of COPD were approached at the reception area. The investigator explained the purpose of the project and patient participation was discussed. If the patient agreed to participate, informed consent was obtained and HIPAA documents were provided. The MMAS-8 was given to the patient to

complete. The form was completed with the researcher at the patient's request; however, if not requested, the patient independently answered the survey.

The MMAS-8 was collected and scored by the researcher to determine the patient's adherence. Scores < 8 will be deemed non adherent, per the MMSA-8 criteria. After the office visit with the pulmonologist, patients were provided the opportunity to share their understanding of their medication regimen in the exam room. Using teach-back technique, the researcher reeducated the patient regarding their medication regimen, tailored to their needs. The researcher completed the teach-training online and used the teach-back tool kit provided at teachbacktraining.org for patient education. Once patient achieved mastery, the teach-back session ended. Each patient intervention was noted in a notebook to be locked and secured in the researcher's home desk. Data was also gathered one-month post teach-back educational intervention via chart review, to determine if patients experienced any exacerbation events. Medical record numbers were kept on patients' survey sheets in order to have access to their medical records post educational intervention. Charts were gathered at the pulmonary office by the investigator and reviewed 30 days post educational intervention. These exacerbation events consisted of increased worsening of respiratory symptoms that require an office visit, an ER visit, hospitalization and/or intervention via telephonic contact. Events were then counted and recorded on the survey sheet.

All data was secured in the locked private office in the researcher's home desk, including her locked computer. Once survey information was placed into SPSS, all

information will be stored and locked for 3 years. All survey material will be shredded and SPSS information will be deleted from the investigator's private computer.

Data Analysis Procedures

The clinical question looks to see if utilizing an educational intervention (teach-back method) will decrease exacerbation over a 30-day period compared to exacerbation rate 30 days pre-educational intervention. The question is one that looks to determine if differences in patient outcomes, after receiving education regarding medication adherence, yields a decrease in exacerbation events and therefore a positive patient outcome.

The raw data was placed into an Excel spreadsheet naming each variable to prepare for data analysis. The variables consisted of patient number identifier, number of pre-exacerbations, number of post-exacerbations (including type of exacerbation: phone call, office visit, emergency room visit, hospitalization), age, gender, race, level of education and number of medications. Additionally, the questions of the Morsiky Medication Scales-8 questions were placed into the Excel spreadsheet. Once all the information was entered, it was copied and pasted into SPSS. Once placed into SPSS, the demographic variables were grouped in categories that consisted of male, female, younger elder (60-70 years), older elder (71-80 years), and low education (0=elementary and high school), and high education (1=college and graduate school) and the other data were unchanged.

A one-tailed t-test will be calculated to examine if there is a statistically significant difference (decrease) in COPD exacerbation events 30 days post teach-back educational intervention compared to 30 days pre educational intervention. A one-tailed test allots for all the testing of the statistical significance in one direction of interest and completely

disregards the possibility of a relationship between variables in the other direction (University of California Los Angeles, 2016). The independent variable is patient education (teach-back). The dependent variable is the number of exacerbations that occurred post educational intervention.

However, if the data is not normally distributed, McNemar's chi-squared test will be calculated to determine if there was a decrease in exacerbations post educational intervention. McNemar's is a non-parametric test and a form of the chi-squared test for within-subjects designs (Portland State University, 2009). The McNemar's test can be viewed as a type of chi-square test that uses dependent (correlated or paired) data rather than independent (unrelated) samples. This type of statistic is a non-parametric statistical test, noting it is distribution free and can be used with data sets and samples that are not normally distributed (Adedokun & Burgess, 2012). Similar to the paired t-test or the ANOVA, the McNemar's test is used whenever the same individuals are measured twice, matched on some variable, paired in some way, or responses on two measures are used (Portland State University, 2009). Pearson's chi-squared was again used to correlate descriptive statistics as in pre-intervention data analysis.

To determine correlations of demographic data of age and level of education, the parametric test, Pearson correlation coefficient will be calculated. This analysis measures the strength of the linear relationships between normally distributed variables and is appropriate for quantitative data analysis (Darvishan, 2013). If the variables are not normally distributed, Pearson's Chi-Square will be calculated. This non-parametric test compares the tallies or counts of categorical responses between two (or more) independent groups (Hobart and Smith Colleges, n.d.). It is designed to analyze

categorical data, meaning the data has been counted and divided into categories (University of Pennsylvania, 2008). The level of significance for all analysis will be based on a p value less than .05.

Ethical Considerations

All participants were asked to sign an informed consent and the purpose of the project was explained. No participants were compensated or coerced into participating. Participants were informed that no repercussions regarding their care would occur if they did or did not participate. If participants were unable to provide consent, their significant other was informed in the same fashion.

The private pulmonary practice provided consent to partake in this project and no parties were compensated for their participation. No medication was introduced, denied or changed prior to participation in this project. If medication changes occurred, it was related to findings deemed by the physician. All participants were protected in order to not disclose their identity, diagnosis or personal information as survey sheets were numbered, all personal information was locked in the investigator's private office and on the investigator's private computer.

Limitations/Assumptions

There were several limitations. The sample size was small and may be subject to selection bias. Stage of disease, length of diagnosis and comorbidities were not considered and may become confounding variables (Indrayan, 2012). Participants may have experienced self-report bias, and responses of participants may have been biased, as they knew they were being studied. Subjects' smoking history, and comorbid conditions were not considered and could have been reflective of alternate causes of non-adherence.

This data can be generalized to older Americans with COPD but would be difficult to generalize to younger populations. Lastly, the possibility of missed events could have occurred and not provided exact numbers of pre and post educational exacerbation events. This could have resulted from patients being treated at different hospitals, failure to report incident to staff/physicians and failure of staff/ physicians to document events. Exacerbations that did occur could also have been contributed to other factors other than non-adherence to medications, like comorbid conditions, smoking, normal disease progression and climate.

Summary

Exacerbations are the result of various contributing factors in patients with COPD. This quantitative project with a pretest-posttest design looked to determine if patients who were non adherent with their respiratory medication regimen that received teaching regarding medication adherence, would have had decreased exacerbation events.

The literature has noted that patients with poor education and health literacy regarding their disease process and management tend to have outcomes that increase morbidity and mortality. Using techniques like teach-back to educate patients in a manner that fosters self-management and patient empowerment leads to improved outcomes.

Understanding ways to improve medication adherence in COPD can result in improved patient outcomes. This project has revealed statistical and clinical significance in understanding how educational intervention impacted patient outcomes in COPD. It

has also provided data that could be important in considering when managing COPD patients regarding age and gender.

Chapter 4: Data Analysis and Results

It is not known to what degree the use of teach-back technique, as an educational intervention in patients 60-80 years of age with chronic obstructive pulmonary disease (COPD), will affect the number of exacerbations that occur during the 30-day period post educational intervention. The question posed for this project was in patients with COPD, 60-80 years of age who are non-adherent with their medication regimen, does the use of teach-back technique decrease the number of exacerbation events during a 30-day period post educational intervention as compared to the 30-day period prior to using the teach-back technique? Utilizing quantitative methodology with a pretest posttest design, this project sought to discover if an educational intervention, using the teach-back technique, affected patient outcomes regarding COPD exacerbation events.

This chapter presents the results of this practice improvement project to determine if educational intervention, focused on medication adherence in COPD patients, impacted patients exacerbation events 30 days post educational intervention compared to 30 days pre educational intervention. This chapter will also examine if demographic data (age, gender, race and level of education) had an impact on patient outcomes.

Data Analysis Procedures

This project was approved by the IRB at Grand Canyon University in Phoenix, Arizona. The project took place in a private pulmonary practice in south Florida over a 2-week time period totaling 8 days in April 2016. The post educational exacerbations were collected via chart review in May of 2016.

All participants' charts were reviewed to note any exacerbation events that occurred 30 days prior to patient education and once again 30 days post educational intervention.

All patients ranged from 60 -80 years, had a diagnosis of COPD and were on at least one respiratory medication for at least one month. Participants in this project were explained the nature of this project and signed a consent form. They were told participation was optional and would not affect their care. Once patients agreed, they were asked to fill out an 8-point questionnaire (MMAS-8) regarding their medication adherence. If their score was less than 8, they were considered non-adherent and were educated on the importance of medication adherence in the management of their COPD. Patients were then asked to explain in their own words the importance of medication adherence in the management of their COPD.

The clinical question looks to determine if, in COPD patients, 60-80 years of age who are non-adherent with their pulmonary medication regimen, does an educational intervention, using teach-back technique, influence the number of exacerbations events over a 30-day period post educational intervention compared to 30 days pre educational intervention? Data were collected on a survey sheet for demographic information as well as number of respiratory medications and along with 30-day pre and 30-day post educational intervention exacerbation occurrences.

Data were analyzed using SPSS software. The results regarding number of exacerbations were binary and therefore, not normally distributed. Binary data occurs when there is a variable with only two values (StatisticHowTo, 2016). For this project, the investigator looked for a decrease in exacerbations post educational intervention;

however, for statistical analysis, the exacerbations were grouped to note an absence or presence of exacerbations.

Pearson's chi-squared statistic was calculated for pre-intervention data because the sample was not normally distributed and this non-parametric test compares the tallies or counts of categorical responses between two (or more) independent groups (Hobart and Smith Colleges, n.d.). Moreover, this statistic better represents the findings of this project.

In order to calculate the level of education and its correlation to the number of exacerbations pre-intervention and the MMAS-8 results, the education categories were divided in to high level (college and graduate school) and low level (high school and elementary school). In order to calculate age and its correlation to exacerbations pre intervention and the MMAS-8 results, age categories were divided into young elders (60-70 years of age) and old elders (71-80 years of age). The MMAS-8 scores were calculated according to instructions of the author of the questionnaire.

When analyzing post intervention exacerbation decreases, McNemar's chi-squared test was calculated to determine if there was a decrease in exacerbations post educational intervention. McNemar's is a form of the chi-squared test for within-subjects designs (Portland State University, 2009). The McNemar's test can be viewed as a type of chi-square test that uses dependent (correlated or paired) data rather than independent (unrelated) samples. This type of statistic is a non-parametric statistical test, noting it is distribution free and can be used with data sets and samples that are not normally distributed (Adedokun & Burgess, 2012). Similar to the paired t-test or the ANOVA, the McNemar's test is used whenever the same individuals are measured twice, matched on

some variable, paired in some way, or responses on two measures are used (Portland State University, 2009). Pearson's chi-squared was again used to correlate descriptive statistics as in post-intervention data analysis.

Descriptive Data

A total of 43 patients were eligible for this project during the recruitment time period. Of the 43 eligible patients, 12 were excluded as they surpassed the age limit (2 were younger than 60 and 10 were older than 80). There were a total of 31 patients that participated in this project and consisted of 15 males and 16 females. The mean age for patients was 74.4 years. There were 10 patients educated at the graduate level, 17 at the college level, 3 at high school level and 1 at the elementary school level. All patients that participated were Caucasian and therefore, race was not considered in the statistical analysis. (Figures 1 and 2). All patients that participated in the project were considered

low adherence (a score <6 is considered low adherence) with overall adherence scores ranging from 5-.05 with a mean score of .71

Figure 1: Females, age and level of education. N=16

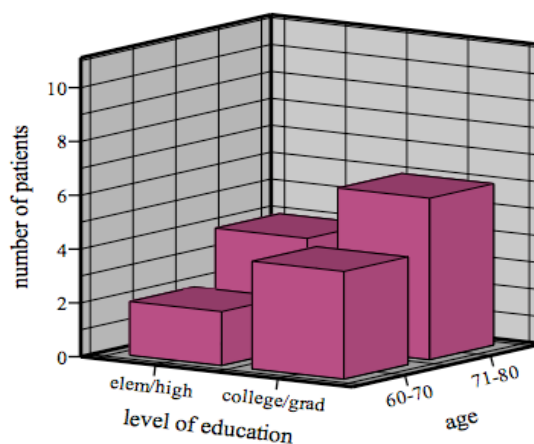
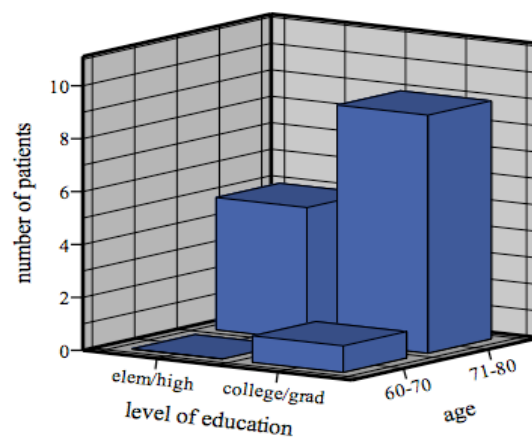


Figure 2: Males, age and level of education. N=15



Results

Thirty days post-intervention, data were collected from each patient's medical record to note if any exacerbation event occurred. Pre-educational intervention, 19

exacerbations were noted in 17 patients. However, post-educational intervention, a reduction of 8 exacerbations in 8 patients occurred. Four patients with pre-educational intervention exacerbations had repeat exacerbations and of these four patients, 2 were younger elders, 3 were males, and 3 were in the higher educational level. Four patients who did not previously exacerbate had new exacerbation events and of these four patients, 3 were older elders, 3 were female, and 3 were in the lower educational level.

Exacerbations were grouped as presence or absence of exacerbation for statistical analysis. Thirteen of the seventeen patients had no exacerbations post-educational intervention. Cross tabulation of pre and post findings using McNemar's chi-squared statistic noted that 10 patients had no exacerbation pre-intervention and 10 patients had no exacerbation post-intervention. Moreover, 4 patients had no exacerbation pre-intervention but 4 patients did have at least one exacerbation post-intervention. There were 13 patients that had at least one exacerbation pre-intervention and 13 patients who had no exacerbations post-intervention. Lastly, 4 patients had at least one exacerbation pre-intervention and 4 patients had at least one exacerbation post-intervention, yielding a statistically significant result ($p=.049$) (Table 1).

Post-educational intervention, younger elders had a higher percentage of exacerbation. However, males and females experienced equal amounts of post-intervention

exacerbations. Patients with a lower education level had a slightly higher percentage of post-intervention exacerbation. No findings were statistically significant. (Table 2).

Table 1: Pre and Post Educational Intervention Exacerbation Cross-tabulation

McNemar's Chi-Squared Test
Post intervention exacerbations
*no exacerbation
**exacerbation

	.00*	1.00**	Total	p value
				.049
Pre intervention	.00	10	4	14
exacerbations	1.00	13	4	17
Total	23	8	31	

Table 2: Pearson's Chi-Squared Correlation of Age, Gender and Level of Education to Exacerbations 30 Days Post-Educational Intervention N=31

	no exacerbation	Exacerbation	% with exacerbation	p value
Age				.241
60-70(young elder)	4	5	55.5%	
71-80 (old elder)	19	3	13.6%	
Total	23	8		
Gender				.916
Female	12	4	25.0%	
Male	11	4	26.6%	
Total	23	8		
Level of education				.319
low(elem/high)	7	4	36.3%	
high(college/grad)	16	4	20.0%	
total	23	8		.

Nineteen exacerbations occurred in 17 patients (2 patients had 2 exacerbations pre educational intervention) 30 days pre-educational intervention. It was noted that although there was no statistically significant difference, younger elders had a greater percentage of exacerbation (N=7: 5 had exacerbation) with 71.4% versus older elders (N=24; 12 had exacerbation) with 50.0%. Gender and its correlation to exacerbation 30 days pre-educational intervention showed that 43.8% of women and 66.7% of men experienced exacerbations. Lastly, level of education and its correlation to exacerbation 30 days pre-educational intervention noted that 45.5% of those in the low educational category (N=11; 5 had exacerbation) and 60% of those in the high educational category (N=20; 12 had exacerbation) experienced exacerbations. (Table 3).

Table 3: Pearson's Chi-Squared Correlation of Age, Gender and Level of Education to Exacerbations 30 Days Pre-Educational Intervention N=31

	no exacerbation	exacerbation	% with exacerbation	p value
Age				.316
60-70(young elder)	2	5	71.4%	
71-80 (old elder)	12	12	50.0%	
Total	14	17		
Gender				.200
female	9	7	43.8%	
male	5	10	66.7%	
Total	14	17		
Level of education				.436
low(elem/high)	6	5	45.5%	
high (college/grad)	8	12	60.0%	
total	14	17		.

The overall results revealed that there was no statistically significant difference noted regarding age and responses to the MMAS-8 (Appendix C).. Scores were correlated with age, gender and level of education. Question 3 (have you ever cut back or stopped taking

your medication(s) without telling your doctor, because you felt worse when you took it?) revealed that 85.7 % of older elders stopped or cut back on their medications compared to 14.2% of younger elders ($p=0.029$) (Table 4). Regarding gender and responses to the MMAS-8, there was no statistically significant difference noted. However, question 6 (when you feel like your breathing is under control, do you sometimes stop taking your medication[s]?) showed clinical significance ($p=.056$) noting that that 93.8% of females and 66.7% males did have an affirmative response. (Table 5). Lastly, regarding level of education and responses to the MMAS-8 responses, it was noted that there was no

indication that level of education played a significant role in medication adherence. No statistical significant findings were noted. (Table 6).

Table 4: Pearson's Chi-Squared Correlation of Age to MMAS-8 Questionnaire Pre-Educational Intervention N=31

Question	Age older elder yes response	Age younger elder yes response	Age Older elder no response	Age Younger elder no response	p value	% of yes response older elder	% of yes response younger elder
Question 1	18	4	6	3	.360	81.81%	18.18%
Question 2	14	5	10	2	.531	73.6%	26.3%
Question 3	24	4	2	3	.029	85.7%	14.2%
Question 4	10	1	14	6	.183	90.9%	9.0%
Question 5	11	1	13	6	.132	91.6%	8.3%
Question 6	18	7	6	0	.141	72.0%	28.0%
Question 7	19	5	5	2	.667	79.1%	20.8%
	Age older elder	Age younger elder	Total % of patients				
Question 8 Likert Scale:					.809		
4=1.00 points	9	3	38.7%				
3=0.75 points	6	2	25.8%				
2=0.50 points	6	2	25.8%				
1=0.25 points	0	0	0.00%				
0=0.00 points	3	0	9.6%				

Table 5: Pearson's Chi-Squared Correlation of Gender to MMAS-8 Questionnaire Pre-Educational Intervention N=31

Question	Female yes response	Female no response	Male yes response	Male no response	P value	% of yes response female	%of yes response male
Question 1	11	5	11	4	.779	68.8%	73.3%
Question 2	9	7	10	5	.552	56.3%	66.7%
Question 3	12	4	14	1	.165	75.0%	93.3%
Question 4	6	10	5	10	.809	37.5%	33.3%
Question 5	6	10	6	9	.552	37.5%	40.0%
Question 6	15	1	10	5	.056	93.8%	66.7%
Question 7	13	3	11	4	.598	81.3%	73.3%
	Females	Males	% of Females	% of Males			
Question 8 Likert Scale:					.423		
4=1.00 points	6	6	37.5%	40.0%			
3=0.75 points	6	2	37.5%	13.3%			
2=0.50 points	3	5	18.8%	33.3%			
1=0.25 points	0	0	0.00%	0.00%			
0=0.00 points	1	2	6.3%	13.3%			

Table 6: Pearson's Chi-Squared Correlation of Level of Education to MMAS-8 Questionnaire Pre-Educational Intervention N=31

Question	Level of Education Low (elem/high) yes response	Level of Education High (college/grad) yes response	Level of Education Low (elem/high) no response	Level of Education High (college/grad) no response	p value	% of yes response Low	% of yes response High
Question 1	9	13	2	7	.324	40.9%	59.0%
Question 2	7	12	4	8	.842	36.8%	63.1%
Question 3	9	17	2	3	.818	34.6%	65.3%
Question 4	5	6	6	14	.390	45.4%	54.5%
Question 5	5	7	6	13	.567	41.6%	58.3%
Question 6	9	16	2	4	.902	36.0%	64.0%
Question 7	8	16	3	4	.643	33.3%	66.6%
	Level of Education Low	Level of Education High	Total % of patients				
Question 8 Likert Scale:					.343		
4=1.00 points	2	10	38.7%				
3=0.75 points	4	4	25.8%				
2=0.50 points	4	4	25.8%				
1=0.25 points	0	0	0.00%				
0=0.00 points	1	2	9.6%				

Summary

This project examined if exacerbation events decreased over a 30-day period post educational intervention. Chapter one detailed how chronic obstructive pulmonary disease is a progressive and pathological condition of the respiratory system, effecting millions worldwide. It also discussed the effects of COPD, exacerbations and how each decrease quality of life relating to increased incidence of morbidity and mortality, particularly when patients are non-adherent to pharmacotherapy. Chapter two focused on COPD and the disease process, noting its growth in the U.S. and globally. Additionally, chapter two discussed how Imogene King's Theory of Goal Attainment has been a guiding force for this project by understanding that the nurse patient relationship plays an important role in attaining positive patient and provider outcomes. Moreover, it provides the concepts needed to understand the individual and their unique needs. Lastly, chapter

two provided ample support from the literature regarding pharmacotherapy, health literacy and patient education and their roles in the management of patients with COPD. Chapter three provided the method, the design and the statistical analysis that was proposed for this project. Despite the changes that were needed for statistical analysis, the methodology remained unchanged and detailed and how this project would be implemented.

Chapter four revealed that medication non-adherence is a factor for this group of COPD patients that were included in this project. Moreover, it has demonstrated statistical and clinical significant findings that patient's stop taking their medication if they perceive they feel worse when taking them or if they feel their respiratory status is improved, without discussion with their healthcare provider. Lastly, statistical significance was noted, as there was a marked decrease in patient exacerbation post educational intervention.

Chapter 5 will discuss this project's findings and expand on how these findings may impact nursing and clinical practice. King's Theory of Goal Attainment will also be highlighted and will identify the strengths of this theoretical framework in the management pharmacotherapy of COPD patients. This chapter will also discuss how this project may provide the platform for further research regarding older Americans, gender differences and how level of education may impact the treatment of COPD.

Chapter 5: Discussion

Chronic obstructive pulmonary disease (COPD) and the consequent exacerbations that occur cause a decrease in quality of life and are a significant contributing factor to patients' morbidity and mortality, particularly when adherence to pharmacotherapy is not optimal. This project was important in understanding how the role of patient education and the nurse patient relationship affect patient outcomes. This project is also important because it sheds light regarding outcomes of aging patients with COPD and perhaps, begins to explore possible gender differences related to COPD and its treatment.

Summary of the Project

The project's clinical question examined if, in COPD patients 60-80 years of age who are non-adherent with their pulmonary medication regimen, does the use of teach-back technique influence the number of exacerbations events over a 30-day period post teach-back intervention compared to 30 days pre teach-back intervention? The project's main focus was to determine if educating patients regarding their COPD medication would cause less exacerbation events 30 days post education.

Chapter one discussed how COPD has evolved and has increased globally, particularly among women. It also expounded on the role of medication adherence and its importance in COPD management. Chapter two provided an extensive literature review that focused on exacerbations, medication adherence, and patient outcomes. It also discussed Imogene King's Theory of Goal Attainment, which was the framework that guided this project, stressing the role of the nurse patient relationship and how each entity brings important aspects to successful patient outcomes and mutual goal setting. Chapter three concentrated on the project methodology, design and instrumentation. It also

included data collection, data analysis, ethical considerations, and limitations of this project. Chapter four provided results of this project.

Summary of the Findings

This project yielded noteworthy statistically and clinically significant findings. It is understood that medication non-adherence is evident among all the COPD patients observed in this project. All participants were considered to have low adherence scores in accordance with the parameters of the MMAS-8 questionnaire regardless of age, gender and level of education. As noted in chapter one, Khodour et al., 2012, explained that medication adherence is an uncertain entity for older patients with COPD as their disease duration is usually longer and risks of comorbidities, adverse side effects, and polypharmacy are related to non-adherence. However, according to this project, age and gender seem to have an influence regarding medication adherence when it comes to stopping medication without consulting a healthcare provider. Statistical significance was calculated regarding stopping medication because it made patients feel worse, noting older elders were more likely to stop than younger elders. Clinical significance was noted regarding patients stopping their medication because they felt well and women were more likely to stop than men. This finding would likely impact patient outcomes and therefore is clinically significant.

Exacerbation events were captured pre and post educational intervention and pre intervention exacerbations occurred in higher percentages in younger elders, males, and those with higher levels of education. Post intervention, there was a statistically significant reduction in exacerbation events compared to pre intervention and younger elders remained at a higher percentage of exacerbation but gender and exacerbation

remained fairly equal. Furthermore, patients that were in the low educational group had a slightly higher percentage of exacerbation occurrences. It is important to note that eight patients had eight post intervention exacerbations. Four patients experienced repeat exacerbations and of those four, 75% were male and in the higher educational level. Four patients experienced new exacerbations and 75% were female and in the lower educational level.

As previously discussed, COPD is a chronic illness and exacerbations are unpredictable but both can be managed. Chapter one discussed the important role patient education plays as Kaptein et al., 2014 explain, patient education is an indispensable component of self-management that changes patient behavior to improve patient outcomes. This is evident by the findings of this project as exacerbation events decreased from nineteen to eight 30 days post educational intervention.

A decrease in exacerbation events is an important finding because as noted in Chapter one, this evidence can advance scientific knowledge and place the focus on treatment goals that include prevention of complications, decrease and delay patient decline all through educational support. Age and gender played a role in findings as well, noting that these factors may be a component to why patient's do or do not exacerbate and even shed new information on how treatment should be approached due to age and/or gender. As we have learned, treatment of heart disease differs for gender as well as age, this may be true in treating COPD. All of the findings encompass that patient education is an important entity in the progression to self-management, patient-centered care and the overall management of COPD and medication adherence, thus addressing patients' health literacy. Therefore, addressing the findings of this project can potentially decrease poor

patient outcomes and subsequently decrease cost of care for this population by obtaining positive outcomes. Less exacerbation indicate greater health, less hospital re-admissions and a decrease in resource utilization.

Implications

The implications of this project demonstrate many factors regarding the management of COPD theoretically, in practice and for the future. The findings of this project may be a crucial stepping-stone to future practice regarding patient education and could generate further research regarding age, gender and level of education and medication adherence and/or in the overall management of COPD.

Theoretical implications. Patients that participated in this project were deemed non-adherent with their COPD medications. Subsequently, post educational intervention there was a substantial decrease in exacerbations compared to pre-education intervention period. Statistically and clinically significant results were correlated with patients independently stopping their medication with age and gender. Level of education played no statistically significant role in exacerbation events or medication adherence in either pre or post intervention data. However, post intervention data revealed that those who exacerbated had mixed levels of education.

The results of this project support the role education plays in positive patient outcomes and is well aligned to King's Theory of Goal Attainment (TGA), which is the theoretical framework that has guided this project. As noted earlier in this project, the University of the Philippines, (2011), explained that King's TGA understands the nurse patient relationship impacts patient outcomes. It also notes the nurse patient relationship is impacted by the environment in which each comes from and the one both share.

Therefore, it provides the perfect foundation to build mutual trust and subsequent goals with patients that are mutually beneficial and place the patient in an empowering position. As previously discussed in chapter one, Wortz et al., (2013) suggested self-management fosters an opportunity for patients to have educational and supportive interventions by providers, and allows patients to increase and improve their skill in managing their illness. As health care continues its evolution to a more patient-centered approach that warrants patient involvement, King's TGA is best suited to foster patient education and subsequent patient independence. King's theory remains timeless and is in concert with the current healthcare mindset.

This project's strengths were few but important. This quantitative project with a pretest/posttest design, demonstrated statistical and clinical significance in areas of pharmacological non-adherence regarding age and gender. It also demonstrated statistical significance regarding patient education and its positive effects on patient outcomes. This project did have several limitations. The participants were older, Caucasian Americans in a suburban setting and provided a snap shot of the challenges faced by this population. However, this may be difficult to generalize to younger non-white patients with COPD. There could have been missed exacerbation events secondary to failure to report exacerbation by patients and/or failure to identify exacerbation in the medical record by physicians and/or office staff. Smoking history, exposure to second hand smoke, disease stage and lung function were not included and could have affected exacerbation events. Comorbid conditions were also not included and could have

influenced exacerbation and medication adherence. The project population was small and time constraints did not allow a more rich data collection.

Practical implications. The evidence discovered from the results of this project should encourage health practitioners to engage patients in the planning of their COPD management and understand that although patients may share the same diagnosis, each patient needs to be cared for differently. Each plan of care should be tailored to be as unique as the patients that are encountered. Again, similar to what is the essence of King's TGA, understanding the patient and their environment makes a difference in goal setting and eventual goal attainment.

Approaching patient care in this way not only fosters positive patient outcomes but also encourages patient independence and self-management. It is critical that practitioners understand that medication adherence should not be assumed and remains an intricate part in the management of COPD and most chronic illnesses. Therefore, it is valuable in practice with patients to establish a dialog with patients and listen to what patients say, even if it is not spoken, and monitor these patients closely to avoid a potential break down in care. Success cannot be an expectation for a patient who cannot follow a plan, regardless of the barrier. It is the responsibility of the health care provider to identify, in conjunction with the patient, the barriers to successful adherence and utilize the information to formulate a plan that is mutual and fosters successful outcomes.

Future implications. As the literature has supported in this project, The United States

is aging and this nation will be faced with an expanding elderly population. This population faces many health care risks, including COPD. The potential of having multiple comorbid conditions with multiple medications prescribed is also a risk. It will be beneficial to consider the impact of comorbid conditions on medication adherence and COPD management.

Recommendations

Although this project was small, there are still implications that are worthy of future investigation and should be considered in practice. Proposals for future projects should include investigation that is both quantitative and qualitative. Recommendations for practice will assist in the provision of care that is holistic and encompasses the patient, the providers and the environment in which the patient will be maintained. The goal would be to have patients reach their optimal level of wellness and have omitted barriers that would prevent positive patient outcomes. Additionally, expanding this project's age range and subject number would be beneficial to better understand how even older patients with COPD manage their disease process and perhaps capture a broader representation of race.

Recommendations for future projects. Quantitative investigation should consider the role of gender in COPD. This project has brought forth evidence that gender may be an influence in the management and presentation of patients with COPD. As in heart disease, it has been discovered that gender plays a role in presentation and management, this may also be the case for COPD. Women's lung capacity is different from men and they can display symptoms earlier, later, and/or different from their men counterparts. Subsequently, their disease process could alter lung parenchyma earlier and cause

increased damage sooner. Women also may benefit from medication regimens that may not be similar to men and lastly, the role women play within their environment, along with their perceptions of the disease and treatment, may cause them to have less focus on their own care. This could shed information regarding non-adherence issues that could quell negative outcomes regarding their COPD process.

Patients with COPD are often managing other chronic comorbid conditions, particularly the elderly. Therefore, it may be reasonable to examine medication adherence in elderly COPD patients and include pharmacotherapy associated with their comorbid conditions. Often patients with multiple medical problems are seen by a variety of care providers and medication regimens can be cumbersome and confounding. Understanding what patients face may help care providers streamline medication regimens and perhaps cause more effective interdisciplinary interaction with care providers and pharmacies to benefit both patient and practice.

Patient exacerbation of COPD is an inflammatory process that has been known to decrease quality of life, decrease life expectancy and cause continued damage to lung tissue. Further research regarding lung function changes post exacerbation over marked time periods will be significantly fruitful. Understanding the patient's recovery time and lung function post exacerbation can help change treatment options, intercept and decrease re-exacerbations and possibly decrease readmission or visits to the emergency department. Thus, decreasing patient burden and decreasing burden on the health care system

This project has shed light that all 31 participants were considered non-adherent with their pharmacotherapy. Specifically, patients discontinued taking their medication

because it either made them feel worse or they felt better. These are broad parameters and therefore, it may be beneficial to practice to qualitatively understand *why* patients stop their medications without informing their physicians. This may present new insight into how patients perceive their medications and disease process. It also provides an opportunity in practice to assess and treat patients more effectively while simultaneously, keeping the patient empowered and engaged by incorporating aspects of care that will educate patients. Considering patients' understanding and worldviews regarding treatment and management of their COPD, as well as their perceptions of COPD, can be an effective tool in patient education and patient compliance. Insight into patient perceptions can make the plan of care easier to follow and adjust and potentially lead to increased patient adherence.

The next steps to foster continued research regarding this project's content would to translate these findings via presentations within the practice that this project took place, prepare this project transcript for publication in nursing and respiratory care journals. Additionally, presentations at seminars related to the management of patients with COPD and chronic illnesses would aide with translation. Moreover, this project may add to the understanding of how gender and age effect the management of COPD. Conducting further research regarding gender and age in the management of COPD could not only provide additional and new data but could garner interest from other health care entities like the NIH and CDC to consider this type of research on a grander scale.

Recommendations for practice. As discussed in chapter one, Wortz et al., 2013 clearly state that COPD is not just a leading cause of morbidity and mortality globally but is frequently managed sub-optimally. The primary practice recommendation from this

project is to customize patient care according to the patient and not the diagnosis.

Addressing specific needs of the individual patients and considering patient's gender and age, can optimize patient success and outcomes.

Additionally, it is recommended that patient education should continue to be at the forefront of patient care. Arming patients with knowledge and understanding of their treatment and their disease empowers patients to partner with their healthcare provider to make appropriate and successful choices regarding their health and health care. Patient success is evident when they are educated and engaged in the process. This means it is the responsibility of the every health care provider in any capacity to ensure patients truly understand what their role is in their care, exactly what the expectations are and to feel able to have an honest dialog with their provider regarding the direction of the plan of care, particularly when outcomes are less than desirable. Knowledge and rational directly related to treatment and disease can lead to increased quality of life and stability of disease by decreasing lung inflammation, exacerbation and scarring.

The information that has been brought forth from this project would be beneficial to many in healthcare including staff nurses, nurse practitioners, nurse educators, physician assistants, respiratory therapists and physicians in the acute, chronic, outpatient and home care environments. Chief nursing officers, hospital and chronic care facility administrators may also benefit from this information as what has been discovered could potentially improve practice outcomes, lead to improvement in patient outcomes, increase

patient satisfaction and decrease hospital readmissions and emergency department utilization.

Conclusion

This project has demonstrated that COPD is a chronic disorder that may require changes in approach according to age and gender. Although COPD and its associated exacerbations can cause an increase in morbidity and mortality, approaches to patient education, specific to patients' needs, may decrease exacerbation events, improve quality of life and have positive outcomes in patients' disease process. Integrating these findings in practice can foster more effective and consistent outcomes in all patients as well as a patient-centered focus to care and perhaps provide a more cost effective option to care for this patient population.

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Appendix A

Survey Sheet

DATE: _____

Name (initials): _____ # _____

Race: _____ Age: _____

of meds _____

Level of Education:

Elementary school: _____

High School: _____

College: _____

Graduate: _____

of exacerbation events pre-education (1 month prior to date of educational intervention):

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

of exacerbation events post educational intervention (through 1 month post education):

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Date: _____ ID: office visit ___ Phone to office ___ ER visit ___ Hospitalization _____

Appendix B

<p>©Morisky Medication Adherence Scale (MMAS-8-Item). This is a generic adherence scale and the name of the health concern can be substituted in each question item.</p>		
<p>You indicated that you are taking medication(s) for your (identify health concern, such as “high blood pressure”). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication.</p>		
<p>(Please mark your response below)</p>		
	No=1	Yes=0
1. Do you sometimes forget to take your [health concern] medication(s)?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medication(s)?		
3. Have you ever cut back or stopped taking your medication(s) without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication(s)?		
5. Did you take your [health concern] medication(s) yesterday?		
6. When you feel like your [health concern] is under control, do you sometimes stop taking your medication(s)?		
7. Taking medication(s) every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your [health concern] treatment plan?		

8. How often do you have difficulty remembering to take all your medication(s)?

Never/rarely.....4

Once in a while.....3

Sometimes.....2

Usually.....1

All the time.....0

Coding Instructions for the ©Morisky Medication Adherence Scale (8-Item)

You will need to reverse the code response in a positive direction for item number 5 and standardize the code for item 8 (0-4), resulting in a scale from low adherence to high adherence. Item 8 is divided by 4 when calculating a summated score. This procedure standardizes the 5-point Likert scale. The total scale has a range of 0 to 8.0. The eight-item compliance scale had an alpha reliability of 0.83 (n= 1367) among patients diagnosed with essential hypertension attending an outpatient clinic of a large teaching hospital. We have used a 75% completion criterion for establishing eligibility.

The median value of all non-missing items would be substituted for the missing item for individuals meeting the eligibility criterion. i.e. if 1 or 2 items are missing, the median values of the other 7 or 8 items would be substituted for the missing item.

Re-codes:

If Item5 = 0 Item5r = 1 (high adherence)
If Item8=4 Item8r = 1 (highest adherence)
If Item8=3 Item8r = .75 (high adherence)
If Item8=2 Item8r = .50 (moderate adherence)
If Item8=1 Item8r = .25 (low adherence)
If Item8=0 Item8r = 0 (lowest adherence)

Adherence Level

Low Adherence (< 6)

Percent

32.1

Medium Adherence (6 to <8)	52.0
High Adherence (= 8)	15.9

Required citation and acknowledgement for the 8-item MMAS are as follows:

Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. *Journal of Clinical Hypertension* 2008; 10(5):348-354

Krousel-Wood MA, Islam T, Webber LS, Re RS, Morisky DE, Muntner P. New Medication Adherence Scale Versus Pharmacy Fill Rates in Seniors With Hypertension. *Am J Manag Care* 2009;15(1):59-66.

Morisky DE, DiMatteo MR. Improving the measurement of self-reported medication nonadherence: Final response. *J Clin Epidemio* 2011; 64:258-263. PMID:21144706

This acknowledgement **is required** to be listed in the acknowledgement on all manuscript submitted for publication and as a footnote on the first Table or Figure that lists the MMAS-8 items.

Use of the ©MMAS is protected by US copyright laws. Permission for use is required.

A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Sciences, UCLA Fielding School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772, dmorisky@ucla.edu.

Appendix C



GRAND CANYON
UNIVERSITY™

3300 West Camelback Road, Phoenix Arizona 85017 602.639.7500 Toll Free 800.800.9776 www.gcu.edu

DATE: April 5, 2016

TO: amelia schreibman, MSN

FROM: Grand Canyon University Institutional Review Board

STUDY TITLE: [863147-1] Utilizing Teach-Back Technique Regarding
Medication Adherence and Its Effects on Exacerbation
Events

IRB REFERENCE #:

SUBMISSION TYPE: New Project

ACTION: APPROVED

APPROVAL DATE: April 5, 2016

EXPIRATION DATE: April 5, 2017

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # [7.7]

Thank you for your submission of New Project materials for this research study. Grand Canyon University Institutional Review Board has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and

a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please remember that informed consent is a process beginning with a description of the study and insurance of participant understanding followed by a signed consent form.

Informed consent must continue throughout the study via a dialogue between the researcher and research participant. Federal regulations require each participant receive a copy of the signed consent document.

Please note that any revision to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All **SERIOUS** and **UNEXPECTED** adverse events must be reported to this office. Please use the appropriate adverse event forms for this procedure. All FDA and sponsor reporting requirements should also be followed.

Please report all **NON-COMPLIANCE** issues or **COMPLAINTS** regarding this study to this office. Please note that all research records must be retained for a minimum of three years.

Based on the risks, this project requires Continuing Review by this office on an annual basis. Please use the appropriate renewal forms for this procedure.

If you have any questions, please contact Stephanie Henkel at 602-639-8010 or stephanie.henkel@gcu.edu. Please include your study title and reference number in all correspondence with this office.

cc:

Appendix D

MMAS-8 License Contract and Copyright Agreement

Required citations and copyright acknowledgement for the MMAS-8 item scale are available on the final license contract and copyright agreement.

In consideration for the right to use certain Morisky proprietary psychometric tools and intellectual property, the undersigned researcher (hereunder "Licensee" or "you") agrees to the following:

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B. Translations: Permission will only be granted to translate the MMAS tools subject to the following requirements: all new translations must be made by contracting with the MAPI Institute and final translations must be approved by the Owner. The MAPI Institute employs the most rigorous standards in the translation process using two native linguistic experts to independently conduct forward and backwards translation; the Owner is actively involved in validating each item in the scale and grants use of the translated scale through a separate license agreement that is linked to the License Agreement Contract/Copyright Agreement. Languages that have already been translated and validated by the MAPI Institute can be requested through the Owner/Developer, Dr. Donald E. Morisky.

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Please print, sign, and scan (PDF) and email *this agreement* to dmorisky@ucla.edu

Please sign and return this contractual agreement in a PDF format, to Professor Morisky and he will provide you (upon receipt of the payment invoice) with pages listing the MMAS-8 items, scoring and re-coding criteria and signature authorizing full use of this copyrighted scale. I agree to use only the English version of the MMAS-8 unless I purchase a validated translation of the MMAS-8 through Professor Morisky. I understand that it is a violation of international copyright laws to either use your own translation and call it the "MMAS-8" or use an existing MMAS-8 scale that has been translated and used for another study. The validated translation is non-transferrable and is linked to a specific license agreement and cannot be reproduced, copied, distributed, placed on the internet, published, or used by another individual. If the licensee violates any copyright laws contained in this licensing agreement they will be solely responsible for a \$5000.00 penalty and any associated legal costs.

Name and Contact Information of Licensee: Amelia Schreibman, ANP, MSN
 Doctor of Nursing Practice Candidate
 Grand Canyon University

Title of Study: Trends of COPD exacerbations 30 days post implementation
 of medication education tools.

Total number of administrations: 200

Signature of developer/owner of the MMAS-8: *Donald E. Morisky*
 Donald E. Morisky, ScD, Developer/Owner of the MMAS-8

Date Signed: December 15, 2015

Signature of Licensee: Amelia Schreibman *Amelia Schreibman*

Date Signed: 12/15/15

Appendix E**CONSENT FORM****Medication Adherence Project****Amelia Schreibman, MSN, ANP-Grand Canyon University**

The purpose of this form is to provide you information that may affect your decision to whether or not to participate in this project and to record consent of those who agree to participate in the project.

Amelia Schreibman, ANP, MSN, from Grand Canyon University, along with Dr. Helen Heiskell, DNP, has invited you to participate in this project.

The purpose of this project is to ask you questions that will help better understand how you take your medicine. This information will help in managing your treatment if it is needed.

If you choose to participate in the project, you will answer 8 questions from a questionnaire and you will circle the answer that best fits you. There are no right or wrong answers. If you chose to participate, the information we learn will be part of a project improvement paper. There will be a minimum of 30 patients that will participate. There will be no difference in the care you will receive if you chose to participate or

decline. If you participate, you may be educated regarding your medication for your breathing problem. Participation will last between 15-30 minutes.

There are no known risks identified in participating in this project, but in any project, there is some possibility that you may be subject to risks that have not yet been identified.

If you chose to participate, this information may assist in understanding better ways to help and treat patients with COPD. If any new information develops regarding this project, you will be informed.

All information obtained in this project is strictly confidential. The results of this project may be used in reports, presentations, and publications, but you will not be identified. In order to maintain confidentiality of your records, Amelia Schreibman will identify each participant using a number code in the order of patient's participation. This information will be secured in a locked office and a locked computer where Amelia Schreibman has the key and code. Amelia Schreibman and Drs. Adelman, Baron and Schreibman will also have access to this information.

Participation in this project is completely voluntary. It is ok for you to say no. Even if you say yes now, you are free to say no later, and withdraw from the study at any time.

Your decision will not affect your relationship with Drs. Adelman, Baron or Schreibman and will not affect your treatment received. There is no payment for your participation in the project.

Any questions you have concerning the project or your participation in the project, before or after your consent, will be answered by Amelia Schreibman. If you have questions about your rights as a subject/participant in this research, or if you feel you have

been placed at risk, you can contact the Chair of the Institutional Review Board, through the College of Doctoral Studies at (602) 639-7804.

This form explains the nature, demands, benefits and any risk of the project. By signing this form you agree knowingly to assume any risks involved. Remember, your participation is voluntary. You may choose not to participate or to withdraw your consent and discontinue participation at any time without penalty or loss of benefit. In signing this

consent form, you are not waiving any legal claims, rights, or remedies. A copy of this consent form will be given (offered) to you.

Your signature below indicates that you consent to participate in the above project.

Name of Participant: _____(printed) Date: _____

Signature: _____

Relationship: _____

"I certify that I have explained to the above individual the nature and purpose, the potential benefits and possible risks associated with participation in this project, have answered any questions that have been raised, and have witnessed the above signature. These elements of Informed Consent conform to the Assurance given by Grand Canyon University to the Office for Human Research Protections to protect the rights of human subjects. I have provided (offered) the subject/participant a copy of this signed consent document."

Signature of Investigator _____

Date _____