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Reducing COPD Exacerbation Among African Americans Affected with COPD in a South Florida Clinic. A Quality Improvement Project

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REDUCING COPD EXACERBATION AMONG AFRICAN AMERICANS AFFECTED WITH COPD IN A SOUTH FLORIDA CLINIC. A QUALITY IMPROVEMENT PROJECT.

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Abstract

Objective: The study aimed to determine if an educational intervention will improve COPD exacerbations in African American population after a 6-week self-management program that includes the proper use of an inhaler.

Methods: Ten patients were recruited in a primary care setting with the assistance of the providers. All patients had to complete a pretest and a posttest to assess their knowledge of inhaler technique, their willingness to engage in self-efficacy disease management, their symptoms improvement and treatment adherence. The Inhaler Device Assessment Tool, the Self-Efficacy for Managing Chronic Disease 6-Item Scale, the CAT test, and the TAI test were the tools used for the project.

Results: In the recruited population, 70 % were females and 30% were males. In the pretest and posttest of the inhaler technique, there is an improvement difference of 1.5 %, with a mean of 3.1 % in the pretest, and 4.6 % in the posttest. The CAT test has a mean of 17.9 with a standard deviation (SD) of 7.25 in the pretest, and a mean of 9.9 and a SD of 6.21. The CAT test has difference of 8. Self-efficacy management shows a difference of 3.4 with a mean value of 53 and 56.4 in the pretest and posttest respectively. Inhaler adherence has a mean value of 46.4 in the pretest and 49.3 in the posttest with a difference of 2.9 in inhaler adherence improvement.

Conclusion: The study reveals that teaching the proper use of an inhaler can improve COPD symptoms and decrease the frequency of COPD exacerbations in African American population after a 6-week self-management program, but further studies are needed to validate the findings.

Keywords: African American**,** chronic obstructive pulmonary disease, COPD exacerbation, inhalation technique, adherence, self-management.

Introduction

COPD exacerbation constitutes one of the leading causes of hospitalization or emergency department visit among COPD patients older than 40-year-old (Sogaard et al., 2016). People with COPD may have four episodes of exacerbation annually (Criner & Han, 2018). According to Sogaard et al. (2016), over 10% of COPD exacerbation attacks necessitate hospital admission. COPD exacerbation is described as an acute escalation of dyspnea, cough and purulent sputum, not responding to routine treatment (Criner & Han, 2018). Researchers have shown that COPD exacerbation is due to respiratory infections in 50-75% of the cases (Sogaard et al., 2016).

Patients affected with chronic obstructive pulmonary disease **(**COPD) may face numerous challenges, such as poor life quality and frequent emergency department visits, due to COPD exacerbation (George & George, 2012). COPD exacerbations are linked with many causes of sickness and death (Bourbeau & Echevarria, 2020). COPD management requires a multidisciplinary team to meet patients' needs (Bourbeau & Echevarria, 2020).

In addition to the disease burden, COPD is linked with significant financial expenses. (Kirsch et al., 2019). One of the main causes of COPD increased expenses is hospital admission and readmission (Derdak, 2017). Patel et al. (2018) explain COPD direct health care expenses were estimated to more than half ($30 billion) of the nationwide anticipated expenditure for COPD in 2010 (estimation: $49.9 billion). Indirect COPD costs related to co-morbidity and lost productivity accounted for $8 billion of the predicted total expenses in 2010 (Patel et al, 2018). The trend of high expenses for COPD is seen globally. Kirsch et al. (2019) reveal that the total direct expenses for COPD are guesstimated to be about 3% (€38.6 billion) of the overall health care financial plan in the European Union. Furthermore, Siddharthan et al. (2018) identify COPD

exacerbations as one of the main causes of morbidity and direct healthcare expenditures in developed countries.

Background

As George (2018) explains, patients with low social interaction and reduced physical activity undergo depression, anxiety and loss of independence and self-reliance, which may conduct to a damaging impact on the individuals and their family. COPD is a condition that can create severe physical and mental limitations and deteriorate life-quality of affected individuals (Cannon, Sriam, Wee-Chung Liew & Jing Sun, 2018). Patients affected with COPD experience severe chronic illness complications which negatively impact health-related quality of life (Bringsvor, 2019). The breathing difficulty associated with COPD leads to frailty that impacts not only the patients' daily activities but also their social contact and productivity. Likewise, Criner and Han (2018) argue physical activities and sleep quality are considerably decreased in 70% and 50% of patients with COPD, respectively.

COPD represents an enormous burden on healthcare cost. As reported by Criner and Han (2018), COPD care expenditures were guesstimated about $49 billion in direct and indirect health care cost in 2010. The numerous comorbidities associated with COPD explain the indirect costs (Criner & Han, 2018). Various evidences have revealed that 9% of people with COPD have an increased probability to be unemployed, and 4% of them have a high possibility to fetch for financial assistance through Social Security Disability Insurance (Criner & Han, 2018). Other factor that can be taking into account is patient adherence to treatment. The multiple medications, inhaler technique, nebulizer and oxygen use involved in COPD management make it difficult for

patients to adhere to treatment, which may be responsible for an increased risk of COPD-related death (George, 2018).

A clear understanding of the pathogenesis and management of COPD exacerbation may assist healthcare clinicians to empower COPD patients with the basic knowledge to improve their overall health and reduce COPD-related hospitalization. This paper intends to conduct a literature review to explore and understand the outcome of implementing a COPD self-management program to assist African Americans with COPD improving their health status and reducing hospitalization rates.

Search Strategies

CINAHL, EBSCO, and PUBMED are the main databases consulted to conduct the literature review. Search strategies using Boolean operators, keywords, phrases, and abbreviations, were used to scrutinize the databanks. The words utilized to search the database were: "(COPD or chronic obstructive pulmonary disease or chronic obstructive airway disease or chronic obstructive lung disease)", "(self-management or self-care or self-regulation or self-monitoring)", " inhaler technique or inhaler method or inhaler management", and "(black or African American or African American or color or minority)".

The search was limited to academic journals published between January 2000 and April 2020. In CINHAL database, the first search retrieved 649 articles. When using Booleans and truncation, the number of articles decreased to 15 articles about COPD, self-management, inhalation technique, and two articles related to African Americans. In PubMed, the initial search showed 45 articles, and the search reduced to 7 articles about COPD, self-management, inhalation technique, and three articles related to African Americans. A total of 22 articles was

chosen, and five of them will be fully scrutinized. The remaining of the articles along with other scholarly reviews will be used as supporting evidence for the project.

Literature Review

COPD Self-Management on Health-Related Quality of Life and Hospitalization

COPD is a usual and permanent lung illness, which is responsible for considerable infirmity, lessens quality of life and augments probability of premature decease (Cannon, Sriam, Wee-Chung Liew & Jing Sun, 2018). Hospital stay and emergency department (E) visits are very frequent among COPD patients. A 2017 Cochrane Airways Group study highlights the effect of COPD self-management on health-related quality of life and hospitalization by paralleling self-care approaches that encompass strategies for acute exacerbations of COPD (AECOPD) vs routine care (Lenferink et al., 2017). The search criteria include studies with randomized controlled trial from 1995 to 2016 conducted for COPD patients. Inclusion criteria for self-management plan comprise a scripted strategy for AECOPD and a repetitive process between participants and clinicians (Lenferink et al., 2017). Patients who participated in a pulmonary rehabilitation program or an exercise training realized at a hospital or rehabilitation center were excluded. Two independent authors gathered and appraised the data. A third author was sometimes involved to solve conflict or to reach agreement. In some instances, to gather further information and to obtain missing data, researchers had communicated to the study authors (Lenferink et al., 2017). Meta-analysis model was used when suitable to search for study results. The systematic review encompasses 22 studies implicating 3,854 participants. Each research had a control group and was followed from 2 to 24 months (Lenferink et al., 2017). The primary search had generated 1811 articles and abstracts, but only 22 articles met the inclusion criteria (Lenferink et al., 2017). The

five elements of the GRADE framework (Grades of Recommendation, Assessment, Development and Evaluation) were used to conduct the review. The quality of evidence for health-related quality of life (HRQoL) was qualified as high. In the study, health-related quality of life was appraised using the St. George's Respiratory Questionnaire (SGRQ). Causes of hospitalization, primary care visits, emergency department visits, and dyspnea symptoms were assessed by the Medical Research Council Questionnaire (MRCQ).

Study Outcome

The finding of the studies has shown that self-management program has shown improvement in HRQoL in COPD patients. The results also reveal that there is a significant decrease in COPD-related hospital admission for patients using self-care strategies for AECOPD as opposed to those receiving routine care. In addition, the study outcomes have open door for further studies incorporating patients' adherence to COPD self-management interventions, COPD associated comorbidities and self-management interventions, and financial appraisal of the application of COPD self-management plans. Patients' literacy constitutes an important obstacle to promote COPD self-management interventions. In the era of Internet and smart technologies, patients' education may be accomplished through audio-visual media.

COPD Impact in the African American Community

Although extensive research studies cover the influence of COPD health-related quality of life (HRQL) and treatment adherence in the general population, very few studies have been conducted in the African American groups. It has been demonstrated that factors such as lung structure, exercise tolerance, comorbidities, depression and literacy level exert a significant impact on HRQL in COPD; however, limited studies have assessed racial influence on HRQL (Han et al.,

2011). Researchers have pointed out that COPD constitutes a critical health concern for African Americans, and death rates related to COPD had augmented faster for African Americans than for white people between 1980 and 2000 (Mina et al., 2012). Likewise, COPD has been recognized as a responsible factor in weakening HRQL in African Americans aged 45 to 65 (Han et al., 2011).

Considering factors such as "age, gender, FEV_1 % predicted, pack-year smoking history, modified medical research council (MMRC) dyspnea scale, 6-min walk distance (6MWD), education, current smoking status, and exacerbation frequency", Han et al. (2011) have conducted a study using the St. George Respiratory Questionnaire (SGRQ) and the adapted Medical Research Council Dyspnea (MMRC) scale to assess the association between HRQL and symptoms. The findings revealed no difference for African Americans and Caucasians with COPD without exacerbations; however, poorer HRQL was observed among African Americans who endure exacerbations, mainly those who were admitted for COPD exacerbations (Han et al., 2011). Sarrazin et al. (2009) indorse the outcome that African Americans are more likely to undergo severe episodes of exacerbations. They pointed out African American people hospitalized at Veterans Administration hospitals with COPD exacerbations were more prone to be admitted to the ICU and obtain automated ventilation (Sarrazin et al., 2009). In a small racial comparison for COPD patients, Han et al. (2011) report African Americans present more dyspnea and lesser HRQL than Caucasians. The relationship between race and HRQL is very complicated, stated Han et al. (2011). Multiple factors may affect HRQL. It is worth mentioning racial inequalities, socio-economic status and education are among the factors that can impact HRQL, which symbolize the social disparities noticed among African Americans (Han et al., 2011).

Limitation and Strength

The study has some limitations and potential bias; for instance, subjects were enrolled through educational organizations, as such, the results of the study may have some types of tertiary-care hospital partiality (Han et al., 2011). The strength of the study is a large number of African Americans taking part in the survey (Han et al., 2011). Han et al. (2011) underscore that it is critical to creating strategies intended to enhance the prevention and management of COPD exacerbations in the African American people.

Disease Management Program for COPD vs Usual Care for COPD

The impact of COPD exacerbation on hospitalization rates is well-known. Rice et al. (2010) elucidate that aggravating symptoms of COPD are accountable for 726,000 hospitalizations and 1.5 million emergency room (ER) encounters in the United State. Due to the burden effects of COPD on health care use, Rice et al. have conducted a randomized control trial study to establish the outcome of disease management for COPD on hospital admission rates and ER visits.

The study has taken place in five Veterans Affairs (VA) hospitals. The study intended to compare the effect of disease management to usual care for COPD patients. The medical board has approved the study, and the patients have provided informed consents (Appendix E). The study encompasses a total of 743 individuals affected with COPD. At the first visit, there were 761 patients, but 18 of them did not meet spirometry measures. The researchers randomly divided the patients into 2 different groups; 371 patients were in the routine care group, and the remaining 372 were attributed to the disease management group.

The intervention for disease management consists of 1- to 1.5-hour training session, an action plan for self-management of exacerbations, and once-a-month follow-up calls from a case manager. The study was a one-year trial. The main result was the combined number of

hospitalization and ED visits per patients over a year. The secondary results comprised hospitalizations and ED visits for all reasons, pulmonary medication use, death, and variation in Saint George's Respiratory Questionnaire.

The training session consisted of COPD general knowledge, inhaler technique observation, medication reconciliation, recommendation regarding smoking cessation, and influenza and pneumococcal vaccination. Each participant obtained a personalized written action plan. The Saint George's Respiratory Questionnaire was used to evaluate the respiratory symptoms in both groups.

The evaluation of the primary outcome was done using a comparative estimation of the mean cumulative functions between disease management and usual care (Rice et al., 2010). For the secondary outcome, the researchers have applied a linear model with log link and negative binomial random to compete hospital admission rates and ED visits, and a general or simplified linear regression function to relate all-cause and site-adjusted mortality rates, total days of hospitalization, total days in the ICU, number of outpatient respiratory medication prescriptions, and variations in quality of life (Rice et al., 2010).The intervention group had a 41% reduction in the primary outcome. The study concluded a disease program can decrease hospitalization and ED visits due to COPD (Rice et al., 2010). The findings support a simple but effective intervention for a COPD disease management strategy to lessen hospital admission and ED visits.

Study Strengths and Limitations.

The study has shown consistency of the results over time and with different subgroup studies (Rice et al., 2010). It is the largest research of disease management in COPD patients (Rice et al., 2010). Previous studies have shown mixed results. Rice et al. (2010) argue the study outcome was identical with the constructive results of those aforementioned

studies despite the significant dissimilarity in the intervention program. The study limitations rely on the fact that all patients in the study were men and have advanced diseases. It is not known if the results of the study will be similar for women or patients with non-advanced diseases. Further comparative studies are needed.

Health Coaching and Self-Management Abilities in Severe COPD

Primary care clinicians thrive to improve the quality of life of COPD patients. It is essential to have available tools or guidelines to fill this purpose. Benzo and McEvoy (2019) have analyzed several randomized studies to elucidate the effect of health coaching conducted by a respiratory therapist or a nurse on self-management abilities. The researchers hypothesized health coaching can enhance self-management skills. Benzo and McEvoy (2019) explain health coaching is able to increase self-management abilities because it is founded in the principle of motivational interviewing, which is described as a concept tailored to the patient and structured in an interactive communication and a change of comportment.

The study aims to parallel the outcome of health coaching provided by a respiratory therapist or a nurse with routine care self-management abilities. Self-management abilities (SMA) will be appraised by the Chronic Respiratory Disease Questionnaire mastery domain (Benzo & McEvoy, 2019). The domain comprises two concepts of SMA, which are self-efficacy to cope with COPD and COPD symptoms and to manage emotional stress due to COPD exacerbations (Benzo & McEvoy, 2019). The research comprises 215 patients who were admitted for an exacerbation of COPD. The patients were randomly distributed to the intervention or the control (Benzo & McEvoy, 2019).

The study design was constructed as a subsequent analysis of previous randomized trial studies that compared a health-coaching practice with routine care based on guideline for patients after hospital discharge for COPD exacerbations. Data was collected from several sites, such as "Mayo Clinic, Rochester, Minnesota, and Health Partners Regions Hospital, Minneapolis, Minnesota". Assignment of patients was randomly done using an online computer-generated simple binomial randomization program into the 2 units (Benzo & McEvoy, 2019). Criteria of inclusion encompass hospitalizations due to COPD as a primary diagnosis and a probability to communicate with a coach by telephone (Benzo & McEvoy, 2019). A committee was responsible to oversee patient accrual, results, obstacles, and procedure observance. The authors compare changes noted at the start, at 6 months and at 12 months of the intervention between the two study branches applying "2-sample, 2-sided t tests with 5% type-1 error rates". The sensitivity of the logistic models was evaluated by means of 10,000 bootstrapped samples. The researchers apply a SAS version 9.4 to compute the results.

The authors conclude that health coaching is effective to reduce hospital readmission, enhances the quality of life, and shows a significant improvement of the Chronic Respiratory Disease Questionnaire mastery score (Benzo & McEvoy, 2019). The change noted in the Chronic Respiratory Disease Questionnaire mastery domain was clinically significant at six months but showed a trend at 12 months with no significant clinical difference. The study reveals health coaching by motivational interviewing empowers the subjects to take control of their health and increases coping strategy for the emotions related to COPD exacerbations.

Study Strength and Limitation

One of the strengths of the study is that it can be replicated due to the fact health coaching is comprehensive and the Chronic Respiratory Disease Questionnaire mastery domain is easy to apply (Benzo & McEvoy, 2019). Prior randomized controlled studies on COPD self-management fail to determine a reduction in COPD exacerbation or hospitalization frequency, or they show an augmentation in death rate. Likewise, the study by Bischoch et al, using the same measure (The Chronic Respiratory Disease Questionnaire) could not demonstrate a change in hospitalization rates. The authors acknowledge the results of the study need to be replicated to ascertain the role of health coaching in COPD management since the types of communication (motivational interviewing) between the coach and the patient might be the reason of that outcome. The absence of replication of the study results constitutes a limitation of the study (Benzo & McEvoy, 2019). Another limitation of the study is the fact the study results did not show a clinical significance in the self-management at 12 months. Further researches are necessary to clarify this outcome. The researchers hypothesize the reduction of health coaching frequency at 3-month after leaving the hospital might the cause of the absence of result at 12 months. Healthcare practitioners may benefit from a patient-personalized self-management program to alleviate the symptom burden of COPD and decrease hospital readmission rates.

Web-Based Videos Training to Improve Inhalation Technique

COPD is a serious illness. People touched by COPD may experience aggravation of the disease that can be fatal or lead to hospital admission or emergency department visits. Inhalation therapy constitutes the main and preferred treatment for COPD (Windisch et al., 2018). Patients have to apply the proper inhaler technique for the medication to be effective. Numerous studies have demonstrated that COPD exacerbations continue to rise due to incorrect inhaler technique.

Researchers specify 90% of patients used improper inhaler technique in experimental studies (Maricoto et al., 2018). According to Maricoto et al. (2018), teaching inhaler technique may decrease the probability of exacerbations and mortality rates in COPD patients. The effect of inhaler training declines over time, which makes it important to continuously reevaluate inhaler technique (Maricoto et al., 2018). Teaching the proper technique for inhalation therapy may be done in direct contact with the patients or via web based. Windisch et al. (2018) have conducted a research to evaluate the relative effects of a web-based video training versus a typical individual training on decreasing inhalation mistakes in patients with severe COPD requiring hospitalization.

The study was a randomized controlled trial conducted at the Department of Pneumology, Cologne Merheim Hospital, University of Witten/Herdecke, Germany, and it was approved by the ethics of the University of Witten/Herdecke and realized in accordance with the Declaration of Helsinki. All patients have given a written informed consent to participate in the study (Maricoto et al., 2018).

Patients were recruited between December 2012 and June 2014. The inclusion criteria were patients with confirmed COPD by full body plethysmography, patients who meet the GOLD-criteria for COPD, and those who use an inhaler prior to hospital admission. Patients were excluded if they had an acute respiratory failure as defined by a pH <7.35, a respiratory rate >23/min at rest, oxygen need of >3L/min. Also, patients with neurological, orthopedic or mental conditions that can alter inhaler treatment were excluded. Patients were aimlessly divided into two groups, one in which they received in-person training by a physician, and the other in which they had web-based video instructions.

Incorrect use of an inhaler was individually analyzed using the standardized checklists, which can be accessed at Checklists - Deutsche Atemwegsliga e.V. (English). It was anticipated that patients who commit two or more mistakes will inadequately perform the inhalation technique undoubtedly; therefore, all those will receive training on inhalation technique.

A physician was responsible to conduct the individualized in-person teaching. Patients had received verbal and physical demonstration of the inhalation process; then, the patients had to practice correctly all steps with teach-back. After, the educator accentuates the steps that were mistakenly done. Finally, the patients ask questions.

Patients in the web-based video training used a tablet device to access the training. Patients may watch the video as many times they estimated it necessary. The educator may assist the patient on how to operate the device to play the video; after that, the educator had no further interaction with the patients.

After 24 hours, patient-related errors were analyzed with the same checklists. The same researchers have assessed both the pre-teaching and post-teaching errors to decrease the risks of researcher bias. Investigators conducted the appraisal were randomly assigned to the type of teaching intervention. Hence, each patient had two different researchers: one for the appraisal of patient-related inhalation mistakes (before and after teaching) and the other one for the teaching intervention. Despite training, more than 40% of the patients were unable to appropriately use the inhalers.

Teaching outcomes and baseline assessment of handling errors were compared by computing the mean difference with 95% confidence interval and conducting a paired t-test independently for personal instruction and web-based video teaching.

The study established that both personal instruction and web-based training when applied to inhalation instruction can considerably enhance the inhalation practice. Nevertheless, non-inferiority of web-based video teaching could not be statistically established due to the unpredictably great number of patients staying incapable to properly use an inhaler post-training in both groups. Therefore, additional studies are required to confirm the practicality of web-based video inhalation teaching for COPD patients. Overall, web-based videos are approximately as efficient as usual personal teaching attended by a physician in ameliorating the inhalation technique in COPD patients.

Study Limitation and Strength

The study had some limitations. First, the low number of participants in the web-based training make it difficult to demonstrate non-inferiority. Secondly, the timeframe of the web-based was not prospectively appraised to determine whether web-based instruction was a time saving approach. Yet, the fact that there was not any need for instructors in the video training kept the healthcare professionals accessible for other services**.** The time span between the two studies was 24-hours, which is estimated to be short. The study encompassed only severe COPD patients that needed hospitalization. Additional studies are needed to appraise the results for moderate case of COPD. Finally, teach-to-goal approach was not applied, which may explain the high volume of failure in both groups.

The strength of the study that it was the first study to compare personal instruction versus web-based video training. The study has demonstrated both methods are effective to improve inhalation technique. The researchers have pointed out that web-based video training was not intended to replace personal instruction; nonetheless, video training is beneficial for it does not

require the presence of a coach, and it is always available. Further studies are still needed to clarify the findings of the study.

COPD: a disease burden

Chronic obstructive pulmonary disease (COPD) is a lung ailment that harmfully affects individuals' life with this condition (Criner & Han, 2018). COPD is a principal cause of morbidity, death, and expenses in the United States and globally (Criner & Han, 2018). It was anticipated that COPD will be the third principal cause of death in this year 2020 (Patel, Coutinho, Lunacsek, & Dalal, 2018). COPD represents the second main cause of functional and physical impairment (Criner & Han, 2018).

COPD is described as continuous constriction of the airway linked to an advanced inflammatory reaction of the respiratory tract provoked by harmful elements or smoke (Robert et al., 2016). Cigarette smoking is the principal factor responsible for COPD development. In addition, numerous evidences have revealed that occupational exposure may provoke COPD in about 15% of cases. It is estimated that 29 million Americans live with COPD, yet only 13 million are aware of it (Criner & Han, 2018). COPD is a serious healthcare concern. Robert et al. (2016) report that COPD has affected over 210 million people globally in 2010. Furthermore, Sharifi et al. (2019) clarify that COPD is a worldwide health problem affecting about 300 million people and causing over 3 million deceases yearly. In the United Stated COPD prevalence is estimated to be 37% (Sharifi et al, 2019).

COPD represents an enormous affliction that disturbs not only the affected individuals but also the clinicians and the community. Kiley & Gibbons (2017) explain many Americans are

unmindful of the danger represented by COPD despite the several works engendered by the healthcare authority, scholastic organization and other supporters.

COPD Impact on Hospitalization Rates, Readmission and Healthcare Cost

COPD exacerbations bring a heavy load on individuals affected by the disease. The acute respiratory distress of COPD is accompanied by a high risk of morbidity and mortality (Sadatsafavi et al., 2018). Researchers have been argued COPD exacerbations increase hospitalization rates and healthcare costs. As stated by Baker, Zou, and Su (2013) acute exacerbation of COPD is the most significant source of hospitalizations and readmissions in the United States.

An average of 700,000 COPD patients get admitted to the hospital annually, and it was estimated at $32 billion in direct expenses in the year 2010 (Goto et al., 2017). In a study conducted in eight different states in the US from 2006 to 2012, researchers have found 1,161,207 hospital admissions for COPD; among them, 845,465 had a high probability for 30-day readmissions (Goto et al., 2017). Additionally, the study reveals that COPD 30-day readmission remains elevated due to patients' comorbidities, unsatisfactory care and accessibility to health care (Goto et al., 2017). It is meant to explain decrease hospital admission and 30-day readmission is crucial to enhance healthcare quality and cut expenditure related hospitalizations.

While COPD by itself constitutes a critical encumbrance on healthcare, it inflicts a more substantial impact of healthcare expenses when linked with other health-related morbidity and mortality. Mannino et al., (2015) explain comorbidities generally determine the quality of health, health cost and disease evolution of patients with COPD. In a retrospective observational study, Mannino et al. (2015) have shown COPD associated with various comorbid conditions consumes an excessive amount of money and asset uses. Besides, COPD associated with comorbidities

increases the prevalence of ED visits that lead to hospitalizations (50.1% vs 9.5% with no comorbidities). The findings of the study correlate with other studies in terms of healthcare cost and impact of comorbidities on COPD-related hospitalizations albeit there is insufficient information concerning indirect expenses due to COPD and comorbidities (Mannino et al., 2015). Moreover, while it is important to treat other diseases associated with COPD, the treatment of COPD remains the same, and patients' comorbidities should be managed as individuals are not affected by COPD (Mannino et al., 2015). The study concludes additional research is needed to comprehend the management of COPD and other comorbid conditions. It understood from this research, healthcare providers need to be alert about other diseases that can influence health care outcomes when caring for COPD patients.

COPD Impact on Patients' Welfare (Productivity, Disability)

COPD patients experience mediocre life quality. It has been reported COPD patients are physically and emotionally affected. Patients' perceptions and comportments about COPD and its effect on their welfare have been outstandingly overlooked (Jarab et al., 2018). Difficulty breathing is responsible for the lack of activity of patients with COPD. Jarab et al. (2018) argue shortness of breath causes COPD patients COPD to avoid or slow down on physical activities. Besides, individuals with severe COPD find it difficult to accomplish simple tasks, which makes them rely on family or caregivers (Jarab et al., 2018). Frailty associated with COPD makes affected patients isolated themselves and decreases their willingness to participate in social or leisure activities, which leads to anxiety and depression. As stated by Jarab et al. (2018), patients explain that their depression and anxiety are related to their inability to manage, and their panic is due to breathing difficulty. The physical and psychosocial effects of COPD on patients' quality of life need to be

taken into consideration when caring for COPD patients since they may negatively impact treatment outcomes.

COPD Self-Management Program

COPD is a manageable and avertable disease, yet numerous patients continue to experience recurrent episodes of exacerbations which represent recurrent factors of hospital stays and death (Bourbeau et al., 2016). Management of COPD focuses on making the exact diagnosis, averting additional threats, monitoring symptoms and controlling complications (Make, 2003). COPD management should highlight ailment self-care to improve patients' wellbeing. Healthcare clinicians need to develop a concerted self-management program to integrate patients into their health decision-making. Make (2003) emphasizes a cooperative self-management strategy identifies the patients' responsibility in their health evaluations and the healthcare practitioners' role as mentors and promoters of the patients' health choices. Cannon et al. (2016) explain self-management program aims to promote people's modifications of comportment which improves their overall health with the main objective of enhancing both performance and quality of life.

Various studies have been conducted on the effect of COPD self-management programs on individuals' quality of life and health outcome; none of the studies has established a standard of actions to universalize. A self-management program needs to be specific to the individuals' positive or negative attitudes, comorbidities, social status, age, and level of education (Benzo, Abascal-Bolado, & Dulohery, 2016). A study on self-management among Chinese patients with COPD led by Wang, Nygårdh, Zhao, and Mårtensson (2016) reveals that being active and financially independent and being young adults have a constructive impact on self-management. In addition, self-management interventions encompass COPD training, an exacerbation action

strategy, and physical activity information (Cannon et al., 2016). COPD self-management program has been proven to be effective to better individuals' quality of life and welfare, yet it is important to highlight which parts of self-management programs are the most helpful at enhancing COPD patients' well-being (Cannon et al., 2016). Healthcare clinicians need to be aware of the impact of self-management interventions in improving COPD patients' health outcomes to promote a well-structured program in everyday patient care.

Inhaler Use and COPD Patients

Patients affected with COPD often benefit from the use of bronchodilators in the form of inhalers. Adequate use of an inhaler and patients' treatment adherence have a critical impact on patients' symptom relief. There are numerous types of therapies that can improve clinical outcomes for COPD patients; nonetheless, explaining the medical management of COPD is beyond the scope of this project. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) report specifies inhaled short-acting bronchodilators (beta-2 agonist and/or muscarinic antagonist, and corticosteroid) is instrumental in the management of COPD exacerbations (Jardim & Nascimento, 2019).

Inhalation treatment for COPD aims to transport the medication to the targeted location of action to diminish the risk of systemic absorption, to accomplish enhancement of symptoms and quality of life, and to decrease occurrence and gravity of exacerbations (Dougall, Bolt, Semchuk, & Winkel, 2016). Researchers have shown that current inhalers, besides their potential to manage COPD symptoms, are not accomplished the intended use due to the suboptimal inhaler technique (Usmani et al., 2018). Prescribers need to be aware of the numerous factors that can impede inhaler use to assist patients to receive a full benefit of the medication. Dougall, Bolt, Semchuk, and

Winkel (2016) argue to select the suitable devices for the specific patient those aspects of the inhaler need to be considered:

- "Simplicity of setup
- Ease of use
- Cue that dose is taken
- Need for dose counting
- Locking mechanism
- Dexterity required
- Inspiratory capacity
- Affordability".

Therewithal, patients' age, level of education and associated comorbidities may impair their facility to properly use the inhaler (Dougall, Bolt, Semchuk, & Winkel, 2016). Training such as direct observational technique and individual matching inhaler are critical to enhancing the inhaler technique. Usmani (2019) argues healthcare practitioners' role is instrumental in inhaler use, and he further explains the most efficient teaching strategy encompasses vocal coaching coupled to a physical exhibition. While arguing the role of healthcare practitioners and patients' education to improve inhalation technique for COPD people, a study by Sanchis, Gich, and Pedersen (2016) reveals inappropriate inhaler use in patients with asthma and COPD has not improved over the past 4 decades despite patients' education and technology improvement. The study suggests creating tools that can evaluate inhaler- specific qualities of the procedure (Sanchis, Gich, & Pedersen, 2016).

COPD Treatment Adherence

While COPD is a manageable disease, it remains a healthcare challenge due to acute aggravation of symptoms. COPD patients often endure poor disease outcome that results in hospital admission or emergency room visits. COPD is a chronic and progressive illness that necessitates affected individuals to adhere to prescribed medicines for treatment to be effective. Numerous researchers have found that improving COPD patient's health outcomes is strictly attached to treatment adherence (Jardim & Nascimento, 2019). Rogliani et al. (2017) state COPD is an ongoing ailment that needs affected individuals to constantly take their prescribed medicines for a better result, yet treatment adherence is very small, which results in the poor outcome. Despite the negative impact of non-adherence on patients' welfare, adherence to COPD treatment remains obstinately low. It is fundamental to identify and tackle barriers to treatment adherence to promote patients' well-being.

Rogliani et al. (2017) stipulate adherence obstacles comprise various factors that can be associated with the treatment, to the affected individuals and the health care clinicians. A study by Bourbeau and Bartlett (2008) demonstrates the numerous causes that can alter patients' treatment adherence. Factors related to patients are the patient's health viewpoint, mental capabilities, self-efficacy, age, and comorbid conditions (Bourbeau & Bartlett, 2008). Other factors influencing treatment adherence include types of medication, medication route of administration, patients' social assistance, level of knowledge, and patient-providers bond (Bourbeau & Bartlett, 2008).

Assessment of COPD Treatment Non-Adherence

The understanding of the impact of treatment adherence on COPD outcomes had led researchers to investigate patients' level of adherence to treatment. In an attempt to evaluate COPD adherence management, numerous tools have been created, and researchers have conducted

several studies. Scholars have developed numerous strategies to gauge patients' non-adherence to prescribed medication. Rogliani et al. (2017) have mentioned different methods such as pharmacy refill approaches, electronic monitoring, and self-report measures; nevertheless, such methods carry substantial restrictions. Likewise, López-Campos, Quintana-Gallego, and Carrasco-Hernández, (2019) have proposed other parameters to appraise inhaler's treatment adherence, such as clinical monitoring, biochemical measurement, electronic monitoring, and general and specific questionnaires. While those strategies have provided clear insights in COPD clinical adherence, they cannot specify if the patients have effectively taken the medications (López-Campos, Quintana-Gallego & Carrasco-Hernández, 2019). It is understood, assessing treatment adherence is individual-specific, and healthcare providers need to take the opportunity to foster self-management and treatment adherence through patients' education and motivation at each visit.

Interventions to Improve Quality of Life and Adherence in African American Community

In spite it is well known the negative impact of non-adherence on COPD management, adherence to prescribed medication remains substantially minute. Scholars have determined that an average of 50% of medicines ordered for chronic illnesses are not taken appropriately, yet adherence rates for asthma and COPD are even lower with an approximation extending from 22% to 78% (George & Bender, 2019). It is fundamental to foster strategies that can enhance adherence among individuals affected by COPD. Communication between patients and the healthcare team is pivotal to boost patient adherence (Rogliani et al., 2017). Continuous dialogues between clinicians and patients to evaluate adherence, exacerbation prevention and inhaler technique at every encounter is critical to optimize and maintain patient adherence. George & Bender (2019) argue effective communication by clinicians assists to improve patient satisfaction and adherence,

which in turn enhances health quality and decreases health care costs. Also, patients' participation in their healthcare decisions may play an important role in improving adherence. Mutual decision making between patients and health care providers in the choices of medications and treatment regimen based on patient preferences and values are instrumental to promote adherence; however, sharing-decision making needs to be guided by the well-versed available treatment taking into account probable risks and benefits (George & Bender, 2019). Improving patient-provider communication faces challenging hurdles, with time being the most important obstacle.

Patient education is recognized as a significant element to stimulate adherence. As explained by Rogliani et al. (2017), clear comprehension of treatment may assist the patient to alter patient's opinion about treatment burden, and subsequently to increase COPD treatment adherence and lessen hospital stay. Patient's health knowledge is a pivotal factor to ponder when creating training and intervention strategies, so these strategies can be carried out at a suitable level to facilitate adherence to treatment (George & Bender, 2019). Applying a multidisciplinary team and using smart technologies may be useful to improve adherence. Community pharmacists can positively influence COPD treatment adherence and inhalation technique instruction; nonetheless, more information is needed to fully understand the role of community pharmacists (Rogliani et al., 2017). Information technology applying text messages, electronic device reminders and phone calls may also influence adherence; however, patients might find it bothersome to incessantly receive numerous reminders (López-Campos, Quintana-Gallego & Carrasco-Hernández, 2019). Finally, medication expenditures, inhaler types and patient conditions need to be taking into consideration when reinforcing inhalation adherence (López-Campos, Quintana-Gallego &

Carrasco-Hernández, 2019). Healthcare clinicians should be mindful of adherence issues and take advantage to teach patients at every visit.

Conclusion

COPD is an important healthcare concern. It is the third leading cause of mortality in the US. Targeting COPD patients is critical to tackling the weight the disease put on people's quality of life and healthcare costs. Researchers have demonstrated African Americans' HRQL is more likely to be impacted by COPD exacerbations, and death related to COPD are higher among young African American adults. It is paramount to implement strategies that can improve the health and life quality of affected individuals, avert and manage exacerbations and complications, and decrease hospitalizations and mortalities. Treatment adherence and proper inhaler technique are promising interventions to assist African Americans in COPD self-management. Patient-provider communication, patient participation, personalized coaching, electronic reminders through phone calls and text messages are proven strategies that can be implemented to alleviate COPD burden for touched African American people. It is no doubt that a greater insight of exacerbations and plans intended to edify the prevention and management of COPD exacerbations in the African American people is imperative. Ejike (2019) stipulates that making healthcare affordable and creating ethnically insightful policies to overcome healthcare obstacles will support developing the welfare of African American patients with COPD.

The Project

Project Question

Will an educational intervention improve COPD exacerbations in African American population after a 6-week self-management program that includes the proper use of an inhaler?

P: African Americans with COPD.

I: Proper use of an inhaler

C: Current practice.

O: Reduction of COPD exacerbation and hospital admission.

Definition of Terms

Adherence

Adherence has been defined as the "active, voluntary, and collaborative involvement of the patient in a mutually acceptable course of behavior to produce a therapeutic result", (Ho, Bryson, & Rumsfeld, 2009). Patients' willingness to take their medicines is crucial in health care. It is important for patients to agree with the practitioners that they understand the need to take their prescribed medicines and to be effectively involved in their health care for better outcome. As reported by Ho, Bryson, & Rumsfeld, 2009), "Drugs don't work in patients who don't take them".

COPD: Chronic obstructive pulmonary disease.

COPD Exacerbation

COPD exacerbation is described as an acute aggravation of dyspnea, cough and purulent sputum, not responding to the usual treatment (Criner & Han, 2018). With an acute exacerbation, the patient is often unable to breathe and carry out his or her daily activities. Patients who experience a COPD exacerbation often seek treatment in the emergency department or being admitted to the hospital. COPD exacerbation increases healthcare cost and hospitalization rates.

Self-management

As defined by the Meriam-Webster dictionary, “Self-management is about “finding the self-control and mastery needed to take control of one's work”. In healthcare, self-management is an important concept that helps the patients to be actively and efficiently partake in their care to improve their quality of life. Lorig (1993) explains self-management is the process of mastering and applying the skills and knowledge necessary to live a satisfying life while enduring chronic ailments. The use of self-management in healthcare helps to improve patients’ quality of life and decrease healthcare cost (Lorig, 1993).

Self-Efficacy

Self-efficacy is the fact that one believes he is able and capable of achieving a particular behavior or a cognitive conduct (Lorig, 1993). Self-efficacy will motivate and empower the patients to self-manage their chronic conditions and enhance their quality of life.

Introduction

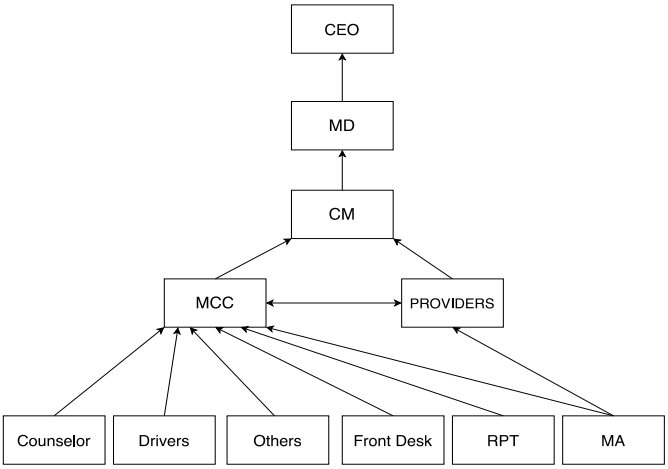
Managing COPD is very complex. The effect of COPD on affected people and family members is very burdensome. It is fundamental for primary care clinicians to tailor treatment for each patient. Primary care clinicians represent the principal point of contact for COPD patients, delivering approximately 80% of their health care (Sethi, 2018). With that information in mind, the project leader, with the assistance of a team composed of healthcare workers, non-clinical and administrative people, intends to conduct a COPD self-management project at a Clinical Center located in Miami.

The Medical Center provides scheduled and urgently needed, culturally competent primary and specialty care services to residents of Liberty City in Miami. These services include but are not limited to physical examination, cholesterol screening, blood sugar screening and

control, blood pressure screening and control, spirometry testing, optometry service, and other specialty services via telemedicine.

As the practice organization shapes the basis of all primary care settings, it is pivotal to highlight the operational structure of the institution. The Medical Center North West, Miami (NW office) is part of a large corporation. The corporate office is located in Homestead, Florida where the owner and Chief Executive Officer, and the administrative staff are situated. The NW office staff is composed of a medical director (MD), a center manager (CM) assisted with a system manager (named MCC: Medical Care Coordinators), healthcare providers, a registered nurse (RN), a registered pharmacy technician (RPT), medical assistants and front-desk clerks. Other employees at the practice are the dietary, the cosmetic, the environmental services and the drivers. **Table-1.**

Table-1-Organizational Structure



The project aims at decreasing COPD exacerbation and hospital readmission rate among COPD patients in the NW office. The project's main focus is to educate patients on proper inhaler technique. An assessment of the current practice relating to the management of COPD patients in the setting has guided the project leader to fathom the change needed for the project.

Miami NW Office Practice Standard (The Immersion Site Current Practice)

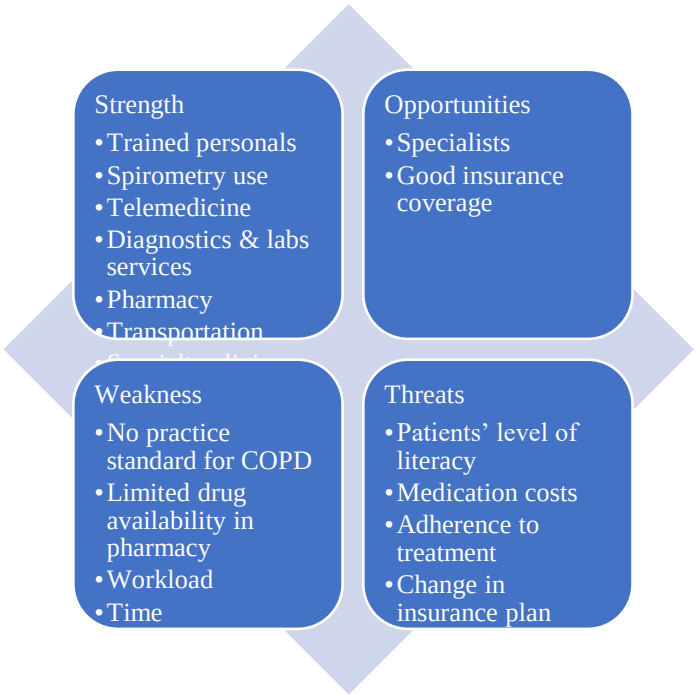
In the Miami NW office, there is no standard practice for COPD management. The providers have in their position a booklet named "Common Diseases", where they can find information related to the most common pathologies found in primary care. With regard to COPD management, few data are available. It is recommended to use the GOLD guidelines to treat COPD patients. Care is provided according to the providers' knowledge and understanding of the guidelines. One of the important policies of the clinic is the recommendation to have six encounters in a 30-day interval with all patients who were hospitalized for any causes. This protocol is interesting for it intends to prevent a 30-day hospital readmission, but there is no standard for follow-up with the patients during those visits. Most patients found it cumbersome and are not adherent to the treatment. It turns out to be ineffective to achieve that goal. In addition, most of the providers argued this protocol should be case based; for instance, they argue not all causes of hospitalization require six post-hospitalization appointments; for instance, a patient hospitalized for non-cardiac chest pain alleviated with regular pain medications does not need to be seen six times in 30-day after discharge.

The clinical staff administrators have put in place specialty clinics to manage diseases such as diabetes and COPD. The idea is to lower A1c level and prevent COPD exacerbations and hospital admission. Either a medical director or a nurse practitioner is in charge of that respective

specialty clinic. This operation is done through telemedicine; a nurse or the provider who regularly sees the patient participates in that encounter. Once again, there is no practice standard. Finally, Miami NW office offers services such cardiology, nephrology and infectious diseases via telemedicine.

It is current practice to conduct spirometry tests for all adult patient regardless of smoking status. There is no emphasis to make an early diagnosis of COPD. Most patients either already have the diagnosis of COPD or get diagnosed when they become symptomatic. Inhaler technique is seldom assessed. Patient's education about the use of an inhaler is addressed in order to only differentiate the rescue inhaler from the maintenance inhaler. There is a deficiency in continuous reminder or education about inhaler technique. The table below highlights the main elements of strength, weakness, opportunities and weakness of the organization (Table-3).

SWOT Analysis



GOLD Recommendations

According to Global initiative for chronic Obstructive Lung Disease (GOLD, 2020) guidelines, patients who present symptoms of dyspnea, long-lasting cough or phlegm production, and/or a history of exposure to COPD risk factors should be diagnosed with COPD. The diagnosis needs to be confirmed with spirometry value. GOLD (2020) guidelines reveal "the presence of a post-bronchodilator FEV1/FVC < 0.70 confirms the presence of persistent airflow limitation and thus of COPD in patients with appropriate symptoms and significant exposures to noxious stimuli". Spirometry alone should not be considered to make the diagnosis; patients' risk factors and associated symptoms are additional elements to consider making the diagnosis of COPD (GOLD, 2020). Systematic spirometry screening is not recommended for the general population (GOLD, 2020). COPD case-finding is an important strategy to identify undiagnosed patients with COPD. GOLD (2020) promotes performing spirometry in symptomatic patients and/or patients with COPD related risk factors. Nevertheless, early detection of COPD has no effect on COPD treatment plan and outcome (GOLD, 2020).

Methodology

Project Goals and Outcomes

COPD constitutes a healthcare challenge. COPD symptoms impact negatively people' s quality of life, and affected individuals comprehend frequent exacerbations as a substantial chronic affliction preventing them from doing their daily activities (Miravitlles & Ribera, 2017). According to GOLD (2020), the principal objectives of treating COPD are to alleviate symptoms, slow disease development, avert and treat exacerbations, improve lung function, and decrease mortality.

The project aligns to the objectives of GOLD 2020 and aims to reduce COPD exacerbation frequency, which, in turn, will decrease hospital admission rates and improve the health-related quality of life (HRQL) of African Americans affected with COPD. The CAT and the Inhaler Device Assessment Tool (IDAT) were the main outcome variables to compute by comparing the pretest and posttest survey results. Alshabanat et al. (2017) argue patient education, disease management and follow-up can significantly reduce COPD exacerbation, hospital admissions and length of stay (LOS).

COPD symptoms are linked with a clinically important deterioration in the quality of life. Improving the quality of life of COPD patients is a central point for healthcare management (Ahmed, Neyaz & Aslami, 2016). Researchers have applied numerous questionnaires to assess COPD symptoms and disease prognosis. The COPD Assessment Test (CAT) was used in this project for its simplicity and its short time to fill out. Other available tests are the Clinical COPD Questionnaire (CCQ), the Airways Questionnaire 20 (AQ20), the COPD Severity Score (COPDSS), and the St. George's Respiratory Questionnaire (Miravitlles et al., 2015). The CAT is a dependable tool to assess individuals' health status and has a scaling range of 0-40, with the higher number indicating worst health status (CAT, 2018)- **Appendix B1-B2.** The test should be administered every two to three months to identify symptoms variations and tendencies in CAT scale. A variation of 2 in the score indicates significant change in the health status and the quality of life (CAT, 2018).

Description of the Program Structure

The project was implemented at the Miami NW office. Before implementation of the project, formal approval (Appendix F) was obtained from the office manager. Ten patients were recruited. Each patient had signed an informed consent letter to participate in the project.

The office providers had helped to recruit COPD patients who are willing to participate in the program. The RPT was responsible to call patients on a monthly basis for medication refill and/or pick up. The project manager has used YouTube videos to illustrate the inhaler technique.

Due to Covid-19, all interaction and teaching were done remotely using smart technologies. The providers assisting with the recruitment had contacted the participants via phone to introduce the project. Upon agreement, the participants had electronically received and signed the consent. The project leader had educated the patients in a one-to-one basis using virtual channel. Other means of communication were text messages and emails with the patients' permission. No messages had carried patients' personal data or identifiers. The project leader had sent the links of the video training and the survey through emails or text messages.

Inhaler Technique Survey in the NW Office

Proper inhaler technique being an important aspect in the management of COPD patients, it is fundamental to appraise the knowledge of the healthcare workers on how to adequately use an inhaler. In a brief survey, the project manager has assessed that the RN, the MAs, the RPT and the nurse practitioner are sufficiently competent in inhaler technique (Metered dose inhalers, MDIs). Competency was described as the aptitude to illustrate 100% of the steps appropriately, and any participants completing less than 100% was provided additional training until competency was established. The outcome showed the RN, the MA missed one step of a proper inhaler technique, and the RPT missed two steps. The nurse practitioner has adequately

completed all steps of the inhaler technique. This appraisal gives insight to initiate a training session for the RN, the MAs and the RPT before implementing the project.

Participants' risks and benefits

The clinical providers had assisted in the recruitment of the patients. Participating in the project was voluntary, and there were no financial incentives to be a member of the project. All partakers had signed an informed consent. They had agreed to partake in all meetings and consent to be phoned at least once a week. Patients' personal information or identity were not be collected or shared to any entities. There were no risks to physically or mentally harm the patients.

Reliability and Validity of the Measuring Tools Applied in the Project

The project manager has used the COPD Assessment Test (CAT) and the Self-Efficacy for Managing Chronic Disease 6-item Scale to shepherd the project. It is fundamental to inquire about the reliability and validity of any tools before they can be used in a scholarly project. The CAT is a self-administered questionnaire that assesses the patients' welfare. The CAT has a scale from 0 to 40 (Table-2), with the higher number indicating worst health status. A study by Karloh et al. (2016) concluded that the CAT is an important tool that meet the research criteria to classify as dependable and valid, and it is a responsive instrument to assess health-related quality of life of the COPD patients.

Besides, the project leader has applied the Self-Efficacy to Manage Chronic Disease Scale (Appendix A) to assess the patients' self-management capabilities to manage their COPD-related symptoms. The Chronic Disease Self-Management Program (CDSMP) consists of a list of skills and knowledge that will explain the patients' aptitudes to cope with their diseases (Lorig

et al., 2014). The scale encompasses 6 items ranked from one to 10, with one being not at all confident, and 10 being totally confident. To assess the practicality of the SEMCD, Lorig et al. (2014) direct a study to appraise the effectiveness of the program in patients with serious mental disorders. The authors determined CDSMP is a globally accessible resource that can empower the patients to take control over their chronic ailments (Lorig et al., 2014).

Resources Required

Upon project approval, the project manager has started the recruitment process with the assistance of the providers, and he has informed the administrative staff of the medical center each further step of the project. Resources that were available and applied during this project were the office manager, all clinical practitioners, one RN, two medical assistants and a RPT. The providers' roles consisted to identify the COPD patients who can participate in the project, and with the project leader, explain the purpose of the recommendation and answer any enquiries the patients may have. The medical assistants helped with taking vital signs, doing spirometry test and other related aids deemed necessary per the office providers. The RN participated in educating the patients and reinforcing patients' adherence to the inhaler. The RPT kept records of medication refill, called patients for reminders, and handed over pamphlets related to inhaler technique to the patients. Also included are other employees of the American Care Center, as well as select members of Florida International University, including faculty. COVID-19 protocols were applied at every single step of the project.

IRB Protocol Exemption

The project instigator has submitted an Institutional Review Board (IRB) human protocol for review by the IRB committee. After a meticulous review of the IRB protocol, the Florida

International University (FIU) Office of Research Integrity has approved the project for implementation. See the IRB approval in Appendix G.

Tools and Data Analysis

As previously stated, the project leader has used *YouTube* video to teach proper inhaler technique. The National Asthma Council (NAC) provides great quality and very informative videos on inhaler technique. The project manager has used the NAC video to provide the training. Providers and patients can access the videos following this link: https://www.nationalasthma.org.au/living-with-asthma/how-to-videos/how-to-use-mdi.

It is crucial to appraise patients' improvement in learning the proper use of an inhaler. The Inhaler Device Assessment Tool (IDAT) is an excellent tool that can assist healthcare providers to successfully assess patient's understanding of the technique. The IDAT (Appendix D1-D4) provides information on all different steps to assist the patients. Being able to pinpoint patients' knowledge and mistakes while performing the technique is paramount for teaching improvement.

Patients' adherence is an important factor for successful treatment. To understand the reasons for treatment failure, it is fundamental to start by ruling out non-adherence as a cause of treatment fiasco. The test of adherence to inhalers (TAI) is an excellent tool to gauge adherence. A study by Castillo et al. (2019) concludes the TAI is a "good method to measure a bad compliance." The project manager has used the TAI test (Appendix C) to evaluate inhaler adherence.

After application of the project, the project leader has employed quantitative data and graphs to assess and illustrate the project results.

Weekly meetings. Due to COVID-19, the project manager had kept in touch with the patients via phone calls, text messages, and virtual conferences when possible. A total of six-weekly encounters had taken place. During each weekly and one-to-one meeting, participants were presented with a different topic while restating the previous week's topics. All the participants were adhered to the plan.

Week	Topic	Activities
1	Participants' expressing their views of COPD, self-efficacy, self-management -Inhaler technique.	Pre-assessment survey. Use of the following material from : https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0020/401483/CATest.pdf https://www.selfmanagementresource.com/docs/pdfs/English_-_self-efficacy_for_managing_chronic_disease_6-item.pdf https://www.nationalasthma.org.au/living-with-asthma/how-to-videos
2	-Reinforce week one material -Teach back -Quit smoking	-Questioning participants on week one material. Use of the following material from https://www.nationalasthma.org.au/living-with-asthma/how-to-videos for teaching and demonstration

3	Reinforce week 1, 2 -Expressing feelings -Lifestyle change	Participants Testimonials Use of the following material from https://www.nationalasthma.org.au/living-with-asthma/how-to-videos http://www.taitest.com/docs/Cuestionario_en.pdf
4	Reinforce week 1, 2, 3 -Compliance assessment -Teach back	Participant testimonials Use of the following material from https://www.nationalasthma.org.au/living-with-asthma/how-to-videos
5	Reinforce week 1- 4 - Inhaler technique.	Inhaler technique demonstration: https://www.nationalasthma.org.au/living-with-asthma/how-to-videos https://use-inhalers.com/patients-handouts#Flyersn
6	Reinforce week 1-6. - Relationship with Provider. Encouragem	Post Assessment survey https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0020/401483/CATest.pdf https://www.selfmanagementresource.com/docs/pdfs/English_-_self-efficacy_for_managing_chronic_disease_6-item.pdf Small reception with light refreshment. (Cancelled due to COVID-19)

	ents to participants	

Permission to use these teaching materials were entirely approved by each organization.

Conceptual Underpinning and Theoretical Framework

Bandura's Self-Efficacy Theory

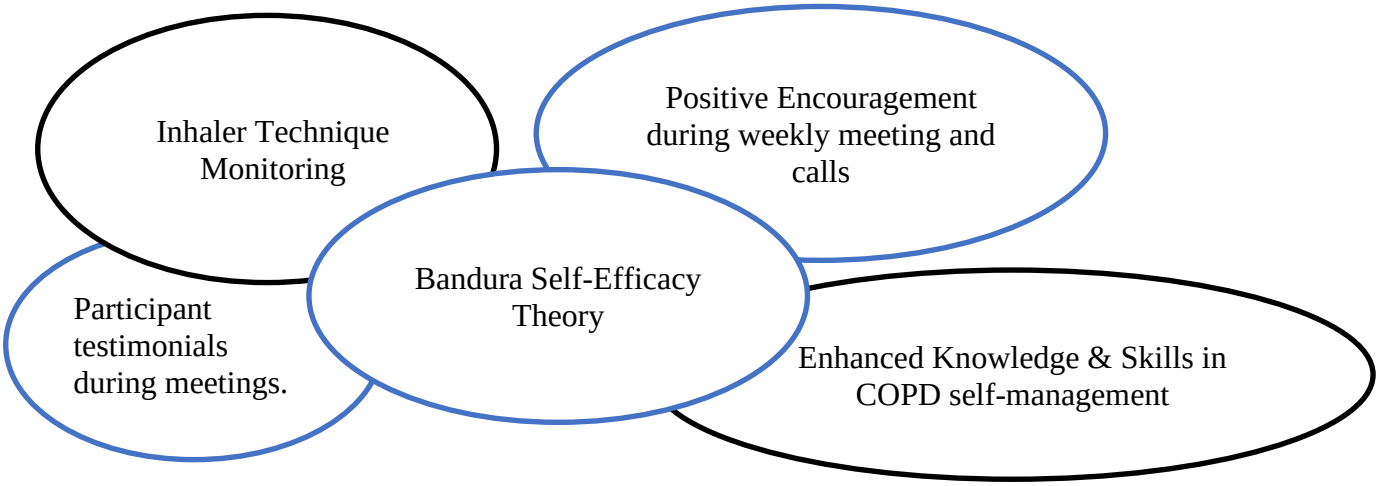
Bandura's Self-Efficacy Theory represents the hallmark of this project. It is assumed that anticipations of individual effectiveness help establish whether behavioral management will be started, how much determination will be consumed, and how much it will be endured when facing obstacle and unpleasant experiences (Bandura, 1977). According to Bandura (1977), "Persistence in activities that are subjectively threatening but in fact relatively safe produces, through experiences of mastery, further enhancement of self-efficacy". Improving COPD self-management is the focus for behavioral change for this project. Self-efficacy theories define how people sense, reason, encourage themselves and act. A strong awareness of efficacy improves individual achievements and personal welfare (Bandura, 1994). People who are confident in their aptitudes are more likely to stay resilient after facing obstacles. Bandura (1994) explain self-assured people envision high expectations and remain devoted to them. They increase and sustain their determinations in case of disappointment and associate defeat with inadequate information and dexterities which they can acquire.

To implement Bandura's "expectations of self-efficacy's" the project leader had involved the participants in interactive training about COPD self-management to improve their assurance in self-management. Bandura (1994) describes people's beliefs in their efficacy into four

principal foundations: “mastery experiences, vicarious experiences, verbal or social persuasion, and somatic and emotional states”. People tend to be motivated when they acquire the skills needed, when other people are previously succeeded in the same experience, when influenced or encouraged by others, and finally their feeling about the experience, which will define their senses of power or weakness. Figure 1 illustrates the model (see below).

Figure 1. Model of Self-Efficacy Theory.

Figure 2. Bandura’s Model of Self-Efficacy Theory modified in Terms of COPD.



Conceptual Framework

COPD inflicts a heavy load on patients, families and healthcare providers and policymakers. Strategy to manage COPD symptoms and exacerbations have been implemented, yet COPD continues to affect patient quality of life. It is anticipated that a self-management program can assist to alleviate this issue. Zhang et al (2013) have identified five domains of COPD self-management: "symptom management, daily life management, emotion management, information management, and self-efficacy". The project aims to improve quality of life of COPD patients and to decrease hospital admission due to COPD exacerbations. Since self-efficacy empowers patients to take control over their disease. The project aligns with the structure of self-efficacy to increase adherence to treatment, which, in turn, will decrease symptoms exacerbations. Asymptomatic patients will be more involved in daily activities and will frequent emergency department and/or hospital admission less often.

Figure 3.

Results

The project manager sought to accomplish the following goals: a decrease in COPD exacerbation frequency by teaching the proper use of an inhaler. Encouraging self-efficacy and promoting patient adherence are important factors to reach that goal.

A total of ten patients were selected to conduct a pretest and post evaluation. All ten patients had completed the study. Parameters to evaluate were the CAT, Inhaler Device Assessment Tool (IDAT), the TAI, and the Self-Efficacy for Managing Chronic Disease 6-item Scale. The project outcomes are illustrated in the tables below.

Patient Demographics

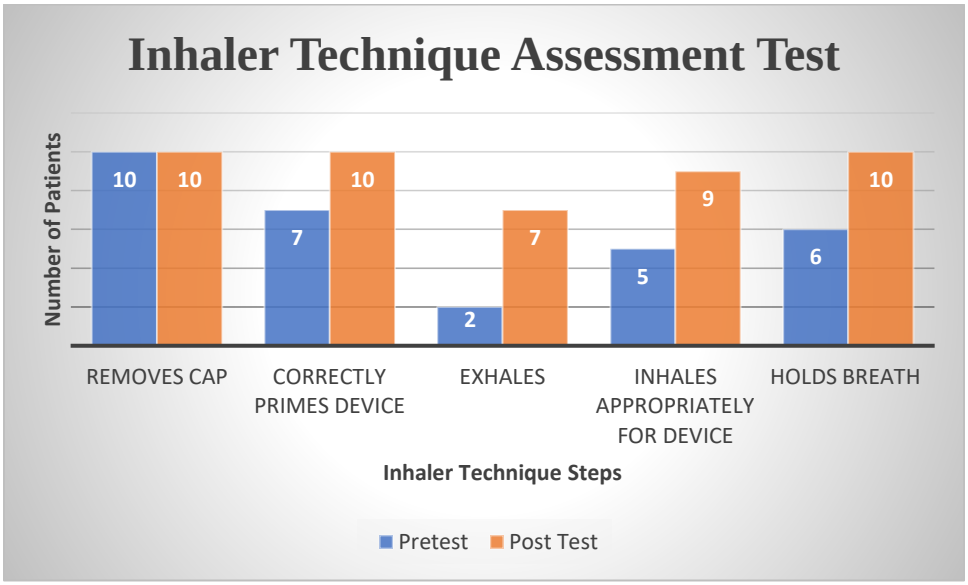
In the recruited population, 70 % were females and 30% were males. All patients were African Americans; 70% of them were over 65-year-old, and 30% below 65-year-old. They all have a confirmed COPD diagnosis, and they have at least 2 different inhalers: a rescue inhaler and a maintenance inhaler.

Gender	**Number *n=10***	**Percentage**
Males	3	30 %
Females	7	70 %
Age	**Number *n=10***	**Percentage**
Under 65	3	30%
Over 65	7	70%
Ethnicity	**Number *n=10***	**Percentage**
African Americans	10	100%

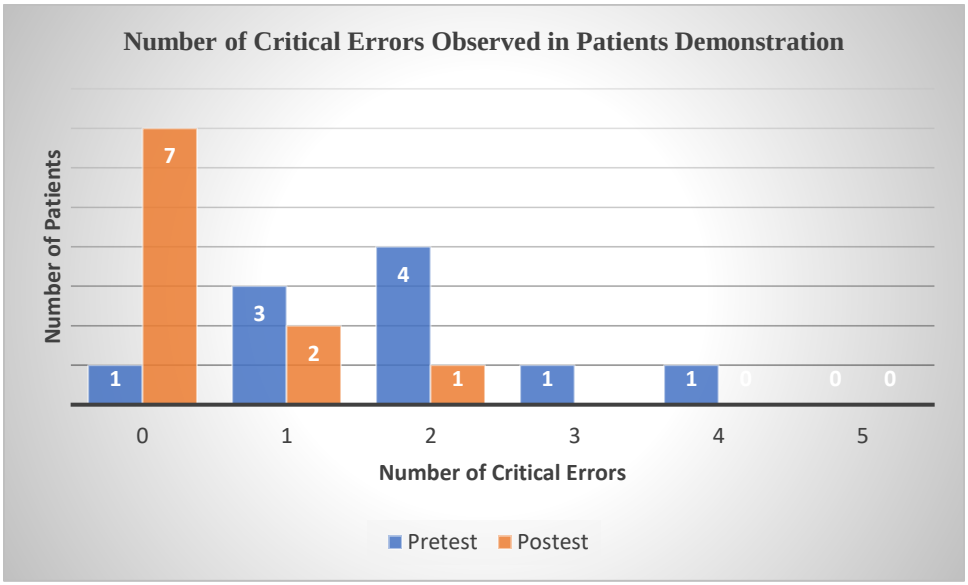
Inhaler Device Assessment Tool (IDAT)

For the inhaler assessment test, a checklist was utilized. Each participant underwent a pretest and a posttest. The mean in the pretest was 3.1 with a SD 1.43, and the mean was 4.6 in the posttest with a SD 0.48, which reflects a 1.5 improvement post teaching-***Table 2-A.*** In addition, there is a clear difference in the number of critical errors in the pretest and the posttest. In the pretest, 10% of patients had completed the technique with no errors, 30% had committed one error, 40% had perpetrated 2 errors, 10% had carried out three mistakes, and 10% had missed 4 steps. In the posttest, 70% of patients had successfully completed all steps of the inhaler technique, 20% had commit one mistake, and finally 10% had missed 2 steps-***Table 2-B.*** No one has committed three or four errors in the posttest. The results support a clear amelioration in the inhaler technique.

Inhaler Device Assessment Tool (IDAT) - ***Table 2. A***



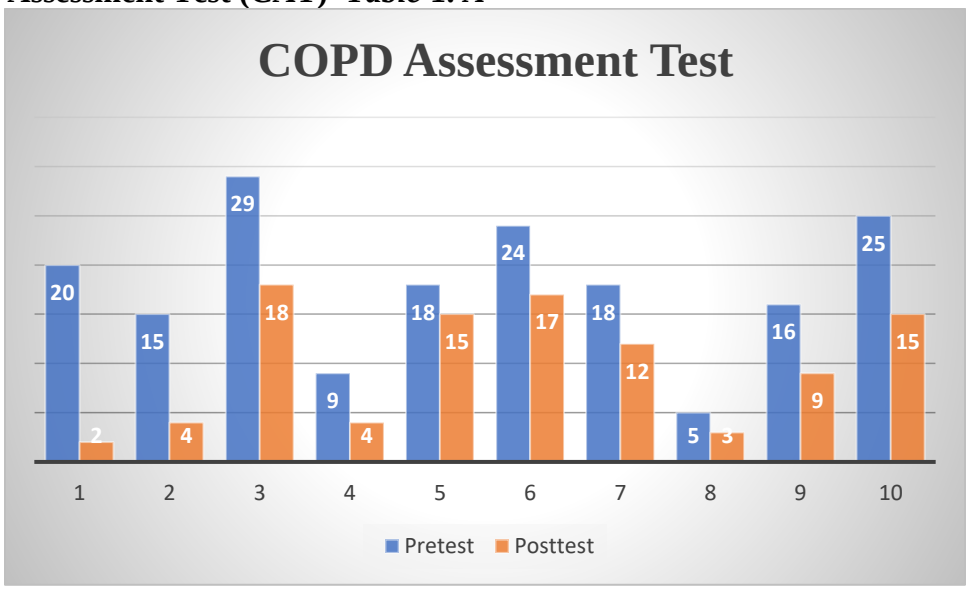
Critical Errors Observed in Patient Demonstrations- *Table-2. B*



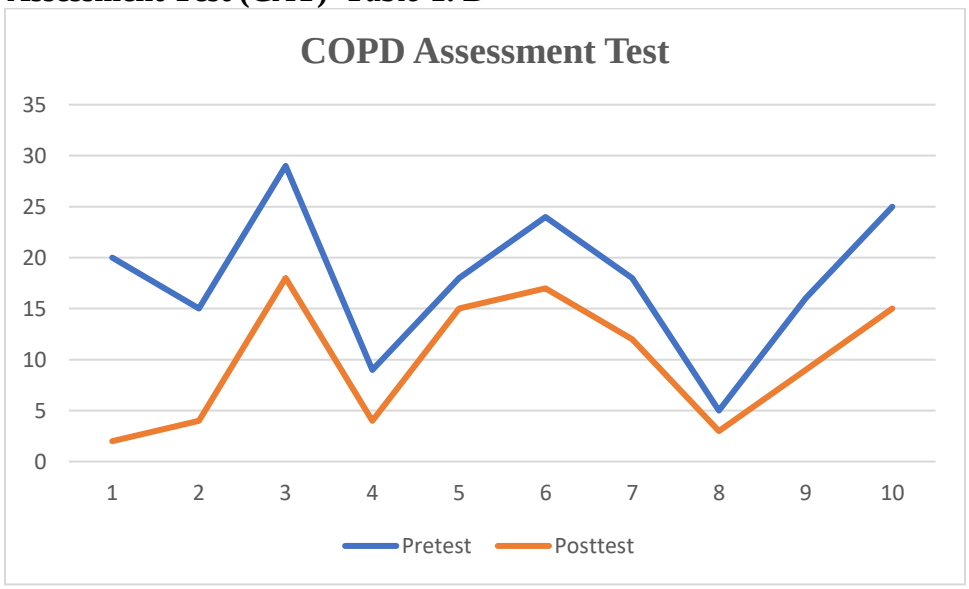
COPD Assessment Test (CAT)

In the CAT, the pretest has a mean of 17.9 with a standard deviation (SD) of 7.25. The posttest has a mean of 9.9 and a SD of 6.21. The difference between the pretest and the posttest shows an improvement significance of 8 (***Table 1-A & 1-B).*** Besides, the CAT is divided in five categories according to patients 'symptoms: normal or good health, low, medium, high and very-high. In the pretest, 10% of patients present with good health compared to 40% of patients in the posttest. The pretest and the posttest show similar rates in the low and medium groups respectively 10% and 50%. In the high classification, the pretest has a percentage of 30%, compared to nil in the posttest. No patients fall in the very-high classification of the CAT (***Table 1-C)***.

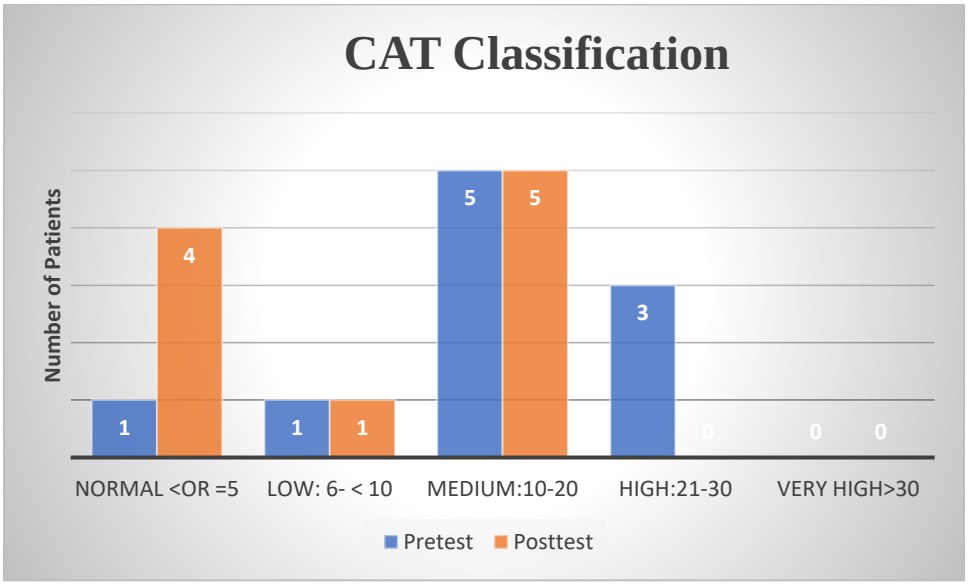
COPD Assessment Test (CAT)- *Table-1. A*



COPD Assessment Test (CAT)- *Table-1. B*



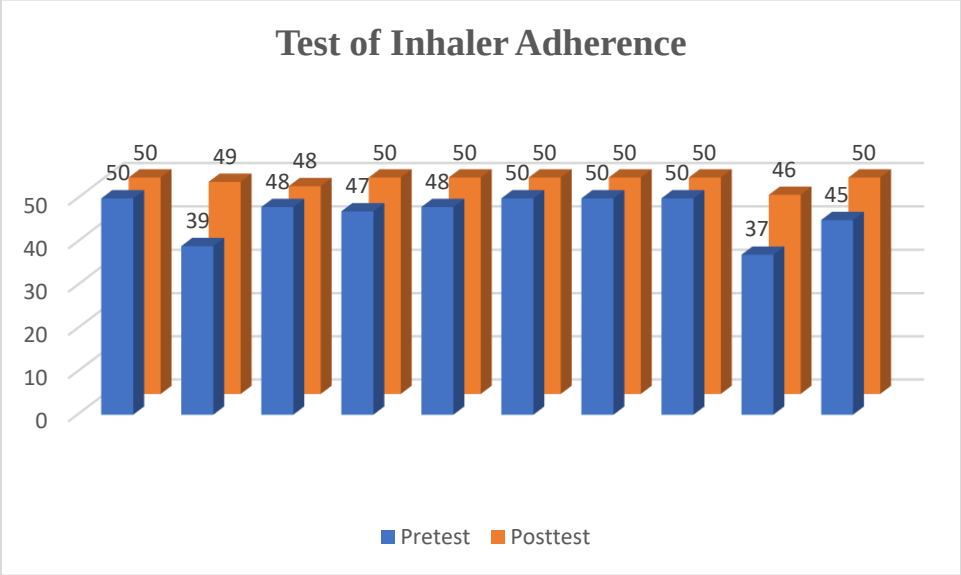
CAT Classification- *Table-1. C*



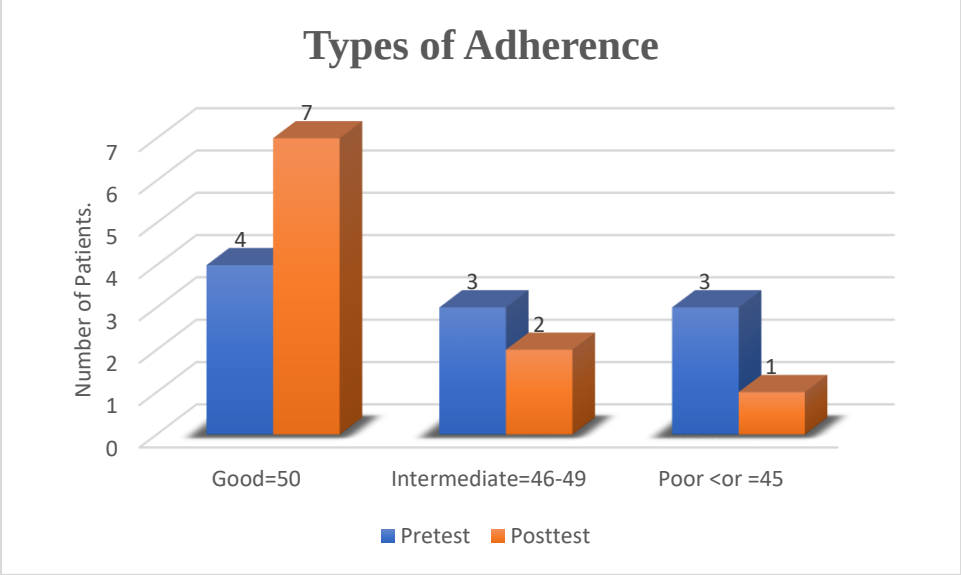
Test of Adherence to Inhaler (TAI)

Inhaler adherence has a mean value of 46.4 with a SD of 14.23 in the pretest, and a mean value of 49.3 with a SD of 4.01 in the posttest, which reveals a difference of 2.9 in inhaler adherence improvement (***Table 3-A)***. the Test of Adherence to Inhaler (TAI) allows to classify patients' adherence as good, intermediate or poor. In the pretest, 40% of patients have a good adherence to the inhaler as opposed to 70% of patients in the posttest. In the intermediate adherence, the results show 30% and 20% in the pretest and posttest respectively. A percentage of 30% of participants have a poor adherence to the inhaler in the pretest compared to 10% in the posttest ***(Table 3-B)***.

Test of Inhaler Adherence- ***Table-3. A***



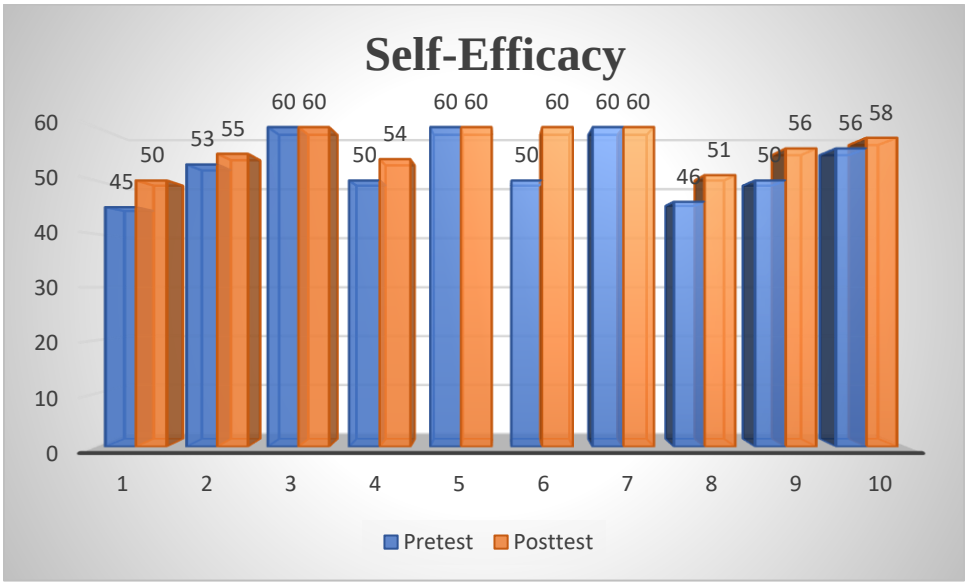
Types of Adherence-*Table-3. B*



Self-Efficacy for Managing Chronic Disease 6-item Scale (SEMCD6S)

In the SEMCD6S, the result indicates a difference in improvement of 3.4 with a mean value of 53 and a SD of 17.20 in the pretest, and a mean value of 56.4 with a SD of 11.56 in the posttest ***(Table 4)***.

Self-Efficacy-*Table 4*



Discussion

Limitation and Strength

The project aims to decrease COPD exacerbation frequency among African Americans. This QI project provides data to back-up the interventions selected to reach the project goals. The project strength is its concordance with the findings of previous studies that reveals that proper inhaler technique can decrease symptoms of COPD patients and COPD exacerbation rates. A study by Ramadan et al. (2020) concluded that a proper inhaler technique is imperative for effective management of respiratory ailments. Other factors that reinforce the strength of the project are the validity of the tools used, such as COPD assessment test (CAT) and the Self-Efficacy for Managing Chronic Disease 6-item Scale. However, an important limitation of the project is the sample size of 10 participants. A sample calculation was not included in the project. For that reason, the results study should be translated with caution. Sample size is crucial

for a project reliability since it can modify the outcome in either directions regarding medical decisions (Faber & Fonseca, 2014). Besides, the small sample size, the 6-week timeframe of the project constitutes a debatable factor for the study reliability. The actual pandemic COVID-19 has affected the face-to-face training and the impact of Bandura' self-efficacy might have on patients' behavior. It is important to conduct further studies to understand how remote training, patient education and socio-economic status can impact the outcome of the project. Pothirat et al. (2015) argue inhaler technique in patients affected with COPD without direct coaching was generally disappointing, mainly in poorly educated patients.

Implications for Advanced Practice Nursing

Taking care of COPD patients may be challenging for healthcare providers. Patients' education is an important parameter to take into account while planning care for sick patients. Nurse practitioners (NPs) have a crucial role to improve the quality of life of COPD patients. Bai et al. (2017) explain that smoking cessation exerts a positive impact in the natural history of COPD. NPs can assist patients in quitting smoking by providing suitable and consistent education on the beneficial effect of stopping smoking.

The dyspnea associated with COPD may impair patients' interaction and socialization, which may lead to depression, anxiety and loss of autonomy and self-sufficiency (George, 2018). NPs may also help COPD patients to enhance their physical activity. NPs can educate patients with COPD about appropriate exercise and breathing technique that can increase their exercise tolerance and physical activities. Researchers have shown that regular physical activities are linked to a decrease in lung function deterioration and COPD risks among smokers (Bai et al., 2017).

COPD constitutes a financial burden on healthcare (Kirsch et al., 2019), and COPD exacerbation is the most frequent cause of hospitalization among COPD patients (Sogaard et al., 2016). Studies have revealed that proper inhaler technique can decrease frequency of COPD exacerbation and improve patient's life quality. NPs are well placed to provide COPD patients the training required to appropriately use the inhaler. NPs are important providers to decrease health care cost and hospital admission by promoting healthy behavior and self-efficacy skills among patients affected with COPD. NPs in their holistic approach to health care and guided by well-versed guidelines epitomize the core component to ease the burden of COPD over affected people.

Dissemination and Sustainability

A PowerPoint presentation about this educational process will be offered to faculty and peers of the medical centers, and in FNA conference. Additionally, the results of this project will be submitted to the Florida International University (FIU) DNP Program Director: Dr. T. Maltseva, to Dr. Garcia as the CEO of the medical center, to other DNP peers and nursing students, and to the Journal for Nurse Practitioners.

The project results and implications have to be evaluated regularly to ensure and uphold high quality healthcare. Mortimer, Isherwood, Wilkinson, & Vaux (2018) emphasize a QI project can be sustained if the teams are trained to achieve the uppermost value enhancements. The project manager will coach the providers to understand the need for ongoing assessment of the inhaler technique among patients affected with COPD. In addition, the project leader will strengthen the importance of using the CAT and the IDAT tools by the providers to periodically assess and monitor patient outcome. The practitioners need to promote self-efficacy theory to

enhance patient self-care engagement. Finally, it is pivotal to introduce new approaches coupled with willingness and motivation toward change as ways to improve clinical practice. Silver et al. (2016) state to accomplish maintainable change, quality improvement initiatives must become the innovative method of functioning rather than some additional measures included into standard medical treatment.

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Appendix A

Self-Efficacy for Managing Chronic Disease 6-Item Scale

1. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

2. How confident are you that you can keep the physical discomfort or pain of your disease from interfering with the things you want to do?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

3. How confident are you that you can keep the emotional distress caused by your disease from interfering with the things you want to do?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

4. How confident are you that you can keep any other symptoms or health problems you have from interfering with the things you want to do?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

5. How confident are you that you can do the different tasks and activities needed to manage your health condition so as to reduce you need to see a doctor?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

6. How confident are you that you can do things other than just taking medication to reduce how much you illness affects your everyday life?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Impact Level of COPD on Health Status using the CAT Score. Appendix B1

CAT Score	Impact Level	Possible management considerations
5	Upper limit of normal in healthy non- smokers	
< 10	Low	• Smoking cessation • Annual influenza vaccination • Reduce exposure to exacerbation risk factors • Therapy as warranted by further clinical assessment.
10 – 20	Medium	Patient has room for improvement – optimize management In addition to the guidance provided for patients with low impact CAT scores consider: • Reviewing maintenance therapy – is it optimal? • Referral for pulmonary rehabilitation • Ensuring best approaches to minimizing and managing exacerbations • Reviewing aggravating factors – is the patient still smoking?
21 – 30	High	Patient has significant room for improvement In addition to the guidance for patients with low and medium impact CAT scores consider: • Referral to specialist care (if you are a primary care physician) Also consider: • Additional pharmacological treatments • Referral for pulmonary rehabilitation • Ensuring best approaches to minimizing and managing exacerbations
> 30	Very high	Same as above (21-30)

Table-2. Adapted from CAT (2018).

Appendix B2

Your name:_____

Today's date:_____

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional to measure the impact that COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers and test score can be used by you and your healthcare professional to help improve the management of your COPD and gain the greatest benefit from the treatment.

For each item below, place a mark (X) in the box that best describes your current situation. Please ensure that you only select one response for each question.

Example: I am very happy [0] [X] [2] [3] [4] [5] I am very sad

			SCORE
I never cough	0 1 2 3 4 5	I cough all the time	
I have no phlegm (mucus) on my chest at all	0 1 2 3 4 5	My chest is full of phlegm (mucus)	
My chest does not feel tight at all	0 1 2 3 4 5	My chest feels very tight	
When I walk up a hill or a flight of stairs I am not out of breath	0 1 2 3 4 5	When I walk up a hill or a flight of stairs I am completely out of breath	
I am not limited to doing any activities at home	0 1 2 3 4 5	I am completely limited to doing all activities at home	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	I am not confident leaving my home at all because of my lung condition	
I sleep soundly	0 1 2 3 4 5	I do not sleep soundly because of my lung condition	
I have lots of energy	0 1 2 3 4 5	I have no energy at all	
		TOTAL SCORE	

A COPD assessment test was developed by an interdisciplinary group of international COPD experts with support from GSK. GSK's activities in connection with the COPD assessment test are monitored by a supervisory council that includes external, independent experts, one of which is chair of the council.

Appendix C

	Score
1. How often did you forget to take your regular inhalers in the last 7 days? ☐ 1. Always ☐ 2. More than half ☐ 3. About half ☐ 4. Less than half ☐ 5. None	
2. You forget to take your inhalers: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
3. When you are feeling well, you stop taking your inhalers: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
4. At the weekend or when you go on holiday, you stop taking your inhalers: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
5. When you are anxious or sad, you stop taking your inhalers: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
6. You stop taking your inhalers out of fear of potential side effects: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
7. You stop taking your inhalers because you believe that they are of little help in treating your condition: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
8. You take fewer inhalations than prescribed by your doctor: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
9. You stop taking your inhalers because you believe that they interfere with your day-to-day or work life: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	
10. You stop taking your inhalers because you have trouble paying for them: ☐ 1. Always ☐ 2. Almost always ☐ 3. Sometimes ☐ 4. Almost never ☐ 5. Never	

A healthcare professional responsible for the patient must answer the following two questions according to the data that appears in the patient's medical record (question 11) and after confirming their inhalation technique (question 12).

11. Does the patient know or remember the regimen (dose and frequency) that they were prescribed? ☐ 1. No ☐ 2. Yes	
12. The patient's inhalation technique for the device: ☐ 1. Has critical errors ☐ 2. Has no critical errors or is correct	
TOTAL SCORE	

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Appendix D1

Inhaler Device Assessment Tool - Form A1: MDI

Type of inhalation device (**Check one**): ☐ MDI ☐ MDI plus spacer ☐ MDI plus spacer with mask

Instructions. Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.
When using this checklist as a teaching guide: For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

Sequence of Critical Steps & Criteria		Score Circle 1 or 0		Coaching
1 Removes cap.		1	0	
Score 1 if:	*Score 0 if*:			
✓ MDI: Removes cap from the mouthpiece.	☐ Forget to remove cap(s).			
✓ MDI plus spacer: Removes cap(s), AND inserts canister into spacer correctly.	☐ Metal canister of MDI not in plastic mouthpiece correctly			
✓ MDI plus spacer with mask: Removes cap(s), inserts canister mouthpiece into spacer.	☐ Other:			
2 Correctly primes device.		1	0	
Score 1 if:	*Score 0 if*:			
✓ MDI: Shakes the inhaler AND inhaler is upright	☐ Forget to shake.			
✓ MDI plus spacer with mask: Shakes and delivers only 1 spray in the chamber, after on face with a good seal.	☐ Device held incorrectly (e.g., upside down).			
	☐ Other:			
3 Exhales.		1	0	
Score 1 if:	*Score 0 if*:			
✓ Exhales completely or breathes out to the end of a normal breath before putting apparatus to mouth.	☐ Does not exhale fully.			
✓ MDI plus spacer: Hear a hissing sound.	☐ Other:			
✓ MDI plus spacer with mask: Good fit of mask (nose and mouth covered).				
4 Inhales appropriately for device.		1	0	
Score 1 if:	*Score 0 if*:			
✓ MDI: Positioned 2-3 finger widths away from widely opened mouth. At the same time starts to breathe in slowly and depresses the inhaler to release 1 puff of medication. Continues breathing in slowly for about 5 seconds. Position with chin up.	☐ Head not correctly positioned.			
	☐ Block spray with teeth or tongue.			
	☐ Blue or yellow Aerochamber: Hear a musical sound or whistling; breathing in too quickly.			
✓ MDI plus spacer: Puts the mouthpiece of spacer in the mouth, lips closed tightly around it, presses the inhaler. Breathes in slowly and deeply through the mouth for about 5 seconds.	☐ Does not synchronize breathing in with puff (MDI alone).			
	☐ Inhales through nose.			
✓ MDI plus spacer with mask: Good seal over nose and mouth, press the inhaler, slow tidal breathing (that is, regular breathing in and out).	☐ Delivering 2 sprays at once in the chamber for 1 inhalation.			
	☐ Cough provoked by inhalation.			
	☐ Other:			
5 Holds breath.		1	0	
Score 1 if:	*Score 0 if*:			
✓ Person holds breath to count of 10 seconds.	☐ Holds breath for less than 10 seconds.			
✓ Lips kept closed while holding breath.	☐ MDI plus spacer with mask: Holds breath in and out less than 6 times per dose of medication. (child <6 years)			
✓ MDI plus spacer with mask: No breath hold (see tidal breathing above)				
✓ Person waits 30-60 seconds before repeating process	☐ Other:			
Date: _____ dd/mm/yyyy	**TOTAL SCORE**			

Appendix D2

Inhaler Device Assessment Tool - Form A2

Type of inhalation device: MDI plus spacer

Instructions. Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.

When using this checklist as a teaching guide: For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

Sequence of Critical Steps & Criteria		Score Circle 1 or 0		Coaching
1 Removes cap. *Score 1 if:* ✓ Removes cap, AND inserts canister into spacer correctly.	*Score 0 if:* ☐ Forgets to remove cap. ☐ Metal canister of MDI not inserted correctly into plastic holder. ☐ Forgets to monitor medication doses and MDI is empty. ☐ Other:	1	0	
2 Correctly primes device. *Score 1 if:* ✓ Shakes the MDI upright with the spacer/mask.	*Score 0 if:* ☐ Forgets to shake. ☐ Device held incorrectly (e.g., upside down). ☐ Other:	1	0	
3 Exhales. *Score 1 if:* ✓ Exhales completely or breathes out to the end of a normal breath before putting the spacer to mouth ✓ For younger child (4-6 years): With correct seal on mouthpiece may exhale into spacer.	*Score 0 if:* ☐ Forgets to exhale. ☐ Does not exhale completely. ☐ Other:	1	0	
4 Inhales appropriately for device. *Score 1 if:* ✓ Puts the mouthpiece of spacer in the mouth, lips closed tightly around it, depress MDI. ✓ Breathes in slowly and deeply through the mouth for about 5 seconds. ✓ For younger child (4-6 years): during exhalation depress the MDI and breathe in slowly and deeply through the mouth as able.	*Score 0 if:* ☐ Head not correctly positioned or with slouching posture. ☐ Blocks spray with teeth or tongue. ☐ Inhales through the nose. ☐ Breathes in too quickly (hear a whistling or musical sound from spacer). ☐ Delivers 2 sprays at once for 1 inhalation. ☐ Other:	1	0	
5 Holds breath. *Score 1 if:* ✓ Holds breath to count of 10 seconds. ✓ Lips are kept closed while holding breath. ✓ Waits 30-60 seconds before repeating process	*Score 0 if:* ☐ Holds breath less than 10 seconds. ☐ Does not wait 30-60 seconds between doses. ☐ Other:	1	0	
Date: _____ dd/mm/yyyy	**TOTAL SCORE**			

Appendix D3

Inhaler Device Assessment Tool - Form A3

Type of inhalation device: MDI plus spacer with mask

Instructions. Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.

When using this checklist as a teaching guide: For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

Sequence of Critical Steps & Criteria		Score Circle 1 or 0		Coaching
1 Removes cap. *Score 1 if:* ✓ Removes cap, AND inserts canister into spacer correctly. ✓ Ensure infant or toddler is positioned correctly and securely.	*Score 0 if*: ☐ Forgets to remove cap. ☐ Infant/toddler not positioned correctly. ☐ Forgets to monitor medication doses and MDI is empty. ☐ Other:	1	0	
2 Correctly primes device. *Score 1 if:* ✓ Shakes the MDI upright with the spacer/mask. ✓ Delivers only 1 spray in the chamber, after mask on face with a good seal.	*Score 0 if*: ☐ Forgets to shake. ☐ Device held incorrectly (e.g., upside down). ☐ Other:	1	0	
3 Exhales. *Score 1 if:* ✓ Good fit of mask (nose and mouth covered). Hold the device by the mask securely to the face. ✓ Exhalation valve must be present and move with inhalation and exhalation.	*Score 0 if*: ☐ Exhalation valve missing or not functioning. ☐ Inadequate seal of mask over nose and mouth. ☐ Other:	1	0	
4 Inhales appropriately for device. *Score 1 if:* ✓ Good seal over nose and mouth, press the inhaler, slow tidal breathing (that is, regular breathing in and out). ✓ Count 6 to 8 breaths.	*Score 0 if*: ☐ Mask not securely held to infant/ toddler's face. ☐ Delivers 2 sprays at once for 1 inhalation. ☐ Tidal breathing for less than 6-8 breaths. ☐ Other:	1	0	
5 Holds breath. *Score 1 if:* ✓ As above for tidal breathing. ✓ Waits 30-60 seconds before repeating process	*Score 0 if*: ☐ As above for tidal breathing. ☐ Does not wait 30-60 seconds between doses. ☐ Other:	1	0	
Date: _____ dd/mm/yyyy	**TOTAL SCORE**			

Appendix D4

Inhaler Device Assessment Tool - Form B

Type of inhalation device (**Check one**): ☐ Diskus® ☐ Turbuhaler®

Instructions. Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.

***When using this checklist as a teaching guide:** For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

Sequence of Critical Steps & Criteria		Score Circle 1 or 0		Coaching
1 Removes cap.		1	0	
Score 1 if:	*Score 0 if:*			
✓ Diskus: Opens the Diskus apparatus using the thumb grip (a click heard when it is open all the way).	☐ Forget to open Diskus or remove outside cover of Turbuhaler.			
✓ Turbuhaler: Removes the outside cover.	☐ Forget to remove cap (Turbuhaler).			
	☐ Other:			
2 Correctly primes device.		1	0	
Score 1 if:	*Score 0 if:*			
✓ Diskus: Slides the lever as far as it will go until a click is heard.	☐ Device held incorrectly (e.g., upside down).			
✓ Turbuhaler: Turns the colored grip or base ring all the way in one direction until it stops, then back again until a click is heard.	☐ If click not heard for Turbuhaler or Diskus.			
	☐ Other:			
3 Exhales.		1	0	
Score 1 if:	*Score 0 if:*			
✓ Exhales normally before putting the apparatus to the mouth.	☐ Turbuhaler/Diskus: Exhaling into device.			
	☐ Does not exhale fully.			
	☐ Other:			
4 Inhales appropriately for device		1	0	
Score 1 if:	*Score 0 if:*			
✓ Diskus: With mouthpiece to the lips and position chin up, inhales quickly and deeply.	☐ Not a good seal between the mouth and mouthpiece of any device.			
✓ Turbuhaler: Puts the mouthpiece between the lips, position chin up, and breathes in quickly and forcefully through the mouth.	☐ Head not correctly positioned.			
	☐ Block spray with teeth or tongue.			
	☐ Cannot synchronize breathing in with puff.			
	☐ Inhales through nose.			
	☐ Cough provoked by inhalation.			
	☐ Turbuhaler or Diskus breathing in slowly.			
	☐ Other:			
5 Holds breath.		1	0	
Score 1 if:	*Score 0 if:*			
✓ Person holds breath to count of 10 seconds.	☐ Holds breath for less than 10 seconds.			
✓ Lips kept closed while holding breath.	☐ Other:			
Date:_____ dd/mm/yyy	Time:	**TOTAL SCORE**		

Appendix E

Consent to Participate in A COPD Self-Management Program

You are being asked to participate in a Doctorate in Nursing Project titled, "***Reducing COPD exacerbations frequency among African Americans with COPD"***

You were chosen because your primary care providers at the American Care Center selected you.

You are willingly participating in the project.

The purpose of the project is to:

1. Assist you to properly use an inhaler.
2. Help you make healthier decisions in regard to smoking, exercise activities, and lifestyle.
3. Increase your understanding of COPD and its complications
4. Empower you as a person with COPD to better care for yourself
5. Empower you with the knowledge required to enhance your breathing capability.

During the program you are expected to:

- Practice the inhaler technique.
- Make healthy living habit, and include physical activities into your daily routine
- Attend 6 weekly meetings for 30 minutes at the Center. To be included in the project, you must agree to attend at least 5 of the meetings.
- Accept a once-a-week phone call to monitor your improvement while in the program.

Risks/Deceptions of Being in this Program: There are no anticipatable (or expected) risks.

There may be unknown risks.

Benefits of Being in the program: The benefits of participation are learning to manage your COPD better, learn how to avoid damaging complication of the disease, and understand steps to avert an exacerbation of COPD.

Confidentiality: Your identity will not be revealed during or after the project. The records of this project will be held strictly confidential. We will not include any information in any report we may publish that would make it possible to identify you. Your identity will not be disclosed in any material that is published.

Payments: You Will Not Receive Any Payment for Your Participation in This Project. The decision to participate in this project is exclusively up to you. You may decline to take part in the project *at any time*. Your decision will not result in any loss or benefits to which you are otherwise entitled.

Questions and Concerns: You have the right to ask questions about this program and to have those questions answered during or after the program.

Consent: Your autograph below specifies that you have decided to volunteer as a research participant for this quality improvement program, and that you have read and comprehended the aforesaid information. You will be given a signed and dated copy of this form to keep, along with any other printed documents considered necessary by the project manager.

Participant Name (print): _____

Participant Signature: _____

Date: _____

Project Leader Signature: _____

Date: _____

Appendix F

Medical Center Manager Approval Letter

American Care Medical Centers

June 8,2020

Dear Mr. Orelus,

We would like to thank you for your "Reduction of COPD exacerbation among African American rate" proposal. After a careful analysis, I have decided to grant you permission to begin your study, effective June 8,2020. We support this effort and will provide any assistance necessary for the successful implementation of this study.

We believe that this is a valuable charitable endeavor that will significantly decreased the amount of hospital admission and improve our African American community who suffers with COPD. Thanks again for the proposal and we looking forward to working with you.

Sincerely,

Whitney M. Baron
Center Manager

American Care of Northwest
1521 Northwest 54th Street
Miami, Florida 33142
Ph: 786-594-0000
Fax: 786-955-2216

Appendix G

IRB Approval Letter

FIU | FLORIDA INTERNATIONAL UNIVERSITY

Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To: Dr. Dana Sherman
CC: Jean Pierrot Orelus
From: Maria Melendez-Vargas, MIBA, IRB Coordinator
Date: July 20, 2020
Protocol Title: "Reducing COPD exacerbation among African Americans affected with COPD"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-20-0363 **IRB Exemption Date:** 07/20/2020
TOPAZ Reference #: 109283

As a requirement of IRB Exemption you are required to:

1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at http://research.fiu.edu/irb.

MMV/em