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Implementation of a Nicotine Assessment Tool to COPD Patients in an Observation Unit

by

Nilsa Black-Mead, MSN, CRNP

A DNP PROJECT

Submitted in partial fulfillment of the requirements for the

Degree of Doctor of Nursing Practice

to

The School of Graduate Studies

of

The University of Alabama in Huntsville

HUNTSVILLE, ALABAMA

2019

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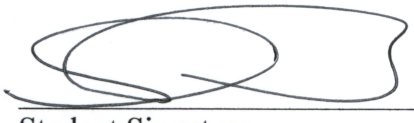

Student Signature

3-13-19

Date

DNP PROJECT APPROVAL FORM

Submitted by Nilsa M. Black-Mead in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice and accepted on behalf of the Faculty of the School of Graduate Studies by the DNP project committee.

We, the undersigned members of the Graduate Faculty of The University of Alabama in Huntsville, certify that we have advised and/or supervised the candidate on the work described in this DNP project. We further certify that we have reviewed the DNP project manuscript and approve it in partial fulfillment of the requirements for the degree of Doctor of Nursing Practice.

3-13-2019 Louise O'Keefe Committee Chair
(Date)

DNP Program Coordinator

College of Nursing, Associate Dean for Graduate Studies

College of Nursing, Dean

Graduate Dean

DEDICATION

I would like to dedicate this project to my parents, my father who is watching from above, and my mother Carmen who always persuaded me to be my very best. I also want to dedicate this work to my daughters for who I hope to lead by example. Finally, I would like to dedicate this project to my loving husband. I am eternally grateful for his support, love, and encouragement throughout this journey.

ACKNOWLEDGMENTS

I am sincerely grateful for the support and guidance of Dr. Louise O'Keefe and The University of Alabama in Huntsville, College of Nursing who made possible the completion of this project. I am also extremely thankful to Dr. Laura Satcher who contributed with her valuable time, knowledge, and advice throughout this project making this quality project a success. Furthermore, I will always be grateful for the participation of Huntsville Hospital Observation Unit physicians, without their willingness this project couldn't have been possible. Finally, I want to thank my husband, his encouragement and reinforcement made this journey conceivable.

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ABSTRACT

The School of Graduate Studies

The University of Alabama in Huntsville

Degree: Doctor of Nursing Practice College: Nursing

Name of Candidate: Nilsa M. Black-Mead

Title: Implementation of a Nicotine Addiction Assessment Tool to COPD Patients in an Observation Unit.

PICOT Question: Does educating clinicians in the use of a smoking cessation survey increase the use of the Tobacco Cessation – Nicotine Addiction Questionnaire (NAQ), and the use of smoking cessation interventions including Nicotine Replacement Therapy (NRT) in COPD patients admitted to an Observation Unit (OU)?

Background: COPD is the third leading cause of death, affects more than fifteen million Americans, and causes serious long-term disabilities and premature death. Smoking is the most significant risk factor for developing COPD, accounting for as many as eight out of ten COPD related deaths, harming nearly every organ of the body affecting a person's overall health. COPD in the setting of ongoing smoking causes high utilization of resources to the US' health care system resulting in substantial economic expenditures with frequent provider visits and recurrent hospitalizations due to acute exacerbations requiring chronic medical therapy.

Purpose: To implement an educational intervention to clinicians caring for COPD patients with ongoing tobacco dependence admitted to an OU for acute COPD exacerbation. This intervention should improve clinician awareness on the use of the NAQ to guide in the utilization of smoking cessation interventions during the OU stay and after discharge.

Implementation: A convenience sample of six clinicians providing care to smokers admitted to an OU for acute COPD exacerbation was selected to participate. This quality improvement project, using a pre/post-test design based on a retrospective medical chart review over six months, assessed clinicians' knowledge and education tool effectiveness after the implementation of a 20-minute educational training via a PowerPoint presentation. Pre/post variables included utilization of the NAQ, smoking cessation teaching, NRT utilization during OBS stay, NRT prescribed at discharge, and smoking cessation treatment offered at discharge.

Results: A total of 60 charts were abstracted pre- and post-intervention. All (100%) of the participating physicians demonstrated an increase in the utilization of the NAQ, smoking cessation education, and NRT orders during the OU stay. There was statistically significant improvement in the utilization of the NAQ ($p = .000$) and smoking cessation education ($p = .000$). Despite an improvement in NRT use during the OU stay following training, there was not statistically significance ($p = .203$). Adversely, there was a decrease in prescribing NRT at discharge post-intervention. However, there was an increase in smoking cessation resources offered at discharge without statistically significant differences between groups ($p = .073$).

Discussion: Although the benefits of smoking cessation have been identified in many settings, COPD continues to grow at a frightening rate. This project contributes by preparing DNP nurses to focus on COPD prevention strategies and the importance of continuing education among clinicians, particularly in regards to smoking cessation, a known detrimental public health issue in the US. Additionally, this project demonstrates how physicians are receptive of teaching and practice change to promote positive impact in patients. However, this project emphasizes the need for future research to develop tailored smoking cessation interventions to promote smoking abstinence in a chronic population whose behavior changes are essential for their welfare.

Implementation of a Nicotine Assessment Tool to COPD Patients in an Observation Unit

Identification of the Problem

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease consisting of a group of diseases including emphysema, chronic bronchitis, and asthma, causing airflow limitations, and in advanced cases obstruction (Centers for Disease Control & Prevention [CDC], 2011). According to the American Lung Association (ALA), (2015), COPD is the third leading cause of death, affecting more than fifteen million Americans, and causing severe long-term disabilities and premature death. Smoking is the most significant risk factor for developing COPD, accounting for as many as eight out of ten COPD related deaths (CDC, 2017b). COPD in the setting of ongoing tobacco use causes high utilization of resources and significant economic expenditures to the United States' (US) health care system. According to an article by Guarascio, Ray, Finch, and Self (2013), given the alarming growth rate of COPD, it is imperative to understand the economic impact that a disease of this magnitude can have on the US health care system, potentially imposing a substantial burden and threat to public health.

Tobacco use is the largest preventable cause of death and disease in the US with approximately 480,000 Americans dying from tobacco-related illnesses each year, and more than 16 million Americans suffering from at least one disease caused by smoking (US Department of Health and Human Services [HHS], 2014). Smoking-related illnesses in the US cost more than $300 billion each year, including nearly $170 billion for direct medical care for adults and more than $156 billion in lost productivity (US DHHS, 2014). The result is an increase in usage of resources with frequent provider visits and recurrent hospitalizations due to acute disease exacerbations requiring chronic medical therapy.

The World Health Organization (WHO) has recognized COPD as a significant public health hazard and smoking has been acknowledged as the primary causative factor. Tobacco use drastically increases the risk of disease and is associated with comorbidities that are known to cause death including cancer, cardiovascular disease, respiratory disease, and perinatal complications. Therefore, smoking harms nearly every organ of the body and affects a person's overall health (CDC, 2017a) including a reduction in fertility, and increased risks for birth defects and miscarriages. Additionally, smoking causes adverse effects on teeth and gum health resulting in tooth loss, increased risk for cataracts and type 2 diabetes, and a decrease in bone health and immune system function.

The COPD Foundation (2017) suggests that 9.1% of Americans are affected by COPD in Alabama (AL), the second highest state rate in the nation. The Burden of Tobacco in Alabama report prepared by the AL Department of Public Health (2011) suggests the decline in adult smoking prevalence in AL has been slower than nationwide with a median smoking rate falling at 0.44 percent in comparison to the national rate at 0.70 percent per year. More specific, in an Observation Unit within a North AL Hospital, an average of 40% (142) of the 356 monthly admissions in 2017 were for acute COPD exacerbation. Furthermore, the health care costs in AL, directly caused by smoking, amount to $1.88 billion annually with losses of $2.71 billion in productivity each year due to smoking (Campaign for Tobacco-Free Kids, 2017).

Nearly forty percent of smokers attempt to quit yearly according to Caplan, Stout, and Blumenthal (2011), but only four percent of them achieve complete smoking cessation. As discussed in the Current Medical Diagnosis and Treatment (2017), smokers who receive advice to quit from their providers are 1.6 times more likely to attempt quitting, but only 20%, out of over 70% of smokers who see a clinician each year, receive smoking cessation counseling or

support at all. Pires-Yfantouda, Absalom, and Clements (2013) reported that a significant factor for patients with chronic diseases is adherence to treatment and sustainability of the recommended behavior changes. Therefore, tobacco use, as discussed in the Patterson and colleagues (2017) study, is a chronic relapsing condition that requires a treatment maintenance approach so that abstinence can be sustained.

A review of the literature in 2013 by Carpenter and colleagues suggests that factors contributing to stagnant smoking rates include the low overall use of evidence-based treatment among smokers attempting to quit. Nicotine replacement therapy (NRT) is among one of the most used and effective treatments for tobacco use dependence, and it can be used in concurrence with other smoking cessation interventions to assist in increasing abstinence rates. Providing dual treatment tailored to patients including counseling and NRT should be utilized to guide and accommodate smokers' needs to prevent nicotine withdrawal and improve cessation rates. Abstinence from tobacco use should be the paramount goal for healthcare providers' clinical interventions despite the amount of tobacco use.

Purpose of the project

It is imperative to partner with other healthcare providers to identify public health gaps and to create specific goals aimed at prevention and control of COPD through smoking cessation education. The purpose of this project is to implement an educational intervention to clinicians caring for COPD patients with ongoing tobacco dependence admitted to an OU for acute COPD exacerbation. The outcome of the clinician education intervention was measured by an increase in the use of the Nicotine Addiction Questionnaire (NAQ), and the use of NRT after education was provided. This intervention potentially improves clinician awareness on the use of the NAQ to guide in the utilization of smoking cessation interventions during the Observation Unit (OU)

stay and after discharge. Ideally, there was a reduction in tobacco use, a decrease in re-admission rates, and ultimately improvement in patients' health outcomes and quality of life. This review was completed using a retrospective chart review.

PICOT question – Does educating clinicians in the use of a smoking cessation survey increase the use of the Tobacco Cessation – Nicotine Addiction Questionnaire, and the use of smoking cessation interventions including Nicotine Replacement Therapy in COPD patients admitted to an Observation Unit?

Review of Evidence

Search Strategy

A structured search of the literature using PRISMA was conducted to determine the current evidence regarding COPD in the setting of ongoing tobacco use, nicotine addiction, smoking cessation training to clinicians, and smoking cessation. The databases used were PubMed/Medline, Cochrane and CINAHL. Keyword searches were used to review MeSH headings. The keywords included: smoking cessation, COPD, tobacco use, smoking and health, nicotine addiction, clinician education and smoking, and nicotine replacement therapy and smoking cessation. The search of the literature revealed that smoking cessation is a complex problem in the US and there are apparent gaps regarding the utilization of smoking cessation interventions. Articles obtained from the search were reviewed, and subsequently, the ancestry method was used to expand the literature review. Limiters included research articles, systematic reviews, clinical practice guidelines, within the past eight years, peer-reviewed, evidence-based practice, English or Spanish language, and adult population.

Smoking Cessation Programs

A mixed methods design study of a three-session urban hospital smoking cessation program by Patterson and colleagues (2017), was examined utilizing quantitative and qualitative tools to assess predictors of smoking cessation program enrollment and attendance; and treatment-seeking participation and preferences. A retrospective chart review was conducted for all pulmonary clinic patients who smoked and were referred to the cessation program. Demographic, smoking behavior, cardiopulmonary, and health status variables of a 253 sample were extracted. Additionally, within a subsample (N = 41) of the population, a qualitative assessment of the beliefs and barriers to smoking cessation and physical activity were evaluated. Results show that of the 58% of the pulmonary subjects enrolled in the cessation program; 16% of the total sample completed the entire sessions. Patients with COPD or with a family history of having a mother with a history of cancer were more likely to attend the program. Patients who wanted to quit smoking and who preferred to be more physically active stated stronger beliefs about the inability to engage in these behaviors. In conclusion, smoking cessation program attendance in this sample of mostly African-American smokers was poor. Data within the study design provides evidence of how limited knowledge about the risks and benefits for smoking cessation, increased activity, and inadequate access to formal cessation pharmacotherapy treatment, may be priority intervention targets (Patterson et al., 2017). Additionally, those without a COPD diagnosis and no family history of a mother diagnosed with cancer may be high-priority targets to promote cessation program uptake among this population. Furthermore, according to Patterson and colleagues (2017), increased knowledge and access to safe forms of physical activity may also provide some benefit.

Aumann, Tedja, and von der Schulendurg (2016) conducted a qualitative analysis of experiences of COPD patients with existing smoking cessation programs and their preferences for improvement. An eighteen guideline-based interview for COPD patients who were current or past smokers and had made at least one attempt to stop smoking in the past five years was conducted and included in the study. The interviews were audiotaped, transcribed verbatim, and interviews evaluated using content analysis. Broad and different experiences with pharmaceutical, behavioral and alternative approaches were found that supported or negatively influenced patients with the smoking cessation process. The pharmaceutical approaches were viewed as an expensive selection with many side effects but were found to help stop cravings temporarily. Also, the weak structure and impersonal content of the seminars for smoking cessation negatively influenced group connection and consequently reducing the patients' motivation to stop smoking. Other methods including acupuncture and hypnosis were mostly ineffective in stopping tobacco use, but in instances served as motivational strategies. In conclusion, negative experiences with smoking cessation were explained by the patients' lack of motivation or resolution.

An observational study by Oostveen, van der Galien, Smeets, Hollinga, and Bosmans (2014) was conducted to assess the effectiveness of pharmacotherapy in behavioral therapeutic smoking cessation programs. During the study, national suppliers, general practitioners, and healthcare centers offered four different programs (behavioral therapy, behavioral support combined with nicotine replacement therapy (NRT), behavioral support combined with smoking cessation medications, and behavioral support combined with NRT and smoking cessation medications) to assess effectiveness in smoking cessation. Logistic regression and multilevel logistic analysis were performed to examine the efficacy of the programs. As a result, it was

established that behavioral support combined with smoking cessation medications had the most substantial number of participants quit smoking as compared to the reference program of behavioral support alone. Furthermore, it was the most cost-effective for general practitioners and healthcare organizations. Behavioral support combined with NRT had a significant amount of patients quitting smoking; however, the reference program range was smaller. In conclusion, behavioral therapy combined with smoking cessation aids/medications appears the most effective program of all.

Barriers to hospitalized patients participating in a free smoking cessation support program were identified in a pilot study performed by York, Kane, Beaton, Keown, and McMahan (2017). During the study, medical-surgical patients who smoke were surveyed to determine their perceived barriers to quitting smoking and their participation in a free smoking cessation support program. This study employed a cross-sectional, descriptive design. A 27-item tool based on previous cessation surveys and stakeholder interviews were developed and given to a convenience sample of 79 current smokers in acute care medical-surgical units at a community hospital. Approximately one-half of the participants were previously unsuccessful in attempts to quit smoking within the past year. A strong correlation was found between readiness to quit and motivation to quit. Participants' greatest fears about stopping were becoming tense or nervous, experiencing mood swings, fear of failure, and weight gain. Additionally, near 50% of the participants had partners who smoked. A vast majority of participants were willing to speak with a registered nurse after discharge, but only 40% were agreeable to attend a free smoking cessation program. In conclusion, the patient's spouse, family, and friends must be included in the program to increase support. The goal of the smoking cessation strategies should be directed at decreasing anxiety levels and increasing motivation to participate.

Pires-Yfantouda, Absalom, and Clemens (2013) conducted a systematic review to establish the most effective smoking cessation intervention approach for smokers with COPD. Two independent reviewers evaluated randomized controlled trials and quasi-randomized controlled trials using a quality assessment form developed from the selection criteria. The studies indicated that psychosocial interventions combined with pharmacotherapy are effective in smoking cessation at twelve months post-intervention, although the effect is not statistically significant due to small sample size and heterogeneity between the studies. Also, this review indicated the effectiveness of psychosocial treatment for people with or without COPD symptoms at twelve months, despite not having an apparent effect on disease severity. This analysis also emphasizes the difficulty of maintaining attendance at community locations in comparison to acute or research settings. In conclusion, a combination of pharmacotherapy and psychosocial support appears to be the best approach to take to stop smoking, although a lengthy intervention does not necessarily result in better outcomes (Pires-Yfantouda, Absalom & Clemens, 2013).

Predictors of Smoking Cessation

A pragmatic randomized controlled trial to determine the effect of smoking cessation, at six months, using a two week pre-cessation period with nicotine replacement therapy including nicotine patches or nicotine gum was conducted in New Zealand. Eleven hundred adults who called a Quitline (telephone smoking cessation toll-free line) during March 2006-May 2007 for support to stop smoking were chosen. Participants in the pre-cessation group were provided with vouchers for two weeks of nicotine patches and gum before their chosen quit day, followed by usual care (8 weeks of nicotine patches and gum and support phone calls), or usual care alone. Questionnaires were administered to both groups at baseline, quit day, one week,

three months, and six months. As a result, using NRT two weeks before the target-quit day was safe and well tolerated by the participants but did not offer benefits over the usual care. However, when compared with other pre-cessation NRT studies an overall small benefit was found. Limitations in this study include lack of blinded treatment allocation due to the nature of the intervention, the intervention variation in the type and strength of the NRT used, and user errors. Given the substantial health benefits of smoking abstinence, the search for cessation strategies with greater efficacy and wider appeal must continue (Bullen, Howe, Lin, Grigg, Laugesen, &…Rodgers, 2010).

Embedded within a prospective population-based cohort study in Rotterdam, the Terzikan and colleagues (2016) study evaluated the prevalence and incidence of COPD in smokers and non-smokers enrolled adults (>45 years) diagnosed with COPD based on pre-bronchodilator obstructive spirometry or diagnosed by the general provider or pulmonologist. There were a total of 14,619 participants in the study. Of those 1,993 had COPD, 689 cases were prevailing ones, and 1,304 cases were incident ones. The overall COPD incident rate was 8.9/1000, and the incident rate was higher in males and smokers. The proportion of female COPD participants without a history of smoking was 27.2%, while the proportion of male COPD participants was 7.3%. The prevalence of COPD in the Rotterdam study is 4.7%, and the overall incidence is 9/1000, which includes a higher incidence in males and smokers. The study suggested this rate increased progressively with age, was higher in men than women, and in "always" smokers compared to "never" smokers. In conclusion, the study demonstrates that the incidence of COPD is higher in men than in women and in elderly than in younger participants. The proportion of "never" smokers among COPD cases is substantial and higher in females than in males (Terzikhan et al., 2016).

In 2012, one qualitative study aim was to examine why smokers diagnosed with COPD do not quit smoking. Eklund, Nilsson, Hedman, and Lindberg (2012), chose a purposive sample of participants in an ongoing case-control study of COPD that were invited to participate using a semi-structured interview. Ten smokers, the first five men and five women who responded to the inquiry and gave informed consent were included in the study. A qualitative content analysis was used to analyze the data. Results indicated that subjects were controlled by a longstanding habit that was difficult to break despite their knowledge about the harmful effects of smoking and the long-term consequences of COPD. Participants described incidents in their lives as reasons for never finding the right time to stop smoking. Also, demands to quit smoking from other people could lead to continued tobacco use or relapsing after cessation, as they did not want to be patronized. They expressed desire in receiving support from their relatives and care providers despite wanting to decide to quit smoking on their own. In conclusion, for successful smoking cessation, it is essential to understand the difficulties in smokers' experiences and the influence on their efforts to stop smoking. It is imperative to ensure that the smoker has validated internal motivation and a desire to quit smoking to be able to achieve successful, lasting smoking cessation.

Associations between health literacy and established predictors of smoking cessation were evaluated during a multiple linear regression analysis conducted by Stewart and colleagues in 2013. Data were previously collected as part of a more extensive study evaluating health risk messages, and from it, a multiple linear regression analysis was performed to examine relations between 402 low-socioeconomic status, racial/ethnically diverse smokers' health literacy and predictors of smoking cessation. Predictors included nicotine dependence, smoking outcome expectancies, smoking risk perceptions and knowledge, self-efficacy, and intentions to quit or

reduce smoking. As a result, it was demonstrated that lower health literacy was associated with higher nicotine dependence, more positive and less negative smoking outcome expectancies, less knowledge about smoking health risks and lower risk perceptions (Stewart et al., 2013). These associations continued to be meaningful even after controlling for demographics and low socioeconomic status-related factors. Therefore, the results provide the first evidence that low health literacy may serve as an important and independent risk factor for poor smoking cessation outcomes among this population of racially and ethnically diverse smokers.

Using data from the Ontario Tobacco Survey longitudinal study Zhang, Cohen, Bondy, and Selby (2015) used logistic regression analysis to examine the association between duration of NRT use and smoking cessation. Data from the Ontario Tobacco Survey was collected in three phases between July 2005 and December 2009. Logistic regression with generalized estimating equations was utilized to examine the association between NRT use and quitting smoking. Smokers were recruited and followed for three interviews at six months intervals after baseline data was collected. Smoking cessation, cessation aids, and duration use were measured at each follow-up interview. Variables that influence the use of NRT and smoking cessation were also examined. This study found that the majority of smokers did not use any NRT when making attempts to quit smoking and when using NRT, they used it for less than the recommended duration of 8-12 weeks. There was no overall association between NRT use and quitting when the duration of use was not taken into consideration. The use of NRT for less than four weeks was associated with reduced likelihood of cessation and NRT used for more extended periods of time was associated with higher likelihood of cessation. A potential limitation of this study includes the reliance upon self-reported cessation status due to the social stigma placed on

smoking and loss to follow-up threatening the validity of the findings (Zhang, Cohen, Bondy & Selby, 2015).

Effectiveness of smoking cessation training to clinicians

Providing physicians with education for in office-based smoking cessation to increase adherence to Public Health Services (PHS) Clinical Practice Guidelines on treating tobacco use and dependence demonstrated that compliance with the PHS tobacco guidelines could be significantly improved (Caplan, Stout, & Blumenthal, 2011). Thirty-five physicians serving predominantly African American patients were recruited. To promote the use of the PHS guideline an educational intervention training of two sessions was developed. Data collection to determine tobacco control practice behavior among participating providers took place before training and at six months following training. A total of 308 charts were reviewed pre- and post-intervention. Charts were scored using the five A's system (ask, advise, assess, assist, arrange) awarding one point for each of the A's employed during the patient visit. All charts had evidence of using the first A (ask), and all charts had a statistically significant increase pre- to post-intervention for the other four A's. No data was collected on smoking abstinence among the patients who received the intervention.

A mixed-methods evaluation of the effectiveness of tailored smoking cessation training for healthcare practitioners who have regular contact with older adults was performed by Kerr, S., Whyte, R., Watson, H., Tolson, D., and McFadyen, A. K. (2011) to assess satisfaction with the training, the participants' learning, and any resultant changes in behavior. A two-group parallel design randomized controlled trial, followed by semi-structured qualitative interviews on 56 participants of 47 nurses and nine allied health professionals was conducted using a two-factor (group and time) repeated measure analysis of variance. A 1-day brief intervention

smoking cessation training followed by validated measures of knowledge, attitudes, and practices were utilized to assess learning and behavior at baseline, one week and three months post-training. Satisfaction levels with the training were high with significant improvement in the knowledge and attitudes of the participants' post-training, with a noticeable, but non-significant improvement in practice. This study suggested the effectiveness of a 1-day training course for practitioners, but further research is recommended.

In 2014 Buchbinder, Wilbur, Zuskov, McLean, and Sleath, performed a mixed-methods study of a patient-provider communication teachable moments and missed opportunities for smoking cessation counseling in a hospital emergency department (ED). The purpose was to examine how physicians and nurse practitioners capitalize on “teachable moments” for health education to offer spontaneous smoking cessation counseling to patients presenting to the ED with a primary complaint of back pain. Audio-recorded encounters were transcribed word for word. Transcripts were reviewed to determine whether smoking was discussed. Two-thirds of the 52 patients-providers encounters were smokers. It was noted providers missed opportunities for smoking cessation education 70% of the time. There were eleven patient-provider encounters providing teachable smoking cessation counseling. Four primary strategies for creating teachable moments were identified: positive reinforcement, encouragement, assessing readiness, and offering concrete motivating reasons (Buchbinder, 2014). Most clinicians missed the opportunity for smoking cessation counseling despite ED visits being recognized as a significant opportunity for patients to receive counseling in health care behavior change including smoking cessation. More research is necessary to determine the specific mechanisms by which teachable moments can be utilized to encourage behavior change.

Smoking contributing factors

In a 2014 prospective analysis by Peian and colleagues to detect a correlation among smoking, depression, anxiety, and death in subjects with COPD, data was collected and analyzed from 7,787 subjects with COPD in fourteen rural communities. Logistic regression was utilized to evaluate the interactions and relative excess risk due to interaction. The study showed that the interaction of current smoking and depression symptoms increased the death risk with significant biological interactions. Three measures to estimate biological interactions included: relative excess risk attributed to interaction relative to the risk without exposure, the attributable proportion of disease due to interaction which is caused by interaction in subjects with both exposures, and the synergy index when there is excess risk from both exposures when there is a biological interaction relative to the risk from both exposures without interaction. The biological interactions increased with increasing years or pack per years of smoking. Similarly, the combined effect of current smoking and anxiety symptoms increased the risk of death with significant biological interactions and increasing years or pack per years of smoking. In conclusion, the longer the duration of smoking and the increase in packs per year, the higher the risk of depression and anxiety. The effect of genetic factors and lifestyle on death was not considered in this study.

Pascal, Trofor, Lotrean, Filipeanu, and Trofor (2017), observed 60 patients diagnosed with COPD to assess depression, anxiety, and panic disorders and the correlation with tobacco use, disease severity, and quality of life. In the study, nearly 40% of the sample was smokers with a median cigarettes pack per year of 34.3. The subjects were asked to complete a questionnaire to assess demographic data, medical history, smoking status, COPD staging and issues related to anxiety, depression, and panic attacks; and the impact of COPD on quality of

life. The COPD stages were assessed according to the GOLD criteria, while anxiety and depression were evaluated using the Hospital Anxiety and Depression Scale. Additionally, panic attacks were evaluated based on the International Classification of Disease Ten (ICD-10) criteria. Impact of COPD on patients' quality of life was determined using the COPD Assessment Test (CAT). Finally, dyspnea was evaluated through the Modified Medical Research Council Dyspnea Scale. Results indicated that anxiety and depression were constant findings among COPD patients; however, this was unrelated to tobacco use. Smokers and ex-smokers had similar scores concerning anxiety, depression and the presence of panic attacks. Statistical outcomes revealed a significant correlation between anxiety, depression, and panic disorders with COPD symptom intensity and with the related quality of life. These findings emphasize the need to routinely screen for anxiety, depression, and panic attacks among COPD patients.

Community-based participatory research to decrease smoking prevalence in a high-risk young adult population and the evaluation of these students against nicotine and tobacco addiction by Mendenhall, Harper, Henn, Rudser, and Schoeller in 2014 was conducted to generate knowledge in an attempt to solve community challenges. This project was designed to alleviate the stress that students attribute to smoking through the engagement of local medical and mental health providers in partnership with students, teachers, and administrators at a Minnesota-based Job Corps. Interventions utilized to help with students stress during the project included physical activities, non-physical activities, purposeful modifications to the campus' environment and rules/policies, and on-site smoking cessation education with peer support. The purpose of the study was to assess the types of stress most predictive of smoking behavior and nicotine dependence, and to which activities students participated in that were most predictive for readiness to change. Qualitative data was collected through five campus-wide surveys.

Stressors identified included struggles to find a job, financial difficulties, family conflict, lack of privacy or autonomy, missing family or home, and dealing with the Job Corps rules. Students preferred physically active activities however the nonphysical ones were most predictive of favorable change. Of the respondents, approximately one third were nicotine dependent, of those nearly a half intended to quit within one month, and 74% attempted to quit within six months. Missing data was a limitation of the study and not all perceived stressors were captured.

The search of the literature resulted in multiple facts, statistics including prevalence, morbidity and mortality databases, and several primary and secondary articles/studies. Initially, the search for articles related to smoking cessation generated a large number of results. Statistics were mostly generated through the Centers for Disease Control and Prevention (CDC), American Lung Association (ALA) and U.S. Department of Health and Human Services (HHS). After adding keywords including "COPD" or "addiction" to the search, the results became considerably smaller with only a few studies. Despite the differences in study duration, study location, and varying sample size, the importance of abstaining from tobacco use and the impact of COPD with ongoing tobacco use in the United States' healthcare system was evident in the findings among this literature review (American Lung Association [2015], CDC [2017], COPD Foundation [2017], U.S. DHHS [2014], & WHO [2018]).

Conceptual Framework

Pender's Health Promotion Model Theory (HPMT) offers a framework for determining barriers for smoking cessation and identifies strategies focusing on helping patients achieve a higher level of well-being. It offers a systematic approach to assist in identifying variables, interpreting findings, and validating nursing and medical interventions to encourage health promotion, behavior change, and successful smoking cessation. Pender's HPMT focuses on three

areas: individual characteristics and experiences, behavior-specific cognitions and effect, and behavioral outcomes. This theory states that each patient has unique personal characteristics and experiences that affect subsequent actions (Nursing Theory, n. d.).

The HPMT encourage clinicians to provide positive resources to help smokers achieve behavior change, and prevent illness. Health promotion and positive behavior change are the ultimate desired behavioral outcomes of this model. COPD patients who continue to smoke should actively modify their behavior to promote change in their environment and themselves to make healthy lifestyle choices.

As healthcare providers, nurses and nurse practitioners constitute a significant part of the interpersonal environment, directly influencing patients who smoke to promote behavioral change through their lifespan. Patients with COPD and ongoing smoking must focus on changing prior behavior and the frequency of similar behavior in the past. Clinicians can directly or indirectly influence patients to engage in health-promoting behaviors to advocate change and smoking cessation. Stopping smoking and engaging in health-promoting behavior is the endpoint directed toward attaining optimal well-being, personal fulfillment, and productive living (Nursing Theory, n.d.).

Implementation

Setting

This project was conducted in Huntsville Hospital OU, a sixteen-bed unit within an 87-bed emergency department in a level one hospital in north Alabama. The OU is a closed, discrete protocol-driven unit with an average census of 339 patients monthly and an average median length of stay of 17.4 hours (2018). Five physicians and one nurse practitioner staff the unit providing around-the-clock coverage. Patients admitted to this OU should have a straightforward

diagnosis, a clear plan of treatment, and should have a reasonable plan for discharge in 24-48 hours.

Population

A convenience sample of six physicians providing care to COPD patients with ongoing tobacco use admitted to an OU for acute COPD exacerbation was selected to participate. Participants are family practice physicians, N=4 females and N=2 males, averaging from 5-20 years of experience with ages ranging from 34 to 52 years old. Their participation was strictly voluntary, and they were asked to sign a consent form (Appendix A).

Design

The need for the project emerged because the NAQ was not being utilized in the OU to assess COPD smokers' level of nicotine addiction. This quality improvement project, using a pre-test/post-test design based on a medical chart review, assessed physicians' knowledge and education tool effectiveness after the implementation of a teaching session. Retrospective patients' chart review was utilized to gather data before and after the education intervention. Clinicians providing care for COPD patients with ongoing tobacco use admitted to the OU received a 20-minute educational orientation and training session via a PowerPoint presentation (see Appendix B) aimed at increasing their knowledge and awareness regarding the tobacco cessation NAQ. Items in the NAQ (see Appendix C) were reviewed to improve understanding and facilitate application of the NAQ. This education tool should assist in guidance for smoking cessation interventions including Nicotine Replacement Therapy (NRT), education, and available resources utilization during the OU admission and at discharge. The smoking cessation interventions entail NRT such as nicotine patches and smoking cessation resources at discharge including the free phone line 1-800-QUITNOW.

Measures

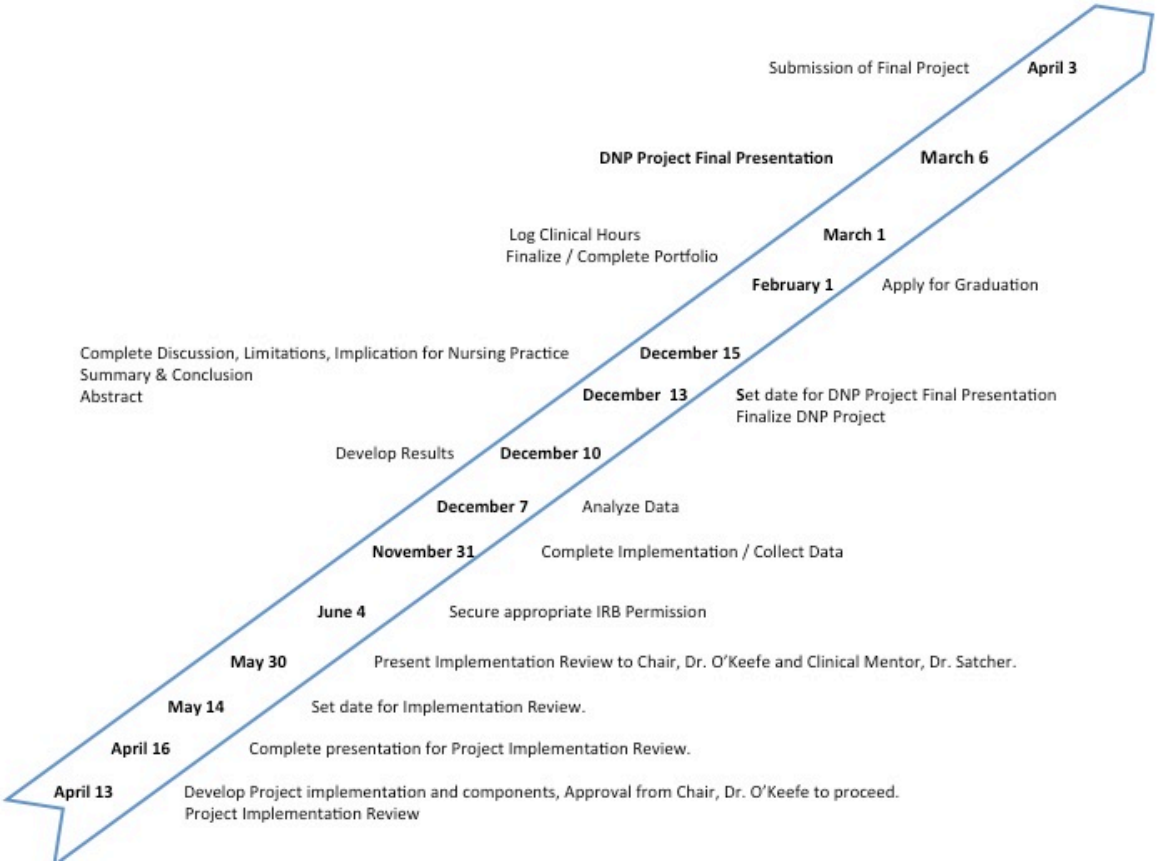
After obtaining Institutional Review Board (IRB) approval (see Appendix D), the principal investigator in this project:

1. Retrospectively captured the charts of COPD patients with ongoing smoking seen in the OU for an acute COPD exacerbation before education was provided. The health records were obtained through Wellsoft electronic medical record. This provided the pre-test data for the project with a total patient sample size of 30 charts of COPD patients seen over a three months period.
2. Retrieved data regarding the smoking cessation education physicians provided to COPD patients, the utilization of the NAQ and its application in guiding smoking cessation interventions during the OU stay and at discharge. This data was the pre-test baseline and did only include those patients whose prior to the orientation and training of the clinicians were not on nicotine replacement therapy.
3. After consent to participate was signed, physicians received the NAQ PowerPoint presentation education training (see Appendix B). Physicians were informed the project is completely voluntary and it will not affect their employment if they wish not to participate. Consent forms and all patients' information has been confidentially archived and password protected in the principal investigator laptop computer accessible only to the evaluator. Physicians were assigned a discreet number to be used during all statistical data entries to ensure anonymity.
4. After education was provided to the physicians, the principal investigator reviewed 30 charts of COPD patients with ongoing tobacco use admitted to the OU for a period of three months to retrieve data regarding the smoking cessation education clinicians

provided to COPD patients and the effectiveness in the utilization of the NAQ. In addition, data was retrieved regarding the utilization of the NAQ in guiding smoking cessation-including NRT use for prevention of nicotine withdrawals during the OU stay and at discharge. The data generated the post-test results to assess if teaching provided to physicians was effective.

5. SPSS software was utilized to obtain descriptive statistics and tTest statistical analysis to compare pre-intervention and post-intervention groups. The goal of the analysis was to demonstrate a trend in positive physicians' practice change to knowledge (i.e., smoking cessation NAQ, patient teaching, and NRT use) to serve as an indication of project intervention success.

Scholarly Project Timeline



Evaluation

The primary objective of this project was to implement quality improvement education training to clinicians with the purpose of improving knowledge and utilization of the NAQ designed to guide in decision-making on patients' smoking cessation interventions during the OU stay and after discharge to prevent nicotine withdrawals and facilitate abstinence. The long term goal is to promote smoking cessation among COPD patients admitted to the OU with acute COPD exacerbation and stop disease progression, thereby, reducing re-admission rates, and improving patients' health outcomes and quality of life.

Clinicians' knowledge was evaluated by retrospectively capturing charts of COPD patients with continued smoking seen in the OU for acute COPD exacerbation for three months

before and after physicians' education was provided. Smoking cessation education physicians provided to those patients and the utilization of the NAQ were assessed. In addition, education effectiveness was determined by evaluating physicians smoking cessation teaching to patients, the use of the NAQ, their implementation on smoking cessation interventions such as prescribing of NRT patches to alleviate nicotine withdrawal during and after discharge, and smoking cessation recommendations of available resources to sustain abstinence after discharge.

Results

Of the six physicians initially approached, five (83.3%) agreed to participate in the project. One of the providers did not have an opportunity to participate in the project because he terminated employment in the OU prior to project implementation. The final sample of the project thus included five family practice physicians (4 females and 1 male).

This project focused on patient-provider encounters during an OU stay for acute COPD exacerbation of patients with ongoing tobacco dependence. A total of 60 charts were abstracted both pre- and post-intervention. Table 1 depicts the demographic information (age, race, and gender) of the patients which chart encounters were reviewed.

Table 1 - Demographic Information (N = 60)

	Total	Pre-Intervention Group 1	Post-Intervention Group 2
Age	60	30	30
- Mean	60.30	61.77	58.83
- Median	59.50	60.50	59.00
- Standard Deviation	8.954	9.216	8.587
Gender	60	30	30
- Female	26	17	9
- Male	34	13	21
Race	60	30	30
- Caucasian	48	22	26
- African-American	11	7	4
- Other	1	1	0

Pre- and Post variables assessed included: utilization of the NAQ, smoking cessation teaching, NRT utilization during OBS stay, NRT prescribed at discharge, and smoking cessation treatment offered at discharge. All (100%) of the participating physicians demonstrated an increase in the utilization of the NAQ, smoking cessation education, and NRT orders during the OU stay (see Figures 1-3). Furthermore, there was statistically significant improvement in the utilization of the NAQ ($p = .000$) and smoking cessation education ($p = .000$). However, even when NRT use during the OU stay improved following the training (see Figures 3), it was not statistically significant ($p = .203$).

Table 2 illustrates the changes in percentage after the implementation of the Nicotine Assessment Tool to COPD Patients in the OU.

Table 2 – Percentages of changes before and after intervention

	Pre-Intervention Group 1	Post-Intervention Group 2
Was NAQ used?	0.0%	63.3%
Was smoking cessation education provided?	50.0%	93.3%
Was NRT ordered during OBS stay?	43.3%	60.0%
Was NRT prescribed at discharge?	6.7%	3.3%
Was any other smoking cessation treatment offered at discharge?	6.7%	23.3%

The NAQ was not used with the pre-intervention group (0%) but was utilized 63.3% of the time with the post-intervention group. Smoking cessation was provided 50% of the time pre-intervention and 93.3% post-intervention. Similarly, NRT was ordered 43.3% of the time for patients among group 1 (pre-intervention) versus 60.0% among group 2 (post-intervention). Adversely, there was a decrease in prescribing NRT at discharge post-intervention. Lack of medical insurance coverage or financial resources and direct follow up care after discharge potentially prevented physicians from prescribing NRT at discharge (Figure 4). However, there

was an increase in the recommendations of smoking cessation resources available to smokers during discharge of patients in the post-intervention group (see Figures 5) without statistically significant differences between groups ($p = .073$).

Discussion

This project characterizes the importance of continuing education among clinicians, particularly in regards to smoking cessation, a known detrimental public health issue in the United States. Health care providers must focus on implementing smoking cessation interventions in response to preventing and managing long-term conditions caused by smoking. The evaluation of the training provided to physicians in the OU demonstrated a significant improvement in their knowledge and interventions administered to the post-intervention group. Analysis of physicians' practice after the application of the educational tool clearly demonstrated a positive change and overall improvement in practice. Project objectives were met when participating physicians overcame the barrier of lack of time related to the rapid pace of patient care in an OU and were able to use the NAQ as a tool to guide in NRT utilization, and smoking cessation interventions.

Although many research studies about smoking cessation are focused on outpatient or inpatient settings, OU visits represent a valuable opportunity for patients to receive counseling in tobacco use abstinence and health behavior change. This is especially important in the population group often seen in an OU who are uninsured and do not have a primary care provider. This project is similar to other studies that have also demonstrated that physicians and health care providers can be trained to successfully deliver smoking cessation interventions (Caplan, 2011). Physicians' willingness to participate in this project demonstrated the need and demand for this type of training education.

Limitations

This project has several potential limitations. First, physicians' sample size was small making it difficult to obtain significant results pre- and post-training and practice change at large. Second, the length of chart review was short, and longer period pre/post-intervention would have provided a larger patient sample for chart review. Additionally, a potential source of bias was the convenience sample of providers who were familiar with the project administrator. Furthermore, the lack of medical insurance and direct follow-up of patients after discharge potentially dissuaded the physicians in prescribing NRT.

A substantial limitation of this project was that no data was collected on smoking abstinence among either one of the groups after discharge. As a result, this project does not allow for any conclusions regarding the ultimate long-term goal of smoking cessation counseling and the benefits of NRT utilization to minimize nicotine withdrawals and influence patients to stop smoking. However, there was increased physician compliance in the implementation of the nicotine assessment tool and positive practice change. Despite these limitations, this project contributes valuable information by providing evidence of the effectiveness of clinicians' education.

Application to Practice

Smoking is a modifiable risk factor that should be treated aggressively to target the delay of further advancement of COPD. Clinicians and this patient group of COPD smokers should be educated on the awareness of the warning signs and risk factors of COPD, particularly smoking which is the leading cause of COPD. Therefore, providers should focus on encouraging adherence to treatment and long-term maintenance aimed at behavior change and smoking cessation to avoid recurrent acute COPD exacerbations, further increased in healthcare

expenditure, and decreased productivity affecting patient's quality of life. Clinicians should utilize assessment tools designed to assess the intensity of physical addiction to nicotine to provide an ordinal measure of nicotine dependence and to guide NRT to promote smoking cessation and assist with the withdrawal of symptoms. Furthermore, health care providers must be involved in advocating smoking cessation interventions and providing support to hospital programs and policies already in place.

DNP prepared nurses ought to concentrate on COPD prevention strategies starting with education to clinicians and patients. Education should be directed at reducing and eliminating smoking, advocating for prompt utilization of NRT, and referral to tobacco cessation programs. Further, nurses and providers must continue research directed at developing and improving patients' education about COPD risk factors, continuity of care strategies to prevent acute COPD exacerbations, a transition of care plan of action to prevent re-admissions, and post-discharge follow up to improve compliance among patients. Consequently, health care providers must work together at advocating for patients to decrease the incidence of acute COPD exacerbations by providing smoking cessation interventions including NRT to reduce nicotine withdrawals, improve abstinence rates, and improve patient's outcomes and quality of life.

Conclusion

Tobacco use is the leading cause of preventable illness and death in the US. Therefore, smoking cessation is the single most important step smokers can take to improve their-quality of life. The primary aim of implementing evidence-based smoking cessation interventions during patient-provider encounters in a COPD population is the key to improving the health and well being of this consumer group. This project demonstrated that physicians are receptive to teaching and practice change to promote positive impact in patients. However, this project

emphasizes the need for future research to develop-tailored smoking cessation interventions to promote smoking abstinence in a chronic population whose behavior changes are essential for their welfare.

Professional Journal

The Journal of the American Association of Nurse Practitioners (JAANP)

A. Scope of Journal:

The JAANP is a monthly scholarly, peer-reviewed journal for Advanced Practice Registered Nurses (APRN's) and the official journal for all members of the American Association of Nurse Practitioners (AANP). The readers of the JAANP are mostly primary care NPs and other APRN's, who provide care in domestic and international settings where they serve clients of all ages, manage a broad spectrum of acute and chronic conditions, prescribe a variety of medications and treatments, and function to the full scope of advanced practice nursing in their respective states and countries.

The JAANP encourages submission of scholarly articles addressing a broad range of topics appropriate to advanced practice nursing in the United States and internationally. Of particular interest in the current evolving health care delivery system are quantitative, qualitative, and mixed methods research studies answering new and novel problems; outcomes research addressing in particular issues directly affected by APRNs/NPs; cost-effectiveness or economic analysis of health care interventions used by APRNs/NPs; systematic reviews and meta-analyses of scientific literature of the benefits and harms of health care interventions; education research mainly related to NPs in DNP programs; health policy analysis related to advanced practice nursing in state, national, or international environments; practice improvement or quality improvement projects; and other new and evolving advanced practice nursing issues.

International submissions that address new or novel advanced practice nursing issues throughout the world are also encouraged. Manuscripts must be original, unpublished works submitted for the exclusive use of the JAANP per the current author guidelines (See Appendix A). Several types of research manuscripts may be appropriate for JAANP; however, the focus of the research must relate to NP practice.

B. Aims of Journal:

The JAANP supports the mission of AANP to lead Nurse Practitioners (NP's) in transforming patient-centered health care with a vision of high-quality health care for all by the patient's provider of choice. The mission of the JAANP is to help serve the information needs of NPs and others with interest in advanced practice nursing and patient-centered health care. Their collective vision is high-quality health care for all by the patient's provider of choice. JAANP organizational core values promote integrity, excellence, professionalism, leadership, and service, which is reflected in the way our members have embraced advanced education, lifelong learning, and the continued evolution of advanced practice nursing.

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TABLES

Table 1 - Demographic Information (N = 60)

	Total	Pre-Intervention Group 1	Post-Intervention Group 2
Age	60	30	30
- Mean	60.30	61.77	58.83
- Median	59.50	60.50	59.00
- Standard Deviation	8.954	9.216	8.587
Gender	60	30	30
- Female	26	17	9
- Male	34	13	21
Race	60	30	30
- Caucasian	48	22	26
- African-American	11	7	4
- Other	1	1	0

Table 2 – Percentages of changes before and after intervention

	Pre-Intervention Group 1	Post-Intervention Group 2
Was NAQ used?	0.0%	63.3%
Was smoking cessation education provided?	50.0%	93.3%
Was NRT ordered during OBS stay?	43.3%	60.0%
Was NRT prescribed at discharge?	6.7%	3.3%
Was any other smoking cessation treatment offered at discharge?	6.7%	23.3%

FIGURES

t-Test results using ANOVA

Figure 1 – Was the NAQ used during OU stay?

ANOVA

Was the NAQ used?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	6.017	1	6.017	50.091	.000
Within Groups	6.967	58	.120		
Total	12.983	59			

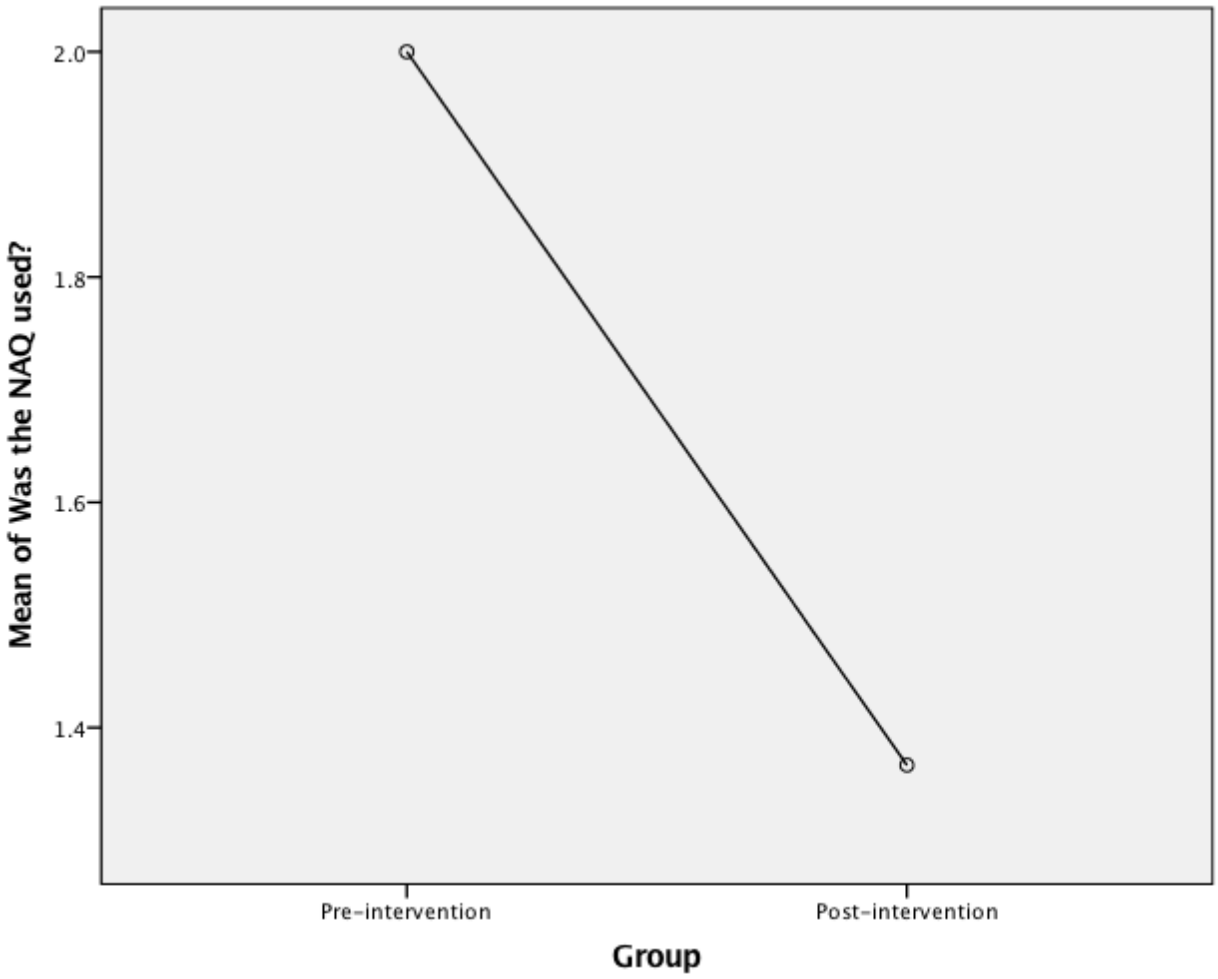


Figure 2 – Was smoking education provided during OU stay?

ANOVA

Was smoking education provided?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	2.817	1	2.817	17.441	.000
Within Groups	9.367	58	.161		
Total	12.183	59			

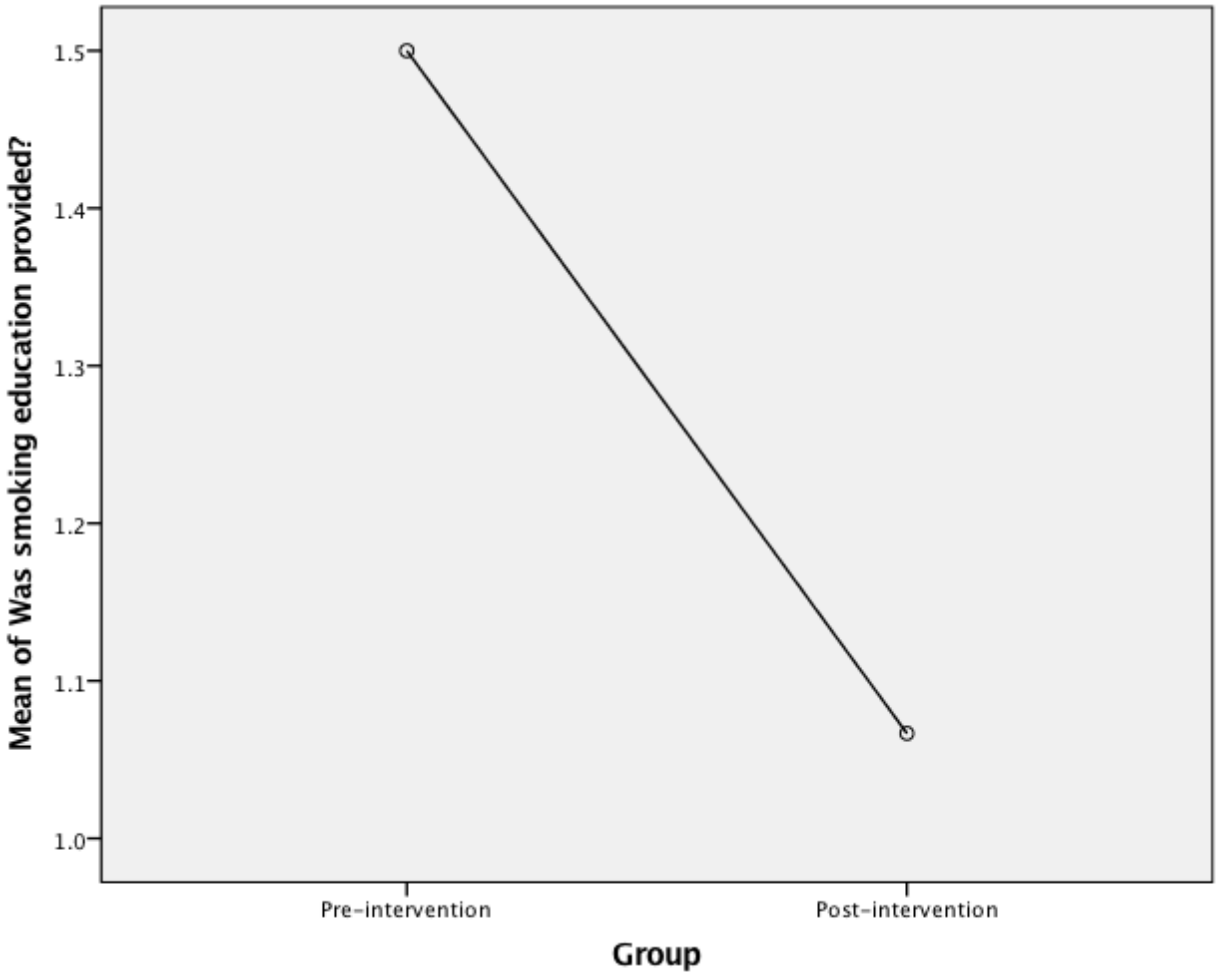


Figure 3 – Was NRT ordered during OU stay?

ANOVA

Was NRT ordered during OBS stay?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.417	1	.417	1.659	.203
Within Groups	14.567	58	.251		
Total	14.983	59			

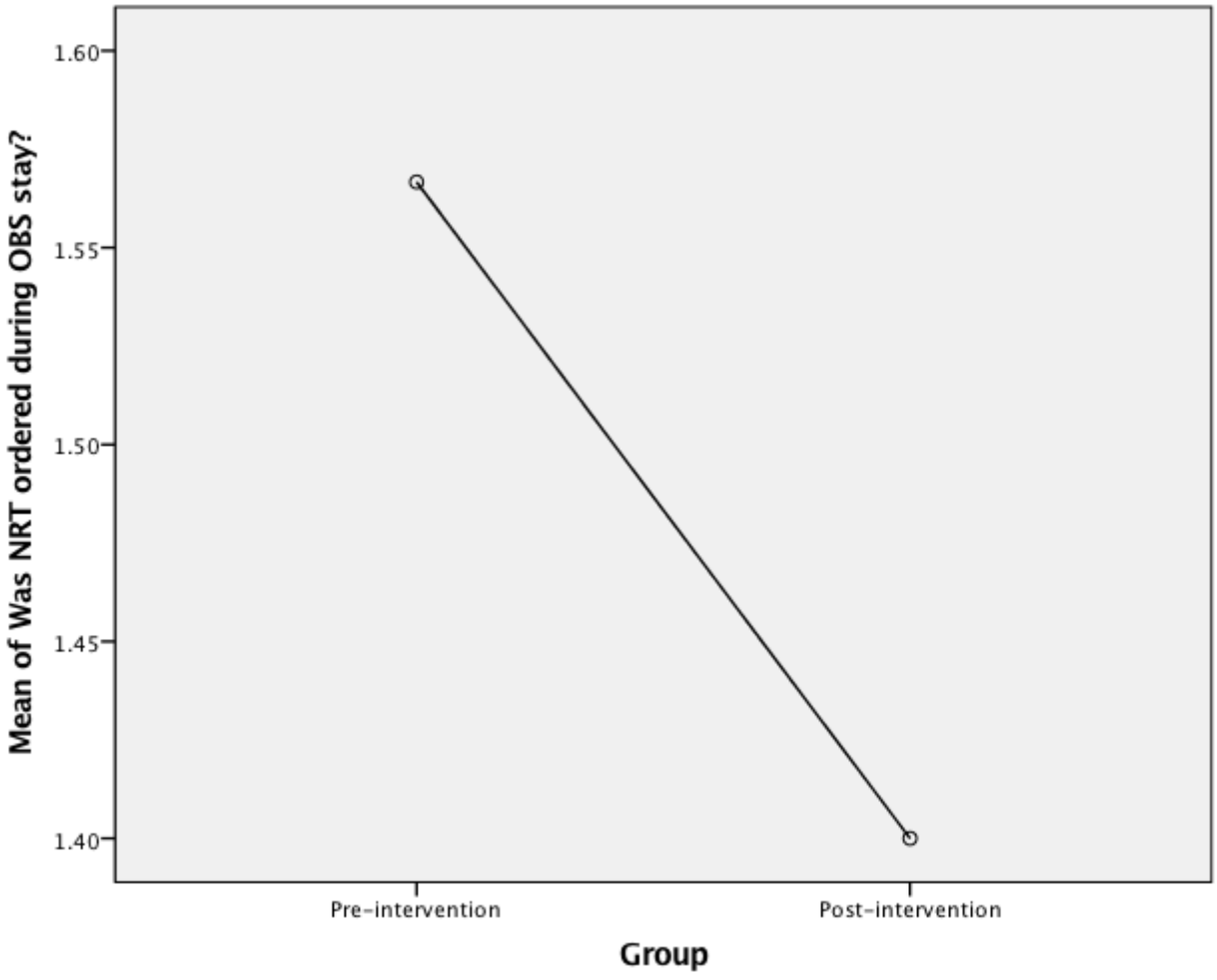


Figure 4 – Was NRT prescribed at discharge from OU?

ANOVA

Was NRT prescribed at discharge?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.017	1	.017	.341	.561
Within Groups	2.833	58	.049		
Total	2.850	59			

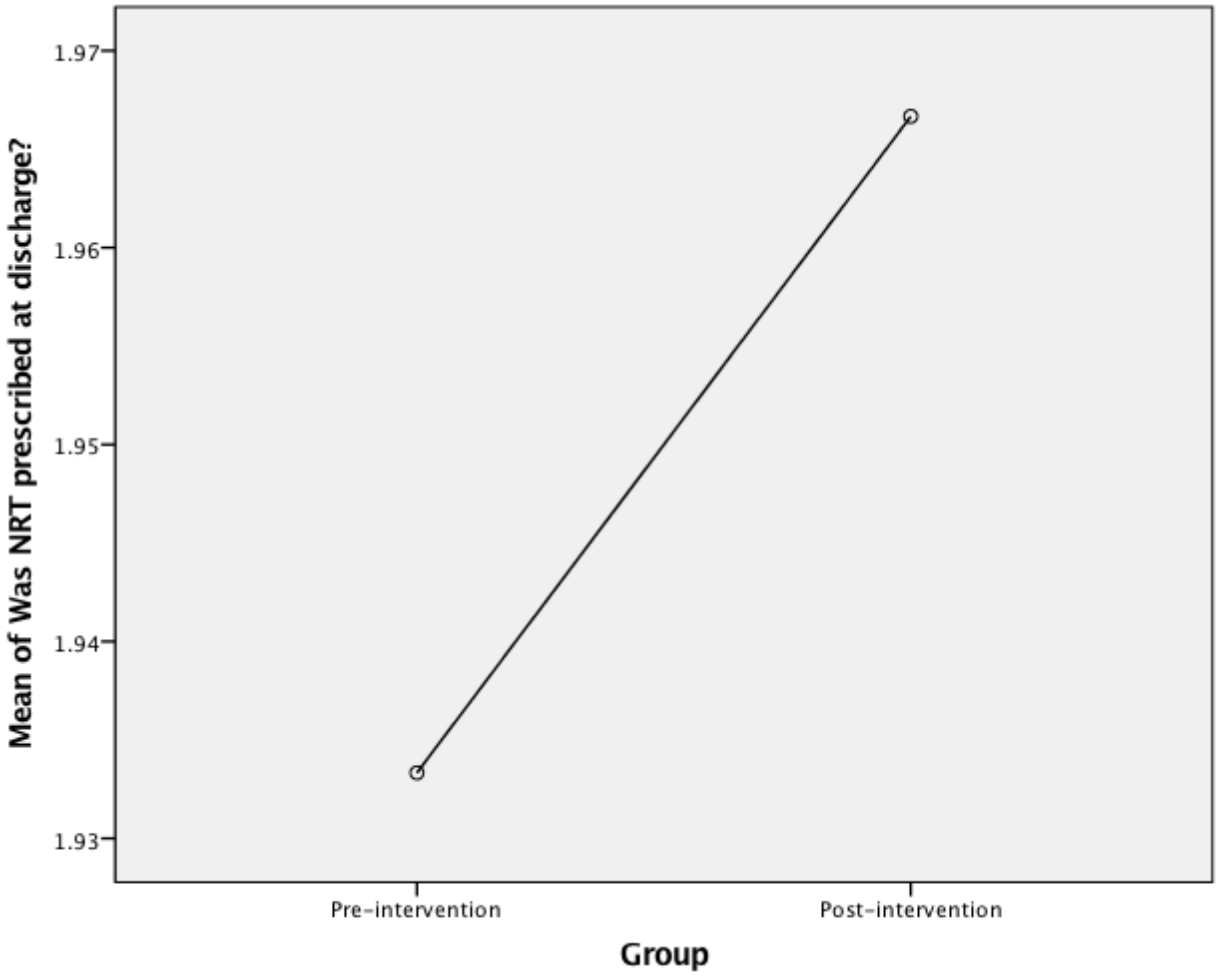
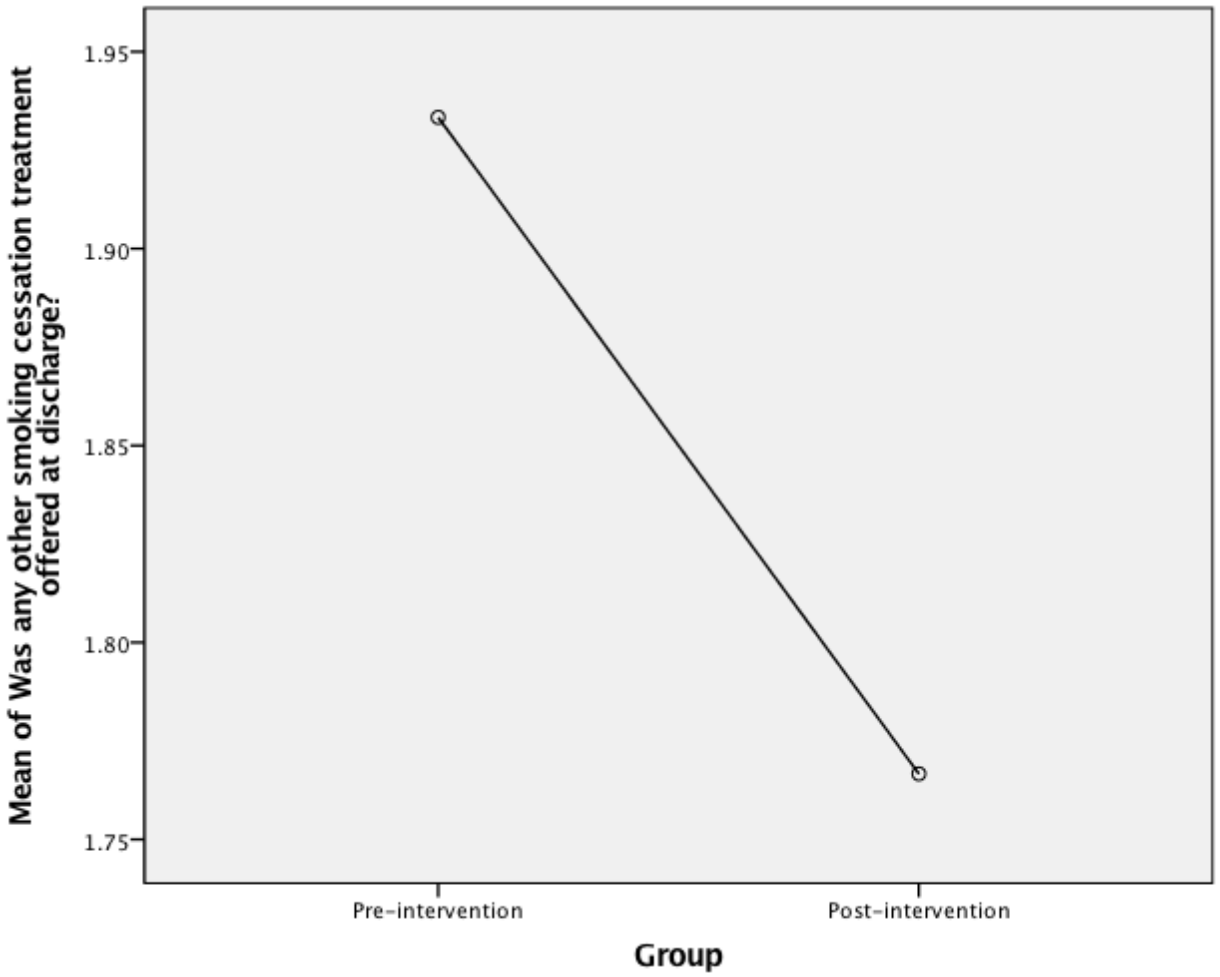


Figure 5 – Was any other cessation treatment offered at discharge from OU?

ANOVA

Was any other smoking cessation treatment offered at discharge?

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.417	1	.417	3.341	.073
Within Groups	7.233	58	.125		
Total	7.650	59			



APPENDIX A

Consent Form
Implementation of a Nicotine Assessment Tool to COPD Patients in an Observation Unit

You are invited to participate in a research study about the use of a smoking cessation questionnaire in COPD patients admitted to an observation unit. This intervention will potentially improve awareness on the use of the Nicotine Addiction Questionnaire in guiding care and instituting smoking cessation interventions during the OU stay and at discharge.

The primary investigator is Nilsa M. Black-Mead, MSN, CRNP, a doctor of nursing practice student from The University of Alabama in Huntsville, College of Nursing.

PROCEDURE TO BE FOLLOWED IN THE STUDY: Participation in this project is completely voluntary. Once written consent is given, an educational session will be provided about a Nicotine Addiction Questionnaire. This power point presentation will take approximately 20-30 minutes. Retrospective patients' chart review will be utilized to gather data before and after the educational intervention. The purpose of the chart review is to evaluate if any change in clinicians practice occurred after the education session is provided.

DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: There are no expected risks associated with your participation.

EXPECTED BENEFITS: One of the benefits expected is improved clinician awareness on the use of the NAQ to guide in the utilization of smoking cessation interventions during the Observation Unit (OU) stay and at discharge. Ideally there will be a reduction in tobacco use, a decrease in re-admission rates, and ultimately improvement in patients' health outcomes and quality of life. Results from his project can benefit society by decreasing or stopping smoking among COPD patients to improve health outcomes, quality of life and improve productivity as members of society. Please see the section below for incentives and compensation for participation in this study.

INCENTIVES AND COMPENSATION FOR PARTICIPATION: None.

CONFIDENTIALITY OF RESULTS: Participants will be assigned a discrete number to be used to record data collected through the chart review, and these numbers will be made

available only to those researchers (myself and the Chair of my Committee Dr. Louise O'Keefe) directly involved with this project, thereby ensuring strict confidentiality. The purpose of the discrete number is to assure balance statistics among providers. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number.

FREEDOM TO WITHDRAW: You are free to withdraw from the project at any time. You will not be penalized because of withdrawal from the project. Investigators reserve the right to remove any participant from the session without regard to the participant's consent.

CONTACT INFORMATION: If you have any questions, please ask them now. If you have questions later on, you may contact the Principal Investigator Nilsa M. Black-Mead, in Huntsville, AL, at 256-694-8088 or at nmb0001@uah.edu or the faculty supervisor Dr. Louise C. O'Keefe, in Huntsville, AL, at 256-824-2100 or at louise.okeefe@uah.edu. If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6101 or email the IRB chair Dr. Bruce Stallsmith at irb.@uah.edu.

If you agree to participate in our research please sign and date below.

This study was approved by the Institutional Review Board at UAH and will expire in one year from <date of IRB approval>.

_____ _____

Name (Please Print) Signature Date

APPENDIX B

DNP Project Clinicians Education Presentation.pptx

APPENDIX C

Tobacco Cessation Nicotine Addiction Questionnaire

1. How soon after you wake up do you smoke your first cigarette?
    a. 0-5 minutes = 3 points
    b. 6-30 min = 2 points
    c. 31-60 min = 1 point
    d. > 60 min = 0 points
2. Do you find difficult to refrain from smoking in places where it is forbidden (e.g., church)?
    a. Yes = 1 point
    b. No = 0 points
3. Which cigarette would you be the most unwilling to give up?
    a. First in the morning = 1 point
    b. Any of others = 0 points
4. How many cigarettes per day do you smoke?
    a. 31 or more = 3 points
    b. 21-30 = 2 points
    c. 11-20 = 1 point
    d. 10 or less = 0 points
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?
    a. Yes = 1 point
    b. No = 0 points
6. Do you smoke if you are so ill that you are in bed most of the day?

a. Yes = 1 point

b. No = 0 points

- A high level of addiction will rank between 7-10 points.
- A medium level of addiction will rank between 4-6 points.
- A low level of addiction rank between 0-3 points.)

APPENDIX D

THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

☒ Expedited (see pg 2)
☐ Exempted (see pg 3)
☐ Full Review
☐ Extension of Approval

September 19th 2018

Nilsa Black-Mead
Department of Computer Science
University of Alabama in Huntsville

Dear Mrs. Black-Mead,

The UAH Institutional Review Board of Human Subjects Committee has reviewed your proposal, *Implementation of a Nicotine Assessment Tool to COPD Patients in an Observation Unit,* and found it meets the necessary criteria for approval. Your proposal seems to be in compliance with this institutions Federal Wide Assurance (FWA) 00019998 and the DHHS Regulations for the Protection of Human Subjects (45 CFR 46).

Please note that this approval is good for one year from the date on this letter. If data collection continues past this period, you are responsible for processing a renewal application a minimum of 60 days prior to the expiration date.

No changes are to be made to the approved protocol without prior review and approval from the UAH IRB. All changes (e.g. a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc) must be prospectively reviewed and approved by the IRB before they are implemented. You should report any unanticipated problems involving risks to the participants or others to the IRB Chair.

If you have any questions regarding the IRB's decision, please contact me.

Sincerely,

Bruce Stallsmith

Bruce Stallsmith
IRB Chair
Professor, Biological Sciences

Expedited:

☐ Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

☐ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Exempt

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior [1] in which information is obtained in a manner that human subjects cannot be identified directly or through identifiers linked to the subjects and any disclosure of the human subject's responses outside the research would NOT place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior if (a) the human subjects are elected or appointed public officials

or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The research is not FDA regulated and does not involve prisoners as participants.

☐ Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs;(iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency and does not involve prisoners as participants.

☐ Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. The research does not involve prisoners as participants.

[1] Surveys, interviews, or observation of public behavior involving children cannot be exempt.

APPENDIX E

HUNTSVILLE HOSPITAL

101 Sivley Road
Huntsville, AL 35801
(256) 265-1000
huntsvillehospital.org

July 10, 2018

Nilsa M. Black-Mead, CRNP
4713 Autumn Dusk Drive
Owens Cross Roads, AL 35763

RE: Request for Exemption from Institutional Review Committee Review - "Implementation of a Nicotine Assessment Tool to COPD Patients in an Observation Unit"

Dear Ms. Black-Mead:

Thank you for forwarding the Institutional Review Committee Exemption from Review Application to me for your proposed data collection study. Dr. John Cox, Chair of IRC, and I have reviewed your information, and this study qualifies and has been approved for Exemption from IRC review.

Please note: Any proposals or anticipated changes to the project must be submitted to the IRC Coordinator and approved by the IRC Chair prior to implementation. An Exemption from Review Update Form must be submitted on an annual basis if the study remains open. When your project closes, please advise me by letter or email.

Please contact Medical Records, for medical record access and HIPAA compliancy information, if necessary. If you have any questions or I can be of further service, please feel free to call me at (256)265-6990.

Sincerely,

Allison E. Greene, Division Assistant/
Institutional Review Committee Coordinator

cc: John B. Cox, MD, Chair, IRC
Laura Satcher, MD
Louise O'Keefe, PhD

/Enclosure

APPENDIX F

Author Guidelines

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