Maintenance COPD Medication to Reduce Readmissions and Improve Quality of Life

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Abstract

Purpose: This study examines COPD patients' quality of life after using maintenance inhaler for one year and investigates the effects of maintenance COPD therapy related to exacerbation-related hospital readmissions.

Methods: This capstone project emerged from a larger COPD study. The design was a retrospective longitudinal descriptive project. This descriptive project followed individuals with COPD over time regarding their health status and attitudes towards their quality of life. Participant's quality of life was measured with the St. George's Respiratory Questionnaire for COPD (SGRQ-C). The information obtained from the SGRQ-C questionnaire was analyzed using SPSS software.

Data regarding COPD readmissions was obtained from the EMR at a hospital in the Midwest. COPD readmissions of patients discharged on fluticasone furoate/vilanterol and COPD readmissions of those not discharged on fluticasone furoate/vilanterol were monitored and documented.

Results: The total quality of life score was statistically significant (p=0.008) and clinically significant with a change of more than 4 units (205.62), concluding the impact of COPD on overall health status, lessened. Readmissions were markedly reduced when the patient was discharged on the maintenance inhaler.

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Maintenance COPD Medication to Reduce Readmissions and Improve Quality of Life

A steady rise of chronic obstructive pulmonary disease (COPD) exacerbations should be a concern for all those associated with healthcare. More than 11 million people in the United States have been diagnosed with COPD; millions more Americans may have the disease without even knowing it. In 2010, there were 1,468,000 visits to the emergency department due to COPD exacerbations (Centers for Disease Control and Prevention, 2015). One solution to addressing this health issue is utilizing daily maintenance COPD therapy in primary care. By examining past and current research, a change can be made.

The purpose of this capstone project was a two-fold: (1) to determine if the quality of life (QOL) of patients with chronic obstructive pulmonary disease COPD improves after one year of maintenance inhaler use, and (2) to determine the incidence of hospital readmissions, for patients with a primary diagnosis of COPD, within 30 days of starting daily COPD maintenance therapy.

The overarching goal of the capstone project findings was to demonstrate the importance of maintenance therapy in adults with COPD to primary care providers. To accomplish this goal, the following two clinical questions were answered: (1) does the QOL improve in patients with COPD after using once-daily fluticasone furoate/vilanterol inhalation over the course of one year, and (2) does maintenance COPD therapy of once-daily fluticasone furoate/vilanterol inhalation affect the number of COPD exacerbation-related hospital readmissions within 30 days after starting therapy? Collaboration with experts at a pulmonary clinic, designated time for researcher, adequate resources, and ensuring sufficient follow-up for participants supported the success of carrying out this project. Implementation of this capstone project provided an analysis of aggregate data and evidence to improve patient outcomes, improve patients' quality of life, and produce best practice change.

Outcomes

This capstone project had the following two expected outcomes: (1) illustrate that adult COPD patients' quality of life has improved after one year of using maintenance inhaler, and (2) demonstrate that daily maintenance therapy affects COPD exacerbation-related hospital readmissions. The patient's quality of life while using daily fluticasone furoate/vilanterol inhalation was measured by using the St. George's Respiratory Questionnaire for COPD patients (SGRQ-C) (see Appendix A). The rate of COPD exacerbation-related readmissions was determined by any person admitted to the hospital after starting fluticasone furoate/vilanterol inhalation therapy. While implementing the outcomes, it was the author's hope to increase primary care providers' (PCP) knowledge and commitment in prescribing maintenance COPD therapy.

Assessment of the Organization

To gain a comprehensive understanding of COPD, PCPs need to understand the importance of maintenance COPD medication. To genuinely pass this message along, the acceptance and support of the organization is required. The development of daily COPD therapy being the mainstay in COPD management was the goal of a Midwest pulmonary clinic. This standard is evidence-based and needs to be promoted in primary care. The drive of this capstone project and the associated organization was completed to increase awareness of using a daily inhaler to control COPD and improve patients' quality of life.

Review of the Literature

COPD is a well-known disorder; the exacerbation symptoms which accompany the disease, unfortunately, are very burdensome for the patient, provider, state, and nation. COPD diagnosis, management, doctor visits, hospitalization, and quality of life is included in the

Centers for Disease Control and Prevention (Centers for Disease Control and Prevention) national surveillance system. This system also incorporates up-to-date summary charts, diagrams, graphs, and figures representing respiratory disease correlated with profession (Centers for Disease Control and Prevention, 2011). The National Center for Chronic Disease Prevention and Health Promotion covers many attributes of COPD. Several individuals in the country are unaware that they have COPD, resulting in millions not accounted for (Centers for Disease Control and Prevention, 2011). COPD has major risk factors and epidemiological links.

Compared to adults without COPD, adults with COPD were more likely to report: cost was an obstacle to health care, poor/fair health status, limited activity due to health condition, fourteen or more poor mental health days in the past 30 days, and no exercise in the past month (Centers for Disease Control and Prevention, 2011). To explore further into COPD costs, recent estimates suggest that the collective costs connected to treatment of acute exacerbations are between $3.2 billion and $3.8 billion. The annual healthcare costs are ten-fold greater for patients with COPD associated with acute exacerbations than for patients with COPD but without exacerbations (Blanchette, Gross, & Altman, 2014). Of those patients hospitalized for COPD exacerbation, one in five will be readmitted within 30 days (Shah, Press, Huissingh-Scheetz, & White, 2016). Per Shah et al. (2016), 10% to 55% of readmissions related to COPD exacerbations may be preventable.

There is a robust amount of evidence supporting maintenance treatment to decrease exacerbations in COPD patients. Several studies show the positive nature of daily COPD medication (Blanchette et al., 2014; Dransfield et al., 2013; Ferguson & Make, 2016; Martinez et al., 2013; and McKeage, 2014). The mainstay of pharmaceutical therapy includes inhaled bronchodilators given by themselves or in addition to inhaled glucocorticoids (Ferguson &

Make, 2016). Maintenance medication is not utilized nearly enough with only about 30% of COPD patients receive prescriptions for maintenance therapy (Blanchette et al., 2014). This project focused on the evidence found in the analysis of aggregate data derived from a study completed by Pulmonary Infectious Disease Associates (2015). In their randomized, double-blind study, the efficacy, safety, and tolerability of the fixed combination fluticasone furoate/vilanterol inhalation is examined. In a detailed medical literature review completed by Blanchette, Gross, and Altman (2014), combined results showed that maintenance therapy—including a long-acting cholinergic antagonist or a long-acting beta-2 adrenergic agonist—reduced the incidence of exacerbations by 17%.

Maintenance therapy for moderate-to-severe COPD patients was analyzed in a randomized, 24-week, parallel-group, double-blind and placebo-controlled study (Martinez et al., 2013). A placebo was compared with two different strengths of fluticasone furoate/vilanterol (FF/VI), along with equal dose strengths of the individual medications. The study—a level II evidence rating—concluded that FF/VI delivers quick and substantial continuous improvement in the forced expiratory volume over 1 second (FEV1). Improvement in FEV1 was not found to be true when testing fluticasone furoate alone (Martinez et al., 2013). Dransfield et al. (2013) completed a similar study that followed patients over a year. The trial included two replicate double-blind parallel-groups. Pooled analysis of the two groups included 3255 participants with COPD and compared fluticasone-vilanterol (200/25mcg) results with vilanterol (25mcg) alone. A similar outcome to Martinez et al. (2013) was discovered. Both doses of fluticasone-vilanterol (200/25mcg and 100/25 mcg) were shown to make moderate improvements in symptoms and improve health related quality of life. It should be mentioned that while only a small number of patients were affected, the rate of pneumonia was increased in the fluticasone-vilanterol

combination groups (Dransfield et al., 2013). According to McKeage (2014), fluticasone furoate/vilanterol has improved adherence—taken only once a day—when weighed against inhaled corticosteroids. Furthermore, increased pulmonary function was demonstrated. Rapid and persistent improvements of FEV1 were established as early as day one compared to the placebo. Once-daily fluticasone furoate/vilanterol was tolerated at a satisfactory level in the all the trials (12 week, 24-week, and 12-month). With the treatment, headache and nasopharyngitis were the most common adverse events. The study was noted to be a randomized, double-blind, and multicentre analysis. The key terms used in the literature search are provided in Appendix B.

Conceptual and Theoretical Framework

Advanced nurse practitioners can use the health promotion model to promote the practice of daily maintenance COPD medication. Nola Pender first published the health promotion model; this model is a descriptive model regarding health behavior (Butts & Rich, 2015). Included within the model are three categories: (1) personal experiences and traits, (2) behavior-specific reasoning and influences, and (3) behavior results (Butts & Rich, 2015). In the health promotion model, it is stressed that self-expectations are a significant part in shaping behavior. The concept of readiness for health change relates very closely to the health promotion model.

Timing was critical with this project. Patients had to be willing to take part in their own health; if they were not, it created a barrier when implementing the COPD control intervention. Being ready for change is required by all patients. One antecedent in readiness for change is when the individual is faced with a health concern. COPD creates a problem when it starts to restrict the person’s ability to complete tasks or roles. When daily function is compromised, readiness for change is triggered. An individual is more likely to carry out a behavior and be

devoted to change if their self-efficacy and their perceived ability to do a behavior is high (Yin Kwan Ho, Berggren, & Dahlborg-Lyckhage, 2011). Initiating a patient on daily COPD medication and convincing the need for continuation of therapy before the patient is hindered physically can also be an obstacle. Understanding the patient's readiness for change can help overcome the previously mentioned hurdles.

The analysis of the concept, readiness for change, is a necessary part of the process of developing a reflective practice. Nursing has a critical position in assessing a patient's readiness to control COPD. By breaking down the concept and recognizing the attributes, antecedents, and consequences, one can collaborate with the patient when developing goals and while planning change. Advance practice nurses and PCPs can provide a vital link amongst changes in practice. Revealing the impact that COPD maintenance medication has on quality of life and exacerbations was the vital link. Clinicians can create the perfect condition to support change for the patient. Family nurse practitioners' skills and understanding will aid in evaluating the patient's readiness for change status and determining interventions necessary to facilitate daily medication adherence. The hope of this author is that daily COPD medication is not prescribed only when the provider wishes, but it is prescribed because a clinical practice guideline is set in place to ensure the patient has pertinent maintenance therapy.

Methodology

Population Inclusion Criteria

This capstone project emerged from a larger COPD study. The following inclusion and exclusion criteria was developed from the original study. Informed consent was obtained from the original study and can be found in Appendix C.

The study population was composed of participants who had established a clinical history

of COPD in accordance with the definition by the American Thoracic Society/European Respiratory Society (2016). Participants were eligible for enrollment in the study if they met all the following inclusion criteria. The participant must have signed and dated a written informed consent prior to the study. The participant was monitored in the outpatient setting. The age of the participants was 40 years or older at visit one. The participants were either male or female. Female participants were eligible if they had non-child bearing potential, or had child bearing potential but had a negative pregnancy test and agreed to acceptable contraceptive methods used consistently and correctly (abstinence, oral contraceptive—either combined or progestogen alone, injectable progestogen, implants of levonorgestrel, estrogenic vaginal ring, percutaneous contraceptive patches, IUD, male partner sterilization, and/or the double barrier method: condom and an occlusive cap).

The participants had to be a current or former cigarette smoker with a history of cigarette smoking of ≥ 10 pack-years at screening (visit one) [number of pack years = (number of cigarettes per day/20) x number of years smoked]. Participants had to score ≥10 on the COPD assessment test (CAT) at screening and had a post-albuterol/salbutamol FEV1/FVC (forced vital capacity) ratio of <0.70 at initial visit. Furthermore, it was required that participants received daily maintenance treatment for their COPD for at least three months prior to screening. Participants were required to demonstrate one of two criteria: a post-bronchodilator FEV1 <50% predicted normal and a documented history of ≥ 1 moderate or severe COPD exacerbation in the previous 12 months; OR a post-bronchodilator 50% ≤ FEV1 <80% predicted normal and a documented history of ≥ 2 moderate exacerbations or a documented history of ≥ 1 severe COPD exacerbation (hospitalization) in the previous 12 months. Finally, liver function tests on the participants had to be as the following: alanine aminotransferase (ALT) 2x upper limit of normal,

alkaline phosphatase ≤ 1.5x upper limit of normal, and bilirubin ≤ 1.5x upper limit of normal.

Inclusion criteria for readmissions was tracked with the Electronic Medical Record (EMR) at a Midwest, non-profit, hospital and included all participants who were previously admitted and discharged on maintenance medication and subsequently, were readmitted with a primary diagnosis of COPD.

Population Exclusion Criteria

Criteria adherence is essential and participants were not allowed to deviate from the specified requirements. The exclusion criteria had a specific set of guidelines and they are summarized in the following statements. Participants who were pregnant or planned on becoming pregnant could not enroll in the study. Those with an asthma diagnosis were excluded, however, participants with a prior history of asthma were eligible if they had a current diagnosis of COPD. Participants were dismissed if they have COPD with the underlying cause being α1-antitrypsin deficiency.

Participants were omitted if they had any other respiratory disorder including active tuberculosis, lung cancer, significant bronchiectasis, sarcoidosis, lung fibrosis, pulmonary hypertension, or interstitial lung disease. Participants with lung volume reduction surgery within 12 months prior to screening were unable to participate. Furthermore, participants who had risk factors for pneumonia such as HIV, Lupus, Parkinson’s Disease, or Myasthenia Gravis could not enter the study. Participates could not start the clinical trial if they had pneumonia or severe COPD exacerbation that had not resolved at least 14 days prior to visit one; other respiratory tract infections must have been resolved at least seven days prior to screening.

A participant was prohibited to start the study if they had an abnormal chest x-ray that revealed evidence of significant abnormality not believed to be due to the presence of COPD.

Participants were excluded if they had historical or current evidence of clinically significant cardiovascular, neurological, psychiatric, renal, hepatic, immunological, gastrointestinal, urogenital, nervous system, musculoskeletal, skin, sensory, endocrine or hematological abnormalities that were uncontrolled. Significant was defined by the investigator if he/she believed the disease would put the safety of the participant at risk. With the exception of Gilbert's syndrome or asymptomatic gallstones, unstable liver disease excluded the participant.

Participants with any of the following at visit one were excluded: myocardial infarction or unstable angina in the last six months, unstable or life threatening cardiac arrhythmia requiring intervention in the last three months, and/or New York Heart Association (NYHA) class IV heart failure. Additionally, an abnormal and clinically significant 12-lead electrocardiogram (ECG) finding would exclude a participant. An abnormal finding that excluded a participant from entering the trial was defined as a 12-lead tracing that was interpreted as, but not limited to, any of the following: atrial fibrillation with rapid ventricular rate > 120 beats per minute, sustained or nonsustained ventricular tachycardia, second degree heart block Mobitz type II and third degree heart block (unless pacemaker or defibrillator had been inserted), or QTcF ≥500 msec in participants with QRS<120 msec and QTcF ≥530 msec in participants with QRS ≥ 120msec.

Further exclusions included a history of allergy or hypersensitivity to any corticosteroid, anticholinergic/muscarinic receptor antagonist, beta2-agonist, lactose/milk protein or magnesium stearate or a medical condition such as narrow-angle glaucoma, prostatic hypertrophy or bladder neck obstruction that, in the opinion of the Investigator contraindicated study participation. Participants with carcinoma that had not been in complete remission for at least five years were excluded; however, those who had carcinoma in situ of the cervix, squamous cell carcinoma and

basil cell carcinoma of the skin were not excluded based on the five-year waiting period if the participant had been considered cured by treatment. A participant was eliminated from the study if they required ≥ 3L/min of long-term resting oxygen therapy. Participants who were medically unable to withhold their albuterol/salbutamol for the four-hour period required prior to spirometry testing at each study visit were exempt. Any participant who had participated in the acute phase of a Pulmonary Rehabilitation Program within four weeks prior to initial visit or those who planned to enter the acute phase of a Pulmonary Rehabilitation Program during the study were eliminated. Finally, any participant with a known or suspected history of alcohol or drug abuse within the last two years, those at risk of non-compliance, those with the inability to read, and/or those who have questionable validity of consent were also omitted.

For the readmission data collection from a Midwest non-profit hospital, participants were excluded if they were readmitted with a diagnosis other than COPD.

Setting

This capstone project stemmed from another already-in-progress research study. Therefore, the project took place at the site consistent with the original research, plus an additional site. First, the quality of life questionnaire was administered to qualifying participants in a Midwest pulmonary clinic. The second site for readmission data was located at a Midwest, non-profit, hospital. This hospital uses an EMR system to document their patients' diagnoses. Any COPD-related admission or readmission was recorded. With the hospital's permission, the investigator gained access to all documented COPD readmissions. Written support was acquired from both sites for this project.

Ethical Considerations

Participant information was kept confidential throughout the data collection and analysis on a password protected computer. Data will be destroyed by this author after two years by shredding documents and deleting files stored on the password protected computer. Answers from the SGRQ-C was extracted from a larger study's database. No participant names were released. The investigator was not aware of the identity of any participants involved in the study. All participants provided written consent. Written consent was obtained in the clinic prior to the start of the study. Participants were identified with a specific case number only. Hospital readmission data were also anonymously extracted. An Excel spreadsheet of the desirable categories was produced by the hospital EMR. The case manager who had access to the database computed and provided the spreadsheet to this author.

Design

Original Study

The purpose of the original study was to evaluate the efficacy and safety of Fluticasone furoate (FF)/ Vilanterol (VI). The study was completed to determine if the drug was safe and effective at preventing COPD exacerbations. Information regarding how the drug affects the body and the health of the participant was collected through several tests, procedures, and questions. The effects of the drug was compared after the completion of the study. Patients participated in the study for a little over a year—which included seven clinic visits. At each visit, the participant had the following procedures performed: a physical exam, breathing tests, vital signs, ECG, mouth and throat exam, blood draw, and pulse oximetry. Furthermore, the participants were asked to answer COPD questionnaires, discuss cigarette use, respond to activity questions, and complete the participants' eDiary—which was used to record the

participants' symptoms, daily.

Capstone Project

The design of this capstone was a retrospective longitudinal descriptive project. This descriptive project followed individuals with COPD over time regarding their health status and attitudes towards their quality of life. This project involved participants within the original study who answered a questionnaire to determine the effects of maintenance medication on quality of life. Furthermore, the data collected regarding readmissions related to COPD exacerbations from the hospital involved extracting data using existing records on the EMR at a Midwest non-profit hospital.

The final portion of this capstone involved the investigator compiling data found in the project analysis. The results were presented to primary care providers to facilitate discussion regarding practice change in the clinical setting. Based on the investigator's findings, policy change on COPD management with daily maintenance medication fostered a foundation for the future development of a microsystem change at the institutional level.

Potential challenges in descriptive studies include small sample size and potential participant dropouts. Furthermore, the data collected from the hospital was obtained via the EMR. The EMR allowed for quick access to COPD readmission records, however, the investigator had no control over the data that were collected. For instance, there may have been inconsistencies in charting or misdiagnoses, but one was not able to explore or ask questions about possible inaccurate data.

Data Collection

In the original study, the St. George's Respiratory Questionnaire for COPD patients (SGRQ-C) was administered to qualifying participants—those started on daily fluticasone

furoate/vilanterol inhalation—at the beginning of therapy and at every follow-up appointment. The SGRQ-C contains 40 segments developed to measure the health status and quality of life in patients with airway obstruction diseases (St. George's University of London, 2000-2016). In the SGRQ-C, the scores were calculated in three categories: symptoms, activity, and impacts (psycho-social), as well as a total score. The scores were collected at each appointment; a measurement score that changed a minimum of four units was considered clinically relevant. Sensitivity to this tool has been demonstrated in clinical trials. Furthermore, the psychometric testing of this questionnaire has demonstrated its repeatability, reliability, and validity (St. George's University of London, 2000-2016).

The English version of the SGRQ showed >0.70 reliability, using Cronbach's alpha, for all components except the one-year symptom-reporting component (Barr et al., 2000). Construct validity was strengthened when all SGRQ components (except one-year symptoms) correlated ($p \leq 0.01$) with the Medical Research Council (MRC) Dyspnea scale, a six-minute walk (6MW), all Short-Form (SF)-36 health survey concept scores, and 80% of the Chronic Respiratory Questionnaire (CRQ) domains (r=0.30-0.72). Discriminate validity was shown to discriminate better between disease-severity groups—based on patient self-reports of disease severity—than did pulmonary function tests and the 6MW (Barr et al., 2000).

COPD-only version of the SGRQ, the SGRQ-C, is shorter, includes the best of the original items, no longer requires a recall period, and produces scores equivalent to the existing instrument (Meguro, Barley, Spencer, & Jones, 2007). Items were removed from the SGRQ due to lack of response (n=1), misfit to the Rasch Model (n=8), and disordered responses (n=1). The two versions' scores were slightly different. Therefore, the scoring algorithm was revised to produce scores equivalent to the original (Meguro et al., 2007).

Participants who were discharged through the Emergency Department (ED) or discharged after being hospitalized with the primary diagnosis of COPD were placed in a distinct database. Patients prescribed once daily fluticasone furoate/vilanterol at discharge were identified and acknowledged within the database. Any ED visits or hospital readmissions within 30 days of initiating the inhaler were recorded by the case manager, who had access to the database. Subsequently, this database was located and accessed from hospital's EMR; this author received the statistics regarding the number of readmissions from the medical records' department. No patient identifiers were released to this author. In this project, the demographics of the participants were not be available for access through the EMR.

Data Analysis

The QOL data that was analyzed for this capstone project were extracted from a larger clinical trial taking place at a Midwest Pulmonary clinic. The extensive trial involved mechanism of the drug and genetics of the participant. Nineteen participants answered the St. George's Respiratory Questionnaire for COPD patients (SGRQ-C) at their first visit and at their one year follow-up appointment. The answers to the SGRQ-C were collected for both time frames and the scoring was completed using the SGRQ-C manual for guidance.

The participants' answers to the three components in the SGRQ-C were analyzed and scored. Each response in the questionnaire had a unique empirically derived 'weight'. The lowest possible weight was zero and 100 was the highest. The total score was calculated by summing the weights to all the positive responses in each component. The results were calculated and then analyzed for statistical significant by utilizing a 95% confidence interval and setting the alpha level at 0.05. The threshold for a clinically significant difference between a patient's initial response and for changes within the participants' subsequent responses was four

units. The mean scores for the total score and each component of the SGRQ-C was reported. The following calculation was used to compute the total score:

$$\text{Score} = \frac{100 \times \text{Summed weights from all positive items in the questionnaire}}{\text{Sum of weights for all items in the questionnaire}}$$

The information obtained from the SGRQ-C questionnaire was analyzed using SPSS software. The intent was to compare QOL ratings between patients' initial SGRQ-C score—completed prior to therapy—and their last SGRQ-C score—completed one year after starting maintenance inhaler. Quantitative data analysis was illustrated by utilizing a two-tailed t-test to compare the two groups' mean scores.

Data regarding COPD readmissions was obtained from the EMR at a hospital in the Midwest from April 2015 through December of 2015. In the collection of the pertinent information, the focus was on the following two categories: COPD readmissions of patients discharged on fluticasone furoate/vilanterol and COPD readmissions of those not discharged on fluticasone furoate/vilanterol.

Results

A total of 19 participants successfully completed the SGRQ over a one year period. The participants' pre-test scores were compared to their post-test scores. All participants completed their pre-test questionnaire prior to therapy and completed their post-test questionnaire after one year of once-daily fluticasone furoate/vilanterol inhalation therapy. A two-tailed t-test was computed using the SPSS software. The results of each category from the SGRQ-C can be found in *Table 1*.

	PRE-Test	POST-Test

	Mean (SD)	Mean (SD)	*p*-value
TOTAL	1833.64 (342.28)	1628.02 (309.75)	0.008*
SYMPTOMS	404.92 (95.3)	348.75 (107.31)	0.002*
IMPACTS	712.08 (224.33)	581.75 (168.17)	0.006*
ACTIVITY	716.64 (184.5)	697.52 (191.82)	0.647

Table 1: SGRQ-C Results (*$p = < 0.05$)

Scores in the SGRQ-C are expressed as overall impairment, where 100 represents worst possible health status and 0 indicated best possible health status. The pre-test and post-test total mean scores were 1833.64 (342.28) and 1628.02 (309.75), respectively. The total score was statistically significant (p=0.008) and clinically significant with a change of more than 4 units (205.62). When looking at the three categories within the SGRQ-C separately, the symptom and impact categories were found to be clinically significant (348.75, 107.31, p=0.002; 581.75, 168.17, p=0.006 respectively); whereas the activity category was found not clinically significant (697.52, 191.82, p=0.647).

The results of the total score within the SGRQ-C questionnaire shows a decrease impact of the disease on overall health. With the *symptoms* category improving after a year of therapy, one can conclude the frequency and severity of respiratory symptoms in participants were diminished. The *impact* category covers a range of aspects concerned with social functioning and psychological disturbances resulting from airways disease (St. George's University of London, 2000-2016). The *impact* category looked at the patient's perception of how big of problem their COPD is and how their chest troubles has affected their life. The participants improved in the

impact category after one year of maintenance therapy, which enabled them to enjoy more activities outside the house.

It must be noted that the sub-category *activity* was not found to be statistically significant (697.52, 191.82, p=0.647). The activity component looks at activities that are limited by breathlessness. Many of the activity questions discussed activities of daily living (e.g. bathing, getting dressed). The results suggest patient's activities of daily living (ADLs) were not affected by the maintenance inhaler. Participants with mild to moderate COPD would be able to complete ADLs prior to therapy. Perhaps, much of the sample did not have severe COPD prior to therapy initiation. Although there were no changes in activity category, the benefits of maintenance therapy on overall health and disease impact outweigh this.

By comparing readmissions of those on the inhaler to all COPD readmissions, the results effectively demonstrated how daily fluticasone furoate/vilanterol is beneficial in the hospital setting. Readmissions were markedly reduced when the patient was discharged on the maintenance inhaler. The line graph in *Figure 1* shows the breakdown of the two categories previously mentioned. *Figure* 1 shows COPD readmissions rates were reduced in participants who were started on fluticasone furoate/vilanterol (Breo) inhaler upon discharge.

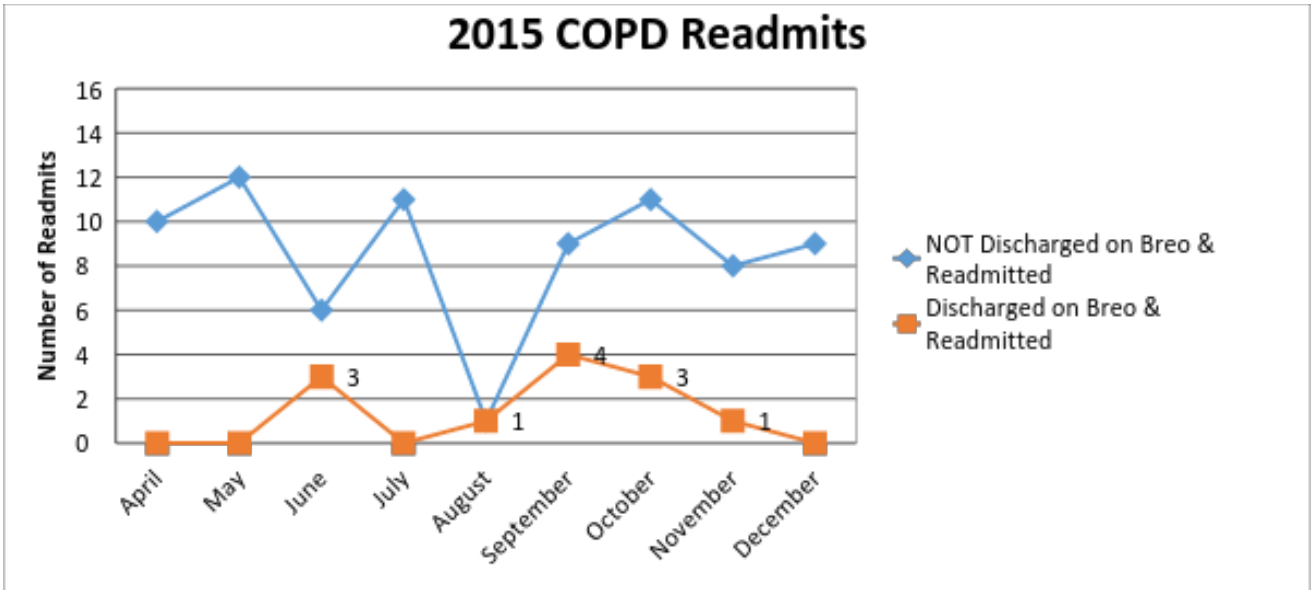

Figure 1: Hospital readmissions of patients with COPD.

Significance/Implications

A reduction of COPD readmissions is one way to improve care and reduce hospital costs. The Hospital Readmission Reduction Program (HRRP) currently penalizes hospitals if COPD exacerbation admissions exceed a higher than expected 30-day rehospilization rate (Joynt & Jha, 2013). Thus, penalizations due to COPD readmissions could be eliminated by ensuring the patient is on maintenance therapy, has access to refills, and are educated on proper use of inhaler when they are discharge. Maintenance COPD therapy will improve the health of patients with COPD and cut down on COPD- related healthcare costs.

These results will expectantly open the door to policy and practice change in COPD management. There is a significant issue in this nation with an increase of COPD exacerbations. From the information this project displayed, it is clear to see maintenance COPD therapy should be the mainstay of practice guidelines regarding the disorder. Advanced practice nurses and medical providers must be encouraged to start maintenance therapy as soon as COPD is

diagnosed. Clinicians should use the information presented to them to shape policy and practice change in the COPD population.

An acute COPD exacerbation can cause a patient to miss several days of work (Blanchette, et al., 2014). Another significant perspective that stems from this capstone project focuses on employers of any business. A potential implementation could incorporate employer-sponsored plans. For example, employer-supported policies would focus on reimbursement designs that correlate with their business goals of productivity and lessened absenteeism, while providing benefit plans that promote maintenance therapies for clients with chronic health conditions, such as COPD (Blanchette et al., 2014).

Limitations/ Future Research

Limitations of this project included a small sample size. Therefore, one may consider the statistical power of the research weakened. To improve this study, the sample size must increase to ensure it is representing the whole COPD population accurately. Furthermore, patients in this capstone were observed in only one hospital and one clinic. It would be worth repeating this study in more hospitals/clinics—perhaps, in a larger hospital to ensure the population is not specific to one regional area. Future research related to this topic could compare types of maintenance inhalers. Additionally, research completed to determine at what point for patient's diagnosed with COPD is the best time to start maintenance therapy would be beneficial.

Conclusion

This capstone project confirmed the following two outcomes: (1) adult COPD patients' quality of life improves after one year of using maintenance inhaler, and (2) that daily maintenance therapy affects COPD exacerbation-related hospital readmissions. Previously collected data shows 10% to 55% of readmissions related to COPD exacerbations may be

preventable by utilizing daily maintenance therapy (Per Shah et al., 2016). Maintenance COPD medication is a key solution to the steady rise of COPD exacerbations. The findings of this project showed that readmission rates were decreased when patients were prescribed a daily maintenance inhaler upon discharge. Reduced readmission rates leads to health care savings and minimizes hospital penalties. Reduced admissions for the patient means less stress and disruption of daily living. Furthermore, the total score in the quality of life portion of this capstone was statistically significant (1628.02, 309.75, p=0.008). This means the patient's ability to function at a usual level of activity improved. One could conclude that the impact of COPD on enjoyment of life, general well-being, and mental status was lessened. For patients, this leads to a more active life with decreased healthcare costs.

References

American Thoracic/European Respiratory Society. (2016). *ATS official documents*. Retrieved from American Thoracic Society: https://www.thoracic.org/statements/.

Barr, Judith T., Schumacher, G.E., Freeman, S., LeMoine, M., Bakst, A., Jones, P.W. (2000). American translation, modification, and validation of the St. George's Respiratory Questionnaire. *Clinical Therapeutics,* 22(9), 1121-1145. doi:10.1016/S0149-2918(00)80089-2.

Blanchette, C. M., Gross, N. J., & Altman, P. (2014). Rising costs of COPD and the potential for maintenance therapy to slow the trend. *American Health & Drug Benefits, 7*(2), 98-106. Retrieved from www.AHDBonline.com.

Butts, J. B., & Rich, K. L. (2015). *Philosophies and Theories for Advanced Nursing Practice* (2nd ed.). Burlington, MA: Jones & Bartlett Learning.

Centers for Disease Control and Prevention (CDC) (2011). *COPD among adults in Iowa*. Retrieved from www.cdc.gov/copd/maps/docs/pdf/IA_COPDFactSheet.pdf.

Centers for Disease Control and Prevention (CDC) (2015, January 15). *Indicator definitions-Chronic Obstructive Pulmonary Disease (COPD)*. Retrieved from http://www.cdc.gov/cdi/definitions/chronic-obstructive.html.

Dransfield, M. T., Bourbeau, J., Jones, P. W., Hanania, N. A., Mahler, D. A., Vestbo, J.,...Lettis, S. (2013). Once-daily inhaled fluticasone furoate and vilanterol versus vilanterol only for prevention of exacerbations of COPD: two replicate double-blind, parallel group, randomised controlled trials. *Lancet Respiratory Medicine, 1*(3), 186. doi:10.1016/S2213-2600(13)70040-7.

Ferguson, G. T., & Make, B. (2016, January 21). *Management of stable chronic obstructive*

pulmonary disease. Retrieved from http://www.uptodate.com/contents/management-of-stable-chronic-obstructive-pulmonary-disease?source=search_result&search=management+of+stable+COPD&selectedTitle=1%7E150.

Joynt, K.E., Jha, A.K. (2013). Characteristics of hospitals receiving penalties under the hospital readmissions reduction program. *JAMA, 309*(4):342-343. doi:10.1001/jama.2012.94856.

Martinez, F. J., Boscia, J., Feldman, G., Scott-Wilson, C., Kilbride, S., Fabbri, L.,...Calverley, P. M. (2013). Fluticasone furoate/vilanterol (100/25; 200/25ug) improves lung function in COPD: a randomised trial. *Respiratory Medicine, 107*(4), 550-559. doi:10.1016/j.rmed.2012.12.016.

McKeage, K. (2014). Fluticasone furoate/vilanterol: A review of its use in chronic obstructive pulmonary disease. *Drugs, 74*, 1509-1522. doi:10.1007/s40265-014-0269-6.

Meguro, M., Barley, E.A., Spencer, S., Jones, P.W. (2007). Development and validation of an improved, COPD-specific version of the St. George Respiratory Questionnaire. *Chest*, 132(2), 456-463. Doi:10.1378/chest.06-0702

Pulmonary/ Infectious Disease Associates. (2015). 52 week, randomized, double-blind study, comparing the efficacy, safety, and tolerability of the fixed dose triple combination inhaler. *LH Clinical Research Center.*

Shah, T., Press, V., Huisingh-Scheetz, M., White, S. (2016) COPD readmissions: Addressing COPD in the era of value-based health care. Chest, 150(4), 916-926. Doi: 10.1016/j.chest.2016.05.002.

St. George's University of London. (2000-2016). *St. George's Respiratory Questionnaire*. Retrieved August 26, 2016, from Health Status Research: http://www.healthstatus.sgul.ac.uk/.

Weldam, S. M., Schuurmans, M. J., Rani, L., & Lammers, J. J. (2013). Evaluation of Quality of Life instruments for use in COPD care and research: A systematic review. *International Journal Of Nursing Studies*, *50*(5), 688-707. doi:10.1016/j.ijnurstu.2012.07.017.

Yin Kwan Ho, A., Berggren, I., & Dahlborg-Lyckhage, E. (2011). Diabetes empowerment related to Pender's Health Promotion Model: A meta-synthesis. *Nursing and Health Sciences, 12*, 259-267. doi:10.1111/j.1442-2018.2010.00517.x.

Appendix A

ST. GEORGE'S RESPIRATORY QUESTIONNAIRE for COPD patients

(SGRQ-C – US English)

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

ID :_____

Date :_____/_____/_____(dd/mm/yy)

Before completing the rest of the questionnaire:

Please check one box to show how you describe your current health:

Very good Good Fair Poor Very poor

Version: 1st Sept 2005

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Questions about how much respiratory trouble you have.

Please check () ONE box for each question:

Question 1. I cough:

most days a week..... a

several days a week……. b

only with respiratory infections….. c

not at all……...… d

Question 2. I bring up phlegm (sputum):

most days a week..... a

several days a week……..... b

only with respiratory infections… c

not at all…… d

Question 3. I have shortness of breath:

most days a week..... a

several days a week……... b

not at all……. c

Question 4. I have attacks of wheezing:

most days a week..... a

several days a week……..... b

a few days a month..... c

only with respiratory infections… d

not at all……..… e

Question 5. How many respiratory attacks did you have during the last year?

3 or more attacks…..... a

1 or 2 attacks…….……... b

none……..... c

Question 6. How often do you have good days (with few respiratory problems)?

no good days….....….…..... a

a few good days…...…...…….... b

most days are good…..... c

every day is good…..…… d

Question 7. If you wheeze, is it worse when you get up in the morning? No……..

……

Yes……

St. George's Respiratory Questionnaire PART 2

8. How would you describe your respiratory problems? Please check () ONE:

Cause me a lot of problems or are the most important physical problem I have…….…… a

Cause me a few problems……. b

Cause no problems…….…….. c

9. Questions about what activities usually make you feel breathless.

For each statement please check () in the box that applies to you these days:

	True	**False**
Washing or dressing yourself……..…….……..		a
Walking around the house…….……...……		b
Walking outside on level ground…….…….		c
Walking up a flight of stairs…….....		d
Walking up hills…….……...…….....		e

10. Some more questions about your cough and breathlessness.

For each statement please check () in the box that applies to you these days:

	True	False
Coughing hurts…….....		a
Coughing makes me tired……..……		b
I am short of breath when I talk…….		c
I am short of breath when I bend over……...		d
My coughing or breathing disturbs my sleep…….....		e
I get exhausted easily……...……...		f

11. Questions about other effects that your respiratory problems may have on you.

For each statement please check () in the box that applies to you these days:

	True	False
My cough or breathing is embarrassing in public …….		a
My respiratory problems are a nuisance to my family, friends or neighbors…….....		b
I get afraid or panic when I cannot catch my breath……...…		c
I feel that I am not in control of my respiratory problems……..		d
I have become frail or an invalid because of my respiratory problems..		e
Exercise is not safe for me……..		f
Everything seems too much of an effort…….		g

12. These are questions about how your activities might be affected by your respiratory

problems.

For each statement please check () in the box that applies to you because of your respiratory problems:

	True	False
I take a long time to get washed or dressed……..	a	
I cannot take a bath or shower, or I take a long time to do it……...	b	
I walk slower than other people my age, or I stop to rest…….	c	
Jobs such as household chores take a long time, or I have to stop to rest……	d	
If I walk up one flight of stairs, I have to go slowly or stop….....	e	
If I hurry or walk fast, I have to stop or slow down…….	f	
My breathing makes it difficult to do things such as walk up hills, carry things upstairs, light gardening such as weeding, dance, bowl or play golf …	g	
My breathing makes it difficult to do things such as carry heavy loads, dig in the garden or shovel snow, jog or walk briskly (5 miles per hour), play tennis or swim…….....	h	

13. We would like to know how your respiratory problems usually affect your daily life.

For each statement please check () in the box that applies to you because of your respiratory problems:

	True	False
I cannot play sports or do other physical activities……...	a I	
cannot go out for entertainment or recreation……	b	
I cannot go out of the house to do the shopping……..……	c	
I cannot do household chores……	d	
I cannot move far from my bed or chair……	e	

14. How do your respiratory problems affect you?

Please check () ONE:

They do not stop me from doing anything I would like to do…… a

They stop me from doing one or two things I would like to do…… b

They stop me from doing most of the things I would like to do……... c

They stop me from doing everything I would like to do…….…... d

Thank you for completing this questionnaire.

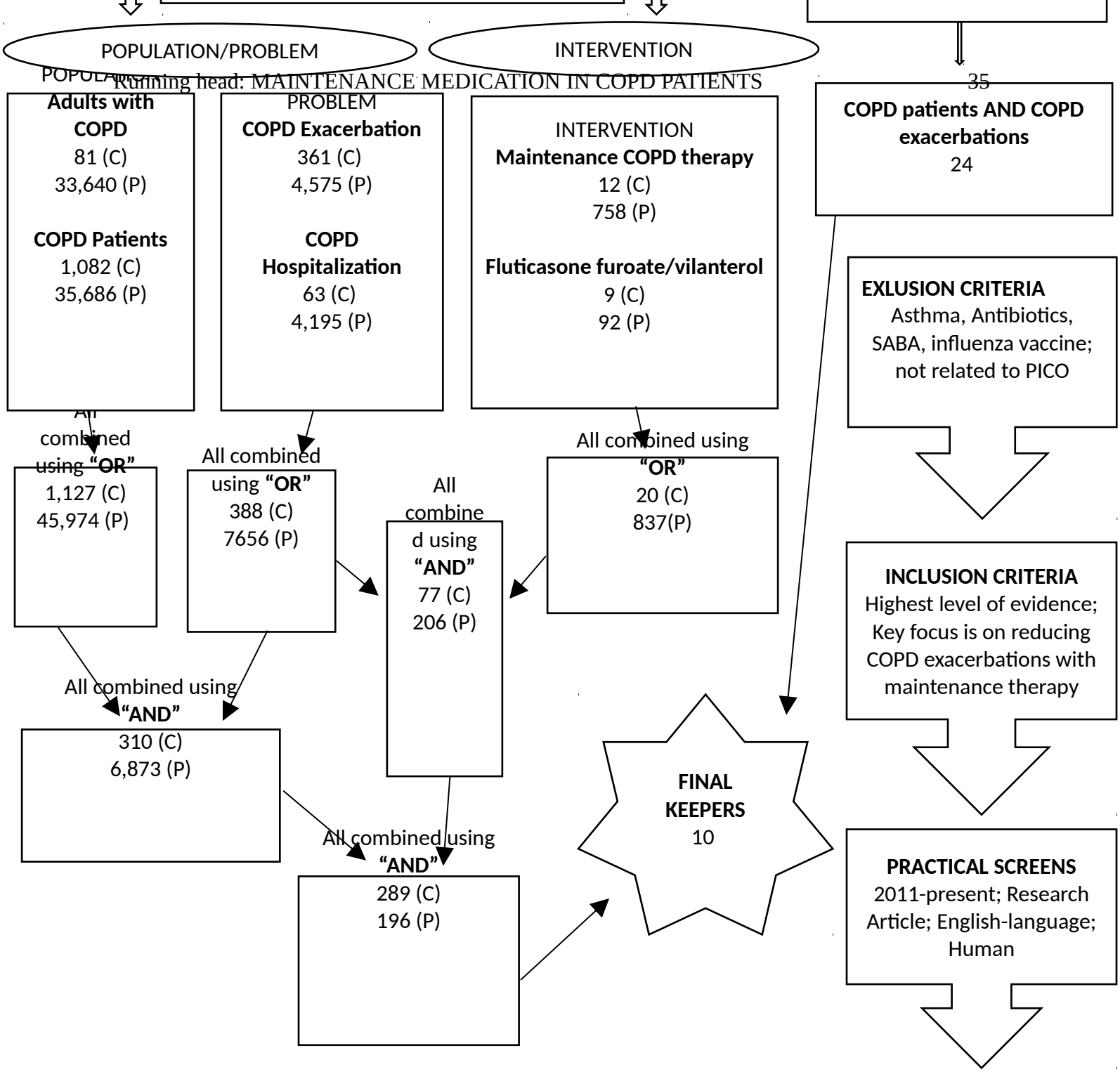
Before you finish, would you please make sure that you have answered all the questions.

Appendix B: Literature Search

In adults with chronic obstructive pulmonary disease (COPD), does receiving maintenance COPD therapy of once-daily fluticasone furoate/vilanterol inhalation, compared to not receiving maintenance COPD therapy, reduce the number of COPD exacerbation-related readmissions within 30 days after starting therapy and improve quality of life?

Search Completed in CINAHL plus with full text

COCHRANE Database of Systematic Reviews



Appendix C: Informed Consent from Original Study

CONSENT and Authorization for the Twelve month Main study to compare three investigational medication in patients with Chronic Obstructive Pulmonary Disease (COPD) who have a history of COPD exacerbation Clinical Research Study

By signing below, I show that:

- The study has been explained to me in a language I understand.
- I have discussed the study with the study doctor or study nurse and have asked questions.
- I am satisfied with the answers.
- I have had enough time to make my decision.
- I freely agree to take part in the study described.
- I have been given names of study staff who I can call if I have any questions about the study.
- I agree that study staff and others may have access to my medical and personal information for use as described in this form.
- I know what will happen to my blood samples collected for this study.
- I know I can leave the study at any time without giving a reason.
- I know that the study doctor can ask me to stop taking part in the study at any time and he/she will tell me the reasons why.
- I know that I cannot be in another study while I am taking part in this study.
- I agree that my information may be shared with people who are not healthcare providers and that the information would no longer be protected by US federal privacy rules (such as “HIPAA”)
- I agree that the study doctor may tell my doctor that I am taking part in a study.

- It has been explained to me that I have not waived my legal rights by signing this document. I will receive a copy of this signed and dated document to take with me.

Signature Date

Printed Name

A researcher or the study staff member going over the informed consent must also sign each consent.

By signing below, I show that:

- I have given this form and explained the study to the subject and what will happen to his/her blood samples collected during the study.
- I have given the subject the chance to ask questions and I have answered them to his/her satisfaction.
- I have given the subject enough time to think and decide whether or not he/she wants to participate in the study. I explained that he/she may talk with others before making a decision.
- A copy of this signed and dated Informed Consent Form has been provided to the subject.

Signature of study staff conducting consent Date

Printed name of study staff