Implementing GOLD Strategy for Patients with COPD in Primary Care

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a chronic, progressive illness frequently encountered by primary care clinicians. The Global Initiative for Chronic Lung Disease (GOLD) strategy offers the most robust evidence-based recommendations about the diagnosis and management of COPD. Understanding and utility of GOLD in primary care is limited. Goals of the project, to improve the quality of care for COPD patients, were based on Triple Aim Initiatives, COPD National Action Plan, and Healthy People 2020. The quality improvement project implemented a one-time staff and provider education about GOLD strategy in caring for COPD patients in a primary care setting. The quality improvement project also implemented a revised in-house spirometry testing workflow which incorporated GOLD strategy recommendations. Data outcomes were derived from chart audits and EHR metric reports for 120 COPD patients at a primary care clinic. Outcomes from the four-month project showed increased rates of GOLD strategy recommendations. There was an increase in the rates of spirometry confirmed diagnosis, increased rates of tobacco cessation counseling, increased rates of COPD Assessment Test performance, increased rates of tobacco cessation by COPD patients, and decreased rates of prescriptions for inhaled corticosteroids. The workflow was adopted into clinical practice at the site after completion of the implementation project.

Key words: COPD, chronic obstructive lung disease, spirometry, pulmonary function testing, primary care providers, primary care, GOLD, global initiative for chronic lung disease, education

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Chapter One: Overview of Chronic Obstructive Pulmonary Disease

Chronic Obstructive Pulmonary Disease (COPD) affects 16 million people in the United States (NIH, 2017). COPD is an incurable, progressive, yet preventable chronic illness of reduced lung function, with millions of people still undiagnosed (NIH, 2017). The National Institutes of Health released the COPD National Action Plan in 2015 to unify advancements in treatment and policy for COPD. The Action Plan identifies key goals for diagnosing and managing this devastating disease. Goal 2 of the Action Plan provided foundational principles for the project. "Improve the diagnosis, prevention, treatment, and management of COPD by improving the quality of care delivered across the healthcare continuum" (NIH, 2017, p.11).

Applying the internationally recognized, evidence-based recommendations from the Global Initiative for Obstructive Lung Disease (GOLD) strategy into primary care practice was the aim of this project. Primary care clinicians are in a unique position to translate goals into clinical practice. This chapter will explore the background of COPD and current clinical practice standards from GOLD strategy for the diagnosis, treatment, and management of this disease. A brief overview of the quality improvement project that adapted GOLD strategy into a rural primary care practice will also be explored.

Background of COPD

COPD is a progressive disease of airway obstruction, now the 4th leading cause of death in the US (CDC, 2018). Features of both emphysema (hyperinflation of distal airspaces) and chronic bronchitis (persistent overproduction of mucus and cough) are present in COPD (McPhee, Papadakis & Rabow, 2018). COPD patients usually present between ages 40 and 60 with symptoms of breathlessness, cough, and/or copious phlegm (mucus).

GOLD strategy is a collaborative effort of multiple professional organizations guiding international standards for the diagnosis, management, and prevention of COPD. GOLD defines COPD as a disease "characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases" (GOLD, 2019, p.1). COPD is irreversible, and the prognosis is poor once significant airway limitation has occurred. Treatment aims to relieve symptoms, minimize exacerbations, and reduce complications and mortality (Cash & Glass, 2017). Early detection allows for earlier treatment.

Risks. Primary tobacco use, predominantly cigarette smoking, is the single most important modifiable risk factor in the development of COPD in the developed world. Over 80% of COPD patients report a history of tobacco use (NIH, 2017). Smoking is only one factor, and research is ongoing to better understand other risks, particularly in developing nations. The most recent update of GOLD (2019) noted the inclusion of several additional risk factors in the development of COPD: indoor air pollution, occupational exposures, genetic factors, age and sex, lung growth and development, socioeconomic status, asthma and airway hyper-reactivity, chronic bronchitis, and a history of respiratory infections.

Statistics. According to the CDC's 2014-2015 Behavioral Risk Factor Surveillance System, COPD has an age-adjusted national prevalence of 5.9%, while North Carolina (NC) prevalence is 7% (Sullivan et al., 2018). Prevalence in southeastern NC is estimated between 7.1 and 10% (Zhang et al., 2014). Death rates in the US from COPD in 2014 were 39.1 per 100,000 persons, a small decline from 43.3 calculated in 2008 (CDC, 2018). Deaths from COPD decreased for men in the period 1999 to 2014, while rates for women did not (CDC, 2018).

Social determinants of health. Lower socioeconomic status, whether defined by income or education, increases COPD prevalence by three-fold throughout the world (Pleasants, Riley, & Mannino, 2016). An increased prevalence of COPD has been reported in US and NC households with income less than $25,000 a year, persons identifying as unable to work, those without a high school diploma, divorced/separated/widowed, and current/former smokers (CDC, 2012). Compounding this problem is the well-established connection between tobacco use and low socioeconomic status (Wang et al., 2018). The National Advisory Committee on Rural Health and Human Services recently published a policy brief identifying barriers to care for COPD patients in rural, isolated communities, including a lack of specialist care (2019).

Comorbidities and symptom burden. The disabling nature of COPD symptoms is profound for the patients experiencing them. "A population literally struggling for breath is, in consequence, unproductive" (Quaderi & Hurst, 2018, p.1). Specialized components of the Behavioral Risk Factor Surveillance Survey (BRFSS) 2011 data include behaviors and quality of life questions for those living with COPD. Nationally, 17.6% of respondents reported a hospital or ED visit for COPD symptoms within the previous 12 months (CDC, 2012). NC data demonstrated a similar rate of 17.7%. Of national respondents, approximately 64% reported a significant effect of breathlessness on their daily life; NC respondents experienced this 4% more (CDC, 2012). These findings give context to the frequent finding of anxiety and depression in COPD patients. COPD progression also results in weight loss, malnutrition, muscle atrophy, and anorexia. Other frequently found comorbid conditions include lung cancer, cardiovascular disease, hypertension, peripheral vascular disease, and osteoporosis (GOLD, 2019).

Exacerbations. Exacerbations are defined as an acute increase in respiratory symptoms that result in additional therapy beyond normal daily variance (GOLD, 2019). Exacerbations

vary in severity but lead to frequent provider visits, increased hospital utilization, secondary respiratory infections, and suboptimal medication use. Strategies aimed at reducing burden and cost should focus on reducing exacerbations, slowing the decline of pulmonary function, and reducing adverse symptoms (Ford et al., 2015).

Significance of the Clinical Problem

General goals of treatment for COPD are improvements in quality of life and reducing the frequency of exacerbations (Cash & Glass, 2017). GOLD strategy provides an evidenced-based step-wise approach to the diagnosis, assessment, and treatment of COPD.

Spirometry testing is the diagnostic standard to evaluate airflow obstruction and establish the diagnosis of COPD. Stages of disease progression are based on spirometry results: the ratio between predicted and actual forced expiratory volume (GOLD, 2019). Recently GOLD strategy has placed increasing emphasis on evaluating respiratory symptoms to guide treatment, rather than staging alone (GOLD, 2019). Updated recommendations included a standardized treatment process, known as the refined ABCD assessment tool (Appendix A).

The ABCD assessment tool identifies exacerbation history (along the y-axis) and reported symptoms (along the x-axis). The categories defined by boxes A, B, C, and D, are then used to identify appropriate pharmacological treatment. There are two questionnaires recommended by GOLD to evaluate symptoms. In years past, the Modified British Medical Research Council (mMRC) questionnaire, which focused exclusively on dyspnea, was most often used. With the 2017 update, GOLD endorsed the COPD Assessment Test (CAT), which identifies symptoms beyond breathlessness alone (Appendix B).

There are several algorithms derived from GOLD strategy for practitioners to utilize, which combine symptom assessments with spirometry values in guiding pharmacological

treatment. The COPD Foundation offers the "COPD pocket consultant" a practical clinical tool which was utilized for the project (Appendix C; Yawn et al., 2017). Other important considerations in COPD management include smoking cessation interventions, regular assessment of inhaler technique, and pneumococcal and influenza vaccinations.

COPD Care in the Local Clinic

COPD is a complex illness largely overlooked until recent years. Recommendations for treatment have not been fully adopted and utilized in the primary care setting. Primary care providers are frequently the first to identify and treat COPD, and early intervention can move care towards Action Plan goals.

In a free, rural primary care clinic for low-income, uninsured adults in North Carolina, two components of GOLD strategy were routinely utilized. First, staff performed in-house spirometry to diagnose COPD. Second, providers counseled patients on tobacco cessation during routine visits. Both spirometry diagnosis and tobacco cessation data are tracked with quarterly chart audits. The clinic's goal was to incorporate more standards of care to improve symptom management and disease progression for COPD patients. The project proposed to improve clinic uptake of GOLD strategy in accordance with COPD National Action Plan Goals 2: improving diagnosis and treatment.

Question Guiding Inquiry

Population. Primary care providers and nursing staff at the clinic were the population. Patients with suspected or diagnosed COPD would benefit from the improved diagnosis and treatment as recommended in GOLD strategy.

Intervention. First, education was provided to the clinic staff about GOLD strategy in primary care. Education included spirometry performance and interpretation, CAT symptom

questionnaire use, tobacco cessation, inhaler education, and medication recommendations. Second, a revised workflow for spirometry visits was created for providers and staff. Changes were made directly into the clinic's electronic health record (EHR).

Comparison. This intervention was compared to current care for COPD patients at the clinic: spirometry testing and tobacco cessation counseling. Chart audit data in June 2019 of patients diagnosed with COPD revealed a 96% rate of smoking cessation interventions and a 58% of spirometry confirmed diagnosis. The clinic desired to improve both measures though no specific rate was defined.

Outcomes. The outcome of the project was measurable improvements in selected components of GOLD strategy including spirometry rates, tobacco cessation counseling documentation, tobacco cessation rates, CAT symptom questionnaire, inhaled corticosteroid prescription rates, and healthcare utilization in the form of ED/hospitalizations. These measures were evaluated with EHR generated reports and chart audits. Outcomes were congruent with the COPD National COPD Action Plan goals and the Triple Aim Initiative.

Summary

COPD is a debilitating disease marked by a progressive loss of lung function over time. COPD disproportionately affects people in rural locations and those with lower socioeconomic status. Initiatives to improve COPD care include the COPD National Action Plan and Healthy People 2020 goals. Goals for COPD treatment are intended to manage symptoms, decrease risks of exacerbations, and improve mortality from this illness. GOLD strategy is an internationally recognized, evidence-based set of recommendations that can be adapted at the primary care level to diagnosis and treat COPD.

The project site was engaged in pursuing measures to improve care for suspected and diagnosed COPD patients. The project aimed to improve the diagnosis and management of COPD by educating staff on GOLD strategy and providing a revised workflow for spirometry visits. The intent of this project was to improve the lives of patients with a quality improvement plan that operationalized best care practices.

Chapter Two: Review of the Literature

GOLD strategy is the international standard for the diagnosis and management of COPD. The adaptation of this strategy into clinical practice has varied worldwide. Reasons include knowledge gaps and accessibility of recommendations, geographic location, prevalence, the complexity of healthcare systems, ongoing research, and availability of treatment options. Ongoing advancements in understanding and treatment of COPD have complicated the ability to adopt standards of care to the primary care level.

This chapter will examine the ways in which GOLD strategy has been implemented in the literature. Recent and ongoing research about specific aspects of the GOLD strategy, the utility of standardized questionnaires, and pharmacological management will be examined for use in clinical practice. Data regarding implementation strategies for GOLD strategy in primary care and further literature strategies will be reviewed. Applicability of the literature review to the proposed project will be discussed.

Literature Appraisal Methodology

Sampling strategies. Search terms for literature review included the following: "outpatient", "out-patient", "primary care", "global initiative for chronic obstructive lung disease", "GOLD", "GOLD guidelines", "COPD", "chronic obstructive pulmonary disease", "global strategy for the diagnosis, management, and prevention of COPD". PubMed, Scopus, and OneSearch were used. Results were limited to literature published within the past 5 years, peer-reviewed, and written in English. One exception to the time limitation was made: the 2007 study by Foster, Yawn, Maziar, Jenkins, Rennard, & Casebeer, which was the first and only formal evaluation of GOLD strategy applied to clinical practice. Further limitations included those containing abstract details for outpatient COPD management, GOLD recommendations

adherence, implementation of GOLD recommendations, specific instruments of GOLD recommendations including COPD Assessment Test (CAT), and the Modified British Medical Research Council (mMRC) questionnaires. The total number of articles retrieved with these parameters was 724; total articles reviewed with abstract data were 86; articles selected for critical review were 53 (Appendix D).

Ongoing search strategies included manual reviews using revised search terminology adapted to the needs of the project. Close attention was paid to the International Journal of COPD, whose literature was the most robust and current.

Evaluation criteria. Inclusion criteria included the following: literature reviews, systematic reviews of randomized controlled trials, meta-analysis, guidelines, guideline summaries, reviews of guidelines, expert opinions, cohort/observational studies, case study, and survey studies. All levels of evidence were considered, and I, II, IV, V, and VI levels of evidence were utilized in the review.

Exclusion criteria included findings related to drug trials for COPD medications, oxygen supplementation, surgical interventions, pulmonary rehabilitation studies, examinations of co-morbidities, asthma and asthma/COPD overlap, and studies and reviews of COPD interventions in settings other than outpatient or primary care. A literature matrix provides a summary review of all included sources (Appendix E).

Literature Review Findings

The 2019 GOLD Global Strategy for Prevention, Diagnosis, and Management of COPD is the most recent update to the international standards of care for COPD. National organizations, including the American Thoracic Society, American College of Chest Physicians, and American College of Physicians, use GOLD strategy to produce clinical practice guidelines.

Many components of GOLD strategy are common throughout the literature: use of post-bronchodilator (BD) spirometry values for diagnosis, medication adherence that includes a long-acting BD with the presence of significant symptoms, pneumococcal vaccinations, smoking cessation counseling, and inhaler technique education. GOLD (2019) offers the ABCD assessment tool as an algorithm for medication guidance to initiate and titrate treatment based on symptoms (Appendix B). The COPD Foundation offers the "COPD pocket consultant" intended for both primary care and hospital bedside providers (Appendix C). Adherence and implementation of GOLD strategy vary in the literature.

Implementation initiatives in primary care practice. Research trials and data regarding implementation strategies applying GOLD strategy to primary care settings are rare. Integrated disease management (IDM) is a model that has been used to implement COPD recommendations into clinical practice. A Cochrane review by Kruis et al. (2013) evaluated 26 randomized control trials of IDM involving approximately 2000 patients. While the definition of IDM was broad, important GOLD strategies such as smoking cessation, medication adherence, and self- management/patient education strategies were included. Self-reported quality of life, exercise tolerance, reduced hospital admissions, and length of stay were notable findings (Kruis et al., 2013).

Clinical decision support systems (CCDSS) have also been used in practice to implement recommendations in primary care. CCDSS interventions are computerized point-of-care reminders embedded within the electronic workflow, such as forms, templates, alerts, reminders, and order sets, giving suggestions about clinical care (Fathima, Peiris, Naik-Panvelkar, Saini, & Armour, 2014). The authors reviewed 16 randomized control trials of CCDSS for asthma and COPD care in primary care, representing an array of interventions (Fathima et al., 2014).

Overall, 75% of the studies demonstrated statistically significant improvements in clinical outcomes for patients and process quality measures in practice (Fathima et al., 2014).

Adherence to GOLD strategy in primary care. Studies evaluating general adherence to GOLD strategy in primary care are limited and demonstrate the gap in clinical application. Historical data from Foster et al. (2007) notes that bridging the gap between evidence and practice has been a challenge from the first GOLD document. The study, sponsored by the COPD Foundation, surveyed more than 700 primary care physicians. Over 60% of physicians considered their COPD education inadequate, and 45% were unaware of clinical practice recommendations (Foster et al., 2007).

A recent examination of the literature shows a similar picture, with a wide range of GOLD strategy adopted into clinical practice. Sehl, O'Doherty, O'Connor, O'Sullivan, & O'Regan (2018) reviewed 11 quantitative studies describing varying use of spirometry, awareness of recommendations, medication management, vaccination status, documentation of smoking cessation counseling, and inhaler teaching. Two common barriers to practice emerged in this review: time constraints and lack of familiarity with guidelines. This information was an important consideration in developing the education portion of the project.

GOLD strategy and clinical practice guidelines underscore post-bronchodilator spirometry as the primary diagnostic tool for COPD. Yet, the application of this recommendation is inconsistent. In one retrospective chart analysis in the US, only 27% of 1500 COPD patients had documentation of spirometry (Belletti, Lui, Zacker & Wogen, 2013). Barrencheguren et al. (2015) examined a database of 40,000 newly diagnosed patients with COPD with similar results: nearly half had no spirometry data in the health record.

The "Continuing to Confront COPD International Physician Survey" sought to examine the application of COPD practice recommendations by comparing respiratory specialist physicians to primary care physicians (Davis et al., 2015). Case-study response surveys showed that 82% of primary care physicians routinely used spirometry for diagnosis, compared to 100% of respiratory specialists (Davis et al., 2015). Overall knowledge varied considerably, with 85% of primary care providers noting awareness of any COPD guideline, compared to only 58% awareness of GOLD strategy specifically (Davis et al., 2015). Of those acknowledging GOLD strategy, 59% described an actual change to their practice (Davis et al., 2015).

Some practices are successfully translating knowledge into practice. A randomized trial of 700 Chinese patients with COPD evaluated patient outcomes between an intervention group (provider education on GOLD strategy) and a control group (usual care). The study showed a statistically significant difference in 6-minute walk distance, self-reported symptoms via mMRC questionnaire, and quality of life measures for the intervention group patients (Jiang et al., 2015). The provider education included four training sessions with topics covering smoking cessation, spirometry confirmed diagnosis, and medication recommendations (Jiang et al., 2015). Their results demonstrate that provider education directly impacts patient outcomes.

Symptom assessment tools. Beginning in 2011, GOLD strategy was updated to include assessment of symptoms in addition to spirometry for the management of COPD (GOLD, 2019). The CAT and mMRC questionnaires have been incorporated in the ABCD assessment tool. Severity increases with the assessment tools' letters: A (low risk, fewer symptoms), B (low risk, more symptoms), C (high risk, fewer symptoms), D (high risk more symptoms). Clinicians are faced with a challenge; however, when determining which questionnaire to use.

The GOLD 2019 strategy recommends the CAT specifically, noting that dyspnea is not the only measurement of symptom burden in COPD (GOLD, 2019). Data regarding the utility of these tools is ongoing. Gupta, Pinto, Morogan, & Bourbeau (2014) measured psychometric properties of the CAT, deeming it internally consistent, responsive to actual healthcare utilization, and reproducible over time. In a separate systematic review and meta-analysis, the CAT was demonstrated to have significant predictive abilities; impressively, the CAT predicted COPD exacerbations, worsening of health status, depression, and mortality (Karloh, Mayer, Maurici, Pizzichini, Jones, & Pizzichini, 2016).

Evidence does reveal flaws in the scoring of the CAT and mMRC. One recent study concluded that the ABCD classification of COPD patients was significantly different, depending upon which of these questionnaires were used (Karloh et al., 2016). Multiple examinations of existing data suggest that cutoff points for the questionnaires described in the ABCD assessment tool are not equivalent and need more research (Karloh et al., 2016; Mapel, Dalal, Johnson, Becker, & Hunter, 2015).

Use of bronchodilators. As with the general uptake of GOLD strategy, there is varying adherence in use of recommended inhaled medications for COPD in primary care. Recent literature describes frequent BD prescriptions without spirometry confirmed diagnosis (Sehl et al., 2017; Overington et al., 2014). GOLD strategy recommends that COPD severity should be staged with spirometry and symptoms assessed prior to prescribing medications (2019).

Historical data from Foster et al. (2007) demonstrates prescriptive practices incongruent with GOLD strategy. In physician self-reported practices, only 36% of primary care physicians used recommended long-acting BD medications for specific categories of COPD. Responses in the “Continuing to Confront COPD International Physician Survey” indicated that neither

primary care providers nor respiratory specialists were particularly adherent to recommendations for inhaled medications (Davis et al., 2015). In one example, both types of providers were only 60% concordant with recommended bronchodilator medications (Davis et al., 2015).

Inhaled corticosteroids (ICS) have been another mainstay of treatment, most recently supported in drug trials for use in severe COPD and frequent exacerbations (Riley & Sciurba, 2019). However, ICS may be overused, providing minimal benefits and notable risks of use including an increased incidence of bacterial pneumonia and oral thrush (Riley & Sciurba, 2019). Sehl et al. (2017) found 30% of physicians utilizing ICS as an initial medication regardless of stage. Similarly, Davis et al. (2015) noted the use of ICS as initial treatment for mild stages of COPD. Overuse of combined triple therapy (both types of long-acting bronchodilators together with ICS) is consistently noted in the literature (Overington et al., 2014; Sehl et al., 2017; Davis et al., 2015). In one observational study involving claims-based data, 75% of COPD patients with documented triple therapy did not have the appropriate GOLD category of disease to justify use per GOLD strategy (Simeone et al., 2017).

Costs of COPD care and management. The chronic nature of COPD and increased medical interventions during disease progression create burden of cost to the healthcare system and patients. A recent review of the literature by ur-Rehman (2019) showed the average length of stay in the US for COPD exacerbation was 4.8 days. Depending on disease severity, this can be two to three times a year (GOLD, 2019). Hospitalizations are an enormous cost of care per patient with COPD, estimated at $6,852 annually. Emergency Department costs alone were $2380 annually (ur Rehman et al., 2019). This is directly influenced by disease severity and exacerbation frequency. Early and frequent interventions that utilize best practice are important in reducing the overall cost of care for COPD patients (ur Rehman et al., 2019). Reducing the

overall cost of care is an essential focus of the Triple Aim Initiatives recommended by the Institutes for Healthcare Improvement.

Limitations of Literature Review Process

Adherence and implementation practices in the primary care setting have not been well researched. “There are very few studies assessing the effect of COPD guideline implementation on patient outcomes, and this is an area that requires further research” (Overington et al., 2014, p.1593). In addition, no studies were found pertaining to rural primary care management of COPD. Also, there was no clear evidence of the role of the nurse practitioner in the care of patients with COPD. Most studies have been conducted in the medical specialty fields of pulmonology and pharmacology.

Discussion

Conclusion of findings. There are limited data describing implementation strategies for GOLD strategy in primary care. There has been wide variation in the clinical application of GOLD, frequently cited in studies utilizing chart reviews and provider surveys. Major gaps in the application of GOLD strategy include spirometry diagnosis, knowledge of recommendations, and prescriptive practices. Frequently identified barriers in adherence to using GOLD recommendations include time constraints, lack of familiarity with recommendations, and complexity of recommendations (Overington et al., 2014; Sehl et al., 2018). The most recent version of GOLD 2019 “pocket guide” is 44 pages in length.

A review of the literature demonstrates a need for provider and staff education on GOLD recommendations. It is important that education on GOLD strategy emphasizes spirometry-based diagnosis and understandable algorithms for treatment recommendations. Methods used to

evaluate the implementation of GOLD strategy would be best measured by chart audits, which have been proven to be useful in past studies evaluating adherence.

Advantages and disadvantages of findings. Providing education to providers about GOLD strategy is a demonstrated need in the literature. Increasing awareness of GOLD strategy in clinical practice has the potential to improve the quality of life, disease progression, and healthcare costs for care of COPD patients. These goals are congruent with the 2015 COPD National Action Plan for translating recommendations into practice. In addition, Healthy People 2020 goals include measures for reducing hospitalization, mortality, and improving quality of life for COPD patients.

Disadvantages include the lack of implementation strategies in the literature for education in primary care. There is limited information about which education tools work best for COPD specifically. Further research is also needed to identify the best methods of dissemination of information in primary care settings. Other disadvantages included conflicting information about symptom questionnaires and whether the CAT and mMRC should be considered interchangeable when using treatment algorithms.

Utilization of findings in practice change. Project implementation plans focused on teaching and consideration of time constraints for providers and staff. Education plans were designed to succinctly address GOLD strategy for the assessment, diagnosis, treatment, and management of COPD at the primary care level.

Recommendations made by Overington et al. (2014), based on a review of methods used for other chronic diseases, were applicable to the project design. The accessibility of recommendations at point-of-care locations, providing an active/live education opportunity, and incorporating reminders within the EHR were strategies notable to the project (Overington et al.,

2014). Adjustments were made directly in the clinic EHR for ease of access and improved workflow.

Summary

This chapter has identified the need for improved education about GOLD strategy in primary care. Clinical application of GOLD strategy varies throughout the literature, with lack of knowledge and time constraints identified as primary barriers to care. The project's intent was to bring education and actionable strategies based on GOLD to the project site. These goals were aligned with COPD National Action Plan goals and Healthy People 2020 goals.

Chapter Three: Theory and Concept Model for Evidence-based Practice

Theoretical and conceptual frameworks are integral to develop, implement, and evaluate the project. This chapter will describe important concepts of the project, the theoretical basis of the project, and the conceptual model selected to guide implementation. Concepts explored will include COPD, GOLD, exacerbations, symptom burden, and project outcome. The Diffusion of Innovations Theory (DOIT) was the overall theoretical basis for the project, guiding the development of education and workflow strategies, and identifying appropriate communication channels for dissemination. The Plan-Do-Study-Act (PDSA) conceptual model guided the implementation and evaluation of the interventions. Current examples of theory and conceptual model used in the literature will be identified.

Concept Analysis

Major concepts of the project include COPD, GOLD recommendations, exacerbations, and symptom burden. The outcome concept is the improvement in the spirometry visit workflow conducted at the clinic. Outcomes were measurable patient outcomes derived from EHR queries and chart audits.

COPD. COPD is a progressive disease of airway obstruction, exhibited by hyperinflation of distal airspaces and the persistent overproduction of mucus and cough (McPhee, Papadakis & Rabow, 2018). Because COPD is a progressive, chronic, and irreversible disease of airway destruction, treatment goals aim to relieve symptoms, minimize exacerbations, and reduce complications and mortality (Cash & Glass, 2017). Spirometry is the diagnostic test used to confirm COPD definitively. Comparing rates of forced expiratory volume, or the amount of air in a forced exhalation, using a bronchodilator medication is the diagnostic standard (GOLD, 2019).

GOLD. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) is a collaborative effort of professional organizations guiding international standards for the diagnosis, management, and prevention of COPD. GOLD was originally developed as a think tank, later creating a scientific committee that produces evidence-based recommendations for the management of COPD (GOLD, 2019). The formal GOLD Strategy document is revised every five years. Science committee members have clinical and academic expertise, and disclosures of interest are updated yearly. Levels of evidence are ranked with each subsequent report, with grades A to D assigned to each recommendation in published reports (GOLD, 2019). GOLD defines its objectives to recommend management strategies, increase public awareness of the disease, implement and evaluate effective programs for diagnosis and treatment, and promote COPD research (GOLD, 2019).

Exacerbations. Exacerbations are acute increases in symptoms of COPD, causing a change in treatment, such an outpatient adjustment in medication or intensive interventions within a hospital setting. Exacerbations, often triggered by respiratory infections or environmental irritants, are a combination of increased hyperinflation, gas trapping, and inflammation, with reduced expiratory flow, resulting in significantly increased dyspnea (GOLD, 2019). The goals of COPD management are focused on reducing the frequency and severity of exacerbations (Cash & Glass, 2017).

Symptom burden. Symptom burden is the fluctuating pattern of dyspnea, cough, wheezing, chest tightness, and sputum production in the COPD patient that negatively affects quality of life (GOLD, 2019). All aspects of life are affected by symptom burden, including employment, physical activity, activities of daily living, nutritional status, sleep patterns, family functioning, self-perception, and mood. Symptom burden changes through the course of illness

are relative to exacerbation periods and are directly linked to increased utilization of healthcare resources (Ding, Small, & Holmgren, 2017). Increasing frequency and severity of exacerbations are indicative of progressing disease severity, loss of lung function, and worsening of COPD.

Project Outcome. A revised spirometry visit workflow is the project outcome. This will be evidenced by measurable data concerning rates of spirometry performed, documentation of the CAT symptom questionnaire, tobacco cessation counseling, rates of tobacco cessation, inhaled corticosteroid use, and healthcare utilization.

Theoretical Framework

Naming the theory. The Diffusion of Innovation Theory (DOIT) developed by Everett Rogers is the conceptual theory for this project. DOIT provides a framework with which to understand how innovations are spread and utilized (Rogers, 2003). While DOIT was first identified in the context of agricultural innovations, it has been adopted in a variety of disciplines, including public health, medicine, nursing, social work, and behavioral health (Hayden, 2017). DOIT is versatile in research, quality improvement, and implementation strategies.

The Diffusion of Innovation Theory (DOIT) is a model that explains how and why new ideas are spread. DOIT varies by the culture where an idea is being spread, the characteristics of the adopters, and the innovation-decision process (Hayden, 2017). DOIT contains four main constructs: the innovation (or idea), channels through which the idea is communicated, time, and the social system through which this occurs. Each of these components has important aspects relative to the uptake of an idea.

Characteristics of innovation are defined as relative advantage, trialability, complexity, and compatibility. Communication channels are defined as the vehicle through which people

obtain information about innovation, primarily through mass media and interpersonal means (Rogers, 2003). The social system can be several individuals, groups, or organizations "engaged in solving a joint problem to accomplish a goal" (Hayden, 2017, p.483). Individuals within the social system are referred to as adopters. Adopter categories are defined by how rapidly or slowly, they adopt an innovation over time. Time is defined as the rate at which information is shared, and innovations are adopted. From quick to slow rates, adopters are defined in the following categories: innovators, early adopters, early majority, late majority, and laggards (Rogers, 2003). The overall process of accepting an innovation has five stages: knowledge, persuasion, decision, implementation, and confirmation. A schematic model of these elements of the DOIT can be seen in Appendix F.

Examples of DOIT in the literature. Many aspects of DOIT have been utilized in healthcare quality improvement. Care plans, care management strategies, and care bundles have recently been explored on a broad scale using DOIT as a theoretical model for systematic reviews. Dementia care plans in the outpatient setting were examined to understand varying rates of success. DOIT constructs of attributes of innovation, communication channels, and characteristics of adopters were reviewed across practice locations and implementation plans (Khanassov, Vedel, & Pluye, 2014). Approached from this theoretical perspective, limitations, and facilitators of implementation were clearly identified, and strategies for improvement were developed. Care management plans for other disease types have been reviewed in a similar manner. Miake-Lye et al. (2017) systematically reviewed over 1400 responses to the National Survey of Physician Organizations Review survey. Using DOIT, their answers were analyzed by innovation characteristics, revealing that prior experience and simplicity were critical to the adoption of care plans, regardless of disease type (Miake-Lye et al., 2017).

In another context, hospital discharge care bundles for COPD were evaluated as an innovation using DOIT. Responses from 13 focus groups identified challenges in staffing, infrastructure, process, use of improvement methodology, and patient involvement (Lennox et al., 2014). With staff as adopters, the authors identified the need to engage staff early and consistently, clearly identify roles of the team, and encourage personal ownership.

In research similar to the project, DOIT was used to evaluate a COPD screening program at an indigent clinic (Estes, Short, Bowser, & Boyle, 2014). A novel COPD screening questionnaire was used to identify patients who were then assessed and treated with GOLD recommended measures. Using DOIT in post-implementation evaluation, the intervention was determined to be too resource-intensive and unsustainable.

Application to practice change. Two major constructs of DOIT guided the project: characteristics of innovations and communication channels. Innovations of the project are defined as the education modules and revised spirometry workflow.

Optimizing characteristics of the innovation (relative advantage, trialability, complexity, and compatibility) will guide the development of education modules and workflow. Relative advantage of the innovation was illustrated by the project's foundation in current GOLD strategy. The trialability of the innovation was demonstrated by piloting the education modules and workflow with staff during implementation. Trialability was enhanced by regular communication with staff and providing workforce support for spirometry visits during implementation. Complexity was reduced by providing innovation that was sensitive to the time constraints of staff. Complexity was reduced by integrating multiple components of the workflow directly into the EHR. Eliciting feedback from the site champion and key stakeholders

during the development and implementation stages of the innovation further optimized each of these characteristics.

Channels of communication that distribute information about the innovation are both interpersonal and electronic. The innovation was disseminated electronically with clinic intranet and public internet. Education modules were available at a live session and offered in electronic form to all other staff at the clinic. Types of adopters, early, late, and laggards, were identified during communication about the innovation. Interpersonal communication occurred individually with staff during all phases of the project, including the project leads' weekly presence at the clinic. Interpersonal communication strategies were more likely to improve the uptake by late adopters and laggards.

Evidence-Based Practice Change Theory

Naming the Change Model. The Plan-Do-Study-Act (PDSA) model has become a versatile change model in healthcare quality improvement. Originally developed by Walter A. Shewhart in the 1920s, the Plan-Do-Check-Act cycle was further developed by W. Edwards Deming in Japan after WWII to improve production in the industry (Butts & Rich, 2018). This model encourages a detailed looked at a process, with repeated cycles of improvement. As the name implies, PDSA has four phases: plan, do, study, and act (Butts & Rich, 2018). The Plan cycle defines a problem within a process and identifies potential solutions. The Do cycle includes small-scale testing of the change identified in the planning cycle. The Study (or Check) cycle evaluates and analyzes the results of the Do cycle. The Act cycle can include either implementing the successful changes to formal practice or applying results to evolve the next Plan cycle.

PDSA in the literature. A review of the literature shows a multitude of applications of the PDSA model in health care. In one study, care for opiate-dependent neonates in a hospital was dramatically improved by utilizing 11 PDSA cycles over the course of three years (Holmes et al., 2016). Overall hospital costs were reduced in the study, including length of stay for infants and pharmacological interventions. Meanwhile, organization improvements occurred, including standardizing assessment tools, improving family education, and increasing family participation in care (Holmes et al., 2016).

Stover and Harpin (2015) also used the PDSA model, through seven cycles in two years, for the psychiatric patients of an emergency department. Using the PDSA model, wait times were reduced, enabling these patients to receive appropriate care quickly.

Application of PDSA to practice change. There were great advantages to using the PDSA quality improvement process in the project. During the project, PDSA provided a framework to quickly adapt feedback from staff, providers, and stakeholders during the 12-week implementation phase.

PDSA cycles provided the project lead and staff the opportunity to give feedback about the revised spirometry workflow. The rapid cycle PDSA model allowed the revised spirometry workflow to be implemented, assessed, altered and then implemented again with each cycle. For formal PDSA cycles with clinic staff, the workflow was developed and implemented in the "Plan" phase. Staff were observed by the project lead while performing the spirometry visits during the "Do" phase. A feedback session occurred after these visits in the "Study" phase, and results reviewed with the project champion. In the "Act" phase, adjustments were finalized and adopted into the workflow. Ultimately the PDSA structure elucidated evaluation and recommendations for sustainability at the site.

Summary

This chapter has explored the most important concepts of the project and identified the outcome as a concept. Theoretical frameworks and conceptual models of change have been identified to aid in the creation, revision, implementation, and evaluation of the project. The Diffusion of Innovation Theory provides a theoretical framework for the creation and adaptation of education and revised workflow. The PDSA conceptual change model will provide a systematic way of revising the workflow with staff input. The refinement of the project was guided by the theoretical and change models, which support sustainability after completion.

Chapter Four: Pre-implementation Plan

This chapter will describe the creation of the project and steps taken before implementation at the site. The project intent and detailed development will be discussed. A risk assessment will be detailed, and an overview of the approval process will be given. Specific data collection and evaluation of the project will be described.

Project Purpose

The purpose of this quality improvement project was to increase staff and provider awareness of best practices for the diagnosis and management of COPD in an outpatient setting. The project was based on the 2019 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Strategy. In line with GOLD strategy, the clinic was already performing spirometry testing visits for suspected and diagnosed COPD patients. A goal of the project was to improve the current spirometry testing visit workflow within the electronic health record (EHR). A checklist of actionable GOLD strategy-based items within the EHR was created for providers to utilize during patient visits. The project site was a free primary care clinic serving low-income, uninsured adults in rural southeastern NC.

The success of the project was evaluated by rates of the following for active COPD patients at the clinic: spirometry testing, tobacco cessation counseling, tobacco cessation, use of COPD symptom questionnaires, prescriptions for inhaled corticosteroids, and health care utilization (ED use and sick visits). No personal health information was collected. Implementation of the improved spirometry workflow was to begin in September 2019. Weekly spirometry visits were planned, and chart audits were to be conducted from August through December. The project's goal, to improve the diagnosis, treatment, and management of COPD, was in line with Healthy People 2020 goals for COPD and the 2017 COPD National Action Plan.

Project Management

Organizational readiness for change. Site representatives showed interest in the project idea from the initial discussion. The site champion and director had been considering strategies for grant funding and improved outcomes for COPD patients. Readiness for change was demonstrated by enthusiasm, willingness to discuss development at regular intervals, and providing suggestions. Site champion and site director supplied resources in the form of time, staff, and supplies to support the planning and implementation of the project.

Interprofessional collaboration. The site champion, the only full-time provider at the clinic, played a vital role in the development and planning for project implementation. The site champion assisted in the development of spirometry workflow and provided valuable insight into the needs of COPD patients and clinic staff. The site director supported the implementation by offering expertise in the area of EHR workflow, creating and generating EHR reports for data collection, and supplying resources to perform spirometry in the clinic. Nursing staff performing spirometry included one full-time staff and two volunteers who were to provide feedback about the workflow during PDSA process improvement. The project lead took the lead role in communicating about the project to the site and facilitating discussion about the project. The project lead communicated with each discipline, from provider to administrative staff, with information about the project relevant to their role, and it functions within the project intent.

Risk management assessment. A risk assessment was performed by the project lead using a strengths, weaknesses, opportunities, and threats (SWOT) analysis. Risk assessment is a valuable tool to identify the internal and external influences that surround a project or plan. Positive and negative implications of a project can be identified, described, and explored in this way prior to implementation.

The strengths of the project included a direct benefit to COPD patients by increasing the efficiency of the encounter between patients and staff. Sustainability and ease of use were potential strengths of the project since changes to the workflow and actionable items were built directly into the clinic's EHR.

The weaknesses of the project included the limitations of staff and resources. The project site was a free clinic operating on a limited budget with few paid staff. Teaching a new process and creating additional workload for staff and volunteers were identified as a weakness.

Opportunities for the project included the acquisition of data for COPD patients to be used for potential grant funding. The project allowed the clinic to enhance its alignment with the policy and practice recommendations of the National Institutes of Health, Rural Health Initiative, and Healthy People 2020 goals. Other opportunities included a workflow strategy framework that could be used for other types of standardized testing performed at the clinic.

Threats to the project included the complexity of the patient population. Patients often have discordant care related to loss of insurance, leading to high rates of no-shows and cancellations. Time was another threat to the project. Changes in data trends are often limited in short project periods. In addition, not all active COPD patients had a provider or spirometry visit during the implementation phase, making data collection skewed towards patients with newly diagnosed COPD.

Organizational approval process. The project was the result of an existing relationship between the project lead and the site. The project lead had been a volunteer at the clinic for over a year prior to the project. The site champion and director were approached in the fall of 2018 with the project idea. Two brainstorming sessions occurred following the initial conversation.

The site champion and director provided feedback about current and future goals for measures in the COPD population, particularly smoking cessation and healthcare utilization.

Additional meetings occurred in the Spring of 2019; email and telephone conversations communicated changes to the project idea during that time. Concerns about staff support, time, and resource limitations inherent to the free clinic were addressed at regular intervals. With the project lead offering to perform spirometry testing, as had been done in a volunteer capacity, the site representatives were confident and supported the implementation phase of the project. The site director provided an organizational support letter as final approval to conduct the project at the clinic (Appendix G).

Information technology. Information technology for use in the project included AllScripts Professional™, the EHR management system used by the clinic. The site director and project lead were able to edit templates within AllScripts Professional™, allowing an improved electronic workflow for clinic staff and providers. The site director and project lead created reports with AllScripts Professional™ generating reports for evaluation of outcome measures. No patient-specific demographics or protected health information was collected. The following Microsoft© applications were used when creating education for the clinic and communicating with the clinic: Word, PowerPoint, Excel, and Outlook Email.

Cost Analysis of Materials Needed for Project

Costs related to the project were minimal. Documents requiring paper copies were printed at the site. Education materials, spirometry visit workflow directions, and symptom questionnaires were stored on the clinic server after printing. The "COPD pocket consultant" guides were ordered in quantity enough for the clinic, requiring only a small shipping fee. A

clinical staff meeting provided an opportunity for on-boarding and education on GOLD strategy. Appendix H contains an itemized budget for the project with an estimated cost of $82.50.

Plans for Institutional Review Board Approval

The project site did not have an IRB or a formal approval process for the project. Approval occurred by meeting with the site champion and director to explain the intended purpose of the project and implementation plan. A letter of approval from the site was drafted, reviewed, and completed (Appendix G). The project lead completed the University IRB verification process using the IRB QI/Program Evaluation Self-Certification Tool. After obtaining approval from the faculty lead, the tool was submitted online. The project was deemed quality improvement, and immediate response was received, stating that IRB review was not required (Appendix I).

Plan for Project Evaluation

Demographics. Participants in the project were providers and nurses at the clinic. The clinic staff was composed of the director, nurse practitioner provider, registered nurse, and two certified medical assistants. Volunteers at the clinic included multiple registered nurses, physician assistants, nurse practitioners, and physicians with varying hours and patient interaction. Two registered nurse volunteers and the staff registered nurse were performing spirometry visits. Information about the project and education modules developed by the project lead was made available to all volunteers and staff.

Primary outcomes for the project were evaluated by a monthly review of COPD patient's charts and reports generated via AllScripts Professional™. No personal health information was gathered, and no subjects were identified. COPD patients included in data capture included

active patients, defined as having had a visit within the year 2019, that had a documented diagnosis of COPD in the EHR.

Outcome measurement. Monthly queries were created within AllScripts Professional™ to trend and track GOLD strategy components for active patients with a COPD diagnosis at the clinic: the presence of spirometry results, tobacco use status, tobacco cessation counseling codes, CAT symptom questionnaire codes, and inhaled corticosteroid prescriptions. Data were reported in monthly percentages and later displayed in graphs (Appendix J). Data collected from chart audits examining healthcare utilization were similarly displayed (Appendix K).

Outcome A. Rates of spirometry results documented in the EHR were an outcome measure of the project. Standard practice at the site was an annual EHR generated query of these rates. A new query was developed to capture monthly rates of spirometry for suspected and diagnosed COPD patients. Rates of spirometry results were evidence of GOLD strategy adherent clinical practice. Post-bronchodilator spirometry is the definitive diagnostic tool for COPD (GOLD, 2019).

Outcome B. Rates of tobacco cessation counseling documented in the EHR was an outcome measure of the project. Monthly queries were generated to determine the number of COPD patients receiving tobacco cessation counseling during a visit to the clinic. Percentages and frequencies were reported.

Outcome C. Rates of tobacco cessation of COPD patients was an outcome measure of the project. Monthly queries were generated to determine the number of COPD patients whose tobacco use status was *non-user*. Rates of tobacco cessation counseling and tobacco cessation are important to the treatment of COPD; tobacco use is the most important modifiable lifestyle factor (GOLD, 2019).

Outcome D. Rates of CAT symptom questionnaire use documented in the EHR were an outcome measure of the project. Monthly queries determined the number of COPD patients who complete the CAT symptom questionnaire. Assessing symptoms with a standardized tool is an important component of GOLD strategy (GOLD, 2019). Assessing the use of the questionnaire indicated uptake of the revised spirometry visit workflow.

Outcome E. Rates of inhaled corticosteroid use were an outcome measure of the project. Monthly queries determined the number of COPD patients who had an active ICS or ICS combination prescription. The most recent GOLD strategy recommends reserving inhaled corticosteroids for more advanced stages of the disease, exacerbations, and asthma/COPD overlap.

Outcome F. Healthcare utilization of COPD patients was an outcome measure of the project evaluated by a review of patient charts. Charts were reviewed by the project lead to track the percentages of COPD patients with ED/hospital visits during the months of September, October, and November. A retrospective chart audit on COPD patient's visits during the same period in 2018 period was conducted for the comparison. Data collected from the chart reviews were entered into an Excel spreadsheet identifying the number of ED visits/hospitalizations and primary symptoms reported (Appendix K). Capturing healthcare utilization data was important to the project site and offered insight into managing exacerbations in the COPD patient population, congruent with GOLD strategy and Healthy People 2020. Respiratory Diseases objectives RD-11 and RD-12 of HealthyPeople2020 specifically identify reductions in hospitalizations and ED visits related to COPD as target goals.

Evaluation tool. Data collected from generated reports and chart reviews were entered into an Excel spreadsheet for data analysis. Two tools were used for data collections: GOLD

Strategies Component tool (Appendix J) and Healthcare Utilization tool (Appendix K). Outcomes were reported as descriptive statistics, using percentages, and data was later displayed in tables and graphs.

Data analysis. Data were analyzed according to improvements in rates of outcome measures A-F as described above, which are integral to the clinical application of GOLD strategy. While GOLD strategy offers recommendations to improve the diagnosis, treatment, and management of COPD, no formal benchmarks have been established. The clinic goal was 70% spirometry for COPD patients and 100% tobacco cessation counseling. The National COPD action plan and Healthy People 2020 have no benchmarks for outcome measures.

Data management. Data was collected through the clinic EHR using system-generated reports and individual chart audits, then transferred to an Excel spreadsheet (Appendix J; Appendix K). No patient identifiers were used when creating system generated reports; the fields were limited to *currently active patients* and *patients with a COPD diagnosis*. Data were analyzed by the rates of specific outcomes. Clinic generated medical record numbers were captured by the report query and used to identify redundancies during chart audits.

The site champion and site director had access to the data, and storage methods were in compliance with clinic and university protocol. Allscripts generated reports were available through the Allscripts software and backed up with the Allscripts server. Data entered into Excel was stored on a password-protected computer in a locked office at the clinic. Any paper documents collected for chart audits stayed onsite at the clinic and were shredded after use.

Summary

This chapter has outlined the overall creation and development of the project. As part of the pre-implementation process, the project was deemed as quality improvement, not requiring

further IRB review. The relationship with the project site was mutually beneficial and supportive in planning and development. Risk analysis offered insight into aspects of the project needing consideration, especially the resource limitations at the project site. Data outcomes related to GOLD strategy for COPD patients were considered from initial idea through pre-implementation planning. Data collection and analysis included tracking and trending the rates of specific patient outcomes in COPD management to evaluate uptake of the improvements in clinic workflow. Descriptive statistics were used to describe outcome data, displayed with tables, graphs, and figures.

Chapter Five: Implementation Process

This chapter will describe the setting, participants, and implementation process. The implementation period was August through December 2019, with weekly onsite visits by the project lead. Participants were staff and volunteers at the clinic, caring for COPD patients. The project lead performed weekly spirometry testing and PDSA cycles to evaluate the revised workflow developed for spirometry testing. Meanwhile, during the implementation period, the project lead tracked data from reports developed from the site electronic health record (EHR). The data outcome measures were derived from key points of GOLD strategy.

Setting

The project took place at a community-based primary care clinic in rural southeastern NC. The clinic is a 501(c)3 non-profit organization, unaffiliated with any organization or institution. Funding is provided by grants, individual and corporate donations, church and civic group donations, and fundraisers. The clinic serves qualifying low-income, uninsured adults currently residing in the county. Overall the clinic serves approximately 1200 people a year. At the start of the project, there were 113 active patients with a diagnosis of COPD. Many other patients were awaiting spirometry testing to evaluate COPD as a suspected diagnosis. The clinic interest in the project was improved patient care for COPD patients, as well as improved funding for grant and private donations. Aspects of the project were congruent with patient-centered medical home measures. Improvements in care and outcomes for COPD patients were also in line with the values and mission of the clinic.

Participants

Participants included the nursing staff and providers at the clinic who interact with COPD patients. Inclusion criteria included any nurse or provider, paid or volunteer, working in the

clinic at the time of the project. Nurses included one full-time employee, two volunteers currently providing support for spirometry visits, and another volunteer who collaborated with the project lead to make EHR modifications for the project. Providers include one full-time employee and up to four volunteer providers who saw patients during implementation. The full-time provider, also the project champion, was the primary provider for the purpose of the project. The primary provider was notified of completed spirometry visit results during the implementation period as part of the new workflow strategy. The primary provider then viewed results and signed off on encounters, making any changes to treatment plans and follow up.

Recruitment

Participants were a convenience sample due to their employment or volunteering schedules at the clinic during project implementation. Onboarding of staff and providers occurred during a clinical staff meeting held on August 29 in which the project lead presented an educational module about the current GOLD strategy for care of COPD patients, an overview of the DNP project, and modifications to documentation in the EHR. Regular informal communication about the project occurred during weekly visits by the project lead. Site champion and site director assisted in engaging staff and providers informally during daily operations at the clinic during project implementation.

Informal conversations about the project with staff and volunteers prior to implementation were brief but encouraging. Perceived barriers prior to implementation included time and resource limitations. Employed staff is few, and each has a large scope of responsibilities and obligations related to the free clinic's operations.

Implementation Process

The implementation process occurred during the Fall semester of 2019, from late August through December. The project lead was present at the clinic weekly for spirometry visits, staff follow-up, and data gathering during the implementation period.

EHR revisions. Prior to the implementation period, automated monthly reports were created in the EHR by the project lead and site director. These reports provided the data outcomes described in Chapter Four, demonstrating the effects of the project on COPD patient care. The project lead examined these reports each month to track and trend outcomes data of the project (Appendix J; Appendix K).

The project lead and site director made several modifications to the EHR to improve visit workflow. First, a shortcut to commonly used orders was created for providers to access within the "COPD" diagnosis portion of the "Assessment & Plan." Second, the CAT questionnaire was flagged as a lab result within the EHR so that staff and providers could enter and track this data over time (Appendix B). Third, changes were made to the "results" portion of the "in-house spirometry procedure" for more accurate documentation during spirometry visits.

Education modules and materials. At the start of implementation, the project lead presented education during a regularly scheduled clinical staff meeting on August 29th. The lead shared a brief synopsis of the project and information about GOLD strategy for COPD. Providers were instructed on changes to EHR workflow applicable to care of COPD patients at the clinic. Special attention was given on the use of the COPD Assessment Test (CAT) for symptom assessment and the COPD Pocket Consultant to guide treatment (Appendix B; Appendix C). All materials, including the PowerPoint presentation, were made available in a binder placed in the volunteer provider office. The CAT questionnaire and COPD Pocket

Consultant were made available on the quick reference wall in the exam room hallway. Nursing staff education occurred one-on-one with the project lead each week as the spirometry visit workflow was developed. Two step-by-step workflow documents were created for spirometry visit performance and spirometry documentation (Appendix L; Appendix M). These documents were made available in hard copy form with the equipment and electronically.

Project lead visits. Prior to implementation, the project lead volunteered at the site and conducted spirometry testing. The project lead was on-site each Wednesday to perform spirometry visits during implementation to improve staff buy-in of the project and revise and evaluate the workflow in practice. During implementation, the project lead facilitated teaching, assisting, and observing staff perform the revised spirometry workflow using the PDSA framework at regular intervals.

The project lead gathered and evaluated data monthly on outcomes A-F: spirometry results, tobacco use status, tobacco cessation counseling, CAT symptom questionnaire, and inhaled corticosteroid prescriptions. Each of the outcomes measured an aspect of GOLD strategy for primary care and was trended to evaluate for the uptake of the project. Data were collected and entered in Excel spreadsheets (Appendix J).

The charts of active COPD patients were evaluated for ED use and hospitalizations related to COPD during the same three-month period (September, October, and November) in 2018 and 2019, outcome G. Data was collected and entered in an excel spreadsheet on an ongoing basis throughout the implementation period (Appendix K).

PDSA cycles. PDSA cycles of the spirometry visit, formal and informally, occurred during the project implementation. The first three PDSA cycles involved an informal self-assessment of the visit workflow by the project lead. Informal PDSA cycles were focused on

streamlining the workflow for timeliness, capturing relevant data patient history information, and optimizing documentation. Formal PDSA cycles evaluated monthly data outcome trends and observation of nurses conducting spirometry visits. During the final PSDA cycle, nurses performed spirometry visits independently with revised workflow instructions and provided final feedback to the project lead. The final version of the workflow was made available with spirometry equipment and on the clinic server (Appendix L; Appendix M).

Plan Variation

Aspects of the project plan were revised during implementation, without deviating from the overall purpose of the project or requiring any change in data collection. The opportunity for both onboarding and educating multiple providers and staff during the clinical meeting occurred at the start of implementation, eliminating the need for a separate information session. As the project began, availability of staff and volunteers to observe and conduct spirometry visits was more limited than expected; as a result, one-on-one teaching of the revised spirometry visit and formal PDSA cycles were reduced in number. Timeline for teaching and PDSA cycles was delayed by a change in equipment. During the project, current equipment required parts that were no longer being manufactured related to age and the accuracy of the machine was questioned. The site champion and site director agreed that new equipment was needed, and a spirometer was secured with minimal interruption to the project or scheduled spirometry visits. The project lead was responsible for learning and teaching the new equipment to staff and volunteers, which resulted in the delayed engagement of nurses.

Summary

This chapter has described the specific details of project implementation. Participants and setting have been defined. Strategies for communicating information about the project to

site participants and recruitment details have been discussed. The implementation strategy for the project lead has been detailed: pre-implementation EHR adaptations and education materials, the performance of spirometry and PDSA cycles with staff, and data collection during implementation. Variations in the plan have been described, adding context to the project implementation phase.

Chapter Six: Evaluation of the Practice Change Initiative

This chapter will describe the final data outcomes of the implementation project. Short, intermediate, and long-term outcomes will be identified. Findings will be characterized and visually displayed to demonstrate their relevance to practice change at the site. The significance of each of the data outcome findings will be discussed, demonstrating relevance to GOLD strategy. Successful uptake of the project and a trajectory towards sustainable change after implementation will be described.

Participant Demographics

Project participants were staff and providers at the clinic. During the project implementation period, there were six providers present at the site who were made aware of the changes to spirometry visit workflow, use of the CAT questionnaire, and the COPD pocket consultant. During the project implementation period, there were three staff and volunteers who directly performed the in-house spirometry visits with patients. Participants' identities were kept confidential, and no other demographic data was obtained.

Aspects of care for COPD patients defined the outcome measures. A COPD diagnosis in the site's EHR and active patient status (defined as at least one visit in the 2019 calendar year) were the only demographic criteria included. There was a total of 109 patients with the diagnosis of COPD at the beginning of the project compared to 126 patients at the end of the project. The increase in numbers reflects both newly diagnosed patients with COPD as well as new patients entering the practice with the diagnosis of COPD. No other demographic variables were collected for project outcome measures.

Intended Outcomes

The primary project outcome was successful uptake of the revised spirometry visit workflow. This was demonstrated through the following short, intermediate, and long-term outcomes.

The short-term outcome of the project was educating providers and staff on relevant components of GOLD strategy for primary care. This outcome was met through the education session offered at the start of implementation, as described in Chapter Five. An additional short-term outcome was the creation and revision of a workflow for in-house spirometry based on existing process at the site (Appendix L; Appendix M). Several informal PDSA cycles aided in the design of a final process to be adopted.

Intermediate outcomes were identified as provider application of GOLD strategy and use of the revised spirometry visit workflow. These outcomes were evaluated by systematically measuring components of GOLD strategy relevant to patient care at the project site. As described in Chapter Five, rates of spirometry, tobacco cessation counseling, tobacco cessation, use of the CAT questionnaire, and inhaled corticosteroid (ICS) prescriptions rates were measured at the beginning and monthly during implementation. These outcomes demonstrated the impact of the education session and spirometry visit workflow. Improvements in these areas, displayed in Table 1, show the influence of the project on patient care.

The long-term outcome of the project is the continued use of the spirometry visit workflow and application of GOLD strategy after project completion. Long term outcomes can be evaluated by the project site in the future using the queries developed during implementation. Long term outcomes were not assessed during implementation, given the short duration of the project period.

Findings. Project-specific findings, derived from data collected during the project, showed positive impacts on patient care at the site. These included increased rates of spirometry, increased tobacco cessation counseling, increased tobacco cessation, use of the CAT questionnaire, and a decrease in prescriptions for inhaled corticosteroids. Table 1 shows the measurable changes in practice through implementation. This table displays data outcomes for each measure of the project. Rates, described as percentages, are shown for each month of data collection. Trends for these measures demonstrate practice changes congruent with GOLD strategy. They also reveal the successful uptake of education and workflow created for the site.

Table 1

Percentage Rates of COPD Patients Related to GOLD strategy Components

	September	October	November	December	January
Spirometry	63.7	67.3	70.7	70.5	71.4
Tobacco Users	85.3	85	85.3	86	83.3
Cessation Counseling	97.2	97.3	97.4	97.1	99
ICS prescriptions	73.4	72.6	71.6	72.1	65
CAT questionnaire	0	10.6	15.5	17	20.6

Initial rates of spirometry at the project site were 63.7% with gradual improvements to 71.4% in the four-month implementation period. This reflects an overall increase of 7.7% during implementation. While there are no national standards, GOLD strategy recommends that all patients with COPD have the diagnosis confirmed with spirometry (GOLD, 2019). The project

provided an overall increase in spirometry rates at the site, underscoring the importance of a spirometry confirmed diagnosis.

Rates of tobacco cessation counseling, which were near 100% before implementation, rising from 97.2% initially to 99% after project implementation. The standard of care specified by GOLD strategy is that all tobacco users with COPD be counseled to quit. There are a variety of methods to explore based on provider and patient preference, availability, and the topic should be addressed as every encounter (GOLD, 2019). Tobacco cessation counseling was incorporated directly into the spirometry visit workflow (Appendix L; Appendix M). As the most important modifiable risk factor, tobacco cessation at the primary care level is crucial to the management of COPD.

Rates of tobacco use by patients with COPD showed a slight decrease during project implementation. While chart audits revealed that no patients successfully quit during the project implementation, it was noted that some COPD patients were already non-users when they entered care at the site during the implementation period. The small but 2% decrease in COPD patients using tobacco remains significant, demonstrating that clinician contact and counseling may play a role in aiding patients to quit.

Rates of CAT questionnaire usage increased from a baseline of zero, as this was a new practice change. The CAT questionnaire was previously unknown to many of the project participants. During monthly chart audits, it was seen that providers used the CAT questionnaire during routine patient encounters, an unanticipated but positive finding beyond the project intent. This combined use demonstrated a robust uptake of the questionnaire into clinical practice. Overall, CAT questionnaire usage went from 0 to 20.6% of patients with COPD over the four-month implementation period. As has been previously described, this a significant factor in the

treatment and pharmacological management of patients with COPD (GOLD, 2019). The implications of CAT use overall are the improved assessment and treatment of COPD patients, as recommended by GOLD strategy.

Initial rates of ICS prescriptions were 73.4% prior to implementation, decreasing to 65% by end of the four-month project. This slight decrease reflects an improvement consistent with GOLD strategy recommendation. This was potentially reinforced by the availability of the COPD pocket consultant in the clinic after the education sessions. GOLD strategy recommends the use of ICS for more advanced stages of COPD or refractory symptoms and exacerbations (GOLD, 2019). Rates declined by 8% overall during project implementation.

Healthcare utilization was determined to be unchanged between the same four-month period in 2018 and 2019. There was a total of 3 ED visits/hospitalizations related to COPD in the year 2018 compared the same number of ED visits/hospitalizations related to COPD seen in 2019. No further review was conducted related to this outcome and is not reflected in Table 1.

Summary

Findings from data collected during the project implementation period have been described and displayed in this chapter. Measurable data outcomes reveal successful practice change and improved patient care of COPD patients congruent with GOLD strategy. The primary outcome of the project was met, as well as the short-term and intermediate goals. The workflow was successfully adapted into practice, and GOLD strategy was applied in patient care by providers and staff at the project site.

Chapter Seven: Implications for Nursing Practice

The American Association of Colleges of Nursing defined eight essentials in 2006 for doctoral nursing education and practice. The DNP project, in general, fulfills these essentials in various ways throughout the process of development, implementation, synthesis, and dissemination. This chapter will describe how each of the essentials was integrated into this project. Implications for practice and specific examples related to each essential will be discussed.

Practice Implications

Essential I: Scientific underpinnings for practice. This essential engages nurses at the highest level of science, combining physical science with theory to evaluate and implement evidenced-based practice (AACN, 2006). As applied to the project, this essential was demonstrated by the integration of clinical knowledge and practice. Examples of this essential in the project included both the education component and PDSA workflow improvements. Understanding the pathophysiology and pharmacology of COPD provided the basis for applying diagnosis, treatment, and management recommendations as outlined in GOLD strategy. This knowledge was then synthesized and presented to a variety of clinical roles. The project lead also used the PDSA model as the theoretical basis for practical application of the quality improvement project. Spirometry visit workflow was improved systematically using the PDSA model. Implications to practice include the practical use of the PDSA model to improve an existing workflow. Other implications for future practice include the ability to synthesize and present relevant information to primary care clinicians.

Essential II: Organization and systems leadership for quality improvement and systems thinking. This essential prepares the doctoral nurse to understand, engage, and promote

best practice at the highest level of a healthcare organization and patient care delivery (AACN, 2006). As applied to the project, this essential was demonstrated in the development of the project to address the specific needs of the project site. Special care was taken to develop a quality improvement project that would limit the burden on staff and resources while also improving outcomes for patients. Implications for practice include lessons learned about adapting a quality improvement project to a free clinic with minimal staff and resources. An example of this essential included building data collection tools upon existing measures at the project site for a specific population, COPD patients. Another example was the project lead's ability, as an existing volunteer at the project site, to perform spirometry for patients during the project period, which in turn provided ample opportunity to evaluate and adjust workflow and support staff at the site.

Essential III: Clinical scholarship and analytical methods for EBP. This essential prepares the doctorate nurse to critically evaluate and translate clinical knowledge into practice (AACN, 2006). Related to the project, the rigorous review of current literature informed the project design for best practice in COPD diagnosis, treatment, and management. Implications for practice include the ability to create and utilize a literature matrix, synthesize information, and present topics to an interdisciplinary audience. Examples of this essential included developing a thorough working knowledge of best practice specified in GOLD strategy, developing education and project components, and providing a short education module to interdisciplinary staff. The project lead was able to critically evaluate guidelines, standards of care, and clinical tools for practice (such as the COPD pocket consultant used for the project) to develop and implement the project. Implementation of the project utilized the PDSA model framework to design, perform, evaluate, and adapt the workflow for spirometry visits. These

methods have implications for future nursing practice, providing practical application of the PDSA rapid cycle framework to improve an existing process.

Essential IV: Information systems/technology and patient care technology for the improvement and transformation of healthcare. This essential prepares the doctoral nurse to utilize and adapt rapidly changing healthcare technologies to best benefit patient care (AACN, 2006). As related to the project, this essential is defined as learning and adapting the project site's electronic health record (EHR) to meet the design of the project. Implications to nursing practice included improved informatics literacy and maintaining a multidisciplinary perspective on informatics systems. For example, the project included strategic adjustments of EHR workflow for efficiencies in clinicians' time, thereby creating more meaningful encounters with patients. Specific changes made to the EHR included: spirometry visit templates, order sets for providers, inhaler medication lists, and report queries for project data collection.

Essential V: Healthcare policy for advocacy in healthcare. This essential prepares the doctoral nurse to critically analyze policy and demonstrate leadership in the public health sphere (AACN, 2006). As applied to the project, this essential was demonstrated by the project's alignment with COPD National Action Plan Goal 5: "Translate national policy, educational, and program recommendations into research and public health care actions" (NIH, 2017). Information technology in healthcare, through the EHR and data collection, is an important way in which practice standards become action. Implications for future nursing practice include the experience of adopting an EHR to meet best practice standards. Another implication to practice includes the successful implementation of a quality improvement project which translated measurable patient-related data outcomes. This essential was demonstrated by clinical

application of the COPD Assessment Test (CAT) symptom questionnaire into patient visits as a lab value. In this way, a standardized assessment tool was operationalized into practice.

Essential VI: Interprofessional collaboration for improving patient and population health outcomes. This essential prepares the doctoral nurse to understand and communicate with other healthcare disciplines as a leader in the team-based approach to healthcare (AACN, 2006). As applied to the project, this essential was demonstrated in communication between disciplines throughout all phases of the project. The primary collaboration was between project lead, site director, staff NP, and staff nurses. Implications for practice include timely, constructive communication, feedback, and collaboration about project goals. Examples from the project include the following: leading the interprofessional team, reviewing and revising education components with project champion, modifying the EHR in collaboration with the site director, relationship building with the common goal of improving COPD patient care, and the unexpected task of teaching new spirometry equipment to staff during implementation. Another important example of interprofessional collaboration included the revised spirometry visit structure, which standardized communication among care team members. The use of the COPD pocket consultant was another example of a standardized communication tool among providers at the site.

Essential VII: Clinical prevention and population health for improving the nation's health. This essential focuses on the doctoral nurse as an advocate for population-level healthcare change to promote health and wellness through the lifespan (AACN, 2006). As applied to the project, this essential was demonstrated in the project's alignment with COPD National Action Plan Goal 2: "Improve the diagnosis, prevention, treatment, and management of COPD by improving the quality of care delivered across the health care continuum" (NIH,

2017). Implications to practice include increased awareness of COPD management and the translation of COPD National Action Plan goals into future practice. Specific examples of this essential include the dissemination of COPD best practices into the local community: volunteer providers and staff at the clinic will bring the principles learned about GOLD strategy through the project into various other practices throughout the community in which they work. Examples of improvement in population health included improved rates of spirometry for diagnosing COPD, increased tobacco cessation counseling, decreased rates of tobacco use, and decreased rates of inhaled corticosteroid use.

Essential VIII: Advanced nursing practice. This essential prepares the doctoral nurse to fully integrate their education and training into clinical practice (Moran, Burson, & Conrad, 2017). Implications of future practice include full understanding of the advanced practice nurse role in improving the health of populations. In the project, this was demonstrated by relationship-building with site staff including the having a practicing nurse practitioner as project champion. The project lead's future practice and quality improvement initiatives are now informed by collaborating with a knowledgeable and experienced nurse practitioner clinician. The project lead, having successfully designed, implemented, and evaluated a quality improvement project, has demonstrated practicing to the full extent of education and training in the primary care setting.

Summary

This chapter has included the eight essentials of DNP education and the relevance of each essential to the DNP project. During phases of development, implementation, and evaluation, the project lead was able to utilize scientific process and current technology, translate knowledge into practice, design practice changes through multidisciplinary collaboration, with the ultimate

goal of improving COPD patient outcomes at the project site. The DNP essentials have been demonstrated with specific examples, and implications for further nursing practice have been explored. In summary, the DNP project has provided extensive educational and experiential training in all realms of the eight DNP essentials.

Chapter Eight: Final Conclusions

This chapter will describe the conclusions of the project and the importance of data outcome findings. A description of how COPD care at the project site improved during the four-month implementation period will be provided. Project's strengths and weaknesses and implications to practice will be discussed.

Significance of Findings

The project outcomes demonstrate that standard care measures can positively influence patient outcomes for COPD patients at a primary care site. By creating awareness of GOLD strategy and implementing a standard procedure for spirometry visits, COPD management showed measurable improvement.

Project outcomes, described in Chapter Six, were developed from GOLD strategy and National COPD Action Plan goals. The project outcomes showed an improvement in several components of best practice. Key findings associated with improvement in care for patients with COPD included: increased rates of spirometry, increased counseling for tobacco cessation, and symptom assessment through use of the CAT questionnaire. The outcomes demonstrated efficiency of care and evidenced-based treatment at work in clinical practice. Such strategies can potentially decrease the likelihood of exacerbation rates and hospitalizations. Triple Aim Initiatives, to improve the quality of care, the health of populations, and cost, were also advanced for COPD patients with the work of this project.

The project positively impacted the staff and providers at the site. The site welcomed the project, new information about COPD management was shared, and rural health grant funding was bolstered by the data generated in the project. Additionally, staff and volunteers performing spirometry visits remarked positively on several components of the project. Staff and volunteers

appreciated the revised visit structure, remarking on its' ability to accomplish multiple tasks in a single patient encounter.

Volunteer and staff providers were eager to use the COPD pocket consultant, a useful strategy for the dissemination of information. As many providers and staff work in settings beyond the project site, there was great potential for expanding GOLD strategy into community practice, reaching a higher population of patients with COPD.

Project Strengths and Weaknesses

The strengths of the project included functionality and adaptability. Convenient hardcopy evidence-based materials were provided to the clinic, including the PowerPoint education module, COPD pocket consultant, and spirometry visit workflow. Data outcomes generated from the project were efficiently utilized to support grant funding opportunities for the year 2019. By the end of implementation, one staff and one volunteer were independently completing spirometry visits using the revised workflow. These various examples demonstrate that the project was adaptable, serving more than one purpose for the site.

Interprofessional collaboration was also identified as a key strength of the project. By increasing awareness of GOLD strategy across several disciplines in the clinic, there was a more unified approach to the care of COPD patients. Interprofessional communication also improves the understanding of various roles at the site.

Another strength of the project was improved education for patients with COPD. The revised spirometry workflow successfully included two essential points of education: tobacco cessation and inhaler use. Including time for both education pieces in the revised spirometry workflow, patients gained tools for disease self-management.

Provider education was another strength of the project. The introduction of the CAT questionnaire and COPD pocket consultant was an integral component to sustaining practice change. These tools standardized the large quantity of information contained in the 2019 GOLD strategy into a quick reference and were received with enthusiasm by the providers.

An increase in the number of spirometry visits performed was another strength of the project. Weekly scheduled visits, compared to the usual standard of monthly, allowed for flexibility in scheduling for patients, opportunities for evaluation of the workflow with PDSA cycles, and input from the staff and volunteers. An increased number of visits also allowed for enough time in teaching the workflow to staff and volunteers.

The weaknesses of the project included setbacks with equipment and change in EHR systems. Spirometry equipment failures early in the implementation period were unexpected. It was the project lead's responsibility to learn and teach the new equipment to staff, which delayed revising the spirometry visit workflow. This change delayed teaching the new process to staff and volunteers. Another unexpected event was a change of EHR systems at the end of implementation that led to a gap in documentation. The revised workflow, which focused on EHR specific aspects of documentation, could not be directly applied to the new system. However, the essential points of the workflow can be adapted to the new system.

Project Limitations

Project limitations were anticipated before implementation. Limitations of support staff, time, and budget were expected because of the site's free and charitable status. Staffing was a limitation and consisted of one staff and one volunteer available to carry on the spirometry visits after completion.

Recruitment of additional volunteers, via email and in person, was initiated but unsuccessful. The frequency of visits was another limitation. While the project lead was able to conduct weekly spirometry visits during implementation, spirometry visits resumed a monthly frequency after that. The project time frame was a limitation with only four-month implementation period for collection of data on COPD care and management. Healthcare utilization as a data outcome measure was also difficult to quantify because of the limited time frame of the project.

Project Benefits

Patient care and efficiency were some of the most important overall benefits of the project. Improvements in the care of patients with COPD was crucial, in line with National COPD Action Plan goals, and demonstrated clearly in the data outcomes. While the project did not conduct a cost saving analysis, there were great potential cost savings associated with improved COPD care. Reduced exacerbations and decreased hospital/ED use are directly in line with Triple Aim Initiatives and Healthy People 2020 goals. Direct costs per patient with COPD, defined as medications and diagnostics, ED visits, and hospitalizations, as well as outpatient consultations, were recently estimated at $10,367 annually in the US (ur Rehman et al., 2019). Costs are directly influenced by disease severity and exacerbation frequency; therefore, the importance of early and frequent intervention at the primary care level cannot be underestimated (ur Rehman et al., 2019). This project has demonstrated ways in which best practice in an outpatient setting improve the downstream effects of COPD.

The efficiency of care was another significant benefit of the project. The spirometry visit was designed to meet several goals and education points during one single encounter with COPD patients. Many patients at the site struggle with reliable transportation; therefore, maximizing

visit efficiency is vital. Having a standardized procedure, repeatable for each spirometry visit, greatly benefits the project site (Appendix L; Appendix M). Other benefits included the zero cost of the project. Minimal disruption to the overall workflow of the clinic was another benefit. Spirometry visits were conducted in a similar manner and time frame.

Practice Recommendations

It is recommended that the practice continues with the revised spirometry workflow. The site should strongly consider adapting the revised workflow into the new EHR system. The workflow can be altered for documentation purposes, focusing on the implementation of the CAT questionnaire, tobacco cessation counseling, and inhaler education into the workflow. A potential improvement could be the evaluation of the new spirometry equipment functionality and direct linkage with the new EHR. This type of connectivity would limit the steps required in workflow and documentation.

It is also recommended that the site continue to utilize the COPD pocket consultant in practice. Fifty copies of the pocket guide were given to the clinic for future use, and information was provided about obtaining more at a minimal cost. This pocket guide contains the CAT questionnaire, treatment, and medication recommendations, tobacco cessation and vaccination guides, and more. COPD pocket consultant is also available in the form of a free web-based smartphone app. These are essential clinical decision-making tools for the care and management of COPD patients, which can become an essential force for practice change beyond the project site.

It is recommended that GOLD strategy awareness continue to increase beyond the scope of this project. Keeping advised of treatment updates using continuing education on GOLD strategy is a key component of continuing advanced provider practice. As the education was

available to providers who work in wider community settings, this project reached more staff and patients than was originally intended. Greater community awareness of GOLD further advanced the ultimate aims of the COPD National Action, Healthy People 2020 goals, and Triple Aim Initiatives.

Final Summary

To conclude, the implementation project successfully improved COPD patient care at the project site. The clinical implications of the project, seen in the data outcomes, demonstrate that the project successfully improved the care of patients with COPD in an outpatient setting. Staff and providers were engaged in the education, workflow changes, and outcome measures, and plan to adopt the workflow into clinical practice. Education and a revised workflow improved COPD patient care at the site. COPD National Action Plan goals were advanced by this project, providing community and clinic awareness of GOLD strategy and improving COPD patient care outcomes. Ultimately, this project served the Triple Aim Initiatives: to improve the quality of care, the health of populations, and reduce cost.

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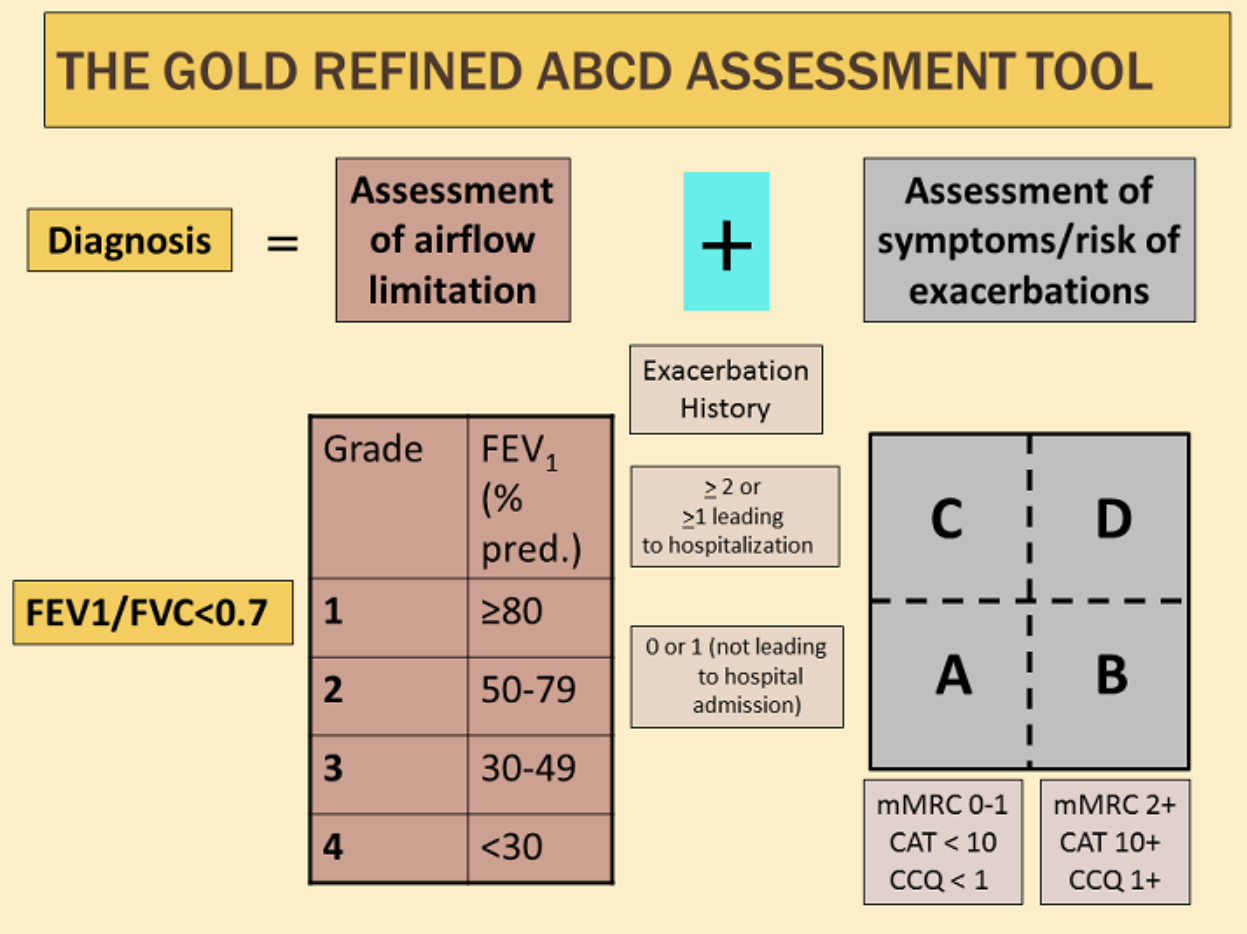
Appendix A

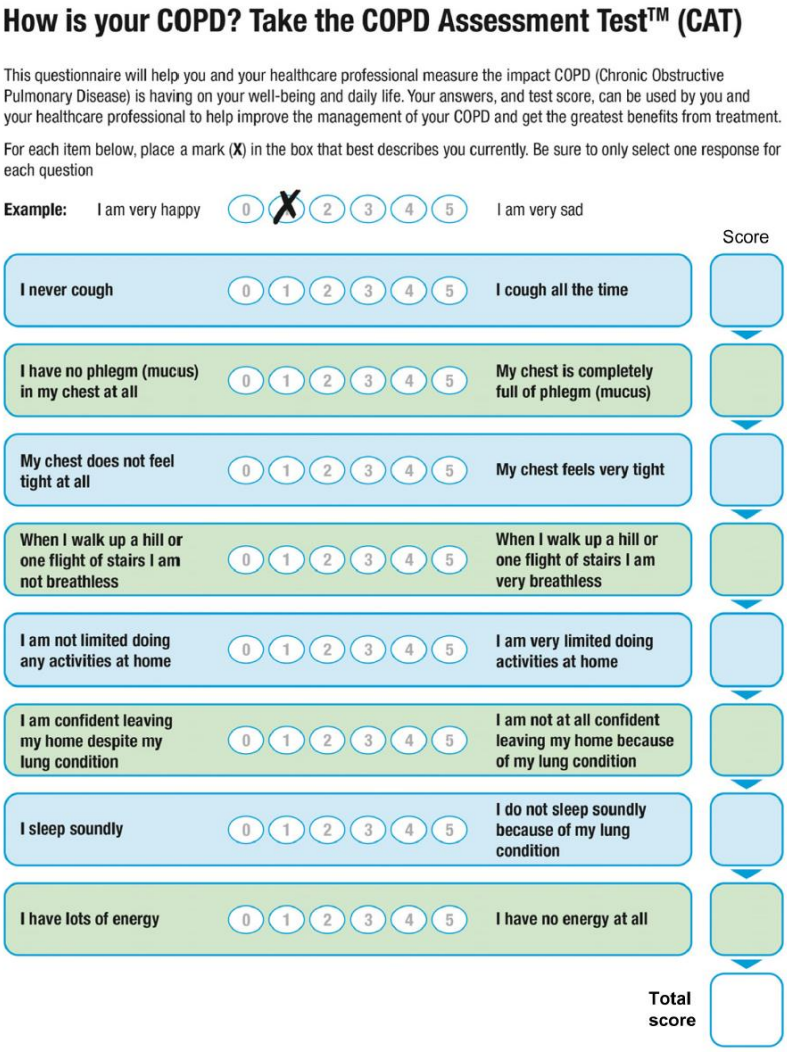
Refined ABCD Assessment Tool



The refined ABCD assessment tool. FEV1: forced expiratory volume; FVC: forced vital capacity; mMRC: modified Medical Research Council; CAT: COPD Assessment Test. Adapted from Global Initiative for Chronic Obstructive Lung Disease (GOLD), (2019). *Global strategy for the diagnosis, management, and prevention of COPD.*

Appendix B

CAT Symptom Questionnaire



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

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

For each item below, place a mark (**X**) in the box that best describes you currently. Be sure to only select one response for each question

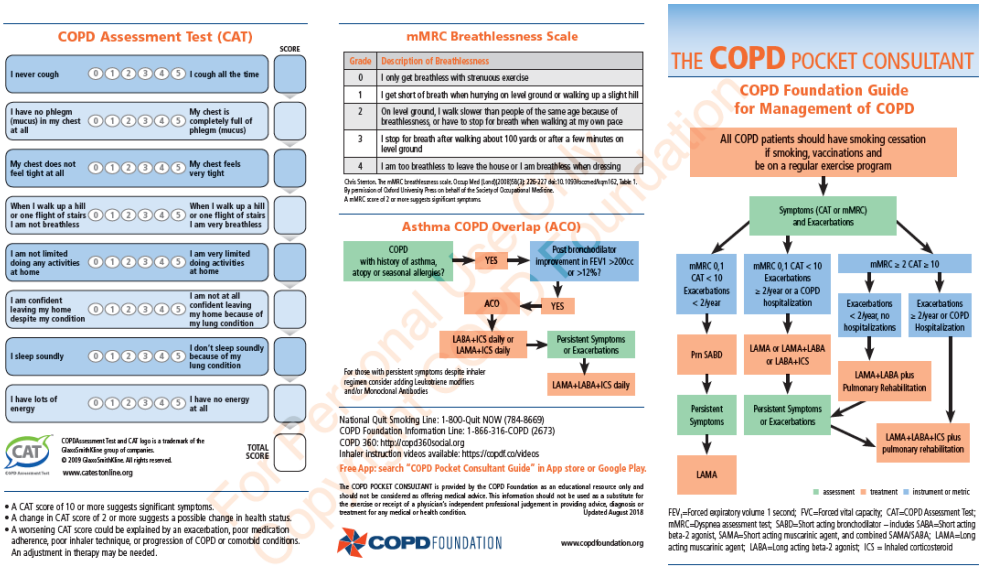
Example: I am very happy 0 X 2 3 4 5 I am very sad

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

COPD assessment test (CAT), for use with refined ABCD assessment tool. Adapted from "Development and first validation of the COPD Assessment Test" by P.W. Jones, G. Harding, P. Berry, I. Wiklund, W.H. Chen, & N.K. Leidy, 2009, *European Respiratory Journal*, *34*(3), 648-654. Copyright 2009 by GlaxoSmithKline.

Appendix C

COPD Pocket Consultant



COPD Assessment Test (CAT)

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

CAT COPD Assessment Test

COPD Assessment Test and CAT logo is a trademark of the GlaxoSmithKline group of companies. © 2009 GlaxoSmithKline. All rights reserved. www.catestonline.org

- A CAT score of 10 or more suggests significant symptoms.
- A change in CAT score of 2 or more suggests a possible change in health status.
- A worsening CAT score could be explained by an exacerbation, poor medication adherence, poor inhaler technique, or progression of COPD or comorbid conditions. An adjustment in therapy may be needed.

mMRC Breathlessness Scale

Grade	Description of Breathlessness
0	I only get breathless with strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness, or have to stop for breath when walking at my own pace
3	I stop for breath after walking about 100 yards or after a few minutes on level ground
4	I am too breathless to leave the house or I am breathless when dressing

Chris Stenton. The mMRC breathlessness scale. Occup Med (Lond) (2010;60(8)) 226-227 doi:10.1093/occmed/kqp162, Table 1. By permission of Oxford University Press on behalf of the Society of Occupational Medicine. A mMRC score of 2 or more suggests significant symptoms.

Asthma COPD Overlap (ACO)

For those with persistent symptoms despite inhaler regimen consider adding Leukotriene modifiers and/or Monoclonal Antibodies

National Quit Smoking Line: 1-800-Quit NOW (784-8669)
COPD Foundation Information Line: 1-866-316-COPD (2673)
COPD 360: http://copd360social.org
Inhaler instruction videos available: https://copdf.co/videos

Free App: search "COPD Pocket Consultant Guide" in App store or Google Play.

The COPD POCKET CONSULTANT is provided by the COPD Foundation as an educational resource only and should not be considered as offering medical advice. This information should not be used as a substitute for the exercise or receipt of a physician's independent professional judgement in providing advice, diagnosis or treatment for any medical or health condition. Updated August 2018

COPD FOUNDATION www.copdfoundation.org

THE COPD POCKET CONSULTANT

COPD Foundation Guide for Management of COPD

All COPD patients should have smoking cessation if smoking, vaccinations and be on a regular exercise program

FEV_1=Forced expiratory volume 1 second; FVC=Forced vital capacity; CAT=COPD Assessment Test; mMRC=Dyspnea assessment test; SABD=Short acting bronchodilator – includes SABA=Short acting beta-2 agonist, SAMA=Short acting muscarinic agent, and combined SAMA/SABA; LAMA=Long acting muscarinic agent; LABA=Long acting beta-2 agonist; ICS = Inhaled corticosteroid

Assess Severity Domains

Each domain may have therapeutic implications.

Spirometry Grades:

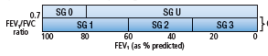
SG 0 Normal spirometry does not rule out emphysema, chronic bronchitis, asthma, or risk of developing either exacerbations or COPD.

SG 1 Mild: Post bronchodilator FEV_1/FVC ratio<0.7, $FEV_1 \geq 60\%$ predicted.

SG 2 Moderate: Post bronchodilator FEV_1/FVC ratio<0.7, $30\% \leq FEV_1 < 60\%$ predicted.

SG 3 Severe: Post bronchodilator FEV_1/FVC ratio<0.7, $FEV_1 < 30\%$ predicted.

SG U Undefined: FEV_1/FVC ratio$\geq$0.7, FEV_1<80% predicted. This is consistent with restriction, muscle weakness, and other pathologies.



Regular Symptoms: dyspnea at rest or exertion, cough, sputum. Use COPD Assessment Test (CAT) or mMRC Breathlessness Scale to follow course of disease.

Exacerbations: two or more in the past year, especially if FEV_1<50% predicted suggests high risk.

Oxygenation: severe hypoxemia: resting O2 sat≤88% or arterial pO2<55 mmHg episodic hypoxemia: exercise or nocturnal desaturation.

Emphysema: reduced density on CT scan, can be localized, abnormal high lung volumes, abnormal low diffusion capacity.

Chronic bronchitis: cough, sputum most days for at least 3 months in at least 2 years.

Comorbidities: defining and treating comorbid conditions, particularly cardiovascular, anxiety and depression, are critical components of COPD care.

- For those well controlled (0-1 exacerbation in the past year and no COPD hospitalizations) on triple therapy (LAMA+LABA+ICS) consider stepping down with careful follow up to LAMA+LABA, especially if there is a history of recurrent pneumonias, osteoporosis or cataracts.
- The presence of eosinophilia may help select those exacerbators who could benefit from addition of ICS.
- The higher the CAT score, the greater the exacerbation risk.
- For those with recurrent exacerbations despite inhaled regimen consider:
  a. Adding PDE4 Inhibitor Roflumilast (if chronic bronchitic) and/or
  b. Adding Macrolide (if not active smoker) as immune modulator.
- COPD patients with FEV_1<60% should have O2 saturation assessed.
  a. Resting O2 sats≤88% merit assessment for Oxygen therapy.
  b. COPD patients with O2 sats≤88% should have arterial blood gas tested and if significant hypercapnea consider for sleep study and potential noninvasive ventilation.
- COPD patients with FEV_1<45% should undergo evaluation for Lung Volume Reduction – surgical or bronchoscopic.
- Annual low-dose CT scan for lung cancer screening – ages 55-79 years with 30 packyears and cigarette smoking in the last 15 years.

Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Beta 2 Agonists - Short Acting (SABA)				
Albuterol	90 (HFA-MDI)	0.63/3 ml 1.25/3 ml 2.5/3 ml		4-6
Levalbuterol	45 (HFA-MDI)	0.63/3 ml 1.25/3 ml		6-8
Beta 2 Agonists - Long Acting (LABA)				
Salmeterol	50 (DPI)			12+
Arformoterol		15 mcg/2ml		12+
Formoterol Fumarate		20 mcg/2ml		12+
Indacaterol Maleate	75 (DPI)			24
Olodaterol	5 (SMI)			24
Anticholinergics - Short-Acting (SAMA)				
Ipratropium Bromide	17 (HFA-MDI)	0.5/2 ml		4-6
Anticholinergics - Long-Acting (LAMA)				
Tiotropium	18 (DPI)			24
Tiotropium	5 (SMI)			24
Aclidinium Bromide	400 (DPI)			12
Glycopyrrolate Bromide	15.6 (DPI)			12
Umeclidinum	62.5 (DPI)			24
Glycopyrrolate		25 mcg/1 ml		12
Long-Acting Anticholinergic plus Long-Acting B2-Agonist (LAMA/LABA)				
Umeclidinium / Vilanterol	62.5/25 (DPI)			24
Tiotropium / Olodaterol	5/5 (SMI)			24
Glycopyrrolate / Formoterol Fumarate	18/9.6 (MDI)			12
Glycopyrrolate / Indacaterol	15.6/27.5 (DPI)			12
Short Acting Anticholinergic plus B2-Agonist (SAMA/SABA)				
Ipratropium Bromide / Albuterol	20/100 (SMI)	0.5/2.5/3 ml		4-6

COPD patients should be tested for alpha-1 antitrypsin deficiency, the genetic form of COPD. www.alpha-1foundation.org

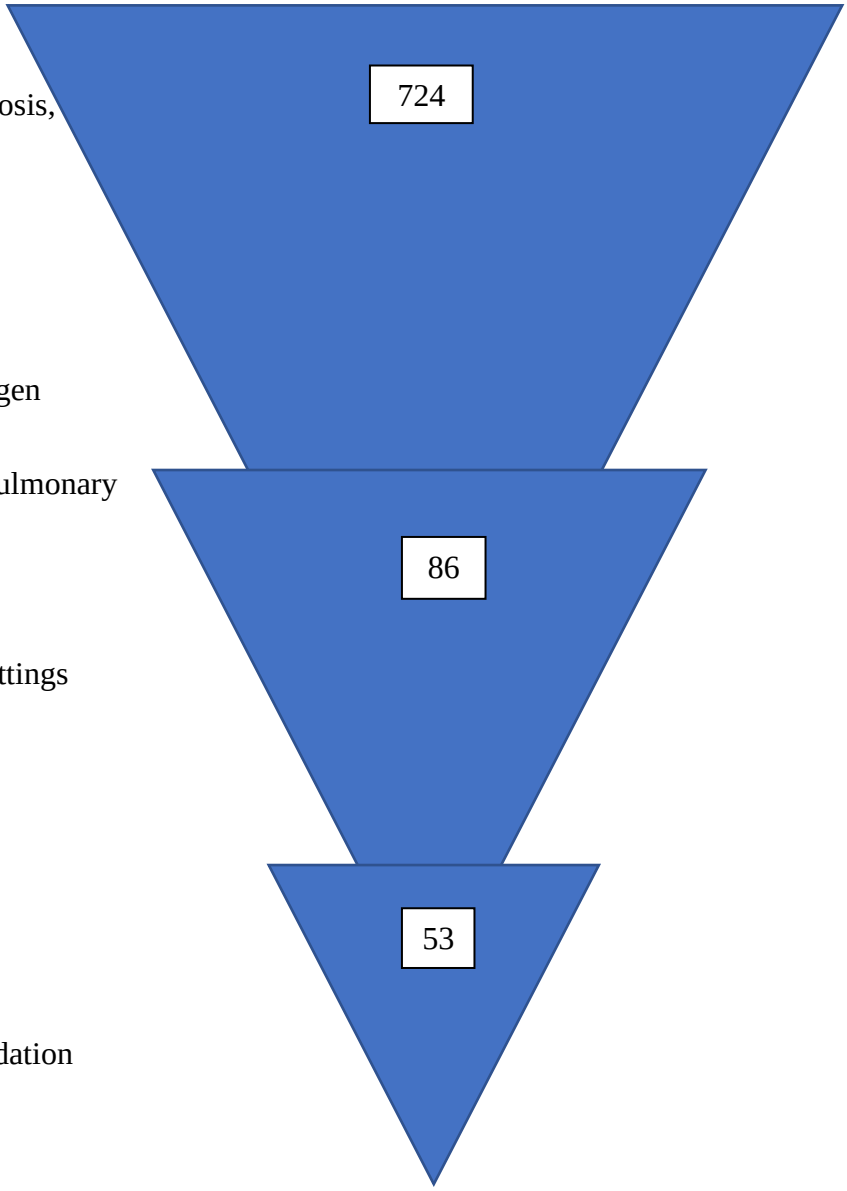
Drug	Inhaler (mcg)	Solution for Nebulizer (mg)	Oral	Duration of Action (hours)
Methylxanthines				
Theophylline (SR)			100-600 mg (Pill)	Variable, up to 24
Mucolytic				
N-acetylcysteine (NAC)			600mg	12
Inhaled Glucocorticosteroids (ICS)				
Beclomethasone Dipropionate*	40, 80 (HFA)			12
Budesonide*	90, 180 (DPI)	0.25/2 ml 0.5/2 ml		12
Fluticasone Propionate*	44-220 (HFA) 100, 250 (DPI)			12
Fluticasone Furoate*	100, 200 (DPI)			24
Mometasone*	220 (DPI)			24
Ciclesonide*	80, 160 (HFA)			12
Inhaled Glucocorticosteroid plus Long Acting B2-Agonists (ICS/LABA)				
Budesonide / Formoterol	80/4.5* 160/4.5 (HFA)			12
Fluticasone / Salmeterol	100/50* 250/50 500/50* (DPI)			12 12 12
Fluticasone / Salmeterol*	45/21 113/14 (DPI) 115/21 230/21 (HFA)			12 12 12 12
Mometasone Furoate / Formoterol Fumarate Dihydrate*	100/5 200/5 (HFA)			12
Fluticasone Furoate / Vilanterol	100/25 (DPI) 200/25			24 24
Inhaled Glucocorticosteroid plus Long Acting Anticholinergic plus Long Acting B2-Agonist				
Fluticasone /Umeclidinium/ Vilantrol	100/62.5/25 (DPI)			24
Phosphodiesterase 4 (PDE4) Inhibitor				
Roflumilast			500 mcg	24

*FDA only approved for Asthma
HFA: Hydrofluoroalkane MDI: Metered Dose Inhaler DPI: Dry Powder Inhaler SMI: Soft Mist Inhaler

Appendix D

Literature Search Flow Diagram

724 published articles in the last 5 years using search terms GOLD, COPD, primary care, global strategy for the diagnosis, management and prevention of COPD.



86 articles after excluding drug trials, oxygen supplementation, surgical interventions, pulmonary rehabilitation studies, co-morbidities, asthma and asthma/COPD overlap, and settings other than primary care.

53 articles with relevant abstract information containing GOLD recommendation adherence, COPD care management, implementation of GOLD in primary care, questionnaires.

Appendix E

Literature Matrix

Article	**Level of Evidence** (I to VII)	**Data/Evidence Findings**	**Conclusion or Summary**	**Use of Evidence in EBP Project Plan**
Davis et al. (2015)	VI	International survey of physicians in 12 countries, 1307 total. Primary care providers (PCP) use spirometry @ 82%, Respiratory Specialists (RS) 100%; RS 93% likely to report awareness of GOLD strategy (vs PCP 58%). PCPs/RSs really no difference in GOLD-concordant meds. PCPs/RSs prescription (1st/2nd choice) patterns in agreement with	RSs are slightly better at the awareness of and action on GOLD guidelines than PCPs. Worldwide there is variation about knowledge and application of GOLD guidelines.	Part of implementation strategies at the project site should be aimed at understanding the use of the ABCD assessment tool to better adherence to guidelines for medications.

		GOLD for a category B patient was 38% versus 67%. For GOLD C PCPs/RSs were concordant 40% vs 38%; w/ D type was nearly the same 57%/58%.		
Miravitlles et al. (2017)	review but not systematic	Review examining the role of LABDs (long-acting bronchodilators), administered as monotherapy or as part of dual or triple combination therapy, w/ focus on the effect on exacerbations. Did not discuss methods AT ALL. 26 clinical trials and studies included.	Caution should be used with regard to ICS, as GOLD recommends, w/ suggested use for patients with asthma overlap or those who continue w/ frequent exacerbations despite LABA/LAMA therapy.	Educating primary care providers about medications is important, especially in cautioning against the overuse of ICS. Algorithm for exacerbations.

Sehl et al. (2018)	V	A literature review examining adherence to GOLD guidelines (diagnosis, pharmacological, non-pharmacological) varies considerably among PCPs.	Adherence to spirometry for appropriate diagnosis and classification varies widely. The largest gaps were related to spirometry, GOLD categorization, vaccination status, smoking cessation, inhaler use, and referral to pulmonary rehab. Barriers to adherence include lack of familiarity with guidelines and time constraints.	Educating primary care providers about spirometry diagnosis, use of ABCD assessment tool for medication therapies, vaccines, and smoking cessation counseling is needed.

Overington et al. (2014)	V	General overview review of GOLD adherence, no method listed, studies cited are measuring different aspects. Clinical practice compares to GOLD guidelines very poorly. One US study showed that only 56% of pt received treatment concordant w/ GOLD (meds). Another US study showed 3% of patients (chart reviews) met all three guideline components for (spirometry, management of comorbidities, and risk reduction strategies).	Adherence to GOLD guidelines is not optimal and varies widely. Good for finding primary sources.	Educating providers is needed; formulating a plan for implementation is needed

Riley & Sciurba (2019)	I	Expert opinion/clinical review/education module by JAMA about current standards/guidelines for "diagnosis and outpatient management of COPD): 26 clinical trials, 21 meta-analysis, 25 observational studies, 18 guidelines were synthesized for this review	GOLD guidelines reiterated; however, a new algorithm (with same principles) is offered to simplify treatment (first and second-line options) based on the category of GOLD (by spirometry) and symptom burden	Further evidence of GOLD guideline strategies; another way to describe and detail the information supporting the need for specific components of guidelines (pharmacological , non-pharm, spirometry, vaccinations, smoking cessation)

Karloh et al. (2016)	I	17 studies were systematically reviewed to identify clinical outcomes and classification of GOLD stages of COPD. Different proportions of patients in each GOLD category were found using the MRC>2 and CAT>10, with a 13% difference in distribution depending on the tool used.	CAT is useful in overall clinical assessment, with a good prediction of exacerbations, health deterioration, depression, and mortality. It is not equivalent to the MRC using current cut off points.	CAT questionnaire is independently verified as a useful tool, but should not be used interchangeably with other questionnaires. Only one tool should be implemented at the practice.
Gupta et al. (2014)	I	A systematic review of the CAT assessment test examined 36 studies that were prospective cohorts or cross-sectional. Internal consistency was good, test-retest reliability was good. Most studies of the CAT	Literature reviewed supports the reliability and validity of the CAT. Compared to the MRC, GOLD	CAT questionnaire is valid and reliable, appropriate to use for the proposed project.

		had fair methodological quality. MCID (a minimum clinically important difference) was inconsistent. Validity was examined using Pearson's and Spearman's' correlation range.	categories were different.	
Barrenchegure n et al. (2015)	IV	Population-based epidemiological study of approximately 40,000 people in Spain examining initial diagnosis of COPD, categorizations, use of bronchodilators and ICS, and exacerbation patterns. Only 78% of COPD patients received treatment after diagnosis. 17% of exacerbators were untreated; 13% of	initial treatment patterns of COPD do not comply with GOLD guidelines; ICS is overused, some patients are not treated with medications initially at all, and more progressed illnesses were	Worldwide adherence to GOLD guidelines is not optimal; education for primary care will be relevant and useful

		severe disease COPDers were untreated; 50% of all COPD patients were prescribed ICS alone or in combo at initial diagnosis. FLAW: 1/2 of patients diagnosed with COPD were not spirometry confirmed	not appropriately treated	
Mapel, Dalal, Johnson, Becker, & Hunter (2015)	IV	445 patients with COPD were reclassified into categories using the MRC and CAT. MRC reclassified 47% of patients; CAT reclassified 41%. MRC showed a relatively equal distribution of patients within the ABCD categories, while CAT distributed more patients into B & C categories. FLAW: all	GOLD questionnaires reclassify patients into different categories based on the tool, making treatment seemingly more subjective rather than less. HOWEVER, the design of this	CAT and MRC questionnaires seem to categorize patients differently; critical to pick one tool, teach it, and remain consistent

		patients were diagnosed with pre-bronchodilator spirometry (not post-bronchodilator spirometry, which is the undisputed best practice standard)	study is flawed from the start r/t use of pre-BD spirometry and seems heavily biased against GOLD recommendations for using symptom burden questionnaires.	
Jiang et al. (2015)	II	1 yr. cluster-randomized field trial, 711 COPD patient in a primary care practice in China; comparing GOLD guideline intervention group to the usual care control group. Found a significant difference between groups in 6-minute walk distance and quality of life scores	Adherence to GOLD guidelines does improve outcomes related to symptom burden, self-reported quality of life, and 6-minute walk distance.	A well-designed study showing adherence outcomes in primary care does improve life for COPD patients

		(using MRC symptom burden questionnaire)		
Fathima et al. (2014)	I	A systematic review of 19 Randomized control trials- most conducted w/ asthma patients. The use of CCDSS (computerized clinical decision support systems) improved asthma and COPD care 74% of the studies, with statistically significant improvement in the primary outcomes measured.	Not sure if this is generalizable to COPD patients; improvements in processes identified, whether this translates to good patient outcomes was not addressed specifically.	The only study with some strategies defined to disseminate information about guidelines, using CCDSS — very general applicability to the proposed project.

Parker et al. (2013)	I	PLANNED RCT for implementation of GOLD guidelines. Using evaluation/feedback/focus groups, three tools of dissemination were developed: "a computerized patient activation tool (an interactive iPad with wireless data transfer to the spirometer); a web-based COPD guideline tool to be used by primary care providers as a decision support tool; and a COPD patient education toolkit to be used by the practice team." Next phase (with results still unpublished) "RCT will be performed	Results not yet published	The results of this study would be key to implement strategies for the proposed project.

		with one year of intervention within 30 primary care practices." The effectiveness of materials will be evaluated, and clinically relevant outcomes will be compared to usual care.		
Foster et al. (2007)	VI	Survey of 784 primary care physicians regarding education needs for diagnosis, treatment, and management of COPD. 55% were aware of GOLD, yet only 25% used them to guide decisions.	GOLD guidelines have not yet reached primary care providers. Choices made by physicians in the case study surveys showed non-adherent diagnosis, treatment, and management of COPD. Internet	Can't find anything more recent w/ survey data of physician responses about how they are using recommendations . Therefore, Historical reference for adaptation of GOLD guidelines, after

			technologies are recommended to improve the education of clinicians about GOLD guidelines.	their initial release In 2002. Results about how physician responses corresponded to GOLD guidelines are not representative of current practice, as the guidelines have been updated several times since. The need expressed by physicians for more education and adaptation of guidelines to primary care remains relevant.

Bryant et al. (2013)	I	Systematic review of effectiveness of interventions designed to improve medication adherence in a COPD population. 5 studies were examined, with interventions including: brief counseling, monitoring and feedback about inhaler use with electronic communication, and multi-component interventions with self-management strategies and interdisciplinary teamwork.	Overall, continued improved adherence in long term post-intervention periods was not ideal, with between 70-85% continued adherence.	There are not a lot of interventions designed to improve medication adherence in COPD patients, outcomes are not robust, and more research is needed to see what would work.
Dekhuijzen et al. (2013)	I	Literature review of GINA (asthma) and GOLD (COPD) guidelines to determine inhalation device-	"These results indicate that there is a considerable lack of clear and	Specific patient teaching about inhaler device usage would be worthwhile to

		specific guidance. Limited information was found, with less than 2% demonstrating and testing correct inhalation technique: less than 3% of pages or references or tables/figures dedicated to devices. Results in ACCP/ACAAI device selection guideline were the best (54% of pages, 88% of tables/figures and 82% of references), however they are not disease specific.	specific guidance regarding inhalation devices in current asthma/COPD guidelines."	include in this project
Baker, Zou, & Su (2014)	IV	Retrospective observational study, using insurance claims data, of nearly 20,000 COPD patients (primary or secondary diagnosis) examining patterns of	There was not a significant difference in LABD use in the pre- and post-hospitalization period,	Importance of education about the use of LABD for certain categories of COPD in this project

		bronchodilator use in the time frame prior to and just after hospitalization for exascerbation. 40% patients filled a prescription for LABD in the 90 days prior to hospitalization; 56% patients filled a LABD prescription in the 90 days after.	suggesting that many COPD patients are undertreated or inappropriately managed with medications.	
Simeone et al. (2017)	IV	A retrospective study using claims data in a four year period for the use of triple therapy (both LABD +ICS), as well as to characterize patients on triple therapy for concordance with GOLD guidelines (per stage of illness). 25% of all COPD patients received triple therapy.	Triple therapy is not being used appropriately in clinical practice	Educating clinicians about GOLD guidelines will help prevent the overuse of medications (such as ICS or triple therapy)

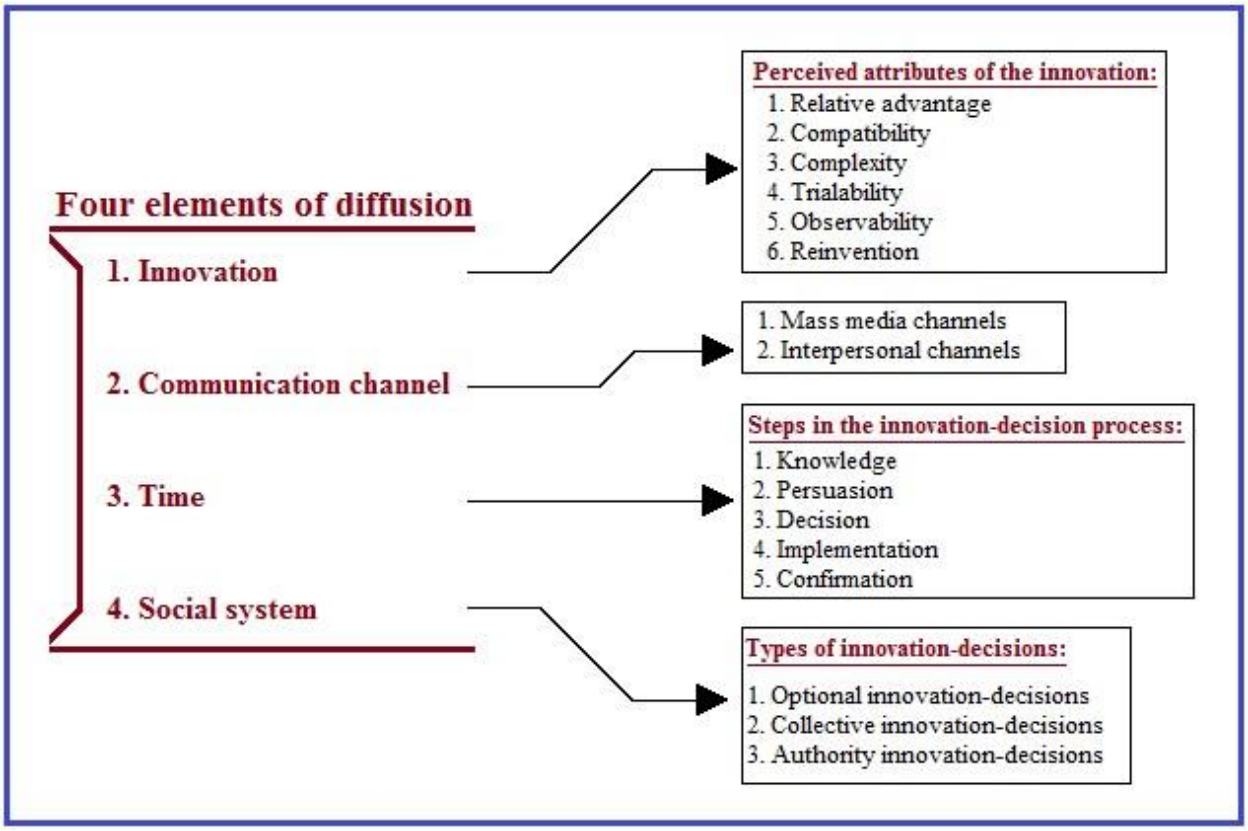
		75% of those patients receiving triple therapy were of the lowest severity of illness, contrary to GOLD guidelines.		
Casanova et al. (2015)	IV	An observational cohort of 768 Spanish patients with COPD, comparing the predictive abilities of the CAT and MRC questionnaires. Higher scores, regardless of questionnaire, were similar in sensitivity and corresponded to higher mortality.	Again, problems with the cut off values, with suggestions for new thresholds to have MRC and CAT more aligned with each other.	Thresholds for equivalency may be something to consider when teaching; however, consistent use of one tool is going to be best practice
Kruis et al. (2013)	I	Systematic review and meta-analysis of 26 trials involved approximately 3000 patients in 11 countries, in all types of healthcare settings	IDM improved quality of life measures, exercise capacity, reduced hospital	This data is important to the proposed project in terms of measurable data. Hospital

		(primary, secondary, and tertiary care). Integrated disease management interventions were examined, defined as at least 2 of the following: education/self-management, exercise, psychosocial, smoking cessation, medication management, nutrition, follow-up/communication, multidisciplinary team, financial interventions.	admissions, and hospital days per person.	utilization (ER or admissions) and this data demonstrate that IDM (though loosely defined) does improve outcomes.
Belletti, Liu, Zacker, & Wogen, 2013	IV	A cross-sectional, retrospective study of 1500+ medical records (11 primary care sites) to measure adherence to GOLD recommendations. Measured the following:	Only 27% had spirometry values; 25% comorbid management; 32% risk reduction	Adaptation of GOLD recommendations in primary care is inconsistent.

		spirometry values in the record, comorbid conditions treatment, risk reduction measures		

Appendix F

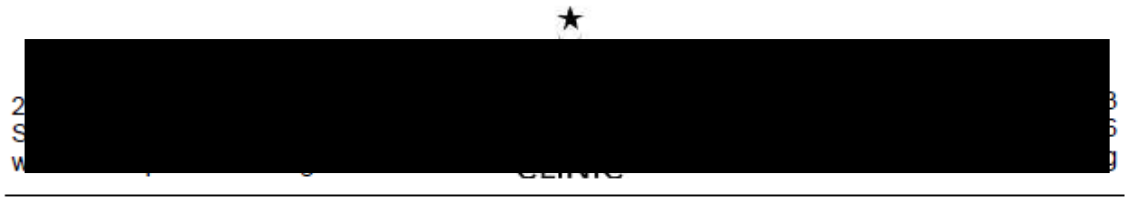
Diffusion of Innovation Theory



Visualization of the four main elements in the diffusion of innovations (Rogers, 2003).

Appendix G

Project Site Letter of Support



April 5, 2019

To East Carolina University College of Nursing:

We [redacted] reviewed Jenny Perkins's DNP project proposal "GOLD Innovation". Ms. Perkins has organizational support and approval to conduct her project within our practice. We understand that the timeframe for this project is from the date of this letter through April 30, 2020. Implementation at our practice will occur August through December 10, 2019, unless otherwise negotiated. We understand that for Mrs. Perkins to achieve completion of the DNP program, dissemination of the project will be required by the University which will include a public presentation related to the project, and a manuscript submission will be encouraged.

[redacted] has deemed this project as a process development. Our organization is aware that this project will be processed through the University and Medical Center Internal Review Board of East Carolina University (UMCIRB). [redacted] does not have an Internal Review Board (IRB).

Please contact me if you have questions or require further information from our organization.

Sincerely,

[redacted]

Executive Director

Appendix H

Project Expense Budget

Line Item	Unit Cost	Unit Quantity	Total
Hospitality			
Food/Drink	$30	1	$30
Materials			
Lamination	$1	20	$20
COPD pocket consultants (free) shipping cost required	$17.50	1	$17.50
Printing	0.10	150	$15.00
Total Expenses			$82.50

Appendix I

IRB Process Self-Certification Tool

Quality Improvement/Program Evaluation Self-Certification Tool

Purpose:
Projects that do not meet the federal definition of human research pursuant to 45 CFR 46 do not require IRB review. This tool was developed to assist in the determination of when a project falls outside of the IRB's purview.

Instructions:
Please complete the requested project information, as this document may be used for documentation that IRB review is not required. Select the appropriate answers to each question in the order they appear below. Additional questions may appear based on your answers. If you do not receive a STOP HERE message, the form may be printed as certification that the project is "not research", and does not require IRB review. The IRB will not review your responses as part of the self-certification process.

Name of Project Leader:

Jenny Perkins

Project Title:

Implementation of GOLD Strategy in Management of COPD population

Brief description of Project/Goals:

The purpose of this quality improvement project is to increase staff and provider awareness of best practices for the diagnosis and management of COPD in an outpatient setting. The project will be based on the 2019 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Strategy. The clinic is currently performing spirometry testing visits for suspected and diagnosed COPD patients, in line with GOLD strategy. The project will improve the spirometry visit workflow within the electronic health record (EHR). The project will create a checklist of actionable, GOLD strategy-based items within the EHR for providers to utilize during patient visits. The project will occur at New Hope Clinic, a free primary care clinic for uninsured adults in rural southeastern NC. Success of the project will be evaluated by tracking and trending the following for active COPD patients at the clinic: rates of spirometry testing, tobacco cessation counseling, tobacco cessation, use of COPD symptom questionnaires, use of bronchodilator inhalers, and health care utilization (ED use and sick visits). No personal health information will be collected. Implementation of the improved spirometry workflow will begin in August 2019. Weekly spirometry visits will be performed, and chart audits will be conducted from August 26 to December 9. The project's goal, to improve the diagnosis, treatment, and management of COPD, is in line with Healthy People 2020 goals for COPD and the 2017 COPD National Action Plan.

Will the project involve testing an experimental drug, device (including medical software or assays), or biologic?

○ Yes
● No

Has the project received funding (e.g. federal, industry) to be conducted as a human subject research study?

○ Yes
● No

Is this a multi-site project (e.g. there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

- ○ Yes
- ● No

Is this a systematic investigation designed with the intent to contribute to generalizable knowledge (e.g. testing a hypothesis; randomization of subjects; comparison of case vs. control; observational research; comparative effectiveness research; or comparable criteria in alternative research paradigms)?

- ○ Yes
- ● No

Will the results of the project be published, presented or disseminated outside of the institution or program conducting it?

- ● Yes
- ○ No

Would the project occur regardless of whether individuals conducting it may benefit professionally from it?

- ● Yes
- ○ No

Does the project involve "no more than minimal risk" procedures (meaning the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests)?

- ● Yes
- ○ No

Is the project intended to improve or evaluate the practice or process within a particular institution or a specific program, and falls under well-accepted care practices/guidelines?

- ● Yes
- ○ No

Based on your responses, the project appears to constitute QI and/or Program Evaluation and IRB review is not required because, in accordance with federal regulations, your project does not constitute research as defined under 45 CFR 46.102(d). If the project results are disseminated, they should be characterized as QI and/or Program Evaluation findings. Finally, if the project changes in any way that might affect the intent or design, please complete this self-certification again to ensure that IRB review is still not required. Click the button below to view a printable version of this form to save with your files, as it serves as documentation that IRB review is not required for this project. 6/18/2019

Appendix J

Evaluation Tool: GOLD Strategy Components

	Total COPD patients	Spirometry results (Outcome A)	Tobacco users (Outcome C)	Tobacco cessation counseling (Outcome B)	ICS prescriptions (Outcome E)	CAT questionnaire (Outcome D)
September %		63.70%	85.30%	97.20%	73.40%	0%
Sept # patients	109	72	93	90	80	0
October %		67.30%	85%	97.30%	72.60%	10.60%
Oct # patients	113	76	96	93	82	12
November %		70.70%	85.30%	97.40%	71.60%	15.50%
Nov # patients	116	82	99	97	83	18
December %		70.50%	86%	97.10%	72.10%	17%
Dec # patients	122	86	105	102	88	21
January %		71.40%	83.30%	99%	65%	20.60%
Jan # patients	126	90	105	104	82	26

Appendix K

Evaluation Tool: Healthcare Utilization

	ED/hospitalizations related to COPD
Raw data # of visits 2018	3
% visits 8/28/2018-12/30/2018	2%
Raw data # of visits	4
% visits 8/28/2019-12/30/2019	3.20%

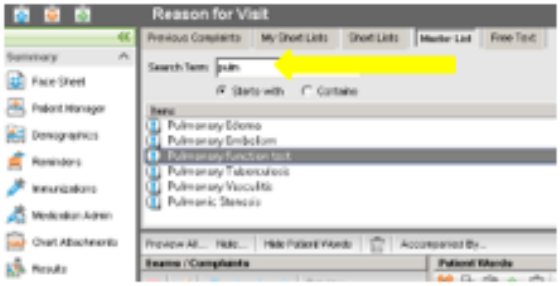
Appendix L

Spirometry Visit Workflow

Spirometry - Documentation

- Open Patient Chart
- Obtain & record VITAL SIGNS: 02, HR, & HT
  - Notify provider if heart rate > 100

- Add REASON FOR VISIT-
  - select *'master list'*
    - search for *'pulmonary function test'*



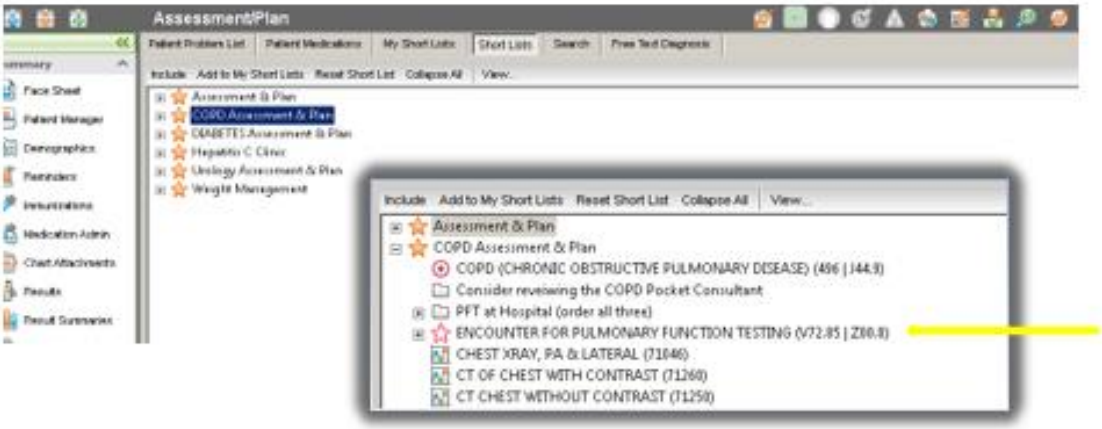
- Add VITAL SIGNS *if not already entered by triage*

- Go to HISTORY
  - Add Past Medical Hx/Problem-
    - only 1 needed, relevant to testing (i.e., tobacco use, chronic cough, etc.)
  - Add Social Hx- TOBACCO USE
    - Verify accuracy
      - Include "Prior Use" AND "Non-User/Non-Smoker" if patient has quit
    - Edit status to include start age of smoking and quit date as needed
  - Add Medication Hx
    - Include all (*if not already entered by triage*) with attention to current inhaler use
  - Add Diagnostic Test
    - Select 'PFT' and date completed

Encounter will now look like this:

- Check to see if PFT has already been ordered by provider in the EMR. If not, proceed to:
- ASSESSMENT & PLAN
  - Select "My Short Lists"
  - Select "COPD"
  - Select "Encounter for Pulmonary Function Test" which includes the orders needed for the visit:
    - Albuterol and nebulizer
    - PFT (as lab result(
    - CAT questionnaire, STOP-BANG questionnaire (as lab result)
    - Tobacco cessation counseling

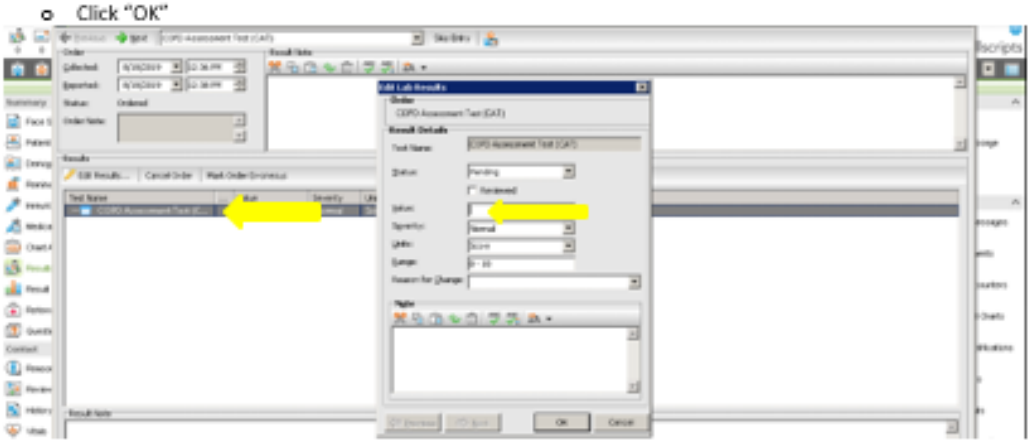
As seen here:



After Easy One Air Spirometry testing, print or view results in EasyOne Connect for results entry in AllScripts.

- Go to RESULTS main screen (left side of screen)
  - Choose "Procedures"
    - Select "Pulmonary Function Testing" ---- "NHC 2019"
  - Lab values from Easy One Air :
    - Pre-test FEV1 % predicted
    - Pre-test FVC % predicted
    - Post-test FEV1/FVC ratio
    - Interpretation
  - Click "OK"

- While in RESULTS main screen for "Procedures"
  - Click "Reassign Notification" to B. Fairchild for PFT results
  - Click "FINALIZE" for the following:
    - PFT results
    - Albuterol & nebulizer use
    - smoking cessation counseling
- While in RESULTS main screen, choose "Labs"
  - Find and enter questionnaire results into COPD Assessment Test (**CAT**) & **STOP-BANG**
  - Click "OK"



FINAL STEP ---- SEND ENCOUNTER

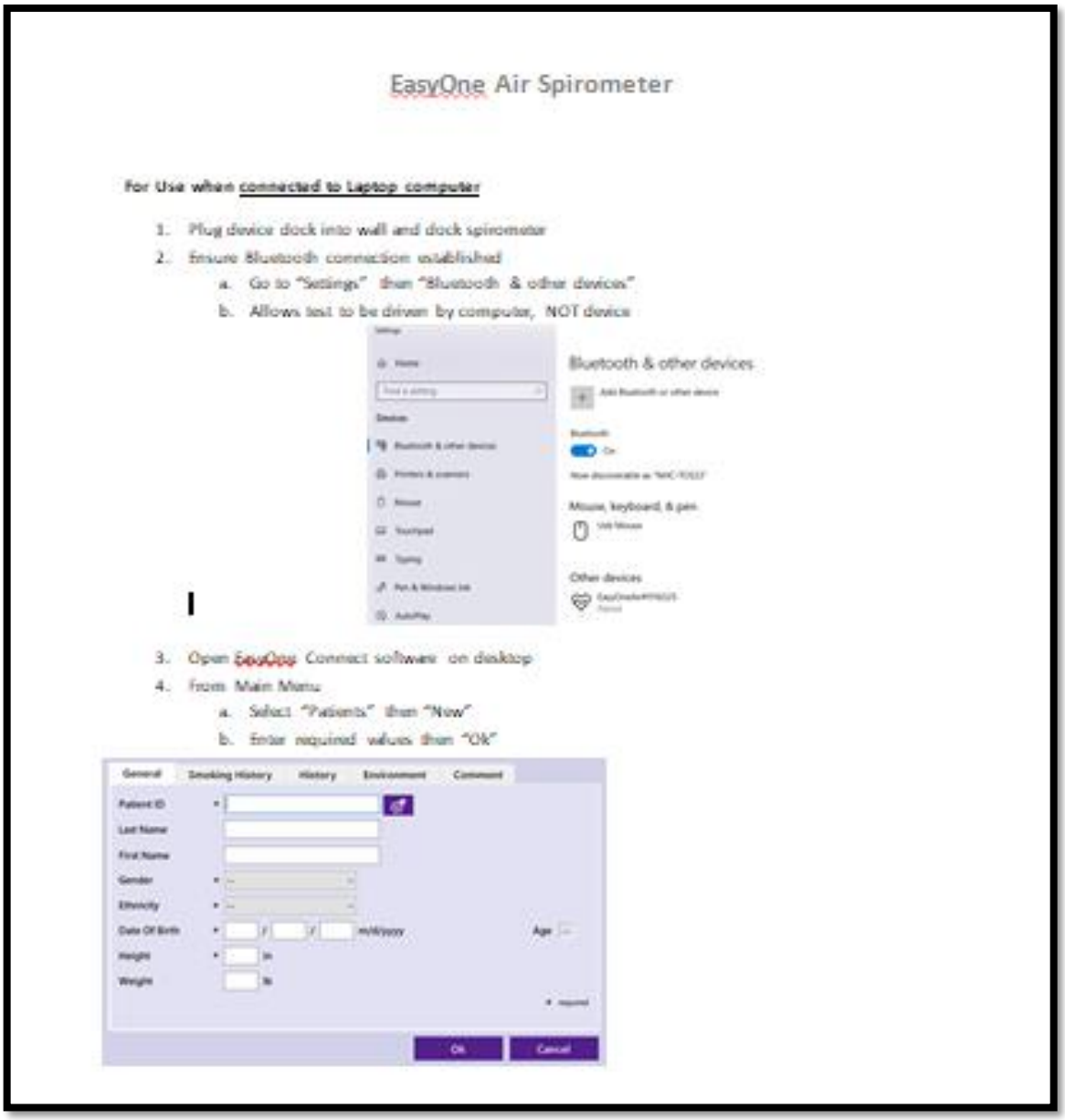
- Forward chart to B. Fairchild (or ordering provider) who will then review and sign off
- Encounter will contain the documented history, PFT results, and questionnaires as shown

HARD COPY PAPERWORK:

- On the paper encounter sheet for patient check-out, mark the boxes for:
  - Procedure/lab: 'Spirometry'
  - Nebulized albuterol medication administration
- Place printed PFT report, CAT, and STOP-BANG in the appropriate bin for scanning into the chart

Appendix M

EasyOne Air Spirometer Instructions



5. From the menu of patients, highlight name and select "Test"
    a. Undock the device, place Flow Tube into opening, with device and tube arrows aligned
    b. Choose "PVC" (pre- and post- bronchodilator spirometry)
        i. If "device not connected" error message shows, return to main menu, ensure the spirometer is "on", allow time for device to connect, and select "Test" again
    c. Follow instructions from the software for testing
        i. Initial step will be blocking Flow Tube airway, using plastic sleeve/glove
        ii. Select incentive for patient to watch their own effort (Candle/ Balloon/Monkey)
        iii. Select "Add trial" with each attempt
            1. Follow instructions/suggested changes exactly as stated
6. Administer albuterol nebulized once pre-test trials are complete (ideally after 3 adequate trials)

7. Set timer for 15 minutes after completion of nebulizer and complete the following:

    - CAT (COPD Assessment Test) questionnaire (hardcopy)
    - STOP-BANG (hardcopy)
    - Brief tobacco cessation counseling, give Quitline brochure
    - Review inhaler use (if needed)
        - Videos available by medication name in folder "Spirometry Visits"

8. Spirometer will turn "off" when left unattended during this interval
    a. Turn device back "on"
    b. Return to Main Screen
    wait for device to reconnect to software
    c. Reselect the patient and choose "PVC" testing
        i. Select "Add Post" for post- testing trials

9. At test completion, select "Print Results"
    a. Printer is automatically connected to Kyocera

Spirometry FAQs:

- ✓ If at any time the device turns "off" or connectivity is lost, turn the device on, restart the software and continue by selecting patient and entering "add trail" or "add post" as needed
- ✓ Patient can complete test standing or seated
- ✓ Use nose clips and make seal with lips (not teeth)
- ✓ Coaching tips: Maximum inhale, for maximum exhale
    - "Blow out hard and fast like a fire extinguisher"
    - "Keep blowing"

For EasyOne Air use independently, without Laptop

1. Plug docked device into wall & turn on Power
2. Select "Patients" & "New" – then follow all instructions to enter patient information required for testing
3. Select "PVC" test for that patient
4. Continue likewise for subsequent patients

After completion of testing, results can be downloaded to EasyOne software when computer is available via Bluetooth connection *OR* direct USB connection