The Effectiveness of Action Plan Implementation by Primary Care Providers on the Frequency of Preventable Acute Care Visits for Adults with COPD

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Abstract

COPD is the 3rd leading cause of death in the U.S. and 4th in the world. The economic burden of COPD in the U.S. in 2010 was almost \$50 billion, which included almost \$30 billion in direct healthcare costs due primarily to hospitalizations following exacerbations. Self-management skills fostered in a patient-centered primary care setting are essential for symptom control and the prevention or early detection of the exacerbations and complications that lead to healthcare utilization. However, adequate self-management is difficult due to the complex heterogeneity of COPD. Poor symptom control results in more frequent but preventable hospital visits and an accelerated functional decline. Patients with COPD often have increased health risks due to chronic co-morbid conditions and wide variations in clinical, functional, and behavioral patient presentations that challenge practitioners to develop, modify, and reinforce components of effective care plans whose success depends upon patient self-management.

This paper describes the design and implementation of *BREATHE for a Better Life*, a primary care pilot program for adults focused on self-management. As a practice inquiry project (PIP), *BREATHE* sought to demonstrate the effectiveness of an action plan on controlling the symptoms of COPD or COPD with asthma to optimize daily function and quality of life. Quality measures included the frequency of acute medical visits for respiratory complaints, spirometry values, and COPD Assessment Test (CAT) scores tracked over a two-month implementation period. Despite the brief nature of the intervention, results revealed gaps in care, provided opportunities for workflow improvements, and substantiated the need to evaluate and incorporate patients' self-perceptions of health into a comprehensive care plan. The PIP's supervising physician committed to continuing *BREATHE* for a minimum of one year and will continue to collect data in anticipation of significant results to support its value and sustainability.

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Chapter One: Statement of the Problem, Aims, and Objectives

Chronic obstructive pulmonary disease (COPD) and asthma are two of the most common diagnoses leading to frequent but preventable hospital emergency department (ED) visits and admissions across the globe (Ehteshami-Afshar, FitzGerald, Doyle-Waters, & Sadatsafavi, 2016; Hasegawa, Tsugawa, Tsai, Brown, & Camargo, 2014b). Medical care plans for adults with COPD and COPD with asthma are essential to help patients manage their diseases (Bourbeau et al., 2013). However, disease management is complicated by considerable variations in symptom manifestation and individual patient needs. Although COPD and asthma are distinct chronic diseases, symptoms overlap which further complicates diagnosis and management (Kim & Rhee, 2010; Nakawah, Hawkins, & Barbandi, 2013). Additionally, a lack of primary care accessibility and fragmented healthcare delivery systems contribute significantly to low patient health literacy and poor disease control, which in turn affects daily function, quality of life, and increases risk for early mortality (Doran, Raven, & Rosenheck, 2013; Newham et al., 2017).

BREATHE for a Better Life was developed as a primary care pilot program for adults using evidence-based guidelines with a focus on self-management. As a practice inquiry project (PIP), BREATHE sought to demonstrate the effectiveness of an action plan on controlling the symptoms of COPD or COPD with asthma to optimize daily function and quality of life. Quality measure outcomes included the frequency of acute medical visits for respiratory complaints, spirometry values, and COPD Assessment Test (CAT) scores tracked over a two-month implementation period. This PIP also assessed additional health factors influencing COPD management including comorbidities, age, smoking history, influenza and pneumococcal vaccinations, and personal health goals.

Problem Background

COPD is a progressive but manageable disease. Yet it is the 3rd leading cause of death in the U.S. and 4th in the world (Global Initiative for Chronic Obstructive Lung Disease (GOLD), 2017; Guarascio, Ray, Finch, & Self, 2013). The economic burden of COPD in the U.S. in 2010 according to the American Lung Association (2013) was almost \$50 billion, which included almost \$30 billion in direct healthcare costs due primarily to hospitalizations following exacerbations. Uncontrolled COPD also affects the economy in terms of lost productivity by the patients and those who are absent from work to care for them (Ford et al., 2015). In a 2011 nationwide survey, 4.2% of adults in Hawai'i self-reported a diagnosis of COPD, with prevalence and associated costs of COPD projected to increase due to aging and smoking (American Lung Association, 2013). A study by Khakban et al. (2017) projected an 155% increase in the number of individuals newly diagnosed with COPD between 2010 and 2030, and an 182% increase in the burden of corresponding inpatient care.

Asthma and COPD share symptomology, which influences the accurate diagnosis and their corresponding management as separate diseases (Kim & Rhee, 2010; Nakawah, Hawkins, & Barbandi, 2013). Asthma-COPD overlap syndrome (ACOS) is a recent concept recognizing the complexity and increased healthcare burden of these two distinct diseases as comorbidities (Joo, Han, Lee, & Rhee, 2017). Thus is it critical to consider the impact of asthma on population health and COPD management. The numbers of children and adults with asthma worldwide are projected to increase by 100 million by 2025 (Ehteshami-Afshar et al.,,2016). In 2007 the annual cost of asthma in the U.S. was \$56 billion, of which just over \$50 billion was attributed to direct healthcare costs (American Lung Association, 2012). From 2000 to 2009, asthma prevalence increased across the U.S. with Hawai'i experiencing an increase from less than 7.5%

to greater than 9% (Zhang, Morrison-Carpenter, Holt, and Callahan, 2013). In 2011, statistics show 96,595 adults in Hawai'i had an asthma diagnosis (American Lung Association, 2012). Additionally, asthma has a major economic impact due to the loss of productivity due to its prevalence among younger, working-age adults (Ehteshami-Afshar et al., 2016).

Self-management skills fostered in a patient-centered primary care setting are essential for symptom control and the prevention or early detection of exacerbations and complications of chronic diseases (Howcroft, Walters, Wood-Baker, & Walters., 2016; Gatheral, et al., 2017). However, adequate self-management is difficult due to the complex heterogeneity of COPD (Agusti et al., 2010; Centers for Disease Control and Prevention (CDC), 2011). Patients with COPD often have increased health risks due to chronic co-morbid conditions such as hypertension, diabetes, heart disease, and smoking (Ke et al., 2016). Wide variations in clinical, functional, and behavioral patient presentations challenge practitioners to develop, modify, and reinforce components of effective care plans whose success depends upon patient self-management. Poor symptom control results in more frequent but preventable hospital visits, and ultimately an accelerated functional decline. Primary healthcare is tasked with empowering individuals to self-manage COPD and COPD with asthma for optimal health outcomes.

One approach to self-management support is the implementation of a patient-centered, team-based, individualized action plan (Fromer, 2011; Newham et al., 2017). Yet action plans for COPD are often misunderstood and underutilized (Ring et al., 2011). Studies indicate action plans for individuals with COPD or COPD with asthma may lack required monitoring, modification, and patient education for optimal effectiveness (Howcroft, 2016).

Excellent healthcare requires time, resources, and expertise, and United States (U. S.) medical technology and skills are globally among the most advanced. Yet a 2014 comparative

analysis of 11 industrialized nations revealed the U. S. healthcare system provided the worst healthcare at the greatest per capita expense (Davis, Stremikis, Schoen, & Squires, 2014). The problem of providing equitable, effective healthcare to all residents of the U. S. has worsened over the past few decades as the number of uninsured and underinsured Americans remains high, health costs increase, and the rates of chronic and disabling conditions such as COPD and asthma in an aging population continue to rise (Zutshi et al, 2013).

Problem Statement

COPD and asthma symptoms significantly compromise quality of life for patients and their families as well as contribute to a major burden on healthcare resources. Individuals with COPD or COPD with asthma frequently seek medical care for preventable events related to their disease processes due to a lack of self-management capabilities, guidance, and support. Healthcare over-utilization indicates the complex, heterogeneity of COPD and COPD with asthma and suggests an urgent need to standardize an evidence-based, patient-centered, primary care approach to chronic disease management.

Aims and Objectives

COPD and asthma action plans are validated tools for empowering patients and families to optimize control, function, and quality of life. The purpose of this PIP was to evaluate the effectiveness of individualized action plan implementation by primary care providers (PCPs) on the frequency of preventable acute care visits for respiratory complaints by individuals with COPD or COPD with asthma to achieve anticipated short-term and long-term outcomes. Table 1 describes the aims and objectives with which the BREATHE project strives to promote healthcare support and self-management skills for individuals with COPD and COPD with asthma.

Table 1. Aims and objectives

Aims	Objectives
Aim 1. Design a primary care chronic respiratory disease self-management pilot program for adults.	 Partner with key healthcare organizations serving adult patients with COPD and COPD with asthma. Identify organization-specific personnel, equipment, and workflows that support a quality-driven, comprehensive, primary care pilot program targeting the healthcare needs of patients with COPD and COPD with asthma. Based on identified healthcare resources and national guidelines, determine measures for monitoring effectiveness and sustainability of the primary care self-management pilot program. Establish a timeline for evaluation, modification, and end date of the primary care self-management pilot program.
Aim 2. Implement the chronic respiratory disease self-management pilot program designed to serve the needs of East Hawaii adults receiving primary care services.	 Present the chronic respiratory disease management program to all members of the healthcare team (defined in Chapter 3), including patients and their personal support networks. Collaborate with the healthcare team to implement individualized care plans with an emphasis on patient education and support for symptom control, medication management, preventive care, and behavioral modification. Collect data that enables program assessment and modification according to the established measures and timeline. Collect financial data to estimate the financial viability of the primary care self-management pilot program
Aim 3. Program evaluation by stakeholders.	 Upon completion of the pilot program, analyze clinical and financial data. Disseminate findings with an evaluation form to stakeholders for feedback. Analyze evaluation form results. Based on evaluation form results, recommend system-based changes for healthcare quality improvement.

Significance of the Problem

The *BREATHE for a Better Life* program emphasizes consistent reinforcement of individualized action plans and patient self-management (Fromer, 2011; Newham et al., 2017), using a multi-disciplinary approach that combines ongoing subjective and objective primary care assessments, strict medication management, behavioral health interventions, patient and caregiver education, and self-management promotion (Zwerink et al., 2014). *BREATHE* targets short-term outcomes including increased patient engagement, shared decision-making between clinicians and patients, optimal daily function with symptom control, and patient satisfaction (see Table 2). In the long term, expected outcomes include consistent patient self-management; fewer preventable ED visits, admissions, urgent care visits, and PCP visits for respiratory complaints; reduced mortality rates; and decreased healthcare costs (see Table 2). The ultimate aim is that sustained implementation of the *BREATHE* intervention program will improve symptom control, slow disease progression, and prevent or minimize exacerbations that lead to hospitalization, thus optimizing daily function and quality of life.

Table 2. Short Term and Long Term Outcomes

Short Term Outcomes	Long Term Outcomes
 Patient engagement and empowerment Shared decision-making Improve daily function and quality of life Improve workflows Decreased provider burden 	 Decrease frequency and severity of exacerbations Prevent or minimize complications Control costs Increase provider accessibility Consistent self-management

Chapter Two: Project Description and Review of Literature

Chapter two provides a review of literature (ROL) investigating and synthesizing research findings on the negative impact of COPD and COPD with asthma. Additionally, the ROL discusses the role of actions plans in the effective management of COPD and COPD with asthma. Finally, this chapter establishes the theoretical framework for the proposed self-management action plan pilot program.

Pathophysiology

Understanding where COPD and asthma symptoms overlap has important implications for disease management, frequency of acute care visits, and life expectancy (Kim & Rhee, 2010; Nakawah et al., 2013; Vaz Fragoso, Murphy, Agogo, Allore, & McAvay, 2017). COPD is a systemic, progressive, inflammatory condition with incompletely reversible airflow limitation characterized by structural alterations in lung tissue resulting from continuous exposure to noxious particles such as cigarette smoke (GOLD, 2017). In contrast, asthma is an inflammatory hypersensitivity reaction causing reversible airflow obstruction (The Global Initiative for Asthma (GINA), 2017). Yet a 2008-2012 national study using data from the Medical Expenditure Survey found 17.4% of patients with a self-reported diagnosis of asthma or COPD actually had asthma-COPD overlap syndrome (ACOS) (Vaz Fragoso et al., 2017). In contrast, a Hawai'ibased survey in 2008 showed 43.2% of adults self-reported a diagnosis of both COPD and asthma (Bradbury, Pobutsky, Reyes-Salvail, Baker, & Tottori, 2010). This high rate suggests patients and possibly providers may be confused about the differences between these diagnoses and thus may lack the corresponding knowledge and skills for optimal management. Studies of ACOS are increasing to clarify clinical guidelines and improve health outcomes (Joo et al., 2017).

Frequent but preventable acute care visits by individuals with COPD and COPD with asthma have myriad causes with one common complaint: Breathlessness. The GOLD (2017) and GINA (2017) reports were created by an international team of healthcare experts and are used worldwide as a guideline for COPD and asthma management, respectively. The GOLD (2017) report lists chronic and progressive dyspnea as the most characteristic symptom of COPD and a major cause of the disability and anxiety leading to acute care visits. The GINA (2017) report states asthma is similarly characterized by airflow limitation causing breathlessness, although asthma is variably described as a combination of dyspnea, wheeze, chest tightness, and cough. Goals for both COPD and asthma focus on reducing exacerbation risks, relieving the impact of symptoms on daily function, and promoting a sense of well-being. The shared sensation of breathlessness for patients with COPD and asthma leading to frequent but preventable acute care visits suggests a need for improved longitudinal self-management, while differences due to the etiology and pathophysiology distinct to each disease becomes important in the approach to treatment and development of an individualized action plan (GINA, 2017; GOLD, 2017). These differences are outlined in Table 3.

COPD Diagnosis and Treatment

Spirometry is an objective, noninvasive, reproducible test of airflow limitation. Spirometry test values identify characteristics of obstructive and restrictive forms of lung disease, and thus are necessary to diagnose and monitor COPD progression and treatment (GOLD, 2017). COPD is confirmed by the post-bronchodilator forced expiratory volume in one second (FEV₁) divided by the forced vital capacity (FEV₁/FVC) value of less than 0.70 and the FEV₁% predicted value represents the patient's effort in comparison to the volume predicted based on age, sex, height, and race (GOLD, 2017). The FEV₁% predicted is used to assign the

Table 3. A Comparison of Primary Features for COPD and Asthma*

Primary features	COPD	Asthma
Cause	Associated with exposure to	Airway inflammatory
	inhaled noxious particles or gases	hypersensitivity response
Age of onset, average	After age 40 years	Before age 20 years
Airflow limitation	Incompletely reversible	Reversible – can be spontaneous, in an immediate response to bronchodilator treatment, or in response to an inhaled corticosteroid (ICS) over time.
Chest x-ray results, lung structure	Hyperinflation	Normal (unless disease is advanced)
Lung function	Permanent structural changes cause chronic abnormal lung function.	Lung function may be normal between symptoms.
Symptoms - dyspnea, cough, wheeze, sputum production	Chronic dyspnea and regular sputum production are characteristic. Chronic cough is often the earliest sign.	Symptom combinations vary. Isolated cough is seldom due to asthma.
Symptoms - timing and frequency	Symptoms are persistent and progressive despite treatment.	Symptoms vary in timing and frequency; can be seasonally or even year to year.
Family, social, and past medical Hx	Family Hx positive for COPD or other chronic respiratory diseases. Risk increases with a history of smoking, asthma, respiratory infections, and childhood exposure to toxins.	Family Hx positive for asthma or other allergic conditions.
Spirometry results and classification (measured while stable)	$FEV_1/FVC < 0.70 \ and:$ $Stage \ 1/Mild$ $FEV_1 \ge 80\% \ predicted$ $Stage \ 2/Moderate$ $50\% < FEV_1 < 80\% \ predicted$ $Stage \ 3/Severe$ $30\% < FEV_1 < 50\% \ predicted$ $Stage \ 4/very \ severe$ $FEV_1 < 30\% \ predicted$	FEV ₁ /FVC > 0.75. Results often indicate variable airflow limitation.
*Table modified from Go	old (2017) and Gina (2017).	

grade or severity of airflow limitation from 1 to 4. GOLD (2017) guidelines propose improved treatment specificity can be achieved by further refining classification into a group from A to D

using the number of exacerbation in the prior year plus the score from a symptoms assessment tool such as the COPD Assessment Test (CAT).

The CAT was commissioned and funded by GlaxoSmithKline and developed by experts who continue to review and update the standards (CAT Governance Board, 2016). The CAT is a validated assessment tool measuring the impact of COPD on quality of life (QoL) (see Appendix A). Ideally the CAT should be administered to every patient with a COPD diagnosis, then readministered every two to three months or with changes in health status (CAT Governance Board, 2016). For the CAT, the Minimum Clinically Important Difference (MCID) is defined as a change of 2 or more units in the total score, suggesting a meaningful alteration in the GOLD grade or severity that should be explored. Increasing CAT scores without evidence of acute medical services can be an indicator of unreported exacerbations, leading to an increased risk for morbidity and mortality (CAT Governance Board, 2016; Lee et al., 2013). The CAT is a brief, simple, and inexpensive method for encouraging dialogue with patients about their symptoms and establishing a baseline that, in conjunction with spirometry, help effectively guide treatment (Dal Negro, Bonadiman, & Turco, 2014; GOLD, 2017; Lee et al., 2013).

Inflammation and injury from repeated exposure to lung pollutants over time, particularly cigarette smoke, are the main risk factors for COPD (GOLD, 2017). Action plan preventive measures focus on smoking cessation. Counseling and individual goal setting supported by nicotine replacement therapy available as gum, transdermal patch, lozenge, inhaler, nasal spray, and sublingual tablet are recommended. Varenicline, bupropion, and nortriptyline may also be used to support smoking cessation in the absence of contraindications and in conjunction with behavior modification therapy (GOLD, 2017).. Although e-cigarettes are used as a form of nicotine replacement therapy, its safety and efficacy are controversial and therefore not

recommended (GOLD, 2017).

The influenza and pneumococcal polysaccharide vaccines (PPSV23) are recommended for all individuals with a chronic pulmonary disease (Walters, Tang, Poole, & Wood-Baker, 2017). Additionally, the pneumococcal conjugate (PCV13) is recommended for all adults 65 years and older and for immunocompromised adults 19 years and older with certain high risk conditions. The intervals for PCV13 and PPSV23 are determined by CDC guidelines addressing age, co-morbid conditions, and past history of PPSV23 and PCV13 administration (CDC 2018; GOLD, 2017; Immunization Action Coalition, 2018).

Individuals with COPD demonstrate an increased risk for anxiety related to disease progression and severity (Eisner et al., 2010; Newham et al., 2017). Anxiety management is a key preventive measure for COPD symptom management that should include counseling and ongoing patient and caregiver education, and may require pharmacotherapy with anti-depressants and anti-anxiolytics (Usmani, Carson, Cheng, Esterman, & Smith, 2011). Non-pharmaceutical approaches in addition to behavioral health counseling include a healthy diet, maintaining a healthy body weight, physical activity to enhance muscle strength and lung capacity, and avoidance of allergen triggers.

Respiratory pharmacotherapy reflects disease complexity and is an essential component of an individualized action plan. Medications are prescribed to maximize daily function, reduce the frequency and severity of exacerbation, decrease anxiety, and support smoking cessation (Criner et al., 2015; GINA, 2017; GOLD, 2017). Table 4 lists some medications commonly prescribed in the outpatient setting to treat COPD (GOLD, 2017). Pharmacotherapy must be individualized according to disease severity, co-morbid conditions, potential drug interactions,

Table 4: Some Commonly Used Medications in the Outpatient Setting

Drug	Route	Duration of Action (hours)	
Short	acting beta ₂ -agonists (SABA)		
Salbutamol/albuterol	Hand-held inhaler, nebulizer	4-6	
Levalbuterol	Hand-held inhaler, nebulizer	6-8	
Short Acting A	nticholinergic/Antimuscarinic	(SAMA)	
Ipratropium bromide	Hand-held inhaler, nebulizer	6-8	
Long .	Acting Beta ₂ -agonists (LABA)		
Formoterol	Hand-held inhaler, nebulizer	12	
Olodaterol	Hand-held inhaler	24	
Salmeterol	Hand-held inhaler	12	
Long Acting A	nticholinergic/Antimuscarinic	(LAMA)	
Tiotropium	Hand-held inhaler	24	
Umeclidinium	Hand-held inhaler	24	
SA	ABA+SAMA combination		
Salbutamol+ipratropium	Nebulizer	6-8	
LA	ABA+LAMA combinations		
Olodaterol+tiotropium	Hand-held inhaler	24	
Vilanterol+umeclidinium	Hand-held inhaler	24	
LABA + Inha	led Corticosteroid (ICS) combi	nations	
Formoterol+budesonide	Hand-held inhaler	Differs by drug	
Formoterol+mometasone	Hand-held inhaler	Differs by drug	
Salmeterol+fluticasone	Hand-held inhaler	Differs by drug	
Vilanterol+fluticasone	Hand-held inhaler	Differs by drug	
Methylxanthine			
theophylline	Oral	Variable up to 24	
Phosphodiesterase-4 inhibitor			
Roflumilast	Oral	Consult specialist	
Oral glucocorticoids: To treat acute, severe exacerbations			
Oxygen: To treat severe resting hypoxemia			

and functional status. Adherence to proper medication use is essential for optimal effect and to avoid adverse short and long-term medication effects (Fan et al., 2016).

Both short-acting and long-acting beta2-agonists and antimuscarinic drugs are used to relieve bronchoconstriction and improve FEV₁ (GOLD, 2017). Short-acting formulations, commonly known as SABAs (short-acting beta2-agonists) and SAMAs (short-acting antimuscarinics), are recommended for immediate relief as needed in urgent or emergent situations. Long-acting formulations, correspondingly known as LABAs and LAMAs, are additionally prescribed for maintenance use when symptoms are not adequately controlled. Combination SABA/SAMA or LABA/LAMA therapies are shown to be effective at lower doses than monotherapy, and may be a superior treatment for some individuals. Combination LABA/LAMA is recommended as a next step for individuals with poor response to long-acting monotherapy.

The next step in pharmacotherapy is defined by moderate to severe COPD as manifested by repeated exacerbations despite the use of LABA/LAMA combination. An inhaled glucocorticoid (ICS) used in combination with a LABA is indicated (GOLD, 2017). A triple therapy of LABA/LAMA/ICS is indicated for severe disease, defined as persistent symptoms and frequent exacerbations despite LABA/ICS use. Monitoring closely for response to treatment and opportunity to withdraw ICS is recommended (GOLD, 2017). In refractory COPD, a phosphodiesterase-4 (PDE-4) inhibitor may be considered. The efficacy and safety of theophylline is considered controversial and discussion is not within the scope of this paper (GOLD, 2017).

Oxygen therapy for individuals with moderate moderate resting or activity-induced oxygen desaturation does not show clear benefit in time to death or first hospitalization over no

supplemental oxygen therapy (The Long-Term Oxygen Treatment Trial Research Group, 2016). Moderate desaturation is defined as Spo_2 , 89 to 93% while resting or $Spo_2 \ge 80\%$ for ≥ 5 minutes and <90% for ≥ 10 seconds during the 6-minute walk test (The Long-Term Oxygen Treatment Trial Research Group, 2016). However, individuals with severe hypoxemia experience improved quality of life and survival rates on oxygen therapy and should receive it (GOLD, 2017). Severe hypoxemia is defined as pulse oxygen saturation less than 88% or arterial oxygen tension less than 55 mmHg.

Comorbidities in addition to asthma contribute significantly to the complex management and prognosis of COPD. Anemia, cardiovascular disease, cancer, diabetes, chronic kidney disease, connective tissue diseases, and sleep apnea are examples of conditions that directly impact oxygen transport or immune system function (Mannino et al., 2015; Schwab et al., 2017). Symptomology of conditions such as obesity, congestive heart failure (CHF), musculoskeletal conditions, and anxiety can obscure the accurate assessment and thus the treatment of a new diagnosis or acute exacerbation of COPD (Negewo, Gibson, & McDonald, 2015). Furthermore, exacerbation or complication of any one chronic condition aggravates comorbid conditions, impacts decision-making about medications and procedures, and delays recovery. In a study by Schwab et al. (2017), 92% of 52,643 COPD patients had at least one of 11 comorbidities with findings that support an increase in healthcare utilization and poor health outcomes.

Incidence and Prevalence of Acute Utilization

Nationally, the number of ED visits for COPD or bronchiectasis increased from an estimated 1,480,363 in 2006 to 1,787,612 in 2011, with about 20% of those visits leading to admissions (Ford, 2015). Within the general trend of increased hospital visits, older age and disease progression are particularly strong predictors of frequent but preventable acute care visits

for COPD. In Hawai'i, 1,595 hospitalizations and 1,294 ED visits in 2008 had COPD as the primary diagnosis, 63% of which were for patients over 65 years of age. Elsewhere in the U.S., multiple studies have documented the relationship between older age (above 65 years), frequent ED visits, and COPD exacerbation. In California and Florida, nearly 30% of COPD patients visited the ED two or more times in a one-year period due to an acute exacerbation of their disease; these 28,894 patients were also significantly more likely to be older and have low socioeconomic status (Hasegawa et al., 2014b). Similarly, Ke et al. (2016) found that patients with a low FEV1% (mean value of 37.2%, Stage 3 severe disease) were 69 years old, on average, and more likely to experience COPD exacerbation and overall hospital utilization. Moreover, 17.2% of patients in the Ke et al. (2016) study with low-FEV1% had a documented co-diagnosis of asthma.

While COPD studies focused on age and disease progression as the cause of symptoms leading to ED visits, studies of adults with asthma reported inadequate treatment as the underlying cause of symptoms leading to ED visits. In a nine-month Saudi Arabian study of 450 adults, Al-Jahdali et al. (2012) discovered 86.7% of patients with asthma visited the ED primarily to obtain a bronchodilator and 75.1% needed oxygen. Al-Jahdali and colleagues (2012) reported 81.6% of patients stopped their ICS therapy when they felt better and 74.7% did not know what triggered their asthma symptoms. Finally, 36.5% of patients had three or more ED visits per year, which was highly associated with uncontrolled asthma (p=0.0063) and irregular follow up outpatient visits (p=0.0328) (Al-Jahdali et al., 2012).

A chart review of 1,002 adults with asthma coordinated through a consortium of 23 medical centers in Japan revealed 22% (218) had two or more ED visits in a one-year period (Watase, Hagiwara, Chiba, Camargo, & Hasegawa, 2015). For one-third of those patients in

Japan, findings linked three or more ED visits with current smoking and lack of treatment with ICS (Watase, et al., 2015). Similarly, an analysis of 1,890 charts from 48 U.S. EDs showed 28% of patients had one to two visits in the prior year, 11% had three to five, and 7% had six or more (Hasegawa et al., 2014a). Uninsured or underinsured adults, lower household income, and a lack of treatment with ICS were associated with a higher frequency of ED visits (Hasegawa et al., 2014a).

A study involving 1,678 adults in Southeast Virginia showed those with asthma are about 87% more likely to visit the ED one or more times within the year and are 78% more likely to report poor health for five or more days within the month prior to the reporting period than those without asthma (Behr, Diaz, & Akpinar-Elci, 2016). The Behr, Diaz, and Akpinar-Elci (2016) study also reported a higher frequency of primary care utilization by patients with asthma, but did not describe the type of services rendered. This raises questions about the types and quality of interventions performed during outpatient encounters.

The Centers for Disease Control and Prevention (CDC) (2011) performed an analysis of data collected between 2001 to 2009 from National Health Interview Surveys (NHIS) and Behavioral Risk Factor Surveillance System (BRFSS) surveys about provider-initiated patient education supporting asthma self-management. This study showed only 54.8% of patients reported receiving education specific to symptom recognition, and 63.8% reporting receiving education explaining how to respond to an asthma exacerbation (CDC, 2011). Additionally, only 29.9% of adults with asthma reported having a written action plan (CDC, 2011).

Self-Management Action Plans

The literature indicates that many of the hospital visits for patients with COPD and COPD with asthma were preventable based on what is known about COPD and asthma

pathophysiology. For adults with COPD and COPD with asthma, self-management optimized by health literacy, functional capability, healthy lifestyle behaviors, and support from a collaborative primary care team are factors for successful disease management (Fromer, 2011). A self-management approach requires utilization of population-level evidence-based standards of care to design service delivery protocols prioritizing patient-driven interventions (Lodewijckx et al., 2012; Parker et al., 2013). The action plan integrates feedback from multi-disciplinary team members and the electronic health record (EHR) system to track, evaluate, modify, and share patient progress and ongoing needs.

Self-management is a term used to describe the process of taking responsibility for one's own daily care to maintain optimal health (Kuhn et al., 2015; Zwerink et al., 2011). In a meta-analysis of 26 studies on self-management interventions (SMIs) to optimize quality of life and reduce hospital visits for patients with COPD, results showed overall that patients receiving SMIs including behavior change techniques (BCT), symptom management, and physical activity had significantly fewer ED visits compared to those who received traditional care (Newham, 2017). A Cochrane Review of 29 studies by Zwerink and associates (2011) similarly found a statistically significant association between self-management education for adults with COPD and decreased breathlessness, improved quality of life, and reduced number of hospital visits. However, Zwerink et al. (2011) did not make recommendations for self-management interventions due to the diversity of the programs included in the review.

Successful control of COPD and COPD with asthma depends upon provider implementation of treatment guidelines and continuity of care to support patient self-management. Action plans for asthma are evidence-based tools specifically designed to facilitate patient self-management (Kuhn et al., 2015), and are becoming increasingly more important in

an effective multi-disciplinary approach toward COPD management (Jalota & Jain, 2016).

Action plans are considered a standard of care shown to improve self-management through patient empowerment, with a corresponding decrease in the preventable exacerbations and complications leading to frequent ED visits and hospitalizations (Howcroft, et al., 2016; Peytremann-Bridevaux, Arditi, Gex, Bridevaux, & Burnand, 2015). An action plan is a formally written, yet simple and inexpensive approach that promotes self-management through reinforcement of patient education on medication use, trigger avoidance, symptom recognition and response, and maintaining healthy lifestyle behaviors that address issues such as comorbidities, smoking cessation, diet, and physical activity (Howcroft et al., 2016; Peytremann-Bridevaux et al., 2015).

Kuhn et al. (2015) developed and implemented an electronic asthma action plan (eAAP) through the Carolinas HealthCare Systems, then compared outcomes for patients managed with an eAAP versus those who were not. Of the actively managed 50,000 pediatric and adult patients diagnosed with asthma, PCPs took initiative to implement the eAAP with 4,259 children (82%) and 915 adults (18%) (Kuhn et al., 2015). Results for children measured at three, six, and 12 months showed a statistically significant association with a decrease in exacerbations, oral steroid prescriptions, and ED visits (Kuhn et al., 2015). While findings for adults were not statistically significant at six and 12 months, at three months there was a 34% decrease in exacerbations (p<0.05) and oral steroid prescriptions (p<.001) associated with implementation of an eAAP (Kuhn et al., 2015). The disparity between rates of initiated eAAPs for children versus adults raises an important question about whether adults with asthma received adequate evaluation and treatment.

A systematic review of 19 studies conducted in five countries over an 11-year period revealed a deficit in the use of asthma action plans (Ring et al., 2011). Ring et al. (2011) found that a gap between theoretical benefits of an action plan and clinical practice resulted from a misperception by practitioners of their patients' capabilities, a tendency to focus on medical aspects versus including psychosocial influences, and the need to involve patients in its development. Ring and associates (2011) concluded misdirected action plan implementation leads to a cycle of under-utilization and misunderstanding of its purpose and effectives leading to consequent uncontrolled disease (Ring et al., 2011).

Financial Viability

COPD management programs have the potential to produce substantial cost savings (Maeng et al., 2016). A randomized controlled trial of a disease management intervention for COPD patients at high risk for exacerbations at five U.S. Veterans Affairs medical centers produced a cost per patient per year (PPPY) of \$650 and an average cost savings of \$593 PPPY (Dewan, Rice, Caldwell, and Hilleman, 2011). A one-year study found that action plan self-management support yielded an average cost savings of \$201 per COPD patient per month (Chuang, Levine, & Rich, 2011). Furthermore, the total return on investment was \$103,748, which suggests the financial viability of COPD care management programs and thus warrants further study to prompt increased payer support for such services (Chuang et al., 2011).

Implementation of an individualized COPD action plan requires PCPs to team up with non-providers who possess skills and knowledge of chronic disease management. However, the expense of appropriately trained staff is a barrier to most practices, and such services are not covered by commercial payers or Medicaid. Three reimbursement factors are influential. First, Medicare has developed billable codes with specific criteria for services by licensed non-

providers for episodic transitional care management (TCM) from hospital to outpatient settings (Centers for Medicare and Medicaid Services (CMS), 2016b), and longitudinal chronic care management (CCM) (CMS, 2015). Second, Medicare has developed an Advanced Alternative Payment Model (APM) program called Comprehensive Primary Care Plus (CPC+) which funds services by licensed non-providers to improve health outcomes for patients with chronic diseases such as COPD (CMS, 2016a). Based on the health status and psychosocial needs of a practice's Medicare population, CMS calculates a care management fee which is paid quarterly specifically to fund quality improvement interventions (CMS, 2016a). Third, the Advanced APM supports accurate ICD-10 coding, evaluation and management (E&M) coding, and current procedural terminology (CPT) coding to optimize reimbursement by all payers while facilitating cost and labor-effective resource allocation.

Summary of the reviewed COPD and asthma studies is that exacerbation prevention and disease control interventions are inconsistent and insufficient. Multiple risk factors keep prevalence rates high while the struggle to self-manage distressing symptoms and complex medical regimens send adults to the hospital more often than necessary, generating significant healthcare costs. However, improving health literacy and establishing a reliable action plan in collaboration with members of the primary healthcare team addresses the heterogeneity of disease processes, patients, and clinical practices. Proper action plan implementation empowers patients to successfully self-manage their symptoms through the proper use of medications, avoiding triggers, and regular visits with a PCP. Successful self-management is a positive predictor of patient satisfaction, optimal daily and long-term function, and decreased healthcare resource utilization with corresponding cost control.

Theoretical Framework

One response to the U. S. healthcare crisis is the Patient Centered Medical Home (PCMH) model, which promotes proactive, team-based, system-wide quality healthcare that values relationships and prioritizes the equitable delivery of healthcare services for all individuals. The PCMH model originated in Hawai'i in 1979 as the outcome of a campaign for comprehensive, continuous pediatric primary care, particularly for children with chronic diseases and disabilities (Sia, Tonniges, Osterhus, & Taba, 2004). The concept continued to evolve in Hawai'i throughout the 1980s, resulting in the implementation of the Hawai'i Healthy Start Home Visiting Program; the Hawai'i Emergency Medical Services for Children Program; the Hawai'i Medical Association physician training program for Children with Special Health Care Needs; and the provision of family support, education, and healthcare to infants and toddlers under the Hawai'i Early Intervention Program (Sia et al., 2004).

As depicted in Figure 1, the five core components of the modern PCMH model guide healthcare practices to provide services that are: 1) patient-centered, 2) comprehensive, 3) coordinated, 4) accessible, and 5) grounded in a systems-based, operationalized approach that prioritizes quality and safety (Gerteis & Kantz, 2015; Zutshi et al., 2013). PCMH healthcare redesign strategies aim to maximize service quality and patient outcomes without discrimination; ensure experiential satisfaction for patients, caregivers, and healthcare professionals; and control healthcare expenditures (Williams et al., 2012).

Findings from a review by the Patient-Centered Primary Care Collaborative (PCPCC) of 21 recent scholarly studies, state government reports, and industry reports included improved healthcare resource utilization, increased patient satisfaction, cost savings, and improvements in quality of care and population health metrics (Nielsen, Gibson, Buelt, Grundy, & Grumbach,

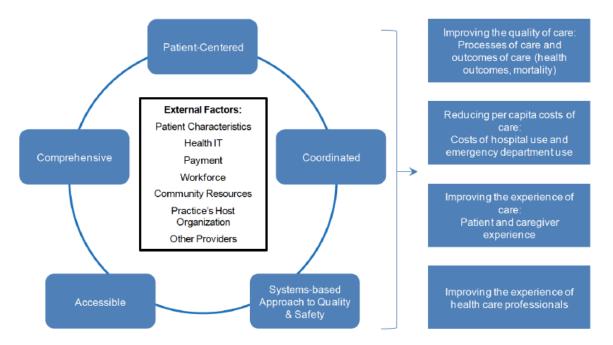


Figure 1. Conceptual framework for the effectiveness of the medical home

Zutshi et al.. (2013). Reproduced with expressed permission from the Agency for Healthcare Research and Quality (AHRQ) (see Appendix B).

2015). The positive outcomes highlighted in this annual report by Nielsen et al. (2015) suggest that embracing the PCMH model results in sustainable quality transformation at the practice level and at the community level. Results have prompted national payment reform measures incorporating attributes of the PCMH model through the 2010 Patient Protection and Affordable Care Act (PPACA), including programs with the Centers for Medicaid and Medicare Services (CMS) and the creation of Accountable Care Organizations (ACOs) (National Conference of State Legislatures (NCSL), 2012). However, a national survey of 1,325 small to medium-sized primary care practices on the integration of the PCMH model revealed that larger practices of 13-19 physicians were significantly more likely to have the internal resources and pay-for-quality incentives that supported implementation of PCMH processes than single and two-physician practices (Rittenhouse et al., 2011).

Thus, 30 years after the initial successes of a pediatric patient-centered model Hawai'i faces significant challenges to planning and implementing the current PCMH model from limited provider and community resources, geographical barriers, intricate healthcare legislation, and health insurance inequities (Stange et al., 2010; Williams et al., 2012). The diversity and complexity of individuals, healthcare practices, and community culture pose additional challenges that seem to defy equitable, sustainable solutions. Thus, PCMH-inspired practice transformation is an end goal best achieved through small changes over time built on the identified strengths of all stakeholders (Schottenfeld et al., 2016; Zutshi et al., 2013). Success hinges on leadership with a commitment to practice-wide, sustainable change and transparent communication. If communities establish practices dedicated to promoting the PCMH model, professional and patient relationships founded on trust and nurtured by the consistency and continuity of expert healthcare services are enabled (Stange et al., 2010; Williams, 2012).

Population Health Significance and Concepts

The World Health Organization (WHO) defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, n.d., para. 1). However, chronic, complex diseases such as COPD and asthma with their high risk for progression and disability pose unique challenges to achieving a state of health for patients, healthcare professionals, government leaders, and community agencies. Costs from COPD are increasing due to rising incidence, prevalence, and poor disease management. This phenomenon is attributable to aging and smoking, and is influenced by a provider shortage. In addition to direct healthcare costs, uncontrolled chronic disease also affects the economy in terms of lost productivity by the patients and those who are absent from work to care for them.

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Action plans target the complex, specialized needs of adults with COPD and COPD with asthma. Population-level, evidence-based standards of care are used to design service delivery protocols prioritizing patient-driven interventions with a focus on self-management (Williams et al., 2012). The action plan integrates feedback from multi-disciplinary team members and the electronic health record (EHR) system to track, evaluate, modify, and share patient progress and ongoing needs. Action plan implementation is an achievable, PCMH-inspired approach aimed at engaging and empowering individuals to self-manage the symptoms and stressors associated with their chronic diseases. Effective self-management plans promote increased stability, function, and quality of life. Although precise components of care vary widely depending upon available healthcare resources and diverse patient demographics, the PCMH model supports the use of an action plan as a standardized self-management approach with generalizable outcomes across diverse populations and geographies.

Chapter Three: Project Design and Evaluation Plan

This chapter describes the methods used to implement the aims and objectives proposed in the project. The components of the *BREATHE* project will be articulated as they direct the implementation of the project. The steps taken to meet the aims and objectives are described. Ethical assurance and resource utilization are discussed.

Data is lacking on the relationship between individualized patient-centered action plans and successful self-management of COPD and asthma in east Hawai'i Island primary care practices. Using a quality improvement approach, this PIP examined the effects of implementing a written action plan utilizing evidence-based practices for the management of COPD with or without asthma in the primary care setting. This PIP formed the foundation for a practice site pilot program entitled *BREATHE for a Better Life*, which focused on essential interventions and longitudinal RN care management promoting self-management and optimal QoL outcomes for patients with COPD with or without asthma.

The logic model guided development of this PIP's methodology and evaluation plan (see Appendix C). A logic model is a visual roadmap that describes the essential components of a program and their relationships to each other. The structure of a logic model provides clarity and guides the evaluation process to determine whether activities and outcomes occurred as expected (Petersen & Peikes, 2013). Specific project outcome measures included 1) the number of exacerbations defined as acute respiratory complaints; 2) the number of exacerbations leading to hospital ED visits, admissions, urgent care, or PCP visits during participation in the program; 3) spirometry values, and 4) pre- and post-participation CAT scores. Components of the *BREATHE* for a Better Life program are based on the evidence presented in the ROL. BREATHE stands for:

- B Baseline spirometry and CAT scores
- R Reconcilation and review of all medications regularly, acutely, and with changes in status
- E Eliminate smoking. Provide cessation counseling and support, as appropriate
- A Action Plan initiation with regular reviews and updates
- Trigger avoidance. Identify allergens and minimize exposure.
- H Healthy lifestyle behaviors
- E Educate patients, families, and caregivers. Evaluate understanding and willingness to adhere to the care plan with modifications as indicated

BREATHE is a conceptual model developed by the project director based on the literature derived from COPD research and the GOLD standards. The BREATHE novel approach has not been previously used in other studies or projects.

Human Subjects Protection and Ethical Assurance

Prior to the BREATHE project, the primary clinic site featured pro-active RN care manager patient-interaction and regular chart reviews of patients with COPD. Informed consent was obtained from patients to incorporate action plan development into their existing health care and to participate in two brief surveys (see Appendix D). To ensure confidentiality, each patient received a unique identification code that linked him or her to the program outcome, and all participant-related data was filed securely within the practice site. Ethical standards of this PIP were reviewed and approved by the University of Hawai'i Institutional Review Board (IRB) (see Appendix E). Health Insurance Portability and Accountability Act (HIPAA) regulations were strictly enforced. Healthcare was provided equitably regardless of patient demographics or ability to pay.

A Memorandum of Agreement (MOA) was signed with the participating agency (see Appendix F). The principle investigator had no conflicts of interest or financial relationships with commercial interests. Faculty in the University of Hawai'i at Hilo Doctor of Nursing Practice program supervised this study.

Project Setting and Target Population

The community-based collaborator on this project was a primary care family practice in East Hawai'i Island employing the PCMH model. The practice's direct patient-care staff includes one physician, one certified physician's assistant (PA-C), three registered nurses (RN) trained in care management, and four front office staff cross-trained as medical assistants (MAs). A licensed mental health counselor (LMHC), a psychologist, and a registered dietician nutritionist (RDN) were available on-site for internal referral.

All patient encounters were conducted face-to-face at the practice site, by portal messaging, or by phone. The target population included adults 18 years and older with a diagnosis of COPD with or without asthma and a history of at least one hospital ED visit, admission, urgent care visit, or acute PCP visit for a respiratory complaint within the six to 12 months prior to project start date. Potential participants were identified through an electronic registry of ICD-10 codes J44.0, J44.1, and J44.9, followed by a chart review conducted to filter for the following exclusion criteria: 1) non-English speaking individuals, and/or 2) any diagnosis of dementia or mental health disorder that precludes the capacity for self-management, as determined by the PCPs.

Data Collection and Instruments

A single template designed by the PIP enabled PCPs to create an individualized action plan with each patient (see Appendix G). Components of the individualized action plan were based on GOLD (2017) and GINA (2017) guidelines and action plan templates from the American Lung Association (2017) for COPD and asthma. COPD symptom recognition and self-management interventions formed the core of the action plan. Additional elements of the action plan reflected the project's measurable metrics of spirometry values, CAT scores, and

number of medical visits for acute respiratory complaints. The action plan was enhanced by a medication list, personalized behavioral or lifestyle goals, and a personalized check list to address immunizations, emergency contacts, and advanced directives.

Spirometery aids the practitioner in identifying and differentiating between obstructive and restrictive respiratory conditions. The FEV₁ and FVC values obtained from spirometry are used to diagnose COPD and grade its severity. Medical assistants (MAs) in the PIP practice site trained with varying methods used office spirometry equipment to obtain initial spirometry values. Pulmonary function Tests (PFTs) include spirometry and tests for lung volumes and diffusion capacity. PFTs for this PIP conducted by experts in the local hospital respiratory department were also ordered for each participant for comprehensive and reliable findings.

As described in the ROL, the CAT is a validated instrument evaluateing the impact of symptoms on quality of life and can assist in predicting a high risk for exacerbation (Lee et al., 2014). Scores range from zero to 40. Five or below is normal, less than 10 indicates low impact, 10 to 20 indicates medium impact, greater than 20 indicates high impact, and greater than 30 indicates very high impact. The Minimum Clinically Important Difference (MCID) is defined as a change of 2 or more units in the total score, suggesting a meaningful alteration in health status (CAT Governance Board, 2016). Increasing CAT scores without evidence of acute medical services can be an indicator of unreported exacerbations, leading to an increased risk for morbidity and mortality (CAT Governance Board, 2016; Lee et al., 2013). Express permission to use the CAT was obtained from GlaxoSmithKline (see Appendix H).

Action plans were updated at each visit and scanned into the patient's EHR by clinic staff. De-identified, coded patient data including COPD severity, medications; frequency of hospital ED, admissions, and PCP visits; spirometry results; vaccination history; and patient

goals were collected from the action plans and stored on an excel spreadsheet. CAT scores were also de-identified, coded, and stored on an Excel spreadsheet. Additional information collected for analysis included age, smoking history, and co-morbid conditions as risk factors for exacerbations and complications.

Data Analysis Methods

Electronic medical records and paper-based documents were reviewed for the identified outcome measures. CAT results were interpreted by the provider according to the established scoring range and used to guide action plan modifications. Frequency of hospital ED visits, admissions, urgent care visits, and acute PCP visits for a respiratory complaint during the program's duration were compared to the frequency during the six months prior to the program's start date. Spirometry scores were analyzed for changes in lung function to confirm diagnosis, and COPD severity was objectively graded according to the GOLD (2017) scale.

Project Implementation

The purpose of this practice inquiry project (PIP) was to evaluate the effectiveness of individualized action plan implementation by PCPs on the frequency of preventable acute care visits for respiratory complaints by individuals with COPD and COPD with asthma. Specific aims and objectives were satisfied through a quality improvement approach supported by the PCMH model of health care delivery (see Table 5 for details).

Aim 1. Design a primary care chronic respiratory disease management program for adults.

Objective 1: A partnership was developed with a healthcare organizations serving adult patients with COPD and asthma.

Objective 2: An on-site assessment was conducted.

Objective 3: Measures for monitoring effectiveness and sustainability of the primary care management program were determined.

Objective 4: A timeline for evaluation, modification, and end date was established.

Aim 2. Implement the chronic respiratory disease management program designed to serve the needs of East Hawai`i adults receiving primary care services.

Objective 1: The project was formally presented to all members of the healthcare team.

Objective 2: Individualized care plans were generated and implemented.

Objective 3: Clinical data were collected and recorded.

Objective 4: Financial data were collected.

Aim 3. Stakeholders evaluate the project.

Objective 1: Clinical and financial data were analyzed.

Objective 2: Findings and a program evaluation form were disseminated to stakeholders.

Objective 2: Evaluation form results were analyzed and summarized.

Objective 3: Recommendations were offered to the practice site physician.

Table 5. Implementation of aims and objectives

Aims	Objectives	Progress
	Partner with key healthcare organizations serving adult patients with COPD and COPD with asthma.	Developed a collaborative partnership with the site physician at a healthcare organization serving adult patients with COPD and asthma. Met regularly with key practice site personnel to explain the program and assess readiness for a quality improvement project.
Aim 1. Design a	2. Identify organization-specific personnel, equipment, and workflows that support a quality-driven, comprehensive, primary care pilot program targeting the healthcare needs of patients with COPD and COPD with asthma.	Identified existing site resources that could serve as components for success, including an electronic medical record (EHR) system; a RN care manager; and team-based, patient-centered workflows.
primary care chronic respiratory disease self-management pilot program for adults.	3. Based on identified healthcare resources and national guidelines, determine measures for monitoring effectiveness and sustainability of the primary care self-management pilot program.	Identified the following components for successful monitoring, including chart surveillance with secure data collection and storage of specified clinical outcome measures, and effective bidirectional communication between stakeholders.
	5. Establish a timeline for evaluation, modification, and end date of the primary care self-management pilot program.	Obtained approval from the University of Hawai'i at Hilo School of Nursing Scientific Review Committee (SRC), the University of Hawai'i Institutional Review Board (UH IRB), and with the practice site through a Memorandum of Agreement (MOA). The site physician agreed to conduct weekly team meetings to evaluate the project's progress and modify as needed. The project end-date was March 31, 2018. A project summary and evaluation form were disseminated to stakeholders within the following two weeks.

Aim 2. Implement the chronic respiratory disease self-management pilot program designed to serve the needs of East Hawaii adults receiving primary care services.	1.	Present the chronic respiratory disease management program to all members of the healthcare team (defined in Chapter 3), including patients and their personal support networks.	The project was formally presented to all members of the healthcare team through a series of brief meetings. The program was described to potential participants during a face-to-face encounter. Willing participants signed a general consent form that also outlined patient rights and permitted the use of deidentified, aggregated data for clinical quality improvement purposes.	
	2.	Collaborate with the healthcare team to implement individualized care plans with an emphasis on patient education and support for symptom control, medication management, preventive care, and behavioral modification.	The healthcare team used the standardized <i>BREATHE</i> template to generate individualized care plans with an emphasis on patient self-management. The RN Care Manager initiated an individualized care plan with each participant. Patients had 24/7 access to health care services via phone and secure electronic portal messaging, same day acute care appointments and RN care management, and scheduled PCP follow-up visits to support health promotion and early intervention.	
	3.	Collect data that enables program assessment and modification according to the established measures and timeline.	Outcome data from electronic and paper-based health records were recorded on an Excel spreadsheet, reviewed weekly, and tabulated at the project's close. Data was stored at the practice site in a secured physical filing system and within the password-protected EHR.	
	4.	Collect financial data to estimate the financial viability of the primary care self-management pilot program	Expenditures and revenue estimates were generated based on data from the practice site's financial statements for 2017.	
Aim 3. Program evaluation by stakeholders.	1.	Upon completion of the pilot program, analyze clinical and financial data.	Clinical data collected from the EHR and the written action plan were synthesized and analyzed. Financial data were collected from the practice's 2017 estimated profit and loss statement for 2017 to generate a break-even analysis without profit target.	
	2.	Disseminate findings with an evaluation form to stakeholders for feedback.	All healthcare team members involved in direct patient care completed project evaluation forms regarding project processes. The form was designed to determine appropriateness of the action plan, identify issues with implementation, and assess its clinical usefulness (BetterEvaluation, 2016).	
	3.	Analyze evaluation form results.	Evaluation form results were analyzed and summarized; see chapters 4 and 5.	
	4.	Based on evaluation form results, recommend system-based changes for healthcare quality improvement.	The site physician received a summary report of all findings as well as recommendations for program quality improvement and sustainability.	

Chapter Four: Results

BREATHE for a Better Life was designed as a primary care COPD program for adults incorporating a COPD Action Plan as its foundation to promote patient self-management. Data generated from action plan development and facilitation were categorized and summarized. This chapter describes the implementation process and findings.

Implementation Process

Aim 1. Design a primary care chronic respiratory disease management program for adults.

A collaborative partnership was initiated in two meetings held with the site physician on August 08, 2017 and November 21, 2017. The supervising physician signed a Memorandum of Agreement (MOA) for the project on November 11, 2017. Two subsequent meetings to assess readiness for a quality improvement project were held with key practice site personnel including the Office Administrator, the Nursing Supervisor, and two registered nurse (RN) care managers. A project overview was introduced to five medical assistants (MA) who are cross-trained as receptionists. The University of Hawai'i at Hilo (UHH) School of Nursing (SON) Director, the UHH vice Chancellor for Academic Affairs approved the MOU between the practice site and the university. The UHH SON Scientific Review Committee (SRC) approved the project proposal in December 2017. The SRC-approved proposal application was submitted to the UH IRB on December 08, 2017, and approved for implementation on January 23, 2018.

The practice site had initiated the concept of primary team-based care over 10 years ago when it incorporated behavioral health providers, and expanded the concept in 2013 when the first RN care manager was hired. The practice site hired a second RN care manager in 2016, and a third RN care manager in 2017 when it was accepted into the Medicare CPC+ (2016a) quality

performance program. A fourth RN was hired in 2018 to further expand access. At the start of the project, the practice site had several existing resources that could support a quality-driven, comprehensive, primary care program targeting the healthcare needs of patients with COPD and asthma. On-site personnel resources included a psychologist (Psy.D) and a licensed mental health counselor (LMHC), a registered dietician nutritionist (RDN), the Office Administrator, the Nursing Supervisor, the RN care managers, and the MA/receptionist staff. The practice was equipped with a digital spirometer, an electronic health records (EHR) system, and quality improvement efforts promoting ongoing evaluation and modification of workflows targeting patient education and RN care management support.

The project used chart surveillance, with both manual and electronic data collection, to monitor the effectiveness of the primary care management program. Input from the practice site personnel was communicated through a secure, internal messaging system and during scheduled meetings. Quality data for the PIP were collected and reviewed a minimum of once per week to monitor progress. Weekly meetings with the practice site physician and additional personnel were held to evaluate the project's progress, identify strengths and weaknesses, and make modifications accordingly.

The primary outcome of interest was the frequency of hospital ED visits, admissions, urgent care visits, and acute PCP visits for an acute respiratory complaint during the BREATHE program, compared to the frequency during the twelve months prior to the program's start date. Additional measures included values for the CAT, FEV₁/FVC, and FEV₁. Types of co-morbid conditions, smoking status, prescribed respiratory medications, age, gender, and administration of influenza and pneumococcal vaccines were identified as additional health factors relevant to

developing evidence-based preventive and maintenance care plans. Outcomes and measures will be addressed in greater detail later in this chapter.

Aim 2. Implement the chronic respiratory disease management program designed to serve the needs of East Hawai'i adults receiving primary care services. Collect and summarize data.

The healthcare team used an electronic registry to identify 64 potential participants, who were then screened for eligibility. Eligible patients were adults 18 years and older with an encounter recording ICD-10 codes J44.0, J44.1, or J44.9 and a history of at least one hospital ED visit, admission, urgent care visit, or PCP visit with a respiratory complaint within the 6 months prior to project start date. Exclusion criteria included non-English speaking individuals and any diagnosis of dementia or mental health disorder that precluded the capacity for self-management, as determined by the PCP. Once filtered for exclusion criteria, the total potential population was approximately 34 individuals.

The healthcare team then contacted potential participants by phone, electronic portal messaging, or during an office visit to determine interest. Fourteen patients either declined to participate or did not respond to phone or portal messages, which brought the total potential population to approximately 20. Eleven patients were recruited during face-to-face encounters by February 28 to enable running the project with a single cohort for one full month.

Each interested participant met with a healthcare team member to discuss the *BREATHE* for a Better Life program purpose and details of the consent form. Once the consent form was signed, healthcare staff explained and administered the CAT, completed medication reconciliation, and provided patient education. Staff then reviewed the risks and benefits of vaccinations with patients and suggested they update emergency contacts and complete an

advanced directive. Patients and staff worked together to establish a minimum of one personal goal.. Participants were informed that a written, individualized COPD Action Plan would be

Table 6. Summary of defined measures

Participant ID	FEV1/FVC*	FEV1 % predicted	GOLD level*	CAT score	ED	Hospital admission	Urgent	PCP	PCP March 1-31	
		*				(retrosp		2018		
1	0.34/0.60	32/61	3/2	19	1	1	1	3	0	
2	0.68/0.62	75/80	2/1	30	1	0	0	2	1	
3	0.40	61	2	12	0	0	0	0	1	
4	0.76	76	2	17	0	0	0	0	0	
5	0.66	90	1	6	0	0	1	0	0	
6	0.59	52	2	6	0	0	0	0	0	
7	0.31	36	3	16	0	0	0	2	0	
8	none	none	none	16	0	0	0	4	0	
9	0.62	36	3	9	0	0	0	0	0	
10	0.57	120	1	22	0	0	0	1	0	
*office/hospi	*office/hospital									

created and printed for them. The eleventh participant subsequently withdrew, leaving a final cohort of ten participants. The project end-date was March 31, 2018. At the project's conclusion, data from the defined measures were summarized (see Table 6). Additional health information included in the action plan was collected and summarized. Findings are described in the following paragraphs.

Results

Spirometry results were collected from retrospective EHR data, testing in the office during the project period, and pulmonary lung function testing ordered at a local hospital.

Respiratory Department during the project period. Office-based spirometry provided FEV₁/FVC values ranging from 0.31 to 0.68 confirming a COPD diagnosis for eight participants (see Figure 2). Participant 4 had a value of 0.76, and participant 8 did not have a spirometry value. Hospital

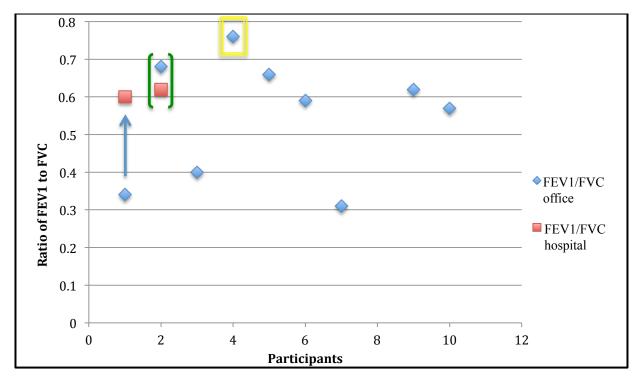


Figure 2. FEV1/FVC Values

respiratory department-based pulmonary function tests (PFTs) were ordered for all participants as a component of the *BREATHE* program. PFT results re-confirmed a COPD diagnosis for participants 1 and 2. Notably, the FEV1/FVC value for participant 1 rose from 0.34 to 0.60. PFTs for the remaining eight participants were either not yet scheduled or scheduled but not completed during the project duration.

CAT results for 20% of participants scored between 21 and 31, 50% scored between 11 and 20, and 30% of participants scored between 5 and 10. FEV₁ results showed 20% of participants scored greater than 80% of predicted values, 40% of participants scored between 50% and 80%, and 30% scored between 30% and 50% (see Figure 3). CAT scores and FEV₁ results were charted relative to each other to determine any pattern of inverse correlation between COPD severity and patients' perceptions of the negative impact COPD symptoms have on their quality of life (QoL).

Figure 3. FEV1 results relative to CAT scores

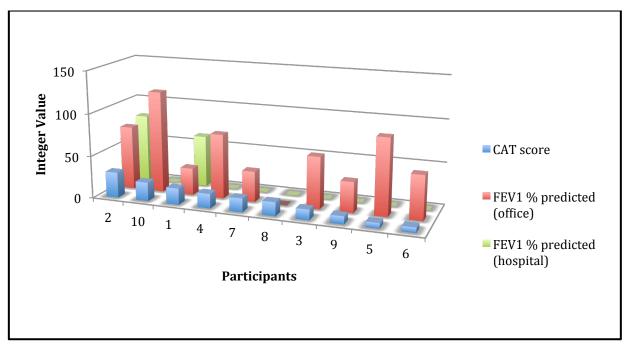
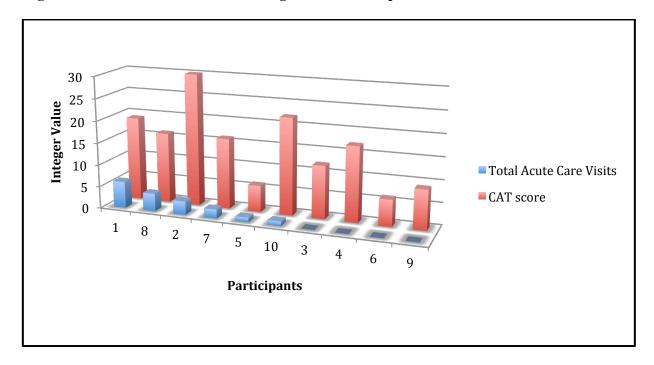


Figure 4. Total acute care visits during the look-back period relative to CAT scores



For medical visits related to acute respiratory complaints during the 6-month look-back period defined as September 01, 2017 through February 28, 2018, participant 1 had one hospital admission, one ED visit, one urgent care visit, and two PCP visits. Participant 8

had four PCP visits. Participant 2 had one ED visit and two PCP visits. Participant 7 had two PCP visits. participant 5 had one urgent care visit, and participant 10 had one PCP visit. Acute care visits and CAT scores were charted relative to each other to determine any positive correlations (see Figure 4).

During the project implementation period defined as March 1-31, 2018, participants 1 and 2 had one PCP visit each. Participants 4, 6, and 9 had no acute visits. Participants 2,and 5 were each seen once by their PCP for acute respiratory symptoms during the PIP implementation period. Respiratory medication for participant 2 was changed from a LAMA to a LABA/LAMA, hospital PFT results were discussed, and patient education focused on respiratory symptom management during this PCP visit. Participant 5 was evaluated for a possible allergic reaction to her LAMA, which was discontinued. There were no urgent care visits, hospital ED visits, or hospital admissions for acute respiratory complaints during the implementation period.

Figure 5. Summary of participants' co-morbid conditions

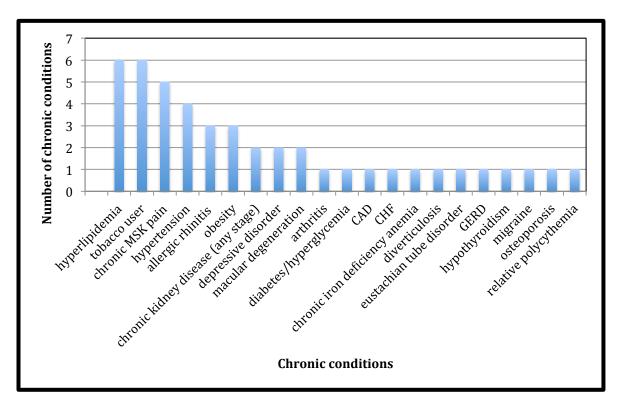
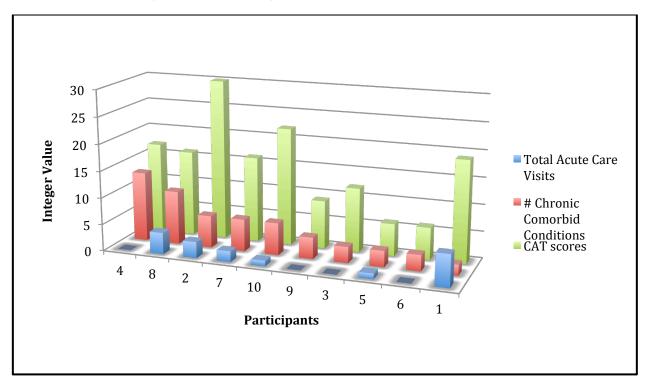


Figure 5 displays a summary of the 25 documented comorbid conditions for this participant cohort. Sixty percent of participants had a diagnosis of current tobacco use, 60% had hyperlipidemia, 50% had chronic musculoskeletal pain, and 40% had hypertension. Obesity and allergic rhinitis were each diagnosed in 30% of participants.

The number of comorbid conditions, frequency of acute medical visits, and CAT scores were charted relative to each other to determine any positive correlations between medical complexity and the number of acute medical visits, or between medical complexity and QoL with variable results (see Figure 6). Including COPD, participant 4 had a total of 13 comorbid conditions, a medium level CAT score, and no acute care visits. However, participant 8 had 10 comorbid conditions, also had a medium level CAT score, but had four acute care visits. Including COPD, 30% of participants had a total of six comorbidities and 30% had three. Participant 9 had a total of four comorbidities, and participant 2 had two.

Figure 6. Comparison between the number of acute medical visits, the number of comorbid conditions, and CAT scores,



Appropriate medication prescription and use are essential for management. As discussed in the ROL, medications are prescribed according to a combination of the impact of symptoms represented by the CAT score, FEV1 percent predicted values that translate into GOLD severity levels, and the number of acute care visits. Table 7 illustrates the number and types of medications originally prescribed to each participant and the three indicators for prescribing as discussed in the ROL. Notably, participant 3 had no respiratory medications. Ninety percent of participants were prescribed a short-acting albuterol inhaler (SABA). In addition to the SABA, 30% of participants were prescribed albuterol for nebulization. Participant 6 did not have a maintenance medication, defined as a long-acting muscarinic receptor antagonist (LAMA) or a long-acting beta2-agonist (LABA). Thirty percent of participants were originally prescribed monotherapy with a long-acting muscarinic receptor antagonist (LAMA) and 20% were prescribed a combination of a (LABA) plus a LAMA. Participant 2 was changed from a LAMA

Table 7. Medications and prescription indicators

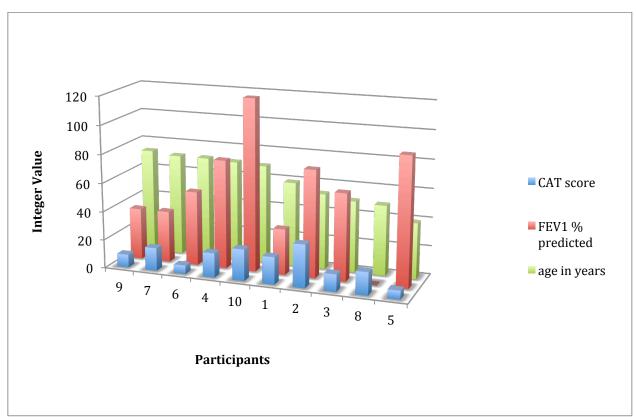
	Albuterol	Albuterol			**************************************	CAT	GOLD	#
Participant	inhaler	nebulizer	LAMA	LABA/LAMA	ICS/LABA	Score	Level	Acute
								Care
								Visits
1	✓	✓		✓		19	2	6
2	✓		/ -	→ 		30	1	3
3						12	2	0
4	✓	✓			~	17	2	0
5	✓		~			6	1	1
6	✓					6	2	0
7	✓			~		16	3	2
8	✓	✓	~		~	16	none	4
9	✓					9	3	0
10	✓		Ordered			22	1	1
			but not					
			picked up					
			due to					
			finances					

^{*}Medication for participant 2 was changed during the implementation period based on his GOLD severity level, CAT, and number of acute care visits.

to a LABA/LAMA and was the only medication change made during the implementation period. Twenty percent of participants were prescribed a combination of a LABA plus an inhaled corticosteroid (ICS). Participant 8 was prescribed triple therapy, which is defined as a LAMA plus a LABA and an ICS.

FEV1, CAT scores, and age in years, and pack years were charted to determine patterns of correlation in the influence of age (see Figure 7) and pack years (see Figure 8) on disease severity and the participants' self-perception of health and quality of life. Fifty percent of participants were 69 to 73 years, 30% were within the range of 50 to 59 years, one was 49 years, and the youngest was 39 years. Participant 4 had a pack year history of over 100 years. Thirty percent of participants had a history of 50 to 60 pack years, 20% had 40 to 49 years, 30% had 30 years, and participant 5 had 23 years.





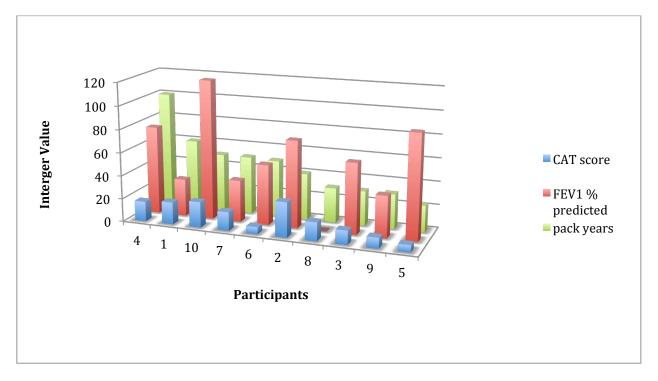


Figure 8. Relationship between FEV1, CAT scores, and pack years

Fifty percent of participants were current cigarette smokers, 40% were former cigarette smokers, and participant 7 was a former cigarette smoker now smoking e-cigarettes. Two former smokers had quit dates in January 2018. Ninety percent of participants had a history of 30 or more pack years.

Participants were instructed to set at least one, measurable personal health goal that demonstrated a positive correlation with smoking status (see Table 8). Fifty percent of participants chose personal health goals related to decreasing smoking or continuing cessation efforts. Participant 10 stated early in the initial interview he would not stop smoking cigarettes and declined further discussion about it, but stated he would start swimming again. Participant 7 was convinced that smoking e-cigarettes was a satisfactory solution, declined further discussion about it, and determined that taking care of his dogs kept him happy and therefore healthy. Two

Table 8. Smoking status and personal goals

Participant	Current Smoker	Former Smoker	Quit Date	Pack years	Personal Goals
1		~	01/08/2018	60	Continue smoking cessation
2	~		n/a	40	Decrease # daily cigarettes
3	~		n/a	30	Decrease # daily cigarettes
4	~		n/a	100+	Decrease # daily cigarettes
5		~	01/03/2018	23	Continue smoking cessation
6		>	2016	49	Spend quality time with family
7		>	2014; now smokes e-cigs	50	Take care of his dogs
8	>	>	n/a	30	Eliminate diet soda, increase water intake
9		>	uncertain	30	Continue regular exercise
10	~		n/a	50	Start swimming again

participants were former smokers with two or more years cessation whose goals included enjoying family time and continuing a regular exercise program. The 20% of participants with quit dates in January 2018 had the same goal to continue smoking cessation. Thirty percent of participants had goals to set a smoking cessation date and meanwhile pledged to decrease the number of daily cigarettes. Participant 8 declined all conversation regarding smoking cessation and set a goal to eliminate diet soda and increase daily water intake. In the process of setting personal goals, psychosocial factors of significance arose including one participant who stated he could not afford the high co-pay for his respiratory medications, and one participant who was on week-day furlough from prison.

Table 9: Vaccinations

Participant	Age	Influenza	PPSV23	PCV13
1	59	✓	✓	n/a
2	53			n/a
3	50			n/a
4	70	✓	✓	✓
5	39			n/a
6	71		✓	
7	71			✓
8	49			n/a
9	73			
10	69	✓		✓

Recommended vaccinations for individuals with COPD are influenced by age and comorbid conditions. They include influenza, pneumococcal 23, and pneumococcal 13 (see Table 9). No participants in this cohort had a specified high risk condition that warranted PCV13. Participant 4 was the only one current on all recommended vaccinations. Participant 10 was current on influenza and PCV13. Participant 1 was current on influenza and PPSV23, participant 6 was current on PPSV23, and participant 7 was current on PCV13. Fifty percent of participants had not received any recommended vaccinations.

A total fixed cost estimate was made based on rough calculations of direct and indirect fixed costs provided by the practice site administrative team (see Table 10). These figures were calculated to reflect the approximate cost of staffing this PIP using units of service (UOS) or 26.6 operational hours, as appropriate. Total revenue was estimated using an average reimbursement for UOS defined as an office visit performed by a provider, a chronic care management encounter performed by a RN, and CMS chronic care management fees as discussed in the ROL.

Table 10. Expenditure and revenue estimates

Expense	Notes	Rate	Cost
Physician	1 FTE	\$77/hr x (0.33 hr/patient) x 20	\$462
RN care manager	0.5 FTE	\$33/hr X (1hr/patient) x 20	\$660
Medical assistant	1 FTE	\$16/hr x (1.33 hr/patient) x 20	\$426
Administrator	1 FTE	\$23/hr x (1.33 hr/patient) x 20	\$612
Receptionist	1 FTE	\$16/hr x (1.33 hr/patient) x 20	\$426
Biller	1 FTE	\$19/hr x (1.33 hr/patient) x 20	\$505
Medical supplies		\$4/hr x 26.6 hrs	\$106.
Subtotal (direct fixed costs)			\$3,197
Rent and insurance			\$638
Utilities			\$266
Office supplies			\$1,050
EHR fees			\$239
Durable medical equipment			
depreciation (>5 years old)*			-
Laptops/desktops depreciation			
(>5 years old)*			<u>-</u>
Furniture (>5 years old)*			-
Subtotal (indirect fixed costs)			\$2193
Total fixed costs (TFC) (direct + indirect costs)			\$5,390
99213 Office visit (performed by physician)			\$1,780
99847 Chronic care management for Medicare			\$940
patients (performed by RNCM)			\$7 4 0
RNCM** fees covered by CMS CPC + program fees			\$660
Total revenue			\$3,380

^{*}A replacement value can be calculated if the project continues beyond 7 weeks. For the short-term purposes of this PIP, replacement values would require significant assumptions and therefore will not be applied.

**RNCM: RN care manager

Total direct fixed costs related to the project included salaries and wages for the healthcare team, and were estimated to be \$3,197. An estimate of total indirect fixed costs defined as normal operational expenses including facility overhead and equipment totaled \$2,193 and was absorbed by the practice. Estimated total fixed costs were \$5,390. Revenue was defined by E&M codes for office visits and chronic care management for Medicare patients, and by CMS CPC+ program payments. Estimated total revenue was \$3,380, which projected a positive \$183 balance of revenue compared to cost.

Table 11: Providers' Project Evaluation Results

Questio	n (paraphrased)*	M.M., MD	A.M., RN	K.H., RN	W.M., RN	total
	well organized	5	5	5	5	20
	accurate	5	5	5	5	20
The action plan	easy to initiate and maintain	5	5	3	5	18
was	helpful at identifying health trends	5	5	5	5	20
	helpful for patient education	5	5	5	5	20
Patients	self-management	4	5	4	4	17
improved	health	5	5	4	3	17
Patient satisfaction	Patient satisfaction			5	4	19
Plan to continue us	5	5	4	5	19	
	total		45	40	41	170
*For full versions of	of the evaluation questions, se	e Appendix	κ I.			

Aim 3. Stakeholders evaluate the project.

Evaluation forms were distributed to the project's one supervising physician and three RN care managers with 100% response (see Table 11). Each evaluation was worth 45 points. Feedback from the evaluation forms was subsequently compiled and analyzed. Overall the project earned 94% on the evaluation. Questions 6 and 7 about patients' improvement in demonstrating self-management skills and health outcomes reported the lowest total scores. Full points were awarded for the program organization, information accuracy, and usefulness of the action plan for practitioners. K.H. had the least involvement as an RN in the project implementation and also the lowest total score. A.M.had the greatest involvement in the project implementation as an RN and also the highest score. M.M. as the supervising MD awarded the project a score of 98%. Findings and recommendations were submitted to the supervising physician.

Chapter 5: Discussion, Implications for Practice, and Conclusion

This PIP aimed to evaluate the effectiveness of actions plans implemented as a key component of the primary care *BREATHE for a Better Life* self-management program for adults with COPD or COPD with asthma. The primary goal was to measure any correlation between the frequency of acute care visits for a respiratory complaint and action plan implementation. Spirometry and CAT scores were also tracked. *BREATHE* was the mnemonic used to develop the components of the program. This chapter reviews the outcomes evaluated by the *BREATHE* initiative with emphasis on the first four sections of the mnemonic. Additionally, the limitations of the project, and implications for practice are discussed.

Discussion

Overall, findings from this PIP helped to define some of the myriad, significant challenges to predicting the course of COPD management. Action plan implementation enabled practitioners to better understand how patient heterogeneity and complexity influences treatment decisions and RN care manager interventions. Gaps in care were identified, resulting in the prompt development and implementation of new clinical tools by the PIP director to address those gaps. Discussion below will emphasize the BREATHE components.

B – **Baseline spirometry and CAT scores**. Ten participants were recruited based on an existing diagnosis of COPD, defined as J44.0, J44.1, or J44.9. Of the nine participants with an existing office-based spirometry, seven FEV₁/FVC results ranging from 0.31 to 0.68 supported a COPD diagnosis according to GOLD guidelines. Office spirometry testing was conducted by the MAs trained with varying methods. The question of accuracy, reliability, and validity due to the quality of the machine, a lack of machine calibration, and potential differences in test administration was raised. Consequently hospital-based PFTs were ordered for all participants to

establish an accurate baseline assessment. Participants 1 and 2 were the only individuals to complete hospital PFTs within the project implementation period. Participant 2's results were consistent with the office-based values with a difference of 9%, but participant 1's value increased 55% from 0.36 to 0.60 – which her action plan suggested was attributable to taking test during an exacerbation in the outpatient setting. Participant 4 with a result of 0.76 was recommended for re-evaluation to consider COPD with asthma overlap and any consequent modifications of the medical and self-management plans, as suggested by the Kim and Rhee (2010), Nakawah et al. (2013), and Vaz Fragoso et al. (2017) studies.

In agreement with GOLD (2017), project data showed the participant sample had similar age and smoking history to past studies of COPD patients.. The project expected that older patients and smokers would have more severe COPD (as represented by the FEV₁ % predicted value translated into a GOLD severity level), and higher self-perceptions of health as measured by the CAT. Participants 1 and 7 followed this pattern with high GOLD levels, medium-impact CAT scores, and more than three medical visits within the 6-month retrospective period. However, participant 9, who also had a high GOLD level, had a low impact CAT score and no medical visits. In contrast, participant 2 with a GOLD level 2 had the highest CAT score at 30 (high impact), three medical visits within the retrospective period, and one PCP visit during the project implementation period. The remaining three participants with GOLD level 2 demonstrated greater diversity in CAT scores ranging from 6 to 17 and no medical visits. In short, no clear pattern emerged between GOLD level and CAT scores. Moreover, contrary to the study by Ke et al. (2016) there was no clear pattern between the FEV₁ value and the number of acute visits for a respiratory complaint.

The supervising physician stated that Participant 4's current health status is actually a noticeable improvement since coming to the practice several years ago when her chronic diseases were uncontrolled and she was in the office frequently for a variety of complaints. Over approximately the past two years, she has been keeping regular PCP appointments and managing her comorbidities, which supports the concept that a sense of control is a critical factor in decreasing preventable healthcare utilization.

Comparisons between CAT scores, the number of acute medical visits, and the number of co-morbid conditions yielded similarly inconclusive patterns of patients' self-perception of well-being, healthcare utilization, and overall baseline health as represented by the number of chronic co-morbid conditions. Due to the brief duration of the project, it was difficult to fully determine the relationship between these measures and further research is required.

R – Reconcile and review all medications. Prescribed medications were reviewed by the supervising physician and the RN care managers according to GOLD (2017) guidelines. Participant 3's medical care plan reflected decisions made by the provider assigned to him during his incarceration prior to the project implementation period. His PCP visit was pending after the implementation period, at which time the supervising physician expected to make care plan modifications based on a thorough patient interview, physical examination, results of his CAT, and results of his hospital PFTs and serum lab tests if completed as ordered. After initiation of a COPD action plan it was discovered that participant 10 was not using the prescribed LAMA due to cost. This alerted the RN care manager to explore options to assist the participant in obtaining his medication, including referral to the Office of Aging and Disability for social services and discussion with the patient regarding his eligibility for Medicaid. Additionally, the LAMA for participant 2 was changed to a LABA/LAMA based on his two acute visits with respiratory

complaints and a CAT score of 30 indicating a high impact level of symptoms on daily QoL. Participant 8 was the only patient prescribed all possible medications, yet had no spirometry score. She is recommended for re-evaluation after completing her hospital PFTs which were pending during the project implementation period. The medication reviews initiated by the action plan demonstrated value and versatility as an effective tool for medication management and to identify health disparities.

E – Eliminate smoking. One hundred percent of participants had a smoking history and findings suggested cigarette smoking was a prominent issue for 80% of participants. The impact of cigarette smoke and other respiratory toxins on lung health was discussed with all participants. Twenty percent of participants were current smokers who refused to discuss smoking cessation, and participant 7 was a former cigarette smoker who smoked e-cigarettes instead and was unwilling to quit. Thirty percent of participants were current smokers who set a personal goal to decrease the number of cigarettes per day. Twenty percent of former smokers had quit dates within two months of the project initiation and prioritized continued smoking cessation as personal goals. Practitioner awareness of smoking prevalence was raised and the need for ongoing smoking cessation counseling was reinforced. This raises a critical issue of personal choice related to self-management and the importance of employing continuous, versatile strategies that identify barriers to and support for smoking cessation.

A – Action plan. According to provider evaluations, the action plan information was accurate and useful and program implementation was well organized. Provider evaluations of this project reported the lowest total scores on questions about patient engagement, improved self-management skills, and improved health outcomes. Likely, the program needed more time to determine the true influence of the action plan on measurable patient improvement in self-

management and in health outcomes. However, patients expressed to providers their satisfaction with the action plan and the program's concepts. Patients were informed that the project ended on March 31, but several commented that they appreciated the program's commitment to provide continuing targeted care management under the supervision of their PCP. Trigger avoidance, healthy lifestyle behaviors, and education as the remaining three components of the mnemonic were integrated into every encounter.

Implications for Practice

Cost of care is a concern for providers who implement new programs that impact work productivity. Thus, cost analysis of this project was an essential tool to validate feasibility. The BREATHE model and action plan tool effectively and efficiently outlined evidence-based standards of care formatted as an inexpensive, comprehensive checklist. This approach enabled the identification of practice strengths, and opportunities to address gaps in care and improve patient health literacy and engagement using readily available resources and workflows.

Budget estimates were based on 20 patients as the maximum sample size for this project, and 40 units of service (UOS). A UOS for this project was defined as a PCP visit billed as 99212 to 99215 depending upon complexity and acuity of the visit. Additionally, UOS for this project can be defined as the sum of time spent per month on alternative visits that can be billed as a CCM service. For the purposes of this project, a reimbursement rate of \$89 for a physician billing 99213 in Hawai'i was determined, which is an average of private insurance reimbursements (\$100) and Medicare reimbursements (\$77) (Riley, Withy, Rogers, DuBose-Morris, & Kurozawa, 2017). The practice site capacity also permitted one exam room for a 30-minute session with the RN care manager for 20 hours per week for a total of 40 potential visits per week, which can be billed as a 99211. Alternative visits are defined specifically as phone

Table	e 12.	Breal	k-even	anal	ysis v	vitho	ut prof	it targ	get

uos	Fixed costs per unit	Variable costs per unit	Total costs	Total costs per unit	Price (revenue per unit)	Total revenue	Break- even
40	\$135	\$50	\$7,398	\$135	\$85	\$3,400	(\$3,998)
60	\$90	\$50	\$8,396	\$140	\$85	\$5,100	(\$3,296)
80	\$68	\$50	\$9,395	\$117	\$85	\$6,800	(\$2,595)
100	\$54	\$50	\$10,394	\$104	\$85	\$8,500	(\$1,894)
120	\$45	\$50	\$11,393	\$95	\$85	\$10,200	(\$1,193)
140	\$39	\$50	\$12,392	\$89	\$85	\$11,900	(\$492)
160	\$34	\$50	\$13,390	\$84	\$85	\$13,600	\$210
180	\$30	\$50	\$14,389	\$80	\$85	\$15,300	\$911
154	\$35	\$50	\$13,091	\$85	\$85	\$13,090	(\$1)

calls and secure electronic patient portal messaging. Access is a key component of comprehensive chronic disease management, and the PCMH model emphasizes alternative visits such as those proposed by this project to address such shortages while still providing high quality care (Jackson, Powers, & Chatterjee, 2013).

Appropriate and adequate staffing is a capacity issue addressing both the cost of staffing and the revenue generated for comprehensive chronic disease management sustainability beyond the duration of this project. The practice site absorbed costs incurred by additional front office and billing staff time dedicated to project facilitation. The practice site allocated equipment, supplies, and space for use by the PIP director. Total fixed cost estimates were made for revenue and expenditures based on rough calculations provided by the administrative team and used to generate a break-even analysis without profit target. The analysis revealed 154 UOS are required to break even without profit (see Table 12), and this information was used by the administrative team to determine financial sustainability of the *BREATHE* program for one additional year.

It was especially encouraging to receive 44 out of 45 possible points on the project evaluation from the site physician who was instrumental in the implementation and facilitation of this PIP. The physician commented that projects such as this one should be initiated earlier in order to have more time for development and evaluation of impact, and she is committed to continuing the project for at least another year.

Implications for practice were provided as recommendations to the supervising physician. The *BREATHE for a Better Life* program used the action plan as the foundation for organizing, facilitating, and monitoring evidence-based interventions for COPD management. The action plan enabled patients to better understand how COPD impacted their lives and gave patients and providers a reliable reference to assist in enhancing effective self-management skills and encourages thoughtful conversation about symptoms, medications, personal health goals, and important action steps that were either completed or recommended. Providers and patients were informed in a structured, consistent fashion of opportunities to close care gaps to improve health outcomes and quality of life.

The project provided an opportunity to enhance workflows. Providers could see at a glance a summary of the patient's current health status and needed interventions such as medication changes and immunizations. Findings encouraged regular competency checks and training for RNs and MAs for interventions such as office spirometry testing, medication review, and motivational interviewing. An algorithm clarifying CDC guidelines for pneumococcal administration was created after an observation by the RN care manager that the criteria are complicated, and it is expected to improve ordering performance (see Figure 9). The action plan inspired plans for smoking cessation training and improving the counseling process.

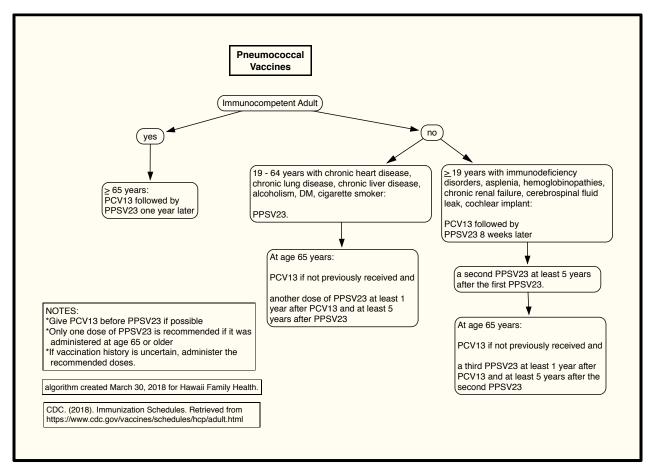


Figure 9. Pneumococcal vaccines

The *BREATHE for a Better Life* program is an ongoing opportunity to risk stratify and target individuals at high risk for exacerbations and complications, enabling RN care managers to provide longitudinal care management emphasizing care plan adherence and self-management goals. RN care management supports and empowers patients as they strive to optimize health and function, and is a billable service that can contribute to financial sustainability.

The practice site for this project participates in a CMS QPP program called CPC+, hired RN care managers, and is striving to develop a chronic disease, longitudinal care management program. The leadership recognizes the value of team-based, patient-centered care in effective chronic disease management and the potential for this project to improve the quality of their healthcare services overall with consequent financial benefits despite a provider shortage in a

competitive market. The supervising physician commented that a key benefit of the project was now having the COPD self-management tool to reinforce patient teaching about discrepancies that can exist between having a progressive disease process that still requires management even when they are feeling well. Alternatively, when patients have respiratory complaints the provider is triggered to further investigate or consider co-morbid conditions. This tool can be modified by adding or deleting components as needed to enhance practice.

Project limitations were influenced primarily by the two-month implementation period. The number of participants was low due to a short recruitment period, which was necessary to maintain a single cohort with consistent data collection. Additionally, hospital respiratory department PFTs were ordered but due to scheduling restrictions only two participants were able to complete the testing within the project implementation period. There was an insufficient amount of time for monitoring healthcare utilization. Finally, subsequent CAT scores were recommended every three months for meaningful evaluation of interventions on self-management, thus it was inappropriate to administer a post-implementation CAT at the project's close.

Conclusion

COPD is a significant burden through its impact on quality of life, healthcare utilization, and cost of care. COPD complexity and heterogeneity demand considerable time to accurately diagnose and manage, and the symptom exacerbation patterns are unclear. Yet this PIP demonstrated that there are values to patient engagement in self-management, and to the action plan as a tool. Findings helped stakeholders gain new medical knowledge, a deeper understanding of the psychosocial needs and thoughts of our patients, and personal approaches to delivering service. The project generated new and useful tools, and it expanded on the practice

site's established team-based, patient-centered philosophy. For these reasons, the supervising physician committed to continue the program for a minimum of one year with focused RN care management and data collection in anticipation of significant results to support its value and sustainability, and sharing this knowledge with other practices. Working together to empower patients through the use of medical expertise and compassion, our communities can overcome the challenges of COPD and BREATHE for a better life.

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Appendix A: COPD Assessment Test (CAT)

COPD Assessment Test		http://www.catestonline.org	/english/indexEN.htm
Name:	Today's Da	te:	TM SPREKITÉ TIESÈ
This questionnaire will help you and	Take the COPD Assessment Test (O your healthcare professional measure the impact COPD (res and test score, can be used by you and your healthcare eatment.	Chronic Obstructive Pulmonary Disease) is havi	ng on your f your COPD
Example: I am very happy	(X) (2)(3)(4)(5)	I am sad	SCORE
I never cough	012345	I cough all the time	
I have no phlegm (mucus) in my chest at all	012345	My chest is full of phlegm (mucus)	
My chest does not feel tight at all	012345	My chest feels very tight	
When I walk up a hill or one flight of stairs I am not breathless	012345	When I walk up a hill or one flight of stairs I am very breathless	
I am not limited doing any activities at home	012345	I am very limited doing activities at home	
I am confident leaving my home despite my lung condition	012345	I am not at all confident leaving my home because of my lung condition	
l sleep soundly	012345	I don't sleep soundly because of my lung condition	
I have lots of energy	012345	I have no energy at all	
COPD Assessment Test and CAT k group of companies. ©2009-2016 GlaxoSmithKline grou	ogo is a trade mark of the GlaxoSmithKline p of companies. All rights reserved.	CLICK TO GET YOUR TOTAL SCORE!	
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Appendix B: Agency for Healthcare Research and Quality (AHRQ) Permission

University of Hawaii Mail - Granted: Permission to use Figure 1 wit...

https://mail.google.com/mail/u/0/?ui=2&ik=1614b90d66&jsver=Z-...



Deborah Fried <dmfried@hawaii.edu>

Granted: Permission to use Figure 1 with citation

Carp, Karen (AHRQ/OC) < Karen.Carp@ahrq.hhs.gov>
To: Deborah Fried < dmfried@hawaii.edu>
Cc: "Lewin, David (AHRQ/OC)" < David.Lewin@ahrq.hhs.gov>

Please let me or David Lewin know if you need anything else.

Thu, Mar 29, 2018 at 10:28 AM

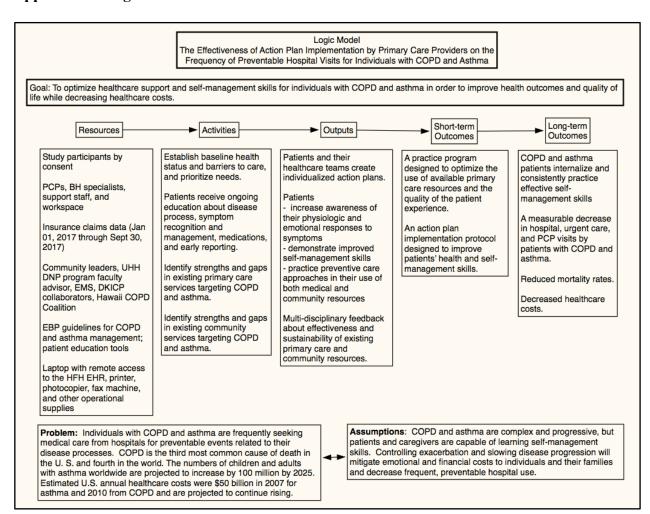
Michiko, I found out that this Figure was created by our contractor, so we don't have a hi-res version. I have attached a .pdf I was able to create, but I don't know if it's a better version than what you had. Sorry, but it's the best we can do

You have AHRQ's permission to use the attached image in your paper, using this citation:

Zutshi, A., Peikes, D., Smith, K., Genevro, J., Azur, M., Parchman, M., & Meyers, D. (2013). *Figure 1. Conceptual Framework for the Effectiveness of the Medical Home* in The medical home: What do we know, what do we need to know? A review of the earliest evidence on the effectiveness of the patient-centered medical home model. (AHRQ Publication No. 12(14)-0020-1-EF). Rockville, MD: Agency for Healthcare Research and Quality

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Appendix C: Logic Model



Appendix D: Patient Consent Form



Family Health
Consent to Participate in a Quality Improvement Project



You are invited to participate in a project to improve the quality of our healthcare services. The purpose of the project, entitled *BREATHE for a better life*, is to collect information about how a self-management program for individuals with COPD can help them control symptoms and maximize quality of life.

Activities and Time Commitment: Your participation begins when you sign this consent form. The project will conclude on March 31, 2018. All participants will complete a survey at the beginning of the project, and again at the end. The survey consists of 8 questions. It will take about 15 minutes. The questions focus on how symptoms such as shortness of breath and coughing affect your daily life, and someone in the office will be available to assist you with it. Also, you and your primary care provider (PCP) will create a written Action Plan together that explains your medications and ways to control symptoms. Part of the Action Plan will be scheduling regular check-in visits either by phone, by secure electronic portal message, or in the office. The frequency of visits will depend on how well you are doing.

Benefits and Risks: The direct benefit to you is individualized support to help you self-manage your COPD or asthma. Results will help us to improve care and continue this project so that others can also benefit. There are no identifiable risks by participating.

Privacy and Confidentiality: All data will be kept secure in a locked filing cabinet in a locked office or on a password protected computer. Only authorized personnel will have access to the information. All findings will be reported only as number totals, which protects your privacy and confidentiality. Your name or any other information that can identify you will not be used in reporting.

Voluntary Participation: Your participation in this project is completely voluntary. You may stop participating at any time. If you stop participation in the study, there will be no penalty or loss to you. Your choice to participate or not participate will not affect your rights to receive services at Hawaii Family Health.

Questions: If you have any questions about this study, please call 808-933-2399. If you agree to participate in this project, please sign and date this signature page and return it to Hawaii Family Health.

Please keep this copy of the informed consent for your records and reference.

Signature(s) for Consent:
I give permission to join the research project entitled, BREATHE for a Better Life.
Participant's Name (Print):
Participant's Signature:
Person Obtaining Consent: Name (Print):
Signature:
Date:
Thank you.

Appendix E: University of Hawai'i Institutional Review Board Letter of Approval



Office of Research Compliance **Human Studies Program**

TO: Davis, Alice, University of Hawaii at Hilo, School of Nursing

D'haem, Rebecca, University of Hawaii at Hilo, School of Nursing, Fried, Deborah, BSN

FROM: Rivera, Victoria, Interim Dir, Ofc of Rsch Compliance, Social & Behavioral

The Effectiveness of Action Plan Implementation by Primary Care Providers on the Frequency of PROTOCOL TITLE:

Preventable Acute Care Visits for Individuals with COPD and COPD with Asthma

FUNDING SOURCE:

PROTOCOL NUMBER:

APPROVAL PERIOD: Approval Date: January 12, 2018 Expiration Date:

NOTICE OF APPROVAL FOR HUMAN RESEARCH

1960 East-West Road **Biomedical Sciences Building B104** Honolulu, Hawai'l 96822 Telephone: (808) 956-5007 Fax: (808) 956-8683 An Equal Opportunity/Affirmative Action Institution

Appendix F: Memorandum of Agreement

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This MEMORANDUM OF AGREEMENT entered into by and between the

University of Hawaii at Hilo School of Nursing located at 200 West Kawili Street, Hilo,

Hawaii 96720, (hereinafter referred to as the "University") and ______, located at

Company

Address

(hereafter called the "Agency").

WITNESSETH

WHEREAS IT IS AGREED by the aforesaid parties to be of mutual interest and advantage that the students enrolled in the University (hereinafter, "Student") be given the benefit of scholarly activities by providing certain services for the Agency, and

WHEREAS the University as of this date authorizes the execution of agreement to allow such services,

NOW THEREFORE, the University effects the following Agreement with said

Agency for a mutually agreed upon Student to perform scholarly activities. This Agreement is to be governed by the following terms:

- A. SPECIFIC RESPONSIBILITIES OF THE UNIVERSITY. The University agrees to:
- Develop, in consultation with Agency, curriculum, plan, and conduct a prescribed educational program for Student scholarly activities.
- Require that all designated instructors and Students abide by the policies,
 procedures, rules and regulations of the Agency and all applicable laws, rules and regulations while in Agency's facilities.
- Recognize and acknowledge that, by virtue of entering into this Agreement and performing the obligations stated in the Agreement, the University and its employees, agents,

DNP Projects 2/21/17

and Students may have access to certain information of the Agency that is confidential and constitutes valuable, special, and unique property of the Agency. Neither the University, nor any employee, agent, or Student shall at any time, either during or subsequent to the term of this Agreement, disclose to others, use, copy or permit to be copied, without the Agency's express prior written consent, any confidential or proprietary information of the Agency, including but not limited to, information which concerns the Agency's licensees and applicants, costs, or business, which is not otherwise available to the public. The University agrees to educate its Students and employees about the confidentiality of the Agency's information. Prior to, and as a condition precedent to, Student participation in the educational program under the terms of this Agreement, the University shall require Students to execute a confidentiality agreement developed by the Agency, a copy of which Agreement is attached as Exhibit "A" to this Agreement. The provisions of this paragraph shall survive expiration or other termination of this Agreement regardless of the cause of the termination.

4. Recognize and acknowledge that its employees and agents shall perform their duties under this Agreement in a manner that is consistent with currently approved methods and standards of practice for a person in like circumstances, and in accordance with applicable standards set forth by law or ordinance or applicable accreditation agencies, such as the Joint Commission Accreditation of Healthcare Organizations (JCAHO). University shall further require the Students to perform their duties in a manner that is consistent with currently approved methods and standards of practice for a student in like circumstances and in accordance with applicable standards set forth by law or ordinance or by applicable accreditation agencies.

- 5. Be responsible for damages or injury caused by the University's agents, officers, and its employees in the course of their employment, to the extent that the University's liability for such damage or injury has been determined by a court or otherwise agreed to by the University, and the University shall pay for such damages and injury to the extent permitted by law and approved by the Legislature. The provisions of this paragraph shall remain in full force and effect notwithstanding the expiration or termination of this Agreement.
- Inform Students that they and/or their parent/guardian or spouse will be financially responsible for whatever emergency care is necessary for illness or accident occurring while providing services.

B. SPECIFIC RESPONSIBILITIES OF THE AGENCY. The Agency agrees to:

- Provide scholarly activities for the Student as designated in the objectives of the practicum course.
- Provide staff members meeting qualifications as mutually agreed upon and as specified by the educational program who will be responsible for working with Students in the scholarly activities at the Agency.
- 3. Reserve the right, exercisable in its sole discretion, to immediately exclude any Student from its premises and/or program in the event that such Student's conduct or state of health is deemed objectionable or detrimental, having in mind the proper administration of Agency and the best interest of the licensees, applicants and consumer public. As soon as practicable but no later than five (5) days after the Agency exercises its right under this provision, the Agency shall provide notice of same to the University.

C. BOTH PARTIES MUTUALLY AGREE THAT THIS AGREEMENT:

- Does not provide for any payment or exchange of money or financial obligations.
 Neither party shall incur any financial obligation on behalf of the other party.
- Shall be in full force effective from September 1, 2016 and forward, until otherwise amended or terminated in the manner noted below.
- 3. This Agreement contains the entire understanding of the parties with respect to the subject matter hereof and supersedes all prior agreements, oral or written, and all other communications between the parties relating to such subject matter

4. Termination.

- a. Either party may terminate this Agreement without cause by giving one semester's notice in writing to the other party at the addresses herein-above set forth. Such termination shall not take effect, however, with regard to Students already enrolled until such time as those Students have completed their respective enrolled courses, provided that the Agency continues to provide the applicable service at that location.
- 5. This Agreement shall prohibit discrimination against any individual based on attributes that are not related to performance, including, but not limited to, race, color, creed, religion, age, physical handicap, and sex as prescribed by, but not limited to, the following laws: Title VI of the Civil Rights Act of 1964 as amended, Age Discrimination Act of 1975, Titles VII and VIII of the Public Health Services Act as amended, Title IX of the Education Amendments of 1972, Section 504 of the Rehabilitation Act of 1973 and those laws and acts relating to nondiscrimination in employment.
- 6. It is understood and agreed by both the Agency and the University that in no case shall the Student in learning situations replace regular staff.

- The Agency and the University agree to cooperate through mutual effort toward a successful program.
- 8. Both parties mutually agree that under no circumstance shall this Agreement, nor any of its provisions, be construed to state, indicate, mean, or imply that the Students are third party beneficiaries under this Agreement, or that the Students are entitled to any rights, contractual or otherwise, under this Agreement.
- 9. No provision of this Agreement shall be interpreted for or against any party on the basis that such party was the draftsman of such provisions, and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provision of this Agreement.
- 10. This Agreement may be executed in two (2) or more counterparts, each and all of which shall be deemed an original and all of which together shall constitute but one and the same instrument.
- 11. This agreement shall be construed in accordance with the laws of the State of Hawaii.
 The provisions of this paragraph shall survive expiration or other termination of this
 Agreement regardless of the cause of the termination.
- 12. A waiver by either party of a breach or failure to perform hereunder shall not constitute a waiver of any subsequent breach or failure.
- 13. The captions contained herein are used solely for convenience and shall not be deemed to define or limit the provisions of this Agreement.
- 14. University Students, employees, and agents are not by reason of this Agreement, employees or agents of the Agency for any purpose, and the University and the University's employees, agents and Students shall not be entitled to claim or receive from the Agency any

vacation, sick leave, retirement, workers' compensation, unemployment insurance, or other benefit provided by the Agency to its employees. It is also understood and agreed that under no circumstance is any student of the University to be considered an agent, officer and/or employee of the University. The provisions of this paragraph shall survive expiration or other termination of this Agreement regardless of the cause of the termination.

15. This Agreement constitutes the entire Agreement of the parties with respect to the subject matter hereof and supersedes any and all oral or written Agreements, understandings, and communications relating to such subject matter between the parties hereto prior to the date hereof. This Agreement may be modified or amended only a writing duly authorized and executed by both parties to this Agreement. This Agreement may not be amended or modified by oral agreements or understandings between the parties, unless the same shall be reduced to writing duly authorized and executed by both by parties.

By:	By: Michelle Mitchell, MD President/CEO Hawaii Family Health Date By: Dr. Alice Davis Director School of Nursing University of Hawaii at Hilo Date Approved: By: DR. Ken Hon Vice Chancellor for Academic Affairs University of Hawaii at Hilo	Approved:	Recommend Approval:
Approved: By: DR. Ken Hon Vice Chancellor for Academic Affairs University of Hawaii at Hilo	Approved: By: DR. Ken Hon Vice Chancellor for Academic Affairs University of Hawaii at Hilo	By:Michelle Mitchell, MD President/CEO	By: Dr. Alice Davis Director School of Nursing
By: DR. Ken Hon Vice Chancellor for Academic Affairs University of Hawaii at Hilo	By: DR. Ken Hon Vice Chancellor for Academic Affairs University of Hawaii at Hilo	Date	Date
Date	Date		By:
			Date

Appendix G: Sample Action Plan



My Individualized Action Plan

My Name	Date	

GREEN ZONE: I am doing well.

SYMPTOMS

- My breathing is good.
- My appetite is good.
- I can perform my usual activities without feeling breathless.
- I am not coughing or my cough is minimal.
- I am not wheezing or my wheeze is minimal.
- I have no mucus or a small amount of mucus that is normal for me.
- I can sleep well at night.
- I do not need my quick-relief medicine.

ACTIONS

- Take daily medications as prescribed.
- Avoid cigarette smoking, exposure to cigarette smoke, and other known triggers.
- Continue with a healthy diet and regular physical activity.

YELLOW ZONE: My symptoms are flaring up

SYMPTOMS

- I am having some difficulty breathing or I am more breathless than usual.
- I have less energy for my daily activities.
- I am coughing or wheezing more than usual or my chest feels tight.
- I am using my quick relief inhaler or nebulizer more often.
- I have more mucus than usual for me, or it is thicker than usual.
- I feel like I have a "chest cold."
- I am not sleeping well; my symptoms wake me up.
- My appetite is poor.
- My medicine is not helping.
- My ankles are swelling more than usual.

ACTIONS (examples)

- Continue to take daily medications.
- Use quick-relief medication every
- Avoid cigarette smoke and other known triggers.
- Rest.
- Contact your PCP if symptoms do not improve.
- Take a nebulizer treatment (if indicated

 specify type, dose, and frequency)
- Start an oral corticosteroid (if indicated
 specify type, dose, and frequency)
- Start an antibiotic (if indicated specify type, dose, and frequency)

RED ZONE: I need urgent medical care	
SYMPTOMS	ACTIONS
I have severe breathlessness even at rest.	 Go immediately to the hospital or call 911
 I a not able to do any activity because of my difficulty breathing. 	 While getting help, use your quick- relief medication (indicate frequency)
 I am not able to sleep because of my difficulty breathing. 	
 I feel confused or very drowsy. 	
My chest hurts.	
 I have a fever or chills 	
 I am coughing up blood 	

Control Medication(s) Name	How much to take and how to take it	When to take it	photo
e.g. tiotropium/Spiriva Respimat	Inhale 2 puffs	Once every day	Spiritive Respimate Spirit
Quick Relief Medication	How much to take	When to take it	photo
e.g. albuterol/Proair	Inhale 2 puffs	Every 4 to 6 hours AS NEEDED for wheezing or shortness of breath. Do NOT take more than 12 inhalations in 24 hours.	PO DE LA CASTA DE

Medical Visi	its	
Date	Туре	Reason
	(ED, admission, PCP)	e.g. symptoms: short of breath,
		wheezing, coughing e.g. Dx: URI, bronchitis, pneumonia

My Goals			
Type	Amount	Timeline	
e.g. I will stop smoking cigarettes	My quit date is tomorrow, 08/19/17	For the next week	
e.g. I will go swimming at the	One day per week	For the next month	

pool		
e.g. I will remove the old	There are three rugs.	Within the next 7 days.
throw-rugs from my bedroom		

My Checklist		
Item	Yes/No (Date completed)	Action
Flu vaccination	Yes (12/01/17)	Annual flu shot in 2018
PCV13	Yes (09/05/16)	none
PPSV23	No	prescribed
Emergency contact		
information is current.		
Advanced Directive is current	Yes current.	Bring a copy of Advanced
and on file.	No, not on file.	Directive to the PCP office.

Spirometry				
	Date	Date	Date	
FEV_1				
FEV ₁ /FVC				

COPD Assessment Test (CAT)							
Date	Score	Impact Level	Recommendations				
	e.g. 6	Low	Stop smoking.				
			Flu shot.				
			Start Spiriva as directed.				
			Next PCP appointment in 1 month.				

Appendix H: GlaxoSmithKline Letter of Permission



Five Moore Drive Research Triangle Park North Carolina 27613

Tel. +1 (919) 606-7851

November 30, 2017

D. Michiko Fried University of Hawaii at Hilo Email: dmfried@hawaii.edu Cell: 818-795-9725

To: Ms. Fried,

Thank you for requesting permission to use the COPD Assessment Test™ (the "Instrument"). We understand you are interested in using the Instrument as part of your Doctor of Nursing Practice (DNP) project to evaluate the effectiveness of individualized action plan implementation by primary care providers on the frequency of preventable acute care visits for respiratory complaints. The Instrument would be administered to the target population at the project's initiation to establish a quality of life baseline measurement and to guide care plan decision-making, and re-administer every three months or as needed for action plan and intervention updates.

GlaxoSmithKline is pleased to grant you permission to use, reproduce and distribute paper and electronic PDF copies of the Instrument in English for the U.S., solely in connection with this project subject to the following conditions listed below:

- Except for limited re-formatting you may not modify the COPD Assessment Test (CAT) or combine it with other instruments without prior written approval
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- All trademark and copyright information must be maintained as they appear on the bottom of the COPD Assessment Test (CAT) and on all copies
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- 5. You acknowledge that GlaxoSmithKline owns the IP in the COPD Assessment Test (CAT) and agree to include an acknowledgment on any websites, documents or other materials referencing, reproducing or otherwise using the Instrument that GlaxoSmithKline owns the IP in the COPD Assessment Test (CAT).
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- 7. You shall ensure that any third party who receives a copy of the Instrument from you shall not further disseminate, reproduce or otherwise copy the Instrument without GlaxoSmithKline's prior permission. The foregoing shall not apply where the Instrument is given by you to healthcare professionals so that they may provide a copy of the Instrument to patients and those healthcare professionals shall be entitled to use, copy and reproduce the Instrument and provide a copy to patients for the purposes of assessing COPD only.
- 8. Where the Instrument is distributed by you to a healthcare professional in accordance with the terms of this letter agreement, you shall procure that each healthcare professional to whom you disseminate the COPD Assessment Test (CAT) shall include an acknowledgment on any websites, documents or other materials

referencing, reproducing or otherwise using the Instrument that GlaxoSmithKline owns the IP in the COPD Assessment Test.

There is no charge for the foregoing permission. By signing this agreement, you have permission to use the Instrument for the project defined above and GlaxoSmithKline strictly prohibits the reproduction or use of this Instrument for any other purpose without prior written consent. We reserve the right to revoke our permission at any time and, upon such revocation, you shall cease, and procure that each third party to whom you have distributed the Instrument shall cease, using, copying, reproducing and distribution of the Instrument; however, such revocation will not affect any use by you of the Instrument, or reproduction of data acquired through the use of the Instrument, in accordance with the permission granted herein, prior to such revocation. Unfortunately, we cannot make, and hereby disclaim, any representations or warranties about this Instrument, including any warranties as to additional permissions that may be required for its use.

Please confirm our understanding by signing and returning a signed copy of this letter agreement. Once you receive a signed copy, it will be your confirmation and you may proceed with your proposed use of the Instrument.

Agreed to and accepted:	
D. Michiko Fried University of Hawaii at Hilo	GlaxoSmithKline
Signatufe: Mille Ful	Signature:
Name (in print): D. Michiko Fried	Name (in print): Matthew Can
Title: Registered Nurse, Doctor of Nursing Practice student	Title: Manager
Institution: University of Hawaii at Hila	Institution: GSK USVEO
Date: 12-01-2817	Date: 12/1/2017

Appendix I: Healthcare Provider Project Evaluation Form

BREATHE for a better life											
	Healthcare Provider Project Evaluation Form										
	Name	·	Date								
	Please answer the following questions on a scale of 1 to 5:										
	1	2	3	4	5						
	Disagree	Disagree	Neutral	Agree	Agree						
	completely	somewhat		somewhat	completely						
1. 2. 3.	2. The Action Plan information was accurate.										
4.											
	modifications.	_	•								
5.											
	management.										
6.											
7.											
8.											
9.	I will continue to	initiate and maintain	Action Plans with my	patients.							
10.	For any scores of	1 or 2, please describe	e why you disagreed.								
11.	11. Additional comments or suggestions:										
1											