Improving Chronic Health Diseases Through Structured Smoking Cessation Education Provided in a Rural Free Clinic

by

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Abstract

Significance: Smoking is the leading cause of preventable death and contributes to many chronic health diseases. A strong correlation exists between cigarette smoking and its negative impact on chronic diseases. However, quitting smoking is challenging. The annual quit success rates remain low at roughly 7%. A high prevalence of smokers with chronic disease is prominent among the underserved population due to limited access to care and lack of health literacy, leading to poor health outcomes. **Purposes/Methods:** A quasi-experimental one-group pilot study with a pre- and post-test design was conducted as a part of a quality improvement project at a rural Free Clinic to improve smoking cessation and chronic disease management. Two 20-minute structured individual smoking cessation education sessions were provided. Pharmacotherapy was offered as free through a medication assistance program and based on provider-patient shared decisions as part of their traditional smoking cessation care for smokers at the Free Clinic. Outcome measurements included (a) readiness to quit smoking, (b) nicotine dependence, (c) pharmacotherapy use rate, (d) smoking cessation success rate, and (e) chronic disease health outcomes. Pairwise paired t-test, Cochran Q, and Friedman's test were used to compare initial, 1-month, and 3-month study results of demographic, nicotine dependence, laboratory data, intention to quit smoking, and perceived quality of life. **Findings:** 32 smokers initially participated in this study, but attrition occurred with 43.8% (n = 14) at 3-month follow-up visits. About 20% of smokers chose to use pharmacotherapy, especially heavy smokers. One participant (5%) successfully quit smoking by a 3-month follow-up. However, this small sample size limited to measure the statistical significance. Our intervention was shown to improve readiness to quit, reduce nicotine dependency, and decrease the amount of tobacco smoked. Fagerström test was conducted to have higher sensitivity to measure the improvement of nicotine

dependence (p = 0.0001) from baseline to 3-month follow-up, compared with CAGE questionnaires. **Clinical Implication/Conclusions:** Underserved, low-income populations tend to have less accessibility and affordability to health care resources for quitting smoking and endure several comorbidities with poor health outcomes related to smoking. Despite the small sample size limitation, this pilot study demonstrated the feasibility and effectiveness of increasing motivation and reducing smokers' nicotine dependence in a rural Free Clinic.

Keywords: smoking cessation, education, chronic disease, health outcome, behavioral therapy, pharmacotherapy, rural population, free clinic

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Dedication

With genuine gratitude and warm regard, I dedicate this thesis work to my devoted husband, Timothy, and my four boys, Gabriel, Mateo, Quinton, and Zane. Tim and boys, thank you for being patient when I needed you to be, thank you for being understanding when I needed you to be, and most importantly, thank you for being my backbone when I felt weak and discouraged. My In-laws: Ray and Joanna, both have been my praying cheerleaders throughout this endeavor. You both knew exactly how I needed help; you always reached out and helped me when I was too distracted to ask for help, thank you. To my mother, Odili; sisters, Keren, Loida, and Angela; and brothers, Juan, Ezequiel, and Tony; thank you for being my Familia and listening to me while I cried on the phone and complained of how difficult it was for me to focus and finish up. Thank you for your everyday prayers and the help with the boys. To my Abuelita, who is no longer with us, you have taught me to keep faith and trust in the Lord to move forward for my family. I also want to dedicate this work to my late sister Kezia and brother Oscar, gone forever from our loving eyes but never forgotten through memories. I love you and miss you both, all beyond words. May you find peace and happiness in Paradise!

Last but not least, I am dedicating this work to my church family at Slate Mountain Church. Thank you. My love for you all can never be quantified. God bless you.

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Chapter I. Introduction

Cigarette smoking is the leading cause of preventable death in the United States and is responsible for more than 480, 800 deaths each year (Centers for Disease Control and Prevention [CDC], 2018). The 2018 CDC report stated that smokers die 10 years earlier than non-smokers. Tobacco use accounts for multiple chronic diseases, including cardiovascular disease (CVD) and peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), osteoporosis, diabetes, gastroesophageal reflux disease (GERD), and even cancer. Mental health diseases have also been shown related to tobacco use, specifically anxiety and depression (CDC, 2018).

Chronic health diseases affect about 133 million Americans, and by the year 2020, this number is estimated to increase to 157 million Americans, especially CVD and COPD (National Health Council, 2014). Smoking leads to an increase in individuals seeking medical attention with new developing or worsening chronic disease conditions, which distresses the economy overall. Chronic diseases require ongoing treatment and monitoring without a cure; this succumbs to financial burdens on patients and their families. The United States spends a total of $300 billion on addressing smoking-related illnesses each year (CDC, 2018). Chronic diseases such as hypertension, hyperlipidemia, and CVDs can be prevented through healthy behavioral modification. Smoking cessation can prevent the worsening of CVDs or stroke events.

Smoking cessation is challenging because the nicotine itself has addictive characteristics. When someone smokes a cigarette, they inhale nicotine, and nicotine then goes into the bloodstream and causes a release of dopamine, causing euphoria. The annual quit success rates remain low at roughly 7% (Babb et al., 2017; Truth Initiative, 2018; U.S. Food and Drug Administration [FDA], 2020). Evidence shows that the success rates of quit-smoking with pharmacotherapy use are higher than ex-smokers who quit smoking without pharmacotherapy.

However, even with pharmacotherapy use, the success rate of quit-smoking remains low between 20 and 27% (Baker et al., 2016; Cinciripini et al., 2018; Petty, n.d.; Stapleton et al., 2013). Furthermore, many tobacco smokers experience relapse after their first quit attempt, and five to seven failures commonly precede successful smoking cessation (Petty, n.d., para. 25). Low socioeconomic status patients are shown to have limited access to health care (Campaign for Tobacco-Free Kids [CT-FK], 2015). A higher prevalence of cigarette smoking and its related chronic diseases are observed in rural underserved areas. Those patients have less access to appropriate smoking cessation education and medication therapy, are more likely to be heavy smokers and get diagnosed with chronic disease or cancers at later stages, and have poor compliance with pharmacotherapy and regular clinic visits to manage chronic disease (CT-FK, 2015).

Free Clinics are the prime place of health care access sought by underserved and uninsured populations. The *U.S. Preventive Services Task Force* (USPSTF) recommends that health care providers screen all adults for tobacco use and treat them with evidence-based behavioral interventions and medications for smoking cessation (USPSTF, 2015). Successful smoking cessation requires counseling with an extended commitment and frequent positive reinforcement. Providers at Free Clinic are equipped with the competencies of smoking cessation therapies. To improve the health outcomes in this population, it is critical for Free Clinic providers to consider incorporating smoking cessation education and or pharmacotherapy use as part of chronic disease management for their patient care.

Organization and Need Assessment

The Caring Hearts Free Clinic of Patrick County is located in Stuart, Virginia. Patrick County is a medically underserved rural area with 17,665 population and 14.2% of the

population living in poverty in 2017 (United States Census Bureau, 2018; Virginia Department of Health [VDH], 2019). The residents of Patrick County have limited access to health care; the county does not have a Community Hospital for emergency care. Therefore, the residents are forced to drive an hour to the nearest hospital. The Caring Hearts Free Clinic provides services to residents who are uninsured and meet a low-income status.

In 2014, VDH (2015) reported that 33.9% of Virginians 18 years and older had smoked at least 100 cigarettes in their lifetime and now smoke every day, some days, or use chewing tobacco, snuff, or snus. Comparably, a high prevalence of cigarette smokers was identified at the Free Clinic, along with a high prevalence of comorbid chronic diseases in this underserved population. Several Chronic Disease Management Educator Specialists work in town and provide education focused on chronic disease management to county residents at the local family practices. However, their education contents do not include smoking cessation; they only offer regular disease management education. Also, there is no Smoking Cessation Specialist/Educator in Patrick County, including at the Caring Hearts Free Clinic.

Smoking cessation education provided at the Free Clinic currently includes traditional smoking cessation services consisting of a brief assessment, education, and advice during routine patient clinic visits. The Caring Hearts Free Clinic also provides a Medication Assistance Program (MAP) that assists low-income patients with getting their medications at no cost (P. Wright, personal communication, November 5, 2019). The clinic facilitates the approval process between the patient and the drug company. To participate in this program and receive benefits, patients will have to complete a process before getting approved for MAP. The patient must provide proof that medication assistance is needed through financial documents. The clinic then sends these documents and a prescription for the medication to the drug company for approval.

Usually, the approval process for MAP can take up to 2 to 6 weeks (P. Wright, personal communication, November 5, 2019).

With this MAP program, patients qualified to receive care at the Free Clinic based on their low income and can participate and access the smoking cessation medication at no cost. Usually, MAP-approved pharmacotherapy includes Chantix and Nicotrol inhalers. The Free Clinic assists patients with getting these medications being financially covered. In addition to MAP, Bupropion, which is another standard smoking cessation medication, is often assisted with financial coverage using a coupon from the Good Rx website: "this method helps make the medication more affordable" (P. Wright, personal communication, November 15, 2019).

Despite these services, patients at the Free Clinic continue to smoke cigarettes and show little improvement in their chronic health conditions with traditional education on smoking cessation. Additionally, some patients relapse and start smoking again for various reasons, even after successfully quitting smoking. Smoking cessation is complicated and requires time commitment by both providers and patients. Providers in primary care settings should be adept at smoking cessation therapies. They should incorporate the effective smoking cessation program as part of chronic pain management for their patients. The traditional 5-minute or less smoking cessation during their 15-minutes chronic disease management clinic encounter is insufficient to support patients to quit smoking successfully. Providers should consider providing a more structured education and counseling session and reinforcing and monitoring compliance to help patients quit smoking and maintain cessation without relapse.

Purpose of the Study

A smoking cessation program was designed as a quality improvement project to improve smoking cessation rates and chronic disease health outcomes through structured education and

pharmacotherapy assistance in a rural Free Clinic, different from the traditional smoking cessation approach. Usually, brief smoking cessation education is provided during their routine clinic visit. However, the busy practice environment in the primary care setting limits the capability to provide good quality structured smoking cessation education to patients and monitor and reinforce their compliance to quit smoking.

This study aims to evaluate the effectiveness of moderately structured smoking cessation education sessions in (a) readiness to quit smoking, (b) nicotine dependence, (c) smoking cessation pharmacotherapy use, (d) smoking cessation success rate, and (e) chronic disease health outcomes, using a one-group pre- and post-test design. Patients received 20-minute individual sessions after patients were seen by their providers for their chronic disease management during their initial and 1-month follow-up visits. It was provided through the most appropriate method each time (i.e., via in-person clinic visit, phone call, or Updox videoconferencing). At the Free Clinic, smoking cessation pharmacotherapy was offered to all smokers as part of traditional care, and medication was provided as free through MAP. The decision to start smoking cessation pharmacotherapy was made based on the patient-provider shared decision and patients' preference.

Three-month follow-up visits are standard care for patients with chronic diseases and initiate smoking cessation medication. This study measured its effects at the initial visit, 1-month, and 3-month follow-up. Self-reported surveys were used to measure and compare the following outcomes at the initial visit, 1-month follow-up, and 3-month follow-up visits: (a) readiness to quit smoking, (b) nicotine dependence, (c) smoking cessation pharmacotherapy use, and (d) smoking cessation success rate. Nicotine dependence was measured by two tools such as a modified CAGE and Fagerström questionnaire. Also, vital signs and blood laboratory data

were used to measure clinical outcomes. Blood laboratory findings on the chronic disease were used to measure and compare the (e) chronic disease outcomes at the initial visit and 3-month follow-up.

The independent variable of this study was defined as the participants receiving a structured and moderately intense individual smoking cessation education. The dependent variable in this study included (a) readiness to quit smoking, (b) nicotine dependence, (c) smoking cessation pharmacotherapy use, (d) smoking cessation success rate, and (e) chronic disease health outcomes measured by surveys and clinical data. See Appendix A for the detailed intervention and study variables measured at the initial visit and 1-month and 3-month follow-ups.

Research Question

Study question 1 (readiness to quit). For smokers who live in a rural community (P), will their readiness to quit smoking (O) differ at 1-month and 3-month follow-ups after receiving smoking cessation education (I), compared with baseline (C)?

- Null Hypothesis (H0): Readiness to quit smoking will not differ at baseline, o1ne-month follow-up, and 3-month follow-up.
- Alternative Hypothesis (Ha): Readiness to quit smoking will differ at baseline, 1-month follow-up, and 3-month follow-up.

Study question 2 (nicotine dependence). For smokers who live in a rural community (P), will their nicotine dependence (O) differ at 1-month and 3-month follow-ups after receiving individual smoking cessation education (I), compared with baseline (C)?

- Null Hypothesis (H0): Nicotine dependence will not differ at baseline, 1-month follow-up, and 3-month follow-up.

- Alternative Hypothesis (Ha): Nicotine dependence will differ at baseline, 1-month follow-up, and 3-month follow-up.

Study question 3 (pharmacotherapy use). For smokers who live in a rural community (P), will smoking-cessation pharmacotherapy use (O) differ at 1-month and 3-month follow-ups after receiving structured and moderately intense individual smoking cessation education (I), compared with baseline (C)?

- Null Hypothesis (H0): Pharmacotherapy use will not differ at baseline, 1-month follow-up, and 3-month follow-up.
- Alternative Hypothesis (Ha): Pharmacotherapy use will differ at baseline, 1-month follow-up, and 3-month follow-up.

Study question 4 (smoking cessation success rate). In rural smokers who have chronic diseases (P), will a structured individual smoking cessation education (I) affect smoking cessation rates (O) within 3 months, compared with the baseline (C)?

- Null hypothesis (H0): The smoking cessation success rate will not differ among baseline, 1-month follow-up, and 3-month follow-up.
- Alternative hypothesis (Ha): The smoking cessation success rates will differ among baseline, 1-month, and 3-month follow-ups.

Study question 5 (chronic disease outcomes). In smokers who have chronic diseases (P), will a structured individual smoking cessation education (I) impact their chronic disease health outcomes (O) within 3 months, compared with the baseline (C)?

- Null hypothesis (H0): Chronic disease health outcome will not differ at 3-month follow-up, compared with the baseline.

- Alternative hypothesis (Ha): Chronic disease health outcome will be different at 3-month follow-up, compared with the baseline.

Theoretical Framework

Health belief model (HBM) and the behavioral change theory (BCT) were used as a guide to help participants successfully quit smoking in this study, which was also used in previous studies for smoking cessation (Black et al., 2019; Nahar et al., 2019). The HBM helps predict health behavior and willingness to change unhealthy behaviors such as smoking cessation. The BCT is helpful for explaining how motivated an individual is to make changes and live a healthier lifestyle. According to HBM and BCT models, people adapt their behaviors when they are motivated to change. The readiness and motivation to change can be affected by modifying factors such as (a) perceived health status, (b) perceived susceptibility to poor health outcomes, (c) benefits of change (e.g., quitting smoking), and (d) barriers to change (e.g., quitting smoking).

Black et al. (2019) identified successful *Behavioral Change Techniques (BTech)* for quitting smoking in their systematic review of 142 smoking cessation trials. It includes quitting, abstinence, medication adherence, and treatment engagement. It has shown critical to successfully quitting smoking or maintaining a non-smoking status *(*as shown in *Table 1* in *Black et al., 2019).* See definitions of each technique below.

- Quit: ceasing tobacco smoking
- Abstinence: maintaining a non-tobacco smoker state
- Medication adherence: using smoking cessation medication in appropriate dosages at appropriate times

- Treatment engagement: engaging and completing components of smoking cessation treatment

These four techniques above have been shown to benefit in the following areas defined:

- Quitting: to increase the likelihood of the participant ceasing tobacco smoking
- Abstinence: to increase the probability of the participant maintaining their non-tobacco smoker state
- Medication adherence: to increase the likelihood of the participant using their smoking cession medication in appropriate dosages at appropriate times
- Treatment engagement: to increase the likelihood of the participant engaging with and completing components of the smoking cessation treatment

Secondly, Black et al. (2019) also reviewed the characteristics of delivery methods for behavior changes (e.g., tailored vs. not tailored; active participation vs. passive reception) to reach successful smoking cessation. They observed that the tailored intervention, based on recipients' characteristics and active involvement, was correlated with successful behavior changes (Black et al., 2019).

By combining Black et al.'s *BCTech* with HBM and BCT, a diagram was developed to help participants adopt a healthier lifestyle (see Appendix B for *Diagram of Health Belief Model for Behavioral Change*). This diagram explains that based on modifying factors, the participant will perceive their susceptibility, benefits, and barriers to quitting smoking and take part in smoking cessation interventions. The participant's likelihood following the interventions will be based on their characteristics and preferences and depend on their motivation and empowerment to participate actively. This process can ultimately impact the participant to change their smoking behavior to improve their chronic disease outcomes.

To support successful smoking cessation, maintain abstinence, and medication compliance, the *BCTech* addressed in Black et al. (2019) was incorporated into our study's intervention to improve the participants' likelihood of changing their behavior. Medication and *BCTech* were selected based on the participant's characteristics and preferences. Using these models, providers can assist patients who smoke cigarettes and have chronic diseases to quit smoking effectively. Smokers with chronic disease were assisted in reflecting their current health status, measuring their barriers and benefits to quit smoking, measuring their readiness and motivation to quit smoking, and learning the available smoking cessation therapies. To overcome the financial obstacles of accessing smoking cessation medication therapy, free medication assistance was provided using MAP. Active participation required for behavioral changes included setting up a quit date, keeping follow-up appointments, complying with taking prescribed smoking cessation medication, and following a plan to maintain a non-smoker state.

This project was designed to increase smoking cessation success rates and, thus, improve chronic disease health outcomes by promoting smoking cessation education in a rural Free Clinic serving an underserved population. The Caring Hearts Free Clinic in Patrick County, Virginia demonstrated a significant prevalence of smokers with chronic diseases. However, this county lacks the support to lower the number of smokers with chronic diseases. Patients uninsured use the Free Clinic to manage their chronic health diseases. Providers at the Free Clinic are the first and last health care resource to provide smoking cessation education and treatment to patients while managing their chronic diseases. Using a theoretical framework with the HBM, BCT, and MAP provided by the Caring Hearts Free Clinic, an individualized plan approach can be formed with the patient to gear towards successful smoking cessation.

Conceptual Definition of Variables

- Smoking Cessation: It is usually called quitting smoking or stopping smoking, and it refers to the process of discontinuing tobacco smoking (Wikipedia, 2021).
- Therapy: It refers to treatment intended to relieve or heal a disorder (Lexico, n.d.).
- Smoking Cessation Success Rate: It refers to the percentage of users who report that they have not smoked at all in the past 30 days when asked 6 months after their quit date (Amato, 2021). For this study, the smoking cessation success rate will be defined as the participant not smoking in the last 30 days when asked at their 1-month and 3-month follow-up visits.
- Nicotine Dependence: It refers to an addiction to tobacco products caused by the drug nicotine. It involves physical and psychological factors that make it difficult to stop using tobacco (CAMH, n.d.).
- Chronic Disease: It refers to conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both (CDC, n.d.).
- Underserved Population: It refers to disadvantaged populations because of their ability to pay, ability to access care, ability to access comprehensive healthcare, or other disparities for reasons of race, religion, language group, or social status (Your Dictionary, n.d.).
- Free Clinic: Volunteer-based, safety-net health care organizations that provide a range of medical, pharmacy, or behavioral health services at no cost to predominately uninsured and economically disadvantaged individuals (IAFCC, n.d.).

Chapter II. Literature Review

Search Strategies and Results

A systematic review approach was utilized to (a) locate and review correlations between smoking and chronic health diseases, (b) identify the practical interventions of quitting smoking, and (c) measure the effects of smoking cessation on chronic health improvement. Search engines used through the Radford University McConnell Library included the Cochrane Database of Systematic Reviews, CINAHL, MEDLINE, and PubMed. Supplementary search engines such as UpToDate and Google Scholar were also used to obtain articles. The advanced search was performed, and reports with full text available and written in the English language were included.

Keywords included smoking, chronic disease, chronic health condition, hypertension (HTN), diabetes, respiratory disease, cardiovascular disease (CVD), chronic obstructive pulmonary disease (COPD), plaque, cerebrovascular disease, smoking cessation, and education. A total of 33 articles were listed after inserting keywords into the search engines. Of the 33 articles, nine articles were eliminated due to (a) lack of relevancy to the subject, (b) being older than 10 years, or (c) being focused on a specific population such as pregnant women or adolescents. A total of 24 studies met the inclusion/exclusion criteria and were relevant to this study's aim. Among those 24 studies, six studies evaluated the correlation between smoking and chronic diseases (see Appendix C for *The Impact of Smoking on Chronic Diseases*). Sixteen studies measured smoking cessation effects on improving chronic disease health outcomes. Among those, four articles measured and evaluated biochemical markers as the chronic disease health outcome (see Appendix D for *Measuring Biochemical Markers for Smoking Cessation and Improvement in Chronic Disease*).

An additional search was done to identify effective smoking cessation interventions for successful smoking cessation, using the following keywords: smoking cessation treatments, quitting smoking, pharmacotherapy, 5 As intervention, individual smoking cessation sessions, group smoking cessation sessions, Chantix versus Bupropion for quitting smoking, behavioral therapy, nicotine replacement therapy (NRT), and 5 Rs intervention for unwilling to quit. A total of 119 articles were listed, and seven articles were selected to determine effective intervention, including smoking cessation education (n = 3) and pharmacotherapy (n = 4). Four articles were used to explore the effectiveness of different smoking cessation pharmacotherapy and its success rates for quitting smoking. Three articles were used to explore the different ways of delivering behavioral therapeutic sessions.

Correlation Between Smoking and Chronic Disease

About 14% (34.4 million) of U.S. adults aged 18 years or older were reported smoking cigarettes. Among those, 16 million (46.5%) live with one or more smoking-related chronic diseases (CDC, 2019). Many studies support the harmful effects of smoking on health outcomes in chronic disease. Moreover, cigarette smoking is responsible for more than 480,800 deaths each year, and smokers have been shown to die 10 years earlier than non-smokers (CDC, 2018).

The followings describe the impact of smoking on chronic disease in cardiovascular and peripheral vascular disease, diabetes mellitus, respiratory disease, gastroesophageal reflux disease, and even psychiatric/mental diseases (Bowden et al., 2012; Colak et al., 2015; Kondo et al., 2019; Maddatu et al., 2017; Manhapra & Rosenheck, 2017).

Cardiovascular & peripheral vascular disease. Cardio and peripheral vascular diseases are common chronic diseases caused by the smoking-related atherosclerosis process. A systematic review by Kondo et al. (2019) emphasized the strong association among Japanese

smokers and their increased chance of having atherosclerotic CVD. A high prevalence of atherosclerotic CVD was observed in smokers who use heat-not-burn tobacco (i.e., battery-operated cigarettes heat up to 350°C) and smokers who use conventional cigarettes (Kondo et al., 2019). They also reported that current smokers with normal to high-normal blood pressure (120-139/75-89mmHg) are known to be at increased risk for CVD compared to those who are non-smokers with normal to high-normal blood pressure.

In their meta-analysis, Kondo et al. (2019) proposed that smoking cigarettes provoked endothelial injury and dysfunction. The process begins with the oxidative stress response releasing inflammatory cytokines and reducing nitric oxide's bioavailability, which results in oxidation of low-density lipoprotein and atherosclerotic changes, leading to endothelial injury and dysfunction (Kondo et al., 2019). In a meta-analysis of 32 studies, Kondo et al. (2001) and Goldenberg et al. (2003) (as cited in Kondo et al., 2019) reported smoking-induced sudden ruptures of coronary plaques: This increased risk of developing cerebral aneurysms, subarachnoid hemorrhage (95% Cl 2.48-3.46), and cerebral infarction (95% Cl 1.71-2.16). These diseases can all lead to sudden death in current smokers (Kondo et al., 2019).

Diabetes. Another common chronic disease associated with cigarette smoking is diabetes. Kondo et al. (2019) reported that smoking causes insulin resistance and increases central fat accumulation, leading to diabetes mellitus. An accumulating number of studies have demonstrated a strong correlation between smokers and hyperglycemia (Eliasson, 2003; Maddatu et al., 2017; Sari et al., 2018). Maddatu et al. (2017) conducted a review of population-based studies that have linked cigarette smoking with an increased risk of Type 2 diabetes. Their review observed a higher hemoglobin A1c (HbA1c) in female and male smokers than non-smokers. Individuals who smoked more than one pack of cigarettes a day had more abdominal

obesity compared to individuals who never smoked (95% Cl: 1.16-3.21), and individuals who smoke cigarettes have a lower pancreatic b cell function compared to individuals who never smoked (58.1 vs. 90.1; 95% Cl: 17.8-43.5, $p < 0.001$) (Maddatu et al., 2017). Furthermore, Maddatu et al. reported that both primary smoking and secondary smoking through nicotine exposure could induce a pro-inflammatory metabolic reaction that can impact insulin sensitivity and b cell function.

Not only does smoking increase the chances of an individual becoming a diabetic, but individuals with a history of diabetes can also worsen their blood glucose levels by smoking tobacco. In a cross-sectional study by Sari et al. (2018), a comparison was made between blood glucose and HbA1c levels in diabetic smoking patients and nonsmoking diabetic patients. Their study included patients with an average age of 57 and with a history of diabetes. Sari et al. (2018) found no difference in HbA1c readings ($p > 0.05$) and in fasting blood glucose readings in both groups. However, there was a difference noticed in the postprandial glucose readings between both groups, higher in smokers ($p < 0.05$) (Sari et al., 2018).

Measuring the Effects of Smoking Cessation on Chronic Health Outcomes

Several studies have attempted to measure the effect of smoking cessation on chronic health conditions. While the number of published articles with self-reported smoking cessation outcomes severely outweighs the amount of biochemically proven smoking cessation outcomes, a few studies demonstrated useful, cost-effective tests to measure the effect of smoking cessation.

Abel et al. (2005) conducted a large cohort study using 784 healthy smokers who took Bupropion 300 mg/d for 7 weeks. In this study, they were able to biochemically confirm the effect of smoking cessation by reviewing inflammatory markers such as White Blood Cells

(WBCs) and Absolute Neutrophil Counts (ANCs). These biomarkers are an essential part of the inflammatory process and explain how smoking contributes to CAD (Abel et al., 2005). In their study, WBC counts and ANCs were measured at 7 weeks and 52 weeks. Other measurements included the patients' smoking status measured at 7 weeks and 52 weeks. At 52 weeks, participants who quit smoking, compared to those who did not quit smoking, had a significant decline from baseline WBC count and ANC count; $p < 0.001$. The decrease in WBC counts and ANC can be demonstrated as "possibly reflecting a decrease in an underlying state of tobacco-induced inflammation" (Abel et al., 2005, p. 1028).

Gepner et al. (2011) also performed a 1-year, prospective, double-blind, randomized, placebo-controlled clinical trial to measure smoking cessation effects. Lipoproteins were examined in a group of 923 patients on smoking cessation medications (Bupropion & NRT) and received individual counseling sessions (Gepner et al., 2011). In their study, smoking and smoking cessation are shown to be associated with weight gain, but smokers' "lipid profile is characterized by higher total cholesterol and triglycerides with lower levels of high-density lipoprotein cholesterol" (Gepner et al., 2011, p. 2). Of the 923 participants, 36.2% reported quitting smoking after 1 year. Individuals who quit smoking gained more weight compared to those who continued to smoke (4.6kg vs 0.7kg, $P < 0.001$), but actually showed an increase in their HDL cholesterol when compared to those who continued to smoke (total HDL particles [1.0 vs -0.3mcmol/L, $p < 0.001$], large HDL particles [0.6 vs 0.1 mcmol, $p = 0.003$]) (Gepner et al., 2011). Gepner et al. (2011) demonstrated that smoking cessation helps increase HDL levels but can cause weight gain. However, the patient benefits from these changes as this will reduce their risk for CVD.

Colak et al. (2015) conducted a prospective cohort study with 94,079 randomly selected Danish descent natives from the national Danish Civil Registration System in 2003. Amongst the 94,079 participants, 5,691 had asthma, and among the asthma patients, 2,304 never smoked, 2,467 were former smokers, and 920 were current smokers. Colak et al. (2015, p. 173) examined respiratory symptoms, lung function, and inflammatory and allergic biomarkers in the systemic circulation. They also calculated the risks for asthma and COPD exacerbation, pneumonia, lung cancer, MI, ischemic heart disease, and ischemic stroke, which were compared among the three groups. Forced expiratory volume in one second (FEV1) and the forced vital capacity (FVC) are used to measure lung function. Systemic circulation of inflammatory markers (e.g., c-reactive protein, fibrinogen, leukocyte counts, and neutrophils) and allergy detection markers (e.g., eosinophils and immunoglobulin E) were measured (Colak et al., 2015). Compared to never smokers without asthma, a multivariate-adjusted hazard ratio for asthma exacerbation was 11. In former smokers with asthma, it was 13, and in current smokers with asthma, it was 18 (Colak et al., 2015). A multivariate-adjusted hazard ratio for COPD exacerbation was 1.5 for never smokers, 1.6 for former smokers, and 2.4 for current smokers. These findings support that smoking tobacco leads to a poor prognosis for asthma patients and the risk for lung cancer, cardiovascular comorbidities, and even death for current smokers with asthma (Colak et al., 2015).

In a prospective cohort study, Yeh et al. (2010) tested diabetes risk before and after smoking cessation. The study reviewed 10,892 individuals who initially did not have diabetes from 1987 to 1989 through interview follow-ups over 17 years. Baseline visits were from 1987 through 1989, follow-up clinic visits were 3 years apart, and annual telephone contacts were conducted until 2004 (Yeh et al., 2010). Study variables included height and weight, blood

pressure, serum glucose level, HDL, and leukocyte count. At the 3-year follow-up after smoking cessation, blood pressure decreased, and HDL increased. Serum glucose was measured and showed that smokers had a greater risk of developing diabetes than non-smokers with a pooled adjusted relative risk for diabetes of 1.44 (CI, 1.31 to 1.58).

Challenges and Barriers to Quit Smoking

Quitting smoking is challenging. Previous studies report that the success rates for smoking cessation are as low as 7%-28% after 1 year of pharmacotherapy use (Baker et al., 2016; Cinciripini et al., 2018; Petty, n.d.; Stapleton et al., 2013; Truth Initiative, 2018). Furthermore, many tobacco smokers are reported to experience an average of five to seven failures preceding successful smoking cessation (Petty, n.d., para. 25).

There is a rich scholarly dialogue with known barriers that impedes successful smoking cessation, including quitting and maintaining abstinence. These barriers may include fear of weight gain, becoming anxious, experiencing mood swings, and fear of relapsing (Gregor et al., 2008; Karas et al., 2018; and Robles et al., 2016). Gregor et al. (2008) conducted a study among daily smokers to understand the perceived barriers to smoking cessation. They found that individuals with high anxiety sensitivity are more prone to smoking to escape emotional distress temporarily. Another reported barrier to successful smoking cessation is the lack of knowledge regarding the adverse effects and the correct use of smoking cessation pharmacotherapy (Pacek et al., 2018). Noticeable weight gain, stress, anxiety, or depression can often be experienced while trying to quit smoking, and these are common reasons why some fail to quit smoking. Patients' behavior to nicotine addiction and their body's inability to overcome withdrawal symptoms also play a significant role and can lead to relapsing (Gregor et al., 2008).

Smoking in Underserved Population

Evidence showed that smoking prevalence among uninsured populations (34%) is higher than those having private insurance (18%) (Pleis & Lethbridge-Cejku, 2007). Although smokers with low socioeconomic status (SES) attempt to quit smoking as those with high SES, successful quit smoking rates among those with low SES are shown significantly as low as about half of those with higher SES (Kotz & West, 2009). Smokers in lower socioeconomic groups have been reported to experience limited access to health care and receive smoking cessation advice from family/friends and/or professionals than smokers in higher socioeconomic groups. They are also less likely to have an opportunity to receive structured smoking cessation education sessions or use smoking cessation medication therapy, resulting in less success to quit smoking and poor comorbid chronic disease outcomes (Kotz & West, 2009; Van Wijk et al., 2019; Vidrine, 2009; Ward, 2004).

Role of Free Clinic in Smoking Cessation and Chronic Disease Management

Free Clinics are often the last resources to receive health care treatment for uninsured populations. According to the nationwide survey in 2010 (Darnell, 2010), Free Clinics are reported to serve an average of 747 new patients per clinic per year and 1,796 total unduplicated patients. Free Clinics reported providing a mean of 3,217 medical visits and 825 dental visits per clinic per year. Collectively, there are 1,007 Free Clinics in the United States, and each year they serve about 1.8 million patients who are primarily uninsured. Nationally, they provide approximately 3.1 million medical visits and 300,000 dental visits annually (Darnell, 2010). Free Clinics are an optimal place to access those underserved populations with low SES and provide smoking cessation education sessions. Most patients who visit Free Clinics are shown to have multiple chronic diseases, with 78% of patients having three or more chronic diseases (Pockey et

al., 2012). Considering that smoking is associated with poor outcomes in chronic disease, Free Clinics should take initiatives to provide effective smoking cessation education.

Effective Intervention for Smoking Cessation

Effective smoking cessation interventions should assist patients in quitting smoking and maintaining abstinence by empowering patients. Currently, the mainstreams of smoking cessation therapy include (a) smoking cessation education, (b) pharmacological treatment, and (c) behavioral health therapy (Rigotti, 2018).

Smoking cessation education using the 5 As and 5 Rs. Studies recommend that all the smoking cessation education and interventions be tailored uniquely in an individualized approach because not everyone has the same triggers or motive to start smoking cigarettes, nor do they share the same medical condition. Rigotti (2018) suggests using the "5 As" approach when first encouraging smoking cessation. The 5 As includes **A**sking about tobacco use, **A**dvising to quit, **As**sessing readiness to quit, **A**ssisting smokers who are ready to quit, and **A**rranging a follow-up appointment.

Stage A1. Ask about tobacco use. Smoking cessation starts with an understanding of the current status of smoking. Several nicotine products are available (e.g., cigars, pipes, smokeless tobacco, water pipes/hookas, and bidis) (Rigotti, 2018). When assessing the patient's tobacco use, a full assessment should be completed; for instance, determine how often the patient is smoking; which tobacco product is being used; the degree of nicotine dependence; any history of quit attempts, and the methods used to quit; and how soon after waking up the person has their first cigarette in the morning. The degree of nicotine dependence is essential in helping the patient because "a smoker's degree of nicotine dependence predicts the difficulty that he or she will have in quitting and the intensity of treatment likely to be required" (Rigotti, 2018, para. 16).

A2. Advising to quit. Advising the patient to quit can coincide with educating the patient about their chronic health disease and how smoking cessation will improve their condition.

Appropriate screening of chronic disease and complications in smokers with high risk for cardiovascular and stroke disease helps discuss smoking cessation and chronic disease status. Rodondi et al. (2008) did an observational pre/post-pilot study to assess the feasibility of carotid artery atherosclerotic plaque screening test in 30 daily cigarette smokers and to assess its effectiveness to support patients quit smoking. In terms of intervention, all participants in the study went through counseling for smoking cessation and did Nicotine Replacement Therapy (NRT), had a carotid ultrasound, and were provided with an educational tutorial on atherosclerosis (Rodondi et al., 2008). Another intervention by Rodondi et al. included assessing the participants' readiness to quit and smoking cessation status at baseline and 2-month follow-ups. Studies showed that screening the participants for carotid plaques motivated them to quit smoking with increased intention to quit smoking (7.4 to 8.4 out of 10.0, $p = .02$) (Rodondi et al., 2008). The study demonstrated the feasibility of providing smoking cessation education and pharmacotherapy incorporating the carotid is possible to improve chronic health diseases.

Rodondi et al.'s (2012) study of 12-month long-term follow-up evaluated the impact of carotid plaque doppler screening and 7 minutes of structured explanation on smoking cessation and chronic disease health outcome among 536 smokers aged 40 to 70 years. The smoking cessation success rate was slightly higher in the carotid screening group than the control group (24.9% in the carotid screening group vs. 22.1% in the control group, $p > 0.05$). However, they did not find statistical differences. No significant differences were observed in the smoking cessation rate and chronic disease outcomes between the carotid screening and control groups.

Chronic disease outcomes included blood pressure, hemoglobin A1C, and mean absolute risk change in the Framingham risk score (Rodondi et al., 2012).

A3. Assessing readiness to quit. This can be as simple as asking the patient if they would like to quit smoking. Depending on the patient's response, the patient's stage of change will be determined. The patient would most likely be in any of the five different stages of change: pre-contemplation, contemplation, preparation, action, or maintenance stage (Rigotti, 2018).

In a study done by Sciamana et al. (2000), they compared several measures of motivation to quit smoking in hospitalized patients enrolled in a smoking cessation program in the hope of finding a more straightforward method to use in a clinical setting. Also, they measured the readiness level to quit smoking based on the five stages of changes mentioned by Rigotti (2018). They described their stages of change as pre-contemplation (not considering quitting in the next 6 months), contemplation (planning on quitting in the next 6 months), preparation (planning on quitting in the next month with past quitting experience), action (the first 6 months after quitting), and maintenance (6 months or more after quitting) (Sciamana et al., 2000). However, after collecting data during face-to-face counseling sessions, they found that a simple three questionnaire tool was just as suitable if not better than a multiple-item clinical measurement tool. For instance, simply asking patients, "How likely is it that you will stay off cigarettes after you leave the hospital?" with possible answers as "not likely," "somewhat likely," and "very likely" can accurately predict smoking cessation at 12 months. Sciamana et al. (2000) supported their findings by saying 93.4% of patients stating "not likely" as their answer are genuinely not likely to quit smoking (i.e., each measure of motivation to quit is independently associated with cessation, $p < 0.001$).

A4. Assisting smokers who are ready to quit. The quitting process begins by "setting a quit date within the following two to four weeks" (Rigotti, 2018, para. 10). Supporting patients to quit smoking will include a combination of behavioral support and pharmacotherapy (Rigotti, 2018). The first line of pharmacotherapies for smokers entails the combination of NRT (a long-acting NRT and a short-acting NRT) and or starting the patient on Chantix or Bupropion. The use of medications to assist with smoking cessation is to help reduce nicotine withdrawal (e.g., anxiety, insomnia, irritability, weight gain, restlessness), thus making the process more comfortable for the patient to stop using cigarettes (Rigotti, 2018). A NicoDerm patch is a long-acting NRT, and chewing gums or lozenges are short-acting NRTs. Circumstances in which Bupropion is considered the choice of treatment over Chantix is when the patient has failed a Chantix quit attempt. Other circumstances for the choice of Bupropion are the patient having a history of depression, the patient wishes to avoid gaining weight, and if the cost is an issue for the patient (Rigotti, 2018). A well-known source of behavioral support for patients living in the United States and are interested in quitting smoking is the 1-800-Quit-Now hotline. Both health care providers and patients should have access to this hotline as a helpful resource.

A5. Arrange a follow-up appointment. After agreeing on a quit date, a follow-up visit is recommended within 2 weeks (Rigotti, 2018). The 2-week follow-up visit allows the health care provider to provide reinforcement, assess response to medications, change treatment therapies if needed, and assess any adverse side effects from the patient's medications.

Considering some smokers may not be ready to quit smoking, a 5 Rs approach can help motivate smokers unwilling to quit. The 5 Rs include **R**elevance, **R**isks, **R**ewards, **R**oadblocks, and **R**epetition (Rigotti, 2018).

1R. Relevance is used to help the patient determine why quitting smoking is personally important to them (Rigotti, 2018). Motivational information such as the patient having children, experiencing difficulty breathing, or having worsening chronic health disease can have the greatest influence on the patient. Another significant relevant factor that can impact the patient's motivation to quit could be their previous experience with quitting smoking.

2R. Risks are used to assess the patient's knowledge of the negative consequences of smoking (Rigotti, 2018). Emphasizing the risks of smoking and the harm that it causes to one's health can help motivate the patient to quit. For example, telling the patient that smoking increases their risk of having a stroke or heart attack, getting cancer, or developing COPD can help with motivating.

3R. Rewards can be used to help the patient identify the potential benefits of quitting smoking (Rigotti, 2018). Highlighting rewards such as improving health, saving money, or feeling better about oneself can reward quitting smoking.

4R. Roadblocks can present barriers or impediments to the smoker attempting to quit (Rigotti, 2018). Helping the patient to identify these barriers can add to the patient's motivation to quit smoking. Some examples of roadblocks can include lack of support, withdrawal symptoms, weight gain, or depression (Rigotti, 2018). Noting treatments that could address the patient's barriers is essential. For example, if the patient is experiencing weight gain and depression, this patient's best medication treatment would be Bupropion.

5R. Motivational interventions should be ***Repeat***ed at each clinical visit for unmotivated smokers (Rigotti, 2018).

Pharmacological Therapy

Pharmacology therapy is one of the mainstreams of smoking cessation therapy. Commonly used smoking cessation pharmacotherapy includes Chantix, Bupropion, and Nicotine Replacement Therapy (e.g., gum, transdermal patch, nasal spray, and oral inhaler). According to research, there is no single medication that is strictly recommended for smoking cessation therapy. Several medications can be given in combination or as a monotherapy. The choice of medication is dependent on patient preference, tolerance to the drug, and contraindications. For instance, individuals who have a history of seizures should not take Bupropion. Furthermore, pregnant women should be advised not to take Chantix (see Appendix E for a summary of pharmacological therapy for smoking cessation).

Cinciripini et al. (2018) examined a randomized controlled trial to determine if Chantix and Bupropion combination treatment would be more effective than taking Chantix alone in 385 smokers who smoked one pack of cigarettes a day in an outpatient clinic. The age of patients ranged from 25 to 65 years. The combination group consisted of 163 participants who took Chantix and Bupropion for 12 weeks and 166 participants took Chantix only for 3 months. Follow-up visits were made at the end of 3 months, 6 months, and 12 months. In this study, a 3-month follow-up smoking cessation rate was not measured. Rather, they examined the treatment retention rates at 3-month follow-up, and it was 67.86% in Chantix use alone group and 80.98% in the combined Chantix and Bupropion group, respectively (Cinciripini et al., 2018). Withdrawal symptoms and adverse effects were measured at a 6-month follow-up and were low in both groups. Lastly, there were no differences at 12 months of smoking cessation between two pharmacology groups [odds ratio (OR) = 0.91, 95% confidence interval (CI) = 0.50–1.64].

Chantix and Bupropion treatment combination did not make any difference in increasing smoking cessation (Cinciripini et al., 2018).

Similarly, Stapleton et al. (2013) conducted a randomized controlled approach to examine and compare the effectiveness of NRT, Bupropion, and the combined therapy of NRT plus Bupropion in a sample size of 1,071 smokers over 6 months. The participants in this study had an average age of 41. Four hundred and nine participants took Bupropion alone, 244 participants took Bupropion plus NRT, and 418 participants took NRT alone (Stapleton et al., 2013). Group support sessions were provided 1 week after chosen quit dates and then again at 2, 3, and 4 weeks after quitting smoking. Smoking cessation rates were higher in patients with Bupropion (27.9%) than patients with NRT (24.2%) alone. Although the findings were not significantly different (odds ratio = 1.21, 95% confidence interval = 0.883–1.67), the smoking cessation rate in patients' combination therapy (24.2%) was similar to taking the medications alone. Despite these results, the study showed Bupropion was the most effective in individuals with depression than taking NRT ($\chi 2 = 2.86$, $p = 0.091$) (Stapleton et al., 2013).

In another study, Baker et al. (2016) conducted a randomized controlled trial to compare the effects of nicotine patch versus Chantix alone versus combination NRT over a 26-week quit rate in Wisconsin communities. A total of 1,086 individuals took part in the study and were over 17 years of age. Five follow-up visits occurred 1 week before the target quit date, on the quit date, and then at weeks 1, 4, and 12 weeks after the target quit date. Four hundred and twenty-four participants took Chantix only, 241 did a nicotine patch only, and 421 did a nicotine patch plus Chantix. At 26 weeks, smoking cessation rates were 22.8% in nicotine patch users, 23.6% in Chantix users, and 26.8% in Chantix plus NRT users (p = ns). At 52-week follow-up, smoking cessation rates were 20.8% in nicotine patch users, 19.1% in Chantix users, and 20.2% in

Chantix plus NRT users. There were no noticeable differences in treatment for smoking cessation. However, this study reported that Chantix produced more significant side effects with dreams, gastroesophageal upset, insomnia, and sleepiness than the nicotine patch (Baker et al., 2016).

In a randomized controlled trial with 174 highly dependent smokers ages 18 to 65, Rose and Behm (2016) compared the benefits of combination (Chantix and Bupropion) and Chantix alone to 122 nicotine patches non-responders and 52 nicotine patch responders. The study was conducted over 12 weeks with follow-up visits at 2 weeks before the participants quit date and then again at 1, 3, 7, and 11 weeks after the quit date. The results concluded that for patients with high dependence of smoking (nicotine patch responders and non-responders), the combination of Chantix with Bupropion was most beneficial in helping with smoking cessation compared to Chantix alone; 71.0% versus 43.8% (odds ratio = 3.14; 95% confidence interval = 1.11–8.92, p = .016) (Rose & Behm, 2016).

Behavioral Therapy

Several studies showed the benefits of behavioral therapy along with medication use to aid in smoking cessation. Whether it is provided individually or in a group setting, benefits are still attained. Likewise, phone calls and text messaging have also been explored to provide smoking cessation support.

Stead and Lancaster (2017) conducted a systematic review of quasi-randomized trials that included 49 studies and 19,000 participants to analyze the most effective individual behavioral counseling for smoking cessation after at least 6 months of program sessions. Comparisons were made between the following areas: (a) individual counseling versus no counseling but with brief advice or self-help materials, (b) more intensive versus less intensive individual counseling, and

(c) comparisons between counseling methods matched for contact time. Within their results, Stead and Lancaster found that individual counseling is much more helpful than when counseling is provided as brief advice, during usual care, or through self-help materials (Risk Ratio [RR] 1.57, 95% confidence interval [CI] 1.40 to 1.77; 27 studies, 11,100 participants).

Similarly, this result was consistent even when the providers did not offer any medications. Other articles supported the added benefit of medications such as NRT with individual sessions to support smoking cessation (RR 1.24, 95% CI 1.01 to 1.51; 6 studies, 2662 participants). When Stead and Lancaster compared brief individual counseling sessions to intense counseling, benefits were higher with the intense counseling sessions (RR 1.29, 95% CI 1.09 to 1.53; 11 studies, 2920 participants), supporting individual cessation sessions is effective to help with quitting smoking.

Stead et al. (2017) also examined and compared the effectiveness of (a) group therapy, (b) self-help, (c) individual counseling, and (d) traditional casual intervention without individual sessions or counseling for smoking cessation for at least 6 months of progression sessions. They also considered trials that compared more than one group session. A total of 66 trials met the criteria for their search. This search generated results for 13 trials, showing a higher cessation rate in a group session than a self-help program (N = 4395, RR 1.88, 95% CI 1.52 to 2.33). In addition, 14 trials also showed an increase in smoking cessation with a group program compared to brief support from a health care provider (N = 7286, RR 1.22, 95% CI 1.03 to 1.43). Stead et al. (2017) concluded that group therapy is much more beneficial to smoking cessation than less intensive interventions and self-help approaches in their systematic review.

Another way of providing supportive behavioral therapy is using text messaging, known as Short Messaging Service (SMS). Spohr et al. (2015) conducted a meta-analysis to review the

efficacy of SMS text messaging interventions for smoking cessation. Randomized controlled trials measured the effectiveness of smoking cessation intervention using text messaging only on cessation rate and conducted a 3- to 6-month follow-up. Thirteen studies were reviewed and met their criteria. The study concluded that in addition to an in-person intervention, text messaging could add mild to moderate benefits than in-person intervention only (Spohr et al., 2015).

Summary

In summary, an association has been shown to link smoking and chronic health diseases such as cardiovascular disease, diabetes mellitus, hypertension, and respiratory diseases, adding to chronic disease management burdens and worsening symptoms. Smoking cessation education, pharmacotherapy, and behavioral therapy support mainstream smoking cessation therapy. The 5 As approach has been recommended as a tool to motivate and support individuals who are willing to quit smoking and successfully quit smoking. Pharmacotherapy ranges from NRT to Chantix and Bupropion. The success rate of quitting smoking was similar among NRT, Chantix, and Bupropion as the first-line therapy at a rate of 20.8% and 27.9%, with a median average of 24.2%. The use of combined NRT with Chantix or Bupropion had shown a higher smoking cessation rate, ranging from 20.8% and 27.9%. The combined therapy of NRT with Chantix or Bupropion has shown to have a better success rate to quit smoking, but no statistical significance is found. The combination of Chantix and Bupropion has demonstrated the highest smoking cessation rate, up to 76.0% among other matches, and thus, this combination is recommended in patients who failed NRT therapy.

Behavioral therapies are essential and valuable to support quitting smoking. They can be delivered through individual and group sessions considering videoconferencing and telephone communication (e.g., phone calls, text messaging). Evidence showed that intensive sessions

(either individual or group sessions) using telephone communication when in-person sessions are not delivered could effectively support quitting smoking and avoiding relapsing. Limited evidence exists to demonstrate the efficacy of measuring smoking cessation against chronic health improvements. More studies are needed, including biomarkers and vital signs, to measure the chronic disease progress after smoking cessation.

Chapter III. Methodology

Study Design

This study is a part of the quality improvement project, aiming to increase smoking cessation rates and improve chronic disease health outcomes in a Free Clinic located in Patrick County. The researcher led the study and provided two 20-minute structured and moderately intense smoking cessation education sessions over 3 months. A quasi-experimental one-group, pretest-posttest study design was done to evaluate its effectiveness on smoking cessation and chronic disease. The effects of this smoking cessation project were measured by (a) readiness to quit smoking, (b) nicotine dependence, (c) smoking cessation pharmacotherapy use, (d) smoking cessation success rate, and (e) chronic disease health outcome.

Study Subjects and Settings

Adults 18 years and older, who reported a positive smoking history, have one or more chronic diseases for longer than 3 months, and who are cared for at the Caring Hearts Free Clinic of Patrick County were recruited as study subjects. Chronic disease in this study is defined as having one or more of the following diseases: hypertension, hyperlipidemia, diabetes mellitus, obesity, coronary artery disease, and COPD. Participants who smoked at least one or more cigarettes per day were included. Among those, only those who agreed to participate and receive smoking cessation education were included. Patients who did not speak English, were unable to consent, were already taking a smoking cessation medication, and who only vape, sniff, or snuff the nicotine or use electronic cigarettes other than a conventional cigarette for smoking were excluded. Bupropion is often used to treat anxiety, depression, and smoking cessation. Smokers taking Bupropion to treat their anxiety or depression, not as a smoking cessation aid, were also included. Considering a power of .80 and an αlpha of 0.05, a suitable sample size in a one-group

study with a pre- and post-test was calculated as 64 (Free Statistics Calculator Version 4.0, n.d.). However, our study is preliminary. A minimum sample size of 30 has been allowed and recommended as the rule of thumb in preliminary research in the previous studies (NCSS Statistical Software, n.d.). Thus, a minimum of 30 study subjects was targeted as the sample size.

Study Instruments/Tools

Pre- and post-survey tools. Survey questionnaires were used to measure study outcomes on (a) the participants' readiness to quit smoking using a 1-4 Likert scale, (b) nicotine dependence using both modified CAGE screening and a Fagerström questionnaire, and (c) whether they quit smoking or not (see Appendix F for *CAGE Questionnaire for Smoking* & Appendix G for *Brief Fagerström Test for Nicotine Dependence*).

Modified questionnaires for CAGE (see Appendix F)**.** A modified CAGE questionnaire was used in this study to measure the participants' nicotine dependence. According to the *American Academy of Family Physicians (AAFP)* (Rustin, 2000), the CAGE questionnaire was initially developed and used for alcoholism addiction (Rustin, 2000). However, the CAGE questionnaire was often modified and introduced to screen patients for other addictive behaviors, including nicotine dependence. The CAGE acronym stands for the following: **C**-cut down, **A**-annoyed or angry, **G**-guilty, and **E**-eye opener. The CAGE questionnaires for smoking behavior were revised in this study based on the questions provided by AAFP (Rustin, 2000). Each questionnaire for CAGE was scored using a "yes = 1" and "no = 0." The total score of CAGE questionnaires was from 0 to 4 points. Two "yes" responses out of four questions were considered a positive screening test for nicotine dependence. The correlation coefficient sensitivity and specificity for CAGE scores of alcohol dependence range from 0.54 and 0.66, respectively (Aertgeerts et al., 2004, p. 33). The sensitivity and specificity of the modified

CAGE score for nicotine dependence are less represented in research studies as this tool is most often used for alcohol abuse screening.

The Fagerström questionnaire (see Appendix G). The Fagerström questionnaire was also used to measure nicotine dependence in this study. Unlike the CAGE questionnaire, it was primarily developed to screen the participant's physical dependency on nicotine (Rustin, 2000). Originally, this tool consists of six assessment questions (Rustin, 2000). However, for this study, a modified version of the Fagerström questionnaire with two questions was used (Heatherton et al., 1991): (1) how soon after you wake up do you smoke your first cigarette? and (2) how many cigarettes do you smoke each day? Heatherton et al. (1991) reported that the brief Fagerström test with the revised two questions was shown to improve the scale, especially related to biochemical measures of heavy smoking.

Each question was scored using a 0-3 Likert scale. The total score is calculated from two questionnaires, ranging from 0 to 6 points. When scoring for the Fagerström questionnaire, the higher scores were interpreted as stronger nicotine dependence. The patients were classified into three categories of physical nicotine dependence, depending on the total score. For instance, 5 or 6 points meant heavy nicotine dependence, 3 to 4 points indicated moderate dependence, and 0 to 2 points showed light nicotine dependence.

According to Pérez-Ríos et al. (2009), the Fagerström test for nicotine dependence is considered a gold standard tool for diagnostic accuracy. The sensitivity and specificity of the Fagerström nicotine dependence test are reported as 76.2% and 96.2%, respectively (Pérez-Ríos et al., 2009, p. 3).

Education tools. The pamphlet "*Put It Out Before It Puts You Out*" was developed based on the evidence-based practice guidelines (see Appendix H). It provides brief information on

cigarette smoking and its connection to chronic health disease and helpful tips on taking steps to quit smoking (AAFP, 2015; Godfredsen & Prescott, 2011; Rigotti, 2018). Resources for common hotlines and apps can also be viewed on the back of the pamphlet. Additionally, evidence-based recommendations for medication dosage and administration were provided for the most commonly used smoking cessation medications (AAFP, 2015; Godfredsen & Prescott, 2011; Rigotti, 2018).

Smoking cessation pharmacotherapy algorithm (see Appendix E). A smoking cessation pharmacotherapy algorithm was developed in this study using evidence-based research recommendations (Rigotti, 2018) to select a smoking cessation medication. Two experts also reviewed it, including primary care providers (PCPs) at the clinic. PCPs followed this algorithm while considering the patient's medication preference and the PCP's expertise.

Implementation Plan

Preparation Phase

Preparation. The study was proposed and explained to the clinic staff at the Caring Hearts Free Clinic. The study's overviews, including purpose, objectives, timelines, and recruitment process of the study, were discussed with the executive director, nurse practitioners, and the receptionist of the Free Clinic. A letter of support and approval was obtained from the Free Clinic to conduct the study. A total amount of $1,050.00 from the Free Clinic was provided to compensate participants for their participation with gift cards of $15 during their 1-month follow-up visit and $20 during their 3-month follow-up visit. Institutional Review Board approval from Radford University was obtained. All members of the research team completed the CITI Program Training. HIPPA and the standards of care for smoking cessation and chronic disease management were strictly followed throughout the study.

Recruitment/Informed consent. The clinic secretary and PCP retrieved a list of identified smokers. This process was done by the clinic secretary using an electronic medical record (EMR) filter search to locate reported smokers. The initial contact of patients for recruitment was made by the secretary using phone calls to seek their participation in the study. Another recruitment strategy used was asking participants to take part in the study during their scheduled clinic visits. While seeking the patient's participation, patients were screened and confirmed as cigarette smokers and had one or more chronic diseases. Those who agreed to participate and were already in the clinic were asked to partake in the study that day, or they were given the option to schedule an appointment for their subsequent chronic disease management (see Appendix I for an *Intervention Timeline and Workflow Checklist for Smoking Cessation*).

Participants were first seen by their PCP for their chronic disease management. During this time, their PCP confirmed their willingness to initiate smoking cessation, and they were then referred to the researcher for a smoking cessation education session. The researcher then began the study procedures.

Implementation Phase

Blue stickers were applied to the chart to distinguish the patients who agreed to participate in the study from other patients in the clinic. The researcher obtained voluntary informed consent from the patient after explaining the study's purpose, duration, procedures, risks, and benefits; and before implementing the baseline survey and education session.

Overall, two 20-minute education/counseling sessions were provided during the initial and 1-month follow-up visits. The post-surveys were collected after providing the education session at the initial encounter, 1-month, and 3-month follow-up visits. Each survey took

approximately 2-5 minutes to complete. Educational sessions and surveys were delivered either at the clinical site, phone call, or via Updoc video conferencing.

In addition to the education/counseling sessions, participants could initiate a smoking cessation medication therapy prescribed by their PCP. The standard treatment duration for smoking cessation medication therapy is 12 weeks. During the 12-week therapy, PCPs usually follow up with their patients at 1 month and 3 months after the initiation of smoking cessation medication therapy. In this study, 1-month follow-up phone calls or clinic visits were made to assess smoking status, monitor for any side effects from the medication (if the participant has started a smoking cessation medication), and address any health concerns. During the study, if the patient decided they did not want to initiate a smoking cessation medication, they continued to receive education and resources from the researcher.

Pre-survey. The researcher provided survey hand-out questionnaires to be filled out by the participant—the pre-survey collected demographic data, smoking status, nicotine dependence, and readiness to quit smoking. The approximate time to complete the pre-survey was 2-5 minutes.

Initial day. Depending on the participant's response to the questionnaire, if the patient was ready to quit, they moved forward with a smoking cessation plan (i.e., education, medication, counseling, and choose a quit date). Participants received 20-minute smoking cessation education by the researcher verbally and using the written educational material. The educational pamphlet was reviewed with the participant, and a copy was given to them (refer to Appendix H for the educational pamphlet). The researcher answered any questions or concerns during this time as well. The 5 As approach was used to assess the participants' knowledge of smoking cessation, readiness to quit, and assist the participants in quitting smoking. Before

ending the first session, some participants picked a quit date (within 1 to 2 weeks). Then, with the collaboration of the PCP, participants were started on an appropriate smoking cessation medication based on the patient's preference.

Those participants who were not ready to quit during the initial visit continued to receive smoking cessation education. They were asked if they would like to continue in the study in the hope of having a change in mind. The 5 Rs were used for those patients who were reluctant to quit smoking.

As stated earlier, the Caring Hearts Free Clinic provides medication financial assistance coverage through MAP. If the patient's smoking cessation medication preference were Chantix or a Nicotrol inhaler, a delayed time of 2 to 6 weeks was expected to have the medication available through the funding program. Thus, the researcher was made aware by the clinic staff when the patient was approved for Chantix or Nicotrol inhaler financial coverage. Follow-up visits were kept as scheduled regardless of medication choice, and individual phone call follow-ups were made at 2 weeks and 1 month to ensure close monitoring.

Blood tests (e.g., Hgb A1c, total cholesterol, triglycerides HDL, and LDL) and vitals (e.g., blood pressure, temperature, heart rate, respiration rate, oxygen saturation, and weight) were obtained from the participants' EMR and documented to measure the pre-intervention outcome.

Phone call follow-up at week 2. Individual phone calls were made at week 2 to ensure close monitoring when the patient was not in the office. If the participant initiated a smoking cessation medication, medication compliance and side effects were evaluated and communicated to the relevant provider. Any concerns received by the participants were also communicated to their PCP by the researcher, or the participants were encouraged to share their concerns with

their PCP. Once their problems or concerns were expressed to the relevant providers, a provider-patient shared decision was made. The option to change medication or stop a medication was carried out by the PCP. The patient also had the opportunity to withdraw from the study at any time.

One-month follow-up. At 4 to 6 weeks or 1-month follow-up, another 20-minute educational session was provided either at the clinic visit, over the phone, or via Updoc videoconferencing. Participants were seen individually in a private room for encounters at the clinic site after being seen by their provider. This follow-up visit kept the same procedure as the initial visit using the 5As approach. In addition, (a) education sessions were provided with an education brochure if needed, (b) a short 1-month follow-up survey was conducted, (c) medication adherence and side effects were evaluated, (d) smoking status was evaluated, (e) patients were helped with identifying triggers and barriers to quit, and (f) strategies to overcome any barriers and motivations were discussed. During this visit, the patient was compensated with a $15 gift card.

Three-month follow-up. Their PCP followed up patients at 3 months as part of their usual chronic disease management schedule. The participants' success or failure in smoking cessation and any improvement in their chronic disease symptoms were recorded using a post-intervention survey questionnaire and put into their medical chart. Patients were compensated with a $20 gift card.

Blood tests (e.g., Hgb A1c, total cholesterol, triglycerides HDL, and LDL) and vitals (e.g., blood pressure, temperature, heart rate, respiration rate, oxygen saturation, and weight) were obtained from the participants' EMR and documented to measure post-intervention outcome.

Data Collection/Storage Plan

Pre- and post-survey. The pre-survey results were collected at the beginning of the study. Post-survey results were collected after providing education at the initial visit and then again at 1-month and 3-month follow-up visits. This survey was collected and stored in the patient's chart, with 3-month follow-up visits being a standard part of care for chronic disease management. The demographic data and chronic disease data were asked during the initial survey. The smoking-related data, smoking cessation medication-related data, and chronic disease-related outcome were asked at the initial visit, 1-month, and 3-month follow-up using post-surveys (see Appendix A).

Clinical data. Chronic disease management is usually cared for by PCPs every 3 to 6 months. As part of chronic disease monitoring and management, laboratory tests were ordered. Retrospectively, the available blood test results (i.e., Hgb A1c, total cholesterol, triglycerides HDL, and LDL) and vitals (e.g., blood pressure, temperature, heart rate, respiration rate, oxygen saturation, and weight) were collected at the initial and 3-month follow-up visits. The patients' blood tests at their initial visit were not ordered if their recent blood tests were done within the past 3 months and were available; these results were considered their baseline clinical data.

Data security/storage. The researcher had access to the electronic medical chart and received a passcode provided by the clinic to access the Updoc videoconference system and participant contact phone number, which were used as alternative methods to deliver educational sessions and complete the survey questionnaires.

The variables, including identifiable information from the patient (i.e., the first four letters of the last name with participation number such as Jame01), were matched and de-identified for study identification (ID). A file, including matched personal-identified information

and study ID number, was securely locked away in a cabinet kept in a locked room at the Free Clinic. Each participant was assigned a study ID and was required to enter their study ID on the surveys, which helped match the pre- and post-survey and clinical data for comparison. All study variables collected from the survey and collected as clinical data obtained from the patients' EMR (i.e., vitals and blood lab results) were de-identified and stored in a separate password-encrypted Excel file in a secured whale H drive of Radford University.

Evaluation Plan

Study Variables

The demographic, smoking-related, and chronic disease comorbidity data were measured to evaluate the correlation between the variables at baseline, 1-month, and 3-month follow-up. The primary outcome variable for this study was the success of smoking cessation. The other outcome variables included a readiness to quit smoking, the severity of nicotine dependence, smoking cessation pharmacotherapy use, smoking cessation rate, and chronic disease health outcome measured by surveys and clinical data. Detailed lists of study variables are provided in Appendix I.

Study Analysis

Frequency and percentage for nominal/categorical variables and mean and standard deviation for continuous variables were used to describe the demographic data, smoking-related data, smoking cessation success rate, and chronic disease-related outcome data.

Cochran's Q and Friedman's tests were used to calculate the differences in study outcomes between the data collected at the initial visit and during the different follow-up visits within the 3 months. A pairwise paired *t*-test was used as a post-test analysis for smoking

behavior and nicotine dependence to compare all possible pairs of one group out of three time periods of collected data.

Ethical Considerations

The anticipated risk or harm from participating in this research study was no more than the nature of standard smoking cessation treatment provided by PCPs to smokers. The current evidence supports the effectiveness of smoking cessation medication when pharmacotherapy is offered combined with behavioral therapy and counseling. As with any drugs, some participants reported the side effects of selected medications. Examples of the reported adverse reactions included changes in appetite and nightmares with Chantix; and agitation, insomnia, headache, and stomach pain with Bupropion.

As stated earlier, this study also required collecting participants' identified health information retrieved from their EMR. To minimize the risk of a breach of patient-identified information, several attempts were provided. All identifying information was de-identified. Access to the study data was limited to study researchers only. Only aggregate data was used to report the results of this study. All data collected from the survey were stored in a secured password-protected computer and/or a locked cabinet.

Overview

The different study materials (i.e., survey, educational brochure, smoking cessation algorithm, and theoretical framework) were developed to guide participants to reach a goal of smoking cessation. The Free Clinic supporting this study with a $1,050.00 grant and providing medication assistance through the MAP program demonstrated the willingness of change for this community to serve the low-income population better. The materials and steps taken in this study were used to evaluate whether the proposed initiative model is feasible and valuable to help

participants at a Free Clinic to assist participants in reducing the number of cigarettes smoked over 3 months.

Chapter IV. Results

A total of 32 participants initially participated in this research study. The participants (a) received individual smoking cessation education at the initial and 1-month follow-up visit, (b) participated in MAP and received smoking cessation medication therapy as part of their patient care treatment plan provided by their PCP at the Free Clinic, (c) were followed-up with a phone call at 2 weeks, and (d) had a 1-month and 3-month follow-up visit as their usual care of chronic disease management with their PCP.

All 32 participants continued in this study up until 1-month follow-up. However, a significant attrition rate occurred between the 1-month and 3-month follow-up visits, with 43.8% attrition rate (n = 14), leaving a sample size of 18 by 3-month follow-up visits. The primary reason for the attrition was due to 57.1% (n = 8) of the attrited patients obtaining insurance through Medicare, Medicaid, or other private insurance and establishing care with a different primary care provider at other clinic sites. This caused those patients to no longer qualify to receive their care at the Free Clinic. And, several patients, 42.8% (n = 6) of the attrited patients, did not show up to their 3-month follow-up visit.

Demographic Characteristics

Fifty-three percent of the participants were males, and the average age of the participants was 49, ranging from 25 to 63 years of age. White/Caucasian was noted to be the dominant ethnic background for the participants in this study, with 91%. The two other ethnic backgrounds included 3% Black/African Americans and 6% Hispanic/Latinos. All 32 participants in this study were smokers and reported having one or more chronic health diseases. Twenty-eight percent reported having diabetes, 47% had hypertension, 34% had hyperlipidemia, 9% had coronary artery disease, and 62% reported having chronic obstructive pulmonary disease. Participants who

had three or more of these chronic health diseases were counted as 25%. Other chronic diseases reported by the same participants included 62% of the participants also had anxiety, depression, asthma, and gastroesophageal reflux diseases (see Table 1).

Table 1

Demographic Data

		Frequency (%) or Mean ± SD (N = 32)
Gender	Female	15 (47%)
	Male	17 (53%)
Age		49.22 ± 10.28
Ethnicity	White/Caucasian	29 (91%)
	Black/African American	1 (3%)
	Hispanic/Latino	2 (6%)
	Asian	0
	Native/Pacific Islander	0
	Others	0
Chronic Disease	DM	9 (28%)
	HTN	15 (47%)
	Hyperlipidemia	11 (34%)
	CAD	3 (9%)
	COPD	5 (16%)
	Others	20 (62%)
Chronic Disease With 3 or More*	*3 or more from DM, HTN, HPL, CAD, COPD, not Others)	8 (25%)

Note. SD = standard deviation; % = percentage; DM = diabetes mellitus; HTN = hypertension; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease

Smoking-Related Outcomes

Readiness to quit smoking. In the survey questionnaire, the participants were asked about their intentions to quit smoking. At the initial visit, 65% of the participants reported they were “very unlikely” to quit smoking. There were no specific changes at the 1-month follow-up, with 62% reporting they were “very unlikely” to quit smoking. However, there was a noticeable improvement in the participants’ responses to their intention to quit smoking by 3-month follow-up visit. Participants who responded with “very unlikely” to quit smoking were decreased from

65% to 17%. At the 3-month follow-up visit, 66% reported they were "somewhat likely" to quit smoking, and 17% reported "likely" to quit smoking. The participants' intention to quit smoking showed a statistically significant increase over the 3 months of this study, *p*-value < 0.0001 (see Table 2).

Table 2

Effects of Smoking Cessation on Smoking-Related Outcomes

	Baseline Freq. (%) or Mean ± SD (N = 32)	1-month Freq. (%) or Mean ± SD (N = 32)	3-months Freq. (%) or Mean ± SD (N = 18)	 Cochran Q's or Friedman's *p* value
Readiness to Quit Smoking				
Intention to Quit Smoking Category (0-3)	0 = 7 (21%) 1 = 21 (65%) 2 = 4 (12%) 3 = 0 (0%)	0 = 8 (25%) 1 = 20 (62%) 2 = 4 (12%) 3 = 0 (0%)	0 = 0 (0%) 1 = 3 (17%) 2 = 12 (66%) 3 = 3 (17%)	< 0.0001 (8.02e-05)
Readiness to Quit Smoking	0.90 ± 0.59	0.87 ± 0.61	2 ± 0.59	< 0.0001 (6.0e-09)
Quit Smoking Rate				
Quit Smoking	0 (0%)	0 (0 %)	1 (5%)	N/A
CAGE Score				
C- Cut Down	91%	91%	94%	0.096
A- Annoyed or Angry	62%	59%	67%	0.9048
G- Guilty	62%	69%	61%	0.8948
E- Eye Opener	25 (78%)	16 (50%)	11 (61%)	0.1054
Total CAGE Score (0-4)	2.93± 1.04	2.68± 0.93	2.89± 0.83	0.6600
CAGE Category (Y/N)	29 (91%)	29 (91%)	17 (94%)	0.1819
Fagerström Score				
Fag: Eye Opener (0-3)	2.12± 0.83	1.34 ±1.09	2.22 ±1.51	0.0028*
Fag: Smoking Amount (0-3)	0.97± 0.86	0.47± 0.62	0.56± 0.78	0.0017*
Fag: Total (0-6)	3.09± 1.44	1.80 ±1.44	2.27 ±1.90	< 0.0001* (2.275e-05*)
Fag: Category (0-3) 0 = **Quit** 1 = **Light** 2 = **Moderate** 3 = **Heavy**	 0: 0 (0%) 1: 12 (37%) 2:14 (44%) 3: 6 (19%)	 0: 0 (0%) 1: 20 (62%) 2: 12 (38%) 3: 0 (0%)	 0: 1 (5%) 1: 9 (50%) 2: 5 (28%) 3: 3 (17%)	 0.0016*
Fag. Cat. (combined % of pts with M+H Nicotine Dependency)	Mod + H = 63%	Mod + H = 38%	Mod + H = 45%	0.0016*

Note. Freq = frequency; B = baseline; 1m = 1-month; 3m = 3-month; Fag = Fagerström; Cat = category; Mod = moderate; H = heavy. Intention to quit smoking (scored 0-3) *; a higher score represents more likely to quit smoking. CAGE score (scored 0-4) *; a higher score of two yes or more represents a positive smoker. Fagerström score (scored 0-6; 0-3) *; a higher score and category represents a greater nicotine dependence.

Nicotine dependence using CAGE questionnaire. In this study, there were no significant differences in the total score for the CAGE questionnaire among baseline (2.93), 1-month (2.68), and 3-month (2.89) follow-up visits, with a *p*-value 0.6600 (see Table 2). Further post-test analysis was used to determine differences in CAGE scores between two timelines at baseline, 1-month, and 3-month visits, using the pairwise paired *t*-test. No statistical significance was observed in any of the paired *t*-tests with a *p*-value > 0.05.

Nicotine dependence using the Fagerström questionnaire. Along with CAGE scores, the Fagerström questionnaire was also used to measure the participants' dependence on nicotine. A higher score indicated higher nicotine dependence. Different from the CAGE score, the total Fagerström scores were significantly reduced from the baseline (3.09± 1.44) to the 1-month follow-up (1.80 ±1.44) and the 3-month follow-up visit (2.27 ±1.90) with a *p*-value of 0.0001. When using the Fagerström category with either quit smoking, light smoker, moderate smoker, or a heavy smoker, the percentage of patients who are moderate or heavy smokers significantly reduced from 38% at 1-month to 45% at 3-month follow-up, compared with 63% at baseline (see Table 2).

Further post-test analysis was conducted to appreciate the differences in Fagerström scores between two timelines at baseline, 1-month, and 3-month visits, using the pairwise paired t-test. Significant differences were observed between baseline and 1-month (*p*-value < 0.0001) and 3-month follow-up (*p*-value 0.0041) visits. However, no significance was observed in the scores between 1-month and 3-month visits, with *a p*-value of 0.1450.

Smoking cessation pharmacotherapy use. The most commonly prescribed smoking cessation medications in this study were Chantix and Bupropion. Financial assistance was provided for Chantix using the clinic's MAP program, and a Good Rx coupon was provided for Bupropion. During the 1-month follow-up visit, a total of seven participants (21%) started the smoking cessation pharmacotherapy: four participants (12%) were started on Chantix, and three participants (9%) were started on Bupropion. No participants were started on a Nicotine Patch. One participant developed side effects with Chantix, and this participant later changed their medication to Bupropion. Among the seven patients who started on the medication at 1-month follow-up, four patients (22%) were continuously on smoking cessation pharmacotherapy (2 = Chantix, 1 = Bupropion, and 1 = Combined Chantix + Bupropion); two patients dropped out due to having insurance and not qualifying to receive care at the Free Clinic, and one patient did not show up at their 3-month follow-up appointment. No participants were started on a Nicotine Patch during the 3-month follow-up visits.

Smoking cessation success rate. As related to the participants' success rate of quitting smoking, only one participant successfully quit smoking by 3-month follow-up visit in this study; this was calculated as 5% (1 out of 18). Due to the small sample size and the significant attrition rate (43.8%), this result is limited to conclude the effects of a successful smoking cessation rate.

Chronic Disease Health Outcome

Clinical outcomes, including vital signs and laboratory data, were also examined by looking through the participants' EMR.

Vitals. Vitals (i.e., weight, systolic blood pressure, diastolic blood pressure, temperature, heart rate, respiratory rate, and O_2 saturation) were examined during the participants' initial visit

and 3-month follow-up visits to evaluate the effects of smoking cessation. There were no statistically significant results noticed when comparing the initial visit to the 3-month visit for most vitals reviewed (*p*-value > 0.05), except for the O_2 saturation (*p*-value 0.0363). In this study, the average O_2 saturation during the initial visit was 97.4, and during the 3-month visit, the average O_2 saturation decreased to 96.6. Although the change of O_2 saturation was minimal, the decrease was statistically significant (see Table 4).

Laboratory. Laboratory data were also examined during the initial and 3-month follow-up visits. Hgb A1c, total cholesterol, triglyceride, LDL, and HDL were evaluated to determine whether smoking cessation impacted the participants' chronic disease health outcomes. When comparing the initial visit data to the 3-month follow-up data, there were no statistically significant results (see Table 4).

Table 4

Impact of Smoking Cessation on Chronic Disease

		Initial visit	3-month	Pair-T test *p*-value
Vitals	Weight	217 +/-63.44	223 +/-60.0	0.9934
	Systolic BP	130.4 +/-19.5	128.1 +/- 15.4	0.9101
	Diastolic BP	84.0 +/- 14.9	80.7 +/-7.9	0.3518
	Temperature	97.7 +/- 0.58	97.3 +/- 0.5	0.3917
	Heart Rate	84.5 +/- 15.3	85.3 +/- 14.3	0.8763
	Respiratory Rate	18.4 +/- 1.3	18.3 +/- 0.8	0.8572
	O_2 Sat	97.4 +/- 1.0	96.6 +/- 1.2	0.0363*
Blood Lab's	Hgb A1c	6.6 +/- 1.9	6.37 +/- 1.6	0.7291
	Total Cholesterol	185.6 +/- 41.8	186.6 +/- 45.1	0.9221
	Triglyceride	215.5 +/- 155.9	231.0 +/- 184.8	0.7255
	LDL	100.5 +/- 32.3	100.6 +/- 28.5	0.8506
	HDL	45.6 +/- 13.6	44.8 +/- 15.2	0.8323

Note. BP = blood pressure; O_2 Sat = oxygen saturation; Lab's = laboratory; Hgb A1c = hemoglobin A1c; LDL = low-density lipoprotein; HDL = high-density lipoprotein

Quality of life or health perception. Participants were asked how they perceived their quality of life (QOL) as a cigarette smoker living with chronic disease. The first question asked if they noticed an overall improvement in their QOL since cutting back on the number of cigarettes smoked. These questions were only asked at 1-month follow-up and 3-month follow-up visits. At the one-month follow-up visit, 44% of participants reported "yes," and 56% reported "no." At the 3-month follow-up visit, 67% reported "yes," and 33% reported "no." As a result, an increase in the number of patients who perceived their quality of life improved. It was 44% at the 1-month follow-up to 67% at the 3-month follow-up visit. However, this was not statistically significant to the participants' reported QOL, *p*-value 0.799 (see Table 5).

Another health perception question asked the participants to rate the following statement: "My chronic disease interferes with my life." This question was also only asked during the 1-month and 3-month follow-up visits. The responses were given a number ranging from 0 to 4. A higher number represented a more significant interference of chronic disease to their daily life. Minimal differences were noticed between 1-month (2.59 ± 1.19) and 3-month (2.61± 1.09) responses, but no significance was observed with a *p*-value of 0.4800 (see Table 5).

Table 5

Perceived Quality of Life

Post Survey	1-month (N = 32)	3-month (N = 18)	*p*-value
Overall Health QOL-Improvement	Yes: 14 (44%) No: 18 (56%)	Yes: 12 (67%) No: 6 (33%)	0.799
Interference of Chronic Disease on Daily Life (0-4) *	2.59 ± 1.19	2.61± 1.09	0.4800

Note. Level of Interference of Chronic Disease on Daily Life (scored 0-4) * A higher score represents a greater Interference.

Chapter V. Discussion

Smoking cessation is challenging because the nicotine itself has addictive characteristics. The annual quit success rates in the United States were reported as low as 7% (Truth Initiative, 2018). According to a 2015 national survey, about 70% of current adult smokers in the United States wanted to quit, and half of the current adult smokers had attempted to quit smoking in the past year. However, only 7% successfully quit for 6-12 months (Babb et al., 2017; FDA, 2020).

Factors Affecting Readiness to Quit Smoking

Several studies discussed the factors that affect readiness to quit smoking. While there are several different reasons for why someone may not be ready to quit smoking, they may have thought about quitting, are thinking about quitting, or are actively quitting. As part of a community-based smoking cessation program called "Quit and Win Contest," Rayens et al. (2008) did a cross-sectional study and measured the readiness to quit smoking among 333 current and recent smokers in a rural community in Kentucky and evaluated the psychosocial and demographic factors that affect readiness to quit smoking; these factors included (a) partner support for quit smoking, (b) stressful life events, (c) depressive symptoms, and (d) demographic characteristics. In this study, readiness to quit smoking was classified into four levels based on the five stages of change and the transtheoretical model of change, including pre-contemplation, contemplation, preparation, action, and maintenance. They observed that a significant predictor for readiness to change was having positive partner support for quitting smoking ($p = .002$) (Rayens et al., 2008).

Several studies were done in the rural communities and have shown that SES does not make a specific difference in the readiness to quit smoking (Clare et al., 2014; Edwards et al., 2007; Kotz & West, 2009). In a cross-sectional study with a population living in a disadvantaged

area, Edwards et al. (2007) observed that around 40-50% of participants were ready to quit smoking, especially in middle-aged adults. Also, the readiness to quit smoking and awareness of cessation services was similar between individuals with low and high SES. However, smokers of lower SES reported that they received less advice to quit smoking from health professionals, family, and friends, and showed lower rates of quit smoking, especially among people aged 25-44 years, compared with older adults aged 65-74 years.

Similarly, Cox et al. (2008) reported baseline characteristics, including the readiness to quit smoking among 750 adults in 50 rural primary care clinics in the state of Kansas, as part of their clinical trial to evaluate a disease management program for smoking cessation. They addressed nicotine dependence as a chronic disease within their study's existing primary care system and provided interventions of combined pharmacotherapy, telephone counseling, and physician feedback repeatedly over 2 years through a program called "KAN-QUIT." In their study, the population's readiness in the rural clinics was high as 91% of the smokers were highly motivated and confident to quit smoking. Using the five stages of change, 61% showed contemplation phase and 30% in the preparation phase to quit smoking. Only 9% showed reluctance to quit smoking.

Our study showed that our population was reluctant to quit smoking with a higher rate of lack of readiness (86%), compared with the previous studies (9-50%). It could be that most of our participants were Caucasian (91%). Rayens et al. (2008), in their study with rural people in Kentucky, reported that minority smokers were more likely ready to quit smoking compared to Caucasians (p = .04). Despite the high baseline reluctance to quit smoking, our study observed that readiness to quit smoking is correlated to nicotine dependence and can be improved with smoking cessation education. Assessment of readiness to quit smoking, smoking cessation

education by providers to support patients to quit smoking, and connecting patients with supporting groups would be critical to improve their readiness and quit smoking successfully.

Effects of Intervention: Readiness, Nicotine Dependence & Smoking Cessation Rate

Readiness to quit smoking. Readiness to quit smoking plays an essential factor in the treatment of nicotine dependence. In a urology office, Bjurlin et al. (2013) provided a 5-minute brief smoking cessation intervention with and without nicotine replacement therapy (NRT) to reduce the complication of smoking. They measured the number of attempts to quit and the abstinence at 1 year as the outcomes. They also measured the readiness score at baseline using Fagerström. They observed that the readiness to quit smoking was significantly correlated to increase quit-smoking rates and the number of attempts to quit smoking. Intervention group (12.2% in brief session without NRT group, OR = 9.91; 19.5% in a brief session with NRT group; OR = 4.44) were more likely to have 1-year abstinence than the usual group (2.6%). Patients who received the brief smoking cessation intervention were significantly more likely to attempt to quit (OR 2.31, $p = 0.038$; Bjurlin et al., 2013).

Nicotine dependence/smoking cessation rate. Several studies have shown that both pharmacotherapy and counseling are effective for successful smoking cessation (Babb et al., 2017; Baker et al., 2016; Cinciripini et al., 2018; Petty, n.d.; Stapleton et al., 2013), with combined therapy as the most effective (Carpenter et al., 2004; Chan et al., 2011; Cincirpini et al., 2018; Rose & Behm, 2016). The success rates of quitting smoking after 1 year with pharmacotherapy usage have improved as high as 15 to 27%, which is twice or three times higher than for smokers using non-pharmacotherapy (Baker et al., 2016; Cinciripini et al., 2018; Petty, n.d.; Stapleton et al., 2013).

Carpenter et al. (2004) conducted a randomized controlled trial to evaluate and compare the effectiveness of different smoking cessation therapy to provide a successful reduction in smoking at 6-month follow-up for smokers who are reluctant to quit. Carpenter et al. (2004) found that a 24-hour quit attempt over 6 months was measured in three groups (NRT + reduction counseling + brief advice vs. Motivational advice + brief advice vs. No treatment). Attempts to quit smoking were higher in individuals who received motivational advice (51%) than individuals in the reduction counseling group (43%), compared with individuals without treatment (16%) ($p < 0.01$). Furthermore, 7-day absence of smoking cessation was 23% in the motivational advisement group, 18% in the NRT + reduction counseling group, and 4% in the no-treatment group ($p < 0.01$) (Carpenter et al., 2004). Similarly, in a population-based analysis of a 1996 California Tobacco survey, Zhu et al. (2000) also measured the abstinence rate from smoking over the past year. They observed that the abstinence rate was higher among individuals with NRT (15.2%) than individuals without smoking cessation pharmacotherapy (7.0%).

Zhu et al. (2000) conducted the cross-sectional study from the population-based survey data. They reported that one-fifth or 19% of their 4,480 study participants who attempted to quit smoking used one or more forms of assistance of self-help materials, counseling, and/or NRT. They compared the smoking cessation success rates in five different groups, including (a) no smoking group, (b) self-help materials, (c) counseling, (d) NRT, and/or (e) combined therapy of NRT and counseling. The study showed that smoking cessation rates over 1 year were more significant in all individuals who used assistance than the no assistance group. However, within the four groups who sought assistance, no significant variation of smoking cessation rates was found (i.e., self-help 20.0%, counseling 21.5%, NRT 30.3%, and counseling + NRT 23.7%; $p > 0.05$).

Our study tested the hypothesis of whether intense individual smoking cessation education and provision of pharmacotherapy use through MAP program can make a difference in smoking cessation success rates from a traditional smoking cessation therapy within 3 months among smokers who have chronic health diseases in a rural Free Clinic. Significant attrition (n = 14, 43.8%) occurred during 3-month follow-up periods. Those patients either obtained their insurance through Medicare, Medicaid, or other private insurance (n = 8), making those patients not qualified to receive their care at the Free Clinic, or did not show up at the 3-month follow-up visit (n = 6). Ultimately, only one participant (5%) successfully quit smoking within 3 months after receiving structured and moderately intense individual smoking cessation education, making it unable to test the null hypothesis due to the small sample size. However, our study observed that the intervention was significantly effective in reducing nicotine dependence and reduce the number of cigarettes smoked even within 3 months. Nicotine dependence measured by the Fagerström questionnaire was reduced at the 3-month follow-up (2.27± 1.90), compared to baseline (3.09 ±1.44, $p = 0.0001$). The percentage of heavy smokers was also significantly reduced from 63% at baseline to 38% at 1-month follow-up and 45% at 3-month follow-up, respectively ($p < 0.01$).

Lastly, Chan et al. (2011) compared smoking reduction rates after 6 months in two intervention groups NRT + counseling + adherence intervention vs. NRT + counseling without adherence) and observed that tobacco reduction rates were higher in the group that received counseling with NRT with adherence (50.9%) than the group that received NRT and counseling without adherence interventions (25.7%). These findings of Chan et al.'s (2011) study stressed the importance of reinforcement intervention to improve medication adherence and improve smoking cessation and the sustainability of quit smoking over a more extended period. In our

study, two smoking education sessions were provided at the initial visit. A 1-month follow-up visit and reinforcement follow-up phone calls were made at 2 weeks after the initial visit. No attrition was observed between the initial visit and 1-month follow-up. All attritions occurred between 1-month and 3-month follow-up visits. Close follow-up with reinforcement phone calls every 2 to 3 weeks may help minimize the attrition, increase the quit-smoking success rates, and reduce the relapse by assisting the maintenance of abstinence.

Measurement of Nicotine Dependence: CAGE Score versus Fagerström Score

The two main tools used to measure nicotine dependence in this study were Fagerström and CAGE questionnaires. Nicotine dependence has shown improvement at 1-month and 3-month follow-ups compared with baselines, using both Fagerström and CAGE questionnaires. However, statistical significance in reducing nicotine dependence was observed when measuring nicotine dependence with the Fagerström questionnaire.

The Fagerström questionnaire for nicotine dependence is the most common test for assessing nicotine dependence in clinical settings (Fagerström et al., 2012). Differently, the CAGE tool was initially used as a screening tool for alcohol dependence. Still, this questionnaire has often been modified and used to screen patients for different addictive disorders, including cigarette smoking (Rustin, 2000). Our study could be the first study to report the comparison findings of two tools to measure their effectiveness to monitor the effective intervention on nicotine dependence. The possible explanation for why the CAGE questionnaire demonstrated no significance in our study could be because the CAGE tool was modified and not an original tool to assess nicotine dependence. Our study suggested that the Fagerström questionnaire demonstrated greater sensitivity and specificity over the CAGE tool for identifying nicotine

dependence and monitoring the improvement in nicotine dependence with smoking cessation therapy.

Pharmacotherapy Use

Our study participants received the two individual moderately structured smoking cessation education sessions and one reinforcement follow-up phone-call at 2 weeks after the initial education session. Also, they chose to choose the pharmacotherapy as free, supported by the medication assistant program (MAP), based on the patient-provider shared decision, which was the traditional practice in this Free Clinic. Thus, our study evaluated how the education session and MAP program affect the participation of pharmacotherapy. Out of 32 patients, only seven patients chose to participate in pharmacotherapy use (4 = Chantix, 3 = Bupropion) (n = 7, 22%). Similarly, 22% (n = 4) were also taking smoking cessation medication at a 3-month follow-up visit. All patients who started pharmacotherapy at 1 month continued their pharmacotherapy at 3 months except two persons who dropped out due to having insurance and one person who did not show up to their 3-month follow-up.

Our study observed that heavy nicotine dependency (N.D.) smokers are less likely to feel ready to quit smoking (20%) than light N.D. smokers (25%) at the baseline and are more likely to choose to get the smoking cessation pharmacotherapy assistance (50% in heavy N.D. smokers vs. 16.7% in light N.D. smokers) to quit smoking, based on the medication use data at a 1-month follow-up. However, in both heavy and light N.D. smokers, smoking cessation intervention in our study showed effectiveness to improve the readiness to quit smoking (from 20% to 90% in light N.D. smokers and 25% to 75% in heavy N.D. smokers) and reduce nicotine dependence (reduction of the number of individuals with heavy/moderate nicotine dependence from 63% to 45%) over 3 months, compared with the baseline. This finding is similar to the previous studies.

Shiffman et al. (2008) reported that heavy smokers and individuals having more nicotine dependence are more likely to choose pharmacotherapy treatment. In another study, mail surveys of 9,630 U.S. adult smokers from a national research panel compared smokers who had not used NRT in a quit attempt (Shiffman et al., 2005). They found that NRT users were higher in heavier smokers, and they demonstrated greater nicotine dependence on the Fagerström test for N.D.

Chronic Disease Health Outcome

Effective smoking cessation is known to decrease the progression and adverse treatment outcomes for various chronic diseases. Previous studies support smoking cessation and its health benefits to improve total cholesterol, LDL, HDL, lipids, Hgb A1c, and hypertension (Clair et al., 2013). However, the improvements in chronic diseases can be observed later, several months after stop-smoking. Gritz et al. (2007) suggested that significant intervention effects on cessation are detected at 6 months to a year follow-up.

Cardiovascular effects. Several studies reported that smoking cessation is beneficial to reduce blood pressure, increase HDL, and produce better glucose control (Gapner et al., 2011; Yeh et al., 2010). Conversely, in a randomized controlled trial of 20 primary health care centers in Southern Sweden, 400 habitual smokers were recruited to investigate the effects of serum lipids, plasma fibrinogen, plasma insulin, plasma c-peptide, and blood glucose in smokers who had quit after 4 months (Nilsson et al., 1996). There were two groups, the intervention group of 98 subjects and the control group of 156 subjects. As Nilsson et al. (1996) reported, 48% of the subjects in the intervention group had quit smoking, and 91% of the control subjects were still daily smokers during the study period. In the intervention group, weight increased by 2.7 kg, and HDL cholesterol level had increased by 11% ($p < 0.001$). Also, Hgb A1c had risen by 2% in the

control group ($p < 0.05$). Overall, Nilsson et al. (1996) reported that smoking cessation was associated with increased HDL but did not affect glucose tolerance.

In comparison, our study did not find specific changes in total cholesterol, LDL, HDL, lipids, Hgb A1c, and hypertension measured at 3-month follow-up visits, compared with baseline. This reason could be due to our study being carried out over 3 months. A 3-month follow-up is not sufficient to see any clinical changes after 30 days of smoking cessation. Additionally, it could be because participants in our study only cut back on the number of cigarettes smoked or decreased in their nicotine dependence rather than altogether quitting smoking.

Lung effects. According to UPMC (University of Pittsburgh Medical Center, Western Maryland, 2018), not smoking half a day helps to eliminate the body of carbon monoxide present in cigarettes, which accumulates in the body over time; this then helps with increasing the oxygen levels in your body. As the lungs healing process occurs from the damage of nicotine, lung functioning begins to improve after 30 days without smoking. Patients will notice the improvement in shortness of breath and cough as well as improvement in tolerating activities (UPMC Western Maryland, 2018, para. 2).

Willemse et al. (2004) reviewed several longitudinal and cross-sectional studies and found that lung function (FEV1) and respiratory symptoms such as cough, phlegm, and wheeze have been shown to improve after smoking cessation. However, the reversibility of smoke-induced changes differs between smokers with and without chronic diseases such as COPD or chronic bronchitis; lung function improvement after quitting smoking is minimal in patients who already have an underlying lung disease. Willemse and his colleagues (2004) suggested that although structural changes in COPD patients do not reverse after smoking cessation, FEV1

decline can be slowed after quit smoking. This could partly be due to reduced inflammation in patients with chronic respiratory diseases (Willemse et al., 2004). Our study did not measure the FEV1 or other lung function indicators. Instead, O2 saturation was measured at baseline and 3-month follow-up. The O2 saturation was reduced from 97.4% at baseline to 96.6% at 3-month follow-up with a statistical significance of p value < 0.05. However, clinical significance of the difference of 0.8% reduction of O2 saturation is unremarkable. The percentage of patients who have COPD was 16%. The baseline O2 saturation was higher in non-COPD patients (97.5%) than COPD patients (96.7%), which was similar at 3-month follow-up (96.6% in non-COPD patients vs. 96.3% in COPD patients). In both groups, the O2 saturation was reduced after 3-month follow-up visits, which was the opposite direction than our expectation. Among the patients (n = 18) who completed a 3-month follow-up, O2 saturation was reduced from 96.7% to 96.3% in COPD patients (n = 2) and from 97.5% to 96.6% in non-COPD patients (n = 16). This insignificant finding could be because the follow-up periods in our study were not adequate for patients to measure the actual effect of smoking cessation on lung function changes or because O2 saturation may be less sensitive than FEV1 function to measure effects of smoking cessation on lung function. Further study is needed with more extended follow-up periods.

Weight gain. Concern about weight gain has been a common barrier to quitting smoking or a reason for relapse. Germeroth and Levine (2018) found post-smoking cessation weight gain concerns are associated with cessation difficulty, quit-date delay, and reduced smoking frequency. However, the evidence on the weight gain related to smoking cessation is mixed. In a prospective community-based cohort study using the Framingham Offspring Study collected from 1984 through 2011, Clair et al. (2013) assessed the smoking status and evaluated weight changes, blood glucose level control, along with cardiovascular disease complications every 4

years before and after smoking cessation. Clair et al. (2013) reported that the median 4-year weight gain was more significant for recent quitters than long-term quitters (0.0-0.9 kg vs. 2.7-3.4 kg). The weight gain phenomenon for recent quitters was more critical in patients with diabetes than without diabetes (3.6 kg in the D.M. group vs. 2.7 kg in the non-DM group, $P < .001$). Our study found that weight gain occurs during the first 3 months of smoking cessation although statistical significance was found ($p = 0.993$). These results are consistent with Clair et al.'s (2013) report that weight gain is more prominent in recent quitters than in long-term abstinent patients. A long-term study is required to see if the weight gain observed is resolved over time. And, further study is needed to measure whether diabetes poses a higher risk for weight gain during the early phase of quit-smoking. In contrast, Filozof et al. (2004) observed that lower socioeconomic status and heavier smoking are predictors of higher weight gain and that weight gain from smoking cessation can be likely caused by genetic factors.

Concerns or fear of smoking cessation weight gain were also often reported by the participants in our study. However, a weight increase observed at 3-month follow-up (223 ± 60.0) was minimal, compared with baseline (217 ± 63.44). No specific statistical significance was observed in weight gain before and after the smoking cessation therapy ($p > 0.05$). Previous study (Clair et al., 2013) showed that weight gain is more prominent in recent quitters. Thus, our finding of weight gain within 3-month follow-up could support the previous findings. Smoking results from a behavioral health concern to relieve anxiety with smoking and a habit to put something into their mouth to replace smoking. Recent quitters have reported that they seek more food or candy as a replacement for cigarettes. Weight gain after smoking cessation could be related to those smokers seeking to satisfy their craving, relieve their anxiety, and try avoiding relapses. Education on withdrawal symptoms, diet, exercising, and anxiety experienced while

quitting smoking should be incorporated into the patient's smoking cessation plan and chronic disease management.

Challenges and Limitations

The great challenge of our study was the attrition rate that occurred. A percentage of 43.8% of our participants dropped out of the study before reaching 3-month follow-up visits. Primary reasons for this attrition were a combination of the participants' obtaining health insurance (n = 8; 57.1%), which disqualifies them from receiving care at the Free Clinic or simply not showing up to their scheduled appointments (n = 6; 42.8%). Patients who are seen at the Free Clinic must be uninsured; otherwise, they cannot be seen at the Free Clinic. This study's significant attrition rate resulted in a small sample size, which limited the generalization of the study findings. Findings were inconclusive to appropriately measure whether the smoking cessation therapy was effective to successfully quit smoking and improve chronic disease health outcomes within a 3-month follow-up period.

Free Clinics are the last available health care net for people who have low income and are uninsured. These patients are likely to seek care only when they are sick, not for annual physical exams or regular check-ups for chronic disease management. They could be more likely to be challenged to comply with follow-up visits and or medication adherence due to financial burdens (Kotz & West, 2009; Van Wijk et al., 2019; Vidrine, 2009; Ward, 2004). Several similar challenges were experienced in our study throughout the 3-month follow-up periods. A significant percentage (86%) of smokers expressed a lack of interest to quit smoking at baseline, and some participants continued to smoke while taking medications to treat their chronic health diseases. Other challenges in this study included the participants' noncompliance with medication adherence. Some participants did not take their prescribed smoking cessation

medication correctly or continued to smoke while taking medication for chronic disease management.

Efforts to provide smoking cessation education and medication assistance availability and affordability to the underserved population are critical. Considering the characteristics of these populations, it is recommended to consider incorporating adherence intervention every 2 to 4 weeks along with smoking cessation therapy to improve the compliance of follow-up visits and medication compliance. Also, considering the possible high attrition rates in free clinics, future studies with a more extended follow-up period and larger sample size are recommended to measure the short-term and long-term effect of the combined smoking cessation therapy on quit smoking rates and improve chronic disease outcomes.

Clinical Implication

Our study showed that smoking cessation intervention effectively decreased the number of cigarettes smoked and reduced nicotine dependence within the 3 months of therapy. The results in this study also support that smoking cessation education, counseling, and pharmacotherapy can be a positive reinforcement both for patients wanting to quit smoking and for patients who are reluctant to quit smoking by providing the available resources, supporting the shared-decision process, and providing a partnership to support the smoking cessation process from the set-up of quit smoking date, withdrawal management, to relapse prevention. Simply asking and advising a patient to quit smoking using the 5As approach and screening of readiness can help a patient make progress towards successfully quitting smoking. The 5Rs approach can assist those patients who are reluctant to quit smoking. This study supports smoking cessation education with and without pharmacotherapy and can help patients improve their readiness to quit smoking and decrease their nicotine dependence.

Conclusion

Smoking has been a significant attributor to poor outcomes of chronic health disease management. Significantly, studies have shown that low-income, medically underserved populations are less likely to receive advice from professionals and use smoking cessation resources. However, they wish to quit smoking like the high-income population, resulting in significantly low rates to quit smoking successfully. This study showed that the proposed intervention of combined therapy of smoking cessation education and pharmacotherapy use through medication assistant program is feasible in the free clinic settings and effective to improve the readiness to quit smoking and reduce nicotine dependence even within 3 months. However, our study was inconclusive to measure the effect of successful quit smoking rates due to the small sample size. Also, our study may be the first study to report that the Fagerström questionnaire tool for nicotine dependence was more sensitive to measure and monitor patients' nicotine dependence changes over time. Free clinics can play a critical role in accessing these populations and improving smoking cessation and chronic disease outcomes. Incorporating smoking cessation therapy while managing patients' chronic diseases is essential to improve overall health outcomes. Using the 5As and 5Rs approach can be an excellent treatment plan for smokers to assess and promote readiness to quit smoking and empower patients to quit smoking. Health care providers should incorporate close and frequent follow-up visits to avoid relapse while providing smoking cessation education and medication therapy.

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Appendix A. Interventions, Study Variable & Data Collection Schedule

	Initial Visit -Baseline (Clinic Visit)	**Initial Visit-Post Education (Clinic Visit)**	**Week 2 F/U (Clinic Visit, Updox Videoconferencing, Phone Call)**	**1 Month F/U (Clinic Visit, Updox Videoconferencing, Phone Call)**	**3 Month F/U (Clinic Visit)**
INTERVENTIONS					
Education Session	X (with pamphlet)		X	X (with pamphlet)	X (with pamphlet)
Counseling	X		X	X	X
Medication Treatment-Evaluation & Compliance	start/plan start date based on medication preference		X	X	X
OUTCOME MEASURES					
Survey	**Baseline**	**Post Education**		**1-month**	**3-months**
Demographic Data	X				
Chronic Disease-Data	X				
Education Tool-Effectiveness/Easiness		X		X	X
Smoking Status	X		X	X	X
Nicotine Dependence	X			X	X
Medication List- Used for Smoking Cessation	X			X	X
Smoking Cessation Medication-Side Effects	X		X	X	X
Smoking Cessation Medication-Compliance	X		X	X	X
Readiness to Quit Smoking	X	X		X	X
Smoking Cessation Success Rate	X			X	X
Chronic-Disease QOL	X			X	X
Clinical Data					
Vital Sign (SBP)	X				X
Vital Sign (DBP)	X				X
Temperature	X				X
Heart Rate	X				X
Respirations	X				X
Oxygen Saturation	X				X
Weight	X				X
Hg A1C	X				X
HDL, total	X				X
LDL	X				X
Total, Cholesterol	X				X
Triglyceride	X				X

Appendix B. Diagram of Health Belief Model for Behavioral Change

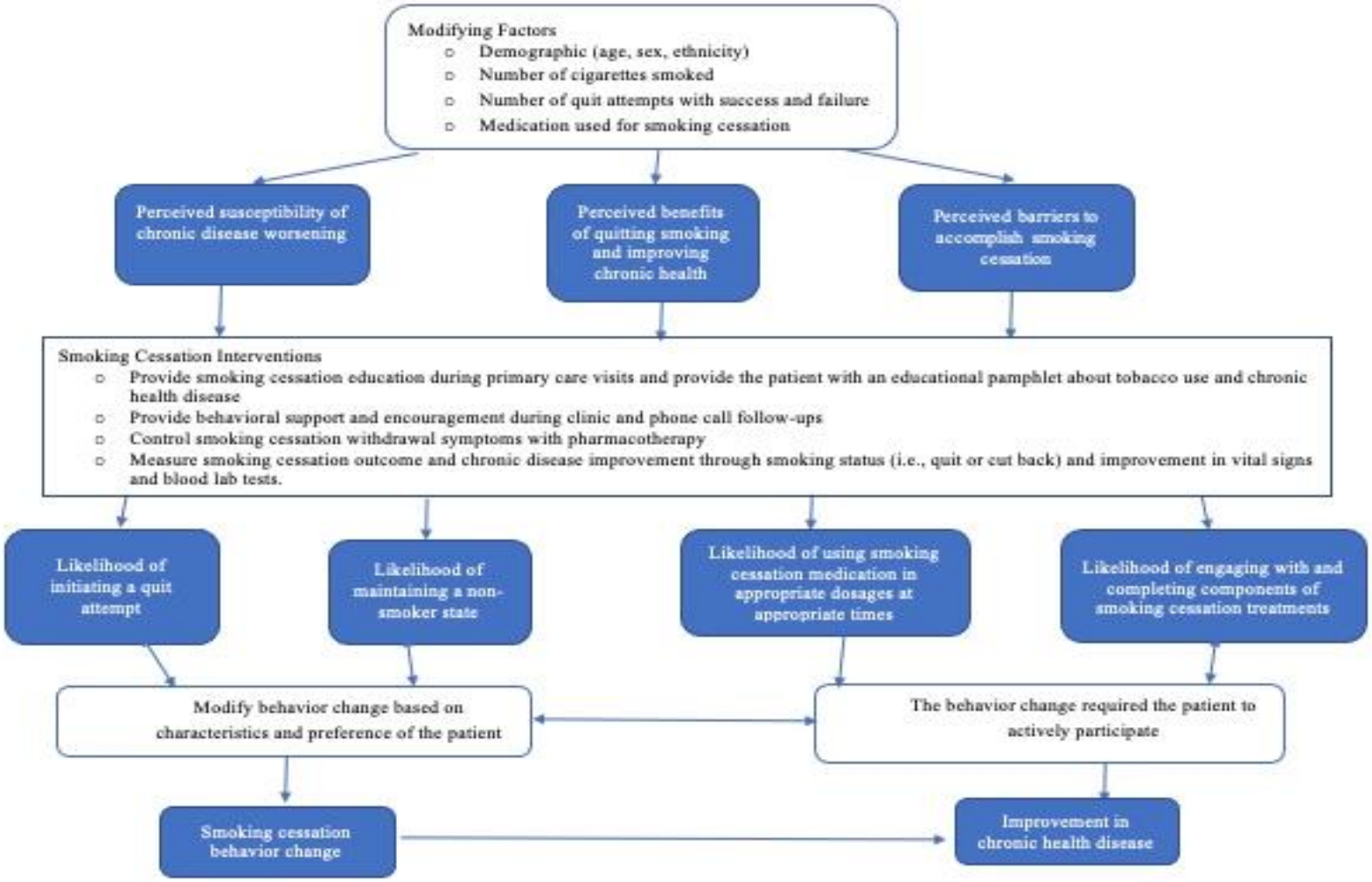


Diagram was modified from the study of Black, N., Williams, A. J., Javornik, N., Scott, C., Johnston, M., Eisma, M. C., Michie, S., Hartmann-Boyce, J., West, R., Viechtbauer, W., Bruin, M. de, & de Bruin, M. (2019).

Appendix C. Literature Review: The Impact of Smoking on Chronic Disease

Author & Year	Level/ Quality of Evidence	Study Design	Sample	Setting	Smoking Status	Chronic Health Disease	Intervention	Findings
Bowden et al., 2012.	Level II	RCT	*N* = 13,900; 18-81 years old.	Telephone Based Tobacco Cessation Program Across the U.S.	Smokers	Chronic Condition, Obese, Overweight, Depressed.	3-month, 6-month, and 12-month phone call follow-ups. The study used the behavior change theories to ask question based on the Health Belief Model, Transtheoretical Model of Change, and motivational interviewing techniques.	The presence of multiple chronic conditions negatively affects the likelihood that the participant will cease tobacco use at the three-month, six-month, and 12-month follow-up markers and was significant ($p < .05$).
Eliasson, 2003	Level I	Systematic Review	Population based study in diabetic men and women.	_____	Smokers, tobacco users.	Diabetes, neuropathy, macrovascular diabetes, retinopathy.	_____	There is a strong associations between tobacco use, the development of diabetes, glycemic control, and diabetic complications (micro- and macrovascular).
Kohata et al., 2016	Level II	Prospective Cohort Study	*N* = 191; 141 successfully quit smoking (success group), 50 did not quit smoking (failure group) at 1 year after treatment.	Osaka City University Hospital and Uehonmachi-Watanabe Clinic, Japan.	Cigarette smokers.	GERD	Patients treated with Varenicline (Chantix) were asked to fill out a self-report questionnaire about their smoking habits, gastrointestinal symptoms, and health related quality of life (HR-QOL) before and 1 year after smoking cessation. The prevalence of GERD, frequency of symptoms, and HR-QOL scores were compared. The associations between clinical factors and newly developed GERD were considered.	The number of patients that experienced improvement in GERD in the success group was significantly higher than in the failure group (43.9% in the success group versus 18.2% in the failure group, $p<0.05$). The BMI of the patients within the success group significantly increased from 22.5 ± 3.6 kg/m2 at baseline to 23.3 ± 3.5 kg/m2 ($p<0.01$) at 1 year after the treatment, while the BMI of patients within the failure group did not change (22.9 ± 3.4 kg/m2 at baseline versus 22.8 ± 3.4 kg/m2 at 1 year after therapy, $p = 0.62$). Smoking Cessation showed

								improvement in both GERD and HR-QOL.
Kondo et al., 2019	Level I	Systematic Review	Japanese smokers reviewed. For the year 2010 Japan smokers were 36.3% for men and 7.5% for women. For the year 2017 29.4% for men and 7.2% for women	Japan	Smokers using heat-not-burn tobacco (battery operated cigarettes that heats up to 350°C) and conventional cigarettes.	Diabetes Mellitus, HTN, CVD, HF, Venous thrombus embolism, Atrial fibrillation	_____	Current smoking increases hospitalization for HF. Smoking Promotes HTN and metabolic syndrome, which both increase the risk for CVD. Evidence indicates that even smoking just 1 cigarette daily and secondhand smoke increase the threat of CVD.
Maddatu et al., 2017	Level I	Systematic Review	Population based study.	_____	Smokers.	Diabetes mellitus-type 2. Insulin sensitivity and pancreatic β cell dysfunction.	_____	Epidemiologic studies demonstrate a clear association between cigarette smoking and an increased risk of T2D & clinical data suggest an effect of smoking and nicotine on body composition, insulin sensitivity, and pancreatic β cell function.
Manhapra et al., 2017	Level II	Observational study	N = 519, 918 diagnosed with tobacco use disorder; N = 2,691, 840 without a diagnosis of tobacco use disorder. Veterans receiving Veterans Health Administration (VHA) care nationally in fiscal year 2012 who were diagnosed.	Veterans' Health Administration (VHA)	Cigarette smokers.	MI, CHF, PVD, CVA, COPD, cancer, diabetes mellitus, hepatic disease, renal disease, and HIV.	National VHA administrative records in Fiscal Year (FY) 2012 were used to identify all veterans with a diagnosis of one of the well-known chronic medical illnesses known to be caused by cigarette smoking and/or whose outcomes were worsened by cigarette smoking.	In FY 2012 3,211,758 VHA service users were identified with one or more smoking-related chronic medical illnesses. Among them, 16.19% (519,918) had a diagnosis of tobacco use disorder and the rest did not have such a diagnosis (2,691,840).
Pascal et al., 2017	Level II	Observational Study	*N* = 60; 52 men, 8 women. Age > 40 with COPD smokers with a history of depression, anxiety, or panic attack. 38.3% were smokers and 61.7% were ex-smokers in the last 12 months).	Clinic of Pulmonary Diseases from Iași, Romania.	smokers and ex-smokers in the last 12 months. medium packs-years was 34.3 and the medium Fagerstrom score was 7.5.	COPD, Anxiety, depression, panic attack. Cardiovascular co-morbidity.	assess anxiety, depression and panic disorders among patients diagnosed with COPD and to investigate their correlation with disease severity, quality of life as well as tobacco use.	Mean distribution of anxiety and depression symptoms scores among COPD subjects were 10.65 ± 3.5 and 9.93 ± 3.8, respectively. Smokers and ex-smokers had similar scores. Dyspnea was evaluated through Modified Medical Research Council Dyspnea Scale (mMRC), anxiety and depression (assessed by HAD scale) were

								found to correlate significantly (r = 0. 54, p ≤ 0.001). mMRC scores obtained significant correlations with the score for anxiety (r = 0.71, p ≤ 0.001), score for depression (r = 0.34, p = 0.019), and panic events (r = 0.551, p ≤ 0.001). COPD Gold stages were correlated significantly with scores obtained for anxiety (r = 0.307, p = 0.001). In conclusion, the results of this study indicate that anxiety, depression and panic attacks were constant characteristics among COPD patients- regardless of their current tobacco use.
Sari et al., 2018	Level II	Cross-Sectional Study	*N* = 60; 30 diabetic smoking patients and 30 non-smoking diabetic patients. Age 50-60-year-old with a diagnosis of diabetes for the past 5 to 10 years.	Endocrine Clinic University of Sumatera Utara Hospital, Indonesia.	Cigarette smokers.	Diabetes.	Questionnaire based interview. Patients fasting blood glucose, postprandial blood glucose, Hgb A1c levels were all measured by a diagnostic analyzer.	There was a significant difference in postprandial glucose level between smokers' group and non-smokers group ($p < 0.05$). Overall, compared to the non-smoking diabetics group, in the smoking diabetic group fasting blood glucose, postprandial blood glucose, and Hgb A1c were higher by $p = 0.325$, $p = 0.016$, and $p = 0.412$.

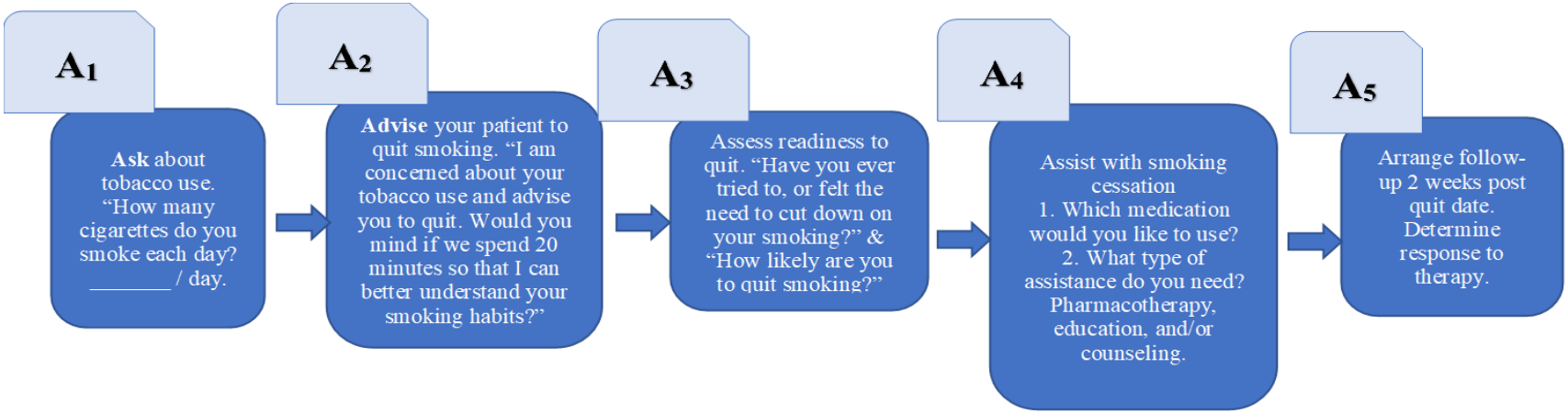
Appendix D. Literature Review: Measuring Biochemical Markers for Smoking Cessation and Improvement in Chronic Disease

Author & Year	Level/ Quality of Evidence	Study Design	Sample	Setting	Smoking Status	Chronic Health Disease Mechanism	Biochemical Marker/Variables	Outcome
Abel et al., 2005	Level II	RCT in a large cohort study.	***N*** **=** 784; *N* = 214 received Bupropion SR & *N* = 215 received placebo	Palo Alto, California; Rochester, Minnesota; Boston, Massachusetts; Providence, Rhode Island; and Portland, Oregon.	Healthy Smokers; Smoked at least 15 cigarettes/day	Compared with nonsmoker, smokers have higher levels of cholesterol, increased platelet reactivity, and elevated levels of inflammatory markers such as C-reactive protein and fibrinogen. Inflammation may be an important mechanism by which smoking leads to cardiovascular disease. There is an association between smoking and an increase in WBC's and ANC's.	ANC WBC	There is a positive relationship between cigarette smoking and both WBC count and ANC in a large cohort of healthy smokers. At 52 weeks, continuously abstinent subjects, compared with continuing smokers, had a greater decline from baseline in WBC count (1.2±1.9 X 10^9/L vs 0.1±1.9 X 10^9/L; *P* < .001) and ANC (1.0±1.6 X 10^9/L vs 0.2±1.5 X 10^9/L; *P* < .001).
Colak et al., 2015	Level II	Prospective Cohort Study	*N* = 94,079; N = 5,691 reported asthma and *N* = 2,304 never smokers, *N* = 2,467 former smokers, and *N* = 920 current smokers. Age 20-100	Copenhagen General Population.	Never, former, and current cigarette smoker.	Asthma and COPD is associated with complications, cardiovascular comorbidities, and higher mortality in some individuals.	Blood pressure HDL, LDL, non-fasting blood glucose, BMI. FEV1/FVC, c-reactive protein, fibrinogen, leukocytes, neutrophils, eosinophils, immunoglobulin E.	Compared with never-smokers without asthma, individuals with asthma hada higher prevalence of respiratory symptoms and airflow limitation, which was most pronounced among smokers

Gepner et al., 2011	Level II	RTC, prospective, double-blind, randomized, placebo-controlled trial.	*N* = 1,504 current smokers; mead age N = 45.4 N = 923 subjects who returned at 1 yr visit;	Madison and Milwaukee, Wisconsin communities	21.4 cigarettes/day.	smokig is associated with a more atherogenic lipid profile characterized by higher total cholesterol and triglycerides with lower levels of high-density lipoprotein cholestrol (HDL-C).	LDL, VLDL, HDL, cholesterol, triglycerides, BMI, serum glucose, hsCRP. Hgb A1.	Despite gaining more weight (4.6 kg [5.7] vs. 0.7 kg [5.1], p<0.001], abstainers had increases in high-density lipoprotein cholesterol (HDL-C) (2.4 [8.3] vs. 0.1 [8.8] mg/dL, p < 0.001], total HDL (1.0 [4.6] vs. −0.3 mcmol/L [5.0], p<0.001) and large HDL (0.6 [2.2] vs. 0.1 [2.1] mcmol/L, p=0.003) particles, compared with continuing smokers. Significant changes in low-density lipoprotein (LDL) cholesterol and particles were not observed. After adjustment, abstinence from smoking (p<0.001).
Yeh et al., 2010	Level II	Prospective cohort study.	*N* = 10,892; middle-aged adults (45-64) who initially did not have diabetes in 1987 to 1989.	The Atherosclerosis Risk in Communities (ARIC) study.	Cigarette smokers	An extensive body of literature consistently identifies cigarette smoking as a risk factor for incident diabetes. Therefore, smoking cessation should decrease diabetes risk among current smokers, perhaps by reducing systemic inflammation, which is a well-established risk factor for incident diabetes	Fasting glucose, total triglyceride level, HDL, cholesterol, leukocyte counts. BMI	During 9 years of follow-up, 1,254 adults developed type 2 diabetes. A graded relationship existed between pack-years of smoking and incidence rates of type 2 diabetes.

Appendix E. Smoking Cessation Algorithm

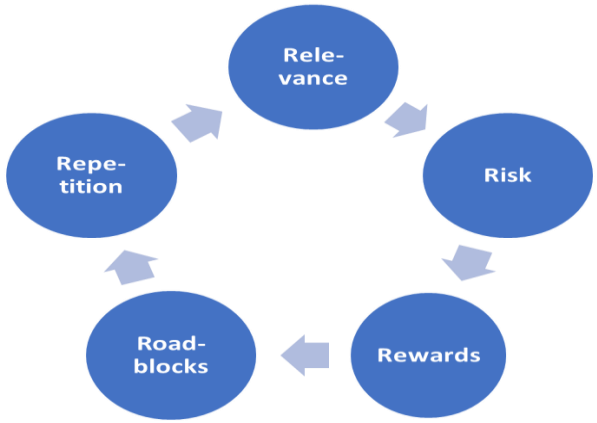
PHASE ONE: START WITH SMOKING SECCESSION EDUCATION AND RISK SCREENING.



MOTIVATIONAL INTERVIEWING

Explore the **5 R's** using reflective listening:

Relevance: Why is quitting relevant to health, family, social situation?
Rewards: Potential benefits of quitting- improving chronic health, money, taste & smell
Risk: Acute (shortness of breath), chronic (CVD, COPD, HTN, Hyperlipidemia, diabetes, asthma)
Roadblocks: Withdrawal symptoms, fear of failure, weight gain
Repetition: Repeat 5 R's every time the patient visits the clinic



PHASE TWO: CONSIDER STARTING PHARMACOTHERAPY AND CONTINUE WITH EDUCATION.

1. Pick a quit-date within two weeks
2. Add Smoking Cessation Medication (See the below first-line pharmacotherapy medication)
   : Please tailor the selection of medication based on individual patient's needs and preferences.
   a. NRT vs. Chantix vs. Bupropion
      i. NRT:
         - 10 + CPD: Add a 21mg patch to current dose
         - 6-9 CPD: Add a 14mg patch to current dose
         - 1-5 CPD: Add a 7mg patch to current dose
         - Maximum is 84mg (4 X21mg)
      ii. Chantix:
         - 0.5mg once daily for 3 days, then
         - 0.5mg twice daily for 4 days, then
         - 1mg twice daily for the remainder of 12-week course
         - Titrate up to minimize GI effects
         - Quit smoking 1 week after starting Chantix
      iii. Bupropion:
         - 150 mg daily for 3 days, then
         - 150mg twice daily thereafter
         - Recommend treating for at least 12 weeks
         - Start 1 week before target quit date

First Line Pharmacotherapy.

	Chantix	Nicotine Replacement Therapy (NRT)	Bupropion
Advantages	Most effective - highest quit rates. No drug interactions except with NRT (may increase risk of adverse events.)	Safe in stable cardiac disease. Patch is the most effective form of NRT.	Minimal weight gain, helps depression, can use with NRT, as effective as NRT.

Quit Date	7-14d (up to 35) after starting	Same day up to 4 weeks after starting	7-10d after starting
Caution	Risk of increased cardiac events in patients with heart disease; Steven-Johnson Syndrome; angioedema; erythema multiforme. Reduce dose in renal disease. Contraindications: pregnant women should avoid.	Inhaler: still has nicotine when finished - dispose properly Patch: OK if smokes, leave patch on and try to quit again	Seizures, mood changes, suicide, drug interactions. Contraindications: Seizure disorders, bulimia/anorexia (recent or remote),
Side Effects	Nausea, nightmares, insomnia	Patch: abnormal dreams/insomnia (remove before bed) All other forms of NRT- mouth irritation, dyspepsia	Dry mouth, constipation, agitation, insomnia, headache, tremor
Dose	Day 1 - 3: 0.5mg PO once daily Day 4 - 7: 0.5mg PO BID Day 8 - onwards: 1mg PO BID x 12 - 24 weeks	Patch: different doses tapered over 12 weeks Inhaler: cartridge=10mg nicotine+1mg menthol, PRN max12/d Gum: Nicorette® (2/4mg); Thrive® (1/2mg), max 20/d Spray: 1mg per spray, 1-2 sprays q30-60m, max 4 sprays/hr Lozenges: 2mg(<25 cig/day); 4mg(>25 cig/day), max20/d	150mg SR PO qam x 3d; then BID x 7-12 weeks

PHASE THREE: FOLLOW UP MONITORING FOR COMPLICANCE AND EFFECTIVENESS.

3. Follow-up in 1-4 week post quit date and assess smoking status
    a. If still smoking → reinforce with 5A's and 5R's education strategies: assess the barriers such as side effect and withdrawal symptoms, provide alternative options to overcome triggers and reasons for relapse
    b. If effective → continue the same medication and follow instructions
    c. If not effective → consider switching to another medication or adding another medication

Appendix F. CAGE Questionnaire for Smoking

CAGE Questionnaire for Smoking

. Have you ever tried to, or felt the need to cut down on your smoking?
. Do you ever get annoyed when people tell you to quit smoking?
. Do you ever feel guilty about smoking?
. Do you ever smoke within one-half hour of waking up (Eye-opener)?

---

*—*Two "yes" responses constitute a positive screening test*.

Adapted with permission from Lairson, D.R., Harrist, R., Martin D.W., Ramby, R, Rustin, T.A., & Swint, J.M, et al. (1992). Screening for patients with alcohol problems: severity of patients identified by the CAGE. *Journal of Drug Education*; 22:337-52. doi: 10.2190/H8QV-KAYU-QBYH-1LN3

Appendix G. Brief Fragerström Test for Nicotine Dependence

Brief Fagerström Test for Nicotine Dependence

Answer the two questions below. Check your total score against the scoring key.

1. How soon after waking do you smoke your first cigarette?
   - Less than five minutes (3 points)
   - 5 to 30 minutes (2 points)
   - 31 to 60 minutes (1 point)

2. How many cigarettes do you smoke each day?
   - More than 30 cigarettes (3 points)
   - 21 to 30 cigarettes (2 points)
   - 11 to 20 cigarettes (1 point)

SCORING KEY: 5 to 6 points = heavy nicotine dependence; 3 to 4 points = moderate nicotine dependence; 0 to 2 points = light nicotine dependence.

FIGURE 1.

Adapted with permission from Heatherton, T. F., Kozlowski, L. T., Frecker, R. C., & FAGERSTROM, K. O. (1991). The Fagerström test for nicotine dependence: a revision of the Fagerstrom Tolerance Questionnaire. *British journal of addiction*, *86*(9), 1119-1127. DOI: 10.1111/j.1360-0443.1991.tb01

Appendix H. Education Pamphlet

Medications	Administration[3]
Nicotine gum	One piece every hour Maximum: ≤ 24 pieces/day No food or drink for 30 minutes before and during use.
Nicotine inhaler	Inhale as needed (eg., every 1 to 2 hours) Maximum: 16 cartridges/day
Nicotine lozenge	One piece every 1 to 2 hours Maximum: 5 lozenges/6 hours 20 lozenges/day No food or drink for 30 minutes before and during use
Nicotine patch	Apply 1 new patch daily May start patch before quit date Rotate application site
Bupropion	150 mg/day for 3 days, then 150 mg twice a day Start 1 to 2 weeks before quit date
Chantix	0.5 mg/day for 3 days, then 0.5 mg twice a day for 4 days, then 1 mg twice a day Start 1 to 2 weeks before quit date May be started up to 4 weeks prior to quit date

1-800-QUIT-NOW (1-800-784-8669)

Quitline's can be used to speak to counselors who are trained to specifically help guide you to quit smoking. Information and support are available in both English & Spanish.

The quitSTART and QuitGuide apps are 24/7 smoke free apps that can help you quit smoking by providing tips, inspiration, and help with challenges.

SmokefreeTXT
Sign up by texting the word "QUIT" TO 47848 from your phone answer a few questions and you will start receiving messages (1 to 5 per day).

1.American Academy of Family Physicians. (2015). Quit Smoking Guide.
2.Godtfredsen, N. S., & Prescott, E. (2011). Benefits of smoking cessation with focus on cardiovascular and respiratory comorbidities. The Clinical Respiratory Journal, 5(4), 187-194. doi:10.1111/j.1752-699X.201100262.x
3. Rigotti, N. A. (2018). Uptodate: Pharmacotherapy for smoking cessation in adults. Retrieved from https://www-uptodate-com.lib-proxy.radford.edu/contents/pharmacotherapy-for-smoking-cessation-in-adults?search=overview%20of%20smoking%20cessation%20management%20in%20adults&source=search_result&selectedTitle=6~150&usage_type=default&display_rank=6.

Put It Out Before It Puts You Out

Noemi James, RN, BSN.
Radford University FNP Student.

Did you know smoking cigarettes affects your chronic health conditions?...
Smoking is the leading cause of preventable death and is the reason for many chronic health diseases. Studies have shown there is a connection between cigarette smoking and chronic health diseases (e.g. diabetes, hypertension, high cholesterol, asthma, chronic obstructive pulmonary disease, heart burn, stroke, heart attack)[1-2]. Within 6 months, health benefits tend to improve when you stop smoking [2]. You can see improvements in:

- **Cholesterol**
- **Blood Pressure**
- **Blood Sugar**
- **Breathing with Less Respiratory Exacerbations**

Whether you smoke cigarettes or use other nicotine products, following these 5 steps will put you on a path to better health.

Five key steps to quit smoking:

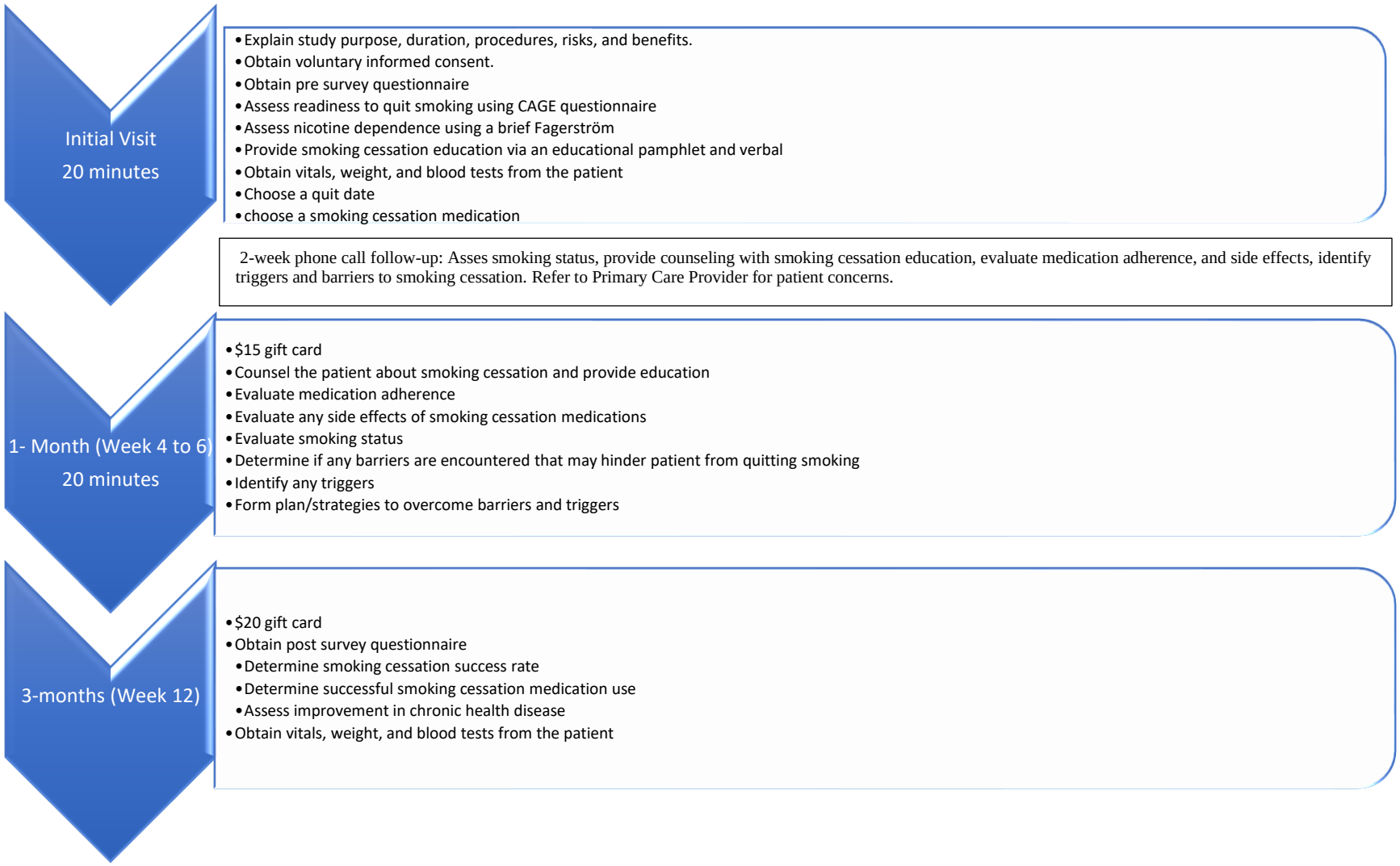
1. **Get ready**
2. **Get support and encouragement**
3. **Learn new skills and behaviors**
4. **Get medicine and use it correctly**
5. **Be prepared for relapse or difficult situations**

- **Get ready by getting rid of all cigarettes, ashtrays, and other objects that trigger your urges to smoke.**
- **Make a commitment to quit. Ideally, your quit date should be free of major stress. Pick a day within the next 2 weeks when you will have the least exposure to the things that trigger your urge to smoke.**
- **Ask for support from family & friends before you quit. Counseling and support from programs can be very helpful in successfully quitting.**
- **Change your routines to distract yourself from urges to smoke.**
- **Using nicotine replacement products or another medicine to treat your nicotine withdrawal symptoms doubles your chances of successfully quitting smoking.**

  -Most people who quit smoking gain some weight. Plan and eat a healthy diet that includes fresh fruits and vegetables. Avoid foods that are high in fat and sugar.
- **What if you slip?**

  -Admit you slipped. Immediately identify the trigger that caused the slip. Talk positively to yourself and promise yourself you won't slip again.

Appendix I. Intervention Timeline and Workflow Checklists For Smoking Cessation



Appendix J. Study Variables

<u>Demographic Data</u> ▪ Age, sex, ethnicity <u>Chronic Disease Comorbidity/Smoking History Data</u> • Presence of HTN, HPL, DM, obesity, CAD, COPD. • Prior use of smoking cessation (Long-acting NRT- NicoDerm patch, Chantix, Bupropion or others) <u>Smoking Cessation Medication-Related General Data</u> • Medication selected for smoking cessation therapy • Name of smoking cessation medication currently taking (Chantix, Bupropion, Nicotine patch, Nicotine inhaler, Nicotine Lozenge or Gum, None). • Efficacy of medication in helping with smoking cessation • Side Effect during medication	<u>Smoking-Related Outcome Data</u> ▪ Readiness to Quit (Likely, Somewhat Likely, Very Unlikely, Extremely Unlikely) ▪ Nicotine dependence based on the Fagerström Test (Heavy, Moderate, Light) and CAGE ▪ Number of cigarettes smoked per day (0, 11-20, 21-30, >30 per day) ▪ The success of quitting smoking (complete quitting of smoking, yes/no) <u>Chronic Disease Health Outcome Data</u> ▪ Chronic disease interferes with my life (strongly disagree, disagree, neutral, agree, strongly agree) ▪ Improvement in overall health (Yes, No) ▪ Vital sign: blood pressure, temperature, heart rate, respiration rate, oxygen saturation, and weight ▪ Blood test: Hgb A1C, total cholesterol, Triglycerides, HDL, LDL