




November 2020

Effect of an Intervention to Improve Smoking Cessation Treatment in a Federally Qualified Healthcare Clinic

Shirley A. Camp
Georgia College and State University

Follow this and additional works at: <https://kb.gcsu.edu/thecorinthian>

 Part of the [Community Health and Preventive Medicine Commons](#), [Family Practice Nursing Commons](#), [Health Communication Commons](#), [Health Services Research Commons](#), [Interprofessional Education Commons](#), [Public Health Education and Promotion Commons](#), and the [Translational Medical Research Commons](#)

Recommended Citation

Camp, Shirley A. (2020) "Effect of an Intervention to Improve Smoking Cessation Treatment in a Federally Qualified Healthcare Clinic," *The Corinthian*: Vol. 20 , Article 13.
Available at: <https://kb.gcsu.edu/thecorinthian/vol20/iss1/13>

This Article is brought to you for free and open access by the Undergraduate Research at Knowledge Box. It has been accepted for inclusion in The Corinthian by an authorized editor of Knowledge Box.

INTRODUCTION

Statement of the Problem

While significant progress has been made in the reduction of tobacco use in the United States over the last decade (Centers for Disease Control and Prevention [CDC], 2018b) the smoking prevalence rates among the socially and economically disadvantaged populations remain high (CDC, 2018b). As a result, these vulnerable populations carry a disproportionate economic, morbidity, and mortality burden that is related to tobacco use (CDC, 2018b; Flocke, Hoffman, Park, Birkby; Trapl et al., 2017). There is cost-effective, and evidence-based treatment available for tobacco use dependence (Fiore et al., 2008; Stead, Koilpillai, Fanshawe, and Lancaster, 2016), but aspects of that treatment are not being delivered consistently to this population (Roberts, Kerr, & Smith, 2013; Twyman, Bonevski, Paul, and Bryant, 2014). The purpose of this research is to improve access to evidence-based behavioral health referrals and pharmacotherapy for tobacco use dependence treatment for the vulnerable population served by the federally qualified health clinic (FQHC) study clinic.

Background

With the inhalation of tobacco smoke, the body is exposed to more than 7000 toxic chemicals and at least 70 carcinogens (American Cancer Society [ACS], 2017). Some of the chemicals in and produced by burning tobacco and its additives include nicotine, hydrogen cyanide, formaldehyde, lead, arsenic, ammonia, radioactive uranium, benzene, carbon monoxide, and nitrosamines (United States Department of Health and Human Services [USDHHS], 2014, ACS, 2017).

According to the American Lung Association (2019) *State of Tobacco Control Report*, seven out of ten smokers *wish to quit*. Only 4 to 7 % of individuals who attempt to stop smoking can do it “cold turkey” (Fiore et al., 2008). Getting support from the healthcare provider, which includes counseling and medication, doubles the chances for a successful quit attempt (ACS, 2018). For most smokers, quitting is *more than just willpower*. On average, smokers may attempt to quit 6-11 times before they succeed (ACS, 2018).

A disproportionate burden in the vulnerable population. Despite the progress in reducing smoking prevalence among the general population within the United States (CDC, 2018), there exist significant healthcare disparities related to

tobacco use within certain populations in the United States (CDC, 2018b). Health equity is defined in public health as the opportunity for all to “reach their full health potential” (Whitehead & Dahlgren, 2006). According to Whitehead & Dahlgren (2006), no one should be prevented from achieving this potential because of their social position or social circumstance. Health equity as it relates to tobacco use prevention and control is the opportunity for everyone to live a healthy, tobacco-free life, regardless of their level of education, sexual orientation, the job they have, gender identity, whether they have a disability, or their race (CDC, 2015). *Best Practices* (Whitehead & Dahlgren, 2006) recommends that to further reduce overall tobacco use and second-hand exposure, attention to reducing tobacco use and second-hand exposure in the population groups that bear the greatest burden of tobacco use will help to reduce those disparities.

Prevalence and factors related to tobacco use in vulnerable populations. In general, the smoking prevalence rates are higher among males, those who are aged 25-64 years, individuals with less education, American Indians/Alaska Natives, individuals of multiple races, uninsured, or insured through Medicaid, individuals living below the poverty line, those who have a disability, and individuals who are part of the lesbian, gay, bisexual, or transgender community, and those who are living in the Midwest or the South (CDC, 2018b). In 2016, the estimated percentage of adults (18 years and older) who are currently smoking is at 15.5% (37.8 million), in striking contrast to prevalence rates with vulnerable populations (Jamal et al, 2018). According to Jamal et al., (2018), the prevalence rates in the U.S. (2016) as it relates to race/ethnicity were: American Indians and Alaskan Natives-31.8%, Asians (non-Hispanic)-9.0%, Blacks (non-Hispanic)-16.5%, Hispanics-10.7%, Multiple Races (non-Hispanic)-25.2%, and Whites (non-Hispanic)-16.6%.

According to the CDC’s Morbidity and Mortality Weekly Report (2015), adults in the United States who are on Medicaid or are uninsured engage in tobacco use at a rate of more than double of those adults who have either private health insurance or are on Medicare. In comparison, only 12.9% of adults who have private insurance smoke, and only 12.5% of Medicare recipients currently smoke (CDC, 2015). According to the 2014 National Health Interview Survey (NHIS), 29.1% of Medicaid patients smoke, and 27.95 % of uninsured patients currently smoke.

Health Risks Associated with Tobacco Use. There is no safe way to use tobacco products. (ACS, 2017). About 50% of those smokers, if they continue to smoke, will die because of their tobacco use, and they will die younger than non-smokers (ACS, 2017). Tobacco use shortens the lives of male smokers by 12 years, and female smokers by 11 years (ACS, 2017). The American Cancer Society (2017) reports that the use of tobacco increases cancer risk, and accounts for thirty (30%) of all cancer deaths. Smoking tobacco is responsible for eighty

(80%) of all lung cancer deaths in the United States. While the risk for lung cancer is significant and especially hard to treat, the risk for other cancers is also high (i.e. mouth, larynx, pharynx, esophagus, kidney, cervix, liver, bladder, pancreas, stomach, colon, and myeloid leukemia). Also, the risks for lung cancer and other related diseases are increased for those individuals who are exposed to second-hand smoke (ACS, 2017). Cigar smokers are four to ten times more likely to die secondary to cancers of the throat, larynx, esophagus, and mouth than individuals who do not smoke (ACS, 2017).

Economic costs attributable to tobacco use. Because of the higher smoking prevalence rates among vulnerable populations, there is also a significant economic impact that is attributable to tobacco use. The global cost for tobacco use accounted for nearly 2% of the world's gross domestic product in 2012, or \$1,436 billion US dollars, according to the World Health Organization (WHO) (Boyles, 2017, Goodchild, 2017). A global economic impact analysis was completed by WHO and the World Bank (Goodchild, 2017). That study measured both the direct cost of smoking (i.e. hospital admissions and treatment) and the indirect costs using the validated human capital methods (HCM) which calculates the value of human capital loss due to death and illness. Global working years lost due to smoking-related illness and death totaled 26.8 million. The indirect costs of smoking-related diseases were estimated to be \$1,014 billion (US dollars) with disability accounting for \$357 billion and death accounting for \$939 billion (Goodchild, 2017).

Smoking-related costs totaled an estimated 3% of the gross domestic product of the United States (Goodchild, 2017). For every smoking attributed death, there are at least thirty (30) people that live with a smoking-related disease. Smoking-related illness in the United States results in more than \$300 billion per year, which is nearly \$170 billion in direct medical care for adults and more than \$256 billion in lost productivity (ACS, 2018).

Positive health and economic impact of smoking cessation. According to the National Cancer Institute (NCI) *Smokefree.gov* website (2019), within hours of quitting tobacco use, the individual's blood pressure and heart rate decrease, and the risk of heart attack is reduced. Risks for hearing loss, and overall vision is decreased, and night vision is improved. The risk for premature aging and excessive wrinkling of the skin is reduced. Risks for the formation of harmful blood clots is reduced. The individual can expect a brighter smile, less shortness of breath with exertion, stronger bones, reduction of serum cholesterol, and normalization of white blood cells following smoking cessation (National Cancer Institute [NCI], 2019). For an extensive list of positive health outcomes following smoking cessation (See Appendix A for a complete list of positive health outcomes) (WHO, 2014.).

Tobacco use prevention and control activities are public health's "best buy" (CDC, 2018a). These activities are considered comprehensive and have demonstrated that they reduce the number of people who currently smoke, and therefore reduce tobacco-related health care costs and hospitalizations by up to \$55 for every dollar spent on prevention (CDC, 2018a).

Cost-effective and evidence-based treatment recommended. The Department of Health and Human Services, Public Health Service published updated clinical practice guidelines in *Treating Tobacco Use and Dependence* (Fiore et al., 2008) that provided evidence-based and cost-effective treatment (See Appendix B for the 10 Key Recommendations). As part of those guidelines, they utilized the conceptual framework of motivational interviewing and recommended the 5A's (See Appendix C) and 5 R's (See Appendix D) models to be used by healthcare providers when treating tobacco dependence. In 2014, the United States Preventive Services Task Force reiterated the guidelines as "A" recommendations for the reduction of tobacco use (See Appendix E). Implementation of these recommendations is generally incorporated in the tobacco use prevention and control activities at the global, national, and state-level (WHO, 2017, USDHHS, 2013, Chung, Lavender and Bayakly, 2016). In 2018, Barua, and Rigotti et al., published the *American Academy of Cardiology Expert Consensus Decision Pathway on Tobacco Cessation Treatment* (Appendix F) providing their recommendations for treatment of cardiac patients that are currently using tobacco that also reflect similar recommendations as the original guidelines.

Global and national approach to the tobacco use epidemic. Tobacco use remains the world's leading cause of premature mortality and smoking-related morbidity (WHO, 2015). The American Cancer Society web site (Drope et al., 2018) estimates that there are currently one billion smokers in the world. Tobacco use is the leading cause of preventable mortality because of the association of smoking-related diseases that result in nearly six million deaths per year (WHO, 2015). To gain some perspective, the combined mortality annually from tuberculosis, human immunodeficiency virus (HIV), and malaria are less than the tobacco-related deaths per year (WHO, 2011). Based on current projections, tobacco use is expected to be responsible for eight million deaths or 10% of global deaths by 2030. The strong association with tobacco use and lower socioeconomic status continues to generate increasing health disparities at both the global and national levels (Van Schayck et al., 2017). To confront this epidemic, the United Nations General Assembly in 2011 adopted a declaration that committed the members to a 25% reduction in premature mortality from non-communicable diseases by 2025, which includes a 30% reduction in smoking prevalence (United Nations, 2011). Tobacco control policies generated by the World Health Organization (WHO, 2015), an agency of the United Nations, as developed by the Framework Convention on Tobacco Control (FCTC) has been successful in

reducing smoking prevalence. Article 14 of the FCTC addresses the treatment of tobacco dependence and insists that cessation support is an essential component of treatment and works synergistically with the other tobacco control measures (WHO, 2015). While many of the public health efforts recommended by WHO has been successful in preventing individuals from commencing the use of tobacco, many individuals who are addicted to the nicotine in tobacco that will need the assistance of a healthcare provider to stop smoking tobacco (Van Schayck et al., 2017). WHO (2015) has suggested that primary care is the most suitable healthcare setting for providing advice and treatment for smoking cessation. According to Raw, Mackay, and Reddy (2016), only 15% of the world's population has access to this smoking cessation support. According to *WHO FCTC: High Level of Ratification, Low Level of Full Implementation Report* (WHO Regional Office for Europe, 2018), the WHO Framework Convention on Tobacco Control (FCTC) is a legally binding treaty for cost-effective tobacco control has nearly 50 countries (out of 53) who have committed to implementation but still have not fully implemented the policies that they have agreed to in the FCTC.

Significant strides have been made in the reduction of smoking and tobacco use within the United States (CDC, 2018b). According to the CDC (2018b), cigarette smoking among U.S. adults (aged 18 years or above) has declined from 20.9% in 2005 to 17.9% in 2016. In 2015, an estimated 52.8 million adults were former smokers. Of the 36.5 million current adult smokers, 49.2 percent stopped smoking for a day or more in the preceding year because they were trying to quit smoking completely (ALA, 2018, CDC, 2015).

The findings from the *National Health Interview Survey (NHIS)* indicate that the percentage of adults who have quit smoking increased from 50.8% in 2005 to 59% in 2016 (CDC, 2018). According to the CDC (2018b), more people are quitting, and those that remain smoking have decreased the number of cigarettes smoked. Cigarette smoking among U.S. adults has been reduced by 50% since 1964, according to the CDC (2018b). While this gradual decline is to be celebrated, tobacco use *remains* the leading cause of preventable morbidity and mortality (CDC, 2018b) in the United States. Smoking-related diseases result in premature deaths of more than 480,000 Americans per year (CDC, 2018b), or about 1 in 5 deaths (USDHHS, 2014). For every person who dies from tobacco use, there are 30 Americans who suffer from smoking-attributable diseases (CDC, 2018b). According to Jamal et al., (2018), more males smoke than females, ages 25-64 years constitute the largest group of smokers, the lower the education the higher the smoking prevalence, and those individuals who live below the poverty level are more likely to smoke. Jamal et al. (2018) report that adults that smoked daily, eighty-seven percent had tried their first cigarette by 18 years of age, and ninety-five percent by the age of 21.

According to the American Lung Association (2018), nearly 9.3% of high school students use tobacco, and 2.3% of middle school students are current smokers of tobacco.

In *Healthy People 2020* (USDHHS, 2013), the overall goal regarding tobacco use was to reduce illness, disability, and death related to tobacco use and secondhand smoke exposure in the United States. Objective TU-4 sets the target at 8% (adult smokers who have successfully stopped smoking within the past 6 months to 1 year), and 80% (of adults aged 18 years and older who have attempted to stop smoking in the past 12 months) (USDHHS, 2013). Healthcare system change objectives included increasing Medicaid coverage for nicotine dependency pharmacotherapy that was evidence-based (TU-9). The target for increasing tobacco cessation counseling in office-based ambulatory care settings (TU-10.1) is 21.1% (% of visits among current tobacco users who are adults being seen at office-based ambulatory care settings who had tobacco cessation counseling provided or ordered during that visit). Also, the objectives included increasing tobacco cessation counseling in substance abuse, and mental health care settings (USDHHS, 2013).

Georgia and North Central Public Health Districts approach to tobacco use. Based upon updated 2018 data from the *CDC's Behavioral Risk Factor Surveillance System (BRFSS)*, The United Health Foundation (2018) has determined that the State of Georgia's overall smoking prevalence rate is 17.1%. According to the *2016 Georgia Tobacco Use Surveillance Report* (Chung, Lavender, & Bayakly, 2016), the State of Georgia had 1.35 million adult smokers, over 10,000 adults in Georgia die from smoking-related diseases per year, and the economic costs are staggering with 3.2 billion dollars in lost productivity and 1.8 billion dollars in healthcare costs attributed to smoking based upon the *CDC's Behavioral Risk Factor Surveillance System 2014* data. Other significant conclusions from the *2016 Georgia Adult Disparities in Tobacco Use Report* (Chung, Lavender & Bayakly, 2016) included: In Georgia, smoking prevalence is highest among non-Hispanic whites (19.3%, or 785,000) followed by Hispanics (15.6%, 92,000), and non-Hispanic blacks (14.6%, 201,000) (Chung et al, 2106). Smoking cigarettes are 6 times more likely among adults without a high school education (31.8%) than with a college education (5.6%). Adult males (40.7%) that do not have a high school education are more likely to smoke in comparison to all other groups (Chung et al., 2016). Approximately 25% of Georgia adults do not have any type of health insurance (Chung et al., 2016). Forty-five (45) percent of non-Hispanic white smokers and twenty-nine (29) percent of non-Hispanic Black smokers do not have any form of health insurance. Based upon the 2014 BRFSS data, cigarette smoking is higher among individuals who are employed in construction (32.2 %), food preparation (31.4%), and transportation and material

moving occupations (27.8%) (Chung et al., 2016). Almost 21% of stroke patients in Georgia are current smokers (Chung et al., 2016). For patients who have had a heart attack, 22% were current smokers. And one-fourth (25%) of adults who suffer from asthma continue to smoke (Chung, et al., 2016). According to Gvinianidze and Tsereteli (2012), about 72,500 potential years of life were lost in Georgia during the year 2008 due to active smoking, with most of the burden being related to cancer and cardiovascular diseases.

The estimated number of adult smokers for the North Central Public Health District is 54,000, and the smoking prevalence is 16.8 percent according to the 2014 BRFSS data (Georgia Department of Health, 2016). The North Central Health District is comprised of Baldwin, Bibb, Crawford, Hancock, Houston, Jasper, Jones, Monroe, Peach, Putnam, Twiggs, Washington and Wilkinson counties (North Central Public Health, 2019).

FQHC clinics in the U.S. and FQHC study clinics prior approach.

While tobacco use poses serious health risks for the general population, the density of high-risk populations that are treated at FQHC clinics results in a smoking prevalence rate of 25.8, an average of 5.2% percentage points (Range, -4.9 to 20.9) higher among FQHC clinics (Flocke et al., 2017).

According to Flocke et al., (2017), Georgia has 23 FQHCs serving a total of 156,980 patients, and 36,182 of those patients currently smoke. This equates to an average smoking prevalence rates within FQHC clinics in Georgia at 25.3% (Range: 6.0-48.8) in comparison to 22.4% tobacco use in Georgia's population.

Before the commencement of the study, an FQHC study clinic smoking prevalence report was generated from the electronic health record for 2017 and 6 months of 2018. Based on the data provided by FQHC EHR, it is estimated that the smoking prevalence rate was 32.5% (K. Arispe [personal communication, April 18, 2018]). These statistics support the premise that the population frequently served at the FQHC study clinics are at a higher risk for ongoing tobacco abuse without the usual ability to access evidence-based smoking cessation treatment secondary to lower socioeconomic status, and lack of insurance.

The FQHC clinics had previously implemented changes in the EHR to include prompts on smoking status and desire to quit smoking in response to the national guidelines for the treatment of tobacco use dependence. The support staff routinely asks incoming patients a series of evidenced-based questions to determine tobacco use status, the level of nicotine dependence (based on the frequency of smoking cigarettes), and validate tobacco cessation pharmacotherapy listed in current medications. When the patient is seen by the health care provider, and the system identifies the patient as a current smoker, the anticipation is that the provider will enter the advice to quit under preventive counseling and whether the patient desires to make a quit attempt. Within the preventive and counseling

sections of the electronic health record, several options are provided to select evidence-based treatment to facilitate easy documentation of smoking cessation treatment. Informal discussions with healthcare providers before the intervention provided valuable information by the identification of barriers perceived by the administrative and healthcare providers. When the higher prevalence rates were demonstrated for the administrative and healthcare provider team, there was an interdisciplinary organizational effort to work to reduce the smoking prevalence rate at the FQHC study clinic and agreement to support the efforts of the principal investigator to develop an intervention that may have the potential to increase the delivery of evidence-based smoking cessation treatment and indirectly reduce the smoking prevalence rate for their vulnerable populations.

Significance of the Problem

Research about smoking cessation treatment is extensive. Upon careful analysis of systematic reviews and meta-analysis studies, national guidelines have been generated for tobacco use dependence treatment. Evidence-based interventions were recommended in those guidelines, but subsequent studies demonstrate that the translation of those guidelines into clinical practice is not occurring consistently.

The research highlights that the *assistance with* and *arranging for* behavioral health referrals and smoking cessation pharmacotherapy (as recommended by national guidelines) is where the deficiencies remain in the delivery of evidence-based smoking cessation treatment. Additional studies have researched factors that impact the full implementation of those guidelines, including the lack of education and training, lack of resources, and concerns about the cost of the counseling and pharmacotherapy (Colomar et al., 2014; Himelhoch et al., 2014; Van Schayck et al., 2017).

Gaps in the literature included studying the impact of a multicomponent intervention (focused educational training and provision of quick reference materials) on the referral and prescribing behaviors of healthcare providers in an FQHC setting within a southeastern state.

According to Flocke et al. (2017), the prevalence rates for tobacco use in federally qualified healthcare clinics (FQHC) averages 5.2 percentage points higher (range -4.9 to 20.9) when compared to the general population of the United States. As an FQHC, the healthcare clinicians at the study clinic have the responsibility to provide smoking cessation treatment to its vulnerable populations. They need to address the FQHC study clinics estimated the smoking prevalence of 32% (K. Arispe [personal communication April 18, 2018]) to further reduce the health disparities that are occurring in their population because of the tobacco use epidemic in Middle Georgia.

Even a small improvement in smoking cessation referrals and treatment can yield substantial improvements in quality of life for those patients who can stop smoking.

Purpose Statement

The purpose of this research is to improve access to evidence-based behavioral health referrals and pharmacotherapy for tobacco use dependence treatment for the vulnerable population served by the FQHC study clinic healthcare clinicians. The goal of this study is to find a solution for the lack of consistent delivery of “Assistance” and “Arrangement” (5 A’s Model) of the U.S Public Health Guidelines for Tobacco Use Dependence Treatment (Fiore, et al., 2008) as it relates to behavioral health referrals and pharmacotherapy for smoking cessation.

Specific aim 1. To develop a multicomponent intervention for the FQHC clinician participants that is based upon the conceptual framework of Kotter’s Change Theory (Kotter, 2014) assists in the translation of evidence to clinical practice and addresses the identified barriers to implementation of the clinical guidelines as it relates to behavioral health referrals and pharmacotherapy.

Specific aim 2. Measure the impact of the provision of the multicomponent intervention to determine if it has improved the delivery of behavioral health referrals and pharmacotherapy by comparing the data before the intervention to the data retrieved at eight weeks following the intervention and determining if there is a statistical or clinical significance. Participants will be encouraged to utilize the evidence-based *5A’s and 5R’s Model* to deliver smoking cessation therapy.

Specific aim 3. Measure the percentage of current smokers who have been advised to quit that are motivated to make a quit attempt and compare with other research studies that have ascertained the percentage of current smokers that wish to make a quit attempt.

Specific aim 4. Describe the sample characteristics and correlate the individual characteristics to improvement in the delivery of behavioral health referrals and pharmacotherapy for smoking cessation.

Clinical Questions

Clinical question 1. How does education about smoking cessation and the provision of quick reference materials affect referrals to behavioral counseling and prescribing smoking cessation pharmacotherapy with healthcare providers at federally qualified healthcare centers in one southeastern state within an eight-week period?

Clinical question 2. What percentage of Self-Identified Current Smokers (SICS) expressed a willingness to attempt quitting?

Clinical question 3. What provider characteristics are associated with increased smoking cessation referrals/treatment?

Definitions and Terms

Federally Qualified Healthcare Center (FQHC) Study Clinic. Community-based outpatient clinics that have qualified for specific reimbursement systems under Medicare and Medicaid to provide primary care services in underserved areas (Health Resources and Services Administration [HRSA], 2018).

Current smoker. “An adult who has smoked 100 cigarettes in his or her lifetime, and who currently smokes cigarettes.” (CDC, 2019).

Smoking status of the patient. A designation that is recorded in the electronic health record of the FQHC study clinic based upon several questions about cigarette smoking as a *current smoker, former smoker, never smoked, and smoking status unknown*.

Participant. A healthcare clinician (i.e. MD, DO, NP, PA) providing primary care during the designated periods at one of the five participating FQHC study clinics and have agreed to voluntarily participate (signed informed consent), and who were present at the provider meeting when the intervention occurred. Principal Investigator (PI) was not a participant.

Multi-component intervention [Phase 1]. An intervention comprised of an educational presentation on July 25, 2018, provision of a quick reference handbook to the participants, and revisions in the electronic health record system to facilitate documentation of the qualifying smoking cessation treatment.

Pre-Intervention data collection [Phase 2]. Patient data retrieved from a retrospective electronic health record review at the FQHC study clinic for 8 weeks pre-intervention for each participant.

Post-Intervention data collection [Phase 3]. Patient data retrieved from a retrospective electronic health record review at the FQHC study clinic for 8 weeks post-intervention for each participant.

Candidate. Patients that are identified in the electronic health record as current smokers, who have been counseled to quit within the last 24 months, who are interested in quitting smoking, and have not been provided quitline or handouts in 12 months.

Compliance. Data retrieved from retrospective chart review that documented *any of the following* as it relates to behavioral health referrals: 1) Healthcare provider counseling for smoking cessation, or 2) Healthcare provider referral to mental health clinician for face-to-face or group supportive counseling, or 3) Referral to smoking cessation classes, or 4) Referral to the Georgia Tobacco Quitline by the provision of telephone numbers or initiating an electronic or fax

referral, or 5) Provision of written materials that provided community resources for behavioral health for smoking cessation therapy.

Data retrieved from retrospective chart review that documented *any of the following* prescriptions ordered, recommended, or referred to an entity to which they could obtain the following medications or smoking cessation medications identified as current medications in the electronic health record for the visit in which the patient is seen when deemed eligible: 1) Bupropion SR (Zyban, Wellbutrin); 2) Nicotine gum; 3) Nicotine inhaler; 4) Nicotine Lozenge; 5) Nicotine Nasal Spray; 6) Varenicline (Chantix); 7) Or any combination thereof.

Data retrieved from retrospective chart review that documented the following is considered compliance: 1) behavioral health referral or 2) pharmacotherapy for smoking cessation or 3) provided either or both.

Current smokers who expressed a desire to quit. Self-identified current smokers who have expressed a desire to quit smoking or agreed to attempt to quit smoking or was provided with a behavioral health referral or pharmacotherapy for smoking cessation (implied consent).

Literature Review and Synthesis

The literature review will provide a summary of the clinical practice guidelines *Treating Tobacco Use and Dependence* (Fiore, et al., 2008), the *Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions* published by the U.S. Preventive Services Task Force (2015), and the *American College of Cardiology (ACC) Expert Consensus Decision Pathway on Tobacco Cessation Treatment* (Barua, R. S. and Rigotti, N. A., et al., (2018). Studies demonstrating the efficacy of behavioral counseling and pharmacotherapy for smoking cessation (Fiore et al., 2008, Papakadis et al., 2016, Piper et al, 2018) will be included in the review. Studies reviewed suggest primary care providers are uniquely positioned to deliver effective tobacco cessation treatment with a brief intervention using the 5 A's and 5 R's model as recommended by Fiore, et al. (2008). The provision of the evidence-based treatment using these models by primary care providers results in higher smoking cessation quit rates (Fiore et al., 2008; Stead, Koilpillai, Fanshawe, and Lancaster, 2014). However, the literature suggests that referrals for behavioral health and prescriptions for smoking cessation treatment were not being consistently delivered (Twyman, Bonevski, Paul, and Bryant, 2014). The literature review includes studies that identified the perceived barriers by health care providers to the delivery of this treatment and identified factors (i.e. healthcare provider characteristics, education) that improved the delivery of the evidence-based

smoking cessation treatment (Colomar et al., 2014; Himelhoch, Riddle & Goldman, 2014). And finally, the review of literature includes a summary of Kotter's Theory of Organizational Change.

A review of the literature was performed using the following databases: CINAHL Complete, CINAHL Plus with Full Text, Cochrane Database of Systematic Reviews, MEDLINE with Full Text, Psychology and Behavioral Sciences Collection, and Google. Keywords used in the literature search included: tobacco use, tobacco cessation, primary care, theories of behavior change, health professionals.

Evidence-Based Treatment for Tobacco Use Dependence and Its Delivery

This section of the literature review will provide a summary of the clinical practice guidelines (Fiore, et al., 2008), the recommendations for tobacco smoking cessation published by the U.S. Preventive Services Task Force (2015), and the American College of Cardiology decision pathway for providing tobacco cessation treatment (Barua, R. S. and Rigotti, N. A., et al., (2018). Studies demonstrating the efficacy of behavioral counseling and pharmacotherapy for smoking cessation (Fiore et al., 2008, Papakadis et al., 2016, Piper et al, 2018) will be included in the review. The literature review also suggests that primary care providers are uniquely positioned to deliver this evidence-based treatment and that the interventions recommended result in more successful quit attempts and increased smoking abstinence (Fiore et al., 2008). Studies will be included in the literature review that suggests that the evidence-based treatment recommended is not being delivered consistently (Twyman, Bonevski, Paul, and Bryant, 2014).

Clinical Guidelines. *Treating Tobacco Use and Dependence* (Fiore, et al., 2008), was published by the U.S. Department of Health and Human Services, providing clinical practice guidelines for tobacco cessation treatment (See Appendix B for the 10 key recommendations). Fiore et al. (2008) strongly suggest that effective tobacco interventions require coordinated interventions on the part of clinicians, and health care systems and the environment should foster and support tobacco intervention as an essential component of healthcare delivery. Fiore et al. (2008) also recommend that clinicians should be provided the training and support to assist in the delivery of consistent, effective interventions to assist their patients in smoking abstinence. Fiore et al. (2008) conclude that the most effective way to get healthcare providers to intervene is to provide them with the multiple evidence-based treatment options, provide institutional support for them to use those treatments, and create the environment where a failure to intervene is not within the standard of care.

In Chapter 3 *Clinical Interventions for Tobacco Use and Dependence* (Fiore et al., 2008), the guidelines provide the rationale for healthcare providers to

make treatment of tobacco use a clinical priority: 1) Clinicians can make a difference even with minimal intervention (less than three minutes); 2) there is growing evidence that smokers that receive this advice and assistance are reporting greater satisfaction with their healthcare, and 3) it is cost-effective. Fiore et al. (2008) recommend the provision of this treatment with the use of the 5A's and the 5 R's Model. For the patient who is *unwilling to quit*, Fiore et al. (2008) recommend that the clinician use motivational interviewing techniques as delineated by the 5 R's Model: 1) relevance, 2) risks, 3) rewards, 4) roadblocks, and 5) repetition. Fiore et al. (2008) provided evidence that suggested that the use of the 5 R's increases future quit attempts.

Preventive Services Recommendations for Tobacco Smoking Cessation. In 2015, the United States Preventive Services Task Force published the *Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions* recommended that healthcare providers determine the tobacco status of all adults, advise them to stop using tobacco, and provide them with behavioral interventions and the FDA approved pharmacotherapy for smoking cessation. Subsequently, a research plan has been developed to study the effectiveness of smoking cessation interventions (USPSTF, 2018) which may be instrumental in the development of updated treatment guidelines (See Appendix E for the recommendations).

Tobacco Cessation Treatment Decision Tree. *American College of Cardiology (ACC) Expert Consensus Decision Pathway on Tobacco Cessation Treatment* (Barua, R. S. and Rigotti, N. A., et al., (2018) provided a comprehensive tobacco cessation treatment decision-making tree with the acknowledgment that consistent delivery remains a significant challenge (See Appendix F for the decision-making tree).

Research Suggesting that Combinations of Pharmacotherapy May be Effective. A more recent study (Piper et al., 2018) suggested behavioral health interventions and combinations of pharmacotherapy were more effective when compared to the usual care (10 minutes of in-person counseling, 8 weeks of a nicotine patch, and referral to quitline services) at 4, 8, 16 and 26 weeks to abstinence-optimized treatment (3 weeks of pre-quit mini-lozenges, 26 weeks of nicotine patch and mini-lozenges, three in-person and eight phone counseling sessions and 7-11 automated calls to prompt medication use). Key outcomes were self-reported along with biochemically confirmed 7-day point prevalence.

Unique Position to Deliver Tobacco Dependence Treatment. Primary care providers are in a unique position for helping tobacco users. If all primary care providers routinely ask about tobacco use and advise tobacco users to stop, they have the potential to reach more than 80% of all tobacco users per year; trigger 40% of cases to make a quit attempt; and help 2-3% of those receiving brief advice quit successfully (WHO, 2014). The research (Fiore et al., 2008) suggests that this

brief intervention by healthcare clinicians during a patient's routine visit can provide a cost-effective, and evidence-based treatment for tobacco dependence. According to Danesh, Paskett, and Ferketich (2014), healthcare providers in primary care can make significant contributions to the reduction of the smoking prevalence rates of their patients. Patients who are advised to quit smoking are 1.6 times more likely to do so upon the advice of a healthcare provider (Danesh et al, 2014; Wray, Funderburk, Acker, Wray & Maisto, 2018).

Lack of Consistent Delivery. The research suggests that the delivery of evidence-based treatment is not occurring consistently (Papadakis, 2016). Assisting and arranging for the provision of behavioral health and pharmacotherapy for smoking cessation is an essential component of the evidence-based treatment (Fiore et al., 2008). According to Kruger et al. (2016), current cigarette-only smokers who visited a health professional in the last 12 months self-reported that only 6.3% had received both counseling and medication for smoking cessation within the past year. Also, Kruger et al. (2016) reported that 3.8% was referred to a smoking cessation class or program, 3.7% were referred to one-on-one counseling and 2.6% were referred to a telephone quitline. Based upon their conclusions, current cigarette-only smokers who reported receiving all 5 A's during a recent clinic visit were more likely to use counseling, medication, or a combination of counseling and medication, compared to smokers who received one or none of the 5 A's components.

With the enactment of the *Medicare Access and CHIP Reauthorization Act* (2015), healthcare providers are now routinely documenting smoking status and the provision of advice to quit (CMS, 2018). However, assistance with and arranging for behavioral counseling, medications, programs, and other supports for smoking cessation treatment is suboptimal (Roberts et al., 2013; Stead et al., 2016).

Guidelines for tobacco use dependence are readily available for healthcare providers to assist in the provision of evidence-based treatment for smoking cessation. Increasing the number of health care providers that deliver the evidence-based, brief interventions for tobacco use prescribed by the Public Health Service Clinical Practice Guideline will expose more tobacco users to evidence-based treatments and will result in more successful quit attempts and tobacco abstinence (Fiore et al., 2008, USPSTF, 2014, Barua et al., 2018, Piper et al., 2018). These guidelines and recommendations include the benefits of assistance with and arranging for behavioral health and pharmacotherapy for smoking cessation. However, the research suggests that is not being done with consistency. Hence, the importance of reviewing the literature that identifies the barriers that are perceived by healthcare providers that interfere with the successful delivery of this treatment.

Theoretical Framework

In the award-winning *8-Step Process for Leading Change* (1996), Kotter described a methodology that provides a process for implementing successful

change in organizations. This 8-Step process is delineated in the following paragraphs.

Creating a sense of urgency. The first step in the process is creating a sense of urgency (Kotter, 2014). He suggests that people need to see and feel the need for change and that your actions and behaviors (not just your words) must communicate that need for change. Without that sense of urgency, he states that the change is doomed for failure.

Building a guiding coalition. The second step is building a guiding Coalition (Kotter, 1996) in which he suggests that the traditional hierarchical structure of most companies cannot quickly adjust to the constantly changing environment that can enable it to take advantage of new opportunities or challenges. He recommends that a coalition of effective people within the organization guide the changes, coordinate it, and communicate its activities (Kotter, 2014).

Formulate a strategic vision and initiatives. The third step is to formulate a strategic vision and initiatives. This is important to demonstrate how the change is different from the past, and by tying the initiatives directly to the vision (Kotter, 2014).

Enlist a volunteer Army. The fourth step is to enlist a volunteer army because it is only when large numbers of people buy-in and understand the urgency to drive change that large-scale change can occur (Kotter, 2014). Without additional volunteer help, the efforts are limited.

Remove Barriers. The fifth step is to enable action by removing barriers which he states that by removing barriers inefficiencies in the process will provide the freedom to work and generate long-lasting impact (Kotter, 2014).

Enable Short Term Wins. The sixth step is to enable short term wins by recognizing and communicating results early on and often that track progress and energizes volunteers to continue persisting (Kotter, 2014).

Sustain acceleration. The seventh step is to sustain acceleration by pressing harder with the first successful results and being relentless with ongoing change until the vision has been realized (Kotter, 2014).

Institutionalize the Change. The eight-step in the process is to institutionalize the change with the articulation of the connections between the new behaviors and the success of the organization and continue until the old habits are replaced (Kotter, 2014).

This 8-step process developed by Kotter (1996, 2014) was used as the framework for the development of the design of the study, the educational presentation, the development of the quick reference materials provided to the healthcare providers, and the dissemination of the results of the study. Data was provided during the educational presentation that demonstrated a 33% smoking

prevalence at the FQHC study clinic which is substantially higher than the general population. The international, national, and state targets for reduction in smoking prevalence were provided to demonstrate the lack of compliance with those goals to create a sense of urgency. The principal investigator met with administrative staff, and incorporated staff responsible for quality improvement to ensure that we built a strategic coalition to determine what type of research would be beneficial to the FQHC study clinic. An information technology expert, with specialized knowledge in retrieving data and managing the electronic health record at the study clinic, was recruited to assist in the project. Analysis of the documentation of the patient's current smoking status, advice given to quit smoking, and the provision of the smoking cessation treatment. Frequent communication with the information technology officer occurred, and initial data was shared with the study clinic administrative staff resulting in energizing the individuals involved. Once the results were obtained, and the analysis was completed, communication of the information occurred at the monthly provider meeting to provide important feedback.

Methodology

Project Description

This is a translational research project that was designed to address the need for improving the delivery of evidence-based smoking cessation treatment for a specific clinical setting within a specific geographical area. An educational intervention was delivered utilizing Kotter's change theory along with the provision of quick reference materials. In addition several changes were made to the electronic health record to provide prompts to support provider documentation of smoking status and smoking cessation interventions.

The purpose of this study was to determine the impact of a multi-component intervention on behavioral health referrals for smoking cessation treatment and/or the number of prescriptions for smoking cessation pharmacotherapy by healthcare providers during visits in five (5) federally qualified healthcare clinic in the southeast.

Setting

The clinics were all located in two separate cities approximately 90 miles from a large southeastern metropolitan city. All clinics were operated by the same business entity. These clinics are designated federally qualified healthcare clinics (FQHCs) responsible for the provision of primary healthcare for vulnerable

populations for their area. Sixteen healthcare providers are employed at the clinics [4 MD's, 1 DO, and 11 APRN's (including part-time APRN who is the PIC for this study)]. There is numerous support staff that is tasked with the registration, and provision of care during the patient's visit. Medical Assistants are responsible for requesting and entering smoking status information of the patient into the electronic healthcare upon arrival and entering verification of the current medication list.

Population and Sample

The population is healthcare clinicians that provide primary health care at FQHCs. A convenience sample was recruited from the providers at the FQHC study clinics located at five different locations. Most providers agreed to voluntarily participate. Even though the primary investigator (PI) was a provider at the clinic, there was no participation in the study by the PI. All participants who commenced the study continued to participate until its completion.

Protection of Human Subjects

The Georgia College and State University and the Middle Georgia State University Institutional Review Board approved this research proposal. Also, approval of the research proposal was sought from the Executive Director and Medical Director of the federally qualified healthcare clinic where the study was to be conducted. All participants were given oral and written information about the study and provided a consent form to be signed (see Informed Consent as Appendix G).

The paper surveys collected at the meeting will remain in the possession of the PI and will be placed in a locked file cabinet drawer and retained for one year. After one year, the surveys will be shredded to ensure confidentiality and discarded securely. Data files that contain any protected health information will be maintained for three years in a password protected electronic file maintained by the FQHC study clinic. Any data will only be reported in the aggregate form for any publication or dissemination. Any data file placed on PI's personal computer will be devoid of any patient names or medical record numbers and will also be password protected. If not in the personal possession of the PI, will be maintained in a locked cabinet.

Data Collection Procedures

The data collection for this study was completed in three phases using a retrospective medical chart review. An information technology expert incorporated the required prompts into the EHR and ran the reports to obtain compliance data. Phase I data collection occurred during the intervention with the participant characteristics questionnaire. Phase II data collection was collected immediately following the recruitment of the participants and consisted of a retrospective electronic medical chart review of all patients seen by the participants

for the period of eight- weeks before the intervention. Phase III data collection was retrieved by a retrospective electronic chart review for all patients seen by participants during the eight- weeks following the intervention.

Smoking Prevalence Rate for FQHC Study Clinic. Once IRB approval was received, aggregate data were retrieved from the FQHC study clinics (5 clinical practices) electronic health records to determine the total number of adult (18 years of age or older) patients seen for 2017 and determine the total number of adults who were identified as current smokers for 2017 to ascertain the smoking prevalence rate for this FQHC study clinic.

Phase 1. Following the educational intervention, all healthcare provider participants were asked to complete a demographic questionnaire (See Appendix H). It is estimated that the length of time to complete was approximately 10 minutes or less. The additional time for the participants to complete the brief interventional counseling and treatment may have added approximately 10 minutes to the length of the office visit, which did not excessively burden either the healthcare provider participant or the patient during the visit.

Phase 2. Following the intervention, data was collected from the EHR for all patients seen by *each participant* to determine the number of patients who were candidates to receive the qualifying behavioral and pharmacotherapy smoking cessation treatment and the number that received the above for the time eight-weeks before the intervention. The percentage of current smokers that received the qualifying treatment was calculated by dividing that number by the number of patients seen by that provider. An aggregate percentage for all participants was also calculated for this period. Also, data was collected to determine the number of current smokers who were willing to make a quit attempt.

Phase 3. Upon completion of the Post Intervention period (8 weeks after intervention), the same data using the same variables were retrieved from the electronic health record for all the participants individually for the eight weeks after the intervention. The individual and aggregate percentages were also calculated for this period. The difference in percentages between these two periods was used for comparison regarding the delivery of “qualifying treatment” to eligible current smokers by healthcare provider participants.

Intervention

The multi-component intervention was developed based upon Kotter’s theory of individual and organizational change (Kotter, 2014) and the identified barriers and factors that impacted the consistent delivery of the evidence-based smoking cessation treatment. The multicomponent intervention was comprised of an educational intervention that provided healthcare providers with evidence-based smoking cessation treatment, the design, background and methodology of the proposed study, quick reference smoking cessation materials, and the

programming changes made to the electronic health records to facilitate easy documentation for the provision of qualifying behavioral health and pharmacotherapy for smoking cessation.

Educational Intervention. The purpose of the educational intervention was to address identified barriers in published studies (i.e. lack of education and training regarding the delivery of smoking cessation treatment, concern about the cost of pharmacotherapy, lack of resources, etc.) and based upon Kotter's steps of success in leading change (Kotter, 2014) within organizations (See Appendix I for the content delivered at the educational intervention).

Quick Reference Materials. Materials were collected, copied and placed in a notebook by PI to provide a permanent reference book that could be quickly accessed by the participant during a patient's visit that would refresh their memory about the specific data, information, community resources, and where documentation will be required to ensure accurate data retrieval for the study (See Appendix I for the content included in those notebooks).

Changes Made to FQHC study clinic electronic health care record. The following changes were made to the EHR to improve the ease of documentation for the provision of behavioral health referrals and documentation of pharmacotherapy for smoking cessation treatment. These changes were discussed at the provider meeting.

Instrumentation

No instruments were used to obtain data for this study. Participants completed a short demographic questionnaire with questions about race, gender, type of provider, years of practice, smoking status, and age group.

Variables

Clinical Question 1. *Before-After* is a binary variable with the following values: 0=Phase II Pre-intervention Period (8 weeks before) and 1= Phase III Post Intervention Period (8 weeks after). *Candidate* is a binary variable created by transformation, that indicates if the patient was a candidate for checking to determine if they were referred with the following values: 0=No and 1= Yes. *Compliant* is a categorical variable that indicates if the candidate had a referral for tobacco cessation treatment (either counseling and/or pharmacotherapy) with the following values: 0=No, 1=Yes, and 3=NA-Patient was not a candidate. *Compliance Percentage* is a transformational continuous ratio variable that indicates the percentage of compliance by each provider.

Clinical Question 2. What percentage of Self-Identified Current Smokers (SICS) expressed a willingness to attempt quitting?

Tobacco Users documented during the visit is a binary (YES/NO) variable with the following values: 0=No and 1=Yes. *Quit Interest* is a categorical variable that indicates the patient's level of interest in quitting tobacco use with the following values: 0=Interest in Quitting not Documented, 1=Not Ready to Quit,

2: Not Ready to Quit- found in Progress Notes, 3= Thinking about Quitting, 4=Thinking about Quitting-found in Progress Notes, 5= Ready to Quit. The previous variables were transformed into a categorical variable *Ready or Considering Quitting* with the following values: 0= Not Ready, 1: Ready to Quit or Considering Quitting, 2= Unknown b/c interest not documented.

Clinical Question 3. What provider characteristics are associated with increased smoking cessation referrals/treatment?

Age of Healthcare Participant. A continuous variable that indicates the actual age of the participant on the date of the intervention.

Type of Provider. A nominal variable that indicates the type of provider.

Race. This is a nominal variable that indicates the race of the provider.

Years of Practice. A continuous variable that indicates the number of years that the provider has been in practice on the date of the intervention.

Gender. A nominal binary variable that indicates the provider's gender.

Smoking Status. A nominal variable that indicates what the smoking status is for the provider.

Improvement. A transformational continuous variable that indicates if there is an improvement in the percentage of patients that received the qualifying treatment by the healthcare participant (Phase III treatment - Phase II treatment).

Plan for Data Analysis

Following a careful review of the clinical research questions that needed to be answered, and determining the study design, a plan for data analysis was devised. Clinical Question #1 is a causal question that seeks information about the effect of an intervention on an outcome. Clinical Question #2 is seeking to determine if the percentage of smokers that wish to quit within the FQHC study clinic is similar to other national statistics and studies. Clinical Question #3 is a relational question that seeks information about the relationship among variables, and whether there is an association between the independent variable and the dependent variable.

For each variable, the level of measurement will be determined and put into SPSS Version 24. Each of the values associated with that variable will also be entered. Excel files where the original data were downloaded into the SPSS Version 24 data file. Only one individual was responsible for retrieving and analyzing the data by a retrospective medical chart review after the algorithms were developed to ensure continuity and reduce bias. Any duplicate files of patients seen more than once during the designated period were removed. A determination as to whether the variable is dependent or independent was done. For any nominal data, graphic representations were created using pie graphs showing frequencies and percentages, and descriptive statistics were run. For any interval or ratio data variables, the descriptive statistics were run to demonstrate

the mean, median, and mode, range, percentiles, and levels of skewness and kurtosis were run. A graphic histogram was created to determine if there was a normal distribution, and statistical normality tests for small sample sizes were used to determine if there was a normal distribution. Box Plots were also used to determine normality, and to determine if there were significant outliers. Scatter Plots were used to determine if there were any associations between the healthcare participant characteristics (i.e. age, years of practice, gender, smoking status) and the Improvement variable. For Clinical Question #1, descriptive statistics will be used to describe the Difference continuous variable (Post-Intervention Percentage – Pre-Intervention Percentage). In addition to the above, inferential statistics that will be used is the Wilcoxon Ranked Test, if the results are non-parametric for the paired sample testing.

For Clinical Question #2, simple descriptive statistics will be run to determine the percentage of current smokers that wish to quit.

For Clinical Question #3, descriptive statistics will be used for all independent and dependent variables. As stated above graphics will be used to demonstrate the percentages in the form of pie graphs and histograms. For any variables that are normally distributed, parametric inferential testing will be done by Pearson's Correlation. For the non-parametric testing required secondary to lack of normality, Spearman's Rho will be utilized for binomial variables and ordinal variables. When correlating nominal categorical variables with continuous ratio variables, chi-square analysis will be performed using SPSS Version 24 for all the above.

TimeLine

The timeline for this study commenced after IRB approval. Phase 1 began with the educational intervention and the recruitment of the participants. Phase 2 started following the educational intervention and retrospectively collected data for 8 weeks before the intervention. Phase 3 commenced 8 weeks post-intervention, and retrospectively collected data from the intervention until 8 weeks post-intervention.

Budget

The monetary cost for this project is estimated to be \$300.00 for printing costs of the quick reference materials, and printing of dissemination materials. The federally qualified healthcare clinic sponsored the costs of notebooks used for the quick reference materials, and the costs of utilizing a programmer to retrieve electronic health data. The APRN completing the intervention donated time for preparing and delivering the educational intervention and preparation of the quick reference notebooks. There were no additional costs that occurred during the study.

Conclusion

The project, setting, and population to be studied have been described in detail. The protection of human subjects and the data to be collected has been provided. All data collection procedures have been delineated for all phases of the study. The multicomponent intervention has been described to provide an overview of the content. The variables subject to statistical testing have been given for each clinical question. The plan for data analysis using SPSS Version 24 has been described, as well as the budget and timeline for the translational clinical project.

Results

The healthcare participants were recruited using convenience sampling. Data was gathered by retrospective medical record review after participants were recruited to collect for pre-intervention and post-intervention data. SPSS Version 24 (IBM, 2016) was used to calculate the statistical results of this study.

Clinical Question 1. How does education about smoking cessation and the provision of quick reference materials affect referrals to behavioral counseling and prescribing smoking cessation pharmacotherapy with healthcare providers at federally qualified healthcare centers in one southeastern state within an eight-week period? The Wilcoxon Rank test was run since the data was not normally distributed. A comparison of the pre-intervention compliance and post-intervention compliance showed an improvement of 11% ($Z=-2.09$, $p=.037$). Health care providers improved in their referrals of patients for smoking cessation treatment.

Clinical Question 2. What percentage of Self-Identified Current Smokers (SICS) expressed a willingness to attempt quitting? Descriptive statistics were run to determine the percentage of current smokers that have expressed a willingness to attempt quitting during the Post Intervention Period. Out of the identified tobacco users, 254 (61%) individuals were identified as interested in or thinking about quitting. These results are similar to the Center for Disease Control (2018) statistics (70%) who have expressed a desire to quit.

Clinical Question 3. What provider characteristics are associated with increased smoking cessation referrals/treatment?

Age Variable. Spearman's Rank-Order Correlation was run since the data for age and improvement were not normally distributed. Data indicated that the clinical question as to whether age and improvement were positively correlated was not supported. There was no significant positive correlation between age and improvement ($r=.042$, $p=.891$).

Years of Practice. Spearman's Rank-Order Correlation analysis was run since the data for the variable of years of practice and improvement were not normally distributed. Data indicated that clinical question as to whether years of practice and improvement were positively correlated was not supported. There

was no significant positive correlation between years of practice and improvement ($r=.127$, $p=.891$).

Gender Variable. Spearman's Rank-Order Correlation analysis was run since the data for the variable of gender (binomial) and improvement was not normally distributed. Data indicated that clinical question as to whether gender and improvement were positively correlated was not supported. There was no significant positive correlation between gender and improvement ($r^s=.058$, $p=.851$).

Race variable. Pearson's Chi-square analysis was run used to test the clinical question as to whether race and improvement were positively correlated. There was no significant correlation between race and improvement ($X^2=.853$, $df(2)$, $p=.653$).

Type of Provider. Pearson's Chi-square analysis was run to test the clinical question as to whether the type of provider and improvement were positively correlated. There was no significant positive correlation between the type of provider and improvement ($X^2=(3.494)$, $df=2$, $p=.174$).

Smoking Status. Pearson's Chi-Square analysis was run to test the clinical question as to whether the smoking status of the provider and improvement were positively correlated. There was no significant positive correlation between smoking status and improvement ($X^2=1.477$, $df=1$, $p=.224$). It should be noted that the sample did not include any current smokers, so the reliability of these statistical results could be called into question.

As it relates to Clinical Question #1, 17.4% of all "eligible" candidates received the "qualifying treatment" during the pre-intervention period. Following the implementation of the intervention, 28.96% of all "eligible" candidates received the "qualifying treatment". This resulted in 34 more patients or an 11% ($Z=-2.09$, $p=.037$) increase in the number of patients who have received the "qualifying treatment" during the post-intervention period. The result for Clinical Question #2 showed that the patients at the FQHC study clinic wished to quit smoking at a similar rate to the national statistics produced by the CDC (2018). The result for Clinical Question #3 showed no statistically significant positive correlation for any of the healthcare provider characteristics to improvement in the delivery of behavioral health and pharmacotherapy for smoking cessation treatment.

Discussion

Limitations

The small size of the sample (n=13) and the necessity of using a convenience sampling method reduced the ability to generalize the results of this study (Kellar and Kelvin, 2013). The outcome dependent variable measuring the difference in compliance with the provision of the “qualifying treatment” was measured after 8 weeks secondary to the time limitations for an academic translational project. The study could have been improved by examining the long-term effect of the multi-component intervention and the sustainability of the effect of the interventions by measuring the level of compliance after 6 months. Because the study only studied the impact on the healthcare provider in the delivery of the smoking cessation treatment and not the impact on the patient’s smoking abstinence, it did not result in the ability to determine the causal effect of the delivery of the smoking cessation treatment. Another limitation of this study is that during the intervention, instructions were given to where the documentation of compliance should be entered into the electronic health record to optimize the collection of that data. Since no instructions had been given before the documentation during the pre-intervention period it may have resulted in a decreased documentation of that delivery of that treatment.

One other factor that may have influenced the outcome of this study was the lack of incorporation of physicians in the presentation of the educational information. It might have provided some additional credibility to the information from the perspective of other physician providers.

As the quick reference materials were being developed, the difficulty in locating community resources for both behavioral health for smoking cessation and smoking cessation classes became evident. It would have been more helpful to have discovered these resources in our community, or at least been able to ascertain those resources in neighboring communities.

Some data collection issues became evident following some investigation. It was determined that not every medical assistant refreshed the data with each visit regarding smoking status. Rather than simply addressing the demographic and practice characteristics in the participant survey, it would have been more helpful to develop a validated and reliable survey tool for the healthcare providers that could determine their level of self-efficacy before and after the intervention.

Strengths

The strengths of this study include the fact that nearly all healthcare providers voluntarily engaged as participants in the study without any attrition. This demonstrated their interest in being a part of a quality improvement project that would benefit their patients for the FQHC study clinic.

Future Research

As an extension of the current research, determine whether the statistically significant impact of the educational training and the use of the reference materials on the healthcare providers could be retained at six months. Research for the future should focus on the impact of the use of interventions using web site applications and text messaging for smoking cessation.

Summary

This translational clinical project provided answers to the clinical questions studied. The data collected and analyzed for Clinical Question #1 during Phase II (pre-intervention) and Phase III (post-intervention) demonstrated a statistically significant ($Z=-2.09$, $p=.037$) increase in compliance (provision of “qualifying treatment” to “eligible” patients) following the multicomponent intervention. A comparison of the pre-intervention compliance and post-intervention compliance showed an improvement of 11%.

The data collected and analyzed for Clinical Question #2 during Phase III (post-intervention) demonstrated that the current smokers at the FQHC study clinic wished to quit smoking (61%). According to national statistics generated by the CDC (2017), approximately 70% of current smokers wished to quit. These results demonstrate that the desire to quit at the FQHC study clinic is similar to national data.

The data collected and analyzed for Clinical Question #3 during Phase One from the Healthcare Provider Survey (i.e. age, years of practice, race, provider type, smoking status) was determined to have no positive correlation to the healthcare provider improvement in compliance.

Conclusion

Significant progress has been made in the reduction of tobacco use in the United States, but the smoking prevalence among the socially and economically disadvantaged populations (i.e. individuals who are homeless, uninsured, LGBT, and living with HIV) is significantly higher than the general population (CDC, 2018b). This results in this population carrying a disproportionate burden of tobacco-related mortality and morbidity (CDC, 2018b). There is a cost-effective and evidence-based treatment for tobacco use dependence (Fiore et al, 2008), but the delivery by primary care providers to this population (Tyman, Bonevski, Paul, and Bryant, 2014) is inconsistent. The study focused on determining whether the delivery of a multicomponent intervention (i.e. educational session, quick reference materials, and prompts in the electronic health records) to the health care providers ($n=13$) at a federally qualified health care clinic would result in an improvement of behavioral health referrals and pharmacotherapy for smoking cessation. A retrospective review of the 8 weeks before the intervention, and 8

weeks after the intervention, was conducted to examine changes in provider compliance with smoking cessation treatment guidelines. The data collected suggested that there was a statistically significant increase in compliance with the delivery of the qualifying treatment ($Z=-2.09$, $p=.037$) following the intervention. The study also examined the relationship between demographic characteristics of providers and improvement in provider compliance with no significant positive correlations. Additional research is needed to examine whether this improvement in compliance can be sustained at six months.

References

- Abdullah, A. S., Stillman, F. A., Yang, L., Luo, H., Zhang, Z., & Samet, J. M. (2013). Tobacco use and smoking cessation practices among physicians in developing countries: a literature review (1987-2010). *International journal of environmental research and public health*, *11*(1), 429-55. DOI:10.3390/ijerph110100429
- American Cancer Society. (2017). Harmful chemicals in tobacco products. Retrieved from https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/carcinogens-found-in-tobacco-products.html?_ga=2.231645980.288609715.1545243068-1156338317.1545243068
- American Cancer Society. (2018). Deciding to quit smoking and making a plan. Retrieved from <https://www.cancer.org/healthy/stay-away-from-tobacco/guide-quitting-smoking/deciding-to-quit-smoking-and-making-a-plan>
- American Lung Association. (2018). State of tobacco control-2018. Retrieved from <https://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/2018>
- American Lung Association. (2019). State of tobacco control-2019. Retrieved from <https://www.lung.org/our-initiatives/tobacco/reports-resources/sotc/2019>
- Anderson, P. and Jane-Llopis, E. (2004). How can we increase the involvement of primary health care in the treatment of tobacco dependence? A meta-analysis. *Addiction* *99*(3), 299-312.
- Arispe, K. (2018). Smoking Prevalence Report. (Personal Communication on April 18, 2018).

Baggett, T., Tobey, M.L. & Rigotti, N.A. et al. (2013). Tobacco Use among Homeless People; Addressing the Neglected Addiction. *N Engl J Med*, 369, 201-204. DOI: 10.1056/NEJMp1301935

Barua, R. S., and Rigotti, N. A., et al., (2018). ACC expert consensus decision pathway on tobacco cessation treatment. *Journal of American College of Cardiology*, 72(25), 1-34.

Boyles, S. (2017). WHO: Global cost of smoking nearly 2% of world GDP. Retrieved from <https://www.medpagetoday.com/pulmonology/smoking/62828>

Centers for Disease Control and Prevention. (n.d.). Health Effects-Smoking & Tobacco Use. Centers for Disease Control and Prevention. Retrieved from <http://www.cdc.gov/tobacco/basicinformation/healtheffects/index.htm>

Centers for Disease Control and Prevention, National Center for Health Statistics. (2010). Healthy people 2020. Retrieved from <https://www.healthypeople.gov/m>

Centers for Disease Control and Prevention. (2012). Quick stats: Current smoking among men aged 25–64 years, by age group and veteran Status—National Health Interview Survey (NHIS), United States, 2007–2010. *Morbidity and Mortality Weekly Report*, 61(45), 929.

Centers for Disease Control and Prevention. (2013). Trends in smoking before, during, and after pregnancy—Pregnancy Risk Assessment Monitoring System, United States, 40 sites, 2000-2010). *Morbidity and Mortality Weekly Report* 62(SS06), 1–19

Centers for Disease Control and Prevention. (2013). Vital Signs: Current Cigarette Smoking Among Adults Aged>18 Years with Mental Illness-United States, 2009-2011. *Morbidity and Mortality Weekly Report* 62 (05), 81–7.

Centers for Disease Control and Prevention. (2015). National Center for Health Statistics. National Health Interview Survey-2015. Analysis performed by the American Lung Association Epidemiology and Statistics Unit using SPSS software.

Centers for Disease Control and Prevention. (2014). Quick Stats: Current Smoking Among Men Aged 25-64, by Age Group and Veteran Status-National

Health Interview Survey (NHIS), United States 2007-2010. *Morbidity and Mortality Weekly Report*, 61(45), 929

Centers for Disease Control and Prevention. (2014). Current Cigarette Smoking Among Adults-United States, 2005–2013. *Morbidity and Mortality Weekly Report*, 69(47), 1108–12.

Centers for Disease Control and Prevention. (2015). *Best Practices User Guide: Health Equity in Tobacco Prevention and Control*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.

Centers for Disease Control and Prevention. (2017). Quitting smoking among adults-United States, 2000–2015. *Morbidity and Mortality Weekly Report* 65(52), 1457-64.

Centers for Disease Control and Prevention. (2018a). Truth initiative: Inspiring tobacco-free lives. Retrieved from: <https://truthinitiative.org/tobacco-use-georgia>

Centers for Disease Control and Prevention. (2018b). Smoking is down, but almost 38 million American adults still smoke. Retrieved from <https://www.cdc.gov/media/releases/2018/p0118-smoking-rates-declining.html>

Chung, A., Lavender, A., Bayakly, R. (2016). *Georgia Adult Disparities in Tobacco Use Report*. Georgia Department of Public Health, Health Protection, Epidemiology, Chronic Disease, Healthy Behaviors, and Injury Epidemiology Section.

Colomar, M., Tong, V., Morello, P., Farr, S., Lawin, C., Dietz, P.,.....Althabe, F. (2014). Barriers and promoters of an evidence-based smoking cessation counseling during prenatal care in Argentina and Uruguay. *Matern Child Health J*, 19, 1481-1489. DOI: 10.1007/s10995-014-1652-3

Crenshaw, W, (2015). Health leaders want to cut the smoking rate in the Macon area. *Telegraph*. Retrieved from <https://www.macon.com/news/local/article43288590.html>

- Danesh, D., Paskett, E.D., & Ferketich, A.K. (2014). Disparities in receipt of advice to quit smoking from health care providers: 2010 National Health Interview Survey. *Prev Chronic Dis*, 11, E131. Retrieved from <http://dx.doi.org/10.5888/pcd11.140053>
- Drope et al. (n.d.) *Tobacco Atlas 6th ed.* Retrieved from the American Cancer Society website at <https://tobaccoatlas.org/authors/>
- Fiore, M.C. Jaen, C. R., Baker, T.B., et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.
- Flocke, S.A., Hoffman, R., Eberth, J.M., Park, H., Birkby, G., Trapl, E., & Zeliadt, S. (2017). The prevalence of tobacco use at federally qualified health centers in the United States. *Prev Chronic Dis* 14(E29). DOI: <http://dx.doi.org/10.5888/pcd14.160510>.
- Georgia Department of Health, (2016). Adult tobacco use in Georgia: 2016 data summary. Retrieved from <https://dph.georgia.gov/sites/dph.georgia.gov/files/2016%20Adult%20Tobacco%20Use%20in%20Georgia.pdf>
- Goodchild, M., et al. (2017). “Global economic cost of smoking-attributable disease”. *Tob Control*; DOI:10.1136/tobaccocontrol-2016-053305.
- Gvinianidze, K., & Tsereteli, D. (2012). Tobacco smoking-attributable mortality and years of potential life lost in Georgia. *Georgian Med News*, 206, 52-7.
- Health Resources and Services Administration (HRSA). (2018). Retrieved from <https://www.hrsa.gov/opa/eligibility-and-registration/health-centers/fqhc/index.html>
- Himelhoch, S., Riddle, J., and Goldman, H. H. (2014). Barriers to implementing evidence-based smoking cessation practices in nine community mental health sites. *Psychiatry online*. Retrieved from <https://doi.org/10.1176/appi.ps.201200247>
- IBM Corp. (2016). IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.
- Institute of Medicine. (2009). *Combating Tobacco in Military and Veteran Populations.* Washington: The National Academies Press
- Institute of Medicine. (2015). *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products.* Washington: The National Academies Press.

- Jamal, A., King, B., Neff, L., Whitmill, J., Babb, S., & Graffunder, C. (2016). Current cigarette smoking among adults — United States, 2005–2015. *Morbidity and Mortality Weekly Report*, 65(44);1205–1211.
- Jamal, A., Phillips, E., Gentzke, A.S., et al. (2018). Current Cigarette Smoking Among Adults—United States, 2016. *Morbidity and Mortality Weekly Report*, 67, 53-59. DOI: <https://www.cdc.gov/mmwr/volumes/67/wr/mm6702a1.htm>
- Kotter, J.P. (1996). *8 Step Process for Leading Change*. Boston: Harvard Business School Press.
- Kruger, J., O’Halloran, A., Rosenthal, A., Babb, S.D., Fiore, M. C. (2016). Receipt of evidence-based brief cessation interventions by health professionals and use of cessation assisted treatments among current adult cigarette-only smokers: National Adult Tobacco Survey, 2009-2010. *BMC Public Health*, 16, 141 DOI: 10.1186/s12889-016-2798-2
- Lipari, R., & Van Horn, S. (2017). Smoking and mental illness among adults in the United States. Retrieved from https://www.samhsa.gov/data/sites/default/files/report_2738/ShortReport-2738.html
- Martell, B.N., Garrett, B.E., Caraballo, R.S. (2016). Disparities in Adult Cigarette Smoking—United States, 2002-2005, and 2010-2013. *Morbidity and Mortality Weekly Report*, 65, 753-758. DOI: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6530a1.htm>
- Mdodo, R., Frazier, E.L., Dube, S.R., Mattson, C.L., Sutton, M.Y., Brooks, J.T., & Skarbinski, J. Cigarette Smoking Prevalence Among Adults With HIV Compared With the General Adult Population in the United States: Cross-Sectional Surveys. *Annals of Internal Medicine*, 162,335–44.
- McClave, A. K., McKnight-Eily, L. R., Davis, S. P., & Dube, S. R. (2010). Smoking characteristics of adults with selected lifetime mental illnesses: results from the 2007 National Health Interview Survey. *American Journal of Public Health*, 100(12), 2464-72.

Medicare Access and CHIP Reauthorization Act of 2015. Pub. L. 114-10

- National Cancer Institute. (2019). Benefits of Quitting Smoking. Retrieved from <https://smokefree.gov/quit-smoking/why-you-should-quit/benefitsofquitting>.
- North Central Health District. (2019). About North Central Health District. Retrieved from <http://northcentralhealthdistrict.org/>
- Papadakis, S., Cole, A.G., Reid, R.D., Coja, M., Aitken, D., Mullen, K. Gharib, M., & Pipe, A. (2016). Increasing rates of tobacco treatment delivery in primary care practice: Evaluation of the Ottawa model for smoking cessation. *Ann Fam Med*, 14 (3), 235-243. DOI: 10.1370/afm.1909
- Papadakis, S., Gharib, M., Hambleton, J., Reid, R.D., Assi, R., and Pipe, A.L. (2014). Delivering evidence-based smoking cessation treatment in primary care practice: experience of Ontario family health teams. *Can Fam Physician* 60(7), 362-371.
- Papadakis, S., Cole, A.G., Reid, R.D., Coja, M., Aitken, D., Mullen, K.A., Gharib, M., Pipe, A.L. (2016). Increasing rates of tobacco treatment delivery in primary care practice: Evaluation of the Ottawa Model for smoking cessation. *Ann Fam Med* 14(3), 235-43. DOI: 10.1370/afm.1909
- Patient Protection and Affordable Care Act*, 42 U.S.C. § 18001 et seq. (2010).
- Piper, M.D., Cook, J.W., Schlam, T. R., Jorenby, D. E., Smith, S. S., Collins, L. M., Mermelstein, R., Fraser, D., Fiore, M. C. & Baker, T. B. (2018). A randomized controlled trial of an optimized smoking treatment delivered in primary care. *Annals of Behavioral Medicine*, 52(10), 854-864. <https://doi.org/10.1093/abm/kax059>
- Raw, M., Mackay, J. & Reddy, S. (2016). Time to take tobacco dependence treatment seriously. *Lancet [Internet]*. Elsevier Ltd 6736, (1-2). Retrieved from [http://dx.doi.org/10.1016/S0140-6736\(15\)00950-2](http://dx.doi.org/10.1016/S0140-6736(15)00950-2).
- Roberts, N.J., Kerr, S.M., & Smith, S.M. (2013). Behavioral interventions associated with smoking cessation in the treatment of tobacco use. *Health Serv Insights*, 11(69), 79-85. DOI: 10.4137/his.S11092
- Substance Abuse and Mental Health Services Administration. (2014). Behavioral Health Trends in the United States: Results from the 2014 National Survey on Drug Use and Health. Retrieved from

<https://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf>

- Siru, R., Hulse, G. K., Khan, R.J., et al. (2010). Motivation to quit smoking among hospitalized individuals with and without mental health disorders. *Australian and New Zealand Journal of Psychiatry* 44, 640-647.
- Stead, L., Koilpillai, P., Fanshawe, T., & Lancaster, T. (2016). Combined pharmacotherapy and behavioural interventions for smoking cessation. [Online]. *Cochrane Database Syst Rev.* 2016;3CD008286. Retrieved from <http://publichealthwell.ie/node/299214>.
- Tobacco-Free Kids. (2018). Broken Promises to Our Children: State-by-State Look at the 1998 Tobacco Settlement 20 Years Later. Retrieved from <https://www.tobaccofreekids.org/what-we-do/us/statereport>
- Twyman, L. Bonevski, B, Paul, C & Bryant, J. (2014). Perceived barriers to smoking cessation in selected vulnerable groups: A systematic review of the qualitative and quantitative literature. *BMJ Open*, 4(12), e006414. DOI:10.1136/bmjopen-2014-006414
- United Health Foundation. (2018). American Health's Rankings Annual Report-2018. Retrieved from <https://www.americashealthrankings.org/explore/annual/measure/Smoking/state/GA>
- US News and World Report (n.d.). Smoking cessation. Retrieved from <https://health.usnews.com/health-conditions/allergy-asthma-respiratory/smoking-cessation/overview> on January 26, 2019.
- U.S. Preventive Services Task Force. (2015). *Final Update Summary: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*. U.S. Preventive Services Task Force. September 2015. Retrieved from <https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1>
- U.S. Preventive Services Task Force. (2018). *Final Research Plan: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Interventions*. U.S. Preventive Services Task Force. July 2018. Retrieved from

<https://www.uspreventiveservicestaskforce.org/Page/Document/final-research-plan/tobacco-smoking-cessation-in-adults-including-pregnant-women-interventions>

- U.S. Department of Health and Human Services. (1998). *Tobacco Use Among U.S. Racial/Ethnic Minority Groups-African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders, Hispanics: A Report of the Surgeon General*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- U.S. Department of Health and Human Services (USDHHS), (2013). *Healthy People-2020*. Washington, D.C.: U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. (2013). *Healthy People 2020*. Retrieved from <https://www.healthypeople.gov/2020/topics-objectives/topic/tobacco-use/objectives>
- US Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General*. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
- United Nations, General Assembly (2011). *Political declaration of the high-level meeting of the general assembly on the prevention and control of non-communicable diseases, A/66/L.1*. Retrieved from http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1.
- Van Schayck, O.C., Williams, S., Barchilon, V., Baxter, N., Jawad, M., Katsaounou, P.A., Kirenga, B.J., Panaltescu, C., Tsillgianni, K.W., Zwar, N. & Ostrem, A. (2017). Treating tobacco dependence: Guidance for primary care on life-saving interventions. Position statement of the IPCRG. *Primary Care Respiratory Medicine* 27 (38), DOI:10.1038/s41533-017-0039-5
- Walker, E. R., McGee, R. E., & Druss, B. G. (2015). Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA Psychiatry*, 72(4), 334-41.

Whitehead, M., & Dahlgren, G. *Leveling Up (Part 1): A Discussion Paper on Concepts and Principles for Tackling Social Inequities in Health*. Copenhagen, Denmark: World Health Organization, Regional Office for Europe; 2006.

World Health Organization (n.d.) Fact Sheet about health benefits of smoking cessation. Retrieved from <https://www.who.int/tobacco/quitting/benefits/en/> World Health Organization. (2011). WHO global report: Mortality attributable to tobacco. Retrieved from http://apps.who.int/iris/bitstream/10665/44815/1/9789241564434_eng.pdf

World Health Organization. (2014). *Toolkit for Delivering the 5A's and 5 R's brief tobacco intervention in primary care*. Geneva, Switzerland; WHO Press. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/112835/9789241506953_eng.pdf;jsessionid=7A3E873BD2237654BF8EF8EAD67425B1?sequence=1

World Health Organization. (2015). WHO on the Global Tobacco Epidemic. Retrieved from http://www.who.int/tobacco/global_report/2015/report/en.

World Health Organization-Regional Office for Europe. (2018). *WHO FCTC: High Level of Ratification, Low Level of Full Implementation Report*. Geneva: World Health Organization.

Wray, J.M., Funderburk, J. S., Acker, J.D., Wray, L.O. & Maisto, S.A. (2018). A meta-analysis of brief tobacco interventions for use in integrated primary care. *Nicotine & Tobacco Research*, 20(12), 1418-1426.

Appendix A

Fact sheet about the health benefits of smoking cessation

1. There are immediate and long-term health benefits of quitting for all smokers.

Beneficial health changes that take place:

- a. Within 20 minutes, your heart rate and blood pressure drop.
- b. 12 hours, the carbon monoxide level in your blood drops to normal.
- c. 2-12 weeks, your circulation improves and your lung function increases.

- d. 1-9 months, coughing, and shortness of breath decrease.
- e. 1 year, your risk of coronary heart disease is about half that of a smoker's.
- f. 5 years, your stroke risk is reduced to that of a nonsmoker 5 to 15 years after quitting.
- g. 10 years, your risk of lung cancer falls to about half that of a smoker, and your risk of cancer of the mouth, throat, esophagus, bladder, cervix, and pancreas decreases.
- h. 15 years, the risk of coronary heart disease is that of non-smokers.

2. People of all ages who have already developed smoking-related health problems can still benefit from quitting.

Benefits in comparison with those who continued:

- a. At about 30: gain almost 10 years of life expectancy.
- b. At about 40: gain 9 years of life expectancy.
- c. At about 50: gain 6 years of life expectancy.
- d. At about 60: gain 3 years of life expectancy.

After the onset of life-threatening disease: rapid benefit, people who quit smoking after having a heart attack reduce their chances of having another heart attack by 50%

3. Quitting smoking decreases the excess risk of many diseases related to second-hand smoke in children.

Quitting smoking decreases the excess risk of many diseases related to second-hand smoke in children, such as respiratory diseases (e.g., asthma) and ear infections.

4. Others benefits.

Quitting smoking reduces the chances of impotence, having difficulty getting pregnant, having premature births, babies with low birth weights and miscarriage.

Source: World Health Organization. (2014). Toolkit for Delivering the 5A's and 5 R's brief tobacco intervention in primary care. Geneva, Switzerland; WHO Press. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/112835/9789241506953_eng.pdf;jsessionid=7A3E873BD2237654BF8EF8EAD67425B1?sequence=1World Health Organization (2014.)

Appendix B

10 Key Recommendations

1. Tobacco dependence may require repetitive interventions, and multiple quit attempts by smokers to accomplish smoking cessation. The research supports that effective treatments are in existence and they can improve the success rate of long-term smoking abstinence;
2. It is imperative that clinicians consistently identify tobacco use status and then treat every tobacco user seen in their health setting;

3. Tobacco cessation treatments are effective for most populations. Healthcare providers should assist every patient willing to make a quit attempt to use the behavioral/counseling treatments and smoking cessation medications that are recommended by this guideline;
4. Brief tobacco dependence treatment can be effective and should be offered as a minimum;
5. Individual, group and telephone behavioral health counseling are effective, and the more intense the treatment the more effective;
6. Numerous medications are available for treatment for tobacco dependence; Clinicians should encourage the use of these medications for all patients attempting to quit smoking, unless medically contraindicated or where there is insufficient evidence of effectiveness. The medications recommended that are proven to increase long-term smoking abstinence: Bupropion SR, Nicotine gum, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine patch, and varenicline. They also recommended that certain combinations can be effective with certain populations;
7. Counseling for smoking cessation and medications are effective either by themselves. The most effective treatment is the combination of counseling and smoking cessation pharmacotherapy. As clinicians we should encourage all making a quit attempt to use both;
8. Telephone quitline counseling is effective with many different population groups, and healthcare providers should ensure that patients should have access to quitlines and promote its use;
9. If a current smoker of tobacco is unwilling to make a quit attempt upon being advised to quit, the healthcare providers should use the evidence-based motivational treatment to increase future quit attempts;
10. The recommended treatment is effective and cost-effective and recommended that insurance plans should ensure that the counseling and smoking cessation pharmacotherapy recommended is a covered benefit.

Source: Fiore, M.C. Jaen, C. R., Baker, T.B. et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline*. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

Appendix C

World Health Organization 5A's Model for Individuals Motivated to Quit

5A's	Action	Strategies for implementation
<p>Ask - Systematically identify all tobacco users at every visit.</p>	<ul style="list-style-type: none"> • Ask ALL your patients at every encounter if they use tobacco and document it. • Make it part of your routine. 	<ul style="list-style-type: none"> • Tobacco use should be asked about in a friendly way – it is not an accusation. • Keep it simple, some sample questions may include: <ul style="list-style-type: none"> – “Do you smoke cigarettes?” – “Do you use any tobacco products?” • Tobacco use status should be included in all medical notes. Countries should consider expanding the vital signs to include tobacco use or using tobacco use status stickers on all patient charts or indicating tobacco use status via electronic medical records.
<p>Advise: Persuade all tobacco users that they need to quit</p>	<ul style="list-style-type: none"> • Urge every tobacco user to quit in a clear, strong and personalized manner. 	<p>Advice should be:</p> <ul style="list-style-type: none"> • Clear – “It is important that you quit smoking (or using chewing tobacco) now, and I can help you.” “Cutting down while you are ill is not enough.” “Occasional or light smoking is still dangerous.” • Strong – “As your doctor, I need you to know that quitting smoking is the most important thing you can do to protect your health now and in the future. We are here to help you.” • Personalized – Tie tobacco use to: <ul style="list-style-type: none"> – <i>Demographics</i>: For example, women may be more likely to be interested in the effects of smoking on fertility than men. – <i>Health concerns</i>: Asthma sufferers may need to hear about the effect of smoking on respiratory function, while those with gum disease may be interested in the effects of smoking on oral health. “Continuing to smoke makes your asthma worse, and quitting may dramatically improve your health.” – <i>Social factors</i>: People with young children may be motivated by information on the effects of second-hand smoke, while a person struggling with money may want to consider the financial costs of smoking. “Quitting smoking may reduce the number of ear infections your child has.” <p>In some cases, how to tailor advice for a particular patient may not always be obvious. A useful strategy may be to ask the patient: – “<i>What</i> do you not like about being a smoker?”</p> <p>The patient’s answer to this question can be built upon by you with more detailed information on the issue raised.</p> <ul style="list-style-type: none"> – Example: Doctor: “What do you not like about being a smoker?” Patient: “Well, I don’t like how much I spend on tobacco.” Doctor: “Yes, it does build up. Let’s work out how much you spend each month. Then we can think about what you could buy instead!”

<p>Assess: Determine readiness to make a quit attempt</p>	<p>Ask two questions in relation to “importance” and “self-efficacy”: 1. “Would you like to be a nontobacco user?” “Do you think you have a chance of quitting successfully?”</p>	<p>Any answer to either question that is Unsure or No indicates that the tobacco user is NOT ready to quit. In these cases, you should deliver the 5 R’s intervention. Question 1 Unsure No Question 2 Unsure No</p> <p>If the patient is ready to go ahead with a quit attempt you can move onto Assist and Arrange steps.</p>
--	---	---

<p>Assist - Help the patient with a quit plan</p>	<ul style="list-style-type: none"> • Help the patient develop a quit plan • Provide practical counseling • Provide intra-treatment social support • Provide supplementary materials, including information on quitlines and other referral resources <p>Recommend the use of approved medication if needed</p>	<ul style="list-style-type: none"> •Use the STAR method to facilitate and help your patient to develop a quit plan: <ul style="list-style-type: none"> – Set a quit date ideally within two weeks. – Tell family, friends, and coworkers about quitting, and ask for support. – Anticipate challenges to the upcoming quit attempt. – Remove tobacco products from the patient’s environment and make the home smoke free. •Practical counseling should focus on three elements: <ul style="list-style-type: none"> – Help the patient identify the danger situations (events, internal states, or activities that increase the risk of smoking or relapse). – Help the patient identify and practice cognitive and behavioral coping skills to address dangerous situations. – Provide basic information about smoking and quitting •Intra-treatment social support includes: <ul style="list-style-type: none"> – Encourage the patient in the quit attempt – Communicate caring and concern – Encourage the patient to talk about the quitting process •Make sure you have a list of existing local tobacco cessation services (quitlines, tobacco cessation clinics, and others) on hand for providing information whenever the patient inquiries about them. •The support given to the patient needs to be described positively but realistically.
--	--	---

<p>Arrange - Schedule follow-up contacts or a referral to specialist support</p>	<p>Arrange - Schedule follow-up contacts or a referral to specialist support</p>	<p>When: The first follow up contact should be arranged during the first week. A second follow up contact is recommended within one month after the quit date.</p> <ul style="list-style-type: none"> •How: Use practical methods such as telephone, personal visit and mail/ email to do the follow-up. Following up with patients is recommended to be done through teamwork if possible. •What: <p>For all patients:</p> <ul style="list-style-type: none"> - Identify problems already encountered and anticipate challenges. - Remind patients of available extra-treatment social support. - Assess medication use and problems. - Schedule the next follow up contact. <p>For abstinent patients:</p> <ul style="list-style-type: none"> - Congratulate them on their success. <p>For patients who have used tobacco again:</p> <ul style="list-style-type: none"> - Remind them to view relapse as a learning experience. - Review circumstances and elicit recommitment. - Link to more intensive treatment if available.
--	--	---

Source: World Health Organization. (2014). *Toolkit for Delivering the 5A's and 5 R's brief tobacco intervention in primary care*. Geneva, Switzerland; WHO Press. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/112835/9789241506953_eng.pdf;jsessionid=7A3E873BD2237654BF8EF8EAD67425B1?sequence=1.

Appendix D

World Health Organization 5R's Model for Individuals Not Motivated to Quit

5R's	Strategies for implementation	Example
Relevance	<p>Encourage the patient to indicate how quitting is personally relevant to him or her.</p> <p>Motivational information has the greatest impact if it is relevant to a patient's disease status or risk, family or social situation (e.g. having children in the home), health concerns, age, sex, and other important patient characteristics (e.g. prior quitting experience, personal barriers to cessation).</p>	<p>HCP: "How is quitting most personally relevant to you?"</p> <p>P: <i>"I suppose smoking is bad for my health."</i></p>
Risks	<p>Encourage the patient to identify potential negative consequences of tobacco use that are relevant to him or her.</p> <p>Examples of risks are:</p> <ul style="list-style-type: none"> • Acute risks: shortness of breath, exacerbation of asthma, increased risk of respiratory infections, harm to pregnancy, impotence, and infertility. • Long-term risks: heart attacks and strokes, lung and other cancers (e.g. larynx, oral cavity, pharynx, esophagus), chronic obstructive pulmonary diseases, osteoporosis, long-term disability, and need for extended care. • Environmental risks: increased risk of lung cancer and heart disease in spouses; increased risk for low birth-weight, sudden infant death syndrome, asthma, middle ear disease, and respiratory infections in children of smokers. 	<p>HCP: "What do you know about the risks of smoking to your health? What particularly worries you?" "</p> <p>P: <i>"I know it causes cancer. That must be awful."</i></p> <p>HCP: "That's right – the risk of cancer is many times higher among smokers."</p>
Rewards	<p>Ask the patient to identify potentially relevant benefits of stopping tobacco use.</p> <p>Examples of rewards could include:</p> <ul style="list-style-type: none"> – improved health; – food will taste better; – improved sense of smell; – saving money; – feeling better about oneself; – home, car, clothing, and breath will smell better; – setting a good example for children and decreasing the likelihood that they will smoke; – having healthier babies and children; – feeling better physically; – performing better in physical activities. – improved appearance, including reduced wrinkling/aging of the skin and whiter teeth. 	<p>HCP: "Do you know how stopping smoking would affect your risk of cancer?"</p> <p>P: <i>"I guess it would be more successful if I quit."</i></p> <p>HCP: "Yes, and it doesn't take long for the risk to decrease. But it's important to quit as soon as possible."</p>

Source: World Health Organization. (2014). Toolkit for Delivering the 5A's and 5 R's brief tobacco intervention in primary care. Geneva, Switzerland; WHO Press. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/112835/9789241506953_eng.pdf;jsessionid=7A3E873BD2237654BF8EF8EAD67425B1?sequence=1.

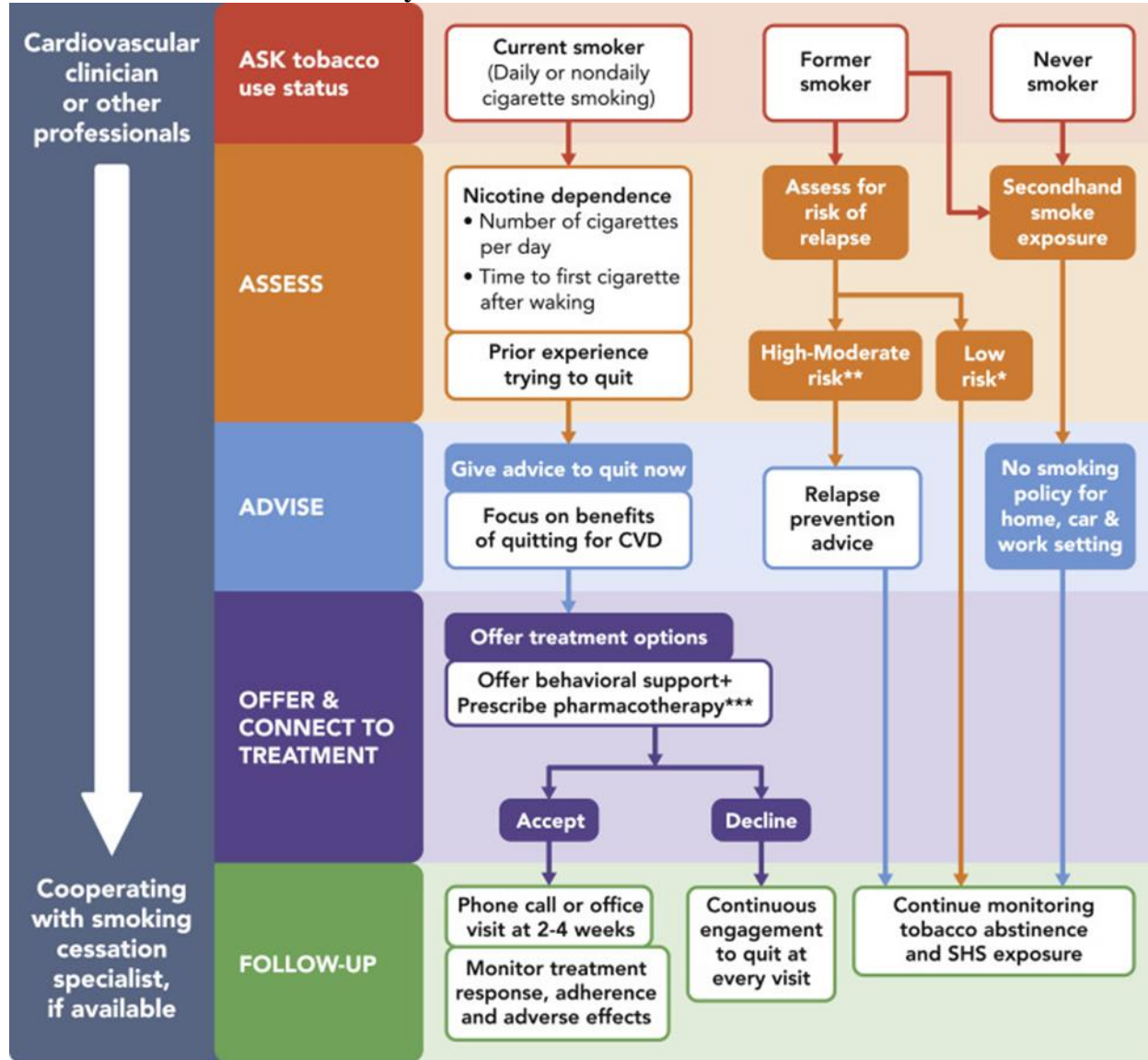
Appendix E

United States Preventive Services Task Force Recommendations

Adults who are not pregnant	The USPSTF recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, and provide behavioral interventions and the U.S. Food and Drug Administration (FDA)-approved pharmacotherapy for cessation to adults who use tobacco.	A
Pregnant Women	The USPSTF recommends that clinicians ask all pregnant women about tobacco use, advise them to stop using tobacco, and provide behavioral interventions for cessation to pregnant women who use tobacco.	A
Pregnant Women	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of pharmacotherapy interventions for tobacco cessation in pregnant women	I
All adults including pregnant women	The USPSTF concludes that the current evidence is insufficient to recommend electronic nicotine delivery systems (ENDS) for tobacco cessation in adults, including pregnant women.	I

Source: U.S. Preventive Services Task Force. (2015). *Final Update Summary: Tobacco Smoking Cessation in Adults, Including Pregnant Women: Behavioral and Pharmacotherapy Interventions*. U.S. Preventive Services Task Force. September 2015. Retrieved from https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummary_Final/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1

Appendix F
Consensus Decision Pathway on Tobacco Cessation Treatment



ABBREVIATIONS:
CVD = cardiovascular disease
SHS = secondhand smoke

*	More than 1 year since last cigarette
**	Refer to Figures 2 and 3
***	If not contraindicated
*	Refer to Tables 1 and 2

Source: Barua, R. S. and Rigotti, N. A., et al., (2018). ACC expert consensus decision pathway on tobacco cessation treatment. Taken from: <https://www.sciencedirect.com/science/article/pii/S0735109718388594?via%3Dihub>

APPENDIX G
INFORMED CONSENT

I, _____, agree to participate in the research “Effect of an Intervention to Improve Smoking Cessation treatment in a Federally Qualified Healthcare Clinic”, which is being conducted by Shirley A. Camp, JD, MSN, FNP-C, who can be reached at (478) 471-2979 or shirley.camp@bobcats.gcsu.edu. I understand that my participation is voluntary; I can withdraw my consent at any time. If I withdraw my consent, my data will not be used as part of the study and will be destroyed.

The following points have been explained to me:

1. The purpose of this study is an interdisciplinary effort to increase access to smoking cessation treatment for the underserved population at XXXXXXXXXXXXX with the provision of a smoking cessation treatment educational intervention that is individualized for a federally qualified healthcare clinic population. In addition, participants will be provided with quick reference materials that will provide information about behavioral healthcare community resources for smoking cessation and the efficacy and cost of smoking cessation pharmacotherapy.
2. The procedures are as follows: you will be asked to listen to an educational intervention conducted by the principal investigator and complete a simple demographic and practice survey. Once you have agreed to participate and signed the informed consent, data will be retrieved from the electronic health record of any patient that you have seen and treated in the previous eight (8) weeks who are self-identified smokers. The determination will be made if they indicated a willingness to quit smoking, and if so, whether they were referred to behavioral counseling (including the Georgia Smoking Quitline) or given prescriptions for smoking cessation pharmacotherapy. Following the educational intervention, the healthcare provider will be expected to implement the recommended treatment and documentation for smoking cessation treatment for all patients that express an interest in quitting tobacco use. For a period of eight (8) weeks following the educational intervention, the same data will be collected to determine if there has been an increase in the percentage of behavioral health referrals and/or smoking cessation pharmacotherapy prescriptions.

3. Your name will be connected to your demographic/practice survey but will be secured and maintained in the sole possession of the Principal Investigator. Following one year, the survey will be confidentially destroyed. Two reports will be generated for the PI per participant by the computer technician with the aggregate patient data. No patient names or nor patient medical record numbers will be provided to PI. No FCPC administration will have access to any of this provider-specific information. Any dissemination of this information for publication will be provided only in the aggregate and without mention of provider names or patient names. Any patient files will be protected by a password-protected file, and a laptop which is placed in a locked secure location, unless in the immediate presence of the principal investigator.
4. You will be asked to sign two identical consent forms. You must return one form to the investigator before the study begins, and you may keep the other consent form for your records.
5. You may find that some questions are invasive or personal. If you become uncomfortable answering any questions, you may cease participation at that time.
6. This research project is being conducted because of its potential benefits, either to individuals or to humans in general. The expected benefits of this study include 1) improving your understanding of the most recent evidence-based smoking cessation treatment that is individualized for the patient population that is treated at a federally qualified healthcare clinic; 2) improving the percentage of self-identified patients that are referred to behavioral counseling for smoking cessation; 3) improving the percentage of patients who are self-identified smokers (SIS) that receive smoking cessation pharmacotherapy (if eligible). Because of the established effectiveness of these two interventions, the resulting increase in smoking quit rates, and abstinence has a substantial economic and health outcomes effect.
7. You are not likely to experience physical, psychological, social, or legal risks beyond those ordinarily encountered in daily life or during the performance of routine examinations or tests by participating in this study.
8. Your responses will be confidential and will not be released in any individually identifiable form without your prior consent unless required by law.
9. The investigator will answer any further questions about the research should you have them now or in the future (see above contact information).

10. In addition to the above, further information, including a full explanation of the purpose of this research, will be provided after the research project has been completed on request.
11. By signing and returning this form, you are acknowledging that you are 18 years of age or older.

Signature of Investigator

Date

Signature of Participant

Date

.....
Research at Georgia College involving human participants is carried out under the oversight of the Institutional Review Board. Address questions or problems regarding these activities to Dr. Whitney Heppner, GC IRB Chair, CBX 090, GC, email: irb@gcsu.edu; phone: (478) 445-0870.

Appendix H

**Effect of an Intervention to Improve Smoking Cessation
Treatment in a Federally Qualified Healthcare Clinic
Healthcare Provider Participant Survey (Phase I)**

Participant Name

Last Name

First Name

Type of Provider (Circle appropriate answer)

MD

NP

PA

Age (Circle appropriate answer) (Years)

18-29

30-39

40-49

50-59

60-69

70 or above

Race (Circle appropriate answer)

Caucasian

African-American

Asian

Other

Gender (Circle appropriate answer)

Female

Male

Years of Practice (Circle appropriate answer)

0-2 years of practice

3-5 years of practice

6-10 years of practice

11-19 years of practice

20 or above years of practice

Smoking Status of Provider

Current

Former

Never

After this data was received, the participants were contacted and requested that they provide their actual age and the years of practice on July 25, 2018, for more accurate statistical purposes.

Appendix I

Effect of an Intervention to Improve Smoking Cessation Treatment in a Federally Qualified Healthcare Clinic Educational Program for Healthcare Providers

Identification of the Problem

Smoking Prevalence Rate at FQHC Study Clinic

International, National and State Goals for Tobacco Control

Primary Care Providers Delivery

Study Design

Clinical Questions

Purpose of the Study

Participation in Study

Background information

Health Risks and Economic Costs Associated with Tobacco Use

Benefits of tobacco cessation

Prevalence among Vulnerable populations

Literature Review

Clinical Guidelines for Tobacco Use Dependence Treatment

Key Recommendations

Review of 5 A's and 5 R's Model

USPSTF Recommendations for Tobacco Use Treatment

American College of Cardiology Decision Tree

Multicomponent Intervention Can Improve Delivery of Smoking Cessation Treatment

**Identification of Barriers and Factors in Delivery of Smoking
Cessation Treatment**

Presentation by Executive Director for Georgia Smoking Quit Line

Presentation by Director of Community Smoking Cessation Classes

Required EHR Documentation to Determine Compliance for Study

**Qualified Behavioral Health Referrals and Pharmacotherapy
for Smoking Cessation Treatment**

Review of Quick Reference Materials

Copy of Clinical Guidelines for Tobacco Use Dependence

Efficacy, Issues, and Costs Associated with Smoking Cessation

Pharmacotherapy

**Insurance Coverage/Costs Associated with Behavioral Health
Referrals and Pharmacotherapy for Smoking Cessation**

**Impact of the Patient Care and Affordability Care Act
(2010)**

Available Coupons for Smoking Cessation

Pharmacotherapy