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

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Abstract

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). As a result, these vulnerable populations carry 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 is inconsistent (Tyman, Bonevski, Paul, & Bryant, 2014). This 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 in the percentage of behavioral health referrals and pharmacotherapy for smoking cessation treatment. A retrospective electronic medical record review of the 8 weeks prior to 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.

Keywords: tobacco use, tobacco cessation, primary care, theories of behavior change, health professionals

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Chapter 1

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).

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).

There are many forms of tobacco on the market (light, hand-rolled, natural, or herbal cigarettes, menthol, cigars, small cigars, kreteks, beedies, hookahs) and there are misconceptions that these forms are safer, or don't cause health issues (ACS, 2017). One cigar can contain the same amount of nicotine as an *entire pack of cigarettes* (ACS, 2017, USDHHS,

2014) and because of the manufacturing process cigars have increased concentrations of nitrates and nitrites. When the cigars are smoked, the nitrosamines that are given off produces some of the most potent carcinogens (ACS, 2017). While there are other forms of tobacco use with significant health effects, the focus of this study is on individuals who have identified themselves as current tobacco smokers (i.e. tobacco cigarettes, small cigars, hand-rolled and cigars).

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). The populations addressed within this next section of the paper are examples of the types of vulnerable populations served at FQHC's.

Race/ethnicity. 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%. American Indians/Alaska Natives (AI/ANs) have the highest prevalence of current smoking than any of the other racial/ethnic groups in the United States (Jamal et al., 2018). Factors that may contribute to this group's prevalence rates involve the ceremonial, medicinal and religious role of tobacco in their culture (USDHHS, 1998). Another factor may be that tobacco that is sold on tribal lands is not generally subject to state and national tobacco taxes. Because this lowers costs of the tobacco, it results in increased usage (USDHHS, 2014). In the Jamal et al., (2018) article, Vietnamese in 2016 had the highest prevalence rates of the Asian population at 24.4%. Non-Hispanic Black adults (2016) had a prevalence rate of 16.5% overall. Interestingly, cigarette smoking among

non-Hispanic Black high school students was only 3.9% compared to 8.0% in the general high school population (Jamal et al., 2018). While it appears that non-Hispanic Blacks don't start smoking in high school at the same rate as other races, that difference doesn't translate to adulthood (Jamal et al., 2018). The smoking prevalence was significantly higher among non-Hispanic Black men (20.2%) than among non-Hispanic Black women (13.5%). During the period from 2005 to 2016, there was a reduction of cigarette smoking prevalence in non-Hispanic Blacks from 21.5% to 16.5% (Jamal et al., 2018). The smoking prevalence rates among Hispanics (10.7 %) is generally lower than other racial/ethnic groups in the United States, except for the non-Hispanic Asians (Jamal et al., 2016). The *National Survey on Drug Use and Health (2010-2013)* demonstrates a differentiation among the Hispanic subpopulations (Martell, Garrett and Caraballo, 2016). Among Hispanic women, the smoking prevalence rate ranged from 11.4% in Central or South Americans to 32.1% in Puerto Rican women (Martell et al., 2016). Among Hispanic men, the range extended from 19.8% for Central or South Americans to 32.1% for Puerto Ricans (Martell et al., 2016). According to the CDC Morbidity and Mortality Weekly Report (Jamal et al., 2016), there was a difference in the smoking prevalence rates within multiracial groups (27.9%).

Lesbian, gay, bisexual and transgender populations. Among the Lesbian, Gay, Bisexual, and Transgender (LGBT) individuals the smoking prevalence (20.5%) rate in the United States is higher than the heterosexual population (15.3%) (Jamal, et al., 2018). The prevalence rate is approximately 36% for transgenders (American Lung Association [ALA], 2018). Factors that may be impacting this rate may be due to the aggressive marketing to these individuals, and with stress related to the stigma and prejudice, they may face (CDC, 2014).

Military. Cigarette smoking prevalence (2011) in the United States among the active duty military (24%) is higher than in the civilian population (19.0%) (CDC, 2012). Male

veterans aged 25-64 years (2007-2010) were more likely to be currently smoking (29%) than non-veterans (24%) (Institute of Medicine, 2009).

Pregnant women. There is a modest decrease in smoking prevalence in pregnant women during and immediately following delivery (2000-2010) according to CDC (2013). In this study, the data from 27 sites which represents 52% of the live births showed that 23% were smoking in the 3 months prior to pregnancy, and that 54.3% of the women reported that they had quit by the last 3 months of pregnancy, and almost 16% were smoking after delivery (CDC, 2013).

Adults living with HIV. For adults living with HIV in 2009, the cigarette smoking prevalence (42.4%) has been estimated to be two times higher than the general population (Mdodo et al., 2015). Because of the advances in treatment, HIV has become a chronic disease, However, cigarette smoking places them at a higher risk for cancer, chronic obstructive pulmonary disease, stroke, HIV related infections, and heart disease (Mdodo et al., 2015).

Individuals with mental health conditions. In the United States, nearly 1 in 5 adults (approximately 45.7 million adults) have some form of mental health condition (CDC, 2013). A mental health condition as defined above is a mental, emotional or behavioral condition that is diagnosable but does not include substance use or developmental disorders (CDC, 2013). The smoking prevalence rate for this population is 36%, whereas that rate is only 21% for adults that do not have mental health conditions (CDC, 2013). Nearly 31% of all cigarettes that are smoked by adults have a mental health condition (CDC, 2013). According to the CDC (2013), thirty-four (34) percent of women and forty (40) percent of men with a mental health condition smoke. At least 33% of individuals with a mental health condition who are above the poverty level smoke, whereas 48% of individuals who have a mental health condition that lives below the

poverty level smoke (CDC, 2013). The overall prevalence of smoking remains stubbornly high with individuals with mental illness (Lipari and Van Horn, 2017). Smoking prevalence for adults with serious psychological distress ranges from 34.3% (phobias or fears) to 88% (schizophrenia) (McClave, Davis, McKnight, & Dube, 2010). It is estimated that 25% of the population within the United States suffers from some form of mental illness or a substance use disorder, and that population is responsible for smoking nearly 40% of all cigarettes smoked by adults (Lipari and Van Horn, 2017). Individuals with substance abuse disorders or mental illness die prematurely about 5 years earlier than the general population (Walker, McGee, and Druss, 2015). The most prevalent causes of death are heart disease, cancer and lung diseases which can be attributed to smoking (Walker, McGee, and Druss, 2015). Substance abusers who smoke cigarettes are four times more likely to experience premature death (Lipari and Van Horn, 2017). In addition, 65.2% of adult smokers reported current alcohol use (compared to non-smokers 48.7%) in 2013. Approximately eighteen (18.9%) percent of adult smokers report concurrent illicit drug use (compared to non-smokers at 4.2%) (Substance Abuse and Mental Health Services Administration [SAMHSA], 2014). Nicotine may be a factor that impacts the prevalence rate because of its mood-altering effects that may temporarily negate the symptoms of mental illness. Hence, the behavioral health population carries a higher risk for cigarette smoking and subsequently nicotine addiction (CDC, 2013). Many of the medications taken by substance abuse and mental health patients can interact with and reduce the efficacy of those medications when combined with tobacco smoke (Lipari and Van Horn, 2017). Individuals with behavioral illness are less likely to sustain smoking abstinence than the general population (CDC, 2013), but many desire to quit (CDC, 2013). Individuals with substance abuse and mental illness are more likely to have a lower annual household income, live under stressful

living conditions, have diminished access to healthcare secondary to the lack of insurance, and access to smoking cessation counseling which makes quitting more difficult (CDC, 2016).

Adults with disabilities. According to Jamal et al., 2018, adults with disabilities have a higher smoking prevalence rate (21.2%) than those adults without disabilities (14.4%). Factors that may contribute to the higher prevalence rate could be the disability is caused by smoking or because of the increased stress associated with disabilities (Jamal et al., 2018).

Homeless. Tobacco use among homeless individuals is four times the prevalence rate of the general population, and nearly 2.5 times more with individuals whose socioeconomic status is at the poverty level or below (Bagget, Tobey & Rigotti, 2013). Factors that increase the risk for tobacco use in homeless individuals are mental illness symptoms, co-existing substance abuse, and higher nicotine dependence (Bagget et al., 2013). Many lack health insurance or a primary care physician which limits their access to evidence-based smoking cessation treatment (Bagget et al., 2013).

Individuals who are uninsured or are on Medicaid. 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.

Tobacco addiction doesn't discriminate – a person can be addicted to the nicotine in cigarettes regardless of race, gender identity, sexual orientation, religion or age. However, smoking is more common in certain populations, including among some racial minorities, low-

income individuals, those with mental illness, and the LGBTQ population which correlates to the population served by FQHC providers. Because of the increased prevalence rates with this population, they carry disproportionate morbidity, mortality and economic burden attributable to smoking-related diseases (CDC, 2018b, Flocke, Hoffman, Park, Birkby, Trapl, et al., 2017).

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). In addition, 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).

Smoking tobacco damages the airways and the alveoli in the smoker's lungs reducing the elasticity and increasing the lungs hyper-reactivity. Damage from smoking starts early, and for as long as the individual continues to smoke the lung function diminishes (ACS, 2017). Because of the body's ability to compensate, it may take years before the damage done becomes obvious and results in a diagnosis of lung disease. According to ACS (2017), smoking tobacco exacerbates both pneumonia and asthma.

The risk for Chronic Obstructive Pulmonary Disease (COPD), which is inclusive of chronic bronchitis and emphysema, increases the longer you smoke and is dependent upon the number of cigarettes smoked (ACS, 2017). Chronic bronchitis causes increased mucus production because of chronic inflammation of the bronchi, over time the bronchus become scarred, and the mucus can block the airways resulting in pneumonia.

Tobacco use damages the cardiovascular system and increases the risk of heart attacks and strokes. Smoking increases the blood pressure, increases the chance of abnormal platelet aggregation and clotting, and lowers the ability to exercise (ACS, 2017). Smoking tobacco reduces the HDL (good) level of cholesterol, thereby reducing the cardioprotective effect. This, in turn, increases the risk for peripheral vascular disease (ACS, 2017).

Since smoking tobacco damages the arteries resulting in a reduction of blood flow to the penis, the risk for male impotence is progressively higher the longer the individual smokes (ACS, 2017). In addition, this same risk is linked to cigar smoking as well (ACS, 2017). Smoking can also impact fertility by affecting the viability of the sperm and increases the risk of birth defects, smaller birth weights, and miscarriage (ACS, 2017).

In addition, there are multiple other ways that the body is diseased secondary to tobacco use. Smoking can affect an individual's health in nearly every aspect by increasing the risk for tooth loss, gum disease, macular degeneration, cataracts, rheumatoid arthritis, peptic ulcers, lower bone density, and diabetes mellitus (Type II). Tobacco smoking reduces the individual's ability to heal wounds, decreases immune system function, and decreases the sense of smell and taste. In addition, it gives individuals bad breath and stained teeth (ACS, 2017).

Harm from cigarette smoking begins even before birth because pregnant women who use tobacco give birth to infants at a higher risk of congenital disorders, lung diseases, sudden death,

and cancer (ACS, 2017). In addition, they have recently discovered that there is an increased risk for infant renal failure, intestinal ischemia and hypertensive heart disease (ACS, 2017).

Nicotine is the chemical in cigarettes that creates the addiction to tobacco. Smokers become physically and psychologically addicted to nicotine making smoking cessation difficult (ALA, 2018, USDHHS, 2014). Nicotine triggers the release of dopamine creating a sense of pleasure and calm, however, once the dopamine is reabsorbed, the symptoms of withdrawal return. The withdrawal symptoms of irritability, anxiety, depression, and difficulty concentrating results in smokers returning to their previous tobacco use (ALA, 2018).

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 dollars 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 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 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). On 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 which 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 have been successful in preventing individuals from commencing the use of tobacco, there are many individuals that 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), there are more people 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 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). In addition, 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 white (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.

Prior to 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 clearly 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 ask 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 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 prior to 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 are able to 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 prior to 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 5 R’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 *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 time 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 the period of 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 the period of 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 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 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).

Needs Assessment and Feasibility

The process for assessing the needs (gaps between the current and desired situation) was accomplished by determining the smoking prevalence rate of the FQHC study clinics and comparing them to the global and national goals for smoking cessation and the current national smoking prevalence rate. The author began the process by researching methods /interventions that have been successful in increasing smoking abstinence. During this needs and feasibility assessment, the determination was made that it was not financially feasible to study patient's smoking abstinence rates, nor introduce an intervention involving mobile texting or software as initially desired. The design of the study was developed based upon the brief intervention

(accomplished through the 5 A's and 5 R's model) to deliver the evidence-based smoking cessation treatment by the healthcare providers at the FQHC study clinic. Based upon an assessment of the delivery of the 5 A's and 5 R's at the study clinic, it was determined that improvement was needed with Assistance (5 A's). The design of the study focused on improving the delivery of that assistance by the healthcare providers using the Fiore et al., (2008) guidelines published by the United States Department of Public Health. The conceptual design of the study was proposed to the administrative team at the FQHC study clinic with the purpose of developing an effective intervention that could address the FQHC study clinic's needs and wants. Consideration of relevant points and concerns of staff (i.e. HIPPA compliance) were integrated into the study design. Several meetings occurred with individuals responsible for the management of the electronic health record to ensure that data retrieval would be reliable and feasible. A commitment from the FQHC study clinic was given to assume the financial costs related to that data retrieval as well as costs associated with quick reference notebooks that were to be distributed at the educational intervention. In addition, the parties agreed to allow the principal investigator to provide the educational intervention and the dissemination of the results during the monthly provider meeting which would provide an effective avenue to recruit healthcare participants for the study. Based upon the fact that the FQHC study clinic was already collecting smoking prevalence data to comply with the Uniform Data Collection (UDS) required by Medicare and Medicaid and were actively looking for ways to improve the delivery of evidence-based smoking cessation treatment, it was mutually beneficial to proceed with the study. The cost expectations and viability for implementation for this design/approach were determined to be within acceptable parameters.

Chapter 2

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 patient 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 a 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 nicotine patch, and referral to quit line 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 the 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. In addition, 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.

Barriers and Factors Involved in the Provision of Smoking Cessation Treatment

The purpose of this section is to review the literature to determine the identified barriers to delivery and to address those barriers in the development of the multi-component intervention utilized in this study. According to Twyman, Bonevski, Paul, & Brayant (2014), there are multiple barriers to the delivery of evidence-based smoking cessation treatment that are common to all vulnerable groups. This review will also identify factors that can result in improving the delivery of the evidence-based treatment.

Barriers. Mental health patients who smoke tobacco are one of the identified vulnerable populations that do not get consistent access to tobacco use dependence treatment. According to Himelhoch et al. (2014), the study's stated goal was to evaluate the resources, barriers, and willingness to use the evidence-based interventions *in mental health settings (emphasis added)*. Ninety-five clinicians participated in the study and only 42% of the clinicians asked patients about smoking, less than 33% advised or assisted in smoking cessation. Only 10% referred to current smokers to smoking quitlines. The major barrier identified in the provision of smoking cessation counseling was a belief that the patients were not interested in quitting (77%). Clinicians reported a willingness to provide the evidence-based smoking cessation interventions if they received training (Himelhoch et al., 2014). The study used an instrument with 5 items (i.e. identification of patient's current smoking status in the health record, prompt to advise the patient to quit, availability of smoking cessation materials, convenient referral system for

smoking cessation groups or quitlines, and the availability of on-site staff to provide brief assistance to individuals motivated to quit) to assess the smoking cessation resources available to the clinician (Himelhoch et al., 2014). To evaluate the barriers to providing smoking cessation treatment, an instrument with 9 items and a 4-point Likert scale was used. The nine items were lack of reimbursement for smoking counseling, lack of clinician time, low success rates in this population, lack of interest in quitting among patients who smoke, inability to afford smoking cessation counseling programs, no place to refer patients for assistance, inability to afford nicotine replacement therapy, inability to afford varenicline or bupropion. The study used an instrument with a 5-point Likert scale to ascertain the utilization of smoking cessation interventions. The eight items included advising patients to quit smoking, asking smokers about their interest in ceasing the use of tobacco, providing brief counseling about how to quit smoking, giving out written smoking cessation material, discussing the use of medications (nicotine replacement therapy, bupropion) to assist in tobacco cessation, referral to someone else in the office for more information about quitting smoking, refer patients for telephone counseling (i.e. telephone quit lines), or suggest a follow-up visit about quitting smoking. Additional barriers were identified by the study as follows: 1) Concerns about the expense of pharmacotherapy; 2) Concerns about expense of behavioral therapy for smoking cessation (59%); 3) Lack of success with smoking cessation for this population (48%); 4) Clinician lack of time (43%); 5) Concern that smoking cessation interventions would increase psychiatric symptoms (23%). Additional barriers to delivery of treatment (Himelhoch et al., 2014) was the lack of availability of smoking cessation resources. While 49% of participating healthcare providers indicated that the smoking status of their patients were identified, other resources were deemed inadequate. As an example, 75% reported not having a way to refer patients to a telephone quitline, 63% rarely received a prompt to advise to quit, and 59% reported rarely

having an on-site referral for smoking cessation counseling (Himelhoch, et al., 2014). Only 26% of the healthcare provider participants reported feeling confident to provide smoking cessation counseling.

According to Himelhoch et al. (2014), the perceptions by the healthcare providers that patients were not interested in quitting was reported (77%). This is not consistent with several studies suggesting that behavioral health patients are just as interested in quitting as the general population (Siru, Hulse, Khan, et al., 2010). According to the CDC (2017), nearly 7 out of every 10 (68%) current smokers in the general population reported in 2015 that they wish to permanently quit tobacco use. According to the U.S. News and World Report website (n.d.) *Smoking Cessation* over seventy percent of the 46 million individuals who are current smokers in the United States wants to quit. Attaining permanent smoking abstinence is difficult, and most require multiple attempts before they can permanently kick the habit.

Colomar et al. (2014) conducted a qualitative study to examine barriers that promoted the delivery of evidence-based smoking cessation counseling in Argentina and Uruguay during prenatal care. The goal of this study was to understand the barriers that influenced the provision of smoking cessation counseling to pregnant women. The barriers perceived by 52 healthcare professional participants included inadequate knowledge and motivation to intervene without adequate remuneration or encouraging feedback, perceived low self-efficacy, a perception that counseling could be detrimental to the patient-provider relationship, and concerns about inadequate time and large workload. Some of the barriers perceived within the healthcare system were smoking cessation being considered a low priority, and a lack of clinic protocols to implement interventions. However, there are numerous barriers within the primary care setting that can interfere with the delivery of smoking cessation advice and treatment (i.e. need to address acute healthcare issue, and preventive services within a time-limited clinical

visit, confidence in addressing the issue of tobacco use, lack of training and resources, the provider's belief that the brief advice will not be effective, or that their patients are sufficiently motivated to quit, and not wanting to jeopardize the relationship (Van Schayck et al., 2017). The authors of the Himelhoch et al. (2014) study found that the participants reported a desire to adopt evidence-based practices. The study's conclusion was that while barriers were reported they were modifiable through education and training (Himelhoch, et al., 2014).

Factors. Self-Efficacy of the healthcare provider in the delivery of evidence-based smoking cessation treatments, smoking cessation counseling and prescribing medications were important factors in the perception in the ability to deliver the treatment (Papadikas, 2014). According to Abdullah et al., (2013), healthcare provider's smoking behaviors may be a factor in their delivery of tobacco dependence treatment.

Use of Multicomponent Intervention Improves Delivery Rates. According to Papadakis et al. (2016), after a multicomponent intervention was completed, primary care providers were able to deliver smoking cessations at a much higher rate (“Ask: 55.3% vs 1.3%, $P < .001$; Advise: 45.5% vs 63.6%, $P < .001$; Act: 35.4% vs 54.4%, $P < .001$ ”), p. 235). Meta-analyses have suggested that multicomponent interventions, that combine patient-provider, and support by the clinical setting are the most effective in increasing the rates of the 5 A delivery in the primary care settings and increasing sustainable smoking abstinence (Anderson and Jane-Llopis, 2004; Papadakis et al., 2014). There have been several studies that have examined the relationship of educational interventions for healthcare providers and the impact on the provision of evidence-based smoking cessation treatment (Papadakis et al, 2014).

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 tracks 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 for the purpose of creating 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.

Strengths and Limitations of the Literature

Strengths. The clinical practice guidelines *Treating Tobacco Use and Dependence* (Fiore, et al., 2008) strength is evident by the methodology used in their development. They were developed following an extensive meta-analysis of the current literature. The appropriate criteria for evaluating the validity of the studies was utilized. National experts relying on the evidence provided thru the meta-analysis drafted the guidelines. The recommendations provided in 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) which were published after Fiore et al. (2008) are remarkably similar in content with further validates their ongoing relevance. The premise that the combination of behavioral counseling and pharmacotherapy remains the optimal treatment for smoking cessation is well supported by Kruger et al., (2016). The Piper et al. (2018) further validates that behavioral counseling and pharmacotherapy remains the gold standard for smoking cessation treatment, and only adds that combinations of pharmacotherapy may be more effective with certain populations.

Limitations. The reverse side of that argument is that Fiore et al. (2008) was published over 11 years ago. Numerous studies studying new interventions based upon the availability of new technology have been published since (i.e. efficacy of text messaging for smoking cessation treatment, smartphone apps, etc.) and suggest that the guidelines should be updated again.

Synthesis of the Literature

The literature review revealed evidence-based clinical guidelines (Fiore et al., 2008) for tobacco use dependence that remain relevant despite the passage of time. Subsequent recommendations and decision trees for delivery of smoking cessation treatment by the United States Preventive Services Task Force and the American College of Cardiology have reiterated the value of those guidelines. Because there have been recent innovations in software applications and their increased accessibility to the general population, it would be helpful to have another update of those guidelines to incorporate this new technology. The literature is clearly supportive that primary care providers are in a unique position to deliver this evidence-based treatment but that there are barriers that interfere with that delivery. The literature review provided validation that certain factors (i.e. insufficient training, insufficient resources, lack of convenient referral mechanisms, and inability to afford medications and counseling) were barriers to the delivery of the evidence-based smoking cessation treatment (Colomar et al., 2014, Van Scheck et al., 2017). The literature demonstrates that smoking cessation education and the provision of smoking cessation resources to healthcare providers can eliminate several of the barriers identified. Studies have identified that healthcare providers believe that smokers do not want to quit, but the literature reflects that 70% of individuals who smoke wish to quit. The literature also identifies those healthcare characteristics that factor into the delivery of smoking cessation treatment. The evidence from the above studies provided the basis for the development of the multicomponent intervention delivered to the participants of this study. The literature review provided us with the foundation for the development of the multicomponent intervention.

Chapter 3

Methodology

Project Description

This is a translational research project that was designed to address the need of 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. There are sixteen healthcare providers that 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. In addition, 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 survey's will be shredded to ensure confidentiality and discarded in a secure manner. 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 prior to 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 was 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 prior to 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. In addition, 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-week time period after the intervention. The individual and aggregate percentage 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 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 to 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.

Time Line

The timeline for this study commenced after the 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 prior to 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.

Chapter 4

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 ($r^2=.058$, $p=.851$).

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 the behavioral health and pharmacotherapy for smoking cessation treatment.

Chapter 5

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 prior to 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 the 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 demonstrates 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 prior to 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.

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Appendix A

Fact sheet about 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.

10. 15 years, the risk of coronary heart disease is that of a non-smoker's. 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.

10. 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 the 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. There are numerous medications that 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 there are certain combinations that 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.</p> <p>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>
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<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 the 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 (quit lines, tobacco cessation clinics and others) on hand for providing information whenever the patient inquires about them. •The support given to the patient needs to be described positively but realistically.
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<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> <p>•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.</p> <p>•What:</p> <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 next follow up contact. <p>For patients who are abstinent:</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.
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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

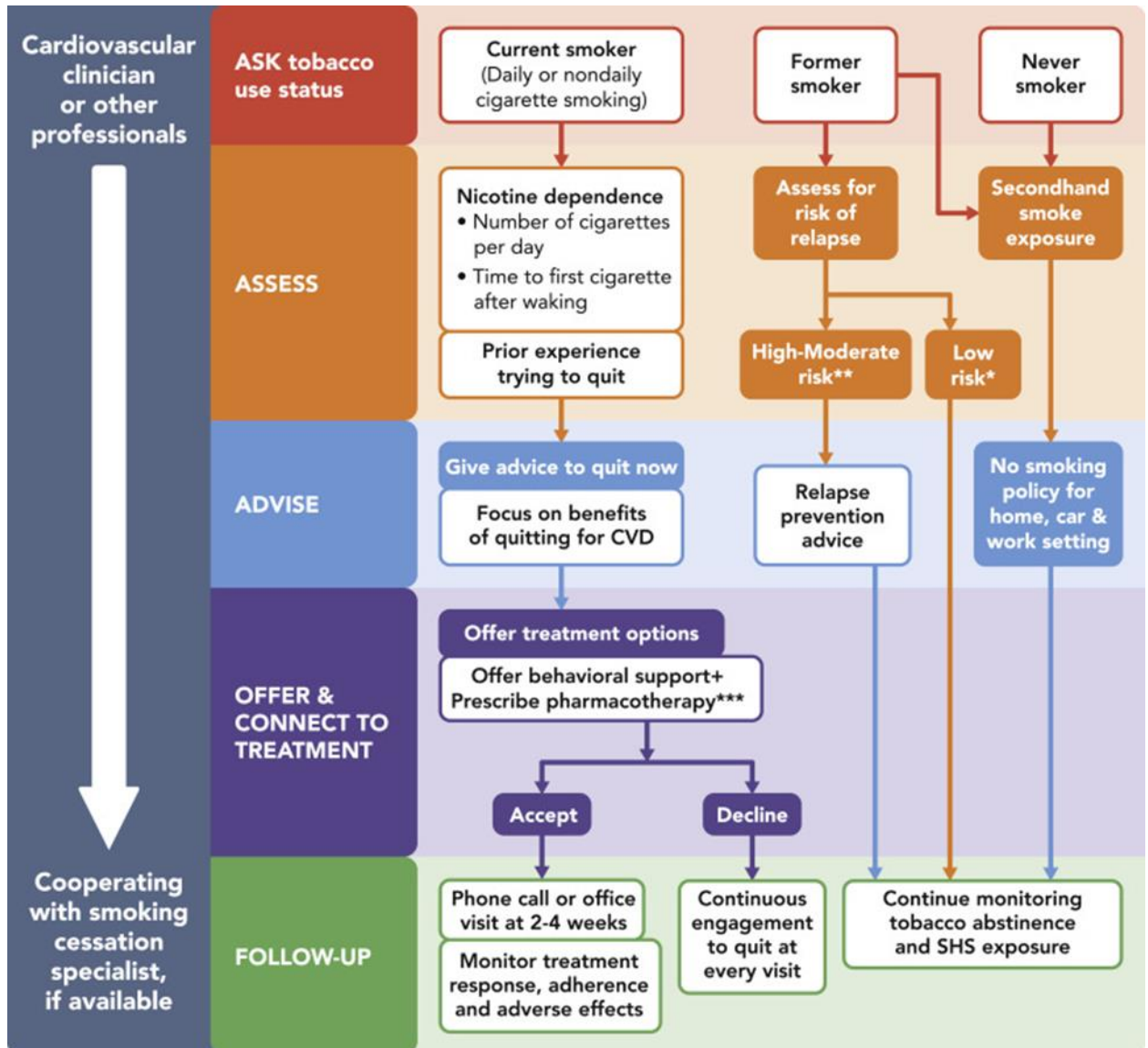
United States Preventive Services Task Force Recommendations

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/UpdateSummaryFinal/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 XXXXXXXXXXXXXXX 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 the purposes of 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 patients who are self-identified 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 individual 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 at the completion of the research project 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

Subsequent to this data being received, the participants were contacted and requested that they provide their actual age and the years of practice on July 25, 2018.

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 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