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Smoking Cessation in Primary Care at the Sequatchie County Health Department: A Practice Change Proposal

Joy Hamilton

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SMOKING CESSATION IN PRIMARY CARE
AT THE SEQUATCHIE COUNTY HEALTH DEPARTMENT:
A PRACTICE CHANGE PROPOSAL

JOY HAMILTON, DNP-BC, DNP
Smoking Cessation in Primary Care at the Sequatchie County Health Department:

A Practice Change Proposal

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March 9, 2014

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Southern Adventist University
School of Nursing
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CHAPTER 1: STATEMENT OF THE PROBLEM

Background and Significance

Tobacco use is the leading preventable cause of death, disease, and disability in the U.S. Each year, around 443,000 people die from smoking or exposure to secondhand smoke, and another 8.6 million suffer from a serious illness from smoking. There have been several recommendations and implications for physicians and other healthcare professionals to play a central role in motivating and assisting patients who smoke to quit (Fiore, M et al., 2008). Healthcare providers are a credible and trusted source of advice to quit, have opportunities to provide this message to most smokers, and can connect patients to cessation counseling and pharmacotherapy. These actions are economical and effective at increasing cessation rates (Macosek, 2006).

About 1 in 5 adults smoke (45.3 million) and, although smoking prevalence has declined from 20.9% in 2005 to 19.3% in 2010, tobacco use is still the most common cause of preventable death and disease in the United States (Centers for Disease Control and Prevention, 2010). Smoking reduces the median survival of smokers on average by 10 years, and beyond the age of 40, each additional year of smoking reduces life expectancy by three months (Doll, 2004). By stopping cigarette smoking, a patient reduces the risk of lung cancer and other diseases by up to 90% and improves survival, even if cessation occurs after the age of 50 years. Nonetheless, habitual smokers find it extremely difficult to successfully stop smoking. Although 70% of smokers would like to quit, and 40% make at least one stopping attempt per year, only three to four percent of smokers per year are successful in stopping long-term on their own (Messer, 2007). The highest risk for relapse is within the first eight days after quitting. Active smoking
cessation interventions by the physician, a clinic staff member, or a counseling service (in-service or telephone counseling) should be initiated before or within the initial week after the planned quit date (Hughes, 2004).

As a result of tobacco use, primarily cigarette smoking, which is the leading cause of preventable morbidity and mortality in the United States (Mokdad, Marks, Stroup, Gerberding, 2004), primary care providers have an opportunity to offer office-based smoking cessation interventions to the 70% of smokers who visit their offices every year (Fiore, 2002). Primary care providers are in a strategic position to help their patients quit smoking. It has been estimated that at least 70% of smokers see a physician each year, and 70% also report a desire to quit and make at least one serious attempt to do so (Lancaster, Stead, 2004). In addition, smokers cite a physician's advice to quit as an important motivating factor for attempting to quit; brief advice from a physician leads to a spontaneous quit rate of two to four percent (Lancaster, Stead, 2004). The National Cancer Institute estimates that if 100,000 physicians were to assist ten percent of their patients who smoke to quit each year, the number of smokers in the United States would decrease at a rate of two million people annually (Ockene, 1987).

Healthy People 2020 provide science-based, national goals and objectives with ten-year targets designed to guide national health promotion and disease prevention efforts to improve the health of all people in the United States. The Healthy People 2020 Tobacco Use objectives are organized into three key areas. The first is the Tobacco Use Prevalence, which involves implementing policies to "reduce tobacco use and initiation among youth and adults" (CDC.gov). Providing educational tools in the school system to encourage cessation, particularly at the middle and high school levels, has been an implementation at the local Health
Departments across the state of Tennessee. The second is the Health System Changes, which is “adopting policies and strategies to increase access, affordability, and use of smoking cessation services and treatments” (CDC.gov). The ability to access information from the CDC website and acquire brochures, handouts, and website information to view, plus educating at the point of care has been utilized and proven efficacious in the local Health Departments here in Southeast Tennessee. Social and Environmental Changes is the third objective by “establishing policies to reduce exposure to secondhand smoke, increase the cost of tobacco, restrict tobacco advertising, and reduce illegal sales to minors” (CDC.gov). Each objective includes a nationally representative and reliable data source, baseline estimate, and target for specific improvements to be achieved by the year 2020 (CDC.gov).

Wadland et al, demonstrated that physicians and their staffs can be trained to successfully deliver office-based smoking cessation interventions and that these interventions significantly improve smoking cessation rates (Wadland, Stoffelmayr, Berger, Crombach, Ives. Enhancing, 1999, Katz, Muehlenbruch, Brown, Fiore, Baker, 2005). Meta-analyses of randomized trials have found a strong dose-response relationship between the duration of counseling (both number of sessions and length of each session) and abstinence rates (Fiore et al., 2008). Clinician counseling sessions greater than ten minutes more than double the rate of abstinence compared to no counseling. Clinician counseling may consist of multiple visits, often weekly, starting before the quit date and continuing for one to two months after the quit date to optimally support a smoker through the quitting process. These programs are more effective than simple self-help interventions, in which smokers are provided with take-home print or audiovisual material to aid them in quitting on their own (Coleman, 2004). Self-help
interventions have proven to be ineffective when offered alone, although take-home materials can augment the efficacy of clinician counseling (Landcaster, 2005).

Currently, Utah has the lowest smoking rate; fewer than ten percent of adults in Utah smoke cigarettes. Kentucky and West Virginia have the highest smoking rates; nearly 26% of adults smoke in both states. Fewer people smoke in the West (about 16%), and more people smoke in the Southeast (about 22%) and Midwest (about 23%) (cdc.gov/vital signs/Tobacco Use/Smoking/index.html).

Most individuals with an addiction to cigarettes started smoking before they turned 18 years old. Tennesseans under the age of 18 will purchase and consume over 16.8 million packs of cigarettes this year (www.tobaccofreekids.org). Approximately 7,600 young people in Tennessee become new youth smokers each year, and 412,000 of today’s Tennessee children will become smokers; 132,000 of them will die prematurely from tobacco related causes (www.tobaccofreekids.org). Unfortunately, most of the patients seen in the primary care setting in Southeast Tennessee, those who are uninsured or underinsured, already smoke and have negative repercussions from their years of tobacco use.

The once commonly held belief that smoking tobacco was harmless, and perhaps even good for some, was shattered on January 11, 1964. The first U.S. Surgeon General’s report on smoking was issued that day, alerting Americans, and the world, to the deadly consequences of smoking. In the 50 years since that report, the U.S. and Tennessee have made remarkable progress, cutting smoking rates significantly, protecting much of the population from harmful secondhand smoke, and saving millions of lives. Still, the battle against tobacco is far from won, and too many people develop or sustain addictions to tobacco products.
“Tobacco use kills more than 440,000 Americans, including 9,700 Tennesseans, every year; it sickens millions more and costs Tennessee $2.6 billion of the nation’s $193 billion in healthcare bills and lost productivity,” said Tennessee Department of Health Commissioner John Dreyzehner, MD, MPH. "Our state is near the bottom, 47th, in smoking rates with a quarter of all adults and more than one in five high school students currently smoking. This is terrible. We can and must do a better job in preventing young people from starting an addiction to nicotine, preventing children and others from being exposed to harmful secondhand tobacco products, and encouraging people to quit through programs like 1-800-QUIT-NOW”


Officials with the Centers for Disease Control and Prevention say the tobacco industry spends eight billion dollars annually, or nearly one million dollars per hour, on marketing and recruiting two new young smokers for every adult who dies from tobacco-related illness. That equates to about $28 per U.S. resident per year. The CDC also reports that states collect about $80 per person per year in tobacco taxes and settlement funds but only spend, collectively, about $1.50 per year per person on tobacco prevention (cdc.gov). Up to one-half of all tobacco users can be expected to die from a tobacco-related disease. The economic burden of tobacco use is estimated to be $197 billion per year, which includes $96 billion in health care costs and an additional $97 billion in productivity losses (World Health Organization Report on the Global Tobacco Epidemic, 2011).

The most important causes of smoking-related mortality are atherosclerotic cardiovascular disease (CVD), lung cancer, and chronic obstructive pulmonary disease (COPD)
Tobacco use also increases the risk of many other acute and chronic diseases, including cancers at many sites other than the lung. An estimated 30% of cancers in the US are tobacco-related (US Department of Health and Human Services, 2005). Smoking cessation is associated with clear health benefits and should always be a major health care goal. Screening all patients for tobacco use and providing all smokers a brief smoking cessation intervention is one of the three most cost-saving clinical preventive services (Maciosek, et al., 2006).

Tennessee and many other states are using the 50th anniversary of the Surgeon General’s report on tobacco to emphasize three shared national goals: 1) Reduce smoking rates to less than ten percent within ten years; 2) to protect all Americans from secondhand smoke within five years; and 3) ultimately eliminate death and disease caused by tobacco. The mission of the Tennessee Department of Health is to protect, promote and improve the health and prosperity of people in Tennessee (http://health.state.tn.us/).

**Prevalence and Tobacco use Patterns**

The prevalence of smoking cigarettes among United States (US) adults has declined from 42.4% in 1965 to 19.3% in 2010 (CDC Report, 2011). However, there has been little decline in adult smoking prevalence since 2005 in contrast to the dramatic declines of past decades. Not all smokers are daily smokers; 78% of smokers smoke every day while 22% smoke less frequently than daily (CDC Vital Signs, 2009).

The pattern of tobacco use in the U.S. varies among socio-demographic groups. A large gender gap in cigarette smoking existed in the 1960s, when over 50% of men and only about
25% of women smoked. This gap has narrowed but not disappeared. Currently, 21.5% of men and 17.3% of women smoke cigarettes (CDC Vital Signs, 2011).

Today, the largest disparities in tobacco use occur in groups defined by education, income, race, and ethnicity. More than one-quarter (28.4%) of individuals without a high school diploma smoke cigarettes, compared to only 11.1% of adults with a college degree. Individuals who have passed the General Education Development (GED) tests smoke at an even higher rate (49.1%) than those without a high school diploma. The CDC also notes current statistics regarding adults with education levels at or below the equivalent of a high school diploma, who comprise nearly half of current smokers, which have the lowest quit ratios 39.9 to 48.8% (CDC Vital Signs, 2011).

Adults with incomes below the federal poverty level are significantly more likely to smoke than adults with higher incomes (28.9 versus 18.3%) (CDC –Vital Signs. MMWR, 2007). Among racial and ethnic groups, smoking prevalence is similar between Caucasians (22.1%) and African-Americans (21.3%) and is lower among Hispanics (14.6%) and Asians (12.0%). Many current smokers are trying to quit. Forty percent of daily smokers report that they did not smoke for more than 24 hours in the past year because they were trying to quit. This rate is even higher among young adult smokers (aged 18 to 24 years), over half of whom made a quit attempt in the past year (Centers for Disease Control and Prevention (CDC). Vital signs: current cigarette smoking among adults aged >or=18 years --- United States, 2009. MMWR Morbidity Mortal Weekly Rep 2010; 59:1135).
Patterns of tobacco use

Turner (2007) concluded his research and noted that almost every adult who currently smokes started smoking by the age of 18. Half of high school students have tried smoking a cigarette, 20 % have smoked a cigarette in the past 30 days, and 8 % smoked frequently, defined as smoking on 20 of the past 30 days (CDC, 2008). Past-month smoking rates among twelfth-grade high school students increased during the 1990s, peaking at 36.4 % in 1997, and have since declined to 20 % (CDC 2008).

The earlier the age at which a person begins smoking, the more likely he or she is to continue into adulthood (Maciosek, Coffield, Edwards, et al., 2006). Within a year of smoking initiation, children inhale the same amount of nicotine per cigarette as adults and experience the craving and withdrawal symptoms, and, unfortunately, tobacco dependence can develop very quickly in children (DiFranza, Savageau, Fletcher, et al., 2007), although the amount smoked may increase for a number of years. By the time they are 20 years old, 80 % of young smokers regret ever having started (Jarvis, 2004).

Risk factors for an adolescent becoming a smoker include having parents or friends who smoke, living with a smoker, having a strained relationship with a parent and/or single parent at home, low level of self-esteem and self-worth, poor academic performance, increased perception of parents' approval of one's smoking, comorbid psychiatric disorders, and the availability of cigarettes (Maciosek, Coffield, Edwards, et al., 2006). An additional risk factor for boys is high levels of aggression and rebelliousness, and for girls, preoccupation with weight and body image is a separate risk factor (Maciosek, et al., 2006). Studies that involved twins have shown a
significant genetic link to both smoking initiation and dependence, although it is likely that they involve different genes (Swan, 1999).

### Nicotine Sources

In addition to cigarettes, tobacco is also smoked in the form of cigars, pipes, and water-pipes. Tobacco in the form of chewing tobacco and snuff is not smoked but is absorbed through the buccal mucosal membrane. Electronic cigarettes (e-cigarettes) use a liquid nicotine cartridge, rather than tobacco.

The smoke from cigars and pipes is not typically inhaled as deeply into the lungs as is cigarette smoke and, for this reason, the risk of lung cancer from smoking cigars and pipes is lower than the risk of smoking cigarettes, but higher than the risk of a nonsmoker (www.cdc.gov/tobacco/sgr/sgr_2004/index.htm).

The use of water pipes (also known as hookah) to smoke tobacco is an emerging form of tobacco smoking in the US, especially among young adults (Primack, Sidani, Agarwal, et al., 2008). Currently, there is only one Hookah lounge located in Hixson, Tennessee. This is a traditional form of tobacco use in the Middle East and the amount of nicotine and toxins varies based on the type of tobacco used and how it is smoked. Water-pipe smoking is also associated with lung cancer and other respiratory diseases (Akl, Gaddam, Gunukula, et al., 2010). One meta-analysis of six cross-sectional studies found that waterpipe smoking negatively affects lung function, particularly in reducing forced expiratory volume in one second (FEV1) and is likely to be a cause of obstructive lung disease (Raad, Gaddam, Schunemann, et al., 2011).

Smokeless tobacco is available as chewing tobacco or snuff. Different processing techniques, particularly “curing”, can result in markedly different contents of toxins in smokeless
products. About three percent of adults in the US use smokeless products, primarily white males of lower socioeconomic status in the southern or western US. Smokeless tobacco is not harmless, although the health risks for certain diseases may be substantially less than with smoking. It may also cause cancer of the oral cavity and provides sufficient nicotine exposure to cause nicotine addiction (Scientific Committee on Emerging and Newly Identified Health Risks. Health effects of smokeless tobacco products. Available at ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_013.pdf).

Electronic cigarettes (e-cigarettes) use an electronic delivery system that aerosolizes nicotine, producing a vapor similar to cigarettes but containing fewer traditional toxins (Yamin, Bitton, Bates, 2010). E-cigarette devices are composed of three parts: a plastic tube, an electronic heating element, and a liquid nicotine cartridge. The user presses a button that simultaneously releases a puff of vaporized nicotine while illuminating the device tip (that simulates the lit end of a cigarette). E-cigarettes do reduce the desire to smoke traditional cigarettes and have been prescribed by clinicians to aid in smoking cessation (Bullen, McRobbie, Thornley, et al., 2010). They are being increasingly used by the general population, mostly as a result of internet advertising and sales. There are many available products that vary greatly in consistency, in nicotine delivery, and in other additives that may have their own toxicity. A 2009 US Food and Drug Administration (FDA) report on e-cigarettes found trace amounts of the harmful solvent diethylene glycol as well as nitrosamines which are known carcinogens. This report also found nicotine in ‘light’ e-cigarettes that were labeled as being nicotine-free. The FDA has not approved the use of any e-cigarettes given safety concerns, particularly related to use in adolescents and potential toxic ingestion among children (fda.gov, 2010). Data from one pilot
study reports common adverse effects of e-cigarettes as dry cough and irritation in the oropharynx (Polosa, Caponnetto, Morjaria, et al., 2011). Whether initial recreational use of e-cigarettes leads to smoking of conventional cigarettes is still unknown.

Despite their increasing popularity, little is known about e-cigarette use, potential for addiction, or long-term health effects from smoking and second-hand smoke. Whether e-cigarettes can help smokers to quit or permanently stop using tobacco products is uncertain (Rigotti, 2012). A randomized trial that compared e-cigarettes with nicotine patches among smokers who wanted to quit found no significant difference in the cessation rates produced by the two treatment arms, although the study was underpowered and could have missed important differences in the effectiveness of e-cigarettes compared with patches (fda.gov, 2010). While this trial suggests that e-cigarettes might have the potential to be smoking cessation aids, further studies will be required to establish the efficacy and safety of e-cigarettes for cessation.

**Purpose**

The US Public Health Service Smoking Cessation Clinical Practice Guideline recommends that all clinicians, including nurses, strongly advise their patients who use tobacco to quit (Fiore, Bailey, Cohen, Dorfman, Goldstein, Gritz, et al., 2000).

The primary purpose of this doctoral scholarly project is to address the growing smoking epidemic concern in the Southeast Region of Tennessee with adults aged 19 to 64 years who are uninsured who seek care at the local health departments, specifically Sequatchie County Health Department. A practice change is proposed and would entail a request for the addition of the patient’s current smoking status as an entity of the vital signs, and an assessment to determine the current stage of change according to the Transtheoretical Model. Changing or modifying a
behavior that is addictive or potentially harmful is difficult for most people. The Transtheoretical Model (TTM) (Prochaska, Norcross, & DiClemente, 1994) incorporates a compilation of previous theories, providing a framework for the stages of progression when deciding to change a problematic behavior. The proposal would include an algorithm which would serve as a guide for primary care providers (PCPs) encompassing the TTM, and would also comprise a recommendation for the evaluation. These three components of the proposal would be in addition to the already established Quit-line that is currently being utilized.

The goal of this practice change would be to provide improved patient care by increasing provider’s adherence to the recommendations of a clinical practice guideline for the assessment and treatment of smoking cessation in the primary care setting.

**Practice Setting**

The setting for this study will be one of the primary care sites in the Southeast Regional Health Departments, Sequatchie County Health Department. Primary care is provided at this rural site where approximately 50-60 patients receive primary care weekly. The clinic’s population is largely made up of Caucasians as well as a small number of African Americans and Hispanics. The majority of patients are between the ages of 19-65 years for primary care. The clinic also provides Family Planning, provides services from a state run program for women, infants and children (WIC), children with special needs (CSS), sexually transmitted infections and diseases (STD).

The support of this scholarly project of addressing the growing epidemic concern of smoking in the Southeast Region was initially discussed with the Southeast Regional medical director who oversees all seven health departments of which only three currently provide
primary care. For this doctoral project, the practice change emphasis will be focused on the three primary care sites which are Sequatchie County Health Department in Dunlap, Grundy County Health Department in Altamont and Bradley County Health Department in Cleveland, Tennessee.

Definitions

Southeast Region Health Department

The Tennessee Department of Health is comprised of eight regions across the state of Tennessee of which Southeast Region is one, which is further subdivided into counties including Bledsoe, Bradley, Franklin, Grundy, Hamilton, McMinn, Marion, Meigs, Polk, Rhea, and Sequatchie. The mission of the Tennessee Department of Health (TDH) is to protect, promote and improve the health and prosperity of people in Tennessee. All 6.45 million Tennesseans, along with those who visit our state, are touched directly or indirectly by TDH operations. One in five, approximately 1.4 million people, are directly served each year through a network of 89 rural and six metropolitan county health departments. Others are affected by inspections of restaurants, healthcare and related facilities; registration or receipt of vital records; protection from communicable illness; licensing of health professionals; specialized laboratory testing and many other services and programs.

Protecting people’s health by preventing problems that contribute to illness, disease and injury is the overall emphasis of the department. Contrary to popular belief of only administration of immunizations at the Health Department, other crucial and indispensable responsibilities include screening, providing and assuring a safety net of care, particularly in medically underserved populations and areas of Tennessee; offering early prenatal care and
proper nutrition to pregnant women and young children; and assuring restaurants, hotels, health facilities and health professionals meet requirements and standards established in Tennessee code. The regulatory work performed by the department impacts more than 10% of Tennessee’s gross domestic product and more than 14% of its workforce (http://health.state.tn.us/ems/RegionalOffice.htm).

The greatest causes of premature death and preventable illness are closely related to the way we live including what and how much we eat, whether we use tobacco, how much we exercise, and what we do to protect our safety. The TDH emphasizes health protection, primarily preventing illness and injury from occurring in the first place. By promoting healthy lifestyles that avoid health risks and educating Tennesseans about the rewards we enjoy when we protect the health of our communities, our families and ourselves, we are all able to enjoy better health.

**QuitLine**

The Tennessee Tobacco QuitLine is a toll-free telephone service that provides personalized support for Tennesseans who want to quit smoking or chewing tobacco. When an individual calls the QuitLine, they are assigned their own quit coach who then assists them in the knowledge and understanding of how to quit using tobacco. Assistance in developing a personalized plan that works for them plus the added advantage of having the same quit coach for an entire year. The quit coach helps individuals figure out what works best for them. With this program, the coach doesn’t tell them what to do, but rather a collaborative effort is encouraged with a quit coach to make changes that fit the individual’s life. In addition to the QuitLine at Sequatchie County Health Department, a smoking survey is completed on an initial and annual visit to ascertain the patient’s current usage of tobacco.
Patient Tobacco Survey

The Patient Tobacco Survey is a six question multiple choice questionnaire with pointed questions directly related to tobacco usage completed by the patient on initial and annual appointments. This survey is completely voluntary and includes a ‘refused’ option as one of the multiple choice answers. Patients are then questioned based on the answers on the questionnaire, and then the provider has the opportunity to address their smoking cessation status (Appendix A).

Health Promotion

Health promotion and disease prevention are essential competencies for nursing at the doctorate of nursing practice level (American Association-of Colleges of Nursing, 2006). Health promotion is often cited as a distinguishing feature of nursing in comparison to the more disease focused practice of physicians. It is the provision of services or implementation of processes that advance health beyond simply preventing or eliminating illness to building capacity that enables individuals and groups to improve their health and well-being (Hutchinson, et al., 2006; Kickbusch, 2003; Larson, 1999). Although health promotion and disease prevention are often used interchangeably, their scope, underlying motivations, and purposes are unique. Health promotion has a broad scope that encompasses the whole client, including bio-psychosocial, cultural dimensions spiritual and the client’s environment. Health promotion assists clients to optimize health and well-being, attain balance, stability, and harmony, strengthen adaptation and expand consciousness (M.P. O’Donnell, 1989, 2009.; Smith, 1990), Health promotion activities include, but are not limited to, the prevention of disease or decreasing risk factors for disease (Pender, Mardaugh, & Parsons, 2006; Smith, 1990).
Program Evaluation

Program evaluation is the systematic inquiry of a program’s activities, characteristics, and outcomes to provide information for decision-making related to the program, to improve program quality or effectiveness, or to inform future programs. Program evaluation is an essential element of translating, sustaining, and improving health promotion programs. Various approaches, models, and categories or types of evaluation serve as guides in conducting evaluation projects. The selection of frameworks depends on the purpose of the evaluation, the resources available, and planned use of the findings (Appendix F).

Five “A’s”

The five “A”s are used to assess for tobacco use and address smoking cessation. The interventions include:

- **Ask**- Implement an office-wide system that ensures that, for every patient at every clinic visit, tobacco-use status is queried and documented.
- **Advice**- Strongly urge all tobacco users to quit in a clear, strong, personalized manner.
- **Assess**- Determine the patient’s willingness to quit smoking within the next 30 days.
- **Assist**- Provide aid for the patient to quit.
- **Arrange**- Schedule follow-up contact, either in person or by telephone. Follow-up contact should occur soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. Congratulate success during each follow-up. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Remind the patient that a lapse can be used as a learning experience. Identify problems already encountered
and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems. Consider use or referral to more intensive treatment (Fiore MC, Jaen C, Baker T, et al., 2008).

Theoretical Framework

Health promotion and risk reduction are processes that advance health beyond simply preventing or eliminating illness to building capacity that enables individuals and groups to improve their health and well-being (Hutchinson et al., 2006; Kickbusch, 2003; Larson, 1999). Assessing, implementing, and evaluating strategies that affect health is a complex undertaking that requires knowledge of comprehensive, logical, relevant theories and models. A theory has been defined as an abstract generalization that offers a systematic explanation of how variables are interrelated (Polit & Beck, 2008). Theories tell how and why things work and how and why one variable is related to another. The Transtheoretical Model (TTM), CREATION, and the Self efficacy theories are appropriate theories used to explain the phenomenon of interest of smoking cessation in the primary care setting (Prochaska, 1992; CREATION Health, 2008; Bandura, 1986).

Transtheoretical Model (TTM)

Prochaska and DiClemente’s stage of change model, the Transtheoretical Model (TTM), is a contemporary psychological model of behavioral change employed to develop efficient interventions to promote healthy behavioral changes. Interventions can be individualized to the needs of individuals in order to achieve optimal results (Tang, Chen, & Chen, 2009). The TTM emphasizes the importance of the readiness for change, hypothesizing that progress through the stages of change is influenced by the pros and cons of changing, self-efficacy, cognitive and
behavioral processes (Prochaska, Redding, & Evers, 2002). The premise of the TTM is that a behavior change is a process, not an event, influenced by motivation levels. It also outlines how people make deliberate changes, especially eliminating problem behaviors and beginning new, healthier behaviors. Behaviors generally progress from low awareness and no intention to change, through high awareness and active efforts to initiate or maintain change. Behaviors also emphasize the importance of the readiness for change, hypothesizing that progress through the stages of change is influenced by the pros and cons of changing, self-efficacy, with cognitive and behavioral processes (Prochaska, Redding, & Evers, 2002).

According to Prochaska (1994) the TTM behavior change is seen as a process that progresses from low awareness and no intention to change, through high awareness and active efforts to initiate or maintain change. The first stage of the TTM is:

- **Pre-contemplation** which is characterized as not currently considering change. During this stage, individuals validate their lack of readiness. Clarification of decision making is discussed, and re-evaluation of current behavior and self-exploration are encouraged.

- The second stage is **Contemplation** where individuals are ambivalent about the impending change or perhaps recognition of the problem and serious thought about the changes are evident.

- **Preparation** is the third phase where there is a conscientious decision to change within a timeframe of one month. There may be some experience with change where persons are trying to change and assistance in problem solving regarding obstacles may need to be investigated and explored.
• **Action** or practicing the new behavior for approximately three to six months is the characteristics of this forth stage of change. The techniques implemented here focus on restructuring cues and social support, bolstering self-efficacy for addressing obstacles and combating feelings of loss.

• The fifth stage of change is **maintenance** where there is a continued commitment to sustaining the new behavior for greater than six months. The techniques involved in this stage of change include a plan for follow-up support, and the discussion of coping with the potential of relapse (Prochaska, Redding, & Evers, 2002).

At the three primary care sites, each of the above mentioned five stages of change will be proposed to be included in the vital signs component section of the progress notes. Interventions may then be individualized to the needs of individuals in order to achieve optimal results.

**CREATION Health Model**

Florida Hospital is a Christian, faith-based hospital that believes in providing Whole Person Care to all patients – mind, body and spirit, through the principals of CREATION Health. CREATION Health is God’s plan for living. This wellness program is based on Biblical principles found in the Creation story and supported by evidence-based science. Learn the best practices of whole person living - mentally and physically along with a strong focus on spirituality and faith. CREATION Health is the 8 principle acronym that defines the way Florida Hospital provides Whole Person Care to all patients-mind, body and spirit (CREATION Health.com).

Choice is the first step toward improving one’s wellbeing according to the CREATION model (2011). Before one can achieve positive changes in any area of their lives, they must
choose to do so. Conscious decision-making is fundamental and essential to experiencing the positive impact of good choices. Deci, Speigel, et al (1982) state that providing one with the ability to choose increases an individual’s sense of personal control and feelings of intrinsic motivation. The authors concluded that choices have powerful motivating consequences and conversely, the absence of choice and control has a variety of detrimental effects on intrinsic motivation, life satisfaction, and one’s wellbeing. Ultimately, smokers have the innate ability of choice to be exercised and applied.

Other entities of the CREATION model that could be relevant are Outlook, Nutrition and Interpersonal relationships which may be directly applied and appropriated in the primary care setting. Outlook refers to how individuals view the world, their lives, and their circle of influence. Outlook also impacts everything one thinks about and does and is essentially a person’s general attitude. Seligmnan (1998) studied the effects of optimism and pessimism and concluded that becoming an optimist consists of simply learning a set of skills about how to talk to oneself when suffering a personal defeat and as the optimism increases, addressing setbacks will be accomplished from a more encouraging perspective. In the primary care setting, outlook may be perceived from the practitioner’s encounter which may be a valuable entity in assessing the stage of change regarding smoking cessation.

Nutrition is one of the most powerful tools we have to promote health and by so doing we can substantially increase disease prevention and be healthier, happier and more energetic (Willett, 1994). Science has demonstrated that fruits and vegetables are incredible promoters of harmonious living. A study done on Chinese women in Singapore- a city in which pollution levels are often high- showed that in non-smokers, eating cruciferous vegetable lowered their
risk of lung cancer by 30%. In smokers, regularly eating cruciferous vegetables reduced lung
cancer risks an amazing 69% (Zhoa, Seow, et al., 2001). Incorporating a healthy, balanced diet
including nuts, seeds, whole grains, large amounts of water to maintain a well hydrated body,
and consuming breakfast daily are wise decisions that individuals can make about nutrition
which can have rich health rewards (CREATION, 2011). The need to introduce to some
smokers and encouraging others toward a healthy balanced diet during encounters in the primary
care setting, could potentially be a positive entity for smoking cessation.

Social connectedness and health have been recognized and evaluated in Dr. Dean
Ornish’s intervention for reversing heart disease. Interpersonal relationships were a surprising
discovery from his perspective. He pointedly states “I’m not aware of any other factor in
medicine – not diet, not smoking, not exercise, not stress, not genetics, not drugs, not surgery –
that has a greater impact on our quality of life, incidence of illness and the premature death from
all causes than does love and intimacy” (Ornish, 1998 pg 2-3). To harmonize with Ornish’s
study, Stead (2005) concluded that group therapy allowed smokers to learn behavioral
techniques among their peers, with the intent of providing mutual support among group members
and it is nearly twice as efficacious as self-help programs (Stead, Lancaster, 2005).

Self-efficacy Theory

According to Bandura (1986), self-efficacy is the most important precondition for
behavior change. Self-efficacy is the belief that one has the power to produce an effect by
completing a given task or activity related to that competency. It also relates to a person’s
perception of their ability to reach a goal, is the belief that one is capable of performing in a
certain manner to attain certain goals, and is based on the premise that it is an expectation that
one can master a situation and produces a positive outcome. The three major factors that influence self-efficacy are behaviors, environment, and personal and cognitive factors. They all affect each other, but the cognitive factors according to Bandura are most important. Bandura also postulates that motivation, performance, and feelings of frustration associated with repeated failures will determine effect and behavior relations. (Bandura, 1986).

The three primary care sites of the Southeast Regional Health Departments serve the uninsured where the providers encourage patients to master their specific situations to produce positive outcomes. Smoking is rampant in these particular communities so empowering the patients who have expressed a desire to quit their tobacco abuse is sanctioned and encouraged.

**Practice Change Model**

Rosswurm and Larrabee (1999) developed a change model which guides practitioners through the full process of evidence-based practice (EBP). The model is based on theoretical and research literature related to evidence-based practice, research utilization, standardized language, and change theory. In this model, practitioners are guided through the entire process of developing and integrating an evidence-based practice change. The model supports evidence-based practice changes derived from a combination of quantitative and qualitative data, clinical expertise, and contextual evidence (Holleman, Eliens, van Vliet, & van Achterberg, 2006). It includes six steps: assessing the need for change, identifying potential interventions and outcomes, synthesizing the best evidence, designing a practice change, implementing and evaluating the practice change, and integrating and maintaining the practice change. (See Figure 1).
The mission of the Tennessee Department of Health (TDH) is to protect, promote and improve the health and prosperity of people in Tennessee. All 6.45 million Tennesseans, along with those who visit our state, are touched directly or indirectly by TDH operations.

The current practice protocol regarding assessments of patients who smoke entails an initial and annual smoking survey that is done by the primary care provider. The information is then entered in a database and later on evaluated by the Health Department’s epidemiologist. In the past year and a half, the project manager for this practice change proposal have seen patients who have returned for their three month follow up and annual visits with essentially the same answers. Unfortunately, the information gained becomes ‘invisible’ to the providers, but per the current protocol, assessment of the patient’s current smoking status should be asked with every
encounter. Interventions presently integrated include referring the patients to other providers, advising over-the-counter cessation medications, and prescribing pharmacologic agents such as Bupropion and Varenicline. Provision of the Tennessee Quit Line information brochure which encourages patients to call and will have the ability to speak with a ‘quit coach’ and learn how to deal with tobacco cravings and other challenges is also distributed during an encounter.
CHAPTER 2: LITERATURE REVIEW

Introduction

In recent years, there has been a proliferation of research studies on the effect of smoking and the negative ramifications in terms of health and quality of patient outcome. The following is a discussion and summary of evidence based literature reviews related to smoking cessation in the primary care setting. The studies were done in the United States, Europe, Asia and Canada and include quantitative and qualitative studies as well as meta-analyses spanning the years of 1995-2014. The project manager began the search using EBSCO, CINAHL, Pub Med, the Cochrane Review and Health Sciences. The following key words and combinations were used: Smoking Cessation in primary care, overview of smoking cessation in management in adults, barriers to smoking cessation and relapse prevention.

On review of nursing research literature, the implementation of evidence-based tobacco treatment guidelines into practice demonstrated that changes in the health care delivery system and clinical workflow patterns can have an extensive effect on cessation rates. Due to the plethora of available literature regarding smoking cessation, this literature review will pertain only to the primary care setting.

Findings

Technology

The role of technology in improving systems approaches to tobacco treatment has been recognized as a positive asset for primary care providers. Information obtained via technology can reduce complexity and customize smoking cessation information through tailored cessation education printed “on the fly” (Shiell, Hawe, & Gold, 2008). The recently enacted American
Recovery and Reinvestment Act of 2009 calls for a $19 billion stimulus package to invest in health information technology (Mandl & Kohane, 2009), including $17.2 billion for financial incentives to physicians and hospitals through Medicare and Medicaid to promote the use of EHRs (Steinbrook, 2009). This investment represents an unprecedented opportunity to the tobacco control research community to develop and test technologies to support evidence-based tobacco treatment.

Ellerbeck, Ahluwalia, Jolicoeur, Gladden, & Mosier (2001), determined via an observational study in the primary care setting that having an assigned smoking cessation non-physician staff member actually increased the frequency of tobacco-related discussions during an encounter, although this was not a significant smoking cessation predictor. In one particular practice, an assigned nurse was designated to provide tobacco cessation intervention and follow-up utilizing technology, and smoking behaviors were addressed in 90% of all patient encounters with smokers.

Despite the benefits of smoking cessation, clinicians are not adequately screening and treating patients who smoke. One study, for example, found that only 50% of smokers seeing a primary care physician in the past year were asked about their smoking or urged to quit (AnAnda, Remington, Sienko, Davis, 1987). An even smaller proportion was counseled to quit. Some of the barriers to clinician intervention include time constraints, a perception that the clinician lacks the skills necessary to be effective in this role, and low expectation of successfully getting smokers to quit (JAMA, 1987).
Smoking Cessation Guidelines

Practice guidelines calling for the treatment of all tobacco users have been released by the Agency for Health Care Policy and Research (AHCPR) and the United States Preventive Health Service. These were based on an exhaustive systematic review and analysis of the scientific literature from 1975 to 1999, and were published in the year 2000 (JAMA 2000). The American Psychiatric Association (APA) also released nearly identical guidelines (Am J Psychiatry, 1996). Clinicians now have available a clearly defined standard of screening and intervention to use with their patients.

The field of smoking cessation treatment itself also is rapidly expanding. Randomized controlled trials of commonly used smoking cessation techniques, including individual, group, and telephone counseling, have demonstrated success in helping smokers quit and maintaining long-term abstinence (JAMA, 2000). In addition, rapid expansion in pharmacotherapy has resulted in multiple drug agents and systems of delivery directed at treating the biologic basis of tobacco addiction.

The AHCPR guidelines recommend that the tobacco use status of every patient treated in a healthcare setting be assessed and documented at every visit (JAMA 2000). This practice has been shown to increase the likelihood of smoking-related discussions between patients and physicians and to increase smoking cessation rates, including smokeless tobacco, tobacco pipes and cigar smoking (Okuyemi, Ahluwalia, Wadland, 2001).

Law, Tang, (1995), acknowledge the importance of specific advice to quit smoking, regardless of the patient's motivational status, which should be underscored. Every patient who smokes should be urged to quit in a clear, strong, and personalized manner. Not every patient
counseled on smoking cessation will be prepared to consider quitting. Nevertheless, it is important that the patient's smoking and motivational status be ascertained at each encounter. In a systematic review of 20 studies conducted in primary care settings, brief (less than five minutes) interventions that included advice to quit smoking resulted in two percent of all smokers quitting, compared with less than one percent of those who received no advice.

A randomized trial found that informing patients of their "lung age" as determined by spirometry (age of a healthy person with the same lung function) doubled quit rates at twelve months (14 versus 6%) (Parkes, Greenhalgh, Griffin, Dent, 2008). The effect did not appear to be altered by whether the lung age was normal or abnormal. There is little evidence that other types of biomedical risk assessment increase smoking cessation rates compared to standard care (Bize, Burnand, Mueller, et al. 2009).

The AHCPR has proposed the model of "5 Rs" in promoting motivation to quit smoking: (Appendix B).

- **Relevance** — Motivational information to a patient is more effective if it is relevant to a patient's circumstances (such as prior quitting experience, disease status, or health concerns).
- **Risks** — The acute and long-term risks of smoking should be stressed. It is most effective if smoking can be tied to the patient's current health or illnesses. For the healthy patient, environmental risks, such as exposing spouses and children to smoking and thereby increasing their risk of ill-health should be included. Smokers should also be made aware that children of smokers are more likely to smoke.
• Rewards — Encourage the patient to identify potential benefits of smoking (such as saving money, performing better in sports, improving the health of children and other household members, etc).

• Roadblocks — Ask the patient to identify barriers or impediments to quitting and note elements of treatment (problem solving, pharmacotherapy) that could address barriers.

• Repetition — Repeat the motivational intervention each time an unmotivated smoker visits the clinic setting.

**Barriers to Smoking Cessation**

The concept of perceived barriers has been used in behavioral medicine for a long time in one form or another. The earliest widespread use of the barriers concept was associated with the Health Belief Model. Webster’s dictionary defines a barrier as “something that impedes or separates”. Interestingly, the concept of barriers to accomplishment of a goal or a specified health behavior is assumed to be so straightforward that it is often left undefined.

Gregory (2012), concluded that barriers to quitting smoking among the general population include psychosocial factors such as anxiety, and depression as well as smoking specific factors like motivation and self-efficacy to quit plus nicotine dependence. Of particular notation, there was a difference in younger and older smokers in the study’s sample. Older smokers had a significantly lower level of nicotine dependence, stress, depressed mood, and a greater prevalence of smoking-related diseases. Older smokers were more likely to achieve biochemically verified abstinence at a 6-month follow-up than younger smokers (7.8% vs 3.1% respectively). Having a smoking related disease did not however, influence quitting among older
adults. For younger smokers, higher self-efficacy to quit and the presence of a smoking related disease increased the odds of abstinence.

Kraemer et al. (2013) examined the role of emotional distress tolerance (DT) in predicting barriers to smoking cessation and number of quit attempts. The sample consisted of regular daily smokers (N= 126; 37 females; Mean age= 36.51, SD = 13.05) who completed self-report measures on affect and smoking. The results indicated after controlling for daily smoking rate and anxiety sensitivity, emotional DT significantly predicted internal barriers to cessation (6.9% unique variance) but not external or addiction-related barriers to cessation. Inconsistent with prediction, emotional DT did not significantly predict number of quit attempts. The authors concluded that these results suggest that individuals who are low in emotional DT believe that quitting smoking will be difficult because it takes away an important affect regulation strategy. They additionally suggested there may be utility in targeting emotional DT in smoking cessation interventions (Kraemer et al., 2013).

Fagan (2007) examined the relationship between smoking cessation counseling self-efficacy, knowledge of smoking cessation counseling, motivation to counsel smokers, and barriers to performing smoking cessation counseling, relative to the smoking cessation counseling stage of change. Healthcare providers (N=296) completed a survey measuring the predictor variables of knowledge, motivation, self-efficacy and perceived barriers. The results indicated that the healthcare providers were knowledgeable about smoking cessation counseling and they had the self-efficacy to perform smoking cessation counseling effectively. The physicians also reported three significant barriers to smoking cessation counseling. The first listed was counseling time was not reimbursable by third party payers; secondly, smoking
interventions were not their responsibility due to lack of training; third, lack of resources for follow-up. There was a negative correlation between self-efficacy for smoking-cessation counseling and barriers to performing smoking-cessation counseling. The authors concluded that the study indicated that there was a moderate negative correlation between smoking cessation counseling self-efficacy and perceived barriers to performing counseling. This fact indicated that as self-efficacy increased, barriers decreased, specifying that environmental influences were associated with the level of self-efficacy (Fagan 2007).

Carter-Pokras et al. (2011) studied and found that Latinos who smoke were less likely than non-Latino white smokers to use pharmaceutical aids such as nicotine replacement therapies or to receive physician advice to stop smoking. This qualitative study further explored barriers and facilitators to smoking cessation among Latino adults in Maryland. Participants were recruited through flyers, information sheets, and site visits at community health clinics and Latino events, and were predominately of Central American origin. The study revealed barriers and facilitators to smoking cessation among Latino adult tobacco users from both smokers' and ex-smokers' perspectives. The authors concluded a notable finding which was social influence (family, friends, or other social environment) played an important role in cessation among Latino smokers, serving as both positive and negative factors of influence for the initiation and success of quitting smoking. Favored by both current smokers and ex-smokers, lay health promoters were effective agents to reach Latinos with smoking cessation interventions. In addition, the low use of cessation services could have been improved by increasing awareness and availability of Spanish-language cessation services (Carter-Pokras et al. 2011).
The prevalence of tobacco use among urban African American persons aged 18 to 24 years not enrolled in college is alarmingly high and a challenge for smoking cessation initiatives (Stillman, Bone, Avila-Tang, Smith, Yancey, Street, & Owings, 2007). The authors concluded from data collected from inner-city neighborhoods in Baltimore, MD, that more than 60 percent of young adults smoke cigarettes. Data from focus groups and surveys indicated that the sale and acquisition of "loosies" (single cigarettes) were ubiquitous and normative and may have contributed to the high usage and low cessation rates. This easy and affordable way to purchase cigarettes from street vendors and stores undermines tax policies, promotes smoking as a normative behavior, and may contribute to high smoking rates in some inner-city communities (Stillman et al., 2007).

China has the largest number of smokers in any country in the world with a smoking prevalence of 66% in adult men and 3% in adult women (Yang et al. 2005). Yet, only a small proportion of current smokers (16%) have indicated an intention to quit (Yang et al. 2001). Lam, Jiang, Chan, & Chee, (2011) conducted a cross-sectional survey of hospital-based healthcare professionals with direct patient contact. This was conducted in Guangzhou in 2006 with a self-administrated questionnaire to investigate their practice of smoking cessation counselling, tobacco-related knowledge and attitudes, and perceived facilitators, barriers and organizational support to cessation intervention practices. Significantly more female physicians who were non-smokers (79.7%) reported "initiation and or advice" smoking cessation interventions than male physicians who were smokers (71.2%) and non-smokers (71.6%). The findings highlighted the need for developing tailored smoking cessation training programs for
physicians according to their smoking status and gender in China (Lam, Jiang, Chan, & Chee
2011).

Caplan, Stout, & Blumenthal, (2011) researched a tobacco cessation program among
African American physicians in private practice and healthcare providers at community health
centers in GA. Data collection to determine tobacco-control practice behaviors among
participating providers took place prior to training and at six months following training.
Identified were six barriers to providing smoking cessation services which included lack of time,
patient un-readiness to change, inadequate resources, language and culture barriers, patient non-
compliance, and inadequate cessation clinical skills on the part of the providers. Of these six
barriers, the study’s intervention addressed only two—inadequate cessation skills and inadequate
resources—but this was sufficient to result in significant behavior change on the part of the
participants. It was determined that the physicians’ inadequate cessation skill was the most
important barrier. This was not surprising, since medical students generally do not receive
adequate training in approaches to smoking cessation. The study concluded that even though
smoking cessation counseling was provided by non-physician staff with good results, it is
likely that results will would be even better when it is a physician who provides—or at least
initiates—the smoking cessation intervention, since patients typically accord physicians the
most respect of any member of the health care team (Caplan, Stout, & Blumenthal, 2011).

In a another study, Akpanudo, Price, Jordan, Khuder, & Price, (2009) researched and
determined that the incidence of smoking among individuals suffering from various forms of
mental illness was inordinately high which was approximately 60% overall, compared to 25% in
the general population. The study also noted that clinical psychologists benefited from a number
of potential advantages in offering smoking cessation counseling and treatment where they have been specially trained in motivational techniques and have special expertise in helping patients change their behaviors. A cross-sectional study of clinical psychologists' smoking cessation practices and perceptions was the study's design. A random sample was surveyed regarding their smoking cessation practices and perceptions (N=352) utilizing the 5A's and 5R's. The results indicated that counselors that had never smoked were almost two times more likely to have higher efficacy expectations than those that were current smokers or ex-smokers (OR = 1.94, 95% CI 1.18-3.12). The most frequently cited perceived barriers to providing smoking cessation counseling were "not the patient's presenting problem," "I do not see this as a priority for my client," and "may interfere with therapy goals." These findings portrayed that clinical psychologists were more concerned that smoking cessation counseling may interfere or be detrimental to the treatment of the primary mental health issue of the client even though studies have demonstrated that concurrent treatment approach to both the presenting mental health issue and tobacco use is feasible (Akpanudo, 2009).

**Cessation in Primary Care**

Law, Tang, (1995) acknowledges the importance of specific advice to quit smoking, regardless of the patient's motivational status, which should be underscored. Every patient who smokes should be urged to quit in a clear, strong, and personalized manner. Not every patient counseled on smoking cessation will be prepared to consider quitting. Nevertheless, it is important that the patient's smoking and motivational status be ascertained at each encounter. In a systematic review of 20 studies conducted in primary care settings, brief (less than five
minutes) interventions that included advice to quit smoking resulted in two percent of all smokers quitting, compared with less than one percent of those who received no advice.

In a randomized controlled trial, Parkes (2008) examined the effect of smoking on quit rate utilizing spirometry in the primary care setting. The objective was to evaluate the impact of telling patients their estimated spirometric lung age as an incentive to quit smoking (N= 560) and aged over 35 years. Independently verified quit rates at 12 months in the intervention and control groups, respectively, were 13.6% and 6.4% (difference 7.2%, P=0.005, 95% confidence interval 2.2% to 12.1%; number needed to treat 14). People with worse spirometric lung age were no more likely to have quit than those with normal lung age in either group. Cost per successful quitter was estimated at 280 pounds sterling (366 euros, $556). A new diagnosis of obstructive lung disease was made in 17% in the intervention group and 14% in the control group; a total of 16% (89/561) of participants. The study concluded that telling smokers their lung age significantly improves the likelihood of them quitting smoking, but the mechanism by which this intervention achieves its effect was unclear.

A relatively new concept is that of “text messaging”. Mobile phone text messaging allows patients to receive personalized smoking cessation support through a series of automated motivational messages. Messages suggest behavioral changes, provide positive feedback, and allow patients to request additional assistance as needed. Randomized trials have found that text messaging is effective for short- and long-term abstinence. In a meta-analysis including two randomized trials of 1905 smokers, text messaging increased self-reported tobacco cessation at four to six week follow-up, compared to control (RR 2.2, 95% CI 1.8-2.7). Whittaker , Borland, Bullen, et al, (2009). In a subsequent trial of 5800 smokers, those randomly assigned to text
Group therapy allows smokers to learn behavioral techniques among their peers, with the intent of providing mutual support among group members and it is nearly twice as efficacious as self-help programs (Stead, Lancaster, 2005). One year quit rates for persons who complete such programs are approximately 20 percent. Despite the efficacy of group therapy, only a minority of smokers are willing to attend them, citing the inconvenience. Group sessions typically include short didactic presentations about the quitting process, group interactions, exercises on self-monitoring of one's smoking habit, some form of tapering method leading to a quit date, development of coping skills, and suggestions among members for relapse prevention. Group therapy allows patients to learn behavioral techniques from several participant perspectives while mutually supporting others attempting to quit (Stead, Lancaster, 2005).

A noteworthy approach regarding smoking cessation in the primary care setting is that of Problem Solving and Skills Training where the smoker anticipating quitting should be encouraged to identify situations or activities that may increase the risk of smoking or relapse (Ussher, 2005). Examples include having smokers within the household or at the workplace, getting into stressful situations, and alcohol use. Once the "danger situations" have been identified, coping skills should be explored. The nature and time course of withdrawal should be described. Learning strategies (cognitive and behavioral) that will reduce negative moods may also be helpful.

Strategies to enhance coping may include making lifestyle changes to reduce stress and improve quality of life (eg, starting an exercise program, learning relaxation techniques). In one randomized trial of 281 female smokers, vigorous exercise, used in conjunction with a cognitive-behavioral smoking cessation program, enhanced short and long-term (up to one year)
abstinence, and delayed weight gain following smoking cessation (Marcus, Albrecht, King, et al., 1999). Further investigation is required to clarify the potential role of exercise programs in promoting smoking cessation.

The smoker should be encouraged by the practitioner to explore how to minimize the time spent in the company of smokers. When other smokers are in the home, the recent ex-smoker could consider negotiating with household members not to smoke within the home or car. Lancaster T, Stead, (2002) concludes that the key to successful quitting is to equip the smoker with as much information as possible about what to expect during quit attempts. Supplementing information discussed during visits and on the telephone with self-help materials may serve both as a reinforcer and a time saving resource for the clinician. These materials include pamphlets or booklets and videos or audio tapes on smoking cessation, a hotline or help line, the internet, and support groups. Several medical centers now have patient resources or learning centers in which patients can access additional self-help materials (Lancaster, Stead, 2002).

A multidisciplinary approach has been researched and proven to be successful in the primary care setting. Zwar, Richmond, Halcomb, et al., (2010) completed a study in recognition of the chronic nature of tobacco dependence, where a multidisciplinary, team-based approach is used, which has been implemented with successful abstinence rates in observational studies. Utilizing other members of the care team, as well as making use of electronic systems to flag a patient's active smoking status, more conversations between patients and clinicians may occur during office visits as part of an overall strategy for a team approach to care. A study that looked at the impact of adding smoking-related vital sign questions to patients' electronic records found
that clinician-documented smoking cessation counseling rates were significantly increased (McCullough, Fisher, Goldstein, et al., 2009). Other studies have looked at non-clinician-based systems approaches to enhancing smoking cessation rates. For instance, one study found that incorporating a smoking cessation template into electronic notes and providing patient education during referrals to clinical pharmacists was an effective method to enhance smoking cessation rates (Ragucci, Shrader, 2009).

Relapse after an attempt at smoking cessation is common. Most smokers make many attempts to quit before they achieve success. The availability of over-the-counter smoking cessation aides means that clinicians will see an increasing number of smokers who have already made multiple unsuccessful attempts to quit. These patients may be highly dependent upon nicotine, making it even more imperative that the clinician be knowledgeable about available treatment options and resources. There is relatively little evidence that specific interventions prevent relapse after smoking cessation, however, it is reasonable to try simple interventions that promote abstinence (Hajek, Stead, West, et al., 2013). The clinician should take every opportunity to encourage and congratulate the patient on quitting. The benefits of smoking cessation can be highlighted by simply asking how their lives have changed since they stopped smoking. An equally important step is to address any problems encountered as a result of abstinence (e.g. weight gain, depression, or change in relationships with other smoking friends or relatives). Fiore, Jaen, Baker, et al., (2008), studied and found that most smokers make many attempts to quit before they achieve success. Smokers should be made aware of this when they are attempting to quit, and when they have relapsed after a quit attempt. The clinician should assess for non-adherence or improper use of cessation aides when a patient who has quit
smoking relapses. Determining the patient's insight into the possible reasons why the attempt failed and explore solutions for the next quit attempt would be an appropriate next step. Screen and treat comorbid conditions that may affect relapse such as depression and also chemical dependency other than nicotine. Referral was another approach for relapse prevention and intervention to a subspecialty clinic or smoking cessation program for the smoker who is heavily dependent upon nicotine or has had multiple unsuccessful attempts. Different types of providers (physicians, nurses, psychologists, dentists) may improve smoking cessation rates; involving multiple types of providers may enhance success. Intensive individual and group counseling also is often effective (Fiore, Jaen, Baker, et al., 2008).

McCullough, Fisher, Goldstein, Kramer, Ripley-Moffitt (2009) studied strategies to improve smoking cessation counseling in clinical settings which are critical to supporting smokers' attempts to quit. This study evaluated the impact of adding two smoking-related vital sign questions in an electronic medical records system on identification, assessment, and counseling for patients who smoke: "Current smoker?" and "Plan to quit?" The method utilized baseline data of no tobacco use assessment, and data after intervention (assessment of tobacco use), which were collected through record review of 899 randomly selected patient visits across 3 outpatient clinics. The results revealed from before to after intervention, identification of smokers increased 18% (from 71% to 84%; P<.001), and assessment for a plan to quit increased 100% (from 25.5% to 51%; P<.005). Among all smokers, cessation counseling increased 26% (from 23.6% to 29.8%; P=.41). Significantly more smokers who received the assessment for a plan to quit received cessation counseling (46% vs. 14%, P<.001). Regression analysis showed that patients receiving an assessment for plan to quit were 80% more likely to receive cessation
counseling (OR 0.209; 95% CI, 0.095-0.456). The authors concluded that Physician-documented counseling rates were significantly higher when patients are asked about smoking and assessed for a plan to quit. Two questions that ask about smoking status and assess plans to quit may provide prompts to increase the likelihood that patients who smoke receive cessation counseling (McCullough, Fisher, Goldstein, Kramer, Ripley-Moffitt (2009).

**Pharmacotherapy**

Pharmacotherapy for smoking cessation aims to reduce the symptoms of nicotine withdrawal, thereby making it easier for a smoker to stop the habitual use of cigarettes. The main medications that have demonstrated efficacy as smoking cessation aids include nicotine replacement, bupropion, and varenicline. Smoking cessation pharmacotherapy should be offered to all smokers making a quit attempt, unless medically contraindicated (Fiore, Jaen, Baker, et al., 2008). Since tobacco use is both a learned behavior and a physical addiction to nicotine for the majority of smokers, the combination of counseling and pharmacologic therapies can produce higher quit rates than either one alone (Rigotti, 2002). Smoking cessation clinical guidelines from the United States Public Health Service consider seven drugs to be first-line agents for tobacco cessation (Fiore, Jaen, Baker, et al., 2008). The Transdermal nicotine patch, Nicotine gum, Nicotine lozenge, Nicotine inhaler, Nicotine nasal spray, Bupropion, and Varenicline are the recommended guidelines and available in some countries are a nicotine mouth spray and sublingual tablets.

The goal of nicotine replacement therapy (NRT) is to provide nicotine to a smoker without using tobacco, thereby relieving nicotine withdrawal symptoms as the smoker breaks the behavior of cigarette smoking. The use of NRT in place of cigarettes avoids exposure to carbon
monoxide that reduces oxygen delivery, to oxidant gases that are atherogenic, and to tars that are carcinogenic.

**Nicotine Replacement Products**

Nicotine replacement products differ in their pharmacokinetics and delivery of nicotine to the circulation (Rigotti, 2002). Nicotine is absorbed transdermally with the nicotine patch, through the nasal mucosa by the nasal spray, or through the oral mucosa with the nicotine chewing gum, mouth spray, lozenge, sublingual tablet, or inhaler. No product delivers nicotine as rapidly as cigarette smoking, a factor that contributes specifically to the dependence-producing properties of cigarettes. The patch has a long-acting, slow-onset pattern of nicotine delivery, producing relatively constant withdrawal relief over 24 hours, but requiring several hours to reach peak levels. Compliance with the patch is high, but the user has no control of nicotine dose to respond to nicotine cravings and withdrawal symptoms during the day. By contrast, the nasal spray and oral forms of nicotine replacement (gum, lozenge, and inhaler) share a short-acting but rapid-onset pattern of nicotine delivery that allows the user flexibility to respond to acute cravings or withdrawal symptoms. However, the nasal and oral forms require repeated use throughout the day, lead to more variable nicotine levels, and require more instruction for correct use. Currently, there are three NRT products which are available in the US without a prescription (patch, lozenge, and gum). Two (nasal spray and oral inhaler) are available by prescription only.

**Electronic cigarettes**

Electronic cigarettes (e-cigarettes) use an electronic delivery system that aerosolizes nicotine. Many e-cigarette products are available that vary in their consistency and nicotine delivery. Several have been studied for smoking cessation, but data supporting their efficacy in
this context are lacking. Electronic cigarettes (e-cigarettes) use an electronic delivery system that aerosolizes nicotine, producing a vapor similar to cigarettes but containing fewer traditional toxins (Yamin, Bitton, 2010). E-cigarette devices are composed of three parts: a plastic tube, an electronic heating element, and a liquid nicotine cartridge. The user presses a button that simultaneously releases a puff of vaporized nicotine while illuminating the device tip (that simulates the lit end of a cigarette). E-cigarettes do reduce the desire to smoke traditional cigarettes and have been prescribed by clinicians to aid in smoking cessation (Bullen C, McRobbie, Thornley, et al., 2010).

E-cigarettes are being increasingly used by the general population, mostly as a result of internet advertising and sales (Etter, 2010). There are many available products that vary greatly in consistency, in nicotine delivery, and in other additives that may have their own toxicity. A 2009 US Food and Drug Administration (FDA) report on e-cigarettes found trace amounts of the harmful solvent diethylene glycol as well as nitrosamines which are known carcinogens. This report also found nicotine in ‘light’ e-cigarettes that were labeled as being nicotine-free. The FDA has not approved the use of any e-cigarettes given safety concerns, particularly related to use in adolescents and potential toxic ingestion among children (fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173327.htm). Data from one pilot study reports common adverse effects of e-cigarettes as dry cough and irritation in the oropharynx (Polosa, Caponnetto, Morjaria,, et al., 2011). Whether initial recreational use of e-cigarettes leads to smoking of conventional cigarettes is unknown.

Despite their increasing popularity, little is known about e-cigarette use, potential for addiction, or long-term health effects from smoking and second-hand smoke. Whether e-
cigarettes can help smokers to quit or permanently stop using tobacco products is uncertain (fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173272010). A randomized trial that compared e-cigarettes with nicotine patches among smokers who wanted to quit found no significant difference in the cessation rates produced by the two treatment arms, although the study was underpowered and could have missed important differences in the effectiveness of e-cigarettes compared with patches (Bullen, Howe, Laugesen, et al.(2013). While this trial suggests that e-cigarettes might have the potential to be smoking cessation aids, further studies will be required to establish the efficacy and safety of e-cigarettes for cessation.

**Relapse Prevention**

Most relapses occur soon after a person quits smoking, yet some people relapse months or even years after the quit date. All clinicians should work to prevent relapse. Relapse prevention programs can take the form of either minimal (brief) or more intensive programs. There is relatively little evidence that specific interventions prevent relapse after smoking cessation (Hajek, Stead, West, et al., 2013), however, it is reasonable to try simple interventions that promote abstinence. The authors conducted randomized or quasi-randomized controlled trials of relapse prevention interventions with a minimum follow-up of six months. They included smokers who quit on their own, were undergoing enforced abstinence, or were participating in treatment programs. They included trials that compared relapse prevention interventions with a no intervention control, or compared a cessation programs with additional relapse prevention components with a cessation programs alone.
The clinician should take every opportunity to encourage and congratulate the patient on quitting. The benefits of smoking cessation can be highlighted by simply asking how their lives have changed since they stopped smoking. An equally important step is to address any problems encountered as a result of abstinence (eg, weight gain, depression, or change in relationships with other smoking friends or relatives). Relapse prevention should be part of every encounter with a patient who has quit recently. (Hajek, Stead, West, et al., 2013). Most smokers make many attempts to quit before they achieve success. Smokers should be made aware of this when they are attempting to quit, and when they have relapsed after a quit attempt. The clinician should assess for non-adherence or improper use of cessation aides when a patient who has quit smoking relapses. Determine the patient's insight into the possible reasons why the attempt failed and explore solutions for the next quit attempt. Screen and treat comorbid conditions that may affect relapse such as depression and/or chemical dependency other than nicotine (Hajek, Stead, West, et al., 2013).
CHAPTER 3 - PROJECT DESCRIPTION

Introduction

The primary care setting is an ideal location for the promotion of smoking cessation through counseling and pharmacological interventions. Smoking cessation options should be offered by PCPs at each office visit. Meta-analyses of clinical trials have found that behavioral counseling and pharmacotherapy with nicotine replacement each has strong evidence of efficacy for smoking cessation, and that the combination of the two methods produces the best results (Stead, Lancaster, 2012). The United States Public Health Service clinical practice guide “Treating Tobacco Use and Dependence: 2008 Update” states that all health professionals need to more effectively engage all patients who smoke (Fiore, et al., 2008). This information is of importance due to a study of 1,898 patients who reported that they had been asked about tobacco use or were advised to quit during their latest visit had a 10% greater satisfaction rating and 5% less dissatisfaction than those who did not report such discussions (Fiore, et al., 2008).

Telephone QuitLine counseling has been effective in the past with diverse populations and has had a broad reach. Therefore, both clinicians and health care delivery systems should continue to ensure patient access to QuitLines and promote QuitLine use. Recent studies, (figure B), however have shown that the Tennessee QuitLine calls has been on the decline and from a personal perspective, a large percentage of patients have not called or gained advice to quit tobacco after getting a QuitLine card or brochure.
McCullough, et al., (2009) studied strategies to improve smoking cessation counseling in clinical settings which are critical to supporting smokers' attempts to quit. This study evaluated the impact of adding two smoking-related vital sign questions in an electronic medical records system on identification, assessment, and counseling for patients who smoke: "Current smoker?" and "Plan to quit?" (McCullough, et al., 2009).
Practice Change

The goal of the practice change is to provide improved patient care by increasing providers’ adherence to the recommendations of a clinical practice guideline for the assessment and treatment of smoking cessation in the primary care setting.

Rosswurm and Larrabee’s model proposed that six phases are involved in a practice change.

- **Assessing the need for a practice change.** The Southeast Regional Health Departments currently does a smoking assessment survey on new and annual patients. The data collected unfortunately becomes ‘invisible’ to the practitioners in terms of patients’ desire to quit or their history of smoking cessation attempts. This information is based solely on observation for approximately one year by the project leader. Formal data collection or research has not been done to validate the findings however, clinical experience has given reasonable support for the need for this practice change. The QuitLine is also used as an intervention where brochures and cards are provided to the patients, but on return visits based on the project leader’s observation, the QuitLine approach has not proven to be an effective intervention. Patients have expressed that they “just don’t call”, “don’t want to call back” after the initial attempt, or they are “not motivated to call”. An official primary meeting is generally held quarterly and an assessment of the current practice of addressing smoking cessation among the providers would be discussed and identification of current and experienced problems would be discussed.

- **Linking the problem with nursing interventions and patient care outcomes.** According to the recent tobacco use update guidelines (Fiore, 2008), increasing evidence has shown
that screening and assessment practices such as expanding vital signs to include tobacco-use status, or other reminder systems to ask about smoking significantly increases the rate of clinician intervention. Presently, the three primary care sites do not include patient’s tobacco use status on the progress notes as a component of the vital signs.

For smokers who are not ready to quit, the clinician’s role is to assess the patient's perspective (of the risks and benefits of continuing to smoke) in order to help the smoker to begin to think about quitting. Most smokers have a general desire to stop smoking, but may not be ready to take specific action to quit, for a variety of reasons. Asking a smoker what he or she likes and does not like about smoking is a way to start. A personalized message concerning a smoking-related health problem may motivate some patients into action. Clinicians can use motivational interviewing techniques to explore a smoker’s feelings, beliefs, ideas, and values regarding tobacco use. The model of "5 Rs" (Relevance, Risks, Rewards, Roadblocks, Repetition) is helpful to motivate smokers who are not ready to quit (Appendix B).

- **Synthesizing the best evidence.** Based on current research, providers should note that simply giving standardized self-help materials (QuitLine) to a patient may have little positive effect on his or her success. Every smoker should be asked if he or she is willing to quit. If the patient wants to attempt to quit, the clinician should guide the patient in selecting an appropriate treatment. It is important to understand the stages of motivation utilizing the TTM, to change behavior in order to plan an effective intervention. Most smokers (80%) fall into one of two of the change categories: pre-contemplation or contemplation. The two distinct groups of individuals need very different approaches to
smoking cessation. Patients who fall into the pre-contemplation stage are not convinced the health hazards associated with smoking apply directly to them. They may not want to make a change in smoking as a health behavior, or they may express doubts about their ability to successfully make a change. The goal for these patients are to instill a sense of doubt about the desire to continue smoking, raise an awareness of the health hazards of smoking and their direct effect on the patient’s health and well-being and communicate the benefits of quitting, exploring the positive perceptions the patient has about smoking may help overcome the resistance commonly seen in this stage of the change process.

Patients in the contemplation stage seek out information about the quit attempt but are unwilling to make a commitment to quit or express self-doubt about their ability to successfully quit. Identifying the positive and negative aspects of continuing to smoke and emphasizing the negative consequences of continuing to smoke will help the contemplator resolve ambivalence toward continuing to smoke.

The use of an algorithm has proven to be an effective tool which integrates the recommendations of the major guidelines and meta-analyses and provides rationales for its treatment decisions. An algorithm suggests a brief assessment followed by use of one to two medications and counseling in most smokers. Because all treatments appear equally effective and have few adverse events, the algorithm suggests clinicians inform smokers of the pros and cons of the different treatments, and recommend use of one or more of each (Bader, McDonald, Selby. 2009). The proposition of having an algorithm for providers to employ during encounters will also be an entity of the proposal for the practice change at the primary care sites.
• **Designing the practice change.** Based on peer reviewed, current evidence based literature, the proposal would entail three entities to supplement, enhance and intensify the already established protocol. The first would be to incorporate the TTM on stages of change and respond appropriately based on their motivation. An added section with the five stages of change from the TTM would be on the progress notes to be addressed with each encounter. Patients would continue to be provided with the Tennessee Quit-line information. The second would be to include the patients' smoking status as a part of the 'vital sign' section which could be determined by the certified nurse's assistances (CAN's). The third proposition would be to have an algorithm as a guide for the necessary approaches for smoking cessation in the primary care setting. This proposal would then be given to the regional medical director to review and then present same to the regional director for the Southeast Region of Health Department for review by the board of directors.

• **Implement and evaluate change in practice.** This practice change project would involve interacting with the Tennessee Department of Health (TDH) patients, their surveys, and chart reviews at the local health departments. The requirements would entail an application to the TDH IRB which would need a review prior to submission to the TDH IRB by the Regional Director and the Medical Director of Community Health Services. A development of a two page executive summary of the project with the research query, methods, eligible population that would be researched and why, data analysis plan, and the potential conclusions and knowledge that will be gained by the project. After approval of the overall plan, then a pilot study would be done for approximately six
months while evaluating the process and outcomes. A decision would then be determined to adapt, adopt or reject the practice change.

- **Integrating and maintaining the change in practice.** Upon acceptance of the proposal, a pilot study would be in order for approximately six months to one year to determine the efficacy of the proposed change and on the annual evaluations of the smoking cessation surveys by the epidemiologist, determining statistical significance would be deemed positive or negative. Communicating the results and the recommended change of the pilot study at the quarterly primary care meeting would be done to ensure appropriate integration into the standards of practice.

**Proposal**

When providers sees a patient for the first they should first assess the patient's tobacco use, the desire to stop smoking, and the history of previous quit attempts, including methods used and their effectiveness (West, 2004). A smoker’s dependence on nicotine can be estimated from the duration of smoking history, the number of cigarettes smoked daily, and how soon after waking up the smoker has his or her first morning cigarette. More dependent smokers have smoked for many years, smoke more cigarettes daily, and smoke within the first 30 minutes of awakening. The smoker's degree of nicotine dependence predicts the difficulty that he or she will have in quitting and the intensity of treatment likely to be required (West, 2004).

Two strategies studied to improve smoking cessation counseling in the clinical setting involves the inclusion of smoking related vital sign questions inquiring of the current tobacco usage and determining the current stage of change. McCullough, et al., (2009), concluded that this approach proved to be beneficial (Appendix F).
The use of an algorithm in the primary care setting has proven to be beneficial by providing a step-by-step procedure for health care practitioners to initiate a smoking cessation protocol into practice. It also serves as a concise, evidence-based resource that can be used by providers during a visit in a timely manner (Jones, 2014). After gaining consent from the publishers from two articles, an algorithm was developed after adapting, and pertained directly to the population at the Southeast Region Health Departments (Appendix D-a, Appendix D-b).

Cost is an important financial concern to the Southeast Region Health Departments and the selection of projects that may contribute most to the attainment of its objectives, given resource constraints, is crucial and fundamental. The three proposed components may be a cost benefit in the future. The projected cost on acceptance of this proposal may entail obtaining additional resources from the CDC’s publication department regarding handouts or brochures for encouraging and maintaining smoking cessation in addition to the already established QuitLine. The algorithm suggests distributing patient centered information depending on the stage of change they are currently experiencing. UpToDate® (UTD) is an already established and consumed computer access to the providers which synthesizes the most recent medical information into evidence-based practical recommendations clinicians trust to make the right point-of-care decisions. With appropriate terminology in the search engine, UTD offers two types of patient education materials, “The Basics” and “Beyond the Basics.” The Basics patient education pieces are written in plain language, at the 5th to 6th grade reading level, and they answer the four or five key questions a patient might have about a given condition. These articles are best for patients who want a general overview and who prefer short, easy-to-read materials. Beyond the Basics patient education pieces are longer, more sophisticated, and more detailed.
These articles are written at the 10th to 12th grade reading level and are best for patients who want in-depth information and are comfortable with some medical jargon.
CHAPTER FOUR: EVALUATION PROCESS

Introduction to the Evaluation Process

On approval of acceptance of the proposal, a six month pilot study of the two additional components of the vital signs and the addition of the TTM's stages of change will be utilized by the six primary care providers in the various counties of East Tennessee. An evaluation survey of the positive or negative effects of the proposed algorithm will then be distributed to each of the providers for a discussion at the following primary care meeting at the Southeast Regional Office in Chattanooga, Tennessee.

CDC Framework for Program Evaluation

The Centers for Disease Control and Prevention (CDC) Framework for Program Evaluation in Public Health provides guidance and structure to aid in the development of a comprehensive evaluation design that meets the evaluation standards set by the Joint Committee on Standards for Educational Evaluation and ensures the evaluation produces relevant, useful information (Centers for Disease Control and Prevention, 1999; Joint Committee on Standards for Educational Evaluation, 2010). The framework consists of six steps: (a) engaging stakeholders, (b) describing the program, (c) focusing the evaluation design, (d) gathering credible evidence (e) justifying the conclusions, and (f) ensuring utilization and sharing lessons learned (Figure 3).
Figure 3. The CDC Program Evaluation Framework

The steps are essential, interdependent, and iterative, but allow the flexibility to tailor an evaluation based on the program’s context and the purpose of the evaluation. The underlying logic of the Evaluation Framework is that good evaluation does not merely gather accurate evidence and draw valid conclusions, but produces results that are used to make a difference.

**Step 1: Stakeholder Engagement**

Program evaluation is one of ten essential public health services and a critical organizational practice in public health. According to CDC (2011), the first step in this process is engaging stakeholders. Stakeholders are people or organizations invested in the program and interested in the results of the evaluation. Representing their needs and interests throughout the process is fundamental to good program evaluation. The participation of stakeholders ensures their perspectives and values are understood, and increases buy-in to the findings and changes made as part of the process (Centers for Disease Control and Prevention, 1999; Minkler, 2005; Patton, 2008).
The evaluation process will include several stakeholders of the Southeast Regional Health Departments including, but not limited to the Regional Director, Medical Director of Community Health Services, Director of Quality Improvement, epidemiologist, providers, staff, and patients as active participants, with each participant providing input from their unique knowledge and experiences. Program evaluation involvement can be empowering and allow each voice to be heard however, it may require a commitment of time and effort that may be hard for some individuals and not feasible for others within the time constraints of the proposal. Patients input will be particularly important because their needs, attitudes, and goals may differ significantly from individuals from the other stakeholders and their perspectives may differ from the health care providers. Stakeholder involvement would be maintained throughout the entire practice change protocol evaluation process.

**Step 2: Program Description**

The second step of the CDC framework is an accurate, comprehensive description of the program. A comprehensive program description clarifies all the components and intended outcomes of the program, thus helping the project manager focus the evaluation on the most central and important questions.

**A comprehensive program description includes the following components:**

**Need.** The public health problem that will be addressed with this practice change is the seemingly lack of smoking cessation among the primary care patients in the Southeast Regional Health Department ages 19-64 years in the past 18 months.
**Targets.** To ensure progress with this public health problem, the attention of the Office of Quality Improvement and the Medical Director of Community Health Services needs to be aroused.

**Outcomes.** The ultimate outcome would be a significant reduction of tobacco use by incorporating the proposed additional vital signs, the algorithm, and the distribution of pertinent brochures based on the patient’s stage of change. Currently, only one intervention, QuitLine brochures, is distributed to the patients with limited information to address TTM stages of change.

**Activities.** During the work up of patients, CNA’s will be able to ask questions pertaining to tobacco use and determine their stage of change. The provider will assess their smoking status and will then distribute the appropriate handout or recommend medications for patients willing to quit or reduce their tobacco usage.

**Outputs.** The tangible capacities that will be produced by this program’s activities would be attaining the ultimate goal of the Tennessee Department of Health Mission: To protect, promote, and improve the health and prosperity of people in Tennessee.

**Resources and Inputs.** In order for these activities to be mounted successfully would include brief training of the CNA’s during the assessment of vital signs, informing the other primary care sites and their providers of the change to the progress notes, sharing the concise algorithm and various treatments for medication use. Regarding cost, these three components of the proposal would eventually prove to be perhaps a cost benefit in terms of a decrease in tobacco usage and consequently a reduction in tobacco related illnesses and diseases due to the easy accessibility to the providers. The projected miniscule cost on acceptance of this proposal may entail obtaining
additional resources from the CDC’s publication department regarding handouts or brochures for encouraging and maintaining smoking cessation in addition to the QuitLine. Regarding documentation forms, a master copy is located on the hard drive which is easily amended by the appropriate staff which are generally printed weekly on an as needed basis.

**Stage of Development.** This program is in its planning stage. After approval of the program by the appropriate committee, then it would progress to the implementation stage.

**Context.** The factors and trends in the larger environment which may influence this program’s success or failure include lack of patient’s motivation to quit tobacco use, providers negligence of addressing tobacco usage at each office visit, and close involvement of the Medical Director.

**Step 3: Focus the Evaluation Design**

According to CDC (2011), the design is to be determined by the purpose and aims of evaluation, the intended uses of the findings by the key stakeholders or decision-makers in a program, and resources available to conduct the evaluation. The design for this proposal for a practice change would look retrospectively at the quit rate prior and the quit rate after implementation of the change. After obtaining IRB approval and completing the necessary required documents, access to the electronic data base and review of charts for the past 18 months would be compared to at least six months’ worth of implementation of the proposal for the practice change.

**Step 4: Gather Credible Evidence**

Evidence gathering in a program evaluation is analogous to data collection in research studies. The data gathered must be credible and relevant for answering the evaluation questions. The use of mixed methods of data collection with qualitative and quantitative data is
recommended to increase the richness and accuracy of the data (Johnson & Onwuegbuzie, 2004; Malterud, 2001). Data sources are determined by the research query and may include client records, individual interviews of participants, staff, and key informants, program policies and procedure manuals.

The recommended combination of qualitative and quantitative data will be used in the evaluation of the proposal for smoking cessation in the practice change.

**Step 5: Conclusions**

This step encompasses analyzing the evidence, making claims about the program based on the analysis, and justifying the claims by comparing the evidence against stakeholders’ values. In the CDC program evaluation framework, conclusions are justified through synthesis of the findings obtained from data analysis interpreted within the conceptual framework and context of the program, and the values of the stakeholders (Baker, Davis, Gallerani, Sanchez, & Viadro, 2000).

This interpretation and judgment concerning the practice change will be performed in collaboration with the key stakeholders. The data analysis results will be presented at the quarterly primary care meetings with the Medical Director, the primary care providers, the registered nurses and some ancillary staff.

**Step 6: Evaluation Use and Dissemination**

The final step in the CDC program evaluation framework is to ensure use of the evaluation findings and lessons learned. To accomplish this step, plans should be made at the very beginning of the program evaluation process. The design must be tailored to achieve the uses intended by the primary stakeholders. The evaluation findings must be credible and any
recommendations made must be feasible to increase the likelihood of their use. The primary uses of the proposal evaluation information will be the Regional Medical Director and the Medical Director of Community Health Services. As directors within public health system, these individuals will anticipate that the program evaluation results would reveal areas of strength and weaknesses in the program and provide insight into the clients’ experiences. This information will provide insight into needed refinements and methods of improving the program. Active participation of these stakeholders in the program evaluation process will perhaps increase the likelihood that they will accept and use the findings. Feedback to and from the users at each step of the evaluation process by email and periodic meetings will maintain involvement and ensure the evaluation continue to be focused, relevant, and useful (CDC, 2005).

The ultimate purpose of a program evaluation is to use the information to improve specific programs. The purpose initially identified early in the evaluation process should guide the use of the evaluation results. The evaluation results can be used to demonstrate the effectiveness of the program, identify ways to improve the current program, modify program planning, and demonstrate accountability. Dissemination involves communicating evaluation procedures or lessons learned to relevant audiences in a timely, unbiased, and consistent manner. Regardless of how communications are structured, the goal for dissemination is to achieve full disclosure and impartial reporting (CDC, 2011).

**Evaluation Method**

The evaluation method proposed for this practice change would consist of both qualitative and quantitative methods. Identifying how many cigarettes are smoked and how often, daily or weekly, would satisfy the quantitative method. Identifying the positive use of the
information provided and what it meant from the patient's perspective would satisfy the qualitative method. Quite often qualitative data can provide contextual meaning to the quantitative data in a project that uses both (Zaccagnini, & White, 2011). Tools that may possibly be utilized would include interviews, written questions and surveys, health factors, and chart reviews.

According to CDC (2011), a logic model is a systematic and visual way to present the perceived relationships among the resources one has to operate the program, the activities ones plans to do, and the changes or results one hopes to achieve. It is a picture of how the project developer believes the program will work and uses a series of diagrams to indicate how parts of the program are linked together or sequenced. The logic model depicted in Figure 4, clearly summarizes all the entities specific for this practice change proposal.

- Inputs – These are materials that the organization or program takes in and then processes to produce the results desired by the program.
- Activities - These are used by the program to manipulate and arrange items to produce the results desired by the program.
- Outputs - Outputs are usually the tangible results of the major processes in the organization. They are usually accounted for by their number, and in this example, the number of calls to the QuitLine or use of prescribed medication.
- Outcomes –These are the results of the impacts on those people who may have benefitted from this program. Outcomes are usually specified in terms of: a) learning, including enhancements to knowledge, understanding, perceptions, attitudes, and behaviors
Promoting Smoking Cessation Among Young People and Adults

Figure 4: Logic Model

http://www.cdc.gov/tobacco/tobacco_control_programs/surveillance_evaluation/evaluation_manual/pdfs/
Data Analysis

Content analysis will be used to analyze the qualitative data obtained from interviews, focus groups, and comments written on participant surveys. The content analysis would be determined by the specific concerns for the practice change, using a simple, systematic, verifiable process. Each interview, focus group discussion, and participant survey comment will be transcribed and each line numbered. Possible descriptive statistics of the data may include frequencies, means and summary statistics. To identify any significant changes in the tobacco survey and patients' smoking cessation status, possible pre and post intervention measures would be analyzed with the paired t test. The level of significance for each analysis would be designated as less than 0.05. Data would be analyzed by using the Statistical Package for Social Sciences (SPSS) Graduate Pack 22.0, student version with the assistance of the epidemiologist and a statistician.
The primary care setting is the ultimate location to promote smoking cessation through counseling and pharmacological aids. Effective smoking cessation options should be promoted by primary care providers at every opportunity and may be reimbursed through private and public health care programs for smoking cessation counseling during a regular office visit.

Assessing tobacco use status during healthcare visits increases the likelihood of smoking-related discussions between patients and clinicians, as well as increases smoking cessation rates. The clinician should assess the patient's cigarette use, the desire to stop smoking, and the history of previous attempts to quit, including methods used and their effectiveness. The importance of specific advice to quit smoking, regardless of the patient's motivational status, should be underscored. Every patient who smokes should be urged to quit in a clear, strong, and personalized manner. Not every patient counseled on smoking cessation will be prepared to consider quitting.

For smokers who are not ready to quit, the clinician's role is to assess the patient's perspective of the risks and benefits of continuing to smoke, in order to help the smoker to begin to think about quitting. Clinicians should also use motivational interviewing techniques to explore a smoker's feelings, beliefs, ideas, and values regarding tobacco use. The USPHS guideline has proposed the model of "5 Rs" (Relevance, Risks, Rewards, Roadblocks, Repetition) in promoting motivation in patients who are unwilling to quit.

The hope and goal of this practice change protocol was to provide improved patient care by increasing providers' adherence to the recommendations of a clinical practice guideline for the assessment and treatment of smoking cessation in the primary care setting. The project
manager has determined that there is sufficient evidence to warrant initiating the process of a practice change. Internal data, though available to TDH staff only, has evidenced the need for a change regarding the assessment and implementation for smoking cessation achievement. A major barrier that was encountered for this practice change implementation was initiating the IRB process, which was quite involved, and required a minimum of twelve weeks before a review by the IRB committee (Appendix H). The field of smoking cessation treatment is rapidly expanding. Randomized controlled trials of commonly used smoking cessation techniques, including individual, group, and telephone counseling, have demonstrated success in helping smokers quit and maintaining long-term abstinence. In addition, rapid expansion in pharmacotherapy has resulted in multiple drug agents and systems of delivery directed at treating the biologic basis of tobacco addiction. The project manager and the medical director discussed at length the possibility of presenting the above mentioned protocol with extensive evidence based literature to confirm the need of a change.
# Appendix - A Tobacco Survey

## Patient Tobacco Survey

This section to be completed by the patient.

### 1. Which tobacco products do you currently use?
*(Check all that apply)*
- [ ] Cigarettes
- [ ] Cigars, pipes, or other *smoking* tobacco
- [ ] Chewing tobacco, snuff, or other *smokeless* tobacco
- [ ] I do not currently use tobacco
- [ ] Refused

### 2. Have you smoked at least 100 cigarettes in your entire life?
*(Check one box)*

- [Y] Yes
- [N] No
- [D] Don’t know/Not sure
- [R] Refused

**NOTE:** 5 packs = 100 cigarettes

### 3. Do you now smoke cigarettes everyday, some days, or not all?
*(Check one box)*
- [E] Everyday
- [S] Some days
- [N] Not at all
- [R] Refused

### 4. How many times during the past 12 months have you stopped smoking for 1 day or longer because you were trying to quit smoking?
*(Check one box)*
- [A] I have not smoked in the past 12 months
- [B] I have not tried to quit
- [C] 1 time
- [D] 2 times
- [E] 3 to 5 times
- [F] 6 to 9 times
- [G] 10 or more times
- [R] Refused

### 5. When you last tried to quit, how long did you stop smoking?
*(Check one box)*
- [A] I have never smoked
- [B] I have never tried to quit
- [C] Less than a day
- [D] 1 to 7 days
- [E] More than 7 days but less than 30 days
- [F] 30 days or more but less than 6 months
- [G] 6 months or more but less than a year
- [H] 1 year or more
- [R] Refused

### 6. Would you like to stop smoking?
*(Check one box)*
- [I] I do not smoke now
- [Y] Yes
- [N] No
- [D] Don’t know/Not sure
- [R] Refused

**STOP.**

Thank you. Please give this sheet to your health care provider.
### Five "R's" to motivate smokers unwilling to quit

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Relevance</strong></td>
<td>Encourage the patient to indicate why quitting is personally relevant, being as specific as possible. Motivational information has the greatest impact if it is relevant to a patient’s disease status or risk, family or social situation (eg, having children in the home), health concerns, age, gender, and other important patient characteristics (eg, prior quitting experience, personal barriers to cessation).</td>
</tr>
</tbody>
</table>
| **Risks** | Ask the patient to identify potential negative consequences of tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. The clinician should emphasize that smoking low-tar/low-nicotine cigarettes or use of other forms of tobacco (eg, smokeless tobacco, cigars, and pipes) will not eliminate these risks. Examples of risks are:  
- Acute risks - Shortness of breath, exacerbation of asthma, harm to pregnancy, impotence, infertility, and increased serum carbon monoxide.  
- Long-term risks - Heart attacks and strokes, lung and other cancers (larynx, oral cavity, pharynx, esophagus, pancreas, bladder, cervix), chronic obstructive pulmonary diseases (chronic bronchitis and emphysema), long-term disability, and need for extended care.  
- Environmental risks - Increased risk of lung cancer and heart disease in spouses; higher rates of smoking in children of tobacco users; increased risk for low birth weight, Sudden Infant Death Syndrome, asthma, middle ear disease, and respiratory infections in children of smokers. |
| **Rewards** | Ask the patient to identify potential benefits of stopping tobacco use. The clinician may suggest and highlight those that seem most relevant to the patient. Examples of rewards include:  
- Improved health  
- Food will taste better  
- Improved sense of smell  
- Save money  
- Feel better about yourself  
- Home, car, clothing, breath will smell better  
- Can stop worrying about quitting  
- Set a good example for and have healthier babies and children  
- Not worry about exposing others to smoke  
- Feel better physically and perform better in physical activities  
- Reduced wrinkling/aging of skin |
| **Roadblocks** | Ask the patient to identify barriers or impediments to quitting and note elements of treatment (problemsolving, pharmacotherapy) that could address barriers. Typical barriers might include:  
- Withdrawal symptoms  
- Fear of failure  
- Weight gain  
- Lack of support  
- Depression  
- Enjoyment of tobacco |
| **Repetition** | The motivational intervention should be repeated every time an unmotivated patient visits the clinic setting. Tobacco users who have failed in previous quit attempts should be told that most people make repeated quit attempts before they are successful. |

Appendix C

Five "A's" for assessing for tobacco use and addressing smoking cessation

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask</td>
<td>Implement an officewide system that ensures that, for every patient at every clinic visit, tobacco-use status is queried and documented. Repeated assessment is not necessary in the case of the adult who has never used tobacco or has not used tobacco for many years, and for whom this information is clearly documented in the medical record.</td>
</tr>
<tr>
<td>Advise</td>
<td>StrONGLY urge all tobacco users to quit in a clear, strong, personalized manner. Advice should be: Clear - &quot;I think it is important for you to quit smoking now and I can help you.&quot; Cutting down while you are ill is not enough. Strong - &quot;As your clinician, 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. The clinic staff and I will help you.&quot; Personalized - Tie tobacco use to current health/illness, and/or its social and economic costs, motivation level/readiness to quit, and/or the impact of tobacco use on children and others in the household.</td>
</tr>
<tr>
<td>Assess</td>
<td>Determine the patient's willingness to quit smoking within the next 30 days: If the patient is willing to make a quit attempt at this time, provide assistance. If the patient will participate in an intensive treatment, deliver such a treatment or refer to an intensive intervention. If the patient clearly states he or she is unwilling to make a quit attempt at this time, provide a motivational intervention. If the patient is a member of a special population (eg, adolescent, pregnant smoker), provide additional information specific to that population.</td>
</tr>
<tr>
<td>Assist</td>
<td>Provide aid for the patient to quit. These actions are summarized in the accompanying table.</td>
</tr>
<tr>
<td>Arrange</td>
<td>Schedule follow-up contact, either in person or by telephone. Follow-up contact should occur soon after the quit date, preferably during the first week. A second follow-up contact is recommended within the first month. Schedule further follow-up contacts as indicated. Congratulate success during each follow-up. If tobacco use has occurred, review circumstances and elicit recommitment to total abstinence. Remind the patient that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems. Consider use or referral to more intensive treatment.</td>
</tr>
</tbody>
</table>

Appendix D-1: Algorithm Permission

Joy Hamilton
To: Hughes, John R [john.hughes@med.uvm.edu]

Thanks Mr. Hughes. This information will be included in my proposal to the Medical Director of the Southeast Region.

Joy Hamilton

From: Hughes, John R [john.hughes@med.uvm.edu]
Sent: Tuesday, March 18, 2014 8:06 AM
To: Joy Hamilton
Subject: RE: Smoking Algorithm

No need to ask permission

From: Joy Hamilton [mailto:joyh@southern.edu]
Sent: Monday, March 17, 2014 5:01 PM
To: Hughes, John R
Subject: Smoking Algorithm

Good Day Mr. Hughes,

My name is Joy Hamilton and I'm currently pursuing my Doctor of Nurse Practitioner degree at Southern Adventist University. I'm a primary care provider working at the Health Department in a rural community. My project involves a practice change regarding smoking cessation in primary care.

My purpose for contacting you is to gain permission to include in a proposal for a practice change from "An Algorithm for Choosing Among Smoking Cessation Treatments". I have found the information concise and informative. If this would be a possibility for me to include this algorithm in my proposal, it would be greatly appreciated.

Thanking you in advance,
Joy Hamilton. APN-BC
Appendix D-2: Algorithm Permission

Smoking Cessation Algorithm

Joy Hamilton

To: aog@med.unc.edu

Tuesday, April 08, 2014 4:36 PM

Hello,

My name is Joy Hamilton and I'm currently pursuing my Doctor of Nurse Practitioner degree at Southern Adventist University. I'm a primary care provider working at the Health Department in a rural community. My project involves a practice change regarding smoking cessation in primary care.

My purpose for contacting you is to gain permission to include in a proposal for a practice change the algorithm from "Tobacco Cessation Algorithm.doc". I have found the information concise and informative which would be appropriate in serving the underserved and uninsured population that we see here at the local Health Department. If this would be a possibility for me to include this algorithm in my proposal, it would be greatly appreciated.

Thanking you in advance.

Joy Hamilton, APN-BC

From: Goldstein, Adam O. [adam_goldstein@med.unc.edu]
Sent: Tuesday, April 08, 2014 7:14 PM
To: Joy Hamilton
Cc: Ripley-Moffitt, Carol
Subject: RE: Smoking Cessation Algorithm

Yes- please ensure Carol that it is ours though.
Ag
Appendix D-3: Algorithm Permission

From: Joy Hamilton [mailto:joyh@southern.edu]
Sent: Tuesday, April 08, 2014 7:18 PM
To: Goldstein, Adam O.
Subject: RE: Smoking Cessation Algorithm

Thanks for the permission, however I'm not too sure who Carol is. I am writing from Dunlap, Tennessee and called the number on the web site and spoke with Mark who gave me your contact information.

To give the appropriate credit for the algorithm, who should I list?

Thanks,
Joy Hamilton

RE: Smoking Cessation Algorithm

Goldstein, Adam O. [adam_goldstein@med.unc.edu]

To: Joy Hamilton
Cc: Ripley-Moffitt, Carol [carol_ripley-moffitt@med.unc.edu]

Tuesday, April 08, 2014 7:20 PM

Carol is the Program Director of our Nicotine Dependence Program. I just want to be sure you are using the correct algorithm. She can approve tomorrow.

Thanks!

Ag
Algorithm D-4: Algorithm Permission

Joy, can you please send a copy of the algorithm and where you obtained it. If it is from a textbook, we may need to get publisher's permission.

There was no website...just that 'tobacco cessation algorithm.doc' listed and the algorithm was there with the UNC info on top. It was not connected to any website. Only 2 pages. Did you access it and see the algorithm I'm referring to?

Can you send me a copy or the address of the website?

This was at the bottom of the page. tobacco cessation algorithm.doc It's only a pdf with the UNC information on the top.

Thanks
Appendix D-5: Algorithm Permission

Is there any way you can send me a copy, i.e. scan into a pdf or send as a document? This does not sound familiar to me and it may be from another UNC department. If I could see the UNC information, as well as the algorithm that would help. How did you come across this?

From: Joy Hamilton [mailto:joyh@southern.edu]
Sent: Wednesday, April 09, 2014 12:13 PM
To: Ripley-Moffitt, Carol
Subject: RE: Smoking Cessation Algorithm

There was no web site...just that ‘tobacco cessation algorithm.doc’ listed and the algorithm was there with the UNC info on top. It was not connected to any web site. Only 2 pages. Did you access it and see the algorithm I’m referring to?
Appendix D-6: Algorithm Permission

RE: Smoking Cessation Algorithm

Joy Hamilton

To: Ripley-Moffitt, Carol [carol_ripley-moffitt@med.unc.edu]

From: Ripley-Moffitt, Carol [carol_ripley-moffitt@med.unc.edu]
Sent: Wednesday, April 09, 2014 1:45 PM
To: Joy Hamilton
Subject: RE: Smoking Cessation Algorithm

Ok, as I suspected, this is from UNC Internal Medicine and is quite old, 2007. In addition, it references materials to give to patients that may no longer be in print. I would recommend a more recent article and diagram such as:

http://ac.els-cdn.com/S0740547213000342/1-s2.0-S0740547213000342-main.pdf?_tid=3ea04c08-c00e-11e3-80e6-00000aacc362&acdnat=1397065496_79a2ce3c1e3083694947991f764a15d9

or you can certainly use the UNC model, and substitute titles for available educational materials

Good luck on your project, and let me know if you have questions,

Carol
Joy Hamilton [Joy.Hamilton@tn.gov]

To: Joy Hamilton

From: Allyson Cornell
Sent: Wednesday, April 23, 2014 12:18 PM
To: Joy Hamilton
Subject: RE: Practice Change Proposal Revised

Joy,
I think this is a great proposal. I know you put a lot of time and work into creating this, and I definitely think this could benefit our patients in their attempts to stop smoking. I will definitely forward this on to Dr. Beville, Medical Director of Community Health Services, for her review. I also think the information you have collected, regarding tobacco cessation, would be great to share at our next primary care meeting with all our primary care providers.
Thank you so much,
Dr. Cornell

Allyson Cornell M.D.
Regional Medical Director
Tennessee Department of Health, Southeast Region
540 McCallie Avenue
Suite 450
Chattanooga, Tennessee 37402
Sequatchie County Health Department

Tobacco Cessation Algorithm

**ASK about Tobacco Use**

- No
  - No action. Document in progress notes Screen in 12 months.
- Yes
  - ADVICE to quit
    - ASSESS stage

**Precontemplation**
- Give patient “Quitting Smoking” From UTD/Quitine
- Motivate to quit with “5 R’s”
  - RELEVANCE
  - RISKS
  - REWARDS
  - ROADBLOCKS
  - REPETITION

**Contemplation**
- Give patient “You Can Quit” folder/ “Assisting pts with smoking cessation” UTD and review

**Preparation**
- Give patient “Assisting pts with smoking cessation” UTD. Review Cessation Materials and Resources
- ASSIST to quit:
  - Counsel/Educate about quitting, assess desire for NRT, alert to other cessation resources
  - Preparation: Set quit date in next 2 weeks
  - Action: Quit today
  - RX for Nicotine Patch +/- short acting nicotine product (gum, lozenge, inhaler)
  - +/- Bupropion
  (Consider varenicline if NRT failed)
  - ARRANGE FOLLOW UP:
    - Recommend 1 mo & 3 mo PCP
    - Schedule call approx 1 week after appt or quit date

**Action**
- If counseled 3-10 minutes, mark 99406 and ICD-9 “305.1” on billing sheet
- If counseled >10 minutes, mark 99407 and ICD-9 “305.1” on billing sheet

**Maintenance**
- Give patient “Preventing and Managing relapse in smokers” UTD

If counseled 3-10 minutes, mark 99406 and ICD-9 “305.1” on billing sheet
If counseled >10 minutes, mark 99407 and ICD-9 “305.1” on billing sheet
### Stages of change

- **Precontemplation** – not thinking about quitting over the next 6 months
- **Contemplation** – thinking about quitting over the next 6 months
- **Preparation** – thinking about quitting within the next 30 days
- **Action** – actively trying to quit
- **Maintenance** – no tobacco use in last 6 months

### Pharmacotherapy for Smoking Cessation

<table>
<thead>
<tr>
<th></th>
<th>Trade Name</th>
<th>Starting Dose</th>
<th>Full Dose/Duration</th>
<th>Average Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine patch Rx</td>
<td>Nicoderm CQ®; Habitrol®; Prostep®</td>
<td>21 mg/d for 6 weeks</td>
<td>Then 14 mg/d for 2 wks, then 7 mg/d for 2 wks</td>
<td>$4.00/d, $120/mo</td>
</tr>
<tr>
<td></td>
<td>Nicotrol®</td>
<td>15 mg/d for 6 weeks (16 hrs/d)</td>
<td>Then 10 mg x 2 wks, then 5 mg x 2 wks</td>
<td>$5.50/d, $165/mo</td>
</tr>
<tr>
<td>Nicotine gum OTC</td>
<td>Nicorette®</td>
<td>Start on quit date.</td>
<td>1 tab/hr for 6 wks, then 1 tab/2 - 4 hrs for 2 wks, then 1 tab/4 - 8 hrs for 2 wks</td>
<td>$6.00/d, $180/mo</td>
</tr>
<tr>
<td>Nicotine lozenge OTC</td>
<td>Commit®</td>
<td>2 mg tab/hr for ≤ 25 cig/day use 4 mg tab</td>
<td>1 tab/hr for 6 wks, then 1 tab/2 - 4 hrs for 2 wks, then 1 tab/4 - 8 hrs for 2 wks</td>
<td>$6.60/d, for low use.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mg tab/hr for ≤ 25 cig/day use 4 mg tab</td>
<td>1 tab/hr for 6 wks, then 1 tab/2 - 4 hrs for 2 wks, then 1 tab/4 - 8 hrs for 2 wks</td>
<td>$17.00/d max usage.</td>
</tr>
<tr>
<td>Nicotine nasal spray Rx</td>
<td>Nicotrol NS®</td>
<td>1 to 2 doses/hr (most need minimum of 8 doses/day)</td>
<td>Continue for 6 – 8 wks, then taper gradually over 4 – 6 wks</td>
<td>$6.50 /d, low use.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10 mg cartridges used over 20 mins (6 to 16 cartridges per day). Tx for 3 mo then decrease use over 6-12 weeks.</td>
<td>At least 6 cartridges/d for 3 – 12 wks; max of 16 cartridges/d</td>
<td>$17.00/d max usage.</td>
</tr>
<tr>
<td>Nicotine inhaler Rx</td>
<td>Nicotrol Inhaler®</td>
<td>20 mins (6 to 16 cartridges per day). Tx for 3 mo then decrease use over 6-12 weeks.</td>
<td>At least 6 cartridges/d for 3 – 12 wks; max of 16 cartridges/d</td>
<td>$6.50 /d, low use.</td>
</tr>
<tr>
<td>Bupropion SR; Bupropion XL Rx (avoid w/ sz hx)</td>
<td>Zyban®; Wellbutrin SR®; Wellbutrin XL®</td>
<td>Start 2 weeks before quit date; 150 mg QD for 3 days; then BID-spaced 8 hrs</td>
<td>Continue 150 mg BID for 7 to 12 weeks</td>
<td>$2.50/d, $72/mo</td>
</tr>
<tr>
<td>Varenicline Rx</td>
<td>Chantix®</td>
<td>Start 1 week before quit date; Days 1-3 = 0.5mg QDay, days 4-7 = 0.5 mg BID</td>
<td>Continue 1 mg BID weeks 2 through 12; may continue an additional 12 weeks if necessary</td>
<td>$4.60/d, $138/mo</td>
</tr>
</tbody>
</table>
# Common Adverse Effects to Smoking Cessation Products

<table>
<thead>
<tr>
<th>Nicotine Patch</th>
<th>Nicotine gum or lozenge</th>
<th>Nicotine nasal spray</th>
<th>Nicotine inhaler</th>
<th>Bupropion</th>
<th>Varenicline</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Local skin irritation</td>
<td>• Lightheadedness</td>
<td>• Nasal or throat irritation</td>
<td>• Throat or mouth irritation</td>
<td>• Dry Mouth</td>
<td>• Insomnia</td>
</tr>
<tr>
<td>• Insomnia (w 24 hr dosing)</td>
<td>• Nausea and vomiting</td>
<td>• Sneezing</td>
<td>• Unpleasant taste</td>
<td>• Nausea</td>
<td>• Headache</td>
</tr>
<tr>
<td>• Vivid dreams</td>
<td>• Throat or mouth irritation</td>
<td>• Coughing</td>
<td>• Insomnia</td>
<td>• Abnormal dreams</td>
<td>• Seizure disorder</td>
</tr>
<tr>
<td>• Sleep Disturbances</td>
<td>• Eye irritation</td>
<td>• Rhinitis</td>
<td>• Constipation</td>
<td>• Nausea</td>
<td>precaution: history</td>
</tr>
<tr>
<td></td>
<td>• Runny nose</td>
<td>• Dyspepsia</td>
<td>• Agitation</td>
<td>• Vomiting</td>
<td>of psychiatric</td>
</tr>
<tr>
<td></td>
<td>• Patients with allergies/asthma</td>
<td>• Hiccups</td>
<td>• Change in mood or behavior</td>
<td>• Stomach upset</td>
<td>illness</td>
</tr>
<tr>
<td></td>
<td>should not use</td>
<td>• Headache</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• Insomnia</td>
<td>• Asthma/COPD</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>Should not use</td>
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<td>contraindication:</td>
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<td></td>
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<td></td>
<td>seizure disorder</td>
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</tr>
</tbody>
</table>

- Patients with history of psychiatric illness should not use Bupropion.
References


Smoking Cessation in Primary Care: A Practice Change

A PROPOSAL TO: Dr. Allyson Cornell

April 17, 2014

Sequatchie County Health Department

Submitted by:
Joy Hamilton, APN, DNP (Student)
CURRENT ISSUE
Tobacco use is the leading preventable cause of death, disease, and disability in the US. About 1 in 5 adults smoke (45.3 million) and, although smoking prevalence has declined from 20.9% in 2005 to 19.3% in 2010, tobacco use is still the most common cause of preventable death and disease in the United States (Centers for Disease Control and prevention, 2010).

LOCAL CHALLENGE
Primary care clinicians are in a strategic position to help their patients quit smoking. Currently, the primary care sites have access to the QuitLine to distribute to patients during encounters.

According to the 2008 New Guideline on Treating Tobacco use and Dependence, increasing evidence shows that screening and assessment practices such as expanding vital signs to include tobacco-use status, or other reminder system to ask about smoking significantly increase the rate of clinician intervention.

Based on recent observations, the current recommended approach of the QuitLine surveys with the suggested interventions have seemingly appeared to inadequately reduce tobacco usage at the primary care sites.

A practice change is being proposed and entails the following:

- A request for the addition of the patient’s current smoking status as an entity of the vital signs.
- An assessment to determine the current stage of change according to the Transtheoretical Model. Changing or modifying a behavior that is addictive or potentially harmful is difficult for most people. The Transtheoretical Model (TTM) (Prochaska, Norcross, & DiClemente, 1994) incorporates a compilation of previous theories, providing a framework for the stages of progression when deciding to change a problematic behavior.
- Inclusion of an algorithm which will serve as a guide for primary care providers (PCPs) encompassing the TTM.

These three components of the proposal would be in addition to the already established QuitLine that is currently being utilized.

The goal of this practice change would be to provide improved patient care by increasing provider’s adherence to the recommendations of a clinical practice guideline for the assessment and treatment of smoking cessation in the primary care setting.
Currently, the certified nurses’ assistance gets the vital signs and records them in their appropriate slots.
Sequatchie County Health Department

Tobacco Cessation Algorithm

ASK about Tobacco Use

No

No action. Document in progress notes. Screen in 12 months.

Yes

ADVISE to quit

ASSESS stage

Precontemplation

Give patient “Quitting Smoking” from UTD/Quitine

Contemplation

Give patient “You Can Quit” folder/ “Assisting pts with smoking cessation” UTD and review

Motivate to quit with “5 R’s”

- RELEVANCE
- RISKS
- REWARDS
- ROADBLOCKS
- REPETITION

Preparation

Give patient “Assisting pts with smoking cessation” UTD. Review Cessation Materials and Resources

ASSIST to quit:

Counsel/Educate about quitting, assess desire for NRT, alert to other cessation resources

Preparation: Set quit date in next 2 weeks

Action: Quit today

RX for Nicotine Patch +/- short acting nicotine product (gum, lozenge, inhaler) +/- Bupropion
(Consider varenicline if NRT failed)

ARRANGE FOLLOW UP:

Recommend 1 mo & 3 mo PCP
Schedule call approx 1 week after appt or quit date

Maintenance

Give patient “Preventing and Managing relapse in smokers” UTD

If counseled 3-10 minutes, mark 99406 and ICD-9 “305.1” on billing sheet
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<td>Runny nose</td>
<td>Rhinitis</td>
<td>Constipation</td>
<td>Nausea</td>
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<td>Jaw discomfort</td>
<td>Patients with allergy/asthma should not use</td>
<td>Patients with Asthma/COPD should not use</td>
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<td>Vomiting</td>
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<td>Precaution: history of psychiatric illness</td>
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PRACTICE CHANGE

SUMMARY

Tennessee Department of Health Mission: To protect, promote, and improve the health and prosperity of people in Tennessee.

Increasing evidence shows that screening and assessment practices such as expanding vital signs to include tobacco-use status or other reminder system to ask about smoking significantly increases the rate of clinician intervention.

The primary care setting is an ideal location to promote smoking cessation through counseling and pharmacological aids. The US Preventive Services Task Force recommends asking about tobacco use in all adults which may be accomplished by using the 5-A model to assist PCP's implement Tennessee Department of Health's cessation protocol. This system encourages clinicians to ask patients about their smoking status, advise smokers to quit, assess their readiness to quit, assist them with their smoking cessation effort, and to arrange for follow-up visits or contact (Fiore, M.C., Jaen, C., & Baker, T., et al., 2008).

Patients who use tobacco but are unwilling to quit should be approached with the "5 R's" of motivational intervention (Relevance, Risks, Rewards, Roadblocks, and Repetition) (Fiore, M.C., Jaen, C., & Baker, T., et al., 2008).

The developed evidence-based treatment protocol algorithm is an easy-to-follow tool that facilitates the incorporation of smoking cessation counseling during patient encounters. During brief encounters, this algorithm may provide a concise pathway for providers to follow in addition to the ability to bill for reimbursable services using the outlined CPT codes (CPT, 2014).

Regarding cost, these three components of the proposal would eventually prove to be perhaps a cost benefit in terms of a decrease in tobacco usage and consequently a reduction in tobacco related illnesses and diseases due to the easy accessibility to the providers. The projected miniscule cost on acceptance of this proposal may entail obtaining additional resources from the CDC's publication department regarding handouts or brochures for encouraging and maintaining smoking cessation in addition to the QuitLine.

This project manager is respectfully seeking permission to implement the above practice change proposal at all three primary care sites for a pilot study for approximately six
months. To determine efficacy of this practice change proposal, a follow-up six months “Patient Tobacco Survey” would also be requested to then be evaluated by the appropriate personnel deemed by the Southeast Regional Health Department.
References

Evaluation Plan Outline

Southeast Regional Health Department

Smoking Cessation in Primary Care

Prepared by:

Joy Hamilton
Sequatchie County Health Department

April 27, 2014
1. Introduction

The primary purpose of this project is to address the growing smoking epidemic concern in the Southeast Region of Tennessee with adults aged 19 to 64 years who are uninsured who seek care at the local health departments, specifically Sequatchie County Health Department. A practice change is proposed and would entail a request for the addition of the patient's current smoking status as an entity of the vital signs, and an assessment to determine the current stage of change according to the Transtheoretical Model. Changing or modifying a behavior that is addictive or potentially harmful is difficult for most people.

Evaluation Purpose

- What does this evaluation strive to achieve?
  Determine the efficacy of the added component to the vital signs section, and address individual needs regarding stages of change relating to tobacco use.

- What is the purpose of this evaluation?
  The purpose of this evaluation is to attempt to reduce the amount of smokers who are uninsured and live in rural communities. A good evaluation does not merely gather accurate evidence and draw valid conclusions, but produces results that are used to make a difference regarding smoking cessation in this community which is the ultimate goal.

- How will findings from the evaluation be used?
  The ultimate purpose of a program evaluation is to use the information to improve specific programs. The purpose initially identified early in the evaluation process should guide the use of the evaluation results. The evaluation results can be used to demonstrate the effectiveness of the program, identify ways to improve the current program, modify program planning, and demonstrate accountability. Dissemination involves communicating evaluation procedures or lessons learned to relevant audiences in a timely, unbiased, and consistent manner. Regardless of how communications are structured, the goal for dissemination is to achieve full disclosure and impartial reporting (CDC, 2011).

  Information will be disseminated among the other primary care sites in the Southeast region and eventually across the state of Tennessee once deemed effective, valuable, and successful.

Stakeholders

- Who are the stakeholders for this evaluation?
  The Regional Medical Director, the Medical Director of Community Health Services, and the Director of Office of Quality Improvement.
Table F.1. Stakeholder Assessment and Engagement Plan

<table>
<thead>
<tr>
<th>Stakeholder Name</th>
<th>Stakeholder Category</th>
<th>Interest or Perspective</th>
<th>Role in the Evaluation</th>
<th>How and When to Engage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director of Community Health Services</td>
<td>Primary Stakeholder</td>
<td>Budget for direct and indirect costs</td>
<td>Gives the initial and final acceptance of the Proposal</td>
<td>Initially and at the completion of the project</td>
</tr>
<tr>
<td>Regional Medical Director</td>
<td>Secondary Stakeholder</td>
<td>Works closely with the providers</td>
<td>From a clinical perspective, able to view firsthand the process from the provider's perspective</td>
<td>Throughout the entire process</td>
</tr>
<tr>
<td>Director of Office of Quality Improvement</td>
<td>Tertiary Stakeholder</td>
<td>Overall Quality improvement for the uninsured patients</td>
<td>Collaborates with the Medical Directors of Community Health Services</td>
<td>Initially for the IRB process and at the completion</td>
</tr>
</tbody>
</table>

2. **What is the goal?**

The goal of this practice change would be to provide improved patient care by increasing provider’s adherence to the recommendations of a clinical practice guideline for the assessment and treatment of smoking cessation in the primary care setting.

**Need**

- **What is the need for what you are evaluating?**

  Reduction in tobacco use

**Target Population**

- Uninsured or underinsured adults ages 19-64 years

**Stage of Development**

- **Is it in the planning or implementation stage?**

  This is in the planning stage
Resources/Inputs

What resources are available to support what is being evaluated?
Time

Activities

• What specific activities are undertaken (or planned) to achieve the outcomes?

Addition of tobacco use assessment to be included in the vital signs section of the progress notes, inclusion of an assessment of change using the Transtheoretical Model, and a concise algorithm to assist the provider at the point of care.

Outputs

• What are some of the outcomes?

The increased number of calls to the QuitLine, or use of prescribed or OTC medications.

Outcomes

• What are the program’s intended outcomes?

Increased knowledge and use of cessation services

• What do you ultimately want to change as a result of your activities?

A reduction in tobacco related mortality and morbidity
3. **EVALUATION DESIGN**

**Stakeholder Needs**

- Who will use the evaluation findings?
  The Regional Medical Director, the Medical Director of Community Health Services, and the Director of Office of Quality Improvement.
What do they need to learn from the evaluation?

The major issue is to approach tobacco users from different perspectives based on their current stage of change. Determining if there is a reduction in tobacco use with the use of the tobacco assessment in the vital signs section, and the appreciation of the concise algorithm.

• What do intended users view as credible information?
  Evidence based research

Evaluation Design

• What is the design for this evaluation?
  The design for this proposal for a practice change would look retrospectively at the quit rate prior and the quit rate after implementation of the change—both for a six month period. This comparison would be determined by the tobacco surveys done on initial and annual visits.

DATA COLLECTION

Data Collection Methods

• Will new data be collected and compiled to answer the evaluation questions or will secondary data be used?
  New data will be collected for 6 months after implementation; secondary data will be used for retrospective analysis and will also be obtained from the data base analysis archived in the electronic system

• What methods will be used to collect or acquire the data?
  Tobacco surveys done annually and on initial encounters, unstructured self-report utilizing a three question questioner, informal conversation done during the actual encounters, and chart reviews.

• Will a sample be used? If so, how will the sample be selected?
  Purposive Sampling: Only smokers who are actually motivated and willing to quit smoking assessed during encounters for follow up return visits, initial and annual visits. Patients generally are open and honest in terms of their need or desire to quit.

• How will the data be protected?
  Charts are currently paper and with strict observance of HIPPA compliance with coding in Excel utilizing a numerical and letter system to de-identify the charts on the project manager’s computer which is password protected. Charts are locked in an office every evening and accessed by the office supervisor, medical director and project manager.
Paper surveys will be distributed and a focus group interview will be used to obtain in-depth information from a group of participants who have decreased their daily cigarette amount to those who have gained the victory over tobacco use information of their intervention. No more than ten open-ended questions will be used and presented to approximately four to fifteen people who have never had prior interaction. A moderator will be determined and an informed consent will be obtained prior to audio recordings.

5. **Data Analysis and Interpretation**

**Indicators and Standards**

- What are some measurable or observable elements that can tell you about the performance of what is being evaluated?

  During monthly or quarterly follow up visits, a reduction in the amount of cigarettes smoked, or patients who have actually quit tobacco use. An assessment of documentation compliance will be done to the other practitioners at their sites.

- What constitutes “success”?

  Determining an awareness of stage of change from the providers’ perspective and to assist with subsequent visits, and a reduction in the quantity of cigarettes smoked on a daily basis to total abstinence.

**Analysis**

- What method will you use to analyze your data

  Content analysis will be used to analyze the qualitative data obtained from interviews, focus groups, and comments written on participant surveys. Descriptive Statistics of the data may include frequencies, means and summary statistics. To identify any significant changes in the tobacco survey and patients’ smoking cessation status, possible pre and post intervention measures would be analyzed with the paired t test.

**Interpretation**

- Who will you involve in drawing, interpreting, and justifying conclusions?

  The epidemiologist and the Director of the Office of Quality Improvement

6. **COMMUNICATING**

- What actions will be taken to promote evaluation use?
Presentations and open discussions at the quarterly primary care meetings

- How will evaluation findings be used?
  After the pilot study, the amended progress notes with the algorithm will be a permanent part of the records

- Who is responsible for implementing evaluation recommendations?
  The Regional Medical Director

Communication

- What methods will you use to communicate with evaluation stakeholders?
  A PowerPoint presentation at the quarterly primary care meetings.

7. EVALUATION MANAGEMENT

Evaluation Team

- Who will implement this evaluation?
  Medical director, RN’s, APN’s and MD’s

Roles and Responsibilities of the Evaluation Team Members

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<tr>
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<th>Responsibilities</th>
</tr>
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<tbody>
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<td>Oversees the clinical aspects for providers</td>
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<td>APN’s/MD’s</td>
<td>Primary Care Practitioners</td>
<td>Point of care services</td>
</tr>
<tr>
<td>Charge Nurse/RN</td>
<td>In charge of the CNA’s</td>
<td>Oversees the CNA’s and their documentations</td>
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</table>

Data Collection Management

- What data will be collected?
  Comparing the results of the Tobacco Survey before and after the implementation of the proposed practice change in the electronic system

- What activities are needed to carry out the data collection successfully? When should each of these activities be completed?
Presentations and open discussions at the quarterly primary care meetings

- How will evaluation findings be used?
  After the pilot study, the amended progress notes with the algorithm will be a permanent part of the records

- Who is responsible for implementing evaluation recommendations?
  The Regional Medical Director

Communication

- What methods will you use to communicate with evaluation stakeholders?
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Data Collection Management

- What data will be collected?
  Comparing the results of the Tobacco Survey before and after the implementation of the proposed practice change in the electronic system

- What activities are needed to carry out the data collection successfully? When should each of these activities be completed?
After six months of the pilot study, a comparison will be made to determine the efficacy of the change in the progress notes, and a formal discussion with the providers to assess the feasibility of the proposed change.

Data Analysis Management

- What data will be analyzed, how, and when?

Content analysis will be used to analyze the qualitative data obtained from interviews, focus groups, and comments written on participant surveys. The content analysis will determine the specific concerns for the practice change, using a simple, systematic, verifiable process. Each interview, focus group discussion and participant survey comment will be transcribed and each line numbered.

<table>
<thead>
<tr>
<th>Analysis to Be Performed</th>
<th>Data to Be Analyzed</th>
<th>Person(s) Responsible</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content Analysis</td>
<td>Tobacco surveys</td>
<td>Project manager</td>
<td></td>
</tr>
<tr>
<td>Correlation procedures</td>
<td>Information gained</td>
<td>Project manager and Medical Director</td>
<td></td>
</tr>
<tr>
<td></td>
<td>from the providers</td>
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<td></td>
</tr>
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</table>

 Communicating and Reporting Management

- What are the target audiences for reporting the progress made on the evaluation and/or evaluation findings?

MD’s, APN’s, RN’s, and the Regional Medical Director

- What is the purpose of the communications with this audience?

To ensure knowledge of the current evidence based information for assisting and empowering our smoking population

- What is the most appropriate type of communication method to use with this audience, for this purpose?

Open discussions, oral presentations, at the quarterly primary care meetings

- When will the communication take place?

Summer of 2014

Timeline

- When will planning and administrative tasks occur?

After IRB approval
• When will any pilot testing occur?
  Once approval of the practice change has been determined
• When will formal data collection and analysis tasks occur?
  After approximately 6 months
• When will information dissemination tasks occur?
  After review and discussion of the proposal, acceptance and then implementation

Evaluation Budget

• What is the cost for this evaluation?
  The projected miniscule cost on acceptance of this proposal may entail obtaining additional resources from the CDC’s publication department regarding handouts or brochures for encouraging and maintaining smoking cessation in addition to the QuitLine. Additional costs may also include reprinting charts, surveys, questioners and additional personal time by the project manager.