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Evaluation of the use of electric cigarettes in a rural smoking cessation program

Jona Ely

UNIVERSITY OF NORTHERN COLORADO

Greeley, Colorado

The Graduate School

EVALUATION OF THE USE OF ELECTRIC CIGARETTES IN A RURAL SMOKING CESSATION PROGRAM

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Doctor of Nursing Practice

Jona Ely

College of Natural and Health Sciences
School of Nursing
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has been approved as meeting the requirement for the Degree of Doctor of Nursing Practice in College of Natural and Health Sciences in School of Nursing, Program of Nursing Practice

Accepted by the Research Committee

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Catherine E. Dingley, Ph.D., Research Advisor

_____

Rhonda Squires, Ph.D., Committee Member

_____

Pamela Kinder, MD, Agency Member

Accepted by the Graduate School

_____

Linda L. Black, Ed.D., LPC
Acting Dean of the Graduate School and International Admissions

EXECUTIVE SUMMARY

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The purpose of this Doctor of Nursing Practice capstone project was to evaluate a structured rural smoking cessation program that integrated electric cigarettes as an additional option to other standard interventions. The aims of the program evaluation were to develop an evaluation design and methodology to guide data collection and analysis, analize findings, and provide recommendations regarding the current program and future usage or changes.

The Donabedian and bridge evaluation models provided the framework to evaluate the smoking cessation program, make recommendations for future applications, potential improvements, and determine elements of the program that should be continued in its current state.

After obtaining Institutional Review Board approval, 44 participants were recruited to participate in the smoking cessation program evaluation. The results indicated 14 (32%) quit smoking and seven (16%) switched to e-cigarettes. Of the remaining 23 participants, 13 (30%) successfully cut down to less than half of their starting tobacco use level with the use of e-cigarettes. Of the 14 participants who quit, 10 used e-cigarettes exclusively and the other four also used Bupropion (two) or Chantix (two). Of the seven who switched to e-cigarettes, three used only e-cigarettes and four used e-cigarettes and Bupropion. Of the 13 participants who cut down to less than half of

their starting amount of tobacco cigarettes, seven were only using e-cigarettes and six were using e-cigarettes and Bupropion. Program participants' success rate at cessation or switching to e-cigarettes exclusively was double both the national and state averages of 21-24%, resulting in a significant harm reduction for patients and families.

Recommendations from the evaluation included continuing the program with modifications to educational materials and follow up strategies, using different types of staff for implementation, and using the program as a model for other agencies or organizations.

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I would like to thank my family and close friends for their support and patience throughout this seemingly never-ending endeavor. Finally, I would like to dedicate this project to my father for his encouragement, endless support, and unwavering belief in my abilities to succeed even when I had doubts. Thanks dad!

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CHAPTER I

STATEMENT OF THE PROBLEM

Background and Significance

Tobacco use remains the leading preventable cause of death, disease, and disability in the United States (National Institute on Drug Abuse [NIDA], 2010). A 2012 report from the Center for Disease Control and Prevention (CDC) indicated that the adverse effects related to smoking account for an estimated 443,000 deaths (or nearly one in five deaths) each year in the United States. Exposure to secondhand smoke can also cause death and diseases (NIDA, 2010). Every year 126,000 Americans are exposed to secondhand smoke and almost 50,000 nonsmokers die from diseases related to secondhand smoke annually. A 2009 Morbidity and Mortality report (CDC, "Morbidity and Mortality Report") indicated that in 2008, an estimated 20.6% (46 million) adults in the United States were current cigarette smokers; among those, 45.3% (20.8 million) had stopped smoking for one day or more during the preceding 12 months in an attempt to quit.

Smoking cessation is challenging and frequently requires multiple attempts before an individual is able to quit. Switching from tobacco cigarettes to a nicotine replacement therapy (NRT) is standard practice in smoking cessation programs. However, most smokers do not find the current NRT products to be as satisfying as cigarettes as they provide nicotine at doses and rates of delivery that are a poor substitutes for cigarettes

(Houezec, McNeill, & Britton, 2011). There is a promising new smoking cessation aide on the market called electronic cigarettes (e-cigarettes). An e-cigarette is an electrical device that attempts to simulate the act of smoking a tobacco cigarette. Most of them are composed of a rechargeable, battery-operated heating element, a replaceable or refillable cartridge, and an atomizer that converts the contents in the cartridge to vapor that is inhaled by the user. Multiple choices for the strength of nicotine in the liquid or the cartridges range from placebo to full strength (24 mg) and are also available in multiple flavors. The e-cigarette alleviates the health risks related to second hand smoke and promises to be far more effective at increasing the success rate of tobacco cessation.

Problem Statement

Primary care providers in a rural northern Colorado region noted that in their community-based practice, smoking rates and related health problems were higher than both the state and national averages (CDC, 2012). After the realization that there were very few available resources to assist local residents with smoking cessation, a program was developed and implemented in a selected rural primary care setting that offered the e-cigarette as an alternative means of NRT or harm reduction. The e-cigarette was chosen as the alternative method in response to the poor success rate and potential adverse side effects of the current approved smoking cessation options. For a smoker, the health risks of continuing to smoke tobacco cigarettes far outweigh the risks of any NRT they might choose including e-cigarettes (Cobb, Byron, Abrams, & Shields, 2010; Tobacco Vapor Cigarette Association [TVECA], 2010). Although the smoking cessation program was developed with implementation goals and objectives, no systemic formal evaluation plan was included. This capstone project was initiated to create and perform

an evaluation plan for the smoking cessation program and to make recommendations for current and future participants in this program.

Purpose

The purpose of this DNP capstone project was to evaluate a structured smoking cessation program that integrated e-cigarettes as an additional option to other standard interventions. The aims of the program evaluation were to develop an evaluation design and methodology to guide data collection and analysis, analyze findings, and provide recommendations regarding the current program and future usage and/or changes.

Theoretical Frameworks

The Donabedian (1972) model and the bridge evaluation model (Sieloff, 1999) were used to evaluate the program and provided the basis for this capstone project. These two models served as the foundation for the evaluation plan to define and describe objectives, describe and measure indicators of success, and utilize outcome measurements. The Donabedian and bridge models provided the framework to evaluate the program, make recommendations for future applications and potential improvements, and determine elements of the program that should be continued in their current state.

Donabedian Model

The literature review of the Donabedian model revealed its use in multiple program evaluations. According to Donabedian (1972), the definition of evaluation is

> the use of scientific method and rigorous and systemic collection of research data to assess the effectiveness of organizations, services and programs in achieving predefined objectives For health services, it is used to see if they fulfill their stated goals, targets or objectives. (p. 103)

It is based on the collection of data about the structure, process, and outcomes of the service as well as the appropriateness of the service (Donabedian, 1972). Evaluations can

be formative or summative. A formative evaluation involves the collection of data while the program is active--the goal is is to develop or improve the program. A summative evaluation involves collecting data about an active or terminated program--the goal is to decide whether the program should be continued or repeated (Donabedian, 1972).

Program evaluation is the systemic investigation of the worth or merit of a program. A program evaluation can show evidence of acheivement of program goals, identify effective program components, determine why some program components are effective while others are not, identify potential program improvements, and provide information on a program's cost effectiveness (Donabedian, 1972). The first step in a program evaluation is to identify the purpose of the evaluation and develop evaluation questions based on program inputs (processes) and expected outcomes. The next step is to develop an evaluation design and methodology to guide data collection and analysis. This requires identification of the data necessary to answer evaluation questions, methods of data collection, sampling strategy, and data collection instruments (Donabedian, 1972). The data are then analyzed, findings are interpreted, and recommendations are made.

The Donabedian model first originated in 1966 and has guided work regarding the elements used to evaluate and compare health care quality for over four decades (Donabedian, 1972; Mitchell, Ferketich, & Jennings, 1998). Donabedian's (1972) framework specifies that structure influences process, influences outcomes, and is easy to use for theory testing and organizing data. For example, Donabedian's model influenced the Quality Assessment/Quality Assurance Movement of the 1970s, the Total Quality Management Movement of the late 1980s, and more recent performance measurement initiatives (Larson & Muller, 2002/2003). It was used to (a) evaluate patient satisfaction

for diabetic patients (Westaway, Rheeder, VanZyl, & Seagar, 2003); (b) evaluate how the structure and process affect the outcome in a nursing facility (Cook, 2002); (c) evaluate the structure of models serving adults with mental retardation/developmental disabilities (Pulcini & Howard, 1997); (d) apply the Donabedian model as the framework for bariatric surgery (Smitz Naranjo & Viswanatha Kaimal, 2011); (e) evaluate patient preception of nursing service quality (Kobayashi, Takemura, & Kanda, 2011); (f) review the quality of care in systemic lupus erythematosus patients (Lawson & Yazdany, 2012); and (g) assess patient satisfaction with quality of care in a large teaching hospital (Tasso et al., 2002) to mention just a few examples.

The Donabedian (1972) structure-process-outcome model uses three criteria to evaluate a health care program:

1. Structure measures: Focus on conditions under which the care is provided and evaluates the inputs and resources into the services. It is the organizational framework for the activities that happen within the health service.
2. Process measures: Focus on what a health care provider does to maintain or improve patients' health. These are the activities themselves (i.e., screening, diagnosis, treatment, education).
3. Outcome measures: Focus on changes in health status that are attributable to health care. They refer to the effectiveness of activities that are measured by mortality and morbidity rates, complication rates, disability, quality of life, and patient satisfaction. They measure the impact on patients and communities.

Bridge Evaluation Model

The bridge evaluation model was first implemented in 1999 by Debra Sieloff (1999). "The bridge symbolism represents the structure over open waters (the evaluation environment) that can transport the evaluation manager from the beginning of the evaluation (the question) to the end (finding the answer to the question)" (Sieloff, 1999, p. 14). The bridge also serves to illustrate the flexibility of the model (like two-way traffic on a bridge): the evaluation manager can modify the evaluation plan, the data collection tools, use of data, reporting methods, and post evaluation evaluation systems much like a traveler can change directions on a bridge (Sieloff, 1999). The bridge evaluation model could be used to "evaluate the worth or merit of any form of program, problem, service, product, or issue" (Sieloff, 1999, p. 15). This model could be used to identify the judgement methods including defination of standards and collection of relevant data. It could then be used to apply the standards to determine the value, quality, utility, effectiveness, or significance of the evaluation's objective.

Based on the work of Worthen, Sanders, and Fitzpatrick (1997), the bridge evaluation model illustrates the process and factors that determine the outcome of an evaluation. This model illustrates the evaluation process and the following elements (Sieloff, 1999):

1. Plan/design: Define the purpose, use, type, approach, resources, reporting methods, protocol, and schedule.
2. Data collection: Include new and existing data. Gather both qualitative and quantitative data using methods that will achieve the evaluation objective, are unbiased, and appropriate.

3. Testing and Assessing: Data, data resources, situational context, reliability, and accuracy. Test validity, completeness, and correctness of data. Look at such things as rival information, exceptions, varying perspectives from observers, discrepancies, reactions, and evaluator effects.
4. Report the evaluation findings. Include introduction, evaluation, conclusion, and recommendations that incorporate an assessment of the achievement of objectives, violation of any ethical or legal principles, alterations of original evaluation needs, value of the evaluation's accomplishment, process and outcome of the data testing, expectations to identify performance levels, and results achieved via the evaluation system.
5. Evaluation: Test the usefulness or identify learning opportunities for future applications.

The Donabedian (1972) and bridge evaluation models (Sieloff, 1999) provided the framework to evaluate the smoking cessation program, make recommendations for future applications, potential improvements, and determine elements of the program that should be continued in its current state. These frameworks provided a concise, easy-to-follow structure to identify the objectives, collect the data, evaluate the tools used to collect the data, evaluate whether the objectives were met, and provide recommendations for changes and future use (Donabedian, 1972, Sieloff, 1999).

CHAPTER II

PROJECT DESCRIPTION AND DESIGN

Literature Review and Supporting Data Synthesis

Tobacco Use and Smoking Cessation

More deaths are caused by cigarette smoking each year than from all other causes including human immunodeficiency virus (HIV), alcohol and drug use, motor vehicle injuries, and murders and suicides combined. The Centers for Disease Control and Prevention (CDC; 2011) reported that smoking causes an estimated 90% of all lung cancer deaths in men, 80% of lung cancer deaths in women, and an estimated 90% of all deaths related to chronic obstructive lung disease. Smoking also increases the risk of coronary heart disease and stroke by two to four times compared to nonsmokers. The report also indicated that cigarette smoking reduces circulation in the body by narrowing blood vessels and puts smokers at risk for developing peripheral vascular disease and abdominal aortic aneurysms. Cigarette smoking causes multiple lung diseases including emphysemia, bronchitis, asthma exacerbations, and chronic airway obstruction, and is also associated with lower bone density and an increased risk of hip fractures (CDC, 2012). In women, cigarette smoking has also been shown to increase infertility, preterm delivery, stillbirth, low birth weight, and sudden infant death syndrome (CDC, 2012).

In the state of Colorado, the highest rate of smoking occurs in adults age 18-44. Smoking prevalence is the highest in adults with a high school education level or lower,

those living below the federal poverty level, and those with other substance abuse problems (CDC, 2009). American Indians have the highest incidence of smoking at 36.1%, followed by Caucasians at 16.5% (CDC, 2011).

There are currently five different nicotine replacement therapies (NRT) approved for use by the Food and Drug Administration: nicotine chewing gum, transdermal patches, nasal sprays, inhalers, and lozenges. All of the current NRTs have been shown to have similar efficacy and side effect profiles (Stead, Perera, Bullen, Mant, & Lancaster, 2008). Prescription medications approved to help with tobacco cessation currently include bupropion (Zyban) and varenicline (Chantix). Bupropion reduces the symptoms of nicotine withdrawal, is usually well tolerated, and can be taken with NRTs (American Cancer Society, 2011). Varenicline is a newer prescription medication and works by interfering with nicotine receptors in the brain. Varenicline can be very effective at helping with tobacco cessation but has multiple reported side effects: headaches, nausea, vomiting, trouble sleeping, unusual dreams, flatulence, changes in taste, depressed mood, changes in behavior, and thoughts of or attempted suicide (American Cancer Society, 2011). It is also expensive with poor coverage on most prescription plans.

According to the CDC in 2009, the success rate for an individual attempting to quit "cold turkey" was between 4% to 7%. Any of the NRTs could double this number from 8% to 14%; Bupropion could increase the cessation rate by approximately 20% and Varenicline by approximately 33%. The success rate with combination therapies is still only approximately 25% (CDC, 2009). This means that three out of four smokers will still fail in their attempts to quit smoking. Users most often relapse due to withdrawal

symptoms, stress, and weight gain. Although nicotine is extremely addictive and can be toxic if ingested in large doses, it does not cause cancer. The complex mixture of chemicals in tobacco is the known carcinogen. There are over 7,000 chemicals in tobacco cigarettes and over 70 of them have been proven to be carcinogenic (CDC, 2009).

Electric Cigarettes

E-cigarettes offer a novel approach to smoking cessation as they can be used long term, deliver a dose of nicotine that can be decreased gradually until at placebo level, are significantly cheaper than tobacco cigarettes, and mimic cigarette smoking activities so the smoker does not have to give up his or her behavior. By using an e-cigarette instead of a tobacco cigarette, an individual can still ingest the same amount of nicotine but none of the 7,000 carcinogens found in tobacco cigarettes.

An extensive literature review revealed a limited number of studies that specifically evaluated the use of e-cigarettes for smoking cessation. The three studies that were found were double blind, randomized, and had no stockholder involvement (Cahn & Siegel, 2010; Eisenberg et al., 2008; Stead, Perera, Bulle, Mant, & Lancaster, 2008). No evidence was found indicating e-cigarettes caused or contributed to increased harm. All of the available studies that did test the contents of e-cigarettes indicated they were much safer than tobacco cigarettes (Bullen, Thornley, Glover, Lin, & Laugensen, 2010; Cahn & Siegel, 2010; Foy, Bombick, Doolittle, Mosberg, & Swauger, 2004; Laugesen, 2008; Meckley et al., 2004; Patskan & Reininghaus, 2003; Roethig, Kinser, Lau, & Wang, 2005; Stabbert et al., 2003; Terpstra et al., 2003; Tewes, Meisgen, Veltel, Roemer, & Patskan, 2003;Werley et al., 2008). Most of the studies found no harmful

chemicals in e-cigarettes; the few that did find trace amounts of carbon monoxide and diethylene glycol were between a 500-fold to 1400-fold reduction in the concentration of that found in tobacco cigarettes (Cahn & Siegel, 2010).

A report from the U.S. Food and Drug Administration (USFDA; 2010) tested two different e-cigarettes and found nicotine in both products and very low levels of tobacco-specific nitrosamines and impruities. However, the report failed to present standard protocols for proper study design with regard to the testing of the control device (nicotrol inhaler), documenting the number of samples tested, and failed to present statistical analyses when quantifiable results were obtained. The FDA stated the level of impurities found was not quantifiable and was below the limit of quantification (WebMD, 2011).

A review of the consumer literature revealed approximately 90% of e-cigarette users were attempting to quit smoking and all had previously smoked tobacco cigarettes (All Electronic Cigarette Brands: Comparisons and Reviews, 2011; Etter, 2010). An extensive literature review found no studies that actually used e-cigarettes as a smoking cessation aide in a structured smoking cessation program. The significant gap in the literature indicates a need to further investigate this product which is currently on the market and being used by consumers. This capstone project could prove to be a starting point to evaluate the efficacy of ecigarettes as a smoking cessation aide. The literature did show there was extensive information and feedback on comsumer review sites that indicated e-cigarettes were used frequently and effectively as a smoking cessation aide (All Electronic Cigarette Brands, 2011).

The greatest concerns and complaints from consumer reviews were the variations in the dosage of nicotine delivered, technical/mechanical defects or failure of the e-

cigarettes, and lost effectiveness toward the end of use of the cartridge (All Electronic Cigarette Brands, 2011). Over 40 brands of e-cigarettes were identified; the starter kits ranged in price from $30 to $200 (see Table 1). The cost of the nicotine cartridges or liquid nicotine is $2.00 versus the average $5.00 for a pack of tobacco cigarettes (All Electronic Cigarette Brands, 2011). After a thorough review of multiple brands of e-cigarettes, the brands BluCigs (2012) and SmokeTip (2012) had the best consumer review ratings and were the e-cigarette brands recommended in this program. Both brands scored at least a four out of five on five different areas: battery, vapor, service, cost/value, and overall from over 200 reviews. Both brands are made in the United States and the nicotine cartridges are made from FDA approved ingredients. The BluCig has a one year warranty and the SmokeTip has a lifetime warranty. Both brands come in a variety of flavors and nicotine doses and both offer free shipping to anywhere in the United States (BluCigs, 2012; SmokeTip, 2012). The cost analysis data indicated the only smoking cessation alternative cheaper than e-cigarettes was Bupropion. As discussed earlier, Bupropion has a 24% success rate (CDC, 2009).

The literature review supported the need for more rigorous research using double blind, randomized controlled trials and meta-analyis evaluating the safety and efficacy of e-cigarettes for use in tobacco cessation. In addition, current research demonstrates the need for more systematic regulation of e-cigarette manufacturers regarding the technical quality of their products. After a review of the evidence available thus far, it is apparent that e-cigarettes provide a greater benefit as an intervention for smoking cessation than a risk for added harm. They show significant potential to increase the smoking cessation

rate as smokers will not have to give up their behavior or their nicotine until they are ready.

Table 1

Cost Analysis of Nicotine Replacement Therapy and Prescription Medications for Smoking Cessation

Replacements	Cost Per Day	Cost Per Month
Nicotine Patches	Average $2.70-$4.70 each/ use 1 per day	Average $81-$141 per month
Nicotine Gum	Average $0.35-$0.63 each/ chew 1 every 1-2 hours	Average $126-$227 per month
Nicotine Lozenges	Average $0.49 each/ suck on one every 1-2 hours	Average $177 per month
Nicotine Oral Inhaler	$7.80 per day	$234 per month
Nicotine Nasal Inhaler	$6.66per day	$200 per month
Bupropion Oral Medication	$0.90-$1.66 per day	$27-$50 per month
Varenicline Oral Medication	$5.96-$6.4 per day	$179-$192 per month
BluCig	$2.00 per day	$60 per month
SmokeTip	$1.59 per day	$47.70 per month

Note. In store cost analysis done February 2012 at Walgreens and Walmart, Craig, Colorado. Information based on 1 pack per day/smoker.

Description of the Kinder Family Clinic Smoking Cessation Program and Population

Kinder Family Clinic is a rural physician-owned health care clinic that serves the residents of Moffat County and multiple surrounding areas of northwestern Colorado. It

is one of few health care resources in the area and offers care to all ages for both acute and chronic problems. Many of the acute and chronic problems are caused by or exacerbated by tobacco use. The Kinder Family Clinic Smoking Cessation Program was implemented in response to the poor cessation rates related to current smoking cessation therapy options and offers an alternative therapy for smoking cessation as a means for harm reduction for those individuals who are not interested in quitting but would be willing to switch to e-cigarettes as an alternative to smoking regular tobacco cigarettes. This rural area is extremely limited regarding access to smoking cessation treatment and education. The Kinder Family Clinic Smoking Cessation program was a six month program implemented on a trial basis and will be continued or changed based on this program evaluation. The program included established patients who were current smokers who chose to participate.

Theoretical Framework Used for the Smoking Cessation Program

The transtheoretical model (TTM; Prochaska & DiClemente 1983; Prochaska, DiClemente, & Norcross, 1992; Prochaska, DiClemente, & Velicer, 1985) and the five stages of change originally developed by James Prochaska provided the foundation for the Kinder Family Clinic Smoking Cessation Program. The TTM provided a structured evidence-based framework to assist in evaluating an individual's readiness to quit smoking and support for the smoking cessation process (Woody, DeCristofaro, & Carlton, 2008). The stages of change described in the model represent a time period as well as a set of tasks needed to move from one stage to the next. There are five stages of change; for each stage, different change processes and relational stances provide optimal progress. Individuals typically recycle through these five stages an average of three to

four times before they actually overcome their addiction (Prochaska, 1992; Prochaska & DiClemente, 1983; Prochaska et al., 1985; Prochaska, Velicer, DiClemente, & Fava, 1988). The five stages included the following:

1. Precontemplation*:* The individual has no intention to change their behavior. Individuals in this stage are unaware or under-aware that they have a problem. However, family, friends, and employers are well aware that the patient has a problem.
2. Contemplation*:* The individual has some intention to change but no behavior. Individuals in this stage are aware that they have a problem, are seriously thinking about overcoming it, but have made no effort or commitment to change. Many individuals in this stage struggle with positive evaluations of their dysfunctional behavior and the amount of effort, energy, and loss they feel to overcome their problem. They may remain stuck in this stage for a long period of time.
3. Preparation*:* The individual intends to change and early inconsistent behavioral attempts to change are made. Individuals in this stage have made some reduction in their problem behavior, intend to take action within the next month, but have not yet reached the point for effective action.
4. Action*:* The individual has consistent behavioral performance for less than six months. This is the stage where an individual is modifying their behavior to overcome the problem. The action stage requires considerable commitment of effort and energy to change the behavior. An individual is

classified in this stage if they have quit their behavior for a period from one day to six months.

5. Maintenance*:* The individual has had consistent behavioral performance for at least six months. This is the stage where the individual must work to prevent a relapse and is consistently engaging in a new positive, incompatible behavior. This period extends from six months to an indeterminate period (Prochaska 1992; Prochaska & DiClemente, 1983; Prochaska et al., 1985, 1988).

The majority of addicted individuals are not in the action stage (Prochaska 1992; Prochaska & DiClemente, 1983; Prochaska et al., 1985, 1988). Only 10-15% of smokers are prepared for action, approximately 30-40% are in the contemplation stage, and 50-60% are still in the precontemplation stage. The amount of progress an individual makes during treatment tends to be a function of their pre-treatment stage. To treat all smokers as if they are all in the same stage is naïve, yet that has been the approach used in most traditional treatment programs (Prochaska et al., 1992). Treatment programs designed to help individuals progress just one stage in a month can double their chances of taking action on their own (Prochaska et al., 1992). Relapes are almost inevitable and are part of the process of working toward life-long change (Zimmerman, Olsen, & Bosworth, 2000). Effective treatment programs need to assess an individual's stage of readiness for change and tailor interventions accordingly (Prochaska et al., 1992).

The concepts of addiction were used as a secondary framework for this smoking cessation program. Nicotine addiction is the most common form of chemical dependence in the United States (American Society of Addiction Medicine, 2008). Addiction is

important to take into account when designing smoking cessation interventions as withdrawal symptoms impede quitting (Andersen, 2007). Avoiding withdrawal symptoms is the number one reason why individuals fail in their attempt at smoking cessation (Andersen, 2007). Nicotine replacement therapy is an effective way to deal with the physiological addiction to tobacco as it prevents nicotine withdrawal symptoms (Andersen, 2007).

Smoking Cessation Program Objectives

The main objective of this program was to offer a new smoking cessation option that could dramatically improve the overall smoking cessation rate of all populations. The second objective was to provide an alternative to tobacco cigarettes for those individuals not interested in quitting smoking but willing to switch to a much safer and cheaper alternative.

Implementation Methods and Tools Used for Program

Participant Recruitment

The goal was to recruit patients from Kinder Family Clinic Practice and the surrounding community who were willing to participate in the program. The objectives were as follows:

1. Identify Kinder Family Clinic patients who are current smokers using the clinic's electronic health record (EHR) system--"Practice Partner."
2. Send a survey to those patients identified as current smokers (see Appendix A). Based on return survey results, identify patients willing to participate in the program who wished to quit or who were willing to switch from tobacco cigarettes to e-cigarettes.

3. Provide each participant with informed consent regarding program to read and sign prior to participation (see Appendix B for consent and Appendix K for Institutional Review Board approval).

Pre-intervention Assessment

The goal was to obtain pre-intervention assessments of participants to determine smoking history, demographics, likelihood to change and be successful, and baseline nicotine dose. The objectives were as follows:

1. Evaluate participants' stage of change, smoking status, length of time they smoked, number of cigarettes per day, previous attempts to quit, past interventions used for smoking cessation, and demographic information including age, gender, education level (a former smoker was defined as an individual who was actively trying to quit and had not smoked in at least 24 hours).
2. Build The Stages of Change questions (see Appendices C and D) into the smoking cessation template in Practice Partner EHR and use as the framework for this program to assist in evaluating an individual's readiness to quit smoking. Knowing which stage of change an individual is in was thought to help tailor the information and guidance provided to maximize success with smoking cessation.
3. Evaluate nicotine dependence using the revised Fagerstrom nicotine tolerance test (FNTT; Heatherton, Kozowski, Frecker, & Fagerstrom, 1991). This test was used to determine the baseline nicotine dose for e-cigarettes for smoking cessation (see Appendix E).

Intervention

The goal was the implementation of a structured, systematic smoking cessation program using the “Five A’s” model for treating tobacco use and dependence to include options to either help smokers quit entirely or switch from tobacco cigarettes to electric cigarettes (see Appendix F). The objectives were as follows:

1. Develop program by reviewing current literature for best practices in smoking cessation related to addiction, frameworks for behavior change, nicotine replacement therapies and prescription medications, and patient education.
2. Adopt and adapt selected education materials based on the "5 A's" model (see Appendix F) for treating tobacco use and dependence developed by the Colorado Collaborative Clinical Guidelines (2004).
3. Provide staff development and education regarding program details, patient data, and Practice Partner EHR prior to implementation.
4. Discuss options for smoking cessation with each participant at initiation of program and allow the participant to choose which cessation method he or she would like to try. Provide written information on different cessation options, success rate, risks, and benefits at the initiation of the program (see Appendix G).
5. Provide written information on dangers of smoking and benefits of quitting, support, and resources to help with quitting at the initiation of program to each participant (Colorado Collaborative Clinical Guidelines, 2004).

6. Develop a plan and timeline to decrease nicotine dose based on nicotine dependence, personal preference, desire to quit, and health risks for each participant and evaluate their nicotine dose during each follow-up phone call.
7. If the participant chooses to try e-cigarettes, provide written information on BluCig and SmokeTip e-cigarettes (the two e- brands recommended for this program) regarding cost, availability, and nicotine dosage options (see Appendices H and I).
8. Develop and implement a follow-up plan that integrates phone calls or office visits for each program participant at two weeks, one month, three months, and six months. Document follow-up data in Practice Partner EHR (see Appendix J) that includes evaluation questions regarding smoking status, nicotine dosage, e-cigarette likability, usage, and comments.

Tools Used in Program

- The five stages of change used as the framework for this project (pre-contemplation, contemplation, preparation, action, and maintenance) provided a structured evidence-based framework to assist in evaluating an individual's readiness to quit smoking and support for the smoking cessation process (see Appendix D). Knowing which stage of change an individual was in helped tailor the information and guidance provided to maximize success with smoking cessation. It was used to help predict the individual's success rate at smoking cessation (see Appendices C, D, and F).

- The revised Fagerstrom Test for Nicotine Dependence (FTND; Heatherton et al., 1991) was used to assess each participant's degree of physical dependence on nicotine. The Fagerstrom Tolerance Questionnaire (FTQ; Fagerstrom, Hughes, Rasmussen, & Callas, 2000) is a 10-item questionnaire and the questions are scored on a 5-point Likert scale; the total score is the mean rating across all 10 items. The assumption was the higher the score the greater the degree of addiction. The questions were used to assess the degree of urgency an individual felt to restore nicotine levels to a given threshold after nighttime abstinence and to evaluate the urge the individual had to maintain their nicotine threshold during waking hours. This test was used to evaluate the baseline nicotine dose for NRT or e-cigarette for smoking cessation (see Appendix E).
- Pre-intervention surveys were completed by participants at onset of program regarding demographic information, smoking history, previous quit attempts, and methods tried.
- Education material on the effects of smoking and benefits of quitting accessed through the Colorado Collaborative Clinical Guidelines (2004) were provided to each patient at the initiation of program.
- Informational material was provided to participants regarding effectiveness, cost, and potential side effects of different cessation methods at initiation of program.
- Information on the two chosen e-cigarettes (BluCig and SmokeTip) that were used in this program regarding cost, nicotine doses and flavors, and

accessibility was provided to participants at initiation of the program (see Appendices H and I).

- Phone calls to participants during implementation and at completion of program regarding smoking status, decrease in number of cigarettes if still smoking, nicotine level if using e-cigarette, type of e-cigarette they chose, and comments regarding e-cigarette likability, usability, durability.

Program Evaluation Objectives and Design

The objectives of this capstone project were to evaluate the Kinder Family Clinic Smoking Cessation Program using the Donabedian and bridge evaluation models regarding its structure, processes, and outcomes (Donabedian, 1972; Sieloff, 1999). These theoretical frameworks provided the foundation for evaluating the extent to which the program met each specified goal and objective, possible barriers and facilitators, and recommendations for future improvements**.**

Donabedian Model

Structural measures evaluated the facility or setting used, human resources including qualifications and experience, and the organizational resources including the Practice Partner EHR and size of the practice and program.

Process measures evaluated for this program included the screening, treatment, education, and follow-up phone surveys of participants.

Outcome measures evaluated for this program included participation level, demographic data of participants, success rate of participants, e-cigarette data, and improvement to quality of life.

Bridge Evaluation Model

By incorporating the bridge evaluation model into the evaluation process, human factors critical to an evaluation's success were also taken into account. According to Sieloff (1999), the bridge evaluation model included the following:

1. Goal Identification: What is to be evaluated? What problem is the evaluation intended to address? What is the purpose of the evaluation? How can the essential program activities be linked to the goal? How do time and resource factors affect the evaluation goal?
2. Interpersonal Relationships: Will the interpersonal relationships support the efficient and effective implementation of the evaluation plan? What kind of communication might improve the evaluation implementation and reporting system? What kind of bias exists regarding the program being evaluated and those who can influence the evaluation design, data, and use?
3. Ethics: What are the essential program activities and are they legal/ethical? How will the type and use of data be collected for the evaluation? How and by whom will the information be used? What use will the evaluation findings serve and is it ethical?
4. Politics: Why is the evaluation being requested? Who will participate and what are their roles in the evaluation? What political use will the evaluation findings serve, if any? Who else needs to know about the evaluation findings (e.g., stakeholders)?

5. Determination: Can the evaluation design meet the evaluation goal given the scope and context of the evaluation's purpose? Who will use the evaluation findings? How will the determination affect stakeholders?

Bridge Model Technical Factors

1. Design: Create an evaluation plan and design the evaluation system in accordance with the goals. This could include criteria and objectives, type of evaluation (formative or summative), evaluator, purpose, evaluation approach, data-collection requirements-tools-protocol, resources and supplies, environmental considerations, and reporting methods.
2. Collect Data: Gather qualitative or quantitative data in accordance with the evaluation plan using methods that achieved the objectives. This could include survey instruments, private interviews, group interviews, previously collected related data, and observations including tests and document review.
3. Test/Assess: Synthesize the findings from the qualitative and quantitative methods to test the validity, completeness, or correctness of the data.
4. Report: Prepare the report for the target audience in accordance with the evaluation plan to include the introduction, evaluation, conclusions, and recommendations. This might include achievement of evaluation objectives, noted violations of ethical principles, alterations in the original evaluation needs, value of the evaluation's accomplishment, the process and outcomes of the data assessment, and results achieved via the evaluation system.

5. Evaluation Results: Perform an evaluation on the effectiveness of the evaluation using the model.

Congruence of Organization's Strategic Plan to Project

Kinder Family Clinic was completely supportive of this program with the focus on improving the health of the community. The clinic is a private physician-owned health care clinic in rural northwest Colorado located in Craig. Kinder Family Clinic is staffed by a Family Nurse Practitioner, Dr. Pamela Kinder, who is a neurologist and the owner of the clinic; two receptionists; and two medical assistants. The clinic seeks to expand family practice patients and focus on health promotion and disease prevention practices and programs. The mission statement for Kinder Family Clinic is to provide excellent care in a nurturing, welcoming environment to the people of the Yampa Valley. The goals of Kinder Family Clinic are (a) to provide quality care for each patient; (b) to recognize, respect, and appreciate each team member's individuality and talents; (c) to utilize the skills of each individual; (d) to have more understanding of our patients' needs; to have a safe and healthy working environment; and (e) to make Kinder Family Clinic successful. The visions for the future for the clinic are (a) to work to become increasingly recognized as providing the highest quality care available in the profession as measured by patient satisfaction and cost effectiveness; (b) to provide leadership in the community by actively participating in professional and community groups; and (c) to commit to excellence and respond to our patients with a level of care that exceeds their expectations (Kinder Family Clinic, 2011).

Resources

Resources needed to implement program into Kinder Family Practice included the following:

- Patient questionnaire on stages of change, addiction level, baseline nicotine dose, and demographic data. It was provided to each participant to complete at initiation of program and was also built into the Smoking Cessation Template in Practice Partner (Kinder Family Clinic, 2011).
- Educational material on effects of smoking and benefits of quitting prepared by Colorado Collaborative Clinical Guidelines (2004) were provided to each participant at initiation of program.
- Informational material on all options for smoking cessation including effectiveness, cost, and potential side effects provided to each participant at initiation of program (see Appendix G).
- Information on BluCig and SmokeTip e-cigarette regarding cost of kit and replacement nicotine cartridges, doses and flavors of nicotine cartridges, and where it can be purchased (see Appendices H and I) were provided to each participant at initiation of program.
- Time to send survey, review responses, and contact participants of program.

Risks

No risks were identified related to the use of electric cigarettes compared to tobacco cigarettes; the data show them to actually reduce the health related risks seen with tobacco cigarettes.

Benefits

E-cigarettes could become a new option to help with smoking cessation if proven to be effective, diminishing or alleviating the risks associated with tobacco cigarettes and second-hand smoke. E-cigarettes are also cheaper than tobacco cigarettes and many of the other smoking cessation options, which would be more financially beneficial to individuals.

CHAPTER III

EVALUATION PLAN

The evaluation plan provides a systematic outline of the processes implemented to meet the aims of the program evaluation and include the following:

1. Clear identification of the purpose of the evaluation
2. Evaluation questions based on program structure, inputs (processes) and expected outcomes
3. Design and methodology to guide data collection and analysis
4. Recommendations based on the interpretation of the data analysis

Purpose of the Evaluation

The purpose of this evaluation was to determine achievement of program goals, identify effective program components, determine why some program components were effective while others were not, identify potential program improvements, and provide information on the program's cost effectiveness and outcomes. The Donabedian (1972) and bridge (Sieloff, 1999) models were used as a framework to guide the elements of the evaluation.

The following questions guided the program evaluation and were answered through collection and analysis of specific data:

Q1 Were the stated goals and objectives of the program met, not met, or partially met?

Each program goal (outlined in Chapter II) was assessed based on appropriate and applicable data (see Table 2).

Table 2

Program Goals and Objectives

Goal	Objective
Recruit patients from Kinder Family Clinic Practice and the surrounding community who were willing to participate in the program.	• Identify Kinder Family Clinic patients who are current smokers using the clinic's EHR system "Practice Partner". • Send a survey to those patients identified as current smokers. (Appendix A). Based on return survey results, identify patients who were willing to participate in the program who wished to quit, or who were willing to switch from tobacco cigarettes to e-cigarettes. • Provide each participant with informed consent regarding program to read and sign prior to participation.
Obtain pre-intervention assessment of participants to determine smoking history, demographics, likelihood to change and be successful, and baseline nicotine dose.	• Evaluate participants' stage of change, smoking status, length of time they smoked, number of cigarettes per day, previous attempts to quit, past interventions used for smoking cessation, demographic information including age, gender, education level. (A former smoker was defined as an individual that was actively trying to quit and had not smoked in at least 24 hours.) • Build The Stages of Change questions (Appendix C), into the smoking cessation template in Practice Partner EHR, and use as the framework for this program to assist in evaluating an individual's readiness to quit smoking. Knowing which stage of change an individual is in was thought to help tailor the information and guidance provided to maximize success with smoking cessation. • Evaluate nicotine dependence using the Fagerstrom Nicotine Tolerance Test (FNTT). (This test was used to determine the baseline nicotine dose for e-cigarettes for smoking cessation (Appendix E).)
Implementation of a structured, systematic smoking cessation program using the "Five A's" Treating Tobacco Use and Dependence to include options to either help smokers quit entirely or switch from tobacco cigarettes to electric cigarettes (Appendix F).	• Develop program by reviewing current literature for best practices in smoking cessation related to addiction, frameworks for behavior change, NRTs and prescription medications, and patient education. • Adopt and adapt selected education materials based on The "5 A's" model (Appendix F), for treating tobacco use and dependence that was developed by the Colorado Collaborative Clinical Guidelines (Colorado Collaborative Clinical Guidelines, 2004). • Provide staff development and education regarding program details, patient data, and Practice Partner EHR prior to implementation. • Discuss options for smoking cessation with each participant at initiation of program, and allow the participant to choose which cessation method he or she would like to try. Provide written information on different cessation options, success rate, risks, and benefits at the initiation of the program. • Provide written information on dangers of smoking and benefits of quitting, support, and resources to help with quitting at the initiation of program to each participant (Colorado Collaborative Clinical Guidelines, 2004). • Develop a plan and timeline to decrease nicotine dose based on nicotine dependence, personal preference, desire to quit, and health risks for each participant and evaluate their nicotine dose during each follow-up phone call. • If the participant chose to try e-cigarettes, provide written information on "blu cig" and "smoke tip" e-cigarettes, which were the two e-cigarette brands recommended for this program, regarding cost, availability, nicotine dosage options. • Develop and implement a follow-up plan that integrates phone calls or office visits for each program participant at 2 weeks, 1 month, 3 months, and 6 months. Document follow-up data in Practice Partner EHR (Appendix H) that includes evaluation questions regarding smoking status, nicotine dosage, e-cigarette likability, usage, and comments.

Q2 Were the structural components (facility/setting, human resources, organizatonal resources, EHR, tools) effective and how did they contribute to the value of the program?

Table 3 presents the structural measures utilized to evaluate the collected data.

Table 3

Structural Measures

Evaluate	Data	Data Collection
Usefulness of written education on smoking cessation. 1. Packet from Colorado Collaborative Guidelines 2. Smoking Cessation Options 3. Cost Comparison of NRT 4. Information on Blu Cig and Smoketip E-cigarettes	Subjective Data provided by program participants on effectiveness of cessation options, cost information, and whether it was appropriate and adequate.	Phone interviews to all program participants with focused questions regarding feedback on program's educational materials.
Electronic Health Records (EHR) used for program "Practice Partner".	Usability and reliability of EHR for data collection, management, and analysis	Determination by primary investigator and staff at completion of program, based on ability to collect and quantify necessary data from EHR.
Staff education regarding Kinder Family Clinic smoking cessation program.	Staff education on program details, patient data, and use of EHR for program.	In person survey of staff
Framework used for program.	TTM model (Stages of Change) used to evaluate participants readiness to quit smoking.	Stages of Change of participant collected at initiation and completion of program. Determination/ assessment by primary investigator.
Fagerstrom Tolerance Test	Effectiveness, reliability, validity, and accuracy of test regarding nicotine addiction level of program participants.	Gather and evaluate data from pre-intervention survey and comments from participants during follow up phone calls regarding nicotine level.
Pre-participation Survey 1. Questionnaire 2. Mail Survey	Evaluate information collected on survey regarding whether questions appropriate, all inclusive, recommended additions, or changes. Mail survey vs. other options for communication (emails, text messages, website).	Phone interview to participants with focused questions. Response rate to mail surveys, participant and staff opinions and recommendations.
Phone calls as chosen method of contact and follow-up with participants.	Phone calls as appropriate and adequate communication choice for program. What other methods of communication could have been used.	Response rate of participants to phone calls. Participant and staff recommendations regarding other options for communication.
Necessary qualifications of program administrator/provider.	Qualifications of primary investigator. What other staff could have been used to implement this program and necessary qualifications	Determination of primary investigator using literature for context regarding needed education level to implement and administer program.
Program Sustainability and Usability.	Recommendations on whether program should continue, recommended changes, and other potential settings for program.	Outcome data and cost analysis regarding program use, changes, and other settings appropriate for use.

Q3 Were the processes used for the program effective and how did they contribute to the value?

Table 4 presents the processes used to measure the effectiveness of the program.

Table 4

Process Measures

Evaluate	Data	Data Collection
Identify all current smokers at Kinder Family Clinic and those willing to participate in smoking cessation program.	Were all current smokers identified and were they all sent an invitation to participate in smoking cessation program using e-cigarettes.	Use Practice Partner EHR to identify current smokers, identify those willing to participate based upon results from return survey.
Usefulness of The Stages of Change and participation in program.	Was this particular model useful for determining participation in program?	Stage of change of participants at initiation and completion of program. Was the model applicable to the study participants and did it provide a framework for the implementation/ intervention?
Usefulness of determining nicotine addiction level of participants at initiation and completion of program.	Determine nicotine addiction level to determine appropriate baseline nicotine dose for e-cigarette.	Use the Fagerstrom Tolerance Test to determine nicotine level, correlation with participant self-report.
Phone Call Follow-up Response of participants.	Were phone follow ups at 2 weeks, 1month, 3months, and 6 months effective and did they contribute to the participant's overall success?	Use EHR and excel spreadsheet to evaluate phone contact with each participant.

Q4 What were the outcomes of the program and how do they compare with anticipated outcomes and outcomes of other standard practices?

Table 5 presents how the outcomes of the program were measured and how they compared with anticipated outcomes.

Table 5

Outcome Measures

Evaluate	Data	Data Collection
Current smokers that are patients at Kinder Family Clinic and participants in program.	Number of current smokers and number of participants of program.	Use EHR and excel spreadsheet to collect data.
Demographic information of participants	Age, gender, ethnicity, race, and education level of participants.	Quantify data gained from pre-participation survey and EHR.
E-cigarettes 1. Smoking cessation rate of participants at completion of program that had not smoked in at least a month. 2. Participants that switched from tobacco cigarettes to e-cigarettes. 3. Participants that decreased use of tobacco cigarettes to at least less than half of usage from initiation to completion of program by using e-cigarettes.	Cessation rate, and harm reduction rate of participants.	Data obtained from phone call f/u with participants, use EHR and spreadsheet to quantify data.
Nicotine addiction level of participants	Nicotine level of participants at initiation and completion of program using Fagerstrom Tolerance Test.	Data obtained from pre-intervention survey and phone call follow up with participants, use EHR and spreadsheet to quantify data.
Participant perspectives regarding e-cigarettes.	Document comments regarding e-cigarette satisfaction, effectiveness, cost, reliability, accessibility, and improvement on quality of life.	Data obtained from phone call f/u with participants, use EHR and spreadsheet to quantify data.

Q5 Was the program cost effective?

The following costs and/or revenue were related to the program: (a) human resources or time spent collecting "current smoker status" on Kinder Family Clinic patients from Practice Partner EHR; (b) time spent on copying and preparing the invitations for mailing; (c) cost of mailing the 640 invitations to Kinder Family Clinic

patients identified as current smokers; (d) time spent by the primary investigator gathering educational information; (e) time and cost of copying the educational data; (f) time spent by primary investigator with each participant completing survey, providing educational material, e-cigarette information, and smoking cessation counseling; (g) time spent by primary investigator performing follow-up phone calls to each participant at two weeks, one month, three months, and six months; (h) projected cost to health care system if they kept smoking; and (i) reimbursement for the smoking cessation program clinic visits based on payor source.

Data Collection and Analysis

Specific tools were used to assess the degree to which each program goal was met as well as the specific evaluation questions. In some cases, standardized tools were used while other evaluation questions required survey tools developed specifically for this program.

- An electronic health record system (Practice Partner EHR) was used to identify potential participants and collect and maintain patient data/ information throughout the program.
- The main frameworks used for evaluating this program were the Donabedian (1972) model and the bridge evaluation model (Sieloff, 1999).
- The TTM model Five Stages of Change evaluated a participant's readiness to quit.
- The Fagerstrom Tolerance Test was used to evaluate participants' nicotine addiction level and to recommend baseline nicotine dose.

- The participant survey that included questions on demographic information, smoking history, previous quit attempts, and methods tried was provided to each participant at initiation of program.
- Education material on the effects of smoking and benefits of quitting was accessed through the Colorado Collaborative Clinical Guidelines (2004).
- Informational materials were provided to participants regarding effectiveness, cost, and potential side effects of different cessation methods.
- Information was provided on the two chosen e-cigarettes (Blu Cig and Smoke Tip) used in this program regarding cost, nicotine doses and flavors, and accessibility.
- Phone calls were made to participants during implementation and at completion of program regarding smoking status, decrease in number of cigarettes if still smoking, nicotine level if using e-cigarette, and comments regarding e-cigarette likability, usability, durability.

Recommendations

Following systematic analysis of the data, recommendations were developed regarding how to continue this program more effectively. The data interpretation was conducted to determine what elements of the program should undergo revisions, additions and/or deletion, and what other potential options exist for effective implementation (e.g., other settings, use of different types of staff). Finally, outcome measures were interpreted to determine feasible program goals for the future.

CHAPTER IV

RESULTS

Presentation of the results of the program evaluation are organized based on the purpose of the evaluation and the five primary evaluation questions as outlined in Chapter III: Evaluation Plan. This results chapter describes the achievement of the program goals, effective program components, potential program improvements, cost effectiveness, and program outcomes. The findings are also presented using Donabedian's (1972) model of structure, process, and outcomes.

Data Analysis and Findings

Q1 Were the stated goals of the program met, not met, or partially met?

Each program goal (outlined in Chapter II) was assessed based on appropriate and applicable data. Table 6 shows whether each program goal was met, partially met, or not met.

Table 6

Goals and Objectives Met, Partially Met, or Not Met

Goal	Met, Partially Met or Not Met	Objective	Met, Partially Met or Not Met
Recruit patients from Kinder Family Clinic Practice and the surrounding community who were willing to participate in the program.	Met	• Identify Kinder Family Clinic patients who are current smokers using the clinic's EHR system "Practice Partner". • Send a survey to those patients identified as current smokers. (Appendix A). Based on return survey results, identify patients who were willing to participate in the program who wished to quit, or who were willing to switch from tobacco cigarettes to e-cigarettes. • Provide each participant with informed consent regarding program to read and sign prior to participation.	Objective results addressed in Structure, Process, and Outcomes Measures.
Obtain pre-intervention assessment of participants to determine smoking history, demographics, likelihood to change and be successful, and baseline nicotine dose.	Partially Met	• Evaluate participants' stage of change, smoking status, length of time they smoked, number of cigarettes per day, previous attempts to quit, past interventions used for smoking cessation, demographic information including age, gender, education level. (A former smoker was defined as an individual that was actively trying to quit and had not smoked in at least 24 hours.) • Build The Stages of Change questions (Appendix C & D), into the smoking cessation template in Practice Partner EHR, and use as the framework for this program to assist in evaluating an individual's readiness to quit smoking. Knowing which stage of change an individual is in was thought to help tailor the information and guidance provided to maximize success with smoking cessation. • Evaluate nicotine dependence using the Fagerstrom Nicotine Tolerance Test (RTQ). (This test was used to determine the baseline nicotine dose for e-cigarettes for smoking cessation (Appendix B).	Objective results addressed in Structure, Process and Outcomes Measures.
Implementation of a structured, systematic smoking cessation program using the "Five A's" Treating Tobacco Use and Dependence to include options to either help smokers quit entirely or switch from tobacco cigarettes to electric cigarettes (Appendix E).	Met	• Develop program by reviewing current literature for best practices in smoking cessation related to addiction, frameworks for behavior change, NRTs and prescription medications, and patient education. • Adopt and adapt selected education materials based on The "5 A's" model (Appendix E), for treating tobacco use and dependence that was developed by the Colorado Collaborative Clinical Guidelines (Colorado Collaborative Clinical Guidelines, 2004). • Provide staff development and education regarding program details, patient data, and Practice Partner EHR prior to implementation. • Discuss options for smoking cessation with each participant at initiation of program, and allow the participant to choose which cessation method he or she would like to try. Provide written information on different cessation options, success rate, risks, and benefits at the initiation of the program. • Provide written information on dangers of smoking and benefits of quitting, support, and resources to help with quitting at the initiation of program to each participant (Colorado Collaborative Clinical Guidelines, 2004). • Develop a plan and timeline to decrease nicotine dose based on nicotine dependence, personal preference, desire to quit, and health risks for each participant and evaluate their nicotine dose during each follow-up phone call. • If the participant chose to try e-cigarettes, provide written information on "blu cig" and "smoke tip" e-cigarettes, which were the two e-cigarette brands recommended for this program, regarding cost, availability, nicotine dosage options. • Develop and implement a follow-up plan that integrates phone calls or office visits for each program participant at 2 weeks, 1 month, 3 months, and 6 months. Document follow-up data in Practice Partner EHR (Appendix G) that includes evaluation questions regarding smoking status, nicotine dosage, e-cigarette likability, usage, and comments.	Objective results addressed in Structure, Process and Outcomes Measures.

The program was successful in meeting many of the goals and objectives that were outlined. As planned, all 640 identified patients who were current smokers at Kinder Family Clinic were sent an invitation to participate in the smoking cessation program. However, of the 640 who were invited to participate, only 48 chose to do so and 44 completed the program. All participants completed the pre-participation survey, were provided educational material on smoking cessation and e-cigarettes, were evaluated on their stage of change, and were provided the Fagerstrom nicotine tolerance questionnaire to determine baseline nicotine dose. Interviews with staff revealed they perceived they were adequately educated regarding details of the program. The chosen method of follow-up contact by phone was not effective as only 10 (21%) of the participants were successfully contacted at all four follow-up calls and four (8%) were not contacted at all. The remaining 34 (71%) were successfully contacted at least once. The electronic health record platform, Practice Partner, was found to lack the capabilities to successfully track multiple patients with multiple data points. Thus, a separate Excel spreadsheet was created to document and track the data for this program.

Q2 Were the structural components (facility/setting, human resources, organizational resources, EHR, tools) effective and how did they contribute to the value of the program?

Table 7 shows whether the structural components were effective and contributed value to the program.

Table 7

Effectiveness and Value of Structural Measures to the Program

Measure	Effectiveness	Notes/Value to the Program
Usefulness of written education on smoking cessation.		The education material on the effects of smoking and benefits of quitting provided to all participants which was obtained through the Colorado Collaborative Clinical Guidelines was actually found to be quite **ineffective** at increasing success rate of quitting or switching to e-cigarettes within this participant group (Colorado Collaborative Clinical Guidelines, 2004).
1. Packet from Colorado Collaborative Guideline	Ineffective	At the completion of the program, only two participants stated they had called the Colorado Quit Line, one stated "they were a joke", and the other said "they weren't very helpful and they weren't supportive of e-cigarettes so I never called back." The Colorado Quit Line is a state funded program and does not recognize or support e-cigarettes as cessation method. For this type of program it is thought that the information provided by the State of Colorado on tobacco cessation **would not be the most effective** or appropriate regarding the use and recommendations for e-cigarettes as a NRT for smoking cessation or harm reduction.
2. Smoking Cessation Options and Cost Comparison of NRT.	Effective	All 44 participants questioned at the completion of the program regarding the informational material provided regarding effectiveness, cost, and potential side effects of different cessation methods stated they thought it was effective and informative, especially when comparing the cost of different NRT (Appendix G). Ten of the participants commented on the cost of the approved NRT vs. e-cigarettes and how much cheaper e-cigarettes were.
3. Information on BluCig and SmokeTip E-cigarettes	Partially Effective	Eight participants also stated that the information provided on the two chosen e-cigarettes (BluCig and SmokeTip) that were used in this program regarding cost, nicotine doses and flavors, and accessibility were helpful. There were multiple comments regarding how much cheaper e-cigarettes were compared to tobacco cigarettes and several participants commented that was a reason to switch in itself. However, this information should have been much more inclusive regarding different brands, nicotine doses, cost, and accessibility of e-cigarettes. One of the recommended brands for this program was only available through the internet which was thought to decrease its usability. One of the local brands which came highly recommended by five of the participants was the "Mystic" e-cigarette, which could be found at multiple convenience stores and Walmart. The cost of the kit was approximately $30 (includes three nicotine cartridges, two e-cigarette batteries, and a wall charger). The replacement cartridges come in three different strengths (1.4 mg, 1.8 mg, and 2.4 mg) and the cost is $13/5 cartridges or $20/10 cartridges regardless of nicotine dose. The cost savings on these replacement cartridges is equivalent to $2.00/pack of cigarettes compared to the average price of $5.00/pack of cigarettes, or a $3.00 savings per pack. Based on this participant feedback, the "Mystic" e-cigarette would be recommended due to easy availability, and cost savings related to tobacco cigarettes.

(Table continues)

Table 7 Continued

Measure	Effectiveness	Notes/Value to the Program
Usability and reliability of EHR "Practice Partner" for data collection and analysis.	Partially Effective	Upon review of Practice Partner EHR, it was found to be easy to use for individualized data but the system was not able to adequately or accurately track and quantify data regarding multiple patients in a reliable way. An Excel spreadsheet was used at the completion of this program to quantify results. For future program participation within this same setting, or in other settings, a better program is recommended that can more accurately identify current smokers within the practice and that is able to accurately and easily track participants and the related information.
Staff education regarding Kinder Family Clinic smoking cessation program.	Effective	Focused questions to staff determined that they felt they were adequately informed and educated regarding program
Usefulness of the TTM model Five Stages of Change Framework used for program.	Ineffective	The TTM model Five Stages of Change that was used to evaluate a participant's readiness to quit, was **not** found to be an effective tool for this program, as all participants were found to be in the "action stage" or they would not have participated in the program. The TTM model could be still be used in a clinic setting to identify what stage of change a current smoker is in, and their readiness to quit or willingness to even receive cessation information/education. It could be used along with the "5 A's" to encourage patients to quit smoking at each health care visit, but is not recommended as the basis for this type of cessation program (Colorado Collaborative Clinical Guidelines, 2004).
Fagerstrom Tolerance Test effectiveness, reliability, validity, and accuracy of to measure nicotine addiction level of program participants.	Effective	The Fagerstrom Tolerance Test was used to evaluate participants' nicotine addiction level and to recommend baseline nicotine dose. This was an excellent tool to use to evaluate addiction level and choose appropriate baseline nicotine dose to prevent withdrawal symptoms, which is the most common reason to start smoking tobacco cigarettes again (Fagerstrom, Hughes, Rasmussen, & Callas, 2000). This tool was found to be easy to use and understand, applicable, and an effective way of determining baseline nicotine levels. The correlation between the nicotine level on the FTT and what the participant stated they used was consistently the same.
Pre-participation Survey 1. Questionnaire 2. Mail Survey	Partially Effective	The participant questionnaire included questions on demographic information, smoking history, previous quit attempts, and cessation methods tried. It was found to be an effective method to collect baseline data; however, it is recommended that a follow-up questionnaire be provided to all participants at the end of the program. It is also recommended to create multiple or alternative methods of communication with participants such as email, website, or text messaging, instead of limiting communication to phone or in office follow-up. It is felt this would have improved the participation rate and the follow-up contact.

(Table continues)

Table 7 Continued

Measure	Effectiveness	Notes/Value to the Program
Phone calls as chosen method of contact and follow-up with participants.	Partially Effective	The follow-up method chosen for this program was found to be a poor choice. It was limited strictly to phone calls at two weeks, one month, three months, and six months after each participant started the program. The success rate of contact at each planned follow-up was only 10 of 44 participants or 23%. However, all but four participants were contacted at least once during the program, so overall the successful participation was 92%. Unfortunately, since this program was limited strictly to phone contact, two of the four participants that were never contacted, had the wrong phone number listed for their contact information. Had there been other methods of contact implemented at the start of the program the successful follow-up rate could have been 100%. The follow-up questions regarding current smoking status, decrease in number of cigarettes if still smoking, nicotine level if using e-cigarette, comments regarding e-cigarette likability, usability, durability were found to be helpful and appropriate. However, it is thought that there is some other important information that could have been gathered from participants' opinion regarding appropriate frequency of follow-up contact, preferred method of contact, preferred duration of the program, and recommended support material or advice
Necessary qualifications and bias of program administrator/provider.	Partially Effective	The primary investigator for this program was a certified Family Nurse Practitioner with 20 years of nursing experience, and 12 years' experience as a nurse practitioner working in a rural setting and treating chronic disease, tobacco abuse and its multiple related health problems. Although this experience and education was beneficial to the development and implementation of the initial program, it is thought that this program could be implemented by multiple individuals with varying levels of education or experience. This program could easily be implemented by multiple staff members, such as a medical assistant, licensed practical nurse, or even receptionist, and overseen by a primary care provider. Once the structure is developed for the program, any interested party could provide the necessary ongoing education and follow-up. There could be bias on the side of the primary investigator due to the fact that the same individual developed, implemented, and evaluated the program. Steps to remove or limit bias included having a set structure to the program, ensuring the same information, questionnaire, and educational material was provided to all participants in the same manner, and that all names or other identifying information were removed from the results.
Program Sustainability and Usability	Effective	This program could be useful in multiple settings. Due to the financial benefits, and the accessibility of e-cigarettes this program could be used in several health care settings such as indigent and urgent care clinics, private and specialty clinics, public health facilities, hospitals, and long term care facilities. The fact that, at this time, e-cigarettes can be used in places where tobacco cigarettes are prohibited and that they are less than half the cost of tobacco cigarettes and other NRT (Appendix G) makes e-cigarettes an affordable, accessible, cheaper NRT option. The main constraint that would inhibit the use of e-cigarettes in any government funded facility is that they are not an FDA approved NRT and probably never will be.

Q3 Were the processes used for the program effective and how did they contribute to the value?

Table 8 indicates the processes used for the program, whether they were effective, and how they contributed to the value of the program.

Table 8

Effectiveness and Value of Process Measures to the Program

Measure	Effectiveness	Notes/Value to the Program
Identify all current smokers at Kinder Family Clinic and those willing to participate in smoking cessation program.	Partially Effective	Kinder Family Clinic 3000 patients: 640 identified as current smokers and sent invitation to participate in program. (Equivalent to the national and state average at 21% (CDC, 2012). 48 responded to invitation and started program (7.5% of smokers (Practice Partner Electronic Health Records, 2011). 44 participants finished program (6.9%. Though this participation rate was quite dismal, it was higher than the national average of 4 % (CDC, 2012). However, due to misinformation on the part of patients, failure to document on the part of Kinder Family employees, or failure of Practice Partner EHR to accurately track this information, it is possible and probable, that the actual number of current smokers is much higher.
Usefulness of The Stages of Change and participation in program.	Ineffective	All participants were in action stage in at the initiation of the program. At completion of program, seven participants were still smoking or had started smoking so were no longer considered to be in the action stage but back in the contemplation or pre-contemplation stage. Of the remaining 37 participants 21 of them had quit (14) or switched to e-cigarettes (7) so were considered to be in the maintenance stage. The remaining 16 participants had either cut down to smoking less than half of where they started (3) or had cut down to less than half and were using e-cigarettes (13) at the completion of the program so were still considered to be in the action stage.
Usefulness of determining nicotine addiction level of participants at initiation and completion of program.	Effective	Determining participants" nicotine addiction level at the onset of the program was helpful in determining their baseline nicotine dose for e-cigarette and correlated with their successful cessation rate or ability to switch to e-cigarettes.

(table continues)

Table 8 Continued

Measure	Effectiveness	Notes/Value to the Program
Determine whether all participants received educational handouts at initiation of program. 1. Information on effects of smoking and benefits of quitting. 2. Information on NRT options and cost comparison. 3. Information on e-cigarette options, cost, availability, nicotine dosage, and flavor options.	Effective	Through evaluation of EHR documentation and participant response it was determined 100% of participants were provided educational material.
Phone Call Follow-up Response of participants.	Partially Effective	Number of participants contacted **all 4 attempts = 10 (21%)** Number of participants contacted **on 3 attempts = 11 (23%)** Number of participants contacted **on 2 attempts = 7 (15%)** Number of participants contacted **on 1 attempt = 16 (33%)** Number of participants **never contacted = 4 (8%)** **Total participants contacted at least once = 44 (92%)**

Q4 What were the outcomes of the program and how do they compare with anticipated outcomes and outcomes of other standard practices?

Kinder Family Clinic has a patient population of 3,000; of this patient group, 640 (21%) were identified as current smokers. Of the 640 current smokers who were sent an invitation to participate in the Kinder Family Clinic Smoking Cessation Program, 48 responded and started the program; 44 (92%) completed the program. Of the 44 participants who completed the program, 15 were male and 29 of them female. All 44 participants were non-Hispanic/White and ranged in age from 20-75; the largest percentile (30%) were in the 51-60 age group and 25 (57%) had a high school education or less (see Table 9).

Table 9

Participant Demographics

Participant	Male	Female	Total Percentile
Age			
20-30	3	3	6
3140	3	5	8
41-50	4	4	8
51-60	3	10	13
61-70	2	5	7
71 and Over	0	2	2
Total	15	29	44
Race/Ethnicity			
Non-Hispanic/White	15	29	44
Education Level			
Some High School	2	4	6
High School Diploma/GED	7	12	19
Trade School	5	2	7
Associate's Degree	1	7	8
Bachelor's Degree	0	2	2
Master's Degree	1	1	2

The participants were provided the Nicotine Tolerance Test (RTQ) at the initiation of the program to determine baseline nicotine level. The participants were provided the RTQ at the initiation of the program to determine baseline nicotine level. Of the 44 participants who completed the program, 39 (89%) were determined to be at either the full strength or light strength nicotine dose. Upon completion of the program six months later, only 23 (52%) participants were still using either the full or light nicotine dose and 16 (36%) had decreased down to placebo (0 mg) level (see Tables 10, 11, and 12).

Table 10

Nicotine Addiction Levels of Participants at Initiation of Program and at Six Months

Categories of RTQ scores (nicotine levels) for all participants N= 44	# of Participants based on RTQ scores at beginning of program	# of Participants based on RTQ scores who did not complete program	# of Participants based on RTQ scores at completion of program (6 months)
Full (16 mg)	22	2	12
Light (12 mg)	21	2	11
Ultra Lights (8 mg)	5	0	5
Placebo (0 mg)	0	0	16
Total	48	4	44

Note. $N = 44$.

Participants who completed the six-month program had either stopped smoking tobacco cigarettes and no longer used other cessation interventions, stopped smoking tobacco but continued to use either e-cigarettes, or a combination of e-cigarettes and medication (see Table 11).

Table 11

Nicotine Levels of Participants Following Completion of Smoking Cessation Program

Nicotine Levels	Beginning of Program	Completion of Program (6 months)
Nicotine levels of participants who quit smoking tobacco and no longer use e-cigs or medication		
Full (16 mg)	7	
Light (12 mg)	4	
Ultra Light (8 mg)	1	
Placebo (0 mg)	2	
Total	**14**	
Nicotine levels of participants who switched to e-cigarettes		
Full	6	4
Light	0	2
Ultra Light	1	1
Placebo	0	0
Total	**7**	**7**
Nicotine levels of participants who were using both tobacco cigarettes and e-cigarettes		
Full	3	2
Light	9	8
Ultra Light	1	3
Placebo	0	0
Total	**13**	**13**

Table 12

Success Rate of Participants Using E-cigarette as Tobacco Cessation Method

Choice of Cessation Method at Beginning of Program	Total	Quit Both Tobacco Cigarettes and E-cigarettes	Switched Completely to E-cigarettes	Still Smoking Same amount of Tobacco Cigarette	Cut Down to < Half	Smoking and E-Cigarette/ Cut Down to < Half of Tobacco Cigarette
E-Cigarette Brand						
BlueCig	5	1	2	0	0	2
SmokeTip	6	3	1	1	0	1
Other	15	6	0	4	1	4
E-Cigarette & Bupropion						
BluCig	2	0	0	0	0	2
SmokeTip	5	1	1	1	0	2
Other	9	1	3	1	2	2
E-Cigarette & Chantix						
Blu Cig	1	1	0	0	0	0
Smoke Tip	1	1	0	0	0	0
Total	**44**	**14**	**7**	**7**	**3**	**13**

The use of e-cigarettes for smoking cessation was determined to be a successful alternative to other NRT. Fourteen participants (32%) quit smoking both tobacco and e-cigarettes and seven (16%) switched to e-cigarettes and were no longer smoking tobacco cigarettes. This indicated a success rate for smoking cessation of 48%f, which was much higher than the national average of only 25% (CDC, 2009). Of the remaining 23 participants, 13 of those (30%) successfully cut down to less than half of their starting tobacco use level with the use of e-cigarettes, thus showing a large decrease in their harm reduction level. Of the 14 participants who quit, 10 used e-cigarettes exclusively, two were also using Bupropion and two were also using Chantix. Of the seven who switched to e-cigarettes, three were only using e-cigarettes and four were using e-cigarettes and

Bupropion. Of the 13 participants who cut down to less than half of starting amount of tobacco cigarettes, seven were only using e-cigarettes and six were using e-cigarettes and Bupropion.

Q5 Was the program cost effective?

Table 13 presents information concerning the cost effectiveness of the smoking cessation program.

Table 13

Cost Effectiveness of the Smoking Cessation Program

Measure	Actual (Possible) Cost	Reimbursement	Notes/Comments
The human resources or time spent collecting "current smoker status" on Kinder Family Clinic patients from Practice Partner EHR.	$22	$0	Done by receptionist ($11/hr x 2 hours)
Time spent on copying and preparing the invitations for mailing.	$33	$0	Done by receptionist ($11/hr x 3 hours)
Cost of mailing the 640 invitations to Kinder Family Clinic patients identified as current smokers.	$288	$0	640 x .45 = $288 **If invitation sent via text, email, or posted on website it would have been free.**
Time spent by the primary investigator gathering educational information.	$200 (**$30**)	$0	Primary Investigator ($50/hr x 4 hours). This would not need to be collected again for continuation of program, and any updates or additions to material could easily and effectively be done by ancillary staff. **Medical Assistant ($15/hr x 2 hours = $30)**
Time and cost of copying the educational data	$22	$0	Done by receptionist ($11/hr x 2 hours)
Time spent by primary investigator with each participant completing survey, providing educational material, e-cigarette information, and smoking cessation counseling.	$800 **($60)**	$2400	48 x $50 = $2400 20 min appointment per participant = 16 hrs total/$150 hr Primary Investigator ($50 hr x 16 hours = $800) **Medical Assistant (Group visit x 4 x $15/hr = $60)** The re-mbursement rate for the office visit for Tobacco Cessation is approximately $50, depending on which commercial insurance. Group visits would be a much more cost effective alternative, and could be done by ancillary staff.

(table continues)

Table 13 Continued

Measure	Actual (Possible) Cost	Reimbursement	Notes/Comments
Time spent by primary investigator performing follow-up phone calls to each participant at two weeks, one month, three months, and six months.	$1600 **($150)**	$0	Primary Investigator ($50 hr x 32 hours = $1600) **Medical Assistant ($15/hr x 10 hours = $150). Time spent on phone calls, and sending and replying to emails, text messages, and website.** Follow-up phone calls could have been done by ancillary staff making it much more affordable, and if alternative methods of follow-up (email, website, text messages) had been an option that would have also make program more cost effective.
Total	$2965 **($605)**	$2400	Although the actual costs showed a loss of $565 on the program, had it been set up differently so that ancillary staff were responsible for most of the participate information, group visits vs individual visits, and alternative means of communication the cost of program implementation would be much lower and would have actually show a profit of $1795 or more.
Projected cost to health care system if they kept smoking	Hard to quantify.	Hard to quantify.	The actual savings to health care system is hard to measure, but could be substantial if the death, disease, and disability related to cigarette smoking were reduced by half what the current statistics show. It would also reduce deaths and disease related to secondhand smoke exposure

The following positive comments and recommendations were made regarding e-cigarette satisfaction, reliability, cost, and improvement to quality of life:

- "Blu Cig is not the same but effective. I quit completely using it."
- "Blu Cig does help alleviate desire to smoke, but still smoking a few regular cigarettes a day."

- "E-cigarettes too heavy, needs to hang from lip more comfortably, but I like the nicotine part and feel like I got my nicotine fix okay."
- "It doesn't compare to the real thing but it helps relieve nicotine cravings really well."
- "It really helps when I can't smoke a regular one and I have cut down to 2-3 regular cigarettes a day."
- "I like the price! It really helped my breathing and diabetes, makes me want to move around more."
- "Definitely takes craving away and helps if you want to quit."
- "I think they work when I use them, but I'm not completely quit, down to 2-3 tobacco cigarettes/day."
- "Taste much better than a cigarette! I like the cinnamon as doesn't remind me of a cigarette, but they are much harder to draw, and heavier than I would like."
- "I decided to just "switch brands" to e-cigarette, still using daily, haven't had a regular cigarette in 3 months and I don't want one."
- "I'm down to less than a pack from 2 pack/day using my e-cigarette. I use it every day and really think I can quit completely using it."
- "I cut down to less than half on tobacco cigarettes using my Blu Cig, still using daily, but I don't like how heavy they are."
- "I think they work well, but I don't like how heavy they are."

Only three negative comments were given by the participants: "I just didn't like them; I don't like the taste or the feel of them," "I hate e-cigs; they don't taste anything like cigarettes," and "Didn't help with craving at all."

Challenges and Unintended Consequences

Specific challenges existed related to the practice setting for this program given the rural nature and patient demographics. Most of the participants had a high school education or less and many worked at blue collar jobs. Evidence showed that this group had the highest rate of smoking and was the group least likely to quit (CDC, 2012). The specific opportunity related to this program was the small population that chose to participate. Most of the individuals who chose to participate in this program were

previously established patients at the health care with a prior established relationship with the primary investigator. This conceivably made them more willing to participate in the program, consider smoking cessation options, or at least be willing to try the e-cigarette as an alternative to tobacco cigarettes.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

Based on the results of this project evaluation, I strongly recommend this program continue in its current setting and be shared with other agencies and institutions. Unfortunately, the participation rate was only 7.5% of the 640 Kinder Family Clinic patients who were identified as current smokers. However, 21 (48%) of the 44 participants either quit or switched to e-cigarettes. While smoking cessation provides the greatest risk reduction, switching to e-cigarettes substantially decreases the risk of tobacco related conditions. Of the remaining 23 participants, 13 had cut down to less than half of their previous smoking level and only seven were still smoking the same amount at the end of the program as when they started. This success rate is double both the national and state averages of 21 and 24%, respectively (CDC, 2009).

This program should also be expanded and extended outside the scope of the Doctor of Nursing Practice program to increase the success rate of Kinder Family Clinic patients for smoking cessation or harm reduction. The focus should include an ongoing evaluation of patients who choose to participate in the program and their continued success rate with cessation or harm reduction should be documented at least annually in their EHR.

Summary of Evaluation Findings and Recommendations

The program evaluation resulted in the following recommendations:

- For future programs within this same setting or in other settings, use a different EHR system or data collection program that can more easily and accurately identify and track data from multiple participants at multiple points.
- Have multiple staff members involved in the education and counseling of participants and the collection of follow-up data.
- For cost effectiveness, have a primary care provider oversee the program and have ancillary staff implement the program.
- Provide multiple methods of contact to participants including phone, in office follow-up, text, email, and website at the initiation of the program and follow-up according to participant preference.
- Find an alternative tool to the TTM for this type of program to encourage increased participation.
- Continue using The Fagerstrom Tolerance Test as a tool to evaluate addiction level and choose appropriate baseline nicotine; this tool was determined to be reliable, applicable, and an effective way of determining baseline nicotine levels.
- Continue use of a baseline participant questionnaire including questions on demographic information, smoking history, previous quit attempts, and cessation methods tried; however, standardize the process so the same questionnaire is provided to all participants at the end of the program. It is

also recommended that information regarding appropriate frequency of follow-up contact, preferred duration of the program, and recommended support material or advice be asked of participants.

- Find alternative educational material on the effects of smoking and benefits of quitting for this type of program; it is not recommended to refer participants to the Colorado Quit Line as they do not support the use of e-cigarettes as a cessation method at this time.
- Continue providing informational material regarding the effectiveness, cost, and potential side effects of different cessation methods as many participants found this information helpful. It is also recommended to continue providing information regarding different brands, nicotine doses, cost, and accessibility of e-cigarettes but to include more information on the cost and accessibility of local options.
- Continue the program in its current setting with the above changes and share this program with any other agency or institution interested in using e-cigarettes as a smoking cessation option or a harm reduction method.

Implications for Practice

I plan to use the results from this study to continue to improve the health of my patients through the use of e-cigarettes as a smoking cessation method or as a "harm reduction" method by switching from tobacco cigarettes to e-cigarettes. I also plan to share the results of this project with other clinicians. The American Association of Public Health Physicians, The Department of Community Health Sciences, The American Council on Science and Health, and The Tobacco Harm Reduction Research

Committee currently support the use of e-cigarettes for use in smoking cessation. I intend to disseminate my results with those entities and others in the hopes of conducting further research on the use of e-cigarettes as a smoking cessation method or as a harm reduction method.

Implications for practice based on the evidence gained from this study could be significant. The e-cigarette completely alleviates the health risks related to second hand smoke and dramatically reduces or alleviates the risks to current smokers by removing the carcinogens found in tobacco cigarettes. E-cigarettes are also much cheaper than tobacco cigarettes. A smoker can slowly reduce the amount of nicotine until they are at a placebo level, thus reducing or alleviating the symptoms of nicotine withdrawal. E-cigarettes provide a new alternative to other NRT options, they are the most like tobacco cigarettes in their delivery form, they are the one of the most affordable NRT options available, and individuals can use them as a smoking cessation option or as a harm reduction method.

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APPENDIX A

SMOKING SURVEY

SMOKING SURVEY

1. Current Smoker _____ Former Smoker (actively trying to quit, has been at least 24 hours since last cigarette)_____

2. Have you tried to quit? Yes____ No_____ How Many Times?_____

3. What have you tried to help you quit? (Check all that apply)
   - Nicotine Patches_____
   - Nicotine Gum _____
   - Nicotine Lozenges _____
   - Nicotine Nasal Spray _____
   - Nicotine Inhaler _____
   - Chantix _____
   - Zyban/Bupropion _____
   - "Cold Turkey"_____
   - Electric Cigarettes _____
   - Other _____

4. What method/methods were most successful in helping you quit? _____

   _____

5. Are you interested in trying to quit again? Yes____ No____

6. Would you be interested in participating in a study evaluating the above cessation options, or would you be interested in switching to an electric cigarette to reduce the health risks of the harmful carcinogens found in tobacco cigarettes? Yes____ No_____

7. Male_____ Female_____ Age_____ Ethnicity: Hispanic___ Non-Hispanic____

   Race: White___ African American___ Native American____ Asian/Pacific Islander___

8. Education Level: (mark highest level)
   - Some High School_____
   - High School Diploma _____
   - Trade School_____
   - Associates Degree _____
   - Bachelor's Degree _____
   - Master's Degree _____
   - Doctorate _____

APPENDIX B

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Identification of Investigators & Purpose of Study

You are being asked to participate in a research study conducted by Jona Ely, FNP-C at Kinder Family Clinic, and Doctor of Nursing Practice student at the University of Northern Colorado. The purpose of this study is to evaluate whether electric cigarettes are an effective smoking cessation alternative. This study will contribute to the researcher's completion of her capstone project and doctoral degree.

Research Procedures

Should you decide to participate in this research study, you will be asked to sign this consent form once all your questions have been answered to your satisfaction. This study consists of a survey and interviews that will be administered to individual participants at Kinder Family Clinic or by phone. You will be asked to provide answers to a series of questions related to your previous and present smoking habits, smoking cessation options, and interest in quitting. You will also be provided information on all currently approved smoking cessation options plus electric cigarettes. If you chose a prescription alternative you will be provided a prescription and recommendations for follow-up. You may also chose to try more than one cessation option at a time as that has been shown to be more effective.

Time Required

Participation in this study will require your participation in an initial evaluation, and a follow-up phone call or office visit (as deemed appropriate related to your health history and needs) at two weeks, one month, three months, six months, and one year.

Risks

The investigator does not perceive more than minimal risks from your involvement in this study. Electric cigarettes have not been shown to have any greater health risks than tobacco cigarettes. However, at this time they are not currently approved as a smoking cessation option and have not been proven to be safe or effective.

Benefits

Potential benefits from participation in this study include complete smoking cessation; or a decrease in health related risks by switching to a safer alternative than tobacco cigarettes; a financial benefit related to decreased cost of e-cigarettes compared to tobacco cigarettes; alleviation of secondhand smoke effects; and convenience of being able to use e-cigarette anywhere.

Confidentiality

The results of this research will be included in the investigator's capstone evaluation and outcomes. The results of this project will be coded in such a way that the respondent's identity will not be attached to the final form of this study. The researcher retains the right to use and publish non-identifiable data. While individual responses are confidential, aggregate data will be presented representing averages or generalizations about the responses as a whole. All data will be stored in a secure location accessible only to the researcher. Upon completion of the study, all information that matches up individual respondents with their answers will remain in the patient's electronic health record at Kinder Family Clinic.

Participation & Withdrawal

Your participation is entirely voluntary. You are free to choose not to participate. Should you choose to participate, you can withdraw at any time without consequences of any kind.

Questions about the Study

If you have questions or concerns during the time of your participation in this study, or after its completion, or you would like to receive a copy of the final aggregate results of this study, please contact:

Jona Ely, FNP-C
Kinder Family Clinic
Phone: (970) 826-0911
Email: kinderfamilyclinic@yahoo.com

Giving of Consent

I have read this consent form and I understand what is being requested of me as a participant in this study. I freely consent to participate. I have been given satisfactory answers to my questions. The investigator provided me with a copy of this form. I certify that I am at least 18 years of age.

_____
Name of Participant (Printed)

_____ _____
Name of Participant (Signed) Date

_____ _____
Name of Researcher (Signed) Date

APPENDIX C

MEASURING CHANGE PROCESSES

MEASURING CHANGE PROCESSES

Forty Core Items Measuring Ten Change Processes With Varimax-Rotated Component Loadings From Two Samples

Item

Consciousness Raising

1 recall articles dealing with the problem of quitting smoking.
I think about information from articles and advertisements on how to stop smoking.
1 recall information people had given me on how to stop smoking.
I recall information people had personally given me on the benefits of quitting smoking.

Self-Liberation

I tell myself can choose to smoke or not.
I tell myself am able to quit smoking if I want to.
I tell myself that if I try hard enough I can keep from smoking.
I make commitments not to smoke.

Dramatic Relief

Warnings about health hazards of smoking move me emotionally.
Dramatic portrayals of the evils of smoking affect me emotionally.
I react emotionally to warnings about smoking cigarettes.
Remembering studies about illnesses caused by smoking upset me.

Environmental Reevaluation

I am considering the belief that people quitting smoking will help to improve the world.
I stop to think that smoking is polluting the environment.
I consider the view that smoking can be harmful to the environment.
I am considering the idea that the world could be a better place without my smoking.

Helping Relationship

Special people in my life accept me the same whether I smoke or not.
I can be open with at least one special person about my experience with smoking.
I have someone who listens when I need to talk about my smoking.
I have someone whom I can count on when I'm having problems with smoking.

Stimulus Control

I remove things from my home that remind me of smoking.
I keep things around my place of work that remind me not to smoke.
I remove things from my place of work that remind me of smoking.
I put things around my home that remind me not to smoke.

Counterconditioning

Instead of smoking, I engage in some physical activity.
I find that doing other things with my hands is a good substitute for smoking.
When I am tempted to smoke, I think about something else.
I do something else instead of smoking when I need to relax or deal with tension.

Social Liberation

I see "No Smoking" signs in public buildings.
I notice that public places have sections set aside for smoking.
I find society changing in ways that make it easier for the nonsmoker.
I notice that nonsmokers are asserting their rights.

Self-Reevaluation

My dependency on cigarettes makes me feel disappointment in myself.
I get upset when I think about my smoking.
I reassess the fact that being content with myself includes changing the smoking habit.
I consciously struggle with the issue that smoking contradicts my view of myself as a caring and responsible person.

Reinforcement Management

I can expect to be rewarded by others if 1 don't smoke.
I am rewarded by others if I don't smoke.
Other people in my daily life try to make me feel good when I don't smoke.
I reward myself when I don't smoke.

APPENDIX D

THE STAGES OF CHANGE MODEL AND CHANGING BEHAVIOR FOR YOUR HEALTH

STAGES OF CHANGE MODEL

Stage in transtheoretical model of change	Patient stage	Incorporating other explanatory/treatment models
Precontemplation	Not thinking about change May be resigned Feeling of no control Denial: does not believe it applies to self Believes consequences are not serious	Locus of Control Health Belief Model Motivational interviewing
Contemplation	Weighing benefits and costs of behavior, proposed change	Health Belief Model Motivational interviewing
Preparation	Experimenting with small changes	Cognitive-behavioral therapy
Action	Taking a definitive action to change	Cognitive-behavioral therapy 12-Step program
Maintenance	Maintaining new behavior over time	Cognitive-behavioral therapy 12-Step program
Relapse	Experiencing normal part of process of change Usually feels demoralized	Motivational interviewing 12-Step program

Information from Prochaska, J.O., DiClemente, C. C., & Norcross, J. C. (1992). In search of how people change. *American Psychology*; *47*, 1102-1104, and Miller, W. R, & Rollnick, S. (1991). *Motivational interviewing: Preparing people to change addictive behavior.* New York: Guilford.

PROCESSES OF CHANGE

Process of change	Description
Consciousness raising	Learning about the problem behavior
Self-reevaluation	Determining how one thinks about oneself with respect to the problem behavior
Self-liberation	Making a commitment to act
Counterconditioning	Substituting alternative behaviors for the problem behavior
Stimulus control	Avoiding the problem behavior
Reinforcement management	Rewarding oneself
Helping relationships	Talking about the problem with people who care
Dramatic relief	Expressing feelings about the problems
Environmental re-evaluation	Environmental support for changing problem behaviors
Social liberation	Evaluating how the problem behavior affects others

(Andersen, 2007)

CHANGING BEHAVIOR FOR YOUR HEALTH

1. On the line below, mark where you are now on this line that measures change in behavior. Are you not prepared to change, already changing or someplace in the middle?

Not prepared to change Already changing

---

2. Answer the questions below that apply to you.

- If your mark is on the left side of the line:
  How will you know when it's time to think about changing?
  What signals will tell you to start thinking about changing?
  What qualities in yourself are important to you?
  What connection is there between those qualities and "not considering a change"?
- If your mark is somewhere in the middle:
  Why did you put your mark there and not further to the left?
  What might make you put your mark a little further to the right?
  What are the good things about the way you're currently trying to change?
  What are the not-so-good things?
  What would be the good result of changing?
  What are the barriers to changing?
- If your mark is on the right side of the line:
  Pick one of the barriers to change and list some things that could help you overcome this barrier.
  Pick one of those things that could help and decide to do it by _____ (write in a specific date).
- If you've taken a serious step in making a change:
  What made you decide on that particular step?
  What has worked in taking this step?
  What helped it work?
  What could help it work even better?
  What else would help?
  Can you break that helpful step down into smaller pieces?
  Pick one of those pieces and decide to do it by _____ (write in a specific date).
- If you're changing and trying to maintain that change:
  Congratulations! What's helping you?
  What else would help?
  What are your high-risk situations?
- If you've "fallen off the wagon":
  What worked for a while?
  Don't kick yourself--long-term change almost always takes a few cycles.
  What did you learn from the experience that will help you when you give it another try?

3. The following are stages people go through in making important changes in their health behaviors. All the stages are important. We learn from each stage.
We go ***from*** "not thinking about it" ***to*** "weighing the pros and cons" ***to*** "making little changes and figuring out how to deal with the
real hard parts" ***to*** "doing it!" ***to*** "making it part of our lives."
Many people "fall off the wagon" and go through all the stages several times before the change really lasts.

The Readiness to Change Ruler can be used with patients contemplating any desirable behavior, such as smoking cessation, losing weight, exercise or substance-abuse cessation.
Information from references 4, 26 and 27. (Zimmerman, Olsen, & Bosworth, 2000)

APPENDIX E

THE REVISED FAGERSTROM TOLERANCE QUESTIONNAIRE

The Revised Tolerance Questionnaire (RTQ)

1. How many cigarettes a day do you smoke? (circle one)

10 or less 11-15 16-20 21-25 26 or more

2. How deeply do you inhale? (circle one)

1	2	3	4	5
I do not Inhale		Moderately		Very Deeply

3. How often do you smoke more in the morning than during the rest of day? (circle one)

1	2	3	4	5
Never		About Half the Time		Always

4. How often do you smoke your first cigarette of the day within 30 minutes of waking? (circle one)

1	2	3	4	5
Never		About Half the Time		Always

5. How difficult would it be for you to give up your usual first cigarette of the day? (circle one)

1	2	3	4	5
Not Difficult		Somewhat Difficult		Extremely Difficult

6. How difficult do you find it to refrain from smoking in places where it is forbidden (e.g., in church, at the library, cinema, etc.)? (circle one)

1	2	3	4	5
Not Difficult		Somewhat Difficult		Extremely Difficult

7. How often do you smoke when you are sick with a cold, the flu, or are so ill that you are in bed most of the day? (circle one)

1	2	3	4	5
Never		About Half the Time		Always

8. On average, about how much of each cigarette do you smoke? (circle one)

1/3 or less ½ 2/3 ¾ ALL

9. On average, how often do you inhale? (circle one)

1	2	3	4	5
Never		About Half the Time		Always

10. On average, how often do you hold cigarette smoke in your lungs for a moment or two before exhaling?

1	2	3	4	5
Never		About Half the Time		Always

Scoring: All items are scored on a 5-point Likert scale. The total RQT score is the mean rating across all 10 items. The higher the score the higher the nicotine addiction level. (Table by Tate and Schmitz, 1993)

APPENDIX F

THE "5 A's" MODEL FOR TREATING TOBACCO USE AND DEPENDENCE

THE “5 A’s” MODEL FOR TREATING TOBACCO USE AND DEPENDENCE

Ask about tobacco use Identify and document tobacco use status of every patient at every visit.

Advise to quit in a clear, strong and personalized manner urge every tobacco user to quit.

Assess For current tobacco user, is the tobacco user willing to make a quit attempt at this time?
For the ex-tobacco user, how recent did you quit and are there any challenges to remaining abstinent?

Assist For the patient willing to make a quit attempt, offer medication and provide or refer for counseling or additional behavioral treatment to help the patient quit.
For patients unwilling to quit at this time, provide motivational interventions designed to increase future quit attempts.
For the recent quitter and any with remaining challenges, provide relapse prevention

Arrange All those receiving the previous A’ s should receive follow-up.

APPENDIX G

SMOKING CESSATION DRUG CLASSIFICATION AND DOSAGE

Pharmacotherapy Treatments: Smoking Cessation Drug Classification and Dosages

Tips to use in tobacco cessation efforts:
Tobacco use is to be approached as a chronic relapsing condition.
If limited on time, Ask, Advise, and Refer to the Colorado QuitLine (1.800.QUIT.NOW).
The average smoker has 4-7 attempts before successful abstinence.
Combination therapy of >1 form of Nicotine Replacement Therapy (NRT) or NRT + Zyban can increase long-term quit rates.

Adverse Side Effects/Treatment Tips
(• = possible side effects)
These are general categories; individual patient reactions may vary.

Precautions
(Ø=contraindicated)
Consult package insert for full list of precautions, contraindications, use in pediatrics, and drug interactions.

	Category	Drugs	Recommended Dosage	Recommended Duration	Relative Cost Index: 1ppd = $$ (av $120/mo)	Jaw pain/mouth or throat soreness; throat/ nasal/ mouth irritation	Dry mouth, xerostomia	Orthostasis possible	Local skin reaction	Insomnia, abnormal or change in dreams	Headache	Gi: nausea, gas, dyspepsia, constipation	Sedation, drowsiness	Recent Myocardial Infarction; severe arrhythmias, unstable angina	Patients with dental problems or TMJ	Patients w/ seizure disorders, bulimia or anorexia nervosa (eating disorders)	Patients with bipolar and schizophrenia; recent MAO use	Suicidal Risk: Black Box Warning	Pregnancy (weigh risk vs. benefit)
First Line	NRT (nicotine replacement therapy)	Nicotine Patch/transdermal (NicoDerm CQ, Habitrol, Nicotrol)	> 10 cigs/day: use 21 mg/24 hrs for 6-8 wks, then 14 mg/24 hrs for 2-4 weeks, then 7mg/24 hrs for 2-4 weeks < 10 cigs/day: use 15 mg/16 hrs for 6 weeks	Up to 10 weeks	OTC $ available from QuitLine with program enrollment				•	•	•	•		Ø					Cat D
		Nicotine Gum (Nicorette)	1-24 cigs/day: 2 mg gum (every 1- 2 hrs up to 24 pieces/day) 25+ cigs/day: 4 mg gum (every 1- 2 hrs up to 24 pieces/day) No food or drink 15 minutes before use	Up to 12 weeks	OTC $$$	•				•		•		Ø	Ø				Cat C
		Nicotine Lozenge (Commit)	2 mg for those who smoke their first cigarette more than 30 min after waking 4 mg for those who smoke their first cigarette within 30 min of waking No food or drink 15 minutes before use	Up to 12 weeks: wks 1- 6: 1 loz/ 1-2 hrs wks 7-9: 1 loz/ 2-4 hrs wk 10-12: 1 foz/ 4-8 hrs	OTC $$	•					•	•		Ø					Cat D
		Nicotine Oral Inhaler (Nicotrol Inhaler)	6-16 cartridges/day; puff each cartidge for up to 20 minutes Each cartridge 4 mg 10 puffs inhaler=1 puff cigarette	Up to 12 weeks, then gradual decrease over 6 - 12 weeks	prescription $$	•					•			Ø					Cat D
		Nicotine Nasal Spray (Nicotrol NS)	8-40 sprays/day: 1 dose = 1 spray/ nostril 1-2 doses/ hr (maximum 5 doses/hr or < 40 doses/day)	Up to 3 - 6 months	prescription $$	•						•		Ø					Cat D
	Medications	Bupropion SR (Zyban)	150 mg/day for 3 days, then 150 mg/day BID from day 4 to end of treatment (begin treatment 1-2 weeks pre-quit)	Up to 12 weeks Maintenance up to 6 months	prescription $$					•	•					Ø	Ø	Ø	Cat C
		Varenicline (Chantix)	0.5 mg/day on days 1-3, 0.5 mg BID on days 4-7, then 1 mg BID from day 8 to end of treatment (begin treatment 7 days pre-quit date)	12 weeks treatment additional 12 weeks to enhance cessation	prescription $$					•	•	•							Cat C
Second Line	Drugs not approved for smoking cessation by the FDA	Clonidine (Catapres)	0.10 mg/day for wk 1, increasing by 0.1 mg/day each week as needed up to .75 mg/day OR patch/week	Up to 10 weeks	prescription $		•	•			•		•	Ø		Ø			Cat C
		Nortriptyline (Aventyl, Pamelor)	25 mg/day for week 1, increasing to 75 -100 mg/day	Up to 12 weeks	prescription $		•	•					•	Ø		Ø	Ø	Ø	Cat C

References:
The Medical Letter Vol 48 Aug 2006
American Family Physician Vol 74, No 2 July 2006
Treating Tobacco Use and Dependence; US Department of Health and Human Services Public Health Service, June 2000
FDA package inserts

For important updates, special clinical considerations, and effectiveness information, visit **www.coloradoguidelines.org/tobacco**

2nd revision: 2/2007
1st revision: 11/2004
Original: 9/2002

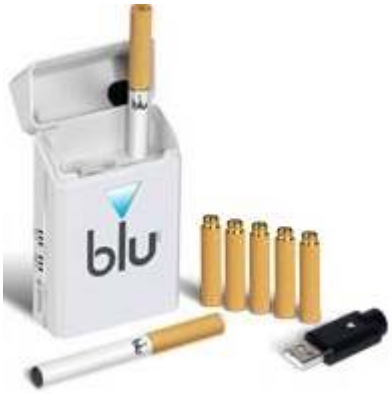
APPENDIX H

BLU CIG ELECTRONIC CIGARETTE

Blu cigs is the hip electronic cigarette brand. All flavors are exclusively made in the USA by Johnson Creek in their FDA registered facility. The new Premium pack adds better functionality, improved performance and additional technology to enhance the social and individuality aspect of electronic smoke. The starter kit price for **blu cigs** is $69.95 - $79.95. We recommend buying a starter kit with 2 batteries or more. This "2 piece" electronic cigarette model comes with atomizer and cartridge combined called cartomizer.
Visit site to buy

Starter Kit Price(s): (*)	$69.95 - $79.95
User Ratings:	Overall (4.15) Battery Life Smoke/Vapor Cust. Service Cost/Value Rating Trend: (up) Based on 270 user reviews.
Leave a Review	
Coupon / Promotion Code:	Currently blu cigs does not offer any general coupon or discount codes like 10% off. Take advantage of our rebate: Get $10 Rebate
Free Shipping:	FREE Shipping Get FREE Shipping
Price per Cartridge	~$2
One Cartridge equates to:	250 puffs
Money Back Guarantee:	30 days
LED Color:	blue
blu cigs Warranty:	1 year

Visit site to buy
FREE Shipping



blu cigs Starter Kit

Blu's smoke juice flavors are made in the USA!

blu cigs Flavors
Tobacco, Menthol, Cherry, Java, Vanilla

Nicotine Levels
Full 16mg, Light 12mg, Ultra Light 8mg, Zero: 0mg

Misc. Info
* Blue tip
* USA Made Smoke Juice
* Pack recharges batteries and holds cartridges.
* Smallest and lightest ecig.

More Info

blu cigs Electronic Cigarette Details

What are Blu Cigs? Blu Cigs are the latest in Electronic smoking. The blu cigarette pack offers the unique ability to charge on the go (blu cig PPC)! Blu Cig is all about giving you the freedom to smoke anywhere without tobacco and tar!

Blu cigs starter kit includes:

* 1 pack to hold 5 cartridges/cartomizers and charges your batteries on the go!
* 2 electronic cigarette batteries
* 1 wall charger & 1 USB charger
* 5-pack of flavor cartridges in the flavor and strength of your choice
* 30 day money back guarantee and a one year warranty

Advanced Features of the Premium Pack

- New, patented Social feature
- No screw charging with battery management system that continually monitors and charges the spare battery
- Easy charge icons located on the side so you can see the battery level and charging progress of the pack and spare battery at any time
- Mini USB for data management and efficient charging

APPENDIX I

SMOKE TIP ELECTRONIC CIGARETTE

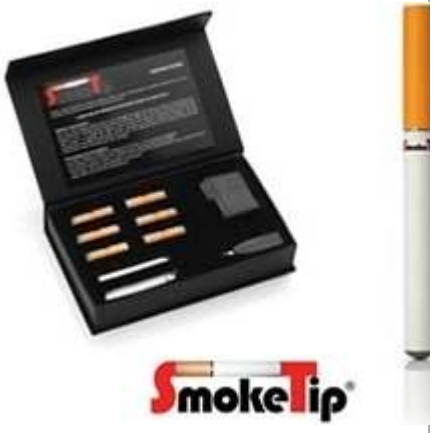
SMOKE TIP ELECTRONIC CIGARETTE

SmokeTip delivers the easiest drag system - almost effortless. Replacement cartridges deliver over 250 puffs per unit. The starter kit price for **SmokeTip** is $59.95. We recommend to buy a starter kit with 2 batteries or more. This "2 piece" electronic cigarette model comes with atomizer and cartridge combined called cartomizer. Visit site to buy

Starter Kit Price(s): (*)	$59.95
User Ratings:	Overall (4.61) Battery Life Smoke/Vapor Cust. Service Cost/Value Rating Trend: (unchanged) Based on 214 user reviews.
Leave a Review	
Coupon / Promotion Code:	10% off purchase: ecig365PLUS Get $10 Rebate
Free Shipping:	FREE Shipping Get FREE Shipping
Price per Cartridge	~$1.59-$1.99
One Cartridge equates to:	1.25 pack
Money Back Guarantee:	30 days
LED Color:	red
SmokeTip Warranty:	100% UNCONDITIONAL LIFETIME WARRANTY

Visit site to buy

FREE Shipping



SmokeTip Starter Kit

SmokeTip Flavors
Regular, Menthol, Mild Menthol, Cowboy, Almond, Apple, Banana, Cherry, Chocolate, Clove, Coffee, Cinnamon, Grape, Orange, Peach, Pineapple, Strawberry, Vanilla, Watermelon

Nicotine Levels
Full Flavor, Light, Ultra Light, No Nicotine

Misc. Info
Great product at low price

More Info

SmokeTip Electronic Cigarette Details

SmokeTip works like traditional cigarette smoking. It delivers the enjoyment of smoking (the touch and taste) without the harmful 2000+ chemicals or problems caused by tobacco smoke. The exciting new SmokeTip product design is the key to making this happen. There is no flame with SmokeTip: the small electronic cigarette includes a rechargeable battery and replaceable cartridges that provide the smoking experience, without tobacco! Inhaling on the SmokeTip gives all the same sensations of smoking. However, the unit releases only simulated smoke (vapor mist), that evaporates in the air.

For any reason, at any time, under any circumstance if your SmokeTip battery stops working you get a free replacement - no gimmicks no hassles! You don't even need a receipt! Please visit SmokeTip's website for details.

APPENDIX J

PRACTICE PARTNER TEMPLATES

Progress Notes

Date Printed: 04/24/12

Name: Mouse, Minnie ID: 14969 SEX:F AGE:36 years

04/24/12 : 10:50am
Tobacco Use Disorder:

Insert BMI from today:

Subjective:

This 36 years old female presents with a history of tobacco abuse:
Years of smoking:
Packs per day:
Type of tobacco use (i.e., cigarettes, cigars, snuff, chewing):
Symptoms of nicotine addiction:
Desire to quit:
Children in the house:
Other household members who smoke:
Family members or friends who desire patient to quit smoking:
Alcohol:
Illicit drugs:

Stage of Change:
Pre-contemplation (no intention of changing behavior)
Contemplation (intends to change or quit behavior in next six months)
Preparation (intends to take change or quit behavior within the next month)
Action (currently changing or quitting behavior)
Maintenance (have changed or quit behavior for at least 6 months)

Fagerstrom Tolerance Score:

Cessation Options:
Nicotine Replacement Therapy:
Chantix
Bupropion
Electric Cigarettes
none

Any medication side effects or adverse reactions?
If so, what?

Review of systems:
Ears, Nose, Mouth, Throat
Cardiovascular
Respiratory
Gastrointestinal

Significant history of:
Hypertension:
Cerebrovascular disease:
Coronary heart disease:
Congestive heart failure:
Hyperlipidemia:
COPD/Asthma:
Peptic Ulcer Disease:
Esophagitis/Gastritis:
Osteoporosis:

Past Medical History:
Seasonal Allergies

SURGERIES: tonsillectomy

Current Medications:

Rx: AMITRIPTYLINE HCL 50MG 1TAB at bedtime - days, 30, Ref: 11
Rx: DILATRATE-SR 40MG 1 TAB twice daily - days, 60, Ref: 11
Rx: DESIPRAMINE HCL 50MG 1 TAB HS - days, 30, Ref: 11
Rx: PAROXETINE HCL 10MG 1 TAB once daily - days, 30, Ref: 11
Rx: COUMADIN 7.5MG 1 TAB once daily - days, 30, Ref: 0
Rx: DILANTIN INFATABS 50MG 1 TAB once daily - days, 30, Ref: 11
Rx: TEGRETOL 200MG 1 TAB four times daily - days, 120, Ref: 11
Rx: AMOXICILLIN-POT CLAVULANATE 600-42.9 MG/5ML 5ML twice daily - days, 0, Ref: 0
Rx: NICOTINE INHALER 4mg 6-16 cartridge/day 90 days, 1, Ref: 2

Social History:
Marital Status: Married
Exercise: yes
Tobacco: no
Recreational Drug Use: none
Alcohol: Social
Caffeine: yes
Occupation: Beautician
Sleep Habits: Trouble falling asleep
Birth control: pill
DNR/Living will: yes
Stressors: family
Pharmacy: K-Mart

Objective:
General:
Nose:
Mouth:
Teeth/Gums:
Pharynx:
Neck:
Heart:
Lungs:
Abdomen:
Extremities:

Assessment:
TOBACCO USE DISORDER : 305.1

Plan:
Laboratory:
XRay:
Diagnostic Tests:

Medication:
Patient informed that nicotine patches were available OTC.
-Place each morning (start on quit date) on a relatively hairless place between the neck and waist
-Switch to different brand if skin irritation occurs
-Remove patch at bedtime to avoid vivid dreams or sleep disturbance

Patient informed that nicotine gum was available OTC. Patient advised to use 8-24 pieces daily to park the gum in the cheek after chewing for a while.

Patient informed that nicotine lozenges were available OTC. Patient advised to use 9-20 lozenges daily and to let them dissolve, and not swallow them.

Patient given Rx for nicotine oral inhaler (Nicotrol) and advised that the usual dose was 6-16 cartridges daily. Advised that the inhaler could cause mild mouth irritation, throat irritation, and cough, and that tolerance to these effects usually occurs within a day.
Nicotine Inhaler: 4mg: : 6-16 cartridge/day: 90: 1: 2

Patient given Rx for nicotine nasal spray (Nicotrol NS) and advised that the usual dose was 2 sprays, 8-40 times daily. Advised that the spray could cause brief stinging and burning of the nasal mucosa, throat irritation, and sneezing/cough, and that these effects usually

Progress Notes **Page: 3**

Date Printed: 04/24/12

Name: Mouse, Minnie ID: 14969 SEX:F AGE:36 years

improve in about a week.
Nicotine Nasal: 0.5mg: 1-2/Nos: Q 1hr PRN: 60: 1: 1

Patient given Rx for varenicline (Chantix) and encouraged to start 1 week before quit date. Start with 0.5 mg Qd x 3 days then increase to 0.5 mg bid for 4 days, then to increase to 1.0 mg bid for the remaining 12 weeks of treatment.
Chantix Starter Pack: : : as directed: 30: 1 pack: 0
Chantix: 1mg : 1 PO : BID: 60: 30: 1

Patient given Rx for bupropion sustained release and encouraged to start 1 week before quit date. Start with 150 mg QAM x 3 days then increase to 150 mg bid.
Bupropion SR: 150mg: 1 PO: BID: 90: 30: 2

E-Cigarette Information:
The patient was informed that there are currently no actual studies regarding the use of e-cigarettes as a smoking cessation option, and that they are not supported by the FDA as a NRT.
The patient was given information regarding the benefits of e-cigarettes including alleviating health risks related to secondhand smoke, available nicotine levels (including placebo), reduction of harm by giving up tobacco cigarettes, option to still have their "vice", and the financial benefits.
Information was provided on BluCig and SmokeTip regarding cost, warranty, availability, and dosing.

Smoking Counseling: V65.4
Health Maintenance: Smoking Counseling X
Patient Education: A strong, clear, personalized message was given to the patient, urging smoking cessation. I encouraged informing friends, family, and coworkers of plans to quit with a request for support. I encouraged the patient to remove all cigarettes from the home, work, and car. We reviewed any previous quit attempts and lessons learned from them. I advised the patient that drinking alcohol or associating with other smokers were associated with failure or a relapse. Patient was informed of cessation options, success rate of options, potential side effects and adverse reactions, and that some patients benefit from combination of cessation options, and that at least 3-6 months of treatment would be needed.

Follow-up:

SIGNED BY JONA ELY, FNP (JK) 04/24/2012 10:58AM
REVISED BY JONA ELY, FNP (JK) 04/24/2012 11:11AM

APPENDIX K

APPROVALS

UNIVERSITY of
NORTHERN COLORADO

Institutional Review Board

DATE:	April 15, 2013
TO:	Jona Ely, MSN, FNP-C, DNP Student
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[431141-3] Evaluation of the Use of Electric Cigarettes in a Rural Smoking Cessation Program
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	April 14, 2013

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

Kinder
Family Clinic

Pamela Kinder, M.D., Neurology
Dennis Kinder, M.D., Internal Medicine
Jona Ely, F.N.P., Family Nurse Practitioner

February 27, 2012

University of Northern Colorado
Greeley, CO

To Whom It May Concern:

This letter is to support Jona Ely's Capstone Project for her Doctor of Nursing Practice Degree. Jona is pursuing a project that will help us better treat tobacco abuse. She is conducting a study to determine whether electric cigarettes are an effective smoking cessation alternative. She is utilizing our medical record system to "track" patients. The outcome will allow us to better determine not only more effective interventions for tobacco abuse, but how well we currently identify and treat these patients; it will also allow our practice to better follow outcome measures.

Kinder Family Clinic supports Ms. Ely's research project, and is happy to provide her the space, time and computer support necessary to accomplish this project. I am hopeful that the project will affect our patient care in a positive manner.

Sincerely,

Pamela R. Kinder, M.D.
Owner, Kinder Family Clinic

Mountain Medical Specialists
P.O. Box 1435 • 595 Russell Street • Craig, Colorado 81626 • (970) 826-0911 Office • (970) 826-0910 Fax

Statement of Mutual Agreement
University of Northern Colorado
DNP Capstone Project
To Evaluate a Rural Smoking Cessation Program that used Electric Cigarettes as a Cessation Method or for Harm Reduction
Jona Ely
April 2012

Kinder Family Clinic is a private physician owned health care clinic in rural Northwest Colorado. The clinic is a family oriented service and provides care to all ages of patients. Most of the individuals in the area have a high school education or less and most work at blue collar jobs. There is evidence to show that this group has the highest rate of smoking and is the group least likely to quit.

The goal of this project is to evaluate an already existing structured smoking cessation program focused on patient assessment, education, and routinely scheduled follow up in a primary care setting. The purpose of this project is to evaluate this programs tools, methods, data, and structure to determine whether it was effective in helping individuals stop smoking or stop using tobacco cigarettes if they are not interested in quitting.

As both a University of Northern Colorado student and an employee of Kinder Family Clinic, the author will have access to confidential records of patients evaluated. Strict confidentiality will be maintained at all times and no patient identifying information will appear in any printed materials produced or communication of any kind. Only information regarding how the evaluation process is conducted, statistical data regarding patient demographics, smoking history, past interventions / treatments used for smoking cessation, and cessation success will appear.

The DNP Capstone Project will include a final report and abstract along with potential publication in an appropriate professional journal and oral presentation. Kinder Family Clinic will retain property rights to any information containing its name. As community member on the Capstone Committee Dr. Pamela Kinder will agree to participate in the review and approval of both the proposal and final version of the project and be present by phone for both defense meetings. Any written and oral communication regarding the project will be done with the permission of University of Northern Colorado representative Dr. Catherine Dingley, Capstone Committee Chair.

Signatures:

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Dr. Catherine Dingley, Capstone Committee Chair

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Dr. Rhonda Squires

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Dr. Pamela Kinder, M. D., Owner of Kinder Family Clinic

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Jona Ely, DNP Candidate