A PRACTICE IMPROVEMENT PROJECT INCORPORATING TOBACCO CESSATION EDUCATION INTO A DOCTOR OF NURSING PRACTICE PROGRAM

A Dissertation
Submitted to the Graduate Faculty
of the
North Dakota State University
of Agriculture and Applied Science

By

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In Partial Fulfillment of the Requirements
for the Degree of
DOCTOR OF NURSING PRACTICE

Major Program:
Nursing

December 2022

Fargo, North Dakota

North Dakota State University
Graduate School

Title

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

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ABSTRACT

Tobacco use is a global epidemic and is one of the largest public health threats the world has faced killing over eight million people annually. Smoking-related illnesses cost the United States $300 billion annually. Unfortunately, only 31% of those attempting to quit smoking in 2015 used evidenced-base cessation treatments. When behavioral and pharmacotherapy are combined, cessation rates increase by 82%. With tobacco use being the leading cause of U.S. preventable death and with 70% of tobacco users visiting a primary care facility annually, it is essential that providers appropriately and accurately address tobacco use and cessation.

This practice improvement project designed tobacco cessation education for implementation into North Dakota State University's (NDSU) Doctor of Nursing Practice (DNP) coursework in a health promotion course for 18 family nurse practitioner students. The online program, Rx for Change: Clinician Assisted Tobacco Cessation, was completed by the DNP students. Rx for Change was designed by Purdue College of Pharmacy to educate clinicians about the negative health effects of tobacco use and enhance providers' knowledge to deliver comprehensive tobacco cessation counseling services. After completion of the modules, the coinvestigator reviewed tobacco use epidemiology, health effects of tobacco, FDA-approved pharmacotherapy for tobacco treatment, North Dakota-specific resources, and coding and billing for tobacco cessation in primary care. Additionally, students participated in interactive patient scenarios and received a tobacco cessation toolkit for providers.

NDSU DNP students' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation was assessed through a pre- and 2.5 months post-education questionnaire. The participants' (a) motivation and confidence in helping people quit

tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation increased dramatically pre- to post-education for all questions with the exception of question one in which case all participants strongly agreed in both the pre- and post-education questionnaire. The results of this practice improvement project will provide direction for tobacco cessation education for future NDSU DNP coursework and for incorporation into other DNP or health professions curriculum.

ACKNOWLEDGMENTS

First and foremost, I wish to thank Dr. Kelly Buettner-Schmidt from the very bottom of my heart for her expertise, encouragement, positivity, and great patience she has provided to me throughout this process. I am grateful beyond words and I know your support is a huge reason this project has been successful and purposeful. I would also like to thank my wonderful committee members: Dr. Mykell Barnacle, Dr. Brody Maack, and Dr. Elizabeth Crisp Crawford. They helped this project to be well-rounded and thorough, and I am thankful for their time, hard work, and expertise. A special thanks to Dr. Mykell Barnacle and Dr. Dean Gross for championing this project and allowing me to implement this into their DNP course at NDSU seamlessly.

I would also like to thank Dr. Karen Hudmon with the Purdue University College of Pharmacy and Kara Backer with the North Dakota Department of Health and Human Services. Their guidance and expertise was indispensable in the fruition of this project.

Last and certainly not least, I would like to thank my family. My husband, Brennan, has been encouraging and understanding with unwavering support of my academic and professional pursuits.

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INTRODUCTION

Background and Significance

Tobacco use is a global epidemic and is one of the largest public health threats the world has faced (World Health Organization, 2021), killing over eight million people annually. Tobacco use is the leading cause of preventable death in the United States (Centers for Disease Control and Prevention [CDC], n.d.a) with about 1 in 5 deaths due to smoking or secondhand smoke. Most people are aware of the harmful effects of tobacco, including cardiovascular disease, lung cancer, and lung disease. However, tobacco use has also been linked to a multitude of diseases including endocrine disorders, rheumatologic disease, eye disease, reproductive disorders, and 12 different types of cancer (U.S. Department of Health and Human Service [USDHHS], 2014). The mortality rate for people who smoke is 3 times higher than those who have never smoked (CDC, n.d.b.). Furthermore, smoking related illnesses cost the United States $300 billion annually. Healthy People 2030 focuses on preventing people from starting to use tobacco as well as helping those who do use tobacco to successfully quit (Office of Disease Prevention and Health Promotion [OODPHP], n.d.). The Healthy People 2030 goal is to reduce the adult tobacco use rates, which includes cigarettes, cigars, e-cigarettes, and smokeless tobacco, from 20.1% to 16.2%.

Fortunately, in 2015, over two-thirds (68%) of the smoking population wanted to stop smoking and, in 2018, 55% of people who smoke attempted to quit (CDC, n.d.b.). Unfortunately, in 2018, only 7.5% of adult smokers successfully quit (Creamer et al., 2019). Quitting was defined as smoking cessation for at least six months among current smokers who smoked for longer than two years and former smokers who quit within the past year. Although 70% of people who smoke visit a primary care provider annually, only 56% of those adults received

advice to quit in 2015 (CDC, n.d.b.; Kruger et al., 2016). It is essential that primary care providers adequately address tobacco use and counsel patients with the best evidence-based cessation strategies.

People use many forms of tobacco including cigarettes, smokeless tobacco, cigars, water-pipes, and electronic nicotine delivery systems (ENDS), such as e-cigarettes. In 2017, 23.4% of North Dakota (N.D.) adults used some form of tobacco (North Dakota Department of Health and Human Services [NDDHHS], 2022). In 2019, 17% of N.D. adults smoked cigarettes, making cigarettes the most common form of tobacco product used by this population, compared to the lower 2019 average of 14% of the U.S. adult population who smoked cigarettes (CDC, 2019; NDDHHS, 2022). The remaining N.D. adult tobacco product use included: smokeless tobacco at 6.6%, cigars at 4.3%, e-cigarettes at 22.1% (NDDHHS, 2022). A concerning, rising epidemic is tobacco use by youth. In 2019, 35.5% of N.D.'s high schoolers, grade 9-12, used some form of tobacco with e-cigarettes being the most common form at 33.1%. In 2019, over half (52.8%), of N.D.'s high schoolers had tried e-cigarettes. In 2019, 4.4% of N.D.'s high schoolers used smokeless tobacco, 5.2% smoked cigars, and 8.3% smoked cigarettes.

Utilizing the primary care delivery system to address tobacco cessation is crucial. Often, providers assess for tobacco use and inform patients of the harmful effects. However, far too few providers provide, or refer patients to, evidence-based tobacco cessation treatments such as pharmacological interventions or behavioral interventions (Rojewski et al., 2019). Therefore, educating providers and future providers on how to address tobacco use and tobacco cessation is essential. Educating current and future providers on the best clinical practice guidelines is needed to increase the number of patients receiving appropriate tobacco cessation treatment. The U.S. Preventative Service Task Force ([USPSTF], 2021) recommends utilizing the 5 A's approach:

Ask about tobacco use, advise to quit, assess willingness to quit, assist in quitting, and arrange a follow-up. The 2020 U.S. Surgeon General's Report on Smoking Cessation referred to the 5 A's as the gold standard for delivering brief cessation tobacco cessation in primary care.

Problem Statement

With tobacco use being the leading cause of preventable death in the U.S and 70% of tobacco users visiting a primary care facility annually, it is essential that providers are able to appropriately and accurately address tobacco use and cessation (CDC, n.d.a; Kruger et al., 2016). Evidence-based tobacco cessation treatments including combined behavioral and pharmacotherapy increase cessation rates by 82% when compared to the usual care and minimal intervention (Patnode et al., 2015). In the United States, 55% of smokers attempted to quit within the last year (CDC, n.d.b.). Unfortunately, only 31.2% of those who tried to quit used evidence-based cessation treatments, and only 7.4% were successful in cessation (Babb et al., 2017). Due to the high volume of tobacco users seeing a primary care provider annually, along with available evidence-based tobacco cessation treatments, having primary care providers who are knowledgeable and skilled in tobacco cessation treatments is essential to curb the tobacco epidemic. Therefore, I proposed a practice improvement project by conducting a quasi-experimental, quantitative study implementing tobacco cessation education into the Doctor of Nursing Practice (DNP) program at North Dakota State University (NDSU)

Purpose

The purpose of this evidence-based practice improvement project was to determine if implementing tobacco cessation education into the coursework of the DNP program at NDSU would improve the participants' knowledge, motivation and confidence in helping people quit

tobacco, and comfort with providing information on about cessation medications, programs and services, and referrals for evidence-based tobacco cessation.

Objectives

1. Identify and modify tobacco cessation education for implementation into NDSU's DNP program by January 31st, 2022.
2. Implement a tobacco cessation module for implementation into NDSU's DNP program by April 30, 2022.
3. Evaluate change in students' knowledge and the effectiveness of the educational session, as evidenced by a) successful completion of three knowledge check questionnaires incorporated into the modules, and b) increased participants' motivation and confidence in helping people quit tobacco and comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation as measured through a pre- and 2 months post-education questionnaire.

THEORETICAL FRAMEWORK AND LITERATURE REVIEW

Chapter 2 includes a list of definitions and a description of the Transtheoretical Model (TTM). The TTM is a model that helps to identify and support the stages of the tobacco cessation decision-making process (Prochaska & DiClemente, 1983). Chapter 2 also includes a review of literature on tobacco cessation in primary care. The review is divided into the following sections: (a) nicotine addiction and withdraw, (b) health benefits of tobacco cessation, (c) current tobacco cessation practice and practice gaps, (d) behavioral interventions and supports for tobacco cessation, (e) 5 A's brief intervention approach, (f) pharmacotherapy for tobacco cessation, and (g) alternative cessation methods. Additionally, there is an overview of the tobacco cessation education program, Rx For Change: Behavioral Counseling and Pharmacotherapy (University of California [U.C.] Regents, n.d.), that was implemented in the NDSU DNP curriculum for this project.

List of Definitions

Tobacco

The Oxford English Dictionary (n.d.c) defines tobacco as "the leaves of the tobacco-plant dried and variously prepared, forming a narcotic and sedative substance widely used for smoking, also for chewing, or in the form of snuff." The World Health Organization (2020) includes cigarettes, waterpipe tobacco, smokeless tobacco, cigars, cigarillos, roll-your-own tobacco, pipe tobacco, bidis, and kreteks as forms of tobacco. Along with these forms of tobacco, this study includes electronic nicotine delivery systems (ENDS) products as tobacco. ENDS products encompass many different terms such as vapes, vaporizers, vape pens, e-cigarettes, or e-pipes (U.S. Food and Drug Administration [FDA], n.d.). The FDA and the CDC recently included all ENDS products as a form of noncombustible tobacco as the nicotine in the product

is derived from tobacco (CDC, n.d.c; FDA, n.d.). American Indians and Alaskan Natives use traditional tobacco for ceremonial or medicinal purposes and tobacco is considered a sacred plant (CDC, 2019). Commercial tobacco is tobacco in which nicotine and other harmful chemicals are added and not used for ceremonial or religious purposes. In this study, tobacco will be referring to commercial tobacco. The operational definition of tobacco for this study is any substance containing nicotine that is smoked, chewed, or vaped that can lead to adverse health outcomes.

Cessation

The Oxford English Dictionary (n.d.a) defines cessation as "discontinuing, stoppage; either permanent or temporary." The term "cessation" is used in the context of quitting of tobacco products. Although complete or final cessation is the goal of tobacco cessation, this can be difficult to measure. The 2020 U.S. Surgeon General's Report on Cessation describes multiple definitions of cessation depending upon different surveys used for adults and youth. The varied surveys assessed past year quit attempts, smoking cessation for one day or longer, or smoking at the time of the survey. This study defines cessation based upon the materials provided by Rx for Change (U.C. Regents, n.d.) and incorporated into this study's education. Therefore, the operational definition of cessation for this study is not using tobacco products in the past six months.

Education

The Oxford English Dictionary (n.d.b) defines education as "the culture or development of personal knowledge or understanding." Operationally, education will be the modules on tobacco cessation incorporated into the NDSU DNP program.

Theoretical Framework

The TTM framework identifies and supports the stages of the decision-making process to create a behavior change, especially a habitual behavior (Prochaska & DiClemente, 1983). Prochaska and DiClemente developed the TMM framework in the 1970s after examining the smoking cessation behaviors of 872 adults. Prochaska and DiClemente determined that people who were able to successfully quit smoking were mentally ready to do so. TMM focuses on the decision-making process of the individual with behavioral change as a continuous, cyclical process instead of a quick, decisive process. The model identifies six predictable stages that individuals move through to adopt a healthy behavior or stop an unhealthy one. TTM stages of change include precontemplation, contemplation, preparation, action, maintenance, and termination (Table 1). Individuals can move successively through these stages or can relapse into a previous stage at any time throughout the change process becoming an iterative effort.

Table 1. Transtheoretical Model of Change

Stage	Description
1. Precontemplation Stage	Patient has no intention to quit tobacco use in near future
2. Contemplation Stage	Patient is contemplating quitting tobacco use.
3. Preparation Stage	Patient intends to quit tobacco use soon.
4. Action Stage	Patient has quit tobacco use.
5. Maintenance Stage	Patient has been tobacco-free for at least six months; the goal is to prevent relapse.

Note. Adapted from "Stages and processes of self-change of smoking: Toward an integrative model of change," by J. Prochaska & C. DiClemente, 1983, *Journal of Consulting and Clinical Psychology 51*(3), 390–395.

Regarding tobacco cessation, it is imperative that a provider is able to identify what TTM stage an individual is in. The provider will then be able to better assist the patient in moving to the next stage and achieving successful cessation. The provider role is discussed below for each

stage of the TTM. A study of diabetic smokers (n = 772) in a primary care facility found significantly higher rates of smoking cessation at 12 months when their care was tailored based upon the TTM stage of the participants (Pérez-Tortosa et al., 2015). The intervention group had 12-month continued cessation rate of 26.1% compared with the control group rate of 17.8%.

In the first stage, precontemplation, an individual is not intending to make any change in their behavior in the next 6 months (Prochaska & DiClemente, 1983). Those who are in the precontemplation stage may be unaware of their behavior as harmful or they could be discouraged by a previous failed cessation attempt (Singer, 2007). A provider must individualize the interventions at precontemplation stage to help the patient accept that their tobacco use is problematic and harmful to themselves and others.

The second stage, contemplation, is a stage in which the individual intends to change their at-risk behavior, tobacco use, within the next 6 months. In the contemplation stage, the individual is aware of the negative effects of their tobacco use, however, they are unwilling to change at that very moment (Prochaska & DiClemente, 1983). The individual places an equal emphasis on both the perceived positive and negative effects of tobacco cessation. For example, the individual will note the positive health benefits of tobacco cessation but is also aware of the irritability that will follow with nicotine withdrawal. A provider can individualize care in the contemplation stage by providing reinforcement of the benefits of tobacco cessation, assist the patient in exploring the patient's perceived barriers to cessation, and explore the patient's perceived negative outcomes of the behavior change (Singer, 2007).

The third stage is preparation. In the preparation stage, the individual plans to make behavior changes that moves them closer to tobacco cessation within the next 30 days (Prochaska & DiClemente, 1983). In the preparation stage, the individual is ready to make a

behavior change in the near future and may have developed some action plans for tobacco cessation. During the preparation stage, a provider can discuss the various evidence-based tobacco cessation support such as behavioral interventions, pharmacotherapy, and quitlines (Singer, 2007).

The fourth stage is the action stage. It is in the action stage where the individual has made behavior changes, such as tobacco cessation, and the patient intends to keep moving forward in tobacco cessation (Prochaska & DiClemente, 1983). When an individual is in the action stage, it is important for a provider to continue to closely monitor and follow-up with the patient. There is high likelihood of tobacco use relapse due to withdrawal symptoms in this stage (Singer, 2007).

The fifth and final TTM stage is the maintenance stage. During the maintenance stage, the individual has remained tobacco free for greater than six months (Prochaska & DiClemente, 1983). In the maintenance stage, the individual is less tempted to relapse and feel more empowered. Providers need to continue to reinforce the health behavior change. (Singer, 2007).

Literature Review

Search Strategy

A health science librarian assisted literature search was conducted from September of 2020 through October of 2021 to review evidence regarding a) tobacco use; b) health effects of tobacco use; and c) recommended treatment guidelines using three databases: Cochrane Database of Systematic Reviews (Cochrane), PubMed, and Cumulative Index to Nursing and Allied Health Literature (CINAHL). Search criteria included all adults, peer-reviewed journals, full-text articles published in the English language, including clinical trials, reviews, systematic reviews, and evidence-based clinical guidelines published between 2015 and 2021. Keywords in the search included “tobacco cessation,” AND “smoking cessation.” AND “primary care,” AND

"education." An additional review of grey literature was conducted including factsheets, government documents, committee reports, and committee guidelines. A handpicked secondary search of references lists was also reviewed for possible inclusion (See Appendix A for a PRISMA flow diagram of the search strategy).

Nicotine Addiction and Withdrawal

To understand tobacco use and cessation, it is essential to understand nicotine's effect on the brain. There are numerous reasons that one decides to use tobacco, but there are three reasons in particular that contribute to continue tobacco use once initiated and that make cessation difficult: tolerance and dependence, withdrawal, and cue-induced craving. (University of North Carolina (UNC) School of Family Medicine, 2019). Nicotine binds to nicotinic acetylcholine receptors (nAChRs) in the brain and once bound, three key neurotransmitters are released: dopamine, serotonin, and norepinephrine. Stimulated nAChRs receptors become desensitized and upregulated which is experienced in the tobacco user as tolerance. Tolerance and increased stimulated nAChRs leads to a large amount of nicotine needed to produce the neurotransmitters. With continued high levels of neurotransmitters, one develops dependence on nicotine. When serum nicotine levels drop, one may experience withdrawal symptoms that include: irritability, anxiety, cravings to use tobacco, difficulty concentrating, increased appetite, restlessness, depressed mood, and insomnia (American Psychiatric Association, 2013). Symptoms of withdraw are primarily related to low levels of the neurotransmitters listed above (UNC School of Family Medicine, 2019). About one half of daily tobacco users experience nicotine withdrawal when they do not use tobacco for 48 hours (Hughes, 2007). Nicotine replacement therapy (NRT) is useful in decreasing the intensity and frequency of nicotine withdrawal symptoms (Hartmann-Boyce et al., 2018). If NRT is not used, withdrawal symptoms typically

resolve within 2 - 3 weeks (UNC School of Family Medicine, 2019). Cue induced cravings occur in tobacco users when one is presented with a signal that one associates with tobacco use. These cues can include the smell of a cigarette, tobacco advertisement, or exposure to an environment associated with tobacco use such as a bar. These cues can trigger a tobacco craving due to a relative decline in dopamine release. These cravings typically last only 3 - 5 minutes. Cue induced cravings can be minimized and managed with pharmacological and psychosocial tools. Varenicline and bupropion are medications used to reduce urges to smoke and NRT can be used to reduce the intensity of the tobacco craving (Cahill et al., 2016; Hartmann-Boyce et al., 2018; Howes et al., 2020). These pharmacological interventions are discussed later.

Health Benefits of Tobacco Cessation

The U.S. Surgeon General's Report on Smoking Cessation (USDHHS, 2020) identified the multitude of health benefits that occur with smoking cessation. The report described the evidence that smoking cessation reduces the risk of a variety of cancers including: lung, laryngeal, esophageal, pancreatic, bladder, stomach, colorectal, liver, cervical, kidney, and acute myeloid leukemia. The report also noted that lung cancer risk decreased steadily after smoking cessation occurs when compared to those who continue to smoke. For those who quit smoking, the risk of lung cancer decreased by approximately 50% after 10 - 15 years when compared to those who continue to smoke. Smoking cessation decreased one's risk of many chronic health conditions including cardiovascular disease, coronary heart disease, chronic respiratory disease. Of note, smoking cessation can decrease stroke risk to that of those who never smoked. The 2020 U.S. Surgeon General's Report on Smoking Cessation also concluded that smoking cessation improved quality of life and reduced mortality overall.

Current Tobacco Cessation Practice and Practice Gaps

Although evidence-based tobacco cessation interventions are available, they have not been widely adapted into practice. In 2018, 55% of adult smokers made a quit attempt, however, only 7.5% of those were successful in tobacco cessation for six to twelve months (CDC, n.d.b; Creamer et al., 2019). In 2015, 56% of adult smokers received advice to quit from a healthcare professional (CDC, n.d.b.; Kruger et al., 2016). Unfortunately, in 2015, only 31.2% of those who tried to quit used evidence-based cessation treatments, with 6.8% reported using counseling, 29% reported using pharmacotherapy, and 4.7% reported using both counseling and pharmacotherapy (Babb et al., 2017). Evidence-based tobacco cessation treatments, including combined behavioral and pharmacotherapy, increase cessation rates by 82% when compared to the usual care and minimal intervention (Patnode et al., 2015). Thus, it is essential that providers follow evidence-based tobacco cessation strategies to treat tobacco use disorder. Unfortunately, the majority of practicing physicians report feeling inadequately trained to assist their patients in smoking cessation (Strayer et al., 2011).

Behavioral Interventions and Supports for Tobacco Cessation

Nicotine use and addiction is complex. Since it truly is a physiologic and psychologic addiction, behavioral interventions assist in reducing or eliminating the nicotine addiction. Nicotine addiction is similar to alcohol addiction in that group therapy, such as alcoholics anonymous for alcohol use disorder, is effective (USPTF, 2021). The US Preventive Service Task Force (USPSTF, 2021) latest recommendations for tobacco cessation included the use of behavioral therapy. The USPSTF noted with high certainty that behavioral interventions for tobacco cessation in adults was effective as a stand-alone therapy as well as when combined with pharmacotherapy.

A systematic review of 65 studies (Stead et al., 2016) found that when behavioral therapy is used in adjunct with pharmacological treatment for tobacco cessation, there is an increased likelihood of quitting by 10 - 20%. Behavioral support that can increase the likelihood of quitting includes provider advice, nurse advice, one-on-one counseling, group counseling, and advice via telephone or "quitlines." The USPSTF (2021) also noted more success in quit rates when behavioral therapy sessions occurred greater than three times and with four more sessions showing the largest effect on quit rates. Behavioral therapy sessions that were typically more than 30 minutes but less than 300 minutes were effective (Stead et al, 2016).

Group-based therapy

A systematic review (Stead et al., 2017) of 66 trials examined the effect group-delivered behavioral interventions had on smoking cessation at least six months after the intervention. Stead et al. compared cessation rates between those who were offered self-help methods on smoking cessation to those who utilized a group behavioral intervention for smoking cessation. The trials showed an increased likelihood of smoking cessation by 50 - 130% when group behavior therapy was used compared to a self-help program. There was also low quality evidenced that there was a slight increase in quit rates in group therapy when compared to brief support from a healthcare professional.

Quitline

Quitlines are an effective telephone-based tobacco cessation resource available in every U.S. state (CDC, n.d.d; USDHHS, 2020). Quitlines are an effective population-based approach that has been shown to increase quit attempts (USDHHS, 2020). Quitlines can provide behavioral and pharmacological support for smoking cessation. A Cochrane systematic review (Matkin et al., 2019) of 104 trials (n = 111,653 participants), found that telephone counseling

increased quit rates in adults. The trials that included smokers who contacted the quitlines themselves and received multiple sessions of proactive counseling yielded cessation rates 1.38 times higher than those provided with self-help materials or brief counseling. In the trials that included those that did not call a quitline, but rather, received a telephone call from the quitlines, cessation rates were 1.35 higher than those who did not receive the telephone counseling. Since primary care providers typically have 18 minutes per visit, quitlines are a cost effective and evidence-based strategy to assist in tobacco cessation (USDHHS, 2020).

NDQuits Cessation

North Dakota's quitline, NDQuits, began in 2004. NDQuits is a phone and web program providing free tobacco treatment counseling to N.D. residents (North Dakota Department of Health [NDDoH], 2021). NDQuits also provides NRT including patches, gum, or lozenges to those who qualify as uninsured or underinsured. Tobacco use in N.D. is higher in rural areas, with 49.5% of ND's population considered rural. In person tobacco cessation services are more challenging to access in a rural community, making NDQuits a vital resource (K. Backer, personal communication, September 23, 2021). Of the 434 survey respondents who enrolled in NDQuits, after 7 months, 31% had not used tobacco in the last month (NDDoH, 2021). Additionally, 84% of the respondents had quit tobacco for at least one day. In addition to helping fund NDQuits, the North Dakota Department of Health and Human Services (NDDHHS) provides funding for healthcare systems to implement tobacco cessation programs (K. Backer, personal communication, September 23, 2021). The funding allows for the following:

1. Training staff as tobacco treatment specialists (TTS) and continuing education to maintain certification. Trained staff build and implement tobacco treatment protocols for the health system.

2. All seven FDA-approved tobacco cessation medications for patients willing to make a quit attempt and engage in cessation counseling (NDQuits). Patients must be on both a long-acting and short-acting medication.
3. Electronic health record enhancements to drive workflow – tobacco use screening, tobacco treatment documentation, and data extraction.
4. Efficient referral to NDQuits via the EHR (e-Referral).

5 A's: A Brief Intervention

The 5 A's is a useful tool for guiding and evaluating a behavior change. It was originally developed by the National Cancer Institute to assist physicians in facilitating smoking cessation (Strayer et al., 2011). The 5 A's has since been used for a multitude of behavioral change practices including lifestyle modification and alcohol misuses. The 5 A's is intended to help providers provide brief and effective tobacco cessation treatment. Use of the 5 A's yields higher motivation for smokers to quit (Quin et al., 2009). The 5 A's approach should take no more than three to five minutes of a 20-minute visit (Pollak, et al., 2016; WHO, 2014).

The 5 A's tobacco cessation include five distinct steps for facilitating tobacco cessation in primary care (USPSTF, 2021). The five steps include *Ask, Advise, Assess, Assist, and Arrange* (Table 2). The 2020 U.S. Surgeon General's Report on Smoking Cessation referred to the 5 A's as the gold standard for delivering brief cessation tobacco cessation in primary care. A systematic review of 49 trials (Lancaster & Stead, 2017) including approximately 19,000 participants, concluded that individualized counseling, including the 5 A's, led to improved tobacco cessation rates. The authors concluded that cessation rates were improved between 40% and 60% with the use of the 5 A's. Patients who receive all 5 A's throughout their visit instead of just one or none, had an increase in receipt of counseling including individual, group, or

telephone quitline counseling (Kruger et al., 2016). The 5 A's is beneficial in that it helps to individualize tobacco treatment. Emphasis is placed on the importance of determining a patient's level of interest in tobacco cessation which helps to tailor the assistance provided as well as the follow-up (USDHHS, 2020).

The 5 A's is used in the Rx for Change program (U.C. Regents, n.d.) and fits the aim of this project. After completion of the program, participants should have the tools and knowledge to help facilitate tobacco cessation through pharmacotherapy, support groups, quitlines, and behavioral management. For this reason, I chose the 5 A's instead of the other abbreviated approach called AAR: *Ask, Advise, Refer*. While the *Ask, Advise, Refer* approach is successful, it tends to be more of a unilateral conversation and is a great starting point if time and proper tobacco cessation training is lacking (USDHHS, 2020). Moreover, the 5 A's involves the patient in shared decision making with the addition of the following A's: Assess, Assist, Arrange. Shared decision making is crucial in tobacco cessation because it individualizes care by involving a provider's knowledge and expertise with the patient's values and preferences. The *Ask, Advise, Refer* approach is one of the recommended approaches in the newest USPSTF (2020) tobacco cessation guidelines and can be used as a handoff to another provider with tobacco treatment knowledge (K. Backer, personal communication, September 23, 2021).

Table 2. The 5 A's

A	Action
Ask	Discuss the importance of asking every patient about their tobacco use at every visit
Advise	Discuss how providers should advise patients to quit in a clear, strong, and personalized manner.
Assess	Discuss how providers can assess one's willingness to make a quit attempt.
Assist	Discuss how providers should assist all patients interested in quitting with prescription evidence-based pharmaceutical aids, referrals to support groups, telephone quit-lines, and behavioral management, as well as encourage social support.
Arrange	Discuss with providers to schedule a follow-up visit or phone call within the first week after a quit date.

Note. Adapted from Toolkit for delivering the 5 A's and 5 R's brief tobacco interventions in primary care. World Health Organization. (2014).

Barriers to the 5 A's approach

While there is robust evidence about the effectiveness of brief tobacco cessation counseling, providers have not consistently addressed tobacco use in their patients (Babb et al., 2017). Perceived barriers to incorporating the 5 A's approach for tobacco cessation include, but are not limited to, perceived lack of time, lack of knowledge on how to assist in tobacco cessation, concern about stigmatizing patients, inadequate institutional support, and confusing insurance cessation coverage (USDHHS, 2020). It was found that patients who smoke trust and respect providers more when they address their tobacco use and are more satisfied when the provider discusses cessation (Holla et al., 2018). Even brief advice (<3 minutes) has shown to

improve cessation rates and is highly cost effective (USDHHS, 2020). To further assist in the perceived time constraint, certain aspects of the 5 A's approach can be delegated to members of the healthcare team besides the provider. This lessens provider burden while still emphasizing cessation to the patient.

Reimbursement Barrier

The Affordable Care Act (ACA) requires insurers to cover tobacco treatment use and dependence (Kaiser Family Foundation, 2015). The ACA requires insurers to cover services that fall under grade A or B recommendations by the USPTF and both tobacco treatment counseling and medication meet these requirements. Since reimbursement for tobacco treatment can be seen as a barrier to providers, it is important to know how to code services to be appropriately compensated. Preventative counseling current procedural terminology (CPT) codes 99406 and 99407 is for counseling lasting between 3 - 10 minutes or greater than 10 minutes, respectively. A diagnostic code of nicotine dependence, F17.20, must also be included in the billing. The preventative counseling codes, 99406 and 99407, can be billed along with an evaluation and management (E/M) code such as 99213 and 99214.

Pharmacotherapy for Tobacco Cessation

The FDA approved seven pharmacotherapy products to aid tobacco cessation, including two non-nicotine medications, varenicline and sustained release bupropion, and five nicotine containing products for nicotine replacement therapy (NRT). The USPSTF (2021) recommends these same medications for tobacco cessation. These medications are discussed next. A full pharmacologic product guide for smoking cessation, that includes product dose, precautions, adverse effects, advantages, disadvantages, as well as the average cost of the product, is in Appendix B.

Varenicline

Varenicline is an FDA-approved cessation medication that reduces the nicotine withdrawal symptoms while also reducing the rewarding effects that lead to nicotine dependence (Rigotti et al., 2021). Varenicline binds to the alpha-4 beta-2 nicotinic receptors in the brain and acts a partial agonist. When it is bound to the nicotinic receptor, nicotine from tobacco products is unable to bind, thus making tobacco use less rewarding. Furthermore, since varenicline is a partial agonist to the nicotinic receptor, withdrawal and craving symptoms are reduced. A Cochrane systematic review (Cahill et al., 2016) assessed varenicline's effectiveness and also compared varenicline to other FDA-approved cessation medications and identified 26 studies comparing cessation rates in those who received Varenicline with those who received placebo. Those who received varenicline were 2.24 times more likely to quit smoking. Cahill et al. also identified five studies comparing varenicline to bupropion, concluding that cessation rates were 1.39 times higher in those that used varenicline. Bupropion is discussed separately later in this section. Cahill et al. identified eight trials comparing varenicline to nicotine replacement therapy (NRT), cessation rates were 1.25 higher for people who used varenicline.

The standard varenicline dosing is 0.5 mg once daily for three days, 0.5 mg twice daily for four days, and 1 mg twice daily for the remainder of the treatment (Lexicomp, n.d.c). Duration of treatment is 12 weeks and consideration may be given to extending treatment up to a year. Cahill et al. (2016) assessed four studies comparing a low dose varenicline to placebo. Low dose varenicline was a maintenance dose of 1 mg daily, either taken once or split into two divided doses of 0.5 mg. Cahill et al. concluded that cessation rates while taking low dose varenicline was still over twice as effective as the placebo. Those who were taking low dose varenicline had cessation rates 2.08 times higher than the placebo group. Low dose varenicline

may help to reduce the most common side effects that are associated with the usual varenicline dose. The most common side effects that occur in >10% of those taking varenicline include nausea, vomiting, abnormal dreams, depressed mood, headache, insomnia, and irritability (Lexicomp, n.d.c).

Bupropion

Bupropion sustained release is another FDA-approved tobacco cessation aid. Bupropion is an antidepressant medication and, like most antidepressants, the mechanism of action is not well understood (Lexicomp, n.d.a). It is a norepinephrine-dopamine reuptake inhibitor. It is thought that bupropion helps aid in tobacco cessation by blocking the effects of nicotine, alleviating withdrawal symptoms, and reducing a depressed mood (Howes et al., 2020). A Cochrane systematic review (Howes et al., 2020) of 46 studies found that that when bupropion is used as a standalone cessation therapy, cessation rates were 1.64 times greater compared to placebo. The standard dose of bupropion for tobacco cessation is 150 mg for the first three days and then 150 mg twice daily for the remainder of treatment (Lexicomp, n.d.a). The duration of treatment is 12 weeks, and this may be extended an additional 12 weeks if needed. Current recommendations are to prescribe bupropion one week prior to the target quit day, as it takes five to seven days to reach steady serum levels (Rigotti et al., 2021). Bupropion can continue as maintenance therapy for up to a year if needed (Lexicomp, n.d.a). Conversely, if no cessation progress is made within seven weeks of starting bupropion, success is unlikely, and it can be discontinued. Bupropion is contraindicated in those with a seizure disorder as it lowers the seizure threshold.

A systematic review (Howes et al., 2020) also assessed three studies comparing combining bupropion and varenicline for smoking cessation Varenicline was discussed

previously. Howes et al. concluded that the combination of medications does not improve cessation rates when compared to varenicline alone. Howes et al. also reviewed combining bupropion with NRT and compared it to NRT alone for tobacco cessation, concluding that combing NRT and bupropion did not improve cessation rates when compared to NRT alone. However, pooled analysis of 4 studies (n = 1991) found that combing NRT and bupropion led to cessation rates that were 1.24 times greater than when bupropion was used as standalone therapy (Sui, 2015). Therefore, it would be appropriate to add NRT to bupropion therapy. NRT is discussed separately later in this section.

Nicotine Replacement Therapy

NRT is a group of FDA-approved medications that comes in five forms that include a nicotine patch, gum, lozenge, inhaler, and nasal spray (USDHHS, 2020). The first three, nicotine patch, gum, and lozenge, are over-the-counter forms while the latter two, inhaler and nasal spray, require a prescription. NRT is formulated for absorption into the blood stream through the oral mucosa, nasal mucosa, or the dermis to avoid gastrointestinal adverse effects. Nicotine replacement therapy helps to treat the physical tobacco addiction by temporarily replacing the nicotine usually received from tobacco products and helps avoid the toxic components that are associated with combustion and other additives in tobacco products. NRT produces serum nicotine levels that are lower than the serum nicotine level associated with a traditional cigarette. Also, the serum nicotine level does not peak as quickly with NRT when compared to traditional cigarette use. Thus, NRT helps aid in reducing withdraw symptoms and control urges to help aid in tobacco cessation. A Cochrane systematic review (Hartmann-Boyce et al., 2018) of 136 studies found with high certainty that using any form of NRT increased one's likelihood of

tobacco cessation by 50% to 60% when compared to placebo or a non-NRT control group. NRT comes in a long-acting form as well as a fast-acting form and is discussed next.

Long-acting nicotine replacement therapy

The nicotine transdermal patch is the only long-acting form of nicotine replacement therapy currently available, providing a fairly continuous serum nicotine level (Rigotti et al., 2021). This continuous nicotine dose helps to provide consistent relief from withdraw symptoms for over 24 hours. The nicotine transdermal patch is easy to use and has a high level of compliance. Nicotine patch doses range from 5 mg to 52.5 mg delivered over 24 hours (Lindson et al., 2019). The dose is dependent on how much tobacco is consumed throughout a day, such as cigarettes per day. Standard transdermal nicotine patches come in 7 mg, 14 mg, and 21 mg dosages that are delivered over a 24-hour period (Lexicomp, n.d.b). If one smokes greater than ten cigarettes per day, it is recommended to begin with 21 mg/day for six weeks, 14 mg/day for the following two weeks, and 7 mg/day for the last two weeks. For those who smoke less than 10 cigarettes a day, it is recommended to use 14 mg/day for six weeks and 7 mg/day for two weeks. Adjustments to these doses may be required during initial therapy. If one is experiencing increased nicotine withdrawal symptoms, the dose may need to be increased and a lower dose may be needed, if side effects are experiences. Extension of therapy may be indicated if cessation progress has been made but it not yet successful. Cessation rates are higher for those that use nicotine transdermal patches for an extended period time of 24 weeks when compared to those who use the patch for eight weeks (Rigotti et al., 2021).

Short-acting nicotine replacement therapy

The FDA-approved short acting nicotine replacement therapy include nicotine lozenges, gum, inhaler, and nasal spray (Rigotti et al., 2021). Short-acting nicotine NRT can be used

throughout the day to help one manage cravings and urges. Nicotine nasal spray takes about ten minutes to reach peak serum nicotine levels while the other short-acting NRT forms take about 30 minutes to reach peak serum nicotine levels. However, even the nicotine nasal spray does not deliver nicotine as quickly as smoking a cigarette. Nicotine gum and lozenges are dosed similar. If one has a cigarette within 30 minutes of waking up, then 4 mg gum or lozenge is appropriate (Lexicomp, n.d.b). If one has a cigarette greater than 30 minutes after awakening, then 2 mg gum or lozenge is used. NRT treatment is typically 12 weeks, with extensions if cessation is not complete. See Appendix B for further dosing information on nicotine gum, lozenges, spray, and inhaler.

Combination nicotine replacement therapy

A Cochrane systematic review (Lindson et al., 2019) of 63 studies comparing combining a long-acting NRT (patch) with short-acting NRT (gum, lozenge, inhaler, or nasal spray) with use of a single NRT method, found with high certainty that when combination NRT is used, smoking cessation was 15% to 36% more likely to be successful. Lindson et al. also found using higher doses of short-acting NRT and higher doses of long-acting NRT resulted in higher cessation rates. More specifically, there were higher cessation rates with use of a 21 mg nicotine transdermal patches compared to a 14 mg patch. Additionally, increased cessation rates were observed when using 4 mg nicotine gum compared to a 2 mg nicotine gum dose. Combination NRT works to help consistently curb tobacco withdrawal symptoms with a nicotine patch as well as aid in reducing cravings and urges to use tobacco with a short-acting NRT.

Cost of pharmacotherapy

Over the counter (OTC) NRT medications are typically not covered by insurance companies with the exception of Medicaid (UNC School of Family Medicine, 2019).

Approximate NRT gum/lozenge use is 5-20 pieces/day, with an average of 10 pieces/day. The average cost for 10 pieces/day for 12 weeks equals $33 - $43. For a nicotine inhaler, the average cost for 12-weeks' is $2,024. Medicare usually requires prior authorization to pay for a nicotine inhaler. Prescription tobacco cessation medications, bupropion and varenicline are covered by insurance. Insurance premiums for bupropion range from approximately $18 - $163 for 100 tablets of 150 mg. Insurance premiums for varenicline range from approximately $18 - $163 for a 30-day supply of 1 mg tablets.

Alternative Cessation Methods

Many people may try alternative tobacco cessation methods that are not FDA-approved pharmacotherapy and not recommended by the USPSTF 2020 guidelines discussed in the section prior. Alternative methods include, but are not limited to, e-cigarettes, hypnotherapy, cold turkey, acupressure, and acupuncture. The next sections discuss the efficacy of these alternative cessation methods.

E-cigarettes

In 2021, in the United States, 11.3% of high school students and 2.8% of middle school student used e-cigarettes, and in 2019, 4.5% of U.S. adults used e-cigarettes daily (CDC, n.d.c.). Of the current e-cigarette users, 43% high school students and 17% of middle school students used e-cigarettes more than 20 of the last 30 days. Adults commonly used e-cigarettes for smoking cessation. However, e-cigarettes are currently not an FDA-approved smoking cessation aid (FDA, n.d.). The use of e-cigarettes as a cessation method is currently a complex, controversial, and ongoing topic. Both the current USPSTF (2021) guidelines and the 2020 U.S. Surgeon General's Report on Smoking Cessation do not recommend the use of e-cigarettes for smoking cessation. Due to lack of regulation, and the uncertainty of the long-term effects of e-

cigarettes, there are currently no clinical practice guidelines that recommend e-cigarette use for smoking cessation (Buettner-Schmidt et al, 2021). However, a Cochrane systematic review (Hartmann-Boyce et al., 2021) of 61 studies (n = 16,759 participants) assessed e-cigarette use in smoking cessation. It showed moderate-certainty evidence that cessation rates were 1.53 times greater in those who were randomly assigned to nicotine-containing e-cigarettes compared to those who were randomized to NRT. There was also moderate certainty evidence that cessation rates were 1.94 times greater in those who were assigned to nicotine-containing e-cigarettes compared to those assigned to non-nicotine e-cigarettes. While e-cigarettes may be a safer alternative to combustible cigarettes, they are still a nicotine-containing tobacco product with significant health risks (Buettner-Schmidt et al.,2021; Truth Initiative, 2017; USDHHS, 2020). Some argue that since e-cigarettes may be less harmful, they should be an acceptable alternative to traditional combustible cigarettes (Truth Initiative, 2017). Others argue the ENDS harms are not yet fully known. Also, e-cigarettes still contain nicotine which further aids in one's nicotine addiction. Moreover, e-cigarettes have been notoriously marketed to youth (Truth Initiative, 2017; USDHHS, 2020). Although, e-cigarettes may be less harmful than combustible cigarettes, e-cigarettes are marketed to new users, youth. As described previously, youth e-cigarette use rates are high and the USPSTF (2021) does not recommend the use of e-cigarettes for tobacco cessation, including pregnant persons.

Of adults who smoke e-cigarettes, 36.9% also smoke combustible cigarettes and are known as dual users (CDC, n.d.c). Goniewicz et al.'s (2018) study of 5,105 participants assessed serum levels of biomarkers of exposure to tobacco-related toxicants in e-cigarette users and compared them to those who used combustible cigarettes, dual users, and never tobacco users.

Goniewicz et al. found that dual users had the highest levels of tobacco related toxicants, followed by combustible cigarette users. This provides evidence of the dangers of dual use.

Cold Turkey

The "cold turkey" approach to cessation is when one quits abruptly with no treatments or interventions. Due to the nature of nicotine addiction, the six-month cessation rate for those who attempt to quit cold turkey is 3% - 5% (Truth Initiative, 2017). Quitting without any FDA-approved medications makes one more likely to experience withdrawal symptoms. Tobacco users smoking more than a half pack of cigarettes/day are less likely to quit smoking cold turkey.

Acupuncture

Acupuncture is a technique promoted to assist in smoking cessation by reducing nicotine withdrawal symptoms. A Cochrane systematic review (White et al., 2014) of 38 studies compared acupuncture to a variety of different interventions for smoking cessation. The overall quality of evidence was moderate, and it was found that acupuncture for smoking cessation is less effective than NRT and less effective than counseling. Additionally, acupuncture is not an FDA approved cessation method.

Hypnotherapy

Hypnotherapy is a widely promoted smoking cessation method intended to weaken the desire to smoke. A Cochrane systematic review (Barnes et al., 2019) of 14 studies (n = 1926 participants) compared hypnotherapy with 22 different control interventions, the authors concluded that there was no reliable evidence that hypnotherapy yielded higher cessation rates than other interventions of no treatment for smoking cessation. Of note, the USPSTF Guidelines (2021) do not recommend hypnotherapy for smoking cessation and hypnotherapy is not an FDA-approved method for smoking cessation

Rx for Change

Rx for Change: Clinician Assisted Tobacco Cessation (Rx for Change) is a program designed by Purdue College of Pharmacy created to educate clinicians about the negative health effects of tobacco use and enhance providers knowledge to deliver comprehensive tobacco cessations counseling services (U.C. Regents, n.d.). The Rx for Change program drew heavily from USDHHS's Clinical Practice Guidelines for Treating Tobacco Use and Dependence (2008) and is intended for use by healthcare providers, nurses, and pharmacists. The U.S. Surgeon General helped create and promotes the USPHS-Rx for Change program (USDHHS, 2008). Rx for Change includes evidence-based pharmacotherapy guidelines and behavioral interventions. Rx for Change has modules for specialties including but not limited to primary care, pharmacy, behavioral health, and cardiology. The module chosen for this project is titled Rx for Change: Behavioral Counseling and Pharmacotherapy, this module's objectives are listed next:

1. List five health risks associated with chronic tobacco use.
2. Understand the 5 A's for promoting tobacco cessation among patients: Ask, Advise, Assess, Assist, and Arrange.
3. Counsel a tobacco user on the proper use of the all first-line pharmacologic agents (including dosing, instructions on use, potential side effects, and precautions).

Rx for Change is free of charge, easily accessible, updated frequently to include evidence-based practices, and has undergone external review from key experts in the field, it is an advantageous and practical program to implement (U.C. Regents, n.d.). Because Rx for Change will be incorporated into the NDSU DNP Program as part of this dissertation project, the content in the Rx for Change: Behavioral Counseling and Pharmacotherapy program is fully described in the methods section of this paper.

METHODS

Overall Project Design

The design of this evidence-based practice improvement project was a quasi-experimental, quantitative, educational intervention with pre- and post-education questionnaires. Using the best evidence available, this project educated future NDSU DNP providers on effective and evidence-based tobacco cessation treatment and counseling. The purposes and objectives of this project are included in Chapter One.

Implementation Plan

Evidence-based Practice Model and Logic Model

The evidence-based practice model guiding this project was the Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care (Appendix C; Iowa Model Collaborative, 2017). The Iowa model helps facilitate implementation of evidence-based practice into real-life practice. The Iowa model uses feedback loops to analyze, evaluate, and modify the implementation of evidence-based practice in healthcare. I chose this model because of the step-by-step process it provides for putting evidence-based guidelines into practice. These steps include identifying an issue, stating the purpose, forming a team, synthesizing a body of evidence, designing the practice change, sustaining the practice change, and disseminating the results. The Iowa model allowed for a feedback loop at any point in the process to reevaluate the process. See Appendix C for a visual representation of the Iowa model. Permission to use the model was obtained from the University of Iowa Hospitals and Clinics (Appendix D).

The initial step of the Iowa Model (Iowa Model Collaborative, 2017) is the identification of the problem or triggers for an organization. Most providers feel inadequately trained to assist their patients in smoking cessation and only 57% of adult smokers receive advice from their

provider to quit smoking (Creamer et al., 2019; Strayer et al., 2011). Only 31% of those who tried to quit smoking in 2015 used evidence-based cessation treatments and when behavioral and pharmacotherapy is combined, cessation rates increase by 82% (Babb et al., 2017; Patnode et al., 2015). The NDSU DNP program educates future family nurse practitioners and there was not formal tobacco cessation content in the coursework.

The next step in the Iowa model is to determine if the topic is a priority for the organization (Iowa Model Collaborative, 2017). If the topic is a priority, the project is more likely to obtain resources and be successful. To assess if this project would be a priority, the coinvestigator discussed with Dr. Mykell Barnacle, NDSU DNP associate professor of practice, the importance of providers learning about tobacco cessation treatment and counseling to better serve patients. Dr. Barnacle volunteered the class she teaches, Nurs 810 Health Promotion, to include the tobacco cessation content. The dissertation chair of this project, Dr. Kelly Buettner-Schmidt, also expressed enthusiasm for incorporating tobacco cessation education into the NDSU DNP coursework.

After tobacco cessation treatment education was deemed a priority by the faculty of the NDSU DNP program, the next step was to form a team of stakeholders to help develop, evaluate, and implement the practice change (Iowa Model Collaborative, 2017). The project team, who also are the dissertation committee, includes:

1. The coinvestigator who is a NDSU DNP student- Jillian Doan.
2. The dissertation committee chair, and primary investigator, who is a NDSU professor of nursing with an extensive background in tobacco cessation research - Kelly Buettner-Schmidt, PhD, RN.
3. A NDSU assistant professor of practice in nursing- Dr. Mykell Barnacle, DNP.

4. A NDSU associate professor and vice chair of pharmacy practice and a certified tobacco treatment specialist - Brody Maack, PharmD, CTTS.
5. A NDSU associate professor in NDSU's Communications Department with expertise in tobacco prevention - Dr. Elizabeth Crisp Crawford.

Dr. Mykell Barnacle was crucial for the implementing this project into the DNP coursework during her Nurs 810 Health Promotion coursework and Dr. Brody Maack was crucial in the development and critique of the tobacco cessation education. The coinvestigator also worked closely with an associate professor of pharmacy practice at Purdue University, Dr. Karen Hudmon, who helped to create the Rx for Change online modules and is a certified tobacco treatment specialist.

The next step in the Iowa Model is to assemble, appraise, and synthesize a body of evidence (Iowa Model Collaborative, 2017). Cochrane Database of Systematic Reviews, PubMed, CINAHL, grey literature, and government documents were used to conduct a literature review. Search strategy, inclusion criteria, and exclusion criteria are discussed in Chapter Two and the PRISMA flow diagram is in Appendix A.

The next step in the Iowa Model is to design and pilot the proposed change in practice (Iowa Model Collaborative, 2017). With the committee's guidance, the coinvestigator developed the project to incorporate tobacco cessation education into the NDSU DNP coursework. Following the project proposal and subsequent IRB approval, this coinvestigator implemented tobacco cessation education into the NDSU DNP coursework for the graduating class of 2024. Data was collected and analyzed and the results written. It is anticipated that the tobacco cessation education will be incorporated into the NDSU DNP coursework in future years.

Following implementation, continued evaluation is needed to identify any gaps in information or new information that needs to be included.

Lastly, dissemination of results is needed for professional learning and is the final step of the Iowa Model (Iowa Collaborative, 2017). The results will be shared during the defense of this project with the dissertation committee. Dissemination will also include a poster presentation at NDSU in 2023 and will be published in the NDSU ProQuest Dissertations & Theses Global. Consideration will be given to publishing the project in a peer-reviewed journal.

Figure 1. Logic Model

NAME OF PROGRAM/PROJECT:
A Practice Improvement Project Incorporating Tobacco Cessation Education into a Doctor of Nursing Practice Program

OBJECTIVES:

1. Identify and modify tobacco cessation education for implementation into NDSU's DNP program by January 31, 2022.
2. Implement a tobacco cessation module for implementation into NDSU's DNP program by April 30, 2022.
3. Evaluate change in students' knowledge and the effectiveness of the educational session, as evidenced by a) successful completion of three knowledge check questionnaires incorporated into the modules, and b) increased participants' motivation and confidence in helping people quit tobacco and comfort with providing information on about cessation medications, programs and services, and referrals for evidence-based tobacco cessation as measured through a pre- and 2 months post-education questionnaire.

INPUTS	OUTPUTS		OUTCOMES		
	Activities	Outputs	Short-term	Medium-term	Long-term
Participants Tobacco cessation education counseling modules ND specific tobacco cessation resources Dissertation Committee Faculty teaching the Nurs 810 course allowing the project to occur in the course NDSU Statistician NDSU DNP Students	Provision of evidence-based tobacco cessation counseling education to the DNP students Assessment of participants' motivation and comfort with providing information Analyze assessment data Report findings Disseminate project	NDSU DNP students completing the evidence-based tobacco cessation counseling education Assessment completed Data analysis conducted Findings reported Project disseminated	100% of the cohort completes the tobacco cessation education	Students report an increase in participants' motivation and confidence in helping people quit tobacco and comfort with providing information on about cessation medications, programs and services, and referrals for evidence-based tobacco cessation 2.5 months after completion of education	The education is embedded into future NDSU DNP coursework Patients of NDSU DNP graduates have an increased rate of receiving evidence-based tobacco treatment, increased rates of quit attempts, and increased rates of smoking cessation

Setting

This practice improvement project took place in the NDSU DNP program for both the Bismarck and Fargo, N.D., locations. The NDSU DNP program prepares students to provide advanced nursing care as a family nurse practitioner and is accredited by the Commission on Collegiate Nursing Education (North Dakota State University, n.d.). This education module was implemented in the Nurs 810 Health Promotion course during the spring semester of 2022 in the months of April through May.

Sample

The purposive sample population included an entire class or cohort of first year NDSU DNP students who will graduate in May of 2024. The DNP students participating in the project have completed their Bachelor of Science in Nursing, have been accepted into the NDSU DNP program, and have a current unencumbered license as a registered nurse. The students that participated in this study were in their second of eight total semesters of the NDSU DNP program. All admitted students were bachelor-prepared registered nurses with 18 students admitted to the program annually. There was no exclusion criteria for the NDSU DNP class/cohort selected. The sample size was 18 student participants.

Recruitment

Recruitment of the NDSU DNP students occurred through their Nurs 810 Health Promotion course that was taught by Dr. Mykell Barnacle, one of the dissertation committee members associated with this project. The coinvestigator attended the participants' Health Promotion course on April 4, 2022, two weeks prior to the beginning of the project, to recruit participation by verbally explaining the project. At that time, the coinvestigator also verbally recruited participants to voluntarily complete the pre-education questionnaire. The questionnaire,

that included a Qualtrics link, was distributed via email using the students' school associated email address on April 4th, 2022, the same day that the coinvestigator attended the course for recruitment. All students in the course were allowed five minutes in class to complete the questionnaire. This was to ensure the participants had time to complete the questionnaire prior to the education. Dr. Barnacle included the Rx for Change modules in the participant's class coursework and the students received points upon completion of the Rx for Change modules. The participant's required coursework did not include completion of the pre- and post-education questionnaire. The pre- and post-education questionnaire were not associated with a grade and were optional for the participants.

The coinvestigator also attended the participants course on July 27th, 2022, 2.5 months after the education, to recruit voluntary participation in the post-education questionnaire. The questionnaire, that included a Qualtrics link, was distributed via email using the students' school associated email address on July 27th, 2022, the same day the coinvestigator attended the course. Similar to the pre-education questionnaire, all students in the course were allowed five minutes in class to complete the questionnaire to ensure the participants have time to complete the questionnaire prior to the education. The coinvestigator's contact information was provided to the participants via Blackboard and email. There was no compensation to the participants. However, participants were eligible to claim 2.5 contact hours for continuing education free of charge from Purdue University Continuing Nursing Education. In N.D., registered nurses must complete 12 contact hours of continuing education within the previous two years to renew their nursing license. Since all participants were registered nurses, completion of the education modules may be beneficial.

Ethical Considerations

Prior to implementation of this project, NDSU IRB approval was obtained (Appendix E). Completion of the online education modules was a part of participants' required coursework, but completion of the pre- and post-education questionnaires was voluntary. Participants were able to withdraw or not complete the questionnaire without consequence. The participant's choice to complete or not complete the questionnaire was not be made known to the project investigators or course faculty. The coinvestigator attended the participant's course pre- and post-education to explain that completion of the questionnaire implies consent to participate in the study and that participation is voluntary and anonymous. There was also five minutes allowed in their course for time to complete the questionnaires. All students typically use their laptops during class time and thus other students did not know who did or did not complete the questionnaire. The participants in this project were not part of a vulnerable population.

Educational Intervention

This study provided online education of evidence-based tobacco cessation treatment through Rx for Change: Behavioral Counseling and Pharmacotherapy along with a 90 minute in-class session presented by the coinvestigator to first year NDSU DNP graduate students enrolled in Nurs 810. Rx for Change: Behavioral Counseling and Pharmacotherapy was a free, online educational program that consisted of three modules:

1. Clinician Assisted Tobacco Cessation
2. Assisting Patients to Quit
3. Cessations Aids

Each module consisted of a PowerPoint video presentation followed by a series of knowledge questions that must be answered before advancing to the next module. A participant

must get 100% of the knowledge questions correct before advancing to the next module. There were unlimited attempts to complete the quiz. The knowledge questions for all three modules are in Appendix F.

Module 1

Module 1, Clinician Assisted Tobacco Cessation, was 30 minutes in length, followed by five knowledge questions. Key concepts covered in Module 1 included: the epidemiology of tobacco, tobacco use prevalence, components of tobacco smoke, diseases, deaths, and health complications associated with tobacco, smoking cessation benefits, principles of nicotine addiction, nicotine pharmacodynamics, nicotine withdrawal, and drug interactions with smoking. See Appendix G for Module 1 slides.

Module 2

Module 2, Assisting Patients to Quit, was 56 minutes in length followed by 10 knowledge questions. Key concepts covered in Module 2 included: the 5 A's, assessing readiness to quit through the TTM, addressed stress, withdrawal, weight gain, triggers, quit day, tobacco use log, cognitive and behavioral strategies, and quitlines. Module 2 also provided practical language cues to use in patient interactions such as:

1. "Do you ever plan to quit?"
2. "What might be some of the benefits of quitting now rather than later?"
3. "What would have to change in order for you to decide to quit sooner?"

See Appendix H for Module 2 slides.

Module 3

Module 3, Cessation Aids, was 52 minutes in length followed by 10 knowledge questions. Module 3 included information on all seven FDA-approved tobacco cessation

medications. The information provided in Module 3 included aspects of the medications that are needed to safely prescribe or recommend them to a patient such as the mechanism of action, indications, side effects, contraindications, pharmacokinetics, dosing, and effectiveness. See Appendix I for Module 3 slides.

In-class Presentation

The three modules were completed by participants prior to the coinvestigator's presentation in the scheduled class time. The class time with students was 90 minutes during which the coinvestigator presented a PowerPoint reviewing the following:

- Tobacco use prevalence
- Health effects of tobacco
- FDA-approved pharmacotherapy for tobacco treatment
- ND specific resources for tobacco cessation
- Coding and billing for tobacco cessation in primary care

Additionally, a brief video (19 minutes) discussing ENDS use was presented and the coinvestigator presented tobacco cessation patient scenarios to the students that required participation to practice motivational interviewing. Both the ENDS video and patient scenarios presented were created by RxForChange. The PowerPoint slides are in Appendix J. The coinvestigator provided the participants a toolkit in class that included information regarding:

- 5 A's tobacco cessation counseling guide sheet (University of California Regents, n.d.)
- Cognitive and behavioral strategies to cope with quitting
- Withdraw symptom information sheet
- Fagerstrom test for nicotine dependence (Heatherton et al., 1991)
- NDQuits information

- Billing and coding for tobacco cessation in primary care (UNC School of Family Medicine, 2019).
- Pharmacologic product guide (University of California Regents, n.d.)
- Drug interactions with tobacco smoke

See Appendix K for toolkit.

Resources

Personnel

This practice improvement project required multiple personnel from the NDSU DNP program, including the principal investigator and coinvestigator, the dissertation committee members identified previously in the list of stakeholders which includes the course faculty, participating NDSU DNP students, and outside tobacco cessation experts. The outside tobacco cessation experts included Dr. Karen Hudmon and Ms. Kara Backer. Dr. Hudmon is a Professor of Pharmacy at Purdue University and she helped create the Rx for Change program (University of California Regents, n.d.). Ms. Backer is the tobacco cessation coordinator for NDDHS and holds a National Certificate in Tobacco Treatment Practice. The coinvestigator identified an existing online tobacco cessation counseling education program with the guidance of Dr. Kelly Buettner Schmidt and Dr. Brody Maack. Enthusiasm from Dr. Mykell Barnacle, the NDSU DNP assistant professor of practice who taught the course where the modules were incorporated was needed to ensure successful incorporation of the education modules into the DNP coursework. Additionally, the NDSU DNP students must value the education to incorporate in their upcoming clinical rotations and future practice.

Technology

Technology needed for this project included email to communicate the pre- and post-education questionnaire as well as instructions for participants to access the Rx for Change

modules (U.C. Regents, n.d.). Rx for Change online website was utilized by the participants to complete the tobacco cessation education modules. PowerPoint was utilized by the coinvestigator to present information in the in-class session. Development and dissemination of the online questionnaire was accessed through NDSU Qualtrics.

Budget

The project required minimal expenses to create and implement. Participation in the study was voluntary for the DNP students. However, a grade was attached to the completion of the modules in the assigned course. Therefore, there will be no monetary compensation. The pre- and post-education questionnaire was administered via Qualtrics, available at no cost through NDSU. There is no cost associated with accessing the Rx for Change modules.

Timeline

This project took place between January 2021 and February 2023. See Table 3 for specific dates and objectives. The table divides the project into pre-implementation, implementation, and evaluation steps.

Table 3. Project Implementation Plan

Completion Date	Pre-Implementation	Implementation	Evaluation
January-August 2021	Meet with stakeholders to identify support.		
August -November 2021	Develop project proposal		
December 2021	NDSU dissertation committee proposal meeting and obtain NDSU IRB approval		

Table 3. Project Implementation Plan (continued)

Completion Date	Pre-Implementation	Implementation	Evaluation
March 14, 2022		Coinvestigator attend class to recruit participants	Administer pre-education questionnaire to participants to evaluate motivation and confidence in helping people quit tobacco and comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation
March 15-27, 2022		Students complete Rx for Change Modules	
March 28, 2022		Coinvestigator to hold in class education session	
May 30, 2022			Administer post-education questionnaire to participants to evaluate participants' motivation and confidence in helping people quit tobacco and comfort with providing information on about cessation medications, programs and services, and referrals for evidence-based tobacco cessation
August-December 2022			Analyze data and write results and discussion chapters of the dissertation
January 2023			Defend and begin dissertation dissemination

Note. NDSU = North Dakota State University; IRB = Institutional Review Board (IRB)

Clinical Evaluation/Outcomes/Data Analysis

Short-term outcomes of this project included that 100% of the cohort would participate and complete the tobacco cessation education. The coinvestigator would determine the number of participants, that is the number of students enrolled in Nurs 810 Health Promotion, at the time of implementation of the educational intervention and again at the end of the intervention. It was assumed all would complete the education as it is a course requirement. An intermediate outcome was that participants would report an increase in participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation 2.5 months after completion of the education. This was assessed through an 11 item pre- and post-education questionnaire (Appendices L and M). One long-term outcome was that NDSU would retain the tobacco education into the DNP coursework. A second long-term outcome was that patients of NDSU DNP graduates would have an increased rate of receiving evidenced based tobacco treatment, increased rates of quit attempts, and increased rates of smoking cessation. However, these long-term outcomes were not measured in this project.

An 11-item questionnaire compared (a) the participants' motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation pre-education to 2.5 months post-education (Appendices M and N). The questionnaire was adapted from Cunningham et al. (2015) and Buettner-Schmidt et al. (2017). Written permission to utilize Cunningham's questionnaire was obtained (Appendix L). The items in the original Cunningham questionnaire had acceptable internal validity as indicated by the Cronbach's alpha scores that ranged from 0.71 - 0.81. The original questionnaire from Cunningham et al. (2015) included data

that assessed the participant's tobacco cessation activity or behavior in practice. This section was excluded from this project as participants were DNP students and were following varying providers in their clinical rotation and thus, these questions, would not accurately reflect the participants but rather, their preceptor. The questionnaire was to be distributed via email utilizing a Qualtrics link and using the students' school associated email address.

The pre-education questionnaire link was to be emailed to the participants on April 4th, 2022, one month prior to when the Rx for Change modules needed to be completed. The coinvestigator was to briefly attend the participants' Health Promotion course on April 4th, 2022 and request participants complete the questionnaire. The coinvestigator was to make it known to the participants that the questionnaire was entirely optional and anonymous. The pre-education questionnaire was to also collect demographic data from the participants including: gender, previous tobacco cessation training, years of nursing experience, and tobacco use of any kind in the last year. All students in the course were to be allowed five minutes in class to complete the questionnaire, to ensure the participants had adequate time to complete the questionnaire prior to the education. There was to be an introduction paragraph in Qualtrics before the questionnaire began that stated completing the questionnaire implied consent to participate in the study and that the participants could withdraw or not complete the questionnaire at any time without consequence.

An email link with the Qualtrics questionnaire was to be emailed to the participants on July 27, 2022, 2.5 months after the education. At that time, the coinvestigator was to briefly attend the participants' summer course and asked that they complete the questionnaire. Again, the coinvestigator was to make it known to the participants that completion of the questionnaire implied consent, that the questionnaire was entirely optional and anonymous, and that the

participants could withdraw or not complete the questionnaire at any time without consequence. All students in the course were allowed five minutes in class to complete the questionnaire to increase participation.

Data Management and Analysis

Data was to be gathered using Qualtrics and downloaded onto the coinvestigator's password protected laptop. No identifying information was gathered. Raw data was available to share with the dissertation chair, dissertation committee members, and a NDSU professor of statistics in statistics for analysis. After data analysis was completed and the dissertation was approved, all data was to be deleted from the student's computer.

RESULTS

Presentation of Results

This chapter presents data analysis results including descriptive statistics and frequencies for the demographics and key questionnaire findings. The participant data was not paired, therefore, the statistician determined that there was no credible statistical analysis to test for statistical difference between the pre- and post-education questionnaire (Appendices M and N). There were 18 students enrolled in the Nurs 810 Health Promotion course and eligible to participate in the project. The pre-education questionnaire (Appendix M) was available to the participants on April 4, 2022, 17 students completed it for a 94% response rate. The co-investigator conducted the in-class presentation on May 9, 2022. The post-education questionnaire (Appendix, N) was available to the participants on July 27, 2022, approximately 2.5 months after the in-class education, 16 students completed it for an 89% response rate.

Demographics

Demographic data was collected only on the pre-education questionnaire (Table 4).

Table 4. Demographics of Questionnaire Responders (N = 17)

Demographic	n	%
Gender		
Female	17	100
Male	0	0
Years of nursing experience		
1-2 years	0	0
3-5 years	12	70.6
6-10 years	5	29.4
11-15 years	0	0
15+ years	0	0
Have you used any form of tobacco within the last 30 days?		
Yes	0	0
No	17	100
Have you had any previous tobacco training?		
Yes	0	0
No	17	100

All 17 participants were female, and a majority had 3-5 years of nursing experience (n = 12), while the remaining had 6-10 years of experience (n = 5). No participants had used tobacco products within the last 30 days and no participants had any previous tobacco training. It can be deduced that the one student not completing the questionnaire was female since all students this semester were female.

Objective One

The first objective was to identify and modify tobacco cessation education for implementation into NDSU's DNP program by January 31, 2022. This objective was met. The

tobacco cessation education that was identified and modified was explained in detail in Chapter Three Methods. Table 5 provides the activities and evaluation of this objective.

Table 5. Objective One Activities and Evaluation

Objective	Activity	Evaluation
Identify and modify tobacco cessation education for implementation into NDSU's DNP program by January 31, 2022	Researched and reviewed tobacco cessation education modules available Identified information lacking within modules, specifically information on e-cigarette use and ND specific resources Collaborated with Karen Hudmon from Rx for Change to design the in-class presentation information for reviewing module information and included a video on e-cigarettes created by Rx For Change Reviewed ND specific tobacco cessation resources and collaborated with Kara Backer from NDDHHS to include resources in the in-class presentation and toolkit.	Rx for Change: Behavioral Counseling and Pharmacotherapy modules chosen to be used In-class presentation reviewed key tobacco cessation information from the modules as well as included information on e-cigarettes and ND specific resources available Toolkit included information regarding the 5 A's tobacco cessation counseling guide sheet, cognitive and behavioral strategies to cope with quitting, withdraw symptom information sheet, Fagerstrom test for nicotine dependence, NDQuits information, tobacco cessation billing and coding information, pharmacologic product guide, and drug interaction with tobacco smoke

Note. NDSU = North Dakota State University; DNP = Doctorate of Nursing Practice; ND = North Dakota; NDDHHS = North Dakota Department of Health and Human Services

Objective Two

Objective two was to implement a tobacco cessation module into NDSU's DNP program by April 30, 2022. This objective was met. The tobacco cessation modules and in-class

presentation were implemented into the Nurs 810 Health Promotion course in the NDSU DNP program. The intervention, scheduled for April 30, 2022, was completed a few days later on May 9, 2022. See Table 6 for activities and evaluation of this objective.

Table 6. Objective Two Activities and Evaluation

Objective	Activity	Evaluation
Implement a tobacco cessation module into NDSU's DNP program by April 30, 2022	Rx for Change: Behavioral Counseling and Pharmacotherapy modules incorporated into the Health Promotion Nurs 810 course Participants completed Rx for Change modules between April 4 and May 9, 2022 The coinvestigator completed the in-class presentation on May 9, 2022	18 students completed the Rx for Change modules and attended the in-class presentation

Note. NDSU = North Dakota State University; DNP = Doctor of Nursing Practice

Objective Three

Objective 3a

Objective 3a evaluated the change in students' knowledge and the effectiveness of the educational session, as evidenced by successful completion of three knowledge check questionnaires (Appendix F) incorporated into the modules. Objective 3a was met.

The course instructor informed the coinvestigator that all students enrolled in the Nurs 810 Health Promotion course completed all three modules which was evidenced by their completion certification that was submitted to the instructor. To receive the completion certification, all knowledge questions must be answered correctly. The questionnaires could be taken as many times as needed to get 100% of the questions correct. Therefore, all participants were able to

answer all questions correctly, but it was not possible to see the number of questionnaire attempts.

Objective 3b

Objective 3b evaluated the effectiveness of the educational session by evaluating participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation as measured through an 11-item questionnaire, completed pre- and 2.5 months post-education (Appendices M and N; Table 7). Objective 3b was met. Pre- to post-education questionnaire completion rates decreased from 94% to 89%. Since the same number of students had the opportunity to complete both questionnaires, this discrepancy was due to a participant's choice not to complete the post-education questionnaire. The results of the questionnaire are shown in Table 7.

Table 7. Results of the Pre-Education and 2.5 Months Post-Education Questionnaire.

Questions	Pre-Education n = 17		2.5 Months Post-Education n = 16	
	n	%	n	%
Motivation / Confidence				
Q1: It is important, as a practitioner, to know whether a patient/client uses tobacco				
Strongly agree	17	100	16	100
Agree	0	0	0	0
Disagree	0	0	0	0
Strongly disagree	0	0	0	0
Q2: It is important, as a practitioner, to know whether a patient/client has regular exposure to secondhand smoke				
Strongly agree	13	76.4	14	87.5
Agree	4	23.5	2	12.5
Disagree	0	0	0	0
Strongly agree	0	0	0	0
Q3: I am motivated to help tobacco users quit				
Strongly agree	10	58.8	14	87.5
Agree	6	35.2	2	12.5
Disagree	1	5.8	0	0
Strongly disagree	0	0	0	0
Q4: How comfortable are you in talking with patients/clients about tobacco use				
Very comfortable	4	23.5	12	75.0
Somewhat comfortable	7	41.2	3	18.8
Not very comfortable	5	29.4	1	6.3
Not comfortable at all	1	5.9	0	0

Table 7. Results of the Pre-Education and 2.5 Months Post-Education Questionnaire (continued)

Questions	Pre-Education n = 17		2.5 Months Post-Education n = 16	
	n	%	n	%
Motivation / Confidence				
Q5: I am confident that I can explore issues related to quitting smoking, even with someone not interested in quitting.				
Very confident	1	5.9	5	31.3
Somewhat confident	6	35.3	10	62.5
Not very confident	9	52.9	1	6.3
Not confident at all	1	5.9	0	0
Q6: I am confident that I can personalize the benefits of quitting with each individual tobacco user.				
Very confident	1	5.9	6	37.5
Somewhat confident	4	23.5	9	56.3
Not very confident	11	64.7	1	6.3
Not at all confident	1	5.9	0	0
Q7: I am confident that I know if a patient has regular exposure to secondhand smoke.				
Strongly Agree	1	5.9	3	18.8
Agree	5	29.4	10	62.5
Disagree	11	64.7	3	18.8
Strongly Disagree	0	0	0	0
Comfort in Providing Information				
Q8: How comfortable are you in providing information about medications that help in quitting tobacco?				
Very comfortable	1	5.9	6	37.5
Somewhat comfortable	6	35.3	9	56.3
Not very comfortable	6	35.3	1	6.3
Not comfortable at all	4	23.5	0	0

Table 7. Results of the Pre-Education and 2.5 Months Post-Education Questionnaire (continued)

Questions	Pre-Education n = 17		2.5 Months Post-Education n = 16	
	n	%	n	%
Q9: How comfortable are you in providing information about programs and services that help aid in quitting (quit lines, counseling etc.)?				
Very comfortable	1	5.9	8	50.0
Somewhat comfortable	5	29.4	6	37.5
Not very comfortable	10	58.9	2	12.5
Not comfortable at all	1	5.9	0	0
Q10: I am confident that I can provide information about programs and services that help in quitting (quitlines, counseling, etc).				
Very confident	1	5.9	6	37.5
Somewhat confident	3	17.6	9	56.3
Not very confident	12	70.6	1	6.3
Not at all confident	1	5.9	0	0
Q11: I am confident that I can provide information about medications that can help in quitting tobacco.				
Very confident	1	5.9	4	25.0
Somewhat confident	5	29.4	10	62.5
Not very confident	11	64.7	2	12.5
Not at all confident	0	0	0	0

Motivation and Confidence in Helping People Quit Tobacco. Questions one through seven were a self-assessment of participants' motivation and confidence regarding helping people quit tobacco. Pre-education, all participants strongly agreed that it was important, as a practitioner, to know whether a patient/client uses tobacco; this remained the same 2.5 months post-education.

Regarding secondhand smoke, pre-education, all participants either strongly agreed (76.4%) or agreed (23.5%) that it was important, as a practitioner, to know whether a patient/client had regular secondhand smoke exposure. At 2.5 months post-education, the level of agreement slightly improved (87.5% strongly agreed and 12.5% agreed) that it was important.

Regarding being motivated to help tobacco users quit, pre-education, all but one participant either strongly agreed (58.8%) or agreed (35.2%) that they were motivated to help tobacco users quit. One participant (5.9%) disagreed with being motivated to help tobacco users quit. At 2.5 months post-education, the level of agreement increased with all either strongly agreed (87.5%) or agreed (12.5%) with being motivated to help tobacco users quit.

Regarding comfort in talking with patients about tobacco use, pre-education, two-thirds of the participants reported being either very comfortable (23.5%) or somewhat comfortable (41.2%). And, 35.3% were either not very comfortable or not comfortable at all. At 2.5 months post education, only 1 participant (6.3%) disagreed with this and the level of agreement improved with 75% of participants reporting being very comfortable in talking with patients about tobacco use.

Regarding confidence in exploring issues related to exploring issues related to quitting smoking, even when someone is not interested, pre-education, two-fifths of the participants reported being either very confident (5.9%) or somewhat confident (35.3%). And, 58.8% were either not very confident or not confident at all. At 2.5 months post-education, all but 1 participant reported being either very confident or somewhat confident and the level of agreement improved with 31.3% reporting being very confident.

Regarding confidence in knowing if a patient has regular secondhand smoke exposure, about one-third either strongly agreed (5.9%) or agreed (29.4%) to knowing this information.

And, 64.7% disagreed. At 2.5 months post-education, three participants (18.8%) still disagreed with knowing if a patient has regular secondhand smoke exposure, with 81.3% of the participants either strongly agreeing or agreeing.

Regarding personalizing the benefits of quitting with each individual tobacco user, less than one-third of participants were either very confident (5.9%) or somewhat confident (23.5%). And, 70.9% were either not very confident or not confident at all. At 2.5 months post education this improved with all but one participant (93.8%) were either very confident or somewhat confident in personalizing the benefits of quitting with each individual tobacco user.

Comfort in Providing Information about Cessation Medications, Programs and Services, and Referrals for Evidence-Based Tobacco Cessation. Questions eight through eleven was a self-assessment of the participants comfort and confidence in providing information and referrals for evidence-based tobacco cessation aids. Responses to all questions in this section increased from pre-education to 2.5 months post-education.

Regarding comfort in one's ability to provide information about tobacco cessation medications, pre-education, less than one-half of the participants were either very confident (5.9%) or somewhat confident (35.3%). And, 58.8% of the participants were either not very comfortable or not comfortable at all. At 2.5 months post-education, all but one participant (93.7%) was either comfortable or somewhat comfortable in providing information about medications.

Regarding comfort providing information about programs and services that aid in tobacco cessation, pre-education, about one-third of the participants were either very comfortable (5.9%) or somewhat comfortable (29.4%). And, 64.8% of the participants were either not very comfortable or not comfortable at all. At 2.5 months post-education, all but two participants

(87.5%) were either comfortable or somewhat comfortable in providing information about programs and services.

Regarding confidence in providing information about medications that help in quitting tobacco, pre-education, about one-third of the participants were either very confident (5.9%) or somewhat confident (29.4%). And, 64.7% of the participants were either not very confident or not confident at all. At 2.5 months post-education, all but two participants (87.5%) were either very confident or somewhat confident in providing information about medications that help in quitting tobacco.

Lastly, regarding confidence in providing information about programs and services, pre-education, less than one-fourth of the participants were either very confident (5.9%) or somewhat confident (17.6%). And, 76.5% of the participants were either not very confident or not confident at all. At 2.5 months post-education, all but one participant (93.7%) were confident in providing information about programs and services that help in quitting.

DISCUSSION AND RECOMMENDATIONS

Discussion

The purpose of this evidence-based practice improvement project was to determine if implementing tobacco cessation education into the coursework of the DNP program at NDSU would improve DNP students' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation. The project included the development and implementation of an educational intervention that included video modules completed independently by the students, an in-class presentation, an in-class video, in-class patient scenarios, and a toolkit. All videos and the patient scenarios were created by RxForChange (University of California Regents, n.d.).

The participants completed an 11-item Likert scale questionnaire that assessed (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation. Fortunately, all 18 participants completed the online modules, knowledge check questionnaires, and attended the in-person presentation as it was part of their assigned coursework. Pre- and post-education questionnaire completion rates were high at 94.4% and 88.9% respectively.

Objective One

Objective one was to identify and modify tobacco cessation education for implementation into NDSU's DNP program. This was completed by identifying an existing tobacco cessation education through RxForChange (University of California Regents, n.d.), collaborating with staff from RxForChange to add a video about ENDS use and cessation and to add interactive patient

scenarios, creating a presentation on ND specific information, and creating a toolkit for participants.

Objective Two

Objective two was to implement a tobacco cessation module for implementation into NDSU's DNP program. The modules were implemented into the DNP program and all eligible participants completed the online modules and attended the in-person presentation.

Objective Three

Objective 3a

Objective 3a evaluated the change in participants' knowledge and the effectiveness of the educational session through successful completion of the three knowledge check questionnaires (Appendix F) incorporated into the modules. All participants correctly answered all questions. However, because they were able to take the questionnaire repeatedly, some participants may have simply memorized the answers. Therefore, the questionnaire may not be a valid measure of increased in knowledge and educational effectiveness.

Objective 3b

Objective 3b evaluated the effectiveness of the educational session by evaluating participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation as measured through a pre- and 2.5 months post-education questionnaire, and are discussed separately next.

Motivation and Confidence in Helping People Quit Tobacco. Motivation in knowing about patients' tobacco use and being motivated to help users quit was high pre-education, with all participants either strongly agreeing or agreeing with both motivation questions except for

one participant for one question. For both questions, post-education, the level of agreement increased to more than 87.5% of participants strongly agreeing, and none disagreeing. Although with one less participant answering post-education, that participant could have been the one that disagreed with the one question pre-education. Given the high level of motivation pre-education, and increasing levels of agreement post-education, it may be appropriate to assume that future DNP students would also be motivated to acquire the knowledge and skills to be effective tobacco cessation counselors.

Comfort in talking with patients about their tobacco use also improved greatly from pre-education to 2.5 months post-education. Post-education, only one participant reported being not very comfortable talking with patients about tobacco use and 75% feeling very comfortable.

Confidence in one's ability to explore issues related to quitting when someone is not interested in quitting and ability to personalize the benefits of quitting improved dramatically for both questions from pre-education to 2.5 months post-education. Pre-education, less than half of the participants reported being somewhat or very confident. At 2.5 months post-education, responses increased with all but one participant being either somewhat or very confident in the provision of these items.

There were two questions regarding regular secondhand smoke exposure; one question evaluated importance, as a practitioner, to know if a patient has regular exposure to secondhand smoke and the second question evaluated one's confidence in their ability to know if a patient has regular secondhand smoke exposure. While every participant agreed or strongly agreed with the importance of knowing if a patient had secondhand smoke exposure pre- and post-education, three participants were not confident in knowing if a patient has secondhand smoke exposure post-education. Motivation and confidence in helping people quit tobacco does not seem

appropriate to be tied to knowledge on exposure to secondhand smoker, thus, a recommendation for future studies is to not include this question to measure motivation and confidence in helping people quit tobacco. Interestingly, there was only a brief mention of secondhand smoke in the education, given the scores, it does not appear necessary to increase the quantity of education on secondhand smoke.

The motivation and confidence findings are encouraging, since the participants' motivation and confidence in helping people quit tobacco was improved and sustained 2.5 months after the education. It may be appropriate to assume that future DNP students, with education, will be similarly motivated and confident in helping patients quit tobacco.

Comfort in Providing Information about Cessation Medications, Programs and Services, and Referrals for Evidence-Based Tobacco Cessation. Comfort and confidence in one's ability to provide information about cessation medications and programs and services improved dramatically for all questions from pre-education to 2.5 months post-education. Pre-education the responses ranged from approximately 25%-40% of participants being either somewhat or very comfortable and confident. Post-education, responses increased with about 90% being either somewhat or very comfortable and confident in the provision of these items.

Interesting, only one or two participants disagreed on each of the four questions related to comfort and confidence in providing information. There was a slightly higher confidence than comfort regarding providing information on tobacco cessation programs and services and slightly higher comfort than confidence in providing information on tobacco cessation medications. Since the questionnaire results were not paired, we could not assess the individual participant's responses associated with the items above. Regardless, from the results of the post-education questionnaire, a conclusion can reasonably be made that participants had an increase in

comfort and confidence providing information and referrals for evidence-based tobacco cessation aids. It may be appropriate to assume that with education, future DNP students would also be comfortable and confident in providing this information.

Summary of 3b

Objective 3b evaluated the effectiveness of the educational session by evaluating participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation as measured by a pre- and 2.5 months post-education questionnaire.

The participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation increased dramatically pre-education to post-education for all 11 questions with the exception of question one in which case all participants strongly agreed in both the pre- and post-education questionnaire. The outcomes of this project suggest that implementing tobacco cessation education into a DNP program is an effective approach to increase future primary care providers' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation.

Based on the results discussed above, it can be concluded that there was an increase in motivation and confidence and comfort with providing information that was sustained 2.5-months after the education. This increase will likely prove to be beneficial in the DNP student's ability to be a successful tobacco cessation counselor.

Recommendations

Recommendations for Education Institutions

The findings of this project support the need to educate current and future primary care providers on evidence-based tobacco cessation counseling. Evidence-based cessation treatment increases cessation rates by 82% when compared to the usual intervention (Patnode et al., 2015). With 70% of people who smoke visiting a primary care provider annually and only 56% receiving advice to quit, paired with the results of this project, the need for formal tobacco cessation education is imperative (CDC, n.d.b.; Kruger et al., 2016). It would be prudent to include formal tobacco cessation counseling education into the coursework of all future primary care providers. A recommendation is to include evidence-based tobacco treatment including pharmacological interventions and behavioral interventions into primary care provider curricula. Additionally, a recommendation is to include interactive patient scenarios, information about local tobacco cessation resources, and information regarding coding and billing for tobacco treatment in primary care curricula.

While participants' responses to the questionnaire demonstrated dramatic improvement from pre- to post-education, there is still room for improvement by increasing the response rates from agree and somewhat comfortable and confident to strongly agree and very comfortable and confident. Therefore, another recommendation is to dedicate more time to the in-person education allowing for more practice case scenarios or other active learning strategies. Due to some informal feedback provided by students, there is a recommendation to split the tobacco cessation content into different courses in the nurse practitioner program curriculum. The behavioral aspect and motivation interviewing portion of tobacco cessation could remain

included in the health promotion course and the pharmacology tobacco cessation content could be included in the pharmacology course.

Additionally, future presenters should practice the educational technology aspects, including video and sound, to better facilitate classroom learning. For the participating school, NDSU, continued use of the tobacco cessation education is recommended. Because the three knowledge check questionnaires (Appendix F) incorporated into the module may not be a valid measure of increased in knowledge and educational effectiveness, it is recommended that it be determined if some essential knowledge questions should be included in the course's final exam.

A recommendation is to follow the Iowa Model (Iowa Model Collaborative, 2017) with continued evaluation and modification to the tobacco cessation education because tobacco use treatment is constantly evolving.

Due to the current gap in patients receiving evidence-based tobacco cessation treatment, a recommendation is that current primary care providers complete tobacco cessation counselling education. This should improve the number of patients receiving evidence-based tobacco cessation treatment leading to increased cessation rates.

Recommendations for Future Research

While this project's outcomes show an increase in participants' (a) motivation and confidence in helping people quit tobacco and (b) comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation, there may still be barriers in carrying out tobacco cessation counseling in practice. Substantial increase in patients receiving evidence-based tobacco cessation treatment may not occur with these barriers still in place. Barriers may include perceived lack of time and

inadequate institutional support (USDHHS, 2020). These barriers are important to address in future research.

Actual patient outcomes, such as cessation attempts, medication use, quit rates, or use of cessation services were not assessed in this project. A recommendation for future research would be to examine the effect that tobacco cessation education for primary care providers has on patients' tobacco cessation success.

The online modules took approximately 138 minutes to complete and the in-class presentation was approximately 90 minutes in length. This made a total of almost 4 hours of tobacco cessation content delivered to participants. More research is needed to determine the best amount of time that should be allocated to tobacco cessation for providers to best assess and treat nicotine dependence.

Additionally, a recommendation for future research is to pair pre- and post-education data sets to enable determination of statistical significance and, thereby, effectiveness of the intervention. Pairing the data sets will allow to test for a statistical significance of the education in participants' motivation and confidence in helping people quit tobacco and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation. Showing effectiveness of the intervention will be required before the intervention can be published in a peer-reviewed journal. Publication of this intervention likely would advance NP education, advance tobacco prevention and control efforts, and improve public health. Therefore, replication of this study with appropriate data collection to assess for statistically significant change is recommended.

The terms "confidence" and "comfort" were used in eight of the eleven questions in the questionnaire. The original questionnaire (Cunningham et al., 2015) did not define the terms

"confidence" or "comfort." While the terms seem to be closely related, they are different and it may be beneficial to define these two terms. Perhaps, confidence in knowing the tobacco cessation information comes before comfort in providing information. It may be beneficial to reach out to the creator of the original questionnaire to define these terms.

While confidence and comfort in providing information about cessation medications was evaluated in the questionnaire, confidence and comfort in prescribing was not. With nurse practitioners having prescribing authority, it may be worth explicitly evaluating participants confidence and comfort in prescribing tobacco cessation medications. Additionally, it was shown that this intervention improved participants' comfort and confidence in discussing tobacco cessation, a sensitive health topic, with patients. It is possible that the intervention, scenarios, and practice with tobacco cessation has also helped participants' comfort and confidence in addressing other sensitive health topics such as weight loss, alcohol use, or sexual practices with patients. This is an important topic that could be assessed in future research.

Investigators replicating this project may want to delete the questions related to secondhand smoke exposure for reasons previously discussed. Alternatively, the secondhand smoke questions could be measured separately from motivation and confidence in helping people quit tobacco use.

ENDS products are frequently used by adults as a tobacco cessation aid and are becoming increasing popular among youth. The most recent data shows between 2021 and 2022, ENDS use among high schoolers increased from 11.3% to 14.1% and from 2.8% to 3.3% in middle schoolers (U.S. Food and Drug Administration, 2022). This practice improvement project did include information regarding ENDS products in the form of a 19-minute educational video. However, a recommendation would be to include a comprehensive and stronger emphasis on

ENDS use in regard to cessation and harm reduction. While ENDS may be less harmful than traditional cigarettes, they are currently not an FDA-approved smoking cessation aid and do not come without risk (CDC, n.d.c; FDA, n.d.). A recent study of physicians (n = 2058) reported that 70% of physicians are being asked about ENDS by patients (Delnevo et al., 2022). Additionally, almost 40% endorsed the belief that getting smokers to quit smoking cigarettes is the target, even if that means switching to less harmful forms of tobacco like ENDS. This new data furthers the recommendation to enhance ENDS education. This new data furthers the recommendation to enhance ENDS education, with the emphasis being on ENDS not being approved for cessation.

Emerging Tobacco Products

Heated tobacco products are devices that heat a processed tobacco leaf and aerosolize nicotine to be inhaled (CDC, 2022). These products are new to the U.S. market and are increasing in popularity. Adult use of these products increased from 1.4% to 2.7% from 2017 to 2018. In 2020, 2.4% of middle schoolers and high schoolers used heated tobacco products in the last 30 days. The harmful effects of nicotine associated with these products are still present as discussed in Chapter two. A recent Cochrane review of 13 studies was completed and 11 of the studies were randomized control trials, all of which were funded by tobacco companies (Tattan-Birch et al., 2022). There was insufficient evidence to determine a difference in risk of adverse or serious adverse events in those who used heated tobacco products compared to those who smoke cigarettes, use smokeless tobacco, or quit smoking (n = 1713). There was moderate certainty evidence that heated tobacco products are associated with lower toxicants and carcinogens than traditional cigarettes (n = 382). It was determined that more independently funded research is needed to determine the long-term effects and safety of heated tobacco products. Heated tobacco products are not an FDA approved cessation method as their effect on

cessation has not been studied (CDC, 2022). It is recommended to include information regarding these new tobacco products in tobacco cessation education.

See Appendix O for a list of all recommendations discussed in this section.

Dissemination

The results of this project were presented to the dissertation committee during the defense of this project. After its completion and approval, the dissertation will be published and available on ProQuest Dissertations & Theses Global for review. It will also be provided to the Director of the Tobacco Prevention and Control Program at the NDDHHS. Additionally, with the results of this project, the co-investigator will be creating a guide for other DNP programs to implement tobacco cessation counseling education into their curriculum.

Strengths and Limitations

Several limitations were associated with this project. The first limitation was time allotted for the in-person presentation. With 90 minutes and some minor technology delays, the time was limited to have participants participate in multiple interactive patient case scenarios. Practicing motivational interviewing with interactive patients could increase participants' motivation and confidence in helping people quit tobacco and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation even further.

The post-education questionnaire was completed after participants had started their first clinical hours in primary care. Thus, it is possible that there are confounding variables contributing to the increase participants' motivation and comfort with providing information. These variables could include information from preceptors or simply practical experience seeing patients. However, this limitation could also reflect that participants' motivation and confidence

in helping people quit tobacco and comfort with providing information about cessation medications, programs and services, and referrals for evidence-based tobacco cessation acquired from the education remained elevated even after seeing patients in real practice.

Lastly, a limitation of this project is that the pre- and post-education data sets were not paired. Since the data was not paired, conclusions based upon statistically significant changes in participants' motivation, confidence, and comfort cannot be determined in regard to the effectiveness of the education.

Conclusion

Tobacco use is a global epidemic and tobacco cessation is essential for public health improvement. This project indicates that family nurse practitioner students' knowledge, motivation and confidence in helping people quit tobacco, and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation can be improved through evidence-based tobacco cessation education incorporated into their school coursework. With less than one-third of tobacco users trying to quit using evidence-based cessation treatments, it is essential that family nurse practitioners and other primary care providers better assist patients in tobacco cessation. Tobacco use disorder is complex and has a multitude of health implications. It is paramount that a nurse practitioner has the knowledge and tools to individualize patient care to include tobacco cessation pharmacotherapy, behavioral interventions, motivational interviewing, and programs and services. Incorporating tobacco cessation counseling education into the coursework of a family nurse practitioner program is imperative to strengthen future providers' ability to provide evidence-based cessation treatment to improve health outcomes and decrease morbidity and mortality from tobacco use.

Application to DNP Roles

The outcomes of this project indicate that implementing tobacco cessation education into the NDSU DNP program was an effective approach to increase future nurse practitioners' knowledge, motivation and confidence in helping people quit tobacco, and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation. Family nurse practitioners play a key role in advancing tobacco prevention and control efforts to improve public health.

Executive Summary

Tobacco use is a global epidemic and is one of the biggest public health threats the world has ever faced (World Health Organization, 2020), killing over eight million people a year. Unfortunately, only 31% of those who tried to quit smoking in 2015 used evidenced-based cessation treatments and when behavioral and pharmacotherapy is combined, cessation rates increase by 82% (Babb et al., 2017; Patnode et al., 2015). Since 70% of tobacco users visiting a primary care facility annually, it is essential that providers are able to appropriately and accurately address tobacco use and cessation (CDC, n.d.a; Kruger et al., 2016).

The purpose of this evidence-based practice improvement project was to determine if implementing tobacco cessation education into the coursework of the Doctor of Nursing Practice (DNP) program at North Dakota State University (NDSU) would improve the participants' knowledge, motivation and confidence in helping people quit tobacco, and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation.

The coinvestigator designed tobacco cessation education for implementation into the NDSU DNP coursework in a health promotion course for 18 family nurse practitioner students. The education consisted of an online program, an in-class presentation, and a tobacco cessation toolkit.

The online program, Rx for Change: Clinician Assisted Tobacco Cessation was completed by the DNP students. It is a program designed by Purdue College of Pharmacy created to educate clinicians about the negative health effects of tobacco use and enhance providers' knowledge to deliver comprehensive tobacco cessation counseling services (U.C. Regents, n.d.). See Appendices G, H, & I for the PowerPoint slides.

After completion of the online Rx for Change modules, the coinvestigator reviewed tobacco use epidemiology, health effects of tobacco, FDA-approved pharmacotherapy for tobacco treatment, North Dakota-specific resources, and coding and billing for tobacco cessation in primary care (Appendix J). Additionally, interactive patient scenarios were presented and a tobacco cessation toolkit for providers was given to the participants. The toolkit (Appendix K) included information regarding:

- 5 A's tobacco cessation counseling guide sheet (University of California Regents, n.d.)
- Cognitive and behavioral strategies to cope with quitting
- Withdraw symptom information sheet
- Fagerstrom test for nicotine dependence (Heatherton et al., 1991)
- NDQuits information
- Billing and coding for tobacco cessation in primary care (UNC School of Family Medicine, 2019).
- Pharmacologic product guide (University of California Regents, n.d.)
- Drug interactions with tobacco smoke

NDSU DNP students' motivation and confidence in helping people quit tobacco and comfort with providing information on cessation medications, programs and services, and referrals for evidence-based tobacco cessation was assessed through a pre- and 2 months post-education 11 item questionnaire. The participants' motivation and confidence in helping people quit tobacco and comfort with providing on cessation medications, programs and services, and referrals for evidence-based tobacco cessation increased dramatically pre-education to post-education for all questions with the exception of question one in which case all participants strongly agreed in both the pre- and post-education questionnaire. See Table 7. The results of this

practice improvement project will help to provide direction for tobacco cessation education into the NDSU DNP coursework in future years to come as well as serve as a guide for other professional programs to add or improve tobacco cessation education into their coursework.

REFERENCES

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). https://doi.org/10.1176/appi.books.9780890425596

American Lung Association. (2021). *State of Tobacco Control 2021: North Dakota Highlights*. https://www.lung.org/research/sotc/state-grades/highlights/north-dakota

Babb, S., Malarcher, A., Schauer, G., Asman, K., & Jamal, A. (2017). Quitting smoking among adults—United States, 2000-2015. *Morbidity and Mortality Weekly Report, 65*(52), 1457-1464. https://dx.doi.org/10.15585/mmwr.mm6552a1

Barnes J., McRobbie H., Dong C.Y., Walker N., Hartmann-Boyce J. (2019). Hypnotherapy for smoking cessation. *Cochrane Database of Systematic Reviews, 6.* https://doi10.1002/14651858.CD001008.pub3

Buettner-Schmidt, K., Miller, D.R., Larson, M., Maack, B., Orr, M., McDaniel, B., & Mills, K. (2017). Chiropractic practices: Systems change for effective tobacco cessation. Fargo, ND: North Dakota State University, School of Nursing.

Buettner-Schmidt, K., Swanson, K., Maack, B., Barnacle, M. Miller, D., Orr, M., & Hatlen Gag, M., (2021). E-cigarettes for tobacco cessation: Not the solution. *The Nurse Practitioner, 46*(12), 7-11. https://doi:10.1097/01.NPR.0000798228.69915.64

Cahill, K., Lindson-Hawley, N., Thomas, K. H., Fanshawe, T. R., & Lancaster, T. (2016). Nicotine receptor partial agonists for smoking cessation. *The Cochrane Database of Systematic Reviews*, *5.* https://doi.org/10.1002/14651858.CD006103.pub7

Centers for Disease Control and Prevention. (2022). *Heated tobacco products*. U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/basic_information/heated-tobacco-products

Centers for Disease Control and Prevention. (n.d.a.) *Office on Smoking and Health*. U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/about/osh/index.htm

Centers for Disease Control and Prevention. (n.d.b.). *Smoking and tobacco use: Fast facts and fact sheets*. U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm

Centers for Disease Control and Prevention (n.d.c.). *About electronic cigarettes (E-cigarettes).* U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm

Centers for Disease Control and Prevention (n.d.d.). *Quitlines and other cessation resources.* U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/patient-care/quitlines-other/index.html

Centers for Disease Control and Prevention. (2019). *Behavioral risk factor surveillance system*. U.S. Department of Health and Human Services. https://www.cdc.gov/brfss/index.html

Creamer M.R., Wang T.W., Babb S., Cullen K.A., Day H., Willis G., Jamal A., Neff L. (2019). Tobacco product use and cessation indicators among adults — United States, 2018. *Morbidity and Mortality Weekly Report, 68*(45), 1001-1019. https://doi.org/10.15585/mmwr.mm6845a2

Cunningham, J.K., Floden, L.L., Howerter, A.L., Matthews, E., Gordon, J.S., & Muramota, M.L. (2015). Complementary and alternative medicine (CAM) practitioners' readiness for tobacco intervention training: Development and psychometric properties of a new measure. *Advances in Integrative Medicine,* 2(2), 90-95. https://doi.org/10.1016/j.aimed.2014.10.012

Delnevo, C. D., Jeong, M., Teotia, A., Bover Manderski, M. M., Singh, B., Hrywna, M., Wackowski, O. A., & Steinberg, M. B. (2022). Communication between US physicians and patients regarding electronic cigarette use. *JAMA Network Open*, *5*(4), e226692–e226692. https://doi.org/10.1001/jamanetworkopen.2022.6692

Goniewicz, M.L., Smith, D.M., Edwards, K.C., Blount, B.C., Caldwell, K.L., Feng, J., Wang, L., Christenson, C., Ambrose, B., Borek, N., Van Bemmel, D., Konkel, K., Erives, G., Stanton, C.A., Lambert, E., Kimmel, H.L., Hatsukami, D., Hecht, S.S., Niaura, R.S., Travers, M., . . . Hyland, A.J. (2018). Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes. *The Journal of the American Medical Association.* https://doi:10.1001/jamanetworkopen.2018.5937

Hartmann-Boyce, J., Chepkin, S. C., Ye, W., Bullen, C., & Lancaster, T. (2018). Nicotine replacement therapy versus control for smoking cessation. *The Cochrane Database of Systematic Reviews*, *5*. https://doi.org/10.1002/14651858.CD000146.pub5

Hartmann-Boyce, J., Hong, B., Livingstone-Banks, J., Wheat, H., & Fanshawe, T.R. (2019). Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. *Cochrane Database of Systematic Reviews.* https://doi.org/10.1002/14651858.CD009670.pub4

Hartmann-Boyce, J., McRobbie, H., Butler, A.R., Lindson, N., Bullen, C., Begh, R., Theadoulou, A., Notley, C., Rigotti, N.A., Turner, T., Fanshawe, T.R., Hejek, P. (2021). Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews.* https://doi.org/10.1002/14651858.CD010216.pub6

Heatherton T.F., Kozlowski L.T., Frecker R.C., & Fagerstrom K. (1991). The Fagerstrom test for nicotine dependence: A revision of the Fagerstrom tolerance questionnaire. *British Journal of Addiction*, 86, 1119-1127.

Holla, N., Brantley, E., & Ku, L. (2018). Physicians' recommendations to Medicaid patients about tobacco cessation. *American Journal of Preventive Medicine*, *55*(6), 762–769. https://doi.org/10.1016/j.amepre.2018.07.013

Howes, S., Hartmann-Boyce, J., Livingstone-Banks, J., Hong, B., & Lindson, N. (2020). Antidepressants for smoking cessation. *The Cochrane Database of Systematic Reviews*, *4*. https://doi.org/10.1002/14651858.CD000031.pub5

Hughes, J. (2007). Effects of abstinence from tobacco: Valid symptoms and time course. *Nicotine & Tobacco Research, 9(3), 315-327.* https://doi.org/10.1080/14622200701188919

Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing*, 14(3), 175-182. https://doi:10.1111/wvn.12223

Kaiser Family Foundation (2015). *Preventative services covered by private health plans under the Affordable Care Act.* https://www.kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/

Kruger, J., O'Halloran, A., Rosenthal, A. C., Babb, S. D., & Fiore, M. C. (2016). Receipt of evidence-based brief cessation interventions by health professionals and use of cessation assisted treatments among current adult cigarette-only smokers: National Adult Tobacco Survey, 2009-2010. *BioMed Central Public Health*. *16*,141. https://doi.org/10.1186/s12889-016-2798-2

Lancaster, T. & Stead, L.F. (2017). Individual behavioral counseling for smoking cessation. *Cochrane Database of Systematic Reviews*, 3. https://doi.org/10.1002/14651858.CD001292.pub3

Lexicomp. (n.d.a) Bupropion : Drug information. *UpToDate.* Retrieved August 8, 2021 from https://www.uptodate.com/contents/bupropion-drug-information

Lexicomp. (n.d.b). Nicotine : Drug information. *UpToDate.* Retrieved August 10, 2021 from https://www.uptodate.com/contents/nicotine-drug-information

Lexicomp. (n.d.c) Varenicline : Drug information. *UpToDate.* Retrieved August 11, 2021 from https://www.uptodate.com/contents/varenicline-drug-information

Lindson, N., Chepkin, S. C., Ye, W., Fanshawe, T. R., Bullen, C., & Hartmann-Boyce, J. (2019). Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. *The Cochrane Database of Systematic Reviews*, *4*. https://doi.org/10.1002/14651858.CD013308

Matkin, W., Ordóñez-Mena J.M., & Hartmann-Boyce J. (2019). Telephone counselling for smoking cessation. *Cochrane Database of Systematic Reviews, 5.* https:doi:10.1002/14651858.CD002850.pub4.

North Dakota Department of Health (2021). Key findings about NDQuits in fiscal year 2020 (July 1, 2019-June 30, 2020). https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Reports/NDQuits_FY20_Report.pdf

North Dakota Department of Health and Human Services (2022). *Tobacco surveillance data.* https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Tobacco_Surveillance_Data.pdf

North Dakota Department of Public Instruction (2019). *Safety and health. North Dakota Youth Risk Behavior Survey.* https://www.nd.gov/dpi/districtsschools/safety-health/youth-risk-behavior-survey

North Dakota State University. (n.d.). Doctor of Nursing Practice. *School of Nursing.* Retrieved March 10, 2021, from https://www.ndsu.edu/nursing/degrees/dnp/

Office of Disease Prevention and Health Promotion. (n.d.). Tobacco use. *Healthy People 2030*. U.S. Department of Health and Human Services. https://health.gov/healthypeople/objectives-and-data/browse-objectives/tobacco-use

Oxford English Dictionary (n.d.a). Cessation. *Oxford English Dictionary.* Retrieved October 7, 2021, from https://www.oed.com/view/Entry/30058

Oxford English Dictionary (n.d.b). Education. *Oxford English Dictionary.* Retrieved October 7, 2021, from https://www.oed.com/view/Entry/59584

Oxford English Dictionary (n.d.c) Tobacco. *Oxford English Dictionary.* Retrieved October 7, 2021, from https://www.oed.com/view/Entry/202743

Patnode, C.D., Henderson, J.T., Thompson, J.H., Senger, C.A., Fortmann, S.P., & Whitlock, E.P. (2015). Behavioral counseling and pharmacotherapy interventions for tobacco cessation in adults, including pregnant women: A review of reviews for the U.S. Preventive Services Task Force. *Annals of Internal Medicine, 163(8),* 608-621. https://doi.org/10.7326?M15-0171

Pérez-Tortosa, S., Roig, L., Manresa, J. M., Martin-Cantera, C., Puigdomènech, E., Roura, P., Armengol, A., & Advani, M. (2015). Continued smoking abstinence in diabetic patients in primary care: A cluster randomized controlled multicenter study. *Diabetes Research and Clinical Practice*, *107*(1), 94–103. https://doi.org/10.1016/j.diabres.2014.09.009

Pollak, K.I., Tulsky, J.A., Bravender, T., Ostbye, T., Lyna, P., Dolor, R. J., Coffman, C.J., Bilheimer, A., Lin, P.H., Farrell, D., Bodner, M.E., & Alexander, S.C. (2016). Teaching primary care physicians the 5 A's for discussing weight with overweight and obese adolescents. *Patient Education and Counseling*, *99*(10), 1620–1625. https://doi.org/10.1016/j.pec.2016.05.007

Prochaska, J.O. & DiClemente, C.C. (1983). Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of Consulting and Clinical Psychology, 51*(3), 390–395. https://doi.org/10.1037/0022-006X.51.3.390

Quinn, V.P., Hollis, J.F., Smith, K.S., Rigotti, N.A., Solberg, L.I., Hu, W., & Stevens, V.J. (2009). Effectiveness of the 5-As tobacco cessation treatments in nine HMOs. *Journal of General Internal Medicine*, *24*(2), 149–154. https://doi.org/10.1007/s11606-008-0865-9

Rigotti, N.A., Aronson, M.D., Hasmeena K., & Kunins, L. (2021) Pharmacotherapy for smoking cessation in adults. *UpToDate.* Retrieved August 8, 2021 from https://www.uptodate.com/contents/pharmacotherapy-for-smoking-cessation-in-adults

Rojewski, A. M., Bailey, S. R., Bernstein, S. L., Cooperman, N. A., Gritz, E. R., Karam-Hage, M. A., Piper, M. E., Rigotti, N. A., & Warren, G. W. (2019). Considering systemic barriers to treating tobacco use in clinical settings in the United States. *Nicotine & Tobacco Research, 21(11),* 1453–1461. https://doi.org/10.1093/ntr/nty123

Sarna, L., Bialous, S. A., Zou, X. N., Wang, W., Hong, J., Wells, M., & Brook, J. (2016). Evaluation of a web-based educational programme on changes in frequency of nurses' interventions to help smokers quit and reduce second-hand smoke exposure in China. *Journal of Advanced Nursing*, *72(1),* 118-126. https://doi:10.1111/jan.12816

Singer, E. (2007). The transtheoretical model and primary care: 'The times they are a changin.' *Journal of the American Academy of Nurse Practitioners*, *19(1),* 11-14. https://doi.org/10.1111/j.1745-7599.2006.00189.x

Sui, A. (2015). Behavioral and pharmacotherapy interventions for tobacco smoking cessation in adults, including pregnant women: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine 163(8),* 622-634. https://doi.org/10.7326/M15-2023

Stead, L.F., Carroll, A.J., & Lancaster, T. (2017) Group behaviour therapy programmes for smoking cessation. *Cochrane Database of Systematic Reviews, 3.* https://doi.org/10.1002/14651858.CD001007.pub3

Stead, L.F., Koilpillai P., Fanshawe, T.R., & Lancaster, T. (2016) Combined pharmacotherapy and behavioral interventions for smoking cessation. *Cochrane Database of Systematic Reviews.* https://doi.org/10.1002/14651858.CD008286.pub3

Strayer, S.M., Martindale, J. R., Pelletier, S.L., Rais, S., Powell, J., & Schorlin, J.B. (2011). Development and evaluation of an instrument for assessing brief behavioral change interventions. *Patient Education and Counseling*, *83*(1), 99-105. https://doi.org/10.1016/j.pec.2010.04.012

Tattan-Birch, H., Hartmann-Boyce, J., Kock, L., Simonavicius, E., Brose, L., Jackson, S., Shahab, L., & Brown, J. (2022) Heated tobacco products for smoking cessation and reducing smoking prevalence. *Cochrane Database of Systematic Reviews, 3.* https://10.1002/14651858.CD013790.pub2

Truth Initiative (2017). Read this before trying to quit 'cold turkey.' https://truthinitiative.org/research-resources/quitting-smoking-vaping/read-trying-quit-smoking-cold-turkey

University of California Regents. (n.d.) Rx for Change: Tobacco Cessation Behavioral Counseling and Pharmacotherapy Program. https://ce.pharmacy.purdue.edu/courses/course/index.php?categoryid=20

U.S. Department of Health and Human Services (2008). *Treating tobacco use and dependence : 2008 an update.* https://www.ncbi.nlm.nih.gov/books/NBK63952/

U.S. Department of Health and Human Services. (2014). *The health consequences of smoking—50 years of progress: A report of the Surgeon General*. https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf

U.S. Department of Health and Human Services. (2020) *Smoking cessation: A report of the Surgeon General.* https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf

U.S. Food and Drug Administration. (n.d.) FDA's deeming regulations for e-cigarettes, cigars, and all other tobacco products. Retrieved August 11, 2021 from https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/fdas-deemingregulations-e-cigarettes-cigars-and-all-other-tobacco-products

U.S. Food and Drug Administration. (2022) Results from the annual national youth tobacco survey. https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey

U.S. Preventive Service Task Force. (2021). Interventions for tobacco smoking cessation in adults including pregnant persons. *Journal of American Medical Association. 325*(3), 265-279. https://doi.org/10.1001/jama.2020.25019.

University of North Carolina School of Family Medicine (2019). 2019 training manual – Duke-UNC tobacco treatment specialist training program. North Carolina Department of Health and Human Services.

White A.R., Rampes H., Liu J.P., Stead L.F., Campbell J. (2014). Acupuncture and related interventions for smoking cessation. *Cochrane Database of Systematic Reviews.* https://doi.org/10.1002/14651858.CD000009.pub3

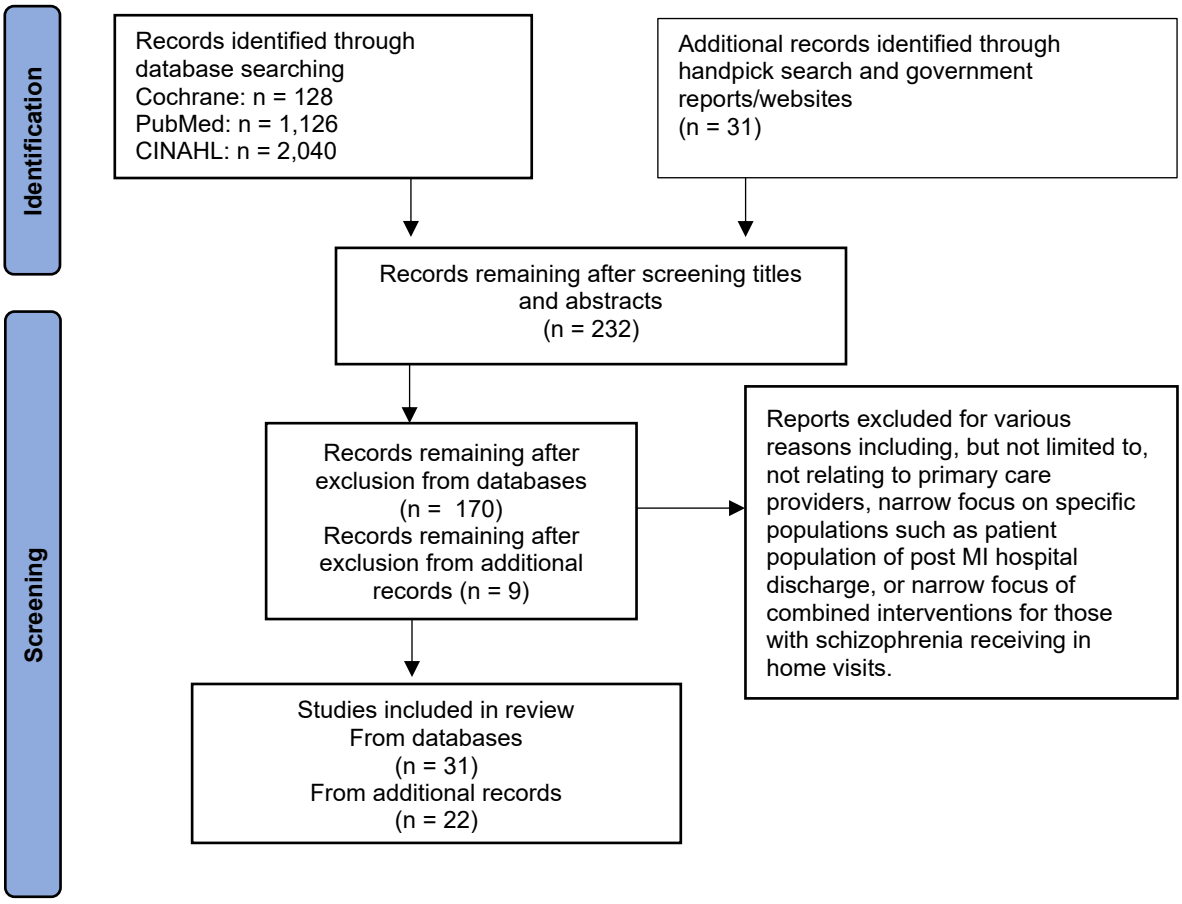
World Health Organization [WHO] (2020). *Tobacco*. https://www.who.int/news-room/fact-sheets/detail/tobacco

World Health Organization (2014). Toolkit for delivering the 5 A's and 5 R's brief tobacco interventions in primary care. https://apps.who.int/iris/bitstream/handle/10665/112835/9789241506953_eng.pdf

APPENDIX A: PRISMA FLOW DIAGRAM

Identification of studies via databases

	"Tobacco cessation" AND "primary care"	"Smoking Cessation" AND "primary care"	"Smoking cessation" AND "primary care" AND "education"	"tobacco cessation"	Totals
Cochrane Reviews	n = 15	n = 26	n = 4	n = 83	128
PubMed	n = 148	n = 225	n = 88	n = 665	1,126
CINAHL	n = 198	n = 709	n = 573	n = 560	2,040
Total	n = 361	n = 960	n = 665	n = 1,308	3294
Limits: 2015- October 2020, English language, Adults, Systematic Reviews, Randomized Control Trials, Meta-Analysis *Exclusions applied: non-English, ages other than adults, editorials, commentaries, clinical trials* *Number of duplicates were not identified- but there were many across databases and searches*					



APPENDIX B: PHARMACOLOGIC PRODUCT GUIDE

Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	**Lozenge**	**Transdermal Patch**	**Nasal Spray**	**Oral Inhaler**		
Product	**Nicorette**[1]**, Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint (various)	**Nicorette**[1]**, Generic** **Nicorette**[1] **Mini** OTC 2 mg, 4 mg; cinnamon, cherry, mint	**Habitrol**[2]**, NicoDerm CQ**[1]**, Generic** OTC 7 mg, 14 mg, 21 mg (24-hr release)	**Nicotrol NS**[3] Rx Metered spray 10 mg/mL nicotine solution	**Nicotrol Inhaler**[3] Rx 10 mg cartridge delivers 4 mg inhaled vapor	**Generic** (formerly Zyban) Rx 150 mg sustained-release tablet	**Chantix**[3] Rx 0.5 mg, 1 mg tablet
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Concomitant therapy with medications/conditions known to lower the seizure threshold ▪ Hepatic impairment ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years) ▪ Treatment-emergent neuropsychiatric symptoms[5] **Contraindications:** ▪ Seizure disorder ▪ Concomitant bupropion (e.g., Wellbutrin) therapy ▪ Current or prior diagnosis of bulimia or anorexia nervosa ▪ Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines ▪ MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors	▪ Severe renal impairment (dosage adjustment is necessary) ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years) ▪ Treatment-emergent neuropsychiatric symptoms[5]
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours* Weeks 7–9: 1 piece q 2–4 hours* Weeks 10–12: 1 piece q 4–8 hours* **while awake* ▪ Maximum, 24 pieces/day ▪ During initial 6 weeks of treatment, use at least 9 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours* Weeks 7–9: 1 lozenge q 2–4 hours* Weeks 10–12: 1 lozenge q 4–8 hours* **while awake* ▪ Maximum, 20 lozenges/day ▪ During initial 6 weeks of treatment, use at least 9 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime); before recommending, rule out other factors that might be contributing (e.g., drug interaction between caffeine and tobacco smoke, other medications, and lifestyle factors) ▪ Duration: 8–10 weeks	1–2 doses/hour* (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa **while awake* ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ During intial 6-8 weeks of treatment, use at least 8 doses/day ▪ Gradually reduce daily dosage over an additional 4-6 weeks ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 12 weeks	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours* **while awake* ▪ Best effects with continuous puffing for 20 minutes ▪ During initial 6 weeks of treatment use at least 6 cartridges/day ▪ Gradually reduce daily dosage over the following 6-12 weeks ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	150 mg po q AM x 3 days, then 150 mg po bid ▪ Do not exceed 300 mg/day ▪ Begin therapy 1–2 weeks **prior** to quit date ▪ Allow at least 8 hours between doses ▪ Avoid bedtime dosing to minimize insomnia ▪ Dose tapering is not necessary ▪ Duration: 7–12 weeks, with maintenance up to 6 months in selected patients	Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid ▪ Begin therapy 1 week **prior** to quit date ▪ Take dose after eating and with a full glass of water ▪ Dose tapering is not necessary ▪ Dosing adjustment is necessary for patients with severe renal impairment ▪ Duration: 12 weeks; an additional 12-week course may be used in selected patients ▪ May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks

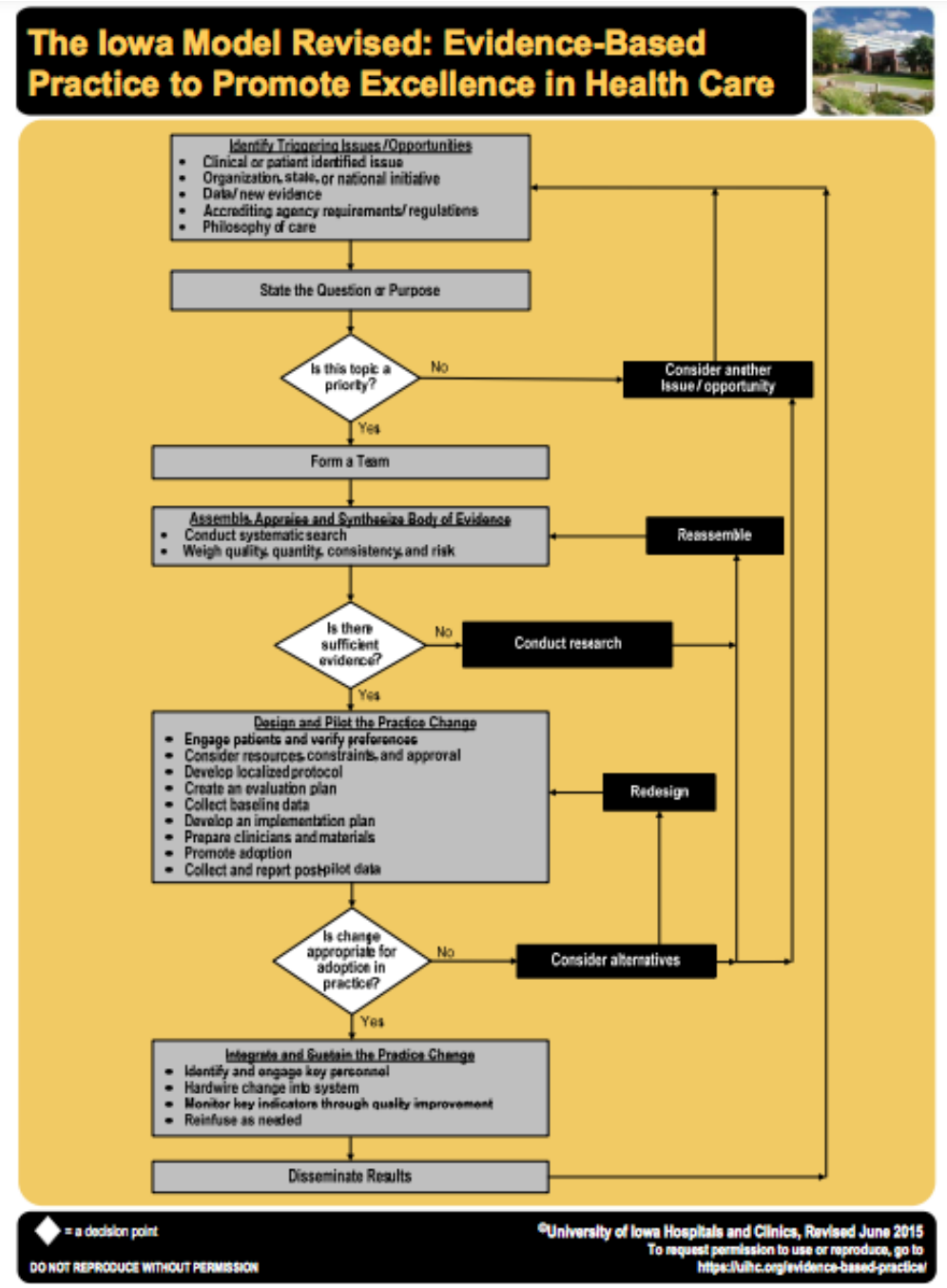
	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	Lozenge	Transdermal Patch	Nasal Spray	Oral Inhaler		
Adverse Effects	▪ Mouth and throat irritation ▪ Jaw muscle soreness ▪ Hiccups ▪ GI complaints (dyspepsia, nausea) ▪ May stick to dental work ▪ Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release): – Lightheadedness/dizziness – Nausea/vomiting – Hiccups – Mouth and throat irritation	▪ Mouth and throat irritation ▪ Hiccups ▪ GI complaints (dyspepsia, nausea)	▪ Local skin reactions (erythema, pruritus, burning) ▪ Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Ocular irritation/tearing ▪ Sneezing ▪ Cough	▪ Mouth and/or throat irritation ▪ Cough ▪ Hiccups ▪ GI complaints (dyspepsia, nausea)	▪ Insomnia ▪ Dry mouth ▪ Nausea ▪ Anxiety/difficulty concentrating ▪ Constipation ▪ Tremor ▪ Rash ▪ Seizures (risk is 0.15%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)	▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Headache ▪ Flatulence ▪ Constipation ▪ Taste alteration ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges ▪ Relatively inexpensive	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges ▪ Relatively inexpensive	▪ Once-daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others ▪ Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours ▪ Relatively inexpensive	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Might delay weight gain ▪ Might be beneficial in patients with depression ▪ Can be used in combination with NRT agents ▪ Relatively inexpensive (generic formulations)	▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Offers a different mechanism of action for patients who have failed other agents ▪ Most effective cessation agent when used as monotherapy
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease ▪ Cost of treatment	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F) ▪ Cost of treatment	▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms[4] (see PRECAUTIONS)	▪ Patients should be monitored for potential neuropsychiatric symptoms[4] (see PRECAUTIONS) ▪ Cost of treatment
Cost/day[6]	2 mg or 4 mg: $1.90–$5.49 (9 pieces)	2 mg or 4 mg: $2.97–$4.23 (9 pieces)	$1.52–$3.49 (1 patch)	$9.64 (8 doses)	$16.38 (6 cartridges)	$0.72 (2 tablets)	$17.20 (2 tablets)

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Dr. Reddy's.
[3] Marketed by Pfizer.
[4] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.
[5] In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.
[6] Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2021.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

APPENDIX C: IOWA MODEL REVISED



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APPENDIX D: PERMISSION TO USE IOWA MODEL

Kimberly Jordan - University of Iowa Hospitals and Clinics <survey-bounce@survey.uiowa.edu>
Thu 11/4/2021 7:57 AM
To: Doan, Jillian

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care*. Click the link below to open.

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APPENDIX E: NDSU IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

02/23/2022

Dr. Kelly Patricia Buettner-Schmidt
Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #IRB0004095, “A Practice Improvement Project Incorporating Tobacco Cessation Education Into a Doctor of Nursing Practice Program”

NDSU Co-investigator(s) and research team:

- Kelly Patricia Buettner-Schmidt
- Jillian Beth Doan

Approval Date: 02/23/2022
Expiration Date: 02/22/2025
Study site(s): This practice improvement project will take place in the NDSU DNP program for both the Bismarck and Fargo, N.D., locations. The NDSU DNP program prepares students to provide advanced nursing care as a family nurse practitioner and is accredited by the Commission on Collegiate Nursing Education (North Dakota State University, n.d.). This education module will be implemented in the NURS 810 Health Promotion course during the spring semester of 2022.
Funding Agency:
The above referenced human subjects research project has been determined exempt (category 1,2) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, *Protection of Human Subjects*).

Please also note the following:

- The study must be conducted as described in the approved protocol.
- Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Promptly report adverse events, unanticipated problems involving risks to subjects or others, or protocol deviations related to this project.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.

NDSU has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

RESEARCH INTEGRITY AND COMPLIANCE
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | ndsu.research@ndsu.edu
Shipping Address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX F: RX FOR CHANGE KNOWLEDGE QUESTIONS

1. According to the CDC, the prevalence of smoking among ADULTS in the US is approximately: Select one:
a. 8%
b. 14% **Correct**
c. 25%
d. 30%
Feedback: The latest CDC survey in 2018 of adult smoking in the US shows a prevalence of 13.7%.

2. When inhaling from a cigarette, nicotine will reach the brain in approximately:
Select one:
a. 5 seconds
b. 15 seconds **Correct**
c. 1 minute
d. 10 minutes
Feedback: Studies by Benowitz et al. in 2009 as well as many other studies show that nicotine reaches the receptor sites in the brain in approximately 15 seconds.

3. For most people who quit smoking, nicotine withdrawal symptoms will generally subside within:
Select one:
a. 24 to 48 hours
b. 7 days
c. 2 to 4 weeks **Correct**
d. 6 months
Feedback: The study, Hughes JR. (2007). Effects of abstinence from tobacco: valid symptoms and time course. Nicotine Tob Res 9:315–27, verifies that nicotine withdrawal symptoms generally subside within two to four weeks in most smokers.

4. The following compound is responsible for the majority of drug interactions with smoking:
Select one:
a. Nicotine
b. Polycyclic aromatic hydrocarbons **Correct**
c. Carbon monoxide
d. Ammonia
Feedback: Polycyclic aromatic hydrocarbons According to several studies (Kroon 2007; Schein, 1995; Zevin & Benowitz, 1999), polycyclic aromatic hydrocarbons are responsible for the drug interactions with smoking, not nicotine.
5. On average, cigarette smokers die approximately ____ years younger than do nonsmokers.
Select one:
a. 2 years
b. 5 years
c. 10 years **Correct**

d. 15 years
Feedback: 10 years A study conducted by Oxford University Professor Richard Doll, a leading cancer epidemiologist, published in 2004, confirmed that, on average, smokers die ten years younger than nonsmokers

6. Which of the following is NOT a component of the "5 A's" for tobacco cessation intervention? Select one:
a. Ask: ask patients about their tobacco use
b. Aware: make patients aware of health consequences of smoking **Correct**
c. Assess: assess patient's readiness to quit
d. Arrange: arrange follow-up care
Feedback: Aware: make patients aware of health consequences of smoking The Clinical Practice Guideline for Treating Tobacco Use and Dependence defines the 5 A's as: ASK, ADVISE, ASSESS, ASSIST, and ARANGE.

7. What is the number for the national toll-free Quit Line? Select one:
a. 1-800 STOP CIGS
b. 1-800 QUIT NOW **Correct**
c. 1-800 NO SMOKE
Feedback: 1-800 QUIT NOW 1 800 QUIT NOW was established as the national toll free telephonic quit line number in 2004.

8. A 28 year-old restaurant manager comes to your clinic with lower back pain that he attributes to long hours of standing. He has been to the clinic three times in the last five years with minor complaints. He smokes between one and two packs a day and claims that it relieves the stress of his job. He reports that he has never seriously tried to quit. If the patient clearly indicates that he is not willing to make an attempt to quit at this time, which of the following would be the most beneficial response/action of the clinician? Select one:
a. Employ motivational interviewing techniques to increase the likelihood that he will attempt to quit in the future. **Correct**
b. Provide patient education information about the risks of smoking and ask him to give you a call after he has had a chance to read it.
c. Negotiate with the patient in order to get him to cut down the number of cigarettes he smokes per day.
d. Recognize his autonomy and indicate that you will raise the issue with him again on his next visit.
Feedback: Employ motivational interviewing techniques to increase the likelihood that he will attempt to quit in the future. Motivational interviewing has been shown to help a hesitant patient find concrete, internal reasons to quit more so than the other techniques mentioned. It is a recommended approach for counseling, per the 2008 Clinical Practice Guideline.

9. A 51 year-old woman is coming to see you as a new patient. She is now living with her daughter and son-in-law, who will be having their first child in three months. She has been a smoker all of her adult life and has made a couple of attempts to quit in the past, but has not been successful for more than a couple of months. She wants to quit smoking by the time the baby is

born. Which of the following strategies is likely to be the most effective in helping this patient quit smoking? Select one:
a. Recommend FDA-approved medication plus counseling **Correct**
b. Connect the patient to a support group
c. Recommend FDA-approved medication plus healthy-lifestyle patient education materials
d. Refer the patient to a counselor plus frequent return visits
Feedback: Recommend FDA-approved medication plus counseling The Clinical Practice Guideline meta-analysis shows that the most effective way to quit smoking is to combine a behavior change program with one of the seven FDA approved cessation medications.

10. This patient is now seeing you four months later. She admits to still sneaking an occasional cigarette, which she smokes in the bathroom under the ventilation fan, when the baby's crying wakes her up at night. It is winter and too cold to go outside to smoke. How would you advise that she deal with the situation? Select one:
a. Make her feel guilty for her behavior
b. Discuss specific coping techniques for the situation **Correct**
c. Refer her to an MD for anxiety medication
Feedback: Discuss specific coping techniques for the situation Teaching a patient alternative ways of coping with urges to smoke has been shown to ensure long term cessation success as opposed to making the person feel guilty or implying that they need anxiety medication

11. Which of the following is proven to increase a patient's success with quitting? Select one:
a. Receiving counseling assistance from a health-care provider
b. Participation in multiple counseling sessions
c. Receiving counseling assistance from multiple types of health-care providers
d. All of the above **Correct**
Feedback: The Clinical Practice Guideline review of best practices clearly indicates that receiving any type of behavioral counseling increases a patient's chance of success. However, multiple sessions and/or multiple providers increase success to a greater degree.

12. A 25 year-old graduate student has scheduled an appointment for her annual physical. During the visit you discuss her smoking (~half pack/day) and she expresses interest in quitting. She has been smoking since she was 18. You suggest a nicotine patch and provide the telephone number of the tobacco quit line. You promise to call her after she has started using the patch to see how she is progressing and to offer counseling. Which of the following would you avoid as an element of practical counseling? Select one:
a. Helping her recognize trigger situations
b. Providing basic information about smoking and quitting
c. Scaring the patient into quitting by showing her pictures of diseased lungs **Correct**
d. Developing coping skills
Feedback: Scaring the patient into quitting by showing her pictures of diseased lungs Years of experience from clinicians nationwide has clearly shown that scaring patients into quitting is not an efficacious strategy. The Clinical Practice Guideline review of the literature shows that helping her recognize her specific trigger situations and teaching her coping skills to deal with them, as well as providing factual information about smoking and quitting, significantly increases the chance of success.

13. A 63 year-old retired general contractor is seeing you because he is starting to experience shortness of breath when playing with his grandchildren. He is currently a 1 pack a day smoker but acknowledges that he has smoked up to 3 packs a day when he was younger. He tells you that he would like to stop smoking. After a brief counseling session, he agrees to use the nicotine patch and identifies a quit date of two weeks from today. How soon would you follow-up with this patient? Select one:
a. Between one and two weeks after his quit date
b. On or within a few days of his quit date **Correct**
c. Before the patient's prescription runs out
d. This should be negotiated with the patient
Feedback: On or within a few days of his quit date Abundant anecdotal evidence shows that patients benefit most from behavioral counseling and clinician support on or as close to their quit day as possible.

14. A 40 year-old is seeing you to get pain medication for a knee injury he suffered playing softball. He tells you that he smoked his last cigarette the previous week and has been using OTC nicotine gum to help maintain his abstinence. He has been dealing with urges with heavier use of the gum. What basic information would you share with this patient to support his abstinence? Select one:
a. Explain the types of withdrawal symptoms that he may experience.
b. Suggest ways that he can avoid temptations and trigger situations.
c. Discuss ways to integrate other desired lifestyle changes into his smoking abstinence.
d. All of the above would be appropriate. **Correct**
Feedback: The Clinical Practice Guideline recommends behavior change techniques, lifestyle modification information, and general education on what to expect when quitting as important components of a successful quit so any of these strategies would be appropriate depending on the specific needs of this patient.

15. This same patient then tells you that he is having a particularly difficult time not smoking after meals. What could you suggest that he do to deal with the temptation in this specific situation? Select one:
a. Just make yourself get through it
b. Brush your teeth immediately after each meal **Correct**
c. Reduce the total number of meals per day
Feedback: Brush your teeth immediately after each meal Specific coping techniques, such as brushing one's teeth, to deal with trigger situations has been shown to significantly increase long term quit rates in many studies done over the last twenty years.

16. Use of an FDA-approved nicotine replacement therapy medication for smoking cessation approximately _____ patients' chances of quitting smoking for 5 or more months. Select one:
a. doubles **Correct**
b. tiples
c. quadruples
d. unclear because data are lacking

Feedback: Based on numerous studies with all five NRT formulations (Cahill et al., 2012; Stead et al., 2012; Hughes et al., 2014), using any one of these cessation medications generally doubles a patient's chance of success.

17. For which of the following nicotine replacement therapy products is dosing based on time-to-first cigarette (TTFC)? Select one:
a. Nicotine oral inhaler
b. Nicotine gum
c. Nicotine lozenge
d. B and C **Correct**
Feedback: According to the Transdisciplinary Tobacco Use Research Center (TTURC) Tobacco Dependence Phenotype Workgroup (2007) time to first cigarette in the morning is a key indication of level of nicotine dependence. (Nicotine Tob Res 9 (Suppl 4):S555–S570.) As such, the use of gum and/or lozenge is a way to dose the medication based on the initial research for product approval.

18. Mr. Crosby comes to the pharmacy for a refill of his medicines. He tells you that he has been taking Zyban (bupropion SR) 150mg BID for 10 days and that his last cigarette was 5 days ago. He states that he is having difficulty sleeping. You advise him to: Select one:
a. Eliminate the second dose of the day
b. Take the second dose of the day earlier, but not less than 8 hours after the first dose of the day **Correct**
c. Not make any changes in his dosing regimen
Feedback: Take the second dose of the day earlier, but not less than 8 hours after the first dose of the day Per package insert, doses must be taken at least 8 hours apart.

19. Which of the following side effects of Varenicline tends to be most common among patients? Select one:
a. Heartburn
b. Insomnia
c. Nausea **Correct**
d. Cough
Feedback: During the initial research studies for approval of the use of Varenicline in smoking cessation, nausea was recorded as the most common side effect among trial participants. It continues to be the primary side effect reported by users. (Pfizer package insert, 2013)

20. When using nicotine gum, lozenge, or oral inhaler, patients should be advised not to eat or drink anything other than water:
Select one:
a. 15 minutes before using the medication
b. While using the medication
c. 15 minutes after using the medication
d. A and B **Correct**
Feedback: A and B Label use instructions for these three products indicate that patients should not eat or drink anything other than water while using the medication, and for 15 minutes prior to use.

21. RC is a 35-year-old male who comes to your pharmacy regularly for his medications. His profile consists of a medication for hypertension and an asthma inhaler. He is 10 pounds overweight, maintains a reasonably healthy diet, and swims three times a week. He smoked almost a pack of cigarettes a day for 15 years but quit "cold turkey" three days ago, because he had been experiencing increased shortness of breath over the past several months.
Today he tells you that he has quit smoking. He says he has been very agitated and has had trouble sleeping the past two nights. He also expresses strong urges to smoke, especially upon waking in the morning. It is clear that he would benefit by using a medication to alleviate his withdrawal symptoms. After discussing his withdrawal symptoms and the non-prescription medication options with you, he chooses the NicoDerm CQ transdermal patch. Which of the following is TRUE regarding the proper use of the nicotine patch? Select one:
a. The patch should not be worn while swimming.
b. Discontinue patch use immediately if there are any signs of redness at the application site.
c. If experiencing difficulty sleeping, he can try removing the patch at bedtime and applying a new patch in the morning. **Correct**
d. The initial dose should be one 14 mg patch applied daily.
Feedback: If experiencing difficulty sleeping, he can try removing the patch at bedtime and applying a new patch in the morning. The label instructions for using NicoDerm CQ state that the patch can be removed at bedtime and a new one applied in the morning for those experiencing sleep disturbances while wearing the patch for 24 hours.

22. FB, a 33-year-old female, requests your assistance with stopping smoking. Upon questioning, you gain the following information: She has smoked 15 cigarettes per day for 15 years and has one previous failed quit attempt when she was able to abstain for two weeks. She has a history of bulimia and moderate but controlled hypertension and is not pregnant. Currently the only meds she is taking is atenolol 25 mg QD. Based on the above information, which of the following medications would NOT be appropriate for FB? Select one:
a. Nicotine gum
b. Nicotine nasal spray
c. Varenicline
d. Bupropion SR **Correct**
Feedback: Bupropion SR Bupropion is contraindicated for those individuals with bulimia per current label instructions.

23. A 57-year-old male, who had been smoking about 1 pack per day, started using the 21 mg nicotine patch 7 days ago. He states that the patch is working well, but he still is experiencing some intermittent, situational urges to smoke, especially after eating, which was his primary trigger. What would be the most appropriate adjustment to medication therapy? Select one:
a. No adjustment; the urges to smoke should lessen within a week
b. Increase the nicotine patch to 42 mg (21 mg x 2 patches) daily
c. Add a short-acting NRT formulation, such as the gum or lozenge as needed **Correct**
d. Switch to an e-cigarette as needed for situational cravings
Feedback: Add a short-acting NRT formulation, such as the gum or lozenge as needed New FDA regulations based on extensive independent research shows that adding a short acting NRT formulation in addition to using the patch is both safe and effective in reducing withdrawal symptoms for those in which monotherapy is not successful.

24. AJ is a 40-year-old female interested in starting OTC nicotine replacement therapy for her upcoming quit attempt. She is participating in a group cessation class and has set a quit date 10 days from now. She has been smoking for 20 years and currently smokes 1½ packs of cigarettes daily. Her only other medical problem is exercise-induced asthma, for which she takes albuterol prn. If AJ were interested in the nicotine patch, which of the following regimens would be most appropriate during the initial four to six weeks of treatment: Select one:
a. 42 mg daily
b. 21mg daily **Correct**
c. 14 mg daily
d. 7 mg daily
Feedback: 21mg daily According to label instructions, the 21 mg patch is indicated for those individuals smoking more than 10 cigarettes a day.

25. Which of the following counseling points is appropriate to discuss with AJ regarding the nicotine patch? Select one:
a. Patch should be worn for 16 hours.
b. It is OK to cut the patch.
c. Should be applied to a low-friction area of the body, generally between neck and waist. **Correct**
d. Common side effects of the patch are dry mouth and nausea.
Feedback: Should be applied to a low-friction area of the body, generally between neck and waist. According to label instructions, the patch should be placed in a dry, clean, hairless, location on the body where there is not a lot of friction that could cause the patch to fall off, i.e. back of neck, upper chest.

APPENDIX G: RX FOR CHANGE MODULE 1 SLIDES

Rx for CHANGE

Clinician-Assisted Tobacco Cessation

TRAINING OVERVIEW

- Epidemiology of Tobacco Use
- Nicotine Pharmacology & Principles of Addiction
- Drug Interactions with Smoking
- Assisting Patients with Quitting
- Aids for Cessation

EPIDEMIOLOGY of TOBACCO USE

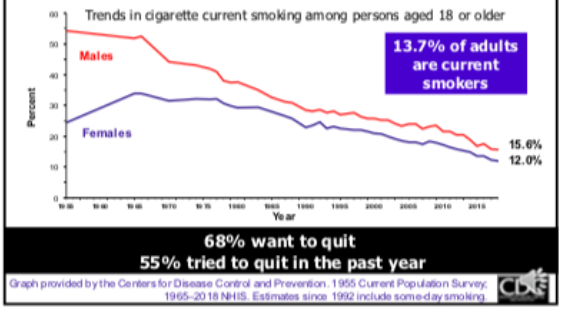
"CIGARETTE SMOKING…

is the chief, single, avoidable cause of death in our society and the most important public health issue of our time."

C. Everett Koop, M.D., former U.S. Surgeon General

All forms of tobacco are harmful.

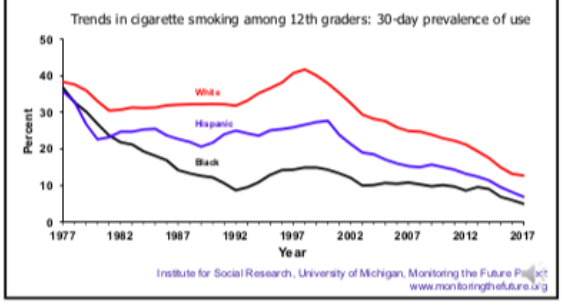
TRENDS in ADULT SMOKING, by SEX—U.S., 1955–2018



68% want to quit
55% tried to quit in the past year

Graph provided by the Centers for Disease Control and Prevention. 1955 Current Population Survey; 1965–2018 NHIS. Estimates since 1992 include some-day smoking.

TRENDS in TEEN SMOKING, by ETHNICITY—U.S., 1977–2017



Institute for Social Research, University of Michigan, Monitoring the Future Project
www.monitoringthefuture.org

COMPOUNDS in TOBACCO SMOKE

An estimated 4,800 compounds in tobacco smoke, including 16 proven human carcinogens

Gases

- Carbon monoxide
- Hydrogen cyanide
- Ammonia
- Benzene
- Formaldehyde

Particles

- Nicotine
- Nitrosamines
- Lead
- Cadmium
- Polonium-210

Nicotine is the addictive component of tobacco products, but it does NOT cause the ill health effects of tobacco use.

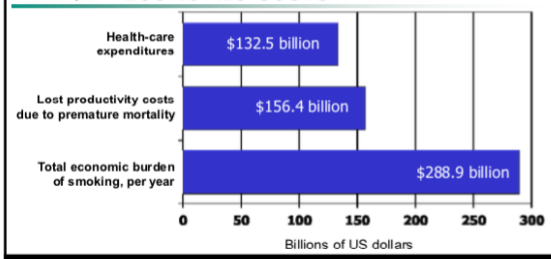
ANNUAL U.S. DEATHS ATTRIBUTABLE to SMOKING, 2005–2009

		Percent of all smoking-attributable deaths
Cardiovascular & metabolic diseases	160,600	33%
Lung cancer	130,659	27%
Pulmonary diseases	113,100	23%
Second-hand smoke	41,280	9%
Cancers other than lung	36,000	7%
Other	1,633	<1%

TOTAL: >480,000 deaths annually

U.S. Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.*

ANNUAL SMOKING-ATTRIBUTABLE ECONOMIC COSTS



Societal costs: $19.16 per pack of cigarettes smoked

U.S. Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.*

2014 REPORT of the SURGEON GENERAL: HEALTH CONSEQUENCES OF SMOKING

MAJOR DISEASE-RELATED CONCLUSIONS:

- Cigarette smoking is causally linked to diseases of nearly all organs of the body, diminished health status, and harm to the fetus.
  - Additionally, smoking has many adverse effects on the body, such as causing inflammation and impairing immune function.
- Exposure to secondhand smoke is causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children.
- Disease risks from smoking by women have risen over the last 50 years and for many tobacco-related diseases are now equal to those for men.

U.S. Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.*

HEALTH CONSEQUENCES of SMOKING

- Cancers
  - Bladder/kidney/ureter
  - Blood (acute myeloid leukemia)
  - Cervix
  - Colon/rectum
  - Esophagus/stomach
  - Liver
  - Lung
  - Oropharynx/larynx
  - Pancreatic
- Pulmonary diseases
  - Asthma
  - COPD
  - Pneumonia/tuberculosis
  - Chronic respiratory symptoms
- Cardiovascular diseases
  - Aortic aneurysm
  - Coronary heart disease
  - Cerebrovascular disease
  - Peripheral vascular disease
- Reproductive effects
  - Reduced fertility in women
  - Poor pregnancy outcomes (e.g., congenital defects, low birth weight, preterm delivery)
  - Infant mortality
- Other: cataract, diabetes (type 2), erectile dysfunction, impaired immune function, osteoporosis, periodontitis, postoperative complications, rheumatoid arthritis

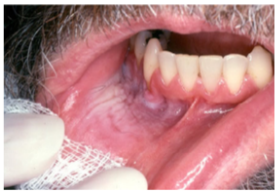
U.S. Department of Health and Human Services (USDHHS). (2014). *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General.*

HEALTH CONSEQUENCES of SMOKELESS TOBACCO USE

Periodontal effects
- Gingival recession
- Bone attachment loss
- Dental caries

Oral leukoplakia

Cancer
- Oral cancer
- Pharyngeal cancer



Oral Leukoplakia
Image courtesy of Dr. Sol Silverman - University of California San Francisco

2006 REPORT of the SURGEON GENERAL:
INVOLUNTARY EXPOSURE to TOBACCO SMOKE

- Second-hand smoke causes premature death and disease in nonsmokers (children and adults)
- Children:
  - Increased risk for sudden infant death syndrome (SIDS), acute respiratory infections, ear problems, and more severe asthma
  - Respiratory symptoms and slowed lung growth if parents smoke
- Adults:
  - Immediate adverse effects on cardiovascular system
  - Increased risk for coronary heart disease and lung cancer
- Millions of Americans are exposed to smoke in their homes/workplaces
- Indoor spaces: eliminating smoking fully protects nonsmokers
  - Separating smoking areas, cleaning the air, and ventilation are ineffecti

There is no safe level of second-hand smoke.

U.S. Department of Health and Human Services (USDHHS). (2006).
The Health Consequences of Involuntary Exposure to Tobacco Smoke: Report of the Surgeon General

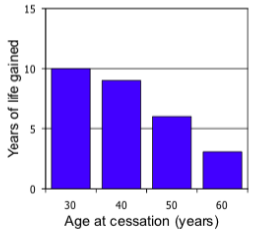
QUITTING: HEALTH BENEFITS

Time Since Quit Date

Circulation improves, walking becomes easier Lung function increases	2 weeks to 3 months	Lung cilia regain normal function
	1 to 9 months	Ability to clear lungs of mucus increases Coughing, fatigue, shortness of breath decrease
Excess risk of CHD decreases to half that of a continuing smoker	1 year	
	5 years	Risk of stroke is reduced to that of people who have never smoked
Lung cancer death rate is approximately half that of a continuing smoker	10 years	
	after 15 years	Risk of CHD is similar to that of people who have never smoke

SMOKING CESSATION: REDUCED RISK of DEATH

- Prospective study of 34,439 male British doctors
- Mortality was monitored for 50 years (1951–2001)



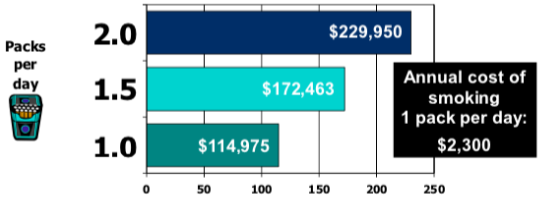
On average, cigarette smokers die approximately 10 years younger than do nonsmokers.

Among those who continue smoking, at least half will die due to a tobacco-related disease.

Doll et al. (2004). *BMJ* 328(7455):1519–1527.

FINANCIAL IMPACT of SMOKING

Buying cigarettes every day for 50 years at $6.30 per pack*
(does not include interest)



Annual cost of smoking 1 pack per day: $2,300

* Average national cost, as of November 2019. Campaign for Tobacco-Free Kids, 2019.

EPIDEMIOLOGY of TOBACCO USE: SUMMARY

- The prevalence of smoking has reduced over time, and fewer than one in five adults are current smokers
- Nearly half a million U.S. deaths are attributable to smoking annually
- Smoking costs the U.S. an estimated $288.9 billion annually
- For the individual, smoking a pack-a-day costs $2,300 annually, plus associated health-care costs
- At any age, there are benefits to quitting smoking

NICOTINE PHARMACOLOGY and PRINCIPLES of ADDICTION

NICOTINE ADDICTION
U.S. Surgeon General's Report

- Cigarettes and other forms of tobacco are addicting.
- Nicotine is the drug in tobacco that causes addiction.
- The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.

U.S. Department of Health and Human Services. (1988). *The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General.*

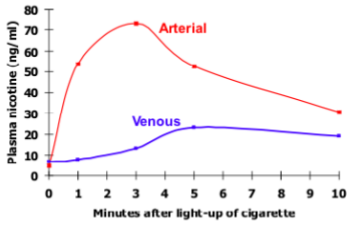
NICOTINE ABSORPTION:
BUCCAL (ORAL) MUCOSA

The pH inside the mouth is 7.0.

Acidic media (limited absorption)	**Alkaline media** (significant absorption)
Cigarettes	Pipes, cigars, spit tobacco, oral nicotine products

Beverages can alter pH, affect absorption.

NICOTINE DISTRIBUTION



Nicotine reaches the brain within 10–20 seconds.

Henningfield et al. (1993). *Drug Alcohol Depend* 33:23–29.

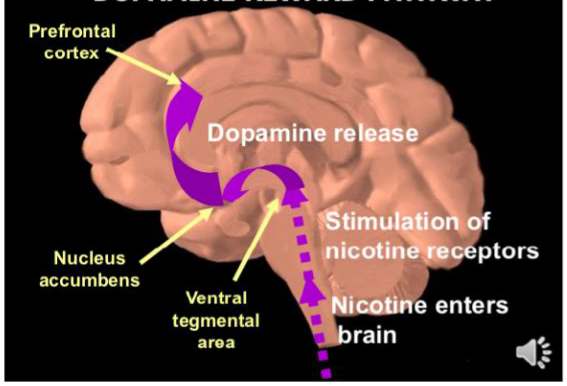
NICOTINE PHARMACODYNAMICS (cont'd)

Central nervous system
- Pleasure
- Arousal, enhanced vigilance
- Improved task performance
- Anxiety relief

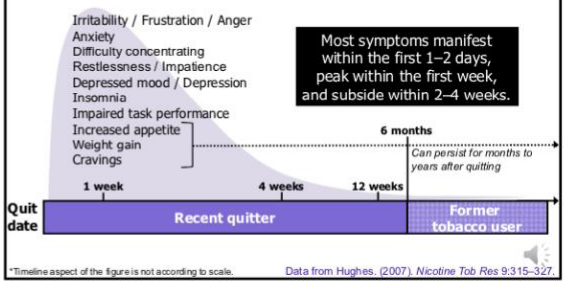
Cardiovascular system
- ↑ Heart rate
- ↑ Cardiac output
- ↑ Blood pressure
- Coronary vasoconstriction
- Cutaneous vasoconstriction

Other
- Appetite suppression
- Increased metabolic rate
- Skeletal muscle relaxation

DOPAMINE REWARD PATHWAY



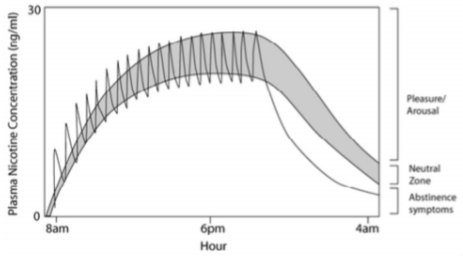
NICOTINE WITHDRAWAL SYMPTOMS:
Time Course*



*Timeline aspect of the figure is not according to scale.

Data from Hughes. (2007). *Nicotine Tob Res* 9:315–327.

NICOTINE ADDICTION CYCLE



Reprinted with permission. Benowitz. (1992). *Med Clin N Am* 2:415–437.

FACTORS CONTRIBUTING to TOBACCO USE

Individual
- Sociodemographics
- Genetic predisposition
- Coexisting medical conditions

Tobacco Use

Pharmacology
- Alleviation of withdrawal symptoms
- Weight control
- Pleasure, mood modulation

Environment
- Tobacco advertising
- Conditioned stimuli
- Social interactions

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TOBACCO DEPENDENCE: A 2-PART PROBLEM

Tobacco Dependence

Physiological	Behavioral
The addiction to nicotine	The habit of using tobacco
↓ Treatment	↓ Treatment
Medications for cessation	Behavior change program

Treatment should address the physiological **and** the behavioral aspects of dependence.

NICOTINE PHARMACOLOGY and ADDICTION: SUMMARY

- Tobacco products are effective delivery systems for the drug nicotine.
- Nicotine is a highly addictive drug that induces a constellation of pharmacologic effects, including activation of the dopamine reward pathway in the brain.
- Tobacco use is complex, involving the interplay of a wide range of factors.
- Treatment of tobacco use and dependence requires a multifaceted treatment approach.

DRUG INTERACTIONS with SMOKING

PHARMACOKINETIC DRUG INTERACTIONS with SMOKING

Drugs that may have a *decreased effect* due to induction of CYP1A2:

- Bendamustine
- Caffeine
- Clozapine
- Erlotinib
- Fluvoxamine
- Haloperidol
- Olanzapine
- Pirfenidone
- Riociguat
- Ropinirole
- Tasimelteon
- Theophylline
- Irinotecan (clearance increased and systemic exposure decreased, due to increased glucuronidation of its active metabolite)

Smoking cessation will reverse these effects.

DRUG INTERACTION: TOBACCO SMOKE and CAFFEINE

- Constituents in tobacco smoke induce CYP1A2 enzymes, which metabolize caffeine
  - Caffeine levels increase ~56% upon quitting
- Challenges:
  - Nicotine withdrawal effects may be enhanced by increased caffeine levels
  - Insomnia can be due to ↑ caffeine levels or a side effect of a smoking cessation drug (e.g., 24-hr nicotine patch, bupropion SR, varenicline)
- Decrease caffeine intake by ~50% when quitting; suggest limit caffeine, especially after early afternoon for individuals with a typical bedtime

DRUG INTERACTIONS WITH TOBACCO SMOKE

Many interactions between tobacco smoke and medications have been identified. Note that in most cases it is the tobacco smoke—not the nicotine—that causes these drug interactions. Tobacco smoke interacts with medications through pharmacokinetic (PK) and pharmacodynamic (PD) mechanisms. PK interactions affect the absorption, distribution, metabolism, or elimination of other drugs, potentially causing an altered pharmacologic response. The majority of PK interactions with smoking are the result of induction of hepatic cytochrome P450 enzymes (primarily CYP1A2). Smokers may require higher doses of medications that are CYP1A2 substrates. Upon cessation, dose reductions might be needed. PD interactions alter the expected response or actions of other drugs. The amount of tobacco smoking needed to have an effect has not been established, and the assumption is that any smoker is susceptible to the same degree of interaction. **The most clinically significant interactions are depicted in the shaded rows.**

Drug/Class	Mechanism of Interaction and Effects
Pharmacokinetic Interactions	
Alprazolam (Xanax®)	• Conflicting data on significance, but possible ↓ plasma concentrations (up to 50%); ↓ half-life (35%).
Bendamustine (Treanda®)	• Metabolized by CYP1A2. Manufacturer recommends using with caution in smokers due to likely ↓ bendamustine concentrations, with ↑ concentrations of its two active metabolites.
Caffeine	• ↑ Metabolism (induction of CYP1A2); ↑ clearance (56%). Caffeine levels likely ↑ after cessation.
Chlorpromazine (Thorazine®)	• ↓ Area under the curve (AUC) (by 36%) and serum concentrations (by 24%). • ↓ Sedation and hypotension possible in smokers; smokers may require ↑ dosages.
Clopidogrel (Plavix®)	• ↑ Metabolism (induction of CYP1A2) of clopidogrel to its active metabolite. • Clopidogrel's effects are enhanced in smokers (≥10 cigarettes/day): significant ↑ platelet inhibition, ↓ platelet aggregation; while improved clinical outcomes have been shown, may also ↑ risk of bleeding.
Clozapine (Clozaril®)	• ↑ Metabolism (induction of CYP1A2); ↓ plasma concentrations (by 18%). • ↑ Levels upon cessation may occur; closely monitor drug levels and reduce dose as required to avoid toxicity.
Erlotinib (Tarceva®)	• ↑ Clearance (24%); ↓ trough serum concentrations (2-fold).

PHARMACODYNAMIC DRUG INTERACTIONS with SMOKING

Smokers who use combined hormonal contraceptives have an increased risk of serious cardiovascular adverse effects:

- Stroke
- Myocardial infarction
- Thromboembolism

This interaction **does not** decrease the efficacy of hormonal contraceptives.

Women who are 35 years of age or older AND smoke at least 15 cigarettes per day are at significantly elevated risk.

APPENDIX H: RX FOR CHANGE MODULE 2 SLIDES

ASSISTING PATIENTS with QUITTING

TOBACCO DEPENDENCE: A 2-PART PROBLEM

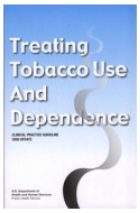
Tobacco Dependence

Physiological	Behavioral
The addiction to nicotine	The habit of using tobacco
Treatment	Treatment
Medications for cessation	Behavior change program

Treatment should address the physiological and the behavioral aspects of dependence.

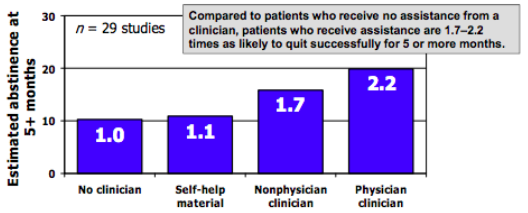
CLINICAL PRACTICE GUIDELINE for TREATING TOBACCO USE and DEPENDENCE

- Update released May 2008
- Sponsored by the U.S. Department of Health and Human Services, Public Heath Service with:
  - Agency for Healthcare Research and Quality
  - National Heart, Lung, & Blood Institute
  - National Institute on Drug Abuse
  - Centers for Disease Control and Prevention
  - National Cancer Institute



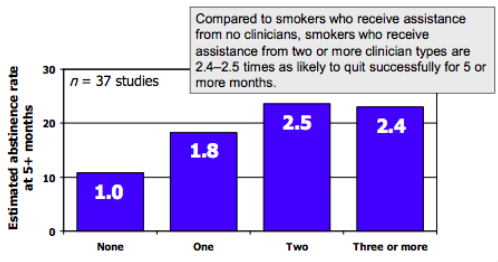
EFFECTS of CLINICIAN INTERVENTIONS

With help from a clinician, the odds of quitting approximately doubles.



Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

The NUMBER of CLINICIAN TYPES CAN MAKE a DIFFERENCE, too



Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

WHY SHOULD CLINICIANS ADDRESS TOBACCO?

- Tobacco users expect to be encouraged to quit by health professionals.
- Screening for tobacco use and providing tobacco cessation counseling are positively associated with patient satisfaction (Barzilai et al., 2001; Conroy et al., 2005).

Failure to address tobacco use tacitly implies that quitting is not important.

Barzilai et al. (2001). *Prev Med* 33:595–599; Conroy et al. (2005). *Nicotine Tob Res* 7 Suppl 1:S29–S34.

The 5 A's

- ASK
- ADVISE
- ASSESS
- ASSIST
- ARRANGE

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

The 5 A's (cont'd)

ASK about tobacco use

- "Do you ever smoke or use other types of tobacco or nicotine, such as e-cigarettes?"
  - "I take time to ask all of my patients about tobacco use—because it's important."
- "Condition X often is caused or worsened by smoking. Do you, or does someone in your household smoke?"
- "Medication X often is used for conditions linked with or caused by smoking. Do you, or does someone in your household smoke?"

The 5 A's (cont'd)

ADVISE tobacco users to quit (clear, strong, personalized)

- "It's important that you quit as soon as possible, and I can help you."
- "Cutting down while you are ill is not enough."
- "Occasional or light smoking is still harmful."
- "I realize that quitting is difficult. It is the most important thing you can do to protect your health now and in the future. I have training to help my patients quit, and when you are ready, I will work with you to design a specialized treatment plan."

The 5 A's (cont'd)

ASSESS readiness to make a quit attempt

ASSIST with the quit attempt

- Not ready to quit: enhance motivation (the 5 R's)
- Ready to quit: design a treatment plan
- Recently quit: relapse prevention

The 5 A's (cont'd)

ARRANGE follow-up care

Number of sessions	Estimated quit rate*
0 to 1	12.4%
2 to 3	16.3%
4 to 8	20.9%
More than 8	24.7%

* 5 months (or more) postcessation

Provide assistance throughout the quit attempt.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

The 5 A's: REVIEW

ASK	about tobacco USE
ADVISE	tobacco users to QUIT
ASSESS	READINESS to make a quit attempt
ASSIST	with the QUIT ATTEMPT
ARRANGE	FOLLOW-UP care

The (DIFFICULT) DECISION to QUIT

- Faced with change, most people are not ready to act.
- Change is a process, not a single step.
- Typically, it takes multiple attempts.

HOW CAN I LIVE WITHOUT TOBACCO?

HELPING PATIENTS QUIT IS a CLINICIAN'S RESPONSIBILITY

TOBACCO USERS DON'T PLAN TO FAIL. MOST FAIL TO PLAN.

Clinicians have a professional obligation to address tobacco use and can have an important role in helping patients plan for their quit attempts.

THE DECISION TO QUIT LIES IN THE HANDS OF EACH PATIENT.

ASSESSING READINESS to QUIT

Patients differ in their readiness to quit.

STAGE 1: Not ready to quit in the next month

STAGE 2: Ready to quit in the next month

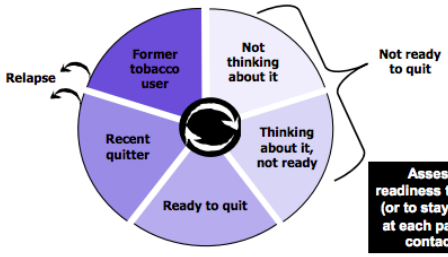
STAGE 3: Recent quitter, quit within past 6 months

STAGE 4: Former tobacco user, quit > 6 months ago

Assessing a patient's readiness to quit enables clinicians to deliver relevant, appropriate counseling messages.

ASSESSING READINESS to QUIT (cont'd)

For most patients, quitting is a cyclical process, and their readiness to quit (or stay quit) will change over time.



ASSESSING READINESS to QUIT (cont'd)

STAGE 1: Not ready to quit

Not thinking about quitting in the next month

- Some patients are aware of the need to quit.
- Patients struggle with ambivalence about change.
- Patients are not ready to change, yet.
- Pros of continued tobacco use outweigh the cons.

GOAL: Start thinking about quitting.

STAGE 1: NOT READY to QUIT Counseling Strategies

DO

- Strongly advise to quit
- Provide information
- Ask noninvasive questions; identify reasons for tobacco use
- Raise awareness of health consequences/concerns
- Demonstrate empathy, foster communication
- Leave decision up to patient

DON'T

- Persuade
- "Cheerlead"
- Tell patient how bad tobacco is, in a judgmental manner
- Provide a treatment plan

STAGE 1: NOT READY to QUIT Counseling Strategies (cont'd)

Consider asking:

"Do you **ever** plan to quit?" → If NO: Advise patients to quit, and offer to assist (if or when they change their mind).

If YES ↓

"What might be some of the benefits of quitting now, instead of later?"

Most patients will agree: there is no "good" time to quit, and there are benefits to quitting sooner as opposed to later.

"What would have to change for you to decide to quit sooner?"

Responses will reveal some of the barriers to quitting.

STAGE 1: NOT READY to QUIT Counseling Strategies (cont'd)

The 5 R's—Methods for enhancing motivation:

- Relevance
- Risks
- Rewards
- Roadblocks
- Repetition

Tailored, motivational messages

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

ASSESSING READINESS to QUIT (cont'd)

STAGE 2: Ready to quit

Ready to quit in the next month

- Patients are aware of the need to, and the benefits of, making the behavioral change.
- Patients are getting ready to take action.

GOAL: Achieve cessation.

STAGE 2: READY to QUIT Three Key Elements of Counseling

- Assess tobacco use history
- Discuss key issues
- Facilitate quitting process
  - Practical counseling (problem solving/skills training)
  - Social support delivered as part of treatment

STAGE 2: READY to QUIT Assess Tobacco Use History

- Praise the patient's readiness
- Assess tobacco use history
  - Current use: type(s) of tobacco, amount
  - Past use: duration, recent changes
  - Past quit attempts:
    - Number, date, length
    - Methods/medications used, adherence, duration
    - Reasons for relapse

STAGE 2: READY to QUIT Discuss Key Issues

- Reasons/motivation to quit
- Confidence in ability to quit
- Triggers for tobacco use
  - What situations lead to temptations to use tobacco?
  - What led to relapse in the past?
- Routines/situations associated with tobacco use
  - When drinking coffee
  - While driving in the car
  - When bored or stressed
  - While watching television
  - While at a bar with friends
  - After meals or after sex
  - During breaks at work
  - While on the telephone
  - While with specific friends or family members who use tobacco

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Stress-Related Tobacco Use

THE MYTHS

- "Smoking gets rid of all my stress."
- "I can't relax without a cigarette."

THE FACTS

- There will always be stress in one's life.
- There are many ways to relax without a cigarette.

Smokers confuse the relief of withdrawal with the feeling of relaxation.

STRESS MANAGEMENT SUGGESTIONS:

Deep breathing, shifting focus, taking a break.

On average, quitters gain 9 to 11 pounds, but there is a wide range.

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Concerns about Weight Gain

- Discourage strict dieting while quitting
  - Encourage healthful diet and meal planning
  - Suggest increasing water intake or chewing sugarless gum
  - Recommend selection of nonfood rewards
- When fear of weight gain is a barrier to quitting
  - Consider pharmacotherapy with evidence of delaying weight gain (bupropion SR or 4-mg nicotine gum or lozenge)
  - Assist patient with weight maintenance or refer patient to specialist or program

STAGE 2: READY to QUIT
Discuss Key Issues (cont'd)

Concerns about Withdrawal Symptoms

- Most pass within 2–4 weeks after quitting
- Cravings can last longer, up to several months or years
  - Often can be ameliorated with cognitive or behavioral coping strategies
- Refer to Withdrawal Symptoms Information Sheet
  - Symptom, cause, duration, relief

Most symptoms manifest within the first 1–2 days, peak within the first week, and subside within 2–4 weeks.

STAGE 2: READY to QUIT
Facilitate Quitting Process

- Discuss methods for quitting
  - Discuss pros and cons of available methods
  - Pharmacotherapy: a treatment, not a crutch!
  - Importance of behavioral counseling
- Set a quit date
- Recommend Tobacco Use Log
  - Helps patients to understand when and why they use tobacco
  - Identifies activities or situations that trigger tobacco use
  - Can be used to develop coping strategies to overcome the temptation to use tobacco

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Tobacco Use Log: Instructions for use

- Continue regular tobacco use for 3 or more days
- Each time any form of tobacco is used, log the following information:
  - Time of day
  - Activity or situation during use
  - "Importance" rating (scale of 1–3)

- Review log to identify situational triggers for tobacco use; develop patient-specific coping strategies

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

- Discuss coping strategies
  - Cognitive coping strategies
    - Focus on retraining the way a patient thinks
  - Behavioral coping strategies
    - Involve specific actions to reduce risk for relapse

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Cognitive Coping Strategies

- Review commitment to quit
- Distractive thinking
- Positive self-talk
- Relaxation through imagery
- Mental rehearsal and visualization

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Cognitive Coping Strategies: Examples

- Thinking about cigarettes doesn't mean you have to smoke one:
  - "Just because you think about something doesn't mean you have to do it!"
  - Tell yourself, "It's just a thought," or "I am in control."
- As soon as you get up in the morning, look in the mirror and say to yourself:
  - "I am proud that I made it through another day without tobacco."
- Reframe how you think about yourself:
  - Begin thinking of yourself as a non-smoker, instead of as a struggling quitter

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

Behavioral Coping Strategies

- Control your environment
  - Tobacco-free home and workplace
  - Remove cues to tobacco use; actively avoid trigger situations
  - Modify behaviors that you associate with tobacco: when, what, where, how, with whom
- Substitutes for smoking
  - Water, sugar-free chewing gum or hard candies (oral substitutes)
- Minimize stress where possible, obtain social support, take a break, and alleviate withdrawal symptoms

STAGE 2: READY to QUIT
Facilitate Quitting Process (cont'd)

- Provide medication counseling
  - Promote adherence
  - Discuss proper use, with demonstration
- Discuss concept of "slip" versus relapse
  - "Let a slip slide."
- Offer to assist throughout quit attempt
  - Follow-up contact #1: first week after quitting
  - Follow-up contact #2: in the first month
  - Additional follow-up contacts as needed
- Congratulate the patient!

ASSESSING
READINESS to QUIT (cont'd)

STAGE 3: Recent quitter

Actively trying to quit for good

- Patients have quit using tobacco sometime in the past 6 months and are taking steps to increase their success.
- Withdrawal symptoms occur.
- Patients are at risk for relapse.

GOAL: Remain tobacco-free for at least 6 months

STAGE 3: RECENT QUITTERS
Evaluate the Quit Attempt

- Tailor interventions to match each patient's needs
- Status of attempt
  - Ask about social support
  - Identify ongoing temptations and triggers for relapse (negative affect, smokers, eating, alcohol, cravings, stress)
  - Encourage healthy behaviors to replace tobacco use
- Slips and relapse
  - Has the patient used tobacco/inhaled nicotine at all—even a puff?
- Medication adherence, plans for termination
  - Is the regimen being followed?
  - Are withdrawal symptoms being alleviated?
  - How and when should pharmacotherapy be terminated?

STAGE 3: RECENT QUITTERS
Facilitate Quitting Process

Relapse Prevention

- Congratulate success!
- Encourage continued abstinence
  - Discuss benefits of quitting, problems encountered, successes achieved, and potential barriers to continued abstinence
  - Ask about strong or prolonged withdrawal symptoms (change dose, combine or extend use of medications)
  - Promote smoke-free environments
- Schedule additional follow-up as needed

ASSESSING
READINESS to QUIT (cont'd)

STAGE 4: Former tobacco user

Tobacco-free for 6 months

- Patients remain vulnerable to relapse.
- Ongoing relapse prevention is needed.

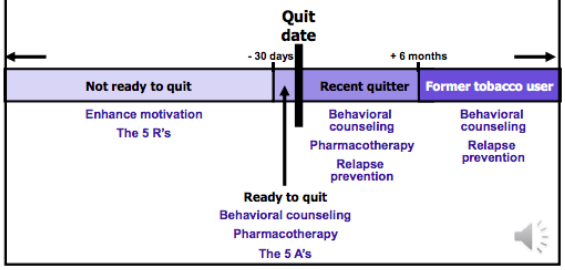
GOAL: Remain tobacco-free for life.

STAGE 4:
FORMER TOBACCO USERS

- Assess status of quit attempt
- Congratulate continued success
- Inquire about and address slips and relapse
- Plans for termination of pharmacotherapy
- Review tips for relapse prevention

Continue to assist throughout the quit attempt.

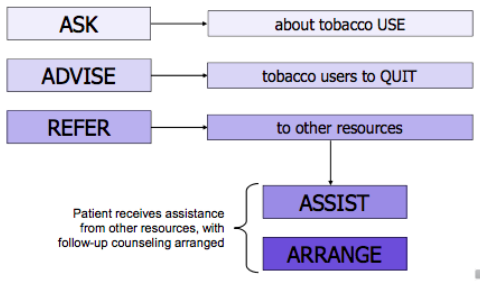
READINESS to QUIT: A REVIEW



COMPREHENSIVE COUNSELING: SUMMARY

- Routinely identify tobacco users (ASK)
- Strongly ADVISE patients to quit
- ASSESS readiness to quit at each contact
- Tailor intervention messages (ASSIST)
  - Be a good listener
  - Minimal intervention in absence of time for more intensive intervention
- ARRANGE follow-up
  - Use the referral process, if needed

BRIEF COUNSELING: ASK, ADVISE, REFER



BRIEF COUNSELING: ASK, ADVISE, REFER (cont'd)

- Brief interventions have been shown to be effective
- In the absence of time or expertise:
  - Ask, advise, and refer to other resources, such as local group programs or the toll-free quitline **1-800-QUIT-NOW**

This brief intervention can be achieved in less than 1 minute.

WHAT ARE "TOBACCO QUITLINES"?

- Tobacco cessation counseling, provided at no cost via telephone to all Americans
- Staffed by highly trained specialists
- Up to 4–6 personalized sessions (varies by state)
- Some state quitlines offer pharmacotherapy at no cost (or reduced cost)
- Up to 30% success rate for patients who complete sessions

Most health-care providers, and most patients are not familiar with tobacco quitlines.

WHEN a PATIENT CALLS the QUITLINE

- Caller is routed to language-appropriate staff
- Brief Questionnaire
  - Contact and demographic information
  - Smoking behavior
- Choice of services
  - Individualized telephone counseling
  - Quitting literature mailed within 24 hrs
  - Referral to local programs, as appropriate

Quitlines have broad reach and are recommended as an effective strategy in the 2008 Clinical Practice Guideline.

MAKE a COMMITMENT...

Address tobacco use
with all patients.

At a minimum,
make a commitment to incorporate brief tobacco interventions as part of routine patient care.

Ask, Advise, and Refer.

The RESPONSIBILITY of HEALTH PROFESSIONALS

It is **inconsistent**
to provide health care and
—at the same time—
remain silent (or inactive)
about a major health risk.

TOBACCO CESSATION is an important component of THERAPY.

DR. GRO HARLEM BRUNTLAND, FORMER DIRECTOR-GENERAL of the WHO:

"If we do not act decisively, a hundred years from now our grandchildren and their children will look back and seriously question how people claiming to be committed to public health and social justice allowed the tobacco epidemic to unfold unchecked."

USDHHS. (2001). *Women and Smoking: A Report of the Surgeon General*. Washington, DC: PHS.

APPENDIX I: RX FOR CHANGE MODULE 3 SLIDES

AIDS for CESSATION

METHODS for QUITTING

- Nonpharmacologic
  - Counseling and other non-drug approaches
- Pharmacologic
  - FDA-approved medications

Counseling and medications are both effective, but the combination of counseling and medication is more effective than either alone.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

PHARMACOLOGIC METHODS: FIRST-LINE THERAPIES

Three general classes of FDA-approved drugs for smoking cessation:

- Nicotine replacement therapy (NRT)
  - Nicotine gum, patch, lozenge, nasal spray, inhaler
- Psychotropics
  - Sustained-release bupropion
- Partial nicotinic receptor agonist
  - Varenicline

PHARMACOTHERAPY

"Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations* for which there is insufficient evidence of effectiveness."

* *Includes pregnant women, smokeless tobacco users, light smokers, and adolescents.*

Medications significantly improve success rates.

Fiore et al. (2008). *Treating Tobacco Use and Dependence: 2008 Update. Clinical Practice Guideline.* Rockville, MD: USDHHS, PHS, May 2008.

NRT: RATIONALE for USE

- Reduces physical withdrawal from nicotine
- Eliminates the immediate, reinforcing effects of nicotine that is rapidly absorbed via tobacco smoke
- Allows patient to focus on behavioral and psychological aspects of tobacco cessation

NRT products approximately doubles quit rates.

NRT: PRODUCTS

Polacrilex gum
- Nicorette (OTC)
- Generic nicotine gum (OTC)

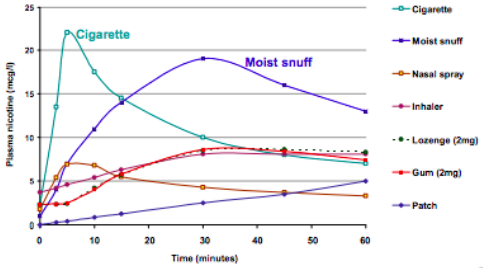
Lozenge
- Nicorette Lozenge (OTC)
- Nicorette Mini Lozenge (OTC)
- Generic nicotine lozenge (OTC)

Transdermal patch
- NicoDerm CQ (OTC)
- Generic nicotine patches (OTC, Rx)

Nasal spray
- Nicotrol NS (Rx)

Inhaler
- Nicotrol (Rx)

PLASMA NICOTINE CONCENTRATIONS for NICOTINE-CONTAINING PRODUCTS



NRT: PRECAUTIONS

- Patients with underlying cardiovascular disease
  - Recent myocardial infarction (within past 2 weeks)
  - Serious arrhythmias
  - Serious or worsening angina

NRT products may be appropriate for these patients if they are under medical supervision.

NICOTINE GUM
Nicorette; generics

- Resin complex
  - Nicotine
  - Polacrilin
- Sugar-free chewing gum base
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg; original, cinnamon, fruit and mint (various) flavors

NICOTINE GUM: DOSING

Dosage is based on the "time to first cigarette" (TTFC) as an indicator of nicotine dependence

Use the 2 mg gum:
If you smoke your first cigarette more than 30 minutes after waking

Use the 4 mg gum:
If you smoke your first cigarette of the day within 30 minutes of waking

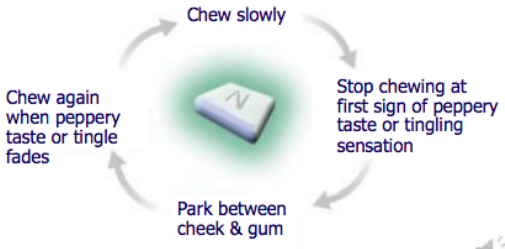
NICOTINE GUM: DOSING (cont'd)

Recommended Usage Schedule for Nicotine Gum		
Weeks 1–6	**Weeks 7–9**	**Weeks 10–12**
1 piece q 1–2 h	**1 piece q 2–4 h**	**1 piece q 4–8 h**
DO NOT USE MORE THAN 24 PIECES PER DAY.		

NICOTINE GUM: DIRECTIONS for USE

- Chew each piece very *slowly* several times
- Stop chewing at first sign of peppery taste or slight tingling in mouth (~15 chews, but varies)
- "Park" gum between cheek and gum (to allow absorption of nicotine across buccal mucosa)
- Resume slow chewing when taste or tingle fades
- When taste or tingle returns, stop and park gum in different place in mouth
- Repeat chew/park steps until most of the nicotine is gone (taste or tingle does not return; generally 30 minutes)

NICOTINE GUM: CHEWING TECHNIQUE SUMMARY



NICOTINE GUM: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine pieces of gum daily
- The effectiveness of nicotine gum may be reduced by some foods and beverages:
  - Coffee
  - Wine
  - Juices
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using nicotine gum.

NICOTINE GUM: ADD'L PATIENT EDUCATION (cont'd)

- Chewing gum will *not* provide same rapid satisfaction that smoking provides
- Chewing gum too rapidly can cause excessive release of nicotine, resulting in
  - Lightheadedness
  - Nausea and vomiting
  - Irritation of throat and mouth
  - Hiccups
  - Indigestion

NICOTINE GUM: ADD'L PATIENT EDUCATION (cont'd)

- Side effects of nicotine gum include
  - Mouth soreness
  - Hiccups
  - Dyspepsia
  - Jaw muscle ache
- Nicotine gum may stick to dental work
  - Discontinue use if excessive sticking or damage to dental work occurs

NICOTINE GUM: SUMMARY

ADVANTAGES

- Might serve as an oral substitute for tobacco
- Might delay weight gain
- Can be titrated to manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Might be problematic for patients with significant dental work
- Proper chewing technique is necessary for effectiveness and to minimize adverse effects
- Gum chewing might not be acceptable or desirable for some patients

NICOTINE LOZENGE

Nicorette Lozenge and Nicorette Mini Lozenge; generics

- Nicotine polacrilex formulation
  - Delivers ~25% more nicotine than equivalent gum dose
- Sugar-free mint, cherry flavors
- Contains buffering agents to enhance buccal absorption of nicotine
- Available: 2 mg, 4 mg

NICOTINE LOZENGE: DOSING

Dosage is based on the "time to first cigarette" (TTFC) as an indicator of nicotine dependence

Use the 2 mg lozenge:

If you smoke your first cigarette more than 30 minutes after waking

Use the 4 mg lozenge:

If you smoke your first cigarette of the day within 30 minutes of waking

NICOTINE LOZENGE: DOSING (cont'd)

Recommended Usage Schedule for the Nicotine Lozenge		
Weeks 1–6	**Weeks 7–9**	**Weeks 10–12**
1 lozenge q 1–2 h	**1 lozenge q 2–4 h**	**1 lozenge q 4–8 h**
DO NOT USE MORE THAN 20 LOZENGES PER DAY.		

NICOTINE LOZENGE: DIRECTIONS for USE

- Use according to recommended dosing schedule
- Place in mouth and allow to dissolve slowly (nicotine release may cause warm, tingling sensation)
- Do not chew or swallow lozenge
- Occasionally rotate to different areas of the mouth
- Lozenges will dissolve completely in about 20–30 minutes

NICOTINE LOZENGE: ADDITIONAL PATIENT EDUCATION

- To improve chances of quitting, use at least nine lozenges daily during the first 6 weeks
- The lozenge will *not* provide the same rapid satisfaction that smoking provides
- The effectiveness of the nicotine lozenge may be reduced by some foods and beverages:
  - Coffee
  - Juices
  - Wine
  - Soft drinks

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine lozenge.

NICOTINE LOZENGE: ADD'L PATIENT EDUCATION (cont'd)

- Side effects of the nicotine lozenge include
  - Nausea
  - Hiccups
  - Cough
  - Heartburn
  - Headache
  - Flatulence
  - Insomnia

NICOTINE LOZENGE: SUMMARY

ADVANTAGES

- Might serve as an oral substitute for tobacco
- Use might delay weight gain
- Can be titrated to manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome

TRANSDERMAL NICOTINE PATCH
NicoDerm CQ; generic

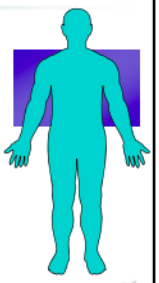
- Nicotine is well absorbed across the skin
- Delivery to systemic circulation avoids hepatic first-pass metabolism
- Plasma nicotine levels are lower and fluctuate less than with smoking

TRANSDERMAL NICOTINE PATCH: DOSING

Product	Light Smoker	Heavy Smoker
NicoDerm CQ	**≤10 cigarettes/day** Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	**>10 cigarettes/day** Step 1 (21 mg x 6 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)
Generic	**≤10 cigarettes/day** Step 2 (14 mg x 6 weeks) Step 3 (7 mg x 2 weeks)	**>10 cigarettes/day** Step 1 (21 mg x 4 weeks) Step 2 (14 mg x 2 weeks) Step 3 (7 mg x 2 weeks)

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE

- Choose an area of skin on the upper body or upper outer part of the arm
- Make sure skin is clean, dry, hairless, and not irritated
- Apply patch to different area each day
- Do not use same area again for at least 1 week

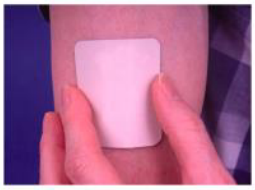


TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Remove patch from protective pouch
- Peel off half of the backing from patch

TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Apply adhesive side of patch to skin
- Peel off remaining protective covering
- Press firmly with palm of hand for 10 seconds
- Make sure patch sticks well to skin, especially around edges



TRANSDERMAL NICOTINE PATCH: DIRECTIONS for USE (cont'd)

- Wash hands: Nicotine on hands can get into eyes or nose and cause stinging or redness
- Do not leave patch on skin for more than 24 hours—doing so may lead to skin irritation
- Adhesive remaining on skin may be removed with rubbing alcohol or acetone
- Dispose of used patch by folding it onto itself, completely covering adhesive area

TRANSDERMAL NICOTINE PATCH: ADDITIONAL PATIENT EDUCATION

- Water will not harm the nicotine patch if it is applied correctly; patients may bathe, swim, shower, or exercise while wearing the patch
- Do *not* cut patches to adjust dose
  - Nicotine may evaporate from cut edges
  - Patch may be less effective
- Keep new and used patches out of the reach of children and pets
- Remove patch before MRI procedures

TRANSDERMAL NICOTINE PATCH: ADD'L PATIENT EDUCATION (cont'd)

- Irritation at the patch site (generally within the first hour):
  - Mild itching
  - Burning
  - Tingling
- Additional possible side effects:
  - Vivid dreams or sleep disturbances
  - Headache

TRANSDERMAL NICOTINE PATCH: ADD'L PATIENT EDUCATION (cont'd)

- After patch removal, skin may appear red for 24 hours
  - If skin stays red more than 4 days or if it swells or a rash appears, contact health care provider—do not apply new patch
- Local skin reactions (redness, burning, itching)
  - Usually caused by adhesive
  - Up to 50% of patients experience this reaction
  - Fewer than 5% of patients discontinue therapy
  - Avoid use in patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)

TRANSDERMAL NICOTINE PATCH: SUMMARY

ADVANTAGES

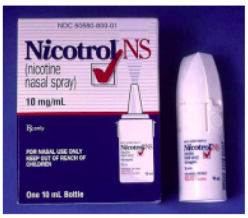
- Once-daily dosing associated with fewer adherence problems
- Of all NRT products, its use is least obvious to others
- Can be used in combination with other agents; delivers consistent nicotine levels over 24 hrs

DISADVANTAGES

- When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms
- Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)

NICOTINE NASAL SPRAY
Nicotrol NS

- Aqueous solution of nicotine in a 10-ml spray bottle
- Each metered dose actuation delivers
  - 50 mcL spray
  - 0.5 mg nicotine
- ~100 doses/bottle
- Rapid absorption across nasal mucosa



NICOTINE NASAL SPRAY: DOSING & ADMINISTRATION

- One dose = 1 mg nicotine (2 sprays, one 0.5 mg spray in **each** nostril)
- Start with 1–2 doses per hour
- Increase prn to *maximum* dosage of 5 doses per hour or 40 mg (80 sprays; ~½ bottle) daily
- For best results, patients should use at least 8 doses daily for the first 6–8 weeks
- Termination:
  - Gradual tapering over an additional 4–6 weeks

NICOTINE NASAL SPRAY: DIRECTIONS for USE (cont'd)

- Prime the pump (before first use)
  - Re-prime (1-2 sprays) if spray not used for 24 hours
- Blow nose (if not clear)
- Tilt head back slightly and insert tip of bottle into nostril as far as comfortable
- Breathe through mouth, and spray once in each nostril
- Do not sniff or inhale while spraying

NICOTINE NASAL SPRAY: ADDITIONAL PATIENT EDUCATION

- What to expect (first week):
  - Hot peppery feeling in back of throat or nose
  - Sneezing
  - Coughing
  - Watery eyes
  - Runny nose
- Side effects should lessen over a few days
  - Regular use during the first week will help in development of tolerance to the irritant effects of the spray
- If side effects do not decrease after a week, contact health care provider

NICOTINE NASAL SPRAY: SUMMARY

ADVANTAGES

- Can be titrated to rapidly manage withdrawal symptoms
- Can be used in combination with other agents to manage situational urges

DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Nasal administration might not be acceptable/desirable for some patients; nasal irritation often problematic
- Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease

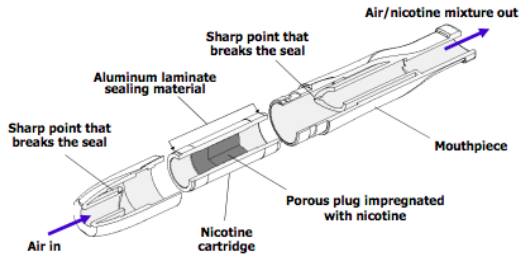
NICOTINE INHALER
Nicotrol Inhaler

- Nicotine inhalation system consists of:
  - Mouthpiece
  - Cartridge with porous plug containing 10 mg nicotine and 1 mg menthol
- Delivers 4 mg nicotine vapor, absorbed across buccal mucosa

NICOTINE INHALER: DOSING

- Start with at least 6 cartridges/day during the first 3-6 weeks of treatment
  - Increase prn to *maximum* of 16 cartridges/day
  - In general, use 1 cartridge every 1-2 hours
- Recommended duration of therapy is 3 months
- Gradually reduce daily dosage over the following 6–12 weeks

NICOTINE INHALER: SCHEMATIC DIAGRAM



Reprinted with permission from Schneider et al. (2001). *Clinical Pharmacokinetics* 40:661–684. Adis International, Inc.

NICOTINE INHALER: DIRECTIONS for USE

- During inhalation, nicotine is vaporized and absorbed across oropharyngeal mucosa
- Inhale into back of throat or puff in short breaths
- Nicotine in cartridges is depleted after about 20 minutes of active puffing
  - Cartridge does *not* have to be used all at once—try different schedules (e.g., 5 minutes at a time) to find what works best
  - Open cartridge retains potency for 24 hours
- Mouthpiece is reusable; clean regularly with mild detergent

NICOTINE INHALER: ADDITIONAL PATIENT EDUCATION

- Side effects associated with the nicotine inhaler include:
  - Mild irritation of the mouth or throat
  - Cough
  - Headache
  - Rhinitis
  - Dyspepsia
- Severity generally rated as mild, and frequency of symptoms declined with continued use

NICOTINE INHALER: ADD'L PATIENT EDUCATION (cont'd)

- Use inhaler at room temperature (>60°F); in cold environments, the delivery of nicotine vapor may be compromised
- Use the inhaler longer and more often at first to help control cravings (best results are achieved with frequent continuous puffing over 20 minutes)
- Effectiveness of the nicotine inhaler may be reduced by some foods and beverages

Do NOT eat or drink for 15 minutes BEFORE or while using the nicotine inhaler.

NICOTINE INHALER: SUMMARY

ADVANTAGES

- Might serve as an oral substitute for tobacco
- Can be titrated to manage withdrawal symptoms
- Mimics the hand-to-mouth ritual of smoking
- Can be used in combination with other agents to manage situational urges

DISADVANTAGES

- Need for frequent dosing can compromise adherence
- Cartridges might be less effective in cold environments (≤60°F)

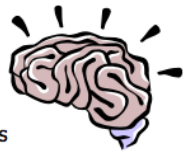
BUPROPION SR

Zyban; generics

- Nonnicotine cessation aid
- Sustained-release antidepressant
- Oral formulation

BUPROPION: MECHANISM of ACTION

- Atypical antidepressant thought to affect levels of various brain neurotransmitters
  - Dopamine
  - Norepinephrine
- Clinical effects
  - ↓ craving for cigarettes
  - ↓ symptoms of nicotine withdrawal



BUPROPION: PHARMACOKINETICS

Absorption
- Bioavailability: 5–20%

Metabolism
- Undergoes extensive hepatic metabolism (CYP2B6)

Elimination
- Urine (87%) and feces (10%)

Half-life
- Bupropion (21 hours); metabolites (20–37 hours)

BUPROPION: CONTRAINDICATIONS

- Patients with a seizure disorder
- Patients with a current or prior diagnosis of bulimia or anorexia nervosa
- Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates and antiepileptic drugs
- Patients taking MAO inhibitors (within 14 days of initiating or discontinuing therapy)

BUPROPION: WARNINGS and PRECAUTIONS (cont'd)

Bupropion should be used with caution in the following populations:

- Patients with an elevated risk for seizures, including:
  - Severe head injury
  - Concomitant use of medications that lower the seizure threshold (e.g., other bupropion products, antipsychotics, tricyclic antidepressants, theophylline)
  - Severe hepatic impairment
- Patients with underlying neuropsychiatric conditions

For a comprehensive listing of warnings and precautions, refer to the manufacturer's prescribing information.

BUPROPION: WARNINGS and PRECAUTIONS

- Neuropsychiatric symptoms and suicide risk
  - Changes in mood (including depression and mania)
  - Psychosis/hallucinations/paranoia/delusions
  - Homicidal ideation
  - Aggression/hostility/anxiety/panic
  - Suicidal ideation, suicide attempt, completed suicide

FDA boxed warning removed Dec 2016

Advise patients to stop taking bupropion SR and contact a health care provider immediately if symptoms such as agitation, depressed mood, or changes in behavior or thinking that are not typical are observed or if the patient develops suicidal ideation or suicidal behavior.

BUPROPION SR: DOSING

To ensure that therapeutic plasma levels of the drug are achieved, patients should begin therapy 1 to 2 weeks PRIOR to their quit date.

Initial treatment
- 150 mg po q AM for 3 days

Then...
- 150 mg po bid for 7–12 weeks
- Doses must be administered at least 8 hours apart
- Tapering not necessary when discontinuing therapy

BUPROPION: ADVERSE EFFECTS

Common side effects include the following:
- Insomnia (avoid bedtime dosing)
- Dry mouth

Less common but reported effects:
- Tremor
- Skin rash

BUPROPION SR: SUMMARY

ADVANTAGES

- Oral dosing is simple and associated with fewer adherence problems
- Might delay weight gain
- Bupropion might be beneficial in patients with depression
- Can be used in combination with NRT agents

DISADVANTAGES

- Seizure risk is increased
- Several contraindications and precautions preclude use in some patients
- Patients should be monitored for neuropsychiatric symptoms

VARENICLINE
Chantix

- Nonnicotine cessation aid
- Partial nicotinic receptor agonist
- Oral formulation

VARENICLINE: MECHANISM of ACTION

- Binds with high affinity and selectivity at $\alpha_4\beta_2$ neuronal nicotinic acetylcholine receptors
  - Stimulates low-level agonist activity
  - Competitively inhibits binding of nicotine
- Clinical effects
  - ↓ symptoms of nicotine withdrawal
  - Blocks dopaminergic stimulation responsible for reinforcement & reward associated with smokin

VARENICLINE: PHARMACOKINETICS

Absorption

- Virtually complete (~90%) after oral administration; not affected by food

Metabolism

- Undergoes minimal metabolism

Elimination

- Primarily renal through glomerular filtration and active tubular secretion; 92% excreted unchanged in urine

Half-life

- 24 hours

VARENICLINE: WARNINGS and PRECAUTIONS

- Neuropsychiatric symptoms and suicide risk
  - Changes in mood (including depression and mania)
  - Psychosis/hallucinations/paranoia/delusions
  - Homicidal ideation
  - Aggression/hostility/anxiety/panic
  - Suicidal ideation, suicide attempt, completed suicide

FDA boxed warning removed Dec 2016

Advise patients to stop taking varenicline and contact a health care provider immediately if symptoms such as agitation, depressed mood, or changes in behavior or thinking that are not typical are observed or if the patient deve suicidal ideation or suicidal behavior.

VARENICLINE: WARNINGS and PRECAUTIONS (cont' d)

In some patients, use of varenicline has been associated with:

- Seizures
- Enhanced effects of alcohol
- Accidental injury
- Cardiovascular events
- Angioedema and hypersensitivity reactions
- Serious skin reactions

These are rare events and most have not been causally linked to varenicline us

VARENICLINE: STANDARD DOSING

Patients should begin therapy 1 week PRIOR to their quit date. The dose is gradually increased to minimize treatment-related nausea and insomnia.

	Treatment Day	Dose
Initial dose titration	Day 1 to day 3	0.5 mg qd
	Day 4 to day 7	0.5 mg bid
	Day 8 to end of treatment*	1 mg bid

* Up to 12 wee

VARENICLINE QUIT APPROACHES

FIXED QUIT approach
- Set quit date for 1 week after starting varenicline
- Continue treatment for 12 weeks

FLEXIBLE QUIT approach
- Start taking varenicline and pick a quit date between 8 to 35 days from treatment initiation
- Continue treatment for 12 weeks

GRADUAL QUIT approach
- Start taking varenicline and reduce smoking by 50% within the first 4 weeks, an additional 50% in the next 4 weeks, and continue until complete abstinence by 12 weeks

Images from: https://www.pfizerpro.com/product/chantix/hcp/quit-approaches

VARENICLINE: ADVERSE EFFECTS

Common adverse effects include the following:
- Nausea
- Insomnia
- Abnormal dreams
- Headache

Less common adverse effects:
- Gastrointestinal (flatulence, constipation)
- Taste alteration

VARENICLINE: ADDITIONAL PATIENT EDUCATION

- Doses should be taken after eating, with a full glass of water
- Nausea and insomnia are usually temporary side effects
  - If symptoms persist, notify your health care provider
- May experience vivid, unusual or strange dreams during treatment
- Use caution driving, drinking alcohol, and operating machinery until effects of quitting smoking with varenicline are known

VARENICLINE: SUMMARY

ADVANTAGES
- Oral dosing is simple and associated with fewer adherence problems
- Offers a different mechanism of action for persons who have failed other agents

DISADVANTAGES
- Should be taken with food or a full glass of water to reduce the incidence of nausea
- Patients should be monitored for potential neuropsychiatric symptoms
- Post-marketing surveillance data indicate potential for neuropsychiatric symptoms and adverse effects not shown to be prevalent in randomized trials

VARENICLINE and BUPROPION SR: Safety Update

The "EAGLES study": FDA-mandated clinical trial
- 8,144 participants (4,116 with a psychiatric disorder)
- 140 multinational centers
- 24-week, double-blind; active and placebo-controlled:
  - **Varenicline:** standard dosing, 12 wks
  - **Bupropion SR:** standard dosing, 12 wks
  - **Nicotine patch:** 21 mg/day with standard taper, 12 wks
  - **Placebo:** 12 wks
- All arms: 13 counseling visits, 11 telephone calls
- Follow-up through 24 wks; outcome = continuous abstinence

"EAGLES" = Evaluating Adverse Events in a Global Smoking Cessation Study
Anthenelli RM et al. Lancet 2016;387:2508-2520.

The "EAGLES" STUDY: Safety Data (Weeks 9-24)

Incidence of Moderate or Severe Neuropsychiatric Adverse Events

Patient cohort	Varenicline	Bupropion SR	Nicotine patch	Placebo
Non-psychiatric	1.3%	2.2%	2.5%	2.4%
Psychiatric	6.5%	6.7%	5.2%	4.9%

No significant differences in neuropsychiatric events by treatment arm

Anthenelli RM et al. Lancet 2016;387:2508-2520.

The "EAGLES" STUDY: Efficacy Data (Weeks 9-24)

Continuous abstinence

Patient cohort	Varenicline	Bupropion SR	Nicotine patch	Placebo
Non-psychiatric	25%	19%	18%	11%
Psychiatric	18%	14%	13%	8%

Highest efficacy with varenicline

Anthenelli RM et al. Lancet 2016;387:2508-2520.

COMBINATION PHARMACOTHERAPY

Regimens with enough evidence to be 'recommended' first-line

- **Combination NRT**
  - Long-acting formulation (patch)
    - Produces relatively constant levels of nicotine

  PLUS

  - Short-acting formulation (gum, lozenge, inhaler, nasal spray)
    - Allows for acute dose titration as needed for nicotine withdrawal symptoms
- **Bupropion SR + Nicotine Patch**

TREATMENT OPTIONS

Multiple Treatment Comparison Meta-Analysis

Comparison	Odds ratio (95% CI)
Nicotine gum vs Placebo	**1.7** (1.5–1.9)
Bupropion SR vs Placebo	**1.9** (1.6–2.1)
Nicotine patch vs Placebo	**1.9** (1.7–2.1)
Other NRT* vs Placebo	**2.0** (1.8–2.4)
Combination NRT vs Placebo	**2.7** (2.1–3.7)
Varenicline vs Placebo	**2.9** (2.4–3.5)

*Includes nicotine nasal spray, lozenge, and inhaler

Strong evidence that combination NRT and varenicline are more effective than bupropion SR or NRT monotherapy

Cahill et al. (2013). *Cochrane Database Syst Rev* 5:CD009329.

COMBINATION NRT: Treatment Regimens

- **Nicotine patch**
  Dose: 21 mg/day x 4–6 wks → 14 mg/day x 2 wks → 7 mg/day x 2 wks

PLUS

- **Nicotine gum or lozenge** (2 mg/4 mg; based on TTFC)
  Dose: Use 1 piece q 1–2 hours as needed

OR

- **Nicotine inhaler** (10 mg cartridge; delivers 4 mg nicotine vapor)
  Dose: Use 1 cartridge q 1–2 hours as needed

OR

- **Nicotine nasal spray** (0.5 mg/spray)
  Dose: Use 1 spray in each nostril q 1–2 hours as needed

IDENTIFY KEY ISSUES to STREAMLINE PRODUCT SELECTION*

- Do you prefer a prescription or non-prescription medication?
- Would it be a challenge for you to take a medication frequently throughout the day, e.g., a minimum of 9 times?
  - With the exception of the nicotine patch, all NRT formulations require frequent dosing throughout the day.
  - If patient is unable to adhere to the recommended dosing, these products should be ruled out as monotherapy because they will be ineffective.

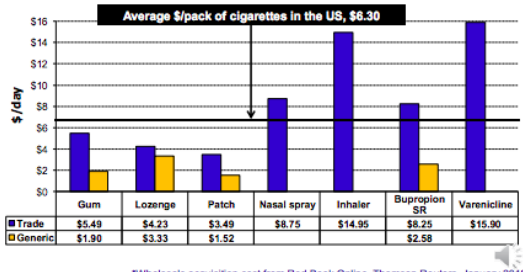
Asking these two questions will significantly reduce the time required for product selection.

* Product-specific screening, for warnings/precautions/contraindications and personal preferences, is also essential.

ADHERENCE IS KEY to QUITTING

- Promote adherence with prescribed regimens.
  - Daily use (use according to dosing schedule, NOT as needed)
  - Full duration of treatment regimen
- Use according to dosing schedule, NOT as needed.
- Consider telling the patient:
  - "When you use a cessation product it is important to read all the directions thoroughly before using the product. The products work best in alleviating withdrawal symptoms when used correctly, and according to the recommended dosing schedule."

COMPARATIVE DAILY COSTS of PHARMACOTHERAPY



	Gum	Lozenge	Patch	Nasal spray	Inhaler	Bupropion SR	Varenicline
Trade	$5.49	$4.23	$3.49	$8.75	$14.95	$8.25	$15.90
Generic	$1.90	$3.33	$1.52			$2.58	

*Wholesale acquisition cost from Red Book Online, Thomson Reuters, January 2019

SUMMARY

- To maximize success, interventions should include counseling and one or more medications
- Clinicians should encourage the use of effective medications by all patients attempting to quit smoking
  - Exceptions include medical contraindications or use in specific populations for which there is insufficient evidence of effectiveness
- First-line medications that reliably increase long-term smoking cessation rates include:
  - Bupropion SR
  - Nicotine replacement therapy (gum, lozenge, patch, nasal spray, inhaler)
  - Varenicline
- Varenicline and combination NRT approaches demonstrate the highest level of efficacy

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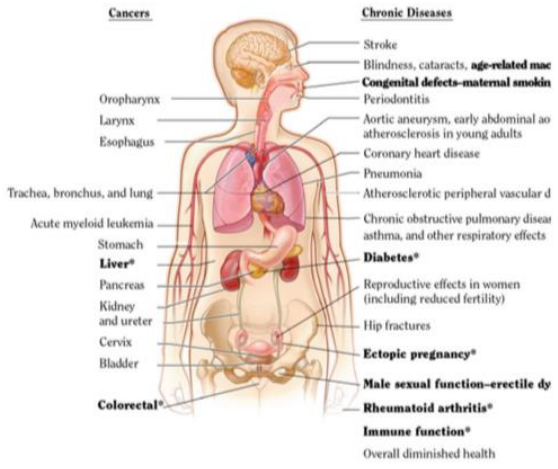
APPENDIX J: IN-CLASS PRESENTATION SLIDES

What is the problem?

- In 2019:
- 23.4% of adults in N.D. used tobacco products
  - 17% smoked cigarettes
- 19.7 % of adults in the U.S. used tobacco products
  - 14% smoked cigarettes
- ND youth (grade 9-12): 35% used tobacco products
  - 33% used e-cigarettes
  - 52% had tried an e—cigarette

(CDC, n.d.a; North Dakota Department of Health 2021b).

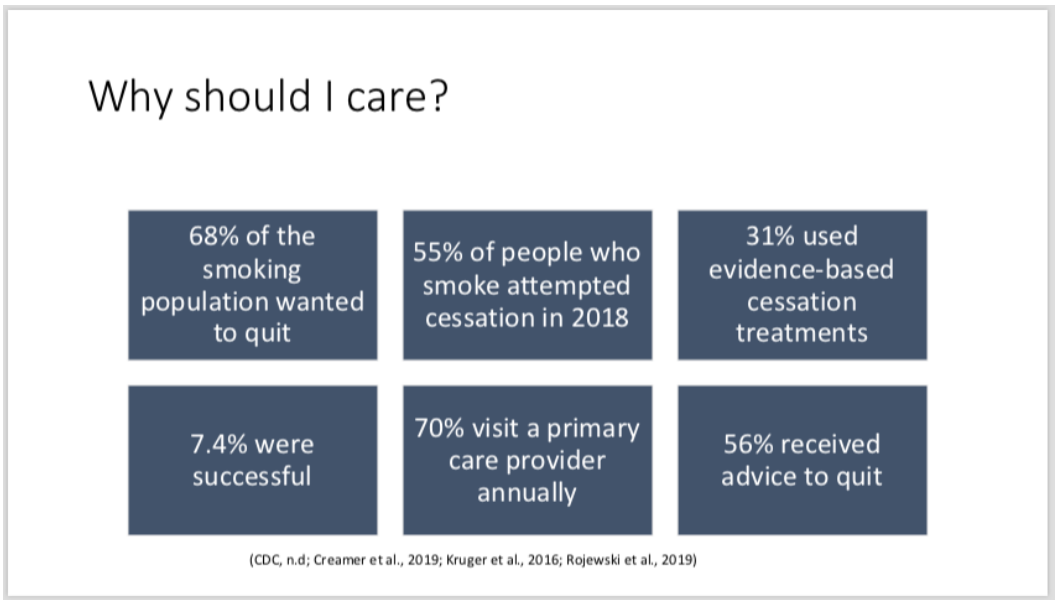
Speaker notes: In 2019 almost 20% of U.S. adults used any tobacco product, with 14% using cigarettes. North Dakota, like most health statistics, ranks worse than the national average, with 23.4% of the adult population using some form of tobacco in 2019 That is almost 1 in 4 that are still using some form of tobacco. 35.5% of N.D.'s high schoolers used some form of tobacco with e-cigarettes being the most common form at 33.1%. over half of N.D.'s high schoolers had tried e-cigarettes.



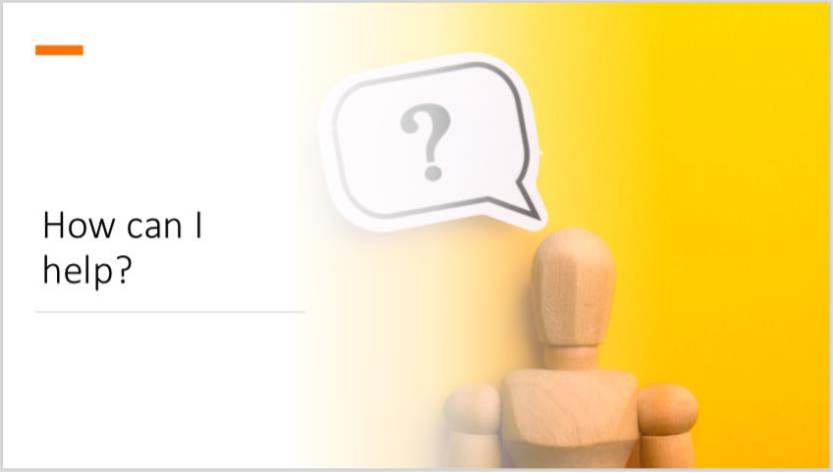
(U.S. Department of Health and Human Services, 2020)

Figure 1. Health effects of smoking. (CDC, 2021)

Speaker notes: Tobacco use is the leading cause of preventable death in the United States with about 1 in 5 deaths due to smoking or secondhand smoke. Smoking causes much more than just lung cancer. Most people are aware of the harmful effects of tobacco, including cardiovascular disease, lung cancer, and lung disease. However, tobacco use has also been linked to a multitude of diseases including endocrine disorders, rheumatologic disease, eye disease, reproductive disorders, and 12 different types of cancer. The bold text shows health problems that were recently discovered and added to the surgeon general report that have been linked to tobacco use.



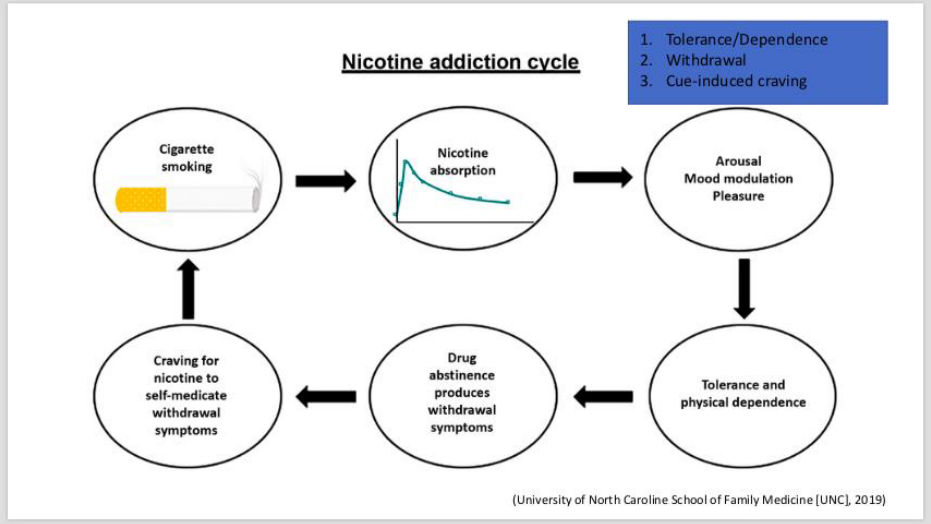
Speaker notes: Fortunately, in 2015, over two-thirds (68%) of the smoking population wanted to stop smoking and, and over half of the people who smoke of people attempted to quit. Unfortunately, only 31.2% of those who tried to quit used evidenced-based cessation treatments, and only 7.4% were successful in cessation. Although 70% of people who smoke visit a primary care provider annually, only 56% of those adults received advice to quit in 2015. Perceived barriers from providers in primary care for tobacco cessation include, perceived lack of time, lack of knowledge on how to assist in tobacco cessation, concern about stigmatizing patients, inadequate institutional support, and confusing insurance cessation coverage. I hope the modules and this presentation help to provide you with some tools and knowledge today to overcome these perceived barriers. The lack of knowledge on how to assist in tobacco cessation is huge factor in providers addressing tobacco use with their patient- it is similar to alcohol misuse- many providers are not comfortable or confident in how to address these addictions and this leads to simply not addressing tobacco use.



Speaker notes: Now that you guys have completed the Rx for change modules- Hopefully, you feel a little more confident in answering this question of how you can help patients successfully quit. For starters, t was found that patients who smoke trust and respect providers more when they address their tobacco use and are more satisfied when the provider discusses cessation. Even brief advice (<3 minutes) has shown to improve cessation rates and is highly cost effective (USDHHS, 2020). It is essential that primary care providers adequately address tobacco use and counsel patients with the best evidenced-based cessation strategies.
Using the 5 A's with motivational interviewing you can collaborate with patients to help create an individualized plan to help assist patients in their cessation journey (USDHHS, 2020).

(WHO, 2021)

Speaker notes: I think this is a great perspective for us to review and especially for patients to visualize. Many people have smoked for so long they believe the damage is done and there is no benefit to quitting. For example, within just 1 year of cessation- the risk of CHD is about half that of a smoker.

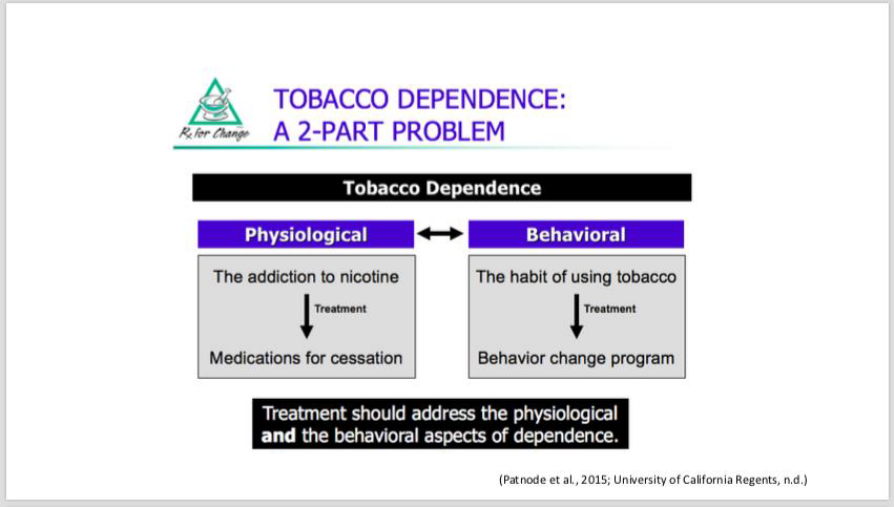


Speaker notes: There are numerous reasons that one decides to use tobacco, but there are three reasons in particular that contribute to continue tobacco use once initiated and that make cessation difficult: 1. Tolerance and dependence 2. Withdrawal 3. Cue-induced craving

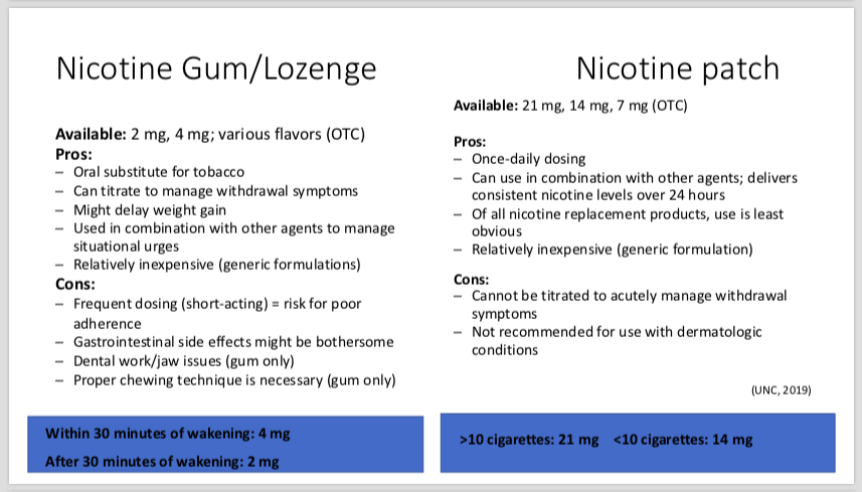
Understanding and reviewing the nicotine addiction cycle is crucial in understanding how to treat tobacco use. Nicotine when absorbed binds to nicotinic receptors in the brain and once bound, three key neurotransmitters are released: dopamine, serotonin, and norepinephrine. Dopamine induces feelings of euphoria and pleasure. Stimulated nicotinic receptors become desensitized and upregulated which is experienced in the tobacco user as tolerance. The tobacco user will need large amount of nicotine to produce those 3 neurotransmitters. With continued high levels of neurotransmitters, one develops dependence on nicotine. When serum nicotine levels drop, one will likely experience withdrawal symptoms that includes: irritability, anxiety, cravings to use tobacco, difficulty concentrating, increased appetite, restlessness, depressed mood, and insomnia. These withdraw symptoms are primarily related to low levels of the neurotransmitters. In the toolkit- there is a withdrawal symptom information sheet that is helpful for providers and also helpful to give to patients. This helps to empower patients to know why they are feeling this way. It shows the withdrawal symptom, the cause of this symptom, how long it will likely last, and how to relieve it.

The 3rd reason cessation is difficult to treat. Cue induced cravings occur in tobacco users when someone is presented with a signal that they associate with tobacco use. The signals can anything – such as the smell of a cigarette. These cues can trigger a tobacco craving due to a relative decline in dopamine release. These cravings typically last only 3 - 5 minutes.

Nicotine replacement therapy (NRT) is useful in decreasing the intensity and frequency of nicotine withdrawal. If a patient decides not to use NRT -withdrawal symptoms are much stronger but will typically resolve within 2 - 3 weeks on their own. Cue induced cravings can be minimized and managed with pharmacological and psychosocial tools. Varenicline and bupropion are medications used to reduce urges to smoke and NRT can be used to reduce the intensity of the tobacco craving.



Speaker Notes: Tobacco dependence is a chronic condition that requires a two-prong approach for treatment to be effective. As it is shown on the diagram here –there is a physiological aspect and a behavioral aspect. Studies show when you combine the behavioral aspect and pharmacotherapy/physiologic aspect in treating tobacco use –cessation rates increase by 82% when compared to the usual care and minimal intervention (Patnode et al., 2015). Treating nicotine withdrawal with medications helps with the physiologic aspect of tobacco dependence (University of California Regents, n.d.) Additionally, helping patients recognize/overcome cues/cravings for tobacco helps to treat the behavioral aspect of tobacco dependence. Both the physiologic and behavioral aspects need to be addressed to adequately treat tobacco dependence.



Speaker notes: Nicotine replacement therapy:

Nicotine replacement patch is the long acting form.

- provides a continuous level of serum nicotine
- nicotine levels lower than when you smoke cigarettes
- this low serum level help with prevent nicotine withdrawal symptoms.

Short acting nicotine replacement- Gum/lozenge (nasal spray or inhaler)

-help with cravings/urges that tobacco users experience.

The biggest key factor that in using these medications is getting the correct dose. The correct dose is so important. Since these are OTC, many patients try to dose these on their own, but the dose is often not correct.

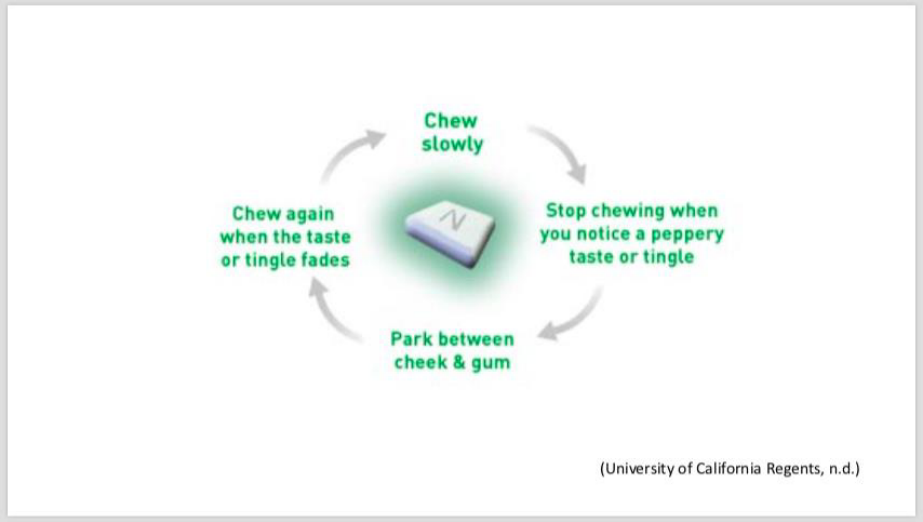
2 things you need to know when prescribing or recommending NRT to determine dose

1. How many cigarettes a day do you smoke (doses the patch)
2. How quickly do you smoke your first cigarette after waking up in the morning (doses the gum)

With both of these forms of nicotine replacement therapy, it is important to individualize the plan.

Proper use- gum/lozenge every 1-2 hours initially while awake. That is very frequent. The frequency helps to get that spike of nicotine and spike of dopamine that they are used to getting with cigarettes.

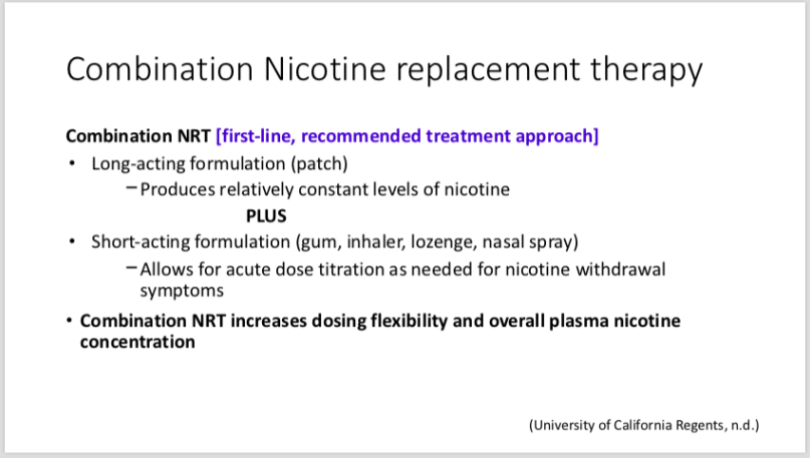
1. Can take up to 30 minutes to reach peak nicotine concentration in brain- cravings last about 5 minutes- so if you have a craving- and pop in a lozenge- it is likely too late to take effect. –talk with patients about this- if they know driving is a trigger- start chewing on some gum about 20-30 minutes before getting into the car.
2. Individualize the plan- Follow up is important as you will likely be titrating these medications. This is why it is so important to understand the nicotine withdrawal and cravings and be able to help teach your patients.



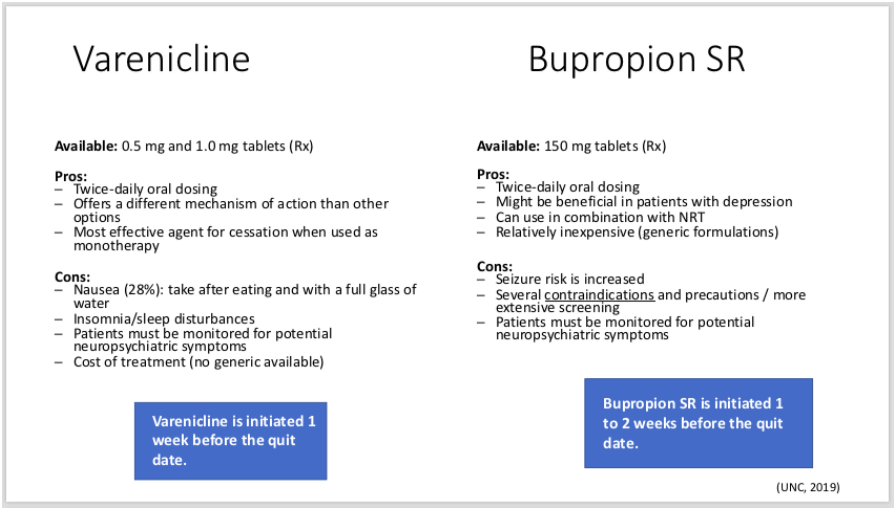
Speaker notes: Nicotine gum: Directions for use.

Nicotine gum is not like ordinary chewing gum. It is a specially formulated nicotine delivery system that must be chewed properly for optimal results. When chewed like ordinary gum, nicotine will be released rapidly leading to adverse effects including hiccups, heartburn, or gastric upset

- Chew each piece of gum very *slowly* several times.
- Stop chewing at the first sign of peppery taste or slight tingling sensation in the mouth.
- "Park" the gum between the cheek and gum to allow absorption of nicotine across the buccal mucosa (mouth lining).
- When the taste or tingling dissipates (generally about 1–2 minutes), slowly resume chewing.
- When the taste or tingling returns, stop chewing and park the gum in a different place in the mouth. Parking the gum in different areas of the mouth will decrease the incidence of mucosal irritation.
- The chew/park steps should be repeated until most of the nicotine is gone. At this point, the taste or tingling does not return. On average, each piece of gum lasts 30 minutes.

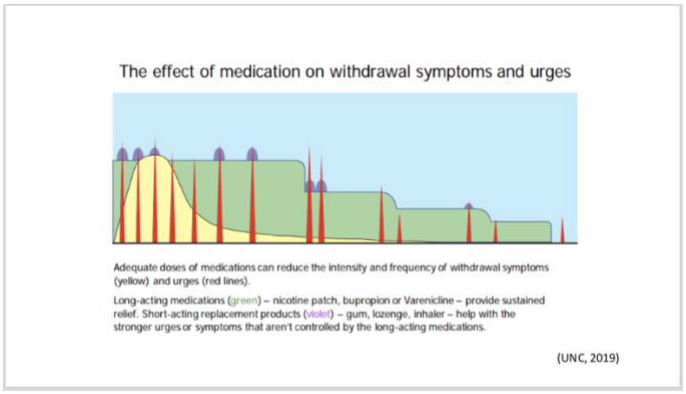


Speaker Notes: Combination nicotine replacement therapy is combining a long acting form (ie the nicotine patch) with a short acting form (ie nicotine the gum or lozenge) and it treats both nicotine withdrawal and cravings. It is highly effective. A Cochrane review of 63 studies compared single NRT with combination NRT therapy and it found that tobacco users are 15-36% more likely to be successful in quitting (Lindson et al., 2019).



Speaker Notes: Varenicline binds to the nicotinic receptor. The nicotinic receptor releases dopamine, serotonin, and norepinephrine. When varenicline is bound to the receptor, nicotine products cannot bind to it. This mechanism is actually making cigarettes less enjoyable for the user. It also acts as a partial agonist, meaning it releases some of the neuro transmitters to decrease withdrawal and cravings. Bupropion SR is an anti-depressant (Wellbutrin) norepinephrine- dopamine reuptake inhibitor It blocks the effects of nicotine, alleviates withdrawal symptoms, and reduces depressed mood. It is contraindicated in those with a seizure disorder.

Both Varenicline and Bupropion are long acting drugs that help treat nicotine withdrawal.



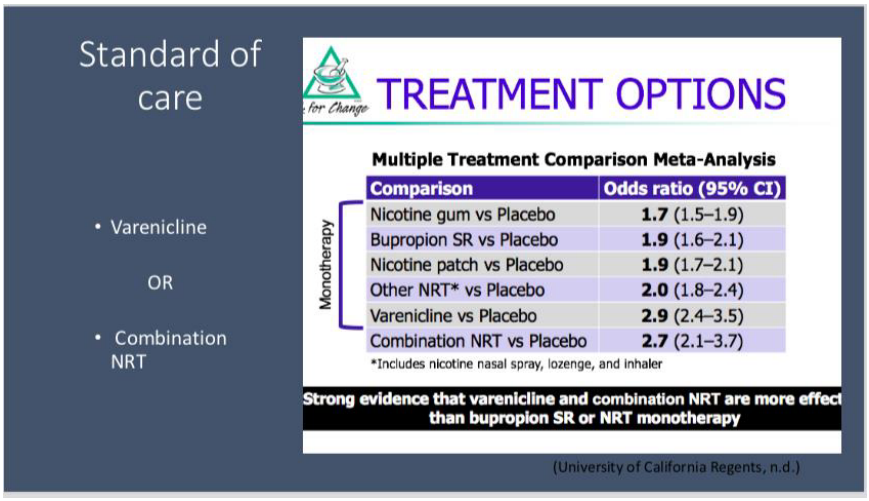
Speaker Notes: Visual that shows the effect of different medications on withdrawal symptoms/urges.

-Yellow represents withdrawal symptoms that a patient will experience.

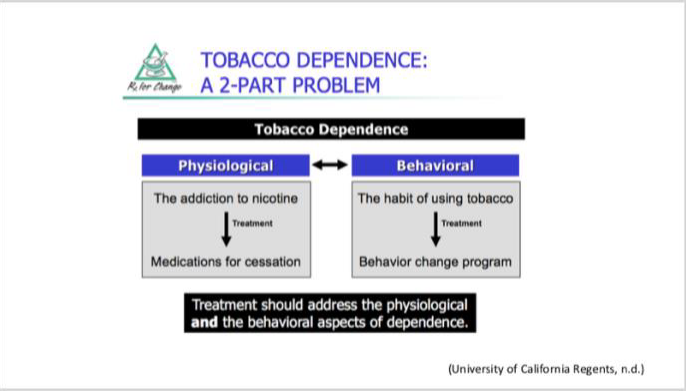
-Red lines represent urges.

-Long-acting medications, like the nicotine patch, bupropion, or varenicline are represented by the green.

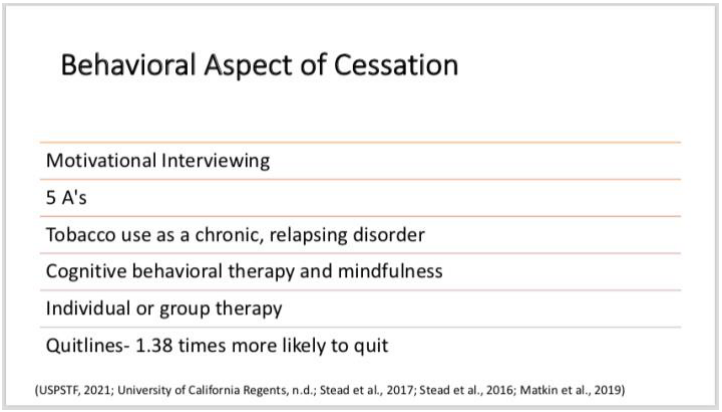
Short-acting products like the nicotine gum/lozenges are represented by the purple and help with the stronger urges that the long-acting medications cannot control.



Speaker Notes: Here is a summary of the results of a meta-analyses for monotherapy and combination NRT versus placebo. While all of the approaches show the odds of quitting that are higher than placebo, there is strong evidence that combination NRT and varenicline are the most effective. Although patient preference is a key factor for regimen selection, these higher odds ratios are clinically significant. The increased efficacy of combo NRT and varenicline should be considered when providing guidance to patients who are attempting to quit.

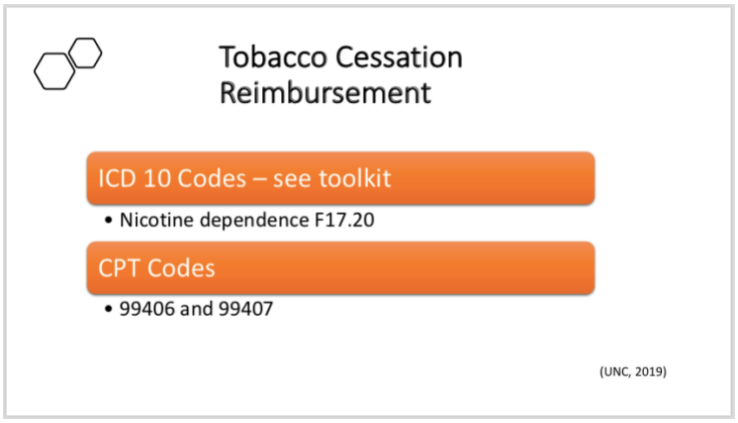


Speaker Notes: Again, this is the visual of tobacco dependence requiring a two-prong approach. We have discussed the physiologic aspect. The next section will review the behavioral aspect of tobacco dependence.

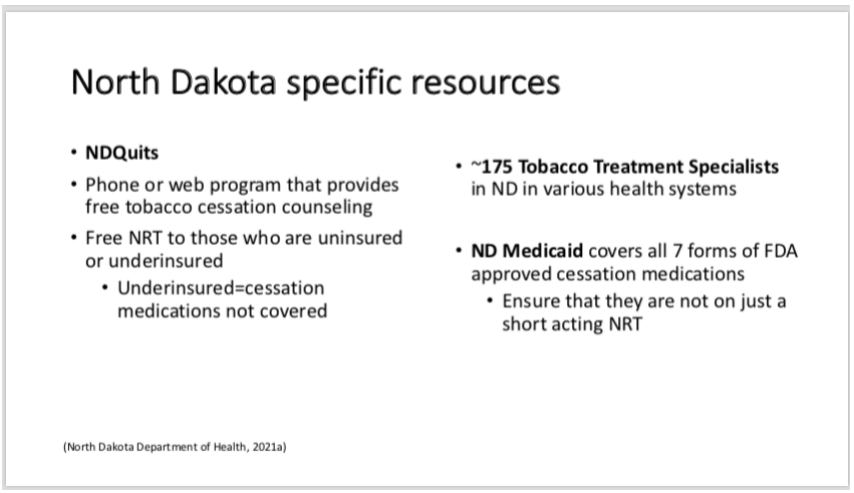


Speaker Notes: The behavioral aspect of cessation is very complex. Motivation interviewing is often used in tobacco use treatment. It involves asking open ended questions, affirming, reflective listening, summarizing. Utilizing the 5 A's is used to ask about tobacco use, advise to quit, assess readiness to quit, assist with quitting, and arrange follow up (USPSTF, 2021). It is important to view tobacco use as a chronic, relapsing disorder and remember that often, people will have a number of quit attempts. In your toolkit there is a section titled Coping with Quitting: Cognitive and Behavioral strategies. This is a great handout for patients. The handout explores different strategies to use such as distractive thinking, positive self talk, tips on dealing with stress, alcohol, and being around other tobacco users (University of California Regents, n.d.). CBT and mindfulness both have been shown to be effective in treating tobacco use (University of California Regents, n.d.). Individual and group therapy have been found to be effective as stand-alone therapy for tobacco cessation but are more effective when used in combination with medications. (Stead et al., 2017; Stead et al., 2016) Quitlines are proactive counseling via the phone/web. A Cochrane review showed those who utilized quitlines were 1.38 time more likely to quit than if they were just given self help materials to review (Matkin et al., 2019).

Speaker Notes: Virtual Patients were utilized through the RxForChange website that give feedback on responses chosen.

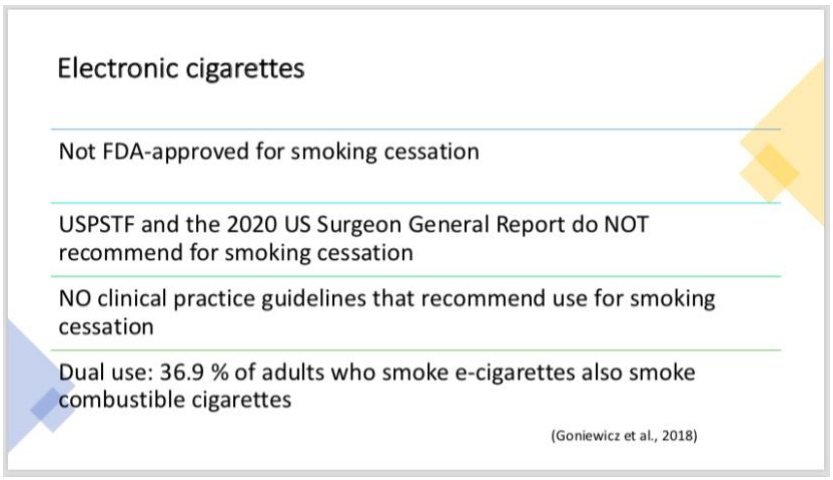


Speaker Notes: Since reimbursement for tobacco treatment can be seen as a barrier to providers, it is important to know how to code services to be appropriately compensated. The Affordable Care Act (ACA) requires insurers to cover tobacco treatment use and dependence. The ACA requires insurers to cover services that fall under grade A or B recommendations by the USPTF and both tobacco treatment counseling and medication meet these requirements (Kaiser Family Foundation, 2015). Preventative counseling current procedural terminology (CPT) codes 99406 and 99407 are smoking and tobacco cessation counseling codes . 99406- counseling lasting between 3 - 10 minutes and 99407- counseling greater than 10 minutes. A diagnostic code of nicotine dependence, F17.20, must also be included in the billing. The preventative counseling codes, 99406 and 99407, can be billed along with an evaluation and management (E/M) code such as 99213 and 99214 (UNC, 2019).

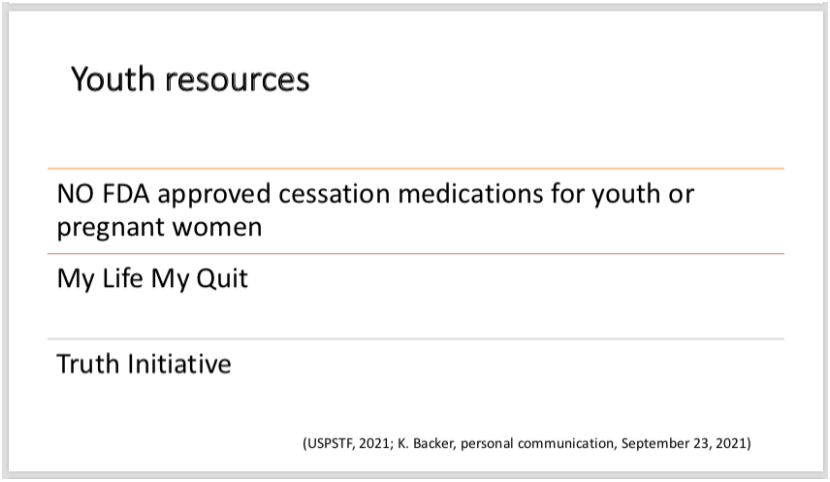


Speaker Notes: ND quits is a free program that provides tobacco cessation counseling via the phone or online to north Dakota residents. NDQuits did a survey of 434 people who utilized NDQuits within the last year and 31% of them did not have tobacco within the last month Also, NDQuits has funding that will cover NRT for those in the program AND those who are uninsured or underinsured. NRT is OTC, so many insurances will not cover it. NDQuits can help patients get OTC NRT covered or for free. Certified Tobacco Treatment Specialists (TTS): there are about 175 TTS in ND from all different disciplines (inpatient/outpatient providers, pharmacists, nurses, respiratory therapists, behavioral health). All can make recommendations for medications and help with counseling. ND Medicaid- covers all 7 forms of FDA approved cessation medications.

Speaker Notes: E-cigarette video from RxForChange shown next



Speaker Notes: E-cigarettes are currently not an FDA-approved smoking cessation aid. Both the current USPSTF guidelines and the 2020 U.S. Surgeon General's Report on Smoking Cessation do not recommend the use of e-cigarettes for smoking cessation (USPSTF, 2021). Due to lack of regulation, and the uncertainty of the long-term effects of e-cigarettes, there are currently no clinical practice guidelines that recommend e-cigarette use for smoking. Although, e-cigarettes may be less harmful than combustible cigarettes, e-cigarettes are marketed to new users, youth. As described previously, youth e-cigarette use rates are high and the USPSTF (2021) does not recommend the use of e-cigarettes for tobacco cessation, including pregnant persons. Dual use: Of adults who smoke e-cigarettes, 36.9% also smoke combustible cigarettes and are known as dual users. The serum nicotine levels in dual users is significantly higher that when used alone. Additionally- their risk of cardiovascular events is higher in dual users than in those who only use combustible cigarettes Goniewicz et al., 2018).



Speaker Notes: Unfortunately, there are no FDA approved cessation medications for youth or pregnant women (USPSTF, 2021). We need to be asking youth about their nicotine use at every visit as well. And to clarify that you are asking about e-cigarettes, JULs, pods systems, mods. My life my quit (ND Quits) teens can text a number and get a coach to use motivational interviewing and cognitive-behavioral techniques to help teens

- Develop a quit plan.
- Identify triggers for tobacco use.
- Practice refusal skills.
- Obtain ongoing support for changing behaviors.

Teens who participate in the program receive:

- Five, one-on-one coaching sessions usually scheduled every 7-10 days
- provides education materials designed for teens, with input from teens.

This is all done by phone, by text message or by online chat

Truth initiative is a very similar platform to my life my quit - they also address opioid use. ND is thinking of partnering with Truth initiative instead of My life my quit in the future. Both are free right now and both are effective.

References

Buettner-Schmidt, K., Swanson, K., Maack, B., Barnacle, M. Miller, D., Orr, M., & Hatlen Gag, M., (2021). E-cigarettes for tobacco cessation: Not the solution. *The Nurse Practitioner, 46*(12):7-11. doi: 10.1097/01.NPR.0000798228.69915.64

Centers for Disease Control and Prevention (CDC) (n.d.). *Smoking and tobacco use*. U.S. Department of Health and Human Services. https://www.cdc.gov/tobacco/about/osh/index.htm

Creamer M.R., Wang T.W., Babb S., Cullen K.A., Day H., Willis G., Jamal A., Neff L. (2019). Tobacco product use and cessation indicators among adults — United States, 2018. *Morbidity and Mortality Weekly Report. 68*(45);1001-1019. https://doi.org/10.15585/mmwr.mm6845a2

Goniewicz, M.L., Smith, D.M., Edwards, K.C., Blount, B.C., Caldwell, K.L., Feng, J., Wang, L., Christenson, C., Ambrose, B., Borek, N., Van Bemmel, D., Konkel, K., Erives, G., Stanton, C.A., Lambert, E., Kimmel, H.L., Hatsukami, D., Hecht, S.S., Niaura, R.S., Travers, M., . . . Hyland, A.J. (2018). Comparison of nicotine and toxicant exposure in users of electronic cigarettes and combustible cigarettes. *The Journal of the American Medical Association.* doi:10.1001/jamanetworkopen.2018.5937

Hartmann-Boyce, J., Chepkin, S. C., Ye, W., Bullen, C., & Lancaster, T. (2018). Nicotine replacement therapy versus control for smoking cessation. *The Cochrane Database of Systematic Reviews, 5*(5). https://doi.org/10.1002/14651858.CD000146.pub5

Hartmann-Boyce, J., Hong, B., Livingstone-Banks, J., Wheat, H., & Fanshawe, T.R. (2019). Additional behavioural support as an adjunct to pharmacotherapy for smoking cessation. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD009670.pub4

Howes, S., Hartmann-Boyce, J., Livingstone-Banks, J., Hong, B., & Lindson, N. (2020). Antidepressants for smoking cessation. *The Cochrane Database of Systematic Reviews*, *4*(4). https://doi.org/10.1002/14651858.CD000031.pub5

Kaiser Family Foundation (2015). *Preventative services covered by private health plans under the Affordable Care Act.* https://www.kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/

Kruger, J., O'Halloran, A., Rosenthal, A. C., Babb, S. D., & Fiore, M. C. (2016). Receipt of evidence-based brief cessation interventions by health professionals and use of cessation assisted treatments among current adult cigarette-only smokers: National Adult Tobacco Survey, 2009-2010. *BioMed Central Public Health. 16*,141. https://doi.org/10.1186/s12889-016-2798-2

Lindson, N., Chepkin, S. C., Ye, W., Fanshawe, T. R., Bullen, C., & Hartmann-Boyce, J. (2019). Different doses, durations and modes of delivery of nicotine replacement therapy for smoking cessation. *The Cochrane database of systematic reviews*, *4*(4). https://doi.org/10.1002/14651858.CD013308

Matkin, W., Ordóñez-Mena J.M., & Hartmann-Boyce J. (2019). Telephone counselling for smoking cessation. *Cochrane Database of Systematic Reviews*. https:doi:10.1002/14651858.CD002850.pub4.

North Dakota Department of Health (2021a). Key findings about NDQuits in fiscal year 2020 (July 1, 2019-June 30, 2020). https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Reports/NDQuits_FY20_Report.pdf

North Dakota Department of Health (2021b). *Tobacco surveill*
https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Reports/
https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Tobacco

Patnode, C.D., Henderson, J.T., Thompson, J.H., Senger, C.A., Fortmann, S.P., & Whitlock, E.P. (2015) Behavioral counseling and pharmacotherapy interventions for tobacco cessation in adults, including pregnant women: a review of reviews for the U.S. Preventive Services Task Force. *Annals of Internal Medicine.* https://doi.org/10.7326?M15-0171

Stead, L.F., Koilpillai P., Fanshawe, T.R., & Lancaster, T. (2016) Combined pharmacotherapy and behavioral interventions for smoking cessation. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD008286.pub3

Stead, L.F., Carroll, A.J., & Lancaster, T. (2017) Group behaviour therapy programmes for smoking cessation. *Cochrane Database of Systematic Reviews.* https://doi.org/10.1002/14651858.CD001007.pub3

Rojewski, A. M., Bailey, S. R., Bernstein, S. L., Cooperman, N. A., Gritz, E. R., Karam-Hage, M. A., Piper, M. E., Rigotti, N. A., & Warren, G. W. (2019). Considering systemic barriers to treating tobacco use in clinical settings in the United States. *Nicotine & Tobacco Research 21*(11), 1453–1461. https://doi.org/10.1093/ntr/nty123

University of California Regents. (n.d.) Rx for Change: Tobacco Cessation Behavioral Counseling and Pharmacotherapy Program. https://ce.pharmacy.purdue.edu/courses/course/index.php?categoryid=20

U.S. Preventive Service Task Force. (2021). *Interventions for tobacco smoking cessation in adults including pregnant persons.* Journal of American Medical Association. *325*(3), 265-279. https://doi.org/10.1001/jama.2020.25019,

U.S. Department of Health and Human Services. (2020) *Smoking cessation: a report of the Surgeon General.* https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf

University of North Caroline School of Family Medicine (2019). 2019 training manual – Duke-UNC tobacco treatment specialist training program. North Carolina Department of Health and Human Services.

World Health Organization (2021). *Tobacco: Health benefits of smoking cessation.* https://www.who.int/news-room/questions-and-answers/item/tobacco-health-benefits-of-smoking-cessation

APPENDIX K: TOBACCO CESSATION TOOLKIT

Tobacco Cessation Toolkit

STEP One: ASK about Tobacco Use

➲ Suggested Dialogue

- ✓ Do you ever smoke or use other types of tobacco or nicotine, such as e-cigarettes?
  - – I take time to talk with all of my patients about tobacco use—because it's important.
- ✓ Condition X often is caused or worsened by exposure to tobacco smoke. Do you, or does someone in your household smoke?
- ✓ Medication X often is used for conditions linked with or caused by smoking. Do you, or does someone in your household smoke?

STEP Two: ADVISE to Quit

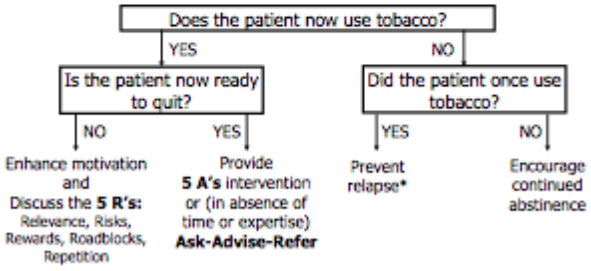
➲ Suggested Dialogue

- – Quitting is the most important thing you can do to protect your health now and in the future. I have training to help my patients quit, and when you are ready I would be more than happy to work with you to design a treatment plan.
- – Prior to imparting advice, consider asking the patient for permission to do so – e.g., "May I tell you why this concerns me?" [then elaborate on patient-specific concerns]

STEP Three: ASSESS Readiness to Quit

➲ Suggested Dialogue

- – For current tobacco users: What are your thoughts about quitting? Might you consider quitting sometime in the next month?



* Relapse prevention interventions are not necessary if patient has not used tobacco for many years and is not at risk for re-initiation.

Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update.* Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.

STEP Four: ASSIST with Quitting

Rx for Change

- ✓ **Assess Tobacco Use History**
  - Current use: type(s) of tobacco, amount, time to first cigarette
  - Past use:
    - – Duration of tobacco use
    - – Recent changes in levels of use
  - Past quit attempts:
    - – Number of attempts, date of most recent attempt, duration
    - – Methods used previously—What did or didn't work? Why or why not?
    - – Prior medication administration, dose, adherence, duration of treatment
    - – Reasons for relapse
- ✓ **Discuss Key Issues** (for the upcoming or current quit attempt)
  - Reasons/motivation for wanting to quit (or avoid relapse)
  - Confidence in ability to quit (or avoid relapse)
  - Triggers for tobacco use
  - Routines and situations associated with tobacco use
  - Stress-related tobacco use
  - Concerns about weight gain
  - Concerns about withdrawal symptoms
- ✓ **Facilitate Quitting Process**
  - Discuss methods for quitting: pros and cons of the different methods
  - Set a quit date: ideally, less than 2 weeks away
  - Recommend Tobacco Use Log
  - Discuss coping strategies (cognitive, behavioral)
  - Discuss withdrawal symptoms
  - Discuss concept of "slip" versus relapse
  - Provide medication counseling: adherence, proper use, with demonstration
  - Offer to assist throughout the quit attempt
- ✓ **Evaluate the Quit Attempt** (at follow-up)
  - Status of attempt and engagement in quitting program; "slips" and relapse
  - Medication compliance, extent to which nicotine withdrawal is being alleviated with current regimen, and plans for discontinuation of medication(s)

STEP Five: ARRANGE Follow-up Counseling

- ✓ Monitor patients' progress throughout the quit attempt. Follow-up contact should occur during the first week after quitting. A second follow-up contact is recommended in the first month. Additional contacts should be scheduled as needed. Counseling contacts can occur face-to-face, by telephone, or by e-mail. Keep patient progress notes.
- ✓ Address temptations and triggers; discuss strategies to prevent relapse.
- ✓ Congratulate patients for success and reinforce need for continued support.

TOBACCO CESSATION COUNSELING GUIDESHEET

COPING WITH QUITTING: COGNITIVE AND BEHAVIORAL STRATEGIES

COGNITIVE STRATEGIES focus on retraining the way a patient thinks. Often, patients will deliberate on the fact that they are thinking about a cigarette, and this leads to relapse. Patients must recognize that thinking about a cigarette doesn't mean they need to have one.	
REVIEW COMMITMENT TO QUIT	Each morning, say, "I am proud that I made it through another day without tobacco!" Remind oneself that cravings and temptations are temporary and will pass. Announce, either silently or aloud, "I am a nonsmoker, and the temptation will pass."
DISTRACTIVE THINKING	Use deliberate, immediate refocusing of thinking toward other thoughts when cued by thoughts about tobacco use.
POSITIVE SELF-TALKS, PEP TALKS	Say, "I can do this," and remind oneself of previous difficult situations in which tobacco use was avoided.
RELAXATION THROUGH IMAGERY	Center mind toward positive, relaxing thoughts.
MENTAL REHEARSAL, VISUALIZATION	Prepare for situations that might arise by envisioning how best to handle them. For example, envision what would happen if offered a cigarette by a friend—mentally craft and rehearse a response, and perhaps even practice it by saying it aloud.
BEHAVIORAL STRATEGIES involve specific actions to reduce risk for relapse. These strategies should be considered prior to quitting, after determining patient-specific triggers and routines or situations associated with tobacco use. Below are strategies for several of the more common cues or causes for relapse.	
STRESS	Anticipate upcoming challenges at work, at school, or in personal life. Develop a substitute plan for tobacco use during times of stress (e.g., use deep breathing, take a break or leave the situation, call a supportive friend or family member, use nicotine replacement therapy).
ALCOHOL	*Drinking alcohol can lead to relapse.* Consider limiting or abstaining from alcohol during the early stages of quitting.
OTHER TOBACCO USERS	*Quitting is more difficult if the patient is around other tobacco users. This is especially difficult if another tobacco user is in the household.* During the early stages of quitting, limit prolonged contact with individuals who are using tobacco. Ask co-workers, friends, and housemates not to smoke or use tobacco in your presence.
ORAL GRATIFICATION NEEDS	Have nontobacco oral substitutes (e.g., gum, sugarless candy, straws, toothpicks, lip balm, toothbrush, nicotine replacement therapy, bottled water) readily available.
AUTOMATIC SMOKING ROUTINES	Anticipate routines associated with tobacco use and develop an alternative plan. Examples: MORNING COFFEE: change morning routine, take shower before drinking coffee, drink tea instead of coffee, take a brisk walk shortly after awakening. WHILE DRIVING: remove all tobacco from car, have car interior detailed, listen to an audio book or talk radio, use oral substitutes. WHILE ON THE PHONE: stand while talking, limit call duration, change phone location, keep hands occupied by doodling or sketching. WHILE WATCHING TV: sit in a different chair, rearrange furniture, consider watching in a different room, keep hands busy by squeezing a stress ball. AFTER MEALS: get up and immediately do dishes or take a brisk walk after eating, brush teeth, call supportive friend.
POST-CESSATION WEIGHT GAIN	Do not attempt to modify multiple behaviors at one time. If weight gain is a barrier to quitting, engage in regular physical activity and adhere to a healthful diet (as opposed to strict dieting). Carefully plan and prepare meals, increase fruit and water intake to create a feeling of fullness, and chew sugarless gum or eat sugarless candies. Consider use of pharmacotherapy shown to delay weight gain.
CRAVINGS FOR TOBACCO	Cravings for tobacco are temporary and usually pass within 5–10 minutes. Handle cravings through distractive thinking, take a break, do something else, take deep breaths.

Withdrawal Symptoms Information Sheet

Quitting tobacco use brings about a variety of physical and psychological withdrawal symptoms. For some people, coping with withdrawal symptoms is like riding a roller coaster—there can be sharp turns, slow climbs, and unexpected plunges. **Most symptoms begin within the first 1 to 2 days, peak within the first week, and subside within 2 to 4 weeks.** Report new symptoms to your health-care provider, especially if severe. Consider the impact of recent medication changes and your caffeine intake.

Symptom	Cause	Duration	Relief
Chest tightness	Tightness is likely due to tension created by the body's need for nicotine or may be caused by sore muscles from coughing.	A few days	▪ Use relaxation techniques ▪ Try deep breathing ▪ Use of a nicotine medication might help
Constipation, stomach pain, gas	Intestinal movement decreases for a brief period.	1–2 weeks	▪ Drink plenty of fluids ▪ Add fruits, vegetables, and whole-grain cereals to diet
Cough, dry throat, nasal drip	The body is getting rid of mucus, which has blocked airways and restricted breathing.	A few days	▪ Drink plenty of fluids ▪ Avoid additional stress during first few weeks
Craving for a cigarette	Nicotine is a strongly addictive drug, and withdrawal causes cravings.	Frequent for 2–3 days; can happen for months or years	▪ Wait out the urge, which lasts only a few minutes ▪ Distract yourself ▪ Exercise (take walks) ▪ Use of a nicotine medication might help
Depressed mood	It is normal to feel sad for a period of time after you first quit smoking. Many people have a strong urge to smoke when they feel depressed.	1–2 weeks	▪ Increase pleasurable activities ▪ Talk with your clinician about changes in your mood when quitting ▪ Get extra support from friends and family
Difficulty concentrating	The body needs time to adjust to not having constant stimulation from nicotine.	A few weeks	▪ Plan workload accordingly ▪ Avoid additional stress during first few weeks
Dizziness	The body is getting extra oxygen.	1–2 days	▪ Use extra caution ▪ Change positions slowly
Fatigue	Nicotine is a stimulant.	2–4 weeks	▪ Take naps ▪ Do not push yourself ▪ Use of a nicotine medication might help
Hunger	Cravings for a cigarette can be confused with hunger pangs; sensation may result from oral cravings or the desire for something in the mouth.	Up to several weeks	▪ Drink water or low-calorie liquids ▪ Be prepared with low-calorie snacks
Insomnia	Nicotine affects brain wave function and influences sleep patterns; coughing and dreams about smoking are common.	1 week	▪ Reduce caffeine intake by about half (and none after lunchtime, to improve sleep), because its effects will increase with quitting smoking ▪ Use relaxation techniques
Irritability	The body's craving for nicotine can produce irritability.	2–4 weeks	▪ Take walks ▪ Try hot baths ▪ Use relaxation techniques

Adapted from materials from the National Cancer Institute.

FAGERSTRÖM TEST FOR NICOTINE DEPENDENCE (ADULTS)

		Score
1.	**How soon after you wake up do you smoke your first cigarette?**	
	❑ Within 5 minutes	3
	❑ 6–30 minutes	2
	❑ 31–60 minutes	1
	❑ After 60 minutes	0
2.	**Do you find it difficult to refrain from smoking in the places where it is forbidden (e.g., in church, at the library, in cinema)?**	
	❑ Yes	1
	❑ No	0
3.	**Which cigarette would you hate most to give up?**	
	❑ The first one in the morning	1
	❑ Any other	0
4.	**How many cigarettes/day do you smoke?**	
	❑ 10 or less	0
	❑ 11–20	1
	❑ 21–30	2
	❑ 31 or more	3
5.	**Do you smoke more frequently during the first hours after waking than during the rest of the day?**	
	❑ Yes	1
	❑ No	0
6.	**Do you smoke if you are so ill that you are in bed most of the day?**	
	❑ Yes	1
	❑ No	0

Total Score: ☐

Heatherton TF, Kozlowski LT, Frecker RC, Fagerström K-O. The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* 1991;86:1119–1127.

Score of:	1-2=low dependence	5-7= moderate dependence
	3-4= low to moderate dependence	8 + = high dependence

Utilizing NDQuits and ND Medicaid

The 2020 U.S. Surgeon General Report (SGR) on Smoking Cessation states that **cessation medications and behavioral counseling are severely underutilized.**

The SGR reports that 40% of patients are not advised by healthcare providers to quit tobacco. In North Dakota, that percentage is **49%.**[A]

[A]2019 ND Adult Tobacco Survey

ASK

Screen for tobacco use - including vaping and synthetic nicotine - ***every visit, every time.***

ADVISE

"Quitting [type of tobacco] is one of the most important things you can do to improve your health."

REFER & CONNECT

A proactive referral reduces the barrier for the patient to connect with cessation resources.

- Tobacco Treatment Specialist (TTS)
- Local Public Health Unit
- NDQuits

PRESCRIBE

Order cessation medications, including over-the-counter meds because the motivation to quit changes. Having the prescription assists patients when they are ready and reduces the barrier of making another appointment. Insurances may cover medications.

TOBACCO CESSATION COUNSELING COVERAGE EXPANDS TO ALL ND MEDICAID MEMBERS

- ND Medicaid will now cover tobacco cessation counseling for all members for dates of services on or after January 1, 2022.
- If an ND Medicaid member has primary health care coverage through another payer, the primary payer must be billed first.
- Counseling must be provided face-to-face by or under the supervision of a physician or other health care professional who is legally authorized to furnish such services under state law and within their scope of practice and is enrolled as a ND Medicaid provider.
  - ◊ CPT Code 99406 - Smoking and tobacco cessation counseling visit; intermediate, greater than three minutes up to 10 minutes.
  - ◊ CPT Code 99407 - Smoking and tobacco cessation counseling visit;

NDQuits is a free phone and online cessation resource.

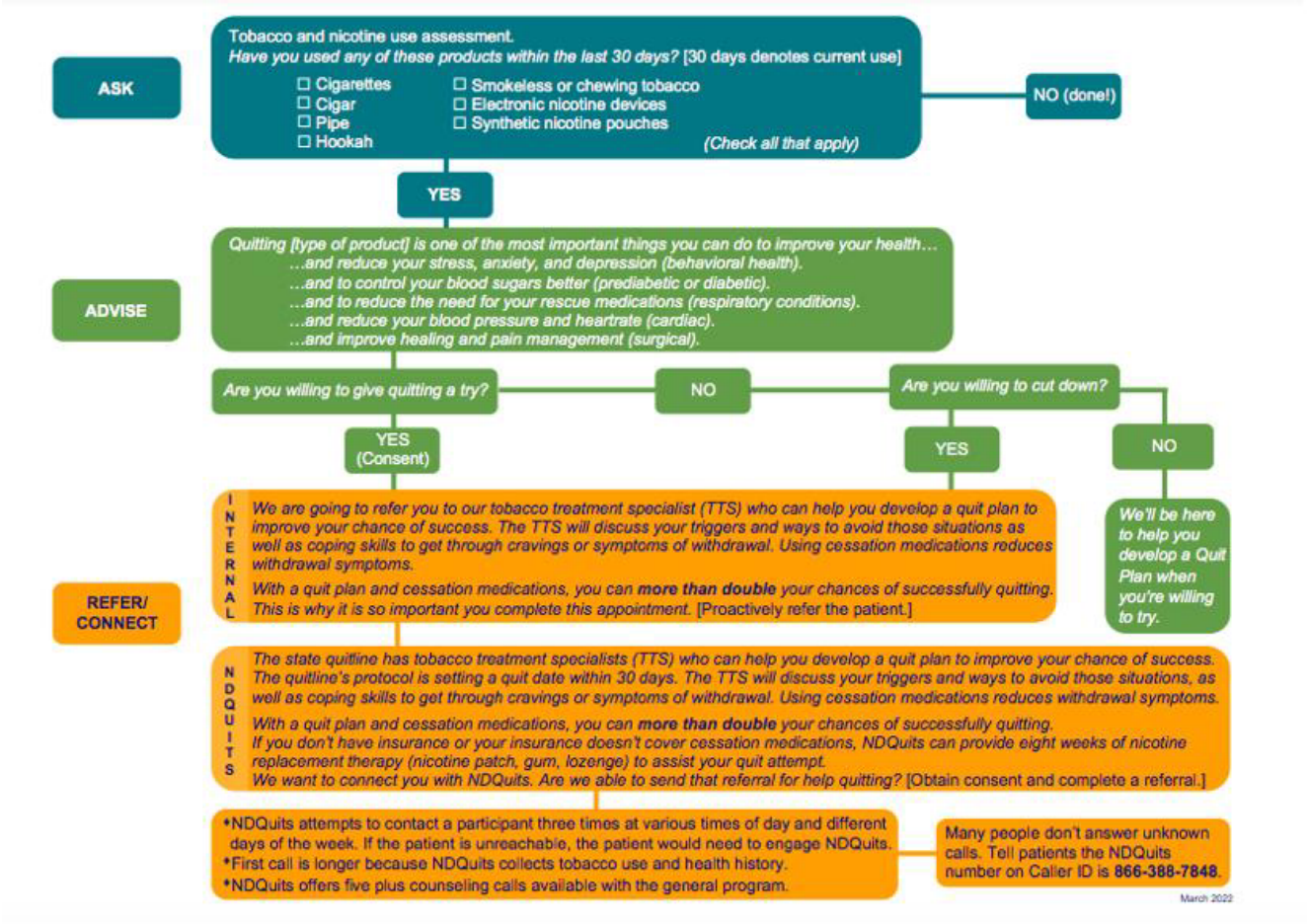
- Nicotine replacement therapy (NRT) is available to those who are uninsured or underinsured. Underinsured is having insurance, but the NRT is not covered.
- Specialized protocols for priority populations:
  - ◊ Pregnancy Postpartum Program
  - ◊ American Indian Commercial Tobacco Program
  - ◊ My Life My Quit is for those under age 18 and is an online, e-chat, and texting program. Text or call 1-855-891-9989 or short code to text is 36072.
- 1-800-QUIT-NOW or ndquits.health.nd.gov
- 30-day quit rate for fiscal year 2021 was 32.8%. The national benchmark is 30%.

PHARMACOTHERAPY COVERED BY ND MEDICAID

- Providers write prescriptions for cessation medications, including over-the-counter medications.
- Patients receive the medications from their pharmacy. Patients must be compliant with treatment.
  - ⇒ Varenicline and nicotine patch are allowed for 12 weeks every 6 months *when used consecutively**. Either medication is allowed with all other products.
  - ⇒ Varenicline treatment can be extended to 24 weeks of continuous treatment if patient is abstinent and uses the medication consecutively.*
  - ⇒ Bupropion is allowed for 90 days every 6 months *when used consecutively** and is allowed with all other products.
  - ⇒ Nicotine gum, lozenge, inhaler, and spray are allowed for 90 days every 6 months *when used consecutively.** Any short-term medication must be prescribed with nicotine patch, varenicline, or bupropion.

*No delay in refills

March 2022


ASK
Tobacco and nicotine use assessment.
Have you used any of these products within the last 30 days? [30 days denotes current use]
☐ Cigarettes
☐ Cigar
☐ Pipe
☐ Hookah
☐ Smokeless or chewing tobacco
☐ Electronic nicotine devices
☐ Synthetic nicotine pouches
(Check all that apply)
NO (done!)
YES
ADVISE
Quitting [type of product] is one of the most important things you can do to improve your health…
…and reduce your stress, anxiety, and depression (behavioral health).
…and to control your blood sugars better (prediabetic or diabetic).
…and to reduce the need for your rescue medications (respiratory conditions).
…and reduce your blood pressure and heartrate (cardiac).
…and improve healing and pain management (surgical).
Are you willing to give quitting a try?
NO
Are you willing to cut down?
YES (Consent)
YES
NO
REFER/ CONNECT
INTERNAL
We are going to refer you to our tobacco treatment specialist (TTS) who can help you develop a quit plan to improve your chance of success. The TTS will discuss your triggers and ways to avoid those situations as well as coping skills to get through cravings or symptoms of withdrawal. Using cessation medications reduces withdrawal symptoms.
With a quit plan and cessation medications, you can more than double your chances of successfully quitting.
This is why it is so important you complete this appointment. [Proactively refer the patient.]
We'll be here to help you develop a Quit Plan when you're willing to try.
NDQUITS
The state quitline has tobacco treatment specialists (TTS) who can help you develop a quit plan to improve your chance of success. The quitline's protocol is setting a quit date within 30 days. The TTS will discuss your triggers and ways to avoid those situations, as well as coping skills to get through cravings or symptoms of withdrawal. Using cessation medications reduces withdrawal symptoms.
With a quit plan and cessation medications, you can more than double your chances of successfully quitting.
If you don't have insurance or your insurance doesn't cover cessation medications, NDQuits can provide eight weeks of nicotine replacement therapy (nicotine patch, gum, lozenge) to assist your quit attempt.
We want to connect you with NDQuits. Are we able to send that referral for help quitting? [Obtain consent and complete a referral.]
•NDQuits attempts to contact a participant three times at various times of day and different days of the week. If the patient is unreachable, the patient would need to engage NDQuits.
•First call is longer because NDQuits collects tobacco use and health history.
•NDQuits offers five plus counseling calls available with the general program.
Many people don't answer unknown calls. Tell patients the NDQuits number on Caller ID is 866-388-7848.
March 2022

Billing and Coding for Tobacco Cessation in Primary Care

Code	Description
99406	Smoking and tobacco use cessation counseling visit; intermediate, **greater than 3 minutes up to 10 minutes**
99407	Smoking and tobacco use cessation counseling visit; intermediate, **greater than 10 minutes**

Diagnosis Codes allowed for 99406/99407:

When billing for these services providers must use an ICD-10 F17 code or a Z code. The F codes are used if the patient is dependent on tobacco. The Z codes are used if there is not dependence on tobacco. The Z codes cannot be combined with an F17 code.

F CODES

ICD-10 Diagnosis Code	Description: All with Nicotine Dependence
F17.200*	Product unspecified, uncomplicated
F17.201*	Product unspecified, in remission
F17.203	Product unspecified, with withdrawal
F17.208	Product unspecified, with other nicotine-induced disorders
F17.209	Product unspecified, with unspecified nicotine-induced disorders
F17.210*	Cigarettes, uncomplicated
F17.211*	Cigarettes, in remission
F17.213	Cigarettes, with withdrawal
F17.218	Cigarettes, with other nicotine-induced disorders
F17.219	Cigarettes, with unspecified nicotine-induced disorders
F17.220*	Chewing tobacco, uncomplicated
F17.221*	Chewing tobacco, in remission
F17.223	Chewing tobacco, with withdrawal
F17.228	Chewing tobacco, with other nicotine-induced disorders
F17.229	Chewing tobacco, with unspecified nicotine-induced disorders

F17.290*	Other tobacco product, uncomplicated
F17.291*	Other tobacco product, in remission
F17.293	Other tobacco product, with withdrawal
F17.298	Other tobacco product, with other nicotine-induced disorders
F17.299	Other tobacco product, with unspecified nicotine-induced disorders

Z CODES

ICD-10 Diagnosis Code	Description: All with Nicotine Dependence
Z57.31	Occupational exposure to environmental tobacco smoke • May not be used with Z77.22 exposure to environmental smoke
Z77.22	Contact with and suspected exposure to environmental smoke • May not be used with a F17.2 tobacco dependence or Z72 tobacco use code.
Z71.6	Counseling and Medicaid Advice – tobacco abuse counseling
Z72.0	Problems Related to Lifestyle and tobacco use not otherwise specified
Z87.891	Personal history of nicotine dependence • May not be used with F17.2 current nicotine dependence code.
Z13.89	Encounter for screening for other disorder. Use for tobacco use screening.

The preventative counseling codes, 99406 and 99407, can be billed along with an evaluation and management (E/M) code such as 99213 and 99214.

Pharmacologic Product Guide: FDA-Approved Medications for Smoking Cessation

	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	**Lozenge**	**Transdermal Patch**	**Nasal Spray**	**Oral Inhaler**		
Product	**Nicorette**[1]**, Generic** OTC 2 mg, 4 mg original, cinnamon, fruit, mint (various)	**Nicorette**[1]**, Generic** **Nicorette**[1] **Mini** OTC 2 mg, 4 mg; cinnamon, cherry, mint	**Habitrol**[2]**, NicoDerm CQ**[1]**, Generic** OTC 7 mg, 14 mg, 21 mg (24-hr release)	**Nicotrol NS**[3] Rx Metered spray 10 mg/mL nicotine solution	**Nicotrol Inhaler**[3] Rx 10 mg cartridge delivers 4 mg inhaled vapor	**Generic** (formerly Zyban) Rx 150 mg sustained-release tablet	**Chantix**[3] Rx 0.5 mg, 1 mg tablet
Precautions	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Temporomandibular joint disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Underlying chronic nasal disorders (rhinitis, nasal polyps, sinusitis) ▪ Severe reactive airway disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Recent (≤ 2 weeks) myocardial infarction ▪ Serious underlying arrhythmias ▪ Serious or worsening angina pectoris ▪ Bronchospastic disease ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years)	▪ Concomitant therapy with medications/conditions known to lower the seizure threshold ▪ Hepatic impairment ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years) ▪ Treatment-emergent neuropsychiatric symptoms[5] **Contraindications:** ▪ Seizure disorder ▪ Concomitant bupropion (e.g., Wellbutrin) therapy ▪ Current or prior diagnosis of bulimia or anorexia nervosa ▪ Simultaneous abrupt discontinuation of alcohol or sedatives/benzodiazepines ▪ MAO inhibitors in preceding 14 days; concurrent use of reversible MAO inhibitors	▪ Severe renal impairment (dosage adjustment is necessary) ▪ Pregnancy[4] and breastfeeding ▪ Adolescents (<18 years) ▪ Treatment-emergent neuropsychiatric symptoms[5]
Dosing	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 piece q 1–2 hours* Weeks 7–9: 1 piece q 2–4 hours* Weeks 10–12: 1 piece q 4–8 hours* **while awake* ▪ Maximum, 24 pieces/day ▪ During initial 6 weeks of treatment, use at least 9 pieces/day ▪ Chew each piece slowly ▪ Park between cheek and gum when peppery or tingling sensation appears (~15–30 chews) ▪ Resume chewing when tingle fades ▪ Repeat chew/park steps until most of the nicotine is gone (tingle does not return; generally 30 min) ▪ Park in different areas of mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*1st cigarette ≤30 minutes after waking:* 4 mg *1st cigarette >30 minutes after waking:* 2 mg Weeks 1–6: 1 lozenge q 1–2 hours* Weeks 7–9: 1 lozenge q 2–4 hours* Weeks 10–12: 1 lozenge q 4–8 hours* **while awake* ▪ Maximum, 20 lozenges/day ▪ During initial 6 weeks of treatment, use at least 9 lozenges/day ▪ Allow to dissolve slowly (20–30 minutes) ▪ Nicotine release may cause a warm, tingling sensation ▪ Do not chew or swallow ▪ Occasionally rotate to different areas of the mouth ▪ No food or beverages 15 minutes before or during use ▪ Duration: up to 12 weeks	*>10 cigarettes/day:* 21 mg/day x 4–6 weeks 14 mg/day x 2 weeks 7 mg/day x 2 weeks *≤10 cigarettes/day:* 14 mg/day x 6 weeks 7 mg/day x 2 weeks ▪ Rotate patch application site daily; do not apply a new patch to the same skin site for at least one week ▪ May wear patch for 16 hours if patient experiences sleep disturbances (remove at bedtime); before recommending, rule out other factors that might be contributing (e.g., drug interaction between caffeine and tobacco smoke, other medications, and lifestyle factors) ▪ Duration: 8–10 weeks	1–2 doses/hour* (8–40 doses/day) One dose = 2 sprays (one in **each** nostril); each spray delivers 0.5 mg of nicotine to the nasal mucosa **while awake* ▪ Maximum – 5 doses/hour or – 40 doses/day ▪ During intial 6-8 weeks of treatment, use at least 8 doses/day ▪ Gradually reduce daily dosage over an additional 4-6 weeks ▪ Do not sniff, swallow, or inhale through the nose as the spray is being administered ▪ Duration: 12 weeks	6–16 cartridges/day Individualize dosing; initially use 1 cartridge q 1–2 hours* **while awake* ▪ Best effects with continuous puffing for 20 minutes ▪ During initial 6 weeks of treatment use at least 6 cartridges/day ▪ Gradually reduce daily dosage over the following 6-12 weeks ▪ Nicotine in cartridge is depleted after 20 minutes of active puffing ▪ Inhale into back of throat or puff in short breaths ▪ Do NOT inhale into the lungs (like a cigarette) but "puff" as if lighting a pipe ▪ Open cartridge retains potency for 24 hours ▪ No food or beverages 15 minutes before or during use ▪ Duration: 3–6 months	150 mg po q AM x 3 days, then 150 mg po bid ▪ Do not exceed 300 mg/day ▪ Begin therapy 1–2 weeks **prior** to quit date ▪ Allow at least 8 hours between doses ▪ Avoid bedtime dosing to minimize insomnia ▪ Dose tapering is not necessary ▪ Duration: 7–12 weeks, with maintenance up to 6 months in selected patients	Days 1–3: 0.5 mg po q AM Days 4–7: 0.5 mg po bid Weeks 2–12: 1 mg po bid ▪ Begin therapy 1 week **prior** to quit date ▪ Take dose after eating and with a full glass of water ▪ Dose tapering is not necessary ▪ Dosing adjustment is necessary for patients with severe renal impairment ▪ Duration: 12 weeks; an additional 12-week course may be used in selected patients ▪ May initiate up to 35 days before target quit date OR may reduce smoking over a 12-week period of treatment prior to quitting and continue treatment for an additional 12 weeks

	Nicotine Replacement Therapy (NRT) Formulations					Bupropion SR	Varenicline
	Gum	Lozenge	Transdermal Patch	Nasal Spray	Oral Inhaler		
Adverse Effects	▪ Mouth and throat irritation ▪ Jaw muscle soreness ▪ Hiccups ▪ GI complaints (dyspepsia, nausea) ▪ May stick to dental work ▪ Adverse effects more commonly experienced when chewing the lozenge or using incorrect gum chewing technique (due to rapid nicotine release): – Lightheadedness/dizziness – Nausea/vomiting – Hiccups – Mouth and throat irritation	▪ Mouth and throat irritation ▪ Hiccups ▪ GI complaints (dyspepsia, nausea)	▪ Local skin reactions (erythema, pruritus, burning) ▪ Sleep disturbances (abnormal or vivid dreams, insomnia); associated with nocturnal nicotine absorption	▪ Nasal and/or throat irritation (hot, peppery, or burning sensation) ▪ Ocular irritation/tearing ▪ Sneezing ▪ Cough	▪ Mouth and/or throat irritation ▪ Cough ▪ Hiccups ▪ GI complaints (dyspepsia, nausea)	▪ Insomnia ▪ Dry mouth ▪ Nausea ▪ Anxiety/difficulty concentrating ▪ Constipation ▪ Tremor ▪ Rash ▪ Seizures (risk is 0.15%) ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)	▪ Nausea ▪ Sleep disturbances (insomnia, abnormal/vivid dreams) ▪ Headache ▪ Flatulence ▪ Constipation ▪ Taste alteration ▪ Neuropsychiatric symptoms (rare; see PRECAUTIONS)
Advantages	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges ▪ Relatively inexpensive	▪ Might serve as an oral substitute for tobacco ▪ Might delay weight gain ▪ Can be titrated to manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges ▪ Relatively inexpensive	▪ Once-daily dosing associated with fewer adherence problems ▪ Of all NRT products, its use is least obvious to others ▪ Can be used in combination with other agents; delivers consistent nicotine levels over 24 hours ▪ Relatively inexpensive	▪ Can be titrated to rapidly manage withdrawal symptoms ▪ Can be used in combination with other agents to manage situational urges	▪ Might serve as an oral substitute for tobacco ▪ Can be titrated to manage withdrawal symptoms ▪ Mimics hand-to-mouth ritual of smoking ▪ Can be used in combination with other agents to manage situational urges	▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Might delay weight gain ▪ Might be beneficial in patients with depression ▪ Can be used in combination with NRT agents ▪ Relatively inexpensive (generic formulations)	▪ Twice-daily oral dosing is simple and associated with fewer adherence problems ▪ Offers a different mechanism of action for patients who have failed other agents ▪ Most effective cessation agent when used as monotherapy
Disadvantages	▪ Need for frequent dosing can compromise adherence ▪ Might be problematic for patients with significant dental work ▪ Proper chewing technique is necessary for effectiveness and to minimize adverse effects ▪ Gum chewing might not be acceptable or desirable for some patients	▪ Need for frequent dosing can compromise adherence ▪ Gastrointestinal side effects (nausea, hiccups, heartburn) might be bothersome	▪ When used as monotherapy, cannot be titrated to acutely manage withdrawal symptoms ▪ Not recommended for use by patients with dermatologic conditions (e.g., psoriasis, eczema, atopic dermatitis)	▪ Need for frequent dosing can compromise adherence ▪ Nasal administration might not be acceptable or desirable for some patients; nasal irritation often problematic ▪ Not recommended for use by patients with chronic nasal disorders or severe reactive airway disease ▪ Cost of treatment	▪ Need for frequent dosing can compromise adherence ▪ Cartridges might be less effective in cold environments (≤60°F) ▪ Cost of treatment	▪ Seizure risk is increased ▪ Several contraindications and precautions preclude use in some patients (see PRECAUTIONS) ▪ Patients should be monitored for potential neuropsychiatric symptoms[5] (see PRECAUTIONS)	▪ Patients should be monitored for potential neuropsychiatric symptoms[5] (see PRECAUTIONS) ▪ Cost of treatment
Cost/day[6]	2 mg or 4 mg: $1.90–$5.49 (9 pieces)	2 mg or 4 mg: $2.97–$4.23 (9 pieces)	$1.52–$3.49 (1 patch)	$9.64 (8 doses)	$16.38 (6 cartridges)	$0.72 (2 tablets)	$17.20 (2 tablets)

[1] Marketed by GlaxoSmithKline.
[2] Marketed by Dr. Reddy's.
[3] Marketed by Pfizer.
[4] The U.S. Clinical Practice Guideline states that pregnant smokers should be encouraged to quit without medication based on insufficient evidence of effectiveness and theoretical concerns with safety. Pregnant smokers should be offered behavioral counseling interventions that exceed minimal advice to quit.
[5] In July 2009, the FDA mandated that the prescribing information for all bupropion- and varenicline-containing products include a black-boxed warning highlighting the risk of serious neuropsychiatric symptoms, including changes in behavior, hostility, agitation, depressed mood, suicidal thoughts and behavior, and attempted suicide. Clinicians should advise patients to stop taking varenicline or bupropion SR and contact a health care provider immediately if they experience agitation, depressed mood, or any changes in behavior that are not typical of nicotine withdrawal, or if they experience suicidal thoughts or behavior. If treatment is stopped due to neuropsychiatric symptoms, patients should be monitored until the symptoms resolve. Based on results of a mandated clinical trial, the FDA removed this boxed warning in December 2016.
[6] Approximate cost based on the recommended initial dosing for each agent and the wholesale acquisition cost from Red Book Online. Thomson Reuters, January 2021.

Abbreviations: MAO, monoamine oxidase; NRT, nicotine replacement therapy; OTC, over-the-counter (nonprescription product); Rx, prescription product.

For complete prescribing information and a comprehensive listing of warnings and precautions, please refer to the manufacturers' package inserts.

DRUG INTERACTIONS WITH TOBACCO SMOKE

Many interactions between tobacco smoke and medications have been identified. Note that in most cases it is the tobacco smoke—not the nicotine—that causes these drug interactions. Tobacco smoke interacts with medications through pharmacokinetic (PK) and pharmacodynamic (PD) mechanisms. PK interactions affect the absorption, distribution, metabolism, or elimination of other drugs, potentially causing an altered pharmacologic response. The majority of PK interactions with smoking are the result of induction of hepatic cytochrome P450 enzymes (primarily CYP1A2). Smokers may require higher doses of medications that are CYP1A2 substrates. Upon cessation, dose reductions might be needed. PD interactions alter the expected response or actions of other drugs. The amount of tobacco smoking needed to have an effect has not been established, and the assumption is that any smoker is susceptible to the same degree of interaction. **The most clinically significant interactions are depicted in the shaded rows.**

DRUG/CLASS	MECHANISM OF INTERACTION AND EFFECTS
Pharmacokinetic Interactions	
Alprazolam (Xanax®)	• Conflicting data on significance, but possible ↓ plasma concentrations (up to 50%); ↓ half-life (35%).
Bendamustine (Treanda®)	• Metabolized by CYP1A2. Manufacturer recommends using with caution in smokers due to likely ↓ bendamustine concentrations, with ↑ concentrations of its two active metabolites.
Caffeine	• ↑ Metabolism (induction of CYP1A2); ↑ clearance (56%). Caffeine levels likely ↑ after cessation.
Chlorpromazine (Thorazine®)	• ↓ Area under the curve (AUC) (36%) and serum concentrations (24%). • ↓ Sedation and hypotension possible in smokers; smokers may require ↑ dosages.
Clopidogrel (Plavix®)	• ↑ Metabolism (induction of CYP1A2) of clopidogrel to its active metabolite. • Enhanced response to clopidogrel in smokers (≥10 cigarettes/day): ↑ platelet inhibition, ↓ platelet aggregation; improved clinical outcomes have been shown (smokers' paradox; may be dependent on CYP1A2 genotype); tobacco cessation should still be recommended in at-risk populations needing clopidogrel.
Clozapine (Clozaril®)	• ↑ Metabolism (induction of CYP1A2); ↓ plasma concentrations (by 18%). • ↑ Levels upon cessation may occur; closely monitor drug levels and reduce dose as required to avoid toxicity.
Erlotinib (Tarceva®)	• ↑ Clearance (24%); ↓ trough serum concentrations (2-fold).
Flecainide (Tambocor®)	• ↑ Clearance (61%); ↓ trough serum concentrations (25%). • Smokers may need ↑ dosages.
Fluvoxamine (Luvox®)	• ↑ Metabolism (induction of CYP1A2); ↑ clearance (24%); ↓ AUC (31%); ↓ Cmax (32%) and Css (39%). • Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Haloperidol (Haldol®)	• ↑ Clearance (44%); ↓ serum concentrations (70%); data are inconsistent therefore clinical significance is unclear.
Heparin	• Mechanism unknown. ↑ clearance; ↓ half-life. Smoking has prothrombotic effects. • Smokers may need ↑ dosages due to PK and PD interactions.
Insulin, subcutaneous	• Possible ↓ insulin absorption secondary to peripheral vasoconstriction. • Smoking may cause release of endogenous substances that cause insulin resistance. • PK & PD interactions likely not clinically significant, but smokers may need ↑ dosages.
Irinotecan (Camptosar®)	• ↑ Clearance (18%); ↓ serum concentrations of active metabolite, SN-38 (~40%; via induction of glucuronidation); ↓ systemic exposure resulting in lower hematologic toxicity and may reduce efficacy. • Smokers may need ↑ dosages.
Methadone	• Possible ↑ metabolism (induction of CYP1A2, a minor pathway for methadone). • Carefully monitor response upon cessation.
Mexiletine (Mexitil®)	• ↑ Clearance (25%; via oxidation and glucuronidation); ↓ half-life (36%).
Nintedanib (OFEV®)	• Decreased exposure (21%) in smokers. • No dose adjustment recommended, however, patients should not smoke during use.

Pharmacokinetic Interactions (continued)	
Drug/Class	**Mechanism of Interaction and Effects**
Olanzapine (Zyprexa®)	• ↑ Metabolism (induction of CYP1A2); ↑ clearance (98%); ↓ serum concentrations (12%). • Dosage modifications not routinely recommended but smokers may need ↑ dosages.
Pirfenidone (Esbriet®)	• ↑ Metabolism (induction of CYP1A2); ↓ AUC (46%) and ↓ Cmax (68%). • Decreased exposure in smokers might alter efficacy profile.
Propranolol (Inderal®)	• ↑ Clearance (77%, via side-chain oxidation and glucuronidation)
Riociguat (Adempas®)	• ↓ Plasma concentrations (by 50–60%). • Smokers may require dosages higher than 2.5 mg three times a day; consider dose reduction upon cessation.
Ropinirole (Requip®)	• ↓ Cmax (30%) and ↓ AUC (38%) in study with patients with restless legs syndrome. • Smokers may need ↑ dosages.
Tasimelteon (Hetlioz®)	• ↑ Metabolism (induction of CYP1A2); ↓ drug exposure (40%). • Smokers may need ↑ dosages.
Theophylline (Theo-Dur®, etc.)	• ↑ Metabolism (induction of CYP1A2); ↑ clearance (58–100%); ↓ half-life (63%). • Levels should be monitored if smoking is initiated, discontinued, or changed. Maintenance doses are considerably higher in smokers; ↑ clearance also with second-hand smoke exposure.
Tizanidine (Zanaflex®)	• ↓ AUC (30–40%) and ↓ half-life (10%) observed in male smokers.
Tricyclic antidepressants (e.g., imipramine, nortriptyline)	• Possible interaction with tricyclic antidepressants in the direction of ↓ blood levels, but the clinical significance is not established.
Warfarin	• ↑ Metabolism (induction of CYP1A2) of R-enantiomer; however, S-enantiomer is more potent and effect on INR is inconclusive. Consider monitoring INR upon smoking cessation.
Pharmacodynamic Interactions	
Benzodiazepines (diazepam, chlordiazepoxide)	• ↓ Sedation and drowsiness, possibly caused by nicotine stimulation of central nervous system.
Beta-blockers	• Less effective BP and heart rate control effects, possibly caused by nicotine-mediated sympathetic activation. • Smokers may need ↑ dosages.
Corticosteroids, inhaled	• Smokers with asthma may have less of a response to inhaled corticosteroids.
Hormonal contraceptives (combined)	• ↑ Risk of cardiovascular adverse effects (e.g., stroke, myocardial infarction, thromboembolism) in women who smoke and use combined hormonal contraceptives. Ortho Evra patch users shown to have 2-fold ↑risk of venous thromboembolism compared with oral contraceptive users, likely due to ↑ estrogen exposure (60% higher levels). • ↑ Risk with age and with heavy smoking (≥15 cigarettes per day) and is quite marked in women ≥35 years old.
Serotonin 5-HT_1 receptor agonists (triptans)	• This class of drugs may cause coronary vasospasm, caution for use in smokers due to possible unrecognized CAD.
Adapted and updated, from Zevin S, Benowitz NL. Drug interactions with tobacco smoking. An update. *Clin Pharmacokinet* 1999;36:425–38 and Kroon LA. Drug interactions with smoking. *Am J Health-Syst Pharm* 2007;64:1917–21.	

APPENDIX L: PERMISSION TO USE PRE- AND POST-EDUCATION QUESTIONNAIRE

Cunningham, James K - (jkcunnin) <jkcunnin@arizona.edu>
Mon 11/22/2021 10:29 AM
To: Doan, Jillian <jillian.b.glass@ndsu.edu>

Hi Jillian,

Yes, you are welcome to use the questionnaire. Glad it has been helpful. Good luck with your research project.

Kind regards,

Jim

James K. Cunningham, PhD
Director, Policy & Program Research
Dept. of Family and Community Medicine, College of Medicine
Health Promotion Sciences, College of Public Health
The University of Arizona

From: Doan, Jillian <jillian.b.glass@ndsu.edu>
Sent: Sunday, November 21, 2021 9:13 AM
To: Cunningham, James K - (jkcunnin) <jkcunnin@arizona.edu>
Subject: [EXT]Permission to use RTTI questionnaire

External Email

Hello Dr. Cunningham,

My name is Jillian Doan and I am a Doctor of Nursing Practice student at North Dakota State University. I am developing a dissertation project that incorporates tobacco cessation education into the graduate family nurse practitioner program at NDSU. I found your article "Complementary and Alternative (CAM) practitioners' readiness for tobacco intervention training: Development and psychometric properties of a new measure" extremely beneficial in my research. With your permission, I would like to use and reproduce the CAM RTTA questionnaire from this study in my project. My dissertation chair, Dr. Kelly Buettner-Schmidt-PhD, has also used the questionnaire in her work and has found them beneficial in evaluation.

Please let me know if you have any questions or if you need any additional information from me.

Thanks for the consideration,

Jillian Doan
NDSU DNP Student
jillian.b.glass@ndus.edu
(701) 429-1701

APPENDIX M: PRE-EDUCATION TOBACCO CESSATION QUESTIONNAIRE

	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
1. It is important, as a practitioner, to know whether a patient/client uses tobacco				
2. It is important, as a practitioner, to know whether a patient/client has regular exposure to secondhand smoke				
3. I am motivated to help tobacco users quit.				
	Very Comfortable	**Somewhat Comfortable**	**Not Very Comfortable**	**Not Comfortable at all**
4. How comfortable are you in talking with patients/clients about tobacco use.				
	Very confident	**Somewhat Confident**	**Not Very Confident**	**Not Confident at all**
5. I am confident that I can explore issues related to quitting smoking, even with someone not interested in quitting.				
6. I am confident that I can personalize the benefits of quitting with each individual tobacco user.				
7. I am confident that I know if a patient has regular exposure to secondhand smoke.				
	Very Comfortable	**Somewhat Comfortable**	**Not Very Comfortable**	**Not Comfortable at all**
8. How comfortable are you in providing information about medications that help in quitting tobacco?				
9. How comfortable are you in providing information about programs and services that help				

aid in quitting (quit lines, counseling etc.)?				
	Very Confident	**Somewhat Confident**	**Not Very Confident**	**Not Confident at all**
10. I am confident that I can provide information about programs and services that help in quitting (quitlines, counseling, etc).				
11. I am confident that I can provide information about medications that can help in quitting tobacco.				
Demographic Questions				
12. What is your gender?				
	Male			
	Female			
	Non-binary / third gender			
	Prefer not to say			
13. How many years of nursing experience do you currently have?				
	1-2 years			
	3-5 years			
	6-10 years			
	11-15 years			
	15+ years			
14. Have you used any form of tobacco in the last year?				
	Yes			
	No			
15. Have you had any previous tobacco cessation training?				
	Yes			
	No			

With written permission obtained from Cunningham to use RTTI in this study. Adapted from Cunningham, J. K., Floden, L. L., Howerter, A. L., Matthews, E., Gordon, J. S., & Muramoto, M. L. (2015). Complementary and Alternative Medicine (CAM) practitioners' readiness for tobacco intervention training: Development and psychometric properties of a new measure. Advances in Integrative Medicine, 2(2), 90-95. https://doi.org/10.1016/j.aimed.2014.10.012

APPENDIX N: POST-EDUCATION TOBACCO CESSATION QUESTIONNAIRE

	Strongly Agree	**Agree**	**Disagree**	**Strongly Disagree**
1. It is important, as a practitioner, to know whether a patient/client uses tobacco				
2. It is important, as a practitioner, to know whether a patient/client has regular exposure to secondhand smoke				
3. I am motivated to help tobacco users quit.				
	Very Comfortable	**Somewhat Comfortable**	**Not Very Comfortable**	**Not Comfortable at all**
4. How comfortable are you in talking with patients/clients about tobacco use.				
	Very confident	**Somewhat Confident**	**Not Very Confident**	**Not Confident at all**
5. I am confident that I can explore issues related to quitting smoking, even with someone not interested in quitting.				
6. I am confident that I can personalize the benefits of quitting with each individual tobacco user.				
7. I am confident that I know if a patient has regular exposure to secondhand smoke.				
	Very Comfortable	**Somewhat Comfortable**	**Not Very Comfortable**	**Not Comfortable at all**
8. How comfortable are you in providing information about medications that help in quitting tobacco?				
9. How comfortable are you in providing information about programs and services that help				

aid in quitting (quit lines, counseling etc.)?				
	Very Confident	**Somewhat Confident**	**Not Very Confident**	**Not Confident at all**
10. I am confident that I can provide information about programs and services that help in quitting (quitlines, counseling, etc).				
11. I am confident that I can provide information about medications that can help in quitting tobacco.				

APPENDIX O: RECOMMENDATIONS

Recommendations for Educational Institutions	
1.	Include formal tobacco cessation counseling education into the coursework of all future primary care providers • Pharmacological interventions • Behavioral interventions • Interactive patient scenarios • Local tobacco cessation resources • Coding and billing for tobacco treatment
2.	Tobacco cessation treatment knowledge questions should be included in the course's final exam
3.	Split the tobacco cessation content into more than one course
Recommendations for Future Research	
1.	Examine the effect that tobacco cessation education for primary care providers has on patient's tobacco cessation success
2.	Pair pre- and post-education data sets to enable determination of statistical significance and, thereby, effectiveness of the intervention
3.	Evaluate participants confidence and comfort in prescribing tobacco cessation medications
4.	Define "comfort" and "confidence" as there seems to be an overlap in meaning
5.	Potentially delete questions related to secondhand smoke exposure Alternatively, the secondhand smoke questions could be measured separately from motivation and confidence in helping people quit tobacco use
6.	Include a comprehensive and stronger emphasis on ENDS use in regard to cessation and harm reduction
7.	Include information about new and emerging tobacco products