ELECTRONIC NICOTINE DELIVERY SYSTEMS: YOUTH PREVENTION AND CESSATION DISCUSSIONS BY PRIMARY CARE PROVIDERS

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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

Youth use of electronic nicotine delivery systems (ENDS) has increased over the last several years, necessitating proactive steps by primary care providers (PCP) including discussing ENDS health effects with youth and providing cessation counseling. The CDC recommends that people under age 25 should not use ENDS. Brief counseling about use of tobacco products is cost-effective and beneficial to patients' health. PCPs need current, accurate information about ENDS to deliver comprehensive preventive services and cessation counseling to a vulnerable adolescent population.

The purposes of this practice improvement project were to increase PCPs' knowledge, patient discussions, and cessation referrals related to ENDS use. Key informant interviews with two PCPs were conducted with five identified themes combined with best practice recommendations into an educational session for PCPs and nurses.

Surveys assessed PCPs for increased knowledge, motivation, confidence, and comfort in discussing ENDS use with their patients and for increased tobacco cessation activities. A retrospective chart review evaluated the education's impact on the rates of PCP-patient discussions about ENDS use and cessation referrals by PCPs.

The education resulted in increased knowledge, motivation, confidence, and comfort in discussing ENDS use, cessation medications, cessation treatment within PCP practices and referral for treatment outside of PCP practices. Although not confirmed by the chart review, PCPs reported the likelihood to change their practices in relation to ENDS counseling and referral. PCPS also reported at three-months post-education increased activity in treating patients within PCP practice as well as referring to ENDS treatment outside of PCP practice.

Recommendations include that all PCPs should receive more education about how to talk to their youth and young adult patients about ENDS use and about the resources available to help them quit using ENDS. Clear and readily available clinical guidelines are needed to support PCPs' efforts and modifications of the chart review software is needed for improved assessment of PCP practices. Youth should also receive education about ENDS use so that they are able to make informed decisions about behaviors that may negatively impact their health.

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Last and certainly not least, I would be remiss without thanking my family. My husband has always offered an ear to listen or a shoulder to cry on when things seemed overwhelming and has always ensured my Excel spreadsheets are perfectly formatted. My parents and siblings have been patient and understanding about my schedule and have consistently supported me and my academic and professional pursuits. I look forward to celebrating with them soon.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

ENDS	Electronic Nicotine Delivery Systems
USDHHS	United States Department of Health and Human Services
YRBS	Youth Risk Behavior Survey
NDDPI	North Dakota Department of Public Instruction
PCP	Primary Care Provider
THC	Tetrahydrocannabinol
EVALI	E-cigarette/Vaping Associated Lung Injury
CDC	Centers for Disease Control and Prevention
USFDA	United States Food and Drug Administration
AAR	Ask, Advise, Refer
EHR	Electronic Health Record
CINAHL	Cumulative Index to Nursing and Allied Health Literature
MeSH	Medical Subject Heading
NDDH	North Dakota Department of Health
NYTS	National Youth Tobacco Survey
ACE2	Angiotensin-Converting Enzyme 2
USPSTF	United States Preventive Services Task Force
NRT	Nicotine Replacement Therapy
MI	Motivational Interviewing
TRA	Theory of Reasoned Action
SVCC	Sanford Valley City Clinic
NDSU	North Dakota State University
LPN	Licensed Practical Nurse

RN .....Registered Nurse

MD .....Medical Doctor

PA .....Physician Assistant

CAM .....Complimentary Alternative Medicine

CHAPTER ONE: INTRODUCTION

Background and Significance

Electronic nicotine delivery systems (ENDS) are battery-operated devices that may deliver nicotine by converting nicotine-containing liquid to vapor, which is then inhaled into the lungs of the user (U.S. Department of Health and Human Services [USDHHS], 2020). ENDS are also called a 'vape' or 'e-cigarette.' The aerosolized liquid typically not only contains nicotine, but flavoring, heavy metals, and other potentially carcinogenic substances as well. ENDS are not considered safe for anyone, especially in people younger than age 25, pregnant women, or any adults who are not already using tobacco products.

Use of ENDS increased markedly over the past two years. In 2019, 10.5% of middle school students and 27.5% of high school students in the United States had used ENDS products in the past 30 days, which was estimated to be approximately 5 million students (Cullen et al., 2019). According to the 2017 Youth Risk Behavior Survey (YRBS), approximately 8.0% of middle school students and 28.1% of high school students in North Dakota were current ENDS users (North Dakota Department of Public Instruction [NDDPI], 2017a; 2017b). Current use was defined as having used ENDS at least one day in the past 30 days. In 2019, these rates increased; the YRBS indicated that 10.3% of North Dakota middle school students and 33.1% of North Dakota high school students were current users of ENDS (NDDPI, 2019a; 2019b). This data indicates an increasing number of affected individuals, necessitating primary care providers (PCPs) to address the past and current use and health implications of ENDS use and to provide current, relevant information to their patients.

In addition to the alarming increasing prevalence of ENDS use, the health effects related to ENDS use are numerous. The negative health effects of nicotine have been well-studied,

although there are not long-term studies relating to ENDS use. However, ENDS users can achieve equivalent concentrations of nicotine in their blood as smokers, linking ENDS to the negative health outcomes associated with nicotine use. Most recently, research shows that youth who use ENDS are both more likely to contract COVID-19 and are more likely to develop symptomatic infection (Stanford Medicine, 2021).

Health concerns of ENDS include inhalation of nicotine, heavy metals, and toxic chemicals in ENDS aerosol and combustion of the devices themselves (USDHHS, 2018). In addition, research suggests that use of ENDS in adolescence may lead to future use of cigarettes and other drugs (USDHHS, 2018). The negative health impacts of cigarette smoking are well known and include cancer, heart disease, stroke, lung diseases, diabetes, chronic obstructive pulmonary disease, emphysema, chronic bronchitis, and decreased life expectancy (Centers for Disease Control [CDC], 2019b).

Furthermore, the use of nicotine during adolescence has been linked to altered brain development, as well as predisposing its users to develop addictions to other drugs (USDHHS, 2018). There are also negative outcomes related to maternal use of nicotine, including increased risks for Sudden Infant Death Syndrome, disruptive behaviors and attention deficit disorders, mood disorders, and auditory processing delays (USDHHS, 2016). The use of ENDS, especially those containing THC products, has recently been linked to serious lung illnesses, also known as e-cigarette/vaping-associated lung injury (EVALI; CDC, 2019a).

While ENDS have been promoted by some as a helpful tool for smoking cessation, the U.S. Food and Drug Administration (FDA) has not approved ENDS as an aid for smoking cessation (FDA, 2019a). Furthermore, the use of ENDS as a smoking cessation aid has not been shown to be more effective than other methods, and the long-term safety and efficacy has yet to

be demonstrated (Franks, Sando, & McBane, 2018). The USPSTF (2021) reports that there is insufficient evidence to assess the balance of benefits and harms of electronic cigarettes for tobacco cessation and that patients who use tobacco should be provided with proven and effective cessation methods. Most adults who use ENDS to attempt to quit smoking may simply use traditional cigarettes in addition to the ENDS, and dual use is associated with failed smoking cessation attempts (Orellana-Barrios, 2015; USDHHS, 2020).

Adolescents are part of a highly impressionable and vulnerable age group. They are attempting to gain independence, make decisions about career paths and further education, and find social acceptance. Adolescents' role within their peer group is crucial. Producers of ENDS emerged in popularity by marketing to a wide audience via large-scale advertising campaigns and reached adolescents via television advertisements and other forms of social media (Duke et al., 2014). Currently, due to advertising regulations and restrictions, ENDS are primarily marketed through direct marketing at the point of sale and online (Loukas et al., 2019).

Research suggests that dissemination of correct information about the health implications of ENDS use may be effective in reducing the use of ENDS in adolescents (Choi & Forster, 2013). As PCPs have the opportunity to interact regularly with their patients, they are in a "strategic position" to help patients discontinue use of tobacco products and ENDS (Park et al., 2015, p. 1510).

While ENDS use is relatively new for adolescents, the same principles for smoking cessation apply, beginning with addressing the use of ENDS at each visit. The CDC recommends people who do not already smoke should not start using ENDS, and that ENDS are not recommended for use in anyone under 25 (USDHHS, 2018). It is necessary to provide accurate

information about ENDS use and the health implications at each clinic visit as part of health promotion.

For adolescents who are using tobacco products, the CDC recommends PCPs ask about tobacco use at each visit. The preferred method for addressing tobacco cessation is the 5 A's method of ask, advise, assess, assist, and arrange (USDHHS, 2020). The AAR method of asking about tobacco use, advising the patient to quit, and referring to appropriate resources for cessation is also an appropriate method of addressing tobacco cessation (USDHHS, 2020)

Problem Statement

Youth use of ENDS has rapidly increased over the last several years, necessitating proactive steps by PCPs including discussing the health effects of ENDS with youth and providing cessation advice and resources. Although the recommendations for ENDS use vary for adult users and the long-term health effects of ENDS use are not yet fully understood, the CDC recommends that people under age 25 should not use ENDS (USDHHS, 2020). Brief counseling about use of tobacco products is cost effective and beneficial to patients' health (Maciosek et al., 2017). PCPs need current accurate information about ENDS to deliver comprehensive preventive services to a vulnerable adolescent population (Pepper, McRee, & Gilkey, 2014).

Purpose

The purposes of this project were to increase PCP knowledge of ENDS, increase PCP patient discussions regarding ENDS, and increase cessation referrals.

Project Objectives

The objectives for the project were to:

1. Assess current barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews of PCPs.

2. Develop an educational session for PCPs about the current research regarding the use of ENDS, the health implications, cessation referral resources, and appropriate electronic health record (EHR) documentation.
3. Implement an educational session for PCPs based on current research and results of key informant interviews.
4. Evaluate change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, and comfort in discussing ENDS and increased tobacco cessation activities, through PCP surveys.
5. Assess and compare rates of PCP discussion about ENDS and rates of cessation referral three months pre-education and three months post-education by conducting retrospective chart reviews.

CHAPTER TWO: LITERATURE REVIEW AND THEORETICAL FRAMEWORK

Literature Review

Search Strategy

Information related to ENDS was largely available as government sources and grey literature; therefore, hand-searching was used to obtain data and statistics regarding use, regional prevalence, components of ENDS, health impacts of ENDS, and information specific to ENDS. However, a formal literature review was performed regarding tobacco cessation counseling and the PCP role in tobacco cessation.

Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, Cochrane Library, and HealthSource: Nursing/Academic Edition were used to search for articles on PCPs and tobacco cessation using the keywords "health personnel," "primary healthcare," "tobacco cessation," "attitude of health personnel," and "electronic nicotine delivery systems." Keywords were chosen as Medical Subject Headings (MeSH) to incorporate only the desired information, and the searches were restricted to major MeSH terms/major subject headings when possible to incorporate relevant information.

Only articles and data published within the last five years, or after 2015, were included in the literature review of the PCP role in tobacco cessation. Exclusion criteria included studies or articles with a narrow focus or those not applicable to primary medical care, such as studies about tobacco cessation in dentistry. Age was not an exclusion criterion in order to encompass the overall role of primary care PCPs in tobacco cessation. In sum, 31 articles were included in the final review of evidence. Eight of the articles included were added from hand-searching and government sources. The search strategy is detailed in Appendix A.

History of ENDS

ENDS are also known as “personal vaporizers, vape pens, e-cigars, e-hookah, vaping devices, mod systems or pod systems” (American Academy of Pediatrics [AAP], 2019, para. 1). The earliest record of ENDS is a United States patent for a “smokeless nontobacco cigarette” in 1965 (USDHHS, 2016). The patent was an early attempt at reducing the harmful inhalation of tobacco and paper by replacing it with heated, flavored vapor (USDHHS, 2016). The Favor Smokeless Cigarette, introduced in 1986, was another early non-combustible device marketed as an alternative “nicotine-containing tobacco product” (USDHHS, 2016). However, the first modern iteration of an ENDS appeared in a Chinese patent in 2003 for an electronic atomizing cigarette, which entered the Chinese market in 2004 (USDHHS, 2016). This device was most popular in China as a tobacco cessation device and was introduced in the United States as such in 2010. Chinese innovation has had a significant influence on the global ENDS market; by 2014, an estimated 90% of the ENDS products circulating throughout the world were produced in mainland China (USDHHS, 2016).

Generations of ENDS

At the time of this review, there were four generations of ENDS. First-generation ENDS appeared relatively similar to traditional cigarettes and were developed and marketed as healthy alternatives. The first-generation ENDS were activated by simply inhaling on the device and were often disposable. In contrast to later generations of ENDS, the first-generation devices had nicotine solutions, or ‘e-liquids’, sold in pre-filled cartridges. Second-generation ENDS were more technologically advanced, and some had a refillable tank for e-liquid. These devices also had longer lasting or rechargeable batteries, and may have had power buttons that users pushed to activate the delivery of nicotine. Devices called ‘tanks’ belonged in this category of ENDS.

Third- and fourth-generation ENDS occurred in a variety of shapes and sizes and were the most versatile and different from traditional cigarettes. Devices called ‘mods,’ or devices modified to fit the user’s needs, or ‘pods’ such as JUUL devices, belonged to the later generations of ENDS (USDHHS, 2016). Refer to Figure 1 for a visual representation of the generations of ENDS.

Figure 1

Generations of ENDS

Note. Adapted from “E-cigarette, or vaping, product visual dictionary” by Centers for Disease Control and Prevention, n.d.b., *E-cigarette, or vaping, product visual dictionary.* (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf). In the public domain.

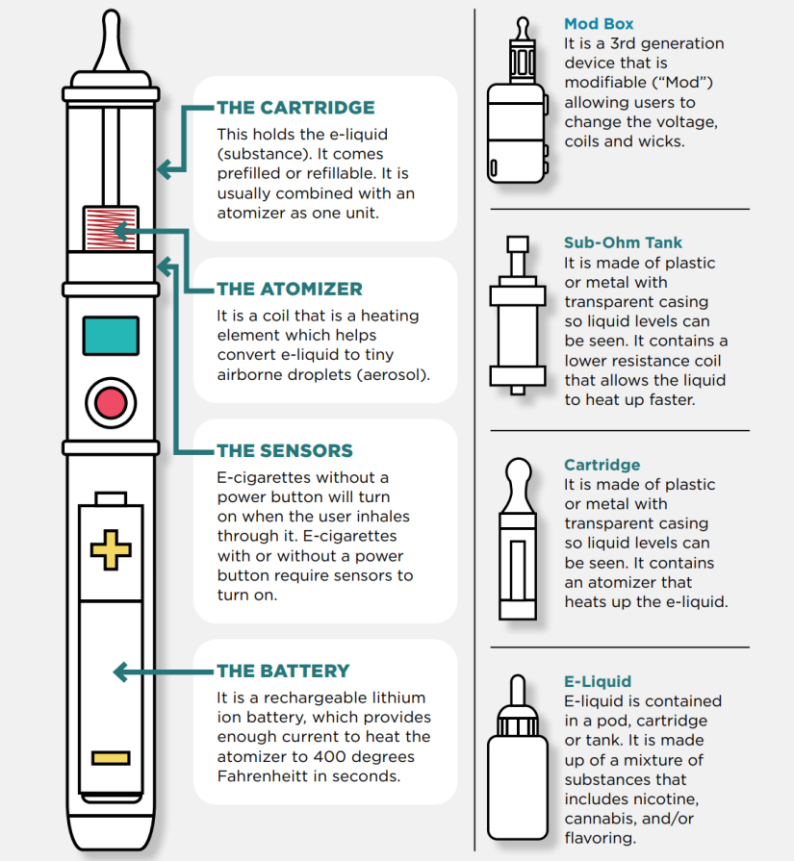
Components of ENDS

Basic knowledge of the components of an ENDS is important to understanding how the device functions and any health-related concerns associated with them. As shown in Figure 2 below, the main parts include the cartridge, which contains the e-liquid; the atomizer, which heats the e-liquids and converts it to aerosolized droplets for inhalation; the sensor, which turns

the device on and/or detects inhalation and delivers the aerosol; and the battery, which provides the power to heat the atomizer. As previously mentioned, the batteries were rechargeable in later generations of ENDS, as opposed to a finite battery life seen in earlier generations of ENDS.

Figure 2

Components of ENDS



Note. Adapted from "E-cigarette, or vaping, product visual dictionary" by Centers for Disease Control and Prevention, n.d.b., *E-cigarette, or vaping, product visual dictionary.* (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/pdfs/ecigarette-or-vaping-products-visual-dictionary-508.pdf). In the public domain.

Freebase Nicotine and Nicotine Salts. The form of nicotine contained in ENDS and traditional cigarettes varies, which has a substantial effect on popularity and delivery of nicotine content. Freebase nicotine, which is used in traditional cigarettes and earlier generations of ENDS has a higher (more alkaline) pH (CDC, 2020b). Nicotine salts are used in JUUL and other

newer generations of ENDS devices. Nicotine salts have a lower pH (more acidic) than free base nicotine and allow inhalation of especially high levels of nicotine. Nicotine salts produce less irritating vapor than traditional ENDS, which use free-base nicotine. Use of nicotine salts may increase the potential for dependence, especially among younger people.

JUUL

Popularity of JUUL

The emergence of JUUL as an ENDS product in 2015 largely contributed to the widespread popularity of ENDS among youth; in 2018, JUUL held a "49.6% dollar share and 31.1%-unit share of the ENDS market" (Willett et al., 2019, p. 115). The popularity of JUUL is partly attributed to the innovative and inconspicuous design of the device, as well as the wide variety of available flavorings of e-liquid cartridges. However, the rate of nicotine delivery of the device is 1.25-2.7 times faster than a traditional cigarette and delivers similar or higher nicotine concentrations to other e-liquids and traditional cigarettes, which also adds to the appeal of the JUUL for its consumers (Gotts, Jordt, McConnell, & Tarran, 2019; Willett et al., 2019).

JUUL began advertising its product in 2015 with large, colorful advertising such as billboards, magazine advertisements, and YouTube videos (Bach, 2018). The FDA is monitoring JUUL's strategy of targeting younger people with use of e-liquid flavors that appeal to younger people and misleading younger people to believe that JUUL products are less harmful than traditional cigarettes (USFDA, 2019b). Currently, JUUL continues to advertise on Twitter, Instagram, and other forms of social media. While JUUL's page on Instagram and website are age-restricted, their Twitter is not age-restricted, and youth can still view hashtags pertaining to JUUL and its products without verifying their age (Bach, 2018). However, the FDA has enforced regulations that JUUL could not classify their devices as 'modified risk tobacco products,' in

accordance with the need to prove that their product is less harmful with scientific evidence prior to attaining this classification (USFDA, 2019b).

JUUL and Big Tobacco

JUUL secured a large and continuing part of the tobacco product landscape with a sale of 35% of its shares to Altria, the company with the largest share of the United States' cigarette market at 55%, in 2018 (Levy et al., 2019). This partnership was surprising in some ways, given that many use JUUL products and other ENDS as a method of tobacco cessation, despite lack of FDA approval for smoking cessation. The partnership was beneficial to the success of JUUL, as other ENDS products and companies will attempt to emulate the widespread success and popularity of JUUL (Levy et al., 2019). Newer devices like Blu, Vuse, and NJOY currently compete for the market share of ENDS with JUUL (Bach, 2018). Furthermore, Altria may be able to provide guidance on navigating negative health claims and securing wider retail product placement for JUUL. The association with JUUL products may help Altria enter the realm of smoking alternatives and appeal to the more health-conscious consumer (Levy et al., 2019).

Use of ENDS in Adolescents

National use

According to a study conducted by the American Medical Association and funded by the FDA and CDC, ENDS use among high school students in the United States increased between 2011 and 2015 from 1.5% to 16.0% (Cullen et al., 2019). Rates of use then declined in 2016 and remained unchanged in 2017, with about 11.3% to 11.7% of surveyed high school students reporting current ENDS use. However, a "substantial increase" in rates of use between 2017 and 2018 spurred the U.S. Surgeon General to declare ENDS use as a national epidemic (p. 2096). In 2019, 27.5% of the surveyed high school students and 10.5% of the surveyed middle school

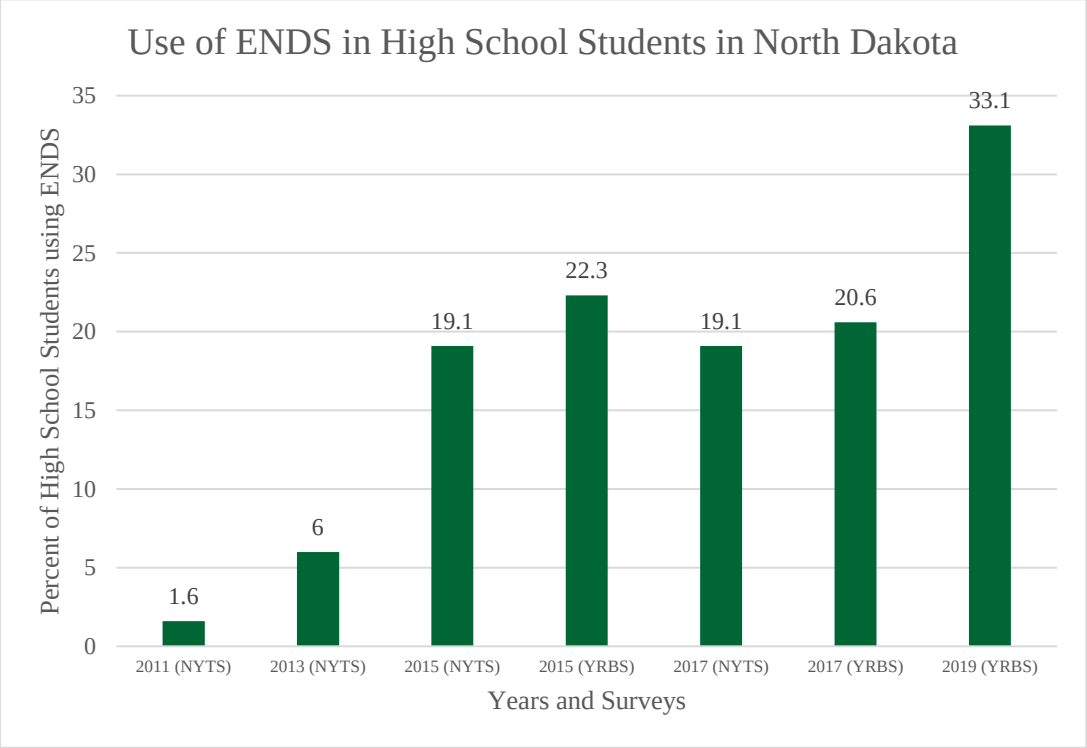
students nationwide reported current ENDS use, indicating the prevalence of use is still high. Five million middle and high school students are current users of ENDS and one million are daily users.

North Dakota

Rates of ENDS use in North Dakota are also increasing. According to the data from the 2017 Youth Risk Behavior Survey (YRBS), approximately 8.0% of middle school students in North Dakota were current ENDS users, with current use defined as having used ENDS at least one day in the past 30 days, while 28.1% of high school students in North Dakota were current ENDS users (NDDPI, 2017a, NDDPI, 2017b). In 2019, these rates increased; the YRBS indicated that 10.3% of North Dakota middle school students and 33.1% of North Dakota high school students were current users of ENDS (NDDPI, 2019a, NDDPI, 2019b). Additionally, 33.5% of North Dakota's high school students reported having used an ENDS in the past 30 days (North Dakota Department of Health [NDDH], 2019). The increase in rates of ENDS use in North Dakota is depicted in Figure 3.

Figure 3

ENDS use in High School Students in North Dakota



Note: NYTS = National Youth Tobacco Survey; YRBS = Youth Risk Behavior Survey. Adapted from "Tobacco surveillance data" by North Dakota Department of Health, 2019. (https://www.health.nd.gov/sites/www/files/documents/Files/HSC/CHS/Tobacco/Tobacco_Surveillance_Data_Table.pdf). In the public domain.

Adolescents as Vulnerable Population

Advertising

Youth are a vulnerable population in general and have increased susceptibility both to peer pressure and to advertising; youth are twice as sensitive to tobacco advertising as adults (Truth Initiative, 2020). Advertising for traditional cigarettes on television has been prohibited in the United States since 1971. The FDA oversees ENDS advertisement; however, ENDS are largely unregulated (USDHHS, 2016). Restrictions on advertising occur in the case of inaccurate

claims, such as that ENDS are satisfactory for cessation or that they are healthier than traditional cigarettes.

According to the 2016 Surgeon General's Report on e-cigarettes, most youth believed ENDS to be less harmful than traditional cigarettes and felt they did not have enough information to determine perceived harm of using these devices (USDHHS, 2016). Furthermore, approximately two-thirds of adolescent and young adult users were unaware that JUUL ENDS devices always contain nicotine (CDC, 2020).

According to the 2019 National Youth Tobacco Survey (NYTS), the most common reason for initiating ENDS use in middle and high school students was curiosity (Wang et al., 2019). Additional reasons for trying ENDS included flavors of e-liquids, seeing family members or friends using the devices, or wanting to do tricks with ENDS. The NYTS also examined youth exposure to marketing and advertisement about ENDS. According to the survey, 69.3% of middle and high school students reported exposure to specific ENDS advertising.

Flavoring of ENDS e-liquids influences the use of ENDS, especially among youth. According to the 2016 Surgeon General's Report on e-cigarettes, middle and high school students who were not already smokers were more likely to use flavored e-liquids and were more likely to use sweeter flavor varieties (USDHHS, 2016). Conversely, adults and people who already smoke cigarettes were more likely to prefer unflavored or menthol varieties of e-liquids. Younger people who tried ENDS cited the interesting flavors as reasons for their experimentation with ENDS. Younger people were also more susceptible to advertising featuring flavored e-liquids; this exposure increased their desire to try ENDS compared with advertising featuring non-flavored e-liquids.

Social media marketing plays an important role in the appeal of ENDS for youth and young adults, who "expect a large degree of personalization, customization, and instant gratification" as consumers (Daniel et al., 2018, p. 99). Social media influencers and celebrities are perceived as trusted and informative sources and therefore can effectively promote a social media strategy to "convince users that it is acceptable to continue smoking" (p. 99). Furthermore, the online presence of social media influencers has created an interactive vaping community, replete with flavor suggestions and tricks using ENDS devices, that spans multiple online platforms and facilitates interaction between users and provides continued support for ENDS use.

In relation to ENDS advertising, a study performed by researchers in Texas indicated that youth and young adults are susceptible to ENDS advertising and may become users of ENDS after viewing the advertisements (Loukas et al., 2019). The researchers followed a group of adolescents (ages 12-17) and young adults (ages 18-29) for 2.5 years and monitored their exposure to advertising and ENDS use. During the study, 58.0% of adolescents saw advertising for ENDS in stores, 44.0% saw advertising on television, and 14.0% began using ENDS during the study. Furthermore, adolescents were twice as likely to begin using ENDS after exposure to advertisement in a store. The young adult participants saw advertising for ENDS online and in retail stores, and about 25.0% of these participants began using ENDS. The young adults were 1.3 times more likely to begin using ENDS after seeing an advertisement in a store or on television. The placement of ENDS marketing in stores was also important. Retail stores provided "cues and opportunities for immediate response" by displaying marketing near checkout counters near where ENDS products were available for purchase (p. 5).

Regulations of ENDS

In 2016, the FDA finalized a rule to amend the previously enacted Family Smoking Prevention and Tobacco Control Act to extend their jurisdiction to the regulation of ENDS products, including "the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories" (USFDA, 2020, para. 8). The FDA also requires ENDS to carry a label stating that they contain nicotine and ensure consumers are aware of the addictive nature of nicotine products. Furthermore, recent legislation prohibits the sale of ENDS to individuals under the age of 21, raising the minimum age of sale from age 18, as well as an "enforcement policy on unauthorized flavored cartridge-based e-cigarette products, including fruit and mint flavors," (para. 10) which have historically been more popular with youth ENDS users. The distribution, importing, and manufacturing processes of ENDS products must also comply with FDA regulations.

Each state is responsible for tobacco prevention and cessation programs, although the CDC provides guidelines on key elements of these programs and how much funding should be set aside for these programs (Campaign for Tobacco Free Kids [Tobacco Free Kids], 2019a). The CDC guidance includes programs for prevention of youth and adult tobacco use, eliminating secondhand smoke exposure, public health information and mass media campaigns aimed at tobacco cessation and prevention, other cessation efforts, and surveillance and monitoring of the programs for desired outcomes. States are responsible for enacting and enforcing smoke-free laws, which require workplaces and public places to be smoke-free (Tobacco Free Kids, 2020b). States have the option to add a tobacco tax above the existing federal tax (Tobacco Free Kids, 2019b).

North Dakota enacted a statewide smoke-free law in 2012 and ranks fourth in the country for funding spent on tobacco prevention (Tobacco Free Kids, 2020a). ENDS use is restricted under the statewide smoke-free law, and therefore ENDS cannot be used in public places or places of employment and within 20 feet of an entrance (Public Health Law Center, 2020). Although North Dakota state law still requires an individual to be 18 to purchase ENDS devices or e-liquid, the federal law of 21 years or older to purchase supersedes state law (Public Health Law Center, 2020; USFDA, 2020).

Health Effects of ENDS

The long-term effects of prolonged ENDS use are not yet known, simply because ENDS only recently gained popularity and widespread use. Short-term health implications, such as acute illnesses related to ENDS use are known. In general, ENDS and any tobacco products are considered unsafe for use in those under 25 years of age due to the effects of nicotine on the developing brain, including impaired concentration, cognition, and mood changes (CDC, 2016).

Nicotine Content and Dependence

The addictive nature of nicotine is well-established; addiction applies to nicotine contained in ENDS as well as traditional cigarettes. Nicotine is a psychomotor stimulant drug that acts on the neurotransmitters of the brain. Dopamine is released in response to nicotine, which potentiates a positive feedback loop; the user has a pleasurable response in the brain from the release of dopamine and continues to use the product (USDHHS 2014, USDHHS 2016).

E-liquids usually contain nicotine. However, it is difficult to measure the exact concentration of the nicotine content in ENDS aerosol for a variety of factors (USDHHS, 2016). The nicotine content varies based on concentration of the e-liquid, inhalation length and depth, duration of time between inhalations, battery voltage, and heater resistance. A study performed

in North Dakota tested 70 samples of e-liquids and compared the advertised nicotine concentration of the e-liquids to the actual nicotine concentration of the e-liquids (Buettner-Schmidt et al., 2016). Up to 10% variation in the advertised versus measured nicotine concentration was considered acceptable, but 51% of the samples were still outside the labeled concentrations. Notably, of the 23 samples reported to be nicotine-free, 43% contained nicotine. Thus, the plasma nicotine concentrations of ENDS users vary widely based on user behaviors, device, and e-liquid refills.

Cardiovascular Effects

The cardiovascular effects of smoking cigarettes are well-established; including increased heart rate, blood pressure, and cardiac output, which increase myocardial oxygen demand (USDHHS, 2016). Receptors for nicotine exist throughout the body in addition to the brain as previously discussed. Nicotine can trigger carcinogenesis, or cancer formation, throughout the body where the nicotine receptors exist and can inhibit or interfere with normal cell function throughout the body (USDHHS, 2014). Nicotine can also affect normal inflammation processes by increasing C-reactive protein expression at a cellular level, which contributes to atherosclerotic activity (USDHHS, 2016).

Currently, there is limited evidence to suggest that ENDS users whose plasma nicotine concentrations are increased have increased heart rates (USDHHS, 2016). As an increased heart rate is seen in cigarette users as well, the evidence suggests a possible correlation between negative cardiovascular outcomes and ENDS use.

Maternal and Fetal Effects

Effects of nicotine on maternal-fetal outcomes are well-established. Nicotine crosses the placenta and can be found in fetal tissue as early as seven weeks gestation (USDHHS, 2016).

Fetal exposure to nicotine is associated with disruption of fetal brain development and can occur both through placental transfer of nicotine and secondhand or passive smoke exposure in utero. Since ENDS users can achieve equivalent levels of plasma nicotine concentration to traditional cigarette smokers, the use of ENDS in pregnancy presents similar concerns.

Nicotine exposure during pregnancy has been linked to Sudden Infant Death Syndrome, as fetal exposure to nicotine can affect lung development and predispose an infant to apneic episodes, which are significant risk factors for Sudden Infant Death Syndrome (USDHHS, 2016). Fetal nicotine exposure is linked to altered development of the corpus callosum of the brain, which can result in cognitive deficits later in life. Fetal nicotine exposure is also linked to language development and deficits in auditory processing by interfering with the brain pathways that determine the response to sound stimuli. This exposure is associated with increased likelihood of disruptive behavior and attention deficits later in life, as well as predisposing the child to obesity, drug use, and nicotine use.

Youth Health Effects

As previously discussed, nicotine is highly addictive through activation of neurotransmitters. This is particularly worrisome for adolescents using nicotine and ENDS, as there is substantial evidence that youth use of nicotine adversely affects brain development (USDHHS, 2016). Adolescence and young adulthood are vital periods of brain development and are susceptible times to brain injury. During adolescence, the process of myelination occurs, which involves coating neurons with a fatty, protective layer to promote faster information transmission and more advanced brain functions. Myelination occurs primarily in the frontal lobe of the brain during adolescence, which controls executive functioning, impulse control, and decision-making. The brain also goes through a process called pruning, which involves deletion

of unnecessary synapses in the brain and allows for increased concentration in adulthood. The prefrontal cortex of the brain, which governs working memory, planning, and impulse control, is also developing during adolescence. Risky, impulse-driven behavior in adolescence is largely attributed to lack of maturity of the frontal lobe and prefrontal cortex. When nicotine is introduced to the developing brain, it can interfere with the myelination process, which can result in learning difficulties, cognitive impairment, mood disorders, and attention deficits. Early introduction of nicotine to the developing brain can also interfere with the developing reward pathways in the brain, predisposing adolescents to use of other drugs in the future and can increase the severity of future dependence on nicotine.

ENDS Effects not Related to Inhalation

While the effects of nicotine and ENDS use are mostly related to inhalation of the e-liquids, there are also serious concerns related to non-inhalation issues with the devices (USDHHS, 2016). Though not numerous, there have been reports of fires and explosions related to ENDS use, which can cause minor to serious damage to faces and hands. Death and fire damage to homes have also been reported. The explosions largely occurred while the device's battery was charging; overcharging lithium batteries can lead to thermal runoff and can cause other portions of the device to be propelled or explode.

Ingestion of the e-liquid for ENDS is also a serious concern not related to inhalation of an ENDS (USDHHS, 2016). Sudden ingestion of e-liquid containing nicotine can cause nicotine poisoning, which can lead to tachycardia, seizure, and death. This has led to regulation of e-liquids, requiring them to be packaged in child-proof containers.

Secondhand Exposure to ENDS

The exhalation of ENDS aerosol contains a variety of substance and exposes non-ENDS users to these substances (USDHHS, 2016). The effect of aerosol exhalation on air quality is dependent on a number of factors, including number of puffs and depth of inhalation of the ENDS and ventilation and air flow in a room or area. This is significant for non-smoking children in homes where individuals use ENDS and the children are consistently exposed in a small space. While there is insufficient information about long-term effects of passive exposure to ENDS exhalation, modeling of health risks of passive ENDS exposure is inconclusive. However, some data suggests that prolonged passive exposure to nicotine and propylene glycol exceeds standards for noncarcinogenic health effects. Other data suggests that only ENDS users, rather than bystanders, should worry about exposure to propylene glycol and vegetable glycerin.

COVID-19

While long-term studies on the association between COVID-19 and tobacco use are not available due to the relative novelty of the virus, initial data from the Chinese COVID-19 patients indicate that patients had a higher rate of mortality if they had underlying medical conditions such as cardiovascular disease or chronic respiratory diseases (World Health Organization, 2020). Smoking and use of tobacco products are linked to development of cardiovascular and lung diseases; therefore, it is reasonable to be concerned about the use of tobacco products and adverse health outcomes with COVID-19.

In the case of COVID-19, the spike proteins on the surface of the virus bind to a receptor protein in the lungs called Angiotensin-Converting Enzyme 2 (ACE2), infecting the cell (Stanford Medicine, 2021). The infected cells are destroyed during the process of viral replication, causing widespread lung damage. Nicotine exposure increases the production of the

ACE2 receptor protein in the lungs, thus increasing the binding sites for the COVID-19 virus and making viral replication easier. Transmission may increase through ENDS use, as many young adults and adolescents may be sharing devices and therefore transmitting respiratory particles to one another.

A study conducted in May 2020 surveyed over 4,000 adolescents and young adults age 13-24 nationwide and found that those who had ever used ENDS products were five times more likely to be diagnosed with COVID-19 (Gaiha et al., 2020). Individuals who had ever been dual-users (ENDS products and traditional cigarettes) were seven times more likely to be diagnosed with COVID-19. While many younger patients diagnosed with COVID-19 had no symptoms or mild symptoms, dual-users in the past 30 days were 4.7 times more likely to have symptoms of COVID-19 infection such as cough, fatigue, dyspnea, and fever.

EVALI

Between August and September 2019, many individuals nationwide sought medical care with non-specific complaints of respiratory illness, such as fever, cough, headache, myalgias, sore throat, dyspnea, and fatigue (Chatham-Stephens et al., 2019). While the symptoms were difficult to differentiate from influenza, pneumonia, or other respiratory illnesses, patients were linked by their use of ENDS and especially with e-liquids containing THC (CDC, 2020c). Some THC e-liquids contain vitamin E acetate, which is used to dilute the THC products for use in the ENDS products and is believed to the causative agent of EVALI. Bronchoalveolar lavage samples, obtained from 51 patients confirmed to have EVALI, were tested for vitamin E acetate and other dilutive agents. Of these samples, 48 contained vitamin E acetate, which was not identified in any of the samples from the control group of healthy individuals (CDC, 2020c). The

imaging of lungs of patients with EVALI appear to have ground-glass nodules and opacities, which is consistent with lung injury from inhalation of toxic substances (Thakrar et al., 2020).

After announcing that e-liquids containing THC and vitamin E acetate were likely the causative agent of EVALI and public awareness of the health risk of ENDS use increased, there has been a steady decline in the amount of hospitalized EVALI patients nationwide. However, as of February 2020, there have been 2,807 hospitalized cases or deceased patients of EVALI reported to the CDC with 68 confirmed deaths related to EVALI (CDC, 2020c).

Cobalt Lung

One case has been confirmed of cobalt lung in the United States, otherwise known as giant cell interstitial pneumonia, related to vaping. Cobalt lung associated with ENDS use is also believed to be linked to e-liquids containing THC products (Fels Elliott et al., 2019). Giant cell interstitial pneumonia is more commonly associated with heavy metal inhalation which can be related to occupational exposures. The previously healthy woman was diagnosed with cobalt lung had been using THC e-liquid in her ENDS for six months, and when tested, the e-liquid contained cobalt which could have been released from the heating coil or the reservoir casing of the ENDS due to the high temperatures at which the e-liquid must be heated. The patient's lung function, which was initially markedly reduced, improved after three months of treatment but was still reduced from her baseline.

Tobacco Cessation

There are a number of strategies for tobacco cessation, including counseling, motivational interviewing, medication therapy, and interventions for cessation at a clinic and health system level.

Tobacco cessation discussions should begin with either the 5 A's method of 'Ask', 'Advise', 'Assess', 'Assist', and 'Arrange' or its shortened counterpart, the AAR method, which consists of 'Ask', 'Advise', and 'Refer' (USDHHS, 2020). Clinicians can use the "Vital Sign" method, in which smoking status is treated as a vital sign and similarly recorded at each visit (USPSTF, 2021). The 5 A's method was developed after research by the National Cancer Institute in the 1980s suggested that a systematic approach to addressing tobacco cessation with patients could help patients quit and lower population rates of tobacco use. The 5 A's method is designed to maximize the probability of a smoker attempting to quit and the probability that the attempt to quit will be successful. However, the AAR method is frequently utilized due to clinical time constraints and is recommended for use by the American Academy of Family Physicians for counseling patients on smoking cessation. It is also recommended by the United States Preventive Services Task Force (USPSTF) to use either the 5 A's method or the AAR method to ask all adults about tobacco use at every healthcare visit (2021).

A study to review the frequency and practices used by PCPs of tobacco cessation revealed that PCPs self-reported that they utilize some of the strategies outlined by the 5 A's Method of tobacco cessation, but they more frequently use the 'Ask' and 'Advise' than the 'Assess,' 'Assist,' and 'Arrange' strategies in counseling their patients. (Bartsch et al., 2016). This may contribute to a gap in providing smoking cessation and care. It has also been noted that patients who smoke and have COPD, a health complication from smoking, are more likely to receive counseling from their PCP using the 5 A's Method than their counterparts who do not have COPD, even though all smokers should receive tobacco cessation counseling (Schauer et al., 2016). It may also be beneficial to begin training PCPs and health professionals during their schooling about the 5 A's Method of tobacco cessation, as they would have more time and

practice for developing their skills of counseling and may have improved efficacy (Hyndman et al., 2018).

Another method of discussing cessation is using a discussion tool. A study of physicians and patients evaluated the validity of the brief Willingness to Quit tool, which is used to assess willingness to quit smoking in current smokers, encourage discussion between PCPs and patients, and develop personalized cessation plans (Baker et al., 2017). The tool was determined to be content valid after a review of literature, conduction of semi-structured, qualitative interviews with current smokers, and then with PCPs about their feedback after using the Willingness to Quit tool. The participating current smokers described the tool as straightforward and found it appropriate for discussion with their PCP during an office visit. This tool may be helpful to PCPs, as discussions about smoking cessation may be difficult to facilitate due to hesitancy or lack of time by the PCP and the willingness to participate by the patient.

Counseling from Adjunct Personnel

Patients may have success with smoking cessation even if they are not counseled by their PCP. Several studies have emerged about the potential of adjunct personnel, such as pharmacists, nurses, chiropractors, and other health personnel about their utility and efficacy of providing smoking cessation counseling. One study discusses the possibility of using nurses to address tobacco cessation in nurse-led wellness visits to PCP offices (Byers et al., 2018). The study indicated that the patients' smoking status was documented significantly more often in nurse-led wellness visits, which provides greater knowledge and opportunity to provide smoking cessation counseling (Byers et al., 2018). The USPSTF recommends provision of behavioral counseling through the advice of providers and nurses, individual counseling, group behavioral interventions, and telephone/mobile phone-based interventions (USPSTF, 2021). This would

include “at least four or more behavior counseling session with 90 to 300 minutes of total contact time” (p. 267).

Another study evaluating the success of a smoking cessation program involved periodic counseling by pharmacists and nurse practitioners and use of pharmacotherapy for cessation **(**Afzal et al., 2017). The study found that patients viewed increased access and support from providers as helpful, and seven of the nine participants were able to achieve smoking cessation at the study’s completion and beyond. Given the different knowledge and training of other health professionals’ roles (nursing, pharmacy, etc.), involvement of personnel other than simply the PCP may be helpful in providing effective and accessible tobacco cessation counseling. Training both pharmacists and PCPs has also been shown to be cost-effective, so the added cost of provision of tobacco cessation training for additional personnel should not affect the decision to involve additional personnel for tobacco cessation (Cantor et al., 2015).

There are numerous studies about the use of chiropractors as adjunct personnel to promote smoking cessation; they are especially helpful as they comprise the largest group of Complimentary Alternative Medicine (CAM) provision in the United States (Buettner-Schmidt et al., 2018). Chiropractors, as with other adjunct personnel, can be trained in tobacco cessation counseling and can effectively demonstrate counseling using the AAR method (Buettner-Schmidt et al., 2018). Other CAM providers such as acupuncturists and massage therapists can be effective in delivering smoking cessation counseling as well, but chiropractors see more patients on a regular basis and therefore reach a larger audience (Muramoto et al., 2016). CAM providers may also be especially effective in delivering cessation counseling to patients, as the patients who seek care from CAM providers tend to represent a “healthy behavior bias,”

meaning that they are more inclined toward healthy behaviors and may be more receptive than patients in a traditional or Western medicine setting (Muramoto et al., 2016).

Motivational Interviewing

MI is a counseling strategy designed to help people with behavior change (Lindson et al., 2019b). MI has also been shown to be efficacious in helping PCPs provide counseling to those patients who are not yet ready to quit smoking; this method may help patients to begin contemplating a change and help motivate them to begin the process (McNamara et al., 2015). However, a meta-analysis of 37 trials of MI in smoking cessation suggests that there is insufficient evidence to support that MI helped more people stop smoking than no cessation treatment at all (Lindson et al., 2019b). Therefore, MI should be utilized as an aid for smoking cessation, rather than relying on MI as the only cessation tactic. Decision aids may also increase cessation knowledge and quit attempts for patients due to their utility in shared decision-making conversations between patients and PCPs (Moyo et al., 2018).

Medications

A historically cost-effective method of tobacco cessation is the provision of free nicotine replacement therapy (NRT), which include controlled amounts of nicotine in the forms of patches, gum, lozenges, inhalers, and nasal sprays to aid with smoking cessation (CDC, 2020a). Combinations of these forms and higher doses of lozenges, gum, and patches are associated with greater success with smoking cessation (Lindson et al., 2019a). A secondary analysis of a randomized control trial evaluated the effect of the provision of nicotine replacement therapy on increased discussions about smoking with PCPs and found that patients who received nicotine replacement therapy were more likely to seek care from their PCPs, possibly influencing overall health and addressing concerns beyond tobacco use and cessation (Kushnir et al., 2018).

Medications other than NRT can also be effective for smoking cessation. According to a meta-analysis, partial nicotine receptor agonists, such as varenicline, increased long-term smoking cessation success by two to three times as compared with smoking cessation attempts without medication aids (Cahill et al, 2016). Varenicline also has higher rates of cessation as compared to bupropion, an antidepressant used in smoking cessation, and traditional NRT. Varenicline may also be helpful for users of smokeless tobacco (Ebbert et al., 2015). Cytisine, a new drug for the United States market that has been used in Europe for cessation, also increased patient's chances of quitting. The USPSTF endorses the use of pharmacotherapy in the forms of nicotine replacement therapy, sustained-release bupropion, and varenicline for smoking cessation (USPSTF, 2021). It is important to note that no medications for tobacco cessation are currently FDA-approved for children and adolescents.

Clinic and Systems Changes

While the cessation of ENDS use has not been widely studied, it is recommended that PCPs utilize some of the same practices as they would for tobacco cessation counseling, such as inquiring about ENDS use at visits, counseling about the health risks, and staying up to date on the latest research and terminology regarding ENDS (Gibson-Young & Martinasek, 2018). The CDC recommends asking about ENDS use when screening for tobacco use, providing education about the risks of tobacco use in general and specifically about ENDS use, and counseling their patients to quit using all tobacco products (USDHHS, 2018). Currently PCPs may be missing opportunities to discuss ENDS use with patients, and the subject of ENDS may be broached by the patient rather than the PCP (Kollath-Cattano et al., 2019). It is also recommended to post resources or provide patient information about ENDS use in the examination rooms of PCP

offices from reliable sources such as the American Academy of Pediatrics (Gibson-Young & Martinasek, 2018, Kollath-Cattano et al., 2019).

Two resources are available to assist users of ENDS to quit. There is a digital program called 'This is Quitting' available for youth users of ENDS through the Truth Initiative, a nonprofit public health organization (Truth Initiative, 2019). The content on ENDS cessation is an addition to the organization's existing digital cessation program for adult tobacco and ENDS users called 'BecomeanEx,' which was developed in collaboration with the Mayo Clinic (Truth Initiative, 2019). National Jewish Health has also developed a cessation program specifically for individuals under 18 called 'My Life My Quit,' which has cessation resources for ENDS users as well as other tobacco products (National Jewish Health, 2020). Many states, including North Dakota, utilize 'My Life My Quit' as part of tobacco cessation resources and quitline programs available through the state's health department.

Suggestions to overcome the barriers to tobacco cessation counseling at health system and clinic levels are available from the U.S. Public Health Service's Clinical Practice Guidelines and the U.S. Preventive Services Task Force (USDHHS, 2020). These include, but are not limited to, implementing a system to identify patients who are tobacco users in the clinic, promoting cessation interventions by healthcare providers through education, resources, and feedback, dedicating a staff member in each clinic to provide nicotine dependence treatment, including nicotine dependence treatments as covered services for those with health insurance.

PCP Role

PCP Variability and Influence

PCPs may be influenced by external factors, including reimbursement for services based on their rates of cessation counseling in their patients (Tan et al., 2018). The introduction of the

Affordable Care Act in 2010 included coverage for tobacco cessation services under both private and public health insurance plans, and Meaningful Use of Electronic Health Records program of 2011 incentivizes PCPs with Medicare reimbursement to document patients' tobacco use and provide brief tobacco cessation counseling (Tan et al., 2018). If PCPs can show documentation of smoking cessation on 80% of their patients age 13 and older, they are eligible to receive performance payments through the program (USDHHS, 2020). After the adoption of these policies, prevalence of receiving tobacco cessation counseling from a PCP increased from 51.4% of patients in 2010 to 60.6% in 2015 (Tan et al., 2018).

PCPs may also be influenced by their own smoking history, knowledge, and personal characteristics. A study which surveyed 302 PCPs found that PCPs who have never smoked were more likely to recommend cessation, set quit dates with patients, recommend smoking cessation groups, and invest greater efforts in patients with health complications related to smoking (Azuri & Nashef, 2016).

Knowledge Gaps

Overall, PCPs are hesitant to counsel about ENDS use because of perceived lack of information or long-term studies about ENDS health effects (Egnot et al., 2015). Since ENDS are new devices, especially in comparison to traditional tobacco products, long-term studies may not be available for decades. While the long-term effects of ENDS use are unknown, two strategies may be employed; the precautionary principle or the potential for harm minimization (Green et al., 2018). Initial research suggested that ENDS were a satisfactory replacement for traditional cigarettes for adults who already smoked, and thus harm may be minimized for these individuals. However, the precautionary principle states that ENDS use should not be endorsed or supported until definitive research is available (Green et al., 2018).

Although Nickels et al. (2017b) reported that there is some evidence that adults with asthma who smoke may experience increases in lung function and decreases in asthma-related symptoms with a short-term trial of ENDS use instead of their current tobacco use, Dr. Brody Maack, Pharmacist and Tobacco Treatment Specialist stated that "in general, I haven't seen any guideline or literature review that would suggest we have enough data to support any claim of safety with [ENDS]" (B. Maack, personal communication, August 6, 2020). Therefore, based on the information currently available, best practice is to recommend FDA-approved smoking cessation medications for current tobacco users and to counsel against initiation of ENDS use for non-smokers (Fong, 2016).

Many PCPs have discussions with their patients about ENDS use, but a substantial number of PCPs tolerate the use of ENDS in their patients and are not deterring their patients from using them, given a lack of confidence in their ability to have these discussions given the lack of evidence-based guidelines or recommendations regarding ENDS use (Nickels et al., 2017a). However, other studies indicate that PCPs are actively counseling their patients against use of ENDS and have negative perceptions of their use, despite the lack of research or evidence available (Ofei-Dodoo et al., 2017).

A study of PCPs in Georgia found that PCPs had an overall lack of knowledge about ENDS in general, as well as ENDS products containing marijuana or THC (Bascombe et al., 2016). Some of the PCPs surveyed believed that ENDS might be helpful in smoking cessation and might be less harmful than traditional tobacco products and overall, felt there needed to be more information and evidence available to inform their practice in counseling patients (Bascombe et al., 2016). Another found that similarly, pediatricians had some knowledge about ENDS use and the tobacco content of ENDS in the pediatric population but desired more

information and felt there could be improvements made to counseling about these products (Gorzkowski et al., 2016).

Literature Review Summary

Although the long-term health effects of ENDS use are not yet fully understood, the CDC recommends that ENDS use is not recommended for people under age 25 (CDC, 2020). ENDS use is also not recommended as a smoking cessation resource for anyone, as people who use ENDS instead of an FDA-approved smoking cessation aid are more likely to become dual-users of traditional tobacco products and ENDS (Buettner-Schmidt et al., 2021). There are significant health effects associated with nicotine; nicotine has negative effects on brain development, impulse control, mood, and cognition in adolescents (USDHHS, 2018). PCPs and other personnel play a significant role in tobacco cessation counseling and must be informed on current practices and information to provide effective cessation counseling to their patients.

Theoretical Framework

The theoretical framework best suited to guide this project was the Theory of Reasoned Action (TRA), developed by Martin Fishbein in 1967 (Montaño & Kasprzyk, 2015). This theory was also used to guide the research study from which the questionnaire for the key informant interviews was obtained. The TRA is guided by the premise that the most important thing in determining an individual's behavior is the intention behind the behavior, or 'behavioral intention'.

Behaviors are influenced by external variables, such as demographics, personality traits, and other differentiating factors (Montaño & Kasprzyk, 2015). Behavioral intentions are also influenced by the preexisting attitudes about the particular behavior, as well as by the 'subjective norms' of the behavior. Individuals' attitudes are determined by the outcome they perceive will

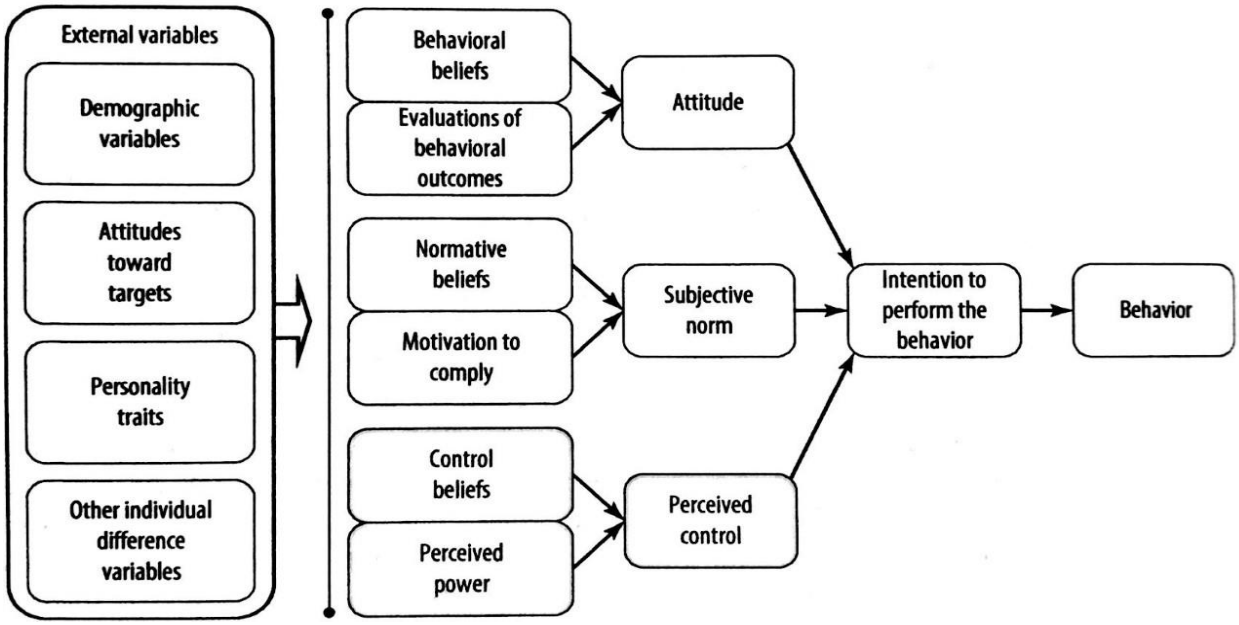
occur from an action or the attributes they perceive of performing the behavior, or 'behavioral beliefs.' For example, an individual who strongly believes that an action will have a positive outcome or that a behavior will have a positive result would have a positive attitude about that particular behavior.

Subjective norms are determined by 'normative beliefs.' (Montaño & Kasprzyk, 2015). If an individual perceived those close and important to him (referents) to approve or disapprove of a behavior and was motivated to comply with their opinions, their normative beliefs would be affected. For example, an individual who perceived referents to approve of a behavior and who was motivated to comply with these expectations would have a positive subjective norm. Subjective norms and attitudes both contribute to the central tenant of the TRA, which is that behavior is directly determined by intention.

For this project, the TRA was exceptionally helpful in understanding the PCPs motivations and attitudes about the way they counseled their youth patients about ENDS use. The questionnaire included aims to understand their behavioral beliefs, their normative beliefs, their attitudes, and their intentions to perform the behavior of counseling about ENDS use in contrast to what their behaviors or practices were. Refer to Figure 4 for a visual representation of the TRA.

Figure 4

Theory of Reasoned Action



Note. From Montaño, D. E. & Kasprzyk, D. (2015). In Glanz, K., Rimer, B. K., & Viswanath, K. (Eds.) *Health behavior: Theory, research, and practice*. (5th ed., pp. 95-124). Jossey-Bass.

CHAPTER THREE: METHODS

Project Design

The project design was a translation of research into clinical practice application in a rural primary care clinic. The design included key informant interviews of PCPs, an educational session for PCPs, pre- and post- educational surveys, and retrospective chart reviews.

Implementation Plan

Revised IOWA Model

The Revised IOWA Model of Evidence-Based Practice guides clinicians in decision making about clinical practices that affect patient care and outcomes (Melnyk & Fineout-Overholt, 2019). The Revised IOWA Model beneficial as a model to guide practice change in a healthcare setting due to its ease of use, applicability, and use of problem-solving steps and feedback loops to continuously modify the project. For this project, the Revised IOWA Model was used to guide implementation of an education session and address the use of ENDS in adolescent and young adult patients in the Sanford Valley City Clinic (SVCC). A visual representation of the Revised IOWA Model and permission to use the Revised IOWA Model in this project are found in Appendices B and C, respectively.

Use of the Revised IOWA Model began with identifying triggers or practice questions by identifying a clinical problem or new knowledge (Buckwalter et al., 2017). In this project, a knowledge-focused trigger existed in that new research and recommendations regarding the use of ENDS and the short-term health implications of use of ENDS were now available. ENDS use may lead to future tobacco smoking, nicotine addiction and changes to the brain because of nicotine use. ENDs use may also affect mood, concentration, and cognition, lead to EVALI, and may lead to injury related to combustion or fire of the device itself (CDC, 2016). During clinical

rotations, the co-investigator observed that PCPs and other clinical staff may have missed opportunities to discuss ENDS use with patients and provide counseling. Therefore, the identification of this opportunity for change based on new research served as a trigger for practice improvement.

The next step in the Revised IOWA Model was determining whether the identified topic is an organizational priority (Buckwalter et al., 2017). Given the significant potential health implications previously discussed and the rapidly increasing numbers of individuals using ENDS regionally and nationally, addressing ENDS use and counseling regarding cessation and/or health risk should be an organizational priority. In conversation with PCPs at the SVCC, some PCPs felt there was not enough research or information on ENDS available to advocate for cessation of ENDS use, and that a process change was needed to specifically address ENDS use with patients when asking them about tobacco and illicit substance use while discussing their overall health. Additional barriers to discussion of ENDS use were determined in two key informant interviews.

Identification of a team was the next step of the Revised IOWA Model (Buckwalter et al., 2017). In this case, the team involved the PCPs at the SVCC, which consisted of three family medicine physicians, three family medicine physician assistants, and one internal medicine physician. It also included the dissertation committee of Kelly Buettner-Schmidt, PhD, RN, FAAN and Tina Lundeen, DNP, FNP-BC from the North Dakota State University (NDSU) School of Nursing, Brody Maack, PharmD, CTTS from the NDSU School of Pharmacy, and Elizabeth Crawford, PhD, as the Graduate Appointee from the NDSU Department of Communication.

Assembly, appraisal, and synthesis of the body of evidence was the subsequent step of the Revised IOWA Model (Buckwalter et al., 2017), which was accomplished through the

literature review. The next step was to determine if there was sufficient evidence to move forward with a practice change. As discussed in the literature review, although the recommendations for ENDS use varied for adult users and the long-term health effects of ENDS use were not yet fully understood, the existing data indicated that ENDS use was not recommended for people under age 25 (CDC, 2020b); therefore, sufficient evidence existed to advance to next steps in the model. The next step of the Revised IOWA Model was to design and pilot the practice change (Buckwalter et al., 2017). The initial study design was described in this chapter; the information obtained from the key informant interviews and the appraisal and synthesis of the body of evidence was used to design and pilot the practice change. After approval by the dissertation committee and the Institutional Review Boards of Sanford Health and NDSU, the pilot was completed.

Setting

The setting for this project was the SVCC in Valley City, ND. Valley City was the largest city in Barnes County, was located in east-central North Dakota, and had an estimated population of 6,380 in 2018 (Valley City Chamber, n.d.). Barnes County had an estimated population of 10,542 as of 2018. The median age of residents in Valley City was 40.2 years old. The average per capita income of a resident of Valley City between 2014 and 2018 was $33,096; 11.4% of the population of Valley City was below the poverty line in 2018 (United States Census Bureau [UCSB], 2018). The majority of Valley City residents were white, 90.8%, with 3.7% Black or African American, 2.2% Hispanic or Latino, 1.4% two or more races, 1.2% American Indian or Alaska Native, 0.7% Asian, and 0.2% Native Hawaiian or Pacific Islander (USCB, 2018). In the years 2014 to 2018, 90.1% of residents aged 25 or greater had achieved a high school diploma or greater level of education and 29.2% achieved a bachelor's degree or higher level of education.

The SVCC employed seven PCPs in Internal Medicine and Family Medicine. Due to the clinic's affiliation with Sanford Health, providers from Fargo specialties such as Podiatry, Orthopedic Surgery, Dermatology, Urology, and Psychiatry periodically traveled to the SVCC for outreach services to provide increased access for Valley City patients. The clinic was connected by a hallway with a Critical Access hospital, which was affiliated with another hospital organization; many of the primary care PCPs employed by the SVCC also cared for patients admitted to the medical-surgical floor of this facility.

The clinic employed Licensed Practical Nurses (LPN) and Registered Nurses (RN) and paired one nurse with each primary care PCP or specialty provider for each day. The nurse was responsible for bringing each patient to the examination room, obtaining their vital signs, asking general questions about the patient's reason for the clinic visit and medications, and assisting the PCP with an examination or procedure as needed.

There were also two nurses whose duties were to triage and/or answer patient phone calls and patient online messages before sending them to the PCPs. The clinic also had an Integrated Health Therapist on-site to assist with counseling and mental health needs for patients, as well as an RN Care Manager to assist with patient follow-up, care coordination, and management services for patients. The SVCC and another Sanford clinic nearby were managed by clinic director of operations and a physician director; there was also a lead physician within the SVCC.

Sample

The study included a purposive sample of the PCPs at the SVCC. This consisted of three Family Medicine physicians, one Internal Medicine physician, and three Family Medicine physician assistants. The providers who visited Valley City as part of outreach specialty services were excluded from the sample, as their visits were much more specialized and did not address

general health concerns or health habits such as tobacco or ENDS use. Nursing staff was invited to education sessions, but did not complete questionnaires after the education sessions, as the questionnaires were specific to PCPs.

The PCPs of the study were recruited via email. The text of the email is included in Appendix I. Participation in the study was voluntary, and the PCPs indicated their consent to participate in the study by completing the questionnaires provided to them after the conclusion of the education session. An informational flyer was also posted in the SVCC break room for reference (Appendix J). The co-investigator was available to answer questions as they arose via telephone or email.

The study also included a chart review of the records of patients aged 13 to 25 seen in the SVCC for an episodic visit (visit for a specific health complaint or concern) or for an annual/well-person visit between August 2020 and February 2021.

Project Interventions

Objective One assessed barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews. To meet Objective One, two key informant interviews were completed prior to development of the education session so that the information obtained could be incorporated into the education session and meet the needs identified. The audio recording of the key informant interviews was immediately transcribed to ensure accuracy and was analyzed using the Constant Comparative Method to determine overall themes; this method was also used in the original study from which the questionnaire was adapted (El-Shahawy, Brown, & Lafata, 2016).

Key Informant Interview Questions

The questions guiding the key informant interviews were based on a qualitative study about PCPs beliefs and practices regarding ENDS use in patients who smoke (El-Shahawy, Brown, & Lafata, 2016). The questionnaire contained a series of open-ended questions which were asked of the PCPs and recorded. The co-investigator then analyzed the PCP answers with the Constant Comparative Method to identify common themes among the responses (El-Shahawy, Brown, & Lafata, 2016).

The responses of the key informants were analyzed using Creswell's method for qualitative analysis, which includes, but is not limited to, constant comparison (Creswell, 2003). This method begins with immersion in the data, reading, and making notes on each questionnaire for the co-investigator to become well-versed in the responses (Creswell, 2003). Constant comparison was completed, which involved comparing all responses against each other and applying codes to similar ideas, and then applying this code throughout all responses to identify patterns or themes (Creswell, 2003). Refer to Appendices D and E, respectively, for the original questionnaire and permission to use the questionnaire.

Education Session

Objectives Two and Three involved development and implementation of an education session for PCPs at the SVCC about the current research regarding use of ENDS, the health implications, cessation referral resources, and appropriate EHR documentation. The education session was developed with attention to the identified barriers based on the data obtained from the key informant interviews and from the appraisal and synthesis of the body of evidence.

Evaluation Plan

Objective Four of this project evaluated change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, and comfort in discussing ENDS and increased tobacco cessation activities, through PCP surveys. PCPs were provided with and completed a paper questionnaire immediately before and after the education session, as well as three months after the session to evaluate increased motivation, confidence, and comfort to discuss ENDS use with patients and increase the amount of tobacco cessation activities, specifically assessing interest in quitting, providing educational materials and medication cessation aids, and treating ENDS use within the PCPs' practices or making necessary referrals outside of their practices.

Education Session Questionnaire

Two questionnaires were administered to the PCPs of the education session; the majority of the questionnaires were the same, but the questionnaire that was administered immediately post-education session contained questions that evaluated the quality of the presentation and the PCPs' likelihood of making changes to their practice based on the information presented. The questionnaire items were adapted from a study that assessed CAM providers and their current practices of discussing tobacco use with their patients (Cunningham et al., 2015). The items also assessed their motivation, confidence, and comfort in discussing ENDS use with their patients and tobacco cessation activities, such as assessing patients' interest in cessation, provision of educational materials or medications as cessation aids, and treatment of ENDS use within the PCPs' practices or referring for ENDS treatment outside of their practices.

Cunningham et al. (2015) developed the questionnaires after a review of literature of assessments about tobacco cessation training and a key informant interview was performed.

After the items of the questionnaire were created, they were reviewed by a national panel of CAM providers. These providers gave feedback on the content of the questions and assured that the question items are well-aligned with the aims of ascertaining the confidence, motivation, and comfort of tobacco use discussions. Psychometric testing of the questionnaire occurred with a variety of statistical techniques; internal validity was acceptable (Cronbach's alpha ranged from 0.71 to 0.81).

The pre-education and three-month post-education questionnaire contained 17 items. The survey assessed PCPs motivation, confidence, comfort and tobacco cessation activities assistance given to patients who use ENDS products. Items 1 and 2 of the questionnaire assessed the PCPs' motivation, items 9 through 12 assess PCPs' confidence, items 13 through 15 assessed PCPs' comfort in addressing ENDS use with patients, and items 3 through 8 of the questionnaire assessed PCPs' tobacco cessation activities. Items 16 and 17 were demographic questions about the PCP's role and years in practice. The immediately post-education questionnaire contained the 17 aforementioned items and also included three questions to evaluate the quality of the educational session and how likely the PCPs were to make changes to their practices based on the content of the educational session. Refer to appendices F and G for the adapted questions and to appendix H for permission to use the questions.

Retrospective Chart Review

Objective 5 of this project assessed and compared the rates of PCP discussion about ENDS and rates of cessation referrals three months pre-education and three months post-education by conducting retrospective chart reviews. The quantitative data was analyzed with the assistance of a statistician and evaluated for statistical and clinical significance.

The clinic practice was for the LPNs and RNs who room the patients to inquire about and document a patient's tobacco history and ENDS use. An example of the tobacco history and ENDS use documentation can be found in Appendix L. The PCP reviewed the information entered by nursing and documented acknowledgement of this information by clicking 'review' in the patient's EHR. After reviewing the patient's use of ENDS, the PCP would discuss the patient's use and make a recommendation for the patient to quit use of tobacco products. The PCP would then place an electronic referral to NDQuits. If the patient was less than 18 years old, the electronic referral triggered the referral to be sent to My Life, My Quit. The My Life, My Quit program provided cessation counseling specific to ENDS use for youth and was available online and by texting or telephone. Subsequently, the PCP would document the discussion and referral in their note from the visit and use the appropriate cessation counseling billing code.

For virtual visits, which occurred through the EHR or through other virtual visit programs, the rooming nurse was not involved in the process. The PCP was responsible for initiating the visit through the virtual visit program, asking the patient all required screening questions and documenting them appropriately. The PCPs conducted the virtual visits from their respective offices.

The data for the retrospective chart review was obtained from primary care PCP charts (medical records) for patients aged 13-25. The plan was to assign each patient reviewed a number, in order to account for multiple visits by the same patient during the time period. It was then planned to review each chart individually to note whether the staff that had roomed the patient asked screening questions about use of tobacco products, if the PCP reviewed the results of the screening questions, if the patient used ENDS, if the PCP delivered cessation counseling to the patient, and if the PCP placed the appropriate referral to a cessation program. A tool for

chart review was developed to aid in the collection of data (Appendix M). All data obtained was planned to be recorded on this spreadsheet.

The chart review software utilized by the SVCC did not allow for individual patient records to be viewed, nor did it permit viewing records associated with each PCP. Therefore, with the assistance of the SVCC Care Manager, a report was compiled of patients aged 13-25 seen in the clinic during the three months prior to the education session and the three months after the education session and was sorted by the type of visit. The types of visit included virtual visits (MyChart Telemed Home visits, Telemed Home Visits, and verbal visits), which were conducted with a telemedicine application or via the telephone. Non-virtual visits (clinic visits, wellness visits, child/teen visits, sports physicals, and other face-to-face visit classifications) were also included. The data was then exported to a spreadsheet and analyzed by the co-investigator. The chart review software was programmed to compile a report of the number of cessation referrals placed to NDQuits or to the TTS during the three-month period pre-education and three-months post-education. Demographic data included patient age; no other patient identifiers were necessary for the chart review, and therefore patient anonymity was maintained. The implementation and evaluation plans are further detailed in Table 1.

Data Management

The data obtained in the chart review was transferred to the co-investigator by secured and encrypted email from the owner of the data, Sanford Health, and entered directly into an Excel spreadsheet. The data was stored on the co-investigator's personal computer, which was password protected and not used by any other individuals. The data did not contain any protected health information such as name, medical record number, or medical conditions. The ages of the

patients were included in the chart review if they were between the ages of 13 and 25. The data was deleted after concluding the evaluation of the data and successful defense of the project.

The questionnaires completed by the PCPs were anonymous and completed on paper. After the participating PCPs completed the survey, they placed their surveys in a folder in order to ensure anonymity of the responses. The questionnaires were kept in the possession of the co-investigator after completion. After the questionnaires were completed the results were transferred onto an Excel spreadsheet, which was kept on the co-investigator's personal computer that was password protected and not used by any other individual. The paper copies were destroyed after the transfer of the results. The data was deleted after concluding the evaluation of the data and successful defense of the project.

The recordings of the key informant interviews and the transcripts of the interviews likewise were kept in the possession of the co-investigator. The recordings and transcripts were destroyed after analysis of the data and successful defense of the project.

Table 1

Objectives and Evaluation

	Objective	Timeline	Activity	Evaluation
1.	Assess current barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews.	October 2020	Perform key informant interviews of 2 PCPs (1 MD and 1 PA)	Complete and analyze interviews. Develop educational session with attention to identified barriers.
2.	Develop an educational session for PCPs about the current research regarding use of ENDS, the health implications, cessation referral resources, and appropriate EHR documentation.	October 2020	Provide educational session for PCPs	Develop education session
3.	Implement an educational session for PCPs based on current research and results of key informant interviews	November 2020	Provide educational session for PCPs	Implement education session Analyze PCP evaluation of education session
4.	Evaluate change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, comfort discussing ENDS and increased tobacco cessation activities, through PCP surveys.	November 2020 (pre- and immediate post-) February 2021 (three months post-)	Disseminate survey to PCPs pre-, immediately post-, and three months post-education session	Collect and analyze survey data
5.	Assess and compare rates of PCP discussion about ENDS and rates of cessation referral three months pre-education and three months post-education by conducting retrospective chart reviews.	February 2021	Perform chart review assessing rates for three months prior to educational session and for three months post-educational session	Compare rates of PCP discussions three months pre-and three months post-intervention

Timeline

The timeline for this project was as follows:

- September 2019-March 2020: Literature review, proposal development
- April 2020: Proposal, Approval by Dissertation Committee

- October 2020: IRB Approval, perform key informant interviews, develop educational session
- November 2020: Implement educational session
- February 2021: Data collection, analysis, and evaluation
- March 2021: Submit dissertation to committee and defend dissertation
- April 2021: Final dissertation submission, present project at NDSU Poster Presentation

Resources

Resources required for the implementation of this project included personal and committee member time, and printing supplies for the PCP surveys. The co-investigator printed and paid for the materials. The education session itself required meeting space, presentation technology, and PCP time. The meeting took place at a previously scheduled clinic staff meeting, which occurred in the conference room of the clinic and did not require any additional meeting space or incur any additional cost. PCPs were already required to attend the meeting at which the information will be presented, so there were no additional costs incurred for PCP compensation. The co-investigator provided a meal for the attendees of the education session. The evaluation of this project required assistance from the SVCC Care Manager to obtain information for the chart review, and from statistical analysts from NDSU; this did not incur any costs.

CHAPTER FOUR: RESULTS

This chapter contains the results of the project by objectives. The chapter also contains all data analysis including the qualitative results of the key informant interviews, the quantitative results of the pre-, immediately post-, and three months post-education session surveys including demographics, and the quantitative results of the retrospective chart review.

Objective One

The first objective identified barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews. See Table 2 below for activities and evaluation associated with this objective. This objective was met.

Table 2

Objective One Activities and Evaluation

Objective	Activity	Evaluation
Assess current barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews.	Perform key informant interviews of 2 PCPs (1 MD and 1 PA)	Complete and analyze interviews. Develop educational session with attention to identified barriers.

Key Informant Interviews

The key informant interviews were performed with two PCPs at the SVCC, one MD and one PA. The interviews were conducted in person while the co-investigator was already at the SVCC for a clinical rotation. The co-investigator and PCPs adhered to masking and social distancing guidelines. The interviews were recorded and immediately transcribed. The recordings were subsequently deleted. The transcripts were then analyzed using the Constant Comparative Method (Creswell, 2003) to determine common themes.

Neither PCP recommended ENDS use for cessation for their patients currently, nor have they routinely done so in the past. PCPs were aware of patients within their practices who used ENDS. Five common themes emerged from the analysis of the key informant interviews: (1) PCPs were aware that ENDS use has negative health impacts, (2) PCPs did not consistently or routinely ask their patients about ENDS use, (3) PCPs were more confident in discussing traditional tobacco product use and cessation than in discussing ENDS, (4) Patients did not usually initiate discussions with PCPs about ENDS use, and (5) PCPs were more likely to counsel younger patients against ENDS use. These themes are discussed further with demonstrative examples from the transcripts of the key informant interviews.

Theme 1: PCPs were aware of negative health consequences related to ENDS use

The PCPs were able to identify some of the negative health impacts for adults and youth related to ENDS use. One PCP noted that "[patients] should not use e-cigarettes because we have increasing evidence of the harms of doing it and really no evidence that it's better than using tobacco." The other PCP declared that ENDS use was "very dangerous" and "highly addictive" especially because "people think that they are more innocent [than traditional tobacco products] but yet, the damage to lungs is even more catastrophic."

Theme 2: PCPs did not consistently or routinely ask their patients about ENDS use

Both PCPs acknowledged that they did not routinely ask their patients about ENDS use. They did not have a systematic way of introducing ENDS use into a patient discussion. One PCP reported, "I rarely think of it, unless the nurse comes and tells me that they already asked them." When asked about how a PCP went about discussing ENDS use, they responded, "I usually would ask if…I can't remember if I say 'vape' or 'use e-cigarettes.'" Furthermore, they admitted, "I'm not as good about asking [about ENDS] as I am about cigarettes."

Theme 3: PCPs were more confident in discussing traditional tobacco product use and cessation than in discussing ENDS

PCPs were able to easily identify their routines for discussing traditional tobacco product use with their patients. One PCP reported that since the protocol in the clinic is for the rooming nurse to inquire about tobacco use first, they will "review what the nurse entered but also confirm" by asking the patient if they have ever smoked. If the patient has ever smoked, the PCP then confirms if they are still smoking and how much. If the rooming nurse has not asked the patient about their tobacco history, the other PCP clarifies the patient's tobacco history with them during the visit.

Furthermore, the PCPs also demonstrated more confidence in cessation counseling for traditional tobacco product users. For example, one PCP reported asking about readiness to quit and if the patient expresses that they are interested in quitting, the PCP would say "we have our Tobacco Treatment Specialist you can meet with, or we can talk about nicotine replacement therapy or medications." The other PCP also regularly assessed readiness to quit in their patients that used traditional tobacco products. Both PCPs reported that they "present it more as 'I'm here to help you,' not as a scolding."

Theme 4: Patients did not usually initiate discussions with PCPs about ENDS use

Both PCPs reported rare instances of their patients inquiring about ENDS use or initiating a discussion about ENDS products. Over the last year, one PCP reported their patients asked about ENDS products "less than ten times" and the other PCP reported having one conversation about ENDS initiated by a patient. One PCP felt patients were more interested in initiating ENDS discussions three to four years ago and asked questions about ENDS use and their use in smoking cessation efforts. Furthermore, one PCP believed ENDS use to be more secretive in

general than traditional cigarettes, as ENDS are "easier to conceal because they're a lot smaller and less smelly…which makes [ENDS use] harder to catch, especially if [patients] are not being forthcoming."

Theme 5: PCPs were more likely to address ENDS use and counsel against ENDS use in younger patients than adults

One PCP mentioned adolescents several times throughout the interview and specifically noted the differences in how they counsel younger patients and older patients. While they were clear that they recommended against ENDS use for all patients, they reported, "I'm more pushy with adolescents because of the research that shows that they are more likely to use regular cigarettes if they do use e-cigarettes. With adults, we don't really have that kind of data." They also admitted that they are "better about asking adolescents, actually, about [ENDS use] than adults."

Objective Two

The second objective was to develop an educational session for PCPs based on the review of literature and the results from the key informant interviews. See Table 3 below for activities and evaluation associated with this objective. This objective was met.

Table 3

Objective Two Activities and Evaluation

Objective	Activity	Evaluation
Develop an educational session for PCPs about the current research regarding the use of ENDS, the health implications, cessation referral resources, and appropriate electronic health record (EHR) documentation.	Provide informational session for PCPs	Develop education session

The content of the educational session developed contained information about the current use of ENDS locally and nationally, health implications of ENDS use with specific attention to COVID-19 as the education session occurred during a peak in COVID-19 cases in the region, resources for cessation referrals, and proper documentation in the EHR. The education session also included recommendations for PCPs to use in discussing ENDS use with their patients, including conversation tools to facilitate PCP- patient discussions, using ENDS-specific terminology when discussing ENDS use, and asking to speak to the patient alone if accompanied by a parent or guardian in order to obtain accurate information from the patient. The co-investigator recommended that the PCP ask the screening question about tobacco and ENDS use after the nurse had already done so to ensure that the patient's ENDS use is being addressed. The education session included a recommendation that the SVCC delegate a staff member to complete training to become a Tobacco Treatment Specialist (TTS), as there would then be a staff member available at the time of a patient's visit to provide cessation counseling. The education session was presented as a PowerPoint (Appendix K).

Objective Three

The third objective was to implement the PCP education session developed from the key informant interviews and review of literature. See Table 4 below for activities and evaluation associated with this objective. This objective was met.

Table 4

Objective Three Activities and Evaluation

Objective	Activity	Evaluation
Implement an educational session for PCPs based on current research and results of key informant interviews	Provide educational session for PCPs	Implement educational session Analyze PCP evaluations of education session

The education session was implemented at the regularly scheduled PCP meeting on November 10, 2020. The PCP meeting lasted two hours, and the co-investigator was allotted 15 minutes of this time to present the educational session. All PCPs at the SVCC were required to attend this meeting, so all seven PCPs employed at the SVCC were in attendance. The education session was also implemented over lunch on December 11, 2020 and December 14, 2020. Nursing staff was invited to the lunch sessions, while only PCPs were invited to the PCP meeting. Time was allowed for participants to ask the co-investigator questions at the end of the presentation. The evaluation questions about the education session were included on the immediate post-education session survey. Of the seven PCPs who attended the session, four (57.1%) completed the evaluation by placing the surveys in an envelope immediately after the completion of the presentation. The results are in Table 5.

Table 5

Education Session Evaluation Results (N=4)

	n	%
How helpful was the information presented during this presentation?		
Very helpful	1	25
Helpful	3	75
Neutral	0	
Slightly unhelpful	0	
Not helpful	0	
Please rate the overall quality of the session		
Excellent	3	75
Good	1	25
Fair	0	
Poor	0	
How likely are you to make changes to your current practices?		
Extremely likely	1	25
Very likely	3	75
Somewhat likely	0	
Not at all likely	0	

All PCPs reported that the education session information was either very helpful or helpful, that the overall quality of the education session was either excellent or good, and that they were either extremely or very likely to make changes to their current practices after the education session. No qualitative comments were provided.

Objective Four

Objective Four was to evaluate change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, and comfort in discussing ENDS and increased tobacco cessation activities. This data was obtained through PCP surveys distributed pre-, immediately post-, and three months post-education session. See Table 6 below for the activities and evaluation associated with Objective Four. This objective was partially met.

Table 6

Objective Four Activities and Evaluation

Objective	Activity	Evaluation
Evaluate change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, and comfort in discussing ENDS and increased tobacco cessation activities, through PCP surveys	Disseminate survey to PCPs pre-, immediately post-, and three months post-education session	Collect and analyze survey data

Demographics of Participating PCPs

Table 7 shows the demographics of survey PCPs, including type of provider and years in practice. The PCPs who attended the sessions but did not complete the surveys included physicians and physician assistants.

Table 7

Demographics of Survey PCPs

	Pre- Education [a]		Immediate Post-Education [a]		Three-Months Post-Education [b]	
	n	%	n	%	n	%
PCP Type						
Physician	2	50	2	50	0	
Physician Assistant	2	50	2	50	2	100
Nurse Practitioner	0		0		0	
Years in Practice						
0 - 3 years	1	25	1	25	0	
4 - 6 years	0		0		0	
7 - 9 years	0		0		0	
10 - 12 years	2	50	2	50	1	50
Greater than 12 years	1		1	25	1	50

Note. PCP = Primary Care Provider
[a] N = 4
[b] N = 2

Four of the seven (57%) PCPs in attendance at the PCP meeting completed the pre- and immediate post-education surveys. Half of the PCPs who completed the surveys were physicians and half were physician assistants. The level of experience of the PCPs surveyed ranged from 0 - 3 years to greater than 12 years. The majority of PCPs had been in clinical practice for greater than 10 years (n = 3, 75%). Two of the seven (28.6%) PCPs in attendance at the PCP meeting completed the three months post-education survey. Both PCPs were physician assistants, and both had been in clinical practice for greater than 10 years (n = 2, 100%).

Motivation

Questions 1 and 2 assessed PCP motivation in discussing ENDS use with patients. The results are in Table 8.

Table 8

Survey Results for Motivation

	Pre- Education [a]		Immediate Post-Education [a]		Three-Months Post-Education [b]	
	n	%	n	%	n	%
Q1: It is important, as a practitioner, to know whether a patient/client uses ENDS						
Strongly agree	0		4	100	2	100
Agree	4	100	0		0	
Disagree	0		0		0	
Strongly disagree	0		0		0	
Q2: I am motivated to help ENDS users quit						
Strongly agree	1	25	3	75	1	50
Agree	3	75	1	25	1	50
Disagree	0		0		0	
Strongly disagree	0		0		0	

Note. ENDS = electronic nicotine delivery systems
[a] N = 4
[b] N = 2

In relation to the importance of knowing whether a patient used ENDS, pre-education, all PCPs (n = 4) reported they agreed that it was important. Immediately post-education, the strength of the agreement improved with all strongly agreeing it was important to know if a patient used ENDS. With two PCPs completing the three months post-education survey, both PCPs continued to strongly agree it was important to know if a patient used ENDS.

PCP responses to motivation to help ENDS users quit are described next. Pre-education, all PCPs either strongly agreed (n = 1, 25%) or agreed (n = 3, 75%) that they were motivated to help ENDS users quit, immediately after the education session, the strength of the agreement increased with more (n =3, 75%) of the PCPs strongly agreeing that they were motivated to help ENDS users quit, while 25% (n = 1) continued to agree they were motivated to help ENDS users

quit. Three months post-education, with two PCPs completing the survey, no change was discernible from either pre- or immediate post-education as one (50%) PCP strongly agreed and one PCP (50%) agreed that they were motivated to help ENDS users quit.

In summary, PCP motivation increased from pre-education to immediate post-education and remained increased three months post-education, and evidence of sustained motivation at the highest strength was noted for at least one PCP.

Confidence

Questions 9 through 12 assessed PCPs' confidence in discussing ENDS use with patients. The results are in Table 9.

Table 9

Survey Results for Confidence

	Pre- Education [a]		Immediate Post-Education [a]		Three-Months Post-Education [b]	
	n	%	n	%	n	%
Q9: I am confident that I can explore issues related to quitting ENDS, even with someone who is not interested in quitting						
Very confident	0		2	50	1	50
Somewhat confident	3	75	1	25	1	50
Not very confident	1	25	1	25	0	
Not at all confident	0		0		0	
Q10: I am confident that I can personalize the benefits of quitting with each individual ENDS user						
Very confident	0		3	75	1	50
Somewhat confident	3	75	1	25	1	50
Not very confident	1	25	0		0	
Not at all confident	0		0		0	
Q11: I am confident that I can provide information about medications that help in quitting ENDS						
Very confident	0		3	75	1	50
Somewhat confident	3	75	0		1	50
Not very confident	1	25	1	25	0	
Not at all confident	0		0		0	
Q12: I am confident that I can provide information about programs and services that help in quitting (quitlines, counseling, etc.)						
Very confident	2	50	3	75	1	50
Somewhat confident	2	50	1	25	1	50
Not very confident	0		0		0	
Not at all confident	0		0		0	

Note. ENDS= Electronic Nicotine Delivery Systems
[a] N = 4
[b] N = 2

PCP responses to confidence in exploration of issues related to ENDS cessation are described next. Prior to the education session, 75% (n = 3) of the PCPs felt somewhat confident that they could explore issues related to ENDS cessation, even with a patient not currently

interested in quitting, while 25% (n = 1) felt not very confident in doing so. Immediately post-education, confidence increased with 50% of PCPs (n = 2) reporting feeling very confident in exploring ENDS cessation with their patients. Three months post-education session, both responding PCPs felt very or somewhat confident about exploring ENDS cessation issues, indicating increased confidence from pre-education to three months post-education for at least one PCP.

PCPs' responses to personalizing the benefits of quitting are described next. Pre-education, 75% (n = 3) of the PCPs felt somewhat confident they could personalize the benefits of quitting with each ENDS user, while 25% (n = 1) felt not very confident in personalizing benefits of quitting. Immediately post-education, confidence increased with all PCPs were either very or somewhat confident in personalizing benefits of ENDS cessation. There was no discernible change from immediately post-education to three months post-education, although overall increased confidence in personalizing benefits of cessation occurred pre-education to three months post-education for at least one PCP.

PCP responses to confidence in providing information about medication to help quit are described next. Pre-education, 75% (n = 3) of the PCPs felt somewhat confident they could provide information about medications that help with ENDS cessation and 25% (n = 1) did not feel very confident in doing so. Immediately post-education, confidence increased with the majority of the PCPs (n = 3, 75%) feeling very confident they could provide information about medications for ENDS cessation. Three months post-education, one PCP either had increased or decreased confidence indicated by a 'somewhat confident' response. There was overall increased confidence from pre-education to 3-months post-education for at least one PCP.

Responses to confidence about providing information about programs for cessation are described next. Pre-education, all PCPs surveyed responded they felt very (n= 2, 50%) or somewhat (n = 2, 50%) confident in their abilities to provide information about cessation resources. Immediately post-education, confidence increased with the majority (n = 3, 75%) of the PCPs feeling very confident in their abilities to provide information about cessation resources. There was no discernible change from immediately post-education to three months post-education.

In sum for the questions assessing PCPs' confidence, confidence increased pre-education to post-education for all questions. In relation to confidence immediate post-education to three-month post-education, evidence of increased confidence remained for the three questions pertaining to exploring issues related to quitting ENDS, personalizing the benefits of quitting, and providing information about medications. The evidence of increased confidence remained for at least one PCP from pre-education to three months post-education for the same three questions. In relation to the fourth question pertaining to confidence about providing information about programs and services, no change was discernible from either immediate post-education to three months post-education or from pre-education to three months post-education; the only change that was evident of increased confidence was pre-education to immediate post-education.

Comfort

Items 13 through 15 of the questionnaire assessed PCP comfort in addressing ENDS use. The results are in Table 10.

Table 10

Survey Results for Comfort

	Pre- Education [a]		Immediate Post-Education [a]		Three-Months Post-Education [b]	
	n	%	n	%	n	%
Q13: How comfortable are you in talking with patients/clients about ENDS use?						
Very comfortable	1	25	3	75	1	50
Somewhat comfortable	3	75	1	25	1	50
Not very comfortable	0		0		0	
Not at all comfortable	0		0		0	
Q14: How comfortable are you in providing information about medications that help in quitting ENDS?						
Very comfortable	0		3	75	1	50
Somewhat comfortable	4	100	0		1	50
Not very comfortable	0		1	25	0	
Not at all comfortable	0		0		0	
Q15: How comfortable are you in providing information about programs and services that help in quitting (quitlines, counseling, etc.)?						
Very comfortable	0		3	75	2	100
Somewhat comfortable	4	100	1	25	0	
Not very comfortable	0		0		0	
Not at all comfortable	0		0		0	

Note. ENDS = electronic nicotine delivery systems
[a] N = 4
[b] N = 2

PCPs' responses to their comfort in discussing ENDS with patients are described next. Pre-education, the majority of PCPs surveyed (n = 3, 75%) felt somewhat comfortable discussing ENDS use with patients. Immediately post-education, comfort increased with the majority of

PCPs (n = 3, 75%) feeling very comfortable in discussing ENDS use. There was no discernible change from immediately post-education to three months post-education.

PCP responses to their comfort in providing information about cessation medications is described next. Pre-education, all (n = 4) PCPs surveyed felt somewhat comfortable in providing information about cessation medication. Immediately post-education, overall comfort increased with the majority of PCPs (n = 3, 75%) feeling very comfortable in providing information about cessation medications, although one PCP decreased in comfort level. From immediate post-education to three months post-education, one PCP either had increased or decreased comfort indicated by a 'somewhat comfortable' response. There was overall increased comfort from pre-education to 3-months post-education for at least one PCP.

PCPs' responses to their comfort in providing information about cessation programs to patients is described next. Pre-education session, all (n = 4) PCPs surveyed felt somewhat comfortable in providing cessation resources to patients. Immediately post-education session, comfort increased as the majority of PCPs (n = 3, 75%) felt very comfortable providing cessation resources to patients. Three months post-education, comfort increased as both responding PCPs felt very comfortable providing cessation resources to patients. There was overall increased comfort from pre-education to three months post-education for two PCPs.

In summary of the questions assessing PCPs' comfort, comfort increased pre-education to post-education for all questions. In relation to comfort immediate post-education to three-month post-education, evidence of increased comfort remained for two questions: providing information about medications and providing information about programs and services to help quitting. The evidence of increased comfort remained for at least one PCP from pre-education to three months post-education for providing information about medications. There was also

evidence of increased comfort for two PCPs from pre-education to three months post-education in relation to providing information about cessation programs.

Tobacco Cessation Activities

Questions three to eight evaluated the PCPs current practices of tobacco cessation activities. The results are in Table 11.

Table 11

Survey Results for Tobacco Cessation Activities

	Pre-Education [a]		Immediate Post-Education [a]		Three-Months Post-Education [b]	
	n	%	n	%	n	%
Do you, as a practitioner, provide any of the following forms of assistance to ENDS users:						
Q3: Assess current interest in quitting?						
Always	2	50	2	50	2	100
Often	1	25	1	25	0	
Sometimes	1	25	1	25	0	
Never	0		0		0	
Q4: Identify the reasons they're thinking of quitting?						
Always	2	50	2	50	1	50
Often	1	25	1	25	0	
Sometimes	1	25	1	25	1	50
Never	0		0		0	
Q5: Offer educational materials or handouts?						
Always	0		1	25	0	
Often	2	50	1	25	0	
Sometimes	2	50	2	50	1	50
Never	0		0		1	50
Q6: Discuss use of medications to help people quit ENDS (like NRT or prescription medications)?						
Always	0		0		0	
Often	1	25	2	50	1	50
Sometimes	3	75	2	50	1	50
Never	0		0		0	
Q7: Treat ENDS dependence within your practice (does the practice offer treatments for people who use ENDS)?						
Always	0		0		1	50
Often	2	50	4	100	0	
Sometimes	2	50	0		0	
Never	0		0		1	50
Q8: Refer to ENDS treatment outside of your practice?						
Always	0		0		0	
Often	0		4	100	2	100
Sometimes	2	50	0		0	
Never	2	50	0		0	

Note. ENDS = electronic nicotine delivery systems

[a] N = 4

[b] N = 2

For Table 11, the same PCPs (n = 4) took the pre-education and immediate post-education surveys. Because the questions were intended to assess current practice, no change between pre-education and immediate post-education was expected, rather a change in responses was only expected from pre-education to three months post-education. However, PCPs' changes in responses were observed pre-education to immediate post-education. Half of the PCPs (n = 2) who completed the pre-education and immediate post-education surveys completed the three months post-education survey.

PCPs' reported assessment of patients' interest in quitting and identifying the reasons patients are thinking of quitting are described next. Pre-education, all (n = 4) of the PCPs assessed patients' interest in quitting and reasons why patients were thinking of quitting, with half (n = 2) of the PCPs always assessing these items and half (n = 2) either often or sometimes assessing these items. As expected, PCP responses to these questions immediately post-education did not change. Of those PCPs completing the three months post-education survey, no change was discernible from either pre-education or from immediate post-education to three-month post-education in the number of PCPs assessing these items. Both PCPs always assessed patients' interest in quitting and for the identification of the reasons why patients were thinking of quitting, 1 (50%) PCP always and 1 (50%) PCP sometimes assessed this.

PCPs' responses to the distribution of educational materials or handouts are described next. Pre-education, all (n = 4) of the PCPs reported that they often (n = 2) or sometimes (n = 2) distributed educational materials or handouts to their patients. Immediately post-education, although change was not expected, it appears one PCP changed her/his response from often to always distributing the educational items to their patients. Three months post-education, there was a decrease in the PCPs who reported distribution of educational materials or handouts to

patient from both pre-education and immediate post-education, with one PCP reporting never distributing these items and one sometimes doing so.

PCPs' responses to discussions of medications for ENDS cessation is described next. Pre-education, all PCPs reported they often (n = 1, 25%) or sometimes (n = 3, 75%) discussed use of medications for ENDS cessation. Immediately after the educational session, although change was not expected, it appears one PCP changed his/her answer from sometimes to often having these discussions. Of those PCPs completing the three months post-education survey, no change was discernible from either pre-education or from immediate post-education to three-month post-education in the discussion of medications for ENDS cessation.

PCPs' responses to treating ENDS dependence within the clinic is described next. Pre-education, all (n = 4) of the PCPs reported treating ENDS dependence within clinic, with half (n = 2) often treating and half (n = 2) sometimes treating ENDS dependence within their practice. Immediately post-education, although change was not expected, two PCPs changed their responses from sometimes to often treating ENDS dependence within their practice. Of the PCPs completing the three months post-education survey, both PCPs responses did change from both pre-education and immediate post-education, with one (50%) PCP reporting they always treated ENDS dependence within their practice, while the other reported they never treated ENDS dependence within the practice.

PCPs' response to referring patients for ENDS treatment outside of the practice is described next. Pre-education, half (n = 2) of the PCPs reported they sometimes referred patients to ENDS treatment outside of their practice and half (n = 2) reported they never do so. Immediately post-education session, although change was not expected, all PCPs changed their responses to often referred patients for ENDS treatment outside of their practice. Of those PCPs

completing the three months post-education survey, change was not discernible from immediate post-education to three-month post-education. However, change from pre-education to three-month education, with more (n = 2) PCPs reporting they often referred to ENDS treatment outside of their practice.

In summary, pre-education, all PCPs reported some level of activity for each of the six current tobacco cessation activities assessed in the survey (assessing interest in quitting, identifying reasons why thinking of quitting, offering educational materials, discussing use of cessation medications, treating ENDS dependence either within their practices or referring to treatment outside of their practices). Although a change in responses was not expected from pre-education to immediate post-education, change in responses did occur in four of the tobacco cessation activities, with responses moving towards more activity for offering educational materials, discussing use of medications, offering treatment for ENDS cessation either within their practices or referring outside their practices.

The three-month post-education survey revealed changes in responses from either pre-education or immediate post-education for four of the six tobacco cessation activities assessed. In focusing specifically from pre-education to three months post education, no apparent change in activity occurred for three activities: assessing current interest in quitting, identifying reasons for thinking of quitting, discussing use of medications for cessation. A slight decrease in activity occurred pre-education to three-month post education in PCPs offering of educational materials or handouts with half (n = 1) of the PCPs indicating never doing so. PCP responses for treating dependence within PCP practices was mixed from pre-education to three months post-education with half (n = 1) increasing frequency to always treating ENDS dependence with practice and half (n = 1) decreasing frequency to never doing so. An increase in reported frequency of

referring to ENDS treatment outside of their practices increased from pre-education to three months post-education with both responding PCPs indicating they often do so.

Objective Five

The fifth objective for this project was to assess and compare rates of PCP-patient discussions about ENDS and rates of cessation referral via a retrospective chart review. See Table 12 below for the activities and evaluation associated with this objective. Objective Five was partially met.

Table 12

Objective Five Activities and Evaluation

Objective	Activity	Evaluation
Assess and compare rates of PCP discussion about ENDS and rates of cessation referral three months pre-education and three months post-education by conducting retrospective chart reviews.	Do chart review assessing rates for three months prior to educational session and for three months post-educational session	Compare rates of PCP discussions three months pre-and three months post-intervention

The data for the retrospective chart review was obtained from the EHR for patients aged 13-25. The co-investigator utilized the chart review program to perform the retrospective chart reviews February 23, 2021 for the period of August 11- November 9, 2020 and November 10, 2020 - February 9, 2021. The quantitative data was analyzed with the assistance of a statistician and evaluated for statistical and clinical significance.

Tobacco History

One component of the retrospective chart review was reviewing documentation of patients' tobacco history. The tobacco history questions should be asked of each patient at every visit to the clinic and their response should be documented. The tobacco history questions were

reviewed to determine whether the patient was a current, former, passive, or never smoker. The results are in Table 13.

Table 13

Tobacco History

	Three months Pre-Education 8/11/2020 – 11/9/2020											Three- Months Post-Education 11/10/2020- 2/9/2021										
	Total Patients	Never User		Uses Tobacco		Quit		Passive Exposure		Not asked		Total Patients	Never User		Uses Tobacco		Quit		Passive Exposure		Not asked	
	N	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%
Type of Visit																						
Clinic Visit	263	200	76.1	33	12.6	12	4.6	18	6.9	0		265	180	67.9	40	15.1	16	6.0	29	10.9	0	
MyChart Telemed Home	59	48	81.4	6	10.2	3	5.1	2	3.4	0		45	33	73.3	4	8.9	4	8.9	3	6.7	1	2.2
Telemed Home Visit (Non-MyChart)	137	95	69.3	12	8.8	4	2.9	16	11.7	10	7.3	80	55	68.8	9	11.3	3	3.8	11	13.8	2	2.5
Verbal Visit	3	2	66.7	1	33.3	0		0		0		4	1	25.0	1	25.0	0		2	50.0	0	
Wellness Visit	26	25	96.2	0		0		1	3.9	0		9	8	88.9	0		0		1	11.1	0	
Child/Teen Visit	37	34	91.9	0		0		3	8.1	0		12	6	50.0	0		0		6	50.0	0	
Sports Physical	32	30	93.8	2	6.3	0		0		0		3	3	100.0	0		0		0		0	
None of the Above	235	171	72.8	19	8.1	7	3.0	19	8.1	19	8.1	175	123	70.3	20	11.4	17	9.7	8	4.6	7	4.0
Total	792	605	76.4	73	9.2	26	3.3	59	7.4	29	3.7	593	409	69.0	74	12.5	40	6.8	60	10.1	10	1.7

During the three-month period prior to the educational session, there were 792 visits to the SVCC by patients ages 13-25 compared to 593 visits three months post-education. Table 13 above shows the number of visits and the classification of each visit: MyChart Telemed Home visits, Telemed Home Visits, and verbal visits all occurred virtually, either via a telemedicine app or via the telephone in the case of verbal visits. Clinic visits, wellness visits, child/teen visits, sports physicals, and other visit classifications that were not virtual were also included. Of these patients, pre-education nearly three-fourths (76.4%) reported never having used tobacco products; post-education this decreased slightly to about two-thirds (69.0%). For both the pre-education and post-education timeframes, about 10% of patients reported being current tobacco users (9.2% and 12.5% respectively). Pre-education, 3.3% (n = 26) were reported as being former tobacco users who had quit; post-education, this increased to 6.8% (n = 40). Pre-education, 7.4% (n= 59) were reported as having passive exposures to tobacco as compared to 10.1% (n = 60) with passive exposures post-education. Of the approximately 4% (n = 29) of the patients who had no tobacco history questions answered pre-education, about one-third (n = 10) had Telemed Home Visits and about two-thirds (n = 19) had other visit classifications. Post-education, approximately 2% (n = 10) of the patients did not have tobacco history questions answered: about one-third (n = 3) had either a Telemed Home Visit or a MyChart Telemed Home Visit, and about two-thirds (n = 7) had other visit classifications.

Tobacco history was documented in 96.3% of visits in the three months prior to the education session and was documented in 98.3% of visits in the three months after the education session. Although assessing for a change in tobacco history documentation was not planned, there was a statistically significant change (Fisher's exact test, p = 0.032; two-sample z-test with

continuity correction, p = 0.042) from three-months pre-education to three-months post-education.

Rates of PCP Discussions and Referrals

The chart review included all seven PCPs from the SVCC. As part of the chart review, the rates of PCP-patient discussions and cessation and education referrals placed by PCPs during the three months prior to the educational session were to be compared to the rates three months post-educational session. Rates of PCP-patient discussion about ENDS use were unable to be assessed, as the chart review software did not allow for individual patient charts to be accessed. Additionally, PCP clinic notes were not available for review. Also, there was no change in the rate of cessation referrals placed, as there were no referrals to tobacco cessation programs or to the TTS ordered pre-education or post-education.

In summary for Objective 5, the rates of PCP-patient discussions were unable to be assessed due to the limitations of the chart review software and the rates of cessation referrals did not change pre-education to post-education. However, unplanned analysis of completion of the tobacco history questions found a significant difference post-education as compared to pre-education.

CHAPTER FIVE: DISCUSSION AND RECOMMENDATIONS

Summary

The purposes of this project were to increase PCP knowledge of ENDS, increase PCP patient discussions regarding ENDS, and increase cessation referrals. Key informant interviews were conducted, and five themes were identified and were found to be consistent with the information obtained in the literature review. The results from the key informant interviews were combined with results from the literature review to inform educational sessions for PCPs and nursing staff. PCPs in attendance were invited to complete pre-, immediate post-, and three-month post-education surveys and to evaluate the quality of the presentation. Overall, the PCPs surveyed reported increased motivation, confidence, and comfort in discussing ENDS use with patients between the pre- and immediate post-education survey. However, the sample size decreased by 50% from the pre- and immediate post-education surveys to the three-month post-education surveys which made determination of trends difficult. The PCPs reported the education session as helpful and the increased motivation, confidence, and comfort may have impacted the PCPs' reported likelihood to make change to their practice after the educational session. Accordingly, the increased motivation, confidence, and comfort, along with the increased likelihood of changing practice may be reflected in the increased self-reported tobacco cessation activities of treating ENDS dependence within PCPs' practices or referring for treatment outside of PCP practices identified at three months post-education. In contrast to this, the chart review revealed that there was no increase between the pre- and post-education in cessation referrals. However, treatment within PCP practice or referral outside of practice may have been documented in the clinic notes, which were not available for assessment by the co-investigator. Interestingly, an unplanned analysis of tobacco history documentation found a

statistically significant change with more documentation from three-months pre-education to three-months post-education, which may indicate the start of successful practice changes.

Discussion

Objective One

Objective One was designed to assess the current barriers to PCP discussion of ENDS use with patients ages 13-25 by conducting key informant interviews of PCPs. The objective was met. The key informant interviews were conducted with two PCPs from the SVCC and utilized a questionnaire adapted from El-Shahawy, Brown, and Lafata (2016). The data was analyzed with the Constant Comparative Method and five common themes were identified.

The theme that PCPs were more confident in discussing traditional product use and cessation than in discussing ENDS with their patients was consistent with information found during the literature review. PCPs have been educated about traditional tobacco use and how to counsel patients effectively using the 5 A's method, AAR method, or motivational interviewing; additionally, the long-term health effects of cigarette smoking are well-established (USDHHS, 2020). Thus, this finding suggests that PCPs overall are hesitant to discuss ENDS use with their patients. This is not surprising given the lack of research about long-term health effects of ENDS use, as well as lack of PCP knowledge about ENDS in general (Egnot et al, 2015)

The theme that patients did not usually initiate discussions with PCPs about ENDS use was also consistent with research found in the literature review. As many youth users of ENDS believe ENDS to be less harmful than traditional cigarettes and may often be unaware of nicotine content in e-liquids contained in their ENDS, there is less perceived risk of use of these devices (CDC, 2020; USDHHS, 2016). Early in the introduction of ENDS into the market, it was suggested that ENDS might be a healthy alternative to traditional cigarettes. Thus, many people

may still be unaware of the negative health impacts associated with youth ENDS use, such as nicotine dependence, learning difficulties, cognitive impairment, and more significant symptoms in diseases such as COVID-19 (Stanford Medicine, 2021; USDHHS, 2016). If there is minimal perceived risk of use of ENDS, patients are unlikely to inquire about ENDS at medical appointments. If the PCP seeks an accurate and complete medical history, initiating the discussion about ENDS use must be the PCP's responsibility.

The themes that although PCPs were able to identify some of the negative health impacts related to ENDS use, they did not consistently or routinely ask their patients about ENDS use were also consistent with the information found in the literature review. However, the PCPs who participated in the key informant interview were more likely to address and counsel against ENDS use in younger patients than in adult patients. This indicated that PCPs were able to identify negative health implications of ENDS use and have formed opinions about their youth patients using ENDS but were not consistently counseling their patients in accordance with the precautionary principle (Green et al., 2018; Ofei-Dodoo et al., 2017). The variability of ENDS products, lack of long-term research about health effects of ENDS use, and perceived or actual time-constraints during visits may contribute to lack of discussions between PCPs and patients about ENDS use (Egnot et al., 2015; USPSTF, 2021). For adults, there is not sufficient evidence to suggest that ENDS use as a tobacco cessation aid is effective, and therefore guidelines recommend that alternative and FDA-approved cessation aids such as varenicline and NRT be used for cessation rather than ENDS, as use of ENDS as a cessation aid often leads to dual use (Buettner-Schmidt et al., 2021). For youth patients, the USPSTF and CDC recommend against youth use of ENDS, so although there is lack of long-term research about health effects, there is clear recommendation against ENDS use for youth, which should be sufficient for PCPs to

provide cessation counseling to youth patients (CDC, 2021; USPSTF, 2021). Given that PCPs were able to verbalize awareness of health impacts that are currently known about ENDS use and youth nicotine use, it is recommended that they ask their youth patients about and advise them against ENDS use and refer to cessation services as appropriate.

Objective Two

Objective Two pertained to development of an educational session for PCPs about the current research regarding the use of ENDS, the health implications, cessation referral resources, and appropriate (EHR) documentation. This objective was met, as the information from PCPs obtained in the key informant interviews was incorporated into an educational session. The education session also included known health implications of ENDS use in youth, conversation tools for discussing ENDS use with patients, referral resources for cessation programs, and proper documentation of ENDS use and referrals that were placed during the visit.

Objective Three

Objective Three pertained to implementation of an educational session for PCPs based on current research and results of key informant interviews. This objective was met. The educational session was presented to the PCPs and nursing staff in person with social distancing requirements maintained; the in-person session may have been helpful in knowledge retention and engagement in the presentation. All surveyed PCPs felt the session information was helpful or very helpful. They also reported positive feelings about the overall quality of the educational session, and reported they were very or extremely likely to make changes to their current practice after the education session. The positive responses regarding the quality of the education session and likelihood to make practice changes were encouraging. Given the positive responses, it

would be reasonable to expect higher rates of PCP-patient discussions about ENDS use and cessation referrals than found in the results as described for Objective Five.

Objective Four

Objective Four pertained to evaluating change in PCP knowledge and the effectiveness of the educational session, as evidenced by increased motivation, confidence, and comfort in discussing ENDS and increased tobacco cessation activities, through PCP surveys. This objective was partially met.

Motivation

Questions one and two referred to the PCPs' reported motivation in discussing ENDS use with patients. Question one inquired whether the PCP believes it is important for the PCP to know whether a patient uses ENDS. Given the increase and continued strength of the PCPs agreement that it is important for PCPs to know about patients' ENDS use, it is reasonable to state that PCPs placed increased importance on knowledge of ENDS use after the completion of the education session. Question two referred to PCPs' motivation to help ENDS users quit. The strength of the agreement that PCPs were motivated to help ENDS user increased pre-education to immediate post-education. However, there was no discernible change at three-month post-education as it was difficult to determine whether one of these two responding PCPs previously more strongly agreed and changed their response to simply 'agree,' or whether the PCPs responses on the three-month post-education survey were the same as their immediate post-education survey. In any case, both PCPs at the three months either strongly agreed or agreed to being motivated to help ENDS users quit.

The data from the chart review may reflect sustained motivation to know about ENDS use, as more patients were asked the tobacco history questions post-education as compared to

pre-education. Similarly, more patients were reported as former tobacco users post-education than pre-education.

In summary, increased PCP motivation was noted from pre-education to immediately post-education and remained increased for at least one PCP overall in the post-education period.

Confidence

Four questions, items 9 through 12, referred to PCPs' confidence in discussing ENDS use with patients including exploring issues related to quitting ENDS, personalizing the benefits of quitting with each individual user, providing information about medications to help quit, providing information on programs and services that help quitting.

PCP confidence increased overall from pre-education to post-education for all responding PCPs and remained increased for at least one PCP at three months post education for three questions: exploration of issues related to quitting ENDS, personalizing the benefits of quitting ENDS, and providing information about medications for cessation. For the fourth question, providing information for cessation programs, confidence increased from pre-education to immediately post-education. It would be expected that overall increased confidence in the first three areas would be reflected in the PCP-patient discussions, which would be recorded in patient notes. However, the visit documentation in the EHR were unable to be reviewed during the chart review. An increase in the referral rates to cessation programs in the three-month post-education period would not be expected, given no discernible change in the level of confidence between the immediate post-education and three-month post-education surveys.

Comfort

Three questions, items 13 through 15, referred to PCPs' reported comfort in discussing ENDS use with patients, providing medication information for ENDS cessation to patients, and providing ENDS cessation resources to patients.

PCP comfort increased overall from pre-education to post-education for all three questions. In relation to comfort immediate post-education to three months post-education, evidence of increased comfort remained for two questions: providing information about medications and providing information about programs and services to help quitting. The evidence of increased comfort remained for at least one PCP from pre-education to three months post-education for the same two questions, providing information about medications and providing information about programs and services to help quitting.

Although there was increased comfort overall from pre-education to post-education, there was only evidence of sustained increased comfort from immediate post-education to three months post-education for two questions: providing information about medications and providing information about programs and services to help quit. There was no evidence of change from immediate post-education to three months post-education for comfort in discussing ENDS use with patients. An increase in the number of PCP-patient discussions three months post-education would not be expected, as there was no discernible change in the level of comfort immediately post-education to three months post-education for discussing ENDS use with patients. It would be expected that sustained increased comfort in providing medication information would be reflected in PCP-patient discussions and recorded in EHR notes, but the notes were not able to be reviewed. It would also be expected that increased comfort in providing information about programs and services to help quitting would be reflected both in PCP-patient

discussions and in an increase in referral rates, especially as both respondents indicated they were very comfortable providing this information. However, the notes were not able to be reviewed, and there was no increase in the rates of referral to cessation programs.

Tobacco Cessation Activities

Six questions, items three through eight, referred to PCPs' reported tobacco cessation activities, specifically assessing interest in quitting, identifying reasons why thinking of quitting, providing educational materials and medication cessation aids, and treating ENDS use within the PCPs' practices or making necessary referrals outside of their practices.

Pre-education, all PCPs reported some level of activity for each of the six current tobacco cessation activities assessed in the survey. Unexpectedly, a change in response occurred between pre-education and immediate post-education, as responses moved towards the PCPs reporting they more often offered educational materials, discussed use of medications for cessation, and offered treatments for ENDS cessation within and outside of their practices by placing referrals. It is possible that after receiving education, the PCPs realized that they in fact did do more cessation activities than they had previously realized. It is also possible that they did not fully understand the question and perhaps felt their responses should change after education.

From pre-education to three months post education, no apparent change in activity occurred for three activities: assessing current interest in quitting, identifying reasons for thinking of quitting, discussing use of medications for cessation. Given there was no reported change for these items, no change in the rate or content of PCP-patient discussions would be expected, although this would be able to be assessed in the clinic notes, which were not accessible during the chart review.

From pre-education to three months post-education session, there was a decrease in the amount of educational materials distributed to patients, which could be attributed to lower numbers of overall clinic visits for patients aged 13-25 during the three months after the educational session. However, it would be expected that the amount of educational materials distributed would increase post-education, as the PCPs were provided with numerous resources to obtain educational materials.

PCP responses for treating dependence within PCP practices was mixed from pre-education to three months post-education, as one PCP (50%) reported increased frequency to always treating ENDS within their practice and one PCP (50%) reported decreased frequency to never doing so. Both responding PCPs self-reported increased frequency of referring to ENDS treatment outside of their practices from pre-education to three months post-education. Treating dependence within the practice and referring to treatment outside of the practice were both desired outcomes of this project, but the reported increased frequency for treatment within or outside of their practices was not supported by the chart review. There was no increase in rates of cessation referrals placed pre-education to post-education, nor was there an increase in rates of referrals to the TTS placed. PCPs may have been documenting treatment of dependence within their practices in clinic notes, but these were not able to be reviewed.

In summary of the tobacco cessation activities, there was no change in reported assessment of current interest in quitting, identifying reasons for thinking of quitting, and discussing use of medications for cessation from pre-education to three-months post-education. This finding was not supported by the chart review, as the individual patient notes were not able to be reviewed. PCPs reported they referred to ENDS treatment outside of their practices more frequently post-education. Although this was a desired outcome, the chart review data did not

support that an increase in ENDS treatment referrals occurred; however, this may have been documented in the clinic notes that were not able to be reviewed.

Objective Four Summary

In summary of Objective Four, there was overall increased motivation, confidence, and comfort and therefore increased knowledge noted between the pre-education and immediate post-education surveys, and this often persisted through the three-month post-education surveys but did not usually increase between immediate post-education and three months post-education. This increased motivation, confidence, and comfort may be reflected in the increased self-reported tobacco cessation activities of treating ENDS dependence within PCP practices or referring for treatment outside of PCP practices. While the increased motivation, confidence, and comfort, along with self-reported increase in treating or referring for ENDS treatment would be expected to have been reflected in the chart review data, the chart review did not show increased rates of cessation referrals within the PCPs' practices or outside of their practices. However, treatment within PCP practice or referral outside of practice may have been document in the clinic notes, which were not available for assessment by the co-investigator. For reported tobacco cessation activities, although there was no change from pre-education to post-education in assessment of current interest in quitting, identifying reasons for thinking of quitting, and discussing use of medications to help quit, all PCPs reported some level of activity for each of these items.

Objective Four was partially met because although there was an overall reported increase in motivation, confidence, and comfort from pre-education to post-education and, therefore, increased knowledge, this was not reflected in the data obtained in the chart review or was not able to be assessed in the chart review.

Objective Five

Objective Five pertained to assessing and comparing rates of PCP discussion about ENDS and rates of cessation referral three months pre-education to three months post-education by conducting retrospective chart reviews. This objective was partially met. The chart review tool created to perform the chart review was not able to be utilized, as all data provided to the co-investigator was in aggregate and was unable to be separated by patient or PCP. Therefore, the rates of PCP-patient discussion were unable to be assessed. It may be that PCPs were most likely to write about PCP-patient discussions about ENDS use in their clinic notes, however, the notes were not available for review. The rates of cessation referral were unchanged from pre-education to post-education; no referrals for tobacco education by the TTS, or to NDQuits were placed pre-education nor post-education. Once again, referrals or PCP-discussions may have been documented in the clinic visit note, which were not available for review. Interestingly, an unplanned analysis of tobacco history documentation found a statistically significant increase from three-months pre-education to three-months post-education, which provides supports that the education session may have been effective.

Of the patients who did not have tobacco history assessed at their visits pre-education, about one-third were registered as Telemed Home visits, indicating they had a virtual visit with a PCP using software that was not associated with Epic. Given that the software was not associated with Epic, it may have been more difficult for the PCP to ask the questions about tobacco history and to document them appropriately. Furthermore, the PCP is responsible for all documentation during a virtual visit, as nursing staff is not involved with these visits. This is a departure from normal procedure, as during an in-clinic visit the rooming nurse would ask the tobacco history questions and the PCP should review their documentation. Thus, the PCPs may have found it

difficult to document appropriately, as it is not part of their normal routine. Similarly, about one-third of the patients in the three-month post-education cohort who did not have tobacco history documented had either MyChart Telemed Home visits or Telemed Home visits using other software, indicating it remained difficult for PCPs to document tobacco history during a virtual visit. Fewer virtual visits occurred in the post-education period than the pre-education period, as virtual visits comprised about one-fourth of the overall visits for 13–25-year-old patients during the three months pre-education and about 20% of the overall visits in the three months post-education. As more visits were able to be conducted in person during the three months post-education, the documentation of tobacco history may have been more thorough, as it was able to be completed in accordance with normal clinic policy. Further education may be needed for PCPs and nursing staff regarding expectations about charting and documentation.

In summary of Objective Five, an unplanned analysis found a statistically significant difference in the number of patients with their tobacco history assessed post-education as compared to pre-education, which was a desired outcome of this project. However, there were not increased referrals for cessation outside of PCPs' practices, nor was there increased cessation treatment within the PCPs' practices. Measuring if there were increased rates of PCP-patient discussions about ENDS use and cessation was not possible due to the restrictions from the chart review software.

Objective Five was partially met, as the chart review data revealed that tobacco history questions were asked significantly more after the education session, but no evidence was available of increased rates of PCP-patient discussions about ENDS use or increased rates of cessation referrals post-education.

Recommendations

Clinic Recommendations

The SVCC has already fulfilled an important recommendation to train one of the RNs as a TTS to ensure the PCPs are able to consult the TTS or refer interested patients to the TTS for tobacco cessation. The PCPs can also consult the TTS if they have questions about tobacco cessation programs or protocols. However, education for the SVCC PCPs about the TTS as a resource, their hours of availability, and how to refer a patient to them might ensure they are more frequently utilized to provide adjunct tobacco cessation counseling. Another recommendation is that the SVCC have additional education sessions for PCPs and nurses after the resolution of the COVID-19 pandemic. The education session occurred during the height of the COVID-19 pandemic in the state, and thus the information presented may not have been of highest priority to the PCPs and nursing staff. Furthermore, because the COVID-19 pandemic occurred, there was less publicity about EVALI and therefore, the PCPs may not have been as aware of the detrimental health effects of ENDS use.

If this project were repeated, identifying a clinic staff member as a champion of the project might be helpful in maintaining motivation for the project and for being available in the clinic for guidance and support of the PCPs. Academic detailing, or "peer-to-peer educational outreach," is used to improve areas of clinical practice by training an individual on the practice change (Agency for Healthcare Research and Quality, 2013, para. 1). Utilizing academic detailing to promote practice change related to ENDS cessation counseling would be recommended.

Posters or other visual aids should be placed in examination rooms, as these may increase awareness of health effects related to ENDS use and might help patients initiate discussions with

PCPs. As teens and young adults are motivated by relationships with peers, ensuring youth have accurate information about ENDS may help spread correct information between peers and friends.

The chart review software utilized to obtain the data for this project did not allow for detailed review of PCP notes, sorting patients by PCP, nor review of type of tobacco product use. Specifically, this meant that ENDS-specific data was not available for review. As use of ENDS increases, it is not only important for PCPs to address ENDS use with patients, but also to measure and analyze the data surrounding patients' ENDS use. Therefore, modifying the chart review software to be specific to PCP and to type of tobacco product is recommended.

Practice and Education Recommendations

Currently, the nursing staff is responsible for asking patients about ENDS use and documenting ENDS use appropriately. However, the results of the key informant interviews showed that PCPs should carry the responsibility of initiating any discussions about ENDS use, as patients are unlikely to initiate these discussions. Furthermore, PCPs should adopt the practice of asking youth patients about and advising them against ENDS use and referring them to cessation services. Further education is recommended for both nursing staff and PCPs about appropriate documentation of tobacco history and entering referrals for within and outside of the clinic appropriately into the EHR. Further education for PCPs about the organizational quality measures for tobacco cessation is also recommended. Inviting a representative from the organization's quality department to speak at an educational session would ensure PCPs understand requirements.

Documentation of the tobacco history questions during virtual visits could be improved by having the nurse ask the tobacco history questions. For example, the nurse could call the

patient prior to the visit to ensure the required documentation was completed and the PCP would have adequate time to address the patient's concerns during the virtual visit.

While continued education of PCPs and RNs is extremely important, community and school-based education for youth about ENDS is also important. Implementation of educational programs about ENDS use, the negative health impacts of nicotine use in youth, and cessation resources in middle school, high school, and higher education institutions could help provide clear evidence and guidelines for students considering use of ENDS and cessation from ENDS. Educating youth and young adults that using ENDS typically indicates that they are consuming nicotine, and that ENDS are tobacco products is also crucial.

Policy Recommendations

E-liquids that contain nicotine must have packaging that labels them as nicotine-containing products, and furthermore, it is important that the advertised nicotine concentration match the product. ENDS should also be included in smoke-free policies and be classified as tobacco products under state law. ENDS products that appeal specifically to youth should be prioritized for legal enforcement (Tobacco Free Kids, 2021; USFDA, 2021).

Based on the literature review and key informant interviews in this project, PCPs desire clearer and readily available guidelines about ENDS use and cessation treatment for ENDS users. Although the USPSTF, American Thoracic Society, and American College of Cardiology have published guidelines about smoking cessation and advise specifically against ENDS use for cessation (Buettner-Schmidt et al., 2021), they may not be well-known and should be provided for PCP use. Large-scale, long-term research specifically related to ENDS use and its health impacts needs to be funded and completed to have sufficient evidence for consistent national practice guidelines surrounding ENDS use by youth.

Recommendation for Future Research

Replication of this project in a larger clinic or with more PCPs is recommended to have statistically significant survey results. This project should be replicated with more than one education session, as additional education may increase behavior change. Incentivizing or requiring staff to attend education sessions and incentivizing PCPs to complete the surveys may be worthwhile. Distributing surveys at different intervals may also be worthwhile. For example, some PCPs at the SVCC appeared confused by the questions about tobacco cessation activities and changed their responses unexpectedly from pre-education to immediately post-education. Administering the survey at one-month post-education and again three months post-education, for example, might more accurately assess changes. Furthermore, if more education sessions were presented over a longer timeframe, the surveys could be administered at regular intervals throughout the time frame.

Repeating the key informant interviews with replication of this project is recommended. The information obtained in the key informant interviews was echoed in the literature review and therefore was not surprising. However, the PCPs' responses during the key interview were helpful in identifying the specific barriers at the SVCC, and therefore, the education session was able to fit the PCPs' identified needs. Based on the TRA, inclusion of more PCPs would be helpful, as the key informant questions are based on the TRA. The TRA can be used to understand motivation and opinions about behavior. If behavior can be more fully understood, it can be addressed and changed. Furthermore, the TRA influenced the education session information, as the content was intended to address the PCPs' behavioral, normative, and control beliefs, as well as the PCPs' motivation to comply and perceived power. By addressing these components of the TRA in the education session, the information presented in the education was

designed to ultimately impact the PCPs' intentions to perform behaviors (addressing ENDS use and providing cessation counseling) and thus influencing PCP behavior change.

Providing clarification for some survey questions, specifically the tobacco cessation activity questions, might also be helpful in future research, as there was an unexpected change between pre-education and immediate post-education responses in this project. These questions could also be removed from the immediate post-education survey altogether to provide more clarity. Clarifying what constitutes cessation treatment within a PCP's practice and if the PCPs have received any previous training in tobacco cessation counseling may also be helpful.

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. The results will also be presented at the NDSU Poster Presentation in May 2021. After this presentation, the poster will be displayed at the SVCC, as posters from previous practice improvement projects completed at the SVCC continue to be displayed as references and reminders.

Strengths and Limitations

Strengths

The strengths of this project were most notably evident in the questionnaires used in the key informant interviews and the pre-, immediate post-, and three months post-education surveys. As these tools had been previously used in larger-scale projects and were determined to be valid and reliable, use of these tools helped to ensure reliability and validity of this project, despite the smaller sample size.

The presentation of the education session was also a strength of this project. PCPs who participated in the immediate post-education survey reported themselves as either very likely or extremely likely to make changes to their practice after the educational session. They also reported the educational session as helpful and reported the session was of excellent quality.

Limitations

One limitation of this project was the small sample size, as it was conducted at one clinic in a rural area. However, the sample size was further reduced as few PCPs who participated in the education session chose to complete the pre-, immediate post-, and three months post-education surveys. Given the small sample size, it was difficult to determine statistical significance. While the co-investigator provided a meal at the education session, it may have been more motivating to provide a small incentive for survey completion in addition.

Another limitation to this study was that the education session took place in November 2020, which was at the peak of the state's COVID-19 pandemic cases. The SVCC had many staff members ill with COVID-19 placing extra strain on the PCPs and remaining staff. The clinic also saw high volumes of patient visits for respiratory complaints and COVID-19 testing, and PCPs were responsible for collaborating with the state's health department to ensure proper quarantine and monitoring precautions were in place. While the PCPs and other staff members participated in this project, it is possible that discussions about ENDS use and cessation may not have taken top priority during many clinic visits during this time period.

The process to complete the retrospective chart review was also a limitation to this project as the planned chart review method could not be followed. The chart review program utilized by the SVCC limited the data able to be obtained. For example, the data was available only in aggregate. While this protected patients' and PCP privacy, the data was not able to be

separated by PCP and analyzed for changes pre- and post-education. Similarly, many PCPs may have discussed ENDS use with their patients and given patients information about cessation resources and may have documented this in their clinic notes. However, as the data was recorded in aggregate without a way to review clinic notes, provider and patient specific data was not able to be assessed. Lastly, the chart review software was only able to capture responses to the tobacco history questions and was not able to provide more detail about the types of products the patients were using and therefore was not able to be specific to ENDS users. While assessing tobacco history questions is certainly important, many youth and young adult users of ENDS do not realize their e-liquids contain nicotine and many do not consider use of ENDS to be tobacco use or smoking. Therefore, tobacco history may not be an accurate representation for the number of young people using tobacco products.

Conclusion

Key informant interviews, performed before the educational session, revealed five themes related to PCPs beliefs and practices regarding ENDS use in patients. Providers were aware of some of the negative health effects of ENDS use and reported that patients did not usually initiate discussions about ENDS. PCPs also reported being more confident in addressing other types of tobacco use and reported not being consistent in asking their patients about ENDS use, although they were more likely to address ENDS use with adolescents than adults. The themes were incorporated into a PCP educational session which was evaluated through surveys and chart reviews. The education resulted in increased knowledge, motivation, confidence, and comfort in discussing ENDS use, cessation medications, cessation treatment within PCP practices and referral for treatment outside of PCP practices. Although not confirmed by the chart review, PCPs reported the likelihood to change their practices in relation to ENDS counseling and

referral and reported at three-months post-education increased activity in treating patients within PCP practice as well as referring to ENDS treatment outside of PCP practice.

This project was especially significant to the DNP role as it is focused on education and health promotion, which are cornerstones of DNP practice, especially in the primary care setting. Education of PCPs on evidence-based practice and health promotion strategies, such as providing them with resources to help their patients with ENDS cessation and tools for conversations with patients surrounding ENDS use helps promote health and wellness and may help with disease prevention.

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APPENDIX A: LITERATURE SEARCH STRATEGY

Identification

Screening

Literature Search Databases

	"Smoking Cessation"[Majr] AND ("Health Personnel"[Majr])	*("Attitude of Health Personnel"[Majr]) AND "Smoking Cessation"[Majr]*	*(("Primary Health Care"[Majr]) AND "Health Personnel"[Majr]) AND "Smoking Cessation"[Majr]*	*(("Attitude of Health Personnel"[Majr]) AND "Smoking Cessation"[Majr]) AND "Primary Health Care"[Majr]*	*("Electronic Nicotine Delivery Systems"[Majr]) AND "Attitude of Health Personnel"[Majr]*
CINAHL	n = 24	n = 35	n = 4	n = 10	n = 9
PubMed	n = 161	n = 73	n = 8	n = 5	n = 15
HealthSource	n = 6	n = 2	n = 6	n = 1	n = 1
Cochrane Reviews	n = 0	n = 0	n = 0	n = 0	n = 0
Trials	n = 22	n = 7	n = 6	n = 3	n = 0

Limits: 2015 to 2020

Total number of abstracts: n= 398

Eligibility

Abstracts screened for inclusion (n = 398)

Removed (n = 256)

Added (n = 8)

Inclusions: (tobacco cessation counseling guidelines, provider attitudes toward tobacco cessation, attitudes toward ENDS, tobacco cessation counseling in primary care)

Abstracts removed: duplicates, articles not available in English, articles not pertaining to/specific to the United States, editorials (n = 256)

Included

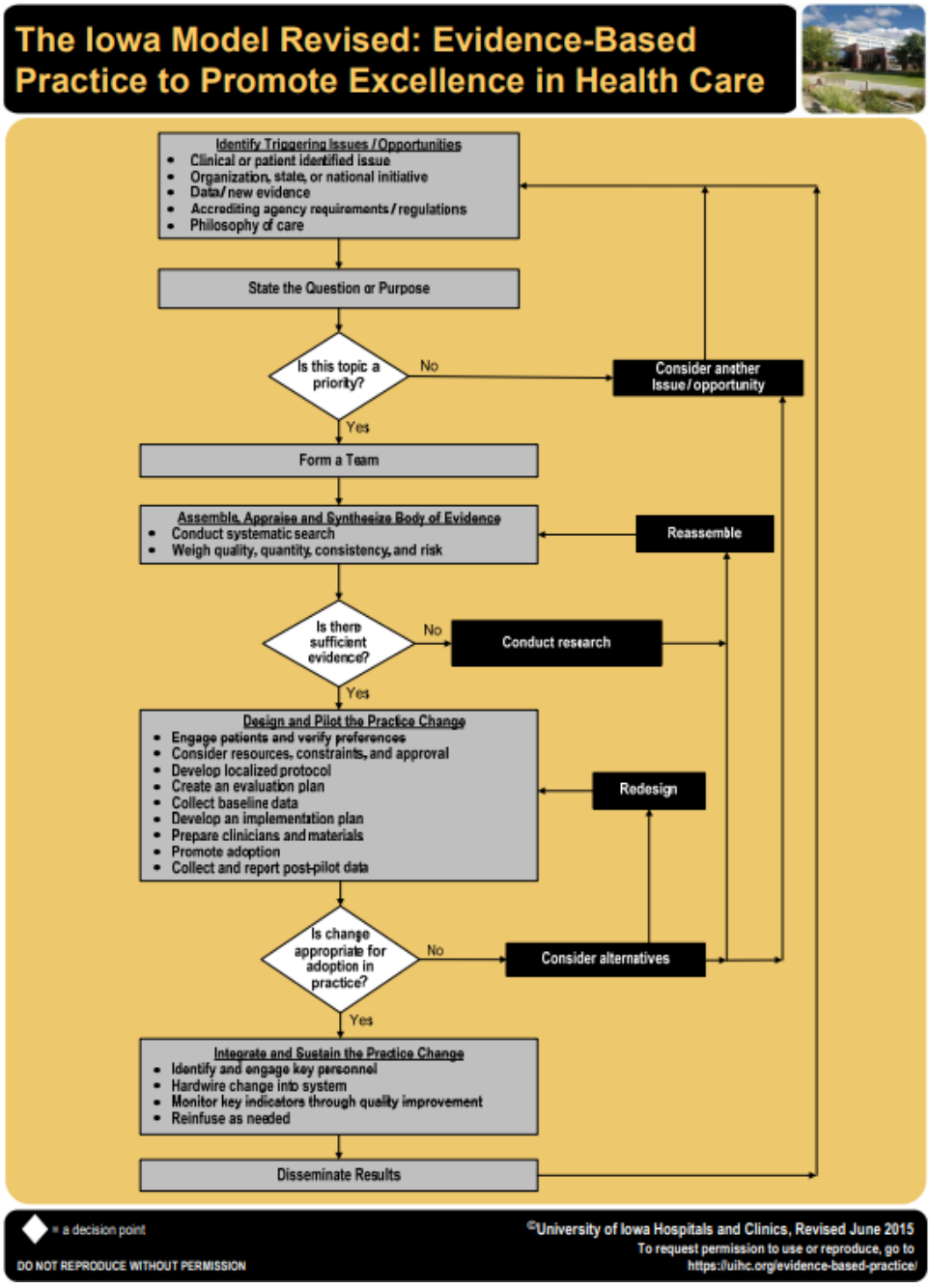
Full-text articles screened for eligibility (n = 150)

Full-text articles removed: articles/interventions not pertaining to/specific to primary medical care, inappropriate populations (n = 119)

Included in final evidence review

(n =31)

APPENDIX B: IOWA MODEL REVISED



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APPENDIX C: PERMISSION TO USE IOWA MODEL

Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qemailserver.com>
Sun 2/16/2020 4:51 PM
Christianson, Sarah

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.

The Iowa Model Revised (2015)

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

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Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

APPENDIX D: QUESTIONNAIRE FOR KEY INFORMANT INTERVIEWS

1. How do you typically ask your patients about their tobacco use status?
2. How do you go about counselling patients who are current tobacco users?
3. Have you ever asked any of your patients about their e-cigarette use?
   If yes, How did you go about doing that?
4. Have any of your patients ever asked you about e-cigarettes?
   If yes, Can you estimate how often over the past year? AND Can you tell me a typical question patients asked?
5. Do you know if any of your patients use e-cigarettes?If yes, What are your thoughts about that?
6. Did you recommend e-cigarettes to any of your patients?
   If yes → continue probing Was there something specific about the patient that led you to recommend/NOT recommend it? What was it about the patient? Something they said?
7. What are your thoughts regarding e-cigarettes and other modes of tobacco use? > How do you think e-cigarettes compare to other available tobacco products?
8. What are your thoughts regarding e-cigarettes and smoking cessation? > How do you think e-cigarettes compare to other cessation aids available?
9. Are there specific patients to whom you might be more or less likely to recommend e-cigarettes? > Give me an example of a patient to whom you are most likely/least likely to recommend e-cigarettes.

Note: Adapted from "Primary care physicians' beliefs and practices regarding e-cigarette use by patients who smoke: A qualitative assessment" by El-Shahawy, O., Brown, R., & Lafata, J., 2016. (https://doi.org/10.3390/ijerph13050445). In the public domain.

APPENDIX E: PERMISSION TO USE QUESTIONNAIRE FOR KEY INFORMANT INTERVIEWS

From: Christianson, Sarah <sarah.hutton@ndsu.edu>
Sent: Sunday, March 01, 2020 9:49 PM
To: El Shahawy, Omar <Omar.ElShahawy@nyulangone.org>
Subject: Permission for use of Interview Questions

[EXTERNAL]
Hello,

My name is Sarah Christianson, and I am a Doctor of Nursing Practice student at North Dakota State University. I am developing a dissertation project on the use of e-cigarettes in rural North Dakota and determining any deterrents for primary care providers to discuss e-cigarette use with their patients. I found your article, "Primary Care Physicians' Beliefs and Practices Regarding E-Cigarette Use by Patients Who Smoke: A Qualitative Assessment" useful in my research. With your permission, I would like to use and reproduce the semi-structured interview questions from this study in my project.

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

Thank you very much,

Sarah Christianson, BSN, BA, RN, DNP Student
Graduate Teaching Assistant, North Dakota State University
sarah.hutton@ndus.edu, (719) 351-7420

From: El Shahawy, Omar <Omar.ElShahawy@nyulangone.org>
Sent: Sunday, March 1, 2020 8:56 PM
To: Christianson, Sarah <sarah.hutton@ndsu.edu>
Subject: RE: Permission for use of Interview Questions

Good luck Sarah,
This sounds great- what is published is public domain. If you need more input or comments/suggestions on your work, I would be more than happy to help.

Best,
Omar

Omar El Shahawy, MD, MPH, PhD
Assistant Professor, Section on Tobacco, Alcohol and Drug Use
Department of Population Health, New York University School of Medicine

Assistant Professor of Global Health
Division of Global Health, NYU College of Global Public Health

NYU Langone Health
180 Madison Avenue
17th floor, Office: 17-50
New York, NY 10016

T 646-501-3587
omar.elshahawy@nyulangone.org

APPENDIX F: QUESTIONNAIRE FOR PCPS PRE- AND THREE MONTHS POST-EDUCATION

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. It is important, as a practitioner, to know whether a patient/client uses ENDS	☐	☐	☐	☐
2. I am motivated to help ENDS users quit.	☐	☐	☐	☐

Do you, as a practitioner, provide any of the following forms of assistance to ENDS users:

	Always	Often	Sometimes	Never
3. Assess current interest in quitting?	☐	☐	☐	☐
4. Identify the reasons they're thinking of quitting?	☐	☐	☐	☐
5. Offer education materials or handouts?	☐	☐	☐	☐
6. Discuss use of medications to help people quit ENDS (like NRT or prescription medications)?	☐	☐	☐	☐
7. Treat ENDS dependence within your practice (does the practice offer treatments for people who use ENDS)?	☐	☐	☐	☐
8. Refer to ENDS treatment outside of your practice?	☐	☐	☐	☐

I am confident that:

	Very Confident	Somewhat Confident	Not Very Confident	Not at All Confident
9. I can explore issues related to quitting ENDS, even with someone who is not interested in quitting.	☐	☐	☐	☐
10. I can personalize the benefits of quitting with each individual ENDS user.	☐	☐	☐	☐
11. I can provide information about medications that help in quitting ENDS.	☐	☐	☐	☐
12. I can provide information about programs and services that help in quitting (quitlines, counseling, etc.)	☐	☐	☐	☐

How comfortable are you in:

	Very Comfortable	Somewhat Comfortable	Not Very Comfortable	Not at All Comfortable
13. Talking with patients/clients about ENDS use?	☐	☐	☐	☐

14. Providing information about medications that help in quitting ENDS?	☐	☐	☐	☐
15. Providing information about programs and services that help in quitting (quitlines, counseling, etc.)?	☐	☐	☐	☐

The following questions are demographic questions about your practice.

16. What is your profession?
    a. Physician
    b. Physician Assistant
    c. Nurse Practitioner

17. How many years have you been in clinical practice?
    a. 0-3 years
    b. 4-6 years
    c. 7-9 years
    d. 10-12 years
    e. Greater than 12 years

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 G: QUESTIONNAIRE FOR PCPS IMMEDIATELY POST-EDUCATION

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. It is important, as a practitioner, to know whether a patient/client uses ENDS	☐	☐	☐	☐
2. I am motivated to help ENDS users quit.	☐	☐	☐	☐

Do you, as a practitioner, provide any of the following forms of assistance to ENDS users:

	Always	Often	Sometimes	Never
3. Assess current interest in quitting?	☐	☐	☐	☐
4. Identify the reasons they're thinking of quitting?	☐	☐	☐	☐
5. Offer education materials or handouts?	☐	☐	☐	☐
6. Discuss use of medications to help people quit ENDS (like NRT or prescription medications)?	☐	☐	☐	☐
7. Treat ENDS dependence within your practice (does the practice offer treatments for people who use ENDS)?	☐	☐	☐	☐
8. Refer to ENDS treatment outside of your practice?	☐	☐	☐	☐

I am confident that:

	Very Confident	Somewhat Confident	Not Very Confident	Not at All Confident
9. I can explore issues related to quitting ENDS, even with someone who is not interested in quitting.	☐	☐	☐	☐
10. I can personalize the benefits of quitting with each individual ENDS user.	☐	☐	☐	☐
11. I can provide information about medications that help in quitting ENDS.	☐	☐	☐	☐
12. I can provide information about programs and services that help in quitting (quitlines, counseling, etc.)	☐	☐	☐	☐

How comfortable are you in:

	Very Comfortable	Somewhat Comfortable	Not Very Comfortable	Not at All Comfortable
13. Talking with patients/clients about ENDS use?	☐	☐	☐	☐
14. Providing information about medications that help in quitting ENDS?	☐	☐	☐	☐
15. Providing information about programs and services that help in quitting (quitlines, counseling, etc.)?	☐	☐	☐	☐

The following questions are demographic questions about your practice.

16. What is your profession?
    d. Physician
    e. Physician Assistant
    f. Nurse Practitioner

17. How many years have you been in clinical practice?
    f. 0-3 years
    g. 4-6 years
    h. 7-9 years
    i. 10-12 years
    j. Greater than 12 years

Please complete the following education session evaluation questions.

18. How helpful was the information presented during this webinar? Circle one:
    a. Very helpful
    b. Helpful
    c. Neutral
    d. Slightly unhelpful
    e. Not helpful

19. Please rate the overall quality of the session. Circle one:
    a. Excellent
    b. Good
    c. Fair
    d. Poor

20. How likely are you make changes to your current practices? Circle one:
    a. Extremely likely
    b. Very likely
    c. Somewhat likely
    d. Not at all likely

21. Any other comments:

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 H: PERMISSION TO USE QUESTIONNAIRE FOR PCPS PRE- AND POST-EDUCATION

Re: Permission to use RTTI questions

Cunningham, James K - (jkcunnin) <jkcunnin@arizona.edu>
Thu 4/9/2020 9:09 PM
To: Christianson, Sarah <sarah.hutton@ndsu.edu>

Hi Sarah,

Glad to hear that the instrument has been of use to you and Dr. Buettner-Schmidt. You have our permission to use and reproduce the the CAM RTTI questionnaire. Good luck with your dissertation!

Jim

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

From: Christianson, Sarah <sarah.hutton@ndsu.edu>
Sent: Thursday, April 9, 2020 9:10 AM
To: Cunningham, James K - (jkcunnin) <jkcunnin@arizona.edu>
Subject: [EXT]Permission to use RTTI questions

External Email

Hello Dr. Cunningham,

My name is Sarah Christianson, and I am a Doctor of Nursing Practice student at North Dakota State University. I am developing a dissertation project on the use of e-cigarettes in rural North Dakota and determining any deterrents for primary care providers to discuss e-cigarette use with their patients. I found your article, "Complementary and Alternative Medicine (CAM) practitioners' readiness for tobacco intervention training: Development and psychometric properties of a new measure" useful in my research. With your permission, I would like to use and reproduce the CAM RTTI questionnaire from this study in my project. My dissertation chair, Dr. Kelly Buettner-Schmidt, has also used these questions in her work and has found them very helpful and applicable to her research.

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

Thank you very much,

Sarah Christianson, DNP-S, BSN, BA, RN
Graduate Teaching Assistant, North Dakota State University
sarah.hutton@ndus.edu, (719) 351-7420

APPENDIX I: RECRUITMENT EMAIL TO PCPS

Hello,

My name is Sarah Christianson, and I am a Doctor of Nursing Practice student at North Dakota State University. For my dissertation project, I am interested in learning about the amount of discussion that occurs between providers and their adolescent and young adult patients regarding the use of electronic nicotine delivery systems (ENDS). I am also interested in learning about the amount of cessation referrals that are placed by providers for these patients. I would like to provide you with a brief (10-15 minute) presentation of the most recent recommendations regarding ENDS use and strategies with which to counsel your patients.

Participants will be asked to complete a brief questionnaire about the content immediately before and immediately after the presentation. Participants will also be asked to complete the questionnaire three months after the presentation. Completion of the questionnaire will take approximately five minutes per questionnaire. Your completion of these questionnaires is **not** mandatory but would be greatly appreciated. Three months after the presentation, I plan to perform a chart review to analyze the rates of provider discussion of ENDS use with their patients and rates of cessation referrals placed. Each provider's individual responses to the questionnaires and individual rates of documentation will not be released. I do not foresee any risks or discomforts from participation in this project.

Please contact either the principal investigator for this project: Dr. Kelly Buettner-Schmidt via email: kelly.buettner-schmidt@ndus.edu or (701) 231- 8232, or me (co-investigator) via email: sarah.hutton@ndus.edu or via telephone: (719) 351-7420 with any questions or concerns you may have. You may also contact the Human Subjects Protection Office for

questions or concerns about the research via telephone: (701) 231-8995 or via email: ndsu.irb@ndsu.edu. Thank you for your time and for your consideration of this project.

Sincerely,

Sarah Christianson, DNP-S, BSN, BA, RN
North Dakota State University

APPENDIX J: INFORMATIONAL FLYER

E-cigarette use in Adolescent and Young Adult Patients

- Who: Primary Care Providers at Sanford Valley City Clinic
- What: Presentation during Provider Meeting about addressing e-cigarette use with adolescent and young adult patients at each visit to the clinic and discussing cessation and referral to cessation resources
- When: During Provider Meeting
- Why: Rates of e-cigarette use in North Dakota are rapidly increasing. Use of e-cigarettes and other nicotine-containing products have numerous negative health consequences for young people who use them
- How does this affect me?
  - You will be asked to complete a survey before and after the presentation, as well as three months after the presentation. Participation is completely **voluntary** and greatly appreciated. Responses to the survey will be anonymous and individual responses will not be shared.
  - A chart review will be completed three months after the presentation. Individual rates of e-cigarette discussions and referrals will not be released.
- How can I get more information?
  - Contact Sarah Christianson, (719) 351-7420, sarah.hutton@ndus.edu

APPENDIX K: EDUCATION SESSION SLIDES

Electronic Nicotine Delivery Systems in Youth and Young Adults

Sarah Christianson, BSN, BA, RN, DNP Student
North Dakota State University
November 10, 2020

1

Objectives

- Increase primary care provider knowledge of ENDS, increase primary care provider patient discussions regarding ENDS, and increase cessation referrals
- Inform primary care providers about prevalence and health effects of ENDS use
- Describe the role of the primary care provider in cessation counseling
- Provide resources for primary care provider use with youth and young adult patients

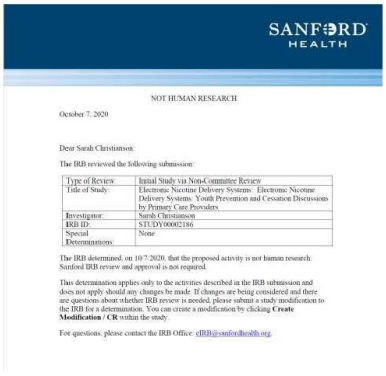
2

Project Evaluation

- Provider questionnaire
  - Assessing comfort, confidence, and motivation about discussing ENDS use with patients and making cessation referrals
  - Pre-presentation
  - Immediately post-presentation
  - 3 months post-presentation
  - Responses are anonymous and recorded in aggregate
  - Participation is **not** mandatory, consent indicated by completion of questionnaire
- Chart review
  - If providers are reviewing ENDS use with patients
  - If providers are placing appropriate referrals
  - Comparing 3 months pre-presentation and 3 months post-presentation
  - Responses are anonymous (for patients and providers) and recorded in aggregate
  - Educational (not punitive)

3

IRB Approval



SANFORD HEALTH

NOT HUMAN RESEARCH

October 7, 2020

Dear Sarah Christianson:

The IRB reviewed the following submission:

Type of Review:	Initial Study via Non-Committee Review
Title of Study:	Electronic Nicotine Delivery Systems: Electronic Nicotine Delivery Systems: Youth Prevention and Cessation Discussions by Primary Care Providers
Investigator:	Sarah Christianson
IRB ID:	STUDY00002186
Special Determinations:	None

The IRB determined, on 10/7/2020, that the proposed activity is not human research. Sanford IRB review and approval is not required.

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please submit a study modification to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

For questions, please contact the IRB Office: eIRB@sanfordhealth.org.

NDSU NORTH DAKOTA STATE UNIVERSITY

September 9, 2020

Dr. Kelly Boettner-Schmidt
School of Nursing

Re: IRB Determination of Exempt Human Subjects Research
Protocol #PH21038, "Electronic Nicotine Delivery Systems: Youth Prevention and Cessation Discussions by Primary Care Providers"

NDSU Co-investigator(s) and research team: Sarah Christianson
Date of Exempt Determination: 9/9/2020 Expiration Date: 9/8/2023
Study site(s): NDSU Funding Agency: n/a
The above referenced human subjects research project has been determined exempt (category 1; 2(ii)) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original protocol materials with updated information sheet received 9/2/2020.

Please also note the following:
• If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
• 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.
• Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
• Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

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

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult https://www.ndsu.edu/research/for_researchers/research_integrity_and_compliance/institutional_review_board_irb/. This Institution has an approved Federal Wide Assurance with the Department of Health and Human Services: FWA00005439.

4

Youth Use of ENDS Rapidly Increasing

Youth use of electronic nicotine delivery systems (ENDS) has rapidly increased over the last several years.

United States

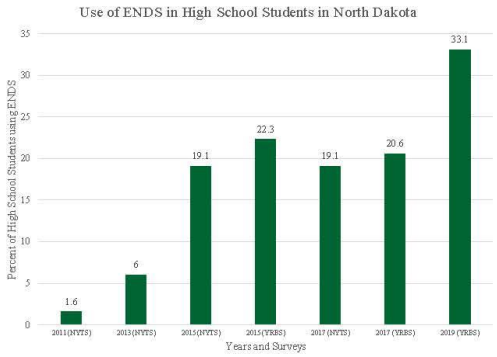
ENDS use among high school students in the U.S. increased between 2011 and 2015 from 1.5% to 16.0% (Cullen et al., 2019)

2019: 27.5% of the surveyed U.S. high school students and 10.5% of the surveyed U.S. middle school students were current ENDS users, or 5 million current ENDS users in these age groups
(Cullen et al., 2019)

North Dakota

2017: 28.1% of surveyed N.D. high school students and 8.0% of N.D. middle school students were current ENDS users
(NDDPI, 2017a; 2017b)

2019: 33.1% of surveyed N.D. high school students and 10.3% of N.D. middle school students were current ENDS users
(NDDPI, 2019a; 2019b)



5

Why does this matter?

- Numerous health effects related to tobacco product use in youth and young adult patients (USDHHS, 2018)
- Long-term research about the health effects of ENDS is not yet available, as these products are so new (USDHHS, 2018)
- Youth and young adult patients are impressionable and may not be well-informed about the tobacco products they are using (Truth Initiative, 2020c)

6

Health Effects of ENDS

- Health Effects of Nicotine and ENDS use
  - Nicotine dependence (USDHHS, 2014; 2016)
  - Cardiovascular (USDHHS, 2014; 2016)
  - Maternal/fetal (USDHHS, 2016)
  - Youth (USDHHS, 2016)
  - Not related to inhalation (USDHHS, 2016)
  - Secondhand exposure (USDHHS, 2016)
  - EVALI (CDC, 2020)
  - Cobalt Lung (Fels Elliott et al., 2019)

7

Health Effects of ENDS

ENDS and COVID-19

- Online survey of youth, n = 4,351, May 2020
- Youth ENDS users were 5 – 7 times more likely to contract COVID-19 than nonusers.
  - Also more likely to experience COVID-19 symptoms

(Gaiha et al, 2020)

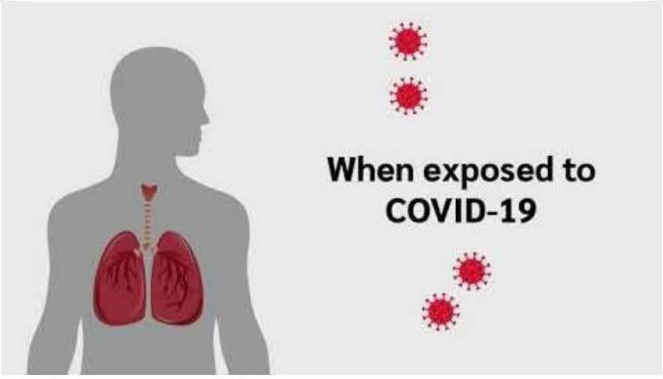
Tobacco and COVID-19?

- Tobacco increases angiotensin converting enzyme 2
  - Helps COVID-19 virus attach to cells once in body
- Cilia are damaged with tobacco product use
  - Easier entry of COVID-19 into lungs
- Tobacco product use damages neutrophils and macrophages, making it more difficult to combat viral illnesses
- Increased cough with tobacco use products spreads droplets
- Hand-to-mouth contact with tobacco use can spread viruses more easily

(Mass General Hospital for Children, 2020)

8

Health Effects of ENDS



(Stanford Medicine, 2020b)

9

Current Recommendations

- Recommendations for ENDS use vary for adult users and the long-term health effects of ENDS use are not yet fully understood

  The CDC recommends that people under age 25 should not use ENDS (USDHHS, 2020).
- PCPs need current, accurate information about ENDS to deliver comprehensive preventive services to a vulnerable adolescent population (Pepper, McRee, & Gilkey, 2014).

10

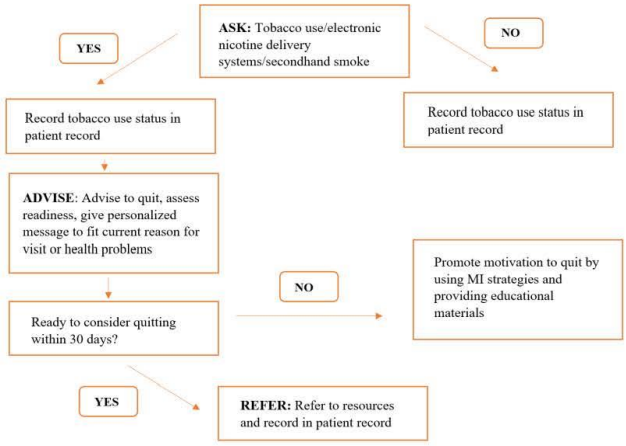
Current Recommendations

Using the AAR method of brief tobacco cessation counseling:

- Ask every patient about tobacco use at every visit
  - Ask if patient is current, former, or never tobacco user
  - Ask what kind of tobacco product is used and how often
    - Including electronic tobacco products such as e-cigarettes, vapes, mods, JUUL, and smokeless tobacco
  - Ask if they're interested in quitting all tobacco products
- Advise every tobacco product user to quit
  - If the patient is not yet ready to quit, let them know you are available to answer any questions and to help them quit when they are ready
- Refer to cessation resources
  - Quit, don't switch

(American Lung Association, 2020)

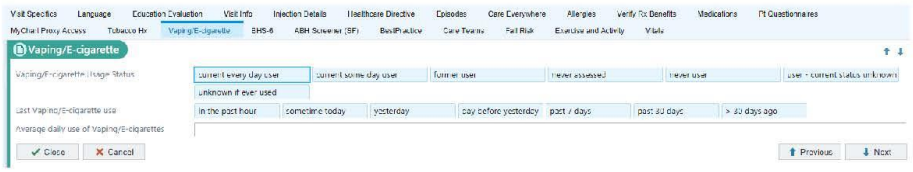
11



(Buettner-Schmidt et al., 2017)

12

Role of Primary Care Provider



(Sanford Health, n.d.)

13

Role of Primary Care Provider

- **Begin:** "I take time to ask all of my patients about tobacco use because it is an important part of your health" **then**
- **Ask**: "Are you a current, former, or never tobacco product tobacco user?"
  - If the response is: "I don't smoke," you can follow up with: "Have you ever used any other forms of tobacco products including e-cigarettes, vapes, mods, JUUL, or smokeless tobacco?"
    - If the response is: "I vape," you can follow up with: "How often? What device?"
    - If the response is: "I vape. That's how I quit smoking," you can follow up with: "How often? What device? Do you ever use other tobacco products in addition to vaping?"

(American Lung Association, 2020; Buettner-Schmidt et al., 2017)

14

Role of Primary Care Provider

- Start a conversation and ask open-ended questions
- "Are a lot of people vaping at school?" or "What do you think about vaping?"
- "What do you already know about how tobacco use is affecting your _____?"

(American Lung Association, 2020)

15

Role of Primary Care Provider

- If a patient has answered that they do use tobacco products:
- **Ask:**
  - "Are you ready to quit?"
  - "The most important thing you can do to improve your health is to quit smoking, and I have resources that can help. What is your level of interest in quitting within the next 30 days if I provide help for you?"
  - Ask patients to identify potential negative consequences of smoking
  - Ask patients to identify potential benefits of stopping and highlight the most beneficial
  - Ask patients to identify barriers to quitting and address the barriers
- **Advise:**
  - Advise every tobacco product user to quit
  - Use clear, nonjudgmental, and personalized suggestions for quitting
  - Employ teachable moment, linking positive benefits of quitting that may be specific to a tobacco-related or chronic condition
  - Remind the patient that most people make repeated quit attempts before they are successful

(American Lung Association, 2020; Buettner-Schmidt et al., 2017)

16

Role of Primary Care Provider

- If the patient is interested in quitting:
  - "We have resources that can help you quit that include…"
  - "We can refer you to NDQuits here in the office, and NDQuits will contact you soon. How does that sound?"
  - "As you will have a follow up appointment in/for (insert time or reason), we will check in then to see how your quit attempt is going. If you have any questions or if there are any ways that we can support your quit attempt, please contact us at any point. We are here to help and support you."

  (Buettner-Schmidt et al., 2017)

17

Role of Primary Care Provider

- If the patient uses tobacco but is not yet ready to quit:
  - "I hear you saying you're not ready to quit right now. I'm here to help when you're ready."
  - "If you change your mind, here is a number you can call to get support."

  (Buettner-Schmidt et al., 2017)

18

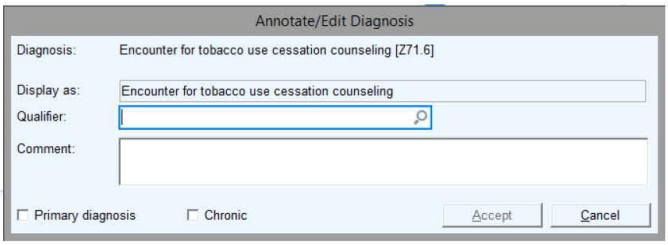
Role of Primary Care Provider

- Use pharmacotherapy for at least 12 weeks for appropriate patients
- Treat those at risk for relapse for at least 6 months
  - Persistent, strong urges to smoke
  - Higher dependence
  - Comorbid medical/psychiatric illness
  - Past substance abuse
  - Unable to quit on target date
- ENDS users may require several dose changes due to unknown nicotine content in products previously used

(American Lung Association, 2020)

19

Role of Primary Care Provider



(Sanford Health, n.d.)

20

Resources

- Tobacco Treatment Specialist
  - In-clinic resource for counseling and support for patients
- Referral to counseling
  - Behavioral changes
- Literature and posters in exam rooms
  - Information for patients who aren't comfortable discussing use or questions with provider
  - Also serve as reminders for staff to ask patients about tobacco product use with every visit

21

Resources

(USFDA, n.d.)

22

Resources

(USFDA, n.d.)

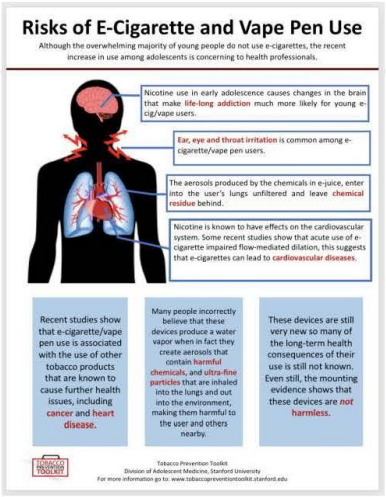
23

Resources

(Stanford Medicine, 2020a)

24

Resources

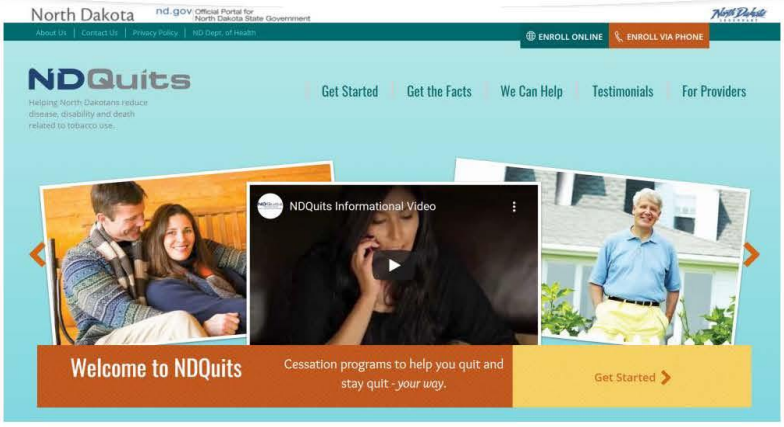


(Stanford Medicine, 2020a)

25

Resources

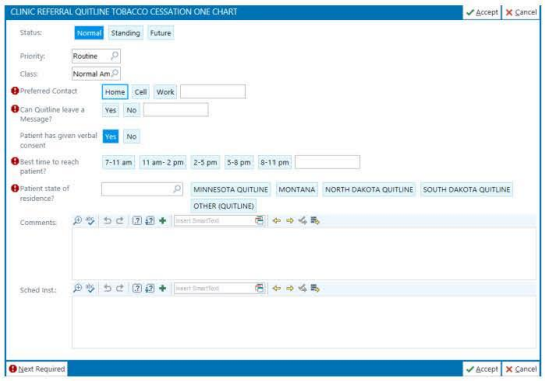
ND Quits



(NDDH, 2015)

26

Resources



(Sanford Health, n.d.)

27

Resources

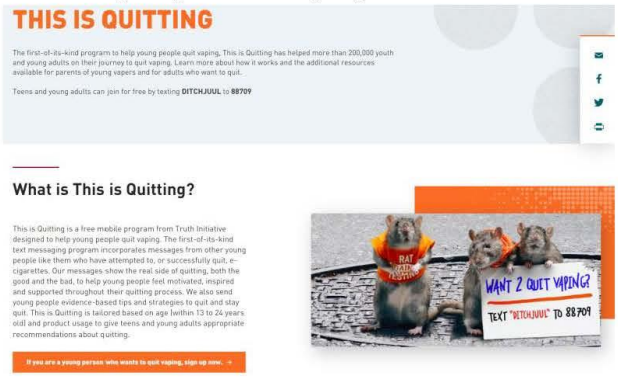
MyLifeMyQuit: For teens who use ENDS

(National Jewish Health, 2020)

28

Resources

This is Quitting: For teens and young adults who use ENDS



(Truth Initiative, 2020b)

29

Resources

BecomeAnEx: For adult users of cigarettes and ENDS

(Truth Initiative, 2020a)

30

Resources

Ask, Advise, Refer to Quit Don't Switch: Webinar training for providers

(American Lung Association, 2020)

31

Questions?

32

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33

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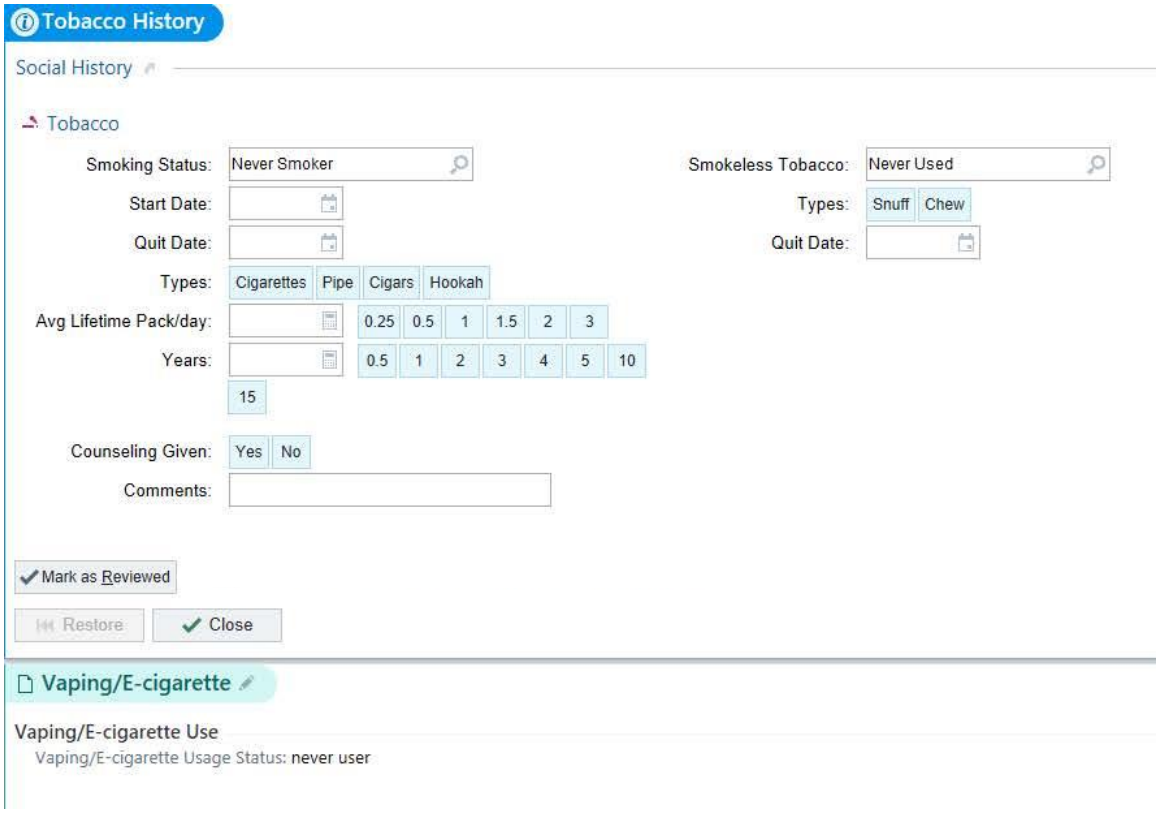
34

APPENDIX L: DOCUMENTATION OF ENDS USE IN EHR



APPENDIX M: CHART REVIEW TOOL

I10

	A	B	C	D	E	F	G
1	Patient code	Patient age	Tobacco use questions completed	Provider reviewed tobacco use	ENDS user?	Cessation counseling provided?	Referral placed?
2							
3							
4							
5							
6							
7							
8							
9							

APPENDIX N: NDSU IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

September 9, 2020

Dr. Kelly Buettner-Schmidt
School of Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH21036, "Electronic Nicotine Delivery Systems: Youth Prevention and Cessation Discussions by Primary Care Providers"

NDSU Co-investigator(s) and research team: Sarah Christianson
Date of Exempt Determination: 9/9/2020 Expiration Date: 9/8/2023
Study site(s): NDSU Funding Agency: n/a
The above referenced human subjects research project has been determined exempt (category 1, 2(i)) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original protocol materials with updated information sheet received 9/2/2020.

Please also note the following:
• If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
• 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.
• Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
• Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

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

Kristy Shirley

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult https://www.ndsu.edu/research/for_researchers/research_integrity_and_compliance/institutional_review_board_irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

APPENDIX O: SANFORD IRB DETERMINATION

SANFORD HEALTH

NOT HUMAN RESEARCH

October 7, 2020

Dear Sarah Christianson:

The IRB reviewed the following submission:

Type of Review:	Initial Study via Non-Committee Review
Title of Study:	Electronic Nicotine Delivery Systems: Electronic Nicotine Delivery Systems: Youth Prevention and Cessation Discussions by Primary Care Providers
Investigator:	Sarah Christianson
IRB ID:	STUDY00002186
Special Determinations:	None

The IRB determined, on 10/7/2020, that the proposed activity is not human research. Sanford IRB review and approval is not required.

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please submit a study modification to the IRB for a determination. You can create a modification by clicking **Create Modification / CR** within the study.

For questions, please contact the IRB Office: eIRB@sanfordhealth.org.

APPENDIX P: EXECUTIVE SUMMARY

Electronic nicotine delivery systems (ENDS) are battery-operated devices that may deliver nicotine by converting nicotine-containing liquid to vapor, which is then inhaled into the lungs of the user (U.S. Department of Health and Human Services [USDHHS], 2020). ENDS are also called a 'vape' or 'e-cigarette.' The aerosolized liquid typically not only contains nicotine, but flavoring, heavy metals, and other potentially harmful substances as well.

Youth and young adult use of ENDS has been associated with a number of health problems. Most ENDS contain nicotine, a highly addictive chemical that can have negative effects on brain development, impulse control, mood, and cognition in adolescents (United States Department of Health and Human Services [USDHHS], 2018). Young people who have ever used ENDS were more likely to contract COVID-19 and have symptomatic COVID-19 infections (Stanford Medicine, 2021).

Youth use of electronic nicotine delivery systems (ENDS) has rapidly increased over the last several years, both across the United States and in North Dakota (Cullen et al., 2019; North Dakota Department of Public Instruction [NDDPI] 2017a; 2017b; 2019a; 2019b). The Centers for Disease Control recommends that people under age 25 should not use ENDS (USDHHS, 2018). The United States Preventive Services Taskforce (2021) recommends that no one should use ENDS as a way to stop using traditional cigarettes; using ENDS is not proven to be effective as a smoking cessation aid and is not approved for use. Primary care providers (PCP) must take proactive steps to combat this issue, including talking to their youth and young adult patients about their ENDS use, the negative health impacts of ENDS use, and how they can help young people to quit using ENDS. PCPs need current and accurate information about ENDS so that

they can effectively counsel their youth and young adult patients about ENDS (Pepper, McRee, & Gilkey, 2014) and refer for cessation as appropriate.

This project focused on a primary care clinic in North Dakota which employed seven PCPs. Two of the PCPs were interviewed about how they addressed ENDS use with their youth and young adult patients and if there were any barriers to addressing ENDS use. The PCP responses showed that they were aware of some of the negative health consequences related to ENDS use, but that the PCPs did not regularly initiate discussions with patients about their ENDS use.

Education was developed and presented for the PCPs at a regularly scheduled monthly meeting at the clinic. The education focused on the negative health impacts of ENDS use in youth and young adult patients, how the PCPs could talk to their patients about ENDS use, and resources and programs available to help their youth and young adult patients to quit using ENDS.

Before, immediately after, and three months after the education session, surveys were distributed to the PCPs. The surveys asked about the PCPs' motivation, confidence, and comfort in addressing ENDS use with their patients and how they currently addressed ENDS use. Overall, PCPs reported increased motivation, confidence, and comfort after the education session. A chart review of the electronic health record (EHR) was done after the education session. The chart review did not reflect increased rates of electronic referrals to programs that help patients quit ENDS after the education session, but the PCPs could have written about their discussions with patients in their visit notes, which were not available for review. However, there was a statistically significant increase in how often patients were asked questions about their tobacco history, which could indicate an early change in PCP practice.

All PCPs should receive more education about how to talk to their youth and young adult patients about ENDS use and about the resources available to help them quit using ENDS. Youth should also receive education about ENDS use so that they are able to make informed decisions about behaviors that may negatively impact their health. Additional research about the long-term health effects of ENDS use is also needed.