Summarizing NDSU's Newest Tobacco Prevention Publication:
"E-cigarettes for Tobacco Cessation: Not the Solution"

By Kelly Buettner-Schmidt, PhD, RN, FAAN

In December 2021, the North Dakota State University Tobacco Control and Prevention Research Team published an article[1] in the journal, The Nurse Practitioner. I am happy to provide a description of our article for this newsletter. While this article was written for nurse practitioners (NPs), it pertains to all primary care providers, including physicians, physician assistants, nurse practitioners, pharmacists, and others. The majority of the below content is directly from that article. The article is available under the Creative Commons CC-BY-NC-ND license and permits non-commercial use of the work as published, without adaptation or alteration provided the work is fully attributed. I encourage you to read the full article directly as it is freely available to read, print, and use in your work from this link: https://journals.lww.com/tnpj/Fulltext/2021/12000/E_cigarettes_for_tobacco_cessation__Not_the.2.aspx

In the article, we describe how primary care NPs frequently encounter patients who use ENDS, sometimes for tobacco cessation (cessation). We discuss how clinician involvement in tobacco cessation increases the likelihood of patients successfully quitting tobacco[2] and that ENDS are not recommended for cessation because of health risks, lack of Food and Drug Administration (FDA) approval, and other reasons. We share that NPs can positively impact patients' cessation efforts without using ENDS, and that many resources are available to aid them in this process.

The basics of nicotine addiction are described and that when ENDS were first introduced into the United States, some speculated that ENDS could be effectively used for cessation. However, more than half of the people who start using ENDS for cessation simply transfer their nicotine dependence to ENDS,[2] often becoming dual users.[3] We share the great concern that ENDS use among adolescents is associated with increased initiation of cigarette smoking and increased frequency and intensity of both regular cigarette and e-cigarette usage,[4] and that the use of ENDS products among adolescents leads to increased dependence upon nicotine products.[3] We describe that after years of market availability, three separate clinical practice

guidelines (CPGs) recommend against the use of ENDs for tobacco cessation because of quality control concerns, insufficient data to demonstrate that the benefits outweighs the risks, and the availability of effective cessation tools. In the article, we provide details on why ENDS products are not an effective, safe, or approved means of cessation for either adults or adolescents.

ENDS Products

Our article discusses the trends in youth cigarette and ENDS use and the impact of poly-tobacco use. We describe that although the FDA regulates ENDS,[5] ENDS products are not FDA approved for cessation. We detail the several FDA-approved nicotine replacement therapies (NRTs) for cessation and how NRT dosage calculation is based on the patient's specific nicotine consumption to ensure minimal symptoms of withdrawal during cessation. We state that there are ample well-tested FDA-approved products available for cessation.

Quality Control Concerns

We cite the Public Health Law Center in stating that, at this time, there is no legally required quality control of ENDS products; therefore, these products are manufactured without FDA oversight of quality. We discuss three important quality control issues: inaccuracy of nicotine content, the processes of compounding-in-shop (CIS) of e-liquids, and FDA involvement.

Inaccurate nicotine content

A different, recent publication is our previous systematic review[6] of 20 scientific articles published worldwide. We stated that almost half of the studies found inaccurate nicotine labeling of ENDS products,[6] with some samples varying more than 100% from the label.[18-217-10]

This audience may recall our 2019 North Dakota study[11] of nicotine-containing e-liquid products purchased from 35 vape shops and other tobacco specialty shops across North Dakota. In The Nurse Practitioner article[1], we briefly describe how our 2019 study supports the findings of the systematic review,[6] with only 3.8% of the 238 e-liquid samples meeting the American E-Liquid Manufacturing Standards Association (AEMSA) guidelines.[12] The AEMSA states that the nicotine content of all products containing e-liquids must be within 10% of the labeled amount.

In 2019[11], we also examined the nicotine content of compounded in shop (CIS) samples, that is, samples that are either an e-liquid made entirely on site or a premade liquid to which the shop staff added extra nicotine (considered manufacturing by the FDA cite). In The Nurse Practitioner article[1], we detail the tremendous discrepancy between the actual nicotine content to

the labeled content, including the top range of 213% above the indicated nicotine content.[11] We also include that none of the 25 CIS samples met the AEMSA guideline. Other findings of the nicotine content labels are discussed in the article.

CIS processes

CIS processes were *directly observed* during our 2019 study.[11] CIS ingredients include nicotine, flavorings, and other chemicals. As you read the CIS processes we described, I think you will find the process alarming and likely harmful to the users.

We discuss that because of the inconsistencies in compounding and labeling, users cannot assume accuracy of e-liquid nicotine content. We describe the implications this has for individuals who are using e-liquids as a means of cessation. Importantly, we state that these issues go away when patients use FDA-approved cessation products under the care of a health professional. There were additional labeling concerns, and I encourage you to read about those concerns in the article.[1]

FDA involvement

The article details the FDA's regulation of ENDS including that ENDS manufacturers are required to file a premarket application and it is illegal to market ENDS without this authorization.[13] We clarify that most ENDS products have not been FDA authorized. We express our concern that given the overwhelming number of products available, the FDA states that they are unable "to take enforcement action against every illegally marketed tobacco product."[13] In addition, we describe the Public Health Law Center statements that if there are no drug claims (such as for cessation), then there are no specific quality standards or regulations for the manufacturing processes of e-cigarettes and, that currently, no e-cigarette or similar product has been approved as a drug product. Therefore, no e-cigarettes are affected by the requirements that apply to FDA-regulated drugs.

Concerns Related to Using E-Liquids and ENDS for Quitting Tobacco Use

We describe how e-cigarette use mimics both the physiological and psychological satisfaction of smoking and that this close imitation to cigarette smoking may be why cigarette users struggle with e-cigarette cessation, even when they originally intended to use e-cigarettes to stop all tobacco use.[14] We provide a table on ENDS many health risks and provide details on e-cigarette or vaping product use-associated lung injury (EVALI).

Clinical Guidelines Relating to ENDS

Patients using nicotine often ask whether ENDS are safe and effective and whether they can be used for cessation from traditional tobacco products. We discuss that many worldwide studies have attempted to answer that question and share three difficulties that clinicians face in interpreting those studies. I encourage you to share the article with the primary care providers you interact with.

Of interest to primary care providers may be the section in the article describing three CPGs or recommendations trying to summarize all the studies to determine whether ENDS can be recommended for cessation. The three CPGs / recommendations include 1) the 2018 recommendation by the American College of Cardiology's Decision Pathway[15] on tobacco cessation treatment, 2) the 2020 American Thoracic Society's CPG[16] for medication treatment in adult tobacco users, and 3) the 2021 US Preventive Services Task Force[17] recommendations and statement that "evidence on the use of e-cigarettes for tobacco smoking cessation in adults, including pregnant persons, is insufficient, and the balance of benefits and harms cannot be determined."

We include that NPs need to be aware of the many ENDS risks and the lack of evidence supporting ENDS as a cessation method. We state that avoidance of ENDS products should be recommended; however, when that is not possible, approaching ENDS products in the same manner as other tobacco products supports patients' attempts to achieve cessation for tobacco products including ENDS.

Conclusion

We conclude the article by stating: "The science is still developing on the short- and long-term effects of ENDS on health and tobacco cessation efforts. Quality control of ENDS products is lacking. The actual nicotine content in ENDS products is often unknown, making it difficult to calculate the replacement of cigarettes with ENDS, while ensuring equivalent levels of nicotine. Conversely, FDA-approved treatment medications are safe, effective, and have well-established dosing aimed at minimizing nicotine withdrawal and maximizing cessation success. Currently, there are no health care provider guidelines that recommend ENDS as a safe or effective means for cessation. The authors concur with current science-based guidelines that ENDS use for tobacco cessation is not recommended. NPs can recommend the cessation products approved by the FDA."

Reference and link for article in The Nurse Practitioner

Buettner-Schmidt, K., Swanson, K., Maack, B., Barnacle, M., Miller, D., Orr, M., & Hatlen Gag, M. (2021). E-cigarettes for tobacco cessation: Not the solution. *The Nurse Practitioner*, *6*(12):7-11. doi: 10.1097/01.NPR.0000798228.69915.64
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Table 1: ENDS Use-Associated Risks

ENDS Factors Compromising Cessation Efforts
Lack of tobacco cessation efficacy
Inability to accurately dose nicotine for tobacco cessation (risk of nicotine withdrawal and/or nicotine-related side effects)
Lack of quality control oversight
Inaccurate nicotine content
Inconsistencies of in-shop compounding and labeling
Direct Risks of ENDS Use
Youth exposure to nicotine
Unknown safety of inhaling e-liquid additives
Risk of acute e-liquid nicotine poisoning
E-cigarette or vaping product use-associated lung injury (EVALI)
Device battery fires/explosions

Abbreviation: ENDS, electronic nicotine delivery systems.

Source: Buettner-Schmidt, K., Swanson, K., Maack, B., Barnacle, M., Miller, D., Orr, M., & Hatlen Gag, M. (2021). E-cigarettes for tobacco cessation: Not the solution. *The Nurse Practitioner*, *6*(12):7-11. doi: 10.1097/01.NPR.0000798228.69915.64 https://journals.lww.com/tnpj/Fulltext/2021/12000/E_cigarettes_for_tobacco_cessation__Not_the.2.aspx