

Common Measures to Evaluate Flavored Tobacco Products: Recommendations From the Tobacco Centers for Regulatory Science (TCORS) Flavored Tobacco Products Measurement Subcommittee

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Abstract

Introduction: Flavored electronic nicotine delivery systems (ENDS) and tobacco products are associated with the initiation and progression of tobacco use. With recent restrictions around flavored products, it is critical to measure both the product and the flavor being used. The Tobacco Centers of Regulatory Science (TCORS) Flavored Tobacco Products Measurement Subcommittee (FTPMS) was established to develop core measures to assess flavored tobacco and ENDS product usage, facilitate data harmonization, replicability, and comparisons across studies.

Aims and Methods: The FTPMS used a mixed-method approach to inform the development of recommended measures (first use, current use, reasons for use) to assess tobacco and ENDS product flavors. This included reviewing existing surveys, identifying priority areas, developing new measures, cognitive testing, and finalization of recommended measures.

Results: Recommended measures were selected from national surveys (e.g. PATH study) and survey items used in TCORS studies to evaluate first use, current use, and reasons for use of tobacco and ENDS products. Response options were expanded for questions about specific flavors and adapted to allow for assessments relevant to recent federal policies. Supplemental measures were developed for researchers conducting more in-depth research around flavored products.

Conclusions: Using an expert consensus process supplemented with cognitive testing, the FTPMS developed recommendations for core and supplemental measures for flavored tobacco and ENDS products. Harmonizing data on these factors for flavored tobacco and ENDS products are critical for researchers and may provide actionable evidence to federal, state, and local regulators and policymakers, as well as support evaluations of policies restricting flavors in these products.

Implications: The development of core measures to assess first use, current use, and reasons for use of flavored tobacco and ENDS products will facilitate data harmonization, replicability, and comparisons across studies conducted in different samples or across communities with varying levels of regulation for these products. Use of these standardized measures will allow for a greater understanding of the role of flavors and helps to build a more robust evidence base to inform regulatory decisions to reduce tobacco and ENDS use at the population level.

Introduction

Flavored tobacco products, including flavored electronic nicotine delivery systems (ENDS), have become popular in the United States, particularly among youth,^{1,2} and have been associated with the initiation and progression of tobacco use in youth, young adults, and adults.^{3,4} While research around the role of flavored e-cigarettes and long-term tobacco cessation is limited,⁵ the rapid uptake among youth caused great concern among many in the medical and public health community. In February 2020, the US Food and Drug Administration's Center for Tobacco Products (FDA CTP) restricted availability

in the United States of unauthorized flavored cartridge-based ENDS, with the exception of tobacco and menthol.⁶ Following this, in April 2022, CTP announced a proposed rule banning menthol cigarettes and flavored cigars.⁷ Similarly many state and local jurisdictions in the United States, as well as countries around the world, have implemented restrictions on certain flavored tobacco and ENDS products (e.g. Massachusetts, European Union, Mauritania, Niger, Canada), flavored ENDS (e.g. New York, New Jersey, Finland), or the sale of all tobacco and ENDS products (e.g. Beverly Hills, CA, Bhutan); however, these policies vary significantly regarding what products

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are regulated and what flavors are included.⁸⁻¹¹ In the United States, with recent federal regulation as well as proliferating restrictions at the local level, it is increasingly important to measure both the specific tobacco or ENDS product and the flavor being used by consumers. In addition, given that many of these restrictions include an exemption for menthol while restricting the availability of mint, it is particularly critical to assess products marketed as “menthol” separately from “mint” flavor. ENDS and smokeless tobacco products are sold in a number of mint-based options, including “menthol”, “mint”, “spearmint”, “wintergreen”, “peppermint”, “smooth mint”, and others. Previously, most research studies and surveillance systems measured use of “mint” and “menthol” as one flavor category, resulting in limited understanding of prevalence of these separate flavors and changes in use when restrictions on “mint” are implemented. However, given recent regulations in the United States and around the world, specificity is critical in assessing flavored tobacco and nicotine product use to examine behavior patterns as well as enforcement and compliance with these product restrictions.

In light of the evolving tobacco and ENDS product market, there is limited consistency in how key constructs relevant to regulation (i.e. flavors, frequency of use, reasons for use) are measured across studies, making it challenging to compare findings between studies for similar tobacco and ENDS products. The Tobacco Centers of Regulatory Science (TCORS), an initiative funded by the FDA CTP in collaboration with the National Institutes of Health, is designed to provide data on the toxicity, addiction, health effects, behaviors, communication, and marketing of tobacco and ENDS products, as well as understand the impact of potential FDA regulatory actions.¹² One goal of these centers is to develop and use common measures, where appropriate, to maximize the opportunities for synthesis and comparisons across multiple research studies, and enhance interpretation of the evidence for end-users of data including regulators and policymakers. To support the Common Measures Initiative, the coordinating center for the TCORS also known as the Center for Coordination of Analytics, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (TRS) established subcommittees in specific areas. The Flavored Tobacco Products Measurement Subcommittee (herein referred to as FTPMS) was established in October 2019 and included leading flavored tobacco and ENDS product researchers that conduct scientific studies evaluating perceptions and use of flavored tobacco and ENDS products. The main goal of the FTPMS was to develop recommendations around a core or minimal set of measures that could be used across studies to assess the use of flavored tobacco and ENDS products, including facilitating data harmonization, replicability, and comparisons across study samples and results. The FTPMS also developed recommendations around supplemental measures for researchers conducting more in-depth research around flavored products.

Methods

Overview

The FTPMS used a mixed-methods approach to inform development of recommended core and supplemental measures to assess tobacco and ENDS product flavors. We first conducted a review of existing survey questions about flavored tobacco and ENDS products, then a preliminary consensus process

among the subcommittee members to identify priority areas and develop new measures, followed by cognitive testing of new and adapted survey items, and then a subsequent consensus process to finalize recommended measures. Below we describe our approach to these activities.

Review of Existing Measures

An initial step, we conducted a comprehensive review of measures from national tobacco surveys (e.g. Population Assessment for Tobacco and Health (PATH) study, National Youth Tobacco Survey), and surveys from TCORS and other grant-funded studies. Summary tables of measures across multiple constructs were developed for both youth and adults and shared with FTPMS members to facilitate discussion. Several constructs of interest were examined including ENDS brands used, ever (lifetime) use, first use, current use (including frequency, duration, and intensity), dependence, context, or reasons for use including for cessation, device characteristics and ownership, flavor preference, first, and current flavor use, nicotine content, purchase behavior, and secondhand smoke.

Consensus Process to Identify Priority Areas and Develop New Measures

FTPMS members reviewed the full list of existing measures and independently identified constructs and measures from this list relevant for flavored tobacco and ENDS product use and reasons for use. The group subsequently held a series of meetings to discuss gaps in measurement and came to consensus on three constructs (first use, current use, and reasons for use) as priority areas to standardize measures. Survey questions to assess two of the constructs, first use, and current use of flavored tobacco products were easily identifiable; however, few studies assessed reasons for use of “flavored” versus “unflavored” products. Questions about reasons for use did exist in the general context of reasons for using any tobacco products; however, they were not specific to flavored tobacco products, including users’ interpretation, and understanding of the term “unflavored”. Therefore, the FTPMS developed new survey questions adapted from PATH to assess reasons for using flavored tobacco and ENDS products. Some of the questions compared flavored products to unflavored or “tobacco” flavored products. This format was adapted from the PATH study survey questions that compared reasons for using different tobacco and ENDS products with cigarettes.^{13,14} Select reasons for use measures were extracted from open-ended responses about reasons for using flavored ENDS products from a Yale TCORS study.¹⁵ The FTPMS also identified supplemental measures that may be of interest to investigators conducting in-depth research around flavors. Consensus was reached on supplemental measures through discussion.

Cognitive Testing of New and Adapted Measures

To better understand how the proposed new and adapted measures were understood by respondents, cognitive testing was conducted with 16 adult users of flavored tobacco and ENDS products ([Supplementary Table S1](#)). Because measures around flavored tobacco use in national youth surveys are identical to those in adult surveys (e.g. PATH study, NYTS), adults were recruited for this qualitative work. Participants first completed an online survey followed by an in-depth

Table 1. Recommended Core Measures to Assess First Use and Current Use of Flavored Tobacco and Ends Products

Construct	Text	Source(s)
First use	<ul style="list-style-type: none"> When you first started using [PRODUCT], were they flavored to taste like menthol, mint, clove, spice, fruit, chocolate, alcoholic drinks, candy, or other sweets? (Yes, No, Don't Know, Refused) Which flavor did you first start using? If multiple flavors were mixed together, choose all that apply. (list of flavors, other, and Don't Know, refused) 	PATH Study
Current use	Is your usual cigarette brand menthol or non-menthol? (Menthol, Non-Menthol, Both, No Usual Type)	University of Vermont TCORS
Current use	In the past 30 days, [were/was] any of the [PRODUCT] you used flavored to taste like menthol, mint, clove, spice, fruit, chocolate, alcoholic drinks, candy, or other sweets? (Yes, No, Don't know, Refused) Which flavors have you used in the past 30 days? Choose all that apply. (list of flavors, other, and Don't Know, refused)	PATH Study
Current use	Check all the flavors you most commonly use. (Check all that apply.) Out of all the flavors you most commonly use, which one flavor is your absolute favorite? (Only check one answer) (list of flavors, other, and Don't Know, refused)	Roswell Park Comprehensive Cancer Center TCORS
Reasons for use	<i>Preamble Text:</i> The next questions are about the reasons people use flavored [PRODUCT]. Please select which reasons apply to you. I use flavored [PRODUCT] because...	
Reasons for use	[PRODUCT] comes in flavors I like. Flavored [PRODUCT] are more affordable than other tobacco products. Using flavored [PRODUCT] helps people quit smoking cigarettes. Flavored [PRODUCT] might be less harmful to me compared to tobacco flavored [PRODUCT]. (Yes, No, Don't know, Refused)	PATH Study (adapted)
Reasons for use	I like the way flavored [PRODUCT] smells. Flavored [PRODUCT] doesn't bother non-tobacco users. Flavored [PRODUCT] are easier to use compared to tobacco flavored [PRODUCT]. I find flavored [PRODUCT] more appealing. (Yes, No, Don't know, Refused)	Yale TCORS (adapted)

interview to assess their interpretation and decision-making process for specific survey questions ([Supplementary Table S2](#)). As there was uncertainty about user's interpretation of the terms "unflavored" and "tobacco flavored," probing was also conducted on these terms. Overall, the cognitive interviews focused on (1) assessing respondents understanding of new survey items, (2) understanding how respondents interpreted the terms "unflavored" and "tobacco-flavored," which were used as comparisons in several items, and (3) evaluating whether the items would be easier to answer with a specific product comparison.

Consensus on Recommended Measures

Findings from the cognitive testing resulted in further discussion among FTPMS members and refinements in the wording of recommended measures. The group came to consensus on the final set of recommended core and supplemental measures to assess flavored tobacco and ENDS products.

Results

To evaluate the first use and current use of tobacco and ENDS products, recommended measures were selected from national surveys (i.e. PATH study) and survey items used in TCORS studies. Response options included a comprehensive list of flavors and allowed for writing in other flavors. Response options included, "mint" and "menthol" as separate categories to allow for assessments of recent policy changes.

Recommended measures for reasons for use of flavored products were developed by adapting survey items from national surveys (i.e. PATH study) and further refined through

cognitive testing. Several measures include the possibility of adaptation of the question to the tobacco or ENDS product class being asked about in both the preamble as well as the specific questions. For example, the measures examining reasons for use include a fill variable ("[PRODUCT]") that allows the investigator to insert the appropriate product (i.e. "e-cigarette" or "tobacco products") into the introduction as well as the measures in that construct. Recommended measures for first use, current use, and reasons for use and their source are presented in [Table 1](#).

Recommended Supplemental Measures

Supplemental measures for current use, preferences, and experience for flavored tobacco and ENDS products were also developed for researchers conducting in-depth research around flavored products ([Table 2](#)).

Discussion

Using a consensus process and cognitive testing, FTPMS developed recommendations for core and supplemental measures to assess flavored tobacco and ENDS products. Accurate assessment of flavored products is critical to tobacco regulatory science, as flavors relate to addiction, health effects, behaviors, and marketing of tobacco and ENDS products. However, measuring flavored product use is challenging given the rapidly changing market and policy environment. Studies have found that the tobacco industry is adept at evolving products to circumvent regulations, particularly when it comes to flavors.¹⁶ Policymakers need accurate and reliable data to support policies to regulate these products, particularly policies that

Table 2. Recommended Supplemental Measures to Assess Current Use, Preferences, and Sensation Experiences of Flavored Tobacco and ENDS Products

Construct	Text	Source(s)
Current use	<p>Out of all the flavors you most commonly use, which would you say is the one you use most often? (only check one answer)</p> <ul style="list-style-type: none"> • Menthol • Mint • Clove or spice • Fruit • Chocolate • An alcoholic drink (such as wine, cognac, margarita, or other cocktails) • Candy or other sweets • Tobacco flavor • Some other flavor <p>Specify _____ (if selected participant is prompted to write in name)</p> <ul style="list-style-type: none"> • Don't Know • Refused <p>If you typically use NON-tobacco and NON-menthol flavor, and tobacco and menthol flavors were the only flavors commercially available for e-cigarettes would you:</p> <ul style="list-style-type: none"> • use tobacco flavor • use menthol flavor • make my own flavors • buy flavors that are not tobacco or menthol illegally, which are unregulated • I already use tobacco and/ or menthol flavors • I would no longer use e-cigarettes 	Roswell Park Comprehensive Cancer Center TCORS
Flavor preference (e-liquid)	<p>How would you say you feel about vaping tobacco flavored e-liquid?</p> <ul style="list-style-type: none"> • like it a lot • like it a little • could tolerate it • don't like it at all • would rather smoke cigarettes 	Roswell Park Comprehensive Cancer Center TCORS
Menthol flavor preference (e-liquids)	<p>How would you say you feel about vaping menthol flavored e-liquid?</p> <ul style="list-style-type: none"> • like it a lot • like it a little • could tolerate it • don't like it at all • would rather smoke cigarettes 	Roswell Park Comprehensive Cancer Center TCORS
Flavor sensation experience	<p>Have you ever tried a flavor(s) that made you feel sick?</p> <ul style="list-style-type: none"> • Yes • No 	Roswell Park Comprehensive Cancer Center TCORS

reduce access and appeal for these products among youth. While these recommendations cover only a select number of domains (first use, current use, reasons for use), using these measures will increase comparability across studies and a more comprehensive understanding of flavored products.

A major challenge with pooling data and findings from studies examining consumer perceptions and use of flavored products is the lack of standardized measures. Although many studies assess flavored product use, variations in questions limit the ability to compare use patterns and reasons for use across studies. The recommended measures, while not an exhaustive list, can be used to improve comparability across studies, with limited participant burden.

Supplemental measures provide additional options for researchers conducting in-depth investigation of flavored product use, while also providing standardized measures for comparisons across studies. Going forward, these measures can be implemented and adapted with the evolving tobacco product market (e.g. oral nicotine products). Standardizing measures across studies will be invaluable for understanding flavored product perceptions and use patterns within studies,

as well as strengthening the ability to compare perceptions and use across studies that focus on different populations.

Limitations of recommended measures include the small sample size for cognitive testing. A broader sample may have resulted in different interpretations and might have provided alternate responses during the discussion. Nevertheless, the cognitive testing was conducted with diverse demographic groups and geographic locations. It is noted that cognitive testing of the recommended measures was only conducted in adults; however, measures assessing tobacco use and reasons for use are comparable for adults and youth in several national surveys. Therefore, we are confident that the recommended measures would be understood by youth as well. Also, while the FTPMS worked diligently to collect all possible measures used in tobacco and ENDS studies, it is possible that other measures exist to evaluate flavored tobacco and ENDS products that were not considered when developing these recommendations. To address this possible limitation, the FTPMS consulted several national surveys that include questions on flavored tobacco and ENDS products, all of which have undergone extensive testing processes, as well as experts from the tobacco control

and TCORS research community, particularly those who work on research focused on flavors.

Harmonizing data on first use, current use, and reasons for use of flavored products may provide actionable evidence to regulators and support policies restricting these products. Use of standardized measures will promote comparisons across studies conducted with different samples or across communities with varying levels of regulation for these products, allow for greater understanding of the role of flavors in tobacco and ENDS product use, and support regulatory levers to reduce tobacco and ENDS use at the population level.

Supplementary Material

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at <https://academic.oup.com/ntr>.

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Declaration of Interests

MLG received research grant from Pfizer and served on scientific advisory board to Johnson and Johnson, manufacturers of smoking cessation medications.

Data Availability

This manuscript describes measures recommended for surveillance of flavored tobacco product use. As such, no specific dataset is available or shared.

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