PREVALENCE, DETERMINANTS, AND IMPACT OF MENTHOL CIGARETTE SMOKING AMONG U.S. ADOLESCENTS

By

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(Under the Direction of Melissa Hallow)

ABSTRACT:

BACKGROUND: Everyday, >2,500 U.S. adolescents try their first cigarette, and menthol cigarettes serve as starter products. This study measured trends in youth menthol cigarette smoking, association between menthol cigarette smoking and current e-cigarette use, public support for tobacco flavor ban (including menthol), and tobacco price inequalities by flavor variety.

METHODS: Data sources included: (1) 2011-2015 National Youth Tobacco Survey, a school-based survey of U.S. 6-12th graders; (2) 2016 *Summer Styles*, a national survey of U.S. adults; and (3) 2011-2016 Nielsen retail scanner data, a database comprising tobacco purchase price and item data acquired from the scanner systems of retail outlets within the continental U.S. Orthogonal polynomials were used to measure menthol cigarette smoking trends during

2011-2015. Association between youth menthol cigarette smoking and current e-cigarette use was measured using a marginal structural logistic regression model. Correlates of public support for tobacco flavor ban were measured using generalized linear models. Tobacco price inequalities were analyzed within and across different products, including manufactured cigarettes, roll-your-own cigarettes, little cigars, and moist snuff.

RESULTS: Among all 6-12th graders, declines occurred in menthol (6.1% to 3.1%) and nonmenthol (5.1% to 3.4%) cigarette smoking during 2011-2015 (all p-trend<0.05); no significant change however occurred in menthol use among current cigarette smokers (54.3% to 47.9%). Menthol cigarette smokers had higher odds than nonmenthol smokers of reporting current e-cigarette use (aOR=1.56, 95%CI=1.24-1.97). A pack of menthol manufactured cigarettes cost 3, 4, and 7 times more than mentholated cigarette-pack-equivalents of little cigars, moist snuff, and roll-your-own cigarettes respectively. Furthermore, mentholated varieties were cheaper than other flavors or non-flavored varieties for roll-your-own cigarettes, little cigars, and moist snuff. Support for tobacco flavor ban was 34.8%, 48.4%, and 52.0% among current, former, and never tobacco users respectively. Among both U.S. adults overall and current tobacco users, adults concerned about adolescent smoking initiation were more likely to support a tobacco flavor ban. Similarly, adult tobacco users living with children had higher support than those living with none (Adjusted prevalence ratio=1.38; 95%CI=1.05-1.82).

CONCLUSION: Menthol cigarettes might be slowing progress in reducing youth smoking. Prohibiting menthol cigarettes and closing price inequalities could benefit public health.

INDEX WORDS: Menthol; cigarettes; flavor; addiction; policy; marketing

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DEDICATION

I dedicate this work to my loving wife, Dr. Uyoyo Agaku, my daughter, Salvia Agaku, and my entire family who have been a constant source of encouragement.

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BACKGROUND AND MOTIVATION

Tobacco use is the leading cause of preventable morbidity and mortality in the U.S., and adolescence is a critical period for tobacco initiation [1, 2]. Menthol and other tobacco flavor additives increase the attractiveness of tobacco products, mask the harshness of tobacco smoke, and increase the ease of smoking among naïve smokers or experimenters [1]. To reduce tobacco initiation among youth, the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) authorized the U.S. Food and Drug Administration (FDA) to regulate the design, manufacture, and marketing of products meeting the statutory definition of "tobacco products" [3]. Using that authority, FDA in 2009 prohibited all cigarette constituents or additives that impart a "characterizing flavor" to cigarette or cigarette smoke (e.g., fruit, candy, or clove flavors), with the exception of menthol [4].

The U.S. market share of menthol cigarettes has seen a modest increase since menthol became the only "characterizing flavor" allowed in cigarettes; from 29% in 2009 to 31% in 2013. [5]. However, even in the decade prior to FDA's prohibition of other characterizing flavors in cigarettes, menthol cigarettes had a greater market share than any other type of flavored cigarettes [5, 6]. Analyses of U.S. Federal Trade Commission data for 1,294 cigarette varieties sold in the nation during 1998

showed that 32% of cigarettes were “menthol”; 23% were “flavored”; while 68.7% of those designated as either “menthol” or “flavored” were menthol (some menthol brands were also designated as “flavored”) [6].

In 2011, FDA’s Tobacco Products Scientific Advisory Committee (TPSAC) reviewed the available evidence on the public health impact of menthol cigarettes, and recommended a removal of menthol cigarettes from the U.S. market place, a recommendation that was highly applauded by professional groups such as the American Academy of Pediatrics [7, 8]. FDA however did not act on this recommendation, and in July 2013 issued an “Advanced Notice of Proposed Rulemaking” seeking newer scientific evidence for its decision making about menthol cigarettes [9].

In response to the apparent delay by FDA in proposing a ruling on menthol cigarettes, several groups in the public health community have strongly advocated for urgent action to protect youth. In July 2016, the National Association for the Advancement of Colored People adopted a resolution at its 107th Annual Convention to support efforts at the state and local levels to restrict the sale of menthol cigarettes and other flavored tobacco products [10]. Shortly thereafter, The African American Tobacco Control Leadership Council (AATCLC) wrote a letter to President Obama dated August 10, 2016, requesting the President to “please direct the FDA to issue a proposed rule to remove ***all*** flavored tobacco products, including ***mentholated cigarettes***, from the marketplace” (Italics and boldface theirs) [11]. AATCLC petitioned for a ban on flavored tobacco products on the basis that

smoking is not only an issue of critical public health importance, but "equally an issue of social justice", citing the disproportionate use of flavored tobacco products among African Americans [11].

Taken together, these recent developments bring to the fore three major considerations in relation to comprehensive regulatory action on menthol cigarettes and other flavored tobacco products. *First, while FDA is the lead federal agency with regulatory authority under FSPTCA, tremendous gains in tobacco prevention and control can be achieved through efforts at the state and local levels.* FSPTCA preserves the authority of state, local, and tribal governments to regulate tobacco products in specific respects [3]. Hence, it is important to encourage tobacco control efforts at state and local levels to help protect millions of U.S. youth from tobacco-related morbidity and mortality. Tobacco control efforts at state and local levels can also form the template for federal regulation of tobacco products. It is therefore vital to produce surveillance data at state and local levels for evidence-based tobacco control policy at subnational levels. *Second, timely surveillance and translational research should accompany advocacy efforts to help inform FDA's regulation of menthol cigarettes.* Novel perspectives on current patterns and trajectories of tobacco use, especially as they differ between menthol and nonmenthol cigarette smokers, will be of use to FDA in decision-making about menthol cigarettes. *Third, efforts to reduce aggregate tobacco consumption need to be comprehensive and include the breadth of flavored tobacco products on the U.S. market, not only menthol cigarettes.* Imbalances in regulatory policy between cigarettes and other

non-cigarette tobacco products might have relatively little impact in reducing aggregate tobacco use because any reduced consumption of cigarettes could be offset by increased use of other products [12].

These three considerations form the underpinning for this dissertation's five aims, which are presented at the end of this chapter after an overview of the extant literature on flavored tobacco products in general and menthol cigarettes in particular. Subsequent chapters address each aim in detail using both national and state-specific data, and employing a variety of data sources, methodologic approaches and perspectives. This research fills some of the current gaps in knowledge and practice regarding menthol cigarettes and contributes to the body of knowledge needed by FDA, state, and local governments for tobacco regulation.

REVIEW OF THE LITERATURE

Overview of flavor perception: Tobacco smoke is an aerosol produced from combustion of tobacco, and comprises colloidal particles (also referred to as total particulate matter or TPM), dispersed in a gas medium [13, 14]. Chemical substances used as flavor additives may be distributed in either the TPM component of smoke, or the volatile phase component, or both [14]. Flavor additives are derived from a broad range of chemical compounds, including organic acids, amino acids, alcohols, aldehydes, amines, anhydrides, esters, ethers, imides, ketones, lactones, phenols, pyridines, pyrazines, pyrroles, sulfur compounds, herbs,

essential oils, and hydrocarbons, among others [14-17]. Menthol belongs to the chemical class of alcohols [14].

Flavor perception is composed of three different sensations: taste, aroma and "mouthfeel" (also referred to as chemesthesis or haptic impressions, e.g., cooling, "throat grab" or "biting" sensations) [15]. Taste and aroma are special sensations while mouthfeel is a general (somatic) sensation [18]. All three sensations arise from stimulation of specific cranial nerves (CN) in the orofacial complex, including the chorda tympani nerve (CN VII) which registers taste; the olfactory nerve (CN I) which registers smell or aroma; and the trigeminal nerve (CN V) which registers feeling factors [15, 18, 19]. The composite of all three sensations (taste, aroma and feeling factors) gives rise to the integrated reaction that is smoke flavor [15, 18].

Smokers' self-rated importance of each of these sensations to overall cigarette smoking satisfaction differs by smoker age and duration of smoking [20, 21]. Younger, less experienced smokers generally consider taste to be more important and are better able to tolerate smoke with less astringent properties i.e., smoke with mild, smoothing effects [20]. In contrast, older, more experienced smokers generally prefer stronger concentrations of flavors capable of inducing greater chemesthetic effects [20].

Chemosensory properties of menthol: Research shows that tobacco design and chemosensory characteristics (e.g., flavors) contribute to conditioned aspects of tobacco use, independent of the direct effects of nicotine [22-24]. Evidence

that nicotine alone does not explain smokers' physiological and psychological tobacco dependence includes limited efficacy of nicotine replacement therapy for smoking abstinence; comparability of de-nicotinized cigarettes with nicotine-containing cigarettes in terms of perceived reward; and lack of positive mood effects of pure nicotine even in abstinent smokers [25-35].

Menthol reinforces nicotine addiction, particularly among adolescents who have heightened preferences for sweet taste and report high use of flavored products [36-39]. Menthol exerts potent pharmacologic effects, which reduce the harshness and irritation from nicotine [40-45]. Research shows that the neurobiological effects of menthol among smokers are not attenuated with repeated exposure [40]. The desirable chemosensory properties of menthol such as its cooling, smoothing, anesthetic and soothing effects arise from interactions with specific neuronal receptors. For example, the cooling effect of menthol occurs from its interaction with thermal receptors in the airway [41-43]. Menthol's smoothing effect (i.e., masking of the harshness of tobacco smoke) arises from its interaction with nociceptors and desensitization of nicotinic cholinergic receptors [44, 45]. Menthol stimulates the trigeminal nerve to elicit chemesthetic effects in the mouth and throat [46]. In addition, menthol is involved in the activity of the dopaminergic system that modulates neurobiological processes associated with learned behavior, pleasure, and chemosensory reward [47].

The majority of cigarettes sold in the U.S. (>90%) contain menthol in them, even those designated as nonmenthol cigarettes [48]. The concentration of menthol

in brands designated as menthol cigarettes averages > 0.3% by weight [48]. Brands designated as non-menthol cigarettes contain between 0.01 to 0.03% menthol content by weight [48]. Menthol concentrations vary widely even within brands designated as menthol [48, 49]. At lower concentrations, menthol exerts cooling and anesthetic effects that are desirable to naïve smokers; at higher concentrations, it produces burning and irritating effects which are desirable to more established smokers [48]. Research shows that the levels and types of flavor chemicals in some tobacco products are similar to those found in several brands of candy and flavored soft drinks [50]. Mint flavorings in certain smokeless tobacco products even surpass levels in confectionary products [51].

The menthol cigarette market: Globally, menthol cigarettes are likely to see a decline in market share as more countries enact laws banning them, especially in economic blocs such as the European Union [52]. In the U.S., menthol cigarettes enjoy a third of all cigarette market shares. Over the past few decades in the U.S., the market shares of menthol brands and "full flavor" (i.e., high tar) brands have moved in opposite directions [5]. While "high tar" brands have seen a drastic decline in market shares because of strong negative perceptions regarding the health risks of tar exposure, menthol cigarettes have increasingly seen a larger share of the U.S. cigarette market [5]. According to the U.S. Federal Trade Commission, the share of U.S. cigarettes with tar yields greater than 15mg declined from 98% in 1967, to 13.6% in 2010 whereas the share of menthol cigarettes increased from 20% to 31% during the same time period [5].

For commercial applications in cigarette manufacture, menthol may be derived from multiple sources, including several members of the mint family such as peppermint, cornmint, and spearmint plants, and could be added at several stages during cigarette manufacture [53]. Several top selling cigarettes brands in the U.S. in terms of retail volume sales are primarily menthol brands, including Newport, Marlboro Menthol and Kool [54]. Newport has consistently ranked as the second most popular cigarette brand in the country (after Marlboro) in terms of both overall market share (13% in 2014) and reported prevalence of use among youth smokers [54, 55].

In terms of product design, there are two broad formulations of menthol cigarettes sold in the U.S. – standard cigarettes with menthol filters (96.4% of all menthol cigarettes by percentage retail volume), and cigarettes with menthol capsules in or near the filter that the smoker crushes to release additional menthol (3.6% of all menthol cigarettes) [54]. Flavor release technology allows the smoker to increase the menthol delivery at a chosen point to sustain or enhance the chemosensory effects of the flavor [56]. The flavor precursor is nonvolatile under normal storage conditions, but becomes activated once the smoker crushes the capsule.

The menthol cigarette market in the U.S. continues to evolve with the introduction of new menthol varieties by leading cigarette manufacturers [54]. According to the Euromonitor International [54], RJ Reynolds introduced three menthol varieties on the U.S. market between 2008 and 2011– Camel Crush; Camel

Core Menthol; and Camel Crush Bold. Phillip Morris also recently introduced some new menthol varieties including Marlboro NXT (2012) and Marlboro Rich Blue (2014) [54]. During 2014, approximately 9.3% and 11.9% of Camel and Marlboro retail shares respectively, comprised menthol varieties [54].

Taxable removals data (actual cigarette sales) from the Alcohol and Tobacco Tax and Trade Bureau during 2000-2011 showed that declines occurred in total sales for both menthol and nonmenthol cigarettes in the U.S. [57]. However, sales for nonmenthol cigarettes declined to a greater extent (37%; 323.2 billion sticks in 2000 to 202.9 billion sticks in 2011) than menthol cigarettes (20%; 112.4 billion sticks in 2000 to 89.9 billion sticks in 2011) [57]. Approximately 89% of the total decline in cigarette consumption was attributable to nonmenthol cigarettes [57].

Population studies of flavored tobacco product use: Cigarette manufacturers have long targeted African Americans with menthol brands; not surprisingly, African Americans have a disproportionately high prevalence of menthol cigarette smoking [20, 58-60]. Menthol cigarettes also serve as a starter product for the over 2,600 youth under the age of 18 years who smoke their first cigarette each day [61, 62]. Data from the 2013-2014 Population Assessment of Tobacco and Health (PATH) study of U.S. adolescents aged 12-17 years showed that 50.1% of cigarette smokers, 65.4% of cigar smokers, 68.9% of conventional smokeless tobacco product users, 81.2% of snus users, 81% of e-cigarette users, and 88.7% of hookah users, *first tried* a flavored product [62]. Data from the 2014 National Youth Tobacco Survey (NYTS) further showed that most youth *maintain*

use of flavored products [36]. Among U.S. 6-12th graders who reported past 30-day use of tobacco products during 2014, most used flavored products, including 63.3% of e-cigarette users, 60.6% of hookah users, 63.5% of cigar smokers, 53.6% of cigarette smokers, and 58.8% of smokeless tobacco users [36].

Similar findings have been reported in other countries. During 2010-2011, 51.8% of Canadian 9-12th graders who reported past 30-day use of a tobacco product used a flavored variety [63]. During 2012, 19% of adults in the EU reported that the most significant factor that made them start smoking was the taste or smell of tobacco [64]. EU member states with the highest proportions of tobacco users reporting smoking initiation because of flavors were Austria (38%), Slovakia (25%), Italy (33%), Greece (29%), Bulgaria (29%), and Czech Republic (29%) [64]. More so, among all EU smokers, the most common cited factor as being important to smokers when choosing a brand was the taste of the tobacco (84% of tobacco users) [64].

Disparities exist in the use of menthol cigarettes by annual household income, education, sexual orientation, and age [60, 65]. A lot of research has focused on youths in particular because among adults who currently smoke, 88% started smoking before age 18 years, and 98% started before age 21 [1]. Studies show that menthol cigarettes increase product appeal, experimentation and regular smoking as well as the likelihood of addiction and the degree of addiction in youth smokers [67-73]. Menthol smokers report more cigarettes smoked per day and are less likely to successfully quit, particularly among African Americans [74]. Modeling done by TPSAC led to the conclusion that the observed prevalence of overall cigarette

smoking with availability of menthol cigarettes is higher than the counterfactual prevalence if menthol cigarettes were not available, for the whole population, and for youth and African Americans [8].

Regulation of menthol cigarettes: The World Health Organization's (WHO) Tobacco Regulatory Science Group recommends a ban on menthol cigarettes by member countries of the WHO Framework Convention on Tobacco Control [75]. The European Union (EU) parliament voted for a ban on menthol cigarettes in 2013 [76]. This EU ban will come into full effect in 2020 and will apply to both manufactured cigarettes as well as roll-your-own cigarettes [52, 76]. Menthol cigarettes have also been prohibited or restricted in Australia, Brazil, Chile, Ethiopia, Moldova, Turkey, and several Canada provinces including Nova Scotia, Alberta, Ontario, Quebec and New Brunswick [77, 78].

In the U.S., federal regulation of tobacco products falls under the purview of FDA. Established in 1906, FDA is part of the U.S. Department of Health and Human Services, one of the U.S. Federal executive departments [79]. FDA exercises regulatory authority over foods and dietary supplements, drugs, medical devices, radiation-emitting products, vaccines, blood and biologics, animal and veterinary products, cosmetics, and tobacco products [80]. Like most agencies in the executive branch, FDA can only act on laws enacted by congress. From 1997-2016, there were over 345 testimonies by FDA officials before House and Senate Committees and Subcommittees, several of which were congressional oversight hearings [81]. Congressional committees to which FDA testified during this period included House

Committee on Energy and Commerce, Subcommittee on Health; House Committee on Government Reform and Oversight, Subcommittee on Human Resources, House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations; House Committee on Commerce, Subcommittee on Oversight and Investigations; House Committee on Education and Workforce, Subcommittee on Oversight and Investigations; Senate Committee on Governmental Affairs, Subcommittee on Oversight of Government Management, Restructuring, and the District of Columbia.

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Act (FSPTCA), giving FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products [3]. FSPTCA's provisions allow FDA to:

- ✓ Regulate cigarettes, roll-your-own tobacco, and smokeless tobacco and any other products deemed via regulation to be subject to FDA authority as "tobacco products".
- ✓ Create the Center for Tobacco Products within the FDA and convene a Tobacco Products Scientific Advisory Committee (TPSAC).
- ✓ Ban certain characterizing flavors which apply to any product meeting the definition of a "cigarette". Section 907 of the Act stipulates the following Special Rule for Cigarettes: "Beginning 3 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not

contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this Act applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph".

- ✓ Prevent sales except through direct, face-to-face exchanges between retailer and a consumer.
- ✓ Fund FDA regulation of tobacco products through a user fee on the manufacturers of certain tobacco products sold in the U.S., based on their U.S. market share.
- ✓ Restrict tobacco marketing and sales to youth, including **v**ending machine sales (except in adult-only facilities), sale of packages of fewer than 20 cigarettes, tobacco-brand sponsorships of sports and entertainment events or other social or cultural events, and free giveaways of sample cigarettes and brand-name non-tobacco promotional items.
- ✓ Require warning labels on smokeless tobacco and cigarette packages covering at least 30% and 50% respectively of the two principal sides of the package. For advertisements, the warning label statements must cover at least 20% of the area of the ad for both smokeless tobacco and cigarettes.

- ✓ Ensure "modified risk" claims are supported by scientific evidence.
- ✓ Require tobacco companies and importers to disclose all ingredients in Tobacco Products and seek FDA approval for any new tobacco products.
- ✓ Require tobacco company owners and operators to register annually and open their manufacturing and processing facilities for FDA inspection biennially.
- ✓ Implement standards for tobacco products to protect public health, including regulation of nicotine and ingredient levels.

Under FSPTCA, FDA is however prohibited from [3]:

- × Affecting any authority of the Secretary of Agriculture under existing law regarding the growing, cultivation, or curing of raw tobacco. This prohibits FDA from promulgating regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.
- × Affecting any authority of the Secretary of the Treasury. This prohibits FDA from limiting or affecting any State, tribal, or local taxation of tobacco products.
- × Banning a class of tobacco products, such as all cigarettes, all smokeless tobacco products, all cigars, all pipe tobacco, or all roll-your-own tobacco products.
- × Prohibiting the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets.

- Establishing a minimum age of sale of tobacco products to any person older than 18 years of age.
- Requiring the reduction of nicotine yields of a tobacco product to zero
- Banning the import of the banned items for personal consumption, only for "sale or distribution". For example, although clove cigarettes are prohibited in the U.S. under FSPTCA, individuals can still import them into the U.S., as long as this is for personal consumption and not for sale or distribution.

Regarding the reference to menthol as a "*characterizing flavor"* in FSPTCA, TPSAC and the larger body of science clearly shows that menthol is not merely a "flavor" but rather is a potent drug by virtue of its pharmacologic effects, including its cooling, smoothing, and anesthetic properties, which increase product appeal and the potential for abuse liability among youths [40-47]. Public health experts have called for FDA to prohibit the use of menthol *as an additive* in cigarettes rather than *as a "characterizing flavor*" in cigarettes [82]. A challenge with regulating menthol as a "characterizing flavor" is the fact that "characterizing flavor" is not defined in FSPTCA, rather the term alludes to a primary *discernable* flavor in cigarettes or other tobacco products. The absence of a clear, quantitative cut-off for the levels of menthol that would render it "characterizing" creates several uncertainties within a regulatory context. For example, are levels of menthol "characterizing" if they impart only subtle or vague flavor notes? It is difficult to define an absolute "characterizing" threshold for menthol given its complex interactions with nicotine, as well as individual differences in flavor perception [15].

The *de facto* definition of "characterizing flavor" which FDA has applied to other flavor additives that are included in FSPTCA is that the tobacco products containing these additives not be *advertised* as containing these additives [82]. FDA's enforcement of the ban on characterizing flavors has similarly been largely dependent on *observations* of marketing violations as noticed and reported by members of the public [83, 84]. TPSAC's recommendation to FDA in 2011 however was for the "removal of menthol cigarettes from the marketplace" [8].

STATEMENT OF PROBLEM AND SIGNIFICANCE

The U.S. tobacco control landscape has evolved considerably over the past few years, including shifts in the menthol segment of the cigarette market, introduction of novel tobacco products, and the passage of the deeming rule on August 8, 2016, which gives FDA authority over e-cigarettes, hookahs, and cigars in addition to other previously regulated products [3, 54, 85]. These changes underscore the need for timely population and market research on menthol cigarettes, particularly on how menthol might be influencing emerging tobacco use behaviors among youth, so as to inform evidence-based public health practice, programs, and policy. Below are several critical gaps in knowledge and practice in relation to menthol cigarettes that this dissertation aims to fill.

1. What is a valid case definition to discriminate menthol from nonmenthol cigarette smokers using self-reported data? Accurate measurements are critical for tobacco surveillance, evaluation, and research. Currently however, there is no standard definition of self-reported menthol

cigarette smoking. This makes it challenging to compare prevalence estimates between studies, as it is difficult to ascertain whether observed differences reflect *actual differences* in menthol cigarette smoking versus *measurement differences*. Although there are a few objective markers of menthol cigarette smoking, they are difficult to implement in school-based surveys of youth because of certain limitations. For example, while Universal Product Codes have been used for several years in NHANES (household-based survey) for adult menthol surveillance, their utility in school-based surveys is limited because this requires students to have their usual cigarette pack on hand during the survey – a requirement that might be difficult to get parental or school consent [58]. In the absence of objective measures of menthol use, it is impossible to use routine methods for measuring accuracy of an index test, e.g., estimates of sensitivity or specificity, to determine which of the several index definitions of self-reported menthol cigarette smoking among youth is most valid. This study used alternate approaches to determine which definition of self-reported menthol cigarette smoking has optimal validity in estimating population menthol cigarette smoking among youth, based on comparisons with certain benchmarks.

2. What are recent temporal, geographic, and demographic trends in menthol and nonmenthol cigarette smoking among U.S. adolescents?

Monitoring prevalence, trends, and patterns of menthol cigarette smoking at national and state levels is critical for FDA, state, and local regulation of menthol cigarettes. Surveillance of menthol cigarette smoking in the general population and

its subgroups is also necessary to identify and eliminate disparities through tailored interventions. No study to date has examined state-specific prevalence estimates of menthol cigarette smoking. In addition, no study has measured temporal trends in prevalence of menthol cigarette smoking among a national sample of U.S. middle and high school students. As shown in Table 1.1, a series of modifications in the survey questions used to measure menthol use in NYTS during 1999-2011 made it impossible to measure long-term trends in menthol cigarette smoking prevalence nationally. Although surveillance studies based on NSDUH, a national household-based survey found no significant change in menthol cigarette smoking among 12-17-year-old cigarette smokers during 2004-2010 [60, 66], the U.S. tobacco landscape has changed dramatically since then with the introduction of newer menthol varieties which are popular among youth [54]. Between 2008 and 2014, several new menthol varieties were introduced into the U.S. cigarette market, including Camel Crush; Camel Core Menthol; Camel Crush Bold, Marlboro NXT and Marlboro Rich Blue [54]. These market changes underscore the need for more recent surveillance data on menthol cigarette smoking to better understand existing and emerging patterns of menthol cigarette smoking among U.S. youth. To fill these gaps in knowledge, this study measured national temporal trends in self-reported menthol cigarette smoking among U.S. students in grades 6-12 during 2011-2015. The study also measured state-specific prevalence of menthol cigarette smoking among middle and high school students in 22 states for which data were available.

3. What is the association between menthol cigarette smoking and use of emerging tobacco products such as e-cigarettes? Since 2014, e-cigarettes have become the most common tobacco product used among U.S. middle and high school students [85]. Some e-cigarette manufacturers have targeted menthol cigarette smokers by marketing e-cigarette flavors branded after popular menthol cigarettes such as "Kool" or "Newport" [86-88]. The basis for concern about use of e-cigarettes among youth lies in their potential for both individual and population-level harm [89]. Exposure to nicotine during adolescence may negatively affect brain development and might increase the risk for tobacco-related morbidity and mortality [89]. E-cigarette use among smokers may also slow or prevent smoking cessation, while increasing nicotine addiction, and risk of disease [89]. This study investigated potential gateway effects between menthol cigarette smoking and use of e-cigarettes and other flavored emerging tobacco products. This is of paramount importance for formulating sound FDA regulations regarding flavors to prevent perpetuation of tobacco use through dual or poly-tobacco use behaviors. Current FDA regulations on e-cigarettes do not address flavors.

4. Are tobacco manufacturers targeting youth with packaging elements such as flavor names? Do price differentials exist within and across tobacco products by flavor variety? The 1998 Master Settlement prohibited Tobacco Companies from targeting youth with tobacco products [90]. In addition, FSPTCA prohibited the use of any descriptor that falsely implies that one tobacco product is less harmful than another [3]. Tobacco companies however have a

history of creating innovative strategies to circumvent marketing restrictions [91]. Hence 'tobacco industry watch' is a key aspect of tobacco control [92]. This study investigated the use of flavor names as a marketing strategy by tobacco companies to instill perceptions of reduced harm, hedonistic reward, or to target specific population groups with tobacco products.

Closely related to the use of tobacco flavor names as a marketing strategy is the issue of price inequalities by tobacco flavor variety. No study has empirically evaluated price differences within and across tobacco products by flavor type nationally and within states. This is important considering the fact that U.S. cigarette manufacturers spend billions of dollars annually ($7.64 billion in 2013) on cigarette discounts [5]. Knowing whether certain tobacco products that appeal to youth are priced differentially to increase their affordability could inform interventions by state and local governments to reduce such price inequalities, and consequently, reduce youth access. This study used retail scanner data to measure price differences within and across tobacco products (cigarettes, roll-your-own cigarettes, little cigars, and moist snuff) by flavor type.

5. What are prevalence and determinants of public support for a complete tobacco flavor ban (including menthol)? Widespread public support for policy change that runs across geographic and political spectra provides compelling evidence for policy makers [93]. With the recent passage of the deeming rule [94], measuring public support for a tobacco flavor ban could potentially be useful to FDA for future rulemaking, not only for menthol in cigarettes, but also for

all other tobacco products considering no regulation on flavors currently exists for cigars, e-cigarettes, hookahs, and smokeless tobacco. Determining variations in public support for a tobacco flavor ban can also inform development of tailored mass media educational campaigns and public service announcements about tobacco use.

An example of the importance of public support to policy change can be seen with 'Tobacco 21', a strategy to raise the legal age of tobacco purchase to 21 years, which has received widespread support among U.S. adults [95-99]. Consequently, several jurisdictions have passed laws raising the legal age to 21, including in Massachusetts, New Jersey, Hawaii, California, Illinois, Missouri, Kansas, Mississippi, Maine, Arizona, Arkansas, Michigan, Ohio, and New York [99]. The 2013 vote by the EU parliament to ban menthol cigarettes was similarly preceded by high level of public support; 63% of all EU adults supported such a policy in 2012, according to a study conducted by the European Commission [64]. This study therefore examined prevalence and correlates of public support for a tobacco flavor ban in the US.

SPECIFIC AIMS, OBJECTIVES, AND HYPOTHESES

As shown in Figure 1.1, this dissertation covers the following five areas regarding menthol cigarettes: case-definitional issues (measurements); surveillance; emerging tobacco products; price/marketing; and public support for flavor regulation. Table 1.2 provides an overview of study aims, population, and data sources.

Aim 1: **Identify a definition of self-reported menthol cigarette smoking status among U.S. adolescents that has optimal validity**

- Evaluate the construct validity of four different definitions of self-reported menthol cigarette smoking, and recommend a definition with optimal validity.
- Measure predictors of misclassification of menthol status reported by adolescent smokers.

Hypotheses: A definition of menthol cigarette smoking that accounts for both self-classified menthol status as well as cigarette brand information will be more valid than one based on only self-classified menthol status. Misclassification of menthol status will be highest among population subgroups with highest prevalence of menthol use.

Aim 2: **Examine temporal, geographic, and demographic trends in Menthol Cigarette Smoking among U.S adolescents.**

- Measure temporal trends in prevalence of menthol and nonmenthol cigarette smoking among U.S. middle and high school students, overall and by population subgroups, during 2011-2015.
- Measure state-specific prevalence estimates of menthol cigarette smoking among middle and high school students in 22 states with available data during 2012-2016.
- Identify predictors of menthol cigarette smoking among U.S. middle and high school students who reported past 30-day (current) cigarette smoking.

Hypotheses: Trend slopes during 2011-2015 will differ between menthol and nonmenthol cigarettes. Differences in menthol cigarette smoking will exist among groups defined by race/ethnicity, sex, geographic region, and other socio-demographic characteristics.

Aim 3: **Measure the association between menthol cigarette smoking and use of e-cigarettes and other flavored non-cigarette tobacco products among U.S. adolescents**

- Measure the association between menthol cigarette smoking and current use of e-cigarettes and other flavored non-cigarette tobacco products.
- Ascertain whether reasons for e-cigarette use differ between menthol and nonmenthol cigarette smokers.
- Decompose differences in e-cigarette use between menthol and nonmenthol cigarette smokers to determine how much of this gap is attributable to differential self-rated importance of flavors and other design and marketing characteristics.

Hypotheses: Menthol cigarette smokers will be more likely to use e-cigarettes and other flavored non-cigarette tobacco products. Higher self-rated importance of flavors among menthol cigarette smokers will account for some of the difference in e-cigarette use prevalence between menthol and nonmenthol cigarette smokers.

Aim 4: **Determine market-level determinants of menthol use, including the potential role of tobacco marketing activities and pricing at an ecologic level**

- Perform a qualitative evaluation of tobacco flavor names to gain an insight into how tobacco companies use these as a marketing strategy to target youth.
- Compare retail prices *between* cigarettes, smokeless tobacco products, cigars, and roll-your-own (RYO) cigarettes to understand cross-product inequalities in tobacco price
- Compare trends and inequalities in retail prices by flavor variety *within* each class of tobacco product, i.e., cigarettes, smokeless tobacco, cigars, and RYO cigarettes.

Hypotheses: Consistent with tobacco industry's record of targeting youth with tobacco products [1], tobacco companies are likely using packaging and branding elements e.g., flavor names, to target youth with tobacco products. Price differences will exist across and within tobacco products, with flavored varieties having lower price.

Aim 5: **Measure prevalence and determinants of public support for a tobacco flavor ban in the US**

- Measure the proportion of U.S. adults that support banning use of all flavor additives in all tobacco products

- Measure determinants of public support for a tobacco flavor ban

Hypotheses: Variations in public support for a tobacco flavor ban will exist by tobacco use status and will be higher among non-tobacco users. Subgroups with higher burden of menthol or flavored tobacco product use will be more likely to support a tobacco flavor ban, conceivably because of concerns about the role of flavors in youth smoking initiation.

ORGANIZATION OF THE STUDY

Aims 1, 2, 3, 4, and 5 of the study are in chapters 2, 3, 4, 5, and 6 respectively. Each of these chapters is in a manuscript-style format, with a stand-alone abstract, introduction, methodology, results, discussion, conclusions, and references. Chapter 7 summarizes the major conclusions and implications from the study's five aims. All data used in this study were de-identified population-level data or market data and hence the research was deemed as non-human subject research in line with the U.S. Department of Health and Human Services' Federal Wide Assurance for the protection of Human subjects (45 CFR Part 46) [100].

REFERENCES

1. U.S Department of Health and Human Services. Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012

2. U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

3. United States Public Laws. Public Law 111-31 [H.R. 1256] Jun. 22, 2009 Family Smoking Prevention And Tobacco Control Act. 111 P.L. 31;123 Stat. 1776;2009 Enacted H.R. 1256;111 Enacted H.R. 1256. Available at https://www.congress.gov/bill/111th-congress/house-bill/1256.

4. U.S. Food and Drug Administration. *FDA NEWS RELEASE: Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law*. *Available at*

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm. Accessed 09/16/ 2016.

5. Federal Trade Commission. Federal Trade Commission Cigarette Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf.

6. Federal Trade Commission. "TAR," NICOTINE, AND CARBON MONOXIDE OF THE SMOKE OF 1294 VARIETIES OF DOMESTIC CIGARETTES FOR THE YEAR 1998. Available at https://www.ftc.gov/sites/default/files/documents/reports/2000-report-tar-nicotine-and-carbon-monoxide-covering-1998/1998tarnicotinereport_0.pdf.

7. AAP Applauds Menthol Cigarette Restrictions Recommended by Expert FDA Panel. Available at https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Aplauds-Menthol-Cigarette-Restrictions-Recommended-by-Expert-FDA-Panel.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token. Accessed on 09/17/2016.

8. Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations.

Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/tobaccoproductsscientificadvisorycommittee/ucm269697.pdf. Accessed 09/15/2016.

9. U.S. Food and Drug Administration. FDA invites public input on menthol in cigarettes. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm361966.htm. Accessed 09/14/2016.

10. Truth Initiative. NAACP delegates endorse push to say no to menthols. Available at http://truthinitiative.org/news/naacp-delegates-endorse-push-say-no-menthols. Accessed 09/28/2016.

11. The African American Tobacco Control Leadership Council. Letter to President Obama Available at http://www.savingblacklives.org/letter-to-president-obama/. Accessed 11/28/2016

12. Agaku, I.T. and H.R. Alpert, *Trends in annual sales and current use of cigarettes, cigars, roll-your-own tobacco, pipes, and smokeless tobacco among U.S. adults, 2002-2012*. Tobacco control, 2016. **25**(4): p. 451-457.

13. Huber, G.L., *Physical, Chemical, And Biologic Properties Of Tobacco, Cigarette Smoke, And Other Tobacco Products*. Seminars In Respiratory Medicine 10 (4):297-332, 1989. Bates Number 87665671-87665707. Available at

https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=hqbl0115. Accessed 09/30/2016.

14. Leffingwell JC, Young HJ, Bernasek E, RJR. *Tobacco flavoring for smoking products*. 1972: RJ Reynolds. Bates number 515806191/6265. Available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=gyvy0102. Accessed 09/30/2016.

15. *PART XIII Flavor And Flavor Evaluation. Chapter 47 flavor evaluation of cigarettes*. 1974: RJ Reynolds. Bates number 504677261/7293.Available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=mpcc0093. Accessed 09/30/2016.

16. *Smoke cracked. Researchers isolate key flavor ingredients of tobacco in cigarette smoke-pack 'enriched flavor' into new merit*. 1976: Philip Morris. Bates number 2061198935. Available at http://legacy.library.ucsf.edu/tid/nmr06a00. Accessed 09/30/2016.

17. Jenkins, C.R., *Effect of Pyrazines and Indoles*. 1976: British American Tobacco. Bates number 102877689-102877701. Available at http://legacy.library.ucsf.edu/tid/tza66a99. Accessed 09/30/2016.

18. *Taste & Olfaction*. 1987: RJ Reynolds. Bates number 509859364/9400. Available at http://legacy.library.ucsf.edu/tid/kou63d00. Accessed 09/30/2016.

19. Clinically Oriented Anatomy, 7th Edition, by Keith L. Moore, Arthur F. Dalley II, and Anne M. R. Agur, Baltimore, MD: Lippincott Williams & Wilkins, 2014.

20. Kreslake, J.M., G.F. Wayne, and G.N. Connolly, *The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior.* Nicotine Tob Res, 2008. **10**(4): p. 705-15.

21. Ayo-Yusuf, O.A. and I.T. Agaku, *The association between smokers' perceived importance of the appearance of cigarettes/cigarette packs and smoking sensory experience: a structural equation model.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2015. **17**(1): p. 91-97.

22. Carpenter, C.M., G.F. Wayne, and G.N. Connolly, *The role of sensory perception in the development and targeting of tobacco products.* Addiction (Abingdon, England), 2007. **102**(1): p. 136-147.

23. Henningfield, J.E., et al., *Conference on abuse liability and appeal of tobacco products: conclusions and recommendations.* Drug and alcohol dependence, 2011. **116**(1-3): p. 1-7.

24. Krasnegor, N.A., *The behavioral aspects of smoking: introduction.* NIDA research monograph, 1979. **(26)**(26): p. 1-6.

25. Brenhouse, H.C., K.C. Sonntag, and S.L. Andersen, *Transient D1 dopamine receptor expression on prefrontal cortex projection neurons: relationship to enhanced motivational salience of drug cues in adolescence.* The Journal of neuroscience : the official journal of the Society for Neuroscience, 2008. **28**(10): p. 2375-2382.

26. Buchhalter, A.R., L. Schrinel, and T. Eissenberg, *Withdrawal-suppressing effects of a novel smoking system: comparison with own brand, not own brand, and de-nicotinized cigarettes.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2001. **3**(2): p. 111-118.

27. Caggiula, A.R., et al., *Importance of nonpharmacological factors in nicotine self-administration.* Physiology & Behavior, 2002. **77**(4-5): p. 683-687.

28. Dar, R. and H. Frenk, *Do smokers self-administer pure nicotine? A review of the evidence.* Psychopharmacology, 2004. **173**(1-2): p. 18-26.

29. Donny, E.C. and M. Jones, *Prolonged exposure to denicotinized cigarettes with or without transdermal nicotine.* Drug and alcohol dependence, 2009. **104**(1-2): p. 23-33.

30. Gross, J., J. Lee, and M.L. Stitzer, *Nicotine-containing versus de-nicotinized cigarettes: effects on craving and withdrawal.* Pharmacology, biochemistry, and behavior, 1997. **57**(1-2): p. 159-165.

31. Perkins, K.A., et al., *Acute negative affect relief from smoking depends on the affect situation and measure but not on nicotine.* Biological psychiatry, 2010. **67**(8): p. 707-714.

32. Rose, J.E., *Nicotine and nonnicotine factors in cigarette addiction.* Psychopharmacology, 2006. **184**(3-4): p. 274-285.

33. Rose, J.E., et al., *Dissociating nicotine and nonnicotine components of cigarette smoking.* Pharmacology, biochemistry, and behavior, 2000. **67**(1): p. 71-81.

34. Rose, J.E., et al., *Reinforcing effects of nicotine and non-nicotine components of cigarette smoke.* Psychopharmacology, 2010. **210**(1): p. 1-12.

35. West, R., et al., *A comparison of the abuse liability and dependence potential of nicotine patch, gum, spray and inhaler.* Psychopharmacology, 2000. **149**(3): p. 198-202.

36. Corey, C.G., et al., *Flavored Tobacco Product Use Among Middle and High School Students--United States, 2014.* MMWR.Morbidity and mortality weekly report, 2015. **64**(38): p. 1066-1070.

37. De Graaf, C. and E.H. Zandstra, *Sweetness intensity and pleasantness in children, adolescents, and adults.* Physiology & Behavior, 1999. **67**(4): p. 513-520.

38. Desor, J.A. and G.K. Beauchamp, *Longitudinal changes in sweet preferences in humans.* Physiology & Behavior, 1987. **39**(5): p. 639-641.

39. Desor, J.A., L.S. Greene, and O. Maller, *Preferences for sweet and salty in 9- to 15-year-old and adult humans.* Science (New York, N.Y.), 1975. **190**(4215): p. 686-687.

40. Rosenblatt, M.R., et al., *Olfactory thresholds for nicotine and menthol in smokers (abstinent and nonabstinent) and nonsmokers.* Physiol Behav, 1998. **65**(3): p. 575-9.

41. Bautista, D.M., et al., *TRPA1 mediates the inflammatory actions of environmental irritants and proalgesic agents.* Cell, 2006. **124**(6): p. 1269-82.

42. Macpherson, L.J., et al., *More than cool: promiscuous relationships of menthol and other sensory compounds.* Mol Cell Neurosci, 2006. **32**(4): p. 335-43.

43. Voets, T., et al., *The principle of temperature-dependent gating in cold- and heat-sensitive TRP channels.* Nature, 2004. **430**(7001): p. 748-54.

44. Hans M. Project report: The effects of stimulation with tobacco related compounds (TRCs) on nicotinic acetylcholine receptors in a model of sensory irritation. Richmond: Philip Morris USA, July 2005–March 2006. Bates Number 3015942511-3015942523. Available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=ypfh0150. Accessed 09/30/2016.

45. Reeh PW, Kichko T., Project report: Irritant actions on isolated rodent trachea. Nuremberg: Philip Morris and USA. Bates Number 3034627712-3034627737. Available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=yrny0218. Accessed 09/30/2016.

46. Abe, J., et al., *TRPM8 protein localization in trigeminal ganglion and taste papillae.* Brain Res Mol Brain Res, 2005. **136**(1-2): p. 91-8.

47. Henderson, B.J., et al., *Menthol Alone Upregulates Midbrain nAChRs, Alters nAChR Subtype Stoichiometry, Alters Dopamine Neuron Firing Frequency, and Prevents Nicotine Reward.* J Neurosci, 2016. **36**(10): p. 2957-74.

48. Ferris Wayne, G. and G.N. Connolly, *Application, function, and effects of menthol in cigarettes: a survey of tobacco industry documents.* Nicotine Tob Res, 2004. **6 Suppl 1**: p. S43-54.

49. Celebucki, C.C., et al., *Characterization of measured menthol in 48 U.S. cigarette sub-brands.* Nicotine Tob Res, 2005. **7**(4): p. 523-31.

50. Brown, J.E., et al., *Candy flavorings in tobacco.* The New England journal of medicine, 2014. **370**(23): p. 2250-2252.

51. Chen, C., et al., *Levels of mint and wintergreen flavorants: smokeless tobacco products vs. confectionery products.* Food and chemical toxicology : an international journal published for the British Industrial Biological Research Association, 2010. **48**(2): p. 755-763.

52. European Commission. Public Health. Revision of the Tobacco Products Directive. Available at http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf. Accessed 09/16/2016.

53. Lorillard. Menthol. Bates number 99503699-99503743. Available at https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/#id=kmfn0034. Accessed 09/30/2016.

54. Euromonitor. (2015). Cigarettes in the US. Statistics retrieved March 23, from Euromonitor Passport Database.

55. *Cigarette brand preference among middle and high school students who are established smokers - United States, 2004 and 2006.* MMWR Morb Mortal Wkly Rep, 2009. **58**(5): p. 112-5.

56. Jenkins, R.W. and K.F. Podraza, *A Review Of The Flavor Release Technology Developed At Philip Morris*. 1984: Philip Morris. Bates number 2056446519/6596. Available at http://legacy.library.ucsf.edu/tid/tza66a99. Accessed 09/30/2016.

57. Delnevo, C.D., A.C. Villanti, and G.A. Giovino, *Trends in menthol and non-menthol cigarette consumption in the U.S.A.: 2000-2011.* Tob Control, 2014. **23**(e2): p. e154-5.

58. Caraballo, R.S. and K. Asman, *Epidemiology of menthol cigarette use in the United States.* Tob Induc Dis, 2011. **9 Suppl 1**: p. S1.

59. Gardiner, P.S., *The African Americanization of menthol cigarette use in the United States.* Nicotine Tob Res, 2004. **6 Suppl 1**: p. S55-65.

60. Giovino, G.A., et al., *Differential trends in cigarette smoking in the USA: is menthol slowing progress?* Tob Control, 2015. **24**(1): p. 28-37.

61. Substance Abuse and Mental Health Services Administration, "Results From the 2014 National Survey on Drug Use and Health: Detailed Tables." Available at http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab4-10a.Accessed 09/30/2016.

62. Ambrose, B.K., et al., *Flavored Tobacco Product Use Among U.S. Youth Aged 12-17 Years, 2013-2014.* Jama, 2015. **314**(17): p. 1871-1873.

63. Minaker, L.M., et al., *Flavored tobacco use among Canadian students in grades 9 through 12: prevalence and patterns from the 2010-2011 youth smoking survey.* Prev Chronic Dis, 2014. **11**: p. E102.

64. European Commission. Special Eurobarometer 385. Attitudes of Europeans Towards Tobacco. Available at http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco__en.pdf. Accessed 09/30/2016.

65. Fallin, A., A.J. Goodin, and B.A. King, *Menthol cigarette smoking among lesbian, gay, bisexual, and transgender adults.* Am J Prev Med, 2015. **48**(1): p. 93-7.

66. Substance Use and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Recent Trends in Menthol Cigarette Use. The NSDUH Report. Rockville, MD, 2011.

67. Ahijevych, K. and B.E. Garrett, *The role of menthol in cigarettes as a reinforcer of smoking behavior.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S110-6.

68. Hersey, J.C., et al., *Are menthol cigarettes a starter product for youth?* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2006. **8**(3): p. 403-413.

69. Klausner, K., *Menthol cigarettes and smoking initiation: a tobacco industry perspective.* Tobacco control, 2011. **20 Suppl 2**: p. ii12-9.

70. Kreslake, J.M., G.F. Wayne, and G.N. Connolly, *The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2008. **10**(4): p. 705-715.

71. Kreslake, J.M. and V.B. Yerger, *Tobacco industry knowledge of the role of menthol in chemosensory perception of tobacco smoke.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S98-101.

72. Rising, J. and L. Alexander, *Marketing of menthol cigarettes and consumer perceptions.* Tobacco induced diseases, 2011. **9 Suppl 1**: p. S2-9625-9-S1-S2.

73. Yerger, V.B., *Menthol's potential effects on nicotine dependence: a tobacco industry perspective.* Tobacco control, 2011. **20 Suppl 2**: p. ii29-36.

74. Muilenburg, J.L. and J.S. Legge, Jr., *African American adolescents and menthol cigarettes: smoking behavior among secondary school students.* J Adolesc Health, 2008. **43**(6): p. 570-5.

75. World Health Organization. Advisory note: banning menthol in tobacco products WHO Study Group on Tobacco Product Regulation (TobReg). Available at http://www.who.int/tobacco/publications/prod_regulation/menthol-advisory-note/en/. Accessed 09/17/2016.

76. European Commission - Press release. 10 key changes for tobacco products sold in the EU. Available at http://europa.eu/rapid/press-release_IP-16-1762_en.htm. Accessed 09/15/2016.

77. Framework Convention Alliance. Canadian provinces first in world to ban menthol flavouring. Available at http://www.fctc.org/fca-news/opinion-pieces/-canadian-provinces-first-to-ban-menthol-flavouring. Accessed 09/15/2016.

78. Tobacco Control Legal Consortium. How Other Countries Regulate Flavored Tobacco Products. Available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-2015.pdf. Accessed 09/15/2016.

79. The White House. The Executive Branch. Available at https://www.whitehouse.gov/1600/executive-branch. Accessed 11/28/2016.

80. FDA. Federal Food, Drug, and Cosmetic Act (FD&C Act). Available at http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/. Accessed 11/28/2016.

81. FDA. Testimony. Available at http://www.fda.gov/NewsEvents/Testimony/. Accessed 11/28/2016.

82. Docket ID: FDA-2013-P-0435. Comment on citizen petition asking the U.S. Food and Drug Administration to prohibit menthol as a characterizing flavor in cigarettes. Available at **https://tobacco.ucsf.edu/fda-should-ban-menthol-additive-not-undefined-characterizing-flavor**. Accessed 11/28/2016.

83. FDA. Letter to Tobacco Control Groups on Cigarettes Containing Certain Characterizing Flavors. Available at **http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm183199.htm.** Accessed 11/28/2016.

84. Federal Register Notice: Enforcement of General Tobacco Standard Special Rule for Cigarettes. Federal Register Volume 74, Number 185 (Friday, September 25, 2009). Available at https://www.gpo.gov/fdsys/pkg/FR-2009-09-25/html/E9-23144.htm. Accessed 11/28/2016.

85. Singh, T., et al., *Tobacco Use Among Middle and High School Students--United States, 2011-2015.* MMWR.Morbidity and mortality weekly report, 2016. **65**(14): p. 361-367.

86. ECF. Menthol Suggestions. Available at https://www.e-cigarette-forum.com/forum/threads/menthol-suggestions.143176/. Accessed 09/15/2016.

87. ECF. Who sells the closest to Newport flavor e-juice? Available at https://www.e-cigarette-forum.com/forum/threads/who-sells-the-closest-to-newport-flavor-e-juice.215508/. Accessed 09/15/2016.

88. Newport e liquid from Nuports.com. Available at https://www.youtube.com/watch?v=qV86HVHHFu0.

89. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease

Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

90. Master Settlement Agreement. Available at http://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf. Accessed 09/15/2016.

91. Connolly, G.N. and H.R. Alpert, *Has the tobacco industry evaded the FDA's ban on 'Light' cigarette descriptors?* Tobacco control, 2014. **23**(2): p. 140-145.

92. WHO REPORT on the global TOBACCO epidemic, 2008-The MPOWER Package. Available at http://www.who.int/tobacco/mpower/mpower_report_full_2008.pdf. Accessed September 13, 2016.

93. Paul Burstein. The Impact of Public support on Public Policy: A Review and an Agenda. Political Research Quarterly March 2003 vol. 56 no. 1 29-40. doi: 10.1177/106591290305600103.

94. Federal Register. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act;Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Available at https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the. Accessed 09/14/2016.

95. Committee on the Public Health Implications of Raising the Minimum Age for Purchasing Tobacco Products, Board on Population Health and Public Health Practice, Institute of Medicine; Bonnie RJ, Stratton K, Kwan LY, editors. Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products. Washington (DC): National Academies Press (US); 2015 Jul 23.

96. King BA, Jama AO, Marynak KL, Promoff GR. Attitudes Toward Raising the Minimum Age of Sale for Tobacco Among U.S. Adults. Am J Prev Med. 2015 Oct;49(4):583-8. doi: 10.1016/j.amepre.2015.05.012.

97. Lee JG, Boynton MH, Richardson A, Jarman K, Ranney LM, Goldstein AO. Raising the Legal Age of Tobacco Sales: Policy Support and Trust in Government, 2014-2015, U.S. Am J Prev Med. 2016 Dec;51(6):910-915.

98. Winickoff JP, McMillen R, Tanski S, Wilson K, Gottlieb M, Crane R. Public support for raising the age of sale for tobacco to 21 in the United States. Tob Control. 2016 May;25(3):284-8.

99. Tobacco Twenty One. State by State. Available at http://tobacco21.org/state-by-state/. Accessed 11/28/16

100. Department of Health and Human Services. Code of Federal Regulations. Title 45 Public Welfare. Part 46 protection of human subjects. Available at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html. Accessed 09/28/2016.

TABLES AND FIGURES

Table 1.1 Changes in menthol surveillance in the National Youth Tobacco Survey, 1999-2015.

Period	Question wording	Categorical response options
1999-2002	"Is the brand of cigarettes you usually smoked during the past 30 days mentholated?"	"I didn't smoke cigarettes in past 30 days"; "I do not have a usual brand"; "Yes, it is a menthol brand"; "No, it is not a menthol brand"
2004-2009	"Are the cigarettes you usually smoke menthol cigarettes?"	"I don't smoke cigarettes"; "Yes"; "No".
2011-2015	"Menthol cigarettes are cigarettes that taste like mint. During the past 30 days, were the cigarettes that you usually smoked menthol?"	"I did not smoke cigarettes during the past 30 days"; "Yes"; "No"; "Not sure".

Table 1.2 Overview of study aims, population, exposures, and outcomes

	Aim 1	Aim 2	Aim 3	Aim 4	Aim 5
Study population	• U.S. middle and high school students	• U.S. middle and high school students	• U.S. middle and high school students	• U.S. tobacco market on an ecologic level	• U.S. adults aged 18 years or older
Research theme	• Validity of definitions of menthol cigarette smoking with self-reported data among U.S. adolescents	• Trends in menthol and nonmenthol cigarette smoking among U.S. adolescents.	• Association between menthol cigarette smoking and current use of electronic cigarettes and other non-cigarette flavored tobacco products among U.S. adolescents	• Evaluation of marketing and pricing of flavored tobacco products on the U.S. market	• Public support among U.S. adults for a tobacco flavor ban
Translational area	• Surveillance (measurements)	• Surveillance (trends)	• Emerging tobacco products	• Marketing and economics of tobacco control	• Public policy and product regulation
Outcomes	• Current (past 30-day) menthol cigarette smoking	• Trends in current smoking of menthol and nonmenthol cigarettes	• Current use of e-cigarettes • Current use of any non-cigarette flavored tobacco product	• Emergent themes from qualitative evaluation of brand names • Standardized dollar prices across and within tobacco products by flavor variety	• Public support for a tobacco flavor ban in the U.S.
Data source	• 2009-2015 National Youth Tobacco Survey	• 2011-2015 National Youth Tobacco Survey; 2012-2016 Youth Tobacco Survey (22 states)	• 2014-2015 National Youth Tobacco Survey	• 2011-2016 Retail scanner data acquired from Nielson company	• 2016 *Summer Styles* Survey
Scope	• National	• National and state-specific	• National	• National and state-specific	• National

Figure 1.1 Scope of research in relation to major tobacco control domains

Chapter 2 - VALIDITY OF DEFINITIONS OF MENTHOL CIGARETTE SMOKING WITH SELF-REPORTED DATA AMONG U.S. ADOLESCENTS[1]

[1] Agaku IT, Dobbin K, Muilenburg J, Hallow K, et al. To be submitted to *Nicotine and Tobacco Research*.

ABSTRACT

INTRODUCTION: No standard definition of self-reported menthol cigarette smoking exists, and the use of objective menthol markers in school-based surveys is difficult because of poor biomarker performance (e.g., menthol glucuronide), or logistical challenges (e.g., Universal Product Codes). This study measured validity of different definitions of self-reported menthol cigarette smoking among U.S. adolescents.

METHODS: Data were from the 2009-2015 National Youth Tobacco Survey (NYTS), a school-based survey of U.S. 6-12th graders. NYTS asked respondents about their usual cigarette *type* (self-classified menthol status) and *brand* (preferred brand smoked). These two variables were used to create the following definitions of menthol cigarette smoking: brand-type concordance, brand and/or type, and type-only definitions. Internal and external benchmarks were used to measure construct validity. The internal benchmark was defined using the standard past 30-day measure of current cigarette smoking (P30D) under the hypothesis that sum of menthol and nonmenthol prevalence, if valid, should approximate P30D prevalence. The 2008-2010 National Survey on Drug Use and Health (NSDUH) was used as an external benchmark to measure agreement with the index definitions on the percentage of current cigarette smokers aged 12-17 years old that reported menthol use. NSDUH was used as a benchmark because of its precise cigarette brand information. Multivariable logistic regression was used to determine predictors of

misclassified menthol status (brand-type discordance) using pooled 2011-2015 NYTS data.

RESULTS: Overall prevalence of current cigarette smoking among all respondents in 2009 was 12.0% with the internal benchmark (P30D); versus 12.4% (brand-type concordance definition); 13.3% (brand and/or type definition); and 20.4% (type-only definition). Overall prevalence of menthol use among past 30-day cigarette smokers aged 12-17 years was 56.7% with the external benchmark (2008-2010 NSDUH) versus the following estimates with the index definitions from 2009 NYTS: 54.2% (brand-type concordance); 57.1% (brand and/or type); and 45.7% (type-only). The odds of misclassified menthol status were higher among blacks (aOR=16.85; 95%CI=12.87-22.07), and Hispanics (aOR=3.05; 95%CI=2.35-3.97) than whites, but lower among males (aOR=0.65; 95%CI=0.53-0.80) than females, and among high than middle school students (aOR=0.73; 95%CI=0.58-0.92).

CONCLUSIONS: The brand-type concordance definition had high internal validity and could be used for menthol smoking surveillance among U.S. adolescents.

INTRODUCTION

Accurate surveillance of youth menthol cigarette smoking is critical to inform tobacco control efforts [1, 2]. Most cigarettes sold in the U.S. have menthol in them, including those designated as nonmenthol brands [3]. During 2008-2010, 79% of cigarette brand families had at least one variety designated as mentholated [4]. Measurement of menthol cigarette smoking among youth poses unique challenges because of cognitive and social biases associated with self-reported use [5]. However, with a market share of 31% and with high youth appeal and use [5-7], accurate and timely surveillance of menthol cigarette smoking among youth is paramount.

Currently, there is no standard definition of menthol cigarette smoking with self-reported data. This makes it difficult to determine if observed temporal, geographic, or demographic differences reflect differences in actual use versus differences in definition of usage patterns. Even within the same surveillance system such as the National Youth Tobacco Survey (NYTS), multiple definitions of menthol cigarette smoking exist. Corey and colleagues defined menthol cigarette smokers in NYTS as persons who usually smoked an exclusively menthol brand or reported that their cigarette type was menthol [8]. Hersey et al., defined menthol use status based on consistency of responses between self-classified cigarette type and usual cigarette brand smoked [9]. Other researchers have used self-classified menthol status without brand adjustment [10]. Unfortunately, in some studies, no

information is provided on how menthol cigarette smoking was defined [11]. Establishing valid and reliable operational definitions for self-reported menthol cigarette smoking among youth is important for evidence-based public health practice, policy, and programs as the tobacco control landscape in the U.S. continues to evolve [12].

Although a few objective markers of menthol cigarette smoking exist, e.g., menthol glucuronide (a biomarker), and universal product codes (barcode technology), both of these markers are difficult to implement in school-based surveys because of either poor biomarker performance or logistical challenges. Menthol glucuronide is limited by its short half-life of roughly one hour in urine or plasma and its nonspecificity to menthol in cigarettes (i.e., low sensitivity and specificity) [13]. Use of UPCs requires that respondents have their usual cigarette pack on hand during the survey – a requirement that might be difficult to get parental or school consent in school-based surveys of youth [5]. Given the absence of a true "gold standard" in this context, it is impossible to use standard approaches such as calculations of sensitivity or specificity, to determine the validity of the different definitions of self-reported menthol cigarette smoking used in the literature. This study therefore used alternate approaches to measure the construct validity of definitions of self-reported menthol cigarette smoking among U.S. youth.

Specific research questions were: (1) which definition of self-reported menthol cigarette smoking has optimal validity when compared to certain benchmarks? (2)

What factors are associated with misclassification of reported menthol cigarette smoking among U.S. adolescents?

METHODOLOGY

NYTS design and questionnaire

Data were from the 2009-2015 waves of NYTS, a school-based, paper and pencil survey of U.S. students in grades 6-12 attending public and private schools in the 50 U.S. States and D.C. From 2011 onwards, NYTS has been conducted annually; prior to 2011 however, it was a biennial survey. NYTS collects information on socio-demographic variables (age, sex, race/ethnicity, grade, and school level) as well as tobacco-related measures.

Respondents in NYTS are asked two separate questions regarding their usual cigarette *type* (self-classified menthol status) and their usual cigarette *brand* (preferred choice of brand smoked). The cigarette *type* question in 2009 NYTS was as follows: "Menthol cigarettes are cigarettes that taste like mint. During the past 30 days, were the cigarettes that you usually smoked menthol?" Categorical responses were "I did not smoke cigarettes during the past 30 days"; "Yes"; or "No". The cigarette *brand* question was as follows: "During the past 30 days, what brand of cigarettes did you usually smoke? (CHOOSE ONLY ONE ANSWER)". Categorical responses were: "I did not smoke cigarettes during the past 30 days"; "I did not smoke a usual brand"; "American Spirit"; "Camel"; "GPC, Basic, or Doral"; "Kool"; "Lucky Strike"; "Marlboro"; "Newport"; "Parliament"; "Virginia Slims";

"Some other brand not listed here". These two questions have been used historically to define menthol cigarette smoking status in the tobacco control literature [8-10].

Index case definitions of menthol cigarette smoking

The cigarette *type* and *brand* questions were used to create four definitions of menthol cigarette smoking. To supplement information on cigarette brand measured in NYTS, retail scanner data from the Nielsen Company were used to classify the named brands in NYTS into the following categories: exclusively nonmenthol brands, i.e., ≥99% of sales were nonmenthol (Lucky Strike); exclusively menthol brands, i.e., ≥99% of sales were menthol (Newport, and Kool); and mixed brands (American Spirit; Camel; GPC, Basic, Doral; Marlboro; Parliament; Virginia Slims, and "Some other brand not listed here" [the vast majority of U.S. brand families exist in both menthol and nonmenthol varieties]). The four definitions of menthol cigarette smoking status were as follows (Figure 2.1).

(a) Brand-Type Concordance definition: Menthol smokers were respondents who reported their cigarette type as mentholated and their cigarette brand as either exclusively menthol or mixed (n=1,423; cells H and J, Figure 2.1). Nonmenthol smokers were respondents who reported their cigarette type as nonmentholated and their cigarette brand as either exclusively nonmenthol or mixed (n=1,177; cells O and P, Figure 2.1). Mixed brands were included as possible concordance in both cases because it was impossible to definitively rule out or rule in menthol use for mixed brands based on the brand information alone; the cigarette type information

was thus confirmatory. Persons with missing, indeterminate (e.g., "no usual brand"), or discordant brand-type cigarette information were excluded. Brand-type discordance was measured for only exclusive brands and was defined as conflicting information for cigarette type and cigarette brand usually smoked (e.g., persons who indicated they smoked an exclusive *menthol* brand but conflictingly reported that their cigarette type was *nonmentholated,* or vice versa; cells I or N, Figure 2.1).

(b) Brand and/or Type definition: Menthol smokers were respondents who either reported that their cigarette brand was exclusively menthol, *or* that their cigarette type was mentholated (n=1,668; cells H, J, and N, Figure 2.1). Nonmenthol smokers were respondents who reported their cigarette brand was mixed or exclusively nonmenthol *and* their cigarette type was nonmentholated (n=1,177; cells O and P, Figure 2.1). Persons with missing, or indeterminate information were excluded.

(c) Type-only definition*:* Menthol cigarette smoking status was determined only by the cigarette type question without any brand adjustment. Menthol smokers were respondents who reported that their cigarette type was mentholated (n=2,288; cells G, H, I, J, K, and L; Figure 2.1). Nonmenthol smokers were respondents who reported that their cigarette type was nonmentholated (n=2,703; cells M, N, O, P, Q, and R; Figure 2.1).

(d) Extended definition: Considering that inconsistent and missing responses are relatively common occurrences within self-administered surveys of youth, an

extended definition was considered that examined possible/probable/likely cases of menthol or nonmenthol smokers. This was a broader definition that aimed to reduce the number of persons excluded because of indeterminate information regarding their cigarette smoking or menthol use status. Respondents with inconsistent responses on past 30-day smoking between the cigarette type and brand questions (i.e., indicated on one question that they did not smoke cigarettes in the past 30 days, but conflictingly provided a positive indication of past 30-day smoking on the other) were taken to be smokers, and were not excluded. Respondents with information for at least one of the two parent variables (i.e., cigarette type or cigarette brand questions) were accounted for, regardless of whether they had missing, or indeterminate, or conflicting information for the other. Whenever there was conflicting information between cigarette brand and cigarette type responses, the cigarette brand information took precedence (assumed to be more accurate and reliable than a subjective determination of menthol content in cigarette type). As shown in Figure 2.1, menthol smokers were those who smoked an exclusively menthol brand or mentholated cigarettes (n=2,579; cells B, H, N, T, G, J, K, and L, Figure 2.1). Nonmenthol smokers were those who smoked exclusively nonmenthol brands or nonmentholated cigarettes (n=2,466; cells C, I, O, U, M, P, Q, and R, Figure 2.1). Respondents with missing or indeterminate information for *both* parent variables were excluded.

Benchmarks for measuring validity of index definitions

Two separate criteria were used as benchmarks to determine how well the four index definitions performed comparatively: (1) an internal benchmark, used to measure internal validity and overall coherence of the different index definitions; (2) an external benchmark, used to measure the agreement between menthol prevalence derived from each index definition and the benchmark.

Internal benchmark

The internal benchmark used was the standard past 30-day measure of cigarette smoking among youth (henceforth, P30D), as measured with the following question in 2009 NYTS: "During the past 30 days, on how many days did you smoke cigarettes?" Categorical response options were "0 days," "1 or 2 days," "3 to 5 days," "6 to 9 days," "10 to 19 days," "20 to 29 days," and "all 30 days". Respondents who indicated any option other than "0 days" were classified as current cigarette smokers.

This P30D measure was deemed an appropriate internal benchmark for the following reasons. (1) It is a universally accepted measure of current cigarette smoking status among youth and produces valid prevalence estimates; (2) The P30D measure was separate from the cigarette *type* and cigarette *brand* questions used to define menthol status in NYTS, and could thus be used as an independent standard. The test of internal validity for each of the index definitions was expressed as follows:

$$\hat{P}_o(P30D) \cong \hat{P}_{menthol} + \hat{P}_{nonmenthol}$$

In other words, overall cigarette smoking prevalence ($\hat{P}_o$) among all respondents as measured with the standard P30D measure should approximate the sum of menthol cigarette smoking prevalence and nonmenthol cigarette smoking prevalence (given these are the only two flavor varieties in which cigarettes are sold on the U.S. market).

External benchmark

Published (Giovino et al, 2015) prevalence estimates for menthol cigarette smoking among past 30-day cigarette smokers aged 12-17 years old from the 2008-2010 National Survey on Drug Use and Health (NSDUH) were used as an external benchmark to measure agreement with corresponding prevalence estimates derived from the four index definitions. NSDUH is a national household-based survey of persons aged ≥12 years old and was chosen as an external benchmark for the following reasons: (1) it had more precise information on cigarette brands than NYTS (57 separate brands were measured in NSDUH versus 11 in NYTS). Giovino and colleagues adjusted self-classified menthol use status with retail scanner cigarette brand data to reduce misclassification. (2) The use of audio computer-assisted self-interviews in NSDUH allowed respondents to select and verify their usual brand smoked (3) The ability to restrict analyses to the same target population of persons aged 12-17 years in both surveys was desirable to allow direct comparisons around similar calendar period. Although the sampling frame of NYTS

(school-based survey) differs from NSDUH (household-based survey), the target populations are inherently similar for persons aged 12-17 years because >97% of persons in that age group are enrolled in regular school based on data from the U.S. Census Bureau [14].

Statistical Analyses

Measurement of validity of index definitions

All validity measurements were performed with 2009 NYTS to allow comparison with 2008-2010 NSDUH. For the internal benchmark, the denominator for all analyses was all respondents in both middle and high school who completed the 2009 NYTS questionnaire (n= 22,679). For the external benchmark, the denominator for all analyses was respondents aged 12-17 years old who reported smoking cigarettes within the past 30 days (n = 2,184).

Sensitivity analyses were performed to determine whether current smokers with and without information on the menthol content of their preferred product differed systematically from each other. Three dependent variables were used to estimate the magnitude of this non-response bias: reported history of daily cigarette smoking (smoked every day at some point during their lifetime), established cigarette smoking (smoked ≥1/2 a cigarette pack in entire lifetime), and reported symptoms of psychological dependence on tobacco (frequently experienced cravings after brief periods of tobacco abstinence).

Measurement of factors associated with misclassification of menthol status

Data were pooled from the 2011-2015 NYTS (n=101,648) to afford sufficient sample size for brands with only a few users. The survey weights were appropriately rescaled for the pooled dataset by dividing the sampling weights by 5 to produce robust standard errors. Marginal and joint distributions of brand and type responses were computed to explore extent of misclassification for exclusively menthol or nonmenthol brands overall and by sociodemographic and tobacco use characteristics.

Multivariable logistic regression analyses were used to explore factors associated with reported brand-type discordance (i.e., misclassified menthol status, n=1,011) during 2011-2015. Independent variables measured were age, sex, race/ethnicity, school level, total number of cigarettes smoked in lifetime (proxy for duration of smoking), and usual source of obtaining cigarettes, i.e., purchase vs. social sources (proxy for disposable income). Because of relatively high (>0.3) polychoric correlation between several independent variable pairs (e.g., school level or lifetime cigarettes smoked and age; school level and lifetime cigarettes smoked; as well as age or school level and usual purchase of cigarettes), multiple logistic regressions were fitted iteratively for the different independent variables of interest, adjusting for race/ethnicity and sex as appropriate. All data were weighted to account for the complex survey design and all analyses were performed using SAS-Callable SUDAAN (V.11.0.1) and R (V 3.2.2).

RESULTS

Of study participants in 2009 NYTS, 51.2% were male while 48.8% were female. By race/ethnicity, 56.7% were non-Hispanic white, 15.1% were non-Hispanic black, 19.2% were Hispanic, 3.5% were Asian, and the remainder included persons of multiple race, American Indians/Alaska Native, and Native Hawaiians/Other Pacific Islanders. In total, 43.6% of participants were in middle school while 56.4% were in high school.

Measurement of validity of index definitions

Internal benchmark

As shown in Figure 2.2 and Table 2.1, overall prevalence of current cigarette smoking among all middle and high school students was: 12.0% (P30D measure); 12.4% (brand-type concordance definition); 13.3% (brand and/or type definition); 20.4% (type-only definition); and 21.1% (extended definition). Absolute difference in prevalence between the internal benchmark and each of the index definitions was 0.4 percentage points for the brand-type concordance definition; 1.3 percentage points for the brand and/or type definition; 8.4 percentage points for the type-only definition; and 9.1 percentage points for the extended definition.

Of persons classified as current cigarette smokers using the P30D measure (n=2,746), the proportion that had relevant information to classify them as menthol or nonmenthol smokers using the different index definitions was as follows: 78.6% using the brand-type concordance definition; 84.4% using the Brand and/or Type

definition; 96.7% using the Type-only definition, and 97.8% using the extended definition.

Systematic differences existed between smokers with information on menthol status and those with no such information. After adjusting for sex and race/ethnicity, P30D smokers who were missing information on menthol status based on the brand-type concordance definition were less likely than those with menthol information of reporting being established smokers (aOR=0.44; 95%CI =0.35-0.56); having a history of daily smoking (aOR=0.49; 95%CI=0.34-0.72) or reporting symptoms of psychological dependence on nicotine (aOR=0.61; 95%CI=0.46-0.79). Similar P30D cigarette smokers missing menthol information on the brand and/or type definition were less likely to report being established smokers (aOR=0.43; 95%CI =0.33-0.57); having a history of daily smoking (aOR=0.46; 95%CI=0.35-0.60) or reporting symptoms of psychological dependence (aOR=0.72; 95%CI=0.55-0.93). Although missing values were small based on the type-only, or the extended definitions, analyses showed similar trend.

External benchmark

In total, 86.9% of 2009 NYTS respondents were aged 12-17 years. As shown in Figure 2.3, overall prevalence of menthol use among past 30-day cigarette smokers was 56.7% for NSDUH, 54.2% for the brand-type concordance definition, 57.1% for the brand and/or type definition, 45.7% for the type-only definition, and 50.7% for the extended definition. Absolute difference in prevalence between the

external benchmark and each of the index definitions was 2.5 percentage points for the brand-type concordance; 0.4 percentage points for the brand and/or type; 11.0 percentage points for the type-only definition; and 6.0 percentage points for the extended definition.

Notably, non-Hispanic blacks had the lowest prevalence of menthol cigarette smoking of any race/ethnic group based on the type-only definition (41.2%), but conversely had the highest prevalence of any race/ethnic group based on NSDUH (94.9%), brand-type concordance definition (78.4%), brand and/or type definition (85.6%), and the extended definition (59.4%).

Measurement of factors associated with misclassification of menthol status

Approximately 81.0% of current smokers in 2011-2015 NYTS confirmed having a usual brand; the distribution of brands smoked among these individuals was as follows: Marlboro (42.1%); Newport (26.6%); Camel (15.2%); American Spirit (2.7%); Kool (2.3%); Virginia Slims (0.8%); Lucky Strike (0.6%); GPC/Basic/Doral (0.5%); Parliament (0.5%); and some other brand not otherwise specified (8.7%). As shown in Figure 2.4, misclassification of self-designated menthol status was observed even for exclusively mentholated or nonmentholated brands. Among usual smokers of Newport brand, 51.9% made a correct self-designation as menthol smokers, 32.5% incorrectly classified themselves as nonmenthol smokers, whereas 15.7% were not sure. Similarly, among usual smokers of Kool brand, 46.0% correctly identified themselves as menthol smokers, 26.4% incorrectly as nonmenthol smokers, while 27.6% were not sure. Stratified results for the exclusive menthol

brands by socio-demographic characteristics are shown in Table 2.2. For usual smokers of the exclusively nonmenthol brand Lucky strike, 37.0% correctly identified themselves as nonmenthol smokers, 34.0% incorrectly as menthol smokers, while 29.0% were not sure. Self-classified menthol status for the leading mixed brands (Marlboro and Camel) overall and by socio-demographic characteristics are presented in Table 2.3.

Within adjusted analyses depicted in Table 2.4, the odds of brand-type discordance were higher among non-Hispanic blacks (aOR=16.85; 95%CI = 12.87-22.07), Hispanics (aOR=3.05; 95%CI=2.35-3.97), and non-Hispanic other race (aOR=2.79; 95%CI = 2.00-3.89) compared to non-Hispanic whites. Odds decreased with increasing number of cigarettes smoked in lifetime, and were 0.73, 0.51, 0.40, 0.30, and 0.18 among smokers who had smoked 2-5 individual sticks, 1/2 pack, 1 pack, <5 packs, and ≥5 packs of cigarettes respectively, compared to those who had smoked less than 1 cigarette in their lifetime (all $p<0.05$). The odds of a discordant brand-type response were lower among males compared to females (aOR=0.65; 95%CI=0.53-0.80), among high compared to middle school students (aOR=0.73; 95%CI=0.58-0.92), and among those who purchased their own cigarettes compared to those who obtained their cigarettes from social contacts (aOR=0.57; 95%CI=0.46-0.69).

DISCUSSION

These findings indicate that both brand-ajdusted definitions (the brand-type concordance and the brand and/or type) had high internal validity and yielded prevalence estimates that were in agreement with NSDUH. The brand-type concordance definiton had greater internal validity than the brand and/or type. Conversely, estimates from the brand and/or type definition were in greater agreement with NSDUH, possibly because this definition aligned most to that used in NSDUH (discordant responses in the NSDUH benchmark were corrected to reflect the menthol designation of the cigarette brand) [7]. The type-only definition had the worst performace overall; stratified estimates from this definition were incongruous with well documented patterns of menthol cigarette smoking among certain population subgroups. For example, blacks had the lowest prevalence of menthol cigarette smoking among all race/ethnicity groups based on the type-only definition– a finding that contradicts a large body of scientific research [5, 7, 15]. The degree of bias with self-classified menthol status was especially high among blacks, Hispanics, females, middle school students, and smokers who do not buy their cigarettes.

Being the most stringent definition, the brand-type concordance definition had the largest number of excluded observations from discordant, indeterminate, or missing responses. The proportion of P30D smokers who did not have relevant information to classify them as menthol or nonmenthol smokers using the different

index definitions was 21.4% with the brand-type concordance definition; 15.6% using the brand and/or type definition, 3.3% using the type-only definition, and 2.2% using the extended definition. Regardless of definition however, smokers without information on menthol were *less likely* than those with such information of being established smokers, reporting a history of daily smoking, or showing symptoms of nicotine dependence. This suggests that prevalence estimates with current definitions are conservative estimates of true population menthol use prevalence considering that experimenters are more likely to smoke menthol cigarettes, which they use as starter products [9, 15-20]. The magnitude of this bias is likely to be small because of the modest amount of missing values, as well as the fact that prevalence of cigarette smoking overall is low among early adolescents, who are characterized by the identified smoking parameters, i.e., experimenters, nondaily smokers, and persons with low nicotine dependence [5].

These findings underscore the need for enhanced efforts to improve accuracy of youth menthol surveillance. The text-only format of menthol survey questions in NYTS coupled with the inability to disaggregate cigarette families— some of which have both menthol and nonmenthol varieties (e.g., Marlboro) [12, 21]— potentially increases likelihood of misclassification. Surveillance enhancements such as the use of skip patterns, more nuanced assessment of cigarette brands, as well as the use of illustrated questions that incorporate pictures with the text questions, could potentially mitigate extent of misclassification of menthol status. Conceivably, the impact of misclassification bias on surveillance estimates will likely be greatest for

brands with the biggest retail share, including Marlboro (40.5%), Newport (12.7%), and Camel (8.6%) [12].

Limitations

This study has several limitations. First, there is potential for misclassification of menthol use status in NYTS with the self-reported data. Specifically, the question of whether differences in reported menthol use status reflect differences in actual use, versus differences in willingness to report on menthol use status will be challenging to quantify precisely among demographic group with high rates of menthol acceptability and use (e.g., blacks) [23-26]. Second, analyses of discordant brand-type responses focused on only three brands that were exclusively menthol or nonmenthol (Newport, Kool, and Lucky Strike) since there was no way to definitively ascertain discordance for mixed brands. Third, NYTS collected information on 11 specific brands which account for ~70% of the market [12]. Hence, this study classified the response "Some other brand not listed here" as a mixed brand, potentially misclassifying certain brands not assessed in NYTS but which are either exclusively menthol (e.g., Salem), or nonmenthol (e.g., Old Gold, Viceroy, Kent, Winston) [7, 12]. The magnitude of this misclassification bias is however likely to be very small considering that with the exception of Viceroy (market share in 2014 ~ 2.3%), all the other brands listed above control a negligible share of the market [12]. Thus, the overwhelming majority of brands aggregated together as "Some other brand not listed here" are indeed mixed brands.

CONCLUSION

Definitions of menthol cigarette smoking that accounted for both self-classified and brand-designated menthol status (i.e., brand-type concordance and brand and/or type definitions) showed high internal validity and produced prevalence estimates that were in agreement with NSDUH. Self-classified menthol status alone yielded invalid estimates of menthol use because of misreporting. Future surveillance studies on youth menthol cigarette smoking should use a brand-adjusted definition such as the brand-type concordance definition, to reduce the magnitude of bias in reported prevalence, especially among groups with high rates of misclassification, such as blacks, Hispanics, females, middle school students, and smokers who do not buy their cigarettes.

REFERENCES

1. World Health Organization. Advisory note: banning menthol in tobacco products WHO Study Group on Tobacco Product Regulation (TobReg). Available at http://www.who.int/tobacco/publications/prod_regulation/menthol-advisory-note/en/. Accessed 09/17/2016.
2. WHO REPORT on the global TOBACCO epidemic, 2008-The MPOWER Package. Available at http://www.who.int/tobacco/mpower/mpower_report_full_2008.pdf Accessed September 13, 2016.
3. Ferris Wayne, G. and G.N. Connolly, *Application, function, and effects of menthol in cigarettes: a survey of tobacco industry documents.* Nicotine Tob Res, 2004. **6 Suppl 1**: p. S43-54.
4. Loomis, B. Trends in menthol cigarette sales, price, and promotion in the United States. 2010. Accessed at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsSci entificAdvisoryCommittee/UCM234655.pdf.
5. Caraballo, R.S. and K. Asman, *Epidemiology of menthol cigarette use in the United States.* Tob Induc Dis, 2011. **9 Suppl 1**: p. S1.

6. Federal Trade Commission. Federal Trade Commission Cigarette Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf.

7. Giovino, G.A., et al., *Differential trends in cigarette smoking in the USA: is menthol slowing progress?* Tob Control, 2015. **24**(1): p. 28-37.

8. Corey, C.G., et al., *Flavored Tobacco Product Use Among Middle and High School Students--United States, 2014.* MMWR.Morbidity and mortality weekly report, 2015. **64**(38): p. 1066-1070.

9. Hersey, J.C., J.M. Nonnemaker, and G. Homsi, *Menthol cigarettes contribute to the appeal and addiction potential of smoking for youth.* Nicotine Tob Res, 2010. **12 Suppl 2**: p. S136-46.

10. Muilenburg, J.L. and J.S. Legge, Jr., *African American adolescents and menthol cigarettes: smoking behavior among secondary school students.* J Adolesc Health, 2008. **43**(6): p. 570-5.

11. Yu, M., *Tobacco use among American Indian or Alaska Native middle- and high-school students in the United States.* Nicotine Tob Res, 2011. **13**(3): p. 173-81.

12. Euromonitor. (2015). Cigarettes in the US. Statistics retrieved March 23, from Euromonitor Passport Database.

13. Gelal A, Jacob P 3rd, Yu L, Benowitz NL. Disposition kinetics and effects of menthol. *Clinical Pharmacology & Therapeutics* 1999;66(2):128-35.

14. United States Census Bureau. School Enrollment: Current Population Survey 2011 – Detailed Tables. Available at http://www.census.gov/hhes/school/data/cps/2011/tables.html. Accessed 09/18/2016..

15. Hersey, J.C., et al., *Are menthol cigarettes a starter product for youth?* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2006. **8**(3): p. 403-413.

16. Klausner, K., *Menthol cigarettes and smoking initiation: a tobacco industry perspective.* Tobacco control, 2011. **20 Suppl 2**: p. ii12-9.

17. Kreslake, J.M. and V.B. Yerger, *Tobacco industry knowledge of the role of menthol in chemosensory perception of tobacco smoke.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S98-101.

18. Kreslake, J.M., et al., *Tobacco industry control of menthol in cigarettes and targeting of adolescents and young adults.* Am J Public Health, 2008. **98**(9): p. 1685-92.

19. Nonnemaker, J., et al., *Initiation with menthol cigarettes and youth smoking uptake.* Addiction, 2013. **108**(1): p. 171-8.

20. Wackowski, O. and C.D. Delnevo, *Menthol cigarettes and indicators of tobacco dependence among adolescents.* Addict Behav, 2007. **32**(9): p. 1964-9.

21. Federal Trade Commission. "TAR," NICOTINE, AND CARBON MONOXIDE OF THE SMOKE OF 1294 VARIETIES OF DOMESTIC CIGARETTES FOR

THE YEAR 1998. Available at https://www.ftc.gov/sites/default/files/documents/reports/2000-report-tar-nicotine-and-carbon-monoxide-covering-1998/1998tarnicotinereport_0.pdf.

22. Federal Register. Proposed Data Collection Submitted for Public Comment and Recommendations. Available at https://www.federalregister.gov/documents/2016/08/10/2016-18937/proposed-data-collection-submitted-for-public-comment-and-recommendations. Accessed 09/30/2016.

23. Landrine, H., et al., *Cigarette advertising in Black, Latino, and White magazines, 1998-2002: an exploratory investigation.* Ethnicity & disease, 2005. **15**(1): p. 63-67.

24. Anderson, S.J., *Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents.* Tob Control, 2011. **20 Suppl 2**: p. ii20-8.

25. Balbach, E.D., R.J. Gasior, and E.M. Barbeau, *R.J. Reynolds' targeting of African Americans: 1988-2000.* Am J Public Health, 2003. **93**(5): p. 822-7.

26. Healton, C.G., et al., *Prohibiting menthol in tobacco products: a policy whose time has come.* Addiction, 2010. **105 Suppl 1**: p. 5-7.

TABLES AND FIGURES

Table 2.1 Comparison of smoking prevalence derived from the index case definitions of menthol cigarette smoking status [a] versus the internal benchmark [b], overall and by selected demographic variables, NYTS 2009

			P30D	BTC	BAOT	Type	Extended
Overall		Menthol		6.60%	7.6%	9.30%	10.70%
		Nonmenthol		5.80%	5.50%	11.10%	10.40%
		Total	**12.00%**	**12.40%**	**13.3%**	**20.40%**	**21.10%**
Sex	**Male**	Menthol		6.90%	7.9%	9.20%	10.50%
		Nonmenthol		7.20%	6.90%	13.00%	12.40%
		Total	**13.40%**	**14.20%**	**15.1%**	**22.20%**	**22.90%**
	Female	Menthol		6.30%	7.3%	9.40%	10.90%
		Nonmenthol		4.30%	4.00%	9.10%	8.20%
		Total	**10.50%**	**10.50%**	**11.6%**	**18.50%**	**19.10%**
Race/Ethnicity	**White**	Menthol		6.80%	7.3%	9.40%	10.00%
		Nonmenthol		7.00%	6.70%	11.30%	10.90%
		Total	**13.10%**	**13.80%**	**14.3%**	**20.70%**	**21.00%**
	Black	Menthol		4.60%	6.9%	6.70%	9.70%
		Nonmenthol		1.20%	1.10%	8.70%	6.70%
		Total	**6.50%**	**5.80%**	**8.1%**	**15.40%**	**16.40%**
	Hispanic	Menthol		8.10%	9.8%	10.90%	13.60%
		Nonmenthol		6.10%	5.70%	13.40%	12.30%
		Total	**13.50%**	**14.20%**	**15.8%**	**24.40%**	**25.90%**
	Asian	Menthol		4.50%	4.6%	8.10%	8.40%
		Nonmenthol		3.30%	3.10%	5.80%	5.90%
		Total	**6.40%**	**7.80%**	**7.9%**	**13.90%**	**14.30%**
	Other	Menthol		13.00%	13.9%	20.30%	16.10%
		Nonmenthol		11.70%	10.40%	14.70%	19.30%
		Total	**26.70%**	**24.70%**	**25.4%**	**35.00%**	**35.40%**
	Multi-race	Menthol		13.00%	7.9%	20.30%	16.10%
		Nonmenthol		11.70%	10.40%	14.70%	19.30%
		Total	**26.70%**	**24.70%**	**14.1%**	**35.00%**	**35.40%**

Note: BTC =Brand-type concordance definition; BAOT = Brand and/or type definition; Type = Type only definition; Extended = Extended definition.

a For each of the index case definitions, overall prevalence of cigarette smoking was calculated as the sum of menthol and nonmenthol cigarette smoking prevalence.

b Defined as any response other than "0 days" to the question "During the past 30 days, on how many days did you smoke cigarettes?"

Table 2.2 Distribution of correct ("Yes"), incorrect ("No") and uncertain ("Not sure") self-classified menthol status among smokers of Newport and Kool brands, National Youth Tobacco Survey, 2011-2015

Characteristic	NEWPORT						KOOL					
	Yes, % (95% CI)	N	No, % (95% CI)	N	Not sure, % (95%CI)	N	Yes, % (95% CI)	N	No, % (95% CI)	N	Not sure, % (95%CI)	N
Overall	51.85 (48.53, 55.15)	1299	32.5 (29.78, 35.33)	916	15.66 (13.50, 18.09)	410	46.03 (38.91, 53.33)	110	26.38 (19.84, 34.15)	76	27.59 (20.53, 35.98)	63
Age, years												
≤ 12	27.92 (19.56, 38.14)	38	47.09 (37.37, 57.04)	64	24.99 (17.71, 34.04)	36	23.57 (10.04, 46.02)	7	36.97 (16.45, 63.61)	8	39.46 (18.23, 65.57)	8
13-14	35.73 (29.85, 42.09)	162	41.57 (35.51, 47.90)	223	22.69 (18.87, 27.03)	108	31.22 (17.21, 49.77)	16	31.81 (17.96, 49.86)	15	36.97 (20.31, 57.45)	18
15-16	51.2 (46.03, 56.34)	450	31.99 (27.88, 36.40)	306	16.81 (12.69, 21.94)	144	58.75 (47.33, 69.31)	47	22.67 (13.79, 34.94)	25	18.58 (10.98, 29.68)	15
≥17	61.19 (56.85, 65.37)	646	27.98 (24.70, 31.52)	320	10.83 (8.64, 13.50)	121	43.34 (30.70, 56.91)	39	25.02 (16.75, 35.62)	27	31.64 (19.17, 47.47)	22
Grade level												
6th	24.61 (16.74, 34.66)	32	44.9 (34.64, 55.62)	51	30.48 (21.91, 40.67)	34	30.93 (13.44, 56.34)	6	37.93 (17.79, 63.30)	7	31.15 (12.30, 59.33)	6
7th	29.16 (20.00, 40.40)	52	44.05 (35.00, 53.52)	95	26.78 (20.07, 34.77)	50	29.17 (9.78, 61.01)	4	35.13 (10.93, 70.50)	4	35.7 (14.22, 65.03)	7
8th	39.8 (29.46, 51.15)	102	32.54 (23.75, 42.76)	110	27.66 (15.47, 44.39)	55	33.14 (15.76, 56.76)	11	25.7 (10.90, 49.44)	9	41.16 (18.33, 68.56)	10
9th	48.7 (42.18, 55.25)	178	34.11 (28.72, 39.95)	142	17.19 (12.66, 22.92)	63	55.73 (38.74, 71.49)	20	23.65 (11.30, 42.96)	11	20.62 (10.70, 36.02)	10
10th	51.44 (45.59, 57.25)	235	35.49 (30.29, 41.05)	164	13.08 (9.78, 17.27)	71	55.2 (37.79, 71.42)	25	26.31 (14.88, 42.17)	15	18.49 (8.47, 35.74)	9
11th	59.26 (53.44, 64.83)	322	27.02 (22.56, 32.00)	160	13.72 (10.38, 17.93)	78	48.88 (30.09, 68.00)	22	18.48 (9.58, 32.67)	11	32.64 (14.44, 58.16)	8
12th	62.71 (57.44, 67.70)	371	28.59 (24.05, 33.60)	187	8.7 (6.26, 11.96)	53	41.86 (26.70, 58.73)	20	33.14 (20.39, 48.96)	18	25 (12.70, 43.30)	10
School level												
Middle School	33.59 (27.53, 40.25)	186	38.49 (31.99, 45.42)	256	27.92 (20.75, 36.42)	139	31.74 (19.39, 47.34)	21	31.27 (18.45, 47.78)	20	36.99 (22.00, 54.98)	23
High School	56.07 (52.34, 59.73)	1106	31.1 (28.23, 34.13)	653	12.83 (10.91, 15.03)	265	50.68 (42.80, 58.52)	87	25.39 (18.57, 33.69)	55	23.93 (16.44, 33.46)	37
Sex												
Male	55.9 (51.43, 60.29)	736	30.74 (27.01, 34.75)	461	13.36 (11.31, 15.71)	205	46.94 (38.22, 55.86)	62	29.2 (20.81, 39.30)	47	23.86 (16.43, 33.30)	33
Female	47.43 (43.32, 51.58)	555	34.59 (30.77, 38.63)	450	17.97 (14.45, 22.14)	200	44.74 (32.95, 57.15)	47	22.24 (14.64, 32.31)	28	33.01 (21.04, 47.68)	30
Race/ethnicity												
White, non-Hispanic	69.56 (64.99, 73.77)	552	21.15 (17.96, 24.75)	178	9.29 (6.62, 12.89)	66	51.68 (34.66, 68.32)	27	20.47 (11.44, 33.91)	14	27.84 (13.33, 49.20)	11
Black, non-Hispanic	30.63 (25.42, 36.39)	224	47.13 (42.59, 51.72)	374	22.24 (18.78, 26.13)	155	34.06 (19.77, 51.98)	16	44.21 (28.74, 60.90)	28	21.73 (9.14, 43.39)	8
Asian, non-Hispanic	44.63 (25.79, 65.16)	16	34.63 (19.25, 54.06)	12	20.74 (8.29, 43.08)	7	14.88 (3.36, 46.77)	2	63.27 (31.80, 86.43)	5	21.84 (6.32, 53.65)	3
Other, non-Hispanic	58.82 (49.73, 67.35)	115	29.42 (21.78, 38.43)	68	11.76 (7.51, 17.94)	33	34.91 (20.62, 52.54)	12	21.56 (9.23, 42.65)	8	43.53 (24.65, 64.49)	11
Hispanic	45.7 (41.36, 50.12)	352	35.36 (30.52, 40.52)	255	18.94 (14.59, 24.20)	128	55.33 (43.26, 66.80)	46	18.07 (10.83, 28.59)	19	26.6 (17.89, 37.62)	26
Past 30 days smoked												
1-2 days	40.51 (35.25, 45.99)	232	42.04 (36.65, 47.61)	255	17.46 (13.41, 22.40)	105	43.55 (29.79, 58.38)	23	26.8 (15.94, 41.41)	13	29.66 (16.69, 47.02)	15
3-5 days	57.79 (48.96, 66.14)	146	25.98 (19.79, 33.30)	91	16.23 (11.52, 22.38)	46	51.91 (28.41, 74.59)	9	21.97 (7.77, 48.48)	5	26.12 (7.77, 59.75)	3
6-9 days	62.24 (52.08, 71.43)	99	24.24 (16.63, 33.91)	43	13.52 (8.59, 20.64)	23	71.21 (42.46, 89.24)	9	26.38 (9.51, 54.98)	8	2.41 (0.30, 16.70)	1
10-19 days	73.33 (62.51, 81.93)	148	20.84 (13.03, 31.64)	37	5.82 (3.00, 10.99)	15	56.57 (35.02, 75.90)	13	16.1 (5.15, 40.42)	5	27.32 (11.95, 51.02)	5
20-29 days	78.96 (72.15, 84.47)	135	13.26 (8.95, 19.21)	30	7.77 (4.39, 13.39)	16	69.92 (30.46, 92.50)	6	25.4 (5.28, 67.51)	2	4.68 (0.57, 29.71)	1
All 30 days	79.35 (73.75, 84.01)	372	15.77 (12.24, 20.08)	75	4.88 (2.90, 8.10)	24	64.68 (48.18, 78.29)	25	17.48 (8.34, 33.01)	8	17.85 (8.24, 34.44)	7
Total cigarettes smoked in lifetime												
1 or more puffs only	13.96 (9.77, 19.54)	46	59.45 (52.04, 66.45)	195	26.6 (20.68, 33.49)	91	32.31 (14.89, 56.55)	8	33.08 (17.62, 53.34)	15	34.61 (15.25, 60.90)	9
1 cigarette	16.39 (9.85, 26.03)	25	48.31 (35.16, 61.71)	61	35.29 (21.93, 51.43)	31	22.21 (5.25, 59.54)	3	37.31 (10.54, 75.04)	5	40.48 (8.32, 83.59)	2
2-5 cigarettes	24.73 (18.99, 31.52)	99	46.35 (39.46, 53.40)	196	28.92 (21.71, 37.38)	98	39.92 (22.33, 60.55)	13	35.34 (18.47, 56.87)	12	24.74 (11.90, 44.45)	10
1/2 pack	45.81 (39.21, 52.55)	126	40.01 (33.45, 46.95)	126	14.18 (10.46, 18.95)	49	51.96 (32.42, 70.91)	14	12.41 (4.31, 30.83)	5	35.64 (18.09, 58.12)	6
1 pack	50.81 (42.97, 58.60)	96	33.85 (26.54, 42.01)	78	15.34 (10.52, 21.84)	32	41.16 (18.60, 68.17)	7	44.4 (19.35, 72.65)	5	14.45 (4.89, 35.67)	5
<5 packs	62.41 (55.82, 68.56)	212	26.19 (20.92, 32.25)	97	11.41 (8.02, 15.97)	40	44.65 (23.39, 68.07)	11	29.89 (13.46, 53.90)	9	25.46 (9.95, 51.35)	5
≥5 packs	82.25 (78.16, 85.72)	667	13.82 (11.07, 17.11)	117	3.93 (2.53, 6.07)	36	64.67 (51.94, 75.61)	41	18.45 (10.60, 30.14)	13	16.88 (9.12, 29.14)	11

Note: Estimates based on <30 persons are imprecise because of inflated relative standard errors. CI=confidence interval

Table 2.3 Distribution of responses of "Yes", "No" and "Not sure" for cigarette type among smokers of Marlboro and Camel brands, National Youth Tobacco Survey, 2011-2015

	MARLBORO						CAMEL					
Characteristic	**Yes, % (95%CI)**	**N**	**No, % (95%CI)**	**N**	**Not sure, % (95%CI)**	**N**	**Yes, % (95%CI)**	**N**	**No, % (95%CI)**	**N**	**Not sure, % (95%CI)**	**N**
Overall	34.64 (32.30, 37.05)	1345	56.43 (54.04, 58.79)	2100	8.93 (7.86, 10.13)	389	51.96 (48.43, 55.48)	748	37.06 (33.63, 40.63)	519	10.97 (8.88, 13.48)	166
Age, years												
≤ 12	25.68 (18.12, 35.05)	44	55.87 (45.92, 65.37)	93	18.45 (11.22, 28.81)	33	45.13 (28.85, 62.52)	34	32.26 (19.67, 48.10)	33	22.61 (13.75, 34.88)	31
13-14	29.4 (24.89, 34.36)	199	53.5 (48.11, 58.82)	371	17.1 (13.49, 21.43)	122	34.96 (29.23, 41.16)	100	38.35 (30.84, 46.47)	110	26.69 (20.03, 34.60)	63
15-16	34.59 (30.96, 38.41)	467	56 (52.19, 59.75)	695	9.41 (7.70, 11.44)	132	55.7 (49.97, 61.29)	273	36.11 (30.26, 42.42)	166	8.18 (5.73, 11.56)	48
≥17	37.45 (34.44, 40.56)	631	57.82 (54.78, 60.81)	930	4.72 (3.74, 5.95)	101	58.01 (52.46, 63.36)	336	38.4 (33.06, 44.02)	205	3.6 (2.09, 6.12)	20
Grade level												
6th	22.5 (14.06, 34.00)	39	53.36 (38.64, 67.52)	70	24.14 (14.69, 37.03)	31	36.4 (18.75, 58.66)	23	35.8 (22.67, 51.49)	26	27.8 (16.47, 42.91)	28
7th	33.95 (25.71, 43.29)	71	47.77 (39.18, 56.50)	120	18.28 (12.35, 26.21)	48	38.83 (26.73, 52.47)	36	33.6 (20.19, 50.32)	44	27.57 (17.09, 41.28)	24
8th	32.04 (25.75, 39.06)	108	50.14 (43.56, 56.70)	187	17.82 (13.43, 23.26)	65	34.99 (27.26, 43.60)	60	43.35 (33.34, 53.95)	61	21.65 (14.95, 30.29)	35
9th	30.27 (25.26, 35.81)	167	56.29 (50.62, 61.80)	293	13.43 (10.28, 17.36)	74	46.35 (37.56, 55.38)	78	38.83 (30.63, 47.73)	69	14.82 (9.35, 22.67)	27
10th	35.79 (31.22, 40.63)	251	57.16 (52.37, 61.83)	357	7.05 (4.94, 9.97)	51	64.05 (56.06, 71.32)	157	29.86 (22.35, 38.64)	75	6.09 (3.64, 10.01)	18
11th	35.93 (31.27, 40.86)	298	58.04 (53.29, 62.65)	475	6.03 (4.64, 7.80)	64	50.11 (42.86, 57.34)	159	45.13 (38.02, 52.45)	119	4.76 (2.56, 8.70)	13
12th	37.04 (33.47, 40.76)	391	59.03 (55.37, 62.59)	586	3.94 (2.89, 5.34)	53	61.02 (54.01, 67.60)	223	34.93 (28.34, 42.16)	120	4.05 (2.14, 7.52)	14
School level												
Middle School	30.7 (26.07, 35.76)	218	50.03 (44.88, 55.19)	377	19.27 (15.62, 23.54)	144	36.5 (29.65, 43.96)	119	38.71 (30.67, 47.41)	131	24.79 (18.83, 31.90)	87
High School	35.24 (32.65, 37.92)	1107	57.84 (55.28, 60.37)	1711	6.91 (5.96, 8.01)	242	56.61 (52.55, 60.57)	617	36.93 (33.05, 41.00)	383	6.46 (4.83, 8.59)	72
Sex												
Male	33.68 (30.87, 36.61)	749	58.33 (55.35, 61.25)	1226	7.99 (6.80, 9.37)	211	50.04 (45.42, 54.66)	419	38.5 (34.18, 43.02)	299	11.46 (8.85, 14.70)	95
Female	36.15 (32.72, 39.73)	592	53.77 (50.22, 57.28)	859	10.08 (8.36, 12.11)	176	55.48 (50.49, 60.36)	324	35.08 (30.41, 40.05)	214	9.44 (6.96, 12.70)	67
Race/ethnicity												
White, non-Hispanic	34.31 (31.48, 37.26)	783	59.14 (56.16, 62.05)	1276	6.55 (5.36, 7.98)	155	53.63 (48.34, 58.84)	356	39.33 (33.95, 44.98)	249	7.04 (4.86, 10.12)	44
Black, non-Hispanic	35.35 (22.93, 50.12)	42	49.71 (36.87, 62.58)	66	14.94 (9.14, 23.48)	19	37.03 (24.46, 51.63)	22	48.42 (33.41, 63.72)	29	14.55 (5.28, 34.23)	9
Asian, non-Hispanic	30.62 (19.95, 43.87)	25	53.51 (40.63, 65.94)	41	15.87 (7.54, 30.38)	10	43 (25.42, 62.55)	18	42.04 (24.27, 62.15)	12	14.95 (5.09, 36.55)	4
Other, non-Hispanic	36.35 (29.92, 43.30)	115	56.26 (49.33, 62.95)	173	7.39 (5.07, 10.66)	32	55.61 (43.86, 66.76)	64	32.63 (22.48, 44.73)	41	11.76 (6.05, 21.64)	17
Hispanic	36.46 (32.83, 40.26)	339	48.99 (45.54, 52.46)	488	14.54 (11.92, 17.62)	156	51.85 (46.16, 57.49)	271	32.69 (27.39, 38.48)	175	15.45 (11.50, 20.46)	83
Past 30 days smoked												
1-2 days	30.44 (26.77, 34.38)	270	56.85 (52.75, 60.87)	474	12.71 (10.07, 15.90)	128	49.55 (42.55, 56.58)	181	37.39 (30.68, 44.62)	123	13.05 (8.56, 19.41)	51
3-5 days	34.65 (28.98, 40.80)	158	58.28 (52.10, 64.22)	227	7.06 (4.89, 10.10)	39	70.14 (61.27, 77.71)	104	26.09 (18.82, 34.95)	46	3.78 (1.74, 8.00)	11
6-9 days	45.67 (39.18, 52.31)	126	44.77 (38.21, 51.52)	134	9.56 (5.79, 15.39)	27	64.12 (50.10, 76.08)	63	30.71 (19.63, 44.58)	30	5.18 (2.16, 11.87)	7
10-19 days	46.03 (39.12, 53.10)	165	49.5 (42.54, 56.48)	190	4.47 (2.35, 8.33)	15	61.73 (51.31, 71.17)	92	31.99 (23.02, 42.52)	45	6.29 (2.52, 14.82)	9
20-29 days	46.22 (38.07, 54.57)	157	50 (41.77, 58.24)	148	3.78 (1.84, 7.61)	12	65.05 (53.70, 74.92)	57	34.39 (24.62, 45.68)	32	0.56 (0.08, 4.01)	1
All 30 days	39.21 (34.66, 43.96)	283	58.05 (53.32, 62.63)	366	2.74 (1.74, 4.29)	26	67.22 (58.61, 74.81)	122	26.52 (19.44, 35.06)	50	6.26 (3.25, 11.71)	13
Total cigarettes smoked in lifetime												
1 or more puffs only	13.46 (9.23, 19.22)	39	65.01 (57.80, 71.60)	196	21.53 (16.20, 28.02)	67	27.47 (17.84, 39.79)	34	56.95 (46.07, 67.20)	68	15.57 (9.14, 25.27)	28
1 cigarette	11.3 (6.45, 19.07)	19	71.12 (60.41, 79.90)	76	17.58 (11.17, 26.57)	26	42.61 (29.01, 57.42)	27	39.59 (26.43, 54.45)	27	17.81 (8.39, 33.89)	14
2-5 cigarettes	26.49 (20.42, 33.61)	122	56.7 (49.96, 63.20)	268	16.81 (13.10, 21.31)	90	33.32 (26.14, 41.36)	81	45.09 (36.82, 53.64)	93	21.6 (14.80, 30.40)	46
1/2 pack	32.78 (27.68, 38.32)	130	56.94 (51.41, 62.31)	218	10.28 (7.16, 14.55)	50	43.34 (32.26, 55.14)	73	45.34 (34.70, 56.43)	65	11.31 (6.04, 20.21)	19
1 pack	36.41 (30.30, 42.99)	121	54.84 (47.99, 61.50)	175	8.75 (5.65, 13.31)	33	62.9 (52.00, 72.64)	85	27.86 (20.26, 36.99)	46	9.24 (4.05, 19.70)	11
<5 packs	40.3 (35.41, 45.40)	240	51.72 (46.73, 56.68)	293	7.97 (5.52, 11.39)	44	68.79 (60.59, 75.96)	156	25.4 (19.22, 32.77)	64	5.81 (2.52, 12.82)	14
≥5 packs	40.75 (37.15, 44.44)	651	56.03 (52.44, 59.55)	831	3.23 (2.36, 4.41)	57	63.36 (56.99, 69.30)	271	32.61 (26.74, 39.07)	129	4.03 (2.33, 6.90)	18

Note: Estimates based on <30 persons are imprecise because of inflated relative standard errors. CI=confidence interval

Table 2.4 Multivariable logistic regression analyses of determinants of brand-type discordance (misclassified menthol status), NYTS, 2011-2015 (n = 1,011)

Characteristics	**aOR (95% CI)**	***p*-value Wald F**
Race/ethnicity		<0.001
White, non-Hispanic	1.00 (referent)	
Black, non-Hispanic	16.85 (12.87-22.07)	
Other, non-Hispanic	2.79 (2.00-3.89)	
Hispanic	3.05 (2.35-3.97)	
Gender		<0.001
Male	0.65 (0.53-0.80)	
female	1.00 (referent)	
School level		0.009
Middle school	1.00 (referent)	
High school	0.73 (0.58-0.92)	
Total cigarettes smoked in lifetime		<0.001
≤1 cigarette	1.00 (referent)	
2-5 cigarettes	0.73 (0.53-0.99)	
1/2 pack	0.51 (0.37-0.7)	
1 pack	0.40 (0.27-0.59)	
<5 packs	0.30 (0.21-0.42)	
≥5 packs	0.18 (0.13-0.24)	
Usual source of getting tobacco		<0.001
Did not buy (other means)	1.00 (referent)	
Bought their tobacco products	0.57 (0.46-0.69)	
Age, years		<0.001
≤ 12	1.00 (referent)	
13-14	0.94 (0.63-1.41)	
15-16	0.78 (0.52-1.18)	
≥17	0.56 (0.38-0.84)	

Brand / Type	No past 30-day smoking	Exclusive Menthol brand	Exclusive Non menthol brand	Mixed brand	No usual brand	Missing	Total
No past 30-day smoking	**A** **16,912** 76.54%	**B** **32** 0.18%	**C** **2** 0.00%	**D** **105** 0.53%	**E** **55** 0.18%	**F** **251** 1.04%	**17,357** 78.47%
Menthol cigarette	**G** **625** 2.56%	**H** **576** 2.38%	**I** **6** 0.08%	**J** **847** 3.39%	**K** **129** 0.45%	**L** **105** 0.33%	**2,288** 4.43%
Non menthol cigarette	**M** **1,032** 3.88%	**N** **245** 0.97%	**O** **13** 0.05%	**P** **1,164** 5.01%	**Q** **188** 0.82%	**R** **61** 0.24%	**2,703** 10.96%
Missing	**S** **140** 0.52%	**T** **20** 0.11%	**U** **0** 0.00%	**V** **45** 0.19%	**W** **15** 0.09%	**X** **111** 0.48%	**331** 1.38%
Total	**18,709** 83.51%	**873** 3.63%	**21** 0.13%	**2,161** 9.11%	**387** 1.54%	**528** 2.09%	**22,679** 100%

Figure 2.1 Samples and percentages for different definitions of menthol use status, National Youth Tobacco Survey, NYTS 2009

Note: Current shading represents the extended definition, black = menthol; grey = nonmenthol.
Brand-type concordance definition: Menthol users = cells H and J; nonmenthol users= cells O and P
Brand and/or type definition: Menthol users = cells H, J, and N; nonmenthol users= cells O, and P;
Type-only definition: Menthol users = cells G, H, I, J, K, and L; nonmenthol users= cells M, N, O, P, Q, and R
Extended definition: Menthol users = cells B, H, N, T, G, J, K, and L; nonmenthol users = cells C, I, O, U, M, P, Q, and R

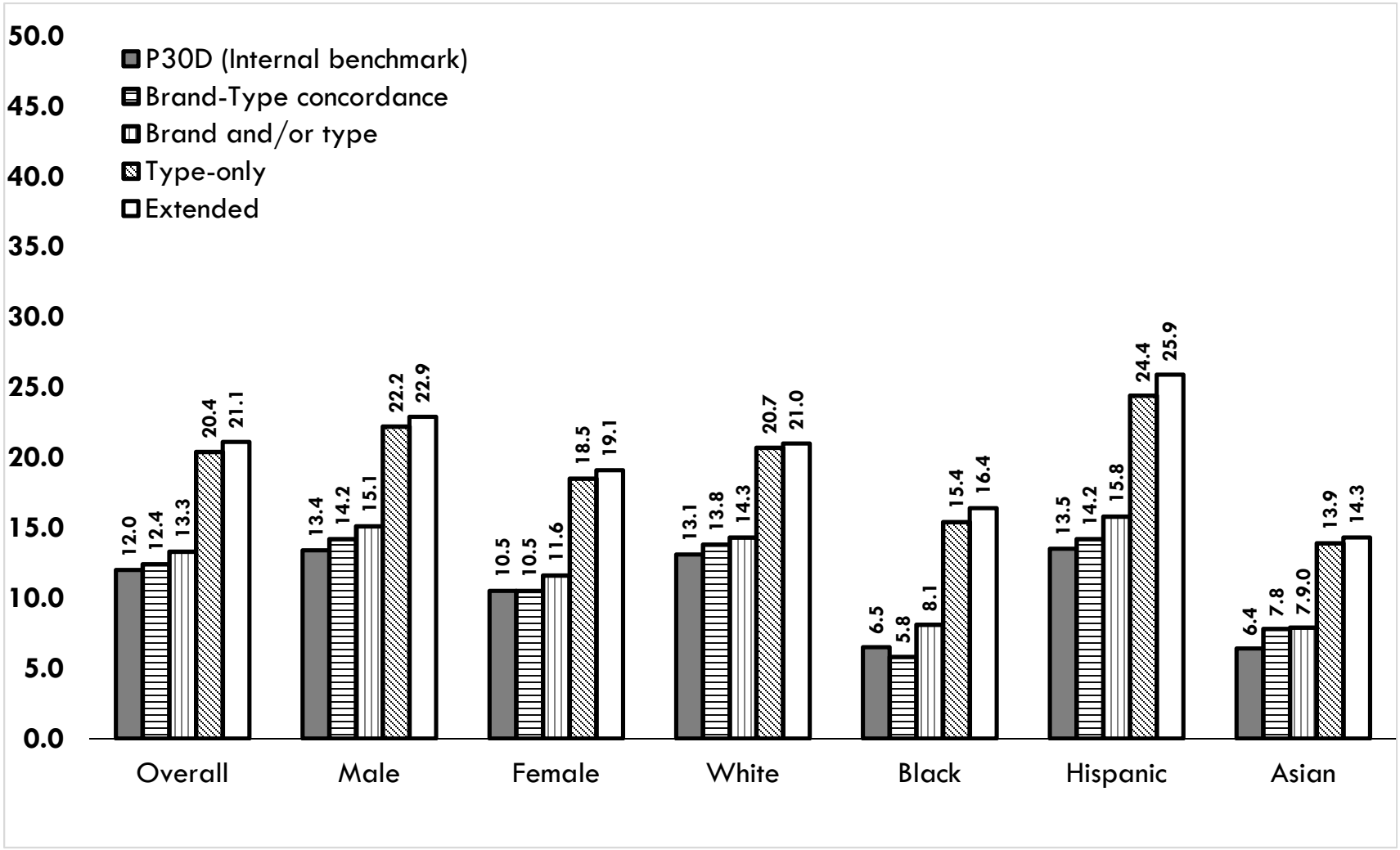

Figure 2.2 Cigarette smoking prevalence estimates derived from the index case definitions of menthol cigarette smoking versus the internal benchmark (standard past 30-day measure of current smoking, P30D), overall and by selected demographic variables, NYTS 2009

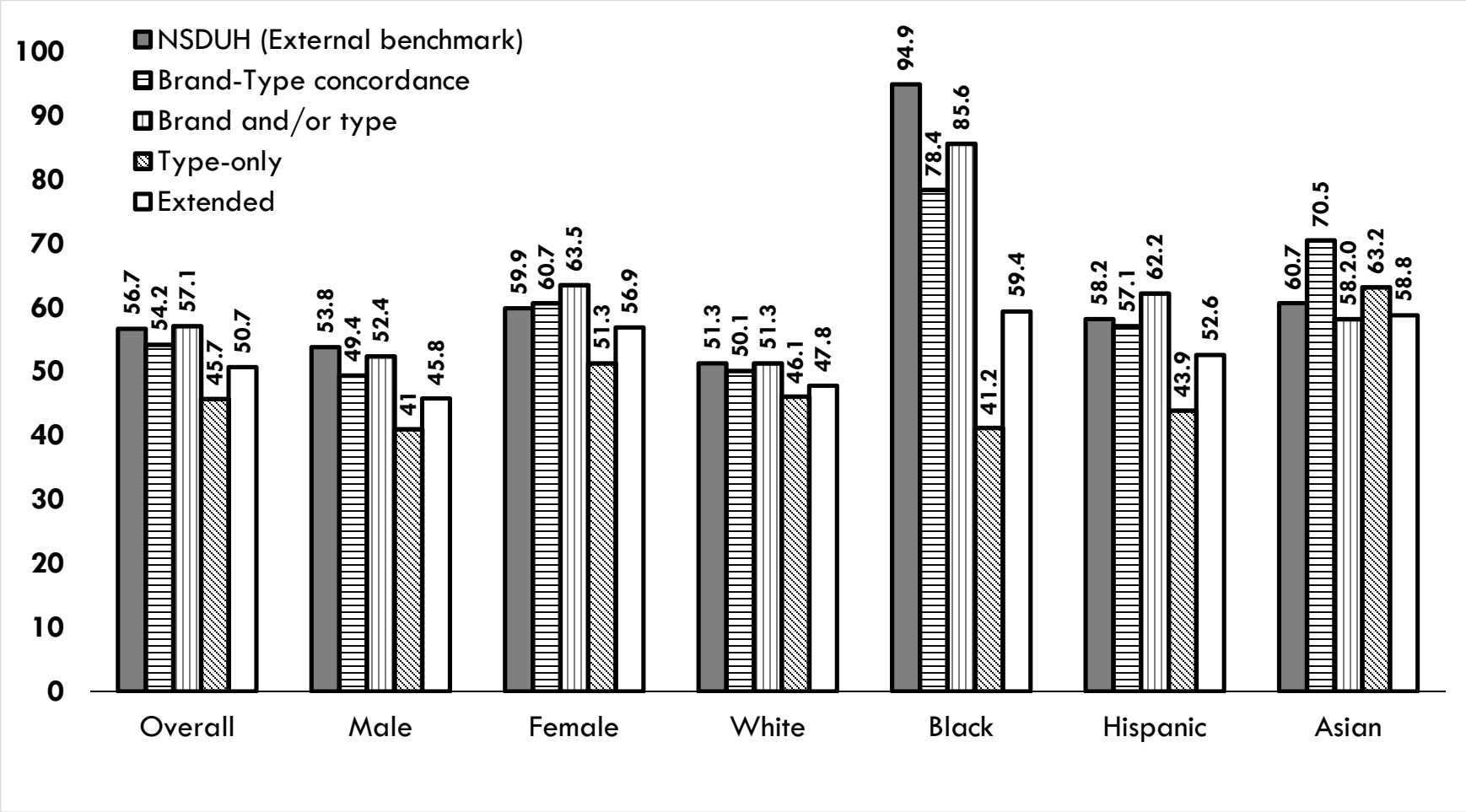

Figure 2.3 Percentage of past 30-day cigarette smokers that used menthol cigarettes as calculated from the index case definitions of menthol cigarette smoking in 2009 NYTS versus the external benchmark 2008-2010 National Survey on Drug Use and Health, NSDUH), overall and by selected demographic variables

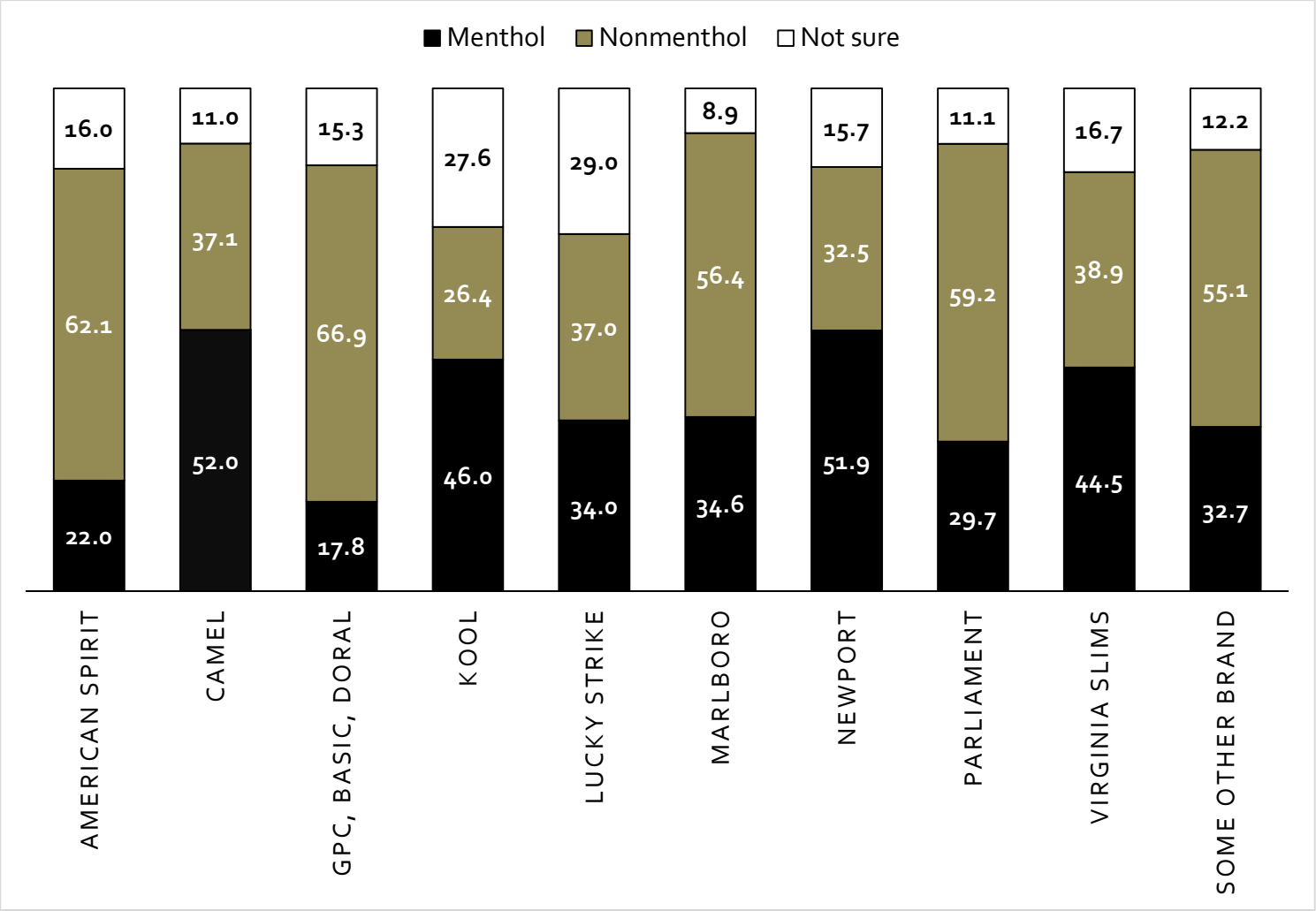

Figure 2.4 Cross tabulation of self-classified menthol status and brand usually smoked, National Youth Tobacco Survey, 2011-2015

Chapter 3 - TRENDS IN MENTHOL AND NONMENTHOL CIGARETTE SMOKING AMONG U.S. MIDDLE AND HIGH SCHOOL STUDENTS[2]

[2] Agaku IT, Dobbin K, Muilenburg J, Hallow K, et al. To be submitted to *Pediatrics*.

ABSTRACT

BACKGROUND: The U.S. cigarette market has evolved in recent years, with introduction of several new menthol brands by leading cigarette manufacturers such as RJ Reynolds and Phillip Morris. Menthol cigarette smoking surveillance among youth is critical to identify emerging trends and disparities for evidence-based public health practice, policies and programs at national, state and local levels. No previous study has analyzed national temporal trends or state-specific prevalence of menthol cigarette smoking among U.S. middle and high school students. This study measured temporal, geographic, and demographic patterns of menthol cigarette smoking among 6-12th graders during 2011-2016.

METHODS: National data were from the 2011-2015 National Youth Tobacco Survey; state-specific data were from the 2012-2016 Youth Tobacco Survey (22 states). Target population for both surveys comprised 6-12th graders in public and private schools. Menthol cigarette smoking was defined using the brand-type concordance definition. Trends during 2011-2015 were measured using orthogonal polynomials in a logistic regression model, adjusting for school level, sex, and race/ethnicity. Multivariable logistic regression was used to explore correlates of menthol smoking among a national sample of current cigarette smokers.

RESULTS: Among all 6-12th graders nationally, declines occurred in menthol (6.1% to 3.1%) and nonmenthol (5.1% to 3.4%) cigarette smoking during 2011-2015 (all p-trend<0.05); no significant change however occurred in menthol

use among current cigarette smokers (54.3% to 47.9%). State-specific prevalence estimates of menthol use among current cigarette smokers ranged from 29.07% (Illinois) to 65.44% (Mississippi) among middle-schoolers; and from 40.51% (Ohio) to 72.74% (South Carolina) among high-schoolers. The strongest predictor of menthol use among current cigarette smokers was being black compared to white (aOR=3.19; 95%CI=1.31-7.82). Odds of menthol use were also higher among current smokers reporting a health condition (aOR=1.51), exhibiting truant behavior (aOR=1.37), purchasing their own tobacco products (aOR=1.75), having high nicotine dependence (aOR=1.72), and reporting exposure to pro-tobacco advertisements (aOR=2.07) (all $p<0.05$).

CONCLUSION: Although smoking prevalence declined significantly for both menthol and nonmenthol cigarettes among all students, the proportion of current cigarette smokers reporting menthol use remained unchanged and disparities persisted. Barrier-free clinical cessation counseling, increased tobacco prices and restrictions on pro-tobacco marketing could help reduce these disparities.

INTRODUCTION

Cigarette sensory characteristics (e.g., taste, smell, or visual stimuli) can reinforce smoking behavior and enhance nicotine self-administration [1-4]. Menthol as a cigarette additive is more than just a flavor; menthol is involved with neurobiological processes that trigger reward pathways in the brain through quick dopamine release [5, 6]. Menthol also exerts a range of sensory effects on the airways such as anesthesia, cooling, and smoothing, thus masking the harshness of tobacco smoke and increasing appeal and ease of smoking among naïve smokers [7-11]. Menthol cigarettes are very attractive to youth [12, 13], and their use is higher among adolescents than among adults [14]. Menthol cigarettes serve as starter products for youth and can increase the likelihood of smoking initiation and nicotine addiction [10, 15-17].

As cigarette manufacturers have steadily lowered cigarette tar levels over the past decades in response to negative public perception about tar exposure and the attendant health risks, menthol cigarettes have increasingly occupied a larger share of the U.S. cigarette market, from 16% in 1963 to 31% in 2013 [18]. This increase in menthol market share comes despite a decrease in overall cigarette consumption within the U.S. over the past decade [19, 20]. Most cigarette brands on the U.S. market contain a menthol variety and some of the leading brands are primarily menthol, including Newport, Marlboro Menthol, and Kool [21, 22]. Cigarettes designed as menthol brands are more likely to have low tar levels (<15mg); be filtered; be “slim”; be long or ultra-long; and be packaged in soft packs

[23]– design features that appeal to specific population niches including females, and youth [24, 25]. The tobacco industry has long targeted blacks in particular with menthol cigarettes [10, 26].

The FDA's Tobacco Products Scientific Advisory Committee (TPSAC) concluded that on a population level, menthol cigarette marketing increases cigarette smoking prevalence beyond anticipated prevalence if such cigarettes were not available for the whole population, and for youth and African Americans [13]. TPSAC and several other health organizations including the American Academy of Pediatrics, the World Health Organization Study Group on Tobacco Product Regulation, and the African American Tobacco Control Leadership Council, have called for the removal of menthol cigarettes from the marketplace to protect youths [13, 27, 28, 29]. In view of the adverse effects of menthol cigarettes on public health, several countries have passed varying laws prohibiting or restricting menthol cigarettes, including the European Union member states, Australia, Brazil, Chile, Ethiopia, Moldova, Turkey, and several Canadian provinces (Nova Scotia, Alberta, Ontario, Quebec and New Brunswick) [30, 31].

As FDA considers new scientific information regarding menthol cigarettes to help guide regulation of menthol cigarettes in the U.S. [32], continued surveillance of trends in menthol cigarette smoking among youth is necessary to identify emerging usage patterns and inform tobacco prevention and control efforts at national, state, and local levels. Data from the 2004-2010 National Survey on Drug Use and Health (NSDUH) showed no significant change in menthol cigarette

smoking among youth aged 12-17 years despite a significant decrease in nonmenthol cigarette use within this age group [14, 33]. There is paucity of more recent data describing trends and subgroup variations in menthol cigarette use among U.S. adolescents. Among U.S. students in grades 6-12 in particular, no study has analyzed temporal trends in menthol cigarette smoking because of a series of modifications in the questions used to measure menthol cigarette smoking within the National Youth Tobacco Survey (NYTS), rendering measurement of long-term trends impossible (slightly different questions were fielded during 1999-2002; 2004-2009; and 2011-2015) [34]. In addition, no study to date has analyzed state-specific prevalence of menthol cigarette smoking among U.S. youth. To fill these gaps in knowledge, this study measured recent prevalence, trends and determinants of menthol and nonmenthol cigarette smoking among U.S middle and high school students nationally. State-specific prevalence estimates of menthol cigarette smoking were also analyzed among US middle and high school students in 22 states with available data.

METHODOLOGY

Data sources

Nationally representative data were from five waves (2011-2015) of the NYTS, a cross-sectional, school-based, self-administered, survey of U.S. students in grades 6–12. NYTS' universe includes public and private schools in the 50 U.S. States and D.C. The survey uses a probabilistic, three-stage sampling design

comprising primary sampling units (counties), schools, and classes. Sample sizes (n) and overall response rates (%) were: 2011 (n=18,866; 72.7%); 2012 (n=24,658; 73.6%); 2013 (n=18,406; 67.8%); 2014 (n=22,007; 73.3%); 2015 (n=17,711; 63.4%).

State-specific data were from the Youth Tobacco Survey (YTS), which like NYTS, is a cross-sectional, school-based, self-administered, survey of U.S. students in middle and high school (a few states have data for only one school level, middle or high). YTS questions are standardized and the core questions are identical to NYTS thus allowing for direct comparisons of state-specific prevalence estimates to each other, as well as to nationally. The survey uses a probabilistic, two-stage sampling design comprising schools and classes. During 2012-2016, YTS data were available for the following 22 states: Arizona, Connecticut, Georgia, Hawaii, Illinois, Indiana, Kansas, Louisiana, Minnesota, Mississippi, North Carolina, North Dakota, Nebraska, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Wisconsin, and West Virginia. Sample sizes ranged from 950 (Kansas) to 4,688 (Illinois) among middle school students, and from 962 (Ohio) to 4,556 (Illinois) among high school students.

Measures

Menthol Cigarette smoking status

Because self-classified menthol status is subject to misreporting [12], menthol cigarette smoking status was defined based on concordance between respondents' report of their usual cigarette *type* and their usual cigarette *brand*. The cigarette

type question was “Menthol cigarettes are cigarettes that taste like mint. During the past 30 days, were the cigarettes that you usually smoked menthol?” Response options were: “I did not smoke cigarettes during the past 30 days”; “Yes”; “No”; or “Not sure”. The cigarette brand question was “During the past 30 days, what brand of cigarettes did you usually smoke? (CHOOSE ONLY ONE ANSWER)”. The brands surveilled in NYTS were classified into three categories based on their market shares for menthol and nonmenthol cigarettes [22]. (1) Exclusively nonmenthol brands (Lucky Strike) (2) Exclusively menthol brands (Newport, and Kool). (3) Mixed brands (American Spirit; Camel; GPC, Basic, Doral; Marlboro; Parliament; Virginia Slims, and ‘some other brand not listed here’[the majority of brands not referenced in NYTS are available in both menthol and nonmenthol varieties]) [22].

Menthol smokers were those who smoked an exclusively menthol or mixed brand, *and* reported that their cigarette type was menthol. Nonmenthol smokers were those who smoked an exclusively nonmenthol or mixed brand *and* reported that their cigarette type was nonmenthol. Missing, indeterminate (e.g., “not sure”), or discordant brand-type responses were excluded. To reduce misclassification, persons who reported they smoked “no usual brand” were excluded since this could imply smoking different brands either within the same, or across different menthol designations.

Other tobacco-related characteristics

Tobacco-related variables included time to first cigarette on waking (proxy for nicotine dependence), number of days smoked in past 30 days; estimated number of cigarettes smoked in lifetime (proxy for smoking duration), past-year quit attempt, intention to quit smoking, and perception all tobacco products are dangerous. Frequent (i.e., "Sometimes"/ "Most of the time"/ "Always" vs "Never"/ "Rarely") exposure to pro-tobacco advertisements on four media —Internet, newspapers/magazines, retail stores, and TV/movies—was measured and a composite variable created as the sum of distinct exposure sources reported by each respondent (range: 0-4).

Socio-demographic and lifestyle Characteristics

Socio-demographic characteristics were age, sex, race/ethnicity, school level, and grade. Considering that cigarette manufacturers have marketed menthol cigarettes by highlighting certain themes such as success, "acceptable rebellion", risk taking, and healthfulness [16, 35-37], these constructs were measured as possible correlates of menthol cigarette use. Usual source of obtaining cigarettes (i.e., purchase vs. social sources e.g., friends) was used as a proxy for disposable income. Past 30-day truant behavior was used as a proxy for rebelliousness; students were said to have exhibited truant behavior if they reported they missed "at least one class period because [they] skipped or "cut" or just did not want to be there". Students were classified as having a health condition if they reported

"serious difficulty concentrating, remembering, or making decisions" because of "a physical, mental, or emotional condition".

Hypotheses

Three null hypotheses were tested: (1) There was no change in the trend for smoking of menthol or nonmenthol cigarettes among U.S. middle and high school students during 2011-2015 (2) The trend slopes for menthol and nonmenthol cigarettes did not differ during 2011-2015 (3) There were no subgroup variations in menthol cigarette smoking among U.S. middle and high school students.

Analyses

All data were weighted to yield state-specific or nationally representative estimates as appropriate. State-specific prevalence estimates were calculated separately for middle and high school students per YTS sampling design. To measure national trends, relative and annual percentage changes, as well as adjusted linear and quadratic trends were computed, both among all students overall, as well as among current cigarette smokers. Relative percentage change (RPC) describes the absolute change in prevalence between the first and last year expressed as a percentage of the first year. Annual percentage change (APC) describes the rate at which the prevalence changes per year during the entire study period under the assumption of constant change. A linear trend describes a monotonically increasing or decreasing prevalence, which can be modelled with a straight line. A quadratic trend describes a curvilinear change; the coefficient of a

quadratic trend describes both the direction and steepness of the curvature (a positive value indicates an upwards curvature while a negative value indicates a downwards curvature). APCs were computed using Joinpoint regression. Estimates of linear and quadratic trend were calculated using orthogonal polynomials in a binary logistic regression model controlling for school level, sex, and race/ethnicity to account for population changes during the study period. The Z-statistic below was used to test the null hypothesis that the difference between two given slopes (β_1, β_2) was equal to zero using the standard errors (SE) of the respective slopes.

$$Z=\frac{\beta_1-\beta_2}{\sqrt{SE.\beta_1{}^2+SE.\beta_2{}^2}}$$

Within-group differences in prevalence were tested using a standard chi-squared test for nominal variables and a trend test for ordinal variables. Exploratory multivariable logistic regression analyses were performed to measure predictors of menthol cigarette use among current cigarette smokers using 2015 NYTS data (previous survey iterations did not have information on several measures of interest). The independent variables of interest were school level, race/ethnicity, sex, time to first cigarette on waking, presence of a health condition, past-year quit attempt, perceived harm of all tobacco products, truant behavior, disposable income, and exposure to pro-tobacco advertisements. Because of relatively high (>0.3) polychoric correlation between several independent variable pairs, separate logistic regression models were iteratively fitted for the different independent variables, adjusting each model for school level, race/ethnicity and sex

as appropriate. All data analyses were performed using R V.3.2.3 and NCI's Joinpoint V.4.0.1 software.

RESULTS

Table 3.1 shows the distribution of study participants in NYTS during 2011-2015. Most of the study participants were non-Hispanic white and in high school. The distribution of genders was roughly equal across years.

State-specific prevalence of menthol cigarette smoking, YTS 2012-2016

State-specific prevalence estimates of menthol use are shown separately for middle and high school students in Table 3.2. Among high school students, prevalence of current cigarette smoking ranged from 7.31% (New York) to 17.45% (Louisiana). As shown in Figure 3.1, the proportion of high school current cigarette smokers who smoked menthol cigarettes ranged from 40.51% (Ohio) to 72.74% (South Carolina) with a median of 55.57% among all states with available data.

Among middle school students, prevalence of current cigarette smoking ranged from 0.83% (Connecticut) to 5.23% (Louisiana). As shown in Figure 3.2, the proportion of middle school current cigarette smokers who smoked menthol cigarettes ranged from 29.07% (Illinois) to 65.44% (Mississippi) with a median of 41.12% among all states with available data.

National Trends in Menthol and nonmenthol cigarette smoking among all students, NYTS 2011-2015

Table 3.3 shows trends in menthol and nonmenthol cigarette smoking among all U.S. middle and high school students. A significant linear decline was observed during 2011-2015 in overall menthol cigarette smoking, from 6.1% to 3.1% (APC= -15.7; 95%CI= -18.3, -13.1; *p*-trend<0.05; Figure 3.3). With the exception of 6th graders and non-Hispanic other race students, significant linear declines were observed among all population subgroups defined by age, grade level, school level, sex, and race/ethnicity. A significant quadratic trend for menthol cigarette smoking was seen only among persons aged ≤12 years old (ß=0.68; *p*-trend<0.05).

Overall prevalence of nonmenthol cigarette smoking declined significantly during 2011-2015 among all U.S. middle and high school students, from 5.1% to 3.4% (APC=-11.6; 95%CI=-18.8, -3.7; *p*-trend<0.05). Significant linear declines in nonmenthol cigarette smoking occurred among all population subgroups, except persons aged ≤12 years old, 7th, 9th, and 10th graders, and non-Hispanic other race students. Significant quadratic trends were observed in nonmenthol cigarette smoking among four subgroups: 13-14 year olds (ß=0.30), middle schoolers (ß=0.35), non-Hispanic other race students (ß=0.59), and Hispanics (ß=0.30) (all *p*-trend<0.05).

A comparison of slopes for linear trends between menthol and nonmenthol cigarettes showed no difference overall and among all population subgroups except for 10th graders. Quadratic trends differed between menthol and nonmenthol

cigarettes for all students overall as well as persons aged 13-14 years or ≥17 years, 8th and 9th graders, high schoolers overall, males, and Hispanics.

National Trends in Menthol and nonmenthol cigarette smoking among current cigarette smokers, NYTS, 2011-2015

Linear trends in menthol cigarette smoking during 2011-2015 remained stable for all smokers overall as well as among all subgroups, except the following among whom significant declines occurred: 15-16 year olds (ß=-0.37), 9th graders (ß=-0.54), 10th graders (ß=-0.49), and those reporting smoking up to 1 cigarette pack in their lifetime (ß=-0.45) (all *p*-trend<0.05). The only significant quadratic change observed was among smokers aged 13-14 years old (ß=-0.37; *p*-trend<0.05).

Analyses of subgroup differences within each survey year revealed significant variations in menthol cigarette smoking as shown in Table 3.4. Prevalence of menthol use increased linearly (*p*-trend <0.05) with increasing grade level in 2012 but was non-significant in all other years. Prevalence also increased linearly with increasing number of total cigarettes smoked in lifetime in each survey year, except 2013. By school level, the proportion of current cigarette smokers who smoked menthol cigarettes was significantly higher among high school compared to middle school students in 2011, 2012, and 2015. Non-Hispanic black smokers had the highest prevalence of menthol cigarette smoking of all race/ethnic groups every year (70.3% in 2015). Prevalence of menthol use among female cigarette smokers was significantly higher than among male cigarette smokers in 2011 and 2015, but did not differ in 2012, 2013, and 2014.

Since menthol and nonmenthol prevalence among current cigarette smokers are complementary (adding to 100% in each year), the trends for nonmenthol cigarette smoking among current smokers are the reverse of those described above for menthol use.

Predictors of menthol use among current cigarette smokers, NYTS 2015

Results of multivariable logistic regression analyses for correlates of menthol use among current cigarette smokers are in Table 3.5. Non-Hispanic black smokers had higher odds of being menthol smokers compared to whites (aOR=3.19; 95%CI=1.31-7.82). Other characteristics positively associated with menthol use included smoking first cigarette within one hour of waking (aOR=1.72), having a health condition (aOR=1.51), reporting truant behavior (aOR=1.37), purchasing one's own tobacco products (aOR=1.75), and reporting exposure to a medium of pro-tobacco advertising (aOR=2.07) (all $p<0.05$).

DISCUSSION

Although smoking prevalence declined significantly for both menthol and nonmenthol cigarettes among all students during 2011-2015, the proportion of current cigarette smokers reporting menthol use did not change significantly, consistent with previously reported trends [14]. This study also highlighted certain high risk groups for menthol use, including the youngest age groups as well as racial minorities. For persons aged ≤12 years among all students, a year-on-year increase in menthol cigarette smoking prevalence occurred between 2014 (0.5%) and

2015 (0.8%), causing a significant upward quadratic trend despite year-on-year declines in the preceding years. Similarly, among all students, sixth graders were the only subgroup by grade level in which the relative percentage change between 2011 and 2015 showed a larger decline for nonmenthol cigarettes (-63.2) than for menthol cigarettes (-33.2). When examined within the denominator of current cigarette smokers, sixth graders saw a large increase in menthol cigarette use, from 38.8% in 2011, to 54.6% in 2015, even though this increase was non-significant because of small sample sizes in this group. Notably, while the issue of menthol cigarette smoking has mostly been focused around African Americans, Hispanic youth also showed disproportionately high prevalence of menthol cigarette use – higher than blacks in all years when considering the denominator as all students (5.5% in Hispanics, 2.7% in blacks during 2013), and approaching prevalence of blacks in some years taking current cigarette smokers as denominator (62.7% in Hispanics, 65.7% in blacks during 2013). Menthol might be slowing progress in reducing overall smoking among these groups, indicating the need for tailored public health interventions.

Current cigarette smokers with a health condition had increased likelihood of reporting menthol use, likely from the misperception that menthol cigarettes are safe, or safer than nonmenthol cigarettes [16, 38, 39]. This misperception might be driven by menthol's usage in cold remedies [8], as well as the fact that menthol masks many cigarette smoke attributes that might be perceived as harmful among youth (e.g., harshness, or tobacco taste) [10]. More so, menthol cigarettes are

heavily marketed using flavor descriptors with health connotations, e.g., “cool”, “fresh”, “clean”, despite FDA’s ban on the use of any descriptor that might suggest that one brand is less harmful than another [37, 40]. There is insufficient evidence that smokers of menthol cigarettes face a different risk of tobacco-attributable diseases than smokers of nonmenthol cigarettes [13].

Previous research on internal tobacco industry documents identified two groups of menthol smokers – naïve smokers who use menthol because they cannot tolerate the harshness of tobacco smoke and who thus seek mild menthol products (mostly younger smokers), and established smokers who seek out strong menthol flavors and associated cooling sensations (mostly black males) [10]. The tobacco industry has targeted both groups of menthol smokers with a wide variety of mentholated products on the market, with varying levels of menthol concentration [41]. Brands such as Kool that have high levels of menthol are more attractive to established than newer smokers [10]. This might partly explain the linear increase in menthol use prevalence with increasing number of cigarettes smoked in lifetime, as well as the higher odds of menthol use among smokers with higher nicotine dependence.

Youth who purchased their own tobacco products were more likely to report menthol cigarette use. Conceivably, for youth with low purchasing power, the type of cigarettes smoked might be a greater function of what is available from their social contacts rather than their own individual preferences. Youth are generally

price sensitive, and most obtain tobacco products from sources that typically involve an older person, through ways such as borrowing from someone else, being given by an older person, taking cigarettes from a store or a family member, among others [42]. Considering that nonmenthol cigarettes are more commonly used among adult cigarette smokers [12], it is plausible to expect a finding of higher nonmenthol use among youth who rely on adult smokers for their cigarettes. Conversely, youth who purchase their own cigarettes might have greater flexibility in choosing their preferred brand, with mentholated cigarettes being a clear favorite among youth [13].

Declines in overall cigarette smoking (menthol and nonmenthol combined) were observed consistent with other studies. Singh et al reported a decline in current cigarette smoking prevalence among U.S. middle schoolers during 2011-2015, from 4.3% to 2.3% [43]; a similar decline was observed in this study, from an overall 2011 prevalence of 4.4% (2.2% menthol, plus 2.2% nonmenthol), to an overall 2015 prevalence of 2.4% (1.1% menthol, plus 1.3% nonmenthol). Consistent declines between the two studies were also noted for high school students. These large declines in cigarette smoking among both middle and high school students are likely attributable to several advances in comprehensive tobacco control over the past few years. These include the 2009 Children's Health Insurance Program Reauthorization Act (CHIPRA), which raised federal taxes on cigarettes, and the 2009 FSPTCA, which utilized product regulation to attack the problem of smoking among youth [44, 45]. Other evidence-based measures which have been

implemented include comprehensive smoke-free laws as well as hard-hitting mass media campaigns about the health risks of tobacco use [46].

Despite the progress made in tobacco prevention and control in the past decades, the potential for abuse liability and widening of disparities with menthol cigarettes underscores the need for intensified efforts at national, state, and local levels [47]. FDA should consider the regulation of menthol cigarettes and other flavored products a public health priority as recommended by TPSAC. State, local, and tribal governments can also implement restrictions on sales of flavored products as well as other proven population-level interventions to help denormalize cigarette smoking and reduce prevalence among youth [46]. Health professionals, including pediatricians, are trusted sources of health information and can play a role in educating youth smokers about the health consequences of all tobacco use, including menthol cigarettes, and also providing cessation support [48].

Strengths and Limitations

This study's strength is the use of nationally representative data to measure recent trends in menthol and nonmenthol cigarette smoking. In addition, this is the first study to measure state-specific prevalence estimates of menthol use among U.S. adolescents. Limitations to this study include the fact that self-reported smoking and menthol use might be subject to misclassification. These data also apply only to youths who attend school. However, according to the Current Population Survey, 98.5% of U.S. youths aged 10-13 years and 97.1% of those 14-17

years were enrolled in a traditional school in 2011 [49]. Hence, these findings apply to most school-aged youth. Finally, YTS data were available for only 22 states since not all states administer the survey.

CONCLUSION

Although smoking prevalence declined significantly for both menthol and nonmenthol cigarettes among all students, the proportion of current cigarette smokers reporting menthol use did not change significantly during 2011-2015. Menthol might be slowing progress in reducing overall smoking prevalence among young adolescents (those less than 12 years old) and racial minorities. Prohibiting menthol in cigarettes, coupled with comprehensive tobacco control and prevention efforts can help reduce prevalence of cigarette smoking among U.S. youth.

REFERENCES

1. Carpenter, C.M., G.F. Wayne, and G.N. Connolly, *The role of sensory perception in the development and targeting of tobacco products.* Addiction (Abingdon, England), 2007. **102**(1): p. 136-147.
2. Ahijevych, K. and B.E. Garrett, *The role of menthol in cigarettes as a reinforcer of smoking behavior.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S110-6.
3. Kreslake, J.M. and V.B. Yerger, *Tobacco industry knowledge of the role of menthol in chemosensory perception of tobacco smoke.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S98-101.
4. Yerger, V.B., *Menthol's potential effects on nicotine dependence: a tobacco industry perspective.* Tobacco control, 2011. **20 Suppl 2**: p. ii29-36.
5. Palmatier, M.I., et al., *Effects of nicotine on olfactogustatory incentives: preference, palatability, and operant choice tests.* Nicotine Tob Res, 2013. **15**(9): p. 1545-54.
6. Touzani, K., R.J. Bodnar, and A. Sclafani, *Neuropharmacology of learned flavor preferences.* Pharmacol Biochem Behav, 2010. **97**(1): p. 55-62.

7. Ahijevych, K. and B.E. Garrett, *Menthol pharmacology and its potential impact on cigarette smoking behavior.* Nicotine Tob Res, 2004. **6 Suppl 1**: p. S17-28.

8. Eccles, R., *Menthol and related cooling compounds.* J Pharm Pharmacol, 1994. **46**(8): p. 618-30.

9. Ferris Wayne, G. and G.N. Connolly, *Application, function, and effects of menthol in cigarettes: a survey of tobacco industry documents.* Nicotine Tob Res, 2004. **6 Suppl 1**: p. S43-54.

10. Kreslake, J.M., G.F. Wayne, and G.N. Connolly, *The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior.* Nicotine Tob Res, 2008. **10**(4): p. 705-15.

11. Kreslake, J.M. and V.B. Yerger, *Tobacco industry knowledge of the role of menthol in chemosensory perception of tobacco smoke.* Nicotine Tob Res, 2010. **12 Suppl 2**: p. S98-101.

12. Caraballo, R.S. and K. Asman, *Epidemiology of menthol cigarette use in the United States.* Tob Induc Dis, 2011. **9 Suppl 1**: p. S1.

13. Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/tobaccoproductsscientificadvisorycommittee/ucm269697.pdf. Accessed 09/15/2016.

14. Giovino, G.A., et al., *Differential trends in cigarette smoking in the USA: is menthol slowing progress?* Tob Control, 2015. **24**(1): p. 28-37.

15. Hersey, J.C., J.M. Nonnemaker, and G. Homsi, *Menthol cigarettes contribute to the appeal and addiction potential of smoking for youth.* Nicotine Tob Res, 2010. **12 Suppl 2**: p. S136-46.

16. Kreslake, J.M., et al., *Tobacco industry control of menthol in cigarettes and targeting of adolescents and young adults.* Am J Public Health, 2008. **98**(9): p. 1685-92.

17. Nonnemaker, J., et al., *Initiation with menthol cigarettes and youth smoking uptake.* Addiction, 2013. **108**(1): p. 171-8.

18. Federal Trade Commission. Federal Trade Commission Cigarette Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf.

19. Agaku, I.T. and H.R. Alpert, *Trends in annual sales and current use of cigarettes, cigars, roll-your-own tobacco, pipes, and smokeless tobacco among U.S. adults, 2002-2012.* Tobacco control, 2016. **25**(4): p. 451-457.

20. Delnevo, C.D., A.C. Villanti, and G.A. Giovino, *Trends in menthol and non-menthol cigarette consumption in the U.S.A.: 2000-2011.* Tob Control, 2014. **23**(e2): p. e154-5.

21. Loomis, B. Trends in menthol cigarette sales, price, and promotion in the United States. 2010. Accessed at

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsSci entificAdvisoryCommittee/UCM234655.pdf.

22. Euromonitor. (2015). Cigarettes in the US. Statistics retrieved March 23, from Euromonitor Passport Database.

23. Federal Trade Commission. "TAR," NICOTINE, AND CARBON MONOXIDE OF THE SMOKE OF 1294 VARIETIES OF DOMESTIC CIGARETTES FOR THE YEAR 1998. Available at https://www.ftc.gov/sites/default/files/documents/reports/2000-report-tar-nicotine-and-carbon-monoxide-covering-1998/1998tarnicotinereport_0.pdf.

24. Cook, B.L., et al., *One size does not fit all: how the tobacco industry has altered cigarette design to target consumer groups with specific psychological and psychosocial needs.* Addiction (Abingdon, England), 2003. **98**(11): p. 1547-1561.

25. Carpenter, C.M., G.F. Wayne, and G.N. Connolly, *Designing cigarettes for women: new findings from the tobacco industry documents.* Addiction, 2005. **100**(6): p. 837-51.

26. Balbach, E.D., R.J. Gasior, and E.M. Barbeau, *R.J. Reynolds' targeting of African Americans: 1988-2000.* Am J Public Health, 2003. **93**(5): p. 822-7.

27. The African American Tobacco Control Leadership Council. Letter to President Obama Available at http://www.savingblacklives.org/letter-to-president-obama/. Accessed 11/28/2016

28. World Health Organization. Advisory note: banning menthol in tobacco products WHO Study Group on Tobacco Product Regulation (TobReg). Available at http://www.who.int/tobacco/publications/prod_regulation/menthol-advisory-note/en/. Accessed 09/17/2016.

29. AAP Applauds Menthol Cigarette Restrictions Recommended by Expert FDA Panel. Available at https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Aplauds-Menthol-Cigarette-Restrictions-Recommended-by-Expert-FDA-Panel.aspx?nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token&nfstatus=401&nftoken=00000000-0000-0000-0000-000000000000&nfstatusdescription=ERROR%3a+No+local+token. Accessed on 09/17/2016.

30. Framework Convention Alliance. Canadian provinces first in world to ban menthol flavouring. Available at http://www.fctc.org/fca-news/opinion-pieces/-canadian-provinces-first-to-ban-menthol-flavouring. Accessed 09/15/2016.

31. Tobacco Control Legal Consortium. How Other Countries Regulate Flavored Tobacco Products. Available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-2015.pdf. Accessed 09/15/2016.

32. U.S. Food and Drug Administration. FDA invites public input on menthol in cigarettes. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm361966.htm. Accessed 09/14/2016.

33. Substance Use and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Recent Trends in Menthol Cigarette Use. The NSDUH Report. Rockville, MD, 2011.

34. Centers for Disease Control and Prevention. National Youth Tobacco Survey (NYTS). Available at http://www.cdc.gov/tobacco/data_statistics/surveys/nyts/.

35. Hendlin, Y., S.J. Anderson, and S.A. Glantz, *'Acceptable rebellion': marketing hipster aesthetics to sell Camel cigarettes in the US*. Tob Control, 2010. **19**(3): p. 213-22.

36. Cortese, D.K., M.J. Lewis, and P.M. Ling, *Tobacco industry lifestyle magazines targeted to young adults*. J Adolesc Health, 2009. **45**(3): p. 268-80.

37. Healton, C.G., et al., *Prohibiting menthol in tobacco products: a policy whose time has come*. Addiction, 2010. **105 Suppl 1**: p. 5-7.

38. Anderson, S.J., *Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents*. Tob Control, 2011. **20 Suppl 2**: p. ii20-8.

39. Brennan, E., et al., *Are young people's beliefs about menthol cigarettes associated with smoking-related intentions and behaviors?* Nicotine Tob Res, 2015. **17**(1): p. 81-90.

40. U.S. Food and Drug Administration. Tobacco Products. Light, Low, Mild or Similar Descriptors. Available at http://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm2023661.htm. Accessed 09/15/2016.

41. Celebucki, C.C., et al., *Characterization of measured menthol in 48 U.S. cigarette sub-brands.* Nicotine Tob Res, 2005. **7**(4): p. 523-31.

42. Everett Jones, S. and R.S. Caraballo, *Usual source of cigarettes and alcohol among U.S. high school students.* J Sch Health, 2014. **84**(8): p. 493-501.

43. Singh, T., et al., *Tobacco Use Among Middle and High School Students--United States, 2011-2015.* MMWR.Morbidity and mortality weekly report, 2016. **65**(14): p. 361-367.

44. Congressional Budget Office. H.R. 2, Children's Health Insurance Program Reauthorization Act of 2009. http://www.cbo.gov/publication/20472.

45. United States Public Laws. Public Law 111-31 [H.R. 1256] Jun. 22, 2009 Family Smoking Prevention And Tobacco Control Act. 111 P.L. 31;123 Stat. 1776;2009 Enacted H.R. 1256;111 Enacted H.R. 1256. Available at https://www.congress.gov/bill/111th-congress/house-bill/1256.

46. Centers for Disease Control and Prevention (2014). Best Practices for Comprehensive Tobacco Control Programs. Available at

http://www.cdc.gov/tobacco/stateandcommunity/best_practices/pdfs/2014/comprehensive.pdf. Accessed 09/17/2016.

47. Henningfield, J.E., et al., *Conference on abuse liability and appeal of tobacco products: conclusions and recommendations.* Drug and alcohol dependence, 2011. **116**(1-3): p. 1-7.

48. *A clinical practice guideline for treating tobacco use and dependence: A U.S. Public Health Service report. The Tobacco Use and Dependence Clinical Practice Guideline Panel, Staff, and Consortium Representatives.* JAMA, 2000. **283**(24): p. 3244-54.

49. United States Census Bureau. School Enrollment: Current Population Survey 2011 – Detailed Tables. Available at http://www.census.gov/hhes/school/data/cps/2011/tables.html. Accessed December 22, 2012.

TABLES AND FIGURES

Table 3.1 Socio-demographic characteristics of study participants, N (%), National Youth Tobacco Survey, 2011-2015

Characteristics	2011			2012			2013			2014			2015		
	MS	HS	ALL	MS	HS	ALL	MS	HS	ALL	MS	HS	ALL	MS	HS	ALL
AGE															
≤ 12	3525 (41.17)	24 (0.21)	3589 (18.16)	4996 (44.80)	26 (0.22)	5037 (19.75)	3446 (43.54)	16 (0.13)	3479 (19.20)	4431 (42.41)	19 (0.13)	4461 (18.69)	3376 (41.77)	14 (0.12)	3412 (18.56)
13-14	5025 (56.11)	936 (9.95)	6004 (29.86)	6373 (53.03)	1210 (9.79)	7590 (28.71)	4461 (54.08)	1003 (10.56)	5470 (29.61)	5717 (55.16)	1105 (10.32)	6835 (29.99)	4607 (55.89)	955 (10.23)	5567 (30.33)
15-16	273 (2.47)	4704 (51.72)	5009 (30.27)	234 (1.94)	6189 (50.51)	6430 (29.22)	177 (2.25)	5027 (50.19)	5212 (29.13)	239 (2.31)	5575 (49.89)	5839 (29.00)	169 (2.26)	4797 (49.93)	4975 (28.86)
≥ 17	22 (0.25)	4010 (38.12)	4069 (21.71)	25 (0.23)	5457 (39.49)	5498 (22.32)	10 (0.13)	4123 (39.11)	4157 (22.05)	12 (0.12)	4682 (39.66)	4715 (22.33)	10 (0.08)	3661 (39.71)	3688 (22.24)
GRADE															
6	2721 (33.19)	n/a	2721 (14.37)	3701 (33.65)	n/a	3701 (14.76)	2635 (33.53)	n/a	2635 (14.69)	3357 (31.63)	n/a	3357 (13.89)	2552 (33.16)	n/a	2552 (14.63)
7	3038 (33.48)	n/a	3038 (14.50)	4037 (33.26)	n/a	4037 (14.59)	2692 (33.38)	n/a	2692 (14.63)	3541 (34.23)	n/a	3541 (15.04)	2845 (33.09)	n/a	2845 (14.60)
8	3121 (33.33)	n/a	3121 (14.44)	3929 (33.09)	n/a	3929 (14.51)	2784 (33.09)	n/a	2784 (14.50)	3521 (34.14)	n/a	3521 (15.00)	2773 (33.75)	n/a	2773 (14.89)
9	n/a	2513 (27.84)	2513 (15.79)	n/a	3262 (27.32)	3262 (15.34)	n/a	2624 (27.28)	2624 (15.33)	n/a	2885 (27.19)	2885 (15.25)	n/a	2512 (27.32)	2512 (15.27)
10	n/a	2327 (25.79)	2327 (14.62)	n/a	3113 (25.76)	3113 (14.46)	n/a	2586 (25.76)	2586 (14.47)	n/a	2933 (25.54)	2933 (14.32)	n/a	2509 (25.70)	2509 (14.36)
11	n/a	2393 (23.76)	2393 (13.47)	n/a	3344 (23.87)	3344 (13.40)	n/a	2499 (23.93)	2499 (13.44)	n/a	2817 (23.99)	2817 (13.45)	n/a	2282 (23.89)	2282 (13.35)
12	n/a	2487 (22.61)	2487 (12.82)	n/a	3180 (23.05)	3180 (12.94)	n/a	2481 (23.02)	2481 (12.94)	n/a	2764 (23.28)	2764 (13.05)	n/a	2130 (23.09)	2130 (12.90)
SEX															
Male	4369 (50.78)	4832 (50.86)	9284 (50.98)	5865 (51.04)	6458 (51.09)	12369 (51.08)	4073 (51.12)	5091 (51.29)	9216 (51.25)	5289 (50.84)	5834 (49.74)	11150 (50.24)	4044 (51.17)	4889 (51.16)	8958 (51.18)
Female	4447 (49.22)	4819 (49.14)	9315 (49.02)	5797 (48.96)	6439 (48.91)	12275 (48.92)	4037 (48.88)	5097 (48.71)	9177 (48.75)	5093 (49.16)	5536 (50.26)	10645 (49.76)	4085 (48.83)	4516 (48.84)	8622 (48.82)
RACE/ETHNICITY															
White, non-Hispanic	3045 (54.18)	3875 (56.83)	6982 (55.66)	5687 (52.61)	6114 (54.85)	11814 (53.86)	3530 (50.87)	4414 (53.08)	7960 (52.05)	3950 (52.20)	4858 (54.15)	8820 (53.23)	3480 (52.66)	4374 (54.09)	7865 (53.36)
Black, non-Hispanic	1727 (13.79)	1550 (14.43)	3322 (14.16)	1366 (13.67)	1741 (14.02)	3114 (13.86)	1324 (15.35)	1767 (14.52)	3097 (14.87)	1426 (13.70)	1789 (15.28)	3226 (14.62)	1118 (13.84)	1284 (13.45)	2405 (13.60)
Asian, non-Hispanic	236 (2.88)	324 (3.62)	568 (3.33)	502 (3.48)	601 (3.80)	1106 (3.66)	309 (3.16)	498 (4.44)	809 (3.89)	366 (3.32)	564 (3.39)	932 (3.36)	376 (3.68)	248 (2.92)	625 (3.25)
Other, non-Hispanic	779 (7.61)	606 (5.82)	1398 (6.61)	986 (7.29)	1110 (6.65)	2105 (6.93)	766 (8.18)	779 (6.69)	1549 (7.31)	902 (7.30)	836 (6.62)	1741 (6.92)	573 (5.38)	575 (6.42)	1153 (5.98)
Hispanic	2844 (21.55)	3217 (19.30)	6125 (20.24)	2614 (22.94)	3098 (20.68)	5733 (21.69)	1694 (22.44)	2455 (21.28)	4181 (21.88)	3069 (23.48)	2975 (20.56)	6081 (21.87)	2157 (24.44)	2654 (23.13)	4849 (23.81)

TOTAL	8880	9720	18600	11667	12899	24566	8111	10190	18301	10419	11399	21818	8170	9433	17603
	(43.31)	(56.69)	(100.00)	(43.86)	(56.14)	(100.00)	(43.82)	(56.18)	(100.00)	(43.93)	(56.07)	(100.00)	(44.12)	(55.88)	(100.00)

Note: MS = Middle school; HS = High school; n/a =not applicable. Proportions shown are column percentages.

Table 3.2 Menthol cigarette smoking among current cigarette smokers, Youth Tobacco Survey for 22 states, 2011-2016

State	Year	High school			Middle school		
		N	Current cigarette smoking % (95% CI)	Menthol use among current cigarette smokers % (95% CI)	N	Current cigarette smoking % (95% CI)	Menthol use among current cigarette smokers % (95% CI)
Arizona	2015	¶	¶	¶	1,402	3.16 (2.04-4.28)	46.62 (37.38-55.86)
Connecticut	2015	2,292	5.63 (3.65-7.61)	47.64 (35.90-59.37)	2,474	0.83 (0.48-1.19)	44.99 (12.35-77.63)*
Hawaii	2015	1,911	7.38 (5.69-9.07)	68.04 (59.16-76.92)	2,244	2.98 (2.12-3.85)	48.44 (37.70-59.19)
Illinois	2015	4,556	9.91 (7.19-12.63)	56.16 (42.59-69.72)	4,688	2.01 (1.24-2.78)	29.07 (15.08-43.05)
Louisiana	2015	895	17.45 (17.45-17.45)	56.45 (56.45-56.45)	1,265	5.23 (3.40-7.07)	40.83 (25.75-55.92)
Mississippi	2016	1,641	9.90 (8.02-11.79)	65.09 (58.15-72.04)	1,878	3.01 (1.99-4.02)	65.44 (50.87-80.02)
North Carolina	2015	3,420	9.35 (7.52-11.18)	56.02 (50.78-61.26)	3,496	2.34 (1.69-2.99)	43.82 (28.14-59.49)
North Dakota	2015	1,885	12.45 (9.74-15.15)	45.97 (37.82-54.12)	1,926	3.59 (2.29-4.89)	44.00 (31.09-56.91)
Ohio	2015	962	8.85 (8.85-8.85)	40.51 (40.51-40.51)	1,231	2.61 (2.61-2.61)	40.63 (40.63-40.63)
South Carolina	2015	1,483	11.91 (9.43-14.4)	72.74 (62.35-83.14)	1,421	3.19 (3.19-3.19)	41.12 (41.12-41.12)
West Virginia	2015	1,671	16.23 (13.41-19.06)	45.60 (39.86-51.34)	1,901	4.56 (2.93-6.19)	29.29 (20.43-38.14)
Georgia	2013	1,776	11.95 (9.52-14.38)	61.48 (54.59-68.36)	2,100	3.19 (2.12-4.25)	46.36 (35.40-57.32)
Indiana	2013	2,718	13.73 (11.32-16.14)	52.36 (42.82-61.90)	2,483	3.72 (2.72-4.73)	41.70 (28.45-54.95)
Kansas	2012	1,118	12.95 (9.95-15.95)	46.77 (34.46-59.09)	950	2.56 (1.25-3.88)	39.09 (16.71-61.48)
Minnesota	2014	2,265	10.62 (8.77-12.48)	48.52 (41.70-55.33)	1,978	1.64 (0.64-2.64)*	34.47 (16.75-52.19)
Nebraska	2013	2,461	11.74 (9.74-13.73)	55.12 (47.53-62.72)	1,882	2.51 (1.59-3.43)	45.13 (33.14-57.13)
New Jersey	2015	3,909	8.17 (6.24-10.09)	53.68 (43.64-63.72)	2,105	1.17 (0.61-1.73)	39.93 (13.32-66.53)*
Pennsylvania	2015	2,017	10.26 (7.54-12.99)	62.42 (53.84-71.01)	2,668	1.28 (0.72-1.84)	58.19 (38.87-77.51)
Wisconsin	2014	1,236	10.71 (10.71-10.71)	58.30 (58.30-58.30)	1,254	1.85 (0.93-2.76)	41.11 (17.91-64.31)
New York	2014	4366	7.31 (5.44-9.00)	65.42 (48.10-83.00)	3943	1.05 (0.58-2.00)	45.36 (28.00-63.00)
Oklahoma	2013	1,531	15.10 (13.30-17.00)	54.80 (48.00-62.00)	3,080	4.82 (3.71-5.92)	33.01 (20.96-45.06)
South Dakota	2015	¶	¶	¶	2,375	2.75 (0.73-4.77)*	34.26 (15.37-53.15)

¶ Data not available for state

* Estimates with relative standard error >30%

Table 3.3 Trends in Menthol and nonmenthol cigarette smoking among all students, National Youth Tobacco Survey, 2011-2015

Type	Characteristics	2011		2012		2013		2014		2015		RPC	APC	ALT	AQT
		% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N		AAPC (95% CI)	Coeff. (se)	Coeff. (se)
Menthol	**Overall**	**6.1 (4.9-7.3)**	**937**	**5 (4.3-5.7)**	**1047**	**4.1 (3.4-4.8)**	**720**	**3.5 (2.8-4.1)**	**670**	**3.1 (2.5-3.6)**	**502**	-49.2	**-15.7 (-18.3, -13.1)**	**-0.59 (0.09)†**	**0.04 (0.09)**
	Age: ≤ 12 years	1.5 (0.9-2.1)	54	0.9 (0.4-1.4) *	33	0.5 (0.2-0.7)	18	0.5 (0.3-0.7)	27	0.8 (0.5-1.2)	26	-46.7	-20.1 (-47.8, 22.4)	-0.47 (0.23)†	0.68 (0.25)†
	13-14 years	2.6 (2.1-3.2)	145	2.3 (1.8-2.9)	155	1.7 (1.2-2.3)	100	1.6 (1.1-2.1)	92	1.2 (0.8-1.5)	65	-53.8	-17.4 (-21.9, -12.6)	-0.70 (0.14)†	-0.08 (0.16)
	15-16 years	8.2 (6.4-10.1)	326	7.1 (5.9-8.2)	392	5.3 (4-6.6)	242	4.1 (3.2-5.1)	219	4 (3.1-5)	179	-51.2	-18.4 (-24.7, -11.5)	-0.70 (0.12)†	0.07 (0.12)
	≥17 years	12.1 (9.8-14.4)	408	9.8 (8.2-11.3)	464	9.5 (7.9-11.1)	359	8 (6.1-9.8)	327	6.7 (5.2-8.1)	231	-44.6	-12.7 (-17.5, -7.6)	-0.49 (0.12)†	-0.02 (0.11)
	Grade: 6th	1.2 (0.6-1.8)	39	0.8 (0.4-1.1)	26	0.6 (0.3-1.0) *	15	0.7 (0.3-1.1)	27	0.8 (0.4-1.2)	24	-33.3	-8.9 (-26.6, 13.2)	-0.34 (0.27)	0.43 (0.29)
	7th	2.5 (1.6-3.4)	63	1.3 (0.8-1.8)	49	0.8 (0.3-1.4) *	25	1.2 (0.2-2.2) *	30	0.9 (0.5-1.3)	25	-64.0	-20.9 (-38.8, 2.4)	-0.67 (0.26)†	0.33 (0.28)
	8th	3 (2.2-3.8)	81	2.9 (2-3.8)	97	2.4 (1.4-3.3)	65	1.3 (0.8-1.8)	48	1.5 (0.9-2.1)	38	-50.0	-18.5 (-31, -3.8)	-0.71 (0.18)†	-0.03 (0.20)
	9th	6.1 (4.3-8)	127	5.1 (3.9-6.2)	142	3.4 (2.4-4.3)	87	3.1 (2.2-4)	81	2.4 (1.5-3.4)	57	-60.7	-21.6 (-28.5, -14)	-0.93 (0.16)†	-0.04 (0.16)
	10th	9.4 (7.1-11.7)	173	8.3 (6.6-10.1)	218	5.7 (4.1-7.2)	126	4.5 (3.3-5.6)	121	4.1 (2.9-5.4)	86	-56.4	-20.8 (-27.4, -13.5)	-0.75 (0.15)†	0.09 (0.15)
	11th	9.6 (7-12.1)	200	7.6 (6-9.2)	233	7.1 (5.4-8.7)	158	6.5 (5-8.1)	154	5.5 (3.8-7.1)	125	-42.7	-11.5 (-16.4, -6.4)	-0.43 (0.15)†	0.05 (0.14)
	12th	12 (9.6-14.4)	241	10.2 (8.2-12.3)	274	10.4 (8.5-12.4)	234	8 (5.9-10.2)	200	7.2 (5.4-9.1)	141	-40.0	-11.5 (-18, -4.5)	-0.45 (0.13)†	-0.03 (0.13)
	School: Middle	2.2 (1.7-2.7)	183	1.6 (1.2-2.1)	172	1.3 (0.8-1.7)	105	1.1 (0.7-1.4)	105	1.1 (0.7-1.4)	87	-50.0	-16.8 (-25.2, -7.4)	-0.61 (0.15)†	0.16 (0.17)
	High	9.1 (7.3-10.9)	741	7.7 (6.6-8.8)	867	6.5 (5.4-7.5)	605	5.4 (4.3-6.5)	556	4.7 (3.8-5.6)	409	-48.4	-15.5 (-16.5, -14.4)	-0.59 (0.11)†	0.02 (0.10)
	Sex: Male	6.7 (5.4-8)	528	5.6 (4.7-6.5)	586	4.4 (3.5-5.2)	381	3.8 (3-4.7)	379	3.3 (2.6-3.9)	278	-50.7	-16.4 (-19.3, -13.4)	-0.62 (0.10)†	0.02 (0.11)
	Female	5.5 (4.2-6.8)	399	4.4 (3.7-5.1)	461	3.9 (3.2-4.6)	339	3.1 (2.5-3.7)	284	2.9 (2.3-3.5)	220	-47.3	-14.8 (-19.1, -10.3)	-0.57 (0.11)†	0.06 (0.11)
	Race/ethnic: White	6.5 (4.8-8.2)	431	5.1 (4.2-6.1)	524	4.2 (3.2-5.2)	347	4 (3.1-5)	341	2.9 (2.2-3.7)	226	-55.4	-16.6 (-22.4, -10.3)	-0.60 (0.13)†	0.01 (0.13)
	Black	4.6 (2.9-6.4)	100	3.7 (2.5-4.8)	79	2.7 (1.7-3.7)	73	1.4 (0.9-2)	47	1.4 (0.7-2.2)	35	-69.6	-29.4 (-40.6, -16.1)	-1.02 (0.25)†	0.01 (0.23)
	Other	5.6 (4.1-7.1)	87	4.3 (3.1-5.4)	125	3.9 (2.6-5.1)	79	3.2 (2-4.4)	76	3.9 (2.1-5.7)	51	-30.4	-11.6 (-22.8, 1.4)	-0.36 (0.18)	0.25 (0.18)
	Hispanic	6.6 (5.6-7.7)	309	5.9 (4.9-6.9)	290	5.5 (4.3-6.7)	198	3.6 (2.7-4.5)	170	3.9 (3.1-4.7)	165	-40.9	-13.4 (-20.8, -5.3)	-0.55 (0.11)†	0.00 (0.10)
Non-Menthol	**Overall**	**5.1 (4.4-5.9)**	**773**	**4.2 (3.5-5)**	**952**	**3.8 (3.2-4.5)**	**534**	**3.1 (2.6-3.6)**	**567**	**3.4 (2.6-4.1)**	**484**	-33.3	**-11.6 (-18.8, -3.7)**	**-0.39 (0.10)†**	**0.10 (0.09)§**
	Age: ≤ 12 years	1.2 (0.8-1.6)	49	1.1 (0.7-1.5) *	47	0.6 (0.3-1)	23	0.8 (0.4-1.1)	37	0.8 (0.3-1.2)	21	-33.3	-11.6 (-25.4, 4.8)	-0.37 (0.25)	0.09 (0.27)
	13-14 years	3.3 (2.6-3.9)	164	2.3 (1.6-3)	175	1.7 (1.2-2.2)	79	1.5 (1.1-1.9)	100	1.8 (1.4-2.2)	92	-45.5	-14.7 (-29, 2.4)	-0.56 (0.12)†	0.30 (0.14)†§
	15-16 years	6 (4.7-7.4)	247	5.3 (4.4-6.3)	311	4.2 (3.1-5.3)	167	4.4 (3.4-5.5)	206	4 (2.7-5.3)	135	-33.3	-9.9 (-16.2, -3.1)	-0.30 (0.15)†	0.09 (0.14)
	≥17 years	10 (8.4-11.6)	307	8.4 (6.6-10.2)	418	9.5 (7.8-11.2)	263	5.5 (4.2-6.7)	216	7.1 (5.6-8.7)	234	-29.0	-10.6 (-25.4, 7.1)	-0.38 (0.11)†	0.03 (0.11)§
	Grade: 6th	1.9 (0.8-2.9)	43	1.3 (0.8-1.8) *	38	0.6 (0.2-1) *	17	0.6 (0.3-0.9)	29	0.7 (0.2-1.2)	15	-63.2	-24.3 (-43.4, 1.1)	-0.88 (0.32)†	0.45 (0.33)
	7th	1.7 (0.9-2.4)	54	1.6 (0.8-2.4) *	64	0.9 (0.4-1.5)	24	0.9 (0.4-1.3)	31	1.2 (0.7-1.7)	34	-29.4	-12.5 (-30.7, 10.5)	-0.42 (0.24)	0.32 (0.27)
	8th	3.1 (2.3-3.9)	87	2.4 (1.5-3.4)	99	2 (1.2-2.7)	44	1.3 (0.8-1.8)	44	2.2 (1.3-3)	43	-29.0	-12.2 (-29.8, 10)	-0.57 (0.19)†	0.32 (0.18)§
	9th	4.8 (3.5-6.1)	100	4.1 (3.1-5.1)	130	3.7 (2.2-5.1)	76	3.2 (2.4-3.9)	85	2.9 (1.5-4.3)	58	-39.6	-12.1 (-13.7, -10.5)	-0.37 (0.20)	0.01 (0.20)§
	10th	6.1 (4.1-8)	120	5 (3.9-6.2)	139	4.2 (3-5.3)	80	4.9 (3.7-6.2)	113	4.4 (2.9-5.9)	74	-27.9	-5.8 (-16.9, 6.7)	-0.22 (0.18)¶	0.16 (0.17)
	11th	8.5 (6.4-10.6)	165	7.4 (5.8-9)	210	7.3 (5.5-9.1)	125	5.6 (3.9-7.3)	132	5.9 (4.4-7.3)	114	-30.6	-9 (-14.9, -2.7)	-0.36 (0.14)†	0.00 (0.14)
	12th	11 (9-12.9)	195	9.1 (6.7-11.5)	271	9.7 (7.4-12)	165	5.6 (4.3-7)	126	7.5 (5.5-9.6)	143	-31.8	-12.3 (-26.8, 5)	-0.42 (0.13)†	0.09 (0.13)
	School: Middle	2.2 (1.7-2.7)	184	1.8 (1.2-2.3)	201	1.1 (0.8-1.5)	85	0.9 (0.7-1.2)	104	1.3 (1-1.7)	92	-40.9	-19.1 (-35.6, 1.7)	-0.59 (0.13)†	0.35 (0.14)†
	High	7.4 (6.2-8.6)	580	6.3 (5.1-7.4)	750	6.1 (4.9-7.2)	446	4.8 (3.9-5.7)	456	5 (3.9-6.1)	389	-32.4	-10.4 (-16.2, -4.3)	-0.34 (0.11)†	0.06 (0.10)§
	Sex: Male	6.2 (5.3-7.2)	453	5 (4.1-5.8)	552	4.7 (3.9-5.6)	309	3.6 (2.9-4.3)	344	3.8 (2.9-4.6)	296	-38.7	-12.9 (-20.1, -5.1)	-0.43 (0.10)†	0.09 (0.10)§
	Female	4 (3.1-4.9)	304	3.5 (2.8-4.3)	400	2.9 (2.3-3.6)	224	2.5 (2-3.1)	216	2.9 (2.2-3.6)	184	-27.5	-9.9 (-19.9, 1.2)	-0.32 (0.13)†	0.12 (0.12)
	Race/ethnic: White	5.8 (4.7-6.9)	367	5.2 (4.2-6.2)	574	5.2 (4.2-6.2)	335	3.7 (3-4.5)	303	3.9 (2.8-5)	265	-32.8	-10.8 (-19.1, -1.6)	-0.37 (0.12)†	-0.01 (0.11)
	Black	1.8 (1.2-2.5)	36	1.3 (0.7-1.9)	33	1.4 (0.7-2.1)	33	0.8 (0.4-1.3)	23	0.6 (0.3-0.9) *	17	-66.7	-22.8 (-32.6, -11.4)	-0.73 (0.25)†	-0.24 (0.26)
	Other	4.9 (3.4-6.5)	78	3.1 (2.2-4.1)	107	2.3 (1.3-3.3)	49	2.3 (1.5-3.2)	51	3.6 (2.4-4.7)	61	-26.5	-7.8 (-31.8, 24.7)	-0.30 (0.18)	0.59 (0.19)†
	Hispanic	5.7 (4.7-6.6)	274	4.5 (3.5-5.4)	225	3.3 (2.3-4.2)	103	3.1 (2.5-3.8)	162	3.5 (2.7-4.3)	122	-38.6	-13.7 (-24.6, -1.3)	-0.44 (0.11)†	0.30 (0.12)†§

Note: RPC=Unadjusted relative percentage change; APC=unadjusted Annual Percentage Change, ALT=Adjusted Linear Trend; AQT=Adjusted Quadratic Trend. Unless indicated, all races are non-Hispanic. Highlighted cells show significant within-group differences within each year.

¶ Slopes for nonmenthol linear trends differed significantly from corresponding trend for menthol use.

§ Slopes for nonmenthol quadratic trends differed significantly from corresponding trend for menthol use.

† Statistically significant linear or quadratic trends during 2011-2015

***** Estimates with relative standard error ≥30%

Table 3.4 Trends in Menthol cigarette smoking among current smokers, National Youth Tobacco Survey, 2011-2015

Characteristics	2011		2012		2013		2014		2015		RPC	AAPC	ALT	AQT
	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	% (95% CI)	N	%	AAPC (95% CI)	Coeff. (se)	Coeff. (se)
Overall	54.3 (49.6-58.9)	937	54.1 (49.4-58.8)	1047	51.8 (46.7-56.9)	720	53 (47.1-58.9)	670	47.9 (42.5-53.2)	502	-11.8	-2.6 (-5.5, 0.4)	-0.20 (0.11)	-0.07 (0.11)
Age, years														
≤12	55.4 (43.4-67.4)	54	45.2 (28.8-61.5)	33	42.7 (23.3-62.1)	18	40.3 (24-56.7)	27	52.1 (37.1-67.1)	26	-6.0	-2.8 (-13.9, 9.8)	-0.19 (0.29)	0.56 (0.33) [a]
13-14	44.7 (38.6-50.7)	145	50 (41.3-58.8)	155	50.3 (42-58.6)	100	50.9 (40.4-61.5)	92	39.5 (31-47.9)	65	-11.6	-0.7 (-11.3, 11.1)	-0.12 (0.17)	-0.38 (0.17) [†]
15-16	57.8 (51.3-64.3)	326	56.9 (51.9-62)	392	55.9 (47.1-64.7)	242	48.2 (39.9-56.5)	219	50.1 (40.3-59.8)	179	-13.3	-4.4 (-8.4, -0.1)	-0.37 (0.17) [†]	-0.03 (0.17)
≥17	54.7 (48.9-60.6)	408	53.7 (46.8-60.6)	464	50 (43.5-56.4)	359	59.3 (51.7-67)	327	48.3 (41.5-55.2)	231	-11.7	-1.3 (-9.2, 7.4)	-0.09 (0.14)	-0.07 (0.14)
Grade														
6th	38.8 (27.6-49.9)	39	37.7 (22.8-52.7)	26	52.2 (28.7-75.6)	15	52.5 (35-70)	27	54.6 (34.3-74.9)	24	40.7	10.4 (2.1, 19.3)	0.42 (0.39) [b]	-0.05 (0.42)
7th	60 (51.2-68.8)	63	44.4 (31.5-57.4)	49	46.2 (30.7-61.6)	25	58.4 (32.2-84.6)	30	43.7 (31.7-55.8)	25	-27.2	-6.9 (-17.3, 4.9)	-0.25 (0.27)	-0.01 (0.30) [b]
8th	49 (40.7-57.3)	81	54.4 (42.9-65.9)	97	54.8 (40.8-68.8)	65	49.3 (38.9-59.7)	48	41.5 (29-53.9)	38	-15.3	-2.3 (-11.3, 7.6)	-0.11 (0.23)	-0.35 (0.26)
9th	56.1 (48.4-63.8)	127	55.3 (48.4-62.3)	142	47.8 (36.8-58.7)	87	49.7 (41.3-58)	81	45.8 (30.3-61.2)	57	-18.4	-4.9 (-8.9, -0.6)	-0.54 (0.22) [†]	-0.07 (0.22)
10th	60.8 (51.5-70)	173	62.5 (55.8-69.2)	218	57.7 (48.6-66.7)	126	47.4 (38.6-56.3)	121	48.5 (37.5-59.5)	86	-20.2	-7.3 (-14.3, 0.3)	-0.49 (0.21) [†]	-0.08 (0.20)
11th	52.9 (43.8-62)	200	50.5 (43.5-57.5)	233	49.3 (42.2-56.5)	158	53.9 (44.2-63.5)	154	48.2 (39.1-57.3)	125	-8.9	-1.1 (-6, 4.1)	-0.09 (0.19)	0.04 (0.18) [b]
12th	52.2 (45.6-58.9)	241	52.9 (44.5-61.3)	274	51.8 (43.9-59.8)	234	58.7 (49.7-67.7)	200	49 (41.8-56.3)	141	-6.1	-0.2 (-7, 7.1)	-0.01 (0.16)	-0.14 (0.16)
School														
Middle	50.2 (44.5-55.8)	183	48.1 (38.9-57.3)	172	52.3 (43.4-61.1)	105	53.3 (41.8-64.7)	105	44.9 (37.3-52.5)	87	-10.6	-1.4 (-7.2, 4.9)	-0.02 (0.16) [c]	-0.19 (0.17)
High	55.2 (49.9-60.4)	741	55.1 (49.8-60.4)	867	51.7 (45.7-57.7)	605	53.1 (46.8-59.5)	556	48.2 (41.5-54.8)	409	-12.7	-2.8 (-5.8, 0.2)	-0.24 (0.13)	-0.06 (0.12)
Sex														
Male	52 (46.6-57.3)	528	53.1 (48-58)	586	48.1 (41.8-54.3)	381	51.6 (44.8-58.5)	379	46.3 (40.6-52)	278	-11.0	-2.7 (-6.9, 1.7)	-0.18 (0.12)	-0.09 (0.13)
Female	58.2 (50.9-65.5)	399	55.4 (49.7-61)	461	57 (51-63)	339	55.1 (48.3-62)	284	50 (42.9-57)	220	-14.1	-2.7 (-6.5, 1.2)	-0.24 (0.15)	-0.06 (0.14)
Race/ethnicity														
White	52.7 (47.1-58.3)	431	49.8 (43.7-55.8)	524	44.9 (38.3-51.4)	347	51.9 (44.2-59.6)	341	43 (35.2-50.8)	226	-18.4	-3.4 (-10.5, 4.2)	-0.23 (0.15)	0.00 (0.14)
Black	71.9 (61.8-82.1)	100	73.8 (64.1-83.5)	79	65.7 (54.1-77.4)	73	63.2 (48.9-77.5)	47	70.3 (55.8-84.9)	35	-2.2	-2.2 (-8.1, 4)	-0.27 (0.31)	0.25 (0.30) [d]
Other	53.3 (43.8-62.8)	87	57.7 (48.9-66.6)	125	62.7 (52.7-72.6)	79	57.9 (48-67.7)	76	52 (39.3-64.8)	51	-2.4	0.6 (-8.1, 10.1)	-0.06 (0.22) [d]	-0.28 (0.22)
Hispanic	53.8 (47.5-60.2)	309	56.9 (51.7-62.2)	290	62.5 (54.5-70.5)	198	53.6 (46.2-61)	170	52.5 (46.3-58.6)	165	-2.4	-1.1 (-8.1, 6.4)	-0.10 (0.13)	-0.28 (0.14) [†]
Total cigarettes smoked in lifetime														
≤1 cigarette	32.6 (23.4-41.8)	56	30 (22.8-37.2)	54	33.7 (22.3-45.1)	41	34.9 (24.5-45.3)	50	23.9 (15.3-32.5)	37	-26.7	-3.1 (-16.5, 12.4)	-0.12 (0.23)	-0.32 (0.25)
2-5 cigarettes	32.7 (22.1-43.4)	79	46.3 (35.3-57.2)	97	47.3 (34.3-60.2)	59	41.3 (30.1-52.5)	68	42.6 (33.8-51.5)	54	30.3	2.1 (-11.2, 17.2)	0.11 (0.22) [e]	-0.39 (0.23)
1/2 pack	52.4 (44.2-60.6)	88	50.1 (41.9-58.3)	119	44.4 (33.3-55.5)	64	46.5 (33.2-59.9)	60	53.8 (42.5-65.1)	59	2.7	-0.4 (-7.8, 7.7)	-0.03 (0.21)	0.31 (0.22) [e]
1 pack	60.5 (51.3-69.6)	82	53.1 (43.7-62.6)	91	57.9 (44.4-71.3)	53	57.6 (46.4-68.8)	67	44.2 (32.3-56)	47	-26.9	-4.2 (-13, 5.4)	-0.45 (0.22) [†]	-0.14 (0.24)
<5 packs	60.8 (53.6-68)	163	64.7 (57-72.4)	218	54.2 (44.4-64)	116	57.4 (48.3-66.6)	105	55.5 (45-66)	76	-8.7	-3 (-9.2, 3.5)	-0.26 (0.19)	-0.03 (0.19) [e]
≥5 packs	61.8 (55.4-68.2)	437	58.2 (52-64.5)	437	56.1 (49-63.2)	369	61 (53.1-68.9)	301	54.1 (45.2-63)	213	-12.5	-2 (-6.9, 3.1)	-0.17 (0.18)	0.02 (0.17) [e]
Past 30 days smoked														
1-2 days	47.3 (40.5-54.1)	176	47.6 (42-53.2)	220	48.6 (39.7-57.4)	134	44.7 (36.7-52.7)	138	46.3 (39.1-53.4)	118	-2.1	-1.0 (-3.5, 1.7)	-0.09 (0.15)	-0.05 (0.16)
3-5 days	53.8 (46-61.6)	106	60.4 (50.6-70.2)	132	59.4 (49-69.8)	83	60.4 (47.5-73.4)	80	49.5 (35.9-63)	64	-8.0	0.3 (-8.7, 10.3)	-0.16 (0.24)	-0.36 (0.22)
6-9 days	64 (53.4-74.7)	78	65.6 (55.6-75.5)	85	50.7 (38.3-63)	66	62.1 (48.9-75.3)	54	61.7 (48-75.4)	35	-3.6	-1.8 (-10.9, 8.3)	-0.18 (0.29)	0.27 (0.27) [f]
10-19 days	65.5 (57.8-73.3)	124	60.2 (51.4-69)	118	58.8 (46-71.6)	96	55.4 (43.9-67)	58	66.1 (56.9-75.3)	55	0.9	-0.3 (-7.1, 6.9)	-0.11 (0.21)	0.27 (0.22) [f]
20-29 days	65.3 (52.5-78.1)	93	59.1 (50.6-67.5)	105	66.2 (54.1-78.2)	75	59.7 (44.4-75)	57	57.3 (45.6-69)	49	-12.3	-2.0 (-8.6, 5.1)	-0.10 (0.28)	0.00 (0.28) [f]
All 30 days	65.3 (57.5-73.2)	230	60.4 (51.9-68.8)	213	55.8 (47.2-64.5)	187	69.7 (60.6-78.7)	153	53.9 (42-65.8)	94	-17.5	-0.9 (-12.1, 11.7)	-0.19 (0.23)	-0.02 (0.22)

Note: RPC=Unadjusted relative percentage change; AAPC=Average Annual Percentage Change (unadjusted), ALT=Adjusted Linear Trend; AQT=Adjusted Quadratic Trend. Unless indicated, all races are non-Hispanic. Trends for nonmenthol cigarette use are not shown separately because menthol and nonmenthol use estimates among current smokers are complementary and add to 100%. Highlighted cells show significant within-group differences in each year.

† Statistically significant linear or quadratic trends during 2011-2015

[a]Significantly different trend compared to ≥17 year olds

[b] Significantly different trend compared to 12th graders

[c]Significantly different trend compared to High school students

[d]Significantly different trend compared to non-Hispanic whites

[e]Significantly different trend compared to experimenters (≤1 cigarette/life)

[f]Significantly different trend compared to those who smoked 1-2 days

Table 3.5 Predictors of menthol cigarette use among current cigarette smokers Model (n=986)

Characteristics	**Levels**	**Unadjusted**	**Adjusted**
		OR (95% CI)	OR (95% CI)
	Male (referent)		
Sex	Female	1.16 (0.90-1.49)	1.17 (0.90-1.52)
	Middle (referent)		
School level	High	1.14 (0.72-1.81)	1.23 (0.77-1.96)
	White, non-Hispanic (referent)		
	Black, non-Hispanic	3.15 (1.26-7.85)	3.19 (1.31-7.82)
	Other, non-Hispanic	1.44 (0.83-2.51)	1.45 (0.85-2.49)
Race/ethnicity	Hispanic	1.47 (0.98-2.20)	1.42 (0.96-2.12)
	> 1 hour (referent)		
Time to first cigarette after waking	≤ 1 hour	1.62 (1.05-2.48)	1.72 (1.10-2.67)
Presence of "a physical, mental, or emotional condition [that results in] serious difficulty concentrating, remembering, or making decisions	Not reported (referent)		
	Reported	1.60 (1.18-2.17)	1.51 (1.07-2.14)
	None (referent)		
Past-year cigarette quit-attempt	≥ 1 past quit attempt	1.24 (0.89-1.73)	1.25 (0.90-1.75)
	"Strongly agree" or "agree" (referent)		
Perception that 'All tobacco products are dangerous'	"Strongly disagree" or "disagree"	1.25 (0.87-1.79)	1.30 (0.92-1.85)
Past 30-day truant behavior [missed, skipped or "cut" at least one class period because of not wanting to be there]	Not reported (referent)		
	Reported	1.43 (1.05-1.94)	1.37 (1.01-1.87)
	Social sources (referent)		
Usual source of obtaining tobacco products	Purchased their tobacco products	1.57 (1.06-2.33)	1.75 (1.12-2.74)
	No exposure to ads from any source (referent)		
	Exposure to ads from 1 source	1.67 (0.98-2.84)	2.07 (1.21-3.52)
Exposure to pro-tobacco advertisements over the internet, newspapers/magazines, retail stores, or TV/movies.	Exposure to ads from multiple sources	1.08 (0.62-1.90)	1.31 (0.77-2.22)
	Unknown	3.77 (2.04-6.96)	4.70 (2.60-8.49)

Note: Multiple logistic regression models were fitted, each adjusting for school level, sex and race/ethnicity.

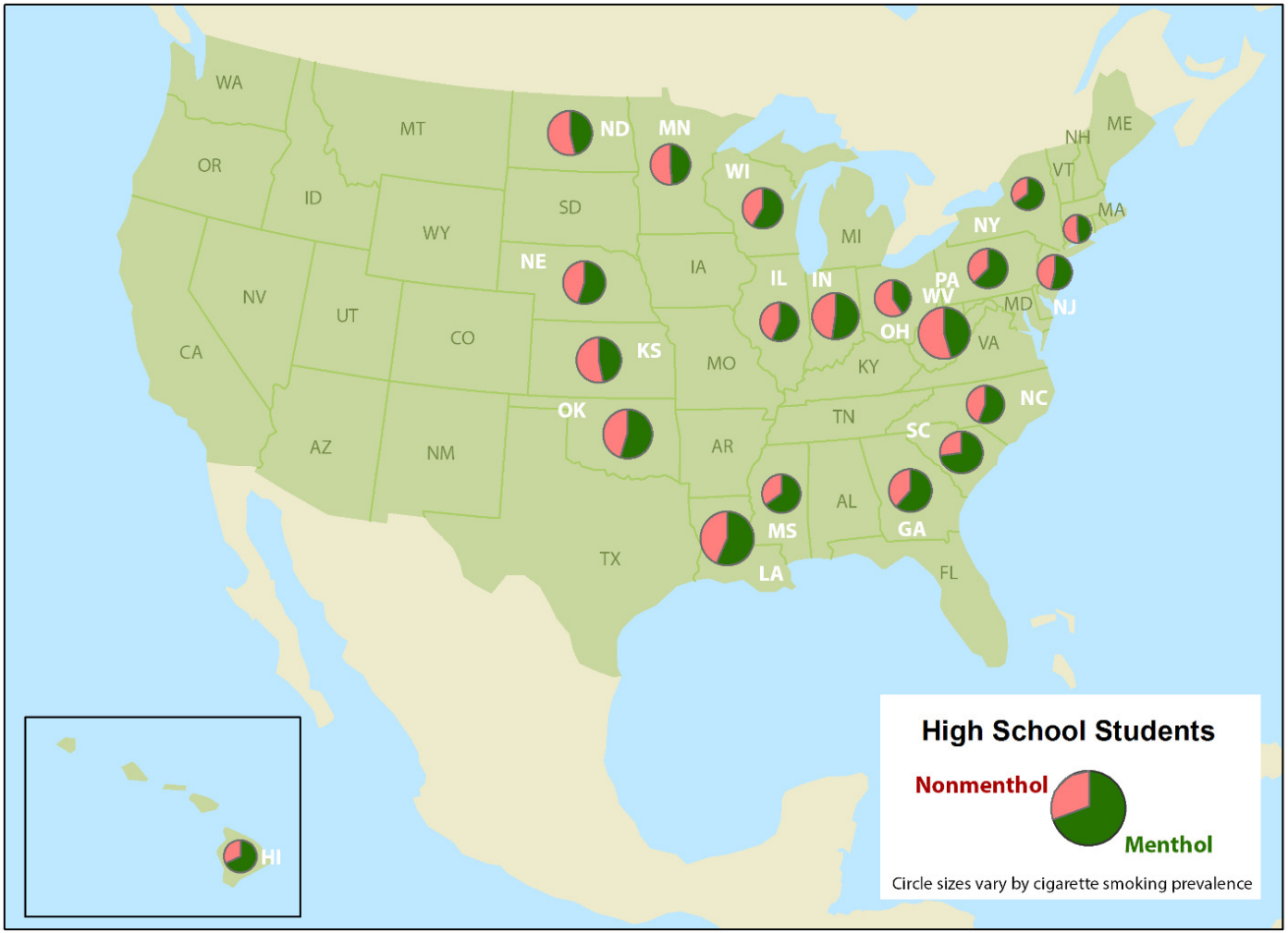

Figure 3.1 Bivariate map showing current cigarette smoking prevalence and the percentage of cigarette smokers that used menthol cigarettes among high school students, by state, 2012-2016 Youth Tobacco Survey

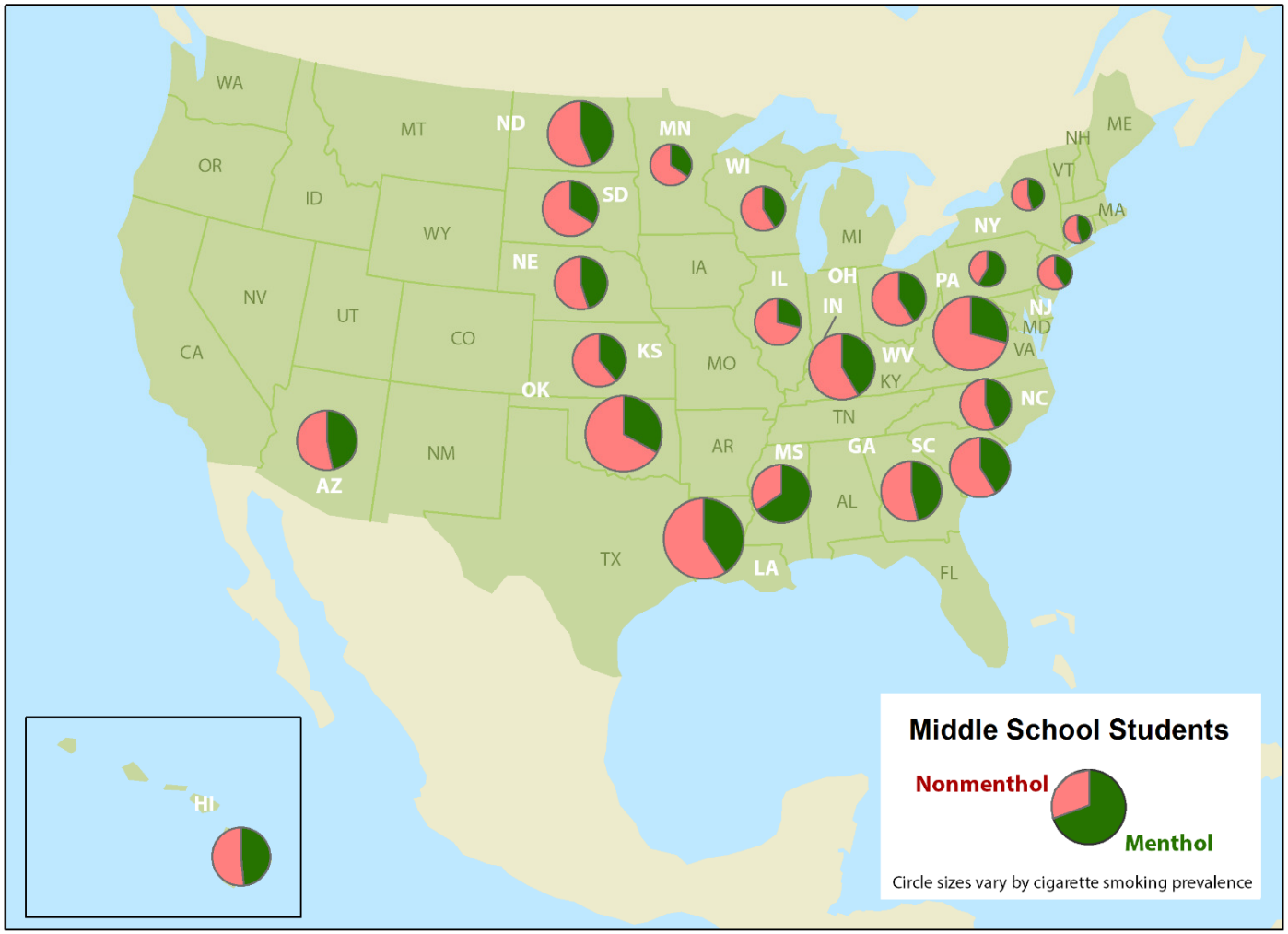

Figure 3.2 Bivariate map showing current cigarette smoking prevalence and the percentage of cigarette smokers that used menthol cigarettes among middle school students, by state, 2012-2016 Youth Tobacco Survey

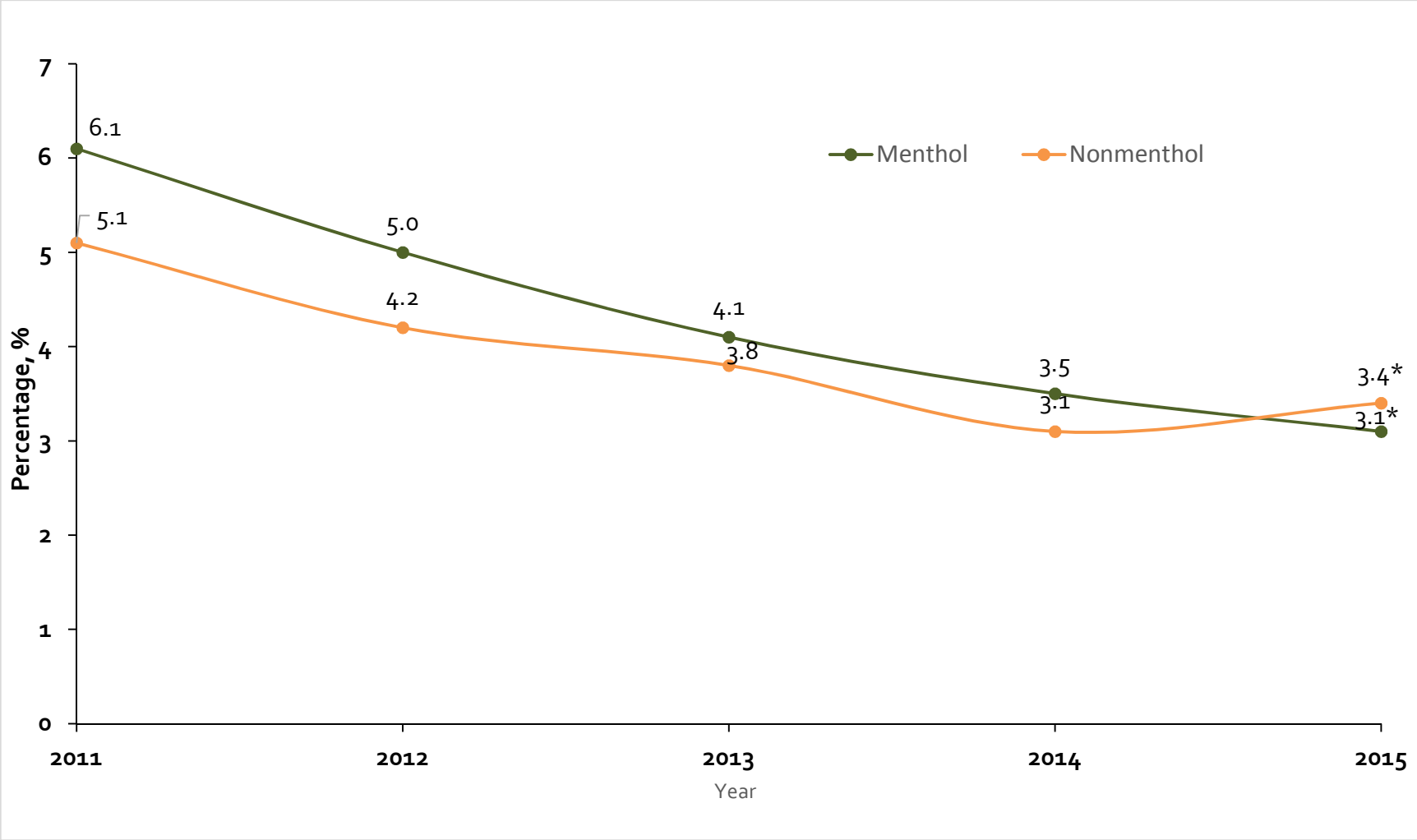

Figure 3.3 Trends in smoking of menthol and nonmenthol cigarettes among all U.S. middle and high school students, 2011-2015

*Significant linear decline during 2011-2015

Chapter 4 -ASSOCIATION BETWEEN MENTHOL CIGARETTE SMOKING AND CURRENT USE OF ELECTRONIC CIGARETTES AND OTHER NON-CIGARETTE FLAVORED TOBACCO PRODUCTS AMONG U.S. ADOLESCENTS[3]

[3] Agaku IT, Dobbin K, Muilenburg J, Hallow K, et al. To be submitted to *Journal of Adolescent Health.*

ABSTRACT

BACKGROUND: Among U.S. 6-12th graders, 2011-2015 saw a decline in cigarette smoking, an increase in e-cigarette use, and a plateauing in aggregate tobacco use. E-cigarette manufacturers have targeted menthol cigarette smokers by marketing e-cigarette flavors branded after popular menthol cigarettes e.g., "Newport". Such targeted marketing could increase the likelihood of e-cigarette initiation among menthol cigarette smokers. The basis for concern about e-cigarette use among cigarette smokers is that this dual use behavior may slow/prevent smoking cessation. This study examined the association between menthol cigarette smoking and e-cigarette use among U.S. students in grades 6-12.

METHODS: Data were from the 2014-2015 (N=39,718) National Youth Tobacco Survey of U.S. 6-12th graders. Reasons for e-cigarette use by self-reported menthol status were compared using chi-squared tests. Multivariable logistic regression was used to estimate the association between menthol cigarette smoking and current e-cigarette use. Blinder-Oaxaca decomposition analyses were performed to separate the total effect of menthol cigarette smoking on e-cigarette use into direct (unexplained) and indirect (explained/mediatory) effects.

RESULTS: Current e-cigarette use prevalence was higher among menthol (58.5%) than nonmenthol (47.5%) cigarette smokers (p<0.001). Certain reasons for e-cigarette use differed between menthol versus nonmenthol cigarette smokers respectively, including for smoking cessation (26.2% vs. 18.4%, p=0.0163); imitation

of celebrity role models (4.4% vs. 1.1%, p=0.0013); attractive flavors (45.8% vs. 34.5%, p=0.004); and situational use in areas with smoking prohibitions (29.5% vs. 21.7%, p=0.0109). Logistic regression analyses among all cigarette smokers revealed higher odds of current e-cigarette use among menthol than nonmenthol cigarette smokers (aOR=1.56, 95%CI=1.24-1.97); analyses restricted to cigarette smokers who first tried cigarettes before any other tobacco product yielded consistent results (aOR=1.40, 95%CI=1.06-1.85). Within Blinder-Oaxaca decomposition analyses, e-cigarette marketing exposure (aOR=1.09), attractive flavors (aOR=1.22), situational e-cigarette use (aOR=1.08), and nicotine addiction (aOR=1.16), all were significant (p<0.05) explanatory factors.

CONCLUSION: Current e-cigarette use was higher among menthol than nonmenthol cigarette smokers. Differential e-cigarette marketing exposure, addiction and self-rated importance of flavors and situational e-cigarette use between menthol and nonmenthol cigarette smokers explained higher e-cigarette use among menthol cigarette smokers. These findings raise concerns about dual use and potential for perpetuation of tobacco use among menthol smokers.

INTRODUCTION

Electronic cigarettes (e-cigarettes) are the most commonly used tobacco product among U.S. youth; 3 million students in grades 6-12 reported current (past 30-day) use in 2015 [1]. During 2011-2015, aggregate tobacco use prevalence among U.S. middle and high school students remained unchanged despite significant declines in cigarette smoking prevalence among both middle (4.3% to 2.3%) and high school students (15.8% to 9.3%), partly because of dramatic increases in e-cigarette use prevalence among middle (from 0.6% to 5.3%) and high school students (from 1.5% to 16.0%) [1]. E-cigarette manufacturers have targeted menthol smokers by marketing e-cigarette flavors branded after popular menthol cigarettes such as “Kool” or “Newport” [2]. Such targeted marketing could increase the likelihood of e-cigarette initiation among menthol cigarette smokers. Furthermore, because of conditioned aspects of chemosensory experiences such as taste [3], it is plausible that adolescents who smoke menthol cigarettes might be more likely to experiment with other flavored products such as e-cigarettes.

The basis for concern about use of e-cigarettes among youth lie in their potential for both individual and population-level harm [4]. Exposure to nicotine during adolescence may negatively affect brain development and can result in nicotine addiction [4]. E-cigarette use among cigarette smokers may slow or prevent smoking cessation, thus increasing nicotine addiction and risk of tobacco-

attributable disease. On a societal level, e-cigarettes may also renormalize tobacco use, and create challenges for enforcement of comprehensive smoke-free policies.

E-cigarettes are attractive to many youth because of their wide array of flavors, including those for fruit, candy, beverage, bakery, spice, and menthol [5, 6]. A recent study in Connecticut showed that youth in high school were more likely to cite attractive flavors as a reason for experimenting with e-cigarettes compared to those in college (47.2% vs. 32.8% respectively), a finding consistent with the fact that preference for sweet wanes with increasing age [3-6]. Youth who experiment with e-cigarettes because of attractive flavors are more likely to use it longer than those who try out of mere curiosity [10]. Unlike regular cigarettes in which use of all "characterizing flavors" (except menthol) is prohibited [11], current regulations for e-cigarettes do not limit flavors. Menthol is available in e-cigarettes in both pre-packaged and modifiable designs that allow users to customize their menthol concentration using menthol extracts such as menthol drops or crystals [2]. In view of FDA's extended regulatory authority over a broad range of tobacco products including e-cigarettes under the deeming rule [12], it is imperative to understand the role of design characteristics such as flavors in encouraging dual use among youth in order to inform regulatory policy.

Although menthol cigarettes have undergone extensive research in relation to their public health impact, most of these studies proceeded the era of e-cigarettes. The entire 2011 report of the Tobacco Products Scientific Advisory Committee

(TPSAC) to FDA on the public health impact of menthol cigarettes has no mention of e-cigarettes [13]. In July 2013, FDA issued an Advanced Notice of Proposed Rulemaking seeking additional information to help guide decision making about menthol cigarettes [14]. Some of the knowledge gaps identified by FDA were differences between menthol and nonmenthol cigarettes as they relate to menthol's likely effect on smoking cessation and attempts to quit [14]. Uptake of new aspects of tobacco use behaviors among youth smokers, including the initiation of e-cigarettes or other novel tobacco products, is relevant to this agenda because of the implications for sustained tobacco product use. E-cigarettes might contribute to a perpetuation of tobacco use if they lead to smoking initiation among those who would not have started otherwise, a continuation of tobacco use among current smokers who would have quit, or a relapse to tobacco use among former smokers who would have remained quit.

No study has examined the association between menthol cigarette smoking and use of e-cigarettes or other flavored non-cigarette tobacco products (NCP) among U.S. adolescents. To fill this gap in knowledge, this study used nationally representative data of U.S. students in grades 6-12 during 2014-2015 to test the hypothesis that the likelihood of e-cigarette use will be different among menthol compared to nonmenthol cigarette smokers. Secondarily, mediational analyses were performed to explore how menthol cigarette smoking alters likelihood of e-cigarette use.

METHODOLOGY

Data source

Data were from the 2014 (n=22,007) and 2015 (n=17,711) waves of the National Youth Tobacco Survey (NYTS), a cross-sectional, paper and pencil survey of U.S. middle and high school students administered in a classroom setting. The universe of NYTS comprises U.S. students attending public and private schools in grades 6–12 in the 50 U.S. States and D.C. Sampling procedures were probabilistic and conducted without replacement at three stages: (1) Primary Sampling Units (2) Schools and (3) Classes. Overall response rates were 73.3% and 63.4% in 2014 and 2015 respectively. Only the 2014 and 2015 waves of NYTS were used for this study because previous waves did not collect information for several variables of interest, such as tobacco product of initiation, which was needed to restrict analyses to those who started tobacco use with cigarettes.

Measures

Menthol Cigarette smoking status

Menthol cigarette smoking was defined based on concordance between self-reported cigarette type and cigarette brand. Cigarette type was determined as follows: “Menthol cigarettes are cigarettes that taste like mint. During the past 30 days, were the cigarettes that you usually smoked menthol?” Response options among past 30-day smokers were “Yes”; “No”; or “Not sure”. Cigarette brand was determined as follows: “During the past 30 days, what brand of cigarettes did you

usually smoke? (CHOOSE ONLY ONE ANSWER)". Response options for brands smoked were collapsed into three categories based on their market shares: (1) exclusively nonmenthol brands— "Lucky Strike" (2) Exclusively menthol brands— "Newport", and "Kool" and (3) mixed brands— "American Spirit"; "Camel"; "GPC, Basic, Doral"; "Marlboro"; "Parliament"; "Virginia Slims", and "Some other brand not listed here". Persons with no usual brand were excluded to reduce the likelihood of misclassification.

Menthol smokers were respondents whose cigarette brand was an exclusively menthol or mixed brand, *and* who reported that their cigarette type was menthol. Nonmenthol smokers were respondents whose cigarette brand was an exclusively nonmenthol or mixed brand, *and* who reported that their cigarette type was nonmenthol. Missing information for either cigarette type or brand; persons with "no usual brand"; those "not sure" of their cigarette type; and those with discordant brand-type responses were excluded.

Product and Sequence of tobacco initiation

NYTS collected information from respondents regarding the estimated number of cigarettes they had smoked in their lifetime (cumulative), which tobacco product they tried first, and age at smoking initiation. Former cigarette smokers were respondents who last smoked a cigarette >30 days ago. Never cigarette smokers were respondents who had never puffed on a cigarette.

E-cigarettes and any flavored NCP Use

Respondents were asked about their ever (≥1 time in lifetime) and current (≥1 time in past 30 days) use of e-cigarettes. Data were also collected on current use of NCPs that were "flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate or other sweets", including cigars, cigarillos, little cigars, chewing tobacco, snuff, or dip, e-cigarettes, hookah, pipe, snus, or dissolvable tobacco products. Students who reported using ≥1 flavored NCP on at least one occasion within the past 30 days were classified as current any flavored NCP users.

In 2015 NYTS only, reasons for e-cigarette use were determined with the question "What are the reasons why you have used electronic cigarettes or e-cigarettes?" Multiple-option responses were: (1) "Friend or family member used them". (2) "To try to quit using tobacco products, such as cigarettes", (3) "They cost less than other tobacco products, such as cigarettes". (4) "Famous people on TV or in movies use them". (5) "They are less harmful than other forms of tobacco, such as cigarettes". (6) "They are available in flavors, such as mint, candy, fruit, or chocolate". (7) "They can be used in areas where other tobacco products, such as cigarettes, are not allowed". (8) Other reasons.

Nicotine addiction, Relative Harm Perception, and pro-tobacco social influences

Nicotine addiction was measured with four indexes, which were used within mediational analyses. (1) Time to first cigarette after waking (≤1 hour vs. >1 hour). (2) Presence of "strong cravings" for tobacco within the past 30 days. (3) Report of

frequent (i.e., “sometimes”, “often” or “always”) symptoms of psychological dependence (i.e., strong cravings after a few hours of not using tobacco). (4) Report of frequent symptoms of physical dependence (i.e., restlessness and irritability after a period of not using tobacco).

Participants’ relative harm perception about tobacco products was measured with the questions: (1) “How strongly do you agree with the statement ‘All tobacco products are dangerous?” Affirmative responses were “Strongly agree” or “Agree” (vs. “Strongly disagree” or “Disagree”). (2) “How much do you think people harm themselves when they use e-cigarettes some days but not every day?” Responses indicative of perceived harm were “Some harm” or “A lot of harm” (vs. “No harm” or “a little harm”).

Respondents also answered questions on use of e-cigarettes by their peers and household members, as well as their own exposure (“sometime”, “most of the time” or “always” vs. “rarely” or “never”) to pro-tobacco advertisements on the Internet, in newspapers/magazines, at retail stores and on TV/movies.

Socio-demographic Characteristics

Socio-demographic characteristics included sex, race/ethnicity, school level, and grade. Usual source of obtaining tobacco products (purchase vs. social contacts e.g., friends) was used as a proxy for disposable income.

Analyses

Prevalence estimates of ever e-cigarette use, current e-cigarette use, and current any flavored NCP use were computed and compared within subgroups using the standard chi-squared test for nominal variables and a trend test for ordinal variables. Among ever e-cigarette users, reasons for e-cigarette use among menthol cigarette smokers, nonmenthol cigarette smokers, former cigarette smokers, and never cigarette smokers were calculated; statistical testing was however restricted to menthol vs. nonmenthol cigarette smokers only to avoid multiple comparisons. Multivariable logistic regression analyses were used to measure the relationship between menthol cigarette smoking status and two separate outcomes: current e-cigarette use (primary outcome) and current any flavored NCP use (secondary outcome). The models for both outcomes adjusted for school level, race/ethnicity, sex, and age at smoking initiation (proxy for duration of smoking) as confounders.

To mitigate temporality bias (reverse causation) considering that e-cigarette users might equally transition to using menthol cigarettes because of flavor appeal, two separate denominators were analyzed for both the primary and secondary outcomes. The first denominator was all current cigarette smokers regardless of their tobacco product of initiation; the second was current cigarette smokers who reported cigarettes as the first tobacco product they ever tried.

Because of non-random missingness for some independent variables including school level, race/ethnicity, and age of smoking initiation, stabilized

inverse proportionality weights (IPW) were used within a marginal structural model to control for both selection bias and confounding [15]. To account for the complex survey design, final weights were created that incorporated both IPW and survey sampling weights (SSW) as a function of the product of both weights [16]. Within sensitivity analyses, the estimates generated from the combined IPW*SSW were compared to those from IPW and SSW separately.

Blinder-Oaxaca decomposition analyses were performed among all cigarette smokers (regardless of product of initiation) to separate the total effect of menthol cigarette smoking on e-cigarette use into direct (unexplained) and indirect (explained/mediatory) effects [17, 18]. The *ldecomp* module in Stata was used to perform a domain-by-domain decomposition controlling for age, sex, and race/ethnicity as appropriate [17]. Nine broad domains of explanatory factors or constructs were measured: socio-demographic characteristics; proximal (peer and family) pro-tobacco social influences; e-cigarette marketing; smoking cessation; price/access; harm reduction; attractive flavors; situational e-cigarette use in areas with smoking prohibitions; and nicotine addiction. For each of these domains, estimates of total, direct and indirect effects were calculated, and are presented as odds ratios (OR). To generate 95% confidence intervals, bootstrapped standard errors based on 50 sampling replicates were used. Since only the 2015 iteration of NYTS collected data on certain measures (e.g., reasons for e-cigarette use), Blinder-Oaxaca decomposition analyses were restricted to 2015 NYTS alone. All other

multivariable analyses were with pooled 2014-2015 NYTS data to enhance statistical power. All data were analyzed using Stata V.11, and R V.3.2.3.

RESULTS

Reasons for e-cigarette use between menthol vs nonmenthol cigarette smokers

Of menthol and nonmenthol cigarette smokers combined, 68.2% (n= 1,364) reported initiating tobacco use with cigarettes (69.4% vs. 66.9% for menthol and nonmenthol cigarette smokers respectively, p=0.3076). Figure 4.1 shows the reasons for e-cigarette use among menthol cigarette smokers, nonmenthol cigarette smokers, former cigarette smokers, and never cigarette smokers. The following reasons for e-cigarette use were significantly higher among menthol compared to nonmenthol cigarette smokers respectively: to try to quit regular cigarettes (26.2% vs. 18.4%, p=0.0163); imitation of celebrity role models (4.4% vs. 1.1%, p=0.0013); attractive flavors (45.8% vs. 34.5%, p=0.004); and situational use in areas with smoking prohibitions (29.5% vs. 21.7%, p=0.0109). All other reasons for e-cigarette use were not significantly different by menthol cigarette smoking status. Use by family/friends was the most common reason for e-cigarette use by former cigarette smokers, never cigarette smokers, and nonmenthol cigarette smokers. In contrast, attractive flavors were the most common reason for e-cigarette use among menthol cigarette smokers.

E-cigarette and flavored NCP use by menthol cigarette smoking status

Compared to nonmenthol cigarette smokers, menthol cigarette smokers reported significantly higher prevalence of ever e-cigarette use (84.9% vs. 78.2%, p=0.010) and current e-cigarette use (58.5% vs. 47.5%, p<0.001). Among menthol cigarette smokers, no subgroup differences in current e-cigarette use were observed except by sex (63.0 vs. 53.1% for males and females respectively, p=0.0313). Among nonmenthol cigarette smokers, differences in current e-cigarette use were seen by school level (50.0% vs. 35.2% for high and middle school students respectively, p=0.0051) and lifetime number of cigarettes smoked, with prevalence of e-cigarette use increasing linearly with increasing lifetime number of cigarettes smoked (p-trend<0.001). The following groups of menthol cigarette smokers had significantly higher prevalence of e-cigarette use compared to their nonmenthol cigarette smoking counterparts: males, 8th and 10th graders, persons aged ≤12 years and 15-16 years old, non-Hispanic whites, Hispanics, both middle and high school students, and those who had smoked 2-5 cigarettes in their lifetime (all p<0.05).

As shown in Table 4.1, prevalence of current use of any flavored NCP use was higher among menthol compared to nonmenthol cigarette smokers (73.8% vs. 57.6% respectively, p<0.001). Among menthol cigarette smokers, prevalence of any flavored NCP use increased with increasing number of cigarettes smoked (p-trend<0.001); no differences were observed by other characteristics. Among nonmenthol cigarette smokers, prevalence of any flavored NCP differed by school level (p<0.001) and sex (p=0.0014), and also increased with increasing age, grade,

and lifetime number of cigarettes smoked (all p-trend<0.001). Higher prevalence of current any flavored NCP use was seen among menthol cigarette smokers compared to their nonmenthol smoking counterparts within the following groups: non-Hispanic whites, Hispanics, persons who reported lifetime usage of ≤1 cigarette and ≥5 packs, all levels of sex, age, school level, and grade (except 9th and 12th) (all p<0.05).

Multivariable logistic regression analyses revealed that menthol cigarette smokers were significantly more likely to be current e-cigarette users compared to nonmenthol cigarette smokers; both within the model that included all cigarette smokers regardless of product of initiation (AOR=1.56, 95%CI=1.24-1.97), as well as the model restricted to smokers who tried cigarettes first (AOR=1.40, 95%CI=1.06-1.85; *Table 4.2*). Similarly, menthol cigarette smokers were significantly more likely to be current users of any flavored NCP compared to nonmenthol cigarette smokers, both within the model with all cigarette smokers (AOR=2.12, 95%CI=1.67-2.68), and the model with only those who tried cigarettes first (AOR=2.33, 95%CI=1.71-3.20; *Table 4.3*). Results from sensitivity analyses for models with IPW alone or SSW alone yielded comparable results for both the primary and secondary outcomes.

Decomposition of differences in e-cigarette use between menthol and nonmenthol smokers

Table 4.4 shows results for total, direct, and indirect results from domain-by-domain decomposition of differences in e-cigarette use by menthol cigarette smoking status. The total effect of menthol cigarette smoking on e-cigarette use was

significant in all models, effect size ranging from OR=1.57 to OR=1.70. A total effect of OR=1.57 indicates that overall, the odds of being a current e-cigarette user among menthol cigarette smokers was 1.57 times as large as the odds for nonmenthol cigarette smokers.

A direct effect of menthol cigarette smoking status on e-cigarette use was also significant in all models; effect size ranged from OR=1.38 with disposable income as explanatory variable, to OR=1.69 with age or race/ethnicity as explanatory variables. A direct effect of OR=1.69 for age as an explanatory factor indicates that menthol cigarette smokers would have 1.69 times higher odds of being current e-cigarette users than nonmenthol cigarette smokers when age is kept constant at the level of menthol cigarette smokers.

An indirect effect was significant for six models measuring the following exploratory factors or constructs: smoking cessation (OR=1.07), price/access (OR=1.22), e-cigarette marketing exposure (OR=1.09), flavors (OR=1.22), situational e-cigarette use (OR=1.08), and nicotine addiction (OR=1.16; all $p<0.05$). An indirect effect of OR=1.16 for nicotine addiction indicates that nonmenthol smokers would have 1.16 higher odds of being current e-cigarette users if they had the same level of nicotine addiction as menthol cigarette smokers. Expressed as a percentage of the total effect, the indirect effect of attractive flavors explained 37.6% of the total difference between menthol and nonmenthol smokers in their use of e-cigarettes; nicotine addiction explained 30.1%, while price/access explained 37.9%.

DISCUSSION

This study explored the relationship between menthol cigarette smoking and e-cigarette use because of concerns about the role of e-cigarettes in promoting dual use, as well as targeted marketing of e-cigarette flavors at menthol cigarette smokers. The results indicated that prevalence of ever e-cigarette use, current e-cigarette use, and current use of any flavored NCP were all significantly higher among menthol compared to nonmenthol cigarette smokers. The fact that a large part of this difference in e-cigarette use was attributable to menthol cigarette smokers having greater levels of nicotine dependence, e-cigarette marketing exposure, and higher self-ratings of the importance of flavors and the need for situational e-cigarette use, raises concerns about dual use behavior among menthol cigarette smokers. In addition, a quarter (26.2%) of menthol cigarette smokers and about a fifth (18.4%) of nonmenthol cigarette smokers who had ever used e-cigarettes reported using it to quit smoking. There is no conclusive evidence of the effectiveness of e-cigarettes in helping adolescents quit cigarette smoking; even among adults, evidence for the effectiveness of e-cigarettes in cessation remains inconclusive [19]. Smoking cessation counseling can help adolescents to quit smoking; the U.S. Preventive Services Task Force gave a “B” grade for primary care interventions including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents [20].

E-cigarette use by family or friends was the most common reason for using e-cigarettes by nonmenthol cigarette smokers whereas attractive flavors constituted the most common reason for e-cigarette use among menthol cigarette smokers. Flavors and other chemosensory attributes can contribute to conditioned aspects of tobacco use and reinforce smoking behavior [21, 22]. Extensive evidence from a variety of perspectives over many years support the fact that nicotine alone does not explain tobacco addiction, other chemosensory effects and smoking-related cues also play a key role [23-33].

The magnitude of differences in e-cigarette use prevalence between menthol and nonmenthol cigarette smokers was greatest among the youngest groups of smokers, including those aged ≤12 years old and middle schoolers (particularly 8th grade students). Among persons aged ≤12 years, prevalence of e-cigarette use was almost two-fold higher among menthol than nonmenthol cigarette smokers whereas no difference in e-cigarette use existed between menthol and nonmenthol cigarette smokers aged ≥17 years old. More so, the proportion who had ever tried an e-cigarette but no longer used them at the time of the study (i.e., the difference between the proportions of ever and current e-cigarette users) increased with increasing age for both menthol and nonmenthol cigarette smokers but more so for menthol cigarette smokers. This might suggest that younger adolescents who experiment with e-cigarettes may be more likely to sustain the habit compared to older adolescents. It is however also possible that these findings could be a manifestation of age and cohort effects (as a cohort progresses, the cumulative

number of those who have tried e-cigarettes will likely increase, and thus the number who have tried and stopped using e-cigarettes will also increase proportionally). It will be important to investigate these preliminary findings further using a longitudinal cohort design to determine differential trajectories of e-cigarette initiation and usage patterns by age. Early uptake and continued use of tobacco products among young adolescents is an important public health issue considering that early adolescence is a period of rapid brain development, and nicotine exposure during adolescence can lead to addiction and might harm brain development [34-38].

Taken together, these findings suggest that the prevalence of e-cigarette use among cigarette smokers overall might be much reduced if menthol cigarettes were removed from the U.S. market. Under the assumption that prevalent cases of e-cigarette use are equivalent to incident cases by virtue of the relative novelty of e-cigarettes, the attributable fraction for e-cigarette use among menthol cigarette smokers is approximately 20%, given an e-cigarette use prevalence of 58.5% among menthol cigarette smokers and 47.5% among nonmenthol cigarette smokers. Efforts to reduce dual use are critical to accelerating progress in reducing aggregate tobacco use among adolescents, a risk behavior which has remained unchanged in the past half-decade [1].

This study is the first to explore the relationship between menthol cigarette smoking and current use of e-cigarettes and other flavored NCP. Limitations

however exist. First, the cross-sectional data does not allow for causal inferences. Second, tobacco use and menthol status were self-reported and could have been subject to misreporting. Third, these data are not generalizable to youth who are home-schooled, dropouts, or those in special education schools since they are not part of NYTS' sampling frame. However, <5% of U.S. youth aged 10-17 years were not enrolled in a traditional school in 2014 [39]; hence these findings apply to the majority of school-aged students. Finally, because of the cross-sectional nature of the data, it is impossible to disaggregate period, cohort, and age effects.

CONCLUSION

E-cigarettes and any flavored NCP use was significantly higher among menthol compared to nonmenthol cigarette smokers. A large proportion of this difference in e-cigarette use was attributable to higher level of nicotine addiction, greater exposure to e-cigarette advertising, and higher rating of the importance of flavored tobacco products among menthol cigarette smokers. Menthol might be slowing progress in reducing aggregate tobacco use among youth by encouraging dual use with other flavored tobacco products such as e-cigarettes. Evidence-based interventions can help protect youth from initiation and continued use of tobacco products.

REFERENCES

1. Singh, T., et al., *Tobacco Use Among Middle and High School Students--United States, 2011-2015*. MMWR.Morbidity and mortality weekly report, 2016. **65**(14): p. 361-367.
2. ECF. Menthol Suggestions. Available at https://www.e-cigarette-forum.com/forum/threads/menthol-suggestions.143176/. Accessed 09/15/2016.
3. *Taste & Olfaction*. 1987: RJ Reynolds. Bates number 509859364/9400. Available at http://legacy.library.ucsf.edu/tid/kou63d00. Accessed 09/30/2016.
4. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
5. Zhu, S.H., et al., *Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation.* Tobacco control, 2014. **23 Suppl 3**: p. iii3-9.
6. Kong, G., et al., *Reasons for Electronic Cigarette Experimentation and Discontinuation Among Adolescents and Young Adults.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2015. **17**(7): p. 847-854.

7. De Graaf, C. and E.H. Zandstra, *Sweetness intensity and pleasantness in children, adolescents, and adults.* Physiology & Behavior, 1999. **67**(4): p. 513-520.

8. Desor, J.A. and G.K. Beauchamp, *Longitudinal changes in sweet preferences in humans.* Physiology & Behavior, 1987. **39**(5): p. 639-641.

9. Desor, J.A., L.S. Greene, and O. Maller, *Preferences for sweet and salty in 9- to 15-year-old and adult humans.* Science (New York, N.Y.), 1975. **190**(4215): p. 686-687.

10. Bold, K.W., et al., *Reasons for Trying E-cigarettes and Risk of Continued Use.* Pediatrics, 2016. **138**(3): p. 10.1542/peds.2016-0895. Epub 2016 Aug 8.

11. U.S. Food and Drug Administration. *FDA NEWS RELEASE: Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm.* Accessed 09/16/ 2016.

12. Federal Register. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act;Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Available at https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the. Accessed 09/14/2016.

13. Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/tobaccoproductsscientificadvisorycommittee/ucm269697.pdf. Accessed 09/15/2016.

14. U.S. Food and Drug Administration. FDA invites public input on menthol in cigarettes. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm361966.htm. Accessed 09/14/2016.

15. Hernán MA, Robins JM (2016). Causal Inference. Boca Raton: Chapman & Hall/CRC, forthcoming. Available at https://www.hsph.harvard.edu/miguel-hernan/causal-inference-book/. Accessed 09/15/2016.

16. Dugoff, E.H., M. Schuler, and E.A. Stuart, *Generalizing observational study results: applying propensity score methods to complex surveys.* Health Serv Res, 2014. **49**(1): p. 284-303.

17. Maarten L. Buis. Direct and indirect effects in a logit model. Available at http://www.stata-journal.com/sjpdf.html?articlenum=st0182. Accessed 09/15/2016.

18. Marek Hlavac. oaxaca: Blinder-Oaxaca Decomposition in R. Available at https://cran.r-project.org/web/packages/oaxaca/vignettes/oaxaca.pdf. Accessed 09/15/2016.

19. U.S. Preventive Services Task Force. Tobacco Smoking Cessation in Adults and Pregnant Women: Behavioral and Pharmacotherapy Interventions. Available at http://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement147/tobacco-use-in-adults-and-pregnant-women-counseling-and-interventions1. Accessed 05/01/2016.;

20. U.S. Preventive Services Task Force. Tobacco Use in Children and Adolescents: Primary Care Interventions. Available at https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/tobacco-use-in-children-and-adolescents-primary-care-interventions. Accessed 09/16/2016.;

21. Carpenter, C.M., G.F. Wayne, and G.N. Connolly, *The role of sensory perception in the development and targeting of tobacco products.* Addiction (Abingdon, England), 2007. **102**(1): p. 136-147.

22. Henningfield, J.E., et al., *Conference on abuse liability and appeal of tobacco products: conclusions and recommendations.* Drug and alcohol dependence, 2011. **116**(1-3): p. 1-7.

23. Brenhouse, H.C., K.C. Sonntag, and S.L. Andersen, *Transient D1 dopamine receptor expression on prefrontal cortex projection neurons: relationship to enhanced motivational salience of drug cues in adolescence.* The Journal of neuroscience : the official journal of the Society for Neuroscience, 2008. **28**(10): p. 2375-2382.

24. Buchhalter, A.R., L. Schrinel, and T. Eissenberg, *Withdrawal-suppressing effects of a novel smoking system: comparison with own brand, not own brand, and de-nicotinized cigarettes.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2001. **3**(2): p. 111-118.

25. Caggiula, A.R., et al., *Importance of nonpharmacological factors in nicotine self-administration.* Physiology & Behavior, 2002. **77**(4-5): p. 683-687.

26. Dar, R. and H. Frenk, *Do smokers self-administer pure nicotine? A review of the evidence.* Psychopharmacology, 2004. **173**(1-2): p. 18-26.

27. Donny, E.C. and M. Jones, *Prolonged exposure to denicotinized cigarettes with or without transdermal nicotine.* Drug and alcohol dependence, 2009. **104**(1-2): p. 23-33.

28. Gross, J., J. Lee, and M.L. Stitzer, *Nicotine-containing versus de-nicotinized cigarettes: effects on craving and withdrawal.* Pharmacology, biochemistry, and behavior, 1997. **57**(1-2): p. 159-165.

29. Perkins, K.A., et al., *Acute negative affect relief from smoking depends on the affect situation and measure but not on nicotine.* Biological psychiatry, 2010. **67**(8): p. 707-714.

30. Rose, J.E., *Nicotine and nonnicotine factors in cigarette addiction.* Psychopharmacology, 2006. **184**(3-4): p. 274-285.

31. Rose, J.E., et al., *Dissociating nicotine and nonnicotine components of cigarette smoking.* Pharmacology, biochemistry, and behavior, 2000. **67**(1): p. 71-81.

32. Rose, J.E., et al., *Reinforcing effects of nicotine and non-nicotine components of cigarette smoke.* Psychopharmacology, 2010. **210**(1): p. 1-12.

33. West, R., et al., *A comparison of the abuse liability and dependence potential of nicotine patch, gum, spray and inhaler.* Psychopharmacology, 2000. **149**(3): p. 198-202.

34. Dierker, L., et al., *Transitions to regular smoking and nicotine dependence in the Adolescent National Comorbidity Survey (NCS-A).* Annals of Behavioral Medicine : A Publication of the Society of Behavioral Medicine, 2012. **43**(3): p. 394-401.

35. DiFranza, J.R., et al., *Initial symptoms of nicotine dependence in adolescents.* Tobacco control, 2000. **9**(3): p. 313-319.

36. Hu, M.C., et al., *Trajectories of criteria of nicotine dependence from adolescence to early adulthood.* Drug and alcohol dependence, 2012. **125**(3): p. 283-289.

37. O'Loughlin, J., et al., *Nicotine-dependence symptoms are associated with smoking frequency in adolescents.* American Journal of Preventive Medicine, 2003. **25**(3): p. 219-225.

38. Russo, S.J., et al., *The addicted synapse: mechanisms of synaptic and structural plasticity in nucleus accumbens.* Trends in neurosciences, 2010. **33**(6): p. 267-276.

39. United States Census Bureau. School Enrollment: Current Population Survey 2014 – Detailed Tables. Available at

https://www.census.gov/hhes/school/data/cps/2014/tables.html. Accessed 09/17/2016.

TABLES AND FIGURES

Table 4.1 Use of e-cigarettes and any flavored non-cigarette tobacco product (NCP), by menthol cigarette smoking status among U.S. adolescents, NYTS, 2014-2015

	Menthol cigarette smokers				Nonmenthol cigarette smokers			
	Distribution	Prevalence of ever e-cigarette use [a]	Prevalence of current e-cigarette use [b]	Prevalence of current any flavored NCP [c]	Distribution	Prevalence of ever e-cigarette use [a]	Prevalence of current e-cigarette use [b]	Prevalence of current any flavored NCP [c]
	% (N)	% (95% CI)	% (95% CI)	% (95% CI)	% (N)	% (95% CI)	% (95% CI)	% (95% CI)
OVERALL	100.0 (1172)	84.9 (81.3-88.5)*	58.5 (53.4-63.6)*	73.8 (69.8-77.8)*	100.0 (1051)	78.2 (74.2-82.2)	47.5 (41.9-53.1)	57.6 (53.4-61.8)
Sex		***p*=0.580**	***p*=0.031**	***p*=0.053**		***p* =0.278**	***p* =0.509**	***p* =0.014**
Male	54.3 (657)	86.0 (80.7-91.4)	63.0 (56.3-69.8)*	76.7 (72.1-81.3)*	57.8 (640)	80.0 (75.2-84.9)	48.7 (42.1-55.2)	62.3 (57.6-67.0)
Female	45.7 (504)	83.7 (78.2-89.3)	53.1 (46.3-59.9)	70.5 (65.0-76.1)*	42.2 (400)	76.4 (71.1-81.8)	46.0 (38.8-53.2)	51.2 (43.6-58.8)
Grade level		***p*=0.032**	***p*= 0.948**	***p*= 0.779**		***p* =0.002**	***p* = 0.053**	***p* <0.001**
6th	3.5 (51)	71.2 (49.7-92.7)	52.2 (30.9-73.5)	71.8 (55.8-87.8)*	3.1 (44)	69.4 (49.8-89.0)	48.1 (28.3-67.8)	36.2 (15.0-57.4)
7th	5.0 (55)	63.5 (26.8-100.0)	50.4 (20.0-80.8)	70.6 (50.3-90.9)*	4.8 (65)	49.7 (31.1-68.4)	27.0 (14.0-39.9)	29.4 (15.4-43.3)
8th	6.5 (86)	87.9 (79.1-96.7)*	74.0 (62.5-85.6)*	84.0 (75.7-92.4)*	8.2 (87)	71.0 (57.7-84.3)	35.4 (23.4-47.4)	47.9 (34.0-61.8)
9th	12.9 (138)	87.4 (81.3-93.4)	68.7 (58.5-78.9)	77.4 (65.2-89.7)	14.2 (143)	82.4 (73.9-90.9)	56.9 (47.9-65.8)	63.4 (54.9-71.9)
10th	18.5 (207)	85.4 (79.0-91.7)*	62.0 (53.2-70.9)*	73.3 (65.8-80.8)*	20.4 (187)	74.4 (66.3-82.5)	37.1 (28.8-45.3)	51.7 (41.7-61.7)
11th	24.3 (279)	89.1 (84.5-93.7)	55.2 (46.7-63.6)	71.3 (64.5-78.0)*	23.6 (246)	84.5 (78.4-90.5)	53.7 (43.7-63.6)	61.6 (54.6-68.5)
12th	29.3 (341)	84.1 (77.1-91.1)	52.7 (44.1-61.2)	72.8 (65.3-80.2)	25.6 (269)	82.9 (76.4-89.5)	53.3 (43.9-62.7)	66.9 (60.0-73.8)
Age, years		***p*=0.931**	***p*= 0.111**	***p*= 0.501**		***p* =0.004**	***p* = 0.096**	***p* <0.001**
≤ 12	4.0 (53)	89.4 (79.9-99.0)*	72.7 (57.2-88.2)*	66.1 (49.8-82.4)*	4.6 (58)	55.9 (34.4-77.4)	34.5 (17.0-52.1)	22.4 (9.1-35.8)
13-14	12.9 (157)	74.8 (57.8-91.8)	57.4 (42.6-72.2)	78.9 (71.5-86.2)*	15.9 (192)	71.8 (63.4-80.1)	43.3 (33.9-52.6)	54.7 (46.5-62.9)
15-16	35.2 (398)	86 (81.7-90.4)	63.0 (56.7-69.3)*	73.8 (67.4-80.2)*	37.4 (341)	80.2 (75.1-85.2)	48.7 (40.9-56.4)	56.6 (49.6-63.5)
≥17	47.9 (558)	86.3 (81.4-91.2)	54.4 (47.3-61.5)	73.0 (67.7-78.2)*	42.1 (450)	82.2 (77.1-87.2)	49.9 (42.5-57.3)	63.7 (58.0-69.5)
Race/ethnicity		***p*=0.018**	***p*=0.284**	***p*=0.087**		***p* =0.023**	***p* =0.670**	***p* =0.912**
White, NH	58.1 (567)	84.3 (78.6-90.0)	58.8 (51.5-66.1)*	75.4 (70.7-80.2)*	65.0 (568)	82.4 (78.0-86.9)	47.2 (40.0-54.5)	59.4 (54.2-64.6)
Black, NH	6.0 (82)	68.9 (56.8-80.9)	43.0 (29.1-56.9)	58.6 (49.2-68.1)	3.1 (40)	67.1 (50.1-84.0)	55.2 (36.6-73.9)	54.7 (34.3-75.2)
Asian, NH	1.2 (19)	96 (90.2-101.8)	60.7 (32.1-89.4)	69.4 (46.9-91.8)	1.5 (19)	88.7 (76.8-100.0)	66.5 (45.1-87.9)	62.1 (36.4-87.7)
Other, NH	9.3 (108)	90.3 (81.0-99.5)*	57.1 (43.5-70.7)	74.2 (63.6-84.7)	7.4 (93)	70.8 (56.5-85.1)	49.4 (33.8-64.9)	57.1 (42.7-71.4)
Hispanic	25.4 (335)	88.4 (84.2-92.6)*	62.7 (55.8-69.5)*	75.3 (68.9-81.8)*	23 (284)	74.4 (66.7-82.1)	47.8 (40.4-55.2)	56.0 (48.8-63.1)
School level		***p*=0.129**	***p*=0.633**	***p* =0.405**		***p* <0.001**	***p* =0.005**	***p* < 0.001**
Middle School	15.0 (192)	76.2 (61.4-91.0)	61.3 (48.1-74.5)*	76.7 (69.4-84.0)*	16.1 (196)	64.2 (54.5-73.9)	35.2 (26.5-43.9)	40.1 (31.6-48.6)
High School	85.0 (965)	86.3 (82.9-89.7)*	57.8 (52.2-63.4)*	73.2 (68.7-77.6)*	83.9 (845)	81.2 (77.1-85.2)	50.0 (43.9-56.2)	61.1 (56.4-65.7)
Lifetime cigarettes		***p*=0.001**	***p*=0.096**	***p* <0.001**		***p* <0.001**	***p* <0.001**	***p* <0.001**
≤1 cigarette	7.1 (87)	68.7 (54.3-83.0)	44.1 (32.2-56.0)	59 (45.4-72.6)*	17.7 (172)	65.3 (56.0-74.6)	34.8 (24.8-44.8)	37.9 (29.1-46.7)
2-5 cigarettes	10.7 (122)	76.9 (65.9-88.0)	62.0 (49.5-74.6)*	61.6 (50.7-72.4)	15.1 (165)	64.9 (55.0-74.8)	35.8 (28.6-43.1)	55.3 (44.9-65.8)
1/2 a pack	11.0 (119)	80.6 (70.4-90.8)	53.4 (40.4-66.3)	73.3 (62.7-83.8)	11.1 (108)	79.4 (69.4-89.3)	51.5 (39.8-63.2)	56.9 (43.4-70.4)
1 pack/life	9.8 (114)	89.5 (83.1-95.9)*	53.7 (41.6-65.8)	74.0 (62.6-85.4)	9.8 (93)	80.2 (70.0-90.4)	45.9 (29.2-62.7)	66.0 (54.7-77.2)
>1 but <5 packs	16.3 (181)	85.9 (78.8-92.9)	49.8 (39.7-60.0)	71.3 (62.2-80.4)	12.8 (138)	80.7 (72.1-89.4)	49.4 (39.0-59.7)	62.2 (51.6-72.7)
≥5 packs	45.1 (514)	89.7 (83.9-95.4)	65.6 (58.3-72.9)	80.6 (75.9-85.3)*	33.6 (333)	90.7 (86.4-94.9)	59.1 (50.9-67.3)	65.6 (58.9-72.3)

Note: Asterisk (*) indicates that the prevalence estimate is significantly different from the corresponding estimate among nonmenthol cigarette smoking counterparts using a chi-squared test. P values in bold are testing for within-group differences for the measure of interest among menthol and nonmenthol smokers respectively using a chi-squared test for nominal variables (sex, race/ethnicity, and school level) and a trend test for ordinal variables (age group, grade, and number of cigarettes smoked in lifetime). CI=Confidence Interval.

[a] Use of an e-cigarette ≥1 time in lifetime

[b] Past 30-day use of an e-cigarette

[c] Past 30-day use of any flavored non-cigarette tobacco product that was "flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate or other sweets", including cigars, cigarillos, little cigars, chewing tobacco, snuff, or dip, e-cigarettes, hookah, pipe, snus, or dissolvable tobacco products. The question wording of this question measuring current use of any flavored non-cigarette tobacco product changed slightly between 2014 and 2015 NYTS

Table 4.2 Relationship between menthol cigarette smoking and current use of e-cigarettes among U.S. adolescents, NYTS, 2014-2015

Model	**All menthol and nonmenthol cigarette smokers combined regardless of product of initiation (n=2,223)**		**Menthol and nonmenthol smokers combined who reported cigarettes as the first tobacco product that they ever used (n=1,634)**	
	AOR (95% CI)	*p*-value	AOR (95% CI)	*p*-value
Main model				
Survey weights * Inverse proportionality weights	1.56 (1.24-1.97)	<0.001	1.40 (1.06-1.85)	0.018
Sensitivity analyses				
Survey weights only (conventional regression)	1.57 (1.24-1.98)	<0.001	1.43 (1.09-1.88)	0.010
Inverse proportionality weights only	1.61 (1.34-1.92)	<0.001	1.42 (1.13-1.77)	0.002

Note: Adjusted odds ratios (AOR) were computed adjusting for age at smoking initiation (proxy for duration of smoking), sex, race/ethnicity, and school level.

[a] Past 30-day use of an e-cigarette

Table 4.3 Relationship between menthol smoking status and current use of any flavored non-cigarette tobacco product among U.S. adolescents, NYTS, 2014-2015

Model	**All menthol and nonmenthol cigarette smokers combined regardless of product of initiation (n=2,223)**		**Menthol and nonmenthol smokers combined who reported cigarettes as the first tobacco product that they ever used (n=1,634)**	
	AOR (95% CI)	P-value	AOR (95% CI)	P-value
Main model				
Survey weights * Inverse proportionality weights	2.12 (1.67-2.68)	<0.001	2.33 (1.71-3.20)	0.018
Sensitivity analyses				
Survey weights only (conventional regression)	2.14 (1.68-2.72)	<0.001	2.37 (1.72-3.28)	0.010
Inverse proportionality weights only	1.99 (1.65-2.41)	<0.001	2.09 (1.65-2.64)	0.002

Note: Adjusted odds ratios (AOR) were computed adjusting for age at smoking initiation (proxy for duration of smoking), sex, race/ethnicity, and school level.

[a] Past 30-day use of any flavored non-cigarette tobacco product that was "flavored to taste like menthol (mint), alcohol (wine, cognac), candy, fruit, chocolate or other sweets", including cigars, cigarillos, little cigars, chewing tobacco, snuff, or dip, e-cigarettes, hookah, pipe, snus, or dissolvable tobacco products. The question wording of this question measuring current use of any flavored non-cigarette tobacco product changed slightly between 2014 and 2015 NYTS.

Table 4.4 Blinder-Oaxaca decomposition of differences in e-cigarette use between menthol and nonmenthol smokers, NYTS 2015

Domain	Explanatory variables	Total effect [a]	Direct effect [b]	Indirect effect [c]	
Nine broad domains	Variables measured in each domain	OR (95% CI)	OR (95% CI)	OR (95% CI)	% of indirect to total effect [d]
Socio-demographic characteristics	Age, sex, race/ethnicity, school level combined	1.57 (1.23-2.00)	1.65 (1.32-2.06)	0.96 (0.91-1.01)	-10.0
	Age only	1.69 (1.25-2.30)	1.69 (1.25-2.30)	1.00 (0.99-1.01)	-0.2
	Sex only	1.64 (1.29-2.08)	1.68 (1.35-2.10)	0.98 (0.94-1.01)	-5.0
	School only	1.67 (1.24-2.24)	1.66 (1.24-2.23)	1.00 (0.99-1.02)	0.5
	Race/ethnicity only	1.65 (1.24-2.19)	1.69 (1.27-2.24)	0.98 (0.94-1.02)	-4.4
Proximal social influences	Reason for e-cigarette use is because of use by friend or family member use, reported use of e-cigarettes by household member or classmates [e]	1.69 (1.31-2.19)	1.56 (1.20-2.03)	1.08 (0.99-1.19)	15.2
Smoking cessation	Reason for e-cigarette use is to quit cigarette smoking	1.68 (1.32-2.15)	1.57 (1.21-2.04)	1.07 (1.02-1.12)	12.5*
Price/Access	Usual source of cigarettes by buying vs other sources, reason for e-cigarette use is because of price.	1.68 (1.28-2.19)	1.38 (1.10-1.72)	1.22 (1.11-1.33)	37.9*
E-cigarette marketing exposure	Internet, retail, newspaper/magazine, and TV/movie e-cigarette advertisements; reason for e-cigarette use is because famous people on TV/movies use them	1.63 (1.19-2.24)	1.51 (1.12-2.03)	1.09 (1.01-1.16)	16.9*
Harm reduction	Perceived relative harmfulness of e-cigarettes and other tobacco products, reason for e-cigarette use because of reduced harm	1.57 (1.19-2.08)	1.49 (1.13-1.95)	1.06 (0.98-1.14)	12.5
Flavors	Use of flavored tobacco products other than cigarettes or e-cigarettes, reason for e-cigarette use is because of flavors	1.70 (1.32-2.16)	1.39 (1.12-1.73)	1.22 (1.10-1.36)	37.6*
Situational use of e-cigarettes	Reason for e-cigarette use is to access tobacco in places were cigarette smoking is not allowed	1.68 (1.31-2.16)	1.57 (1.23-2.01)	1.08 (1.01-1.15)	13.8*
Nicotine addiction	Time to first cigarette, past 30-day tobacco cravings, symptoms of physical and psychological dependence	1.64 (1.24-2.17)	1.41 (1.06-1.88)	1.16 (1.06-1.27)	30.1*

Note: Asterisks (*) indicate statistically significant indirect effects ($p<0.05$). CI=confidence interval.

[a] On the log-odds scale, the sum of direct and indirect effects yields the total effect. On the odds ratio scale, the product of the two effects yields the total effect.

[b] The direct effect of menthol status was obtained by comparing the proportion of menthol smokers with the counterfactual proportion of nonmenthol smokers if they had the same distribution of explanatory variables as menthol smoker

[c] The indirect effect was obtained by comparing the proportion of nonmenthol smokers that use e-cigarettes with the counterfactual proportion of nonmenthol smokers if they had the distribution of explanatory variables as menthol smokers.

[d] A negative effect indicates a dampening effect on total effect

[e] Measured with the question "Out of every 10 students in your grade at school, how many do you think use electronic cigarettes or e-cigarettes?"

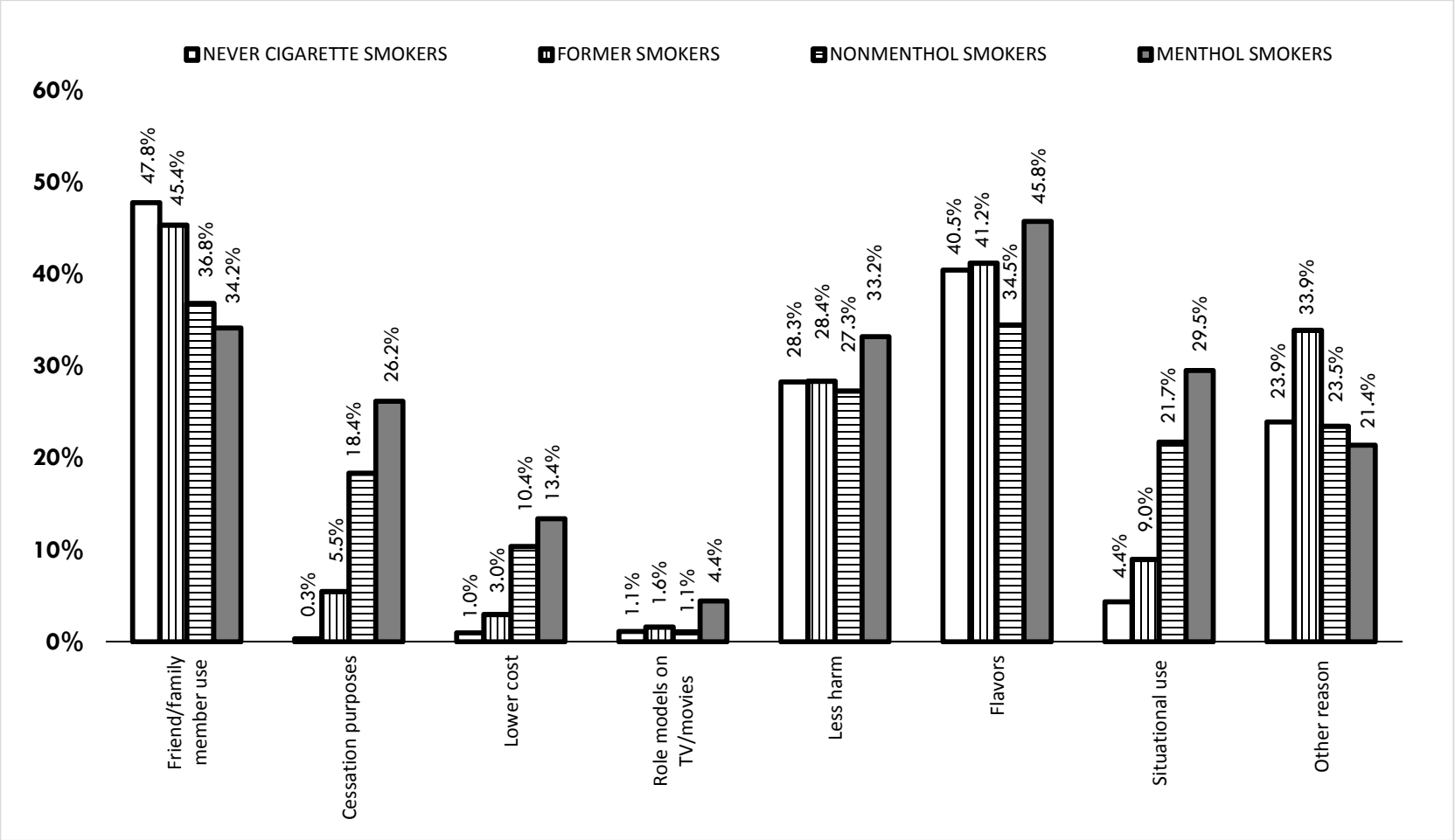

Figure 4.1 Reasons for use of e-cigarettes by never cigarette smokers, former cigarette smokers, nonmenthol cigarette smokers, and menthol cigarette smokers, NYTS 2015

Note: Analyses restricted to those who had ever used an e-cigarette based on 2015 NYTS data. Total number of menthol smokers =502, ever used e-cigarette = 429; total number of nonmenthol smokers =484, ever used e-cigarette = 396; total number of never smokers =13,677, ever used e-cigarette = 1,918; total number of former cigarette smokers =2,211, ever used e-cigarettes = 1,484

Chapter 5 -WHAT'S IN A NAME: EVALUATION OF BRAND TAGS, DESCRIPTORS AND PRICING OF FLAVORED TOBACCO PRODUCTS ON THE U.S. MARKET, 2011-2016[4]

[4] Agaku IT, Dobbin K, Muilenburg J, Hallow K, et al. To be submitted to *Tobacco Control Journal.*

ABSTRACT

BACKGROUND: Individual-level determinants of flavored tobacco product use are well known. However, less research has explored market-level factors that might encourage flavored tobacco product use. This study investigated the role of flavor names as a marketing strategy, as well as price inequalities across and within tobacco products by flavor variety.

METHODS: Retail scanner data for tobacco sales made in the continental U.S. during October 22, 2011—January 9, 2016 were acquired from the Nielson Company for manufactured cigarettes (henceforth, cigarettes), roll-your-own cigarettes, cigars, and smokeless tobacco products. Universal Product Codes were used to classify tobacco flavors as mentholated, flavored (e.g., fruit, candy), or nonflavored. Flavor names were qualitatively reviewed, coded and thematically analyzed. Average dollar prices during 2015 were computed for each tobacco product by flavor variety. All prices were standardized to a cigarette pack or cigarette pack equivalent (CPE).

RESULTS: The number of distinct flavor names evaluated were as follows: cigars, n=230; roll-your-own cigarettes, n=89; smokeless tobacco, n=73; and cigarettes, n=27. Flavors for roll-your-own cigarettes, cigars, and smokeless tobacco included menthol, fruit, spice, alcohol, coffee, or candy varieties. Menthol was the only cigarette flavor. Qualitative analyses of flavor names indicated targeted marketing with themes that were health-oriented (e.g., “Cleaner Smoke Menthol”,

"Low Smoke menthol"), sexually-oriented (e.g., "Kama Sutra splash", "Passion Kiss"), and African-American oriented (e.g., "Black Voodoo", "Black Natural"). National average prices per cigarette pack were $5.52 and $5.47 for mentholated and nonflavored varieties respectively. National average prices per CPE of RYO cigarettes were $0.74, $0.82, and $1.30 for flavored, mentholated, and nonflavored varieties respectively. National average prices per CPE of little cigars were $1.89, $2.51, and $4.77 for mentholated, nonflavored, and flavored varieties respectively. National average prices per CPE of moist snuff were $1.49, $1.64, and $1.78 for mentholated, nonflavored, and flavored varieties respectively.

CONCLUSION: Several tobacco flavor names conveyed misperceptions of reduced harm, underscoring the need for stronger enforcement of existing prohibitions on misleading descriptors suggestive of reduced harmfulness of a tobacco product. State and local governments can reduce existing tobacco price inequalities through strategies such as implementing minimum price laws, and imposing restrictions on tobacco discounts.

INTRODUCTION

Adolescence is a critical developmental period when youth are highly susceptible to tobacco use [1]. Most U.S. adolescent tobacco users start tobacco use with a flavored product, including 50.1% of cigarette smokers, 65.4% of cigar smokers, and 68.9% of conventional smokeless tobacco product users [2]. A large percentage of adult smokers in several other developed countries such as Austria (38%), Italy (33%), Greece (29%), Bulgaria (29%), and Czech Republic (29%) report that flavors were the most significant factor that made them start smoking [3]. Discussions about tobacco flavors in the U.S. have historically focused on menthol in cigarettes, and deservedly so considering the staggering cigarette smoking-attributable morbidity and mortality over the past decades [4, 5]. However, the U.S. tobacco landscape has evolved considerably in recent years; a broader range of novel and modified tobacco products are now available in a plethora of flavors, the use of some of which is almost as prevalent, or even more prevalent, than regular cigarettes among youth [6-8]. Indeed, despite declines in cigarette smoking among U.S. adolescents during 2011-2015, aggregate tobacco use has remained unchanged [8]. Hence, a comprehensive approach that considers the breadth of tobacco products and existing flavors on the U.S. market is important to address overall tobacco use among youth.

Tobacco advertising and promotional activities cause tobacco initiation among youth [1]. An important marketing strategy used by the tobacco industry is

use of product design and packaging elements such as pack shape, color, texture, and size, as has been well documented in previous research [1, 9-16]. One less explored marketing element is tobacco flavor *names*, independent of any chemosensory effects of such flavors. A tobacco flavor name not only provides information, but also potentially serves as a marketing tool to target certain population niches, cue expected sensory effects, or even convey deceptive perceptions of healthfulness [17]. The potential marketing value of flavor names lies in the fact that they are one of the first external packaging elements a potential consumer is exposed to, even before they try the product to experience the taste or olfactory sensations. Appealing or savory flavor names could potentially pique the curiosity of nonusers and possibly lead to experimentation. The valence and arousal associated with certain words and even font characteristics can elicit cognitive and emotional responses [18-20]. Furthermore, the presence of contain descriptors, e.g., words such as “blue” or “organic”, might be taken to be indicative that a tobacco product is less harmful [17, 21]. Although FDA banned the use of descriptors such as “light” or “mild” in 2009, tobacco manufacturers continue to use alternative descriptors and design features to perpetuate such misconceptions [17, 21-24].

Flavor names and what they represent might also be closely tied with the price of tobacco products. For example, flavors that appeal to youth might be lower priced through discounts to make them more affordable [25]. During 2013, U.S. cigarette manufacturers spent $7.64 billion for price discounts, and another $870 million for coupons [26]. In that same year, U.S. smokeless tobacco manufacturers

spent $283 million for discounts and $32 million for coupons [27]. Such promotions lower the retail prices of tobacco products and could attenuate the potential impact of raising tobacco prices [25]. Implementing regulatory measures that will protect youth requires an in-depth knowledge of subterfuge marketing practices employed by the tobacco industry to increase the attractiveness, acceptability, and affordability of tobacco products popular among youth.

No previous study has performed a detailed thematic evaluation of tobacco flavor names, or compared tobacco prices by flavor variety for different tobacco products within the U.S. market. To fill these gaps in knowledge, retail scanner data from actual sales of tobacco products within all states in the continental U.S. were acquired and analyzed with the following objectives: (1) perform a qualitative evaluation of tobacco flavor names to gain an insight into how tobacco companies use these as a potential marketing strategy. (2) Compare average dollar prices between manufactured cigarettes (henceforth, cigarettes), roll-your-own (RYO) cigarettes, cigars, and smokeless tobacco products to understand inequalities in price across products. (3) Compare average dollar prices and trends by flavor variety for each tobacco product assessed to understand potential targeting of flavored products towards youth.

METHODOLOGY

Data Source

Retail scanner data were acquired for cigarettes, RYO cigarettes, cigars (cigarillos, little cigars, and large cigars), and smokeless tobacco products (moist snuff, chewing tobacco, and snus) from the Nielson Company (Nielson) for a 56-month period from October 22, 2011, through January 9, 2016. Nielson collects information on tobacco products purchased within the U.S. at convenience stores (e.g., franchise, chain, and independent stores that may or may not sell gasoline), supermarkets, drug stores, mass merchandisers, dollar stores, club stores, U.S. Defense Commissary Agency commissaries, and Walmart. Representative data for tobacco sales were available for all the 48 states in the continental U.S. (i.e., the entire 50 U.S. states excluding Alaska and Hawaii). Nielson developed and applied proprietary weights to the data to yield estimates representative of each of the 48 states as well as the entire U.S. for all tobacco products assessed.

In each geographic area, data were collected using Universal Product Codes (UPC), a type of bar code technology that is scanned at checkout in U.S. retail stores. UPCs are a series of unique 12-digit numbers, which reveal key item data such as the brand, variety, and quantity purchased. For example, entry of the cigarette UPC number “028200317711” into a barcode database revealed the following information: “Description: Marlboro NXT Regular to Menthol Cigarettes 200 ct; Issuing Country: United States”[28].

Flavor varieties

Consistent with the reference to "characterizing flavors" in the 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) and in FDA food regulations [29, 30], the basis for designating and classifying tobacco flavors was if there was evidence of a characteristic or primary discernable flavor, e.g., menthol, fruit, spice, alcohol, coffee, chocolate, or candy flavor. UPCs were used, along with supplemental information from the brand's website or online retailers where necessary, to classify all sold RYO cigarettes, cigars, and smokeless tobacco products into three mutually exclusive categories: (1) menthol, when the product description referenced menthol or anything mint-like. (2) Other flavors (henceforth referred to as flavored), when the product description referenced a fruit, spice, alcohol, coffee, chocolate, or candy flavor, and (3) Nonflavored, when the product description referenced neither menthol nor flavored varieties. Cigarettes were classified as either mentholated or nonflavored since FDA banned the use of all other "characterizing flavors" in cigarettes in 2009 [31].

Analyses

Qualitative evaluation

Flavor names were qualitatively reviewed for emerging themes based on implicit or explicit messages expressed. Flavor names were coded and identified attributes grouped into definite patterns based on themes.

Standardization of tobacco prices

Because of limited price data within flavor categories for cigarillos, large cigars, chewing tobacco, and snus, quantitative analyses focused on four tobacco product types: manufactured cigarettes, RYO cigarettes, little cigars, and moist snuff. To ensure that *direct* comparisons of dollar prices could be made across these diverse products, unit sales were standardized to cigarette pack or cigarette pack equivalent (CPE). This standardization followed a two-step process that included a within-product standardization of all product types, followed by a cross-product standardization of RYO cigarettes, little cigars, and moist snuff to CPEs. Details are outlined below.

First, unit sales were standardized *within* each class of product based on count or ounces for the most commonly occurring pack size and/or weight within each product category. This was 1 pack of cigarettes (20 sticks); 1 pack of little cigars (20 sticks); 1.5 ounces of RYO cigarettes; and 1.2 ounces of moist snuff. Thus, for example, if a 200 Ct/box of cigarettes was sold for $60, this price per carton would be standardized to price per cigarette pack (20 sticks) as follows: $60 ÷ (200/20) = $6. Similar conversions were done for other tobacco products based on the most common unit of sale. These within-group standardized units however do not allow for direct comparisons across products because of the variability in tobacco content, size, and consumption patterns for cigarettes, RYO cigarettes, little cigars, and moist snuff.

In the second step, the dollar prices for the within-group standardized units were converted to CPEs for RYO cigarettes, little cigars, and moist snuff. Little cigars resemble cigarettes structurally and in the number of sticks per pack; hence 1 pack of 20 little cigars = 1 CPE of little cigars [32]. Dollar price per 1 pack of little cigars was converted to dollar price per 1 CPE of little cigars using the algorithm: price per 1 pack of little cigars * 1. For RYO tobacco, CPEs were computed based on weight; 14.6 g of RYO tobacco = 1 CPE of RYO tobacco as supported by reports of nicotine ratings filed by manufacturers with the Massachusetts Department of Public Health under Massachusetts regulation 105 CMR 660.000 [33]. Dollar price per 1.5 ounces of RYO cigarettes was converted to dollar price per 1 CPE of RYO tobacco using the algorithm: (price per 1.5 ounces * 14.6)/42.52425, where 1.5 ounces = 42.52425g. Moist snuff CPEs were calculated based on daily consumption patterns, with a 1.2-ounce tin taken to be equivalent to 2.5 packs of cigarettes based on previous studies [32, 34]. Dollar price per 1.2 ounces of moist snuff was converted to price per 1 CPE of moist snuff by dividing price per 1.2 ounces by 2.5.

Analyses of price differences and trends

Average prices (nominal dollars) during 2015 were computed, overall and by flavor designation for each tobacco product type. The degree of dispersion in prices was measured using the coefficient of variation. To measure long-term trends in prices during the 56-month study period, nominal prices were adjusted for inflation to constant 2015 dollars using the U.S. Bureau of Labor Statistics' Consumer Price Index [35]. Joinpoint regression was used to calculate average monthly percentage

changes in adjusted prices for each tobacco product, overall and by aggregated flavor category [36]. A total of 49*11 = 539 mutually exclusive Joinpoint regression models were fitted. For each of the 49 separate study sites (U.S. nationally, and each of the 48 states assessed), there were 11 unique combinations of tobacco product type and flavor variety that were analyzed (RYO cigarettes, little cigars, and moist snuff each had 3 flavor varieties; cigarettes had 2 flavor varieties). Statistical significance was set at $p<0.05$. All statistical analyses were performed with NCI's Joinpoint Regression Program V.4.3.1.0, and R V.3.2.3.

RESULTS

Qualitative evaluation of tobacco product Flavor Names

The number of distinct flavor names was most varied for cigars (large, small, and cigarillos combined, n=230), followed by RYO cigarettes (n=89), smokeless tobacco products (snus, chewing tobacco, and moist snuff combined, n=73), and cigarettes (n=27; Table 5.1). Most of the flavor varieties identified for cigars, smokeless tobacco, and RYO cigarettes were a characteristic fruit, spice, alcohol, coffee, chocolate, or candy flavor, whereas menthol was the sole flavor identified in cigarettes.

Some identified themes from qualitative evaluation of flavor names included those that were oriented towards health, hedonistic reward, sex appeal, youth, females, and African Americans.

Several flavor names implicitly or overtly conveyed perceptions of healthfulness, vitality, cleanness, or reduced harm, by referencing fruit (e.g., “Strawberry”, “Mango”, “Apple”, “Watermelon”) or invoking words such as “cool”, “fresh”, “natural”, “clean”, “mellow”, or “smooth” (e.g., “natural menthol”, “low smoke menthol”, “cleaner smoke menthol”, “fresh menthol”, “mellow menthol”, “smooth cool menthol” Figure 5.1). Flavor names referenced both general sensation such as temperature (e.g., “frost”, “icy”, “hot”) as well as special sensation such as taste (e.g., “sweet”, “sour”).

Many flavor names highlighted youth-oriented themes, including sex appeal (e.g., “Kama Sutra splash”, “Queen of sex”, “Passion kiss”), nightlife (e.g., “midnight hour”), juvenility (e.g., “swag”, “kick ass mint”, “On point”), and exotic appeal (e.g., “French vanilla”, “Madagascar vanilla”, “Xotic blend”, “Nordic mint”, “Tropical coconut”) (Figure 5.1). Flavor names referenced a broad range of colors (white, blue, black, pink, red, purple, green, gold, and wine). The colors blue and green were commonly associated with menthol. Female-oriented cigar flavor names included “Pink berry”; “Pink diva”.

Several cigar flavor names contained numerous references to the word “black” or certain stereotypes. Example of such flavor names were “Black Don”, “Black Voodoo”, “Black N Sweet”, “Black Natural”, “Black Signature”, “Black Stinger”, “Hustla Sweet, “OG [original gangster] sweet” [37, 38]). Notably, there was no use of the color descriptor “black” in relation to any non-cigar flavor name

except when used in describing “black berry”, “black cherry” or “black Cavendish”. In addition, some cigar flavor names made implicit references to marijuana, e.g., “OG Kush [a strain of marijuana]”[37], “Purple Haze” [a commonly used term in rap music to describe marijuana] [39], and “Rasta sweet” [Rastas are followers of the Rastafari movement and communally smoke marijuana as a means of spiritual enlightenment] [40, 41].

Overall Tobacco Prices, National and State-Specific Variations

National average price for cigarettes were the highest of all assessed tobacco products; a pack of cigarettes cost 77.8% more than a CPE of RYO cigarettes, 71.56% more than a CPE of moist snuff, and 47.59% more than a CPE of little cigars (Figure 5.2, Figure 5.3). The coefficient of variation in total prices across states during 2015 was 0.23 for cigarettes, 0.31 for moist snuff, 0.37 for RYO cigarettes, and 0.53 for little cigars.

National average price for a pack of cigarettes in 2015 was $5.49, ranging from $3.86 in Missouri to $9.5 in New York (Table 5.2). Average cigarette prices by U.S. census region were as follows: Northeast ($7.54), West ($5.78), Midwest ($5.68), and South ($4.87).

National average price for a CPE of RYO cigarettes in 2015 was $1.22, ranging from $0.59 in Kentucky, to $2.78 in Washington State. By U.S. census region, average prices for RYO cigarettes were as follows: West ($2.22), Northeast ($1.52), Midwest ($1.31), and South ($1.23).

National average price for a CPE of little cigars in 2015 was $2.88, ranging from $1.74 in Florida, to $9.57 in Washington State. By U.S. census region, average prices for little cigars were as follows: West ($5.72), Northeast ($4.46), Midwest ($3.34), and South ($2.51).

National average price for a CPE of moist snuff in 2015 was $1.56, ranging from $1.04 in Pennsylvania, to $3.71 in Massachusetts. By U.S. census region, average prices for moist snuff were as follows: Northeast ($2.39), West ($1.97), Midwest ($1.69), and South ($1.44).

Flavor-specific Tobacco Prices, National and state-specific Trends

National average prices for menthol and nonmenthol cigarettes in 2015 were $5.52 and $5.47 respectively. During October 2011-January 2016, significant increases occurred in the national average prices for both menthol and nonmenthol cigarettes (Figure 5.4). During this same 56-month period, menthol cigarette average prices increased significantly in 39 states while nonmenthol cigarette average prices increased significantly in 42 states.

During 2015, national average prices per CPE of RYO cigarettes were $0.74, $0.82, and $1.30 for flavored, mentholated, and nonflavored varieties respectively (Table 5.2). During October 2011-January 2016, a significant decline in national average prices occurred for all three flavor varieties (Figure 5.5). During this same period, by state, mentholated RYO cigarette average prices increased significantly in zero states, nonflavored RYO cigarette average prices increased significantly in 7

states, while flavored RYO cigarette average prices increased significantly in 35 states.

During 2015, national average prices per CPE of little cigars were $1.89, $2.51, and $4.77 for mentholated, nonflavored, and flavored varieties respectively. During October 2011-January 2016, national average price increased for flavored little cigars but declined for nonflavored and mentholated varieties (Figure 5.6). Across states during October 2011-January 2016, mentholated little cigar average prices increased significantly in 11 states, nonflavored little cigar average prices increased significantly in 12 states, while flavored little cigar average prices increased significantly in 29 states.

National average prices per CPE of moist snuff in 2015 were $1.49, $1.64, $1.78 for mentholated, nonflavored, and flavored varieties respectively. During October 2011-January 2016, national average prices increased for mentholated and nonflavored moist snuff, but declined for flavored moist snuff (Figure 5.7). During the same period, flavored moist snuff average prices increased significantly in 30 states, mentholated moist snuff average prices increased significantly in 42 states, while nonflavored moist snuff average prices increased significantly in 43 states.

DISCUSSION

This study indicates that the tobacco industry has used tobacco flavor names as a marketing tool to increase tobacco product appeal and target certain subgroups, including blacks, females, and youth. Notably, despite FDA's ban on the

use of any descriptors such as “light”, “ultra-light”, or “mild” that might imply that a tobacco product is less harmful than another [42], several flavor names were found that contravened this regulation e.g., “low smoke menthol”, or “cleaner smoke menthol”. Connolly et al., previously reported on tobacco industry use of descriptors such as “gold”, “silver”, and “blue” in place of explicitly prohibited descriptors such as “light” or “ultra-light” [23]. These kinds of color descriptors may be perceived by smokers as being less harmful [17, 21, 24]. Many flavor descriptors in this study referenced these and other colors. These subterfuge marketing strategies underscore the need for intensified efforts to monitor marketing activities of the tobacco industry and strongly enforce existing regulations. In addition, marketing of cigars with connotations to marijuana – a controlled substance in many states - might encourage linking of these two behaviors (e.g., smoking of blunt cigars) [43, 44]. Several cigar flavor names appeared to target blacks; which might partly explain the higher prevalence of cigar smoking among blacks compared to any other racial group [8].

This study also revealed wide price inequalities across tobacco products. A pack of mentholated cigarettes cost approximately 3 times an equivalent amount of mentholated little cigars, 4 times an equivalent amount of mentholated moist snuff and 7 times an equivalent amount of mentholated RYO cigarettes. These steep price differentials might encourage the use of cheaper products such as RYO cigarettes as a tax avoidance strategy among youth smokers [45, 46]. Notably, despite the very wide inequalities observed in retail price of cigarettes, RYO cigarettes, and little

cigars, all three products have exactly the same federal excise tax rates under the 2009 Children's Health Insurance Program Reauthorization Act—$1.0066 per CP or CPE [47]. State and local governments could implement tax and nontax measures to close existing price inequalities through specific measures such as implementing and enforcing minimum price laws, restricting discounting or couponing schemes, increasing tobacco retail licensing fees, and implementing disclosure laws for payments or discounts to retailers. Several jurisdictions in the U.S. have adopted other interventions to reduce youth access to tobacco products, including prohibiting or restricting the sales of flavored tobacco products, raising legal purchase age to 21, or increasing local tobacco taxes [48-50].

Within each tobacco product type, striking inequalities in price by flavor variety were also noted, with mentholated varieties being generally cheaper options, particularly for moist snuff, RYO cigarettes, and little cigars. These findings raise concerns about tobacco industry promotional activities to increase youths' access and affordability of flavored tobacco products [25]. Following the 1998 Master Settlement Agreement which prohibited tobacco companies from targeting youth with tobacco marketing in certain media [51], the industry has increasingly turned to unregulated areas such as the retail environment [52-56]. Data from the U.S. Federal Trade Commission during 2002-2013 indicates that price discounts as a percentage of all tobacco marketing expenditures increased from 63.2% to 85.4% for cigarettes, and from 42.2% to 56.2% for smokeless tobacco products [26, 27]. More research is needed to determine differential discounting by

the tobacco industry for flavored and nonflavored tobacco products in geographic areas with different proportional representations of race/ethnicity, or during focal time periods (e.g., when tobacco taxes were increased) [4]. This is important considering the appeal of flavored products among youth. As FDA exercises regulatory authority under the deeming rule in relation to flavors and other aspects of tobacco product design and marketing using authority granted by FSPTCA [57], greater tobacco industry watch will be needed to ensure compliance to regulatory policy. The findings in this study justify these actions.

Strengths and Limitations

The strength of this study is objectively ascertaining tobacco retail prices for each state in the continental U.S. using retail scanner data. The ability to disentangle prices by product type as well as by flavor variety provides valuable insight on price inequalities within and across products and the potential for tax avoidance strategies among price-sensitive populations.

Limitations however exist to this study. First, these data do not account for illicit products purchased on the black market such as contraband, smuggled, or bootlegged cigarettes. Second, these are market-level data and do not contain information on individual-level purchasing characteristics. Third, there is possibility of misclassification of flavor variety. Finally, by design, these analyses do not cover volume sales for each flavor variety and the number of distinct flavor

names within a broad flavor category may not necessarily correspond to distribution of volume sales for that product.

CONCLUSION

This study indicates that flavor names are used by tobacco companies as a marketing strategy to cue expected hedonistic reward, convey misleading information about the relative health risks of certain tobacco products, and target specific population groups, including blacks and youths. Wide inequalities existed across tobacco products; furthermore, mentholated varieties were generally cheaper than other flavors or nonflavored varieties for RYO cigarettes, little cigars, and moist snuff. Efforts are needed to close price inequalities within and across tobacco products at state and local levels, and help reduce access to tobacco products among youth.

REFERENCES

1. U.S Department of Health and Human Services. Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012.
2. Ambrose, B.K., et al., *Flavored Tobacco Product Use Among U.S. Youth Aged 12-17 Years, 2013-2014*. Jama, 2015. **314**(17): p. 1871-1873.
3. European Commission. Special Eurobarometer 385. Attitudes of Europeans Towards Tobacco. Available at http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco__en.pdf, Accessed 09/30/2016.
4. Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmaterials/tobaccoproductsscientificadvisorycommittee/ucm269697.pdf. Accessed 09/15/2016.

5. U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

6. Corey, C.G., et al., *Flavored Tobacco Product Use Among Middle and High School Students--United States, 2014.* MMWR.Morbidity and mortality weekly report, 2015. **64**(38): p. 1066-1070.

7. Zhu, S.H., et al., *Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation.* Tobacco control, 2014. **23 Suppl 3**: p. iii3-9.

8. Singh, T., et al., *Tobacco Use Among Middle and High School Students--United States, 2011-2015.* MMWR.Morbidity and mortality weekly report, 2016. **65**(14): p. 361-367.

9. Borland, R., et al., *The impact of structural packaging design on young adult smokers' perceptions of tobacco products.* Tobacco control, 2013. **22**(2): p. 97-102.

10. Bruce, A.S., et al., *Branding and a child's brain: an fMRI study of neural responses to logos.* Social cognitive and affective neuroscience, 2014. **9**(1): p. 118-122.

11. Carpenter, C.M., G.F. Wayne, and G.N. Connolly, *The role of sensory perception in the development and targeting of tobacco products.* Addiction (Abingdon, England), 2007. **102**(1): p. 136-147.

12. Gallopel-Morvan, K., et al., *Consumer perceptions of cigarette pack design in France: a comparison of regular, limited edition and plain packaging.* Tobacco control, 2012. **21**(5): p. 502-506.

13. Germain, D., M.A. Wakefield, and S.J. Durkin, *Adolescents' perceptions of cigarette brand image: does plain packaging make a difference?* The Journal of adolescent health : official publication of the Society for Adolescent Medicine, 2010. **46**(4): p. 385-392.

14. Moodie, C., K. Angus, and A. Ford, *The importance of cigarette packaging in a 'dark' market: the 'Silk Cut' experience.* Tobacco control, 2012.

15. Ayo-Yusuf, O.A. and I.T. Agaku, *The association between smokers' perceived importance of the appearance of cigarettes/cigarette packs and smoking sensory experience: a structural equation model.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2015. **17**(1): p. 91-97.

16. Doxey, J. and D. Hammond, *Deadly in pink: the impact of cigarette packaging among young women.* Tobacco control, 2011. **20**(5): p. 353-360.

17. Agaku, I.T., et al., *Cigarette design and marketing features are associated with increased smoking susceptibility and perception of reduced harm among smokers in 27 EU countries.* Tobacco control, 2015. **24**(e4): p. e233-40.

18. Bayer, M., W. Sommer, and A. Schacht, *Font size matters--emotion and attention in cortical responses to written words.* PloS one, 2012. **7**(5): p. e36042.

19. Chen, X., B. Liu, and S. Lin, *Is Accessing of Words Affected by Affective Valence Only? A Discrete Emotion View on the Emotional Congruency Effect.* Frontiers in psychology, 2016. **7**: p. 916.

20. Kuchinke, L., et al., *A familiar font drives early emotional effects in word recognition.* Brain and language, 2014. **137**: p. 142-147.

21. Yong, H.H., et al., *Impact of the removal of misleading terms on cigarette pack on smokers' beliefs about 'light/mild' cigarettes: cross-country comparisons.* Addiction (Abingdon, England), 2011. **106**(12): p. 2204-2213.

22. Brown, A., et al., *Do smokers in Europe think all cigarettes are equally harmful?* European journal of public health, 2012. **22 Suppl 1**: p. 35-40.

23. Connolly, G.N. and H.R. Alpert, *Has the tobacco industry evaded the FDA's ban on 'Light' cigarette descriptors?* Tobacco control, 2014. **23**(2): p. 140-145.

24. Mutti, S., et al., *Beyond light and mild: cigarette brand descriptors and perceptions of risk in the International Tobacco Control (ITC) Four Country Survey.* Addiction (Abingdon, England), 2011. **106**(6): p. 1166-1175.

25. Henriksen, L., et al., *Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2012. **14**(1): p. 116-121.

26. Federal Trade Commission. Federal Trade Commission Cigarette Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf.

27. Federal Trade Commission. Federal Trade Commission Smokeless Tobacco Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-smokeless-tobacco-report-2013/2013tobaccorpt.pdf.

28. UPC Database. Available at https://www.upcdatabase.com/item/028200317711. Accessed 09/15/2016.

29. U.S. Food and Drug Administration . Tobacco Products. Section 907 of the Federal Food, Drug, and Cosmetic Act - Tobacco Product Standards. Available at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm263053.htm. Accessed 09/15/2016.

30. U.S. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.22. Accessed 09/15/2016.

31. U.S. Food and Drug Administration. *FDA NEWS RELEASE: Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law. Available at*

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm. Accessed 09/16/ 2016.

32. Connolly, G.N. and H.R. Alpert, *Trends in the use of cigarettes and other tobacco products, 2000-2007*. Jama, 2008. **299**(22): p. 2629-2630.

33. 105 CMR 660.000 Cigarette and Smokeless Tobacco Products: Reports of Added Constituents and Nicotine Ratings. Available at http://www.mass.gov/eohhs/docs/dph/regs/105cmr660.rtf. Accessed 09/16/2016.;

34. Agaku, I.T. and H.R. Alpert, *Trends in annual sales and current use of cigarettes, cigars, roll-your-own tobacco, pipes, and smokeless tobacco among U.S. adults, 2002-2012*. Tobacco control, 2016. **25**(4): p. 451-457.

35. Statistics, U.S. Department of Labor. Bureau of Labor Statistics, *Consumer Price Index*. 2016. Available at http://www.bls.gov/cpi/. Aceesed 09/16/2016.

36. Joinpoint Regression Program, Version 4.0—December 2012;Statistical Methodology and Applications Branch, Surveillance Research Program, National Cancer Institute.

37. Everipedia. Kush. Available at http://www.everipedia.com/Kush, Accessed 09/16/2016.

38. Slang dictionary. Available at http://www.slang-dictionary.org. Accessed 09/16/2016.

39. Crawford, G.E., *Flavoured tobacco products with marijuana names*. Tobacco control, 2007. **16**(1): p. 70.

40. International Encyclopedia of the Social Sciences . Rastafari. Available at http://www.encyclopedia.com/topic/Rastafarianism.aspx. Accessed 09/16/2016.

41. National Geographic Channel. Ganja in the Rastafarian culture. Available at http://channel.nationalgeographic.com/drugs-inc/videos/ganja-in-the-rastafarian-culture. Accessed 09/16/2016.

42. U.S. Food and Drug Administration. Tobacco Products. Light, Low, Mild or Similar Descriptors. Available at http://www.fda.gov/TobaccoProducts/Labeling/Labeling/ucm2023661.htm. Accessed 09/15/2016.

43. Koopman Gonzalez, S.J., L.E. Cofie, and E.S. Trapl, *"I just use it for weed": The modification of little cigars and cigarillos by young adult African American male users.* Journal of ethnicity in substance abuse, 2015: p. 1-14.

44. Montgomery, L. and K. Bagot, *Let's Be Blunt: Consumption Methods Matter Among Black Marijuana Smokers.* Journal of studies on alcohol and drugs, 2016. **77**(3): p. 451-456.

45. Morris, D.S. and M.A. Tynan, *Fiscal and policy implications of selling pipe tobacco for roll-your-own cigarettes in the United States.* PloS one, 2012. **7**(5): p. e36487.

46. U.S. Government Accountability Office (GAO), International Affairs;Tobacco Taxes. http://www.gao.gov/modules/ereport/handler.php?1=1&path=/ereport/GAO-13-279SP/data_center_savings/International_affairs/31._Tobacco_Taxes.

47. Congressional Budget Office. H.R. 2, Children's Health Insurance Program Reauthorization Act of 2009. http://www.cbo.gov/publication/20472.

48. Marynak, K., et al., *State laws prohibiting sales to minors and indoor use of electronic nicotine delivery systems--United States, November 2014.* MMWR.Morbidity and mortality weekly report, 2014. **63**(49): p. 1145-1150.

49. Tobacco Control Legal Consortium. Regulating Flavored Tobacco Products. Available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regflavoredtobaccoprods-.pdf, Accessed 09/16/2016.

50. Tobacco Twenty-one. Critical Issues. Available at http://tobacco21.org/critical-issues, Accessed 09/16/2016.

51. Master Settlement Agreement. Available at http://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf. Accessed 09/15/2016.

52. Feighery, E.C., et al., *Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California.* Tobacco control, 2001. **10**(2): p. 184-188.

53. Loomis, B.R., M.C. Farrelly, and N.H. Mann, *The association of retail promotions for cigarettes with the Master Settlement Agreement, tobacco control programmes and cigarette excise taxes.* Tobacco control, 2006. **15**(6): p. 458-463.

54. Loomis, B.R., et al., *Point of purchase cigarette promotions before and after the Master Settlement Agreement: exploring retail scanner data.* Tobacco control, 2006. **15**(2): p. 140-142.

55. Pierce, J.P. and E.A. Gilpin, *How did the Master Settlement Agreement change tobacco industry expenditures for cigarette advertising and promotions?* Health promotion practice, 2004. **5**(3 Suppl): p. 84S-90S.

56. Ruel, E., et al., *After the Master Settlement Agreement: trends in the American tobacco retail environment from 1999 to 2002.* Health promotion practice, 2004. **5**(3 Suppl): p. 99S-110S.

57. United States Public Laws. Public Law 111-31 [H.R. 1256] Jun. 22, 2009 Family Smoking Prevention And Tobacco Control Act. 111 P.L. 31;123 Stat. 1776;2009 Enacted H.R. 1256;111 Enacted H.R. 1256. Available at https://www.congress.gov/bill/111th-congress/house-bill/1256.

TABLES AND FIGURES

Table 5.1 Flavor names for cigarettes, RYO cigarettes, Cigars, and smokeless tobacco products, Oct 2011-Jan 2016, United States

Tobacco product	Characteristic Menthol flavor	Characteristic Fruit, Beverage, Spice, Candy flavor	Non-characterizing flavors
Cigarettes	Bold taste fresh menthol; bold unique menthol; Cleaner smoke menthol; Cool menthol; Fresh menthol; Green field menthol; Low smoke menthol; Mellow menthol; Menthe; Menthol; Menthol 10; Menthol 94; Menthol blue; Menthol glen; Menthol gold; Menthol green; Mint menthol; Natural menthol; Regular fresh menthol; Regular to menthol; Rich blue menthol; Smooth cool menthol; True menthol	Prohibited	Assorted; Low smoke regular; Non menthol; Regular
RYO Tobacco	Classic menthol; Cool mint; Kick ass mint; Maximint; Menthol; Mint; Mint blend; White mint; Wild mint	Amaretto; Apricot; Assorted; Black cherry; Blue mist; Blueberry; Bourbon whiskey; Bubble gum; Buttered rum; Candy; Cherries jubilee; Cherry; Cherry Cavendish; Cherry liqueur; Cherry vanilla; Citrus mint; Cocktail; Coco jumbo; Coconut; Double apple; Fruit; Fruits molasses; Fuzzy naval; Golden grape; Grape freeze; Grape with berry; Guava; Ice apple; Ice grape mint; Ice raspberry mint; Ice watermelon; Irish peach; Kiwi; Lemon; Liqueur; Mellow blend; Melon; Melon blue; Molasses peach; New York vanilla; Orange peach; Orchard; Passion kiss; Pineapple; Pirates cave; Pomegranate; Pumpkin pie; Queen of sex; Rich cherry Cavendish; Rocket; Rum; Rum maple; Strawberry; Strawberry margarita; Sunrise strawberry; Sweet melon; Tangerine dream; Two apple; Vanilla; Vanilla Cavendish; Velvet peach; Whiskey; Whiskey Cavendish; White peach; Wine berry;	Black Cavendish; Cavendish; Classic; Gold; Golden; Halfzware; Jaybird; Natural; Natural Cavendish; Original; Potrero; Premium; Regular; Robust; Smooth blend;
Cigars (Large, little, and cigarillos)	Clove ultra-menthol; Cool menthol; Coolmint; Extreme menthol; Green; Green menthol; Greene de menthe; Ice menthol; Icy mint; Menthol; Menthol clove; Mint;	Amaretto; Anisette; Apple; Apple martini; Appletini; Apricot; Assorted; Ba boom; Banana; Banana split; Bellini; Berry; Berry fusion burst; Black cane; Black cherry; Black grape; Black mamba; Blackberry; Blu magic; Blue berry; Blue Connecticut; Blue magic; Blueberry; Bourbon; Cafe; Cafe mocha; Calypso cream; Candela honey; Cappuccino; Carribean peach rum; Champagne; Cherry; Cherry clove; Cherry delight; Cherry vanilla; Chocolate; Chocolate	Black Don; Black n sweet; Black natural; Black signature; Black stinger; Black voodoo; Blue mystiq; Candela; Earthy woodsy; Glazed; Golden; Green;

	Mint fusion; Regular; Spearmint;	aroma; Chocolate mint; Cinnamon; Classic sweet; Clove; Clove vanilla; Coconut; Coffee; Cognac; Cognac X 0; Connoisseur; Cosmo; Cream; Double apple; Double barrel rum; Double white grape; Dr green thumb green apple; Dragonberry; Dulce de leche; French vanilla; Fruit punch; G6 grape; Georgia peach; Gold n honey; Golden honey fusion; Grape; Grapes gone wild; Green apple; Honey; Honey berry; Honey bourbon; Hot chocolate; Hustla white grape; Irish cream; Island bash; Islander; Java fusion; Jazz; Karma sutra splash; Krush; Latte; Le prive; Lemon mango; Macchiato; Madagascar vanilla; Mango; Mangolicious; Maracuja; Maybach melon; Melon berry; Mocha; Moontrance; Napa grape; Nectar sweet; On point; Original; Peach; Pina colada; Pineapple; Pineapple express; Pink berry; Pink diva; Pink vanilla; Poco loco; Pumpkin spice; Purple haze; Purple passion grape; Purple wave; Raspberry; Raspberry cream; Red berry; Rozay wine; Rum; Rum clove; Rum fusion; Rum reserve; Show buzz; Soft cherry vanilla; Soft sweet vanilla; Sour apple; Spiced rum; Spicy hot cinnamon; Spicy rum fusion; Sticky sweets caramel peach; Strawberry; Strawberry cheesecake; Strawberry cream; Strawberry lemonade; Summer love; Swag; Swag berry; Sweet cherry; Sweet grape; Sweet honey; Sweet peach; Sweet razz; Sweet strawberry; Tangelo; Tangerine; Tequila; Tequila lime; Tropical; Tropical blast; Tropical blend; Tropical breeze pineapple; Tropical buzz; Tropical coconut; Tropical fusion; Tropical storm; Tropical twist; Tropical twista; Tutti frutti; Vanilla; Vanilla clove; Vanilla cordial; Vanilla mac nut; Vanilla sport; Very berry; Watermelon; Watermelon rum; Wet cherry; Wet mango; Wet mango Kush; Whipped cream; White grape; White vanilla; White wine; Wild apple; Wild berry; Wild cherry; Wild rum; Wild rush; Wine; Wine grape; Xotic berry; Xotic lush; Xtra vanilla;	Green haze; Green karma; Green kb 90; Green sweet; Green sweets; Hazy dayz; Hustla sweet; Jade; Kush; Midnight hour; Napa night; Natural; Natural buzz; Og kush; Og sweet; Original red; Palma blue; Purple; Rasta sweet; Regular; Royale; Sparkling moon; Sticky sweets; Straight up; Sweet; Sweet chaos; Sweet green; Sweet madness; Sweet sport; Trance;
Smokeless tobacco products (chewing tobacco, moist snuff, snus, dissolvable tobacco)	Arctic mint; Classic mint; Classic wintergreen; Cool mint; Cool wintergreen; Frost; Frosted mint; Icy mint; Licorice mint; Menthol; Mint; Mint blend; Mint chill; Mint chocolate; Nordic mint; Original wintergreen; Peppermint; Smooth mint; Spearmint; Spearmint frost; Winterchill; Wintergreen; Wintergreen blend.	Apple; Apple blend; Assorted; Berry; Berry blend; Black wild cherry; Bourbon; Butternut; Cherry; Cinnamon; Cinnamon ice; Citrus blend; Grape; Grenadine; Guava; Gum; Hibiscus ginger; Honey; Java; Jessamine molasses; Licorice; Mango; Mocha; Moonshine; Moonshine blend; Orange molasses; Peach; Peach blend; Scotch; Silver blend; Smooth hickory; Spice; Strawberry; Sweet n smokey; Sweet scotch; Tequila sunrise; Vanilla; Whiskey; Whiskey blend; Wild berry; Wild cherry;	

Table 5.2 Average Prices of cigarettes, little cigars, RYO cigarettes, and moist snuff in 2015, overall and by flavor type, U.S.

State	Cigarettes, CP			Little Cigars, CPE				RYO Cigarettes, CPE				Moist snuff, CPE			
	Total	Nonmenthol	Menthol	Total	NFM	Menthol	Flavored	Total	NFM	Menthol	Flavored	Total	NFM	Menthol	Flavored
U.S. (Total)	$5.49	$5.47	$5.52	$2.88	$2.51	$1.89	$4.77	$1.22	$1.30	$0.82	$0.74	$1.56	$1.64	$1.49	$1.78
Northeast															
Connecticut	$8.23	$8.23	$8.23	$2.76	$2.51	$2.29	$4.82	$1.77	$1.93	$1.12	$1.33	$2.24	$2.20	$2.23	$2.35
Massachusetts	$8.95	$8.93	$9.00	$3.65	$3.17	$2.59	$6.51	$1.90	$2.03	$1.08	$0.93	$3.71	$3.59	$3.71	$4.00
Maine	$6.42	$6.41	$6.48	$2.35	$2.23	$1.72	$8.53	$1.02	$1.04	$0.78	$1.00	$2.65	$2.64	$2.64	$2.86
New Hampshire	$5.78	$5.76	$5.87	$4.40	$3.91	$3.27	$7.91	$1.62	$1.72	$0.94	$1.03	$2.19	$2.22	$2.16	$2.52
New Jersey	$7.58	$7.60	$7.54	$4.17	$3.36	$1.98	$10.97	$2.36	$2.61	$1.17	$0.84	$2.03	$2.02	$2.03	$1.99
New York	$9.50	$9.46	$9.58	$8.37	$8.04	$5.78	$10.39	$1.24	$1.28	$1.08	$1.03	$2.62	$2.62	$2.62	$2.66
Pennsylvania	$5.83	$5.83	$5.83	$3.50	$3.64	$1.95	$4.38	$0.70	$0.77	$0.50	$1.04	$1.04	$1.16	$0.94	$1.12
Rhode Island	$8.07	$8.01	$8.15	$5.46	$6.12	$3.88	$4.08	$1.43	$1.53	$0.70	$1.46	$2.19	$2.17	$2.18	$2.33
Vermont	$7.48	$7.48	$7.47	$5.50	$5.66	$4.40	$6.38	$1.67	$1.86	$1.08	$1.19	$2.81	$2.81	$2.80	$2.96
South															
Alabama	$4.39	$4.30	$4.58	$3.07	$3.06	$1.98	$6.23	$1.02	$1.06	$0.82	$1.00	$1.11	$1.18	$1.03	$1.26
Arkansas	$4.82	$4.69	$5.16	$2.51	$2.33	$2.08	$3.14	$1.65	$1.69	$1.38	$1.49	$1.70	$1.74	$1.68	$1.94
Delaware	$5.79	$5.74	$5.85	$2.25	$2.01	$1.57	$5.30	$0.75	$0.75	$0.56	$1.69	$1.73	$1.75	$1.71	$1.81
Florida	$4.75	$5.19	$4.03	$1.74	$1.48	$1.51	$5.56	$1.74	$1.85	$0.91	$1.59	$2.09	$2.15	$2.01	$2.34
Georgia	$4.27	$4.18	$4.43	$2.18	$2.05	$1.62	$5.17	$1.31	$1.41	$0.52	$1.01	$1.23	$1.27	$1.20	$1.32
Kentucky	$4.30	$4.27	$4.40	$3.06	$3.58	$1.55	$2.45	$0.59	$0.59	$0.53	$0.78	$1.23	$1.28	$1.21	$1.38
Louisiana	$4.66	$4.62	$4.73	$2.16	$1.74	$1.49	$5.47	$1.80	$1.95	$0.94	$1.10	$1.31	$1.41	$1.25	$1.68
Maryland	$6.48	$6.49	$6.47	$3.45	$3.49	$2.35	$4.63	$1.25	$1.33	$0.80	$0.99	$1.75	$1.86	$1.68	$2.06
Mississippi	$4.96	$4.91	$5.04	$1.76	$1.61	$1.51	$4.97	$1.53	$1.66	$0.89	$1.01	$1.24	$1.30	$1.18	$1.40
North Carolina	$4.60	$4.49	$4.77	$2.15	$2.06	$1.56	$3.13	$1.04	$1.10	$0.44	$0.88	$1.22	$1.27	$1.18	$1.28
Oklahoma	$5.23	$5.19	$5.38	$5.14	$4.44	$3.86	$7.10	$1.90	$1.97	$1.20	$1.64	$1.77	$1.88	$1.66	$2.16
South Carolina	$4.96	$4.86	$5.09	$2.00	$1.91	$1.44	$3.40	$0.98	$1.13	$0.41	$0.97	$1.18	$1.24	$1.15	$1.28
Tennessee	$4.63	$4.58	$4.75	$2.73	$2.71	$2.07	$4.02	$0.62	$0.64	$0.46	$0.51	$1.19	$1.26	$1.14	$1.34
Texas	$4.85	$4.80	$5.01	$1.86	$1.71	$1.74	$3.11	$1.74	$1.84	$1.07	$1.73	$1.90	$1.96	$1.80	$2.18
Virginia	$4.85	$4.74	$5.01	$2.08	$2.00	$1.52	$2.80	$0.97	$1.03	$0.39	$0.83	$1.35	$1.48	$1.28	$1.48
West Virginia	$4.31	$4.25	$4.49	$1.97	$2.18	$1.50	$1.74	$0.82	$0.86	$0.46	$0.75	$1.10	$1.17	$1.01	$1.29
Midwest															
Iowa	$5.56	$5.53	$5.64	$3.05	$2.57	$2.08	$5.25	$1.60	$1.68	$0.80	$1.23	$2.09	$2.16	$2.02	$2.31
Illinois	$6.78	$6.77	$6.81	$4.72	$4.24	$2.74	$9.52	$1.51	$1.62	$1.21	$1.28	$1.61	$1.67	$1.58	$1.74
Indiana	$5.21	$5.19	$5.27	$2.10	$2.10	$1.68	$2.60	$0.86	$0.89	$0.58	$1.03	$1.42	$1.50	$1.39	$1.62
Kansas	$5.05	$5.02	$5.12	$2.43	$2.42	$2.01	$3.02	$1.74	$1.81	$0.73	$1.01	$1.23	$1.36	$1.12	$1.49
Michigan	$6.05	$6.03	$6.08	$2.17	$2.17	$1.90	$2.52	$0.85	$0.89	$0.69	$0.84	$1.54	$1.62	$1.51	$1.97
Minnesota	$7.86	$7.87	$7.84	$6.68	$7.04	$4.79	$7.17	$1.05	$1.11	$0.82	$0.58	$2.64	$2.68	$2.62	$2.92
Missouri	$3.86	$3.81	$4.00	$2.21	$2.09	$1.36	$2.99	$1.41	$1.49	$0.92	$0.88	$1.21	$1.31	$1.16	$1.49
North Dakota	$4.83	$4.81	$4.89	$4.41	$4.29	$2.08	$6.84	$1.46	$1.56	$0.53	$0.81	$1.84	$1.92	$1.70	$2.11
Nebraska	$4.88	$4.84	$5.00	$3.00	$2.62	$1.74	$5.35	$1.39	$1.47	$0.62	$0.96	$1.49	$1.60	$1.41	$1.56
Ohio	$5.45	$5.42	$5.50	$2.48	$2.72	$1.82	$2.25	$0.91	$0.94	$0.67	$0.78	$1.34	$1.39	$1.31	$1.44
South Dakota	$5.89	$5.86	$6.00	$4.26	$4.37	$2.46	$5.09	$1.65	$1.72	$0.82	$1.24	$1.71	$1.79	$1.60	$2.06
Wisconsin	$6.70	$6.67	$6.74	$2.55	$2.40	$2.30	$3.57	$1.28	$1.34	$0.91	$1.45	$2.18	$2.40	$2.08	$2.29
West															
Arizona	$6.40	$6.39	$6.45	$5.91	$4.50	$4.41	$6.88	$2.01	$2.10	$1.20	$0.99	$1.50	$1.59	$1.39	$1.70
California	$5.53	$5.60	$5.35	$6.92	$3.21	$3.32	$8.87	$2.27	$3.14	$0.87	$0.82	$1.94	$2.10	$1.80	$2.20
Colorado	$5.15	$5.15	$5.16	$5.39	$3.90	$2.91	$6.40	$2.38	$2.59	$0.67	$1.21	$1.83	$1.96	$1.66	$2.04
Idaho	$4.52	$4.53	$4.50	$3.69	$3.39	$1.59	$7.56	$2.15	$2.33	$0.64	$0.91	$1.70	$1.80	$1.51	$2.15
Montana	$6.08	$6.06	$6.16	$6.20	$6.19	$3.76	$6.37	$1.20	$1.24	$0.73	$1.52	$1.98	$2.05	$1.78	$2.36
New Mexico	$5.99	$6.05	$5.80	$1.91	$1.91	$1.70	$3.08	$2.35	$2.51	$1.11	$1.16	$1.51	$1.59	$1.39	$1.73
Nevada	$5.61	$5.61	$5.61	$2.73	$1.65	$1.44	$8.91	$2.20	$2.33	$0.71	$1.17	$1.72	$1.88	$1.53	$1.92
Oregon	$5.73	$5.76	$5.61	$8.70	$5.47	$2.72	$10.93	$2.75	$3.02	$1.65	$1.14	$2.42	$2.50	$2.36	$2.86
Utah	$5.90	$5.87	$5.99	$7.74	$5.17	$3.55	$8.57	$2.36	$2.48	$0.84	$1.59	$2.53	$2.62	$2.42	$2.72
Washington	$7.78	$7.84	$7.62	$9.57	$7.66	$5.60	$11.57	$2.78	$3.04	$2.01	$1.12	$2.78	$2.87	$2.72	$2.95
Wyoming	$4.84	$4.82	$4.90	$4.16	$3.64	$1.88	$5.36	$1.93	$2.10	$0.76	$1.07	$1.75	$1.86	$1.50	$2.04

Table 5.3 Trends in tobacco prices for cigarettes, little cigars, RYO cigarettes, and moist snuff, Oct 2011-Jan 2016, U.S.

State	Cigarettes, CP			Little Cigars, CPE				RYO Cigarettes, CPE				Moist snuff, CPE			
	Total	NFM	Menthol	Total	NFM	Menthol	Flavored	Total	NFM	Menthol	Flavored	Total	NFM	Menthol	Flavored
U.S. (Total)	0.1	0.1	0.1	NS	-0.1	-0.2	0.2	-0.4	-0.4	-0.8	-0.2	0.1	0.1	0.1	-0.1
Northeast															
Connecticut	<0.1	<0.1	<0.1	-0.2	-0.1	-0.2	NS	-0.1	-0.3	-1.0	1.0	0.1	0.1	0.1	0.1
Massachusetts	0.4	0.4	0.4	0.1	0.1	0.3	0.2	-0.2	-0.3	-0.5	0.3	1.1	1.0	1.2	1
Maine	NS	NS	-0.1	-0.1	-0.2	-0.1	1	-0.3	-0.3	-0.5	NS	0.1	<0.1	0.1	0.1
New Hampshire	<0.1	<0.1	NS	0.3	NS	1.0	1.1	NS	NS	-0.4	0.2	0.4	0.3	0.4	0.3
New Jersey	<0.1	<0.1	<0.1	-0.3	-0.5	-0.4	0.6	0.3	0.1	-1.5	0.1	0.1	0.1	0.1	-0.1
New York	-0.1	-0.1	-0.1	0.1	0.1	-0.4	0.1	-0.9	-0.9	-1.0	-0.3	<0.1	0.1	0.1	-0.1
Pennsylvania	<0.1	0.1	NS	-0.4	-0.5	-0.8	0.4	-0.6	-0.5	-0.7	0.3	-0.1	0.1	-0.2	-0.4
Rhode Island	0.1	0.1	0.1	1.0	1.5	0.9	-1.0	-0.2	-0.4	-2.5	0.5	0.1	0.1	0.1	0.1
Vermont	0.1	0.1	0.1	0.6	0.5	0.6	1.0	-1.0	-1.3	-2.0	-0.5	0.4	0.3	0.4	0.3
South															
Alabama	0.1	0.1	0.1	-0.5	-0.3	-0.9	-0.6	-0.6	-0.8	-0.8	0.6	0.1	0.1	0.1	-0.2
Arkansas	0.3	0.3	0.1	NS	-0.4	NS	0.7	-0.3	-0.5	-0.4	1.2	0.3	0.3	0.3	NS
Delaware	<0.1	<0.1	0.1	-1.1	-1.1	-0.4	-1.0	-1.4	-1.6	-2.9	1.2	0.1	NS	0.1	-0.2
Florida	-0.1	NS	-0.2	-0.2	-0.3	NS	0.3	NS	-0.6	-1.5	1.3	0.1	0.1	0.1	0.2
Georgia	0.1	0.1	0.1	-0.4	-0.5	0.2	0.2	-0.3	-0.4	-1.9	0.7	0.1	0.1	0.2	-0.1
Kentucky	0.1	0.2	0.1	-0.1	-0.2	-0.3	0.4	-0.2	-0.2	-1.1	0.1	0.2	0.1	0.3	-0.1
Louisiana	0.2	0.2	0.2	-0.2	-0.7	0.3	-0.2	0.2	NS	-1.1	0.8	0.2	0.2	0.2	NS
Maryland	NS	NS	NS	NS	0.2	0.4	NS	-1.0	-1.0	-3.0	0.3	0.1	0.1	0.2	NS
Mississippi	0.1	<0.1	0.1	-0.3	-0.6	<0.1	0.9	0.2	0.1	-0.6	0.8	0.2	0.2	0.2	NS
North Carolina	0.1	0.1	<0.1	0.1	NS	-0.1	0.4	-0.9	-0.9	-2.3	0.2	0.1	NS	0.2	-0.1
Oklahoma	0.1	0.1	<0.1	0.5	NS	0.3	1.1	NS	-0.2	-1.3	1.0	0.2	0.2	0.1	0.1
South Carolina	0.1	0.1	0.1	-0.2	-0.3	-0.2	NS	-0.2	NS	-1.7	0.7	<0.1	NS	0.1	-0.2
Tennessee	0.1	0.1	0.1	-0.8	-0.8	-0.5	NS	-2.0	-2.2	-2.2	-0.7	0.1	0.1	0.1	-0.1
Texas	<0.1	NS	0.1	-0.3	-0.3	-0.1	NS	-0.2	-0.3	-0.4	1.2	0.1	0.1	0.1	0.1
Virginia	0.1	0.1	0.1	-0.7	-0.7	-0.2	-1.1	-1.0	-1.1	-3.3	0.3	0.1	NS	0.1	-0.3
West Virginia	0.1	0.2	0.1	-0.1	-0.1	-0.2	-0.2	-0.3	-0.3	-0.8	-0.5	0.1	0.1	0.2	0.2
Midwest															
Iowa	0.1	0.1	<0.1	-0.1	-0.3	NS	0.4	-0.1	-0.3	-1.6	0.5	0.1	0.1	0.2	0.1
Illinois	0.4	0.4	0.4	0.9	0.8	0.4	1.6	NS	-0.2	-0.3	1.4	NS	NS	NS	-0.3
Indiana	0.1	0.1	0.1	-0.4	-0.4	-0.2	-0.2	-0.9	-1.2	-1.3	0.8	0.1	0.1	0.1	-0.1
Kansas	0.3	0.3	0.2	-0.5	-0.3	-0.5	-0.5	0.2	0.1	-2.1	0.9	0.2	0.1	0.2	-0.1
Michigan	0.1	0.1	0.1	-0.1	-0.1	-0.2	-0.2	-0.3	-0.4	-0.4	NS	0.1	0.1	0.2	0.2
Minnesota	0.8	0.8	0.8	1.2	1.2	1.0	1.3	-0.7	-0.9	-1.3	-0.9	1.0	0.9	1.1	0.7
Missouri	0.1	0.1	0.1	-0.5	-0.7	-0.9	NS	0.2	NS	-0.9	0.8	0.2	0.2	0.2	-0.1
North Dakota	0.1	0.1	0.1	NS	NS	-0.6	0.8	-0.3	-0.4	¶	¶	0.2	0.2	0.4	0.2
Nebraska	0.1	0.1	0.1	-0.4	-0.6	-0.6	0.3	NS	-0.2	-1.7	0.6	NS	0.1	NS	-0.1
Ohio	0.2	0.2	0.1	0.2	0.3	-0.1	0.1	-0.4	-0.4	-1.2	NS	0.1	0.1	0.1	-0.3
South Dakota	0.1	0.1	0.1	0.3	0.4	-0.9	0.4	-0.4	-0.6	¶	0.9	0.2	0.2	0.3	0.1
Wisconsin	<0.1	<0.1	<0.1	-0.4	-0.5	-0.6	0.2	-0.4	-0.5	-1.3	0.7	0.2	0.2	0.3	-0.4
West															
Arizona	0.1	<0.1	0.1	NS	-0.1	NS	NS	-0.1	-0.3	-0.2	1.1	-0.1	NS	-0.1	NS
California	0.1	0.1	0.1	NS	-0.7	-0.1	0.2	0.3	0.5	-1.3	0.3	NS	0.1	0.1	-0.1
Colorado	0.1	0.1	<0.1	NS	-0.2	-0.3	NS	0.3	0.1	-2.0	0.6	0.1	0.1	NS	NS
Idaho	0.1	0.1	-0.1	-0.7	-0.9	-2.1	0.5	NS	NS	-2.1	NS	0.1	0.1	0.1	0.2
Montana	NS	<0.1	NS	NS	<0.1	¶	NS	-0.9	-0.9	-0.7	0.8	0.1	0.1	NS	0.3
New Mexico	0.1	0.1	0.1	-1.1	-1.3	-0.6	NS	NS	-0.1	-0.5	0.7	0.1	0.2	0.2	NS
Nevada	0.3	0.3	0.3	-0.7	NS	-0.2	0.4	0.6	0.1	-1.5	1.3	NS	0.1	NS	-0.1
Oregon	0.1	0.1	0.1	0.4	NS	-1.1	0.2	0.2	0.1	-0.8	0.2	0.1	0.1	0.1	0.2
Utah	NS	NS	NS	0.6	0.9	NS	0.3	-0.5	-0.6	-1.9	NS	0.1	0.1	0.1	0.1
Washington	0.1	0.1	0.1	0.3	0.1	NS	0.1	NS	NS	-0.2	-0.1	0.1	0.1	0.1	0.1
Wyoming	0.1	0.1	0.1	NS	-0.3	-1.4	0.4	NS	NS	-1.2	0.6	0.2	0.2	0.2	0.3

¶Trend could not be measured because of missing data points over the study period; NFM = Nonflavored and nonmentholated

Figure 5.1 Emerging themes in qualitative assessment of flavor names for cigarettes, RYO cigarettes, Cigars, and smokeless tobacco products, Oct 2011-Jan 2016, United States

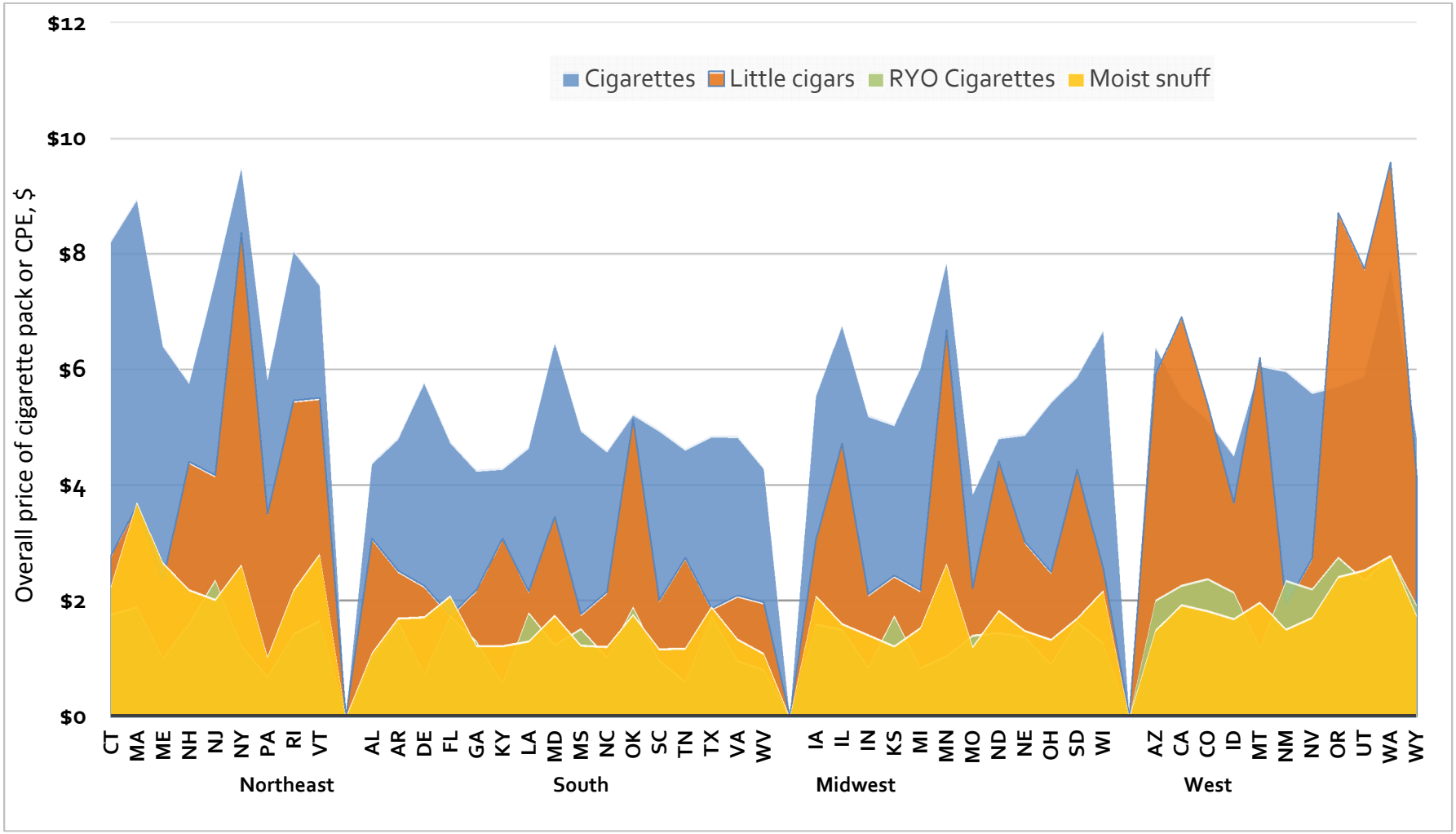

Figure 5.2 Absolute inequalities in standardized prices of cigarettes, little cigars, RYO cigarettes, and moist snuff in 2015, by state, United States

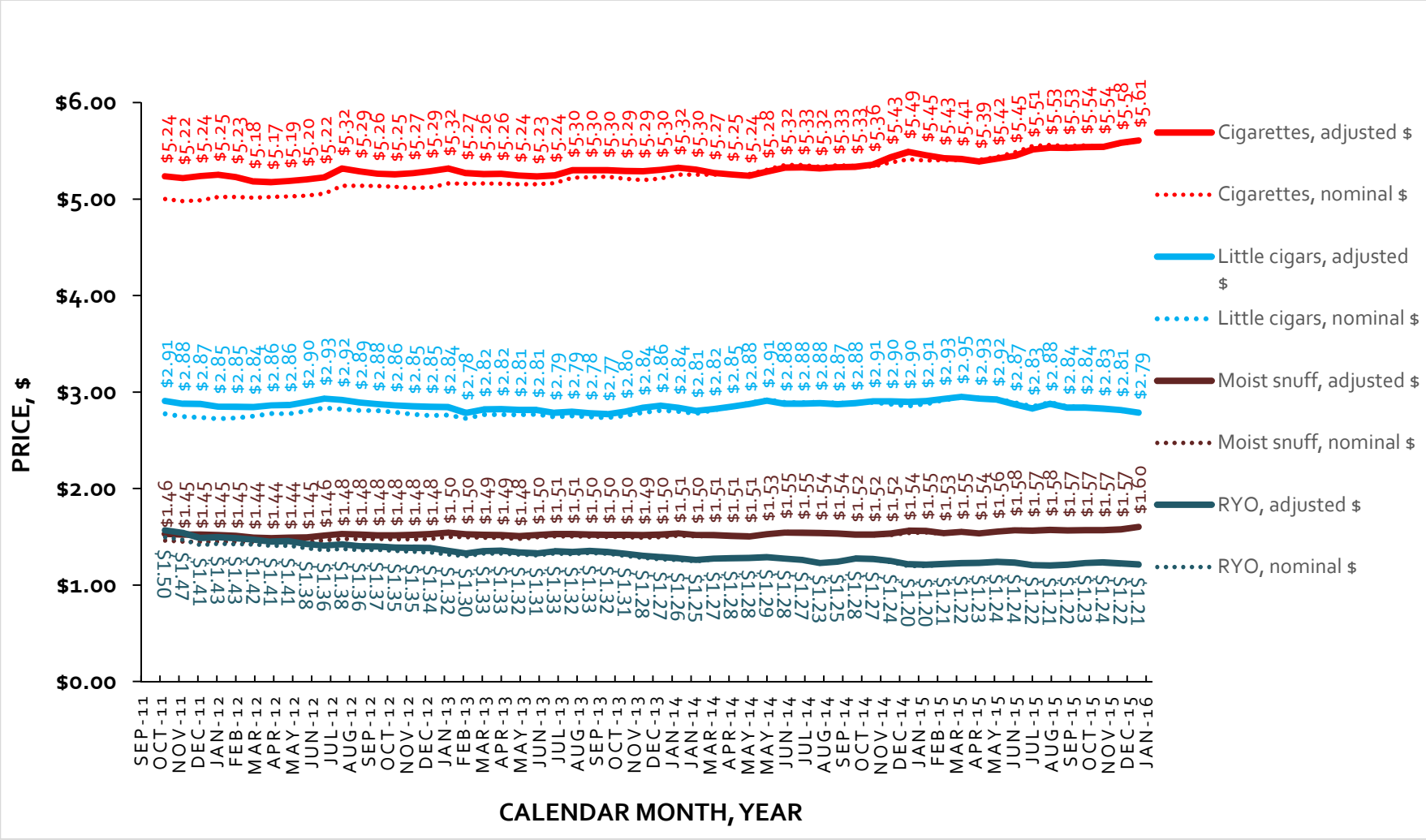

Figure 5.3 Monthly average prices in adjusted (constant 2015 dollars) and nominal dollars for cigarettes, little cigars, moist snuff, and RYO cigarettes, Oct 2011-Jan 2016, United States

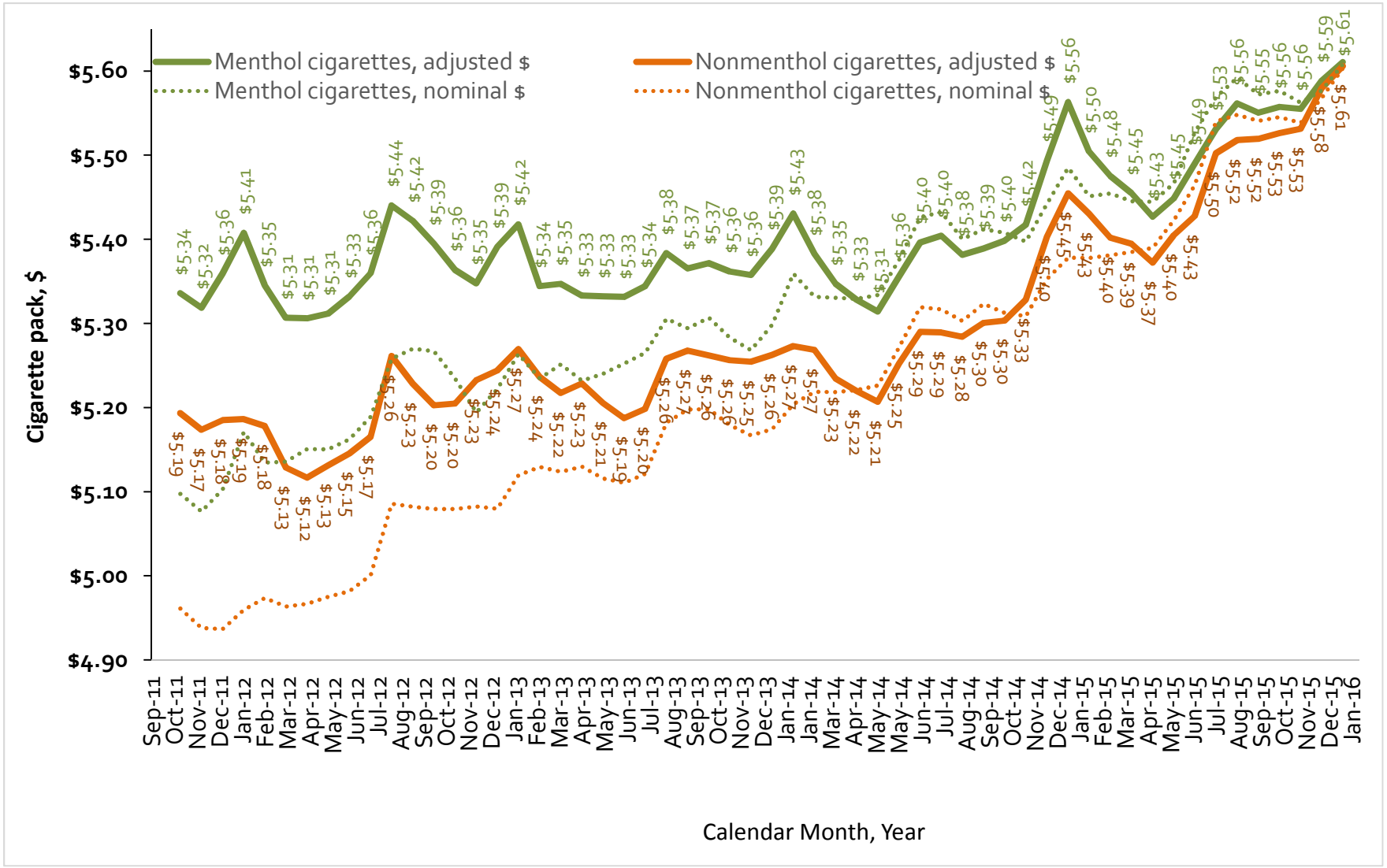

Figure 5.4 Monthly average prices in adjusted (constant 2015 dollars) and nominal dollars per cigarette pack, by flavor type, Oct 2011-Jan 2016, United States

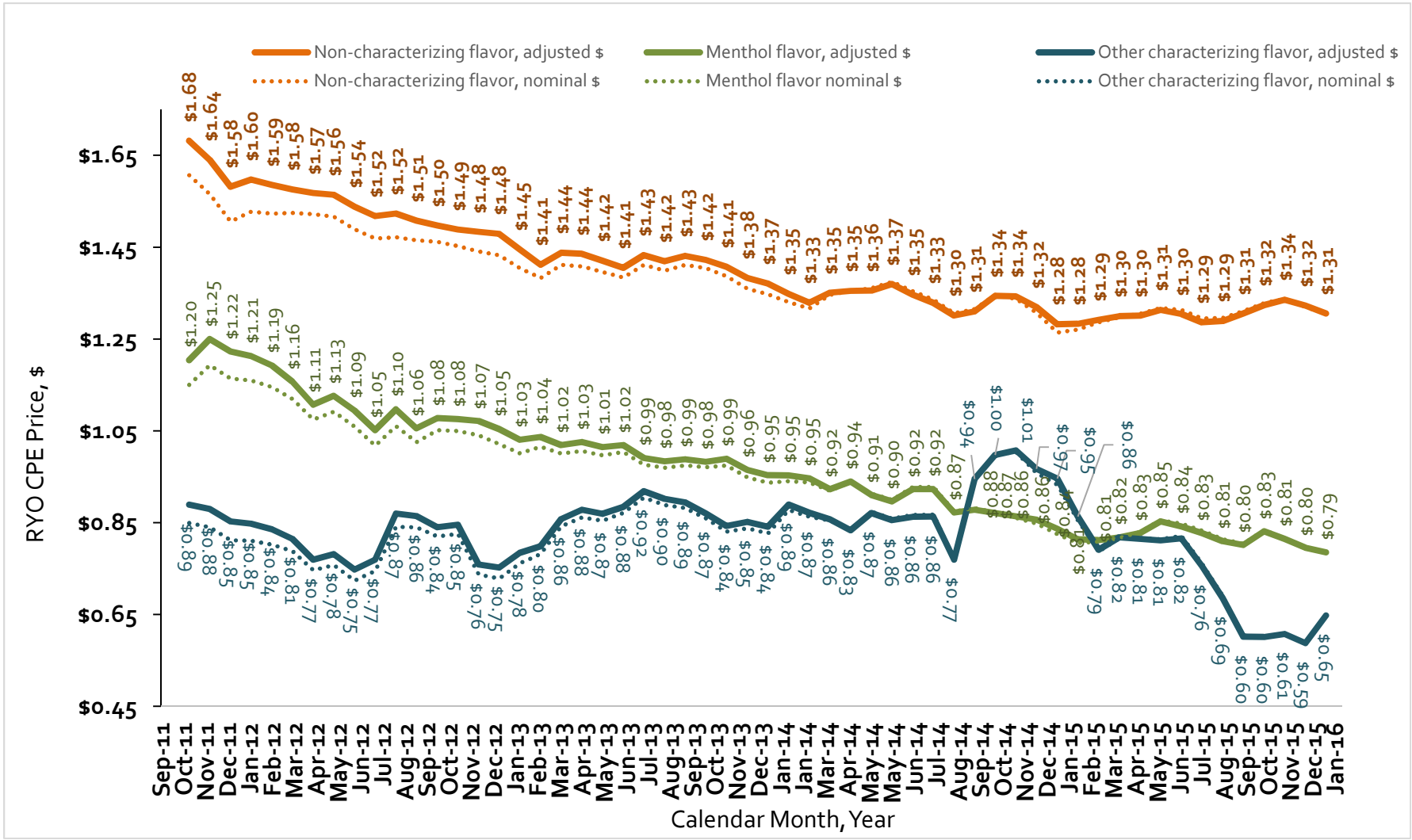

Figure 5.5 Monthly average prices in adjusted (constant 2015 dollars) and nominal dollars per CPE of RYO cigarettes, by flavor type, Oct 2011-Jan 2016, United States

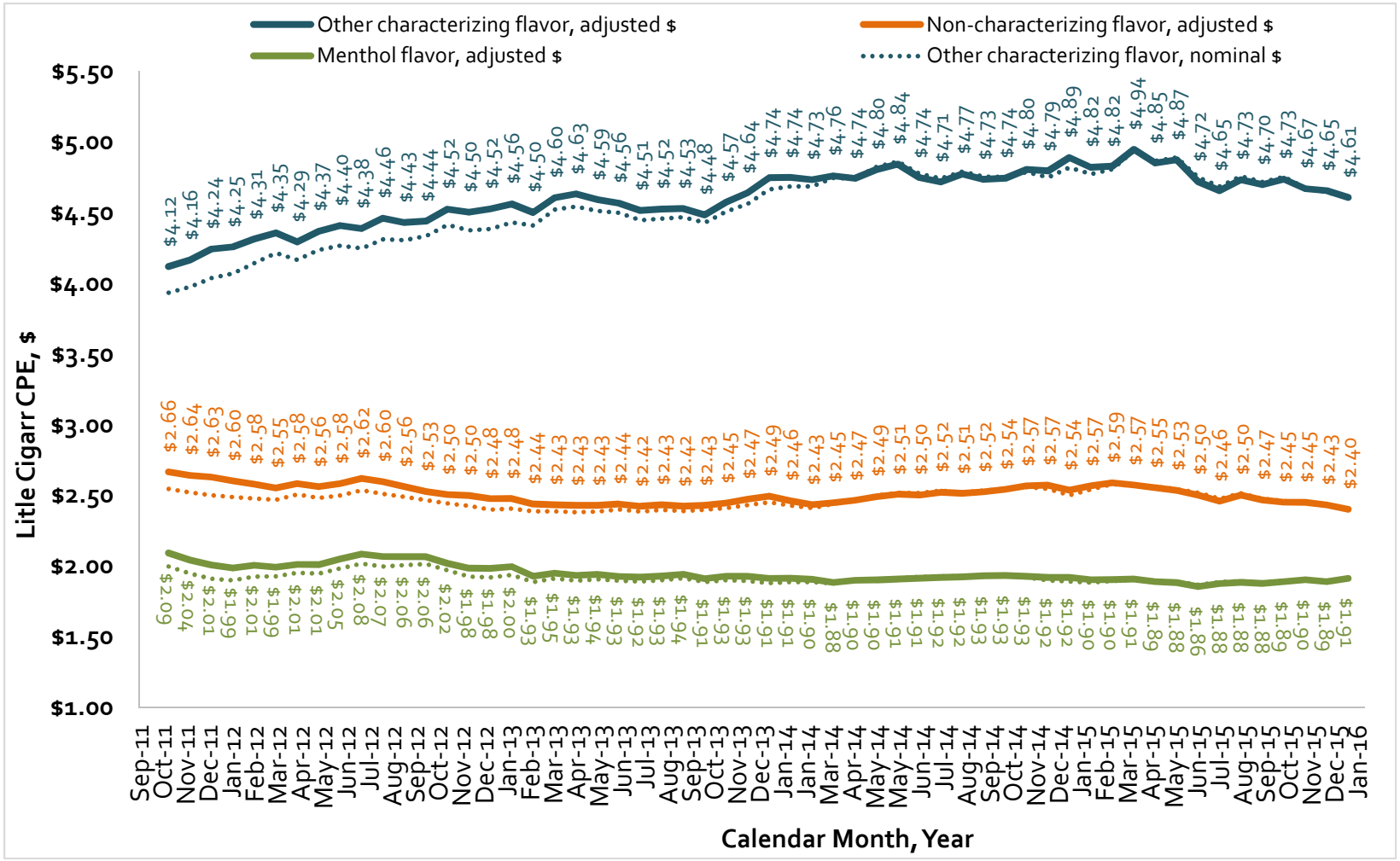

Figure 5.6 Monthly average prices in adjusted (constant 2015 dollars) and nominal dollars per CPE of Little cigars, by flavor type, Oct 2011-Jan 2016, United States

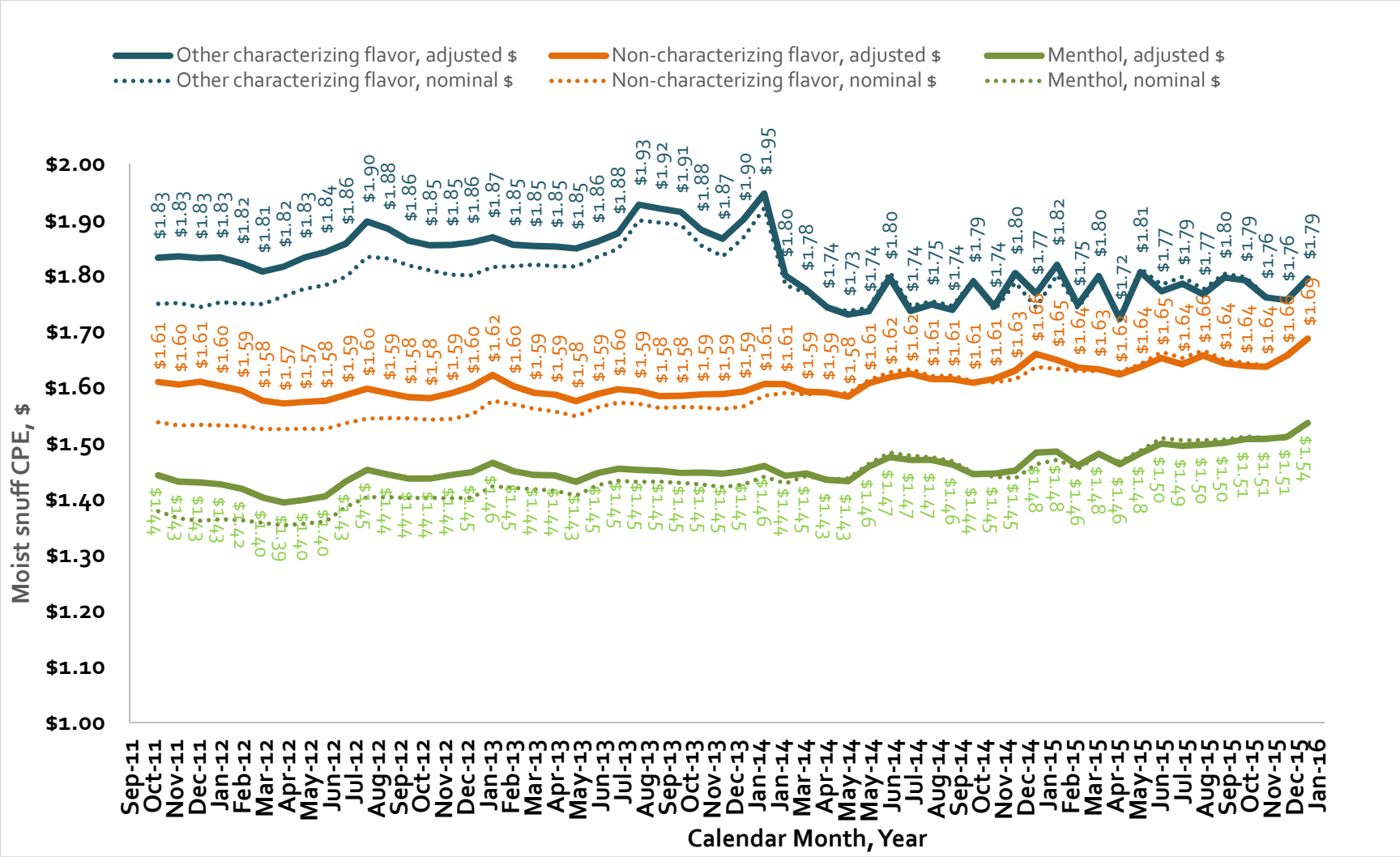

Figure 5.7 Monthly average prices in adjusted (constant 2015 dollars) and nominal dollars per CPE of Moist snuff, by flavor type, Oct 2011-Jan 2016, United States

Chapter 6 - PUBLIC SUPPORT AMONG U.S. ADULTS FOR A TOBACCO FLAVOR BAN[5]

[5] Agaku IT, Dobbin K, Muilenburg J, Hallow K, et al. To be submitted to *American Journal of Public Health.*

ABSTRACT

BACKGROUND: Under authority of the 2009 Family Smoking Prevention and Tobacco Control Act, FDA prohibited all "characterizing flavors" in cigarettes in 2009 (except menthol). FDA recently indicated its intent to also prohibit all "characterizing flavors" (except menthol) in cigars, but not in water pipe/hookahs, e-cigarettes, pipes and smokeless tobacco. This study measured public support for a complete tobacco flavor ban (including menthol) in all tobacco products. This information can be useful to FDA in future proposed ruling on flavored products. Furthermore, knowledge of subgroup variations in public support for a tobacco flavor ban could inform tailored public health programs, e.g., mass media educational campaigns.

METHODS: Data were from the 2016 *Summer Styles*, an online survey of a nationally representative sample of U.S. adults aged ≥18 years (n=4,203). Respondents were asked whether they supported a ban on flavors (e.g., menthol, spicy, sweet, or fruity flavor) in all tobacco products. Weighted prevalence estimates of public support were computed overall and by socio-demographic and tobacco use characteristics. Multivariable generalized linear regression models were used to calculate adjusted prevalence ratios (aPR) for public support for a tobacco flavor ban.

RESULTS: Overall prevalence of public support for a tobacco flavor ban was 47.3% among U.S. adults. By tobacco use status, prevalence was 34.8%, 48.4%, and

52.0% among current, former, and never any tobacco users (p<0.001). By past 30-day tobacco use, prevalence ranged from 26.2% (e-cigarette users) to 41.0% (cigar smokers). Among both the overall U.S. adult population as well as current any tobacco users, adults concerned about adolescent smoking initiation were more likely to support a tobacco flavor ban. Similarly, current any tobacco users living with children in their household were more likely to support a tobacco flavor ban than those living with none (aPR=1.38; 95%CI=1.05-1.82).

CONCLUSION: Approximately half of U.S. adults supported a tobacco flavor ban. Framing of proposed flavor prohibitions around protection of children may garner more support within large segments of the population, even among tobacco users. A tobacco flavor ban could benefit public health by reducing both individual-level (e.g., addiction, toxicity) and population-level (smoking incidence and prevalence) harms of tobacco use.

INTRODUCTION

The use of attractive flavor additives, such as those for an herb, spice, fruit, menthol, alcohol, beverage, candy, chocolate, or coffee in tobacco products can increase smoking appeal [1-4]. Flavors such as menthol provide a smoothing effect on the airways and mask the harshness of tobacco smoke, thereby increasing the ease of experimentation among "newbies" [5-11]. Flavor names (e.g., "cherry", "grape", "apple", "peach", and "berry"), as well as the levels of flavor additives are similar between tobacco products and certain food substances [12, 13]. Incorporating flavors commonly associated with foods and other nutritional substances to a product as harmful as tobacco could diminish relative perceptions of harm among youth, as is indicated by ratings of lower harm for flavored conventional and emerging products compared to regular cigarettes [14, 15]. Flavored tobacco products are very popular among youth [2]; research shows that sweet preferences in humans are highest in adolescence [16-18]. Among U.S. students in grades 6-12 who were current tobacco users in 2014, a large proportion reported using flavored products, including 63.3% of e-cigarette users, 60.6% of hookah users, 63.5% of cigar smokers, 53.6% of cigarette smokers, and 58.8% of smokeless tobacco users [2]. Prohibiting flavor additives in tobacco products can reduce the appeal of tobacco products, as well as the likelihood of initiation, addiction, and relapse among youth [19].

Public support can influence policy through engagement of the citizenry in the legislative process [20]. The U.S. rulemaking process for federal regulations requires the solicitation and careful consideration of comments from the public for proposed rules published in the Federal Register prior to these becoming finalized [21]. Public support is also important for enforcement of tobacco control policies (e.g., reporting violations to regulatory agencies such as FDA) [22]. Hence, measuring public support for tobacco control policies can help inform tobacco control and prevention policy. Research conducted in the European Union (EU) member states in 2012 showed that 63% of all EU adults supported a ban on flavors that make tobacco products more attractive, with support highest in Cyprus (85%), France (71%), Ireland (82%), Belgium (74%), and Finland (71%) [23]. Following this high wave of EU-wide support, the EU parliament in 2013 voted for a ban on menthol in manufactured and roll-your-own cigarettes, which will come into full effect in 2020 [24, 25]. Other countries which have passed or proposed legislation prohibiting or restricting menthol or other flavors in cigarettes are Australia, Brazil, Chile, Ethiopia, Moldova, Turkey, and several Canadian provinces [26, 27].

The 2009 Family Smoking Prevention and Tobacco Control Act (FSPTCA) authorized the U.S. Food and Drug Administration (FDA) to regulate the design, manufacture, and marketing of tobacco products [28]. Under this authority, FDA in 2009 prohibited the use of all “characterizing flavors” in cigarettes, except menthol, even though menthol cigarettes accounted for 29% of cigarette market shares in that year, and more than any other flavored cigarette in the years preceding that

[29-31]. A 2010 U.S. study investigated public support for prohibition of menthol in cigarettes and found that only 20.0% of U.S. adults were in favor [32]. However, several changes have occurred in the U.S. tobacco control landscape since then, including the introduction of several new tobacco products, recent stalls in youth cigarette smoking decline; as well as increased scope of FDA's regulatory authority under the deeming rule [2, 33, 34]. Since August 8, 2016, FDA has extended its oversight over all tobacco products that meet the statutory definition of "tobacco product", including emerging products such as e-cigarettes [33]. FDA intends to prohibit all characterizing flavors in cigars except menthol. This proposed ruling on cigars however does not apply to other types of tobacco products such as water pipe/hookah, e-cigarettes, pipe tobacco and smokeless tobacco products. The continued availability of flavored products structurally similar to cigarettes or cigars (e.g., e-cigarettes, e-cigars) might result in continued access and use of flavored products among youth [12].

No study has measured support for a complete tobacco flavor ban that includes all flavor varieties in all U.S. tobacco products. Knowledge of public support for a tobacco flavor ban can be useful to FDA in proposing future regulatory action regarding the diversity of tobacco products on the U.S. market. Furthermore, knowledge of subgroup variations in support for a tobacco flavor ban could help inform targeted public health programs, such as mass media educational campaigns. For example, low support might be suggestive of groups with less awareness of the health consequences of all tobacco product use, including flavored

products. Conversely, subgroups with greater burden of tobacco product use and tobacco-related morbidity and mortality may show greater support [32], and possibly be more receptive to targeted interventions such as mass media campaigns. The aim of this study was therefore to determine prevalence and correlates of public support for a complete tobacco flavor ban in the US.

METHODOLOGY

Data Source

Data were from the 2016 wave of the *Summer Styles* survey of U.S. adults aged ≥18 years (n= 4,203; response rate=68%). *Summer Styles*, which is conducted by the Porter Novelli Company, is a custom survey; clients develop their own specific research questions which are fielded in the syndicated survey. Several public health organizations routinely use the *Summer Styles* survey as a rapid, real-time mechanism to collect data on trending issues because of the rapid turnover for survey implementation. For this study, development of the questionnaire occurred during January to April, 2016. The finalized study questions were submitted to Porter Novelli and were fielded in the 2016 iteration of *Summer Styles* which occurred during June 24 to July 11, 2016

Participant selection for 2016 *Summer Styles* occurred randomly from a pool of ~55,000 online panelists sampled to be representative of U.S. adults (GfK'sKnowledgePanel®). Panelists are randomly recruited using probability-based

sampling by U.S. postal address to reach respondents regardless of whether or not they have landline phones or Internet access.

For the survey, investigators provided a laptop computer with internet access to households that were not internet-enabled. Investigators also sent email reminders to non-responders on the 3rd and 15th day of the field period. Survey completion times were approximately half an hour.

Respondents were not required to answer any of the questions and could exit the survey at any time. Respondents who completed the survey received 10,000 cash-equivalent reward points. Data were weighted using nine factors: gender, age, household income, race/ethnicity, household size, education, census region, metro status, and prior Internet access. Weights were computed such that underlying distribution of participants on key demographic variables matched U.S. Current Population Survey proportions. A final weight variable is available in the dataset (*weight_summer)* with which all analyses were weighted to yield estimates representative of the U.S. adult population aged ≥18 years.

Measures

Public Support for a tobacco flavor ban

Public support for a tobacco flavor ban was determined with the question "Do you favor or oppose prohibiting flavors such as menthol (mint), spicy, sweet, or fruity flavor, in all tobacco products, including in electronic vapor products, such as electronic cigarettes (e-cigarettes), electronic hookahs (e-hookahs), or vape pens?"

Categorical response options of “Strongly favor” or “Somewhat favor” were treated as an affirmative response for support (vs. “Somewhat oppose” or “Strongly oppose”).

Tobacco-related behaviors and beliefs

The following two questions were asked to measure tobacco usage (1) “Have you ever tried any of the following products, even just one time?”; (2) “In the past 30 days, which of the following products have you used at least once?” For both questions, categorical response options were grouped into seven classes or types of products. These were cigarettes, cigars (including big cigars, little cigars, and cigarillos), smokeless tobacco products (including chewing tobacco/snuff/dip, snus, and dissolvable tobacco products), electronic nicotine delivery systems (including e-cigarettes, e-hookahs, hookah pens, vape pens, e-cigars, e-pipes), loose tobacco products (including pipe tobacco and roll-your-own [RYO] cigarettes), water pipes/hookahs, and other products not specified.

Current any tobacco users were persons who reported using at least one of the seven tobacco product types at least once in the past 30 days. Former any tobacco users were persons who reported ever use of at least one product type, but were not current users of any tobacco product at the time of the study. Never any tobacco users were persons who reported never having used any of the seven tobacco product types in their lifetime.

Considering that the plethora of attractive flavors is a key promotional feature in advertisements of emerging tobacco products such as e-cigarettes, respondents' perceptions about the consequences of adolescents' exposure to such advertisements were measured. The question was framed: "*Please indicate how much you agree or disagree with the following statement: E-cigarettes advertisements can make adolescents think about smoking regular cigarettes*." There were five response options, which were recoded into three categories within this study: (1) Agree ("Strongly agree", or "Somewhat agree"), (2) Undecided ("Neither agree nor disagree"), or (3) disagree ("Somewhat disagree", "Strongly disagree").

Socio-demographic characteristics

Sociodemographic characteristics included sex, age, race/ethnicity, annual household income, U.S. census region, marital status, and presence of any children aged <18 years living in the household. The latter was measured under the hypothesis that parents and guardians of under aged minors would show greater support for bans on flavors attractive to youth.

Analyses

Analyses were performed separately for all U.S. adults and current tobacco users. Prevalence estimates of public support for a tobacco flavor ban were calculated along with 95% confidence intervals (CI), overall and among subgroups. Estimates with relative standard errors ≥ 30% were deemed statistically unreliable and suppressed. Within-group differences were determined with chi-squared tests; a

standard (non-trend) chi-squared test was used for nominal variables while a trend test was used for ordinal variables (age, and annual household income).

To explore predictors of public support for a tobacco flavor ban, multivariable generalized linear regression models were fitted to calculate adjusted prevalence ratios (aPR). The exploratory analyses included as independent variables sex, age, annual household income, presence of any children aged <18 years in household, marital status, perception about the consequences of e-cigarette marketing among adolescents, and current tobacco use status (the latter included only in the model for all U.S. adults overall). To reduce collinearity (e.g., between marital status and presence of any children in household), each independent variable was iteratively modelled, adjusting for age, sex, race/ethnicity, income, and tobacco use status as appropriate (the latter included only in the model for all U.S. adults overall). Prevalence ratios were used rather than odds ratios because of the common outcome, the fact that prevalence ratios are more conservative, as well as the greater ease of interpretation of prevalence ratios [35]. All data were analyzed using R V.3.2.2.

RESULTS

Characteristics of study participants

Of all study participants, 17.8% were current any tobacco users, 42.5% were former any tobacco users, and 39.7% were never any tobacco users. Mean age of all respondents was 47.02 years (SE=0.34). Overall, 48.3% of participants were male,

58.3% were married or living with a partner, 65.1% were non-Hispanic white, and 62.1% had annual household income of $50,000 or higher.

Public Support among all respondents for a tobacco flavor ban

Among all U.S. adults, 47.3% supported a tobacco flavor ban (Table 6.1). Public support for a tobacco flavor ban differed significantly by tobacco use status; prevalence was 34.8%, 48.4%, and 52.0% among current, former, and never any tobacco users ($p<0.001$). Similarly, prevalence of support was 31.9%, 42.5%, and 53.4% among adults who disagreed, were undecided, or agreed, respectively, that exposure to e-cigarette advertisements could lead to cigarette smoking initiation among youth ($p<0.001$). There was however no significant difference in support by sex ($p=0.074$), age group ($p=0.496$), annual household income ($p=0.739$), presence of any children in household ($p=0.164$), race/ethnicity ($p=0.268$), U.S. census region ($p=0.660$), or marital status ($p=0.420$).

Within adjusted analyses among all U.S. adults, current any tobacco users were less likely to support a tobacco flavor ban compared to never any tobacco users (aPR=0.67; 95% CI=0.59-0.77, Table 6.2). Similarly, compared to adults who agreed that e-cigarette advertisements could lead to cigarette smoking initiation among adolescents, support for a tobacco flavor ban was lower among those who were undecided (aPR=0.82; 95%CI=0.74-0.89), or those who disagreed (aPR=0.60; 95%CI=0.51-0.71). All other factors were non-significant in predicting support for a tobacco flavor ban.

Public Support among current any tobacco users for a tobacco flavor ban

Figure 6.1 shows differing public support by type of tobacco product used in the past 30 days (not mutually exclusive groups). Prevalence in descending order was as follows: users of cigars/cigarillos/filtered little cigars, 41.0%; users of smokeless tobacco products, 37.2%; users of loose tobacco products (i.e., pipe and RYO tobacco), 36.7%; users of manufactured cigarettes, 34.9%; and users of e-cigarettes, 26.2%. Approximately 48.4% of persons who reported not using a tobacco product in the past 30 days (including never and former any tobacco users) expressed support for a tobacco flavor ban.

Among current any tobacco users, support for a tobacco flavor ban varied by annual household income; prevalence was highest among those with annual household incomes<$20, 000 (45.3%) and lowest among those earning $20,000-49,999 per annum (27.5%, p=0.024). Prevalence of support was 22.9%, 32.7%, and 41.3% among current any tobacco users who disagreed, were undecided, or agreed, respectively, that exposure to e-cigarette advertisements could lead to cigarette smoking among adolescents (p=0.009). Prevalence was 40.9% among current any tobacco users with any children aged <18 years old living in the household vs. 32.0% among those with no children living in the household (p=0.058). There was no significant difference in public support among current any tobacco users by sex (p=0.327), age group (p=0.432), race/ethnicity (p=0.513), U.S. census region (p=0.099), or marital status (p=0.927).

Within adjusted analyses, the likelihood of public support for a tobacco flavor ban was significantly lower among current any tobacco users living in the Southern (aPR=0.65; 95%CI=0.48-0.90), and the Western U.S. (aPR=0.64; 95%CI=0.43-0.95) compared to those living in the Northeast U.S. (Table 6.2). Public support was significantly higher among adults with any children aged <18 years living in their household compared to those with none (aPR=1.38; 95%CI=1.05-1.82). Furthermore, compared to those who agreed that e-cigarette advertisements could lead to cigarette smoking among adolescents, support was lower among current any tobacco users who disagreed (aPR=0.55; 95%CI=0.36-0.83). All other factors were statistically non-significant.

DISCUSSION

Overall, close to half of U.S. adults supported a tobacco flavor ban. Similar levels of support for tobacco flavor bans have been noted in several other Western countries including Bulgaria (48%), Czech Republic (47%), Austria (53%), Poland (51%), Romania (52%), and Slovenia (53%) [23]. Support for a tobacco flavor ban in this study varied significantly by tobacco use status, with only 1 in 3 of current tobacco users supporting such a prohibition compared to 1 in 2 of never tobacco users, a trend also noted within the EU [23]. By type of tobacco product used, support was lowest among past 30-day e-cigarette users, which might be because flavors are a dominant reason for e-cigarette use in approximately a third (34.3%) of U.S. adult e-cigarette users [36]. The varieties of flavors in e-cigarettes far exceed

those previously documented for any other tobacco product, with one study reporting over 7,764 distinct flavors in 2014 [34].

Although public support for a tobacco flavor ban was lower than that for raising legal tobacco purchase age to 21 (75%) [37], implementing tobacco-free school grounds (86.1%) [38], or prohibiting tobacco sales in pharmacies (66.1%) [39], it is still over twofold higher than that expressed for prohibiting menthol cigarettes during 2010 [32]. This increased support might be because of increased societal awareness of the health consequences of tobacco use. In the past few years, several hard-hitting mass media educational campaigns have been launched warning about the health consequences of tobacco use, including CDC's adult-oriented *Tips from Former Smokers* campaign (launched in 2012), as well as FDA's youth-oriented *The Real Cost* Campaign (launched in 2014) [40-43]. Evaluation studies have shown high public awareness of these ads as well as a demonstrable effect on positive cognitive and behavioral cessation outcomes [40-43].

This study also suggests that framing of proposed flavor prohibitions around the protection of children might garner more support within large segments of the population. Even among current any tobacco users, those who had any children aged <18 years living in their household were significantly more likely to support a tobacco flavor ban than those with no children in their households. Similarly, U.S. adults who believed that tobacco industry marketing of novel tobacco products such as e-cigarettes might lead to initiation of cigarette smoking by children were more

likely to support a tobacco flavor ban. Parents and guardians represent a large segment of the population for whom tobacco educational messaging framed around protection of children might resonate, especially considering that 29% of parents in single parent families, and 14.8% of those in two-parent households reported being current cigarette smokers in 2013 [44]. In its recently adopted Tobacco Products Directive, the European Commission implemented regulations (including a ban on flavors) focused majorly on tobacco products with the highest use among European youth, including manufactured cigarettes and RYO cigarettes [23-25]. Efforts in the U.S. to reduce the appeal of the most prevalent products among youth may benefit public health, particularly regulations that address e-cigarettes, cigarettes, cigars, and hookahs, the most popular products among U.S. adolescents [45].

A tobacco flavor ban could potentially benefit public health by reducing both individual-level (e.g., addiction, toxicity, carcinogenicity, teratogenicity, morbidity, and mortality) and population-level harms (smoking incidence, prevalence, recidivism, per capita tobacco consumption, secondhand smoke exposure, and tobacco-related economic costs) [46]. Between a third and two-thirds of menthol smokers have reported in previous studies that they would try to quit smoking if menthol cigarettes were to be banned [32, 47, 48].

While FDA is the only federal agency with authority to ban characterizing flavors as a design feature in U.S. tobacco products, opportunities exist for state, local, and tribal governments to implement policies that can reduce access to

flavored and other tobacco products among youth in their constituencies. For example, 27 U.S. states have passed comprehensive smoke-free laws prohibiting smoking in indoor areas of worksites, restaurants, and bars [49]; 40 states have laws prohibiting sales of e-cigarettes to minors [50]; over 180 municipalities in 12 states, and the entire states of Hawaii and California, have raised the legal age of tobacco purchase to 21 years [51]. Furthermore, several states and jurisdictions have passed laws restricting sales of various flavored tobacco products [52]. During 2000-2009, 46 states and D.C. increased their cigarette excise tax; 14 states and D.C. further raised their excise tax during 2010-2014 [53]. These immediate legislative actions at the local levels can complement federal regulatory policy on product design, manufacture, and marketing.

Support for a tobacco control policy might be influenced by an interplay of several factors [20, 32], including perceived importance of the issue (i.e., individual, or community-level relevance), health literacy/awareness of the health risks of smoking; burden of tobacco use or its attendant health consequences; extent of perceived curtailment of individual liberties or pleasure by the proposed policy; as well as social, ethical, or economic acceptability of the policy. Among tobacco users, the high support among persons earning <$20,000 might be attributable to the higher burden of tobacco use among this group which lives below the federal poverty line. More so, the reasons for smoking among the lowest income category might be primarily to relieve stress, not necessarily for hedonistic reward or pleasure – an important consideration in brand choice for higher income groups [54]. Differences

in self-rated importance of reasons for smoking, and differential burden of tobacco-related morbidity and mortality, might explain the striking differences in support for a tobacco flavor ban between the group earning <$20,000 versus that earning $20,000-$49,999. There was however no difference in support noted between the two highest income groups ($50,000-$99,999; ≥$100,000) when compared to those earning <$20,000. Tobacco users in the highest income categories may have relatively high support for a tobacco flavor ban because of greater awareness of health risks of smoking. Previous studies have also shown smokers' willingness to adopt or support certain policies (e.g., smoke-free rules) to help with smoking cessation [55].

This study is subject to at least three limitations. First, *Summer Styles* draws respondents from a probability-based Internet panel and does not recruit using population-based probability samples. While this methodology is more accurate than nonprobability-based Internet surveys, it might yield results with limited generalizability, particularly with panel conditioning [56]. Second, all measures were based on self-reports, which could be subject to inaccuracies and biases. For example, there might be some misclassification in self-reported tobacco use history (current, former, and never any tobacco use) because detailed lifetime usage thresholds were not available. The definition of former any tobacco users grouped together persons who might only have puffed on a cigarette once and quit, with smokers reporting a history of several cigarette pack-years. Finally, because of

small sample sizes, support for a tobacco flavor ban could not be examined within exclusive categories of different tobacco product types.

CONCLUSION

A tobacco flavor ban in the U.S. might help reduce the appeal of tobacco products such as menthol cigarettes and emerging products such as e-cigarettes and hookahs. This study showed that approximately half of U.S. adults supported a tobacco flavor ban. Even among tobacco users, support was relatively high among those with minors in their household, or those concerned about smoking initiation among children, suggesting that framing of proposed policy around the protection of children could garner more population support. This finding could be of interest to jurisdictions intending to pass legislation banning the sales of flavored tobacco products. These results could also inform development of targeted programs, educational campaigns, or public service announcements which aim to raise public awareness or motivate action towards policies protecting youth from tobacco use.

REFERENCES

1. Carpenter, C.M., et al., *New cigarette brands with flavors that appeal to youth: tobacco marketing strategies.* Health affairs (Project Hope), 2005. **24**(6): p. 1601-1610.
2. Corey, C.G., et al., *Flavored Tobacco Product Use Among Middle and High School Students--United States, 2014.* MMWR. Morbidity and mortality weekly report, 2015. **64**(38): p. 1066-1070.
3. Lewis, M.J. and O. Wackowski, *Dealing with an innovative industry: a look at flavored cigarettes promoted by mainstream brands.* American Journal of Public Health, 2006. **96**(2): p. 244-251.
4. Manning, K.C., K.J. Kelly, and M.L. Comello, *Flavoured cigarettes, sensation seeking and adolescents' perceptions of cigarette brands.* Tobacco control, 2009. **18**(6): p. 459-465.
5. Alpert, H.R., I.T. Agaku, and G.N. Connolly, *A study of pyrazines in cigarettes and how additives might be used to enhance tobacco addiction.* Tobacco control, 2016. **25**(4): p. 444-450.
6. Sokol, N.A., R.D. Kennedy, and G.N. Connolly, *The role of cocoa as a cigarette additive: opportunities for product regulation.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2014. **16**(7): p. 984-991.

7. Yerger, V.B. and P.M. McCandless, *Menthol sensory qualities and smoking topography: a review of tobacco industry documents.* Tobacco control, 2011. **20 Suppl 2**: p. ii37-43.

8. Ahijevych, K. and B.E. Garrett, *The role of menthol in cigarettes as a reinforcer of smoking behavior.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S110-6.

9. Klausner, K., *Menthol cigarettes and smoking initiation: a tobacco industry perspective.* Tobacco control, 2011. **20 Suppl 2**: p. ii12-9.

10. Kreslake, J.M., G.F. Wayne, and G.N. Connolly, *The menthol smoker: tobacco industry research on consumer sensory perception of menthol cigarettes and its role in smoking behavior.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2008. **10**(4): p. 705-715.

11. Kreslake, J.M. and V.B. Yerger, *Tobacco industry knowledge of the role of menthol in chemosensory perception of tobacco smoke.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2010. **12 Suppl 2**: p. S98-101.

12. Brown, J.E., et al., *Candy flavorings in tobacco.* The New England journal of medicine, 2014. **370**(23): p. 2250-2252.

13. Chen, C., et al., *Levels of mint and wintergreen flavorants: smokeless tobacco products vs. confectionery products.* Food and chemical toxicology : an

international journal published for the British Industrial Biological Research Association, 2010. **48**(2): p. 755-763.

14. Ambrose, B.K., et al., *Perceptions of the relative harm of cigarettes and e-cigarettes among U.S. youth.* American Journal of Preventive Medicine, 2014. **47**(2 Suppl 1): p. S53-60.

15. Kaleta, D., et al., *Perceived Relative Harm of Selected Cigarettes and Non-Cigarette Tobacco Products-A Study of Young People from a Socio-Economically Disadvantaged Rural Area in Poland.* International journal of environmental research and public health, 2016. **13**(9): p. 10.3390/ijerph13090885.

16. De Graaf, C. and E.H. Zandstra, *Sweetness intensity and pleasantness in children, adolescents, and adults.* Physiology & Behavior, 1999. **67**(4): p. 513-520.

17. Desor, J.A. and G.K. Beauchamp, *Longitudinal changes in sweet preferences in humans.* Physiology & Behavior, 1987. **39**(5): p. 639-641.

18. Desor, J.A., L.S. Greene, and O. Maller, *Preferences for sweet and salty in 9- to 15-year-old and adult humans.* Science (New York, N.Y.), 1975. **190**(4215): p. 686-687.

19. Tobacco Products Scientific Advisory Committee. Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations. Available at http://www.fda.gov/downloads/advisorycommittees/committeesmeetingmateri

als/tobaccoproductsscientificadvisorycommittee/ucm269697.pdf. Accessed 09/15/2016.

20. Paul Burstein. The Impact of Public support on Public Policy: A Review and an Agenda. Political Research Quarterly March 2003 vol. 56 no. 1 29-40. doi: 10.1177/106591290305600103.

21. Office of the Federal Register. A Guide to the Rulemaking Process. Available at https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf. Accessed 09/14/2016.

22. Vardavas, C.I., et al., *The role of the non-smoker in enforcing smoke-free laws.* Journal of public health policy, 2011. **32**(1): p. 46-59.

23. European Commission. Special Eurobarometer 385. Attitudes of Europeans Towards Tobacco. Available at http://ec.europa.eu/health/tobacco/docs/eurobaro_attitudes_towards_tobacco__en.pdf. Accessed 09/15/2016.

24. European Commission - Press release. 10 key changes for tobacco products sold in the EU. Available at http://europa.eu/rapid/press-release_IP-16-1762_en.htm. Accessed 09/15/2016.

25. European Commission. Public Health. Revision of the Tobacco Products Directive. Available at http://ec.europa.eu/health/tobacco/docs/dir_201440_en.pdf. Accessed 09/16/2016.

26. Framework Convention Alliance. Canadian provinces first in world to ban menthol flavouring. Available at http://www.fctc.org/fca-news/opinion-pieces/-canadian-provinces-first-to-ban-menthol-flavouring. Accessed 09/16/2016.

27. Tobacco Control Legal Consortium. How Other Countries Regulate Flavored Tobacco Products. Available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-global-flavored-regs-.pdf, Accessed 09/16/2016.

28. H.R.1256 - Family Smoking Prevention and Tobacco Control Act. Available at https://www.congress.gov/bill/111th-congress/house-bill/1256. Accessed 09/14/2016.

29. U.S. Food and Drug Administration. *FDA NEWS RELEASE: Candy and Fruit Flavored Cigarettes Now Illegal in United States; Step is First Under New Tobacco Law. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm183211.htm.* Accessed 09/16/ 2016.

30. Federal Trade Commission. Federal Trade Commission Cigarette Report for 2013. Available at https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2013/2013cigaretterpt.pdf.

31. Federal Trade Commission. "TAR," NICOTINE, AND CARBON MONOXIDE OF THE SMOKE OF 1294 VARIETIES OF DOMESTIC CIGARETTES FOR THE YEAR 1998. Available at

https://www.ftc.gov/sites/default/files/documents/reports/2000-report-tar-nicotine-and-carbon-monoxide-covering-1998/1998tarnicotinereport_0.pdf.

32. Pearson, J.L., et al., *A ban on menthol cigarettes: impact on public support and smokers' intention to quit.* American Journal of Public Health, 2012. **102**(11): p. e107-14.

33. Federal Register. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act;Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Available at https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the. Accessed 09/14/2016.

34. Zhu, S.H., et al., *Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation.* Tobacco control, 2014. **23 Suppl 3**: p. iii3-9.

35. Thompson, M.L., J.E. Myers, and D. Kriebel, *Prevalence odds ratio or prevalence ratio in the analysis of cross sectional data: what is to be done?* Occupational and environmental medicine, 1998. **55**(4): p. 272-277.

36. Patel, D., et al., *Reasons for current E-cigarette use among U.S. adults.* Preventive medicine, 2016.

37. King, B.A., et al., *Attitudes Toward Raising the Minimum Age of Sale for Tobacco Among U.S. Adults.* American Journal of Preventive Medicine, 2015. **49**(4): p. 583-588.

38. Kruger, J., et al., *National and State Attitudes of U.S. Adults Toward Tobacco-Free School Grounds, 2009-2010.* Preventing chronic disease, 2015. **12**: p. E229.

39. Wang, T.W., et al., *Attitudes Toward Prohibiting Tobacco Sales in Pharmacy Stores Among U.S. Adults.* Am J Prev Med, 2016.

40. Duke, J.C., et al., *Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign.* PloS one, 2015. **10**(12): p. e0144827.

41. Duke, J.C., et al., *Impact of a U.S. antismoking national media campaign on beliefs, cognitions and quit intentions.* Health education research, 2015. **30**(3): p. 466-483.

42. McAfee, T., et al., *Effect of the first federally funded U.S. antismoking national media campaign.* Lancet (London, England), 2013. **382**(9909): p. 2003-2011.

43. Neff, L.J., et al., *Evaluation of the National Tips From Former Smokers Campaign: the 2014 Longitudinal Cohort.* Preventing chronic disease, 2016. **13**: p. E42.

44. Child Trends Databank. (2014). Parental smoking. Available at: http://www.childtrends.org/?indicators=parental-smoking. Accessed 09/14/2016.;

45. Singh, T., et al., *Tobacco Use Among Middle and High School Students--United States, 2011-2015.* MMWR.Morbidity and mortality weekly report, 2016. **65**(14): p. 361-367.

46. U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.

47. O'Connor, R.J., et al., *What would menthol smokers do if menthol in cigarettes were banned? Behavioral intentions and simulated demand.* Addiction (Abingdon, England), 2012. **107**(7): p. 1330-1338.

48. Wackowski, O.A., M.T. Manderski, and C.D. Delnevo, *Young adults' behavioral intentions surrounding a potential menthol cigarette ban.* Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco, 2014. **16**(6): p. 876-880.

49. Tynan, M.A., et al., *State and Local Comprehensive Smoke-Free Laws for Worksites, Restaurants, and Bars - United States, 2015.* MMWR.Morbidity and mortality weekly report, 2016. **65**(24): p. 623-626.

50. Marynak, K., et al., *State laws prohibiting sales to minors and indoor use of electronic nicotine delivery systems--United States, November 2014.* MMWR.Morbidity and mortality weekly report, 2014. **63**(49): p. 1145-1150.

51. Tobacco Twenty-one. Critical Issues. Available at http://tobacco21.org/critical-issues, Accessed 09/16/2016.

52. Tobacco Control Legal Consortium. Regulating Flavored Tobacco Products. Available at http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regflavoredtobaccoprods-.pdf, Accessed 09/16/2016.

53. Holmes, C.B., B.A. King, and S.D. Babb, *Stuck in Neutral: Stalled Progress in Statewide Comprehensive Smoke-Free Laws and Cigarette Excise Taxes, United States, 2000-2014.* Preventing chronic disease, 2016. **13**: p. E80.

54. Agaku, I.T., et al., *Cigarette design and marketing features are associated with increased smoking susceptibility and perception of reduced harm among smokers in 27 EU countries.* Tobacco control, 2015. **24**(e4): p. e233-40.

55. Nagelhout GE, Zhuang YL, Gamst A, Zhu SH. Do smokers support smoke-free laws to help themselves quit smoking? Findings from a longitudinal study. Tob Control.2015 May;24(3):233-7. doi: 10.1136/tobaccocontrol-2013-051255.56. Yeager DS, Krosnick JA, Chang L, et al. Comparing the accuracy of RDD telephone surveys and internet surveys conducted with probability and non-probability samples. Public Opin Q. 2011;75(4):709–747. http://dx.doi.org/10.1093/poq/nfr020.

TABLES AND FIGURES

Table 6.1 Percentages with 95% confidence intervals (CI) for support for a tobacco flavor ban among U.S. adults aged ≥18 years, Summer Styles Survey, 2016

Characteristics	All U.S. adults			Current Any Tobacco Users		
	N	% (95% CI)	*P*-value (χ^2)	N	% (95% CI)	*P*-value (χ^2)
Overall	4203	47.3 (45.5-49.1)		731	34.8 (30.5-39.0)	
Sex						
Male	1997	45.6 (42.9-48.2)	0.074	415	33.0 (27.5-38.5)	0.327
Female	2206	48.9 (46.4-51.5)		316	37.3 (30.6-43.9)	
Age, years						
18-24	265	51.5 (44.9-58.1)		38	39.8 (22.4-57.2)	
25-34	538	44.9 (40.0-49.7)		140	31.7 (22.8-40.6)	
35-44	677	48.6 (44.1-53.2)		122	42.4 (31.7-53.1)	
45-54	911	45.4 (41.5-49.3)	0.496	166	28.7 (20.8-36.6)	0.432
55-64	855	47.4 (43.4-51.4)		169	32.9 (24.7-41.1)	
65-74	652	48.5 (44.0-53.1)		77	43.0 (29.0-57.0)	
75+	305	44.8 (38.3-51.3)		19	¶	
Annual income, $						
<20,000	571	46.1 (40.9-51.3)		178	45.3 (35.9-54.6)	
20,000 to 49,999	1156	47.3 (43.7-50.9)	0.739	232	27.5 (20.2-34.8)	0.024
50,000 to 99,999	1350	46.5 (43.3-49.7)		200	35.8 (28.0-43.7)	
≥100,000	1126	48.9 (45.4-52.4)		121	32.2 (22.8-41.5)	
Presence of child <18 years in household						
No	2805	46.5 (44.3-48.7)	0.164	473	32.0 (27.0-37.0)	0.058
Yes	1394	49.3 (46.0-52.6)		255	40.9 (33.0-48.8)	
Race/ethnicity						
White, non-Hispanic	3104	47.9 (45.8-49.9)		527	33.6 (28.7-38.5)	
Black, non-Hispanic	424	41.2 (35.5-46.9)		101	33.3 (22.2-44.4)	
Other, non-Hispanic	122	48.0 (38.2-57.8)	0.268	9	¶	0.513
Hispanic	469	49.4 (44.1-54.8)		73	43.6 (29.9-57.3)	
Multi-race, non-Hispanic	84	42.5 (30.1-54.8)		21	49.0 (24.9-73.1)	
U.S. Census region						
Northeast	777	46.8 (42.6-51.1)		120	44.8 (34.2-55.3)	
Midwest	1027	47.5 (43.8-51.2)	0.660	208	38.1 (29.5-46.6)	0.099
South	1501	46.2 (43.1-49.3)		286	30.4 (24.0-36.8)	
West	898	49.2 (45.3-53.2)		117	31.2 (21.3-41.2)	
Marital status						
Married/living with partner	2626	47.9 (45.7-50.2)		394	35.3 (29.8-40.9)	
Widowed/divorced/separated	771	44.3 (39.9-48.8)	0.420	183	35.3 (26.1-44.4)	0.927
Never married	806	47.6 (43.5-51.7)		154	33.4 (24.4-42.3)	
Perception e-cigarette advertisements could lead to smoking						
Agree	2472	53.4 (51.0-55.8)		341	41.3 (34.9-47.6)	
Undecided	1192	42.5 (39.1-45.9)	<0.001	270	32.7 (25.8-39.6)	0.009
Disagree	505	31.9 (26.9-36.8)		118	22.9 (13.8-31.9)	
Tobacco Use status						
Never any tobacco user[a]	1513	52.0 (48.9-55.0)		N/A		
Former any tobacco user[b]	1941	48.4 (45.7-51.0)	<0.001	N/A		
Current any tobacco user[c]	731	34.8 (30.5-39.0)		N/A		

Note: N/A=Not applicable. Chi squared statistics for age and annual household income were performed with a trend test; all others were performed with a standard chi squared test.

¶ Relative standard error ≥ 30%.

a Never used any of the following tobacco product types in their lifetime: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other products not specified

b Used ≥1 of the following tobacco product types at least once in their lifetime but not in the past 30 days: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other tobacco product not specified.

c Used ≥1 of the following tobacco product types in the past 30 days: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other tobacco product not specified.

Table 6.2 Adjusted Prevalence Ratios (aPR) with 95% confidence intervals (CI) for support for a tobacco flavor ban among U.S. adults aged ≥18 years, Summer Styles Survey, 2016

Characteristics	ALL RESPONDENTS (N=4203) aPR (95% CI)	CURRENT ANY TOBACCO USERS (N=731) aPR (95% CI)
Intercept	0.52 (0.42-0.64)	0.38 (0.22-0.65)
Sex		
Male	1.00 (referent)	1.00 (referent)
Female	1.06 (0.98-1.14)	1.15 (0.91-1.46)
Age, years (Per unit increase)	1.00 (0.99-1.00)	1.00 (0.99-1.01)
Annual income, $		
<20,000	1.00 (referent)	1.00 (referent)
20,000 to 49,999	0.99 (0.86-1.13)	0.60 (0.43-0.84)
50,000 to 99,999	0.95 (0.83-1.08)	0.77 (0.57-1.03)
≥100,000	0.98 (0.86-1.12)	0.73 (0.51-1.04)
Presence of child <18 years in household		
No	1.00 (referent)	1.00 (referent)
Yes	1.07 (0.98-1.17)	1.38 (1.05-1.82)
Race/ethnicity		
White, non-Hispanic	1.00 (referent)	1.00 (referent)
Black, non-Hispanic	0.87 (0.75-1.01)	0.97 (0.67-1.39)
Other, non-Hispanic	0.94 (0.76-1.16)	0.63 (0.13-2.96)
Hispanic	1.02 (0.91-1.15)	1.27 (0.91-1.76)
Multi-race, non-Hispanic	0.88 (0.65-1.19)	1.53 (0.93-2.53)
U.S. Census region		
Northeast	1.00 (referent)	1.00 (referent)
Midwest	1.04 (0.92-1.17)	0.86 (0.63-1.18)
South	1.01 (0.90-1.13)	0.65 (0.48-0.90)
West	1.03 (0.92-1.17)	0.64 (0.43-0.95)
Marital status		
Married/living with partner	1.00 (referent)	1.00 (referent)
Widowed/divorced/separated	0.95 (0.84-1.06)	0.91 (0.66-1.25)
Never married	0.98 (0.88-1.09)	0.86 (0.62-1.18)
Perception e-cigarette ads could lead to smoking		
Agree	1.00 (referent)	1.00 (referent)
Undecided	0.82 (0.74-0.89)	0.78 (0.61-1.01)
Disagree	0.60 (0.51-0.71)	0.55 (0.36-0.83)
Tobacco Use status		
Never any tobacco user[a]	1.00 (referent)	N/A
Former any tobacco user[b]	0.94 (0.86-1.02)	N/A
Current any tobacco user[c]	0.67 (0.59-0.77)	N/A

Note: N/A=Not applicable; aPR= adjusted prevalence ratio

a Never used any of the following tobacco product types, not even once in their lifetime: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other tobacco product not specified.

b Used ≥1 of the following tobacco product types at least once in their lifetime but not in the past 30 days: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other tobacco product not specified.

c Used ≥1 of the following tobacco product types in the past 30 days: cigarettes, cigars, electronic nicotine delivery systems, loose tobacco, water pipes, and other tobacco product not specified.

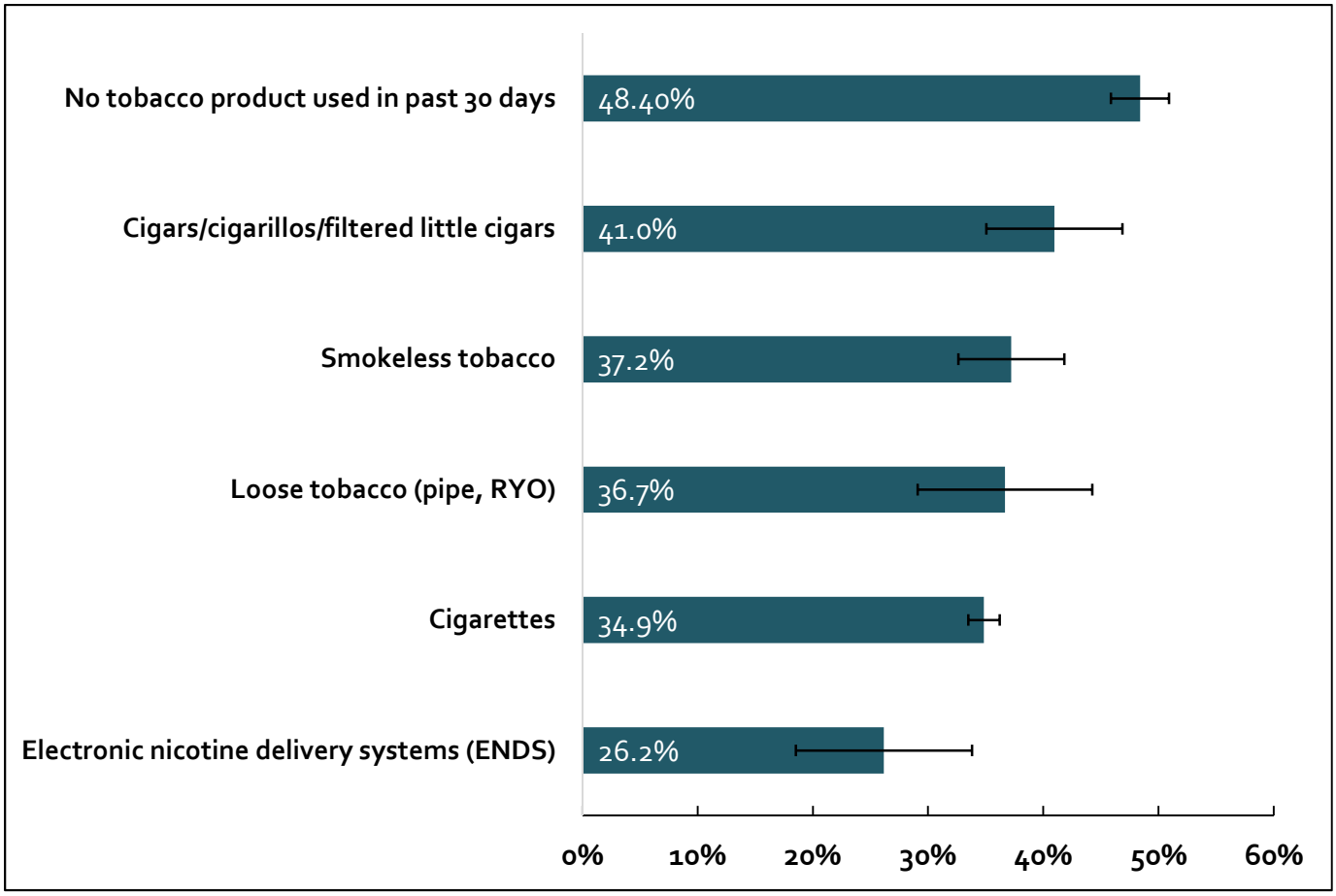

Figure 6.1 Support for a tobacco flavor ban among U.S. adults aged ≥18 years, by type of tobacco product used in the past 30 days, Summer Styles, 2016. Bars represent standard errors.

Note: Groups of tobacco users are not mutually exclusive but represent current use regardless of specified product regardless of other products used. Group of "No tobacco product used in past 30 days" includes both never and former any tobacco users.

Chapter 7 CONCLUSION

MOTIVATION

The motivation for this study included the need for a valid definition of self-reported menthol cigarette smoking; FDA's issuance of an Advanced Notice of Proposed Rulemaking seeking additional research to inform menthol regulation; the introduction of several new menthol cigarette brands by leading cigarette manufacturers with unknown implications for youth usage patterns; and the emergence of novel flavored tobacco products targeted at menthol cigarette smokers [1, 2]. Furthermore, with increasing efforts at state and local levels to reduce access and use of flavored tobacco products among youth [3], it was imperative to provide state-specific data on population-level patterns of use as well as market-level influences such as tobacco price, to help inform public health policy and programs at state and local levels. Finally, in view of FDA's newly extended authority over all tobacco products under the deeming rule, coupled with increased advocacy efforts for menthol regulation by groups in the public health community, there was need to examine public support for a complete tobacco flavor ban in the U.S. [4, 5, 6]. The sections below summarize the key findings and their implications for public health practice.

MAIN FINDINGS

Aim 1 showed that the brand-type concordance definition had high internal validity in measuring menthol cigarette smoking. Conversely, self-classified menthol cigarette smoking status without brand adjustment yielded invalid prevalence estimates of menthol cigarette smoking.

Aim 2 found significant declines in prevalence of menthol and nonmenthol cigarette smoking among all U.S. middle and high school students during 2011-2015. Among current cigarette smokers however, there was no change in use of menthol cigarettes during 2011-2015. Disparities in menthol cigarette smoking were noted across groups defined by race/ethnicity, sex, geographic region, and age.

Aim 3 demonstrated a significant association between menthol cigarette smoking and current use of e-cigarettes among U.S. middle and high school students. Of youth who initiated tobacco use with cigarettes, menthol cigarette smokers had significantly higher odds than nonmenthol cigarette smokers of reporting current use of e-cigarettes and any flavored non-cigarette tobacco product.

Aim 4 performed a qualitative evaluation of tobacco flavor names for tobacco products sold in the continental USA during October 2011-January 2016. Findings revealed tobacco industry targeting of adolescents with flavor names highlighting sex appeal, youthfulness, or healthfulness. Price inequalities existed across and within tobacco products by flavor variety. For example, national average prices for mentholated tobacco products in 2015 were $5.52, $1.89, $1.49, and $0.82 for an

equivalent quantity of cigarettes, little cigars, moist snuff, and roll-your-own cigarettes respectively. Furthermore, mentholated varieties were generally cheaper than other flavors or nonflavored varieties for RYO cigarettes, little cigars, and moist snuff.

Aim 5 found that 1 in 2 U.S. adults supported a complete tobacco flavor ban. Support was higher among never any tobacco users than current any tobacco users. However, even among current any tobacco users, likelihood of support was higher among those who were concerned about adolescent cigarette smoking initiation and those with children aged <18 years living in their household.

IMPLICATIONS

The implications of this study touch on several key areas of tobacco control and prevention, including surveillance and regulatory policy at federal, state, and local levels.

Aim 1 proposes that researchers measuring menthol cigarette smoking use a brand-adjusted definition such as the brand-type concordance definition, to reduce magnitude of bias in reported prevalence, especially among population subgroups with high likelihood of misclassification e.g., blacks, females, and youth who do not purchase their cigarettes. Having a valid definition of menthol cigarette smoking is important because it ensures accurate surveillance of trends in menthol cigarette smoking and reduces confusion in communicating or comparing findings across studies.

Aim 2's finding of a plateauing of menthol use among current cigarette smokers during 2011-2015, coupled with the persistence of disparities among subgroups underscores the need for population-level efforts to reduce overall prevalence as well as inequalities in menthol cigarette smoking through evidence-based interventions. Such interventions include offering barrier-free clinical cessation interventions, imposing restrictions on marketing and sale, and implementing mass-media campaigns that warn about the dangers of tobacco use. In 2014, FDA developed a youth education campaign ("Real Cost") focused on preventing and reducing youth tobacco use, including menthol cigarettes [7, 8]. The continued implementation of proven strategies at national, state, and local levels can help raise awareness among youth about the health risks of tobacco use and reduce smoking prevalence [9].

Aim 3 raises concerns about the potential for perpetuation of tobacco use among menthol cigarette smokers. The overall higher prevalence of e-cigarette use among menthol cigarette smokers, coupled with their distinct reasons for e-cigarette use (e.g., situational use in areas where smoking is prohibited, or because of attractive flavors), raises concerns about dual use. Such dual use behavior might put menthol cigarette smokers at higher risk of nicotine addiction and tobacco-related disease. Educational campaigns are needed to educate youth smokers on proven smoking cessation aids, while increasing barrier-free access to smoking cessation counseling in clinical settings. All health care providers, including

physicians, nurses, dentists, should ask youth if they use tobacco products and advice those who do to quit.

Aim 4 revealed gaps in enforcement and compliance with existing provisions under the Family Smoking Prevention and Tobacco Control Act (FSPTCA) [10]. Several menthol cigarette flavor names conveyed misleading perceptions of reduced harm, e.g., “low smoke menthol”, “natural menthol”, or “cleaner smoke menthol”. This might explain an earlier finding of higher likelihood of menthol use among cigarette smokers with a health condition (Chapter 3). These subterfuge marketing activities undermine the spirit of several policies aimed at protecting youth, including FDA’s 2009 ban on descriptors with misleading health claims, as well the 1998 Master Settlement Agreement, which forbade tobacco companies from taking any action, directly or indirectly, to target youth with tobacco products [10, 11]. FDA should impose stronger restrictions on such deceptive marketing strategies and at the same time ensure stronger enforcement of existing regulations.

Striking price inequalities were also noted within and across tobacco products which could encourage use of cheaper products as a tax avoidance strategy among youth who are generally price sensitive. Efforts are needed at state and local levels to raise tobacco prices and close existing price inequalities by implementing and enforcing minimum price laws, restricting tobacco price discounts increasing tobacco retail licensing fees, and implementing disclosure laws for payments or discounts to retailers.

Aim 5's results are important to public health practice because they demonstrate that framing of proposed flavor prohibitions around protection of children may garner more support within large segments of the population, even tobacco users. A tobacco flavor ban could potentially benefit public health by reducing the population attributable fraction of youth tobacco initiation and nicotine addiction that is due to attractive flavors.

Overall, the contribution of this study is significant as it provides national and state-level prevalence estimates highlighting continued disparities in menthol cigarette smoking, as well as the effects of menthol cigarettes on use of emerging tobacco products among U.S. adolescents. The study also revealed targeted marketing of tobacco products using flavor names and price inequalities in a manner that increases tobacco appeal, affordability and use among youth. Taken together with the fact that 1 of 2 U.S. adults support a tobacco flavor ban, this study provides critical information to FDA as well as to state and local governments for tobacco prevention and control efforts related to flavored tobacco products.

FUTURE DIRECTIONS

For surveillance:

With ongoing plans to transition the National Youth Tobacco Survey from a traditional paper and pencil survey into an electronic survey [12], strategic opportunities exist to improve menthol cigarette surveillance among U.S. middle and high school students. Illustrated questions that incorporate pictures of cigarette

brands with accompanying text questions could be piloted and evaluated in the electronic survey. Use of such illustrated questions that include both pictorial and text elements could potentially reduce the likelihood of misclassification associated with text-only questions.

Surveillance of menthol cigarette smoking among U.S. adolescents could be included as part of the U.S. Department of Health and Human Services *Healthy People* objectives in the future [13]. Establishing menthol cigarette smoking as a core aspect of national surveillance within the *Healthy People* framework is an important step in driving additional prevention efforts, focusing research activities, and reinforcing the need for direct communication about the risks of menthol cigarette smoking, all of which ultimately may help reduce the prevalence of menthol cigarette smoking among adolescents.

Enhanced and sustained efforts by states to include menthol cigarette smoking in youth surveillance systems could help guide planning, program, and policy. Currently about half of states do not have a surveillance system on menthol cigarette smoking among adolescents.

For Research:

Several research gaps still exist with regards menthol cigarette smoking and product regulation [1]. Studies are needed that measure levels of menthol in cigarette brands and sub-brands; compare exposure to smoke-related toxins and carcinogens from menthol and nonmenthol cigarettes; and examine the effects of

menthol and nonmenthol compounds in various tobacco products on both tobacco addiction and toxicants of tobacco smoke [1]. Furthermore, research studies are needed to investigate whether genetic differences in taste perceptions account for the predilection of certain racial and ethnic populations (e.g., blacks) towards menthol cigarettes [1]. As emerging tobacco products, such as e-cigarettes continue to proliferate on the U.S. market, it will be increasingly important to monitor how tobacco companies advertise and promote flavored tobacco products, to ensure disparities in tobacco use are not widened even further.

For Global Tobacco Control:

There is need for global surveillance systems to monitor menthol cigarette smoking among youth in low and middle countries to curb the global tobacco epidemic. Currently, there are no questions measuring menthol cigarette smoking in the core questionnaires of the Global Youth Tobacco Survey, a school-based survey conducted by CDC in collaboration with WHO and other stakeholders [14]. GYTS collects data on students aged 13–15 years using a standardized methodology in about 200 countries. Global menthol surveillance is particularly timely now, given the increased targeting of developing countries by multinational tobacco companies as cigarette smoking continues to decline in developed countries.

ORIGINALITY AND PUBLIC HEALTH RELEVANCE OF STUDY

The scope of this study covers not only menthol cigarettes, but also other types of flavored tobacco products popular among youth. The findings from this study are important for improving menthol surveillance within the US. The study findings also provide evidence that could be potentially useful for tobacco regulation by FDA and states. This study used a multi-disciplinary approach and employed different data sources, including several population-level and market-level data. This study is novel for the following reasons:

(1) This is the first study to undertake a comprehensive evaluation of construct validity of different operational case definitions for self-reported menthol cigarette smoking, and to propose a definition with optimal validity for future surveillance activities.

(2) This is the first study to examine long-term *temporal* trends in self-reported menthol cigarette smoking among U.S. students in grades 6-12. It was impossible for earlier studies to perform a valid trend analyses because of several changes in the NYTS questions used to measure menthol use prior to 2011. This is also the first study to measure *geographic* variations in state-specific prevalence in youth menthol cigarette smoking in 22 states with available data.

(3) This is the first study to investigate the relationship between menthol cigarette smoking and use of novel tobacco products such as e-cigarettes.

(4) This is the first study to perform a qualitative evaluation of tobacco industry use of flavor names as a potential marketing strategy, and to analyze price inequalities across and within different tobacco products by flavor variety, nationally and by state.

(5) This is the first study to measure public support for a complete tobacco flavor ban in the US.

STATEMENT OF CONTRIBUTION

Dr. Israel Agaku conceptualized the study in all its parts, acquired, analyzed, interpreted the data, and wrote the entire dissertation. This report is original in its entirety, and no part of it is has been previously published elsewhere. The findings and conclusions in this report are those of Dr. Agaku and do not necessarily represent the official position of the University of Georgia, or the Centers for Disease Control and Prevention.

REFERENCES

1. U.S. Food and Drug Administration. FDA invites public input on menthol in cigarettes. Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm361966.htm. Accessed 09/14/2016.
2. Euromonitor. (2015). Cigarettes in the US. Statistics retrieved March 23, from Euromonitor Passport Database.
3. Tobacco Control Legal Consortium (TCLC). *Regulating flavored tobacco products [fact sheet]*. 2014. Available from: http://publichealthlawcenter.org/sites/default/files/resources/tclc-guide-regflavoredtobaccoprods-2014.pdf. Accessed 09/30/2016.
4. Federal Register. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act;Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. Available at https://www.federalregister.gov/documents/2016/05/10/2016-10685/deeming-tobacco-products-to-be-subject-to-the-federal-food-drug-and-cosmetic-act-as-amended-by-the. Accessed 09/14/2016.

5. The African American Tobacco Control Leadership Council. Letter to President Obama Available at http://www.savingblacklives.org/letter-to-president-obama/. Accessed 11/28/2016

6. Truth Initiative. NAACP delegates endorse push to say no to menthols. Available at http://truthinitiative.org/news/naacp-delegates-endorse-push-say-no-menthols. Accessed 09/28/2016.

7. U.S Department of Health and Human Services. Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2012

8. Duke, J.C., et al., *Youth's Awareness of and Reactions to The Real Cost National Tobacco Public Education Campaign*. PLoS One, 2015. **10**(12): p. e0144827.

9. FDA. Real Cost Commercial: "Your Teeth" - Menthol Version. Available at https://www.youtube.com/watch?v=15Q5qGgfz_Q. Accessed 09/29/2016

10. United States Public Laws. Public Law 111-31 [H.R. 1256] Jun. 22, 2009 Family Smoking Prevention And Tobacco Control Act. 111 P.L. 31;123 Stat. 1776;2009 Enacted H.R. 1256;111 Enacted H.R. 1256. Available at https://www.congress.gov/bill/111th-congress/house-bill/1256.

11. Master Settlement Agreement. Available at http://publichealthlawcenter.org/sites/default/files/resources/master-settlement-agreement.pdf. Accessed 09/15/2016.

12. Federal Register. Proposed Data Collection Submitted for Public Comment and Recommendations. Available at https://www.federalregister.gov/documents/2016/08/10/2016-18937/proposed-data-collection-submitted-for-public-comment-and-recommendations. Accessed 09/30/2016.

13. U.S. DHHS. Office of Disease Prevention and Health Promotion. About Healthy People. Available at https://www.healthypeople.gov/2020/About-Healthy-People. Accessed 11/28/2016.

14. CDC. Global Tobacco Surveillance System. Available at http://www.cdc.gov/tobacco/global/gtss/. Accessed 11/28/2016