

TCORS 2.0 CAsToR Summer 2023 Symposium

Contributions of computational modeling to tobacco regulation decision making – present and future

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- I have no conflicts of interest.

Why modeling?

SPECIAL ARTICLE

Randomized Trial of Reduced-Nicotine Standards for Cigarettes

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ABSTRACT

BACKGROUND

The Food and Drug Administration can set standards that reduce the nicotine content of cigarettes.

METHODS

We conducted a double-blind, parallel, randomized clinical trial between June 2013 and July 2014 at 10 sites. Eligibility criteria included an age of 18 years or older

From the Departments of Psychology (E.C.D., R.L.D., S.S.D., T.L.) and Medicine (H.T.), University of Pittsburgh, Pittsburgh; the Center for Alcohol and Addiction Studies, Brown University, Providence, RI (J.W.T.); the Division of Biostatistics, School of Public Health (I.S.K., C.T.L.); the Departments

Effect of Immediate vs Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure: A Randomized Clinical Trial

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IMPORTANCE The optimal temporal approach for reducing nicotine to minimally or nonaddictive levels in all cigarettes sold in the United States has not been determined.

OBJECTIVES To determine the effects of immediate vs gradual reduction in nicotine content to very low levels and as compared with usual nicotine level cigarettes on biomarkers of toxicant exposure.

DESIGN, SETTING, AND PARTICIPANTS A double-blind, randomized, parallel-design study with 2 weeks of baseline smoking and 20 weeks of intervention was conducted at 10 US sites. A volunteer sample of daily smokers with no intention to quit within 30 days was recruited between July 2014 and September 2016, with the last follow-up completed in March 2017.

INTERVENTIONS (1) Immediate reduction to 0.4 mg of nicotine per gram of tobacco cigarettes; (2) gradual reduction from 15.5 mg to 0.4 mg of nicotine per gram of tobacco cigarettes with 5 monthly dose changes; or (3) maintenance on 15.5 mg of nicotine per gram

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Changes in Cigarette Consumption With Reduced Nicotine Content Cigarettes Among Smokers With Psychiatric Conditions or Socioeconomic Disadvantage: 3 Randomized Clinical Trials

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Abstract

IMPORTANCE This study is part of a programmatic effort evaluating the effects of reducing nicotine content of cigarettes to minimally addictive levels.

OBJECTIVE To examine whether very low-nicotine-content (VLNC) cigarettes decrease smoking rates and dependence severity among smokers with psychiatric disorders or socioeconomic disadvantage.

DESIGN, SETTING, AND PARTICIPANTS These 3 randomized clinical trials were performed at the University of Vermont, Brown University, and Johns Hopkins University between October 2016 and September 2019. Participants received 12 weeks of exposure to study cigarettes with nicotine content ranging from levels representative of commercial cigarettes (15.8 mg nicotine/g tobacco) to less than a hypothesized addiction threshold (2 mg and 1.4 mg/g). Daily smokers from at-risk populations participated: individuals with affective disorders, exemplifying smokers with mental illness; individuals with opioid use disorder, exemplifying smokers with substance use disorders; and

Key Points

Question Does reducing the nicotine content of cigarettes decrease smoking rates and nicotine dependence severity among adults with psychiatric disorders or socioeconomic disadvantage?

Findings These 3 randomized clinical trials including 775 participants with affective disorders, opioid use disorder, or socioeconomic disadvantage found that reducing nicotine content significantly decreased total cigarettes smoked daily and nicotine dependence severity.



The Impact of Reducing Nicotine Content on Adolescent Cigarette Smoking and Nicotine Exposure: Results From a Randomized Controlled Trial

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Abstract

Introduction: As the science base around the potential benefits of a reduced-nicotine standard for cigarettes grows, information on the potential effects on adolescent smokers is a high priority. The aim of this randomized trial was to test the influence of 3-week exposure to reduced nicotine cigarettes in a sample of adolescent smokers.

Aims and Methods: In this double-blind, two-arm, randomized controlled trial (NCT02587311), following a 1-week baseline, adolescent daily smokers not currently intending to quit (ages 15–19 years, n = 66 randomized) were urn randomized to use either very low nicotine content

What modeling can do

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Original Investigation

The Public Health Gains Had Cigarette Companies Chosen to Sell Very Low Nicotine Cigarettes

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Abstract

Introduction: The U.S. Food and Drug Administration (FDA) has proposed lowering the nicotine content of cigarettes to a minimally addictive level to increase smoking cessation and reduce ini-

Smoking-attributable mortality averted if the tobacco industry had sold only very-low nicotine cigarettes (VLNC) in 1965, 1975, or 1985

(Levy et al., *NTR*, 2021)

Averted mortality compared to status quo (regular nicotine cigarettes) ^a						
Year of VLNC	avSADs ^b 1965-2064	LYG ^c 1965-2064	avSADs ^b 1975-2074	LYG ^c 1975-2074	avSADs ^b 1985-2084	LYG ^c 1985-2084
1965	21 million	272 million				
1975			18.9 million	245.4 million		
1985					16.3 million	211.5 million

^a midpoint estimates; ^b avSADs = averted smoking-attributable deaths; ^c LYG = life-years gained

SPECIAL REPORT

Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States

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Tobacco is addictive, primarily because of the presence of nicotine.¹ Although nicotine itself is not the direct cause of most smoking-related diseases, addiction to nicotine in tobacco is the proximate cause of these diseases because it sustains smoking behavior.^{2,3} Thus, the magnitude of public health harm that is caused by tobacco is inextricably linked to its addictive nature.

There is a continuum of risk for products that deliver nicotine, ranging from the most harmful combusted products (e.g., cigarettes) to medicinal nicotine products. As the most widely used tobacco products, cigarettes are the leading cause of preventable death and disease in the United

dence regarding “the risks and benefits to the population as a whole, including users and non-users of tobacco products,” along with “the increased or decreased likelihood that existing users of tobacco products will stop using such products” and “the increased or decreased likelihood that those who do not use tobacco products will start using such products.”¹³

Simulation models can be used to project the potential population-level effects of regulatory actions.¹⁴ The purpose of this analysis is to quantify the potential public health effects of enacting a regulation in the United States that makes cigarettes minimally addictive by setting

Table 2. Projected Cumulative Number of Smokers in the Baseline Scenario Who Would Not Initiate Smoking in the Policy Scenario.*

Year	Cumulative Reduction in Number of New Smokers		
	5th Percentile	Median	95th Percentile
	<i>millions of persons</i>		
2025	0.6	2.4	4.5
2030	1.1	4.3	8.2
2040	2.0	8.1	15.6
2050	2.9	12.0	23.2
2060	3.9	16.0	31.0
2070	4.9	20.2	39.0
2080	5.9	24.4	47.2
2090	7.0	28.7	55.6
2100	8.0	33.1	64.1

* The projected outcomes are based on the implementation of a nicotine-reduction policy in 2020. Estimates have been rounded to the nearest 100,000.

Table 3. Projected Cumulative Number of Tobacco-Related Deaths Averted and Life-Years Gained after the Implementation of a Nicotine-Reduction Policy in 2020.*

Year	Tobacco-Related Deaths Averted			Life-Years Gained		
	5th Percentile	Median	95th Percentile	5th Percentile	Median	95th Percentile
	<i>millions</i>					
2025	0	0.1	0.1	0.2	0.4	0.7
2030	0.1	0.3	0.5	0.8	1.6	2.7
2040	0.3	0.9	1.4	2.5	6.8	11.5
2050	0.5	1.7	2.8	4.8	17.0	28.9
2060	0.7	2.8	4.3	7.8	33.1	53.9
2070	0.9	4.2	6.2	11.6	54.4	84.7
2080	1.3	5.6	7.9	16.5	79.6	118.0
2090	1.7	7.1	9.6	23.3	106.7	150.8
2100	2.2	8.5	11.2	31.6	134.4	183.0

* Estimates have been rounded to the nearest 100,000.

Product standards banning menthol in cigarettes and all flavors in cigars

TABLE 2—Support Among Blacks for Banning Cigarettes With Menthol: United States, 2009

Demographic Variables	Percentage of Sample (Unweighted)	Support Ban on Menthol (Weighted), % (95% CI)	Support Ban on Menthol, AOR (95% CI)
Overall (n = 303)		75.8 (70.9, 80.7)	
Smoking status**			
Never smoker	64.4	83.4 (78.0, 88.8)	3.83 (1.74, 8.45)
Former smoker	17.8	71.4 (57.7, 85.1)	1.95 (0.74, 5.15)
Current smoker (Ref)	17.8	52.8 (39.4, 66.2)	1.00
Age, y			
18–24 (Ref)	12.5	87.5 (78.1, 96.9)	1.00
25–44	31.0	77.6 (70.0, 85.2)	0.58 (0.21, 1.60)
45–64	38.9	67.1 (56.9, 77.3)	0.39 (0.14, 1.11)
≥ 65	17.5	75.9 (60.3, 91.5)	0.54 (0.15, 1.97)
Education			
< High school ^a	12.2	62.5 (43.1, 81.9)	0.61 (0.19, 1.97)
High school diploma/GED	30.0	83.3 (75.3, 91.3)	1.65 (0.71, 3.81)
Some college	30.7	69.4 (59.6, 79.2)	0.66 (0.31, 1.42)
College (Ref)	27.1	78.3 (69.4, 87.2)	1.00
Gender			
Women	69.3	80.9 (74.7, 87.1)	1.74 (0.95, 3.20)
Men (Ref)	30.4	69.1 (60.9, 77.3)	1.00

Note. AOR = adjusted odds ratio; CI = confidence interval; GED = Graduate Educational Development Exam.
^an < 30.

**P < .001.

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Modeling the Future Effects of a Menthol Ban on Smoking Prevalence and Smoking-Attributable Deaths in the United States

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We used a validated smoking simulation model and data from the

Original research

An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018

Thuy TT Le , David Mendez

► Additional material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2020-056256>).

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ABSTRACT

Background Menthol cigarettes are thought to encourage smoking initiation among youths and young adults and make it more difficult for smokers to quit, thus increasing cigarette harm. However, no study to date has quantified the damage that menthol cigarettes have caused the US population.

Objective To estimate the excess smoking prevalence, smoking initiation, and mortality in the US from 1980 through 2018 that can be attributed to menthol cigarettes.

Methods Using a well-established simulation model of smoking prevalence and health effects and data from the National Health Interview Survey (NHIS), we first reproduced the overall US adult smoking prevalence between 1980 and 2018 (pseudo-R²=0.98) and associated mortality. Then we re-ran the model, assuming that menthol cigarettes were not present in the market over the same period. Finally, we compared both scenarios to quantify the public health harm attributable to menthol over the 1980–2018 period.

Results From 1980 to 2018, we found that menthol cigarettes were responsible for slowing down the decline in smoking prevalence by 2.6 percentage points (13.7% vs 11.1% in 2018). Our results also show that menthol cigarettes were responsible for 10.1 million extra smokers, 3 million life years lost and 378 000 premature deaths during that period.

menthol report⁶ was submitted to the FDA commissioner and indicated that the availability of menthol cigarettes in the market harmed public health by increasing the number of smokers, with resulting premature death and morbidity.⁷ In 2013 and again in 2018, the FDA sought public comment, research results and other information on the impact of menthol cigarettes on smoking initiation, prevalence and other factors to inform regulatory actions that the FDA might take for mentholated cigarettes. However, no specific actions for menthol cigarettes have yet been made.

The conclusions of the 2011 TPSAC menthol report were supported by a simulation analysis that compared a projected status quo scenario over the period from 2010 to 2050 with a scenario in which menthol cigarettes were not available over the same time period. To complement that study, we use the same model as in the TPSAC report to estimate the public health harm (measured as excess mortality, smoking initiation and prevalence) that menthol cigarettes have already caused over 1980–2018, a period similar in length to that in the TPSAC report. Our analysis puts in perspective the magnitude of the harm that menthol cigarettes have already caused in the USA and provides the FDA with additional information about the potential damage of these products.



OPEN ACCESS

Public health impact of a US ban on menthol in cigarettes and cigars: a simulation study

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ABSTRACT

Introduction The US Food and Drug Administration most recently announced its intention to ban menthol cigarettes and cigars nationwide in April 2021. Implementation of the ban will require evidence that it would improve public health. This paper simulates the potential public health impact of a ban on menthol in cigarettes and cigars through its impacts on smoking initiation, smoking cessation and switching to nicotine vaping products (NVPs).

Methods After calibrating an established US simulation model to reflect recent use trends in cigarette and NVP use, we extended the model to incorporate menthol and non-menthol cigarette use under a status quo scenario. Applying estimates from a recent expert elicitation on the behavioural impacts of a menthol ban, we developed a menthol ban scenario with the ban starting in 2021.

to implement a nationwide ban on menthol in cigarettes and cigars.¹⁴ A stronger evidence base is urgently needed about whether such a ban would improve public health.^{15 16}

A small body of research has examined the potential impact of banning menthol in cigarettes. A simulation model¹⁷ projected that a menthol ban would have major impacts on smoking prevalence and smoking-attributable deaths. However, that model simulated a ban starting in 2010 and did not consider the impact of switching to nicotine vaping products (NVPs, also known as e-cigarettes). Additionally, recent evidence finds that a menthol ban would likely increase smoking cessation, with more limited evidence of reducing smoking initiation and switching from smoking to other products.¹⁸ To better gauge the potential impact of a menthol ciga-

Brief report

Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980–2018

David Mendez, Thuy TT Le 

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/tobaccocontrol-2021-056748>).

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ABSTRACT

Background For many years, national surveys have shown a consistently disproportionately high prevalence of menthol smokers among African Americans compared with the general population. However, to our knowledge, no prior study has quantified the harm that menthol smoking has caused on that population. In this work, we estimate the public health harm that menthol cigarettes have caused to the African American community over the last four decades.

Methods Using National Health Interview Survey data, we employed a well-established simulation model to reproduce the observed smoking trajectory over 1980–2018 in the African American population. Then, we repeat the experiment, removing the effects of menthol on the smoking initiation and cessation rates over that period, obtaining a new hypothetical smoking trajectory. Finally, we compared both scenarios to calculate the public health harm attributable to menthol cigarettes over 1980–2018.

Results Our results show that menthol cigarettes were responsible for 1.5 million new smokers, 157 000 smoking-related premature deaths and 1.5 million life-years lost among African Americans over 1980–2018. While African Americans constitute 12% of the total US population, these figures represent, respectively, a staggering 15%, 41% and 50% of the total menthol-related harm.

avoided if menthol cigarettes were banned from the market; and while other studies^{3 5–9} have addressed the historical causes that have made menthol the preferred choice of cigarette products among African Americans, to our knowledge, no prior study has quantified the health harm that menthol smoking has already inflicted on that population.

Following a recent study¹⁰ that calculated the health damage caused by menthol smoking on the entire US population over 1980–2018, the current work estimates the share of such harm borne by the African American community, and its disproportion compared with the total menthol toll in the USA. Our results may be helpful to the Food and Drug Administration as they continue evaluating the benefit of a menthol ban.

METHODS

We used the same simulation model and calibration process as in the Le-Mendez article¹⁰ with parameters specific to the African American population. The model formulation, definition of model parameters and how some parameters were calculated were thoroughly described in Le-Mendez's work.¹⁰ The African American-specific parameters were taken from several data sources described below and summarised in online supplemental table A1.

Examples of future contributions of modeling

- Nicotine reduction
- Menthol ban in combustible products with and without reduced risk products with menthol
- Smoking disparities and the role of tobacco regulations



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Modeling cigarette smoking disparities between people with and without serious psychological distress in the US, 1997–2100

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ABSTRACT

Cigarette smoking rates are significantly higher among people with serious psychological distress (SPD) compared to the general population. US simulation models that project future smoking disparities by SPD status could inform policy interventions, but have not been developed.

We calibrated two compartmental models to the National Health Interview Survey 1997–2018 for populations with and without SPD, calculating smoking prevalence, mortality, and life-years lost by SPD status under different scenarios from 2023 to 2100.

Under the Status Quo, smoking prevalence among women with SPD falls from 27.0% in 2023 to 10.7% in 2100 (men: 30.1% to 12.2%). For women without SPD, it declines from 9.4% to 3.1% (men: 11.5% to 4.0%). The

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Patterns of Birth Cohort-Specific Smoking Histories by Sociodemographic Group in the U.S.

GUEST EDITOR

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