

TCORS 2.0 CAsToR 2023 Symposium

Modeling flavored tobacco use and the impact of flavor restrictions. Challenges and opportunities

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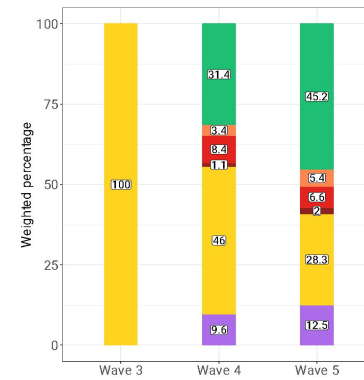
Center for the
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Flavored tobacco products

- Associated with higher rates of youth experimentation and use
- Higher use rates in some population subgroups; youth, women, Black Americans
- Menthol cigarettes associated with lower rates of cessation
- High rates of flavored e-cigarette use among youth
- Flavor restrictions and bans proposed at the federal, state and local level
 - What are the observed and expected impacts?



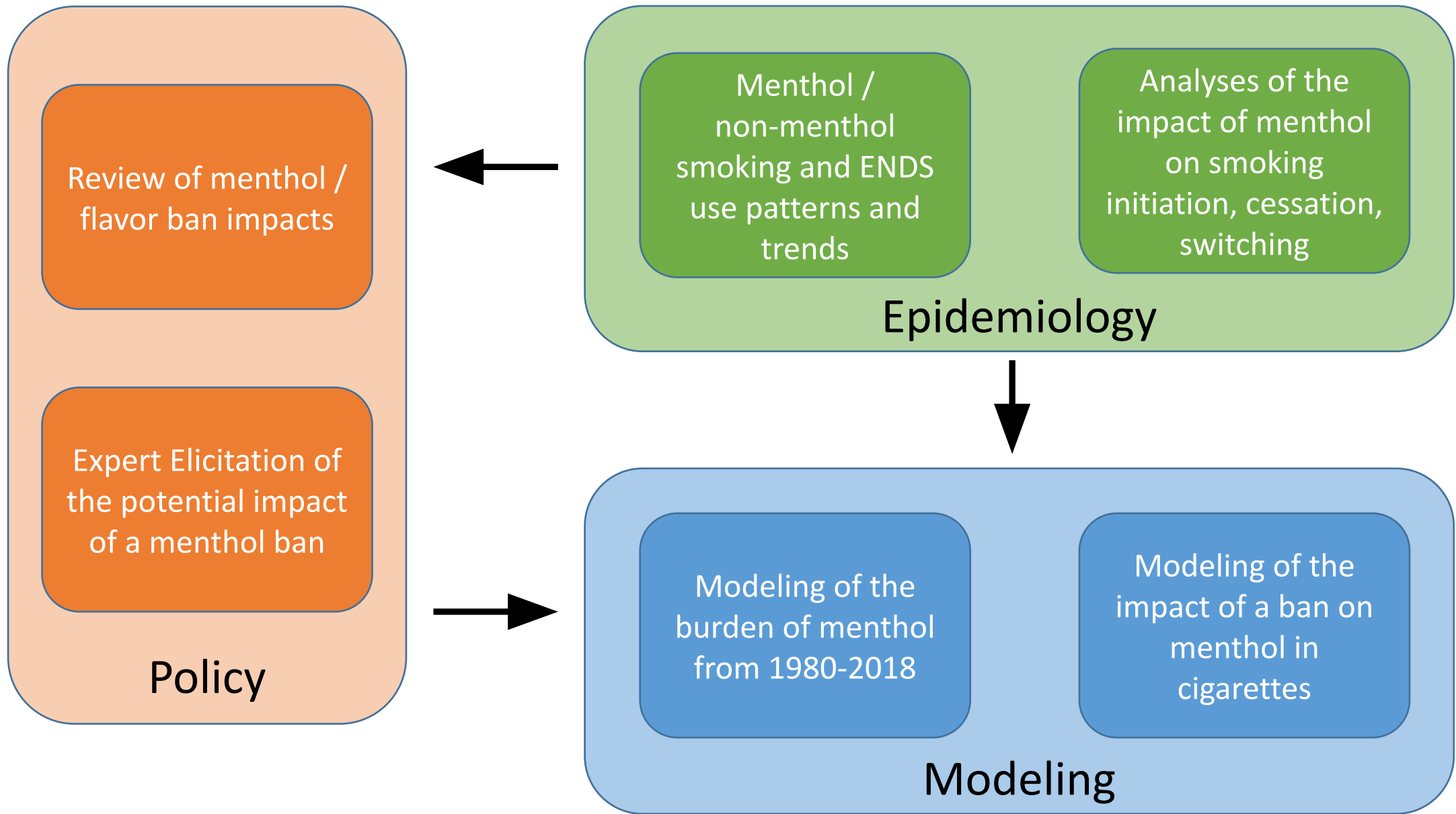
Modeling the impact of regulations

- Under the Tobacco Control Act, the FDA must show that any new rule to regulate the marketing and sale of tobacco products or to regulate the characteristics of the tobacco product is “**appropriate for the protection of the public health**” [Tobacco Control Act, Sec. 906(d)(1) & 907(a)(3)]
- The Act requires the FDA to determine risks and benefits to the population as a whole—including users and nonusers of tobacco products—and to consider the increased or decreased likelihood that existing tobacco product users will stop use, and that those who do not use tobacco products will start use
- Reliable, research-based projections and modeling of behavioral and public health impacts are needed for any FDA effort to determine whether a regulatory action is appropriate for the protection of public health

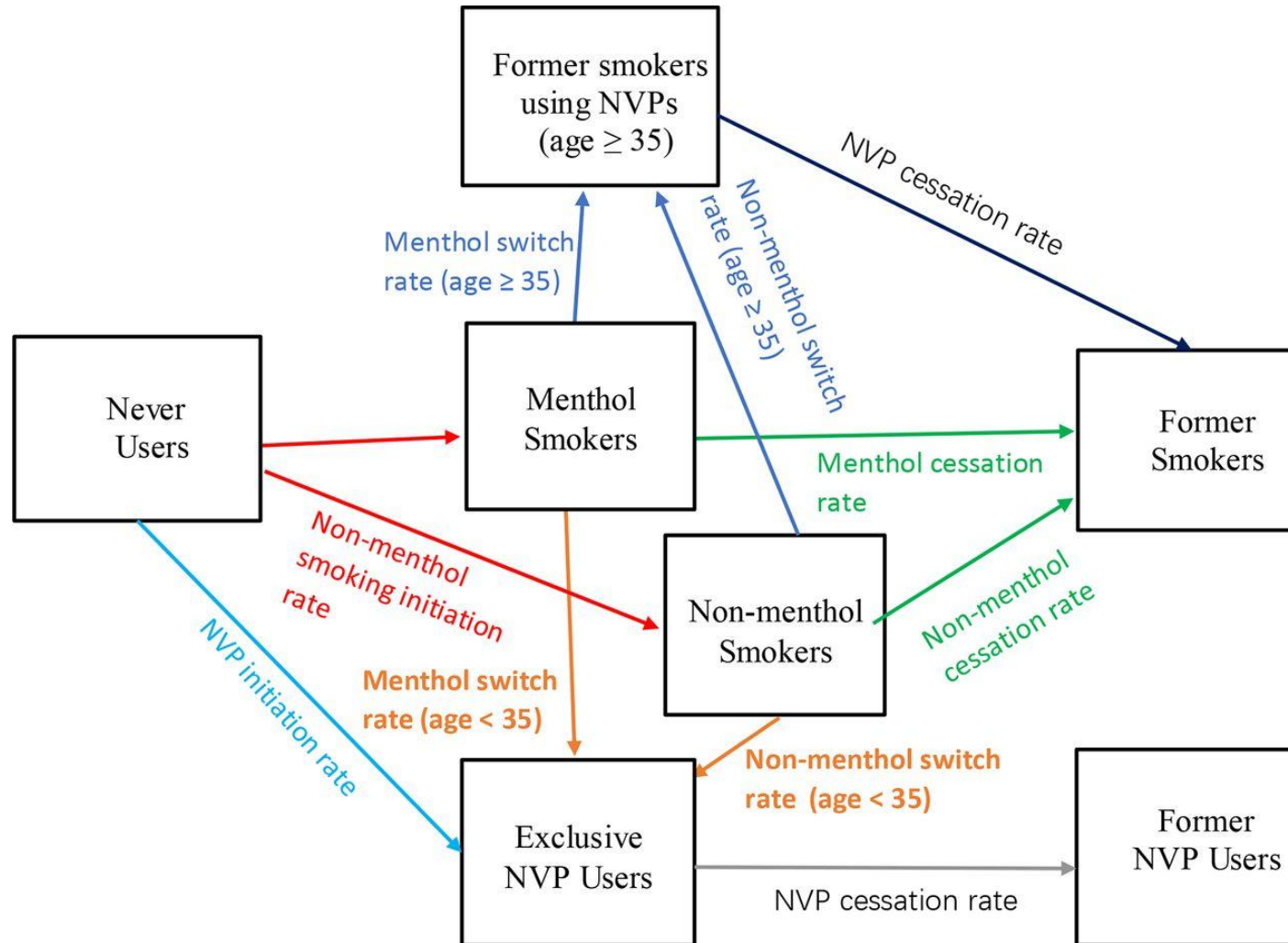
Assessing the impact of flavor restrictions

- Data/information requirements:
 - **Patterns of use of targeted product by flavor categories**
 - E.g. Prevalence of menthol and non-menthol cigarettes by year, sex, age
 - **Transitions to/from alternative products**
 - E.g. Switch rates between flavored and non-flavored products
 - E.g. Transition rates of menthol and non-menthol cigarette use to/from e-cigarette use
 - **Expected effects of flavor restrictions on use of flavored products and alternative products**
 - Transitions of current flavored product users to non-flavored product or alternative products if flavors are banned
 - Transitions of current flavored product users to alternative products (flavored or unflavored depending on the policy/regulation)
 - Potential access to black market or illegal products
 - Transitions to no tobacco use
 - **Health effects of tobacco product use and of flavors (on top of unflavored use)**
- **Simulation and other models are needed accounting for all of the above**

CAsToR Menthol Modeling



Transitions between Smoking and E-cigarette Use States in the Status Quo Scenario



Levy et al, 2021

Menthol in Cigarettes

Menthol is a flavor additive with a minty taste and aroma that is widely used in consumer and medicinal products due to its reported cooling or painkilling properties. Menthol's flavor and sensory effects make menthol cigarettes more appealing and easier to use particularly among new tobacco users, such as youth and young adults. It also interacts with nicotine in the brain to enhance nicotine's addictive effects and makes it more difficult for people to quit smoking.

There are more than **18.5 MILLION** people who currently smoke menthol cigarettes in the U.S.¹

Nearly **85%** of non-Hispanic Black smokers use menthol cigarettes, compared to **30%** of non-Hispanic White smokers.¹



About **49%** of smokers who identify as lesbian, gay, or bisexual (LGB) report smoking menthol cigarettes vs. about **40%** of smokers who do not identify as LGB.¹

Published modeling studies have estimated that if menthol cigarettes were no longer available in the U.S.²:



Up to 650,000 smoking and vaping attributable deaths avoided over 40 years

15%

A 15% reduction in smoking in 5 years

FDA issued proposed product standards in April 2022 to prohibit menthol as a characterizing flavor in cigarettes and prohibit characterizing flavors (other than tobacco) in all cigars. These actions have the potential to significantly reduce disease and death from combusted tobacco product use, the leading cause of preventable death in the U.S., by reducing youth experimentation and addiction, and increasing the number of smokers that quit. Learn more by visiting www.fda.gov/tobacco.

CENTER FOR TOBACCO PRODUCTS

¹National Survey on Drug Use and Health (NSDUH) 2019
Levy, D.T., R. Meza, Z. Yuan, et al. "Public Health Impact of a US Ban on Menthol in Cigarettes and Cigars: A Simulation Study." Tobacco Control, 2021.



Last Updated Sep 2022
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<https://www.fda.gov/media/162350/download>

Menthol ban project results

- Mendez & Le 2021, *“An estimation of the harm of menthol cigarettes in the United States from 1980 to 2018”*
- Le & Mendez 2021, *“Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018”*
- Levy, Meza et al. 2021, *“Modeling the Impact of a Ban on Menthol in Cigarettes”*
- Issabakhsh et al. 2022, *“Public health impact of a US menthol cigarette ban on the non-Hispanic black population: a simulation study”*
- Several more analyses published
 - Systematic review (Cadham et al. 2020)
 - Expert elicitation (Levy et al. 2021)
 - Trend & transition analyses (Brouwer et al. 2021; Patel et al. 2021)
 - Impact of menthol and ENDS use on smoking behaviors (Cook et al. 2021; Brouwer et al. 2021)

What about?

- Flavored e-cigarettes restrictions
- Flavored cigar ban
- Simultaneous restrictions of all flavored products
- Any other possible combination of restrictions
 - What are the policy/regulatory levels?
 - Products included, enforcement, local vs state vs federal

Flavored Tobacco Use Patterns

- Challenges

- Long term data is limited for most products other than cigarettes
- Few national surveys collect data on flavors
- Flavored product landscape is very dynamic
 - New flavors emerging every day
- Small sample sizes when looking at specific sub-groups
- Flavor x subproduct combinations
 - E.g., non-premium flavored cigars

- Opportunities

- Need more research/data on flavored tobacco use patterns
- Characterization of use histories between flavored/unflavored product
 - E.g. do individuals progress from use of flavored cigars to unflavored cigars?

Transitions across products

- Challenges

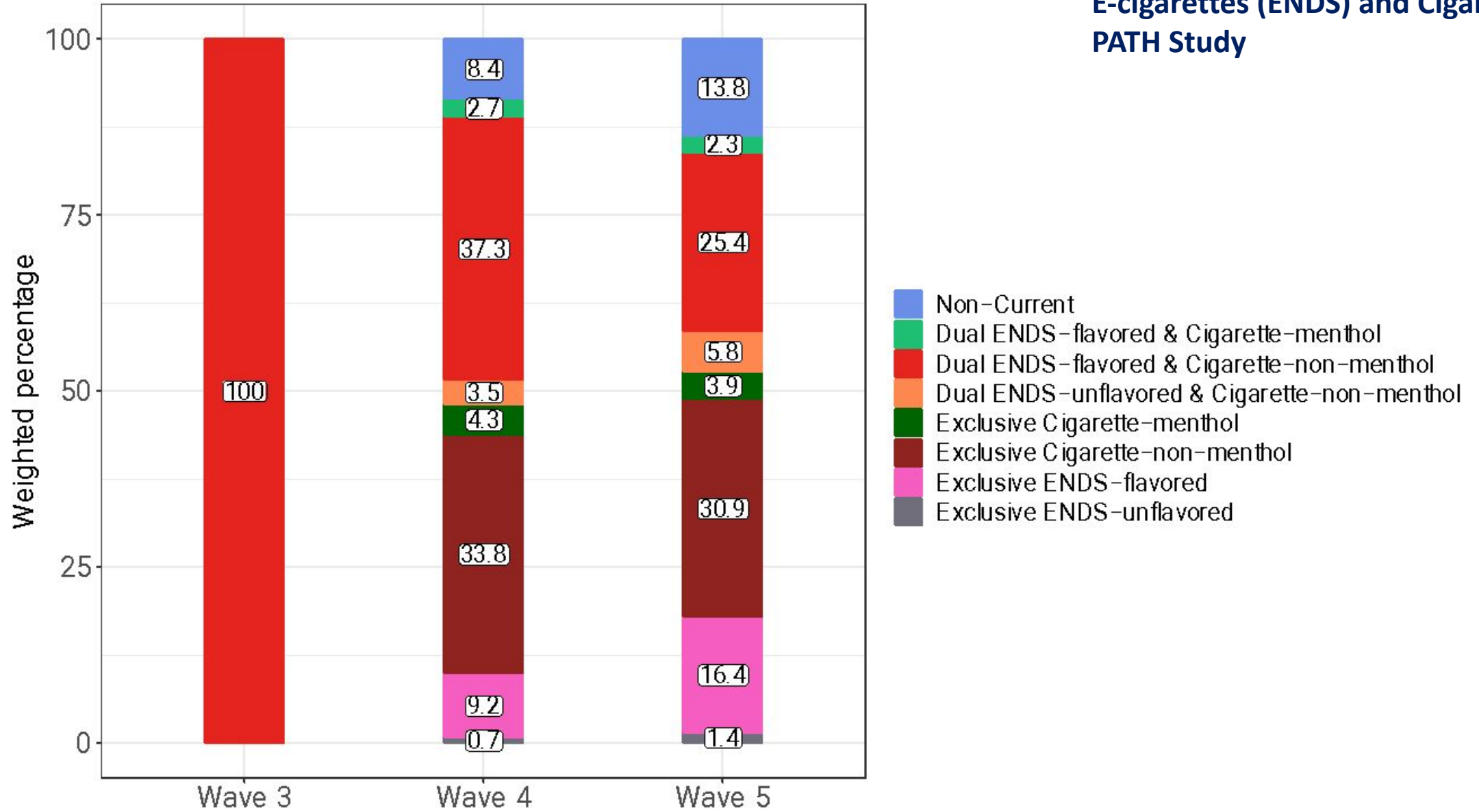
- Lack of data on transitions between alternative products by flavor
 - E.g. transitions between flavored e-cigarettes to/from menthol cigarettes
- Small sample sizes when looking at dual users
- Important variations by sociodemographic groups make it harder to obtain sufficient data to understand transitions

- Opportunities

- Characterization of longitudinal patterns of tobacco use
- Understanding transition patterns across products and alternative preferences critical to maximize public health impacts of flavor restrictions

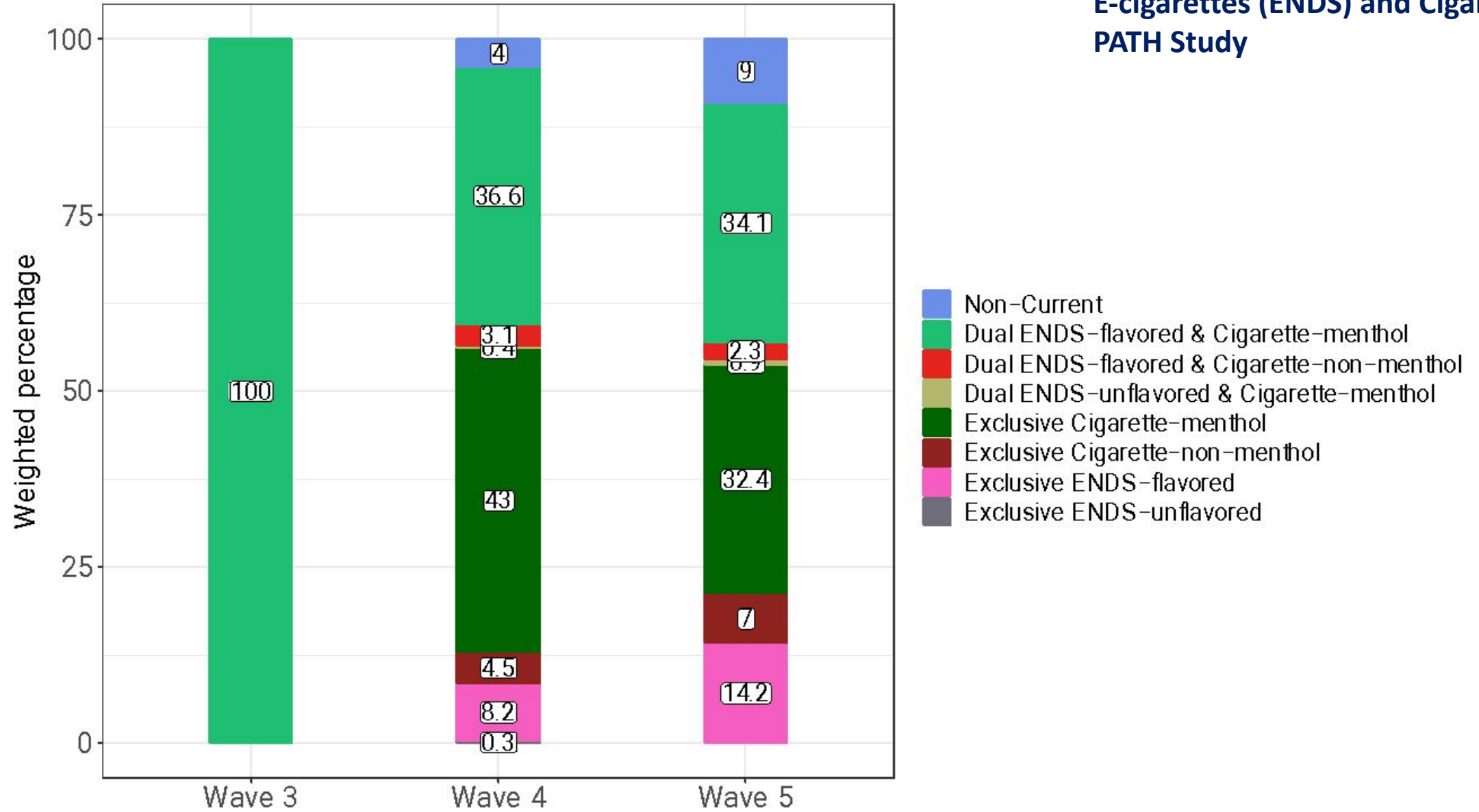
Dual ENDS-flavored & Cigarette-non-menthol users at Wave 3: ages 18+

E-cigarettes (ENDS) and Cigarettes
PATH Study



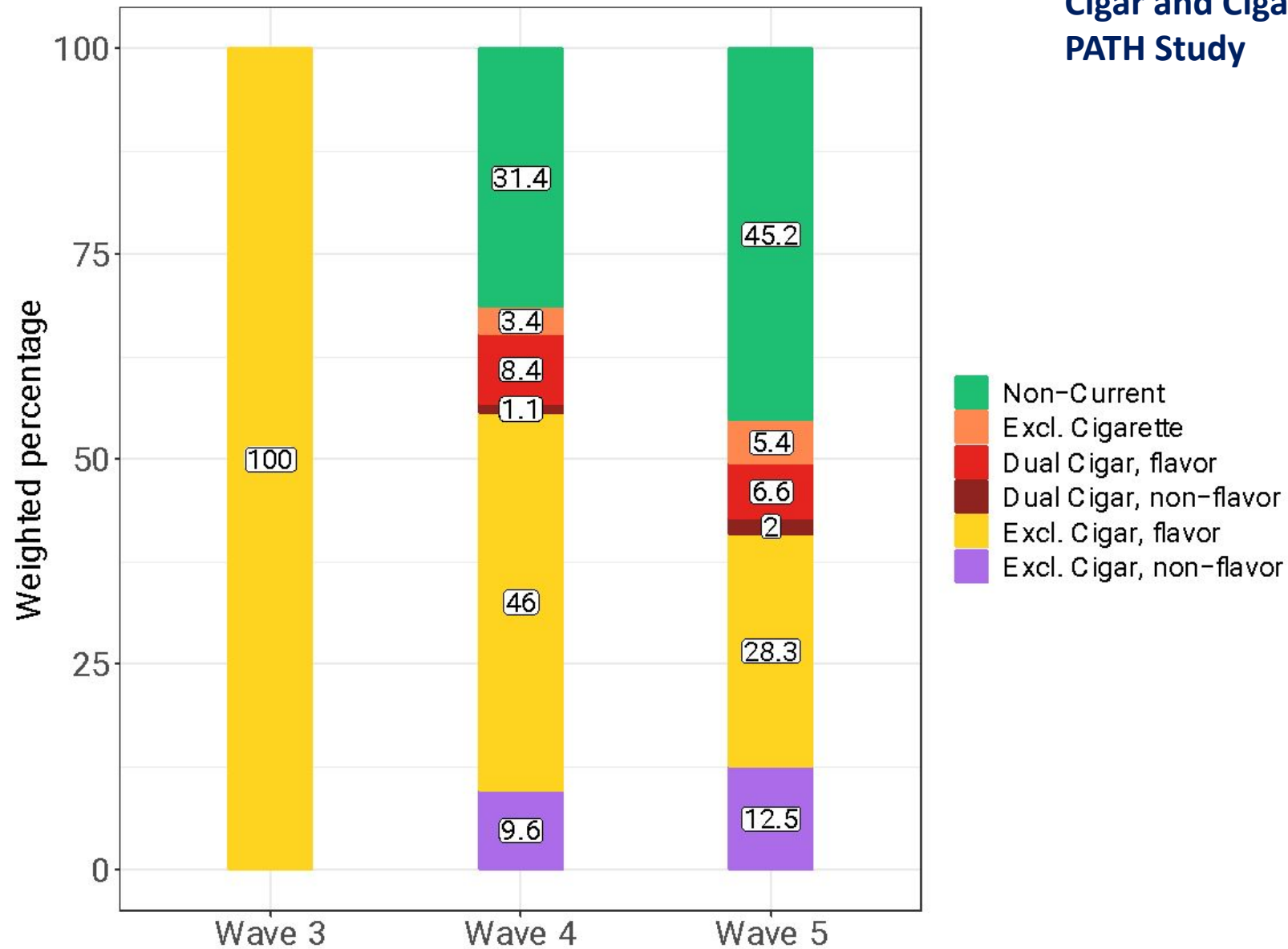
Dual ENDS-flavored & Cigarette-menthol users at Wave 3: ages 18+

E-cigarettes (ENDS) and Cigarettes
PATH Study



Exclusive Cigar, flavor users at Wave 3: ages 18+

Cigar and Cigarettes PATH Study



Flavor restriction effects

- Challenges
 - Limited empirical data on the impact of flavor restrictions
 - Policy information gradient: Cigarettes > ENDS > Cigars > Oral Nicotine and other
 - Differential impact by type of restriction and products included
 - Lack of data on differential impacts by sociodemographic group
 - Simultaneous effects of other policies and other events (e.g. Covid or EVALI)
- Data sources / Opportunities
 - Empirical studies
 - Epidemiologic and econometric analyses of use and sales data before/after restrictions become effective
 - Hypothetical studies
 - Experts - expert surveys and elicitation
 - Users
 - Surveys
 - Discrete choice experiments
 - Experimental tobacco marketplace

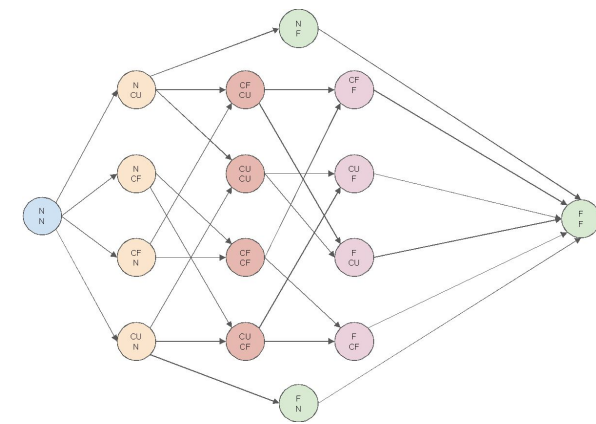
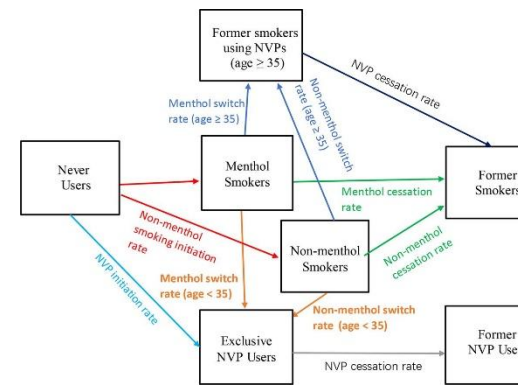
Computational Models

- Challenges

- Few existing models with more than two tobacco products, most have only one
- Adding more products, and breaking products by flavor greatly increases the complexity (number of model states/compartments) and the data needs
- Long history of cigarette smoking modeling and many models developed in recent years of e-cigarettes, but not much for other products
- Lack of cigar models

- Opportunities

- Bring new modeling/data analysis approaches
 - Agent-based models, microsimulation, machine learning
- Opportunity to recruit quantitative scientists into tobacco research



Flavor Restrictions Session

- Background / policy relevance – Villanti / Schneller ✓
- Modeling background ✓
- Policy effects – Yang
- Modeling the impact of flavors – Le
- Modeling the impact of flavor bans/restrictions – Levy, Hammond, Rostron, Jeon



Acknowledgements

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