

Intentions to Use Data and Prevalence Estimates for NJOY ACE® Demonstrate Low Likelihood of Use for Adult Never Smokers and Underage Individuals

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Center for Research and Technology
Tobacco Science Research Conference
September 8-11, 2024

INTRODUCTION

In assessing Premarket Tobacco Applications, FDA considers the risks of initiation by nonusers, including youth, against the benefit of switching among adults who smoke (AS). NJOY ACE PMTAs included evidence regarding AS who completely switched away from cigarettes. Here we share results from two recent studies. The first study evaluated intentions to try/use NJOY ACE 2.0 BLE (NJOY ACE 2.0) products among U.S. Adults (age 21+), including Never Smokers (NS), Former Smokers (FS), and Current Smokers (AS). The study also included a sample of U.S. Youth (13-17). All NJOY ACE 2.0 products have age-gated device access restriction (DAR) technology to further mitigate underage access. The second study estimated brand prevalence of NJOY ENDS among underage individuals in the U.S. (13-20) utilizing data from a nationwide population-based survey, the ALCS Underage Tobacco Use Survey (UTUS). These findings demonstrate a low likelihood of use for NS, FS and youth and simultaneously demonstrate greater likelihood of use for AS.

Behavioral Intentions Study Data

Methods

Study Objective:

Assess perceptions of and behavioral intentions to try or use NJOY ACE 2.0 products with age-gated access restrictions and within key subgroups of the Adult 21+ population (e.g., Current, Former, and Never Smokers) and among Youth (13-17).

Study Design and Sample:

We conducted a cross-sectional online survey among Adult and Youth participants recruited from a probabilistic research panel to assess behavioral intentions to use NJOY ACE products. The study included a total of 2,119 participants:

- The Adult sample consisted of 1,601 U.S. individuals aged 21 years or older (adults who currently smoke cigarettes [AS], adults who formerly smoked cigarettes [FS] and do not currently smoke cigarettes, and adults who never smoked a cigarette [NS]) and who provided consent to participate. Each Adult smoking status cohort was quota-filled to ensure inter-cohort comparison analyses.
- The Youth sample consisted of 518 US individuals aged 13 to 17 years whose parent had first given consent followed by youth assent, and who had heard of “e-cigarettes” or “vaping” prior to participating in the study. The youth cohort was not stratified for smoking status.

Study Measures:

Behavioral Intentions Study results focus on the NJOY ACE 2.0 Blueberry and Watermelon products, which include device access restrictions (DAR), NJOY ACE Rich Tobacco, and combustible cigarettes. Following exposure to the study stimuli (product package and brief description of the product), participants were asked to answer each of the following questions using a 4-point rating scale (*Definitely No*, *Probably No*, *Probably Yes*, *Definitely Yes*):

- Do you think that you will try [a cigarette/Product] soon?
- Do you think you will [smoke a cigarette/ use a [Product]] in the next year?

Responses of “Definitely yes” and “Probably yes” were aggregated in the analyses to infer positive use intentions for the findings discussed here. Analyses included within-cohort comparisons between behavioral intentions for each product. Analyses across cohorts were also conducted for the adult sample (AS, FS, and NS).

Study Stimuli:

NJOY ACE 2.0 Products with DAR	NJOY ACE Product	Comparator Product
<ul style="list-style-type: none">Blueberry 2.4% (BB2.4)Blueberry 5.0% (BB5)Watermelon 2.4% (WM2.4)Watermelon 5.0% (WM5)	<ul style="list-style-type: none">NJOY ACE Rich Tobacco 5.0% (RT5)	<ul style="list-style-type: none">Combustible Cigarette (CC)

Results

Adults 21+:

Across all products, 3.0% or fewer FS and NS indicated positive intentions to try/use NJOY ACE 2.0 products.

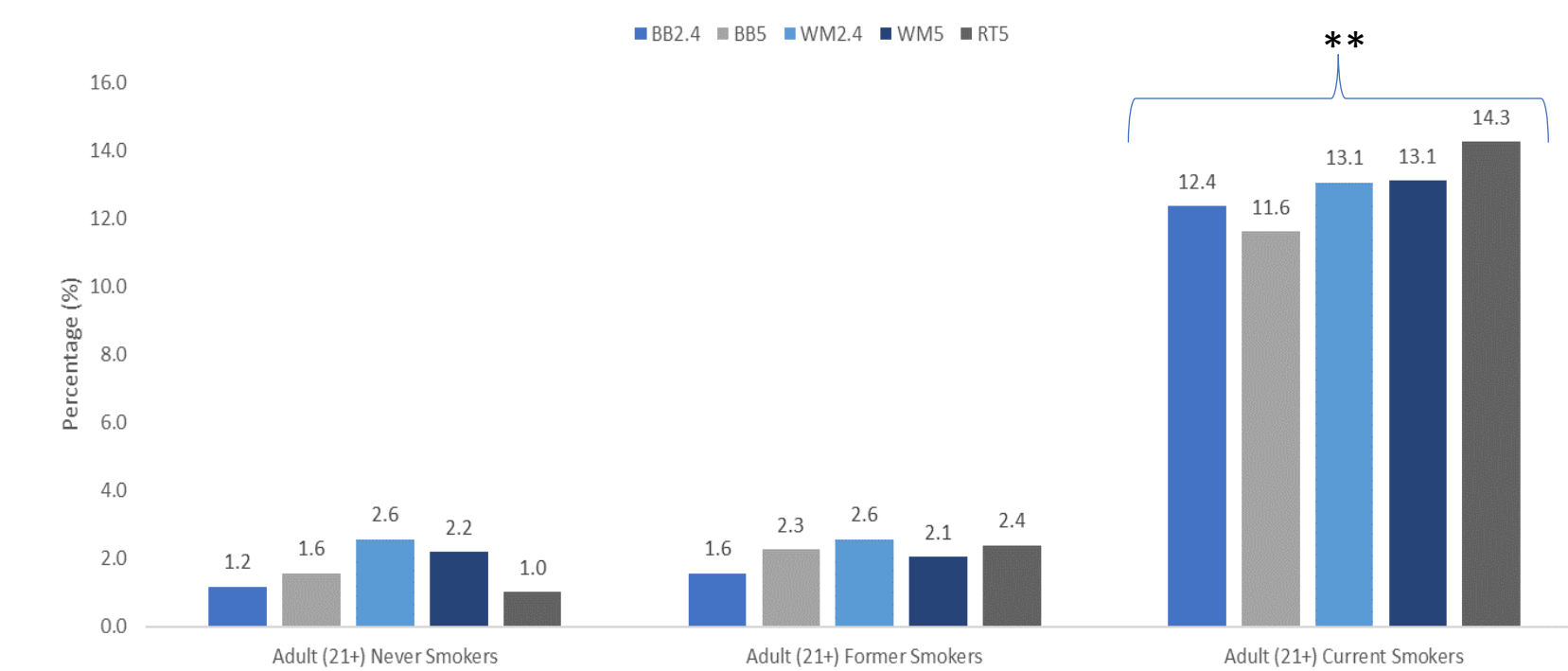
AS showed statistically significantly greater intent to Try Soon (11.85-12.59%), and intent to Try in the Next Year (11.64-13.13%) compared to FS (1.58-2.58% and 1.54-1.88% respectively) and NS (1.19-2.58% and 1.52-3.00% respectively) (all p-values <0.01).

Youth 13-17 :

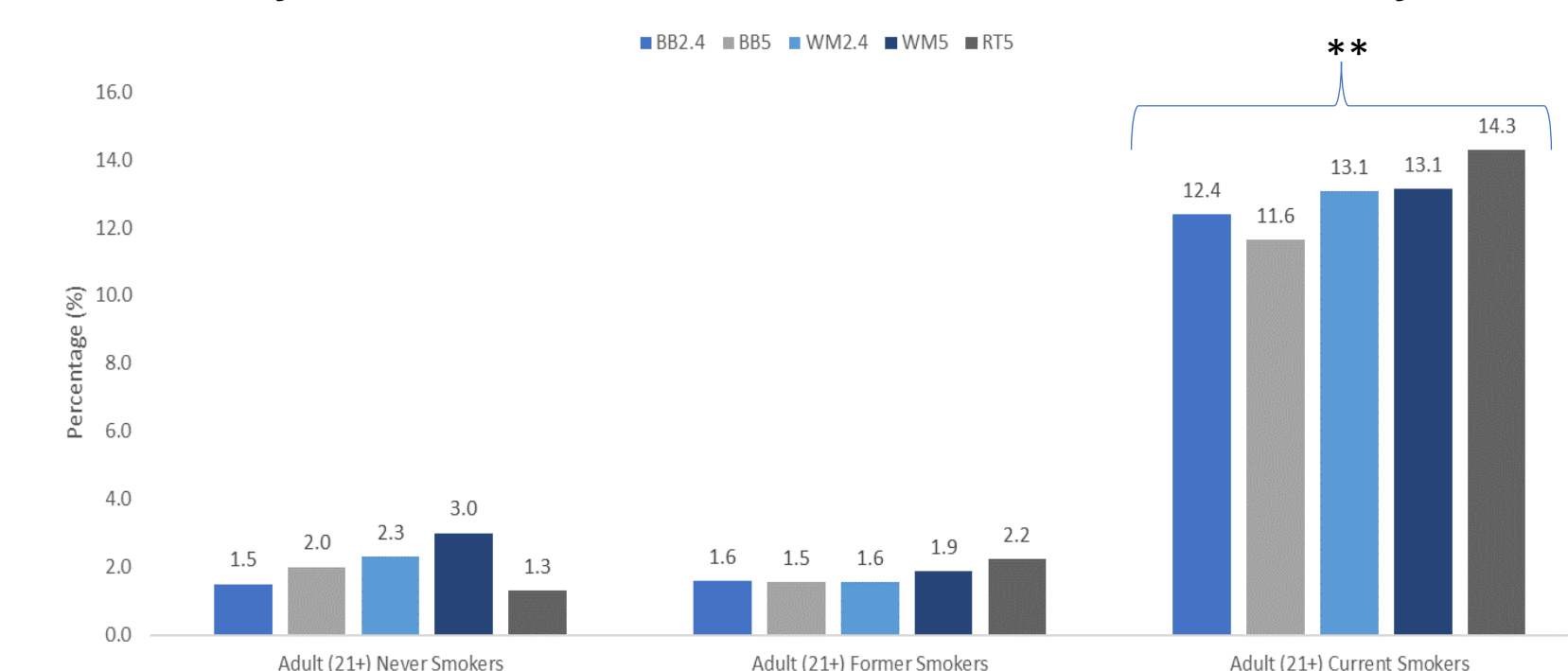
Youth did *not* indicate statistically significantly greater intentions to Try NJOY ACE 2.0 flavored products Soon (4.65%-4.94%) compared to tobacco-flavored RT5 (4.23%) or CC (4.57%) (all p-values >0.05).

Youth did *not* indicate statistically significantly greater intentions to Use NJOY ACE 2.0 flavored products in the Next Year (3.88%-4.76%) than tobacco-flavored RT5 (5.14%) or CC (4.43%) (all p-values >0.05).

Proportion of Adults 21+ who Intended to Try Tobacco-flavored NJOY ACE, Blueberry and Watermelon NJOY ACE 2.0 Soon, by Cohort



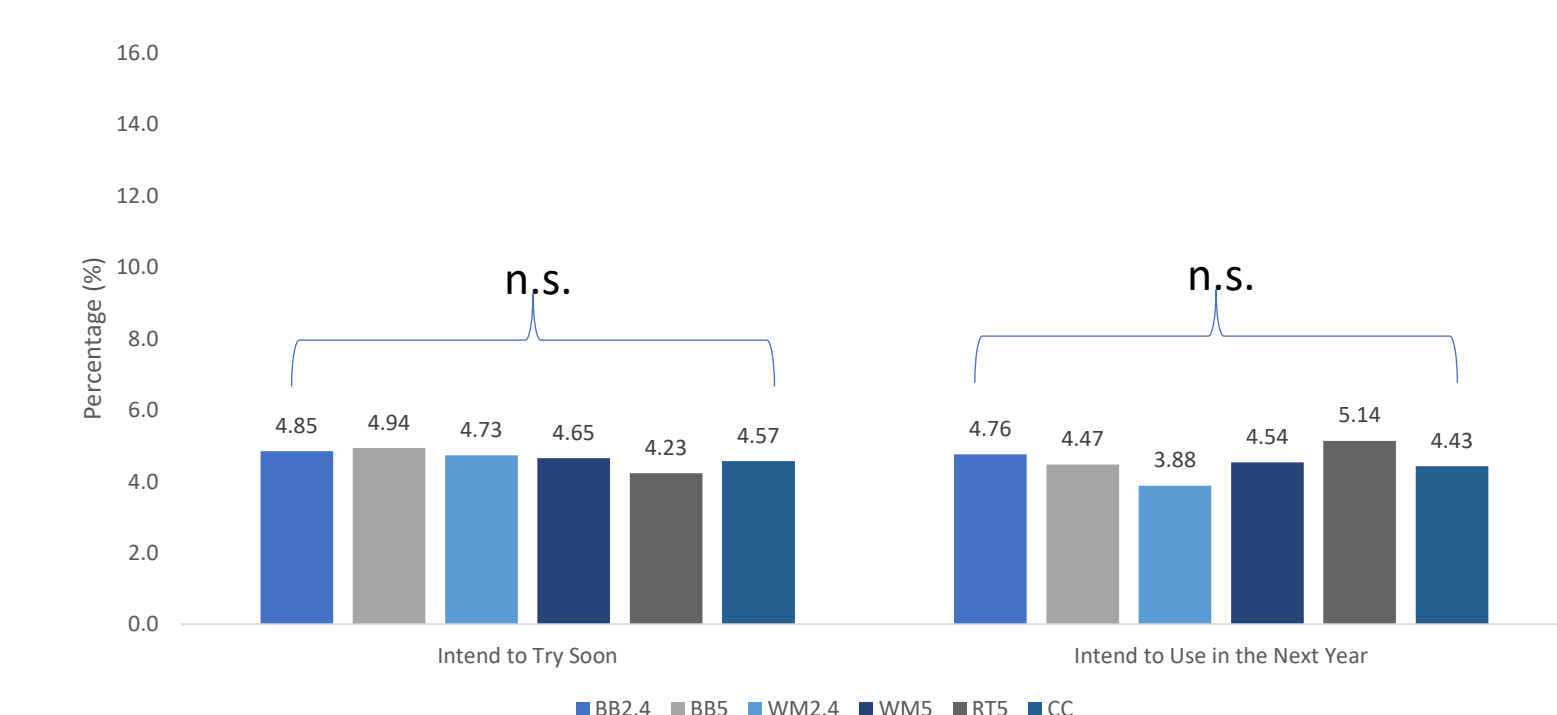
Proportion of Adults 21+ who Intended to Use Tobacco-flavored NJOY ACE, Blueberry, and Watermelon NJOY ACE 2.0 in the Next Year, by Cohort



** Indicates statistically significant differences at p<0.01. Intentions to Try NJOY ACE 2.0 products Soon or to Use them in the Next Year were significantly higher among Adults 21+ who are Current Smokers compared to Former and Never Smokers.

Note: Data on cigarette use intentions are not shown in the above plots. As expected, the vast majority of Adult Smokers (95.0%) indicated positive intentions to try or use cigarettes, compared to 4.0% or less of Former and Never Smokers.

Proportion of Youth (13-17) who Intended to Try/Use Tobacco-flavored NJOY ACE, Blueberry, Watermelon NJOY ACE 2.0, and Cigarettes



'n.s.' indicates non-significant differences in intentions to try/use NJOY ACE 2.0 products or cigarettes (CC).

Adults 21+
Only 3.0% or less of NS and FS intended to try or use NJOY ACE 2.0 products.

AS were significantly more likely to intend to try NJOY ACE 2.0 products than NS and FS.

Youth
Most Youth (95.0% or more) did not intend to Try NJOY ACE 2.0 products Soon or Use them in the Next Year.

Youth **did not** indicate greater intentions to try or use flavored NJOY ACE 2.0 products compared to tobacco-flavored NJOY ACE or CC.

Converging lines of evidence indicate low likelihood of use of NJOY ACE® products among unintended audiences.

National Prevalence Data from the ALCS Underage Tobacco Use Survey

Methods

Objective of Analysis

To estimate the usual brand prevalence of NJOY ENDS among underage individuals in the U.S., we utilized data from a nationwide population-based survey, the ALCS Underage Tobacco Use Survey (UTUS).

UTUS Design

The UTUS is a repeated cross-sectional household survey that draws probability samples of individuals aged 13-20 years. The survey is fielded quarterly and for this analysis four consecutive quarters of data collections were aggregated to produce annual estimates for the years 2021, 2022, and 2023 (N=16,930).

Analysis and Measures

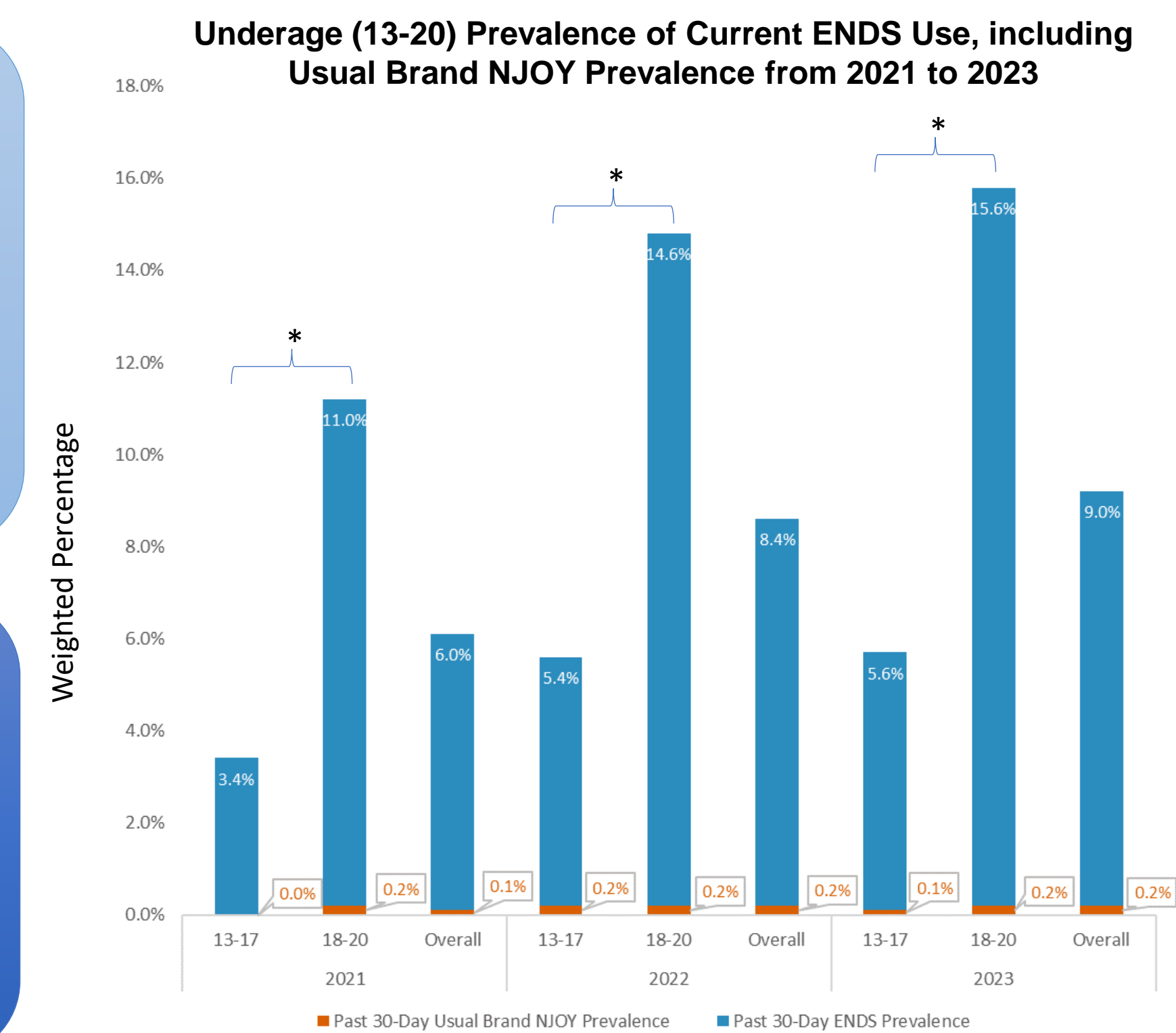
Estimate Past 30-Day ENDS prevalence among Underage Individuals. Consistent with the National Youth Tobacco Survey (NYTS; e.g., Birdsey et al., 2023), estimated prevalence of past 30-day ENDS use in the UTUS is defined as the weighted percentage of respondents who had used e-cigarettes within 30 days prior to taking the survey (Cheng et al., 2023). Specifically, past 30-day prevalence was operationalized as having ever used e-cigarettes (i.e., those who selected “yes” to the survey question “Have you ever used an e-cigarette, even once or twice?”) and use of e-cigarettes on ≥ 1 day during the past 30 days.

Estimate Past 30-Day Usual Brand NJOY prevalence among Underage Individuals. Defined as the weighted percentage of all survey respondents who indicated NJOY as their Only or Usual Brand for the 30-day period prior to taking the survey. Assessed among past 30-day users of ENDS via the survey question “During the past 30 days, what brand of e-cigarettes did you usually use? (select one answer).”

Results

From 2021 to 2023, while 6.0% to 9.0% of underage individuals (13-20) reported past 30-day ENDS use, **past 30-day Usual Brand NJOY prevalence remained consistently low, at less than 0.2%**

Despite significantly higher past 30-day ENDS use among young adults (18-20) from 2021-2023, NJOY Usual Brand use showed no age group differences.



Source: ALCS Underage Tobacco Use Survey (UTUS), data collected between January 2021 and November 2023. Percentages are derived from weighted data. Among ages 13-17, 2021 data contained zero reports of usual use of NJOY brand. Asterisks (*) denote statistically significant differences (p<0.05) in past 30-day prevalence between age groups. There were no statistically significant differences in Usual Brand NJOY prevalence between age groups.

CONCLUSION

Intentions to try or use the products were low among Adult Never Smokers (range 1.19%-3.00%) and the vast majority of Youth (at least 95% across the NJOY ACE Products) did not intend to try or use the NJOY ACE 2.0 products. Additionally, Youth did not show statistically significantly greater intentions to try or use the flavored products compared to the tobacco-flavored products or combustible cigarettes. Further, NJOY ACE 2.0 products with DAR diminish the risk of underage intentions and other studies submitted with the PMTA demonstrated underage access was prevented in virtually all cases.

Additionally, the use of NJOY brand products among underage individuals in the U.S. is rare. National data from our Underage Tobacco Use Survey indicate that while the prevalence of current ENDS product use remained steady between 2021 and 2023, the underage use of NJOY brand consistently remained low during that period. Taken together, these findings support a low likelihood of use for unintended populations (adult nonusers and underage individuals) and simultaneously demonstrate the greatest likelihood of use by the intended population: adult current smokers.

References

- For more information on the UTUS study design, including semi-annual updates on study findings, visit Altria's publicly available science website: <https://sciences.altria.com/science-and-data/survey-data/underage-tobacco-use-survey>, or scan the QR code
- Birdsey, J. (2023). Tobacco product use among US middle and high school students—National Youth Tobacco Survey, 2023. MMWR. Morbidity and Mortality Weekly Report, 72.
- Cheng, H. G., Vansickel, A. R., & Largo, E. G. (2023). Awareness and use of tobacco products among underage individuals: findings from the Altria Client Services Underage Tobacco Use Survey 2020–2022. BMC Public Health, 23(1), 662.



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