



Role of Smoke-free Products in Smoking Cessation

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- All authors are employed by Altria Client Services LLC.



Outline

Background

Evidence of Stopping Smoking with Smoke-free Products

- RCTs
- Longitudinal Actual Use Studies
- Real-world Evidence

Key Takeaways and Implications



What Is the Problem?



Altria Client Services LLC Adult Tobacco Consumer Tracker (ALCS ATCT). *Age 21 or older; prevalence estimates calculated based on reported past 30-day usage of cigarettes based on Apr 2025 to March 2026. VanFrank B, Malarcher A, Cornelius ME, Schechter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. *MMWR Morb Mortal Wkly Rep.* 2024;73:633–641. DOI: <http://dx.doi.org/10.15585/mmwr.mm7329a1>

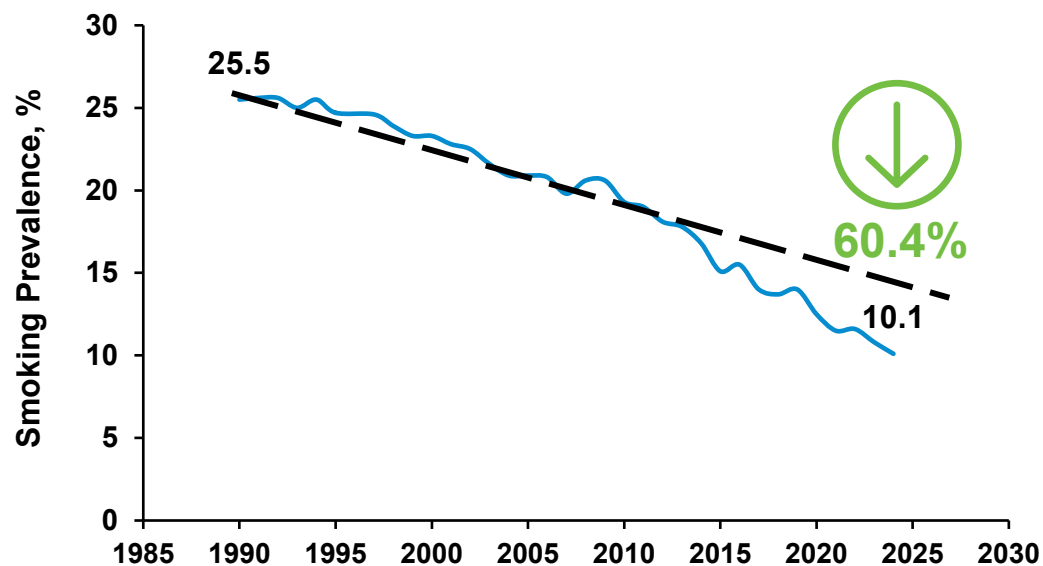


What Are the Solutions?



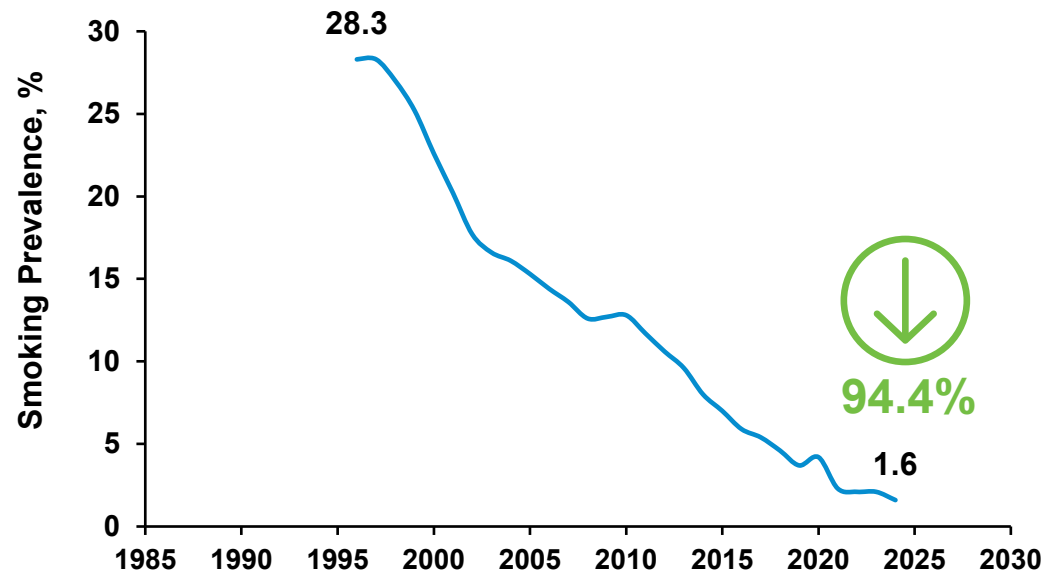
Adult and Youth Smoking Prevalence Continues to Decline

Decline in Adult Smoking Prevalence (1990-2024)



Smoking prevalence as reported in the National Health Interview Survey (NHIS) between 1990-2024 for adults 18+ NHIS definition for adult current smoking is at least 100 cigarettes and currently smoke every day or somedays

Decline in Youth Smoking Prevalence (1996-2024)



Smoking prevalence as reported in the Monitoring the Future (MTF) between peak in 1996 to 2024 among 8, 10 and 12 graders. MTF definition past 30-day smoking



Less Harmful Alternative Nicotine Delivery Products Can Help Reduce Smoking-related Morbidity and Mortality



**PROFESSOR MICHAEL ANTHONY
HAMILTON RUSSELL**
(1932–2009)

“People smoke for nicotine
but die from the tar.”

[A]lternative nicotine delivery products for cessation would need to be **promoted actively** to smokers for them to compete with cigarettes, that **these products** would need to be **available and acceptable to smokers**, and that they would **need to deliver nicotine** sufficiently in order **to satisfy cravings**.

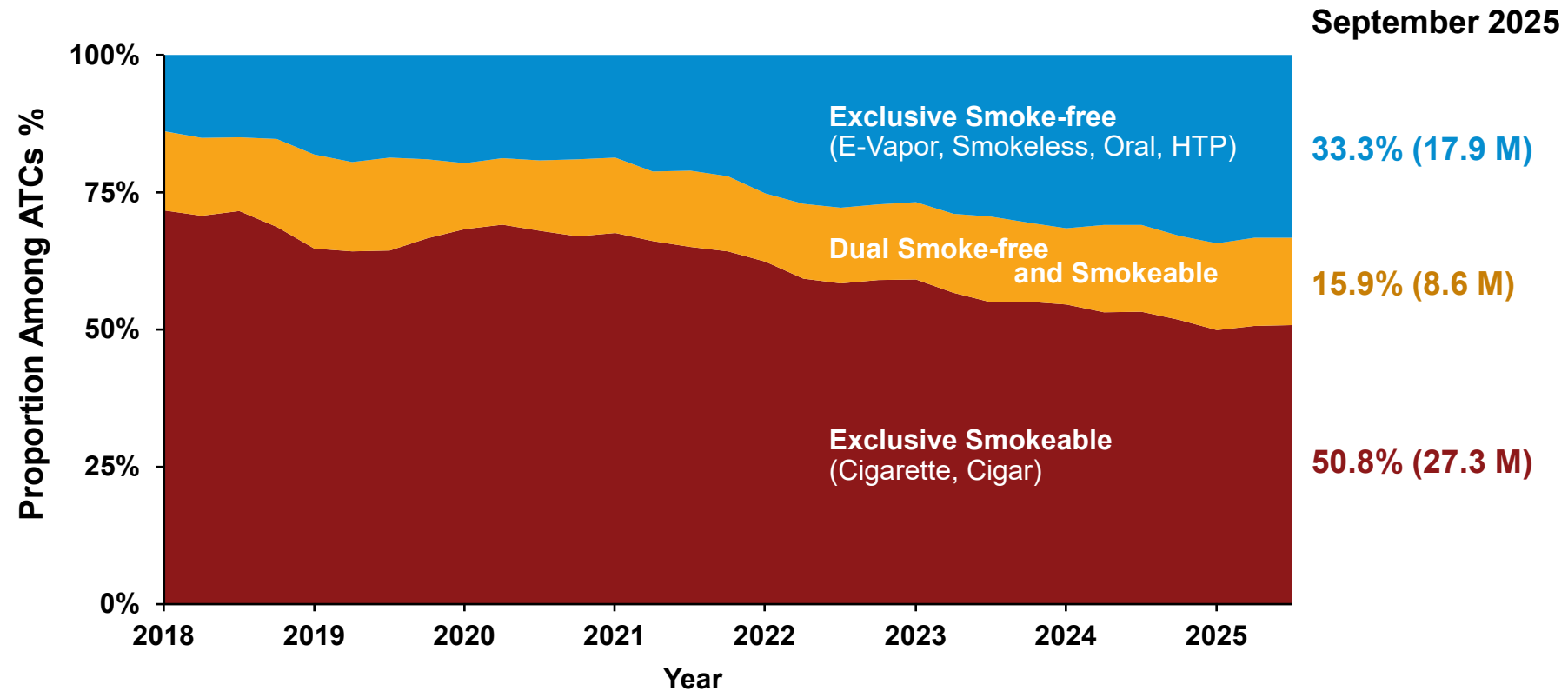
Russell, M.A.H. The future of nicotine replacement.
British Journal of Addiction, 86:653-658 (1991).

[Emphasis added]



Exclusive Use of Smoke-free Products More Than Doubled (2018-2025) Dual Use has Remained Constant

Proportion of ATCs (21+) Using Exclusive Smoke-free, Exclusive Smokeable, or Dual of Both
Source: ATCT (6 Moving-Month Distribution)



Source: Age 21+, ATCT (6mm distribution) RA Jul 2017 to Sep 2025. Numbers may not foot due to rounding. %'s computed on population weights. HNB has data only from Jan 2020
OTPs include hookah, chew, pipe tobacco, etc. Exclusive use of OTPs is not included in base for analysis. Use of OTPs is considered in the count of product usage (as 'Other') in all analysis. Internal docket: 2025-AH-64

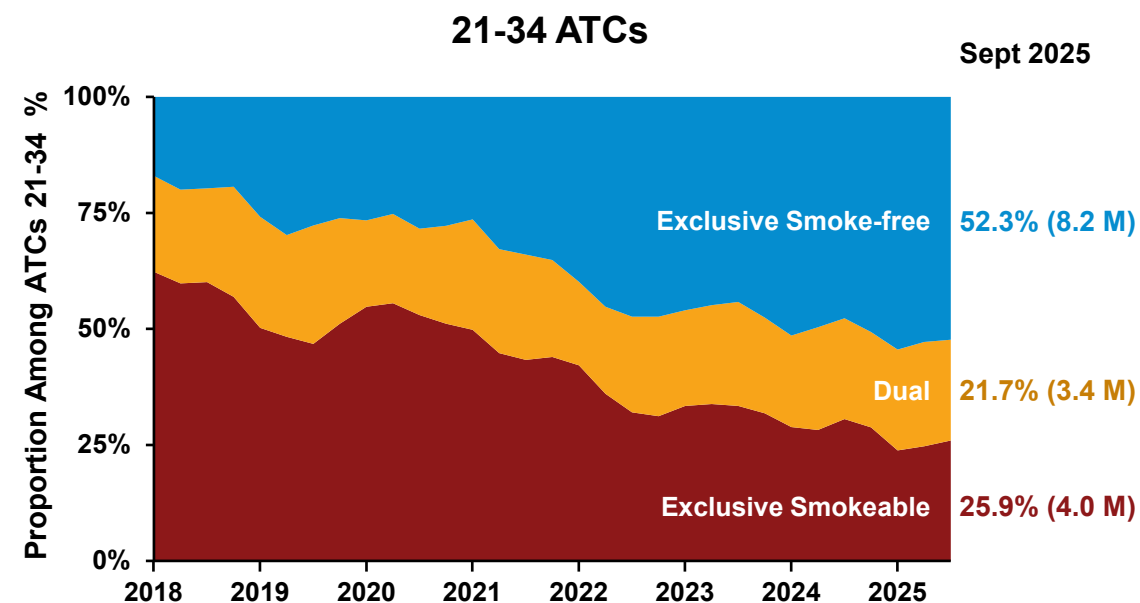
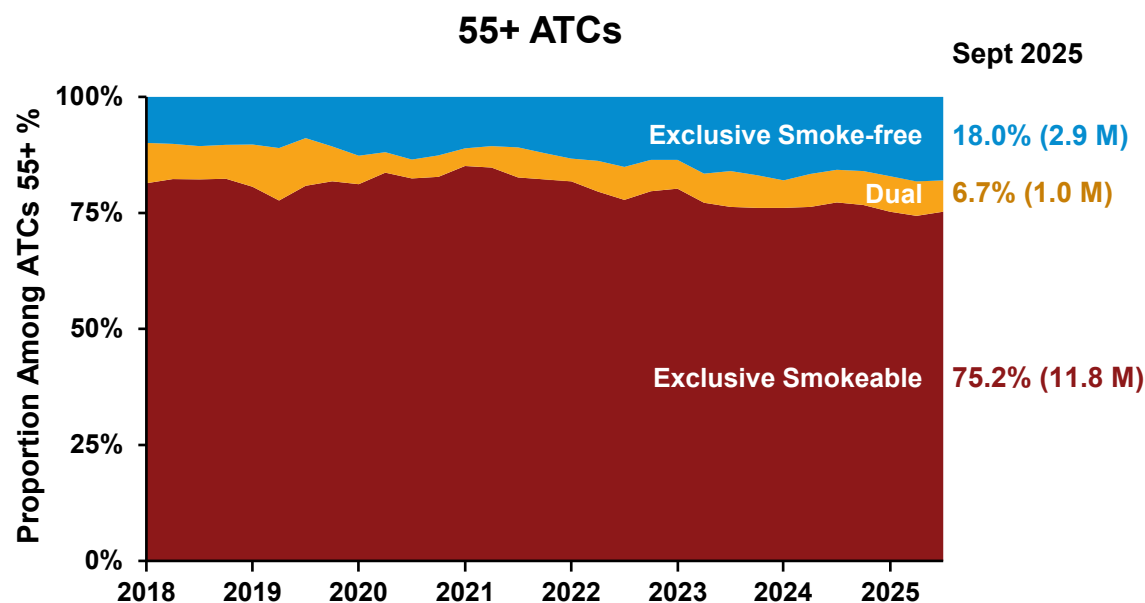


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Among Older (55+) ATCs, the Proportion of Exclusive Smokeable Users Remains High and Relatively Unchanged

Proportion of ATC Subgroups Using Exclusive Smoke-free, Exclusive Smokeable, or Dual of Both
Source: ATCT (6 Moving-Month Distribution)

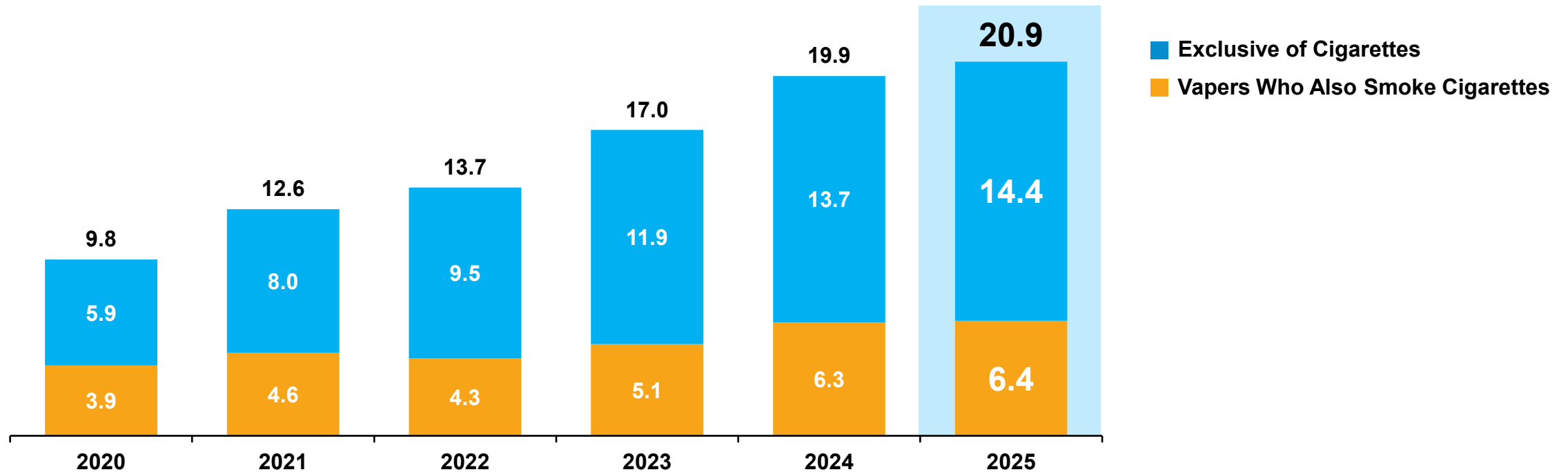


Source: Age 21+, ATCT (6m distribution) RA Jul 2017 to Sep 2025. Numbers may not foot due to rounding. %'s computed on population weights HNB has data only from Jan 2020
OTPs include hookah, chew, pipe tobacco, etc. Exclusive use of OTPs is not included in base for analysis. Use of OTPs is considered in the count of product usage (as 'Other') in all analysis. Internal docket: 2025-AH-64
Examples of exclusive Smoke-free include E-Vapor, Smokeless, Oral, and HNB. Examples of exclusive Smokeable include Cigarettes and Cigars.



E-vapor Is the Predominant Smoke-free Category

Adult* Vapers Past 30-Day Usage
(in millions)



Note: Estimates are based on self-reported use of E-Vapor in the past 30 days. Self-reported product use trends may not correspond with changes in sales or shipment volume.

E-Vapor Exclusive: Using e-vapor exclusive of any other tobacco products. E-Vapor Dual/poly: Using e-vapor and at least one or more tobacco products.*Age 21 or older.

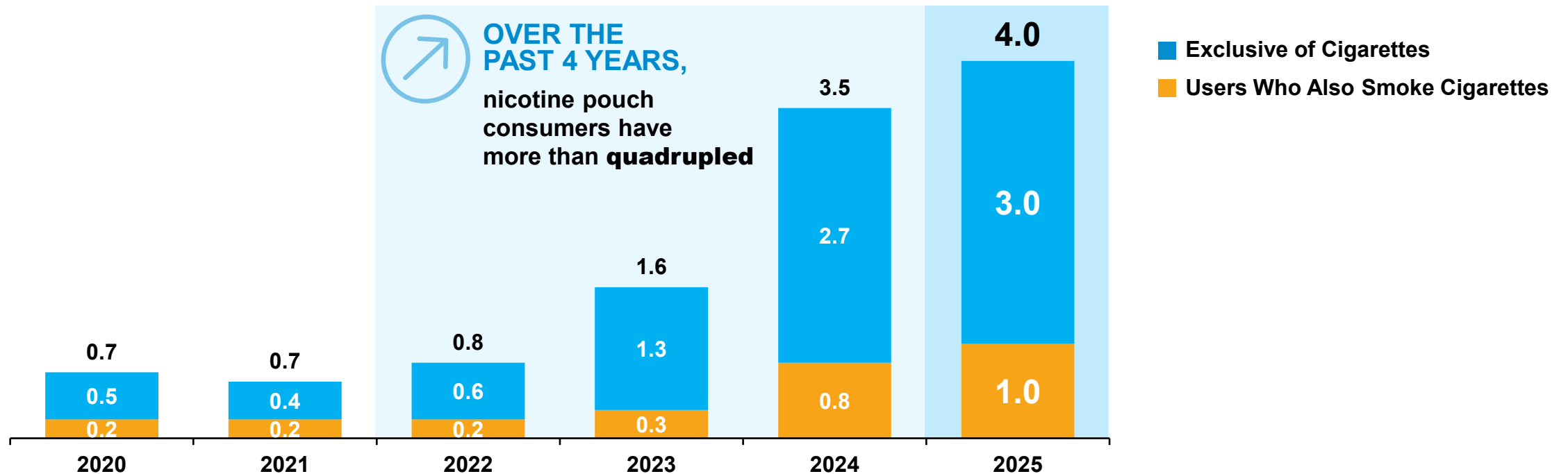
Source: *Age 21+, ATCT RA 12MM ending December 2025. Percentages or numbers may add due to rounding.

Note that the exclusive of cigarette group may include dual users of other tobacco products, which for OTDN products is predominantly ST users and Vapers. Of the 14.4 million, 12.3 million are truly exclusive of all tobacco products and 1.1 million are dual/poly users of other tobacco products.



Oral Nicotine Category Is Rapidly Growing

Adult* Oral Nicotine Product Users Past 30-Day Usage
(in millions)



Note: Estimates are based on self-reported any use of OTDN in the past 30 days. Self-reported product use trends may not correspond with changes in sales or shipment volume.

Exclusive users defined as using only oral nicotine products exclusive of any other tobacco products. *Age 21 or older. Results are based on population weights.

Source: ATCT RA 12MM ending December 2025. Percentages or numbers may add due to rounding. Oral nicotine products that are free of tobacco leaf, including nicotine pouches, lozenges and gum.

Note that the exclusive of cigarette group may include dual users of other tobacco products, which is predominantly ST users and Vapors – Of the 3.0 million, 1.7 million are truly exclusive of all tobacco products and 1.3 million are dual/poly users of other tobacco products.



Outline

Background

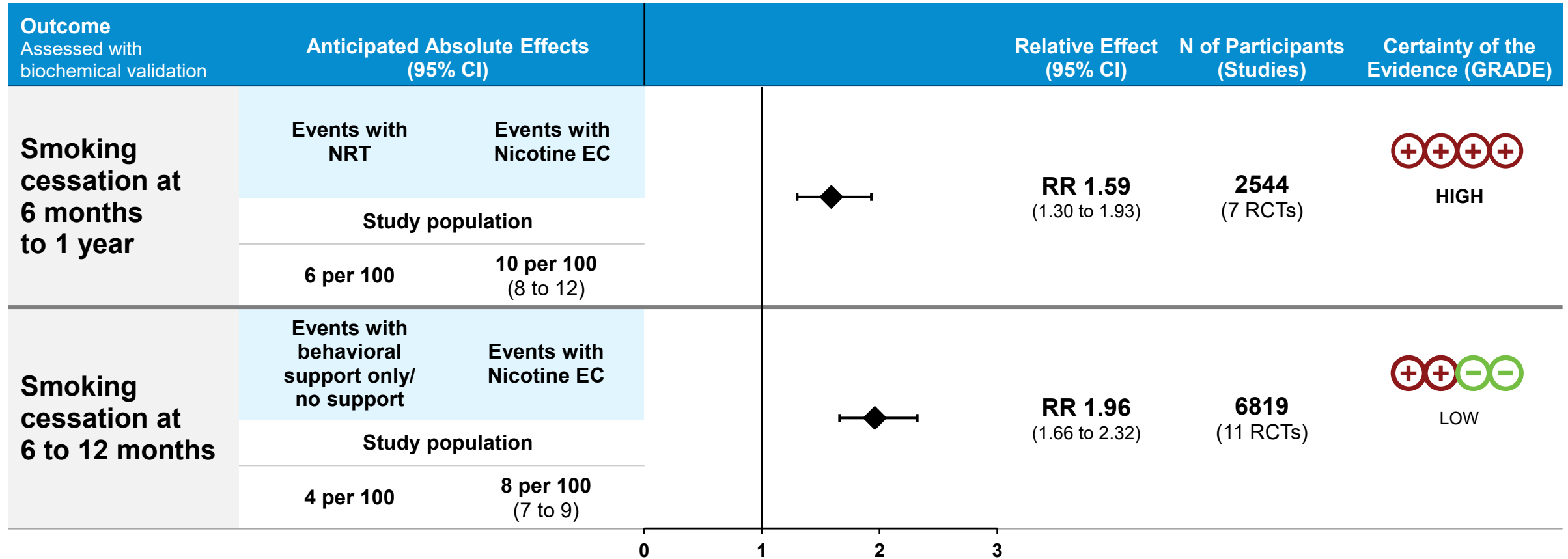
Evidence of Stopping Smoking with Smoke-free Products

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Key Takeaways and Implications



Efficacy of E-cigs for Smoking Cessation



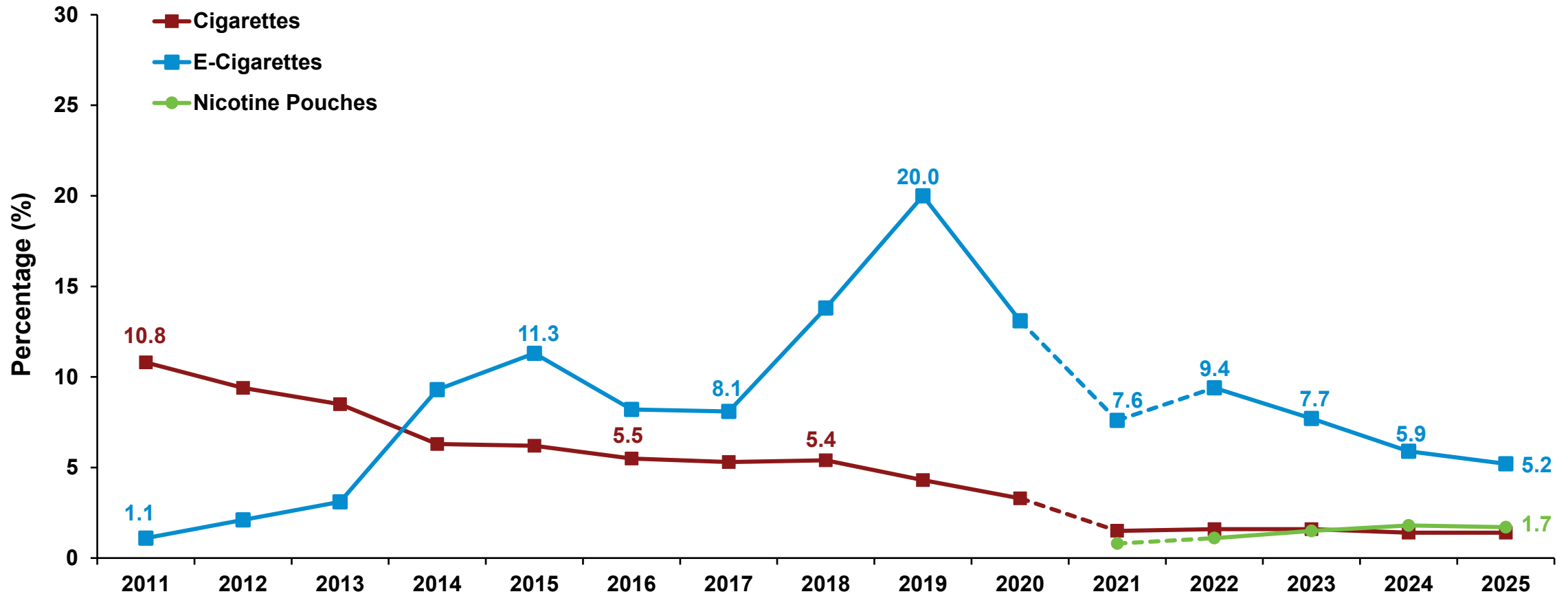
Lindson N, Butler AR, McRobbie H, Bullen C, Hajek P, Wu AD, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Livingstone Banks J, Morris T, Hartmann-Boyce J. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2025, Issue 1. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub9.



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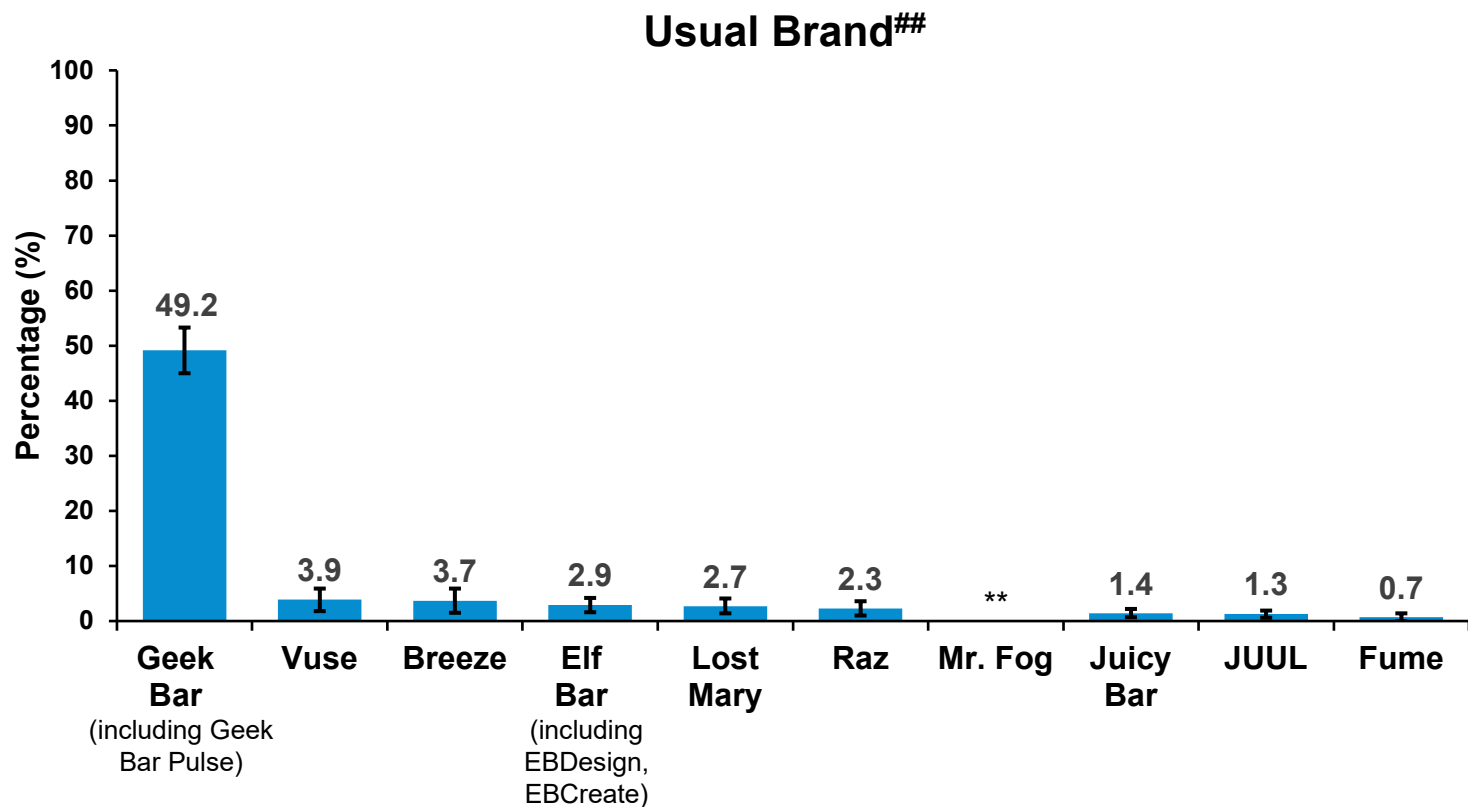
Current Tobacco Product Use Among Middle and High School Students Combined, National Youth Tobacco Survey, 2011-2025



Sources: ALCS analysis of NYTS 2011-2021, [Tobacco Product Use Among Middle and High School Students — United States, 2022](#), [Tobacco Product Use Among U.S. Middle and High School Students — National Youth Tobacco Survey, 2023](#), and [Tobacco Product Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2024](#), ALCS analysis of NYTS 2025.



E-cigarette Use Characteristics Among Middle and High School Students Who Currently Use E-cigarettes



Characteristic	Middle and High School Students (vs. 2024)
Current E-cigarette Use	5.2% (↓ 0.7pp)
Device Type Most Often Used:	
 Disposables	66.3% (↑ 10.7pp)
 Pods or Cartridges	12.0% (↓ 3.6pp)
 Tanks or Mod systems	5.4% (↓ 1.6pp)
Don't know the type	16.4% (↓ 5.4pp)

** Estimate is not statistically reliable due to high CV (>30%).

^{##} If a student currently using e-cigarettes or nicotine pouches reported a single brand when asked, “During the past 30 days, what [e-cigarette/nicotine pouch] brands did you use (Select one or more),” it was reported as the usual brand. Those who selected two or more brands were asked, “During the past 30 days, what brand of [e-cigarettes/nicotine pouches] did you usually use? (Choose only one answer).” Write-in responses were not included in this analysis.

Sources: ALCS analysis of NYTS 2025 and Jamal et al., 2024. NYTS 2025 data were downloaded from National Youth Tobacco Survey (NYTS) | FDA on March 4, 2026.



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Studies on Illicit E-vapor Products Highlight Safety Concerns and the Need for Enforcement and FDA Regulation



“ Our study highlights the hidden risk of these new and popular disposable electronic cigarettes — **with hazardous levels of neurotoxic lead** and carcinogenic nickel and antimony — which stresses the need for urgency in enforcement. ”

[Emphasis added]



Michelle Peace, Ph.D., a forensic toxicologist at VCU, is exposing the dangerous chemicals that lurk in vaping and cannabis products — and the lack of oversight protecting the public. **Her research has uncovered everything from deadly synthetic cannabinoids to brake cleaners, which are inhaled by teens and adults alike.**

Sources: UC Davis, Press Release, [Disposable E-Cigarettes More Toxic Than Traditional Cigarettes](#) (6/25/25); Brett A. Poulin, [Elevated Toxic Element Emissions from Popular Disposable E-Cigarettes](#). ACS Central Science, 2025; VCU News, [Her mission: Clearing the air about the hidden danger in vapes](#) (7/14/25)



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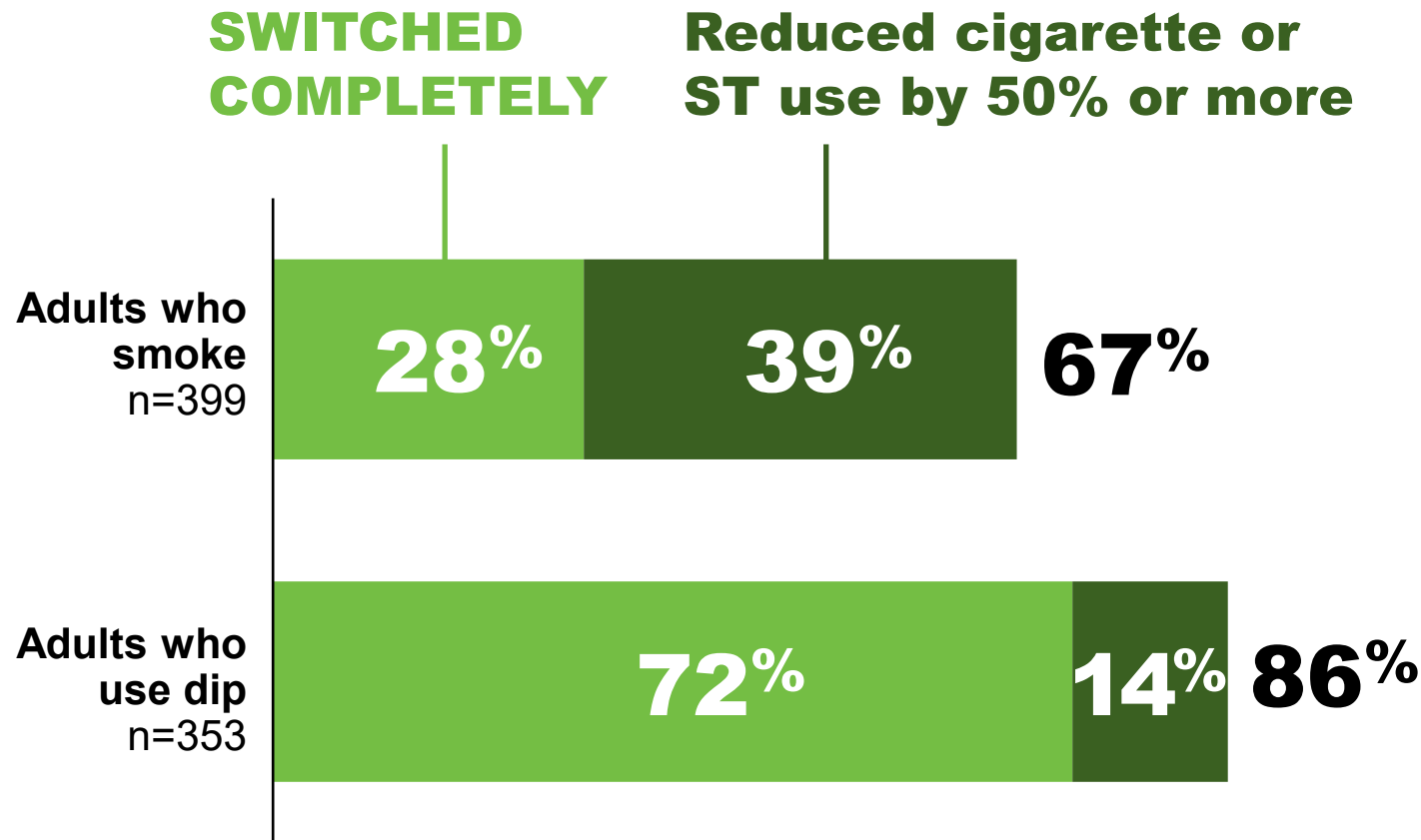
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Large Proportions of Adults Using on! Nicotine Pouches Switched or Reduced Consumption



POPULATION HARM REDUCTION



Dip=Moist Smokeless Tobacco
Source: AUS Study Report and additional ALCS analysis



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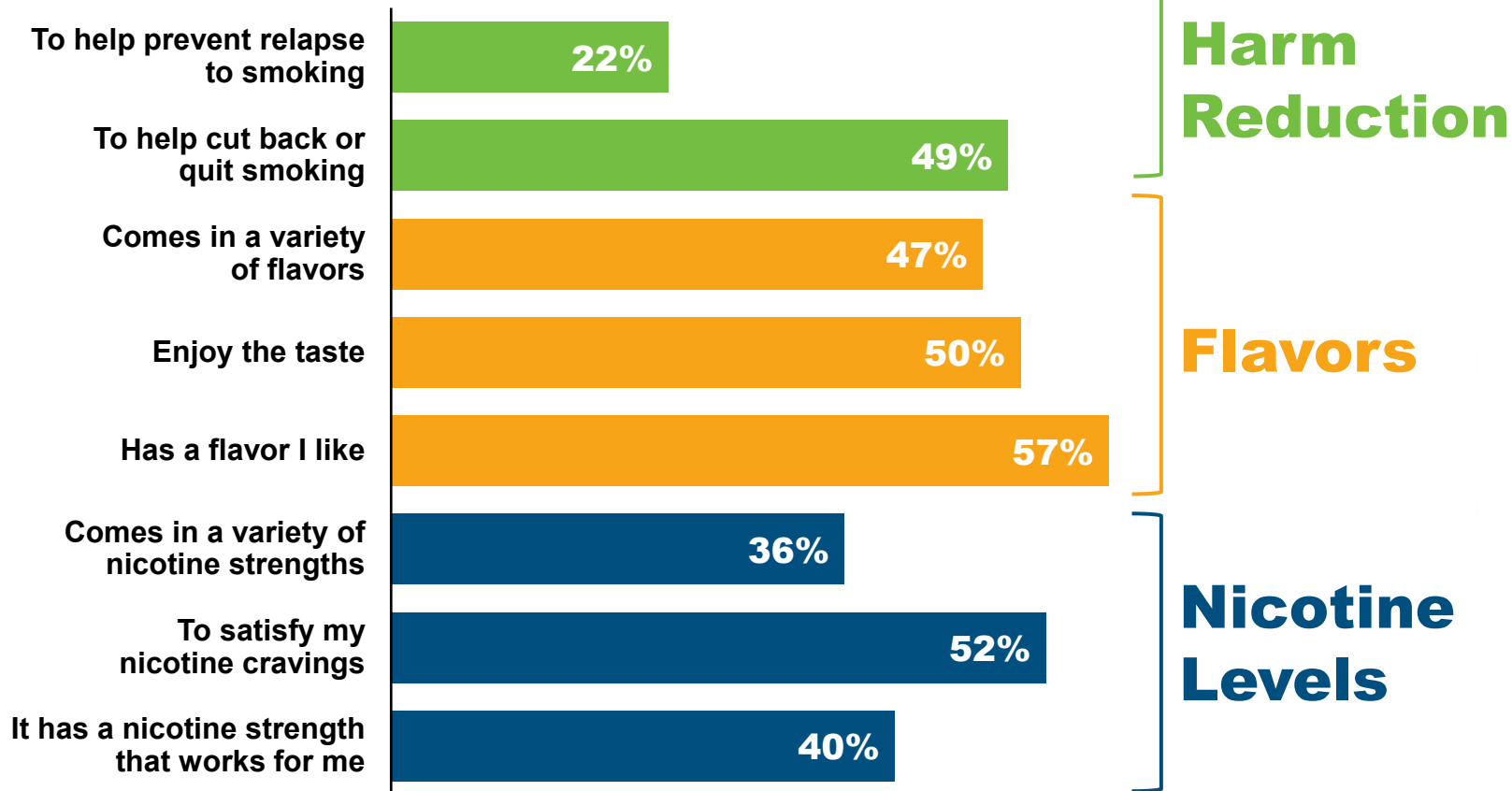
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Reasons for Future Use of on!® Among Adults Who Smoked



POPULATION HARM REDUCTION

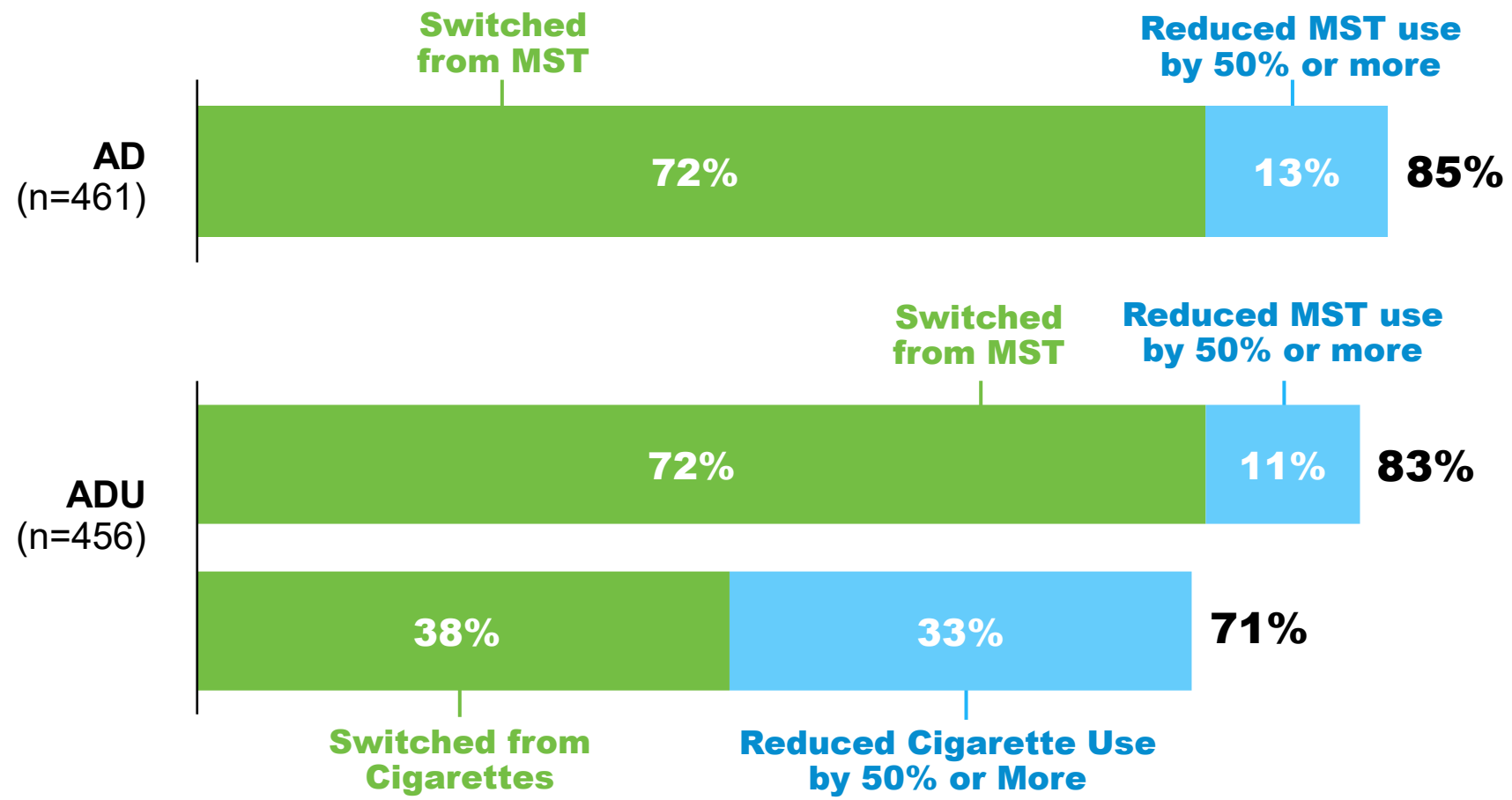
Percentage of Adult Smokers



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Large Proportions of Adults Using on! PLUS Nicotine Pouches Switched or Reduced Consumption

INDIVIDUAL RISK REDUCTION

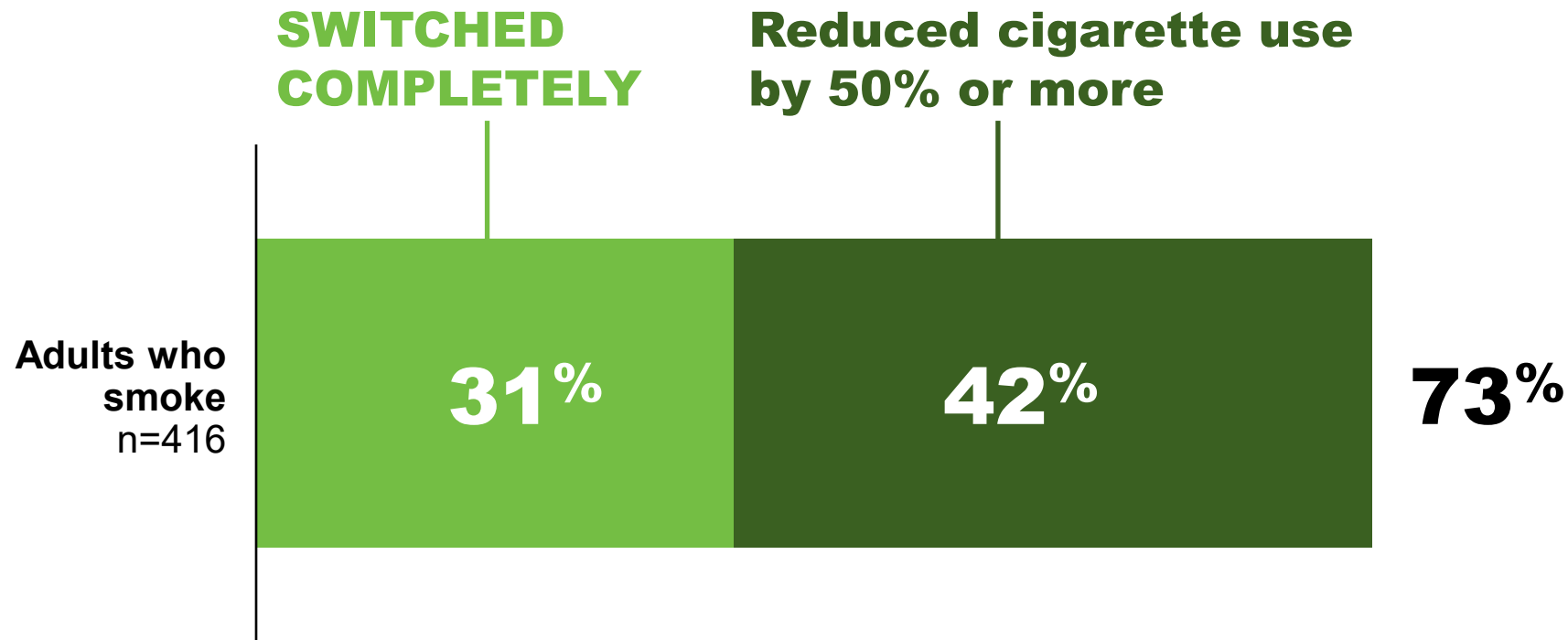


AD=adults who use MST products (snuff/dip); ADU=adults who use MST products and combustible cigarettes concurrently (adults who dual use); MST=moist smokeless tobacco.
 ALCS Final Report Number: ALCS-REG 2022-03-00645, "Tobacco Product Portfolio/Actual Use Study of on! PLUS™ Nicotine Pouches"
 Switching was defined as using the on! PLUS™ and not using MST and cigarettes any day during the last week of Phase 2 (i.e., Week 6) among those who started using on! PLUS™.

Large Proportions of Adults Using PLOOM HTP Switched or Reduced Consumption



POPULATION HARM REDUCTION



ploom



Data shown represent proportion of study participants who report start using research products, stop smoking cigarettes and still using the research products (behavioral switch) at end of Week 6 of the study
Source: AUS Study Report and additional ALCS analysis.



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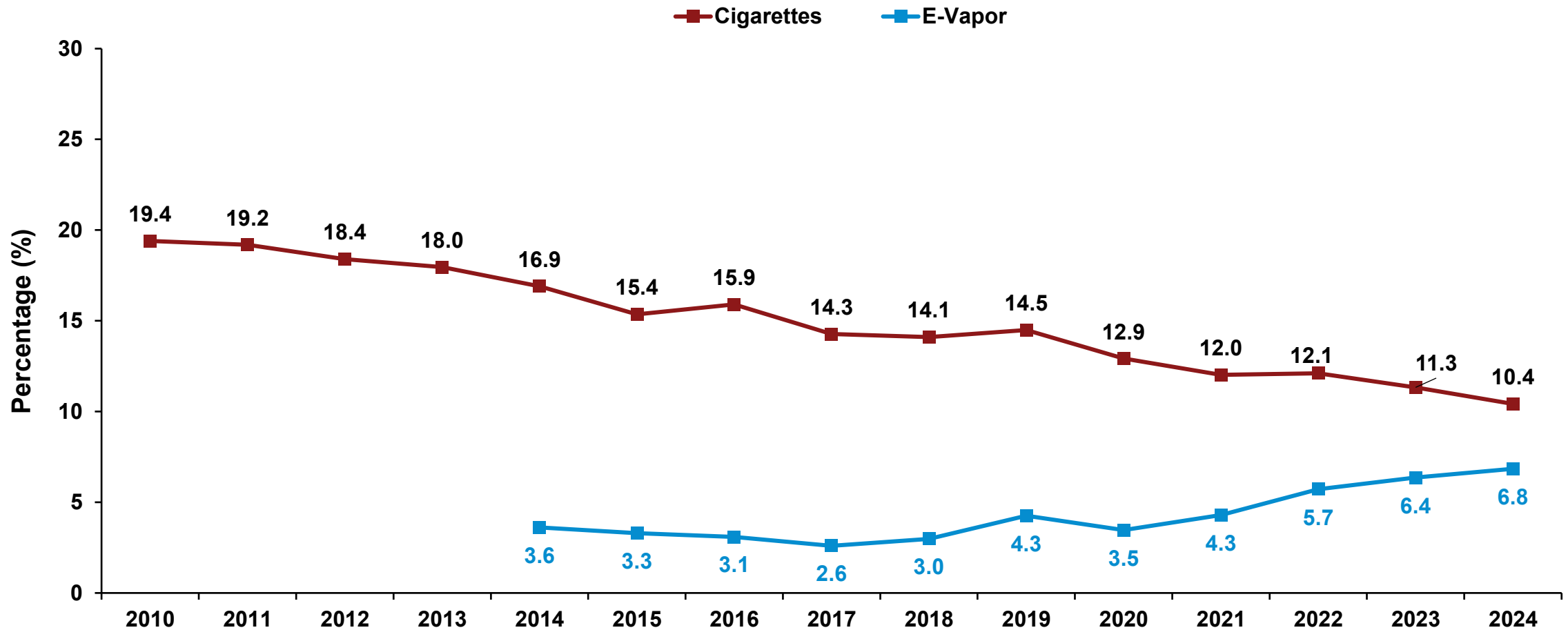
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- Longitudinal Actual Use Studies
- **Real-world Evidence**

Key Takeaways and Implications



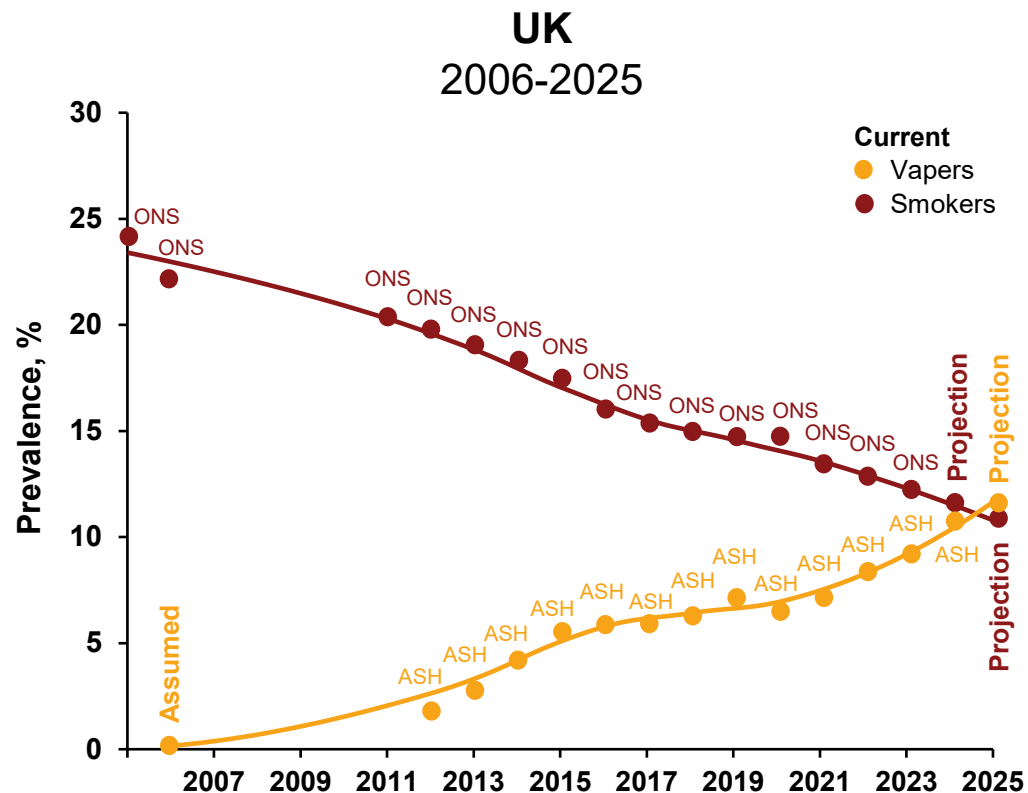
Prevalence of Smoking and Vaping in US 2010-2024



Prevalence is defined as using the product every day or some days (100+ cigarettes).
Source: ALCS Analysis of National Health Interview Survey (NHIS) among adults 21+



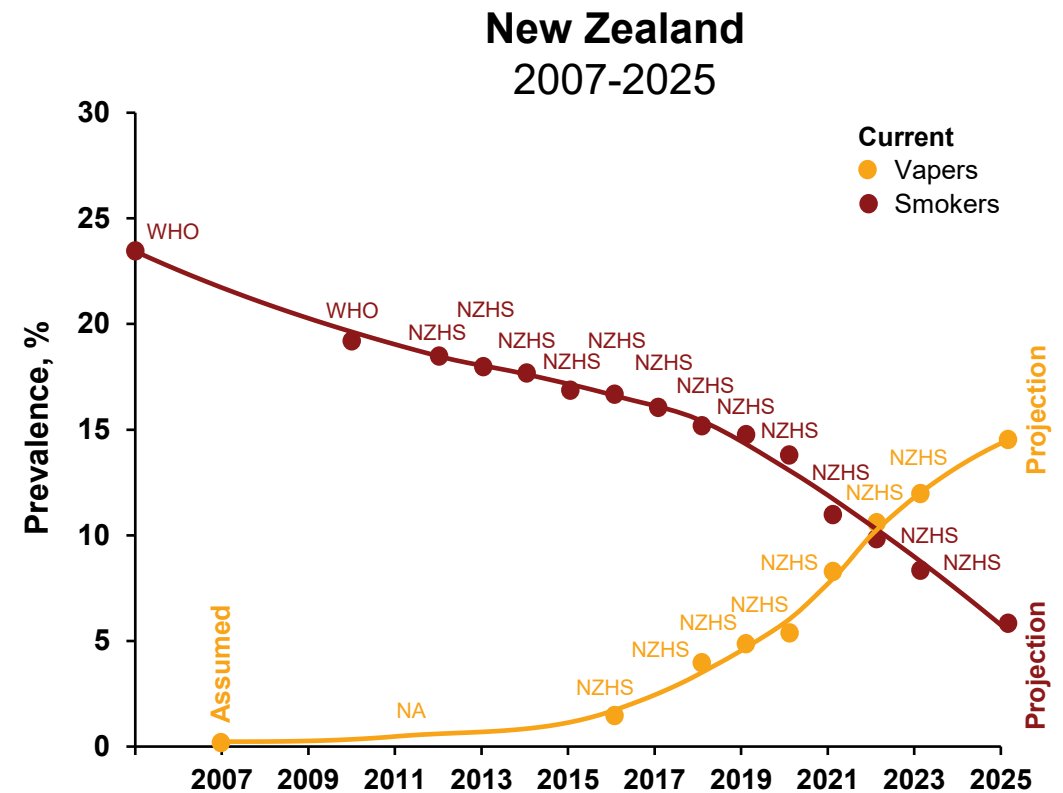
Prevalence of Smoking and Vaping in the UK and New Zealand



GSTHIR 2024.

ONS: Office for National Statistics (2024)

ASH: Action on Smoking and Health (2024)

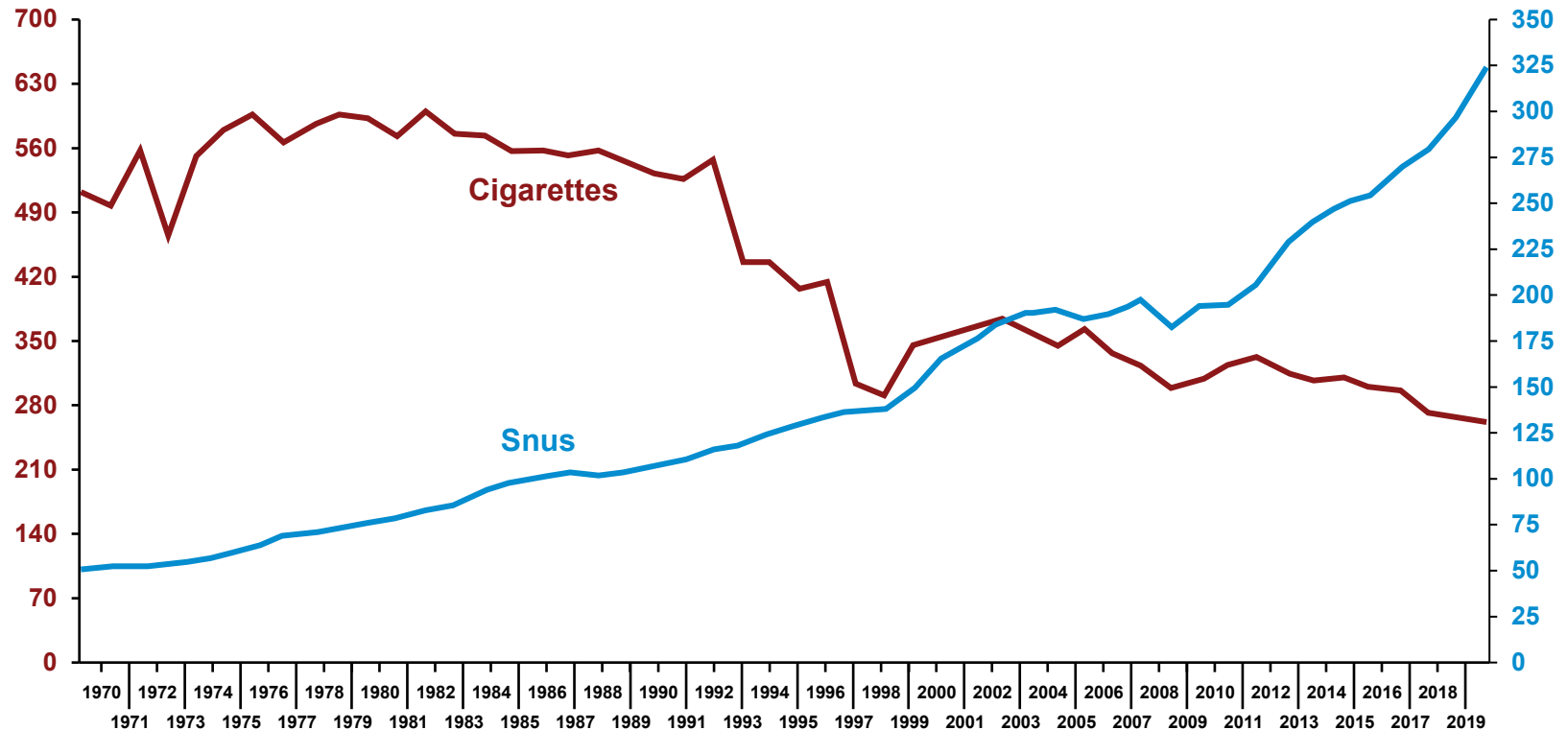


GSTHIR 2024.

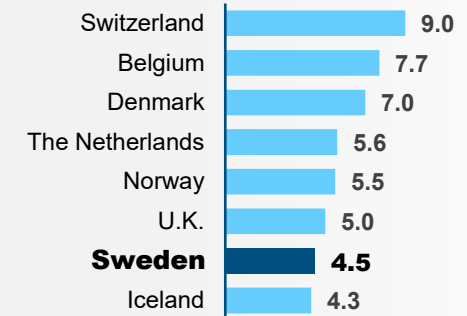
WHO: global report on trends in prevalence of tobacco use 2000-2025, Fourth edition

Harm Reduction Success – Swedish Experience

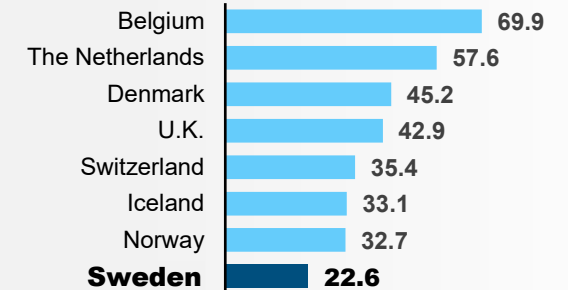
Cigarettes
(million packs)



Oral Cancer incidence rates
among European men*



Lung Cancer mortality rates
among European men*



*per 100,000 by country; Rates are 2002 data and age-standardized (world population).

Source: International Agency for Research on Cancer.

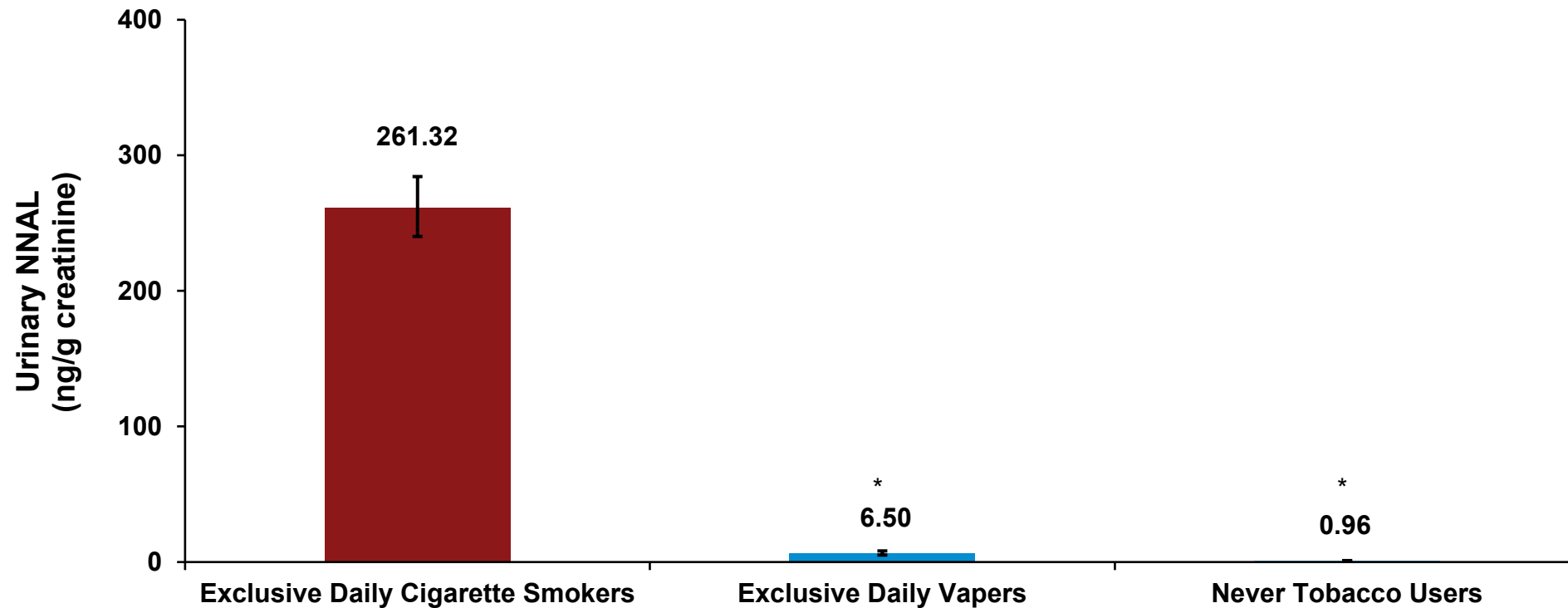
<https://www.swedishmatch.com/Snus-and-health/Tobacco-use-in-figures/> accessed 8/24/21



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Stopping Smoking Confirmed by Biomarkers of Exposure



*denotes statistically significant difference ($p < 0.05$) when compared to exclusive cigarette smokers.

Analysis based on Wave 1 Adult Questionnaire Restricted-Use Files and Biomarker Restricted-Use Files (2013-2014). Sample size: Exclusive Daily Cigarette Smoker ($n=2442$); Frequent Duals ($n=169$); Smokers Who Vape ($n=678$); Vapers Who Smoke ($n=57$); Infrequent Duals ($n=66$); Exclusive Daily Vapers ($n=169$); Never Tobacco Users ($n=1,700$)

Abbreviation: NNAL: 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol; NNK: 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone.

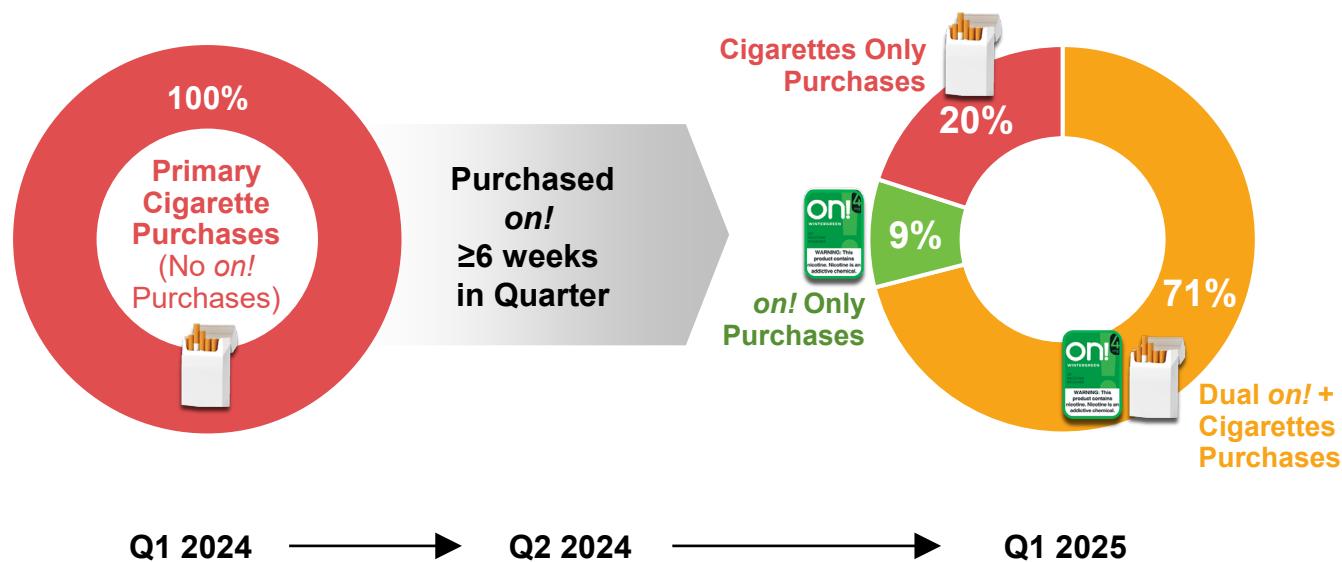
Lizhnyak PN, Noggle B, Wei L, Edmiston J, Becker E, Black RA, Sarkar M. *Harm Reduction J.* 2022 Aug 17;19(1):90.



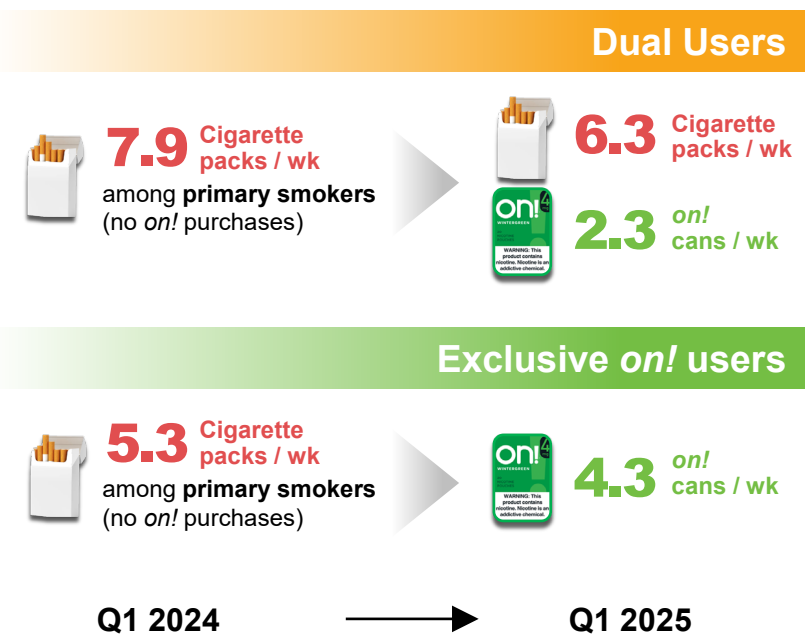
Regular Purchase of *on!* Nicotine Pouches Increases the Likelihood to Switch Away From Cigarettes

Regular purchase of *on!* is associated with complete switching, lower return to only purchasing cigarettes, and, among dual users, reductions in cigarette consumption

Prospective Analyses:
Q1 2025 Status Among Q1 2024 Primary Cigarette Smokers
Who Became *on!* Regular Purchasers in Q2 2024



Changes in Purchase Behavior Among Those Purchasing *on!* in Q1 2025



Source and notes: POS Scan Data WE 2025-03-29; analyses among static LIDs who primarily purchased cigarettes in the pre-period of Q1, 2024 with no prior *on!* purchase history and purchased *on!* regularly in Q2, 2024 and continued to purchase tobacco in Q1, 2025.



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Key Takeaways and Implications





Key Takeaways



Stopping smoking is a complex multi-faceted journey

While many adults are motivated to stop smoking, switching to less harmful alternative sources of nicotine can lead to accidental quitting with low likelihood of relapse



Traditional and novel smoking cessation pharmacotherapy can be complemented by switching to smoke-free products

Smoke-free products like e-cigarettes, nicotine pouches and heated-tobacco products can help those adults who seeking alternative approaches to quit



Adults who are unable or unwilling to quit cigarettes should have the agency to make an informed decision to stop smoking

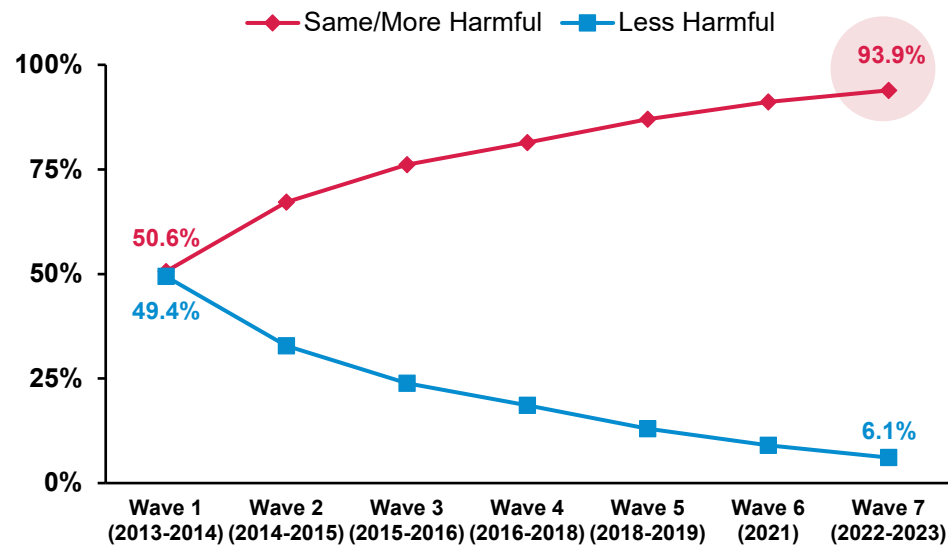
Availability of a range of FDA authorized smoke-free products and accurate information will help them make this informed decision



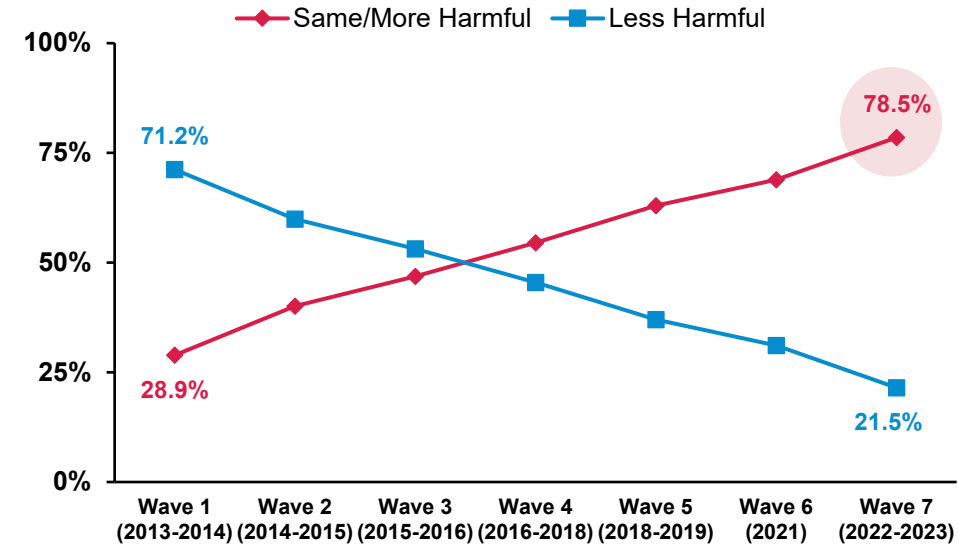
Implications

✓ **Opportunities exist to accelerate transition to complete switching**
Correcting product risk and nicotine misperceptions can facilitate this transition

Current Exclusive Smokers



Dual Users of Cigarettes and E-vapor



¹Based on ALCS analysis of PATH data. Definition of use status: Current Exclusive Smokers: Individuals who currently smoke every day or some days and have smoked 100+ cigarettes, and not currently using e-vapor products; Current dual users of cigarettes and e-vapor: Individuals who currently smoke cigarettes (having smoked 100+ cigarettes) and use e-vapor every day or some days. Question asked: "Is using e-cigarettes or other electronic nicotine products less harmful, about the same, or more harmful than smoking cigarettes?" Based on ALCS analysis of PATH data. Definition of use status: Current dual users of cigarettes and e-vapor: Individuals who currently smoke cigarettes (having smoked 100+ cigarettes) and use e-vapor every day or some days.





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