

Dual-User Transitions as a Function of ENDS Flavors – Findings and Sensitivities

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Introduction

Under Section 910(c)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), evaluation of a new tobacco product considers whether its marketing would be appropriate for the protection of the public health (APPH).¹ Transitions away from combustible cigarette smoking, including cigarette cessation, are therefore important outcomes when evaluating the potential population-health effects of electronic nicotine delivery systems (ENDS).

Using longitudinal data from Waves 3–8 of the Population Assessment of Tobacco and Health (PATH) Study, we evaluated cigarette-use transitions at Wave 8 in relation to prior ENDS use and predominant ENDS flavor.² Analyses examined both cigarette cessation among established smokers and cigarette initiation among established exclusive ENDS users. Multiple sensitivity cohorts were used to assess the robustness of these associations to alternative definitions of established tobacco-product use.

Methodology

Predominant ENDS flavor was defined at each wave based on the flavor respondents reported using most often or exclusively. Respondents were classified at each wave into one of four mutually exclusive tobacco-use states: SOLUS ENDS, SOLUS cigarettes, dual use of ENDS and cigarettes, or neither. “SOLUS” denotes exclusive established use of the specified tobacco/nicotine product (TNP) category. Established-use status was defined according to the criteria specified for each sensitivity cohort in **Table 1**.

Table 1. Sensitivity Cohort Definitions

Sensitivity Cohorts	Definition
Base Cohort	Established Use of a TNP defined as 100+ lifetime uses of a product and reported some day or everyday use of the product.
Restricted Cohort	Established Use of a TNP defined as 100+ lifetime uses of a product and reported some day or everyday use of the product while simultaneously reporting at least one use of the TNP in the past 30 days.
Relaxed Cohort	Established Use of a TNP defined as 100+ lifetime uses of a product and reported some day or everyday use of the product or reporting at least one use of the TNP in the past 30 days.

Endpoints of Interest

Trajectory Analysis (Waves 3-7 → Wave 8)

- Odds of being a former established cigarette smoker at Wave 8 according to predominant use of specific ENDS flavors during any wave from Waves 3-7.

Transition Analysis (Waves 7 → Wave 8)

- Odds of cigarette cessation or initiation between Waves 7 and 8 according to Wave 7 product-use status and predominant ENDS flavor.

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Acknowledgements

The authors are grateful to Thera-Business Inc. for their work and guidance.

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Sensitivity Analyses

Classification of respondent-level tobacco-use status in PATH can vary depending on the survey items and criteria used to operationalize “established use.” To evaluate the robustness of the study findings to these classification decisions, analyses were repeated using alternative definitions of established TNP use. The Base, Restricted, and Relaxed cohorts described in **Table 1** represent progressively different criteria for classifying established use and were used to assess whether estimated associations and conclusions were sensitive to analytical cohort construction.

These alternative definitions resulted in differences in the number of respondents classified as dual users, SOLUS ENDS users, and SOLUS cigarette users at Waves 7 and 8. The resulting sample composition for each sensitivity cohort is summarized in **Table 2**.

Table 2. Sensitivity Samples Snapshot – Number of Respondents by Established Use Status*

Sensitivity Cohorts	Status	Wave 7 Sample Size	Wave 8 Sample Size
Base Cohort	Dual-User	712 (2.1%)	720 (2.3%)
	SOLUS ENDS	1,916 (5.7%)	2,087 (6.6%)
	SOLUS CC	4,644 (13.8%)	3,879 (12.3%)
Restricted Cohort	Dual-User	622 (1.8%)	656 (2.1%)
	SOLUS ENDS	1,801 (5.3%)	2,089 (6.6%)
	SOLUS CC	4,606 (13.7%)	3,828 (12.2%)
Relaxed Cohort	Dual-User	876 (2.6%)	872 (2.8%)
	SOLUS ENDS	2,005 (5.9%)	2,212 (7.0%)
	SOLUS CC	4,825 (14.3%)	4,051 (12.9%)

* Respondents who fall into none of the above categories are omitted from table but are factored into the percentages shown. Samples shown are unweighted.

Statistical Modeling

Survey-weighted logistic regression was used to estimate Wave 8 cigarette-use outcomes. Waves 3–8 analyses used PATH Wave 8 all-wave longitudinal weights, while Wave 7–8 analyses used Wave 8 single-wave weights; variance was estimated using Fay’s method. Models were adjusted for age, race, ethnicity, and sex. Predominant ENDS flavor cohorts with unweighted sample sizes less than 30 were not analyzed³.

Reference groups were respondents without predominant use of the specified flavor for Waves 3–7 analyses, tobacco-flavored ENDS users for Wave 7 flavor analyses, and SOLUS cigarette users for comparisons with Wave 7 dual users.

Results

Sensitivity analyses had a critical role in assessing robustness in findings, with variation in analytical design impacting results.

Across all sensitivity cohorts, **Wave 7 dual users** had significantly higher adjusted odds of cigarette cessation at Wave 8 than **Wave 7 SOLUS cigarette smokers (95% CI range: 1.571–2.957)**. **Candy/Dessert (95% CI range: 1.192–2.256)** or **Fruit (95% CI range: 1.136–1.937)** flavors at any wave was significantly associated with higher adjusted odds of cigarette cessation at Wave 8.

Non-Tobacco vs Tobacco ENDS flavor at Wave 7 was not significantly associated with either cigarette cessation or cigarette initiation at Wave 8

References

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Only two tests held consistent across the sensitivity cohorts: the Trajectory Analysis and the Wave 7–8 product-use Transition Analysis. Because the Wave 7–8 predominant ENDS flavor analyses showed no significant signal, cessation behavior appears to depend on both the time span examined and the predominant flavor used.

Point estimates varied across all analyses, and some altered directionality (positive to negative relative to reference) depending on the sensitivity cohort. Even so, weighted cessation estimates across sensitivity cohorts stayed within close proximity of one another in both the Trajectory Analysis (**Figure 1**) and the product-use Transition Analysis. The remaining sensitivity analyses showed greater variation in estimation results.

Figure 1. Wave 8 Cigarette Quitting by Any Wave 3-7 Predominant Flavor Use*

Flavor	Base Cohort	Restricted Cohort	Relaxed Cohort
Candy or dessert flavored ENDS	55.5%	56.6%	52.4%
Fruit flavored ENDS	50.3%	50.8%	48.1%
Menthol or mint flavored ENDS	41.6%	43.2%	39.1%
Tobacco flavored ENDS	37.6%	38.7%	36.1%

* ENDS flavors shown on x-axis are predominant flavors used at least once at any Wave from Waves 3 to 7.

Limitations

Sensitivity analyses did not assess other TNP use or account for wave-to-wave differences in PATH survey logic.

Conclusion

- Differing magnitudes pertaining to variability of parameter estimates was observed across each of the sensitivity cohorts .
- Across all sensitivity cohorts, Wave 7 dual use and predominant Candy/Dessert or Fruit ENDS flavor use during Waves 3–7 were associated with higher odds of cigarette cessation at Wave 8.
- In Wave 7–8 analyses, non-Tobacco ENDS flavors were not significantly associated with cigarette cessation nor initiation relative to Tobacco flavor, suggesting that extended use-behavior over time varies from more immediate use-behavior.
- Taken together, these findings suggest that tobacco-use states at a point in time are informed by complex temporal and behavioral factors which need to be carefully considered when developing analytical strategies for PATH analyses.

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