The Role of MarkTen® e-Vapor Flavor Variety in Cigarette Smoking Reduction Among Adult Cigarette Smokers Not Planning to Quit Smoking: Results of a 6-Week At-Home Use Study



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Introduction & Objective

Introduction

- FDA issued Draft Guidance related specifically to electronic nicotine delivery devices suggesting that manufacturers provide information regarding "adult appeal of...flavors in their decisions to... cease use of more harmful products, or
- Recent research suggests that flavors may play an important role in continued e-vapor use after trial and some research suggests that non-tobacco flavors may play a pivotal role in aiding transitions from smoking to vaping.
 (e.g. Audrain-McGovern. Strasser. Wilevto 2016; Barbeau. Burba and Siegel 2013; Czoli et al. 2015; Farsalinos et al. 2013; Harrell et al. 2014; Nonnemaker et al. 2015: Pechacek et al. 2016: Shiffman et al. 2015: Simmons et al. 2016; Soule, Rosas, Nasim 2016)
- Prospective. observational study designs can allow an examination of the role of flavors in tobacco use behaviors in a near real world environment.

Objective

This study characterized MarkTen® e-vapor (MT) use behavior, its influence on other tobacco use behavior, and the potential role of flavor variety on behavioral outcomes among adult cigarette smokers.

Methods

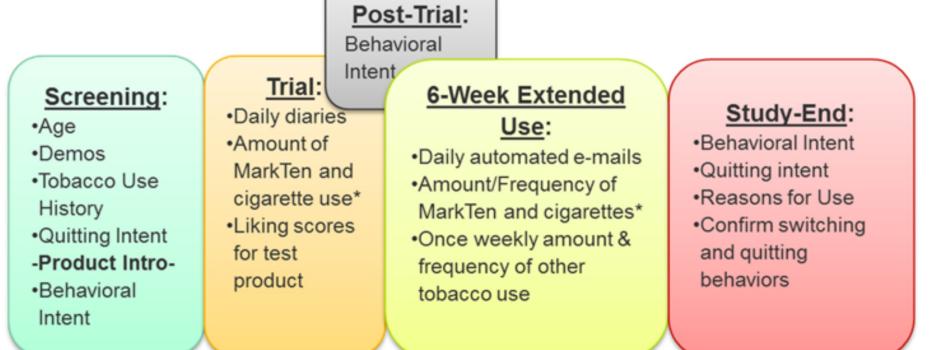
Study Design

We conducted a prospective, observational 8-week, 2-phase, at-home use study in 614 adult cigarette smokers* not planning to quit.

Study Methods

Participants scored a three or higher on a 6-point "intention to try" scale for MarkTen® (MT) products prior to enrollment in Phase 1. During phase 1, participants tried 14 branded MT varieties (1 per day) during a two-week trial. Participants returned for a post-trial visit. Only those who scored a three or higher on a 6-point "intention to use" scale for MT continued to Phase 2. During phase 2, participants had access to the 14 MT varieties and chose the amount and varieties to take home and use over six weeks. Daily surveys captured amount of cigarettes, MT use occasions and number of cartridges (by variety), and other tobacco use in both phases.

Study Overview & Measures



□ Amount: # of occasions/units per day

☐ Behavioral Intentions: Intention to try, use, dual use, switch to the test product

- □ Frequency: # of days per week ☐ Quitting Intentions: Intentions to guit cigarettes/all tobacco in the next 3 months
- □ Liking score: 7-point likability index
- smoking/all tobacco

Demographics

Demographics						
CHARACTERISTIC	CIGARETTE SMOKERS	CIGARETTE SMOKERS/ VAPERS				
BASE (Total Sample)	n = 344	n = 270				
Gender	50% Female	47% Female				
Age						
18-24	7.6%	15.2%				
25-34	26.2%	24.44%				
35-49	41%	36%				
50-64	25.3%	24.4%				
Median Age	40 years	38 years				
Race/Ethnicity	65% White, 20% Black	67% White, 15% Black				
Education	67.7% Some College+	69.6% Some College+				
Employment	73.3% Employed	79.3% Employed				
Median Income Range	\$40-49K	\$40-49K				
Geographic Region	14.8% NE; 21.5% S; 26.5%	13.7% NE; 21% S; 24%				

Screening N = 2,065 2,027 Enrolled: 2-week Trial 441 Lost to Follow-up 406 Product-Related 78 Time Commitment 1,102: 6-week Trial 377 Noncompliant 8 Outliers Final Per

Study Sample Disposition

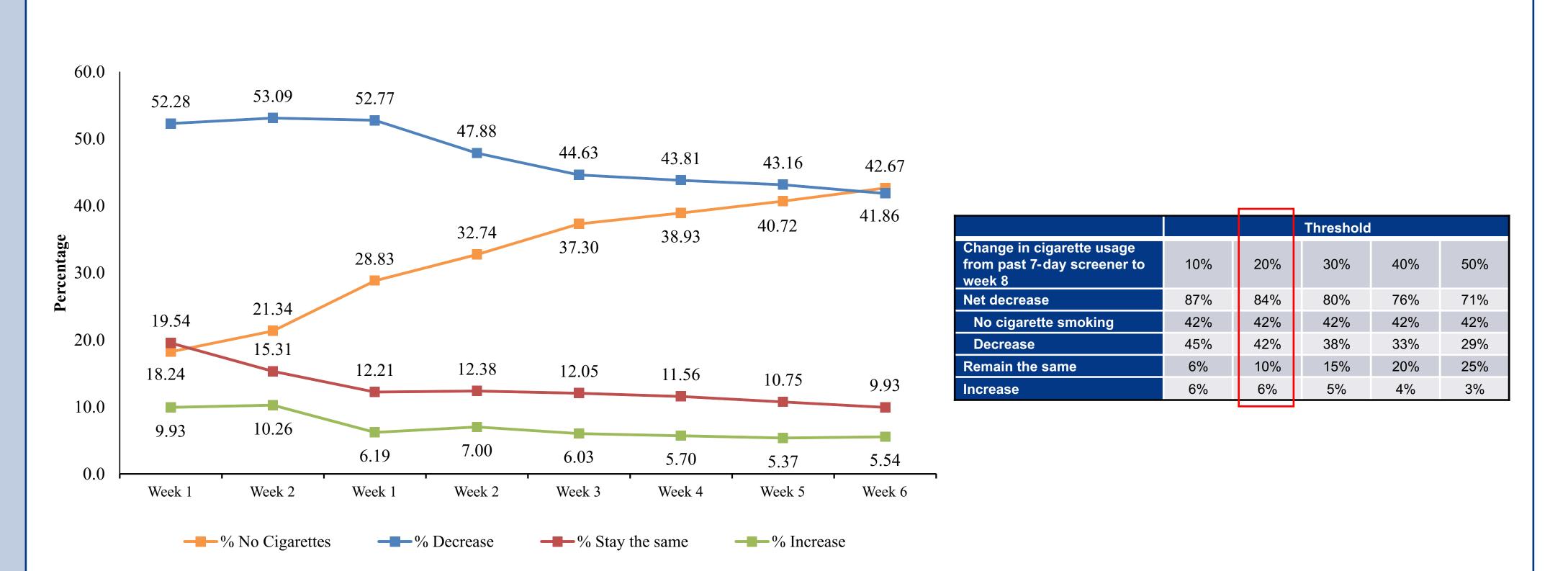
Adult Cigarette Smokers = 344 Adult Dual E-Vapor/Cigarette Users = 270 Exclusive E-Vapor Users= 107 (not reported here)

Tobacco Product Use at Screening

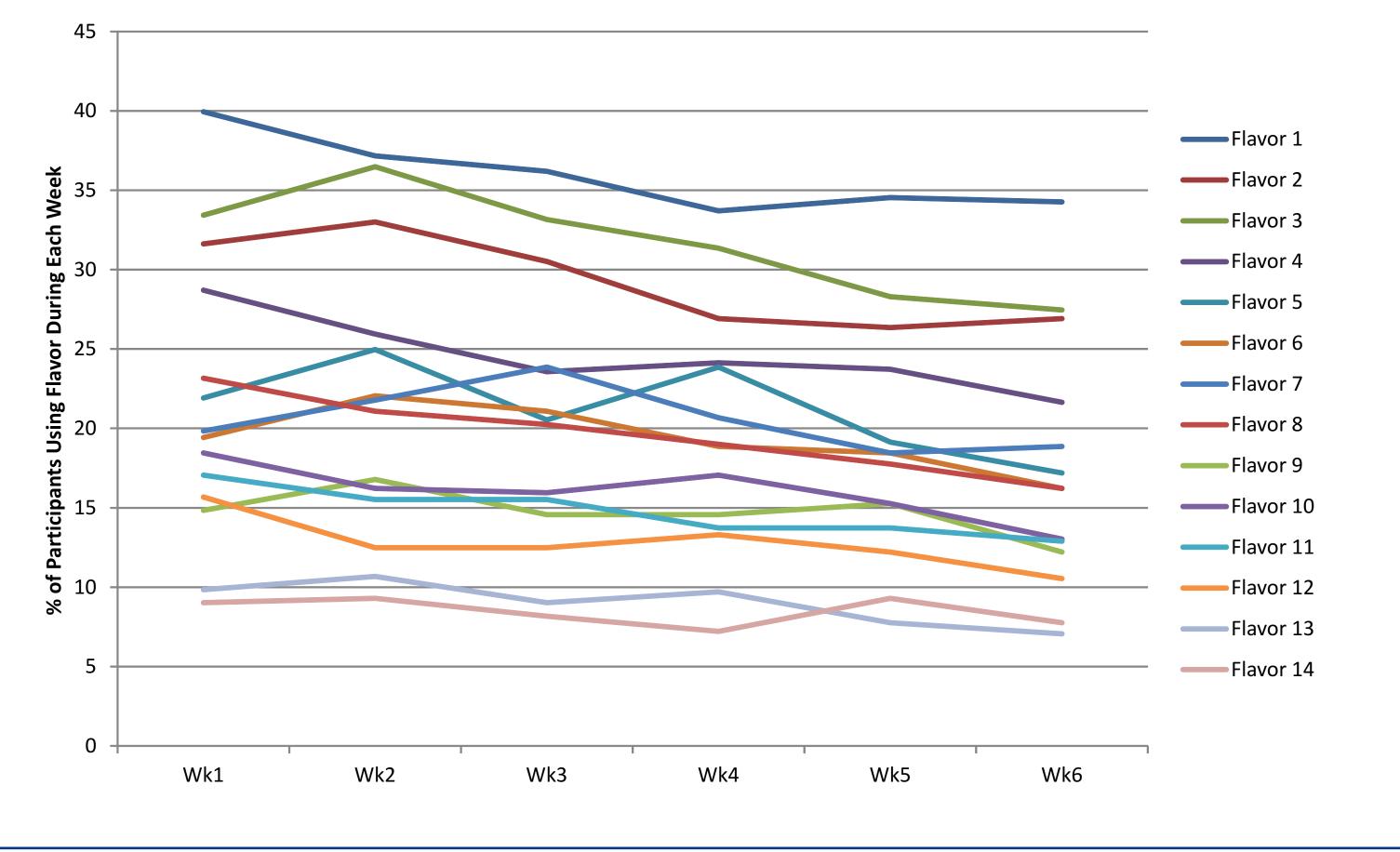
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graphic Region	14.8% NE; 21.5% S; 26.5% MW; 37.2% W	13.7% NE; 21% S; 24% MW; 41% W

*The study also enrolled a group of exclusive e-vapor consumers. Those results are not presented here.

Distribution of Change in Cigarette Use Per Week (Total Sample)



% of Sample Using Each Flavor Variety by Week



Associations Between the Number of MT Flavor Varieties Used and Cigarette Consumption

	M1	M2	M3	M4
	ß (95% CI)	ß (95% CI)	ß (95% CI)	ß (95% CI)
Total sample	-0.4 (-0.7, -0.2)			
Cigarette Smokers		-0.2 (-0.5, 0.04)	-0.2 (-0.5, 0.04)	-0.1 (-0.4, 0.2)
Cigarette Smokers/Vapers		-0.8 (-1.3, -0.4)	-0.8 (-1.3, -0.4)	-0.6 (-1.1, -0.1)

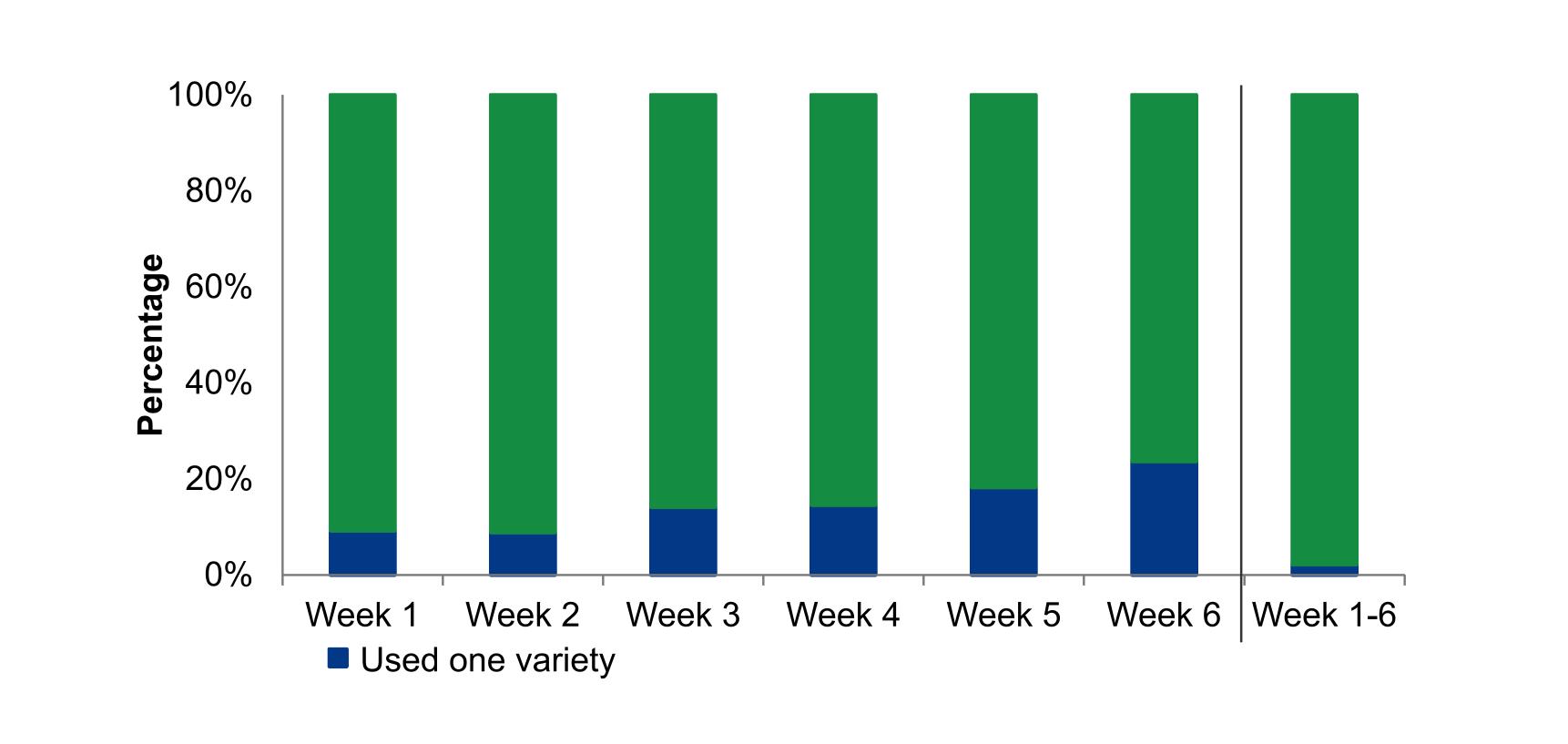
M1 includes number of flavors only. M2 includes a product term between the number of flavors and group assignment. M3 includes variables in M2 and sex, age, income, and being White. M4 includes all variables in M3 and e-vapor consumption. Results of a random-intercept model that included missing values.

Results

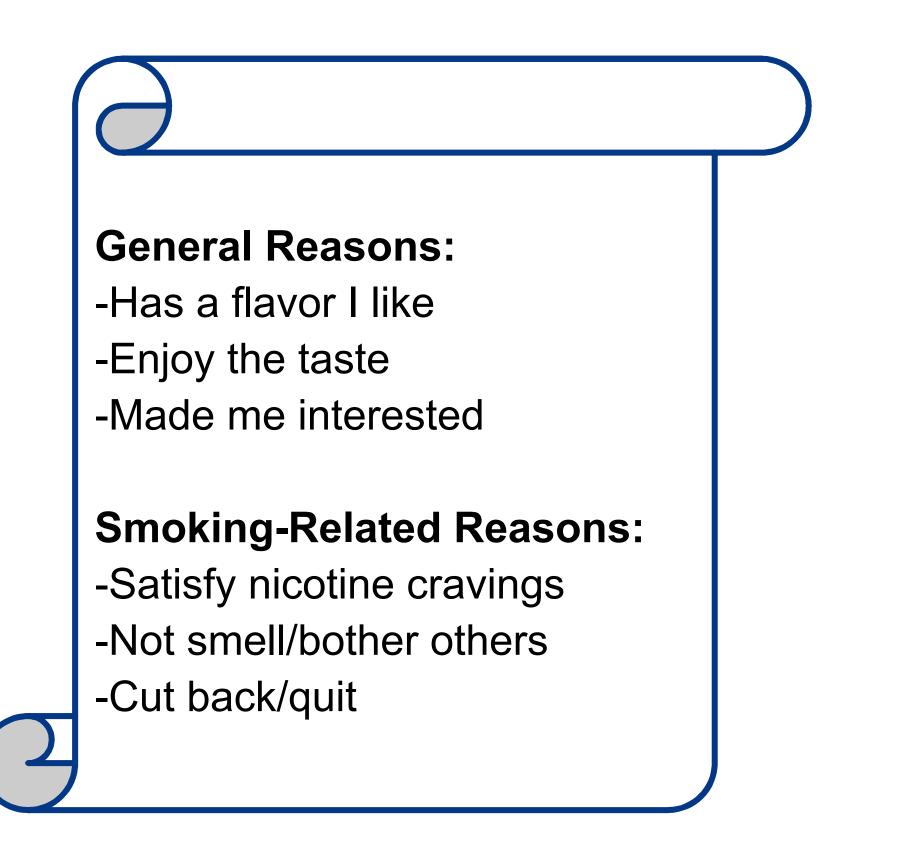
Behavioral Outcomes at Week 6 (Days 36-42)

Behavioral Outcome at Week 6	Total Sample N = 614	Cigarette Smokers N = 344	Cigarette Smokers/ Vapers N = 270
"Started using"* MT e-vapor	81.3%	79.65%	83.3%
"Started using"* MT e-vapor AND reduced** cigarette smoking	36.2%	38.1%	33.7%
"Started using" MT e-vapor AND stopped smoking cigarettes AND still using MT	33.9%	33.7%	34.1%
Other tobacco use	N = 243	N = 93	N = 150
Completely stopped using all "other" tobacco products***	52.3%	62.4%	46%

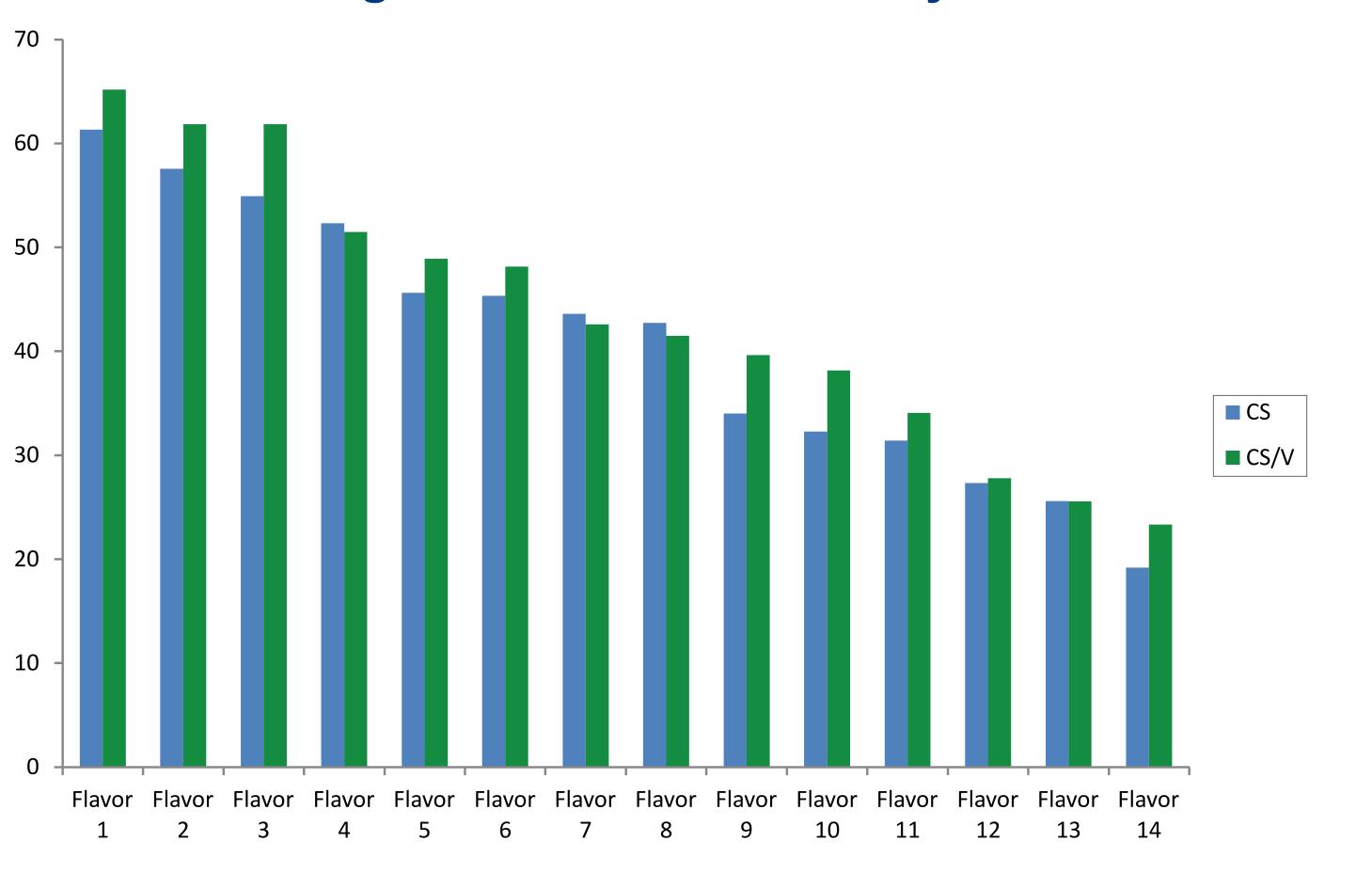
Percentage Used One/More Than One MT Flavor Variety per Week



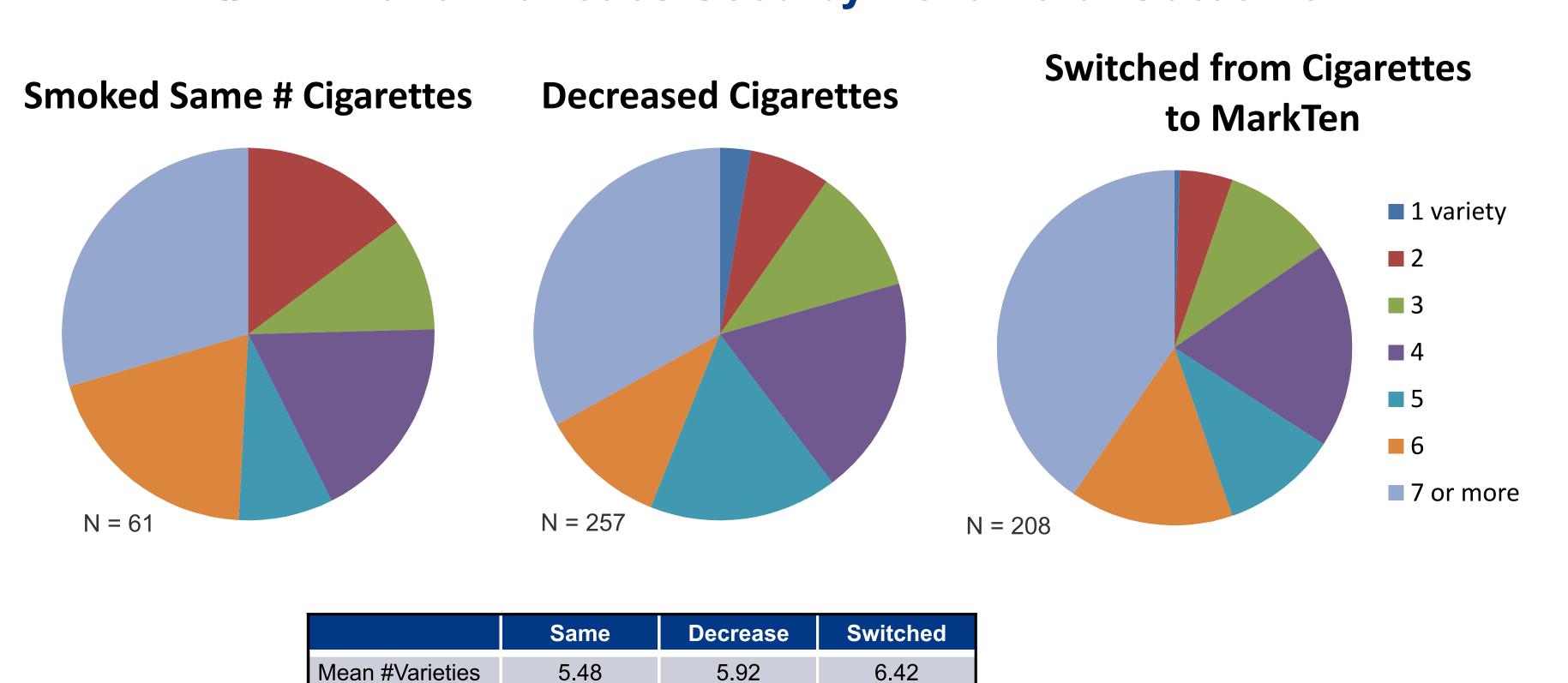
Top Reasons for Continued Use of MT



Percent Using Each MT Flavor Variety: Weeks 1-6



MT Flavor Varieties Used by Behavioral Outcome



Summary & Conclusions

- By week 6 of phase 2, 43% of smokers reported no use of cigarettes, 42% reported a 20% or greater decrease from baseline in cigarettes, 10% remained the same, and 5% increased the number of cigarettes smoked per week.
- 34% stopped smoking cigarettes while still using MT in week 6 (switch).
- Almost 100% of participants used two or more MT flavor varieties during the 6-week period and flavor variety played a role in smoking reduction.
- Over 40% of participants who switched from smoking cigarettes to using e-vapor and 33% of participants that reduced smoking used seven or more MT varieties during the 6-week period.
- A greater number of flavor varieties used was associated with lower levels of cigarette consumption, even after adjusting for overall e-vapor consumption. This association was most robust among baseline cigarette smokers/vapers. • In addition, among participants continuing to use/planning to use MT in the future, 65% selected "has a flavor I like" and
- 55% selected "enjoy the taste" as reasons for use. Results of this study suggest that availability of MT cartridge flavor variety played an important role in adult cigarette smokers' transitions away from potentially more harmful products.
- These findings align with a growing body of literature, which suggests that flavors may play an important role in continued e-vapor use and that flavor variety may play a role in aiding transitions from smoking to vaping. (e.g. Audrain-McGovern, Strasser, Wileyto 2016; Barbeau, Burba and Siegel 2013; Czoli et al. 2015; Farsalinos et al. 2013; Harrell et al. 2014; Nonnemaker et al. 2015; Pechacek et al. 2016; Shiffman et al. 2015; Simmons et al. 2016; Soule. Rosas. Nasim 2016)