The Impact of Trying Electronic Cigarettes on Cigarette Smoking by College Students: A Prospective Analysis

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There has been considerable growth in the availability, marketing, sales, and use of electronic nicotine delivery systems, often referred to as "e-cigarettes," over the past several years. Product sales in the United States have doubled every year since 2008, and securities analysts estimate the e-cigarette market is now approximately a \$2.5 billion industry.¹ E-cigarette use has rapidly increased among adolescents and adults. From 2011 to 2012, rates of ever using e-cigarettes among US middle and high school students doubled from 3.3% to 6.8%.² Similar increases have been seen among US adults.^{3,4} Recent data suggest that e-cigarette use is highest among young adults. Data from the 2012-2013 National Adult Tobacco Survey show that young adults aged 18 to 24 years had a higher prevalence of e-cigarette use (8.3%) than did the adult population as a whole (4.2%).⁵ Similarly, with data from dual frame surveys of national probability samples of adults, McMillen et al. found that current e-cigarette use in 2013 by young adults aged 18 to 24 years (14.2%) was higher than was that among adults aged 25 to 44 years (8.6%), 45 to 65 years (5.5%), and older than 65 years $(1.2\%).^4$

Available data on e-cigarette use by college students are limited, with most coming from single-state or individual campus studies.⁶⁻⁹ College students are an important group to study for several reasons. First, young adulthood is a period of many life transitions and accompanying stress.¹⁰ The tobacco industry is well aware of this vulnerable period and recognizes it as a promising period for tobacco use initiation and transition to addiction.¹¹ Thus, college students are a target market for the tobacco industry.^{11,12} College students are often early adopters of novel products and have historically been at the forefront of societal changes in substance use that later materialize in the general population.¹³ In a cross-sectional study of college students in North Carolina in 2009, Sutfin et al.⁶ found

Objectives. We assessed the impact of trying electronic cigarettes (e-cigarettes) on future cigarette smoking in a sample of smokers enrolled in college.

Methods. In this longitudinal study, first-semester college students at 7 colleges in North Carolina and 4 in Virginia completed a baseline survey and 5 follow-up surveys between fall 2010 and fall 2013. Current cigarette smoking at wave 6 was the primary outcome. Participants (n = 271) reported current cigarette smoking at baseline and no history of e-cigarette use. We measured trying e-cigarettes at each wave, defined as use in the past 6 months.

Results. By wave 5, 43.5% had tried e-cigarettes. Even after controlling for other variables associated with cigarette smoking, trying e-cigarettes was a significant predictor of cigarette smoking at wave 6 (adjusted odds ratio [AOR] = 2.48; 95% confidence interval [CI] = 1.32, 4.66), as were friends' cigarette smoking (AOR = 4.20; 95% CI = 2.22, 7.96) and lifetime use of other tobacco products (AOR = 1.63; 95% CI = 1.22, 2.17).

Conclusions. Trying e-cigarettes during college did not deter cigarette smoking and may have contributed to continued smoking. (*Am J Public Health.* 2015; 105:e83–e89. doi:10.2105/AJPH.2015.302707)

that college students' lifetime prevalence of e-cigarette use was 4.9%, which was higher than were rates of use among other adults at the time,^{14,15} suggesting that college students were early adopters of e-cigarettes.⁶

Additionally, there was an association between e-cigarette use and sensation seeking in bivariate, but not multivariable, models. However, membership in Greek letter organizations was associated with e-cigarette use in multivariable models. These data suggest that college students may be drawn to e-cigarettes owing, at least in part, to their novelty. Finally, college students are an important group to study because they have a unique pattern of cigarette smoking that is often marked by social and occasional smoking.16-18 Studying how e-cigarettes are used by this group and how use may affect cigarette smoking is important for understanding the ultimate public health impact of this product.

Only a handful of longitudinal studies have assessed the relationship between e-cigarette use and subsequent cigarette smoking behavior. However, studying how people use this product is critical to our understanding of the overall public health effects. To date, 6 observational longitudinal studies have been published, with just 3 using population-based samples. Five studies found either no association between e-cigarette use and quitting cigarettes or an association with lower odds of quitting cigarettes,¹⁹⁻²³ with 1 study finding e-cigarette use associated with a reduction in the number of cigarettes smoked.¹⁹ However, only 1 study assessed the intensity of e-cigarette use and associations with quitting cigarettes.24 Results revealed that the most intensive e-cigarette users at follow-up (daily users for at least 1 month) were more likely to have guit smoking (1 month abstinence). However, intermittent e-cigarette use (using e-cigarettes regularly but not daily for more than 1 month) was not associated with increased guitting. Only 1 longitudinal study focused on young adults; to our knowledge, no longitudinal studies have focused on college students.²²

We measured the impact of e-cigarette use during the college years on current cigarette smoking. We included those who reported current cigarette smoking at baseline with no history of e-cigarette use. We measured trying e-cigarettes during the subsequent 4 waves and current cigarette smoking at wave 6, which corresponded to fall 2013. For most participants, wave 6 was during the fall of senior year.

METHODS

Our data are from the Smokeless Tobacco Use in College Students study. The goal of the larger study is to assess trajectories and correlates of smokeless tobacco use in a cohort of college students by surveying them each semester, beginning in their freshman year and continuing through the fall of their senior year. Eleven colleges in North Carolina and Virginia participated in the study, 7 of which are located in North Carolina and 4 in Virginia. Nine are public schools, and 2 are private. School size varies, with undergraduate enrollment ranging from about 4000 to about 23 000. Details about school recruitment can be found elsewhere.^{25,26}

To identify potential members of the cohort, we conducted a screener survey in fall 2010 among all enrolled first-year students.²⁵ A total of 10 528 freshmen at the 11 schools completed the screener survey (response rate of 35.6%), which assessed behaviors including smokeless tobacco use and cigarette smoking. From this sample, we invited students to participate in the longitudinal study. We oversampled smokeless tobacco users, current cigarette smokers, and male students; we randomly sampled all other students.

Procedure

Two weeks after the screener survey, we invited 4902 eligible students to participate in the longitudinal cohort study, of which 3146 (64.2%) completed the baseline fall 2010 survey. We then resurveyed participants in spring 2011, fall 2011, spring 2012, fall 2012, and fall 2013, with excellent retention (80.1%, 78.2%, 79.7%, 80.0%, 79.5%, respectively).

At each wave, we sent all students an e-mail invitation that included information about the survey and a link to a secure Web site for survey completion. We sent nonresponders up to 5 e-mail reminders, a telephone call, and a text reminder. We gave participants a \$15 incentive at baseline, and the incentive increased by \$5 at each wave.

Measures

With the survey, we measured demographics, tobacco use, other substance use, and psychological factors, including sensation seeking.

We measured demographics at baseline, including gender, race (coded as White vs non-White), ethnicity (coded as Hispanic vs non-Hispanic), and mother's educational level (some college or less vs college degree or higher). We assessed membership in Greek letter organizations (fraternities or sororities) at wave 6.

We measured sensation seeking at baseline using the Brief Sensation Seeking Scale developed by Hoyle et al.²⁷ Using a 5-point Likert scale (1 = strongly disagree to 5 = strongly agree), the 8-item scale measures agreement with statements such as "I would like to explore new places and prefer friends who are exciting and unpredictable." We calculated total sensation seeking scores from the average of all items for individuals who answered a minimum of 5 questions on the scale. Higher scores indicate higher levels of sensation seeking. The Cronbach α for the Brief Sensation Seeking Scale was 0.75.

We measured current cigarette smoking and smoking frequency at each survey wave. We asked participants, "Have you ever smoked a whole cigarette?" Response categories were 1 = yes, in the past week; 2 = yes, in the past 30 days but more than a week ago; 3 = yes, in the past 6 months but more than 30 days ago; 4 = yes, in the past year but more than 6 months ago; 5 = yes, more than a year ago; and 6 = no, never. We defined respondents who selected 1 or 2 as current smokers. We also measured smoking frequency as the number of days smoked in the past month. Response options were 0 days, 1 to 2 days, 3 to 5 days, 6 to 9 days, 10 to 14 days, 15 to 19 days, 20 to 29 days, and all 30 days. On the basis of the sample distribution, we created tertilies: 1 to 2 days, 3 to 14 days, and 15 to 30 days.

At wave 6, we measured lifetime use of smokeless tobacco, including chew, dip, snus, and dissolvables; hookah tobacco; little cigars or cigarillos; and large cigars. We created a sum of the number of these tobacco products participants had used at least once in their lifetime. At wave 6, we assessed exposure to peers' smoking by asking if any of the participants' 4 closest friends smoke cigarettes (coded as at least 1 vs none). We measured family smoking at wave 6 with 1 item asking if anyone in the respondents' family, other than themselves, smokes cigarettes (coded as yes vs no).

At each survey wave, we asked participants, "Have you ever used an 'e-cigarette' or an electronic cigarette?" The response categories were 1 = yes, in the past week; 2 = yes, in the past 30 days but more than a week ago; 3 = yes, in the past 6 months but more than 30 days ago; 4 = yes, in the past year but more than 6 months ago; 5 = yes, more than a year ago; and 6 = no, never. We defined trying e-cigarettes as answering 1, 2, or 3 at waves 2 to 5 and still being a current cigarette smoker. We excluded participants who had already tried e-cigarettes by the baseline survey and those who reported first trying e-cigarettes at wave 6.

At wave 6, we measured reasons for e-cigarette use. We asked participants who reported ever use, "Why did you try e-cigarettes?" Response options were "I was curious about the product," "It might be better for my health than smoking cigarettes," "My friends use e-cigarettes," "I can use it in places where cigarette smoking is not allowed," "To help me quit smoking," "To cut down on smoking," and "It doesn't smell bad." We instructed participants to select all responses that applied.

Statistical Analyses

We performed bivariate analyses to examine variables associated with trying an e-cigarette between baseline and wave 5. We conducted analyses using mixed-effects logistic regression models to account for within-school correlation using a random-effect for school.²⁸ We then performed multivariable mixed-effects logistic regression analyses to examine the association between trying an e-cigarette between baseline and wave 5 (predictor) and current cigarette smoking at wave 6 (outcome) after adjustment for potential confounding variables.

We calculated adjusted odds ratios (AORs) and 95% confidence intervals (CIs) for all variables. We performed analyses using GLLAMM in Stata version 12 (StataCorp LP, College Station, TX). We considered a 2-sided P<.05 statistically significant. To examine the impact of missing data on our findings, we

performed bivariate analyses to examine differences in baseline characteristics between the analysis sample (n=271) and the sample with missing data (n=310). We performed a sensitivity analysis for the multivariable mixed-effects logistic regression model predicting cigarette smoking at wave 6 using multiple imputations.^{29,30} We generated 20 imputed data sets (581 observations each) using ICE in Stata version 12. We analyzed results on each data set using GLLAMM and combined them using MICOMBINE.

RESULTS

Of the 3146 members of the cohort, 669 (21.3%) were current cigarette smokers at

baseline with no history of e-cigarette use. We excluded individuals who first tried an e-cigarette between wave 5 and wave 6 (n=73) and those who were not current cigarette smokers when they first tried e-cigarettes (n=15) from our analytic sample. Of the remaining 581 individuals, 323 (55.6%) had sufficient data at intervening waves to determine whether they had tried an e-cigarette while being a current smoker. The analytic sample consisted of the 271 of these 323 individuals who had data on the outcome at wave 6 and other covariates of interest.

A little more than half of the sample of 271 participants were female (51.7%). Table 1 shows the sample demographics. The majority were non-Hispanic (94.1%) and White

(89.7%). Almost 60.0% had a mother with a college degree or higher. Less than one quarter of the sample (24.4%) had joined a Greek letter organization by wave 6. At baseline, about 40.0% reported cigarette smoking only 1 to 2 days per month, 39.5% smoked 3 to 15 days per month, and 21.4% reported smoking more than 15 days per month.

The mean number of tobacco products used in their lifetime was 2.78 (SD = 1.14). Two thirds reported having at least 1 friend who smokes cigarettes and almost 40% reported having a family member who smokes (at wave 6). The mean sensation seeking score was 3.59 (SD = 0.66). Bivariate mixed-effects logistic regression models revealed no significant

Characteristic	Full Sample (n = 271), No. (%) or Mean \pm SD	Tried E-Cigarettes (n = 118), No. (%) or Mean \pm SD	Have Not Tried E-Cigarettes (N = 153), No. (%) or Mean \pm SD	Pª
Gender				.616
Female	140 (51.7)	63 (53.4)	77 (50.3)	
Male	131 (48.3)	55 (46.6)	76 (49.7)	
Race				.097
White	243 (89.7)	110 (93.2)	133 (86.9)	
Non-White	28 (10.3)	8 (6.8)	20 (13.1)	
Ethnicity				.592
Hispanic	16 (5.9)	8 (6.8)	8 (5.2)	
Non-Hispanic	255 (94.1)	110 (93.2)	145 (94.8)	
Mother's education				.012
College degree or higher	161 (59.4)	60 (50.8)	101 (66.0)	
Some college or less	110 (40.6)	58 (49.2)	52 (34.0)	
Greek status (wave 6)				.177
Member or pledge	66 (24.4)	24 (20.3)	42 (27.5)	
Non-Greek	205 (75.6)	94 (79.7)	111 (72.5)	
Baseline smoking frequency, d per mo				< .001
1-2	106 (39.1)	26 (22.0)	80 (52.3)	
3-15	107 (39.5)	47 (39.8)	60 (39.2)	
> 15	58 (21.4)	45 (38.1)	13 (8.5)	
Lifetime other tobacco use (wave 6)	2.78 ±1.14	3.01 ±1.10	2.61 ±1.14	.005
Family member smokes (wave 6)				.036
Yes	107 (39.5)	55 (46.6)	52 (34.0)	
No	164 (60.5)	63 (53.4)	101 (66.0)	
Friend smokes (wave 6)				< .001
Yes	181 (66.8)	93 (78.8)	88 (57.5)	
No	90 (33.2)	25 (21.2)	65 (42.5)	
Baseline mean sensation seeking	3.59 ± 0.66	3.62 ±0.69	3.56 ±0.63	.459

^aP value comparing those who tried e-cigarettes with those who did not.



FIGURE 1—Trying e-cigarettes during college by baseline cigarette smokers (n = 271) with no history of e-cigarette use: North Carolina and Virginia, 2010–2013.

differences on any baseline characteristics between the 271 participants with complete data and the 310 participants not included because of missing data.

Figure 1 displays the percentage of baseline smokers with no history of e-cigarette use who reported having tried e-cigarettes by the follow-up survey wave. The prevalence of having tried an e-cigarette among our sample of 271 increased from 13.3% at wave 2 to 43.5% at wave 5. Table 1 displays sample demographics by trying e-cigarettes. Those who tried e-cigarettes were less likely to have a mother with a college degree or higher (P=.012) but were more likely to smoke cigarettes on more days at baseline (P < .001), have tried more tobacco products in their lifetime (P < .005), have family members who smoke (P=.036), and have friends who smoke (*P*<.001).

To assess the impact of trying e-cigarettes on subsequent cigarette smoking behavior, we conducted a multivariable logistic regression analysis with current cigarette smoking at wave 6 as the outcome. The predictors were demographics as well as several variables known to be associated with cigarette smoking: membership in Greek letter organizations,¹⁶ lifetime other tobacco use, family members'³¹ and friends' smoking,^{32–34} sensation seeking,³⁵ and trying e-cigarettes during waves 2 to 5.

For this analysis, we defined trying e-cigarettes as trying them at 1 or more waves. Results showed that trying e-cigarettes compared with not trying them was associated with increased odds of current cigarette smoking at wave 6 (AOR = 2.48; 95% CI = 1.32, 4.66). The only other variables that predicted current cigarette smoking were reporting 1 or more peers who smoke cigarettes (AOR = 4.20; 95% CI = 2.22, 7.96) and lifetime other tobacco use (AOR = 1.63; 95% CI = 1.22, 2.17; Table 2).

Because we restricted the analysis to only those with complete data, we also conducted a multiple imputation analysis. We performed this analysis on a sample of 581 individuals and included the same independent variables as those in Table 2. Results were very similar to the complete case analyses. Trying e-cigarettes (AOR=2.37; 95% CI=1.26, 4.47), peer smoking (AOR=4.25; 95% CI=2.44, 7.42), and lifetime other tobacco use (AOR=1.58; 95% CI=1.28, 1.95) were still significant predictors of cigarette smoking at wave 6.

We conducted an additional analysis to assess the impact of e-cigarette use at multiple waves, which may or may not have been consecutive, on current cigarette smoking at wave 6. Results indicated that e-cigarette use at 2 or more waves compared with never use was associated with increased odds of current cigarette smoking at wave 6 (AOR = 3.76; 95% CI = 1.81, 7.79); however, use at just 1 wave compared with never use did not predict cigarette smoking at wave 6 (AOR = 1.06; 95% CI = 0.43, 2.64). As in the other analyses, peer cigarette smoking (AOR = 3.96; 95% CI = 2.06, 7.60) and lifetime other tobacco use (AOR = 1.59; 95% CI = 1.18, 2.14) were associated with cigarette smoking at wave 6.

At wave 6, we measured reasons for trying e-cigarettes (Table 3). The vast majority (91.6%) reported curiosity about the product as a reason for trying them. The second most endorsed reason was friends used them (70.2%), followed by beliefs of relative safety compared with cigarettes (69.9%). Lack of odor and use where cigarette smoking is not allowed were both endorsed by half the sample. About 31.0% endorsed cutting down on smoking, whereas the least endorsed response was to help with cessation (20.2%).

DISCUSSION

We prospectively assessed the impact of trying e-cigarettes on subsequent cigarette smoking in a sample of college students who were cigarette smokers at baseline. As found in other studies of college students, our sample of smokers reported mostly occasional cigarette smoking.^{16–18,36} About 40% of our sample reported smoking on just 1 to 2 days in the past month, with another almost 40% reporting smoking on 3 to 15 days per month. Only 21% reported smoking on more than half the days in the past month. This suggests that our sample of smokers consisted largely of occasional smokers.

 TABLE 2—Multivariable Mixed-Effects Logistic Regression Model for Current Cigarette

 Smoking at Wave 6 (n = 271): North Carolina and Virginia, 2010–2013

	Current Cigarette Smoking at Wave 6 AOR (95% CI)	ig at Wave 6
Variable		Р
Tried e-cigarettes	2.48 (1.32, 4.66)	.005
Baseline smoking frequency, d per mo		
>15 vs 1-2	1.91 (0.82, 4.45)	.134
3-15 vs 1-2	1.68 (0.87, 3.23)	.123
Lifetime other tobacco use	1.63 (1.22, 2.17)	.001
Mother has college degree or higher	0.98 (0.53, 1.82)	.959
Male gender	1.10 (0.60, 2.02)	.761
Hispanic	2.04 (0.60, 6.93)	.252
Non-White	0.96 (0.36, 2.55)	.944
Membership in Greek organization	1.13 (0.57, 2.23)	.72
\geq 1 friends who smoke	4.20 (2.22, 7.96)	<.001
\geq 1 family members who smoke	0.99 (0.54, 1.82)	.986
Baseline sensation seeking	1.15 (0.74, 1.81)	.527

Note. AOR = adjusted odds ratio; CI = confidence interval.

Trying e-cigarettes rose dramatically during the 4-year period, which is consistent with cross-sectional studies.²⁻⁴ By wave 5, which for most students in our sample corresponded with fall of junior year (2012), just less than half the sample reported ever using e-cigarettes. This finding is consistent with the growing body of literature that finds that trying e-cigarettes is highest among cigarette smokers.^{3,19} For example, King et al. found that current use of e-cigarettes in 2013 was higher for current daily cigarette smokers (30.3%) and nondaily cigarette smokers (5.4%) or never cigarette smokers (1.4%).³ Those who tried e-cigarettes were less likely to have mothers with a college degree or higher and to have tried more tobacco products. They were also more likely to smoke cigarettes on more days in the past month and to have friends and family members who smoke cigarettes. This suggests that cigarette smoking behaviors and norms are closely tied to trying e-cigarettes. Moreover, friends' use of e-cigarettes was reported as the second most common reason for trying e-cigarettes among our sample. Kong et al. found that friends' use of e-cigarettes was endorsed as a reason for trying e-cigarettes among college students more than among younger ever users, and, as

TABLE 3–Reasons for Trying E-Cigarettes: North Carolina and Virginia, 2010-2013

Reasons for Trying E-Cigarettes	No. (%)	
I was curious about the product.	87 (91.6)	
My friends use e-cigarettes.	66 (70.2)	
It might be better for my health than smoking cigarettes.	65 (69.9)	
It doesn't smell bad.	47 (50.0)	
I can use it in places where cigarette smoking is not allowed.	47 (50.0)	
I use it to cut down on smoking.	29 (30.8)	
I use it to help me quit smoking.	19 (20.2)	

in our study, that it was the second most common reason overall. $^{\rm 37}$

For this population of college students, e-cigarette use may be associated more with novelty seeking than with use as a cessation aid. The vast majority of participants cited curiosity as a reason for use, whereas just one fifth endorsed cessation. Curiosity as a motivator of trying e-cigarettes is consistent with Kong et al.'s mixed-method study of middle school, high school, and college students.³⁷ Using focus groups and survey methodology, they found curiosity to be a commonly identified reason for trying e-cigarettes among all age groups, including college students.

However, these findings diverge from those of Rutten et al. They assessed reasons for e-cigarette use in a sample of established adult smokers.38 More than half of the participants reported quitting (58.4%) or reducing (57.9%) cigarette smoking as reasons for trying e-cigarettes. This suggests that reasons for use may differ between these populations. Two potential motivations for use that we did not measure are availability in a wide range of flavors and interest in the technology. Using focus groups and interviews with young adults in New York City, McDonald and Ling found that flavored solutions are an attractive aspect of e-cigarettes.³⁹ Participants also highlighted the technological nature of the devices as being 1 more "toy" to add to their collection of technology gadgets.

In our sample of largely occasional cigarette smokers, those who tried e-cigarettes were more likely to still be current cigarette smokers at wave 6 than were those who did not try e-cigarettes. Even after controlling for other variables known to be related to cigarette smoking, trying e-cigarettes was a significant predictor of cigarette smoking. We also assessed the association between trying e-cigarettes at more than 1 wave and continued cigarette smoking at wave 6. Results showed that e-cigarette use at 2 or more waves, which may or may not have occurred in consecutive waves, compared with never use, was associated with continued cigarette smoking at wave 6, but e-cigarette use at 1 wave was not. These findings suggest that for college student smokers, trying e-cigarettes and, in particular, repeated e-cigarette use is a predictor of continued cigarette smoking.

Limitations and Strengths

This study is not without limitations. Because we capitalized on an existing longitudinal study, we were able to assess e-cigarette use over a 4-year period. However, we designed the study to assess longitudinal patterns of smokeless tobacco use, so the data available on e-cigarette use were limited. For example, we did not measure e-cigarette frequency, so we were not able to assess the impact of intense versus intermittent e-cigarette use, as Biener and Hargraves did.²⁴

A strength of this study is that it allowed us to observe the natural course of e-cigarette use in a large sample of college students. However, as with any observational study, differences in groups may have been the result of unmeasured variables, even though we controlled for many covariates known to be associated with cigarette smoking. This potential selection bias limited our ability to firmly establish causality; however, we did adjust for several known factors that are associated with cigarette smoking in this population.

This study was also limited in generalizability, because it involved 4-year college students from 2 states.

Conclusions

These findings support a growing body of literature that shows e-cigarette use is not prospectively associated with cessation of cigarettes.^{19–23} However, 1 study found that higher e-cigarette intensity (use daily for at least 1 month) was associated with increased likelihood of quitting.²⁴ More research is needed to determine whether continued, regular e-cigarette use is associated with higher rates of smoking cessation in this population.

To our knowledge, this is the first prospective study of the impact of e-cigarette use on college students' cigarette smoking. Results suggest that for this population, e-cigarette use is associated with continued cigarette smoking, even after controlling for several important covariates. The rapidly changing technology for this product points to the need for more research.

Initial e-cigarette models that closely resembled conventional cigarettes were found to be poor deliverers of nicotine.^{40,41} In recent years, newer models have emerged that include larger batteries and tank systems that can be filled with e-liquid of varying nicotine strengths as well as modifiable products that can be customized by users.^{42,43} These design features, including the amount of nicotine in the solution and battery voltage, have a direct impact on the levels of nicotine users inhale.^{44,45} Future studies should consider how different types of e-cigarettes affect cigarette smoking in this population. ■

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Contributors

E. L. Sutfin led the conceptualization of this article, contributed to measures development and data collection and analysis, and wrote the first draft and subsequent revisions. B. A. Reboussin conducted all statistical analyses. B. Debinski, K. G. Wagoner, J. Spangler, and M. Wolfson contributed to the measures development and conceptualization and reviewed drafts of the article. All authors approved the final article.

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Human Participant Protection

The study protocol was approved by the Wake Forest School of Medicine institutional review board. Additional privacy protection was secured by the issuance of a certificate of confidentiality by the Department of Health and Human Services. Some participating schools also chose to seek their own institutional review board approvals.

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