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Changes in Tobacco Dependence and Association with Onset and Progression of Use by Product Type from Wave 1 to Wave 3 of the Population Assessment of Tobacco and Health (PATH) Study

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# Data Availability Statement:

Data are available in a public, open-access repository, the National Addiction and HIV Data Archive: https://www.icpsr.umich.edu/web/NAHDAP/studies/36498

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#### ABSTRACT

**Introduction.** This study examined trajectories of tobacco dependence (TD) in relationship to changes in tobacco product use, and explored the effects of product-specific adding, switching, or discontinued use on dependence over time.

Methods. Data were analyzed from the first three waves from the Population Assessment of Tobacco and Health (PATH) Study, a nationally representative, longitudinal study of adults and youth in the United States (U.S.). Data included 9556 Wave 1 (2013/2014) adult current established tobacco users who completed all three interviews and had established use at ≥2 assessments. Groups included: users of cigarettes only, e-cigarettes only, cigars only, hookah only, any smokeless only, cigarette + e-cigarette dual users, and multiple product users. A validated 16-item scale assessed TD across product users.

**Results.** Wave 1 e-cigarette only users' who maintained exclusive e-cigarette use increased levels of TD through Wave 3 as did those who added or switched to another product. Wave 1 multiple product users' TD decreased across waves. TD for all other Wave 1 user groups remained about the same. For Wave 1 cigarette only smokers, switching to another product or moving to a pattern of no established use was associated with lower levels of TD than smokers whose use stayed the same. Movement to no established use of any tobacco product was consistently associated with lower TD for all other product users.

**Conclusions.** Except for Wave 1 e-cigarette only users, TD among U.S. tobacco product users was stable over time, with daily users less likely to vary from baseline.

#### IMPLICATIONS

The level of TD among most U.S. tobacco users was stable over the first three waves of the PATH Study and trends in levels of TD were predominantly unrelated to changes in patterns of continued product use. Stable levels of TD suggest a population at persistent risk of health impacts from tobacco. Wave 1 e-cigarette users, including those maintaining exclusive e-cigarette use experienced increasing levels of TD over time, perhaps due to increases in quantity or frequency of their ecigarette product use or increasing efficiency of nicotine delivery over time.

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#### INTRODUCTION

Over the past 25 years, assessment of biological markers suggests that levels of nicotine exposure among persistent smokers in the United States (U.S.) have not changed.<sup>1,2</sup> Consistent with symptoms of tobacco dependence (TD) reflecting drive (e.g., craving) and sustained tobacco use have remained stable for more than a decade among U.S. adult smokers.<sup>3</sup> However, given the increasingly common use of non-cigarette tobacco products, it remains important to study the development and course of physiological and behavioral features used to characterize dependence at the population level.

The Population Assessment of Tobacco and Health (PATH) Study has enabled comprehensive examination of the reliability of multiple indicators of TD across a range of tobacco products. In our previous work,<sup>4</sup> Wave (W) 1 (2013/2014) and W2 (2014/2015) data were analyzed from a U.S. nationally representative sample of 32,320 W1 adult (18 years and older) participants who used any tobacco product in the past 12 months. We validated an instrument using 16 items borrowed from existing scales<sup>4-6</sup> that enables comparison of TD across users of cigarettes, e-cigarettes, cigars, hookah, smokeless, and multiple tobacco products.<sup>7</sup> The TD scale demonstrated strong relationships with urinary biomarkers of total nicotine equivalents, predictive associations with persistent tobacco use, and described associations with changes in patterns of product use.<sup>8,9</sup>

One study, using PATH Study data, examined associations between TD and transitions in tobacco product use across Waves 1 and 2. Adults with high TD were less likely to discontinue cigarette smoking and all tobacco than adults with low dependence.<sup>10</sup> More dependent tobacco users were also more likely to switch among products, and highly dependent cigarette smokers were more likely to add products compared to less dependent smokers. In the current study, we examine patterns of use into W3, which provides the opportunity to examine multiple transitions in use.

Study objectives are to 1) understand trajectories of TD scores in relationship to changes in tobacco use, and 2) explore associations of adding, switching product patterns, or discontinued use

of products with TD across W1-W3. Groups of interest include exclusive users of cigarettes, ecigarettes, cigars, hookah, smokeless tobacco, dual cigarette/e-cigarette users and multiple product users.

# **METHODS**

#### **Study Participants**

Data come from the PATH Study, an ongoing, nationally-representative, longitudinal cohort study of adults in the U.S. The study uses audio computer-assisted self-interviews available in English and Spanish to collect self-reported information on tobacco-use patterns and associated behaviors. Recruitment employed a stratified address-based, area-probability sampling design at W1 that oversampled adult tobacco users, young adults (18 to 24 years), and African-American adults.

Weighted response rates for W1 (2013/2014), W2 (2014/2015), and W3 (2015/2016) adult interviews were 74.0%, 83.2% and 78.4%, respectively. W2 and W3 data collection protocols followed procedures to interview each respondent close to the 1-year anniversary of their participation in the prior wave. Full-sample and replicate weights were created that adjust for the complex sample design (e.g., oversampling at W1) and nonresponse at W1-W3. Combined with the use of a probability sample, the weights allow analyses of the PATH Study data to compute robust estimates for the U.S. population ages 18 years and older.<sup>11</sup> Further details regarding the PATH Study design<sup>12</sup> and data are described in the *PATH Study Restricted Use Files (RUF) User Guide* at https://doi.org/10.3886/Series606. The study was conducted by Westat and approved by the Westat Institutional Review Board.

The current study analyzes data from 9,556 W1 adult current established tobacco users who completed all three interviews and had persistent established use at two or more interviews/waves. A current established cigarette user at W1 was defined as: An adult who has smoked at least 100 cigarettes in his/her lifetime and now smokes every day or some days. For all other tobacco products,

a current established user was defined as an adult who has ever used the product "fairly regularly" and now uses it every day or some days. Mutually exclusive tobacco-user groups at W1 who also completed all three interviews include: cigarette only users (n=5,945), e-cigarette only users (n=287), cigar only (traditional, cigarillo, or filtered) users (n=387), hookah only users (n=248), smokeless tobacco only users (n=620), cigarette plus e-cigarette users (n=498), and users of multiple tobacco products (at least two or more products above or pipe or dissolvable products in the past year other than cigarette plus e-cigarette users) (n=1571).

### **Tobacco Use Outcome**

We defined tobacco product use outcomes at W2 and W3 accordingly: a) Same: Continued established use of same product(s) as in the previous wave, b) Switched: Change in the established use of product(s) from the previous wave, c) Added: Continued established use of the same product(s) and established use of an additional product(s) not reported in the previous wave, and d) No Established Use: No established use of any product in the examined wave. We also indexed use frequency among past 30 day product users and categorized these as: daily users (reported use during all 30 days), or non-daily users (used fewer than 30 days).

# Symptoms of TD at Waves 1-3

The adult interview included 24 symptoms of TD, of which 16 TD symptoms were identified as a scale for use across tobaeco products.<sup>7</sup> Single product users were asked TD items that referred to their specific product in the item/question stem. Dual users of cigarettes and e-cigarettes were offered parallel sets of TD items, one set for each product, but for this analysis, response to items for cigarettes were used to assess TD in the Cigarette+E-Cigarette user group. Users of multiple products were asked TD items that referred broadly to "tobacco" in the item stems and did not receive repeated assessments for each product they reported using. Selected items were derived from the Wisconsin Inventory of Smoking Dependence Motives (WISDM; 11 items),<sup>5</sup> Nicotine Dependence Syndrome Scale (NDSS; 4 items),<sup>4</sup> and Diagnostic and Statistical Manual (DSM) Criteria (1 item).<sup>6</sup> Item response options from original instruments were adapted for the PATH Study. Following scoring

procedures<sup>7</sup>, WISDM and NDSS five-level categorical responses were assigned to three levels by converting options 1, 2-3, and 4-5 to 0, 1, and 2, respectively. The two-level DSM criteria was scored 0 if not present ('No') and 2 if present ('Yes'). A raw sum score of item options will range from 0 to 32 with 2 as the max score for each of the 16 items. Item options also were multiplied by 50 to allow each item to contribute equally to a total score by balancing the uneven number of categories across items in this rating scale and to produce an average TD item score ranging from 0-100, where higher scores represented higher levels of TD.

### Analysis

The primary dependent variable was the TD score at W1-W3. The primary independent variables were W1 tobacco use group and changes in established pattern of tobacco use between W1-W2 and between W2-W3 (Same, Added, Switched, and No Established Use). Covariates included W1 daily tobacco use, age (18-24 years, 25-34 years, and 35 years+), sex (male vs. female), racial/ethnic groups (Non-Hispanic White vs. All other groups), daily use and former tobacco use prior to W1. Growth curve models were constructed to simultaneously evaluate within-person influences of change in patterns of use within each W1 tobacco user group (via time-varying covariates) and between-person influences of demographic characteristics, W1 daily use and former tobacco use prior to W1 on stability and change of TD over time.<sup>13</sup> Time-varying indicators of tobacco use patterns were related directly to TD assessed at the corresponding wave while controlling for the influence of levels of TD at W1 and average changes in TD over waves.<sup>14</sup> Thus, W2 and W3 measures of TD are jointly determined by the underlying intercept and slope growth factors and the impact of the pattern of tobacco use at that wave.

All-waves longitudinal weights with nonresponse adjustments were used with W1-W3 of the adult RUF. The Balanced Repeated Replication method with Fay's adjustment set to 0.3 was used for all analyses of weighted data as computed by the survey package<sup>15</sup> and lavaan.survey package<sup>16</sup> in R.<sup>17</sup> Missing data on age, sex, race, and Hispanic ethnicity were imputed at W1 as described in the PATH Study RUF User Guide. Due to an instrument error, W3 assessments of TD were not available for all respondents (n=1,117/9,556; 12% were imputed). We assumed that the data was missing at

random and was unrelated to product use groupings. We used a multiple imputation (imputed data sets = 20) approach and the mice package<sup>18,19</sup> to incorporate sample weights as a covariate when estimating growth curve models of TD that include W3 assessments.

### RESULTS

#### **Descriptive Analyses**

Weighted sample demographic characteristics are presented in Table 1. Population weighted average TD scores at W1 was 50.62 (se = 0.37) with a standard deviation (TD<sub>sd</sub>) of 29.24 (se=3.05). Population levels of TD for scores 0-18 were considered lower ( $<33^{rd}$  percentile), TD scores 19-55 were considered medium ( $33^{rd} - 65^{th}$  percentile) and TD scores 56-100 were considered highest ( $66^{th}$  percentile) levels of Wave 1 based on weighted terciles for TD scores for respondents who participated in all 3 surveys and had non-missing TD scores (n=13,262). The population standard deviation of TD was used throughout the results to compute standardized estimates (d) of the magnitude of differences in average levels of TD using standard deviation units.

Post-hoc analysis used a Signed Differential Test Functioning (sDTF) statistic to properly account for sampling variability in item parameter estimates<sup>20</sup> when quantifying the amount of any scoring bias in TD between W1 tobacco user groups who reported no current established use but only past year use at W2 (n=381) or W3 (n=580). sDTF suggested minimal bias in comparing expected TD scores to W2 (n=9131) and W3 (n=7901) current users. Very small positive values of sDTF at W2 (sDTF=0.02, 95%CI=0.020, 0.022) and very small negative values at W3 (sDTF=-0.0286, 95%CI=-0.0294, -0.0280) indicated that current tobacco users (reference group) on average scored within one raw unit difference than past year users with the same level of TD (see Supplement Figure 1).

#### **TD Trajectories for Wave 1 Tobacco User Groups**

Figure 1 shows the weighted average level of TD (scaled 0-100) for W1 tobacco user groups across each wave. Weighted latent growth curve models with covariates at W1 were used to compare W1 levels of TD ( $TD_{Intercepts}$ ) and changes in TD ( $TD_{slopes}$ ) across the seven tobacco user groups. Sex, age group, and race-ethnicity each were associated with W1 levels of TD ( $TD_{Intercept}$ ) and changes in TD over the three waves ( $TD_{Slopes}$ ). In this model, being a daily user of tobacco product(s) was significantly associated with higher W1 TD (TD<sub>Intercept</sub>=0.328, se=0.007, p<0.001; d=1.12) and less change in TD (TD<sub>Slopes</sub>=-0.030, se=0.004, p<0.001) than among non-daily tobacco users (Table 2).

Figure 1 shows a stable trajectory of high levels of TD for W1 Cigarette Only users that decreased only slightly through W3. When compared (Table 2) to W1 Cigarette Only users, W1 E-Cigarette Only users had lower levels of TD at W1 (TD<sub>intercept</sub>=-0.24, se=0.02, p<0.01; d=0.82) and had a greater increase (TD<sub>Slope</sub>=0.07, se=0.01, p<0.01) in TD reflecting a moderate increase from W1 to W3 (d=0.41). W1 Cigar Only (TD<sub>Intercent</sub>=-0.16, se=0.02, p<0.01; d=0.55), W1 Hookah Only (TD<sub>Intercept</sub>=-0.15, se=0.03, p<0.001; d=0.51, and W1 Smokeless Only (TD<sub>Intercept</sub>=-0.04, se=0.02, p=0.01; d=0.14) tobacco user groups also had lower levels of TD at W1 than W1 Cigarette Only users although rates of change in TD (TD<sub>slopes</sub>) among these user groups were not significantly different than rates of change among W1 Cigarette Only users. When compared to W1 Cigarette Only users, W1 multiple product users including W1 Cigarette+E-Cigarette (TD<sub>Intercept</sub>=0.03, se=0.01, p=0.02; d=0.10) and W1 Multiple Product users (TD<sub>Intercept</sub>=0.04, se=0.01, p<0.01; d=0.14) had higher levels of TD at W1. W1 Cigarette+E-Cigarette users (TD<sub>Slopes</sub>=-0.01, se=0.007, p=0.21) had rates of change in TD (TD<sub>slopes</sub>) that were not significantly different than rates of change among W1 Cigarette Only users. W1 Multiple Product users (TD<sub>Slopes</sub>=-0.02, se=0.004, p<0.001) had significantly less change in TD than W1 Cigarette Only Users. W1 Hookah Only users reported mean of 8.54 (se=0.84), a level that would fall in the bottom population tertile (<18.75) and would correspond to endorsing less than three TD items (a raw sum score of (8.54/50)\*16=2.7).

### Changes in Pattern of Use Over Waves 1-3 Among W1 Tobacco User Groups

The percent of W1 tobacco user groups who added a product to those used in the previous wave varied across user groups (Supplemental Table 1). At W2, 4.6% of W1 Cigarette+E-Cigarette users and 19.3% of W1 E-Cigarette Only users added a product. At W3, 12.3% of W1 Cigarette+E-Cigarette and 22.6% of W1 Hookah Only users added a product. W1 Cigarette Only, W1 Smokeless Only, and W1 E-Cigarette Only users had the highest rates (range: 59.2%-85.8%) of stability at each subsequent

wave. At W2 and W3, having Switched product use patterns was most common among W1 Multiple Product (W2 = 50.9%; W3 =30.4%) and W1 Cigarette+E-Cigarette (W2 = 47.3%; W3 =28.8%) groups. Transitioning to No Established Use was most common among W1 Hookah Only users (W2 = 13.4%; W3 =29.3%).

# Changes in Patterns of Product Use and Trajectories of TD Among W1 Tobacco User Groups over Waves 1-3

To assess the impact of changes in tobacco use patterns on changes in TD, growth curves were fit to three longitudinal assessments of TD separately for each W1 tobacco user group (Table 3).

## Between-Person Effects on TD Within W1 Tobacco User Groups

Women had higher levels of W1 TD (TD<sub>intercept</sub>) than men within W1 Cigarette Only, W1 E-Cigarette Only, and W1 Cigar Only user groups. Older tobacco users (ages 35 years and older) had higher W1 TD<sub>intercept</sub> than younger users (18-24) among W1 Cigarette Only, W1 Smokeless Only, W1 Cigarette+E-Cigarette and W1 Multiple Product user groups. Among W1 Cigarette+E-Cigarette and W1 Multiple Product users, adults ages 25-34 years and ages 35 years and older had higher levels of TD than adults 18-24 years old. Non-White W1 Cigarette Only and W1 Multiple Product users had lower levels of W1 TD<sub>Intercept</sub> than White users from the same user groups. W1 daily users of tobacco had higher W1 TD<sub>Intercept</sub> than non-daily users across all tobacco user groups. Former use of other tobacco products was associated with higher W1 TD within W1 Cigarette Only and W1 Multiple Product users. Former use of other tobacco products was associated with lower W1 TD among W1 Cigar Only users. Women had greater increases than men in TD<sub>slope</sub> from W1 to W3 among W1 Multiple Product users. W1 E-Cigarette Only users aged 35+ had greater increases in TD<sub>slope</sub> than 18-24 year old users. Non-White users had a slower increase in TD<sub>slope</sub> over time than White users among W1 Cigarette

#### Associations Between Patterns of Use and TD Over Waves 1-3

With adjustment for the levels of TD at W1 and a general increase in TD over time, we evaluated whether change in pattern of use at W2 and W3 were associated with changes in TD not predicted by expected trends in TD over time. Differences in levels of TD for W1 tobacco user groups who stayed the same, switched, or discontinued tobacco use were compared at each wave relative to users who added a product to their pattern of use at the previous wave.

W1 Cigarette Only users who either switched or had no established use at W2 had moderately lower levels of TD than those who added product(s) (Table 3). W1 Cigarette Only users whose product use pattern stayed the same at W2 had levels of TD that were not significantly different than those who added product(s). At W3, the majority (77.3%) of Cigarette Only users stayed the same as their W2 pattern of product use (Supplemental Table 1) and had slightly higher levels of TD at W3 than those who added a product between W2 and W3. Wave 1 Cigar Only and Hookah Only users who stayed the same at W2 had slightly lower TD than similar W1 users who added products. Among W1 E-Cigarette Only, W1 Smokeless Only, W1 Cigarette+E-Cigarette, and W1 Multiple Product users, those who stayed the same and those who Added product(s) at W2 or W3 did not have different levels of TD (p's>0.11) at either W2 or W3. In post-hoc analysis of changes between W1 and W2, among W1 E-Cigarette Only users (n=287), 88±6% (n=34 of 39) who switched products and 83±7% (n=46 of 56) who added products included new use of cigarettes at W2. We did not see a significant difference in W2 TD for W1 E-Cigarette Only users who stayed the same or switched product use patterns at W2 compared to those who added products at W2 (see Table 3). Increasing mean TD trajectories for Wave 1 E-Cigarette Only users who stayed the same across both Wave 2 and Wave 3 are presented along with other W1 user groups in Supplement Figure 2.

W1 Cigarette Only, W1 Cigarette+E-Cigarette, and W1 Multiple Product users who switched patterns of product use at W2 had slightly lower levels of TD than those who added products at W2 (p's<0.01). Relative to W1 Multiple Product users who added products between W2 and W3, W1 Multiple Product users switching patterns of products between W2 and W3 had lower TD at W3. Switching products between W1 and W2 or between W2 and W3 was not associated with corresponding changes in levels of TD among W1 E-Cigarette Only, W1 Cigar Only, W1 Hookah Only or W1 Smokeless Only user groups (p's>0.13).

Post-hoc regressions explored if reductions in W2 TD for W1 user groups who switched patterns of products at W2 differed according to which products they reported using at W2. Models assessed W2 TD among the most common new patterns of use at W2 within W1 Cigarette Only, W1 Cigarette+E-Cigarette, and W1 Multiple Product users. Models included W1 TD and covariates mirroring primary analyses. Among W1 Cigarette Only users who switched at W2 (n=90), TD reductions at W2 were not different (F(1,81)=1.4, p=0.23) among W1 Cigarette Only users switching to E-Cigarette Only (n=73; 84±4%) or other patterns of use (n=17; 16±4%) at W2. Among W1 Cigarette+E-Cigarette users who switched at W2 (n=230), TD reductions (F(2,90)=100.3, p <0.001) were larger among the 15±2% (n=32) who switched to E-cigarette Only than among the 79±2% (n=183) who switched to Cigarette Only. Among W1 Multiple Product users (n=824), 51±2% (n=413) switched to Cigarette Only, 6±1% (n=47) switched to E-cigarette Only, 9±1% (n=78) switched to Cigarette+E-Cigarette, and 34±2% (n=286) switched to another pattern of use. Reduction of W2 TD (F(3,89)=19.1, p <0.001) were larger for those W1 Multiple Product users who switched to Ecigarettes Only than those who switched to Cigarette Only use.

Across all users, W1 tobacco users who had no established use at either W2 or W3 had significantly lower levels of TD (p's $\leq$ 0.05) than those who added products with standardized mean

differences ranging from -0.05 (se=0.02; d=0.17) for Hookah Only users to -0.42 (se=0.05; d=1.44) among Cigarette+E-Cigarette users.

#### DISCUSSION

The PATH Study enables continued monitoring of the impact of product use on addiction to tobacco in the U.S. Initial levels of TD differed between product user groups at the start of W1. W1 Cigarette Only, W1 Smokeless Only, W1 Cigarette+E-Cigarette and W1 Multiple Product users showed higher levels of TD compared to W1 E-Cigarette Only, W1 Hookah Only or W1 Cigar Only users, consistent with more frequent use patterns of products with high levels of nicotine.<sup>7</sup> Analysis of temporal changes across waves suggested W1 Multiple Product users' TD decreased and TD for other user groups remained roughly the same. W1 E-Cigarette Only users were distinguished by a moderate increase in TD from W1 to W3, an increase that was accelerated among older users. W1 E-Cigarette Only users who maintained current established use of only e-cigarettes at W2 and W3 also increased TD from W1 to W3. Former use of other products and adding or switching to product use patterns that included cigarettes was common among W1 E-cigarette Only users, although these factors were not associated with increases in TD observed at subsequent waves. Factors that influence successful switching to non-cigarette products or initiation of E-Cigarette Only use such as susceptibility to rewarding effects of nicotine,<sup>21</sup> comorbid mental health,<sup>22</sup> or other influences can be explored to better understand the increase in TD relative to other tobacco user groups. Differential increases also may be attributed to such factors as increases in quantity or frequency of tobacco use and increasing efficiency of nicotine delivery, as these products continue to evolve their technology. It is also possible that W1 E-Cigarette Only users became more adept at using these devices to extract nicotine more efficiently over time. W1 Multiple Product users' decrease in TD was small although statistically significant. W1 Multiple Product users were more likely to switch to other products across waves. It is possible that switching to other products with lower associated TD (e.g.,

e-cigarettes, cigars, hookah), or falling into a pattern of less consistent use of any products, was responsible for the overall decrease in TD in this group.

For W1 Cigarette Only users, a switch to another product at W2 or discontinued use was associated with lower levels of TD. This makes sense insofar as discontinued use means that W1 Cigarette only users were no longer smoking every day or on some days. While uncommon among W1 Cigarette Only users, switching to non-cigarette tobacco products might lower TD and thus support efforts by users to replace cigarettes with products that potentially yield less nicotine or harmful constituents. Movement to the No Established Use category at W2 or W3 was also consistently associated with lower TD for all other product use groups, probably reflecting less use and nicotine intake. Overall, though, more than 3 of 4 W1 Cigarette Only users continued to use cigarettes only across each wave of the study. Cigarette use and concomitant levels of TD were stable in this group. Recent studies of young adults in a large nationally representative sample (n=15,275) prospectively examined product use transitions over a period of 2.5 years and showed that short-term transitions (<1 year) between use of any product to subsequent use of any other product were equally likely, but affected only a small proportion of the population who were already product users.<sup>23,24</sup> After 2.5 years, the strongest transition probabilities were from initial use of cigarettes to continuing to smoke cigarettes, and from use of any other products including ecigarettes to no current use. W1 Smokeless Only and W1 Cigarette Only users were also likely to persist in a consistent pattern of use across waves. W1 E-Cigarette Only and W1 Cigar Only users also reported high rates of persistent patterns of use. W1 Cigarette + E-cigarette users and W1 Multiple Product users, however, were less likely to remain in these states over time. This relative instability suggests the possibility that these users are not completely satisfied with the products they are using. W1 Cigarette+E-Cigarette users who switched to E-Cigarettes Only at W2 saw a greater decrease in TD than W1 Cigarette+E-Cigarette users who switched to Cigarettes Only at W2. They may be considering cutting down, quitting, or transitioning to a favored product use pattern. W1 Cigarette+E-cigarette users and W1 Multiple Product users had higher W1 TD on average. The

lower TD associated with switching patterns use may suggest success in efforts to reduce exposure though persistent high levels of TD also suggests risk of long-term tobacco use behaviors.

Limitations of collecting assessments approximately every 12-months include a decreased ability to link temporally between-interview changes in product use to TD assessments. We chose to focus on trajectories among continuing tobacco users when attempting to characterize the role of changes in product use patterns; therefore, we do not describe effects of product use changes among those who were able to guit successfully. W3 assessments of TD were not available for all respondents entering the study at W1 and multiple imputation methods were used to support inferences. We retained as a reference group, those who added products. This enabled direct comparisons between users who added or switched products, though we did not test all pairwise combinations (e.g., comparing those who switched to those who stayed the same). The TD scale was validated among current W1 product users. Post-hoc estimation of differences in measurement of TD among past-year users reporting no established use at W2 or W3 did not suggest differences in test functioning and supported comparability of TD scores. The use of cigarette products to estimate TD among W1 Cigarette+E-Cigarette product users may limit precise assessment of dependence in this dual product using group. Other W1 Multiple Product users were asked globally about tobacco products and did not receive assessment of TD on any single product. Determining the utility of ascribing level of tobacco dependence to each product among multiple product users remains a challenge for assessing impacts of TD.<sup>25-28</sup> The relative difference in TD among product users may be useful for gauging population trends; the absence of a 'gold standard' criterion for dependence challenges development of clinical or diagnostic thresholds. Psychometric calibration of TD scores alongside clinically applied metrics such as the WISDM,<sup>5</sup> NDSS<sup>4</sup> and PROMIS<sup>29</sup> dependence instruments could advance development of meaningfully comparable scores.

The level of TD among U.S. tobacco users, except for W1 E-cigarette Only and W1 Multiple Product users, was stable over the first three waves of the PATH Study and trajectories in levels of TD were predominantly unrelated to changes in patterns of continued product use. Stable levels of TD suggest a population at persistent risk of health impacts from tobacco. We observed more change in TD among W1 E-cigarette Only and W1 Multiple Product users compared to W1 Cigarette Only users over time. Escalating TD among W1 E-cigarette Only users was not explained by changes in patterns of use, while decreases in TD among W1 Multiple Product users was associated with switching patterns of product use.

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#### **DECLARATION OF INTERESTS**

Wilson Compton reports long-term stock holdings in General Electric Company, 3M Company, and Pfizer Incorporated, unrelated to this manuscript. K. Michael Cummings provides expert testimony on the health effects of smoking and tobacco industry tactics in lawsuits filed against the tobacco industry. He has also received payment as a consultant to Pfizer, Inc., for services on an external advisory panel to assess ways to improve smoking cessation delivery in health care settings. Raymond Niaura receives funding from FDA CTP via contractual mechanisms with Westat and NIH. Within the past 3 years, he has served as a paid consultant to the Government of Canada via a contract with Industrial Economics Inc. and has received an honorarium for a virtual meeting from Pfizer Inc.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Department of Health and Human Services or any of its affiliated institutions or agencies.

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None

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Table 1. Demographic and Tobacco Use Characteristics of Wave 1 Tobacco User Groups Who Had Established Tobacco Use at Two or More 1 Trbacco User Gr Assessments (n=9556).

Droducts	- Froducts 1571)	%			79.4%	1.0%		20.6%	1.0%			31.0%	1.3%
	=u)	٩			1170			401				650	
arette +	5arette =498)	%			44.4%	2.5%		55.6%	2.5%			13.1%	1.6%
Ciga	р <u>с</u>	٢			205			293				93	
okeless	omy =620)	%			95.6%	1.1%		4.4%	1.1%			10.6%	1.1%
Sm	L)	۲		59	0			30			10	ŝ	
okah	=248)	%			55.8%	3.4%		44.2%	3.4%			72.9%	3.7%
H C	<u>ت</u> '	۲		12	∞		12	0			19	~	
igar	=387)	%			81.9%	2.2%		18.1%	2.2%			19.7%	1.8%
	Ë,	۲		29	7			06			11	6	
arette	-287)	%		43.4	%	3.2%	56.6	%	3.2%		15.3	%	2.1%
E-ci	Ë	<u>د</u>		11	ъ		17	7				64	
irette alv	5945)	%		Þ	50.8%	0.7%		49.2%	0.7%			10.7%	0.4%
Ciga	) i=u	۲		270	00		323	7				967	
		Demographic Factor	Sex		Male	Se		Female	Se	Age Group		18-24	Se

	28.4%	1.5%	40.5%	1.7%		69.6%	1.3%	30.4%	1.3%		20.4%	1.2%	79.6%	1.2%		69.9%
	368		553			1002		569			321		1250			1096
	30.7%	2.4%	56.2%	2.7%		80.3%	1.9%	19.7%	1.9%		%0.6	1.4%	91.0%	1.4%		82.3%
	134		271			377		121			54		444			412
>	19.5%	2.1%	%6.69	2.3%		89.4%	1.4%	10.6%	1.4%		20.4%	1.9%	79.6%	1.9%		52.2%
0.	10		41 0			53 4		86			12 7		49 3			33
	20.8%	3.5%	6.4%	1.9%		45.0%	4.2%	55.0%	4.2%		:	1	1	1		74.4%
	37		13			10 8		14 0			23 6		12			18
	19.7%	2.6%	60.6%	2.8%		61.2%	2.5%	38.8%	2.5%		72.4%	2.5%	27.6%	2.5%		50.8%
	69		19 9	D		20 6		18			27 9		10 8			21
	26.5 %	3.0%	58.2 %	3.5%		76.0 %	3.1%	24.0 %	3.1%		25.2 %	2.6%	74.8 %	2.6%		20.9
	61		16 2			21 3		74			79		20 8			69
	23.2%	0.7%	66.0%	0.7%		69.5%	0.7%	30.5%	0.7%		16.9%	0.6%	83.1%	0.6%		83.8%
	130 5		367 3			391 1		203 4			666		494 6			495
	25-34	Se	35+	Se	Racial/Ethnic Group	Non-Hispanic White	se	Other Groups	se	Tobacco Use	Non-Daily Use	se	Daily Use	se	Former Use of Other Product	No Former Established Use

	1.2%	30.1%	1.2%	intages (%)
		475		ed. All perce
	2.1%	17.7%	2.1%	are unweight
		86		cases (n) a
	2.2%	47.8%	2.2%	Imbers of
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)	2.9%	25.6%	2.9%	ent. Value
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	3.0%	49.2%	3.0%	waves of a:
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%	2.2%	79.1 %	2.2%	e at two o
		21 8		hed us
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ŝ		992		sers wit
	se	Former Established Use	se	Note: Includes tobacco u
	3 4 6 6	3     4     4     3     6     6     7       se     0.5%     2.2%     3.0%     2.9%     2.2%     2.1%     1.2%	3         %         4         3         6         6         1         7.1%         1.2%           se         0.5%         2.2%         3.0%         2.9%         2.9%         2.1%         1.2%           Former Established Use         992         16.2%         8         %         3         49.2%         65         25.6%         4         47.8%         86         17.7%         475         30.1%	3         4         4         3         6         6         1         7         1.2%           se         0.5%         2.2%         3.0%         2.9%         2.2%         2.1%         1.2%         1.2%           Former Exablished Use         992         16.2%         8         %         3         49.2%         65         25.6%         4         47.8%         86         17.7%         475         30.1%           se         0.5%         2.2%         2.9%         2.9%         65         25.6%         4         47.8%         86         17.7%         475         30.1%

D 2 ir than 30%. Table 2.

Growth Model for Tobacco Dependence from Wave 1 to Wave 3 among Wave 1 Tobacco User Groups. Survey weighted models estimate Wave 1 level (Intercept) and rate of change over waves (slopes) with adjustment for sex, age, race/ethnicity, daily use, and former product use.

Status at Wave 1	Intercept	se	р	Slope	se	р
Wave 1 Covariates						
Female	0.039	0.007	0.000	0.005	0.003	0.070
Age 25-34	0.018	0.010	0.079	0.003	0.004	0.404
Age 35+	0.058	0.008	0.000	0.007	0.003	0.033
Non-White	-0.036	0.008	0.000	-0.015	0.003	0.000
Wave 1 Daily Use	0.327	0.010	0.000	-0.034	0.004	0.000
Formerly Used Other Products	0.009	0.007	0.204	0.001	0.003	0.675
Wave 1 User Groups						
Cigarette Only	6	-	-	-	-	-
E-Cigarette Only	-0.240	0.024	0.000	0.071	0.011	0.000
Cigar Only	-0.158	0.024	0.000	0.012	0.007	0.101
Hookah Only	-0.150	0.035	0.000	-0.001	0.007	0.904
Smokeless Only	-0.039	0.016	0.015	0.009	0.006	0.104
Cigarette+E-Cigarette	0.031	0.013	0.022	-0.008	0.007	0.207
Multiple Products	0.035	0.009	0.000	-0.021	0.004	0.000

Note: Measures of TD were rescaled during model estimation by dividing by 100. Estimates can be multiplied by 100 to recapture original metric of 0-100. All models included survey weights. '-' indicates the reference group.

Table 3.

Frequency of tobacco use patterns from Wave 1 to Wave 2, and Wave 2 to Wave 3 among Wave 1 Tobacco User Groups. 0

		Added		Ň	tayed Sam	e		Switched		NoE	stablishec	Use
	۲	%	se	۲	%	se	۲	%	Se	۲	%	se
Wave 1 User												
Group						Wave 1 -> V	Vave 2					
Cigarette Only	614	10.1%	0.5%	5039	85.0%	0.5%	06	1.5%	0.2%	202	3.4%	0.2%
E-Cigarette Only	56	19.3%	2.3%	176	61.9%	2.8%	39	13.4%	2.1%	16	5.3%	1.4%
Cigar Only	99	17.3%	2.2%	235	63.9%	2.8%	49	10.5%	1.8%	37	8.3%	1.1%
Hookah Only	33	14.9%	2.8%	142	56.0%	3.3%	38	15.8%	2.3%	35	13.4%	1.9%
Smokeless Only	44	6.7%	1.0%	527	85.8%	1.7%	16	2.3% <sup>a</sup>	0.7% <sup>a</sup>	33	5.3%	1.1%
Cigarette+E- Cigarette	28	4.6%	%6.0	226	45.4%	2.7%	230	47.3%	2.7%	14	2.7%	0.7%
Multiple Products	138	8.1%	0.7%	551	37.6%	1.5%	824	50.9%	1.4%	58	3.5%	0.5%
Wave 1 User												
Group						Wave 2 -> V	Vave 3					
Cigarette Only	538	8.9%	0.4%	4578	77.3%	0.6%	440	7.2%	0.4%	389	6.5%	0.4%
E-Cigarette Only	39	12.5%	1.9%	171	59.2%	3.1%	47	17.8%	2.6%	30	10.4%	2.1%
Cigar Only	69	15.9%	1.8%	233	63.9%	2.9%	36	9.2%	1.6%	49	11.1%	1.8%

Hookah Only	56	22.6%	2.8%	97	39.6%	3.4%	19	8.5%	2.1%	76	29.3%	3.6%
Smokeless Only	69	9.9%	1.2%	475	78.5%	1.7%	27	3.9%	0.8%	49	7.6%	1.3%
Cigarette+E- Cigarette	59	12.3%	1.6%	257	51.6%	2.3%	147	28.8%	2.0%	35	7.3%	1.3%
Multiple Products	302	18.7%	1.1%	674	44.5%	1.4%	484	30.4%	1.2%	111	6.4%	0.7%
Note: Includes tohac	CO LISERS	with estab	lished use at t	wo or mo	The Waves	of assessment	Values	for numbe	rs of cases (N	) are unv	veighted	AII

percentages (%) are weighted estimates and include standard errors (se). Cells with <sup>a</sup> flagged when the Relative Standard Error (RSE) was greater מוויע כוצוונכח. או than 30% or RSE (1-proportion) is greater than 30%. (1-pro-

Table 4. Growth Model results describing trajectories of Tobacco Dependence (TD) scores across Waves 1, 2, and 3 and effect of time-varying changes

in product use on levels of	f TD at Wave 2	and Wave	, n												
	W1 Cigarette Only	W1 E-Ci <sub>i</sub> On	garette ly	W1 Cig Only	ar	W1 Hook Only	cah	W1 Sm O	okeless nly	W1 (0	Cigarett igarette	e+E-	W1 I Pro	Multipl oducts	a
I	b se p	b se	d	b se	٩	b se	٩	q	e b	q	se	٩	q	se	٩
Time Invariant Status at Wave 1															
Intercept: W1 TD Female C	0.04 0.01 0.00	0.06 0.0	0.01	0.1 0.0 1 4	0.0	- .010.010	0.60 (	0.04 0	06 0.54	0.04	0.03	0.17	0.02	0.02 0	.29
Age 25-34 (	0.00 0.01 0.74	0.01 0.0	)4 0.84	0.0 0.0 1 3	0.7 8 0	.02 0.03 (	0.52 (	.01 0	04 0.75	0.11	0.04	0.00	0.05	0.02 0	.02
Age 35+ (	0.05 0.01 0.00	0.06 0.0	3 0.10	0.0 0.0 1 3	0.6 6 0	.02 0.03 (	0.49 (	0 60.0	04 0.02	0.13	0.04	0.00	60.0	0.02 0	00.
				0.0	0										

0.05

-0.03 0.02

0.20

0.03

-0.04

0.02 0.02 0.23 -0.04 0.04 0.22

4 m

Non-White 0.04 0.01 0.00 -0.03 0.04 0.34

0.0 ı

1 0.2 0.0 0.0

0

0.00 0.02 0.36 0.00 0.05 0.21 0 0.180.080.03 0.29 0.03 0.00 m 9 W1 Daily Use 0.35 0.01 0.00 0.11 0.03 0.00

0.0 0.0 0.1

Formerly Used Other

0.04 0.02 0.03 0.25 0.03 0.03 0.02 0.02 0.40 -0.03 0.02 0.16 ഹ m ഹ -0.06 0.03 0.08 Products 0.03 0.01 0.01

Slope: W1 to W3 Change

in TD

0.0 0.0 0.0

0.76 0.00 0.87 0.09 0.00 0.01 0.01 0.01 -0.05 0.01 0.01 -0.01 0.00 0.02 0.00 0.86 0.68 0.70 0.30 0.52 0.02 0.02 0.02 0.02 0.03 -0.01 -0.03 -0.01 0.00 0.01 0.010.020.78 0.02 0.02 0.29 0.060.050.26 -0.05 0.01 0.00 0.030.020.09 0.01 0.02 0.53 0.010.010.47 0.01 0.02 0.81 0.020.010.13 0.00 0.01 0.77 0.0 0.0 0.4 0.0 0.0 0.3 2 б 0.0 0.0 0.2 2  $\infty$ ഹ 0.0 0.0 0.7 2 -2 -2  $\leftarrow$ - $\sim$ --0.82 0.03 0.07 Age 35+0.00 0.00 0.76 0.06 0.03 0.03 W1 Daily Use 0.05 0.00 0.00 -0.02 0.02 0.32 Female 0.00 0.00 0.40 0.00 0.02 0.05 0.03 Non-White 0.02 0.00 0.00 -0.05 0.02 Age 25-34 0.00 0.00 0.76

 $-0.01 \quad 0.01 \quad 0.30$ 0.57 0.02 -0.01 0.010.010.35 0.02 0.01 0.11 0.0 0.0 0.4 4 - $\leftarrow$ 0.01 0.02 0.69 Products 0.00 0.01 0.83 Formerly Used Other

0.26 0.60 0.00 0.00 0.03 -0.18 0.04 0.00 I I -0.04 0.01 -0.01 0.01 0.01 -0.03 0.02 -0.19 0.03 L Т 0.01 I I 0.56 0.01 0.00 0.18 0.78 0.00 I I 0.02 0.02 0.09 0.02 0.03 0.08 I I -0.05 -0.28 -0.42 -0.01 0.01 0.03 I I 0.03 0.01 0.01 -0.03 0.02 0.09 0.040.030.14 0.11 0.09 0.24 0.09 0.02 0.00 -0.14 0.04 0.00 0.03 0.03 0.19 -0.01 0.03 0.80 0.070.060.19 -0.04 0.04 0.35 0.05 0.02 0.03 -0.22 0.05 0.00 L I Т Т I 1 I I I I I 0.0 0.0 0.0 0.0 0.0 0.4 4 0.0 0.0 0.0 4 0.0 0.0 0.0 0.0 0.0 0.8 0.1 0.0 0.0 2  $\infty$ μ L 2 4 4 m m 4 I 4  $\sim$  $\infty$ ഹ  $\leftarrow$ L -0.55 0.66 Stayed the Same 0.03 0.01 0.00 -0.04 0.05 0.46 0.06 0.06 0.33 No Established Use 0.19 0.02 0.00 -0.16 0.06 0.01 No Established Use 0.21 0.02 0.00 -0.20 0.07 0.00 I Switched 0.02 0.01 0.28 0.03 0.07 Stayed the Same 0.00 0.01 0.65 -0.02 0.03 I Т I I Switched 0.36 0.05 0.00 I L I L I Added Added Time-Varying Status Wave 3 Use Status Wave 2 Use Status

indicates the reference group. For example, W1 Cigarette + E-Cigarette users who reported No Established Use at W3 on average were 42 points Note: Includes tobacco users with established use at two or more waves of assessment. Measures of TD were rescaled during model estimation by dividing by 100. Survey weighted estimates (b) can be multiplied by 100 to recapture original metric of 0-100. se = standard error. '-' lower (W3 Use StatusNo established Use = -0.42) on W3 TD than W1 Cigarette + E-Cigarette users who Added a product.

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**Figure 1**. Survey weighted average level of tobacco dependence (scaled 0-100) for Wave 1 tobacco user groups who had established use at two or more waves of assessment. Dashed lines reflect lower  $(33^{rd}$  percentile; TD <18.75) and higher ( $66^{th}$  percentile; TD > 56.25) levels of Wave 1 weighted terciles for tobacco dependence for respondents who participated in all 3 surveys and had non-missing TD scores at Wave 1 (n=13,262). A raw sum score of item options will range from 0 to 32 with 2 as the max score for each of the 16 items. Item options were multiplied by 50 to achieve a 0-100 scale for the total score. For example, a score of 18.75 on the 0-100 scale would be 6 as a raw sum score (18.75/50) \* 16 = 6.