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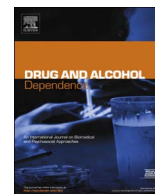
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Indicators of dependence for different types of tobacco product users: Descriptive findings from Wave 1 (2013–2014) of the Population Assessment of Tobacco and Health (PATH) study



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ABSTRACT

Background and aims: With no established standard for assessing tobacco dependence (TD) across tobacco products in surveys, the Population Assessment of Tobacco and Health (PATH) Study provides a unique platform for examining the psychometric properties and validity of multiple indicators of tobacco dependence across a range of tobacco products.

Participants: A U.S. nationally representative sample from the 32,320 adult Wave 1 interviews with analyses focused on 14,287 respondents who were current established users of tobacco products.

Findings: This analysis confirms a single primary latent construct underlying responses to TD indicators for cigarettes, e-cigarettes, cigars, hookah, and smokeless tobacco products. Mutually exclusive past year tobacco-user groups included: cigarette only (n = 8689), e-cigarette only (n = 437), cigar only (traditional, cigarillo, or filtered) (n = 706), hookah only (n = 461), smokeless tobacco only (n = 971), cigarette plus e-cigarette (n = 709), and multiple tobacco product users (n = 2314). Differential Item Functioning (DIF) analyses supported use of 16 of the 24 examined TD indicators for comparisons across tobacco users. With cigarette users as a reference (mean = 0.0, SD = 1.0), we observed a range of TD with hookah (mean = -1.71) and cigar (mean = -1.92) only users being the lowest, and cigarette plus e-cigarette product users being the highest (mean = 0.35). Regression models including sociodemographic factors supported concurrent validity with increased product use frequency and TD among cigarette-only (p < 0.001), e-cigarette only (p < 0.002), cigar (p < 0.001), hookah only (p < 0.001), and smokeless tobacco users (p < 0.001).

Conclusion: The PATH Study Adult Wave 1 Questionnaire provided psychometrically valid measures of TD that enables future regulatory investigations of nicotine dependence across tobacco products.

1. Introduction

Drug addiction is defined as a chronic, relapsing condition that is characterized by compulsive drug seeking and use despite harmful consequences (National Institute on Drug Abuse, 2009). Nicotine has been identified as the key chemical compound that causes and sustains

the addicting effects of tobacco products (United States Department of Health and Human Services (USDHHS), 2010). As a construct, nicotine dependence (ND) unifies the collection of signs, symptoms, and other indicators of the persistent use of tobacco products. Most of the research on the measurement of ND has focused on cigarettes (Fagerstrom, 2012; Shadel et al., 2014; Colby et al., 2000). However,

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with increased use of the many new forms of tobacco and nicotine delivery products that are now on the market (United States Department of Health and Human Services (USDHHS), 2014), it is unclear whether the various symptoms characteristic of ND in cigarette smokers are evident, or valid measures of ND for other, new nicotine-containing products. ND is similarly understudied among individuals who use multiple tobacco products concurrently, a use pattern that may be associated with higher levels and different rates of nicotine delivery relative to those who only use a single product (Allain et al., 2015; Stepanov et al., 2006).

1.1. Assessment of ND

Various conceptual models have been used to characterize symptoms of ND, all of which aim to assess behavioral indicators of intensity and lack of self-control with tobacco (e.g., inability to quit or cut down on use), tolerance and withdrawal symptoms, and continued use despite awareness of harmful consequences. The core elements of the American Psychiatric Association's (APA) *Diagnostic and Statistical Manual of Mental Disorders (DSM)* and the World Health Organization's *International Classification of Diseases (ICD)* drug dependence syndromal classification systems, for example, are the seven domains codified by Edwards and Gross (1976): (1) physiological tolerance, (2) evidence of characteristic withdrawal symptoms, (3) impaired control over substance use, (4) unsuccessful attempts to quit, (5) spending a great deal of time using substance, (6) prioritizing substance use over other activities, and (7) using substance despite physical or psychological health consequences. The APA's DSM provides for a categorical diagnosis of ND by tallying the number of criteria or indicators that are positive for dependence. The most recent DSM-V (American Psychiatric Association, 2013) has replaced the term ND with "tobacco use disorder" and expanded its definition to include social consequences of use and craving. Other self-report measures of TD include the widely used Fagerström Tolerance Questionnaire (Fagerstrom and Schneider, 1989) and its variant, the Fagerström Test for Nicotine Dependence (FTND; Heatherton et al., 1991), the Heaviness of Smoking Index (HSI), the Hooked on Nicotine Checklist (HONC; DiFranza et al., 2002), the Nicotine Dependence Syndrome Scale (NDSS; Shiffman et al., 2004) and the Wisconsin Inventory of Smoking Dependence Motives (WISDM; Smith et al., 2010). These measures purport to assess many of the same ND/TD domains as the APA and ICD systems (e.g., tolerance, withdrawal), but they vary in their coverage of symptoms, the addition of domains reflecting other motives for tobacco use (e.g., cognitive enhancement, social smoking), how questions are framed and worded, and in their psychometric properties and predictive validity (Piper et al., 2008). Theoretical efforts to elaborate the construct of ND continue to explore domains predictive of self-administration of tobacco and difficulty quitting (Piasecki et al., 2010; Piper et al., 2004). Organization of domains into a theoretical framework will guide phenotypic descriptions and identification of appropriate criteria mapping expression of ND among different tobacco users. Pharmacokinetics of nicotine delivery, use patterns, and social constraints clearly differ across tobacco products and suggest room for differential priority or product specific domains to fully characterize development and expression of ND among adults using different tobacco products. Existing schemas were not designed to measure ND on more than one tobacco product or nicotine delivery system. Yet ND domains such as tolerance, withdrawal, and craving may be sufficiently robust to identify common symptoms reflective of ND across products.

1.2. Psychometric studies of dependence

Recently, Strong and colleagues (Strong et al., 2015) examined multiple domains of ND in a longitudinal national study of the United States population, the United States National Epidemiological Survey of Alcohol and Related Conditions (NESARC). The NESARC developed 22

symptoms that fit into the seven DSM-IV ND domains, and proposed additional symptoms that also informed the ND construct. NESARC also measured use of multiple tobacco products, and ND symptoms experienced for each product. An item response modeling approach was used to identify and validate measures that included symptoms to assess ND similarly among cigarette, cigar, smokeless, and poly-tobacco users. Confirmatory factor analytic models supported a single, primary dimension underlying symptoms of ND across tobacco use groups. Differential Item Functioning (DIF) analysis showed that response to symptoms of ND was similar across tobacco use groups, although groups differed in the severity of reported symptoms.

1.3. Current study

With the exception of the study by Strong et al. (2015) that explored ND among cigarette, cigar, and smokeless tobaccos users, assessments of ND/TD have focused on cigarette smoking. The Population Assessment of Tobacco and Health (PATH) Study provides an opportunity to examine multiple domains of dependence using a broad set of items to assess a variety of tobacco products in a nationally representative sample. Specifically, this paper examines psychometric and item response properties of a collection of traditional indicators (e.g., Diagnostic and Statistical Manual of Mental Disorders) as well as other dependence indicators, culled from a variety of TD measures. It refers to tobacco dependence (TD) as the primary latent construct of interest and describes the prevalence of TD, sociodemographic factors and correlates of TD, and patterns of TD, assessed for cigarettes and other combustible and noncombustible tobacco products, including their relationships to intensity of product use.

2. Methods

2.1. Data

Data are from Wave 1 of the PATH Study, conducted from mid-September 2013 to mid-December 2014. The PATH Study is a nationally-representative, longitudinal cohort study. Audio-Computer Assisted Self-Interviews (ACASI) available in English and Spanish are used to collect information on tobacco-use patterns and associated health behaviors. Multi-stage, address-based, area-probability sampling with an in-person household screener served to establish the cohort of youths and adults at Wave 1. Adult tobacco users, young adults ages 18–24, and African Americans were oversampled relative to population proportions. This analysis of 14,287 adult current established users of a tobacco product draws from the 32,320 Adult Interviews (all participants ages 18 years and older). For cigarettes, a current established user is 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 is defined as an adult who has ever used the product "fairly regularly" and now uses it every day or some days. The PATH Study weighting procedures adjusted for oversampling and nonresponse; combined with the use of a probability sample, the weighted data allow the estimates produced by the PATH Study to be representative of the non-institutionalized, civilian US population. Further details regarding the PATH Study design and methods are published by Hyland et al. (2016) and in the User Guide to the PATH Study restricted use files (United States Department of Health and Human Services, 2016), available at <http://doi.org/10.3886/ICPSR36231>. Westat's Institutional Review Board approved the study design and protocol and the Office of Management and Budget approved the data collection.

2.2. Symptoms of tobacco dependence (TD)

The PATH Study questionnaire included 24 TD symptoms derived from four primary instruments, used to represent multiple domains of

Table 1

Tobacco Dependence instruments and questions included in Wave 1 of the PATH Study, examined in item response models, and retained on a final common Tobacco Dependence instrument.

Item Number	Original Instrument	Domain	Question Text	Final Common Instrument
1	HONC	Loss of Control	Do you consider yourself addicted to [product]?	No
2	HONC	Craving	Do you ever have strong cravings to [product]?	No
3	HONC	Craving	Have you ever felt like you really needed [product]?	No
4	WISDM:Primary	Automaticity	I find myself reaching for [product] without thinking about it.	Yes
5	WISDM:Primary	Craving	I frequently crave [product].	Yes
6	WISDM:Primary	Craving	My urges keep getting stronger if I don't use [product].	Yes
7	WISDM:Primary	Loss of Control	Tobacco products control me	Yes
8	WISDM:Primary	Loss of Control	My [product] use is out of control.	Yes
9	WISDM:Primary	Tolerance	I usually want to use [product] right after I wake up.	Yes
10	WISDM:Primary	Craving	I can only go a couple of hours without using [product].	Yes
11	WISDM:Primary	Automaticity	I frequently find myself almost using [product] without thinking about it.	Yes
12	WISDM:Secondary	Negative Reinforcement	Using [product] would really help me feel better if I've been feeling down.	Yes
13	WISDM:Secondary	Cognitive Enhancement	Using [product] helps me think better.	Yes
14	WISDM:Secondary	Social Reinforcement	Most of the people I spend time with are tobacco users.	No
15	WISDM:Secondary	Affiliative Attachment	I [would]feel alone without my [product].	Yes
16	NDSS	Loss of Control	I would find it really hard to stop using [product].	Yes
17	NDSS	Loss of Control	I would find it hard to stop using [product] for a week.	Yes
18	NDSS	Withdrawal	After not using [product] for a while, I need I I would like to use [product] in order to feel less restless and irritable.	Yes
19	NDSS	Withdrawal	After not using [product] for a while, I need to use [product] in order to keep myself from experiencing any discomfort.	Yes
20	DSM:Risky Use	Use Despite Consequences	Do you believe that [product] is causing a health problem or making it worse?	No
21	DSM: Social Impairment	Give Up Activities	In the past 12 months, did you give up or cut down on activities that were enjoyable or important to you because [product] was not permitted at the activity?	No
22	DSM: Impaired Control	Loss of Control	In the past 12 months, did you find it difficult to keep from using [product] in places where it was prohibited?	Yes
23	DSM: Withdrawal	Withdrawal	Withdrawal Syndrome	No
24	Time to First Tobacco	Tolerance	On the days that you smoke, how soon after you wake up do you typically smoke your first cigarette of the day? Please enter the number of minutes or hours.	No

Note: The Final Common Instrument identifies as 'Yes' the 16 items used to compare levels of Tobacco Dependence (TD) across product users. Items labeled 'No' were set aside due to evidence of poor relation to overall levels of TD or differences in how the items measured TD symptoms across products.

TD: the "Hooked on Nicotine Checklist" (3 items), Wisconsin Inventory of Smoking Dependence Motives or WISDM (12 items), the Nicotine Dependence Syndrome Scale (4 items), the Diagnostic and Statistical Manual (DSM) criteria (4 items), and "Time to First Tobacco Use" (1 item). These instruments were subject to cognitive testing to ensure clarity of presentation and ease of understanding during the PATH Study questionnaire development. Positive scores on the DSM withdrawal syndrome were indicated when at least 3 of 7 possible symptoms were endorsed. Time to First Tobacco Use was constructed by converting reported time into minutes and grouping responses into four categories, '< 5', '5-30', '31-60', and '> 60' min.. Past Year symptoms of TD in Wave 1 (W1 current established tobacco users: n = 14,287) from the PATH Study were also examined. Table 1 shows the original instrument and domain targeted by each examined symptom of TD.

2.3. Overview of data analytic plan

This analysis focused on seven mutually exclusive current established tobacco-user groups: cigarette only users (n = 8689), e-cigarette only users (n = 437), cigar (traditional, cigarillo, filtered) only users (n = 706), hookah only users (n = 461), smokeless (smokeless, snus) only users (n = 971), cigarette plus e-cigarette users (n = 709) and multiple tobacco product users (i.e., more than one of following products: cigarette, e-cigarette, cigar, hookah, or smokeless; n = 2314). Item response models (IRM) were used to describe the association between the probability of endorsing symptoms and a common underlying latent trait (Hays et al., 2000). Results from the IRM analyses identified a set of symptoms for use in assessing the equivalence of TD across the tobacco-use groups as well as demographic characteristics associated with levels of TD within each product user group, with estimates of the concurrent strength of associations between TD measures

and corresponding product use. Confirmatory factor analytic models of polychoric correlations using weighted least squares estimation with robust standard errors. Mean- and variance-adjusted X^2 statistics (WLSMV) were used to evaluate unidimensional assumptions of IRM. All reported summaries of percentages are weighted, the replicate weights were used and, where relevant, the Balanced Repeated Replication (BRR) method with Fay adjustment (e.g., Fay = 0.3) was used when analyzing weighted proportions computed with the survey package (Lumley, 2014) in R (R Core Team, 2016).

2.4. Graded item response model (GRM)

The graded item response model (GRM) was selected for this study, given its capacity to include both binary and multiple category response formats. Prior to fitting the GRM, each set of response options was evaluated using a non-parametric item response model to 1) ensure that each increasing option reflected increasing levels of TD (monotonicity) and 2) collapse options that did not provide clear non-overlapping information. The relative strength of association (i.e., discrimination) between each symptom and levels of TD; and the ability to map each symptom within identified levels of TD (i.e., severity threshold) were evaluated. Finally, a series of models isolated and compared each TD symptom report from each tobacco use group in Differential Item Functioning (DIF) analyses. Significant DIF in the discrimination ('a' parameter) and/or severity ('b' parameter) was interpreted when likelihood ratio testing of nested models were statistically significant using a Benjamini-Hochberg (Glickman et al., 2014) adjustment to adjust significance in the context of multiple comparisons.

Table 2 Weighted demographic characteristics of the PATH Study Wave 1 sample of adults who were identified as current established users of any tobacco product.

Demographic Factor	Cigarette (n = 8689)		E-cigarette (n = 437)		Cigat (n = 706)		Hookah (n = 461)		Smokeless (n = 971)		Cigarette + E-cigarette (n = 709)		Multiple Products (n = 2314)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<i>Gender</i>														
Male	4152	51.24%	200	46.89%	533	79.14%	244	56.10%	928	95.92%	318	46.74%	1764	79.19%
Female	4537	48.76%	237	53.11%	173	20.86%	217	43.90%	43	4.08%	391	53.26%	550	20.81%
<i>Age Group</i>														
18–24	1493	10.79%	103	15.77%	257	22.66%	114	35.6%	187	11.57%	138	13.18%	1011	31.96%
25 +	7195	89.21%	334	84.23%	449	77.34%	114	31.68%	784	88.43%	571	86.82%	1303	68.04%
<i>Racial/Ethnic Group</i>														
Non-Hispanic White	5756	69.15%	320	75.40%	334	53.53%	158	21.9%	843	89.23%	543	79.73%	1473	68.22%
Other Non-White	2933	30.85%	117	24.60%	372	46.47%	242	51.94%	128	10.77%	166	20.27%	841	31.78%

Note: Estimates use Balanced Repeated Replication (BRR) method with Fay adjustment (e.g., Fay = 0.3). Any missing demographic information was imputed as detailed in study documentation (PATH Study User Guide).

3. Results

3.1. Descriptive analyses

Among the 32,320 adults in Wave 1, the analytic sample included those who were identified as current established users of any tobacco product (n = 14,287). Weighted demographic characteristics (gender, age, and race/ethnicity) of the W1 current established users of each tobacco product group are presented in Table 2. Missing response for age, gender, race, or Hispanic ethnicity was logically assigned from other PATH data as described in the PATH Restricted Use File Users Guide (United States Department of Health and Human Services, 2016).

3.2. Domains of tobacco dependence symptoms among tobacco use groups

Confirmatory factor models supported assumptions of a single primary dimension of TD. Fit to the unidimensional model was acceptable across cigarette only (Comparative Fit Index (CFI) = 0.96; Tucker-Lewis Index (TLI) = 0.96; Root Mean Square Error of Approximation (RMSEA) = 0.06), e-cigarette only (CFI = 0.99; TLI = 0.99; RMSEA = 0.06), cigar only (CFI = 0.98; TLI = 0.98; RMSEA = 0.04), hookah only (CFI = 0.96; TLI = 0.96; RMSEA = 0.04), smokeless only (CFI = 0.96; TLI = 0.96; RMSEA = 0.07), e-cigarette plus cigarette (CFI = 0.96; TLI = 0.95; RMSEA = 0.07), and multiple product users (CFI = 0.98; TLI = 0.97; RMSEA = 0.06). Three items were omitted from further analyses: (‘most of the people I spend time with are tobacco users.’; ‘tobacco use is causing a health problem.’; ‘giving up activities as tobacco use not allowed.’) due to relatively weak loadings (< 0.30) on the primary factor in more than one tobacco use group. The time to first tobacco use item performed well in all groups except the e-cigarette only and cigarette and e-cigarette use groups with loadings of 0.17, and 0.27 respectively and was retained for further analysis. Subsequent IRM focused first on the 21 items with strong loadings on a single primary dimension and loadings ranging from 0.48–0.89 for cigarette only, 0.17–0.92 for e-cigarette only users, 0.66–0.92 for cigar only users, 0.52–0.94 for hookah only users, 0.45–0.90 for smokeless only users, 0.27–0.87 for cigarette plus e-cigarette users and 0.50–0.91 for users of multiple tobacco products. Final IRM models were used with the retained items to estimate the latent construct of tobacco dependence across all tobacco users.

3.3. Symptom expression across tobacco use groups

Appendix A provides a summary of DIF results for the 21 examined items in 7 separate tobacco use groups, including observed frequencies; the IRM estimated strength of relationship with other symptoms of TD (a: discrimination); levels of TD where each symptom is likely to be observed (b: severity); and based on a common metric, the results of comparisons across tobacco use groups. To facilitate between-group comparisons (Steinberg and Thissen, 2006), levels of TD were expressed relative to the average level observed in the cigarette-only reference group for each analysis. With levels of TD anchored at 0.0 (SD = 1.0) among cigarette only users, mean TD were more than a full standard deviation lower for e-cigarette only users (mean = -1.37; SD = 2.36), cigar only users (mean = -1.92; SD = 2.11), and hookah only users (mean = -1.71; SD = 0.53). Levels of TD also were lower among smokeless only users (mean = -0.46; SD = 2.76) than among cigarette only smokers. The cigarette plus e-cigarette users on average reported slightly higher TD (mean = 0.35; SD = 2.04) and users of multiple tobacco products reported similar levels of TD (mean = -0.04; SD = 2.89) as cigarette only smokers.

3.4. Differences in symptom reports within tobacco use groups

DIF analyses evaluated parameter(s) within IRM designed to isolate group differences in the likelihood of symptom endorsement given

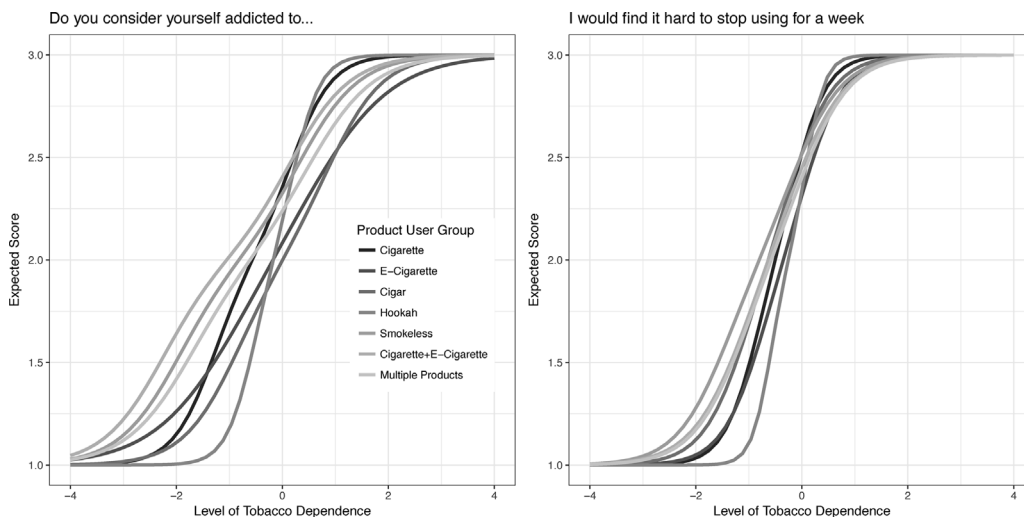


Fig. 1. Item Characteristic Curves (ICC) for a symptom with and a symptom without significant Differential Item Functioning (DIF).

similar levels of TD. Nested and constrained models systematically compared symptom parameters in a series of IRM that examined discrimination and threshold parameters for each symptom comparing each tobacco-use group to the reference group of cigarette only smokers. The series of models isolated item-level comparisons of the strength of relationship with TD and the level of TD associated with responses to the 16 items when assessed within each of the tobacco use groups relative to members of the cigarette only group. Significant multiple degree of freedom Wald tests (e.g., discrimination and thresholds) were followed by single degree of freedom Wald tests with type-one error corrections for these multiple comparisons. The least amount of DIF was observed when comparing e-cigarette only and cigar only users to cigarette only users. When compared to cigarette users, several TD symptoms had slightly weakened relationships with TD among smokeless only, cigarette plus e-cigarette, and multiple tobacco product users. Assessments of the level of TD associated with each symptom response also varied slightly for several symptoms. Despite some variability, a majority of symptoms sustained strong relationships with TD and provided information about the broad range of TD severity. Five symptoms (i.e., two craving, one tolerance, one loss of control and scoring above threshold (> 3 symptoms) for the withdrawal index) showed substantially weakened relationships with TD (e.g., substantially lower discrimination parameter) or a high degree of difference in levels of TD associated with symptom responses (e.g., substantially reduced thresholds). Findings revealed that reasonable comparisons of TD assessments can be made using the same assessments with 16 identified symptoms (see Table 1). Details of the results from DIF analyses are described below for symptoms within each domain.

3.4.1. Craving (5 symptoms)

Of the five symptoms targeting craving, two symptoms (i.e., ‘ever having strong cravings’ and ‘ever feeling the need to use’) failed to assess similar levels of TD across the different tobacco product users. Levels of TD varied significantly depending on the product used. The associations of these craving symptoms with the level of TD varied significantly ($p < 0.001$), suggesting these symptoms may have different meanings for cigarette versus other tobacco user groups. For example, both reports of ‘ever having strong cravings’ and ‘ever feeling the need’ to use the product also had a significantly weakened relationship with overall levels of TD with values of 1.18 and 0.78 for e-cigarette only users while values were 2.27 and 1.79 for cigarette only users. These two symptoms were identified for exclusion from a common instrument. In contrast, the three WISDM craving symptoms assessed TD similarly for cigarette only users, e-cigarette only, cigar only, and hookah only users. Although the strength of association with

overall levels of TD was slightly weaker ($p < 0.001$) among e-cigarette plus cigarette (discrimination = 2.16, 2.36, 1.13), smokeless only (discrimination = 1.65, 1.97, 1.28), and multiple product users (discrimination = 1.98, 2.32, 1.56) relative to cigarette only users (discrimination = 2.97, 3.27, 2.15), these symptoms remained associated with similar levels of TD across user groups.

3.4.2. Loss of control of use (6 symptoms)

The loss of control symptoms reflecting ‘difficulty refraining’ or ‘consider yourself addicted’ were significantly ($p < 0.001$) less strongly related to TD among e-cigarette only (discrimination = 0.41, 1.29) and smokeless only users (discrimination = 0.76, 1.72) relative to cigarette only users (discrimination = 1.27, 2.58). Although the ‘difficulty refraining’ symptom also was slightly weakened among cigarette plus e-cigarette (discrimination = 0.84) and multiple product users (discrimination = 0.79) relative to cigarette only users, there were no significant differences in levels of TD assessed by this item for cigarette plus e-cigarette and cigarette only groups ($p = 0.52$). Because multiple sources of DIF were primarily on one ‘loss of control’ item, it was decided to omit only the ‘consider yourself addicted’ symptom from the common measure. There were no significant differences between cigarette and cigar or hookah users on any of the five remaining loss of control symptoms and all five of these symptoms were retained for the common measure. Fig. 1 displays an example of the magnitude of identified DIF in a symptom identified for exclusion, ‘consider yourself addicted’, relative to a similar symptom to be retained, ‘I would find it hard to stop using for a week’. ICC reflects the probability of observing the expected score for a symptom on the y-axis and level of TD on the x-axis. For the ‘consider yourself addicted’ item, the level of TD associated with increasing scores on this item differed significantly across product users. For example, e-cigarette only users were significantly less likely ($p < 0.001$) and cigar only users significantly more likely ($p < 0.001$) than cigarette only users with similar levels of TD to report experiencing this symptom. In contrast, ICC for the retained symptom, ‘I would find it hard to stop using for a week’ were similar.

3.4.3. Tolerance (2 symptoms)

Two symptoms reflected tolerance: ‘wanting to use tobacco upon awakening’, and ‘using tobacco within 5 min of awakening’. The ‘wanting to use tobacco upon awakening’ symptom performed similarly across all groups with only slightly weaker relationship to overall TD among smokeless only (discrimination = 1.28, $p < 0.001$), cigarette plus e-cigarette (discrimination = 1.13, $p < 0.001$), and multiple product user groups (discrimination = 1.56, $p < 0.001$). In contrast, the ‘using tobacco within 5 min of awakening’ had significantly

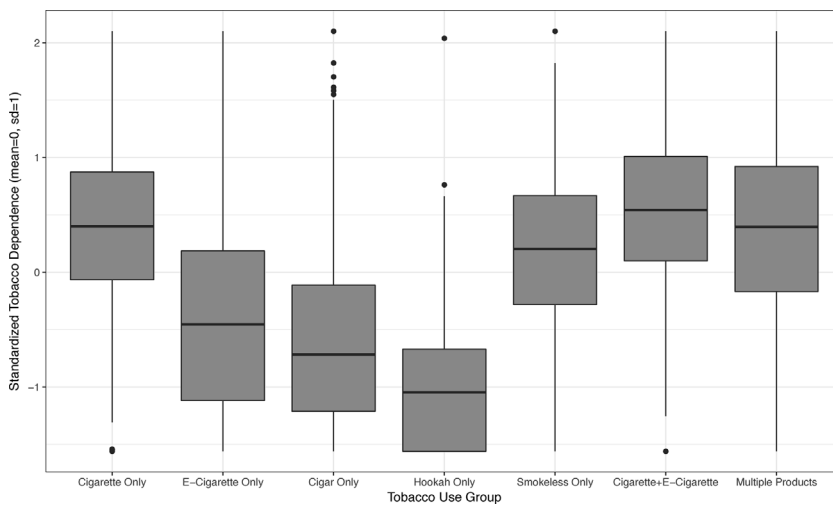


Fig. 2. Distribution of Tobacco Dependence among each product use group.

weakened relationships with overall TD (p 's < 0.05) among e-cigarette only (discrimination = 0.20, p < 0.001), smokeless only (discrimination = 0.59, p < 0.001), cigarette plus e-cigarette (discrimination = 0.35, p < 0.001), and multiple product user groups (discrimination = 1.10). The level of TD associated with 'using tobacco within 5 min' depended on the product user group and was not included on the common measure.

3.4.4. Withdrawal and relief from withdrawal (3 symptoms)

Assessments of using tobacco to 'feel less irritable' or 'keep myself from experiencing any discomfort' were similar across all tobacco use groups. These symptoms' relationships with overall TD were only slightly weaker among smokeless only (discriminations = 1.79, 1.95; p < 0.001), cigarette plus e-cigarette (discriminations = 2.04, 1.75; p < 0.001), and multiple product users (discriminations = 1.81, 1.80; p < 0.001) relative to cigarette smokers (discriminations = 2.83, 2.78). In contrast, while assessment of the presence of three or more withdrawal symptoms reflected TD similarly for hookah only and cigarette only user groups, these symptoms demonstrated significantly weakened relationships with TD or associations with a significantly different severity of TD among e-cigarette only (discrimination = 0.39, p < 0.001), cigarette plus e-cigarette (discrimination = 0.72, p < 0.001), and multiple product use groups (discrimination = 0.55, p < 0.001). Given the number of groups with identified differences we omitted this symptom from the common measure.

3.4.5. Automaticity (2 symptoms)

Two symptoms, 'reaching for tobacco without thinking about it' and 'using tobacco without thinking about it', were reflective of automaticity. Both symptoms performed well across tobacco use groups and were endorsed by users with high levels of TD. These symptoms had slightly weakened relationships with TD among smokeless only (discrimination = 1.07, p < 0.001), cigarette plus e-cigarette (discrimination = 1.46, p < 0.001), and multiple product users (discrimination = 1.48, p < 0.001) when compared to cigarette only users (discrimination = 2.02). With minimal identified differences we retained these two symptoms for the common measure.

3.4.6. Reinforcement symptoms (3 symptoms)

These three symptoms performed effectively across user groups. The symptom reflecting 'feeling alone' without tobacco performed similarly across e-cigarette only, cigar only, and hookah only users when compared to cigarette only smokers. The threshold for endorsing this symptom was slightly lower for cigar only users (threshold1 = -0.31, threshold2 = 0.65, p < 0.001) relative to cigarette only users

(threshold1 = 0.03, threshold2 = 1.10). The symptom 'makes me feel better if I've been feeling down' had a lower threshold for endorsement among cigar only (threshold1 = -1.79, threshold2 = 0.04, p < 0.001), hookah only (threshold1 = -1.37, threshold2 = -0.10, p < 0.001), and multiple product users (threshold1 = -2.06, threshold2 = 0.62, p < 0.001) when compared to cigarette only users (threshold1 = -0.96, threshold2 = 0.64). The symptom reflecting tobacco use 'makes me think better' was similar among cigarette only, e-cigarette only, smokeless only, cigarette plus e-cigarette and multiple product users. This symptom was more likely to be reported by cigar only (threshold1 = -0.86, threshold2 = 0.92, p < 0.001) and hookah only (threshold1 = -0.80, threshold2 = 0.14, p < 0.001) users relative to cigarette only smokers (threshold1 = -0.20, threshold2 = 1.28) with similar levels of TD (p < 0.01). These three symptoms were also slightly less discriminating among smokeless only (discriminations = 0.85, 0.78; p < 0.001), cigarette plus e-cigarette (discriminations = 0.76, 0.94; p < 0.001), and multiple product users (discriminations = 0.83, 0.80; p < 0.001) relative to cigarette only users (discriminations = 1.35, 1.47). This set of effective symptoms was retained for the common measure.

3.5. Concurrent validity of TD

Fig. 2 shows the median and range of TD observed in each of the product use groups. This figure shows the relatively lower levels of TD observed among e-cigarette only, cigar only and hookah only users and the relatively high levels of TD among cigarette only, cigarette plus e-cigarette, and multiple product users. Given lack of comparability of the units to reflect the quantity of different products, we established an ordered grouping of daily and non-daily use groups for cigarette only, e-cigarette only, cigar only, and smokeless only single product use groups using the frequency of use of each product in the past 30 days. Daily tobacco use was reported in 82.4% (\pm 0.66%) cigarette only, 70.1% (\pm 2.12%) e-cigarette only, 30.33% (\pm 2.14%) cigar only, 45.76% (\pm 2.66%) smokeless only user groups. Weighted regression models with p -values adjusted using the Benjamini-Hochberg procedure (Glickman et al., 2014) for multiple tests across products suggested significantly higher level of TD among the daily groups when compared to the non-daily grouping for cigarette only users (mean difference = 1.10, SE = 0.02, $F(1,10) = 2228.5$, p < 0.001), e-cigarette only users (mean difference = 0.40, SE = 0.07, $F(1,10) = 35.1$, p < 0.002), cigar only users (mean difference = 0.97, SE = 0.07, $F(1,10) = 216.4$, p < 0.001), and smokeless only users (mean difference = 0.92, SE = 0.05, $F(1,10) = 311.6$, p < 0.001). The median number of times used in the past month (unweighted median of 2 times per month) was used to calculate high (> 2 times) and low (\leq 2 times)

Table 3
Results from regression models evaluating the relationships of demographic characteristics of the Wave 1 PATH Adult participants who were identified as current established users of any tobacco product with standardized level of TD within each of the product user groups while adjusting for the corresponding frequency of use.

Variable	Cigarette Only			E-Cigarette Only			Cigar Only			Hookah Only ^a			Smokeless Only			Cigarette + E-Cigarette			Multiple Products		
	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)	Estimate	Std. Error	Pr(> t)
(Intercept)	-0.59	0.02	0.00	-0.77	0.10	0.00	-1.07	0.05	0.00	-1.22	0.05	0.00	-0.77	0.06	0.00	-0.21	0.08	0.04	-0.27	0.04	0.00
Gender																					
Male (reference)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Female	0.10	0.02	0.00	0.24	0.08	0.12	0.18	0.08	0.27	0.04	0.04	0.73	0.04	0.10	0.73	0.11	0.05	0.27	0.05	0.05	0.73
Age Group																					
18–24 (reference)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25+	0.08	0.02	0.01	0.01	0.09	0.89	0.05	0.06	0.89	0.01	0.05	0.89	0.31	0.05	0.00	0.32	0.07	0.01	0.23	0.03	0.00
Racial/Ethnic Group																					
Non-Hispanic White (reference)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other-Non-White	-0.13	0.01	0.00	-0.19	0.12	0.14	0.55	0.08	0.55	0.05	0.07	0.86	-0.01	0.08	0.86	-0.12	0.04	0.10	-0.13	0.04	0.07
Product Frequency Group																					
Non-Daily	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Daily	1.07	0.02	0.00	0.37	0.08	0.00	0.94	0.07	0.00	0.41	0.06	0.00	0.90	0.05	0.00	0.59	0.07	0.00	0.78	0.04	0.00

Note: Product frequency group refers to corresponding products among single-product users. Cigarette + E-Cigarette and Multiple Product users examine levels of cigarette smoking.
^a Hookah frequency reflects users above (> 2) or below (< 3) the median number of times using hookah in a month. P-values adjusted using Benjamini-Hochberg correction for multiple comparisons.

frequency groups for hookah only users. Hookah only users with high use reported greater TD than those with low use (mean difference = 0.41, SE = 0.06, $F(1,10) = 48.7$, $p < 0.001$). For the cigarette plus e-cigarette (77.1% ($\pm 2.3\%$) daily cigarette use) and multiple product use (74.6% ($\pm 1.0\%$) daily cigarette use) groups we examined relationships of TD with the frequency of cigarette smoking. Again, significant relationships between frequency of use and levels of TD were observed among cigarette plus e-cigarette (mean difference = 0.64, SE = 0.07, $F(1,10) = 77.9$, $p < 0.001$) and multiple product users (mean difference = 0.82, SE = 0.03, $F(1,10) = 571.4$, $p < 0.001$).

3.6. Demographic correlates of tobacco dependence

Independent relationships of demographic characteristics with TD within each of the product use groups were also examined, adjusting for the corresponding frequency of use (see Table 3). All p -values were adjusted using the Benjamini-Hochberg procedure (Glickman et al., 2014) for multiple tests across products. Among cigarette only ($b = 0.10$, $p < 0.01$), higher levels of TD among women were demonstrated. There were also higher levels of TD among cigarette only ($b = 0.08$, $p < 0.02$) users in the 25+ year-old age groups compared to cigarette only users 18–24. Non-White cigarette only smokers endorsed lower levels of TD ($b = -0.13$, $p < 0.01$) when compared to Non-Hispanic White cigarette only users. There were no significant differences in level of TD across age, gender, or racial ethnicity groups for cigar only or hookah only products (p 's > 0.06). However, there were higher levels of TD among 25+ year-old users of smokeless only ($b = 0.31$, $p < 0.01$), cigarette plus e-cigarette ($b = 0.32$, $p < 0.02$), and multiple product ($b = 0.23$, $p < 0.01$) user groups.

4. Discussion

Overall, indicators of TD, combined from various measures and adapted for use with each specific class of tobacco products, consistently identify a primary single dimension of TD that organizes important variability across users of different tobacco products. With a few exceptions, the bulk of the indicator symptoms (21 of 24) had consistent relationships with the primary TD construct for each product. Moreover, differential item function (DIF) analyses showed that 16 of these 21 symptoms performed in a similar fashion across users of different tobacco products. This suggests that scores on these 16 symptoms (see Table 1) can be used in a common instrument to assess TD across different kinds of tobacco product users.

A common measure allows us to rank levels of TD across different product user groups, and levels of overall TD were indeed found to vary across users of different tobacco products. Compared to cigarette only smokers (the largest subset of tobacco product users at 61%, and with the highest mean level of TD), levels of TD were most comparable for smokeless tobacco only users and for users of multiple tobacco products. The lowest levels of TD relative to cigarette smokers were seen in e-cigarette only users, cigar only users, and hookah only users (see Fig. 2).

It is not surprising that cigarette only as well as cigarette plus e-cigarette users showed the highest levels of TD. Factors that influence TD include product appeal, ease of use, and the frequency and manner in which nicotine is delivered, such as speed and intensity. In addition, more frequent use of each product/multiple products was associated with increased levels of TD, even though the frequency measures we used were only crude estimates of use and exposure. This finding suggests that multiple tobacco product users may be more likely to achieve high levels of exposure to nicotine perhaps because they can easily switch between products to sustain exposure, especially when and where smoking is difficult.

Although delivery of nicotine via smokeless tobacco products is not as rapid as with combustible tobacco, users achieve overall levels that compete with or exceed cigarettes and that may be sustained over

longer periods of time, contributing to dependence potential (Digard et al., 2013). Even though they can deliver substantial doses of nicotine, use of cigars and hookah may be more limited by external circumstances such as environmental restrictions than cigarettes and smokeless tobacco, resulting in overall less exposure. E-cigarettes are in a rapidly evolving product category and vary a great deal in their nicotine content and ability to deliver nicotine. Their use typically accompanies the use of other tobacco products, particularly traditional cigarettes, and sole use of e-cigarettes is not yet widespread. Overall, e-cigarette only users did have a lower level of TD, but increased frequency of use was significantly associated with increasing levels of TD.

Some differences in TD were observed across product user groups according to socio-demographic characteristics. Independent of frequency of use, age showed the most consistent effects, with older smokers generally reporting higher levels of TD for cigarettes, smokeless tobacco, cigarettes plus e-cigarettes, and multiple products. This could reflect the effect of more lifetime experience with these products, as well as unmeasured selection factors.

For cigarette only smokers, again controlling for frequency of use, gender and ethnicity/race effects were also found. The TD level for women who were cigarette only smokers was somewhat higher than for men. The effect was small, but statistically significant. It is not immediately apparent what the implications of this finding might be and this relationship has been observed in some (Kandel et al., 1997; Kandel and Chen, 2000; Smith et al., 2010) but not all population surveys (Breslau et al., 2001). Consistent with previous studies (Breslau et al., 2001; Kandel et al., 1997; Kandel and Chen, 2000; Strong et al., 2001), nonwhite participants showed lower levels of cigarette TD compared to whites, and this effect was most prominent among Hispanics and Blacks. These minority groups typically report less cigarette consumption compared to Whites (Jamal et al., 2015), but frequency of use did not account for the differences in TD observed in this study.

The items omitted from the common measure of TD were set aside from further analyses for different reasons. The first three, reflecting giving up activities to use tobacco, more time spent with tobacco users, and tobacco use causing health problems, loaded weakly on the primary TD factor in more than one tobacco use group during initial confirmatory analysis. The remaining five omitted items showed differential functioning when compared across different tobacco product user groups.

Compared to cigarette only users, time to first use ('using tobacco within 5 min of awakening') had significantly weakened relationships with overall TD among all user groups, and the level of TD associated with this item depended on the product used. Among smokeless tobacco users, endorsement of this item was associated with higher levels of TD while, among cigarette plus e-cigarette and multiple product users, it was associated with lower levels of TD. This suggests that time to first use is sensitive to product characteristics, such as speed of nicotine delivery and perhaps the ability to easily use these products soon after awakening. Therefore, this item should not be routinely considered as a "hallmark" of dependence across tobacco product types, even though it is a consistent predictor of cigarette smoking relapse (Baker et al., 2007). By contrast, the 'wanting to use tobacco upon awakening' item did perform similarly across tobacco product user groups. Positive endorsement of this item may reflect sensitivity to overnight depletion of blood and brain nicotine concentrations, even if this does not translate into immediate tobacco self-administration.

Two of the omitted craving items (i.e., 'ever having strong cravings' and 'ever feeling the need to use') did not assess level of TD similarly across the different tobacco product users, and showed significantly weaker associations especially for the e-cigarette only and e-cigarette plus cigarette user groups. The remaining craving items, however, showed adequate DIF, and this underscores the idea that craving is an important element of TD that carries across product types and users. Finally, the withdrawal item that tallied symptoms (positive if ≥ 3) did not perform well, in contrast to items that tapped feeling the need to

use a product when feeling restless, irritable and discomforted after a period of abstinence. A symptom tally, which essentially weights all symptoms equally, may not assess sufficiently symptom level information that is more closely associated with overall TD.

One limitation of this study is that excluded items, and many items from a variety of other sources that were not selected for use in this study, may perform well and may be associated with product-specific levels of TD. As very little is known about product-specific vs. unique TD characteristics, it is premature to conclude that the results of this study are definitive. Rather, additional studies could expand upon these findings and understand differences and similarities between different tobacco products and their users that contribute to both common and unique dimensions of TD, as well items that differentiate severity of TD along its entire dimension. One strength of the current study is that we were able to construct a measure of TD that covers reasonably well a large range of TD that is common across users of different tobacco products in a nationally representative sample. As we learn more about the motives for use of different tobacco products, it is possible that additional items can be developed that reflect overall TD and product-specific TD dimension across a wider range of severity. Elaboration of current theoretical models (Piper et al., 2008) could suggest additional domains of TD that help predict self-administration and persistent use of new products.

Several questions can be addressed in further research studies. One is how to think about “scoring” TD for multiple tobacco product users. It is possible, for example, that some users may be more dependent on one product (e.g., cigarettes) but less so for other products that are used less frequently. For this, one approach might be to sum item scores across products to develop an index of total burden of TD. A cross-product profile of dependence could also be constructed, but it is not immediately clear how such a profile could be utilized in any practical sense. Finally, the measures described in this paper would be strengthened by further validation. As already noted, it will be important to establish how TD varies across products and frequency of their use, using more fine grained behavioral measurements of use occasions, and product use within occasions (e.g., puff, vape, pinch, pouch, chew per unit time). Further validation of these measures of TD across key demographic factors, and with respect to biomarkers of nicotine exposure (e.g., nicotine, nicotine equivalents) would also be useful, as well as exploring their predictive validity for potentially important outcomes such as escalation of product use and inability to reduce use or quit. Analysis of longitudinal data obtained in subsequent waves of the PATH Study will help to answer some of these questions.

Conflict of interest

Dr. Cummings has received grant funding from the Pfizer, Inc., to study the impact of a hospital based tobacco cessation intervention. He also receives funding as an expert witness in litigation filed against the tobacco industry. Dr. Compton reports long-term stock ownership in General Electric Co., 3M Companies and Pfizer, Inc. Dr. Goniewicz reports having received grants from pharmaceutical companies that manufacture smoking cessation drugs, and has served on advisory boards for some of these companies. All of the above disclosures are unrelated to the submitted paper. In addition, no other authors have financial disclosures to report.

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Contributors

Dr. Strong and Dr. Niura conceptualized and designed the study including the study instruments, carried out analyses, critically reviewed the manuscript and approved the final manuscript as submitted. Drs. Compton, Conway, Cummings, and Hull assisted with the initial proposed analyses, as well as reviewed and approved all analyses. Dr. Taylor, Dr. Hyland, and Dr. Goniewicz lead the PATH project including the design of survey instruments, as well as reviewed, revised, and approved the final manuscript as submitted. All others, including Drs. Pearson, Kirchner, Abrams, Evans, and as well as Ms. Ehlke, Ms. Green, and Ms. Lambert reviewed and approved the initial proposed analyses, as well as reviewed and revised the manuscript, and approved the final manuscript as submitted. All authors have approved the final article.

Disclaimer

The views and opinions expressed in this manuscript are those of the authors only and do not necessarily represent the views, official policy or position of the US Department of Health and Human Services or any of its affiliated institutions or agencies.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.drugalcdep.2017.05.010>.

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