

Juul Labs

Measurement Matters: Psychometric Analysis of the PATH Youth Dependence Scale

12/10/2020

Ryan A. Black, Ph.D. €

Saul Shiffman, Ph.D. £

Michael J. Hannon, M.A. £

€ Juul Labs, Inc. • £ Pinney Associates (consultants to Juul Labs)

Juul Labs Science TM and © 2020 Juul Labs, Inc.

This presentation is intended for sharing with the scientific community. It is not intended for advertising or promotional purposes and is not intended for a general consumer audience.

Juul Labs

JuulLabsScience.com

Dependence on Nicotine-Containing Products: A Key Issue in Tobacco Regulatory Research

Two Types of Measurement

- **Descriptive Attributes** (i.e., Tobacco Use behavior)
 - Minimal psychometric evaluation necessary
- **Unobservable Attributes** (i.e., Dependence)
 - Comprehensive psychometric evaluation necessary

Addiction / Dependence

- 'Psychological dependence is characterized by persistent tobacco-seeking and tobacco-use behaviors, impairment in behavioral control, craving, and inability to abstain consistently.' – MRTPA Guidance
 - Assessed by multi-item self-report scales (e.g., PATH, WISDM, Fagerström)

Facets of Dependence based on DSM-V Tobacco Use Disorder Criteria

- Tolerance
 - Withdrawal
 - More use than intended (frequency or amount)
 - Persistent desire or unsuccessful efforts to control or cut down
 - A great deal of time is spent in activities necessary to obtain nicotine or recover from its effect
 - Important social, occupational or recreational activities are given up or reduced because of nicotine
 - Nicotine use is continued despite physical or psychological problems
 - Daily use of nicotine for at least several weeks
- Abrupt cessation of nicotine use or reduction in the amount of nicotine used, followed within 24 hours by four or more of the following signs:
 - Irritability, frustration, or anger
 - Anxiety
 - Difficulty concentrating
 - Restlessness
 - Decreased heart rate
 - Increased appetite or weight gain
 - Dysphoric or depressed mood
 - Insomnia

Challenges with Measuring Dependence

- Dependence is a **highly complex** construct, requiring sound application of the science of behavioral measurement (psychometrics).
- While there are widely used scales available to measure adults' dependence on cigarette smoking,
- attempting to apply these scales to assessing dependence on ENDS, and
- applying them to other age cohorts (i.e., youth), and
- Applying them to poly-tobacco users as opposed to exclusive users

raises **significant psychometric challenges**.

Examples:

- 8 items in the original PATH Dependence scale for adults do **not** function the same across tobacco categories (Strong et al., 2017)
- Key items on the Fagerström scale intended to measure dependence on cigarettes in adults
 - Do not extend to dependence on ENDS (Browne & Todd, 2018)
 - Required substantial modifications when measuring dependence on cigarettes in youth (e.g., Colby et al., 2000)

Dependence on nicotine-containing products is of interest to regulatory agencies, as it bears on:

- Continued use of regulated products
- Ability of products to displace higher risk products

FDA Guidance

Illustration

‘Summary of All Research Findings’ should include:
Assessment of abuse liability (i.e., the addictiveness, abuse, and misuse potential of the new product and the exposure to nicotine during product use)’

– PMTA guidance

- Despite the challenges in measuring dependence, FDA requires the measurement of dependence on nicotine-containing products when determining:
- Appropriateness for the protection of public health (PMTA)
- Benefit to the population in marketing a product with a modified risk claim (MRTPA)

Population Assessment of Tobacco and Health (PATH)

Study Design

- Nationally representative longitudinal study of tobacco use and health in the United States
- Waves of data collection from the noninstitutionalized, civilian US population
 - **Wave 3: Oct 2015 – Oct 2016**
 - **Wave 4: Dec 2016 – Jan 2018**

Survey Sampling Methodology

- Complex, four-stage, stratified probability sample.

Funding Source

- Food and Drug Administration (FDA)
- National Institute of Health (NIH)

Wisconsin Inventory of Smoking Dependence Motives (WISDM)

- Used in the PATH youth survey
- Initially developed and validated to measure cigarette dependence in adults, but PATH used six adapted WISDM items to measure cigarette and ENDS dependence in youth
- The youth survey administered a subset of six items to current smokers or e-cigarette users
- It is unknown whether use of these six items to assess and compare dependence on ENDS and cigarettes in youth is psychometrically appropriate
- We assessed the psychometric properties of the youth dependence scale using public use datasets representing Waves 3-4 of PATH

PATH (Youth) Dependence Scale

Item [£]	Domain/Factor
I find myself reaching for [insert category] without thinking about it.	Automaticity
I frequently crave [insert category].	Craving
My [insert category] is out of control.	Loss of Control
[insert category] really helps me feel better if I've been feeling down.	Negative Reinforcement
[insert category] helps me think better.	Cognitive Enhancement
I would feel alone without my [insert category].	Affiliative Attachment

[£]Each item describes an experience or symptom related to dependence, with responses on a five-point scale, from 1 = "Not true of me at all" to 5 = "Extremely true of me." Higher scores imply more dependence.

Objectives of this Study

Objectives of this Study

Objectives of this Study

- To determine the reliability and validity of the scale scores obtained from the 6-item scale in assessing cigarette and ENDS dependence in youth who were either dual users of cigarettes and ENDS or exclusive users of either product.
- To determine whether it is psychometrically appropriate to compare scores across scales
- Where psychometrically appropriate, analyses compared dependence on cigarette smoking to dependence on ENDS use.

Objectives of this Study

Psychometric Evaluation Process

Analytic Strategy (iterative)

- Reliability
- Convergent/Discriminant Validity
- **Item Response Function (IRT methods)**
- **Factorial Validity (Dimensionality)**
- **Scale invariance (CFA methods)**

Objectives of this Study

Sample Description

Data were obtained from respondents (12-17 years old) to waves 3 and 4 of the PATH Youth survey who were currently (past 30 day) either:

Dual users

- n=106, 61% female, 68% Caucasian

Exclusive users of Cigarettes

- n=142, 66% female, 57% Caucasian

Exclusive users of ENDS

- n=367, 47% female, 63% Caucasian

Dual Users

Item Response Function

Is the response option scale 'working'?

1 = 'Not true of me at all' to

5 = 'Extremely true of me'

Conclusion

The response options were functioning as expected for both scales, suggesting that higher response options corresponded to higher estimated dependence levels.

IRT Analysis

IRT Generalized Partial Credit Models were estimated on the 6-item cigarette dependence scale and the 6-item ENDS dependence scale to ensure the response options were psychometrically ordered for each item.

Cigarette and ENDS dependence scales

Average trait levels corresponding to each response option were generally ordered

Software

IRT PRO & SAS were used to estimate IRT models

Factorial Validity: Methods and Criteria

Is the scale measuring
'one and only one thing'?

Are the items contributing
meaningfully to
measuring dependence?

- A first-order confirmatory factor analysis (CFA) model was specified to examine the factorial validity for each of the dependence scales
- Goodness of fit was evaluated by three types of fit statistics:
 - **Absolute Fit:** Standardized root mean square residual (SRMR)
 - **Parsimony Correction:** Root mean square error of approximation (RMSEA)
 - **Comparative Fit:** Comparative fit index (CFI)
- Acceptable model fit by the following criteria: SRMR <.08, RMSEA<.10, CFI ≥ .95.
 - Relaxed threshold for the RMSEA (<.10 instead of <.08) to avoid rejecting models which demonstrated marginal fit
- Software
 - CFA models were estimated using IBM SPSS AMOS 26.0
 - Standard ML and Robust ML estimations were applied

Factorial Validity: ENDS Dependence Scale

Conclusion

The scale assessing ENDS dependence in youth who dual use shows factorial validity.

- Localized points of ill fit in the solution
 - The two items that tapped expected positive effects of using the product (i.e., helps me feel better, helps me think better) were discarded
 - One correlated error term was permitted
- Final model yielded acceptable fit (CFI=1.000, RMSEA=.027, SRMR=.012)
- All freely estimated unstandardized parameters were statistically significant ($p < .001$).
- Factor loading estimates revealed that the indicators were strongly related to ENDS dependence (range of $R^2 = .43-.99$).

Factorial Validity: Cigarettes Dependence Scale

Conclusion

The scale assessing cigarette dependence in youth who dual use shows factorial validity.

- Localized points of ill fit in the solution
 - The two items that tapped expected positive effects of using the product (i.e., helps me feel better, helps me think better) were discarded.
- Final model yielded acceptable fit (CFI=1.000, RMSEA<.001, SRMR=.006)
- All freely estimated unstandardized parameters were statistically significant ($p<.001$).
- Factor loading estimates revealed that the indicators were strongly related to cigarettes dependence (range of $R^2=.53-.86$).

Measurement Invariance

Are the scores across the scales 'comparable'?

Metric Invariance

- **Illustration only:** The 'I frequently crave ENDS' item is related to dependence on ENDS to the same degree as the 'I frequently crave cigarettes' item is related to dependence on cigarettes

Scalar Invariance

- **Illustration only:** Individuals who have the same level of dependence on ENDS and cigarettes should have, on average, the same score on the 'I frequently crave ENDS' item and the 'I frequently crave cigarettes' item

Measurement Invariance

Are the scores across the scales 'comparable'?

Conclusion

Measurement invariance **was established**, indicating that valid comparisons can be made between scales among Youth who dual use.

- Measurement invariance between the cigarette dependence scale and ENDS dependence scale was evaluated with three models:
 - Configural Invariance (equal configuration; baseline model)
 - Metric Invariance (equal factor loadings)
 - Scalar Invariance (equal factor loadings and intercepts)
- Model fit was considered significantly degraded (invariance not established) if $\Delta CFI \leq 0.01$ or $\Delta RMSEA \geq 0.015$ or $\Delta SRMR \geq 0.030$ compared to the configural model.
- Baseline model yielded adequate fit (CFI=.978, RMSEA=.087, SRMR=.044)

Findings

- Metric invariance was established
 - $\Delta CFI=0.002$, $\Delta RMSEA=-0.003$, $\Delta SRMR=.004$
- Scalar invariance was established
 - $\Delta CFI=.008$, $\Delta RMSEA=<.001$, $\Delta SRMR=0.004$

Dual Users

Dependence on ENDS Compared to Cigarettes

Mean dependence on cigarettes (1.50, SE = 0.10)
was higher than mean dependence on ENDS (1.33, SE = 0.06,
 $t(100)=2.09$, $p<0.04$).

Note: For both products, approximately two thirds of respondents had the lowest score possible ('1'), indicating dependence experiences are 'not true of me at all'

Dual Users

Summary Findings

- The scale is psychometrically appropriate for comparisons among youth dual users.
- The analyses showed that in this population, ENDS use was associated with lower dependence than was cigarette smoking.

Exclusive Users

Item Response Function

Is the response option scale
'working'?

Conclusion

The response options were functioning as expected for both scales, suggesting that higher response options corresponded to higher estimated dependence levels.

IRT Analysis

IRT Models were estimated on the 6-item cigarette dependence scale and the 6-item ENDS dependence scale to ensure the response options were psychometrically ordered for each item.

Cigarette and ENDS dependence scales

Average trait levels corresponding to each response option were generally ordered.

Exclusive Users

Factorial Validity: Cigarette Dependence Scale

Conclusion

The scale assessing cigarette dependence in youth who exclusively smoke cigarettes shows factorial validity.

- Localized points of ill fit in the solution.
 - The two items that tapped expected positive effects of using the product (i.e., helps me feel better, helps me think better) were discarded
 - One correlated error was permitted
- The final model yielded acceptable fit (CFI=1.000, RMSEA<.001, SRMR=.004)
- All freely estimated unstandardized parameters were statistically significant ($p<.001$).
- Factor loading estimates revealed that the indicators were strongly related to cigarette dependence (range of $R^2=.40-.83$).

Exclusive Users

Factorial Validity: ENDS Dependence Scale

Conclusion

The scale assessing ENDS dependence in youth who exclusively use ENDS shows factorial validity.

- Localized points of ill fit in the solution.
 - The two items that tapped expected positive effects of using the product (i.e., helps me feel better, helps me think better) were discarded
 - One correlated error was permitted
- The final model yielded acceptable fit (CFI=1.000, RMSEA<.001, SRMR=.006)
- All freely estimated unstandardized parameters were statistically significant ($p<.001$).
- Factor loading estimates revealed that the indicators were strongly related to ENDS dependence (range of $R^2=.23-.92$).

Measurement Invariance

Are the scores across the scales 'comparable'?

Conclusion

Measurement invariance was **not** established, indicating that valid comparisons cannot be made between scales among Youth exclusive users

Measurement invariance between the cigarette dependence scale and ENDS dependence scale was evaluated in three steps:

- Configural Invariance (equal configuration; baseline model)
- Metric Invariance (equal factor loadings)
- Scalar Invariance (equal factor loadings and intercepts)

Model fit was considered significantly degraded (invariance not established) if $\Delta CFI \leq 0.01$ or $\Delta RMSEA \geq 0.015$ or $\Delta SRMR \geq 0.030$ compared to the configural model.

Baseline model yielded adequate fit ($CFI=1.000$, $RMSEA < .001$, $SRMR=.004$).

Findings:

- Metric invariance was not established as the model fit degraded substantially ($\Delta CFI=0.016$, $\Delta RMSEA=.078$, $\Delta SRMR=.028$).
- Scalar invariance was also not established ($\Delta CFI=0.028$, $\Delta RMSEA=0.082$, $\Delta SRMR=0.023$).

Exclusive Users

Exclusive Use: Summary Findings

- The scale was **not** psychometrically appropriate for comparisons between youth exclusive users.

Conclusion

Conclusion

- Psychometric analyses reveal that a 4-item version of the PATH WISDM scale:
- may be used to assess and compare dependence on cigarettes and ENDS among youth who dual use
- may be used to assess dependence on cigarettes and ENDS independently among youth who are exclusive users, but scores are not psychometrically comparable across scales
- **Findings reinforce need to formally evaluate psychometric properties of scales used when assessing and comparing dependence across various populations or products.**
- **Without this, their use could lead to inaccurate assessment of dependence, and ultimately influence adoption of ill-advised public health policy.**