

# Changes in Dependence Over One Year among Adult Smokers who Switched Completely or Partially to use of the JUUL System

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## Introduction

- Nicotine is the primary constituent in cigarettes that sustains smoking and leads to dependence on cigarettes.<sup>1,2</sup>
- Electronic cigarettes (e-cigarettes) or “Electronic Nicotine Delivery Systems” (ENDS), deliver nicotine without many of the toxic chemicals in cigarette smoke, which are largely products of combustion.<sup>3,4</sup>
- ENDS are intended to reduce harm by helping smokers who would not otherwise quit in the near term switch away from smoking.
- Researchers and regulators agree that some degree of dependence is necessary if ENDS are to facilitate smokers switching away from cigarettes.<sup>5-7</sup>
- Previous papers comparing dependence on ENDS to dependence on cigarettes are limited by the psychometrics of measures used to assess dependence and by cross-sectional designs.<sup>8-11</sup>
- The current study used a measure of dependence psychometrically validated for quantitative comparison of dependence on cigarettes and ENDS.
- \* This is a secondary analysis of the longitudinal Adult JUUL Switching and Smoking Trajectories (ADJUSST) study<sup>12</sup> to address two questions:
  - How does smokers’ dependence change as they transition from baseline cigarette smoking to subsequent use of JUUL?
  - How does the level of dependence change over 12 months of use?

## Methods

### Participants

- US adult (age ≥21 years) established smokers who purchased a JUUL Starter Kit (JSK) in a retail store or online via JUUL’s website in June to October, 2018 who accepted an invitation to participate in the study.
- Established smokers: at baseline, smoked ≥100 cigarettes lifetime, smoked in the past 30 days, and smoked some days or every day.
- 17,619 adult established smokers provided baseline and at least some follow-up data.

### Assessment of Dependence

- After baseline assessment, participants were invited by email to complete follow-up assessments 1, 2, 3, 6, 9 and 12-month later.
- Dependence was assessed with the Tobacco Dependence Index (TDI), a validated measure from the PATH study (Range: 1-5; higher scores indicate greater dependence),<sup>13,14</sup> validated for assessing and comparing cigarette and ENDS dependence (i.e., specifically developed to be invariant over product).
- Cigarette dependence was assessed at baseline only
- JUUL dependence was assessed at each follow-up among JUUL users
- Participants were classified as having switched if they had not smoked at all (even a puff) in the past 30 days.

### Statistical Analysis

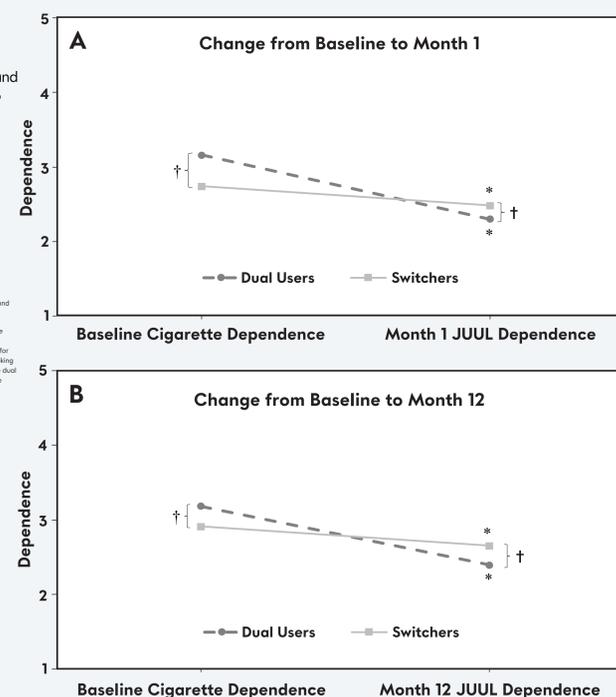
- Transitions from smoking: Paired t-tests assessed changes in dependence from smoking (baseline) to JUUL dependence 1 and 12 months later (separately for switchers and dual users)
- Change over time: Multilevel linear models (MLM) tested the linear association of JUUL dependence level and months since baseline
- Subsample analyses were run among participants who used JUUL at all six follow-ups, out to month 12, separately for smokers consistently switched and those consistently dual using at all 6 follow-ups
- The minimally important difference (MID) in TDI dependence scores was estimated by comparing the Month 1 scores of participants who did and did not switch at Month 2.

## Results

- Sample characteristics: average 32.64 years old, 54.9% male, 78.2% non-Hispanic white, smoking for 12.39 years (SD=10.62); smoked 23.30 days per month (SD=9.48) and 11.07 (SD=8.14) cigarettes per day, mean TDI score for cigarette dependence was 3.02 (SD=1.08) at baseline.
- The MID was estimated to be 0.24 points, which was the difference in Month 1 JUUL TDI scores between those who did vs. did not switch away from smoking at Month 2
- Levels of dependence significantly decreased from baseline cigarette dependence to dependence on JUUL at both month 1 and Month 12, in both participants who switched completely (**Figure 1, Panel A**) and dual users (**Figure 1, Panel B**) at each time-point.
- A model including all observations showed a linear trend in JUUL dependence, estimated at a linear increase of 0.01 TDI points per month,  $p < 0.001$  (**Figure 2**).
- A sample of 734 smokers consistently reported not smoking while reporting using JUUL at every follow-up out to 12 months (**Figure 2**); levels of JUUL dependence increased significantly, at a rate of 0.01 points per month ( $p < 0.001$ ).
- Similar effects – increases of 0.01 points per month ( $p < 0.001$ ) – were seen in 1308 participants who also reported using JUUL at all follow-ups out to 12 months, but were also smoking (dual using) at all time-points (**Figure 2**).

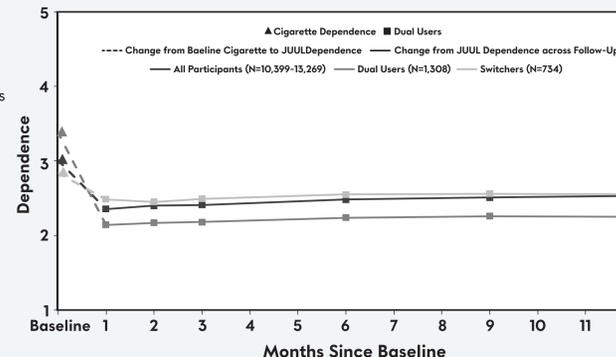
**Figure 1.** Changes in Baseline Cigarette Dependence to JUUL Dependence at 1 and 12 Months among Switchers and Dual Users at each Follow-Up (Mean±SE)

Note: \*Significant decrease from baseline cigarette dependence to subsequent JUUL dependence ( $p < 0.001$ ).  
†Significant difference in dependence between switchers and dual users ( $p < 0.001$ ).  
Changes in TDI dependence scores from baseline cigarette dependence to subsequent JUUL dependence at Month 1 (Panel A) and Month 12 (Panel B) respectively, are shown for two subgroups: smokers who had switched away from smoking at the respective follow-up (solid line) and those who were dual users (i.e., smoking as well as using JUUL) at the respective follow-ups.



**Figure 2.** Changes in Dependence from Baseline Cigarette Dependence to JUUL Dependence across Follow-Up by Switching Status

Note: The figure displays changes in TDI dependence scores over time. The first time point, denoted with a triangle, indicates the baseline TDI score for cigarette dependence. Subsequent timepoints, shown with squares, indicate the course of TDI scores for JUUL dependence (solid line). The dotted line indicates the change from baseline cigarette dependence to initial (1 month) JUUL dependence. The data are shown for all participants and for two subgroups: those who indicated JUUL use and no smoking at all six follow-ups, and those who indicated JUUL use along with smoking (dual use) at all six follow-ups. Corresponding analyses are reported in the text.



## Limitations

- The sample consisted of smokers who purchased a JSK and volunteered for a study
- Cigarette dependence was assessed only at baseline, so the data do not address the trajectory of cigarette dependence in dual users
- Data were not available on use of or dependence on other tobacco products
- Some follow-ups were missed, which could have introduced bias. However, analyses<sup>12</sup> showed that participants who missed follow-ups were not materially different from those who did not

## Strengths

- Use of the TDI, which is validated for assessing and comparing dependence on both cigarettes and ENDS
- A large sample of adult smokers, followed over six time-points for as long as 12 months
- JSK purchasers likely represent more engaged JUUL users who might be deemed at greatest risk for JUUL dependence
- Analyses examined increases independence among participants who reported using JUUL at every follow-up for 12 months, who might be deemed at greatest risk for JUUL dependence
- Analyses helped establish the MID for the TDI scale by reference to prospective prediction of a behaviorally meaningful endpoint – switching completely away from cigarettes

## Conclusions

- Average dependence declined significantly and meaningfully as smokers transitioned from cigarette smoking to use of JUUL; the decline was evident even after JUUL use for 12 months.
- Even among participants who reported consistently using JUUL at all follow-ups over 12 months, the average increase in JUUL dependence was small (0.01 points per month) and did not exceed the minimally important difference for the TDI scale.
- These findings are consistent with multiple studies reporting that dependence on ENDS is lower than dependence on cigarettes<sup>4,8-11</sup>
- These new data add a within-person longitudinal perspective demonstrating:
  - mean decline in dependence as shift from smoking to JUUL
  - little increase in dependence over 12 months of use

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