

# Exhibit 8

## Vaping and the Number of Cigarettes Not Now Smoked: An Additional Means of Assessing the Public Health Impact of E-cigarettes

Neil McKeganey Ph.D., Christopher Russell Ph.D., Farhana Haseen Ph.D.

Centre for Substance Use Research, West of Scotland Science Park, Glasgow, UK

**\*Corresponding author:** Neil McKeganey, Centre for Substance Use Research, West of Scotland Science Park, Glasgow G20 0SP, UK. Email: [mckeganey@csures.org](mailto:mckeganey@csures.org)

**Citation:** McKeganey N, Russell C, Haseen F (2019) Vaping and the Number of Cigarettes Not Now Smoked: An Additional Means of Assessing the Public Health Impact of E-cigarettes. J Plum Respir Med 3: 104. DOI: 10.29011/PROA-104.100004

**Received Date:** 12 December, 2018; **Accepted Date:** 11 February, 2019; **Published Date:** 18 February, 2019

### Abstract

There are multiple ways in which the public health impact of e-cigarettes is being assessed including determining the extent to which these devices are being used by current smokers, former smokers, and never smokers and identifying whether and to what extent e-cigarette use is associated with an increase or decrease in the rate of smoking and smoking cessation. In addition to these domains there is merit also in identifying the quantity of cigarettes not being smoked as a result of e-cigarette use. In this paper we focus on this issue by drawing upon data from a study of adult smokers within the United States using the JUUL starter kit. Comparing the quantity of cigarettes smoked in the month before initiating JUUL use with the quantity of cigarettes smoked after three months of JUUL use demonstrates a reduction in the quantity of cigarettes smoked on the part of 7721 adult smokers from 2,074,664 cigarettes to 551,863. Estimating the quantity reduction in cigarettes smoked could be a useful further means of assessing the impact of e-cigarettes as well as a means of documenting the impact of electronic nicotine delivery systems on the broader tobacco industry.

### Introduction

In assessing the public health impact of electronic cigarettes attention has been directed at determining the extent to which these devices are being used by current smokers, former smokers, and never smokers [1]. With regard to assessing the impact of e-cigarettes on current smokers key questions being asked have to do with determining the extent to which smokers using these devices are smoking more or less as a result of their e-cigarette use [2-5], whether they are combining both smoking and vaping (dual use) thereby potentially increasing rather than reducing their nicotine consumption [6-8] and the rate at which they are quitting smoking or switching to exclusive use of e-cigarettes as an alternative to smoking. With regard to former smokers, key questions being addressed have to do with determining the extent to which former smokers are at increased risk of resuming smoking following their e-cigarette use- perhaps as a result of re-acquiring a dependence upon nicotine [9,10]. With regard to those who have never smoked the focus of research has been on determining the extent to which their use of e-cigarettes has increased their likelihood of initiating smoking following their vaping [11]. Alongside each of

these research questions studies are underway to assess the safety of e-cigarettes, and the relative toxicity of the liquids used within these devices, in the short, medium, and long term [12].

As the popularity of e-cigarettes has increased, attention has also come to be directed at assessing the extent to which these devices are being used vulnerable groups. For example, the Centers for Diseases Control and Prevention within the United States has reported a recent marked increase in the proportion of young people using e-cigarettes [13]. Other research, and evidence reviews, have reported that young people using e-cigarettes are at increased risk of initiating smoking, with e-cigarettes acting as a possible "gateway" to smoking [14-17].

Whilst this range of concerns and questions is clearly crucial in assessing the public health impact of e-cigarettes it is also important to consider what impact e-cigarette may be having on reducing the overall quantity of combustible cigarettes being smoked. In this paper we look at changes in the quantity of cigarettes smoked over a three-month period by adult smokers using the JUUL e-cigarette which is the most widely used e-cigarette currently available within the United States.

## Research Methods

In 2018 we undertook a survey of U.S. adults purchasing a JUUL starter kit either online or in-store. Eligible individuals were U.S. adults aged 21 years and older who had smoked at least 100 cigarettes in their lifetime, who were smoking 'every day' or on 'some days', at the point at which they purchased their first JUUL Starter Kit from either a retail store or online within the past seven days (i.e. a new JUUL user). Individuals were invited to participate in this study via an invitation which appeared on the online JUUL purchase site, and which was included within the packaging of 500,000 JUUL Starter Kits distributed at random to approximately 10,000 licensed retailers of JUUL vapor products across the United States. In total, 9272 adult smokers participated within our survey of whom 7721 provided data on the frequency and intensity of their smoking at baseline and at the three-month follow-up point.

Both the online and retail store invitations provided the individual with a unique six-digit alphanumeric code that enabled the individual to access the online consent form, to determine whether they met the survey eligibility criteria and, if they so choose, to complete the online survey. Each six-digit code was valid for one entry thereby blocking any attempt at multiple survey submissions. Survey completion was timed at around 15 minutes, with participants receiving a \$30 virtual visa payment in return for their participation. Invitations to complete the follow-up survey were automatically emailed to participants after 25 days, with reminder emails sent after 28 days and 31 days. Access to a follow-up survey expired 10 days after the first email invitation was sent.

## Analysis

The primary outcome measure used in our research was past 30-day abstinence from smoking, which was determined at the 90-day follow-up by a "No" response to the question, "In the past 30 days, have you smoked a cigarette, even one or two puffs?" Participants who indicated they had smoked a cigarette in the past 30 days were asked two further questions about the frequency of

their smoking in the past 30 days - "Do you now smoke cigarettes" (every day; some days; not at all), and "On how many of the past 30 days did you smoke cigarettes?" (1-30 days) - and one question about their intensity of smoking in the past 30 days - "On those days that you did smoke, how many cigarettes did you usually smoke each day? A pack usually has 20 cigarettes in it". Participants who did not provide valid answers to these four questions were excluded from the analytic sample.

Analyses of change in the total number of cigarettes smoked over three months were restricted to participants who reported the number of days on which they had smoked any cigarettes in the 30 days prior to the baseline assessment, and the number of cigarettes they typically smoked on each smoking day within that period. The answers to these two questions were used to produce participant's 'number of cigarettes smoked in the 30 days prior to the baseline assessment'. This total number of cigarettes smoked in the 30 days prior to the baseline assessment was then compared to the total number of cigarettes smoked by participants in the 30 days prior to the 3-month follow-up assessment - with survey participants having been asked the same questions about the number of days smoking in the last 30 days and the number of cigarettes smoked on those days. Through comparing these two totals (30 days prior to baseline and 30 days prior to the 3 month follow up) it was possible to calculate how many cigarettes had conceivably not been smoked on the assumption that in the absence of the use of e-cigarettes the quantity of cigarettes that might otherwise have been smoked by survey participants at the 90 day follow up point would have been the same as the rate recorded for the 30 days prior to baseline.

## Results

Changes in the Number of Cigarettes Smoked at Study Outset and at 90 days Follow-up.

In Table 1 below we summarize the data on the demographics of the adult smokers included within the survey and the reported level of smoking over the monitoring period.

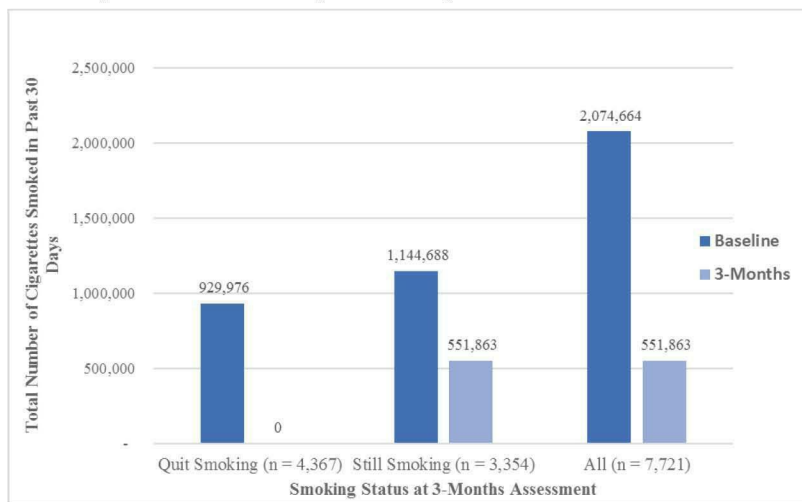
Smoking Status at 3-Months Follow-Up Assessment			
Variable	Smoked in Past 30 Days (n =4,905) N %	No Smoking in Past 30 Days (n =4,367) N %	Total (n =9,272) N %
Demographic Variables			
Sex			
Male	2716 (55.4)	2607 (59.7)	5,323 (57.4)
Female	2120 (43.2)	1706 (39.1)	3,826 (41.3)
Transgender	27 (0.6)	24 (0.5)	51 (0.6)
Missing	42 (0.9)	30 (0.7)	72 (0.8)
Age			

21-24	1339 (27.3)	1731 (39.6)	3,070 (33.1)
25-34	1689 (34.4)	1413 (32.4)	3,102 (33.5)
35-44	1003 (20.4)	621 (14.2)	1,624 (17.5)
45-54	539 (11.0)	339 (7.8)	878 (9.5)
55-64	267 (5.4)	236 (5.4)	503 (5.4)
≥ 65	68 (1.4)	27 (0.6)	95 (1.0)
<b>Smoking and e-cigarette Variables</b>			
<b>Age of first smoking</b>			
≤ 11 years	191 (3.9)	126 (2.9)	317 (3.4)
12 to 14 years	1177 (24.0)	751 (17.2)	1,928 (20.8)
15 to 17 years	1938 (39.5)	1552 (35.5)	3,490 (37.6)
18 to 24 years	1497 (30.5)	1831 (41.9)	3,328 (35.9)
≥ 25 years	87 (1.8)	94 (2.2)	181 (2.0)
Missing	15 (0.3)	13 (0.3)	28 (0.3)
<b>Lifetime years of smoking</b>			
≤ 1 year	315 (6.4)	513 (11.7)	828 (8.9)
1-5 years	1138 (23.2)	1485 (34.0)	2,623 (28.3)
6-10 years	1071 (21.8)	870 (19.9)	1,941 (20.9)
11-20 years	1265 (25.8)	784 (18.0)	2,049 (22.1)
≥ 20 years	1029 (21.0)	601 (13.8)	1,630 (17.6)
Missing	87 (1.8)	114 (2.6)	201 (2.2)
<b>Smoking days in 30 days prior to baseline</b>			
1-9 days	468 (9.5)	819 (18.8)	1,287 (13.9)
10-19 days	456 (9.3)	686 (15.7)	1,142 (12.3)
20-29 days	1031 (21.0)	1085 (24.8)	2,116 (22.8)
30 days	2950 (60.1)	1777 (40.7)	4,727 (51.0)
<b>Cigarettes smoked per day at baseline</b>			
1-9 cigarettes per day	2224 (45.3)	2626 (60.1)	4,850 (52.3)
10-19 cigarettes per day	1609 (32.8)	1134 (26.0)	2,743 (29.6)
≥ 20 cigarettes per day	1072 (21.9)	607 (13.9)	1,679 (18.1)
<b>Days of JUUL use in past 30 days at 3 months</b>			
0 day	35 (0.7)	13 (0.3)	48 (0.5)
1-9 days	394 (8.0)	275 (6.3)	669 (7.2)

10-19 days	725 (14.8)	356 (8.2)	1,081 (11.7)
20-29 days	1040 (21.2)	704 (16.1)	1,744 (18.8)
30 days	2476 (50.5)	2710 (62.1)	5,186 (55.9)
Missing	235 (4.8)	309 (7.1)	544 (5.9)
<b>Yes</b>	568 (11.6)	407 (9.3)	975 (10.5)
<b>No</b>	4335 (88.4)	3958 (90.6)	8,293 (89.4)
<b>Missing</b>	2 (0.0)	2 (0.0)	4 (0.0)

**Table 1:** Demographic, smoking and e-cigarette use characteristics of participants who completed the 3-months follow-up assessment (n = 9,272; 60.0% of ITT sample), by smoking status at the 3 months' follow-up assessment.

The total number of cigarettes smoked by all participants reduced from 2,074,664 cigarettes (103,733 packs) in the 30 days prior to baseline, to 551,863 cigarettes (27,593 packs) in the 30 days prior to the 3 months' assessment. In Figure 1 below we show the reduction in the number of cigarettes smoked across the whole sample and differentiated between the two groups of those who were still smoking at the 3 months follow up assessment and those who reported no smoking at the 3 months' assessment.



**Figure 1:** Total number of cigarettes smoked in the 30 days prior to assessments at baseline and 3 months' follow-up. (7721 represents the number of respondents providing smoking frequency data at both baseline and follow-up).

For those participants who were still smoking at the point of the three months follow up assessment, the reduction in the total number of cigarettes smoked was from 1,144,688 in the month prior to baseline to 551,863 in the month prior to the three-month follow-up assessment (51.8%). For those participants who had quit smoking entirely by the time of their three-month follow up assessment the reduction was from 929,976 in the month prior to the baseline survey to zero in the month prior to the three-month assessment.



## JUUL and the Possible Wider Reduction in the Number of Cigarettes Smoked

In this section we draw upon information on the rate of reduced smoking on the part of our survey participants to consider the possible scale of the reduction in cigarettes smoked on the part of adult smokers more broadly within the U.S. using the JUUL e-cigarette.

According to Mirbolouk et al [18] there were an estimated 10.8 million adult e-cigarette users within the United States in 2016, 54.6% (5,896,800) of whom were current smokers. Whilst there are no data available on the number of adult smokers within the United States using the JUUL device nevertheless market analysts have reported that JUUL is by a large margin the most popular e-cigarette currently being used within the United States

with the JUUL company constituting 71.2% of the dollar value of U.S. e-cigarette market [19]. On that basis it is likely that a large proportion of the estimated 5,896,800 adult's smokers using e-cigarettes within the United States are using a JUUL device.

In Table 2 below we estimate the possible reduction in the number of cigarettes smoked associated with JUUL use on the assumption that somewhere between 20% to 40% of vaping adult smokers within the United States may be using the JUUL device. In calculating the possible reduction in the number of cigarettes being smoked by JUUL using adult smokers we have utilized the rate of reduction in the number of cigarettes smoked identified on the part of our survey participants (an average of 268.6 cigarettes smoked per smoker per month at baseline compared to the 197.2 cigarettes smoked per month per smoker following three months of JUUL use).

Possible % of adult Smokers in U.S. using JUUL e-cigarettes based on Mirbolouk et al (2018) estimate of 5,896,800 adult smokers using e cigarettes in U.S. in 2016	Possible nos of JUUL using adults smokers within the U.S.	Est nos of cigarettes smoked in one month prior to JUUL use calculated on the basis of 268.7 cigarettes per smoker as reported in our survey at baseline	Est nos of cigarettes smoked in one month following JUUL use calculated on the basis of 197.2 cigarettes per smoker as reported in our survey at 3-month follow up	Est nos of cigarettes not smoked in one month following 3-month JUUL use.
20%	1,179,360	316,894,032	232,568,792	84,324,240
30%	1,769,040	475,341,048	348,854,688	126,486,360
40%	2,358,720	633,788,064	465,139,584	168,648,480

**Table 2:** Possible Reduction Cigarettes Smoked Associated with JUUL Nationally.

If 20% of e-cigarette using adult smokers in the U.S. are using JUUL, with the same frequency as our survey respondents, the estimated 1,179,360 adult smokers would have smoked 316,894,032 cigarettes in the month prior to their first JUUL use, with that number reducing by 84,324,240 to 232,568,792 in the month following three months of JUUL use. If 30% of e-cigarette using adult smokers in the U.S. are using JUUL the equivalent reduction would be from 475,341,048 to 348,854,688 (a reduction of 126,486,360 in the number of cigarettes smoked). If 40% of adult e-cigarette using smokers in the U.S. are using JUUL then the reduction in the number of cigarettes smoked would be from 633,788,064 to 465,139,584 (a reduction of 168,648,480 in the number of cigarettes smoked).

Given the scale of that possible potential reduction in the number of cigarettes smoked as a result of three-month JUUL use it is interesting to consider whether anything like that reduction is evident in the data on cigarette sales volume within the United States. According to industry analysts there was a 9 billion reduction in the number of cigarettes sold within the United States between 2016 and 2017 - a 3.5% reduction in the volume of cigarettes sold [20]. Whilst it is not possible on the basis of our data to suggest that the proposed reduction in the number of cigarettes sold is attributable to the effect of any one e-cigarette brand, it is notable

that the reduction in cigarettes smoked obtained by extrapolating from our survey data to a national level is well within the overall reduction in cigarette sales being reported by industry analysts.

## Discussion and Conclusions

In this paper we have sought to produce an estimate of the number of cigarettes that conceivably have not been smoked following three-month use of the JUUL e-cigarette. In addition, we have also considered the scale of the possible reduction in the number of cigarettes smoked at a national level within the U.S. on the part of those adult smokers using the JUUL device. Before discussing these analyses further, it is important to acknowledge the limitations of this study. All of the data presented here on the numbers of cigarettes smoked at baseline, and at the three-month follow-up assessment, are based upon self-report. We have no way of checking the accuracy of the survey participants reports of their smoking behavior in terms of the numbers of days smoking, or the quantity of cigarettes smoked. Having said that there was no advantage for participants in either over or under-reporting the frequency or intensity of their smoking.

It is further important to acknowledge that the calculation of the number of cigarettes prevented from being smoked over the period of e-cigarette use is a hypothesized figure based on the as-

sumption that in the absence of the individual's e-cigarette use, his or her smoking behavior would have continued largely unchanged over the three-month assessment period. It is conceivable that in the absence of the individual's e-cigarettes use other methods of smoking cessation or reduction might have been used. In that event it would be possible to provide a similar calculation as to the hypothesized number of cigarettes not now smoked as a result of the use of those other methods of smoking cessation. Within the present study survey participants did not use other methods of smoking cessation alongside their e-cigarette use over the three months of the monitoring period. Moreover, in a separate study of 11,689 regular adult smokers using the JUUL device more than three quarters of those who managed to quit (64.3% of the original sample) attributed their success to their use of the JUUL device. [21].

On the basis of the evidence presented here there is a substantial reduction in the quantity of cigarettes smoked from baseline to three months amongst a sample of adult smokers using the JUUL e-cigarette. This measure of the quantity of cigarettes not smoked has not previously been offered as a tool for assessing the public health impact of e-cigarettes. Whilst there is clearly some relationship between the total number of cigarettes smoked and the total level of harm resulting from that consumption (at a population level) that relationship is unlikely to be linear. The range and distribution of public health harms flowing from combustible cigarette use will be influenced by, amongst other things, the pattern of smoking, the duration of smoking, the intensity of smoking and the age of initiation of smoking. However, at a population level there is clearly some relationship between the quantity of cigarettes smoked and the harm associated with that smoking such that with the eradication of all smoking one would see a marked diminution, and ultimately the disappearance over time, of all smoking related health harms. On the basis that there is some kind of relationship between the total number of cigarettes smoked and the total amount of smoking related harm, it may well be appropriate for public health agencies and those committed to reducing smoking related health harm to include the quantity of cigarettes not now being smoked as an item in their assessment of progress towards reducing the health harms of smoking combustible tobacco products. Whilst it is not possible to precisely assess the overall reduction in the number of cigarettes smoked at a population level associated with the use of the JUUL e-cigarette nevertheless the magnitude of that effect is likely to be substantial given the large share of the e-cigarette market held by JUUL.

Finally, and in a wholly different context, efforts aiming to quantify the reduction in the number of cigarettes smoked associated with the use of e-cigarettes may be of interest to market analysts advising investors as to where to make their investment and whether those funds should be switched from the traditional tobacco companies to those companies specializing in electronic nicotine delivery systems. It is perhaps for this reason, as much as any other, that major tobacco companies are now investing heavily

in the electronic nicotine delivery business as a possible way of reducing the risk to their core product resulting from a further population shift away from smoking to vaping.

## Acknowledgement

The research reported in this paper was funded by JUUL labs who had no role in the design of the study in the analysis or reporting of the data including in the decision to submit this manuscript for peer reviewed publication. Using the Department of Health and Human Services regulations found at 45 CFR 46.101(b)(2), Advarra Institutional Review Board (IRB) determined the component of this study involving collection of data from individuals who purchased a JUUL Starter Kit in a retail store to be exempt from IRB oversight (Exempt Determination received 5 April 2018; Protocol Number 00024906). Data are also reported by 7,633 age-verified adults who opted in to JUUL Labs Inc.'s internal market research surveys when purchasing JUUL products online. Informed consent to participate was obtained from all participants. The Informed Consent Form used in the current study is available from the corresponding author on reasonable request.

## References

1. U.S. Department of Health and Human Services Food and Drug Administration Center for Tobacco Products (2016) Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems. Guidance for Industry DRAFT GUIDANCE
2. Polosa R, Cibella F, Caponnetto P, Maglia M, Prosperini U, et al. (2017) Health impact of E-cigarettes: a prospective 3.5-year study of regular daily users who have never smoked. *Sci Rep* 7: 13825.
3. Coleman B, Rostron B, Johnson SE, Persoskie, Pearson J, et al. (2018) Transitions in electronic cigarette use among adults in the Population Assessment of Tobacco and Health (PATH) Study. *Waves* 1 and 2 (2013-2015). *Tob Control* 28: 1.
4. McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P (2014) Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev* 12.
5. Kulik C, Nadra E, Glantz S (2018) E-cigarettes Associated With Depressed Smoking Cessation: A Cross-sectional Study of 28 European Union Countries *American Journal of Preventive Medicine* 54: 603-609.
6. Hinton A, Nagaiaia HN, Cooper S, Wewers ME (2018) Tobacco product transition patterns in rural and urban cohorts: Where do dual users go? *Prev Med Rep* 12: 241-244.
7. Robertson L, Hoek J, Blank ML, Richards R, Ling P, et al. (2018) Dual use of electronic nicotine delivery systems (ENDS) and smoked tobacco: a qualitative analysis *Tob Control* 1-7.
8. Morean, M, Krishnan S, O'Malley SS (2018) Comparing cigarette and e-cigarette dependence and predicting frequency of smoking and e-cigarette use in dual-users of cigarettes and e-cigarettes 87: 92-96.
9. Durkin S, Bayly M, Wakefield M (2016) Can e-cigarette ads undermine former smokers? An experimental study. *Tobacco Regulatory Science* 2: 263-277.

10. Dutra L, Glantz S (2014) High International Electronic Cigarette Use Among Never Smoker Adolescents. *Journal of Adolescent Health* 55: 595-597.
11. Murthy VH (2017) E-Cigarette Use Among Youth and Young Adults: A Major Public Health Concern. *JAMA Pediatr* 171:209-210.
12. Zhang G, Wang Z, Zhang K, Hou R, Xing C, et al. (2018) Safety Assessment of Electronic Cigarettes and Their Relationship with Cardiovascular Disease. *Int J Environ Res Public Health* 15: 75.
13. Centers for Disease Control and Prevention (2018) Morbidity and Mortality Weekly Report Notes from the Field Use of electronic Cigarettes and Any Tobacco Product Among Middle and High School Students United States 2011-2018 67: 1276-1277.
14. National Academies of Sciences Engineering and Medicine (2018) Consensus Study Report Public Health Consequences of E-Cigarettes.
15. Etter JF (2017) Gateway effects and electronic cigarettes. *Addiction* 113: 1776-1783.
16. Barrington-Trimis JL, Kong G, Leventhal AM, Liu FF, Mayer M, et al. (2018) e-cigarette Use and Subsequent Smoking Frequency Among Adolescents. *Pediatrics* 2018.
17. Miech R, Patrick ME, O'Malley P, Johnston LD (2016) e-cigarette use as a predictor of cigarette smoking: results from a 1-year follow-up of a national sample of 12th grade students. *Tobacco Control* 26: 2.
18. Mirbolouk M, Charkhchi P, Kianoush S, Uddin SMI, Orimoloye OA, et al. (2018) Prevalence and Distribution of e-cigarette Use among U.S. Adults: Behavioural Risk Factors Surveillance System 2016. *Annals of Internal Medicine* 169: 429-438.
19. Herzog B, Kanada P (2018) Nielsen: Tobacco All Channel Data Thru8/11- Cig Vol Decelerates. Wells Fargo.
20. Maxwell JC (2018) The Maxwell Report: Year End & Fourth Quarter 2017 Cigarette Industry. Richmond, VA. John C. Maxwell Jr.
21. Russell C, McKeganey N, Haseen, F (2018) Transitions in cigarette smoking associated with use of the JUUL vaping device among 18,799 adults in the United States. 2018. Centre for Substance Use Research: Glasgow UK 2018.