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# Electronic nicotine delivery system use, cigarette smoking, and dual use among American Indians

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**Keywords**: American Indians, Electronic Cigarettes, Cigarette Smoking Epidemiologic Studies, Minority Groups, Tobacco Use, Dependence

## ABSTRACT

**Objective**: Little information exists on electronic nicotine delivery system (ENDS) use among American Indians (AI). The objective of this study was to examine use behaviors and dependence among a convenience sample of AI ENDS users, smokers, and dual users.

**Setting**: Southern plains region of the United States

**Participants**: Adults of AI descent who reported being current daily ENDS users (n=27), cigarette smokers (n=27), and dual users (n=28) were recruited in 2016.

**Measures**: Participants completed a detailed questionnaire on tobacco use behaviors. The Hooked on Nicotine Checklist (HONC) was used to assess loss of autonomy over cigarettes and was reworded for ENDS. Dual users completed the HONC twice. Sum of endorsed items indicated severity of diminished autonomy. Comparisons were made with nonparametric methods and statistical significance was defined as $p<0.05$.

**Results**: Among smokers and dual users, median duration smoking was 26.0 and 21.5 years and median cigarettes per day was 10 and 15. Median severity of diminished autonomy over cigarettes did not differ between smokers and dual users (8.0 vs 9.0; p=0.0806). Among ENDS and dual users, median duration of ENDS use was 2.0 and 1.0 years. Most ENDS and dual users reported <20 vape sessions per day (72.0% vs. 72.0%) with ≤10 puffs per session (70.4% vs. 69.2%). Median severity of diminished autonomy over ENDS was similar among ENDS and dual users (4.0 vs 3.0; p=0.6865). Among dual users, severity of diminished autonomy was higher for cigarettes than ENDS (9.0 vs. 3.0; p=<.0001).

**Conclusions**: The dependence potential of ENDS is lower than cigarettes in this sample of AI. This study is informative for public health officials and regulators who are trying to understand

the impact of ENDS and dual use, and for tailoring smoking prevention and cessation interventions for AI.

## Strengths and limitations of this study

- This study provides timely information on use behaviors and dependence in electronic nicotine delivery systems (ENDS) users, cigarette smokers, and dual users of a population with high rates of tobacco-related disease and often underrepresented in epidemiologic and clinical research.
- This study describes a novel method for assessing dependence to ENDS and demonstrate that the dependence potential of ENDS is lower than cigarettes in this sample of American Indians (AI).
- Due to the convenience based sampling approach and eligibility criteria, generalizations to all AI in the Southern Plains should be made with caution.

## INTRODUCTION

With a prevalence of smoking higher than any other major United States (US) race group, American Indians/Alaskan Natives (AI/AN) are at high-risk for tobacco-related disease and death. According to the National Survey on Drug Use and Health, 38.5% of non-Hispanic AI/AN adults smoked cigarettes in 2012 compared to 23.9% of non-Hispanic Whites, 22.6% of non-Hispanic Blacks, 8.3% of non-Hispanic Asians, and 15.2% of Hispanics.[1] Cigarette smoking within the population of AI/AN varies considerably by region and is highest in Alaska (44.3%) and the Northern Plains (43.6%) followed by the East (37.9%) and Southern Plains (35.4%), and lowest in the Southwest (19.6%).[2]

Electronic nicotine delivery systems (ENDS), also referred to as e-cigarettes, are a line of relatively new devices that heat a solution often containing flavorants and nicotine to generate a vapor. In 2016, ENDS were deemed under the regulation of the U.S. Food and Drug Administration Center for Tobacco Products (FDA CTP).[3,4] To inform their regulatory action, the FDA CTP is interested in research that seeks to understand use behaviors and dependence in ENDS users.[5]

Little information exists on ENDS use among AI populations. Few studies have shown that the prevalence of ENDS use is likely higher among AI than other race groups. For example, the 2013 Montana Adult Tobacco Survey (n=5,135) found that 18.8% of AI had ever used ENDS, a prevalence significantly higher than that among Whites (10.5%).[6] Unpublished data from the 2014 Oklahoma Behavioral Risk Factor Surveillance Survey and the 2014 Oklahoma Adult Tobacco Survey showed that approximately 5.0% of AI are exclusive ENDS users and a further

8.5% use both ENDS and cigarettes (dual users) compared to 3.2% and 4.0% of non-Hispanic Whites. Moreover, the odds of ENDS use among current and former smokers was 2.6 times higher among AI than among all other major race groups combined in Oklahoma.[7]

The purpose of the present study was to address the lack of literature on ENDS use among AI by describing socio-demographic and lifestyle characteristics, secondhand smoke exposure, use behaviors, and dependence among exclusive ENDS users, exclusive smokers, and dual users of AI descent residing in the Southern Plains region of the US. The results of this study will be significant for the FDA CTP as well as for public health officials who are trying to understand the impact of ENDS on public health.

## METHODS

### Participant recruitment

This study was approved by the University of Oklahoma Health Sciences Center (# 6317) and the Oklahoma City Area Indian Health Service Institutional Review Board (# P-16-01-OK). From March through October 2016, community-based strategies were employed to recruit adults of AI descent who were in one of three groups of current tobacco use: 1) current exclusive cigarette smokers, 2) current exclusive ENDS users, and 3) concurrent users of cigarettes and ENDS, referred to as dual users. Recruitment strategies included reactive (e.g., advertisements posted to Oklahoma City and Tulsa Craigslist sites) and proactive methods (e.g., study staff attending cultural events, tribal health fairs, and vape shops throughout Oklahoma).

**Participant eligibility**

All participants self-reported AI race, having at least two biological grandparents who were of AI race, being between 18 and 65 years of age, and able to speak, read, and write the English language. Additional inclusion criteria depended on the individual's use of cigarettes and/or ENDS. Eligible cigarette smokers must have smoked at least 5 cigarettes per day for the past 3 months, smoked in the past 24 hours, and not used tobacco products other than cigarettes in the past 3 months. Eligible ENDS users must have used an ENDS every day for the past 3 months and in the past 24 hours, and not used tobacco products other than ENDS in the past 3 months. Eligible dual users must have smoked at least 5 cigarettes per day in the past 3 months, smoked in the past 24 hours, used an ENDS product every day for the past 3 months, and used an ENDS in the past 24 hours, and not used tobacco products other than cigarettes and ENDS in the past 3 months.

Participants were excluded from any group if they regularly used medications for seizures, tuberculosis, or cancer; were currently involved in a tobacco cessation program or used nicotine replacement therapy; were pregnant or breastfeeding; used illicit drugs in the 30 days prior to the study; used alcohol or marijuana on the day of the study.

**Measures**

To further understand extent of AI heritage, all participants reported their total degree of Indian blood. Socio-demographic data collected included age, gender, marital status, education level, and employment status. We collected information on height and weight to calculate body mass

index (BMI). All participants were asked questions on traditional tobacco use and secondhand smoke exposure in the home, vehicle, and if employed, at work.

Among cigarette smokers and dual users, measures of cigarette smoking were collected, including the age when participants first tried part or all of a cigarette (i.e., age of initiation), the age when participants started smoking cigarettes regularly (i.e., age of regular initiation), average cigarettes currently smoked per day (CPD), duration of cigarette smoking, presence of a 24-hour quit attempt in the past 12 months, and use of menthol cigarettes.

Since ENDS are relatively new to the marketplace and often called different names, the following statement, which was adapted from the Population Assessment of Tobacco and Health (PATH)[8], was read by ENDS and dual users prior to collecting information on ENDS use: 'You said you currently use an electronic nicotine product. These products are battery-powered, use nicotine fluid rather than tobacco leaves, and produce vapor instead of smoke. There are many different names for these devices. Some common brands include Fin, NJOY, Blu, e-Go and Vuse.' Generic photos ('cig-a-like'; tank or vapor system; e-cigar; e-pipe; e-hookah) of commonly used ENDS were displayed and participants chose the photo(s) which best resembled the ENDS they currently used. Participants had the option of choosing more than one. Participants were also asked if the ENDS was rechargeable, refillable with "e-liquid", if it used cartridges, and which nicotine concentration they currently used. Since ENDS users often use more than one flavor or mix flavors, participants reported all flavors they currently used.

To assess extent of ENDS use, ENDS and dual users read the following statement provided by the Ontario Tobacco Research Center: 'A session starts from your first puff and ends with your last puff before you take a break to do something else. A session can last for any length of time and involve any number of puffs, depending in the person. Sometimes these are called vape sessions.' Participants then responded to four questions: (1) 'How many sessions have you had with your electronic nicotine product in your lifetime?'; (2) 'In a typical day, how many sessions do you have?'; (3) 'How long does one session typically last for you?'; (4) 'How many puffs do you typically take per session?'. Other variables collected included age of ENDS initiation, age of regular ENDS initiation, and duration of use. Among exclusive ENDS users, we asked if they were a never or former smoker. If they were a former smoker, we asked them to recall their number of CPD when smoked and the time since smoked. We also asked dual users to recall their number of CPD prior to ENDS initiation.

The Hooked on Nicotine Checklist (HONC), a 10-item screening tool developed to assess loss of autonomy over cigarettes,[9] is a reliable and valid measure of loss of autonomy for both novice and experienced cigarettes smokers.[9] Since each of the ten items has face validity, a smoker's endorsement of any one item indicates loss of autonomy, and the sum of endorsed items (0-10) indicates the degree to which autonomy has been lost.[9] We reworded the HONC to assess loss of autonomy over ENDS among ENDS users and dual users. Dual users completed the HONC twice, once with regard to cigarettes and once with regard to ENDS. Loss of autonomy over either cigarettes or ENDS was summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy).

### Biochemical assessment of smoking status

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive assessment of cigarette smoking status.[10] CO was collected to biochemically confirm self-reported cigarette smoking status and therefore help reduce information bias. Clinical studies commonly use a CO value of 10 parts per million (ppm) to discriminate cigarette smokers from non-smokers.[11-15] However, recent studies have shown that a CO level between 6-8 ppm may more accurately classify smoking status. [10,16,17] Cigarette smokers and dual users were included in the study if they had a CO level ≥6 ppm, while ENDS users were included if they had CO levels ≤9 ppm.

### Statistical analysis

This study focused on describing characteristics of cigarette smokers, ENDS users, and dual users of AI descent currently residing in the Southern Plains. Since the study's primary purpose was descriptive, a formal sample size calculation was not performed. Continuous and ordinal measures were described using median values and categorical measures were described by proportions. Scores and frequencies were compared between the three user groups with the nonparametric Kruskal–Wallis test for ordinal or continuous measures and with a Chi-square or Fisher's exact test for categorical measures. A p-value <0.05 was considered statistically significant for comparison among all three user groups. Significant overall tests were followed by testing for differences between the three pairs of groups, and significance was assessed using a Bonferroni adjustment of alpha=0.017. Statistical analysis was conducted in SAS 9.4.

## RESULTS

A total of 95 individuals participated in the study: 35 as cigarette smokers, 28 as ENDS users, and 32 as dual users. Thirteen participants (13.7%) were excluded because their CO values were outside of the range for their given tobacco use group. Therefore, results are presented for the 82 individuals (27 cigarette smokers, 27 ENDS users, and 28 dual users) with CO values in the expected range given their self-reported tobacco use.

**Table 1** displays data on sociodemographic characteristics, traditional tobacco use, and secondhand smoke exposure for the 82 participants. Age distribution differed across the three user groups (p=0.0263). Cigarette smokers were older than ENDS users (p-value=0.0124). The proportion with all four grandparents of AI race was higher in smokers compared with ENDS users (70% versus 22%; p-value=0.0003) and in smokers compared with dual users (70% versus 29%; p-value=0.0011). About one-half (51.2%) reported an Indian blood quantum of at least one-half. The proportion who reported an Indian blood quantum of at least one-half was higher among cigarette smokers compared with ENDS users (70% versus 30%; p-value=0.0028). More than one-half of participants were exposed, in the past 7 days, to combustible tobacco at home (53%) and nearly two-thirds (64%) were exposed to combustible tobacco in a vehicle. The proportion of participants exposed at home was higher among cigarette smokers than ENDS users (61% versus 26%; p-value=0.0129) and among dual users compared with ENDS users (71% versus 26%; p-value=0.0007). The proportion exposed in a vehicle was higher among dual users compared with ENDS users (82% versus 41%; p-value=0.0016). More than one-half (56%) of participants were exposed to combustible tobacco at work in the past 7 days, and this proportion was higher among dual users than ENDS users (77% versus 27%; p-value=0.0080).

**Table 2** presents data on cigarette smoking characteristics. Median CPD was 10 among smokers and 15 among dual users. The distribution of cigarettes per day did not differ between the two user groups (p-value=0.9174). Moreover, a similar proportion of smokers and dual users reporting smoking <1 pack of CPD (59% versus 57%; p-value=0.8736). Distributions of ages when respondents first tried smoking a cigarette and started smoking cigarettes regularly did not differ between user groups. A greater proportion of dual users reported a quit attempt in the previous 12 months than did smokers (57% versus 26%; p-value=0.0190).

**Table 3** presents data on ENDS use behaviors. Median age first tried an ENDS was 28.5 years among ENDS users and 35.0 years among dual users. Median age started using an ENDS regularly was 30.0 years among ENDS users and 36.5 years among dual users. Median duration of ENDS use was 2 years among ENDS and 1 year among dual users. When prompted with the option to select the photo which best represented the ENDS currently being used, the vast majority of ENDS (89%) and dual users (93%) selected a tank or vapor system. The vast majority, if not all, of ENDS users and dual users reported currently using an ENDS which was refillable with e-liquid (89%, 100%) and rechargeable (100%, 96%); while, one-third or less (30%, 33%) reported using cartridges. The majority of both ENDS users (80%) and dual users (69%) reported currently using a nicotine concentration of 12 mg or less. More than one-half of ENDS and dual users reported using fruit (67%, 54%) and candy (52%, 57%) flavored ENDS. Data on number of vape sessions in lifetime, vape sessions per day, puffs per vape session, and length of vape session is also displayed in **Table 3**.

ENDS and dual users were asked questions to assess their smoking status prior to initiation of an ENDS. The vast majority of ENDS users (92.6%) reported being former cigarettes smokers. Among ENDS users who were former cigarette smokers, the median CPD when smoked was 20 and the median duration since smoked cigarettes was 2 years. Dual users were asked to recall CPD before initiation of an ENDS. Median CPD prior to ENDS use was 20, which was higher than the current median of 15 CPD (p-value=0.0109).

**Table 4** presents data on the HONC for loss of autonomy over cigarettes among smokers and dual users. A similar proportion of cigarette smokers (96.3%) and dual users (100%) had a diminished autonomy over cigarettes (p=0.4909). On a scale of 0 to 10, median severity of diminished autonomy over cigarettes was 8 and 9 among smokers and dual users, respectively. Distributions in severity of diminished autonomy over cigarettes did not differ when comparing smokers with dual users (p-value=0.0806). When examining individual items measured by the HONC, a greater proportion of dual users than smokers said 'yes' to items 1 "Have you ever tried to quit cigarettes, but couldn't?" (79% versus 52%; p-value =0.0372) and 2 "Do you smoke now because it is really hard to quit smoking cigarettes?" (75% versus 48%; p-value=0.0405). There was no difference in items 3-10.

**Table 4** also presents data on the adapted HONC for loss of autonomy over ENDS among ENDS users and dual users. A similar proportion of ENDS users (64.3%) and dual users (77.8%) had a diminished autonomy over ENDS (p=0.2707). Median severity of diminished autonomy over ENDS was 4 and 3 among ENDS and dual users, respectively. Distributions in severity of diminished autonomy over ENDS did not differ when comparing ENDS users with dual users (p-

value=0.6865). Moreover, there were no differences in the individual HONC items when comparing ENDS with dual users. To further understand autonomy, we compared loss of autonomy to cigarettes in smokers with loss of autonomy to ENDS in ENDS users. There was no difference in proportions of diminished autonomy when comparing smokers with ENDS users (96% versus 78%; p-value=0.1003). However, distributions in severity of diminished autonomy differed (p-value=0.0077), where smokers had higher scores for severity of diminished autonomy than ENDS users. Furthermore, among dual users, severity of diminished autonomy over cigarettes was higher than severity of diminished autonomy over ENDS (p-value<.0001).

## DISCUSSION

This descriptive study provides novel findings about cigarette smoking and ENDS use in a small sample of AI from the Southern Plains region of the US. Notably, this analysis was the first of its kind to provide an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AI. Studies of this kind are a current research priority of the US Food and Drug Administration (FDA) Center for Tobacco Products, which serves as the regulatory authority for all tobacco products.[5,18] Ultimately, this study provides a more complete picture of the current tobacco use landscape and will be informative for our future research on biomarkers of exposure in this population, as well as for guiding regulatory authorities who are working to understand the impact of ENDS on public health in both general and disparate populations.

Smoke-free homes and workplaces can increase smoking cessation and prevent relapse among former smokers.[19-21] In the present study, more than half of all participants were exposed to combustible tobacco products at home and nearly two-thirds were exposed while in a vehicle.

Additionally, more than half of the participants who were employed reported exposure at work. Comparing user groups, exposure to combustible tobacco at home was more than two times higher among cigarette smokers and dual users than ENDS users. Dual users also had a significantly higher prevalence of exposure to combustible tobacco while in a vehicle and at work than ENDS users. The vast majority of ENDS users in this study reported being former cigarette smokers. Their ability to quit cigarettes may have been a result of smoke-free homes, vehicles, and workplaces, which provided a supportive environment for quitting. Or, smoke-free restrictions may have been implemented after ENDS users quit cigarettes, and now aid in preventing relapse. Due to the cross-sectional nature of this study, we are limited in our ability to assess the directionality of this relationship.

Although AI have the highest rates of cigarette smoking, AI are more likely to be light smokers compared to other race groups.[22,23] For example, a previous study of tobacco use among AI in Oklahoma reported a median of 10 CPD,[22] which is considered a low to moderate number of CPD. In the present study, the median number of CPD among smokers and dual users was 10 and 15, respectively. Despite the relatively low number of CPD, median HONC scores for smokers and dual users were 8 and 9, respectively, which correspond to high levels of dependence. Moreover, AI have been shown to have higher levels of tobacco-related disease compared to other race groups.[24] It may be that AI are smoking in such a manner (e.g., more deeply or for longer duration) which results in higher levels of nicotine and carcinogen intake per cigarette than other race groups.

Attempts to quit smoking are considered a critical step to increasing rates of smoking cessation and, subsequently, reducing the smoking prevalence.[25] Based on data from the 2013 National Health Interview Survey, an estimated 51% of AI smokers reported attempting to quit in the past 12 months.[26] In the present study, the proportion of dual users who made a quit attempt was more than twice the proportion among smokers. This finding supports previous literature linking ENDS use to smoking cessation. For example, in a nationally representative sample of US cigarette smokers (n=2,028), ENDS users had a higher smoking quit attempt (73% versus 46%) and cessation (42% versus 16%) rate than non-ENDS users.[27] We did not ask participants about their reason for using ENDS; however, it is likely that dual users in the present study are similar to those in others studies who report using ENDS to help quit cigarettes.[28-30] Dual users were asked to recall their average CPD before ENDS initiation, which was significantly higher than their current CPD. Future studies are needed to understand the impact of dual use on public health, including the potential to undermine prevention and cessation efforts.

ENDS are part of the diversifying tobacco landscape,[31] and as 2016 the US FDA has had the authority to regulate these devices.[18] Currently, there are several gaps in how to define and classify these devices making the study of ENDS difficult.[3] A major strength of the present study was the number of characteristics collected on ENDS use and the usage of pictures to aid participants in selecting which product they currently used. The vast-majority of ENDS and dual users reported using a tank or vapor system. Additionally, most reported that their ENDS was refillable with e-liquid and rechargeable. The majority of both dual and ENDS users reported using ENDS with nicotine concentrations of 12 mg or less.

Concern surrounds flavored tobacco products as they have been disproportionately used by youth and initiators.[32-34] Due to this, flavored cigarettes, excluding menthol flavor, were prohibited in 2009 as part of the landmark Family Smoking Prevention and Tobacco Control Act.[35] Currently, ENDS come in a variety of flavors. One study identified nearly 8,000 flavors available online and showed that the vast majority of brands offered fruit, candy, and dessert flavors.[36] In the present study the most common flavors among both ENDS and dual users were fruit and candy or sweets. One study found tobacco to be the most common flavor,[37] which was the third most popular flavor among our participants. Interestingly, none of the participants in the present study reported not using any flavor. Regulatory authorities need to consider the potential impact of eliminating flavors, as their prohibition, especially candy or fruit flavors, may not only reduce youth appeal but also the overall appeal to adult ENDS users.

Data on patterns of ENDS use is crucial for understanding the impact of these devices on public health. There are no standard terms or definitions for assessing ENDS behavior. In the present study, participants read a generic definition of a 'vape session' and then were asked questions to characterize their vape sessions. One-third of ENDS users and more than half of dual users reported 100 or less vape sessions in their lifetime. This is surprising since ENDS were used for a median duration of 1 or 2 years and the study eligibility which included using an ENDS every day in the past 3 months. Participants may have had a hard time recalling this number and simply guessed or perhaps the question was worded in a manner that caused confusion. Another explanation is the participants may have underestimated their total number of vape sessions as a result of social desirability. Average number of vape sessions per day varied, with most reporting less than 20 per day. An average of 5-10 puffs per vape session was most common among both

ENDS and dual users. In terms of vape sessions, most lasted for 5 minutes or less among ENDS users; while, the proportion of dual users who reported a vape session lasting 1-2, 3-5, 6-10, and over 10 minutes were similar. In addition to providing a deeper understanding of ENDS use among AI, these findings are relevant for researchers seeking to understand which questions should be used to collect information on patterns of ENDS use.

There are a number of questionnaires with proven utility in assessing dependence to cigarettes. The HONC was used in the present study for assessing loss of autonomy over cigarettes. Advantages over other commonly used questionnaires (e.g., Fagerström Test for Nicotine Dependence), include providing a natural cutpoint where smokers who score a zero have full autonomy over cigarettes.[9] Moreover, the HONC does not include measures on heaviness or frequency of use specific to cigarette smoking (e.g., CPD). Thus, it can be reworded to assess dependence to other tobacco products. In the present study, smokers and dual users had median scores of 8 and 9, respectively, which are considered high levels of dependence. Although there was no difference in proportion of diminished autonomy or severity of autonomy, a higher proportion of dual users than smokers said 'yes' to items 1 and 2 on the HONC, both of which contain language related to quitting smoking. This observation supports the finding that a higher proportion of dual users than smokers attempted to quit smoking cigarettes.

A major component of assessing the public health impact of ENDS use is to understand the dependence potential in both exclusive and dual users. To date, there is no standard method for assessing dependence to ENDS. Since ENDS and cigarettes differ in patterns of use, methods for assessing dependence that can facilitate comparison across products are needed. As previously

mentioned, HONC does not include language on heaviness or frequency of smoking. Thus, we re-worded the HONC in order to assess loss of autonomy over ENDS. With median scores of 4 and 3, ENDS and dual users were no different in loss of autonomy over ENDS. Eissenberg and colleagues developed a questionnaire, which contained items from scales including the HONC, to assess dependence to both cigarettes and ENDS.[38] That study found ENDS users to be less dependent on ENDS than they retrospectively reported having been dependent on cigarettes prior to switching.[38] We did not ask the ENDS users who were former smokers to recall their dependence to cigarettes. However, severity of dependence in ENDS users was found to be one-half of the severity of dependence in smokers. Eissenberg's study also showed dependence to increase with increasing nicotine concentration.[38] The impact of nicotine concentration and other characteristics of ENDS on dependence should be examined in a larger study of ENDS users.

Although this study has the potential to provide important information, it must be considered in light of its limitations. The focus of this study was not on testing of hypotheses, but on describing characteristics of smokers, ENDS users, and dual users of AI descent. Thus we did not incorporate a formal sample size calculation. Consequently, the statistical power may be low. Second, the study population was not randomly sampled, rather participants were enrolled based on convenience using community-based recruitment strategies. Moreover, although AI in the Southern Plains region of the United States were the target population, the source population was the state of Oklahoma. Therefore generalizations to all AI in the Southern Plains should be made with caution as the findings may not be representative. Also, the exclusion criteria may further impact the ability to generalize findings. Of most concern is that individuals who used alcohol on the day of the study were not eligible to participate. Alcohol use is correlated with tobacco use;[39-

[42] thus restricting eligibility to those who did not consume alcohol on the day of the study may harm the external validity of the findings.

In summary, this study provides several novel findings about smoking, ENDS use, and dual use among AI people from the Southern Plains region of the United States. Notably, the results of this study provide timely information on patterns of use and dependence of ENDS and thus addresses a priority research area of the US FDA: studies of ENDS initiation, use, perceptions, dependence and toxicity.[43] Ultimately, this study provides a more complete picture of the current tobacco use landscape and will be informative for future studies, prevention and cessation interventions, and public health officials who are actively trying to understand the impact of ENDS and dual use on public health.

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## CONTRIBUTORSHIP STATEMENT

Conceptualization: DMC TLW DMT LDS JDP JEC LAB

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Project administration: DMC LAB

Supervision: TLW DMT LDS JDP JEC LAB

Data analysis: DMC LAB

Writing of original draft: DMC LAB

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## COMPETING INTERESTS STATEMENT

No competing interests to declare

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## DATA SHARING STATEMENT

Extra data is available by emailing DMC at dcarroll@umn.edu

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**Table 1.** Sociodemographic Characteristics, Traditional Tobacco Use, and Secondhand Smoke Exposure Among All Participants and by User Group

| | All participants (n=82) | Cigarette smokers (n=27) | ENDS users (n=27) | Dual users (n=28) | *p-value* |
|---|---|---|---|---|---|
| Age, median | 41.50 | 46.00[a] | 33.00 | 41.00 | 0.0263 |
| Gender, % | | | | | 0.3592 |
| Male | 37.80 | 48.15 | 29.63 | 35.71 | |
| Female | 62.20 | 51.85 | 70.37 | 64.29 | |
| Marital status, % | | | | | 0.1261 |
| Married/member of unmarried couple | 42.68 | 55.56 | 44.44 | 28.57 | |
| Never married/divorced/separated/widowed | 57.32 | 44.44 | 55.56 | 71.43 | |
| Education level, % | | | | | 0.2567 |
| At least some college | 50.00 | 44.44 | 62.96 | 42.86 | |
| High school diploma, GED or less | 50.00 | 55.56 | 37.04 | 57.14 | |
| Employment status, % | | | | | 0.6162 |
| Employed for wages/self-employed | 53.66 | 59.26 | 55.56 | 46.43 | |
| Other | 46.34 | 40.74 | 44.44 | 53.57 | |
| BMI ($kg/m^2$) category, % | | | | | 0.1333 |
| Normal weight | 24.69 | 11.11 | 30.77 | 32.14 | |
| Overweight or obese | 75.31 | 88.89 | 69.23 | 67.86 | |
| Grandparents American Indian race, % | | | | | 0.0014 |
| 2 | 43.90 | 29.63[ab] | 51.85 | 50.00 | |
| 3 | 15.85 | 0.00 | 25.93 | 21.43 | |
| 4 | 40.24 | 70.37 | 22.22 | 28.57 | |
| American Indian blood quantum, % | | | | | 0.0108 |
| Less than half | 51.22 | 29.63[a] | 70.37 | 53.57 | |
| At least half | 48.78 | 70.37 | 29.63 | 46.43 | |
| Traditional tobacco use in past 3 months, % | | | | | 0.0366 |
| Yes | 17.50 | 33.33 | 7.41 | 11.54 | |
| No | 82.50 | 66.67 | 92.59 | 88.46 | |
| Home smoke exposure in past 7 days, % | | | | | 0.0019 |
| Yes | 53.09 | 61.54[a] | 25.93[c] | 71.43 | |
| No | 46.91 | 38.46 | 74.07 | 28.57 | |
| Vehicle smoke exposure in past 7 days, % | | | | | 0.0048 |
| Yes | 64.20 | 69.23 | 40.74[c] | 82.14 | |
| No | 35.80 | 30.77 | 59.26 | 17.86 | |
| Work policy on using tobacco products*, % | | | | | 0.1496 |
| Not allowed anywhere | 18.18 | 6.25 | 33.33 | 15.38 | |
| Allowed in some or all areas/no policy | 81.82 | 93.75 | 66.67 | 84.62 | |
| Work smoke exposure in past 7 days*, % | | | | | 0.0134 |
| Yes | 56.82 | 68.75 | 26.67[c] | 76.92 | |
| No | 43.18 | 31.25 | 73.33 | 23.08 | |

ENDS: Electronic nicotine delivery system; BMI= body mass index; * Asked only to those who were employed for wages or self-employed; [a] Cigarette smokers significantly different from ENDS users; [b] Cigarette smokers significantly different from dual users; [c] ENDS users significantly different from dual users

**Table 2.** Cigarette Smoking Characteristics Among Cigarette Smokers and Dual Users

| | Cigarette smokers (n=27) | Dual users (n=28) | *p-value* |
|---|---|---|---|
| Cigarettes per day, median | 10.0 | 15.0 | 0.9174 |
| Cigarettes per day, % | | | 0.8736 |
| <1 pack | 59.26 | 57.14 | |
| ≥1 pack | 40.74 | 42.86 | |
| Age of initiation, median | 14.0 | 15.0 | 0.3087 |
| Age of regular initiation, median | 19.0 | 16.5 | 0.0506 |
| Duration of smoking, median | 26.0 | 21.5 | 0.5220 |
| 24-hour smoking quit attempt in past 12 months, % | 25.93 | 57.14 | 0.0190 |
| Smokes mentholated cigarettes, % | 40.74 | 21.43 | 0.1213 |

**Table 3.** Electronic Nicotine Delivery System (ENDS) Use Characteristics Among ENDS and Dual Users

| | ENDS users (n=27) | Dual users (n=28) | *p-value* |
|---|---|---|---|
| Age of ENDS initiation, median | 28.50 | 35.00 | 0.1358 |
| Age of regular ENDS initiation, median | 30.00 | 36.50 | 0.1188 |
| Duration ENDS use, median | 2.0 | 1.0 | 0.7695 |
| Type of ENDS: tank or vapor system, % | 88.89 | 92.86 | 0.6695 |
| Type of ENDS: cig-a-like, % | 7.41 | 21.43 | 0.2516 |
| Type of ENDS: e-cigar, % | 0.00 | 3.57 | 1.0000 |
| Type of ENDS: e-pipe, % | 3.70 | 0.00 | 0.4909 |
| Type of ENDS: e-hookah, % | 0.00 | 0.00 | |
| ENDS is refillable, % | 88.89 | 100.00 | 0.1115 |
| ENDS is rechargeable, % | 100.00 | 96.43 | 1.0000 |
| ENDS uses cartridges, % | 29.63 | 33.33 | 0.7695 |
| Nicotine concentration, % | | | 0.3683 |
| 0mg | 0.00 | 7.69 | |
| 1-5mg | 52.00 | 30.77 | |
| 6-12mg | 28.00 | 30.77 | |
| 13-17mg | 8.00 | 3.85 | |
| 18-24mg | 8.00 | 23.08 | |
| 25mg or more | 4.00 | 3.85 | |
| Tobacco flavor, % | 18.52 | 39.29 | 0.0900 |
| Menthol flavor, % | 14.81 | 3.57 | 0.1927 |
| Clove or spice, % | 7.41 | 17.86 | 0.4216 |
| Fruit, % | 66.67 | 53.57 | 0.3217 |
| Chocolate, % | 7.41 | 14.29 | 0.6695 |
| Alcoholic drink, % | 3.57 | 0.00 | 0.4909 |
| Candy/sweets, % | 51.85 | 57.14 | 0.6936 |
| Other flavor, % | 11.11 | 21.43 | 0.4688 |
| Number of vape sessions in lifetime*, % | | | 0.7872 |
| 100 or less | 33.33 | 52.00 | |
| 101-200 | 12.50 | 8.00 | |
| 201-300 | 8.33 | 8.00 | |
| 301-400 | 12.50 | 8.00 | |
| Over 400 | 33.33 | 24.00 | |
| Average number of vape sessions per day*, % | | | 0.1662 |
| Less than 10 sessions | 28.00 | 52.00 | |
| 10 to 19 sessions | 44.00 | 20.00 | |
| 20 to 30 sessions | 16.00 | 8.00 | |
| Over 30 | 12.00 | 20.00 | |
| Average number of puffs per vape session*, % | | | 0.6995 |
| Under 5 | 14.81 | 23.08 | |
| 5-10 | 55.56 | 46.15 | |
| More than 10 | 29.63 | 30.77 | |
| Average length of vape session*, % | | | 0.4207 |
| 1-2 minutes | 33.33 | 25.00 | |
| 3-5 minutes | 40.74 | 28.57 | |
| 6-10 minutes | 18.52 | 25.00 | |
| Over 10 minutes | 7.14 | 21.43 | |

* Provided by the Ontario Tobacco Research Center

**Table 4.** Results from Hooked on Nicotine Checklist for Assessing Loss of Autonomy Over Cigarettes and Adapted Version for Assessing Loss of Autonomy Over Electronic Nicotine Delivery Systems (ENDS) *

| | Cigarette smokers (n=27) | Dual users (n=28) | ENDS users (n=27) | |
|---|---|---|---|---|
| | *Over cigarettes* | | *Over ENDS* | |
| **Diminished autonomy**, % | 96.30 | 100.00 | 64.29 | 77.78 |
| **Severity of diminished autonomy**, median | 8.00 | 9.00 | 3.0 | 4.0 |
| **Individual items measured in HONC**, % | | | | |
| 1. Have you ever tried to quit cigarettes [using an ENDS], but couldn't? | 51.85 | 78.57 | 18.52 | 18.52 |
| 2. Do you smoke [use your ENDS] now because it is really hard to quit smoking cigarettes [using an ENDS]? | 48.15 | 75.00 | 32.14 | 40.74 |
| 3. Have you ever felt like you were addicted to cigarettes [an ENDS]? | 70.37 | 82.14 | 28.57 | 37.04 |
| 4. Do you ever have strong cravings to smoke [use an ENDS]? | 85.19 | 96.43 | 50.00 | 59.26 |
| 5. Have you ever felt like you really needed a cigarette [an ENDS]? | 92.59 | 100.00 | 57.14 | 59.26 |
| 6. Is it hard to keep from smoking [using an ENDS] in places where you are not supposed to? | 44.44 | 53.57 | 35.71 | 25.93 |
| When you haven't smoked cigarettes [used an ENDS] for a while OR | | | | |
| When you tried to stop smoking cigarettes [using an ENDS]… | | | | |
| 7. …did you find it hard to concentrate because you couldn't smoke a cigarette [use an ENDS]? | 38.46 | 57.14 | 28.57 | 22.22 |
| 8. …do you feel more irritable because you couldn't smoke a cigarette [use an ENDS]? | 74.07 | 71.43 | 25.00 | 48.15 |
| 9. …did you feel a strong need or urge to smoke a cigarette [use an ENDS]? | 81.48 | 89.29 | 57.14 | 59.26 |
| 10. …did you feel nervous, restless, or anxious because you couldn't smoke a cigarette [use an ENDS]? | 55.56 | 75.00 | 28.57 | 37.04 |

*Substitute the underlined word with the words in square brackets for assessing loss of autonomy over ENDS

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation | Page # |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 2 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *6-8* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 9 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6-8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 9 |
| | | (*c*) Explain how missing data were addressed | NA |
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy | NA |
| | | (*e*) Describe any sensitivity analyses | NA |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10 |
| | | (b) Give reasons for non-participation at each stage | 10 |
| | | (c) Consider use of a flow diagram | NA |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 10 |
| | | (b) Indicate number of participants with missing data for each variable of interest | NA |
| Outcome data | 15* | Report numbers of outcome events or summary measures | NA |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 10-13 |

| | | | |
|---|---|---|---|
| | | (*b*) Report category boundaries when continuous variables were categorized | 10-13 |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 18-19 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 18 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 20 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians- results from an observational pilot study

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# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians- results from an observational pilot study

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**Keywords**: American Indians, Electronic Cigarettes, Cigarette Smoking Epidemiologic Studies, Minority Groups, Tobacco Use, Dependence

## ABSTRACT

**Objective**: American Indians (AI) have a high prevalence of ENDS use. However, little information exists on (ENDS) use, either alone or in combination with cigarettes ( dual use), among AI. The objective of this small-scaled study was to examine use behaviors and dependence among exclusive ENDS users and dual users of AI descent. Exclusive smokers were included for comparison purposes.

**Setting**: Oklahoma, United States

**Participants**: Adults of AI descent who reported being exclusive ENDS users (n=27), dual users (n=28), or exclusive cigarette smokers (n=27).

**Measures**: Participants completed a detailed questionnaire on use behaviors. The Hooked on Nicotine Checklist (HONC) was used to assess loss of autonomy over cigarettes and was reworded for ENDS. Dual users completed the HONC twice. Sum of endorsed items indicated severity of diminished autonomy. Comparisons were made with nonparametric methods and statistical significance was defined as $p<0.05$.

**Results**: Median duration of ENDS use was 2 years among ENDS users and 1 year among dual users. Most ENDS and dual users reported <20 vape sessions per day (72.0% vs. 72.0%) with ≤10 puffs per vape session (70.4% vs. 69.2%). Severity of diminished autonomy over ENDS was similar among ENDS and dual users (medians: 4 vs 3; p=0.6865). Among dual users, severity of diminished autonomy was lower for ENDS than cigarettes (medians: 3 vs 9; p=<.0001). Comparing ENDS users to smokers, ENDS users had a lower severity of diminished autonomy (4 vs 9; p=0.0077). Comparing dual users to smokers, median severity of diminished autonomy over cigarettes did not differ (p=0.6865).

**Conclusions**: Severity of diminished autonomy was lower for ENDS than cigarettes in this small sample of AI. Future, adequately-powered, studies should be conducted to fully understand ENDS use patterns and dependence levels in this population.

## Strengths and limitations of this study

- This study provide timely information on use behaviors and loss of autonomy in electronic nicotine delivery systems (ENDS) users, cigarette smokers, and dual users of AI descent, a minority population in the US with high rates of tobacco-related disease and often underrepresented in epidemiologic and clinical research.
- This study describes a novel method for assessing loss of autonomy, a core feature of dependence, in ENDS users and demonstrates that diminished autonomy was lower for ENDS than cigarettes in this small sample of AI tobacco users
- Due to the convenience based sampling approach and eligibility criteria, generalizations to all AI should be made with caution.

## INTRODUCTION

Electronic nicotine delivery systems (ENDS), also referred to as e-cigarettes and vaping devices, are a line of relatively new tobacco products that heat a solution, often containing nicotine and flavorants, to generate an aerosol. Although ENDS aerosol is not harmless, it generally contains fewer toxic chemicals than cigarettes—a statement backed by the United States (US) Surgeon General.[1] In August of 2016, the US Food and Drug Administration Center for Tobacco Products (US FDA CTP) was provided the authority to regulate the manufacturing, distribution, and marketing of ENDS in the US.[2,3] To inform their regulatory action, the US FDA CTP has specifically called for research that seeks to understand use behaviors and dependence in ENDS users.[4]

ENDS use is high among American Indians and Alaskan Natives (AI/ANs).[5,6] According to data from the 2014 US National Health Interview Survey, 11% of non-Hispanic AI/AN adults currently use ENDS compared to 5% of non-Hispanic White adults.[6] Since a commonly reported reason for using ENDS is to help quit or reduce cigarettes[7-9] and AI/ANs have a smoking prevalence higher than any other race group in the US,[10] high rates of dual use among AI/ANs might also be expected. Unpublished data from the 2014 Oklahoma Behavioral Risk Factor Surveillance Survey and the Adult Tobacco Survey showed that approximately 5.0% of AI/ANs are exclusive ENDS users and a further 8.5% are dual users compared to 3.2% and 4.0% of non-Hispanic Whites. A major public health question surrounding dual use is whether this behavior will help or halt smoking cessation efforts.[2]

No information, to our knowledge, currently exists on use behaviors and dependence in ENDS users of AI/AN descent. To address this literature gap, we describe use behaviors and loss of autonomy, a core feature of dependence, in AI exclusive ENDS users and dual users of ENDS and cigarettes. Since cigarette smokers have been used as a comparison group in prior studies of ENDS,[11-13] we also present data on exclusive cigarette smokers of AI descent. The results of this study will be significant for regulatory authorities, such as the US FDA CTP, and public health officials who are actively trying to understand ENDS use behavior and dependence in priority populations such as AIs.

## METHODS

### Participant recruitment

This study was approved by the University of Oklahoma Health Sciences Center (# 6317) and the Oklahoma City Area Indian Health Service Institutional Review Board (# P-16-01-OK). From March through October 2016, community-based strategies were employed to recruit adults of AI descent who were in one of three groups of current tobacco use: 1) current exclusive cigarette smokers, 2) current exclusive ENDS users, and 3) concurrent users of cigarettes and ENDS, referred to as dual users. Recruitment strategies, previously described,[14] included posting recruitment ads on Craigslist and study staff attending cultural events, tribal health fairs, and vape shops in the state of Oklahoma.

### Participant eligibility

This study's inclusion and exclusion criteria were similar to those employed in a previous study of nicotine metabolism among Alaskan Native tobacco users.[15] All participants had to self-report

AI race and at least two biological grandparents of AI race. Additionally, participants were between 18 and 65 years of age, and able to speak, read, and write the English language. Additional inclusion criteria were employed to result in a sample of "regular" users of cigarettes and/or ENDS. A regular cigarette smoker was defined as those who have smoked at least 5 cigarettes per day for the past 3 months, smoked in the past 24 hours, and not used tobacco products other than cigarettes in the past 3 months. A regular ENDS user was defined as someone who used an ENDS every day for the past 3 months and in the past 24 hours, and had not used tobacco products other than ENDS in the past 3 months. Although dual use refers to a heterogeneous group, we defined dual users as those who smoked at least 5 cigarettes per day in the past 3 months and in the past 24 hours, used an ENDS product every day for the past 3 months and in the past 24 hours, and not used tobacco products other than cigarettes and ENDS in the past 3 months.

Participants were excluded from any group if they regularly used medications for seizures, tuberculosis, or cancer; were currently involved in a tobacco cessation program or used nicotine replacement therapy; were pregnant or breastfeeding; used illicit drugs in the 30 days prior to the study; used alcohol or marijuana on the day of the study.

**Measures**

Data on age, gender, marital status, education level, employment status and body mass index (BMI) were collected. Participants were also asked about their use of tobacco for sacred or ceremonial purposes (i.e., traditional tobacco use), a practice common among some AI tribes.[16-18]

Since ENDS are relatively new to the marketplace and often called different names, the following statement, which was adapted from the US Population Assessment of Tobacco and Health (PATH)[19], was read by ENDS and dual users prior to collecting information on ENDS use: 'You said you currently use an electronic nicotine product. These products are battery-powered, use nicotine fluid rather than tobacco leaves, and produce vapor instead of smoke. There are many different names for these devices. Some common brands include Fin, NJOY, Blu, e-Go and Vuse.' Generic photos ("cig-a-like"; tank or vapor system; e-cigar; e-pipe; e-hookah) of commonly used ENDS were displayed and participants chose the photo(s) which best resembled the ENDS they currently used. Participants had the option of choosing more than one. Participants were also asked if the ENDS was rechargeable, refillable with e-liquid, if it used cartridges, and which nicotine concentration they currently used. Since ENDS users often use more than one flavor or mix flavors, participants reported all flavors they currently used.

There is not a standard or commonly accepted method for assessing frequency of ENDS use.[2] In this study, ENDS and dual users read the following statement provided by the Ontario Tobacco Research Center to assess frequency of use: 'A session starts from your first puff and ends with your last puff before you take a break to do something else. A session can last for any length of time and involve any number of puffs, depending in the person. Sometimes these are called vape sessions.' Participants then responded to four questions: (1) 'How many sessions have you had with your electronic nicotine product in your lifetime?'; (2) 'In a typical day, how many sessions do you have?'; (3) 'How long does one session typically last for you?'; (4) 'How many puffs do you typically take per session?'. Other variables collected included age of ENDS initiation, age of regular ENDS initiation, and duration of use. Among exclusive ENDS users, we asked if they

were a never or former smoker. If they were a former smoker, we asked them to recall their number of CPD when smoked and the time since smoked. We also asked dual users to recall their number of CPD prior to ENDS initiation.

There are a number of questionnaires with proven utility in assessing dependence to cigarettes.[20-23] The Hooked on Nicotine Checklist (HONC), a 10-item screening tool, assesses of loss of autotomy in both adolescent and adults.[23,24] Diminished autonomy is a core feature common to all forms of substance dependence, including tobacco dependence.[24] HONC does not include measures on heaviness or frequency of use specific to cigarette smoking (e.g., CPD). Thus, it can be readily modified to assess loss of autotomy to non-cigarette tobacco products, such as ENDS. In the present study, loss of autonomy over cigarettes was summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy). We reworded the HONC to assess loss of autonomy to ENDS. Dual users completed the HONC twice, once with regard to cigarettes and once with regard to ENDS. Loss of autonomy over ENDS was also summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy).

Among dual users and exclusive smokers, measures of cigarette smoking were collected. These measures included the age when participants first tried part or all of a cigarette (i.e., age of initiation), the age when participants started smoking cigarettes regularly (i.e., age of regular initiation), average number of cigarettes currently smoked per day (CPD), duration of cigarette smoking, presence of a 24-hour quit attempt in the past 12 months, and use of menthol cigarettes.

**Biochemical assessment of smoking status**

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive assessment of cigarette smoking status.[25] CO was collected to biochemically confirm self-reported cigarette smoking status and therefore help reduce information bias. A CO value of ≥10 parts per million (ppm) is commonly used to determine eligibility for studies among smokers.[26-30] However, a borderline CO level between 6-9 ppm may also reflect cigarette smoking or among non-smokers it may reflect exposure to secondhand smoke or other sources of CO (e.g., car pollution).[25,31-33] Moreover, prior studies have required CO levels of <6[34] or <10[12,35] for confirming exclusive ENDS use. Based on this information, we did not exclude individuals from any of the three groups with a CO between 6-9 ppm. Thus, ENDS users were included if they had a CO level ≤9 ppm, while cigarette smokers and dual users were included in the study if they had a CO level ≥6 ppm.

**Statistical analysis**

This study focused on describing characteristics of ENDS users, dual users, and smokers of AI descent. Since the study's primary purpose was descriptive, a formal sample size calculation was not performed. Continuous and ordinal measures were described using median values and categorical measures were described by proportions. Scores and frequencies were compared between the three user groups with the nonparametric Kruskal–Wallis test for ordinal or continuous measures and with a Chi-square or Fisher's exact test for categorical measures. A p-value <0.05 was considered statistically significant for comparison among all three user groups. Significant overall tests were followed by testing for differences between the three pairs of

groups, and significance was assessed using a Bonferroni adjustment of alpha=0.017. Statistical analysis was conducted in SAS 9.4.

## RESULTS

A total of 95 individuals participated in the study: 28 ENDS users, 32 dual users, and 35 cigarette smokers. Thirteen participants (13.7%) were excluded because their CO values were outside the range for their given tobacco use group. Therefore, results are presented for the 82 individuals (27 ENDS users, 28 dual users, 27 cigarette smokers) with CO values in the expected range given their self-reported tobacco use. **Table 1** displays data on socio-demographic characteristics and traditional tobacco use for the 82 participants.

**Table 2** presents data on ENDS use behaviors. Median age first tried an ENDS was 28.5 years among ENDS users and 35.0 years among dual users. Median age started using an ENDS regularly was 30.0 years among ENDS users and 36.5 years among dual users. Median duration of ENDS use was 2 years among ENDS and 1 year among dual users. When prompted with the option to select the photo which best represented the ENDS currently being used, the vast majority of ENDS (89%) and dual users (93%) selected a tank or vapor system. The vast majority, if not all, of ENDS users and dual users reported currently using an ENDS which was refillable with e-liquid (89%, 100%) and rechargeable (100%, 96%); while, one-third or less (30%, 33%) reported using cartridges. The majority of both ENDS users (80%) and dual users (69%) reported currently using a nicotine concentration of 12 mg or less. More than one-half of ENDS and dual users reported using fruit (67%, 54%) and candy (52%, 57%) flavored ENDS.

Data on number of vape sessions in lifetime, vape sessions per day, puffs per vape session, and length of vape session is also displayed in **Table 2**.

ENDS and dual users were asked questions to assess their smoking status prior to initiation of an ENDS (data not provided in tables). The vast majority of ENDS users (92.6%) reported being former cigarettes smokers. Among ENDS users who were former cigarette smokers, the median CPD when smoking was 20 and the median duration since smoked cigarettes was 2 years. Dual users were asked to recall CPD before initiation of an ENDS. Median CPD prior to ENDS use was 20, which was significantly higher than the current median of 15 CPD.

**Table 3** presents data on cigarette smoking characteristics among dual users and exclusive smokers. Median CPD was 15 among dual users and 10 among smokers The distribution of cigarettes per day did not differ between the two user groups. Distributions of age when respondents first tried smoking a cigarette and started smoking cigarettes regularly did not differ between user groups. A greater proportion of dual users reported a 24-hour quit attempt in the previous 12 months than did smokers (57% versus 26%).

**Table 4** presents data on the ten individual items from the adapted HONC for loss of autonomy over ENDS. There were no differences in the individual HONC items when comparing ENDS with dual users. The proportion of ENDS users (64.3%) who had a diminished autonomy over ENDS was no different than dual users (77.8%). On a scale of 0 to 10, median severity of diminished autonomy over ENDS was 4 and 3 among ENDS and dual users, respectively (**Figure 1**). Distributions in severity of diminished autonomy over ENDS did not differ when

comparing ENDS users with dual users. To further understand autonomy, loss of autonomy to ENDS in ENDS users was compared with loss of autonomy to cigarettes in smokers. There was no difference in proportions of diminished autonomy when comparing smokers with ENDS users (96% versus 78%). However, distributions in severity of diminished autonomy differed. ENDS users had significantly lower scores for severity of diminished autonomy than smokers (4 vs 8). Furthermore, among dual users, severity of diminished autonomy over ENDS was lower than severity of diminished autonomy over cigarettes (3 vs 9).

The proportion of dual users (100%) with diminished autonomy over cigarettes did not significantly differ from the proportion of cigarette smokers (96.3%). Median severity of diminished autonomy over cigarettes was 9 and 8 among dual users and smokers, respectively. Distributions in severity of diminished autonomy over cigarettes did not differ when comparing dual users with smokers. When examining individual items measured by the HONC, a greater proportion of dual users than smokers said 'yes' to items 1 "Have you ever tried to quit cigarettes, but couldn't?" (79% versus 52%; p-value =0.0372) and 2 "Do you smoke now because it is really hard to quit smoking cigarettes?" (75% versus 48%; p-value=0.0405). There was no difference in items 3-10.

## DISCUSSION

This descriptive study provides novel findings about ENDS use in a small sample of AIs from Oklahoma, a state located in the Southern Plains region of the US. Notably, this analysis was the first of its kind to provide an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Studies of this kind are a current research priority of the US

Food and Drug Administration (FDA) Center for Tobacco Products, which serves as the regulatory authority for all tobacco products in the US.[4,36] Ultimately, this study provides a more complete picture of the current tobacco use landscape and will be informative for our future research on biomarkers of exposure in this population, as well as for guiding regulatory authorities who are working to understand the impact of ENDS on public health in both general and disparate populations.

ENDS are part of the diversifying tobacco and nicotine landscape.[37] Currently, there are several gaps in how to define and classify these devices making research on ENDS difficult.[2] Understanding characteristics of ENDS (e.g., type of device, nicotine concentration and flavor of e-liquid) is important as these characteristics have been shown to influence use behavior.[12] Thus, a major strength of the present study was the number of characteristics collected on ENDS use and the usage of pictures to aid participants in selecting which product they currently used. The vast-majority of ENDS and dual users in this sample reported using a tank or vapor system. Additionally, most reported that their ENDS was refillable with e-liquid and rechargeable. The majority of both dual and ENDS users reported using ENDS with nicotine concentrations of 12 mg or less. These findings are consistent with other epidemiologic surveys that have identified rechargeable and refillable devices to more popular among ENDS users than cartridge-based or disposable ENDS.[12,38]

Concern surrounds flavored tobacco products as they have been disproportionately used by youth and initiators.[39-41] Due to this, flavored cigarettes, excluding menthol flavor, were prohibited in the US in 2009 as part of the landmark Family Smoking Prevention and Tobacco Control Act.[42]

Currently, ENDS, or the e-liquid used in ENDS, come in a variety of flavors. One study identified nearly 8,000 flavors available online and showed that the vast majority of brands offered fruit, candy, and dessert flavors.[43] Flavors are a commonly cited reason for vaping, particularly in youth and young adults.[8,44-47] In the present study the most common flavors among both ENDS and dual users were fruit and candy or sweets. Other studies have also found fruit and candy flavors to be popular among ENDS users.[48,49] Interestingly, none of the participants in the present study reported not using any flavor. Regulatory authorities need to consider the potential impact of eliminating flavors in ENDS, as their prohibition, especially fruit and candy flavors, will not only reduce youth appeal but also the appeal to adult ENDS users.

Data on patterns of ENDS use is crucial for understanding the impact of these devices on public health, especially among priority populations disproportionately affected by tobacco use. There are no standardized methods for assessing ENDS behavior. In the present study, participants read a generic definition of a 'vape session' and then were asked questions to characterize vape sessions. One-third of ENDS users and more than half of dual users reported 100 or less vape sessions in their lifetime. This is surprising since ENDS were used for a median duration of 1 or 2 years and the study eligibility which included using an ENDS every day in the past 3 months. Participants may have had a hard time recalling this number and simply guessed or perhaps the question was worded in a manner that caused confusion. Another explanation is the participants may have underestimated their total number of vape sessions as a result of social desirability. Cognitive testing of this measure should be pursued among an adequately-powered sample. Average number of vape sessions per day varied, with most reporting less than 20 sessions per day. An average of 5-10 puffs per vape session was most common among both ENDS and dual

users. In terms of vape sessions, most lasted for 5 minutes or less among ENDS users; while, the proportion of dual users who reported a vape session lasting 1-2, 3-5, 6-10, and over 10 minutes were similar. In addition to providing a deeper understanding of ENDS use among AIs, these findings are relevant for researchers seeking to understand which measures should be used to monitor patterns of ENDS use.

Attempts to quit smoking are considered a critical step to increasing rates of smoking cessation and, subsequently, reducing the smoking prevalence.[50-52] Based on data from the 2013 National Health Interview Survey, an estimated 51% of AI smokers reported attempting to quit in the past 12 months.[53] In the present study, the proportion of dual users who made a quit attempt was more than twice the proportion among exclusive smokers. This finding supports previous literature linking ENDS use to smoking cessation. For example, in a nationally representative sample of US cigarette smokers (n=2,028), ENDS users had a higher smoking quit attempt (73% versus 46%) and cessation (42% versus 16%) rate than non-ENDS users.[54] We did not ask participants about their reason for using ENDS; however, there is a possibility that dual users in the present study are similar to those in others studies who report using ENDS to quit cigarettes.[7-9] Dual users were asked to recall their average CPD before ENDS initiation, which was significantly higher than their current CPD. Additionally, although there was no difference in proportion of overall loss of autonomy measures, a higher proportion of dual users than smokers said 'yes' to items 1 and 2 on the HONC, both of which contain language related to quitting smoking. This observation supports the finding that a higher proportion of dual users than smokers made a smoking quit attempt. Future cohort studies, such as the US Population

Assessment of Tobacco Use and Health, are needed to assess the causal relationship between dual use and smoking cessation.

A major component of assessing the public health impact of ENDS use is to understand the dependence potential in both exclusive and dual users. Since ENDS and cigarettes differ in patterns of use, methods for assessing dependence that can facilitate comparison across products are needed. In the present study, HONC was used to assess diminished autonomy—a core feature of tobacco dependence.[24] With median scores of 4 and 3, ENDS and dual users were no different in loss of autonomy over ENDS. Eissenberg and colleagues recently developed a questionnaire, which contained measures from a variety of scales including the HONC, to assess dependence to both cigarettes and ENDS.[13] Eissenberg found ENDS users to be less dependent on ENDS than they retrospectively reported having been dependent on cigarettes prior to switching.[13] Although we did not ask ENDS users who were former smokers to recall their loss of autonomy to cigarettes, severity of loss of autonomy in ENDS users was one-half of the severity of loss of autonomy in smokers. Future research comparing dependence scores in ENDS users and smokers while controlling for potential confounding factors, such as age, are needed.

**Limitations**

Although this study has the potential to provide important information, it must be considered in light of its limitations. The focus of this pilot study was not on testing of hypotheses, but on describing characteristics of ENDS users, dual users, and smokers of AI descent. Thus we did not incorporate a formal sample size calculation. The small sample size also restricted our ability to control for potential confounders (e.g., gender, age), which have been shown to influence

tobacco use behaviors and dependence scores. Second, the study population was not randomly sampled, rather participants were enrolled based on convenience using community-based recruitment strategies. Therefore generalizations to all AIs, including those residing in Oklahoma, should be made with caution. Also, the exclusion criteria may further impact the ability to generalize findings. Of most concern is that individuals who used alcohol on the day of the study were not eligible. Alcohol use is correlated with tobacco use;[55-58] thus restricting eligibility to those who did not consume alcohol may harm the external validity of the findings. Third, this study relied on self-report and thus prone to recall bias. Lastly, several of the ENDS measures (e.g, adapted version of HONC) have yet to be validated. Future studies should be conducted to determine the sensitivity and specificity of these measures.

**Conclusion**

This study provides an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Ultimately, this study helps to provide a more complete picture of the current tobacco use landscape among AIs and will be informative for regulators as well as public health officials who are actively trying to understand behavior and dependence among ENDS users.

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## CONTRIBUTORSHIP STATEMENT

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## COMPETING INTERESTS STATEMENT

No competing interests to declare

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## DATA SHARING STATEMENT

No additional data available.

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**Table 1.** Sociodemographic Characteristics and Traditional Tobacco Use Among All Participants and by User Group

| | All participants (n=82) | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | *p-value* |
|---|---|---|---|---|---|
| Age, median | 41.50 | 33.00[a] | 41.00 | 46.00 | 0.0263 |
| Gender, % | | | | | 0.3592 |
| Male | 37.80 | 29.63 | 35.71 | 48.15 | |
| Female | 62.20 | 70.37 | 64.29 | 51.85 | |
| Marital status, % | | | | | 0.1261 |
| Married/member of unmarried couple | 42.68 | 44.44 | 28.57 | 55.56 | |
| Never married/divorced/separated/widowed | 57.32 | 55.56 | 71.43 | 44.44 | |
| Education level, % | | | | | 0.2567 |
| At least some college | 50.00 | 62.96 | 42.86 | 44.44 | |
| High school diploma, GED or less | 50.00 | 37.04 | 57.14 | 55.56 | |
| Employment status, % | | | | | 0.6162 |
| Employed for wages/self-employed | 53.66 | 55.56 | 46.43 | 59.26 | |
| Other | 46.34 | 44.44 | 53.57 | 40.74 | |
| BMI ($kg/m^2$) category, % | | | | | 0.1333 |
| Normal weight | 24.69 | 30.77 | 32.14 | 11.11 | |
| Overweight or obese | 75.31 | 69.23 | 67.86 | 88.89 | |
| Traditional/sacred tobacco use in past 3 months, % | | | | | 0.0366 |
| Yes | 17.50 | 7.41 | 11.54 | 33.33 | |
| No | 82.50 | 92.59 | 88.46 | 66.67 | |

ENDS: Electronic nicotine delivery system; BMI= body mass index; * Asked only to those who were employed for wages or self-employed; [a]ENDS users significantly different from cigarette smokers at $p<0.05$

**Table 2.** Electronic Nicotine Delivery System (ENDS) Use Characteristics

| | ENDS users (n=27) | Dual users (n=28) |
|---|---|---|
| Age of ENDS initiation, median | 28.50 | 35.00 |
| Age of regular ENDS initiation, median | 30.00 | 36.50 |
| Duration ENDS use, median | 2.0 | 1.0 |
| Type of ENDS: tank or vapor system, % | 88.89 | 92.86 |
| Type of ENDS: cig-a-like, % | 7.41 | 21.43 |
| Type of ENDS: e-cigar, % | 0.00 | 3.57 |
| Type of ENDS: e-pipe, % | 3.70 | 0.00 |
| Type of ENDS: e-hookah, % | 0.00 | 0.00 |
| ENDS is refillable, % | 88.89 | 100.00 |
| ENDS is rechargeable, % | 100.00 | 96.43 |
| ENDS uses cartridges, % | 29.63 | 33.33 |
| Nicotine concentration, % | | |
| 0mg | 0.00 | 7.69 |
| 1-5mg | 52.00 | 30.77 |
| 6-12mg | 28.00 | 30.77 |
| 13-17mg | 8.00 | 3.85 |
| 18-24mg | 8.00 | 23.08 |
| 25mg or more | 4.00 | 3.85 |
| Tobacco flavor, % | 18.52 | 39.29 |
| Menthol flavor, % | 14.81 | 3.57 |
| Clove or spice, % | 7.41 | 17.86 |
| Fruit, % | 66.67 | 53.57 |
| Chocolate, % | 7.41 | 14.29 |
| Alcoholic drink, % | 3.57 | 0.00 |
| Candy/sweets, % | 51.85 | 57.14 |
| Other flavor, % | 11.11 | 21.43 |
| Number of vape sessions in lifetime*, % | | |
| 100 or less | 33.33 | 52.00 |
| 101-200 | 12.50 | 8.00 |
| 201-300 | 8.33 | 8.00 |
| 301-400 | 12.50 | 8.00 |
| Over 400 | 33.33 | 24.00 |
| Average number of vape sessions per day*, % | | |
| Less than 10 sessions | 28.00 | 52.00 |
| 10 to 19 sessions | 44.00 | 20.00 |
| 20 to 30 sessions | 16.00 | 8.00 |
| Over 30 | 12.00 | 20.00 |
| Average number of puffs per vape session*, % | | |
| Under 5 | 14.81 | 23.08 |
| 5-10 | 55.56 | 46.15 |
| More than 10 | 29.63 | 30.77 |
| Average length of vape session*, % | | |
| 1-2 minutes | 33.33 | 25.00 |
| 3-5 minutes | 40.74 | 28.57 |
| 6-10 minutes | 18.52 | 25.00 |
| Over 10 minutes | 7.14 | 21.43 |

* Provided by the Ontario Tobacco Research Center

**Table 3.** Cigarette Smoking Characteristics Among Cigarette Dual Users and Smokers

| | Dual users (n=28) | Cigarette smokers (n=27) |
|---|---|---|
| Cigarettes per day, median | 15.0 | 10.0 |
| Cigarettes per day, % | | |
| <1 pack | 57.14 | 59.26 |
| ≥1 pack | 42.86 | 40.74 |
| Age of initiation, median | 15.0 | 14.0 |
| Age of regular initiation, median | 16.5 | 19.0 |
| Duration of smoking, median | 21.5 | 26.0 |
| 24-hour smoking quit attempt in past 12 months, % | 57.14[a] | 25.93 |
| Smokes mentholated cigarettes, % | 21.43 | 40.74 |

[a] Dual users significantly different from cigarette smokers at $p<0.05$

**Table 4.** Results from Hooked on Nicotine Checklist for Assessing Loss of Autonomy Over Cigarettes and Adapted Version for Assessing Loss of Autonomy Over Electronic Nicotine Delivery Systems (ENDS)[¶]

| | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | |
|---|---|---|---|---|
| | *Over ENDS* | | *Over cigarettes* | |
| **Individual items measured in HONC**, % | | | | |
| 1. Have you ever tried to quit cigarettes [using an ENDS], but couldn't? | 18.52 | 18.52 | 78.57 | 51.85 |
| 2. Do you smoke [use your ENDS] now because it is really hard to quit smoking cigarettes [using an ENDS]? | 32.14 | 40.74 | 75.00 | 48.15 |
| 3. Have you ever felt like you were addicted to cigarettes [an ENDS]? | 28.57 | 37.04 | 82.14 | 70.37 |
| 4. Do you ever have strong cravings to smoke [use an ENDS]? | 50.00 | 59.26 | 96.43 | 85.19 |
| 5. Have you ever felt like you really needed a cigarette [an ENDS]? | 57.14 | 59.26 | 100.00 | 92.59 |
| 6. Is it hard to keep from smoking [using an ENDS] in places where you are not supposed to? | 35.71 | 25.93 | 53.57 | 44.44 |
| When you haven't smoked cigarettes [used an ENDS] for a while OR | | | | |
| When you tried to stop smoking cigarettes [using an ENDS]… | | | | |
| 7. …did you find it hard to concentrate because you couldn't smoke a cigarette [use an ENDS]? | 28.57 | 22.22 | 57.14 | 38.46 |
| 8. …do you feel more irritable because you couldn't smoke a cigarette [use an ENDS]? | 25.00 | 48.15 | 71.43 | 74.07 |
| 9. …did you feel a strong need or urge to smoke a cigarette [use an ENDS]? | 57.14 | 59.26 | 89.29 | 81.48 |
| 10. …did you feel nervous, restless, or anxious because you couldn't smoke a cigarette [use an ENDS]? | 28.57 | 37.04 | 75.00 | 55.56 |

[¶]Substitute the underlined word with the words in square brackets for assessing loss of autonomy over ENDS

**Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes**

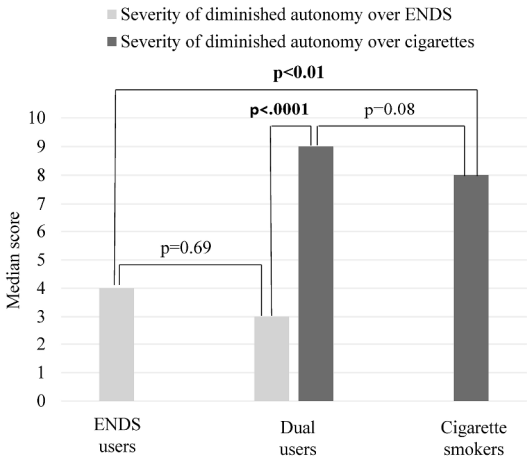


Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes

279x361mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation | Page # |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 2 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *6-8* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 9 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6-8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 9 |
| | | (*c*) Explain how missing data were addressed | NA |
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy | NA |
| | | (*e*) Describe any sensitivity analyses | NA |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10 |
| | | (b) Give reasons for non-participation at each stage | 10 |
| | | (c) Consider use of a flow diagram | NA |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 10 |
| | | (b) Indicate number of participants with missing data for each variable of interest | NA |
| Outcome data | 15* | Report numbers of outcome events or summary measures | NA |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 10-13 |

| | | | |
|---|---|---|---|
| | | (*b*) Report category boundaries when continuous variables were categorized | 10-13 |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 18-19 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 18 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 20 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians- results from an observational pilot study

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# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians- results from an observational pilot study

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**Keywords**: American Indians, Electronic Cigarettes, Cigarette Smoking Epidemiologic Studies, Minority Groups, Tobacco Use, Dependence

## ABSTRACT

**Objective**: American Indians (AI) have a high prevalence of ENDS use. However, little information exists on (ENDS) use, either alone or in combination with cigarettes (dual use), among AI. The objective of this small-scaled study was to examine use behaviors and dependence among exclusive ENDS users and dual users of AI descent. Exclusive smokers were included for comparison purposes.

**Setting**: Oklahoma, United States

**Participants**: Adults of AI descent who reported being exclusive ENDS users (n=27), dual users (n=28), or exclusive cigarette smokers (n=27).

**Measures**: Participants completed a detailed questionnaire on use behaviors. The Hooked on Nicotine Checklist (HONC) was used to assess loss of autonomy over cigarettes and was reworded for ENDS. Dual users completed the HONC twice. Sum of endorsed items indicated severity of diminished autonomy. Comparisons were made with nonparametric methods and statistical significance was defined as $p<0.05$.

**Results**: Median duration of ENDS use was 2 years among ENDS users and 1 year among dual users. Most ENDS and dual users reported <20 vape sessions per day (72.0% vs. 72.0%) with ≤10 puffs per vape session (70.4% vs. 69.2%). Severity of diminished autonomy over ENDS was similar among ENDS and dual users (medians: 4 vs 3; p=0.6865). Among dual users, severity of diminished autonomy was lower for ENDS than cigarettes (medians: 3 vs 9; p=<.0001). Comparing ENDS users to smokers, ENDS users had a lower severity of diminished autonomy (4 vs 8; p=0.0077). Comparing dual users to smokers, median severity of diminished autonomy over cigarettes did not differ (p=0.6865).

**Conclusions**: Severity of diminished autonomy was lower for ENDS than cigarettes in this small sample of AI. Future, adequately-powered, studies should be conducted to fully understand ENDS use patterns and dependence levels in this population.

## Strengths and limitations of this study

- This is the first study to provide use and dependence data on electronic nicotine systems (ENDS) users of American Indian (AI) descent, a minority population in the US with high rates of tobacco-related disease and often underrepresented in epidemiologic and clinical research.
- This study describes a novel method for assessing loss of autonomy, a core feature of dependence, in ENDS users by adapting the Hooked on Nicotine Checklist.
- Due to the small sample size, convenience based sampling approach, and eligibility criteria, generalizations to all AIs in Oklahoma should be made with caution.
- This study relied on self-report and thus prone to recall bias.

## INTRODUCTION

Electronic nicotine delivery systems (ENDS), also referred to as e-cigarettes and vaping devices, are a line of relatively new tobacco products that heat a solution, often containing nicotine and flavorants, to generate an aerosol. Although ENDS aerosol is not harmless, it generally contains fewer toxic chemicals than cigarettes—a statement backed by the United States (US) Surgeon General.[1] In August of 2016, the US Food and Drug Administration Center for Tobacco Products (US FDA CTP) was provided the authority to regulate the manufacturing, distribution, and marketing of ENDS in the US.[2,3] To inform their regulatory action, the US FDA CTP has specifically called for research that seeks to understand use behaviors and dependence in ENDS users.[4]

ENDS use is high among American Indians and Alaskan Natives (AI/ANs).[5,6] According to data from the 2014 US National Health Interview Survey, 11% of non-Hispanic AI/AN adults currently use ENDS compared to 5% of non-Hispanic White adults.[6] Since a commonly reported reason for using ENDS is to help quit or reduce cigarettes[7-9] and AI/ANs have a smoking prevalence higher than any other race group in the US,[10] high rates of dual use among AI/ANs might also be expected. Unpublished data from the 2014 Oklahoma Behavioral Risk Factor Surveillance Survey and the Adult Tobacco Survey showed that approximately 5.0% of AI/ANs are exclusive ENDS users and a further 8.5% are dual users compared to 3.2% and 4.0% of non-Hispanic Whites. A major public health question surrounding dual use is whether this behavior will help or halt smoking cessation efforts.[2]

No information, to our knowledge, currently exists on use behaviors and dependence in ENDS users of AI/AN descent. To address this literature gap, we describe use behaviors and loss of autonomy, a core feature of dependence, in AI exclusive ENDS users and dual users of ENDS and cigarettes. Since cigarette smokers have been used as a comparison group in prior studies of ENDS,[11-13] we also present data on exclusive cigarette smokers of AI descent. The results of this study will be significant for regulatory authorities, such as the US FDA CTP, and public health officials who are actively trying to understand ENDS use behavior and dependence in priority populations such as AIs.

## METHODS

### Participant recruitment

This study was approved by the University of Oklahoma Health Sciences Center (# 6317) and the Oklahoma City Area Indian Health Service Institutional Review Board (# P-16-01-OK). From March through October 2016, community-based strategies were employed to recruit adults of AI descent who were in one of three groups of current tobacco use: 1) current exclusive cigarette smokers, 2) current exclusive ENDS users, and 3) concurrent users of cigarettes and ENDS, referred to as dual users. Recruitment strategies, previously described,[14] included posting recruitment ads online and study staff attending cultural events, tribal health fairs, and vape shops in the state of Oklahoma.

### Participant eligibility

This study's inclusion and exclusion criteria were similar to those employed in a previous study of nicotine metabolism among Alaskan Native tobacco users.[15] All participants had to self-report

AI race and at least two biological grandparents of AI race. Additionally, participants were between 18 and 65 years of age, and able to speak, read, and write the English language. Additional inclusion criteria were employed to result in a sample of "regular" users of cigarettes and/or ENDS. A regular cigarette smoker was defined as those who have smoked at least 5 cigarettes per day for the past 3 months, smoked in the past 24 hours, and not used tobacco products other than cigarettes in the past 3 months. A regular ENDS user was defined as someone who used an ENDS every day for the past 3 months and in the past 24 hours, and had not used tobacco products other than ENDS in the past 3 months. Although dual use refers to a heterogeneous group, we defined dual users as those who smoked at least 5 cigarettes per day in the past 3 months and in the past 24 hours, used an ENDS product every day for the past 3 months and in the past 24 hours, and not used tobacco products other than cigarettes and ENDS in the past 3 months.

Participants were excluded from any group if they regularly used medications for seizures, tuberculosis, or cancer; were currently involved in a tobacco cessation program or used nicotine replacement therapy; were pregnant or breastfeeding; used illicit drugs in the 30 days prior to the study; used alcohol or marijuana on the day of the study.

**Measures**

Data on age, gender, marital status, education level, employment status and body mass index (BMI) were collected. Participants were also asked about their use of tobacco for sacred or ceremonial purposes (i.e., traditional tobacco use), a practice common among some AI tribes.[16-18]

Since ENDS are relatively new to the marketplace and often called different names, the following statement, which was adapted from the US Population Assessment of Tobacco and Health (PATH)[19], was read by ENDS and dual users prior to collecting information on ENDS use: 'You said you currently use an electronic nicotine product. These products are battery-powered, use nicotine fluid rather than tobacco leaves, and produce vapor instead of smoke. There are many different names for these devices. Some common brands include Fin, NJOY, Blu, e-Go and Vuse.' Generic photos ("cig-a-like"; tank or vapor system; e-cigar; e-pipe; e-hookah) of commonly used ENDS were displayed and participants chose the photo(s) which best resembled the ENDS they currently used. Participants had the option of choosing more than one. Participants were also asked if the ENDS was rechargeable, refillable with e-liquid, if it used cartridges, and which nicotine concentration they currently used. Since ENDS users often use more than one flavor or mix flavors, participants reported all flavors they currently used.

There is not a standard or commonly accepted method for assessing frequency of ENDS use.[2] In this study, ENDS and dual users read the following statement provided by the Ontario Tobacco Research Center to assess frequency of use: 'A session starts from your first puff and ends with your last puff before you take a break to do something else. A session can last for any length of time and involve any number of puffs, depending in the person. Sometimes these are called vape sessions.' Participants then responded to four questions: (1) 'How many sessions have you had with your electronic nicotine product in your lifetime?'; (2) 'In a typical day, how many sessions do you have?'; (3) 'How long does one session typically last for you?'; (4) 'How many puffs do you typically take per session?'. Other variables collected included age of ENDS initiation, age of regular ENDS initiation, and duration of use. Among exclusive ENDS users, we asked if they

were a never or former smoker. If they were a former smoker, we asked them to recall their number of CPD when smoked and the time since smoked. We also asked dual users to recall their number of CPD prior to ENDS initiation.

There are a number of questionnaires with proven utility in assessing dependence to cigarettes.[20-23] The Hooked on Nicotine Checklist (HONC), a 10-item screening tool, assesses of loss of autotomy in both adolescent and adults.[23,24] Diminished autonomy is a core feature common to all forms of substance dependence, including tobacco dependence.[24] HONC does not include measures on heaviness or frequency of use specific to cigarette smoking (e.g., CPD). Thus, it can be readily modified to assess loss of autotomy to non-cigarette tobacco products, such as ENDS. In the present study, loss of autonomy over cigarettes was summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy). We reworded the HONC to assess loss of autonomy to ENDS. Dual users completed the HONC twice, once with regard to cigarettes and once with regard to ENDS. Loss of autonomy over ENDS was also summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy).

Among dual users and exclusive smokers, measures of cigarette smoking were collected. These measures included the age when participants first tried part or all of a cigarette (i.e., age of initiation), the age when participants started smoking cigarettes regularly (i.e., age of regular initiation), average number of cigarettes currently smoked per day (CPD), duration of cigarette smoking, presence of a 24-hour quit attempt in the past 12 months, and use of menthol cigarettes.

**Biochemical assessment of smoking status**

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive assessment of cigarette smoking status.[25] CO was collected to biochemically confirm self-reported cigarette smoking status and therefore help reduce information bias. A CO value of ≥10 parts per million (ppm) is commonly used to determine eligibility for studies among smokers.[26-30] However, a borderline CO level between 6-9 ppm may also reflect cigarette smoking or among non-smokers it may reflect exposure to secondhand smoke or other sources of CO (e.g., car pollution).[25,31-33] Moreover, prior studies have required CO levels of <6[34] or <10[12,35] for confirming exclusive ENDS use. Based on this information, we did not exclude individuals from any of the three groups with a CO between 6-9 ppm. Thus, ENDS users were included if they had a CO level ≤9 ppm, while cigarette smokers and dual users were included in the study if they had a CO level ≥6 ppm.

**Statistical analysis**

This study focused on describing characteristics of ENDS users, dual users, and smokers of AI descent. Since the study's primary purpose was descriptive, a formal sample size calculation was not performed. Continuous and ordinal measures were described using median values and categorical measures were described by proportions. Scores and frequencies were compared between the three user groups with the nonparametric Kruskal–Wallis test for ordinal or continuous measures and with a Chi-square or Fisher's exact test for categorical measures. A p-value <0.05 was considered statistically significant for comparison among all three user groups. Significant overall tests were followed by testing for differences between the three pairs of

groups, and significance was assessed using a Bonferroni adjustment of alpha=0.017. Statistical analysis was conducted in SAS 9.4.

## RESULTS

A total of 95 individuals participated in the study: 28 ENDS users, 32 dual users, and 35 cigarette smokers. Thirteen participants (13.7%) were excluded because their CO values were outside the range for their given tobacco use group. Therefore, results are presented for the 82 participants (27 ENDS users, 28 dual users, 27 cigarette smokers) with CO values in the expected range given their self-reported tobacco use. **Table 1** displays data on socio-demographic characteristics and traditional tobacco use for the 82 participants.

**Table 2** presents data on ENDS use behaviors. Median age first tried an ENDS was 28.5 years among ENDS users and 35.0 years among dual users. Median age started using an ENDS regularly was 30.0 years among ENDS users and 36.5 years among dual users. Median duration of ENDS use was 2 years among ENDS and 1 year among dual users. When prompted with the option to select the photo which best represented the ENDS currently being used, the vast majority of ENDS (89%) and dual users (93%) selected a tank or vapor system. The vast majority, if not all, of ENDS users and dual users reported currently using an ENDS which was refillable with e-liquid (89%, 100%) and rechargeable (100%, 96%); while, one-third or less (30%, 33%) reported using cartridges. The majority of both ENDS users (80%) and dual users (69%) reported currently using a nicotine concentration of 12 mg or less. More than one-half of ENDS and dual users reported using fruit (67%, 54%) and candy (52%, 57%) flavored ENDS.

Data on number of vape sessions in lifetime, vape sessions per day, puffs per vape session, and length of vape session is also displayed in **Table 2**.

ENDS and dual users were asked questions to assess their smoking status prior to initiation of an ENDS (data not provided in tables). The vast majority of ENDS users (92.6%) reported being former cigarettes smokers. Among ENDS users who were former cigarette smokers, the median CPD when smoking was 20 and the median duration since smoked cigarettes was 2 years. Dual users were asked to recall CPD before initiation of an ENDS. Median CPD prior to ENDS use was 20, which was significantly higher than the current median of 15 CPD.

**Table 3** presents data on cigarette smoking characteristics among dual users and exclusive smokers. Median CPD was 15 among dual users and 10 among smokers The distribution of CPD did not differ between the two user groups. Distributions of age when respondents first tried smoking a cigarette and started smoking cigarettes regularly did not differ between user groups. A greater proportion of dual users reported a 24-hour quit attempt in the previous 12 months than did smokers (57% versus 26%).

**Table 4** presents data on the ten individual items from the adapted HONC for loss of autonomy over ENDS. There were no differences in the individual HONC items when comparing ENDS with dual users. The proportion of ENDS users (64.3%) who had a diminished autonomy over ENDS was no different than dual users (77.8%). On a scale of 0 to 10, median severity of diminished autonomy over ENDS was 4 and 3 among ENDS and dual users, respectively (**Figure 1**). Distributions in severity of diminished autonomy over ENDS did not differ when

comparing ENDS users with dual users. To further understand autonomy, loss of autonomy to ENDS in ENDS users was compared with loss of autonomy to cigarettes in smokers. There was no difference in proportions of diminished autonomy when comparing smokers with ENDS users (96% versus 78%). However, distributions in severity of diminished autonomy differed. ENDS users had significantly lower scores for severity of diminished autonomy than smokers (4 vs 8). Furthermore, among dual users, severity of diminished autonomy over ENDS was lower than severity of diminished autonomy over cigarettes (3 vs 9).

The proportion of dual users (100%) with diminished autonomy over cigarettes did not significantly differ from the proportion of cigarette smokers (96.3%). Median severity of diminished autonomy over cigarettes was 9 and 8 among dual users and smokers, respectively. Distributions in severity of diminished autonomy over cigarettes did not differ when comparing dual users with smokers. When examining individual items measured by the HONC, a greater proportion of dual users than smokers said 'yes' to items 1 "Have you ever tried to quit cigarettes, but couldn't?" (79% versus 52%; p-value =0.0372) and 2 "Do you smoke now because it is really hard to quit smoking cigarettes?" (75% versus 48%; p-value=0.0405). There was no difference in items 3-10.

## DISCUSSION

This descriptive study provides novel findings about ENDS use in a small sample of AIs from Oklahoma, a state located in the Southern Plains region of the US. Notably, this analysis was the first of its kind to provide an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Studies of this kind are a current research priority of the US

FDA CTP, which serves as the regulatory authority for all tobacco products in the US.[4,36] Ultimately, this study provides a more complete picture of the current tobacco use landscape and will be informative for our future research on biomarkers of exposure in this population, as well as for guiding regulatory authorities who are working to understand the impact of ENDS on public health in both general and disparate populations.

ENDS are part of the diversifying tobacco and nicotine landscape.[37] Currently, there are several gaps in how to define and classify these devices making research on ENDS difficult.[2] Understanding characteristics of ENDS (e.g., type of device, nicotine concentration and flavor of e-liquid) is important as these characteristics have been shown to influence use behavior.[12] Thus, a major strength of the present study was the number of characteristics collected on ENDS use and the usage of pictures to aid participants in selecting which product they currently used. The vast-majority of ENDS and dual users in this sample reported using a tank or vapor system. Additionally, most reported that their ENDS was refillable with e-liquid and rechargeable. The majority of both dual and ENDS users reported using ENDS with nicotine concentrations of 12 mg or less. These findings are consistent with other epidemiologic surveys that have identified rechargeable and refillable devices to more popular among ENDS users than cartridge-based or disposable ENDS.[12,38]

Concern surrounds flavored tobacco products as they have been disproportionately used by youth and initiators.[39-41] Due to this, flavored cigarettes, excluding menthol flavor, were prohibited in the US in 2009 as part of the landmark Family Smoking Prevention and Tobacco Control Act.[42] Currently, ENDS, or the e-liquid used in ENDS, come in a variety of flavors. One study

identified nearly 8,000 flavors available online and showed that the vast majority of brands offered fruit, candy, and dessert flavors.[43] Flavors are a commonly cited reason for vaping, particularly in youth and young adults.[8,44-47] In the present study the most common flavors among both ENDS and dual users were fruit and candy or sweets. Other studies have also found fruit and candy flavors to be popular among ENDS users.[48,49] None of the participants in the present study reported not using any flavor. Regulatory authorities need to consider the potential impact of eliminating flavors in ENDS, as their prohibition, especially fruit and candy flavors, will not only reduce youth appeal but also the appeal to adult ENDS users.

Data on patterns of ENDS use is crucial for understanding the impact of these devices on public health, especially among priority populations disproportionately affected by tobacco use. There are no standardized methods for assessing ENDS behavior. In the present study, participants read a generic definition of a 'vape session' and then were asked questions to characterize vape sessions. One-third of ENDS users and more than half of dual users reported 100 or less vape sessions in their lifetime. This is surprising since ENDS were used for a median duration of 1 or 2 years and the study eligibility which included using an ENDS every day in the past 3 months. Participants may have had a hard time recalling this number and simply guessed or perhaps the question was worded in a manner that caused confusion. Another explanation is the participants may have underestimated their total number of vape sessions as a result of social desirability. Cognitive testing of this measure should be pursued among an adequately-powered sample. Average number of vape sessions per day varied, with most reporting less than 20 sessions per day. An average of 5-10 puffs per vape session was most common among both ENDS and dual users. In terms of vape sessions, most lasted for 5 minutes or less among ENDS users; while, the

proportion of dual users who reported a vape session lasting 1-2, 3-5, 6-10, and over 10 minutes were similar. In addition to providing a deeper understanding of ENDS use among AIs, these findings are relevant for researchers seeking to understand which measures should be used to monitor patterns of ENDS use.

Attempts to quit smoking are considered a critical step to increasing rates of smoking cessation and, subsequently, reducing the smoking prevalence.[50-52] Based on data from the 2013 National Health Interview Survey, an estimated 51% of AI smokers reported attempting to quit in the past 12 months.[53] In the present study, the proportion of dual users who made a quit attempt was more than twice the proportion among exclusive smokers. This finding supports previous literature linking ENDS use to smoking cessation. For example, in a nationally representative sample of US cigarette smokers (n=2,028), ENDS users had a higher smoking quit attempt (73% versus 46%) and cessation (42% versus 16%) rate than non-ENDS users.[54] We did not ask participants about their reason for using ENDS; however, there is a possibility that dual users in the present study are similar to those in others studies who report using ENDS to quit cigarettes.[7-9] Dual users were asked to recall their average CPD before ENDS initiation, which was significantly higher than their current CPD. Additionally, although there was no difference in proportion of overall loss of autonomy measures, a higher proportion of dual users than smokers said 'yes' to items 1 and 2 on the HONC, both of which contain language related to quitting smoking. This observation supports the finding that a higher proportion of dual users than smokers made a smoking quit attempt. Future cohort studies, such as the US Population Assessment of Tobacco Use and Health, are needed to assess the causal relationship between dual use and smoking cessation.

A major component of assessing the public health impact of ENDS use is to understand the dependence potential in both exclusive and dual users. Since ENDS and cigarettes differ in patterns of use, methods for assessing dependence that can facilitate comparison across products are needed. In the present study, HONC was used to assess diminished autonomy—a core feature of tobacco dependence.[24] With median scores of 4 and 3, ENDS and dual users were no different in loss of autonomy over ENDS. Eissenberg and colleagues recently developed a questionnaire, which contained measures from a variety of scales including the HONC, to assess dependence to both cigarettes and ENDS.[13] Eissenberg found ENDS users to be less dependent on ENDS than they retrospectively reported having been dependent on cigarettes prior to switching.[13] Although we did not ask ENDS users who were former smokers to recall their loss of autonomy to cigarettes, severity of loss of autonomy in ENDS users was one-half of the severity of loss of autonomy in smokers. Future research comparing dependence scores in ENDS users and smokers while controlling for potential confounding factors, such as age, are needed.

**Limitations**

Although this study has the potential to provide important information, it must be considered in light of its limitations. The focus of this pilot study was not on testing of hypotheses, but on describing characteristics of ENDS users, dual users, and smokers of AI descent. Thus we did not incorporate a formal sample size calculation. The small sample size restricted our ability to control for potential confounders (e.g., gender, age), which have been shown to influence tobacco use behaviors and dependence scores. The reason for this pilot study was to determine the feasibility of recruiting AI research participants and collecting data on their ENDS behavior.

The plan is to expand this study by recruiting a larger sample of ENDS users of AI descent and other race groups (e.g., whites, blacks) for comparison purposes. Second, the study population was not randomly sampled, rather participants were enrolled based on convenience using community-based recruitment strategies. Therefore, generalizations to all AIs, including those residing in Oklahoma, should be made with caution. Also, the exclusion criteria may further impact the ability to generalize findings. Of most concern is that individuals who used alcohol on the day of the study were not eligible. Alcohol use is correlated with tobacco use;[55,56] thus restricting eligibility to those who did not consume alcohol may harm the external validity of the findings. Third, this study relied on self-report and thus prone to recall bias. Lastly, several of the ENDS measures (e.g, adapted version of HONC) have yet to be validated. Future studies should be conducted to determine the sensitivity and specificity of these measures.

## Conclusion

This study provides an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Ultimately, this study helps to provide a more complete picture of the current tobacco use landscape among AIs and will be informative for regulators as well as public health officials who are actively trying to understand behavior and dependence among ENDS users.

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## CONTRIBUTORSHIP STATEMENT

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## COMPETING INTERESTS STATEMENT

No competing interests to declare

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## DATA SHARING STATEMENT

No additional data available.

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**Table 1.** Sociodemographic Characteristics and Traditional Tobacco Use Among All Participants and by User Group

| | All participants (n=82) | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | *p-value* |
|---|---|---|---|---|---|
| Age, median | 41.5 | 33.0[a] | 41.0 | 46.0 | 0.0263 |
| Gender, % | | | | | 0.3592 |
| Male | 37.8 | 29.6 | 35.7 | 48.2 | |
| Female | 62.2 | 70.4 | 64.3 | 51.9 | |
| Marital status, % | | | | | 0.1261 |
| Married/member of unmarried couple | 42.7 | 44.4 | 28.6 | 55.6 | |
| Never married/divorced/separated/widowed | 57.3 | 55.6 | 71.4 | 44.4 | |
| Education level, % | | | | | 0.2567 |
| At least some college | 50.0 | 63.0 | 42.9 | 44.4 | |
| High school diploma, GED or less | 50.0 | 37.0 | 57.1 | 55.6 | |
| Employment status, % | | | | | 0.6162 |
| Employed for wages/self-employed | 53.7 | 55.6 | 46.4 | 59.3 | |
| Other | 46.3 | 44.4 | 53.6 | 40.7 | |
| BMI ($kg/m^2$) category, % | | | | | 0.1333 |
| Normal weight | 24.7 | 30.8 | 32.1 | 11.1 | |
| Overweight or obese | 75.3 | 69.2 | 67.9 | 88.9 | |
| Traditional/sacred tobacco use in past 3 months, % | | | | | 0.0366 |
| Yes | 17.5 | 7.4 | 11.5 | 33.3 | |
| No | 82.5 | 92.6 | 88.5 | 66.7 | |

ENDS: Electronic nicotine delivery system; BMI= body mass index; * Asked only to those who were employed for wages or self-employed; [a]ENDS users significantly different from cigarette smokers at $p<0.05$

**Table 2.** Electronic Nicotine Delivery System (ENDS) Use Characteristics

| | ENDS users (n=27) | Dual users (n=28) |
|---|---|---|
| Age of ENDS initiation, median | 28.5 | 35.0 |
| Age of regular ENDS initiation, median | 30.0 | 36.5 |
| Duration ENDS use, median | 2.0 | 1.0 |
| Type of ENDS: tank or vapor system, % | 88.9 | 92.9 |
| Type of ENDS: cig-a-like, % | 7.4 | 21.4 |
| Type of ENDS: e-cigar, % | 0.0 | 3.6 |
| Type of ENDS: e-pipe, % | 3.7 | 0.0 |
| Type of ENDS: e-hookah, % | 0.0 | 0.0 |
| ENDS is refillable, % | 88.9 | 100.0 |
| ENDS is rechargeable, % | 100.0 | 96.4 |
| ENDS uses cartridges, % | 29.6 | 33.3 |
| Nicotine concentration, % | | |
| 0mg | 0.0 | 7.7 |
| 1-5mg | 52.0 | 30.8 |
| 6-12mg | 28.0 | 30.8 |
| 13-17mg | 8.0 | 3.9 |
| 18-24mg | 8.0 | 23.1 |
| 25mg or more | 4.0 | 3.9 |
| Tobacco flavor, % | 18.5 | 39.3 |
| Menthol flavor, % | 14.8 | 3.6 |
| Clove or spice, % | 7.4 | 17.9 |
| Fruit, % | 66.7 | 53.6 |
| Chocolate, % | 7.4 | 14.3 |
| Alcoholic drink, % | 3.6 | 0.0 |
| Candy/sweets, % | 51.9 | 57.1 |
| Other flavor, % | 11.1 | 21.4 |
| Number of vape sessions in lifetime*, % | | |
| 100 or less | 33.3 | 52.0 |
| 101-200 | 12.5 | 8.0 |
| 201-300 | 8.3 | 8.0 |
| 301-400 | 12.5 | 8.0 |
| Over 400 | 33.3 | 24.0 |
| Average number of vape sessions per day*, % | | |
| Less than 10 sessions | 28.0 | 52.0 |
| 10 to 19 sessions | 44.0 | 20.0 |
| 20 to 30 sessions | 16.0 | 8.0 |
| Over 30 | 12.0 | 20.0 |
| Average number of puffs per vape session*, % | | |
| Under 5 | 14.8 | 23.1 |
| 5-10 | 55.6 | 46.2 |
| More than 10 | 29.6 | 30.8 |
| Average length of vape session*, % | | |
| 1-2 minutes | 33.3 | 25.0 |
| 3-5 minutes | 40.7 | 28.6 |
| 6-10 minutes | 18.5 | 25.0 |
| Over 10 minutes | 7.1 | 21.4 |

* Provided by the Ontario Tobacco Research Center

**Table 3.** Cigarette Smoking Characteristics Among Cigarette Dual Users and Smokers

| | Dual users (n=28) | Cigarette smokers (n=27) |
|---|---|---|
| Cigarettes per day, median | 15.0 | 10.0 |
| Cigarettes per day, % | | |
| <1 pack | 57.1 | 59.3 |
| ≥1 pack | 42.9 | 40.7 |
| Age of initiation, median | 15.0 | 14.0 |
| Age of regular initiation, median | 16.5 | 19.0 |
| Duration of smoking, median | 21.5 | 26.0 |
| 24-hour smoking quit attempt in past 12 months, % | 57.1[a] | 25.9 |
| Smokes mentholated cigarettes, % | 21.4 | 40.7 |

[a] Dual users significantly different from cigarette smokers at $p<0.05$

**Table 4.** Results from Hooked on Nicotine Checklist for Assessing Loss of Autonomy Over Cigarettes and Adapted Version for Assessing Loss of Autonomy Over Electronic Nicotine Delivery Systems (ENDS)[¶]

| | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | |
|---|---|---|---|---|
| | *Over ENDS* | | *Over cigarettes* | |
| **Individual items measured in HONC**, % | | | | |
| 1. Have you ever tried to quit cigarettes [using an ENDS], but couldn't? | 18.5 | 18.5 | 78.6 | 51.9 |
| 2. Do you smoke [use your ENDS] now because it is really hard to quit smoking cigarettes [using an ENDS]? | 32.1 | 40.7 | 75.0 | 48.2 |
| 3. Have you ever felt like you were addicted to cigarettes [an ENDS]? | 28.6 | 37.0 | 82.1 | 70.4 |
| 4. Do you ever have strong cravings to smoke [use an ENDS]? | 50.0 | 59.3 | 96.4 | 85.2 |
| 5. Have you ever felt like you really needed a cigarette [an ENDS]? | 57.1 | 59.3 | 100.0 | 92.6 |
| 6. Is it hard to keep from smoking [using an ENDS] in places where you are not supposed to? | 35.7 | 25.9 | 53.6 | 44.4 |
| When you haven't smoked cigarettes [used an ENDS] for a while OR | | | | |
| When you tried to stop smoking cigarettes [using an ENDS]… | | | | |
| 7. …did you find it hard to concentrate because you couldn't smoke a cigarette [use an ENDS]? | 28.6 | 22.2 | 57.1 | 38.5 |
| 8. …do you feel more irritable because you couldn't smoke a cigarette [use an ENDS]? | 25.0 | 48.2 | 71.4 | 74.1 |
| 9. …did you feel a strong need or urge to smoke a cigarette [use an ENDS]? | 57.1 | 59.3 | 89.3 | 81.5 |
| 10. …did you feel nervous, restless, or anxious because you couldn't smoke a cigarette [use an ENDS]? | 28.6 | 37.0 | 75.0 | 55.6 |

[¶]Substitute the underlined word with the words in square brackets for assessing loss of autonomy over ENDS

**Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes**

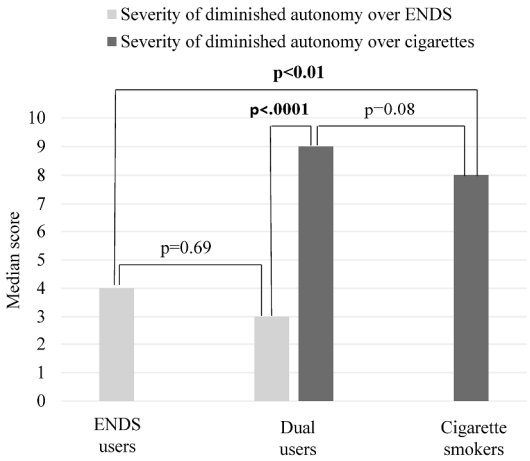


Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes

279x361mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation | Page # |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 2 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *6-8* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 9 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6-8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 9 |
| | | (*c*) Explain how missing data were addressed | NA |
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy | NA |
| | | (*e*) Describe any sensitivity analyses | NA |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10 |
| | | (b) Give reasons for non-participation at each stage | 10 |
| | | (c) Consider use of a flow diagram | NA |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 10 |
| | | (b) Indicate number of participants with missing data for each variable of interest | NA |
| Outcome data | 15* | Report numbers of outcome events or summary measures | NA |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 10-13 |

| | | | |
|---|---|---|---|
| | | (*b*) Report category boundaries when continuous variables were categorized | 10-13 |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 18-19 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 18 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 20 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians--results from an observational study

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# Electronic nicotine delivery system use behavior and loss of autonomy among American Indians- results from an observational study

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**Keywords**: American Indians, Electronic Cigarettes, Cigarette Smoking Epidemiologic Studies, Minority Groups, Tobacco Use, Dependence

## ABSTRACT

**Objective**: American Indians (AI) have a high prevalence of ENDS use. However, little information exists on (ENDS) use, either alone or in combination with cigarettes (dual use), among AI. The objective of this small-scaled study was to examine use behaviors and dependence among exclusive ENDS users and dual users of AI descent. Exclusive smokers were included for comparison purposes.

**Setting**: Oklahoma, United States

**Participants**: Adults of AI descent who reported being exclusive ENDS users (n=27), dual users (n=28), or exclusive cigarette smokers (n=27).

**Measures**: Participants completed a detailed questionnaire on use behaviors. The Hooked on Nicotine Checklist (HONC) was used to assess loss of autonomy over cigarettes and was reworded for ENDS. Dual users completed the HONC twice. Sum of endorsed items indicated severity of diminished autonomy. Comparisons were made with nonparametric methods and statistical significance was defined as $p<0.05$.

**Results**: Median duration of ENDS use was 2 years among ENDS users and 1 year among dual users. Most ENDS and dual users reported <20 vape sessions per day (72.0% vs. 72.0%) with ≤10 puffs per vape session (70.4% vs. 69.2%). Severity of diminished autonomy over ENDS was similar among ENDS and dual users (medians: 4 vs 3; p=0.6865). Among dual users, severity of diminished autonomy was lower for ENDS than cigarettes (medians: 3 vs 9; p=<.0001). Comparing ENDS users to smokers, ENDS users had a lower severity of diminished autonomy (4 vs 8; p=0.0077). Comparing dual users to smokers, median severity of diminished autonomy over cigarettes did not differ (p=0.6865).

**Conclusions**: Severity of diminished autonomy was lower for ENDS than cigarettes in this small sample of AI. Future, adequately-powered, studies should be conducted to fully understand ENDS use patterns and dependence levels in this population.

## Strengths and limitations of this study

- This is the first study to provide use and dependence data on electronic nicotine systems (ENDS) users of American Indian (AI) descent, a minority population in the US with high rates of tobacco-related disease and often underrepresented in epidemiologic and clinical research.
- This study describes a novel method for assessing loss of autonomy, a core feature of dependence, in ENDS users by adapting the Hooked on Nicotine Checklist.
- Due to the small sample size, convenience based sampling approach, and eligibility criteria, generalizations to all AIs in Oklahoma should be made with caution.
- This study relied on self-report and thus prone to recall bias.

## INTRODUCTION

Electronic nicotine delivery systems (ENDS), also referred to as e-cigarettes and vaping devices, are a line of relatively new tobacco products that heat a solution, often containing nicotine and flavorants, to generate an aerosol. Although ENDS aerosol is not harmless, it generally contains fewer toxic chemicals than cigarettes—a statement backed by the United States (US) Surgeon General.[1] In August of 2016, the US Food and Drug Administration Center for Tobacco Products (US FDA CTP) was provided the authority to regulate the manufacturing, distribution, and marketing of ENDS in the US.[2,3] To inform their regulatory action, the US FDA CTP has specifically called for research that seeks to understand use behaviors and dependence in ENDS users.[4]

ENDS use is high among American Indians and Alaskan Natives (AI/ANs).[5,6] According to data from the 2014 US National Health Interview Survey, 11% of non-Hispanic AI/AN adults currently use ENDS compared to 5% of non-Hispanic White adults.[6] Since a commonly reported reason for using ENDS is to help quit or reduce cigarettes[7-9] and AI/ANs have a smoking prevalence higher than any other race group in the US,[10] high rates of dual use among AI/ANs might also be expected. Unpublished data from the 2014 Oklahoma Behavioral Risk Factor Surveillance Survey and the Adult Tobacco Survey showed that approximately 5.0% of AI/ANs are exclusive ENDS users and a further 8.5% are dual users compared to 3.2% and 4.0% of non-Hispanic Whites. A major public health question surrounding dual use is whether this behavior will help or halt smoking cessation efforts.[2]

No information, to our knowledge, currently exists on use behaviors and dependence in ENDS users of AI/AN descent. To address this literature gap, we describe use behaviors and loss of autonomy, a core feature of dependence, in AI exclusive ENDS users and dual users of ENDS and cigarettes. Since cigarette smokers have been used as a comparison group in prior studies of ENDS,[11-13] we also present data on exclusive cigarette smokers of AI descent. The results of this study will be significant for regulatory authorities, such as the US FDA CTP, and public health officials who are actively trying to understand ENDS use behavior and dependence in priority populations such as AIs.

## METHODS

### Participant recruitment

This study was approved by the University of Oklahoma Health Sciences Center (# 6317) and the Oklahoma City Area Indian Health Service Institutional Review Board (# P-16-01-OK). From March through October 2016, community-based strategies were employed to recruit adults of AI descent who were in one of three groups of current tobacco use: 1) current exclusive cigarette smokers, 2) current exclusive ENDS users, and 3) concurrent users of cigarettes and ENDS, referred to as dual users. Recruitment strategies, previously described,[14] included posting recruitment ads online and study staff attending cultural events, tribal health fairs, and vape shops in the state of Oklahoma.

### Participant eligibility

This study's inclusion and exclusion criteria were similar to those employed in a previous study of nicotine metabolism among Alaskan Native tobacco users.[15] All participants had to self-report

AI race and at least two biological grandparents of AI race. Additionally, participants were between 18 and 65 years of age, and able to speak, read, and write the English language. Additional inclusion criteria were employed to result in a sample of "regular" users of cigarettes and/or ENDS. A regular cigarette smoker was defined as those who have smoked at least 5 cigarettes per day for the past 3 months, smoked in the past 24 hours, and not used tobacco products other than cigarettes in the past 3 months. A regular ENDS user was defined as someone who used an ENDS every day for the past 3 months and in the past 24 hours, and had not used tobacco products other than ENDS in the past 3 months. Although dual use refers to a heterogeneous group, we defined dual users as those who smoked at least 5 cigarettes per day in the past 3 months and in the past 24 hours, used an ENDS product every day for the past 3 months and in the past 24 hours, and not used tobacco products other than cigarettes and ENDS in the past 3 months.

Participants were excluded from any group if they regularly used medications for seizures, tuberculosis, or cancer; were currently involved in a tobacco cessation program or used nicotine replacement therapy; were pregnant or breastfeeding; used illicit drugs in the 30 days prior to the study; used alcohol or marijuana on the day of the study.

**Measures**

Data on age, gender, marital status, education level, employment status and body mass index (BMI) were collected. Participants were also asked about their use of tobacco for sacred or ceremonial purposes (i.e., traditional tobacco use), a practice common among some AI tribes.[16-18]

Since ENDS are relatively new to the marketplace and often called different names, the following statement, which was adapted from the US Population Assessment of Tobacco and Health (PATH)[19], was read by ENDS and dual users prior to collecting information on ENDS use: 'You said you currently use an electronic nicotine product. These products are battery-powered, use nicotine fluid rather than tobacco leaves, and produce vapor instead of smoke. There are many different names for these devices. Some common brands include Fin, NJOY, Blu, e-Go and Vuse.' Generic photos ("cig-a-like"; tank or vapor system; e-cigar; e-pipe; e-hookah) of commonly used ENDS were displayed and participants chose the photo(s) which best resembled the ENDS they currently used. Participants had the option of choosing more than one. Participants were also asked if the ENDS was rechargeable, refillable with e-liquid, if it used cartridges, and which nicotine concentration they currently used. Since ENDS users often use more than one flavor or mix flavors, participants reported all flavors they currently used.

There is not a standard or commonly accepted method for assessing frequency of ENDS use.[2] In this study, ENDS and dual users read the following statement provided by the Ontario Tobacco Research Center to assess frequency of use: 'A session starts from your first puff and ends with your last puff before you take a break to do something else. A session can last for any length of time and involve any number of puffs, depending in the person. Sometimes these are called vape sessions.' Participants then responded to four questions: (1) 'How many sessions have you had with your electronic nicotine product in your lifetime?'; (2) 'In a typical day, how many sessions do you have?'; (3) 'How long does one session typically last for you?'; (4) 'How many puffs do you typically take per session?'. Other variables collected included age of ENDS initiation, age of regular ENDS initiation, and duration of use. Among exclusive ENDS users, we asked if they

were a never or former smoker. If they were a former smoker, we asked them to recall their number of CPD when smoked and the time since smoked. We also asked dual users to recall their number of CPD prior to ENDS initiation.

There are a number of questionnaires with proven utility in assessing dependence to cigarettes.[20-23] The Hooked on Nicotine Checklist (HONC), a 10-item screening tool, assesses of loss of autotomy in both adolescent and adults.[23,24] Diminished autonomy is a core feature common to all forms of substance dependence, including tobacco dependence.[24] HONC does not include measures on heaviness or frequency of use specific to cigarette smoking (e.g., CPD). Thus, it can be readily modified to assess loss of autotomy to non-cigarette tobacco products, such as ENDS. In the present study, loss of autonomy over cigarettes was summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy). We reworded the HONC to assess loss of autonomy to ENDS. Dual users completed the HONC twice, once with regard to cigarettes and once with regard to ENDS. Loss of autonomy over ENDS was also summarized using both continuous scores (0-10) and a dichotomous measure (0=full autonomy; ≥1=diminished autonomy).

Among dual users and exclusive smokers, measures of cigarette smoking were collected. These measures included the age when participants first tried part or all of a cigarette (i.e., age of initiation), the age when participants started smoking cigarettes regularly (i.e., age of regular initiation), average number of cigarettes currently smoked per day (CPD), duration of cigarette smoking, presence of a 24-hour quit attempt in the past 12 months, and use of menthol cigarettes.

**Biochemical assessment of smoking status**

The measurement of exhaled carbon monoxide (CO) level provides an immediate, non-invasive assessment of cigarette smoking status.[25] CO was collected to biochemically confirm self-reported cigarette smoking status and therefore help reduce information bias. A CO value of ≥10 parts per million (ppm) is commonly used to determine eligibility for studies among smokers.[26-30] However, a borderline CO level between 6-9 ppm may also reflect cigarette smoking or among non-smokers it may reflect exposure to secondhand smoke or other sources of CO (e.g., car pollution).[25,31-33] Moreover, prior studies have required CO levels of <6[34] or <10[12,35] for confirming exclusive ENDS use. Based on this information, we did not exclude individuals from any of the three groups with a CO between 6-9 ppm. Thus, ENDS users were included if they had a CO level ≤9 ppm, while cigarette smokers and dual users were included in the study if they had a CO level ≥6 ppm.

**Statistical analysis**

This study focused on describing characteristics of ENDS users, dual users, and smokers of AI descent. Since the study's primary purpose was descriptive, a formal sample size calculation was not performed. Continuous and ordinal measures were described using median values and categorical measures were described by proportions. Scores and frequencies were compared between the three user groups with the nonparametric Kruskal–Wallis test for ordinal or continuous measures and with a Chi-square or Fisher's exact test for categorical measures. A p-value <0.05 was considered statistically significant for comparison among all three user groups. Significant overall tests were followed by testing for differences between the three pairs of

groups, and significance was assessed using a Bonferroni adjustment of alpha=0.017. Statistical analysis was conducted in SAS 9.4.

## RESULTS

A total of 95 individuals participated in the study: 28 ENDS users, 32 dual users, and 35 cigarette smokers. Thirteen participants (13.7%) were excluded because their CO values were outside the range for their given tobacco use group. Therefore, results are presented for the 82 participants (27 ENDS users, 28 dual users, 27 cigarette smokers) with CO values in the expected range given their self-reported tobacco use. **Table 1** displays data on socio-demographic characteristics and traditional tobacco use for the 82 participants.

**Table 2** presents data on ENDS use behaviors. Median age first tried an ENDS was 28.5 years among ENDS users and 35.0 years among dual users. Median age started using an ENDS regularly was 30.0 years among ENDS users and 36.5 years among dual users. Median duration of ENDS use was 2 years among ENDS and 1 year among dual users. When prompted with the option to select the photo which best represented the ENDS currently being used, the vast majority of ENDS (89%) and dual users (93%) selected a tank or vapor system. The vast majority, if not all, of ENDS users and dual users reported currently using an ENDS which was refillable with e-liquid (89%, 100%) and rechargeable (100%, 96%); while, one-third or less (30%, 33%) reported using cartridges. The majority of both ENDS users (80%) and dual users (69%) reported currently using a nicotine concentration of 12 mg or less. More than one-half of ENDS and dual users reported using fruit (67%, 54%) and candy (52%, 57%) flavored ENDS.

Data on number of vape sessions in lifetime, vape sessions per day, puffs per vape session, and length of vape session is also displayed in **Table 2**.

ENDS and dual users were asked questions to assess their smoking status prior to initiation of an ENDS (data not provided in tables). The vast majority of ENDS users (92.6%) reported being former cigarettes smokers. Among ENDS users who were former cigarette smokers, the median CPD when smoking was 20 and the median duration since smoked cigarettes was 2 years. Dual users were asked to recall CPD before initiation of an ENDS. Median CPD prior to ENDS use was 20, which was significantly higher than the current median of 15 CPD.

**Table 3** presents data on cigarette smoking characteristics among dual users and exclusive smokers. Median CPD was 15 among dual users and 10 among smokers The distribution of CPD did not differ between the two user groups. Distributions of age when respondents first tried smoking a cigarette and started smoking cigarettes regularly did not differ between user groups. A greater proportion of dual users reported a 24-hour quit attempt in the previous 12 months than did smokers (57% versus 26%).

**Table 4** presents data on the ten individual items from the adapted HONC for loss of autonomy over ENDS. There were no differences in the individual HONC items when comparing ENDS with dual users. The proportion of ENDS users (64.3%) who had a diminished autonomy over ENDS was no different than dual users (77.8%). On a scale of 0 to 10, median severity of diminished autonomy over ENDS was 4 and 3 among ENDS and dual users, respectively (**Figure 1**). Distributions in severity of diminished autonomy over ENDS did not differ when

comparing ENDS users with dual users. To further understand autonomy, loss of autonomy to ENDS in ENDS users was compared with loss of autonomy to cigarettes in smokers. There was no difference in proportions of diminished autonomy when comparing smokers with ENDS users (96% versus 78%). However, distributions in severity of diminished autonomy differed. ENDS users had significantly lower scores for severity of diminished autonomy than smokers (4 vs 8). Furthermore, among dual users, severity of diminished autonomy over ENDS was lower than severity of diminished autonomy over cigarettes (3 vs 9).

The proportion of dual users (100%) with diminished autonomy over cigarettes did not significantly differ from the proportion of cigarette smokers (96.3%). Median severity of diminished autonomy over cigarettes was 9 and 8 among dual users and smokers, respectively. Distributions in severity of diminished autonomy over cigarettes did not differ when comparing dual users with smokers. When examining individual items measured by the HONC, a greater proportion of dual users than smokers said 'yes' to items 1 "Have you ever tried to quit cigarettes, but couldn't?" (79% versus 52%; p-value =0.0372) and 2 "Do you smoke now because it is really hard to quit smoking cigarettes?" (75% versus 48%; p-value=0.0405). There was no difference in items 3-10.

## DISCUSSION

This descriptive study provides novel findings about ENDS use in a small sample of AIs from Oklahoma, a state located in the Southern Plains region of the US. Notably, this analysis was the first of its kind to provide an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Studies of this kind are a current research priority of the US

FDA CTP, which serves as the regulatory authority for all tobacco products in the US.[4,36] Ultimately, this study provides a more complete picture of the current tobacco use landscape and will be informative for our future research on biomarkers of exposure in this population, as well as for guiding regulatory authorities who are working to understand the impact of ENDS on public health in both general and disparate populations.

ENDS are part of the diversifying tobacco and nicotine landscape.[37] Currently, there are several gaps in how to define and classify these devices making research on ENDS difficult.[2] Understanding characteristics of ENDS (e.g., type of device, nicotine concentration and flavor of e-liquid) is important as these characteristics have been shown to influence use behavior.[12] Thus, a major strength of the present study was the number of characteristics collected on ENDS use and the usage of pictures to aid participants in selecting which product they currently used. The vast-majority of ENDS and dual users in this sample reported using a tank or vapor system. Additionally, most reported that their ENDS was refillable with e-liquid and rechargeable. The majority of both dual and ENDS users reported using ENDS with nicotine concentrations of 12 mg or less. These findings are consistent with other epidemiologic surveys that have identified rechargeable and refillable devices to more popular among ENDS users than cartridge-based or disposable ENDS.[12,38]

Concern surrounds flavored tobacco products as they have been disproportionately used by youth and initiators.[39-41] Due to this, flavored cigarettes, excluding menthol flavor, were prohibited in the US in 2009 as part of the landmark Family Smoking Prevention and Tobacco Control Act.[42] Currently, ENDS, or the e-liquid used in ENDS, come in a variety of flavors. One study

identified nearly 8,000 flavors available online and showed that the vast majority of brands offered fruit, candy, and dessert flavors.[43] Flavors are a commonly cited reason for vaping, particularly in youth and young adults.[8,44-47] In the present study the most common flavors among both ENDS and dual users were fruit and candy or sweets. Other studies have also found fruit and candy flavors to be popular among ENDS users.[48,49] None of the participants in the present study reported not using any flavor. Regulatory authorities need to consider the potential impact of eliminating flavors in ENDS, as their prohibition, especially fruit and candy flavors, will not only reduce youth appeal but also the appeal to adult ENDS users.

Data on patterns of ENDS use is crucial for understanding the impact of these devices on public health, especially among priority populations disproportionately affected by tobacco use. There are no standardized methods for assessing ENDS behavior. In the present study, participants read a generic definition of a 'vape session' and then were asked questions to characterize vape sessions. One-third of ENDS users and more than half of dual users reported 100 or less vape sessions in their lifetime. This is surprising since ENDS were used for a median duration of 1 or 2 years and the study eligibility which included using an ENDS every day in the past 3 months. Participants may have had a hard time recalling this number and simply guessed or perhaps the question was worded in a manner that caused confusion. Another explanation is the participants may have underestimated their total number of vape sessions as a result of social desirability. Cognitive testing of this measure should be pursued among an adequately-powered sample. Average number of vape sessions per day varied, with most reporting less than 20 sessions per day. An average of 5-10 puffs per vape session was most common among both ENDS and dual users. In terms of vape sessions, most lasted for 5 minutes or less among ENDS users; while, the

proportion of dual users who reported a vape session lasting 1-2, 3-5, 6-10, and over 10 minutes were similar. In addition to providing a deeper understanding of ENDS use among AIs, these findings are relevant for researchers seeking to understand which measures should be used to monitor patterns of ENDS use.

Attempts to quit smoking are considered a critical step to increasing rates of smoking cessation and, subsequently, reducing the smoking prevalence.[50-52] Based on data from the 2013 National Health Interview Survey, an estimated 51% of AI smokers reported attempting to quit in the past 12 months.[53] In the present study, the proportion of dual users who made a quit attempt was more than twice the proportion among exclusive smokers. This finding supports previous literature linking ENDS use to smoking cessation. For example, in a nationally representative sample of US cigarette smokers (n=2,028), ENDS users had a higher smoking quit attempt (73% versus 46%) and cessation (42% versus 16%) rate than non-ENDS users.[54] We did not ask participants about their reason for using ENDS; however, there is a possibility that dual users in the present study are similar to those in others studies who report using ENDS to quit cigarettes.[7-9] Dual users were asked to recall their average CPD before ENDS initiation, which was significantly higher than their current CPD. Additionally, although there was no difference in proportion of overall loss of autonomy measures, a higher proportion of dual users than smokers said 'yes' to items 1 and 2 on the HONC, both of which contain language related to quitting smoking. This observation supports the finding that a higher proportion of dual users than smokers made a smoking quit attempt. Future cohort studies, such as the US Population Assessment of Tobacco Use and Health, are needed to assess the causal relationship between dual use and smoking cessation.

A major component of assessing the public health impact of ENDS use is to understand the dependence potential in both exclusive and dual users. Since ENDS and cigarettes differ in patterns of use, methods for assessing dependence that can facilitate comparison across products are needed. In the present study, HONC was used to assess diminished autonomy—a core feature of tobacco dependence.[24] With median scores of 4 and 3, ENDS and dual users were no different in loss of autonomy over ENDS. Eissenberg and colleagues recently developed a questionnaire, which contained measures from a variety of scales including the HONC, to assess dependence to both cigarettes and ENDS.[13] Eissenberg found ENDS users to be less dependent on ENDS than they retrospectively reported having been dependent on cigarettes prior to switching.[13] Although we did not ask ENDS users who were former smokers to recall their loss of autonomy to cigarettes, severity of loss of autonomy in ENDS users was one-half of the severity of loss of autonomy in smokers. Future research comparing dependence scores in ENDS users and smokers while controlling for potential confounding factors, such as age, are needed.

**Limitations**

Although this study has the potential to provide important information, it must be considered in light of its limitations. The focus of this study was not on testing of hypotheses, but on describing characteristics of ENDS users, dual users, and smokers of AI descent. Thus we did not incorporate a formal sample size calculation. The small sample size restricted our ability to control for potential confounders (e.g., gender, age), which have been shown to influence tobacco use behaviors and dependence scores. The reason for this study was to determine the feasibility of recruiting AI research participants and collecting data on their ENDS behavior. The

plan is to expand this study by recruiting a larger sample of ENDS users of AI descent and other race groups (e.g., whites, blacks) for comparison purposes. Second, the study population was not randomly sampled, rather participants were enrolled based on convenience using community-based recruitment strategies. Therefore, generalizations to all AIs, including those residing in Oklahoma, should be made with caution. Also, the exclusion criteria may further impact the ability to generalize findings. Of most concern is that individuals who used alcohol on the day of the study were not eligible. Alcohol use is correlated with tobacco use;[55,56] thus restricting eligibility to those who did not consume alcohol may harm the external validity of the findings. Third, this study relied on self-report and thus prone to recall bias. Lastly, several of the ENDS measures (e.g, adapted version of HONC) have yet to be validated. Future studies should be conducted to determine the sensitivity and specificity of these measures.

## Conclusion

This study provides an in-depth description of ENDS use, including both exclusive use and dual use with cigarettes, among AIs. Ultimately, this study helps to provide a more complete picture of the current tobacco use landscape among AIs and will be informative for regulators as well as public health officials who are actively trying to understand behavior and dependence among ENDS users.

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## CONTRIBUTORSHIP STATEMENT

Conceptualization: DMC TLW DMT LDS JDP JEC LAB

Funding acquisition: DMC TLW LAB

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Review and editing: DMC TLW DMT LDS JDP JEC LAB

## COMPETING INTERESTS STATEMENT

No competing interests to declare

## ACKNOWLEDGEMENTS

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## DATA SHARING STATEMENT

No additional data available.

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**Table 1.** Sociodemographic Characteristics and Traditional Tobacco Use Among All Participants and by User Group

| | All participants (n=82) | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | *p-value* |
|---|---|---|---|---|---|
| Age, median | 41.5 | 33.0[a] | 41.0 | 46.0 | 0.0263 |
| Gender, % | | | | | 0.3592 |
| Male | 37.8 | 29.6 | 35.7 | 48.2 | |
| Female | 62.2 | 70.4 | 64.3 | 51.9 | |
| Marital status, % | | | | | 0.1261 |
| Married/member of unmarried couple | 42.7 | 44.4 | 28.6 | 55.6 | |
| Never married/divorced/separated/widowed | 57.3 | 55.6 | 71.4 | 44.4 | |
| Education level, % | | | | | 0.2567 |
| At least some college | 50.0 | 63.0 | 42.9 | 44.4 | |
| High school diploma, GED or less | 50.0 | 37.0 | 57.1 | 55.6 | |
| Employment status, % | | | | | 0.6162 |
| Employed for wages/self-employed | 53.7 | 55.6 | 46.4 | 59.3 | |
| Other | 46.3 | 44.4 | 53.6 | 40.7 | |
| BMI ($kg/m^2$) category, % | | | | | 0.1333 |
| Normal weight | 24.7 | 30.8 | 32.1 | 11.1 | |
| Overweight or obese | 75.3 | 69.2 | 67.9 | 88.9 | |
| Traditional/sacred tobacco use in past 3 months, % | | | | | 0.0366 |
| Yes | 17.5 | 7.4 | 11.5 | 33.3 | |
| No | 82.5 | 92.6 | 88.5 | 66.7 | |

ENDS: Electronic nicotine delivery system; BMI= body mass index; * Asked only to those who were employed for wages or self-employed; [a]ENDS users significantly different from cigarette smokers at $p<0.05$

**Table 2.** Electronic Nicotine Delivery System (ENDS) Use Characteristics

| | ENDS users (n=27) | Dual users (n=28) |
|---|---|---|
| Age of ENDS initiation, median | 28.5 | 35.0 |
| Age of regular ENDS initiation, median | 30.0 | 36.5 |
| Duration ENDS use, median | 2.0 | 1.0 |
| Type of ENDS: tank or vapor system, % | 88.9 | 92.9 |
| Type of ENDS: cig-a-like, % | 7.4 | 21.4 |
| Type of ENDS: e-cigar, % | 0.0 | 3.6 |
| Type of ENDS: e-pipe, % | 3.7 | 0.0 |
| Type of ENDS: e-hookah, % | 0.0 | 0.0 |
| ENDS is refillable, % | 88.9 | 100.0 |
| ENDS is rechargeable, % | 100.0 | 96.4 |
| ENDS uses cartridges, % | 29.6 | 33.3 |
| Nicotine concentration, % | | |
| 0mg | 0.0 | 7.7 |
| 1-5mg | 52.0 | 30.8 |
| 6-12mg | 28.0 | 30.8 |
| 13-17mg | 8.0 | 3.9 |
| 18-24mg | 8.0 | 23.1 |
| 25mg or more | 4.0 | 3.9 |
| Tobacco flavor, % | 18.5 | 39.3 |
| Menthol flavor, % | 14.8 | 3.6 |
| Clove or spice, % | 7.4 | 17.9 |
| Fruit, % | 66.7 | 53.6 |
| Chocolate, % | 7.4 | 14.3 |
| Alcoholic drink, % | 3.6 | 0.0 |
| Candy/sweets, % | 51.9 | 57.1 |
| Other flavor, % | 11.1 | 21.4 |
| Number of vape sessions in lifetime*, % | | |
| 100 or less | 33.3 | 52.0 |
| 101-200 | 12.5 | 8.0 |
| 201-300 | 8.3 | 8.0 |
| 301-400 | 12.5 | 8.0 |
| Over 400 | 33.3 | 24.0 |
| Average number of vape sessions per day*, % | | |
| Less than 10 sessions | 28.0 | 52.0 |
| 10 to 19 sessions | 44.0 | 20.0 |
| 20 to 30 sessions | 16.0 | 8.0 |
| Over 30 | 12.0 | 20.0 |
| Average number of puffs per vape session*, % | | |
| Under 5 | 14.8 | 23.1 |
| 5-10 | 55.6 | 46.2 |
| More than 10 | 29.6 | 30.8 |
| Average length of vape session*, % | | |
| 1-2 minutes | 33.3 | 25.0 |
| 3-5 minutes | 40.7 | 28.6 |
| 6-10 minutes | 18.5 | 25.0 |
| Over 10 minutes | 7.1 | 21.4 |

* Provided by the Ontario Tobacco Research Center

**Table 3.** Cigarette Smoking Characteristics Among Cigarette Dual Users and Smokers

| | Dual users (n=28) | Cigarette smokers (n=27) |
|---|---|---|
| Cigarettes per day, median | 15.0 | 10.0 |
| Cigarettes per day, % | | |
| <1 pack | 57.1 | 59.3 |
| ≥1 pack | 42.9 | 40.7 |
| Age of initiation, median | 15.0 | 14.0 |
| Age of regular initiation, median | 16.5 | 19.0 |
| Duration of smoking, median | 21.5 | 26.0 |
| 24-hour smoking quit attempt in past 12 months, % | 57.1[a] | 25.9 |
| Smokes mentholated cigarettes, % | 21.4 | 40.7 |

[a] Dual users significantly different from cigarette smokers at $p<0.05$

**Table 4.** Results from Hooked on Nicotine Checklist for Assessing Loss of Autonomy Over Cigarettes and Adapted Version for Assessing Loss of Autonomy Over Electronic Nicotine Delivery Systems (ENDS)[¶]

| | ENDS users (n=27) | Dual users (n=28) | Cigarette smokers (n=27) | |
|---|---|---|---|---|
| | *Over ENDS* | | *Over cigarettes* | |
| **Individual items measured in HONC**, % | | | | |
| 1. Have you ever tried to quit cigarettes [using an ENDS], but couldn't? | 18.5 | 18.5 | 78.6 | 51.9 |
| 2. Do you smoke [use your ENDS] now because it is really hard to quit smoking cigarettes [using an ENDS]? | 32.1 | 40.7 | 75.0 | 48.2 |
| 3. Have you ever felt like you were addicted to cigarettes [an ENDS]? | 28.6 | 37.0 | 82.1 | 70.4 |
| 4. Do you ever have strong cravings to smoke [use an ENDS]? | 50.0 | 59.3 | 96.4 | 85.2 |
| 5. Have you ever felt like you really needed a cigarette [an ENDS]? | 57.1 | 59.3 | 100.0 | 92.6 |
| 6. Is it hard to keep from smoking [using an ENDS] in places where you are not supposed to? | 35.7 | 25.9 | 53.6 | 44.4 |
| When you haven't smoked cigarettes [used an ENDS] for a while OR | | | | |
| When you tried to stop smoking cigarettes [using an ENDS]… | | | | |
| 7. …did you find it hard to concentrate because you couldn't smoke a cigarette [use an ENDS]? | 28.6 | 22.2 | 57.1 | 38.5 |
| 8. …do you feel more irritable because you couldn't smoke a cigarette [use an ENDS]? | 25.0 | 48.2 | 71.4 | 74.1 |
| 9. …did you feel a strong need or urge to smoke a cigarette [use an ENDS]? | 57.1 | 59.3 | 89.3 | 81.5 |
| 10. …did you feel nervous, restless, or anxious because you couldn't smoke a cigarette [use an ENDS]? | 28.6 | 37.0 | 75.0 | 55.6 |

[¶]Substitute the underlined word with the words in square brackets for assessing loss of autonomy over ENDS

**Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes**

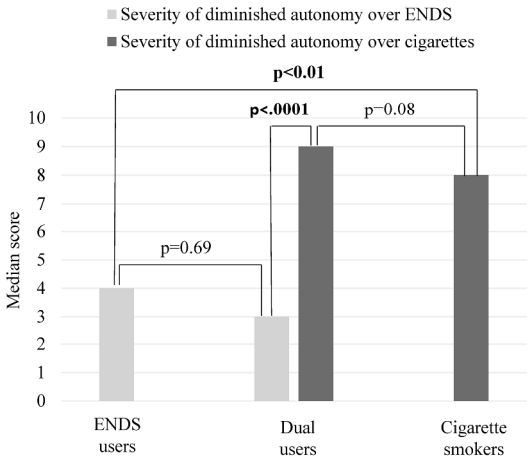


Figure 1. Median Severity of diminished autonomy over ENDS and/or cigarettes

279x361mm (300 x 300 DPI)

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

| | Item No | Recommendation | Page # |
|---|---|---|---|
| **Title and abstract** | 1 | (*a*) Indicate the study's design with a commonly used term in the title or the abstract | 2 |
| | | (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | 2 |
| **Introduction** | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4-5 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 5 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5 |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | *6-8* |
| Bias | 9 | Describe any efforts to address potential sources of bias | 9 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | 6-8 |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | 9 |
| | | (*b*) Describe any methods used to examine subgroups and interactions | 9 |
| | | (*c*) Explain how missing data were addressed | NA |
| | | (*d*) If applicable, describe analytical methods taking account of sampling strategy | NA |
| | | (*e*) Describe any sensitivity analyses | NA |
| **Results** | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 10 |
| | | (b) Give reasons for non-participation at each stage | 10 |
| | | (c) Consider use of a flow diagram | NA |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 10 |
| | | (b) Indicate number of participants with missing data for each variable of interest | NA |
| Outcome data | 15* | Report numbers of outcome events or summary measures | NA |
| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 10-13 |

| | | | |
|---|---|---|---|
| | | (*b*) Report category boundaries when continuous variables were categorized | 10-13 |
| | | (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | NA |
| **Discussion** | | | |
| Key results | 18 | Summarise key results with reference to study objectives | 13 |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 18-19 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 19 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 18 |
| **Other information** | | | |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 20 |

*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.