BMJ Open

Electronic nicotine delivery system (ENDS) use during smoking cessation: a qualitative study of 40 Oklahoma quitline callers

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013079
Article Type:	Research
Date Submitted by the Author:	23-Jun-2016
Complete List of Authors:	Vickerman, Katrina; Optum, Center for Wellbeing Research Beebe, Laura; University of Oklahoma Health Sciences Center, Biostatistics and Epidemiology Schauer, Gillian; Battelle Memorial Institute, Battelle Public Health Center for Tobacco Research; Centers for Disease Control and Prevention, Guest Researcher, Office on Smoking and Health Magnusson, Brooke; Optum, Center for Wellbeing Research King, Brian; Centers for Disease Control and Prevention, Office on Smoking and Health
Primary Subject Heading:	Smoking and tobacco
Secondary Subject Heading:	Public health, Qualitative research
Keywords:	PUBLIC HEALTH, QUALITATIVE RESEARCH, smoking cessation, electronic nicotine delivery systems, e-cigarettes, quitlines

SCHOLARONE™
Manuscripts

Electronic nicotine delivery system (ENDS) use during smoking cessation: a qualitative study of 40 Oklahoma quitline callers

Katrina A. Vickerman, PhD, Laura A. Beebe, PhD, Gillian L. Schauer, PhD, Brooke Magnusson, MA, & Brian A. King, PhD, MPH

For peer review only

Author Note

Katrina Vickerman and Brooke Magnusson, Center for Wellbeing Research, Optum (formerly Alere Wellbeing, Inc.), Seattle, WA. Laura A. Beebe, University of Oklahoma Health Sciences Center. Gillian L. Schauer, Battelle Public Health Center for Tobacco Research, Battelle Memorial Institute, Seattle, WA, Guest Researcher, Office on Smoking and Health, Centers for Disease Control and Prevention, Atlanta, GA. Brian King, Office on Smoking and Health, Centers for Disease Control and Prevention, Atlanta, GA.

Correspondence concerning this article should be addressed to Katrina Vickerman, Optum Cener for Wellbeing Research, 999 Third Avenue, Suite 2000, Seattle, WA. Tel. 206-876-2363; fax: 206-876-2101. Email: Katrina.Vickerman@optum.com

Abstract word count: 300 (limit 300)

Number of tables/ figures: 2 (limit 5)

ABSTRACT

Objectives: Approximately ten percent (40 thousand) of U.S. quitline enrollees who smoke cigarettes report current use of Electronic Nicotine Delivery Systems (ENDS); however, little is known about callers' ENDS use. Our aim was to describe why and how quitline callers use ENDS, their beliefs about ENDS, and the impact of ENDS use on callers' quit processes and use of FDA-approved cessation medications.

Design: Qualitative interviews conducted 1-month post-registration. Interviews were recorded, transcribed, double-coded, and analyzed to identify themes.

Setting: Oklahoma Tobacco Helpline

Participants: 40 callers aged ≥18 who were seeking help to quit smoking, were using ENDS at registration, and completed ≥1 program calls.

Results: At 1-month post-registration interview, 80% of callers had smoked cigarettes in the last 7 days, almost two-thirds were using ENDS, and half were using cessation medications. Nearly all believed ENDS helped them quit or cut down on smoking; however, participants were split on whether they would recommend cessation medications, ENDS, or both together for quitting. Confusion and misinformation about potential harms of ENDS and cessation medications were reported. Participants reported using ENDS in potentially adaptive ways (e.g., using ENDS to cut down and NRT to quit, and stepping down nicotine in ENDS to wean off ENDS after quitting) and maladaptive ways (e.g., frequent automatic ENDS use, using ENDS in situations they didn't previously smoke, cutting down on smoking using ENDS without a schedule or plan to quit), which could impact the likelihood of quitting smoking or continuing ENDS use.

Conclusions: These qualitative findings suggest quitline callers who use ENDS experience confusion and misinformation about ENDS and FDA-approved cessation medications. Callers also use ENDS in ways that may not facilitate quitting smoking. Opportunities exist for quitlines

For peer review only

to educate ENDS users and help them create a coordinated plan most likely to result in completely quitting combustible tobacco.

Strengths and limitations of this study

- Dual users of cigarettes and ENDS who were in the middle of an attempt to quit smoking were interviewed at 1-month post-quitline registration, which allowed for timely reporting of quitting strategies and experiences using ENDS and cessation medications.
- In depth qualitative interviews were completed with 40 dual users of cigarettes and ENDS to obtain detailed reports of experiences from a range of ENDS users.
- Interviews were recorded, transcribed, and double coded to increase the trustworthiness of extracted themes.
- Findings from this small sample of Oklahoma Tobacco Helpline enrollees may not generalize to all ENDS users.

For peer review only

INTRODUCTION

Use of Electronic Nicotine Delivery Systems (ENDS), including electronic cigarettes (e-cigarettes), has increased considerably in recent years, particularly among current and former cigarette smokers.[1,2] In 2014, 47.6% of current cigarette smokers and 55.4% of recent former cigarette smokers had ever tried an e-cigarette.[3] ENDS use among current smokers who call state quitlines is also common; state quitlines are free, typically phone-based tobacco cessation programs available in all 50 states in the United States.[4] In 2012, approximately one-third of quitline enrollees reported ever using ENDS,[5] and from 2013-2015, approximately 10% reported current use at registration.[6] An estimated half of these individuals reported using ENDS to try to quit smoking cigarettes.[5,6]

Although ENDS may be commonly used by adults as a smoking cessation aid, they have not been approved by the U.S. Food and Drug Administration (FDA) for this purpose. To date, there is no conclusive scientific evidence that ENDS are effective for long-term cessation from conventional cigarettes,[7-11] and the long-term health impacts of ENDS use among adults is uncertain.[8,12,13] In light of this uncertainty, health professionals and treatment providers are seeking to identify the best way to help smokers who are using ENDS during their smoking cessation process. However, limited information is available about quitline callers' experiences using ENDS and their knowledge and beliefs about the products. This information is critical to help quitlines determine how best to address ENDS use given that an estimated 40,000 ENDS users call quitlines each year for help quitting traditional tobacco products.[4,6]

For peer review only

Few studies have assessed factors related to ENDS use among U.S. quitline callers. Accordingly, this study employed qualitative methods to assess quitline callers' opinions about and experiences using ENDS, including their beliefs about ENDS and smoking cessation, interactions with quitline counselors about ENDS, and perceptions of ENDS versus FDA-approved medications, including nicotine replacement therapy (NRT).

METHODS

Participants

Pre-notification letters were mailed to 65 randomly selected participants who met study eligibility criteria approximately three weeks after Oklahoma Tobacco Helpline registration. Letters included a study overview and stated that study staff would be in contact about the study. Participants were 40 state quitline callers who wanted to quit smoking and called the Oklahoma Tobacco Helpline between November 2014 and February 2015. A minimum sample size target of 40 was selected to ensure inclusion of diverse ENDS users.

Participants were reached via phone, provided informed consent, and completed an interview approximately one month after registration with the Helpline. Callers were eligible for the study if they: 1) smoked conventional cigarettes; 2) were currently using ENDS; 3) spoke English; 4) requested a Helpline intervention; 5) were 18 or older,; 6) completed at least one call with a quit coach lasting at least 5 minutes; and 7) provided consent for follow-up contact. Pregnant callers were excluded. Four participants used another form of tobacco product (e.g., pipe, smokeless tobacco) in addition to cigarettes and ENDS at the time of registration. A $49 gift card to Amazon or Walmart was provided to participants who completed the interview. All study procedures were approved by the University of Oklahoma Institutional Review Board.

For peer review only

The Helpline Program

All participants were enrolled in a one-call or five-call phone-based cessation program, which also included a two or eight-week supply of NRT, a printed quit guide, and access to an interactive online cessation resource.[14] Callers without insurance and with Medicaid insurance were eligible for the five-call program, while callers with insurance other than Medicaid were eligible for the one-call program. Coaching calls focus on developing a quit plan, building skills for coping with cravings and triggers, enlisting social support, and using FDA-approved cessation medications.[15,16]

With regard to using ENDS to quit smoking, Helpline Quit Coaches were trained to not encourage or promote the use of ENDS for quitting tobacco and to provide education that there is not empirical evidence proving ENDS are safe and effective cessation tools. Smokers interested in switching to ENDS would not be discouraged from doing so and would be educated that the safety of long-term use of ENDS is unclear.[17]

Interviews

Interviews were conducted over the phone in private offices by two female Graduate Research Assistants at the University of Oklahoma College Of Public Health. Interviewers were enrolled in graduate training in epidemiology, had received extensive training in research methods, had interviewing experience from previous studies, and received training in qualitative interviewing techniques. Interviewers followed a semi-structured interview guide and were encouraged to ask additional probing questions. Topics discussed in the interviews included reasons for ENDS use, current ENDS and tobacco use, Helpline experience, experience with FDA-approved cessation

For peer review only

medications, ENDS use details, and intentions to quit. Interviews lasted 35.2 minutes on average (range: 22.1-61.5 minutes), were audio recorded, and transcribed verbatim. A series of questions requesting feedback about the interview were also asked of the first eight participants.

Coding and Analysis

Template analysis was used to guide the coding process.[18] A preliminary deductive codebook was developed after reading five transcripts. The codebook then evolved through an iterative approach; additional inductive codes were derived from the data and added during the coding process. Coding focused on identifying themes in participants' responses to questions. Themes were then further organized into larger concepts, while grounding all identified themes in participant's words. Four individuals coded the interviews. Each interview was double-coded. Double-coding was reviewed and consensus was reached for each interview. For analyses of coded data, a constant comparative and descriptive approach was employed.[19,20] Analyses were conducted in MAXQDA.[21]

RESULTS

Participants

Respondents were an average of 45 years old, 65% female, 73% white non-Hispanic, 68% high school degree or less education, and predominately low income (65% less than $25,000 annual income) (*Table 1*). Participants ranged in number of quit attempts prior to contacting the Helpline: for 6 their Helpline enrollment was a first quit attempt, 15 had 1-2 previous attempts, 10 had 3-4 previous attempts, and 9 had 5 or more previous attempts. Thirty-three participants enrolled in the five-call program and 7 enrolled in a one-call program. All received a 2- or 8-week supply of NRT from the quitline. Participants completed 1.7 calls (*SD*=1.12) during the program on average.

For peer review only

At registration, 19 reported using ENDS every day, with the remaining 21 participants reporting nondaily ENDS use; 33 reported using a tank system style ENDS (which is refilled with e-liquid by the user) and 37 said they were thinking about quitting ENDS in addition to cigarettes. About half reported they were using ENDS to quit smoking, 13 said they were cutting down to quit smoking, and 3 said they were only using ENDS to reduce smoking.

Table 2 displays products participants were using at the time of the qualitative interview. Thirty-two had smoked cigarettes in the last 7 days, 25 were using ENDS, and 21 were using an FDA-approved cessation aid. Twenty-nine of the participants were using two or three sources of nicotine (i.e., cigarettes, ENDS, and/or NRT).

Interview Themes

How Participants Reported using ENDS and FDA-approved Cessation Medications

Descriptions of ENDS use

Participants discussed using ENDS as a quitting aid, as a bridge product when smoking was not allowed, and for a recreational experience. Callers also described using ENDS as a partial replacement for cigarettes—either as part of a cut down to quit strategy or, as a small number reported, using ENDS only for cutting down on cigarettes (not for completely quitting).

When asked whether ENDS helped them to quit or cut down on smoking, most participants believed ENDS helped them cut down on or quit cigarettes, including quitting completely (n=7), quitting temporarily (n=7), and cutting down without quitting (n=21). For example, one participant who quit temporary and was using ENDS during their current quit attempt described:

> *To begin with, it [ENDS] took the place of the cigarette and I still got the nicotine…I totally didn't smoke for like 4 months. At that point, if I picked one [a cigarette] up and*

For peer review only

tasted it, I didn't like the way it tasted. I didn't care for the light headed effect you got from it that comes with not smoking it. You don't smoke, that's the way a cigarette affects you…I have been [using cigarettes] for about the last month. We had some medical issues come up and a lot of stress and I just fell back into it, but [I'm] moving away from it. I'm doing the vapor stick more than the cigarettes... I have the patches, but I haven't started them.

Alternatively, one participant felt ENDS caused him to smoke more, and a small number reported that ENDS did not change their smoking.

When asked what they liked and what they did not like about using ENDS, participants reported both positive and negative perceptions of ENDS use. However, overall, nearly all reported they were satisfied with their ENDS device. Positive aspects of ENDS use included features of the ENDS use experience (e.g., convenience of taking a puff quickly as desired versus lighting and finishing a cigarette; smell; taste; flavors), environmental factors (e.g., no second or thirdhand smoke, ash trays or lighted fire; can use where can't smoke; less distracting to use while driving), positive health attributions or beliefs about ENDS (e.g., experiencing health benefits such as breathing more easily or no problems), beliefs that ENDS helped with quitting or cutting down (e.g., behavioral substitute, control cravings, avoid weight gain), nicotine delivery and concentration options (e.g., receiving needed nicotine; can taper nicotine or use no nicotine ENDS), cost of ENDS, and others' reactions to ENDS use (others prefer ENDS, no judgement of use).

Negative perceptions of ENDS use were also reported, including features of the ENDS device (leaks, hard to maintain, weight/size/look, battery, breaks), beliefs that ENDS are harmful or

For peer review only

potentially harmful to health, that ENDS don't help in quitting smoking (not satisfying, insufficient nicotine, doesn't help all of the time, increases urge to smoke), concerns about ENDS habit (addictive, continues hand to mouth habit), cost of ENDS (particularly to start), and the learning curve for use (process to find right device or learn to use, hard transition from smoking). Over a third of participants reported negative experiences or minor side effects, primarily coughing or sore throat/burning in back of throat. Individual participants reported headache, pain in lungs, dry mouth, dehydration, and concern that ENDS worsened COPD symptoms.

Descriptions of FDA-approved Cessation Medication Use

When asked about past experiences using FDA-approved cessation medications, nearly all participants reported positive or mixed experiences. One participant described her positive experiences with cessation medications: "The patch is excellent because it takes the edge off." Other participants had mixed experiences. For example, a participant explained, "Chantix worked for me but sometimes [insurance] wouldn't pay for it and I can't afford it…My system on the patch – it rejects it." Only three participants reported that cessation medications were not perceived as helpful. For example, one participant described: "I have tried patches, the gum, the lozenges, and everything else and nothing has worked." Over half of the participants reported experiencing a side effect or reaction to an FDA-approved cessation medication, including bad dreams, skin reactions (rash, itchiness, burning sensation), emotional changes, upset stomach, sore or itchy throat, feeling jittery, or having an abnormal taste in the mouth.

A quarter of participants reported they weren't using an FDA-approved cessation medication at the time of their interview because their quit date was still in the future and they were waiting to

For peer review only

start NRT until their quit date. Some participants shared beliefs that they should not use patches and smoke; for example, "I put the patch on and I still smoked some…I would think, 'I'm just gonna have to take this patch off because you aren't supposed to smoke and wear the patch,' so I just took [the patch] off."

Preferences for ENDS vs FDA-approved cessation medications for quitting smoking

Participants were split on preferred methods for quitting smoking; similar numbers recommended an FDA-approved cessation medication only, ENDS only, and using both at the same time. In addition, several participants reported no preference between ENDS and cessation medications. Several participants noted openness to trying any options that might work for them: "anyone [who] wants to quit smoking [should] try any method there is, because no person works the same."

Participants who recommended an FDA-approved cessation medication explained that medications helped with quitting or urges and had better nicotine delivery. For example, one participant described: "When I put it [patch] on, physically I don't crave a cigarette…that doesn't happen with the e-cigarette." Some participants also noted concerns about ENDS as a reason for their choice including believing ENDS are harmful or not knowing enough about safety, concerns about the addictiveness of ENDS or the hand to mouth habit, that using ENDS is not completely quitting, and insufficient nicotine delivery. One participant explained:

> *You're swapping out one cloud of smoke for another cloud of smoke [with ENDS] …You still have the habit of putting something in your mouth. You still have the habit of blowing something out of your mouth...What is the difference? I mean there's no evidence out there that proves that's [ENDS use] any better than actual smoking cigarettes…If you're*

For peer review only

gonna quit nicotine, quit nicotine all together. If you're trying to quit smoking, I guess you probably need to hit up on that nicotine patch.

Participants who felt ENDS were more helpful for quitting highlighted the importance of ENDS as a behavioral substitute for the hand to mouth habit of smoking, felt ENDS provided a better transition from smoking, believed ENDS helped avoid weight gain during quitting, liked that they could use ENDS as needed, liked the throat hit from ENDS, and preferred the option to step down on nicotine. For example, one participant shared,

It [patch] was a lot harder because you have the patch [and] there is [a] no smoking period…The hand to mouth gesture is there, it's like integrated in your system I think, if you smoke for a long time. So it would be a lot harder to go from smoking a cigarette to having the patch on your arm. That's really hard to do. In my thought process, vaping to quit will actually be a better thing because there's still that interaction between hand to mouth versus food going hand to mouth.

Most of these participants noted side effects with FDA-approved cessation medications or that cessation medications did not work well for them in the past or did not provide sufficient nicotine. Finally, participants who believed it was most helpful to use both FDA-approved cessation medications and ENDS together for quitting provided several explanations. Some noted this approach would be preferred especially for long time smokers, some felt ENDS were doing more to help with quitting, and some felt an FDA-approved cessation medication was doing more. Some in this group of participants recommended using patches and then ENDS (with or without nicotine) as a stopgap for relapse or when urges were high, noting that patches alone were not enough.

For peer review only

Misinformation and Confusion about Relative Harm of ENDS and FDA-approved Medication

Views on Relative Harm of Products

Slightly more than half of the participants ranked FDA-approved cessation medications as least harmful, just less than half ranked ENDS as least harmful, and a few felt FDA-approved cessation medications and ENDS were equally harmful. Some participants ranked FDA-approved cessation medications as more harmful than ENDS due to their reactions to FDA-approved cessation medications. For example, one participant explained, "I would put [patches] in the rank close to the cigarette, [because they] make your heart beat really fast." Some participants provided explanations for their ranking choices that involved misinformation about ENDS, FDA-approved cessation medications, or nicotine, as described in the next section. Several participants also expressed lack of confidence in their knowledge about the relative harm of products, for example, stating, "I would probably have to say that I don't know. I think the vapor's more harmful. I really do not know."

Misinformation and Confusion about ENDS

Participants reported several inaccurate beliefs about the safety and constituents of ENDS. Some participants expressed beliefs that ENDS and the aerosol ENDS produce are completely safe. For example, one participant said, "There's not any chemicals in [ENDS] like there are in actual cigarettes", and another stated, "It's a vapor, I mean, you're not really hurting anybody. You could smoke it inside the building." One participant reported believing she was not receiving any nicotine from ENDS; she explained, "[When] I use the e-cigarette, I really don't think I am getting the nicotine or anything in my lungs because it evaporates. I think I am just getting a taste of nicotine."

For peer review only

Views on Long-Term ENDS Use

When asked what they thought about long-term use of ENDS, almost equal numbers were concerned, supportive, and unsure. Some participants' explanations reflected confusion or misbeliefs about ENDS. Participants who had concerns about long-term ENDS use either believed that ENDS are harmful or detrimental to health or thought ENDS may have negative impacts if used long-term, but often thought short-term use was probably okay. Those who were unsure often saw benefits to ENDS use (not smoking, feeling healthier) or hadn't personally experienced any negative impacts of using ENDS, but either (1) expressed uncertainty about long-term use due to unknown constituents of ENDS, the potential impact of aerosol on lungs, or using an addictive product or (2) did not know what to think about long-term use (i.e., did not know because they had not read or heard anything about it or believed there are conflicting opinions on this subject). Participants who said they were supportive of long-term use were most likely to report inaccurate information about ENDS, such as that ENDS and the aerosol it produces are completely safe (i.e, the aerosol is just water vapor) or that there were no concerns as long as one used ENDS products that did not contain nicotine. Some of these participants also noted the relative benefit of using ENDS rather than cigarettes.

Misinformation about FDA-approved Cessation Medications

Some participants also made statements that reflected concerns about the safety of NRT or how to use NRT. For example, one participant stated, "The patch has definitely got tar in it." Another participant who believed the patch and ENDS were equally harmful explained, "with the patch, the nicotine [is] being absorbed into your skin – that is chemicals, so that is not good." A third participant who rated patches as more harmful than ENDS shared, "I don't really know how to

For peer review only

explain it…it's just that I'm scared to use them [patches]." Another participant ranked NRT as more harmful than ENDS because of concerns about overdosing on NRT.

Concerns about Nicotine

Some participants focused on the safety of nicotine regardless of whether it was delivered from ENDS or FDA-approved cessation medications. One participant stated: "Nicotine in pure form causes Alzheimer's." Two participants believed their 0 milligram nicotine ENDS product was the least harmful product, "because nicotine is bad for you;" both participants were still smoking cigarettes at the time of the interview. Several others were also unsure whether ENDS or NRT was more harmful or ranked NRT as more harmful because they viewed nicotine dependence or use as the main concern. Several ranked ENDS as less harmful than the nicotine patch because they believed ENDS deliver less nicotine.

Strategies used for Incorporating ENDS in Smoking Cessation Plans

Potentially adaptive quit strategies

Based on the participants' descriptions for how they incorporated ENDS into their smoking cessation plan, we identified five examples of potentially adaptive strategies. Some participants were using ENDS only, but decided to or planned to switch to using a patch along with a no-nicotine ENDS: "I'm trying something different now that I got my patches in. I'm going to use patches for the nicotine. And then I'm going to fill my e-cig with the zero nicotine. That way I have the habit still and I'm getting the nicotine, but I can cut back with the patches." Second, other participants used NRT, such as the patch, and used ENDS with nicotine when cravings were high to avoid picking up a cigarette. Third, multiple participants discussed stepping down the milligrams of nicotine in their ENDS liquid to wean off nicotine. For example, one

For peer review only

participant described: "It [ENDS] took the place of the cigarette and I still got the nicotine and you're able to cut down the amount of nicotine you get in the vapor. You can get it in a 24, 18, 12, 7, 2, or 0 [mg/ml nicotine concentration] and I just stepped down." Fourth, several participants used ENDS to cut down and completely replace smoking cigarettes, and then switched to the patch to quit both cigarettes and ENDS. Finally, a small number of participants completely switched from cigarettes to ENDS or cut down cigarettes by replacing with ENDS and eventually fully replaced all cigarettes with ENDS.

Potentially Maladaptive Quit Strategies

Four types of potentially maladaptive strategies for incorporating ENDS into smoking cessation plans were identified. First, more than half of the participants reported using ENDS in situations where they did not or could not smoke, most frequently at work, in their car, at home, or in stores. Second, a group of participants had difficulty describing their ENDS use because it had become a frequent, automatic behavior. One participant explained, "I can't even count to be honest with you…I just go 'oh look, I want this' and I grab it. I have a lanyard that's around my neck all day long." Third, several participants who were cutting down to quit, described partially replacing cigarettes with ENDS, but choosing to smoke a cigarette when they were stressed or their cravings were high. Fourth, while some participants described a plan for reducing nicotine intake and weaning off ENDS, others were cutting down to quit without a plan or schedule.

What is the Role of the Quitline?

ENDS users were asked what they remembered from their conversation with Quit Coaches about ENDS. Half remembered some conversation with their Quit Coach about ENDS. The top four messages participants reported receiving from Quit Coaches were: concerns expressed about ENDS, much is unknown about ENDS, use encouraged or "ENDS are okay", and avoid dual use

For peer review only

of ENDS and cigarettes. One participant described how use was discouraged: "I told them I used vapors and they informed me that there [were] no FDA regulations on it and they suggested I didn't use those at all." Conversations about ENDS with Quit Coaches had varying impact for different participants. The aforementioned participant described that she felt the quitline was "very much discouraging use…I blew it off…to each their own on their opinions on vaping. I don't see anything wrong with vaping." However, another participant stated that her conversation with the Quit Coach changed her view of ENDS: "He made a really, really good point that they are not regulated and you don't know what is in it. He really put an idea in my head." Several participants reported action or belief changes following their conversation with a coach.

Participants were also asked what other messages they would like from the quitline about ENDS. The majority had no response or didn't know. Several requested more information in general or about the safety of ENDS. A few participants had hoped to hear that it was a good idea to vape or that ENDS are helpful with quitting. Another participant described that she assumed she should stop using ENDS before starting NRT because the quitline recommended "that you discontinue all nicotine intake other than the lozenges and the gum," but an explicit conversation about guidance on using ENDS and patches would have been helpful. Overall, approximately three quarters of the 40 participants said they would recommend other ENDS users call the quitline.

DISCUSSION

Analysis of interviews with 40 quitline callers who were using ENDS during an attempt to quit cigarette smoking revealed themes that may be relevant to consider when approaching treatment

For peer review only

with dual users of cigarettes and ENDS. ENDS products were used in multiple ways, including as a cessation aid, a partial replacement for smoking prior to quitting, a bridge product when unable to smoke, and an enjoyable experience. In contrast, FDA-approved cessation medications were typically discussed only in the context of cessation, highlighting the added complexity of counseling smokers using ENDS. The majority of participants had positive use experiences with ENDS, as well as with some FDA-approved cessation medications. However, participants were split on whether FDA-approved cessation medications, ENDS, or using both FDA-approved cessation medications and ENDS simultaneously worked best for them for quitting smoking. In addition, some participants shared inaccurate beliefs about ENDS, FDA-approved cessation medications, and nicotine. Participants' beliefs about the products, whether accurate or inaccurate, can likely impact how and whether participants incorporate ENDS and FDA-approved cessation medications into their quit plan. Findings from these interviews suggested that state quitline callers who use ENDS would benefit from additional education about ENDS, FDA-approved cessation medications, nicotine, and the relative harm of these products. Specifically, quitlines and other health professionals have an opportunity to provide information about ENDS and quitting that will maximize the likelihood of helping individual smokers quit completely. Information callers receive may also impact what information they share with others about ENDS and their use of ENDS around others, including children.

The effectiveness of ENDS use for promoting long-term cessation from conventional cigarettes is uncertain.[7-11] However, many smokers report using ENDS to help them quit smoking,[5,6,22] and some former smokers report successfully using ENDS to quit.[23-29] Based on principles of behavior change, strategies were noted by respondents in this study that may be less likely to result in harm during a quit process (potentially adaptive strategies), including using patches and

For peer review only

ENDS together similar to combination therapy, using ENDS to cut down and FDA-approved cessation devices to quit completely, and fully replacing cigarettes with ENDS. Potentially maladaptive strategies of cutting down using ENDS were also noted, including using ENDS in places they did not previously smoke, using ENDS in a frequent unplanned manner, and cutting down to quit without a plan or schedule. ENDS use in situations participants did not previously smoke may serve to increase nicotine dependence, undermine the impact of tobacco free policies, expose others to secondhand aerosol, and establish dual use of ENDS and cigarettes. Smokers who cut down to quit, but continue to smoke in high craving situations, may not develop coping skills for stress or cravings in difficult situations and may experience the remaining cigarettes they smoke as particularly reinforcing. Finally, research has shown that cutting down to quit without a plan or schedule is less likely to be effective.[30-31] These findings suggest that treatment providers may find it useful to identify and discuss maladaptive strategies during smoking cessation treatment. Future research is also warranted to better understand how ENDS and cessation medication are used together during a quit attempt, as well as the effectiveness of these strategies.

Previous studies suggest that ENDS experimentation or use may help to motivate a quit attempt.[10-32] It is possible that some smokers who try ENDS will have a positive experience that may bolster their motivation and intention to quit (e.g, feeling healthier, managing cravings, reducing cigarettes per day), which appeared to be the case for some in this study. Although research has shown that reducing cigarette consumption is not sufficient to fully reduce health risks of smoking,[33-35] cigarette reduction may be a step towards quitting for individuals who have been unable to stop abruptly. Some research suggests that a cut-down-to-quit strategy that is guided on a schedule may yield similar outcomes as abrupt quitting;[31,36,37] however, cutting

For peer review only

down to quit has been found to be less effective in real-world samples.[38] In the present study, it was uncertain how aware participants were of the importance of completely quitting combustible tobacco. Given the number using a cut-down-to-quit strategy, this represents an important area for future research.

This study is subject to at least five limitations. First, the findings from this small sample may not generalize to all ENDS users. Second, the sample may also include more ENDS "treatment failures" than in the general population; if smokers had successfully quit using their ENDS device, they could have been less likely to call the quitline for assistance.[7] Third, most callers had completed one quitline call, and some had a limited memory of the call. Interviewing callers after they had an opportunity to complete more calls could yield different information. Fourth, it was not possible to fully account for the type of ENDS device used, use topography, or proficiency/experience as a user. Given that these characteristics can impact nicotine delivery,[39-40] these factors may have influenced preferences for use of ENDS versus FDA-approved cessation medications for quitting smoking. Finally, it was unclear if timing of the interviews (e.g. New Year and holidays) may have led to delayed quit dates, or if that was part of the quitting process for individuals in this sample.

In conclusion, in this sample of 40 ENDS users who contacted a state quitline for help quitting smoking, some ENDS users had confusion or misinformation about ENDS, FDA-approved cessation medications, nicotine, and the relative harm of these products. ENDS were being used in ways that were unlikely to help with quitting smoking, as well as in ways that may potentially facilitate quitting smoking. These findings suggest that quitlines have a unique opportunity to educate a significant number of ENDS users and to help them create a coordinated quit plan most

For peer review only

likely to result in completely quitting combustible tobacco. These findings also suggest important avenues for future research. Strategies for educating smokers about ENDS and, if necessary, changing inaccurate beliefs about products warrant development and testing. Additionally, future research could examine whether use of cut-down-to-quit strategies and relapse experiences are different for individuals who use ENDS during their quit process. Finally, for quitline callers who plan to use ENDS as part of their quit attempt, research is warranted to determine whether certain information about ENDS or behavioral support from the quitline may improve callers' success with quitting smoking.

For peer review only

FOOTNOTES

Acknowledgements: The authors would like to thank and acknowledge Erica Salmon and Kristina Muramoto for coding interviews, Lacy Brame, MS and Dana Mowls, MPH for conducting the participant interviews, and Susan Zbikowski, PhD and Ann Malarcher, PhD for input on the study design.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: KV and BM report funding from Centers for Disease Control and Prevention during the conduct of the study and are employees of Optum (formerly Alere Wellbeing, Inc.), the provider of quitline services for participants in this study; LB reports grants from Oklahoma Tobacco Settlement Endowment Trust during the conduct of the study; no other relationships or activities that could appear to have influenced the submitted work.

Funding: This project was funded in part by Centers for Disease Control & Prevention Contract #200-2014-M-60619 and the Oklahoma Tobacco Settlement Endowment Trust. The findings and conclusions in this report are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

Contributions: KV, LB, GS, and BM contributed to the interview guide and coding methodology. LB oversaw participant interviews. KV and BM (with two other coders) coded interviews. KV led the analysis of coded data, performed the literature review, and took primary responsibility for writing the paper. All authors contributed to the conceptualization of the study, study design, interpretation of data, and the preparation of the manuscript. All authors approved the final version of the manuscript.

Data sharing: no additional data available.

For peer review only

REFERENCES

1. Regan AK, Promoff G, Dube SR, et al. Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA. *Tob Control* 2013;22(1):19-23. doi:10.1136/tobaccocontrol-2011-050044.
2. King BA, Patel R, Nguyen KH, et al. Trends in awareness and use of electronic cigarettes among US adults, 2010-2013. *Nicotine Tob Res* 2015;17(2):219-227. doi:10.1093/ntr/ntu191.
3. Schoenborn MPH, Gindi RM. Electronic Cigarette Use Among Adults: United States, 2014. NCHS Data Brief 2015; 217:1-8.
4. North American Quitline Consortium (NAQC) (2015). Results from the 2013 NAQC Annual Survey of Quitlines Webinar Presentation, North American QuitlineConsortium (NAQC), Phoenix, Ariz, USA, 2013. Accessed July 23, 2015: http://www.naquitline.org/?page=2013Survey
5. Vickerman KA, Carpenter KM, Altman T, et al. Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine Tob Res* 2013;15(10):1787-1791. doi:10.1093/ntr/ntt061.
6. Vickerman KA, Beebe L , Schauer G, et al. *ENDS Users Who Call Quitlines: Surveillance Data and Research Findings.* 2015 Annual North American Quitline Consortium (NAQC) Conference; 2015: Atlanta, GA.
7. McRobbie H, Bullen C, Hartmann-Boyce J, et al. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev* 2014;12:CD010216. doi:10.1002/14651858.CD010216.pub2.
8. Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation* 2014;129(19):1972-1986. doi: 10.1161/CIRCULATIONAHA.114.007667.
9. Bullen C, Howe C, Laugesen M, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* 2013;382(9905):1629-1637. doi: 10.1016/S0140-6736(13)61842-5.
10. Caponnetto P, Campagna D, Cibella F, et al. EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. *PLoS One* 2013;8(6):e66317. doi:10.1371/journal.pone.0142287.
11. Bernstein SL. Electronic cigarettes: more light, less heat needed. *Lancet Respir Med* 2016;4(2):85-87. doi: 10.1016/S2213-2600(16)00010-2.
12. Farsilinos KE, Kistler KA, Gillman G, et al. Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins. *Nicotine Tob Res* 2015;17(2):168-174. doi:10.1093/ntr/ntu176.
13. Fagerstrom K, Etter JF, Unger JB. E-cigarettes: a disruptive technology that revolutionizes our field? *Nicotine Tob Res* 2015;17(2):125-126. doi:10.1093/ntr/ntu240.
14. Nash CM, Vickerman KA, Kellogg ES, et al. Utilization of a Web-based vs integrated phone/Web cessation program among 140,000 tobacco users: an evaluation across 10 free state quitlines. *J Med Internet Res* 2015 Feb 4;17(2):e36. doi:10.2196/jmir.3658.
15. Bandura A. Social Cognitive Theory. In: Annals of child development, Vol 6. Six theories of child development. R. Vasta (Ed). Greenwich, CT: JAI Press; 2015:1-60.
16. US PHS Guidelines. Treating tobacco use and dependence: 2008 update. Rockville, MD: U.S. Department of Health and Human Services; Public Health Services; 2008.
17. AWI (2014) Alere Position Statement on E-Cigarettes. Checking on the best way to cite this document.
18. King N. Using templates in the thematic analysis of text. In: Cassell C, Symon G, eds. Essential Guide to Qualitative Methods in Organization Research. London: SAGE Publications 2004:256-270.
19. Patton MQ. Qualitative Research & Evaluation Methods. 3rd edition. Thousand Oaks, CA: SAGE Publications 2001.
20. Sandelowski M. Whatever happened to qualitative description?. *Res Nurs Health* 2000;23(4):334-40.
21. MAXQDA, software for qualitative data analysis, 1989-2016, VERBI Software – Consult – Sozialforschung GmbH, Berlin, Germany.

For peer review only

22. Brown J, West R, Beard E, et al. Prevalence and characteristics of e-cigarette users in Great Britain: Findings from a general population survey of smokers. *Addictive Behaviors* 2014;39:1120-1125. doi:10.1016/j.addbeh.2014.03.009.
23. Barbeau AM, Burda J, Siegel M. Perceived efficacy of e-cigarettes versus nicotine replacement therapy among successful e-cigarette users: a qualitative approach. *Addict Sci Clin Pract* 2013;8:5. doi:10.1186/1940-0640-8-5.
24. Etter JF. Electronic cigarettes: a survey of users. *BMC Public Health* 2010;10:231 doi:10.1186/1471-2458-10-231.
25. Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011;106(11):2017-2028. doi:10.1111/j.1360-0443.2011.03505.x.
26. Etter JF, Bullen C. A longitudinal study of electronic cigarette users. *Addict Behav* 2014;39(2):491-494. doi:10.1016/j.addbeh.2013.10.028.
27. Foulds J, Veldheer S, Berg A. Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. *Int J Clin Pract* 2011;65(10):1037-1042. doi:10.1111/j.1742-1241.2011.02751.x.
28. Siegel MB, Tanwar KL, Wood KS. Electronic cigarettes as a smoking-cessation: tool results from an online survey. *Am J Prev Med* 2011;40(4):472-475. doi:10.1016/j.amepre.2010.12.006.
29. Dawkins L, Turner J, Roberts A, et al. 'Vaping' profiles and preferences: an online survey of electronic cigarette users. *Addiction* 2013;108(6):1115-1125. doi:10.1111/add.12150.
30. Lindson-Hawley N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database Syst Rev* 2012;11:CD008033. doi:10.1002/14651858.CD008033.pub3.
31. Cinciripini PM, Lapitsky L, Seay S, et al. The effects of smoking schedules on cessation outcome: can we improve on common methods of gradual and abrupt nicotine withdrawal? *J Consult Clin Psychol* 1995;63(3):388-399.
32. Wagener TL, Meier E, Hale JJ, et al. Pilot Investigation of Changes in Readiness and Confidence to Quit Smoking After E-Cigarette Experimentation and 1 Week of Use. *Nicotine Tob Res* 2014;16(1):108-114. doi:10.1093/ntr/ntt138.
33. USDHHS. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Atlanta, GA.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
34. Bjartveit K, Tverdal A. Health Consequences of Smoking 1-4 Cigarettes per Day. *Tobacco Control* 2005; 14(5):315-20. doi:10.1136/tc.2005.011932.
35. Tverdal A, Bjartveit K. Health Consequences of Reduced Daily Cigarette Consumption. *Tobacco Control* 2006; 15(6): 472–80. doi: 10.1136/tc.2006.016246.
36. Lindson-Hawley N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database Syst Rev* 2012;11:CD008033. doi:10.1002/14651858.CD008033.pub3.
37. Beard E, McNeill A, Aveyard P, et al. Association between use of nicotine replacement therapy for harm reduction and smoking cessation: a prospective study of English smokers. *Tob Control* 2013;22(2):118-122. doi:10.1136/tobaccocontrol-2011-050007.
38. Schauer GL, Malarcher AM, Babb SD. Gradual reduction of cigarette consumption as a cessation strategy: prevalence, correlates, and relationship with quitting. *Nicotine Tob Res* 2015;17(5):530-538. doi:10.1093/ntr/ntu172.
39. Talih S, Balhas Z, Eissenberg T, et al. Effects of user puff topography, device voltage, and liquid nicotine concentration on electronic cigarette nicotine yield: measurements and model predictions. *Nicotine Tob Res* 2015;17(2):150-157. doi:10.1093/ntr/ntu174.
40. Davis B, Dang M, Kim J, et al. Nicotine concentrations in electronic cigarette refill and do-it-yourself fluids. *Nicotine Tob Res* 2015;17(2):134-141. doi:10.1093/ntr/ntu080.

For peer review only

Table 1. Demographics and Tobacco use Characteristics for Respondents as Reported at Registration (*N* = 40)

	N	%
Age - Mean ± (SD)	45.0 (14.1)	
Gender – Female	26	65.0
Education		
Less than high school	11	27.5
High school degree / GED	16	40.0
Some college/trade school or college/trade school degree	13	32.5
Race/Ethnicity		
White, non-Hispanic	29	72.5
Black or African American, non-Hispanic	5	12.5
American Indian or Alaskan Native, non-Hispanic	5	12.5
Other race, non-Hispanic	1	2.5
Health insurance status		
Uninsured	18	45.0
Medicaid	8	20.0
Commercial	8	20.0
Medicare	5	12.5
"Does not know"	1	2.5
Employment status - employed	19	47.5
Chronic condition[1]– one or more	21	52.5
Mental health condition[2] – one or more	25	62.5
Time to First Use of Tobacco (TTFU)		
Within 5 minutes	17	42.5
6 – 30 minutes	14	35.0
More than 30 minutes	6	15.0
Missing	3	7.5
Cigarette use per day (cpd) - Mean ± (SD)	16.1 (12.3)	
Number of years used tobacco – 20+ years	28	70.0
Annual Income		
Less than $10,000 per year	18	45.0
$10,000 - $25,000 per year	8	20.0
More than $25,000 per year	12	30.0
Missing	2	5.0

[1] Chronic conditions included Asthma, Chronic Obstructive Pulmonary Disease (COPD), Coronary Artery Disease (CAD), and Diabetes (Type II).

[2] Mental health conditions included attention deficit hyperactivity disorder (ADHD), anxiety disorder, bipolar, depression, gambling addiction, posttraumatic stress disorder (PTSD), schizophrenia, and substance use disorder.

For peer review only

Table 2. Current Tobacco and ENDS Use During Qualitative Interview at 1-Month Post-Registration (*N* = 40)

	N	%
Current ENDS use		
Every Day	10	25.0
Some days	15	37.0
Rarely	6	15.0
Not at all	9	22.5
Current tobacco use		
Within the last 24 hours	28	70.0
Within the last 7 days, but more than 24 hours ago	4	10.0
Within the last month, but more than 7 days ago	5	12.5
Within the last 3 months, but more than 1 month ago	2	5.0
Have you used NRT or cessation medications since registration 1 month ago?		
Yes	28	70.0
No	12	30.0
Current use of NRT or cessation medications[1]		
Yes	21	52.5
No	19	47.5
Current Dual Use of Products: Cigarettes, ENDS, and NRT or cessation medications[2]		
Cigarettes & ENDS	10	25.0
Cigarettes, ENDS, and NRT/Meds	9	22.5
Cigarettes & NRT/Meds	6	15.0
Cigarettes only	7	17.5
ENDS & NRT/Meds	4	10.0
ENDS only	2	5.0
NRT/Meds only	2	5.0

[1] Participant reported currently using NRT or a cessation medication, or if current use was unclear, participant discussed recent use of NRT or cessation medication (i.e., within the last 7 days).

[2] Definitions of current use: any cigarette use in the last 7 days, current every day or some days ENDS use (excludes rarely and not at all), and current NRT/meds use defined as described in table note 1.

For peer review only

Consolidated criteria for reporting qualitative research (COREQ): a 32- item checklist for interviews and focus groups

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description
Domain 1: Research team and reflexivity Personal Characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview or focus group? Pg 6.
2. Credentials	What were the researcher's credentials? *E.g. PhD, MD* Pg 1, Pg 6
3. Occupation	What was their occupation at the time of the study? Pg 6
4. Gender	Was the researcher male or female? Pg 6
5. Experience and training	What experience or training did the researcher have? Pg 6
Relationship with participants	
6. Relationship established	Was a relationship established prior to study commencement? Pg 5. No.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research* Pg 5.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* Pg 5.
Domain 2: study design Theoretical framework	
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* Pg 7.
Participant selection	
10. Sampling	How were participants selected? *e.g. purposive, convenience,*

For peer review only

	consecutive, snowball Pg 5.
11. Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email* Pg 5.
12. Sample size	How many participants were in the study? Pg 5.
13. Non-participation	How many people refused to participate or dropped out? Reasons? Pg 5.
Setting	
14. Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace* Pg 6.
15. Presence of non-participants	Was anyone else present besides the participants and researchers? Pg 6.
16. Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date* Pg 7, Pg 25.
Data collection	
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? Pg 6-7.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many? Pg 6-7.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data? Pg 7.
20. Field notes	Were field notes made during and/or after the interview or focus group? Not explicitly discussed. Answers to some of the questions were recorded in Excel during the interview.
21. Duration	What was the duration of the interviews or focus group? Pg 7.
22. Data saturation	Was data saturation discussed?

For peer review only

	Pg 5.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction? No; not described as part of methods on pgs 5-7.
Domain 3: analysis and findings Data analysis	
24. Number of data coders	How many data coders coded the data? Pg 7.
25. Description of the coding tree	Did authors provide a description of the coding tree? Pgs 8-17. Not in the form of a table or figure. Codes identified for each content area are reported in each section of the results on pages 8-17 (e.g., descriptions of use, beliefs about products, strategies for incorporating ENDS in smoking cessation plans, role of the quitline).
26. Derivation of themes	Were themes identified in advance or derived from the data? Pg 7.
27. Software	What software, if applicable, was used to manage the data? Pg 7.
28. Participant checking	Did participants provide feedback on the findings? No; not described as part of methods on pgs 5-7.
Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.*g. participant number* Pgs 8-17.
30. Data and findings consistent	Was there consistency between the data presented and the findings? Yes. Pgs 7-17, 25-26.
31. Clarity of major themes	Were major themes clearly presented in the findings? Pgs 8-17.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? Pgs 8-17.

For peer review only

BMJ Open

Electronic nicotine delivery system (ENDS) use during smoking cessation: a qualitative study of 40 Oklahoma quitline callers

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2016-013079.R1
Article Type:	Research
Date Submitted by the Author:	19-Dec-2016
Complete List of Authors:	Vickerman, Katrina; Optum, Center for Wellbeing Research Beebe, Laura; University of Oklahoma Health Sciences Center, Biostatistics and Epidemiology Schauer, Gillian; Battelle Memorial Institute, Battelle Public Health Center for Tobacco Research; Centers for Disease Control and Prevention, Guest Researcher, Office on Smoking and Health Magnusson, Brooke; Optum, Center for Wellbeing Research King, Brian; Centers for Disease Control and Prevention, Office on Smoking and Health
Primary Subject Heading:	Smoking and tobacco
Secondary Subject Heading:	Public health, Qualitative research
Keywords:	PUBLIC HEALTH, QUALITATIVE RESEARCH, smoking cessation, electronic nicotine delivery systems, e-cigarettes, quitlines

SCHOLARONE™
Manuscripts

Electronic nicotine delivery system (ENDS) use during smoking cessation: a qualitative study of 40 Oklahoma quitline callers

Katrina A. Vickerman, PhD, Laura A. Beebe, PhD, Gillian L. Schauer, PhD, Brooke Magnusson, MA, & Brian A. King, PhD, MPH

Author Note

Katrina Vickerman and Brooke Magnusson, Center for Wellbeing Research, Optum (formerly Alere Wellbeing, Inc.), Seattle, WA. Laura A. Beebe, University of Oklahoma Health Sciences Center. Gillian L. Schauer, Battelle Public Health Center for Tobacco Research, Battelle Memorial Institute, Seattle, WA, Guest Researcher, Office on Smoking and Health, Centers for Disease Control and Prevention, Atlanta, GA. Brian King, Office on Smoking and Health, Centers for Disease Control and Prevention, Atlanta, GA.

Correspondence concerning this article should be addressed to Katrina Vickerman, Optum Center for Wellbeing Research, 999 Third Avenue, Suite 2000, Seattle, WA. Tel. 206-876-2363; fax: 206-876-2101. Email: Katrina.Vickerman@optum.com

Abstract word count: 300 (limit 300)

Number of tables/ figures: 2 (limit 5)

For peer review only

ABSTRACT

Objectives: Approximately ten percent (40,000) of U.S. quitline enrollees who smoke cigarettes report current use of Electronic Nicotine Delivery Systems (ENDS); however, little is known about callers' ENDS use. Our aim was to describe why and how quitline callers use ENDS, their beliefs about ENDS, and the impact of ENDS use on callers' quit processes and use of FDA-approved cessation medications.

Design: Qualitative interviews conducted 1-month post-registration. Interviews were recorded, transcribed, double-coded, and analyzed to identify themes.

Setting: Oklahoma Tobacco Helpline

Participants: 40 callers aged ≥18 who were seeking help to quit smoking, were using ENDS at registration, and completed ≥1 program calls.

Results: At 1-month post-registration interview, 80% of callers had smoked cigarettes in the last 7 days, almost two-thirds were using ENDS, and half were using cessation medications. Nearly all believed ENDS helped them quit or cut down on smoking; however, participants were split on whether they would recommend cessation medications, ENDS, or both together for quitting. Confusion and misinformation about potential harms of ENDS and cessation medications were reported. Participants reported using ENDS in potentially adaptive ways (e.g., using ENDS to cut down and NRT to quit, and stepping down nicotine in ENDS to wean off ENDS after quitting) and maladaptive ways (e.g., frequent automatic ENDS use, using ENDS in situations they did not previously smoke, cutting down on smoking using ENDS without a schedule or plan to quit), which could impact the likelihood of quitting smoking or continuing ENDS use.

Conclusions: These qualitative findings suggest quitline callers who use ENDS experience confusion and misinformation about ENDS and FDA-approved cessation medications. Callers also use ENDS in ways that may not facilitate quitting smoking. Opportunities exist for quitlines

For peer review only

to educate ENDS users and help them create a coordinated plan most likely to result in completely quitting combustible tobacco.

Strengths and limitations of this study

- Dual users of cigarettes and ENDS who were in the middle of an attempt to quit smoking were interviewed at 1-month post-quitline registration, which allowed for timely reporting of quitting strategies and experiences using ENDS and cessation medications.
- In depth qualitative interviews were completed with 40 dual users of cigarettes and ENDS to obtain detailed reports of experiences from a range of ENDS users.
- Interviews were recorded, transcribed, and double coded to increase the trustworthiness of extracted themes.
- Findings from this small sample of Oklahoma Tobacco Helpline enrollees may not generalize to all ENDS users.

For peer review only

INTRODUCTION

Use of Electronic Nicotine Delivery Systems (ENDS), including electronic cigarettes (e-cigarettes), has increased considerably in recent years, particularly among current and former cigarette smokers.[1,2] In 2014, 47.6% of current cigarette smokers and 55.4% of recent former cigarette smokers had ever tried an e-cigarette.[3] ENDS use among current smokers who call state quitlines is also common; state quitlines are free, typically phone-based tobacco cessation programs available in all 50 states in the United States.[4] In 2012, approximately one-third of quitline enrollees reported ever using ENDS,[5] and from 2013-2015, approximately 10% reported current use at registration.[6] An estimated half of these individuals reported using ENDS to try to quit smoking cigarettes.[5,6]

Although ENDS may be commonly used by adults as a smoking cessation aid, they have not been approved by the U.S. Food and Drug Administration (FDA) for this purpose. To date, there is no conclusive scientific evidence that ENDS are effective for long-term cessation from conventional cigarettes,[7-11] and the long-term health impacts of ENDS use among adults is uncertain.[8,12,13] In light of this uncertainty, health professionals and treatment providers are seeking to identify the best way to help smokers who are using ENDS during their smoking cessation process. However, limited information is available about quitline callers' experiences using ENDS and their knowledge and beliefs about the products. This information is critical to help quitlines determine how best to address ENDS use given that an estimated 40,000 ENDS users call quitlines each year for help quitting traditional tobacco products.[4,6]

For peer review only

Few studies have assessed factors related to ENDS use among U.S. quitline callers. Accordingly, this study employed qualitative methods to assess quitline callers' opinions about and experiences using ENDS, including their beliefs about ENDS and smoking cessation, interactions with quitline counselors about ENDS, and perceptions of ENDS versus FDA-approved medications, including nicotine replacement therapy (NRT).

METHODS

Participants

Pre-notification letters were mailed to 65 randomly selected participants who met study eligibility criteria approximately three weeks after Oklahoma Tobacco Helpline registration. Letters included a study overview and stated that study staff would be in contact about the study. Nineteen could not be reached after multiple attempts and six refused participation. Forty state quitline callers who wanted to quit smoking and called the Oklahoma Tobacco Helpline between November 2014 and February 2015 completed the interview. A minimum sample size target of 40 was selected to ensure inclusion of diverse ENDS users with regard to reasons for ENDS use. The interview team agreed that saturation was reached after 40 participants.

Participants were reached via phone, provided informed consent, and completed an interview approximately one month after registration with the Helpline. Callers were eligible for the study if, at the time of registration, they: 1) currently smoked conventional cigarettes; 2) were currently using ENDS as assessed by a standard quitline question ("Do you currently use electronic cigarettes, e-cigarettes or vapor cigarettes?"); 3) spoke English; 4) requested a Helpline intervention; 5) were 18 or older; 6) completed at least one call with a quit coach lasting at least 5 minutes; and 7) provided consent for follow-up contact. Pregnant callers were excluded. Four

For peer review only

participants used another form of tobacco product (e.g., pipe, smokeless tobacco) in addition to cigarettes and ENDS at the time of registration. A $49 gift card to Amazon or Walmart was provided to participants who completed the interview. All study procedures were approved by the University of Oklahoma Institutional Review Board.

The Helpline Program

All participants were enrolled in a one-call or five-call phone-based cessation program, which also included a two or eight-week supply of NRT, a printed quit guide, and access to an interactive online cessation resource.[14] Intensity of Helpline service is determined by insurance status: Callers with no insurance are eligible for the five-call program and 8-weeks of NRT, while callers with Medicaid also receive the five-call program but only 2-weeks of NRT from the Helpline. Callers with private insurance are eligible for the single-call program and 2-weeks of NRT. Coaching calls focus on developing a quit plan, building skills for coping with cravings and triggers, enlisting social support, and using FDA-approved cessation medications.[15,16]

With regard to using ENDS to quit smoking, Helpline Quit Coaches were trained to not promote the use of ENDS for quitting tobacco and to provide education that there is not empirical evidence proving ENDS are safe and effective cessation tools. Smokers interested in switching to ENDS would not be discouraged from doing so and would be educated that the safety of long-term use of ENDS is unclear.[17]

Interviews

Interviews were conducted over the phone in private offices by two female Graduate Research Assistants at the University of Oklahoma College of Public Health. Interviewers were enrolled in

For peer review only

graduate training in epidemiology, had received extensive training in research methods, had interviewing experience from previous studies, and received training in qualitative interviewing techniques. Interviewers followed a semi-structured interview guide and were encouraged to ask additional probing questions. Topics discussed in the interviews were selected to investigate current gaps in knowledge about how ENDS were perceived and used by quitline callers. Topics included reasons for ENDS use, current ENDS and tobacco use, Helpline experience, experience with FDA-approved cessation medications, ENDS use details, and intentions to quit. Interviews lasted 35.2 minutes on average (range: 22.1-61.5 minutes), were audio recorded, and transcribed verbatim. A series of questions requesting feedback about the interview were also asked of the first eight participants.

Coding and Analysis

Template analysis was used to guide the coding process.[18] A preliminary codebook was developed after reading five transcripts. The codebook focused on topics queried during the interview and themes that arose in participants' responses. Themes were then further organized into larger concepts (e.g., if initially separated topics yielded similar themes and were best grouped together), while grounding all identified themes in participant's words. Four individuals coded the interviews. Each interview was double-coded. Double-coding was reviewed and consensus was reached for each interview. For analyses of coded data, our primary aim was to describe themes present in the data. We used a constant comparative approach, repeatedly returning to the transcripts and codes to ensure the accuracy and increase the depth of our summary of themes and to extract exemplary participant quotations.[19,20] Analyses were conducted in MAXQDA.[21]

For peer review only

RESULTS

Participants

Respondents were an average of 45 years old, 65% female, 73% white non-Hispanic, 68% high school degree or less education, and predominately low income (65% less than $25,000 annual income) (*Table 1*). Participants ranged in number of quit attempts prior to contacting the Helpline: for 6 their Helpline enrollment was a first quit attempt, 15 had 1-2 previous attempts, 10 had 3-4 previous attempts, and 9 had 5 or more previous attempts. Thirty-three participants enrolled in the five-call program and 7 enrolled in a one-call program. All received a 2- or 8-week supply of NRT from the quitline. Participants completed 1.7 calls (*SD*=1.12) during the program on average.

At registration, 19 reported using ENDS every day, with the remaining 21 participants reporting nondaily ENDS use; 33 reported using a tank system style ENDS (which is refilled with e-liquid by the user) and 37 said they were thinking about quitting ENDS in addition to cigarettes. All but one of the daily ENDS users used tank systems. About half reported they were primarily using ENDS to quit smoking, 13 said they were cutting down to quit smoking, and 3 said they were only using ENDS to reduce smoking.

Table 2 displays products participants were using at the time of the qualitative interview. Thirty-two had smoked cigarettes in the last 7 days, 25 were currently using ENDS, and 21 were currently using an FDA-approved cessation aid. Twenty-nine of the participants were using two or three sources of nicotine (i.e., cigarettes, ENDS, and/or NRT).

Interview Themes

For peer review only

How Participants Reported using ENDS and FDA-approved Cessation Medications

Descriptions of ENDS use

Participants discussed using ENDS as a quitting aid, as a bridge product when smoking was not allowed, and for a recreational experience. Callers also described using ENDS as a partial replacement for cigarettes—either as part of a cut down to quit strategy or, as a small number reported, using ENDS only for cutting down on cigarettes (not for quitting completely).

When asked whether ENDS helped them to quit or cut down on smoking, most participants believed ENDS helped them cut down on or quit cigarettes, including quitting completely (*n*=7), quitting temporarily (*n*=7), and cutting down without quitting (*n*=21). For example, one participant who quit temporarily and was using ENDS during her current quit attempt described:

> *To begin with, it [ENDS] took the place of the cigarette and I still got the nicotine…I totally didn't smoke for like 4 months. At that point, if I picked one [a cigarette] up and tasted it, I didn't like the way it tasted. I didn't care for the light headed effect you got from it that comes with not smoking it. You don't smoke, that's the way a cigarette affects you…I have been [using cigarettes] for about the last month. We had some medical issues come up and a lot of stress and I just fell back into it, but [I'm] moving away from it. I'm doing the vapor stick more than the cigarettes... I have the patches, but I haven't started them.*

Alternatively, one participant felt ENDS increased his urge to smoke and caused him to smoke more, and a small number reported that ENDS did not change their smoking. The latter participants noted that ENDS did not work for them because they were still smoking; one explained that carrying and maintaining their ENDS device was inconvenient.

For peer review only

When asked what they liked and what they did not like about using ENDS, participants reported both positive and negative perceptions of ENDS use. However, overall, nearly all reported they were satisfied with their ENDS device. Positive aspects of ENDS use included features of the use experience (e.g., convenience of taking a puff quickly as desired versus lighting and finishing a cigarette; smell; taste; flavors), environmental factors (e.g., no second or thirdhand smoke, ash trays or lighted fire; can use where cannot smoke; less distracting to use while driving), positive health attributions or beliefs about ENDS (e.g., health benefits such as breathing easier and less coughing, perceiving ENDS are healthier than cigarettes), beliefs that ENDS helped with quitting or cutting down (e.g., behavioral substitute, control cravings, avoid weight gain), nicotine delivery and concentration options (e.g., receiving needed nicotine; can taper nicotine or use no nicotine ENDS), cost of ENDS, and others' reactions to ENDS use (others prefer ENDS, no judgement of use).

Negative perceptions of ENDS use were also reported, including features of the ENDS device (leaks, hard to maintain, weight/size/look, battery, breaks), beliefs that ENDS are harmful or potentially harmful to health, that ENDS do not help in quitting smoking (not satisfying, insufficient nicotine, does not help all of the time, increases urge to smoke), concerns about ENDS habit (addictive, continues hand to mouth habit), cost of ENDS (particularly to start), and the learning curve for use (process to find right device or learn to use, hard transition from smoking). Over a third of participants reported negative experiences or minor side effects, primarily coughing or sore throat/burning in back of throat. Individual participants reported headache, pain in lungs, dry mouth, dehydration, and concern that ENDS worsened COPD symptoms.

For peer review only

Descriptions of FDA-approved Cessation Medication Use

When asked about past experiences using FDA-approved cessation medications, nearly all participants reported positive or mixed experiences. One participant described her positive experiences with cessation medications: "The patch is excellent because it takes the edge off." Other participants had mixed experiences. For example, a participant explained, "Chantix worked for me but sometimes [insurance] wouldn't pay for it and I can't afford it…My system on the patch – it rejects it." Only three participants reported that cessation medications were not perceived as helpful. For example, one participant described: "I have tried patches, the gum, the lozenges, and everything else and nothing has worked." Over half of the participants reported experiencing a side effect or reaction to an FDA-approved cessation medication, including bad dreams, skin reactions (rash, itchiness, burning sensation), emotional changes, upset stomach, sore or itchy throat, feeling jittery, or having an abnormal taste in the mouth.

A quarter of participants reported they were not using an FDA-approved cessation medication at the time of their interview because their quit date was still in the future and they were waiting to start NRT until their quit date. Some participants shared beliefs that they should not use patches and smoke; for example, "I put the patch on and I still smoked some…I would think, 'I'm just gonna have to take this patch off because you aren't supposed to smoke and wear the patch,' so I just took [the patch] off."

Preferences for ENDS vs FDA-approved cessation medications for quitting smoking

Participants were split on preferred methods for quitting smoking; similar numbers recommended an FDA-approved cessation medication only, ENDS only, and using both at the same time. In addition, several participants reported no preference between ENDS and cessation

For peer review only

medications. Several participants noted openness to trying any options that might work for them: "anyone [who] wants to quit smoking [should] try any method there is, because no person works the same."

Participants who recommended an FDA-approved cessation medication explained that medications helped with quitting or urges and had better nicotine delivery. For example, one participant described: "When I put it [patch] on, physically I don't crave a cigarette…that doesn't happen with the e-cigarette." Some participants also noted concerns about ENDS as a reason for their choice including believing ENDS are harmful or not knowing enough about safety, concerns about the addictiveness of ENDS or the hand to mouth habit, that using ENDS is not completely quitting, and insufficient nicotine delivery. One participant explained:

> *You're swapping out one cloud of smoke for another cloud of smoke [with ENDS]…You still have the habit of putting something in your mouth. You still have the habit of blowing something out of your mouth...What is the difference? I mean there's no evidence out there that proves that's [ENDS use] any better than actual smoking cigarettes…If you're gonna quit nicotine, quit nicotine all together. If you're trying to quit smoking, I guess you probably need to hit up on that nicotine patch.*

Participants who felt ENDS were more helpful for quitting highlighted the importance of ENDS as a behavioral substitute for the hand to mouth habit of smoking. They felt ENDS provided a better transition from smoking, believed ENDS helped avoid weight gain during quitting, liked that they could use ENDS as needed, liked the throat hit from ENDS, and preferred the option to step down on nicotine. For example, one participant shared,

> *It [patch] was a lot harder because you have the patch [and] there is [a] no smoking period…The hand to mouth gesture is there, it's integrated in your system I think, if you*

For peer review only

smoke for a long time. So it would be a lot harder to go from smoking a cigarette to having the patch on your arm. That's really hard to do. In my thought process, vaping to quit will actually be a better thing because there's still that interaction between hand to mouth versus food going hand to mouth.

Most of these participants noted side effects with FDA-approved cessation medications or that cessation medications did not work well for them in the past or did not provide sufficient nicotine. Finally, participants who believed it was most helpful to use both FDA-approved cessation medications and ENDS together for quitting provided several explanations. Some noted this approach would be preferred especially for long time smokers, some felt ENDS helped them with quitting more than cessation medications, and some felt an FDA-approved cessation medication helped them more with quitting than the ENDS product. Some in this group of participants recommended using patches and then ENDS (with or without nicotine) as a stopgap for relapse or when urges were high, noting that patches alone were not enough.

Misinformation and Confusion about Relative Harm of ENDS and FDA-approved Medication

Views on Relative Harm of Products

Participants were asked to rank ENDS, NRT, and cigarettes from most to least harmful and explain their rankings. Slightly more than half of the participants ranked FDA-approved cessation medications as least harmful, just less than half ranked ENDS as least harmful, and a few felt FDA-approved cessation medications and ENDS were equally harmful. All ranked cigarettes as most harmful. Some participants ranked FDA-approved cessation medications as more harmful than ENDS due to their reactions to FDA-approved cessation medications. For example, one participant explained, "I would put [patches] in the rank close to the cigarette, [because they] make your heart beat really fast." Some participants provided explanations for

For peer review only

their ranking choices that involved misinformation about ENDS, FDA-approved cessation medications, or nicotine, as described in the next section. Several participants also expressed lack of confidence in their knowledge about the relative harm of products, for example, stating, "I would probably have to say that I don't know. I think the vapor's more harmful. I really do not know."

Misinformation and Confusion about ENDS

Participants reported several inaccurate beliefs about the safety and constituents of ENDS. Some participants expressed beliefs that ENDS and the aerosol ENDS produce are completely safe. For example, one participant said, "There's not any chemicals in [ENDS] like there are in actual cigarettes", and another stated, "It's a vapor, I mean, you're not really hurting anybody. You could smoke it inside the building." One participant reported believing she was not receiving any nicotine from ENDS; she explained, "[When] I use the e-cigarette, I really don't think I am getting the nicotine or anything in my lungs because it evaporates. I think I am just getting a taste of nicotine."

Views on Long-Term ENDS Use

When asked what they thought about long-term use of ENDS, almost equal numbers were concerned, supportive, and unsure. Some participants' explanations reflected confusion or misbeliefs about ENDS. Participants who had concerns about long-term ENDS use either believed that ENDS are harmful or detrimental to health or thought ENDS may have negative impacts if used long-term, but often thought short-term use was likely okay. Those who were unsure often saw benefits to ENDS use (not smoking, feeling healthier) or had not personally experienced any negative impacts of using ENDS, but either (1) expressed uncertainty about

For peer review only

long-term use due to unknown constituents of ENDS, the potential impact of aerosol on lungs, or using an addictive product or (2) did not know what to think about long-term use (i.e., did not know because they had not read or heard anything about it or believed there are conflicting opinions on this subject). Participants who said they were supportive of long-term use were most likely to report inaccurate information about ENDS, such as that ENDS and the aerosol it produces are completely safe (i.e., the aerosol is just water vapor) or that there were no concerns as long as one used ENDS products that did not contain nicotine. Some of these participants also noted the relative benefit of using ENDS rather than cigarettes.

Misinformation about FDA-approved Cessation Medications

Some participants also made statements that reflected concerns about the safety of NRT or how to use NRT. For example, one participant stated, "The patch has definitely got tar in it." Another participant who believed the patch and ENDS were equally harmful explained, "with the patch, the nicotine [is] being absorbed into your skin – that is chemicals, so that is not good." A third participant who rated patches as more harmful than ENDS shared, "I don't really know how to explain it…it's just that I'm scared to use them [patches]." Another participant ranked NRT as more harmful than ENDS because of concerns about overdosing on NRT.

Concerns about Nicotine

Some participants focused on the safety of nicotine regardless of whether it was delivered from ENDS or FDA-approved cessation medications. One participant stated, "Nicotine in pure form causes Alzheimer's." Two participants believed their 0 milligram nicotine ENDS product was the least harmful product, "because nicotine is bad for you;" both participants were still smoking cigarettes at the time of the interview. Several others were also unsure whether ENDS or NRT

For peer review only

are more harmful or ranked NRT as more harmful because they viewed nicotine dependence or use as the main concern. Several ranked ENDS as less harmful than the nicotine patch because they believed ENDS deliver less nicotine.

Strategies used for Incorporating ENDS in Smoking Cessation Plans

Participants described how they used ENDS devices during their smoking cessation process. We categorized these behaviors into potentially adaptive and maladaptive quit behaviors. These categories were not mutually exclusive; some participants reported behaviors that may be less likely to harm their quit process or possibly help with quitting (potentially adaptive) as well as behaviors that may be more likely to establish a separate ENDS habit or were less likely to reduce smoking (potentially maladaptive).

Potentially Adaptive Quit Behaviors

Based on the participants' descriptions for how they incorporated ENDS into their smoking cessation plan, we identified five examples of potentially adaptive behaviors. Some participants were using ENDS only, but decided to or planned to switch to using a patch along with a no-nicotine ENDS: "I'm trying something different now that I got my patches in. I'm going to use patches for the nicotine. And then I'm going to fill my e-cig with the zero nicotine. That way I have the habit still and I'm getting the nicotine, but I can cut back with the patches." Second, other participants used NRT, such as the patch, and used ENDS with nicotine when cravings were high to avoid picking up a cigarette. Third, multiple participants discussed stepping down the milligrams of nicotine in their ENDS liquid to wean off nicotine. For example, one participant described, "It [ENDS] took the place of the cigarette and I still got the nicotine and you're able to cut down the amount of nicotine you get in the vapor. You can get it in a 24, 18,

For peer review only

12, 7, 2, or 0 [mg/ml nicotine concentration] and I just stepped down." Fourth, several participants used ENDS to cut down and completely replace smoking cigarettes, and then switched to the patch to quit both cigarettes and ENDS. Finally, a small number of participants completely switched from cigarettes to ENDS or cut down cigarettes by replacing with ENDS and eventually fully replaced all cigarettes with ENDS.

Potentially Maladaptive Quit Behaviors

Four types of potentially maladaptive behaviors for incorporating ENDS into smoking cessation plans were identified. First, more than half of the participants reported using ENDS in situations where they did not or could not smoke, most frequently at work, in their car, at home, or in stores. Second, a group of participants had difficulty describing their ENDS use because it had become a frequent, automatic behavior. One participant explained, "I can't even count to be honest with you…I just go 'oh look, I want this' and I grab it. I have a lanyard that's around my neck all day long." Third, several participants who were cutting down to quit, described partially replacing cigarettes with ENDS, but choosing to smoke a cigarette when they were stressed or their cravings were high. Fourth, while some participants described a plan for reducing nicotine intake and weaning off ENDS, others were cutting down to quit without a plan or schedule.

What is the Role of the Quitline?

ENDS users were asked what they remembered from their conversation with Quit Coaches about ENDS. Half remembered some conversation with their Quit Coach about ENDS. The top four messages participants reported receiving from Quit Coaches were: concerns about ENDS, much is unknown about ENDS, use encouraged or "ENDS are okay", and avoiding dual use of ENDS and cigarettes. One participant described how use was discouraged, "I told them I used vapors

For peer review only

and they informed me that there [were] no FDA regulations on it and they suggested I didn't use those at all." Conversations about ENDS with Quit Coaches had varying impact for different participants. The aforementioned participant described that she felt the quitline was "very much discouraging use…I blew it off…to each their own on their opinions on vaping. I don't see anything wrong with vaping." However, another participant stated that her conversation with the Quit Coach changed her view of ENDS, "He made a really, really good point that they are not regulated and you don't know what is in it. He really put an idea in my head." Several participants reported action or belief changes following their conversation with a coach.

Participants were also asked what other messages they would like from the quitline about ENDS. The majority had no response or did not know. Several requested more information in general or about the safety of ENDS. A few participants had hoped to hear that it was a good idea to vape or that ENDS are helpful with quitting. Another participant described that she assumed she should stop using ENDS before starting NRT because the quitline recommended "that you discontinue all nicotine intake other than the lozenges and the gum," but an explicit conversation about guidance on using ENDS and patches would have been helpful. Overall, approximately three quarters of the 40 participants said they would recommend other ENDS users call the quitline.

DISCUSSION

Analysis of interviews with 40 quitline callers who were using ENDS during an attempt to quit cigarette smoking revealed themes that may be relevant to consider when approaching treatment with dual users of cigarettes and ENDS. ENDS products were used in multiple ways, including as a cessation aid, a partial replacement for smoking prior to quitting, a bridge product when

For peer review only

unable to smoke, and an enjoyable experience. In contrast, FDA-approved cessation medications were typically discussed only in the context of cessation, highlighting the added complexity of counseling smokers using ENDS. This contrast likely contributes to NRT and ENDS being used differently. For example, some participants discussed waiting to use NRT until their quit date or stopping NRT use if they relapsed to smoking; these use "rules" were not discussed for ENDS. The majority of participants had positive use experiences with ENDS, as well as with some FDA-approved cessation medications. However, participants were split on whether FDA-approved cessation medications, ENDS, or using both FDA-approved cessation medications and ENDS simultaneously worked best for them for quitting smoking.

In addition, some participants shared inaccurate beliefs about ENDS, FDA-approved cessation medications, and nicotine. Participants' beliefs about the products, whether accurate or inaccurate, can likely impact how and whether participants incorporate ENDS and FDA-approved cessation medications into their quit plan. Findings from these interviews suggested that state quitline callers who use ENDS would benefit from additional education about ENDS, FDA-approved cessation medications, nicotine, and the relative harm of these products. Specifically, quitlines and other health professionals have an opportunity to provide information about ENDS and quitting that will maximize the likelihood of helping individual smokers quit completely. Information callers receive may also impact what information they share with others about ENDS and their use of ENDS around others, including children.

The effectiveness of ENDS use for promoting long-term cessation from conventional cigarettes is uncertain.[7-11] However, many smokers report using ENDS to help them quit smoking,[5,6,22] and some former smokers report successfully using ENDS to quit.[23-29] Based on principles of

For peer review only

behavior change, strategies were noted by respondents in this study that may be less likely to result in harm during a quit process (potentially adaptive behaviors), including using patches and ENDS together similar to combination therapy, using ENDS to cut down and FDA-approved cessation devices to quit completely, and fully replacing cigarettes with ENDS. Potentially maladaptive behaviors of cutting down using ENDS were also noted, including using ENDS in places they did not previously smoke, using ENDS in a frequent unplanned manner, and cutting down to quit without a plan or schedule. ENDS use in situations participants did not previously smoke may serve to increase nicotine dependence, undermine the impact of tobacco free policies, expose others to secondhand aerosol, and establish dual use of ENDS and cigarettes. Smokers who cut down to quit, but continue to smoke in high craving situations, may not develop coping skills for stress or cravings in difficult situations and may experience the remaining cigarettes they smoke as particularly reinforcing. Finally, research has shown that cutting down to quit without a plan or schedule is less likely to be effective.[30-31] These findings suggest that treatment providers may find it useful to identify and discuss maladaptive behaviors during smoking cessation treatment. Future research is also warranted to better understand how ENDS and cessation medication are used together during a quit attempt, as well as the effectiveness of these strategies.

Previous studies suggest that ENDS experimentation or use may help to motivate a quit attempt.[10-32] It is possible that some smokers who try ENDS will have a positive experience that may bolster their motivation and intention to quit (e.g., feeling healthier, managing cravings, reducing cigarettes per day), which appeared to be the case for some in this study. Although research has shown that reducing cigarette consumption is not sufficient to fully reduce health risks of smoking,[33-35] cigarette reduction may be a step towards quitting for individuals who have

For peer review only

been unable to stop abruptly. Some research suggests that a cut-down-to-quit strategy that is guided on a schedule may yield similar outcomes as abrupt quitting;[31,36,37] however, cutting down to quit has been found to be less effective in real-world samples.[38] In the present study, it was uncertain how aware participants were of the importance of completely quitting combustible tobacco. Given the number using a cut-down-to-quit strategy, this represents an important area for future research. Additionally, varying reasons and methods for using ENDS, varying experiences with using ENDS while quitting smoking, and changes in ENDS use from registration to the one month interview highlight that the concept of "dual use" of ENDS and cigarettes is not unidimensional. Future research is important to examine how patterns of dual use change over time, particularly during different phases of a smoker's quit process, taking into account current reasons for use. For example, using ENDS to prevent relapse with some brief smoking lapses may need to be viewed differently than long-term use of ENDS to cut down on smoking with no plans to quit smoking completely.

This study is subject to at least five limitations. First, the findings from this small sample may not generalize to all ENDS users. Second, the sample may also include more ENDS "treatment failures" than in the general population; if smokers had successfully quit using their ENDS device, they could have been less likely to call the quitline for assistance.[7] Third, most callers had completed one quitline call, and some had a limited memory of the call. Interviewing callers after they had an opportunity to complete more calls could yield different information. Fourth, it was not possible to fully account for the type of ENDS device used, use topography, or proficiency/experience as a user. Given that these characteristics can impact nicotine delivery,[39-40] these factors may have influenced preferences for use of ENDS versus FDA-approved cessation medications for quitting smoking. Finally, it was unclear if timing of the interviews

For peer review only

(e.g. New Year and holidays) may have led to delayed quit dates, or if that was part of the quitting process for individuals in this sample.

In conclusion, in this sample of 40 ENDS users who contacted a state quitline for help quitting smoking, some ENDS users had confusion or misinformation about ENDS, FDA-approved cessation medications, nicotine, and the relative harm of these products. ENDS were being used in ways that were unlikely to help with quitting smoking, as well as in ways that may potentially facilitate quitting smoking. These findings suggest that quitlines have a unique opportunity to educate a significant number of ENDS users and to help them create a coordinated quit plan most likely to result in completely quitting combustible tobacco. These findings also suggest important avenues for future research. Strategies for educating smokers about ENDS and, if necessary, changing inaccurate beliefs about products warrant development and testing. Additionally, future research could examine whether use of cut-down-to-quit strategies and relapse experiences are different for individuals who use ENDS during their quit process. Finally, for quitline callers who plan to use ENDS as part of their quit attempt, research is warranted to determine whether certain information about ENDS or behavioral support from the quitline may improve callers' success with quitting smoking.

For peer review only

FOOTNOTES

Acknowledgements: The authors would like to thank and acknowledge Erica Salmon and Kristina Muramoto for coding interviews, Lacy Brame, MS and Dana Mowls, MPH for conducting the participant interviews, and Susan Zbikowski, PhD and Ann Malarcher, PhD for input on the study design.

Competing Interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: KV and BM report funding from Centers for Disease Control and Prevention during the conduct of the study and are employees of Optum (formerly Alere Wellbeing, Inc.), the provider of quitline services for participants in this study; LB reports grants from Oklahoma Tobacco Settlement Endowment Trust during the conduct of the study; no other relationships or activities that could appear to have influenced the submitted work.

Funding: This project was funded in part by Centers for Disease Control & Prevention Contract #200-2014-M-60619 and the Oklahoma Tobacco Settlement Endowment Trust. The findings and conclusions in this report are those of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention.

Contributions: KV, LB, GS, and BM contributed to the interview guide and coding methodology. LB oversaw participant interviews. KV and BM (with two other coders) coded interviews. KV led the analysis of coded data, performed the literature review, and took primary responsibility for writing the paper. All authors contributed to the conceptualization of the study,

For peer review only

study design, interpretation of data, and the preparation of the manuscript. All authors approved the final version of the manuscript.

Data sharing: no additional data available.

For peer review only

REFERENCES

1. Regan AK, Promoff G, Dube SR, et al. Electronic nicotine delivery systems: adult use and awareness of the 'e-cigarette' in the USA. *Tob Control* 2013;22(1):19-23. doi:10.1136/tobaccocontrol-2011-050044.
2. King BA, Patel R, Nguyen KH, et al. Trends in awareness and use of electronic cigarettes among US adults, 2010-2013. *Nicotine Tob Res* 2015;17(2):219-227. doi:10.1093/ntr/ntu191.
3. Schoenborn MPH, Gindi RM. Electronic Cigarette Use Among Adults: United States, 2014. NCHS Data Brief 2015; 217:1-8.
4. North American Quitline Consortium (NAQC) (2015). Results from the 2013 NAQC Annual Survey of Quitlines Webinar Presentation, North American QuitlineConsortium (NAQC), Phoenix, Ariz, USA, 2013. Accessed July 23, 2015: http://www.naquitline.org/?page=2013Survey
5. Vickerman KA, Carpenter KM, Altman T, et al. Use of electronic cigarettes among state tobacco cessation quitline callers. *Nicotine Tob Res* 2013;15(10):1787-1791. doi:10.1093/ntr/ntt061.
6. Vickerman KA, Beebe L , Schauer G, et al. *ENDS Users Who Call Quitlines: Surveillance Data and Research Findings.* 2015 Annual North American Quitline Consortium (NAQC) Conference; 2015: Atlanta, GA.
7. McRobbie H, Bullen C, Hartmann-Boyce J, et al. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev* 2014;12:CD010216. doi:10.1002/14651858.CD010216.pub2.
8. Grana R, Benowitz N, Glantz SA. E-cigarettes: a scientific review. *Circulation* 2014;129(19):1972-1986. doi: 10.1161/CIRCULATIONAHA.114.007667.
9. Bullen C, Howe C, Laugesen M, et al. Electronic cigarettes for smoking cessation: a randomised controlled trial. *Lancet* 2013;382(9905):1629-1637. doi: 10.1016/S0140-6736(13)61842-5.
10. Caponnetto P, Campagna D, Cibella F, et al. EffiCiency and Safety of an eLectronic cigAreTte (ECLAT) as tobacco cigarettes substitute: a prospective 12-month randomized control design study. *PLoS One* 2013;8(6):e66317. doi:10.1371/journal.pone.0142287.
11. Bernstein SL. Electronic cigarettes: more light, less heat needed. *Lancet Respir Med* 2016;4(2):85-87. doi: 10.1016/S2213-2600(16)00010-2.
12. Farsilinos KE, Kistler KA, Gillman G, et al. Evaluation of Electronic Cigarette Liquids and Aerosol for the Presence of Selected Inhalation Toxins. *Nicotine Tob Res* 2015;17(2):168-174. doi:10.1093/ntr/ntu176.
13. Fagerstrom K, Etter JF, Unger JB. E-cigarettes: a disruptive technology that revolutionizes our field? *Nicotine Tob Res* 2015;17(2):125-126. doi:10.1093/ntr/ntu240.
14. Nash CM, Vickerman KA, Kellogg ES, et al. Utilization of a Web-based vs integrated phone/Web cessation program among 140,000 tobacco users: an evaluation across 10 free state quitlines. *J Med Internet Res* 2015 Feb 4;17(2):e36. doi:10.2196/jmir.3658.
15. Bandura A. Social Cognitive Theory. In: Annals of child development, Vol 6. Six theories of child development. R. Vasta (Ed). Greenwich, CT: JAI Press; 2015:1-60.
16. US PHS Guidelines. Treating tobacco use and dependence: 2008 update. Rockville, MD: U.S. Department of Health and Human Services; Public Health Services; 2008.
17. AWI (2014) Alere Position Statement on E-Cigarettes. Checking on the best way to cite this document.
18. King N. Using templates in the thematic analysis of text. In: Cassell C, Symon G, eds. Essential Guide to Qualitative Methods in Organization Research. London: SAGE Publications 2004:256-270.
19. Patton MQ. Qualitative Research & Evaluation Methods. 3rd edition. Thousand Oaks, CA: SAGE Publications 2001.
20. Sandelowski M. Whatever happened to qualitative description?. *Res Nurs Health* 2000;23(4):334-40.
21. MAXQDA, software for qualitative data analysis, 1989-2016, VERBI Software – Consult – Sozialforschung GmbH, Berlin, Germany.

For peer review only

22. Brown J, West R, Beard E, et al. Prevalence and characteristics of e-cigarette users in Great Britain: Findings from a general population survey of smokers. *Addictive Behaviors* 2014;39:1120-1125. doi:10.1016/j.addbeh.2014.03.009.
23. Barbeau AM, Burda J, Siegel M. Perceived efficacy of e-cigarettes versus nicotine replacement therapy among successful e-cigarette users: a qualitative approach. *Addict Sci Clin Pract* 2013;8:5. doi:10.1186/1940-0640-8-5.
24. Etter JF. Electronic cigarettes: a survey of users. *BMC Public Health* 2010;10:231 doi:10.1186/1471-2458-10-231.
25. Etter JF, Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011;106(11):2017-2028. doi:10.1111/j.1360-0443.2011.03505.x.
26. Etter JF, Bullen C. A longitudinal study of electronic cigarette users. *Addict Behav* 2014;39(2):491-494. doi:10.1016/j.addbeh.2013.10.028.
27. Foulds J, Veldheer S, Berg A. Electronic cigarettes (e-cigs): views of aficionados and clinical/public health perspectives. *Int J Clin Pract* 2011;65(10):1037-1042. doi:10.1111/j.1742-1241.2011.02751.x.
28. Siegel MB, Tanwar KL, Wood KS. Electronic cigarettes as a smoking-cessation: tool results from an online survey. *Am J Prev Med* 2011;40(4):472-475. doi:10.1016/j.amepre.2010.12.006.
29. Dawkins L, Turner J, Roberts A, et al. 'Vaping' profiles and preferences: an online survey of electronic cigarette users. *Addiction* 2013;108(6):1115-1125. doi:10.1111/add.12150.
30. Lindson-Hawley N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database Syst Rev* 2012;11:CD008033. doi:10.1002/14651858.CD008033.pub3.
31. Cinciripini PM, Lapitsky L, Seay S, et al. The effects of smoking schedules on cessation outcome: can we improve on common methods of gradual and abrupt nicotine withdrawal? *J Consult Clin Psychol* 1995;63(3):388-399.
32. Wagener TL, Meier E, Hale JJ, et al. Pilot Investigation of Changes in Readiness and Confidence to Quit Smoking After E-Cigarette Experimentation and 1 Week of Use. *Nicotine Tob Res* 2014;16(1):108-114. doi:10.1093/ntr/ntt138.
33. USDHHS. The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General. Atlanta, GA.: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
34. Bjartveit K, Tverdal A. Health Consequences of Smoking 1-4 Cigarettes per Day. *Tobacco Control* 2005; 14(5):315-20. doi:10.1136/tc.2005.011932.
35. Tverdal A, Bjartveit K. Health Consequences of Reduced Daily Cigarette Consumption. *Tobacco Control* 2006; 15(6): 472–80. doi: 10.1136/tc.2006.016246.
36. Lindson-Hawley N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. *Cochrane Database Syst Rev* 2012;11:CD008033. doi:10.1002/14651858.CD008033.pub3.
37. Beard E, McNeill A, Aveyard P, et al. Association between use of nicotine replacement therapy for harm reduction and smoking cessation: a prospective study of English smokers. *Tob Control* 2013;22(2):118-122. doi:10.1136/tobaccocontrol-2011-050007.
38. Schauer GL, Malarcher AM, Babb SD. Gradual reduction of cigarette consumption as a cessation strategy: prevalence, correlates, and relationship with quitting. *Nicotine Tob Res* 2015;17(5):530-538. doi:10.1093/ntr/ntu172.
39. Talih S, Balhas Z, Eissenberg T, et al. Effects of user puff topography, device voltage, and liquid nicotine concentration on electronic cigarette nicotine yield: measurements and model predictions. *Nicotine Tob Res* 2015;17(2):150-157. doi:10.1093/ntr/ntu174.
40. Davis B, Dang M, Kim J, et al. Nicotine concentrations in electronic cigarette refill and do-it-yourself fluids. *Nicotine Tob Res* 2015;17(2):134-141. doi:10.1093/ntr/ntu080.

For peer review only

Table 1. Demographics and Tobacco use Characteristics for Respondents as Reported at Registration (*N* = 40)

	N	%
Age - Mean ± (SD)	45.0 (14.1)	
Gender – Female	26	65.0
Education		
Less than high school	11	27.5
High school degree / GED	16	40.0
Some college/trade school or college/trade school degree	13	32.5
Race/Ethnicity		
White, non-Hispanic	29	72.5
Black or African American, non-Hispanic	5	12.5
American Indian or Alaskan Native, non-Hispanic	5	12.5
Other race, non-Hispanic	1	2.5
Health insurance status		
Uninsured	18	45.0
Medicaid	8	20.0
Commercial	8	20.0
Medicare	5	12.5
"Does not know"	1	2.5
Employment status - employed	19	47.5
Chronic condition[1]– one or more	21	52.5
Mental health condition[2] – one or more	25	62.5
Time to First Use of Tobacco (TTFU)		
Within 5 minutes	17	42.5
6 – 30 minutes	14	35.0
More than 30 minutes	6	15.0
Missing	3	7.5
Cigarette use per day (cpd) - Mean ± (SD)	16.1 (12.3)	
Number of years used tobacco – 20+ years	28	70.0
Annual Income		
Less than $10,000 per year	18	45.0
$10,000 - $25,000 per year	8	20.0
More than $25,000 per year	12	30.0
Missing	2	5.0

[1] Chronic conditions included Asthma, Chronic Obstructive Pulmonary Disease (COPD), Coronary Artery Disease (CAD), and Diabetes (Type II).

[2] Mental health conditions included attention deficit hyperactivity disorder (ADHD), anxiety disorder, bipolar, depression, gambling addiction, posttraumatic stress disorder (PTSD), schizophrenia, and substance use disorder.

For peer review only

Table 2. Current Tobacco and ENDS Use During Qualitative Interview at 1-Month Post-Registration (*N* = 40)

	N	%
Current ENDS use		
Every Day	10	25.0
Some days	15	37.0
Rarely	6	15.0
Not at all	9	22.5
Current tobacco use (not including ENDS)		
Within the last 24 hours	28	70.0
Within the last 7 days, but more than 24 hours ago	4	10.0
Within the last month, but more than 7 days ago	5	12.5
Within the last 3 months, but more than 1 month ago	2	5.0
Have you used NRT or cessation medications since registration 1 month ago?		
Yes	28	70.0
No	12	30.0
Current use of NRT or cessation medications[1]		
Yes	21	52.5
No	19	47.5
Current Dual Use of Products: Cigarettes, ENDS, and NRT or cessation medications[2]		
Cigarettes & ENDS	10	25.0
Cigarettes, ENDS, and NRT/Meds	9	22.5
Cigarettes & NRT/Meds	6	15.0
Cigarettes only	7	17.5
ENDS & NRT/Meds	4	10.0
ENDS only	2	5.0
NRT/Meds only	2	5.0

[1] Participant reported currently using NRT or a cessation medication, or if current use was unclear, participant discussed recent use of NRT or cessation medication (i.e., within the last 7 days).

[2] Definitions of current use: any cigarette use in the last 7 days, current every day or some days ENDS use (excludes rarely and not at all), and current NRT/meds use defined as described in table note 1.

For peer review only

Consolidated criteria for reporting qualitative research (COREQ): a 32- item checklist for interviews and focus groups

Developed from:
Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description
Domain 1: Research team and reflexivity Personal Characteristics	
1. Interviewer/facilitator	Which author/s conducted the interview or focus group? Pg 6.
2. Credentials	What were the researcher's credentials? *E.g. PhD, MD* Pg 1, Pg 6
3. Occupation	What was their occupation at the time of the study? Pg 6
4. Gender	Was the researcher male or female? Pg 6
5. Experience and training	What experience or training did the researcher have? Pg 6
Relationship with participants	
6. Relationship established	Was a relationship established prior to study commencement? Pg 5. No.
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.*g. personal goals, reasons for doing the research* Pg 5.
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. *Bias, assumptions, reasons and interests in the research topic* Pg 5.
Domain 2: study design Theoretical framework	
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? *e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis* Pg 7.
Participant selection	
10. Sampling	How were participants selected? *e.g. purposive, convenience,*

For peer review only

	consecutive, snowball Pg 5.
11. Method of approach	How were participants approached? e.*g. face-to-face, telephone, mail, email* Pg 5.
12. Sample size	How many participants were in the study? Pg 5.
13. Non-participation	How many people refused to participate or dropped out? Reasons? Pg 5.
Setting	
14. Setting of data collection	Where was the data collected? e.*g. home, clinic, workplace* Pg 6.
15. Presence of non-participants	Was anyone else present besides the participants and researchers? Pg 6.
16. Description of sample	What are the important characteristics of the sample? *e.g. demographic data, date* Pg 7, Pg 25.
Data collection	
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested? Pg 6-7.
18. Repeat interviews	Were repeat interviews carried out? If yes, how many? Pg 6-7.
19. Audio/visual recording	Did the research use audio or visual recording to collect the data? Pg 7.
20. Field notes	Were field notes made during and/or after the interview or focus group? Not explicitly discussed. Answers to some of the questions were recorded in Excel during the interview.
21. Duration	What was the duration of the interviews or focus group? Pg 7.
22. Data saturation	Was data saturation discussed?

For peer review only

	Pg 5.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction? No; not described as part of methods on pgs 5-7.
Domain 3: analysis and findings Data analysis	
24. Number of data coders	How many data coders coded the data? Pg 7.
25. Description of the coding tree	Did authors provide a description of the coding tree? Pgs 8-17. Not in the form of a table or figure. Codes identified for each content area are reported in each section of the results on pages 8-17 (e.g., descriptions of use, beliefs about products, strategies for incorporating ENDS in smoking cessation plans, role of the quitline).
26. Derivation of themes	Were themes identified in advance or derived from the data? Pg 7.
27. Software	What software, if applicable, was used to manage the data? Pg 7.
28. Participant checking	Did participants provide feedback on the findings? No; not described as part of methods on pgs 5-7.
Reporting	
29. Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.*g. participant number* Pgs 8-17.
30. Data and findings consistent	Was there consistency between the data presented and the findings? Yes. Pgs 7-17, 25-26.
31. Clarity of major themes	Were major themes clearly presented in the findings? Pgs 8-17.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes? Pgs 8-17.

For peer review only