

## PEER REVIEW HISTORY

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### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	Electronic nicotine delivery system (ENDS) use during smoking cessation: a qualitative study of 40 Oklahoma quitline callers
<b>AUTHORS</b>	Vickerman, Katrina; Beebe, Laura; Schauer, Gillian; Magnusson, Brooke; King, Brian

### VERSION 1 - REVIEW

<b>REVIEWER</b>	Jennifer Pearson Schroeder Institute for Tobacco Research and Policy Studies at Truth Initiative
<b>REVIEW RETURNED</b>	26-Jul-2016

<b>GENERAL COMMENTS</b>	<p>OVERALL - This manuscript presents data from qualitative interviews of 40 Quitline callers who used ENDS. Interviews focused on perceptions and use of ENDS and cessation medications during a quit attempt. The manuscript is a contribution to the literature on and describes the confusing landscape of products for smokers interested in quitting. I recommend publication, but have a few questions that I hope the authors will find useful for improving their manuscript.</p> <p>Stylistically, I recommend reviewing the manuscript for informal grammar (such as use of contractions outside of quotes) or instances of imprecise choice of words (such as referring to ENDS as "doing more to help with quitting" -- what do you mean by that exactly?). This isn't a required revision; however, as a reader, I was often distracted by the conversational style of the manuscript.</p> <p><b>INTRODUCTION</b> This section is appropriate and well done - no comments.</p> <p><b>METHOD</b> 1. Please give more information on how you chose the final sample size of 40. What kind of diversity (racial/ethnicity, age, type of device used) were you hoping to achieve? Why is this diversity important to the purpose of your research? Did you reach saturation? 2. How did you define "current" ENDS use? 3. How did you ascertain participants' type of ENDS (tank, cigalike, etc)? 4. Do you have any training text or a script that you could insert in the Methods to give the reader more information about how coaches were told to speak about ENDS? I could see how callers would be confused about ENDS if coaches had to walk the very thin line between not discouraging ENDS use but also telling callers that there was no evidence they were effective. That's a difficult message for a layperson to accurately interpret.</p>
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	<p><b>RESULTS</b></p> <ol style="list-style-type: none"> <li>1. What proportion of daily and non-daily ENDS users used tank systems?</li> <li>2. Table 2: Does "current tobacco use" include ENDS?</li> <li>3. Did participants report multiple reasons for use? Which one was most common?</li> <li>4. "One participant felt that ENDS caused him to smoke more, and a small number reported that ENDS did not change their smoking." Did participants tell you why they thought they smoked more/ENDS use did not change their behavior?</li> <li>5. Page 9, line 40 "breathing more easy or no problems" -- is "no problems" a typo? "More easy" = "easier"?</li> <li>6. Harm ranking - I'm not clear from the results what respondents were ranking. Were they supposed to chose (which is more harmful, cessation medication or ENDS?), or were they comparing ENDS and cessation medication to cigarettes? What's the comparator here?</li> <li>7. Misinformation about ENDS - did anyone say that they thought ENDS were more dangerous than cigarettes? Evidence strongly suggests that is a misperception as well.</li> <li>8. I really like the "Strategies for incorporating ENDS in smoking cessation plans" section - in my opinion, this is the most useful and novel data in the manuscript. However, some of the "adaptive" and "maladaptive" strategies could easily overlap. For example, anyone using the "adaptive" strategies could also use ENDS indoors (indeed, vapers claim this is a major "benefit" of ENDS use), or use them constantly throughout the day without thinking. The adaptive and maladaptive sections do not strike me as distinct quit strategies. Is there a better way to define these categories? Or, did you observe a real difference in how people talked about using ENDS as cessation aids, with the "adaptive" strategy individuals not reporting, for example, use in places where they could not smoke or deliberate use throughout the day (vs. automatic use)? Perhaps you could keep these categories but discuss how often these strategies were evident in the same person's experience. Or, perhaps you should rethink the name of the categories. (Is automatic use a "strategy"?) To be a little flip, these categories strike me as "behaviors cessation treatment specialists like" vs. "behaviors cessation treatment specialists don't like." What are you really trying to describe and categorize here?</li> </ol> <p><b>DISCUSSION</b></p> <ol style="list-style-type: none"> <li>1. How, if at all, do your data speak to the concept of "dual use" and how this behavior pattern should be measured and researched?</li> <li>2. How do you think the multiple utilities of ENDS vs. the single utility of cessation medication affect use of these products, if at all? Did people speak about this at all?</li> </ol>
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<b>REVIEWER</b>	Maria Cooper University of Texas School of Public Health (UTHealth), Austin Regional Campus U.S.A.
<b>REVIEW RETURNED</b>	11-Oct-2016

<b>GENERAL COMMENTS</b>	This study investigates US quitline callers' reasons for ENDS use as well as their beliefs about ENDS and the impact of ENDS on their quitting process. The article is well conceptualized and designed and importantly highlights areas for future research on ENDS and
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	<p>cigarette cessation. This manuscript would be strengthened by several points of clarification, primarily in the Methods section.</p> <p>Page 5: 40 participated and 65 were mailed letters. Does this mean that the other 15 did not respond, were not called, or refused to participate? Please clarify briefly.</p> <p>Page 5: Authors state that the sample size of 40 was “selected to ensure inclusion of diverse ENDS users.” Qualitative research often refers to data saturation (a point in data collection when interviews no longer reveal new information) to determine sample size. But authors don’t describe whether data saturation was reached. Please describe why or why not data saturation was used in determining sample size.</p> <p>Page 6: Please clarify: “callers without [private?] insurance and with Medicaid insurance ...”</p> <p>Page 6: Consider adding information on how the interview guide developed? Based on a particular theory? Or gaps in research / current knowledge of ENDS? Or another way?</p> <p>Page 7: Please elaborate on the Coding and Analysis section. The reader would benefit from more explanation or simply an example of the deductive codebook and the inductive codes (i.e., deductive codebook was made up of a priori codes which were hypothesized to appear, I’m assuming, and the inductive codes which I’m assuming were new codes that were developed after reviewing the data).</p> <p>Page 7: Please elaborate or clarify for the reader what “a constant comparative and descriptive approach” means</p> <p>Page 7: Results: Why did some receive 2 and other 8 week supply of NRT? Did this depend on insurance as well?</p> <p>Page 8: Please clarify: “25 were [current?] ENDS users and 21 were using cessation aid [currently?]”</p>
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**VERSION 1 – AUTHOR RESPONSE**

Reviewer: 1

Reviewer Name: Jennifer Pearson

OVERALL - This manuscript presents data from qualitative interviews of 40 Quitline callers who used ENDS. Interviews focused on perceptions and use of ENDS and cessation medications during a quit attempt. The manuscript is a contribution to the literature on and describes the confusing landscape of products for smokers interested in quitting. I recommend publication, but have a few questions that I hope the authors will find useful for improving their manuscript.

Stylistically, I recommend reviewing the manuscript for informal grammar (such as use of contractions outside of quotes) or instances of imprecise choice of words (such as referring to ENDS as "doing more to help with quitting" -- what do you mean by that exactly?). This isn't a required revision; however, as a reader, I was often distracted by the conversational style of the manuscript.

Authors’ response #1: We have reviewed the manuscript for informal grammar and unclear words and made relevant changes throughout the manuscript.

## INTRODUCTION

This section is appropriate and well done - no comments.

Authors' response #2: Thank you.

## METHOD

1. Please give more information on how you chose the final sample size of 40. What kind of diversity (racial/ethnicity, age, type of device used) were you hoping to achieve? Why is this diversity important to the purpose of your research? Did you reach saturation?

Authors' response #3: We aimed to include a range of ENDS users, particularly with regard to reasons for ENDS use (i.e., users reporting they were primarily using ENDS to quit cigarettes, to cut down on cigarettes, or for other reasons such as in places they cannot use combustible cigarettes). Based on previous quantitative data collected through the quitline, we anticipated some groups, such as people reporting they are using ENDS primarily in places they can't use combustible cigarettes, would be present in smaller numbers (Vickerman et al, 2015). We estimated that reaching a minimum of 40 would allow us to interview several ENDS users in each of these groups and have some diversity in terms of participant demographics, while still reaching saturation in themes. We strove to capture the gamut of reasons that quitline callers were using ENDS to increase the utility of our qualitative findings for informing education and treatment refinements for smokers who also use ENDS. Letter invitations were mailed out in batches based on participants' week of registration. We stopped mailing letters as interviewers agreed that saturation was reached and we were nearing our goal of 40 interviews. By attempting follow-up calls with all 65 participants who were mailed invitation letters, we achieved the 40 participant sample size.

To more clearly relay this approach in the manuscript, the following text was added: "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." (See page 5)

2. How did you define "current" ENDS use?

Authors' response #4: We selected "current" ENDS users based on their yes/no response to a standard quitline registration question that was already in use. When the ENDS registration question was first added in 2013, we were attempting to identify people who were using ENDS rather than people who had just tried ENDS once or twice (e.g., at that time we were hearing more about callers trying free samples in malls, etc). The wording of this question was changed after this study to provide a more objective assessment of ENDS use (i.e., use in the last 30 days).

To address the reviewer's comment, we added the exact wording of the question used to identify potential participants in the text: "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?");..." (See page 5)

3. How did you ascertain participants' type of ENDS (tank, cigalike, etc)?

Authors' response #5: At the time of registration, the following question was asked: "What type of e-cigarette do you currently use? Answer options: Cartridge, Disposable, Tank". We reported in the text: "33 reported using a tank system style ENDS". (See page 8)

4. Do you have any training text or a script that you could insert in the Methods to give the reader more information about how coaches were told to speak about ENDS? I could see how callers would be confused about ENDS if coaches had to walk the very thin line between not discouraging ENDS use but also telling callers that there was no evidence they were effective. That's a difficult message for a layperson to accurately interpret.

Authors' response #6: We agree that is a challenge with the protocol being used by coaches during the study. We did our best to succinctly summarize the key points of the protocol on ENDS. One of the purposes of this study was to assess what participants heard during and remembered from their conversations with coaches to determine if confusion was present. Guidance for coaches is available through longer documents and from ongoing group and individual supervision. Coaches do not use scripts to lead them through calls.

Given that the current length of the manuscript is already in excess of the journal's prescribed limits, no additional text has been added to the manuscript in response to the reviewer's comment.

## RESULTS

1. What proportion of daily and non-daily ENDS users used tank systems?

Authors' response #7: Overall, we only had 7 non-tank users at registration; the majority of our sample used tank systems. All but one of the daily ENDS users used tank systems. The majority of non-daily ENDS users also used tank systems.

We do already report: "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)..." Additionally, we have added to the text, "All but one of the daily ENDS users used tank systems." (See page 8).

2. Table 2: Does "current tobacco use" include ENDS?

Authors' response #8: Thank you for this question. No, "current tobacco use" does not include ENDS use. Participants were specifically asked about last cigarette or other tobacco use and were asked not to include ENDS.

To address this comment and avoid potential confusion, we clarified the text in Table 2 as follows: "Current tobacco use (not including ENDS)".

3. Did participants report multiple reasons for use? Which one was most common?

Authors' response #9: With regard to reasons for use reported at registration, participants were asked their primary reason for using ENDS using the following standard registration questions:

Are you currently using e-cigarettes to quit other tobacco, to cut down on other tobacco, or neither of these reasons?

If answer is Neither

Which of these best describes your use of e-cigarettes?

I use when I can't smoke/use other tobacco

I've tried e-cigarettes, but I'm not planning to continue using them

Other

We discussed reasons for ENDS use at the time of registration during the interview as well using similar questions. We then asked additional probing questions, as needed, to gain a better understanding of why participants were using ENDS when they enrolled in the program. The data

reported on pg. 8 provides these results (“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”); we added the “primarily” in the revised draft to make it clearer what we are describing with these results (See page 8). These conversations were focused on participant’s primary reasons for using ENDS, although we agree that participants could have multiple reasons for use. For example, some participants also discussed reasons they started using ENDS (e.g., quit smoking, cut down on smoking, recommendation from family or friend, due to health event or belief ENDS are healthier, seeing others use ENDS, trying something new, cost, for use when they cannot smoke, etc), but this was not a central focus of our coding or this paper.

4. "One participant felt that ENDS caused him to smoke more, and a small number reported that ENDS did not change their smoking." Did participants tell you why they thought they smoked more/ENDS use did not change their behavior?

Authors’ response #10: The participant who smoked more appeared to feel ENDS increased the urge to smoke. Most participants who said ENDS use did not change their behavior simply stated it didn’t work for them and/or they were still smoking. One noted they found it inconvenient to carry their ENDS device and “keep up with it” and preferred carrying cigarettes, which they could just throw away.

To address this issue in the manuscript, we’ve added more detail to the text in this section as follows: “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.” (See page 9)

5. Page 9, line 40 "breathing more easy or no problems" -- is "no problems" a typo? "More easy" = "easier"?

Authors’ response #11: Thank you for noting this. The text has been corrected to read as follows: “...positive health attributions or beliefs about ENDS (e.g., health benefits such as breathing easier and less coughing, perceiving ENDS are healthier than cigarettes),...”. (See page 10)

6. Harm ranking - I'm not clear from the results what respondents were ranking. Were they supposed to choose (which is more harmful, cessation medication or ENDS?), or were they comparing ENDS and cessation medication to cigarettes? What's the comparator here?

Authors’ response #12: We added clarifications in this section to explain that participants were ranking ENDS, NRT, and cigarettes from most to least harmful. All ranked cigarettes as the most harmful.

The text now reads: “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.” (See page 13)

7. Misinformation about ENDS - did anyone say that they thought ENDS were more dangerous than cigarettes? Evidence strongly suggests that is a misperception as well.

Authors’ response #13: In this sample, when explicitly asked to rank the three products, all ranked cigarettes as most harmful (see added text in authors’ response #12 above). Therefore, we

have not added any additional text to the manuscript to address this comment.

However, we did see some evidence of this misperception in responses to other questions or discussion topics. For example, in the 'Preferences for ENDS vs FDA-approved cessation medications for quitting smoking' section, we shared a quote that included, "I mean there's no evidence out there that proves that's [ENDS use] any better than actual smoking cigarette" (See page 12), suggesting the misperception you note was present in some participant's thought processes.

8. I really like the "Strategies for incorporating ENDS in smoking cessation plans" section - in my opinion, this is the most useful and novel data in the manuscript. However, some of the "adaptive" and "maladaptive" strategies could easily overlap. For example, anyone using the "adaptive" strategies could also use ENDS indoors (indeed, vapers claim this is a major "benefit" of ENDS use), or use them constantly throughout the day without thinking. The adaptive and maladaptive sections do not strike me as distinct quit strategies. Is there a better way to define these categories? Or, did you observe a real difference in how people talked about using ENDS as cessation aids, with the "adaptive" strategy individuals not reporting, for example, use in places where they could not smoke or deliberate use throughout the day (vs. automatic use)? Perhaps you could keep these categories but discuss how often these strategies were evident in the same person's experience. Or, perhaps you should rethink the name of the categories. (Is automatic use a "strategy"?) To be a little flip, these categories strike me as "behaviors cessation treatment specialists like" vs. "behaviors cessation treatment specialists don't like." What are you really trying to describe and categorize here?

Authors' response #14: Thank you. We agree that this is some of the most useful and novel data in the manuscript. We changed the word "strategies" to "behaviors" throughout the manuscript. The behaviors do overlap. We have made edits to make this clearer. Some individuals who reported using adaptive behaviors also reported maladaptive behaviors—these were not intended to be distinct and holistic quitting methods, but components of how ENDS were used during quitting.

We added these clarifications to the results section:

"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)." (See page 16)

We did not include anything about prevalence of the behaviors because these were all behaviors reported by participants in response to open-ended questions. We did not ask participants whether or not they used each of the strategies, thus we do not believe we have a good estimate of how often the strategies were evident, particularly given our small sample and qualitative focus.

## DISCUSSION

1. How, if at all, do your data speak to the concept of "dual use" and how this behavior pattern should be measured and researched?

Authors' response #15: To address the issue of dual use, we have expanded the Discussion section to include the following text:

"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.” (See page 21)

2. How do you think the multiple utilities of ENDS vs. the single utility of cessation medication affect use of these products, if at all? Did people speak about this at all?

Authors’ response #16: We agree that the multiple utilities of ENDS has the potential to impact how participants use and think about ENDS, particularly in relation to the typical single utility of cessation medications (which is standardly accompanied by recommendations for how to use the products for quitting). We did not find that participants directly verbalized how the multiple utilities of ENDS use might affect their use, but participants did express confusion about how to use ENDS and requested more information about ENDS. However, an explicit connection to the multiple utilities of ENDS was not provided by participants.

Some participants did discuss usage rules for NRT that were not discussed for ENDS, which likely relates to the multiple utilities of ENDS. We have added this sentence to the discussion to address this point: “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.” (See page 19).

Reviewer: 2

Reviewer Name: Maria Cooper

This study investigates US quitline callers’ reasons for ENDS use as well as their beliefs about ENDS and the impact of ENDS on their quitting process. The article is well conceptualized and designed and importantly highlights areas for future research on ENDS and cigarette cessation. This manuscript would be strengthened by several points of clarification, primarily in the Methods section.

Page 5: 40 participated and 65 were mailed letters. Does this mean that the other 15 did not respond, were not called, or refused to participate? Please clarify briefly.

Authors’ response #17: We continued to follow-up with all callers who were mailed invitation letters until all attempts were made. Twenty-five of the 65 participants did not complete an interview. We added the following sentence to the manuscript to clarify the reasons these ENDS users did not complete an interview: “Nineteen could not be reached after multiple attempts and six refused participation.” (See page 5)

Page 5: Authors state that the sample size of 40 was “selected to ensure inclusion of diverse ENDS users.” Qualitative research often refers to data saturation (a point in data collection when interviews no longer reveal new information) to determine sample size. But authors don’t describe whether data saturation was reached. Please describe why or why not data saturation was used in determining sample size.

Authors’ response #18: Please see author response #3 above.

Page 6: Please clarify: “callers without [private?] insurance and with Medicaid insurance ...”

Authors’ response #19: Callers without insurance were callers with no insurance (no private or



government health insurance or “uninsured”). To help clarify this point and the question below about amount of NRT provided, we changed the sentence to read, “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.” (See page 6)

Page 6: Consider adding information on how the interview guide developed? Based on a particular theory? Or gaps in research / current knowledge of ENDS? Or another way?

Authors’ response #20: The interview guide topics were developed to address current gaps in knowledge of how ENDS were being used and thought about by quitline callers. This is now more explicitly stated in the text as follows: “Topics discussed in the interviews were selected to investigate current gaps in knowledge about how ENDS were perceived and used by quitline callers.” (See page 7)

Page 7: Please elaborate on the Coding and Analysis section. The reader would benefit from more explanation or simply an example of the deductive codebook and the inductive codes (i.e., deductive codebook was made up of a priori codes which were hypothesized to appear, I’m assuming, and the inductive codes which I’m assuming were new codes that were developed after reviewing the data).

Authors’ response #21: Thank you for this recommendation. We have made additions to the Coding and Analysis section to provide more explanation about our coding process and analysis steps. Given the approach that was followed, coupled with length constraints, we do not believe that demarcating inductive versus deductive codes is warranted or will enhance the utility of the content for readers. This revised section now reads as follows:

“Template analysis was used to guide the coding process.<sup>18</sup> 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.<sup>19,20</sup> Analyses were conducted in MAXQDA.<sup>21</sup>” (See page 7)

Page 7: Please elaborate or clarify for the reader what “a constant comparative and descriptive approach” means

Authors’ response #22: Thank you for this recommendation. A constant comparative approach means that an iterative process was used to both code the interviews individually, and synthesize findings in comparison to other interviews, while focusing on similarities and differences in the interviewee context, perspective, and experience. We have edited our description in the text to increase clarity regarding our approach; please see author response #21 for changes made to this section.

Page 7: Results: Why did some receive 2 and other 8 week supply of NRT? Did this depend on insurance as well?

Authors’ response #23: Yes, the amount of NRT provided depended on a participant’s insurance type/plan. This matter has been clarified in the Methods as follows: “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.” (See page 6)

Page 8: Please clarify: “25 were [current?] ENDS users and 21 were using cessation aid [currently?]”

Authors’ response #24: The text in question has been clarified as follows: “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.” (See page 8)

#### VERSION 2 – REVIEW

<b>REVIEWER</b>	Maria Cooper University of Texas Health Science Center at Houston (UT Health), School of Public Health, Austin Regional Campus
<b>REVIEW RETURNED</b>	23-Jan-2017

<b>GENERAL COMMENTS</b>	The authors have addressed all of my comments adequately. I have no further comments or questions.
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