

Qualitative Study on Acute Nicotine Toxicity Warnings for E-Liquids: Moderator Guide
RESEARCH QUESTIONS (For Reference Only)

Secondary Research Questions-Addressed in Section 4.1: ENDS Users Handling and Storage of Liquid Nicotine

1. How do consumers refer to liquid nicotine? (e.g., liquid nicotine, e-liquid, vape juice, e-juice)?
2. Where do consumers store their ENDS products at home?
 - Are ENDS users with children in the household concerned about child accidental exposure to ENDS liquid?
 - Do consumers with children in the household handle or store their ENDS product to minimize risk of children accessing the product?
3. How do consumers handle their ENDS products?
 - Do consumers report taking any precautions when refilling their ENDS products?
4. Do consumers report unintended exposure to ENDS liquid?
 - What are potential scenarios of accidental exposure to liquid nicotine among ENDS users? Are they concerned about it? How often does it happen?

Primary Research Questions –Addressed in Section 4.2: ENDS Users Understanding and Feedback on Draft Electronic Nicotine Delivery Systems (ENDS) Labeling for Acute Nicotine Toxicity Warnings for E-Liquids (ANTWEL)

1. What information do people take away from the draft ANTWEL? Are they learning any new information?
2. Are certain ANTWEL statements or statement elements confusing to consumers?
 - What are the least confusing ways to talk about acute toxicity (e.g., fatal, poison, deadly, can kill you)?
 - Do statements that use the phrase 'by accident' confuse consumers?
 - Are statements that combine the Addiction Warning and ANTWEL Warning confusing to participants?
3. Which ANTWEL do consumers like the least?
4. Which approaches are the clearest for conveying specific ANTWEL content:
 - What are the clearest terms for describing the *hazard*? (e.g., e-liquid, this product, nicotine)?
 - What are the clearest ways to inform consumers of the ways e-liquid can pose acute toxicity or harm (e.g., routes of exposure, harm to children)?
 - What are the clearest ways to inform consumers of what to do in case of accidental contact (e.g., call Poison Control Center, seek medical help)?
5. What are consumers' reactions to the WARNING vs DANGER signal words?

Questions regarding consumer reactions to draft ANTWEL for reference only (addressed in 4.3)

1. Do consumers find icons/symbols helpful in understanding the ANTWEL (with/without text)?
2. Do consumer believe that the use of colors in the ANTWEL would help to increase the label's visibility?
3. Do consumers report any issues with legibility for warnings based on proportion of principal display panels (30% vs 50%)?
4. Do consumers report any issues with legibility for warnings based on font size?
5. Do consumers read both the Addiction and ANTWEL statements when they are presented side-by-side in one label? Do consumers find the information confusing?

6. Do consumers believe that they would read or pay attention to information found in secondary packaging (e.g., box enclosing the products and inserts/onserts) in real-world settings?

1. MODERATOR INTRODUCTION (5 minutes)

Welcome and thank you for participating in today/tonight's discussion. My name is _____ . You have been asked to participate in today/tonight's discussion because you use or have used electronic nicotine products such as e-cigarettes, vape pens, mods, and hookah pens. Today I would like to get your reactions to some labels that might be found on these products in the future. Before we begin, I want to go over a few ground rules for our discussion tonight, which will last about an hour.

- Your participation is voluntary and you have the right to not answer any question or withdraw from the study at any time.
- If at any time you are uncomfortable with my questions, you can choose not to answer. Just let me know that you prefer not to answer.
- Everything we discuss today will be kept private to the extent allowable by law. Your name and contact information, which only the study staff knows, will not be given to anyone else, and no one will contact you after this discussion is over. [youth groups: nothing you say here will be shared with your parent or guardian]
- Tonight's discussion will be audio-recorded. The recordings will help me write the final report and will be kept in a secure location and then destroyed at the end of the study. No names will be mentioned in the final report created from our discussion.
- Behind me is a one-way mirror. Behind that are some of my colleagues. We are also video streaming our group discussion for some colleagues who couldn't be here. They're watching to make sure that I ask you all the questions I have for you today. Near the end of our conversation, I'm going to go into the back and see if they have any last-minute questions for you.
- Most importantly, there are no right or wrong answers. I want to know your opinions. I do not work for the people sponsoring this research and I didn't create anything we are going to look at, so don't hold back on giving me your honest opinions.
- I'm not a medical doctor or an expert on smoking or tobacco, so I can't answer specific questions about those topics.
- Please silence your cell phones.
- Do you have any questions before we begin?

2. WARM-UP/ICE BREAKER (5 minutes)

Names: Everyone introduces themselves.

Icebreaker: What would you be doing if you were not here?

3. OVERVIEW OF DISCUSSION

The only tobacco products we'll be talking about today are electronic nicotine products such as e-cigarettes, vape pens, mods, tanks, and hookah pens.

You're all here tonight because you reported that you use some sort of electronic nicotine product. These products go by different names and are battery-powered. They typically use a nicotine liquid, although the amount of nicotine can vary and some may not contain any nicotine at all. During our discussion, you'll hear me use the term 'e-cigarette' or 'e-cig', and when I do, I'm referring to this whole group of products . It's just easier if I stick to one term I can use. However, you can use whatever term you're used to - and in fact, I'd prefer you talk about it however you normally do.

General Probes – Apply throughout:

- If topic moves to other tobacco products - Remind participants that in this discussion, we are asking them to only focus on ENDS products.

4. FOCUS GROUP DISCUSSION

4.1 DISCUSSION OF E-LIQUID TERMINOLOGY AND ACCIDENTAL EXPOSURE TO E-LIQUIDS (~15 minutes)

1. *Think of what you pour into your or e-cigarette when you refill it. Or, think of what is in cartridges that you might replace in your e-cigarette. What do you call this substance?*
[MODERATOR SHOWS PARTICIPANTS A BOTTLE CONTAINING E-LIQUID AND CARTRIDGES/CARTOMIZERS]. *What would you call the stuff that is in the bottle or in the cartridge?*

Additional Probes:

- (if no one spontaneous brings up 'e-liquid'): *If you heard someone referring to this as 'e-liquid,' would you understand what he or she was referring to?*

[Transition]: *Ok, so you mentioned a few different terms... for our discussion today, I'm going to refer to this as e-liquid.*

2. *Where do you normally keep or store your e-liquid/cartridges when you're not using it/them? Why do you keep them there?*
[FOR ADULT CARTRIDGE USERS, PROBE ON CARTRIDGES. FOR ADULT OPEN ENDS USERS, PROBE ON E-LIQUID. FOR YOUTH, ASK WHERE THEY KEEP E-LIQUID AND/OR CARTRIDGES]
3. *When you refill your e-liquid or replace the cartridge, walk me through the steps that you take.*
 - *How do you usually handle your e-liquid?*
4. *Have you ever accidentally gotten e-liquid on your skin or eyes? Or maybe accidentally swallowed it?*
 - o *If yes, can you describe what happened?*
 - o *What would you have done differently to avoid this?*

4.2DISCUSSION OF ANTWEL ON CARDSTOCK (25 minutes)

4.2A DISCUSSION OF INDIVIDUAL ANTWEL ON CARDSTOCK

I am now going to show you several warning statements that might be used in the future on labels for e-cigarettes or e-liquid containers or cartridges. These statements are supposed to warn people who see them about the potential risks of e-liquid. All of these statements are true. For each statement, I will ask you a few questions to get your thoughts about it. Try not to compare them as we go – we will do that at the very end.

NOTE TO MODERATOR: IF PARTICIPANTS REMARK THAT THE CONTAINERS WOULD BE TOO SMALL TO LEGIBLY DISPLAY THE STATEMENTS IN 4.2A, TELL PARTICIPANTS “I know that some of these statements are long and might be tough to put on a small container of e-liquid. Try not to consider how it would fit on a specific container for right now– I’d like you to concentrate on the words.”

[EACH FOCUS GROUP WILL BE EXPOSED TO 6 TOTAL CARDSTOCK STIMULI. MODERATOR SHOWS WARNINGS ONE AT A TIME. THE MODERATOR DISPLAYS EACH STATEMENT ON A BOARD IN FRONT OF THE ROOM AT 50 PT FONT (EXCEPT FOR 36 PT FONT AND 20 PT FONT FOR THE SECOND-TO-LAST AND LAST CARDSTOCK STIMULI). REPEAT OF THE FOLLOWING ITEMS FOR EACH WARNING STATEMENT. BE SURE TO FOCUS PARTICIPANTS ON THE CONTENT AND WORDING OF THE STATEMENTS, NOT WHETHER THEY WILL FIT ON PRODUCTS OR GRAPHICS THAT SHOULD GO WITH THEM/NOT GO WITH THEM].

GROUP DISCUSSION ON EACH WARNING STATEMENT ON CARDSTOCK

1. *Overall, what are your thoughts about this warning statement? Do you like it, not like it? Why?*
2. *Was there any information in this statement that was new or surprising to you? Which part?*
3. *In this statement, what was confusing, unclear, or hard to understand?*
4. *Which part of the statement is the most useful or informative? Why?*
5. *Are there any words or parts of this statement that you would take out or do not think are needed?*

[REPEAT ITEMS 1-6 EXERCISE FOR EACH OF THE 6 CARDSTOCK STIMULI]

4.2B COMPARATIVE ASSESSMENT OF ANTWEL ON CARDSTOCK

[SHOW ALL 6-7 CARDSTOCK STIMULI ON THE BOARD IN FRONT OF THE GROUP. ALSO, ASK PARTICIPANTS TO REFER TO LAST PAGE OF WORKBOOK THAT HAS ALL 6 CARDSTOCK STIMULI]

1. Now I want you to look at the all the statements on the last page. These are all of the ones you've looked at so far:

- Please circle the statement that was the best at letting you know the hazard or danger? [ask for which statement and reasons why]
- Please put an X next to the statement that was the best at showing different ways in which e-liquid might be harmful? [ask for which statement and reasons why]
- Please put the letter C next to the statement that was the best at telling you what to do in case you come in contact with e-liquid? [ask for which statement and reasons why]
- Last, go ahead and cross out the statement that you liked the least. [ask for which statement and reasons why]

2. Some of these statements said "DANGER" and some said "WARNING". What are some differences between a "danger" and a "warning"? Is one more likely to get your attention? Which one and why?

4.3 DISCUSSION OF ANTWEL ON ACTUAL PRODUCTS

4.3A DISCUSSION FOR SECONDARY PACKAGING FOR BOXES (8 minutes)

TRANSITION: I am now going to show you several warning labels that might be used in the future on electronic nicotine products. Some of these have the statements we just discussed. For each warning label, I will ask you a few questions to get your thoughts about it. Try not to compare them as we go – we will do that at the very end. Please just focus on the WARNING label when answering the question, not on the bottle or the rest of the label or anything else.

[EACH FOCUS GROUP WILL BE EXPOSED TO 4 SECONDARY PACKAGING LABELS FOR BOXES. MODERATOR SHOWS LABELS DISPLAYED ON BOXES ONE AT A TIME, REPEAT QUESTIONS/PROBES FOR EACH SECONDARY PACKAGING LABEL. EACH PARTICIPANT WILL HAVE HIS/HER OWN BOX TO VIEW]

1. Overall, what are your thoughts about this warning label? Do you like it, not like it? Why?

2. What parts of the warning label helped to get your attention?

- Icons/symbols
- Colors
- 30% vs. 50% of Label

3. Do you think you would take the time to read this label if it was found on a box for e-liquids or cartridges? Why or why not?

[AFTER ALL PARTICIPANTS HAVE VIEWED ALL 4 SECONDARY PACKAGING LABELS ON BOXES, FOR PARTICIPANTS WHO VIEW STIMULI 4B AND 5B, ASK]

Both of these labels have information about different things that can happen if you use e-liquid. One thing is related to addiction (point to content for Addiction warning) and the other thing is related to poisoning (point to content for ANTWEL).

5. Between these two labels, which one did you think did the best job in providing information about both addiction and poisoning? Why?

4.3B FOR PRIMARY PACKAGING FOR E-LIQUID BOTTLES (5 minutes)

TRANSITION: *I am now going to show you some warning labels that might be used in the future on labels found on e-liquid bottles. For each warning label, I will ask you a few questions to get your thoughts about it. Try not to compare them as we go – we will do that at the very end.*

[EACH FOCUS GROUP WILL VIEW 2 PRIMARY PACKAGING FOR E-LIQUID BOTTLES. MODERATOR SHOWS LABELS ONE AT A TIME, REPEAT ITEMS FOR EACH PRIMARY PACKAGING LABEL. EACH PARTICIPANT WILL HAVE HIS/HER OWN BOTTLE TO VIEW]

1. Overall, what are your thoughts about this warning label? Do you like it, not like it? Why?
2. On this warning label, what was confusing, unclear, or hard to understand?
3. Do you think you would take the time to read the warning label if it was found on a bottle of e-liquid? Why or why not?

4.3C FOR INSERTS/ONSERT (5 minutes)

TRANSITION: *“Next, we will look at some warning statements you’d find on a piece of paper insert inside a box of cartridges or a tag hanging on a bottle of e-liquid.” For each statement, I will ask you a few questions to get your thoughts about it. Try not to compare them as we go – we will do that at the very end.*

[MODERATOR PRESENTS THE PARTICIPANTS WITH THE BOXES WITH THE INSERTS IN THE BOX, OR WITH E-LIQUID BOTTLES WITH THE ONSERT/TAG. PARTICIPANTS ARE INSTRUCTED TO REMOVE THE INSERT FROM THE BOX AND THEN TO READ INSERT. REPEAT ITEMS FOR EACH SECONDARY PACKAGING LABEL. EACH PARTICIPANT WILL HAVE HIS/HER OWN INSERT/ONSERT TO VIEW]

1. Overall, what are your thoughts about this warning label? Do you like it, not like it? Why?
2. On this warning label, what was confusing, unclear, or hard to understand?
3. Do you think you would take the time to read this label if it was found inside the packaging/box (ASK FOR INSERTS)/ on a bottle of e-liquid (ASK FOR ONSERT/TAG)? Why or why not?

5. CLOSING (1 minute)

That concludes the questions I have for you. Let me check in the back to see if there are any additional questions they have for you.

[RETURN TO ROOM TO ASK QUESTIONS FROM OBSERVERS; IF NO QUESTIONS COMPLETE CLOSING]

I would like to thank you for coming here today and participating in this discussion. This research was sponsored by the Food and Drug Administration, also known as the FDA. FDA would like to thank you for sharing your opinions as they will be very useful in helping them to understand people's reactions and thoughts about the tobacco products we have talked about. If you want to get more information on the health effects of vaping there is more information on the FDA website at fda.gov/tobacco. In addition, we have handouts with additional information about the potential risks of nicotine exposure if you would like to take one home.