The Impact of Oral Ethanol and Vaped Ethanol on the Evaluation of Impairment

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HM20018402/ NCT04522973

Initial approval date by VCU IRB: 6/25/2020, Last amendment:

9/5/2024

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   E-cigarettes have become very popular in the US among adults and youth. E-cigarettes typically contain nicotine along with flavors and vehicles (for example, propylene glycol and vegetable glycerin), but they can also contain other drugs, such as ethanol.

   A survey of the e-liquids in our research group's inventory alone contained a range of ethanol concentrations, from 0.7 to 206 mg/mL. Nearly 4% of the samples contained ethanol concentrations > 100 mg/mL (17). Another research team assessed 31 commercially available e-liquids and found the highest concentration of ethanol was 23.5% or 235 mg/mL (18). Ethanol in e-liquids could be used as a vehicle for flavorants, as a thinning agent for the e-liquid, or as a pharmacologically active ingredient (17,18,19). Evaluation of volatile chemicals in the e-liquids and aerosolized from e-liquids showed ethanol in both the e-liquid and the aerosol.

   "Chain vaping" is an e-cigarette use behavior identical in practice to chain smoking and is well documented in e-cig user forums. Some have described vaping an entire day, either passively or actively, as a cigarette smoker does. Some discuss vaping "hard" for 10-15 minutes, some consume 10-20 ml per day, and some advice as to maximizing battery life and coil replacement for others who chain vape (32,33). A 10 ml per day vaping habit, if consuming a product that is 20% ethanol, would be inhaling as much as 1.6 g of ethanol. Vaping ethanol as a way to get drunk without the calories is also commonly debated in forums, and a cautioned activity (34). Even though inhaling ethanol happens over a longer course of time than drinking ethanol, potentially mitigating some effects of the ethanol, it is not known definitively. A single published study evaluated the impact of vaping ethanol (23.5%) on subjective drug effects, BAC, and urine ethyl glucuronide (EtG). While they allowed for both directed puffing (10 puffs) and ad lib puffing, they demonstrated zero impact to subjective drug effects, significant change in dexterity performance, and 15% of the participants had detectable EtG / EtS in the urine after ad lib puffing (no plasma ethanol was detected after the 10-puff use period).They concluded that increased risk may be an issue with vaping ethanol without a subject aware of his/her level of impairment (18). Limitations to this study include (i) participants were allowed to ad lib vape, meaning that the investigators were unable to record how much ethanol was consumed in each puff; (ii) they did not use impairment techniques relevant to or understood by law enforcement (i.e. Standardized Field Sobriety Test), and (iii) the dexterity performance conclusion could be the result of a learned performance as opposed to being impacted by impairment. It was also not demonstrated in the manuscript that they evaluated the wait period between vaping and the preliminary breath test.

   References:

   17. Poklis, J., Wolf, C., and Peace, M. (2017) Ethanol concentration in 56 refillable electronic cigarettes liquid formulations determined by headspace gas chromatography with flame ionization detector (HS-GC-FID). Drug Test Anal, 9(10), 1637-1640.
   18. Valentine, G., Jatlow, P., Coffman, M., Nadim, H., Gueorguieva, R., and Sofuoglu, M. (2016) The Effects of Alcohol-Containing E-Cigarettes on Young Adult Smokers. Drug Alcohol Depend, 159, 272-276.
   19. (2017) 5 Ways To Make E-Juice Thinner. Vape Passion. https://www.vapepassion.com/ways-to-make-ejuice-thinner/. Accessed April 17, 2018.
   32. (2017) How Much Do You Vape Daily? E-CigaretteForum. https://www.e-cigarette-forum.com/threads/how-much-do-you-vape-daily.810453/. Accessed April 15, 2018.
   33. (2016) What's your favorite setup for chain vaping? E-Liquid Recipes. http://forum.e-liquid-recipes.com/t/whats-your-favorite-setup-for-chain-vaping/84369. Accessed April 15, 2018.
   34. (2013) Smoking Alcohol: The Dangerous Way People Are Getting Drunk. Time Magazine. http://healthland.time.com/2013/06/05/smoking-alcohol-the-dangerous-way-people-are-getting-drunk/. Accessed April 15, 2018.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   This study is designed to evaluate whether or not vaping ethanol from e-cigarettes affects the pharmacokinetics of ethanol, alone or in combination with oral ethanol consumption. The purpose of this study is to determine whether or not ethanol-containing e-cigarettes impact ethanol breath tests, field sobriety tests, ethanol metabolites and biomarkers of inflammatory response and oxidative stress in oral fluid, urine, and plasma, with and without oral ethanol administered.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The aim of this study is to assess the interaction between oral and vaped ethanol on blood ethanol levels, breath tests, the standardized field sobriety test (SFST), ethanol metabolites and biomarkers of inflammatory response and oxidative stress in oral fluid, urine, and plasma, and a subjective assessment of ethanol's effects.

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   The benefits of this research are of a scientific nature, which will specifically inform and potentially impact the criminal justice sector in addition to the general societal understanding of the effects of ECIGs. In particular, the use of ECIGs has become increasingly popular, with some liquids containing ethanol. There is significant lack of information about ECIGs and vaping ethanol. It is not known if vaping ethanol will impact the field sobriety test performed at DUI stops. It is not known if vaping ethanol will impact the tests measuring impairment by the walk-and-turn, the one-legged stand, or horizontal gaze nystagmus. Additionally, it is not known if vaping will interfere with the breath test, which requires a 15-20 minute observed wait period before blowing into the device. The results of this study will inform criminal justice practice, to include court testimony, and policing protocols. It will also inform future work regarding the physiological and subjective effects of ECIG use in e-cigarette users.

5. * **Describe any potential for direct benefits to participants in this study:**
   None.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
   There is no potential direct social impact of this study.

7. **Upload a supporting citation list if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Peace CITI	MRPeace CITI Refresher Certificate.pdf	0.01	9/5/2024 2:33 PM	Alison Breland	Other	Yes
View	TelegRAM advertisement	VCU TelegRAM ad.docx	0.01	9/11/2023 1:44 PM	Melody Falter	Recruitment/Advertising	Yes
View	Additional advertisements - Facebook/Instagram	Ethanol #2 facebook_instagram ads 9.11.2023_MF.docx	0.01	9/11/2023 1:43 PM	Melody Falter	Recruitment/Advertising	Yes
View	Advertisement #2 - Flyer	Ethanol 2 Flyer (1).png	0.01	9/11/2023 12:47 PM	Melody Falter	Recruitment/Advertising	Yes
View	Letter regarding data breach	Breach Notification Template ethanol study #2 for IRB submission.docx	0.01	7/27/2023 12:07 PM	Alison Breland	Study reminders/communications	Yes
View	Transportation form	Transportation form_CHANGES ACCEPTED 7.13.2023.docx	0.05	7/13/2023 11:29 AM	Alison Breland	Other	Yes
View	Website study description	Study description for website CHANGES ACCEPTED 7.13.2023.docx	0.05	7/13/2023 11:28 AM	Alison Breland	Recruitment/Advertising	Yes
View	Consent form	E2_ICF_Ethanol_changes ACCEPTED 6.9.2023.pdf	0.22	6/22/2023 2:21 PM	Alison Breland	Consent/Assent/Information Sheet	Yes
View	Phone, e-mail, texting scripts	E2_Phone, e-mail, texting scripts_changes ACCEPTED 6.9.2023.docx	0.13	6/9/2023 2:41 PM	Ashlee Sawyer	Recruitment/Advertising	Yes
View	ICF voice over ppt	Ethanol Part 2_ Virtual Consent_revised 5.19.2023.pptx	0.04	6/9/2023 2:40 PM	Alison Breland	Consent/Assent/Information Sheet	Yes
View	Advertisement	ECIG ad for ethanol study 21-55.png	0.01	5/19/2023 11:40 AM	Alison Breland	Recruitment/Advertising	Yes
View	Additional questions for police officer	Additional questions for police officer administering SFST and PBT during sessions.docx	0.01	5/19/2023 10:41 AM	Alison Breland	Research Measure	Yes
View	BP results info	BP results info 1.30.2023.docx	0.01	1/30/2023 3:35 PM	Alison Breland	Other	Yes
View	COVID-19 questions (retired in HM20018402_Ame5)	No longer using.docx	0.02	1/27/2023 1:22 PM	Alison Breland	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Screening Measure	E2_BaselineSurvey_changes accepted 6.9.2022.docx	0.07	6/9/2022 3:09 PM	Ashlee Sawyer	Research Measure	Yes
View	Biochemical Results Record Sheet	Biochemical Results changes accepted 6.7.2022.docx	0.03	6/7/2022 10:42 AM	Ashlee Sawyer	Research Measure	Yes
View	Additional driving and memory VAS items	Additional driving and memory VAS items.docx	0.01	4/11/2022 11:09 AM	Alison Breland	Research Measure	Yes
View	AUDIT Questionnaire	No longer using 9.29.2021.docx	0.02	9/29/2021 2:26 PM	Ashlee Sawyer	Research Measure	Yes
View	DSMP	DSMP ethanol study 2.docx	0.01	6/14/2020 6:16 PM	Alison Breland	Other	Yes
View	CSTP Registry Consent and Screening Questions	CSTP registry and consent questions 4.14.2020 current items.docx	0.01	5/9/2020 8:23 AM	Alison Breland	Consent/Assent/Information Sheet	Not Applicable
View	Breland CV	abbCV_updated 3.25.2020.doc	0.01	5/9/2020 8:16 AM	Alison Breland	CV/Biosketch	Yes
View	Pre-Session Checklist	E2_Pre-session checklist_04.03.2020.docx	0.01	5/7/2020 8:32 PM	Ashlee Sawyer	Research Measure	Yes
View	Respiratory Symptoms Questionnaire	E2_Pre-Session Symptoms Questionnaire_05072020.docx	0.03	5/7/2020 8:31 PM	Ashlee Sawyer	Research Measure	Yes
View	Privacy Certificate	Peace Privacy Certificate 032519 ABB_Ethanol2.pdf	0.01	1/15/2020 1:12 PM	Ashlee Sawyer	Other	Not Applicable
View	SFST Procedures	SFST_Procedures.pdf	0.01	1/13/2020 10:51 AM	Ashlee Sawyer	Research Measure	Yes
View	SHAS Questionnaire	SHAS Questionnaire.docx	0.01	1/13/2020 10:48 AM	Ashlee Sawyer	Research Measure	Yes
View	GLMS Questionnaire	gLms original.docx	0.01	1/13/2020 10:47 AM	Ashlee Sawyer	Research Measure	Yes
View	Labeled Hedonic Scale	Ethanol - LHS.docx	0.01	1/13/2020 10:47 AM	Ashlee Sawyer	Research Measure	Yes
View	Direct Effects of Vaping Questionnaire	DEV VAS.docx	0.01	1/13/2020 10:46 AM	Ashlee Sawyer	Research Measure	Yes
View	BAES Questionnaire	BAES Questionnaire.docx	0.01	1/13/2020 10:46 AM	Ashlee Sawyer	Research Measure	Yes
View	Lipato Biosketch	Lipato Biosketch.pdf	0.01	1/13/2020 10:45 AM	Ashlee Sawyer	CV/Biosketch	Yes
View	Peace CV	Peace CV January 2019 Academic.pdf	0.01	1/13/2020 10:44 AM	Ashlee Sawyer	CV/Biosketch	Not Applicable
View	Peace Grant	Peace Through the Looking Glass ECig3 Proposal FINAL.pdf	0.01	1/13/2020 10:43 AM	Ashlee Sawyer	Funding Proposal	Not Applicable

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   75

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   Fifteen participants will be needed to complete this study. In order to obtain 15 participants who complete the entire study, we may consent up to 75 individuals. Fifteen participants is based on an Monte Carlo based power analysis using the specified experimental design with repeated measures ANOVA. The Monte Carlo study used 10,000 samples to determine the number of participants needed to achieve a power of 0.8. This study showed that to detect a 10% change due to the alcohol in the device using a Student's two sample T-test with Satterthwaite approximation for the degrees of freedom, there is a need for at least 10 participants. We would like to obtain 15 participants to ensure that we are adequately powered to detect smaller effects.

4. * **List the study inclusion criteria:**
   Individuals must be 21-55, willing to provide informed consent, and attend the lab sessions as needed. Participants must agree to use designated products according to study protocol. Before being eligible to participate, participants must report daily use of an e-cigarette for at least 3 months. Participants must also (1) typically consume at least 1 drink per drinking episode (women) and at least 2 drinks per drinking episode for (men), (2) drink alcohol at least 1 time per week, and (3) not currently be seeking alcohol treatment.

5. * **List the study exclusion criteria:**
   Individuals with the following self-reported current, diagnosed medical condition(s) will be excluded automatically: heart-related conditions (e.g., recent heart attack/stroke, coronary heart disease), severe immune system disorders (e.g., HIV/AIDS, multiple sclerosis), respiratory disorders (e.g., COPD, asthma), kidney diseases, liver diseases (e.g., cirrhosis), or seizures.

   Individuals with other self-reported current, diagnosed medical conditions (e.g., diabetes, thyroid disease, lyme disease) will be considered for exclusion after consultation with the PI and medical monitor. Participants with any medical condition/medication that may affect participant safety, study outcomes, or biomarker data will be excluded based on these consultations.

   Participants with self-reported current, diagnosed psychiatric conditions or who report current psychiatric treatment or psychotropic medication use will be excluded. Individuals with past month use of cocaine, opioids, benzodiazepines, and methamphetamine will be excluded. Individuals who report using marijuana greater than 15 days in the past 30 and/or alcohol greater than 25 days in the past 30 days will be excluded. Participants must test negative for all drugs at screening (amphetamine, barbiturates, benzodiazepines, cocaine, THC, methadone, methamphetamine, opiates [which includes heroin, morphine, oxycodone, oxymorphone, hydrocodone, and hydromorphone], phencyclidine, propoxyphene, and tri-cyclic antidepressants) and prior to each session. Participants must also have a negative breath alcohol test at screening and before each session.Participants currently seeking alcohol treatment will be excluded. Participants who choose not to answer question related to inclusion/exclusion criteria will be excluded. Those who are breast-feeding or test positive for pregnancy (by urinalysis) at screening will be excluded. Participants who weigh less than 110 pounds will be excluded.

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - ○ Included
   - ○ Excluded - safety concerns if participants are unable to communicate with the study team
   - ● **Excluded - instruments/measures only validated in English**

- ◯ Excluded - no prospect of direct benefit to individual participants
- ◯ Excluded - minimal risk study
- ◯ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ◯ Excluded - other reason [provide an explanation in next question]

7. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   Because e-cigarettes and liquids, as well as alcohol, are not legally able to be purchased or used by those below the age of 21, we are excluding youth who are 20 years or younger.

Background, Rationale & Goals Section Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
This study is designed to evaluate whether or not vaping ethanol from e-cigarettes affects the pharmacokinetics of ethanol, alone or in combination with oral ethanol consumption. The purpose of this study is to determine whether or not ethanol-containing e-cigarettes impact ethanol breath tests, field sobriety tests, ethanol metabolites and biomarkers of inflammatory response and oxidative stress in oral fluid, urine, and plasma, with and without oral ethanol administered.

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The aim of this study is to assess the interaction between oral and vaped ethanol on blood ethanol levels, breath tests, the standardized field sobriety test (SFST), ethanol metabolites and biomarkers of inflammatory response and oxidative stress in oral fluid, urine, and plasma, and a subjective assessment of ethanol's effects.

3. * **Choose all types of recruitment materials that may be used and upload them below:**
- [x] **E-mail invitations**
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [x] **TelegRAM announcements**
- [x] **Website text**
- [ ] Study-specific web sites (provide the design and text)
- [x] **Social Media**
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] Psychology Research Participant Pool (SONA) study descriptions
- [ ] Scripts for announcements made to groups
- [ ] Other recruitment document
- [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

***1.** Identification of potentially eligible participants or secondary data/specimens of interest.*
- What database(s) will be queried to identify secondary data/specimens
- How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- How potential participants' contact information will be obtained

***2.** Recruitment procedures to invite participation in the study (when applicable):*
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact, approach, or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
Participants will be recruited via word-of-mouth and advertisements that will be posted as flyers around the community, in newspapers, on Craigslist, and possibly on social media sites such as Facebook and/or Twitter. Any postings on internet sites will use exactly the same information that is presented in those previously approved flyers (we will use advertisements that are already approved as part of the CSTP registry: HM20002567 and/or and advertisement associated with this specific usage protocol). Potential participants will make the initial contact via telephone by calling the phone number provided on the advertisements or by going to the website provided on the advertisements. Please

note that for the initial screening, we will use a multi-study screening process/registry described in HM20002567. Participants who appear eligible based on the initial screening questionnaire (in HM20002567 and attached) are then contacted (either via phone or e-mail), told about this study using the website study description (via phone or e-mail), and if interested, participants are invited for an in-person screening, where consent for this study will be obtained.

Individuals who are participants in other, ongoing CSTP studies (participants with whom we have a pre-existing relationship) may be verbally referred to this study, and directed to either call the laboratory or visit the website indicated on the advertisements/flyers, if they are interested.

Participants who are eligible and who choose to enroll may be contacted via text, phone, or e-mail for appointment reminders if they agree (see scripts).

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

   ○ Yes

   ● **No**

6. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

   1. A statement explaining the study design
   2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
   3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
   4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

   See the help text for additional guidance
   Participants will first be screened via phone or online, via a multi-study screening process/registry described in HM20002567 (see attachment "Registry consent form and questions"). Participants can tell study staff if they are interested in screening for a particular study only. All screening data collected from participants who choose to join the registry will be used in this study.

   Participants who appear eligible will then be scheduled for an in-person screening visit (the in-person screening visit is part of this protocol, not part of the registry process). Next, the consent form will be read to participants either using a pre-recorded voice-over Power Point presentation, or in person by research staff, and participants will have the opportunity to ask questions to research staff via Zoom (for communication between the participant and staff from inside the session room to outside the session room) both during the presentation and afterwards. Participants will also complete other forms (see in-person screening forms: these will be completed via RedCap). Participants will also be asked to give a urine sample for drug testing and pregnancy testing (if applicable), and staff will complete the biochemical test results form. Participants will be weighed and have their height recorded. Participants will also be asked to take an ethanol breath test that must be negative for ethanol, as well as a carbon monoxide test (a measure of combustible tobacco use). Participants will be able to view other questionnaires (Direct Effects of Vaping Questionnaire, Biphasic Alcohol Effects Scale, SHAS Questionnaire, Labeled Hedonic Scale, the General Labeled Magnitude Scale, and several items about driving and memory), via computer. In addition, they will be familiarized with all the equipment that will be used in the study, and will be asked to practice taking 2-3, 4 second puffs from the e-cigarette we will use in the study, as we will ask them to take 4 second puffs in the study and want to be sure this is done accurately. Practice puffs will be taken using 0 mg nicotine liquid with zero or trace amounts of ethanol.

   After screening and informed consent, eligible participants will enroll in this study. A total of 15 participants are needed to complete the study. Once enrolled, participants will attend the lab for four additional experimental sessions (approximately 6 hours each) where participants will either receive a beverage with 0% oral ethanol or 20% oral ethanol present. Oral ethanol dose administration will be calculated per participant body weight and using Widmark's reduction factors of 0.68 and 0.55 for men and women, respectively. For the oral alcohol dose, a 20% ethanol solution (v/v) will be made with either orange juice or cranberry juice and 40% ethanol vodka and then served to participants on an empty stomach. This concentration was chosen to facilitate absorption of ethanol and emptying of the stomach, with the understanding that low concentrations of ethanol lead to lower concentration gradients in the stomach and high concentrations irritate the gastric mucosa, increasing mucosal secretions that inhibit gastric secretions. A BAC of 0.08 g% will be the target, with an assumed peak venous BAC between 45-60 minutes. The alcohol placebo will be served with 1 ml of vodka floated on the surface to give the drink an alcohol scent, and we may rim the cup with vodka as well. This procedure is in line with previous research having demonstrated that individuals report that this beverage contains alcohol. Beverages will be served in a plastic cup, and consumed within 20 minutes.

   Participants will then use an "open system" ECIG (Kangertech Sub Box Mini C) filled with either 0% ethanol-containing liquid, or approximately 20% ethanol-containing liquid (neither liquid will contain nicotine). The liquids are available over the counter and will be purchased from an online vendor and we will test for percent ethanol. Participants will be asked to take 10 4-second puffs from the e-cigarette device two times over the course of each session.

   The design of this study is within-subjects, thus, all participants will complete four sessions that differ by the

combination of ethanol in the e-liquid and oral administration through beverages. Sessions will be ordered by Latin-square. Each session will be separated by at least 48 hours. The approximate total time that participants will be in the laboratory is 25 hours (1 hour for screening and 24 hours for sessions).

Participants will be asked to abstain from food 2 hours prior to arrival and ethanol 24 hours prior to arrival. Each session will begin with a 60-minute waiting period (to be sure that participants have not eaten prior to assessments, which can interfere with testing). Pregnancy (via urine), drug (via urine), and breath alcohol concentration (BrAC via probationary breath test or PBT, which involves blowing through a tube) will be confirmed negative prior to each session. The session will then commence with insertion of a venous catheter and a reading of heart rate and blood pressure.

Then, subjective measures will be completed (BAES, SHAS, DEV, LHS, and GLMS questionnaires, and several questions about driving and memory, see attachments). Next, baseline blood, breath, and oral fluid samples will be collected. Also, a Standardized Field Sobriety Test (horizontal and vertical gaze nystagmus with the DAX recording device, walk-and-turn, one-legged stand; see documents for the SFST procedures) will be conducted by a trained, plain-clothed VCU police officer.

Participants will drink the placebo ethyl alcohol (EtOH) drink or 20% EtOH drink within 10 minutes. Blood, urine, oral fluid, and breath will also be collected at pre-determined intervals for 300 minutes. Participants will vape 10 times with 4-second puffs 45 minutes after the beverage is consumed. Participants will be asked to take additional puffs from the e-cigarette toward the end of the elimination period, at 240 minutes.

During puffing, equipment will be used to measure puffs (puff topography). The equipment consists of a mouthpiece that is attached to the e-cigarette, which is attached to tubing that is attached to a box and computer that measures aspects of puffing. We have used this equipment in many previous studies.

At the end of each session, participants will be offered snacks before leaving (i.e., granola bars, chips, juice, and similar). Participants will be released at a time point in which the BAC will be <0.05 g%.

In the event that the venous catheter stops working and only one additional sample is needed (sample #6), venipuncture may be used instead of placing a new catheter for one sample, as in this case, venipuncture will be more comfortable for the participant. On any given session, there will still be no more than 3 "sticks" permitted, including for catheter insertion and for venipuncture.

Experimental session timeline (times approximate):

Participant arrives, pregnancy test, drug test, CO, BrAC test, BP and HR reading
-60 waiting period
-30 Catheter Insert
-10 Questionnaires
0 min Baseline Blood (B), Breath (Br), Oral Fluid (OF), and SFST
15 min Drink first 1/2 of beverage
25 min Drink second 1/2 of beverage
35 min B, OF
40 min OF
45 min Br
55 min OF, Br, SFST
75 min B,OF, Br
85 min Vape 10x 4-seconds
90 min B, OF, Br, SFST, questionnaires
125 min Br
155 min Br
200 min Br
235 min B, OF, Br
245 min Vape 10x 4-seconds
250 min B, OF, Br, SFST, questionnaires
280 min OF, Br
310 min Br, Urine (BAC must be <.05 g% before participant can leave), BP and HR reading

Please note that if a participant belches before the PBT breath test is scheduled to be administered, the session may be prolonged, as belching can interfere with the PBT.

Also, if participants need to use the bathroom during the session, we will ask for an additional urine sample at that time.

At the end of each session, the police officer will be asked two hypothetical questions about whether or not, if in the field, they would have made an arrest based on the results of the SFST and PBT (see questions in documents). No participants will actually be arrested.

Finally, if the study nurse has any concerns about a participant's blood pressure, we may give the participant information about blood pressure (see documents).

Transportation: Participants will be offered transportation via Uber for each session (not for the screening visit). For the sessions, participants must either have someone else drive them to and from the session, or use Uber(both ways). Study staff can schedule Uber rides for participants using our Center account, which can also be set up to communicate directly with participants. This involves Center staff entering the participant's name and phone number