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Responses to E-cigarette Message Source and Presentation

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Study Protocol

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INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE
Identifying and examining the effects of source and presentation on responses to electronic cigarette public education messages in young adult vapers and non-vapers - Part 1

2. EXTERNAL IRB REVIEW HISTORY*
NA

3. PRIOR APPROVALS:
NA

Conflict of Interest (COI):
NA

Clinical Engineering Department:
N/A

Biohazardous Agents:
NA

Radiation*:*
NA

Students as Subjects*:*
NA

Data Science Core & Recruitment Core:
NA

UMCCTS Protocol Review Committee (PRC)
NA

4. OBJECTIVES*
The goal of the study is to conduct a crowdsourced testing to examine the effects of source and presentation of e-cigarette educational messages among young adults who currently vape and do not vape but are susceptible. The objectives are to examine young adults' self-reported responses toward message source (expert vs. peer), message sidedness (one-sided vs. two-sided), and messages combining both (source x message sidedness) about anti-e-cigarette messages.

Aim 1: To determine the optimal message source and presentation type for young adult vapers and susceptible non-vapers to increase acceptance of e-cigarette education messages and e-cigarette harm perceptions.
H1. Vapers will report greater message acceptance and harm perceptions than peer and two-sided messages.

Aim 1: Which message source and sidedness strategy is effective for susceptible non-vapers?

H1. Susceptible *non-vapers will report greater message acceptance and harm perceptions to expert and one-sided messages.*

Please note that all procedures will be conducted online and there will be no direct in-person interaction between researchers and participants.

5. BACKGROUND*

Young adults (18-24-year-olds) in the U.S. have the highest rates of e-cigarette use (vaping),[1] with 16-19% of this population identifying as current users, 44-48% ever users, and 11-16% susceptible never users.[2] Vaping can lead to nicotine addiction and initiation of cigarette smoking[3–7] and is associated with cognitive and affective disorders among young adults.[8] The U.S. Food and Drug Administration (FDA) has prioritized educating about the health harm of vaping among young adults. However, young adults may avoid[9,10] or reject[11] the current education messages, especially if they currently vape[12–14] or perceive the messages as "controlling."[15] It is urgently needed to increase acceptance of e-cigarette education messages[16] to influence their e-cigarette harm perceptions and vaping behaviors.[17–20]

Using a trusted source[21–24] and presenting messages appropriately[25,26] can increase message acceptance. According to persuasion theories, one's tobacco use status may influence individuals' response to a source and presentation of messages because vapers and susceptible non-vapers differ in their attitudes and personal relevance regarding tobacco use.[25,27–29] Unfortunately, no research has yet examined the impact of a message source[22,30] and presentation[25,31,32] on young adults' responses to e-cigarette education messages based on their vaping status. Evidence from research with cigarette smokers suggests that vapers will respond defensively to e-cigarette education messages, but susceptible non-vapers will not.[12,33] Vapers may trust a tobacco health information source with similar attributes (e.g., peer young adults)[29,34] and accept messages with balanced perspectives that both present negative health effects of vaping and acknowledge their potential reasons for vaping (two-sided; e.g., "vaping can be appealing if others are using it, but it can harm your health").[25,31,35] On the other hand, susceptible non-vapers may trust a source with credentials (e.g., scientists) [36–38] and accept information-only messages (one-sided; e.g., "vaping can harm your health").[13,35] Thus, it is critical to understand and use a trusted source and present messages that are appropriate for vapers and susceptible non-vapers to optimize vaping cessation and prevention efforts, making it an important area of study to improve current messaging.

The proposed research is guided by biobehavioral theories of tobacco regulatory science,[39,40] psychology,[15,41] and communication.[42,43] By using previously tested education messages,[44] we will determine an optimal combination of message source and presentation type to increase message acceptance and e-cigarette harm perceptions. We will compare the effects of two sources (expert and peer) and two message presentation types (one-sided and two-sided) for young adult vapers and susceptible non-vapers. We will use crowdsourcing (N=800) for post-test self-report measures (message acceptance, harm perceptions) to determine optimal messaging. The goal of this study is to determine optimal message source and presentation for young adult vapers and susceptible non-vapers to increase message acceptance and harm perceptions using crowdsourcing.

6. INCLUSION AND EXCLUSION CRITERIA*

We will recruit 800 young adults between the ages of 18 and 24 years old (50% current vapers and 50% susceptible non-vapers) via Prolific crowdsourcing platform. Prolific is an on-demand,

self-service data collection. Prolific helps you recruit high quality research participants to take part in your study, survey or experiment (https://www.prolific.com/). Participants will be 18 and older and based in the United States. We will not include participants who are not fluent in English. Prisoners or adults who are unable to consent will not be included in the study. Pregnant women may be in the study if they choose, but we will not seek pregnant people to be in the study.

We will screen for e-cigarette use susceptibility of non-vaper participants. Potential participants will be recruited from Prolific and directed to a screener survey. Participants are susceptible to e-cigarette use if they respond to the tobacco use susceptibility question items (Have you ever been curious about using an e-cigarette? (1=Not at all curious, 5=Very curious); How likely is that you will try an e-cigarette, even one or two puffs, any time soon? (1=Very unlikely, 5=Very likely); How likely is that you will try an e-cigarette, even one or two puffs, any time during the next year? (1=Very unlikely, 5=Very likely); If one of your best friends were to offer you an e-cigarette, would you use it? (1=Very unlikely, 5=Very likely) in anything other than 1=not at all/very unlikely. We will collect participants' Prolific ID, a unique anonymous identifier, to create the list of eligible participants to participate in the 20-minute study. We expect that we will need 640 number of people identified as non-vapers to complete the screener and to have a complete sample for the 20 minute study, which will consist of susceptible non-vapers and vapers.

Prolific.com provides individuals who are eligible for each of the categories we are recruiting. We do not need to screen the participants for this. We can just click our preferences for those in the study.

7. STUDY-WIDE NUMBER OF SUBJECTS*
NA

8. STUDY-WIDE RECRUITMENT METHODS*
NA

9. STUDY TIMELINES*
An individual's participation in the study will be one-time for 20 minutes. We expect to complete the study within six months of enrolling the first participant.

10. STUDY ENDPOINTS*
The primary outcome measures include self-reported measures of message acceptance and harm perceptions. Secondary outcome measures include reactance, message liking, source trust, attitudes, and behavioral intentions.

11. PROCEDURES INVOLVED*

Non-vaper participants (regardless of their susceptibility) will first complete the online consent (i.e., STUDY00001220-Screener Consent_Fact Sheet_04.06.24.docx) and screener survey on

Qualtrics to determine their eligibility for susceptibility and will receive $1.00 via Prolific for participating in a 5-minute study. We will use the list of eligible participants from the screener survey, who will have been identified as susceptible, to participate in the 20-minute study, as described below.

Eligible participants will complete an online consent (STUDY00001220-Consent_Fact Sheet.v3.013124.docx) and tobacco use questions on a Qualtrics survey before random assignment to one of four experimental conditions in a 2 (Source: expert and peer) X 2 (Presentation: one-sided and two-sided) design. First, participants will view the source description within their assigned condition and view 18 random-ordered messages. See Appendix A. Copies of the messages. They will rate each message for perceived message effectiveness (PME),[45] a widely used measure of message acceptance by the FDA's tobacco health communication campaigns.[46,47] They will also rate e-cigarette harm perceptions,[48] psychological reactance (resistance to the message),[49] message liking,[50,51] and source trust.[52] The process will repeat 18 times, once for each message. Afterwards, participants will complete posttest survey questions about their demographics, attitudes about vaping,[46] and behavioral intentions to vape.[53] We will check manipulation of the source manipulation by asking participants to indicate the source of the message they saw after the first three messages. After completing the study, they will receive $4.00 via Prolific per its policies for participating in a 20-minute survey. At the end of the study, participants will be extensively debriefed about the hypothetical nature of the message source and the health harm of using any tobacco products, provided with an information sheet about the health effects of e-cigarettes and resources for the Quitlines across the U.S. See Appendix B-1 and B-2 for information about nicotine health harms and resources to quit. They will also complete a questionnaire assessing their understanding of the information regarding quitting resources. At the end of the survey, each participant is given a unique code to input into Prolific to receive compensation. We will double-check responses on our end of the survey and approve them to compensate participants.

12. DATA AND SPECIMEN BANKING*

We will not collect any information directly linked to the identity of individual subjects. It is possible that IP addresses may be collected. We will de-identify the dataset by removing IP addresses. The data will be stored in UMass Chan Medical School OneDrive indefinitely and will be accessible to the PI and the research coordinator. De-identified dataset will be available to other researchers upon request.

13. Data Analysis and Management*

Scores for each measure will be summed and averaged across all messages for each vaping status population. A multi-attribute decision-making MADM framework[54] will be used to produce a dataset containing data on participant response to each message with source + presentation type. Crowdsourced data will be merged with the Study part 2 data (psychophysiological testing) to rank messages and determine optimal message type.

Once the crowdsourced and psychophysiological data collection is complete, we will use the MADM framework[54] to determine the optimal combination of message source and presentation type. We will create a decision matrix in which each row represents a message type (source + presentation) and each column (attribute) represents a construct via the crowdsourced and

psychophysiological studies. Each message type will receive an average score for each self-report (e.g., message acceptance, harm perceptions) and psychophysiological measure (e.g., heart rate, skin conductance, eye-tracking) for each vaping status. The overall rank for each message type will be calculated by taking the average of ranking scores of the crowdsourced and psychophysiological data across the measures within each message type. Each measure will be equally weighted, as a previous study using MADM has indicated no differences in ranks when weighting psychophysiological or self-report measures differently.[54] We will use statistical software (e.g., Stata, SPSS, R) to conduct analysis.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*

The study presents minimal risk to participants for participating in the study. However, there is a possibility of the breach of confidentiality. Participants can opt out of the survey at any time during the study. Additionally, participants' identities will never be revealed. Names, addresses, email addresses, or any other identifying information will not be collected. Participants are identified by a unique, randomly generated code at the end of the survey only to ensure they have completed it and are compensated.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*

NA

16. RISKS TO SUBJECTS*

Risks to subjects involve being uncomfortable answering questions about tobacco use or seeing messages about negative health effects of using e-cigarettes.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

NA

18. VULNERABLE POPULATIONS*

- **Students or employees:** Students or employees of the University of Massachusetts Medical School will be eligible to enroll. Contacts with the study participants will be for assessment purposes only.
- **Adults unable to consent:** They are ineligible to participate.
- **Subjects who are not yet adults (infants, children, teenagers)**: Individuals under the age of 18 are ineligible to participate.
- **Pregnant women:** Pregnant women may be included in this research study. These requirements will be followed: No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.
- **Neonates of uncertain viability or non-viable neonates:** NA
- **Prisoners:** We will not enroll or conduct research procedures with individuals that are known to be prisoners. We will not obtain any information regarding participants' incarceration status.

19. MULTI-SITE RESEARCH*

NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*
NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*
Results of this research may be shared with other researchers upon request. We will not collect information linked to the identity of individual subjects. Additionally, dataset will be de-identified to remove any identifying information, such as IP addresses, prior to sharing with other researchers.

22. SETTING
The study will take place online via Prolific, an online crowdsourcing platform. Participants may participate in the survey in any setting (e.g., home, library, computer lab) with computer or mobile devices with Internet access. The research team will conduct data entry and analysis from Albert Sherman building. It is possible that the research team conducts data entry and analysis outside the campus (e.g., research team members' home). In such cases, they will be using the UMass Medical computer with the UMass Medical Secure network."

23. RESOURCES AVAILABLE
The **PI** and **postdoctoral fellow** are responsible and accountable for the implementation of the study in accordance with the proposed plan. The postdoctoral fellow is responsible for obtaining the informed consent. The PI and the postdoctoral fellow hold a doctoral degree and has extensive human subjects research experience including the conduct of a variety of studies relevant to the current study. The postdoctoral fellow will devote 50% of their time to ensure the launch and completion of this study, as well as data cleaning, analysis, and dissemination.
The PI and/or postdoctoral fellow will meet with any staff member involved with this research via Zoom and in person to ensure that they are fully informed about the protocol and the research procedures. Furthermore, the PI and/or postdoctoral fellow will meet with the staff members at least once a week to review their specific duties and functions (e.g., setting up study, data analysis).

24. LOCAL RECRUITMENT METHODS
We will recruit U.S. young adults (N=800; 18-24 years) identified as vapers (n=400) and susceptible non-vapers (n=400) to collect self-report measures. Vapers are defined as those who have vaped in the past 30 days,[2,55] and susceptible non-vapers are defined as those who have never vaped, or those who have ever vaped but not in the past 30 days, but are susceptible to use as determined by the Susceptibility to Use Tobacco Products questionnaire.[56] We will use Prolific, a crowdsourcing platform.[57] Prolific is optimal for this type of behavioral experiment[58] because it allows a rapid collection of high quality data.[57] Our team has successfully recruited participants and completed studies using Prolific.[59,60] Using an online convenience sample has yielded comparable results with probability samples in prior tobacco survey research studies.[61,62] We will use Prolific's screening features to recruit participants based on their vaping status (vapers and susceptible non-vapers), age (18-24 years), English fluency, and location (U.S.). We will use all data assurance measures (e.g., attention checks, manual review, bot inspection) for data quality, as we have done in past crowdsourced studies.[59,63] Participants sign up to be on the

Prolific platform as participants and can self-select what studies they want to participate in. However, the study will not use advertisements to directly recruit participants for this study. Participants who complete the study will receive $4.00 via Prolific per its policies for participating in a 20-minute survey. This study will not be advertised specifically to recruit UMass Chan students. It is possible that UMass Chan students who signed up to be on the Prolific platform might participate in the study.

25. LOCAL NUMBER OF SUBJECTS

800 individuals who are age between 18 and 24 years old, speak English, current residents of the United States will participate in the study.

26. CONFIDENTIALITY

Questionnaire data will be collected using the Qualtrics data collection system via Prolific. IP addresses will not be collected. No identifiable data will be collected via the Qualtrics research system. Data will be collected anonymously with no direct or indirect link or awareness of who participated in the study. All data will be stored on a secure UMass Chan server. Data will be password protected and stored for seven years, then destroyed as is the standard in the health communication field.

Dr. Stevens and the research coordinator (postdoctoral fellow) will be responsible for file maintenance. Participant consent form and survey and data will be stored on a password protected storage on a UMass Chan Medical secured network. Files will be reviewed once per week to ensure all documentation is securely stored.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

All study activities will be conducted in a private setting. Subjects will be told that they can skip any question they wish.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

This research presents minimal risk. No funds have been set aside for compensation.

29. ECONOMIC BURDEN TO SUBJECTS

None.

30. CONSENT PROCESS

Informed consent will be obtained using a Fact Sheet. All members of the research team will be trained in Human Subjects and HIPAA policies and procedures and the handling of data to ensure confidentiality in order to obtain Institutional Review Board (IRB) approval from UMass Chan. Researchers' contact information (phone and email) will be provided with study description for participants to ask questions.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

We will use a Fact Sheet to indicate that we will not document consent in writing since the research is minimal risk and involves no procedures that require a signature outside of the research context.

32. DRUGS OR DEVICES
NA

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Appendix A. Copies of the messages

** Before seeing each message, participants will view one of the four directions below according to their assigned source condition.*

Condition	**Expert**		**Peer**	
	Expert 1 Government health org	**Expert 2 Medical school researcher**	**Peer 1 Young adults**	**Peer 2 Influencers**
Directions	Imagine that a world-renowned	Imagine that your doctor	Imagine that your best friend	Imagine that a social media

	scientist wrote this message.	wrote this message.	wrote this message..	influencer that you follow wrote this message.

Messages with Sidedness Manipulation

One-sided	Two-sided
Sleek design hides a deadly truth that can harm your health. Vapes contain ingredients that can cause cancer.	You may want to vape because of the sleek design. But these cool looks hide a deadly truth. Vapes contain ingredients that can cause cancer.
Vapes have ingredients that cause lung disease and cancer that are not “just vapor.”	You may want to vape because you may think it’s “just vapor.” But that’s not true. Vapes have ingredients that cause lung diseases and cancer.
Most vapes have formaldehyde, a toxic chemical. You wouldn't drink formaldehyde. Why would you vape it?	You may want to vape because you don’t think it’s bad for you. But don’t vape. Most vapes have formaldehyde, a toxic chemical. You wouldn’t drink formaldehyde. Why would you vape it?
You may have trouble breathing from vaping. Vape flavors may cause lung damage	Vapes come in cool flavors that can make you want to vape. But these flavors can cause lung damage and trouble breathing.
Chemicals in these vape flavors can hurt your lungs.	Tempting flavors like cinnamon roll and very vanilla can make you want to vape. But in truth? Chemicals in these vape flavors can hurt your lungs.
Chemicals in these vape flavors can cause cell and lung damage.	We get why you may want to vape. Vapes come in flavors like sugar and spice and everything nice. But NOPE. Chemicals in vapes can cause cell and lung damage.
People who vape are more likely to have signs of depression. What a vibe check.	You may want to vape for cool vibes. But don’t trade it with your mental health. People who vape are more likely to have signs of depression. What a vibe check.
The coughing caused by lung damage from vaping? Not a good look.	You may want to vape because Influencers make vaping look cool. But don’t be tricked by social media. The coughing caused by lung damage? That’s not a good look.
You know what will never be cool? The lung damage caused by vaping.	You may want to vape because vaping is going viral. But you know what will never be cool? The lung damage caused by vapes.
Vape addiction is REAL. If you’ve been extra salty lately, that might be nicotine withdrawal.	You may want to vape for good mood. But vaping can make you feel worse. Have you or

	your friends been extra salty lately? That might be nicotine withdrawal. Vape addiction is REAL.
Nicotine addiction means losing your independence. Don’t get chained to your vape.	You may feel free when you’re vaping. But nicotine addiction means losing your independence. Don’t get chained to your vape.
Take a hard pass at catchy terms like “JUUL Buzz.” It just means nicotine addiction.	Seeing catchy terms like “JUUL Buzz” can make you want to vape. But that just means nicotine addiction. Hard pass.
Don't get hooked by the flavors. Some pods have as much nicotine as a whole pack of cigarettes.	The flavors can make you want to vape. But don’t get hooked by the flavors. Some pods have as much nicotine as a whole pack of cigarettes.
You’re not just vaping flavor. Don’t get hooked. Some pods contain as much nicotine as 20 cigarettes.	You may want to vape because vape companies say that you're just vaping flavor. But don’t get hooked. Some pods contain as much nicotine as 20 cigarettes.
Most vape products contain nicotine. Don't get hooked by the flavors. Nicotine addiction won't give you much of a choice.	The limitless flavors can make you want to vape. But don't get hooked. Most vape products contain nicotine. Nicotine addiction won't give you much of a choice.
JUUL pods contain nicotine - as much as a pack of cigarettes. Do your friends get salty if they haven't had a hit? That's nicotine addiction.	It may be fun to hit that vape with your friends. But do your friends get salty if they haven’t had a hit? That’s nicotine addiction. JUUL pods contain nicotine - as much as a pack of cigarettes.
Nicotine addiction makes people moody and hard to be around, which really kills the vibe.	You may want to hit that vape with your friends. But vaping with friends leads to fighting with friends. Nicotine addiction makes people moody and hard to be around, which really kills the vibe.
Don’t trade nicotine addiction to be on trend. You’ll be hooked forever.	You may want to vape because it’s today’s big thing, but you’ll be hooked forever. Don’t trade nicotine addiction to be on trend.

Appendix B-1.

Health harm of nicotine

Thank you for taking our survey.

E-cigarettes are not safe. If you vape e-cigarettes, you could be inhaling seriously addictive levels of nicotine. Nicotine in tobacco can damage your brain, increase the chance of having a heart attack, and decrease your immune system. Any tobacco products – including e-cigarettes, cigarettes, e-cigarettes, smokeless tobacco like dip, cigars, cigarillos, hookah, roll-your-own – are always dangerous. The only safe tobacco is NO tobacco. For more information about the harms of tobacco and nicotine, please visit:
https://therealcost.betobaccofree.hhs.gov/vapes

https://www.thetruth.com/breathofstressair?cid=vap_search_googlepaidsearch_truth_brand_BOSA&gad=1&gclid=CjwKCAjwtuOlBhBREiwA7agf1mx8urYu2Ws_aoxOKuvW7id_4yUBQItPrScQfVuvxlnwzL-cQrkQ4xoCefIQAvD_BwE

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Appendix B-2.

Quit vaping or support someone in their quit attempt

My Life, My Quit

My Life, My Quit™ is a specially designed program to help young people quit vaping or other tobacco products. **My Life, My Quit™** provides five free and confidential coaching sessions by phone, live texting, or chat with a specially-trained youth coach. You can text "Start My Quit" to 36072 or call toll-free 1-855-891-9989 for real-time coaching. You can also visit mylifemyquit.com to sign up online, chat with a live coach, get information about vaping and tobacco, and activities to help them quit. The program can send out materials and a certificate at the end of the program.

This is Quitting

This is Quitting powered by **truth®** is a texting program for young people who want to quit vaping. It is a free, confidential 60-day program during which participants receive texts with information, tips, and support. They receive daily text messages to help them prepare to quit and supportive texts from young people who have been through the program and know what it's like to quit. They can also text COPE, SLIP, STRESS, or MORE at any time for instant support, or

MASSINFO for information specific to Massachusetts. Young people can sign up even if you they aren't ready to quit – the texts they receive will give them strategies and practice quits to help build confidence and help them feel ready to quit.

To enroll in the program, youth text "VapeFreeMass" to 88709. Youth can also connect with their school nurse, counselor, or coach to help get them started.

Parents and other adults can also text QUIT to 202-899-7550 to sign up to receive text messages designed specifically for parents of vapers.

Source: National Jewish Health (2023). MyLifeMyQuit. https://www.mylifemyquit.com/

eIRB Section 7.0 Attachments Upload Checklist

Follow How to Manage Files in eIRB and upload the following items as applicable to your submission. This checklist is provided for your convenience and is not a requirement for review.

	Investigator Study Plan
	Sponsor protocol
	Research portion of the grant
	Human subjects portion of the grant
	Written approvals from ancillary reviews (Clinical Engineering, COI, IBC, PRC, RSC, Students as Subjects, etc.)
	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.
	Data collection sheets, case report forms, etc.
	Surveys, measures, instruments, etc.
	Measures to assess capacity to consent
	DMC or DSMB charter
	Data safety monitoring plan
	Adverse event log
	Investigator brochure or package insert for drugs
	Instructions for use or approved FDA labeling for devices
	Sponsor justification or FDA documentation for non-significant risk device study
	IND or IDE documentation
	Patient information sheet for Humanitarian Use Device
	Approval order for Humanitarian Use Device
	Product labeling for Humanitarian Use Device
	HIPAA waiver
	HIPAA authorization
	Authorization to contact form
	Consent form(s)
	Assent forms(s)
	Fact sheet(s)
	Multi-site communication plan
	Study staff training plan
	SOPs or Manuals of Operations

	Screening log
	Compensation log
	Certificates of translation or translator attestations
	Data use agreements, memoranda of understanding,
	Documentation of data/specimen anonymity (i.e., provider will never break the code)