Graphic Messages to Prevent E-Cigarette Use Among Latino and African American Adolescents: A Randomized Controlled Trial

Study Protocol and Statistical Analysis

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Graphic Messages to Prevent E-Cigarette Use Among Latino and African American Adolescents: A Randomized Controlled Trial

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1. PURPOSE OF STUDY

The aim of this randomized controlled trial is to examine the effectiveness of newly developed, theoretical-based graphic messages at preventing future vaping use among African American and Latino adolescents. The images have been iteratively tested in a user-design model and incorporates four main theoretical constructs: health reward, financial reward, self-efficacy, and social norms. We will assess pre- and post-exposure reactions on likelihood of future vaping among African American and Latino adolescents (n=360).

2. BACKGROUND AND RATIONALE

Although conventional cigarette smoking has markedly declined over the past several decades among adolescents (ages 12 to 17), there has been substantial increases in the use of emerging tobacco products among these populations in recent years (Wang et al., 2018). From a product initially marketed as a smoking cessation aid, e-cigarette use, or vaping, rose 900% between 2011 and 2015 among adolescents (from 3% to 27%) and is now two to three times more common among adolescents than among adults (Wang et al., 2018). Vaping products have completely transformed the landscape of nicotine use in youth, combining advanced technology, attractive design, and flavors (now available via online sources), fueled by aggressive marketing and social media promotion (Huang et al., 2019; Kim et al., 2020).

While e-cigarettes *may* support smoking cessation (Hartmann-Boyce et al., 2016; Kalkhoran & Glantz, 2016; Malas et al., 2016), there is robust evidence that exposure to nicotine during adolescence and young adulthood is not only associated with increased rates of use of other substances (Kandel & Kandel, 2014), but also that such use has long-term effects on the developing brain (Yuan, 2015). Chemical and heavy metal exposure from e-cigarettes, added flavorings, and risk of acute injuries and toxicity are a public health concern (Rubinstein et al., 2018). Vaping has been connected to 2,807 lung injury cases and 68 deaths in the US (as of November 2019) (Centers for Disease Control, 2020) and should be considered an increasing public health concern.

There is an urgent need to prevent vaping among adolescents. Adolescence is a period characterized by tobacco-use initiation, experimentation, and progression to long-term addicted behaviors (Sussman & Arnett, 2014; Thompson et al., 2018). Moreover, adolescence offers a critical window for prevention and cessation interventions to produce long-term reductions in tobacco-related morbidity and mortality (Jha et al., 2013; Pirie et al., 2013). In a cross-sectional survey looking at the current vaping prevalence in a diverse sample of 7th, 9th, and 11th grade

students in a Title I school district in New Jersey (n=963; 66% Latinos, 37% White, and 36% African Americans) found a prevalence of 19% (compared to 6% for cigarettes) and 55% of students were susceptible to future vaping (no differences by race and ethnicity) (Tercyak et al., 2021). Despite the adverse health effects, high prevalence, and high susceptibility of future vaping among AYAs, there is a lack of effective messages and communication channels to prevent initiation. Overcoming the burden of vaping among AYAs demands affordable, accessible, and effective preventive solutions.

To date, we know little about whether messages can prevent vaping among AYAs and, if so, what messages and delivery formats may be most effective. One study found that chemical and anti-industry warning messages on television advertisements reduce intention to purchase e-cigarettes (Sanders-Jackson et al., 2015). Another study found that addiction warnings increase perceived harms and addictiveness of e-cigarettes and decrease thoughts about vaping, but only when these warnings were text-based – not on print advertisements (Mays et al., 2016). One limitation of both studies is the lack of representation of Latino and African American AYAs. This leaves a substantial gap in communication research for vaping prevention among racial and ethnic minority groups. As the adolescent vaping epidemic continues to grow, there is an urgent need to develop, test, and implement messages and communication channels for vaping prevention.

3. ADMINISTRATIVE ORGANIZATION

The University of Rochester Medical Center (URMC) is recognized nationally and internationally for its excellence. The URMC schools and researches support and work with lines of research on contemporary parameters that acknowledge the need for a translational approach, traversing different realities. The existing structure, both human and material resources, was prepared to collaborate with making results available to the community quickly and effectively. The work developed and the structure existent for research attracts about 3,000 students, professionals, and researchers interested in joining leading-edge scientific studies and health activities, related to common or rare diseases. At the same time, patients feel confident in seeking the necessary assistance in their services to preserve and improve their health.

Scientists research different topics and areas to improve care and make new treatments available to patients faster. "Investigating Cancer and Improving Care," "Discovering New Pathways to the Molecular Basis of Human Diseases," "Combating Infections and Vaccines Research," "Leading the way to find new treatments for brain diseases," "Keeping the body moving," and "Making children healthier and happier" are examples of URMC investment. To carry out all this work, the University of Rochester School of Medicine and Dentistry has received, in the last five years, financial resources that amount to more than the US $ 1.18 billion. The investment in biomedical research, financing federal entities, places the URMC in a prominent position (26^{th}) among the various medical centers in the USA. The use of advanced and comprehensive methodologies resulted in the Clinical and Translational Sciences Award from the National Institutes of Health. The effort generates the receipt of funds continuously totaling US$ 86 million, in addition to a US$ 19 million grant for integrating the coordination of the top 50 academic medical centers in the country that are part of the Clinical and Translational Science Awards Program.

Several departments and centers work individually and jointly to achieve high-quality results. Among the Departments, the Public Health Sciences (PHS) works to improve health and health care among diverse populations through research, learning, and community partnerships. The research fields explored have several objects, ranging from childhood to older ages, considering food, environment, and everything that involves human health and can impact the individual and the population in general. For this, there are six important programs (Epidemiology and Health Services Research; Master's program in Public Health, Epidemiology; Clinical Investigations; and Health Services Research). PHS research is diverse, including research in behavioral interventions (e.g., smoking research program), environmental health (e.g., etiology of environmentally induced illnesses), maternal child health (e.g., racial/ethnic disparities in pregnancy outcomes), global health (e.g., improving linkage to and retention in HIV continuum of care in China), nutrition (e.g., infant feeding), and health policy and outcomes (nursing home policies that impact the quality of care for the elderly). Population's priorities and concerns, including the needs of minority and underserved communities, define PHS research.

Finally, an important highlight should be given to the Comprehensive Area-Wide Smoking Cessation Program Available through the Center for Community Health & Prevention. UR Medicine provide free smoking cessation counseling sessions for UR Medicine patients. The University of Rochester's experience in this field and the existing structure can be added to other outreach and research activities for the prevention of all smoking-related illnesses.

4. STUDY DESIGN

This study is a randomized controlled trial (RCT) with a heterogenous sample of 360 African American and Latino adolescents (ages 12-17) who do not vape; equal representation of Latinos and African Americans (180 African American adolescents and 180 Latino adolescents). After completing a preliminary baseline survey, participants will be randomized in equal numbers and representation to receive one of four (4) theoretical-based graphic messages: 1) Financial Reward, 2) Health Reward, 3) Self-efficacy, and 4) Social Norms. These graphic messages were developed in a previous research phase (STUDY00005312) using participatory research methods. See Appendix for the messages. We will assess pre- and post-exposure measures on the susceptibility of future vaping-use among African American and Latino adolescents.

5. INCLUSION AND EXCLUSION CRITERIA

Eligible individuals will 1) self-identify as African American/Black and/or Hispanic/Latino, 2) know how to read and speak English and/or Spanish, 3) be at least 12, but no greater than 17 years old, 4) have never used e-cigarettes, and 5) have access to a device that will be able to connect to the online survey (e.g., desktop, laptop, tablet, and/or smartphone). Exclusion criteria include: 1) not identifying as African American/Black and/or Hispanic/Latino, and 2) using e-cigarettes. Eligibility assessment will be conducted by study staff in the participant's language of preference, either English or Spanish.

6. RECRUITMENT METHODS

For this study, we will partner with schools (e.g., Hackensack High School) and community-based organizations (e.g., Ibero American Action League) to identify and refer potential adolescents. We plan to advertise this study via printed and electronic materials (e.g., study flyers). Parents/caregivers interested will be referred to research staff to obtain parent permission and child assent. Our research team consists of a culturally diverse group of Latinos and African Americans, which will help build rapport with the participants and their parents/caregivers.

7. CONSENT PROCESS

We will not obtain written informed consent for participating in this study. Instead, we will provide informational sheets to both the parents/guardians and the adolescents. In accordance with Police 701 of Informed Consent, this study requests a waiver of documentation because the research involves no more than minimal risk and involves procedures for which written consent is normally required outside the research context. This study represents no greater than minimal risk because it is a study of a non-sensitive nature. We will obtain parents'/guardians' permission over the phone. Then, we will obtain adolescents' assent via REDCap by clicking "Yes, I assent to participate in the study" after reading the informational sheet. The informational letter will also contain language describing the study, the risk and benefits, and team contact information in case they have questions. Adolescents will also have the opportunity to discuss the study and ask questions by contacting the research staff. Participants will be informed that their participation is completely confidential and voluntary, and that participation may end at any time during the assessment. If an individual chooses to stop participation or withdraw from the study, the de-identified data collected will be kept by the study team.

8. STUDY PROCEDURES

Once parents'/guardians' permission and adolescent's assent has been obtained, participants (n=360) will complete an individual baseline assessment on sociodemographic characteristics and susceptibility to future vaping. The survey will be hosted in REDCap, a secure, web-based system that has user-level access control. Each participant will receive a unique username and password to access the survey. At the end of the baseline assessment, participants will be randomized in equal number and representation to receive one of four (4) graphic messages: 1) health reward, 2) financial reward, 3) self-efficacy, and 4) social norms. The appropriate graphic message, available in English and Spanish, will be displayed in REDCap. Participants will be instructed to view the graphic messages carefully on their devices (e.g., desktop, laptop, tablet, and/or smartphone) and for as long as they wish. We will assess immediate post-exposure measures on susceptibility to future vaping (primary outcome). Study measures on susceptibility to future vaping are comprised of valid items derived from out and others' research. We will assess three items: (1) Are you curious about using e-cigarettes (vaping)?; (2) Do you think that you will use e-cigarettes (vaping) in the next 12 months?; and (3) If one of your best friends were to offer you an e-cigarette, would you use it? Responses include 1= definitely not, 2= probably not, 3= probably yes, 4= definitely yes. Participants will receive $25 gift card for their time at the end of the assessment.

9. RISK TO SUBJECTS

The risk for this study is minimal. Loss of privacy of personal information is a small risk. Only Dr. Cartujano (Principal Investigator) and research team will have access to study data. **Adequacy of Protection against Risks.** Issues covered in the information sheet will include a description of study procedures, the time involved, the right to withdraw at any time without penalty, procedures used to protect participant anonymity, use of data, and potential benefits and risks of participating in the study.

10. POTENTIAL BENEFITS TO SUBJECTS

Participation in this study may prevent subjects from vaping. Moreover, this study will examine the effectiveness of newly designed, theoretical-based graphic messages at preventing future vaping use among African American and Latino adolescents.

11. COSTS FOR PARTICIPATION

Participation in this study is at no financial cost to the participants.

12. PAYMENT FOR PARTICIPATION

Subjects will be compensated for their participation in the study by receiving a $25 gift card. In order to maintain anonymity of subject participants, those who complete the survey will be redirected to a code to claim an Amazon® gift card.

13. SUBJECT WITHDRAWALS

Subjects will be informed that they may withdraw from the study at any time without prejudice and compilation of that person's data will cease as of the date of his/her written request for withdrawal. It is possible that individuals might not want to participate and/or may withdraw from the study, and that is their right. If a subject withdraws before completing the three phases, data collected until the point of withdrawal remains part of the study database and may not be removed. Other subjects will replace subjects withdrawn from the study. We do not anticipate any circumstances in which subjects will be withdrawn from the research without their consent.

14. PRIVACY AND CONFIDENTIALITY OF SUBJECTS AND RESEARCH DATA

The PI and research staff have completed all required training through the Collaborative Institutional Training Initiative (CITI), including the Human Subjects Protection and Good Clinical Practice Training. Subjects will be limited to interactions with the research staff only for this study. Collected data and all analysis of the data will adhere to HIPAA and institutional patient confidentiality requirements. More specifically, a coding system will be used for which a unique identifier will be assigned to each participant. Each subject whose data is collected will be assigned a unique study number. All electronic data will be managed using REDCap, a secure, web-based system that has user-level access control. Data will be stored for six years after completion of the study, per RSRB policy. This data will only be accessible to the PI and research staff. francisco_cartujano@urmc.rochester.edu UR data security requirements will be followed (http://www.rochester.edu/it/policy/index.html).

15. DATA AND SAFETY MONITORING PLAN

Some identifiers will be collected such as name and electronic mail. All the identifiable data will be coded, removing the identifiers and assigning a unique study ID/code to protect the identity of the subject. Any sensitive data will not be collected.

Data Management and Transfer

Dr. Francisco Cartujano will access the data to conduct analyses. Data will be summarized and tables to be presented to Co-Investigators. Dr. Cartujano will be responsible for maintaining the security of the data.

All data will be stored on a URMC password protected computer only accessible by the investigator team. URMC password protected computers are only accessible by the P.I. and/or research staff. Electronic data will be managed using REDCap, a secure, web-based system that has user-level access control. Analytical datasets will be stored on secure servers that also limit access to the investigator team. All identifiers (names and contact information including emails) will be kept separately and will not include in any reports or potential publications. Data collected will be maintained securely with limited access. Records will be retained in accordance with regulatory, organizational and sponsor requirements, but no less than six (6) years following the completion of the research. Disposal of records will be done in such a manner that no identifying information can be linked to research data.

17. DATA ANALYSIS PLAN

We first will perform descriptive statistics to evaluate randomization success, nonresponses, and missing data. Mean and median will be presented for continuous variables, and frequencies will be presented for categorical variables. The outcome measures will be defined as (1) a binary variable of susceptibility to future vaping (0= definitely not, 1= probably not, probably yes, definitely yes) to ease interpretation of results, and (2) the overall susceptibility score aggregating three items. Bivariate analyses will be performed, followed by multivariable modeling to compare different message groups. Logistic regression model and the analysis of covariance (ANCOVA), respectively, will be performed to control for potential confunding, and inflated type I error rate will be adjusted in multiple testing. We will also assess differences within messages by theoretical construct (reward, self-efficacy, and social norms). **Power Analysis.** The goal of this pilot analysis is to provide preliminary data for future studies, including the possible effect size. Using the ANCOVA analysis for the power calculation, we expect the effect size to be 1.05 (standardized mean difference in the aggregated score) between message groups.

18. FUTURE RESEARCH PLANS

We will report the results of this research in one or more publications in academic journal(s) to advance knowledge pertaining to effective communication with Latino and African American adolescents regarding vaping prevention. Additionally, we will disseminate our findings at national and international conferences. We have identified a request for applications

to pursue support for this line of research through the trans-NIH Tobacco Regulatory Science Program (RFA-OD-19-019). An FDA and NIH defined priority research area is to understand how to effectively communicate to the public and vulnerable populations regarding nicotine and the health effects of tobacco products.

19. REFERENCES

- Centers for Disease Control. (2020). Outbreak of lung injury associated with the use of e-cigarette, or vaping, products. Centers for Disease Control. Available at: https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html.
- Hartmann-Boyce, J., McRobbie, H., Bullen, C., Begh, R., Stead, L. F., & Hajek, P. (2016). Electronic cigarettes for smoking cessation. The Cochrane Database of Systematic Reviews, 9(9), CD010216. https://doi.org/10.1002/14651858.CD010216.pub3
- Huang, J., Duan, Z., Kwok, J., Binns, S., Vera, L. E., Kim, Y., Szczypka, G., & Emery, S. L. (2019). Vaping versus JUULing: how the extraordinary growth and marketing of JUUL transformed the US retail e-cigarette market. Tobacco control, 28(2), 146–151.
- Jha, P., Ramasundarahettige, C., Landsman, V., Rostron, B., Thun, M., Anderson, R. N., McAfee, T., & Peto, R. (2013). 21st-century hazards of smoking and benefits of cessation in the United States. The New England journal of medicine, 368(4), 341–350.
- Kandel, D. B., & Kandel, E. R. (2014). A molecular basis for nicotine as a gateway drug. The New England journal of medicine, 371(21), 2038-2039.
- Kalkhoran, S., & Glantz, S. A. (2016). E-cigarettes and smoking cessation in real-world and clinical settings: A systematic review and meta-analysis. The Lancet. Respiratory Medicine, 4(2), 116–128.
- Kim, M., Watkins, S. L., Koester, K. A., Mock, J., Kim, H. C., Olson, S., Harvanko, A. M., & Ling, P. M. (2020). Unboxed: US Young Adult Tobacco Users' Responses to a New Heated Tobacco Product. International journal of environmental research and public health, 17(21), 8108.
- Malas, M., van der Tempel, J., Schwartz, R., Minichiello, A., Lightfoot, C., Noormohamed, A., Andrews, J., Zawertailo, L., & Ferrence, R. (2016). Electronic cigarettes for smoking cessation: A systematic review. Nicotine & Tobacco Research, 18(10), 1926–1936.
- Mays, D., Smith, C., Johnson, A. C., Tercyak, K. P., & Niaura, R. S. (2016). An experimental study of the effects of electronic cigarette warnings on young adult nonsmokers' perceptions and behavioral intentions. Tobacco induced diseases, 14, 17.
- Pirie, K., Peto, R., Reeves, G. K., Green, J., Beral, V., & Million Women Study Collaborators (2013). The 21st century hazards of smoking and benefits of stopping: a prospective study of one million women in the UK. Lancet, 381(9861), 133–141.
- Rubinstein, M. L., Delucchi, K., Benowitz, N. L., Ramo, D. E. (2018). Adolescent exposure to toxic volatile organic chemicals from e-cigarettes. Pediatrics, 141(4), e20173557.
- Sanders-Jackson, A., Schleicher, N. C., Fortmann, S. P., & Henriksen, L. (2015). Effect of warning statements in e-cigarette advertisements: an experiment with young adults in the United States. Addiction, 110(12), 2015–2024,
- Sussman, S., & Arnett, J. J. (2014). Emerging adulthood: Developmental period facilitative of the addictions. Evaluation & the health professions, 37(2), 147–155.

- Tercyak, K. P., Phan, L., Gallegos-Carrillo, K., Mays, D., Audrain-McGovern, J., Rehberg, K., Li, Y., Cartujano-Barrera, F., & Cupertino, A. P. (2021). Prevalence and correlates of lifetime e-cigarette use among adolescents attending public schools in a low income community in the US. Addictive behaviors, 114, 106738.
- Thompson, A. B., Mowery, P. D., Tebes, J. K., & McKee, S. A. (2018). Time trends in smoking onset by sex and race/ethnicity among adolescents and young adults: Findings from the 2006-2013 National Survey on Drug Use and Health. Nicotine & tobacco research: Official journal of the Society for Research on Nicotine and Tobacco, 20(3), 312–320.
- Yuan, M., Cross, S. J., Loughlin, S. E., & Leslie, F. M. (2015). Nicotine and the adolescent brain. The Journal of Physiology, 593(16), 3397–3412.
- Wang, T. W., Gentzke, A., Sharapova, S., Cullen, K. A., Ambrose, B. K., & Jamal, A. (2018). Tobacco product use among middle and high school students - United States, 2011-2017. MMWR. Morbidity and mortality weekly report, 67(22), 629–633.

20. APPENDIX

Financial reward

Health reward

Social norms

Self-efficacy