Effects of Messages About Very Low Nicotine Cigarettes: Insights from Focus Groups, a Discrete Choice Experiment, and a Randomized Clinical Trial

Lucy Popova

Associate Professor, Health Policy & Behavioral Sciences

Director, Postdoctoral Fellowship in Global Tobacco Research

School of Public Health, Georgia State University

Disclosure

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Many thanks!

Di Pei *

David Ashley

Katherine Henderson

Hue Duong

Charity Ntansah *

Emily Hackworth

James Hardin

James Thrasher

Bo Yang

Reed Reynolds *

Nicotine Regulation Timeline

The NEW ENGLAND JOURNAL of MEDICINE

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SOUNDING BOARD FREE PREVIEW

Establishing a Nicotine Threshold for Addiction -- The Implications for Tobacco Regulation

Neal L. Benowitz, M.D., and Jack E. Henningfield, Ph.D.

On February 25, 1994, the Food and Drug Administration (FDA) released a letter to the Coalition on Smoking or Health announcing its intention to consider regulating cigarettes. The agency's premises were that the vast majority of tobacco users self-administer the product for the drug effects of nicotine and to sustain addiction and that cigarette manufacturers control the levels of nicotine in cigarettes to maintain this addiction. The FDA further raised the possibility of regulating cigarettes on the basis of their nicotine content to prevent addiction.On February 28, 1994, the ABC news program Day One presented evidence that tobacco manufacturers . . .

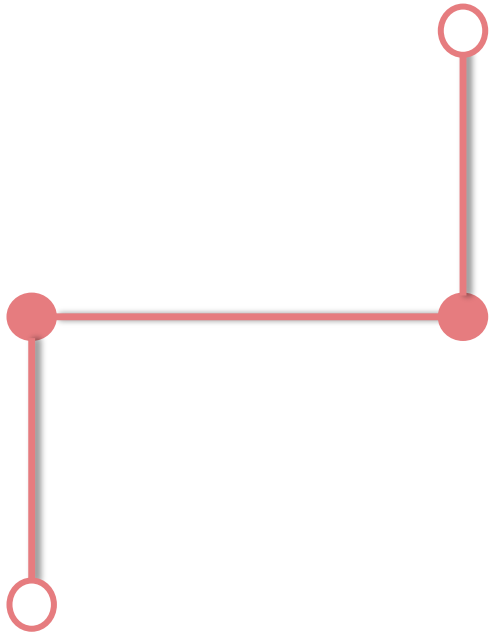
July 14, 1994
N Engl J Med 1994; 331:123-125
DOI: 10.1056/NEJM199407143310212

1994
Benowitz & Henningfield, NEJM

- Nicotine content in cigarettes should be limited to 0.4 – 0.5 mg per cigarette to prevent addiction in users

Nicotine Regulation Timeline

2009
FSPTCA grants FDA authority to regulate tobacco products



1994
Benowitz & Henningfield, NEJM

Family Smoking Prevention and Tobacco Control Act - An Overview

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To protect the public and create a healthier future for all Americans, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed into law on June 22, 2009, gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.

Nicotine Regulation Timeline

2009
FSPTCA grants FDA authority to regulate tobacco products

1994
Benowitz & Henningfield, NEJM

2015
Donny et al, NEJM

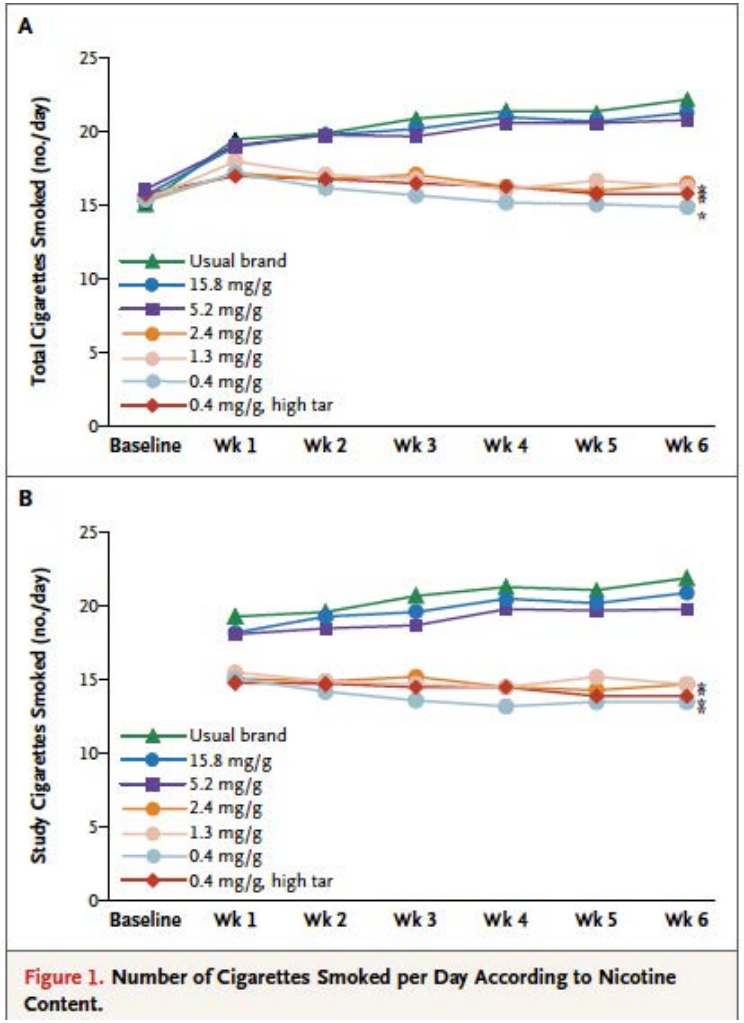


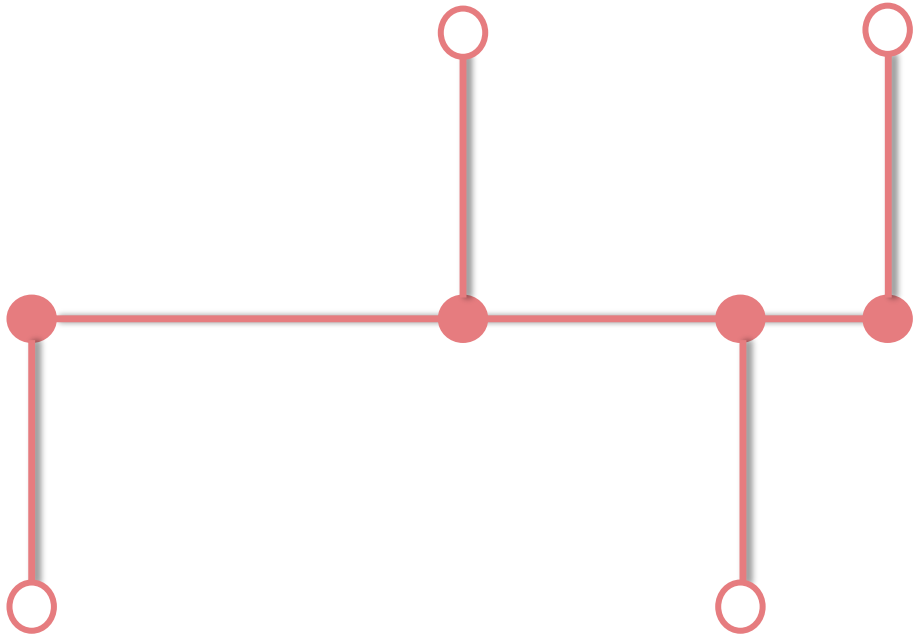
Figure 1. **Number of Cigarettes Smoked per Day According to Nicotine Content.**

- Reduce cigarette consumption, nicotine dependency, craving & biomarkers of exposure to nicotine

Nicotine Regulation Timeline

2009
FSPTCA grants FDA authority to regulate tobacco products

2017
FDA announces comprehensive approach to nicotine regulation



1994
Benowitz & Henningfield, NEJM

2015
Donny et al, NEJM

- "The agency's new tobacco strategy has two primary parts: reducing the addictiveness of combustible cigarettes while recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health."

Nicotine Regulation Timeline

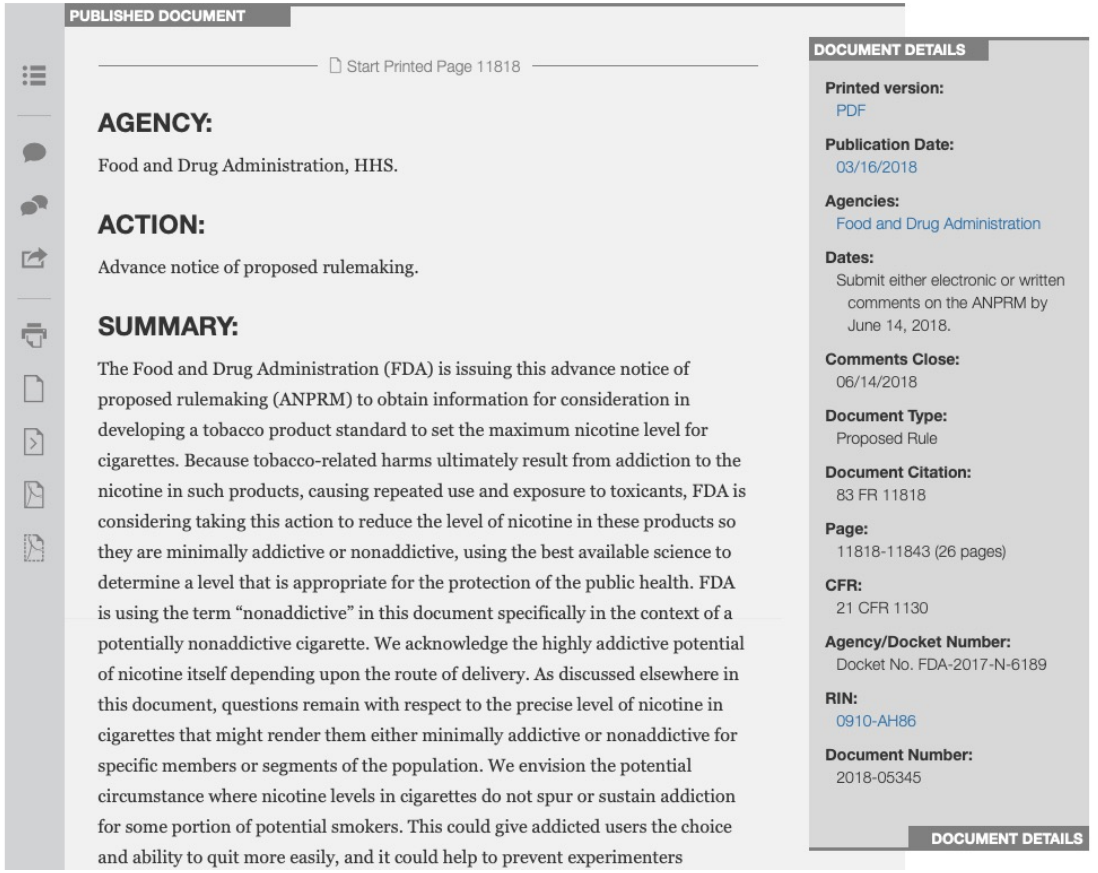
1994
Benowitz & Henningfield, NEJM

2009
FSPTCA grants FDA authority to regulate tobacco products

2015
Donny et al, NEJM

2017
FDA announces comprehensive approach to nicotine regulation

2018
FDA issues low nicotine ANPRM



Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

A Proposed Rule by the Food and Drug Administration on 03/16/2018

PUBLISHED DOCUMENT

Start Printed Page 11818

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Advance notice of proposed rulemaking.

SUMMARY:

The Food and Drug Administration (FDA) is issuing this advance notice of proposed rulemaking (ANPRM) to obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes. Because tobacco-related harms ultimately result from addiction to the nicotine in such products, causing repeated use and exposure to toxicants, FDA is considering taking this action to reduce the level of nicotine in these products so they are minimally addictive or nonaddictive, using the best available science to determine a level that is appropriate for the protection of the public health. FDA is using the term "nonaddictive" in this document specifically in the context of a potentially nonaddictive cigarette. We acknowledge the highly addictive potential of nicotine itself depending upon the route of delivery. As discussed elsewhere in this document, questions remain with respect to the precise level of nicotine in cigarettes that might render them either minimally addictive or nonaddictive for specific members or segments of the population. We envision the potential circumstance where nicotine levels in cigarettes do not spur or sustain addiction for some portion of potential smokers. This could give addicted users the choice and ability to quit more easily, and it could help to prevent experimenters

DOCUMENT DETAILS

Printed version: PDF

Publication Date: 03/16/2018

Agencies: Food and Drug Administration

Dates: Submit either electronic or written comments on the ANPRM by June 14, 2018.

Comments Close: 06/14/2018

Document Type: Proposed Rule

Document Citation: 83 FR 11818

Page: 11818-11843 (26 pages)

CFR: 21 CFR 1130

Agency/Docket Number: Docket No. FDA-2017-N-6189

RIN: 0910-AH86

Document Number: 2018-05345

DOCUMENT DETAILS

Nicotine Regulation Timeline

1994
Benowitz & Henningfield, NEJM

2009
FSPTCA grants FDA authority to regulate tobacco products

2015
Donny et al, NEJM

2017
FDA announces comprehensive approach to nicotine regulation

2018
FDA issues low nicotine ANPRM

2022
New Zealand announced legislation to reduce nicotine content in tobacco products

Smokefree Aotearoa 2025 Action Plan - Auahi Kore Aotearoa Mahere Rautaki 2025

This plan sets out the actions we will take over the next four years and beyond to achieve Smokefree Aotearoa 2025 and ultimately end the harm smoking causes.

Published online: 09 December 2021

Smoking tobacco products kills approximately 4,500 to 5,000 people every year in New Zealand – that is around 12 to 13 deaths every day due to smoking or exposure to second-hand smoke.

Since the Māori Affairs Committee's Inquiry into the tobacco industry in Aotearoa and the consequences of tobacco use for Māori in 2010, more than 50,000 New Zealanders have died of smoking-related causes.

This action plan sets out the actions we will take over the next four years and beyond to achieve Smokefree Aotearoa 2025.

Our 2025 goal is for a daily smoking prevalence of less than five percent for all population groups.

We will know we are succeeding when we achieve our outcomes:

1. Eliminate inequities in smoking rates and smoking-related illnesses
2. Create a smokefree generation by increasing the number of children and young people who remain smokefree
3. Increase the number of people who successfully quit smoking

To achieve these outcomes, we will take action under six focus areas:

1. Ensure Māori leadership and decision-making at all levels
2. Increase health promotion and community mobilisation
3. Increase evidence-based stop smoking services
4. Reduce the addictiveness and appeal of smoked tobacco products
5. Reduce the availability of smoked tobacco products
6. Ensure manufacturers, importers and retailers meet their legal obligations

Find all our supporting resources on the Smokefree Aotearoa 2025 Action Plan page.

Nicotine Regulation Timeline

2009
FSPTCA grants FDA authority to regulate tobacco products

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FDA announces comprehensive approach to nicotine regulation

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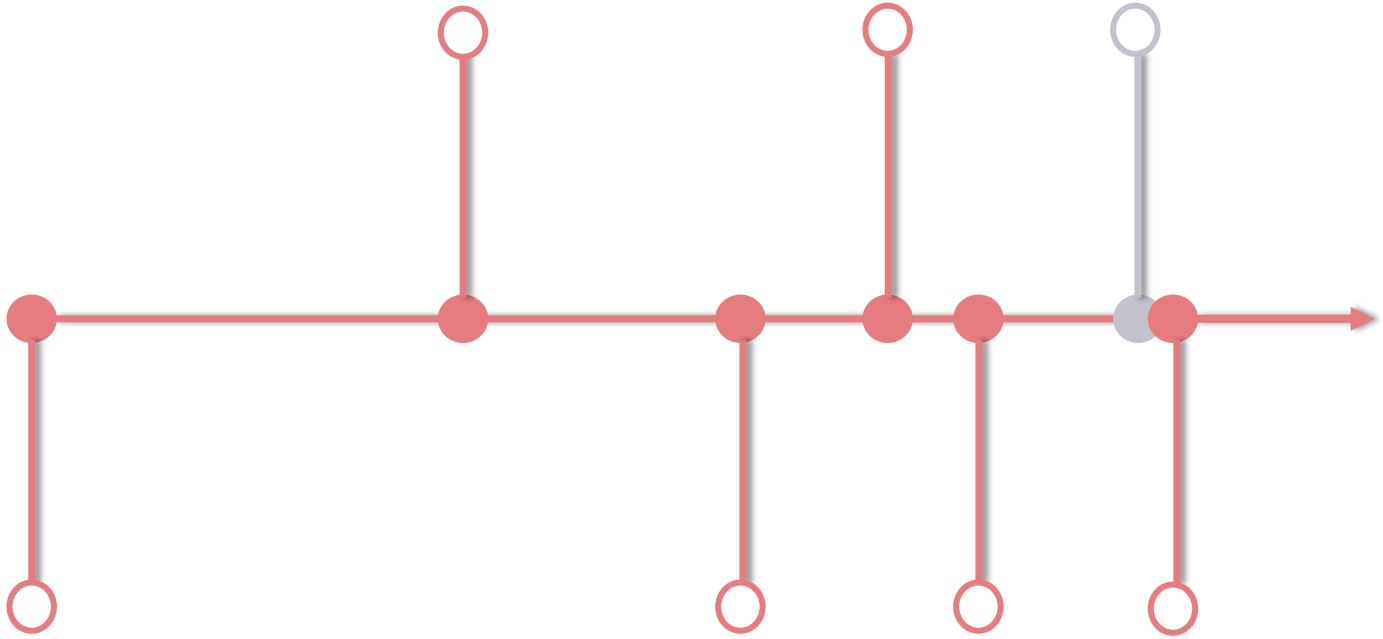
New Zealand announced legislation to reduce nicotine content in tobacco products



1994
Benowitz & Henningfield, NEJM

2015
Donny et al, NEJM

2018
FDA issues low nicotine ANPRM

2022
US FDA announced plans to issue a proposed rule for a reduced nicotine standard

FDA NEWS RELEASE

FDA Announces Plans for Proposed Rule to Reduce Addictiveness of Cigarettes and Other Combusted Tobacco Products

Potential Rule Would Propose to Establish a Maximum Level of Nicotine in Cigarettes with the Goal of Reducing Youth Use, Addiction and Death

Share Tweet LinkedIn Email Print

For Immediate Release: June 21, 2022

Español

Today, the Biden-Harris Administration published plans for future potential regulatory actions that include the U.S. Food and Drug Administration's plans to develop a proposed product standard that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other combusted tobacco products. The goal of the potential rule would be to reduce youth use, addiction and death.

Each year, 480,000 people die prematurely from a smoking-attributed disease, making tobacco use the leading cause of preventable disease and death in the United States. Additionally, tobacco use costs nearly $300 billion a year in direct health care and lost productivity.

While nicotine is not what makes smoking cigarettes so toxic, it's the ingredient that makes it very hard to quit smoking. Addiction to nicotine in combusted products is the main driver of sustained use of these products. In fact, more than half of adult cigarette

Communication about VLNCs

Focus groups – develop and pretest messages about very low nicotine cigarettes (VLNCs)

Discrete choice experiment – assess the impact of different attributes in messages about VLNCs

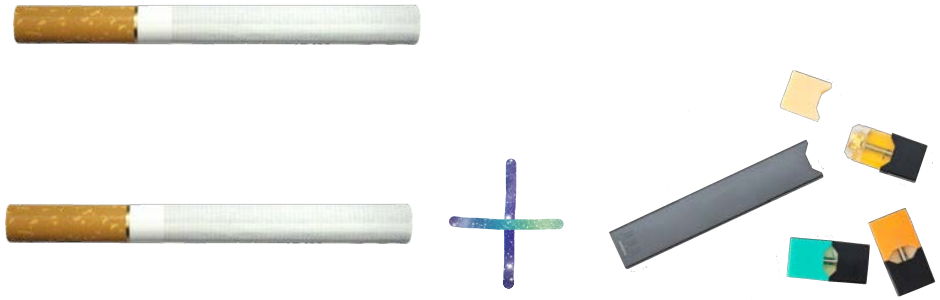
Randomized clinical trial – test messages about VLNCs in combination with messages about e-cigarettes

Focus groups – develop and pretest messages about very low nicotine little cigars and cigarillos (LCCs)

Discrete choice experiment – assess the impact of different attributes in messages about very low nicotine LCCs

POPULATIONS OF INTEREST

- Current exclusive smokers
- Current dual users
- Young adult non-smokers (18-29)
- Former smokers



FOCUS GROUPS STUDY

'It brings light to what you really put into your body': a focus group study of reactions to messages about nicotine reduction in cigarettes

Hue Trong Duong [1], Emily E Loud [2], James F Thrasher,[2] Katherine C Henderson [3], David L Ashley [3], Lucy Popova [3]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/tobaccocontrol-2020-056312).

[1]Department of Communication, Georgia State University, Atlanta, Georgia, USA
[2]Department of Health Promotion, Education and Behavior, Arnold School of Public Health, University of South Carolina, Columbia, South Carolina, USA
[3]School of Public Health, Georgia State University, Atlanta, Georgia, USA

Correspondence to
Dr Lucy Popova, School of Public Health, Georgia State University, Atlanta, GA 30302, USA; lpopova1@gsu.edu

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ABSTRACT

Objective In 2017, the US Food and Drug Administration (FDA) announced a proposed regulation to lower nicotine in cigarettes to minimally addictive levels to help smokers quit. We sought to explore effective message strategies communicating about nicotine reduction in cigarettes across the different key audiences that the regulation is most likely to influence.

Methods We designed four types of messages: efficacy messages, risk messages, a message about alternative sources of nicotine and a compensation message. Sixteen virtual focus groups were conducted in Atlanta and San Francisco in April–May 2020. Data were analysed in NVivo 12.0 using a thematic analysis approach.

Findings Exclusive smokers were receptive to both efficacy messages and risk messages. Dual users were the only group that was open to resorting to alternative sources of nicotine. Former smokers were critical of these messages as promoting the new kinds of cigarettes and potentially encouraging initiation and relapse of smoking. Non-smokers felt that efficacy messages downplayed the risks of smoking and did not scare people away from smoking. Presenting information that very low nicotine cigarettes (VLNCs) still contain harmful chemicals made smokers question continued smoking in the absence of nicotine and view VLNCs as harmful.

Conclusions Messages communicating about nicotine reduction in cigarettes might help to motivate smokers to quit and can correct the misperceptions that VLNCs are less harmful. The FDA should consider specific target audiences and use different messages that complement each other in communicating about this regulation.

INTRODUCTION

Tobacco use remains a global public health challenge.[1] While all tobacco products are harmful, combusted cigarettes have the biggest impact and are responsible for nearly half a million premature deaths each year in the USA.[2] Quitting cigarettes is difficult because the nicotine in cigarettes makes them addictive.[3] Reducing nicotine in cigarettes, therefore, aims to help smokers quit. It has been estimated that reducing nicotine in cigarettes can save millions of lives.[4] In 2017, the US Food and Drug Administration (FDA) proposed an unprecedented regulation to lower nicotine in cigarettes to minimally addictive levels while spurring innovation in lower-risk nicotine products so that smokers who cannot otherwise quit all nicotine products have viable less harmful alternatives.[5] No other country has adopted such a policy. One key to successful policy implementation is to effectively communicate this regulation and its objectives to diverse consumers. However, such communication is challenging.

The main goal of reducing nicotine in cigarettes to non-addictive levels is to help smokers quit. However, very low nicotine cigarettes (VLNCs) could be perceived as harmless, which can discourage quitting.[6–8] While nicotine is not the main cancer-causing ingredient in cigarettes, around 80% of US adults believe that nicotine causes serious smoking-related harms.[9] VLNCs may be misunderstood by adolescents and young adults, resulting in smoking initiation among individuals who may not have initiated smoking with traditional cigarettes. There is evidence that adolescents perceive VLNCs as less harmful than other tobacco products[9] and have limited understanding of the mechanisms of nicotine addiction,[10 11] which may result in misperceptions of the VLNC policy. Additionally, former smokers could relapse because they might think that VLNCs are less harmful than traditional cigarettes or that they would be less likely to become addicted to smoking again. Furthermore, smokers believe that they would need to compensate for the low amount of nicotine by consuming more cigarettes or inhaling more intensely,[12] although existing evidence does not support of this belief.[13–15] Thus, messages communicating about VLNCs need to inform people of the regulation and its purpose and effectively dispel misperceptions.

To date, little research has investigated ways to communicate about VLNCs.[16] Thus, this study aimed to explore effective message strategies to communicate about VLNCs across the different key audiences that the regulation is most likely to influence. This study provides the FDA with evidence to identify and evaluate ways to communicate about VLNCs to the public.

METHODS

Message design

We tested four types of the messages (figure 1):

1. Three efficacy messages (*Beat cravings*, *Break the bond* and *Reason to quit*) focused on empowering smokers and increasing their self-efficacy. The messages were positively framed, suggesting that quitting smoking would be easier when the nicotine is gone and featured positive imagery, showing smokers taking control and prevailing over cigarettes (eg, by smashing them with a fist).

1. Risk messages

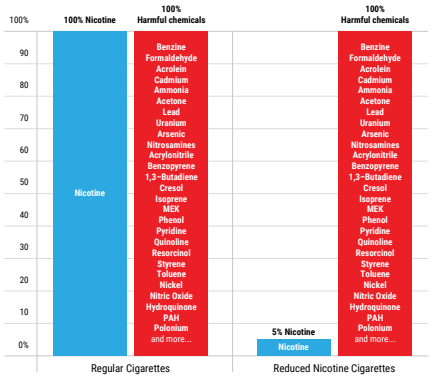
~~NICOTINE~~
BENZENE
FORMALDEHYDE
VINYL CHLORIDE
ARSENIC
CADMIUM
AMMONIA
CARBON MONOXIDE
HYDROGEN CYANIDE

What's your reason for smoking?

Soon, all cigarettes will have 95% less nicotine than they currently have.

Nicotine is the #1 chemical in cigarettes that hooks you and keeps you smoking. But it is not the most **harmful chemical in cigarettes.**

So when the nicotine is gone, which of these chemicals will keep you coming back for more?



The FDA will soon require all cigarettes for sale to have reduced nicotine.

These cigarettes will still have all the harmful chemicals.

But reduced nicotine will make them less addictive.

So young people will not get hooked and smokers will be able to quit more easily.

3. Compensation message

2. Efficacy messages

BREAK THE BOND

Soon, the FDA will require all cigarettes to have 95% less nicotine than they do now.

Nicotine is the #1 chemical in cigarettes that hooks you and keeps you smoking.

When the nicotine is gone, quitting smoking will be easier.

A great reason to quit.

The FDA will soon require all cigarettes for sale to have reduced nicotine.

These cigarettes will still have all the harmful chemicals.

But reduced nicotine will make them less addictive.

So young people will not get hooked and smokers will be able to quit more easily.

You can beat the cravings

Nicotine is the #1 chemical in cigarettes that hooks you and leaves you craving more.

The FDA now requires all cigarettes to have 95% less nicotine than they used to.

Reducing nicotine in cigarettes can help reduce addiction and make it easier to quit.

3. Alternatives message

Consider the alternatives

Nicotine is the #1 chemical in cigarettes that hooks you and keeps you addicted.

Now, all tobacco products that you burn: cigarettes, little cigars, cigarillos, pipe tobacco — have 95% less nicotine than they used to.

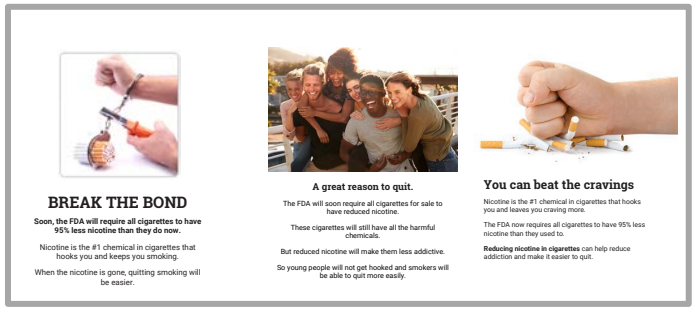
This nicotine reduction helps remove addiction to smoking and will make it easier to quit smoking.

And if you still need nicotine, you can still get it from less harmful alternatives, like nicotine gum, patches, or e-cigarettes.

RISK MESSAGES

“It's scary. It's just not something that comes to mind when you are smoking. So, it brings light to what you really put into your body.” (Current exclusive smoker)

“Most people, they go to smoke cigarettes, because they're stressed. And so, you know, once you don't have that stress relief no more, there's really no point. Like nobody wants smelly hair. Nobody wants yellow teeth. No. These are all things that people care about in their image. They care about their image. They're getting nothing out of it. There's no point in smoking.” (Non-smoker)

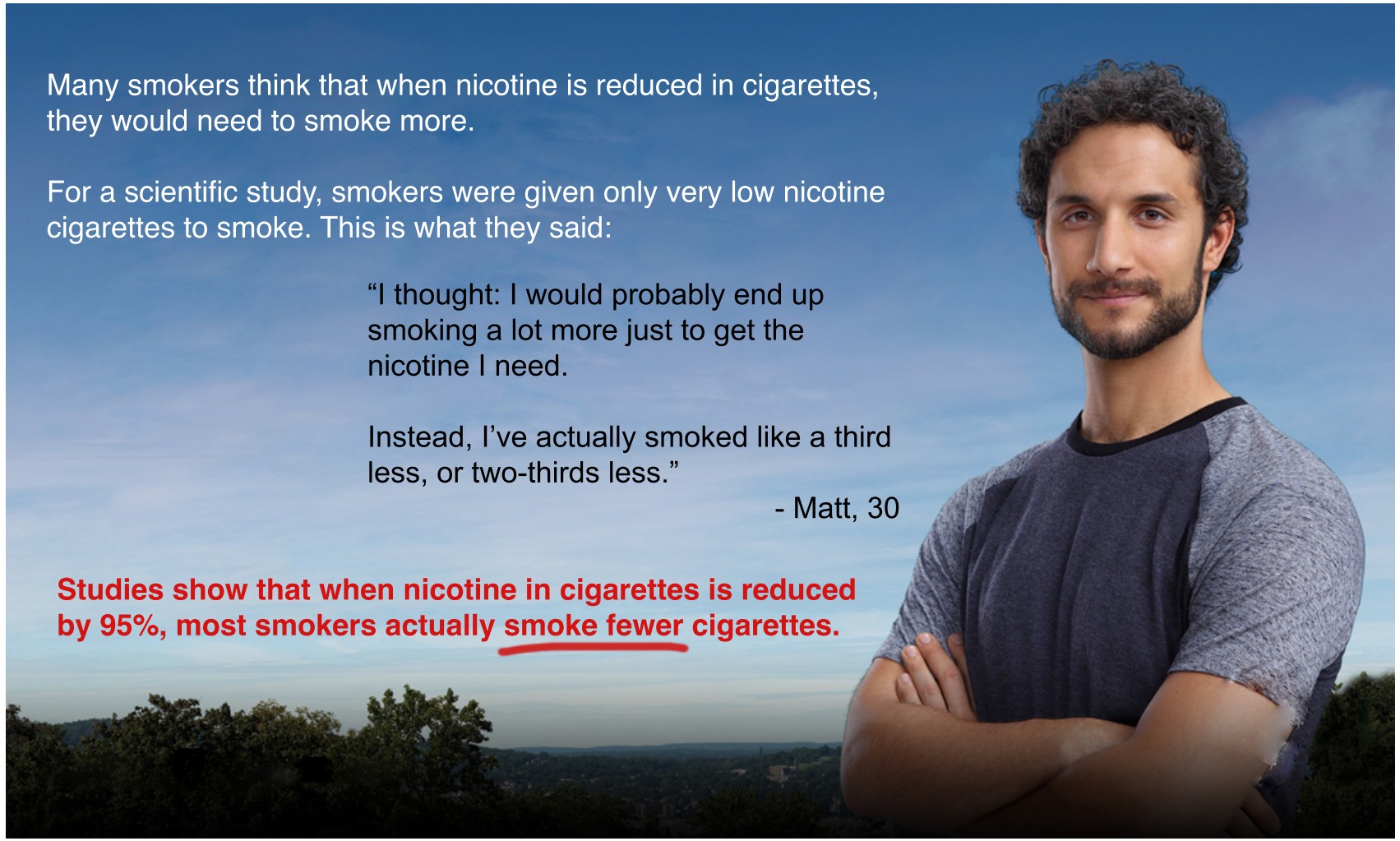


EFFICACY MESSAGES

”If they legitimately lower the levels of nicotine, that’s going to bring a lot of hope to people having trouble letting go of the cigarettes” (Exclusive smoker)

Perceived as less effective than risk messages

Mismatch between message and text



Liked the message

Wanted more data

Consider the alternatives

Nicotine is the #1 chemical in cigarettes that hooks you and keeps you addicted.

Now, all tobacco products that you burn: cigarettes, little cigars, cigarillos, pipe tobacco — have 95% less nicotine than they used to.

This nicotine reduction helps remove addiction to smoking and will make it easier to quit smoking.

And if you still need nicotine, you can still get it from less harmful alternatives, like nicotine gum, patches, or e-cigarettes.

“this is paid for by the e-cigarette folks”

“hypocritical”

Dual users will switch regardless.

DISCRETE CHOICE EXPERIMENT

OPEN ACCESS

Messaging about very low nicotine cigarettes (VLNCs) to influence policy attitudes, harm perceptions and smoking motivations: a discrete choice experiment

Reed M Reynolds ,[1] Lucy Popova ,[2] David L Ashley ,[2] Katherine C Henderson ,[2] Charity A Ntansah,[3] Bo Yang ,[4] Emily E Hackworth,[3] James Hardin,[5] James Thrasher[3]

► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/tc-2022-057577).

[1]Communication Department, University of Massachusetts Boston, Boston, Massachusetts, USA
[2]School of Public Health, Georgia State University, Atlanta, Georgia, USA
[3]Department of Health Promotion, Education and Behavior, Arnold School of Public Health, University of South Carolina, Columbia, South Carolina, USA
[4]Department of Communication, University of Arizona, Tucson, Arizona, USA
[5]Department of Epidemiology & Biostatistics, Arnold School of Public Health, University of South Carolina, Columbia, South Carolina, USA

Correspondence to
Dr Reed M Reynolds, Communication Department, University of Massachusetts, Boston, MA 02125, USA; rreynolds25@gsu.edu

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ABSTRACT

Background To reduce smoking and the harms it causes, countries, including the USA, are considering policies to reduce nicotine in combustible tobacco to minimally addictive levels. Effective messages about very low nicotine cigarettes (VLNCs) and this policy are crucial in combating misperceptions threatening the policy's effectiveness.

Data and methods A discrete choice experiment assessed messages about VLNCs. Participants were 590 adults who smoked exclusively, 379 adults who both smoked and used e-cigarettes, 443 adults who formerly smoked and 351 young adults who never smoked (total n=1763). Seven message attributes were varied systematically (source, harm, chemicals, nicotine, satisfaction, addictiveness and quitting efficacy). Outcomes were selection of messages that generated the most positive attitude towards reduced nicotine policy, the greatest perceived harmfulness of VLNCs, and most strongly motivated quitting and initiating behaviour for VLNCs.

Results Information about specific harms and chemicals of VLNCs had the largest effects on selection of messages as eliciting more negative attitudes towards VLNCs policy, increasing perceived VLNC harmfulness, increasing motivation to quit VLNCs and decreasing motivation to try VLNCs. Messages with information about quitting efficacy were selected as more motivating to quit among those who smoke, but also more motivating to try VLNCs among those who do not smoke.

Conclusion Harm and chemical information can be prioritised to ensure VLNCs are not misperceived as less harmful than regular cigarettes. Messages about increased quitting efficacy and reduced addictiveness associated with VLNCs may backfire if presented to those who do not smoke.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ The public misperceives the harmfulness, addictiveness and behavioural consequences of very low nicotine cigarettes (VLNCs).

WHAT THIS STUDY ADDS

⇒ Information about specific harms and chemicals were the most influential message attributes and were perceived to amplify risk perceptions, encourage quitting and discourage trying VLNCs.

⇒ Portraying VLNCs as easier to quit and less addictive was perceived to increase interest in trying VLNCs among those who do not smoke, including people who never smoked and who used to smoke.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Effective messaging can influence policy attitudes, risk perception and behavioural motivation regarding VLNCs.

⇒ Audience characteristics should be considered, especially when describing positive attributes of VLNCs.

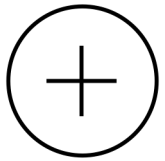
⇒ Information on harms of VLNCs appear most influential in preventing adoption by non-smoking adults.

INTRODUCTION

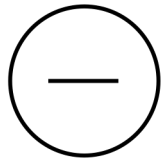
In 2018, The US Food and Drug Administration (FDA) issued an advanced notice of proposed rulemaking to limit nicotine content in combusted cigarettes to minimally or non-addictive levels,[1] amounting to approximately a 95% reduction in nicotine concentration.[2] In 2022, the US FDA announced plans to issue a proposed rule for a reduced nicotine standard.[3] This policy is intended to minimise the levels of the chemical in cigarettes that causes smoking dependence,[4 5] thereby helping people who smoke to quit more easily and keeping experimenters (primarily youth) from a lifetime of smoking. This policy has potential to substantially reduce smoking-related occurrence of lung disease, cancer and death[6–8] by preventing people who do not smoke from initiating and becoming addicted to smoking, as well as encouraging people who smoke to quit or adopt less harmful alternatives.[2 9–11] Meanwhile, New Zealand has announced plans to implement such a policy by 2025.[12]

Maximising the positive impact of a reduced nicotine policy may depend on public acceptance and understanding of very low nicotine cigarettes (VLNCs), as prior research has raised concerns about the public reaction to such a policy.[13–16] Although a reduced nicotine policy confers multiple benefits, including reductions in smoking behaviour

DISCRETE CHOICE EXPERIMENTS (DCE)



- Allow for simultaneous evaluation of multiple attributes

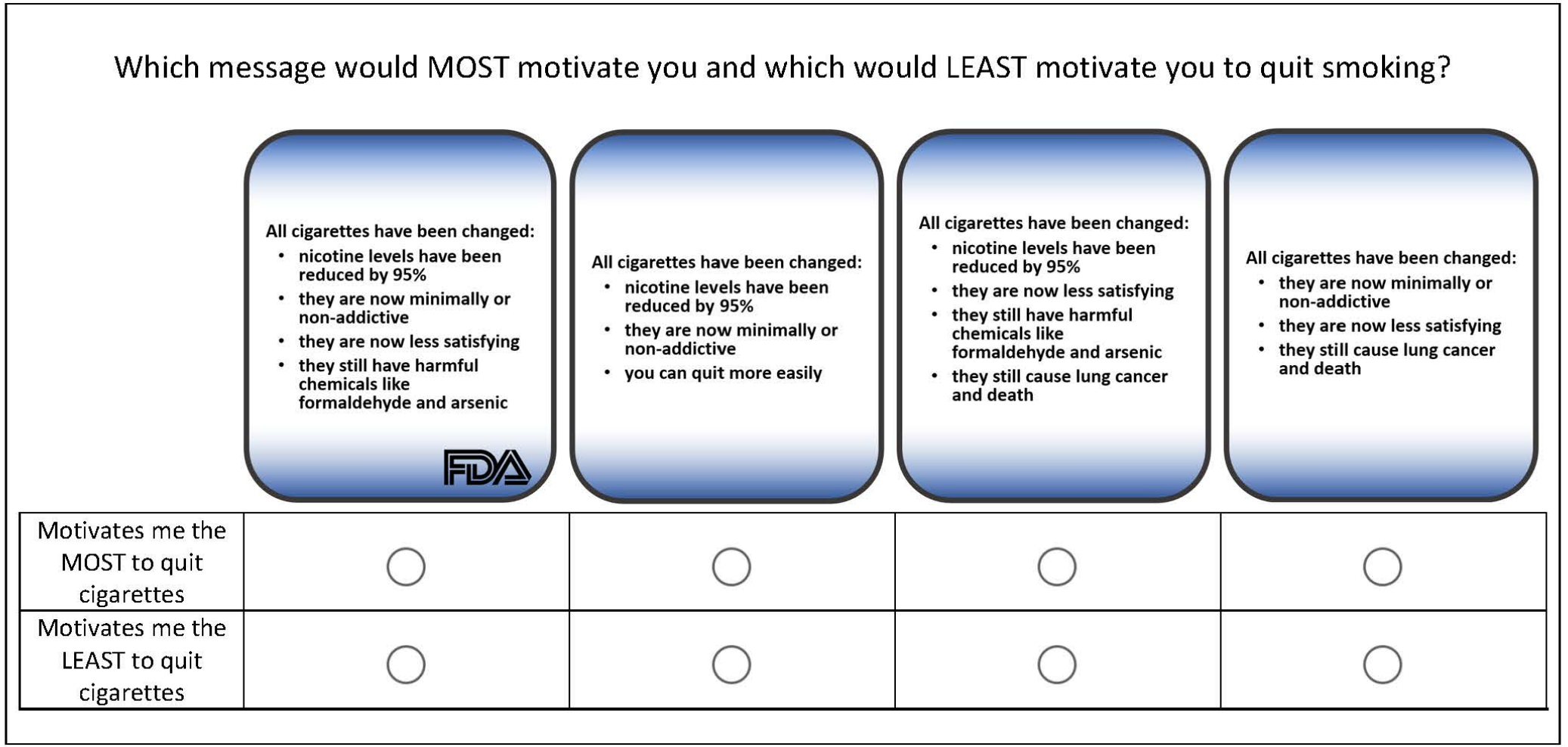


- Only preferences/message perceptions, not message effects

VLNC MESSAGE ATTRIBUTES

Message Feature	Content
Source Information	FDA Logo
Chemicals the same	“they still have harmful chemicals like formaldehyde and arsenic”
Harm the same	“they still cause lung cancer and death”
Nicotine Reduced	“nicotine levels have been reduced by 95%”
Satisfaction Reduced	“they are now less satisfying”
Addictiveness Reduced	“they are now minimally or non-addictive”
Quitting Efficacy Increased	“you can quit more easily”

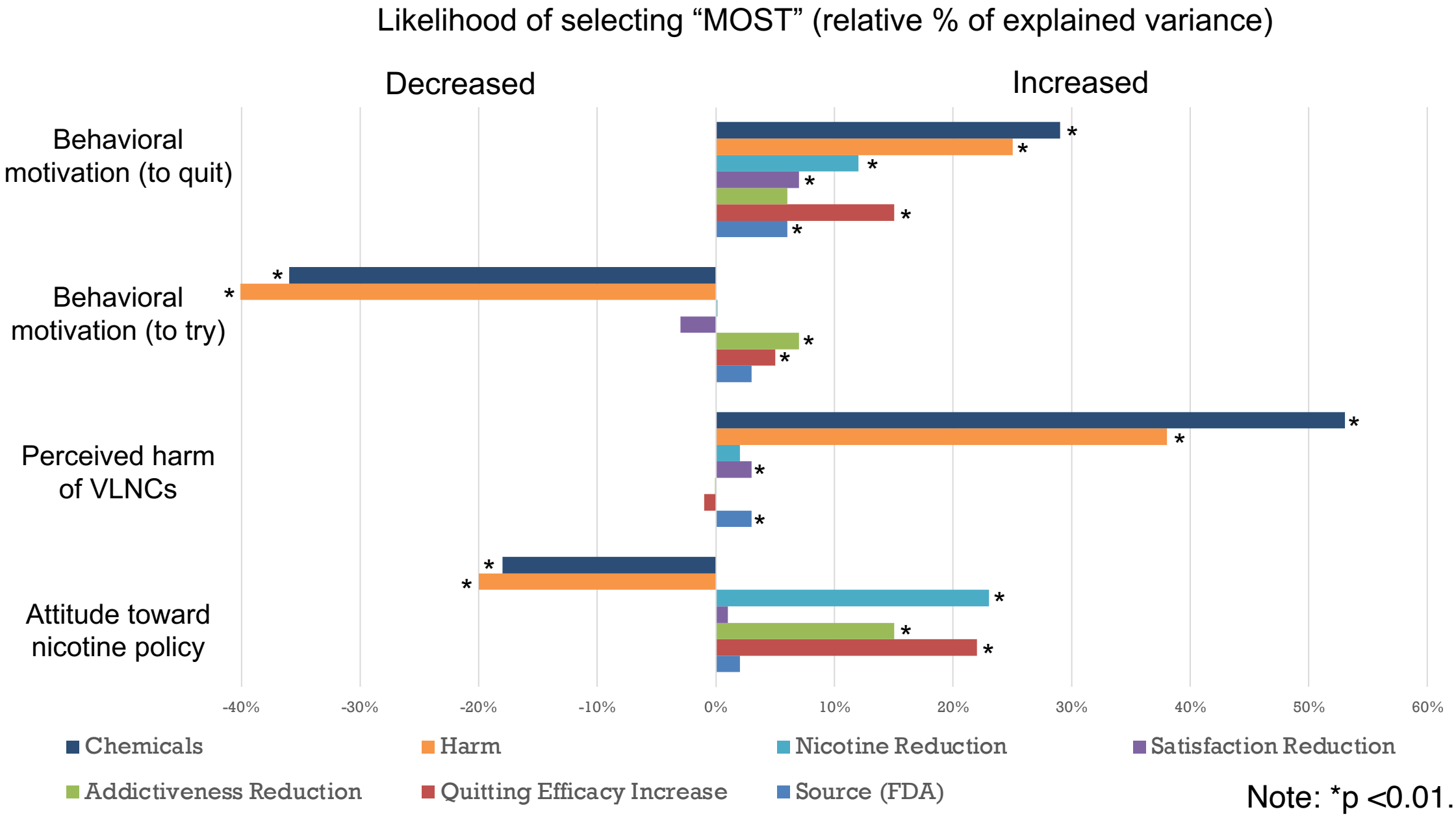
Figure 1. Example choice set for VLNC message DCE.



OUTCOMES

- Which message would make you feel most POSITIVE/NEGATRIVE about the policy of reducing nicotine in cigarettes?
- Which message would MOST/LEAST make you think cigarettes are harmful?
- Which message would MOST/LEAST motivate you to quit smoking? (exclusive smokers & dual users)
- Which message would MOST/LEAST interest you in trying cigarettes? (former smokers & nonsmokers)

Relative importance of VLNC message features for each DCE task



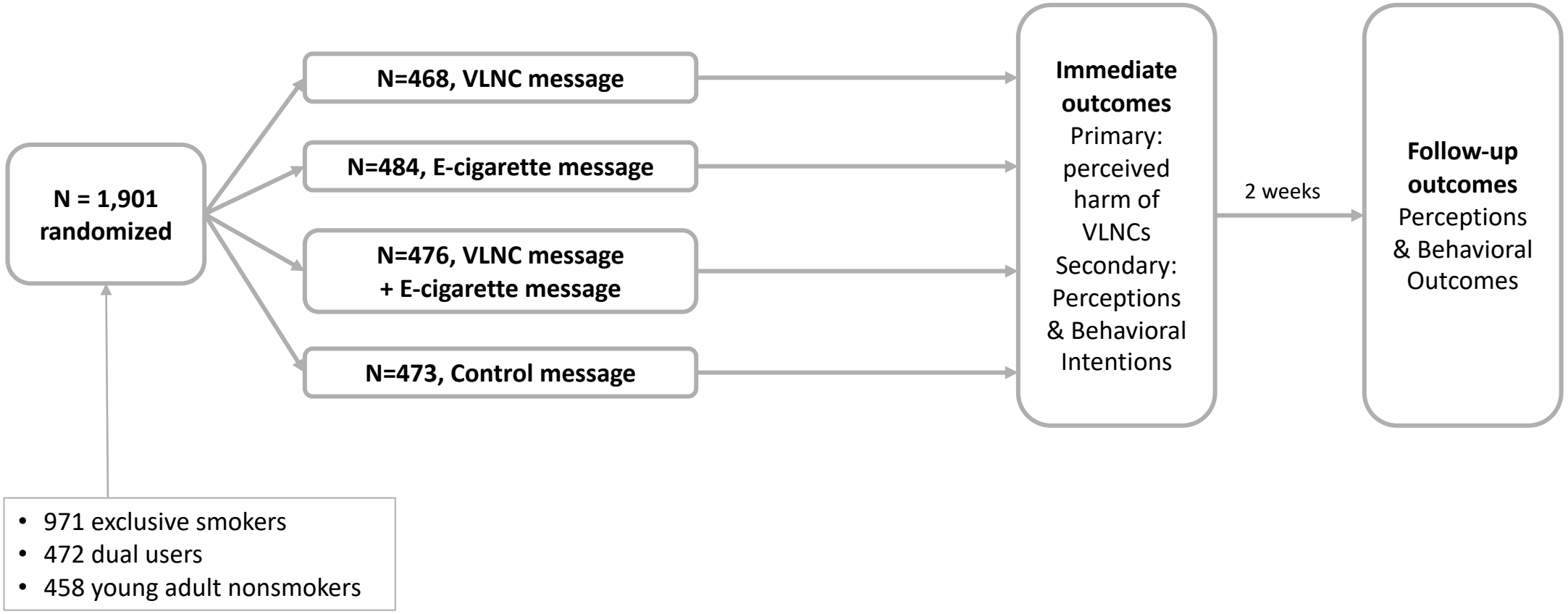
Note: *p <0.01.

CONCLUSIONS

- Harm & chemicals information – consistently influential
- Motivation to quit is potentially responsive to multiple messages that can be used simultaneously
- Communicating about products and policy differently?

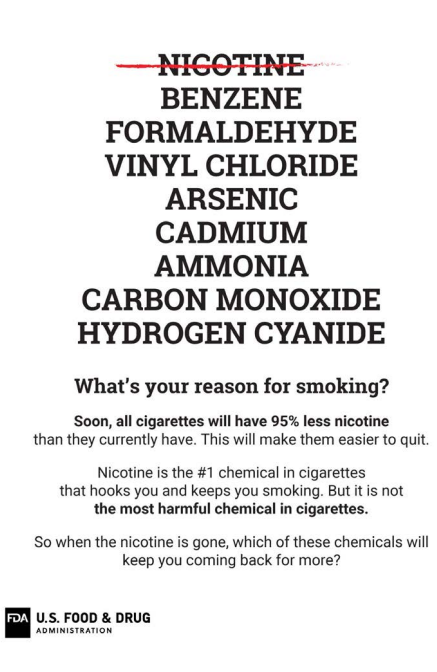
RANDOMIZED CLINICAL TRIAL

Study Design & Sample



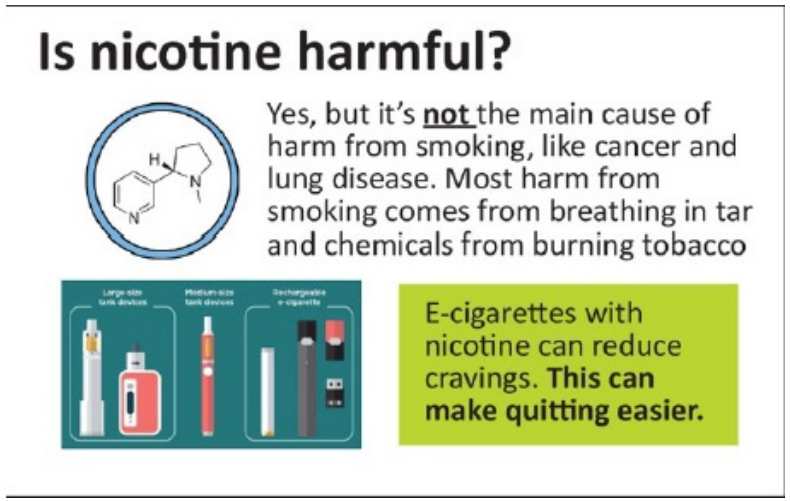
Spring 2023

VLNC Messages




Chemicals in Reduced Nicotine Cigarettes
CARBON MONOXIDE
Found in exhaust fumes
VINYL CHLORIDE
Used in plastic material
CYANHYDRIC ACID
Used in gas chambers
METHANOL
Used as rocket fuel
POLONIUM 210
Radioactive element
ACETONE
Solvent
DDT
Insecticide
NICOTINE
Used as insecticide
Cigarettes with 95% less nicotine
will still have all the harmful chemicals...
but they will make it easier to quit.
FDA U.S. FOOD & DRUG
ADMINISTRATION

E-cigarette Messages



STILL SMOKING?

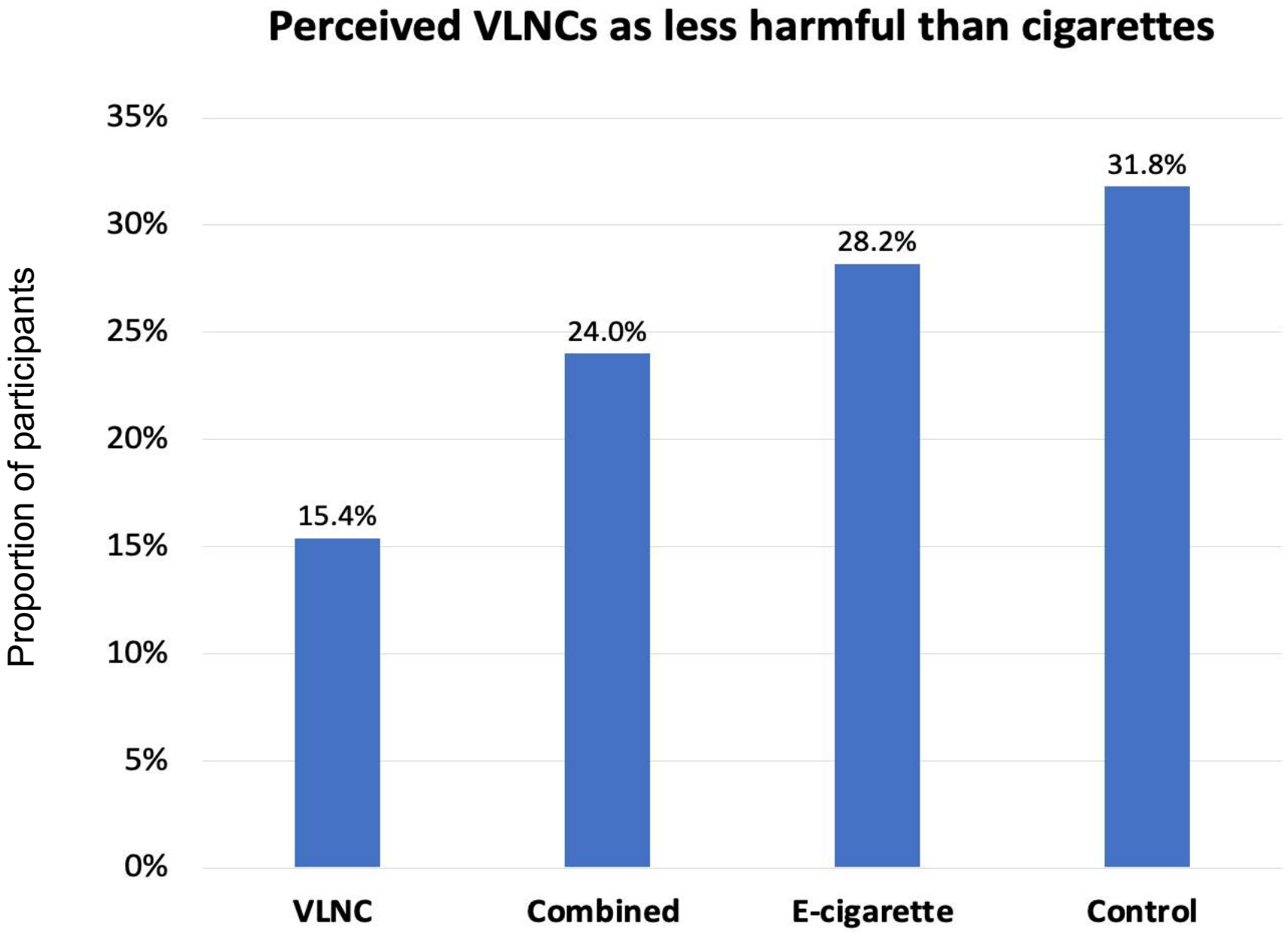
Cigarette smoke contains

9 TIMES

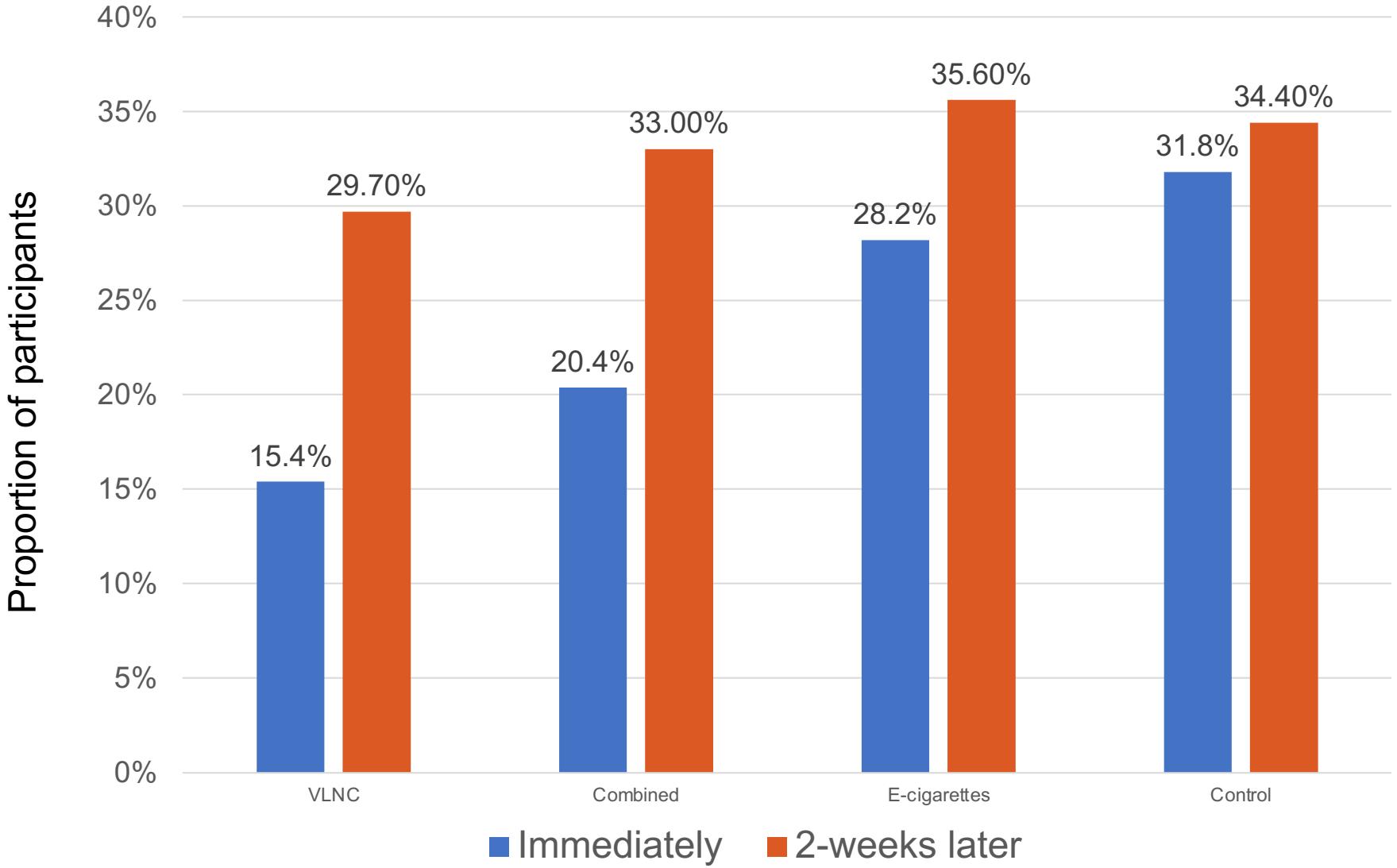
more toxic ingredients than e-cigarette vapor.

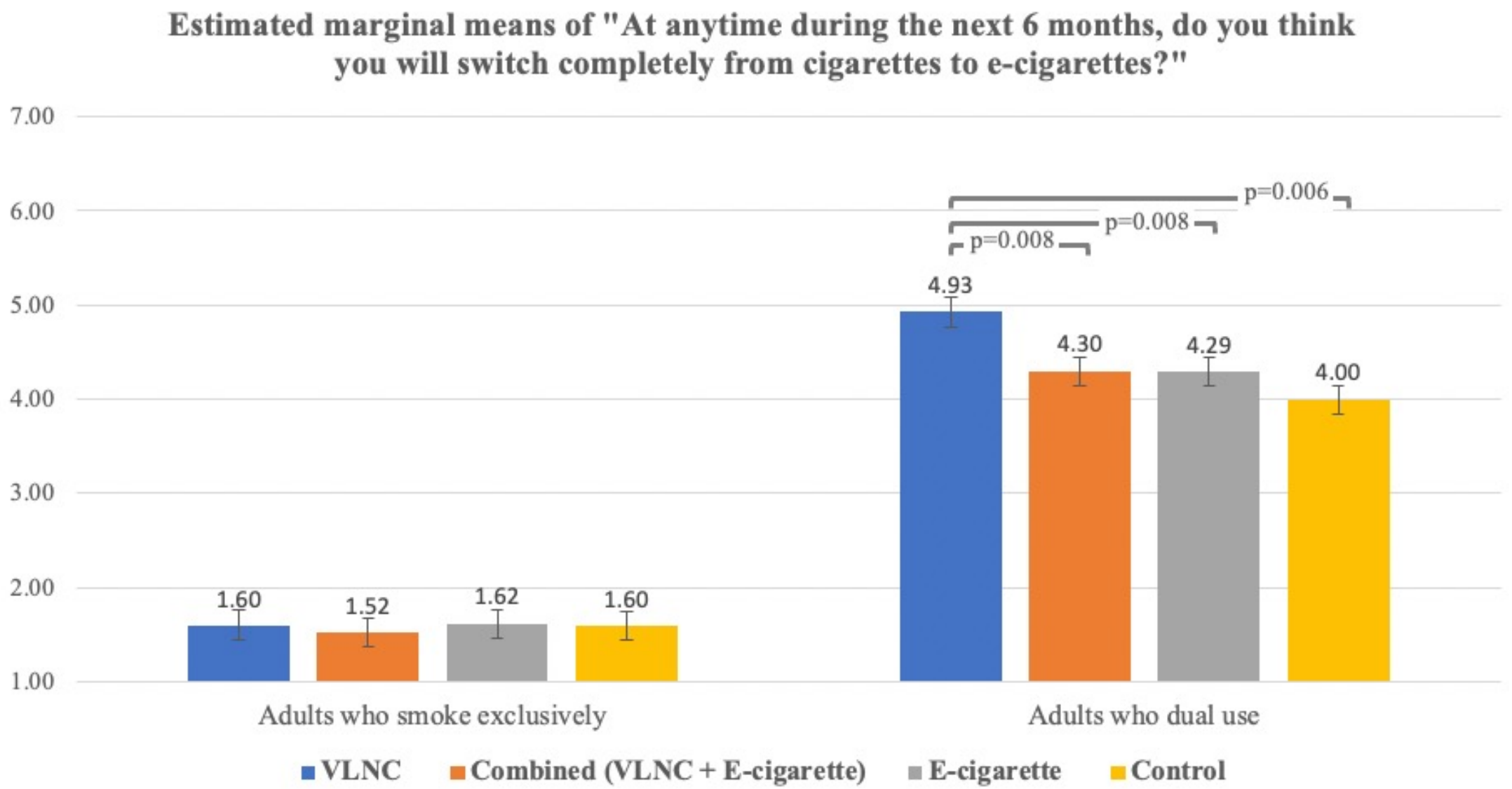
If you are a smoker and you're not ready to quit for good, you can lower the number of toxic ingredients you breathe in by switching to e-cigarettes completely.

A message from your Public Health Department


Perceived VLNCs as less harmful than cigarettes
Proportion of participants
35%
30%
25%
20%
15%
10%
5%
0%
15.4%
24.0%
28.2%
31.8%
VLNC
Combined
E-cigarette
Control

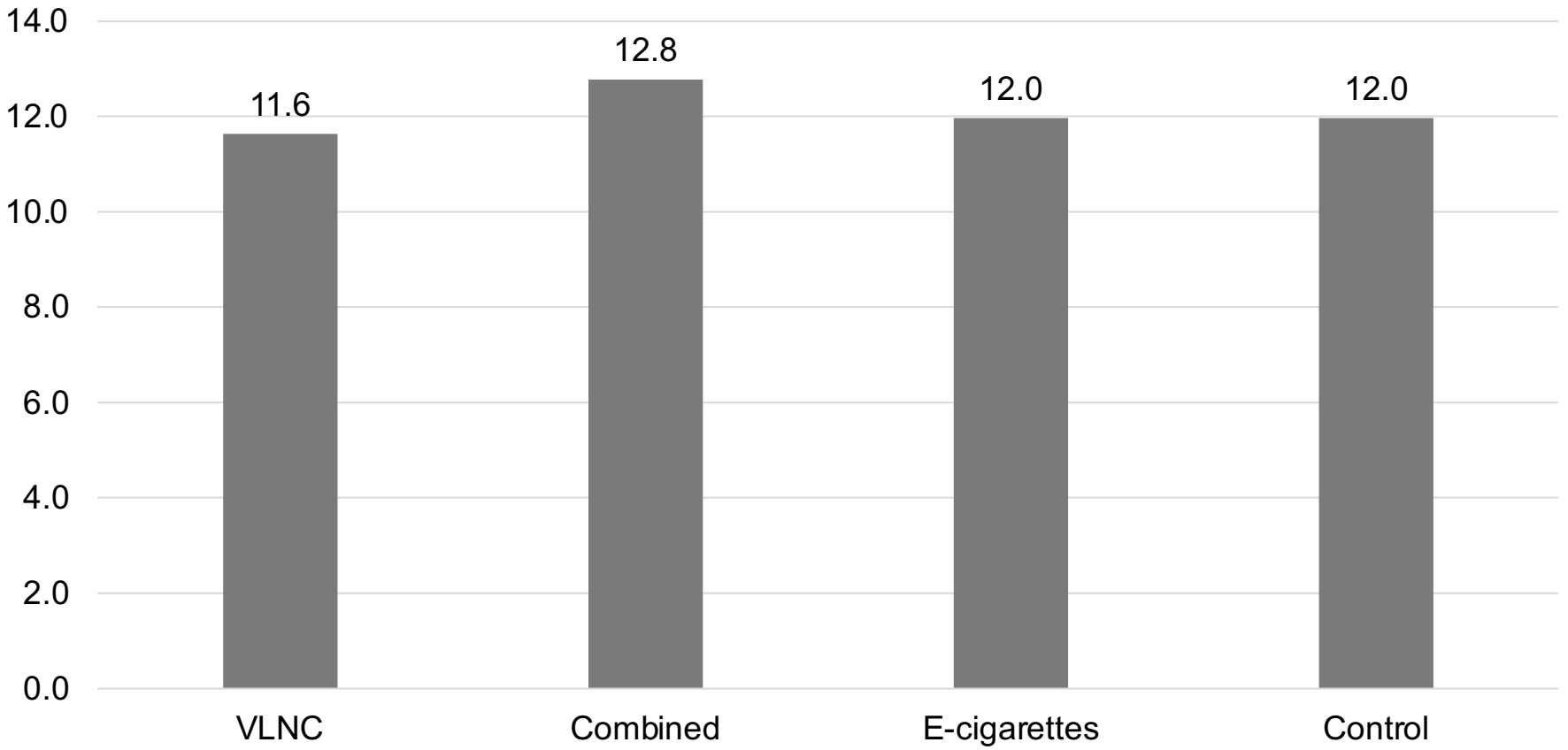
Perceived VLNCs as less harmful than cigarettes





Main effect of condition (p=.004), main effect of smoking status (p<.001), interaction effect (p=.004)

Cigarettes per day in the past 2 weeks (measured at 2-week follow up)



CONCLUSIONS

- VLNCs messages were effective in increasing perceived harm
- Combining messages about VLNCs with messages about e-cigarettes did not significantly enhance the desired outcomes

THANK YOU!

Lucy Popova
lpopova1@gsu.edu