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
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Di Pei *
David Ashley
Katherine Henderson
Hue Duong

Charity Ntansah *
Emily Hackworth
James Hardin
James Thrasher

Bo Yang

Reed Reynolds *
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

Family Smoking Prevention and Tobacco Control Act - An Overview

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.

1994
Benowitz & Henningfield, NEJM
Nicotine Regulation Timeline

2009
FSPTCA grants FDA authority to regulate tobacco products

1994
Benowitz & Henningfield, NEJM

2015
Donny et al, NEJM

- 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

- “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.”

**Timeline Details**

- **1994**: Benowitz & Henningfield, NEJM
- **2015**: Donny et al, NEJM
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

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...
Nicotine Regulation Timeline

- **2009**
  - FSPTCA grants FDA authority to regulate tobacco products

- **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

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**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 edition: 19 December 2021

Smoking tobacco products kills approximately 4,000 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 30,000 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 harms.
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 affordability and appeal of smoked tobacco products.
5. Increase the availability of smoking cessation 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

1994
Benowitz & Henningfield, NEJM

2009
FSPTCA grants FDA authority to regulate tobacco products

2009
Benowitz & Henningfield, NEJM

2017
FDA announces comprehensive approach to nicotine regulation

2017
Donny et al, NEJM

2018
FDA issues low nicotine ANPRM

2018
FDA issues low nicotine ANPRM

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

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

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

For Immediate Release: June 21, 2022

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 $154 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
'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 \(1,2\), Emily E Loud \(1,2\), James F Thrasher \(1,2\), Katherine C. Henderson \(1,2\), David L Ashley \(1,2\), Lucy Popova \(1,2\)

ABSTRACT

Objective To explore the views of smokers and people who do not smoke about the effectiveness of a proposed regulation to reduce nicotine levels in cigarettes.

Methods Four focus groups were conducted with regular smokers and people who do not smoke, in which they were asked to explore the views of smokers and people who do not smoke about the effectiveness of a proposed regulation to reduce nicotine levels in cigarettes.

Findings Findings from the focus groups were presented to the participants in a focus group discussion. The participants were asked to discuss the views of smokers and people who do not smoke about the effectiveness of a proposed regulation to reduce nicotine levels in cigarettes.

Introduction

The introduction provides a brief overview of the study and its objectives.

Methods

The methods section describes the research design, data collection methods, and analysis techniques used in the study.

Findings

The findings section presents the results of the study, with emphasis on the key findings.

Discussion

The discussion section interprets the findings and discusses their implications, comparing them with existing literature and addressing limitations.

Conclusion

The conclusion section summarizes the main findings and provides recommendations for future research.

Abbreviations

The abbreviations section lists any abbreviations used in the study, along with their definitions.

References

The references section contains a list of all the sources cited in the study, formatted according to the chosen citation style.
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.

### 1. Risk messages

<table>
<thead>
<tr>
<th>Chemicals</th>
<th>Regular Cigarettes</th>
<th>Reduced Nicotine Cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzene</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Formaldehyde</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Acrolein</td>
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<td>100%</td>
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<tr>
<td>Cadmium</td>
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<tr>
<td>Ammonia</td>
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<td>100%</td>
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<tr>
<td>Acetone</td>
<td>100%</td>
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<tr>
<td>Lead</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Uranium</td>
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<tr>
<td>Arsenic</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Nitrosamines</td>
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<tr>
<td>Acrylonitrile</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Benzopyrene</td>
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<tr>
<td>1,3-Butadiene</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Cresol</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>Isoprene</td>
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<td>100%</td>
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<tr>
<td>MEK</td>
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<td>100%</td>
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<td>Phenol</td>
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<td>100%</td>
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<td>Pyridine</td>
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<td>Quinoline</td>
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<tr>
<td>Resorcinol</td>
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<td>Styrene</td>
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<td>100%</td>
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<td>Toluene</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nickel</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Nitric Oxide</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Hydroquinone</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td>PAH</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Polonium</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>and more...</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

### 2. Efficacy messages

**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.
“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)
"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
Many smokers think that when nicotine is reduced in cigarettes, they would need to smoke more.

For a scientific study, smokers were given only very low nicotine cigarettes to smoke. This is what they said:

“I thought: I would probably end up smoking a lot more just to get the nicotine I need.

Instead, I’ve actually smoked like a third less, or two-thirds less.”

- Matt, 30

Studies show that when nicotine in cigarettes is reduced by 95%, most smokers actually smoke fewer cigarettes.
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.
Messaging about very low nicotine cigarettes (VLNCs) to influence policy attitudes, harm perceptions and smoking motivations: a discrete choice experiment

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

ABSTRACT

Background To reduce smoking and the harms it causes, countries, including the USA, are considering policies to reduce nicotine in combustible tobacco to minimal additive 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 500 adults who smoked exclusively, 279 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 VOC harms, 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 do not 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.

INTRODUCTION

In 2016, The US Food and Drug Administration (FDA) issued an advanced notice of proposed rulemaking to limit nicotine content in combustible cigarettes to minimal non-addictive levels,4 amounting to approximately a 95% reduction in nicotine concentration.5 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, thereby helping people who smoke to quit more easily and encouraging experiences (primarily youth) from a lifetime of smoking. This policy has potential to substantially reduce smoking-related incidence of lung disease, cancer and death6 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.7–10 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

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 promoting adoption by non-smoking adults.

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Information on harms of VLNCs appear most influential in promoting adoption by non-smoking adults.
DISCRETE CHOICE EXPERIMENTS (DCE)

- Allow for simultaneous evaluation of multiple attributes

- Only preferences/message perceptions, not message effects
### VLNC MESSAGE ATTRIBUTES

<table>
<thead>
<tr>
<th>Message Feature</th>
<th>Content</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source Information</td>
<td>FDA Logo</td>
</tr>
<tr>
<td>Chemicals the same</td>
<td>“they still have harmful chemicals like formaldehyde and arsenic”</td>
</tr>
<tr>
<td>Harm the same</td>
<td>“they still cause lung cancer and death”</td>
</tr>
<tr>
<td>Nicotine Reduced</td>
<td>“nicotine levels have been reduced by 95%”</td>
</tr>
<tr>
<td>Satisfaction Reduced</td>
<td>“they are now less satisfying”</td>
</tr>
<tr>
<td>Addictiveness Reduced</td>
<td>“they are now minimally or non-addictive”</td>
</tr>
<tr>
<td>Quitting Efficacy Increased</td>
<td>“you can quit more easily”</td>
</tr>
</tbody>
</table>
Figure 1. Example choice set for VLNC message DCE.

<table>
<thead>
<tr>
<th>Motivates me the MOST to quit cigarettes</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>All cigarettes have been changed:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• nicotine levels have been reduced by 95%</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>• they are now minimally or non-addictive</td>
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<tr>
<td>• they are now less satisfying</td>
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<tr>
<td>• they still cause lung cancer and death</td>
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</tbody>
</table>
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

Likelihood of selecting “MOST” (relative % of explained variance)

- Decreased
- Increased

Behavioral motivation (to quit)
- Behavioral motivation (to try)
- Perceived harm of VLNCs
- Attitude toward nicotine policy

Relative importance of VLNC message features:
- Chemicals
- Harm
- Addictiveness Reduction
- Quitting Efficacy Increase
- Source (FDA)
- Satisfaction Reduction

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

N = 1,901 randomized

- N=468, VLNC message
- N=484, E-cigarette message
- N=476, VLNC message + E-cigarette message
- N=473, Control message

Immediate outcomes
Primary: perceived harm of VLNCs
Secondary: Perceptions & Behavioral Intentions

Follow-up outcomes
Perceptions & Behavioral Outcomes

2 weeks

• 971 exclusive smokers
• 472 dual users
• 458 young adult nonsmokers

Spring 2023
VLNC Messages

Cigarettes with 95% less nicotine will still give you all the diseases... but they will make it easier to quit.

Chemicals in Reduced Nicotine Cigarettes

Soon, all cigarettes will have 95% less nicotine than they have now. They will be easier to quit.

What would reduced nicotine cigarettes give you?

Warning: Reduced nicotine cigarettes cause fatal lung disease.

COPD is America’s #3 killer and it has no cure.

Cigarettes with 95% less nicotine can still cause the same diseases, but they will make it easier to quit smoking.

What’s your reason for smoking?

Soon, all cigarettes will have 95% less nicotine than they currently have. This will make them easier to quit.

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?
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

Cigarettes with 95% less nicotine will still have all the harmful chemicals... but they will make it easier to quit.
E-cigarette Messages

Take the first step to better health.
Choose e-cigarettes instead of traditional cigarettes if you’re not ready to quit smoking for good.

Switching to e-cigarettes completely can reduce your risk for health issues like trouble breathing, yellow teeth, and gum disease.

STILL SMOKING?
Cigarette smoke contains 9 TIMES more toxic ingredients than e-cigarette vapor.

If you smoke cigarettes, the healthiest option is to quit for good. If you’re not ready to quit, switching to e-cigarettes completely can decrease your risk for things like shortness of breath, gum disease, and lung cancer, giving you as much as 10 more years to spend with the people you love.

Is nicotine harmful?
Yes, but it’s not the main cause of harm from smoking, like cancer and lung disease. Most harm from smoking comes from breathing in tar and chemicals from burning tobacco.

E-cigarettes with nicotine can reduce cravings. This can make quitting easier.

Your health is in your hands: so why are you still smoking?
Smoking causes serious health issues, like EMPHYSEMA, LUNG DISEASE, and multiple types of CANCER.

Reduce your risk by switching to e-cigarettes completely if you’re not ready to quit smoking for good, and take back control of your health.
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

- VLNC: 15.4%
- Combined: 24.0%
- E-cigarette: 28.2%
- Control: 31.8%
Perceived VLNCs as less harmful than cigarettes

- VLNC: 29.70%
- Combined: 33.00%
- E-cigarettes: 28.2%
- Control: 31.8%

Proportion of participants

Immediately: 15.4%, 20.4%, 28.2%, 34.0%
2-weeks later: 29.70%, 33.00%, 35.60%, 34.40%

Legend: Immediately (blue), 2-weeks later (orange)
Estimated marginal means of "At anytime during the next 6 months, do you think you will switch completely from cigarettes to e-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)

- VLNC: 11.6
- Combined: 12.8
- E-cigarettes: 12.0
- Control: 12.0
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

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. This will make them easier to quit.

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?