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Randomized Experimental Test of a Reduced-Exposure Message for an Ecigarette: Comprehension and Related Misperceptions

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Abstract

Switching from cigarette smoking to electronic nicotine delivery systems (ENDS) reduces exposure to toxic substances. Yet, many smokers believe ENDS are at least as harmful as smoking, making them less likely to switch from cigarettes to ENDS. Effectively communicating reduced-exposure information is critical, but such messages must be properly understood. This online study evaluated comprehension of a factual message indicating that smokers who switch completely away from smoking to JUUL-brand ENDS can reduce their exposure to harmful chemicals in cigarette smoke. Participants were 12,557 adults 18+ (smokers, dual users, former and never users of tobacco) randomized to see the reduced-exposure message or to a Control condition. After exposure to the message, the majority of smokers (89%) understood the need to switch completely from cigarettes to JUUL to achieve reduced exposure. Most smokers and nonusers (>75%) did not misperceive JUUL as completely eliminating exposure to harmful chemicals, and >85% understood that using JUUL has risk. Exposure to the message improved understanding of the intended audience for JUUL. Individuals with limited health literacy showed modestly lower comprehension, regardless of condition. Ensuring adequate comprehension of messages about reduced exposure from ENDS is important to ensuring that such messaging can benefit public health.

Introduction

A growing body of scientific evidence suggests that e-cigarettes, or electronic nicotine delivery systems (ENDS), are less harmful than combustible cigarettes [1, 2]. Indeed, a comprehensive review by the National Academy of Sciences, Engineering, and Medicine (NASEM) concluded that, except for nicotine, exposure to potentially toxic substances from ENDS is significantly lower than that from cigarettes [2]. Such reductions have been demonstrated for several specific ENDS, including JUUL[®] [3]. Studies have also demonstrated reductions in biomarkers of potential harm such as inflammation and oxidative stress, when smokers switch to ENDS [4-7].

However, multiple studies show that many smokers believe that using ENDS is at least as harmful as smoking cigarettes, and such misperceptions are increasing over time [8-10]. This has important implications for public health, as smokers holding such misperceptions are less likely to adopt ENDS [11, 12] and to switch away from cigarette smoking using ENDS [10]. Therefore, it is important to communicate accurate scientific information about the reduction in toxicants exposures when smokers switch from smoking to ENDS. The legislation governing FDA's regulation of tobacco products provides for such "reduced exposure" messaging.

However, effectively communicating reduced-exposure messages is challenging. Core elements of the message need to be understood. Crucially, they should not be misunderstood in ways that might undermine potential public health benefits, such as promoting the concept that ENDS have no toxicant exposures at all. Accordingly, it is important to evaluate comprehension of such messaging. While public health effects of messaging will ultimately derive from changes in risk perceptions and changes in behavior, proper comprehension of the message is a foundational predicate for those effects. Here, we report on message comprehension, including substantial *mis*understanding of the message; other papers address message believability and effects on overall risk perceptions and behavioral intentions.

Comprehension was tested for a reduced-exposure message indicating that smokers who switch completely away from smoking to a particular ENDS product (JUUL-brand ENDS; henceforth "the ENDS product" or "JUUL") can reduce their exposure to harmful chemicals in cigarette smoke and the exposure of others around them. These message-testing data come from a large, randomized experiment in which adults with varying tobacco-use histories were randomized to be exposed to either the reduced-exposure message, expressed as part of an advertisement for the ENDS product, or to the same advertisement without reduced-exposure messaging. The study evaluated comprehension of two key message elements: the fact that *lower* exposure did not imply *no* exposure, and the fact that smokers need to switch completely away from smoking to achieve the full benefit. Relatedly, the study assessed participants' perception of the intended audience for the product; i.e., that it is not intended for non-users of tobacco. Comprehension.

Materials and Methods

Design

Data come from a large online experiment in which adult participants were randomized to be exposed to a statement about reduced exposure to harmful chemicals (Test condition) as part of a video about the JUUL ENDS product, or to see the identical video without reduced exposure messaging (Control condition). Participants were adults (18+) of varying tobacco-use profiles and histories, recruited both online through existing consumer research panels and offline through mall and street intercepts. After being shown the video, message comprehension was assessed in participants in the Test condition (i.e., among those who saw the message). All participants were assessed for risk perceptions and for their perceptions of the intended users of the ENDS product.

This research was deemed exempt by an institutional review board (IRB), and participants provided informed consent. Participants recruited from existing research panels were compensated with panel points, and those recruited in-person were compensated \$35.

Participants

Participants were 12,557 adults, 18+ years old. (Young adults below the age of legal purchase (21+) were included by design to assess young adult responses; sub-analyses of this subset are reported in a separate paper). Participants were recruited into four "Tobacco Use Groups": (1) current cigarette smokers ("Smokers"), (2) current dual users of both cigarettes and ENDS products ("Dual Users"), (3) former tobacco product users ("Former Users"), and (4) never established tobacco product users ("Never Users"). These are described in Table I.

Table I. Tobacco Use Groups

| | | Cigaret | rette Smoking ENDS use | | Other tobacco products | | |
|---------------------------|-------|------------------------------|--------------------------------------|------------------------|--------------------------------------|-------------------|--------------------------------------|
| | Ν | Current | History | Current | History | Current | History |
| Smokers | 3,485 | Every day or some days | 100+ cigarettes | None | Allowed | Allowed | Allowed |
| Dual Users | 1,756 | Every day or some days | 100+ cigarettes | Every day or some days | 100+ ENDS uses | Allowed | Allowed |
| Former Users | 1,857 | None ^a | Possibly established ^b | None ^a | Possibly established ^b | None ^a | Possibly established ^b |
| Never (established) Users | 5,459 | None ^a | 0-99 cigarettes ^c | None ^a | 0-99 ENDs uses ^c | None ^a | 0-99 uses† |

^a No use in the preceding 6 months. ^b Former Users were intended to be persons who had been established users of one or more tobacco products, but who had not used tobacco in 6+ months. However, due to a programming error, Former Users were included only if they had been established users (i.e., having met lifetime criteria) of all the tobacco products that they reported having tried.

^c Never established users could have used one or more tobacco products, but never to the point of being considered established users (i.e., 100 uses).

Demographic quotas for age and gender (nested), race/ethnicity, geographic region and educational attainment based on the Center for Disease Control and Prevention's 2019 National Health Interview Survey were set within each Tobacco Use Group in an attempt to increase representativeness to the US population. However, a programming error impeded enforcement of these quotas early in recruitment, causing Former Users and Never Users – the most numerous groups in the population – to exceed their quotas and deviate from demographic quotas. This resulted in low weighting efficiencies for these groups (.50 and .56, respectively); accordingly, Tobacco Use Groups were not weighted to match the demographic targets.

Besides needing to fit into one of these Tobacco Use Groups that had not met quota, participants had to be US residents with internet access. Individuals were not eligible to participate if: they were unable to read, speak, or understand English; they had participated in tobacco-related research in the past month; they or a family or household member were currently or formerly employed by the tobacco industry or a company involved in the conduct of the study; or they were in litigation with a tobacco company.

A total of 14,816 people completed the survey between August and October 2021. Of these, 2,259 participants were removed as invalid responders if they: were speeders (completed the survey in $\leq 1/3$ the median completion time), failed an attention check (where respondents were directed to choose a particular response), failed a manipulation check (checking if respondent had actually looked at the study stimulus), provided risk perception responses suggesting inattention (e.g., rating "Smoking 10 cigarettes daily for the rest of your life" as "0% harmful to health" or as less harmful than "Not using any tobacco products"), were living in the same household as other participants, and/or provided survey responses contradicting screening

eligibility criteria. The randomization scheme was effective in balancing the two study conditions on key demographic variables (see Table II).

Video Stimuli

All participants were shown a brief (<1 minute) online video advertisement describing the ENDS product, explaining that the product is an alternative to cigarettes for adult smokers, comes in tobacco and menthol flavors, provides smokers with a familiar experience and does not create ash or smoke. The ad included the mandated nicotine warning required on all ENDS products in the US. The advertisement and message language were refined in preliminary qualitative and mixed-methods work with 144 smokers and non-users of tobacco products (Supplementary Figure 1).

For the Test condition only, the video concluded with the following reduced-exposure message text, which was both displayed and voiced over (Supplementary Material):

"JUUL does not burn tobacco or produce smoke. EVIDENCE TO DATE SHOWS: Switching completely from cigarettes to JUUL reduces exposure to harmful chemicals in cigarette smoke to you and to those around you."

This message is consistent with the reduced-exposure message authorized by the U.S. Food and Drug Administration (FDA) for IQOS [14], a reduced-exposure cigarette, and is supported by analyses of JUUL aerosol chemistry [15], toxicology [3], and biomarker studies [7, 16, 17], as well as an exhaled-breath study [18] relevant to bystanders' exposures.

Participants could view the video as many times as they wished, and it was available for re-view via a link during parts of the survey. As the proposed message is not yet authorized by FDA for

dissemination, after the survey, participants were shown a debriefing statement (Supplementary Material).

Outcome Measures

Relevant outcome measures are presented in Supplementary Table I and described below. These measures were sourced from prior research [19] or national surveys (National Adult Tobacco Survey); [20], or were developed for purposes of this study and refined through rounds of cognitive testing with tobacco users and non-users, including young adults (ages 21 to 29) and individuals with limited health literacy.

Message Comprehension

Comprehension of the message was assessed with two multiple-choice items, presented in random order. These items were developed to directly assess understanding of two key concepts: "completely switching" ("Based only on this health information, what do smokers have to do to reduce their exposure to harmful chemicals in cigarette smoke?" Response options: "Stop smoking completely and only use JUUL / Reduce how many cigarettes they smoke by half and use JUUL / Keep smoking the same number of cigarettes and use JUUL / None of the above / Don't know") and "reduce exposure" ("Smokers who switch completely from cigarettes to JUUL will have _____." Response options: "More / The same amount / Less / No exposure" "to harmful chemicals" and "don't know").

The message was shown on the same screen as the comprehension items, and participants could click on a link to re-view the full video if desired, as this was intended as a test of comprehension, not memory (as recommended by FDA, [21]).

Absolute Risk Misperceptions

There is concern that exposing people to a message of reduced exposure might lead them to conclude that use of the ENDS product carries no risk at all. This risk misperception was assessed in two ways: (1) rating the product as "Not at all harmful" on a 4-point Harm item (Not at all / Somewhat / Moderately/ Very harmful), and (2) rating use of the ENDS product "10 times per day for the rest of your life" as "0% harmful to health" on the Risk Rating Task (11-point rating scale from 0% to 100% harmful to health using 10% increments). See Supplementary Table I for details.

Perception of Intended Audience

Participants in both the Test and Control conditions were asked about their perception of the intended users of the ENDS product. Any response that included "People who do not currently smoke or use tobacco" was considered incorrect. A response of only "Current cigarette smokers" was considered correct. A response of "Current e-cigarette users" (with or without also endorsing "Current cigarette smokers") was considered acceptable.

Health Literacy

Health literacy was evaluated with the Newest Vital Sign (NVS; [22]), a reliable and valid assessment [22] that has been used in electronic self-administered form [23], including in assessments of comprehension of reduced-risk messages [24]. The NVS asks participants to read a nutrition label and answer six questions about it. Scores >3 indicate adequate health literacy (AHL), and lower scores indicate possible limited health literacy (LHL).

Analysis

By design, Smokers who were and were not planning to quit smoking cigarettes in the next 30 days had been recruited in equal numbers for other analyses. To balance their representation

among Smokers, these cohorts were weighted to reflect their actual population proportions [25]. Among Dual Users, current users of JUUL were down-weighted from 50% to 30%, to reflect the then-current JUUL market share.

Message comprehension was analyzed descriptively. Chi-square tests were used to compare Absolute Risk Misperceptions and Perception of Intended Audience by condition and health literacy status. To assess whether any observed differences by health literacy were due to the message or more generally a main effect of health literacy, logistic regression models tested the health literacy × condition interaction.

Results

As seen in Table II, the sample was middle aged, majority female and White, non-Hispanic, but with a substantial fraction of Black and Hispanic individuals. Half had annual household income below \$50,000, most had not completed college, and about one quarter demonstrated limited health literacy. There were demographic differences between Tobacco Use Groups as expected. For example, compared to other groups, Smokers had lower educational attainment, Dual Users were younger, and Former users were older. Test and Control samples were well matched (Supplementary Table II).

| | 0 | Tobacco Use Group | | | | | | |
|-----------------------------|---------------------------------------|----------------------|-------------------------|---------------------------|--------------------------|--|--|--|
| | Overall - (N=12,557) | Smokers (N=3,485) | Dual Users (N=1,756) | Former Users (N=1,857) | Never Users (N=5,459) | | | |
| | n (%) | n (%) | n (%) | n (%) | n (%) | | | |
| Age (M[SD]) | 49.98 (17.11) | 46.40 (14.64) | 37.43 (12.11) | 61.58 (14.20) | 52.37 (17.62) | | | |
| Sex | | | | | | | | |
| Male | 4,526 (36.0%) | 1,575 (45.2%) | 852 (48.5%) | 529 (28.5%) | 1,570 (28.8%) | | | |
| Female | 7,988 (63.6%) | 1,900 (54.5%) | 895 (51.0%) | 1,327 (71.5%) | 3,866 (70.8%) | | | |
| Other | 43 (0.3%) | 10 (0.3%) | 9 (0.5%) | 1 (0.1%) | 23 (0.4%) | | | |
| Race/Ethnicity ^a | | | | | | | | |
| White, non-Hispanic | 9,883 (78.7%) | 2,593 (74.4%) | 1,361 (77.5%) | 1,558 (83.9%) | 4,371 (80.1%) | | | |
| Black, non-Hispanic | 878 (7.0%) | 365 (10.5%) | 104 (5.9%) | 86 (4.6%) | 323 (5.9%) | | | |
| Hispanic or Latino | 1,049 (8.4%) | 340 (9.8%) | 165 (9.4%) | 134 (7.2%) | 410 (7.5%) | | | |
| Other, non-Hispanic | 670 (5.3%) | 170 (4.9%) | 112 (6.4%) | 74 (4.0%) | 314 (5.8%) | | | |
| Education ^b | · · · · | ~ / | · · · · · | · · · · · | × / | | | |
| High school degree or less | 3,624 (28.9%) | 1,432 (41.1%) | 691 (39.4%) | 466 (25.1%) | 1,035 (19.0%) | | | |
| Some college | 4,387 (34.9%) | 1,500 (43.0%) | 789 (44.9%) | 679 (36.6%) | 1,419 (26.0%) | | | |
| College graduate or more | 4,546 (36.2%) | 553 (15.9%) | 276 (15.7%) | 712 (38.3%) | 3,005 (55.0%) | | | |
| Income ^a | | ~ / | · · · · · | · · · · | | | | |
| <\$25,000 | 2,718 (21.6%) | 1,070 (30.7%) | 515 (29.3%) | 306 (16.5%) | 827 (15.1%) | | | |
| \$25,000-\$49,999 | 3,512 (28.0%) | 1,188 (34.1%) | 536 (30.5%) | 494 (26.6%) | 1,294 (23.7%) | | | |
| \$50,000-\$74,999 | 2,556 (20.4%) | 617 (17.7%) | 321 (18.3%) | 427 (23.0%) | 1,191 (21.8%) | | | |
| \$75,000-\$99,999 | 1,587 (12.6%) | 314 (9.0%) | 170 (9.7%) | 262 (14.1%) | 841 (15.4%) | | | |
| ≥\$100,000 | 2,178 (17.3%) | 296 (8.5%) | 214 (12.2%) | 364 (19.6%) | 1,304 (23.9%) | | | |
| Marital Status | , , , , , , , , , , , , , , , , , , , | ~ / | · · · · · | · · · · | | | | |
| Married | 5,465 (43.5%) | 1,114 (32.0%) | 527 (30.0%) | 970 (52.2%) | 2,854 (52.3%) | | | |
| Living with Partner | 1,428 (11.4%) | 600 (17.2%) | 366 (20.8%) | 127 (6.8%) | 335 (6.1%) | | | |
| Widowed | 784 (6.2%) | 185 (5.3%) | 43 (2.4%) | 212 (11.4%) | 344 (6.3%) | | | |
| Divorced/Separated | 1,896 (15.1%) | 679 (19.5%) | 271 (15.4%) | 337 (18.1%) | 609 (11.2%) | | | |
| Never Married | 2,984 (23.8%) | 907 (26.0%) | 549 (31.3%) | 211 (11.4%) | 1,317 (24.1%) | | | |
| Limited Health Literacy | 3,045 (24.2%) | 1,133 (32.5%) | 538 (30.6%) | 387 (20.8%) | 987 (18.1%) | | | |

Table II. Participant demographics by each of the Tobacco Use Groups

^aAs there were some missing values for race/ethnicity and income, columns may sum to less than 100%. ^bHigh school degree or less = responses of "some high school or less," "GED," "high school graduate"; Some college = responses of "trade or technical school," "some college"; College graduate or more = responses of "college graduate," "post graduate degree"

Message Comprehension

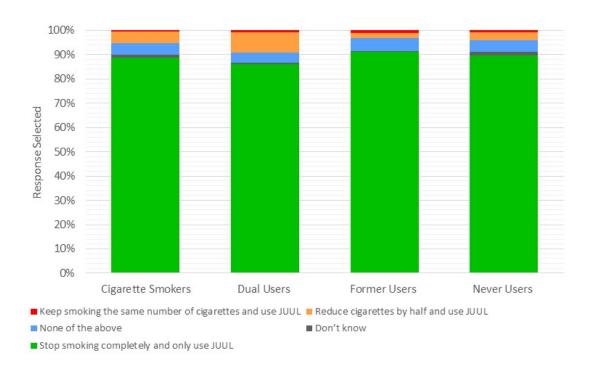
Switching Completely

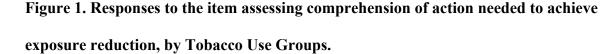
A large majority of participants (>85% across Tobacco Use Groups), including Smokers,

understood that the message was communicating that smokers must stop smoking completely to

achieve the asserted reductions in exposure (Figure 1). Comprehension was also relatively high

among LHL individuals (81.6%), though lower than among AHL (91.4%).





Exposure Reduction

More than 80% of participants in each Tobacco Use Group accurately understood that the message was communicating a *reduction* in exposure to harmful chemicals (Figure 2, top panel). However, 17.2% of Smokers, 9.5% of Dual Users, 18.4% of Former Users, and 13.0% of Never Users misinterpreted the message to indicate that switching from cigarettes to the ENDS product would result in no exposure to harmful chemicals. Most LHL individuals (73.3%) also understood that the message was communicating a reduction in exposure, though this was lower than the rate for AHL (87.3%). A higher percentage of LHL individuals than AHL individuals (23.9% vs. 11.9%, p<0.001) misunderstood the message to be communicating an elimination in exposure to harmful chemicals.

Figure 2. This figure provides the percentage of participants in each Tobacco Use Group who (1) provided a response of "Less exposure to harmful chemicals" to the Exposure Reduction item (green), (2) provided a response of "More exposure to harmful chemicals" to the Exposure Reduction item (blue), (3) provided a response of "The same amount of exposure to harmful chemicals" to the Exposure Reduction item (yellow), (4) selected "don't know" to the Exposure Reduction item (gray), and (5) misunderstood the message to be communicating an elimination of exposure to harmful chemicals found in cigarette smoke (orange/red). The top panel further breaks out the last category by those who indicated that the ENDS product was at least "Somewhat harmful" to their health on the Harm item (orange) and those who indicated that use of the ENDS product was "Not at all harmful" to their health on the Harm item (red). The bottom panel further breaks out the last category by those who indicated that the ENDS product was >0% harmful to their health on the Risk Rating task (orange) and those who indicated that use of the ENDS product was 0% harmful to their health on the Risk Rating item (red).

Understanding that JUUL involves some exposure to harmful chemicals, and is harmful to use. (a) Absolute Harm scale



Absolute Risk Misperceptions: Harm Item

Some participants misunderstood the message to indicate that smokers switching to the ENDS product would have no exposure to harmful chemicals. The concern was that these individuals might then perceive use of the ENDS product as being not at all harmful. Accordingly, analyses examined the misperception that the ENDS product was not at all harmful. The vast majority of participants across Tobacco Use Groups rated use of the ENDS product as at least "Somewhat harmful" to their health on the Harm item; Former and Never users exhibited the lowest rates of exhibiting risk misperception (endorsing "Not at all harmful") on this item (Table III). Exposure to the message significantly increased this misperception among Smokers, Former and Never Users (see Table III).

| | | | | Tobacco U | Jse Group | | | | |
|---------------------------|------------------------|----------------------|-----------------------|--------------------|-----------------------|--------------------|------------------------|----------------------|--|
| | Smo | kers | Dual | Dual Users | | Former Users | | Never Users | |
| | Control $(N=1,807^a)$ | Message (N=1,678) | Control (N=932) | Message (N=824) | Control (N=942) | Message (N=915) | Control (N=2,854) | Message (N=2,605) | |
| Harm Item | | | | | | | | | |
| Not at all harmful | 3.7% | 7.2% | 8.0% | 10.6% | 2.2% | 4.5% | 1.2% | 2.9% | |
| At least somewhat harmful | 96.3% | 92.8% | 92.0% | 89.4% | 97.8% | 95.5% | 98.8% | 97.1% | |
| | $\chi^2(df=1) = 20.70$ | | $\chi^2(df=1) = 3.65$ | | $\chi^2(df=1) = 7.29$ | | $\chi^2(df=1) = 19.55$ | | |
| | | p<0.001 | | p=0.056 | | p=0.007 | | p<0.001 | |
| Risk Rating Task | | | | | | | | | |
| 0% (No Risk) | 0.9% | 2.8% | 3.0% | 2.7% | 0.4% | 1.4% | 0.2% | 1.1% | |
| >0% (Some Risk) | 99.1% | 97.2% | 97.0% | 97.3% | 99.6% | 98.6% | 99.8% | 98.9% | |
| | $\chi^2(d)$ | <i>f</i> =1) = 16.54 | $\chi^2(df=1) = 0.14$ | | $\chi^2(df=1) = 5.08$ | | $\chi^2(df=1) = 15.66$ | | |
| | | p<0.001 | | p=0.706 | | p=0.024 | | p<0.001 | |

Table III. Absolute Risk Misperception by Condition and Tobacco Use Group

LHL = Limited Health Literacy, AHL = Adequate Health Literacy

Sample sizes are unweighted, percentages are weighted ^a N=1,805 for % harmful to health metric

Importantly, among those who responded that the message asserted no exposure to harmful chemicals on the Exposure Reduction comprehension item, 81.1% of Smokers, 69.2% of Dual Users, 85.7% of Former Users, and 88.2% of Never Users nevertheless indicated that use of the ENDS product would be harmful to their health. That is, overall, very few participants exposed to the message (4% or less) across Tobacco Use Groups thought the message communicated "No exposure" to harmful chemicals and also believed the ENDS products were not harmful to their health (Figure 2, top panel).

Absolute Risk Misperceptions: Risk Rating Task

While exposure to the message significantly increased risk misperception among Smokers, Former Users, and Never Users, observed rates of absolute risk misperception on the Risk Rating Task were low, particularly among nonusers (Table III). Further, 92.3% of those who, on the Exposure Reduction Comprehension item, had said that the message implied no exposure to harmful chemicals rated the ENDS product as harmful on this task. Overall, very few participants exposed to the message (<2%) across Tobacco Use Groups thought the message communicated "No exposure" *and* believed the ENDS product would not harm their health (Figure 2, bottom panel).

Logistic regression was used to assess whether the impact of the message on absolute risk misperception differed between participants based on health literacy status (condition x health literacy status interaction), with separate models for two outcomes: (1) rating use of the ENDS product as "Not at all harmful" on the Harm item and (2) rating it as "0% harmful to health" on the Risk Rating Task. In both models, individuals with LHL were more likely than AHL individuals to misperceive the ENDS product as being without risk, that is, indicating that use of the ENDS product was "Not at all harmful" on the Harm item (7.3% vs 3.2%, p<0.001); and

rating use of the ENDS product as "0% harmful to health" on the Risk Rating Task (2.9% vs.

0.8%, p<0.001). However, these misperceptions were unrelated to exposure to the message: there

was a main effect of literacy status, but no literacy by message interaction (see Table IV).

| | b | SE | df | $LR \chi^2$ | p-value |
|------------------|--------|-------|----|-------------|---------|
| Harm Item | | | | | |
| Intercept | -3.006 | 0.047 | | | |
| Health Literacy | 0.442 | 0.047 | 1 | 81.93 | < 0.001 |
| Condition | 0.333 | 0.047 | 1 | 51.76 | < 0.001 |
| Condition × HL | 0.045 | 0.047 | 1 | 0.93 | 0.335 |
| Risk Rating Task | | | | | |
| Intercept | 4.193 | 0.083 | | | |
| Health Literacy | -0.639 | 0.083 | 1 | 55.51 | < 0.001 |
| Condition | -0.416 | 0.083 | 1 | 26.98 | < 0.001 |
| Condition × HL | -0.089 | 0.083 | 1 | 1.15 | 0.284 |

 Table IV. Impact of the Message on Absolute Risk Misperceptions by Health Literacy

 Status

All analyses weighted

LR = Likelihood Ratio, HL = Health Literacy

Perception of Intended Audience.

Overall, the vast majority of participants (93.1%) indicated that smokers were the intended users of the ENDS product. Exposure to the message significantly increased the likelihood that participants perceived smokers as the intended users of the ENDS product (from 91.4% to 95.1%, p<0.001) and decreased the likelihood that they considered non-users of tobacco (from 12.8% to 5.7%, p<0.001) or current ENDS users (from 50.5% to 26.8%, p<0.001) as the intended audience. Importantly, for Former and Never Users, exposure to the message reduced the likelihood that respondents saw the product as intended for non-users like themselves, by 67.4% and 55.7%, respectively (Table V).

| Tobacco Use Group | Condition | N | Current cigarette smokers % | Current e-cigarette users % | Current cigarette smokers and e-cigarette users % | People who do not currently smoke or use tobacco % | None of the above / Don't know % |
|----------------------|-----------|-------|-----------------------------------|-----------------------------------|--|---|---|
| C | Control | 1,807 | 55.5% | 3.2% | 30.6% | 7.4% | 3.4% |
| Smokers | Message | 1,678 | 72.9% | 1.2% | 18.0% | 3.8% | 4.1% |
| Devil | Control | 932 | 48.5% | 4.5% | 34.6% | 10.0% | 2.4% |
| Dual Users | Message | 824 | 68.6% | 1.9% | 22.0% | 5.6% | 1.9% |
| E a mar an U a ann | Control | 942 | 35.0% | 3.8% | 38.3% | 17.1% | 5.7% |
| Former Users | Message | 915 | 68.4% | 2.1% | 21.1% | 5.6% | 2.8% |
| Name | Control | 2,854 | 38.0% | 2.8% | 39.6% | 15.7% | 3.9% |
| Never Users | Message | 2,605 | 67.4% | 0.9% | 22.7% | 6.9% | 2.0% |

Table V. Perception of Intended Audience Responses by Condition and Tobacco Use Group

Sample sizes are unweighted, percentages are weighted

There was a significant main effect for health literacy status (Table VI): those with LHL were

less likely than those with AHL to select "current cigarette smokers" and/or "current e-cigarette

users" (84.4% vs. 88.3%) and more likely to select non-users as the intended users (10.7% vs.

9.0%). There was no health literacy x condition interaction, suggesting that these

misunderstandings were not due to the message, per se.

| | b | SE | df | $LR \chi^2$ | p-value |
|------------------------------|--------|-------|----|-------------|---------|
| "Current cigarette smokers" | | | | •• | - |
| and/or "Current e-cigarette | | | | | |
| users"+ | | | | | |
| Intercept | 1.933 | 0.032 | | | |
| Health Literacy | 0.147 | 0.032 | 1 | 19.97 | < 0.001 |
| Condition | -0.388 | 0.032 | 1 | 156.01 | < 0.001 |
| Condition × HL | -0.010 | 0.032 | 1 | 0.09 | 0.758 |
| "People who do not currently | | | | | |
| smoke or use tobacco" * | | | | | |
| Intercept | -2.323 | 0.038 | | | |
| Health Literacy | 0.083 | 0.038 | 1 | 4.51 | 0.034 |
| Condition | -0.436 | 0.038 | 1 | 143.30 | < 0.001 |
| Condition × HL | 0.010 | 0.038 | 1 | 0.07 | 0.797 |

| Table VI. Impact of the Message on Perception of Intended Audience by Health Literacy |
|---|
| Status |

All analyses weighted

LR = Likelihood Ratio, HL = Health Literacy

⁺ These responses are considered correct/acceptable

*This response is incorrect

Discussion

This study demonstrated good comprehension of key points conveyed in the reduced-exposure

message tested in this study. Very large majorities understood that switching to an ENDS

product such as JUUL would reduce but not completely eliminate smokers' exposure to harmful

chemicals in cigarette smoke. Correspondingly, large majorities attributed some degree of risk to

the ENDS product. Additionally, almost 90% of smokers – for whom this aspect of the message is most relevant – understood that achieving the claimed exposure reduction required stopping smoking completely. Almost 90% of smokers also understood that the ENDS product was meant for smokers, and exposure to the message improved correct understanding of the intended audience, such that over 90% of those who saw the message understood that it was not intended for non-users of tobacco. Participants with AHL were more likely to answer questions correctly, but there was no evidence that the lower performance of LHL individuals was due to the message itself promoting confusion.

The tested message asserted that smokers switching to JUUL would experience reduced exposure to harmful chemicals in cigarette smoke. Less than 15% of those who saw the message reported they thought the message implied *no* exposure to harmful chemicals in cigarette smoke. One issue in this assessment is that both the message and the question referred to "harmful chemicals *in cigarette smoke*" (italics added) and the message noted that JUUL does not produce cigarette smoke. Thus, participants may have concluded that there was no exposure to chemicals in cigarette smoke, while still believing that JUUL exposed users to some harmful chemicals. Consistent with this, even respondents who stated that the ENDS product produced no exposure to harmful chemicals in cigarette smoke rarely attributed no risk of harm to the ENDS product. Less than 3% of respondents understood the message to mean no exposure to harmful chemicals and attributed no risk to the ENDS product.

Nearly 90% of those who saw the message also understood that smokers should stop completely to achieve reductions in exposure to harmful chemicals. Some smokers (\sim 5%) and dual users (\sim 8%) understood the message to imply that smokers could reduce such exposures by cutting their cigarette consumption in half. This was not an unreasonable inference. While it was not

what the message stated, the conclusion is factually correct: cutting cigarette consumption by at least half does reduce exposure to toxicants in cigarette smoke, by approximately half the amount achieved through completely stopping smoking [16, 26]. This is not necessarily an example of what Seidenberg et al [27] label the 'exclusive-to-dual' halo effect, in that participants stated that substantial reductions in cigarette consumption were necessary to achieve reduced exposure.

Although the message communicated reduced exposure from ENDS, it reduced by over 50% the misunderstanding that ENDS products are meant for non-users of tobacco. Among participants who saw the message, >90% saw current smokers and not non-tobacco users as intended audiences for JUUL.

As expected, individuals with more limited health literacy demonstrated less understanding of the topics tested. This is typical in tests of comprehension, both of medication labels [28] and modified risk messages for tobacco products [24]. However, comprehension was always at least 75% even among limited-literacy individuals. Differences by health literacy were also small; absolute differences by health literacy are often 10% or more [29]; the differences we observed were smaller. Importantly, in each case where the effect of the message, per se, could be evaluated, there was no evidence that exposure to the message promoted misunderstanding among LHL individuals. LHL individuals demonstrated less understanding of the topics, but this was equally true whether they saw the message or not.

The study evaluated a particular expression of the reduced-exposure concept, with features that may have affected the findings. The message language was deliberately kept simple, for example referring to "harmful chemicals," without listing chemical names that some participants may find unfamiliar and difficult to interpret [30]. Aerosol chemistry research supporting the tested

message compared chemicals in JUUL aerosol to those in cigarette smoke [15] by assaying 53 harmful or potentially harmful chemicals, but the levels of 40 of these chemicals were too low in JUUL aerosols to even be detected or quantified. Overall, reductions compared to cigarette smoke averaged 98%, with small variations among chemicals. However, the message did not try to quantify the degree of reduction or try to link reductions in exposure to particular disease risks, although such features have been advocated for tobacco-control messaging [30]. Quantification can be confusing to consumers, especially those with limited numeracy [31], and guidance on health communication suggests avoiding it in most instances [32, 33]. In general, the literature suggests that simpler messages are more likely to be understood, especially by individuals with limited health literacy, and are preferred by consumers [34].

The study was subject to some limitations. The sample was not fully representative of US adults, though it was diverse with respect to smoking and tobacco use status and many sociodemographic variables. The NVS scale used to assess health literacy has a substantial element of numeracy as well as health-literacy per se. Nevertheless, it is a useful indicator of health literacy [22] and had the advantage of being suitable for online administration. Errors in the programming led to former smokers being restricted to those who had become established users of every tobacco product they had tried, which was not the intention. This is unlikely to have affected comprehension.

These analyses only evaluated participants' comprehension of the message, i.e., whether they understood what the message intended to communicate. They do not address whether participants believed or agreed with the message, how the message affected their overall risk perceptions, or their intentions to use JUUL. However, demonstrating that participants understood the message and did not materially misinterpret it is a fundamental predicate to evaluating those downstream effects, which will be addressed in detail in additional papers. As noted, the study evaluated a particular expression of reduced exposure for a particular ENDS product – JUUL. The results may differ for other messages or even other products.

The study also had substantial strengths, in that it had a very large and diverse sample that included a large subset of individuals with limited health literacy and a range of tobacco use histories. The availability of risk perception data along with comprehension data helped clarify how participants interpreted the message.

In summary, data indicated that the exposure-reduction message tested was generally understood and facilitated respondents' understanding that JUUL is intended for smokers, and not for nonusers of tobacco. The simplicity of the message may have facilitated comprehension. Comprehension is a necessary but not sufficient characteristic of a reduced-exposure message that can benefit the public health. Further analysis is needed to assess the effect of the message on risk perceptions and intention to use ENDS in adult populations varying in smoking status.

Declaration of Interest Statement

Authors S.A.M. and R.A.B. are employees of Juul Labs, Inc. Through PinneyAssociates, Inc, authors S.S. and M.A.S. provide consulting to Juul Labs, Inc. on tobacco harm reduction, on an

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Data Availability Statement

Due to the nature of the research, due to legal and commercial reasons, supporting data is not

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References

- 1 McNeill A, Simonavičius E, Brose LS *et al.* Nicotine vaping in England: an evidence update including health risks and perceptions, September 2022. A report commissioned by the Office for Health Improvement and Disparities. London: Office for Health Improvement and Disparities. 2022.
- 2 National Academies of Sciences Engineering and Medicine. *Public health consequences of e-cigarettes*. Washington, DC: The National Academies Press,2018.
- 3 Talih S, Salman R, El-Hage R *et al.* Characteristics and toxicant emissions of JUUL electronic cigarettes *Tob Control* 2019;**28**:678-680. First published on 2019/02/13, 10.1136/tobaccocontrol-2018-054616.
- 4 Edmiston JS, Webb KM, Wang J *et al.* Biomarkers of Exposure and Biomarkers of Potential Harm in Adult Smokers Who Switch to e-Vapor Products Relative to Cigarette Smoking in a 24-week, Randomized, Clinical Trial *Nicotine Tob Res* 2022;**24**:1047-1054. First published on 2022/02/09, 10.1093/ntr/ntac029.
- 5 Kanobe MN, Jones BA, Nelson P *et al.* Part three: a randomized study to assess biomarker changes in cigarette smokers switched to Vuse Solo or Abstinence *Sci Rep* 2022;**12**:20658. First published on 2022/12/01, 10.1038/s41598-022-25054-z.
- 6 Akiyama Y, Sherwood N. Systematic review of biomarker findings from clinical studies of electronic cigarettes and heated tobacco products *Toxicol Rep* 2021;**8**:282-294. First published on 2021/02/09, 10.1016/j.toxrep.2021.01.014.
- 7 Shiffman S, Oliveri DR, Goldenson NI *et al.* Comparing Adult Smokers who Switched to JUUL vs Continuing Smokers: Biomarkers of Exposure and of Potential Harm and Respiratory Symptoms under review.

- 8 McNeill A, Brose L, Calder R *et al.* E-cigarettes: an evidence update: Public Health England, 2015.
- 9 Tattan-Birch H, Jackson SE, Ide C *et al.* Evaluation of the Impact of a Regional Educational Advertising Campaign on Harm Perceptions of E-Cigarettes, Prevalence of E-Cigarette Use, and Quit Attempts Among Smokers *Nicotine Tob Res* 2020;**22**:1148-1154. First published on 2019/12/15, 10.1093/ntr/ntz236.
- 10 Kim S, Shiffman S, Sembower MA. US adult smokers' perceived relative risk on ENDS and its effects on their transitions between cigarettes and ENDS *BMC Public Health* 2022;**22**:1771. First published on 2022/09/20, 10.1186/s12889-022-14168-8.
- 11 Brose LS, Hitchman SC, Brown J *et al.* Is the use of electronic cigarettes while smoking associated with smoking cessation attempts, cessation and reduced cigarette consumption? A survey with a 1-year follow-up *Addiction* 2015;**110**:1160-1168. First published on 2015/04/23, 10.1111/add.12917.
- 12 Elton-Marshall T, Driezen P, Fong GT *et al.* Adult perceptions of the relative harm of tobacco products and subsequent tobacco product use: Longitudinal findings from waves 1 and 2 of the population assessment of tobacco and health (PATH) study *Addict Behav* 2020;**106**:106337. First published on 2020/03/08, 10.1016/j.addbeh.2020.106337.
- 13 Andrus MR, Roth MT. Health literacy: a review *Pharmacotherapy* 2002;**22**:282-302. First published on 2002/03/20, 10.1592/phco.22.5.282.33191.
- 14 U.S. Food and Drug Administration. FDA authorizes marketing of IQOS Tobacco Heating System with 'reduced exposure' information. Silver Spring, MD: U.S. Food and Drug Administration, 2020.
- 15 Chen X, Bailey P, Yang C *et al.* Targeted Characterization of the Chemical Composition of JUUL Systems Aerosol and Comparison with 3R4F Reference Cigarettes and IQOS Heat Sticks *Separations* 2021;**8**:168. 10.3390/separations8100168.
- 16 Cohen G, Goldenson NI, Bailey PC *et al.* Changes in Biomarkers of Cigarette Smoke Exposure After 6 Days of Switching Exclusively or Partially to Use of the JUUL System with Two Nicotine Concentrations: A Randomized Controlled Confinement Study in Adult Smokers *Nicotine Tob Res* 2021;**23**:2153-2161. First published on 2021/06/24, 10.1093/ntr/ntab134.
- 17 Jay J, Pfaunmiller EL, Huang NJ *et al.* Five-Day Changes in Biomarkers of Exposure Among Adult Smokers After Completely Switching From Combustible Cigarettes to a Nicotine-Salt Pod System *Nicotine Tob Res* 2020;**22**:1285-1293. First published on 2019/11/07, 10.1093/ntr/ntz206.
- 18 Oldham MJ, Sehgal A, Cohen G *et al.* Room air constituent concentrations from use of electronic nicotine delivery systems and cigarettes using different ventilation conditions *Sci Rep* 2021;**11**:1736. First published on 2021/01/20, 10.1038/s41598-021-80963-9.
- 19 U.S. Food and Drug Administration. U.S. Smokeless Tobacco Company Modified Risk Tobacco Product (MRTP) Application. Retreived from <u>https://www.fda.gov/tobacco-products/advertising-and-promotion/us-smokeless-tobacco-company-modified-risk-tobacco-product-mrtp-application</u> 2022.
- 20 Centers for Disease Control and Prevention. National Adult Tobacco Survey (NATS). Retreived from <u>https://www.cdc.gov/tobacco/data_statistics/surveys/nats/index.htm</u> 2018.
- 21 U.S. Food and Drug Administration. Guidance for Industry: Labeling OTC Human Drug Products. Retreived from <u>https://www.fda.gov/media/76481/download</u> 2009.

- 22 Weiss BD, Mays MZ, Martz W *et al.* Quick assessment of literacy in primary care: the newest vital sign *Ann Fam Med* 2005;**3**:514-522. First published on 2005/12/13, 10.1370/afm.405.
- 23 Mansfield ED, Wahba R, Gillis DE *et al.* Canadian adaptation of the Newest Vital Sign(c), a health literacy assessment tool *Public Health Nutr* 2018;**21**:2038-2045. First published on 2018/04/26, 10.1017/S1368980018000253.
- 24 Pillitteri JL, Shiffman S, Sembower MA *et al.* Assessing comprehension and perceptions of modified-risk information for snus among adult current cigarette smokers, former tobacco users, and never tobacco users *Addict Behav Rep* 2020;**11**:100254. First published on 2020/05/30, 10.1016/j.abrep.2020.100254.
- 25 U.S. Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse *et al.* Population Assessment of Tobacco and Health (PATH) Study [United States] Public-Use Files. Retreived from https://www.icpsr.umich.edu/web/NAHDAP/studies/36231, 2021.
- 26 Anic GM, Rostron BL, Hammad HT *et al.* Changes in Biomarkers of Tobacco Exposure among Cigarette Smokers Transitioning to ENDS Use: The Population Assessment of Tobacco and Health Study, 2013-2015 *Int J Environ Res Public Health* 2022;**19**. First published on 2022/02/16, 10.3390/ijerph19031462.
- 27 Seidenberg AB, Popova L, Ashley DL *et al.* Inferences beyond a claim: a typology of potential halo effects related to modified risk tobacco product claims *Tob Control* 2020. First published on 2020/10/14, 10.1136/tobaccocontrol-2019-055560.
- 28 Davis TC, Wolf MS, Bass PF, 3rd *et al.* Low literacy impairs comprehension of prescription drug warning labels *J Gen Intern Med* 2006;**21**:847-851. First published on 2006/08/03, 10.1111/j.1525-1497.2006.00529.x.
- 29 U.S. Food and Drug Administration. 2018 TPSAC Meeting Materials and Information. Available at <u>https://www.fda.gov/advisory-committees/tobacco-products-scientific-advisory-committee/2018-tpsac-meeting-materials-and-information</u> 2018.
- 30 Noar SM, Kelley DE, Boynton MH *et al.* Identifying principles for effective messages about chemicals in cigarette smoke *Prev Med* 2018;**106**:31-37. First published on 2017/09/12, 10.1016/j.ypmed.2017.09.005.
- 31 Wackowski OA, O'Connor RJ, Diaz D *et al.* '95% less harmful'? Exploring reactions to quantitative modified risk claims for snus and e-cigarettes *Tob Control* 2022;**31**:730-736. First published on 2021/03/24, 10.1136/tobaccocontrol-2020-056303.
- 32 Centers for Disease Control and Prevention. The CDC Clear Communication Index. Available at <u>https://www.cdc.gov/ccindex/index.html</u> 2021.
- Mani NS, Ottosen T, Fratta M *et al.* A health literacy analysis of the consumer-oriented COVID-19 information produced by ten state health departments *J Med Libr Assoc* 2021;**109**:422-431. First published on 2021/10/12, 10.5195/jmla.2021.1165.
- Kapsak WR, Schmidt D, Childs NM *et al.* Consumer perceptions of graded, graphic and text label presentations for qualified health claims *Crit Rev Food Sci Nutr* 2008;48:248-256. First published on 2008/02/16, 10.1080/10408390701286058.