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Impact of Pictorial Cigarette Warnings Compared With Surgeon General's Warnings on Understanding of the Negative Health **Consequences of Smoking**

Jessica K. Pepper, PhD1, Anh Nguyen Zarndt, PhD2, Matthew E. Eggers, MPH1, James M. Nonnemaker, PhD¹, David B. Portnoy, PhD²

¹Center for Health Policy Science & Tobacco Research, RTI International, Research Triangle Park, NC

²US Food and Drug Administration, Center for Tobacco Products, Silver Spring, MD

Abstract

Introduction: The Family Smoking Prevention and Tobacco Control Act requires cigarette packages and advertisements to bear health warnings with "color graphics depicting the negative health consequences of smoking."

Aims and Methods: This study assessed whether new US Food and Drug Administration developed pictorial cigarette warnings (PCW) increased understanding of smoking-related risks relative to the current Surgeon General's (SG) warnings. In March-May 2019, adolescent and adult smokers and nonsmokers participated in an online experiment with three sessions completed over approximately 2 weeks. Participants viewed 1 of 16 PCW (treatment conditions) or an SG warning (control) on mock cigarette packages and advertisements. Measures assessed whether warnings provided new information, induced thinking about risks, changed smoking-related health beliefs, and were accurately recalled, among other outcomes.

Results: The majority of PCW (13 conditions) resulted in greater learning of new information, higher self-reported learning, and greater reports of thinking about smoking risks; they were viewed as more informative, understandable, and attention-drawing compared with the control condition. Most participants believed the warning were factual, although 8 PCW were perceived as less factual than the control. There were changes toward more agreement with health beliefs for 11 PCW between Sessions 1 and 2 and 7 PCW between Sessions 1 and 3. Participants in all treatment conditions were more likely than control condition participants to correctly recall the warning. Across outcomes, PCW related to addiction, death, and quitting did not perform as well as other PCW.

None declared.

Supplementary Material

Corresponding Author: Jessica K. Pepper, PhD, Center for Health Policy Science & Tobacco Research, RTI International, 3040 E. Cornwallis Road, PO Box 12194, Research Triangle Park, NC 27709, USA. Telephone: 919-316-3180; Fax: 919-541-6683; jpepper@rti.org.

Declaration of Interests

A Contributorship Form detailing each author's specific involvement with this content, as well as any supplementary data, are available online at https://academic.oup.com/ntr.

Conclusions: Many of the PCW tested increased understanding of the risks associated with cigarette smoking relative to current SG warnings.

Implications: The Tobacco Control Act requires cigarette packages and advertisements to bear PCW depicting the negative health consequences of smoking. This study tested whether any of 16 newly proposed PCW increased understanding of smoking-related risks relative to existing SG warnings. Results suggest that most PCW tested, particularly those related to less widely known health effects, resulted in greater learning of new information, higher self-reported learning, and greater reports of thinking about smoking risks compared with SG warnings. These results, along with other factors, informed the US Food and Drug Administration's selection of proposed PCW.

Introduction

Section 201 of the Family Smoking Prevention and Tobacco Control Act (TCA) (Pub. L. 111–31) requires cigarette packages and advertisements to bear health warnings with "color graphics depicting the negative health consequences of smoking" to promote greater public understanding of the risks associated with tobacco use. In 2011, the US Food and Drug Administration (FDA) issued a rule with nine pictorial cigarette warnings (PCW; sometimes described as "graphic health warnings"), but those warnings were ruled to be unconstitutional. FDA then began developing and testing new PCW that would be consistent with the Tobacco Control Act and the First Amendment. A previous study assessed which of a set of revised text statements promoted greater public understanding of cigarette smoking when compared with the text statements from the Tobacco Control Act. FDA selected text statements based on study results and paired them with concordant images to create 16 PCW for testing in the present study.

PCW can educate the public about the effects of cigarette smoking and exposure to secondhand smoke.^{3–5} After implementation of new PCW, international longitudinal studies have shown increases in knowledge of smoking-related effects such as mouth cancer,^{6–8} bladder cancer,⁹ throat cancer,¹⁰ peripheral vascular diseases,^{6,8,10} blindness,^{9–11} impotence,^{7,12} stroke,^{7,10} and harm to unborn babies.¹⁰ Experimental and cross-sectional survey research also demonstrate the effectiveness of PCW for increasing knowledge^{13–15} and enhancing cognitive elaboration (thinking about smoking-related risks^{3,5,16–19}).

This study compared 16 PCW to the current text-only Surgeon General's (SG) warning statements (ie, the US *status quo*) displayed on mock cigarette packages and advertisements to assess whether these PCW increase understanding of the risks associated with cigarette smoking.

Materials and Methods

Stimuli Development

A previous study² informed the selection of text statements for inclusion on the PCW. FDA developed concordant color photorealistic images to accompany the statements. Concept images were developed using source materials provided by FDA medical experts and underwent initial concept testing using 53 in-depth individual interviews with adolescents and adults (OMB control number 0910–0796, "Qualitative Study of Perceptions

and Knowledge of Visually Depicted Health Conditions"); findings informed concept refinement. Photorealistic images were then developed by a Certified Medical Illustrator and tested in 20 focus groups with 170 adolescents and adults. Images were refined based on focus group findings and then paired with the concordant statements to create PCW.

Participants

Participants were recruited from a national online panel of adults managed by Lightspeed. This panel is a nonprobability convenience sample recruited via social media, online recruitment (eg, banner placements), and affiliate corporate networks. Participants received "LifePoints" valued at approximately \$10.00 as compensation for each session completed.

Recruitment focused on adolescent (aged 13–17) current smokers and those susceptible to smoking, young adult (aged 18–24) smokers and nonsmokers, and older adult (aged 25) smokers and nonsmokers for a final sample of 9760 participants.

Study Procedures

In March 2019, potential participants received an email inviting them (or their child) to participate in a web-based study and completed an online screener survey. Those who met eligibility criteria provided consent/assent and were randomly assigned to a study condition. In the control condition (condition 0), participants saw a random selection of one of the four SG warnings. In the treatment conditions (conditions 1–16), participants saw one PCW. All warnings were displayed on a mock cigarette package depicted in a three-dimensional, rotatable model and on a mock cigarette advertisement; the package and advertisement stimuli were displayed in randomized order (Supplementary Figures S1–S4). We refer to the 16 PCW conditions by the abbreviated names listed in the Warning column in Table 2. Two conditions used the same statement but different images (diseased lungs in chronic obstructive pulmonary disease [COPD] 1 and man with oxygen in COPD 2); because the images differed, these conditions were treated as distinct warnings. Supplementary Figure S5 includes all warnings. In all analyses, stimuli exposure is considered the joint exposure to both formats.

There were three online sessions. In Session 1 (~12 min), participants completed a baseline assessment of beliefs about the negative health consequences of cigarette smoking (health beliefs); were then exposed to cigarette warning stimuli according to condition assignment; and subsequently completed assessments of new information, self-reported learning, and other reactions to the stimuli. One to two days following completion of Session 1, participants were invited to complete Session 2. In Session 2 (~8 min), participants were re-exposed to the warning stimuli they were shown in Session 1 and completed the same set of health belief measures. Fourteen days after Session 2, participants were invited to complete Session 3. In Session 3 (~5 min), participants completed the same set of health belief measures and a measure of warning recall.

Measures

New Information (Session 1)—Participants responded to "Before today, had you heard about the specific smoking-related health effect described in the warning?" Responses were recoded as 1 (No or I'm not Sure) or 0 (Yes).²⁰

Self-Reported Learning (Session 1)—Participants responded to "To what extent did you learn something new from this warning that you did not know before?" on a 7-point scale from 1 (Not at all) to 7 (Very much).²¹

Thinking About Risks (Session 1)—Participants responded to "How much does this warning make you think about the health risks of smoking?" Responses were recoded as 1 (Somewhat or A lot) or 0 (A little or Not at all).^{6,16}

Attention (Session 1)—Participants responded to three items: "This warning grabbed my attention"; "I would notice this health warning if I saw it"; and "I would read or look closely at this health warning if I saw it on cigarette packages or ads" each using a 5-point scale from 1 (Strongly disagree) to 5 (Strongly agree). 22,23 These items were scaled and treated as continuous in linear regressions.

Warning Perceptions (Session 1)—Participants rated warnings on *informativeness* on a 7-point scale from 1 (Not at all informative) to 7 (Very informative)²⁴ and *understandability* on a 7-point scale from 1 (Hard to understand) to 7 (Easy to understand). Participants rated *factualness* by responding to "Would you say that this warning is an opinion or a fact?" recoded as 0 (Opinion) or 1 (Fact).²⁵

Health Beliefs (Sessions 1, 2, and 3)—In the Session 1, 2, and 3 surveys, participants rated their level of agreement from 1 (Strongly disagree) to 5 (Strongly agree) with health belief items that corresponded with specific health conditions in a PCW. ²⁶ For example, level of agreement with "Smoking causes head cancer" and "Smoking causes neck cancer" indicated health belief for the Head and neck cancer PCW. Ten warnings had multiple corresponding health belief items; the items for each of these warnings were scaled and treated as continuous in linear regressions. Six warnings had only one corresponding health belief item; these items were not recoded and were analyzed using ordinal regression.

Recall (Session 3)—In Session 3, participants viewed four warnings in random order. Control participants were shown the four SG warnings (one of which they previously viewed). Treatment condition participants were shown the PCW they previously viewed along with three other randomly selected PCW. Participants were asked "You recently took a survey in which you were shown a cigarette pack and advertisement with a warning on it. Which label do you remember seeing?" Responses were coded as 1 (accurate) if participants correctly selected the warning they previously viewed and as 0 (inaccurate) if anything else was selected.

Smoking Status—To be considered *susceptible to smoking*, adolescents must have never tried a cigarette and respond anything other than "definitely not" to at least one of four items

assessing smoking curiosity, potential future experimentation, expecting to smoke in the next year, and willingness to smoke if offered a cigarette by a friend.²⁷

Current smoking status was defined as having smoked in the past 30 days (for adolescents) or having smoked at least 100 lifetime cigarettes and now smoking every day or some days (for adults). Adults were considered nonsmokers if they now smoked "not at all."

Sociodemographic Characteristics—Sociodemographic items assessed gender, age, and race/ethnicity. Among adults only, education, income, sexual orientation, and health literacy²⁸ were also assessed. Participants were considered to have adequate health literacy if they correctly answered the question "If a person is at high risk for heart disease, which of the following levels of low-density lipoprotein cholesterol is best?" after reading facts about cholesterol. We included this measure because it provides context to how well the sample can interpret health-related information such as that conveyed in the warnings.

Analyses

Responses to Warnings—We compared means (using linear regression) or proportions (using logistic regression) between each treatment group with a single control group (representing the average scores across the four SG warnings) for a total of 16 separate analyses per dependent variable: new information, self-reported learning, thinking about risks, attention, and warning perceptions.

Changes in Health Beliefs—To determine the PCW's impact on corresponding health beliefs, we examined how differences in health beliefs from Session 1 to 2 and Session 1 to 3 differed between those exposed to PCW and SG warnings (ie, the difference in difference health belief score). For PCW with multiple, scaled health belief items, linear regression models examined whether the pre–post differences varied by condition; coefficients are the predicted difference in difference health belief scores. Significant, positive coefficients indicate that there is greater pre–post change in agreement for the health belief in the treatment relative to control condition. Significant, negative coefficients indicate greater pre–post change in agreement in the control condition. For PCW with a single health belief item, we used ordinal logistic regressions. The sign of the coefficient indicates the direction of the relationship between study condition and changes in health beliefs. Significant, positive coefficients favor the PCW as described above; significant, negative coefficients favor the control condition.

Recall—We used logistic regression to examine the proportion of respondents in the treatment and control conditions at Session 3 who accurately recalled the warning that they were exposed to at Sessions 1 and 2. Significant odds ratios (ORs) greater than 1 indicate greater recall among those exposed to a PCW than a control warning.

Regression models included indicator variables for age group (ie, adolescents, young adults, and older adults) and smoking status (ie, current smoker or nonsmoker [adults]/ susceptible[adolescents]) as covariates to account for potential associations between age, smoking status, and outcomes of interest. In this manuscript, the term "significant" refers to statistical significance after adjustment of multiple comparisons using the Benjamini—

Hochberg procedure, assuming a two-tailed test and false discovery rate of $0.05.^{29}$ All analyses were performed using Stata v.14.1 (using robust standard errors) and included all participants with valid data at each session. Supplementary Table S1 summarizes outcomes by condition.

Results

Participant Characteristics and Attrition

At Session 1 (n = 9760), 23.6% were adolescents, 21.2% were young adults, and 55.2% were older adults. Among all participants, 55.6% were female and 74.8% were non-Hispanic White (Table 1). Among adults, 35.8% had some college education and 34.4% had a college degree or more. Just over half of adults (51.9%) had incomes of less than \$50 000 annually, and 71.4% of adults correctly answered the health literacy item. Per the study design, among adolescents, 17.8% were current smokers and 82.2% were nonsmokers susceptible to smoking. Among adults, nearly half (49.8%) were current smokers. Participant characteristics for Session 2 (n = 4913; median of 2 days following Session 1) and Session 3 (n = 3360; median of 15 days following Session 2) appear in Table 1.

Between Sessions 1 and 2, the attrition rate was 48.8% for the control condition and 48.1%–52.5% for the treatment conditions. Between Sessions 1 and 3, the attrition rate was 66.1% for the control condition and 61.7%–70.4% for the treatment conditions.

New Information

As shown in Table 2, 27.9% of control condition participants and 22.8% (Addictive) to 88.7% (Cataracts) of participants in treatment conditions described the warning they viewed as new information. Participants were significantly more likely to describe a PCW as providing new information relative to the control in 13 conditions: Harm children (OR: 1.37, 95% confidence interval [CI]: 1.11–1.69), Fatal lung disease in nonsmokers (OR: 1.55, 95% CI: 1.26–1.91), Head and neck cancer (OR: 8.09, 95% CI: 6.44–10.16), Bladder cancer (OR: 14.63, 95% CI: 11.19–19.14), Stunt fetal growth (OR: 1.73, 95% CI: 1.40–2.12), Clogged arteries (OR: 2.64, 95% CI: 2.15–3.23), COPD 1 (OR: 1.48, 95% CI: 1.20–1.83), COPD 2 (OR: 1.48, 95% CI: 1.20–1.83), Erectile dysfunction (OR: 7.65, 95% CI: 6.10–9.60), Amputation (OR: 7.26, 95% CI: 5.79–9.11), Diabetes (OR: 10.64, 95% CI: 8.34–13.58), Macular degeneration (OR: 11.81, 95% CI: 9.17–15.21), and Cataracts (OR: 14.45, 95% CI: 11.08–18.86). One warning (Addictive) was less likely to be considered new information than the control condition (OR: 0.61, 95% CI: 0.47–0.78).

Thinking About Risks

As shown in Table 2, 69.6% of control condition participants and 69.5% (Quit now) to 87.5% (Amputation) of treatment condition participants thought about the health risks of smoking in response to the warning. PCW were significantly more likely to result in participants thinking about the health risks of smoking in 14 conditions relative to the control condition: Harm children (OR: 2.38, 95% CI: 1.82–3.10), Kill you (OR: 1.70, 95% CI: 1.34–2.17), Fatal lung disease in nonsmokers (OR: 1.94, 95% CI: 1.52–2.49), Head and

neck cancer (OR: 2.70, 95% CI: 2.05–3.55), Bladder cancer (OR: 2.14, 95% CI: 1.66–2.77), Stunt fetal growth (OR: 2.00, 95% CI: 1.55–2.57), Clogged arteries (OR: 2.05, 95% CI: 1.59–2.63), COPD 1 (OR: 2.25, 95% CI: 1.73–2.91), COPD 2 (OR: 2.13, 95% CI: 1.64–2.75), Erectile dysfunction (OR: 1.56, 95% CI: 1.23–1.98), Amputation (OR: 3.52, 95% CI: 2.60–4.75), Diabetes (OR: 2.11, 95% CI: 1.63–2.72), Macular degeneration (OR: 2.64, 95% CI: 2.01–3.46), and Cataracts (OR: 1.71, 95% CI: 1.34–2.17).

Self-Reported Learning

The mean rating of self-reported learning in the control condition was 3.02 (Table 2) and ranged from 2.66 (Addictive) to 5.70 (Macular degeneration) in the treatment conditions. Participants' self-reports of learning were significantly higher for 13 warnings compared with the control condition: Harm children (*B*: 0.31, 95% CI: 0.10–0.52), Fatal lung disease in nonsmokers (*B*: 0.64, 95% CI: 0.43–0.84), Head and neck cancer (*B*: 1.96, 95% CI: 1.78–2.13), Bladder cancer (*B*: 2.37, 95% CI: 2.19–2.54), Stunt fetal growth (*B*: 0.74, 95% CI: 0.54–0.94), Clogged arteries (*B*: 1.20, 95% CI: 1.00–1.40), COPD 1 (*B*: 0.70, 95% CI: 0.50–0.90), COPD 2 (*B*: 0.78, 95% CI: 0.58–0.99), Erectile dysfunction (*B*: 2.21, 95% CI: 2.04–2.39), Amputation (*B*: 2.28, 95% CI: 2.11–2.46), Diabetes (*B*: 2.43, 95% CI: 2.26–2.60), Macular degeneration (*B*: 2.58, 95% CI: 2.41–2.74), and Cataracts (*B*: 2.37, 95% CI: 2.20–2.54). Self-reported learning was lower for Addictive (*B*: –0.44, 95% CI: –0.64 to –0.24), Kill you (*B*: –0.30, 95% CI: –0.51 to –0.10), and Quit now (*B*: –0.44, 95% CI: –0.63 to –0.25) than for control condition.

Attention

The mean rating of attention (Table 2) in the control condition was 3.39 and ranged from 3.68 (Quit now) to 4.18 (Amputation) in the treatment condition. Participants in all 16 treatment conditions indicated greater attention to warnings than participants in the control condition. Effects ranged from *B*: 0.33 (95% CI: 0.24–0.41) for Quit now to *B*: 0.83 (95% CI: 0.75–0.91) for Amputation.

Warning Perceptions

The mean rating of informativeness (Table 3) in the control condition was 4.94 and ranged from 4.61 (Quit now) to 5.95 (Amputation) in the treatment conditions. Participants perceived the PCW as more informative than the control in 13 conditions: Harm children (*B*: 0.54, 95% CI: 0.38–0.69), Fatal lung disease in nonsmokers (*B*: 0.69, 95% CI: 0.54–0.84), Head and neck cancer (*B*: 0.78, 95% CI: 0.63–0.92), Bladder cancer (*B*: 0.95, 95% CI: 0.81–1.09), Stunt fetal growth (*B*: 0.91, 95% CI: 0.77–1.05), Clogged arteries (*B*: 0.88, 95% CI: 0.74–1.03), COPD 1 (*B*: 0.76, 95% CI: 0.62–0.90), COPD 2 (*B*: 0.77, 95% CI: 0.63–0.92), Erectile dysfunction (*B*: 0.95, 95% CI: 0.81–1.09), Amputation (*B*: 1.13, 95% CI: 0.99–1.26), Diabetes (*B*: 0.90, 95% CI: 0.76–1.04), Macular degeneration (*B*: 1.12, 95% CI: 0.99–1.26), and Cataracts (*B*: 0.86, 95% CI: 0.72–1.00). One warning (Quit now) was perceived as less informative than the control condition (*B*: –0.33, 95% CI: –0.49––0.17).

The mean rating of understandability (Table 3) was 5.83 in the control condition and 5.82 (Quit now) to 6.25 (Amputation) in the treatment conditions. Participants rated the warnings in 15 treatment conditions as more understandable than did participants in the control

condition: Addictive (*B*: 0.39, 95% CI: 0.25–0.53), Harm children (*B*: 0.52, 95% CI: 0.38–0.66), Kill you (*B*: 0.42, 95% CI: 0.27–0.57), Fatal lung disease in nonsmokers (*B*: 0.41, 95% CI: 0.27–0.56), Head and neck cancer (*B*: 0.44, 95% CI: 0.30–0.58), Bladder cancer (*B*: 0.46, 95% CI: 0.32–0.60), Stunt fetal growth (*B*: 0.58, 95% CI: 0.45–0.71), Clogged arteries (*B*: 0.55, 95% CI: 0.41–0.68), COPD 1 (*B*: 0.47, 95% CI: 0.34–0.61), COPD 2 (*B*: 0.53, 95% CI: 0.40–0.67), Erectile dysfunction (*B*: 0.47, 95% CI: 0.33–0.61), Amputation (*B*: 0.60, 95% CI: 0.46–0.74), Diabetes (*B*: 0.54, 95% CI: 0.40–0.67), Macular degeneration (*B*: 0.44, 95% CI: 0.29–0.58), and Cataracts (*B*: 0.47, 95% CI: 0.33–0.61).

As shown in Table 3, the majority of participants considered the warning they viewed to be factual. Specifically, 86.1% of control condition participants and 64.0% (Diabetes) to 87.9% (Quit now) of treatment condition participants reported that the warning they saw was factual. Participants were less likely to consider eight of the PCW as factual compared with the control condition: Fatal lung disease in nonsmokers (OR: 0.70, 95% CI: 0.53–0.92), Head and neck cancer (OR: 0.53, 95% CI: 0.41–0.68), Bladder cancer (OR: 0.43, 95% CI: 0.33–0.55), Erectile dysfunction (OR: 0.53, 95% CI: 0.41–0.69), Amputation (OR: 0.66, 95% CI: 0.50–0.86), Diabetes (OR: 0.44, 95% CI: 0.34–0.56), Macular degeneration (OR: 0.59, 95% CI: 0.45–0.77), and Cataracts (OR: 0.38, 95% CI: 0.30–0.49).

Changes in Health Beliefs from Session 1 to 2

As seen in Table 4, coefficients were positive and significant for 9 of the 10 warnings with health belief scores on a linear scale, representing net positive increases in agreement with health beliefs for those PCW after accounting for changes in health beliefs in the control condition: Head and neck cancer (*B*: 0.50, 95% CI: 0.37–0.63), Bladder cancer (*B*: 0.60, 95% CI: 0.47–0.74), Clogged arteries (*B*: 0.18, 95% CI: 0.07–0.29), COPD 1 (*B*: 0.12, 95% CI: 0.04–0.21), Erectile dysfunction (*B*: 0.41, 95% CI: 0.28–0.53), Amputation (*B*: 0.56, 95% CI: 0.43–0.69), Diabetes (*B*: 0.74, 95% CI: 0.59–0.89), Macular degeneration (*B*: 0.58, 95% CI: 0.46–0.70), and Cataracts (*B*: 0.66, 95% CI: 0.52–0.80). The coefficients for ordinal regression models of nonscaled health beliefs were significant and positive (toward higher levels of agreement with the health belief in the PCW condition compared with the control condition) for two of the six PCW: Fatal lung disease in nonsmokers (*B*: 0.50, 95% CI: 0.08–0.92) and Stunt fetal growth (*B*: 1.02, 95% CI: 0.54–1.49). The coefficients were significant and negative (toward lower levels of agreement with the health belief in the PCW condition compared with the control condition) for Addictive (*B*: –1.03, 95% CI: –1.64 to –0.41). Means and proportions for these models appear in Supplementary Tables S2–S4.

Changes in Health Beliefs (Sessions 1–3)

As seen in Table 4, coefficients from the linear models (ie, the predicted difference in difference between treatment and control conditions) were positive and significant for 6 of the 10 warnings with scaled health beliefs: Head and neck cancer (*B*: 0.25, 95% CI: 0.11–0.40), Bladder cancer (*B*: 0.36, 95% CI: 0.19–0.52), Amputation (*B*: 0.37, 95% CI: 0.23–0.51), Diabetes (*B*: 0.25, 95% CI: 0.08–0.42), Macular degeneration (*B*: 0.26, 95% CI: 0.13–0.40), and Cataracts (*B*: 0.33, 95% CI: 0.18–0.49). There was a net positive increase in agreement with health beliefs for those PCW after accounting for changes in health beliefs in the control condition. For nonscaled health beliefs, there was one significant

difference between treatment and control conditions (Fatal lung disease in nonsmokers, *B*: 0.59, 95% CI: 0.10–1.08) toward higher levels of agreement with the health belief in the PCW condition compared with the control condition. Means and proportions for these models appear in Supplementary Tables S2–S4.

Recall of Warnings

As seen in Table 5, 25.7% of control group participants accurately recalled the SG warning they were exposed to; between 49.4% (Clogged arteries) and 73.8% (Amputation) of the treatment group participants accurately recalled the PCW (Table 5). Participants in all 16 treatment conditions were more likely to accurately recall which warning they had seen than were participants in the control condition. Effects ranged from OR: 2.99 (95% CI: 2.07–4.32) for Clogged arteries to OR: 9.42 (95% CI: 6.33–14.02) for Kill you.

Discussion

The purpose of this study was to test whether any of the 16 PCW increased understanding of the negative health consequences of cigarette smoking relative to existing SG warnings. Relative to the control condition, respondents were more likely to state they learned new information for 13 of PCW and less likely to state they learned new information for one PCW. Self-reported learning was higher in 13 PCW and lower in 3 PCW conditions relative to the control condition. Relative to the control, 14 PCW were more likely to make participants think about the health risks of smoking, and 8 PCW were less likely to be seen as factual. Relative to the control, perceived informativeness was higher for 13 PCW and lower for 1 PCW, and perceived understandability was higher for 15 PCW. Participants reported paying more attention to the warning for all PCW relative to the control.

Between Sessions 1 and 2, 11 PCW resulted in greater net positive changes in agreement with health beliefs. One PCW resulted in greater net negative changes in agreement with health beliefs. From Session 1 to 3, seven PCW resulted in greater net positive changes in agreement with health beliefs. Participants in all 16 PCW conditions were more likely to correctly recall which PCW they had seen than participants in the control condition were to recall which SG warning they had seen.

Overall, relative to the average of the SG warnings, many of the PCW were reported to be new information; led to thinking about risks; resulted in greater self-reported learning, perceived informativeness, and perceived understandability; and increased agreement with accurate health beliefs over time. Nearly three-quarters or more of participants reported that the warning they viewed was a fact, although half of the PCW were seen as less likely to be factual than SG warnings. Participants who viewed SG warnings in the study were likely viewing something they had seen in real life, particularly so if they were cigarette smokers. In contrast, participants who viewed PCW were inherently viewing something novel. Findings regarding "new information" support this explanation: for seven of the eight PCW seen as less factual than SG warnings, the proportion of respondents describing the content as new information was high (approximately 75%–90%). The novelty of the PCW could lead to skepticism. ^{30,31} It is possible that more people would perceive the PCW as

factual when viewing them repeatedly in a "real world" context as they currently see SG warnings.

Some of the PCW did not perform as well as others on some outcomes. In particular, the warnings for Addictive, Kill you, and Quit now were often not significantly different from the control condition or were less likely to result in a given outcome (eg, they produced lower levels of self-reported learning compared with the controls or did not lead to a net positive improvement in accurate health beliefs between sessions). Participants may have muted responses to these warnings because they viewed the content as obvious; it is widely known that smoking is addictive and can kill you and that quitting has positive health effects, even if individuals do not fully understand the extent of these smoking risks and cessation benefits. 32–38

Limitations

Study limitations include the use of digital stimuli, which may decrease external validity; however, we minimized the lack of realism by enabling participants to rotate and interact with the 3D cigarette packages, which were displayed in the same size as real cigarette packages. Although two sessions of stimuli exposure may not be enough to generate changes in some outcomes, we found effects for both short-term (Sessions 1–2) and longer-term (Sessions 1–3) changes in health beliefs.

Although the study included six subgroups (adolescents susceptible to smoking, adolescent current smokers, young adult current smokers, young adult nonsmokers, older adult current smokers, and older adult nonsmokers), the study was not designed or powered to examine within-groups differences. Per general guidance from the Department of Education's What Works Clearinghouse (WWC), attrition between Sessions 1 and 2 was high but acceptable due to low differential attrition.³⁹ The WWC does not provide guidance about acceptable attrition for a second follow-up.

In addition, the survey used a convenience sample rather than a probability sample, and the results are not nationally representative. Generating a representative sample of the size necessary for this study would have been cost prohibitive. The large and diverse membership of the panel allows for targeting adequate numbers of those in the specified tobacco use status groups and to obtain a reasonable degree of demographic diversity in each of the targeted subgroups and the overall sample. Despite efforts to have the study population reflect the demographic makeup of the larger population, the nature of convenience samples still limits the generalizability of the results from this study. Because of the experimental design, these limitations in generalizability do not affect the internal validity, and thus the conclusions, of the study.

Conclusions and Future Directions

This study shows that most of the PCW tested can increase understanding of the negative health consequences of cigarette smoking compared with SG warnings. These results, along with results from a previous study² and other factors, informed FDA's selection of proposed PCW for cigarette packages and advertisements in the United States.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1.

Participant Characteristics by Session (Combining Adolescent and Adult Samples Unless Otherwise Noted)

Gender			
Male	4337 (44.4%)	2298 (46.8%)	1601 (47.6%)
Female	5423 (55.6%)	2615 (53.2%)	1759 (52.4%)
Age: mean (SD)	36.2 (20.5)	43.0 (21.2)	45.9 (20.4)
Age group			
Adolescent (aged 13-17)	2301 (23.6%)	949 (19.3%)	561 (16.7%)
Young adult (aged 18-24)	2071 (21.2%)	617 (12.6%)	273 (8.1%)
Older adult (aged 25)	5388 (55.2%)	3346 (68.1%)	2526 (75.2%)
Race/ethnicity			
White, non-Hispanic	7301 (74.8%)	3842 (78.2%)	2666 (79.3%)
Black, non-Hispanic	870 (8.9%)	404 (8.2%)	265 (7.9%)
Other or multiracial, non-Hispanic	511 (5.2%)	217 (4.4%)	139 (4.1%)
Hispanic	1078 (11.0%)	450 (9.2%)	290 (8.6%)
Education ^a			
Less than HS	201 (2.7%)	91 (2.3%)	66 (2.4%)
HS or GED	2015 (27.0%)	1060 (26.7%)	737 (26.3%)
Some college	2674 (35.8%)	1391 (35.1%)	954 (34.1%)
College or more	2569 (34.4%)	1422 (35.9%)	1042 (37.2%)
Annual household income ^a			
\$0-\$19 999	1406 (18.8%)	687 (17.3%)	443 (15.8%)
\$20 000-\$49 999	2467 (33.1%)	1354 (34.2%)	970 (34.7%)
\$50 000-\$74 999	1538 (20.6%)	808 (20.4%)	576 (20.6%)
\$75 000 or more	2048 (27.5%)	1115 (28.1%)	810 (28.9%)
Region			
Northeast	2018 (20.7%)	1012 (20.6%)	696 (20.7%)
Midwest	2351 (24.1%)	1255 (25.5%)	872 (26.0%)
South	3444 (35.3%)	1675 (34.1%)	1137 (33.8%)
West	1947 (19.9%)	971 (19.8%)	(46.5%)

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	Session 1 $(n = 9760)$	Session 1 ($n = 9760$) Session 2 ($n = 4913$) Session 3 ($n = 3360$)	Session 3 $(n = 3360)$
Sexual orientation ^a			
Heterosexual	6635 (89.0%)	3630 (91.6%)	2583 (92.3%)
LGB or other b	824 (11.0%)	334 (8.4%)	216 (7.7%)
Health literacy a,c (correct response)	5325 (71.4%)	2876 (72.6%)	2065 (73.8%)
Smoking status			
Adolescent susceptible to smoking d	1891 (19.4%)	737 (15.0%)	425 (12.6%)
Adolescent current smoker $^{\mathcal{C}}$	410 (4.2%)	212 (4.3%)	136 (4.0%)
Adult nonsmoker $^{\it f}$	3741 (38.3%)	2086 (42.5%)	1466 (43.6%)
Adult current smoker ^g	3718 (38.1%)	1878 (38.2%)	1333 (39.7%)

GED = general education diploma; HS = high school; LGB = lesbian, gay, or bisexual; SD = standard deviation.

 a Item only asked of young adult and older adult respondents (aged $\,$ 18).

 b -LGB or other" includes identifying as homosexual, gay, or lesbian; bisexual; or something else.

Participant correctly answers the question "If a person is at high risk for heart disease, which of the following levels of low density lipoprotein (LDL) cholesterol is best?" after reading facts about cholesterol.

 $d_{\rm Has}$ not smoked in past 30 days and responds anything other than "definitely not" to at least one of four items assessing susceptibility.

 e Smoked in the past 30 days.

 $f_{\rm Currently\ smokes\ "not\ at\ all."}$

 $^{\mathcal{G}} S moked~100$ cigarettes in lifetime and now smokes every day or some days.

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Table 2.

Differences by Condition in New Information, Thinking About Risks, Self-Reported Learning, and Attention

		New	New information	Thinking	Thinking about risks	Self-re	Self-reported learning	A	Attention
Condition	Warning (abbreviated term)	% endorsing	% endorsing OR (95% CI)	% endorsing	% endorsing OR (95% CI)	Mean (SD)	Mean (SD) Coeff. (95% CI)	Mean (SD)	Coeff. (95% CI)
0 (Control)	Average of the four SG warnings	27.9%	REF	%9:69	REF	3.02 (2.09)	REF	3.39 (0.94)	REF
1	Addictive	22.8%	$0.61 (0.47, 0.78)^{a}$	70.0%	1.11 (0.89, 1.39)	2.66 (2.02)	$-0.44 (-0.64, -0.24)^{a}$	3.69 (0.90)	$0.36(0.27, 0.45)^{a}$
2	Harm children	40.7%	$1.37 (1.11,1.69)^a$	83.3%	2.38 (1.82 3.10) ^a	3.51 (2.13)	$0.31 (0.10, 0.52)^{a}$	4.02 (0.90)	$0.68 (0.60, 0.77)^{a}$
3	Kill you	34.2%	1.04 (0.83,1.29)	73.9%	$1.70 (1.34, 2.17)^{a}$	2.83 (2.13)	$-0.30 \ (-0.51, -0.10)^{a}$	3.99 (0.89)	$0.67 (0.59 0.76)^{a}$
4	Fatal lung disease in nonsmokers	41.9%	$1.55 (1.26, 1.91)^a$	77.3%	1.94 (1.52 2.49) ^a	3.72 (2.13)	$0.64 (0.43, 0.84)^{a}$	3.80 (0.92)	$0.51 (0.42 0.60)^{a}$
5	Quit now	27.8%	0.95 (0.76,1.19)	%5.69	1.18 (0.94,1.47)	2.75 (1.97)	$-0.44 (-0.62, -0.25)^{a}$	3.68 (0.86)	$0.33 (0.24, 0.41)^{a}$
9	Head and neck cancer	%6.08	$8.09 (6.44,10.16)^{a}$	84.5%	$2.70(2.05, 3.55)^a$	5.20 (1.72)	$1.96 (1.78, 2.13)^a$	4.06 (0.84)	$0.66(0.58, 0.75)^{a}$
7	Bladder cancer	87.2%	$14.63 (11.19, 19.14)^a$	80.0%	$2.14 (1.66, 2.77)^a$	5.52 (1.73)	$2.37 (2.19 2.54)^{a}$	3.97 (0.88)	$0.61 (0.52 \ 0.69)^{a}$
∞	Stunt fetal growth	40.0%	$1.72 (1.40, 2.12)^a$	78.9%	$2.00 (1.55, 2.57)^{a}$	3.65 (2.04)	$0.74 (0.54, 0.94)^{a}$	3.95 (0.83)	$0.67 (0.58, 0.75)^{a}$
6	Clogged arteries	52.1%	$2.64 (2.15, 3.23)^a$	80.2%	$2.05 (1.59 \ 2.63)^{a}$	4.13 (2.13)	$1.20 (1.00, 1.40)^{a}$	3.79 (0.88)	$0.52 (0.44, 0.61)^{a}$
10	COPD 1 <i>b</i>	33.1%	$1.48 (1.20, 1.83)^a$	80.5%	$2.25 (1.73, 2.91)^a$	3.53 (2.05)	$0.70 (0.50, 0.90)^{a}$	3.83 (0.84)	$0.51 (0.43, 0.60)^{a}$
11	${\tt COPD}~2^{\mathcal C}$	25.7%	$1.48 (1.20, 1.83)^a$	79.2%	$2.13(1.64, 2.75)^a$	3.57 (2.14)	$0.78 (0.58, 0.99)^a$	3.89 (0.88)	$0.57 (0.49 \ 0.66)^{3}$
12	Erectile dysfunction	78.8%	$7.65 (6.10, 9.60)^{a}$	77.2%	$1.56 (1.23, 1.98)^a$	5.42 (1.68)	$2.21 (2.04, 2.39)^a$	3.80 (0.84)	$0.47 (0.38, 0.56)^{a}$
13	Amputation	74.7%	$7.26(5.799.11)^{a}$	87.5%	$3.52(2.60, 4.75)^a$	5.41 (1.79)	$2.28 (2.11, 2.46)^a$	4.18 (0.76)	$0.83 (0.75, 0.91)^{a}$
14	Diabetes	87.2%	$10.64 (8.34, 13.58)^{a}$	76.6%	$2.11 (1.63, 2.72)^a$	5.62 (1.62)	$2.43 (2.26, 2.60)^a$	3.94 (0.77)	$0.61 (0.53, 0.69)^{a}$
15	Macular degeneration	82.6%	$11.81 (9.17,15.21)^{a}$	81.4%	2.64 (2.01,3.46) ^a	5.70 (1.66)	2.58 (2.41,2.74) ^a	3.98 (0.90)	$0.71 (0.62 \ 0.79)^{a}$
16	Cataracts	88.7%	$14.45 (11.08, 18.86)^{a}$	75.6%	$1.71 (1.34, 2.17)^{a}$ 5.56 (1.74)	5.56 (1.74)	$2.37 (2.20, 2.54)^{a}$	3.88 (0.79)	$0.56(0.48,0.64)^{3}$

CI = confidence interval; COPD = chronic obstructive pulmonary disease; OR = odds ratio; SD = standard deviation; SG = Surgeon General's warning. Percentages represent the proportion of participants within each condition who endorsed that the warning was new information or resulted in thinking about risks. Regressions control for age group and smoking status.

 $^{^{\}it a}{\rm Significant}$ after adjustment for multiple comparisons.

 $[\]frac{b}{b}$ Image of diseased lungs.

 $^{^{}c}$ Image of man with oxygen.

Table 3.

Differences by Condition in Warning Reactions

		Perceived inf	Perceived informativeness	Perceived un	Perceived understandability	Perceived factualness	ıalness
Condition	Description	Mean (SD)	Coeff. (95% CI)	Mean (SD)	Coeff. (95% CI)	% endorsing	OR (95% CI)
0 (Control)	Average of the four SG warnings	4.94 (1.65)	REF	5.83 (1.54)	REF	86.1%	REF
1	Addictive	4.90 (1.65)	-0.05 (-0.22, 0.11)	6.06 (1.34)	$0.39 (0.25, 0.53)^{a}$	86.4%	1.07 (0.78, 1.45)
2	Harm children	5.36 (1.52)	$0.54 (0.38, 0.69)^{a}$	6.24 (1.19)	$0.52 (0.38, 0.66)^a$	83.1%	0.94 (0.70, 1.27)
3	Kill you	4.95 (1.75)	0.17 (0.00, 0.34)	5.92 (1.57)	$0.42 (0.27, 0.57)^{a}$	85.5%	0.99 (0.73, 1.34)
4	Fatal lung disease in nonsmokers	5.43 (1.54)	$0.69 (0.54, 0.84)^{a}$	5.98 (1.47)	$0.41 (0.27, 0.56)^{a}$	77.5%	$0.70 (0.53, 0.92)^{a}$
\$	Quit now	4.61 (1.59)	$-0.33 (-0.49, -0.17)^{a}$	5.82 (1.43)	0.12 (-0.04, 0.27)	87.9%	1.01 (0.75, 1.37)
9	Head and neck cancer	5.68 (1.40)	$0.78 (0.63, 0.92)^a$	6.14 (1.27)	$0.44 (0.30, 0.58)^{a}$	71.6%	$0.53 (0.41, 0.68)^{a}$
7	Bladder cancer	5.81 (1.41)	$0.95 (0.81, 1.09)^{a}$	6.13 (1.38)	$0.46 (0.32, 0.60)^a$	%0.99	$0.43 (0.33, 0.55)^{a}$
∞	Stunt fetal growth	5.59 (1.38)	$0.91 (0.77, 1.05)^{a}$	6.15 (1.33)	$0.58 (0.45, 0.71)^{a}$	83.9%	0.93 (0.69, 1.25)
6	Clogged arteries	5.65 (1.41)	$0.88 (0.74, 1.03)^{a}$	6.15 (1.29)	$0.55 (0.41, 0.68)^{a}$	85.2%	1.14 (0.83, 1.57)
10	$copd_1b$	5.55 (1.37)	$0.76(0.62, 0.90)^{a}$	6.14 (1.27)	$0.47 (0.34, 0.61)^{a}$	85.4%	1.23 (0.89, 1.70)
111	${\sf COPD}\ 2^{\mathcal{C}}$	5.52 (1.39)	$0.77 (0.63, 0.92)^a$	6.24 (1.17)	$0.53 (0.40, 0.67)^{a}$	83.8%	1.26 (0.91, 1.73)
12	Erectile dysfunction	5.77 (1.35)	$0.95 (0.81, 1.09)^{a}$	6.18 (1.19)	$0.47 (0.33, 0.61)^{a}$	72.4%	$0.53 (0.41, 0.69)^{a}$
13	Amputation	5.95 (1.25)	$1.13 (0.99, 1.26)^{a}$	6.25 (1.39)	$0.60 (0.46, 0.74)^a$	76.7%	$0.66(0.50, 0.86)^a$
14	Diabetes	5.68 (1.40)	$0.90 (0.76, 1.04)^{a}$	6.21 (1.22)	$0.54 (0.40, 0.67)^{3}$	64.0%	$0.44 (0.34, 0.56)^{a}$
15	Macular degeneration	5.86 (1.37)	$1.12 (0.99, 1.26)^{a}$	6.12 (1.40)	$0.44 (0.29, 0.58)^{a}$	73.7%	$0.59 (0.45, 0.77)^{a}$
16	Cataracts	5.67 (1.35)	$0.86 (0.72, 1.00)^{a}$	6.17 (1.30)	$0.47 (0.33, 0.61)^{a}$	65.5%	$0.38 (0.30, 0.49)^a$

CI = confidence interval; COPD = chronic obstructive pulmonary disease; OR = odds ratio; SD = standard deviation; SG = Surgeon General's warning. Percentages represent the proportion of participants within each condition who endorsed that the warning was factual. Regressions control for age group and smoking status.

 $^{^{\}it a}{\rm Significant}$ after adjustment for multiple comparisons.

 $[\]frac{b}{b}$ Image of diseased lungs.

Image of man with oxygen.

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Table 4.

Regressions of Difference in Difference Health Belief Scores Between Sessions 2 and 1 and Between Sessions 3 and 1, by Condition

Condition vs. Control	Sessions 1–2 ($n = 4913$)	Sessions 1–3 $(n = 3360)$
	Coefficient (95% CI)	Coefficient (95% CI)
Addictive ^b	$-1.03 (-1.64, -0.41)^{a}$	-0.39 (-1.08, 0.30)
Harm children ^b	0.32 (-0.15, 0.79)	-0.21 (-0.79, 0.37)
Kill you^b	0.09 (-0.42, 0.61)	-0.26 (-0.82, 0.30)
Fatal lung disease in nonsmokers b	$0.50 (0.08, 0.92)^{a}$	$0.59 (0.10, 1.08)^{a}$
Quit now b	0.29 (-0.13, 0.72)	-0.06 (-0.54, 0.42)
Head and neck cancer $^{\mathcal{C}}$	$0.50 (0.37, 0.63)^{a}$	$0.25 (0.11, 0.40)^{a}$
Bladder cancer $^{\mathcal{C}}$	$0.60 (0.47, 0.74)^{a}$	$0.36 (0.19, 0.52)^{a}$
Stunt fetal growth b	$1.02 (0.54, 1.49)^{a}$	-0.02 (-0.58, 0.54)
Clogged arteries $^{\mathcal{C}}$	$0.18 (0.07, 0.29)^{a}$	-0.01 (-0.13, 0.12)
COPD 1 <i>c,d</i>	$0.12 (0.04, 0.21)^{a}$	-0.08 (-0.19, 0.04)
${ m COPD}~2^{G,\mathcal{C}}$	0.01 (-0.09, 0.11)	-0.10 (-0.20, 0.00)
Erectile dysfunction $^{\mathcal{C}}$	$0.41 (0.28, 0.53)^{a}$	0.10 (-0.05, 0.24)
$Amputation^{\mathcal{C}}$	$0.56 (0.43, 0.69)^{a}$	$0.37 (0.23, 0.51)^{a}$
$Diabetes^\mathcal{C}$	$0.74 (0.59, 0.89)^{a}$	$0.25 (0.08, 0.42)^{a}$
Macular degeneration $^{\mathcal{C}}$	$0.58 (0.46, 0.70)^{a}$	$0.26 (0.13, 0.40)^{a}$
$Cataracts^{\mathcal{C}}$	$0.66(0.52,0.80)^{a}$	$0.33 (0.18, 0.49)^{a}$

pulmonary disease; PCW = pictorial cigarette warning. Cronbach's alpha for scaled items: Head and neck cancer (0.84), Bladder cancer (0.94), Clogged arteries (0.93), COPD 1 (0.85), COPD 2 (0.85), Control = average of the four Surgeon General warnings for the relevant health belief. Regressions control for age group and smoking status. CI = confidence interval; COPD = chronic obstructive Erectile dysfunction (0.87), Amputation (0.89), Diabetes (0.94), Macular degeneration (0.90), and Cataracts (0.94).

 $^{^{\}it a}{\rm Significant}$ after adjustment for multiple comparisons.

 $^{^{}b}$ There was only one health belief item relevant to this PCW, so the reported result is the coefficient from the ordinal regression.

GHealth belief items relevant to this PCW were scaled, and the reported result is the coefficient from the linear regression. The coefficient represents: (follow-up session mean for PCW - Session 1 mean for PCW) – (follow-up session mean for Control – Session 1 mean for Control) where follow-up is either Session 2 or Session 3.

V JOHHITO

dimage of diseased lungs.

Emage of man with oxygen.

Table 5.

Warning Recall by Condition

Condition	Description	% Recall	OR (95% CI)
0 (Control)	Average of four SG warnings	25.7%	REF
1	Addictive	64.9%	5.63 (3.85, 8.22) ^a
2	Harm children	61.6%	7.64 (5.17, 11.31) ^a
3	Kill you	63.7%	9.42 (6.33, 14.02) ^a
4	Fatal lung disease in nonsmokers	66.7%	5.20 (3.55, 7.61) ^a
5	Quit now	62.8%	5.15 (3.60, 7.37) ^a
6	Head and neck cancer	58.1%	4.89 (3.38, 7.06) ^a
7	Bladder cancer	57.8%	5.39 (3.70, 7.86) ^a
8	Stunt fetal growth	66.7%	6.13 (4.08, 9.20) ^a
9	Clogged arteries	49.4%	2.99 (2.07, 4.32) ^a
10	COPD 1 ^b	58.1%	4.14 (2.86, 5.99) ^a
11	COPD $2^{\mathcal{C}}$	57.8%	4.23 (2.92, 6.12) ^a
12	Erectile dysfunction	61.4%	4.69 (3.20, 6.88) ^a
13	Amputation	73.8%	8.73 (5.88, 12.98) ^a
14	Diabetes	62.3%	4.90 (3.39, 7.08) ^a
15	Macular degeneration	60.8%	4.87 (3.37, 7.05) ^a
16	Cataracts	53.0%	3.44 (2.41, 4.91) ^a

CI = confidence interval; COPD = chronic obstructive pulmonary disease; OR = odds ratio; SG = Surgeon General's warning. Due to a technical error with the online survey platform, the question assessing accuracy of warning recall did not function properly for 197 Session 3 participants. These cases were removed from the analysis of recall. Thus, the analytic sample size in this table is 3163 (197 less than the overall Session 3 sample size of 3360)- Regressions control for age group and smoking status.

 $[^]a\!\!$ Significant after adjustment for multiple comparisons.

 $b_{\mbox{Image of diseased lungs.}}$

^CImage of man with oxygen.