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Original Investigation

Influence of Warning Statements on Understanding of the Negative Health Consequences of Smoking

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Abstract

Introduction: Pursuant to the Tobacco Control Act (TCA), the US Food and Drug Administration (FDA) is developing new cigarette health warnings to convey the negative health consequences of cigarette smoking.

Aims and Methods: This study assessed which of 15 revised warning statements (10 on topics similar to TCA statements and 5 on other topics) promoted greater understanding of cigarette smoking risks relative to TCA statements. In February 2018, adolescent and adult smokers and adolescents susceptible to smoking ($n = 2505$) completed an online experiment. Control condition participants viewed TCA statements; treatment condition participants viewed combinations of TCA and revised statements. Analyses compared revised statements to TCA statements on the same health topic or to randomly selected TCA statements if there were no statements on the same topic.

Results: Relative to TCA statements, 12 of 15 revised statements were more likely to be considered new information, and 12 resulted in more self-reported learning. Three revised statements made participants think more about health risks than TCA statements; the reverse was true for one revised statement. Participants rated most TCA and revised statements as moderately believable and informative. Seven revised statements were found to be less believable and factual, and one revised statement more believable and factual. Treatment condition participants correctly selected more smoking-related health conditions than control condition participants (13.79 versus 12.42 of 25).

Conclusions: Findings suggest that revised statements can promote greater understanding of cigarette smoking risks. Results informed FDA's selection of warning text that was paired with images for testing in a follow-up study.

Implications: The US FDA may adjust the text of the cigarette warning statements provided in the TCA if the revised statements promote greater public understanding of the negative health consequences of cigarette smoking. Most of the revised warning statements tested were more likely to be considered new information and resulted in more self-reported learning compared with paired TCA statements, providing support for using revised statements as part of cigarette health warnings. These results informed the development of pictorial cigarette warnings by FDA that were tested in a follow-up study and included in a proposed rule.

Introduction

To fulfill its statutory obligation under the Family Smoking Prevention and Tobacco Control Act (TCA) (Pub. L. 111-31), the US Food and Drug Administration (FDA) has been developing new cigarette health warnings that depict the negative health consequences of cigarette smoking. In 2011, FDA issued a final rule that included nine pictorial cigarette warnings. After a losing a legal challenge that the warnings were unconstitutional,¹ FDA began creating new warnings consistent with the TCA and the First Amendment. FDA's new cigarette health warnings will include textual warning statements and accompanying concordant images depicting the negative health consequences of smoking.

Although the public generally understands that smoking causes certain illnesses (eg, lung cancer), knowledge gaps and misperceptions remain.²⁻⁵ For example, there is lower awareness for non-respiratory illnesses related to tobacco use than for respiratory illnesses.³⁻⁵ Observational^{6,7} and experimental^{3,8} evidence indicates that pictorial cigarette warnings increase understanding of the negative health consequences of smoking.⁹⁻¹⁴ For example, the introduction of pictorial warnings in Canada increased awareness that smoking causes impotence and mouth and throat cancer.⁷ Another study found that warnings (including both text-only and pictorial warnings) increased knowledge that smoking causes certain health conditions, particularly those less often associated with smoking, like gangrene and impotence.³

Congress provided that FDA may adjust the text of the nine warnings provided in Section 201 of the TCA (TCA statements) if the revised statements would "promote greater public understanding of the risks associated with the use of tobacco products." The goal of this study is to assess which, if any, of the revised statements developed by FDA promote greater understanding of cigarette smoking when compared with the TCA statements. Greater understanding could take the form of learning more information about health conditions a person already knows to be linked to smoking or learning about the existence of tobacco-related health conditions that were previously unknown by the consumer.

Materials and Methods

Formative Research for Statement Development

To develop and refine the text for the revised statements, FDA conducted a literature review and analyzed data related to knowledge and misperceptions about cigarettes and smoking. FDA then reviewed the list of smoking-related health consequences identified in the reports of the Surgeon General, including the health consequences first established as causally linked to cigarette smoking in the 2014 report,¹⁵ and examined the relevant epidemiological evidence.

Adult smokers and adolescents (aged 16–17) susceptible to smoking provided qualitative feedback on the draft warning statements through 16 in-person focus groups (*Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions*, OMB No. 0910-0674). Based on focus group feedback (results not shown), some warning statements were dropped; others were refined for clarity and simplicity and to better explain causal mechanisms. The 15 revised statements focus on less well-known health consequences of cigarette smoking (eg, blindness), whereas the 9 TCA statements cover more well-known health consequences (eg, addiction). FDA focused on lesser-known health consequences in the revised statements because messages with novel information (ie,

few people know the information in the message) provide an opportunity to increase public understanding.¹⁶ The statements tested in this study (15 revised and 9 TCA) appear in [Table 1](#).

Participants

Participants ($n = 2505$) were recruited from a national online panel of adults managed by Lightspeed. This panel is a non-probability convenience sample recruited via social media, online recruitment (eg, banner placements), and affiliate corporate networks. Recruitment focused on adolescent current smokers (aged 13–17), adolescents susceptible to smoking (aged 13–17), young adult smokers (aged 18–24), and older adult smokers (aged ≥ 25).

Study Procedures

In February 2018, potential participants received an email inviting them (or their child) to participate in a web-based study and completed an online screener survey to assess eligibility. Those who met the eligibility criteria provided consent/assent and were randomly assigned to one of the treatment conditions or the control condition. Participants then completed the study in two phases, both of which occurred during a single session lasting approximately 15 min.

Phase 1

Participants in the control condition viewed the nine TCA statements presented in a random order. Participants in each of the treatment conditions viewed eight of the TCA statements and one of the revised statements in a random order. All statements were shown as plain text. In each treatment condition, the revised statement replaced a TCA statement on a similar health topic or, if there were no TCA statements on a similar topic, a randomly selected TCA statement that was the same for everyone in that condition. There were 5 revised statements that did not have a TCA statement with a similar topic and 10 with a similar topic. For example, the revised statement on bladder cancer replaced a TCA statement on the same topic (smoking causes cancer) in one treatment condition. In another treatment condition, the revised statement about diabetes replaced the randomly selected TCA statement about fatal lung disease in smokers for all participants in that condition because there were no TCA statements about diabetes. The revised statement about chronic obstructive pulmonary disease (COPD) was separately compared with both the TCA statements about fatal lung disease in smokers and fatal lung disease in nonsmokers, resulting in 16 treatment conditions for the 15 revised statements.

After viewing each statement in their assigned condition, participants completed measures assessing whether the information about the health effect was new, whether it resulted in self-reported learning, and how much the statement made them think about the health risks of smoking. The warning statement remained on the screen as they answered these questions; the series of questions was repeated for each of nine warning statements in their assigned condition.

After viewing all statements in their assigned condition, participants advanced to a new screen where they responded to questions assessing health beliefs specific to topics covered in the warnings.

Phase 2

Next, all participants viewed a set of nine warning statements during a single exposure. Participants from the control condition viewed all nine TCA statements again. Participants from the

Table 1. Warning Statements and Comparisons

Statement	Abbreviated term used in manuscript	TCA statement to which revised statement was compared
Tobacco Control Act (TCA)		
Warning: Cigarettes are addictive.	Addictive	N/A
Warning: Tobacco smoke can harm your children.	Harm children	N/A
Warning: Cigarettes cause fatal lung disease.	Fatal lung disease in smokers	N/A
Warning: Cigarettes cause cancer.	Unspecified cancer	N/A
Warning: Cigarettes cause strokes and heart disease.	Strokes and heart disease	N/A
Warning: Smoking during pregnancy can harm your baby.	Harm your baby	N/A
Warning: Smoking can kill you.	Kill you	N/A
Warning: Tobacco smoke causes fatal lung disease in nonsmokers.	Fatal lung disease in nonsmokers	N/A
Warning: Quitting smoking now greatly reduces serious risks to your health.	Quit now	N/A
Revised		
Warning: Smoking causes mouth and throat cancer.	Mouth and throat cancer	Unspecified cancer
Warning: Smoking causes head and neck cancer.	Head and neck cancer	Unspecified cancer
Warning: Smoking causes bladder cancer, which can lead to bloody urine.	Bladder cancer	Unspecified cancer
Warning: Smoking during pregnancy causes premature birth.	Premature birth	Harm your baby
Warning: Smoking during pregnancy stunts fetal growth.	Stunt fetal growth	Harm your baby
Warning: Smoking during pregnancy causes premature birth and low birth weight.	Low birth weight	Harm your baby
Warning: Secondhand smoke causes respiratory illnesses in children, like pneumonia.	Respiratory illness in children	Harm children
Warning: Smoking can cause heart disease and strokes by clogging arteries.	Clogged arteries	Strokes and heart disease
Warning: Smoking causes COPD, a lung disease that can be fatal.	COPD	Fatal lung disease in nonsmokers and Fatal lung disease in smokers ^a
Warning: Smoking causes serious lung diseases like emphysema and chronic bronchitis.	Emphysema and bronchitis	Fatal lung disease in smokers
Warning: Smoking reduces blood flow, which can cause erectile dysfunction. ^b	Erectile dysfunction	Harm your baby
Warning: Smoking reduces blood flow to the limbs, which can require amputation. ^b	Amputation	Strokes and heart disease
Warning: Smoking causes type 2 diabetes, which raises blood sugar. ^b	Diabetes	Fatal lung disease in smokers
Warning: Smoking causes age-related macular degeneration, which can lead to blindness. ^b	Macular degeneration	Addictive
Warning: Smoking causes cataracts, which can lead to blindness. ^b	Cataracts	Harm your baby

COPD = chronic obstructive pulmonary disease.

^aThe revised statement about COPD was separately compared with both the Fatal lung disease in smokers and Fatal lung disease in nonsmokers TCA statements (ie, two treatment conditions associated with this statement).

^bThe revised statement was compared with a randomly selected TCA statement because there was no TCA statement on a similar topic as the revised statement.

treatment conditions viewed nine revised statements, including one statement apiece focused on pregnancy, secondhand smoke, heart disease/stroke, lung disease, blood flow, diabetes, and blindness, and two statements on cancer. After viewing the nine statements, participants endorsed which of a set of health conditions they believed were caused by smoking or secondhand smoke exposure.

This study was approved by the Institutional Review Board at RTI International, FDA's Research Involving Human Subjects Committee, and the Office of Management and Budget (OMB Control No. 0910-0848).

Measures

Because FDA's goal for these warnings is to promote greater understanding of the negative health consequences of smoking and the warnings are intended to educate the public, study outcomes

included new information, self-reported learning, thinking about risks, and health beliefs. We did not assess smoking intention or behavior or emotional responses to warnings because these outcomes were not relevant to that goal.

Phase 1 Outcomes

New Information

Participants responded to "Before today, had you heard about the specific smoking-related health effect described in the warning statement?" (adapted from Elango et al.¹⁷). Responses were coded as 1 (No or Not Sure) or 0 (Yes).

Self-Reported Learning

Participants responded to "To what extent did you learn something new from this warning statement that you did not know before?" on a 7-point scale from 1 (Not at all) to 7 (Very Much).¹⁸

Thinking About the Risks

For each statement, participants responded to the item, “How much does this warning statement make you think about the health risks of smoking?” Responses were coded as 1 (Somewhat or A lot) or 0 (A little or Not at all).^{10,19}

Perceptions of Statements (Believability, Informativeness, and Perceived Factualness)

Participants rated each statement on a 7-point scale from 1 (Not at all believable) to 7 (Very believable)^{20,21} and from 1 (Not at all informative) to 7 (Very informative).²² Participants also responded to the item, “Would you say that this warning statement is an opinion or a fact?” Responses were coded as 1 (Fact) or 0 (Opinion).²³

Topic-Specific Health Beliefs

For each health condition, the survey included an item or series of items in which respondents were asked to rate their level of agreement from 1 (Strongly disagree) to 5 (Strongly agree) with a belief about a negative health consequence corresponding to the warning statement for that condition.²⁴ For example, level of agreement with “Smoking causes head cancer” and “Smoking causes neck cancer” indicated the health belief for the revised statement “Smoking causes head and neck cancer.” There were 12 warning statements with more than one relevant health belief item; for each statement, the items were scaled²⁵ and treated as continuous in linear regressions. Three warning statements had only one relevant health belief item per statement; these items were not recoded and were analyzed using ordinal regression.

Phase 2 Outcomes

Overall Measure of Health Beliefs

In response to the item, “Which, if any, of the following conditions do you think *smoking* can cause?” participants selected as many health conditions from a list of 20 as they believed were linked to smoking or “None of the above.” In response to the item, “Which, if any, of the following conditions do you think *secondhand smoke* can cause?” participants selected from a list of two smoking-related health conditions or “None of the above.” Finally, participants selected from three smoking-related health conditions or “None of the above” in response to the item, “Which, if any, of the following conditions do you think *smoking during pregnancy* can cause?”³

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, anticipating future smoking, and willingness to smoke if offered a cigarette by a friend.²⁶ Current smoking status was defined as having smoked in the past 30 days (for adolescents) or having had smoked at least 100 lifetime cigarettes and now smoking every day or some days (for adults).

Other Measures

Sociodemographic items assessed gender, age, and race/ethnicity. Among adults only, education, income, sexual orientation, and health literacy²⁷ were also assessed.

Analyses

We conducted regression analyses to assess the extent to which revised statements promoted greater public understanding of the negative health consequences of smoking as compared with TCA statements. For the first part of *Phase 1*, we conducted analyses at the statement level by comparing a revised statement with a TCA statement on the same health topic. For the five revised statements that did not have a corresponding TCA statement on the same topic, we compared the revised statement with a randomly selected TCA statement. For binary outcomes (new information, thinking about risks, and perceived factualness), we used logistic regression. For continuous outcomes (self-reported learning, thinking about risks, believability, and informativeness), we used linear regression.

For the second part of *Phase 1*, we conducted condition-level comparisons for agreement with health beliefs. These analyses used linear regressions for scaled health belief items and ordinal logistic regressions for non-scaled health belief items.

For the *Phase 2* analyses, we used linear regressions to examine differences between treatment and control groups in the average number of health conditions respondents believed could be caused by smoking, exposure to secondhand smoke, and smoking during pregnancy.

All regressions were estimated in Stata version 14.1 using robust standard errors. Each model included indicator variables for age group (adolescents aged 13–17; young adults aged 18–24; and older adults aged ≥ 25) as covariates to account for potential associations between age and outcomes of interest. We controlled for multiple comparisons using the Benjamini–Hochberg procedure, assuming a two-tailed test and false discovery rate of 0.05.²⁸ [Supplementary Table S1](#) summarizes outcomes by condition.

Results

Participant Characteristics

Of the 2505 participants, 49.6% were male and 67.9% were White, non-Hispanic ([Table 2](#)). Among the 1669 adults, 39.7% had a high school education, and 33.7% had some college education. Most adults were heterosexual (85.5%) and had adequate health literacy based on the validated measure used in this study²⁷ (60.9%). Per the study design, approximately half (49.9%) of the 836 adolescents were current smokers, and half (50.1%) were susceptible to smoking.

Phase 1: Comparisons at the Level of the Warning Statement

New Information

As shown in [Table 3](#), 12 revised statements resulted in participants reporting that the warning was new information relative to TCA statements. Specifically, respondents were more likely to say that a health effect was new information for the following revised statements relative to the paired TCA statement: Head and neck cancer (odds ratio [OR]: 13.26, 95% confidence interval [CI]: 7.20–24.4), Bladder cancer (OR: 28.15, 95% CI: 14.74–53.72), Premature birth (OR: 2.28, 95% CI: 1.09–4.75), Stunt fetal growth (OR: 2.49, 95% CI: 1.21–5.13), Low birth weight (OR: 2.47, 95% CI: 1.21–5.03), Clogged arteries (OR: 2.50, 95% CI: 1.41–4.43), Erectile dysfunction (OR: 24.43, 95% CI: 12.26–48.66), Amputation (OR: 10.79, 95% CI: 6.10–19.08), Diabetes (OR: 16.01, 95% CI: 8.97–28.57), Macular degeneration (OR: 36.90, 95% CI: 17.66–77.07), and

Table 2. Participant Characteristics

	Total sample	Adolescent (aged 13–17), <i>n</i> (%) or mean (SD)	Young adult smoker (aged 18–24), <i>n</i> (%) or mean (SD)	Older adult smoker (aged ≥25), <i>n</i> (%) or mean (SD)
Total sample makeup, <i>n</i> (% of sample)	2505 (100%)	836 (33.4%)	833 (33.2%)	836 (33.4%)
Gender				
Male	1242 (49.6%)	314 (37.6%)	562 (67.5%)	366 (43.8%)
Female	1263 (50.4%)	522 (62.4%)	271 (32.5%)	470 (56.2%)
Age: mean (SD)	28.38 (16.12)	15.60 (1.30)	21.72 (1.86)	47.78 (13.78)
Race/ethnicity				
White, non-Hispanic	1702 (67.9%)	517 (61.8%)	516 (61.9%)	669 (80.0%)
Black, non-Hispanic	263 (10.5%)	84 (10.0%)	118 (14.2%)	61 (7.3%)
Other or multiracial, non-Hispanic	209 (8.3%)	101 (12.1%)	65 (7.8%)	43 (5.1%)
Hispanic	331 (13.2%)	134 (16.0%)	134 (16.1%)	63 (7.5%)
Education ^a				
Less than HS	118 (7.1%)	–	83 (10.0%)	35 (4.2%)
HS or GED	663 (39.7%)	–	362 (43.5%)	301 (36.0%)
Some college	563 (33.7%)	–	274 (32.9%)	289 (34.6%)
College or more	325 (19.5%)	–	114 (13.7%)	211 (25.2%)
Annual household income ^a				
\$0–\$19 999	463 (27.8%)	–	287 (34.6%)	176 (21.1%)
\$20 000–\$49 999	587 (35.3%)	–	266 (32.0%)	321 (38.5%)
\$50 000–\$74 999	293 (17.6%)	–	123 (14.8%)	170 (20.4%)
\$75 000 or more	320 (19.2%)	–	154 (18.6%)	166 (19.9%)
Region				
Northeast	476 (19.0%)	168 (20.1%)	152 (18.2%)	156 (18.7%)
South	981 (39.2%)	322 (38.5%)	336 (40.3%)	323 (38.6%)
Midwest	584 (23.3%)	204 (24.4%)	174 (20.9%)	206 (24.6%)
West	464 (18.5%)	142 (17.0%)	171 (20.5%)	151 (18.1%)
Sexual orientation ^a				
Heterosexual	1426 (85.5%)	–	662 (79.7%)	764 (91.4%)
LGB or other ^b	241 (14.5%)	–	169 (20.3%)	72 (8.6%)
Health literacy ^{a,c} (correct response)	1015 (60.9%)	–	517 (62.2%)	498 (59.6%)
Smoking status				
Susceptible nonsmoker ^d	–	419 (50.1%)	–	–
Current smoker ^e	–	417 (49.9%)	833 (100.0%)	836 (100.0%)

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

^aItem only asked of young adult and older adult respondents (aged ≥18).

^b“LGB or other” includes identifying as homosexual, or gay or lesbian; bisexual; or something else.

^cParticipant 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.

^dAdults must be current smokers to be eligible.

^eCurrent smoking among adolescents is smoking any of the past 30 days. Current smoking among adults is ever smoking 100 cigarettes and now smoking some days or every day.

Cataracts (OR: 42.61, 95% CI: 20.73–87.55). The revised statement about COPD was more likely to be considered new information when compared with the TCA statement Fatal lung disease in smokers (OR: 2.14, 95% CI: 1.22–3.77) but not when compared with the TCA statement Fatal lung disease in nonsmokers. In addition, there was no difference in the proportion of respondents reporting that the revised statements provided new information relative to TCA statements for the Mouth and throat cancer, Respiratory illness in children, and Emphysema and bronchitis statements.

Self-Reported Learning

Self-reported learning (Table 3) was higher for 12 revised statements relative to their paired TCA statements, including Head and neck cancer (*B*: 1.52, 95% CI: 1.05–1.99), Bladder cancer (*B*: 1.81,

95% CI: 1.33–2.28), Stunt fetal growth (*B*: 0.75, 95% CI: 0.21–1.28), Respiratory illness in children (*B*: 0.73, 95% CI: 0.25–1.21), Clogged arteries (*B*: 0.66, 95% CI: 0.19–1.13), Emphysema and bronchitis (*B*: 0.86, 95% CI: 0.35–1.38), Erectile dysfunction (*B*: 1.42, 95% CI: 0.93–1.90), Amputation (*B*: 1.53, 95% CI: 1.09–1.97), Diabetes (*B*: 1.56, 95% CI: 1.09–2.03), Macular degeneration (*B*: 2.12, 95% CI: 1.64–2.60), and Cataracts (*B*: 1.85, 95% CI: 1.38–2.33). The revised statement on COPD resulted in more learning when compared with the TCA statement Fatal lung disease in smokers (*B*: 1.05, 95% CI: 0.56–1.53) but not when compared with the TCA statement Fatal lung disease in nonsmokers. In addition, self-reported learning did not differ between revised and TCA warnings for the statements about Mouth and throat cancer, Premature birth, and Low birth weight.

Table 3. Comparisons of Revised Statements With Assigned TCA Statements (Listed in Table 1) for New Information, Self-Reported Learning, and Thinking About Risks

Comparison	Revised statement tested	New information ^b			Self-reported learning ^c			Thinking about risks ^d		
		Revised: % describing as new information	TCA: % describing as new information	OR (95% CI)	Revised: mean (SD)	TCA: mean (SD)	Regression coefficient (95% CI)	Revised: % think about risk	TCA: % think about risk	OR (95% CI)
1	Mouth and throat cancer	12.9	12.2	1.07 (0.54 to 2.15)	2.51 (2.09)	2.39 (2.08)	0.13 (-0.39 to 0.65)	68.0	68.9	0.96 (0.59 to 1.58)
2	Head and neck cancer	64.2	12.2	13.26 (7.20 to 24.4) ^a	3.92 (1.77)	2.39 (2.08)	1.52 (1.05 to 1.99) ^a	68.9	68.9	1.00 (0.61 to 1.64)
3	Bladder cancer	78.9	12.2	28.15 (14.74 to 53.72) ^a	4.19 (1.86)	2.39 (2.08)	1.81 (1.33 to 2.28) ^a	70.8	68.9	1.10 (0.66 to 1.81)
4	Premature birth	17.6	8.8	2.28 (1.09 to 4.75) ^a	2.94 (2.24)	2.43 (2.17)	0.52 (-0.01 to 1.04)	64.9	70.9	0.76 (0.46 to 1.24)
5	Stunt fetal growth	19.0	8.8	2.49 (1.21 to 5.13) ^a	3.17 (2.22)	2.43 (2.17)	0.75 (0.21 to 1.28) ^a	68.0	70.9	0.87 (0.53 to 1.44)
6	Low birth weight	19.0	8.8	2.47 (1.21 to 5.03) ^a	2.93 (2.17)	2.43 (2.17)	0.52 (0.00 to 1.03)	68.0	70.9	0.87 (0.52 to 1.44)
7	Respiratory illness in children	31.8	23.0	1.56 (0.93 to 2.63)	3.30 (1.95)	2.56 (2.15)	0.73 (0.25 to 1.21) ^a	74.3	68.9	1.31 (0.79 to 2.17)
8	Clogged arteries	32.0	16.2	2.50 (1.41 to 4.43) ^a	3.36 (2.03)	2.70 (1.96)	0.66 (0.19 to 1.13) ^a	64.6	66.9	0.90 (0.56 to 1.47)
9	COPD ^e	36.7	41.9	0.80 (0.50 to 1.29)	3.26 (2.03)	2.86 (1.99)	0.41 (-0.07 to 0.88)	71.4	56.8	1.94 (1.19 to 3.17) ^a
10	COPD ^f	29.3	16.2	2.14 (1.22 to 3.77) ^a	3.38 (2.00)	2.33 (2.07)	1.05 (0.56 to 1.53) ^a	76.9	61.5	2.13 (1.27 to 3.56) ^a
11	Emphysema and bronchitis	22.4	16.2	1.50 (0.83 to 2.72)	3.19 (2.22)	2.33 (2.07)	0.86 (0.35 to 1.38) ^a	78.2	61.5	2.29 (1.36 to 3.84) ^a
12	Erectile dysfunction	69.4	8.8	24.43 (12.26 to 48.66) ^a	3.85 (1.87)	2.43 (2.17)	1.42 (0.93 to 1.90) ^a	55.1	70.9	0.50 (0.30 to 0.81) ^a
13	Amputation	66.2	16.2	10.79 (6.10 to 19.08) ^a	4.23 (1.78)	2.70 (1.96)	1.53 (1.09 to 1.97) ^a	77.7	66.9	1.75 (1.04 to 2.96)
14	Diabetes	75.5	16.2	16.01 (8.97 to 28.57) ^a	3.90 (1.92)	2.33 (2.07)	1.56 (1.09 to 2.03) ^a	56.5	61.5	0.81 (0.51 to 1.30)
15	Macular degeneration	75.5	8.8	36.90 (17.66 to 77.07) ^a	4.38 (1.72)	2.25 (2.17)	2.12 (1.64 to 2.60) ^a	71.4	55.4	2.01 (1.24 to 3.26) ^a
16	Cataracts	79.7	8.8	42.61 (20.73 to 87.55) ^a	4.28 (1.81)	2.43 (2.17)	1.85 (1.38 to 2.33) ^a	64.2	70.9	0.73 (0.45 to 1.20)

Regressions control for age group. CI = confidence interval; COPD = chronic obstructive pulmonary disease; OR = odds ratio; TCA = Tobacco Control Act.

^aSignificant after adjustment for multiple comparisons.

^bParticipants responded "no" or "not sure" (instead of "yes") to the question, "Before today, had you heard about the specific smoking-related health effect described in the warning statement?"

^cScale from 1 = "Not at all" to 7 = "Very much."

^d"Not at all" or "A little" coded as 1 and "Somewhat" or "A lot" coded as 0.

^eCompared with fatal lung disease in nonsmokers.

^fCompared with fatal lung disease in smokers.

Thinking About Risk

Respondents were statistically significantly more likely to say that the revised statement made them think about the relevant health risk more than the TCA statement for COPD compared with Fatal lung disease in smokers (OR: 2.13, 95% CI: 1.27–3.56) and with Fatal lung disease in nonsmokers (OR: 1.94, 95% CI: 1.19–3.17), Emphysema and bronchitis (OR: 2.29, 95% CI: 1.36–3.84), and Macular degeneration (OR: 2.01, 95% CI: 1.24–3.26; Table 3). For the Erectile dysfunction statement, participants were significantly less likely to say it made them think about the health condition than were participants who viewed the randomly assigned TCA statement (OR: 0.50, 95% CI: 0.30–0.81). There were no differences by condition in thinking about risks for the following revised statements: Mouth and throat cancer, Head and neck cancer, Bladder cancer, Premature birth, Stunt fetal growth, Low birth weight, Respiratory illness in children, Clogged arteries, Amputation, Diabetes, and Cataracts.

Perceptions of Statements

For the three statement perception outcomes (believability, informativeness, and perceived factualness), descriptive statistics and regression results with 95% CIs appear in Table 4. In general, participants rated all statements as moderately believable (range of mean ratings 3.69–4.88 for revised statements and 3.74–4.89 for TCA statements) and moderately informative (range of mean ratings 3.87–4.72 for revised statements and 3.57–4.14 for TCA statements). Participants also perceived the majority of statements to be factual (range 56.1%–92.5% for revised statements and 61.5%–87.8% for TCA statements).

Participants rated one revised statement as more believable than its paired TCA statement (COPD versus Fatal lung disease in nonsmokers, $B: 0.95$) and seven revised statements (Head and neck cancer, Bladder cancer, Erectile dysfunction, Amputation, Diabetes, Macular degeneration, and Cataracts; range from $B: -1.13$ to $B: -0.55$) as less believable than their paired TCA statements. There were no differences in ratings of believability for the other seven statements: Mouth and throat cancer, Premature birth, Stunt fetal growth, Low birth weight, Respiratory illness in children, Clogged arteries, COPD versus Fatal lung disease in smokers, and Emphysema and bronchitis.

Respondents considered three revised statements (Respiratory illness in children, COPD versus Fatal lung disease in nonsmokers and versus Fatal lung disease in smokers, and Macular degeneration) to be more informative than their paired TCA statements (range from $B: 0.54$ to $B: 0.79$). There were no differences in ratings of informativeness for Mouth and throat cancer, Head and neck cancer, Bladder cancer, Premature birth, Stunt fetal growth, Low birth weight, Clogged arteries, Emphysema and bronchitis, Erectile dysfunction, Amputation, Diabetes, and Cataracts.

Finally, respondents were more likely to perceive one revised statement (COPD versus Fatal lung disease in nonsmokers) as factual (OR: 3.20) and less likely to perceive seven revised statements (Head and neck cancer, Bladder cancer, Erectile dysfunction, Amputation, Diabetes, Macular degeneration, and Cataracts) as factual compared with their paired TCA statements (range from OR: 0.18 to OR: 0.49). There were no differences in ratings of factuality for revised versus TCA warnings for these statements: Mouth and throat cancer, Premature birth, Stunt fetal growth, Low birth weight, Respiratory illness in children, Clogged arteries, COPD versus Fatal lung disease in smokers, and Emphysema and bronchitis.

Topic-Specific Health Beliefs

In the linear regressions where multiple health belief items addressed the same health topic (Table 5), four revised statements had higher mean scores than their control statements: Mouth and throat cancer ($B: 0.29$, 95% CI: 0.10–0.48), Amputation ($B: 0.27$, 95% CI: 0.07–0.47), Diabetes ($B: 0.38$, 95% CI: 0.15–0.61), and Macular degeneration ($B: 0.35$, 95% CI: 0.14–0.57). There were no differences in mean scores for Head and neck cancer, Bladder cancer, Respiratory illness in children, Clogged arteries, COPD versus either TCA comparison, Emphysema and bronchitis, Erectile dysfunction, and Cataracts. In the ordinal logistic regressions where only one health belief item addressed a given health topic (ie, the statements about Premature birth, Stunt Fetal growth, and Low birth weight), there were no differences between revised and TCA statements Supplementary Table S2.

Phase 2: Comparisons at the Level of the Study Condition

Overall Health Beliefs

In general, the number of health effects believed to be associated with cigarette smoking and secondhand smoke was significantly larger among respondents in the treatment versus control condition. Specifically, respondents who saw only revised statements endorsed an average of 10.00 (standard deviation [SD] 5.57) of 20 smoking-related conditions versus 8.71 (SD 5.11) for those seeing only TCA statements ($B: 1.29$, 95% CI: 0.45–2.13) and 1.46 (SD 0.68) of 2 secondhand-smoke-related conditions versus 1.34 (SD 0.71) for those seeing only TCA statements ($B: 1.42$, 95% CI: 1.04–1.93). They also endorsed 13.79 (SD 6.46) of the 25 total health conditions versus 12.42 (SD 6.08) for those seeing only TCA statements ($B: 1.37$, 95% CI: 0.37–2.37). There were no differences between those who saw revised statements and those who saw TCA statements in the number of pregnancy-related health beliefs.

Discussion

The primary aim of this study was to assess which, if any, of the revised statements promote greater understanding of risks associated with cigarette smoking when compared with TCA statements. In general, relatively few participants reported that TCA statements were new information. When TCA statements and revised statements on the same health topic were compared, the revised statements were often considered new information to more participants. When the revised statement described a health topic not covered in any of the TCA statements, two-thirds or more of respondents described the revised statements as new information. In contrast, for health topics that were only described in TCA statements and not revised statements (ie, the statements about death, cessation, and addiction), only a minority of participants described those topics as new information. The findings about health beliefs suggest that seeing the revised statements is generally associated with greater ability to accurately identify smoking-related health conditions.

Although most people understand that smoking is harmful, there are still substantial gaps in their knowledge of smoking-related health conditions.^{2–5} These gaps present an opportunity to raise awareness and promote learning of new information about less well-known health consequences of cigarette smoking. Ratings were generally high for both TCA and revised warning statements for measures of new information and self-reported learning. However,

Table 4. Perceptions of Statements' Believability, Informativeness, and Perceived Factualness for Received Statements Compared With Assigned TCA Statements (Listed in Table 1)

Comparison	Believability ^b				Informativeness ^c				Perceived Factualness ^d	
	Revised: mean (SD)	TCA: mean (SD)	Regression coefficient (95% CI)	Revised: mean (SD)	TCA: mean (SD)	Regression coefficient (95% CI)	Revised: % describing as factual	TCA: % describing as factual	OR (95% CI)	
1	4.77 (1.33)	4.80 (1.37)	-0.03 (-0.33 to 0.28)	4.10 (1.69)	4.04 (1.81)	0.06 (-0.34 to 0.46)	88.4	87.2	1.13 (0.56 to 2.3)	
2	3.72 (1.81)	4.80 (1.37)	-1.08 (-1.44 to -0.70) ^a	3.87 (1.73)	4.04 (1.81)	-0.17 (-0.57 to 0.23)	56.1	87.2	0.18 (0.1 to 0.33) ^a	
3	3.69 (1.85)	4.80 (1.37)	-1.11 (-1.48 to -0.70) ^a	4.15 (1.80)	4.04 (1.81)	0.11 (-0.30 to 0.52)	69.4	87.2	0.32 (0.17 to 0.59) ^a	
4	4.78 (1.37)	4.89 (1.30)	-0.10 (-0.4 to 0.2)	4.48 (1.54)	4.14 (1.72)	0.34 (-0.03 to 0.71)	83.1	87.8	0.68 (0.35 to 1.31)	
5	4.87 (1.39)	4.89 (1.30)	-0.01 (-0.31 to 0.29)	4.33 (1.72)	4.14 (1.72)	0.19 (-0.2 to 0.58)	79.6	87.8	0.54 (0.28 to 1.01)	
6	4.77 (1.41)	4.89 (1.30)	-0.12 (-0.42 to 0.19)	4.43 (1.55)	4.14 (1.72)	0.29 (-0.08 to 0.66)	87.8	87.8	1.00 (0.49 to 2.02)	
7	4.59 (1.50)	4.49 (1.54)	0.11 (-0.23 to 0.45)	4.39 (1.50)	3.85 (1.75)	0.54 (0.17 to 0.91) ^a	82.4	75.7	1.52 (0.86 to 2.7)	
8	4.55 (1.47)	4.51 (1.40)	0.04 (-0.28 to 0.37)	4.39 (1.52)	4.04 (1.70)	0.35 (-0.01 to 0.72)	81.0	83.8	0.82 (0.44 to 1.51)	
9	4.69 (1.42)	3.74 (1.77)	0.95 (0.58 to 1.32) ^a	4.44 (1.55)	3.84 (1.82)	0.60 (0.21 to 0.99) ^a	83.0	61.5	3.20 (1.82 to 5.61) ^a	
10	4.88 (1.20)	4.60 (1.48)	0.28 (-0.02 to 0.59)	4.72 (1.20)	3.93 (1.84)	0.79 (0.42 to 1.16) ^a	92.5	85.8	2.06 (0.95 to 4.5)	
11	4.85 (1.41)	4.60 (1.48)	0.26 (-0.07 to 0.58)	4.37 (1.63)	3.93 (1.84)	0.44 (0.05 to 0.84)	91.8	85.8	1.90 (0.89 to 4.06)	
12	3.93 (1.65)	4.89 (1.30)	-0.95 (-1.28 to -0.6) ^a	4.00 (1.74)	4.14 (1.72)	-0.14 (-0.53 to 0.25)	65.3	87.8	0.24 (0.13 to 0.44) ^a	
13	3.96 (1.68)	4.51 (1.40)	-0.55 (-0.90 to -0.10) ^a	4.37 (1.54)	4.04 (1.70)	0.33 (-0.03 to 0.70)	68.9	83.8	0.42 (0.24 to 0.74) ^a	
14	3.72 (1.93)	4.60 (1.48)	-0.87 (-1.26 to -0.40) ^a	4.01 (1.92)	3.93 (1.84)	0.08 (-0.35 to 0.50)	61.2	85.8	0.25 (0.14 to 0.45) ^a	
15	3.93 (1.69)	4.74 (1.64)	-0.82 (-1.19 to -0.40) ^a	4.21 (1.68)	3.57 (1.98)	0.63 (0.21 to 1.05) ^a	65.8	79.7	0.49 (0.29 to 0.83) ^a	
16	3.76 (1.79)	4.89 (1.30)	-1.13 (-1.48 to -0.70) ^a	4.17 (1.76)	4.14 (1.72)	0.03 (-0.37 to 0.42)	61.5	87.8	0.20 (0.11 to 0.37) ^a	

Regressions control for age group. CI = confidence interval; COPD = chronic obstructive pulmonary disease; OR = odds ratio; SD = standard deviation; TCA = Tobacco Control Act.

^aSignificant after adjustment for multiple comparisons.

^bOn a scale from 1 = "Not at all believable" to 7 = "Very believable."

^cOn a scale from 1 = "Not at all informative" to 7 = "Very informative."

^dResponses of "fact" coded as 1 and "opinion" coded as 0.

^eCompared with fatal lung disease in nonsmokers.

^fCompared with fatal lung disease in smokers.

Table 5. Linear Regressions for Topic-Specific Health Beliefs for Revised Statements Compared With Assigned TCA Statements (Listed in Table 1)

Comparison	Revised statement tested	Mean (SD), health belief score		Regression coefficient (95% CI)
		Revised ^b	TCA ^b	
1	Mouth and throat cancer	4.27 (0.74)	3.98 (0.93)	0.29 (0.10 to 0.48) ^a
2	Head and neck cancer	3.43 (1.00)	3.33 (1.05)	0.10 (-0.14 to 0.33)
3	Bladder cancer	3.41 (1.01)	3.26 (0.97)	0.15 (-0.07 to 0.38)
7	Respiratory illness in children	3.98 (0.87)	3.82 (0.90)	0.17 (-0.03 to 0.37)
8	Clogged arteries	4.00 (0.88)	3.89 (0.83)	0.12 (-0.08 to 0.32)
9	COPD ^c	4.32 (0.64)	4.18 (0.80)	0.14 (-0.03 to 0.3)
10	COPD ^d	4.38 (0.71)	4.18 (0.80)	0.19 (0.02 to 0.37)
11	Emphysema and bronchitis	4.25 (0.60)	4.06 (0.78)	0.19 (0.03 to 0.35)
12	Erectile dysfunction	3.74 (0.91)	3.52 (0.81)	0.22 (0.02 to 0.42)
13	Amputation	3.75 (0.84)	3.48 (0.93)	0.27 (0.07 to 0.47) ^a
14	Diabetes	3.48 (0.98)	3.10 (1.01)	0.38 (0.15 to 0.61) ^a
15	Macular degeneration	3.57 (0.95)	3.21 (0.93)	0.35 (0.14 to 0.57) ^a
16	Cataracts	3.37 (1.10)	3.13 (1.02)	0.24 (0.00 to 0.48)

Regressions control for age group. CI = confidence interval; COPD = chronic obstructive pulmonary disease; SD = standard deviation; TCA = Tobacco Control Act. Cronbach's alpha for scaled health belief items: 0.75 (Mouth and throat cancer), 0.74 (Head and neck cancer), 0.86 (Bladder cancer), 0.81 (Respiratory illness in children), 0.87 (Clogged arteries), 0.78 (COPD), 0.69 (Emphysema and bronchitis), 0.78 (Erectile dysfunction), 0.82 (Amputation), 0.83 (Diabetes), 0.82 (Macular degeneration), and 0.84 (Cataracts).

^aSignificant after adjustments for multiple comparisons.

^bSpecific health belief items vary by condition.

^cCompared with fatal lung disease in nonsmokers.

^dCompared with fatal lung disease in smokers.

the comparisons suggest that, overall, the revised statements had higher levels of these outcomes than the TCA statements.

With some exceptions, revised statements were more likely to be considered new information and result in more self-reported learning than TCA statements when the revised statements were more specific. For example, statements about specific types of cancers, like head and neck cancer and bladder cancer, were more likely to be new information and result in greater learning than a general statement about cancer. Statements about specific problems caused by smoking during pregnancy resulted in more new information and/or self-reported learning than a general statement that smoking causes harm to babies.

Revised statements were also generally more likely to be considered new information and result in more self-reported learning than TCA statements when they addressed health outcomes that were not widely known cancers or lung issues. For example, statements about erectile dysfunction and vision problems were more likely to be new information and result in greater learning than randomly paired statements addressing addiction or lung disease. Collectively, our findings show that exposure to the revised statements can address gaps in understanding of the risks associated with cigarette smoking. Our findings align with studies showing that exposure to cigarette health warnings on specific smoking-related health conditions increases knowledge and understanding of those conditions.^{3,13,19}

There were fewer significant differences between revised and TCA statements for thinking about risks, topic-specific health beliefs, believability, informativeness, and perceived factualness, and the direction of the relationships was mixed. For example, three revised statements were more likely to result in thinking about risks than TCA statements, but the reverse was true for one revised statement. One revised statement was rated as more believable than its paired TCA statement, but the reverse was true for seven revised statements.

For some health topics, the lack of a significant difference between a TCA and revised statement could be due to a ceiling effect. For example, there was no difference in new information between the mouth and throat cancer revised statement and the unspecified cancer TCA statement because knowledge of both was very high. Similar to other studies, the lack of impact of cigarette health warnings on promoting beliefs of the negative health consequences of smoking may be partly attributed to ceiling effects on knowledge of well-known consequences.^{29,30} However, a lack of difference does not necessarily indicate that a given statement, whether revised or TCA, is not useful for improving understanding of the health effects of smoking.

Some of the revised statements had lower levels of believability than other revised statements. Although the revised statements on head and neck cancer, bladder cancer, diabetes, and cataracts were rated as less believable, they were also rated as being new information to most participants. The novelty of the information may have led to lower ratings in believability, aligning with previous research in persuasive messaging.^{31,32} If individuals have not yet integrated bladder cancer, diabetes, or cataracts into their schemas about smoking's health effects, they may still be somewhat skeptical.

Making the public aware of new information about health risks is an important first step toward improving understanding. Whether the information is new or well-known, there is potential to improve understanding by inducing thinking about the risks (ie, cognitive elaboration). Cognitive elaboration is more likely to happen with longer exposures to warnings as would happen in the real world and when warnings are paired with images, as will be tested in a further study.

Limitations

The sample was large, diverse, and included subpopulations for whom these warnings are particularly relevant (eg, adolescents susceptible to smoking). However, the sample was not nationally representative, and thus the results cannot be extrapolated to the

population beyond those in the study sample. Because of the experimental design, these limitations in generalizability do not affect the internal validity, and thus the conclusions, of the study.

Many studies have tested the effects of image-based tobacco product warnings compared with text-only tobacco product warnings,⁹ but this was not the purpose of the present study. Rather, the sole purpose was to assess whether the content of warning statements with revised text would “promote greater public understanding of the risks associated with the use of tobacco products” when compared with statements provided in the TCA. This study relied on a brief, one-time exposure to text-only warning statements. Image-based warnings and warnings that are viewed more than once typically show more robust effects on perceptions and understanding.^{9,33} Thus, these results may underestimate the effect of the warnings on the study’s chosen outcomes. When warnings statements are paired with a concordant image depicting the negative health consequences of smoking and are displayed on cigarette packs and advertisements to which the public would have repeated exposure, the effect on public understanding would likely be greater.³³

Conclusion and Future Directions

This study found that there are opportunities to improve understanding of the negative health consequences of smoking using revised warning statements compared with TCA statements. Revised statements may improve understanding for some health conditions by describing outcomes more specifically (eg, “head and neck cancer” rather than “cancer”) or focusing on health conditions only recently causally linked to smoking, of which the public may not yet be aware. These results support FDA’s decision to adjust the text of some of the warnings per its statutory authority. The results of this study informed the selection of warning statements that were paired with concordant images depicting the negative health consequences of smoking, forming pictorial cigarette warnings that were tested in a follow-up study and included in a proposed rule. The follow-up study exposed participants to the warnings (including images) multiple times in the formats in which they will eventually appear (ie, on packs and advertisements). The results of that study, along with this one, provide scientific support for FDA’s rulemaking to fulfill its statutory obligation under the TCA regarding cigarette health warnings.

Supplementary Material

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>.

Funding

This work was supported by US Food and Drug Administration (Contract No. HHSF223201110005B).

Declaration of Interests

None declared.

Acknowledgments

The authors wish to thank Shireen Fotelargias, Emily Talbert, Courtney Smith, Daniel Gittleston, and Jesse Thompson for their contributions to this project. The findings and conclusions in this report are those of the authors

and do not necessarily represent the official position of the Food & Drug Administration.

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