

Study Summary

Study THS-PBA-03-US

Study Title: Study to Quantitatively Assess THS 2.2 Potential Messages

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Study Summary

Philip Morris International (PMI) conducted this study in the United States from October 2014 to December 2014. The protocol was approved by an Institutional Review Board (IRB) and the participants received complete information about the study and signed an informed consent form (ICF).

Study THS-PBA-03-US

This study summary contains key results. The full results for the study are contained in the study report ([PMI 2015](#)).

Study Title:

Study to Quantitatively Assess THS 2.2 Potential Messages

Principal Investigator:

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Background:

As part of the development program for a candidate Modified Risk Tobacco Product (MRTP), the Tobacco Heating System (THS) 2.2, PMI has undertaken a comprehensive program to study consumer perception and behavior that responds to the United States Food and Drug Administration's (US FDA's) recommendations outlined in the Draft Guidance for Modified Risk Tobacco Product ([Food and Drug Administration 2012](#)).

The THS 2.2 premarket consumer Perception and Behavior Assessment (PBA) program consists of 3 components: A - Scale Development, B - Development and Assessment of Label, Labeling, and Marketing Material, and C - Use Behavior. The goals of Component B are to develop label, labeling, and marketing materials for THS 2.2; to assess comprehension of various aspects of these materials; to assess risk perception based on these materials; and to confirm these label, labeling, and marketing materials generate low intent to use among those for whom THS 2.2 is not intended. The studies of Component B are designed to provide science-based evidence that the THS 2.2 proposed label, labeling, and marketing materials enable the public to fully understand the information concerning modified risk and effectively communicate the risks associated with the product.

The current study involves a set of quantitative assessments that is part of Component B of the PBA program for THS 2.2. The overall aim of this study was to describe the responses of Adult Smokers with and without the Intention to Quit conventional cigarettes (CCs), Adult Former Smokers, and Adult Never Smokers, to five THS 2.2 messages. These messages were intended to be used to inform the development of THS 2.2 label, labeling and marketing material.

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Objectives:

The objective of this study was to evaluate the different THS 2.2 messages and smoking status groups in terms of subjects’:

1. Intent to Use THS 2.2.
2. Comprehension of:
 - The THS 2.2 message as a whole
 - The Evidence Statement
 - The Intended Users Statement
 - The Warning Section
3. Risk Perception of THS 2.2 and the comparators CC, Nicotine Replacement Therapies (NRTs), E-cigarettes, and Cessation.
4. Change in Intention to Quit Smoking (only within adult smokers).

Methodology:

Study Design

The study was a five-arm parallel-group experiment conducted at research facilities in four US cities. The five arms corresponded to the five different THS 2.2 messages, each of them being tested by approximatively equal numbers of subjects from different smoking status groups.

Smoking status groups were defined from self-reported smoking status and intention to quit CC. The four smoking status groups in the Main Sample were defined as: (1) Adult Smokers with no Intention to Quit CC; (2) Adult Smokers with the Intention to Quit CC; (3) Adult Former Smokers; and (4) Adult Never Smokers. Additionally, an oversampling of adult never smokers from the legal age of smoking to 25 years old (LA-25 Adult Never Smokers) was included in the study.

The main study sample was stratified using the following variables:

- City (360 subjects in each of four study sites),
- Smoking status (360 subjects in each smoking status group),
- Sex, and
- Age (Legal Age [LA]-35 years, 36-50 years, ≥ 51 years)

The cities, Chicago, IL; Marlton, NJ; Phoenix, AZ; and Atlanta, GA, were selected to provide a geographically diverse sample of the US population within each of the four US regions defined by the US Census Bureau (i.e., Northeast, Midwest, South, and West).

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Study Methods

Subjects were recruited via telephone by an independent vendor using a proprietary database.

The five THS 2.2 messages consisted of four sections (Figure 1). The THS 2.2 messages had identical THS 2.2 Information Sections and Intended Users Statements, but presented different combinations of Evidence Statements and Warning Sections. The possible combinations are shown in Figure 2.

Allocation to the five THS 2.2 messages was within the 96 strata (4 cities × 4 smoking statuses × 2 sexes × 3 age groups). Allocation of subjects into a specific stratum of one of the different combinations of Evidence Statements and Warnings Sections was done in the order in which a subject enrolled into the stratum.

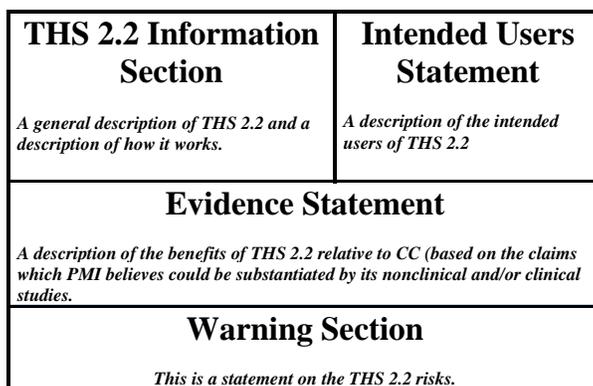


Figure 1. General Structure of THS 2.2 Potential Product Messages

Message 1	Message 2	Message 3	Message 4	Message 5
<p>Evidence Statement 1</p> <p>(reduced exposure)</p> <ul style="list-style-type: none"> When tobacco is burned, it produces many harmful or potentially harmful chemicals. THS 2.2 heats tobacco but does not burn it. With the exception of nicotine, with THS 2.2 there is a significant reduction in the production of harmful or potentially harmful chemicals. 	<p>Evidence Statement 1</p> <p>(reduced exposure)</p> <ul style="list-style-type: none"> When tobacco is burned, it produces many harmful or potentially harmful chemicals. THS 2.2 heats tobacco but does not burn it. With the exception of nicotine, with THS 2.2 there is a significant reduction in the production of harmful or potentially harmful chemicals. 	<p>Evidence Statement 2</p> <p>(reduced exposure)</p> <ul style="list-style-type: none"> THS 2.2 heats tobacco but does not burn it. This significantly reduces the production of harmful or potentially harmful chemicals. Scientific studies have shown that switching completely from cigarettes to THS 2.2 significantly reduces your body's exposure to harmful or potentially harmful chemicals. 	<p>Evidence Statement 2</p> <p>(reduced exposure)</p> <ul style="list-style-type: none"> THS 2.2 heats tobacco but does not burn it. This significantly reduces the production of harmful or potentially harmful chemicals. Scientific studies have shown that switching completely from cigarettes to THS 2.2 significantly reduces your body's exposure to harmful or potentially harmful chemicals. 	<p>Evidence Statement 3</p> <p>(reduced risk)</p> <ul style="list-style-type: none"> THS 2.2 heats tobacco but does not burn it. This significantly reduces the production of harmful or potentially harmful chemicals. Scientific studies have shown that switching completely from cigarettes to THS 2.2 can reduce the risks of tobacco-related diseases
<p>Warning A</p> <ul style="list-style-type: none"> It has not been demonstrated that switching to THS 2.2 reduces the risk of developing tobacco-related diseases compared to smoking cigarettes. THS 2.2 tobacco sticks contain nicotine which is addictive. Using THS 2.2 can harm your health. 	<p>Warning B1</p> <ul style="list-style-type: none"> A significant reduction in the production of harmful chemicals, compared to cigarettes, does not mean a reduction in the risk of developing tobacco-related diseases. THS 2.2 tobacco sticks contain nicotine which is addictive. Using THS 2.2 can harm your health. 	<p>Warning A</p> <ul style="list-style-type: none"> It has not been demonstrated that switching to THS 2.2 reduces the risk of developing tobacco-related diseases compared to smoking cigarettes. THS 2.2 tobacco sticks contain nicotine which is addictive. Using THS 2.2 can harm your health. 	<p>Warning B2</p> <ul style="list-style-type: none"> A significant reduction in your body's exposure to harmful chemicals compared to cigarettes, does not mean a reduction in the risk of developing tobacco-related diseases. THS 2.2 tobacco sticks contain nicotine which is addictive. Using THS 2.2 can harm your health 	<p>Warning C</p> <ul style="list-style-type: none"> Reduced risk does not mean no risk. The best way to reduce your risk of tobacco-related diseases is to completely quit tobacco use. THS 2.2 tobacco sticks contain nicotine which is addictive. Using THS 2.2 can harm your health.

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Figure 2. THS 2.2 Messages - Different Combinations of Evidence Statements and Warnings

The measures and methods of the study are summarized in [Table 1](#). The four main areas of assessments were Intent to Use, Change in the Intention to Quit Smoking, Comprehension, and Risk Perception. Data acquisition was implemented using Computer-Assisted Self Interview (CASI) methodology to ensure consistency in the way questions were presented across interviews. Subjects' participation lasted approximately 45 minutes; they were compensated \$75. At the end of the study assessments, subjects underwent a one-to-one debriefing to address potential misperceptions about THS 2.2 that may have arisen from participation in the study. The debriefing script stated that the various THS 2.2 Messages and information were for research purposes only, had not been demonstrated to be true, that the FDA has not issued any orders authorizing the marketing of THS 2.2 and it had not been approved as an MRTP, and reminded subjects of the risks associated with tobacco consumption.

Table 1. Assessments and Measurement Methods

Dimension (Assessment)	Measurement method
Intent to Use	The Intent to Use Questionnaire (ITUQ) which includes two sets of items common for all smoking status yielded descriptive measures of: <ul style="list-style-type: none"> • Intention to Try (i.e., to sample at least once; 2 items) • Intention to Use (i.e., for continued usage; 2 items)
Change in Intention to Quit Smoking	Closed-ended questions based on Prochaska and DiClemente's Stages of Change model (Prochaska and DiClemente 1982) measured before and after exposure to THS 2.2 message to determine change in Intention to Quit Smoking
Comprehension	Two types of comprehension were assessed: <ol style="list-style-type: none"> 1. "Global comprehension": overall comprehension of the THS 2.2 Message on exposure to harmful chemicals and risk of tobacco-related diseases of using THS 2.2. 2. "Specific comprehension": comprehension of three specific parts of the THS 2.2 Message: the Intended Users Statement, Evidence Statement and Warning Statement. <p>Both types of comprehension were assessed with multiple-choice questions, 5 response options were presented, with 1 correct option, 3 incorrect options and an option for "don't know".</p>
Risk Perception	The Perceived Risk Instrument-Personal Risk (PRI-P) comprised of two domains, each measured by a unidimensional scale: <ol style="list-style-type: none"> 1. Perceived Health Risk 18-item scale 2. Perceived Addiction Risk 7-item scale <p>And complemented by two single items yielding descriptive measures of Perceived Harm to Others</p>

Abbreviations: ITUQ = Intent to Use Questionnaire; PRI-P = Perceived Risk Instrument-Personal Risk; THS 2.2 = Tobacco Heating System 2.2.

Number of Subjects:

There were 2,200 subjects recruited for the study via telephone. Of these, 2,054 subjects met all eligibility criteria and enrolled in the study. The actual Full Sample consisted of 1,713 subjects. The Main Sample included 1,434 subjects and the LA-25 Adult Never Smokers Sample consisted of 358 subjects, including 79 Adult Never Smokers from the Main Sample ([Table 2](#)).

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Table 2. Total Subjects in Study

Contacted	2,200 subjects
Screened at the facility	2,054 subjects
Full Sample	1,713 subjects
Main Sample	1,434 subjects
LA-25 Sample	358 subjects (including 79 adults never smokers from Main Sample)

Inclusion and Exclusion Criteria:

Inclusion Criteria:

- Aged 18 years and above, or above state legal smoking age
- Currently living in the US
- Signed informed consent form
- Ability to understand written and spoken English
- Ability to comply with study procedures in the judgment of the researcher

Exclusion Criteria:

- Employed in the fields of market research, marketing, advertising, media or journalism, law, the tobacco industry, or the health sector
- Participation in a consumer or clinical study in the past three months
- Quit smoking less than 30 days ago
- Started smoking within the last 30 days

Criteria for Evaluation:

This was a descriptive study. No formal hypothesis testing was planned nor conducted.

Sample Size:

Sample size calculation was based on attaining sufficient precision in the measures associated with all study objectives. The effective sample (i.e., the number of subjects who complete all assessments) for the Main Sample was planned to be 1,440 subjects (which provided 288 subjects within each THS 2.2 message and 72 subjects within each THS 2.2 message by smoking status group). The effective sample size for the LA-25 Sample was planned to be 360, which would have provided 72 subjects for each message.

Analysis:

The general analytic approach was descriptive. Categorical outcome measures were described in terms of the number of subjects in each smoking status group and the number and proportion of subjects in each category. Continuous outcome measures were described with mean, standard deviation, median, minimum and maximum. Unadjusted 95% confidence intervals were calculated as interval estimates for the outcome variables. Descriptive summary statistics were presented for the four assessments as follows:

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Intent to Use – proportion of responses for each response category presented by THS 2.2 message and smoking status group for each item.

Change in Intention to Quit Smoking - For current smokers, change in intention to quit was summarized with a switch table (with pre- and post-exposure to THS 2.2 message).

Comprehension - Descriptive statistics of the proportion of subjects correctly answering each question presented by THS 2.2 message for the main sample and LA-25 Adult Never Smokers sample.

Risk Perception – Descriptive statistics of the Perceived Health Risk and Perceived Addiction Risk scale scores and proportion of responses for each response category for the Harm to Others items presented by THS 2.2 message and smoking status group for THS 2.2 and each comparator (i.e., CC, E-cigarettes, NRTs and Cessation).

Summary of Results:

Demographics and Subject Characteristics – By THS 2.2 Message

Demographics and subject characteristics for the Main Sample were similar across the five THS 2.2 message groups and balanced with regard to age, sex, and race (

Assessment	Message				
	1 (N=294)	2 (N=288)	3 (N=289)	4 (N=284)	5 (N=279)
Age (years)					
Mean (SD)	42.7 (13.86)	43.0 (13.80)	43.4 (13.71)	43.0 (14.31)	42.9 (13.68)
Median	42.0	43.0	44.0	42.5	43.0
Min - Max	19 - 74	19 - 82	19 - 82	18 - 80	18 - 77
Age group					
LA-35, n (%)	98 (33.3)	96 (33.3)	96 (33.2)	95 (33.5)	94 (33.7)
36-50, n (%)	95 (32.3)	96 (33.3)	96 (33.2)	95 (33.5)	92 (33.0)
51+, n (%)	101 (34.4)	96 (33.3)	97 (33.6)	94 (33.1)	93 (33.3)
Sex					
Male, n (%)	150 (51.0)	144 (50.0)	145 (50.2)	141 (49.6)	137 (49.1)
Female, n (%)	144 (49.0)	144 (50.0)	144 (49.8)	143 (50.4)	142 (50.9)
Race					
White, n (%)	220 (75.6)	208 (73.2)	213 (74.2)	207 (73.1)	193 (69.9)
Black, n (%)	53 (18.2)	59 (20.8)	55 (19.2)	49 (17.3)	56 (20.3)
Other, n (%)	18 (6.1)	17 (5.9)	19 (6.6)	27 (9.5)	27 (9.7)
Missing, n	3	4	2	1	3
Ethnicity					
Hispanic or Latino, n (%)	23 (7.9)	27 (9.5)	24 (8.4)	28 (9.9)	31 (11.2)
Not Hispanic or Latino, n (%)	268 (92.1)	257 (90.5)	263 (91.6)	255 (90.1)	245 (88.8)
Missing, n	3	4	2	1	3
Education level					
High school and below, n (%)	48 (16.3)	42 (14.6)	42 (14.5)	43 (15.1)	56 (20.1)
Some college and above, n (%)	243 (83.7)	242 (85.4)	245 (85.5)	240 (84.9)	220 (79.9)
Missing, n	3	4	2	1	3

SD = standard deviation.

). Demographics and subject characteristics for the LA-25 Adult Never Smokers sample were similar across the five THS 2.2 message groups.

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Table 3. Summary of Demographics and Other Baseline Characteristics – Main Sample

Assessment	Message				
	1 (N=294)	2 (N=288)	3 (N=289)	4 (N=284)	5 (N=279)
Age (years)					
Mean (SD)	42.7 (13.86)	43.0 (13.80)	43.4 (13.71)	43.0 (14.31)	42.9 (13.68)
Median	42.0	43.0	44.0	42.5	43.0
Min - Max	19 - 74	19 - 82	19 - 82	18 - 80	18 - 77
Age group					
LA-35, n (%)	98 (33.3)	96 (33.3)	96 (33.2)	95 (33.5)	94 (33.7)
36-50, n (%)	95 (32.3)	96 (33.3)	96 (33.2)	95 (33.5)	92 (33.0)
51+, n (%)	101 (34.4)	96 (33.3)	97 (33.6)	94 (33.1)	93 (33.3)
Sex					
Male, n (%)	150 (51.0)	144 (50.0)	145 (50.2)	141 (49.6)	137 (49.1)
Female, n (%)	144 (49.0)	144 (50.0)	144 (49.8)	143 (50.4)	142 (50.9)
Race					
White, n (%)	220 (75.6)	208 (73.2)	213 (74.2)	207 (73.1)	193 (69.9)
Black, n (%)	53 (18.2)	59 (20.8)	55 (19.2)	49 (17.3)	56 (20.3)
Other, n (%)	18 (6.1)	17 (5.9)	19 (6.6)	27 (9.5)	27 (9.7)
Missing, n	3	4	2	1	3
Ethnicity					
Hispanic or Latino, n (%)	23 (7.9)	27 (9.5)	24 (8.4)	28 (9.9)	31 (11.2)
Not Hispanic or Latino, n (%)	268 (92.1)	257 (90.5)	263 (91.6)	255 (90.1)	245 (88.8)
Missing, n	3	4	2	1	3
Education level					
High school and below, n (%)	48 (16.3)	42 (14.6)	42 (14.5)	43 (15.1)	56 (20.1)
Some college and above, n (%)	243 (83.7)	242 (85.4)	245 (85.5)	240 (84.9)	220 (79.9)
Missing, n	3	4	2	1	3

SD = standard deviation.

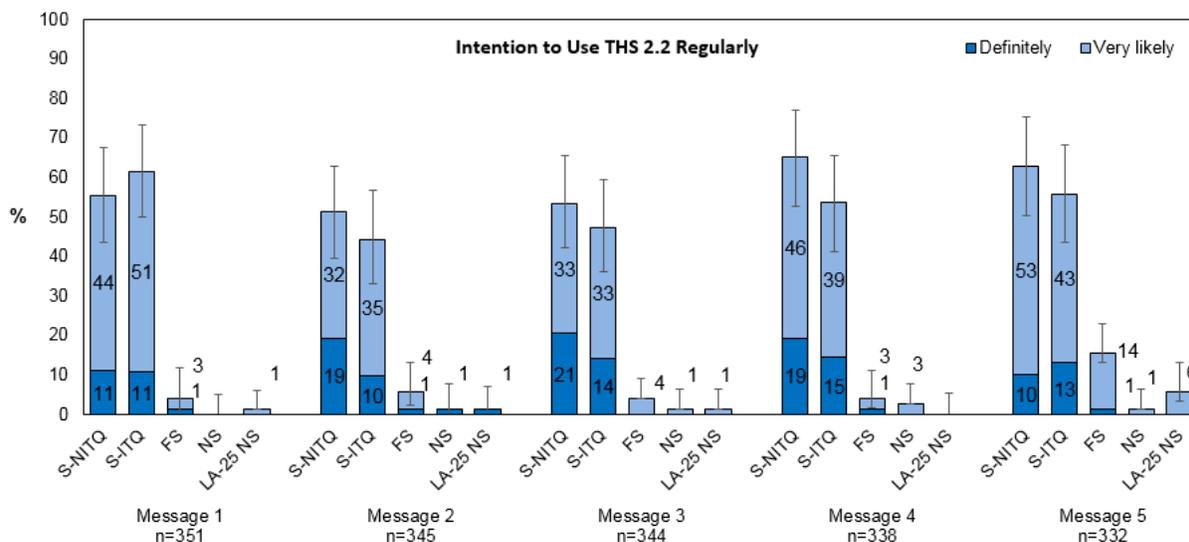
Intent to Use

Results for Intention to Try THS 2.2 were similar to the results for Intention to Use THS 2.2 regularly, considering both THS 2.2 Message and smoking status. Intention to Try THS 2.2 and Intention to Use THS 2.2 were substantial within Adult Smokers with No Intention to Quit CC (for Intention to Try the range was 38% to 57%; for Intention to Use the range was 51% to 65%) and within Adult Smokers with the Intention to Quit CC (for Intention to Try the range was 36% to 54%; for Intention to Use the range was 44% to 61%).

Intention to Try THS 2.2 and Intention to Use THS 2.2 regularly were low among Adult Former Smokers ($\leq 16\%$ for all THS 2.2 Messages), Adult Never Smokers ($\leq 3\%$ for all THS 2.2 Messages), and LA-25 Adult Never Smokers ($\leq 6\%$ for all THS 2.2 Messages). Intention to Use THS 2.2 regularly across all smoking groups is displayed in [Figure 3](#).

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Abbreviations: S-NITQ = Adult Smokers with no Intention to Quit CC; S-ITQ = Adult Smokers with the Intention to Quit CC; FS = Adult Former Smokers; NS = Adult Never Smokers; LA-25 NS = Adult Never Smokers from state legal smoking age to 25 years.

Error bars are the 95% confidence intervals for the “Very likely” and “Definitely” categories combined.

Figure 3. Subjects with a Positive Intention to Use THS 2.2 Regularly Across All Messages

Change in Intention to Quit Smoking

Within Adult Smokers with the initial Intention to Quit CC (prior to exposure to the THS 2.2 Messages), between 83% and 97% of subjects across the different THS 2.2 Messages still had the Intention to Quit CC after exposure to the THS 2.2 Messages.

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Comprehension**Global Comprehension**

The level of comprehension for the question on exposure to harmful and potentially harmful constituents (HPHCs) with THS 2.2 versus CC was 70% of subjects for Message 1, 71% for Message 2, 55% for Message 3, 57% for Message 4, and 51% for Message 5. The level of comprehension for the question on the risk of tobacco-related diseases related to switching from CC to THS 2.2 was 62% of subjects for Message 1, 64% for Message 2, 74% for Message 3, 60% for Message 4, and 81% for Message 5. For both Messages 3 and 5 the proportion of subjects who indicated that THS 2.2 can “eliminate” the risk of tobacco-related diseases was less than 1% (3 out of 568 subjects).

Specific Comprehension

Comprehension level for the “specific comprehension” questions was consistently high across all the THS 2.2 messages for the Intended User Statement (>94% across all message groups), the Evidence Statements (>85% across all message groups) and the Warning (>76% across all message groups) (Table 4). The comprehension results in the LA-25 Adult Never Smokers were similar to those observed in the Main Sample.

Table 4. Specific Comprehension of Intended User, Evidence, and Warning Statements – Main Sample by THS 2.2 Message

Assessment	Statistics	Message				
		1 (N=291 ^a)	2 (N=285 ^a)	3 (N=288 ^a)	4 (N=284 ^a)	5 (N=278 ^a)
Intended User Comprehension – Correct Answer						
THS 2.2 is intended for Smokers who want to continue using tobacco						
n (%)		282 (96.9)	269 (94.4)	274 (95.1)	275 (96.8)	262 (94.2)
95% CI for % correct		(94.2, 98.6)	(91.0, 96.8)	(92.0, 97.3)	(94.1, 98.5)	(90.8, 96.7)
Evidence Comprehension – Correct Answers						
THS 2.2 heats tobacco but does not burn it						
n (%)		282 (96.9)	271 (95.1)	275 (95.5)	271 (95.4)	270 (97.1)
95% CI for % correct		(94.2, 98.6)	(91.9, 97.3)	(92.4, 97.6)	(92.3, 97.5)	(94.4, 98.7)
No significant reduction in nicotine						
n (%)		250 (85.9)	252 (88.4)	NA	NA	NA
95% CI for % correct		(81.4, 89.7)	(84.1, 91.9)			
Reduction in harmful or potentially harmful chemicals						
n (%)		268 (92.1)	261 (91.6)	NA	NA	NA
95% CI for % correct		(88.4, 94.9)	(87.7, 94.5)			
Warning Comprehension – Correct Answers						
THS 2.2 contains nicotine, which is addictive						
n (%)		265 (91.1)	259 (90.9)	265 (92.0)	267 (94.0)	260 (93.5)
95% CI		(87.2, 94.1)	(86.9, 94.0)	(88.3, 94.9)	(90.6, 96.5)	(90.0, 96.1)
Using THS 2.2 can harm your health						
n (%)		222 (76.3)	258 (90.5)	243 (84.4)	263 (92.6)	250 (89.9)
95% CI		(71.0, 81.1)	(86.5, 93.7)	(79.7, 88.4)	(88.9, 95.4)	(85.8, 93.2)
The best way to reduce the risk of tobacco-related diseases is to completely quit tobacco use						
n (%)		NA	NA	NA	NA	241 (86.7)
95% CI						(82.1, 90.5)

Abbreviations: CI = confidence interval; NA = not applicable; THS 2.2 = Tobacco Heating System 2.2.

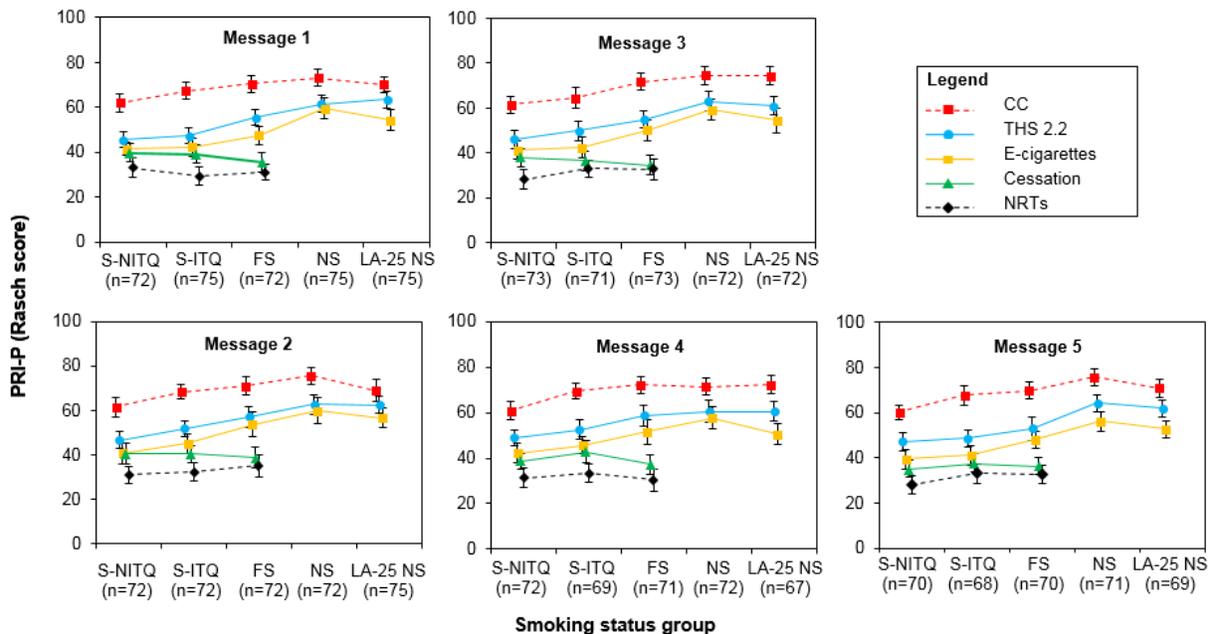
^a Total number of subjects who responded to the question.

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Risk Perception

Results on Perceived Health Risk are shown in Figure 4. For all THS 2.2 Messages, THS 2.2 was rated between the highest risk object (consistently CC) and the lowest risk object (either Cessation or NRTs). For all THS 2.2 Messages, E-cigarettes were also rated as a higher risk than Cessation or NRTs, but consistently lower risk than THS 2.2. Results on Perceived Addiction Risk and Perceived Harm to Others were broadly consistent with results on Perceived Health Risk.



Abbreviations: CC = conventional cigarettes; S-ITQ = smokers with the intention to quit CC; S-NITQ = smokers with no intention to quit CC; ; FS = Adult Former Smokers; NS = Adult Never Smokers; LA-25 NS = Adult Never Smokers from state legal smoking age to 25 years; NRT = nicotine replacement therapy; PRI-P = Perceived Risk Instrument-Personal risk; THS 2.2 = Tobacco Heating System 2.2.

Error bars are the 95% confidence intervals from the mean.

Note: connecting lines are only to highlight clustering of outcomes for each comparator along the y-axis across messages.

Figure 4. Perceived Health Risk of Tobacco Products – By THS 2.2 Message

Conclusions:

The overall aim of this current study was to assess responses to THS 2.2 Messages to be used in the development of THS 2.2 label, labeling and marketing materials in terms of Intent to Use THS 2.2, Change in Intention to Quit Smoking, Comprehension, and Risk Perception.

Intent to Use

In general, the Intention to Try THS 2.2 was similar for Adult Smokers With and Without Intention to Quit CC; 36% to 57% of subjects indicated positive Intention to Try THS 2.2, regardless of the THS 2.2 Message they received. There was also low Intention to Try THS 2.2 among Adult Former Smokers, Adult Never Smokers, and LA-25 Adult Never Smokers; 0% to 6% of subjects reported being very likely or definitely intending to try THS 2.2, regardless of the THS 2.2 Message they received.

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The Intention to Use THS 2.2 followed the same general pattern: 44% to 65% of Adult Smokers With and Without Intention to Quit CC indicated an Intention to Use THS 2.2, regardless of THS 2.2 Message. The Intention to Use THS 2.2 among Adult Former Smokers, Adult Never Smokers, and LA-25 Adult Never Smokers was low: 0% to 16%.

In short, the messages did not appear to have an impact on Intention to Try or Use THS 2.2. Rather, what seemed to define intent is smoking status, specifically, whether an individual is a current smoker or not:

- The status of intending to quit CC did not seem to impact Intent to Try or Use THS 2.2 among Adult Smokers, even though the THS 2.2 messages stated that the product was not intended for “smokers who want to quit.” This finding is consistent with the interpretation that adult smokers intending to quit may view THS 2.2 as an intermediate step toward quitting tobacco, as found for e-cigarettes being used to wean off nicotine products with the aim of eventually becoming completely nicotine-free (Etter 2010, Dawkins 2013).
- The great majority of adult non-smokers (Adult Former Smokers, Adult Never Smokers, LA-25 Adult Never Smokers) indicated no Intent to Try or Use THS 2.2. This suggests that the messages succeeded at not encouraging adult non-smokers to use THS 2.2.

Change in Intention to Quit Smoking

The THS 2.2 Messages did not seem to have a notable impact on Adult Smokers With Intention to Quit; over 80% of subjects still had intention to quit smoking after exposure to the THS 2.2 messages. This suggests subjects correctly understood, as stated in the messages, that the product is not for smokers intending to quit—a finding further supported by the high level of comprehension of the intended user statement found in this study. Furthermore, this finding provides support to the interpretation that Adult Smokers with Intention to Quit and positive Intent to Use THS 2.2 aim to use the product as an intermediate step towards quitting tobacco in a gradual approach (as opposed to “cold turkey”, see Brown 2014). To address this, future studies within the PBA program (e.g. THS-PBA-05-RRC-US) will include a question on intention to “quit all tobacco products”.

Comprehension

Global Comprehension

1. Global Question on Reduced HPHCs with THS 2.2 Compared to CC

The level of comprehension for the question on exposure to HPHCs with THS 2.2 versus CC ranged from 51% (Message 5) to 71% (Message 2). Most subjects who gave incorrect responses for Messages 3, 4 and 5, indicated that HPHC levels with THS 2.2 compared to CC were “reduced by a small amount”, rather than the correct answer that they are “significantly reduced”. Thus, a clear majority of subjects comprehended that HPHC levels with THS 2.2 compared to CC were reduced (80% for Message 3, 82% Message 4 and 87% for Message 5, combining proportions of “significantly reduced” and “reduced by a small amount”), but some subjects were unclear about the degree of this reduction. These results highlight the challenge of communicating the degree of reductions in HPHC levels in language which is specific and unambiguous.

2. Global Question on Reduced Health Risk of THS 2.2 Compared to CC

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Results showed the level of comprehension on disease risk was highest for the *reduced risk* THS 2.2 Message 5 (81%), than for the *reduced exposure* messages (understood well by 60% [THS 2.2 Message 4] to 74% [THS 2.2 Message 3] of subjects across all 4 THS 2.2 Messages). Overall, the *reduced exposure* THS 2.2 Messages (Messages 1, 2, 3, 4) may present a greater challenge on comprehension of disease risk than *reduced risk* message (Message 5), as they may appear to present a contradiction between the statements 1) *with THS 2.2 there is a reduction in exposure to HPHCs* and 2) *there is no established reduction in risk of disease from switching from CC to THS 2.2*. In contrast, the *reduced risk* THS 2.2 Message (Message 5) presented a logical consistency between the two statements: 1) *with THS 2.2 there is a reduction in exposure to HPHCs compared to CC*, and 2) *there is reduced risk of disease from switching from CC to THS 2.2*.

Specific Comprehension

All five THS 2.2 Messages were well comprehended as assessed by the specific questions. The procedure used for specific comprehension testing did not identify particular areas of concern, as questions related to Evidence and Warning comprehension were correctly understood by over 76% of subjects, regardless of smoking status group. Specific comprehension within LA-25 Adult Never Smokers was consistent with the high level with that present in the Main Sample.

Risk Perception

In general, the Perceived Health Risk of THS 2.2 was less than CC and more than E-Cigarettes, with NRTs and Cessation ranked as the lowest risk objects, regardless of message. Similarly, THS 2.2 ranked second to CC in Perceived Addiction Risk as well as in Perceived Harm to Others. The view that THS 2.2 involves less risk than CC and more than other tobacco-related products may stem from the perceived amount of tobacco in the various products. E-cigarettes are often marketed as nicotine delivery devices which do not contain tobacco (Trtchounian 2010) and are also reported to be perceived as carrying a lower health risk than CC (Ambrose 2014, Farsalinos 2014). Thus, we suggest that the presence of tobacco in THS 2.2 leads to a perception of risk for THS 2.2 which is higher than E-cigarettes. This suggestion is also supported by the results of the qualitative THS-PBA-02-US study.

Overall Conclusions

The “reduced risk” THS 2.2 Message (Message 5) was associated with:

- substantial levels of Intent to Use THS 2.2 within the intended section of the population (i.e., Adult Smokers with No Intention to Quit, 63% indicated Intention to Use THS 2.2 regularly).
- low levels of Intent to Use THS 2.2 within Adult Former Smokers (16%) and very low levels of Intent to Use THS 2.2 within Adult Never Smokers (1%).
- substantial levels of Intent to Use THS 2.2 within Adult Smokers with the Intention to Quit (56% indicated Intention to Use THS 2.2 regularly), but also a low level of Change in Intention to Quit Smoking (3% in the next 30 days and 13% in the next 6 months).
- a high level of comprehension (81%) that switching completely from CC to THS 2.2 can reduce the risk of tobacco-related diseases.

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- a level of Risk Perception for the THS 2.2 between CC (the highest risk comparator) and Cessation/NRTs (the lowest risk comparators).

On the basis of these considerations we suggest that the “reduced risk” THS 2.2 Message (Message 5) is suitable for further development into THS 2.2 label, labeling and marketing material. Accordingly, we plan to test label, labeling and marketing material based on the reduced disease risk THS 2.2 Message tested in further studies within the PBA program.

The four “reduced exposure” THS 2.2 Messages (Messages 1 to 4) performed similarly in that they were each associated with:

- substantial levels of Intent to Use THS 2.2 within Adult Smokers with No Intention to Quit CC (i.e., the intended section of the population).
- low levels of Intent to Use THS 2.2 within Adult Former Smokers and Adult Never Smokers (i.e., the unintended section of the population).
- substantial levels of Intent to Use THS 2.2 within Adult Smokers with the Intention to Quit, but also a low level of Change in Intention to Quit.
- patterns of Risk Perception indicating that THS 2.2 was considered lower risk than the highest comparator (CC) and the lowest comparator (Cessation/NRTs). However, results also highlighted the challenge of communicating a “reduced exposure” claim without people inferring some degree of reduced risk for disease.

The THS 2.2 Messages were divergent in terms of comprehension. Therefore, the comprehension results provide a basis for selecting between the four “reduced exposure” THS 2.2 Messages (Messages 1, 2, 3 and 4) for further development. Overall, Message 3 performed better than the other “reduced exposure” THS 2.2 Messages (Messages 1, 2 and 4) in terms of comprehension of the claim that switching to THS 2.2 involves no established reduction in disease risk (74% for Message 3 c.f. 62%, 64% and 60%, for Messages 1, 2, and 4 respectively). Therefore, we consider that Message 3 (if required for an Exposure Modification Order) is appropriate to be developed further into THS 2.2 label, labeling and marketing material.

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List of Abbreviations and Definitions of Terms:

CASI	Computer-assisted self-interview
CC	Conventional cigarette
FDA	Food and Drug Administration
HPHC	Harmful and Potentially Harmful Constituents
ICF	Informed consent form
IRB	Institutional Review Board
ITUQ	Intent to Use Questionnaire
LA	Legal age
MRTTP	Modified Risk Tobacco Product
NRT	Nicotine replacement therapy
PBA	Perception and Behaviour Assessment
PMI	Philip Morris International
PRI-P	Perceived Risk Instrument-Personal Risk
THS 2.2	Tobacco Heating System 2.2
US	United States

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