

# Effects of IQOS health warnings and modified risk claims among young adult cigarette smokers and non-smokers

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## ABSTRACT

**Introduction** Heated tobacco products, including Marlboro IQOS, are available globally. In the USA, IQOS was authorised to be advertised with claims about reduced toxicant exposure relative to cigarettes. The effects of such modified risk claims and health warnings have not been studied among young adult cigarette smokers and non-smokers.

**Methods** In 2020, US young adult (18–30 years, n=1328) cigarette smokers and non-smokers viewed an IQOS ad in a 4 (modified risk claim variations or none) by 3 (warning variations or none) between-subjects experiment. Outcome measures assessed perceived credibility and effectiveness of the health or risk message for discouraging IQOS use, perceived harms, efficacy beliefs, and IQOS use intentions.

**Results** Smokers reported significantly higher ( $p<0.05$ ) perceived credibility, lower perceived effectiveness, higher efficacy beliefs about switching to IQOS and higher intentions to use IQOS than non-smokers. Among smokers, health warnings increased perceived credibility ( $p<0.001$ ) and effectiveness ( $p<0.05$ ), but claims did not affect outcomes examined. Among non-smokers, warnings and claims increased perceived credibility, and warnings increased perceived effectiveness ( $p<0.003$ ). The reduced exposure claim increased non-smokers' intentions to use IQOS ( $b=0.40$ , 95% CI 0.07 to 0.73).

**Conclusions** Among young adult smokers, health warnings increased perceived effectiveness at discouraging IQOS use and perceived credibility. Among non-smokers, warnings and claims increased perceived credibility and warnings increased perceived effectiveness, but the Food and Drug Administration-authorized reduced exposure claim increased intentions to use IQOS. Research is warranted to understand how the content of modified risk claims and health warnings for IQOS affects IQOS use in this population.

## INTRODUCTION

Cigarette companies are marketing heated tobacco products,<sup>1</sup> including Marlboro IQOS. Philip Morris International (PMI), maker of IQOS, has conducted clinical studies indicating IQOS' harmful exposures may be lower than cigarettes.<sup>2</sup> IQOS is available internationally and gaining popularity in some countries.<sup>1 3–5</sup> IQOS marketing emphasising novel technology and making comparisons with cigarettes is contributing to growing use.<sup>1 3–5</sup>

The Food and Drug Administration (FDA) conducts premarket review of new tobacco products before they can be marketed by evaluating risks

and benefits to tobacco users and non-users.<sup>6</sup> In 2019, FDA issued initial IQOS marketing authorisation<sup>7</sup> and in 2020 authorised IQOS 3.0 marketing.<sup>8</sup> With these authorisations IQOS sales are expanding and, although research in the USA remains limited, evidence suggests IQOS awareness is highest among younger adults<sup>9 10</sup> and uptake resembles e-cigarettes shortly after their introduction.<sup>11</sup>

In 2016, PMI also submitted a modified risk tobacco product (MRTP) application to FDA to advertise IQOS with modified risk claims.<sup>2</sup> MRTP applications are also reviewed based on their potential population impact, including among tobacco users and non-users. In 2020, FDA authorised IQOS marketing with a reduced exposure claim (ie, less exposure to harmful chemicals than cigarettes), but denied use of reduced risk and harm claims (ie, lower risks of health harm than cigarettes).<sup>2</sup> IQOS packaging and advertising are also required to display a warning communicating nicotine addiction risks and a Surgeon General's cigarette warning.<sup>2</sup>

Researchers criticised PMI's MRTP application,<sup>12 13</sup> including that consumers are unlikely to understand claims' language about 'switching completely' from cigarettes to IQOS<sup>13</sup> and claims will appeal to young, non-tobacco users.<sup>12 14</sup> Yet there is limited research on how modified risk claims and health warnings—risk messages competing for attention and information processing—affect consumers. Such 'mixed' messages could affect perceived credibility, or the degree to which information is believable and trustworthy, and perceived effectiveness of the information for influencing target behaviours.<sup>12 15 16</sup> Furthermore, the FDA-authorized modified exposure claim is specific to smokers who 'switch completely' from cigarettes to IQOS, which may produce inaccurate risk perceptions and may affect non-smokers.<sup>13 17 18</sup> To our knowledge, there is no research on how modified risk claims affect efficacy beliefs (eg, perceived benefits) about switching.<sup>19</sup> Finally, evidence is inconsistent on how modified risk claims affect IQOS use intentions,<sup>17 18 20</sup> with little research on how claims and health warnings may interact.

We examined the effects of IQOS modified risk claims and health warnings among young adult cigarette smokers and non-smokers, a population vulnerable to modified risk claims<sup>14 21</sup> and IQOS marketing.<sup>14 22–24</sup> We tested study warnings intended to address criticisms of PMI's MRTP application,<sup>12 13</sup> including adding language specific



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to smokers and non-smokers. We examined smoking status differences<sup>25–26</sup> because understanding how IQOS marketing and regulatory measures affect tobacco users and non-users is essential to FDA tobacco regulation, which is formed based on evidence of regulations' population-level impact, including tobacco users and non-users.<sup>27</sup>

## METHODS

### Procedures

We recruited US young adult cigarette smokers and non-smokers in 2020 for an online survey through Qualtrics.<sup>28–32</sup> We enrolled approximately equal numbers of smokers (smoked  $\geq 100$  lifetime cigarettes and now smoked every day or some days)<sup>33</sup> and non-smokers (smoked  $< 100$  lifetime cigarettes or did not smoke every day or some days). After questions about demographics and tobacco use, we randomised participants in a 4 (modified risk claim: no claim, reduced risk, reduced harm, reduced exposure) by 3 (warning: no warning, manufacturer warning, study warning) between-subjects design. Participants viewed a single US IQOS advertisement that appeared in 2019<sup>34</sup> for as long as they wished, then answered outcome questions.

We used the reduced risk, reduced harm and reduced exposure claims from PMI's MRTP application.<sup>35</sup> PMI's MRTP application paired specific warnings to each claim. We used the warnings corresponding to each modified risk claim in our design, and we developed corresponding study warnings communicating the risks of IQOS<sup>12–13–36</sup> with statements targeted to smokers and non-smokers. We presented stimuli in full-screen resolution to maximise readability. The average time of stimuli exposure was 15.4 s (SD 26.1). Online supplemental table 1 displays claims and warnings tested; stimuli are available from the corresponding author.

### Measures

Pre-exposure, we measured demographics, cigarettes smoked per day among smokers, past 30-day use of e-cigarettes and other tobacco,<sup>33</sup> and awareness of IQOS (yes/no). Postexposure, we measured perceived credibility of the 'health or risk message' of the ad and perceived effectiveness of the 'health or risk message' for discouraging IQOS use with a single item each (1=strongly disagree, 5=strongly agree).<sup>15</sup> We assessed perceived harm of IQOS relative to cigarettes and e-cigarettes with a single item each (1=much less harmful, 5=much more harmful) based on FDA's evaluation of MRTP claims for their impact on consumers' perceptions relative to other tobacco products.<sup>12–37–38</sup> We measured perceived benefits of switching (1=not at all likely, 7=very likely) and confidence (1=not at all confident, 7=very confident) that smokers can switch completely to IQOS using a single item each.<sup>19</sup> We measured IQOS use intentions with three items capturing curiosity, interest and likelihood of trying IQOS (1=not at all, 7=very).<sup>25</sup> We averaged these to create a score with higher values indicating stronger intentions (Cronbach's  $\alpha=0.96$ ).

### Statistical analysis

We used SAS V.9.4 for analyses. We stratified analyses by smoking status based on bivariate differences. We used general linear models to analyse the effects of modified risk claims, warnings and their interaction on outcomes with covariates that differed by smoking status (age, sex, education, other tobacco and e-cigarette use, IQOS awareness). For non-significant interactions, we removed them and report the main effects. For significant interactions, we reran the model with a categorical variable reflecting

all experimental conditions to aid interpretation. For significant interactions, we report unstandardised coefficients (b), 95% CI and pair-wise least squares means comparisons with Tukey-Kramer adjustment.

## RESULTS

The sample included 1328 participants. Online supplemental table 2 displays sample characteristics and differences between smokers and non-smokers.

Online supplemental table 3 displays the results for perceived credibility and effectiveness among smokers. There was a significant health warning main effect for perceived credibility ( $F_{2,651}=4.2$ ,  $p=0.015$ ) and perceived effectiveness ( $F_{2,651}=7.1$ ,  $p<0.001$ ). Among smokers, ads with the study warning produced higher perceived credibility versus ads with no warning and ads with the PMI warning and the study warning produced higher perceived effectiveness than ads with no warnings. There were no significant interactions between health warnings and claims on these outcomes among smokers.

Table 1 shows the results for perceived credibility and effectiveness among non-smokers. There was a significant warning by claim interaction for perceived credibility ( $F_{6,675}=2.55$ ,  $p=0.019$ ). Coefficients are shown in table 1 and pair-wise means comparisons are in online supplemental figure 1. Among non-smokers, ads with the reduced harm claim and the PMI warning produced higher perceived credibility versus ads with no claim and no warning. Compared with non-smokers who viewed ads with the reduced harm claim and no warning, nearly all other conditions had significantly greater ( $p<0.05$ ) perceived credibility (online supplemental figure 1). The reduced harm claim and no warning condition is the only condition that did not differ significantly from the no claim and no warning condition. Among non-smokers, there was a significant health warning main effect for perceived effectiveness ( $F_{2,675}=6.0$ ,  $p=0.003$ ; table 1), where ads with the PMI warning and study warning produced higher perceived effectiveness versus ads with no warnings.

Among smokers, there were no significant health warnings or claim effects on perceived harm relative to cigarettes or e-cigarettes (online supplemental table 3). Among non-smokers (table 1), the claims' main effect on perceived harm relative to cigarettes was not significant ( $F_{3,675}=1.66$ ,  $p=0.173$ ), but ads with the reduced harm claim produced greater perceived harms of IQOS relative to cigarettes versus ads with no claims (table 1).

There were no significant effects of the warnings or claims on efficacy beliefs (efficacy of switching, confidence in switching) among smokers (online supplemental table 3) or non-smokers (table 1). Among smokers, there were no significant effects of the warnings or claims on IQOS use intentions (online supplemental table 3). Among non-smokers (table 1), the claim's main effect was not significant ( $F_{3,675}=2.53$ ,  $p=0.056$ ), but non-smokers who viewed ads with the reduced exposure claim reported stronger IQOS use intentions versus ads with no claims ( $b=0.40$ , 95% CI 0.07 to 0.73).

## DISCUSSION

We tested the effects of IQOS warnings and modified risk claims among young adult cigarette smokers and non-smokers. Smokers perceived ads with the study warning to be more credible and the PMI and study warnings to be more effective at discouraging IQOS use regardless of presence of modified risk claims. There were no significant interactions between warnings and claims among smokers. Among non-smokers, there was a significant warning by claim interaction for perceived credibility. For all

**Table 1** General linear model results for non-smokers (n=676)

	Perceived credibility b (CI)	Perceived effectiveness b (CI)	Perceived harm vs cigarettes b (CI)	Perceived harm vs e-cigarettes b (CI)	Efficacy of switching b (CI)	Confidence in switching b (CI)	IQOS use intentions b (CI)
<b>Health warning</b>							
No warning		Ref	Ref	Ref	Ref	Ref	Ref
PMI warning		<b>0.32</b> (0.11 to 0.52)	−0.08 (−0.25 to 0.10)	0.02 (−0.14 to 0.18)	−0.08 (−0.42 to 0.26)	−0.18 (−0.16 to 0.52)	−0.16 (−0.44 to 0.13)
Study warning		<b>0.33</b> (0.12 to 0.54)	−0.04 (−0.21 to 0.14)	0.11 (−0.05 to 0.27)	−0.02 (−0.36 to 0.33)	0.15 (−0.19 to 0.50)	−0.04 (−0.32 to 0.25)
<b>Modified risk claim</b>							
No claim		Ref	Ref	Ref	Ref	Ref	Ref
Reduced risk claim		0.18 (−0.06 to 0.43)	0.11 (−0.10 to 0.32)	−0.03 (−0.21 to 0.16)	−0.13 (−0.54 to 0.27)	−0.20 (−0.61 to 0.20)	0.02 (−0.31 to 0.36)
Reduced harm claim		0.14 (−0.10 to 0.38)	<b>0.21</b> (0.00 to 0.41)	0.12 (−0.06 to 0.30)	0.07 (−0.33 to 0.46)	−0.06 (−0.45 to 0.34)	0.13 (−0.20 to 0.46)
Reduced exposure claim		0.10 (−0.15 to 0.34)	0.20 (−0.01 to 0.40)	0.18 (−0.01 to 0.36)	0.34 (−0.07 to 0.74)	0.20 (−0.20 to 0.60)	<b>0.40</b> (0.07 to 0.73)
Health warning × modified risk claim		n/a	n/a	n/a	n/a	n/a	n/a
No claim and no warning	Ref						
No claim and PMI warning	<b>0.69</b> (0.25 to 1.13)						
No claim and study warning	<b>0.68</b> (0.23 to 1.13)						
Reduced risk claim and no warning	<b>0.58</b> (0.13 to 1.03)						
Reduced risk claim and PMI warning	<b>0.71</b> (0.27 to 1.15)						
Reduced risk claim and study warning	<b>0.51</b> (0.07 to 0.95)						
Reduced harm claim and no warning	−0.03 (−0.47 to 0.41)						
Reduced harm claim and PMI warning	<b>0.75</b> (0.31 to 1.19)						
Reduced harm claim and study warning	<b>0.53</b> (0.10 to 0.97)						
Reduced exposure claim and no warning	<b>0.50</b> (0.05 to 0.94)						
Reduced exposure claim and PMI warning	<b>0.61</b> (0.17 to 1.04)						
Reduced exposure claim and study warning	<b>0.64</b> (0.20 to 1.08)						

The general linear model included demographic and tobacco-related variables that differed significantly between cigarette smokers and non-smokers as covariates, including age, sex, education, other tobacco use, electronic cigarette use and awareness of IQOS. For perceived credibility there was a statistically significant warning × claim interaction, so we reran this model with a categorical variable reflecting all of the warning × claim conditions in this interaction. For all other outcomes the warning × claim interaction was not significant, so we removed it from the models.

Bolded estimates are statistically significant at  $p < 0.05$ .

n/a, not applicable; PMI, Philip Morris International; Ref, reference.

conditions except the reduced harm claim with no warning, non-smokers viewed ads with health warnings and claims to be more credible than ads without warnings or claims. Among non-smokers, all of the warnings tested increased perceived effectiveness, PMI's reduced harm claim increased perceived harm of IQOS relative to cigarettes, and PMI's reduced exposure claim increased IQOS use intentions relative to ads with no claims.

Research indicates young adults are likely to attend to IQOS branding over health warnings<sup>20</sup> and misunderstand 'switching completely' language in modified risk claims.<sup>17</sup> In our study, the text-only claims and warnings may have been insufficient to draw attention from branding, may not have been potent enough (eg, no images) to affect outcomes such as perceived harm, and moderate claim effects may be due to misunderstanding of

'switching completely'. Studies using measures that objectively capture processing of warnings and modified risk claims (eg, eye tracking, physiological measures),<sup>39</sup> including testing warning and claim variations, can build from these results to advance understanding of how young smokers and non-smokers engage with and process such messaging.

Study strengths include examining IQOS warnings and modified risk claims in an at-risk population, rigorous experimental design and policy-relevant outcomes. The results should be interpreted in light of study limitations, including the convenience sample and single-item measures for most outcomes. The warnings and claims tested included complex text displayed during a single, brief exposure, and some elements (eg, amount of text) varied by conditions. This may affect readability, processing and



observed effects. It will be important to examine warnings and claims variations and assess effects prospectively. We focused on intentions to use IQOS as an outcome given the limited availability in the USA currently. In the future it will be important to examine other outcomes, such as smokers' intentions to switch completely from cigarettes to IQOS.

We found that among young adult smokers health warnings increased perceived effectiveness at discouraging IQOS use and perceived credibility. Among non-smokers, nearly all warnings and claims increased perceived credibility, warnings increased perceived effectiveness, and the FDA-authorized reduced exposure claim increased intentions to use IQOS. Studying how young adults engage with and respond to health warnings and modified risk claims variations is an important future direction. Now that PMI is authorized to advertise IQOS with a reduced exposure claim, it is also important to monitor how this claim affects young adult non-smokers' IQOS use to guide future research and regulatory actions.

### What this paper adds

- Heated tobacco products (HTPs), including Marlboro IQOS, are increasingly available globally, and in the USA IQOS was recently authorized to be advertised with modified risk claims.
- This study provides experimental data demonstrating the effects of modified risk claims and health warnings for IQOS advertisements among US young adult cigarette smokers and non-smokers.
- Overall, some health warnings increased perceived credibility and effectiveness of health messages, but IQOS' reduced exposure claim increased IQOS use intentions in non-smokers.
- Our findings highlight the need for continued research on the effects of modified risk claims and health warnings on HTPs such as IQOS among young adults and the need for surveillance of the impact of manufacturers' claims about reduced risks in the population.

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