SSM - Population Health 18 (2022) 101123

Contents lists available at ScienceDirect

SSM - Population Health

journal homepage: www.elsevier.com/locate/ssmph

Risk perception of *IQOS*™ and cigarettes: Temporal and cross-country comparisons

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ARTICLE INFO

Keywords:
Public health
Epidemiology
Harm reduction
Risk perception
Tobacco
Heated tobacco product

ABSTRACT

Background: Risk perception (RP) is central to smokers' decision to switch to smoke-free tobacco and nicotine products (TNP). This study assessed temporal trends in the health RP of a novel heated tobacco product, *IQOS*™, relative to cigarettes, among current *IQOS*™ users.

Methods: The analyses included repeated cross-sectional data from online surveys in Germany (2018–19), Italy (2018–19), and Japan (2016–17, 2017–18, and 2018–19) among a random sample of current adult *IQOS*™ users from local registers of *IQOS*™ users. The health RPs of cigarettes and *IQOS*™ were assessed using the ABOUT™–Perceived Risk instrument, and their difference was described as the relative RP of *IQOS*™ to cigarettes ($RP_{Cig:}IQOS^{TM}$).

Results: After adjustment for covariates, the relative $RP_{Cig:}IQOS^{TM}$ was higher in 2018 than in 2019 (0.93; standard error, 0.33; $P = 0.005$). This was driven by an increase in the RP of *IQOS*™ over time in Italy (2018: 42.6 [95% CI, 41.6–43.5]; 2019: 44.4 [43.4–45.4]) and Japan (2017: 44.0 [43.1–44.9); 2018: 45.9 [45.2–46.7]; 2019: 48.6 [47.9–49.4]), while the RP of cigarettes remained stable.

Conclusions: The relative RP of *IQOS*™ decreased over time, driven by an increase in the RP of *IQOS*™, in agreement with epidemiological studies indicating a temporal reduction in the relative RP of smoke-free TNPs. Continued surveillance of the RP of novel TNPs is warranted to inform effective TNP risk communication and ensure that adults smokers who would otherwise continue to smoke understand the relative risks of novel TNPs.

1. Introduction

It is widely acknowledged that minimizing tobacco-related harm at the population level depends not only on the degree of risk reduction of smoke-free tobacco and nicotine products (**TNP**), such as heated tobacco products and e-cigarettes, but also on their adoption by adults who would otherwise continue to smoke (Abrams et al., 2018; Beaglehole et al., 2019; Smith et al., 2016). A multitude of individual and environmental factors govern the transition from smoking cigarettes to using smoke-free TNPs (Abrams et al., 2018; Beaglehole et al., 2019). One of the key factors that may promote this transition among adult smokers is relative **risk perception (RP).** RP is a complex concept that incorporates perceived risk of a TNP to one's health or to others (Afolalu et al., 2021). RP has often been explored in the literature from a clinical standpoint or from an epidemiological perspective as disease risk, yet consumers' RP have rarely been investigated, particularly in relation to novel TNPs such as heated tobacco products (Afolalu et al., 2021). Qualitative evidence (Britton et al., 2016; East et al., 2021; Evans et al., 2020; Tompkins et al., 2021) and observational studies have demonstrated that the RP of smoke-free TNPs influences current adult smokers' decision to switch to smoke-free TNPs (Cox et al., 2018; Nyman et al., 2019; Yang et al., 2019). Similarly, reviews have concluded that RP could act as a key driver in motivating smokers to quit (Czoli et al., 2017; Erku et al., 2021). Concurrently, epidemiological studies have found that perceiving smoke-free TNPs to be as harmful as cigarettes may either lead some current adult smokers to not try smoke-free TNPs or lead former smokers to relapse to smoking (Camacho et al., 2021). In the context of population harm reduction, this suggests a potential barrier to

Abbreviations: RP, Risk Perception; TNP, Tobacco and Nicotine Product; THR, Tobacco Harm Reduction; LA, Legal Age.

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https://doi.org/10.1016/j.ssmph.2022.101123
Received 21 February 2022; Received in revised form 28 April 2022; Accepted 8 May 2022
Available online 17 May 2022

switching from cigarettes to smoke-free alternatives among existing smokers. Indeed, a growing body of evidence indicates that the correct designation of risk apportioned to smoke-free TNP use vs. cigarette smoking is associated with the greater intention to use and the actual use of the respective TNPs (Gravely et al., 2020; Sutanto et al., 2020). Despite efforts to promote harm reduction strategies, studies across several countries have shown that smokers mistakenly perceive smoke-free TNPs to be as harmful as cigarettes (Abrams et al., 2018; Denlinger-Apte et al., 2021; Fong et al., 2019; Kozlowski & Sweanor, 2018; Wackowski et al., 2019). A recent analysis of the US Health Information National Trends Survey revealed that over half of US adults perceive e-cigarettes to as harmful or more harmful than cigarettes (National Cancer Institute., 2017, 2019, 2020). A further study reported that current adult smokers who have never used e-cigarettes were less likely to perceive e-cigarette use as less harmful than smoking and more likely to be uncertain about their relative harm than former or regular e-cigarette users (Weaver et al., 2020).

Understanding how RP influences smokers' decision to switch to smoke-free TNPs is critical to ensuring that current adult smokers who would otherwise continue to smoke are presented with viable alternatives while ensuring that non-users will not start using the products and existing TNP users who would otherwise stop using such products will not be deterred from quitting all TNPs (East et al., 2021). Misperceptions about the relative RP for smoke-free TNPs have been increasing in recent years. Observational studies indicate that the proportion of current adult smokers who believe smoke-free TNPs are less harmful than cigarettes has declined over the years, while the proportion of individuals who believe they are as harmful or more harmful than cigarettes has increased (Borland et al., 2011; Nyman et al., 2019; Weaver et al., 2020). Considering that RP is a key factor that governs the transition from cigarettes to smoke-free TNPs amongst adult users (Evans et al., 2020; Fong et al., 2019; Weaver et al., 2020; Yang et al., 2019) and is thus central to tobacco harm reduction (THR) strategies, it is critical to monitor the changes in RP over time and explore differences amongst countries in order to inform public health policies.

The present study aimed to assess the temporal trends in the RP of a novel heated tobacco product, *IQOS*^{TM}, relative to the RP of cigarettes, among current adult *IQOS*^{TM} users across different countries. The secondary objective was to examine the association between *IQOS*^{TM} use behaviors and relative RP.

2. Methods

2.1. Study design and participants

The analyses included data from repeated cross-sectional online surveys in Germany (2018 and 2019), Italy (2018 and 2019), and Japan (Years 2016–17, 2017–18, and 2018–19). Details of cross-sectional survey waves are shown in Fig. 1. The overall study design and detailed description of the RP instrument have been described previously (Afolalu et al., 2021; Cano et al., 2018).

Upon purchasing an *IQOS*^{TM} device, *IQOS*^{TM} users were invited to register in a country-specific PMI *IQOS*^{TM} owners database. To ensure that a representative sample of *IQOS*^{TM} users was selected, the age and sex distribution of the PMI *IQOS*^{TM} owners database of the respective country was taken into consideration in each wave of data collection. Subsequently, a random sample of *IQOS*^{TM} users was selected and invited to participate in the online surveys.

Current (i.e., past 30-day, daily, or non-daily), legal age (LA) users of *IQOS*^{TM} who had used >100 *HEETS*^{TM}/*HeatSticks*^{TM} in their lifetime and were residents and fluent in the language of the country of their participation were included in the study. LA users were defined using country-specific age cutoffs: Germany ≥18, Italy ≥18, and Japan ≥20 years, respectively.

Potential participants were invited by email to participate in the study. Participants who accepted the invitation were presented a consent form, which included information about the aim of the study, duration of participation, voluntary nature of participation, confidentiality, use of data, and data privacy. All individuals included in the survey data provided informed consent prior to participation and were compensated for taking part in the research. The study was conducted in accordance with the Declaration of Helsinki and was consistent with Good Epidemiological Practice (German Society for Epidemiology., 2008; International Epidemiological Association., 2007).

2.2. Sample size and sampling frequency

The details on sample size calculations for Japan have been described elsewhere (Afolalu et al., 2021). Briefly, an annual sample size of 2000 *IQOS*^{TM} users was deemed sufficient to estimate a 50% prevalence of combined *IQOS*^{TM} and TNP use with a 95% CI and a precision of ±2.19% (Afolalu et al., 2021; Lwanga et al., 1991). In Germany and Italy, the prevalence of fully converted exclusive *IQOS*^{TM} users was estimated to be 63.4% from the results of an earlier survey (Afolalu et al., 2021). Thus, a sample size of 1384 *IQOS*^{TM} users per year was required for Germany and Italy, respectively, to estimate *IQOS*^{TM} use prevalence with a 95% CI and ±2.5% precision. Each annual survey consisted of four equally spaced waves.

2.3. Questionnaires

Eligible participants completed questions on demographics, the *IQOS*^{TM} Users' Questionnaire (*IQOS*^{TM}-UQ), which included questions about current *IQOS*^{TM} use, current and former use of other TNPs (Afolalu et al., 2021).

2.4. RP measures

The perceived risk of cigarette smoking and *IQOS*^{TM} use were assessed with the validated and publicly available open-source ***ABOUT™–Perceived Risk Instrument, General Version***. The instrument consists of an 18-item scale that measures the perceived risk of product use to the user's physical health, starting with minor immediate manifestations of health risk, such as poor gum health, to more chronic conditions, such as lung cancer. Each item on the scale was rated on a 5-point Likert-like scale ranging from 1 (no risk) to 5 (very high risk) (Cano et al., 2018). From the scores of the 18 rated items, an overall **RP score** ranging from 0 (no risk) to 100 (very high risk) was calculated for cigarette smoking and *IQOS*^{TM} use for each participant (Cano et al., 2018). The difference in RP scores between cigarette smoking and *IQOS*^{TM} use was calculated to derive a measure of the relative RP of *IQOS*^{TM} (relative $RP_{Cig:}IQOS^{TM}$ = $RP_{cigarette}$ – $RPIQOS^{TM}$) for each

	YEAR																							
	2016	2017					2018							2019										2020
	MONTH																							
Country	Dec	Mar	May	Jul	Nov	Dec	Feb	Mar	Apr	Jul	Aug	Sep	Oct	Jan	Feb	Apr	May	Jun	Jul	Sep	Oct	Dec	Jan	
Japan	17-W1	17-W2	17-W3	17-W4	18-W5		18-W6		18-W7	18-W8				19-W9		19-W10					19-W11	19-W12		
Italy								18-W1		18-W2		18-W3		18-W4		19-W5		19-W6	19-W7				19-W8	
Germany								18-W1		18-W2		18-W3		18-W4		19-W5		19-W6	19-W7				19-W8	

Fig. 1. Structure of survey waves in each country by year.
Abbreviations: W, survey wave; Y, study year.

participant. The ABOUT™ Risk instrument and its validation has been extensively detailed elsewhere (Cano et al., 2018; Chrea et al., 2018, p. 7).

2.5. Statistical analysis

Univariate analyses were conducted to assess the association between absolute or relative $RP_{Cig:}IQOS^{TM}$. and the following independent variables: sex (male/female), age groups (18–24, 24–44, and ≥45 years), $IQOS^{TM}$ use behavior (predominant $IQOS^{TM}$/combined cigarette–$IQOS^{TM}$ use), intensity of use (number of *HEETS/HeatSticks* per day, expressed as a categorical variable), country (Germany, Italy, and Japan) and country-specific survey year (2017 and/or 2018, 2019). Overall, the participants were categorized as predominant or combined users of $IQOS^{TM}$ based on their current use of different categories of TNPs and the quantity of TNP use. Predominant $IQOS^{TM}$ use was defined as >95% $IQOS^{TM}$ use for a combined cigarette and $IQOS^{TM}$ user. Combined cigarette–$IQOS^{TM}$ use was defined as $IQOS^{TM}$ use alongside cigarette smoking, at >30% and <70% of the total cigarette–$IQOS^{TM}$ use. $IQOS^{TM}$ users who reported ≤30% combined cigarette–$IQOS^{TM}$ use were not included in the analysis, as they were deemed to be predominant cigarette smokers.

The analyses were performed using the multiple regression standard procedure in SAS 9.4 (SAS Institute). The models were adjusted for sex, age group, and $IQOS^{TM}$ use pattern and intensity. The regression model included data from all countries and from years 2018 and 2019. Additional sensitivity analysis including an interaction term between country and year was performed. Given the varying number of survey years, separate regression models were also computed for 2018 and 2019 for Germany, 2018 and 2019 for Italy, and 2017, 2018, and 2019 for Japan.

3. Results

3.1. Sample characteristics

This study included 2536, 2457, and 5044 participants from Germany, Italy, and Japan, respectively (see Table 1 for country- and survey year-wise sample characteristics). Across the surveys years, Germany and Italy had a balanced proportion of male (56.2% and 50.7%, respectively) versus female (43.1% and 49.3%, respectively) participants, while Japan had a higher proportion of men (80.7%) than women (19.3%). In all three countries, the proportion of participants in the age group 25–44 years (Germany, 50.7%; Italy, 52.8%; and Japan, 64.4%) was higher than that in the LA–24 years group (5.9%, 15.7%, and 5.7%, respectively) and ≥45 years group (43.4%, 31.5%, and 29.9%). Across the survey years, Italy (52.8%) and Japan (77.8%) had a higher proportion of predominant $IQOS^{TM}$ users than Germany (36.6%), where combined cigarette–$IQOS^{TM}$ use was more prevalent. In Japan, daily use of ≥19 *HEETS/HeatSticks* was higher (43.6%) than daily use of ≤6 *HEETS/HeatSticks* (21.7%). In Germany and Italy, daily use of 7–12 *HEETS/HeatSticks* (15.2% and 30.4%, respectively) was higher than daily use of ≤6 *HEETS/HeatSticks* (8.2% and 17.4%, respectively).

3.2. Risk perception: univariate analyses

The RP of cigarettes was higher than that of $IQOS^{TM}$ across all countries and years. The mean values (and 95% CIs) of the absolute and relative $RP_{Cig:}IQOS^{TM}$ are shown in Table 1 and the Supplementary Material. The RP of cigarettes remained stable over time across all countries, while that of $IQOS^{TM}$ declined in Italy and Japan. The relative $RP_{Cig:}IQOS^{TM}$ remained stable in Germany (2018, 16.2 [15.5–17.0]; 2019, 16.5 [15.7–17.2]) and Italy (2018, 21.0 [20.0–21.9]; 2019, 19.6 [18.6–20.5]) but declined in Japan (2017, 19.5 [18.6–20.5]; 2018, 15.9 [15.1–16.6]; 2019, 14.5 [13.8–15.2]).

Univariate analyses showed that the relative $RP_{Cig:}IQOS^{TM}$ was, on average, higher in Italy (20.3 [19.6–20.9]) than in Germany (16.4 [15.8–16.9]) and Japan (16.4 [15.9–16.8]). This indicates that, across the survey years, relative to $IQOS^{TM}$ users in Germany or Japan, $IQOS^{TM}$ users in Italy perceived the risk of cigarettes to be higher than that of $IQOS^{TM}$. The relative $RP_{Cig:}IQOS^{TM}$ was higher among women (18.2 [17.7–18.7) than men (16.9 [16.5–17.3]) and among predominant $IQOS^{TM}$ users (18.8 [18.4–19.3]) than combined cigarette–$IQOS^{TM}$ users (14.9 [14.5–15.4]). The relative $RP_{Cig:}IQOS^{TM}$ was lower in the LA–24 years group (15.7 [14.5–16.9]) than in the 25–44 years (17.2 [16.8–17.6]) and 45+ years groups (17.9 [17.4–18.4]), and it increased with the number of *HEETS/HeatSticks* used (Table 1).

3.3. Risk perception: differences across countries and years

Tables 2 and 3 summarize the multiple regression findings on the association between countries, years, and relative $RP_{Cig:}IQOS^{TM}$ after adjustment for sex, age group, $IQOS^{TM}$ use pattern and intensity. With all other variables (i.e., age, sex, $IQOS^{TM}$ use pattern and intensity) remaining constant, the relative $RP_{Cig:}IQOS^{TM}$ was found to be smaller in Germany and Japan than in Italy; it declined over time and was on average 0.93 points higher (SE 0.33; $P = 0.005$) in 2018 than in 2019 (Table 2).

Additional sensitivity analysis including an interaction term for country–year demonstrated a significant interaction between country and year (Supplementary Table S3).

Considering this significant interaction and given the availability of an additional survey year in Japan, separate regression models were run for each country. Overall, the relative $RP_{Cig:}IQOS^{TM}$ showed a smaller decline in Germany and Italy between 2018 and 2019, respectively (Table 3). In Japan, the relative $RP_{Cig:}IQOS^{TM}$ was greater in 2017 than 2018 and in 2018 than 2019, and decline in relative $RP_{Cig:}IQOS^{TM}$ was larger between 2017 and 2018 than between 2018 and 2019 (Table 3).

3.4. Risk perception: association with $IQOS^{TM}$ use behavior

Across the countries and years, the relative $RP_{Cig:}IQOS^{TM}$ was higher in predominant $IQOS^{TM}$ users than combined cigarette–$IQOS^{TM}$ users when all other variables remained constant (Table 3). This indicated that the difference in RP between cigarettes and $IQOS^{TM}$ was larger among predominant $IQOS^{TM}$ users than combined cigarette–$IQOS^{TM}$ users. This difference was mainly driven by the lower RP of $IQOS^{TM}$ among predominant $IQOS^{TM}$ users.

Relative RP and $IQOS^{TM}$ use intensity showed a positive linear association, with lower *HEETS/HeatStick* consumption being associated with lower relative $RP_{Cig:}IQOS^{TM}$ (Table 3).

4. Discussion

In 2017, the Food and Drug Administration (FDA) introduced a new national nicotine management strategy with the objective of reducing the population health burden of tobacco (Abrams et al., 2018). The new strategy was based on the concept of continuum of harm which acknowledges the existence of a continuum of risk among TNPs, with combusted cigarettes representing the most harmful TNPs. The framework emphasizes the importance of transitioning smokers and TNP users down the risk continuum as a critical step towards improving public health (Zeller & Hatsukami, 2009). Accordingly, in July 2020, the FDA authorized the sale of $IQOS^{TM}$ as a modified-risk tobacco product. The FDA stated that "the issuance of exposure modifications orders is expected to benefit the health of the population as a whole" and that "the Agency determined … that because the $IQOS^{TM}$ Tobacco Heating System heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke" (Food Drug Administration., 2020). Yet, consumers' RP of novel heated tobacco products such as $IQOS^{TM}$ has not been widely investigated. To our knowledge the present study is one of the first studies to assess temporal trends in relative RP between cigarettes and a novel

Table 1
Relative risk perception scores (mean and 95% CI) between cigarettes and IQOS™ by study variable.

Country	Germany								Italy								Japan											
Year	Y1				Y2				Y1				Y2				Y1				Y2				Y3			
Category/Statistic	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*	*N*	*%*	*Mean*	*95% CI*
RP$_{Cigarette}$	–	–	58.5	(57.7, 59.3.)	–	–	58.9	(58.1, 59.7)	–	–	63.7	(63.0, 64.4)	–	–	64.3	(63.6, 65.0)	–	–	63.7	(62.9, 64.6)	–	–	62.1	(62.6, 64.1)	–	–	63.3	(62.6, 64.1)
RP*IQOS^{TM}*	–	–	41.9	(41.0, 42.8)	–	–	42.2	(41.3, 43)	–	–	42.6	(41.6, 43.5)	–	–	44.4	(43.4, 45.4)	–	–	44.0	(43.1, 44.9)	–	–	45.9	(45.2, 46.7)	–	–	48.6	(47.9, 49.4)
RP$_{Cigarettes}$-*IQOS^{TM}*	1274	50.2	16.2	(15.5, 17.0)	1262	49.8	16.5	(15.7, 17.2)	1217	49.5	21.0	(20.0, 21.9)	1240	50.5	19.6	(18.6, 20.5)	1366	13.6	19.5	(18.6, 20.5)	1840	36.5	15.9	(15.1, 16.6)	1838	36.4	14.5	(13.8, 15.2)
Sex																												
Male	717	56.3	16.7	(15.7, 17.7)	708	56.1	16.9	(15.8, 17.9)	543	44.6	20.9	(19.4, 22.3)	702	56.6	19.3	(18.0, 20.6)	1116	81.7	18.8	(17.8, 19.9)	1483	80.6	15.6	(14.8, 16.4)	1473	80.1	14.3	(13.5, 15.0)
Female	547	42.9	15.8	(14.7, 16.9)	547	43.3	16.0	(14.9, 17.2)	674	55.4	21.1	(19.8, 22.3)	538	43.4	19.9	(18.5, 21.3)	250	18.3	22.6	(20.4, 24.8)	357	19.4	17.0	(15.3, 18.7)	365	19.9	15.4	(13.8, 17.1)
Age Group																												
LA–24 years old	84	6.6	14.8	(10.7, 18.8)	65	5.2	18.2	(14.7, 21.6)	140	11.5	17.9	(15.0, 20.8)	246	19.8	16.8	(14.6, 19.0)	79	5.8	16.3	(15.5, 17.0)	112	6.1	11.9	(19.9, 22.9)	97	5.3	12.0	(20.1, 23.7)
25–44 years old	643	50.5	17.0	(15.9, 18.0)	643	51.0	15.9	(14.9, 17.0)	659	54.1	21.3	(20.0, 22.7)	638	51.5	19.3	(18.0, 20.7)	940	68.8	17.9	(15.0, 20.8)	1149	62.4	15.6	(14.6, 19.0)	1159	63.1	14.3	(15.5, 18.9)
≥45 years old	547	42.9	15.6	(14.6, 16.6)	554	43.9	16.9	(15.8, 18.1)	418	34.3	21.4	(19.9, 22.9)	356	28.7	21.9	(20.1, 23.7)	347	25.4	21.3	(20.0, 22.7)	579	31.5	17.2	(18.0, 20.7)	582	31.7	15.3	(19.4, 21.3)
Use Pattern																												
Predominant IQOS™	439	34.5	20.9	(19.7, 22.2)	488	38.7	20.3	(19.0, 21.5)	631	51.8	20.6	(22.3, 25.0)	631	50.9	23.7	(22.3, 25.0)	1297	94.9	20.5	(18.7, 22.3)	1035	56.3	20.7	(14.6, 16.5)	1430	77.8	16.5	(8.4, 15.5)
Combined cigarette–IQOS™	787	61.8	13.9	(13.0, 14.8)	755	59.8	14.1	(13.2, 15.0)	564	46.3	14.0	(16.6, 19.2)	564	45.5	17.9	(16.6, 19.2)	1115	81.6	11.9	(8.6, 15.1)	326	17.7	15.9	(16.0, 18.5)	401	21.8	13.5	(13.4, 15.2)
Use Intensity[a]																												
≤6	265	20.8	13.8	(12.2, 15.5)	229	18.1	12.9	(11.4, 14.4)	207	17.0	17.2	(14.8, 19.7)	272	21.9	17.0	(14.9, 19.0)	131	9.6	16.0	(13.2, 18.8)	154	8.4	13.5	(11.2, 15.8)	195	10.6	10.9	(8.7, 13.1)
7–12	367	28.8	15.2	(13.9, 16.5)	380	30.1	15.4	(14.1, 16.8)	385	31.6	20.5	(18.8, 22.2)	362	29.2	18.6	(16.9, 20.2)	334	24.5	18.6	(16.6, 20.5)	455	24.7	14.8	(13.3, 16.3)	482	26.2	14.5	(13.2, 15.9)
13–18	260	20.4	16.6	(15.1, 18.2)	249	19.7	17.1	(15.5, 18.8)	268	22.0	21.5	(19.7, 23.3)	263	21.2	20.8	(18.8, 22.8)	307	22.5	19.2	(17.3, 21.1)	423	23.0	15.6	(14.1, 17.1)	366	19.9	14.8	(13.2, 16.4)
≥19	382	30.0	18.6	(17.2, 20.1)	404	32.0	19.1	(17.7, 20.6)	357	29.3	23.2	(21.3, 25.0)	343	27.7	21.7	(19.7, 23.7)	594	43.5	21.0	(19.6, 22.5)	808	43.9	17.0	(15.9, 18.2)	795	43.3	15.2	(14.1, 16.3)

Abbreviations: RP, risk perception; LA, legal age to purchase tobacco product (18 years old in Germany, 18 years old in Italy, and 20 years old in Japan).
*Predominant *IQOS^{TM}* use was defined *IQOS^{TM}* use for >95% out of total TNP use. Combined cigarette–*IQOS^{TM}* use was defined as *IQOS^{TM}* use alongside cigarette smoking, at a proportion >30% and <70% of the total TNP use.
[a] *IQOS^{TM}* use intensity measured as number of *HEETS/HeatSticks* consumed per day.

Table 2
Regression coefficients for the regression model including all countries (Germany, Italy, and Japan) and years 2018 and 2019.

	All Countries		
Categories	β	SE	P value
Intercept	19.82	0.57	<.0001
Sex			
Male	−0.47	0.36	0.201
Female	Reference	–	–
Age Group			
LA–24 years old	−2.26	0.65	0.001
25–44 years old	−0.75	0.36	0.039
≥45 years old	Reference	–	–
Use Pattern			
Predominant *IQOS*^{TM} use	4.62	0.37	<.0001
Combined cigarettes-*IQOS*^{TM} use	Reference	–	–
Use Intensity[a]			
≤6	−3.77	0.54	<.0001
7–12	−1.69	0.43	<.0001
13–18	−1.18	0.45	0.009
≥19	Reference	–	–
Year			
2018	0.93	0.33	0.005
2019	Reference	–	–
Country			
Germany	−3.31	0.45	<.0001
Japan	−6.73	0.43	<.0001
Italy	Reference	–	–

Abbreviations: RP, risk perception; LA, legal age to purchase tobacco product (18 years old in Germany, 18 years old in Italy, and 20 years old in Japan).
*Predominant IQOSTM use was defined IQOSTM use for >95% out of total TNP use. Combined cigarette–IQOSTM use was defined as IQOSTM use alongside cigarette smoking, at a proportion >30% and <70% of the total TNP use.
[a] IQOS^{TM} use intensity measured as number of HEETS/HeatSticks consumed per day.

heated tobacco product, *IQOS*^{TM}, among current adult *IQOS*^{TM} users in Germany (2018–19), Italy (2018–19), and Japan (2016–19). Across all countries and years, *IQOS*^{TM} users perceived the risk associated with cigarette smoking as greater than the risk associated with *IQOS*^{TM} use. Importantly, while the RP of cigarettes remained stable over time, RP of *IQOS*^{TM} increased. This was reflected in the gradual decline in the relative RP of *IQOS*^{TM} over time even after adjustment for other TNP use patterns. This decline was more evident in Japan, where survey data were available for three years, and represents a key finding of the evolution of RP of a novel heated tobacco product over time.

Studies have shown that the RP of smoke-free TNPs relative to cigarettes is central to the successful implementation of THR strategies (Brose et al., 2015; Majeed et al., 2017; Morgan & Cappella, 2021). This is because relative RP is a key factor that influences current smokers' decision to switch to smoke-free products, thereby driving the substitution of cigarettes with TNPs with lower content of harmful or potentially harmful compounds (Cox et al., 2018; Czoli et al., 2017; Nyman et al., 2019; Yang et al., 2019). Conversely, any misperceived risk of smoke-free TNPs relative to cigarettes among current adult smokers may adversely affect smokers' intention to try or intention to use smoke-free TNPs or even promote relapse to cigarettes (Camacho et al., 2021; Majeed et al., 2017). Thus, in the context of public health, the present findings are critical, as they indicate that adult *IQOS*^{TM} users accurately perceive the difference in risk associated with cigarettes vs. a smoke-free alternative such as *IQOS*^{TM}.

Adding to the current body of evidence, our findings provide data on temporal changes in the RP of *IQOS*^{TM}, which appears to follow similar trends to other smoke-free TNPs, such as e-cigarettes, as illustrated in repeated cross-sectional studies (Nyman et al., 2019) and longitudinal cohorts (Brose et al., 2015). Using data from the Tobacco Products and Risk Perceptions Survey, an annual cross-sectional survey of a representative oversample of cigarette smokers, Nyman and colleagues found that, between 2017 and 2018, the percentage of US adults who perceived e-cigarettes to be less harmful than cigarettes decreased from 29.3% to 25.8%, while the proportion of this population who perceived e-cigarettes to be more harmful increased (Nyman et al., 2019). The aforementioned studies as well as others (Tan et al., 2017) have attributed the changes in RP to more negative media coverage as well as policy and regulatory changes driven by a rise in youth e-cigarette use. Cox and colleagues found that using only a Tobacco Products Directive's health warning negatively impacted smokers' willingness and intentions to use e-cigarettes, while messages conveying reduced harm were more effective in encouraging smokers to switch to smoke-free products (Cox et al., 2018). In the case of *IQOS*^{TM}, a combination of factors likely drove the sharp decline in its relative RP, as is particularly evident in Japan,

Table 3
Regression coefficients for regression models by country.

	Germany			Italy			Japan		
	β	SE	P value	β	SE	P value	β	SE	P value
Intercept	15.80	0.72	<.0001	20.27	1.05	<.0001	15.50	0.91	<.0001
Sex									
Male	0.56	0.54	0.296	−0.92	0.69	0.181	−1.99	0.58	0.001
Female	Reference	–	–	Reference	–	–	Reference	–	–
Age Group									
LA–24 years old	1.58	1.20	0.185	−3.43	1.08	0.002	−3.13	1.06	0.003
25–44 years old	−0.20	0.55	0.717	−1.07	0.77	0.165	−1.12	0.51	0.028
≥45 years old	Reference	–	–	Reference	–	–	Reference	–	–
Use Pattern[a]									
Predominant *IQOS*^{TM} use	6.24	0.56	<.0001	5.14	0.69	<.0001	2.95	0.57	<.0001
Combined cigarettes-*IQOS*^{TM} use	Reference	–	–	Reference	–	–	Reference	–	–
Use Intensity[b]									
≤6	−4.13	0.80	<.0001	−4.22	1.04	<.0001	−3.17	0.85	0.000
7–12	−2.89	0.68	<.0001	−1.98	0.89	0.027	−1.16	0.58	0.047
13–18	−2.07	0.75	0.006	−1.04	0.96	0.281	−1.15	0.60	0.056
≥19	Reference	–	–	Reference	–	–	Reference	–	–
Year									
2017	–	–	–	–	–	–	5.26	0.58	<.0001
2018	0.18	0.53	0.739	0.90	0.69	0.195	1.37	0.54	0.011
2019	Reference	–	–	Reference	–	–	Reference	–	–

Abbreviations: RP, risk perception; LA, legal age to purchase tobacco product (18 years old in Germany, 18 years old in Italy, and 20 years old in Japan).
[a] Predominant *IQOS*^{TM} use was defined *IQOS*^{TM} use for >95% out of total TNP use. Combined cigarette–*IQOS*^{TM} use was defined as *IQOS*^{TM} use alongside cigarette smoking, at a proportion >30% and <70% of the total TNP use.
[b] *IQOS*^{TM} use intensity measured as number of *HEETS/HeatSticks* consumed per day.

where the data were available closer to the local launch of *IQOS*^{TM} and where a greater decline was observed between years 1 and 2 of the survey. Our findings show that the reduction in relative RP was driven by a deterioration in the RP of *IQOS*^{TM}, a trend that is equally observed for other more established smoke-free TNPs such as e-cigarettes. Concerningly, in Japan, increase in RP of *IQOS*^{TM} was observed particularly among predominant *IQOS*^{TM} users, a finding that warrants further investigation. Future studies should consider conducting an ecological momentary analysis to understand how differences in regulatory environments and changes in policy or external communications may have influenced RP over time. Understanding differences in regulatory environment is critical because it influences communications and information available to consumers, which in turn could influence consumers' RP.

In addition to evaluating differences in regulatory environment, further analysis is required to examine the temporal changes in the different constructs of the RP tool used in the present study. As explained earlier, the RP scale consisted of an 18-item Perceived Health Risk scale ranging from minor illnesses and discomforts such as coughing to long-term diseases such as cancer. Addressing how each of RP of these elements have changed over time may help clarify our findings and elaborate how the perception of these risk elements have changed over time. Although such analysis was beyond the scope of the current analysis, future studies should attempt to examine this issue with emerging new survey data focusing where possible on one region. Qualitative studies will also be required to understand the changes in RP among *IQOS*^{TM} users. Finally, continuous surveillance of the RP of novel TNPs is warranted to ensure that adult users correctly understand the risk associated with different TNPs, particularly smoke-free TNPs such as *IQOS*^{TM}. This is because for THR strategies to be effective, accurate and non-misleading information must be made available to smokers to ensure adult smokers are able to make informed decisions about the risks and benefits of various TNPs to help facilitate their transition from cigarettes to smoke-free TNPs and prevent potential relapse into cigarettes (Svenson et al., 2021).

Interestingly, the present study found that the relative RP of *IQOS*^{TM} is greater among predominant adult *IQOS*^{TM} users than combined cigarette–*IQOS*^{TM} users. Similarly, a higher intensity of *IQOS*^{TM} use, as indicated by the number of *HEETS/HeatSticks* used per day, was associated with a greater relative RP. It could be hypothesized that predominant *IQOS*^{TM} users are driven to become exclusive *IQOS*^{TM} users because of their lower RP relative to cigarettes. Nonetheless, cross-sectional studies do not permit assessment of the direction of the association or establishment of a causal relationship. Consequently, it is not possible to determine whether smokers switched to *IQOS*^{TM} because they perceived it as having less risk or vice-versa. Thus, future randomized controlled trials or longitudinal studies should address the direction of this association and examine how TNP use behavior changes over time based on the RPs of different TNPs (Persoskie et al., 2019). An understanding of the potential causal association between RP and TNP use patterns would help better inform public health decisions.

One of the key strengths of this study is that we used the same instrument to assess temporal changes in the RP of cigarettes and *IQOS*^{TM} in all three countries. Such consistent methodology allows comparison both across survey years and regions. To our knowledge, this is the first study to provide such temporal and global comparisons. In general, a key limitation of tobacco RP studies is the lack of consistency across RP measures (Kaufman et al., 2020). Many studies assess RP using unconditional measures that do not specify the product used, level of exposure, or intensity or timeframe of use (Kaufman et al., 2020). Such inconsistencies might account for some of the discrepancies in tobacco research. In contrast, the present study used a validated measure of RP that has been shown to have good internal and external validity (Cano et al., 2018; Chrea et al., 2018, p. 7).

In terms of limitations, the online surveys reported here rely on self-reported measures, which are prone to social bias, among other biases. However, the large heterogeneous sample and sampling strategy of the present study are likely to have offset such bias. The participants were drawn from an *IQOS*^{TM} owners database, which, could be argued, may have produced a selective sample of participants. However, on average, over 80% of *IQOS*^{TM} users are registered in the *IQOS*^{TM} owners database, and the present analyses included a random sample drawn using country-specific quotas that represented sex, age, and, where appropriate, regional distributions. In contrast, studies that draw samples from more general TNP user populations may suffer from information bias, as the participants may be unfamiliar with novel TNPs and thus ascribe the RP of one TNP to another. Finally, to date, inconsistencies remain in the definition of relative RP — some studies use direct measures of relative RP, where participants are asked a single question about their relative RP of novel smoke-free products vs. cigarettes, while others use more indirect measures, where the RP of each TNP is measured by a separate question, and the relative RP is then calculated as a difference or proportion (Czoli et al., 2017). Further research is required to determine the value of the different methodologies.

In conclusion, the present study demonstrates that the RP of *IQOS*^{TM} is lower than that of cigarettes across the surveyed countries and years; however, the RP of *IQOS*^{TM} does appear to be declining over time. This decline follows the temporal changes observed for other smoke-free products such as e-cigarettes. Further research on the factors that influence the changes in RP over time across countries with varying public health policies and regulations would allow us to evaluate the impact of public health policies and external communications on RP. The latter, in turn, can impact the transition of current adult smokers from cigarettes to reduced-risk smoke-free TNPs. Such research will be critical, considering the recent need for more tailored and accurate relative risk communication of novel TNPs.

Funding

Philip Morris Products S.A. is the sole source of funding and sponsor of this research.

Ethical statement

All surveys were performed in accordance with ethical principles that have their origin in the Declaration of Helsinki. All surveys are consistent with Good Epidemiological Practice, and International Ethical Guidelines for Epidemiological Studies. Before the start of the surveys, a confirmation that approval is not required according to local laws has been obtained from the ethics committee of each market. The protocol for cross-sectional survey in Japan was approved by the Hakata Clinic Institutional Review Board in Fukuoka, Japan (Reference ID: J-186).

Credit statement

P.M., S.R., and S.A. conceptualized the research question. K.F. and N. M. managed and supervised the data collection. S.A., G.K., and B.Z. managed, conducted, and reviewed the data analysis. S.A., M.B., and N. M. wrote the manuscript. All authors read and approved the final manuscript.

Declaration of competing interest

All authors except M.B., G.K. and B.Z. are employees of Philip Morris International. G.K. and B.Z. are employees of ARGUS, a consulting company contracted by Philip Morris International. M.B. is employed by Bajec Senseworks consulting, a consulting company contracted by Philip Morris International.

Acknowledgement

The authors would like to acknowledge the role of Christelle Chrea and Emilie Clerc in developing and validating the ABOUT™–Perceived Risk instrument. The authors would like to acknowledge that the field-work for surveys was coordinated and run by Ipsos UK and Ipsos Japan.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ssmph.2022.101123.

References

Abrams, D. B., Glasser, A. M., Villanti, A. C., Pearson, J. L., Rose, S., & Niaura, R. S. (2018). Managing nicotine without smoke to save lives now: Evidence for harm minimization. *Preventive Medicine, 117*, 88–97.

Afolalu, E. F., Langer, P., Fischer, K., Roulet, S., & Magnani, P. (2021). Prevalence and patterns of tobacco and/or nicotine product use in Japan (2017) after the launch of a heated tobacco product (IQOS®): A cross-sectional study. *F1000Research, 10*, 504.

Beaglehole, R., Bates, C., Youdan, B., & Bonita, R. (2019). Nicotine without smoke: Fighting the tobacco epidemic with harm reduction. *The Lancet, 394*(10200), 718–720.

Borland, R., Cooper, J., McNeill, A., O'Connor, R., & Cummings, K. M. (2011). Trends in beliefs about the harmfulness and use of stop-smoking medications and smokeless tobacco products among cigarettes smokers: Findings from the ITC four-country survey. *Harm Reduction Journal, 8*(1), 1–11.

Britton, J., Arnott, D., McNeill, A., Hopkinson, N., & Physicians, T. A. G. o. t. R. C. o.. (2016). Nicotine without smoke—putting electronic cigarettes in context. *BMJ*, 353.

Brose, L. S., Brown, J., Hitchman, S. C., & McNeill, A. (2015). Perceived relative harm of electronic cigarettes over time and impact on subsequent use. A survey with 1-year and 2-year follow-ups. *Drug and Alcohol Dependence, 157*, 106–111.

Camacho, O. M., Hill, A., Fiebelkorn, S., Jones, J. D., Prasad, K., Proctor, C., & Murphy, J. (2021). Modeling the population health impacts of heated tobacco products in Japan. *Tobacco Regulatory Science, 7*(3), 221–231.

Cano, S., Chrea, C., Salzberger, T., Alfieri, T., Emilien, G., Mainy, N., Ramazzotti, A., Lüdicke, F., & Weitkunat, R. (2018). Development and validation of a new instrument to measure perceived risks associated with the use of tobacco and nicotine-containing products. *Health and Quality of Life Outcomes, 16*(1), 1–15.

Chrea, C., Acquadro, C., Afolalu, E. F., Spies, E., Salzberger, T., Abetz-Webb, L., Cano, S., Arnould, B., Mainy, N., & Rose, J. (2018). *Developing fit-for-purpose self-report instruments for assessing consumer responses to tobacco and nicotine products: The ABOUT™ toolbox initiative*. F1000Research.

Cox, S., Frings, D., Ahmed, R., & Dawkins, L. (2018). Messages matter: The Tobacco Products Directive nicotine addiction health warning versus an alternative relative risk message on smokers' willingness to use and purchase an electronic cigarette. *Addictive behaviors reports, 8*, 136–139.

Czoli, C. D., Fong, G. T., Mays, D., & Hammond, D. (2017). How do consumers perceive differences in risk across nicotine products? A review of relative risk perceptions across smokeless tobacco, e-cigarettes, nicotine replacement therapy and combustible cigarettes. *Tobacco Control, 26*(e1), e49–e58.

Denlinger-Apte, R. L., Pacek, L. R., Ross, J. C., Bansal-Travers, M., Donny, E. C., Hatsukami, D. K., & Carroll, D. M. (2021). Risk perceptions of low nicotine cigarettes and alternative nicotine products across priority smoking populations. *International Journal of Environmental Research and Public Health, 18*(10), 5311. https://www.mdpi.com/1660-4601/18/10/5311.

East, K. A., Tompkins, C. N., McNeill, A., & Hitchman, S. C. (2021). 'I perceive it to be less harmful, I have no idea if it is or not:'a qualitative exploration of the harm perceptions of IQOS among adult users. *Harm Reduction Journal, 18*(1), 1–12.

Erku, D. A., Bauld, L., Dawkins, L., Gartner, C. E., Steadman, K. J., Noar, S. M., Shrestha, S., & Morphett, K. (2021). *Does the content and source credibility of health and risk messages related to nicotine vaping products have an impact on harm perception and behavioural intentions? A systematic review*. Addiction.

Evans, A. T., Henderson, K. C., Geier, A., Weaver, S. R., Spears, C. A., Ashley, D. L., Fritz, M., John, L., & Pechacek, T. F. (2020). What motivates smokers to switch to ends? A qualitative study of perceptions and use. *International Journal of Environmental Research and Public Health, 17*(23), 8865.

Fong, G. T., Elton-Marshall, T., Driezen, P., Kaufman, A. R., Cummings, K. M., Choi, K., Kwan, J., Koblitz, A., Hyland, A., & Bansal-Travers, M. (2019). US adult perceptions of the harmfulness of tobacco products: Descriptive findings from the 2013–14 baseline wave 1 of the path study. *Addictive Behaviors, 91*, 180–187.

Food Drug Administration. (2020). *FDA authorizes marketing of IQOS tobacco heating System with 'reduced exposure' information*. Retrieved 26 April from https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information.

German Society for Epidemiology. (2008). *Guidelines and recommendations to assure good epidemiologic Practice (GEP)*.

Gravely, S., Fong, G. T., Sutanto, E., Loewen, R., Ouimet, J., Xu, S. S., Quah, A. C., Thompson, M. E., Boudreau, C., & Li, G. (2020). Perceptions of harmfulness of heated tobacco products compared to combustible cigarettes among adult smokers in Japan: Findings from the 2018 ITC Japan survey. *International Journal of Environmental Research and Public Health, 17*(7), 2394.

International Epidemiological Association. (2007). *Good Epidemiological Practice (GEP) – IEA Guidelines for proper conduct of epidemiological research*. https://ieaweb.org/IEAWeb/Content/IEA_Publications.aspx.

Kaufman, A. R., Persoskie, A., Twesten, J., & Bromberg, J. (2020). A review of risk perception measurement in tobacco control research. *Tobacco Control, 29*(Suppl 1), s50–s58.

Kozlowski, L. T., & Sweanor, D. T. (2018). Young or adult users of multiple tobacco/nicotine products urgently need to be informed of meaningful differences in product risks. *Addictive Behaviors, 76*, 376–381.

Lwanga, S. K., Lemeshow, S., & Organization, W. H. (1991). *Sample size determination in health studies: A practical manual*. World Health Organization.

Majeed, B. A., Weaver, S. R., Gregory, K. R., Whitney, C. F., Slovic, P., Pechacek, T. F., & Eriksen, M. P. (2017). Changing perceptions of harm of e-cigarettes among US adults, 2012–2015. *American Journal of Preventive Medicine, 52*(3), 331–338.

Morgan, J. C., & Cappella, J. N. (2021). Harm perceptions and beliefs about potential modified risk tobacco products. *International Journal of Environmental Research and Public Health, 18*(2), 576.

National Cancer Institute. (2017). *Hints: Health information national trends survey*. Retrieved https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=9&qid=1282. (Accessed 7 November 2021).

National Cancer Institute. (2019). *Hints: Health information national trends survey*. https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=12&qid=1541.

National Cancer Institute. (2020). *Hints: Health information national trends survey*. Retrieved 20 January 2022 from https://hints.cancer.gov/view-questions-topics/question-details.aspx?PK_Cycle=13&qid=1282.

Nyman, A. L., Huang, J., Weaver, S. R., & Eriksen, M. P. (2019). Perceived comparative harm of cigarettes and electronic nicotine delivery systems. *JAMA Network Open, 2*(11). e1915680-e1915680.

Persoskie, A., O'Brien, E. K., & Poonai, K. (2019). Perceived relative harm of using e-cigarettes predicts future product switching among US adult cigarette and e-cigarette dual users. *Addiction, 114*(12), 2197–2205.

Smith, M. R., Clark, B., Lüdicke, F., Schaller, J.-P., Vanscheeuwijck, P., Hoeng, J., & Peitsch, M. C. (2016). Evaluation of the tobacco heating System 2.2. Part 1: Description of the system and the scientific assessment program. *Regulatory Toxicology and Pharmacology, 81*, S17–S26.

Sutanto, E., Miller, C. R., Smith, D. M., O'Connor, R. J., Gravely, S., Hammond, D., Hyland, A., Cummings, K. M., Quah, A. C., & Fong, G. T. (2020). Perceived relative harm of heated tobacco products (IQOS), e-cigarettes, and cigarettes among adults in Canada: Findings from the ITC Project. *Tobacco Induced Diseases, 18*.

Svenson, M., Green, J., & Maynard, O. (2021). *Tackling smoker misperceptions about E-cigarettes using expert videos*.

Tan, A. S., Lee, C.-j., Nagler, R. H., & Bigman, C. A. (2017). To vape or not to vape? Effects of exposure to conflicting news headlines on beliefs about harms and benefits of electronic cigarette use: Results from a randomized controlled experiment. *Preventive Medicine, 105*, 97–103.

Tompkins, C. N., Burnley, A., McNeill, A., & Hitchman, S. C. (2021). Factors that influence smokers' and ex-smokers' use of IQOS: A qualitative study of IQOS users and ex-users in the UK. *Tobacco Control, 30*(1), 16–23.

Wackowski, O. A., Ray, A. E., & Stapleton, J. L. (2019). Smokers' perceptions of risks and harm from snus relative to cigarettes: A latent profile analysis study. *Addictive Behaviors, 91*, 171–174.

Weaver, S. R., Heath, J. W., Ashley, D. L., Huang, J., Pechacek, T. F., & Eriksen, M. P. (2020). What are the reasons that smokers reject ends? A national probability survey of US adult smokers, 2017-2018. *Drug and Alcohol Dependence, 211*, Article 107855.

Yang, B., Owusu, D., & Popova, L. (2019). Testing messages about comparative risk of electronic cigarettes and combusted cigarettes. *Tobacco Control, 28*(4), 440–448.

Zeller, M., & Hatsukami, D. (2009). The strategic Dialogue on tobacco harm reduction: A vision and blueprint for action in the US. *Tobacco Control, 18*(4), 324–332.