Risk perception of \textit{IQOS}™ and cigarettes: Temporal and cross-country comparisons

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\textbf{A R T I C L E   I N F O}

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\textbf{A B S T R A C T}

\begin{quote}
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, \textit{IQOS}™, relative to cigarettes, among current \textit{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 \textit{IQOS}™ users from local registers of \textit{IQOS}™ users. The health RPs of cigarettes and \textit{IQOS}™ were assessed using the ABOUT™-Perceived Risk instrument, and their difference was described as the relative RP of \textit{IQOS}™ to cigarettes (\textit{RP}_{Cig}/\textit{IQOS}™).

Results: After adjustment for covariates, the relative \textit{RP}_{Cig}/\textit{IQOS}™ was higher in 2018 than in 2019 (0.93; standard error, 0.33; \textit{P} = 0.005). This was driven by an increase in the RP of \textit{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 \textit{IQOS}™ decreased over time, driven by an increase in the RP of \textit{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.
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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
switching from cigarettes to smoke-free alternatives among existing smokers. Indeed, a growing body of evidence indicates that the correct designation of risk associated 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 be 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 (Fast 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™, relative to the RP of cigarettes, among current adult IQOS™ users across different countries. The secondary objective was to examine the association between IQOS™ 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™ device, IQOS™ users were invited to register in a country-specific PMI IQOS™ users database. To ensure that a representative sample of IQOS™ users was selected, the age and sex distribution of the PMI IQOS™ owners database of the respective country was taken into consideration in each wave of data collection. Subsequently, a random sample of IQOS™ 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™ who had used >100 HEETS™/HeatSticks™ 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™ users was deemed sufficient to estimate a 50% prevalence of combined IQOS™ 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™ 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™ users per year was required for Germany and Italy, respectively, to estimate IQOS™ 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™ Users’ Questionnaire (IQOS™-UQ), which included questions about current IQOS™ use, current and former use of other TNPs (Afolalu et al., 2021).

2.4. RP measures

The perceived risk of cigarette smoking and IQOS™ 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) (Cig: RPcig=IQOS™, HeatSticks™=IQOS™). 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™ use for each participant (Cano et al., 2018). The difference in RP scores between cigarette smoking and IQOS™ use was calculated to derive a measure of the relative RP of IQOS™ (relative RPcig=IQOS™/HeatSticks™=IQOS™) for each country. 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).

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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 and the following independent variables: sex (male/female), age groups (18–24, 24–44, and ≥45 years), IQOS use behavior (predominant IQOS combined cigarette–IQOS 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 based on their current use of different categories of TNPs and the quantity of TNP use. Predominant IQOS use was defined as >50% IQOS use for a combined cigarette and IQOS user. Combined cigarette–IQOS use was defined as IQOS use alongside cigarette smoking, at >30% and <70% of the total cigarette–IQOS use. IQOS users who reported ≤50% combined cigarette–IQOS 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 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 for country–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–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 users than Germany (36.6%), where combined cigarette–IQOS 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 across all countries and years. The mean values (and 95% CIs) of the absolute and relative RCig–IQOS are shown in Table 1 and the Supplementary Material. The RP of cigarettes remained stable over time across all countries, while that of IQOS declined in Italy and Japan. The relative RCig–IQOS 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 RCig–IQOS 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 users in Germany or Japan, IQOS users in Italy perceived the risk of cigarettes to be higher than that of IQOS. The relative RCig–IQOS was higher among women (18.2 [17.7–18.7] than men (16.9 [16.5–17.3]) and among predominant IQOS users (18.8 [18.4–19.3]) than combined cigarette–IQOS users (14.9 [14.5–15.4]). The relative RCig–IQOS 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 RCig–IQOS after adjustment for sex, age group, IQOS use pattern and intensity. With all other variables (i.e., age, sex, IQOS use pattern and intensity) remaining constant, the relative RCig–IQOS 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 RCig–IQOS showed a smaller decline in Germany and Italy between 2018 and 2019, respectively (Table 3). In Japan, the relative RCig–IQOS was greater in 2017 than 2018 and in 2018 than 2019, and decline in relative RCig–IQOS was larger between 2017 and 2018 than between 2018 and 2019 (Table 3).

3.4. Risk perception: association with IQOS use behavior

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

Relative RP and IQOS use intensity showed a positive linear association, with lower HEETS/HeatStick consumption being associated with lower relative RCig–IQOS (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 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 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 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 | Year/Statistic | Category/Statistic | N  | %  | Mean  | 95% CI  | N  | %  | Mean  | 95% CI  |
|---------|---------------|--------------------|----|----|-------|---------|----|----|-------|---------|
| Germany |               |                    |    |    |       |         |    |    |       |         |
|         |               | RPcigarette        |    |    |       |         |    |    |       |         |
|         |               | Year Y1            | 1274 | 50.2 | 16.2 | (15.5, 17.0) | 1262 | 49.8 | 16.5 | (15.7, 17.2) |
|         |               | Year Y2            |    |    |       |         |    |    |       |         |
|         |               | Sex                |    |    |       |         |    |    |       |         |
|         |               | Male               | 717 | 56.3 | 16.7 | (15.7, 17.7) | 708 | 56.1 | 16.9 | (15.8, 17.9) |
|         |               | Female             | 547 | 42.9 | 15.8 | (14.7, 16.9) | 547 | 43.3 | 16.0 | (14.9, 17.2) |
|         |               | Age Group          |    |    |       |         |    |    |       |         |
|         |               | LA–24 years old    | 84  | 6.6  | 14.8 | (10.7, 18.8) | 65  | 5.2  | 18.2 | (14.7, 21.6) |
|         |               | 25–44 years old    | 643 | 50.5 | 17.0 | (15.9, 18.0) | 643 | 51.0 | 15.9 | (14.9, 17.0) |
|         |               | ≥45 years old      | 547 | 42.9 | 15.6 | (14.6, 16.6) | 554 | 43.9 | 16.9 | (15.8, 18.1) |
|         |               | Use Pattern        |    |    |       |         |    |    |       |         |
|         |               | Predominant IQOS™  | 439 | 34.5 | 20.9 | (19.7, 22.2) | 488 | 38.7 | 20.3 | (19.0, 21.5) |
|         |               | Combined cigarette-IQOS™ | 787 | 61.8 | 13.9 | (13.0, 14.8) | 755 | 59.8 | 14.1 | (13.2, 15.0) |
|         |               | Use Intensity™     |    |    |       |         |    |    |       |         |
|         |               | ≤6                 | 265 | 20.8 | 13.8 | (12.2, 15.5) | 229 | 18.1 | 12.9 | (11.4, 14.4) |
|         |               | 7–12               | 367 | 28.8 | 15.2 | (13.9, 16.5) | 380 | 30.1 | 15.4 | (14.1, 16.8) |
|         |               | 13–18              | 260 | 20.4 | 16.6 | (15.1, 18.2) | 249 | 19.7 | 17.1 | (15.5, 18.8) |
|         |               | ≥19                | 382 | 30.0 | 18.6 | (17.2, 20.1) | 404 | 32.0 | 19.1 | (17.7, 20.6) |

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™ use was defined as IQOS™ use for >95% out of total TNP use. Combined cigarette–IQOS™ use was defined as IQOS™ use alongside cigarette smoking, at a proportion >30% and <70% of the total TNP use.

a IQOS™ use intensity measured as number of HEETS/HeatSticks consumed per day.
Combined cigaretteIQOSTM use was defined IQOSTM use for (18 years old in Germany, 18 years old in Italy, and 20 years old in Japan). "Predominant IQOSTM use was defined IQOSTM use alongside cigarette smoking, at a proportion >30% and <70% of the total TNP use. aIQOS 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.

| Categories                     | β     | SE   | P value | Intercept |
|--------------------------------|-------|------|---------|-----------|
| All Countries                  | β     | SE   | P value | Intercept |
| Sex                            | -0.47 | 0.36 | 0.201   | 19.82     |
| Male                           | 0.47  | 0.36 | 0.36    | 19.82     |
| Female                         | Reference | -  | -      | -        |
| Age Group                      | -2.26 | 0.65 | 0.001   | -1.28     |
| LA-24 years old                | Reference | -  | -      | -        |
| 25–44 years old                | -0.75 | 0.36 | 0.039   | -0.75     |
| ≥45 years old                  | Reference | - | - | -        |
| Use Pattern                    | 4.62  | 0.37 | <.0001  | 4.62      |
| Predominant IQOSTM use         | Reference | - | | Reference |
| Combined cigarettes-IQOSTM use | 4.62  | 0.37 | <.0001  | 4.62      |
| Use Intensityb                 | ≤6    | -3.77| 0.54    | <.0001    |
| -1.69 | 0.43 | <.0001 | ≤6 | -3.77 |
| 13–18 | -1.18 | 0.45 | 0.009   | 13–18     |
| ≥19 | Reference | - | - | ≥19 |
| Year                           | 0.93  | 0.33 | 0.005   | 0.93      |
| 2018                           | Reference | - | - | Reference |
| Country                        | -3.31 | 0.45 | <.0001  | -3.31     |
| Germany                        | -6.73 | 0.43 | <.0001  | -6.73     |
| Japan                          | 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). *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.

Table 3
Regression coefficients for regression models by country.

| Categories                     | β     | SE   | P value | Intercept |
|--------------------------------|-------|------|---------|-----------|
| Germany                        | 15.80 | 0.72 | <.0001  | 15.80     |
| Italy                          | 20.27 | 1.05 | <.0001  | 20.27     |
| Japan                          | 15.50 | 0.91 | <.0001  | 15.50     |
| Year                           |       |      |         |           |
| 2017                           | -      | -    | -      | -        |
| 2018                           | 0.18  | 0.60 | 0.027   | 0.18      |
| Country                        | -      | -    | -      | -        |
| Germany                        | 6.24  | 0.56 | <.0001  | 6.24      |
| Italy                          | 5.14  | 0.69 | <.0001  | 5.14      |
| Japan                          | 2.95  | 0.57 | <.0001  | 2.95      |

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.
where the data were available closer to the local launch of IQOS™ 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™, a trend that is equally observed for other more established smoke-free TNP s such as e-cigarettes. Concerning, in Japan, increase in RP of IQOS™ was observed particularly among predominant IQOS™ users, a finding that warrants further investigation. Future studies should consider conducting an ecologically 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™ users. Finally, continuous surveillance of the RP of novel TNP s is warranted to ensure that adult users correctly understand the risk associated with different TNP s, particularly smoke-free TNP s such as IQOS™. 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 TNP s to help facilitate their transition from cigarettes to smoke-free TNP s and prevent potential relapse into cigarettes (Svenson et al., 2021).

Interestingly, the present study found that the relative RP of IQOS™ is greater among predominant adult IQOS™ users than combined cigarette-IQOS™ users. Similarly, a higher intensity of IQOS™ 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™ users are driven to become exclusive IQOS™ 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™ 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 RP s of different TNP s (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™ 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 unconditioned 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™ owners database, which, could be argued, may have produced a selective sample of participants. However, on average, over 80% of IQOS™ users are registered in the IQOS™ 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 TNP s 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™ is lower than that of cigarettes across the surveyed countries and years; however, the RP of IQOS™ 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 TNP s. Such research will be critical, considering the recent need for more tailored and accurate relative risk communication of novel TNP s.

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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.
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Appendix A. Supplementary data

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

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